

Radiometer ABL90 Flex Plus Blood Gas Analyser

1. HEALTH AND SAFETY

COSHH Information	
GLP	Good Laboratory Practice H&S includes the use of personal protective equipment (PPE), use of SOPs, clear work place etc. Laboratory PPE includes; Laboratory coat, gloves and eye protection.
Colour Codes	Purple = High Risk } Red = Significant Risk } Blue = Moderate Risk } if GLP is followed Green = Low Risk }

Substance	COSHH Reference	COSHH Score	Hazard	Requirement for Use
Blood and Bodily Fluids	GEN-BSPS-COSHH-00200	Moderate	Biological	GLP, PPE, Appropriate Training/Vaccinations. Appropriate Signage
ABL90 Flex Plus Sensor Cassette	POCT-BSPS-COSHH-001	Low	None	GLP, PPE
ABL90 Flex Plus Solution Pack	POCT-BSPS-COSHH-002	Low	Oxidising (Solution Pack)	GLP, PPE
ctHb Calibration Solution	POCT-BSPS-COSHH-038	Low	None	GLP, PPE

Risk Assessment	RA Reference	Rating	Requirement for Use
POCT Staff Risk Assessment	POCT-BSPS-RA-001	Low/Medium	PPE and GLP. Ensure device is a minimum of 1.5m away from patient beds.
POCT Risk Assessment Clinical Areas	POCT-BSPS-RA-002	Low	PPE, and GLP
POCT Sample Pathway Risk Assessment	POCT-BSPS-RA-003	Refer to document	Refer to document

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2. PERSONNEL AND TRAINING REQUIREMENTS

This device may be operated by any individual who has received appropriate training as detailed in the **BSPS (Berkshire and Surrey Pathology Services) Point of Care Testing (POCT) Training Policy: POCT-BSPS-POL-004**.

It is the responsibility of the user not to deviate from procedures outlined during training. The result obtained at the point of care is the responsibility of the user. Clinical management of the patient based on a point of care result is the responsibility of the clinician.

Training, device maintenance, **governance** and troubleshooting are the responsibility of the POCT team.

3. PURPOSE OF THE EXAMINATION

Blood gas analyses play an important role in the evaluation of critically ill patients. These parameters can change rapidly in unstable patients; in addition, specimens for blood gases must be analysed promptly after collection because of specimen instability. Thus, blood gas analyses are carried out by trained users with analysers located in the most critical areas of the hospital.

The ABL90 FLEX Plus is a portable, automated analyser that measures pH, blood gases, electrolytes, glucose, lactate, urea, creatinine and oximetry in heparinised and electrolyte-balanced whole blood at the Point of Care. **Whole blood may be venous, arterial or capillary.**

Foetal scalp and specified fluid samples may also be used for specific parameters. The table below shows the analytes available.

pH and Gases	Oximetry	Electrolytes	Metabolites
pH (acidity) pCO2 (partial pressure carbon dioxide) pO2 (partial pressure oxygen)	ctHb (total hemoglobin concentration) sO2 (oxygen saturation) FO2Hb (fraction of oxyhemoglobin in total hemoglobin) FCO2Hb (fraction of carboxyhemoglobin in total hemoglobin) FHHb (fraction of deoxyhemoglobin in total hemoglobin) FMetHb (fraction of methemoglobin in total hemoglobin) FHbF (fraction of fetal hemoglobin) ctBil (concentration of total bilirubin in plasma) n.b. Not in use as not currently verified by BSPS POCT.	cK+ (potassium ion concentration) cNa+ (sodium ion concentration) cCa2+ (calcium ion concentration) cCl- (chloride ion concentration)	cGlu (D-glucose concentration) cLac (L(+)-lactate concentration) Urea* Creatinine*

* enabled in clinically relevant settings only

4. PRINCIPLE OF THE PROCEDURE USED FOR EXAMINATIONS

Potentiometry: The potential of an electrode chain is measured by a voltmeter, and related to the concentration of the sample (the Nernst equation). The potentiometric measuring principle is applied in the pH, $p\text{CO}_2$, K^+ , Na^+ , Ca^{2+} , urea and Cl sensors.

Amperometry: The magnitude of an electrical current that flows through an electrode chain is proportional to the concentration of the substance that is oxidized or reduced at a electrode in the chain. The amperometric measuring principle is applied in the cGlu, cLac and creatinine sensors.

Optical $p\text{O}_2$: The optical system for $p\text{O}_2$ 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. This measuring principle is applied in the $p\text{O}_2$ sensor.

Spectrophotometry: Light passes through a cuvette that contains a haemolysed blood sample. The absorption spectrum is used to calculate oximetry parameters. This measuring principle is used for ctHb, $s\text{O}_2$, FO_2Hb , FCOHb , FHHb , FMetHb , FHbF and ctBil.

Activity Vs Concentration

In potentiometry the potential of an electrode chain is related to the activity of a substance not its concentration. The activity of a substance can be considered the effective concentration of a species that takes non-ideality of the medium into account.

Activity and concentration are related by this equation:

$$a_x = \gamma c_x$$

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)

5. PERFORMANCE SPECIFICATIONS

See:

POCT-BSPS-SOP-304-ED-1: ABL90 Flex Plus User Manual

Prior to the introduction of the ABL90 Flex Plus, a verification against comparable laboratory methods and manufacturers performance claims was undertaken. A summary can be found in POCT-BSPS-SOP-304 Appendix 4: ABL90 Flex Plus Measurement Uncertainty Summary and POCT-BSPS-VV-011: Radiometer ABL90 Flex Plus Blood Gas Analyser.

6. SPECIMEN REQUIREMENTS, MEANS OF ID, PATIENT PREPARATION

Tests should only be performed under the order of a Healthcare Professional directly involved in the patients care. Patient consent for the test is inferred if the patient willingly submits to the sample being collected. All patients must be positively identified (where possible) prior to sample collection and the user must ensure that the sample/patient and analyser records correspond.

Whole blood samples requiring blood gas analysis (either venous or arterial) should be collected into heparinised and electrolyte-balanced syringes, Radiometer safePICO syringes (minimum volume 1ml), Radiometer SafeClinitubes or other suitably heparinised capillary tube (with appropriate use of end caps and mixing fleas/wires). In cases of severe hypotension, dehydration or peripheral circulatory failure, and for unconscious patients, measurements from capillary blood may be misleading for certain analytes, such as glucose, and must not be used in these circumstances. An arterial or venous specimen must be used instead.



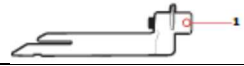


Taking a good sample

- Use a recommended sampler

- Radiometer safePICO syringes and SafeClinitubes are recommended
- Collect from a suitable site
- Radiometer SafePICO syringes require a minimum blood volume of 1ml
- SafeClinitubes (either 45ul for non-urea and creatinine devices or 65ul for urea and creatinine devices) must be completely filled.
- Any air within the syringe/capillary tube must be eliminated immediately (this can be done via a filter cap on the safePICO syringe).
- The samples must be immediately mixed, gently but thoroughly (gently roll a syringe between the palms of the hands and use the flea and magnet for capillary tubes).
- Carefully discard the first drop of blood from syringe samples (or gently push into the lid for Radiometer safePICO syringes) into a suitable waste container to avoid erroneous tHb results.
- Samples should be mixed again prior to analysis, preferably using the device auto-mixer.
- All samples requiring blood gas analysis must be analysed immediately (within 5 minutes). N.B analysis of samples with high pO₂ values must be completed within 5 minutes of collection.
- Samples within syringes and not requiring blood gas analyses may be analysed up to 30 minutes after collection (plastic capillary tubes within 10 minutes). When kept at room temperature.

7. REQUIRED EQUIPMENT AND REAGENTS

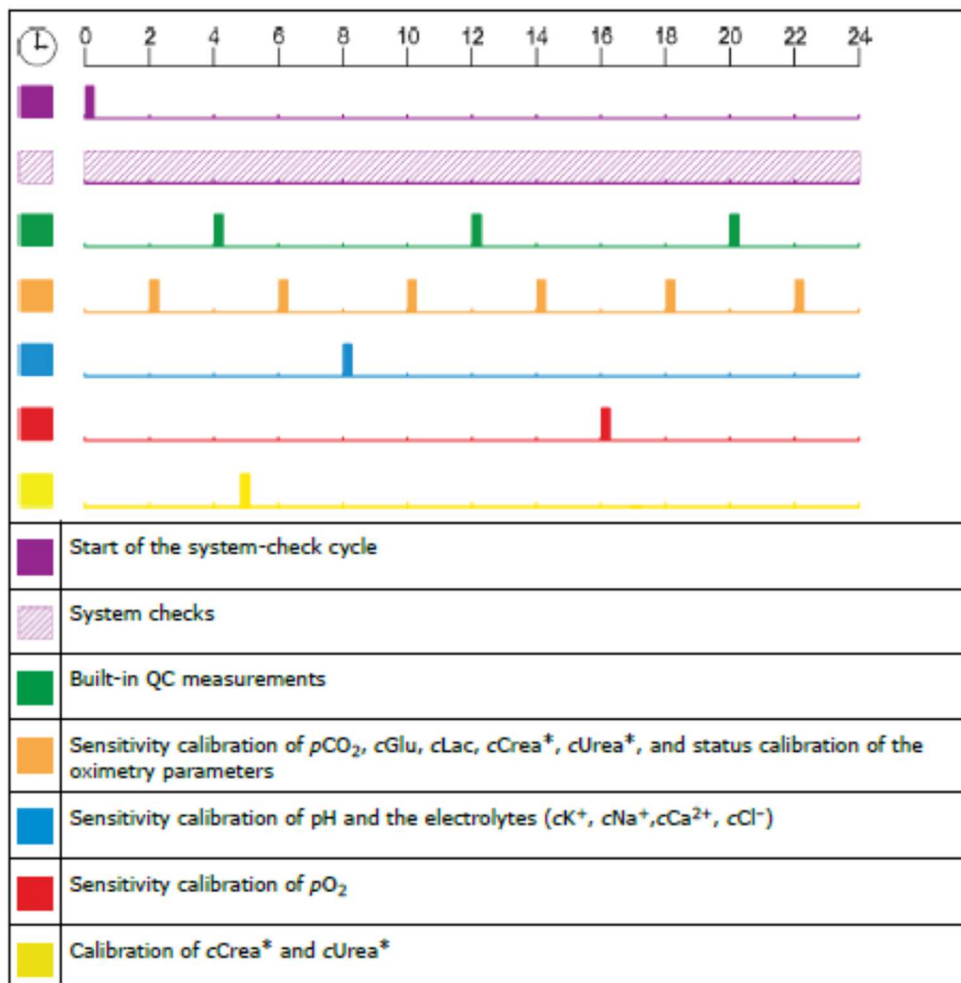
All reagents and consumables are managed and maintained by the POCT Team. Report any issues to your local POCT Team.

Name	Role	Storage	Notes
ABL90 Flex Plus	Analyser	-20 – 60°C	
Solution Pack SP90 Ki (parameter specific part number)	<p>All solutions necessary for the daily operation of the analyser are contained in the solution pack, e.g. calibration, rinse and quality control solutions. Apart from solution consumption in connection with a test, solution is consumed during a number of automatic activities (e.g. calibration and quality control) that runs at fixed intervals.</p> 	2-25 °C	Before installation of the solution pack, remove the top cover of the label on top of the solution pack, so that the biohazard label appears, to remind you that the solution pack must be disposed of as infectious waste after use. 2 Safety pin To activate a new solution pack, remove the safety pin and press the lid down. Replacements in this manual for further information).
Sensor Cassette SC90 Ki (model/parameter specific part number)	<p>The Sensor Cassette contains the detectors for analysis</p> 	2-10°C	From the factory, the sensor cassette comes dry-stored in the sensor cassette pack to ensure a 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. When conditioning the sensor cassette in the analyser, it typically takes 2-4 hours (including a calibration) for the sensor cassette to be ready for measurement. If the conditioning by the analyser is interrupted by the user by pressing Exit conditioning, some of the parameters may subsequently have a "?" in front of them.
Inlet Gasket Holder (903-585)		2-25 °C	Holds the inlet gasket (1). This is where you put your sampling device for aspiration
Inlet Probe (924-455)	Aspirating samples	2-25 °C	
Printer Paper (984-070)		2-25 °C	Paper for the thermal printer
Capillary Tubes/Syringes (942-898 – 65ul) 942-969 – 45ul)	Sampling devices	2-32 °C	
Clot Catcher (906-026)	<p>To prevent clots from entering the analyser</p> 	2-32 °C	
Magnet and mixing Flea	Mixing capillary tube samples	2-32 °C	
cHb Calibrator (944-021)	Calibrating cHb parameter	2-25 °C	

8. CALIBRATION PROCEDURE

The calibration process determines and checks the accuracy with which the Analyser measures its parameters. The process is therefore important in ensuring the reliability of results. Calibrations are performed with solutions (within the solution pack) and ambient air for each of the measured parameters. For details of calibration traceability, see POCT-BSPS-SOP-304 Appendix 5: ABL90 Flex Plus Calibration Traceability.

Calibrations are scheduled on all devices to the manufacturer's recommendation as shown below.



All parameters receive an automatic two point calibration at least every 24 hours with the exception of tHb which is manually calibrated quarterly. In addition to two point calibrations, one point calibrations are performed at regular intervals which may vary depending on consumable replacements, troubleshooting and start up routines. Manual calibrations can also be performed at any time. Sensor drift and status are monitored regularly and any parameters falling outside of tolerated limits will be disabled from use automatically (red cross) until a calibration is successfully completed. Calibrations are staggered and calibration offsets are applied to devices in close proximity to limit the impact of continuous planned downtime. Calibration schedules are verified in the verification report POCT-BSPS-VV-011: Radiometer ABL90 Flex Plus Blood Gas Analyser.

8.1. Performing an unscheduled calibration

- Check that the Analyser is in the Ready mode.
- Press Menu > Start programs > Calibration programs and call a calibration.
- The following options are available:
 - Calibration

Due to significant drift, the cGlu, cLac, Oxi, and pCO2 calibrations have a reduced validity time for the first 24 hours after cold starts and sensor cassette replacements. The first 24 hours, the validity time of the cGlu, cLac, Oxi, and pCO2 calibrations gradually increases to 4 hours (the span between scheduled calibrations). During the first 4 hours, no additional calibrations are scheduled, but a measurement takes up to 3 minutes because a calibration is performed with every measurement. After 4 hours, calibrations are run in fixed intervals according to the information below and a measurement takes 35 seconds.

Time installed	Time between calibrations
0-4 hours	(performed with every measurement)
4-6 hours	15 minutes
6-8 hours	30 minutes
8-12 hours	60 minutes
12-24 hours	240 minutes

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8.2. tHb calibration

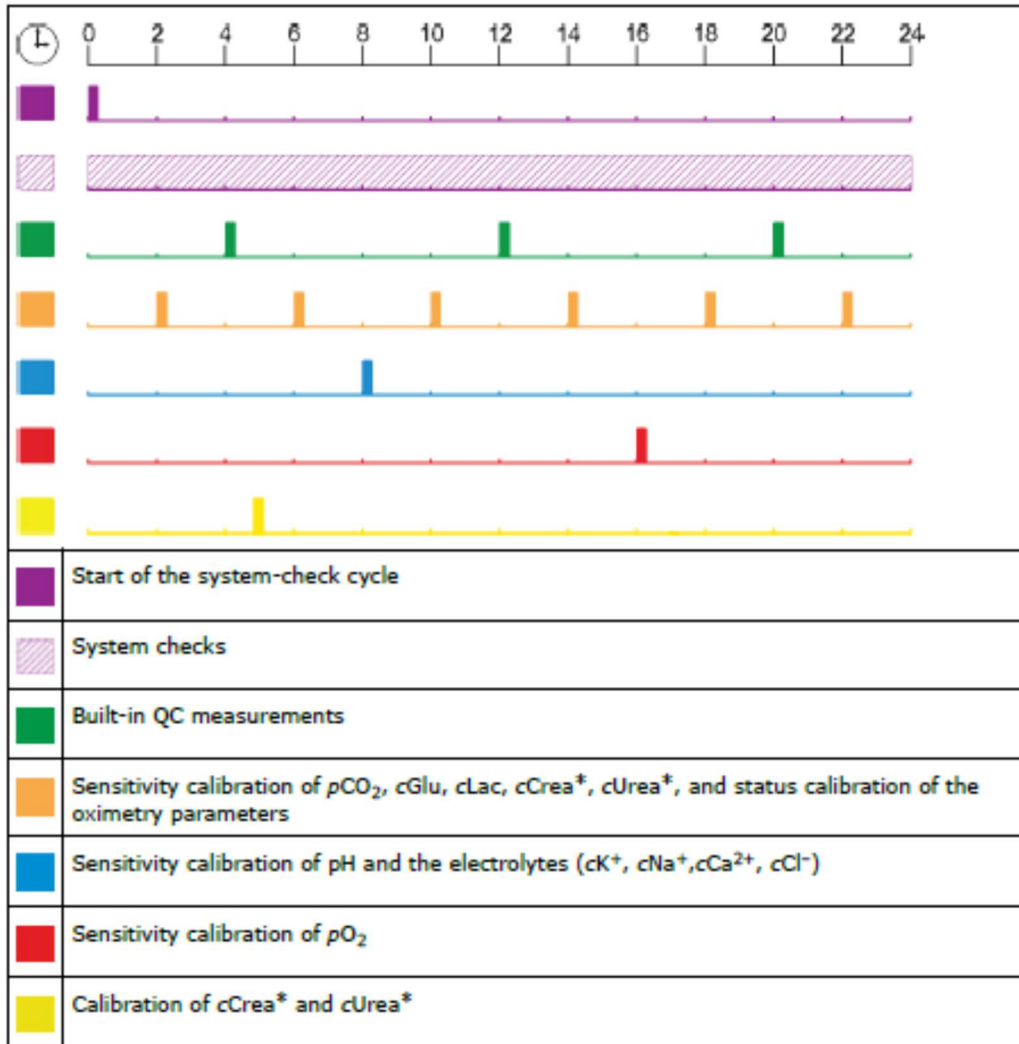
This calibration is used to adjust the analyser's optical system (cuvette factor and wavelength). It is recommended that a tHb calibration is performed every three months on S7770 ctHb Calibration Solution. The calibration can be included in the Calibration schedule.

- Press Menu > Start programs > Calibration programs > tHb calibration
- Enter the barcode information from the S7770 insert, using the barcode reader or the keyboard. To cancel the program, press Close.
- When the barcode has been accepted, tap the top of the S7770 ampoule to collect the liquid at the bottom and break off the ampoule neck, using the ampoule opener.
- Place the ampoule fully in the QUALICHECK adapter.
- Place the adapter tip against the inlet gasket and press the adapter upwards. The probe extends into the ampoule and the S7770 ctHb Calibration Solution is automatically aspirated. NOTICE: Be careful not to bend the probe.
- When prompted by the Analyser, remove the adapter and close the inlet.
- If the calibration results are not accepted, remedy the error and perform a new tHb calibration.

8.3. If a button is greyed out, a calibration cannot be performed.

9. INTERNAL QUALITY CONTROL (IQC) AND EXTERNAL QUALITY ASSURANCE (EQA)

All analysers are quality controlled to the manufacturer's recommendation (as shown below).



Three levels of IQC are performed every 24 hours approximately 8 hours apart for all tests. In addition to scheduled IQC, automatic IQC is performed depending on consumable replacements, troubleshooting and start up routines. Manual IQC testing can also be performed at any time. IQC results are monitored regularly and any parameters falling outside of tolerated limits will be disabled from use automatically (red cross) until a IQC successfully completed.

Oversight of IQC performance is achieved by Monthly Assessment of changes in Measurement Uncertainty using POCT-BSPS-SOP-908: POCT Measurement Uncertainty for Blood Gas Results.

To request a manual IQC measurement, tap: Menu > Analyser status > Quality Control

Select the QC solution required and tap Start QC

External Quality Assessment (EQA)

All devices are registered for the relevant parameters with the WEQAS Blood Gas and Cooximetry EQA scheme. Issues with EQA performance are reported to the Trust via the relevant POCT Committee Meeting,

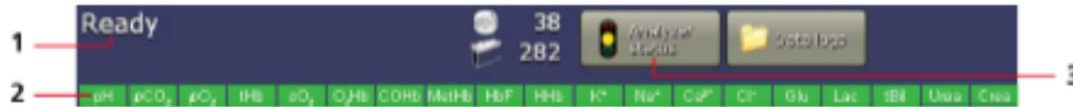
POCT Team only

The following procedure is used to process EQA samples: POCT-BSPS-MAN-6: Receipt and follow up of EQA samples and reports. N.B result suppression/repression should be removed before running cooximetry EQA samples but all settings must be reverted back after analyses. For a guide on how to do this, see Appendix 3; Removing COOX Suppression on the ABL90 Flex Plus.

10. PROCEDURE/METHOD

Standard syringe analysis

10.1. Check that the analyser is in the Ready mode.



10.1.1. Ready is displayed (1)

10.1.2. The colour of the parameter desired is green (2)

10.1.3. Analyze Status is green or yellow (3)

10.2. Wear appropriate PPE.

10.3. Log into the analyser:

10.3.1. Menu > Log In

10.3.2. Scan your unique operator barcode with the integrated barcode reader

10.3.3. You cannot manually enter your operator barcode

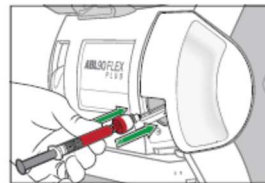
10.4. Gently mix the syringe by rolling gently between the palms.

10.5. Hold the syringe by the barrel and tap the appropriate syringe icon based on the sample to be analysed.

10.6. The analyser opens the inlet

10.7. Place and hold the tip of the syringe firmly in the centre of the inlet gasket


10.8. Push the syringe into the analyser as far as it will go and hold it there until prompted to remove.



10.8.1. NOTICE: Be careful not to bend the probe. Hold the syringe barrel and do not press the plunger.

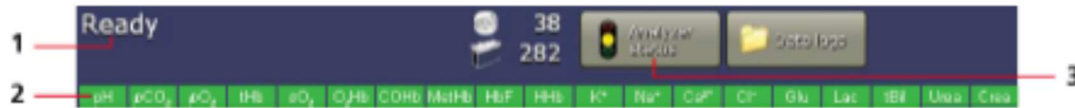
10.8.2. NOTICE: Make sure that the plunger is not pushed back by the probe.

10.9. When prompted by the analyser, remove the sampler, the inlet closes automatically.

10.10. Enter/scan the information required on the Patient identification screen. All fields marked with  are mandatory.

Radiometer safePICO Syringe Analysis

10.11. Check that the analyser is in the Ready mode.



10.11.1. Ready is displayed (1)

10.11.2. The colour of the parameter desired is green (2)

10.11.3. Analyze Status is green or yellow (3)

10.12. Wear appropriate PPE.

10.13. Place safePICO syringe into the mixer on the left hand side of the device

10.13.1. A light will acknowledge the presence of the syringe and automatic mixing begins

10.13.2. When mixing is complete, the light flashes

10.14. Log into the analyser:

10.14.1. Menu > Log In

10.14.2. Scan your unique operator barcode with the integrated barcode reader

10.14.3. You cannot manually enter your operator barcode

10.15. Gently mix the syringe by rolling between the palms.

10.16. Hold the syringe by the barrel and tap the appropriate syringe icon based on the sample to be analysed.

10.17. The analyser opens the inlet


10.18. Place and hold the tip of the syringe firmly in the centre of the inlet gasket

10.19. Push the syringe into the analyser as far as it will go and hold it there until prompted to remove.

10.19.1. NOTICE: Be careful not to bend the probe. Hold the syringe barrel and do not press the plunger.

10.19.2. NOTICE: Make sure that the plunger is not pushed back by the probe.

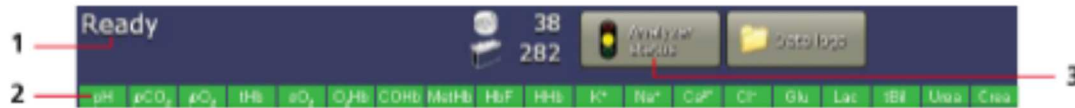
10.20. When prompted by the analyser, remove the sampler, the inlet closes automatically.

10.21. Enter/scan the information required on the Patient identification screen. All fields marked with  are mandatory.

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Capillary Analysis

10.22. Check that the analyser is in the Ready mode.



10.22.1. Ready is displayed (1)

10.22.2. The colour of the parameter desired is green (2)

10.22.3. Analyze Status is green or yellow (3)

10.23. Wear appropriate PPE.

10.24. Log into the analyser:

10.24.1. Menu > Log In

10.24.2. Scan your unique operator barcode with the integrated barcode reader

10.24.3. You cannot manually enter your operator barcode

10.25. Mix the capillary sample by gently moving the mixing flea repeatedly along the length of the capillary with a magnet. Then move the mixing wire to the end of the capillary opposite to that from which the blood is to be aspirated.

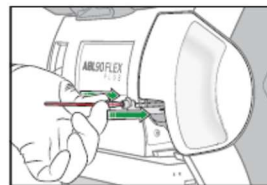
10.26. Remove the end caps of the capillary tube

10.27. Place a clot catcher on the opposite end of the mixing flea (and Vaseline if used)

10.28. Select the appropriate capillary icon based on the sample to be analysed

10.29. Place and hold the clot catcher in the centre of the inlet gasket

10.30. Carefully push the capillary into the analyser as far as it will go and hold it there until prompted to remove.



10.31. When prompted by the analyser, remove the sampler, the inlet closes automatically

10.32. Enter/scan the information required on the Patient identification screen. All fields marked with are mandatory.

Entering Analysis Details

10.33. The following information should be entered to ensure the results are displayed and the correct biological reference intervals are applied. All fields with a hand pointing to it on the analyser are mandatory. All other parameters are non-mandatory but it is recommended as much information is entered as possible. If the hospital number input has patient details available on an associated electronic patient record (EPR), or has been used on the device previously, some fields may be auto-populated. The operator must verify the details entered (and the auto-populated fields) to ensure results are produced and stored on the correct patient record.

10.33.1. Enter the PID as the full hospital number using the scan function or the on-screen keyboard

10.33.1.1. N.B **manual entry** of PID at RBH: the leading 0's must be omitted.

10.33.2. After entering the hospital number the demographics confirmation box should appear. If this does not appear, the operator should check hospital number has been entered correctly (including removal of leading zeros where applicable) and only proceed to manual entry of demographic data after this check has been completed. If the EPR feed is not working this should be reported to Trust IT.

10.33.3. Enter the patients First name using the on-screen keyboard (or verify details)

10.33.4. Enter the Patients Surname using the on-screen keyboard (or verify details)

10.33.5. Enter the Patients sex using the drop-down menu on the right of the screen (or verify details)

10.33.6. Enter the Patients date of birth using the on-screen keyboard (or verify details)

10.34. If all elements of the analysis have been satisfied, the results will be displayed **immediately** on-screen and on the thermal print out (if enabled). Please note the printout will fade over time so it is essential to documents all results according to local policies. **If all requisites have been satisfied, results will appear in the EPR within a few minutes.**

10.35. Press the Log Off icon to log off the analyser.

Guide to Analysis Buttons (Hot Keys)

10.36. Analysis buttons (displayed before sampling) may be used in your clinical area. It is important that the correct analysis button is chosen before proceeding with the analysis. Not choosing a button or selecting the incorrect button may result in:

- 10.36.1. Inaccurate results being produced for parameters for which the sample type is unsuitable,
- 10.36.2. Required parameter(s) not being analysed,
- 10.36.3. Sample wastage,
- 10.36.4. Results generated inappropriately and abnormalities not detected.

If analysis buttons are in use in your clinical area, their function and use will be covered in the training session provided.

Hot Keys

Analysers in or around wards with special requirements e.g. maternity/neonatal or respiratory wards should have access to specialised hot keys which allow for the testing of:

Syringe Modes

- Cord blood venous (pH, pO₂, pCO₂, HCO₃⁻, base excess, lactate)
- Cord blood arterial (pH, pO₂, pCO₂, HCO₃⁻, base excess, lactate)

Capillary Modes

- Glucose only (glucose)
- Foetal blood scalp (pH, lactate)

Mixed Venous (may be requested from any ward)

- Fluid (full profile)

These should only be activated in relevant areas.

Maintenance (POCT Staff Only)

Moving an ABL90 Flex Plus

There may be occasions where devices must be relocated/tests available changed to meet operational, clinical or financial needs.

Changing the setup for urea and creatinine vs non-urea and creatinine is performed as follows:

- Device should have existing solution pack and sensor cassette before starting
- Log on to device using the service code (requires a Service Engineer visit)
- Select Menu>Service>Software>Reconfigure analyser
- Follow instructions to replace solution pack then sensor
- Leave to warm up
- N.B changing from or to urea and creatinine will require a change the default capillary size

Any analysers requiring relocation in or out of departments using Hot Keys need to be checked for activation/deactivation and the appropriate boxes ticked.

Visual representation showing whether the keys are activated must be displayed on the back of each analyser to allow POCT staff to distinguish between activated and deactivated analysers.

If a Hot Key card is not displayed on the back, print POCT-BSPS-SOP-304 Appendix 2. Laminate the page before cutting out the cards along the dotted lines

- tick the appropriate box
- write your hospital initials on the top left hand box
- Place in the plastic pocket at the back of the machine

To activate hot keys:

- 1) Menu > Utilities > Setup > Analysis Setup > Patient Reports
- 2) Create a new report layout, this can be done by selecting “copy” in the bottom left corner while having an existing layout selected OR by selecting “new”

- 3) Select your newly created layout and rename it in the top right corner of the screen. Next modify/check the patient demographics, this can be done by selecting “Edit patient ID layout” on the right-hand side. If you selected “copy” in the previous step these settings may be copied also. Ensure the patient ID layout matches below.

Patient ID	Mandatory
Patient Surname	Mandatory
Patient First name	Mandatory
Patient Gender	Mandatory (optional in neonatal and maternity devices)
Patient Date of birth	Mandatory
FiO2	Mandatory to enter except optional on Neonatal and Maternity. Default 21%
Patient temperature	Default to 37.0C - can be altered
Date and time of test	
Operator name	Mandatory and needs to print name
Machine Serial Number/Name	

- 4) See previous page for parameter linked to each hot key. Select the desired parameter from the left-hand side and use the two arrow keys to move them back and forth. Everything on the right-hand side will be present on the final report. Select “back” in the bottom right corner when you’re finished.
- 5) Modify/check the result layout. This is done in the same way as the patient ID, select “edit patient results layout”. Parameters for each hot key are listed on the previous page.
- 6) Return to the main analyser page and navigate to the sample mode creation menu. Menu > Utilities > Setup > Analysis Setup > Capillary OR Syringe Modes
- 7) Select a blank button within the “Primary Modes” section of the screen. Check the “enable” box on the right-hand side of the screen. Change the “Measuring Program” which can be done on the top right of the screen while the new button is still selected.
- 8) Rename the button and bind it to the new report created earlier. While the button is selected you will see an “Edit Name” button at the bottom of the screen, press it and free type the button name. Next use the “layout” button at the bottom and select the new layout which you’ve created.
- 9) In the bottom left side of the screen select “Parameters” button, ensure to check/un-check all of the appropriate parameters for the button you are creating.

Data transfer to POCcellerator and EPRs is reliant on the IT connections and data held in WinPath Enterprise. The POCT IT Team must be made aware of any analyser location move/set up change to ensure continuity and accuracy of data transfer to EPR.

The POCT Quality Team will also require notification to assess to the impact to departmental operations.

Reagent Delivery and Verification

New reagents (new lot numbers or new shipment) should be verified for use upon installation by performing IQC and calibration. This is performed automatically by the analyser when new reagents are installed. Please refer to POCT-BSPS-MAN-12-Appendix-1 for verification details.

When the first sensor cassette or solution pack of a new lot number or shipment is installed, the verification should be recorded in the POCT reagent acceptance log (POCT-BSPS MAN-12-SDRF-1). Failure of the reagent to pass IQC and calibration should also be recorded on the log and all reagent from that lot/shipment quarantined pending investigation by a senior staff member.

Performing verification at the point that a reagent is put into use poses the risk of a verification failure and subsequent lack of reagents for clinical testing. As rejection of new consumables is a rare occurrence, the risk is mitigated by stocking multiple sizes and lot numbers of ABL90 reagents at the same time. POCT also operates ABL90s at multiple BSPS sites so alternative reagents can be supplied the same day if needed.

N.B to raise credit claims for faulty consumables, follow POCT-BSPS-SOP-304 ED 2: ABL90 Flex Plus Credit Claim Procedure.

Daily

10.37. Check analyser status and trouble-shoot error messages

10.38. View IQC data, inform POCT site Coordinator of any poor IQC data

10.39. Check Solution Pack and Sensor Cassette Capacity

10.39.1. Solution Packs should be changed when the number of activities is less than that required for 1 day or the current pack has reached the onboard stability.

10.39.2. Sensor cassettes should be changed when the number of activities is less than that required for 1 day or the current pack has reached the onboard stability.

10.40. To Change the Solution Pack:

- 10.40.1. Menu > Analyser Status
- 10.40.2. Consumables > Replace > Solution Pack
- 10.40.3. Press to Start Video Guidance
- 10.40.4. Ensure you have the correct replacement solution pack and pull the red protective pin from the pack.
- 10.40.5. Press firmly with the palms of your hands on the lid until the tabs click into the corresponding holes
- 10.40.6. Tap the action completed icon
- 10.40.7. Wait until the used solution pack is released and remove (this contains bio-hazardous material)
- 10.40.8. Place your thumbs on the white part of the solution pack and push into the analyser compartment until it clicks into place
- 10.40.9. The analyser closes the inlet
- 10.40.10. Enter required information, and then click OK.

N.B Solution Packs removed from one analyser 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.

10.41. To Change the Sensor Cassette

- 10.41.1. Menu > Analyser Status
- 10.41.2. Consumables > Replace > Sensor Cassette
- 10.41.3. Press to Start Video Guidance
- 10.41.4. Ensure you have the correct replacement sensor pack and wait until the sensor cassette compartment opens.
- 10.41.5. Remove the used Sensor cassette (this contains bio-hazardous material), click Action Completed

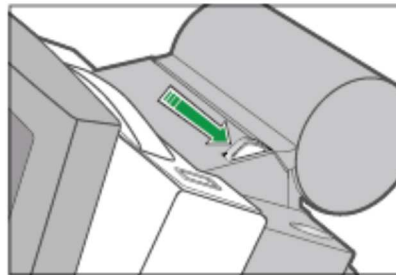
- 10.41.6. Pull of the foil of the new sensor cassette, unscrew the lid and lift out. Click Action Completed.
- 10.41.7. Press new sensor cassette in place and click action completed.
- 10.41.8. Enter required information and Click OK.

N.B A Sensor Cassettes removed from one analyser can be used on the same or other analyser providing:

- The Sensor Cassette is kept right side up after its removal. This prevents damage to the sensors.
- The Sensor Cassette is installed within 2 hours of its removal
- The Sensor Cassette is installed before its **Scheduled to replace** date
- The Sensor Cassette is installed before its **Expiration date**
- The Sensor Cassette has some remaining activities
- The Sensor Cassette was not removed from an analyser during a long-term shutdown procedure.

10.42. Check Printer Paper (if printing is enabled)

- 10.42.1. Ensure sufficient printer paper is installed for routine use. To replace printer paper;
- 10.42.2. Menu > Analyser Status
- 10.42.3. Consumables > Replace > Paper
- 10.42.4. Press the release bottom



- 10.42.5. Open the cover and remove the used paper roll
- 10.42.6. Place the new paper roll ensuring the paper unwinds from below
- 10.42.7. Ensure some paper extends out of the printer
- 10.42.8. Close the cover until it clicks into place
- 10.42.9. Tap the replaced button
- 10.42.10. Enter required information
- 10.42.11. Tap OK.

Weekly

10.43. Clean the inlet gasket

- 10.43.1. Menu > Analyser Status > Other Activities > Inlet Check > Clean inlet gasket
- 10.43.2. Clean with lint free cloth and 70% alcohol.
- 10.43.3. Tap Action completed

10.44. Clean the Touch Screen

- 10.44.1. Place your finger on an area of the screen that is not active to deactivate it, clean with lint free cloth and 70% alcohol.

10.45. Clean the Analyser Exterior

- 10.45.1. Lightly dampen lint free cloth with 70% alcohol, wipe the exterior surfaces of the analyser.

11. INTERFERENCES, CROSS REACTIONS and POTENTIAL SOURCES OF VARIABILITY

Analyses must be performed by trained users only.

The majority of all errors in blood gas testing occur at the pre-analytic phase of the sampling procedure, for example:

- Failure to identify the sample clearly
- Failure to enter patient details correctly on the device
- Use of unsupported/incorrect sample types (preservatives can directly interfere with tests)
- Vigorous mixing the sample
- Not eliminating air from the sample immediately

N.B to ensure the quality of results you must ensure the following. Not following these guidelines may lead to inaccurate results and may expose the user to potentially infectious blood.

- Incorrect usage may lead to inaccurate results.
- Pay close attention to the results. Results errors are explained at the bottom the report.
- Always use the correct sampling devices and correct analysis mode.
- Always use syringes containing balanced heparin and never liquid anticoagulant.
- Always protect against atmospheric interferences (e.g. syringe/capillary end cap).
- Always remove air bubbles from a syringe sample before introducing it into the analyser. Air bubbles may result in erroneous gas results, especially pO_2 values.
- Always mix the sample when collected (and prior to analysis if there is a delay).
- Always eliminate 2-3 drops of blood before syringe analysis (or follow SafePICO procedure).
- Always analyse blood gas samples immediately or within 5 minutes of collection.
- Always analyse syringe samples within 30 minutes.
- Always analyse capillary samples within 10 minutes.
- Old samples will generate inaccurate results.
- Never analyse clotted or unmixed samples.

- Never use samples collected from a drip arm (may lead to dilution).
- Confirm erroneous results before acting upon them, especially:
 - K⁺ (haemolysis falsely increases K)
 - Ca²⁺ (haemolysis falsely decreases Ca²⁺)
 - Hb (accuracy is dependent on proper mixing)
 - Glucose and Lactate (Sodium thiocyanate may cause falsely increased glucose and lactate results)
 - Lactate (Glycolic acid - ethylene glycol degradation product and present in xylitol infusions - may falsely increase Lactate)
 - Cooximetry (Fluorescein, methylene blue, hydroxocobalamin and cyanocobalamin - which have medical applications as contrast dyes - may cause erroneous cooximetry results)
- Always use a clot catcher for capillary samples.
- Never operate the device without prior training.
- Never use the device if not in Ready mode.

The validity of the test results from this analyser must be carefully examined by a clinician and related to the patient's clinical condition, before any clinical decisions are made on the basis of the test results.

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.

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 cCa ²⁺ results
Anticoagulants with ammonium heparin	False cCl ⁻ and cUrea* results
Disodium oxalate with sodium fluoride	Falsely high cNa ⁺ , falsely low cCa ²⁺ and false cGlu and cLac results
Trisodium citrate	False cNa ⁺ , cK ⁺ , cCa ²⁺ , pH, cGlu, and cLac results
EDTA	<ul style="list-style-type: none"> False pH, pCO₂, cNa⁺, cK⁺ and cCa²⁺ results False cCa²⁺, cCrea* and cUrea* results in subsequent patient samples

12. RESULTS

Clinical decision limits are dependent on the clinical utility of the device. Consult local guidelines/protocols for relevant protocols. If you are unsure, ask a senior member of staff in your clinical area.

Measurable ranges are published in:

POCT-BSPS-SOP-304 ED 1: ABL90 Flex Plus Operators Manual

Any result outside of the measurable range will not produce a numerical (quantitative) result. It is not possible to determine quantitative results that lay outside the measurement range of the device

Results are captured electronically on a central database and printed automatically on thermal printer paper.

Results must be transcribed into patient notes and the printer paper will fade over time.

Results outside of the biological reference interval (if provided) are marked with:



Results outside of the Clinical Decision Limit (if provided) are marked with:



Results outside Measuring Range are marked with:



Results marked with '?' are not available. See bottom of report for error explanation.

Where PID is entered correctly, the patient exists within the POCT data manager (occurs automatically after booking the patient into the ward/hospital **via the EPR**) and no issues exist between relevant IT platforms, results will be transmitted to the electronic patient record within a few minutes.

It is the responsibility of the operator to ensure the validity of results produced and to inform POCT of any suspected spurious results. Repeat analysis can be performed at the next nearest analyser.

Abnormal results (see next section) should be highlighted to the clinician caring for the patient immediately.

Results should be used in conjunction with clinical information.

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13. BIOLOGICAL REFERENCE INTERVALS AND CLINICAL DECISION LIMITS

Biological reference intervals and clinical decision limits are dependent on the clinical utility of the device. Consult local guidelines/protocols for relevant ranges. If you are unsure, ask a senior member of staff in your clinical area. Sample type, age and sex related ranges are provided on the device, the device printout (if enabled) and approved EPRs.

The blood gas biological reference intervals for the Radiometer ABL90 Flex Plus analysers have been sourced and selected as per the table below.

	Parameters with Comparative Laboratory Test	Parameters without Comparative Laboratory Test
1	Alignment of ranges with blood sciences laboratory, irrespective of source, unless suitably justified	Tietz 7 th Edition
2	Other, referenced and justified	Radiometer Acute Care Handbook
3		Other, referenced and justified

The following pages show a full list description of the biological reference intervals and their source.

- If a single range is listed, there are no sex or age differences used.
- There are no biological reference intervals for mixed venous blood or fluids, due to the nature of these samples.
- Action limits are dependent on the clinical utility of the device.

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Limitations of the Radiometer ABL90 device have restricted the age bins which can be programmed into the device. Specific limitations are described in the tables below accordingly. Further information can be found in POCT-BSPS-DOC-002-APPENDIX-001: Guidance for Managing Patients Using POCT Results: Blood Gas Analysers: Radiometer ABL90 Flex Plus.

0 – 1 day
2 day to 14 days
15 days to 2m +30 days
3m to 1yr +364 days
2 yrs to 4yr +364 days
5 yrs to 11 yrs+364 days
12 yrs to 13 yrs+364 days
14 yrs to 15 yrs +364 days
16 yrs to 17yrs +364 days
18 years and above

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	Arterial Reference Range (Biological Reference Interval)		Arterial Critical Range (Clinical Decision Limit)	Venous and Capillary Reference Range (Biological Reference Interval)		Venous Critical Range (Clinical Decision Limit)	Source
pH (no units)	7.35 - 7.45		7.20 - 7.60	7.32 - 7.43		None	Tietz 7 th Ed. (4a)
pCO₂ (kPa)	M: 4.7 - 6.4 F: 4.3 - 6.0		2.6 - 9.3	None		None	Tietz 7 th Ed. (4)
pO₂ (kPa)	11.0 - 14.4		<6.0	None		None	Tietz 7 th Ed. (4b)
Sodium (mmol/L)	133 - 146		120 - 150	133 - 146		120 - 150	Pathology Harmony (5)
Potassium (mmol/L)	<18 yrs	3.5 - 4.7	2.8 - 6.0	<=18yrs	3.5 - 4.7	2.8 - 6.0	CALIPER (6)
	>= 18 yrs	3.4 - 4.5		>= 18yrs	3.4 - 4.5		Radiometer ACH (7a)
Chloride (mmol/L)	95 - 108		86 - 114	95 - 108		86 - 114	Pathology Harmony (5)
Ionised Calcium (mmol/L)	1.15 - 1.33		0.78 - 1.58	1.15 - 1.33		0.78 - 1.58	Tietz 7 th Ed. (4)
Urea (mmol/L)	<= 14 days	Device* <=8.2 EPR: 1.0 - 8.2	>25	<= 14 days	Device* <=8.2 EPR: 1.0 - 8.2	>25	Aligned to local laboratory. Paediatrics = CALIPER (8) Adults = Pathology Harmony (5)
	15d - 1yrs	Device* <=6.0 EPR: 1.2 - 6.0		15d - 1yrs	Device* <=6.0 EPR: 1.2 - 6.0		
	2yrs -11yrs	3.2 - 7.9		2yrs -11yrs	3.2 - 7.9		
	12yrs -17yrs	M: 2.6 -7.5 F: 2.6 - 6.8		12yrs -17yrs	M: 2.6 -7.5 F: 2.6 - 6.8		
	>=18 yrs	2.5 - 7.8		>=18 yrs	2.5 - 7.8		

***Potassium:** For more information of biological reference interval differences from the laboratory refer to: POCT-BSPS-DOC-002-APPENDIX-001: Guidance for Managing Patients Using POCT Results:

Blood Gas Analysers: Radiometer ABL90 Flex Plus

***Urea:** The lower limit of the references source is below the reportable range of the device. The range which displays on the device reflects this.

	Arterial Reference Range (Biological Reference Interval)		Arterial Critical Range (Clinical Decision Limit)	Venous and Capillary Reference Range (Biological Reference Interval)		Venous Critical Range (Clinical Decision Limit)	Source
Creatinine (umol/L)	<= 14d	Device* <=82 EPR: 29 – 82	>250	<= 14d	Device: <=82 EPR: 29 – 82	>250	Aligned to local laboratory. PAEDIATRIC = CALIPER (8) Adult = Junge et al. (9)
	15d - 1yrs	Device* <=35 EPR: 9 - 32		15d - 1yrs	Device: <=35 EPR: 9 - 32		
	2yrs - 4yrs	Device* <=38 EPR: 18 – 38		2yrs - 4yrs	Device: <=38 EPR: 18 – 38		
	5yrs -11yrs	Device* <=54 EPR: 27 - 54		5yrs - 11yrs	Device: <=54 EPR: 27 - 54		
	12 yrs - 15yrs	Device: 40 - 72 EPR: Lab**		12 yrs - 15yrs	Device: 40 - 72 EPR: Lab**		
	16yrs - 17yrs	M: 55 - 96 F: 43 – 74		16yrs - 17yrs	M: 55 - 96 F: 43 - 74		
	>= 18yrs	Device M: 64 -104 F: 49 - 90 EPR: Lab**		>= 18yrs	Device M: 64 -104 F: 49 – 90 EPR: Lab**		
Glucose (mmol/L)	4.0 – 11.0		2.5 – 20	4.0 – 11.0		2.5 – 20	JBDS (10) and (11) local consultation.
Lactate (mmol/L)	0.6 – 2.0		>4.0	0.6 – 2.5		>4.0	V = Pathology Harmony (5) A = Diff. from venous based on Tietz (4c)
Total Haemoglobin (g/L)	<=1d	149 – 237	81 – 199 *Lower critical for <14d only	<=1d	149 – 237	81 – 199 *Lower critical for <14d only	Aligned to local laboratories (12)
	2d – 14d	134 – 198		2d – 14d	134 – 198		
	15d – 2mo	94 – 130		15d – 2mo	94 – 130		
	3mo – 1yr	101 – 130		3mo – 1yr	101 – 130		
	2yrs – 4yrs	110 – 138		2yrs – 4yrs	110 – 138		
	5yrs –13yrs	111 – 147		5yrs – 13yrs	111 – 147		
	>= 14yrs	M: 130 - 180 F: 115 – 165		>= 14yrs	M: 130 - 180 F: 115 – 165		

Creatinine: * The lower limit of the references source is below the reportable range of the device. The range which displays on the device reflects this.

**Due to limitations related to age bracket set up on POCT device, patients aged 15 and 18 years of age, will display a different biological reference interval on the device print-out from the EPR. The EPR range is age-specific and aligned with the laboratory range.

	Arterial Reference Range (Biological Reference Interval)		Arterial Critical Range (Clinical Decision Limit)	Venous and Capillary Reference Range (Biological Reference Interval)		Venous Critical Range (Clinical Decision Limit)	Source
O ₂ Saturation (%)	94 – 98			None			Tietz 7 th Ed (4)
Oxyhaemoglobin (%)	91 – 98			None			Local calculation based on device (13)
Carboxyhaemoglobin (%)	0.5 – 1.5			None			Tietz 7 th Ed. (5d)
Methaemoglobin (%)	0.0 – 1.5			None			Tietz 7 th Ed. (5d)
Deoxyhaemoglobin (%)	None			None			N/A
Base excess [calculated] (mmol/L)	– 2.0 to +3.0			None			iSTAT IFU (13)
Bicarbonate [calculated] (mmol/L)	21 – 28			None			Radiometer ACH (7b)
Anion Gap [calculated] (mmol/L)	8 – 16			None			Tietz 7 th Ed. (4e)
Osmolality [calculated]	Test deactivated. Jan 2024			Test deactivated. Jan 2024			N/A
Haematocrit (POCT = % Lab = L/L)	<=1d	44 – 64		<=1d	44 – 64		Aligned to local laboratories (12)
	2d – 2mo	32 – 42		2d – 2mo	32 – 42		
	3mo – 4yrs	36 – 44		3mo – 4yrs	36 – 44		
	5yr – 13yrs	37 – 45		5yr – 13yrs	37 – 45		
	>=14yrs	M: 40 – 54 F: 37 – 47		>=14yrs	M: 40 – 54 F: 37 – 47		

Maternity and Neonatal Specialist Ranges

Sample Type	Analyte	Biological Reference Interval	Clinical Decision Limit	Source
Cord Blood Arterial	pH	7.12 - 7.35	No Limit	White CR et al. (1)
	pO ₂	Device*: <=3.7 EPR: 0.8 - 3.7	No Limit	White CR et al. (1)
	pCO ₂	5.6 - 9.8	No Limit	White CR et al. (1)
	Bicarbonate	18.8 - 28.2	No Limit	White CR et al. (1)
	Base Excess	- 9.3 - 1.5	No Limit	White CR et al. (1)
	Lactate	2.0 - 6.7	No Limit	White CR et al. (1)
Cord Blood Venous	pH	7.23 - 7.44	No Limit	White CR et al. (1)
	pO ₂	2.2 - 5.3	No Limit	White CR et al. (1)
	pCO ₂	3.8 - 7.1	No Limit	White CR et al. (1)
	Bicarbonate	17.2 - 25.6	No Limit	White CR et al. (1)
	Base Excess	- 8.3 - 2.6	No Limit	White CR et al. (1)
	Lactate	No Interval	No Limit	(none listed) White CR et al. (1)
Foetal Scalp	pH	>7.24	<7.21	Hughes et al. (2)
	Lactate	<4.2	>4.8	Clinical Excellence Queensland (3)

*Cord blood arterial pO₂ : The lower limit of the references source is below the reportable range of the device. The range which displays on the device reflects this.

14. LABORATORY INTERPRETATION

There is no routine laboratory validation, interpretation of results or interpretive comments added to results produced at the point of care, even for those that fall outside of biological reference intervals or clinical decision limits. Your local POCT Team can however provide technical and clinical advice if required.

The sodium, potassium, calcium, chloride and glucose assays are routinely available in your local laboratory for confirmation of abnormal results or errors. However it is advisable for monitoring purposes that the same method be used consistently. N.B The laboratory produces total calcium results and the ABL90 devices produces ionised calcium results (approximately 50% total calcium).

The result obtained at the point of care is the responsibility of the user. Clinical management of the patient based on a point of care result is the responsibility of the clinician.

15. DISPOSAL OF SAMPLES AND REAGENTS.

Handle all patient samples and reagents as if they are a potential biohazard. Dispose of materials as per local protocols.

16. REFERENCES

INTERNAL

POCT-BSPS-POL-004	BSPS POCT Training Policy
POCT-BSPS MAN-12 SDRF 1	Reagent Acceptance Spreadsheet
POCT-BSPS-SOP-908:	POCT Measurement Uncertainty for Blood Gas Results
POCT-BSPS-MAN-6:	Receipt and follow up of EQA samples and reports
POCT-BSPS-DOC-002-APPENDIX-001:	Guidance for Managing Patients using POCT Results: Blood Gas Analysers: Radiometer ABL90 Flex Plus
POCT-BSPS-MAN-12 Appendix 1	Reagent Verification Protocol
POCT-BSPS-VV-011:	Radiometer ABL90 Flex Plus Blood Gas Analyser
POCT-BSPS-VV-016:	ABL90 Reverification against Laboratory Analysers (Alinity)

EXTERNAL

1. White CR, Doherty DA, Henderson JJ, Kohan R, Newnham JP, Pennell CE. Benefits of introducing universal umbilical cord blood gas and lactate analysis into an obstetric unit. Aust N Z J Obstet Gynaecol. 2010 Aug;50(4): 318 - 28. doi: 10.1111/j.1479 - 828X.2010.01192.x. PMID: 20716258.
2. Hughes O, Murphy DJ. Comparing second - line tests to assess fetal wellbeing in Labor: a feasibility study and pilot randomized controlled trial. J Matern Fetal Neonatal Med. 2022 Jan;35(1): 91 - 99. doi: 10.1080/14767058.2020.1712704. Epub 2020 Jan 12. PMID: 31928269. *Nb: these reference ranges were originally sourced in NICE CG190 (2014).*
3. Clinical excellence Queensland. Maternity and Neonatal Clinical Guideline. Intrapartum fetal surveillance (IFS). MN19.15 - V7 - R24. December 2019.
4. Rifai, N. Tietz textbook of laboratory medicine. Seventh edition. Edited by R.W.K. Chiu and I. Young. Elsevier.

- a. *pH: Alternative ranges for adults >60yrs are not applied*
 - b. *pO₂: Ranges for the first 30mins – 1h of life are not applied.*
 - c. *A venous lactate range on 0.3 – 1.5 mmol/L and arterial range of 0.3 – 2.0 mmol/L is quoted. To align the venous reference range with the local laboratory (0.6 – 2.5mmol/L), the arterial range will adopt the same lower limit of normal, and an upper limit of normal of 0.5mmol/L less (0.6 – 2.0 mmol/L).*
 - d. *CoHb: non-smokers' range is applied*
 - e. *Anion gap: applied to non-potassium utilising equations, see 454.e5*
5. The Association for Clinical Biochemistry, Institute of Biomedical Science, Royal College of Pathologists [Pathology Harmony Group] (2011). Clinical Biochemistry Outcomes. Available at: <https://www.google.com/url?sa=t&rct=i&q=&esrc=s&source=web&cd=&ved=2ahUKewio-O7i9pgBAxURQ8AKHQxaAtwQFnoECBkQAQ&url=https%3A%2F%2Fwww.acb.org.uk%2Fasset%2FEEA82309-7E93-417D-9B8991B0C65C52FB%2F&usg=AOvVaw0pDzKSNGLSnekoa7oImMy5&opi=89978449>. Accessed (08/09/2023). Stored iPassport
 6. Mary Kathryn Bohn, Alexandra Hall, Siobhan Wilson, Tina Henderson, Khosrow Adeli, Pediatric Reference Intervals for Critical Point-of-Care Whole Blood Assays in the CALIPER Cohort of Healthy Children and Adolescents, American Journal of Clinical Pathology, Volume 156, Issue 6, December 2021, Pages 1030-1037, <https://doi.org/10.1093/ajcp/aqab064>
 7. Radiometer Acute Care Handbook. Available at: <https://www.radiometer.com/en/knowledge-center/handbooks/acute-care-testing-handbook/download> Accessed (08/09/2023) and stored iPassport
 - a. *K⁺: a range spanning the male and female listed range is applied – aligned with laboratory application of a single range for males and females.*
 - b. *Bicarbonate: a range spanning males and females is applied*
 8. Bohn, Mary Kathryn, Wilson, Siobhan, Hall, Alexandra, Massamiri, Youssef, Randell, Ed and Adeli, Khosrow. "Pediatric reference interval verification for common biochemical assays on the Abbott Alinity system" Clinical Chemistry and Laboratory Medicine (CCLM), vol. 59, no. 9, 2021, pp. 1554-1562. <https://doi.org/10.1515/cclm-2021-0336> *nb: No method specific ranges for Radiometer ABL90 were available for urea, alignment to Abbott ranges appropriate based on local method comparison.*
 9. Wolfgang Junge, Baerbel Wilke, Atef Halabi, Gerhard Klein. Determination of reference intervals for serum creatinine, creatinine excretion and creatinine clearance with an enzymatic and a modified Jaffé method. Clinica Chimica Acta. Volume 344, Issues 1-2. 2004. Pages 137-148. ISSN 0009-8981. <https://doi.org/10.1016/j.cccn.2004.02.007>.
 10. Joint British Diabetes Societies for inpatient care. The hospital management of hypoglycaemia in adults with diabetes mellitus. Revised March 2022. Available from: [JBDS 01 Hypo Guideline March 2022.pdf \(amazonaws.com\)](#)

- 11. Joint British Diabetes Societies for inpatient care. The management of diabetic ketoacidosis in adults. Revised June 2021. Available from: [JBDS 02 DKA Guideline amended v2.pdf \(amazonaws.com\)](#)
- 12. Haematology reference ranges BS - BSPS - DOC - 009: Blood Sciences WPE Reference Ranges
- 13. iSTAT Alinity. System Operations Manual. Stored on iPassport: POCT - BSPS - SOP - 308 ED 1: Abbott iSTAT Alinity User Manual.

17. APPENDICES AND ATTACHMENTS

ED 1:	ABL90 Flex Plus User Manual
ED 2:	ABL90 Flex Plus Credit Claim Procedure
ED 3:	ABL90FP Solution pack SP90 / SP90XL Kit insert
ED 4:	BL90FP Solution Pack SP90Ki Kit Insert
ED 5:	ABL90FP Sensor Cassette SC90 / SC90Ki Kit Insert
ED 6:	ABL90FP tHb Calibrator Kit Insert
TRAIN 1:	ABL90 Flex/Flex Plus Training Record
TRAIN 2:	BSPS ABL90 Key Operator Training Competency
TRAIN 3:	Radiometer ABL90 Training for Ward Users
SDRF 1:	ABL90 Flex/Flex Plus Maintenance Sheet
SDRF-002	Template for Analyser Pre-Installation and Setup Configuration Sign-Off
Appendix 1:	ABL90 Flex Plus Troubleshooting Guide
Appendix 2:	ABL90 Flex Plus Hot Key
Appendix 3:	Removing COOX Suppression on the ABL90 Flex Plus
Appendix 4:	ABL90 Flex Plus Measurement Uncertainty Summary
Appendix 5:	ABL90 Flex Plus Calibration Traceability
Appendix 7:	How to Change a Fixed IP Address on the ABL90 Flex Plus
Appendix 8:	ABL90 Oxygen Flow Rate Conversion to FiO2
Appendix 9:	ABL90 Flex Plus List of Current Locations and Tests