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48667.263 GEM® PREMIER 4000: BLOOD GASES WITH WHOLE BLOOD IONIZED CALCIUM, SODIUM, POTASSIUM, GLUCOSE, LACTATE, HEMATOCRIT, AND CO-OXIMETRY

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Approval and Periodic Review Signatures

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Approval	Lab Director	3/11/2021	9.0	Barbara Haller, MD, PhD Barbara Haller	
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Prior History

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Linked Documents

- 48667.264 GEM PREMIER 4000 Initial Orientation & Training
- 48667.265 GEM Premier 4000 - 6 Methods of Competency Record
- 48667.338 GEM PREMIER 4000 Problem Solving Test for Respiratory Care Services
- 48667.340 GEM Premier 4000 Problem Solving Test

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GEM® PREMIER 4000
BLOOD GASES WITH WHOLE BLOOD IONIZED CALCIUM, SODIUM, POTASSIUM, GLUCOSE, LACTATE, HEMATOCRIT, AND CO-OXIMETRY

PURPOSE

The GEM Premier 4000 analyzer with Intelligent Quality Management (iQM) is an advanced, critical care system used by health care professionals to analyze whole blood samples in point of care clinical settings. It provides fast accurate, quantitative measurements of whole blood pH, pCO_2, pO_2, Na^+, K^+, ICA^{++}, Glucose, Lactate, Hematocrit, and CO-Oximetry. These parameters, along with the derived parameters, aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen delivery capacity.

PRINCIPLE

The GEM Premier 4000 analyzer uses potentiometric sensors to measure pH, pCO_2, Na^+, K^+, and ICA, and amperometric sensors to measure pO_2, glucose, and lactate concentrations. Blood conductivity is the method used to measure hematocrit. CO-Oximetry measurements involve chemically lysing the whole blood sample and then utilizing a broad spectrum spectrometer to evaluate the sample at a variety of wavelengths. Automatic one-point, two point and low oxygen calibrations, occur at fixed intervals and help to establish continued instrument accuracy.

GEM PREMIER 4000 ANALYZER

A. The GEM Premier 4000 is comprised of two components**: *the analyzer*** and a ***disposable multi-use cartridge (PAK)***.

B. The ***analyzer*** has the internal logic and processing power necessary to perform analysis. It has a unique color touch screen and a simple set of menus and buttons for user interaction. The instrument guides operators through the sampling process with simple, clear messages and prompts.

C. The ***disposable cartridge PAK*** can measure Blood Gas/Electrolytes/Glucose/Lactate/Hematocrit and CO-Oximetry. All required components for sample analysis are contained in the cartridge, including reagents, sensors, optical cell for CO-Oximetry, sampler, pump tubing, distribution valve, and waste container; enable analysis of 75 to 600 samples.

    a. The PAK is a totally closed analytical system.
    b. The peristaltic pump moves the various fluids (Sample, Process Control Solutions, Reference Electrode Solution and Lysing Solution) into the sensor card and the optical cell and eventually to the waste container. The sensor card and the optical cell reside in two thermal blocks, which maintain the ***temperature at 37°C***, and provide an electrical interface to the sensors and an optical interface to the optical cell.
    c. The sensor card contains all of the sensors in a gas tight chamber. The sensors are all calibrated and monitored with four ***Process Control Solutions (PCS) – A, B, C, and D***.

These solutions are sealed in gas impermeable bags with no headspace, allowing their use over a wide range of ambient temperatures and atmospheric pressures. ***PCS B*** is also used for rinse processes. ***PCS A and PCS B*** are used to set the values of all parameters except for hematocrit and oxygen. *Hematocrit* uses ***PCS B***, and *oxygen* utilizes ***PCS B and PCS C.*** *CO-Oximetry* uses ***PCS B***, a colorless solution, which provides a reference for zero concentration. The ***PCS A and D*** contain well defined concentrations of dyes and their spectral data are used to evaluate, check and qualify the *CO-Oximetry* performance.

D. **GEM 4000 Tests**

a. **pH and pCO_2**, along with their derived parameters Base Excess, HCO_3^-, and TCO_2, define acid-base status.
b. **Arterial pO_2** indicates adequacy of oxygen exchange.
c. **Sodium** (NA) is the major cation of extracellular fluid. It is critical for maintenance of water distribution and osmotic pressure in body tissues.
d. **Potassium** (K) is the major intracellular cation. It is critical for maintaining proper neuromuscular excitability, including respiratory and myocardial function.
e. **Ionized Calcium** (ICA) is critical for functions including hemostasis.
f. **Hematocrit** (HCT) indicates the red cell fraction of the blood, a vital component in determining its oxygen carrying capacity.
g. **Glucose** is the primary energy source, and its blood level is maintained within a fairly narrow range. The most common disorder affecting glucose levels is due to diabetes mellitus, which can cause hyperglycemia (high blood glucose) and hypoglycemia (low blood glucose).
h. **Lactate** is an intermediary product of carbohydrate metabolism and is derived mainly from muscle cells and erythrocytes. Lactate clearance is utilized as a prognostic marker of global tissue hypoxia in circulatory shock and as a diagnostic marker for sepsis. Liver malfunction may influence lactate levels by affecting lactate production or clearance.
i. **CO-Oximetry** evaluates the ability of the blood to carry oxygen by measuring total hemoglobin and determining the percentage of non-functional hemoglobin species.

E. **User-Entered Parameters**

a. **Actual Patient Temperature** (Temp). The default temperature is 37°C. This temperature will be used to calculate pH, pCO_2, and pO_2 unless a different entry is made by the operator. The measured and corrected temperature results, if applicable, are displayed on the View Results Screen and on the Printout.
b. **Barometric Pressure** (BP). The default Barometric Pressure is 760 mmHg. The GEM Premier 4000 Analyzer does not need daily entry of BP for sample analysis, as the solutions are sealed in gas impermeable bags with no headspace.

TESTING PERSONNEL

A. Licensed, qualified and approved Respiratory Therapists, Anesthesia Providers and Registered Nurses
B. Testing personnel are required to take the initial training and competency assessment. Competency assessment (using 6 methods) must be completed after initial training and before technical duties are performed, six months after completion of initial training and annually thereafter.

C. Upon successful completion of the initial training and competency assessment, staff will be issued a barcode operator ID to be able to use the GEM Premier 4000 analyzer. This operator barcode is embedded with unique identifiers specific to each staff member.
IMPORTANT: ***NEVER*** *share your Barcode ID!*

EQUIPMENT and MATERIALS

- IL GEM® Premier 4000 Analyzer
- Cartridge (PAK)
- Ampoule Breaker
- Barcode Scanner
- CVP 1 with CO-Ox
- CVP 2 with CO-Ox
- CVP 3 Hematocrit
- CVP 4 Hematocrit
- GEM System Evaluator 2 (GSE 2)
- RNA Medical CO-ox Linearity Controls
- Linearity (PVP) Solutions
- Printer Paper
- Operator's Guide
- Reference Guide

GENERAL SAFETY INSTRUCTIONS

- Please read the Operating Manual carefully to become acquainted with the analyzer. The manual contains important information for the safe and appropriate installation, operation, transport, storage and maintenance of the GEM® Premier 4000.

SPECIMEN / SAMPLE

A. Universal Precautions should be observed through all phases of the testing procedure.

B. Lyophilized lithium heparin is the anticoagulant of choice for analyzing whole blood specimens on the GEM Premier 4000 analyzer. **NOTE: Specimen collection tubes are NOT a suitable substitution for ARTERIAL Blood Gas analysis or to measure *p*O_2, and Cooximetry (oxygen content or COHb**).

C. When blood gas analysis is combined with electrolyte analysis, syringes should provide a final heparin concentration of no more than approximately 20 IU/ml of blood (per the CLSI guideline).

D. Collection devices should be filled to required volume specifications to ensure proper heparin concentrations. Sample devices that are under filled have a higher concentration of heparin which can interfere with certain assays, such as Sodium and Ionized Calcium.

E. Capillary devices are manufactured to provide a relatively high final heparin concentration due to high frequency of clotting events relative to pediatric sample type. Proper filling of capillary devices with required sample volume eliminates heparin interference due to high heparin concentration.

F. Immediately remove any air bubbles from the syringe, make sure the cap is secured, and mix thoroughly prior to analysis.

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

H. Types of patient samples accepted by the GEM Premier 4000 includes: **Arterial, Venous, Capillary, and Cord (both Cord Arterial and Cord Venous)**.

   a. **Arterial Samples** – the ideal collection for arterial blood sampling is a 1 to 3 mL self-filling plastic, disposable syringe, pre-filled with an appropriate concentration of lithium heparin. **Arterial samples are the preferred source to evaluate *pH*, pCO_2, and pO_2 / blood gas and carboxyhemoglobin (COHb) analysis**. Arterial line collection requires that an appropriate volume be withdrawn initially to ensure the line contains only uncontaminated arterial blood, prior to actual sample collection.
   b. **Capillary Samples** – the ideal collection device for capillary samples is a non-glass capillary tube in order to prevent the possible biohazard that a glass tube may present if it should break. The capillary tube must be coated with lyophilized lithium heparin.
   c. **Venous Samples** – can be used for analyzing pH, pCO_2, electrolytes, glucose, lactate, hematocrit and co-oximetry. **However, specimen collection tubes are NOT a suitable substitution for ARTERIAL Blood Gas analysis or to measure pO_2, and Cooximetry (oxygen content or COHb**).

I. Types of sampling devices accepted by the GEM Premier 4000 includes: capillary tube (NICU only), syringe, specimen collection tubes, CVP, GSE, or PVP Ampules, and Proficiency Test samples (CAP specimen).

J. **Stability and Storage of Specimen** – Samples have different storage condition requirements, depending on the container type:

   a. **Plastic Syringe and Venous Lithium Heparinized Samples**
      1. It is recommended that plastic syringes and venous lithium heparinized samples not be iced. They should be kept at room temperature as long as the blood is analyzed in **30 minutes or less**. Due to metabolic changes in whole blood, samples should be analyzed immediately.
      2. Samples with **more than 30 minutes delay** prior to testing should be recollected**.**
   b. **Capillary Samples**
      1. It should be analyzed **within 5 minutes**. If delay is **greater than 5 minutes,** sample should be recollected**.**
   c. **Minimum Fill Volumes**:
      1. Collection devices for patient specimens should be filled to the required volume specifications to ensure proper heparin concentration. Under filled sample devices have a higher final concentration of heparin which can interfere with certain assays, such as sodium and ionized calcium.
      2. Syringe collection devices should be filled to ensure a final heparin concentration of 20-25 IU/mL of whole blood. Capillary collection devices are manufactured to provide a relatively high final heparin concentration due to

high frequency of clotting events relative to pediatric sample type. Proper filling of capillary devices eliminates heparin interference due to high heparin concentration.

3. Minimum Sampling Volume:
   - 150 µL for pH, pCO2, pO2, Na+, K+, Ca2+, Glu, Lac, Hct, CO-oximetry
   - 100 µL for tHb, O2Hb, COHb, MetHb, sO2
   - 65 µL for capillary samples only

K. **Criteria for Unacceptable Specimen – Redraw the patient if:**

a. Any degree of clotting
b. Specimens with insufficient quantity
c. Incorrectly drawn specimens
d. Incorrectly handled specimens prior to sampling
e. Incorrect anticoagulant

REAGENTS / SUPPLIES AND STORAGE & STABILITY

NOTE: When temperature or relative humidity is outside of defined tolerance limits, corrective actions must be taken and may include, but is not limited to, closing the refrigerator door securely and taking another reading after two hours, submitting a work order to Facilities, and moving contents to another acceptable storage location while problem is being addressed. Always notify unit supervisor/POCT and document all corrective actions taken.

A. **GEM Premier 4000 Analyzer**

a. **Storage:** May be stored at a temperature of -10 to 38°C with a relative humidity of 5 to 95%, non-condensing.

B. **GEM Premier 4000 PAK Cartridge with iQM**

a. No preparation needed.
b. **Storage:** Store at 15 to 25°C.
c. **Shelf-Life Expiration**: Stable at room temperature until the expiration date listed on the package.
d. **On-board Expiration**: Once placed on the instrument the cartridge is stable for 30 days or when the maximum number of tests is used.

C. **GEM Calibration Valuation Product (CVP)**

a. **CVP Level 1 (low) with CO-Ox and CVP Level 2 (high) with CO-Ox**
   1. Available in packs of 10 x 1.8 mL, single level ampules.
   2. Used for all analytes except hematocrit.
   3. **Storage and Stability**: Unopened ampules are stable until the expiration date shown on the label when stored at 2-8°C. If stored at room temperature (15-25°C) stability is up to **8 months** but not past the expiration date printed on the label. DO NOT FREEZE.
   4. **Do not analyze CVP1 or CVP2 for the sole purpose of assessing competency as this material can oxidize the sensors in the cartridge. However, CVP 1 or CVP2**

may be used for assessing competency if it is also being used for qualifying a new cartridge as well.

b. **CVP 3 and CVP 4**
    1. Available in packs of 10 x 1.8 mL, single level ampules.
    2. Used for hematocrit only (ED, OR & NICU only).
    3. **Storage and Stability:** Unopened ampules are stable until the expiration date shown on the label when stored at room temperature (15-25°C). DO NOT FREEZE.

c. Each time the operator inserts a new cartridge, the GEM Premier 4000 Analyzer will prompt him/her to run CVP testing. This process ensures the integrity of the new cartridge allows for overall system analysis and provides a baseline for analytical operation.

NOTE: *To determine how soon you will need a new cartridge, consult the **TEST/DAYS** button on the upper right of the Status Bar. This information enables the operator to schedule cartridge changes at a convenient time.* ***Patient results for an analyte cannot be reported until all levels of CVP pass for the analyte.***

WARNING: *CVP with CO-Ox solutions are sensitive to ambient temperature variations and room air contamination. Ampules equilibrated at temperatures cooler than 22 +/- 1°C will demonstrate pO_2 values HIGHER than those stated on the insert by approximately one percent per °C. Likewise, ampules equilibrated at temperatures above 22 +/- 1°C will demonstrate pO_2 values LOWER than those stated by approximately one percent per °C. There is no significant temperature effect on pH and pCO_2 within the normal range of room temperature.*

d. **LIMITATIONS:** The values obtained from CVP with CO-Ox solutions are sensitive to ambient temperature variations and room air contamination. Use the solution in each ampule immediately upon opening.

D. **GEM System Evaluator (GSE)**

a. **GEM System Evaluator Level 2, (mid/normal)**
    1. Available in packs of 10 x 1.8 mL, single level ampules.
    2. Used for all analytes except hematocrit
    3. **Storage and Stability:** Unopened ampules are stable until the expiration date shown on the label when stored at 2-8°C. If stored at room temperature (15-25°C) stability is up to **4 months** but not past the expiration date printed on the label. DO NOT FREEZE.
    4. This product may be used for troubleshooting and competency assessment. It will also be run at least twice yearly or once every six months according to the IQCP established guidelines.
    5. CVP Warning and Limitations also apply (see above).

E. **RNA Medical CVC 223 CO-Oximeter Calibration Verification Controls**
a. Available in kits containing four ampules of each level (5 levels), 1.2 mL each.
b. Used for Linearity Studies twice yearly or once every 6 months for testing system performance of total hemoglobin, oxyhemoglobin, and carboxyhemoglobin across the analytical reportable range.

c. **Storage and Stability:** Unopened ampules are stable until the expiration date shown on the label when stored at 2-8°C. Avoid exposure to freezing and temperatures greater than 8 °C.

F. **IL Performance Verification Product (PVP)**

a. Used for Linearity Studies twice yearly or once every 6 months.
b. Used for testing system performance of pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Glucose, Lactate, Hematocrit and Total Hemoglobin across the analytical reportable range.
c. **IL critPVP – 4 ampules x 4 x 2.5 mL**
    1. Used for testing system performance of Hematocrit across the analytical reportable range.
    2. **Storage and Stability:** IL critPVP ampules are stable when stored at 15-25°C until the expiration date shown on the label. DO NOT FREEZE.
    3. Use Sample Type “critPVP.”
d. **IL PVP – 4 ampules x 5 x 2.5 mL**
    1. Used for testing system performance of pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Glucose, Lactate, and Total Hemoglobin across the analytical reportable range.
    2. **Storage and Stability:** PVP ampules levels 1 through 5 are stable for 3 months when stored at 15-25°C or until the expiration date shown on the label when stored at 2-8°C. DO NOT FREEZE.
    3. Use Sample Type “PVP.”

    WARNING: *IL PVP solutions are sensitive to ambient temperature variations. Ampules equilibrated at temperatures cooler than 21°C will demonstrate pO_2 values HIGHER than those stated on the insert by approximately one percent per °C. Likewise, ampules equilibrated at temperatures above 23°C will demonstrate pO_2 values LOWER than those stated by approximately one percent per °C. There is no significant temperature effect on pH and pCO_2 within the normal range of room temperature.*

e. **LIMITATIONS:** The values obtained from IL PVP solutions are sensitive to ambient temperature variations and room air contamination. Use the solution in each ampule immediately upon opening.

QUALITY CONTROL

A. **Intelligent Quality Control Management (iQM)**

a. Intelligent Quality Management (iQM) is an automated Quality Assurance system for the GEM Premier 4000 analyzer that replaces the use of External Quality Control (QC). iQM operation in the GEM Premier 4000 analyzer uses the internal Process Control Solutions, external CVP (Calibration Valuation Product) with CO-Ox, CVP Hematocrit and Failure Pattern Recognition (FPR) software to detect and verify cartridge malfunctions and to perform appropriate corrective actions.
b. The iQM operation can be summarized as follows:
    1. Monitors the performance of the system in real-time.
    2. Identifies the potential failure patterns
    3. Automatically performs corrective actions
    4. Automatically documents the failure and corrective action taken.

c. Upon the PAK / cartridge is inserted into the analyzer, the GEM Premier 4000 system reads and records all factory-assigned cartridge information, including lot and serial number, expiration date and Process Control Solution values.
d. External CVP Level 1 & 2, and CVP Level 3 & 4 (for hematocrit test only) solutions must be manually run by the operator to complete the internal calibration process and final accuracy assessment of the iQM cartridge calibration.
e. The reported values for CVP Level 1, 2, 3, and 4 must meet IL's specifications before the iQM cartridge can be used for patient testing. If any analyte fails to fall into the designated ranges, **do not use** that analyte for patient testing. If CVP fails, repeat CVP using a new ampule/vial. A GSE Level 2 solution may be run for troubleshooting purposes or competency assessment. Refer to GSE instructions above.
f. Once the cartridge warm-up and CVP Level 1 & 2, and CVP Level 3 & 4 (for hematocrit test only) are completed, the iQM monitors the status of the system during the cartridge use-life. Upon detecting a problem, the analyzer automatically performs corrective actions that include:
    1. Performing special rinse cycle in case of detecting micro-clots and verifying the cartridge function afterwards.
    2. Permanently disabling failed sensor if its functionality cannot be recovered.
    3. Rejecting cartridge for Process Control Solution stability failure.
    4. Alerting the user upon detecting the presence of interfering substances in a sample.
g. During cartridge operation, the instrument automatically and continuously performs various checks that can be categorized into four groups:
    1. **System Checks**
        I. Basic function checks of the instrument and the cartridge include:
            i. Cartridge fluidic checks, such as sample integrity, presence of Process Control Solutions and peristaltic pump functionality.
            ii. Cartridge mechanical checks, such as proper operation of distribution valve and sampler arm.
            iii. Instrument heater-block checks.
            iv. Instrument light source and spectrometer checks.
            v. Instrument electronic checks.
        II. Any failure in the system checks will lead to an automatic corrective action. The corrective action will include verification of the failure followed by one of the following steps:
            i. Rejecting the cartridge in the case of cartridge-related system failure.
            ii. Halting instrument operation in the case of instrument-related system failure.
    2. **Sensor Checks**
        I. Sensor checks address sensor functionality. The Process Control Solutions A, B, C and D are automatically brought into the sensor card at various intervals to verify sensor operation.
        II. Sensor checks are performed with the following frequencies:
            i. **One-point Process Control Solution B (PCS) frequency**
                - Process Control Solution B is the primary Process Control Solution measured at a minimum **every 30 minutes, after every sample or after every Process Control Solution A, C, and D.**

- Every 3 minutes for a total of 18 minutes following sample interference detection.
- Between one-point Process Control Solution B measurements all sensor outputs are being monitored every 30 seconds, and an automatic one-point PCS will be initiated if excessive drift in any channel is detected.

ii. **Two-point Process Control Solution A and B frequency**
- PCS A is measured at a minimum **every 4 hours.**
- Run 30 minutes after a Process Control Solution C measurement.
- Every hour for 4 hours following iQM clot detection.

iii. **Process Control Solution C frequency**
- PCS C is measured **at least once every 24 hours.**

iv. **Process Control Solution D**
- PCS D is measured **every 12 hours.**
- PCS D is run as an independent check for analytes. It is run based on a fixed time schedule, twice per day.
- The analysis time is linked to the PCS C, once daily measurement. The PCS D measurements occur 2 hours prior to, and 10 hours following the PCS C measurement.

3. **Failure Pattern Recognition Checks (FPR)**
   I. There are several distinct failure patterns, including micro-clot, interference, and sensor malfunction patterns. For additional information refer to GEM Premier 4000 Reference Guide on page 48 – Intelligent Quality Management.
4. **Process Stability Checks**
   I. Process stability check is a method of verifying the Process Control Solution stability throughout the lifespan of the cartridge. This check is performed **at least every 4 hours.**

h. iQM Delta Charts, Corrective Action, and CVP reports are electronically reviewed, signed and saved monthly, or as needed by the Clinical Laboratory Director or their qualified designee.
i. For additional information about Intelligent Quality Management (iQM) refer to GEM Premier 4000 Reference Guide on pages 44-55.

B. **CVP Level 1 & 2 and CVP Level 3 & 4 (for hematocrit test only)**

a. CVP Level 1 & 2 and CVP Level 3 & 4 (for hematocrit test only) is 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.
b. CVP material has lot-specific information which must be entered or scanned by POCT CLS into the analyzer prior to use.
c. POCT Services orders the CVP and makes available to each department.

C. **GEM System Evaluator Level 2**

a. An additional external quality control (mid-range/normal) is the GSE Level 2; GSE can be used for troubleshooting and will also be run at least twice yearly or once every six months according to the IQCP established guidelines.

b. All analytes must pass this quality control test prior to patient testing.
c. GSE material has lot-specific information which must be entered or scanned by POCT CLS into the analyzer prior to use.

D. **Method Comparisons**

a. Patient samples are compared against the reference instrument (GEM1 Hematology) in the Clinical Laboratory on a regular interval. Each department should bring a patient sample to Hematology. All analytes that are reported for clinical purposes are included (ABG parameters, Na K, iCa, HCT, Lactate, Glucose and CO-Oximetry).
b. Method comparisons may also be useful for troubleshooting when patient's results or CAP results are questionable.

E. **Linearity**

a. Must be performed twice yearly or once every 6 months for each GEM4000 instrument.

F. **Proficiency Testing**

a. Per regular schedule proficiency testing samples are run on the primary GEM4000 instrument under the same conditions as patient samples. ***An analyte result should be interpreted with caution and should be REPEATED if the result is erroneous or incalculable.***

GENERAL OPERATION INFORMATION

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

A. **Changes in Color** – signal different conditions:
   a. **GREEN** – fully operational or normal.
   b. **YELLOW** – conditional state, awaiting specific action.
   c. **RED** – stopped or non-functional.
   d. **GRAY/SHADED** – functionality unavailable or not selected.

B. **Operator messages** – provide clear directions to the operators for next steps. These instructions are generally in white boxes with black text.

C. **Password Protection** – prevents unauthorized access to key activities. When prompted, enter your password.

START NEW SAMPLE TAB

A. Once the CVP and GSE testing has been completed, the user will see the **Start New Sample** tab. The status bar along the top of the Start New Sample tab provides quick access to critical information and capabilities.

a. **Analyzer Status** – indicates overall readiness of analyzer for patient sampling. It will turn YELLOW if a specific action is needed (for example, run CVP).

b. **Date/Time** – system clock runs on 24 hour time.
c. **iQM On Button** – iQM is Instrumentation Laboratory's patented Intelligent Quality Management System, which ensures the integrity of the overall analysis system. Quality testing runs automatically in the background.
d. **Network Status Button** – indicates whether the analyzer is connected to a network.
e. **Tests/Days Button** – these figures indicate how many tests/dates remain before you must change the cartridge. Selecting this button will display the exact day/time the cartridge will expire. When either 1 day or 5 tests are reached, the button background color will turn yellow. An expired cartridge cannot be used by the analyzer.
f. **Mail Button** – alerts the operator to incoming system error messages.

B. Touching the blue MENU button in the upper left displays a drop-down menu that provides fast access to other functionality beyond patient sampling.

NOTE: *Menu functions may be password protected and not all operators will have permission level to access all of the menu options.*

a. **Help** – provides access to topic-based training videos.
b. **Search Results** – enables the operator to search patient results.
c. **Management or GEMweb Plus** – not applicable to routine operators.
d. **Diagnostics** – offers access to a range of tasks related to the status of the GEM 4000.
e. **Remove Cartridge** – enables the operator to manually remove a cartridge.
f. Shut Down – allows the operator to shut down the analyzer correctly. **NOTE: Never shut instrument down using the RESTART option in the Menu or the power button unless directed to do so by Technical Support.**

PROCEDURE

A. **Cartridge Insertion and Warm-up**

a. The GEM Premier 4000 automatically notifies operators when it is time to remove the cartridge, i.e., when sample capacity or the end of the cartridge's 30-day onboard lifespan has been reached. In each case the door will automatically open and display a message to the operator to **"REMOVE CARTRIDGE".**
b. 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. In this case notify a Unit Supervisor or Manager before changing the cartridge. Technical support at Instrumentation Laboratory may need to be notified for the cartridge error.
c. If the analyzer power is OFF, press the power switch to turn it ON. The system will automatically begin the power-up cycle.

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

d. Press **Open Door** on the touch screen. The door will release and open slightly. Manually move the door all the way to the left.
e. 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 cartridge. If there is any moisture inside the foil bag DO NOT USE. The cartridge must be at room temperature (15 to 25°C).*

f. 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.
g. Guide the analyzer door to the right to close it and move the cartridge into its final position.
h. **Cartridge warm-up requires 40 minutes**. During this time, the sensors will hydrate, and the analyzer will perform internal checks and processes.
i. In case of power outages, the door can open and user has a limited time to close the door or the cartridge will need to be replaced.

B. **Calibration Valuation Product (CVP) and GEM System Evaluator (GSE) Sampling Procedure**

a. Each time a new cartridge is inserted, the GEM Premier 4000 analyzer will prompt you to run CVP testing. It is necessary to perform CVP when inserting a new cartridge. **GSE Level 2 may be tested as the third external quality control for troubleshooting blood gas issues and as scheduled twice per year, according to IQCP guidelines.**
b. Complete testing will require approximately 30 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.
c. **Press GO!** To begin sampling.
d. Select CVP lot to run. (Be certain to compare LOT number on vial to LOT number on analyzer. They should match exactly.)
e. Immediately prior to use, hold the ampules by the top, above the break line, and shake vigorously for approximately 10 seconds.
f. Gently tap the ampules so the liquid settles back to the bottom.
g. Carefully snap open the ampules using the ampules breaker.

NOTE: *Aspirate samples **immediately after opening**. Any delay in measuring may cause room air contamination and result in lower pCO2 and higher pO2 values than stated in the insert.*

h. The sample probe will emerge from the gray sampling area at the front of the analyzer. Hold the ampules so the end of the sample probe does not touch the bottom.
i. 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/GSE sampling solution.
j. Analyte buttons will continue to display **Run CVP** until all CVP testing required for that analyte is complete.
k. Once testing is completed, 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.
l. If any CVP analyte is out of range and the procedure was followed, press ACCEPT, and then repeat the failed analyte with a new ampule. (If fails 3 times, only the passing

analytes can be used for patient testing. If this occurs, inform POCT Services as soon as possible.) NOTE: Only press EXCLUDE if you have knowingly made a valid error, but enter a comment documenting the reason for the exclusion (e.g., ran the wrong control).

m. **Run the GSE Level 2 twice per year (or once every 6 months) and as needed basis for troubleshooting. GSE 2 can be used for competency assessment.**

n. Click Start New Sample → check all analytes → click "Show All" → click "more" → choose GEM Evaluator as the "Sample Type" → Press Go →
o. Select GSE lot to run. (Be certain to compare LOT number on vial to LOT number on analyzer. They should match exactly.) Click OK.
p. Immediately prior to use, hold the ampules by the top, above the break line, and shake vigorously for approximately 10 seconds.
q. Gently tap the ampules so the liquid settles back to the bottom.
r. Carefully snap open the ampules using the ampules breaker.

NOTE: *Aspirate samples **immediately after opening**. Any delay in measuring may cause room air contamination and result in lower pCO2 and higher pO2 values than stated in the insert.*

s. The sample probe will emerge from the gray sampling area at the front of the analyzer. Hold the ampules so the end of the sample probe does not touch the bottom.
t. 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/GSE sampling solution.
u. Next, under "Enter Information" tab, click Operator ID, then scan your Barcode ID.
v. Click "View Results" for GSE results. Ensure the results are within range before proceeding.
w. If any GSE analyte is out of range and the procedure was followed, press ACCEPT, and then repeat the failed analyte with a new ampule. If the result of an analyte fails 3 times contact POCT Services as soon as possible. Only the passing analytes can be used for patient testing. NOTE: Only press EXCLUDE if you have knowingly made a valid error, but enter a comment documenting the reason for the exclusion (e.g., ran the wrong control).
x. When the CVP Level 1 & 2, CVP Level 3 & 4 (for hematocrit test only) and GSE Level 2 (if tested) testing are 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.

NOTE: CVP AND GSE TESTING MUST PASS PRIOR TO PATIENT TESTING.

C. **Patient Sampling – Syringe and Capillary Samples**

a. **NOTE:** *LABEL ALL COLLECTED SPECIMENS WITH AT LEAST 2 PATIENT IDENTIFIERS (FULL NAME AND MEDICAL RECORD NUMBER OR DATE OF BIRTH) IN THE PRESENCE OF THE PATIENT.*
b. **Plastic syringe samples** should be kept at room temperature as long as the blood is analyzed **within 30 minutes or less**. If not run in 30 minutes, discard and recollect.
c. **Capillary samples** should be analyzed **within 5 minutes**. If not run in 5 minutes, discard and recollect. The capillary surface to blood volume ratio makes capillary samples

susceptible to changes in pO_2, pCO_2, sO_2, O_2Hb, and oxygen content levels when not analyzed within 5 minutes of collection.

d. Samples can be analyzed whenever the instrument displays the "**READY**" screen.
e. Select "**Panel**" to be tested (e.g., ABG, Glucose, or COOX) located on the left corner of the analyzer. **Micro sampling (65uL)** is available only with capillary tubes. A check and a dark green tab indicate that the analyte is operational.
f. Select the sample type by using the drop-down menu under **"Type"**. Choose if the sample is Arterial, Venous, Capillary, Cord or CVP.
g. Press "**GO**"!

BIOHAZARD WARNING: *Use caution when aspirating samples into the system.*

h. The next screen appears which requires the operator to "**Enter Operator Password**". **Scan your barcode** and press Enter. NOTE: if the barcode scanner is not functioning, your operator ID number may be manually entered.

NOTE: ***DO NOT share your barcode ID with anyone.*** *Sharing barcode IDs is prohibited.*

f. For **Syringe samples** – samples must be mixed thoroughly immediately after sample collection and just prior to sampling. Mix the sample for 30 seconds, alternating between inverting and rolling between outstretched palms. Expel all air. Expel a few drops of the sample from the syringe onto a gauze pad to ensure there is no clot in the syringe.

NOTE: *Do not push the syringe luer tip into the black portion of the sampler.*

g. For **Capillary tube sampling** – samples must be mixed thoroughly immediately after collection and just prior to sampling. Roll the capped capillary tube with outstretched palms for at least 5 seconds.
The luer tip will present just below the home area (the sampler will not extend). Place one end of the capillary tube in the luer tip. Tilt the tube slightly until the blood is flush with the end of the capillary tube. 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. 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.*

i. The system will aspirate the sample and display a message "**Aspirating sample**". The instrument will emit an audio prompt when aspiration is complete. "**Remove sample now**" will display on the screen. **Immediately remove the sample** when you hear the "**beep-beep**". The probe will retract into the system.

NOTE: *Dispose sample in a biohazard waste container.*

j. The system will perform analysis. The next screen allows for the **PATIENT ID**. Scan the CSN barcode in the Account field. NOTE: if the barcode scanner is not functioning, the CSN number may be manually entered. A message will display on the screen "*Waiting for demographics from HIS/LIS*". Patient's information will appear. Verify patient's

information. MRN, Patient's Full Name and Date of Birth should match the label sticker on the specimen before pressing Accept button.

k. Comments can be entered on the **Enter Information Screen**. Comments may be a free-text entry or selected from pre-defined entries. Comments cannot be edited or deleted after the sample has been accepted. NOTE: if manually entering the MRN as the Account number, you must also enter the patient's full name (first and last) in the "Comments" field.

l. Click View Results. The screen goes to "**Analyzing**". The results appear on the screen and are automatically released to the permanent record.

Click Start New Sample Tab to Exit.

m. Attach the printed tape on the GEM4000 POCT Results Sheet (See Appendix I). Place this results sheet in the patient's medical chart.

NOTE: ***An analyte result should be interpreted with caution and should be REPEATED if the result is erroneous or does not match the patient's medical presentation.***

n. Review results for any error messages, critical values, linearity failures, reference range warnings – and respond.

D. **Patient Sampling – CORD Samples (Only applicable to the NICU)**

a. Samples can be analyzed whenever the instrument displays the "**READY**" Screen.
b. Select the "**CBG panel**" (Cord Blood Gas).
c. Select the "**CORD**" sample type (e.g., Cord ABG) by using the drop-down menu under **"Type"**.
d. Press "Go"!

BIOHAZARD WARNING: *Use caution when aspirating samples into the system.*

e. The next screen appears which requires you to "**Enter Operator Password**". Scan your barcode and press Enter. NOTE: if the barcode scanner is not functioning, your operator ID number may be manually entered.

NOTE: ***DO NOT share your barcode with anyone.*** *Sharing barcode IDs is not permitted.*

f. 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***.**

g. The system will aspirate the sample and display a message "**Aspirating sample**".
h. "**Remove sample now**" will display on the screen, remove the container promptly.

NOTE: *Dispose sample in a biohazard waste container.*

i. The system will perform analysis. The next screen allows for the **PATIENT ID**. Scan the

CSN barcode. NOTE: if the barcode scanner is not functioning, the CSN number may be manually entered. A message will display on the screen "Waiting for demographics from HIS/LIS". Patient's information will appear. Verify patient's information. MRN, Patient's Full Name and Date of Birth should match the label sticker on the specimen before pressing Accept button. NOTE: if manually entering the MRN as the Account number, you must also enter the patient's full name (first and last) in the "Comments" field.

j. The screen goes to "**Analyzing**". Click View Results. The results appear on the screen and will automatically be released to the permanent record. Patient's results will print out on the tape or printer as well.

Click Start New Sample Tab to Exit.

NOTE: ***An analyte result should be interpreted with caution and should be REPEATED if the result is erroneous or does not match the patient's medical presentation***.

E. **View Results**

a. "**View results**" cannot be accessed until all required fields are completed.
b. To view sample results, select the **View Results** tab. Results are presented as follows:
    1. Measured values – analyte levels measured during patient sample analysis.
    2. CO-Oximetry values – displayed only if one or more CO-Oximetry analytes are selected for measurement.
    3. Derived values – calculated using equations applied to one or more measured analytes.
c. If patient results are outside the **Reference Range** (what is considered within normal limits) they are displayed in black text on a yellow background.
    1. High results – one black arrowhead next to result pointing up
    2. Low results – one black arrowhead next to result pointing down.
d. If patient results are outside the **Critical Values Range** (what is considered critical and requires action) they are displayed in white text on a red background.
    1. High results – two white arrowheads next to result pointing up.
    2. Low results – two white arrowheads next to result pointing down.
e. If patient results are outside the **Reportable Range** (what can be reported off the instrument based on linearity testing), they are displayed in white text on a red background, with extreme value of the reportable range.
    1. High results – white greater than symbol next to result.
    2. Low results – white less than symbol next to result.
f. During EMR (Electronic Medical Records) downtime:
    1. Results will not appear in the EMR. Users may use the approved GEM4000 downtime results form (attach results print out to the designated area on the form) and place in the patient chart.
    2. When the EMR is operational again, any pending results should transmit. If transmission is not successful, results may be manually entered into the EMR. Any manually entered results must be verified for accuracy.
g. **Viewing Patient History**
    1. To view recent sample results, press "**Patient History**". The analyzer will display the most recent test results for the same patient and same sample type as the current sample. Samples older than one month will not be shown. The **delta (Δ) value** represents the difference between values for the current sample and for

the one prior to it.

h. **Search Patient's Results**

1. Choose "**Search Results**" from the drop-down Menu in the upper left corner of the screen.
2. Scan your barcode to access this feature.
3. Enter the search criteria in the **Search Criteria** area. These function as data entry fields or drop-down menus.
4. Date and time frame criteria (lower right-hand corner of the screen) are required for all searches.
5. Enter the Patient ID / MRN (medical record number) / CSN.
6. To view the samples results, press the "**View**" button at the bottom of the screen.
7. To clear the search criteria, press the "**Clear Criteria**" button.
8. Results are displayed in list format, along with the criteria used in the search. All samples that meet the criteria selected by the operator will be displayed. NOTE: Results that do not present with an error code will auto-verify and automatically post in the Electronic Medical Record system.
9. Press "**Print All**" if you want to prints one copy of each sample record resulting from the search.

G. **Removing the Cartridge**

a. When a cartridge has reached its maximum onboard lifespan or test capacity, the cartridge door will automatically open and display a message to the operator to remove the cartridge.
b. GEM Premier 4000 cartridges **cannot be removed and reinserted** into the analyzer. Be sure to check with your Manager or Charge Nurse or Super User before performing this task.
c. Cartridge may be removed prior to maximum onboard lifespan or test capacity. This requires careful consideration to avoid underutilizing a cartridge.
d. Press the blue **Menu** button in the upper left corner of the screen. Select "**Remove Cartridge"**. Enter your password.
e. 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.
f. 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 an appropriately sized biohazard container. The system will now be inactive until you insert a new cartridge.

WARNING: *The cartridge contains a waste bag that contains blood, a potential biohazard. Use universal precautions when handling a used cartridge, including wearing gloves.*
Dispose of it in an appropriately sized biohazard waste container using.

H. **Shutting Down the Analyzer**

a. Shutting down the analyzer is an important step that requires careful consideration before completing. Once the analyzer is shut down, power must be restored within 20 minutes or the cartridge will have to be removed and thrown away.
b. Press the blue Menu button in the upper left while on the Start New Sample tab. Select

"**Shut Down**" from the pull-down menu.

c. The analyzer will prompt you to consider your decision. Press No to return to the Start New Sample tab. Press Yes to continue to shut down. The analyzer will shut off on its own. The analyzer has now been correctly shut down.

g. **CAUTION**: *The GEM Premier 4000 analyzer has a momentary power switch. To power the instrument off, it is necessary to utilize the Shut Down command in the instrument software, which is accessed through the drop-down Menu on the Start New Sample tab. If the power switch is pressed and held for 5 seconds or longer, the instrument will shut down. However, this will result in an illegal shut down, and the instrument software may not be able to recover.* **NOTE: Never shut instrument down using the RESTART option in the Menu or the power button unless directed to do so by Technical Support.**

CALCULATIONS

- All calculations are performed by the GEM Premier 4000 analyzer.

REPORTING / DOCUMENTATION RESULTS

A. **REFERENCE RANGES (WITHIN NORMAL LIMITS)**

ANALYTE	ARTERIAL	VENOUS	CAPILLARY	CORD BLOOD ARTERIAL	CORD BLOOD VENOUS
pH					
Newborn				7.10 - 7.38	7.20 - 7.46
0 to 6 mos	7.25 - 7.45	7.32 - 7.42	7.31 - 7.47		
> 6 to 12 mos	7.30 - 7.45	7.32 - 7.42	7.31 - 7.47		
> 1 yr	7.35 - 7.45	7.32 - 7.42	7.35 - 7.45		
ANALYTE	**ARTERIAL**	**VENOUS**	**CAPILLARY**	**CORD BLOOD ARTERIAL**	**CORD BLOOD VENOUS**
PCO2 (mmHG)					
Newborn				35 - 74	28 - 57
0 to 12 mos	27 - 40	41 - 51	30 - 50		
> 1 yr	35 - 45	41 - 51			
PO2 (mmHG)					
Newborn	50 - 90		30 - 60	6 - 30	16 -43
0 to 12 mos		35 - 50	30 - 60		
> 1 day to 12 mos	80 - 100	35 - 50	30 - 60		
> 1 yr to 65 yrs	80 - 100	25 - 40			
> 65 yrs	75 - 85	25 - 40			
$HCO3^-$, Actual (mmol/L)					
0 to 1 mo	17 - 24	18 - 24			
> 1 mo to 1 yr	19 - 24	18 - 24			
> 1 yr	22 - 26	22 - 29			
Base Excess (BE, ecf, mmol/L) ***GEM Printout (negative numbers)***					
Newborn				-10 to +1	-10 to +2
0 to 1 mo	-10 to -2	-10 to -2	-10 to -2		

1 to 12 mos	-7 to -1	-7 to -1	-7 to -1		
> 1 yr	-2 to +3	-2 to +3	-2 to +3		
Base Excess (BE, ecf, mmol/L) ***Sunquest, LCR display ****					
Newborn				0 - 1	0 - 2
0 to 1 mo	None	None	None		
1 to 12 mos	None	None	None		
> 1 yr	0 - 3	0 - 3	0 - 3		
Base Deficit (BD, mmol/L) ***Sunquest, LCR display ****					
Newborn				0 - 10	0 - 10
0 to 1 mo	2 - 10	2 - 10	2 - 10		
1 to 12 mos	1 - 7	1 - 7	1 - 7		
> 1 yr	0 - 2	0 - 2	0 - 2		

*The Sunquest system cannot display negative numbers. As a workaround negative base excess results are reported as base deficit.

ANALYTE	ALL WHOLE BLOOD SAMPLES	
ELECTROLYTES (WHOLE Blood)		
Na^+	133 - 146 mmol/L for all ages	
K^+		
0 – 2 weeks	3.7 - 5.9 mmol/L	
2 weeks – 1 yr	4.1 - 5.3 mmol/L	
1 – 16 yrs	3.4 - 4.7 mmol/L	
> 16 yrs	3.5 - 5.1 mmol/L	
Ionized Ca^{++}		
0 – 12 mos	0.95 - 1.50 mmol/L	
> 1 yr	1.12 - 1.32 mmol/L	
Glucose (mg/dL), Random (Whole Blood & Fingerstick)		
Newborn – 1 year	50 – 150 mg/dL	
>1 year	70 – 199 mg/dL	
>1 year, Diabetes	≥ 200 mg/dL	
Lactate (mmol/L)		
	ARTERIAL	**VENOUS**
0 – 12 months	0.3 – 2.2 mmol/L	0.3 – 2.9 mmol/L
>1 year	0.5 – 1.6 mmol/L	0.5 – 2.2 mmol/L

HEMATOCRIT

Analyte	**All Whole Blood Samples**	
HCT	**Male**	**Female**
Adult		
>18 yrs	39.8 - 52.2%	34.9 - 46.9%
Pediatric		
Birth	42.0 - 60.0%	
1-7 days	42.0 - 67.0%	
8-14 days	39.0 - 66.0%	
15-30 days	31.0 - 66.0%	
1-2 mos	28.0 - 55.0%	
2-3 mos	28.0 - 42.0%	
3-6 mos	29.0 - 41.0%	
0.5-2 yrs	33.0 - 39.0%	
2-6 yrs	34.0 - 40.0%	
6-12 yrs	35.0 - 45.0%	
12-18 yrs	37.0 - 49.0%	36.0 - 46.0%

CO-Oximetry

	All Whole Blood Samples	
Analyte	**Male**	**Female**
THB (g/dL)		
>18 yrs	13.3 - 17.7	11.7 - 15.7
12 – 18yrs	13.0 - 16.0	12.0 - 16.0
OSAT	95 - 99 %	
COHB	0.5 - 1.5 % (non- smokers)	
METH	< 1.5 %	
Oxygen Content O_2ct (all ages)	15 – 23 Vol %	
Infant Care Center		
OSAT		
0 to 4 hours	85 – 90%	
> 4 hours	95 – 99%	
COHB		
0 – 12 mo.	0.5 - 1.5 %	
METH		
0 – 12 mo.	< 1.5 %	

Pediatric Reference Ranges for THB	
Age	**HGB (g/dL)**
<1 day	13.5-19.5
1-7 days	13.5-22.5
8-14 days	12.5-21.5
15 days - <1 mo	10.0-20.5
1 mo - <2 mos	9.0-18.0
2 mo - <3 mos	9.0-13.5
3 mo - <6 mos	9.5-13.5
6 mos - <2 yrs	10.5-13.5
2 yrs - <6 yrs	11.5-13.5
6 yrs - <12 yrs	11.5-15.5

B. **REPORTABLE RANGES (BASED ON LINEARITY)**

Analyte	Reportable Ranges
pH	6.80 – 7.80
pCO2	10 – 125 mmHg
pO2	20 – 610 mmHg
Na+	100 – 180 mmol/L
K+	1.0 – 10 mmol/L
iCa++	0.5 – 3.0 mmol/L
Gluc	20 – 680 mg/dL
Lac	0.5 – 15.0 mmol/L
Hct	15 – 67 %
tHb	5.0 – 22.5 g/dL
O2Hb	0.0 – 100 %
COHb	0.0 – 100 %
MetHb	0.0 – 100 %
Derived Parameter Reportable Range	
HCO_3 Std	3.0 – 60. 0 mmol/L
HCO_3	3.0 – 60. 0 mmol/L
TCO_2	3.0 – 60. 0 mmol/L
BEecf	-30.0 to 30.0 mmol/L

For results outside of verified linear range, they will be reported as outside reportable range, code **ORR-;** > (greater) or < (less than) reportable range, as appropriate. Related calculated values will be reported as **NCAL** (not calculated).

C. **CRITICAL VALUES, ADULTS (REQUIRES IMMEDIATE ACTION)**

	Source				
Analyte	**Arterial**	**Venous**	**Capillary**	**Cord Blood Arterial**	**Cord Blood Venous**
pH	< 7.20 or > 7.55	< 7.20	< 7.20 or > 7.55	< 7.0	< 7.0
***p*CO$_2$ (mmHg)**	< 25 or > 65	> 75	< 25 or > 65	–	–
***p*O$_2$ (mmHg)**					
> 1 month	< 40	–	–	–	–
Neonate 0 to 30 days	< 40 or > 100	–	< 40 or > 100	–	–
Base Deficit (BD, mmol/L)					
Neonate 0 to 30 days	> 10	–	> 10	> 10	> 10
Na$^+$	< 125 or > 155 mmol/L				
K$^+$	< 3.0 or > 6.0 mmol/L				
Ionized Ca^{++}	< 0.8 or > 1.55 mmol/L				
COHB	>14.9%				
METH	>14.9%				
THB	**0-7 days:** <7g/dL or >22.5 g/dL; **8-30days:** <7g/dL or >21.5 g/dL; >**30 days to adult:** <7g/dL or >20 g/dL				

Metabolic	
Glucose, mg/dL	
> 1 month	<50 or >500
Neonate 0 to 30 days	<50 or >200
Lactate, mmol/L	>3.9

LIMITATIONS AND INTERFERENCES

A. Result or Exception Flags

a. The GEM Premier 4000 analyzer may flag results on the patient report following the completion of the iQM check post-sample analysis.
b. Flagging alerts the operator to a possible sample error that could affect the results of analyte. Situations that could produce exception flags are **microclots** or i**nterferences**.
c. See table for a complete listing of exception flags available on the GEM Premier 4000 analyzer. The following exceptions or flags may be displayed along with the sample results.

Exception Flag/Symbol	Exception Flag Description
incalculable	Result Incalculable
A	Absorbance Error
S	Sulfhemoglobin Interference Detected

	High Turbidity Detected
	Interference Detected
	Micro Clot Detected
	Temporary Sensor Error
	High Methemoglobin Warning
	Sulfhemoglobin and High Methemoglobin Warning
	Corrected for Sulfhemoglobin

d. With auto-verification in place, any result displayed with an **error message or exception flag WILL NOT BE REPORTED** and **TESTING OF THE SAMPLE SHOULD BE REPEATED** (as results can be outside specification claims) when any of the following occurs:
    1. Patient or CAP Results have error flags, e.g. Absorbance error, Micro Clot detected, etc.
    2. The result is immediately followed by a message to the operator indicating that any of the conditions listed in the Exception Table above exists.
    3. **IMPORTANT:** ***If this occurs, staff should repeat the test. If the repeat test still has an error message or flag, send sample to the Clinical Laboratory (2M14) for testing. For any suspicious results, ALWAYS SEND SAMPLE TO THE CLINICAL LABORATORY (2M14).***

B. Auto-verification of results

a. **Results that do not have error messages or exception flags, except for potassium** outside of the linear range, will automatically post to the Electronic Medical Record system.
b. Potassium values outside of the linear range will not be released under auto-verification.
c. Quality assurance reports are regularly reviewed for 1) transmission issues (performed by CLS staff) and 2) results that may need further review (performed by department super users). Follow up actions will take place on an as needed basis.

C. Limitations

Condition	Result
Room Air Contamination	➢ Erroneous results may occur when samples have a very low or high pO_2 content or high HHb levels. ➢ Similarly, pCO_2 may be affected and subsequently pH and Ca^{++} results as well.
Metabolic Changes Due to a Delay in Sampling	➢ 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 hematocrit, and CO-Ox parameters if the

	sample is not properly mixed prior to measurement.
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 warranty, explicit or implied.
Under-Heparinized Sample Due to Using Non-Heparinized Sampling Devices or Inadequate Mixing with Heparinized Devices.	➢ Blood clot can form in the sensor chamber causing various sensor failures if sample is not properly heparinized.
Hemolysis	➢ Hemolyzed samples may result in falsely elevated potassium levels.

B. **Interference**

➢ The following substances can potentially interfere with sample analysis:

a. Severely abnormal plasma osmolarity or abnormal levels of protein or lipids.
b. Hematocrit values reported by GEM 4000 may differ significantly from the values generated by a cell counter. In general, abnormally high protein or lipid values may cause higher hematocrit values and vice-versa.
c. Benzalkonium Chloride: Arterial lines and sampling devices coated with Benzalkonium Chloride cause falsely elevated Sodium and Ionized Calcium readings.
d. Benzalkonium Heparin: Arterial lines and sampling devices coated with Benzalkonium Heparin cause falsely elevated Sodium and Ionized Calcium readings.
e. Thiopental Sodium: May interfere with the Sodium, Potassium, pCO_2 and Ionized Calcium readings.
f. An anesthetic may produce unreliable pO_2 results due to interferences with pO_2 sensor.
g. The following substances may show noticeable interference with certain channels on the GEM Premier 4000 analyzer causing **falsely elevated or falsely lowered results.**
h. Venous blood gas samples collected with BD Vacutainer Plastic Lithium Heparin tubes should not be used when testing carboxyhemoglobin (COHb) using the IL GEM 4000 Instrument. **A clinically significant positive bias (falsely elevated results) with COHb results may occur.**

Substance	Affected Analyte	Substance Concentration Producing Interference
Benzalkonium*	CA^{++}	5 mg/L
Bromide	Cl^-	10 mmol/L
Cyanocobalamin**	CO-Oximetry	0.75 g/L
Dobutamine	Glucose, Lactate	2 mg/dL
Dopamine	Glucose, Lactate	5 mg/dl
Fluoride	Cl^-, Lactate	500 mg/dl
Glycolic Acid	Lactate	1 mmol/L
Hemoglobin Base Oxygen Carriers	Hematocrit	3.2 g/dl
Hydrocobalamin**	CO-Oximetry	0.75 g/L
Hydroxyurea	Glucose, Lactate	0.8 mg/dl
Iodide	Cl^-	3 mmol/L

Oxalate	Cl^-, Lactate	500mg/dl
Salicylate	Cl^-	4 mmol/L
Sulfhemoglobin**	CO-Oximetry	10%
Thiopental*	CA^{++}	30 mg/L
Turbidity**	CO-Oximetry	5% based on turbidity created by Intralipid®†† fat emulsion
Uric Acid	Glucose	20 mg/dL

- * The GEM Premier 4000 analyzer with iQM employs failure pattern recognition checks. These checks include detecting the presence of positively charged lipophilic compounds (e.g. benzalkonium) and negatively lipophilic compounds (e.g., thiopental). The GEM Premier 4000 analyzer offers the operator the ability to enable flagging of patient results if interference patterns for these compounds are detected by iQM.

- ** CO-Oximetry interference is detected and flagged by failure pattern recognition checks.

i. The following substances may show noticeable interference with the sodium, pCO_2, and glucose channel on the GEM Premier 4000 analyzer, causing **falsely low results.**

Substance	Affected Analyte	Substance Concentration Producing Interference
Etomidate	pCO_2	50 mg/L
Fluoride	Glucose	500 mg/dL
Oxalate	Glucose	1000 mg/dL
Sodium Perchlorate	Sodium	20 mg/dL

MAINTENANCE

A. **Routine Cleaning**

a. **Recommended supplies:**

1. Disposable latex or rubber gloves
2. Laboratory coat or jacket
3. Eye protection
4. Soft cleaning cloths
5. Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes
6. PDI Bleach Wipes
7. Biohazard waste bags
8. Non-abrasive cleaning solution

BIOHAZARD WARNING: *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 rubber or latex gloves, eye protection, and a laboratory coat or*

jacket before handling the instrument. Prepare a biohazard waste bag for waste disposal.

b. **Cleaning the Analyzer**

1. There is no need to disconnect the GEM4000 analyzer from AC power when cleaning the touch screen.
2. 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.

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

3. Remove any blood or dust from the outer surface of the instrument case (not screen) using the Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant Wipes. NOTE: If cleaning blood from a patient with possible or confirmed infections (e.g., *Clostridium difficile,* Norovirus), use PDI Bleach Wipes.
4. Always follow the hospital policy for wet contact time.
5. Place any used cloth or paper towel in an appropriate biohazard waste bag.

c. **Installing the Printer Paper in the Paper Area on Top of the System**

1. Press the tab at the top of the system to release the door.
2. Open the door and extend paper guide if desired.
3. Place the roll of paper in the compartment so the paper unfurls from the bottom.
4. Press the door firmly closed.

d. **Disposing the Ampules Breaker**

1. The ampules breaker is a disposable unit and when filled should be disposed of in a suitable biohazard container.

B. **Preventive Maintenance**

a. Instrumentation Laboratory has determined that preventive maintenance is **not required for the first 5 years of service** for the following reasons:

1. The functional performance of the analyzer is determined by the disposable GEM PAK.
2. The instrument tests the electronic and software performance of the system. All internal components have been validated to ensure that no internal adjustments are required within the first 5 years of use.
3. The GEM Premier 4000 analyzer with Intelligent Quality Management monitors the analyzer performance. iQM has a complete range of diagnostic programs that continuously check the unit’s performance and indicates any non-performance to the operator.

C. **Analyzer Repair**

1. If GEM Premier 4000 analyzer is broken or not working, contact Point of Care Testing Service.
2. The Point of Care Testing Service staff may assist with troubleshooting. If it is determined that the analyzer must be repaired, the Point of Care Testing Service staff will arrange for Instrumentation Laboratory to provide a loaner during the interim and will coordinate with Biomedical Services to complete the transaction.
3. **POCT Staff will run Linearity and Method Comparison studies as needed for the loaner and repaired analyzer.** The Clinical Laboratory Director or designee will review the results and sign-off if the repaired instrument is approved for patient testing.

TROUBLESHOOTING

A. **Error Codes Associated with System Malfunctions**

Error Code	Cause of Error	Operator Message
201	Process Control solution not detected	Process control solution not detected. Preparing for cartridge removal. Please wait.
203	Air slug before sample not detected	Sample not detected. Repeat test.
204	Sample not detected	Sample not detected. Repeat test.
220	Sampler luer did not move into position	Sample probe error. Preparing for cartridge removal. Please wait.
222	Air detected within sample during aspiration	Insufficient sample. Repeat test.
223	Air detected within sample during post aspiration	Air detected within sample. Repeat test.
224	Insufficient sample volume for CO-Ox	Insufficient sample for CO-Ox.
230	Block temperature out of valid range	Temperature out of range. Analyzer will be shut down. Contact Technical Support.
236	Power supply voltage out of valid range	Power supply voltage error. Analyzer will be shut down. Contact Technical Support.
240	No air detected before a Process Control solution	Process control solution not detected. Preparing for cartridge removal. Please wait.
241	Rotary valve sensor not found	Rotary valve error. Preparing for cartridge removal. Please wait.
260	Door sensor did not respond	Door failure. Door must be opened manually. Contact Technical Support for assistance.
261	Pump mechanism calibration failed	Cartridge error. Preparing for cartridge removal. Please wait.
264	CO-Ox integration time could not be set	CO-Ox hardware failure. Analyzer will be shut down. Contact Technical Support.
265	Reference voltage out of range	Reference solution not detected. Preparing for cartridge removal. Please wait.
266	Sensor polarization voltages out of range	Voltages out of range. Analyzer will be shut down. Contact Technical Support.
267	Pump mechanism error	Cartridge error. Preparing for cartridge removal. Please wait.

270	Analytical component leak	Cartridge error. Preparing for cartridge removal. Please wait.
280	Diverter and/or mixing solenoid error	Value error. Analyzer will be shut down. Contact Technical Support.
285	CO-Ox neon light calibration failure	CO-Ox hardware failure. Analyzer will be shut down. Contact Technical Support.
288	CO-Ox error (due to spectrometer read error, or other types of error)	CO-Ox hardware failure. Analyzer will be shut down. Contact Technical Support.
289	pO_2 mV is outside threshold when measured during Process Control solution C measurement during cartridge warm-up	iQM error for pO_2. Preparing for cartridge removal. Please wait.
300	The SBC board and CPU temperature is monitored. If the temperature rises to 70°C, a warning is issued. The operator should check the analyzer environment blocked ventilation, excessive ambient temperature, etc.	Temperature out of range. Check ambient.
301	The SBC board and CPU temperature is monitored. If the temperature rises to 90°C, the analyzer is shut down.	Analyzer temperature too high. Analyzer will be shut down. Contact Technical Support.
302	Hard drive showing excessive amount of errors indicating it may fail soon. Operator should perform backup and contact Technical Support.	Hard drive showing excessive errors and may fail soon. Perform backup. Contact Technical Support.
303	One of the LCD backlights failed	LC backlight failed. Contact Technical Support.
304	One of the 4 USB ports on the back panel failed (overload detected)	Disconnect USB device and then reconnect.
305	Overload detected on the CO-Ox USB port	CO-Ox port failure. Analyzer will be reset.
306	Memory error detected	Memory error. Analyzer will be reset.
2010	iQM solution stability check failed	Process control solutions stability failure. Preparing for cartridge removal. Please wait.
2012	Reference sensor voltage is saturated or out of range	Reference voltage error. Preparing for cartridge removal. Please wait.
2014	An error occurred while reading or writing to the cartridge EEPROM	Cartridge ID error. Preparing for cartridge removal. Please wait.
2016	Ground voltage is saturated or out of range	Ground voltage error. Preparing for cartridge removal. Please wait.
2017	Special rinse failed leading to cartridge removal	Micro clot caused solution detect error after sample. Preparing for cartridge removal. Please wait.

B. **Error Codes Associated with Software Malfunctions**

Error Code	Error can occur on: Analyzer, Server or Both	Cause of Error	Message to Operator
3001	Both	The file system check, performed during startup, failed and could not self-correct.	File system check error. System will be reset.

3002	Analyzer	The instrument software could not communicate to the FPGA (hardware).	FPGA communication error. System will be reset.
3004	Analyzer	FPGA (hardware) failed to initialize or reset.	FPGA error. System will be reset.
3006	Analyzer	The DM (Data Management Module) and AM (Analytical Module) could not communicate, or went out of synch.	Internal communications error. System will be reset.
3007	Both	An error during a database operation.	DB error. System will be reset.
3008	Both	An error during a file I/O operation.	File I/O error. System will be reset.
3009	Both	User interface to Data Management Module communication error.	Internal communications error. System will be reset.
3012	Analyzer	An illegal script command or an illegal command argument. The script cannot be executed by the script engine.	Script error. System will be reset.
3013	Analyzer	More than 3 analyzer resets occurred.	Too many resets. Shutting down. Contact Technical Support.
3203	Analyzer	Problem accessing GEMWeb Plus server.	This operation failed. Retry after server is available.
3205	Both	The system cannot perform the requested operation.	The system cannot perform the requested operation.
3206	Both	DM (Data Management software error.	Internal DM software error. System will be reset.

ORDERING INFORMATION

NOTE: Refer to the location IDA page to determine which supplies are applicable to a particular location.

SFGH Pathways No.	Item Description	Vendor	Mfr Catalog No
6007915	Paper Printer for GEM Premier 4000	Cardinal	00024000500
6007916	Breaker Ampoule for GEM Premier 4000	Cardinal	00025000450
6007917	Calibration Validation Product 1	Cardinal	00025000115
6007918	Calibration Validation Product 2	Cardinal	00025000125
6007919	Calibration Validation Product 3	Cardinal	00025000130
6007920	Calibration Validation Product 4	Cardinal	00025000140
H7200107	RNA Medical Co-Ox Calibration Verification Controls	RNA Medical	CVC-223
N/A	GEM System Evaluator 2	Cardinal	00025000102
1021462	Performance Validation Product BG Lytes	Cardinal	00024001515
6008892	Performance Validation Product GEM Crit	Cardinal	00024001516
1043171	Cartridge BG HCT Lytes CO-OX 300 Test IQM	Cardinal	00027430008
1047304	Cartridge BG HCT CO-OX **150** TEST IQM	Cardinal	00027415004
1047305	Cartridge BG HCT CO-OX **300** TEST IQM	Cardinal	00027430004
1047056	Cartridge BG HCT LYTES GL CO-OX **300** TEST IQM	Cardinal	00027430010
1047306	Cartridge BG HCT LYTES GL CO-OX **450** TEST IQM	Cardinal	00027445010

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Hartwell Road, Bedford, MA, 01730.

2. Instrumentation Laboratory Company. (November 2009). *GEM Calibration Valuation Product 2 with Co-Ox Package Insert*. Part Number: 00025000125. Instrumentation Laboratory Company, 180 Hartwell Road, Bedford, MA, 01730.
3. Instrumentation Laboratory Company. (December 2008). *GEM Calibration Valuation Product 3 Hematocrit Package Insert*. Part Number: 00025000130. Instrumentation Laboratory Company, 180 Hartwell Road, Bedford, MA, 01730.
4. Instrumentation Laboratory Company. (October 2012). *GEM Calibration Valuation Product 4 Hematocrit Package Insert*. Part Number: 00025000140. Instrumentation Laboratory Company, 180 Hartwell Road, Bedford, MA, 01730.
5. Instrumentation Laboratory Company. (March 2011). *GEM Premier 4000 Configuration Guide*. Revision 1; includes updates through Software V2.1.2. Part Number: 00025000340. Instrumentation Laboratory Company, 180 Hartwell Road, Bedford, MA, 01730.
6. Instrumentation Laboratory Company. (March 2011). *GEM Premier 4000 Data Management Guide*. Revision 1; includes updates through Software V2.1.2. Part Number: 00025000320. Instrumentation Laboratory Company, 180 Hartwell Road, Bedford, MA, 01730.
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8. Instrumentation Laboratory Company. (July 2006). *GEM Premier 4000 PAK*. Part Number: 000370074 R01. Instrumentation Laboratory Company, 180 Hartwell Road, Bedford, MA, 01730.
9. Instrumentation Laboratory Company. (May 2012). *GEM Premier 4000 Reference Guide*. Revision 2; includes updates through Software V2.1.2. Part Number: 00025000331. Instrumentation Laboratory Company, 180 Hartwell Road, Bedford, MA, 01730.
10. Instrumentation Laboratory Company. (June 2011). *IL Performance Verification Product (PVP)*. Part Number: 0024001515. Instrumentation Laboratory Company, 180 Hartwell Road, Bedford, MA, 01730.
11. Instrumentation Laboratory Company. (June 2009). *IL Hematocrit Performance Verification Product (critPVP)*. Part Number: 00024001516. Instrumentation Laboratory Company, 180 Hartwell Road, Bedford, MA, 01730.

DISTRIBUTION

A. http://www.sfgh-poct.org
B. All GEM Premier 4000 Testing Sites