Radiometer ABL90 FLEX PLUS Operations and Maintenance

Purpose

This procedure provides instructions on ionized calcium testing on the Radiometer ABL90 FLEX PLUS. It includes instructions for processing, storing, and testing specimens, as well as procedures for instrument calibration, quality control, and maintenance.

Principle

The Radiometer ABL90 FLEX PLUS is a sophisticated medical instrument that uses the Ion Selective Electrode (ISE) measurement principle to precisely determine electrolyte values. This test system is a modified-FDA cleared, high complexity assay.

Scope

This procedure is intended for trained Clinical Laboratory Scientists.

Safety Precautions

All staff members performing these procedures must adhere to regional and local workplace safety policies. These will include but may not be limited to:

- Equipment safety, proper body mechanics, sharps exposure
- Proper use of gloves/personal protective equipment while performing these procedures
- Proper handling of regular and biohazardous waste
- Proper cleaning of work area
- Proper handwashing
- Proper storage and disposal of chemical hazardous waste

Policy

The list below states the policies followed by the organization.

- Do not use expired materials.
- Tests must be performed by testing personnel who have been trained and found competent to perform the procedure.
- The laboratory participates in the following CAP proficiency testing survey: AQ.
- The laboratory director or designee reviews quality control (QC) and instrument maintenance records at least monthly.

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Policy, continued

- The laboratory establishes or verifies acceptable ranges for QC materials prior to use.
- If more than one instrument is in-use, the laboratory checks the instruments against each other at least twice a year for comparability of results.
- The laboratory reports results above or below the AMR as "greater than" or "less than" the limits of the AMR.
- The laboratory verifies the AMR at least every six months.

Specimen Storage and Stability

See the table below for specimen storage temperature and stability.

Specimen Source	Storage Temperature	Stability
Serum (tightly capped)	15 - 30°C	24 hours
	2 - 8°C	7 days

NOTE:

- Centrifuge tubes within 4 hours of collection.
- Do not open specimen tubes until they are ready to test. Prolonged exposure to air may cause a decrease in ionized calcium.
- Ensure samples come to room temperature prior to testing.
- Analyze specimen within 10 minutes of de-capping.

Specimen Rejection

The following specimens will be rejected:

- Specimens improperly labeled
- Specimens collected in the wrong tube
- Specimens not meeting storage and stability requirements
- Specimens not stored tightly capped prior to testing
- Hemolyzed specimen

Equipment

- Radiometer ABL90 FLEX PLUS Analyzer
  – Operating Temperature: 15 - 32°C
  – Operating Humidity: 20 – 80%
- Printer Paper (984-070): Onelink #10460292
- Lint-free, non-ionic paper (Kimwipe)
- Sample cups, generic
- Inlet connector gasket (834-662): Onelink #10437114
- Inlet connector gasket holder (903-585): Onelink #10802597

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Radiometer ABL90 FLEX PLUS Operations and Maintenance,
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Reagents / Materials

The following contains the list of reagents/materials required.

Description	Vendor	OneLink	Storage
Solution Pack SP90 944-157 (680 activities) SP90XL 944-457 (980 activities)	Radiometer	 10322045 10646875	2-25°C Onboard Stability: 30 days
Sensor Cassette 946-013	Radiometer	10368573	2-8°C Onboard Stability: 30 days
Cal Ver LQ Blood Gas K727M-5	AUDIT	10627456	2-8°C Equilibrate ampoules at room temperature (15-30°C) for at least 1 hour. Ampoules must be tested within 1 minute of opening.

Calibration

Calibration is performed automatically every 24 hours and in connection with replacements, troubleshooting and startup.

To perform a calibration/recalibration manually:

Step	Action
1	Tap **Menu** > **Analyzer Status**
2	Tap the **Calibrations** button
3	Select **Calibration** as the **Calibration Type**
4	Tap the **Calibration** button
5	The symbols in the **Status** column of the **Calibration log** screen show the overall status of each calibration. **Symbol** / **Description** ✓ The calibration was successful ? An error was found on one or more parameters
6	Document and evaluate results on the Calibration Log. Do not perform patient testing until calibration is verified.

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Radiometer ABL90 FLEX PLUS Operations and Maintenance,
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Quality Control Frequency

Three levels of controls are required to be run:
- Daily on each day of patient testing,
- After each sensor cassette change,
- After each solution pack change,
- After startup, and
- To verify instrument operation when unexpected results are obtained.

Quality Control Procedure

The analyzer uses the three levels of QC solution contained in the Solution Pack to do built-in QC measurements automatically at the required frequency.

Follow the steps below to perform an unscheduled quality control measurement:

Step	Action
1	Make sure analyzer is Ready.
2	Tap **Menu** > **Analyzer status** > **Quality control**
3	Select a QC solution in the Built-in QC field.
4	Tap the **Start QC** button.
5	The symbols in the Solution column of the Quality control part of the Analyzer status screen show the overall status of each QC measurement.

Symbol	Description
✓	The QC measurement was successful
?	An error was found on one or more parameter result.

Quality Control Troubleshooting

Follow the steps below to troubleshoot out-of-range quality control results:

Step	Action
1	Tap **Menu** > **Data logs** > **Quality control log**.
2	Select the measurement marked with a message.
3	Tap the **Result** button.
4	Tap the **Messages** button.
5	Select the message.
6	Tap the **Troubleshoot** button.
7	Follow the instructions on the screen.
8	• If quality control results are still unacceptable after following all analyzer troubleshooting instructions, call Radiometer America Technical Support (800) 736-0600 and notify a Lead/Manager. • Take instrument out of service and do not perform patient testing until the issue is resolved.
9	Document all corrective actions on appropriate log

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Radiometer ABL90 FLEX PLUS Operations and Maintenance, Continued

Quality Control Range Verification

Assayed control ranges for new lots of built-in controls are verified each time a new solution pack is inserted.

Follow the steps below to verify the quality control ranges:

Step	Action
1	Run QC on the new solution pack (performed automatically).
2	Verify QC results are within the expected range.
3	If results are within the expected range, the manufacturer control range has been verified and can be used as the acceptable control range.
4	Review QC data monthly to see if any adjustments need to be made to the set ranges.

Startup / Shutdown of Analyzer

Follow the steps below to start up or shut down the analyzer

Step	Action
	Startup Procedure
1	Push the power switch to the **On** position **(I)**.
2	If the analyzer does not restart, press the standby button on the back of the analyzer.
	Shutdown Procedure
3	**NOTE:** If the analyzer is shut down for more than 2 hours, the Sensor Cassette must be replaced.
4	Tap **Menu** > **Utilities** > **Temporary shutdown**.
5	Tap the **Confirm shutdown** button.
6	Wait until the Windows program tells you that it is shutting down.
7	When Windows program has shut down, push the analyzer power switch to the **Off** position **(O)**.

Patient Test Procedure

Follow the steps below to perform a patient test.

Step	Action
1	Don appropriate PPE.
2	Verify the correct order is placed for the sample: **CALCIUM, IONIZED [82330C]**
3	Make sure the analyzer is **Ready.**
4	Uncap the sample and pour into a sample cup.
5	Hold the sample cup and tap the **Syringe** button. The analyzer opens the inlet. **NOTE**: If performing Proficiency Testing, select **Other modes > Prof. Test.**

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Radiometer ABL90 FLEX PLUS Operations and Maintenance, Continued

Patient Test Procedure, Continued

Step	Action
6	Follow the instructions on the screen.
7	Place and hold the lip of the sample cup against the collar of the Inlet Gasket.
8	Push the sample cup into the analyzer as far as it will go and hold it there. **NOTE:** Make sure that the probe extends into the sample and stays there during sample aspiration.
9	Hold the sample cup in the pushed-in position until the analyzer tells you to remove it. When the analyzer tells you to, remove the test tube. The analyzer closes the inlet.
10	Scan/Enter the sample accession number in the Patient identification screen. If the Patient result screen opens before you have entered the necessary data, tap the **ID** button. **NOTE**: During Cerner downtime, ensure at least two unique patient identifiers are entered when programming samples.

Reference Range

See table below for ionized calcium reference ranges:

Source	Age Range	Reference Range (mmol/L)
Serum	0 – <18 years	1.10 – 1.50
	≥18 years	1.15 – 1.33

Reportable Range (AMR)

0.50 – 2.48 mmol/L

Troubleshooting

If unexpected/questionable results are obtained, or if an analyzer issue is suspected:

- Refer to Troubleshooting section in Radiometer ABL90 FLEX PLUS Instructions for Use
- Contact Radiometer America Technical Support (800) 736-0600
- Notify a Lead/Manager
- Document all issues and corrective actions
- Do not perform patient testing until the issue is resolved

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Radiometer ABL90 FLEX PLUS Operations and Maintenance, Continued

Downtime Procedure

The table below describes different downtime scenarios and potential procedures to continue operations.

If ...	Then, as applicable...
The analyzer becomes inoperable	• Use an alternative analyzer, or • Send samples to another Medical Center
Cerner is down	• Manually order tests on the analyzer using downtime barcode and at least two unique patient identifiers • Review results for acceptability • Manually print/fax patient reports from the analyzer to requesting departments as needed • Reconcile results once Cerner is back in service
KP HealthConnect is down	• Manually order tests in Cerner using downtime requisition forms.

AMR Verification

AMR verification is performed:

- At least every six months,
- When QC shows an unusual trend, shift, or is outside acceptable limits, and the system cannot be corrected to bring control values into the acceptable range, and
- After major preventive maintenance or change of a critical instrument component

To perform AMR verification:

Step	Action
1	Allow AUDIT Cal Ver LQ Blood Gas solutions to equilibrate to room temperature for a minimum of 1 hour prior to measurement.
2	Before sampling, hold the top of the ampule and shake gently. Then, with light tapping, restore all liquid to the bottom.
3	Check that the analyzer is in the **Ready** mode
4	Select **Syringe** and select the **Cal. Verification** mode on the screen.
5	Using the QC Adapter to break open the vial carefully.
6	Place the QC Adapter tip against the inlet gasket and press it upwards. The probe extends into the ampoule and the solution is automatically aspirated.

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Radiometer ABL90 FLEX PLUS Operations and Maintenance, Continued

AMR Verification, Continued

Step	Action
7	Be careful not to bend the probe. Hold on to the adapter when removing the ampoule.
8	When prompted by the analyzer, remove the adapter and close the inlet. Enter information on the Patient ID screen using a dedicated identifier for each solution (e.g. Level1, Level2, etc.).
9	Repeat steps until all levels have been completed in triplicate.
10	Document and evaluate results. Do not perform patient testing until AMR is verified. **Acceptability Criteria:** Calculated mean for each level within TAE of target value.

Instrument Comparison (if applicable)

If more than one instrument is in use, an instrument comparison is performed using one of the following methods at least twice per year:

- Split patient sample studies
- Participation in CAP Quality Cross Check program AQQ.

Follow the steps below to perform an instrument comparison:

If ... — **Then ...**

Performing split patient sample studies

Step	Action
1	Gather at least 5 serum patient specimens (if possible, include both results within and outside the reference ranges). Note: Reference materials validated to have the same response as fresh human specimens may be used when availability or pre-analytical stability of patient specimens is a limiting factor.
2	Follow patient testing procedure to analyze specimens on all analyzers being compared.
3	Compare results. At least 90% of results must be within total allowable error to be acceptable (see **Total Allowable Error** below).

Participating in a CAP Quality Cross Check program

Step	Action
1	Follow CAP Kit Instructions to analyze Quality Cross Check specimens on the analyzers being compared. Submit results to CAP.
2	CAP will evaluate results and send a report.
3	Use CAP acceptability criteria to assess acceptability.

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Radiometer ABL90 FLEX PLUS Operations and Maintenance, Continued

Total Allowable Error (TAE)

± 0.07 mmol/L

Maintenance / Cleaning

Frequency	Required Maintenance
Daily	Clean the inlet gasket
	Clean the analyzer exterior
Semi-Annual (every 6 months)	Replace the inlet gasket holder
	Replace the inlet connector gasket

NOTE: Document completion of maintenance tasks on the maintenance log.

Daily Maintenance: Clean the inlet gasket

Follow the steps below to perform the cleaning and conditioning cycle.

Step	Action
1	Tap **Menu** > **Analyzer status**.
2	Tap the **Other activities** > **Inlet check** > **Clean inlet gasket** buttons.
3	Tap the **Press to start video guidance** button. The analyzer opens the inlet.
4	Make sure the Inlet Probe is not bent. If it is bent, replace it.
5	Dampen a lint-free cloth with water.
6	Tap the **Action completed button**.
7	Gently wipe the inlet gasket and the area around it until it is clean.
8	Tap the **Action completed button**. The analyzer closes the inlet.

Daily Maintenance: Clean the analyzer exterior

Follow the steps below to perform the cleaning and conditioning cycle.

Step	Action
1	Lightly dampen a lint-free cloth with tap water.
2	Put your finger on a part of the screen that is not active and hold it there.
3	Gently wipe the screen.

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Radiometer ABL90 FLEX PLUS Operations and Maintenance,
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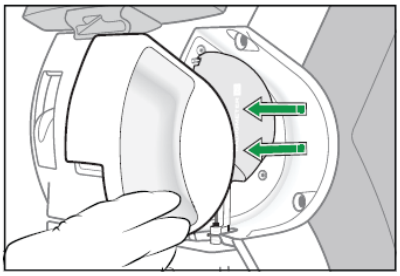
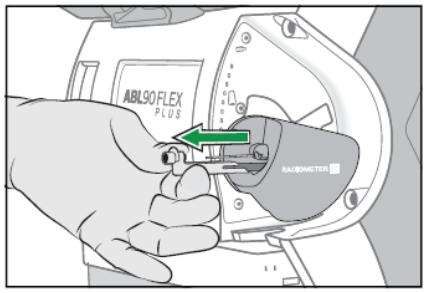
Semi-Annual Maintenance: Replace the inlet gasket holder

Follow the steps below to perform the cleaning and conditioning cycle.

Step	Action
1	Tap **Menu** > **Analyzer status**.
2	Tap the **Other activities** > **Inlet check** > **Repl. Inlet Gasket Holder** buttons.
3	Tap the **Press to start video guidance button**.
4	Pull off the inlet cover. 
5	Tap the **Action completed** button. The analyzer opens the inlet.
6	Pull out the Inlet Gasket Holder. 
7	Tap the **Action completed** button. Put the new Inlet Gasket holder over the slide and insert it. Make sure that the Inlet Probe is in the center of the gasket.
8	Tap the **Action completed** button. The analyzer closes the inlet.
9	Put on the inlet cover. Tap the **Action completed** button.

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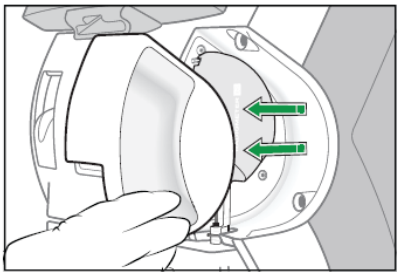
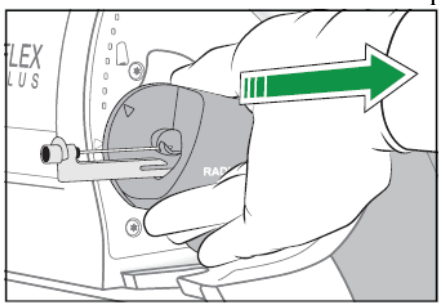
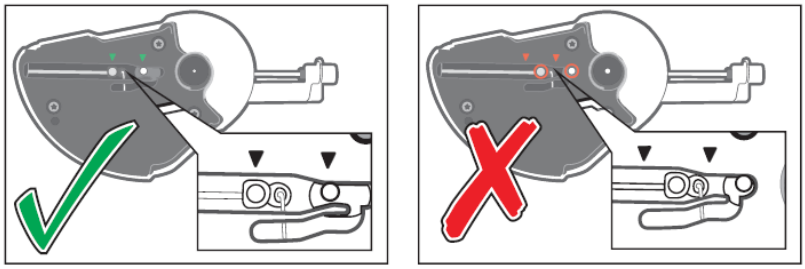
Radiometer ABL90 FLEX PLUS Operations and Maintenance,
Continued

Semi-Annual Maintenance: Replace the inlet connector gasket

Follow the steps below to perform the cleaning and conditioning cycle.

Step	Action
1	Tap **Menu** > **Analyzer status**.
2	Tap the **Other activities** > **Inlet check** > **Repl. Inlet connector gasket** buttons.
3	Tap the **Press to start video guidance button**.
4	Pull off the inlet cover. 
5	Tap the **Action completed** button. The analyzer opens the inlet.
6	Hold the Inlet Module as shown and pull it to the right. 
7	Make sure that the tabs on the inner side of the Inlet Module are in the correct position. 

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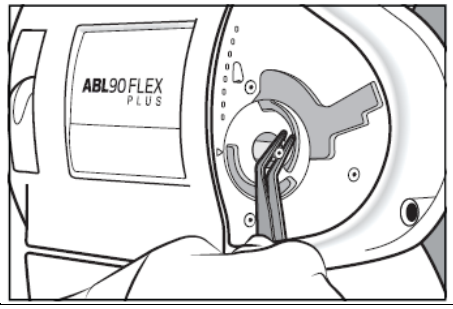
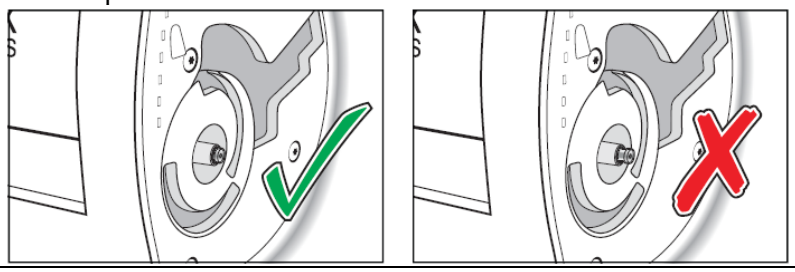
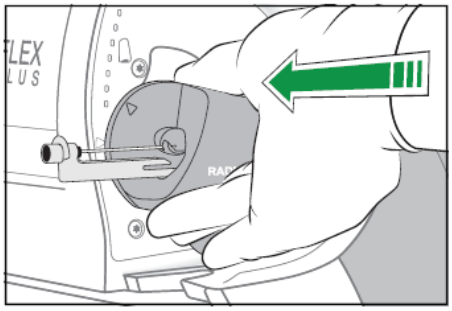
Radiometer ABL90 FLEX PLUS Operations and Maintenance, Continued

Semi-Annual Maintenance: Replace the inlet connector gasket, Continued

Step	Action
8	Tap the **Action completed** button. Pull out the Inlet Connector Gasket with a pair of tweezers. 
9	Tap the **Action completed** button. Put tap water on the new Inlet Connector Gasket.
10	Tap the **Action completed** button. Push the new Inlet Connector Gasket in place as shown. 
11	Tap the **Action completed** button. When the analyzer tells you to, hold the Inlet Module as shown and push the end into the inlet connector until it clicks in place. 
12	Tap the **Action completed** button. The analyzer closes the inlet. Put on the inlet cover.
13	Tap the **Action completed** button.

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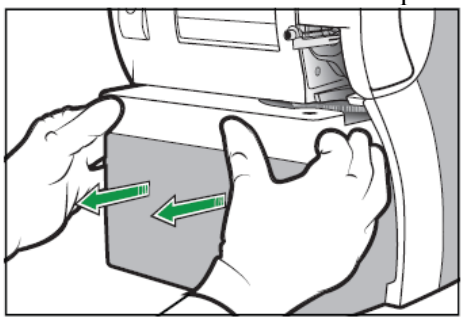
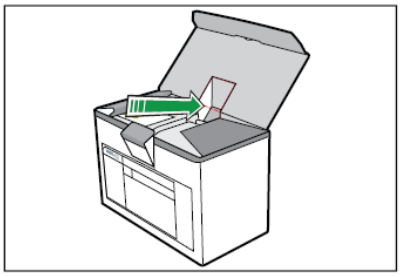
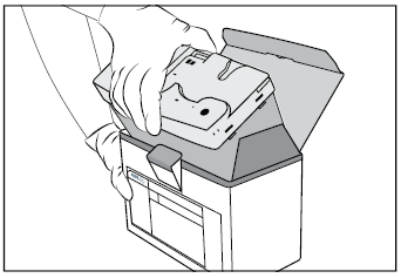
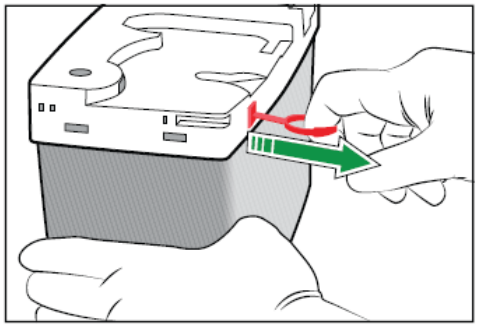
Radiometer ABL90 FLEX PLUS Operations and Maintenance,
Continued

Solution Pack Replacement

Follow the steps below to change the Solution Pack.

Step	Action
1	Tap **Menu** > **Analyzer status**.
2	Tap the **Consumables** > **Replace** > **Solution Pack** buttons.
3	Tap the **Press to start video guidance** button. The analyzer opens the inlet.
4	Wait until the Solution Pack is released.
5	Remove the Solution Pack and dispose of it as biohazardous waste. 
6	Lift the new Solution Pack out of its box as shown.  
7	Pull the red pin out of the new Solution Pack. 

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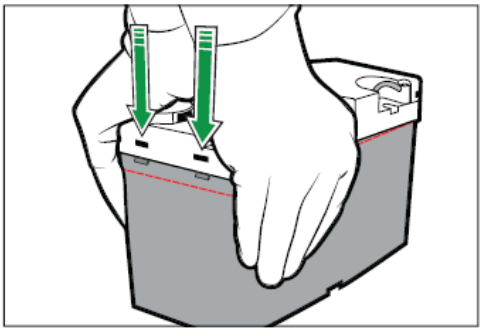
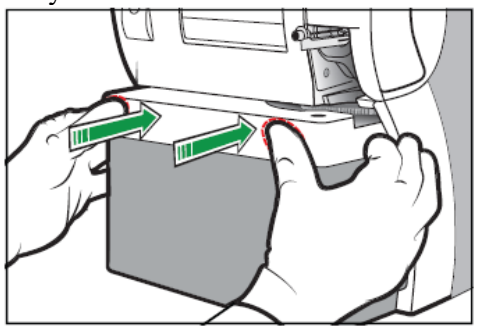
Radiometer ABL90 FLEX PLUS Operations and Maintenance, Continued

Solution Pack Replacement, Continued

Step	Action
8	Put the palms of your hands over the edges of the lid as shown. 
9	Press down firmly and evenly with both hands until the tabs click into the 2 holes. **NOTE:** For the Solution Pack to be activated correctly, both tabs must click in place.
10	Tap the **Action Completed** button.
11	Put your thumbs on the white part of the Solution Pack and push the Solution Pack into its compartment until it clicks in place. The analyzer closes the inlet. 
12	Enter necessary data. Tap the OK button. **NOTE:** A Solution Pack removed from one analyzer can be used on another if these 3 conditions are met: • the Solution Pack is installed before its Scheduled to replace date • the Solution Pack is installed before its Expiration date • the Solution Pack has some remaining activities This data can be seen in the Solution Pack Status screen.

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Radiometer ABL90 FLEX PLUS Operations and Maintenance,
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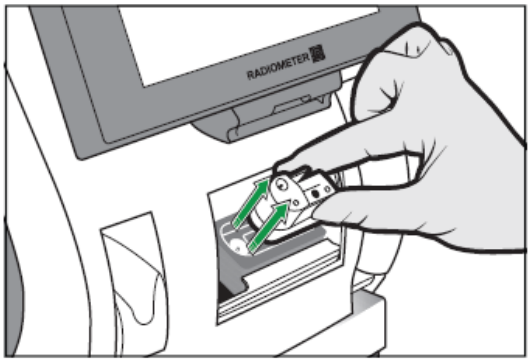
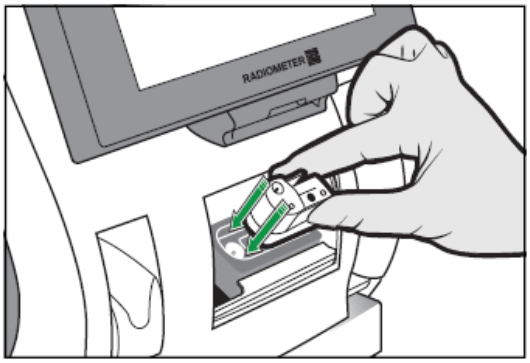
Sensor Cassette Replacement

Follow the steps below to change the Solution Pack.

Step	Action
1	Tap **Menu** > **Analyzer status**.
2	Tap the **Consumables** > **Replace** > **Sensor Cassette** buttons.
3	Tap the **Press to start video guidance** button.
4	Wait until the Sensor Cassette compartment opens.
5	Remove the Sensor Cassette and dispose of it as biohazardous waste. 
6	Tap the **Action Completed** button. Pull the foil off the new Sensor Cassette Pack, unscrew the lid and lift out the Sensor Cassette.
7	Tap the **Action Completed** button. Press the new Sensor Cassette in place. 
8	Tap the **Action Completed** button. Enter the necessary data.

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Radiometer ABL90 FLEX PLUS Operations and Maintenance, Continued

Sensor Cassette Replacement, Continued

Step	Action
9	Tap the **OK** button. **NOTE:** A Sensor Cassette removed from one analyzer can be used on the same or on another ABL90 FLEX PLUS analyzer if these 6 conditions are met. • The Sensor Cassette is kept right side up after its removal. This prevents damage to the sensors. • The Sensor Cassette is installed within 2 hours of its removal • The Sensor Cassette is installed before its Scheduled to replace date • The Sensor Cassette is installed before its Expiration date • The Sensor Cassette has some remaining activities • The Sensor Cassette was not removed from an analyzer during a long-term shutdown procedure This data can be seen in the Sensor Cassette Status screen.

Limitations

The following list describes known limitations with ionized calcium testing:

- For serum ionized calcium testing, anaerobic conditions must be maintained prior to testing. Contact with ambient air will cause a loss of CO2 in the sample and the subsequent rise in pH will cause a reduction in ionized calcium.
- Some medications and endogenous substances may affect results (see **Interfering Substances**). Clinicians must evaluate results based on the patient's entire clinical situation.

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Radiometer ABL90 FLEX PLUS Operations and Maintenance,
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Interfering Substances

The following table lists known interfering substances and their approximate effects on Radiometer ABL90 FLEX PLUS ionized calcium testing. For a full list of substances tested, please refer to the Operator's Manual.

Interfering Substance	Test Concentration	Effect on iCA at 1.25 mmol/L
Benzalkonium chloride	7.5 mcg/mL	+0.14
	10 mcg/mL	+0.18
	15 mcg/mL	+0.27
	30 mcg/mL	+0.62
Bilirubin (conj)	Up to 23.4 mg/dL	No interference
Bilirubin (unconj)	Up to 29.2 mg/dL	No interference
Hemolysis	2%	-0.08
	5%	-0.16
	10%	-0.23
	20%	-0.37
Intralipid	Up to 1000 mg/dL	No interference
Leflunomide	75 mg/L	-0.05
	150 mg/L	-0.09
	225 mg/L	-0.14
	300 mg/L	-0.19
Magnesium	<28 mEq/L	No interference
	30 mEq/L	-0.02
pH	6.8-8.8	-0.04 / pH
Sodium	180 mEq/L	+0.03
Teriflunomide	150 mg/L	No interference
	225 mg/L	-0.04
	300 mg/L	-0.11
Zinc	1111 mcg/dL	+0.02

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Radiometer ABL90 FLEX PLUS Operations and Maintenance,
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Non-Controlled Documents

The following non-controlled documents support this policy:

- Clinical and Laboratory Standards Institute (CLSI), Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling, CLSI guideline C31-A2.
- College of American Pathologists, All Common and Chemistry Testing Checklist
- Radiometer ABL90 FLEX PLUS Instructions for Use
- AUDIT Cal Ver LQ Blood Gas Package Insert

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