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 90 FLEX PLUS.

Solution Pack

The ABL90 FLEX analyzer solution pack provides the necessary information to the analyzer and performs functions including calibration of sensors, quality control, evaluation of accuracy and precision, rinse of measuring system and collection of waste from the analyzer.

Specifications

Specification	Details
Number of activities	Depends on the Solution Pack version. An activity can be a patient or QC measurement, a calibration or a rinse.
Storage temperature	2-25 °C
Storage humidity	20-80 %
Shelf life	Stable until expiration date printed on Solution Pack label
On-board stability	30 days
Expiration date	See the date printed on the Solution Pack label
Contents	• 3 pouches with quality control material • 3 pouches with calibration material • 1 pouch with gas mixture • 2 pouches to hold waste
Chemical composition	Reactive ingredients: See table below. Other ingredients: Biological buffers, salts, enzyme, heparin, surfactant, preservative
Certificates of Traceability	Available by local Radiometer representative
Safety data sheet (SDS)	Available in QA digital shared drive.

Approximate volumes and levels of measurands in the solution pack

Type	Name	Volume (ml)	pH	pCO2mmHg	pO2mmHg	ctHb
S9030	QC1	200	7.2	30	180	0
S9040	QC2	100	6.8	67	N/A	8
S9050	QC3	100	7.5	20	20	12
S1920	CAL 1	200	7.30	35	180	N/A
S1930	CAL 2	100	6.8	N/A	N/A	N/A
S1940	CAL 3	100	N/A	80	N/A	0

Chemical composition of the gas mixture in the solution pack

Volume (mL)	Reactive ingredients		
150 (at sea level)	O2 % = 42.07	CO2 % = 5.61	N2 = 52.32

For optimum sensor performance of the analytical system of the ABL90 FLEX analyzer, a regular changing of solution in the measuring chamber is required. The prescheduled calibration and QC activities are used to fulfill this need and are targeted at maximizing all the solutions in the solution pack. The analyzer uses a solution pack for calibrations, QC, rinse procedures and collection of waste.

Calibration: 3 separate solutions	Used for calibration of each parameter at two analyte concentration levels. The calibration solutions are Cal1, Cal2 and Cal3.
QC solution: Three separate solutions and a gas pouch	Dedicated for QC to cover low, normal and high concentration levels on all measured parameters to represent the relevant physiological measuring range. The gas pouch – for calibration.
Waste pouch	For waste.
Writable chip	Contains all lot-specific solution information.
Solution flow selector	Determines the solution flow. Solution pump Pumps the solutions through the wet section.

Each solution (calibration or QC) has a unique lot number. At the time of production, the actual analyte concentration, the age of the solution and the lifetime of each solution are included in the solution pack smart chip. To ensure a correct assigned value at the time of solution pack installation, adjustments are made after a decay factor evaluation. This is done when the solution pack is installed on the analyzer. The solution pack barcode label contains information about the solution pack lot number that identifies the solution packs assembled in one production lot and includes the expiration date to prevent installation after the expiration date. A solution pack has an in-use lifetime for up to 30 days or until no more activities is left or expiration date is exceeded. Sensor cassettes also have a maximum onboard lifetime of 30 days, dependent on throughput, and cannot be installed after the expiration date.

Sensor Cassette (SC)

Specifications

Specification	Details
Number of tests	Depends on the Sensor Cassette version
Storage temperature	2-8 °C
Storage humidity	20-80 %

Shelf life	When kept in sealed container, Sensor Cassette is stable until expiration date printed on the label of the pack.
On-board stability	30 days Expiration date See date printed on the label of the pack
Contents	One Sensor Cassette in a sealed container.

Upon receiving any controls, solution packs, and/ or sensor cassette from manufacturer, therapist receiving the items will write a ”received” date and ”expiration” date in permanent marker on outside of items. Sensor cassettes will be stored in designated refrigerator per manufacturer guidelines.

Temperature Sensitivity

Maintaining temperature for consumables is important to ensure the accuracy of contents. Therefore, a consumable (sensor cassette, solution pack, or quality control) that is noted to be out of temperature range will be discarded. If analyzer requires a consumable at that time, the analyzer will not process patient samples and will be placed in “down time” until additional new consumables are obtained. Temperature is monitored with a non-certified thermometer and hygrometer for temperature and humidity. A new monitoring device is purchased annually to maintain accuracy.

Waste Disposal

Solution Packs 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. Dispose and handle all used sampling devices, quality control (QC) ampoules, Solution Packs, Sensor Cassettes, Inlet Probes, Inlet Gasket Holders, Inlet Connector Gaskets, and Inlet Modules as biohazardous waste. Unused ore remaining QC used should go into Blue Biohazard Box, and all others into Red Biohazard Boxes as per institutional policy. The disposal of these consumables will be logged on ABL90 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.

Date	Approved by:	Signature
4/14	**A. Duarte, MD** **Medical Director Pulmonary Laboratory** **New policy**	
7/16	**A. Duarte, MD** **Medical Director Pulmonary Laboratory**	

No changes to policy

11/17 **A. Duarte, MD**
Medical Director Pulmonary Laboratory
No changes to policy

8/19 **A. Duarte, MD**
Medical Director Pulmonary Laboratory
No changes to policy

8/21 **A. Duarte, MD**
Medical Director Pulmonary Laboratory
No changes to policy

8/22 **A. Duarte, MD**
Medical Director Pulmonary Laboratory
Changes to policy

8/23 **A. Duarte, MD**
Medical Director Pulmonary Laboratory
Changes to policy