

RUH Bath NHS Foundation Trust – Pathology Department

STANDARD OPERATING PROCEDURE SOP/POCT/62/5

Title: ABL90 FLEX PLUS Blood Gas Analysers

Effective date: 01/02/2024

Summary of Significant Changes at this Revision

Updated EQA sections (9 & 18) to reflect changes in process – always run Gas EQA before Co-Ox EQA - flush analyser and run a QC after Co-Ox EQA

Purpose and Scope	Items Required
This SOP describes the principles and	Radiometer Flex plus analyser.
procedures involved in the analysis of:	Sensor cassette
Blood gases – pH, pCO ₂ , pO ₂	Reagent pack
Bicarbonate – $cHCO_3$	Paper rolls
Electrolytes – Na ⁺ , K ⁺ , ionised Ca ⁺⁺ , Cl ⁻	tHb calibrator
Hb derivatives – COHb, O2Hb, MethHb	Flush kit
Glucose	Heparinised blood gas collection syringes BD A-Line.
Lactate	safePICO with safeTIPCAP, Clinitubes (capillary tubes)
Bilirubin	QualiCheck opener/adapter
Using the Radiometer ABL90 Flex Plus	
blood gas analysers	
	Radiometer user manual;
	- On the intranet POCT page
	- On Q-pulse EXT/POCT/14 (lab staff only)
	- ABL90 Flex Plus quick user guide (FM/POCT/105)
	- ABL90 Flex Plus trouble-shooting guide
Definitions and Abbreviations	Grade / Qualifications Required
POC – Point of Care	Nurse
QC – Quality Control	Midwife
QC – Quality Control IQC – Internal Quality Control	Midwife Assistant grades, e.g. HCA, EDA, MSW, etc.
QC – Quality Control IQC – Internal Quality Control EQA – External Quality Assurance	Midwife Assistant grades, e.g. HCA, EDA, MSW, etc. Doctor
QC – Quality Control IQC – Internal Quality Control EQA – External Quality Assurance QA – Quality Assurance	Midwife Assistant grades, e.g. HCA, EDA, MSW, etc. Doctor Other medical staff Diamodical Calentiat
QC – Quality Control IQC – Internal Quality Control EQA – External Quality Assurance QA – Quality Assurance WEQAS – Welsh External Quality	Midwife Assistant grades, e.g. HCA, EDA, MSW, etc. Doctor Other medical staff Biomedical Scientist
QC – Quality Control IQC – Internal Quality Control EQA – External Quality Assurance QA – Quality Assurance WEQAS – Welsh External Quality Assurance	Midwife Assistant grades, e.g. HCA, EDA, MSW, etc. Doctor Other medical staff Biomedical Scientist Trainee biomedical scientist Associate practitioner (ARD)
QC – Quality Control IQC – Internal Quality Control EQA – External Quality Assurance QA – Quality Assurance WEQAS – Welsh External Quality Assurance ABG – Arterial Blood Gas	Midwife Assistant grades, e.g. HCA, EDA, MSW, etc. Doctor Other medical staff Biomedical Scientist Trainee biomedical scientist Associate practitioner (ABP)
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QC – Quality Control IQC – Internal Quality Control EQA – External Quality Assurance QA – Quality Assurance WEQAS – Welsh External Quality Assurance ABG – Arterial Blood Gas CPAP – Continuous positive airways pressure ISE – Ion Selective Electrodes TB – Tuberculosis Bacilli	Midwife Assistant grades, e.g. HCA, EDA, MSW, etc. Doctor Other medical staff Biomedical Scientist Trainee biomedical scientist Associate practitioner (ABP) Medical lab assistant (MLA) Competencies Required: Current Version of: FM/POCT/COMP/8 - User FM/POCT/COMP/17 - Key operator

Risk Assessment: **Current Version of: RA/POCT/14 –** Available on the POCT intranet page

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1 INTRODUCTION

The Radiometer ABL90 Flex Plus analyser is a pH, blood gas, oximetry, electrolyte and metabolite analysis system that measures oxygen, carbon dioxide, pH, potassium, sodium, calcium, chloride, glucose, lactate, bilirubin and oximetric parameters in whole blood. It is portable and fully automated. It is intended for use in a laboratory environment, near patient or point of care setting. It consists of the analyser, a multi-use disposable sensor cassette, a solution pack, an adjustable colour touch screen and a built-in sample mixer.

2 CLINICAL APPLICATION

2.1 Blood Gases

The measurement of ABGs provides valuable information in assessing and managing a patient's respiratory (ventilation) and metabolic (renal) acid-base and electrolyte homeostasis. It is also used to assess the adequacy of oxygenation. ABGs are used to monitor patients on ventilators, monitor clinically ill non-ventilated patients, establish pre-operative baseline parameters, and regulate electrolyte therapy. Repeat blood gas analysis enables the assessment of oxygen pressure to guide therapy of patients on ventilators or continuous positive airways pressure (CPAP) machines so that the treatment can be adapted to preserve the patient's normal physiological balance.

The measurement of pH and pCO2 (and subsequent calculation of HCO_3) enables the assessment of acid-base balance. This provides the means of identifying many diseases, especially when combined with determination of electrolytes. For further information, please refer to references 1 and 2.

2.2 Electrolytes

Sodium and Potassium

The electrolytes Na⁺ and K⁺ are measured as part of a routine laboratory evaluation of all patients. They are used to evaluate and monitor fluid and electrolyte balance and response to therapy. Sodium is the principal extracellular cation and determinant of extracellular fluid osmolality and volume, and its concentration is the result of a balance between dietary sodium intake and renal excretion. Potassium is the major intracellular cation, and is important in maintaining membrane electrical potential, especially in neuromuscular tissue (most notably, heart muscle). Potassium also contributes to the metabolic portion of acid-base balance. It is a very important test, but especially to those who take diuretics or heart medications.

Chloride

Chloride is the most important anion in bodily fluids and is located mainly in the extracellular area. Chloride is filtered at the glomerulus in the kidneys and is reabsorbed by the renal tubules, passively following sodium. Chloride works with sodium to regulate the acid/base status and may be exchanged for bicarbonates during acid/base disturbances. Hypochloremic alkalosis may occur during extended periods of vomiting, in which chloride is lost in the gastric juices.

Ionised Calcium

Calcium in blood is distributed as free calcium ions (50%), bound to protein (mostly albumin, 40%), and 10% bound to anions such as bicarbonate, citrate, phosphate and lactate. However, only ionised calcium can be used by the body in such vital processes as muscular contraction,

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cardiac function, and transmission of nerve impulses and blood clotting. Patients with renal disease caused by glomerular failure often have altered concentrations of calcium, phosphate, albumin, magnesium and pH. Since these conditions tend to change the ionised calcium independently of total calcium, ionised calcium is the preferred method of accurately monitoring calcium in renal disease.

2.3 Haemoglobin Derivatives (Haemoximetry)

Haemoximetry is used for:

- i) Investigation of the efficiency of haemoglobin oxygenation by the lungs (Hb saturation)
- ii) Measurement of non-oxygen-carrying blood pigments (Carboxyhaemoglobin, Methaemoglobin and Sulphaemoglobin)
- iii) Investigation of patients with likely abnormalities of oxygen carriage and release, e.g. acidosis, alkalosis, hypoxaemia.

Carboxyhaemoglobin is measured in the investigation of possible carbon monoxide exposure and poisoning. Methaemoglobin and Sulphaemoglobin are measured in the investigation of unexplained central cyanosis and possible oxidant drug haemolysis (e.g. sulphonamides, aniline dyes, nitrates and nitrites). Increased levels of Methaemoglobin are seen in patients with HbM haemoglobinopathy or Methaemoglobin-reductase deficiency and flowing oxidant drug exposure. Sulphaemoglobin may occur with exposure to certain drugs, especially sulphonamides.

2.4 Bilirubin (neonatal)

Bilirubin is formed in the reticuloendothelial system during the degradation of erythrocytes. The haem portion from haemoglobin and from other haem-containing proteins is removed, metabolised to bilirubin, and transported as a tightly bound complex with serum albumin to the liver. In the liver, bilirubin is conjugated with glucuronic acid for solubilisation and subsequent transport through the bile duct and elimination via the digestive tract.

The concentration of bilirubin in the plasma of an individual is determined by the balance between production and clearance. Any disease process which disrupts this balance will lead to an increase in plasma bilirubin.

In the new born, the massive red cell destruction occurring in haemolytic disease of the new born, coupled with the immature hepatic handling of bilirubin, can produce elevations of unconjugated bilirubin of $400 - 500 \mu mol/L$ or greater. Such elevations are associated with the risk of developing kernicterus (deposition in the brain with cerebral damage) and levels may be reduced by exchange transfusion.

Also, in premature infants, the poorly developed conjugating mechanism may result in so-called 'physiological' jaundice with markedly raised levels of unconjugated bilirubin, necessitating ultraviolet light treatment or exchange transfusion.

Some drugs can further influence the course and severity of neonatal unconjugated hyperbilirubinaemia caused by the immature hepatic handling of bilirubin by:

a) displacing bilirubin from plasma albumin,

b) inhibiting the glucuronyl transferase system

c) causing haemolysis.

Another reason for measuring bilirubin in neonates is for the diagnosis of Crigler-Najjar syndrome. This harmful congenital disease presents in the first few days of life as jaundice, due to a rise in unconjugated bilirubin levels that may often be high enough to cause kernicterus, and is caused by a deficiency of glucuronyl transferase. In infants who survive, the level of

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bilirubin tends to stabilise, suggesting the existence of alternative pathways of bilirubin excretion.

Rarely, a baby may be born with a congenital condition called biliary atresia, in which the bile ducts do not drain. It usually presents within the first few weeks of life, with jaundice that does not improve with time. This form of hyperbilirubinaemia is largely due to conjugated bilirubin and may be corrected by surgery. Delay in diagnosis of the condition can lead to irreversible liver damage.

2.5 Glucose

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and hypoglycaemia.

Glucose is the major carbohydrate present in the peripheral blood. Oxidation of glucose is the major source of cellular energy in the body. Glucose derived from dietary sources is converted to glycogen for storage in the liver or to fatty acids for storage in adipose tissue. The concentration of glucose in blood is controlled within narrow limits by many hormones, the most important of which is insulin produced by the pancreas. The most frequent cause of hyperglycaemia is diabetes mellitus, resulting from a deficiency in insulin secretion or action. A number of secondary factors also contribute to elevated blood glucose levels. These include pancreatitis, thyroid dysfunction, renal failure, and liver disease.

Hypoglycaemia is less frequently observed. A variety of conditions may cause low blood glucose levels such as insulinoma, hypopituitarism, or insulin-induced hypoglycaemia.

2.6 Lactate

Lactate acts as an early warning signal for hypoxic states in human tissues. Anaerobic glycolysis markedly increases blood lactate and causes some increase in pyruvate levels, especially with prolonged exercise. The common cause for increased blood lactate and pyruvate is anoxia resulting from such conditions as shock, pneumonia and congestive heart failure. Lactic acidosis may also occur in renal failure and leukemia. Thiamine deficiency and diabetic ketoacidosis are associated with increased levels of lactate and pyruvate.

Lactate measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis.

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3 INTRODUCTION TO ABL90 FLEX PLUS ANALYSER

The ABL90 Flex Plus are provided by Radiometer and are connected via Aqure to the laboratory IT system allowing transmission of results into the patient record. The analysers are monitored by the POCT department via Aqure and can be viewed in real time and controlled remotely via this software.

There is a touch screen for communication between operator and the analyser. Below the touch screen is a barcode reader. On the left hand side of the analyser is a built-in sample mixer that can only be used with safePICO samplers with integrated mixing devices (Figure 1 point 3).

Figure 1 – ABL90 FLEX PLUS analyser



Side and Back view:



- 1 Handle
- 2 Thermal printer
- 3 USB port
- 4 Mouse port
- 5 Standby button
- 6 External keyboard port 14 Mains power fuse
- 7 External monitor port 15 Mains power socket
- 8 COM port 16 Serial number
- 9 Network cable port
- 10 USB ports
- 11 Ventilator grid
- 12 Latch for manual release of a Solution Pack
- 13 Power switch ON (|) and OFF (O)

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- 1. 680 Tests
- 2. 980 Tests
- 3. Should be stored at 2-25 °C



- 2. Should be kept sealed at 2-8°C
- 3. Shelf-life (28 days after opened)

Holds the inlet gasket (1), where you put your syringes for aspiration

Inlet Probe

Figure 2 – ABL90 FLEX/FLEX PLUS consumables

There is a closed compartment for housing the sensor cassette. Adjacent to this is the inlet compartment which includes the inlet gasket holder and the inlet probe, which is accessed by raising the sample port. Below this is the solution pack. The battery pack, which is inside the analyser, can hold the charge for maximum of one hour. There is a compartment for the thermal printer paper at the back of the analyser. There is a carrying handle and a USB port located at the top.

Each new sensor cassette and solution pack has a chip containing the associated lot numbers and specific identifying parameters.

The solution pack contains all the solutions necessary for the daily operation of the analyser, e.g. calibration, rinse and quality control solutions. All waste solutions are stored in the solution pack so the pack must be disposed of as infectious waste after use.

The sensors in the sensor cassette are based on thick-film technology – ceramic substrate with printed layers forming microelectrodes and completed with dispensed membranes. The sensors are distributed on two sensor arrays placed in the sensor cassette facing each other and forming the measuring chamber that allows measurement from both sides of the blood sample at the same time. The reference electrode is based on the membrane junction principle to achieve the best possible performance.

From the factory, the sensor cassette comes dry-stored in the sensor cassette pack to ensure long shelf-life. Therefore, a conditioning process, where rinse solution is released to the sensors, must occur before the sensor cassette can be used for measurements. The used sensor cassette should be treated as a biohazard.

Reagents and materials are supplied by Radiometer to the POCT department, they will then be distributed to each location to ensure there are reagents available to use by ward staff. Stock will be reviewed weekly and topped up as required by the POCT team.

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Item	Product Number
Sensor Cassette	946-010 (100 tests)
Sensor Cassette	946-005 (300 tests)
Sensor Cassette	946-008 (600 tests)
Sensor Cassette	946-009 (900 tests)
Sensor Cassette	946-060 (1200 tests)
Solution Pack	944-157 (680 activities)
Solution Pack	944-457 (980 activities)
Inlet Gasket with holder	903-585
Inlet Connector Gasket	834-662
Inlet Probe	924-455
tHb calibration	944-021
Printer Paper	984-070
Clot Catchers	906-026
safePICO self-fill syringe	956-615
safePICO syringe	956-622
safeCLINITUBES	942-962

The expiration date for the solution pack is on the label on the back of the pack. The expiration date for the sensor cassette is found on the back of the sensor. Additionally, all expiration dates are on the relevant boxes. A solution pack can be used on the analyser for up to 30 days, or until there is no more solution left.

Solution packs and sensors cannot be used after their expiration dates, i.e. if a solution pack has five days left on installation it will only be viable on the analyser for five days.

4 METHOD PRINCIPLES

The ABL90 Flex is a cartridge-based blood gas analyser with a replaceable sandwich sensor cassette measuring pH, pO2, pCO2, cNa+, cK+, cCa2+, cCl-, glucose and lactate. Integrated in the analyser is an oximetry module measuring ctHb, sO2, FO2Hb, FHHb, FCOHb, FMetHb, FHbF and bilirubin.

There are four different measuring principles employed in the sensors in the ABL90 FLEX Plus analyser.

4.1 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, pCO2, K+, Na+, Ca2+ and Cl- sensors.

4.2 Amperometry

The magnitude of an electrical current flowing through a sensor chain is proportional to the concentration of the substance being oxidised or reduced at an electrode in the chain. The Amperometric measuring principle is applied in the cGlu and cLac sensors.

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4.3 Optical pO2

The optical system for pO2 is based on the ability of O2 to reduce the intensity and time constant of the phosphorescence from a phosphorescent dye that is in contact with the sample. This measuring principle is applied in the pO2 sensor.

4.4 Spectrophotometry

Light passes through a cuvette containing a haemolysed blood sample. The specific wavelengths absorbed and their intensity generates an absorption spectrum used to calculate oximetry parameters. This measuring principle is used for measuring ctHb, sO2, FO2Hb, FCOHb, FHHb, FMetHb, FHbF and ctBil.

5 REAGENT INFORMATION

5.1 Reagent Requirements

All of the required reagents, quality control and the majority of the calibration material are inside the solution pack.

The solution pack and sensor cassette are replaced when they either become empty or their onboard expiry date is reached (30 days).

5.2 Reagent Preparation

The reagents do not require any preparation as they are all inside of the cassettes/solution packs.

5.3 Materials (Calibrator, Quality Control, EQA)

Each component/consumable is considered to be a lot number in its own right. All of these are self-verifying; therefore, if anything fails, the analyser will reject the consumable. If it completes the required start up, calibrations pass and quality controls pass, this is considered as acceptable. The acceptable values are installed into each consumable through a device chip, which provides all of the necessary information to the analyser.

A tHb calibrator is provided separately and run every three months. To be stored refrigerated until in use.

External Quality Assurance samples from WEQAS will be run through the analysers on a monthly basis. The performance in these schemes will be reviewed by the POCT team and reported to the department.

5.4 Reagent Storage & Stability

Sensor cassettes come in different capacities; the most common ones have 100, 300, 600, 900 and 1200 test capacity. The sensor cassettes must be stored in a temperature-monitored fridge (2-8°C) until required. Before use, the sensor cassette must be removed from the fridge and left at ambient temperature for a minimum of 30 minutes before installing on the analyser.

5.5 Environmental and Safety Controls

Blood is a biohazard. All samples should be handled as potentially infectious. Appropriate Personal Protective Equipment (PPE) should be used at all times.

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Clean all spillages and dispose of cleaning materials, the solution pack and the sensor cassette as clinical waste and according to RUH Trust Policy (ref:605). Solution packs can be disposed into clinical waste bags and sensor cassettes into hard burn or sharps bins.

Material Safety Data Sheets (MSDS) for all solutions in the solution pack are available online and are present in all packs upon delivery.

6 CALIBRATION

The ABL90 Flex Plus analyser utilises a solution pack for all calibrations, QC and rinse procedures, and for the collection of waste fluids. Calibrations are performed automatically in accordance with the calibration schedule. According to the current set up, the ABL90 analysers force the calibration every 2 hours. If Calibration fails for an analyte, the analyser will calibrate again. The internal quality control (IQC), which is programmed to runs 3 times a day automatically on 3 different levels of IQC solution, should be passed after calibration is completed.

The solution pack contains eight foil pouches:

- Three with calibration solutions
- One with a gas mixture
- Three with quality control solutions
- One for waste
- One of the calibration solutions (CAL 1) is also used for rinse.

The calibration solutions and the IQC solutions in the solution pack have a unique lot number. Assigned values for the QC solutions are unique for each individual solution pack because they are adjusted according to the lifetime of the solution pack when installed on the analyser.

Automatic calibrations are done in connection with replacements, troubleshooting and startup

6.1 Manual calibration procedure:

- Check the analyser is in Ready mode.
- Press Menu > Start programs > Calibration programs > Calibration
- Or press Analyser Status > Calibrations > Calibration

6.2 *tHb* Calibration (3 monthly):

- Mix a S7770 ctHb ampoule vigorously for a minimum of 15 seconds then tap the top until all the solution is in the lower part.
- Using the Qualicheck Adapter break the neck of the ampoule.
- Press Menu > Start programs > Calibration programs > tHb calibration.
- Scan the barcode on the insert.
- The analyser will open the inlet then push the adapter with the ampoule as far into the analyser as it will go, ensuring that the radiometer logo faces upwards.
- Hold until the analyser tells you to remove the sample.
- The inlet will close
- Sensitivity results between 80% and 120% without errors are acceptable.

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7 QUALITY CONTROL PROCEDURES

The solution pack contains three levels of QC. Built-in QC measurements are by default performed every 8 hours (one on each level).

04:00 Level A (Red) 12:00 midday Level B (Yellow) 20:00 Level C (Blue)

All reportable parameters are measured. Values are defaulted into the machine by the chip embedded in each solution pack and are lot specific values.

The QC solutions that come from pouches in the solution pack enter the sample path through the inlet as a normal blood sample. The only difference is the position of the inlet that remains in the closed position.

Manual QC procedure:

- Check the analyser is in Ready mode.
- Press Menu > Analyser Status > Quality Control.
- Or press Analyser Status > Quality Control.
- Highlight the built in QC solution to run an unscheduled measurement on.
- Press Start QC to start the measurement

8 METEROLOGICAL TRACEABILITY

See external documents held in qpulse (EXT/POCT/14 traceability 918541)

9 EXTERNAL QUALITY ASSURANCE (EQA)

The purpose of EQA is to assess the accuracy (bias) of results produced compared to target values achieved by other method users nationally. Thus performance is monitored retrospectively. EQA samples should be processed for all analytes on all analysers each month to mimic a patient sample.

COOX EQA samples (red sample bottles) must be kept at 2-8°C and brought to room temperature before analysis, blood gas samples (clear glass vials) must be kept at room temperature.

9.1 **Prior to Analysis** (more details can be found in section 18)

a) Remove the suppression of COOX parameters:

- Log-in
- Press the parameters icon (if available on your log in) Or go to:
- Menu > Utilities > Setup > General Setup > Parameters and input > Parameters
- Highlight ctHb > press *edit*
- Untick the option Repress parameter value in patient result in case of any problems
- Press back
- for sO2, FO2Hb, FCOHb, FMetHb, FHbF, FHHb.

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b) Enable EQA Mode for Sample Analysis:

- Log in
- Press the syringe mode icon (if available on your login) Or go to:
- Menu > Utilities > Setup > Analysis setup > Syringe modes
- From the *Primary Modes* menu, select the bottom right hand button (empty)
- Tick the *button is enabled* option
- Press close

<u>NOTE:</u> STEPS A AND B MUST BE REVERSED ONCE ALL THE EQA SAMPLES ARE ANALYSED!

9.2 Preparation of the EQA samples

Blood gas samples:

- Must be vigorously mixed for 15 seconds, and stood for another 15 seconds to allow the bubbles to settle then analysed immediately.
- Coox samples:
 - Need to reach room temperature but must be used within an hour of removal from fridge.
 - Immediately before analysis the sample should be reconstituted by pressing the red button firmly down (found on the white bottom of the sample pot).
 - The sample should be swirled gently and the cap opened to release pressure then closed to swirl again the sample is then ready for analysis.
 - The reconstituted sample is stable for 15 minutes.

9.3 NOTE: Always run the Blood Gas EQA samples before the Co-Ox Samples

• If there are time constraints, or other issues, the EQA samples do not have to be all run at the same time or on the same day.

9.4 Analysis of the blood gas EQA sample:

- Immediately after preparation the top of the blood gas sample glass vial must be snapped off using a rubber cap or similar. The QualiCheck adapter provided by radiometer can be used.
- The sample can then be placed in the QualiCheck adapter to be presented to the analyser
- Proceed to analyse as a syringe measurement (11.2), selecting the EQA measurement option.
- Enter the sample details as the EQA distribution number and the sample number (ie BG0323 1, 2, 3) to enable positive identification of the results.

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9.5 Analysis of the COOX EQA sample:

- Immediately after preparation:
 - The sample can either be drawn into a syringe using the adapters provided by WEQAS. These can be pushed into the red button at the white end of the EQA sample and the syringe attached (see instructions provided by WEQAS).
 - Or the sample can be decanted into a sarstedt tube (or similar) by opening the red cap and squeezing the soft sides of the sample pot.
- Proceed to analyse using the syringe measurement method (*11.2*) selecting the EQA measurement option (see section 18).
- Enter the sample details as the EQA distribution number (ie CO1023), and the sample number (CO0323 1, 2, or 3) to enable positive identification of the results.

9.6 After analysis of the COOX samples:

- An automatic flush must be performed.
- At least one QC must be run to confirm satisfactory operation.

9.7 Reporting EQA Results

Transcribe the results from the printouts onto the return sheet provided and send this return sheet and all the printouts back to the laboratory (FAO POCT, B38).

10 SAMPLE REQUIREMENTS

Biological material must be considered potentially infectious and handled with universal precautions. There is low overall risk if the test is performed using good working and safe laboratory practice. (Refer to Health and Safety Policy Documents)

The analyser is designed for use with human arterial, venous and capillary whole blood and requires a minimum volume of 45uL (capillary tubes only). Typically, whole-blood arterial or venous specimens are obtained by needle puncture or via an in-line catheter; whole-blood capillary samples can be obtained from the earlobe, finger, heel, scalp, etc

10.1 Specimen Collection and Handling: Blood Gases

Depending on type of samples, different collection tools may be used:

- BD A-Line 3 ml syringes containing calcium balanced lithium heparin (~80IU) (for arterial or venous samples)
- BD Preset Eclipse 3 ml syringes containing calcium balanced lithium heparin (~80IU) (for arterial or venous samples)
- Radiometer *safe*PICO self-fill aspirator with a *safe*TIPCAP containing an integrated mixing device and balanced lyophilised heparin (for arterial samples)
- Radiometer *safe*PICO aspirator with a *safe*TIPCAP containing an integrated mixing device and balanced lyophilised heparin (for venous samples)
- *Radiometer safe*CLINITUBES are recommended for capillary samples on the ABL Flex Plus 45uL

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Blood samples taken in aspirators (syringes or capillaries) should be analysed immediately after air bubbles are removed and blood is mixed although there is a 30 minutes time gap; for safe analysis of sample, 15 minutes is recommended and for capillary tube samples analyse within 10 minutes.

Lithium heparin or balanced heparin salts are the only acceptable anticoagulants for use on the blood gas analyser. Other anticoagulants such as EDTA, citrate, oxalate, fluoride and anticoagulants containing ammonium have a significant effect on several parameters and should not be used.

Different types of anticoagulant may change the concentration of some parameters and give false patient results.

Anticoagulant	Possible effect on patient results
Heparin in liquid form	Biased results on all parameters
Anticoagulants with sodium cations (Na+)	Falsely high cNa+ results
Anticoagulants with sodium and potassium cations (Na+ and K+)	False cNa+, cK+ results
Anticoagulants with Lithium/Zinc heparin	False <i>c</i> Ca2+ results
Anticoagulants with ammonium heparin	False <i>c</i> Cl– and <i>c</i> Urea/BUN* results
Disodium oxalate with sodium fluoride	Falsely high <i>c</i> Na+, falsely low <i>c</i> Ca2+ and false <i>c</i> Glu and <i>c</i> Lac results
Trisodium citrate	False cNa+, cK+, cCa2+, pH, cGlu, and cLac results
EDTA	 False pH, pCO2, cNa+, cK+ and cCa2+ results False cCa2+, cCrea* and cUrea/BUN* results
	in subsequent patient samples

Table 1 – Effect of anticoagulants on measured blood analytes - * Parameters only available on analysers configured to feature creatinine and urea/BUN.

The ideal blood sample for analysis on ABL90 is defined as:

- Taken from the right patient after preparing patient for the procedure
- Collected using recommended aspirator (safePICO or BD) from a suitable site
- Sufficient blood volume is collected
- Air bubbles are removed immediately after taking blood
- Gently mixed immediately after air bubbles are removed
- No clot present

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11 PATIENT TESTING

NOTE: Patient results should be reviewed and acted on by appropriately qualified staff with particular reference to patient's history.

Repeat spurious results or results that do not fit the clinical picture. Confirm abnormal results by sending a sample to the lab (where available).

Ensure any air bubbles are removed immediately after sampling. Always ensure the blood sample is well mixed before analysis and after removal of the air bubbles. This can be done manually by rolling the sample between the palms of your hands. Gentle mixing is required as shaking the sample can cause haemolysis. Alternatively if safePICO samplers are used the syringe should be placed in the built-in sample mixer on the front of the analyser. The mixer starts automatically and stops when the sample has been sufficiently mixed.

11.1 Capillary Measurement

- Capillary samples are mixed using mixing wires (fleas) moving them repeatedly along the tube using a magnet.
- Check the analyser is in Ready mode.
- Logon with your personal barcode
- Select capillary
- Analyser opens the inlet
- If measurement mode can be selected, select measurement mode.
- You may be prompted to select individual parameters if required, if not press continue.
- Remove any capillary caps and place a clot catcher on the end of the tube away from the flea.
- Press the clot catcher against the centre of inlet gasket. The blood is automatically aspirated when the inlet gasket is pushed inwards.
- When prompted by the analyser remove the capillary
- Enter all the essential patient details and any additional details available.

NOTE: When clot catchers are not available, fleas should not be used as they can block the needle.

11.2 Syringe Measurement

- Check the analyser is in Ready mode.
- If using safePICO syringes place on sample mixer port
- Logon with your personal barcode
- Select syringe
- Analyser opens the inlet
- If measurement mode can be selected, select measurement mode.
- You may be prompted to select individual parameters if required, if not press continue.
- Place the syringe tip or safeTIPCAP firmly against the inlet gasket and push it upwards while still holding on to the sample cylinder.
- The inlet probe extends into the syringe and the blood is automatically aspirated.
- When prompted by the analyser remove the sample.
- Enter all the essential patient details and any additional details available.

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11.3 Sample from a specimen tube

- Uncap the tube
- Select the syringe sample on the screen
- Place and hold the lip of the test tube against the collar of the inlet gasket
- Push the test tube into the analyser as far as it will go ensuring that the probe extends into the sample and stays there during sample aspiration.
- Do not allow the probe to enter any gel

11.4 Small specimen tube samples

In the laboratory, if a sample is short (ie paediatric tube), and there is a risk of the probe protruding into the gel of the sample, or if the tube is not full and the probe will not reach the sample, it must be decanted into a sarstedt micro-tube, or hang-in cup, or similar. Follow the steps as above (11.3 Sample from a specimen tube)

When the measurement and clean-up are complete, the analyser will revert back to the 'Ready' screen.

The sample can be disposed of immediately into a burn/sharps bin, according to local health and safety guidelines. (Refer to Health and Safety Policy Documents).

WARNING: Blood spillages should **NOT** be left on the analyser or any surrounding surfaces. You **MUST** clean up after using the analyser

12 REPORTING AND INTERPRETATION

12.1 Interferences and Limitations

Contaminating the blood sample with air will significantly distort the blood gas measurements. Any substance which affects the pH of a sample (eg Aspirin) will affect the iCa due to changes in the dissociation equilibrium. In all cases, the notes and restrictions, such as anticoagulant type in the 'Specimen Collection and Handling' section should be observed.

It is well documented that lactate measurement is not reliable in patients poisoned with ethylene glycol (positive interference).

Various drugs and dyes can cause interference with some parameters, please refer to the Radiometer Operator Manual for full details.

The user should be immediately informed of abnormal deviations of the measurement results, and evaluate the complete picture of the patient or perform expanded tests if necessary.

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12.2 Analytical ranges

Analytical ranges are:

рН	6.30 - 8.00
pCO2	0.67 – 33.3 kPa
pO2	0.00 – 73.3 kPa
cK+	1.5 – 10.5 mmol/L
cNa+	95 – 190 mmol/L
cCa2+	0.40 – 2.70 mmol/L
cCl⁻	70–160 mmol/L
cGlu	0–47 mmol/L
cLac	-0.1 – 31 mmol/L

ctBil	0–690 µmol/L
ctHb	-2.0 – 270 g/L
sO2	-2.0 – 102.0 %
FO2Hb	-2.0 – 103.0 %
FCOHb	-2.0 – 103.0 %
FMetHb	-2.0 – 103.0 %
FHHb	-2.0 – 102.0 %
FHbF	-25 – 121 %

If a result is outside the analytical range the analyser will not display a result. If the result is outside of the normal range or an error has occurred, the analyser will display with the following symbols:

1	Result is above the reference range but below the upper critical limit.
↓	Result is below the reference range but above the lower critical limit.
†	Result is above the upper critical limit but below the upper limit of the reportable range.
¥	Result is below the lower critical limit but above the lower limit of the reportable range.
\$	No result is shown because it is above the upper limit of the reportable range.
^	Note: The analyser can be set up to show the result as greater than the value of the upper limit of the reportable range. For example: All pH results above 7.850 (the upper limit of a pH reportable range) will be shown as >7.850.
¥	No result is shown because it is below the lower limit of the reportable range.
	Note: The analyser can be set up to show the result as less than the value of the lower limit of the reportable range. For example, all pH results below 6.750 (the lower limit of the pH reportable range) will be shown as <6.750.
	No result could be calculated or value outside range of indication.
(blank)	No result shown because it is outside the reportable range.
*	User-defined correction factors were used to calculate the result.
с	A subscript of the letter c shows that the value was calculated from measured and/or keyed-in (input) values. Only shown on derived parameters.
e	A subscript of the letter e shows that the value was estimated. Default values were used to replace measured and/or keyed-in (input) values that were not available. Only shown on derived parameters.

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12.3 Reference ranges

For in use reference ranges please refer to the results printout from analyser.

Reference ranges from Radiometer Medical ApS, Bulletin No: 44, Compendium of Reference Intervals Results Entry (see reference below) was used to guide references ranges provenance of reference ranges can be obtained from Pathology if required.

Analyte	Age/Sex or other	Reference Range	Units
рН	Adults and Children	7.35 - 7.45	
pO2	2 days – 60yrs	11.1 -14.4	kPa
pCO2	Male and Female	4.3-6.4	kPa
cBase(Ecf)c/			
(Base excess)	Male and female	-2.0 to + 2.0	mmol/L
cK+	Male and Female	3.4 – 4.5	mmol/L
cNa+	Male and Female	133-146	mmol/L
cCa²+	Male and Female	1.15 – 1.33	mmol/L
cCl-	Male and Female	95-108	mmol/L
cGlu	Adult	4.0-6.0	mmol/L
cLac	Male and Female	<1.8	mmol/L
ctHb	Male and Female	70 – 175	g/L
s02	Adults and Children	No range	%
O2Hb		90-95	%
COHb		0 - 4.2	%
MetHb		0.04 - 1.52	%

Results must be transcribed into the patient's notes including:

- The date/time of analysis
- The location/name of the blood gas analyser used
- The signature of the operator carrying out the analysis

The print out should not be inserted into the patient notes, as the paper is heat sensitive and the print fades with time.

The results will soon be electronically sent and recorded in the electronic patient record (anticipated summer 2023) but until this is in place, they must be hand written in the patient notes.

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13 ROUTINE MAINTENANCE

For regular cleaning, and for blood spillages, the analyser surfaces must be cleaned with the yellow and white multi-surface detergent wipes (order code VJT233)

For disinfection, and after a blood spillage has been cleaned up, the surfaces must be disinfected with 70% alcohol wipes from the red-lidded tubs (order number VJT057).

Surrounding surfaces can be cleaned with detergent wipes in accordance with local requirements.

Other cleaning materials:

- Mild detergents and soapy water are suitable to be used on the surfaces of the analyser using a lint-free cloth
- A solution of 2-propanol or 70% ethanol on a lint-free cloth can be used on the analyser surfaces to disinfect.
- Water on a lint-free cloth can be used to clean the inlet gasket and analyser screen.

NOTE: DO NOT use green Clinell wipes on any part of this blood gas analyser

13.1 Weekly Maintenance or When Required

The following maintenance should be performed at least once a week or more frequently if required:

- Cleaning the inlet gasket
- Check the solution pack and sensor cassette and change when required.
- Checking the time and date on analyser, and adjusting if required.

13.1.1 Cleaning the inlet gasket

Press Menu > Analyser status > Other activities > Inlet check > Clean inlet gasket

- Tap Press to start video guidance button
- The inlet will open
- Dampen a lint-free cloth with water
- Tap the Action completed button
- Gently wipe the inlet gasket and area around it until clean
- Tap the **Action complete** button
- The inlet will now close

13.1.2 Replacement of Solution Pack

The solution pack and sensor cassette are replaced when they expire, become empty or their on-board expiry date is reached (30 days). Instructions are below.

When prompted to replace the solution pack, the number of tests still available on that pack must be checked. If an error has occurred and there are still a high number of tests left, other

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maintenance such as flushing should be performed to attempt to remedy the error that has occurred (see below).

- Menu > Analyser status > Consumables > Replace > Replace solution pack.
- Tap 'Press to start video guidance' button
- The inlet will open and the solution pack will unlock.
- Remove the used solution pack and dispose of it as infectious waste bag.
- Activate the new pack by pulling out the safety pin.
- Press the lid firmly down by pressing the elevated side down until the side taps click into the side tap holes (Figure 3).
- Tap 'Action complete'
- Insert the new solution pack by pushing it fully into place until a click is heard (see figure 4).
- When prompted by the analyser, close the inlet.
- The operator's name and any notes can be entered now followed by Enter on the keyboard.
- Press 'OK' .



Figure 3 – Preparing a new solution pack



Figure 4 – inserting new solution pack

- 13.1.3 Replacing the Sensor Cassette
 - 1. Tap Menu > Analyzer status.
 - 2. Tap the **Consumables > Replace > Sensor Cassette buttons**.
 - 3. Tap the Press to start video guidance button.
 - 4. Check that you have the correct Sensor Cassette.
 - 5. Wait until the Sensor Cassette compartment opens.
 - 6. Remove the Sensor Cassette and dispose of it as biohazardous waste.
 - 7. Tap the Action Completed button.
 - 8. Pull the foil off the new Sensor Cassette Pack, unscrew the lid and lift out the Sensor Cassette.
 - 9. Tap the Action Completed button.
 - 10. Press the new Sensor Cassette in place
 - 11. Tap the Action Completed button.
 - 12. Enter necessary data.
 - 13. Tap the OK button.

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13.1.4 Replacing the Printer Paper

- 1. Tap Menu > Analyzer status.
- 2. Tap the **Consumables > Replace > Paper buttons**.
- 3. Press the release button.
- 4. Open the cover and remove the used paper roll.
- 5. Put in the new paper roll. Make sure the paper unwinds from below.
- 6. Make sure some paper extends out of the printer.
- 7. Close the cover. The cover must click in place.
- 8. Tap the **Replaced button**.
- 9. Enter necessary data.
- 10. Tap the OK button.

13.1.5 Checking the time and date on analyser

- Press Menu > Utilities > Setup > General Setup > Analyser settings > Time/Date
- If required amend the time or date using the keyboard on the screen.

13.2 Three monthly maintenance (can be performed by laboratory staff)

The tHb calibration must be performed manually every three months. You will require:



- Mix a S7770 ctHb ampoule vigorously for a minimum of 15 seconds then tap the top until all the solution is in the lower part.
- Break the neck of the ampoule and put the Qualicheck Adapter over the end of the ampoule.
- Press Menu > Start programs > Calibration programs > tHb calibration.
- Scan the barcode on the insert.
- The analyser will open the inlet
- Push the adapter with the ampoule as far into the analyser as it will go
- Hold until the analyser tells you to remove the sample.
- The inlet will close
- Sensitivity results between 80% and 120% without errors are acceptable.

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13.3 Maintenance required ad hoc

13.3.1 Replacing the Inlet probe

If the probe is bent, it may be possible to straighten it back to a usable state, follow the steps below to safely remove the probe either to replace or to straighten.

1. Tap **Menu > Analyzer status**.

- 2. Tap the **Other activities > Inlet check > Repl. inlet probe** buttons.
- 3. Tap the Press to start video guidance button.
- 4. Pull off the inlet cover.
- 5. Tap the Action completed button. The analyser opens the inlet.
- 6. Pull out the Inlet Gasket Holder.
- 7. Tap the Action completed button.
- 8. Lift up the Inlet Probe as far as it will go and pull it to the right to remove it.
- 9. Tap the Action completed button.
- 10. Hold the new Inlet Probe in a vertical position and put it in place.
- 11. Lower the Inlet Probe.
- 12. Tap the Action completed button.

13. Put the Inlet Gasket holder over then slide and insert it. Make sure that the Inlet Probe is in the center of the gasket.

Note: Make sure the Inlet Gasket Holder clicks in place.

- 14. Tap the **Action completed** button. The analyser closes the inlet.
- 15. Put on the inlet cover.
- 16. Tap the **Action completed** button.

13.3.2 Replacing the Inlet Gasket Holder

- Menu > Analyser status > Other activities > Inlet check > Repl. Inlet Gasket Holder
- Remove the inlet module as described in 13.3.1 Replacing the Inlet Probe, and reassemble with new inlet gasket.

13.3.3 Replacing the Inlet Connector Gasket

- Menu > Analyser status > Other activities > Inlet check > Repl. Inlet Connector Gasket.
- Remove the inlet module as described in *13.3.1 Replacing the Inlet Probe*, and pull out the inlet connector gasket with a pair of tweezers.
- Dampen the new inlet connector gasket with tap water and push firmly into position ensuring it is correctly seated.
- Replace the inlet module.

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14 TRAINING AND ACCESS TO ANALYSER

14.1 Training and Competency Assessment

This must be completed before an individual is given access to the analyser. Training can be given by the key operator/link trainer on each ward, or by the POCT team during designated training session (see notice near blood gas analyser for locations and times).

Competency forms can be found on the trust intranet by clicking on either of the following links:

- https://www.ruh.nhs.uk/pathology/poct/sops.asp?menu_id=3
- Home » Point of Care Testing » SOPs

Individuals are issued a barcode as their access code, or can use their existing BM or blood track barcode for access. Once the training and competency are complete, forms should be returned to <u>ruh-tr.biochempoc@nhs.net</u> for access to be given.

NOTE: It is against trust policy to share your barcode and allow access for untrained staff. You will be accountable for analyses done in your name.

15 MEASUREMENT OF UNCERTAINTY

See validation data spreadsheet VAL/POCT/45 – Contact POCT for details

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16 TROUBLESHOOTING GUIDE

In the first instance of problems with the analyser please contact your wards Key operator if they are not available the POCT team can be contacted or the Radiometer service department.

POCT team: ext: 6044, email <u>ruh-tr.biochempoc@nhs.net</u> (Mon-Fri 09:00 – 17:15) **Radiometer Itd service department**: 01293 517599 (24/7)

This guide is not extensive please refer to the manual for full details and further information regarding troubleshooting. The manual can be found on the RUH intra net page following the links below:

- https://www.ruh.nhs.uk/pathology/poct/sops.asp?menu_id=3
- Home » Point of Care Testing » SOPs

There is also a hard copy troubleshooting guide near the blood gas analysers.

NOTE: Solution packs and Sensor cassettes are expensive and it is wasteful to replace these in an attempt to rectify a problem if not necessary

16.1 Troubleshooting modes

Troubleshooting	Possible causes	To get out of this mode
mode		
Operator Action Needed	A consumable must be replaced	Follow the text and video instructions on the screen.
Troubleshooting needed	Fluid transport errors were found	Follow the text and video instructions on the screen
Intervention Required	 If the troubleshooting procedures in the Troubleshooting needed mode did not resolve the issue All other possible errors 	 Do the first action shown in the Suggested actions frame. Tap the Test again button. If the analyzer does not go out of Intervention Required mode, do the next action. Tap the Test again button. If the analyzer does not go out of Intervention Required mode, do steps 3 and 4 again. If none of the actions cause the analyzer to go out of Intervention Required mode, contact your local Radiometer representative.

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16.2 To find and troubleshoot messages in the Analyser status screen

1. Tap **Menu > Analyser status**.

- 2. Tap the button adjacent to a yellow or red traffic light.
- 3. Choose an option and follow the steps for it (see following table)

Option	Steps				
To troubleshoot a Recommended action	Follow the instructions on the screen				
To troubleshoot Quality control messages	To troubleshoot errors in the Built-in QC and Ampoule-based QC fields: a) Select the quality control measurement marked by a ?, where we have a symbol. b) Tap the Result button. c) Tap the Result button. c) Tap the Messages button. d) Select the message. e) Tap the Troubleshoot button. f) Follow the instructions on the screen. To troubleshoot messages in the QC Messages field: a) Select the message. b) Tap the Troubleshoot button. c) Follow the instructions on the screen.				
To troubleshoot Calibrations messages	To troubleshoot calibrations marked by a ?. So or symbol. a) Select the marked calibration. b) Tap the Result button. c) Tap the Result button. d) Select the messages button. d) Select the message. e) Tap the Troubleshoot button. f) Follow the instructions on the screen. To troubleshoot messages in the Message field: a) Select the message. b) Tap the Troubleshoot button. c) Follow the instructions on the screen.				
To troubleshoot Consumables or System messages	 a) Select the message. b) Tap the Troubleshoot button. c) Follow the instructions on the screen. 				

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16.3 ABL90 Flex Plus reagent/fluid transport system:

All required reagents for full spectrum of analytes are kept inside packages within the solution pack except for tHb calibration. This also includes IQCs, calibrators and the waste after an analysis is complete.

A schematic of how the solutions are transported within the ABL90 Flex Plus compartments is seen in Figure 5 below.

It is not unusual to find that the analyser's circulatory system has been blocked by the introduction of a poor quality blood sample containing clots.

If a clot is suspected, a flush procedure (see 16.4) must be performed before following any analyser recommendations to replace consumables, as the presence of a clot can fool the automatic trouble-shooting system.



Figure 5 – Fluid/Reagent circulation within the ABL90 FLEX/FLEX PLUS

- 1 Liquid sensor 3
- 2 Hemolvzer
- 3 Oximetry valve
- 4 Liquid sensor 2

5 Reference electrode

- 6 Sensor Cassette
- 7 Optical pO2 sensor
- 8 Liquid sensor 1
- 9 Sample inlet (position for capillary tubes) 23 Pouch with gas mixture
- 10 Sample inlet (position for syringes and
- 11 Peristaltic pump
- 12 Waste valve
- 13 Smart chip
- 14 Solution Pack

- 15 Flow selector (to select a solution/gas)
- 16 Closed position (nothing selected)
- 17 Position to select air

18 • Pouch not in use (SP90) • Pouch with Cal 4 (SP90 Ki)

- 19 Pouch to hold waste
- 20 Pouch with CAL 3 solution
- 21 Pouch to hold clot waste
- 22 Pouch with CAL 1 solution
- 24 Pouch with QC 1 solution test tubes)
- 25 Pouch with CAL 2 solution
- 26 Pouch with QC 3 solution
- 27 Pouch with QC 2 solution
- 28 Electrical shield

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16.4 Flushing the fluid transport system

In case of blocked analyser's circulatory system, follow the video clip instruction on ABL90 using the flush device (provided by the supplier and kept by the ABL90 analyser) to remove the blockage as described below:

WARNING – Risk of infection; ensure gloves and PPE are worn.

- 1. Draw tap water into the Flush Device up to the 2.5 mL mark.
- 2. Pull the plunger of the Flush Device up to the 5 mL mark to draw air into it.
- 3. Tap the Press to start video guidance button.
- 4. Pull off the inlet cover.
- 5. Tap the Action completed button. The analyser opens the inlet.
- 6. Wait until the Solution Pack is ejected.
- 7. Remove the Solution Pack.
- 8. Tap the Action completed button.
- 9. Pull out the Inlet Gasket Holder.
- 10. Tap the Action completed button. The analyser closes the inlet.
- 11. Put a tissue or a cloth under the inlet.
- 12. Tap the Action completed button.

13. Connect the tip of the Flush Device to the waste connector in the Solution Pack compartment.



14. Tap the Action completed button.

15. Hold the Flush Device as shown:



16. Inject a very small quantity of air to fill approximately 1 cm of the tube. 17. Hold the Flush Device as shown:



18. Inject a very small quantity of water to fill approximately 1 cm of the tube.

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- 19. Do steps 15 to 18 again repeatedly to clean the fluid transport system.
- 20. Tap the Action completed button.
- 21. Inject water until an unbroken stream of water comes out of the Inlet Probe. **Note**: The fluid path is flushed, when this is possible.
 - Note: If it is not possible, do steps 15 to 18 and step 21 again.
- 22. Tap the Action completed button.
- 23. Disconnect the Flush Device.
- 24. Remove the tissue or the cloth.
- 25. Tap the Action completed button. The analyser opens the inlet.
- 26. Reinsert the gasket holder. Make sure that the Inlet Probe is in the centre of the gasket and that the Inlet Gasket Holder clicks in place.
- 27. Tap the Action completed button.
- 28. 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 analyser closes the inlet.
- 29. Put on the inlet cover.
- 30. Tap the Action completed button.

Note: Although the analyser is fast and accurate, upon developing a fault, the analyser may not always generate a correct message/instructions to the operators. It is often usual to see wrong advice given as part of ABL90 Flex Plus automated messaging system i.e change the solution pack or change sensor cassette while they are not fully consumed by the analyser. Remember to always flush the analyser as the first cure if any tests left on solution pack or the sensor cassette.

16.5 Raising a credit form

When the above troubleshooting remedies are unsuccessful and if recommended by radiometer technical support or as a recommended action on the analyser/guide, the reagent pack or sensor may need to be replaced.

If replacing a pack due to an error as part of troubleshooting a credit note must be raised to allow the department to be reimbursed for the remaining tests on that sensor or pack. This credit note must be emailed to the POCT team as soon as possible if not immediately (delays in doing so may result in reimbursement not being made).

See Appendix 1 for the description of how to print a credit note. You will need the following information:

- Unique Reference ID, this is the name of the analyser the error occurred on
- Your contact details
- The form should be emailed to:

sales@radiometer.co.uk & ruh-tr.biochempoc@nhs.net & AMHAROLD@beckman.com

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17 APPENDIX 1 – HOW TO OBTAIN A CREDIT CLAIM FORM

Faulty sensor cassettes and solutions packs will only be reimbursed if a credit claim form is submitted within 14 days of the replacement.

The easiest way of doing this is during the replacement of the faulty consumable:

1. In the replacement screen, tap 'Send status to printer'.



2. The analyser will generate and print the credit claim form – see example below:

Credit Claim Form

Contact Name:	Royal United Hospital
Contact Phone:	
Contact email/Fax:	
Credit:	Replacement: urgent standard
Solution Pack Status	
Analyzer ID: Software version: Time: Replacement: Part #: Lot #: Expiration date: Remaining activities: Orip ID: Max. activities: First inserted: ACTIVITY LOG (User)	1393-092R0437N0026 ABL90 Version 3.5 MR5 09/05/2023 09:33 Solution pack removed 944-157 NQ-28 16/08/2023 36 69016554 680 30/03/2023 09:47
Time	Message
09/05/2023 09:33	1344: Solution pack removed
CALIBRATION LOG cLac	NQ-28 - 1474-75 1310: Response error
QUALITY CONTROL A	NQ-28 - 1474-75 0210: Calibration error(s) present
QUALITY CONTROL B cLac	NQ-28 - 1474-75 0210: Calibration error(s) present
QUALITY CONTROL C cLac	NQ-28 - 1474-75 0210: Calibration error(s) present

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3. Ensure the contact details are complete then scan the printout and email it to sales@radiometer.co.uk & ruh-tr.biochempoc@nhs.net & AMHAROLD@beckman.com.

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If the credit claim form was not printed during the replacement, this can be done retrospectively:

- 1. From the main screen, tap 'Data Logs' > 'Replacement Log'
- 2. Select the line correspondent to the removal of the faulty consumable.
- 3. Tap 'Send status to printer'.

bu ben' bo' us	so, ogiti conti Mento Hor	HTRI KT - NAT - C	ar Ct	Giu Lac IBi
Seplacement I	og	Message level	L User	Manager Service
Time	Replacement		Lot	Expiration date
02/08/2019 08:36	Sensor cassette removed		759-175	11/09/2019
02/08/2019 08:33	Sensor cassette removed		759-175	11/09/2019
17/07/2019 10:58	Sensor cassette inserted		759-175	11/09/2019
17/07/2019 10:35	Sensor cassette removed		759-175	11/09/2019
17/07/2019 10:33	Sensor cassette inserted		759-175	11/09/2019
17/07/2019 10:33	Sensor cassette removed		759-175	11/09/2019
04/07/2019 14:52	Sensor cassette inserted		759-175	11/09/2019
04/07/2019 14:51	Sensor cassette removed		0-0	04/07/2019
04/07/2019 14:51	Sensor cassette removed		0-0	04/07/2019
Details				
Operator:		Remaining tests:		100
Note:		Chip ID:		51134991
		Max. tests:		100
		First inserted:		26/06/2019 11:44

- 4. The analyser will generate and print the credit claim form.
- 5. Ensure the contact details are complete then scan the printout and email it to sales@radiometer.co.uk & ruh-tr.biochempoc@nhs.net & AMHAROLD@beckman.com.

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18 APPENDIX 2 - PREPARATION OF THE ANALYSER FOR EQA SAMPLES

18.1 Removing the Suppression of COOX parameters

- Log on to the analyser
- Tap on the 'Parameters' button.
- OR Tap: Menu Utilities Setup General Setup Parameters Input Parameters

pH pCO ₂ p	O_2 tHb sO_2 O	Hb MetHb COHb	HHb HbF M	Na* K	(* Ca²* Cl	Glu Lac	tBil
Param	eter setup						
Parameter	Enabled/locked	Repression	Correction slope	Corr	ection offset	Unit	Out-of-range suppression
pН	Yes / No	Yes	1.000	0.	.000		
pCO ₂	Yes / No	Yes	1.000	0.	.00	kPa	
pO ₂	Yes / No	Yes	1.000	0.	.00	kPa	
ctHb	Yes / No	Yes	1.000	. 0.	.0	g/L	No
sO2	Yes / No	Yes	1.000	3 0.	.0	%	No
FO ₂ Hb	Yes / No	Yes				%	No
FCOHb	Yes / No	Yes		0.	.0	%	No
FMetHb	Yes / No	Yes		0.	.0	%	No
FHbF	Yes / No	Yes	1.000	0		%	No
FHHb	Yes / No	Yes				%	No
cK ⁺	Yes / No	Yes	1.000	0.	.0	mmol/L	
cNa ⁺	Yes / No	Yes	1.000	0		mmol/L	
cCa2*	Yes / No	Yes	1.000	0.	.00	mmol/L	
cCI-	Yes / No	Yes	1.000	0		mmol/L	_
cGlu	Yes / No	Yes	1.000	0.	.0	mmol/L	
cLac	Yes / No	Yes	1.000	0.	.0	mmol/L	
ctBil	Yes / No	Yes	1.000	0		µmol/L	Yes
ctBil	Yes / No	Yes	1.000	0		µmol/L	Yes

• Clicking on each parameter in turn, click on the 'Edit' button, to take you to the following screen:

Cakibration 🔗 6 Ready within 2 minutes pH / pCo, f po, 1 Hb / so, 0,Hb Menth COHb HHb / Hh / so, 0,Hb Menth COHb HHb / Hhb	53 45 HbF	N	Analyzer status	Ct Glu L	s Start ac tBil	
Edit parameter setup						
Parameter: ctBil [µmol/L]			7	8	9	
Repress parameter value in patient result in case of any problems			4	5	6	
Out of range suppression			1	2	3	
			0		4 -1	
Correction slope			-	+		
					Back	

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• Un-tick the 'Repress parameter value...' button.



- Click the 'Back' button
- Repression is now listed as 'No'

Calibratio	on		53 545	Analyzer	Data loga	Start
Ready with	in 15 seconds		043	-		
pH pCO ₂ p	oO ₂ tHb sO ₂ O	Hb MetHb COHb	HHb HbF N	a* K* Ca²* Cl⁻	Glu Lac	tBil
Parame	eter setup					
Parameter	Enabled/locked	Repression	Correction slope	Correction offset	Unit	Out-of-range suppression
pH	Yes / No	Yes	1.000	0.000		
pCO.	Yes / No	Yes	1.000	0.00	kPa	
pO ₂	Yes / No	V	1.000	0.00	kPa	
ctHb	Yes / No	No	1.000	0.0	g/L	No
sO2	Yes / No	res	1.000	0.0	%	No
FO ₂ Hb	Yes / No	Yes			%	No
FCOHb	Yes / No	Yes		0.0	%	No
FMetHb	Yes / No	Yes		0.0	%	No
FHbF	Yes / No	Yes	1.000	0	%	No
FHHb	Yes / No	Yes			%	No
cK⁺	Yes / No	Yes	1.000	0.0	mmol/L	
cNa ⁺	Yes / No	Yes	1.000	0	mmol/L	
cCa2+	Yes / No	Yes	1.000	0.00	mmol/L	
cCI-	Yes / No	Yes	1.000	0	mmol/L	
cGlu	Yes / No	Yes	1.000	0.0	mmol/L	1
cLac	Yes / No	Yes	1.000	0.0	mmol/L	
<i>c</i> tBil	Yes / No	Yes	1.000	0	µmol/L	Yes 文
🍠 Edit	Enable/ Disable	Lock/ Unlock				X Close

• Repeat this for: ctHb, sO2, FO2Hb, FCOHb, FMetHb, FHbF, FHHb

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18.2 Enabling EQA Mode for Sample Analysis

- Tap on the 'Syringe Mode' Button
- OR Tap: Menu Utilities Setup Analysis Setup Syringe Modes

Below is the syringe mode window.

There may be one or more buttons/modes in use.

The default mode is the button that is depressed.

Ready	<pre> 471 141 141</pre>	Analyzer status	📁 Data logs	Start
pH pCO ₂ pO ₂ tHb sO ₂ O ₂ Hb MetHb COH	b HHb HbF	Na ⁺ K ⁺ Ca ²⁺	CI ⁻ Glu Lac	
/ Syringe modes setup				
Syrings 5 65d. short probe		Measuring progr	am: robe	▲ ▼
Secondary modes		The default mod button currently	e when measuring i pressed down.	s the
Measured parameters:				
pH, pCO ₂ , pO ₂ , ctHb, sO ₂ , FO ₂ Hb, FMeth cLac	Hb, FCOHb, FH	Hb, FHbF, cNa⁺, cł	(*, cCa²⁺, cCl⁻, cGl∟	l,
xxx x x x x x x		ayout		X Close

EQA samples must be run in EQA mode (or another long probe mode):

• Click on the bottom right hand button under 'Primary Modes':

Ready	/					0	471 141	8	Analy state	ls /zer	E	Data	logs	9	Start	
pH pC	O ₂ pO ₂ ringe m	tHb odes :	sO2 setup	O₂Hb N	1etHb COHb	HHb	HbF	Na⁺	K*	Ca ^{s*}	CF	Glu	Lac			
	Syring	y Mode of prob	.s .5uL .e		_			Me	asurin	ig prog	ram:		- {		[2
			(Bu	tton is	enable	ed:					

• Click on 'Button is enabled'

This will activate the EQA mode and make it the default profile.

pН	pCO ₂ pO ₂	tHb	sO ₂ O ₂ H	COHb MetHb	HbF	HHb	K*	Na*	Ca ^{a+}	CIT	Glu	Lac		
1	Syringe m	odes se	etup											
	Primar	y modes												
		A					Me	easurin	a prog	am:		ſ		
	Syring	gess 5 650 ort probe					S	65uL	g prog	Girli		-	<u> </u>	
													*	
				EQA - 5 65uL										R
	Eacon	dan i mar	tor		/		Bu	itton is	enable	:d:		U		

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18.3 After analysis of the EQA samples:

1: You MUST change the syringe mode back to its default mode:

- Un-tick 'Button is enabled' when the EQA button is depressed (the button will go blank).
- Click on the **default primary mode button** (usually top left) to depress it.

Primary modes		
Syringe 5 05uL short probe	Measuring program: S 65uL short probe	
	Button is enabled:	

2: You MUST change the suppression of the CoOx parameters back to their original state:

- (see 18.1 above)
- Click on each parameter in turn, click on the **'Edit'** button, and tick the **'Repress** parameter value...' button.
- Do this for: ctHb, sO2, FO2Hb, FCOHb, FMetHb, FHbF, FHHb

3: You MUST confirm that the analyser is operating correctly, as follows:

- Perform an automatic flush.
- Run at least one level of QC.

19 REFERENCES

- Radiometer, ABL90 Flex Plus; Instructions for use code number: 996-178, Version: 201803N
- UKAS, ISO15189:2022
- Tietz, Tietz textbook of clinical chemistry and molecular diagnostics. 5th Edit. Saunders Elsevier 2012
- C. Higgins and Radiometer Medical ApS, Bulletin No: 44, Compendium of Reference Intervals, May 2010, updated September 2018.

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