



Medical Center

Point of Care Testing

Clinical Laboratories

GEM Premier 3000 for Blood Gas, Electrolytes, Ionized Calcium, & Hematocrit in Arterial and Venous Blood

TABLE OF CONTENTS

Purpose	1.0	Tab 1
Scope	2.0	
Personnel	3.0	
Equipment and Materials	4.0	
Specimen Requirements	5.0	
Quality Control	6.0	
Assay Procedure	7.0	
Assay Procedural Notes	8.0	
Limitations of Procedure	9.0	
Result Reporting	10.0	
Records Maintenance	11.0	
References	12.0	
Weekly Comparison Testing	Appendix A	
Cartridge Failure Procedure		Tab 2
Relationship Between Analyzers		Tab 3
Calibration Verification and Linearity		Tab 4
Proficiency Testing		Tab 5
Quality Assurance Policy		Tab 6
Quality Improvement Program		
Employee Competency		Tab 7
Biosafety and MSDS		Tab 8

I. PURPOSE

This procedure provides instructions for using the GEM Premier 3000 instrument: cartridge insertion, patient sampling, quality control, calibration, cartridge replacement, instrument cleaning, and instrument maintenance.

II. SCOPE

This procedure is for the Clinical Laboratories, POCT, Operating Room, and Perfusion Services.

III. PERSONNEL

The Clinical Perfusionists and Anesthesiologists will use this procedure.

IV. EQUIPMENT AND MATERIALS

1. Gem Premier 3000 blood gas instrument, Instrumentation Laboratory. (P/N 570001000).
2. Gem Premier Reagent iQM cartridge (#24315089) for pH, pO₂, pCO₂, Na, K, iCa, Glu, Hct and Lac. Maximum tests = 150 count.
3. Thermal printer paper (#005508).
4. GEM Calibration Validation Product: (CVP) Instrumentation Laboratory. : 20 vials of 4 levels, are provided in the multipak. (#24001587).
 - a. GEM CVP 1 with low pH, pO₂, Na, K, Glu, Lac, and high pCO₂ and iCa.
 - b. GEM CVP 2: with high pH, pO₂, Na, K, Glu, Lac, and low pCO₂ and iCa.
 - c. GEM CVP 3: with low hematocrit values
 - d. GEM CVP 4 with normal hematocrit values.
 - e. CVP 1 and 2 are aqueous buffered bicarbonate solutions containing inorganic salts and organic metabolites, equilibrated with precise concentrations of carbon dioxide and oxygen.
 - f. CVP 3 and 4 are aqueous buffered bicarbonate solution containing inorganic salts and equilibrated with carbon dioxide and oxygen.
 - g. All CVP reagents should be stored at 2 - 8°C; can be stored at room temperature (up to 28°C) up to 12 months if the expiration date on the box is not exceeded.
5. Performance verification product (PVP), Instrumentation Laboratory
 - a. PVP set, multipak. Twenty vials of 5 separate levels are provided for blood gases, electrolyte, Hct, Glu, Lac. (#24001525).
 - b. PVP Crit set, multipak. 16 vials of 4 separate levels are provided for Hct.
 - c. All PVP reagents should be stored at 2 - 8°C; can be stored at room temperature (up to 28°C) up to 12 months if the expiration date on the box is not exceeded.
6. Controls are Critical Care QC, ContrIL 9 (0024001418) for blood gases and electrolytes and GEM critCheck (2309) for hematocrit. See controls for further information.

V. SPECIMEN REQUIREMENTS

1. Whole blood - a 150-uL whole blood sample in a full plastic syringe with balanced heparin is required. Complete anticoagulation is essential as microscopic aggregates in a sample can adversely affect a blood gas analysis.
2. For optimal results, samples should be analyzed within five minutes. If a sample cannot be measured within 15 minutes after drawing, it must be placed in a bath containing ice and water to slow down the metabolic process. Ice water stored samples are stable for up to 30 minutes. The pO₂ value may be affected by the time interval between sampling and analysis. It should be noted that potassium levels are generally affected by icing. Potassium elevations of several mmol/L have been observed after only a few minutes on ice. Adequate precautions should be taken to avoid cell lysis, resulting in falsely elevated potassium values.
3. A specimen is considered unacceptable if it is not run within 15 minutes at the point of patient care or not received in a bath with water and ice, has air bubbles in the syringe, is collected in an inappropriate collection device, is inadequately labeled or if clots are present.
4. Whole blood is most commonly obtained from a radial or brachial artery or from a cardiopulmonary bypass circuit. Venous blood for pulmonary artery blood gases may be drawn in a heparinized syringe or from a bypass circuit. When drawing a sample from the cardiopulmonary bypass circuit, care must be taken to draw outline solutions before sampling to ensure that sample reflects patient's current condition.
5. Samples from other operating rooms. Perfusionists may test samples from another operating room only if the procedure is one that utilizes a perfusionist for cardiopulmonary bypass or a perfusionist is on standby for cardiopulmonary bypass. All samples from other cases where a perfusionist is not utilized must be sent to Clinical Labs.
6. Correct identification of samples received from other operating rooms. When a blood gas sample from a perfusion case is sent to another operating room where the GEM Premier 3000 is located, the perfusionist or Anesthesiologist in the room where the sample was obtained must attach a patient label to the syringe to identify it to avoid improper result reporting. The perfusionist then must affix the patient label to the GEM Premier 3000 and to the OR report form and write the operating room number on the patient labels. Henceforth, whenever the operating perfusionist receives a properly labeled sample from the other operating room, he or she will compare the patient number on the sample to the label affixed to the GEM Premier 3000 to ensure that they are the same. The verified patient number is then entered into the GEM Premier 3000 when the sample is tested.
7. Testing samples from Anesthesiologists. Perfusionist may test samples from anesthesiologists if the procedure they are doing is one that utilizes a perfusionist for cardiopulmonary bypass or a perfusionist is on standby for cardiopulmonary bypass. Since the anesthesiologists do not draw their samples from the heparinized

cardiopulmonary bypass circuit, they must draw their samples with a pre-heparinized blood gas syringe to avoid clotting.

Note: Tissue fluid may affect electrolyte results.

Caution: Do not use anticoagulants other than lithium or sodium heparin.

VI. QUALITY CONTROL

1. Controls are purchased from IL Sensor Systems. The two types of controls are Critical Care QC ContrIL9 and GEM critCheck.
2. The ContrIL9 includes three different vials of aqueous tonometered buffers. These contain known quantities of gases and electrolytes that are used for system quality control checks for pH, pCO₂, pO₂, Na⁺, K⁺, iCa⁺⁺, glucose and lactate at three different physiological levels, Low, Normal, and High.
3. The GEM critCheck solutions are two concentration levels used to evaluate the hematocrit sensor, Low and Normal.
4. Contril9 is stored at 2 - 8°C and is stable until the expiration date. Alternatively, ContrIL9 may be stored for up to 12 months at room temperature (up to 28°C) as long as the expiration date on the box is not exceeded.
5. GEM critCheck QC should be stored at room temperature and is stable for use as long as the expiration date on the box is not exceeded.
6. New Control Lots. Perfusion Service's will confirm the manufacturer's established range on each new lot of controls. New controls will be run concurrently with old controls over a 10 to 30 day period. When a new lot of control material is being evaluated, the key operator will enter the status of the new lot as "Parallel". A minimum of 5 data points should be submitted for evaluation to the Quality Assurance, Clinical Labs and the mean, 1 S. D., and %CV will be calculated and compared with the manufacturer's established range. Once the new lot has passed Q.C. requirements, the key operator will then change the status of the control from "Parallel" to "Active".
7. Control levels and frequency of liquid quality control.
CLIA '88 requires that QCs must be performed before any patient sample testing can begin and that QCs are required for every 8 hours of patient testing. The policy of Clinical Labs is to comply with CLIA '88. Sect. 493.1256(a) – (c)(2) states: *Have a control procedure that monitors the accuracy and precision of the complete analytical process. (and) detects immediate errors due to system failure, adverse environment conditions, and operator performance.*
GEM iQM (Intelligent Quality Management) meets the mandated QC requirements for frequency and levels for all analytes. iQM automatically analyzes a minimum of 2 levels of internal liquid QC every 4 hours and a third level every 24 hours, it evaluates QC data and notifies the operator when results exceed tolerance limits, it initiates corrective actions when tolerance limits are exceeded and disables the affected analyte(s) when self-correction is not achieved, and it continuously performs a series of

function checks that monitor for system failure and adverse environmental conditions, including clots in the patient sample.

Therefore, three levels of blood gas controls and 2 levels of hematocrit controls are required to be performed weekly, in conjunction with iQM being enabled. The display will notify the operator with a flashing “QC due now” prompt and list the control levels to run. If QCs are not performed, the instrument will go into auto-lockout and will not allow the operator to run any blood gases until the QC requirement is satisfied. This QC will always consist of all 3 levels of ContriL9 and two levels of GEM critCheck.

8. Failed controls must be repeated.
 - a. Discard the failed results, try again with a new ampule, if this fails, perform a 2-point calibration, then try again with a new ampule. If the control fails again, notify the supervisor and the POCT Specialist for the correct action to be taken.
 - b. The analyzer will auto-block failed analytes. Exception to repeating failed controls, you can choose to not repeat a control and accept auto-block of the failed analyte. Perfusionist must fill out a Corrective Action Report.
 - c. QC failure will not be cleared for the analyte unless the failure is cleared using the same lot on which it was originally set.
9. Calibration Verification Product (CVP). CVP 1 through 4 must be run after initiation of a new cartridge along with 3 levels of ContriL9 and 2 levels of GEM critCheck.
10. Performance Verification Product (PVP). PVP (5 levels) must be run twice per year (every six months) and must be run after any major service to the instrument.

VII. ASSAY PROCEDURE

1. Patient Sample Analysis
 - a. Specify the sample type by touching ARTERIAL, VENOUS, CAPILLARY, or OTHER at the Ready screen.
 - b. Samples can be analyzed whenever the instrument displays the Ready screen.
 - c. Mix the whole blood sample thoroughly by rolling between your hands or by inverting the syringe.
 - d. Remove the cap and expel all air from the syringe.
 - e. Expel a drop or two of the sample onto a gauze pad.
 - f. If clots are suspected, inspect the sample and if clotted another sample is required.
 - g. “Present sample now” appears. Select OK to begin aspiration.
 - h. Analyze the sample immediately by positioning the sample so that the sampler is near, but not touching the bottom of the syringe plunger.
 - i. Remove the syringe or tube from the sampler when the instrument beeps four times and prompts you to do so.

CAUTION: Care should be taken to remove the sample quickly so as not to bend the sampler.

- j. Enter your operator password by entering the appropriate characters on the keypad, press ENTER.

- k. Enter the Patient ID by entering the appropriate characters on the keypad, press ENTER.
 - l. Verify the patient demographics information. Touch Continue to accept the information, or Cancel to reject it.
 - m. Dispose of sample in a biohazard sharps container.
 - n. The instrument will take 85 seconds to process the sample and display results. During this time, a progress indicator will be displayed. The Patient Information screen will also be displayed to prompt for entry of sample information.
 - o. Press, "accept" to print result or "discard" if necessary.
2. Interference/Micro Clot Checking. The Gem Premier 3000 automatically checks for micro clots and interferences when analyzing patient samples. Reporting of patient results will be delayed while the check is performed. A message will be presented if an interference or clot was detected.
3. Flagging of Patient Results.
 - a. If a micro clot is detected the GEM Premier 3000 will beep three times, display a message, initiate a clot removal cycle, and the instrument will display a message recommending that an external QC be run to verify cartridge performance.
 - b. If interference is detected, the instrument will beep three times, display a message, and rinse the sensors. The message will remain displayed until acknowledged by the operator.
4. Instrument-Aborted Sampling. The instrument will not allow samples to be run if any of the following conditions exist:
 - a. If the Key Operator has enabled mandatory QC and a QC is overdue, the instrument will display *QC is overdue. Please run QC now*. Touch OK to return to the Ready screen to process the required QC.
 - b. If there are no analytes to report for the selected test panel (no analytes are checked in the Analyte Status Area), the instrument will display *No analytes to report. Test cancelled*. Touch OK to return to the Ready screen.
 - c. If a calibration that cannot be interrupted is in progress, the instrument will display a message and return to the Ready screen.
5. Cancellations from Calibrations
 - a. If an interruptible calibration is in progress, the instrument will interrupt the calibration and start the sampling process. To interrupt a calibration press the sample type, i.e. Arterial. After the completion of the patient sample, the calibration that was interrupted will begin again. An operator can interrupt a calibration up to 3 consecutive times.
 - b. The following calibrations cannot be interrupted:
 - i. Two-point calibrations during the first four hours of cartridge life.
 - ii. Two-point calibrations after the first four hours of cartridge life if the three previous two-point calibrations were interrupted for sample analysis.
 - iii. The first one-point calibration after sample analysis.
 - iv. Low O₂ calibrations cannot be interrupted

Note: Do not interrupt a calibration unless it is absolutely necessary to analyze an urgent sample. If a calibration is interrupted, always allow the sample analysis to complete.

6. Weekly Split Patient Testing

- a. Run at least one patient once a week. The Perfusionist assigned to the 0830 case is responsible for ensuring that comparison testing using patient blood gas sample is performed on all three GEM Premier 3000's and that the sample is sent to the Clinical Labs for hematocrit confirmation. If only 2 GEM 3000's are in use, both analyzers must be tested.
- b. At the "Ready" screen, press "Other". Run the blood gas on GEM #1, then immediately on GEM #2, then immediately on GEM #3. Enter the patient ID as the medical record number, followed by "1212".
- c. Save the blood gas and hematocrit printouts from all analyzers and attach to the "Comparison Testing On Wednesday Morning" form. See Appendix A.
- d. Send blood sample to Clinical Labs for routine Hematocrit. Under "other test" write HGRM (form #701-020).
- e. Time must be written on the lab slip and on the "Weekly Comparison Testing Form". Results will be found in the computer by using the time noted on the lab slip. If the lab calls back with the results, fill in the space provided. Or if the lab sends back the lab slip, attach the Lab Hct result to the form.
- f. Attach patient sample label to the "Weekly Comparison Testing Form".
- g. Sign and date form.
- h. Place form and documentation in the "Comparison Testing" binder.
- i. Acceptance Criteria: Tolerance limits for acceptance of results:

i.	pH	:+/- 0.04	Na	:+/-5
ii.	pCO ₂	:+/-5 mmol/L	K	:+/-0.5
iii.	pO ₂	:+/-10% (15% if >200mm)	iCa	:+/-0.10
iv.	Hct	:+/-3%		
- j. If the blood gas results exceed the tolerance limits, repeat with a second patient sample. Attach both printouts to the "Weekly Comparison Testing Form".
- k. Document reason for repeat testing and circle any analytes that exceed acceptance limits.
- l. If after the second repeat, blood gas results again exceed tolerance limits, run controls to verify analyzer performance.
- m. Follow troubleshooting procedure in the GEM Premier 3000 Procedure Manual.

7. Biannual Patient Testing for Blood Gases, Ionized Calcium, Lactate, Glucose and Hematocrit.

- a. A minimum of 5 samples should be run for patient correlations.
- b. Ensure weekly QC's were performed on all GEM Premier 3000's.
- c. Specimens from the OR, NCPL, or clinical labs are acceptable.
- d. All specimens must be run within 30 minutes.
- e. Run all specimens on the NCPL blood gas analyzers. Save an aliquot to run Hematocrit comparisons on the main Hematology analyzer in the Clinical lab.
- f. Acceptable Criteria: Tolerance limits for acceptance of results:

i.	Lactate	:+/- 0.3 mmol/L or 10% (whichever is greater).
ii.	Glucose	:+/- 10% or 6 gm/dl which ever is greater.

- g. If any results exceed the tolerance limits, repeat with additional patient samples.
- h. Give the results to the POCT specialist for review.

VIII. ASSAY PROCEDURAL NOTES

1. Cartridge

- a. Preparation, storage and expiration
 - i. No preparation is required and cartridges are stored at room temperature: 15 to 25°C (59 to 77°F) until their expiration date.
 - ii. Cartridge #24315089, for iQM pH, pO_2 , pCO_2 , Hct, Na^+ , K^+ , Ca^{++} , Glu, Lac, has 150 tests, with a life of 21 days maximum.
 - iii. Cartridge #24330089, for iQM pH, pO_2 , pCO_2 , Hct, Na^+ , K^+ , Ca^{++} , Glu, Lac, has 300 tests, with a life of 21 days maximum.
 - iv. The cartridge may be used up to and including the expiration date shown on the packaging. On-board Expiration: The GEM Premier 3000 PAK iQM cartridge must be replaced when the maximum number of tests is run, or when cartridge use-life is reached, whichever comes first.
- b. Cartridge Removal and Insertion
 - i. Touch "Cartridge" on the top of the main screen, and then touch "Remove Cartridge". The screen will display "Are you sure you want to remove cartridge?" Press Yes.
 - ii. Unlatch the cartridge door on the instrument's right side by sliding the lock handle to the front and opening the door. Ensure that the cartridge is within its expiration date. The GEM Premier 3000 will not accept an expired cartridge.
 - iii. Remove the old cartridge from the compartment by pulling it straight out.
 - iv. Open the foil bag, and remove the new cartridge.
 - v. Check the inside of the foil bag to be sure that it is dry.

Caution: If there is any moisture inside the foil bag, DO NOT USE the cartridge. Open a fresh GEM Premier 3000 PAK cartridge and call Technical Support at Instrumentation Laboratory.

- vi. Grasp the tab end of the plastic protective cover. Pull firmly to remove the cover.

Note: The cartridge must be inserted into the instrument within one minute of removing the protective cover.

- vii. Align the cartridge according to the labels. Using a rapid, smooth, continuous motion, insert the cartridge into the instrument's cartridge compartment.

Note: The cartridge will not insert all the way into the compartment. A small lip of the cartridge will rest on the door. When the instrument has successfully read and validated the barcode and the date/time has been accepted, it will prompt you to close the cartridge door. If the instrument displays a message that the barcode reader did not read the label, follow the directions on the screen to complete the

insertion process. The instrument will make three attempts to read the barcode before prompting the operator to use the barcode wand. If the barcode cannot be read, contact IL Technical Support.

- viii. The instrument will prompt: *Is the date/time correct?* If correct, select YES to proceed with warm-up. Otherwise, select NO to correct the date/time. The instrument will prompt: *Remove cartridge.* Remove the cartridge to begin the process again, changing the date and time when prompted.
- ix. Close the door, and slide the lock handle toward the back of the unit.
- x. The cartridge door will lock. The GEM Premier 3000 will display the Cartridge Warm-up screen.

c. Cartridge Warm-up

- i. Cartridge warm-up requires approximately 30 minutes. Samples cannot be analyzed during cartridge warm-up, but the instrument does allow access to many of the menu commands.
- ii. During cartridge warm-up, the instrument brings the measuring chamber to the proper temperature and performs several rinses and calibrations. If an error occurs during warm-up, the instrument will prompt for removal of the cartridge.
- iii. When cartridge warm-up is complete, the instrument will display that CVP is needed. CVP and aqueous quality controls must be run before any patient sampling resumes.
- iv. The cartridge must be replaced when its use-life or sample capacity has been reached. A cartridge must also be replaced if the power has been off for more than one hour or off more than 20 minutes if blood has rested on the sensors or an "A" or low O₂ calibration is in progress. The instrument displays *Remove and discard the cartridge*, as well as a reason for the removal request.
- v. The instrument saves the data from 20 to 40 cartridges. After 40 cartridges have been inserted, the instrument will prompt you to perform database maintenance.

2. Controls

a. Running Controls

- i. On the "Ready " screen touch "QC", there are three ways to load QC,
 - (a) *Using the Automatic ampule spinner.* Lift the door to the ampule spinner, insert and release the ampule. The reader will now spin the ampule and read the bar code.
 - (b) *Using the automatic bar code wand.* With the bar code wand attached to the instrument, and without lifting the plastic cover, scan the appropriate bar code label on the QC carton. It is important that the correct bar code is scanned.
 - (c) *Using the Manual method.* Perfusionists are to use this option only in the most emergent situations. After pressing "QC", the operator will be prompted to select the correct lot number and level of QC. Double check the label with the lot on the screen before analyzing.

b. Preparing Controls

- i. Mix the solution by vigorously shaking the ampule.
- ii. Gently swirl the solution from the tip of the ampule to restore solution to the bottom part of the ampule. Allow bubbles to dissipate for at least 10 seconds.
- iii. Use the instrument's ampule breaker to snap off the ampule neck.

CAUTION: Analyze QC solution within one minute of opening the ampule.

- iv. Position the ampule on the sampler when the screen instructs you to do so. Make sure the sampler is near, but not touching, the bottom of the ampule. Touch OK.
 - v. Remove ampule **AFTER** the instrument beeps four times and displays the message *Remove the sample*. The instrument will wait two seconds for removal of the sample before withdrawing the sampler.
 - vi. Dispose of ampule in an appropriate waste container.
 - vii. The instrument will take 85 seconds to process the sample and display results. During this time, a progress indicator will be displayed. The Sample Information screen will also be displayed to prompt for entry of sample information.
- c. QC Sample Information
- i. Touch Operator ID, enter Operator ID, and then press OK. Operator ID can be up to 16 alphanumeric characters.
- d. QC Sample Results
- i. Measured results will be displayed along with the expected results. If the measured values fall within the expected range, "Pass" will be displayed. If a measured value falls outside the expected range, the screen and printout indicate a failure with the message "Fail" and an "F" on the hard copy printout next to the analyte, which has failed.
 - ii. QC data is automatically downloaded into an on-board computer memory for future analysis and transferred to disk for record keeping.

Note: The instrument stores all data generated while a cartridge is in service and for at least 20 cartridges.

- e. QC Sample Disposition
- i. Touch the ACCEPT button after the sample has been reviewed and deemed satisfactory and after any user-entered information has been edited.
 - ii. If one or more analytes failed QC, you will be prompted to confirm that the failed QC results will be included in QC lot statistics. If NO is selected, the accept request will be aborted. If YES is selected, the instrument will:
 - (a) Set the sample's disposition to ACCEPTED, and save the sample to the database.
 - (b) Print a sample report.
 - (c) Satisfy the QC schedule.
 - (d) For ACTIVE QC lots, flag any failed analytes as having failed QC for that lot.

- (e) Return to the Ready screen.
 - iii. Touch the DISCARD button after the sample has been reviewed and deemed not valid. No further editing of the sample will be allowed, and **the sample's disposition cannot be changed from DISCARDED**. The instrument will prompt to confirm the disposition. If NO is selected, the discard request will be aborted. If YES is selected, the instrument will:
 - (a) Set the sample's disposition to DISCARDED, and save the sample to the database.
 - (b) Return to the Ready screen.
 - f. QC Failure
 - i. If the screen and printout indicate a failure, re-test with a freshly opened QC ampule of the same level.
 - ii. If results still indicate a failure, use 2-PT CAL on the DIAGNOSTICS menu to run a 2-pt calibration, then repeat with a freshly opened QC ampule of the same level and lot.
 - iii. If the problem persists contact the POCT Specialist and or Technical Support at Instrumentation Laboratory (800) 678-0710.
 - iv. In consultation with the POCT Specialist, determine if the cartridge can be used for those analytes that passed QC.
 - v. Contact IL Technical Services and replace the cartridge if IL gives approval.
 - vi. Obtain a Return Goods Authorization (RGA) number for the cartridge.
 - vii. Download the data to a diskette. Go to Diagnostics, Copy IL, then select the correct cartridge.
 - viii. Insert a new diskette and make a second copy of cartridge data.
 - ix. Write the instrument I.D., cartridge information and "in" and "out" dates on the label of both diskettes.
 - x. Write the RGA number on both diskettes labels.
 - xi. Fill out Corrective Action Form and leave both diskettes with the form in the designated location
 - xii. Copy of the diskette will be sent to IL GEM Division for data analysis. Unused portion of the cartridge will be credited.
 - xiii. If the perfusionist who pulls the cartridge is too busy with the case to contact Instrument Laboratory, he/she must do so at the next available opportunity and before his/her shift ends. He/she is responsible for the completion of the above steps.
- 3. Calibration. GEM Premier 3000 calibrations are automatic and a two-point calibration is used for all parameters. Calibration values are read into the GEM Premier 3000 via the cartridge bar code. When you insert a cartridge, the instrument pumps Reference Solution B into the electrode chamber and hydrates the sensors for 15 minutes. One- and two-point calibrations are performed according to the schedules below.
 - a. Two-point calibrations last approximately 2.5 minutes (4.5 min within the first 6 hrs). During this time, the instrument will remain at the Ready screen. The calibration progress indicator will appear at the bottom of the Ready screen. After calibration, a printout is generated. If all sensors are operating correctly, the printout includes a "No Errors" message. (Note: the content of the Calibration Report is determined by the option chosen during instrument configuration.) If a

slope or drift error is detected, the analyte, which has failed, will be flagged with a “slope error” or a “drift error” message. The instrument will then withhold results for that analyte until sensor performance returns to normal.

- b. One-point calibrations occur every 30 minutes, at a minimum, and after every patient sample.

Calibration Schedules – One Point

Cartridge Life after Warm-up	Calibration Frequency
0.5 to less than 3 hours	every 2 minutes
3 hours to less than 6 hours	every 4 minutes
6 hours to less than 10 hours	every 6 minutes
10 hours to less than 20 hours	every 10 minutes
20 hours to less than 40 hours	every 15 minutes
40 hours to less than 80 hours	every 20 minutes
80 hours or greater	every 30 minutes

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

Calibration Schedules - Two-Point

Cartridge Life after Warm-up	Calibration Frequency
30 min. to less than 50 min.	every 20 minutes
50 min. to less than 80 min.	every 30 minutes
80 min. to less than 2 hours	every 40 minutes
2 hours to less than 8 hours	every hour
8 hours to less than 20 hours	every 2 hours
20 hours to less than 40 hours	every 3 hours*
40 hours or greater	every 4 hours*

Or 20 samples, whichever comes first.

During the recovery following instrument restart, the instrument will perform a one-point or two-point calibration as needed before the Ready screen is displayed, then the calibration frequency will resume according to the previous schedule.

- c. Low O₂ Calibration Schedule

Low O₂ calibrations occur once every 24 hours throughout cartridge life, after warm-up. Following the low O₂ calibration, the instrument will perform one-point calibrations every three minutes for 15 minutes, then return to the previous schedule. The Key Operator determines the exact time of the day for performing the low O₂ calibration during instrument setup.

d. Calibration Failure

If an automatic one- or two-point calibration fails, the GEM Premier 3000 will automatically initiate up to two additional one- or two-point calibration sequences in an effort to recover from a failure. If the sensor does not respond to the automatic two-point calibrations, then the appropriate error message will be printed on the calibration report, and the status indication on screen turns red. There are three actions you may choose to take if these automatic calibrations fail to clear the error:

- i. Continue to use the cartridge and report only the results from the working sensors.
- ii. Initiate a manual two-point calibration.
- iii. If repeated calibrations and or QC failures occur even after changing cartridges and the perfusionist deems the GEM Premier 3000 unusable, the perfusionist may send samples over to the other GEM Premier 3000's or send the sample to Clinical Labs. Refer to the Clinical Lab Stat Procedure in the reference section of the Perfusion Service Lab Manual.

NOTE: Because the instrument will automatically perform up to two one- or two-point calibrations after a calibration error has occurred, if you initiate a manual calibration, you may significantly delay sensor recovery.

e. Calibration Interruption

Calibrations can be interrupted to analyze samples in certain circumstances. If a sample is run when the instrument is performing a calibration that cannot be interrupted, it will display the message *Calibration in progress*.

The following calibrations cannot be interrupted to analyze a patient sample:

- i. Two-point calibrations during the first four hours of cartridge life.
- ii. Two-point calibrations after the first four hours of cartridge life if the three previous two-point calibrations were interrupted for sample analysis.
- iii. Any low O₂ calibration.
- iv. The first one-point calibration after sample analysis.

The following calibrations cannot be interrupted to analyze a QC or CVP sample:

- i. Any low O₂ calibration.
- ii. Any two-point calibration.
- iii. The first one-point calibration after sample analysis.

Note: Do not interrupt calibrations in progress unless it is absolutely necessary to analyze an urgent sample. If a calibration is interrupted, always allow the sample analysis to complete.

4. CVP Sampling

- a. To enter a new lot of CVP material, the Key Operator will press Configuration from the Main Menu, Press iQM Setup, press CVP Material Setup:

- i. To Add a new lot, use the bar code scanner and scan in each new lot, CVP 1 through 4. A beep will sound after the scanning has been successful.
- ii. To delete old or expired CVP material, press Delete, press Yes to delete.
- b. Remove CVP levels 1 through 4 and leave at room temperature at least 8 hours prior to use.
- c. Touch CVP on the Ready screen.
- d. Lift the door to the ampule spinner and insert and release the ampule. The reader will spin the ampule and read the barcode.
- e. If the lot number is not found, the instrument will prompt for a different ampule or for selection of material from a list of defined material.
- f. If the lot number matches the lot number of a defined material, the instrument will prompt for sample aspiration. If the selected material only contains analytes that have failed calibration, the instrument will abort the sampling process.
- g. Prepare the CVP material:
 - i. Mix the solution by vigorously shaking the ampule.
 - ii. Gently swirl the solution from the tip of the ampule to restore solution to the bottom part of the ampule. Allow bubbles to dissipate for at least 10 seconds.
 - iii. Use the instrument's ampule breaker to snap off the ampule neck.

CAUTION: Analyze CVP solution within one minute of opening the ampule.

- iv. Position the ampule on the sampler when the screen instructs you to do so. Make sure the sampler is near, but not touching, the bottom of the ampule. Touch OK.
 - v. Remove ampule AFTER the instrument beeps four times and displays the message *Remove the sample*. The instrument will wait two seconds for removal of the sample before withdrawing the sampler.
 - vi. Dispose of ampule in an appropriate waste container.
 - vii. The instrument will take 85 seconds to process the sample and display results. During this time, a progress indicator will be displayed. The Sample Information screen will also be displayed to prompt for entry of sample information.
- h. CVP Sample Information
 - i. Enter Operator ID as necessary.
 - ii. Enter an optional sample comment to record a short description with the sample. This comment, up to two lines of 24 characters each, will be saved, printed, and transmitted with the sample.
 - i. CVP Sample Results
 - i. Measured results will be displayed along with the expected results. If the measured values fall within the expected range, "Pass" will be displayed. If a measured value falls outside the expected range, the screen and printout indicate a failure with the message "Fail" and an "F" on the hard copy printout next to the analyte, which has failed.

- ii. CVP data is automatically downloaded into an on-board computer memory for future analysis and transferred to disk for record keeping.

NOTE: The instrument stores all data generated while a cartridge is in service and for at least 20 cartridges.

j. CVP Sample Disposition

- i. If one or more of the CVP analytes failed and you select the ACCEPT or DISCARD button, the instrument will prompt with the message: *CVP failure. Perform 2-point calibration before repeating the failed CVP sample.* Touch OK, then initiate a 2-point calibration from the DIAGNOSTICS menu prior to repeating the CVP sample.

NOTE: The sensor status on the Ready screen will not change to Green/OK until all CVP materials associated with that analyte are run and passed. Sensor status will remain as either yellow/Pending CVP, or red/Failed CVP. CVP failures will be cleared when the failed CVP material is run and passed or when the cartridge is replaced.

- ii. Touch the ACCEPT button after the sample has been reviewed and deemed satisfactory and after any user-entered information has been edited. No further editing of the sample will be allowed.
- iii. When you accept a CVP sample, the instrument will:
 - (a) Set the sample's disposition to ACCEPTED, and save the sample to the database.
 - (b) Print a sample report.
 - (c) Satisfy the CVP requirement.
 - (d) Return to the Ready screen.
- iv. Touch the DISCARD button after the sample has been reviewed and deemed not valid for some reason. No further editing of the sample will be allowed, and **the sample's disposition cannot be changed from DISCARDED**. The instrument will prompt to confirm the disposition. If NO is selected, the discard request will be aborted. If YES is selected, the instrument will:
 - (a) Set the sample's disposition to DISCARDED, and save the sample to the database.
 - (b) Return to the Ready screen.

k. CVP Failure

- i. If a measured value falls outside the expected CVP range for an analyte, the screen displays CVP FAIL and highlights any analyte that failed. To correct the failure:
 - (a) Use 2-PT CAL on the DIAGNOSTICS menu to run a 2-pt calibration before trying to repeat the failed CVP run.
 - (b) Repeat the CVP with freshly opened CVP material from the same CVP lot.
- ii. If the failure is corrected, ACCEPT the CVP results.

- iii. If the original failure is corrected but a new analyte fails, repeat the CVP with freshly opened CVP material from the same CVP lot one more time.
- iv. If the failure is corrected, ACCEPT the CVP results.
- v. If the failure is not corrected, remove the cartridge and notify Technical Support (see “5.5 Cartridge Removal”).

NOTE: If a CVP failure persists, the analyte(s) will not be available.

IMPORTANT: Ensure that enough CVP material is on hand toward the end of a lot to clear any existing failure conditions. Only CVP material from the same lot can clear an error condition for that lot.

- vi. If a patient sample is run while an analyte is in the Pending CVP or Failed CVP state, the result will not be reported. On the screen, the result will be flagged with “V” and blanked out. The printed report will display “PENDING CVP” or “FAILED CVP” as appropriate.

NOTE: Upon successful completion of CVP, daily QC’s must be run.

5. Instrument Maintenance

a. Instrument Cleaning

- i. Wipe the outer surface of the case using a soft cloth moistened with a fresh solution of 10% liquid chlorine bleach in water.
- ii. Wipe the surface of the touch screen using a soft cloth moistened with water or a mild, non-bleach cleaning solution.

Caution: Do not use an abrasive cleanser, bleach, or organic solvent, as this will scratch the screen. Do not pour solution directly onto the screen.

- iii. Inspect the area into which the cartridge inserts, and clean as necessary.

b. Instrument Maintenance

- i. Empty Ampule-Breaker Storage Container. Periodically remove the QC ampoule breaker storage container and empty contents into an appropriate container.
- ii. QC solution stains may be removed using a mild cleaning solution.

c. Replace Printer Paper

- i. The MESSAGES button located at the lower right corner of main screen will turn yellow when the internal printer runs out of paper and the end of a roll of paper contains a red stripe.
- ii. Use only paper supplied by Instrumentation Laboratory. Other papers can damage the printer.
- iii. Open the door to the printer paper compartment.
- iv. Move the lever “UP.” The silver lever is located on the upper left hand side.
- v. Remove the spent paper roll.

- vi. Place the new paper roll into the cup in the base of the door, with the paper coming over.
- vii. Push the paper into the printer and thread it over the top roller.
- viii. Move the lever “DOWN.”
- ix. Thread the paper over the door, and close the door.

Note: The GEM Premier 3000 uses thermal paper that can only be printed on one side.

IX. LIMITATIONS OF PROCEDURE

Limitation	Description
Contamination with Room Air	Especially samples having a very low or high pO_2 content. Similarly, pCO_2 may be affected and subsequently pH and Ca^{++} results as well.
Metabolic Changes	Errors can occur due to metabolic changes if there is a delay in the measurement of the samples.
Elevated White Blood Cells or Reticulocyte Counts	Samples will deteriorate more rapidly, even when kept in ice water.
Improper Mixing	Errors will be introduced if the sample is not properly mixed prior to measurement.
Changes to Manufacturer’s Instructions or Method Verification Protocols	Data obtained may be compromised.
Under-Heparinized Sample	Blood clot can form in the sensor chamber causing various sensor failures if sample is not properly heparinized.

1. Interferences

- a. The following substances can potentially interfere with sample analysis:
 - i. Severely abnormal plasma osmolarities or abnormal levels of proteins or lipids.
 - i. Benzalkonium Chloride: Arterial lines and sampling devices coated with Benzalkonium Chloride cause falsely elevated sodium and ionized calcium readings.
 - ii. Benzalkonium Heparin: Arterial lines and sampling devices coated with Benzalkonium Heparin cause falsely elevated sodium and ionized calcium readings.
 - iii. Thiopental sodium: May interfere with the sodium, potassium, pCO_2 and ionized calcium readings.
 - iv. The anesthetic halothane may produce unreliable pO_2 results due to interferences with pO_2 sensor.
- b. The following compounds **did not** show noticeable interference with glucose and lactate determinations at the tested level:

Compound	Test Level	High "Normal" Level
Ascorbic acid (vitamin C)	3 mg/dL	2 mg/dL
Uric acid	20 mg/dL	7 mg/dL
Dopamine	2 mg/dL	0.03 mg/dL
Dobutamine	2 mg/dL	0.03 mg/dL

The following tested drugs may interfere with glucose or lactate determination, causing falsely low readings:

Drug	Interference Observed	High "Normal" Level
Flaxedil	? 2 mg/dL	1.4 mg/dL
Ethanol	? 350 mg/dL	100 mg/dL (toxic)

The following tested drugs may interfere with glucose and lactate determinations, causing falsely elevated readings:

Drug	Interference Observed	Maximum Therapeutic Level
Acetaminophen (Tylenol)	? 15 mg/dL	2 mg/dL
Isoniazide (Nydrasid)	? 2 mg/dL	0.7 mg/dL (toxic)
Thiocyanate	? 10 mg/dL	2.9 mg/dL
Hydroxyurea	? 0.5 mg/dL	2 mg/dL

The following tested anticoagulants may interfere with glucose and lactate determinations, causing falsely low readings:

Anticoagulant	Positive Interference
Sodium fluoride	? 1 g/dL
Potassium oxalate	? 1 g/dL

2. Interference Notes

- a. Cartridges employ Failure Pattern Recognition (FPR) checks. One of the FPR checks that the GEM Premier 3000 recognizes is for the positively charged lipophilic compound Benzalkonium.
- b. Following sample analysis, and analysis of Process Control Solution B, if Benzalkonium Chloride or Benzalkonium Heparin patterns are detected, the following message will be displayed on the analyzer: *Sensor Interference Detected for Na and iCa on last sample likely due to Benzalkonium.*
- c. The GEM Premier 3000 offers the operator the ability to enable flagging of patient results if an interference pattern is detected. In addition, this option, when enabled, delays the reporting of results until Process Control Solution B is evaluated for interference patterns, following sample analysis. If flagging of patient results for an interference is enabled, the following message (plus progress bar) will be presented while the post analysis Process Control Solution B check is underway: *Checking for presence of interference and micro clot.* This message will remain

displayed until the Process Control Solution B analysis is complete. If an interfering substance pattern is detected, the affected blood result(s) will be flagged. In addition, the analyzer will beep three times to alert the operator. The following message disappears only after operator acknowledgment: *Sensor Interference Detected for Na and iCa on last sample likely due to Benzalkonium*

- d. Another FPR check that the GEM Premier 3000 recognizes is for negatively charged lipophilic compounds, such as Thiopental Sodium. Thiopental Sodium is also known by other names, including: thiomebumal sodium, penthiobarbital sodium, thiopentone sodium, thionembutatal, pentothal sodium, nesdonal sodium, intraval sodium, traoanal, and thiothal sodium.
- e. Following sample analysis and analysis of Process Control Solution B, if the associated pattern is detected in Process Control Solution B, the following message will be displayed on the analyzer: *Sensor Interference Detected for xxxxx on last sample (where xxxxx is the analyte or analytes affected).*

X. RESULT REPORTING

- 1. The Patient Sample Results screen is displayed after patient results are ready, and you have touched EXIT at the Patient Information screen (if that screen was presented), and interference/micro clot determination, if enabled, has been completed. The Patient Sample Results screen will be displayed for 90 seconds, the perfusionist must accept or discard the patient sample. The instrument will then return to the Ready screen. Patient results are automatically downloaded into on-board computer memory for future review and documentation.
- 2. Analyte Displayed Ranges

Measured Analytes	Displayed Ranges
PH	6.80 to 7.80
pCO ₂	5 to 115 mmHg
pO ₂	0 to 760 mmHg
Na ⁺	100 to 200 mmol/L
K ⁺	1.0 to 20.0 mmol/L
Ca ⁺⁺	0.10 to 5.00 mmol/L
Hct	15 to 65%
Glucose	20 to 500 mg/dL
Lactate	0.3 to 15 mmol/L

CAUTION: A DASH (-) on the display or printout appears when there is an error in the calculation of the derived parameter.

Derived Analytes	Displayed Ranges
HCO ₃ ⁻	3.0 to 60.0 mmol/L
HCO ₃ ⁻ std	3.0 to 60.0 mmol/L
TCO ₂	3.0 to 60.0 mmol/L
BE(ecf)	-30.0 to +30.0 mmol/L
BE(B)	-30.0 to +30.0 mmol/L
SO ₂ c	0 to 100%
Ca ⁺⁺ (7.4)	0.10 to 5.00 mmol/L

3. Reference Ranges, Adult

		Reference Range	Panic Values	Reportable Range
pH	Arterial	7.35 to 7.45	<7.20 or >7.55	6.8 to 7.8
	Venous	7.31 to 7.41	<7.20	
pCO₂ (mm/Hg)	Arterial 0-1 year	35 to 45	<25 or > 65	5 to 115
	Arterial >1 year	32-48	<25 or > 65	
	Venous	41-51	>75	
pO₂ (mm/Hg)	Arterial 0 to 30 days	80 to 100	<40 or >100	0 to 760
	> 30 days:	83-108	<40	
	Venous	35-40		
NA (mmol/L)		136 to 146	<125 or >155	100 to 200
K (mmol/L)	0- 6 months	3.0 to 5.4	<3.0 or >6.0	0.1 to 20.0
	> 6 months	3.4 to 4.5		
CA⁺⁺ (mmol/L)	0- 6 months:	0.95 to 1.50	<0.80 or >1.55	0.10 to 5.00
	> 6 months:	1.15 to 1.29		
Glucose (g/dL)	Neonate	55 to 115	<40 or >150	20 to 500
	Pediatric & Adult	70 to 199	<60 or >400	
Lac (mmol/L)		0.0 to 2.0		0.3 to 15.0
Hct (%)	0 to 7 days	45 to 67	<25 or > 75	15 to 65
	8 to 14 days	42 to 66		
	2 to 4 weeks	39 to 63		
	1 to 2 months	31 to 55		
	2 to 3 months	28 to 42		

	3 to 6 months	29 to 41		
	6 to 24 months	33 to 39		
	2 to 5 years	34 to 40		
	5 to 12 years	35 to 45		
	Male 12 to 15 years	37 to 49		
	Male 15 to 18 years	38 to 49		
	Male > 18 years	41 to 53		
	Female > 12 years	36 to 46		
HCO₃ (mmol/L)		22-27		Report < or > if outside of reportable range for all tests
BE (mmol/L)	Arterial	-3 to +3		
sO₂c (%)	Arterial	95 to 99 %		

- a. Any result outside the Physician Alert Value must be confirmed and the anesthesiologist and surgeon on the case notified. On the perfusion record, note that the value was confirmed and the time and date physician on the case was notified.

4. Reporting Format

The resolution and units that the instrument uses for reporting of results are shown in the following tables.

Measured Analytes	Resolution	Units
Acid/base	0.01	pH (no units)
pCO ₂ , pO ₂ , A-aDO ₂ , pAO ₂ , P ₅₀ , and BP	1	MmHg
Na ⁺	1	mmol/L
K ⁺	0.1	mmol/L
Ca ⁺⁺	0.01	mmol/L
Temperature		Celsius (°C)
Glucose	1	mg/dL
Lactate	0.1	mmol/L
Hct	1	%

Derived Analytes	Resolution
------------------	------------

		Units
HCO ₃ ⁻	0.1	Mmol/L
HCO ₃ ⁻ std	0.1	Mmol/L
TCO ₂	0.1	Mmol/L
BE(ecf)	0.1	Mmol/L
BE(B)	0.1	Mmol/L
SO ₂ c	1	%
Ca ⁺⁺ (7.4)	0.01	Mmol/L

5. Linearity

pH	6.80 - 7.80
pCO ₂	5 - 115 mmHg
pO ₂	0 - 760 mmHg
Na ⁺	100 - 200 mmol/L
K ⁺	0.1 – 20.0 mmol/L
Ca ⁺⁺	0.1 - 5.0 mmol/L
Glucose	20 - 500 mg/dL
Lactate	0.3 - 15 mmol/L
Hct	15 – 65%

XI. RECORDS MAINTENANCE

1. After a cartridge has been used or expired, download all data to a diskette and deliver to the POCT Specialist for review. See copy cartridge data below.
2. All maintenance records should be maintained on the appropriate form/s and kept in the binder next to the instruments.

3. Copy Cartridge Data

- a. You can copy the data that the instrument has generated while a cartridge is in use whenever the instrument is at the Ready screen, or between instrument acknowledgment of cartridge removal and insertion of a new cartridge.

NOTE: If the disk already contains cartridge data, the instrument will give you the opportunity to replace the disk or overwrite the data.

- b. Touch COPY CART. DATA on the DIAGNOSTICS menu.
- c. Select the cartridge to be copied by touching its entry in the listing.
- d. Touch COPY.
- e. Insert a blank, PC-formatted, high-density 3.5” diskette, with its label facing the front of the instrument.
- f. Touch OK. When copying is complete, the instrument will display a message stating so.
- g. Remove the disk, and touch EXIT.

- h. Write-protect the disk by sliding the square tab on the back of the disk toward the edge to expose the small hole.
- i. Label the diskette with the GEM serial number; insertion date; cartridge serial number and operator initials. Deliver the diskettes to the POCT Specialist.

XII. REFERENCES

1. Procedures for the Collection of Arterial Blood Specimens; Approved Standard-Third Edition. NCCLS document H11-A3, NCCLS 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, 1999
2. Instrumentation Laboratory GEM Premier 3000 Operators Manual, P/N 2400513, 2002.
3. Gornall, A.G.: Applied biochemistry of clinical disorders. Chapter 6, Respiratory Disorders, p. 94, 1980.
4. Burke, M.D.: Blood gas measurements. Post grad. Med. 64:163, 1978.
5. Gradwohl's Blood gas analysis and acid-base balance: Principles & Techniques. Chap. 17, p. 351, 1980. Fleisher & Schwartz.
6. Pesce, A. and Kaplan: Methods in Clinical Chemistry, C.V. Mosby Co., St. Louis, MO, 1987.
7. Shapiro, B. Harrison & Walton: Clinical Application of Blood Gases, Year Book Medical Publishing, Inc., Chicago, IL, 1978.
8. Ng, R. H, et al: Factitious cause of unexpected arterial blood-gas results. N Engl J Med 310:1189-1190, 1984.
9. Westgard, J. O., Groth, T: Power Functions for Statistical Control Rules, Clinical Chemistry, 25:394, 1980.
10. Burnett, R.W., et.al: Recommendations on Whole Blood Sampling, Transport, and Storage for Simultaneous Determination of pH, Blood Gases, and Electrolytes. Journal of the International Federation of Clinical Chemistry, Sept. 1994.
11. Interference Testing in Clinical Chemistry - Proposed Guideline, NCCLS Document EP7-P, Vol 6, No. 13.
12. McMahon McNulty SE, Sharkey SJ, Asam B, Lee JH. 1993. Evaluation of STAT-CRIT hematocrit determination in comparison to Coulter and centrifuge: the effects of isotonic hemodilution and albumin administration. Anesth. Analg. 76:830-834.
13. DJ, Carpenter RL. 1990. A comparison of conductivity-based hematocrit determinations with conventional laboratory methods in autologous blood transfusions. Anesth. Analg. 71:541-544.
14. Hopfer SM, Nadeau FL, Sundra M, Makowski GS. 2004. Effect of protein on hemoglobin and hematocrit assays with a conductivity-based point-of-care testing device: comparison with optical methods. Ann. Clin. Lab. Sc. 34:75-82.

APPENDIX A

WEEKLY COMPARISON TESTING FORM

PURPOSE

To comply with CLIA, Subpart P, 493.1709(a): When a test procedure is performed on multiple instruments, the relationship between the different instruments must be evaluated and defined periodically.

POLICY

Once a week, the Adult Perfusionist assigned to the 0830 case is responsible for ensuring that comparison testing using patient blood gas sample is performed on all GEM Premier 3000's and that the sample is sent to Clinical Labs for hematocrit confirmation. In the event that there is no adult case, the Pediatric Perfusionist assigned to the case in room 10 will be responsible for ensuring the testing is completed.

PROCEDURE

1. Ensure 3 levels of blood gas controls and 2 levels of hematocrit controls were performed within the past week. If not, run all 5 levels of controls.
2. Draw enough blood from a patient for running Blood Gases on all GEM Premier 3000 that are currently in use and for a Routine Hematocrit
3. On the analyzer, at the "Ready" screen, press "Other". Run the blood gas on GEM #1, then immediately on GEM #2, then immediately on GEM #3, or for all analyzers currently in use. Enter the patient ID as the medical record number, followed by "1212".
4. Save the blood gas and hematocrit printouts from all analyzers and attach to this form.
5. Send blood sample to Clinical Labs for a routine Hematocrit. Under "other test" write HGRM (form #701-020).
6. MAKE SURE TO PUT A TIME ON THE LAB SLIP AND ON THIS SHEET. TIME: _____
We will find the results in the computer by using the time.
7. If the lab calls back with the results, fill in the space provided. LAB
HCT: _____
Or if the lab sends back the lab slip, attach the Lab Hct result to this form.
8. Attach patient sample label to this form.
9. Sign and date form.
10. Place form and documentation in the "Comparison Testing" binder.
11. Acceptance Criteria: Tolerance limits for acceptance of results:
pH :+/- 0.04 Na :+/- 5 mmol/L
pCO2: +/-5 mmHg K :+/- 0.5 mmol/L
pO2 :+/-10% (15% if >200) iCa :+/- 0.10
Hct :+/-3 (or 6%)
12. If blood gas results exceed the tolerance limits, repeat with a second patient sample. Attach both printouts to this form.
13. Document reason for repeat testing and circle any analytes that exceed acceptance limits.
14. If after the second repeat, blood gas results again exceed tolerance limits, run controls to verify analyzer performance.
15. Follow troubleshooting procedure in the GEM Premier 3000 Procedure Manual.

Performed by: _____
Date: _____

Place Patient Label Here
