TITLE: POCT IL Gem 4000 Operation and Maintenance Procedure	**Doc #:** 21038
Section: Management System\PLM\General\PLM Website\Point of Care Testing\Blood Gas\	**Version:** 2.1 Current
Document Owner: Point of Care Coordinator	**Effective Date:** 2020/01/24
Final Approval: Dr Manal Elnenaei	

Purpose

This document provides instructions to perform blood gas analysis and maintenance procedures using the IL GEM 4000 in a Point of Care setting.

Abbreviations

pCO_2 = Partial pressure of carbon dioxide
pO_2 = Partial pressure of oxygen
HCO_3^- = Bicarbonate
BE = Base Excess
O_2Ct = Oxygen Content
O_2Hb = Saturation
tHb = Total Hemoglobin
COHb = Carboxyhemoglobin
MetHb = Methemoglobin
Na+ = Sodium
K+ = Potassium
Cl- = Chloride
ICA = Ionized Calcium
ABG = Arterial Blood Gas
VGB = Venous Blood Gas
A/V = Arterial/Venous
CO-ox = CO-oximeter
BP = Barometric Pressure
QC = Quality Control
PVP = Performance Verification Product
CVP = Calibration Valuation Product
OR = Operating Room
FiO_2 = Fraction of inspired oxygen
PSI= Pounds per square inch
IQM = Intelligent Quality Management
POC = Point of Care

Materials

Reagents

Description	Package configuration	Stability
Self-contained cartridge PAKs	Contains all the components required for patient testing.	Cartridges are stable at 15-25°C. The cartridge may be inserted up to and including the use-by (expiration) date shown on the packaging. See on-board stability listed below

Note: Each time a new cartridge is received, mark the date received. Install the cartridge with the oldest received date first. The system will not accept an expired cartridge.

On board cartridge stability

	Number of tests per PAK				
	75	150	300	450	600
Life (Days) after loaded	30	30	30	30	21

Supplies
Kit Arterial Sampler #1
Biohazard wipe
Biohazardous sharps container
Anatomical Waste Red Container
Gem Premium 4000 Printer paper

Materials (Cont')

Fuse -3 Amp, 250 Volt, SLO-BLO fuse, and measures 5 mm x 20 mm. Supplied by BioMed.
3ml lithium heparin syringe , BD, 309585

Equipment
Instrument Laboratories GEM 4000 blood gas analyzer
Ampoule breaker

Note:

- The instrument must be positioned so that is at least 15.2 cm (6 inches) clearance on both sides, back and top for proper air circulation
- If there is no power to the instrument for 20 minutes the cartridge must be replaced

Sample

Sample retention: None

SPECIMEN INFORMATION

• The GEM 4000 analyses arterial or venous whole blood.
Always use the recommended fill volume for sample device chosen (1cc (1ml) for a 3 cc (3ml) syringe).

• Only lithium heparin should be used as anticoagulants. Other anticoagulants may significantly alter the results.

• **Air bubbles in a specimen should be considered a contaminant, (blood gas values may be affected). Any sample containing froth or bubbles is considered an unacceptable sample, and should be recollected.**

• **Samples** should be analyzed within 10 minutes of collection. If it cannot be analyzed in this time frame it should be placed in an ice-water slurry**, where it is stable for 1 hour.**

• Before analyzing the sample, the syringe should be rolled between your palms and gently inverted several times to mix the sample thoroughly and to distribute the anticoagulant. **If the sample is not well mixed before analysis, the results obtained can be falsely decreased or increased.** Mix all samples using a consistent technique.

• If the sample is chilled the mixing time should be increased to ensure that the sample is thoroughly mixed.

• Dispose of used sample collection devices according to institutional infection control policy.

Special Safety Precautions	"Routine Practices" as directed by Health Canada, must be considered as the level of care provided for all patients. Use Health Canada Guidelines for "Routine Practices" to avoid exposure to blood, body fluids and contaminated surfaces. All patient samples, as well as the materials they contact, are to be considered biohazardous and therefore capable of transmitting infection or cross contamination.

Maintenance

Complete *POCT IL GEM 4000 QA Log* (Doc # 24659) for all maintenance as performed.

1. Daily Maintenance

Do not allow water or cleaning solution to enter the unit enclosure.

Step	Action
1.1	Check printer paper and change as required. To install new printer paper 1.1.1 Release the door by pressing the tab at the top of the system 1.1.2 Open the door (extend paper guide if desired). 1.1.3 Place the roll of paper in the compartment so the paper unfurls from the bottom 1.1.4 Press the door firmly closed **Note:** Thermal paper can only be printed on one side.
1.2	Clean exterior surfaces. Remove any blood or dust from the outer surface of the case using a clean, soft cloth moistened with disinfectant.
1.3	Clean touch screen. Wipe the touch screen with a soft cleaning cloth dampened with water. If blood gets splattered on screen - use a mild cleaning solution (10% solution of 70% isopropanol) then rinse with water. **Note:** Do **not** use an abrasive cleaner or any bleach mixture to clean the touch screen, as this will damage the screen.
1.4	 Check cartridge inventory. 1.4.1 Consult the Tests/Days button on the upper right of the Status Bar 1.4.2 Cartridge must be replaced if: 1.4.2.1 Days have exceeded the maximum (see chart in Materials section) 1.4.2.2 All tests have been used 1.4.2.3 If cartridge fails or if a parameter cannot recover after a clot.

Maintenance Cont'd	1.5	Record all activities performed on the *POCT IL GEM 4000 QA log*
	1.6	Retain all maintenance logs in a binder available for review.

2. Replacing cartridge

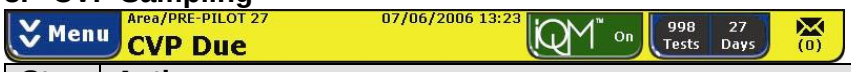
Note:

- Cartridge replacement is performed by key operators who have documented training and competency
- The analyzer requires a minimum of one hour to stabilize after changing the Cartridge
- Do not turn off the analyzer using the power switch. The instrument may not recover from an illegal shutdown.

Step	Action
2.1	Press **Remove Cartridge** on the touch screen.
2.2	Press **Yes** to continue **Note**: If you do not wish to remove the cartridge at this time select **No** to stop the process.
2.3	Move the door all the way to the left
2.4	Remove the cartridge from the analyzer and discard in an Anatomical Waste Red Container. **Note:** Once the cartridge has been removed, it cannot be reinserted
2.5	Clean the bay area and the polyester laminate protective sheet on the bottom as needed. **Note:** The bay area is where the GEM Premier 4000 PAK cartridge is inserted.
2.6	Unpack the new cartridge from its protective wrapper
2.7	Remove the plastic cover from the pump winding area
2.8	Position the cartridge in instrument **Note:** The gray sampling area faces forward.
2.9	Push the cartridge in until you feel resistance **Note:** Approximately one inch of the cartridge will extend beyond the front of the analyzer
2.10	Close the analyzer door (This will move the cartridge into its final position). **Note:** • Do not select open door after loading the cartridge which is available for approximately 20 seconds prior to cartridge warm up. This may cause the cartridge to be rejected. • The analyzer indicates the cartridge is warming up and the clock will count down for the 45 minutes
2.11	Run the external GEM CVP (see Step 3- **CVP Sampling**)

Maintenance Cont'd

3. CVP Sampling



Step	Action
3.1	Run full IQM process. 3.1.1. Run an IQM process by selecting **Menu > Diagnostics > Run IQM Process**
3.2	Press **GO** to begin sampling **Note:** If probe does not extend, instrument is not ready yet.
3.3	Select the correct CVP lot number from the choices on the screen
3.4	Press **OK** to begin CVP testing
3.5	Hold the ampoule only above the break line mix vigorously the CVP solution and gently tap the ampoule until the liquid settles back to the bottom **Note:** For optimum results CVP samples should be kept at temperature between 22 to 25 ºC.
3.6	Snap open the ampoule safely. **Note:** Aspirate samples immediately after opening. GEM CVP solutions are sensitive to ambient temperature variations (gas/liquid equilibrium) and room air contamination (diffusion gradients). Any delay in measuring may cause unacceptable CVP results for pCO_2 and higher pO_2 values.
3.7	Present the opened CVP ampoule to the sampler **Note**: Do not let the end of the sampler touch the bottom.
3.8	Press **OK** to begin aspiration.
3.9	Remove the ampoule immediately upon hearing the audio prompt.
3.10	Dispose of the ampoule in appropriate container
3.11	Press **Accept** if all results are within range. If all results are not within range **Exclude** these results and see step 3.13.
3.12	Repeat steps 3.1 through 3.11 for the remaining CVP.
3.13	When analytes are <u>not</u> within the acceptable range, repeat steps 3.1 - 3.11 with a **new** vial. **Note:** If possible, ask a co-worker to run CVP.
3.14	Replace cartridge if CVP is unsuccessful after 4 attempts. (see procedure 4)

4. Failed Cartridge

Step	Action
4.1	Replace failed cartridge with a new cartridge on instrument. (see procedure 2)

Maintenance Cont'd	4.2	Identify cartridge failure by calling IL Technical Support at 1-800-678-0710 (24 hour line).
	4.3	Enter information in *IL GEM 4000 Cartridge Credit form* (Doc # 11048)
	4.4	Send the Cartridge Credit Form to POC (Fax # 473-7038) and if possible, email POC contact to confirm the fax has been sent.

5. Replacing the fuse

The fuse should be replaced only if, after the power cord is connected to the power source and the power switch is pressed, the analyzer does not respond.

Step	Action
5.1	Unplug the instrument from AC power supply
5.2	Remove the black cover located directly below the power connector using the tabs.
5.3	Remove the old fuse.
5.4	Dispose of the old fuse in a sharps container (suitable for glass).
5.5	Insert the new fuse.
5.6	Replace the cover.
5.7	Reconnect the power cord.
5.8	Turn on the analyzer by briefly pressing the power button on the left side of the back of the analyzer.

Quality Control

Control	Level	Stability
Instrumentation Laboratory External GEM CVP	GEM CVP 1 with CO-Ox Prod#00025000115	Unopened ampoules are stable 15-25°C for 8 months or at 2-8°C until the expiration date shown on the label. DO NOT FREEZE
	GEM CVP 2 with CO-Ox Prod#00025000125	

Control preparation: No preparation is required

Procedure

1. Analyzing samples

Note:

Typing too quickly on keypad may cause computer screen to freeze (Frozen screens cause delays as a shutdown is required)

Step	Action
1.1	Check all analytes required are available **Note**: • Parameter performing a self-fix are flagged and will not be reported • A check and a dark green tab indicates the analyte to be reported.
1.2	Check patient's name and identification on armband and label to be attached to syringe prior to starting sampling procedure.
1.3	**Check the Patient's Temperature**. If the patient's temperature is **<35 or >39** and the patient is not in the OR and it is not an apnea sample, temperature correction is required (see step 1.13).
1.4	1.4..1 Prepare the sample by mixing on two different axis for at least 30 seconds 1.4..2 Direct syringe away from body and expel the first drop of sample onto a tissue, checking for small clots and expelling any air bubbles 1.4..3 If sample is clotted, recollect.
1.5	Run samples as **Arterial or Venous** depending on sample collection site.
1.6	Press GO.
1.7	Type in 5 digit password.
1.8	Press enter.
1.9	Place syringe over end of sampler **Note:** Do not allow the sample to touch black syringe stop
1.10	Press "OK" to begin sampling
1.11	Remove sample after audio prompt.
1.12	Wipe probe with tissue.

<table>
<tr><td rowspan="5">Procedure (Cont')</td><td>1.13</td><td>Press drop down arrow next to Patient Id field hit key enter and barcode patient account number.
Note:
Required fields are indicated with an asterisk (*).
Enter the patient temperature if <35 C or >39 C to obtain corrected PH, PCo2, PO2 values.
Do not temperature correct for samples from OR patients or for Apnea tests.
The patients first and last name and gender will be added by the system once it has confirmed the account number.
.</td></tr>
<tr><td>1.14</td><td>Go to "View Results" tab</td></tr>
<tr><td>1.15</td><td>Examine the blood gas results for any instrument messages. See table below for possible messages.
<table>
<tr><th>Exception Symbol</th><th>Exception Symbol Description</th></tr>
<tr><td>▲</td><td>Outside Reference Range - High</td></tr>
<tr><td>▼</td><td>Outside Reference Range - Low</td></tr>
<tr><td>▲▲</td><td>Outside Critical Limit - High</td></tr>
<tr><td>▼▼</td><td>Outside Critical Limit - Low</td></tr>
<tr><td>></td><td>Outside Reportable Range – Greater Than</td></tr>
<tr><td><</td><td>Outside Reportable Range – Less Than</td></tr>
</table>
<table>
<tr><th>Exception Flag</th><th>Exception Flag Description</th></tr>
<tr><td>incalculable</td><td>Result Incalculable</td></tr>
<tr><td>A</td><td>Absorbance Error</td></tr>
<tr><td>S</td><td>Sulfhemoglobin Interference Detected</td></tr>
<tr><td>T</td><td>High Turbidity Detected</td></tr>
<tr><td></td><td>Interference Detected</td></tr>
<tr><td></td><td>Micro Clot Detected</td></tr>
<tr><td></td><td>Temporary Sensor Error</td></tr>
<tr><td>M</td><td>High Methemoglobin Warning</td></tr>
<tr><td>U</td><td>Sulfhemoglobin and High Methemoglobin Warning</td></tr>
<tr><td>C</td><td>Corrected for Sulfhemoglobin</td></tr>
</table></td></tr>
<tr><td>1.16</td><td>Press Accept if results are acceptable or Reject in results are unacceptable.</td></tr>
<tr><td>1.17</td><td>Remove print out.</td></tr>
<tr><td>1.18</td><td>Attach printout to patient's chart.</td></tr>
</table>

Result Interpretation

1. Expected Values:

Analyte	Reference Range		Analytical Range	Units
	Arterial	Venous		
PH	7.35 - 7.45	7.32 – 7.43	6.8 – 8.0	
pCO2	35 – 45	38 – 50	6 - 150	mmHg
pO2	80 – 100 * Normal lowers 1 mmHg/year >60yrs old		5 – 800	mmHg
HCO_3^-	21 – 28	22 - 29	0 - 99.9	mmol/L
B.E.	-2.0 - +3.0		-29.9 to + 29.9	mmol/L
Na^+	136 – 145	136-145	100 – 200	mmol/L
K^+	3.4 – 5.0	3.4-5.0	0.2 – 20.0	mmol/L
Cl-	98-107	98-107	40 - 170	mmol/L
Glucose	3.8-7.8	3.8-7.8	0.2 – 41.6	mmol/L
ICA	1.15 – 1.27	1.15-1.27	0.10 – 5.00	mmol/L
Lactate	0.5 – 1.7	0.5-1.7	0.3 – 20.0	mmol/L
tHb	140 – 180 (M) 120 – 160 (F)	140 – 180 (M) 120 – 160 (F)	30 – 230	g/L
SO_2	94 – 98	70 -75	-10 - 110	%
O_2 Hb	95 – 98		-10 - 110	%
COHb	<2(Non-smokers) 2- 10 (Smokers)		-10 - 110	%
MetHb	Reference high 1.5	Reference high 1.5	-10 - 110	%

* Refer to Calculation section of this document.

2. Decision and Critical Limits

Result Interpretation (cont'd)

Decision and critical limits for all parameters are highlighted in the results field of the GEM 4000. Report all results outside decision limits to physician.

ANALYTE	LOWER CRITICAL LIMIT	LOWER DECISION LIMIT	UPPER DECISION LIMIT	UPPER CRITICAL LIMIT	Units
pH	< 7.20			> 7.60	
pCO_2	< 20			> 70	mmHg
pO_2	< 60 (< 80 for OR patients)				mmHg
HCO_3^-	< 10	< 15		> 40	mmol/L
Na^+	< 120	< 125	> 155	>160	mmol/L
K^+	< 2.8	< 3.0	> 6.0	> 6.2	mmol/L
Glucose	< 2.5			<=16yr >15.0 >16yr >25.0	mmol/L
ICA	< 0.80			> 1.60	mmol/L
Lactate	No lower limit			> 4.0	mmol/L
tHb	< 70 g/L				g/L
O_2Hb	< 90 (arterial)				%
COHb	No Lower Limit		> 10	> 20	%
MetHb	No Lower Limit		> 5	≥30.0%	%

3. Interpreting Patient Results

Step	Action
3.1	Determine validity of patient results by: 3.1.1 Examining the blood gas results on the instrument screen for any instrument error symbols or messages as indicated on the charts from section 1.15. 3.1.2 If "interfering substances" (indicated on the instrument screen with "incalculable") or an error code appears on the instrument screen DO NOT REPORT results for the parameters affected. ***Note*** Results from both samples of an A/V pair should be reported from the same instrument
3.2	Ensure that any samples run in duplicate meet the criteria indicated in *section 4.*

Result Interpretation (cont'd)	3.3	Ensure the patient's temperature is >35 and <39. Note: If outside limits refer to step 1.13 in the procedure section.
	3.4	Report all COHb >20% immediately
	3.5	If results are unavailable or questionable, use an alternative laboratory method for verification • Example, hemoglobin from Hematology

4. Duplicate Analysis Quality Assurance Protocol

Duplicate analysis should be performed in the following circumstances:

- Inconsistent with the patient's previous results.
- Improbable results (i.e., Sum of pO_2 + pCO_2 > 150 mmHg on room air).
- Questionable results.

When the hemoglobin difference between the A/V pairs exceeds 4 g/L.

4.1 Acceptable Differences for Duplicate Analysis

Test	Acceptable Difference
pH	0.020
pCO_2	3mmHg for pCO_2 <50
pCO_2	4mmHg for pCO_2 >50
pO_2	4% for pO_2 <150
pO_2	7% for pO_2 >150
Na+	3 mmol/L
K+	0.2 mmol/L
ICA	0.08 mmol/L
tHb	4 g/L

- If a result agreement cannot be reached between the repeats, then the parameters which do not replicate cannot be interpreted.
- Sample recollection is recommended
- Incidents where results cannot be reported must be documented in the appropriate POCT *IL GEM 4000 QA Log* and fill a SIMS report.

5. Troubleshooting Quality Control and Patient Sample Results

Refer to the following:

GEM 4000 Operator Training Guide, Section V, Troubleshooting
GEM 4000 Operator's Guide, Section XIV, Error Codes and Operator Messages

Limitations

1. Interfering Substances

1.1 Substances Interfering with the Lactate Measurement

SUBSTANCE	CONCENTRATION TESTED
Fluoride	500 mg/dL
Dopamine	5 mg/dL
Dobutamine	2 mg/dL
oxalate	500 mg/dl
isoniazide	5 mg/dl
Hydroxyurea	0.8 mg/dl
Glycolic Acid	1 mmol/L

1.2 Substances Interfering with the CO-ox Measurement

Any substance that absorbs light in the same regions as whole blood could potentially cause an interference

SUBSTANCE	Concentration Tested
Cyanmethemoglobin	>4%
Sulfhemoglobin	>3%
Hemoglobin based Oxygen Carriers (Hemopure)	3.2 g/dl
Turbidity	5% based on turbidity created by Intralipid fat emulsion

1.3 Substances Interfering with Ionized Calcium

SUBSTANCE	CONCENTRATION TESTED
Benzalkonium	5 mg/L
Thiopental	30 mg/L

1.4 Substances Causing No Noticeable Interference

SUBSTANCE	CONCENTRATION TESTED
Acetaminophen	20 mg/dl
Acetoacetate	2 mmol/L
Ammonium	80 and 3000 µmol/L

Limitations Cont'd

Ascorbic Acid	3 mg/dL
Bilirubin	20mg/dL
Chlorpromazine	0.2 mmol/L
Citrate	12 mmol/L
Ethanol	100 and 350 mg/dL
Evans Blue	10 mg/L
Fetal Hemoglobin	85%
Flaxedil	2 and 5 mg/dL
Halothane	74 and 374 µg/mL
Heparin	100 IU/mL
B-Hydroxybutyrate	2 mmol/L
Ibuprofen	2 mmol/L
Indocyanine Green	10 mg/L
Isoniazide	2 and 5 mg/dL
Maltose	0.2 mg/mL
Methylene Blue	40 mg/L
Pyruvate	2 mmol/L
Thiocyanate	5, 10 and 20 mg/dL

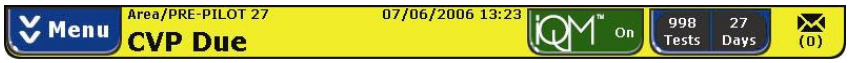
1.5 Other Factors Influencing Results

SUBSTANCE OR FACTOR	PARAMETER	EFFECT	COMMENTS
Time	pO_2	Decreases in glass syringe on ice Increases in plastic syringe on ice	
	pCO_2	Increases in glass syringe on ice	
	pH	Decreased	
	Calcium	Decreased	pH change reduces Calcium
	Lactate	Increased	Due to glycolysis and lactic acid formation

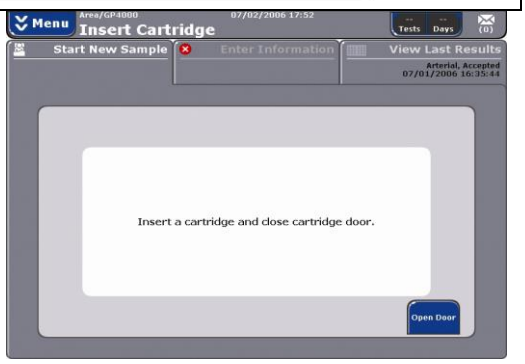
Limitations Cont'd	Tube not full	Calcium	Decreased	Due to incorrect ratio of heparin to sample; heparin chelates Calcium
	Hemolysis	Calcium	Decreased	
	Lipemia	MetHb tHb	Increased	
	Icterus	O_2	Increased	

Procedural Notes

Gem 4000 Condition and Message Chart

Green	Fully operational or normal
	
Yellow	Conditional state, awaiting specific action
	
Red	Stopped or non-functional
Gray/shaded	Functionality unavailable or not selected
	

Operator messages (in white boxes with black text) provide clear directions to for next steps.



Principle	The primary function of the Point-of-Care Blood Gas system is the rapid analysis of arterial and venous samples from patients on mechanical ventilatory support, and to provide rapid and accurate availability of blood gas and electrolyte status.

Related Procedures and Documents	PLM 24659 POC GEM 4000 QA Log PLM 62323 POC GEM 4000 Training Guide PLM 62321 POC GEM 4000 Competency Quiz PLM 11048 CC IL GEM 4000 Cartridge Credit form DT-POC-001 Point of Care Testing Operations CC 85-017 Diagnostic Tests – Requesting, Reporting of results and follow-up

Reference	GEM 4000 Operator's Guide