Quality Control and Acceptability

**Audience**  
All personnel in the Pulmonary Function Clinic.

**Purpose**  
Any measuring instrument used in diagnosis must be checked routinely to assure its reliability.

**Policy**  
There are two methods of performing quality control to evaluate the performance of the system. One method is automatic and the other is a manual method. The ABL80 FLEX analyzer performs periodic System Checks to provide further confidence that the analyzer is performing to specification.

**Automatic QC**  
The ABL80 FLEX analyzer provides automatic quality control analysis for each parameter, measuring at least three levels of quality control material for blood gases. The ABL80 FLEX CO-OX analyzer measures three levels of quality control for all oximetry parameters. The automatic quality control system for the ABL80 FLEX analyzer is referred to as QC 3.

**Schedule**  
These automatic quality control measurements are performed during each System Cycle which is every 8 hours.

**Control Ranges**  
The assigned value and control range for each parameter and level are entered automatically into the analyzer each time a new solution pack is installed. These values can be viewed and printed from the System Information / Solution Pack tab. See 04-10 Data Logs for more information on the System Information screen.

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

**QC records**  
All automatic quality control results are stored in the analyzer’s database. See 04-10 Data Logs or Reference Manual for more information on downloading and printing these records.

**Description of results**
The table of QC results provided with each System Cycle includes the following information:

- Solution ID: the Radiometer ID number of each solution
- Lot: the unique lot number for each of the solutions
- Cycles: the number of cycles remaining in each of the solution pouches at the end of the System Cycle
- Parameter values: the measured QC results for each parameter, each level
- QC#: a unique sequential number assigned to each QC event

**System Checks**

Every 30 minutes the analyzer will perform a System Check to verify the stability and proper function of the analyzer. During 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 cassette 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. This 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 (from the solution pack) and measurements of this solution are recorded. The measurement results from both the sample and the flush (the one-point calibration) are used to determine the final blood sample results. This method ensures compensation for any sensor drift with each sample analysis.

**Manual QC**

In the ABL80 FLEX CO-OX analyzer it is recommended to use the Radiometer brand quality control material QUALICHECK5+ for optimal performance and to take full advantage of the analyzer’s design features such as temperature correction and automatic level detection. Quality control solutions are solutions with predetermined values that cover the clinically relevant ranges for the measured parameters, the objective being to simulate a patient sample.
quality control from Radiometer includes four levels of solutions to cover the entire clinically significant range: low, normal and high.

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.

Radiometer QUALICHECK5 solution information can be entered by scanning the barcode provided in the package insert. Use the Scan button on this screen (or the optional external scanner) to automatically enter the solution ID, Lot, Expiration date and Ranges for each parameter.

QC Acceptability
An out of range QC result is indicated by marking the result with an arrow up or down to the left of the value. A down arrow indicates the results are below the control range and an up arrow indicates values above the control range. In addition, results on the screen are highlighted in red when they fall out of range. An out of range QC result that falls outside the statistical range is indicated by a red highlight (on the screen only) and a double arrow up or down to indicate above or below the range.

The QC plot displays results of all automatic and manual quality control measurements for each parameter and each solution level. All QC results are displayed in a bias plot. This bias plot charts the difference between the measured value and the assigned value for each parameter and each level (bias = measured – assigned). This plotting method allows for continual analysis and trending of analyte performance while eliminating variations due to solution lot changes. The screen provides the following information and controls:

- Parameter: This selection box includes right and left arrows to move sequentially through the list of possible parameters. It also provides a dropdown list to directly select one parameter.
- Solution ID: This selection box includes right and left arrows to move sequentially through the list of possible solutions. It also provides a dropdown list to directly select one solution ID.
- QC Result: This box contains detailed information regarding the highlighted data point on the graph. This data includes the analysis time, measured value, control range (in brackets), bias value (the actual value plotted), lot number and sensor cassette serial number.
Plot area: The plot area provides data over an 11-day period. The upper and lower control limits are represented by the upper and lower lines on the graph. The middle line represents zero bias from the assigned value. The date span is recorded at the bottom of the plot with the most recent date at the far right.

- Circular data points on the graph represent measured values that fell within the control range
- Single arrows on the graph represent values that fell outside the control range but are within the statistical range
- Double arrows on the graph represent values that fell outside both the control range and the statistical range (outlier)
- A triangle at the bottom of the graph represents a measurement that did not result in a numeric value, such as I/A (inactive) or N/C (not calculated)

Print icon: This button allows the user to print a copy of the plot displayed

Group of arrows: This group of arrows moves the cursor to the right or left by one data point, to the first or last point displayed, or adjusts the viewing window to the next or previous set of data points.

QC Statistics  The analyzer provides a series of statistical tables when reviewing automatic QC results.

Each tab on the screen provides information for one of the four solutions analyzed. The tabs are labeled with the solution ID numbers. The following information is provided for the currently installed solution pack:

- Lot: The solution pouch lot number
- n: The number of data points included in the statistical calculations
- Mean: The mean measured value of all data points for this parameter
- Mean Bias: The mean of the bias values (measured value – assigned value) for all data points for this parameter
- SD: The standard deviation of all measured data points for this parameter
- CV%: The coefficient of variation of all measured data points for this parameter

Each tab on the screen also provides the following historical information, which includes data for the current and last nine solution packs:

- n: The number of data points included in the statistical calculations
- Mean Bias: The mean of the bias values (measured value – assigned value) for all data points for this parameter
- SD Bias: The standard deviation of the bias values for all data points for this parameter

This statistical information may be printed by pressing the print icon at the bottom of the screen.
Troubleshooting Procedure

If the QC result is outside of the control range, perform the following:

- Ensure that all storage and handling criteria from the manufacturer's package insert have been followed for the quality control solutions.
- Ensure the correct QC ampoule temperature was entered into the QC Aspiration screen.
- Initiate a manual System Cycle (or two-point calibration) from the main menu.
- Re-analyze the failed QC level (using a new ampoule). Repeat a second time if necessary.
- If the failed QC level remains out of range, replace the sensor cassette.
- If the situation persists after replacing the sensor cassette, replace the solution pack.
- If the situation persists after both consumables have been replaced, contact your local Radiometer representative for assistance.

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.

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