

<b>BLOOD SCIENCES</b>		
<b>DEPARTMENT OF CLINICAL BIOCHEMISTRY</b>		
Title of Document: GEM Premier 5000 POCT Analyser	Q Pulse Reference N <sup>o</sup> : BS/POCT/BG/1	Version N <sup>o</sup> : 3
Authoriser: Ross Mitchell		

## GEM PREMIER 5000 POCT ANALYSER

### 1. INTRODUCTION

#### 1.1 Purpose of the Procedure

The GEM Premier 5000 is a portable critical care system for use by healthcare professionals to rapidly analyse whole blood samples at the point of care.

#### 1.2 Staff

Only healthcare personnel who have been suitably trained and completed a competency assessment may perform a blood gas analysis using the GEM Premier 5000 analyser.

#### 1.3 Related Documents

Document	Q Pulse Ref N <sup>o</sup> :
GEM Premier 5000 Operator's Manual	BS/POCT/EXDOC/4
Blood-Gas and Co-oximetry Service Continuity Plan	BS/POCT/POL/2

### 2. PRINCIPLE OF THE PROCEDURE

Using measurement sensors contained within a sealed reagent PAK<sup>®</sup> GEM PAK, the analyser provides quantitative measurements for pH, *p*CO<sub>2</sub>, *p*O<sub>2</sub>, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin, and CO-Oximetry (tHb, O<sub>2</sub>Hb, COHb, MetHb, HHb) parameters.

Measurement Methodology	
Amperometric:	<i>p</i> O <sub>2</sub> , Glucose, Lactate
Potentiometric:	pH, <i>p</i> CO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup>
Conductivity:	Hct
Optical Measurement following chemical lysing and mixing of the whole blood sample:	CO-Oximetry, tBili

### 3. SPECIMEN REQUIREMENTS

Arterial, venous or mixed venous whole blood

Self-filling plastic, disposable arterial blood sampler (1mL or 3mL) containing >20IU/mL of balanced heparin.

Expel all air.

- Mix syringe samples thoroughly by 5 complete inversions and rolling between the palms to ensure complete anticoagulation.
- Push out a few drops of the sample onto a gauze pad to ensure there is no clot in the syringe tip.
- Analyse within 15 minutes of collection

Capillary whole blood

Plastic capillary tubes coated with lyophilized lithium heparin or electrolyte-balanced heparin.

- Cap and roll gently between the fingers.
- Analyse within 5 minutes whenever possible.

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Fetal Scalp whole blood

R57024-00-SW: Rocket FBS Fetal Blood Sampling Kit with Sampling Wand and plastic 85ul heparinised capillary tubes

- Always fill the tube completely avoiding air bubbles and clots
- Do not mix, shake or roll the filled capillary tube

Pleural Fluid (for pH only)

Minimum sample requirements for the GEM PAK in use are as follows:

Analytes	Sample Volume (µL)
pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup> , Ca <sup>++</sup> , Glu, Lac, tHb, O <sub>2</sub> Hb, COHb, MetHb, HHb, sO <sub>2</sub> , tBili or any combination of Electrochemical* analytes and CO-Oximetry** and/or tBili	150
tHb, O <sub>2</sub> Hb, COHb, MetHb, HHb, sO <sub>2</sub> , tBili and/or tBili	100
pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Cl <sup>-</sup> , Ca <sup>++</sup> , Glu, Lac (Capillary tube sampling only)	65 (Capillary only)

\*Electrochemical analytes = pH, p CO<sub>2</sub>, p O<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Cl<sup>-</sup>, Ca<sup>++</sup>, Glu, Lac, Hct,

\*\* CO-OX = tHb, O<sub>2</sub>Hb, COHb, MetHb, HHb, sO<sub>2</sub>

**All blood samples should be accurately labeled, or transported with, unequivocal patient ID including the hospital number, last name, first name and date of birth . You should also note any relevant clinical information e.g. patient temperature and oxygen therapy.**

#### 4. HEALTH AND SAFETY

All patient samples are a potential infection risk. Follow appropriate procedures (e.g. use gloves). Cover cuts and abrasions on own hands and forearms with water-repellent 'island' type plasters. If hands do become contaminated with blood, wash immediately with soap and water.

All sharps should be disposed of in a sharps bin. Any other used materials should be discarded into clinical waste in accordance with ward/site procedures.

Document	Q Pulse Reference N <sup>o</sup> :
COSSH Assessment	BS/POCT/H&S/COSHH/1
Risk Assessment	BS/POCT/H&S/RA/1

#### 5. EQUIPMENT AND INSTRUMENTATION

GEM Premier 5000 analyser

Uninterruptible Power Supply (UPS)

##### Locations:

Maternity	
Serial Number	Ward/Department
16040275	NICU
16040276	
16040277	CDS
16040279	

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Brunel Building			
Serial Number	Ward/Department	Level	Gate
16040283	AMU (Side A)	0	31
16050293	AMU (Side B)	0	31
16040274	Emergency Department - Resus	0	35
16050291	Emergency Department - Majors	0	35
16040282	Respiratory Testing	1	12
16010201	ICU Pod A	2	37
16040284	ICU Pod B	2	37
16040281	ICU Pod C	2	37
16050287	ICU Pod D	2	37
16050289	Theatres	2	20
16040273	Theatres	3	21
16040278	Respiratory Ward (Side B)	4	27

If the GEM Premier 5000 in a ward/department is unavailable either while the reagent PAK is being replaced, or in event of an analyser failure, blood gas analysis will need to be performed on another analyser.

**6. REAGENTS, STANDARDS, CALIBRANTS AND CONTROLS****6.1 GEM Premier 5000 PAK<sup>®</sup> GEM PAK**

The GEM PAK contains the reagents, sensors, CO-Ox and total bilirubin optical cell, sampler, and waste bag enables the analysis of 75 to 600 samples.

GEM PAKs are stored at room temperature: 15 to 25°C and require no preparation before use. The GEM PAK may be inserted up to and including the use-by (expiration) date shown on the packaging. The system will not accept an expired GEM PAK. The GEM PAK must be replaced when the maximum number of tests are run, or when GEM PAK use-life is reached, whichever comes first. The operator is notified when the GEM PAK must be replaced.

The GEM PAKs stated below may be subject to change to meet test number and/or repertoire requirements of the area.

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Ward/Department	Analyte Menu	On-board Use Life	Number of Tests	Part Number
ICU Pod A	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> , Glu, Lac, tHb, O <sub>2</sub> Hb, COHb, HHb, MetHb, sO <sub>2</sub>	21 days	600	00055360010
ICU Pod B				
ICU Pod C				
ICU Pod D				
ED Majors				
ED Resus				
AMU (Side B)				
Theatres (Gate 20)				
NICU	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> , Glu, Lac, tHb, O <sub>2</sub> Hb, COHb, HHb, MetHb, sO <sub>2</sub> , Bili	21 days	600	00055360011
Respiratory Ward	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> , Glu, Lac, tHb, O <sub>2</sub> Hb, COHb, HHb, MetHb, sO <sub>2</sub>	30 days	450	00055445010
AMU (Side A)				
CDS	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> , Glu, Lac, tHb, O <sub>2</sub> Hb, COHb, HHb, MetHb, sO <sub>2</sub>	30 days	300	00055430010
Theatres (Gate 21)	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> , Glu, Lac	30 days	150	00055415010
Respiratory Testing	pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Cl <sup>-</sup> , Glu, Lac	30 days	75	00055407510

### 6.2 GEM CVP

The GEM Premier 5000 system automatically performs calibration validation utilizing two independent NIST-traceable on-board solutions called Auto PAK Validation or APV. Only after the APV process is successful can samples be performed on the selected analytes.

Each time you insert a GEM PAK that contains total Bilirubin (tBili), the GEM Premier 5000 system will prompt you to run CVP5 testing.

CVP5 ampoules are stored refrigerated 2-8°C. GEM CVP 5 tBili **must be analysed immediately after removal from the refrigerator**. The ampoule material should be deep red in colour when received and remain so until the expiration date. Change of colour to brown and/or inability to achieve listed values can be an indication of deterioration.

Description	Part Number	Traceability
GEM CVP 5 tBili, 10 ampoules x 1.8 mL	00025000145	Ampoules were equilibrated to 22°C and measured at 37°C. Established protocols for GEM CVP are traceable to NIST materials and recognised CLSI methods where available and appropriate.

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## 7. METHOD

### 7.1 Removing the GEM PAK

The GEM Premier 5000 PAK<sup>®</sup> should only be removed when the maximum use-life or test capacity has been reached or in the event of failure. GEM PAKs **cannot** be reused once they have been removed.

- If a GEM PAK has reached its maximum onboard use-life or test capacity, the GEM PAK door will automatically open and display a message to the operator to remove the GEM PAK.
- To remove a GEM PAK prior to its maximum onboard use-life or test capacity, follow the instructions provided below.
  1. Select **Menu>Action>Remove Cartridge**.
  2. Enter your unique POCT Access ID password by scanning your barcode and press **Enter**
  3. As a precaution, the system will ask you whether you want to continue. Press **No** to stop the process and return to the Start New Sample tab. Press **Yes** to continue.
  4. Once you press Yes, the door will click open slightly.

### 7.2 Replacing the GEM PAK:

1. Move the door to the left, grasp the GEM PAK, and pull it gently toward you.
2. Unpack the new GEM PAK from its protective wrapper. Remove the clear plastic cover and desiccant pouch from the pump winding area. Discard the protective wrapper and plastic cover.
3. Position the GEM PAK with the grey sampling area facing forward. Push the GEM PAK in until you feel resistance. Please note that approximately one inch of the GEM PAK will extend beyond the front of the analyser.
4. Guide the analyser door to the right to close it and move the GEM PAK into its final position.
5. In approximately 20 seconds, the analyser will inform you that the GEM PAK is warming up. The clock will count down for the next 40 minutes as the GEM PAK warms up. During this time, the sensors will hydrate, and the analyser will perform internal checks and calibration.
6. After the warm up period is complete, the GEM Premier 5000 system will automatically perform calibration validation utilising two (2) independent NIST-traceable on-board solutions called Auto PAK Validation or APV. Only after the APV process is successful can samples be performed on the selected analytes.

**Used GEM Premier 5000 GEM PAKs should be disposed as clinical waste. They should be placed in 60L yellow-lidded rigid Wiva bins which should, when filled, be sealed before placing into the large yellow clinical waste wheelie bins (labelled HS).**

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**7.3 CVP5 (Calibration Valuation Product) Sampling**

Each time you insert a GEM PAK that contains total Bilirubin (tBili), the GEM Premier 5000 system will prompt you to run CVP5 testing.

This process of performing CVP5 validates the tBili performance of the GEM PAK prior to performing patient samples. Patient results for bilirubin cannot be reported until CVP5 is within acceptable ranges. Analysing CVP5 involves testing one ampoule of solution.

**CAUTION:** GEM CVP5 tBili contains human source material. This product, as with all human based specimens, should be handled with proper safety procedures to minimize the risk of transmission of infectious diseases.


1. The GEM Premier 5000 system will inform you that CVP5 testing is due via the Analyte Status Bar at the bottom of the screen and under each QuikStart button configured with tBili.
2. Select Ampoule Screen.
3. Press CVP button.
4. Scan the 2D barcode on the ampoule label using the barcode scanner. Press OK to begin CVP testing.
5. Enter your unique POCT Access ID-by scanning the barcode and press Enter.
6. GEM CVP 5 tBili should be utilized immediately from refrigerated storage (2-8°C). Immediately prior to use, hold the ampoule by the top above the break line and shake the ampoule with gentle tapping.

**CAUTION: Hold the ampoule only above the break line. Holding the ampoule in your hand will cause the aqueous solution to exceed the recommended testing temperature and can adversely affect CVP results.**

7. Gently tap the ampoule so the liquid settles back to the bottom.
8. Carefully snap open the ampoule.
9. Present the CVP5 ampoule to the sampler, which will emerge from the grey sampling area at the front of the analyser. Hold the ampoule so the end of the sampler does not touch the bottom. Press OK to begin aspiration. The analyser will issue an audio prompt when it has aspirated enough of the CVP sampling solution. Remove the ampoule immediately upon hearing the audio prompt. Dispose of the rest of the ampoule in a sharps bin.
10. The analyser will show you the results of the CVP5 testing. tBili results within range will be indicated in green text with a white background; out-of-range in white text on a red background. If the tBili result is within range, press Accept. In the unlikely event of an out-of-range result, exclude the sample. The tBili analyte button on the Analyte Status Bar will turn green after a successful CVP5 result and acceptance, indicating that tBili is available for sample testing.

If CVP5 does not pass the acceptable range, the operator is prompted to run an iQM2 Process prior to repeating the analysis with a new vial. An iQM2 Process is initiated by selecting **Menu>Diagnostics>Run iQM2 Process**. When the iQM2 Process is complete, run the **new** CVP5 vial. If CVP5 fails the acceptable range two more times either perform samples without tBili or replace the GEM PAK. **Contact POCT Ext: 48422.**

**See Appendix 1- Reagent PAK change on NICU GEM Premier 5000 blood gas analysers**

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**7.4 Patient Sample Analysis**

1. Select the desired Quick Start Button from the Main Screen. The Quick Start Button outlines panel name, sample device, sample volume, and menu.
2. Enter your unique POCT Access ID password by scanning your barcode.
3. The sampler will emerge from its home position.

**Syringe or ampoule sampling** – the sampler will extend from the luer and move approximately 30 degrees from its home position. Present the syringe or ampoule by placing it over the end of the sampler. The sampler should be inserted far enough into the container to allow aspiration but not so far that the sampler touches the bottom of the device.

**Capillary tube sampling** – the sampler will extend from the luer and move approximately 90 degrees from its home position. Tilt the tube slightly until the blood is flush with the end of the capillary. If there is blood or debris on the outside of the capillary tube, wipe the end prior to placing it in the sampler. Present the capillary tube by placing it over the end of the sampler. Select the **Start Aspiration** button. Continue to hold the capillary device during the aspiration process.

4. The system will aspirate the sample and emit an audio/visual prompt when aspiration is complete. Remove the container promptly. The sampler will retract into the system.

**NOTE:** All analysers have been configured to require selecting **OK** again before the sampler will retract. The sampler will still automatically retract if **OK** is not selected within 15 seconds of being presented. A count down timer is displayed.

5. The system will perform analysis while you enter patient information using the alphanumeric keypad (the keypad becomes accessible when you press a button requiring data entry), barcode scanner, or via pre-populated fields imported from the LIS or HIS. Required fields are indicated with an asterisk (\*) and located in the right column marked 'Required'.
6. Sample results cannot be viewed until all required fields have entries made in them.

**Patient Information (required)**

Input Parameter	Maximum Length/Amount
Patient ID (NHS number <b>OR</b> other unique identifier)	24 alphanumeric characters
Patient Last Name	24 alphanumeric characters
Patient First Name	24 alphanumeric characters
Patient Date of Birth	8 digit format

**When entering the Patient ID if the incorrect patient name is displayed another unique identifier such as the NHS number, or the six figure date of birth with the prefix DOB, must be entered and the POCT team notified as soon as possible.**

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**User-Entered Values (not required)**

Entered Parameter	Unit of Measure	Allowable Range Entry
Temperature (Temp)	°C	15.0 to 45.0

The default temperature is 37°C. This temperature will be used to calculate pH, pCO<sub>2</sub> and pO<sub>2</sub> unless a different entry is made by the operator. The measured and corrected temperatures, if applicable, are displayed on the View Results tab and on the printout.

**O2 and Vent Entries (not required)**

Parameter	Description	Unit	Entry Range
FIO <sub>2</sub>	Percent Inspired Oxygen	%	20.0 – 100.0

**Entering Comments**

Comments may be free-text entries or selected from pre-defined entries. Comments cannot be edited or deleted after the sample has been accepted.

**View sample results**

After all required information is completed, patient results may be viewed by selecting the View Results Button.








Results are presented as follows:

**Measured values** – analyte levels measured during patient sample analysis

**Temperature corrected values** – displayed only if a patient temperature has been entered in the Enter Information tab

**Derived values** – calculated using equations applied to one or more measured analytes







The following exceptions or flags may be displayed along with the sample results.

Exception Symbol	Exception Symbol Description
	Outside Reference Range - High
	Outside Reference Range - Low
	Outside Critical Range - High
	Outside Reportable Range – Greater Than
	Outside Reportable Range – Less Than
	Outside CVP Range – High (CVP Results Only)
	Outside CVP Range – Low (CVP Results Only)



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Exception Flags on Results Screen and on Printed Reports

Exception Flag	Exception Flag Description
<b>incalculable</b>	Result Incalculable
	Absorbance Error
	Result Corrected for Sulphaemoglobin
	High Turbidity Detected
	Interference Detected
	Micro Clot Detected
	Temporary Sensor Error

**Patient History**

If a valid patient ID and sample type are entered, the **Patient History** button becomes available. Pressing this button will launch a Patient History screen showing the five most recent samples run in the last month for that patient.

**Please note:** the blood gas sample should be retained until an acceptable result has been obtained. It can then be discarded as clinical waste.

**7.5 Recalling patient results**

The GEM Premier 5000 Data Management system allows you to search for patient results across across the entire GEMweb Plus network from an analyser or PC on the hospital network.

1. Choose Search Results from the drop-down Menu in the upper left corner of the screen. You will need to enter your password to access this feature.
2. Enter the search criteria in the Search Criteria area. These function as data entry fields or drop-down menus
3. To view the samples that meet the selected criteria, press the View button at the bottom of the screen. All samples meeting the search criteria will be displayed on screen.
4. All samples that meet the criteria selected by the operator will be displayed.
5. Details of a specific sample can be accessed by pressing one of the patient name buttons from the sample list.
6. The Patient History button is also available here. Pressing this button will launch a Patient History screen showing the five most recent samples run in the last month for that patient.

**7.6 Installing the Printer Paper**

1. To install the thermal printer paper in the paper area on top of the system:
2. Press the tab at the top of the system to release the door.
3. Open the door.
4. Place the roll of paper in the compartment so the paper unfurls from the bottom.
5. Press the door **firmly** closed.

**NOTE:** The thermal paper can only be printed on one side.

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### 7.7 Cleaning the GEM Premier 5000 and screen

1. Dampen a soft cleaning cloth with water or mild cleaning solution.
2. Carefully wipe the face of the touch screen free of fingerprints and other smudges.
3. Remove any blood or dust from the outer surface.

**CAUTION:** The GEM Premier 5000 analyser processes patient samples that may be highly infectious. When cleaning the instrument use proper technique and care to avoid contaminating yourself or others.

## 8. QUALITY CONTROL

Intelligent Quality Management (iQM<sup>®</sup>) is used as the quality control and assessment system for the GEM Premier 5000 analyser. iQM is an active, quality process control program designed to provide continuous monitoring of the analytical process with real-time, automatic error detection, automatic correction of the system and automatic documentation of all corrective actions, replacing the use of traditional external quality controls. As part of this program, GEM CVP (Calibration Valuation Product) with CO-Ox and are external solutions intended to complete the calibration process and final accuracy assessment of the iQM GEM PAK calibration after initial warm-up. The reported values for GEM CVP must meet manufacturer's specifications before the iQM GEM PAK can be used for patient sample measurements. Once the GEM PAK calibration is verified, the internal iQM Process Control solutions, internal checks and software pattern recognition monitors the status of the system during the GEM PAK use life.

### External Quality Assurance

See EQA Procedure for Point of Care Testing (POCT) Q Pulse Reference N<sup>o</sup>: BS/POCT/GENSOP/1 for details of procurement and reconstitution etc.

All analytes on the GEM Premier 5000 are covered by the WEQAS Blood Gas, Co-oximetry and Bilirubin Schemes.

## 9. LIMITATIONS OF THE EXAMINATION

Room Air	Especially samples having a very low or high $pO_2$ content. Similarly, $pCO_2$ may be affected and subsequently pH and $Ca^{++}$ results as well.
Metabolic Changes	Errors can occur due to metabolic changes if there is a delay in the measurement of the samples.
Elevated White Blood Cells or Reticulocyte Counts	Samples will deteriorate more rapidly, even when kept in ice water.
Improper Mixing	Errors will be introduced for measurement of haematocrit and CO-Ox parameters if the sample is not properly mixed prior to measurement.
Haemolysis	Potassium results will be falsely elevated if the sample is haemolysed.
Under-Heparinised Sample	Blood clot can form in the sensor chamber causing various sensor failures if sample is not properly heparinised.
Changes to Manufacturer's Instructions or Method Verification Protocols	Results obtained may be compromised.
Improper Installation	The instrument must be installed per the manufacturer's instructions. Failure to do so invalidates any warrant, explicit or implied.

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**10. RECORDING AND CALCULATION OF RESULTS**

Results are automatically printed on thermal printer paper and sent to GEM *web* Plus data manager.

**11. REFERENCE RANGES**

Parameter	Arterial Sample	Venous Sample	Unit
pH	7.35 - 7.45	7.32 - 7.43	pH
pCO <sub>2</sub>	4.6 - 6.4	4.6 - 6.4	kPa
pO <sub>2</sub>	11.0 - 14.4	11.0 - 14.4	kPa
Na <sup>+</sup> **	133 - 146	133 - 146	mmol/L
K <sup>+</sup> **	3.5 - 5.3	3.5 - 5.3	mmol/L
Cl <sup>-</sup> **	95 - 108	95 - 108	mmol/L
Ca <sup>++</sup>	1.15 - 1.33	1.15 - 1.33	mmol/L
Glu	3.6 - 5.3	3.6 - 5.3	mmol/L
Lac <sup>**</sup>	0.5 - 2.2	0.5 - 2.2	mmol/L
tHb <sup>**</sup>	120 - 170	120 - 170	g/L
O <sub>2</sub> Hb	95.0 - 98.0	95.0 - 98.0	%
CoHb	<3.0	<3.0	%
MetHb	0.0 - 1.5	0.0 - 1.5	%
HHb	2.0 - 6.0	2.0 - 6.0	%
sO <sub>2</sub>	94.0 - 98.0	94.0 - 98.0	%

Generic reference ranges quoted in GEM Premier 5000 Operator's Manual

\*\* Laboratory reference range

Neonatal bilirubin results should be interpreted according to local guidelines.

**12. MEASUREMENT UNCERTAINTY OF MEASURES QUANTITY VALUES**

Current estimates of measurement of uncertainty are documented in Uncertainty of Measurement for Point of Care Testing Analytes Q Pulse Reference N<sup>o</sup>: BS/POCT/R&D/1

**13. REPORTING AND VALIDATION OF RESULTS**

All results from GEM Premier 5000 are automatically sent to the GEM *web* Plus data manager. Unexpected results **MUST** be confirmed by repeating the analysis using a different GEM Premier 5000 blood gas analyser, taking a fresh blood gas sample or sending the appropriate samples to the Biochemistry/Haematology laboratory.

**14. REFERENCES**

GEM Premier 5000 Operator's Manual Q Pulse Reference N<sup>o</sup>: BS/POCT/EXDOC/4

**APPENDIX 1**

**Reagent PAK change on NICU GEM Premier 5000 blood gas analysers**



Every time you insert a new GEM reagent PAK you will be prompted you to run CVP5 testing. **Please note: CVP5 ampoules are stored in the drugs fridge and must be analysed immediately after removal.**

1. Select 'Ampoules' tab
2. Press CVP button
3. Scan the 2D barcode on the ampoule label & press OK to begin testing
4. Mix the ampoule gently before carefully snapping open
5. Present the CVP5 ampoule to the sampler, press OK to begin aspiration and remove the ampoule immediately upon hearing the audio prompt
6. The analyser will show you the results of the CVP5 testing. tBili results within range will be indicated in green text with a white background; out-of-range in white text on a red background. If the tBili result is within range, press Accept
7. If CVP5 does not pass the acceptable range, run an iQM2 Process by selecting Menu > Diagnostics > Run iQM2 Process before repeating CVP5 testing with a **new** ampoule
8. In the unlikely event that CVP5 fails the acceptable range two more times, either perform samples without tBili on that GEM Premier 5000 analyser or replace the GEM PAK.