Basildon and Thurrock University Hospitals NHS
NHS Foundation Trust

Document Title:	**Standard Operating Procedure for the measurement of Blood Gas, Electrolytes and Haemoglobin derivatives using the Roche Cobas b221 Blood Gas Analyser**
Document Purpose:	Standard Operating Procedure for providing a rapid measurement of Blood Gas, Electrolytes and Haemoglobin derivatives at the Point of Care using the Roche Cobas b221 Blood Gas Analyser
Document Statement:	The Trust will ensure that the risk to patients undergoing Point of Care Testing is minimal by enforcing standards of best practice, as detailed within this procedure.
Document Application:	**This procedure is applicable in all clinical areas**
Responsible for Implementation:	Ward /Department Manager

Main imperatives of this Document are:

This procedure updates and replaces earlier guidance for users of the Roche Cobas b221 Blood Gas Analyser POCT device and describes how the device must:

1. **Be suitable for intended purpose**
2. **Meet safety and quality standards**
3. **Be adequately supported**
4. **Produce results that can be safely and readily recorded**
5. **Complies with standardisation and data transfer policies**

Be operated only by staff trained in their use.

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Author:	POCT Manager	**Review Date:**	August 2011
Sponsor:	Director of Clinical Sciences	**Expiry Date:**	August 2019

Associated Documents

1. Standard principles for preventing hospital acquired infection
2. Decontamination, Disinfection and Sterilisation Policy
3. Health and Safety Policy
4. Incident Reporting Policy and Procedures
5. Policy for Training in the Safe Use of Medical Devices
6. Policy for Provision and Use of Work Equipment
7. POCT Policy
8. POCT Procedure

This Procedure has been Risk Assessed

The full Controlled Document can be accessed through the Master List

Validated by Facilitator:	NICE Guidance and Audit Facilitator	**Date:**
Agreed by Specialist Group:	POCT Committee	**Date: August 2009**
Approved:		**Date: August 2009**

DOCUMENT HISTORY

Revision History

Revision Date	Previous Revision date	Summary of Changes	Changes marked

Standard Operating Procedure for the measurement of Blood Gas, Electrolytes and Haemoglobin derivatives using the Roche Cobas b221 Blood gas analyser

CONTENTS **PAGE**

1. INTRODUCTION

The Roche Blood Gas analyser is designed for use at Point of Care, to produce rapid blood gas results, which may be helpful to healthcare workers in certain clinical situations.

This procedure describes when and how to correctly use the analyser in order to minimise risk to both patients and user. Individuals which have not been trained and competence assessed in the use of the Blood Gas analyser are not authorised to use this procedure. This document has not been written as a substitute for the practical training and competence assessment offered via the Trust POCT team. (Section 9 References (1))

Depending upon combination and configuration the Cobas b221 Blood Gas Analyser is used for the determination of the following parameters in whole blood and QC materials:

- pH
- Blood gas BG (PO_2, PCO_2)
- Electrolyte ISE (Na^+, K^+, Cl^-, Ca^{2+})
- Haematocrit (Hct)
- Metabolite MSS (Glucose and Lactate)
- Total haemoglobin (tHb)
- Oxygen saturation (SO_2)
- Haemoglobin derivative COOX (O_2Hb, HHb, COHb, MetHb)
- Calculated base excess (BE)
- Calculated bicarbonate (HCO_3^-)
- Temperature corrected pH, PO_2, and PCO_2

It is also used for the determination of pH in fluid samples (only available on Florence Nightingale ward to minimise risk of cross infection and downtime of the analyser due to blockages).

2. DEFINITIONS

'POCT'
The Medicines and Healthcare Products Regulatory Agency (MHRA) define point of care testing (POCT) as an analytical test performed for a patient by a healthcare professional outside of the conventional laboratory setting. (Section 9 References (2))

'User'
The 'user' is any person who handles a POCT instrument to produce patient results, carry out maintenance or perform quality assurance checks. This includes Clinicians, Nursing Staff, Healthcare Scientists and Service Engineers.

'Internal Quality Control'
Internal quality control (QC) is a means of determining that the POCT instrument is technically performing correctly at that specific time and that the patient result is reliable before it is released and acted on.

'*External Quality Assessment (EQA)*'

External quality assessment (EQA) is a means of determining how a particular POCT instrument is performing in comparison to similar instruments elsewhere.

3. ROLES AND RESPONSIBILITIES

See POCT Policy (Section 9 References (3))

4. INSTRUCTIONS FOR USE (Section 9 References (4,5))

4.1 Principle

4.1.1 Clinical Indications

Indications for Blood Gas Analysis

Blood gas analysis is used as a tool to enable clinical staff to:

1. Establish the diagnosis and severity of respiratory failure
2. Manage and guide the treatment of patients in intensive therapy units
3. Determine prognosis in critically ill patients
4. Monitor patients during cardiopulmonary surgical procedures or therapy sessions
5. Evaluate the adequacy of ventilation, oxygenation, oxygen-carrying capacity of the blood and acid-base levels in neonates

4.1.2 Principle of Measurement

No sample preparation is required. Analysis is quickly accomplished by attaching the blood gas sample syringe to the machine for aspiration.

***P*O_2**: Use of the Clark measurement principle: measurement of current generated by the reduction of oxygen.

***P*CO_2**: Use of the Severinghouse principle: potentiometric measurement of the pH change in the electrode caused by CO_2.

pH, Na^+, K^+, Ca^{2+}, and Cl^- electrodes 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 chloride membranes. Calculation of these variables also requires the use of a reference electrode – a permanently contacted chloride electrode in the Cobas b221.

Glucose, Lactate: Glucose oxidizes to form gluconolactone using atmospheric oxygen and the glucose-oxidase enzyme; lactate oxidizes to form pyruvate using the lactate oxidase enzyme.
The generated H_2O_2 is determined amperometrically by using manganese dioxide/carbon electrode at 350 mV against an Ag/AgCl reference electrode.

tHb/*SO2*: Light absorption in whole blood is measured at four different wavelengths, the sample is subjected to light radiation and the dispersed light is also evaluated.

COOX: The haemoglobin derivatives are measured spectrophotometrically on the basis of Beer - Lambert law.

Hematocrit: Measurement of the sample's conductivity in the ISE measuring chamber.

4.2 Health and Safety

Gloves must be worn when handling patient samples

Appropriate precautions must be taken when handling syringes and needles so as to avoid sharps injury.

Waste must be disposed of in accordance with Trust Policy.

Analysers should be cleaned only with a soft damp cloth and disinfection wipe.

(Section 9 References (6,7,8,9))

4.3 Precautions

- Use only the power supply fitted, if this or the UPS fail please contact Biochemistry, do not attempt to rectify yourself.
- The instrument should not be used in the presence of flammable agents.
- Do not allow blood or other liquids to enter the instrument via anywhere other than the sample port.
- Blood exposed to the analyser should never be returned to the patient as the sample ports are not sterile.

4.4 Sample Requirement

Blood samples are to be collected in Lithium Heparin blood gas syringes or heparinised glass capillary tubes. In syringe aspiration mode the minimum required volume for measurement of all parameters is 2ml to ensure optimal heparin concentration. Any less than this 2ml could also potentially cause damage to the instrument sample probe. When drawing blood samples with a syringe from a saline filled catheter, withdraw the saline first and make sure that only whole blood is sampled. Any air introduced during sample collection must be expelled. Roll the tightly sealed syringe between the palms of the hand to keep the red blood cells and plasma well mixed. Poorly mixed samples or those containing clots or air may cause inaccurate results.
Pleural fluid for pH should be collected anaerobically into a heparinised blood gas syringe. The sample should be clear, slightly turbid fluids can be used where it is uncertain whether the fluid is infected or not.
In accordance with The British Thoracic Society (BTS) guidelines (See Appendix 1) if the sample contains frank pus this **should not** be analysed through the blood gas analyser. (References Section 9 (10))

4.5 Reagents and Consumables

REAGENTS
S1 rinse solution
S2 fluid pack (Harmful)
S3 fluid pack (for those measuring Glucose and Lactate)
Deproteiniser solution
COOX calibrator

CONSUMABLES
Glu/Lac cassette
Na^+, K^+, iCa^+, PCO_2, PO_2, pH electrodes
COOX cuvette
Junction electrode
Reference electrode
Sensor contact
MSS dummy
Waste bottle
Printer paper
Ampoule adapters (large and small)
Clot catchers
Glass capillary tubes
ABG heparinised syringes
Turn and Dock disc
Fill port
Sample probe
Air filters
Peristaltic pump tubes
Waste separator

QUALITY CONTROL
QC Autotrol Plus Level 1
QC Autotrol Plus Level 2
QC Autotrol Plus Level 3

4.6 Equipment

Cobas b221 blood gas analyser.

4.7 Quality Control (QC)

Internal Quality Control

There are three levels of internal quality control for the blood gas analyser. At least one level is run per day on a schedule determined by the Biochemistry staff and the analyser is programmed accordingly. This schedule should not be changed by ward staff.

Monday:	All 3 levels
Tuesday:	Level 1
Wednesday:	Level 2
Thursday:	Level 3
Friday:	Level 1
Saturday:	Level 2
Sunday:	Level 3

External Quality Control

External Quality Control is sent to the Biochemistry department for monthly analysis.

4.8 Procedure

4.8.1 Maintenance

Blood Gas analyser maintenance is largely carried out by qualified members of the BMS staff of Biochemistry, or trainee BMS under supervision.

The maintenance to be carried out by the ward staff is:

- to clean any blood spillages on or around the blood gas machine with disinfection wipes,
- the replacement of S1 reagent when a bottle becomes empty,
- the replacement of a waste bottle when it becomes full,
- the replacement of the thermal printer paper roll when this runs out

Please contact the Biochemistry laboratory (x 3034) if the blood gas analyser is not performing correctly.

4.8.1.1 Changing Reagents/Emptying waste

Step	Action CHANGING S1 REAGENT or EMPTYING WASTE
1	Gloves should be worn at all times when handling reagent packs.
2	Log into the Cobas b221 using your unique passcode.
3	Open flap on the front of the analyser to allow access to the reagent packs.
4	Identify the S1 reagent to be changed.
5	Lift reagent flap and slide reagent bottle forwards.
6	When changing waste or S1 reagent gently slide new bottle into place and lower flap. If you feel some resistance on the flap do not force it to shut. Instead pull bottle back out and open the lid manually by sliding the white button/tab forward. Take care with hands as this may be quite stiff to move.
7	Discard waste bottles into appropriate clinical waste bags. Please save S1 bottles for use as waste bottles. These are converted by emptying the remnants of the S1 solution into the sluice (rinse solution is not harmful) and removing the sticky label from the front of the bottle.

4.8.1.2 Replacing thermal printer paper

Step	Action CHANGING PAPER
1	Lift the lid off of the printer section by gently lifting from the right hand side.
2	Pull blue lever on right hand edge forward to release the old roll and lift out and discard.
3	Push blue lever back into original position.
4	Remove sticker from the new paper roll and place into holder with the leading edge feeding forward from underneath the roll.
5	Gently feed leading edge of paper into the back of the paper feeder (about 1inch down from top lip). Paper will be automatically fed through the rollers when in the right position.
6	Push feed button to roll the paper on. Push cut button to give a clean edge.
7	Replace lid and try feed and cut buttons in turn to ensure correct placement of the lid on the analyser.

4.8.2 Patient Procedure

Blood gas analysis should only be performed by trained and certified members of staff. All certified staff have been issued with their own unique passcode to be used on the analyser. If you have not been trained please see your ward based link nurse or contact the POCT team (x 8382) for training.
If you allow anyone else to use your unique passcode you are breaking Trust policy and you will lose your access to the analyser.

Step	Action PATIENT SAMPLE
1	Gloves should be worn at all times when handling patient samples.
2	Before collecting a blood sample please expel all liquid heparin from the syringe. Improper heparinisation may cause results to alter. Collect a blood sample from the patient into a plastic ABG syringe. Any air introduced during sample collection must be expelled. Ensure that the blood sample is well mixed, not clotted and does not contain any air.
3	If collecting a sample from a drip arm please remove the fluid from the line before collecting the blood. If this is not performed the results given by the analyser will not be indicative of the patient's health state.
4	Samples collected into blood gas syringes must be analysed within 5 minutes and capillary samples must be analysed **immediately**.
5	Log into the Cobas b221 using your unique passcode.
6	The analyser should read "Ready'' in the top left-hand corner. Select tests required by touching either the blue button on the screen, to turn off the entire channel, or the individual green buttons, to turn off the unwanted parameters. **NB If analysing a fluid for pH you must turn off all other channels before analysis.**
7	Ensure that the blood sample is well mixed, not clotted and does not contain any air. Expel the first drop of sample from the syringe into a paper towel then introduce the syringe to the sample port.
8	Press 'Aspirate Sample' button. If the syringe is sited correctly in the port the green backlight will illuminate. When prompted remove sample container. **WARNING: Never inject samples into the sample port. Injecting during sample aspiration will damage the instrument.**
9	If using a capillary tube change the setting in the top left hand corner (by pushing the capillary button) to reflect this. The sample disc will turn exposing the orange sample port. Place a clot catcher on the end of the capillary tube then gently introduce the clot catcher into the port, and push 'Aspirate sample'. If the

	capillary tube is sited correctly in the port the green backlight will illuminate. When prompted remove sample container. **WARNING: Never analyse blood from a capillary tube without using a clot catcher.**
10	The screen will automatically change to show the ‘‘Measurement’’ screen and a table will be shown for you to input the patient details. Highlight each of the fields in turn and using the keyboard displayed by pushing the ‘Set input value’ button put in the patient’s details. **WARNING: If a patient ID number is not entered the result will not be displayed.**
11	When analysis is complete the results will be displayed on the screen and printed. As the results print onto thermal paper it is not advised to put this directly into the patient’s notes as the print will fade with time. Instead please transcribe the results by hand in accordance with ward protocol. (Section 9 References (11,12,13,14))
12	Additional copies of the results may be printed by pushing the ‘Print’ button displayed in the bottom right hand of the screen.
13	When the analyser comes back to the ‘‘Ready’’ screen it is ready to analyse the next sample. Repeat the above steps for the new sample.

4.8.3 Recalling Results

It may be necessary to print additional copies of patient’s results after they have gone from the screen. In order to do this please follow these instructions:

Step	Action RECALLING RESULTS
1	Log into the Cobas b221 using the passcode 99999.
2	Push the ‘Data Manager’ button (it looks like an open folder and is the button on the far right of the screen).
3	Push the ‘Measurements’ button on the left hand side.
4	Using the arrows on the right hand side of the screen scroll through the results until you highlight the patient in question.
5	Push the icon that looks like a magnifying glass to bring up the tabulated results.
6	Push the ‘Print’ button to obtain a copy.

4.8.4 Trouble Shooting

If a parameter has failed a calibration the respective test box on the screen will be grey and have a red cross through it. A successful calibration is required to unlock the parameter for use. Log into the analyser and then touch the 'Calibration for ''Ready''' button. This starts an automatic calibration for the specific parameter.

If a parameter has failed a QC level the box on the screen will be grey, have a red cross through it and a small picture of an ampoule.

A successful QC check is required to unlock the parameter for use. Log into the analyser then touch the 'Perform QC for Ready' button.

Please contact the Biochemistry laboratory (x3034) or POCT Team (x8382) if after these functions the blood gas analyser is still not performing correctly or if there are any other issues that prevent the analyser from performing as it should.

4.9 Clinical Interpretation and Reference Ranges

The results from the Cobas b221 will display on the screen and print in the following order:

Analyte	Units	Symbol	Adult Reference Interval
pH		**pH**	7.350 – 7.450
Carbon Dioxide	kPa	$\boldsymbol{PCO_2}$	4.67 – 6.00
Oxygen	kPa	$\boldsymbol{PO_2}$	10.67 – 13.33
Oxygen Saturation	%	$\boldsymbol{SO_2}$	75.0 – 99.0
Sodium	mmol/L	$\boldsymbol{Na^+}$	135.0 – 148.0
Potassium	mmol/L	$\boldsymbol{K^+}$	3.50 – 4.50
Ionised Calcium	mmol/L	$\boldsymbol{Ca^{2+}}$	1.120 – 1.320
Glucose	mmol/L	**Glu**	3.3 – 6.1
Lactate	mmol/L	**Lac**	0.4 – 2.2
Haematocrit	%	**Hct**	35.0 – 50.0
Total haemoglobin	g/dL	**tHb**	11.5 – 17.4
Carboxyhaemoglobin	%	**COHb**	0.5 – 2.5
Oxyhaemoglobin	%	$\boldsymbol{O_2Hb}$	95.0 – 99.0
De-Oxyhaemoglobin	%	**HHb**	1.0 – 5.0
Methaemoglobin	%	**MetHb**	0.4 – 1.5

NB Unexpected results should always be checked with a laboratory sample.

Haemoglobin values below 8.0 g/dL or above 18.0 g/dL must be confirmed by the haematology laboratory. Values which trigger a request for blood transfusion **must be** confirmed by the haematology laboratory.

5. IMPLEMENTATION

The test should only be carried out by a trained member of staff. Each staff member takes responsibility for ensuring the quality of all monitoring carried out by him/her. The staff member must ensure their Cobas b221 training is updated and that their competence to perform tests on this instrument is maintained. Practical training and competence assessment is available via the Trust POCT team.

The latest version of this document is available on the Trust Intranet.

6. MONITORING AND AUDIT ARRANGEMENTS

6.1 Competence/proficiency testing of users

Competence/proficiency testing is supplemental to the standard laboratory quality assurance measures. All operators must be assessed before operator passwords are issued allowing user access to the Roche Cobas b221 Blood Gas analyser.

6.2 Audit

Managers are required to regularly monitor and audit use of the Roche Cobas b221 Blood Gas analyser, together with the Point of Care Services Manager, within their ward/department to ensure they are being used in compliance with the POCT policy.

7. CONTENT CONTRIBUTORS

Chairman POCT Committee
Laboratory Manager Biochemistry

8. APPROVAL PROCESS

This Procedure has been approved by the POCT Committee

9. REFERENCES

1. HSC 1999/065 Clinical Governance: Quality in the new NHS, DoH 1999

2. The Medicines and Healthcare products Regulatory Agency, MHRA guidance on the management of POCT and the clinical governance responsibility of Managers (DB2002(02) and (03)) www.mhra.gov.uk

3. POCT Policy, BTUH, April 2009

4. Clinical Pathology Accreditation (UK) Ltd. Standards for the medical laboratory. www.cpa-uk.co.uk

5. Roche Cobas b221 Technical Training Manual, Version 9.0 December 2006

6. Incident Reporting Policy , BTUH, July 2006

7. Incident Reporting Procedures, BTUH, Sept 2006

8. Policy for the Management of Health and Safety, BTUH, March 2008

9. NHLSA Risk Management Standards, 2009/10

10. BTS Guidelines for the management of pleural infection. http://thorax.bmjjournals.com/cgi/content/full/58/suppl_2/ii18

11. Health Records Policy, BTUH, February 2008

12. HSC 1999/665 For the Record

13. Data Protection Act 1998

14. The Royal College of Pathologists. The Retention and Storage of Pathological records and Archives. (3rd Edition 2005) www.rcpath.org

10. APPENDICES

Appendix 1

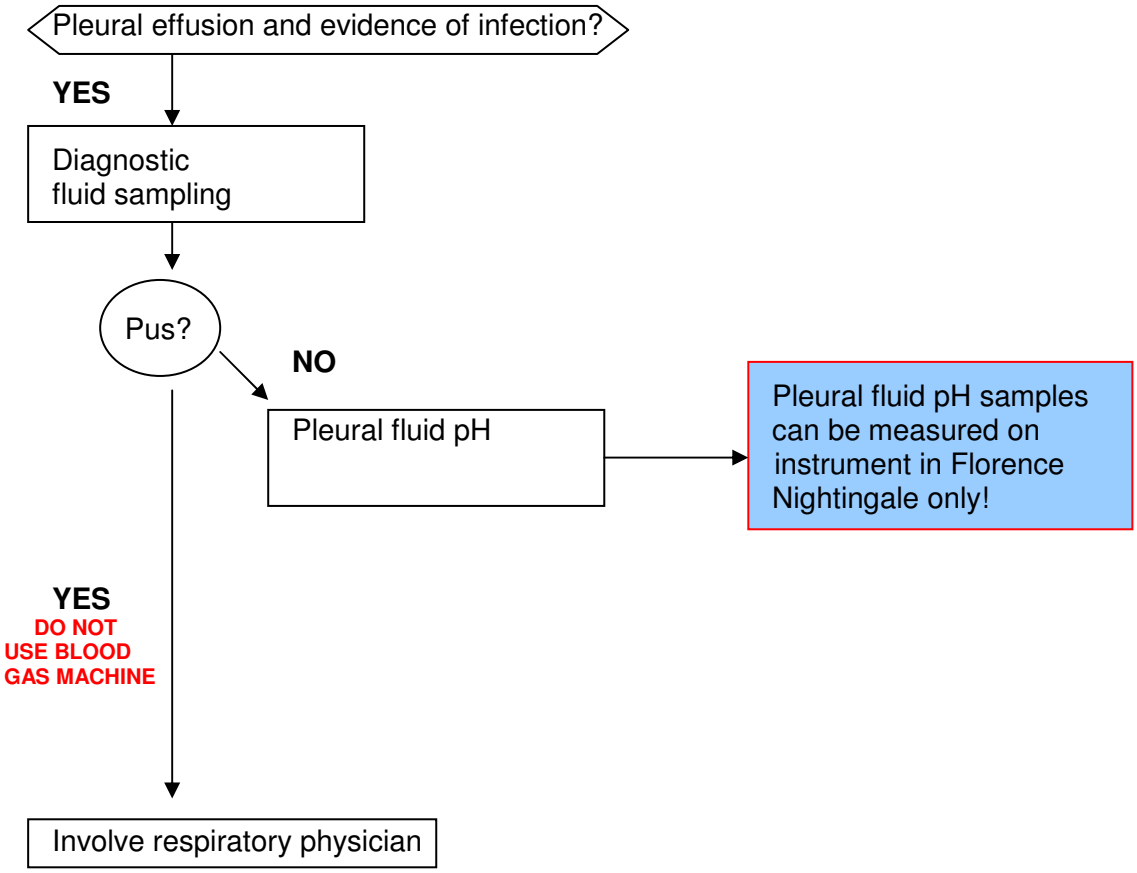


Diagram to show appropriate use of the Blood Gas analyzer for pleural fluid analysis

RECALL OF PREVIOUS RESULTS AND PATIENT TRENDING

Log in using number **99999**
This will give access to patient database.

1. Press grey **Data Manager** icon which looks like a folder or open book, this is located at the top right hand side of the screen
2. Select Measurements Icon
3. Select the patient file and time/date that you require.
4. Press zoom function (looks like magnifying glass and located on bottom left of screen)

This will display results.
Press print for copy

If you require the acid base map,
Select Acid Base Map
Select Continue
Press print for copy (black and white only)

Monitoring patient trends.

Individual parameters e.g. pO2 may be viewed as a trend if there are at least 6 previous and less than 24 results selected. Multiple parameters may also be trended but the graphs may become confusing.

For patient trending of a parameter/parameters
Steps 1-4 as above.
Select Patient Trending Map icon
This will give the option of selecting items e.g. pO2
Highlight the item by selecting it.
Copy item/s across to right hand column using arrow in centre of screen facing to the right.
To remove items highlight item in right hand column and use left facing arrow in centre of screen to remove.
Select date and times required to the period you are interested in.
Select Continue
This will display the start to finish trend using the oldest sample selected as the 0% or baseline. Print if required.

For trending of the acid base map
Steps 1-4 as above
Select Acid Base Map icon
Select date and times required for the period you are interested in.
Select Continue
This will display the start to finish trend with the latest result indicated with a red asterisk. Print if required.

To exit any of the above use the ready icon. To go back a screen select large left facing arrow on top left of screen

SOP for the measurement of Arterial Blood Gas, electrolytes and Haemoglobin derivatives using the Roche cobas b221 Blood Gas Analyser

Reference No: CO/ /
Status: v 1.0

Activated for next measurement.
This parameter is calibrated & QC checks have passed.

This parameter will NOT measure and has been locked out by a Calibration failure
Requires a Calibration for Ready.

This parameter will NOT measure and has been locked out by a QC failure.
Requires a QC for Ready.

This parameter has been permanently de-activated and will not measure.

This parameter has been deactivated for the next measurement.
This parameter is calibrated & QC checked and is ready for selection.

Sample Port position

Syringe Aspiration

Syringe attached to sample port – <u>DO NOT INJECT!</u>
Injecting during sample aspiration will break the instrument

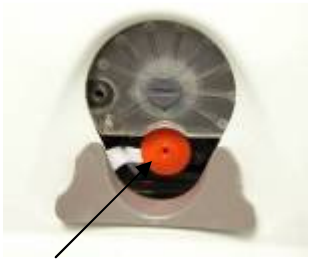
Do not use the Blood Gas analyser unless you have been trained to do so and been issued with a personal barcode I.D.

Please be advised that it is against Trust Policy to allow other Members of staff to use your barcode.

Pleural Fluids <u>MUST</u> be analysed for <u>pH only</u> on Florence Nightingale – see instructions on ward.

Sample Preparation

- Withdraw whole blood using a balanced lithium heparinised syringe/capillary tube and analyse as soon as possible.
- Capillary samples need to be run immediately, syringe samples must be run within 15 minutes
- Samples must be well mixed immediately before analysis. Roll sample between fingers, invert and roll again.
- It is important never to shake the sample as this will fracture the blood cells and affect the results (e.g elevate K+ and lower Hb)
- Expel the first few drops of blood from the syringe, this will remove any clots or air, it is important not to draw air back into the syringe as this will effect the p02 result.
- Ensure that the syringe is sealed with a cap before transporting to the analyser, remove any needles.



NOTE! The Sample Port is completely exposed for capillary aspiration

Capillary Aspiration

<u>ATTACH CLOT CATCHER!</u>

A capillary blood sample must not contain air. A capillary filled to the first black line is sufficient for pH, pCO_2 and pO_2 analysis. Analyse immediately.