RADIOMETER

ABL90 FLEX PLUS analyzer

Operator Training Guide

Index

Limitations of use

About hazards

A hazard symbol shows which instructions an operator must obey to prevent risk to persons or equipment. There are 2 types of hazard.

Hazard type	Hazard symbol	Risk
WARNING	⚠	Death or injury to persons
CAUTION	⚠	Equipment damage

About limitations of use

⚠ ***WARNING – Risk of making incorrect clinical decisions***

A clinician must always interpret patient test results in the relevant clinical context.

Note: Only analyze heparinized and electrolyte-balanced human whole blood samples or dedicated quality control material. If you analyze other sample types, you risk damage to the analyzer and incorrect results on subsequent samples.

No tests on animal blood have been done. Animal blood is different from human blood and the composition of the blood can be different within the same species.

Measurement of *F*HbF

The uncertainty in FHbF measurements exceeds the level that is necessary to measure normal HbF levels in the adult reference range (0-1%). The analyzer can measure FHbF hemoglobin in all types of sample, but the analyzer must be set up to apply an HbF correction to the results.

General warning and cautions

⚠ ***WARNING – Risk of infection***

Only let authorized personnel collect and work with blood samples. Make sure to wear gloves.

⚠ ***WARNING – Risk of electric shock***

Make sure the analyzer is a minimum of 1.5 m from patient beds.

⚠ ***WARNING – Risk of infection***

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. Follow your local regulations.

Introduction

Operator training

Even a simple process or task can become erroneous and complicated without proper and relevant training. To ensure satisfaction and efficient use of this Radiometer product we offer a range of training materials.

ABL90 FLEX PLUS analyzer Operator Training Guide

The operator training guide is a supporting tool for the person training the operators of the device. The guide includes information on how to handle various processes and tasks related to the device. In addition, there are suggestions as to when a task should be demonstrated by the trainer and when it should be performed hands-on by the operator.

Training materials offered for operator training:

Competency check lists to assist operator training on the analyzer.

Other training material

- Acute care testing handbook
- Blood gas preanalytics app

Handbooks can be downloaded from our handbooks at www.myradiometer.com or from www.radiometer.com as mobile applications for smart phones and tablets.

Analyzer overview

Identify the main parts of the analyzer

Printer and handle

Touch screen

Integrated barcode reader

Automatic sample mixing for *safe*PICO syringes (mixing takes seven seconds)

Inlet for sample aspiration

Sensor cassette compartment behind the door

Solution pack with waste pouch, reagents and QC. The QC is built-in and automatic for accuracy.

Fully operational on battery

Good results come from a good sample

General warnings and cautions

WARNING – Risk of infection

Only let authorized personnel collect and work with blood samples. Make sure that you wear gloves.

WARNING – Risk of infection

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. Follow your local regulations.

WARNING – Risk of infection

Make sure you do not prick or scratch yourself on the inlet probe.

What is a good sample?

Characteristics of a good sample (in sequential order)	Why are the characteristics important?
A recommended sampler is used	To prevent incorrect results
The sample is clearly and uniquely identified	To prevent a patient-sample mix-up
The sample is collected from a suitable site	To prevent incorrect results
A sufficient sample volume is collected	If there is no sufficient sample volume, the sample is lost
Air bubbles are removed immediately after collection	To prevent incorrect results
The sample is gently mixed immediately after air bubbles have been removed	To prevent clots in the sample. If there are clots in the sample, it cannot be analyzed by the analyzer.
The sample is not shaken	To prevent hemolysis of the sample. Hemolysis can cause bias on electrolytes, especially cK^+ and urea
The sample is gently mixed again just before it is analyzed	To have a homogeneous sample for the patient sample analysis. Inhomogeneous samples may cause incorrect results.
The sample is analyzed immediately after mixing	To prevent that the sample gets too old. **Note:** For the best results, good samples must be analyzed immediately. When this is not possible, samples must be stored correctly, gently mixed immediately before analysis and analyzed within the time period given in the storage recommendations.

Storage

Storage recommendations

These types of blood samples must be analyzed immediately after they are collected:

- Samples with increased leukocyte or platelet counts
- Samples with an atypical metabolism
- Fetal scalp samples
- Fast-clotting samples
- Samples with high pO_2 values should be analyzed within 5 minutes after they have been collected.

⚠ WARNING – Risk of biased results especially pO_2 results

Interpret with caution the results for samples in capillary tubes as the aerobic sampling technique may cause bias.

Samples that cannot be analyzed immediately after they are collected must be handled and stored correctly before they are analyzed.

Overview of storage recommendations

Sampling device	Type	Handling and storage temperatures	Analyze within this time period
Syringe	Plastic	Keep at room temperature	<30 minutes
Syringe	Glass	Keep at room temperature	<30 minutes
		Keep in water at 0-4 °C. **Note:** Do not keep the sample on ice as it can cause hemolysis	<60 minutes
Capillary tube	Plastic	Keep at room temperature. Samples in *safe*CLINITUBES capillary tubes deteriorates with increased storage time (greater variability of gasses and of tHb measurements).	<10 minutes
Capillary tube	Glass	Keep at room temperature	<10 minutes
		Keep the sample horizontal at 0-4 °C. **Note:** Do not keep the sample on ice as it can cause hemolysis bias on electrolytes, especially cK^+ and urea.	<30 minutes

Syringe samples – preanalytical errors

Sample collection and handling

Training method

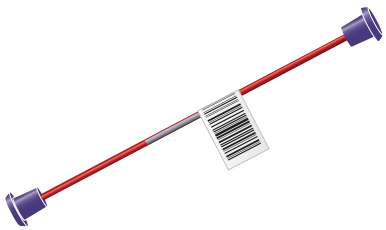
Take the trainee through the possible preanalytical errors and explain how "quality in" equals "quality out"- better sample quality will provide more accurate results.
Emphasize the importance of the following points and adjust your messaging according to local procedures. Demonstrate the steps whenever it seems helpful.

1. Stable respiratory condition

To get a true picture of the patient's respiratory condition the patient should ideally be in a steady state of ventilation:

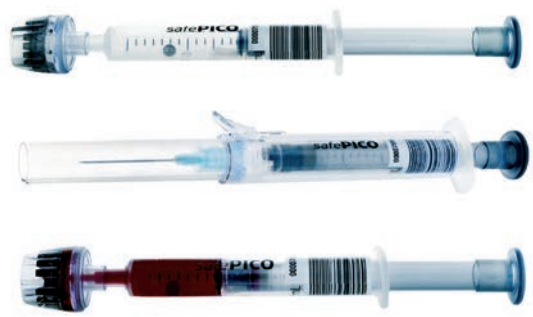
- Patients should be at rest for 5 minutes before sampling
- Ventilatory settings should be unchanged for 20 minutes before sampling
- Pain and anxiety can influence the state of respiration so this should be minimized whenever possible

2. Appropriate patient and sample identification



- Prevent mix-up or loss of samples
- Avoid re-sampling of patients
- Prevent misdiagnosis and wrong treatment
- Facilitate cross-charging
- Avoid litigation and lost billing opportunities

3. Appropriate preheparinized sampler with dry electrolyte-balanced heparin

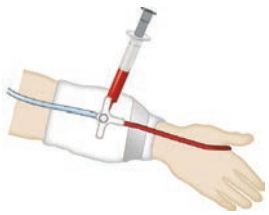


- Heparin is the only anticoagulant recommended by Radiometer
- Slows the clotting process
- If applicable, explain about the different types of heparin: dry electrolyte-balanced/dry non-electrolyte balanced/liquid
- Dry electrolyte-balanced heparin (Na^+, K^+, Ca^{2+}) is preferred

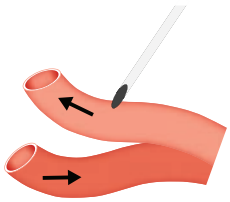
Syringe samples – preanalytical errors, continued

Sample collection and handling

4. Correct volume of blood

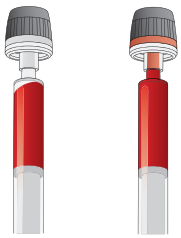


- Fill the sampler according to the recommended fill volume stated by the manufacturer
- Flush solutions used in A-lines must be removed from the sample site to avoid dilution of blood samples
- It is recommended to withdraw a volume equal to three to six times the "dead space" of the catheter system (follow A-line manufacturer's recommendations)



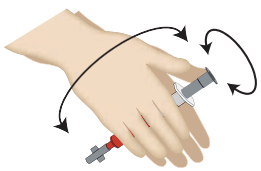
Be aware of possible mixtures of venous and arterial blood. If a self-filling syringe does not fill quickly, it may be because the needle punctured the back of the arterial wall and continued into a vein (with a lower pressure). In that case, a new sample should be taken.

5. Visually inspect sampler and expel all air bubbles



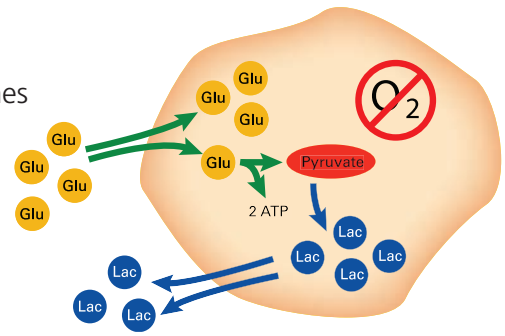
- Air bubbles can affect O_2 and CO_2 values
  For *safe*PICO syringes expel air bubbles through the vented *safe*TIPCAP
- Cap syringe to avoid contact with room air

6. Manual mixing or mixing using the integrated mixing device



Emphasize that mixing makes the sample more homogeneous:

- Mixing reduces sedimentation
- Hemolysis may cause $K^+\uparrow$, $Na^+\downarrow$,$Ca^{2+}\downarrow$ and Urea$\uparrow$
- When mixing manually, follow local guidelines
- Discuss how to mix a sedimented sample, follow local guidelines
- There is no real consensus as to how to invert a syringe – an easy way to mix manually is by rolling the syringe between your palms
- Emphasize that the integrated sample mixer is for *safe*PICO syringes only



7. Analyze quickly

- If not analyzed quickly, the sample will continue to metabolize, causing the following:

pO_2	↓	since O_2 will still be consumed
pCO_2	↑	since CO_2 will still be produced
pH	↓	due to change in CO_2
cCa^{2+}	↑	the change in pH will influence the binding of Ca^{2+} to protein
cGlu	↓	since glucose will be metabolized
cLac	↑	due to metabolism

Syringe samples – how to measure a patient sample

Training method

First, demonstrate how a sample is measured at real-time speed before doing a slow step-by-step demonstration. Let the trainee try the process – both with and without trainer guidance.
Emphasize how the analyzer provides feedback (sound and light indications) and provides on-screen guidance throughout the process.

1. Operator identification

- Sharing barcodes
- Accountability and traceability
- Patient records are kept according to local rules (usually records are kept for many years)

2. "Ready" mode

Point to the analyzer status field and explain how the analyzer will display current activity. The analyzer can only measure samples when the screen shows "Ready".

3. Introducing the sample

Present the following steps on how to introduce the sample.
Then the trainee:

1. Should repeat the steps as a practical exercise.
2. Should be informed that the analyzer will guide with on-screen video, sound and instructions during the process.

During patient sample analysis, make sure that the inlet probe does not touch the plunger of or the fiber disk in the syringe as this may cause the sample to be aspirated incorrectly.
If there is <1.1 mL in a PICO50 sampler or <0.7 mL in a PICO70/*safe*PICO70 sampler, you must be careful with this.

If you have very little sample dead space, consider using the short probe measurement mode.
To avoid bending the inlet probe, hold the sampling device still during sample analysis. If the inlet probe is bent, do not use the analyzer for sample analysis.
If the sample is in a *safe*PICO syringe with a *safe*TIPCAP cap, do not remove the *safe*TIPCAP cap during sample analysis.

Once the inlet is opened, you only have a short time to complete the actions necessary.

Syringe samples – how to measure a patient sample, continued

⚠ WARNING - Risk of incorrect results

- Gently mix the sample to make sure that it is homogeneous.

- Hold the syringe by its barrel.

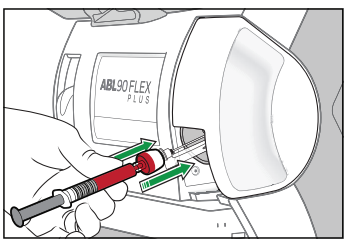
- Press the **Syringe** button.
  The analyzer opens the inlet.

- If measurement mode can be selected, select measurement mode.
  Note: If you selected the wrong mode, tap the **Reselect** button and select the correct mode.
  Note: If the **Other modes** button is available, tap it to get access to more modes.

- Follow the instructions on the screen.

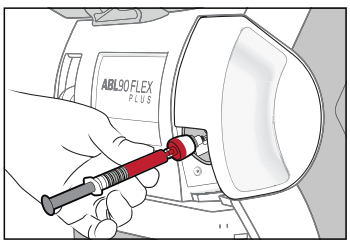
- Place and hold the tip of the syringe in the center of the inlet gasket.

- Push the syringe into the analyzer as far as it will go and hold it there.



⚠ WARNING - Risk of incorrect tHb results

- Hold the syringe in the pushed-in position until the analyzer tells you to remove it.



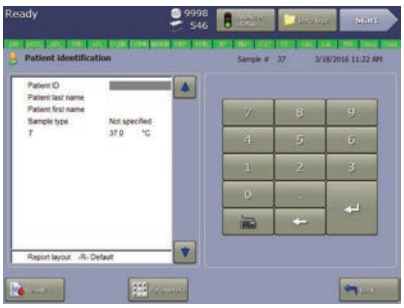
- When the analyzer tells you to, remove the syringe.
  The analyzer closes the inlet.

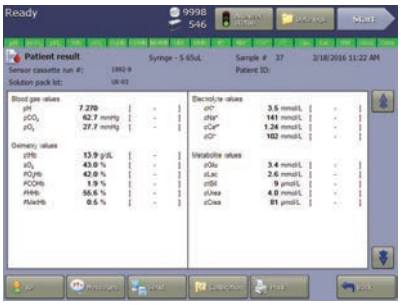
Syringe samples – how to measure a patient sample, continued

4. Appropriate patient information

If applicable, explain how to recognize a mandatory field by the pointing hand.

- You may be able to select measurement mode during sample analysis. If so, you must select a measurement mode, or the analyzer will automatically select the measurement mode set up as default in the setup.
- In the Patient identification screen, it is mandatory to enter data in fields with this icon: 
  The sample will be analyzed, but the results will not be available until data is entered.
- In the **Patient identification screen**, it is possible to change the report layout during sample analysis.





5. View results (on-screen, printout or local information system)

Discuss actions according to local guidelines.

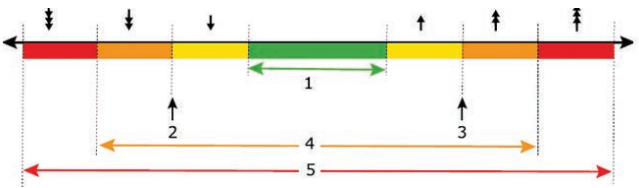
- Critical limits
- Error messages and symbols
- ? = Error
- Reference ranges
- Review printout

6. Documentation and reporting of results – Patient results log

- Result retrieval
- Filtering results (if required)
- Trend facility (if required)
- Acid-base chart

7. About ranges and critical limits

Measurement results are marked by symbols to show where they fall in relation to reference ranges, critical limits, and reportable ranges. The diagram illustrates these relationships.



1 Reference range
2 Lower critical limit
3 Upper critical limit
4 Reportable range
5 Range of indication

8. Log off the analyzer

- Demonstrate how to log off the analyzer manually and how the automatic logoff works
- Discuss the consequences of not logging off

Capillary tube samples – preanalytical errors

Sample collection and handling

Training method

Take the trainee through the possible preanalytical errors and explain how "quality in" equals "quality out" - better sample quality will provide more accurate results. Emphasize the importance of the following points and adjust your messaging according to local procedures. Demonstrate the steps whenever it seems helpful.

1. Stable respiratory condition

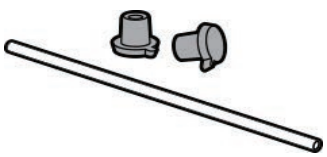
To get a true picture of the patient's respiratory condition, the patient should ideally be in a steady state of ventilation:

- Patients should be at rest for 5 minutes before sampling
- Ventilatory settings should be unchanged for 20 minutes before sampling
- Pain and anxiety can influence the state of respiration so this should be minimized wherever possible.

2. Appropriate patient and sample identification

- Prevent mix-up or loss of samples
- Avoid re-sampling of patients
- Prevent misdiagnosis and wrong treatment
- Facilitate cross-charging
- Avoid litigation and lost billing opportunities

3. Appropriate preheparinized 45 and 70 µL capillary tubes (*safe*CLINITUBES, plastic) or 100 µL capillary tubes (CLINITUBES, glass). **Note:** for analyzers configured to feature creatinine and urea the minumum capillary tube sample volume is 65 µL - C65 mode is applicable.



- Heparin is the only anticoagulant recommended by Radiometer
- Slows the clotting process
- If applicable, explain the different types of heparin: dry electrolyte-balanced heparin/dry non-electrolyte balanced heparin (Na^+, K^+, Ca^{2+}) are preferable
- If using capillary tubes coated with high-concentration sodium heparin, not recommended that you report electrolyte values
- Always gather everything you need before you start (capillary tube, two end caps, magnetic wire, magnetic mixer and an ABL90 FLEX clot catcher).
- Follow local guidelines.

4. Correct volume of blood

- Completely fill the capillary tube with blood
- Minimum size capillary tube is 45 µL when using micromode. When the analyzer is configured to feature creatinine and urea the minimum capillary tube volume is 65 µL
- Do not "milk" the tissue to avoid contamination of the sample with tissue fluid

Capillary tube samples – preanalytical errors, continued

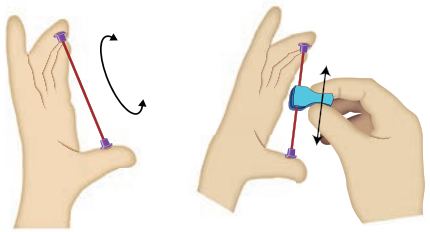
Sample collection and handling

5. Sample should be free of air bubbles

- Air bubbles can affect O_2 and CO_2 values
- Ensure the end caps match the type of capillary tube
- Cap both ends of the sample to avoid contact with room air

6. Mixing

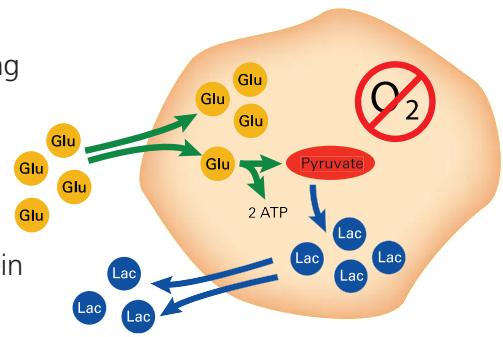
- Mix gently with the mixing wire and magnet to avoid hemolysis of the sample
- Hemolysis may cause $K^+\uparrow$, $Na^+\downarrow$, $Ca^{2+}\downarrow$ and Urea$\uparrow$.
- Mix along the full length of the capillary tube or mix manually by inverting the capillary tube



7. Analyze quickly

- If not analyzed quickly, the sample will continue to metabolize, causing the following:

pO_2	↓	since O_2 will still be consumed
pCO_2	↑	since CO_2 will still be produced
pH	↓	due to change in CO_2
cCa^{2+}	↑	the change in pH will influence the binding of Ca^{2+} to protein
cGlu	↓	since Glucose will be metabolized
cLac	↑	due to metabolism



Capillary samples – how to measure a patient sample

Training method

First, demonstrate how a capillary sample is measured in real-time speed before doing a slow step-by-step demonstration. Let the trainee try the process – both with and without trainer guidance. Emphasize how the analyzer provides feedback (sound and light indications) and provides on-screen guidance throughout the process.

1. Operator identification

- Sharing barcodes
- Accountability and traceability
- Patient records are kept according to local rules (traditionally kept for many years)

2. "Ready" mode

- The analyzer will always display current activity, e.g. QC measurement

3. Remove end caps and attach the ABL90 FLEX Clot Catcher

- Hold the capillary tube by the clot catcher for better control
- Ensure that the clot catcher is placed at the opposite end compared to the mixing wire

4. Introducing the sample

Present the following steps on how to introduce the sample. Then the trainee should repeat the steps as a practical exercise. Inform the trainee that the analyzer will guide with on-screen video, sound and instructions during the process.

Note: Once the inlet is opened, you only have a short time to complete the actions necessary.

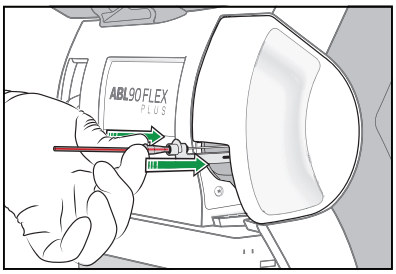
⚠ **WARNING – Risk of incorrect results**

Gently mix the sample to make sure that it is homogeneous.

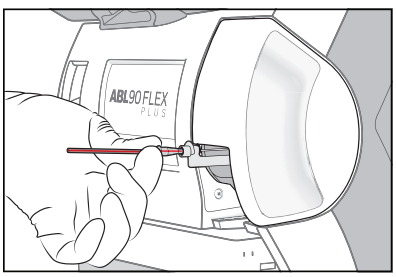
- Move the mixing wire to the end opposite to that from which the sample is to be aspirated.
  Note: If petroleum jelly, such as Vaseline, is used at the puncture area, introduce the capillary sample into the analyzer from the end without petroleum jelly.

Capillary samples – how to measure a patient sample, continued

- Hold the capillary tube and tap the **Capillary** button. The analyzer opens the inlet.
- If measurement mode can be selected, select measurement mode.
  Note: If you selected the wrong mode, tap the **Reselect** button and select the correct mode.
  Note: If the **Other modes** button is available, tap it to get access to more modes.
- Follow the instructions on the screen.
- Place and hold the end with the clot catcher in the center of the inlet gasket.
  Note: If you turn the capillary tube slightly when you place it in the center, it may be easier to put it in the right place.
- Carefully push the capillary tube into the analyzer as far as it will go and hold it there.



- Hold the capillary tube in the pushed-in position until the analyzer tells you to remove it.

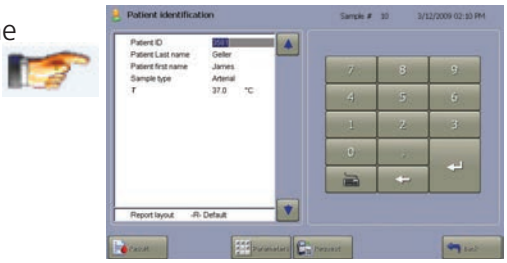


- When the analyzer tells you to, remove the capillary tube.
  The analyzer closes the inlet.
- If necessary, select a different report layout as follows:
  a) Tap the current **Report layout** shown on the screen.
  b) Select a new layout from the list.
  c) Tap the **Select** button.
- Enter the necessary data in the **Patient identification** screen.
  Note: It is mandatory to enter data in fields with this icon:

- If the **Patient result** screen opens before you have entered the necessary data, tap the **ID** button.

Capillary samples – how to measure a patient sample, continued

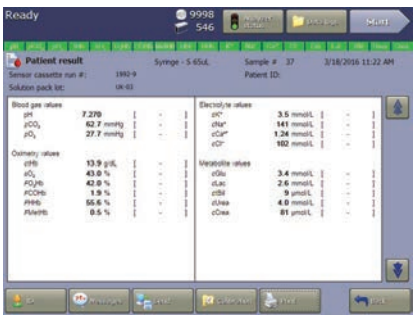
5. Appropriate patient information



If applicable, explain how to recognize a mandatory field by the pointing hand. A mandatory field needs an entry before the results can be shown. Results will be recorded but will not be visible or retrievable without advanced user access.

- Other patient information for calculations or clinical value.
- Follow local guidelines.

6. View results (on-screen, printout or local information system)



Discuss actions according to local guidelines

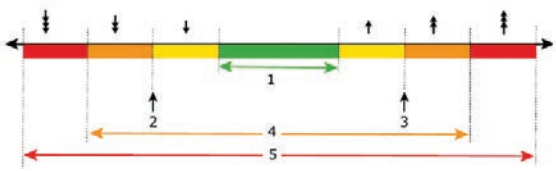
- Critical limits
- Error messages and symbols
- ? = Error
- Reference ranges
- Review printout

7. Documentation and reporting of results – Patient results log

- Result retrieval
- Filtering results (if required)
- Trend facility (if required)
- Acid-base chart

8. About ranges and critical limits

Measurement results are marked by symbols to show where they fall in relation to reference ranges, critical limits and reportable ranges. The diagram illustrates these relationships.



1 Reference range
2 Lower critical limit
3 Upper critical limit
4 Reportable range
5 Range of indication

9. Log off the analyzer

- Demonstrate how to log off the analyzer manually and how the automatic logoff works
- Discuss the consequences of not logging off

Component consumables

Training method

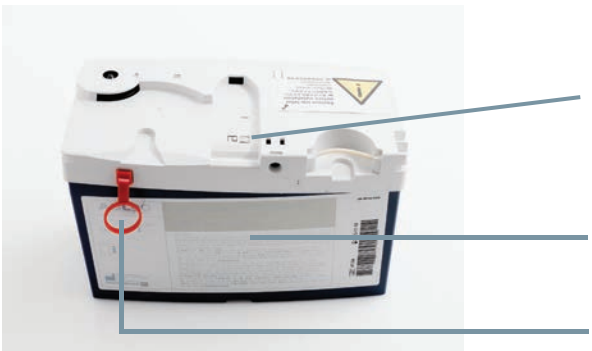
Solution pack

Explain the differences between solution pack SP90, SP90XL and SP90Ki

Explain to the trainee that the solid grey square indicates that the solution pack is for the ABL90 FLEX PLUS

Explain to the trainee that the grey circle indicates that the solution pack is for the ABL90 FLEX PLUS that is configured to feature creatinine and urea

Point out and explain the following details on the solution pack.



Smart chip containing various information, no further scanning of product barcodes necessary

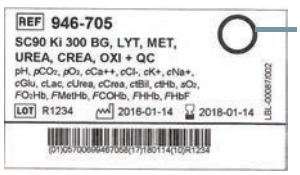
Contains pouches with QC and calibration material, a gas mixture and closed containers to hold liquid waste

Security pin for activation of the solution pack

Sensor cassette

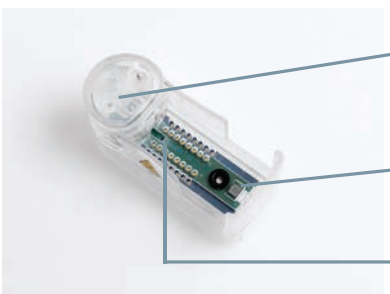
Explain the differences between sensor cassette SC90 and SC90Ki

Explain to the trainee that the solid black square indicates that the sensor cassette is for the ABL90 FLEX PLUS



Explain to the trainee that the black circle indicates that the sensor cassette is for the ABL90 FLEX PLUS configured to feature creatinine and urea

Point out and explain the following details on the sensor cassette.



Reference sensor. Do not shake the sensor cassette! There is no need to mix the solution in the reference sensor.

Smart chip containing various information, no further scanning of product barcodes necessary

Board with sensors. Hemoglobin and bilirubin are measured by the oximetry module built into the analyzer.

Changing consumables, continued

General warnings and cautions

WARNING – Risk of infection
Only let authorized personnel collect and work with blood samples. Make sure that you wear gloves.

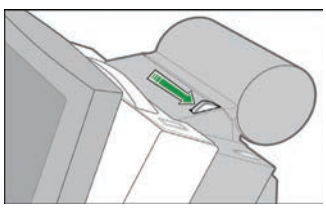
WARNING – Risk of infection
Dispose and handle all used sampling devices, quality control (QC) ampoules, Solution Packs, Sensor Cassettes, Inlet Probes, Inlet Gasket Holders, Inlet Connector Gaskets and Inlet Modules as biohazardous waste. Follow your local regulations.

WARNING – Risk of infection
Make sure you do not prick or scratch yourself on the inlet probe.

WARNING – Risk of infection
Make sure that you wear gloves during replacement and maintenance procedures.

Training method

Demonstrate with participation of the trainee how to replace a consumable in a slow step-by-step guidance. Emphasize how the analyzer provides feedback (sound and light indications) and provides on-screen guidance throughout the process.



Changing the thermal printer paper

- Show how to enter **Analyzer status** on the analyzer screen and find > **Consumables** > **Replace** > **Paper**
- Show where to find and press the release button to open the cover and remove the used paper roll
- Let the trainee place the new paper roll, tell or show that the paper must unwind from below
- Let some paper extend out of the printer
- Close the cover and tell that the cover must “click” to be correctly in place
- Point to the analyzer screen and complete the procedure

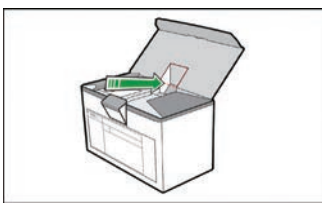
Changing consumables, continued

Changing consumables – solution pack
To see the solution pack status

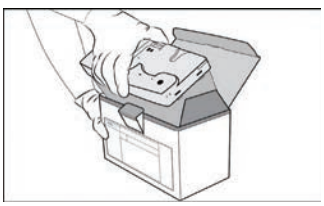
- Tap **Menu** > **Analyzer status** > **Consumables**.
- For more information, tap the **Status** > **Solution Pack** buttons.

To change the solution pack

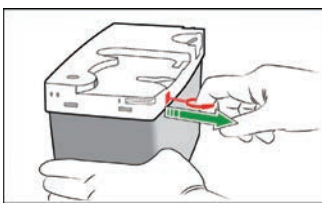
- Show how to enter **Analyzer status** on the analyzer screen and find > **Consumables** > **Replace** > **Replace Solutions**



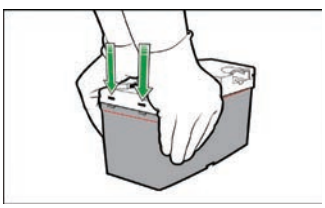
- Ensure that trainee has the correct solution pack that is either SP90, SP90 XL or SP90 Ki
- Let the trainee remove the solution pack and dispose of it as biohazardous waste according to local guidelines



- Take a new solution pack and demonstrate how get it out of the box without pulling or lifting in the pump tube
- Lift the new solution pack out of its box as shown and place it on an level surface
- Now let the trainee try to get the solution pack out of the box

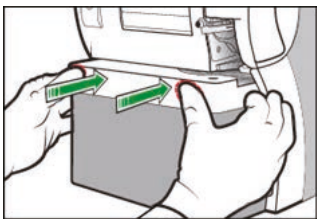


- Let the trainee pull the red pin out of the new solution pack
- Show how to place the palms of your hands over the edges of the lid as shown



- Now let the trainee place their palms and tell them to press down firmly and evenly with both hands until the tabs click into the two holes

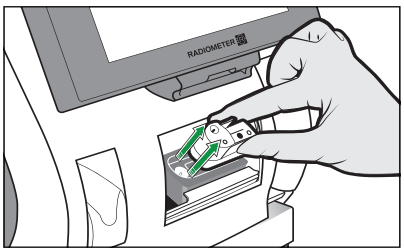
- Emphasize that both tabs must click into place for the solution pack to be activated correctly
- Follow screen instructions
- Let the trainee put their hands on the white part of the solution pack and solution pack and push the solution pack into its compartment until it clicks in place.



- Inlet closes automatically and start-up begins

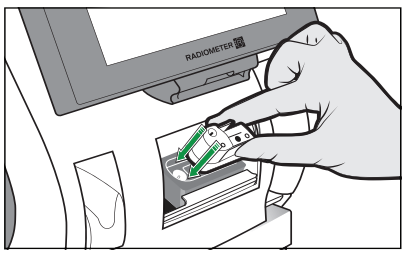
Changing consumables continued

Changing consumables – sensor cassette



Note: The analyzer has to condition a new sensor cassette after it is installed. This process can take up to 4 hours.

- Show on the analyzer screen how to enter **Analyzer status** and find > **Consumables** > **Replace** > **Replace sensor cassette**
- Ensure that trainee has the correct sensor cassette that is either SC90 or SC90 Ki.
- Show how to start the video guidance and wait until the sensor cassette compartment opens



- Let the trainee try to remove the sensor cassette and dispose of it as biohazardous waste according to local guidelines
- Tell that actions have to be confirmed at the analyzer to advance the video guidance, so press **Action Completed**

Let the trainee do all of the following steps:

- Pull the foil off the new sensor cassette pack
- Unscrew the lid and lift out the sensor cassette
- Observe that the trainee press **Action Completed** before putting the new sensor cassette in place
- Follow the on-screen guidance for completing the procedure

Troubleshooting

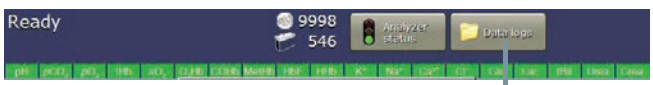
Explain how the trainee can see when the analyzer is ready for use:

The analyzer is ready for use when all three conditions are present.
- The analyzer is in **Ready** mode.
- The color of the tab of the parameters you want to get a result for is green or yellow.
- The color of the traffic light in the **Analyzer status** button is green or yellow.

If applicable, explain about the following points:

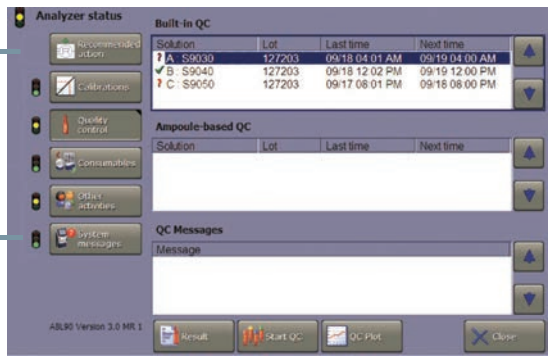
Remaining test cycles:
- Sensor cassette icon – the number adjacent to the icon shows the number of tests that are left.

- Solution pack icon – the number adjacent to the icon shows the number of activities that are left.



Access to the data logs such as **Patient Results Log**

Analyzer status button – the color of the traffic light on the button shows the overall status of the analyzer. Press the button to access detailed status information.



General information

Training method

Take the trainee through the following general information, demonstrating the processes when it seems necessary.

Cleaning the analyzer

Remember to clean the analyzer according to the manufacturer's instructions and additional local guidelines

Compliance

Infection control

Always comply with hospital guidelines regarding collection, handling, and disposal of blood

On-going competency testing

If applicable, discuss training and assessment

Who is your first point of contact?

Laboratory/POC

……

Other

……

Key operator training

Key operator training

To aid key operators who manage devices and provide operator training, in-depth knowledge of device concepts and specifications will be provided in the following pages. The training material is partially based on the operator's manual and is designed to convey information in tables and diagrams for fast interpretation.

We offer a variety of tools to aid the key operator:

- Operator training guides to ensure consistent messaging across training sessions
- Competency check lists for signing off on training sessions

Other training material

- Acute care testing handbook
- Blood gas preanalytics app

Handbooks can be downloaded from our handbooks at www.myradiometer.com or from www.radiometer.com as mobile applications for smart phones and tablets.

Training method

To enhance the trainee's understanding refer to the latest version of the *ABL90 FLEX PLUS Instructions for use*.

Replacements

Storage of consumables

Storage temperatures	ABL90 FLEX PLUS	ABL90 FLEX PLUS configured to feature creatinine and urea
SC storage temperature	2-8°C/35-46°F	2-8°C/35-46°F
SP storage temperature	2-25°C/35-77°F	2-8°C/35-46°F

Always ensure stock rotation.

Replacement intervals for consumables and inlet connector gasket

Consumables	Onboard life
Solution pack SP90	30 days or until number of activities is zero
Solution pack SP90Ki	14 days or until number of activities is zero
Solution pack SP90XL	30 days or until number of activities is zero
Sensor cassette SC90	30 days or until number of activities is zero
Sensor cassette SC90Ki	14 days or until number of activities is zero
Inlet gasket holder	12 months (recommended)
Inlet connecter gasket	12 months (recommended)

Replacements, continued

Can a sensor cassette be used again?

A sensor cassette removed from one analyzer can be used on the same or on another ABL90 FLEX PLUS analyzer if the following seven 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 tests
- The sensor cassette was not removed from an analyzer during a long-term shutdown procedure
- The sensor cassette is moved between analyzers with the same configuration

This data can be seen in the sensor cassette status screen.

Can a solution pack be used again?

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
- the solution pack is moved between analyzers with the same configuration

This data can be seen in the **Solution Pack Status** screen.

For further instructions, please refer to the latest version of *ABL90 FLEX PLUS Instructions for use* under *Replacements and maintenance.*

Cleaning the analyzer

The analyzer must always be kept clean. Exterior surfaces, the inlet gasket and other parts of the analyzer must be cleaned when they are contaminated with blood and/or other liquids.

Further instructions can be found in the latest version of *ABL90 FLEX PLUS Instructions for use* under *Replacements and maintenance.*

Cleaning the inlet gasket

The inlet gasket must be kept clean to make sure that samples can be aspirated correctly.

Required item(s)

A lint-free cloth

⚠ WARNING – Risk of infection

Make sure you do not prick or scratch yourself on the inlet probe.

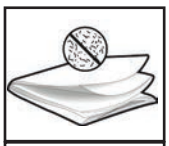
1. Tap **Menu > Analyzer status**.
2. Tap the **Other activities > Inlet check > Clean inlet gasket** buttons.
3. Tap the **Press to start video guidance** button.

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.

To clean the touch screen



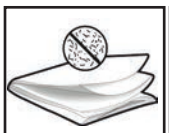
A lint-free cloth

Required item(s)

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

To clean the analyzer exterior

Required item(s)



A lint-free cloth

A mild detergent

Note: Radiometer has not tested whether cleaning wet wipes can be used for this purpose.
Note: The Sensor Cassette compartment and the top surface of the Solution Pack compartment must be cleaned by a Radiometer representatives.

1. Lightly dampen a lint-free cloth with soapy water or a mild detergent
2. Wipe the analyzer exterior

Disinfecting

Follow your local, state and federal guidelines. For further instructions, please refer to the latest version of *ABL90 FLEX PLUS Instructions for use* under *Replacements and maintenance*.

Troubleshooting and guide

Troubleshooting – when is it necessary?

Troubleshooting is necessary when the analyzer goes into **Operator Action Needed, Troubleshooting needed** or **Intervention Required** mode. It may also be necessary to troubleshoot messages in the **Analyzer status** screen.

About advanced troubleshooting

In the troubleshooting modes, **Troubleshooting needed** and **Operator Action Needed**, text and video instructions will guide you through each troubleshooting procedure and show you what to do to get out of the troubleshooting mode.

After each troubleshooting procedure, the analyzer tests to see if the issue has been resolved. If not, a new troubleshooting procedure is shown on the screen. If the guided troubleshooting procedures do not resolve the issue, the analyzer will go into **Intervention Required** mode.

To get out of Operator Action Needed mode

Follow the text and video instructions on the screen.

To get out of Troubleshooting needed mode

Follow the text and video instructions on the screen.

To get out of Intervention Required mode

1. Do the first action shown in the **Suggested actions** frame.
2. Press the **Test again** button.
3. If the analyzer does not go out of **Intervention Required** mode, do the next action.
4. Press the **Test again** button.
5. If the analyzer does not go out of **Intervention Required** mode, do steps 3 and 4 again.
6. If none of the actions cause the analyzer to go out of **Intervention Required** mode, contact your local Radiometer service representative.

Please refer to:

- The *Troubleshooting* chapter in the section *Troubleshooting modes - causes*, in the latest version of the *ABL90 FLEX PLUS Instructions for use.*
- The *ABL90 FLEX PLUS Troubleshooting Guide*

Note: Those staff permitted to carry out the advanced troubleshooting must have appropriate 'boxes' ticked when setting up their access rights under analyzer security.

Quality control and calibrations

Overview of quality control management

Quality control management is important as it evaluates the performance of the analyzer to make sure that the patient results are accurate and precise.
The analyzer manages quality control automatically, but if local, federal or state regulations require additional quality control procedures, operators can do them.

Automatic quality control management (AQM) is the name given to quality control procedures that the analyzer is programmed to do automatically.

About built-in QC measurements

The analyzer uses the three levels of QC solution contained in the solution pack to do built-in QC measurements. These QC solutions are automatically registered in slots A, B and C when a solution pack is installed.

Configuration's consumables	Slot A	Slot B	Slot C
SP90	S9030	S9040	S9050
SP90 Ki	S9230	S9240	S9250

Built-in QC measurement frequency

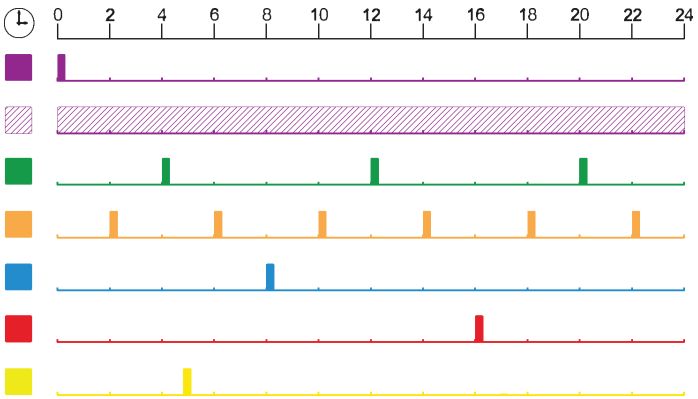
A built-in QC measurement is scheduled by default to be done every 8 hours. One measurement a day is done with each QC solution. Built-in QC measurements are also scheduled by default to be done in connection with these activities:

- Replacement of the solution pack
- Replacement of the sensor cassette
- Startup

You can edit the schedule for built-in QC measurements.

Quality control and calibrations, continued

Here is an overview of the default schedule for system checks, QC and calibration measurements that the analyzer does to make sure that patient results are accurate, precise and reliable.



- Start of the system-check cycle
- System checks: Automatic test sequences done with each measurement and at other times to make sure that all parts of the analyzer operate within specifications.
- Built-in QC measurements
- Sensitivity calibration of pCO_2, *c*Glu, *c*Lac and status calibration of the oximetry parameters
- Sensitivity calibration of pH and the electrolytes (cK^+, cNa^+, cCa^{2+}, cCl^-)
- Sensitivity calibration of pO_2
- Calibration of *c*Crea* and *c*Urea*

* Parameters only available on analyzers configured to feature creatinine and urea.

A status calibration of all parameters (except the oximetry parameters) is done before every patient, QC and sensitivity calibration measurement.

For the ABL90 FLEX PLUS that is configured to feature creatinine and urea a 3-point calibration is set at 05:00. Creatinine and urea calibration parameters are updated but there are no other calibrations at this time

Calibration frequency after a sensor cassette replacement

Calibrations are done more frequently in the 24-hour period that follows a sensor cassette replacement. This has an effect on the number of analyses that can be done per hour during this time period.

Note: A calibration takes up to 2½ minutes.

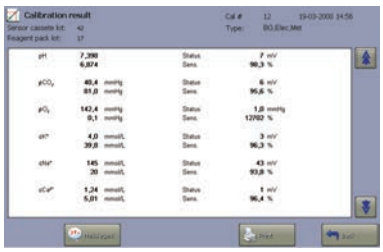
Time period after a replacement	Calibration frequency
0-4 hours	In connection with every measurement
4-6 hours	Every 15 minutes
6-8 hours	Every 30 minutes
8-12 hours	Every hour
12-24 hours	Every 2 hours

For the Sensor Cassette SC90 Ki, the replacement schedule still occurs as listed above. Additionally, the Sensor Cassette SC90 Ki performs a calibration for cCrea and cUrea 3 hours after sensor cassette installation. Calibration of *c*Crea and *c*Urea takes 9 minutes.

Quality control and calibrations, continued

Calibration results

- A calibration result is a combination of numerous smaller calibration activities
- Calibration results from the most recent activity are marked in bold
- Calibration results originating from a previous activity are marked in light gray color
- A calibration result is generated in connection with a measurement, there is a link to the related result
- If a 2-point calibration is initiated, all results are recent activities and therefore marked in bold

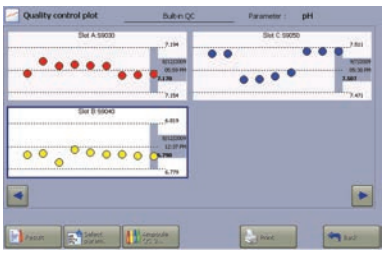


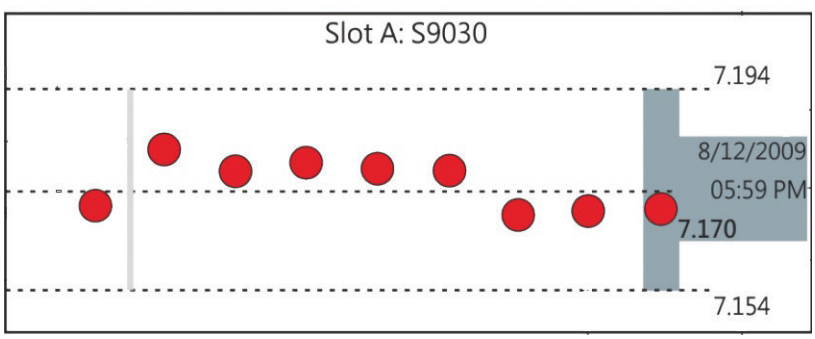
Automated corrective actions

- A comprehensive evaluation ensures that specifications are met and that calibration and QC are correct
- If rejected, the calibration/QC is automatically repeated. All actions are logged and traceable.

Levey-Jennings plot for quality control

- Overview of day-to-day QC variations
- All the measured parameters are checked at low, normal and high concentration levels, covering the relevant physiological measuring range
- QC values that are comparable even if you change a solution pack
- The gray bar marks the change of solution pack and QC lot changes:





Theoretical aspects of the blood gas analyzer

General measuring principles

Introduction

There are four different measuring principles employed in the sensors in the ABL90 FLEX PLUS 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, pCO_2, K^+, Na^+, Ca^{2+}, Cl^- and Urea 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 Glu, Lac and Crea sensors.
- Optical pO_2: The optical system for pO_2 is based on the ability of O_2 to reduce the intensity and time constant of the phosphorescence from a phosphorescent dye that is in contact with the sample.
- Spectrophotometry: Light passes through a cuvette containing a hemolyzed blood sample. The specific wavelengths absorbed and their intensity generate an absorption spectrum used to calculate oximetry parameters. This measuring principle is used for measuring ctHb, sO_2, FO_2Hb, *F*COHb, *F*HHb, *F*MetHb, *F*HbF and ctBil.

Activity vs. concentration

Strictly speaking, in potentiometry the potential of a sensor chain is related to the activity of a substance, and not its concentration.

The activity of a substance can be considered the "effective concentration" of a species, taking non-ideality of the medium into account.

Activity and concentration are related by the following equation:

$a_x = \gamma\, c_x$

where:

a_x = the activity of the species x

γ = the activity coefficient of species x under the measurement conditions (for ideal systems $\gamma = 1$)

c_x = the concentration of species x (mol/L)

Note: To be exact, activity is related to the molality of species x, i.e. the number of mol/kg of solvent. However, molality is converted to concentration (molarity).

Theoretical aspects of the blood gas analyzer

Overview

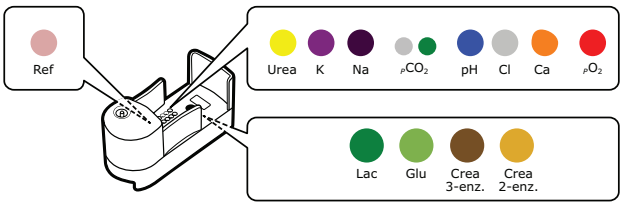
General construction

Sensors

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.

The sensors are located on sensor boards in the sensor cassette.

Top sensor board:



Bottom sensor board:

Note: Creatinine and urea are only featured on the SC90 Ki sensor cassettes.

Parameters

Measured parameters

Ranges of indication and reportable ranges can be found in the *ABL90 FLEX PLUS Instructions for use*. Always consult the latest version of the *ABL90 FLEX PLUS Instructions for use*.

The range of indication for a parameter is the range within which the analyser is physically capable of measuring.

Reportable range is the range of results from a testing system or method over which the analytical performance is claimed. The default reportable range is the range over which Radiometer has validated the analytical performance.

Limitations of the measuring system

Limitations of the measuring system

Please use the latest version of the *ABL90 FLEX PLUS Instructions for use*, *Specifications* chapter.

Analyzer setup

Managing operators

- Analyzers set up for anonymous use: Operators do not have to log on

- The access profile selected for anonymous use specifies the short cut buttons and menus available for anonymous operators

To add an operator on the analyzer

1. Tap **Menu** > **Utilities** > **Setup** > **Analyzer security** > **Operators** and **passwords.**
2. Tap the **Add operator** button.

3. Choose an option and follow the steps for it

Option	Steps
To let the operator log on with an **Operator name**: and a **Password**:	a) Enter a unique ID for the operator. **Note:** Only enter 35 characters, so that the complete ID is seen in the **Logon** screen. **Note:** Do not include characters such as apostrophes (') and slashes (/). b) Enter the password for the operator. **Note:** The password must contain a minimum of 4 characters. c) Enter the password again in the **Confirm:** field below the **Password:** field.
To let the operator log on with a logon barcode	a) Enter or scan in the logon barcode for the operator. **Note:** The logon barcode must be unique and contain a minimum of 4 characters. b) Enter or scan in the logon barcode again in the **Confirm** field below the **Logon - barcode:** field.
To let the operator log on with an **Operator name:** and a **Password:** or with a logon barcode	a) Enter a unique ID for the operator. **Note:** Do not include characters such as apostrophes (') and slashes (/). **Note:** Only enter 35 characters, so that the complete ID is seen in the **Logon** screen. b) Enter the password for the operator. **Note:** The password must contain a minimum of 4 characters. c) Enter or scan in the password again in the **Confirm:** field below the **Password:** field. d) Enter or scan in the logon barcode for the operator. **Note:** The logon barcode must be unique and contain a minimum of 4 characters. e) Enter or scan in the logon barcode again in the **Confirm** field below the **Logon - barcode** field.

Analyzer setup continued:

Managing operators

4. Tap the **Back** button.

Note: If data is not valid, a pop-up message is shown and an acoustic signal is sent.

5. Make sure that the operator is selected.
6. Select an access profile for the selected operator.
7. Tap the **Close** button.

To remove an operator

1. Tap **Menu** > **Setup** > **Analyzer security** > **Operators and passwords**.
2. Select the operator.
3. Tap the **Remove operator** button.
4. Tap the **Close** button.

To add an operator from AQURE

From the **Add operator** page you give the operator access to device types in different departments.
Note: From **Administration** > **Add user** you can create a user of the AQURE system and an operator at the same time.

1. Go to **Operators** and click the **Add operator** button.
2. Fill in the **Personal details**, the **Logon information** and select a **Hospital** and a home Department for the operator.

Note: Operator name, Hospital and home Department name are mandatory.

3. Click the **Save** button.
4. To add more departments select Hospital and Department and click the **Add** button.
5. Select the operator **Role** for the device types.
The role comes from the device. The operator has the same role on all devices of a type.
6. Set the **Lock out date** for the device types.
The **Lock out date** is the date when the operator cannot operate the device.
7. Select **Active** to give the operator access to the device type.
8. Click the **Save** button.

Note: The **Operator comments** field lets you add more information about the operator.

To send all operator data to devices

Note: This procedure deletes all operator data on the devices and sends the operator data saved in the AQURE system to all devices.

1. Go to **Operators.**
2. Click the **Push all operators** button.
3. Click the **OK** button.

Note: If there are existing operators on the analyzers and Central User Management, the users on the analyzer will be deleted when you send operator data to the device.

Notes

Notes

Notes

RADIOMETER

ACUTE CARE TESTING

www.radiometer.com