

OREGON HEALTH & SCIENCE UNIVERSITY  
Hospitals and Clinics  
Point of Care

**Blood Gas, Hemoglobin, Lytes, Lactate, Glucose,  
And Oxygen Saturation by IL GEM 4000**

Principle

The IL GEM 4000 analyzer is used for the measurement of pH, pO<sub>2</sub>, pCO<sub>2</sub>, electrolytes, lactate, O<sub>2</sub> saturation, and hemoglobin in arterial, venous, and mixed-venous blood samples.

Blood gases are obtained to determine if the patient is well oxygenated and to determine the acid base status of the patient. The pH determines if the patient is in an acidic or alkali state, the pO<sub>2</sub> refers to the pressure or tension exerted by dissolved O<sub>2</sub> gas in the blood. The pCO<sub>2</sub> is influenced by respiratory causes only. The O<sub>2</sub> measurement indicates how well the tissues are oxygenated. The oxygenation of blood from the lungs and the circulation of the blood from the heart contribute to the amount of pO<sub>2</sub> measured and renal compensation to the acid/base disturbance. The O<sub>2</sub> saturation is calculated as a ratio and shows the *percentage* of the volume of oxygen carried to the maximum volume which is possible to carry.

Hemoglobin is the main chemical substance within red blood cells and is the compound which transports the major portion of oxygen to the tissues. The IL GEM 4000 optical system is designed to measure total hemoglobin and hemoglobin derivatives.

Blood gases, O<sub>2</sub> saturation, electrolytes, lactate, and hemoglobin are analyzed in the Adult Open Heart rooms in order to monitor patient status during surgery.

Specimen Requirements

Sample Type	Collection Device	Minimum Fill Volume
Arterial, venous, or mixed venous whole blood	Lithium heparin syringe. Plain syringe for highly anticoagulated patients such as those seen in the CVOR.	0.2 mL for a 1.0 mL syringe 0.8 mL for a 3.0 mL syringe 1.5 mL for a 5.0 mL syringe

Expel all air from the syringe and cap it immediately after specimen collection to avoid room air contamination.

Before analyzing the specimen, roll the syringe between your palms and gently invert it several times to mix the specimen thoroughly.

Instrumentation Laboratory recommends the use of devices coated with lyophilized lithium heparin or electrolyte-balanced heparin for use as an anticoagulant. A heparin concentration of 20 to 25 IU/mL of whole blood will prevent clot formation as long as the device is mixed

thoroughly immediately after the sample is obtained. If a device is used that contains a concentration of heparin, which is less than 20 IU/mL of whole blood, it is imperative that the supplier of the device indicate that the concentration is sufficient, when mixed properly, to prevent clot formation for a period time that will allow the sample to be analyzed.

### Interferences

The following substances may show noticeable interference with certain channels on the GEM 4000 analyzer, causing falsely elevated results.

Substance	Affected Analyte	Substance Concentration Producing Interference	Maximum Expected In Vivo Concentration
benzalkonium*	Ca <sup>++</sup>	5 mg/L	10 mg/L
bromide	Cl <sup>-</sup>	10 mmol/L	25 mmol/L
fluoride	Cl <sup>-</sup> , lactate	500 mg/dL	1000 mg/dL (as a blood preservative)
glycolic acid	lactate	1 mmol/L	2.4 mmol/L (toxic)
Hemoglobin Based Oxygen Carriers (Hemopure <sup>®****</sup> )	hematocrit	3.2 g/dL	>6.0 g/dL
hydroxocobalamin**	CO-Oximetry	0.5 g/L	1 g/L
hydroxyurea	glucose, lactate	0.8 mg/dL	2 mg/dL
iodide	Cl <sup>-</sup>	3 mmol/L	3 mmol/L
oxalate	Cl <sup>-</sup> , lactate	500 mg/dL	1000 mg/dL (as a blood preservative)
salicylate	Cl <sup>-</sup>	4 mmol/L	2.9 mmol/L (toxic)
thiopental*	pCO <sub>2</sub> , Ca <sup>++</sup> , K <sup>+</sup>	30 mg/L, 50 mg/L for K <sup>+</sup>	60 mg/L (toxic)
turbidity**	CO-Oximetry	5% based on turbidity created by Intralipid <sup>®****</sup> fat emulsion	3% intralipid is equivalent to turbidity created by a triglycerides conc. = 1500 mg/dL

**Blood collected using catheters anticoagulated with benzalkonium heparin should not be used.**

### Analytical Measurement Range (Linearity)

Analyte	AMR
pH	6.90 - 7.80
pCO <sub>2</sub>	20 - 130 mmHg
pO <sub>2</sub>	35 - 600 mmHg
Sodium	106-180 mmol/L
Potassium	1.2-10.0 mmol/L
Chloride	68-160 mmol/L
iCA	0.3-3.0 mmol/L
Glucose	17-700 mg/dL
Lactate	0.5-16.0 mmol/L
THb	6.0-21.0 g/dL
sO <sub>2</sub>	0.0 - 100.0%
FO <sub>2</sub> Hb	0 - 100% 0.0 - 1.00 fraction

### Reference Range

Analyte	Age	Arterial	Venous
pH	0-2 months	7.30-7.50	7.35-7.45
pH	>2 months	7.37-7.44	7.35-7.45
pCO <sub>2</sub> (mmHg)	0-2 months	30-65	35-50
pCO <sub>2</sub> (mmHg)	>2 months	32-43	35-50
pO <sub>2</sub> (mmHg)	0-2 months	50-75	N/A
pO <sub>2</sub> (mmHg)	2mo-40 yrs	83-108	N/A
pO <sub>2</sub> (mmHg)	>40 years	72-104	30-55
Sodium (mmol/L)	No age limit	134-143	134-143
Potassium (mmol/L)	No age limit	3.4-5.0	3.4-5.0
iCA (mmol/L)	No age limit	1.14-1.32	1.14-1.32
Chloride (mmol/L)	No age limit	97-108	97-108
Glucose (mg/dL)	0 – 1 Day	40-60	40-60
	1 Day – 150 yr	60-99	60-99
Lactate (mmol/L)	No age limit	0.5-1.6	0.5-2.2
HCO <sub>3</sub> (mMol/L)	No age limit	21-28	22-28
Total CO <sub>2</sub>	0-150 yrs	22-28 mmol/L	23-29 mmol/L
Hemoglobin		<b>Male</b>	<b>Female</b>
	0-30 days	10.0-18.0	10.0-18.0
	1-6 months	9.5-14.0	9.5-14.0
	6 mos-2 yrs	10.5-13.5	10.5-13.5
	2-6 yrs	11.5-13-.5	11.5-13.5
	6-12 yrs	11.5-15.5	11.5-15.5
	12-18 yrs	13.0-16.0	12.0-16.0
	18-150 yrs	13.5-17.5	12.0-16.0

## Alert Values

Critical/Alert Values are those results demonstrating such variance from normal as to represent a pathophysiological state with potential of being life threatening unless action is taken quickly. These results must be immediately reported to the care provider and be documented in the test record as to who was contacted, the time of contact, the person making contact, and if relevant, that the results were read back.

Test (Arterial)	Low	High
pH	≤7.25	≥7.55
pCO <sub>2</sub> (mmHg)	≤20	≥70
pO <sub>2</sub> (mmHg)	≤50	NA
Sodium (mmol/L)	≤120	≥160
Potassium (mmol/L)	≤2.5	>6.0
Glucose (mg/dL)	<50	>500
Hemoglobin (mg/dL)	<6.6	>18.9
Hematocrit (%)	<20	>60

## Calibration

1. A one-point calibration (approximately 1 ½ minutes) is performed by the GEM 4000:
  - a. After every sample.
  - b. Every 30 minutes if no sample is run.
  - c. After every Process Control Solution A, C, or D.
  - d. Every 3 minutes for a total of 18 minutes following the sample interference detection.

Between one-point calibrations, all sensor outputs are being monitored every 30 seconds and an automatic one-point calibration will be initiated if excessive drift in any channel is detected.

2. A two-point calibration (approximately five minutes to complete) is performed by the GEM 4000:
  - a. At least every four hours.
  - b. Run 30 minutes after a Process Control C Solution calibration.
  - c. Every hour for 4 hours following iQM clot detection.
3. Process Control C Solution calibration is performed by the GEM 4000:
  - a. Once every 24 hours.
4. Process Control Solution D:

This solution is run as an independent check for analytes (not used for calibration purposes). The first Process Control Solution D is run at least twelve hours after cartridge warm-up. iQM Process Control Solution D check starts approximately 3 days after cartridge insertion, since the first five D measurements are used to establish expected Process Control Solution D values.

Calibrations may be interrupted by pressing the “STAT” button. After pressing the “STAT” button the system will perform a short wash cycle. Shortly after running the sample, the system will automatically perform a calibration.

### Quality Control

Once the iQM cartridge is validated with CVP, the quality control process becomes an automatic part of the iQM cartridge operation. Process Control solutions A, B, C, and D incorporated within the iQM cartridge, along with other iQM process checks, continuously monitor operation of the entire testing process including sensors, fluidics, and electronics, thus eliminating the need to run external quality controls.

### QC Data Management

1. Daily:  
Ensure all parameters are functional before each patient case. Contact customer service at 1-800-678-0710 if any parameter is nonfunctional.
2. Monthly:  
Download all QC and Calibration results and review for trends and outliers.
3. As needed:  
If a trend is seen in the QC or patient results, contact customer service at 1-800-678-0710.

### Procedure

1. Cartridge Insertion:
  - a. If the analyzer power is OFF, press the power switch to turn it ON. The system will automatically begin the power-up cycle (this will take approximately 20 minutes)..
  - b. **NOTE:** The analyzer should remain powered on unless it is being transported to another source without an uninterruptible power source (UPS).
  - c. Press Open Door on the touch screen. You will hear an audio prompt, and the door will release and open slightly. Then move the door all the way to the left.
  - d. Unpack the cartridge from its protective wrapper. Remove the plastic cover from the pump winding area. Discard the protective wrapper and plastic cover.  
**NOTE:** The cartridge must be at room temperature (15-25°C).  
**NOTE:** The cartridge may be inserted up to and including the use by date listed on the label.  
**CAUTION:** Only IL supplied cartridges may be used with this analyzer. The use of non-IL supplied cartridges will invalidate the analyzer warranty and will release IL from any responsibility for analyzer performance.
  - e. Position the cartridge with the gray sampling area facing forward. Push the cartridge in until you feel resistance. Please note that approximately one inch of the cartridge will extend beyond the front of the analyzer.

- f. Guide the analyzer door to the right to close it. This will move the cartridge into its final position.
- g. In approximately 20 seconds, the analyzer will inform you that the cartridge is warming up. The clock will count down for the next 40 minutes as the cartridge warms up. During this time, the sensors will hydrate, and the analyzer will perform internal checks and calibration.

## 2. General Operating Instructions:

The GEM Premier 4000 analyzer is designed for intuitive use, and provides clear direction when you are operating the system.

- a. Expel all air from the syringe. Roll the syringe between your palms and gently invert it several times to ensure proper and consistent sample mixing. Push out a few drops of the sample onto a gauze pad to ensure there is no clot in the syringe tip.
- b. Select Normal or Micro sample by pressing the Normal/Micro toggle button on the left. Micro sampling is available only with capillary tubes.
- c. If necessary, press the FetHb Correct button to enable correction for Fetal Hemoglobin.  
**NOTE:** FetHb correction is not necessary for patients older than 2 months.
- d. Select the analytes to be tested by pressing the green Analyte buttons. A check and a dark green tab indicate that the analyte is operational. Panels, if defined on the left, also enable selection of pre-selected analyte combinations.
- e. Select the sample type/container combination using the drop-down menu under *2. Type*, if it is not already selected.
- f. Press **GO!**

**CAUTION:** Use caution when handling potentially infectious materials.

- g. 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 150  $\mu$ L (complete menu) or 95  $\mu$ L (for cartridges without CO-Ox as a part of the menu) to be aspirated but not so far that the sampler touches the bottom of the device.  
**NOTE:** Do not move the syringe up into the black portion of the sampler.
- h. The system will aspirate the sample and emit an audio prompt when aspiration is complete. Remove the container promptly. The probe will retract into the system. Dispose of the remaining sample as you would medical waste.
- i. The system will perform analysis while you enter patient information on the Enter Information Tab using the alphanumeric keypad (the keypad becomes accessible when you press a button requiring data entry), barcode gun, or pre-populated fields imported from the LIS or HIS( if hooked to an LIS system). Required fields are indicated with an asterisk (\*). Sample results cannot be viewed until all required fields have entries made in them.

### 3. View Sample Results:









After all required patient and sample information have been entered, patient results may be viewed. If required field entries are made, and Auto Accept is **not** enabled, the View Results tab will display automatically following 5 minutes of inactivity.

If Auto Accept is enabled, the operator must select the View Results tab to view patient results. The reason for this is that if Auto Accept is enabled, once the View Results tab is displayed, entries on the Enter Information tab cannot be changed except by an operator with a permission level capable of editing patient and sample demographic information.






- **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
- **CO-Oximetry values** – displayed only if one or more CO-Oximetry analytes are selected for measurement
- **Derived values** – calculated using equations applied to one or more measured analytes



**\*\*\*When the patient is coming off bypass, rerun the sample on the ABL 800 in SOR to confirm the original K+ result prior to reporting. Document both K+ results on the correlation form for that patient. \*\*\*\***

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

#### Exception Flags on Results Screen and on Printed Reports

Exception Flag	Exception Flag Description
	Result Incalculable
	Absorbance Error
	Result Corrected for Sulfhemoglobin
	High Turbidity Detected
	Interference Detected

	Micro Clot Detected
	Temporary Sensor Error

#### 4. Cartridge Removal

Removing the cartridge is generally a task that should be performed only when the analyzer indicates that the cartridge needs to be replaced. A supervisor may decide to manually remove a cartridge when there are a few tests left for convenience (for example, in the operating room when a cartridge change in the middle of a case is not practical). GEM Premier 4000 analyzer cartridges cannot be removed and reinserted into the analyzer. Be sure to consult your supervisor before performing this task.

If a cartridge has reached its maximum onboard use-life or test capacity, the cartridge door will automatically open and display a message to the operator to remove the cartridge.

To remove a cartridge prior to its maximum onboard use-life or test capacity, follow the instructions provided below.

**Note:** Removing the cartridge is a simple operation, but one that requires careful consideration to avoid underutilizing a cartridge.

- a. Press the blue **Menu** button in the upper left corner of the screen. Select **Remove Cartridge**. If requested, enter your password.
- b. As a precaution, the system will ask you whether you want to continue. Press **No** to stop the process and return to the Main Sampling screen. Press **Yes** to continue.
- c. Once you press **Yes**, the door will click open slightly. Move the door to the left, grasp the cartridge, and pull it gently toward you. Dispose of cartridge in an appropriate biohazard container. The system will now be inactive until you reinsert a new cartridge.

**NOTE:** Cartridges cannot be reused once they have been removed.

**CAUTION:** The cartridge contains a waste bag that contains blood, a potential biohazard. Use universal precautions as designated by your facility when handling a used cartridge. Dispose of it in an appropriate biohazard waste container.

### Instrument Maintenance

#### 1. *Installing the Printer Paper*

To install the thermal printer paper in the paper area on top of the system:

- a. Press the tab at the top of the system to release the door.
- b. Open the door and extend paper guide if desired.
- c. Place the roll of paper in the compartment so the paper unfurls from the bottom.
- d. Press the door firmly closed.

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

## 2. *Replacing the Fuse*

There is one fuse that may be replaced by the operator. The fuse is located directly below the power connector and is behind a black cover. The fuse is a 3 Amp, 250 Volt, SLO-BLO fuse, and measures 5 mm x 20 mm. 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.

To replace the fuse:

1. Disconnect the instrument from AC power [AC outlet or uninterruptible power supply (UPS)].
2. Remove the black cover using the tabs.
3. Remove the old fuse.
4. Dispose of the old fuse in a container suitable for glass.

**CAUTION:** Dispose of the fuse using a container that is approved for glass disposal.

5. Insert the new fuse.
6. Replace the cover.
7. Reconnect the power cord.
8. Connect the instrument to a properly grounded and wired AC outlet (AC outlet or UPS).
9. Turn on the analyzer by briefly pressing the power button on the left side of the back of the analyzer.
10. The GEM Premier 4000 analyzer starts its power-up cycle and then displays the Insert Cartridge screen.
11. Insert a new cartridge.

## 3. Instrument Cleaning

### *Routine Cleaning*

The following paragraphs describe how to clean and disinfect the instrument as necessary.

Recommended Supplies:

- a. Disposable gloves
- b. Laboratory coat or jacket
- c. Eye protection
- d. Soft cleaning cloths
- e. 10% chlorine bleach solution
- f. Biohazard waste bags
- g. Non-abrasive, mild cleaning solution

**CAUTION:** The GEM Premier 4000 analyzer processes patient samples that may be highly infectious. When cleaning the instrument use proper technique and care to avoid contaminating yourself or others.

**CAUTION:** Put on gloves, eye protection, and a laboratory coat or jacket before handling the instrument.

**CAUTION:** Prepare a biohazard waste bag for waste disposal.

### Cleaning the Touch Screen

You do not need to disconnect the GEM Premier 4000 analyzer from AC power when cleaning the touch screen. However, be careful to prevent water or cleaning solution from entering the unit enclosure.

To clean the touch screen:

- a. Dampen a soft cleaning cloth with water or mild cleaning solution.
- b. Be sure that the cleaning cloth is only moist, not dripping wet.
- c. Carefully wipe the face of the touch screen free of fingerprints and other smudges.

**CAUTION:** Use only a soft cloth moistened with water or a mild cleaning solution. Do not use an abrasive cleaner or any bleach mixture to clean the touch screen, as this will damage the screen.

**CAUTION:** Make sure the cleaning cloth is only moist, not dripping wet. Avoid letting water or cleaning solution enter the unit enclosure.

### To Clean the Instrument:

- a. Remove the cartridge from the analyzer as described in Section XI: Removing the Cartridge. Discard the cartridge in a biohazard container. Once the cartridge has been removed, it cannot be reinserted.
- b. Shut down the instrument as described in Section XII: Shutting Down the Analyzer.
- c. Disconnect the instrument from AC power supply [AC outlet or uninterruptible power supply (UPS)].
- d. Remove any blood or dust from the outer surface of the case using a clean, soft cloth moistened with the 10% chlorine bleach solution.
- e. Inspect the bay area into which the GEM Premier 4000 PAK cartridge is inserted, and clean the polyester laminate protective sheet on the bottom of the bay as needed.
- f. (Optional) With the AC power cord unplugged from the power source, wipe the AC power cord completely from end to end using a soft cloth moistened with cleaning solution.
- g. If necessary, remove the instrument from the work surface, and clean the work surface using a cloth or paper towel moistened with the 10% chlorine bleach solution.
- h. Place any used cloth or paper towel in an appropriate biohazard waste bag. Seal the bag and dispose of it in accordance your institution's procedures for disposing of materials contaminated with biohazard material.
- i. Reconnect the power cord.

- j. If you disconnected the power cord, connect the instrument to a properly grounded and wired AC outlet (AC outlet or UPS).

**CAUTION:** Check to make sure the plug and cord are dry before engaging the plug.

- k. Turn on the analyzer by briefly pressing the power button on the left side of the back of the analyzer.
- l. The GEM Premier 4000 analyzer starts its power-up cycle and then displays the Insert Cartridge screen.
- m. Insert a new cartridge.

### Calibration Verification and Correlations

1. Calibration verification is performed by IL every 6 months to validate the AMR.
2. Patient correlations are performed every 6 months.

### Reagents

#### 1. Measurement Cartridge:

- a. Shelf-Life Expiration (15-25°C): The cartridge may be inserted up to and including the use-by (expiration) date shown on the packaging. The system will not accept an expired cartridge.
- b. On-board Expiration: The GEM Premier 4000 PAK cartridge must be replaced when the maximum number of tests are run, or when cartridge use-life is reached (30 days), whichever comes first. The operator is notified when the cartridge must be replaced.

#### 2. CVP Control:

GEM CVP 1 and 2 with CO-Ox: Unopened ampoules are stable until the expiration date shown on the label when stored at 2-8°C, or up to 8 months at room temperature (15-25°C), providing storage does not exceed the expiration date. DO NOT FREEZE.

#### 3. PVP Calibrator:

IL PVP™ unopened ampoules are stable when stored at 15-25°C for up to 3 months, or at 2-8°C until the expiration date shown on the label. DO NOT FREEZE.

## References

1. Broughton, J.O., Jr.: Understanding Blood Gases, Article #456.
2. IL GEM 4000 Operator's Manual, January 2008.
3. Tietz, Norbert, W. "Fundamentals of Clinical Chemistry," WB Saunders Company, Philadelphia, 2001, pp 505-517.

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