Arterial Blood Gas Analysis – Radiometer ABL80

Audience All personnel in the Pulmonary Function Clinic.

Policy The purpose of this policy is to define the usage of the Radiometer ABL80 FLEX CO-OX for the analysis of arterial blood gas samples. It will include specimen requirements, wet section of analyzer, sensor calibration, solution, quality control, values, and limitations.

Principle The ABL80 is a portable, automated analyzer that measures pH, blood gases and oximetry. It uses a three-electrode system to measure quantitatively pH, PCO2, and PO2 in blood samples. On the basis of the measured values the analyzer calculates seven derived parameters: plasma and standard bicarbonate, oxygen saturation and oxygen content, total CO2, actual and standard base excess.

Blood gas analysis is used to assess the oxygenation, ventilation, and acid-base status of a patient. Other parameters that are derived from these three parameters are used in the assessment of oxygen content and oxygen delivery.

The optical system is based on a 128-wavelength spectrophotometer with a measuring range of 478-672nm. The spectrophotometer is connected via an optical fiber to a combined hemolyzer and measuring chamber.

Specimen Collection

Under routine conditions, blood gas sampling will be done with the patient breathing room air unless specified by the requesting physician. In these cases, the conditions under which the blood gas sample was drawn will be documented on the blood gas/pulmonary function report. If the patient arrives in the Pulmonary Function Laboratory using supplemental oxygen, and a blood gas with the patient breathing room air is needed, the patient will be taken off of the oxygen for no less than 15 minutes before the blood gas sample is drawn.

The specimen will be obtained from the radial artery only, using a pre-packaged 3 cc syringe with 100 units of lyophilized lithium heparin and a 22 GA x 1-inch needle. The amount of blood required is 1-3 cc's.

Handling Conditions: A blood gas sample will be run within 5 minutes of obtaining the sample. If the sample cannot be analyzed within 5 minutes, the sample will be placed on ice until such a time that it can be analyzed. All air bubbles will be expelled from the sample immediately. Blood samples that are beginning to or have already coagulated are unacceptable for analysis.

Precautions: Those patients receiving anticoagulant therapy must be observed closely. No substances in normal blood will interfere with pH and PCO2 measurements. Blood from patients anaesthetized with nitrous oxide or halothane

may give unreliable PO2 values due to the influence of these anesthetic gases on the PO2 electrode. Patients who have received lipid therapy will have an abnormally high blood lipid content, which causes some interference in pH measurements. Samples from such patients should be labeled so that these contaminants can be taken into account in the interpretation on the results.

Wet Section

Definition

The wet section of the analyzer is where all samples and solutions are transported for measurement, calibration and rinse

Contents of wet section

The main components of the wet section are:

- Sensor cassette
- Internal tubing
- Peristaltic pumps for sample aspiration, calibration and waste
- Valve / manifold assembly
- Solution pack
- Hemolyzer

Solutions

All solutions for the ABL80 FLEX analyzer are contained in the solution pack.

Gases

Gas tanks are not necessary with the ABL80 FLEX CO-OX analyzer .The multiple levels of solutions are tonometered and sealed in gastight disposable pouches, without a gas phase. This eliminates the need for gas tanks, and temperature or barometric pressure corrections.

The table below describes the functions of the main parts of the ABL80 FLEX wet section.

Item	Part	Function
1	Inlet probe	The point of introduction for the sample into the sensor cassette. It also provides a pathway for calibration/QC solution to be flushed to the waste drain.
2	Waste drain luer	Luer which receives waste fluids from the inlet probe during flush cycles.
3	Main waste line	Internal tubing, which provides the pathway for waste fluid transport to the waste pouch contained in the solution pack.
4	Cassette measuring chamber	The area of the cassette which contains the sensor array and where the actual measurements occur for pH, blood gases, electrolytes and

		glucose.
5	Cassette luer	The fluid connection port between the analyzer and the sensor cassette.
6	Pinch valve	Valve used in the measurement of co-oximeter parameters
7	Hemolyzer	Ultrasonic hemolyzer which contains the hemolyzed sample in a cuvette during measurement
8	Liquid sensor	Senses the location of the sample in the pathway, ensuring the sample has successfully been transported through the hemolyzer
9	Spectrometer	Uses a photodiode array to measure the wavelengths of the sample and create an absorption spectrum
10	Sample pump	Provides the pumping mechanism to transport fluids through the hemolyzer and across the cassette sensor array
11	Vent valve	Internal valve that controls the flow of waste fluids into the waste pouch contained in the solution pack.
12	Waste pump	Pump that transports waste fluids to the waste pouch
13	Valves	Internal valves that control the selection and flow of solutions from the solution pack to the sensor cassette
14	Manifold	Interface between the solution pack, valves and the analyzer wet section
15	Fluid port luer	These luers penetrate the valves of the sealed pouches in the solution pack to provide fluid flow.
16	Solution pack	Contains five sealed pouches, four solution pouches and a waste pouch.
17	Solution pouches	Four pouches with precision-tonometered electrolyte solutions and dyes.
18	Waste pouch	Pouch to collect and contain all waste fluids in the system.

Sensor **Definition**

The term sensor refers to an individual sensor as part of the sensing array within a sensor cassette. The electrical signal from each sensor is measured by proprietary analog electronics contained within the analyzer unit.

Measuring Principles

There are four different measuring principles employed in sensors in the ABL80 FLEX CO-OX analyzer.

- **Potentiometry:** The potential of a sensor chain is recorded using a voltmeter, and related to the concentration of the sample (the Nernst equation). The potentiometric measuring principle is applied in the pH and pCO2 sensors.
- **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. The amperometric measuring principle is applied in the pO_2 sensors.
- **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. The conductometric measuring principle is applied in the Hct electrodes and the air-in-sample detection (SC) electrodes.
- **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 first three measuring principles are described in detail in *ABL80 Flex Reference Manual.* Spectrophotometry is described above in Principle. In depth sensor and electrode descriptions and functions are available in section 4 in the *ABL 80 Flex Reference Manual.*

Manual Quality Control Reagents
QUALICHECK 5+Control Solution is recommended by Radiometer for optimal performance of analyzer. All manual QC solutions will be scanned into the analyzer and solution ID fields entered. Solutions include S7730 QUALICHECK5+ Level 1, S7740 QUALICHECK5+Level 2, S7750 QUALICHECK5+Level 3, S7760 QUALICHECK5+Level 4

Sensor Calibration

Sensor calibration is the process of relating sensor electrical outputs to known analyte values. The calibration line slop (sensitivity) of each sensor is derived from the electrical values (end points) obtained by measuring two solutions with different analyte concentrations.

The ABL 80 FLEX CO-OX automatic quality control system calibration process includes the measurement of three solutions with different analyte concentrations. These three measure values are used in different combinations of two points each to establish three two-point calibration lines for each anaylte. One calibration line is consistently used to report sample results. All three calibration lines are used together to evaluate system linearity.

Sensitivity

Sensor sensitivity describes the slope of the calibration line derived from a 2-point calibration. The sensitivity limits for the calibration are set for each sensor.

The following table lists the sensitivity limits for each sensor:

Limits		
Parameter	**Sensitivity Range**	**Unit**
pH	40.0 – 65.0	mV/pH unit
CO_2	30.0 – 75.0	mV/decade pCO_2
O_2	0.002 – 0.052	nA/mmHg

Calibration Levels

All ABL80 FLEX analyzers are equipped with a solution pack. This pack contains precision-tonometered fluids. The tonometry calibration gas mixture is of a known composition.

Gas 1 has a composition of: O2 ~ 25%
CO2 ~ 8%.
N2 = Balance

Gas 2 has a composition of: O2 ~ 24%
CO2 ~ 15.5%.
N2 = Balance

Gas 3 has a composition of: O2 ~ 0%
CO2 ~ 3%.
N2 = Balance

The determination of pCO_2 is also dependent on the pH values.

- Solution 1 has an approximate pH value of 7.40
- Solution 2 has an approximate pH value of 7.00
- Solution 3 has an approximate pH value of 7.60

The partial pressure of CO_2 (pCO_2) and the solution pH values are known and contained in the solution pack smart chip.

System Cycle Calibration is performed during a System Cycle.

Schedule Calibration is performed every 8 hours, with the ability to increase frequency up to every 2 to 4 hours, if desired. A System Cycle is also performed following power-up if the analyzer has been turned off for more than 10 minutes or if turned off without following the appropriate power down process as described in the operator manual.

Blank Calibration

In the ABL80 FLEX CO-OX analyzer a blank (zero) calibration of the CO-Oximeter is performed, using clear solution, during every System Cycle and sensor cassette installation.

Drift The system can be configured to display a drift value for any parameter whose drift value falls outside the acceptable drift criteria between System Cycles. *See chapter 9 in operator manual for enabling.* When enabled and at least one parameter drift value is outside the acceptable criteria, a **Drift** tab will appear on the System Cycle results screen.

Inactivation If the calibration fails, the system will not allow the use to perform sample analysis unless the failed parameter is inactivated. The analyzer can be configured to automatically inactive and re-activate failed parameters.

Procedure For complete operating procedure, see Chapter 4: ABL80FLEX CO-OX Operators Manual.

Measurements:	Operating Conditions
Sample Volume -	For each analysis, the ABL80 requires a sample volume of 105µl of blood
Temperature -	All measurements and calibrations carried out at 37 °C +0.2°C
Analysis/Cycle time	140 seconds

Solution The ABL80 FLEX analyzer utilizes a solution pack for all calibrations, QC, and flush procedures and for the collection of waste fluids. The solution pack contains four foil pouches each filled with calibration solution. These pouches provide multiple solution levels for sensor calibration. Additionally, solution 1 is used for sample flushing procedures. A fifth pouch provides a receptacle for the collection of all waste fluids.

Expiration Date
The shelf-life expiration date for the solution pack is found on the pack label. The expiration date is labeled with an "Install By" symbol () followed by a date in year-month-day format (e.g. 2006-04-23). A solution pack may be installed up to this expiration date and be used on the analyzer for up to 30 days beyond this date or until one or more calibration fluids are fully consumed, whichever occurs first.

Storage
The solution pack storage temperature range for all versions (except REF 944-341) is 5 °C to 25 °C (41 to 77 °F). The solution pack storage temperature range for REF 944-341 is 2 °C to 25 °C (36 to 77 °F). The storage and operating altitude range is sea level to 2290 meters. When stored at this temperature and altitude, the solution pack is stable throughout the shelf-life period, if the protective tape over the fluid ports remains intact.

Beyond this date, the solutions will remain stable and may be used for up to the maximum allowed number of days, when properly installed onto the analyzer.

Solutions
The four solutions contained in the pouches of the solution pack are used for calibration and quality control of all analytes. During sample analysis and quality control measurements this solution also acts as a flush, removing the sample from the sensor

cassette measuring chamber. This solution is also used to manually flush the measuring chamber when using the **Rinse** function.

Pouch Volume

Pouch	1	2	3	4
Volume	440 mL	220 mL	220 mL	220 mL
Cycles	230	110	110	110

Composition
The solution composition includes organic buffers and inorganic salts which provide the following substances with approximate concentrations as given below:

Substance	**Units**	**Solution 1**	**Solution 2**	**Solution 3**	**Solution 4**
pH		7.40	6.90	7.60	
$p\mathrm{CO}_2$	mmHg	35	75	15	
$p\mathrm{O}_2$	mmHg		150	45	210
$c\mathrm{Na}^+$	mmol/L	145	104	160	
$c\mathrm{K}^+$	mmol/L	4	8.5	2.5	
$c\mathrm{Ca}^{2+}$	mmol/L	1.09	2.26	0.55	
$c\mathrm{Cl}^-$	mmol/L	114	79	130	16
cGlu	mmol/L	0	15	5	
Hct	%		12		63

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Results *Preprogrammed Values:*

TEMP – Temperature in °C. Results are indicated at 37°C unless a different value is entered. pH, pCO2, and pO2 are then corrected to the keyed-in value.

Measured Values:
pH – pH Scale
pCO2 – Carbon Dioxide Partial Pressure (mmHg)
pO2 – Oxygen Partial Pressure (mmHg)
tHb – Total hemoglobin (g%)
sO2- Oxygen Saturation in Blood (%)
FO2Hb – Fraction of Oxyhemoglobin (%)

FCOHb – Fraction of Carboxyhemoglobin (%)
FMetHb – Fraction of Methemoglobin (%)

Calculated Values:
Baro – Barometric Pressure (mmHg)
HCO3 – Plasma Bicarbonate (mmol/L)
TCO2 – Total CO2 in Plasma (mmol/L)
SBE – Standard Base Excess in Blood (mmol/L)

Blood Sample Measurements:
Pre-operating Checks – Mix the blood sample with a suitable anticoagulant. Also, mix the sample contents immediately before measuring. Record relevant patient data (i.e., patient temperature, time of sampling, external respiratory assistance, etc.).

IMPORTANT: GLOVES MUST ALWAYS BE WORN WHEN OBTAINING OR ANALYZING BLOOD SAMPLES.

Syringe Sample:

1. Log into analyzer
2. Check that the ABL80's status is READY.
3. Traffic light is displaying green or yellow light
4. Touch screen to *Menu*, then *Analysis*- Aspiration screen appears. Parameters are pre-selected.
5. When prompted, slide handle up to the first position.
6. Guide inlet probe into the sample; ensure tip is fully immersed in the sample.
7. Select the *Aspirate* button to start the measurement.
8. When prompted by the analyzer, remove the syringe and lower inlet probe.
9. Touch Scan on the screen and scan barcode on patient label.

Additional sample information can be put on patient results query. Patient ID number is only required information for ABL80 FLEX CO-CO to process sample.

A new sample may be introduced when the READY button displays.

Calculations The ABL80 calculates the following values based on programmed and measured values.

HCO3 – Plasma Bicarbonate (mmol/L)
TCO2 – Total CO2 in Plasma (mmol/L)
SBE – Standard Base Excess in Blood (mmol/L)

Quality Control

Definition: Any measuring instrument used in diagnosis must be checked routinely to assure its reliability. RADIOMETER has specified the instrument according to a set of accepted reference methods, which inform the operator about its performance characteristics, i.e., inaccuracy and imprecision. Quality control, then, is a method for verifying these specifications by making measurements in the same way as sample measurements, but on a prepared material with predetermined value ranges.

The ABL 80 FLEX CO-OX analyzer provides automatic quality control analysis for each parameter, measuring three level of quality control material for blood gases. The analyzer also measures three levels of controls for all oximetry parameters.

Auto QC: The Pulmonary Function Clinic currently uses the AutoQC3 Solution Pack for all reagents. These automatic quality control measurements are performed during each System Cycle.

The Pulmonary Function Clinic runs a minimum of one sample for each level of control daily (the Pulmonary Function Clinic is in operation from 8am to 5pm Monday through Friday only). The Laboratory's QC program will normally run for one year (i.e., same batch numbers for each control level) unless there is a manufacturing limitation on batch availability. In any case, the program will not run for less than 6 months.

Control Ranges
The assigned value and control range for each parameter are level are entered automatically into the analyzer each time a new solution pack is installed. The values can be viewed and printed from the **System Information/Solution Pack** tab.

Acceptance Criteria
The analyzer automatically assesses all automatic QC results and flags any result that is outside the normal range.

QC Records
All automatic quality control results are stored in the analyzer's database.

QC Results
The table of QC results include the follow information:

- Solution ID
- Lot
- Cycles
- Parameter
- QC #

The quality control results from each System Cycle can be viewed in the System Data Logs.

Automatic QC plot
The QC plot displays result of all automatic quality control measurements for each parameter and each solution level. All QC results are displayed in a bias plot. The plot charts the difference between the measured value and the assigned value for each parameter and each level. This plotting method allows for continual analysis and trending of analyte performance while eliminating variations due the solution lot changes.

System Checks: Every 30 minutes the analyzer will perform a System Check to verify the stability and proper function on the analyzer. During the System Checks, the analyzer will activate the heater circuitry and air detection system. Measurements will be taken on all sensor cassette sensors and a drift evaluation will be performed. Proper communication with the CO-oximeter will also be confirmed.

Corrective Action
The analyzer will automatically perform corrective actions when the results of a System Check are not acceptable. The first phase of this corrective action is to flush the sensor cases and repeat the measurements. If repeat measurements are not acceptable, the system will automatically initiate a System Cycle to fully evaluate the measurement system. The event log records these corrective actions by recording the event along with the acronym C/A (corrective action).

Analysis Check
With every blood sample analysis a System Check with one-point calibration is performed. The specialized System Check is termed an Analysis Check. During analysis, the blood sample is aspirated into the analyzer and sensor measurements are recorded. The sample is then flushed with solution 1 (form the solution pack) and measurements of this solution are recorded. The measurement results from both the sample and the flush are (the one-point calibration) are used to determine the final blood sample results. This method insures compensation for any sensor drift with each sample analysis.

Manual Quality Control
As a second method of quality control, the Pulmonary Function Clinic will analyze manual quality control samples. Manual Quality Controls will be run every 30 days using Radiometer recommended QUALICHECK5+ and Range+ QUALICHECK Control Solution. *In addition when the solution pack or the sensor cartridge is changed, all three levels of manual quality control will be run to verify no significant changes to results have occurred*.

Proficiency Testing

In order to ensure accurate and precise testing, the laboratory utilizes the Survey Program of the College of American Pathologists. In this program, the laboratory evaluates the precision of testing and obtains information about the performance of other laboratories across the country. The survey programs are proficiency testing systems designed to monitor the laboratories results to the national mean, reference laboratories, and/or selected laboratories. The program is designed to show the level of performance in the laboratory and to correct problems. The program consists of the following:

- Processing a series of unknown specimens through routine testing.
- Evaluation of the results of unknowns by CAP via comparison to peer group, selected peer references, and/or accepted medical criteria.
- Computer evaluation from CAP to the laboratory, which displays results in relation to criteria.
- Recognition by participating laboratory of problem areas and development of a correction plan.
- **Staff is prohibited from communicating with each other concerning proficiency samples until after sample questionnaire is submitted to CAP.**
- **Staff is prohibited from communicating with outside laboratories concerning CAP proficiency samples.**

The survey samples are sent quarterly.

Back-up/Send-Out Policy

In the event that the blood gas analyzer is "down" due to maintenance or other reasons and a patient sample needs to be analyzed, the Pulmonary Function Laboratory has an agreement with the Department of Pathology Clinical Chemistry Laboratory to run samples. The Therapist/Technician should call the Laboratory and inform the Supervisor of the need.

Expected Values

Normal Values: Below is a list of the normal measured and calculated values.

Parameter	Expected Values for Measured Parameters	
	Male	Female
pH	7.35 - 7.45	7.35 - 7.45
pCO2 (mmHg)	35 - 48	32 - 45
pO2 (mmHg)	80 - 100	80 - 100
Hbg (g/dL)	13.5 – 17.5	12 – 16
SAT (%)	95 - 99	95 - 99
FO2Hb (%)	94 - 98	94 - 98
FCOHb (%)	0.5 – 1.5	0.5 – 1.5
FMetHb (%)	0 – 1.5	0 – 1.5

	Expected Values for Calculated (Derived)	
Parameters		
HCO3 (mmol/L)	22 – 26	20 – 24
SBE (mmol/L)	-2.4 - +2.3	-3.3 - +1.2
TCO2 (mmol/L)	23 - 27	21 - 25

(Ref. 1; pages 791 and 1388)

Reporting Results: Values falling outside of the above set ranges will be reported to the Manager of the Pulmonary Function Clinic for review and verification.

Results will be reported, in the units described above, on the Pulmonary Function Final Report for those patients receiving routine pulmonary function studies. Special requests for blood gases will be reported in the same manner, although the requesting physician will be called by phone or radio pager and informed of the results immediately.

Critical or Panic Values: Please see Notification of Physician of Critical Level Results Policy and/or Procedure.

Below are the listed reported parameters and the critical levels for each.

pH	<7.30 or >7.50	Hbg	<10 or >17
pCO2	<20 or >55	HbO2%	<90%
pO2	<60	HbCO%	>5%
HCO3	<15 or >38	MetHb%	>2%
BE	>+ or-5		

Limitations

In Vivo Interferences: No substances in normal blood will interfere with pH and pCO2 measurements. Blood from patients anaesthetized with nitrous oxide or halothane may give unreliable pO2 values due to the influence of these anesthetic gases on the pO2 electrode.

Patients, who have received lipid therapy, will have an abnormally high blood lipid content, which causes some interference in pH measurements. Samples taken from such patients should be labeled so that these contaminants can be taken into account in the interpretation of the results.

A thorough chart review is required on each patient that is being tested. If the Therapist discovers, through chart review, that an interfering substance is present, this information will be documented on the patient report.

References

Davidsohn, I., M.D. and Henry, J.B., M.D.: Todd-Sandford Clinical Diagnosis by Laboratory Methods. Philadelphia: W.B. Saunders Co. 15th Ed. (1974).

Operator's and Reference Manual for ABL80. Radiometer Medical ApS (2011).

Shapiro, B.A., Harrison, R.A., Walton, J.R.: Clinical Application of Blood Gases. Chicago: Year Book Medical Publishers Inc. 2nd Ed. (1980).

This form documents the approval and history of the policies and procedures for the Pulmonary Function Laboratory. The Medical Director signs all policies verifying initial approval. Annually thereafter, the Director and/or designee may approve reviews and revisions.

Date	Approved by:	Signature
11/07	**V. Cardenas, MD** **Medical Director Pulmonary Laboratory**	
6/09	**V. Cardenas, MD** **No changes to the policy**	
7/10	**V. Cardenas, MD** **No changes to the policy**	
2/12	**A. Duarte, MD** **Medical Director Pulmonary Function Laboratory** **Changes to policy**	
4/14	**A. Duarte, MD** **Changes to Policy**	