GEM Premier 4000
Blood Gas Analyzer

❖ READ POLICY PRIOR TO STARTING TUTORIAL
Qualified Personnel

- Testing personnel are required to take the Initial Orientation and Training, 6 Methods of Competency Exam, and a second Competency Exam within the first year of certification for this POCT.

- Competency exams are then required annually thereafter.

- Clia ‘88 requires staff to have a high school diploma or a college degree in one of these listed sciences to perform this moderately complex test. Please submit a copy of your HS Diploma or College Degree in Chemical Science, Biological Science, Physical Science (or Nursing) to POCT Services.
Operator Barcodes

- Upon completion of the Initial Orientation and Training, 6 Methods of Competency, and Written Exam, staff will be issued a barcode ID to be able to use the GEM Premier 4000.

- This barcode is embedded with unique identifiers specific to each staff member.

- **NEVER** share your Barcode ID!
Before Testing a Patient

 Orient yourself to your working area:

- Locate the analyzer and cartridge.
- Locate testing supplies:
  - Ampoule breaker
  - Barcode scanner
  - GEM CVP
  - Printer paper
  - Operator manual
Using the GEM Premier 4000 is considered Moderate in complexity by the FDA.

**Purpose:** used to analyze whole blood samples and provide fast, accurate quantitative measurements of whole blood pH, pCO₂, pO₂, Na⁺, K⁺, ICA⁺⁺, Glucose, Lactate, Hematocrit, and CO-Oximetry.
The GEM Premier 4000 Consists of:

- GEM Premier 4000 Analyzer
- Disposable Cartridge (PAK)
  - Store at 15-25°C.
  - Stable at room temperature until the expiration date listed on the package.
  - Once placed in the instrument, the cartridge is stable for 30 days or when the maximum number of test is used.
- Ampoule Breaker
- Barcode Scanner
- Operator Manual
- Printer Paper
Quality Control

- GEM CVP 1 & 2 both with CO-Ox
  - Used for all analytes except hematocrit.
  - Unopened ampules are stable until the expiration date on the label when stored at 2-8°C. If stored at room temperature (15-25°C) stability is up to 8 months from the opening date, up to but not past the expiration date on the label.
  - DO NOT FREEZE.
Quality Control

- **GEM CVP 3 & 4**
  - Used for hematocrit.
  - Unopened ampules are stable until the expiration date on the label when stored at room temperature (15-25°C).
  - **DO NOT FREEZE.**
Quality Control

- **Intelligent Quality Control Management (iQM)**
  - Monitors the performance of the system in real-time.
  - Identifies the potential failure patterns.
  - Automatically performs corrective actions.
  - Automatically documents the failure and the corrective action taken.
Quality Control

Calibration Valuation Product (CVP)

- Intended for the verification of the integrity of the new cartridge every time it is replaced. All levels of CVP must pass for each analyte before the instrument can report patient results.

Patient Comparisons

- Patient samples are compared against the reference instrument (GEM1) in the Clinical Lab on or before the 15th of the month.
- Each department should bring and hand a patient sample in Hematology. This is done once a month by Super Users.
If the analyzer is OFF, press the power switch to turn it ON.

- **NOTE:** the analyzer should remain powered on unless it is being transported to another source without an uninterruptible power source (UPS).

Press “**Open Door**” on the touch screen and manually move the door all the way to the left.
Cartridge Insertion and Warm-Up

- Unpack the cartridge from its protective wrapper.
- Remove the plastic cover from the pump winding area.
- Check the inside of the protective wrapper to be sure that it is dry.
  - **CAUTION:** Do not use expired or leaking cartridges. If there is any moisture inside the foil bag, DO NOT USE. The cartridge must be at room temperature (15-25°C).
Cartridge Insertion and Warm-Up

- Position the cartridge with the gray sampling area facing forward.
- Push the cartridge in until you feel resistance.
- Guide the analyzer door to the right to close it.
- Cartridge warm-up requires 40 minutes.
CVP Sampling

- It is necessary to perform CVP testing only when inserting a new cartridge.
- Patient results for an analyte cannot be reported until all levels of CVP pass for that analyte.
- Complete testing will require approximately 12 minutes. During this time, the analyzer will be unavailable for sampling.
The analyzer will inform you that CVP testing is due via the Status Bar along the top of the Start New Sample Tab, which will be highlighted in yellow with the words, “CVP Due” prominently displayed.
Press GO! To begin sampling.

Select an ampule from the choices on the screen.
CVP Sampling

- Ensure that the lot number and level match what is chosen on screen.
- Immediately prior to use, hold the ampules by the top, above the break line, and shake vigorously for approximately 10 seconds.
CVP Sampling

- Press OK to begin testing.
- Gently tap the ampules so the liquid settles back to the bottom.
- Carefully snap open the ampules using the ampule breaker.
  - **NOTE**: aspirate samples immediately after opening.
- The sample probe will emerge from the gray sampling area in front of the analyzer. Hold the ampule so the end of the sample probe does not touch the bottom.
CVP Sampling

- Press OK to begin aspiration. Remove the ampules immediately upon hearing the audio prompt alerting the operator when the instrument has aspirated enough of the CVP sampling solution.

- Analyte buttons will continue to display Run CVP until all CVP testing required for that analyte is complete.
Once testing is complete, all results within range will be indicated in GREEN text with a white background; out-of-range results will be indicated in WHITE text on a red background.

If all results are within range, press Accept.
CVP Sampling

- If the results are out-of-range, repeat CVP using a new vial. The operator is then prompted to run iQM process prior to repeating the analysis with a new vial.

- To initiate the iQM process:
  - Select Menu> Diagnostics> Run iQM Process

- Run a new vial after completion of the iQM process
If the analytes that failed the acceptable range the first time, fail again, DO NOT USE THE CARTRIDGE.

If the original analytes that failed, pass, but analytes that passed the first time, fail, run a third new vial.

If all results are within range, press Accept.
CVP Sampling

- If you are not able to use a cartridge, contact **IL Technical Support at 1.800.678.0710**.

- When the CVP testing is complete and all analytes are within range, you will see the Start New Sample tab. When all the analyte selection buttons show GREEN and the upper status bar indicates READY, patient sampling can begin.
Patient Sampling

- Universal precautions should be observed through all phases of the testing procedure.
- Use syringes in ABG kit or 1cc tuberculin syringe only. **DO NOT USE SYRINGES WITH NEEDLES ATTACHED.**
- Explain procedure to patient and/or family.
Patient Sampling

- Stability and Storage of Specimens
  - Samples have different storage condition requirements, depending on the container type:
    - **Plastic syringe samples**
      - They should be kept at room temperature as long as the blood is analyzed in 15 minutes or less. Samples should be analyzed immediately.
    - **Capillary Samples**
      - Analyze within 5 minutes. If delay is greater than 5 minutes the sample should be recollected.
    - **Minimum Volume**: 150 μL
Patient Sampling

Stability and Storage of Specimens

- Criteria for unacceptable specimens – REDRAW if:
  - Any degree of clotting
  - Insufficient quantity
  - Incorrectly drawn specimens
  - Incorrectly handled specimens prior to sampling
  - Incorrect anticoagulant
Patient Sampling

- Samples must be labeled with the patient’s identification (at least 2 patient identifiers are needed – full name and medical record number or date of birth).

- Types of patient samples accepted by the GEM premier 4000 includes: Arterial, Venous, Capillary, and Cord (both Cord Arterial and Cord Venous).
Patient Sampling

- Syringe and Capillary Samples
  - Select a pre-defined analyte combination panel
    - Micro sampling (65μL) is available only with capillary tubes.
  - A check and a dark green tab indicate that the analyte is operational

Menu Options for NICU

Menu Options for OR/ED

Menu Options for ICU
Syringe and Capillary Samples

- Select the sample type by using the drop-down menu under “Type”. Choose if the sample is arterial, venous, capillary, cord or CVP.
- Press “GO”.
- The next screen appears which requires the operator to “enter operator password”. Scan your barcode and press enter.
  - Do not share your barcode with anyone. Sharing barcode IDs is prohibited.
Patient Sampling

- For syringe samples, expel all air and mix the sample thoroughly by inverting at least 3 to 5 times and roll between palms for at least 15 seconds.
- Push out a few drops of the sample onto a gauze pad to ensure there is no clot on the syringe.
Patient Sampling

- For syringe or ampule sampling:
  - Present the sample 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 sample touches the bottom of the device.
  - The GEM prompts “Present Sample Now”. Press OK to begin aspiration.
Patient Sampling

- For capillary tube sampling:
  - the luer tip will present just below the home area (the sampler will not extend).
  - Tilt the tube slightly until the blood is flush with the end of the capillary tube. Place one end of the capillary tube in the luer tip.
  - If there is blood or debris on the outside of the capillary tube, wipe the end prior to placing it in the sampler.
  - Do not use excessive force. Hold the exposed end of the tube.
Patient Sampling

- The GEM prompts, “**Present Sample Now**”. Press OK to begin aspiration.
  - **NOTE**: You must have the sample in place before pressing OK or the GEM will aspirate air and results will be erroneous.
- The system will aspirate the sample and display a message “**Aspirating sample**”.
- Immediately remove the sample when you hear the “**beep-beep**” and “**Remove Sample Now**” is displayed on screen.
Patient Sampling

- The system will perform analysis.
- On the next screen enter the Medical Record Number (MRN) manually.
- Patient’s information will appear. Verify the patient’s information. MRN, Patient’s Full Name and Date of Birth should match the label sticker on the specimen.
Patient Sampling

- Comments can be entered on the Enter Information Screen. Comments may be free-text entries of selected from pre-defined entries.

- Wait until results appear on the screen. PRESS "ACCEPT" to release the sample results to the permanent record.

  DO NOT PRESS "SEND"

- Attach the printed tape on the GEM 4000 POCT Results sheet. Place this results sheet in the patient’s medical chart.
◊ **DO NOT PRESS SEND!**

- Hitting SEND button will double post the results in SunQuest, LCR, EDIS or any hospital information systems. This requires a large set of time expenditure to correct and credit.
- When double posting occurs, the patient is charged twice.
Patient Sampling – CORD Samples (NICU ONLY!)

- Select the “CBG Panel”
- Select the “CORD” sample type by using the drop-down menu under “Type”
- Press “GO”.
- Follow same procedures as previously shown.
Patient Sampling

Patient Sampling – **CORD Samples (NICU ONLY!)**

- Comments **MUST BE ENTERED** to SPECIFY TYPE of CORD sample.
- Select “Comments” tab. Select predefined comments. Choose either “CORD Arterial” or “CORD Venous” and press “ADD”.

![Image of patient sampling interface](image-url)
To view sample results, select the **View Results** tab.

- Results outside Reference Range are displayed in black text on a yellow background.
- Results outside the Critical Values Range are displayed in white text on a red background.
- Results outside the Reportable Range are displayed.
Search Patient Results
- Select **Search Results** from the blue drop down Menu.
- Scan your barcode to access this feature.
Search Patient Results

- Enter search criteria in the Search Criteria area.
- Enter Patient ID / MRN.
- Date and time frame criteria are required for all searches.
View Results

- Search Patient Results
  - Press the View button to view results.
Cartridge Removal

- The GEM Premier 4000 automatically notifies operators when it is time to remove the cartridge, i.e., when sample capacity or end of the cartridge’s 30-day on-board lifespan has been reached.

- In each case the door will automatically open and display a message to the operator to “REMOVE CARTRIDGE”.

- Cartridges may be removed prior to maximum onboard use-life or test capacity.

- Examples are leakage or when the sensor is permanently disabled and its functionality cannot be recovered.

- Notify a Unit Supervisor or Manager before changing the cartridge. Tech support and Instrumentation Laboratory may need to be notified for the cartridge error.
Cartridge Removal

- Select the blue Menu button.
- Press Remove cartridge from the drop down tab.
- Enter your password.
Cartridge Removal

☐ The system will ask if you want to continue.

☐ Press No to stop and return to the Start New Sample tab or press Yes to continue.

☐ 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 the cartridge in a biohazard container.
Once the analyzer is shut down, **power must be restored within 20 minutes or the cartridge will have to be removed and thrown away.**

- Press the blue Menu button in the upper left while on the Start New Sample tab. Select “Shut Down” from the pull down menu.

- Press “Yes” to continue to shut down.
Cleaning the Analyzer

- Dampen a soft cleaning cloth with water or mild cleaning solution.
- Carefully wipe the face of the touch screen free of fingerprints and other smudges.
- Remove any blood or dust from the outer surface of the instrument case using a clean, soft cloth moistened with 10% chlorine bleach.
Installing Printer Paper

- Press the tab at the top of the system to release the door.
- Open the door.
- Place the roll of paper in the compartment so the paper unfurls from the bottom.
- Press the door firmly closed.
Ampule Breaker Disposal

- Dispose of filled ampule breakers in a suitable biohazard container.
Analyzer Repair

- Refer to the GEM 4000 Policy for troubleshooting guide.
- If GEM Premier 4000 analyzer is broken or not working, contact Point of Care Testing Services first before attempting to send the analyzer to Instrumentation Laboratory.
- Do not request a loaner without POCT Services approval.
Limitations and Interferences

- Please refer to the Policy and Procedures for information about limitations and interferences for the GEM Premier 4000 Blood Gas Analyzer.
For Further Question or Information Contact POCT Services

SFGH-POCT.org