Solution Pack, Sensor Cassette & Waste Disposal

Audience
All personnel in the Pulmonary Function Clinic.

Purpose
To define and identify a solution pack and sensor cassette. To comply with the local and state regulations while assuring proper disposal of solutions and waste from analyzer.

Policy
The following identifies the solution pack and sensor cassette for the ABL 80 FLEX CO-OX.

Solution Pack

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.

The four solutions contained in the pouches of the solution pack are used for calibration and quality control of all analytes and measured parameters. 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.

Quality management of the system is accomplished using the solution pack that contains multiple levels of precision tonometered electrolyte solutions packaged in gas tight disposable pouches.

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 pack can be installed onto an analyzer)
- Installation date (the date this solution pack was installed onto an analyzer)
- Analyzer serial number (the analyzer onto which this pack was installed)
- Number of allowable days in use
- True (calibration) values for each parameter
- Quality control assigned values and acceptable ranges for each parameter (not included in solution packs for the ABL80 FLEX analyzer with BASIC software configuration)
- Number of cycles for each pouch
- **Version**

**SP type**
- SP80 CO-OX is used in the ABL80 FLEX CO-OX analyzer (REF 944-252)

**Pouches**
The solution pack contains five pouches:
- Four pouches contain NIST traceable solutions with various concentrations of tonometered gases, electrolytes and metabolites
- Metabolites are not included in the SP80 for use with the BASIC software configuration
- Dyes are included in the SP80 CO-OX for use in the oximeter
- Only dyes are included in the SP80 CO-OX for use with the OSM software configuration. There are no tonometered gases, electrolytes or metabolites included.
- The fifth pouch collects all liquid waste, both from the internal solutions and all external solutions including the biohazardous bodily fluids from patient samples. The waste pouch contains an additive, which combines with the liquid waste to form a gel. This gel limits spillage and provides an added level of safety.

The solution pack contains the following components:

<table>
<thead>
<tr>
<th>Item</th>
<th>Part</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Install by date</td>
<td>The last day the solution pack can be installed</td>
</tr>
<tr>
<td>2</td>
<td>Lot number</td>
<td>The lot number of the solution pack</td>
</tr>
<tr>
<td>3</td>
<td>Smart chip</td>
<td>Provides and records specific information pertaining to the solution pack</td>
</tr>
<tr>
<td>4</td>
<td>Solution ports</td>
<td>Access ports for the pouch solutions for use in the analyzer</td>
</tr>
<tr>
<td>5</td>
<td>Waste port</td>
<td>Entry point of waste fluids into waste pouch</td>
</tr>
<tr>
<td>6</td>
<td>Solution pouches</td>
<td>Contain NIST traceable solutions; each pouch contains a unique lot of solutions</td>
</tr>
<tr>
<td>7</td>
<td>Waste pouch</td>
<td>Contains all waste fluids</td>
</tr>
</tbody>
</table>

Temperature 2-25°C or 36-77°F
Expiration date, Lot No. and bar code are printed on side of container – stable for 30 days

The solution composition for the ABL80 FLEX CO-OX solution pack (with CO-OX software configuration) is comparable to the concentrations listed in the table in 04-01. One exception is cCl⁻ in solution 4, which has a concentration of
approximately 74 mmol/L. In addition, dye is present in solution 2 and solution 4 for use in the oximetry system.

**NOTE:** The analyzer will automatically initiate a solution pack verification check following solution pack replacement when there is a sensor cassette installed. This check verifies the integrity of the new solution pack.

### Sensor Cassette

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, blood gas, electrolytes and glucose are contained in a multi-use disposable cassette assembly. The cassette flowcell 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
- Compatible analyzer configuration (the type of analyzer that the sensor cassette can be installed on)
- 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 an analyzer)
- Analyzer serial number (the analyzer onto which this cassette is currently installed)
- Expiration date (date this sensor cassette will expire once installed)

**SC type**

- SC80 CO-OX sensor cassettes are for use in the ABL80 FLEX CO-OX analyzer

The table below describes the function of the parts.

<table>
<thead>
<tr>
<th>Item</th>
<th>Part</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Sensor window</td>
<td>Allows viewing of the measuring chamber. All measuring sensors are located here. Cassettes compatible with the</td>
</tr>
</tbody>
</table>
OSM software do not include a sensor window.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>2</td>
<td>Inlet probe</td>
</tr>
<tr>
<td>3</td>
<td>Inlet handle</td>
</tr>
<tr>
<td>4</td>
<td>Guide</td>
</tr>
<tr>
<td>5</td>
<td>Release latch</td>
</tr>
</tbody>
</table>

**Waste Disposal**

Solution Pack and Sensor Cassettes contain biohazardous solutions and will be disposed of in a RED Biohazard Box (located near analyzer). All waste liquids are transported to the waste pouch contained in the solution pack. This includes blood sample waste. All used solution packs should be considered a biohazard and handled in an appropriate manner. Procedure will be logged on ABL80 FLEX Events Log. Therapist disposing of waste will also document on the ABG Communication Log date, time and action of procedure.

**NOTE: PERSONAL PROTECTIVE EQUIPMENT (PPE) should be worn while performing this task.**

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.

<table>
<thead>
<tr>
<th>Date</th>
<th>Approved by:</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/14</td>
<td>A. Duarte, MD</td>
<td>Medical Director Pulmonary Laboratory</td>
</tr>
<tr>
<td></td>
<td></td>
<td>New policy</td>
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