

Title: **OMNI-S+COBAS b221 Blood Gas Analysers** Effective date: **23/07/2021**

Summary of Significant Changes at this Revision

- Include information on what to do if results fall outside of the measurement interval

<p>Purpose and Scope This SOP describes the principles and procedures involved in the analysis of: Blood gases – pH, pCO₂, pO₂ Bicarbonate – CHCO_3^- Electrolytes – Na⁺, K⁺, ionised Ca⁺⁺, Cl⁻ Hb derivatives – COHb (Carboxyhaemoglobin) etc. Bilirubin (neonatal) Glucose Lactate Using Omni –S and Cobas b221 POC analysers.</p>	<p>Items Required Omni – S analyser. Cobas b221 analyser. Analyser reagents and consumables as supplied by Roche for the running of the POC analysers. Heparinised blood gas collection syringes. Heparinised blood gas collection capillary tubes. Clot catchers. Ampoule adapters. IQC materials.</p> <p>Roche user manual; - Electronic copy on the intranet: (Clinical directory – point of care testing – SOPs for POCT Users - Cobas b221 Operator's Manual). - On Q-pulse EXT/BIO/14 (lab staff only)</p>
<p>Definitions and Abbreviations POC – Point of Care QC – Quality Control IQC – Internal Quality Control EQA – External Quality Assurance QA – Quality Assurance WEQAS – Welsh External Quality Assurance AQC – Auto Quality Control ABG – Arterial Blood Gas CPAP – Continuous positive airways pressure MSS – Metabolite Sensitive Sensors ISE – Ion Selective Electrodes TB – Tuberculosis Bacilli T/D – Turn and Dock</p>	<p>Grade / Qualifications Required Biomedical Scientist Trainee biomedical scientist Medical lab assistant (MLA) Doctor Nurse Emergency Department Assistant (EDA) Clinical support workers (CSW)</p> <p>Competencies Required: Current Version of: FM/CH/TRG/24 (Lab staff) FM/POCT/7 (Users) FM/POCT/8 (Advanced - Users)</p>

Risk Assessment: Current Version of RA/CH/28

Found on the intranet under “Clinical directory” – “point of care testing” – “SOPs for POCT Users” – *BGA risk assesment & Risk assesment BGA (all except ED & ITU).*

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1 INTRODUCTION

The Roche OMNI-S/Cobas b221 POC analysers are used for the measurement of blood gases, electrolytes, haemoglobin derivatives, neonatal bilirubin, glucose and lactate in whole blood, serum, plasma, dialysate (electrolytes only), pleural fluid (pH only) and QC material. In addition to this, there are a number of calculated parameters available e.g. bicarbonate (CHCO_3^-).

2 PROCEDURAL SUMMARY

- Blood gas samples sent to the lab should be received on ice, within 1 hour of sampling via the portering service. Samples should NOT be analysed if received via the pneumatic transfer system.
- Lab samples - request the sample in Ultra using the test code 'GAS'
- On the OMNI-S/Cobas b221 screen, check that the status window displays 'Ready' and the parameter buttons that you require are green.
- Mix the sample well and expel the first few drops to eliminate clots.
- Attach a clot catcher
- Press the syringe firmly to the fill port.
- Inject the sample slowly.
- Remove the syringe when prompted to do so by the analyser.
- NB. Refer to later in the SOP for further details for analysing capillary/small syringe samples.
- While the sample is being analysed, enter the mandatory information (highlighted red) using the touch screen.
- When measurement is complete, remove the printout from the analyser.
- Ward samples – transcribe the results into the patient's notes along with the date +time performed, the location of the analyser used + signature of operator.

- Lab samples - enter the results in Ultra using the 'VRES' program
- Lab samples - Release the results for authorisation from 'VRES'.
- Lab samples - Check the 'Telephone Queue' for any results, which need to be telephoned.

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3 CLINICAL APPLICATION

3.1 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 gases 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 HCO₃⁻) 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.

3.2 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 glomerularly filtered in the kidneys and is tubularly reabsorbed by 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, 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. (See reference 3)

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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.

3.4 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 newborn, the massive red cell destruction occurring in haemolytic disease of the newborn, coupled with the immature hepatic handling of bilirubin, can produce elevations of unconjugated bilirubin of 400 – 500 $\mu\text{mol/L}$ 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 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

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and may be corrected by surgery. Delay in diagnosis of the condition can lead to irreversible liver damage.

3.5 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.

3.6 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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4 METHOD PRINCIPLES

The blood gases and electrolyte concentrations of the sample are all measured by electrodes.

4.1 pH, Na⁺, K⁺, Ca⁺⁺ and Cl⁻electrodes

These are potentiometric electrodes. Special glasses are used as the sensitive element for pH and Na⁺. The potassium and calcium membranes contain special neutral carriers. A special ion exchanger is used for Cl⁻ membranes. Calculations of these variables also requires the use of a reference electrode – a permanently contacted chloride electrode.

4.2 pCO₂ electrode

This is a Severinghouse model - Potentiometric measurement of the pH change in the electrode caused by CO₂.

4.3 pO₂ electrode

This is a Clark electrode - Measurement of current generated by the reduction of oxygen.

4.4 Glucose and Lactate

Are measured in the MSS measuring chamber, by the MSS cartridge, which is a multi-parameter sensor.

Glucose is oxidised by glucose oxidase and atmospheric oxygen to form gluconolactone. Lactate is oxidised by lactate oxidase to form pyruvate. The H₂O₂ generated from these reactions is determined amperometrically using manganese dioxide/carbon electrodes at 350mV.

4.5 Haematocrit

A measurement of the sample's conductivity in the ISE measuring chamber.

Haemoglobin Derivatives and Bilirubin (neonatal) are measured by co-oximetry; they are determined spectrophotometrically based on Beer-Lambert's law. Following haemolysis, absorbency of the sample is measured at various wavelengths and the resulting equation is solved to determine the concentration of the constituent haemoglobin derivatives. Light emitted by a halogen lamp is partially absorbed by the sample, partially transmitted. The transmitted light is directed onto the polychromator, where it is diffracted and imaged onto the surface of a photosensitive device. The resulting electrical signal is used to determine the absorption, and thus the concentration of the haemoglobin derivatives.

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5 REAGENT INFORMATION**5.1 Reagent location**

A supply of reagent packs is kept alongside each analyser as appropriate.

These are:

- S1 Rinse Solution (03260917184) – Wash water
- S2 Fluid Pack (03260925184) – Calibration and reference solutions for the Blood Gas and ISE modules, Na conditioning solution, O₂ zero point solution, cleaning solution.
- S3 Fluid Pack (03260933184) – 4 Calibration solutions for glucose and lactate, MSS standby solution, MSS reference solution.
- Deproteiniser (03110435180) – A stronger cleaning solution for the sample path when necessary.
- tHb Calibrator (03110923035) – A dye solution for the calibration of the CO-OX module.

5.2 Stock solutions

Lab/NICU/A+E/MAU/BBC/Resp/Children's ward – Minimal quantities are held on department, further supplies of reagents are stored in the bulk store in the pathology department.

Stock Quality Control Material is stored in the pathology department cold room.

Only one full mat of each level of QC should be kept on the analyser at a time, because the OMNI-S/Cobas b221 QC drawers are NOT temperature controlled.

When stock is taken to a gas analyser it must be issued to the location on the CIMS system. Stock that should be issued as a complete box not individually:

- both bottles of S1
- both bottles of waste
- whole box of paper (6 rolls)
- whole box of capillary tubes (4 tubes)

Stock that should be issued per individual item:

- 1 matt of AutoQC
- 1 vial of Coox calibrator

Other blood gas stock is supplied as 1 item per pack.

5.3 Reagent preparation

All reagents are supplied ready for use.

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5.4 Reagent Storage & Stability

All the reagents have a storage temperature requirement of 15 - 30°C with the exception of the S3 reagent pack, which must be stored below 25°C.

The Quality Control Material is stored at 2 - 8°C

All the reagents are stable on the shelf until their expiration date, which is printed on the containers. They should not be used beyond this date.

Once on board the analyser, the reagent packs will expire after 42 days, and cannot be used after this time.

5.5 COSHH

Deproteiniser: An aqueous solution of Sodium Hypochlorite (NaOCl) containing ≤ 2% active chlorine. Due to the basic and oxidising character of the reagent local irritations may occur after contact with eyes, skin or mucous membranes.

Deproteiniser is used by lab staff only and any waste solution should be flushed away down the laboratory sluice (in line with POL/HS/1). The plastic bottle should be rinsed and disposed of in the lab plastic recycling.

S1, S2, and S3, packs used on the OMNI-S/Cobas b221 analysers: contain no substances hazardous to health in reportable quantities however, due to the environment and close proximity to patient blood these packs must be treated as clinical waste and disposed of in yellow burn bins.

Waste bottles (used) do contain patient blood as well as used reagents, this poses a biological hazard if user comes into contact with the contents and therefore must be disposed of as clinical waste into yellow burn bins.

The tHb Calibrator/IQC glass ampoules should be disposed of in a sharps container after use.

Refer to the *Safety Data Sheets* in the Roche blood gas analyser Reference Manual for further information.

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6 CALIBRATION

6.1 Blood Gas and ISE Calibration

The OMNI-S/Cobas b221 analysers use two aqueous base solutions for the simultaneous calibration of the pCO₂, pH, Na⁺, K⁺, iCa⁺⁺ and Cl⁻ sensors. This calibration is based on the generation of calibration solutions as part of the calibration process by mixing two stable solutions, calibration solution A and calibration solution B (in the S2 fluid pack).

The pO₂-value of room air, determined by the continuously monitored barometric pressure and a solution with a pO₂ of zero (also in the S2 Fluid pack), are used for the calibration of the pO₂ sensor.

6.2 Glucose and Lactate Calibration (Cobas b221 only)

Calibration of the MSS parameters takes place using 4 solutions, whose weighing concentration forms the basis for determining the measured values. All MSS calibrations are referenced to a reference measurement using a standby solution. This reference measurement is carried out after the calibration solution has been measured.

6.3 Co-Ox Calibration

A charge-coupled device is used to collect the spectral information at several wavelengths in the visible range. Once a day, during the system calibration, a complete wavelength calibration is automatically performed using a built-in light source.

As part of the 3-monthly maintenance, and after any cuvette manipulation, an external tHb-calibrator is used for calibration of the tHb channel.

The following calibrations are automatically initiated and performed by the analyser:

CALIBRATIONS	TIME INTERVALS	DURATION (mins) without MSS	DURATION (mins) with MSS
SYSTEM	EVERY 24 HRS	11	16
1 POINT	EVERY 1 HR	2	3
2 POINT	EVERY 12 HRS	6	11
ELECTRODE EXCHANGE	AS REQUIRED	25	50

When an automatic calibration is imminent, the calibration window at the bottom of the screen flashes red. If it is not interrupted within 20 seconds, the OMNI-S/Cobas b221 will start the calibration. N.B. **Do not interrupt** a calibration once it has started.

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6.4 Calibration for Ready**Failed Calibrations:** Parameters that are grey with a red cross – can be corrected by

- Press: **System > Calibration** (from the Analyser Mode screen)
- Press: **Calibration for 'Ready'** – automatically selects a calibration which will transfer all selected parameters to the 'Ready' state.
- Press: **Start**

Further user-activated calibrations can be initiated following troubleshooting investigations by:

- Pressing: **System > Calibration** (from the Analyser Mode screen)
- Select the relevant calibration (eg PO₂, 2P Cal)
- Press: **Start**

6.5 Storage & Stability

All the calibration solutions have a storage temperature requirement of 15 - 30°C.
All are stable until their expiration date, which is printed on the containers; and an on-board expiration of 42 days. They should not be used beyond these dates.

6.6 COSHH

All the calibration solutions used on the OMNI-S/Cobas b221 analysers contain no substances hazardous to health in reportable quantities. Refer to Safety Data Sheets (Roche OMNI S/Cobas b221 Reference Manual) for further information.

7 METROLOGICAL TRACE

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8 QUALITY CONTROL

IQC is used to ensure analytical precision on a daily basis. The IQC materials control all of the measured parameters on all of the modules (electrolytes, gases, co-oximetry, bilirubin, glucose and lactate.). Calculated parameters e.g. bicarbonate (HCO_3^-) and base excess (BE) are not controlled by IQC as they are a factor of the measured parameters.

The following IQC materials are used:

Auto-trol Plus B Level 1 (Product No. 03321169001)

Auto-trol Plus B Level 2 (Product No. 03321177001)

Auto-trol Plus B Level 3 (Product No. 03321185001)

The OMNI-S/Cobas b221 analysers are set up to do automatic measurement of three QC materials with known values or ranges of expected values - two are analysed on a daily basis, which checks the precision and accuracy of the analyser. The QC results are acceptable if they come within the 2 standard deviation ranges set up on the instrument.

8.1 Locked Out QCs



N.B. Any QC results which violate this rule results in the affected parameter(s) being **locked out** (see icon) until a successful QC measurement is accomplished for the material/level combinations affected.

QC for Ready – This allows locked out QCs to be rerun automatically.

- Press **QC Measurement**
- Press **QC for Ready**
- The locked out QC(s) will be run automatically in turn by the analyser

QC 'lock out' status can be checked by pressing each locked out parameter icon.

This will show which QCs are locked out for that parameter – this can be printed.

8.2 Performing a Manual QC

QCs can be performed manually to determine if the QC failure is due to a problem with AUTOQC sampling.

Having first determined which QC levels / are blocked (as above) remove an ampoule of the relevant QC from the AQC drawer.

- With the analyser in 'Analyser' mode (syringe icon) press :
 - QC measurement>
 - Select level>
 - Start Manual QC
- Present the ampoule to the fill port using an ampoule adapter and press 'Aspirate Sample'
- Remove the sample from the fill port when prompted to do so by the analyser
- Enter your operator ID (lab analyser only)
- Repeat operation if necessary

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The manually used QC ampoules must be registered on the analyser:

- From 'Analyser' mode (syringe icon), open the AQC drawer and press 'details' below the appropriate mat
- 'Remove' the used ampoule from the analyser record by touching the number in the relevant position, so that the icon turns grey
- Go back a page to save

The QC inventory should be checked as part of the weekly maintenance to ensure sufficient QC material is on board.

8.3 Storage & Stability

All the Quality Control materials have a storage temperature requirement of 2 - 8°C.

If kept under these conditions, they are stable until their expiration date, which is printed on the containers. They should not be used beyond this date.

8.4 COSHH

All the Quality Control materials used on the OMNI-S contain no substances hazardous to health in reportable quantities. Refer to Safety Data Sheets (Roche OMNI S/Cobas b221 Reference Manual) for further information.

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.

WEQAS samples are received and analysed for all analytes except Bilirubin, on a monthly basis. Blood Gas and Co-Ox EQA samples are analysed on the lab analyser and are also sent out by the lab to the following departments to be analysed by ward staff: Respiratory Ward, ITU, Cardiac Centre, and Children's Ward – instruction are provided with the samples on how to run samples.

The lab staff will run EQA on the following analysers:
MAU, ED, NICU, BBC

10 SAMPLE REQUIREMENTS

Biological material must be considered potentially infectious and handled with proper 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)

STANDARD OPERATING PROCEDURE SOP/POCT/15/26**Title: OMNI-S+COBAS b221 Blood Gas Analysers Effective date: 23/07/2021****Specimen Collection and Handling: Blood Gases**

Whole blood samples are used, drawn into heparinised syringes or capillaries, all samples must be labelled with the patient details. Samples should be analysed as soon as possible after collection. Air bubbles should be removed from the sample collection container immediately after sampling, and the sample mixed with the anticoagulant by rolling between both hands.

Syringe samples that are not analysed immediately should be sealed and placed on an ice slurry - stable up to 1 hour maximum.

Capillary samples that are analysed within 15 minutes may be retained at room temperature, but should be sealed with end caps. If unable to analyse within 15 minutes, place sample on an ice slurry – stable up to 1 hour maximum.

Lithium heparin or balanced heparin salts are the only acceptable anticoagulants for Blood Gas and ISE analysis. Other anticoagulants such as EDTA, citrate, oxalate, fluoride and anticoagulants containing ammonium have a significant effect on blood pH and should not be used.

10.1 Specimen Collection and Handling:

Electrolytes can be measured on samples collected as above for blood gases and also on heparinised whole blood in a lithium heparin vacutainer and on serum.

10.2 Specimen Collection and Handling: Bicarbonate (CHCO_3^-)

Bicarbonate can be calculated on serum and plasma samples, ie: it is not a measured parameter.

Standard bicarbonate of the blood, is defined as the plasma bicarbonate concentration in blood which has equilibrated at 37°C with a gas mixture having a $\text{PCO}_2 = 40\text{mmHg}$

10.3 Specimen Collection and Handling: Ionised Calcium

Blood should be collected into a Lithium Heparin (green top) vacutainer, which should be completely filled. This should be analysed immediately at point of care, or transported to the laboratory on ice, in order to minimize metabolism. The whole-blood sample should be analysed as soon as possible after receipt.

N.B. A part-filled vacutainer is not acceptable as this increases the final concentration of heparin in the tube to levels that can significantly lower the free calcium levels. Likewise, many widely used blood gas syringes contain concentrations of heparin which can lower the free calcium by 15 – 25%. Liquid heparin can result in the inaccurate measure of low free calcium levels because of both dilution and high final concentrations of heparin.

10.4 Specimen Collection and Handling: Haemoglobin derivatives

There are no special requirements for sample handling – samples should be well mixed before analysis.

Haemoglobin derivatives, predominantly Co-Hb, can be measured on samples collected as above for blood gases and also on whole blood in an EDTA tube.

STANDARD OPERATING PROCEDURE SOP/POCT/15/26**Title: OMNI-S+COBAS b221 Blood Gas Analysers Effective date: 23/07/2021**

10.5 Specimen Collection and Handling: Pleural Fluid pH (Lab Analysis only)

Pleural fluid pH must be measured on an anaerobic (capped) syringe sample sent to the laboratory on ice. This sample type is stable for 2 hours. It must be stated in the clinical details that the sample has a minimal risk of TB.

10.6 Specimen Collection and Handling: Bilirubin (neonatal)

Whole blood samples for the analysis of bilirubin, must be treated as light sensitive:

- Transport the sample container protected from light
- Avoid direct sunlight
- Samples should be analysed immediately after collection

10.7 Specimen Collection and Handling: Glucose and Lactate

There are no special requirements for sample handling.

Samples should be analysed immediately after collection, since sample metabolism causes:

- A decrease in the glucose concentration within a few minutes of collection
- An increase in the lactate concentration within a few minutes of collection

11 PATIENT TESTING

N.B. 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.

11.1 Neonatal Bilirubins

Neonatal staff should refer to the following RUH Neonatal Protocols before carrying out bilirubin analysis:-

NEO-007 - Jaundice in Neonates

NEO-005 - Exchange Transfusion of the Newborn.

A measurement can be started when the fill port is open, the status window displays: **Ready**, and the parameter button is green.

N.B. a minimum volume of 40µl of sample is required per module, even if only one parameter from that module is being measured. Deselect any modules that are not required.

N.B. If an insufficient/inadequate sample has been obtained and the sample fails to be analysed, a repeat sample will have to be obtained from the patient in order to repeat the test(s) – and this must be recorded in the patient's notes – and recorded as an incident in Datix if appropriate.

STANDARD OPERATING PROCEDURE SOP/POCT/15/26**Title: OMNI-S+COBAS b221 Blood Gas Analysers Effective date: 23/07/2021****11.2 Capillary Measurement**

- Attach a clot catcher to the capillary
- Insert the capillary into the sample port
- If the position is correct, the T/D will be backlit in green and the **Measurement** screen appears.
- Press: **Aspirate Sample** until a **beep** is sounded.
- Remove the capillary when prompted, and measurement will start.

11.3 Syringe Measurement

- Mix the sample well and expel any air and the first few drops of blood to eliminate clots
- Attach a clot catcher
- Press the syringe firmly to the fill port.
- If the position is correct, the T/D will be backlit in green and the **Measurement** screen appears
- Inject the sample slowly until a **beep** is sounded.
- Remove the syringe when prompted and measurement will start

11.4 Small Syringe Samples (<100µL)

- Mix the sample well, and expel any air and the first few drops of blood to eliminate clots
- Attach a clot catcher
- Press the syringe firmly to the fill port. If the position is correct, the T/D will be backlit in green and the **Measurement** screen appears.
- Inject the sample *slowly* until you have injected it all.
- There will be no **beep** for small samples
- Remove the syringe from the fill port and press: **Aspirate Sample** on the screen.
- The sample will be moved forward to the optical sensors and on to the BG module and then on to the other modules, depending on the volume of the sample available.
- Alternatively, deselect any modules not required on the sample to make sure that you get the most urgent results (min. 40µL per module).
- Remove the syringe when prompted and measurement will start.

11.5 Bicarbonate (cHCO₃-st) (Lab only)

Bicarbonate can be calculated on serum and plasma samples

- Select the **Bicarbonate** panel
- Place either an '**Adapter for sample Containers**' or an '**Ampoule Adapter**' into the fill port.
- Place the other end of the adapter into the serum or plasma sample
- Press: **Aspirate**
- Remove the sample when prompted, and measurement will start

11.6 Analysing small/paediatric samples for Bicarbonate

- Select the **Bicarbonate** panel
- Fill a blood gas capillary to the first line (50µl) with serum/plasma.
- Introduce the capillary to the fill port.
- Press: **Aspirate**
- Remove the capillary when prompted, and measurement will start

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STANDARD OPERATING PROCEDURE SOP/POCT/15/26**Title: OMNI-S+COBAS b221 Blood Gas Analysers Effective date: 23/07/2021****11.7 Pleural Fluid pH syringe sample (Lab only)**

- N.B. Goggles must be worn when analysing pleural fluid samples
- Attach a clot catcher
- Select the **Pleural Fluid** panel
- Press the syringe firmly to the fill port.
- If the position is correct, the T/D will be backlit in green and the **Measurement** screen appears
- Inject the sample slowly until a **beep** is sounded.
- Remove the syringe when prompted, and measurement will start.

11.8 CO-Hb EDTA sample

- **N.B.** EDTA samples **must not** be put through any modules except the **CO-OX**
- Select the '**CO-OX**' panel (to de-activate the other modules)
- Place either an 'Adapter for sample Containers' or an 'Ampoule Adapter' into the fill port.
- Place the other end of the adapter into the EDTA sample
- Press: **Aspirate**
- Remove the sample when prompted, and measurement will start

11.9 Neonatal Bilirubin sample (Lab only)

- If sufficient sample – run on Cobas 8000 analysers – code '**BIL**'
- If small sample – run whole blood sample on lab blood gas analyser – code '**BAB**'
- 40ul minimum whole blood volume required for analysis on blood gas analyser
- Select '**CO-OX**' only panel button (includes bilirubin)
- Mix sample well
- Draw sample into a blood gas capillary tube + attach clot catcher to analyse
- **Do not use ampoule adapters**
- All '**BAB**' results will go to phone queue – do not need to phone NICU results
- Remember to phone all community bilirubin results.

11.10 Input of Patient Data into Analyser

Once the sample has been introduced into the analyser the data input screen appears.

- Press the Δ and ∇ keys to select an entry.
- Press: **Set input value** to modify the highlighted entry (a keyboard appears on the screen). If the patient is not yet registered (on the analyser)
- Press: **New patient** - and the patient related data will be stored.

After completion of measurement and input of all data, the results will be displayed on the screen and printed

NB Any mandatory input fields will be displayed in red. An input must be made or the measurement values will be rejected and will not be displayed or printed

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

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The sample can be disposed of immediately into a burn bin or 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 Effecting Patient Results**

Contaminating the blood sample with air will significantly distort the blood gas measurements. Transport of the sample to the laboratory via the pneumatic tube system can also affect these parameters, particularly pCO₂. 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.

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

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

12.2 Analytical ranges (measured parameters)MSS module

Parameter	Analytical Range
Glucose	0.5 - 40 mmol/ L
Lactate	0.2 – 20 mmol/L

Electrolyte module

Parameter	Analytical Range
Na	20 – 250 mmol/ L
K	0.2 – 20 mmol/L
Cl	20 – 250 mmol/L
iCa	0.1 – 4.0 mmol/L

Blood gas module

Parameter	Analytical Range
PO ₂	0 – 106.7 kPa
PCO ₂	0.53 – 26.6 kPa
pH	6.0 – 8.0

Co-oximetry module

Parameter	Analytical Range
tHb	30 – 250 g/L
HHb	0.0 – 100.0 %
COHb	0.0 – 100.0 %
MetHb	0.0 – 20.0 %
Bilirubin	51.3 – 855 µmol/L

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For provenance see laboratory quality system reference number: FM/CH/MISC/26

Test	Reference Range		Units
pH	7.350	7.450	
PO2	11.07	14.40	kPa
PCO2	4.27	6.40	kPa
Hct	36.0	53.0	%
Na+	133.0	146.0	mmol/L
K+	3.4	4.5	mmol/L
CA2+	1.150	1.330	mmol/L
tHb	115.00	178.00	g/L
sO2	94.00	98.00	%
O2Hb	94.00	98.00	%
COHb	0.0	3.0	%
HHb	0.0	2.9	%
MetHb	0.0	1.5	% of Hb
Bili	For paediatrics refer to NICU protocols		mg/dL
Glu	4.0	6.0	mmol/L
Lac	0.20	1.80	mmol/L

12.4 Results that Fall Outside the Reference Range

These results must be highlighted to a clinical member of staff looking after the patient if further help or discussion is required the clinical biochemist can be contacted via switchboard (Mon – Fri 9am-5pm) or via consultant connect.

If results do not fit the clinical picture or are unexpected they must be repeated in the laboratory where possible (for ISEs, haemoglobin, Bilirubin, glucose, or lactate), or repeated using another blood gas analyser (for pH, pO₂, pCO₂, sO₂, O₂Hb, COHb, MetHb). A fresh sample should be collected for repeat testing.

12.5 Results Entry**Wards Only**

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

- The date/time of analysis
- The location 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.

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The results are entered into 'Ultra' using the 'Vertical Result Entry' program, taking care not to make any transcription errors.

Results must be checked for accuracy of transcription by a second individual.

In the absence of another member of staff, the BMS can enter the result but must then:

- Exit from the request completely in Ultra,
- re-enter the request / specimen number,
- check the patient demographics,
- check that the manually entered results are correct

BLOOD GAS SYRINGE NOT ON ICE SLURRY

If the blood gas syringe sample does not have a date or time on the sample and the sample is not received on ice slurry – request a MIS followed by GAS (No result available for Blood Gases) and Free Text:-

"Sample not received on ice slurry; Sample unsuitable for Blood Gas analysis. Please repeat if clinically indicated".

BLOOD GAS SYRINGE HAS LARGE AIR BUBBLE

If the blood gas syringe sample has a large air bubble in, request a 'MIS' followed by 'GAS' (No result available for Blood Gases) and Free Text:-

'Sample unsuitable for Blood Gas analysis due large air bubble in the syringe. Please repeat if clinically indicated'.

12.6 Test ProfilesBlood Gases:

- pH
- pCO₂ kPa
- pO₂ kPa
- ctCO₂ mmol/L
- BE mmol/L

Bilirubin:

- Bili µmol/L

Carboxyhaemoglobin:

- COHb %

Pleural Fluid pH

- pH

Bicarbonate

- cHCO₃⁻ mmol/L

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12.7 Limitations**Haemoglobin**

The Hb result obtained from the Cobas b221/Omni S blood gas analysers must not be used in direct patient care – it is to be used as a guide only.

If an Hb is required for direct patient care then an EDTA sample must be sent to the lab.

Any individual using the blood gas analyser Hb in patient care will be responsible for their own actions.

Glucose

Roche state in the Cobas b221/Omni S blood gas analyser Operator manual that:

Due to the current specifications, clinically significant deviations in the range <3 mmol/L can occur compared to other glucose measuring systems, especially in the neonatal field.

This means that for any patient samples that produce a result of <3 mmol/l a repeat sample should be sent to the lab for confirmation.

(NICU were informed of this when the Cobas b221 gas analysers were installed in Feb 2010)

13 MEASUREMENT OF UNCERTAINTY

See equipment module on Qpulse (laboratory quality system) validation and revalidation tabs for recent MoU.

14 REFERENCES

1. Roche OMNI-S/Cobas b221 Reference Manual
2. Roche OMNI-S/Cobas b221 Instructions for Use
3. Principles & Practice of Point-of-Care Testing. *Edited by: Gerald J.Kost*
4. Tietz Textbook of Clinical Chemistry; *Burtis, Carl A., PhD; Ash, Edward R., M.D., 3rd edition.*
5. Roche Cobas b221/OMNI-S system *Frequently Asked Question, Rev. 7.0, 05/2009*

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15 MAINTENANCE (Ward & Lab Staff)

Maintenance actions should be recorded on the maintenance schedule list using:

Quick Access > Maintenance > Do (as well as on the Maintenance tick charts)

15.1 Daily Maintenance

Check fluid levels and replace reagent packs and/or waste container if necessary.

Press:  **>Fill levels**

This screen gives you a display of the current levels of fluid in the fluid packs along with lot number and expiry date details and a date on which a change of bottle is to be expected. Solutions will need to be changed depending on the rate of measurement and/or the onboard stability. Exchange empty bottles, bottles whose usage date have expired, and full waste bottle.

15.1.1 If a fluid pack needs replacing:



- From the main 'Analyser mode' screen
- Open the bottle compartment cover
- The bottle exchange image appears on the display.
- Open the docking mechanism and pull out the bottle/pack to be exchanged.
- N.B. Empty S1 bottles should be kept for use as a waste container – see later.
- Remove the rubber seal from the new pack.
- Insert the new bottle or pack in the corresponding position until it stops.
- The Roche OMNI-S/Cobas b221 recognises the correct bottle or pack and verifies the expiration date. If the bottle has passed its expiration date, the screen displays a warning.
- Close the docking mechanism.
- Close the bottle compartment cover. The solutions are automatically aspirated upwards (detection in the flap) and the appropriate prime and calibration are initiated as required.

15.1.2 If the waste container needs replacing:



- From the main 'Analyser mode' screen
- Open the bottle compartment cover.
- The bottle exchange image appears on the display
- Open the docking mechanism, hold the waste bottle by the grip recesses and remove carefully.
- Discard in accordance with local regulations.
- Prepare a new waste container by taking one of the empty S1 fluid bottles and preparing it by removing the sticker to reveal a 'Waste' sticker underneath.
- If there are no spare waste bottles or empty S1 bottles, the waste container can be emptied for re-use. (Refer to Roche manual for instructions).
- Insert the bottle into the waste bottle position until it engages.

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- Close the docking mechanism
- The fill-level monitoring feature recognizes the waste container as 'empty'. If the waste container to be used is not empty press: **waste fill level**, and enter the fill level (a scaling on the container label gives an approximate value).
- Close the bottle compartment cover.

15.1.3 Check the printer paper:

- Lift the grey cover towards the back of the right hand side of the analyser.
- Check there is sufficient printer paper.
- If insufficient, see below.

15.1.4 To change the printer paper:

- Remove the printer cover
- Open the paper lid
- Lift the blue lever to release the paper
- Remove the empty paper roll
- Ensure the paper has a clean leading edge to help start the paper through the rollers. If necessary, cut the paper at a right angle.
- Place the new paper roll into the holder, so that the roll feeds from the bottom
- (NB the printer paper is heat sensitive on one side only).
- Ensure that the blue printer lever is in the down position.
- Feed in the beginning of the paper according to the instructions on the inside of the lid.
- The paper is automatically pulled into the printer. If the paper is pulled in incorrectly, open the paper cover, open the printer lever and realign the paper, close the printer lever and close the paper lid again.
- Close the paper lid
- If you are having difficulties, refer to the Roche OMNI-S/Cobas b221 Manual.

15.1.5 ISE + Blood Gas Wetting Routine (lab analyser only):



- From ready screen press: **System > Utilities > Fluid Actions > Wetting Routines**
- Select: **Automatic**
- Select ISE from list > **DO**
- Attach sample container – ampoule adapter in serum sample
- Aspirate sample
- Analyser holds sample for approximately 1 minute to wet electrodes
- Repeat procedure for BG
- Back arrow out of the screen once wetting complete
- Press analyser mode (top left icon) to return to ready screen

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15.2 Weekly Maintenance

N.B. WARD ANALYSERS ONLY: The 'LOG OFF' TIMEOUT needs to be extended to 6000sec for maintenance

- Press: **Log on User**
- Type in Operator ID (lower case), enter.
- Scan in operator barcode as the password, enter.
- Select: **Setup** 
- Select: **Times & Intervals > Timeouts > Log Off User**
- **Edit** time to **6000s**
- Carry out maintenance as below
- Remember to repeat procedure to change 'Timeout' time back to **60s** when finished
- Press:  to log off
- Press: **Yes to Log Off** when finished

15.2.1 Cleaning Sample Fill Port/T&D Disk

- Press:  **System > Utilities > Maintenance**
- Arrow down to: **Change Fill Port** (even though only cleaning is being done)
- Press: **Do** and carry out cleaning of fill port and T+D disk as follows:-
 - Pull the sample drip tray forward to remove it from its slot.
 - Clean the drip tray and fill port with a disinfectant wipe (alcohol free).
 - Remove the T/D unit cover.
 - Remove the fill port by rotating the white holder 90° downward and pulling it gently towards you (you may need to gently wiggle it, taking care not to bend the needle which goes into the back of the holder).
 - Use the fill port holder as a tool to turn the screw of the T/D by 90°.
 - Remove and clean/decontaminate the front and back of the T/D disk with a disinfectant wipe (alcohol free).
 - Re-assemble the parts in the reverse order.
 - Press: **Continue**
 - **Please Wait** is displayed while an automatic T+D disk initialisation is carried out
 - Press the 'back page' icon until **Wait for Ready** is displayed
 - The analyser will then carry out a wash before returning to the **Ready** screen
- Press:  **System > Utilities > Maintenance**
- Arrow down to "Clean T&D Disc"
- Press **Done**
- Press ← to exit screens and save
- Can also be used to change the fill port, T+D disk or needle – see Section 9.6 - As Required Maintenance.

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15.2.2 Clean the touch screen

- Press and hold the corner of the touch screen firmly with one thumb to disable the screen
- Clean/decontaminate the screen with a disinfectant wipe (alcohol free).
- **Do not use water and sprays!**

Lab Staff Instruction Only Beyond This Point

15.2.3 Checking the QC Inventory (lab staff only)

- Press: 
- Pull out the AQC drawer (located on the left-hand side of the analyser)
- The 'mat change' screen appears, showing how many vials of each QC material, level and lot no. are left on each mat.

If more mats need to be added:

NB: QC requires refrigeration. It is guaranteed stable on board the analyser for 28 days. Therefore, only one full mat of each level should be on board at any one time. Place a second mat on only when the first mat is down to 2 or 3 ampoules.

- Remove the empty mat from the holder.
- Replace with a new mat of the same level and lot number, checking that the necks of the ampoules are free of air bubbles.
- Press: **Refill**
- The screen will then prompt you to check that the lot number is the same
- Press: **Yes**
- If the mat that you are putting in is not completely full (eg due to breakage), press: Details (founder below corresponding mat), the status of the selected ampoule can be changed.
- Close the AutoQC drawer.

If the new mat is a different lot no. from the existing lot.

- refer to page 34, **New Lot Numbers** of iQC (Appendix)

15.2.4 Setting up the AQC Timer (lab staff only)

This should not need adjusting, but if the information is somehow lost and needs reprogramming


Press:  **>Times & intervals > QC timing**

A little marker ('QC') on the timescale indicates the defined start time(s) and for a better coordination with the QC timing, little markers on the timescale also indicate the defined calibration intervals (System cal = red, 2P cal = green)

If adjustment is required, refer to Roche Manual 'Instructions for use' and select the start time and the appropriate QC level(s) for each day. (*M-1, 2+3; Tu, Th +Sa – 1+2; W, Fri,+ Su-1+3*).

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STANDARD OPERATING PROCEDURE SOP/POCT/15/26**Title: OMNI-S+COBAS b221 Blood Gas Analysers Effective date: 23/07/2021****16 MONTHLY MAINTENANCE****N.B. WARD ANALYSERS ONLY:** The 'LOG OFF' TIMEOUT needs to be extended to 6000s for maintenance (see 15.2)**16.1 Check/Adjust Date and Time.**

- Press  > **Times and intervals > Current date & time**
- Check the displayed date and time are correct.
- If required press: **Set date** and adjust
- If required press: **Set time** and adjust

This process is important due to the reagent registration and expiry times

16.2 Change/Clean Waste Separator/Sensor

- A cleaned waste separator is kept in the lab to exchange for the dirty one – stored in the 'Cleaned Waste Separator' box on the POCT bench.
- **N.B.** First deactivate the analyser by opening the reagent compartment door
- Remove the top cover of the analyser
- The waste separator is the plastic dome positioned at the front left of the analyser
- The waste sensor is the dome-shaped plastic piece situated inside the waste separator, with wires at the base providing the electrical connection
- Remove the waste separator by turning anti-clockwise and lifting out of its location
- Disconnect all the attached tubing
- Remove the waste sensor by pressing evenly on the lugs at either side of the base and carefully levering it out of the waste separator – **N.B. Do not pull on the wires**
- Clean the waste sensor by wiping with a moist paper towel and moisten the black o-ring at the base to make re-insertion easier
- Exchange the dirty waste separator for the clean one, ensure the white plastic insert is in the top channel, and re-attach all the waste tubing
- Insert the waste sensor into the clean waste separator – press on the lugs at the base and push the sensor in evenly, making sure it is fully inserted
- Relocate the waste separator by inserting the lugs at the base into the original location and turn clockwise to re-seat
- Carry out a **Vacuum Pressure Check** → System → Component Test → Control Sensors → Vacuum System
- Change the 'Low Pressure' to 'MAX' in the bottom box
- Turn the vacuum pump 'ON'
- The Low Pressure reading should change to ≈ 800 – 900 mbar
- Turn vacuum pump 'OFF' – the Low Pressure reading should slowly decrease
- Back arrow through the screens to return to the Ready screen
- Replace the analyser cover and close the reagent compartment door
- Clean the dirty waste separator by soaking in deproteiniser for 2 hours, or until it looks clean, and then rinsing in tap water
- Leave to air dry and then store in the 'Cleaned Waste Separator' box ready for re-use

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N.B.The 'LOG OFF' TIMEOUT needs to be extended to 6000s for maintenance (see 15.2). MSS cassettes are stored at 2 – 8°C in the main cold room storage – these must be allowed to equilibrate to room temperature for a minimum of 30 minutes, but ideally for 2 hours, before installation.

16.3.1 Clean MSS Output PP Tube and Clean Jellybean

- Press: **Quick Access > Maintenance**
- Select 'MSS out - change pump tubing' and press **Do**
- Remove the analyser cover.
- Open the tension lever (clear plastic cover).
- Push the white plastic linear bracket upwards
- Remove the tubing and examine for blood or debris
- If dirty flush with water or deprotieniser (if water doesn't clear tubing)
- Dry and reseal on the pump head.
- Slide black tube adapter with jellybean (the rubber bung the peristaltic tubing nipples fit into) out forwards (not up towards the pump tubing)
- Careful not to detach the connected tubing examine for blood or debris
- Remove dirt with tissue moistened with water.
- Reassemble the tube adapter and jellybean
- Close the tension lever and push the white plastic linear bracket downwards.
- Press **Continue** to start the initialization.

16.3.2 MSS Module Cleaning

1. Leave the old MSS Cassette in situ.
2. Remove the S3 fluid pack
3. Fill the shutdown kit with deproteiniser (roughly 50%), place in the position of the S3 fluid pack and call up the filling routine of standby solution x 4


[System>Utilities>Fluid Actions>Fill Routines>Standby Solution]

4. Remove the shutdown kit and flush it out with deionised water.
5. Repeat step 3 with deionised water.
6. Remove the shutdown kit and empty it of any residue water.
7. Repeat step 3 but with the empty shutdown kit.
8. Remove shutdown kit
9. Put the S3 fluid pack removed in step 2 back onboard the analyser.
10. Call up the filling routine of standby solution x 2

[System>Utilities>Fluid Actions>Fill Routines>Standby Solution]

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16.3.3 Change MSS Cassette

- Remove the top analyser cover.
- Open the MSS module cover.
- Open the contact clip and the locking lever.
- Push the reference electrodes slightly to the left and remove the MSS cassette.
- Hold the MSS cassette by the designated handle only, and avoid touching the contacts.
- Insert the new MSS cassette and close the locking lever and the contact clip.
- Read in the barcode from the MSS cassette packaging
- Close the measuring chamber and top cover.
- Follow the instructions on screen to carry out an MSS cassette polarisation.
- Insert a serum or whole blood sample (lithium heparin sample <24 hrs old) via an ampoule adapter
- The MSS cassette is subsequently exposed to liquid, polarised, heated and calibrated.
- If the automatic polarisation is not successful and the MSS parameters are not calibrated, a manual polarisation must be performed :-
- Starting from  analyzer mode.
- Press: **System > Utilities > MSS polarisation.**
- Follow instructions on screen.
- If it still fails to polarize reseal the MSS cassette and repeat polarisation.
- To confirm the MSS cassette is seated correctly and the sample path is not interrupted press:

System>Component test>Control sensors>contact paths>MSS standby solution

- All boxes will have green ticks if OK. If not the MSS may not be seated correctly or may be faulty.
- All 3 QC levels must be performed after every MSS cassette exchange.

BBC only – Switch off Glucose parameter (Setup>Parameters>Miscellaneous settings) – Select glucose and turn all switches off

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17 THREE-MONTHLY MAINTENANCE**17.1 Change the Pre-filter**

- Pull out the air filter from its holder on the rear of the instrument.
- Date a new filter and replace in the holder.


17.2 Calibrate the CO-OX Module

N.B. Inspect the cuvette before performing a calibration for visible dirt or blockages, replace if required.


- Remove an ampoule of tHb calibrator from the package and shake carefully.
- Tap gently to remove any liquid from the head of the ampoule and carefully break it open.
- Insert an ampoule adapter into the ampoule.
- Press: **System > Cal > COOX Cal > Start**
- Using the keyboard icon, enter the **'tHb (target value) in g/L'**, g/dl figure is printed on the calibrator ampoule label – multiply x 10 to get g/l value.
- **'Cuvette replaced?'** – Press: **No**
- Results for the measured and target values will be displayed (+/- 10% is acceptable)
- Press: **Accept** – the calibration values are saved and used to calculate the layer thickness of the cuvette.
- If the cuvette has been replaced, **CO-OX calibration performed** appears instead of the calibration value.
- If the calibration is not acceptable, press: **Reject**. The module is not calibrated and is transferred to an alarm state. A recalibration should be performed. If problems persist, contact Roche for advice.
- **N.B.** Run all 3 levels of QC after completion of the Co-Ox calibration

17.3 Change the T&D Disc

N.B. The **'LOG OFF' TIMEOUT** needs to be extended to 6000s for maintenance (see 15.2).

- See section 15.2.1 for cleaning the Fill port
- Press:  **System > Utilities > Maintenance** then arrow down to: **Change Fill Port**
- When removing the T&D disk discard and replace with new.

17.4 Change the Peristaltic Pump Tubing.

- OMNI-S – Main peristaltic pump only - top left-hand corner of the instrument.
- Cobas b221 – 3 peristaltic pumps (from left to right):-
 - A. Main pump
 - B. MSS output pump
 - C. MSS input pump
- Press:  **Quick Access > Maintenance**
- Select the appropriate pump tube to be changed and press **Do**
- Remove the analyser cover.
- Open the tension lever (clear plastic cover).
- Push the white plastic linear bracket upwards
- Remove the old tubing.

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- Check if the five rollers are easily moveable (in case of malfunction, call Roche).
- Place the new tubing set around the rolling wheel (with the arrow on the grip pointing upwards).
- Close the tension lever.
- Select **Continue** to start initialising routine.
- Press the back page icon until the ready screen is reached.
- The analyser will go into a **System Cal.**
- Replace the analyser cover.

STANDARD OPERATING PROCEDURE SOP/POCT/15/26**Title: OMNI-S+COBAS b221 Blood Gas Analysers Effective date: 23/07/2021****18 SIX - MONTHLY MAINTENANCE****N.B.**The 'LOG OFF' TIMEOUT needs to be extended to 6000s for maintenance (see 15.2).**18.1 Decontamination**

This should be done alongside the electrode replacement, all electrodes will need replacing and all 3 levels of auto QC should be run after calibration.

You will need:

- A shutdown kit
- Deprotieniser
- Deionised water
- Plasma/whole blood/milk for wetting
- Replacement electrodes (see below)

Procedure:

1. System > Wash & cleaning > Decontamination
2. Remove solutions S2 & S3
3. Then press Continue.

Note: Perform all steps in the routine in the correct order, and without interruption.

4. Follow the instructions on the screen.

To complete some steps, you may have to manually perform an action on the system. When this action is complete, press the Confirm action button. The system automatically performs all other steps. To start an automatic action, press the Start process button.

Below is a table of the number of electrodes/tubing that are required for each analyser's six monthly maintenance.

Electrode	ED	MAU	NICU	BBC	Resp	Children's	Lab	SAU
MSS	1	1	1	1	1	1	0	1
Ref-Con	1	1	1	1	1	1	0	1
S-Con	2	2	2	2	2	2	2	2
Ref	2	2	2	2	2	2	2	2
Na	1	1	1	0	1	1	1	1
K	1	1	1	0	1	1	1	1
Ca	1	1	1	0	1	1	1	1
pO2	1	1	1	1	1	1	1	1
pCO2	1	1	1	1	1	1	1	1
pH	1	1	1	1	1	1	1	1
Dummy	1	1	1	4	1	1	1	1

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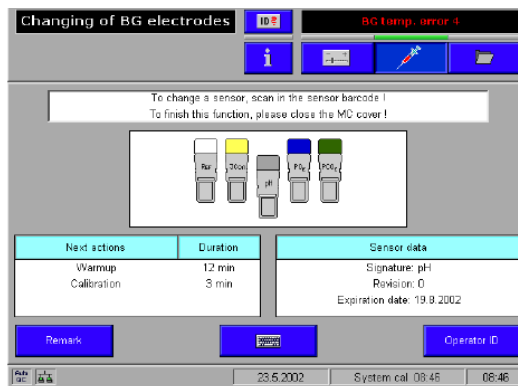
Author: N. Hodges	Checked by: K. Krzywdzinska	Approved by: K. Krzywdzinska	Page 33 of 37
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18.2 Replace All Electrodes

- Remove the top cover and open the measuring chamber cover of the corresponding measurement module, the following screen appears, for the appropriate module.




- Open the locking lever on the left hand side of the module.
- Take hold of the appropriate electrode, move it to the left, and remove it.
- If removing the reference electrode, remove the white connector from the measuring chamber cartridge
- If necessary, clean the measuring chamber with a tissue moistened with 70% isopropanol
- Hold the new electrode vertically and tap lightly with a fingernail to remove any air bubbles from the internal electrolyte solution.
- Insert it into the measuring chamber according to the colour code.
- When replacing the reference electrode, attach the white connector at the end of the tube to the measuring chamber cartridge and insert the tube into the tube-guide channel
- Push all electrodes slightly to the right so that they are all lined up together without any gaps.
- Close the locking lever and run a finger along the top of the electrodes to check that they are correctly placed.
- Scan the barcodes located on the inner packaging of the electrode (or enter manually having pressed the 'keyboard' icon if the scanner is not working)
- The replaced electrode is shown slightly lower than the others displayed on the screen.
- Read: **Next actions**, their duration, and the sensor data.
- Close the measuring chamber and then the top cover.
- A calibration is performed following a warm-up phase.
- After the calibration is complete, perform a QC measurement on all 3 levels.

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19 APPENDIX - NEW LOT NUMBER OF IQC*If the new mat is a **different** lot no. from the existing lot no:*

- To 'empty' the mat position in the AQC drawer of the old lot no
Press:  **Setup > QC material > QC material**
- Select the lot no/level of the old material and press: **Mat**
- Select the mat you want to remove and press: **Delete**
- Press: **Back-a-page** to save

The new lot no. of AQC can be added in 2 ways:

19.1 QC Setup Wizard:-

The quickest way to start the QC Setup Wizard is:

- Open the AQC drawer
- Select: **Yes** to the query: Start up QC Wizard? (Yes or No)
- Scan in new material barcode as instructed
- Press: **Continue**
- Select lot no. for change lot – select the in use lot no. if not already selected
- Select: **Continue with lot change**
- Scan in additional barcodes for the ranges (or enter manually)
- Press: **Continue**
- **Assign Mat** – Press: **Set** under the mat to be used for the new lot no.
- Insert new mat in correct position and close AQC drawer
- **Material was successfully installed** – will be displayed – check material details on screen are correct
- Select: **Exit** – or – **Read in additional material** if required




N.B. It is necessary to go back in to **QC Material** → **Ranges**, to delete some analytes as follows:

- **ALL** analysers - **Delete Cl⁻** line on ranges screen, as Cl⁻ not in use.
- **BBC** analyser **ALSO DELETE K⁺, Na⁺, Ca²⁺, HcT, Met, O2Hb, COHb, SO2, HHb, Bili, Glucose**
- Press the **Back-a-page** icon to save changes then press the **Return to front screen** icon to finish.

STANDARD OPERATING PROCEDURE SOP/POCT/15/26**Title: OMNI-S+COBAS b221 Blood Gas Analysers Effective date: 23/07/2021****19.2 QC Setup Manually:-**

- Select the level of the new material to be entered and press: **Set**
- Scan in the material code on the pack insert, or press: **New** and enter the information manually. The material code contains the information for the material, level, lot number, expiration date and sample types.
- Press: **Back-a-page** to save
- Press: **Ranges** and scan in the additional barcodes for the ranges (or enter manually).

N.B. It is necessary to go back in to **QC Material** → **Ranges**, to delete some analytes as follows

- **All analysers- Delete Cl⁻** line on ranges screen, as Cl⁻ not in use in these departments
- **BBC** analyser **ALSO DELETE** – K⁺, Na⁺, Ca²⁺, HcT, Met, O2Hb, COHb, SO2, HHb, Bili, Glucose
- Press **Back-a-page** to save
- **Assign Mat** - Select the new material from the list and press: **Mat**
- Select the required mat position from the list and press: **Set**
- Press: **Back-a-page** to save the material assignment.
- Press:  to return to the top level of setup mode.
- Press:  to return to analyser mode.
- Pull out the AutoQC drawer – the mat change screen appears.
- Take a full mat of QC ampoules from the package and, checking that the necks of the ampoules are free of air bubbles, place in the defined position of the ampoule block.
- Press: **Refill**. (NB incomplete mat details can be entered by pressing **Details** at this point and amending as necessary)
- OMNI-S prompt: 'is the material the same lot number?' press 'Yes'
- Close the Auto QC drawer.
- Press  **>QC material>change lot**
- Tab down to the current lot and press **Select new lot no** (OMNI-S/Cobas b221 will automatically go on to use this lot number when the current one has finished and will replace it in the QC timer setup)
- Press the **Back-a-page** icon to save changes then press the **Return to front screen** icon to finish.

19.3 If the Auto QC Timer Setup is lost:

Refer to Roche OMNI-S/Cobas b221 Instructions for User Manual for details on how to reprogramme it, selecting the appropriate start time(s) (15 minute increments between each level) and QC levels for each day (Mon-1,2+3; Tu,Th + Sat 1+2; Wed, Fri + Sun 1+3).

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Paper Copy number	Location held
1	Lab – Omni – S SOP Folder
2	NICU – Cobas b221 SOP Folder
3	A+E – Cobas b221 SOP Folder
4	MAU – Cobas b221 SOP Folder
5	BBC – Cobas b221 SOP folder
6	Resp – Cobas b221 SOP folder
7	Children's Ward - Cobas b221 SOP folder
8	SAU - Cobas b221 SOP folder

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