

# GEM<sup>®</sup> PREMIER<sup>™</sup> GEM3500 with iQM<sup>®</sup>

*Operator's Manual • Rev 01 • P/N 26000250 • March 2015*



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Laboratory**

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**Appendix A: CO-Oximetry****Appendix B: Draft Standard Operating Procedure****Appendix C: Warranty**

# 1 Installation

**GEM Systems comply with approved relative European Directives and/or Harmonized Standards.**

Under the Clinical Laboratory Improvement Amendment of 1988 (CLIA '88), the GEM® Premier 3500 has been classified Moderately Complex.

## 1.1 General Information

This manual contains the procedures necessary to operate, maintain and troubleshoot the IL GEM Premier 3500 system (*figure 1.1*).

Personnel responsible for operating and maintaining the instrument should read and understand the included material prior to use.

This manual should be kept near the instrument or in a suitable location for reference as required.

This section includes a general description of the Instrumentation Laboratory GEM Premier 3500 system: product use, principles of operation and instrument description.

**Figure 1.1: GEM Premier 3500 System**



Instrumentation Laboratory will begin using some new symbols in product and instrument labeling. These symbols will be required by some regulatory agencies.

---



Confirms the product meets EU (European Union) guidelines applicable to the product and, in particular, that all safety requirements have been met.

---



Catalog number

---



Consult operating instructions

---



Control

---



Date of manufacture

---



In-vitro diagnostic medical device

---



Number of samples

---



Lot number

---



Serial number

---



Temperature limitation

---



Use-by date (expiration date)

---

## 1.2 Introduction

The Instrumentation Laboratory GEM Premier 3500 may be used with a variety of GEM Premier 3500 PAK® cartridges, such as:

- Blood Gas/Hematocrit
- Blood Gas/Hematocrit/Electrolytes
- Blood Gas/Hematocrit/Electrolytes/Metabolites

The screens that are pictured in this manual are appropriate for the full menu of test capabilities (Blood Gas/Hematocrit/ Electrolytes/Metabolites cartridge). If other cartridges are used, the options on the screens will be relative to the cartridge installed. Specifically, the

Ready and Patient Results screens will reflect only those tests that the installed cartridge is able to perform.

Basic operation and maintenance of the analyzer is similar for all cartridges, and the information in this manual applies to operation with all cartridges.

## 1.3 Using the Manual

Throughout this manual, you should pay particular attention to paragraphs marked as WARNING, CAUTION, BIOHAZARD, or NOTE. These paragraphs will be labeled and contain important information.

---



WARNING: statements provide information about electrical hazards.

---



CAUTION: statements provide information about personal injury hazards and product damage hazards.

---



BIOHAZARD: statements alert the user to potentially biohazardous conditions.

---



NOTE: statements contain important user information.

---

## 1.4 Product Use

The GEM Premier 3500 is designed as a portable system for use by health care professionals to rapidly analyze whole blood samples, in any clinical setting. The instrument provides both measured and calculated results for blood gases, hematocrit, electrolytes, glucose, and lactate.

The instrument may also be used in conjunction with an external IL CO-Oximeter device, the IL 682™ or GEM OPL®, with CO-Ox results integrated into the GEM Premier 3500 results.

### Measured Analytes

The system measures the following whole blood analytes:

---

Hydrogen ion (pH)  
Carbon dioxide partial pressure ( $pCO_2$ )  
Oxygen partial pressure ( $pO_2$ )  
Sodium ion ( $Na^+$ )  
Potassium ion ( $K^+$ )  
Ionized calcium ( $Ca^{++}$ )  
Glucose (Glu)  
Lactate (Lac)  
Hematocrit (Hct)  
\*Total hemoglobin (THb)  
\*Oxyhemoglobin ( $O_2Hb$ )  
\*Carboxyhemoglobin (COHb)  
\*Methemoglobin (MetHb)  
\*Deoxyhemoglobin or reduced hemoglobin (HHb)  
\*Oxygen saturation ( $SO_2$ )  
\* These analytes will be measured only if an IL CO-Oximeter device is attached to the GEM Premier 3500, the CO-Oximeter has been configured in Interface Setup, the analytes have been enabled in Sample Setup, and CO-Ox results are transmitted.

### Derived Parameters

The system calculates the following analytes:

---

Actual bicarbonate ( $HCO_3^-$ )  
Standard bicarbonate ( $HCO_3^{std}$ )  
Total carbon dioxide ( $TCO_2$ )  
Base excess of extracellular fluid (BEecf) (in-vivo)  
Base excess of blood (BE(B)) (in-vitro)  
Oxygen saturation ( $SO_2c$ )  
Ionized calcium standardized to pH 7.4 ( $Ca^{++} (7.4)$ )  
Total Hemoglobin (THbc)  
\*Oxygen Content ( $O_2ct$ )  
\*Oxygen Capacity ( $O_2cap$ )  
Alveolar-arterial oxygen gradient ( $A-aDO_2$ )  
Alveolar oxygen partial pressure ( $pAO_2$ )  
Arterial-alveolar oxygen ratio ( $paO_2/pAO_2$ )  
Respiratory Index (RI)  
Arterial oxygen content ( $CaO_2$ )  
Mixed venous oxygen content ( $CvO_2$ )  
End pulmonary capillary oxygen content ( $CcO_2$ )  
Arterial-mixed venous oxygen gradient ( $a-vDO_2$ )  
Physiologic shunt ( $Q_{sp}/Q_t$ )  
Partial pressure of oxygen at 50% saturation ( $P_{50}$ )

---

\* O<sub>2</sub>ct and O<sub>2</sub>cap are derived on an attached IL CO-Oximeter device and then transmitted to the GEM Premier 3500.

### User-Entered Analytes/Parameters

The system provides space for entering the following analytes, which operators must measure or calculate elsewhere:

- 
- Actual patient temperature (Temp)
  - \*Glucose (Glu)
  - \*Lactate (Lac)
  - \*\*Total hemoglobin (THb)
  - \*\*Oxygen saturation (SO<sub>2</sub>)
  - \*\*Oxyhemoglobin (O<sub>2</sub>Hb)
  - \*\*Carboxyhemoglobin (COHb)
  - \*\*Methemoglobin (MetHb)
  - \*\*Deoxyhemoglobin or reduced hemoglobin (HHb)
  - Fetal hemoglobin percentage (FetHb)
  - Activated partial thromboplastin time (APTT-P)
  - Prothrombin time (PT-P)
  - Prothrombin time - INR (PT INR)
  - Activated clotting time (ACT)
  - Activated clotting time - low range (ACT-LR)
- \* Available only when BG/Hct or BG/Hct/Lyte cartridge is inserted.  
\*\*If an IL CO-Oximeter device has been configured in Interface Setup, these analytes will be available as measured analytes rather than entered analytes.

### User-Entered O<sub>2</sub> and Vent Parameters

- 
- Oxygen (O<sub>2</sub>)
  - Inspired oxygen (%FiO<sub>2</sub>)
  - Tidal volume (V<sub>T</sub>)
  - Mode
  - Mechanical rate (Mech Rate)
  - Spontaneous rate (Spon Rate)
  - Peak pressure (Peak Press)
  - Inspiratory time in seconds (Itime (sec))
  - Inspiratory time percentage (Itime (%))
  - Mean airway pressure (MAP)
  - Peak end expiratory pressure (PEEP)
  - Continuous positive airway pressure (CPAP)
  - Inspiratory bilevel positive airway pressure (BIPAP (I))
  - Expiratory bilevel positive airway pressure (BIPAP (E))



**BIOHAZARD: The operator will always follow normal laboratory practices for handling biohazard substances when operating the GEM Premier 3500, including the use of lab coats, gloves, and shield as appropriate.**

## 1.5 Instrument Description

Because the disposable GEM Premier 3500 PAK cartridge contains all the sensors, solutions, and waste bag, the GEM Premier 3500 requires no extraneous equipment or reagents for calibration or operation.

Setup of the instrument consists of inserting the PAK cartridge into the instrument. Upon insertion of the PAK into the analyzer by the operator, the Process Control Solutions are tested and the sensors slope and intercept are adjusted using the factory-assigned values on the barcode. The instrument then performs a warm-up and automatically calibrates the sensors, all of which takes about 30 minutes. During warm-up, the instrument requires no user intervention. To complete the system calibration, and before the system will accept any patient samples, external CVP solutions must be manually run by the operator to validate the integrity of the Process Control Solutions and the overall performance of the analytical system. The recommended quality control protocol depends upon the type of cartridge inserted.

Intelligent Quality Management (iQM<sup>®</sup>) is an active, continuous, real-time quality assessment process program designed to provide immediate error detection and correction of the system, replacing the use of conventional external controls. See Section 6 for detailed information on iQM.



When an iQM cartridge is used, the operator must run four ampoules of GEM Calibration Validation Product (CVP) after cartridge warm-up to verify and ensure the integrity of the iQM cartridge. From that point on, iQM manages the QC process, replacing the use of external quality control.

If iQM is disabled, IL recommends that operators run quality control material to check system integrity and performance both prior to running patient samples and periodically during cartridge use-life. Quality control schedules during cartridge use-life should follow applicable regulatory compliance guidelines for your institution.

## 1.6 System Components and Features

The GEM Premier 3500 has two primary components: the instrument and a disposable cartridge. In addition, IL quality control materials are available to verify system performance when iQM is disable, and GEM CVP material is available to validate Intelligent Quality Management cartridges. These components are described in the following paragraphs.



**CAUTION: The GEM Premier 3500 system consists of non-interchangeable components. Use only components supplied by Instrumentation Laboratory.**

The GEM Premier 3500 employs 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.

The GEM Premier 3500 provides the following operational features:

- Custom test panels of specific analytes can be configured, then optionally modified by operators before the start of an analysis.
- Status of all analytes are displayed on the screen for quick reference before analyzing samples.
- Temperature-correction of patient samples by manual entry of the patient's temperature.
- Flexible, intuitive configuration to meet individual clinical requirements and applicable regulatory requirements, including setting security level to restrict operation of the instrument.
- Simplified setup, virtually no maintenance, and expanded on-board data management.
- GEM Premier 3500 PAK cartridges include all components necessary to maintain the system, including reagents, sensors, sampler, and waste bag — the GEM Premier 3500 requires no gas tanks, electrode membranes, or extraneous solutions.
- System performance established through automatic iQM process control solutions.
- A unique Intelligent Quality Management (iQM) system used with iQM cartridges that provides immediate, automatic error detection, correction, and documentation.
- Results via hardcopy printouts may be generated for each blood analysis and QC sample.
- Configurable demographic information, such as patient ID, patient name, and comments can be attached to individual samples.
- Stores patient, QC, and iQM process control results from at least the previous 20 cartridges.
- Retrieve previous patient, QC, and CVP results with flexible searching of the sample database.
- Patient, QC, CVP, and iQM process control results can be archived onto a Compact Disc (CD), Digital Video Disc (DVD), or USB storage device (thumb drive), compatible with a standard personal computer.
- Patient, QC, CVP, and iQM process control results can be configured to automatically transfer to a hospital or laboratory information system via standard RS-232 serial ports as well as via an Ethernet connection (wired or wireless).
- On-board barcode readers to input error-free information such as cartridge serial numbers, QC lot numbers, CVP lot numbers, operator IDs, patient IDs, and accession numbers.
- Power interrupt and recovery feature.

## GEM Premier 3500 PAK Cartridge

The primary component of the GEM Premier 3500 is the GEM Premier 3500 PAK cartridge (*figure 1.2*). The cartridge houses all components necessary to operate the instrument, including solutions, sensors, sampler, and a waste bag.

**Figure 1.2: GEM Premier 3500 PAK Cartridge**



Cartridges are available for testing various sets of analytes, with test capacities of 75 to 600. Available cartridges provide from 14 to 21 days of operation (see Section 11.8 for specific cartridge information).

The GEM Premier 3500 automatically notifies operators when it is time to remove the cartridge – when sample capacity has been reached or when cartridge use life expires.

The internal waste bag, which collects used blood and solutions throughout cartridge life, keeps biohazard to a minimum.

The cartridge contains process control solutions with the following approximate concentrations:

Reference Solution A pH 6.9 organic buffer;  $pCO_2 = 63$  mmHg,  $pO_2 = 100$  mmHg,  $Na^+ = 100$  mmol/L,  $K^+ = 7$  mmol/L,  $Ca^{++} = 2.5$  mmol/L, glucose = 150 mg/dL, lactate = 3 mmol/L, surfactant and preservative

Reference Solution B pH 7.40 organic buffer;  $pCO_2 = 34$  mmHg,  $pO_2 = 180$  mmHg,  $Na^+ = 140$  mmol/L,  $K^+ = 3.5$  mmol/L,  $Ca^{++} = 1.0$  mmol/L, surfactant and preservative

Reference Solution C pH 8.0, organic buffer;  $pCO_2 = 33$  mmHg,  $pO_2 = 0$  mmHg, surfactant, preservative; for conditioning the glucose and lactate sensors and for cleaning the sensor chamber

Reference Solution D  $KNO_3 = 1000$  mM/L,  $AgNO_3 = 1$  mM/L, and surfactant

The exact values of all Reference Solutions are read from the cartridge barcode.

The components and processes used to manufacture the process control solutions in GEM Premier 3500 PAK cartridges are traceable to NIST standards. For those analytes where NIST materials are not available, primary analytical standards are used. Material Safety Data Sheets (MSDS) for GEM Premier 3500 PAK cartridges can be requested through Customer Support at Instrumentation Laboratory.

## Cartridge Barcodes

Three barcode labels identify each GEM Premier 3500 PAK cartridge (*figure 1.3*):

**Figure 1.3: Cartridge Barcode Labels**



① A label on the cartridge spine, read by an internal barcode reader as the cartridge is inserted, contains the following information:

- Expiration date: When a cartridge is inserted, the expiration date is compared with the current date. If the comparison indicates the cartridge has passed its expiration date, the GEM Premier 3500 will display a message to remove the cartridge.
- Cartridge type: The test menu available with the cartridge.
- iQM Process Control values: These values are precise values for each analyte.



*NOTE: This barcode can be used for manual entry via the barcode gun if for any reason the internal barcode reader does not detect this label.*

② A “2D” barcode on the label face contains the cartridge type, cartridge lot number, expiration date, and serial number. This information assists Technical Support.

## IL Quality Control Solutions

Instrumentation Laboratory features iQM for Quality Assurance Program. Also, Instrumentation Laboratory offers an external aqueous based material with values representing low, mid and high clinical ranges. Target ranges are available for pH,  $pCO_2$ ,  $pO_2$ ,  $Na^+$ ,  $K^+$ ,  $Ca^{++}$ , Glucose, Lactate, and Hct.

**Figure 1.4: IL CVP Material - GEM CVP Multipak**



IL also offers GEM CVP material for use with iQM cartridges.

## 1.7 Theory of Operation

The purpose of the GEM Premier 3500 system is to provide fast, accurate, quantitative measurements of whole blood pH,  $pCO_2$ ,  $pO_2$ ,  $Na^+$ ,  $K^+$ ,  $Ca^{++}$ , glucose, lactate, and Hct.

- pH and  $pCO_2$ , along with their derived parameters, Base Excess,  $HCO_3^-$ , and  $TCO_2$ , define acid/base status.
- Arterial  $pO_2$  indicates adequacy of  $O_2$  exchange.
- The role of electrolytes in the human body is multiple. Nearly all metabolic processes depend on or vary with electrolytes:
  - Sodium is the major cation of extracellular fluid. It is critical for maintenance of water distribution and osmotic pressure in body tissues.
  - Potassium is the major intracellular cation. It is critical for maintaining proper neuromuscular irritability including respiratory and myocardial function.
  - Ionized calcium is critical for functions including hemostasis.
- Hematocrit indicates the red cell fraction of the blood, a vital component in determining its oxygen carrying capacity.
- Glucose is the primary energy source and its blood level is maintained within a fairly narrow range. The most common disorder in maintaining blood glucose is due to diabetes mellitus, which can cause hyperglycemia (high blood glucose) and hypoglycemia (low blood glucose).
- Lactate is an intermediary product of carbohydrate metabolism and is derived mainly from muscle cells and erythrocytes. Severe oxygen deprivation of tissues due to shock, cardiac decompensation, hematologic disorders, and pulmonary insufficiency leads to "lactic acidosis" and is associated with a significant increase in blood lactate. Liver malfunction may also play an important role in the production of lactate.
- The GEM Premier 3500 uses an estimated hemoglobin value in Base Excess and  $O_2$  saturation calculations (used for  $O_2$  calculations only when an IL CO-Oximeter is not connected to the GEM Premier 3500). The hemoglobin value is derived from the measured hematocrit reading using the THbc/Hct Ratio defined in Configuration (Hemoglobin g/dL = THbc/Hct Ratio X Hct%). The system default Ratio is 0.31.
- The GEM Premier 3500 makes use of potentiometric sensors to measure  $pCO_2$ , pH,  $Na^+$ ,  $K^+$ , and  $Ca^{++}$ . It uses an amperometric electrode to measure  $pO_2$ , glucose, and lactate concentrations. Blood conductivity is the method used to measure hematocrit. Automatic iQM Process Control A, B and C, which occur at fixed intervals, help to establish continued instrument accuracy.

For more information about the GEM Premier 3500's operation, see "Principles of Operation" in Section 10.2.

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# 2 Installation

## 2.1 Installation

This section describes how to install and prepare the GEM Premier 3500 for operation and includes limitation of responsibility of the manufacturer, inspection, installation requirements and procedure, setting the date and time, and inserting a GEM Premier 3500 PAK cartridge.

## 2.2 Limitation of Responsibility of the Manufacturer

Instrumentation laboratory considers itself responsible for safety and electrical performance of this equipment only if:

- assembly operations, extensions, adjustments, modifications or repairs are carried out by persons authorized by IL.
- the electrical installation of the room complies with local, state, and national requirements (including power supply circuit with independent grounding).
- the equipment is used in accordance with these instructions for use.

## 2.3 Inspection

The instrument should be removed from its carton by an authorized IL representative. Check that the instrument and its accessories have not been damaged during transport. If damage to the instrument and/or accessories is noted, notify the carrier within eight days of delivery. The carrier is responsible for any damage caused during transport.

In the event of instrument damage, notify the local company office or authorized agent to facilitate replacement or repair. Please refer to the instrument label, located on the rear panel, to determine the model and serial number before contacting IL Technical Support at 1-800-678-0710 in the USA or your local IL office or distributor.



**NOTE:** Retain all packaging material in the event the GEM Premier 3500 needs to be returned for servicing.

## 2.4 Installation Requirements

The GEM Premier 3500 has specific space, environmental, and power supply requirements. Ensure the requirements have been met prior to system installation.

### Environmental Requirements

The GEM Premier 3500 should be operated at ambient temperatures between 15°C (59°F) to 35°C (95°F) and relative humidity between 5% and 90%. The instrument is intended for inside use only.

The instrument will operate independent of barometric pressure. iQM Process Control Solution bags have zero head space for operation over a wide range of atmospheric pressures with no change in dissolved gas concentration.

This instrument although portable is not designed for use "outside" in the external environment. The GEM Premier 3500 is designed for use inside a facility such as a laboratory, doctor's office, or hospital where power and ground connections are properly connected and monitored.

IL is not responsible for damages resulting from any attempt by any employee or representative of your company to use the GEM Premier 3500 outdoors.

### Power Requirements

The GEM Premier 3500 requires a grounded electrical supply. The switching power supply accommodates 90 to 264 VAC, 50 or 60 Hz.



**NOTE:** The GEM Premier 3500 has electrical filters to protect against line noise. In locations where significant voltage and current fluctuations frequently occur, use a line conditioner or medical equipment grade uninterruptable power supply (UPS) that provides line conditioning.

It is recommended that you use a medical grade UPS, IL part number 00024001201. Please note that if you do not use a recommended medical UPS you may be compromising the hospital leakage current specification.

The GEM Premier 3500 is designed to recover from a power interruption of less than one hour (or within 20 minutes if a low oxygen or "A" process controls solution is in progress, or blood is resting on the sensor). If routine power failures are anticipated, a UPS can enhance system performance when power is resumed. Instrumentation Laboratory recommends that the UPS be grounded when used with the GEM Premier 3500.

A 500VA/300W, 57–63Hz UPS can power the GEM Premier 3500 for one hour.

A 60-minute power interrupt feature allows transport. The instrument cannot be operated during power interruptions.

The GEM Premier 3500 complies with IEC 61010.1. The GEM Premier 3500 exceeds the leakage current as specified in IEC 61010.1. The instrument complies with the medical standard IEC 60601.1 in regards to the primary protection and leakage current.



**WARNING:** To prevent electrical shock to the operator, connect this device to a properly wired and grounded receptacle. Use only the medical grade power cord supplied with the instrument.

## Power Connector

The GEM Premier 3500 power switch is located on the back of the instrument, below the power cord connection. This switch is for the main power supply and controls all power to the instrument.



**CAUTION: This switch must be turned off prior to service and the power cord must be disconnected.**

During normal operation, the GEM Premier 3500 is powered on continuously. Please note the following concerning the power connector and cord:

- the power supply, connector and cord carries Agency approvals.
- maximum power requirements for the GEM Premier 3500 does not exceed 150W
- the power cord provided with the instrument is a certified cord and three-prong, double insulated, grounded (NEMA) receptacle and plug.
- the power supply in the GEM Premier 3500 incorporates a power factor correction in order to prevent harmonic distortions in the power lines and to satisfy requirements for EMC/EMI Standard 61326.

## 2.5 Installation Procedure

### Instrument Setup

1. Place the GEM Premier 3500 in a location that has at least 12 inches (30.5 cm) to the right of the instrument to allow for opening of the cartridge door and adequate ventilation of the instrument's fan.
2. Plug the power cord into a properly grounded and wired receptacle.

The GEM Premier 3500 recognizes the voltage and frequency on the line and adapts to it automatically.

**WARNING:**  To prevent electrical shock to the operator, connect this device to a properly wired and grounded receptacle. Use only the medical grade power cord supplied with the instrument.

3. If a serial port connection will be used, connect the cable to the instrument.
4. If an Ethernet connection will be used, connect the cable to the instrument.
5. Before turning on the instrument, install printer paper using the instructions below.

## Install Printer Paper

The GEM Premier 3500 is shipped without printer paper installed. Printer paper must be installed before operating the instrument. When there is no paper installed, the **Messages** button will turn yellow. For more information about alarms, see “Error Messages, Alarms, and Corrective Actions” in Section 9.6.



**CAUTION: Use only paper supplied by Instrumentation Laboratory. Other papers can damage the printer.**

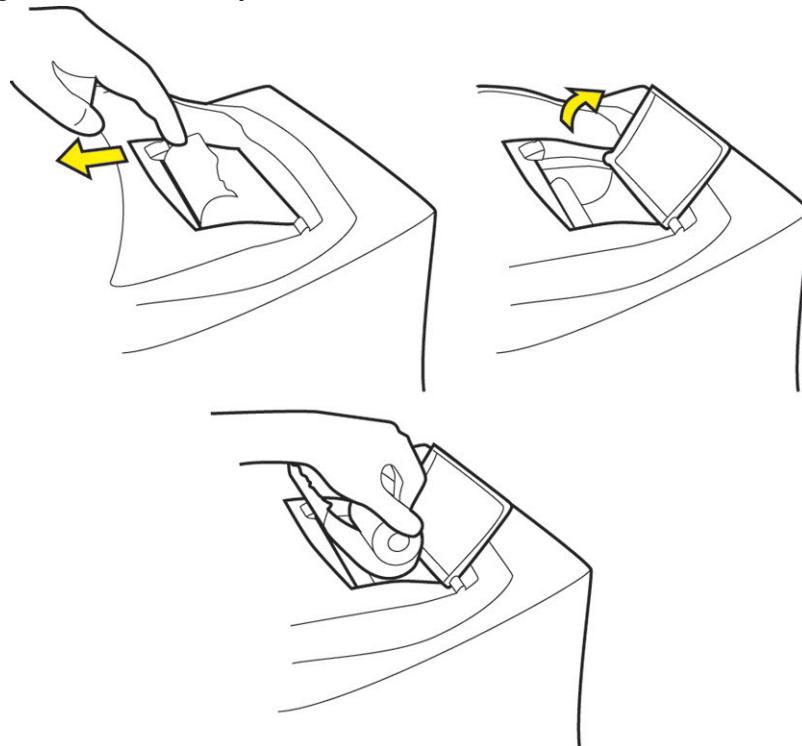
To install the printer paper in the paper area on top of the system (*figure 2.1*):

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.



*NOTE: The GEM Premier 3500 uses thermal paper that can only be printed on one side.*

**Figure 2.1: Printer Paper Installation**



## 2.6 Start Up

**!** **CAUTION:** Before turning on the instrument, make sure all cable connections have been made and printer paper has been installed. See the previous two sections for instructions.

Turn the power switch on the back of the GEM Premier 3500 to ON.

Status: The instrument starts its power-up cycle, which lasts about 1 minute.

The instrument will then display the Insert Cartridge screen (*figure 2.2*). While at this screen, the instrument will remind operators to set the date and time. This screen also allows access to most commands on the menus. In addition, the **Messages** button will be available for viewing of alarm and text messages. (Alarm messages are described in Section 9; text messages in Section 11).

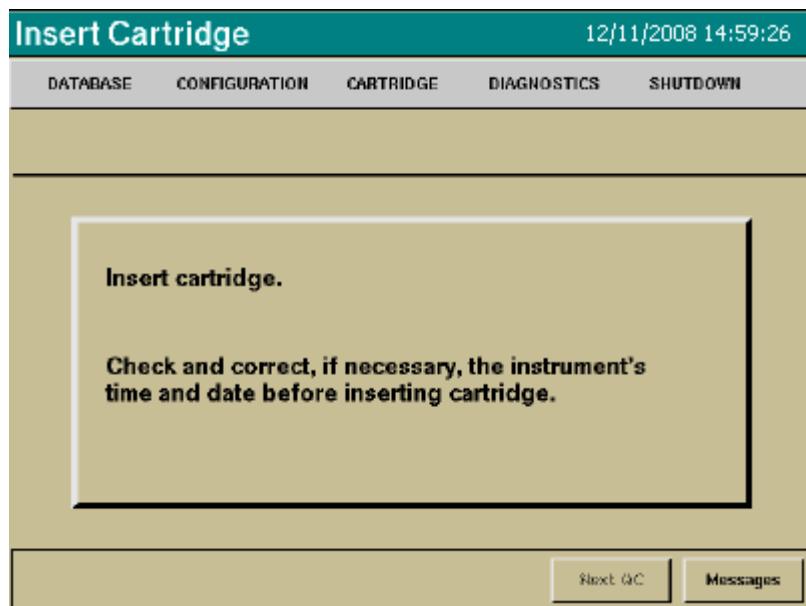


Figure 2.2: Insert Cartridge Screen

## 2.7 Set Date and Time

**!** **CAUTION:** Incorrectly entering the current date may lead to inaccurate pO2 results.

**!** **NOTE:** The date and time can only be changed by a Key Operator.

The GEM Premier 3500 displays the current date and time at the top of all screens. The system date and time can be corrected whenever the Insert Cartridge screen is displayed or whenever a cartridge is not inserted in the instrument or when a new cartridge is inserted, prior to closing the cartridge compartment door. The instrument is configured to automatically track daylight savings time, although the daylight savings time feature can be disabled.

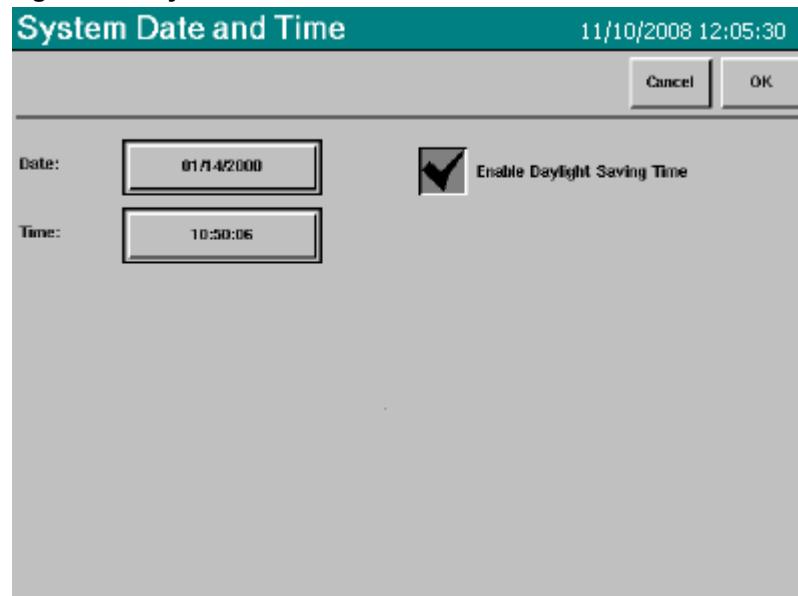
**!** **NOTE:** If Daylight Savings Time is enabled, the time will move forward by one hour on the second Sunday in March, and will fall back by one hour on the first Sunday in November.

Changing the date or time will require an instrument restart. The instrument will display a message and provide the choice of continuing. Restarting the instrument takes about 20 seconds.

The GEM Premier 3500 uses 24-hour time format, from 00:00:00 to 23:59:59, in hours, minutes, and seconds. The date format depends upon the format chosen during software installation. The available formats are described in "Date Format" in Section 3.7.

Following the system restart message, the instrument will display the System Date and Time screen (*figure 2.3*). This screen shows the current settings for the date and time and a checkbox to turn off and on the tracking of daylight savings time.

**Figure 2.3: System Date and Time Screen**



**To Set the Date and Time:**

- At the Insert Cartridge screen, select Configuration, then select Set Date & Time from the Configuration menu.**

Status: The instrument will prompt for a Key Operator Password.

- Enter the Key Operator Password, and touch Enter.**

Status: The instrument will display the message: *Changes to this screen will restart the GEM Operating Software.*

- Touch OK to continue.**

The instrument will display the System Date and Time screen (*figure 2.3*), with the instrument's current date and time displayed.

- To change the date, touch the Date field.**

Status: The instrument will display a keypad for entering the date (*figure 2.4*).

- Enter the correct date using the keypad.**

Status: Use the <- and -> buttons to move the cursor.

- Touch Enter.**

Status: If desired, touch **Cancel** to abort the change and return to the System Date and Time screen.



**Figure 2.4: Set Date Keypad**

The instrument will validate the entered date. If the date is not valid, it will display a message indicating the required correction. When a valid date has been entered, the instrument will transfer the new date to the appropriate field on the System Date and Time screen and remove the keypad.

- To change the time, touch the Time field.**

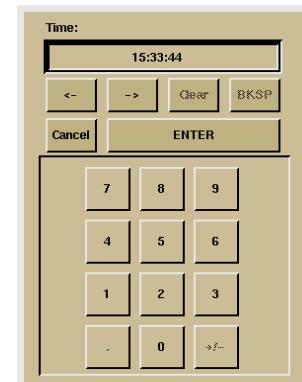
Status: The instrument will display a keypad for entering the time (*figure 2.5*).

- Enter the correct time using the keypad.**

Status: Use the <- and -> buttons to move the cursor.

- Touch Enter.**

Status: If desired, touch **Cancel** to abort the change and return to the System Date and Time screen.



**Figure 2.4: Set Time Keypad**

The instrument will validate the entered time. If the time is not valid, it will display a message indicating the required correction. When a valid time has been entered, the instrument will transfer the new time to the appropriate field on the System Date and Time screen and remove the keypad.

**10. If desired, adjust the checkbox for tracking of daylight savings time.**

Status: By default, this checkbox will be filled, meaning that the instrument will track and adjust its clock for daylight savings time.



NOTE: If Daylight Savings Time is enabled, the time will move forward by one hour on the second Sunday in March, and will fall back by one hour on the first Sunday in November.

**11. Touch OK to leave the System Date and Time screen.**

Status: The instrument will restart and redisplay the Insert Cartridge screen.

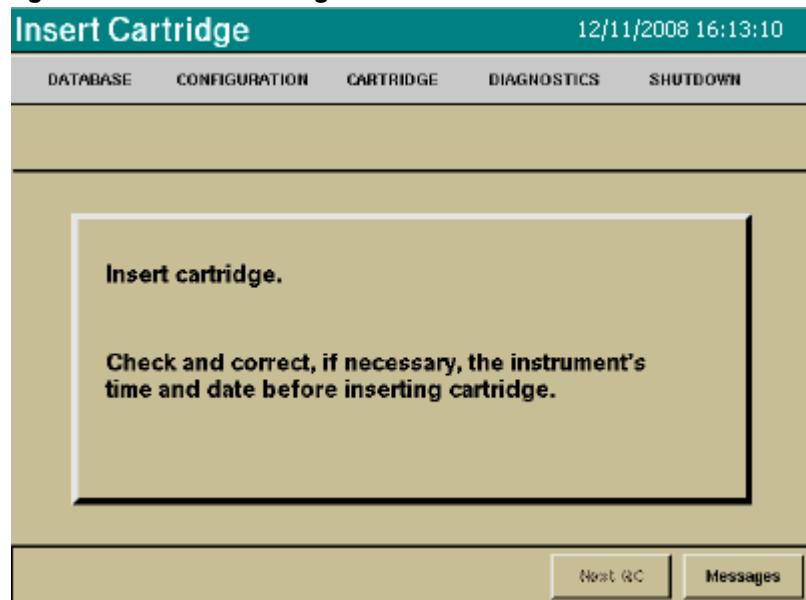
## 2.8 Insert GEM Premier 3500 PAK Cartridge

The GEM Premier 3500 will display the Insert Cartridge screen (*figure 2.6*), to prompt for cartridge insertion whenever a cartridge is not installed. The instrument will remain at this screen until a cartridge is inserted and its barcode successfully read and validated. The following message is then displayed:

*Is instrument date/time correct? If correct, select Yes to proceed with warm-up. Otherwise, select No, then correct the date/time.*

If Yes is selected, the “close the cartridge door” message is displayed. If No is selected, the “remove and reinsert the cartridge” message is displayed.

**Figure 2.6: Insert Cartridge Screen**



**⚠ NOTE:** Once the database contains 40 cartridges, the database is considered “full.” The system will prompt “Cartridge database is full. Would you like to perform database maintenance now?” If Yes is selected, the system will remove data of old cartridges, keeping only the most recent 20 cartridges. IL recommends a regular schedule of copying the data from previous cartridges so cartridge data is not unintentionally lost.

The instrument validates all cartridges by verifying:

- The cartridge is an allowable type (only cartridges with part numbers starting with 26xxxxxx will be accepted). Cartridges from other GEM models will not be accepted.
- The cartridge is new and has not been previously inserted into the instrument. Once a cartridge has been inserted in the GEM Premier 3500, it cannot be reused.
- That the shelf life of the cartridge has not expired.

If the cartridge fails any of the checks, the GEM Premier 3500 will display an appropriate message and prompt for removal of the cartridge.

### To Insert a Cartridge:

1. Unlatch the cartridge door on the instrument's right side by sliding the lock handle to the front and opening the door.
3. Check the label on the foil bag containing the GEM Premier 3500 PAK cartridge to be sure that the cartridge is not past its expiration date.
3. Open the foil bag and remove the cartridge. 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 3500 PAK cartridge and call Technical Support at Instrumentation Laboratory.

4. 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.
5. Align the cartridge according to the labels. Using a rapid, smooth, continuous motion, insert the cartridge into the instrument's cartridge compartment (see figure 2.7).



**NOTE:** The cartridge cannot be inserted all the way into the compartment by hand. A small lip of the cartridge will rest on the door.

**Status:** When the barcode has been successfully read and validated and the date/time has been accepted, the instrument will prompt 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 gun. If the barcode cannot be read, contact IL Technical Support. For an explanation of the barcodes, see Section 1.6.

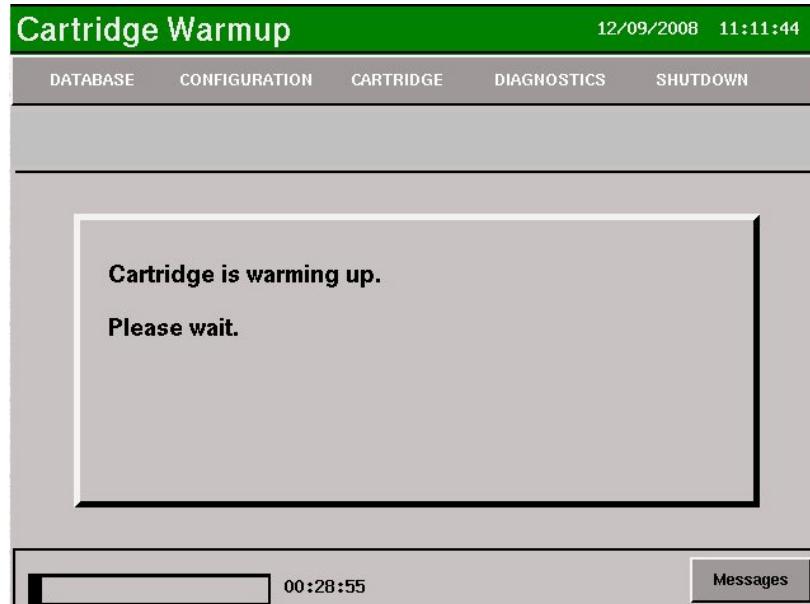
**Figure 2.7: GEM Premier 3500 PAK Cartridge Insertion**



6. The system 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 system will prompt “*Remove Cartridge.*” Remove the cartridge (see Section 4.5) to begin the process again, changing the date and time when prompted.
7. Close the door, and slide the lock handle toward the back of the unit.

Status: The cartridge door will lock. The GEM Premier 3500 will display the Cartridge Warm-up screen (figure 2.8). 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.

**Figure 2.8: Cartridge Warm-up Screen**



During cartridge warm-up, the instrument brings the measuring chamber to the proper temperature. If an error occurs during warm-up, the instrument will prompt for removal of the cartridge (see the instructions for removing a cartridge in Section 4.5).

The GEM Premier 3500 will also determine the type of cartridge that has been inserted. The instrument's response will depend upon how the **iQM Mode** (Section 3.6) is configured:

- If **iQM Mode** is On (Default), it will be left on.
- If **iQM Mode** is Off, the instrument will display the message: *Would you like to enable iQM? If you enable iQM, CVP material should be ready for analysis. Yes/No.* If **Yes** is selected, **iQM Mode** will be turned On. If **No** is selected, **iQM Mode** will remain Off, and the iQM cartridge will be treated as a non-iQM cartridge.

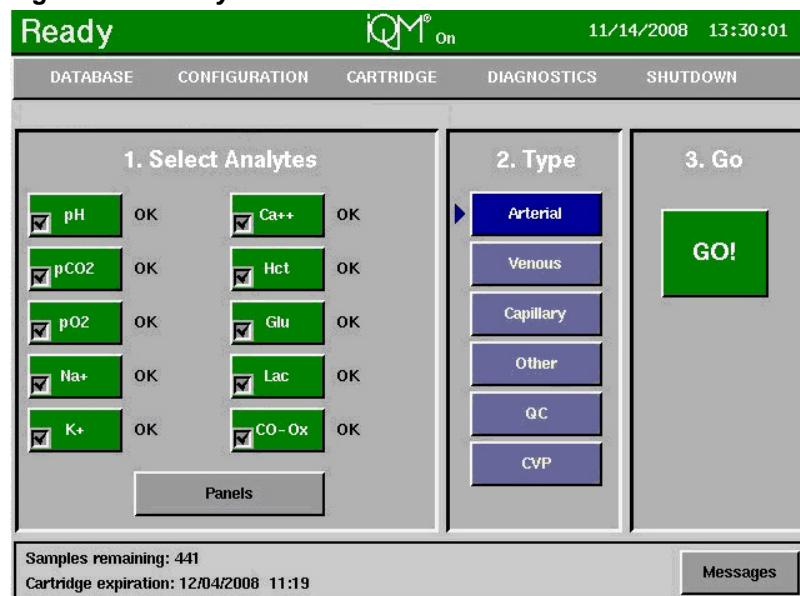
After **iQM Mode** has been configured (On or Off), the mode cannot be changed for the duration of the inserted iQM cartridge. After the cartridge is removed, **iQM Mode** will remain at its current setting but will be available for changing, if desired, by a Key Operator.

For more information about iQM, see Intelligent Quality Management (iQM), Chapter 5.

When cartridge warm-up is complete, the instrument will display the Ready screen. The look of the Ready screen depends upon the cartridge that is inserted and whether iQM Mode is On or Off.

If a cartridge is inserted and iQM Mode is On, the instrument will display a reminder to run all levels of CVP material. After OK is selected, the Ready screen in figure 2.9 will be displayed, and the status of all analytes will be set to "Pending CVP." CVP material must be run before patient sample results can be reported (see "CVP Sampling" in Section 5.3). See "Ready Screen" in Section 4.2 for a description of the Ready screen.

**Figure 2.9: Ready Screen**



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# 3 Configuration

## 3.1 Configuration

The GEM® Premier 3500 has been designed to allow easy configuration to suit individual clinical needs. The instrument's configuration settings are accessed via the **Configuration** menu and are grouped into the following areas:

- Sample Setup, Section 3.4
- QC Setup, Section 3.5
- iQM Setup, Section 3.7
- Instrument Setup, Section 3.7
- Interface Setup, Section 3.8
- Security Setup, Section 3.9
- Restore Default Key Operator Password (KOPW), Section 3.10
- Save Configuration, Section 3.11
- Restore Configuration, Section 3.12
- Set Date and Time, Section 3.13

This section also describes how configuration settings can be copied between instruments and how to set the instrument's date and time. For easy reference, the GEM Premier 3500's configuration settings have been summarized on the next pages.

For security purposes, only the "Key Operator" is allowed to modify the configuration of the GEM Premier 3500. For more information about the GEM Premier 3500's security features, see "Security Setup" in Section 3.9.

## 3.2 Access to Configuration Areas

Use the following steps to access configuration areas:

### 1. Select a command from the Configuration menu.

Status: The instrument will display a keypad to prompt for entry of the Key Operator Password.

All commands except **Restore Config** and **Set Date & Time** will be available whenever the Cartridge Warm-up, Restart, Remove Cartridge, or Ready screens are displayed. The **Restore Config** and **Set Date & Time** commands will only be available when a cartridge is not inserted (when the Insert Cartridge screen is displayed).

### Enter the Key Operator Password.

Status: The instrument will display the main screen for the chosen configuration area.

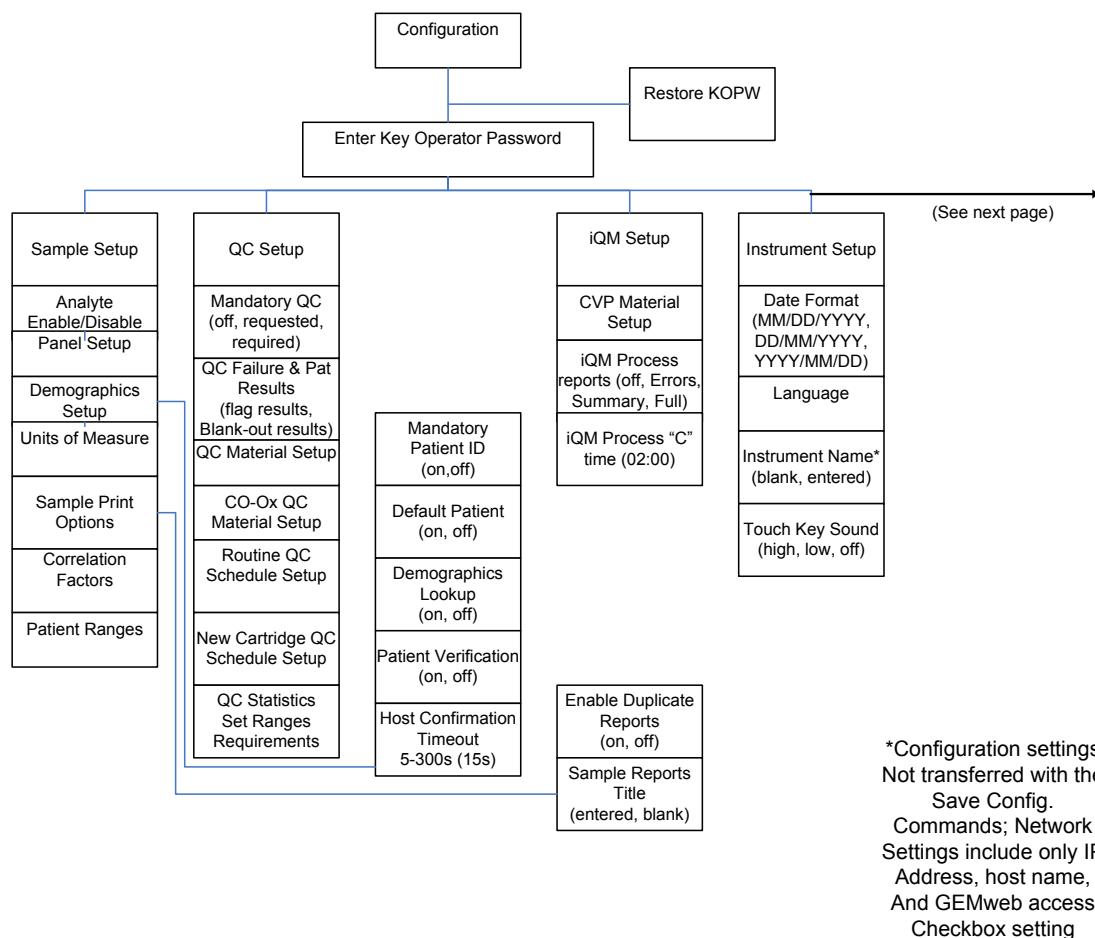
If an incorrect ID is entered, the instrument will prompt for re-entry of the ID.

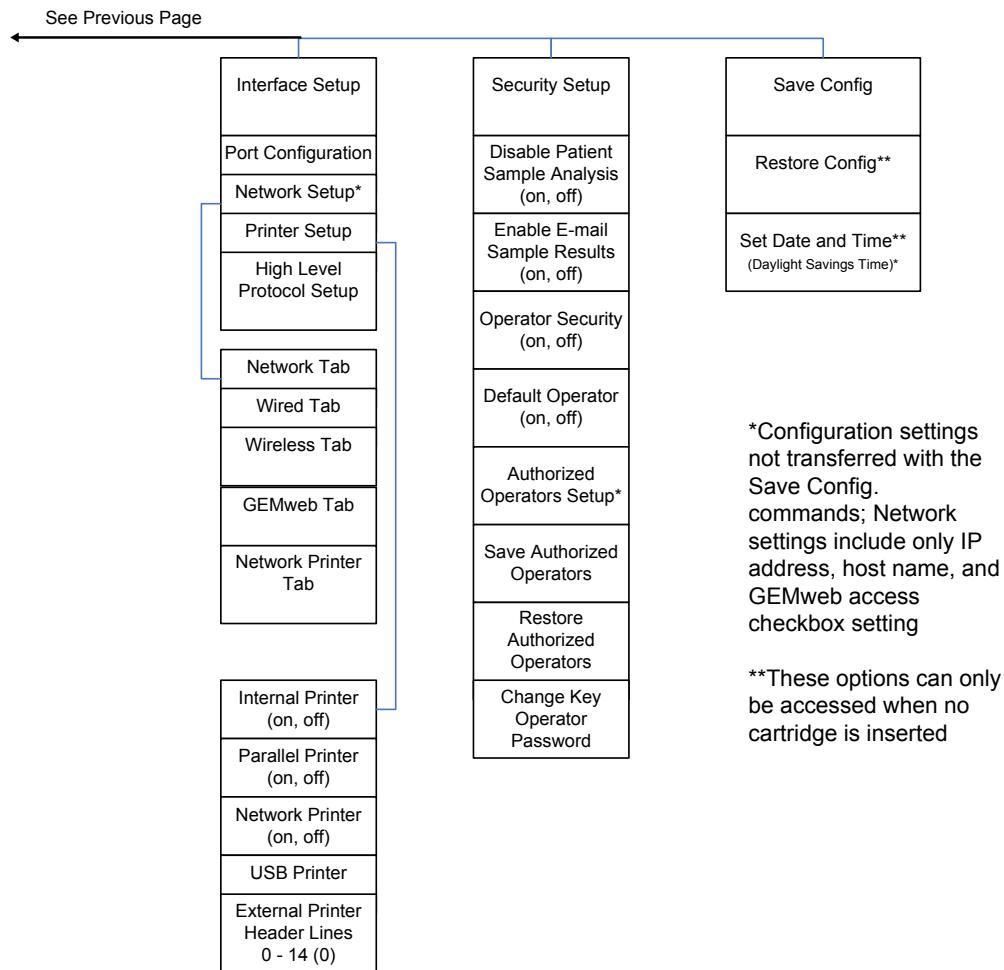


NOTE: To change Key Operator Password, see Change Key Operator Password. To restore the password to its factory default, see “Restore Default Key Operator Password (KOPW)” in Section 3.10.

### 3.3 Configuration Summary

The following charts show the areas of configuration and the options available in each area. The options are described in detail beginning on the page number indicated in the chart. Settings are shown in smaller print, with factory defaults, if applicable, identified in **bold**.





\*Configuration settings not transferred with the Save Config. commands; Network settings include only IP address, host name, and GEMweb access checkbox setting

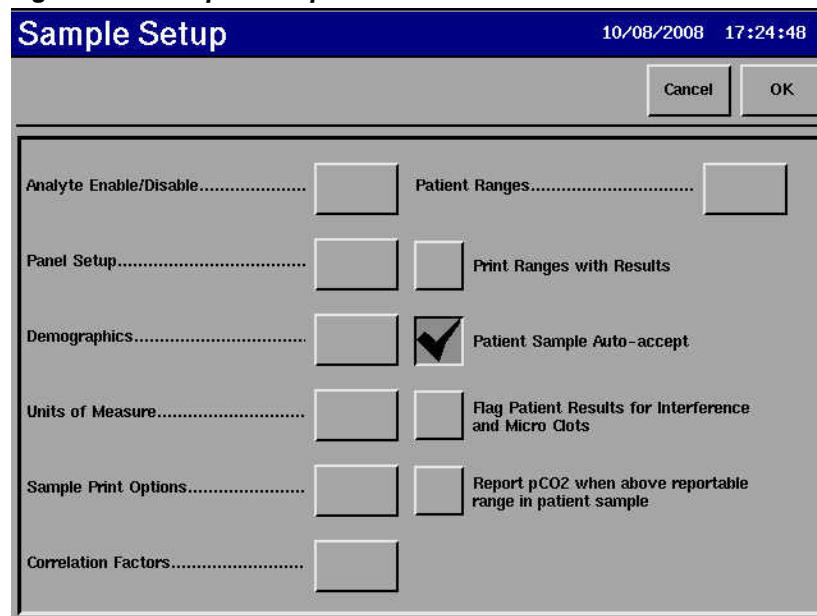
\*\*These options can only be accessed when no cartridge is inserted

### 3.4 Sample Setup

The **Sample Setup** command on the **Configuration** menu can be used to configure certain aspects related to analyzing samples. Some apply to patient samples, while others apply to both patient samples and QC samples, as will be noted. Setup options that apply only to QC samples are covered in "QC Setup" in Section 3.5.

The Sample Setup screen (*figure 3.1*) provides the options shown.

*Figure 3.1: Sample Setup Screen*



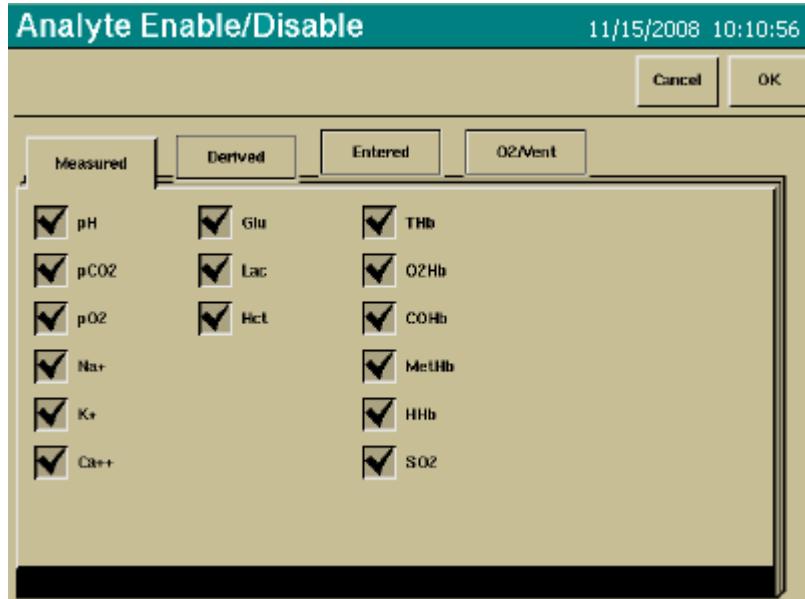
## Analyte Enable/Disable

The **Analyte Enable/Disable** button on the Sample Setup screen displays the Analyte Enable/Disable screen (figure 3.2). This screen is used to determine globally which analytes will be presented to operators when they analyze samples. The instrument will not analyze or report analytes that have been disabled. If all analytes have been disabled, the GEM Premier 3500 will not allow operators to analyze samples.



**NOTE:** Operators may also disable and re-enable analytes that were enabled in configuration on a sample-by-sample basis from the Ready screen.

**Figure 3.2: Analyte Enable/Disable Screen – Measured Tab**



Four tabs are provided for the four types of parameters: Measured, Derived (calculated), Entered, and O<sub>2</sub>/Vent. Touching a tab brings it to the top, displaying its parameters. Touching an analyte's checkbox toggles the analyte between enabled and disabled:

- Enabled. The instrument will analyze and report the analyte as usual. Up to 12 parameters may be enabled on the Entered tab and on the O<sub>2</sub>/Vent tab. There is no limit for the other tabs.



**NOTE:** After enabling an analyte, the appropriate QC solutions, or CVP solutions for iQM cartridges, should be analyzed to verify proper functioning of the sensor.

- Disabled. The GEM Premier 3500 will not analyze or report the analyte.
- If an analyte is disabled, it will remain so until it is enabled again. If an analyte's sensor has passed prior iQM process controls, it will become available immediately after being enabled. Otherwise, it will become available after it passes the next full menu iQM Process, which may be initiated manually with the **iQM Process** command on the **Diagnostics** menu.

## Measured Tab

The Measured tab includes the choices shown in *figure 3.2*

If an IL CO-Oximeter device (IL 682 or GEM OPL) has been configured to one of the GEM Premier 3500's ports (see "Port Configuration under Interface Setup" in Section 3.8), CO-Ox analytes will be available for enabling/disabling on the Measured tab. If no CO-Ox device has been configured, CO-Ox analytes will be available on the Entered tab. Unavailable analytes will appear on the screen; however, they will be disabled, appear in lighter type, and will not be selectable.



*NOTE: The reduced or deoxyhemoglobin (HHb) is not measured on the GEM OPL. The HHb value is derived on the GEM Premier 3500 from the other parameters sent by the GEM OPL. However, HHb is still considered measured.*

## Derived Tab

The Derived tab includes the choices shown in *figure 3.3*

The average barometric pressure (BP) of the geographical area in which the instrument is being used can also be entered at this screen. The BP is used to calculate some derived parameters. An initial value of 760 mmHg will appear.

**Figure 3.3: Analyte Enable/Disable Screen – Derived Tab**

Measured		Derived		Entered		O2/Vent							
<input checked="" type="checkbox"/> Ca++(7.4)	<input checked="" type="checkbox"/> THbc	<input checked="" type="checkbox"/> HCO3-	<input checked="" type="checkbox"/> O2ct	<input checked="" type="checkbox"/> HCO3std	<input checked="" type="checkbox"/> O2cap	<input checked="" type="checkbox"/> TCO2	<input checked="" type="checkbox"/> A-aDO2	<input checked="" type="checkbox"/> BEecf	<input checked="" type="checkbox"/> pAO2	<input checked="" type="checkbox"/> BE(B)	<input checked="" type="checkbox"/> paO2/pAO2	<input checked="" type="checkbox"/> SO2c	<input checked="" type="checkbox"/> RI
<div style="display: flex; justify-content: space-between;"> <span>BP(mmHg) <input type="text" value="760"/></span> <span>BE &amp; Temp-corrected Equations: <input type="button" value="NCCLS"/></span> </div> <div style="display: flex; justify-content: space-between;"> <span>P50 Calculation Parameter: <input type="button" value="SO2"/></span> <span><input type="button" value="Qspf/Qt"/></span> </div>													

The **BE and Temp-corrected Equations** button is used to select the equation to be used to calculate Base Excess and temperature correction. **NCCLS** (the default) specifies the equations recommended by the National Committee of Clinical Laboratory Standards. The **IL** option specifies the equations used in previous models of the GEM Premier and the GEM Premier Plus. See "Calculation of Derived Parameters" in "Specifications" (Chapter 11) for details on the different equations.

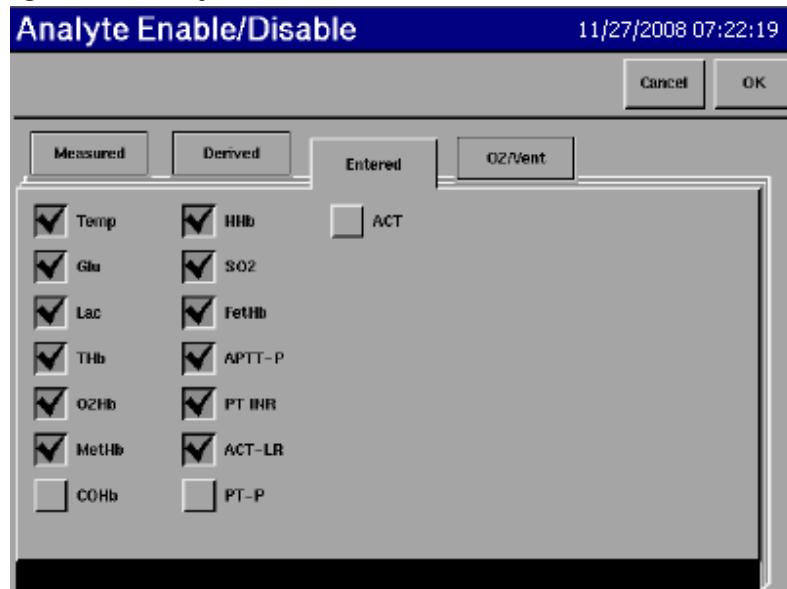
The **P50 Calculation Parameter** button is used to select the either SO2 or O2Hb for use in the P50 equation. The default is SO2. See "Calculation of Derived Parameters" in "Specifications" (Chapter 11).

The **THbc/Hct Ratio** defines the default factor used to calculate THb from measured Hct where THb is used in subsequent calculations or as its own derived parameter.

### Entered Tab

The Entered tab includes the choices shown in *figure 3.4*. Up to 12 parameters may be enabled.

**Figure 3.4: Analyte Enable/Disable Screen – Entered Tab**

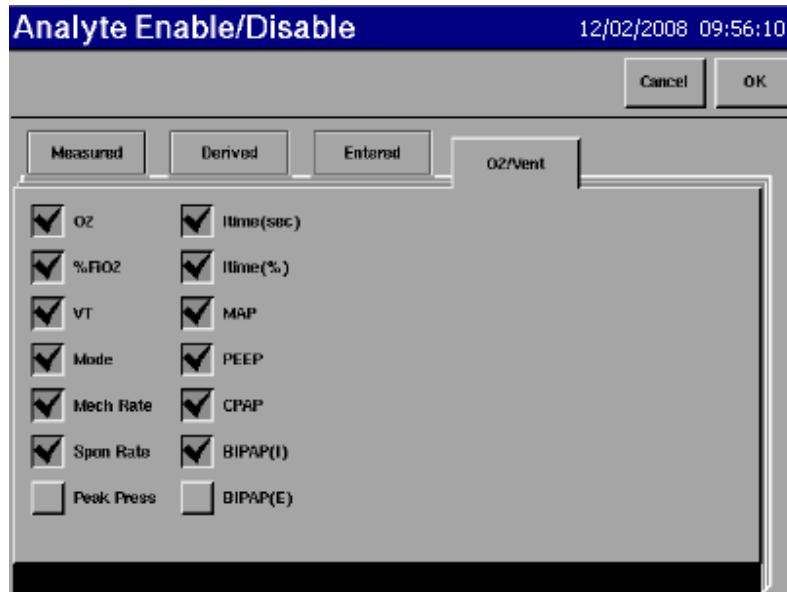


If the instrument has not been configured to work with an IL CO-Oximeter (IL 682 or GEM OPL), CO-Ox analytes will be available on the Entered tab. If an IL CO-Ox device has been configured, CO-Ox analytes will appear on the Measured tab.

### O2/Vent Tab

The O2/Vent tab includes the choices shown in *figure 3.5*. Up to 12 parameters may be enabled.

**Figure 3.5: Analyte Enable/Disable Screen – O2/Vent Tab**



## Panel Setup

The **Panel Setup** button on the Sample Setup screen can be used to define “panels” of analytes the GEM Premier 3500 will report when patient samples (*not* QC samples) are analyzed. This feature allows Key Operators to define test panels that contain only the analytes that they desire reported. One panel may contain all analytes the GEM Premier 3500 is capable of reporting, while a “blood gases only” panel may contain only pH, pO<sub>2</sub>, and pCO<sub>2</sub>. Operators then select the desired panel when they analyze a sample.

The GEM Premier 3500 is delivered with a single, factory default test panel, called “All Analytes.” This panel contains up to nine GEM Premier 3500 analytes (pH, pCO<sub>2</sub>, pO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Glucose, Lactate, and Hct) plus the six measured CO-Ox analytes (THb, O<sub>2</sub>Hb, COHb, MetHb, HHb, and SO<sub>2</sub>).

The default panel cannot be edited or deleted; however, up to nine additional panels can be defined, for a total of 10 panels.

A disabled analyte will be displayed on a defined panel but will not report results.

Each test panel is defined by two attributes:

- 1. Panel Name:** Up to 16 alphanumeric characters by which the panel will be known and referred to when operators select a panel. Panel names cannot be blank, and duplicate names will not be accepted.
- 2. Included Analytes:** A listing of the analytes included in the panel. Analytes are included and excluded by filling or unfilling the checkbox next to each analyte. A filled checkbox indicates that the analyte will be included in the panel. Each panel must have at least one analyte selected.

If analytes that are used to derive other parameters have not been included on a panel, the derived parameters will not be calculated when the panel is used. Derived parameters and their dependencies are described in Section 11 “Specifications”.

The Panel Setup screen (*figure 3.6*) lists the currently defined panels by panel name. A new panel can be created from this screen, or existing panels can be modified or deleted (except for the default panel, All Analytes).



**NOTE:** Once a panel is selected, it will become the default panel until another panel is selected.

**Figure 3.6 Panel Setup Screen**

Panel Setup		11/10/2008 12:18:55
		Print All   Print   Exit   Delete   Add   OK
Panel Name	Analytes	
All Analytes	pH, pCO2, pO2, Na+, K+, Ca++, Glu, Lact, Hct, THb, O2Hb, COHb, MetHb, HHb, SO2	
Blood gases only	pH, pCO2, pO2	
CO-OX-ONLY	THb, O2Hb, COHb, MetHb, HHb, SO2	

### To Create a New Test Panel:

1. Touch Panel Setup on the Sample Setup screen.

Status: The instrument will display the Panel Setup screen.

**2. Touch Add on the Panel Setup screen.**

Status: The instrument will display the Panel Information screen.

**3. Touch Panel Name.**

Status: The instrument will display an alphanumeric keypad.

**4. Type up to 16 alphanumeric characters for the panel name.**

Status: The name can include spaces. Blank names and duplicate names will not be allowed.

**5. Touch Enter to accept the name.**

Status: The instrument will dismiss the keypad, and display the measured analytes.

**6. Choose the analytes to be included and excluded by touching each analytes checkbox to toggle the setting.**

Status: An analyte will be included when its checkbox is filled. It will be excluded when its checkbox is unfilled.

**7. Touch OK to save the panel or Cancel to abort creation of the panel.**

**8. Touch OK again to leave the Panel Setup screen.**

Status: The instrument will display the Sample Setup screen.

**9. Touch OK to leave the Sample Setup screen.**

Status: The instrument will display the Ready screen.

The following chart can be used to record the custom panels that have been created. The panel in the first column, All Analytes, is the default test panel.

GEM Premier 3500 Panel Definitions	Panel Name (up to 16 alphanumeric characters)									
	All Analytes									
Panel #:	1	2	3	4	5	6	7	8	9	10
<b>Measured (15 available; any number may be enabled)</b>										
pH/cH	✓									
pCO <sub>2</sub>	✓									
pO <sub>2</sub>	✓									
Na <sup>+</sup>	✓									
K <sup>+</sup>	✓									
Ca <sup>++</sup>	✓									
Glu	✓									
Lac	✓									
Hct	✓									
<sup>1</sup> THb	✓									
<sup>1</sup> O <sub>2</sub> Hb	✓									
<sup>1</sup> COHb	✓									
<sup>1</sup> MetHb	✓									
<sup>1</sup> HHb	✓									
<sup>1</sup> SO <sub>2</sub>	✓									

<sup>1</sup> These analytes will be available and a part of the default panel only if an IL CO-Ox device has been configured in instrument setup.

## Delete Panels

To delete a panel, touch the panel's name located on the Panel Setup screen, then touch the **Delete** button. The instrument will prompt for confirmation before deleting the panel.

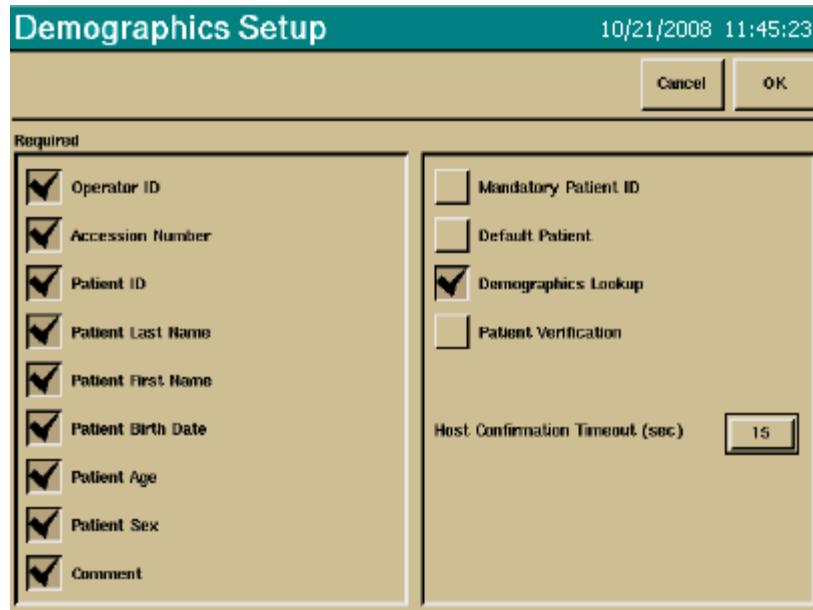
## Modify Panels

To modify a panel, touch the panel's name located on the Panel Setup screen, then touch the **Edit** button. Touch the checkboxes next to the analyte names to fill or unfill them. Then touch the **OK** button to save the panel.

## Demographics Setup

The **Demographics** button on the Sample Setup screen displays the Demographics Setup screen (*figure 3.7*). This screen provides options that determine what information the GEM Premier 3500 collects when operators analyze samples and how that information is collected.

**Figure 3.7: Demographics Setup Screen**



### Requested Demographics

The area on the left side of the Demographics Setup screen displays a list of demographic information that the instrument will use to define samples. By default, the checkbox next to each item is filled. This means the demographic field will be presented during sample analysis to allow the operator to enter the information. An unfilled checkbox means the field will not be presented. If all checkboxes are unfilled, and no user-entered or O<sub>2</sub>/Vent parameters have been enabled, the Patient Information screen will not be presented during sample analysis.

Demographic	Notes
Operator ID	Applies to patient, QC, and CVP samples. If this is deselected (checkbox unfilled), then <b>Operator Security</b> and <b>Default Operator</b> (see "Security Setup" in section 3.9) will be turned Off and unavailable.
Patient ID	If this is deselected (checkbox unfilled), then <b>Mandatory Patient ID</b> , <b>Default Patient</b> , <b>Demographics Lookup</b> , and <b>Patient Verification</b> (see next page) will be turned Off and unavailable.
Patient Last Name	
Patient First Name	
Patient Birth Date	

Patient Sex

Accession Number

Comment      Applies to patient, QC, and CVP samples.

**The Mandatory Patient ID, Default Patient, Demographics Lookup, and Patient Verification** options on the right side of the screen require that the "Patient ID" demographic be selected; they will be turned Off and unavailable if Patient ID is deselected.

The options on the right half of the Demographics Setup screen are interrelated and can be used only in certain combinations. The following table shows the allowable combinations.

The GEM Premier 3500 has been designed to make working with patient demographic information as easy as possible. While the rules discussed in this section may seem complex, the actual operation is easy to use. The instrument provides a wide range of automation: at its simplest setting, the instrument will automatically fill in patient information from previous samples or hospital records. At the other end of the range, operators will have to enter all patient information each time a sample is analyzed.

The way the instrument handles patient information depends upon the settings in **Demographics Setup** in this section. The following table shows the various combinations of options and the corresponding functioning of the instrument.



*NOTE: In the following table, the LIS/DMS will be searched only if the LIS/DMS has been assigned to a port in Interface Setup (Section 3.8).*

Default Patient	Mandatory Patient ID	Demographics Lookup	Patient Verification	How the GEM Premier 3500 will function:
<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	(Default settings) The operator will not be prompted to enter a patient ID before sample aspiration. If an ID is entered at the Patient Information screen, the instrument will use the ID to search for the patient in the last 12 months of accepted samples in its internal database. The corresponding patient information will be used. That information can be edited.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The operator will not be prompted to enter a patient ID before sample aspiration. All patient information is optional; if desired, patient information can be manually entered on the Patient Information screen.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The operator will not be prompted to enter a patient ID before sample aspiration. The Patient Information screen will contain the patient information from the last sample analyzed. That information can be changed.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The operator will be prompted to enter a patient ID. It must be entered before the sample is aspirated. The patient ID will be displayed on the Patient Information screen. The remaining patient information can optionally be manually entered.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	The operator will be prompted to enter a patient ID. It must be entered before the sample is aspirated. The instrument will use the patient ID to search for the patient in its internal database. If the patient last name is found, all patient information will be displayed on the Patient Information screen. All information except patient ID can be changed. If nothing is found, all information except patient ID can be manually entered.

The operator will be prompted to enter a patient ID. It must be entered before the sample is aspirated. The instrument will use the patient ID to search for the patient in the hospital LIS/DMS. If the patient is found, the patient ID and demographics will be presented to the operator for confirmation before the sample is aspirated. If the operator accepts the demographics, the sample will be aspirated. All patient information will be displayed on the Patient Information screen. The information cannot be changed. If the patient is not found, LIS/DMS communication is unsuccessful, or the search is canceled, all information except patient ID can be manually entered.

---

The operator will be prompted to enter a patient ID. It must be entered before the sample is aspirated. The instrument will use the patient ID to search for the patient in its internal database; if the patient last name is not found, it will search the hospital LIS/DMS. If the patient is found at either source, patient ID and demographics will be presented to the operator for confirmation before the sample is aspirated. If the operator accepts the patient demographics, the sample will be aspirated. All patient information will be displayed on the Patient Information screen. The information cannot be changed. If the patient is not found, LIS/DMS communication is unsuccessful, or the search is canceled, all information except patient ID can be manually entered.

---

When a selection is made, the instrument will adjust the other options as appropriate to make an allowable combination.

#### Mandatory Patient ID

**Mandatory Patient ID** on the Demographics Setup screen (*figure 3.7*) determines whether operators will be required to enter a patient ID prior to analyzing a sample.

This checkbox can be toggled between the following settings:

- Off (Default setting). Operators will not be required to enter a patient ID prior to analyzing patient samples. Operators can optionally enter a patient ID at the Patient Demographics screen that is displayed after sample aspiration.
- On. Operators must enter a patient ID before they will be allowed to analyze a patient sample. If an ID is not entered, patient sampling will be aborted.



*In the following descriptions, the term “patient demographic information” refers to the patient demographics that are turned On (filled checkbox) on the left side of the Demographics Setup screen (*figure 3.7*).*

#### Default Patient

The **Default Patient** option determines whether the instrument will use the patient demographic information from the previous patient sample.

This checkbox can be toggled between the following settings:

- Off (Default setting). The instrument will not supply default patient demographic information during sample processing.
- On. The instrument will use the patient demographic information from the previous sample.

#### Demographics Lookup

The **Demographics Lookup** option determines whether the instrument will use the entered patient ID to check its internal database for patient demographic information during sample analysis.

This checkbox can be toggled between the following settings:

- Off. The instrument will not check its database for patient demographic information.
- On (Default setting). The instrument will check the appropriate databases for patient demographic information.

### Patient Verification

The **Patient Verification** option determines whether the:

- instrument will prompt the operator to verify patient demographics before aspirating a sample
- external data management system or hospital LIS/DMS will be searched for patient demographic information.

This checkbox can be toggled between the following settings:

- Off (Default setting). The instrument will not prompt the operator to confirm patient demographics before aspirating a sample.
- On. The instrument will prompt the operator to confirm patient demographics before aspirating a sample.

### Host Confirmation Timeout

This setting is used only when **Patient Verification** is set to On.

The number displayed by **Host Confirmation Timeout** determines the time in seconds that the GEM Premier 3500 will wait to receive information from the hospital LIS/DMS. The default timeout is 15 seconds. Adjust the time if the “*Host communications error*” message is received during sample processing. Touching the number will display a keypad for entering a time between 5 and 300 seconds.

### Units of Measure

The **Units of Measure** button on the Sample Setup screen displays the Units of Measure screen. This screen is used to determine the units the GEM Premier 3500 will use with patient and QC sample results. The chosen units will be used when any existing or future samples are displayed, printed, or transmitted.

Touching the units displayed for an analyte on the Units of Measure screen will toggle through the units available for that analyte. The following units are available:

Parameter	Default Units	Alternate Units
<sup>1</sup> Acid/base	pH (no units)	nmol/L or nEq/L (cH)
<sup>2</sup> pCO <sub>2</sub> , pO <sub>2</sub> , A-aDO <sub>2</sub> , pAO <sub>2</sub> , P <sub>50</sub> and BP	mmHg	kPa
Na <sup>+</sup>	mmol/L	mEq/L
K <sup>+</sup>	mmol/L	mEq/L
Ca <sup>++</sup> , Ca <sup>++</sup> (7.4)	mmol/L	mEq/L or mg/dL
<sup>3</sup> Temperature	Celsius (°C)	Fahrenheit (°F)
Glucose	mg/dL	mmol/L

Lactate	mmol/L	mg/dL
THb, THbc	g/dL	g/L, mmol/L
O <sub>2</sub> ct, O <sub>2</sub> cap, CaO <sub>2</sub> , CvO <sub>2</sub> , CcO <sub>2</sub> , a-vDO <sub>2</sub>	mL/dL	mL/L, mmol/L, Vol%

<sup>1</sup> When alternate units are chosen, the label will change to cH. Selected units also apply to temperature-corrected pH.

<sup>2</sup> Also applies to temperature-corrected ( $pCO_2$  and  $pO_2$ ).

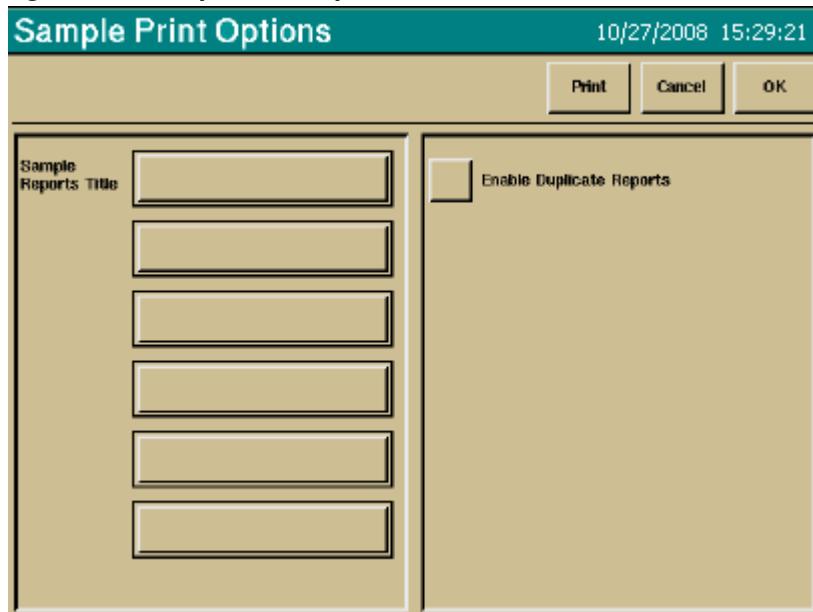
<sup>3</sup> The user can enter either °C or °F on the Patient Information screen, and the instrument will convert the entered temperature to the selected temperature units.

Regardless of the units selected for temperature, the instrument will accept the entered temperature as Celsius if the entered value is between 15.0 and 45.0, or as Fahrenheit if the entered temperature is between 59.0 and 113.0. However, the temperature will always be reported in the units selected in setup.

## Sample Print Options

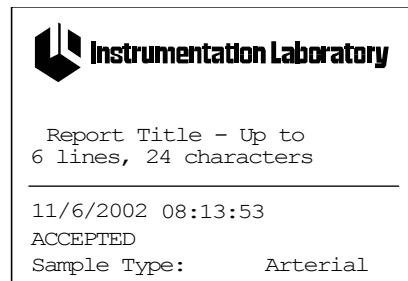
The **Sample Print Options** button on the Sample Setup screen displays the Sample Print Options screen (*figure 3.8*). This screen is used to set options for how sample results will be printed.

**Figure 3.8: Sample Print Options Screen**



### Sample Reports Title

The **Sample Reports Title** fields on the Sample Print Options screen are used to define a custom report title for printing at the top of patient and QC sample printouts (*figure 3.9*). The instrument provides six fields that represent the six available lines in the report title. Each line can contain up to 24 alphanumeric characters.



**Figure 3.9: Sample Reports Title**

Typical information for the report title includes hospital or department name, address, etc. Entering a title will automatically activate it for printing on reports.

- Blank: Off (Default setting). The instrument will not print a custom report title at the top of all printouts.
- Entered: On. The GEM Premier 3500 will print the entered report title at the top of all printouts. The report title will appear on all reports printed after this option is enabled, for both existing and future samples.

#### To Create a Title for Sample Reports:

**1. Touch the first field next to Sample Reports Title on the Print Options screen.**

Status: The instrument will display a keypad for entering the first line of the report title. You may enter up to 24 alphanumeric characters.

**2. Touch Enter to accept the current line.**

Status: The instrument will display the Print Options screen, and the entered information will appear in the field.

**3. Repeat Steps 1 and 2 for each of the remaining fields to add additional lines as desired.**

### Enable Duplicate Reports

**Enable Duplicate Reports** on the Sample Print Options screen determines whether the GEM Premier 3500 will automatically print a duplicate patient sample report after each original printout. Duplicate reports will print with the words *DUPPLICATE REPORT* as the header line. This option affects only patient sample reports.

This checkbox can be toggled between the following settings:

- Off (Default setting). The GEM Premier 3500 will print only one patient sample report after each analysis.
- On. The instrument will automatically print a duplicate report after the original printout.

### Correlation Factors

The **Correlation Factors** button on the Sample Setup screen displays the Correlation Factors screen (*figure 3.10*). This screen allows entry of correlation factors (slope and offset) for each analyte and is used to set options related to how correlation factors will be used.

The entered factor is applied to the sample analyte result before the value is reported, before it is compared to relevant ranges, and before it is used in calculating other derived parameters. Correlation factors will be applied to future samples only and not to samples that have already been run.

**Figure 3.10: Correlation Factors Screen**

**Correlation Factors**      12/24/2008 10:19:27

Print   Cancel   OK

<input checked="" type="checkbox"/> Apply to Arterial, Venous, and Capillary <input type="checkbox"/> Apply to "Other" sample type <input type="checkbox"/> Apply to QC samples	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Slope</th> <th style="text-align: center;">Offset</th> <th></th> </tr> </thead> <tbody> <tr> <td>pH</td> <td style="text-align: center;">1.000</td> <td style="text-align: center;">0.00</td> <td></td> </tr> <tr> <td>pCO<sub>2</sub></td> <td style="text-align: center;">1.000</td> <td style="text-align: center;">0</td> <td style="text-align: center;">mmHg</td> </tr> <tr> <td>pO<sub>2</sub></td> <td style="text-align: center;">1.000</td> <td style="text-align: center;">0</td> <td style="text-align: center;">mmHg</td> </tr> <tr> <td>Na<sup>+</sup></td> <td style="text-align: center;">1.000</td> <td style="text-align: center;">0</td> <td style="text-align: center;">mmol/L</td> </tr> <tr> <td>K<sup>+</sup></td> <td style="text-align: center;">1.000</td> <td style="text-align: center;">0.0</td> <td style="text-align: center;">mmol/L</td> </tr> <tr> <td>Ca<sup>++</sup></td> <td style="text-align: center;">1.000</td> <td style="text-align: center;">0.00</td> <td style="text-align: center;">mmol/L</td> </tr> <tr> <td>Glu</td> <td style="text-align: center;">1.000</td> <td style="text-align: center;">0</td> <td style="text-align: center;">mg/dL</td> </tr> <tr> <td>Lac</td> <td style="text-align: center;">1.000</td> <td style="text-align: center;">0.0</td> <td style="text-align: center;">mmol/L</td> </tr> <tr> <td>Hct</td> <td style="text-align: center;">1.000</td> <td style="text-align: center;">0</td> <td style="text-align: center;">%</td> </tr> </tbody> </table>		Slope	Offset		pH	1.000	0.00		pCO <sub>2</sub>	1.000	0	mmHg	pO <sub>2</sub>	1.000	0	mmHg	Na <sup>+</sup>	1.000	0	mmol/L	K <sup>+</sup>	1.000	0.0	mmol/L	Ca <sup>++</sup>	1.000	0.00	mmol/L	Glu	1.000	0	mg/dL	Lac	1.000	0.0	mmol/L	Hct	1.000	0	%
	Slope	Offset																																							
pH	1.000	0.00																																							
pCO <sub>2</sub>	1.000	0	mmHg																																						
pO <sub>2</sub>	1.000	0	mmHg																																						
Na <sup>+</sup>	1.000	0	mmol/L																																						
K <sup>+</sup>	1.000	0.0	mmol/L																																						
Ca <sup>++</sup>	1.000	0.00	mmol/L																																						
Glu	1.000	0	mg/dL																																						
Lac	1.000	0.0	mmol/L																																						
Hct	1.000	0	%																																						

The formula for the correlation factor for each analyte is:

$$y = mx + b$$

where y is the correlated value, x is the original analyte value, m is the entered slope, and b is the entered offset.

The default value for slope (m) is 1, with a display resolution of x.xxx and no entry range limit.

The default value for offset (b) is 0. Except for pH, the format of the offset will be that of the measured analyte in the units selected in setup. For pH, the units for offset will be the default pH units.

The following procedure may be used to determine slope and offset values:

1. Ensure that the GEM Premier 3500 and the comparison analyzer are maintained and calibrated according to manufacturer's instructions and specifications.
2. Use a large population of samples with balanced distribution over the normal and pathological ranges (at least 100 samples).
3. Analyze samples in duplicate on both instruments. Time between sampling on the two instruments must not exceed 2 to 3 minutes.
4. Remove outliers from data.
5. With the aid of a computer or calculator, perform a linear regression analysis. The GEM Premier 3500 should be treated as the x variable (independent variable), while the instrument used for comparison is used as the y variable (dependent variable).
6. Enter offset intercept and slope values on the Correlation Factors screen.

For more details refer to NCCLS Document EP9-A2, Method Comparison and Bias Estimation using Patient Samples, Approved Guideline - Second Edition.

A checkbox is provided on the Correlation Factors screen to apply the factors to arterial, venous, and capillary samples. The default is set to ON (checked). Additional checkboxes are provided to apply the factors to QC samples and patient samples of type "Other." These options are both set to OFF (unchecked) by default:

- If correlation factors are applied to QC samples, they will be applied to future QC ranges as they are scanned from the insert sheet of the QC material at setup time. **The factors will**

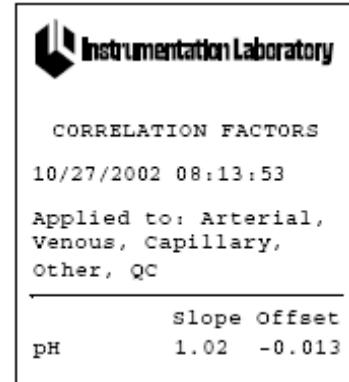
not be applied to previously scanned QC ranges nor to previous, manually entered/edited QC ranges.

 **NOTE:** IL recommends that you not apply correlation factors to QC if the QC results are used in any type of peer comparison group.

- If a checkmark appears in the Apply to “Other” sample types checkbox, the correlation factors will also be applied to patient samples of type “Other.”

 **NOTE:** If correlation factors are **not** applied to “Other,” this sample type can be used for analyzing proficiency samples.

A Correlation Factors report (figure 3.11) may be printed by selecting the **Print** button on the Correlation Factors screen.



**Figure 3.11: Correlation Factors Report**

## Patient Ranges

The **Patient Ranges** button on the Sample Setup screen displays the Patient Ranges screen (figure 3.12). This screen allows entry of reference (normal) ranges and critical limits for all sample types (Arterial, Venous, Capillary, Other), both measured and derived.

**Figure 3.12: Patient Ranges Screen**

Patient Ranges		11/21/2008 15:12:10																																																																
<i>Select type, then enter or edit ranges.</i>																																																																		
		Print All	Print	Cancel	OK																																																													
<input checked="" type="checkbox"/> Arterial <input type="checkbox"/> Measured(GEM)		<table border="1"> <thead> <tr> <th colspan="2">Reference Ranges</th> <th colspan="2">Critical Limits</th> </tr> <tr> <th>Low</th> <th>High</th> <th>Low</th> <th>High</th> </tr> </thead> <tbody> <tr> <td>pH</td> <td>7.10</td> <td>7.44</td> <td>7.00</td> <td>7.60</td> </tr> <tr> <td>pCO<sub>2</sub></td> <td>35</td> <td>40</td> <td>25</td> <td>55</td> <td>mmHg</td> </tr> <tr> <td>pO<sub>2</sub></td> <td>95</td> <td>100</td> <td>80</td> <td>120</td> <td>mmHg</td> </tr> <tr> <td>Na<sup>+</sup></td> <td>136</td> <td>142</td> <td>120</td> <td>155</td> <td>mmol/L</td> </tr> <tr> <td>K<sup>+</sup></td> <td>3.8</td> <td>5.0</td> <td>2.7</td> <td>6.0</td> <td>mmol/L</td> </tr> <tr> <td>Ca<sup>++</sup></td> <td>1.00</td> <td>1.20</td> <td>0.60</td> <td>1.40</td> <td>mmol/L</td> </tr> <tr> <td>Glu</td> <td>70</td> <td>110</td> <td>50</td> <td>300</td> <td>mg/dL</td> </tr> <tr> <td>Lac</td> <td>0.9</td> <td>1.9</td> <td></td> <td>2.3</td> <td>mmol/L</td> </tr> <tr> <td>Hct</td> <td>37</td> <td>50</td> <td>20</td> <td>52</td> <td>%</td> </tr> </tbody> </table>				Reference Ranges		Critical Limits		Low	High	Low	High	pH	7.10	7.44	7.00	7.60	pCO <sub>2</sub>	35	40	25	55	mmHg	pO <sub>2</sub>	95	100	80	120	mmHg	Na <sup>+</sup>	136	142	120	155	mmol/L	K <sup>+</sup>	3.8	5.0	2.7	6.0	mmol/L	Ca <sup>++</sup>	1.00	1.20	0.60	1.40	mmol/L	Glu	70	110	50	300	mg/dL	Lac	0.9	1.9		2.3	mmol/L	Hct	37	50	20	52	%
Reference Ranges		Critical Limits																																																																
Low	High	Low	High																																																															
pH	7.10	7.44	7.00	7.60																																																														
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Lac	0.9	1.9		2.3	mmol/L																																																													
Hct	37	50	20	52	%																																																													

Patient results will be checked against the ranges in effect at the time the sample is analyzed. The ranges are saved with the results so that they may be viewed if the sample is later

recalled or printed. Temperature-corrected values ( $pH(T)$ ,  $pCO_2(T)$ , and  $pO_2(T)$ ), will be checked against the same ranges defined for the non-temperature-corrected parameters.

When the Patient Ranges screen is first displayed, it displays the entry boxes for measured arterial samples. Buttons in the left area of the screen allow selection of other sample types and derived parameters:

- Touching the sample-type button will display a list of available sample types: Arterial, Venous, Capillary, Other. The default is Arterial.
- Touching the analyte-type button will display a list of available analyte types: Measured (GEM), Measured (CO-Ox), Derived (1), Derived (2), and Derived (3). The default is Measured (GEM). These analyte types correspond to instrument analytes as follows:

Measured (GEM)	Nine measured analytes native to the GEM Premier 3500
Measured (CO-Ox)	Six measured analytes native to an attached IL CO-Oximeter device
Derived (1)	The first eight derived parameters
Derived (2)	The second eight derived parameters
Derived (3)	The last four derived parameters

The ranges shown to the right of the buttons will update automatically according to the buttons that have been selected. The initial value of all ranges is blank.

Touching a value will display a numeric keypad for entry or editing of the value. A low value, high value, or both may be entered. If a value is not entered (blank), the instrument will not check patient results against the value.

The resolution of the range values follows the resolution of the parameter being entered. The units follow those selected in setup (see “Units of Measure” in this section) and are displayed to the right of the ranges. If pH is in cH units, the instrument will transpose the low and high range values because the conversion makes the high value lower than the low value.

The instrument will automatically perform the following checks when ranges are entered:

- that the high value is higher than the low value for both ranges (Reference and Critical Limits)
- that the Critical Limit high value is higher than or equal to the high value for the Reference Range when both are entered
- that the Critical Limit low value is lower than or equal to the low value for the Reference Range when both are entered
- that all four values for each analyte fall within the reportable range for the analyte

The Patient Ranges screen also allows printing of reports that show the ranges that have been defined:

Print	Prints the ranges that are currently displayed on the screen.
Print All	Prints the ranges for all sample types (Arterial, Venous, Capillary, and Other) and analyte types (Measured and Derived).

Reference Ranges and Critical Limits may also be automatically printed with patient results. See “Print Ranges with Results,” described in the next section.

## Print Ranges with Results

This checkbox on the Sample Setup screen determines whether ranges entered on the Patient Ranges screen (above) are printed with patient sample results.

- Off. (Default setting) The GEM Premier 3500 will not print Reference Ranges and Critical Limits with patient results.
- On. The instrument will automatically print Reference Ranges and Critical Limits with patient results.

### Patient Sample Auto-Accept

**Patient Sample Auto-Accept** on the Sample Setup screen determines whether the instrument will allow a disposition to be assigned to samples at the Patient Sample Results screen. This checkbox can be toggled between the following settings:

- Off (Default setting). The GEM Premier 3500 will allow the disposition of patient sample results at the Patient Sample Results screen. Samples can be assigned dispositions of ACCEPT or DISCARD with the **Accept** and **Discard** buttons, or can be left in a PENDING state with the **Exit** button.
- On. The instrument will allow exiting the Patient Sample Results screen, without setting a disposition. All samples will automatically be given the ACCEPTED disposition. Turning this option on will not change the status of existing samples; the status of any pending samples must be manually changed if desired.

See “Set Patient Sample Disposition” in 4.3 Patient Sampling Process for more information about setting the disposition of samples.

### Flag Patient Results for Interference and Micro Clots

The GEM Premier 3500 automatically checks for micro clots and interferences when analyzing patient samples. This happens regardless iQM is enabled or disabled. During this check, the following message (plus progress bar) will be displayed:

*Checking for presence of interference and micro clots.*

The **Flag Patient Results for Interference and Micro Clots** option on the Sample Setup screen determines whether patient sample reporting will be delayed until the check is complete and whether patient results will be flagged if anomalies are found:

- Off (Default setting). Patient results will not be flagged. The instrument will perform the check **after** patient results are displayed; patient results will not be delayed, and affected analytes will not be flagged. However, the operator will be presented with a message if an interference or clot was detected in the previous sample. The message will be displayed until dismissed by the operator.
- On. Patient results will be flagged. During sample processing, the instrument will:
  - Delay the reporting of patient sample results until the check is complete (approximately three minutes following sample introduction).
  - Flag affected analytes if any anomalies are found (see “Displayed Exceptions (GEM Premier 3500 Analytes)” in 4.3 Patient Sampling Process).

For more information, see “Failure Pattern Recognition Checks” in 6.1 System Description.

### PCO<sub>2</sub> Trending

This feature allows the GEM Premier 3500 to display patient results that are above the Reportable Range (115 mmHg) but below 150 mmHg for patient trending purposes. These results will be flagged with a “?” next to the number to indicate that the result is above the Reportable Range and **should only be used for patient trending purposes**. Any patient results that utilize a PCO<sub>2</sub> value in a calculation will carry the same “?” flag. This feature can be enabled/disabled through the Sample Setup command on the Configuration menu by

selecting/deselecting the check box: “Report pCO<sub>2</sub> when above reportable range in patient sample” on the GEM Premier 3500.

The Sample Setup screen (*figure 3.12*) provides the options shown.



*NOTE: Enabling this feature will affect the data transmission coming from the GEM Premier 3500. Please consult with your IT department prior to enabling this feature to ensure that your host computer system is compatible with the data.*

**Figure 3.12: Sample Setup Screen with pCO<sub>2</sub> Trending**

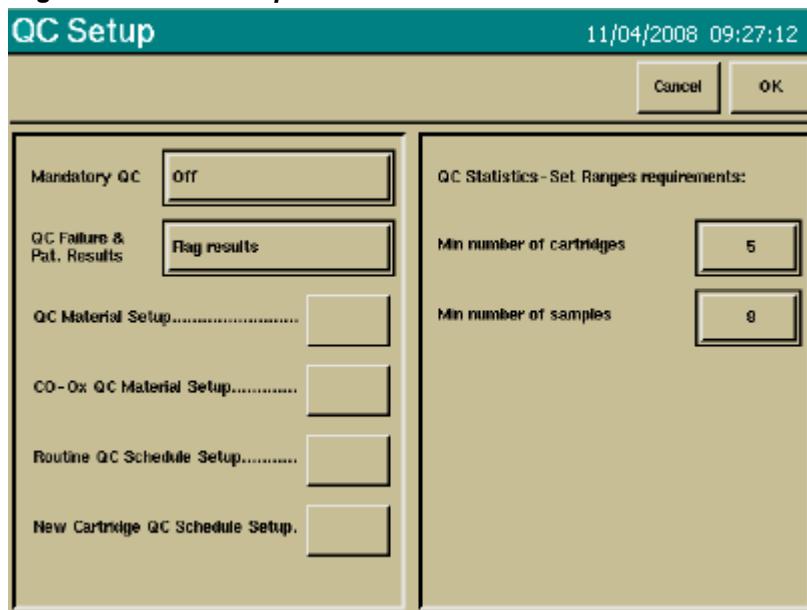
The screenshot shows a software interface titled "Sample Setup" with a timestamp of "10/08/2008 17:24:48". At the top right are "Cancel" and "OK" buttons. Below the title, there are six rows of configuration options, each consisting of a label, two checkboxes, and a descriptive text. Row 1: "Analyte Enable/Disable" (checkbox), "Patient Ranges" (checkbox). Row 2: "Panel Setup" (checkbox), "Print Ranges with Results" (checkbox). Row 3: "Demographics" (checkbox), "Patient Sample Auto-accept" (checkbox, checked). Row 4: "Units of Measure" (checkbox), "Flag Patient Results for Interference and Micro Clots" (checkbox). Row 5: "Sample Print Options" (checkbox), "Report pCO<sub>2</sub> when above reportable range in patient sample" (checkbox). Row 6: "Correlation Factors" (checkbox).

Sample Setup		10/08/2008 17:24:48
Analyte Enable/Disable.....	<input type="checkbox"/>	Patient Ranges..... <input type="checkbox"/>
Panel Setup.....	<input type="checkbox"/>	<input type="checkbox"/> Print Ranges with Results
Demographics.....	<input type="checkbox"/>	<input checked="" type="checkbox"/> Patient Sample Auto-accept
Units of Measure.....	<input type="checkbox"/>	<input type="checkbox"/> Flag Patient Results for Interference and Micro Clots
Sample Print Options.....	<input type="checkbox"/>	<input type="checkbox"/> Report pCO <sub>2</sub> when above reportable range in patient sample
Correlation Factors.....	<input type="checkbox"/>	

### 3.5 QC Setup

The **QC Setup** command on the **Configuration** menu displays the QC Setup screen (*figure 3.13*). This screen provides the options shown:

*Figure 3.13: QC Setup Screen*



The GEM Premier 3500 eases the administrative burden of managing QC when iQM is disabled by providing for requested or required QC sampling, allowing a schedule for QC sampling to be defined, and requiring pre-definition of the material that will be used during QC sampling. Managing the GEM Premier 3500's QC mechanisms involves the following steps:

1. Set **Mandatory QC** to Off, Requested, or Required according to the level of control desired over QC sampling.
2. Specify whether analytes that have failed QC sampling should appear on patient sample reports – see “QC Failure & Patient Results” in this section.
3. Define the QC material to be used in the QC sampling – see “QC Material Setup” in this section.
4. If an IL CO-Oximeter device (IL 682 or GEM OPL) is attached to the GEM Premier 3500, define the QC material to be used with the device.
5. Set up the schedules to which QC sampling should be performed – see “Define QC Schedules” in this section.
6. Specify the desired ranges for QC statistics – see “QC Statistics – Set Ranges Requirements” in this section.

These steps are described in the following sections.

#### Mandatory QC

**Mandatory QC** determines whether the GEM Premier 3500 will prompt operators to perform QC sampling and whether the GEM Premier 3500 will allow operators to analyze patient samples when QC sampling is overdue.

If mandatory QC is Requested or Required, then QC material must be defined and a QC sampling schedule must be entered.



**NOTE:** The GEM Premier 3500 does not provide a default QC schedule and does not check to see that QC material has been defined. To use **Mandatory QC** effectively, both must be defined in conjunction with setting the **Mandatory QC** option.

Individual institutions must determine how often quality control sampling is performed and what materials are analyzed. Check federal and state regulations for information about quality control requirements. See 5.1 "QC Recommendations" for Instrumentation Laboratory's quality control recommendations and CLIA '88 quality control requirements.

**Mandatory QC** can be toggled between the following three settings, which provide an increasing level of QC control:

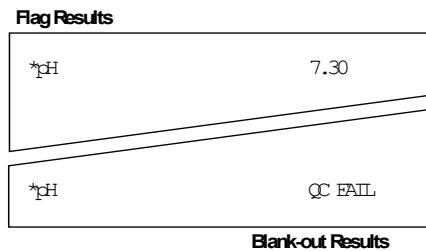
Off	(Default setting). The GEM Premier 3500 will not remind operators to perform QC sampling. Operators will be able to analyze patient samples even when QC has not been performed.
Requested	Touching the <b>Next QC</b> button will display a list of QC due within eight hours of the current time. When QC sampling is due within one hour, the instrument will notify operators by turning the <b>Next QC</b> button yellow on the Ready screen. The instrument <i>will allow</i> continued patient sampling, even when the QC becomes overdue.
Required	When QC sampling is due within one hour, the instrument will notify operators by turning the <b>Next QC</b> button yellow on the Ready screen. When the QC becomes overdue, the <b>Next QC</b> button will flash, and the instrument <i>will not allow</i> continued patient sampling until the QC is analyzed. If operators attempt to analyze a sample, the instrument will notify them that QC sample(s) are due. Because the instrument does not allow continued patient sampling, this effectively creates a hard QC lockout.

## QC Failure & Patient Results

**QC Failure & Patient Results** on the QC Setup screen determines whether the GEM Premier 3500 will withhold patient results from screens and printouts for the analyte values that have failed scheduled or unscheduled QCs. This option can be toggled between the following settings:

Flag Results	(Default setting). When an analyte fails QC, the instrument will place an "*" next to the analyte name on printed and displayed patient results, <i>figure 3.14</i> . The "*" will appear until that analyte passes the failed QC in subsequent QC testing.
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**Figure 3.14: Printout Samples for QC Failure & Pat Results Settings**



Blank-out Results	When an analyte fails QC, the instrument will place an "*" next to the analyte name and QC FAIL will appear for the analyte value on printed and displayed patient results, <i>figure 3.14</i> . This "QC blank-out" will stay in effect until that analyte passes the failed QC in subsequent QC testing.
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The instrument will also blank the values in the appropriate data files and in the RS-232 or Ethernet output. The failed status will be saved with the sample and will not change, even if QC Blank-out is later turned off.



*NOTE: QC Blank-out works only with scheduled or unscheduled QCs that use QC material marked as Active.*

## QC Material Setup

All QC material must be defined before it can be used with the GEM Premier 3500, and only defined QC material will be available for inclusion in scheduled QC. Up to 20 different QC materials may be defined.

When operators analyze a QC sample, they must identify the QC material by either selecting the material from a list or by scanning the QC material barcode. If the barcode is used, the instrument will accept the material only if the lot number matches a lot number of a defined QC material.

QC material is defined by entering the following information:

<b>Lot Number</b>	Up to 10 alphanumeric characters for the lot number. This is the unique identifier for the QC material. Entry of the lot number is mandatory, either manually or by scanning the barcode that comes with IL QC solutions.
<b>Description</b>	Up to 20 alphanumeric characters that describe the QC material. IL recommends that the QC level be included in each description. When the instrument displays available QC material to operators, it will show the lot number and this description. Entry is mandatory.  When IL QC materials are used, the description is automatically taken from the barcode.
<b>Lot Status</b>	Either Parallel (default setting) or Active. A QC material is typically designated as parallel during the transition between lot numbers of a solution, so that operators can compare the results from both lot numbers before bringing the new lot “online.” QC material marked with parallel may not be used in a QC schedule.  Although means and ranges are defined for parallel QC material, <u>the instrument will not apply pass/fail criteria to the results</u> . This means that parallel QC material that fails will not block analytes from being reported in patient results when <b>QC Failure &amp; Patient Results</b> is set to Blank-out.



*NOTE: The Lot Status of QC material cannot be changed from Active to Parallel.*

<b>Analyte Ranges</b>	For each analyte, the target range (minimum/maximum values) is used for the pass/fail assessment of QC results. The GEM Premier 3500 will determine whether an analyte has passed or failed QC by comparing the measured QC results with the ranges defined for the QC material.  Entry of the ranges is optional; however, any analyte that does not have ranges will not be measured or reported when the QC sample is analyzed.  For regulatory reasons, statistically valid QC ranges must be determined by the user, not the manufacturer of the QC material. QC materials supplied by IL provide informational ranges; however, it is at the user's discretion whether these ranges are used.  QC ranges may be entered manually or may be entered by scanning the barcode insert supplied with the solutions, where available.
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QC ranges may also be populated from mean and standard deviation values that have been calculated by the GEM Premier 3500. This method is described in Chapter 5 “QC Statistics”.

**NOTE:** The GEM Premier 3500’s ampoule spinner reads the barcode on each IL Control and GEM critCheck QC ampoule. The barcode contains only the ampoule’s lot number and not any information to define the QC material within.

To define a QC material, touch **QC Material Setup** on the QC Setup screen. This displays the QC Material Setup screen (*figure 3.15*), which lists the lot number, description, and status of all defined QC material. Options are provided for adding, deleting, editing, and printing QC material definitions.

**Figure 3.15: QC Material Setup Screen**

QC Material Setup			12/04/2008 14:12:45						
		Print All		Print	Edit	Delete	Add	OK	
Lot Number	Status	Description							
L900	Active	Control, 9, LOU							
N900	Active	Control, 9, NORMAL							
H900	Active	Control, 9, HIGH							
4115	Parallel	CEMCritCheck, LOU							
5115	Parallel	CEMCritCheck, NORMAL							

To delete a material, touch the desired QC material in the list to highlight it, then touch the **Delete** button. The instrument will prompt to confirm the deletion. When QC material is deleted, references to the material on the Next QC list and in QC scheduling will be removed. QC samples related to the material will remain in the instrument’s database.

To edit a material, touch the desired QC material in the list to highlight it, then touch the **Edit** button. The QC Material Information screen (*figure 3.16*) lists the attributes for the material and allows the attributes to be changed. If the lot number is changed, references to the old lot number on the Next QC list and in QC scheduling will be removed.

**Figure 3.16: QC Material Information Screen**

The screenshot shows the 'QC Material Information' screen. At the top right is the date and time: 10/23/2008 18:22:10. Below it are two buttons: 'Cancel' and 'OK'. On the left, there are three input fields: 'Lot Number' (N900), 'Lot Description' (ContrIL 9, NORMAL), and 'Lot Status' (Active). To the right is a table titled 'QC Ranges' with columns for 'Low' and 'High' values. The table includes rows for pH, pCO2, pO2, Na+, K+, Ca++, Glu, Lac, and Hct. Units for some rows are indicated as mmHg, mmol/L, mg/dL, and %.

	Low	High	
pH	7.13	7.19	
pCO <sub>2</sub>	31	77	mmHg
pO <sub>2</sub>	95	115	mmHg
Na <sup>+</sup>	135	145	mmol/L
K <sup>+</sup>	3.6	4.2	mmol/L
Ca <sup>++</sup>	1.14	1.32	mmol/L
Glu	79	103	mg/dL
Lac	0.8	1.2	mmol/L
Hct			%

The QC Material Information screen lists the analytes in the lot, along with each analyte's low and high values. These ranges are the ranges that were entered when the QC material was defined. Touching any of the low or high analyte values will display a keypad for editing the value.

To print a Material Definition Report (*figure 3.17*) for a single QC material, touch the desired QC material from the QC Material Setup screen to highlight it, then touch the **Print** button. To print a Material Definition Report for all defined QC materials, touch the **Print All** button.

The screenshot shows a 'QC Material Report' from 05/03/2001 at 09:31:56. It includes the lot number (N900), description (ContrIL 9, NORMAL), and status (Active). Below this is a table of QC ranges for pH, pCO2, and pO2.

	QC Range
pH	7.35 – 7.49
pCO <sub>2</sub>	31 – 77
pO <sub>2</sub>	80 – 115

**Figure 3.17: QC Material Report**

### To Define QC Material:

1. Touch QC Material Setup on the QC Setup screen.

Status: The instrument will display the QC Material Setup screen (*figure 3.15*).

2. Touch Add.

Status: The instrument will display the QC Material Information screen (*figure 3.16*).

### For IL solutions, scan the barcode from the QC insert to enter the lot number and ranges.

Status: The GEM Premier 3500 will automatically fill in the lot description and QC ranges from the barcode. Proceed to the last step.

**OR**

**For IL or non-IL QC solutions, touch the Lot Number field to manually enter the lot number, then touch Enter.**

Status: Enter other information for the material using the following steps.

**3. Touch the Lot/Description field, enter a description for the QC material, then touch Enter.**

Status: IL recommends that the level be included in the description of all QC material.

**If desired, touch the Lot Status checkbox to change the status of the QC material from Parallel to Active.**

Status: Lot Status defaults to Parallel.

**4. Enter the pass/fail ranges for each analyte in the QC material.**

Status: Space is provided for each analyte's low and high value. Touching any of the low or high analyte values will display a keypad for entering the value. Enter low and high values.



**NOTE:** If QC samples have been analyzed with a material marked as Parallel, the QC ranges can be determined from statistical values that have been calculated by the GEM Premier 3500. For more information, see Chapter 5 "QC Statistics".

**5. When all values have been entered, touch OK.**

Status: The GEM Premier 3500 will display the QC Material Setup screen with the new QC material listed.

**6. Touch OK again.**

Status: The QC Setup screen will be displayed.

## CO-Ox QC Material Setup

When you have an IL CO-Oximeter device attached to the GEM Premier 3500, you must define the CO-Ox QC material that operators will use. All CO-Ox QC material must be defined before it can be used, and only defined QC material will be available for inclusion in scheduled QC.

When operators analyze a CO-Ox QC sample, they must identify the QC material by selecting the material from a list of defined QC material.

CO-Ox QC material is defined by first selecting the material from a predefined list. The following choices are available: IL Multi-4 Level 1, IL Multi-4 Level 2, IL Multi-4 Level 3, IL Multi-4 Level 4, GEM OPL Yellow, GEM OPL Orange, and Other.

For all material except Other, the instrument will fill in the Lot Description with the name of the selected material. This information cannot be changed. If Other was chosen, the Lot Description will be left blank, and a suitable description can be optionally entered.

After choosing the material, the following information must be entered:

<b>Lot Number</b>	Up to 10 alphanumeric characters for the lot number. This is the unique identifier for the CO-Ox QC material. Entry of the lot number is mandatory.  For GEM OPL optical QC material, where no lot number exists, it is recommended that a lot number in the form of S/N-X be used, where S/N is the serial number on the filter, and X is either Y (for yellow) or O (for orange).
<b>Lot Status</b>	Either Parallel (default setting) or Active. A CO-Ox QC material is typically designated as parallel during the transition between lot numbers of a solution, so that operators can compare the results from both lot numbers before bringing the new lot "online." Lot Status does not apply to

GEM OPL optical QC. CO-Ox QC material marked with parallel may not be used in a QC schedule.

Although means and ranges are defined for parallel CO-Ox QC material, the instrument will not apply pass/fail criteria to the results. This means that parallel CO-Ox QC material that fails will not block analytes from being reported in patient results when **QC Failure & Patient Results** is set to Blank-out.



***NOTE:** The Lot Status of CO-Ox QC material cannot be changed from Active to Parallel.*

**Analyte Ranges** For each analyte, the target range (minimum/maximum values) is used for the pass/fail assessment of CO-Ox QC results. The GEM Premier 3500 will determine whether an analyte has passed or failed QC by comparing the measured QC results with the ranges defined for the CO-Ox QC material.

Ranges are provided for the following analytes:

- GEM OPL optical QC material: THb, O<sub>2</sub>Hb, COHb, and MetHb. Optical QC ranges are printed on the yellow and orange cuvettes.
- All other CO-Ox QC material: THb, O<sub>2</sub>Hb, COHb, MetHb, and HHb. IL Multi-4 ranges are provided on the insert sheet inside the box.

Entry of the ranges is optional; however, any analyte that does not have ranges will not be measured or reported when the QC sample is analyzed.

For regulatory reasons, statistically valid QC ranges must be determined by the user, not by the manufacturer of the QC material (not applicable to GEM OPL Optical QC). CO-Ox QC materials supplied by IL provide informational ranges; however, it is at the user's discretion whether these ranges are used.

CO-Ox QC ranges must be entered manually.

CO-Ox QC ranges may also be populated from mean and standard deviation values that have been calculated by the GEM Premier 3500. This method is described in Chapter 5. "QC Statistics".

To define a CO-Ox QC material, touch **CO-Ox QC Material Setup** on the QC Setup screen. This displays the CO-Ox QC Material Setup screen (*figure 3.18*), which lists the lot number, description, and status of all defined CO-Ox QC material. Options are provided for adding, deleting, editing, and printing CO-Ox QC material definitions.

**Figure 3.18: CO-Ox QC Material Setup Screen**

CO-Ox QC Material Setup			11/07/2008 13:19:54	
Lot Number	Status	Description	Print All	Print
6182-0	Active	CEM OPL Orange		
6182-Y	Active	CEM OPL Yellow		
H0198543	Active	IL Multi-4 Level 1		
H0718633	Active	IL Multi-4 Level 3		

To delete a material, touch the desired CO-Ox QC material in the list to highlight it, then touch the **Delete** button. The instrument will prompt to confirm the deletion. When CO-Ox QC material is deleted, references to the material on the QC Due list and in QC scheduling will be removed. QC samples related to the material will remain in the instrument's database.

To edit a material, touch the desired CO-Ox QC material in the list to highlight it, then touch the **Edit** button. The CO-Ox QC Material Information screen (*figure 3.19*) lists the attributes for the material and allows the attributes to be changed. If the lot number is changed, references to the old lot number on the QC Due list and in QC scheduling will be removed.

**Figure 3.19: CO-Ox QC Material Information Screen**

CO-Ox QC Material Information			12/03/2008 14:22:01	
			Cancel	OK
Lot Number:	1000324		QC Ranges:	Low High
Lot Description:	IL Multi-4 Level 1		THb	16.4 17.4 g/dL
Lot Status:	Active		O2Hb	36.1 40.1 %
			COHb	58.8 62.2 %
			MethHb	-1.0 3.0 %
			HHb	-0.9 1.5 %

The CO-Ox QC Material Information screen (*figure 3.19*) lists the analytes in the lot, along with each analyte's low and high values. These ranges are the ranges that were entered when the CO-Ox QC material was defined. Touching any of the low or high analyte values will display a keypad for editing the value.

To print a Material Definition Report (*figure 3.20*) for a single CO-Ox QC material, touch the desired CO-Ox QC material from the CO-Ox QC Material Setup screen to highlight it, then touch the **Print** button. To print a Material Definition Report for all defined CO-Ox QC materials, touch the **Print All** button.

Instrumentation Laboratory	
QC Material Report	
05/03/2001	09:31:56
<b>Lot Number:</b>	1008324
<b>IL Multi-4 Level 1</b>	
<b>Lot Status:</b>	Active
<b>QC Range</b>	
THb	16.4 - 17.4
O2Hb	36.1 - 40.1
COHb	58.8 - 62.2
MetHb	-1.0 - 3.0
HHb	-0.9 - 1.5

**Figure 3.20: CO-Ox QC Material Report**

#### To Define CO-Ox QC Material:

##### 1. Touch CO-Ox QC Material Setup on the QC Setup screen.

Status: The instrument will display the CO-Ox QC Material Setup screen (*figure 3.18*).

##### 2. Touch Add.

Status: The instrument will display the CO-Ox QC Material Information screen (*figure 3.19*).

##### 3. Choose the CO-Ox material from the list.

Status: The following choices are available: IL Multi-4 Level 1, IL Multi-4 Level 2, IL Multi-4 Level 3, IL Multi-4 Level 4, GEM OPL Yellow, GEM OPL Orange, and Other.

For all but the Other type, The GEM Premier 3500 will automatically fill in the lot description. For Other, optionally enter a suitable description.

##### 4. If desired, touch the Lot Status checkbox to change the status of the QC material from Parallel to Active.

Status: Lot Status defaults to Parallel.

##### 5. Enter the pass/fail ranges for each analyte in the QC material.

Status: Space is provided for each analyte's low and high value. Touching any of the low or high analyte values will display a keypad for entering the value. Enter low and high values.



*NOTE: CO-Ox QC ranges can be determined from statistical values that have been calculated by the GEM Premier 3500 (This does not apply to GEM OPL optical QC). For more information, see Chapter 5 "QC Statistics".*

##### 6. When all values have been entered, touch OK.

Status: The GEM Premier 3500 will display the CO-Ox QC Material Setup screen with the new CO-Ox QC material listed.

##### 7. Touch OK again.

Status: The QC Setup screen will be displayed.

## Define QC Schedules

When you use **Mandatory QC**, you must define the schedule to which QC sampling should be performed.



*NOTE: There is no default QC schedule. Simply turning on **Mandatory QC** will not automatically implement any preset QC sampling. The Key Operator **must** define a QC schedule.*

Scheduled QC can only be set up for QC material that has been defined, including those for attached devices, see QC Material Setup in this section. The QC material must have an active status – QC material marked parallel cannot be scheduled.

The GEM Premier 3500 supports the creation of two types of QC schedules: routine QCs and new cartridge QCs:

- **Routine QC Schedule Setup** on the QC Setup screen is used to specify the lot number of the QC material and the day and time it should be analyzed. The instrument allows up to 250 routine QC schedules to be defined.

Touching the **Routine QC Schedule Setup** button will display the Routine QC Schedule Setup screen (figure 3.21). This screen provides buttons for creating routine QC schedules. It contains a scrollable listing with the currently defined QCs, showing the lot number, day/time for each QC, and a description. The list is initially empty. When schedules are present, they are sorted first by day, then by time, and then by lot number.

*Figure 3.21: Routine QC Schedule Setup Screen*

Routine QC Schedule Setup				10/09/2008 11:14:01
Lot Number	Description	Day Due	Time Due	
L900	ContrIL 9, LOW	Monday	08:00	
N900	ContrIL 9, NORMAL	Monday	09:30	
L900	ContrIL 9, LOW	Tuesday	09:45	
N900	ContrIL 9, NORMAL	Tuesday	12:00	
H900	ContrIL 9, HIGH	Wednesday	09:10	
H900	ContrIL 9, HIGH	Thursday	13:00	

- **New Cartridge QC Schedule Setup** is used to specify the lot number of the QC material that should be analyzed after cartridge warm-up. The instrument allows up to 10 new cartridge QCs to be defined.

Touching the **New Cartridge QC Schedule Setup** button will display the New Cartridge QC Schedule Setup screen. This screen is similar to the screen for Routine QCs, except that no “day/time” field is provided as QCs are run in the order they are listed on the screen.



**NOTE:** Individual institutions must determine how often quality control samples are analyzed. Check federal and state regulations for information about quality control requirements. See "QC Recommendations" in Chapter 5 for Instrumentation Laboratory's quality control recommendations and CLIA '88 quality control requirements.

The QC Schedule Setup screens provide the following options:

- Add** Displays screens for adding a scheduled QC.
- Delete** Touch the desired scheduled QC in the list to highlight it, then touch **Delete** to delete the schedule.
- Print** Touch **Print** to print the Routine QC Schedule Report, *figure 3.22*, or the New Cartridge QC Schedule Report. These reports list information for all scheduled QCs.

**Figure 3.22: Routine QC Schedule Report**

 <b>Instrumentation Laboratory</b>		
Routine QC Schedule		
Day	Time	Lot #
Description		
Mon	08:00	N089
	ContrIL 9, Normal	
Tues	13:30	N900
	ContrIL 9, Normal	
...		

### To Add a Routine Scheduled QC:

1. **Touch the Routine QC Schedule Setup button on the QC Setup screen.**  
Status: The instrument will display the Routine QC Schedule Setup screen, *figure 3.21*.
2. **Touch Add.**  
Status: The instrument will display the lot number and description for all Active QC lots that have been defined with "QC Material Setup" or "CO-Ox QC Material Setup" described in this section.
3. **Touch the desired QC material to highlight it.**
4. **Touch OK.**  
Status: The instrument will display the Select QC Days and Time screen.
5. **Touch the desired day(s) for the QC sample to be analyzed, and enter the desired time.**
6. **Touch Enter to finish creating the routine QC.**  
Status: If the entry is incomplete, the GEM Premier 3500 will display a message with the required corrections. For example, if a time of 28:00:00 was entered, the message would read: *28:00:00 is not a valid time. Please try again.* If no errors are present, the instrument will display the Routine QC Schedule Setup screen with the new scheduled QC in the list.
7. **Touch OK to return to the QC Setup screen.**

### To Add a New Cartridge Scheduled QC:

#### 1. Touch the New Cartridge QC Schedule Setup button on the QC Setup screen.

Status: The instrument will display the New Cartridge QC Schedule Setup screen.

#### 2. Touch Add.

Status: The instrument will display the lot number and description for all Active QC lots that have been defined with "QC Material Setup" described in this section.

#### 3. Touch the desired QC material to highlight it.

#### 4. Touch OK.

Status: The instrument will display the New Cartridge QC Schedule Setup screen with the new QC in the list. The QC material will be added to the bottom of the list. The order of the material in this list determines the order the material will be run when new cartridges are inserted.

#### 5. Touch OK to return to the QC Setup screen.

### QC Statistics – Set Ranges Requirements

To assist with QC range setting for GEM Premier 3500 analytes, the instrument can use the QC results to calculate statistical values for the material.

The options under **QC Statistics – Set Ranges Requirements** let you determine the criterion for when these calculated statistics can be used:

- **Minimum number of cartridges:** A QC material must be used with this number of cartridges before its data will be used to calculate QC ranges. The default is 5 cartridges; it can be set from 1 to 20 cartridges.
- **Minimum number of samples:** Each QC level must have this number of samples run per cartridge before its data will be used to calculate QC ranges. The default is 8 samples; it can be set from 2 to 300 samples.

To enter a value, touch the desired field. Enter a value at the displayed numeric keypad, then press the **Enter** button. The value you entered will be displayed in the field.

For more information, see Chapter 5 "QC Statistics".

## 3.6 iQM Setup

The **iQM Setup** command on the **Configuration** menu displays the iQM Setup screen.

This screen provides the following options:



- **iQM Mode** turns the iQM feature on and off. The default is On.
- **CVP Material Setup** provides options for defining the Calibration Validation Product (CVP) material that will be recognized and accepted by the GEM Premier 3500 when CVP samples are analyzed (see "CVP Sampling" in Chapter 6).
- **iQM Process Reports** provides options that determine when and how much iQM Process data will be printed.
- **iQM Process C Time** allows to set the time of day the daily iQM Process C should be run.



*NOTE: CVP material must be defined prior to analyzing CVP samples.*

### iQM Mode

The **iQM Mode** option turns the iQM feature On or Off:

- Off. Leaving this setting Off allows the use of an iQM cartridge as a traditional cartridge (non-iQM cartridge) by disabling all the special iQM processing that is associated with an iQM cartridge.



*NOTE: The instrument will still check for interferences and micro clots, even when iQM Mode is Off. See "Flag Patient Results for Interference and Micro Clots" in this section.*

When an iQM cartridge with **iQM Mode** set to Off, the instrument will ask if **iQM Mode** should be turned On. The chosen setting will remain in effect until a new cartridge is inserted.

- On (Default setting). If **iQM Mode** is on when an iQM cartridge is inserted, **iQM Mode** will be left enabled and stay enabled for the duration of the inserted iQM cartridge. **iQM mode** cannot be disabled while an iQM cartridge is inserted.

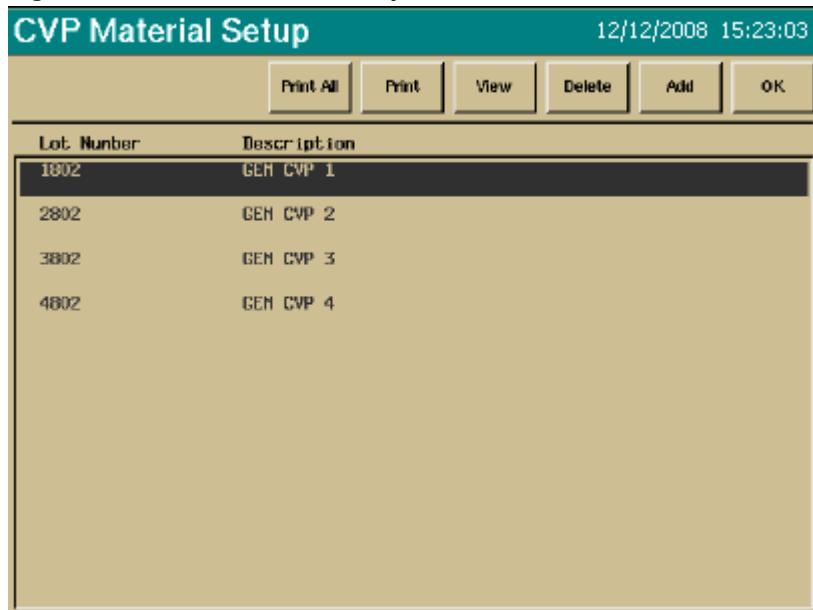
### CVP Material Setup

When CVP samples are analyzed, the CVP material must first be identified to the GEM Premier 3500 (see "CVP Sampling" in Section 6). CVP Material is identified by either selecting it by lot number from the CVP Material List, or by scanning the CVP ampoule barcode using the instrument's ampoule spinner. If the ampoule spinner is used, the instrument will only accept the material if the lot number from the ampoule barcode matches a lot number on the CVP Material List.



*NOTE: The barcode that the GEM Premier 3500's ampoule spinner reads on each IL CVP ampoule contains only the ampoule's lot number and not any information to define the CVP material within.*

**CVP Material Setup** on the iQM Setup screen displays the CVP Material Setup screen (figure 3.23). This screen is used to add CVP material to the CVP Material List. The material will then be recognized and accepted by the GEM Premier 3500 when CVP samples are analyzed.

**Figure 3.23: CVP Material Setup Screen**

The CVP Material Setup screen lists the lot number and description of each defined CVP material. If no CVP material has been defined, the list will be empty, and all buttons except **OK** and **Add** will be unavailable. Up to 20 CVP lots can be defined.

Each box of IL CVP material contains an insert with a barcode that defines the CVP material. The GEM Premier 3500's barcode gun **must be** used to scan the information into the instrument; manual entry is not available, and the scanned information cannot be edited. CVP material is defined by the following information:

**Lot Number:** The lot number of the CVP material from the barcode of the package insert.

**Lot Description:** One of the following, derived from the scanned lot number: GEM CVP 1, GEM CVP 2, GEM CVP 3, GEM CVP 4.

**Analyte Ranges:** The range (Low-High values) from the barcode; used for the pass/fail assessment of CVP sample results.

#### Adding CVP Material Information

To add CVP material, touch the **Add** button on the CVP Material Setup screen to display the CVP Material Information screen (figure 3.24). This screen contains fields for the attributes of the CVP material to be added. All the fields will be blank, and the scanner will be enabled. The instrument will display the message: *Use barcode scanner to enter information*.

To add a new lot of CVP, scan the barcode of the package insert card, which will fill in the analyte ranges, the lot description, and the lot number. The CVP ranges are presented in two columns, with column headings of Low and High. If **Cancel** is selected instead of scanning, the CVP Material Setup screen will be displayed.

The scanned CVP ranges will be converted to the units defined in Configuration ("Units of Measure" described in this section). If pH is in cH units, the Low and High CVP range values on the screen will be transposed because the conversion makes the maximum value lower than the minimum.

**Figure 3.24: CVP Material Information Screen**

The screenshot shows the 'CVP Material Information' screen. At the top right, the date and time are displayed as '10/29/2008 09:58:31'. In the top right corner, there are 'Cancel' and 'OK' buttons. The main area contains a table of CVP ranges for various analytes, followed by two input fields for 'Lot Number' and 'Lot Description'.

CVP Ranges:	Low	High	
pH	7.16	7.24	
pCO <sub>2</sub>	61	79	mmHg
pO <sub>2</sub>	47	59	mmHg
Na <sup>+</sup>	127	135	mmol/L
K <sup>+</sup>	2.4	3.4	mmol/L
Ca <sup>++</sup>	1.40	1.60	mmol/L
Glu	19	31	mg/dL
Lac	0.7	1.1	mmol/L
Hct			%

**Lot Number:** 1802

**Lot Description:** GEM CVP1

Validation of the CVP material information takes place when **OK** is selected on the CVP Material Information screen. The only check performed is to ensure the entered lot is not already defined. The lot number will be checked against the existing lot numbers. If it already exists, the software will display the message *Lot nnnn already exists*. After **OK** is selected, the message will be removed, and the information for the CVP material will be left as is.

#### To Define CVP Material:

1. Touch CVP Material Setup on the iQM Setup screen.

Status: The CVP Material Setup screen will be displayed.

2. Touch Add.

Status: The CVP Material Information screen will be displayed.

3. Scan the barcode from the CVP insert.

Status: The lot number, description, and analyte ranges for the CVP material will be displayed on the CVP Material Information screen.

4. Touch OK.

Status: The iQM Material Setup screen will be displayed. The added CVP material will appear in the list.

5. Touch OK.

Status: The iQM Setup screen will be displayed.

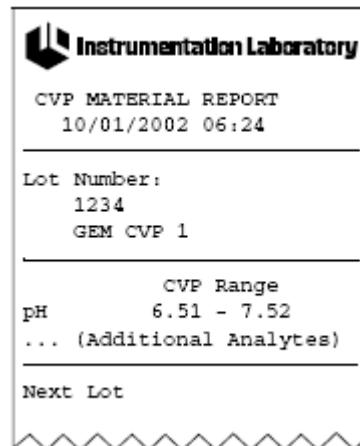
#### Deleting CVP Material

To delete a CVP material, touch the material in the list on the CVP Material Setup screen so that it is highlighted, then touch the **Delete** button. The instrument will prompt for confirmation of the deletion.

CVP samples belonging to a deleted lot will remain in the database. If there is an outstanding CVP failure tied to the deleted lot, the CVP failure will be cleared. A failed CVP status on the Ready screen will be replaced with “Pending CVP” status.

### CVP Material Report

The **Print** and **Print All** buttons on the CVP Material Setup screen will print the CVP Material Report for an individual CVP lot or for all the defined lots. A sample report is shown in *figure 3.25*.



**Figure 3.25: CVP Material Report**

## iQM Process Reports

**iQM Process Reports** on the iQM Setup screen determines when the GEM Premier 3500 will print iQM Process reports and the amount of information that will be printed. iQM Process reports will be saved in the appropriate data files.

iQM Process reports will be sent to the LIS/DMS if LIS/DMS (iQM Process) is set to On in “Interface Setup” in Section 3.8. The frequency of sending the reports will be the same as set for printing reports; however, if printing is Off, iQM Process reports will be sent at the “Errors” frequency.

**iQM Process Reports** can be toggled between the following settings:

Setting	Report will be printed...	Report will contain...
Off (Default)	iQM Process reports will not be printed.	
Summary	After every full iQM Process and iQM Process “C” After iQM Process “B” so that reports appear at least every 30-minutes.	Date and time of iQM Process. iQM Process “B”, “C”, and Full iQM Process. <i>No Errors</i> or an error indicator.
Full	After every full iQM Process and iQM Process “C”. After iQM Process “B” so that reports appear at least every 30-minutes.	Date and time of calibration. iQM Process Type. <i>No Errors</i> or an error indicator. Slope and drift values for all parameters.
Errors	After iQM Process “B”, full iQM Process, and iQM Process “C” errors. After the first successful iQM Process “B”, full iQM	Same as “Summary” Report.

Process, or iQM Process  
“C” following an error.

**Figure 3.26: Sample iQM Process Reports**

“Full” iQM  
Process Report

**Instrumentation Laboratory**

---

FULL iQM PROCESS  
11/24/2008 08:13:53

---

pH	Drift	Error
pCO <sub>2</sub>	Slope	Error
pCO <sub>2</sub>	Drift	Error

---

Instrument S/N: 12004  
Cartridge S/N: 778464

---

ELECTRODE SLOPES

? pH	60	mV/dec
? pCO <sub>2</sub>	63	mV/dec
pO <sub>2</sub>	17	pA/mmHg
Na <sup>+</sup>	62	mV/dec
K <sup>+</sup>	64	mV/dec
Ca <sup>++</sup>	29	mV/dec
Glu	24	pA/mg/dL
Lac	72	pA/mg/dL
Hct	92	mV/mho

---

DRIFT A MEAS A

pH	-0.01	6.89
? pCO <sub>2</sub>	----	---- mmHg
pO <sub>2</sub>	0	121 mmHg
Na <sup>+</sup>	0	102 mM/L
K <sup>+</sup>	0.0	6.7 mM/L
Ca <sup>++</sup>	-0.02	2.57 mM/L
Glu	0	142 mg/dL
Lac	0.0	3.2 mg/dL

---

DRIFT B MEAS B

pH	0.00	7.40
? pCO <sub>2</sub>	----	---- mmHg
pO <sub>2</sub>	0	175 mmHg
Na <sup>+</sup>	0	145 mM/L
K <sup>+</sup>	0.0	3.6 mM/L
Ca <sup>++</sup>	0.00	1.14 mM/L
Glu	0	0 mg/dL
Lac	0.0	0.0 mg/dL
Hct	0	11 %

---

? = Review

“Summary” iQM  
Process Reports

**Instrumentation Laboratory**

---

FULL iQM PROCESS  
11/24/2008 08:13:53

---

pH	Drift	Error
pCO <sub>2</sub>	Slope	Error
pCO <sub>2</sub>	Drift	Error

OR

**Instrumentation Laboratory**

---

FULL iQM PROCESS  
11/24/2008 08:57:20

---

No Errors.

### iQM Process C Time

Because iQM Process C takes approximately 12 minutes, a time field is available to allow you to schedule this calibration. The default time is 02:00. Touching this field presents a keypad to allow you to enter the time of day. The entry range is 00:00 to 23:59.

### 3.7 Instrument Setup

The **Instrument Setup** command on the **Configuration** menu displays the Instrument Setup screen (*figure 3.27*). This screen has options for setting how dates will be displayed, setting the display language, naming the instrument, and turning on and off touch-key sound.

*Figure 3.27: Instrument Setup Screen*



#### Date Format

**Date Format** on the Instrument Setup screen determines how the GEM Premier 3500 will display, print, and record dates. This button can be toggled between the following settings:

MM/DD/YYYY      (Default setting). Example: February 15, 2009 would be 02/15/2009.

DD/MM/YYYY      Example: February 15, 2009 would be 15/02/2009.

YYYY/MM/DD      Example: February 15, 2009 would be 2009/02/15.



*NOTE: The GEM Premier 3500 represents dates with four digits for the year and is thus fully Y2K compliant.*

#### Language

**Language** on the Instrument Setup screen determines what language the GEM Premier 3500 will use to display and print information. GEMweb pages will also be displayed with the chosen language (see “GEMweb” in Chapter 12).

English            (Default setting)

German

Italian

French

Spanish

Japanese         (Kanji) All reports will be printed in English

Chinese

Polish

Swedish

Portuguese

Once a language has been selected, the instrument must be restarted for the language to be changed.

## Instrument Name

Touching the **Instrument Name** field on the Instrument Setup screen will display an alphanumeric keypad for you to enter up to 13 alphanumeric characters to identify the individual instrument. The instrument name is initially blank.

This setting is **not** transferred when configuration settings are copied between instruments. A name must be manually specified for each instrument. See "Save Configuration" in Section 3.11.

## Touch Key Sound

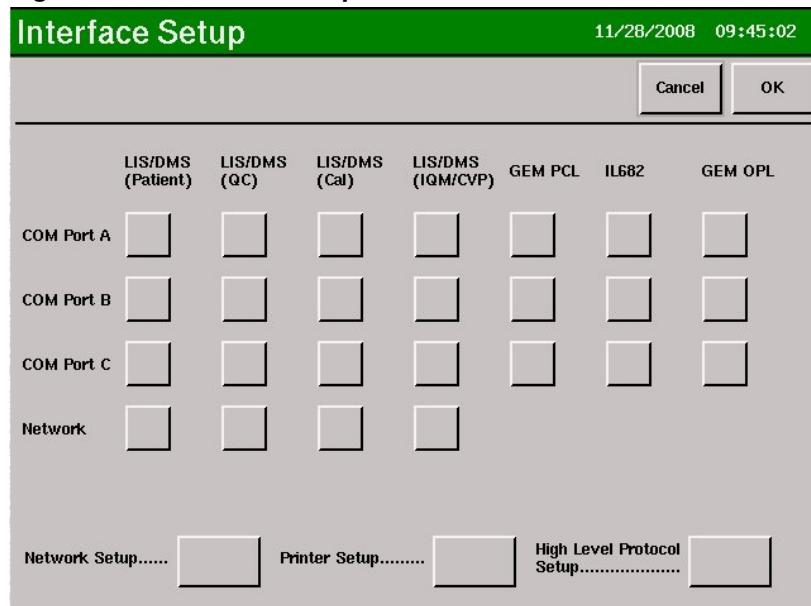
**Touch Key Sound** on the Instrument Setup screen determines whether the GEM Premier 3500 will beep and how loud it will beep when buttons are touched on the touch screen. This option can be toggled between the following settings:

High	High volume setting.
Low	(Default setting). Low volume setting.
Off	No sound.

### 3.8 Interface Setup

The **Interface Setup** command on the **Configuration** menu displays the Interface Setup screen (*figure 3.28*). This screen has options for assigning external devices to the GEM Premier 3500's ports, setting network parameters (**Network Setup**), setting up the printers used by the instrument (**Printer Setup**) and setting up the high level communication's protocol (**High Level Protocol Setup**).

*Figure 3.28: Interface Setup Screen*



#### Port Configuration

The main area of the Interface Setup screen consists of a grid with the instrument's 4 ports listed along the left and possible external devices listed along the top. Checkboxes determine which port each device is assigned to, according to the following rules:

- Each device can be assigned to only a single port.
- If LIS/DMS (Patient), (QC), or (iQM Process) are assigned to a port, they should be assigned to the same port. The instrument does not support sending different sample types to different ports.
- The GEM PCL (or PCL Plus, if available), IL 682, and GEM OPL devices must be assigned to different ports. In addition, the IL 682 and GEM OPL devices cannot be used at the same time because they are both CO-Ox devices.
- If the GEM PCL (or PCL Plus), IL 682, or GEM OPL is assigned to a port, that same port cannot be assigned to an LIS/DMS device (LIS/DMS (Patient), (QC), or (iQM Process)).

When a checkbox is selected, the instrument determines whether the combination of filled checkboxes is a valid combination. If an invalid combination is selected, the instrument will automatically select or deselect the appropriate other checkboxes to make a valid combination.

#### Network Setup

The **Network Setup** button displays the Network Setup screen (*figure 3.29*). This screen enables you to configure the instrument's network settings. Network setup is required only when the GEM Premier 3500 will be connected to one or more of the following devices:

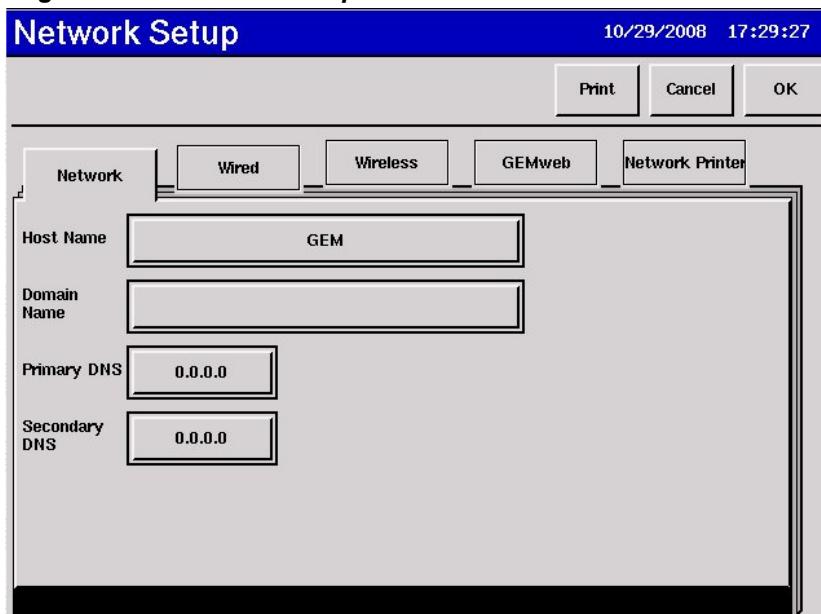
- Personal computer via the hospital intranet in order to use GEMweb
- Network printer
- LIS/DMS (through the Ethernet port)

The Network Setup screen contains five tabs along the top. Touching a tab will display a different area of network setup:

- Network (displayed by default, contains generic network setup parameters)
- Wired (contains setup parameters for the wired Ethernet connection)
- Wireless (contains setup parameters for the wireless connection)
- GEMweb (contains setup parameters for the GEMweb interface)
- Network Printer (contains setup parameters for the network printer)

Setting both the wired and the wireless connection is possible. However, the GEM Premier 3500 software will use the wired connection for transmission if an Ethernet cable is connected. If no Ethernet cable is connected, then the software will use the wireless connection for transmission.

**Figure 3.29: Network Setup Screen – Network Tab**



Options on these tabs are described in the following paragraphs.

When **OK** is selected to exit the Network Setup screen, and changes have been made, the instrument will display the message: *Network setup changes will take effect after instrument shutdown. Select OK to shutdown now.*" Touching **OK** will save the changes and start the shutdown process. Touching **Cancel** will remove the message and redisplay the Network Setup screen.

Touching **Print** on the Network Setup screen will print a report that shows all network setup information.

### Network Tab

The **Network** tab (figure 3.31) provides options for defining the parameters required to connect the GEM Premier 3500 to an Ethernet network:

- Host Name:** The name of the instrument in your institution's DNS system, maximum of 20 characters. The Host Name is required if Network Access is enabled. The Host Name is used as the instrument's URL in the browser, in lieu of the IP address.
- The Host Name is not transferred when configuration settings are copied between instruments. The Host Name must be manually specified for each instrument.
- Domain Name:** The name of the network segment the instrument is connected to. For example, ilww.com. Maximum of 80 characters. This is a required field.
- Primary DNS:** (Domain Name Server) The format is nnn.nnn.nnn.nnn, where nnn is in the range 0-255. This is a required field.
- Secondary DNS:** Defines the backup DNS. The format is nnn.nnn.nnn.nnn, where nnn is in the range 0-255. This is an optional field.

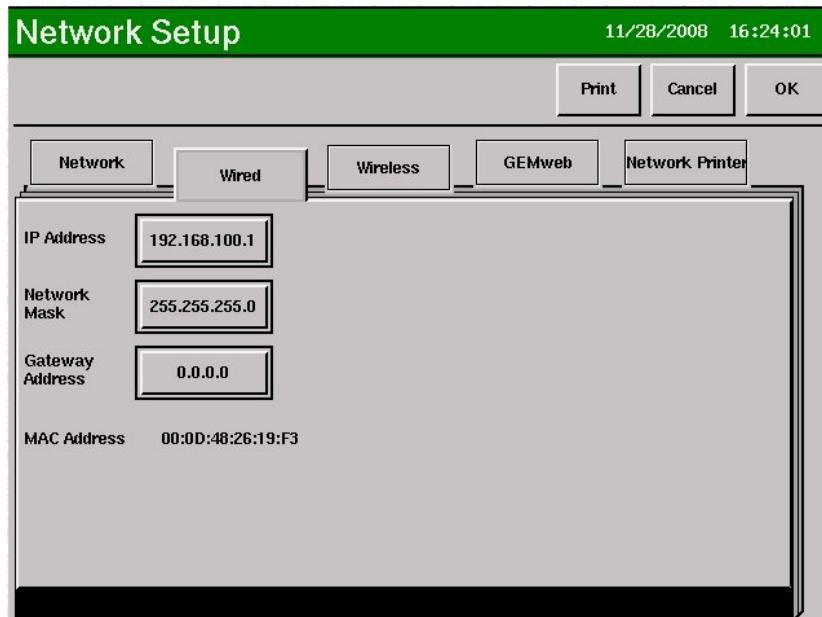


**NOTE:** To prevent two instruments on the same network from having the same address, the IP address and host name are not saved with the **Save Config.** command (see "Save Configuration" in Section 3.11).

### Wired Tab

The **Wired** tab (*figure 3.30*) contains the parameter settings to connect the instrument to a network via an Ethernet cable:

**Figure 3.30: Network Setup Screen – Wired Tab**



- IP Address:** The instrument's static IP address. The format is nnn.nnn.nnn.nnn, where nnn is in the ranges 0-255. The IP Address is a required field for the GEM to communicate via an Ethernet network.
- The IP Address is not transferred when configuration settings are copied between instruments. The IP Address must be manually specified for each instrument.
- Network Mask:** The format is nnn.nnn.nnn.nnn, where nnn is in the ranges 0-255. The Network Mask is required with a default value of 255,255,255,0.

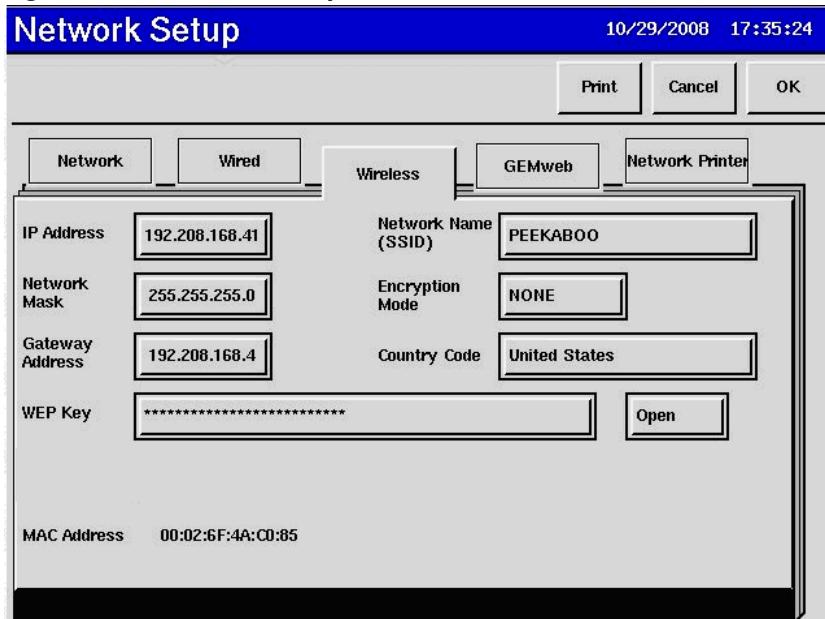
**Gateway Address:** The format is nnn.nnn.nnn.nnn, where nnn is in the ranges 0-255. The Gateway Address is only required if the instrument and client computers are on separate subnets.

**MAC Address:** Shows the hardware address of the instrument's Ethernet card. This address cannot be changed.

### Wireless Tab

The **Wireless** tab (*figure 3.31*) contains the parameter settings to connect the instrument to a wireless network:

**Figure 3.31: Network Setup Screen – Wireless Tab**



**IP Address:** The instrument's static IP address. The format is nnn.nnn.nnn.nnn, where nnn is in the ranges 0-255. The IP Address is a required field for the GEM to communicate via an Ethernet network.

The IP Address is not transferred when configuration settings are copied between instruments. The IP Address must be manually specified for each instrument.

**Network Mask:** The format is nnn.nnn.nnn.nnn, where nnn is in the ranges 0-255. The Network Mask is required with a default value of 255,255,255,0.

**Gateway Address:** The format is nnn.nnn.nnn.nnn, where nnn is in the ranges 0-255. The Gateway Address is only required if the instrument and client computers are on separate subnets.

**WEP Key:** This field sets the key to use for WEP (Wired Equivalent Privacy) security. The WEP Key field is disabled (ghosted) for data entry and set to blank when the Encryption Mode (see below) is neither WEP 64 nor WEP 128. The WEP Key field is enabled for data entry in the following cases:

If the Encryption Mode is WEP 64. In this case, the WEP Key field accepts entries of either 5 alphanumeric characters (0-9, a-z, A-Z) or 10 hexadecimal digits (0-9, a-f, A-F).

If the Encryption Mode is WEP 128. In this case, the WEP Key field accepts entries of either 13 alphanumeric characters (0-9, a-z, A-Z) or 26 hexadecimal digits (0-9, a-f, A-F).



**NOTE:** The WEP Key field will be displayed as a string of asterisk ("\*") characters, one per each character entered.

**WEP Encryption Type:**

This is the field on the right side of the WEP Key field. This entry field defines the type of encryption algorithm to be used. There are two allowed IEEE 802.11 encryption algorithms for the GEM Premier 3500: "Open" or "Shared". The default algorithm is "Open".

**MAC Address:** Shows the hardware address of the instrument's Ethernet card. This address cannot be changed.

**Network Name (SSID):**

The Network Name (SSID) field sets the name of the wireless network the GEM Premier 3500 will connect to. This field accepts a maximum of 32 non-blank characters. This is a required field.

**Encryption Mode:** The Encryption Mode field contains the list of available wireless encryption modes. The GEM Premier 3500 allows the following encryption modes:

None (Default)

WEP 64

WEP 128

**Country Code:** The Country Code field contains the list of available countries whose code is used to define the physical settings of the wireless network adapter. The default country is "United States".



**NOTE:** According to FCC/ITU regulations, the Country Code field should only be changed by an employee or representative of Instrumentation Laboratory, the instrument's manufacturer in this case. For this reason, a special password is necessary to change this field.

### GEMweb Tab

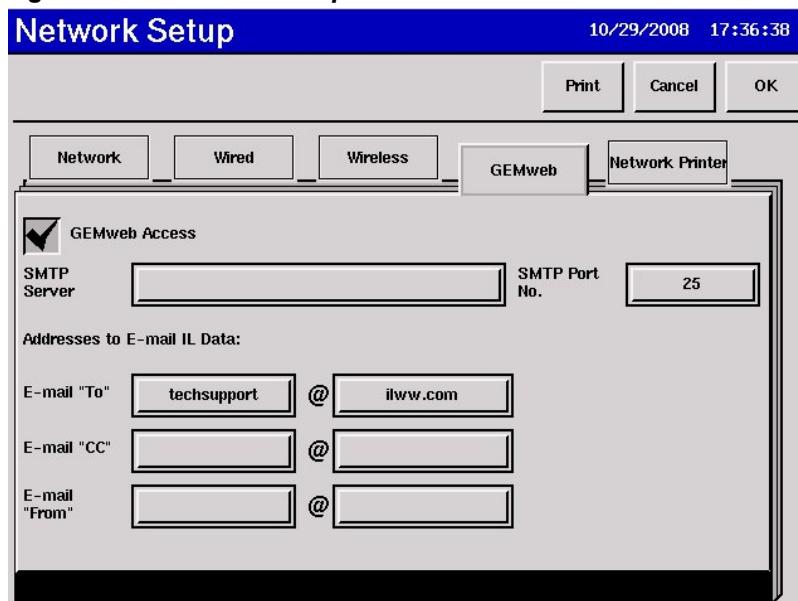
The **GEMweb** tab (*figure 3.32*) provides options for operating the instrument with The GEM Premier 3500 GEMweb feature (see Chapter 12):

**GEMweb Access:** Determines whether the instrument will allow remote connections via GEMweb. This option is Off (unfilled checkbox) by default. When Off, network access by remote users via GEMweb will not be allowed.

The **first time** that this option is turned On (filled checkbox), the instrument will prompt for a GEMweb access code. Contact IL for a 5-digit code, which will only be valid for the single instrument.

The GEMweb Access checkbox setting is not transferred when configuration settings are copied between instruments. Each instrument must be set up for GEMweb access individually.

**Figure 3.32: Network Setup Screen – GEMweb Tab**



- SMTP Server:** The address of the SMTP server. Can be numeric (nnn.nnn.nnn.nnn) or alphanumeric (for example: smtp.hospital2.net). Blank by default. Maximum of 80 characters. Required if you want the instrument to be able to use GEMweb to e-mail information.
- SMTP Port No.:** The port number of the SMTP server. Numeric value 0 - 9999, default = 25. Required if you want the instrument to be able to use GEMweb to e-mail information.
- E-mail "To":** The internet e-mail address to which GEM Premier 3500 IL data will be mailed. Uses the standard e-mail address format of a@b, where a and b are up to 40 characters each and if one is entered the other must be entered. Required if you want the instrument to e-mail cartridge diagnostics data. The default e-mail address is techsupport@ilww.com.
- E-mail "CC":** The internet e-mail address to which GEM Premier 3500 IL data will be copied (if desired). Uses the standard e-mail address format of a@b, where a and b are up to 40 characters. Blank by default.

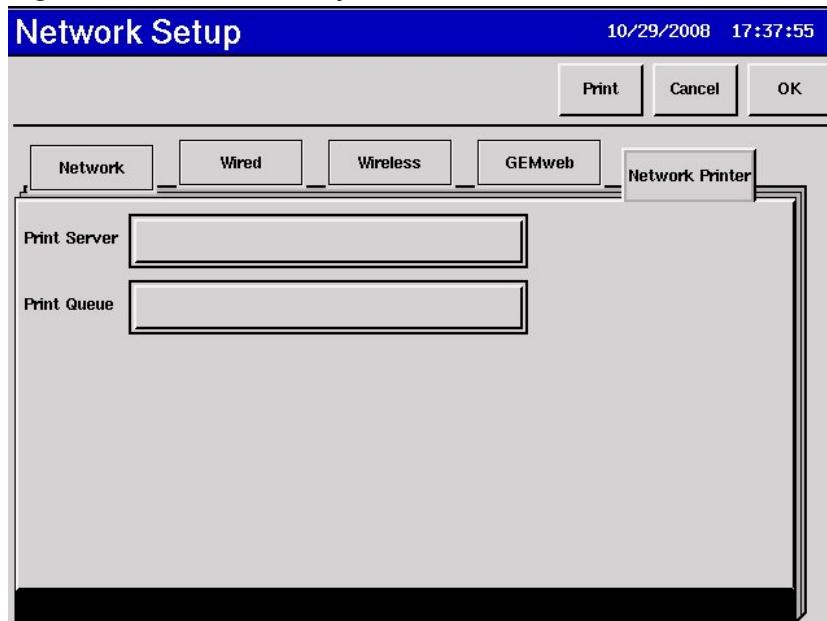
**E-mail “From”:** The return internet e-mail address for IL data sent by the GEM Premier 3500. Uses the standard e-mail address format of a@b, where a and b are up to 40 characters each. Required if you want the instrument to e-mail IL data. The mail server will return the e-mailed IL data to this address if unable to deliver to the “To” or “CC” addresses. The receiver(s) of the e-mail may also use the “Reply” option to return a reply to this address.

### Network Printer Tab

The **Network Printer** tab (*figure 3.33*) provides options for enabling the transmission of reports to a network printer:

- |                     |  |
|---------------------|--|
| <b>Print Server</b> | The address of the network print server. Can be expressed as an IP address (nnn.nnn.nnn.nnn) or an alphanumeric host name (for example, farpoint). Maximum of 25 characters. Blank by default. |
| <b>Print Queue</b>  | The name of the print queue on the network printer. The print queue does not need to be specified if the printer has an automatic queue. Maximum of 25 characters. Blank by default.           |

**Figure 3.33: Network Setup Screen – Network Printer Tab**



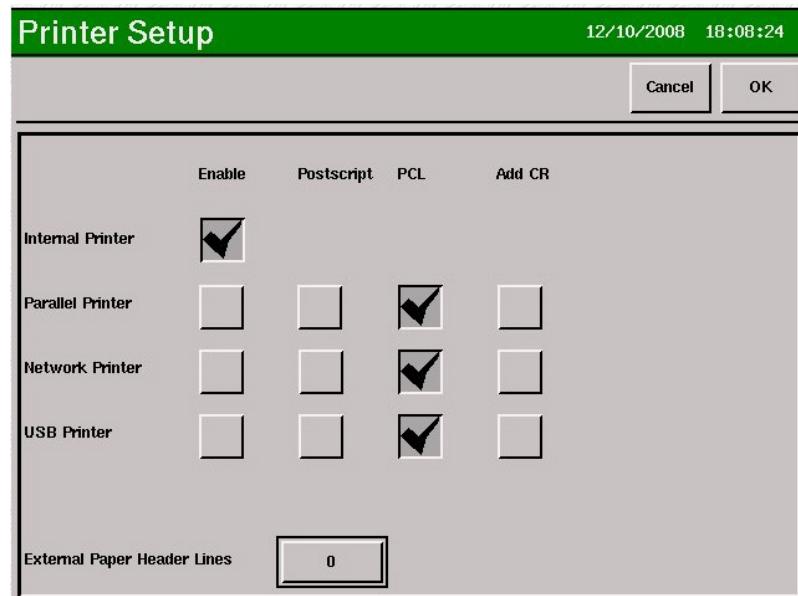
### Printer Setup

The **Printer Setup** button displays the Printer Setup screen (*figure 3.34*). This screen allows you to enable and configure the printers connected to the GEM Premier 3500.

Reports will be printed on all printers that have been enabled (filled checkbox). Note that parallel, network and USB printers can be activated, but not simultaneously.

For a report (automatic or on-demand) to be printed to one or more of the enabled printers, two conditions must be met:

- The printer must be enabled (filled checkbox).
- The report must be “printable” on the selected printer. The following table shows on which printers specific reports can be printed.

**Figure 3.34: Printer Setup Screen**

Report Type	Internal Printer	External Printer (Parallel, Network, USB)
Sample Results (Patient, QC, CVP)	Yes	Yes
QC Statistics	Yes	Yes
iQM Process Results	Yes	No
iQM Reports (all)	No	Yes
All Other Reports (primarily configuration reports)	Yes	No

#### Enable Internal Printer

The **Internal Printer** checkbox on the Printer Setup screen determines whether the instrument's internal thermal printer will be available for printing reports:

- Off. The internal printer will not be used.
- On (Default setting). The instrument will use the internal printer for all reports that are printable on the internal printer.

### Enable Parallel Printer

The **Parallel Printer** checkbox on the Printer Setup screen determines whether reports will be printed on an external printer connected to the instrument's parallel port.



*NOTE: Printing is only allowed on the parallel printer OR the network printer OR the USB printer. The software does not allow the parallel, network and USB printers to be enabled simultaneously.*

- Off (Default setting). The instrument will not print reports to a printer connected to the parallel port.
- On. The instrument will print reports to a printer connected to the parallel port.

### Enable Network Printer

The **Network Printer** checkbox on the Printer Setup screen determines whether reports will be printed on the network printer defined in Network Setup (see "Network Printer Tab" in this section).



*NOTE: Printing is only allowed on the parallel printer OR the network printer OR the USB printer. The software does not allow the parallel, network and USB printers to be enabled simultaneously.*

- Off (Default setting). The instrument will not print reports on a network printer.
- On. The instrument will print reports on a network printer.

### Enable USB Printer

The **USB Printer** checkbox on the Printer Setup screen determines whether reports will be printed on a USB printer connected to one of the instrument's USB ports.



*NOTE: Printing is only allowed on the parallel printer OR the network printer OR the USB printer. The software does not allow the parallel, network and USB printers to be enabled simultaneously.*

- Off (Default setting). The instrument will not print reports on a USB printer.
- On. The instrument will print reports on a USB printer.

### Printer Options

For parallel and network printers, you can also specify the graphics language used by the printer and whether the GEM Premier 3500 should add a carriage return when printing.

You can specify either Postscript or PCL graphics, not both. A graphics mode must be specified in order to print iQM Delta Charts in Chapter 6.

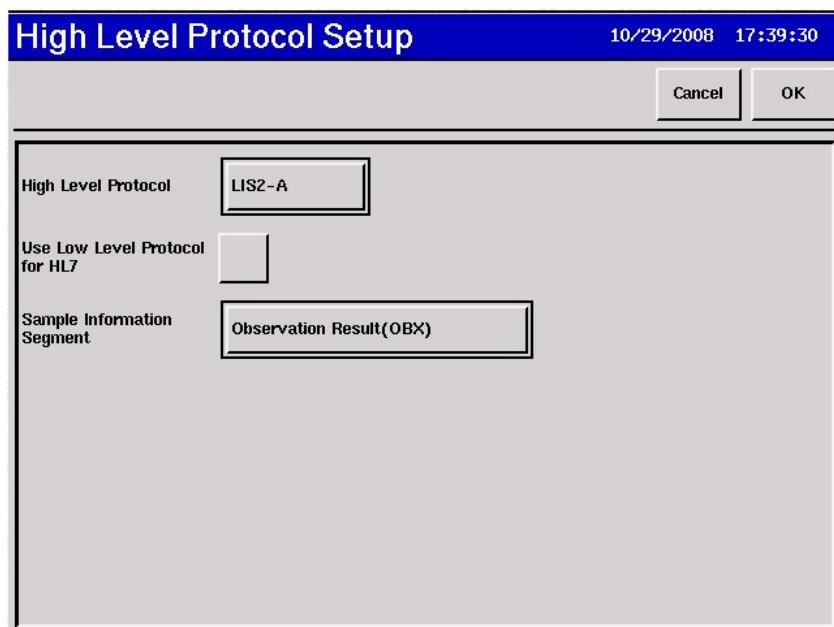
<b>Postscript</b>	Designates the printer as Postscript capable (checkbox filled).
<b>PCL</b>	(Default) Designates the printer as PCL capable (checkbox filled).
<b>Add CR</b>	Determines whether the GEM Premier 3500 will add a carriage return to each printed line to prevent printing problems. This option is off by default.

### External Paper Header Lines

The **External Printer Header Lines** option on the Printer Setup screen determines the number of blank lines (line feeds) the instrument will send before printing each page on an external printer (parallel, network or USB). This option is useful for printing reports on paper with a pre-printed header, such as letterhead. The entry range is 0 through 14, with 0 as the default. Touching this option will display a numeric keypad.

### High Level Protocol Setup

The High Level Protocol Setup button displays the High Level Protocol Setup screen (*figure 3.37*). This screen allows you to configure the high level protocol used for the network interface:



**Figure 3.35: High Level Protocol Setup**

The High Level Protocol Setup screen contains the following configuration fields:

#### High Level Protocol:

The High Level Protocol field provides two selections to choose from: "LIS2-A" or "HL7v2.4". If "LIS2-A" selected, the instrument will use the LIS2-A (or ASTM) protocol to communicate. Otherwise, if "HL7v2.4" is selected, the instrument will use the HL7v2.4 (or HL7) protocol. LIS2-A is selected by default.

#### Use Low Level Protocol for HL7:

The Use Low Level Protocol for HL7 field provides a checkbox to enable or disable the low level protocol when the HL7 protocol is selected for communications. Default is off.



*NOTE: Some LIS vendors require the use of the low level protocol when HL7 is the protocol utilized for communications.*

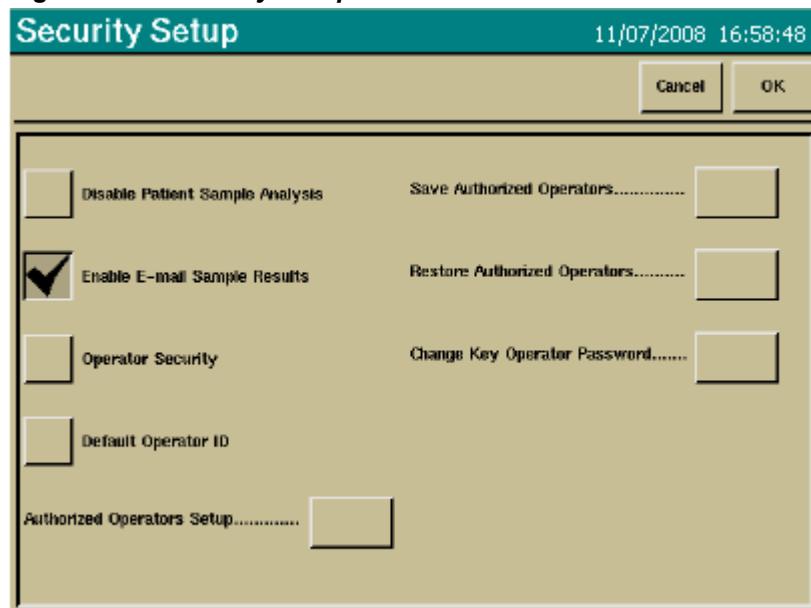
#### Sample Information Segment:

The Sample Information Segment field provides two selections to choose from: "Observation Result (OBX)", and "Notes and Comments (NTE)". This setting is only applicable to the HL7 protocol. Observation Result (OBX) is selected by default.

### 3.9 Security Setup

The **Security Setup** command on the **Configuration** menu displays the Security Setup screen (*figure 3.36*). This screen provides the options shown.

*Figure 3.36: Security Setup Screen*



To restrict access to the GEM Premier 3500's functions, the instrument supports three types of operators: one "Key Operator," many "authorized operators," and "other operators." The single Key Operator may optionally define one or more authorized operators. Other operators are those operators who are not the Key Operator or authorized operators.

For security purposes, the instrument's functions have been divided into four general categories: sample analysis and recall, instrument configuration, network functions, and all other functions. Access to these categories is governed by the following rules:

- **Sample analysis and recall:** If the instrument's Operator Security feature is turned off, then all operators at all times will be able to analyze samples, recall results, remove a cartridge, and shutdown the instrument. If Operator Security has been turned on, then only authorized operators will be able to perform these operations.
- **Instrument configuration:** Only the Key Operator will be able to configure the instrument, including defining authorized operators.
- **Network functions:** Accessible only to authorized operators with network access (see "GEMweb" in Chapter 12).
- **All other functions** will be accessible to all operators at all times.

#### Disable Patient Sample Analysis

The **Disable Patient Sample Analysis** checkbox on the Security Setup screen determines whether patient samples can be run on the instrument.

- Off (Default setting). The GEM Premier 3500 will allow patient sample analysis.
- On. The GEM Premier 3500 will not allow patient sample analysis.

## Enable E-mail Sample Results

The **Enable E-mail Sample Results** checkbox on the Security Setup screen determines whether patient samples can be e-mailed through GEMweb (see Chapter 12).

- Off. The GEM Premier 3500 will not allow patient sample results to be e-mailed via GEMweb.
- On (Default setting). The GEM Premier 3500 will allow patient sample results to be e-mailed via GEMweb.

## Operator Security

**Operator Security** on the Security Setup screen determines whether operators will be required to enter a password prior to analyzing samples, recalling results, removing a cartridge, or shutting down the instrument.



*NOTE: This option will be turned off and unavailable if the Operator ID demographic is not turned on (see "Requested Demographics" under "Sample Setup", Section 3.4).*

This checkbox can be toggled between the following settings:

- Off (Default setting). The GEM Premier 3500 will not request a password prior to sample analysis, data recall, cartridge removal, or instrument shutdown. There will be no restrictions on the instrument's use.  
The instrument will provide space for optional entry of an operator ID on the Sample Data Entry screen during sample processing. Any entered ID, including none, will be accepted. If the **Default Operator ID** option, described in the next section, has been turned on, then the GEM Premier 3500 will display the operator ID for the previous sample. This ID can then be used as is, edited, or cleared.
- On. Operators must enter a password before they will be allowed to analyze samples, recall results, remove a cartridge, shutdown the instrument, or access the instrument remotely via GEMweb. Turning this option On will automatically turn the **Default Operator** option Off.

For security, the GEM Premier 3500 will display a “\*” character in place of each character of the password.

The GEM Premier 3500 will compare the entered password against a list of valid passwords defined with **Define List of Authorized Operators**, see “Security Setup” in Section 3.9. Once validated, the instrument will continue with sample analysis or continue into sample recall.

In sample processing, the associated operator ID will automatically appear on the Sample Data Entry screen and be saved and transmitted with the sample results. A default operator ID will not be allowed, and operators will not be able to edit the operator ID.



*NOTE: The Key Operator Password can be used to analyze samples only if it has also been defined as an authorized operator password.*

## Default Operator ID

**Default Operator ID** on the Security Setup screen determines whether the instrument will display the operator ID from the previous sample on the Sample Data Entry screen during patient and QC sampling.

Turning this option On will automatically turn the **Operator Security** option Off.



*NOTE: This option will be turned off and unavailable if the Operator ID demographic is not turned on (see “Requested Demographics” under “Sample Setup”, Section 3.4).*

This checkbox can be toggled between the following settings:

- Off (Default setting). The instrument will not provide a default operator ID on the Sample Data Entry screen.
- On. The instrument will automatically display the operator ID associated with the previous sample on the Sample Data Entry screen. The operator will then have the option of using that ID as is, entering a new one, or not using one at all. If no operator ID was associated with the previous sample, no operator ID will be displayed.



*NOTE: The instrument will display a default operator ID on the second sample following setting of this option. The first sample will not have a default operator ID displayed because no default ID will be available – the default ID is entered with the first sample.*

## Authorized Operators Setup

The **Authorized Operators Setup** button on the Security Setup screen displays the Authorized Operators Setup screen (*figure 3.37*). This screen lists the existing authorized operators and provides options for adding, modifying, and deleting the operator IDs and passwords that the GEM Premier 3500 uses when **Operator Security** (see “Security Setup”, Section 3.9) is turned on. In addition, the Network Access and GEM Access columns allow the Key Operator to enable network and/or GEM access for each operator. Checkmarks indicate that access is allowed for the operator. The default is OFF for network access (remote access via GEMweb) and ON for GEM access (sample analysis, database queries, etc.).

Authorized operators can be defined by typing them, by scanning them in with the barcode gun, or by reading them from a diskette. The instrument can save the list of authorized operators to a diskette so that a single list may be defined and shared across multiple GEM Premier 3500 instruments.



*NOTE: In order to use the Key Operator Password to analyze samples, that password must be defined as an authorized operator. The Key Operator Password is not initially recognized for analyzing samples.*

The GEM Premier 3500 can store up to 999 operator ID/password combinations. Operator IDs and passwords may consist of up to 16 alphanumeric characters, and spaces are allowed. The instrument will sort the list by operator ID and automatically eliminate duplicate IDs.

**Figure 3.37: Authorized Operators Setup Screen**

Authorized Operators Setup		10/19/2008 17:01:13	
Network Access	GEM Access	Operator ID	Password
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	JOE	2
<input type="checkbox"/>	<input checked="" type="checkbox"/>	LEE	3
<input type="checkbox"/>	<input checked="" type="checkbox"/>	SAM	1



*NOTE: Depending on the barcode type in use at particular institutions, an ID with a leading zero may not be allowable. Some barcode types recognize 01234 and 1234 as the same ID. For more information about the barcode types recognized by the GEM Premier 3500, see “Input/Output Ports” in Specifications, Chapter 11.*

**To Enter Operator IDs and Passwords:**

**1. Touch Authorized Operators Setup on the Security Setup screen.**

Status: The instrument will display the Authorized Operators Setup screen, *figure 3.36*.

**2. Touch Add.**

Status: The instrument will display a keypad for entering the ID.

**3. Enter the Operator ID.**

Status: Touch up to 16 alphanumeric characters on the keypad for the Operator ID. Spaces are allowed.

**OR**

Run the barcode gun over a barcoded operator ID. The ID will be displayed in the keypad window.

**4. Touch Enter to accept the ID.**

Status: The instrument will display a keypad for entering the password.

If **Cancel** is touched instead of **Enter**, creation of a new operator will be aborted, and the Authorized Operators Setup screen will be displayed.

**5. Enter the Password.**

Status: Touch up to 16 alphanumeric characters on the keypad for the Operator password. Spaces are allowed.

Use the <- and -> buttons to move the cursor, **Backspace** to delete the character to the left of the cursor, or **Clear** to delete the entire password.

**OR**

Run the barcode gun over a barcoded password. The password will be displayed in the keypad window.

**6. Touch Enter to accept the password.**

Status: The instrument will display the Authorized Operators screen with the new operator in the list.

If **Cancel** is touched instead of **Enter**, creation of a new operator will be aborted, and the Authorized Operators screen will be displayed.

**7. Enable network access, if desired.**

Status: Touching the field will toggle it between checked and unchecked (the default is unchecked, or OFF). A checkmark will provide the operator with remote access to the instrument via GEMweb (see Chapter 12).

**8. Enable GEM access, if desired.**

Status: Touching the field will toggle it between checked and unchecked (the default is checked, or ON). A checkmark will provide the operator with access to GEM instrument functions (sample analysis, database queries, etc.).

**9. Touch OK to return to the Security Setup screen.**

## Save Authorized Operators

**Save Authorized Operators** on the Security Setup screen can be used to save an instrument's list of authorized operators to CD Disc, DVC Disc, or USB Storage device. The list can then be restored on the same instrument or another instrument with **Restore Authorized Operators** described in the next section. This feature provides an effective mechanism for archiving the list and for transferring the information from one GEM Premier 3500 to another.

### To Save the List of Authorized Operators:

1. Define authorized operators as desired, see "Security Setup", Section 3.9.
  2. Touch Save Authorized Operators on the Security Setup screen.
- Status: The instrument will prompt for insertion of a CD / DVD Disc or USB storage device.
3. Insert a blank CD, DVD or a USB storage device into the disc drive or USB port located on the side of the GEM Premier 3500.
  4. Touch Disc or USB as appropriate. If Disc is selected, touch OK when instrument prompts for insertion of a blank disc.

**Status:** The instrument will display the following messages: *Preparing data for copying. Please wait,* and then: *Writing. Please wait.* After the data is written, the following message will be displayed: *Data has been written.* If an error is encountered during the writing, the following message will be displayed: *Write error. Retry operation.*

5. Remove the CD, DVD or USB storage device, and touch OK.

Status: If the CD, DVD or USB storage media was created for backup purposes, then store the storage media in a safe and secure location. If the media was created for transferring the authorized operators to another instrument, read the information in the following section.

## Restore Authorized Operators

**Restore Authorized Operators** on the Security Setup screen can be used to restore the list of authorized operators from a CD, DVD or USB storage device created by copying that list with **Save Authorized Operators**, see "Security Setup", Section 3.9. The following procedure shows how to restore a list of authorized operators.

### To Restore a List of Authorized Operators:

1. Touch Restore Authorized Operators on the Security Setup screen.

Status: The instrument will prompt for insertion of a CD, DVD or USB storage device that contains the authorized operators file.

2. Insert the CD, DVD or USB storage device containing the authorized ID file into the disk drive or USB port located on the side of the GEM Premier 3500.
3. Touch Disc or USB as appropriate. If Disc is selected, touch OK when instrument prompts for insertion of the proper disc.

Status: The instrument will display the following message: *Copying data to the instrument. Please wait.* When the instrument has copied the file, it will display the following message: *Data has been copied. Remove media.* The new authorized operator file will replace the existing authorized operator file.

If the instrument displays an error message, as a last resort, try **Restore Authorized Operators** again.

4. Remove the CD, DVD or USB storage device, and touch OK.

Status: The instrument will display the Security Setup screen.

## Change Key Operator Password

**Change Key Operator Password** on the Security Setup screen enables the Key Operator to change the Key Operator Password. This is the only password that allows access to the GEM Premier 3500's configuration areas.

### To Change the Key Operator Password:

1. Touch the Change Key Operator Password button on the Security Setup screen.

Status: The instrument will display a keypad.

2. Touch up to 16 alphanumeric characters on the keypad.

Status: Spaces are allowed. For security, “\*” characters will be displayed for the characters you type.

Use the <- and -> buttons to move the cursor, **Backspace** to delete the character to the left of the cursor, or **Clear** to delete the entire password.

3. Touch Enter.

Status: The instrument will prompt for re-entry of the new password to confirm accurate entry.

4. Enter the Key Operator Password again, and touch Enter.

Status: The instrument will confirm that the password has been changed.

### 3.10 Restore Default Key Operator Password (KOPW)

If a user-defined Key Operator Password has been forgotten, the following procedure may be used to restore the factory-default password. For security reasons, this password has not been included in this manual.

#### To Restore the Default Key Operator ID:

1. Select **Restore KOPW** from the Configuration menu.

Status: The instrument will prompt to confirm that the default Key Operator Password should be restored.

2. Insert the **Key Operator Password CD** that has been included with this manual.

3. Select **OK**.

Status: The instrument will display the message *Copying data to instrument. Please wait, then Data has been copied. Remove media.*

4. Select **OK**.

5. Remove the **Key Operator Password CD**.

Status: IL recommends that the **Key Operator Password CD** be stored in a safe and secure location.

### 3.11 Save Configuration

The **Save Config.** command on the **Configuration** menu can be used to save an instrument's configuration to a CD, DVD or USB storage device. The configuration information can then be restored on the same instrument or another instrument with the **Restore Config.** command described in the next section. This feature provides an effective mechanism for system backups and for transferring information from one GEM Premier 3500 to another.

For security and/or identification reasons, this option will not transfer the following configuration information:

- Key Operator Password
- Instrument Name
- Authorized operators list
- Daylight Savings Time setting
- Network settings (please note the High Level Protocol Setup information will be saved)

All other configuration information will be saved. In addition, the instrument will save the version number of the operating software to ensure that the configuration information is restored only to compatible systems.

#### To Save an Instrument's Configuration:

##### 1. Select **Save Config.** from the Configuration menu.

Status: The instrument will display a keypad for entry of the Key Operator Password.

##### 2. Enter the Key Operator Password.

Status: The instrument will prompt for insertion of a CD / DVD Disc or USB storage device (USB).

##### 3. Insert a blank CD, DVD or a USB storage device into the disc drive or USB port located on the side of the GEM Premier 3500.

##### 4. Touch Disc or USB as appropriate. If Disc is selected, touch OK when instrument prompts for insertion of a blank disc.

Status: The instrument will display the following messages: *Preparing data for copying.*

*Please wait,* and then: *Writing. Please wait.* After the data is written, the following message will be displayed: *Data has been written.* If an error is encountered during the writing, the following message will be displayed: *Write error. Retry operation.*

##### 5. Remove the CD, DVD or USB storage device, and touch OK.

##### 6. Write the instrument name, date, and “configuration” on the storage media label.

Status: If the configuration CD, DVD or USB storage media was created for backup purposes, then store the storage media in a safe and secure location. If the media was created for transferring the configuration to another instrument, read the information in the following section.

### 3.12 Restore Configuration

The **Restore Config.** command on the **Configuration** menu can be used to restore the configuration data with the CD, DVD or USB storage device created with the **Save Config.** command described in the previous section.



*NOTE: The Restore Configuration command will only be available when a cartridge is not inserted in the instrument (when the Insert Cartridge screen is displayed).*

Before restoring the information, the instrument will compare the version number of the installed operating software with the version number on the configuration media (CD, DVD or USB storage device). If the two versions are incompatible (the configuration information on the CD, DVD or USB storage device is too old and incompatible), the instrument will abort the restore process and display a message of the incompatibility.

The **Restore Config.** command will not restore the following configuration information. If desired, these settings can be changed manually:

- Key Operator ID – See “Change Key Operator Password” under “Security Setup”, Section 3.9
- Authorized operators list – A single list of operator passwords/IDs can be shared across instruments by creating a master list on one instrument, saving it to CD, DVD or USB storage device, and copying it to the other instruments. See “Save Authorized Operators” under “Security Setup”, Section 3.9.
- Instrument Name – See “Instrument Name” in Section 3.7
- Daylight Savings Time setting – See “Set Date and Time” in Section 3.13.
- Network settings (Please note the High Level Protocol Setup will be restored) – See “Interface Setup” in Section 3.8.

#### To Restore an Instrument’s Configuration:

1. Select **Restore Config.** from the Configuration menu.

Status: The instrument will display a keypad for entry of the Key Operator Password.

2. Enter the **Key Operator Password**.

Status: The instrument will prompt for insertion of a CD, DVD or USB storage device generated with the **Save Config.** command.

3. Insert the CD, DVD or USB storage device containing the configuration files into the disk drive or USB port located on the side of the GEM Premier 3500.

4. Touch Disc or USB as appropriate. If Disc is selected, touch OK when instrument prompts for insertion of the proper disc.

Status: The instrument will display the following message: *Copying data to the instrument. Please wait.* When the instrument has copied the file, it will display the following message: *Data has been copied. Remove media.*

5. Remove the CD, DVD or USB storage device, and touch OK.

6. Restore the settings not copied with Save Config./Restore Config. as desired.

### 3.13 Set Date and Time

 **CAUTION:** Incorrectly entering the current date may lead to inaccurate pO<sub>2</sub> results.

 **NOTE:** The date and time can only be changed by a Key Operator.

The GEM Premier 3500 displays the current date and time at the top of all screens. The system date and time can be corrected whenever the Insert Cartridge screen is displayed or whenever a cartridge is not inserted in the instrument or when a new cartridge is inserted, prior to closing the cartridge compartment door. The instrument is configured to automatically track daylight savings time, although the daylight savings time feature can be disabled.

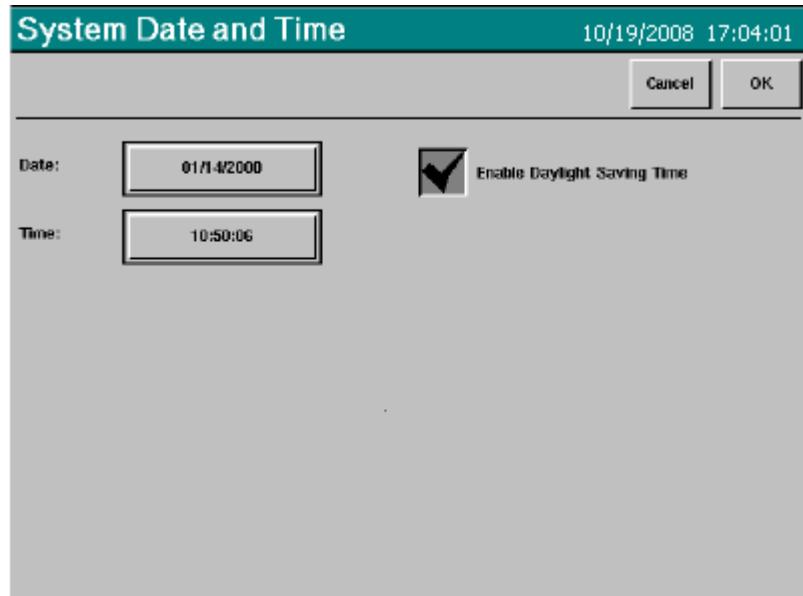
 **NOTE:** If Daylight Savings Time is enabled, the time will move forward by one hour on the second Sunday in March, and will fall back by one hour on the first Sunday in November.

Changing the date or time will require an instrument restart. The instrument will display a message and provide the choice of continuing. Restarting the instrument takes about 20 seconds.

The GEM Premier 3500 uses 24-hour time format, from 00:00:00 to 23:59:59, in hours, minutes, and seconds. The date format depends upon the format chosen during software installation. The available formats are described in "Instrument Setup" in Section 3.7.

Following the system restart message, the instrument will display the System Date and Time screen (*figure 3.38*). This screen shows the current settings for the date and time and a checkbox to turn off and on the tracking of daylight savings time.

**Figure 3.38: System Date and Time Screen**



**To Set the Date and Time:**

- At the Insert Cartridge screen, select Configuration, then select Set Date & Time from the Configuration menu.**

Status: The instrument will display a prompt for entry of the Key Operator Password.

- Enter the Key Operator Password, and touch Enter.**

Status: The instrument will display the message: *Changes to this screen will restart the GEM Operating Software.*

- Touch OK to continue.**

Status: The instrument will display the System Date and Time screen (*figure 3.38*), with the instrument's current date and time displayed.

- To change the date, touch the Date field.**

Status: The instrument will display a keypad for entering the date (*figure 3.39*).

**Figure 3.39: Set Date Keypad**



- Enter the correct date using the keypad.**

Status: Use the <- and → buttons to move the cursor.

- Touch Enter.**

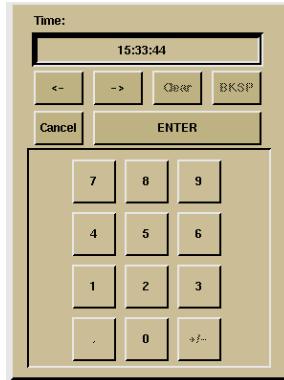
Status: If desired, touch **Cancel** to abort the change and return to the System Date and Time screen.

The instrument will validate the entered date. If the date is not valid, it will display a message indicating the required correction. When a valid date has been entered, the instrument will transfer the new date to the appropriate field on the System Date and Time screen and remove the keypad.

**7. To change the time, touch the Time field.**

Status: The instrument will display a keypad for entering the time (figure 3.40).

**Figure 3.39: Set Date Keypad**

**8. Enter the correct time using the keypad.**

Status: Use the <- and → buttons to move the cursor.

**9. Touch Enter.**

Status: If desired, touch **Cancel** to abort the change and return to the System Date and Time screen.

The instrument will validate the entered time. If the time is not valid, it will display a message indicating the required correction. When a valid time has been entered, the instrument will transfer the new time to the appropriate field on the System Date and Time screen and remove the keypad.

**10. If desired, adjust the checkbox for tracking of daylight savings time.**

Status: By default, this checkbox will be filled, meaning that the instrument will track and adjust its clock for daylight savings time.



*NOTE: If Daylight Savings Time is enabled, the time will move forward by one hour on the second Sunday in March, and will fall back by one hour on the first Sunday in November.*

**11. Touch OK to leave the System Date and Time screen.**

Status: The instrument will restart and redisplay the Insert Cartridge screen.

# 4 Patient Sampling

## 4.1 Patient Sampling

This section describes how to run patient samples on the GEM Premier 3500 and how to remove the GEM Premier PAK cartridge:

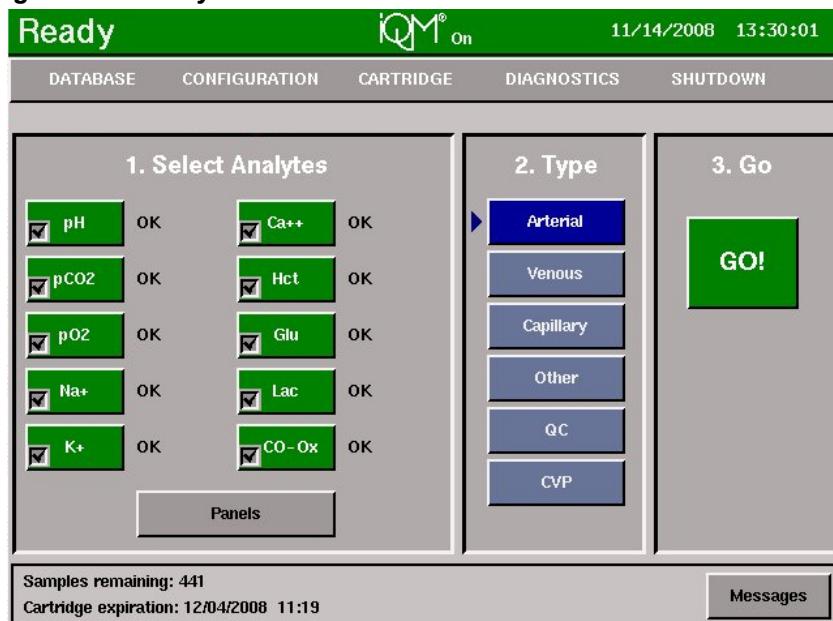
- A description of the Ready screen – Section 4.2
- Instructions for analyzing patient samples – Section 4.3 (See Chapter 5 and 6 for QC and CVP samples respectively).
- Cartridge removal – Section 4.5

## 4.2 Ready Screen

The GEM Premier 3500 is ready to analyze samples whenever it displays the Ready screen. The Ready screen is the primary screen displayed by the instrument. Its look depends whether **iQM Mode** is On or Off:

- if **iQM Mode** is On: the iQM logo will be followed by “On”. As shown in *figure 4.1*.
- if **iQM Mode** is Off: the iQM logo will be followed by “Off”.

*Figure 4.1: Ready Screen*

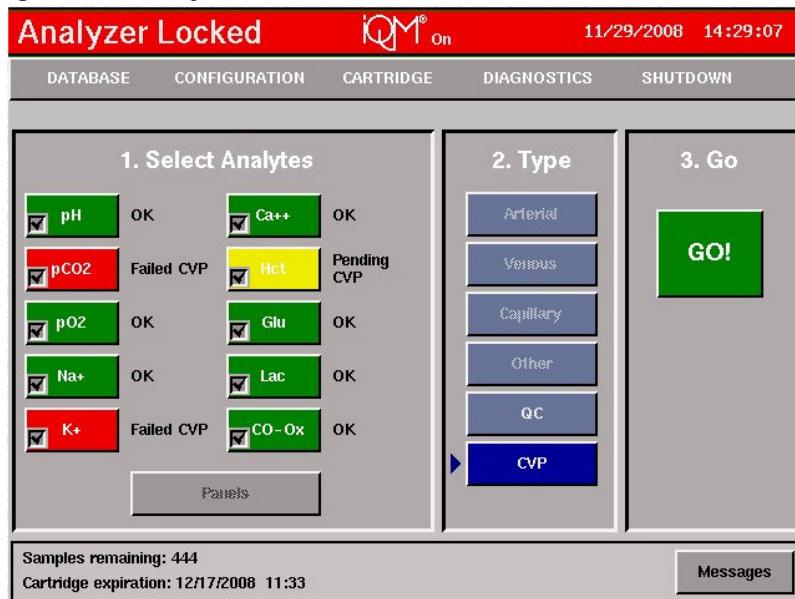


The Ready screen also contains the following information:

- The current date and time, with the date in the format defined in instrument configuration (see “Instrument Setup”, Chapter 3).
- Pull-down menus (see in this section).
- Buttons to analyze the various sample types: **Arterial**, **Venous**, **Capillary**, **Other**, **QC**, and **CVP**. The **CVP** button only appears when **iQM Mode** is set to On. For QC and CVP information see Chapter 5 and 6 respectively.

**⚠ NOTE:** If the Key Operator has disabled sample analysis on the instrument (see “Security Setup” in Chapter 3), the sample type buttons (all except QC and CVP) will be inoperative (ghosted) and the message *Analyzer Locked* will be displayed on top of the screen. See Figure 4.2.

**Figure 4.2. Analyzer Locked**



- The **Panels** button. This button will appear only if test panels have been configured for the instrument in “Sample Setup” (Chapter 3). Test panels provide a way to define the analytes the GEM Premier 3500 will report when patient samples (*not* QC samples) are analyzed. See “2 – Select Test Panel or Analytes (Optional)” in “Patient Sampling Process” (Section 4.3).

Panel selections remain in effect until a new panel choice is made.

**⚠ NOTE:** Choose **Panels** then **All Analytes** to activate all enabled tests.

*All analytes appropriate for the selected QC material will be reported for QC sampling, regardless of the test panel currently in effect.*

- The Analyte Status Area shows the current status of the instrument’s analytes. See “Analyte Status Area” in this section.
- The Status Area displays system information, status messages, and the **Training**, **Next QC**, and **Messages** buttons. See “Status Area” in this section.

## Pull-Down Menus

The GEM Premier 3500 provides pull-down menus at the top of the screen for access to instrument functions other than sampling. The menus are displayed with the Restart, Remove Cartridge, Insert Cartridge, Cartridge Warm-up, and Ready screens.

After exiting from a menu area, the instrument will return to the screen it was at when the menu was accessed. If the instrument has transitioned to a new screen (for example, from Warm-up to Ready), the new screen will be displayed.

All of the menu commands are available at the Ready screen except **Restore Config** and **Set Date & Time** on the **Configuration** menu, which are only available at the Insert Cartridge

screen. The following table describes the menus and commands and references the location in this manual where the command is described.

Menu	Command	Description
Database	<b>Last Sample</b>	Review last analyzed patient sample. See "Review Last Sample Analyzed" (Chapter 8).
	<b>Patient Samples</b>	Review previously analyzed patient samples. See "Recall Patient Sample Results" (Chapter 8).
	<b>QC Samples</b>	Review previously analyzed QC samples. See "Recall QC Sample Results" (Chapter 8).
	<b>CVP Samples</b>	Review previously analyzed CVP samples. See "Recall CVP Sample Results" (Chapter 8).
	<b>All Samples</b>	Review any previously analyzed patient, CVP, or QC samples. See "Recall and Review Samples" (Chapter 8).
	<b>Print iQM Process.</b>	Prints a report for the last full iQM Process. See Chapter 6.
	<b>iQM Reports</b>	View and print iQM reports. See "iQM Reports" (Chapter 5).
Configuration	<b>Sample Setup</b> <b>QC Setup</b> <b>iQM Setup</b> <b>Instrument Setup</b> <b>Interface Setup</b> <b>Security Setup</b> <b>Restore KOPW</b> <b>Save Config.</b> <b>Restore Config.*</b> <b>Set Date &amp; Time*</b>	Options for configuring the GEM Premier 3500. See Chapter 3.  *Available only at the Insert Cartridge screen.
Cartridge	<b>Remove Cartridge</b>	Remove GEM Premier 3500 PAK cartridge. See "Cartridge Removal" Section 4.5.
Diagnostics	<b>Ports</b>	Review the status of instrument's transmission of information to the LIS/DMS and perform diagnostics on the instrument's COM ports and Ethernet port. See "Diagnostics Menu" (Chapter 9).
	<b>Printers</b>	Review the status of instrument's printer and print queue. See "Diagnostics Menu" (Chapter 9).
	<b>System Info.</b>	Review information about instrument's system software and barcode information for the currently inserted GEM Premier 3500 PAK cartridge. See "Diagnostics Menu" (Chapter 9).
	<b>Copy IL Data</b>	Copy diagnostic information for use by Instrumentation Laboratory in solving system problems. See "Diagnostics Menu" (Chapter 9).
	<b>iQM Process</b>	Initiate a full iQM Process. This command will be available only after successful cartridge warm-up.

	See "iQM Process" (Chapter 5).
<b>Copy Cart. Data</b>	Copy information for all samples analyzed. See "Save GEM Premier 3500 PAK Cartridge Data" (Chapter 8).
<b>Copy iQM Data</b>	Copy all iQM data to a diskette. See "Save iQM Data" in Section 8.7.
<b>Shutdown</b>	Shutdown instrument. See "Shutdown & Transport" (Chapter 7).



**CAUTION:** Do not turn off the instrument or disconnect its power source without first shutting down the instrument. Disregarding the shutdown procedure may result in loss of data.

## iQM Status Area

The iQM Status Area (*figure 4.3*) appears at the top of the Ready Screen. This area shows at a glance the status of iQM:

- The title of the area (iQM: On or iQM: Off) reflects the state of **iQM Mode** as set in Configuration (see "iQM Setup" in Chapter 3).



iQM is ON



iQM is OFF

**Figure 4.3: iQM Status Area**

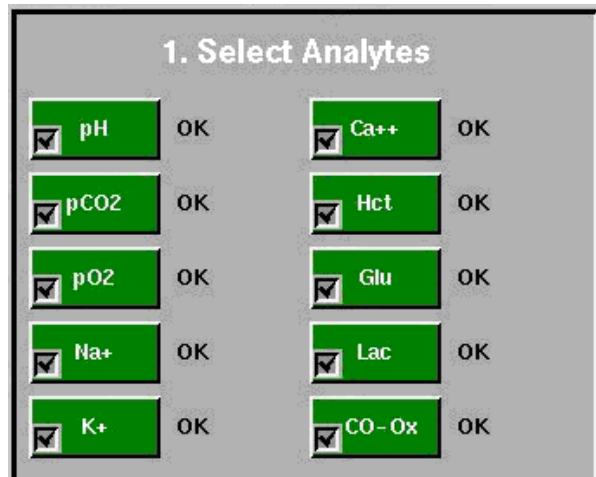
For more information about iQM, see Section 6.

## Analyte Status Area

The Analyte Status Area (*figure 4.4*) displays the current status of analytes and allows temporary disabling of one or more analytes.

### Analyte Status

The background color and message next to each measured analyte shows the analyte's current status.



**Figure 4.4: The Analyte Status Area**

If an IL CO-Oximeter has been configured for use with the GEM Premier 3500 in Interface Setup (see Chapter 3) and the current panel includes at least one CO-Ox analyte, the Status Area will also include CO-Ox status. If the current test panel does not contain CO-Ox analytes, the CO-Ox status will appear but be inoperative or disabled.



**NOTE:** All CO-Ox analytes are initially disabled when an IL CO-Ox device is first configured. The Key Operator must manually enable the desired CO-Ox analytes (see "Sample Setup" in Chapter 3).

Analytes can also have one of the following statuses:

Status	Meaning	Color	Notes
OK	The analyte, and therefore the sensor, is functioning properly.	Green	
<i>iQM Disabled</i>	Analyte disabled by the instrument because of an unrecoverable iQM error, or due to persistent iQM Process failure.	Grey	iQM mode is ON. Cleared (enabled) when cartridge is removed.
<i>Disabled</i>	The analyte has been disabled by the Key Operator with the <b>Enable/Disable Analytes</b> configuration option (see "Sample Setup" in Chapter 3 for a description).	Grey	Remains disabled until enabled by the Key Operator.
<i>Incalculable</i>	Applies to Hct analyte only when Na <sup>+</sup> is not available.	Red	Cleared when Na <sup>+</sup> becomes available or when cartridge is removed.
<i>iQM Error</i>	iQM check/correction is underway or sensor has uncorrected drift or slope error.	Yellow	iQM mode is ON only. Cleared after condition is corrected or after cartridge is removed.
<i>Failed iQM Process</i>	Slope or drift error encountered for the analyte during the last iQM Process (see "iQM Process" in Chapter 5.)	Red	Only when iQM mode is Off. Cleared after next iQM Process passes.
<i>Pending CVP</i>		Yellow	iQM mode is ON only. Cleared after 2 levels of CVP are run and accepted for corresponding analytes or when cartridge is removed.
<i>Failed CVP</i>	Failed CVP range check.	Red	iQM mode is ON. Cleared after failed level of CVP passes or when cartridge is removed.
<i>Failed QC</i>	QC results were incalculable, outside instrument's reportable range, or outside range defined for lot number (see "6 – Review QC Sample Results" in "Patient Sampling Process", Section 4.3.)	Red	Cleared after the failed QC level passes or when cartridge is removed.

If more than one status applies to an analyte, the instrument will display the status with the highest precedence. When that status is cleared, the next highest status will be displayed. In the table above, the non-OK statuses are listed in order of precedence, with highest precedence at the top.

### CO-Ox Analyte Status

The status for CO-Ox will depend upon the individual CO-Ox measured analytes. The CO-Ox button in the Status Area will be labeled with OK, Disabled, or Failed QC.

- If all measured CO-Ox analytes are disabled in setup, the CO-Ox button will be unchecked and unavailable, and the status will be “Disabled.”
- If none of the enabled CO-Ox analytes are part of the current panel, the CO-Ox button will be unchecked and unavailable.
- If at least one of the CO-Ox analytes is enabled and part of the current panel, the CO-Ox button checkbox will be filled.
- If all measured CO-Ox analytes are functioning properly, the CO-Ox button will be green, and the status will be “OK.”
- If one ore more of the CO-Ox analytes has failed QC, the CO-Ox button will be red, and the status will be “Failed QC.”

### Analyte Status vs. Reporting

The status of an analyte determines whether it will be reported during iQM process, patient, QC, and CVP sample analysis:

---

Analyte Status	iQM Process	QC Sample	CVP Sample	Patient Sample
OK	Yes	Yes	Yes	Yes (unless disabled)
<i>iQM Disabled</i>	No	No	No	No
<i>Disabled</i>	No	No	No	No
<i>Incalculable</i>	Yes	Yes	Yes	No
<i>iQM Error</i>	Yes	No	No	No
<i>Failed iQM Process</i>	Yes	No	No	No
<i>Pending CVP</i>	Yes	Yes	Yes	No
<i>Failed CVP</i>	Yes	Yes	Yes	No
<i>Failed QC</i>	Yes	Yes	Yes	Yes (QC Blank-out Off) No (QC Blank-out On)

### Temporary Analyte Disable

Analytes that are functioning properly (OK status) will have a checkbox to their left that can be used to temporarily disable them for the next patient sample. A filled checkbox () indicates the analyte is enabled and will be included in the sampling. Touching the checkbox will toggle it between filled and unfilled (included and excluded), for that sample only.

The CO-Ox status will disable all CO-Ox analytes that are part of the current panel. See “CO-Ox Analyte Status” in this section for the circumstances under which the CO-Ox status will appear.



*NOTE: Analytes that are temporarily disabled by choosing a panel option that does not include all available analytes may not be enabled by touching the checkbox next to the analyte on the Ready screen. Analytes temporarily disabled through choosing a panel option must be enabled by selecting **Panels** and then choosing the **All Analytes** panel (all analytes enabled in configuration).*



*NOTE: The state of the checkboxes and the test panel choice will not affect QC samples. QC analytes will always be reported according to the rules in Analyte Status vs. Reporting in this section.*

### Status Area

The Status Area at the bottom of the Ready screen provides the following information:

- A status message showing the total samples and the number of samples remaining on the current GEM Premier 3500 PAK cartridge. This number **does not include** the number of CO-Ox-only samples.
- The date and time that the current cartridge will expire.
- The **Next QC** button will display a list of the QC that is due to be run within the next eight hours, if any. This button will not be displayed if Mandatory QC is set to “Off” in setup (see Chapter 3). This button will be displayed in yellow when QC is due within the next 60 minutes, and will flash when QC is overdue. See “QC Scheduling” in Chapter 5 for more information about scheduled QC, or “QC Sampling”.
- The **Messages** button will display a list of alarm messages that have been generated by the instrument and also text messages received from network users. The button will be yellow when alarms or messages are present on the Messages screen.

The Messages screen displays alarms and/or text messages in reverse chronological order, with the most recent messages at the top.

Alarm messages are generated for system errors that require immediate operator action, such as the printer being out of paper. See Chapter 9 for a description of common alarm messages and the actions required to correct them.

- During a full iQM process, iQM process “B”, or iQM process “C” the Status Area will contain a progress indicator with a count-down timer to show when the iQM process will be completed.
- During interference and micro clot checks, the Status Area will display the following message, along with a progress indicator:

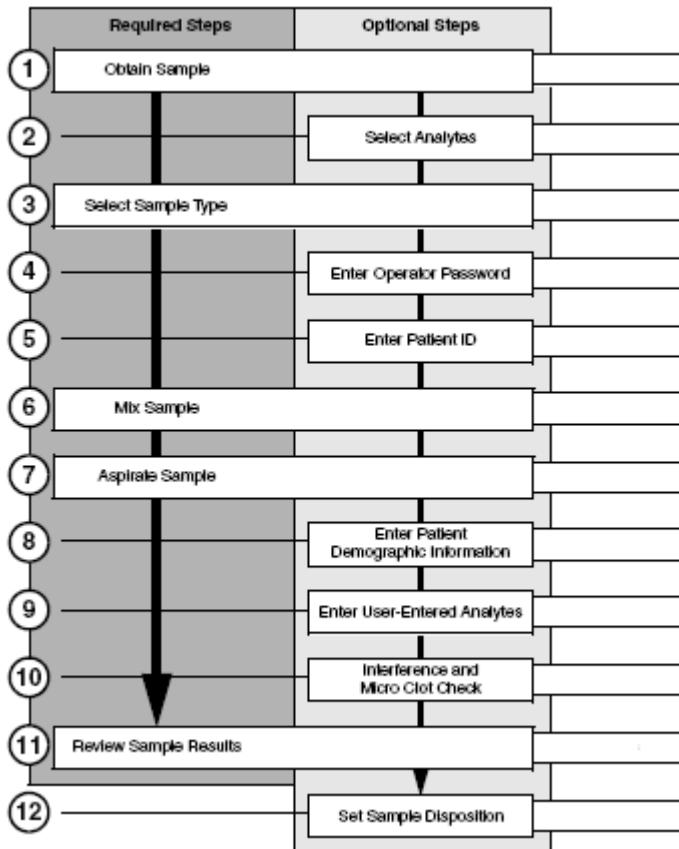
*Checking for presence of interference and micro clots. Please wait for results.*

See “10 – Interference/Micro Clot Check (Flagging On)” in “Patient Sampling Process” (Section 4.3).

### 4.3 Patient Sampling Process

Depending on the needs of your institution, the GEM Premier 3500 can be configured to analyze patient samples with as few as 5 steps, or as many 12. These steps are shown in figure 4.5.

**Figure 4.5: Sampling Process**



These steps are explained in detail in the following sections, which are labeled 1–12 to correspond with the steps above. Sections 2 through 12 also start out with the screen that will be displayed at that point in the sampling process.

## 1 - Obtain Sample<sup>1</sup>



**BIOHAZARD:** Treat all patient specimens as highly infectious. Use proper technique to not contaminate yourself, nor create aerosols.



**CAUTION: An insufficient amount of heparin can lead to sample clotting.**

The use of citrate, EDTA, oxalate, or sodium fluoride anticoagulants may adversely affect sensor performance.

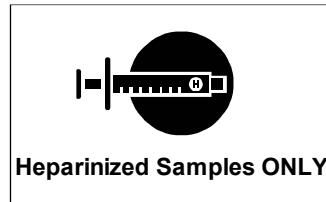
A high concentration of sodium heparin can lead to elevated sodium readings.

High concentrations of lithium and sodium heparin can slightly lower ionized calcium readings.

To ensure the highest possible accuracy for each analysis, follow the recommendations in the following paragraphs when collecting blood. For additional information about sampling precautions, see "Operating Principles and Precautions" in Chapter 10.

### Anticoagulant

Use either sodium or lithium heparin anticoagulants. Dry heparinized syringes are preferred because they ensure sufficient heparin to avert sample clotting yet prevent the dilutional effect of liquid heparin. The final concentration of heparin in the sample should be approximately 25 USP units/mL (IU/mL). Technique, syringe type, and fill volume can all affect the final heparin concentration.



Samples must be mixed thoroughly immediately upon drawing to ensure adequate mixing of the anticoagulant with the blood sample. Proper mixing will help prevent the formation of clots and will create a homogeneous sample.

### Sample Volume

Obtain the minimum sample volume for the cartridge in use as outlined below:

Sample Volume	Cartridge
150uL	BG/Hct/Lytes/Glu/Lac
145uL (capillary mode)	BG/Hct/Lytes/Glu/Lac

<sup>1</sup> Burnett R, Covington A. 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 1994; Volume 6, Issue 4: 115-120.

135uL	BG/Hct/Lytes
135uL	BG/Hct



**NOTE:** If you have an IL CO-Oximeter attached to the GEM Premier 3500, refer to the CO-Oximeter's operator's manual for recommended CO-Oximeter sample volumes.

### Sample Timing

As a common practice, a sample will not need to be iced if it is analyzed within 5 minutes (samples requiring glucose or lactate measurement) or 15 minutes (samples requiring blood gas or electrolytes). Check the policy at your institution.

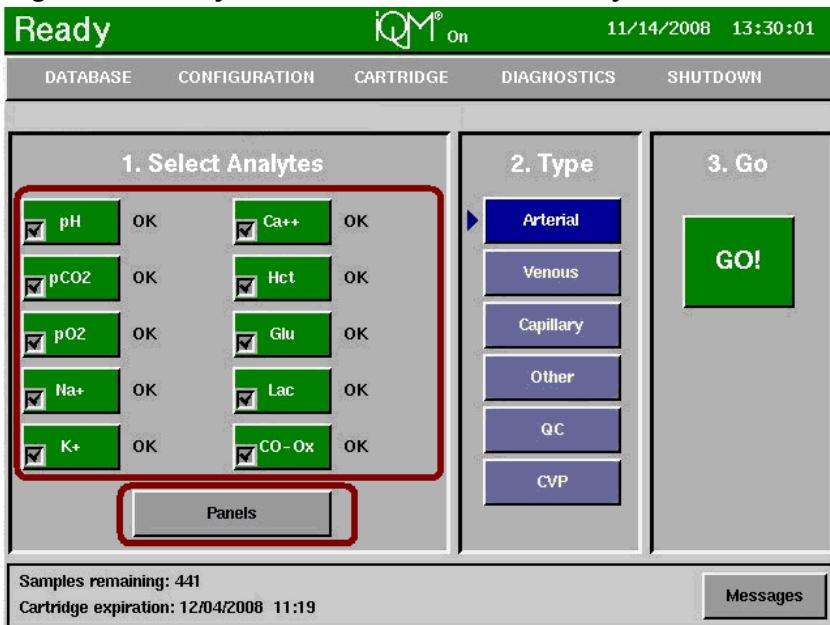
## 2- Select Test Panel or Analytes (Optional)

The GEM Premier 3500 provides two options at the Ready screen (*figure 4.6*) for selecting the analytes to be tested. One or both of the following options can be used with a sample:

- If the Key Operator has defined multiple test panels, use the **Panels** button to select a test panel.
- Touch the individual analyte buttons to dynamically disable specific analytes, creating a one-time test panel.

Values for disabled analytes will not be printed or appear on the screen or in sample data.

**Figure 4.6: Ready Screen – Select Panel or Analytes**



### Select Test Panel

If the Key Operator has defined test panels during setup, the **Panels** button will appear on the Ready screen to allow easy measurement of a preset collection of analytes. For example, a "blood gases only" panel may contain only pH,  $pCO_2$ , and  $pO_2$ . The default test panel includes all native GEM Premier 3500 analytes. CO-Ox analytes will be included if an IL CO-Oximeter has been configured. The analytes in a test panel are shown by the analyte buttons that appear in the Analyte Status Area. Up to nine custom test panels can be defined.

The **Panels** button will not be displayed on the Ready screen if the Key Operator has not defined additional test panels. If no panels were defined, the default panel of **All Analytes** will remain in effect. For more information about test panels, see "Panel Setup" in Chapter 3.

### Disabling Individual Analytes

A one-time test panel can be defined dynamically by touching the checkboxes in the Analyte Status Area to temporarily disable analytes. Checkboxes will be available for all analytes defined for the current panel. The change will be effective for the next patient sample only, after which the analyte checkboxes will revert back to their original settings.

The CO-Ox checkbox will disable all CO-Ox analytes that are part of the current panel. See "Analyte Status Area" in "Ready Screen" (Section 4.2) for the circumstances under which the CO-Ox checkbox will appear.

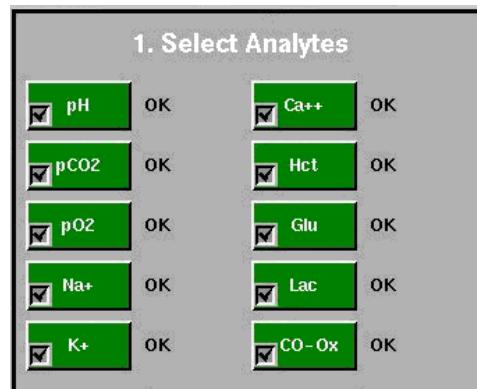


Figure 4.7: Analyte Status Area



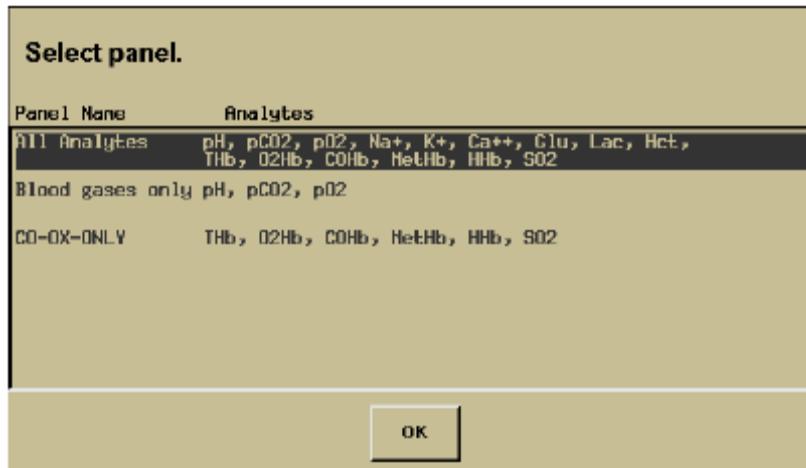
*NOTE: A one-time test panel allows a panel's analytes to be temporarily disabled. It is not possible to enable analytes that were not configured to be in the panel in the first place.*

### To Select a Test Panel:

1. Touch the Panels button on the Ready screen.

Status: The instrument will display the Select Panel screen (figure 4.8).

Figure 4.8: Select Panel Screen



2. Select the desired test panel by touching it to highlight it.

Status: Each test panel in the listing will be displayed with its name and a listing of the analytes included in the panel. The factory default panel (**All Analytes**) will always be the first in the list. The instrument will automatically highlight the last panel used.

3. Touch the OK button.

Status: The instrument will display the Ready screen, and the Analytes Status Area will be updated to reflect the analytes in the chosen panel.

- If desired, the chosen test panel may be refined by disabling analytes in the Analyte Status Area by touching the checkboxes to unfill them. A filled checkbox indicates an analyte will be included in the panel.

### 3 - Select Sample Type (Optional)

 **NOTE:** If an iQM process is in progress, a progress bar will be displayed at the bottom of the Ready screen. Some iQM processes can be interrupted, while others cannot (see "Cancellations from iQM Processes" in this section). In general, **iQM processes should not be interrupted** unless it is absolutely necessary to run an urgent sample.

You may want to select a sample type on the Ready screen: **Arterial**, **Venous**, **Capillary**, or **Other** (see next pages for additional information about Capillary and Other samples) to define a new sample type.

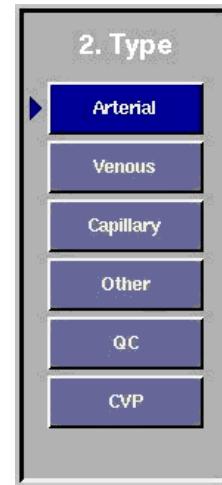


Figure 4.9: Sample Type Buttons

 **NOTE:** All sample type buttons (except QC and CVP) will be inoperative if the Key Operator has disabled patient sample analysis (see "Security Setup" in Chapter 3).

You may want to select the type of the next sample to be analyzed by touching the desired sample type button. As shown in Figure 4.9, the currently selected sample type is "Arterial". The "Arterial" sample button is highlighted with a triangle pointer, and the button background color is dark blue, as opposed to lighter blue for the other non-selected sample types. The selected sample type shall persist from sample to sample until a new sample type is selected.

 **NOTE:** Upon completion of the cartridge warm-up, the GEM Premier 3500 software automatically sets the sample type to "CVP (if iQM Mode is On) as all analytes are in CVP pending state. After the successful completion of CVP (all the CVP levels are run and accepted), the default sample type will be set to "Arterial".

After selecting the sample type (optional), then press the "GO!" button in order to run a sample (see figure 4.10). If none of the conditions described in "Instrument-Aborted Sampling," below, exist, the instrument will do the following after the "GO!" button is selected:



Figure 4.10 Press "GO!" to Run Sample

- Prompt for an operator ID if **Operator Security** (see "Security Setup", Chapter 3) has been enabled.
- Prompt for a patient ID if **Mandatory Patient ID** (see "Sample Setup", Chapter 3) has been enabled.

- If none of the above are true, the instrument will prompt for sample aspiration.

### Instrument-Aborted Sampling

The instrument will not allow samples to be run if any of the following conditions exist:

- If mandatory QC's (see "QC Setup" in Chapter 3) have been enabled by the Key Operator 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. See "QC Scheduling" in Chapter 5 for information about scheduling QC samples.
- 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.
- If an iQM process that cannot be interrupted is in progress, the instrument will display a message and return to the Ready screen. See "Cancellations from iQM processes," below.

### Cancellations from iQM processes

If an interruptible iQM process is in progress, the instrument will interrupt the iQM process and start the sampling process. The following iQM processes cannot be interrupted:

- Full iQM processes during the first four hours of cartridge life
- Full iQM processes after the first four hours of cartridge life if the three previous full iQM processes were interrupted for sample analysis
- iQM processes "C"
- The first iQM process "B" after sample analysis

For more information about iQM processes, see "iQM Process" in Chapter 5.

### Capillary and Other Samples

Some capillary sampling kits will require a tubing adapter in order for the capillary tube to attach to the sampler. See "Pre-Analytical Phase" in Section 10.3 for information about the pre-analytical implications of capillary samples.

The **Other** button on the Ready screen is used to process samples that cannot be classified as arterial, venous, or capillary, such as proficiency samples. The sampling process is the same as for arterial and venous samples. The instrument will attach an "Other" label to all samples processed in this way.

#### 4 - Enter Authorized Operator Password

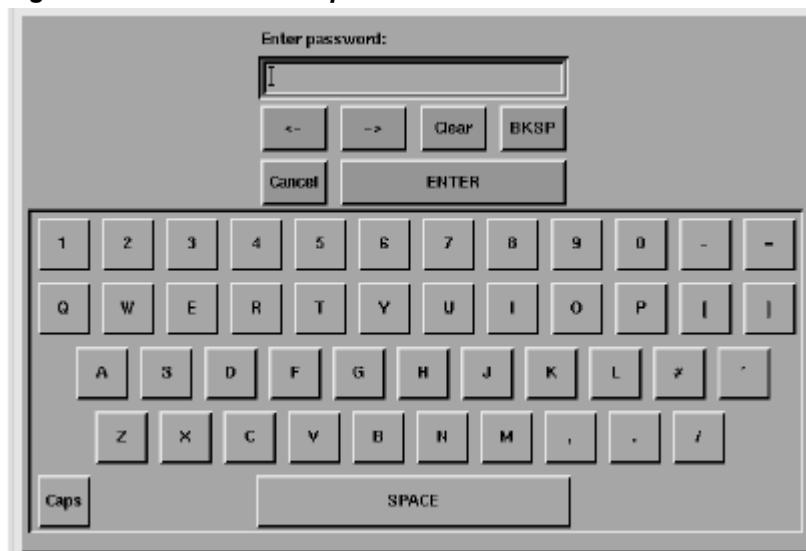
The GEM Premier 3500 will display the Operator Password screen (*figure 4.11*) if **Operator Security** (Chapter 3) has been enabled.

The password can be entered by typing or by scanning with the barcode gun. To proceed with sampling, a password must be entered that matches a password configured by the Key Operator to have GEM access privileges.

For security, the instrument will display “\*” characters to mask the entry of the password. The instrument will automatically place the operator ID associated with the password into the proper field on the Patient Information screen (see “8 – Enter Patient Information” in this section).

For more information about operator IDs and passwords, see **Operator Security** in Chapter 3.

**Figure 4.11: Authorized Operator Password Screen**



#### To Enter an Authorized Operator Password:

1. Run the barcode gun over the barcode.

OR

Touch the desired characters on the keypad.

Status: The GEM Premier 3500 will display “\*” characters in place of the password. If the instrument cannot read the barcode, the password must be entered on the keypad. Report the problem to the Key Operator or Technical Support.

2. Touch Enter.

Status: If the password is not recognized, the instrument will display the message: *Invalid password. Touch OK*. Contact the Key Operator. Otherwise:

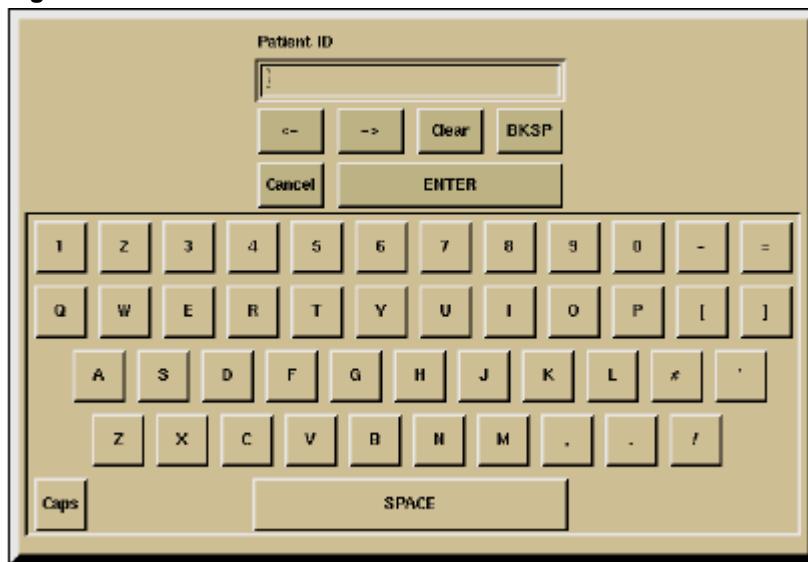
- If the instrument has been configured to require patient IDs, it will prompt for entry of the patient ID.
- If the instrument has not been configured to require patient IDs, it will prompt for aspiration of the sample. For GEM Premier 3500 samples or combination GEM Premier 3500 and CO-Ox samples, proceed to “Mix Sample” in this section. For CO-Ox-only samples” proceed to “CO-Ox-Only samples” in this section.

## 5 - Enter Patient ID

The GEM Premier 3500 will display the Patient ID screen (*figure 4.12*) if the instrument has been configured to require patient identification (**Mandatory Patient ID**, Chapter 3). The ID must be entered to proceed with sampling. The ID can be entered by typing or by scanning with the barcode gun.

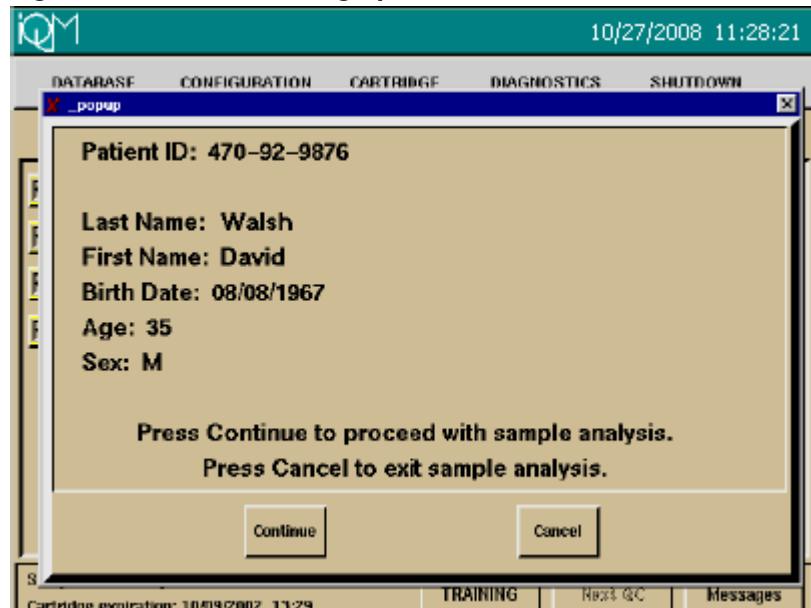
If the instrument has been configured to search for patient demographics (name, age, etc.), it will use the ID to search its internal database and, if configured, the hospital LIS/DMS. Searching of the hospital LIS/DMS can be canceled.

**Figure 4.12: Patient ID Screen**



If patient demographics are found, the information will be displayed for confirmation only (*figure 4.13*) if **Patient Verification** has been enabled. Otherwise, the information will be filled in with no verification prompting, and the information cannot be changed. If information is not found, communication with the hospital LIS/DMS was unsuccessful, or the LIS/DMS search was canceled, a message will be displayed. Patient sampling can continue regardless of whether patient demographics are found.

Retrieved patient demographics will be displayed on the Patient Information screen (*figure 4.17*) later in the sampling process. If information is not found or searching has not been configured, then patient information can be manually entered on the Patient Information screen. See "8 – Enter Patient Information" in this section.

**Figure 4.13: Patient Demographics Confirmation Screen**

For more information about patient demographics options, see “Demographics Setup” (Chapter 3).

#### To Enter a Patient ID:

1. Run the barcode gun over the barcode.

**OR**

1. Touch the desired characters on the keypad.

Status: The GEM Premier 3500 will display the patient ID. If the instrument cannot read the barcode, the ID must be entered on the keypad. Report the problem to the Key Operator or Technical Support.

2. Touch Enter.

Status: If the instrument has been configured to search for the patient information, it will display any found information for confirmation.

- If information is not found, the instrument will display a message. Sampling can continue or be canceled.
- If communication with the LIS/DMS is unsuccessful or the LIS/DMS search is canceled, the instrument will display a message.

3. Touch Continue to proceed with sample processing or Cancel to stop sampling.

Status: For GEM Premier 3500 samples or combination GEM Premier 3500 and CO-Ox samples, proceed to “Mix Sample” in this section. For CO-Ox only samples proceed to “Mix Sample” in this section. For CO-Ox-only samples proceed to “CO-Ox-Only samples” in this section.

#### 6 - Mix Sample



*NOTE: The following steps apply to analysis of GEM Premier 3500 analytes or a combination of GEM Premier 3500 analytes and CO-Oximeter analytes. To sample only CO-Ox analytes, see CO-Ox only samples in this section.*



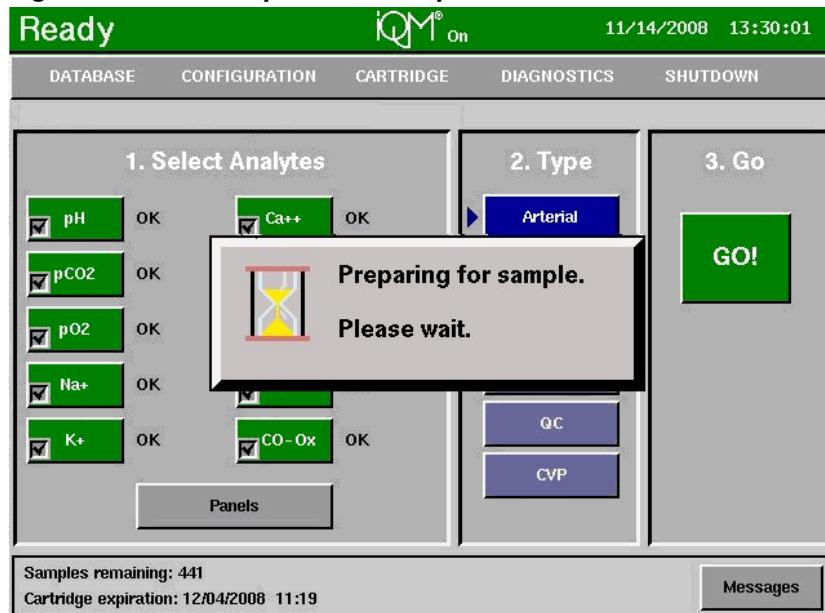
**NOTE:** After pressing the “GO!” button, introducing the operator password (if appropriate), and introducing the patient ID (if appropriate), the small light (LED) situated in the top of the sampling area of the analyzer will automatically turn on. The light will help you see the sampler. After the aspiration of the sample is completed and the sampler retracts, the small light (LED) will automatically turn off.



**CAUTION:** The minimum sample volumes stated in this manual for each cartridge type are required in order for results to be obtained. See “Patient Sampling Process” (Section 4.3) for required sample volumes. When the instrument detects an insufficient sample, it will cancel the test and display the message: *Insufficient sample volume. Test cancelled. Repeat test.*

Immediately before introducing a heparinized blood sample into the instrument, mix the specimen thoroughly. For more information on sample preparation, see “Operating Principles and Precautions” in Chapter 10.

**Figure 4.14: First Aspiration Prompt**

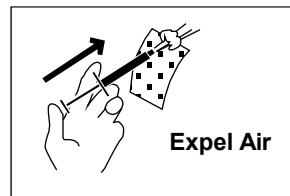


When the instrument is ready to aspirate the sample, it will display a message and progress indicator (figure 4.14). During this time, interruptible iQM processes will be aborted, and the sample probe will be extended.

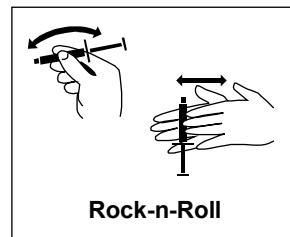
The specimen **must be** mixed thoroughly. The exact mixing interval depends upon several factors, including the degree of settling of the cells, the length of time of iced storage, and the characteristics of the type of syringe.

### To Mix a Sample:

1. **Expel all air from the syringe.**

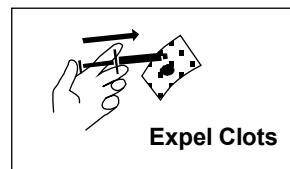


2. **Grasp the syringe firmly by the barrel with a finger tightly over its cap, and repeatedly invert (rock) it at least five times.**



3. **Roll the syringe between outstretched palms at least five times.**
4. **Push out a few drops of the sample onto a gauze pad to prevent the chance of a clot in the tip of the syringe.**
5. **Analyze the sample immediately.**

Status: Proceed to "Aspirate Sample" in this section.



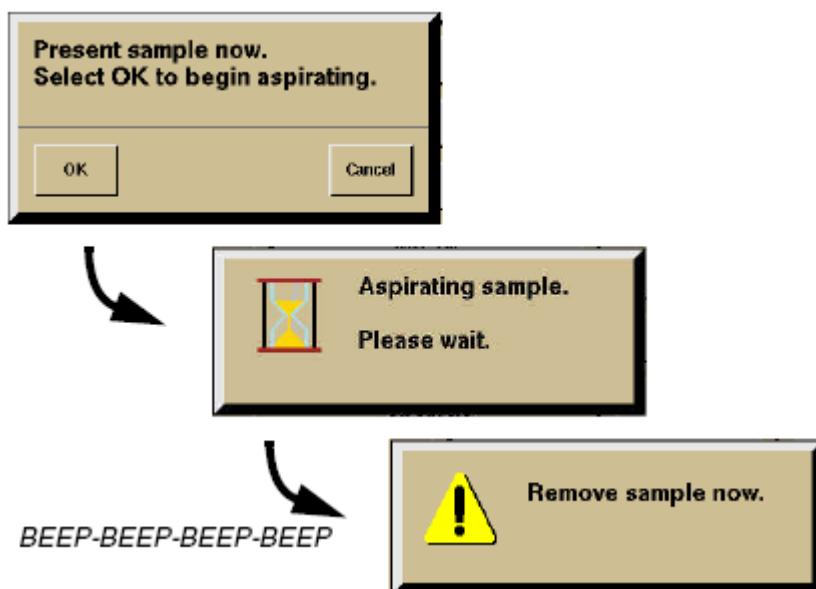
### 7 – Aspirate Sample

 **NOTE:** The following steps apply to analysis of GEM Premier 3500 analytes or a combination of GEM Premier 3500 analytes and CO-Oximeter analytes. To sample only CO-Ox analytes, see CO-Ox-Only Samples in this section.

1. **When the display reads *Present sample now*. Select *OK* to begin, position the sample so that the sampler is near, but not touching, the bottom of the syringe plunger. Then touch *OK*.**

Status: The GEM Premier 3500 will display the message: *Aspirating sample. Please wait.* When the sample has been aspirated, the instrument will beep four times and display the message: *Remove sample now.* The instrument will wait two seconds for removal of the sample before withdrawing the sampler into the instrument.



**Figure 4.15: Aspiration Prompts**

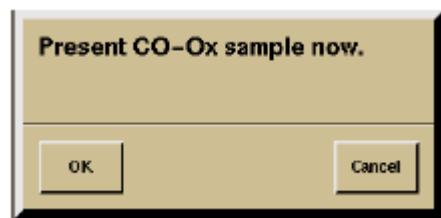
**CAUTION:** In the following step, remove the syringe or capillary adapter quickly so as not to bend the sampler as it is withdrawn into the instrument.

2. Remove the syringe, capillary tube, or capillary and adapter from the sampler, and dispose of it in a biohazard waste container.  
Status: The GEM Premier 3500 will take 85 seconds to process the sample. If the sample analysis includes CO-Ox analytes, the instrument will prompt for introduction of the CO-Ox sample; Step 3 must be completed **within three minutes**.
3. If the sample analysis includes CO-Ox analytes, the display reads **Present CO-Ox sample now**. Touch OK, and introduce the CO-Ox sample to the attached CO-Ox device.  
Status: The CO-Ox sample may be cancelled by touching the **Cancel** button. The instrument will automatically cancel CO-Ox sampling if the **OK** button is not pressed within three minutes.  
If CO-Ox results are not received within three minutes of prompting:
  - If the **OK** button was not pressed and the CO-Ox sample was not introduced, the sample will be reported with GEM Premier 3500 analytes only.
  - If the **OK** button was pressed and no CO-Ox results were received from the CO-Oximeter, the sample will be reported with blank CO-Ox values, and the analytes will be flagged with "?"

#### CO-Ox-Only Samples

If the test panel includes only CO-Ox analytes, the instrument will prompt for introduction of the CO-Ox sample immediately after the sample type has been selected.

4. When the display reads **Present CO-Ox sample now**. Touch OK, and introduce the CO-Ox sample to the attached CO-Ox device.  
Status: The CO-Ox sample can be cancelled by touching the **Cancel** button. The instrument will automatically cancel CO-Ox sampling if the **OK** button is not pressed within three minutes.

**Figure 4.16: First Aspiration Prompt**

## 8 - Enter Patient Information

The Patient Information screen (*figure 4.17*) will be displayed if one or both of the following are true:

- At least one individual demographic item (operator ID, patient ID, patient last and first names, birth date, age, sex, accession number, or comment) is enabled.
- At least one user-entered analyte is enabled.

If both are untrue, the Patient Information screen will not be displayed. If only user-entered analytes are displayed, proceed to “9 – Enter User-Entered Analytes” in this section.

**Figure 4.17: Patient Information Screen – Patient Demographics**

Patient Information		12/07/2008 18:03:17		
Operator ID	37.0			0
Accession Number	Temp (°C)	37.0	Fibrinogen (%)	0
Patient ID	APTT-P (sec)		PT-P (sec)	
Patient Last Name	PT INR		ACT (sec)	
Patient First Name	ACT-LR (sec)			
Patient Birth Date	MM/DD/YYYY			
More Demographics		O2 and Vent Settings		

### Patient Demographics

The way the GEM Premier 3500 handles patient demographic information depends upon how the instrument has been configured and will affect the initial content of the Patient Information screen:

- If the screen does not initially contain any patient demographic information, then the information can be manually entered. Start with the patient ID because the instrument might be configured to use the ID to search for the patient in the last 12 months of accepted samples.
- If the screen initially includes only a patient ID, then the remaining demographic information can be manually entered if desired.

- If the screen initially contains patient demographic information, whether the information can be changed depends upon how the instrument has been configured.

The type of demographic information that the Patient Information screen displays is determined when the instrument is configured. All possible types are described in the following sections. If the demographic is changeable, touching it will display a keypad for entering the required information.

For more information about the GEM Premier's patient demographics options, in Chapter 3.

### **Operator ID**

If the Operator ID is blank, then entering an ID is optional. Operator IDs can contain up to 16 alphanumeric characters, including spaces, and can be entered by typing or by scanning a barcode.

If the ID is not blank, it is either the ID from the last sample analyzed (ID can be changed) or the ID associated with the password entered earlier in the sampling process (ID cannot be changed).

For more information about operator ID settings, see "Security Setup" in Chapter 3

### **Patient ID**

If the Patient ID is blank, then entering an ID is optional. Depending on how the instrument has been configured, entering the ID may initiate a search of the instrument's database for the remaining patient demographic information. Always enter Patient ID first on the Patient Information screen.

If the ID is not blank, it is either the ID entered at the start of sample processing (ID cannot be changed) or the ID from the last sample analyzed (ID can be changed).

Patient IDs can contain up to 16 alphanumeric characters, including spaces, and can be entered by typing or by scanning a barcode.

For more information about patient ID settings, see "Demographics Setup" in Chapter 3.

### **Patient Last name, First Name, Birth Date, Age, and Sex**

If this information is blank, then entry is optional.

 *NOTE: If the Patient ID is also blank, then the instrument may be configured to search for patient demographic information after a Patient ID is entered. Always enter blank Patient IDs first.*

If this information is not blank, then the information is either from the last sample analyzed (information can be changed) or from the instrument's database or the hospital LIS/DMS (information cannot be changed).

The patient names can be entered by typing or by scanning a barcode.

Patient Names (first or last) can contain up to 16 characters each, including spaces. Patient Age is automatically calculated from the birth date, if available, and cannot be changed.

Patient Birth Date follows the date format configured by the Key Operator. Patient Sex can be "M," "F," or "U" (for Unknown).

### **Accession Number**

Accession Number entry is optional. The Accession Number can contain up to 16 alphanumeric characters, including spaces, and can be entered by typing or by scanning a barcode.

### Sample Comment

Sample Comment entry is optional. The Comment can be used to record a short description with a sample. Like all demographic information, the Comment will be printed, saved, and transmitted with the sample.

The Comment can be up to 48 alphanumeric characters, including spaces. The text will appear on two lines of 24 characters each.

### 9 - Enter User-Entered Analytes

User-entered analytes will be displayed on the Patient Information screen (*figure 4.18*) when user-entered analytes have been enabled in configuration. If none have been enabled, then no analytes will appear on the screen.

For more information about analyte configuration options, see “Analyte Enable/Disable” in Chapter 3.

User-entered analytes are presented in two groups: all entered analytes except O<sub>2</sub>/Vent parameters, and O<sub>2</sub>/Vent parameters. If at least one O<sub>2</sub>/Vent parameter has been enabled in setup, the **O2 and Vent Settings** button will be displayed on the screen with the main entered analytes. Touch this button to move to the screen for entering O<sub>2</sub>/Vent parameters.

Touching the field for an individual analyte will display a keypad for entering the required information.

**Figure 4.18: Patient Information Screen – User Entered Analytes**

The screenshot shows the 'Patient Information' screen with the following details:

- Header:** Patient Information, Date: 10/08/2008 18:06:08, OK button.
- Demographic Fields (Left):**
  - Operator ID: [empty]
  - Accession Number: [empty]
  - Patient ID: [empty]
  - Patient Last Name: [empty]
  - Patient First Name: [empty]
  - Patient Birth Date: 19101010
- Analyte Fields (Right):**

Temp (°C)	37.0	FetHb (%)	0
APTT-P (sec)	[empty]	PT-P (sec)	[empty]
PT INR	[empty]	ACT (sec)	[empty]
ACT-LR (sec)	[empty]		
- Buttons:** More Demographics, O2 and Vent Settings.

The following table shows the parameters that may be requested and provides any additional information required for entry of each parameter. The units used for each parameter is configured in "Units of Measure" in Chapter 3.

Entered Parameters	Range/Description
<b>Main User-Entered Parameters</b>	
Temperature	<p>15°C to 45°C (59°F to 113°F)</p> <p>If temperature was not enabled or no temperature is entered, the GEM Premier 3500 will use a default patient body temperature of 37°C.</p> <p>Regardless of the selected units, the instrument will accept the temperature as Celsius if the entered value is between 15.0 – 45.0 and Fahrenheit if it is between 59.0 – 113.0. However, the temperature will always be reported (displayed, printed, transmitted) in the units selected in setup.</p> <p>The instrument will display and record the value of temperature-corrected analytes (<math>pH(T)</math>, <math>pO_2(T)</math>, <math>pCO_2(T)</math>) at the entered temperature <i>and</i> at the default value of 37°C. See "Temperature Correction" in Chapter 11 for information about how the instrument calculates temperature-corrected values.</p>
*Glucose	0 mg/dL to 999 mg/dL (0 mmol/L to 55 mmol/L)
*Lactate	0.0 mmol/L to 30.0 mmol/L (0 mg/dL to 270 mg/dL)
* Only available when BG/Hct or BG/Hct/Lytes cartridges are used.	
**THb	2 g/dL to 25 g/dL
**sO <sub>2</sub>	0% to 100%
**O <sub>2</sub> Hb	0% to 100%
**COHb	0% to 100%
**HHb	0% to 100%

**MetHb	0% to 30%
FetHb	If a non-zero fetal percentage is entered AND an IL 682 CO-Oximeter has been configured as an attached CO-Ox device, the GEM Premier 3500 will use a series of dialog boxes to determine whether fetal correction should be performed.
RHb	0% to 60%
APTT-P	0.0 to 999.9 sec
PT-P	0.0 to 999.9 sec
PT INR	0.0 to 99.9
ACT	0.0 to 9999 sec
ACT-LR	0.0 to 999 sec

#### O<sub>2</sub> and Vent Parameters

O <sub>2</sub>	0.0 to 99.0
FiO <sub>2</sub>	00.0 to 100.0
V <sub>T</sub>	0 to 9999
Mode	Alphanumeric field
Mech rate	0 to 9999

\*\* Displayed as entered parameters if no CO-Oximeter has been configured. Otherwise, they will appear as measured analytes.

Spon rate	0 to 9999
Peak press	0.0 to 999.9
Itime (sec)	0.0 99.9
Itime (%)	0 to 99
MAP	0.0 to 999.9

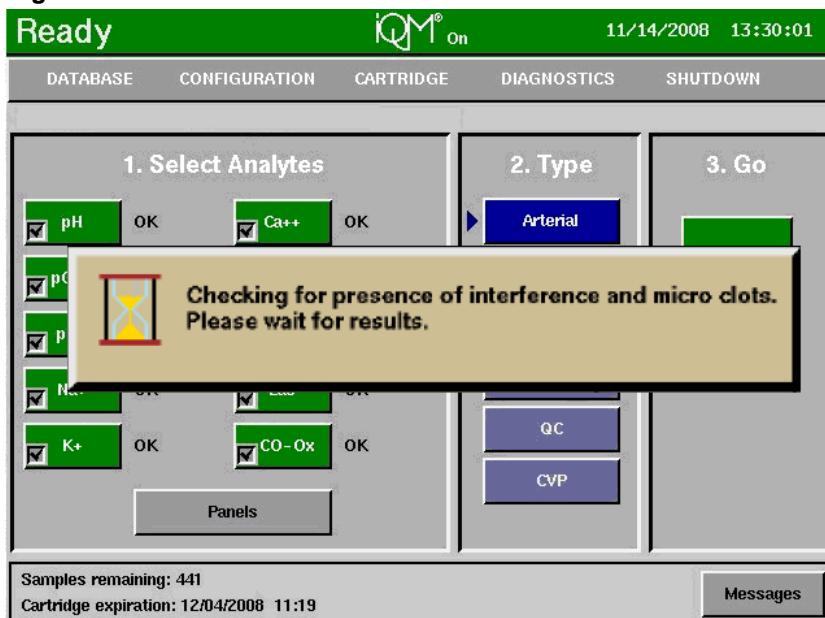
PEEP	0.0 to 99.9
CPAP	0.0 to 99.9
BIPAP (I)	0.0 to 99.9
BIPAP (E)	0.0 to 99.9

## 10 - Interference/Micro Clot Check (Flagging On)

If the GEM Premier 3500 has been configured to flag patient results when interferences or micro clots are detected, it will display a message and progress indicator.

Reporting of patient sample results will be delayed until the check is complete (approximately three minutes from sample introduction). When the check is complete, it will display the Patient Sample Results screen, see "Review Patient Sample Results" in this section.

**Figure 4.19 Interference / Micro Clot Indicators**



**NOTE:** If the instrument has not been set up to flag results, it will display the Patient Sample Results screen as soon as results are available.

The instrument will respond to the check in the following ways:

- If a micro clot is detected on any sensor, the instrument will beep three times, display a message, initiate a clot removal cycle, and:
  - if iQM Mode is "On", automatically check for micro clots again. If the clot could not be removed, then the sensor will be disabled and given "iQM error" status.
  - if iQM Mode is "Off", display a message recommending that an external QC be run to verify cartridge performance.
- If an interference is detected, the instrument will beep three times, display a message, and rinse the sensors. This happens whether iQM is enabled or disabled.

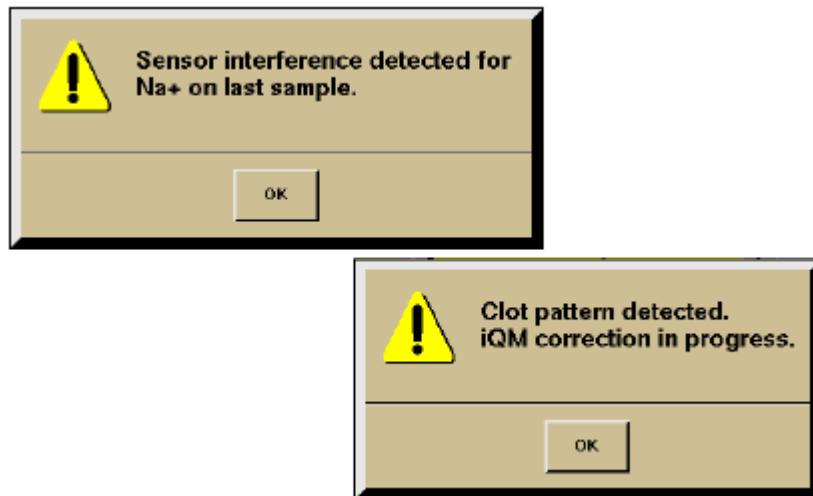
In both cases, the affected analytes will be flagged on the Patient Sample Results screen and on patient sample reports when flagging is enabled. See “Displayed Exceptions (GEM Premier 3500 Analytes)” in this section.

For more information about interference and micro clot checking, see “Flag Patient Results for Interference and Micro Clots” in Chapter 3.



*NOTE: When the pattern for Benzalkonium is identified, Benzalkonium will be identified as the interfering substance present.*

**Figure 4.20: Interference/Micro Clot Messages**

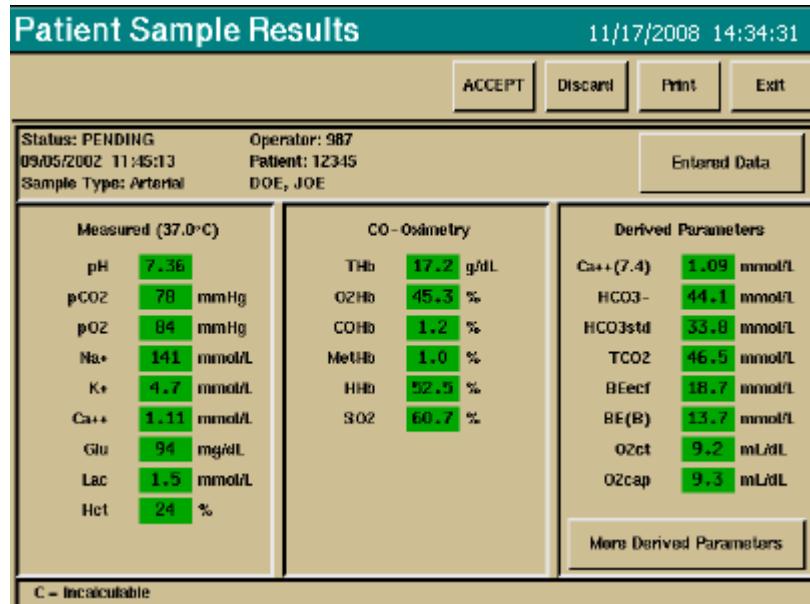


## 11 - Review Patient Sample Results

The Patient Sample Results screen (*figure 4.21*) is displayed after:

- patient results are ready, *and*
- the Patient Information screen has been exited (if that screen was presented), *and*
- interference/micro clot determination, if enabled, has been completed.

**Figure 4.21: Patient Sample Results Screen**



The Patient Sample Results screen will be displayed for 90 seconds. After this time, the instrument will return to the Ready screen as if the **Exit** button had been selected. The disposition of the sample will be set as follows:

- If **Patient Sample Auto-Accept** is On, the sample will be given an ACCEPTED disposition (see “12 – Set Patient Sample Disposition” for a description of sample dispositions). The sample will also be printed and, if configured, sent to the LIS/DMS.
- If **Patient Sample Auto-Accept** is Off, the sample will keep whatever disposition has been assigned by the user. If no disposition has been assigned, it will be left in the PENDING state.

### Interference/Micro Clot Check

If the GEM Premier 3500 has **not** been configured to flag patient results when interference or micro clots are detected, then the instrument will begin the interference/micro clot check after the Patient Sample Results screen is displayed. Affected analytes will not be flagged in the displayed or printed patient results.

If a micro clot is detected, the instrument will beep three times, display a message, initiate a clot removal cycle, and:

- if iQM Mode is “On”, the instrument will automatically check for micro clots again. If a clot is found, then the sensor will be disabled and given “iQM error” status.
- if iQM Mode is “Off”, the instrument will display a message recommending that an external QC be run to verify cartridge performance.

If an interference is detected, the instrument will beep three times, display a message, and rinse the sensors. This happens whether iQM Mode is enabled or disabled. The message will remain displayed until acknowledged by the operator.

For more information about setting the interference/micro clot option, see “Flag Patient Results for Interference and Micro Clots” in Chapter 3.

### Sample Information

The Patient Sample Results screen displays the following sample information near the top of the screen:

- The status (disposition) of the sample. The disposition will initially be PENDING and will change to ACCEPTED or DISCARDED if the sample’s disposition is changed at this screen (see “12 – Set Patient Sample Disposition” later in this section).
- Sample Date and Time
- Sample Type
- Operator ID
- Patient ID
- Patient Name (last name, first name) if available

The **Entered Data** button can be used to review and/or edit the sample information that was entered at the Patient Information screen during sampling. If the sample has an ACCEPTED or DISCARDED disposition, this button will display the information but not allow any edits.



**NOTE:** The Operator ID cannot be edited if Operator Security is turned On (see “Security Setup” in Chapter 3).

### Sample Results

Sample results are presented in four sections: Measured, Temp-Corrected, CO-Oximetry, and Derived Parameters. Only analytes that were enabled for the current test panel (see “2 – Select Test Panel or Analytes (Optional)” in this section. The instrument will use the units configured with “Units of Measure” (see Chapter 3).

The results for each analyte will be displayed with black lettering and a green background if the result is exception-free. Normal ranges and possible exceptions and their display colors and flags are described in this section.



**NOTE:** If correlation factors have been defined (see “Sample Setup” in Chapter 3), the presented results will be adjusted by the entered correlation factors.

The results will include the following information:

---

Title/Block	Content and Order
Measured (37°C)	Results for pH, pCO <sub>2</sub> , pO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup> , Glucose, Lactate, and Hct at 37°C. If the acid/base unit is cH, the parameter name pH will be replaced with cH. The temperature will be in °C or °F as defined in setup.

---

Temp-Corrected  
(XX.X°C)

Results for pH(T),  $pCO_2(T)$ , and  $pO_2(T)$ . This block will be displayed only if a patient's body temperature other than 37°C was entered on the Patient Information screen. If the acid/base unit is cH, the parameter name pH will be replaced with cH. The temperature will be in °C or °F as defined in setup.

---

CO-Oximetry

Results for THb, O<sub>2</sub>Hb, COHb, MethHb, HHb, and SO<sub>2</sub>. Appears only if CO-Ox analytes are part of the current panel.

---

Derived Parameters

Results for the derived parameters that have been enabled in setup. See "Product Use" in Chapter 1 for a listing of possible analytes. If more than eight analytes have been enabled, touch **More Derived Parameters** to display the next group. Repeated selection of this button will loop around to the analytes that were initially displayed. If THb or SO<sub>2</sub> are among the measured analytes, the derived parameters THbc and SO<sub>2</sub>c respectively, will not be recorded.

A temperature-corrected or derived parameter will be considered incalculable if the analyte from which the value is calculated is not reported for any reason (disabled, not in panel, iQM process error, failed QC with **QC Blank-out** On, outside reportable range, or incalculable).

### Reference Ranges

The values on the next page represent a range of normal values for whole blood as analyzed by the GEM Premier 3500. Consider these values only as general guidelines. Patient ranges should be established by individual institutions.

If you are using an IL CO-Oximeter with the GEM Premier 3500, please see the CO-Oximeter operator's manual for reference ranges for that device.

---

Parameter	Arterial	Unit	Arterial	Unit
pH	7.35 to 7.45	pH		
$pCO_2$	35 to 48	mmHg	4.66 to 6.38	pKa
$pO_2$	83 to 108	mmHg	11.04 to 14.36	pKa
Na <sup>+</sup>	136 to 145 <sup>1+2</sup>	mmol/L	136 to 145 <sup>1+2</sup>	mEq/L

---

			L
K <sup>+</sup>	3.4 to 4.5 <sup>1</sup>	mmol/L	3.4 to 4.5 <sup>1</sup> mEq/L
Ca <sup>++</sup>	1.15 to 1.35	mmol/L	4.6 to 5.4 mg/dL
Glu	60 to 95	mg/dL	3.3 to 5.3 mmol/L
Lac	0.5 to 2.2	mmol/L	5 to 20 mg/dL
Hct	35 to 51	%	
HCO <sub>3</sub> <sup>-</sup>	18.0 to 23.0	mmol/L	18.0 to 23.0 mEq/L
TCO <sub>2</sub>	22.0 to 29.0 <sup>1+2</sup>	mmol/L	
BE	-2.0 to +3.0	mmol/L	
SO <sub>2</sub> c	95 to 98	%	
THb	11.7 to 17.4	g/dL	

<sup>1</sup>Plasma (Hep)    <sup>2</sup>Serum**References:**

A) Henry, J.B., Clinical Diagnosis & Management by Laboratory Methods, W.B. Saunders Co., Philadelphia, 18th Edition, 1991.

B) Tietz, N.W., Fundamentals of Clinical Chemistry, W.B. Saunders Co., Philadelphia, 4th Edition, 1996.

C) Bishop, M.L., Duben-Engelkirk, J.L., Fody, E.P., Clinical Chemistry - Principles Procedures Correlations, J.B. Lippincott Co., 2nd Edition, 1992.



**CAUTION:** Patients who have severely abnormal plasma osmolarities or abnormal levels of proteins or lipids may produce hematocrit readings that differ from the values produced by a cell counter. In general, abnormally high plasma osmolarity may cause the GEM Premier 3500 hematocrit to read lower than a cell counter. Abnormally high protein or lipid values may cause higher hematocrit values. In addition, extremely high white blood cell levels, as might be seen with various diseases, may lead to erroneous hematocrit results.

**Arterial lines and sampling devices coated with benzalkonium chloride or benzalkonium heparin may cause falsely elevated sodium and ionized calcium determinations.**

**Critical Values**

Critical values, also known as panic values, are laboratory results that indicate a life-threatening situation for the patient. The following table has been adapted from an extensive national survey conducted by Kost (Kost, GJ: Critical limits for urgent clinician notification at U.S. medical centers. JAMA, 263:704-707, 1990; Kost, GJ: Using critical limits to improve

patient outcome. MLO, 25:22-27, 1993). The listed limits were obtained from 92 U.S. medical centers. In practice, each institution should establish its own set of critical limits and physician notification policy.<sup>2</sup>

Test	Units	Lower Limit	Upper Limit	Comments
<b>Blood Gases</b>				
pH		7.2	7.6	Arterial, capillary
pCO <sub>2</sub>	mmHg	20	70	Arterial, capillary
pO <sub>2</sub>	mmHg	45		Arterial
pO <sub>2</sub>	mmHg	20		Capillary
HCO <sub>3</sub> <sup>-</sup>	mmol/L	10	40	Arterial, capillary
<b>Chemistry</b>				
Na <sup>+</sup>	mmol/L	120	160	Serum
K <sup>+</sup>	mmol/L	2.8	6.2	Serum
Ca <sup>++</sup>	mmol/L	0.78	1.58	Serum
Glu	mg/dL	40	450	Serum
<b>Hematology</b>				
Hct	%	18	60	Adult; first report only

If you are using an IL CO-Oximeter with the GEM Premier 3500, please see the CO-Oximeter operator's manual for critical limits for that device.

#### Displayed Exceptions (GEM Premier 3500 Analytes)

If exceptions appear in the patient sample results, then exception codes will be displayed at the bottom of the screen. When an analyte has an issue for review (an exception), the analyte name will be displayed along with an exception flag. These will be color coded as described in the following table.

Flag	Exception	MTD*	Value	Units	What will be displayed?

<sup>2</sup>Tietz, N.W., Fundamentals of Clinical Chemistry, W.B. Saunders Co., Philadelphia, 4th edition, 1996.

	Analyte disabled	MTD	Line omitted	
	Analyte not in panel	M	Line omitted	
These exceptions will be displayed with the background of the flag in red:				
S	Analyte had slope error in the previous iQM process	M	Blank	Yes
D	Analyte had drift error in the previous iQM process	M	Blank	Yes
C	Result Incalculable	MTD	Blank	Yes
V	CVP is pending for the analyte, or the analyte failed CVP processing	Blank	No	Yes
↑↑ or ↓↓	Exceeds upper or lower range of critical limits but within the reportable range. At least one critical limit, low or high, must have been defined.	MTD	Yes	Yes
These exceptions will be displayed with the background of the flag and analyte value in yellow:				
I**	Interference detected	Yes	Yes	Yes
T**	Micro clot detected	Yes	Yes	
M**	Reference shift error	Yes	Yes	Yes
** These exceptions appear only when the <b>“Flag Patient Results for Interference and Micro Clots” option</b> in “Sample Setup” (Chapter 3) is set to On.				
↑ or ↓	Exceeds upper or lower reference range but not within the critical limits. At least one reference range limit, low or high, must have been defined.	MTD	Yes	Yes

\* Applies to these analytes: M = Measured, T = Temperature  
Corrected, D = Derived

If a slope, drift or calculation error has been reported for Na<sup>+</sup>, the instrument will not report results for Hct until the Na<sup>+</sup> sensor is functioning properly.

If a slope, drift, or calculation error has been reported for pH, the instrument will not report results for pCO<sub>2</sub> until the pH sensor is functioning properly.

### Displayed Exceptions (CO-Oximeter Analytes)

If an IL CO-Oximeter device is being used and exceptions are present, the CO-Ox exceptions for measured and derived parameters will be displayed in a similar way, color coded as described in the following table.

		What will be displayed?	
Flag	Exception	Value	Units
	CO-Ox analyte disabled in GEM Premier 3500	Line omitted	
	CO-Ox analyte not in panel	Line omitted	
These exceptions will be displayed with the background of the flag in red:			
?	Results not received from the attached CO-Ox device	Blank	Yes
?	Result received from CO-Ox device contained an error	Yes	Yes
Q	QC Failure (QC Failure set to "Blank-out results")	Blank	Yes
Q	QC Failure (QC Failure set to "Flag results")	Yes	Yes
These exceptions will be displayed with the background of the flag and analyte value in red:			
↑↑ or ↓↓	Exceeds upper or lower range of critical limits. At least one critical limit, low or high, must have been defined.	Yes	Yes

This exception will be displayed with the background of the flag and analyte value in yellow:

↑	Exceeds upper or lower reference range.	Yes	Yes
or			
↓	At least one reference range limit, low or high, must have been defined.		

\* Applies to these analytes: M = Measured, D = Derived

### Patient History

The **Show History** button can be used to compare a patient's current sample results with the last six accepted samples stored for the same patient and the same sample type. This button will only be available for accepted samples and when the patient was identified with a Patient ID.

Information will be displayed in a table on the Patient History screen. The table will show the nine native GEM Premier 3500 analytes across the top, with rows for each sample. If all seven samples contain only analytes from an IL CO-Oximeter, then only a CO-Ox history table will be shown.

PATIENT HISTORY		
Patient		
ID:	1	
First Name:	JOHN	
Last Name:	SMITH	
Sample Type:	Arterial	
pH (units)		
05/09/1999	09:54	7.25
05/09/1999	09:12	7.22
pCO2 (mmHg)		
05/09/1999	09:54	58
05/09/1999	09:12	57

**Figure 4.22: Patient History Report**

- Analyte QC failures will be noted.
- If an analyte was not measured because it was not part of the test panel or was unavailable due to cartridge type, its entry in the table will be blank.
- If an analyte was operator-entered rather than measured, it will still appear in the history table.
- If any of the samples include CO-Ox analytes, the **CO-Ox** button will be available to see patient history for CO-Ox analytes.
- Touch the **Print** button to print the Patient History Report.

### Patient Sample Report

The instrument will automatically print a Patient Sample Report (*figure 4.23*) when the **Accept** button is selected or if the **Patient Sample Auto-Accept** feature is enabled. The **Print** button

can be used to print the report whenever the Patient Sample Results screen is displayed. The Patient Sample Report can also be printed during sample recall and review (see Chapter 8).

The format of the Patient Sample Report will be slightly different when the report is printed on an external printer because of the wider margins available.



*NOTE: Using transparent tape to affix printed reports for documentation may cause the text in the report to fade. This may cause problems for long-term recordkeeping.*

**Figure 4.23: Patient Sample Report (without CO-Oximetry)**

  <b>Instrumentation Laboratory</b>		
<b>PATIENT SAMPLE REPORT</b>		
Status: PENDING 01/10/2001 08:13:53 Sample Type: Arterial Sample No.: 2 Operator ID: OP 1 Accession No. 0123456789		
<b>Patient</b> ID: 12345 Name: SMITH JOHN Birth Date: 01/10/1960 Age: 42 Sex: M		
<b>Instrument:</b> Model: GEM 3000 S/N: 12001 Name: GEM <b>Instrument:</b> Model: GEM 3000 S/N: 1234 Name: GEM 3000 #1		
<b>Measured (37.0°C)</b> pH                    7.36 #pCO2                75           mmHg #pO2                83           mmHg Na+                 141           mmol/L K+                 4.7           mmol/L Ca++                1.11           mmol/L Glu                 90           mg/dL Lac                 1.4           mg/dL #Hct                24           %		
<b>Temp-Corrected (40.8°C)</b> pH(T)                7.30 #pCO2(T)            90           mmHg #pO2(T)            102           mmHg		
<b>Derived Parameters</b> #Ca++(7.4)            1.09           mmol/L #HCO3-                42.3           mmol/L BEecf                17.2           mmol/L SO2c                96           % #THbc                7.4           g/dL		
<b>Operator Entered</b> Temp                40.8           °C FIO2                8           % SO2                20.0           % O2Hb                5.0           % COHb                30.0           % MetHb                7.0           % APTT-P              10.0           sec PT INR              6.0 ACT                 9           sec ACT-LR              8           sec		
<b>Reference Ranges</b> Low                High pH                7.10           7.44 pCO2              35           40 ... (additional analytes)		
<b>Critical Limits</b> Low                High pH                7.00           7.60 pCO2              25           55 ... (additional analytes)		
!=Outside critical limit #=Outside ref. range		

**Printed Exceptions (GEM Premier 3500 Analytes)**

If exceptions are present in the patient results, the analyte name will be displayed along with an exception flag as indicated in the following chart. See “Displayed Exceptions (GEM Premier 3500 Analytes)” in this section for a description of the impact of these codes.

		What will be printed?	
Flag	Exception	Value	Units
	Analyte disabled	Line omitted	
	Analyte not in panel	Line omitted	
?	Slope Error	Overwritten with “Slope Error”	No
?	Drift Error	Overwritten with “Drift Error”	No
?	Result Incalculable	Dashes (-----)	No
*	CVP is pending for the analyte, or the analyte failed CVP processing	Overwritten with “CVP Failure”	No
*	QC Failure ( <b>QC Failure</b> set to “Flag results”)	Yes	Yes
*	QC Failure ( <b>QC Failure</b> set to “Blank-out results”)	Overwritten with “QC Failure”	No
? <sup>1</sup>	Interference detected	Yes	Yes
? <sup>1</sup>	Micro clot detected	Yes	Yes
? <sup>1</sup>	Reference shift error	Yes	Yes
?	Exceeds High Range of reportable range	> Upper limit	Yes
?	Exceeds Low Range of reportable range	< Lower limit	Yes
#	Exceeds the high or low reference range but not within the critical limits	Yes	Yes
!	Exceeds the high or low critical limit but within the reportable range	Yes	Yes

<sup>1</sup> These exceptions appear only when the **“Flag Patient Results for Interference and Micro Clots” option is On** (see “Sample Setup” Chapter 3).

### Printed Exceptions (CO-Oximeter Analytes)

If an IL CO-Oximeter device is being used and CO-Ox exceptions are present, the CO-Ox exceptions will be displayed in a similar way, as indicated in the following chart. See “Display Exceptions (CO-Oximeter Analytes)” in this section for a description of the impact of these codes.

		What will be printed?	
Flag	Exception	Value	Units
	CO-Ox analyte disabled in GEM Premier 3500	Line omitted	
	CO-Ox analyte not in panel	Line omitted	
?	Results not received from attached CO-Ox device	Dashes (----)	No
?	Results received from CO-Ox device contained an error	Yes	No
*	QC Failure ( <b>QC Failure</b> set to “Blank-out results”)	Overwritten with “QC Failure”	No
*	QC Failure ( <b>QC Failure</b> set to “Flag results”)	Yes	Yes
#	Exceeds upper or lower reference range. At least one reference range limit, low or high, must have been defined.	Yes	Yes
!	Exceeds upper or lower range of critical limits. At least one critical limit, low or high, must have been defined.	Yes	Yes

## 12 - Set Patient Sample Disposition

The disposition of a sample can be set at the Patient Sample Results screen as the final step in patient sample processing.

Sample dispositions provide a data management feature that enables the flagging of samples if and when they have been reviewed and the user-entered information optionally edited.

Setting a sample’s disposition can be automatic or performed manually depending upon how the **Patient Sample Auto-Accept** configuration option has been set (see “Sample Setup” in Chapter 3 for a description of this feature):

- When this option is On, users can review the sample and then exit the Patient Sample Results screen by touching the **Exit** button. The sample will automatically be assigned a disposition of ACCEPTED (see below).
- When this option is Off (the default setting), the user may assign the sample a disposition or leave the sample in a “PENDING” state. The Patient Sample Results screen provides two buttons for setting the disposition:
  - Touching the **Accept** button will assign the sample an ACCEPTED disposition.
  - Touching the **Discard** button will assign the sample a DISCARDED disposition.

Touching the **Exit** button without first selecting one of the disposition buttons will leave the sample as PENDING. The instrument will treat these samples in the following way:

- They can be recalled from the sample database, any user-entered sample information can be edited, and their disposition changed.
- They must be manually printed and transmitted to the LIS/DMS.
- They will always be included with all other samples when the entire sample database is copied (see “Save GEM Premier 3500 PAK Cartridge Data” in Chapter 8).

If a sample has a disposition of PENDING, the **Entered Data** button can be used to review and/or edit the sample information that was entered at the Patient Information screen during sampling. If the sample has an ACCEPTED or DISCARDED disposition, this button will display the information but not allow any edits.

Sample editing may also be done later by recalling the PENDING sample (see “Data Recall” in Chapter 8).



**NOTE:** The Operator ID cannot be edited if **Operator Security** is turned On (see “Security Setup” in Chapter 3).

The following chart shows the relationship between a sample’s disposition and how the instrument will handle the sample:

	Edit?	Auto-Print?	Demand Print?	Auto-Send?	Demand Send?	Copy to Disk?
A	No	Yes	Yes	Yes	Yes	Yes
D	No	No	Yes	No	No	Yes
P	Yes	No	Yes	No	No	Yes

A = Accepted; D = Discarded; P = Pending

#### Buttons for Setting Sample Disposition on Patient Sample Results Screen

##### Exit

When the **Exit** button is selected, the instrument will:

- Save the patient sample to the sample database. If **Patient Sample Auto-Accept** is On (see “Sample Setup” in Chapter 3), the sample will automatically be given an ACCEPTED disposition. If **Patient Sample Auto-Accept** is Off, the sample will be given a PENDING disposition if another disposition has not been assigned (see below).
- Return to the Ready screen.

##### Accept

Only appears when **Patient Sample Auto-Accept** is Off. The **Accept** button can be used after review of the sample has deemed it as satisfactory and after any user-entered sample information has been edited. No further editing of the sample will be allowed, either at the Patient Sample Results screen or if the sample is later recalled from the sample database.

When a patient sample is accepted, the instrument will:

- Refresh the screen to show the ACCEPTED disposition.

- Print the Patient Sample Report, *figure 4.23*. The instrument will automatically print a duplicate report if the **Duplicate Sample Report** configuration option is On (see "Sample Setup" in Chapter 3). The Patient Sample Report will include the same information as Patient Sample Results screen.
- Send the results to the LIS/DMS, if configured (see "Interface Setup" in Chapter 3).

**Discard** Only appears when **Patient Sample Auto-Accept** is Off. The **Discard** button can be used 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**.

When a patient sample is discarded, the instrument will:

- Prompt to confirm the disposition:
  - If **No** is selected, the instrument will remain at the Patient Sample Results screen and leave the sample's disposition unset.
  - If **Yes** is selected, the instrument will refresh to show the DISCARDED disposition.

Discarded samples must be manually printed and transmitted. They will always be included with all other samples when the entire sample database is copied (see "Save GEM Premier 3500 PAK Cartridge Data" in Chapter 8).

## 4.4 Aborted Patient Samples

The instrument will abort patient sample processing under the following circumstances:

- If the **Cancel** button is selected at any point in the sampling process.



*NOTE: Do not cancel a sample when an iQM process has been interrupted to analyze the sample.*

- If a prompt is not responded to within a two-minute period.
- If the instrument encounters a fatal processing error, such as insufficient sample volume.
- If an IL CO-Ox sample is not introduced to the CO-Oximeter or if results are not received from the CO-Oximeter within three minutes, CO-Oximeter samples will be aborted. If the sample also includes GEM Premier 3500 analytes, that part of the sample will not be aborted.
- If CO-Oximeter analytes are a part of a sample that includes GEM Premier 3500 analytes, and the GEM Premier 3500 sampling is aborted, the CO-Ox sampling will also be aborted.

When the GEM Premier 3500 aborts a sample, it will take the following actions:

If sample processing was still at the preparation stage (aspiration was not begun):

- The instrument will not save the sample in the database, and the sample will not be counted toward the total samples available from the cartridge. The instrument will return to the Ready screen.

If sample processing has progressed beyond the point of aspiration, the instrument will:

- Save the sample to the database as ABORTED. All results will be marked unavailable, and the reason the sample was aborted will be noted.
- Count the sample toward the total samples available from the cartridge.

- Not print or transmit the sample.
- Return to the Ready screen.

If CO-Oximeter sample results are not available, the sample results will be flagged with the review symbol (?) and show the analytes with dashes instead of values.

The following chart shows what the instrument will allow operators to do with aborted samples:

Edit?	Auto-Print?	Demand Print?	Auto-Send?	Demand Send?	Copy to Disk?
No	No	No	No	No	Yes

## 4.5 Cartridge Removal

The GEM Premier 3500 will prompt for removal of a GEM Premier 3500 PAK cartridge in the following circumstances:

- The cartridge has reached its time limit of 504 hours (336 hours for 600-test cartridges).
- The cartridge has reached its sample capacity.
- Blood sample or iQM Process “C” solution has rested on the sensors for more than 20 minutes while the instrument was without power.
- Following instrument restart if the instrument has been without power for more than one hour.
- If the cartridge encounters a fatal error.

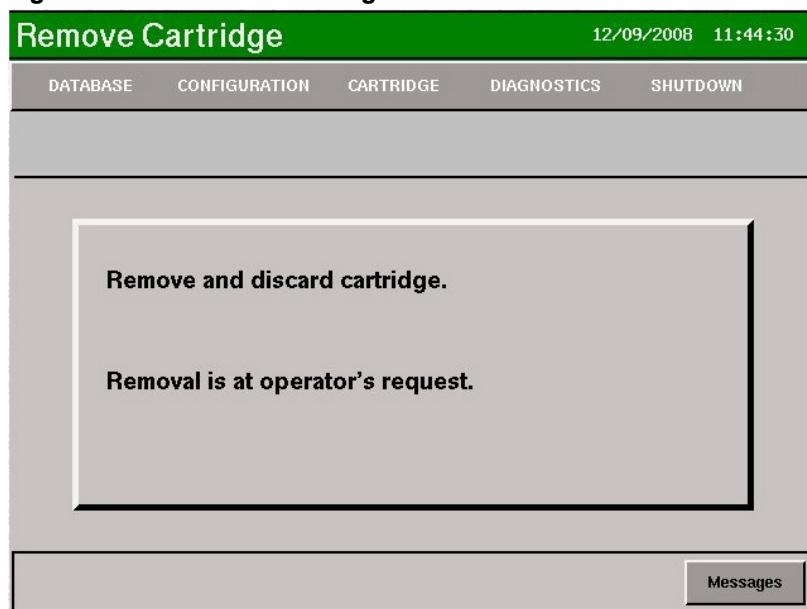
The cartridge can also be removed manually at any time by selecting **Remove Cartridge** on the **Cartridge** menu. If **Operator Security** is turned On (see “Security Setup” in Chapter 3), an authorized operator password will need to be entered before proceeding. The instrument will prompt for confirmation that the cartridge should be removed.



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

When cartridge removal is required, the GEM Premier 3500 will unlock the cartridge door and display the Remove Cartridge screen (*figure 4.24*). This screen will contain a message explaining why the cartridge must be removed.

**Figure 4.24: Remove Cartridge Screen**



The instrument will continue to display the Remove Cartridge screen until the cartridge is removed. During this time, most of the menu commands will be available for performing other instrument tasks. The **Messages** button will be available for viewing of alarm and text messages. (Alarm messages are described in Chapter 9; text messages in Chapter 11).

The GEM Premier 3500 will retain all data for the current cartridge and at least the previous 20 cartridges. See "Save GEM Premier 3500 PAK Cartridge Data" in Chapter 8 for information about how the instrument manages cartridge data and how data can be archived.

#### To Remove a Cartridge:

1. **If the instrument is not displaying the Remove Cartridge screen, select Remove Cartridge from the Cartridge menu, and touch Yes to confirm the request to remove the cartridge.**  
Status: The instrument will display the Remove Cartridge screen.
2. **Slide the lock handle on the cartridge door toward the front of the instrument, and open the door.**
3. **Grasp the cartridge in the compartment, then pull it straight out of the instrument.**
4. **Dispose of the cartridge in an appropriate biohazard container.**

Status: When you have removed the cartridge, the instrument will display the Insert Cartridge screen. See "Insert GEM Premier 3500 PAK Cartridge" in Chapter 2 for instruction for inserting a new cartridge.

# 5 Intelligent Quality Management (iQM)

## 5.1 Intelligent Quality Management

Intelligent Quality Management (iQM) is an automated Quality Assurance system for IL's GEM Premier 3500 that replaces the use of traditional external Quality Control (QC). iQM is designed to help improve the quality of the test results and thus the quality of patient care. iQM continuously monitors operation of the entire testing process, including sensors, fluidics, and electronics, and automatically performs and documents corrective actions upon detecting an error.



iQM is designed to provide immediate error detection and correction, replacing the use of conventional external quality controls. The quality control process becomes an integral part of system operation. iQM is a combination of Process Control (PC) Solutions, Calibration Validation Product (CVP), Failure Pattern Recognition (FPR) software and a variety of system hardware checks. During the use-life of the GEM PAK iQM cartridge, iQM:

- validates the integrity of the cartridge,
- continuously monitors the performance of the system,
- checks for changes that affect analytical performance,
- identifies the source of the change, and
- initiates remedial action, and documents it.



NOTE: To ensure that a total quality management system is adhered to, you should follow local, state and federal regulatory guidelines. As with any analytical device or computer software, there is always the potential for software failure. However, Instrumentation Laboratory conducts rigorous testing and extensive software validation prior to releasing a software revision. If you encounter a rare software error code, it should be reported to your local IL Technical Support Department.

## 5.2 System Description

The following is an overview of iQM and its components:

- Process Control Solutions A, B and C are on-board solutions traceable to National Institute of Standards and Technology (NIST) primary standards, for the analytes available on the GEM Premier 3500. The solutions are tonometered to specific values of pO<sub>2</sub> and pCO<sub>2</sub> and sealed in gas-impermeable foil laminate bags with zero headspace. Each process control solution serves a specific function in the iQM process.
- CVP: Calibration Validation Product for GEM Premier 3500 are ampouled solutions, traceable to NIST primary standards, for the analytes available on the GEM Premier 3500. Two concentration levels are available for all analytes: two levels for pH, pCO<sub>2</sub>, pO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Glucose, Lactate, and two levels for Hematocrit. Analysis of CVP is required following insertion of a new cartridge into the GEM Premier 3500 before analysis of patient samples is permitted. Recovery of CVP must be within specific limits to validate that each sensor is successfully calibrated and that no deterioration of the Process Control Solutions occurred since the initial value assignment at the factory. The iQM process is accomplished through a combination of CVP and the on-board Process Control Solutions.
- FPR Software: The Failure Pattern Recognition software in the GEM Premier 3500 includes the ability to analyze signals from the sensors generated by Process Control Solutions A, B, and C and recognize patterns generated by various sensor and reagent malfunctions. Corrective actions include alerting the user of the problem, attempts by the instrument to recover from the problem, disabling a specific sensor if recovery is not possible, or rejection of the cartridge if needed.
- System Hardware Checks: The GEM Premier 3500 routinely carries out functional checks of vital system hardware components, re-enabling a disabled parameter if the micro clot is washed away, including mechanical subassemblies, electronics and cartridge fluidics.

Intelligent Quality Management process in the GEM Premier 3500 starts at IL where each sensor before it is assembled into the GEM Premier 3500 PAK, is functionally tested for several hours using solutions that are NIST traceable. Sensors that do not meet the specifications are discarded. In addition and before the Process Control Solutions are assembled into the PAK, every lot of PC Solutions is tested and values assigned using NIST traceable standards. Upon insertion of the GEM Premier 3500 PAK into the analyzer, the GEM system reads and records the factory-assigned PC solution values already encoded through the barcode label on each PAK. External CVP solutions must be manually run to validate the integrity of the PC Solutions. After successful installation and validation through CVP, the PAK becomes available for patient sample analysis and iQM assumes control of the analytical system.

iQM automatically checks for possible operator mishandling of the patient sample through iQM checks for sample volume, inadequate anticoagulant, clots, and the presence of interfering compounds in the patient sample. Upon detecting a problem, the analyzer automatically performs corrective actions that include:

- Performing a special rinse cycle if micro-clots are detected, and verifying cartridge function afterwards
- Disabling a failed sensor if its functionality cannot be recovered
- Rejecting a cartridge for process stability failure
- Alerting the user upon detecting the presence of an interfering substance in a sample

During cartridge operation, the instrument automatically and continuously performs various checks that can be categorized in four groups:

- System checks
- Sensor checks
- Failure Pattern Recognition (FPR) checks
- Process stability check

## System Checks

System checks include basic functionality of the instrument and the cartridge. Examples of these checks are:

- Cartridge fluidic checks, such as sample integrity, presence of Process Control solutions, and peristaltic pump functionality
- Cartridge mechanical checks, such as proper operation of the distribution valve and sampler arm
- Instrument heater-block checks
- Instrument electronic checks

Any failure in the system checks will lead to a corrective action. The corrective action will include verification of the failure followed by one of the following steps:

- Rejecting the cartridge if the system failure is cartridge related
- Halting instrument operation if the system failure is instrument related

## Sensor Checks

Sensor checks address sensor functionality. The A, B, and C Process Control solutions are automatically brought into the sensor card at various intervals to verify sensor operation. The solution that is residing in the sensor card is measured, and the drift is determined. The drift is the delta between the measured and expected value.

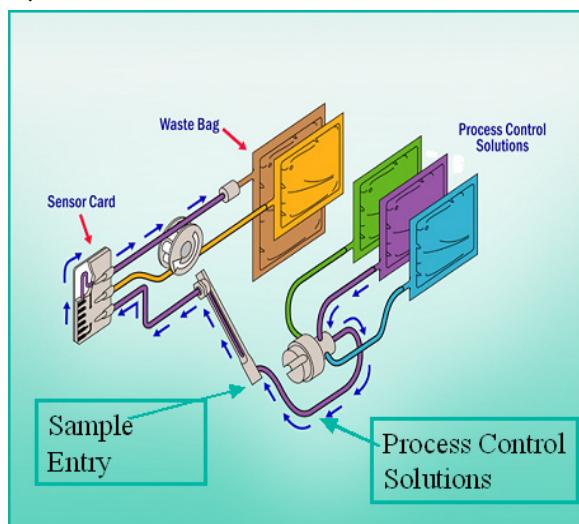
The Process Control solutions are tested with the following frequency:

- Process Control Solution B, or iQM Process B, normally in contact with the sensors between patient samples is monitored every 30 seconds.
- Process Control Solution B is tested at least every 30 minutes or after every patient sample.
- Process Control Solution A, or full iQM Process, is measured at least every 4 hours.
- Process Control Solution C, or iQM Process C, is measured at least every 24 hours.

When iQM Process Control solutions are measured, the measurements are transparent to the user. The measurement can be interrupted at any time to run a sample (except the full iQM measurement within the first four hours of cartridge life, which cannot be interrupted). iQM Process C cannot be interrupted, but the exact time of day it is performed can be specified.

The process of verifying the sensor operation by measuring Process Control solutions is very similar to the process of sample measurement. As indicated in figure 5.1, the Process Control solution path into the sensor card is identical to the path of samples.

**Figure 5.1: iQM PAK schematics with PC Solutions & Patient Sample Flow**



If all measured values in sensor checks are within allowable limits, sensor performance is validated and, as a result, the drifts will be set to zero. If any measurement or slope value is outside the allowable limits, the following corrective actions will take place:

- The parameter result in the subsequent sample report will be suppressed.
- iQM check using FPR as specified in the next session is perform to determine the cause of slope or drift error.
- If the failure persists in two consecutive iQM Process C measurements, in three consecutive full iQM Process measurements, or in 15 consecutive iQM Process B measurements, then the failed parameter will be permanently disabled for the remaining life of the cartridge.

## Failure Pattern Recognition Checks

Failure Pattern Recognition checks were developed through years of investigating field complaints. Two distinct failure patterns were identified: micro-clot related failures and certain sensor malfunctions that are not well detected by other internal checks. Furthermore, certain interference patterns were also identified.

### Micro-Clot Patterns

Micro-clots are small pieces of blood clots or fibrin strands that adhere to a sensor and induce a change in sensor characteristics, such as sluggish response or sensitivity change. Micro-clot patterns are distinct for various sensors. Sensor-check failures are used to identify the presence of micro-clots.

iQM automatically initiates a special rinse cycle using the Process Control C solution upon detecting a micro-clot pattern. When the rinse cycle is complete, iQM checks for a clot pattern on the affected sensor. If a clot pattern still remains, the affected sensor is disabled. If a clot pattern is not detected, the sensor status becomes green (ready for measurement). For the sensor that is disabled because of un-cleared clots, iQM will continue checking the sensor status in the background and will re-enable the sensor once the clot is dislodged during normal operation.

### Sensor Malfunction Patterns

Only pH and  $pCO_2$  and oxygen sensors need additional pattern checks for identifying certain malfunctions. Existing sensor checks are adequate for detecting any malfunctions in other sensors. Normal sensor malfunctions for pH and  $pCO_2$  sensors are identified with existing sensor checks. The specific malfunctions that iQM checks for in these sensors are very rare and slow in progression. Therefore, the Process Control C check that is performed once a day is adequate for detecting these malfunctions.

If a sensor malfunction pattern is detected, the affected sensor is permanently disabled for the remaining life of the cartridge.

### Interference Patterns

Interferences can cause false readings for some of the ion selective electrodes. iQM checks for two interference patterns:

- Positively charged lipophilic compounds – for example, Benzalkonium. This compound can cause falsely elevated readings for sodium and ionized calcium.
- Negatively charged lipophilic compounds – for example, thiopental sodium.

If an interference pattern is detected in a sample, the user is notified. Furthermore, Benzalkonium is specified as the interfering substance if its associated pattern is identified.

### Process Stability Check

The process stability check is a method of verifying Process Control solution stability throughout cartridge use-life. The measured oxygen in the A solution during use-life is compared to the first A solution measurement taken during warm-up. The delta has to be within allowable limits.

The  $pO_2$  in Process Control solution A is used for the process stability check for the following reasons:

- Oxygen is considered the most sensitive parameter for detecting deterioration in Process Control solutions because there is no oxygen buffering in the Process Control solutions.
- The process of measuring oxygen in Process Control solution A utilizes all three Process Control solutions. Therefore, deterioration in any of the Process Control solutions will affect the measured oxygen in Process Control solution A.

If a process stability failure is detected, the cartridge will be rejected.

## 5.3 iQM Configuration Summary

iQM is configured on the GEM Premier 3500 through the **Configuration** menu just as with all other instrument configuration settings. For ease of reference, iQM-related configuration settings are summarized in the following paragraphs; complete iQM configuration information is provided “*iQM Setup*” in Chapter 3.



**NOTE:** For security purposes, only the Key Operator is allowed to modify the configuration of the GEM Premier 3500. See “Access to Configuration Areas” in Chapter 3.

### Sample Setup

The **Sample Setup** command in the **Configuration** menu is used to configure certain aspects related to analyzing samples. The single **Sample Setup** option described below pertains to iQM:

#### Flag Patient Results for Interference and Micro Clots

The GEM Premier 3500 automatically checks for micro clots and interferences when analyzing patient samples. This happens regardless whether iQM is enabled or disabled.

When this option is On (iQM Mode is On), reporting of patient results will be delayed while the check is performed. This allows the instrument to flag analytes if interference or micro clots are detected. When the option is Off (iQM Mode is Off), patient results will not be delayed, and analytes will not be flagged. However, the operator will be presented with a message if an interference or clot was detected in the previous sample. The message will be displayed until dismissed by the operator.

For more information about interference and micro clot detection, see “Failure Pattern Recognition Checks” in this section, “Flag Patient Results for Interference and Micro Clots” in “Sample Setup” (Chapter 3), and “10 - Interference/Micro Clot Check (Flagging On)” in “Patient Sampling Process” (Chapter 3).

### iQM Setup

The **iQM Setup** command on the **Configuration** menu displays the iQM Setup screen, which provides the following options:

- **iQM Mode** turns the iQM feature On and Off. The default is On. If **iQM Mode** is left Off when a cartridge is inserted (please note all GEM Premier 3500 PAKs are iQM PAKs), the instrument will treat the cartridge as a traditional cartridge (non-iQM cartridge) by disabling the special iQM processing that is associated with an iQM cartridge.
- **CVP Material Setup** allows Calibration Validation Product (CVP) material to be defined so that it will be recognized and accepted by the GEM Premier 3500 when CVP samples are analyzed (see “CVP Sampling” below).
- **iQM Process Reports** provides options that determine when and how much iQM Process data will be printed.
- **iQM Process C Time** allows to set the time of day the daily iQM Process C should be run.



**NOTE:** CVP material must be defined prior to analyzing CVP samples.

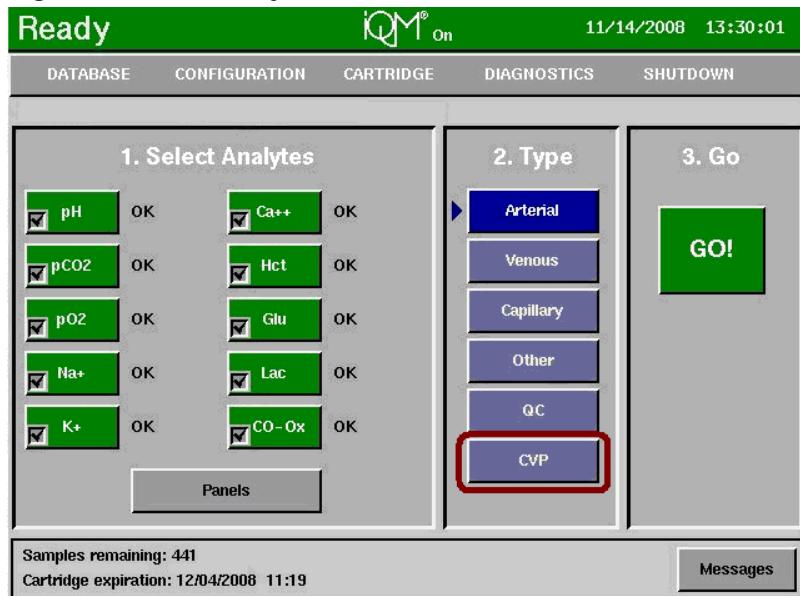
For more information on **iQM Setup**, see “iQM Setup” in Chapter 3.

## 5.4 CVP Sampling

Prior to CVP sampling, CVP material must be defined as described in “CVP Material Setup” under “iQM Setup” in Chapter 3. When iQM Mode is enabled, the instrument will:

- Prompt with the message: *You must run all levels of CVP material to activate the iQM features of this cartridge.* Select the **OK** button to proceed.
- Display the Ready screen, with the status of all analytes set to yellow and labeled “Pending CVP.”
- Display the **CVP** sample type button on the Ready screen (figure 5.2). This button will remain on the Ready screen as long as the iQM Mode is On and a PAK is inserted.

**Figure 5.2: The Ready Screen – CVP Button**



### Analyzing CVP Samples

CVP samples can be analyzed at any time by selecting the “CVP” button as the sample type and pressing the “GO!” button on the Ready screen. The GEM Premier 3500 provides easy-to-follow prompts as a guide through each step of analyzing a CVP sample:

1. If requested, enter an authorized operator password – see “1 – Enter Authorized Operator Password” in this section.
2. Select the CVP material to be used – see “2 - Select CVP Material” in this section.
3. Mix the CVP ampoule, and break off the QC vial top in the ampoule breaker – see “3 – Mix CVP Sample” in this section.
4. Aspirate the CVP sample, then remove the sample when the instrument indicates – see “4 – Aspirate CVP Sample” in this section.
5. Enter information about the CVP sample – see “5 – Enter CVP Sample Information” in this section.
6. Review CVP sample results – see “5 – Review CVP Sample Results” in this section.
7. Set the disposition of the CVP sample – see “7 – Set CVP Sample Disposition” in this section.

These steps are explained in detail in the following sections, which are keyed to the steps 1 – 7 above.

## Cancellations from iQM Processes

If an interruptible iQM Process is in progress, the instrument will interrupt the iQM Process and start the CVP sample. If a full iQM Process is in progress, the instrument will display a message and abort the CVP sampling process.



**NOTE:** Do not interrupt iQM Processes in progress unless it is absolutely necessary to analyze an urgent sample. If an iQM Process is interrupted, always allow the sample analysis to complete.

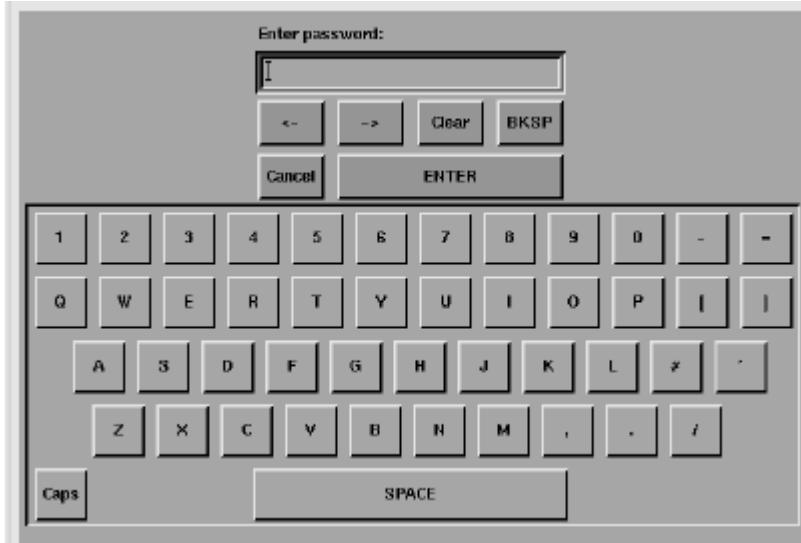
For more information about iQM Process, see “iQM Process” in Chapter 6.

## 1 – Enter Authorized Operator Password

The GEM Premier 3500 will display the Operator Password screen (*figure 5.3*) if it has been configured to require operator IDs.

The password can be entered by typing or by scanning with the barcode gun. To proceed with sampling, a password must be entered that matches a password configured by the Key Operator to have GEM access privileges.

**Figure 5.3: Authorized Operator Password Screen**



For security reasons, the instrument will display “\*” characters to mask the entry of the password. The instrument will automatically place the operator ID associated with the password into the proper field on the CVP Information screen (see “5 – Enter CVP Sample Information” in this section).

For more information about operator IDs and passwords, see **Operator Security** under “Interface Setup” in Chapter 3.

### To Enter an Authorized Operator Password:

1. Run the barcode gun over the barcode.

**OR**

- Touch the desired characters on the keypad.

Status: The GEM Premier 3500 will display “\*” characters in place of the password. If the instrument cannot read the barcode, the password must be entered on the keypad. Report the problem to the Key Operator or Technical Support.

**2. Touch Enter.**

Status: If the password is not recognized, the instrument will display the message: *Invalid password*. Touch OK. Contact the Key Operator. When the password is recognized, the instrument will display the Select CVP Material screen (*figure 5.4*).

## 2 – Select CVP Material

Before CVP samples can be analyzed, the attributes of the CVP material must be stored in the instrument by the Key Operator (see “CVP Material Setup” under “iQM Setup” in Chapter 3).

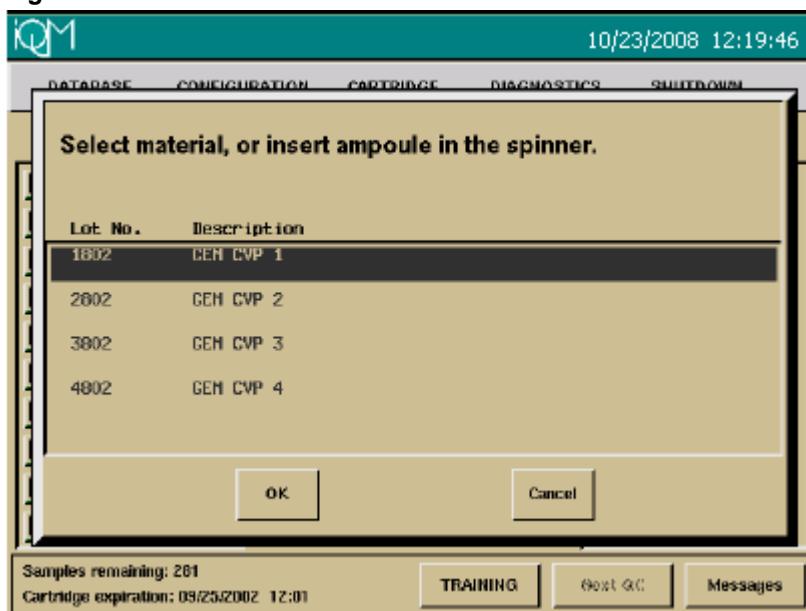


**NOTE:** Because the instrument tracks and reports CVP by the lot number of CVP material, ensure that enough CVP material is on hand toward the end of a lot to clear any existing failure conditions. Only CVP material from the same lot can clear an error condition for that lot.

CVP material to be analyzed is identified at the Select CVP Material screen (*figure 5.4*). This screen shows the lot number and description of all predefined CVP material.

The CVP material is specified by scanning it with the instrument's ampoule spinner or by selecting it from the list on the Select CVP Material screen.

**Figure 5.4: Select CVP Material Screen**



### To Scan the Barcode of GEM Premier 3500 CVP Material:

**1. Choose a GEM CVP ampoule supplied by IL.**

**2. Insert and release the ampoule into the ampoule spinner.**

Status: The instrument will compare the scanned lot number to the lot numbers of defined CVP material:



- If the lot number is not found, the instrument will prompt for use of a different ampoule or selection of material from the list of defined material.
- If the lot number matches the lot number of a defined material, the instrument will prompt for sample aspiration (if the selected CVP material contains only analytes that have failed iQM processes, the instrument will abort the sampling process.)

**3 – Mix CVP Sample**

 **CAUTION: Use only IL-supplied CVP material. Only IL CVP material will satisfy iQM cartridge validation.**

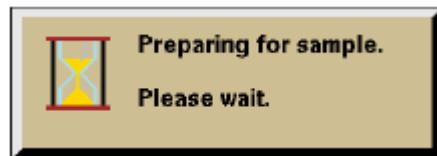
1. **Mix the solution by vigorously shaking the ampoule. Tap the solution from the tip of the ampoule.**
2. **Use the ampoule breaker to snap off the ampoule neck.**

Status: The ampoule breaker provides an easy way to break off the ampoule neck and includes a storage area into which the broken necks fall. To empty the container, pull the drawer out of the instrument.



**NOTE:** CVP solution changes quickly once opened. Proceed with analysis **within 1 minute** of opening the ampoule.

**Figure 5.5: First CVP Aspiration Prompt**



**4 – Aspirate CVP Sample**

1. **With the instrument displaying the message: *Present sample for CVP Lot NNNN*, position the ampoule on the sampler (“NNNN” will be the actual lot number).**



**NOTE:** Make sure the sampler is near but not touching the bottom of the ampoule before touching **OK**.

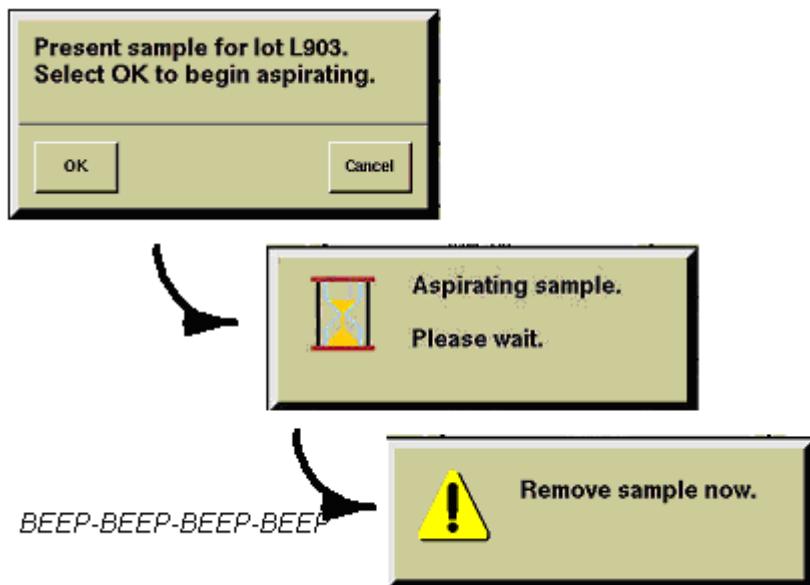


**CAUTION:** In the following step, remove the ampoule quickly when prompted so as not to bend the sampler as it is withdrawn into the instrument.

**2. Touch OK to begin aspirating the sample.**

The GEM Premier 3500 will display the message *Aspirating sample. Please wait.* When the instrument has aspirated the sample, it will beep four times and display the message *Remove sample now. The instrument will wait two seconds for removal of the sample before withdrawing the sampler into the instrument.*

**Figure 5.6 CVP Aspiration Prompts**



**2. Remove the ampoule from the sampler, and dispose of it in a biohazard waste container.**

Status: The GEM Premier 3500 will take up to 85 seconds to process the CVP sample. During this time, the instrument will display a progress indicator and will display the CVP Sample Information screen to prompt for entry of sample data.

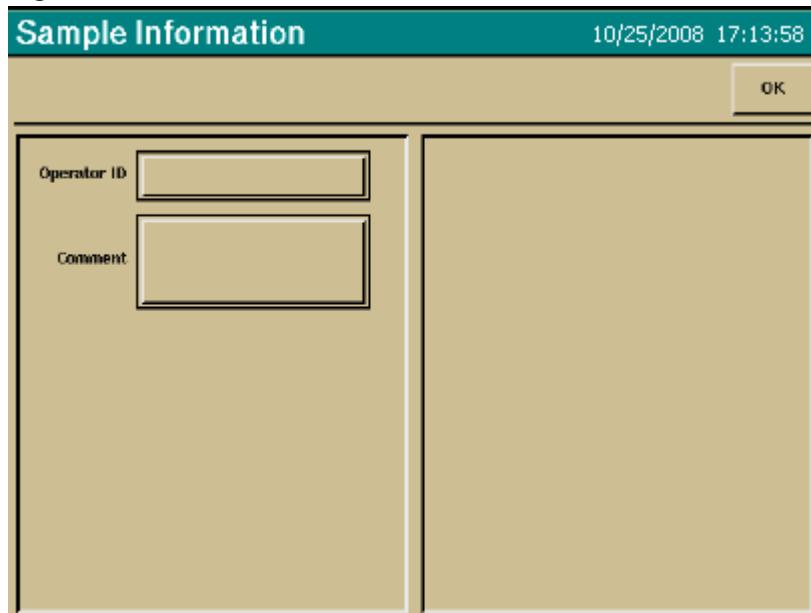
## 5 – Enter CVP Sample Information

The Sample Information screen (*figure 5.7*) will be displayed if at least one individual demographic item (operator ID or comment) is enabled (see “Sample Setup” in Chapter 3).

If no demographics items have been enabled, the Sample CVP Information screen will not be displayed, and the instrument will instead display the CVP Sample Results screen when sample results are available.

Information entered on the CVP Sample Information screen will be saved, displayed, printed, and transmitted with QC sample results.

*Figure 5.7: CVP Information Screen*



### Operator ID

If the Operator ID is blank, then entering an ID is optional. Operator IDs can contain up to 16 alphanumeric characters, including spaces, and can be entered by typing or by scanning a barcode.

If the ID is not blank, it is either the ID from the last sample analyzed (ID can be changed) or the ID associated with the password entered earlier in the sampling process (ID cannot be changed).

For more information about operator ID settings, see “Security Setup” (Chapter 3).

### Sample Comment

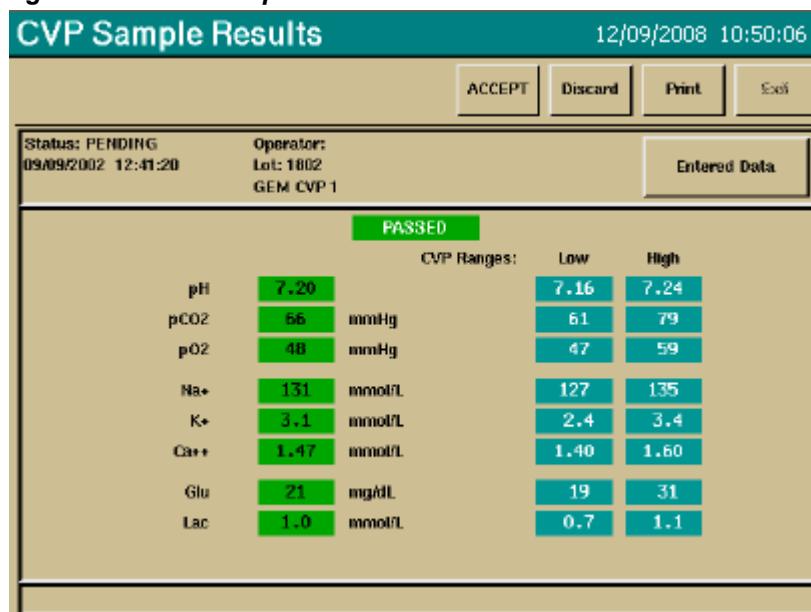
Sample Comment entry is optional. The Comment can be used to record a short description with a sample. Like all demographic information, the Comment will be printed, saved, and transmitted with the sample.

The Comment can be up to 48 alphanumeric characters, including spaces. The text will appear on two lines of 24 characters each.

## 6 – Review CVP Sample Results

Once any required sample information has been entered and the instrument has completed processing the sample, the GEM Premier 3500 will display the CVP Sample Results screen (figure 5.8). The CVP Sample Results screen will remain displayed until either the **Accept** or **Discard** button is selected.

**Figure 5.8: CVP Sample Results Screen**



### CVP Sample Information

The CVP Sample Results screen contains the following sample information near the top of the screen:

- The status (disposition) of the sample. The disposition will initially be PENDING and will change to ACCEPTED or DISCARDED when the sample's disposition is set by touching the **Accept** or **Discard** button.
- Sample Date and Time
- Operator ID
- Lot number, description

The **Entered Data** button is used to review and/or edit the Operator ID and Comment associated with the sample. If the sample has an ACCEPTED or DISCARDED disposition, this button can be used to display the information but not make any changes.



**NOTE:** The Operator ID cannot be edited if **Operator Security** is turned On

### CVP Sample Results

If all analytes passed CVP, the instrument will print the word PASSED with white lettering on a green background. Otherwise, the word FAILED will be printed on a red background.

The analytes will be listed in the same order as they appear on the Ready screen. For comparison, the minimum and maximum values for each analyte will be displayed next to the results. The instrument will use the units configured with "Units of Measure" (see "Sample Setup" in Chapter 3).

### Displayed Exceptions (CVP Material)

When an analyte has an issue for review (an exception), the analyte name will be displayed along with an exception flag. Exception codes will be displayed at the bottom of the CVP Results screen. The flag and value (if displayed) will appear in white. The background of the flag and value will appear in red, even if no value is displayed.

The following table shows the exceptions that may be encountered, in order of precedence.

		What will be displayed?	
Flag	Exception	Value	Units
	Analyte disabled	Line omitted	
S	Analyte had a slope error	Blank	Yes
D	Analyte had a drift error	Blank	Yes
C	Result Incalculable	Blank	Yes
>	Exceeds upper limit of reportable range	> Upper Limit	Yes
<	Exceeds lower limit of reportable range	< Lower Limit	Yes
V	Analyte outside the range established for the CVP lot	Yes	Yes

An analyte will be flagged as having failed CVP for a particular lot when any of the exceptions in the table are encountered for the analyte as long as the sample has been accepted. The CVP failure will be associated with both the analyte and the particular CVP lot that was analyzed.

This CVP failure will be cleared for the analyte and the CVP lot when CVP results have passed and been accepted for a CVP sample run on the **same** CVP lot.

The CVP failure will not be cleared for the analyte unless the failure is cleared on all the lots on which it was originally set. This means that even if an analyte passes CVP with a particular CVP lot, if the analyte has failed CVP with another CVP lot, the failure will not be cleared.

### CVP Sample Report

The instrument will automatically print a CVP Sample Report (*figure 5.9*) when the **Accept** button is selected. The report title will be followed by the words “PASS” or “FAIL” to indicate the overall results of the CVP.

The report can be printed on an external printer whenever the CVP Sample Results screen is displayed by touching the **Print** button. It can also be printed with the options on the **Database** menu to recall and review CVP samples or all samples (see “Recall and Review Samples” in Chapter 8).

**Figure 5.9: CVP Sample Report**

*NOTE: Using transparent tape to affix printed reports for documentation may cause the text in the report to fade. This may cause problems for long-term recordkeeping.*

CVP SAMPLE REPORT		
PASSED		
Status:	ACCEPTED	
12/10/2008 08:13:53		
Sample No.:	2	
Operator:	OPERATOR 12	
CVP Material:	GEM CVP 1	
Lot No.:	0123456789	
Instrument:		
Model:	GEM 3500	
S/N:	12001	
Name:	GEM	
CVP Ranges		
pH	Low	High
pCO <sub>2</sub>	31	77
pO <sub>2</sub>	80	115
Na <sup>+</sup>	135	145
K <sup>+</sup>	3.7	4.8
Ca <sup>++</sup>	1.04	1.22
Glu	79	103
Lac	0.8	1.6
pH	7.36	
pCO <sub>2</sub>	75	mmHg
pO <sub>2</sub>	83	mmHg
Na <sup>+</sup>	141	mmol/L
K <sup>+</sup>	4.7	mmol/L
Ca <sup>++</sup>	1.10	mmol/L
Glu	90	mg/dL
Lac	1.4	mmol/L

**Printed Exceptions (CVP Material)**

If exceptions are present in the CVP results, the analyte name will be displayed along with an exception flag as indicated in the following table.

What will be Printed?			
Flag	Exception	Value	Units
	Analyte disabled	Line omitted	
?	Analyte had a slope error	Overwritten with "Slope Error"	Yes
?	Analyte had a drift error	Overwritten with "Drift Error"	Yes
?	Result Incalculable	Dashes (----)	Yes
?	Exceeds upper limit of reportable range	> Upper Limit	Yes
?	Exceeds lower limit of reportable range	< Lower Limit	Yes
*	Analyte outside the range established for the CVP lot	Yes	Yes

## 7 – Set CVP Sample Disposition

The final step in CVP sample processing is to set the disposition of the sample at the CVP Sample Results screen. Sample dispositions provide a data management feature that enables the flagging of samples if and when they have been reviewed and the user-entered information optionally edited. Dispositions also provide a way to flag whether samples have been used clinically.

The GEM Premier 3500 provides two dispositions: ACCEPTED or DISCARDED. These dispositions correspond to the **Accept** and **Discard** buttons on the CVP Sample Results screen. Any editing of sample information must be completed before accepting or discarding a sample because further editing will not be allowed after the sample's disposition has been set.

The following chart shows the relationship between a CVP sample's disposition and how the instrument will handle the sample:

	Edit?	Auto-Print?	Demand Print?	Auto-Send?	Demand Send?	Copy to Disk?	Add to Statistics?
A	No	Yes	Yes	Yes	Yes	Yes	Yes
D	No	No	Yes	No	No	Yes	No

A = Accepted; D = Discarded

 **NOTE:** CVP samples marked as DISCARDED will not be automatically printed or transmitted. Once a sample is discarded, it cannot be accepted again, and its information cannot be edited.

If one or more analytes failed CVP and the **Accept** or **Discard** button is pressed, the instrument will prompt with the message: *CVP failure. Perform full iQM process before repeating the failed CVP sample.* Touch **OK**, then initiate a full iQM process from the **Diagnostics** menu prior to repeating the CVP sample.

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

**Accept** Touch the **Accept** button after the sample has been reviewed and deemed satisfactory and after sample information has optionally been edited. No further editing of the sample will be allowed, either at the CVP Sample Results screen or if the sample is later recalled from the sample database.

When a CVP sample is accepted, the instrument will:

- Set the sample's disposition to ACCEPTED and save it to the sample database.
- Print the CVP Sample Report. The instrument will automatically print a duplicate report if the Duplicate Sample Report configuration is turned on. The CVP Sample Report will include the same information as CVP Sample Results screen.

- Satisfy the CVP requirement for that CVP level.
  - Return to the Ready screen.
- Discard** 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.  
When a CVP sample is discarded, the instrument will prompt to confirm the disposition. If **No** is selected, the instrument will remain at the CVP Sample Results screen, and the sample's disposition will be left unset. If **Yes** is selected, the instrument will:
  - Set the sample's disposition to DISCARDED and save it to the sample database.
  - Return to the Ready screen.Discarded samples must be manually printed. They will always be included with all other samples when the entire sample database is copied.
- Exit** The **Exit** button will not be available until the CVP sample has been accepted or discarded. When the **Exit** button is selected, the instrument will:
  - Save the CVP sample to the sample database.
  - Return to the Ready screen.

## 5.5 Responding to CVP Sampling Failure

If a measured value falls outside the expected CVP range for an analyte, the screen displays CVP FAIL and highlights any analyte that failed CVP. To correct the failure:

1. Run a full iQM process before trying to repeat the failed CVP run.
2. Repeat the CVP with freshly opened CVP material from the same CVP lot.
3. If the failure is corrected, ACCEPT the CVP results.
4. 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.
5. If the failure is corrected, ACCEPT the CVP results.
6. If the failure is not corrected, remove the cartridge and notify Technical Support (see "Cartridge Removal" in Chapter 4).



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.

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.

## 5.6 Aborted CVP Samples

The instrument will abort CVP sample processing under the following circumstances:

- If the **Cancel** button is selected at any point in the sampling process.



**NOTE:** Do not cancel a sample when an iQM proces has been interrupted to analyze the sample.

- If a prompt is not responded to within a two-minute period.
- If the instrument encounters a fatal processing error, such as insufficient sample volume.

When the GEM Premier 3500 aborts a CVP sample, it will take the following actions:

- If sample processing was still at the preparation stage (aspiration had begun), the instrument will not save the sample in the database, and the sample will not be counted toward the total samples available from the cartridge. The instrument will return to the Ready screen.
- If sample processing had progressed beyond the point of aspiration, the instrument will:
  - Save the sample to the database as ABORTED. All results will be marked unavailable, and the reason the sample was aborted will be noted.
  - Count the sample toward the total samples available from the cartridge.
  - Not print or transmit the sample.
  - Return to the Ready screen.

The following chart shows what the instrument will allow operators to do with aborted samples:

---

Edit?	Auto-Print?	Demand Print?	Auto-Send?	Demand Send?	Copy to Disk?	Add to Statistics?
No	No	No	No	No	Yes	No

## 5.7 iQM Reports

The **iQM Reports** command on the **Database** menu displays the iQM Reports screen (*figure 5.10*). This screen provides three types of iQM reports:

- iQM Delta Chart
- Corrective Action Report
- CVP Report

In addition to local viewing, iQM reports can all be viewed and printed via GEMweb (see Section 12).



**NOTE:** Because of their size, iQM Reports can only be printed on an external printer. See “Printer Setup” under “Interface Setup” (Chapter 3) for information about configuring an external printer.

**Figure 5.10 iQM Reports Screen**

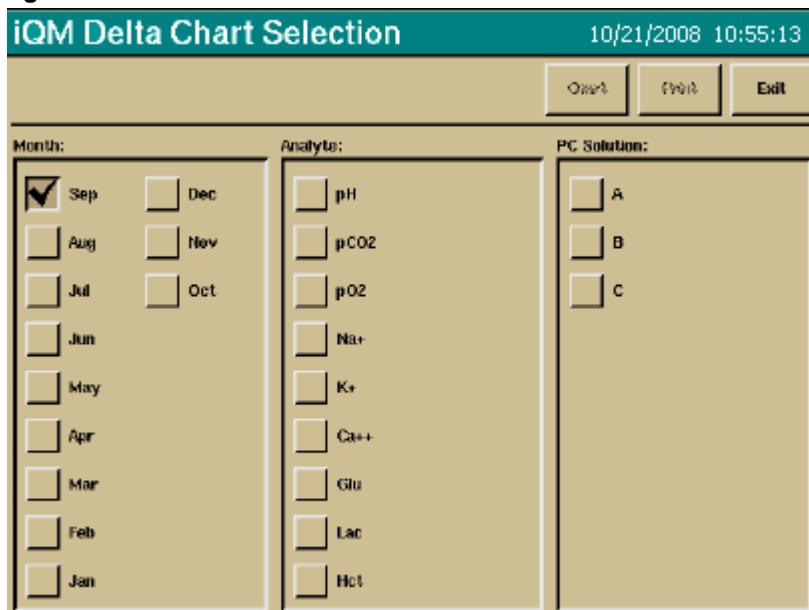


## iQM Delta Chart

Touch **iQM Delta Chart** to display the iQM Delta Chart Selection screen (*figure 5.11*). This screen contains the three parameters that can be specified to generate an iQM Delta Chart:

- The month of the year to chart. Checkboxes are provided for the current month and the preceding 11 months. The month label is in a 3-letter format (Jan, Feb, etc.). The current month is the default.
- The analyte to chart. The analyte options are pH, pCO<sub>2</sub>, pO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Glu, Lac, and Hct.
- The PC solution (A, B, or C) to chart. If “C” is selected, the analyte options will be limited to pH, pCO<sub>2</sub> or pO<sub>2</sub>.

**Figure 5.11: iQM Delta Chart Selection Screen**



The iQM Delta Chart Selection screen provides three buttons:

- |              |   |
|--------------|---|
| <b>Chart</b> | Displays the chart for the selected combination of month, analyte, and PC solution. The <b>Chart</b> button will be ghosted if no combination is selected.  |
| <b>Print</b> | Prints all the charts according to the selected checkboxes. For example, if the only selected box is for the month of June, all June charts will be printed for all analytes and all PC solutions. The instrument will confirm the number of charts that will be printed. |
| <b>Exit</b>  | Dismisses the iQM Delta Chart Selection screen.   |

### iQM Delta Chart Components

The data points plotted for each day will be:

- The minimum delta between the Process Control solution target value and the actual measured value for the selected analyte each day.
- The maximum delta between the Process Control solution target value and the actual measured value for the selected analyte each day.
- The mean delta between the Process Control solution target value and the actual measured values for the selected analyte each day.

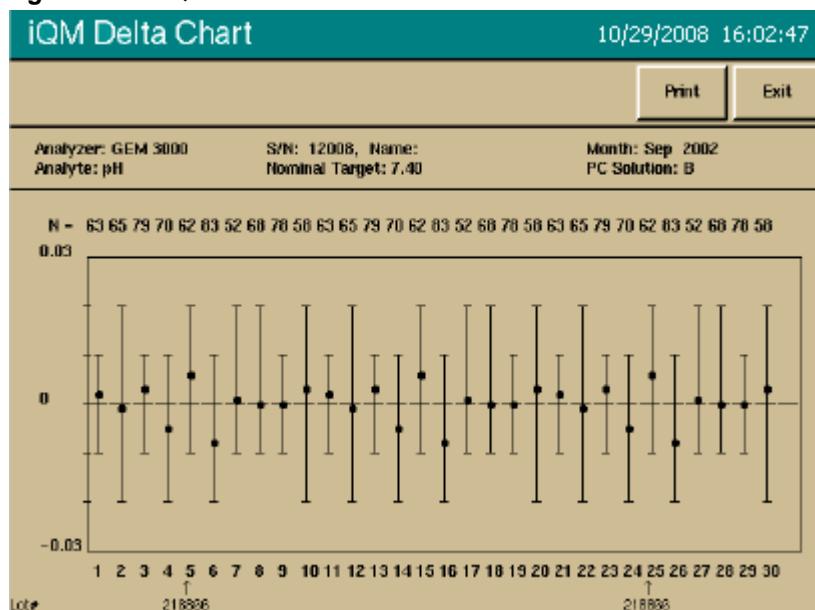


Note: iQM delta points for up to the previous 12 months are stored by the instrument so that they can be charted at any time. These points are collected and stored only while an iQM cartridge is inserted.

The three points will be plotted as shown in *figure 5.12*:

- a short horizontal line denotes the minimum and maximum points
- a round, bolded dot represents the mean delta
- a vertical line connects all three points.

**Figure 5.12: iQM Delta Chart Screen**



NOTE: For iQM Processes C, only one point is typically plotted since iQM Process C is usually performed only once a day.

Delta points during the first 5 hours of cartridge life, and all delta points outside the delta limits, will be excluded from the chart. Delta points that fall outside the delta limits will be included in the "iQM Corrective Action Report" (see next section).

The numbers of points included in the plot are shown on top of the chart as shown in *figure 5.12*. If the number of points exceeds 99, 99 will be shown.

The X-axis of the chart shows the days of the months (1-28, 29, 30, or 31). The Y-axis of the chart shows the delta limits of the analyte being charted, centered on zero. The height of the chart is the same for all cases.

The iQM Delta Chart also includes the date of cartridge insertion (indicated by an arrow), cartridge lot number, and other analyzer identification information. The following buttons are provided:

- Touching **Exit** on the iQM Delta Chart returns to the iQM Delta Chart Selection screen, where a different chart can be displayed or the **Exit** button selected.
- Touch **Print** on the iQM Delta Chart to print the selected chart.



**NOTE:** iQM Delta Charts can also be printed from the iQM Delta Chart Selection screen. See in this section.

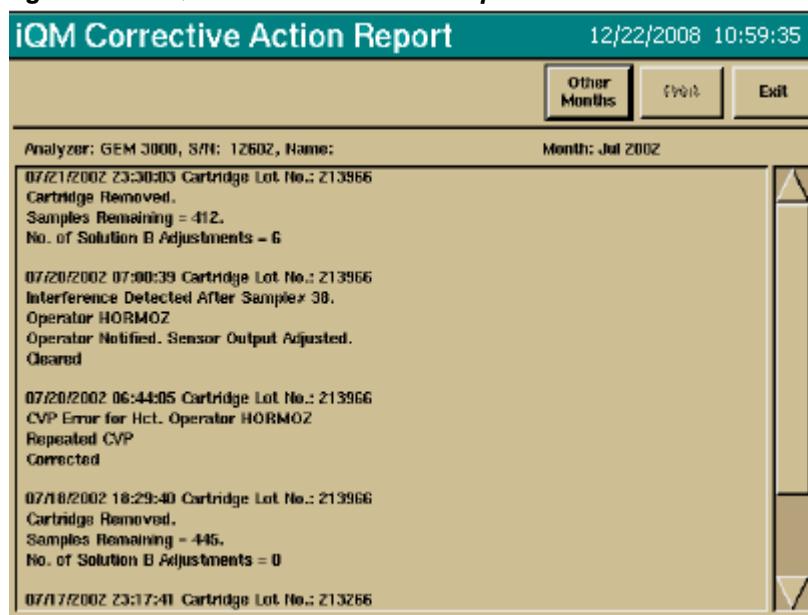
iQM Delta Chart(s) can only be printed on an external printer. The chart will be printed graphically. To enable printing, an external printer must be selected in configuration, and the printer graphics capability (Postscript or PCL) must also be selected. The printed information will be the same as shown on the displayed chart.

## iQM Corrective Action Report

Touch **iQM Corrective Action Report** on the iQM Reports screen to display the iQM Corrective Action Report (iQM CAR). The iQM CAR (*figure 5.13*) displays a reverse-chronological listing of iQM events:

- Date/Time event was logged
- Process Control solution affected
- Operator ID, if entered, if the function included operator interaction
- Detected failure description
- Corrective action description
- Corrective action result
- A Cartridge Removal entry that lists the total number of Process Control solution B adjustments during the cartridge use-life. The adjustments represent total number of minor drift errors that are corrected by reanalyzing Process Control solution B. Events such as interfering substance detection, micro-clot detection, and “fatal” errors will be listed and described as individual events on the iQM CAR.

**Figure 5.13: iQM Corrective Action Report**



The iQM CAR records events in reverse chronological order, with the most recent event shown on top. The detected failure description, corrective action description, and corrective action result are pre-determined text messages that depend on the event type.

### Printing the iQM Corrective Action Report

Touch **Print** on the iQM CAR screen to print the iQM CAR.

iQM Corrective Action Reports can only be printed on an external printer. The chart will be printed graphically or in text format, depending on the external printer mode selected in configuration. The printed information will be the same as shown on the displayed report.

## Calibration Validation Product (CVP) Report

Touch **Calibration Validation Product Report** on the iQM Reports screen to display the CVP Report Selection screen (*figure 5.14*). This screen is used to select the month for the CVP report and then print the report.

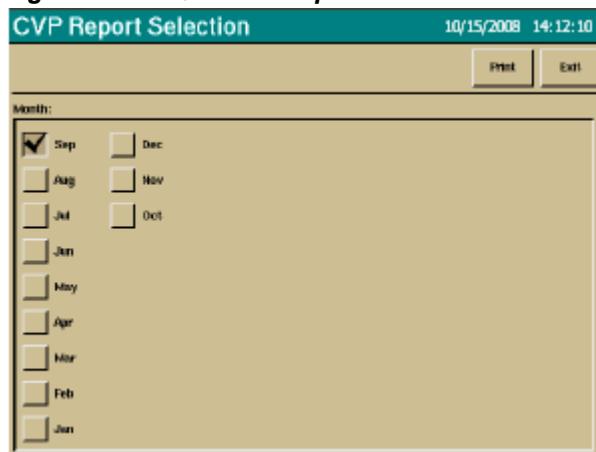
The following information will be presented on the CVP Report:

- IL pre-defined acceptable range for each CVP solution
- The CVP results
- PASS/FAIL status
- CVP Lot Number
- Operator ID, if entered
- Date and Time the CVP sample was processed

Touch **Print** on the CVP Report Selection screen to print the CVP Report on an external printer.

CVP values can be transmitted to an external data management system or LIS as “Quality Control points.”

**Figure 5.14: iQM CVP Report Selection Screen**



## 5.8 iQM Data Transmission

iQM Reports (Delta Charts, Corrective Action Reports and CVP Reports) can be transmitted via the RS-232 (COM) or Ethernet ports, along with patient data, to your host computer. This feature can be enabled through the Interface Setup area on the GEM Premier 3500 by selecting the LIS/DMS (iQM/CVP) check box for the appropriate port (COM A, COM B, COM C or Ethernet). When enabled, the reports will automatically be sent from the GEM Premier 3500 each day. Transmission can also be initiated by an Operator at any time.

The Interface Setup Screen (figure 5.15) provides the options shown.



**NOTE:** Enabling this feature will affect the transmission coming from the GEM Premier 3500. Please consult with your IT department prior to enabling this feature to ensure that your host computer system is compatible with the data.

**Figure 5.15: Interface Setup Screen**

Interface Setup							11/28/2008 09:45:02		
							Cancel	OK	
	LIS/DMS (Patient)	LIS/DMS (QC)	LIS/DMS (Cal)	LIS/DMS (iQM/CVP)	GEM PCL	IL682	GEM OPL		
COM Port A	<input type="checkbox"/>								
COM Port B	<input type="checkbox"/>								
COM Port C	<input type="checkbox"/>								
Network	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>					
Network Setup.....			<input type="checkbox"/>	Printer Setup.....			<input type="checkbox"/>	High Level Protocol Setup.....	<input type="checkbox"/>

# 6 Quality Control and iQM Process

## 6.1 Quality Control and iQM Process

This section provides information about QC recommendations, QC sampling, Parallel QC material, QC scheduling, and QC statistics.

The GEM Premier 3500 provides flexibility in managing quality control. For detailed information about QC configuration, see “QC Setup” in Chapter 3.



*NOTE: The GEM Premier 3500 provides automated quality control through its Intelligent Quality Management (iQM). By default, iQM is activated in the GEM Premier 3500 (see iQM mode in Chapter 3 – iQM Setup). iQM is far superior to any other quality control method available for the GEM Premier 3500. The process of running additional external quality control materials, beyond those recommended in the iQM process (see Section 5), does not offer any additional information or enhance the level of quality.*

## 6.2 QC Recommendations

Individual institutions must decide how often quality control material is analyzed and what levels are analyzed. Check federal and state regulations for information about quality control requirements.

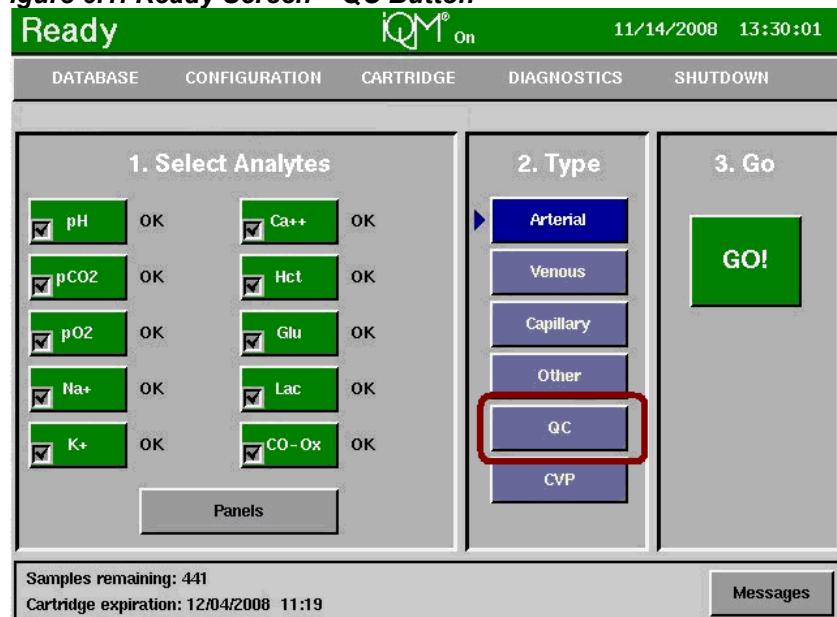
### Manufacturer's Recommendations

1. If iQM is disabled (iQM Mode set to "Off", see "iQM Setup" in Chapter 3), after GEM Premier 3500 PAK cartridges have completed warm-up, run all levels of IL QC solutions prior to analyzing any patient samples.
2. When reinitializing a deselected analyte, perform two levels of IL QC solutions to verify proper functioning of the deselected analyte.

## 6.3 QC Sampling

QC samples can be analyzed at any time by touching the **QC** button on the Ready screen (figure 6.1).

**Figure 6.1: Ready Screen – QC Button**



The instrument provides easy-to-follow prompts that lead through each step in analyzing a QC sample:

1. If requested, enter an authorized operator password – see “1 – Enter Authorized Operator Password” in this section.
2. Select the QC material to be used – see “2 – Identify QC Material” in this section.
2. Mix the QC ampoule, and break off the QC vial top in the ampoule breaker – see “Mix QC Sample” in this section.
2. Aspirate the QC sample, then remove the sample when the instrument indicates – see “Aspirate QC Sample” in this section.



*NOTE: Steps 3 and 4 do not apply to GEM OPL Optical QC testing.*

2. Enter information about the QC sample – see “Enter QC Information” in this section.
2. Interpret the sample results – see “6 – Review QC Sample Results” in this section.
2. Set the disposition of the QC sample – see “7 – Set QC Sample Disposition” in this section.

These steps are explained in detail in the following sections, which are keyed to the steps 1 – 7 above.

## Cancellations from iQM Processes

If an iQM process that cannot be interrupted is in progress, the instrument will display a message and abort the QC sampling process. The following iQM processes cannot be interrupted:

- Any full iQM process
- The first iQM process “B” after power failure recovery
- The first iQM process “B” after sample analysis



*NOTE: Do not interrupt iQM processes in progress unless it is absolutely necessary to analyze an urgent sample. If an iQM process is interrupted, always allow the sample analysis to complete.*

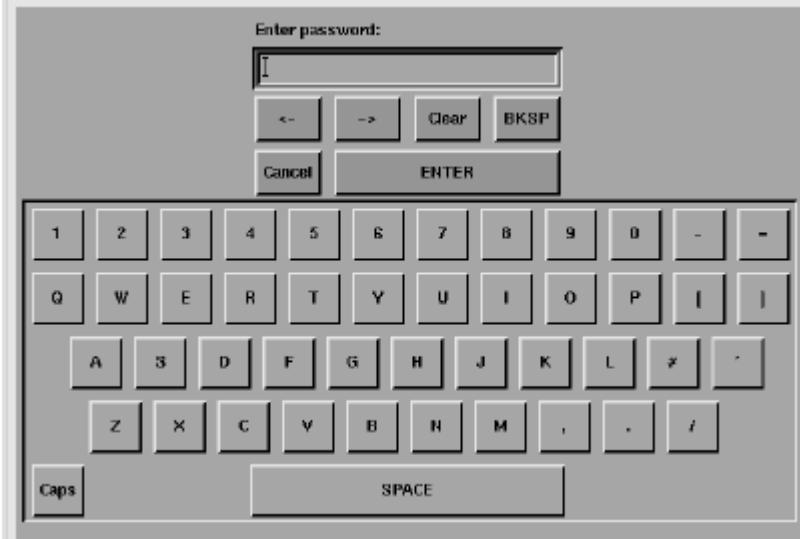
For more information about iQM process controls, see “iQM Process” in Section 6.8.

### 1 - Enter Authorized Operator Password

The GEM Premier 3500 will display the Operator Password screen (*figure 6.2*) if it has been configured to require operator IDs.

The password can be entered by typing or by scanning with the barcode gun. To proceed with sampling, a password must be entered that matches a password configured by the Key Operator to have GEM access privileges.

*Figure 6.2: Authorized Operator Password Screen*



For security reasons, the instrument will display “\*\*” characters to mask the entry of the password. The instrument will automatically place the operator ID associated with the password into the proper field on the Sample Information screen (see “5 – Enter QC Information” in this section).

For more information about operator IDs and passwords, see **Operator Security** (under “Security Setup” in Chapter 3).

### To Enter an Authorized Operator Password:

- Run the barcode gun over the barcode.

OR

Touch the desired characters on the keypad.

Status: The GEM Premier 3500 will display “\*” characters in place of the password. If the instrument cannot read the barcode, the password must be entered on the keypad. Report the problem to the Key Operator or Technical Support.

- Touch Enter.

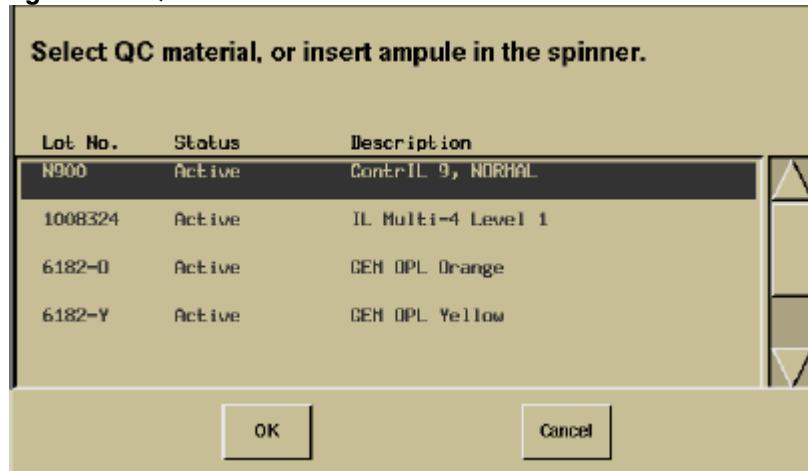
Status: If the password is not recognized, the instrument will display the message: *Invalid password. Touch OK*. Contact the Key Operator. When the password is recognized, the instrument will display the Select Material screen (*figure 6.3*).

### 2 - Identify QC Material

Before a QC sample can be analyzed, the QC material to be used must be identified in the instrument by name and lot number. The GEM Premier 3500 will not allow QC samples to be run until QC material has been defined by the Key Operator. See “QC Material Setup” in Chapter 3 for more information about defining QC material.

Because the instrument tracks and reports QC by the lot number of QC material, it is important to ensure that enough QC material is on hand toward the end of a lot to clear any existing failure conditions. Only QC material from the same lot can clear an error condition for that lot.

**Figure 6.3: QC Material Screen**



The QC Material screen, *figure 6.3*, is used to identify the QC material to be analyzed. This screen shows both QC material that has been defined for the GEM Premier 3500 as well as QC material that has been defined for an IL CO-Ox device. The lot number, description, and lot status (parallel or active) will be displayed. Lot numbers that are part of a scheduled QC that is due with the next eight hours will have an “\*” character next to them.



**NOTE:** See “Active and Parallel QC Material” in Section 6.6 for additional information about the purpose of QC lot status and QC scheduling.

The lot number of the QC material being used can be specified by selecting the QC material from the list and selecting **OK**. GEM Premier 3500 QC material may also be selected by scanning the lot number with the instrument’s ampoule spinner.

### To Scan the Barcode of GEM Premier 3500 QC Material:

1. Choose a GEM QC supplied by IL.
2. Insert and release the ampoule into the ampoule spinner.

The instrument will compare the scanned lot number to the lot numbers of defined QC material:

- If the lot number is not found, the instrument will prompt for use of a different ampoule or selection of material from the list of defined material.
- If the lot number matches the lot number of a defined material, the instrument will prompt for sample aspiration as long as none of the following conditions exist:



- The selected QC material only contains analytes that are disabled (see “Analyte Enable/Disable” in Chapter 3).
- The selected QC material only contains analytes that have failed iQM process controls (see “iQM Process” in Section 6.9).
- No pass/fail ranges were entered for any of the analytes in the QC material (see “QC Material Setup” in Chapter 3).

### 3 – Mix QC Sample



**CAUTION: Use only aqueous-based quality control solutions supplied by Instrumentation Laboratory. Other controls (fluorocarbon-based materials) may damage the sensors and invalidate the cartridge warranty.**

1. Mix the solution by vigorously shaking the ampoule. Tap the solution from the tip of the ampoule.
2. Use the ampoule breaker to snap off the ampoule neck.

Status: The ampoule breaker provides an easy way to break off the ampoule neck and includes a storage area into which the broken necks fall. To empty the container, pull the drawer out of the instrument.



**NOTE: QC solution changes quickly once opened. Proceed with analysis **within 1 minute** of opening the ampoule.**

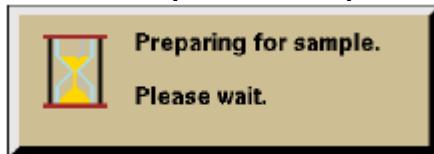
#### 4 – Aspirate QC Sample



**NOTE:** See "CO-Ox QC Samples" in the following pages for information about introducing CO-Ox QC material.

- With the instrument displaying the message: **Present sample for QC Lot NNNN**, position the ampoule on the sampler ("NNNN" will be the actual lot number).

**Figure 6.4: First QC Aspiration Prompt**



**NOTE:** Make sure the sampler is near but not touching the bottom of the ampoule before touching **OK**.

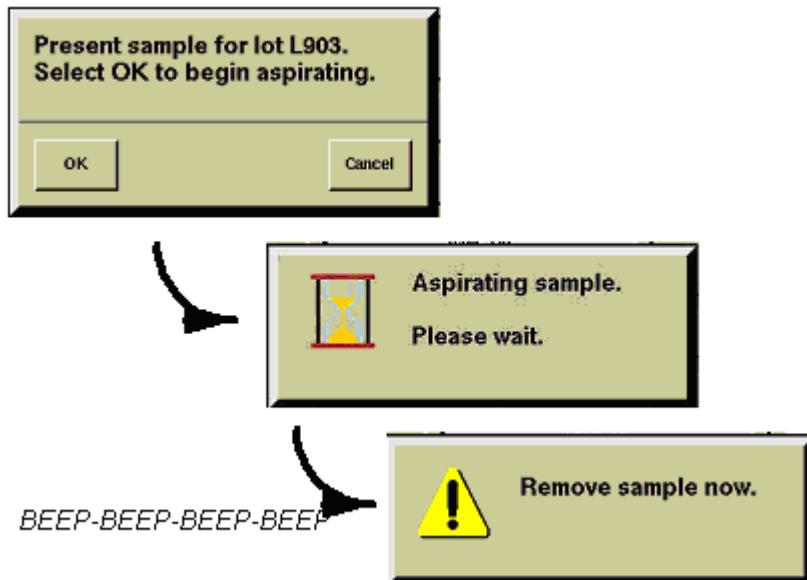


**CAUTION:** In the following step, remove the ampoule quickly when prompted so as not to bend the sampler as it is withdrawn into the instrument.

- Touch **OK** to begin aspirating the sample.

The GEM Premier 3500 will display the message **Aspirating sample. Please wait.** When the instrument has aspirated the sample, it will beep four times and display the message **Remove sample now. The instrument will wait two seconds for removal of the sample before withdrawing the sampler into the instrument.**

**Figure 6.5: QC Aspiration Prompts**



- Remove the ampoule from the sampler, and dispose of it in a biohazard waste container.

**Status:** The GEM Premier 3500 will take up to 85 seconds to process the QC sample. During this time, the instrument will display a progress indicator and will display the Sample Information screen to prompt for entry of sample data.

### CO-Ox QC Samples

Use these steps if the selected QC material is for an IL CO-Ox device.

QCs should be analyzed on the CO-Oximeter as patient samples. This prevents having to enter on the CO-Ox device the QC material information already entered on the GEM Premier 3500.

1. When the display reads **Present sample for CO-Ox QC Lot NNNN** ("NNNN" will be the actual lot number), touch OK, and introduce the CO-Ox sample to the attached CO-Ox device.

Status: The CO-Ox sample may be cancelled by touching the **Cancel** button. The instrument will automatically cancel CO-Ox sampling if the sample is not introduced within three minutes.

The instrument will then display the Sample Information screen to prompt for entry of sample data (see below), followed by the message *Waiting for CO-Ox QC results* and a progress indicator if QC results are still not available. If CO-Ox results are not received within three minutes, the sample will be automatically discarded.

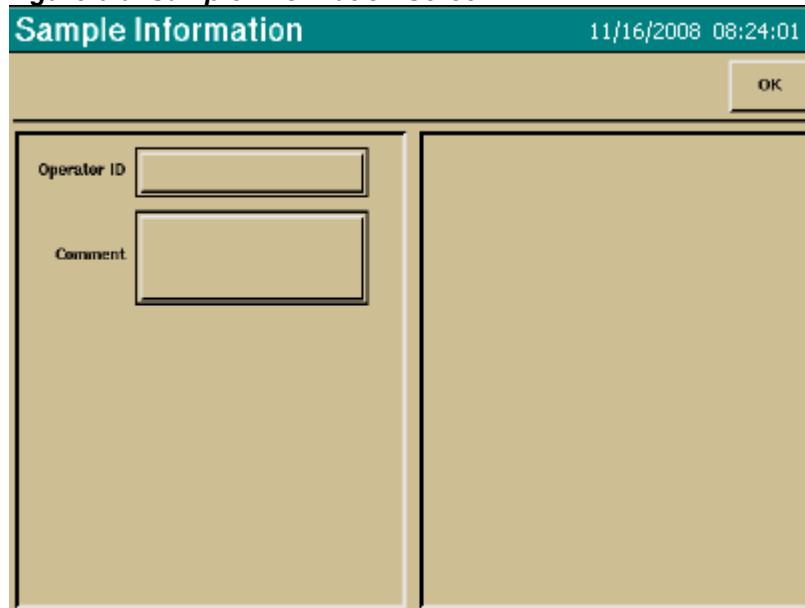
### 5 – Enter QC Information

The Sample Information screen (*figure 6.6*) will be displayed if at least one individual demographic item (operator ID or comment) is enabled (see "Sample Setup" in Chapter 3).

If no demographics items have been enabled, the Sample Information screen will not be displayed, and the instrument will instead display the QC Sample Results screen when sample results are available.

Information entered on the Sample Information screen will be saved, displayed, printed, and transmitted with QC sample results.

**Figure 6.6: Sample Information Screen**



### Operator ID

If the Operator ID is blank, then entering an ID is optional. Operator IDs can contain up to 16 alphanumeric characters, including spaces, and can be entered by typing or by scanning a barcode.

If the ID is not blank, it is either the ID from the last sample analyzed (ID can be changed) or the ID associated with the password entered earlier in the sampling process (ID cannot be changed).

For more information about operator ID settings, see "Security Setup" in Chapter 3.

### Sample Comment

Sample Comment entry is optional. The Comment can be used to record a short description with a sample. Like all demographic information, the Comment will be printed, saved, and transmitted with the sample.

The Comment can be up to 48 alphanumeric characters, including spaces. The text will appear on two lines of 24 characters each.

## 6 – Review QC Sample Results

Once any required sample information has been entered and the instrument has completed processing the sample, the GEM Premier 3500 will display the QC Sample Results screen (*figure 6.7*). The screen shown in *figure 6.7* is for GEM Premier 3500 QC material; see "CO-Oximeter QC Results" in the following pages for information about what is displayed for CO-Ox QCs.

**Figure 6.7: QC Sample Results Screen**

The screenshot shows the 'QC Sample Results' screen. At the top, there are four buttons: 'ACCEPT', 'Discard', 'Print', and 'Exit'. The date and time '12/02/2008 08:27:12' are displayed. Below this, the status is shown as 'PENDING' with the date '09/06/2002 08:28:41'. The operator is listed as '432' with the lot number 'JK-451, Parallel' and 'QC LEVEL 6'. There is a button labeled 'Entered Data'. The main area displays QC results for various parameters:

		PASSED	
		QC Ranges:	
		Low	High
pH	7.36	7.34	7.38
pCO <sub>2</sub>	78 mmHg	72	88
pO <sub>2</sub>	94 mmHg	80	96
Na <sup>+</sup>	141 mmol/L	137	144
K <sup>+</sup>	4.7 mmol/L	4.4	5.0
Ca <sup>++</sup>	1.11 mmol/L	1.00	1.20
Glu	94 mg/dL	88	101
Lac	1.5 mmol/L	1.3	1.7

The QC Sample Results screen will remain displayed until either the **Accept** or **Discard** button is pressed.

### QC Sample Information

The QC Sample Results screen contains the following sample information near the top of the screen:

- The status (disposition) of the sample. The disposition will initially be PENDING and will change to ACCEPTED or DISCARDED when the sample's disposition is changed (see "7 – Set QC Sample Disposition" in this section).
- Sample Date and Time
- Operator ID
- Lot number, description, and status (Active or Parallel) for the QC material

The **Entered Data** button can be used to review and/or edit the Operator ID and Comment associated with the sample. If the sample has an ACCEPTED or DISCARDED disposition, this button can be used to display the information but will not allow any edits.



***NOTE:** The Operator ID cannot be edited if Operator Security is turned On (see "Security Setup" in Chapter 3).*

### QC Sample Results (GEM Premier 3500 QC Material)

If all analytes passed QC, the instrument will print the word PASSED with white lettering and a green background. Otherwise, the word FAILED will be printed with a red background. See "Displayed Exceptions (GEM Premier 3500 QC Material)" in the following sections for information about how the pass/fail criteria is determined. See "Response to a QC Sampling Failure" in Section 6.4 for information about responding to a QC failure.

The analytes will be listed in the same order as they appear on the Ready screen. If a single analyte is not reported, the remaining analytes will move up to fill the unused line. The minimum and maximum values for each analyte will be displayed next to the results for comparison.

If an analyte did not have QC ranges defined for the QC lot, the analyte will not be included in the results.



***NOTE:** If correlation factors have been defined and enabled for QCs (see "Sample Setup" in Chapter 3), the QC results will be adjusted by the entered correlation factors.*

The instrument will use the units configured with "Units of Measure" (see "Sample Setup" in Chapter 3).

### CO-Oximeter QC Results

The results for CO-Ox QC will be displayed in a similar way. If all analytes passed QC, the instrument will print the word PASSED with white lettering and a green background. Otherwise, the word FAILED will be printed with a red background. See "Displayed Exceptions (CO-Oximeter QC)" in the following sections for information about how the pass/fail criteria is determined. See "Response to a QC Sampling Failure" in Section 6.4 for information about responding to a QC failure.

The title of the results screen will be "CO-Ox QC Sample Results." The QC material will be identified with the CO-Ox QC lot number and description.

- These analytes will be reported for the IL 682: THb, O<sub>2</sub>Hb, COHb, MetHb, and HHb.
- These analytes will be reported for the GEM OPL: THb, O<sub>2</sub>Hb, COHb, and MetHb.
- The QC results for SO<sub>2</sub>, O<sub>2</sub>ct, and O<sub>2</sub>cap from the CO-Ox device are not used.

### Displayed Exceptions (GEM Premier 3500 QC Material)

If exceptions appear in the QC results, then exception codes will be displayed at the bottom of the QC Results screen. When an analyte has an issue for review (an exception), the analyte name will be displayed along with an exception flag. The flag and value (if displayed) will appear in white. The background of the flag and value will appear in red, even if no value is displayed.

The following table shows the exceptions that may be encountered, in order of precedence.

		What will be displayed?	
Flag	Exception	Value	Units
Analyte disabled		Line omitted	
S	Slope Error	Blank	Yes
D	Drift Error	Blank	Yes
C	Result Incalculable	Blank	Yes
>	Exceeds High Range of reportable range	Upper limit	Yes
<	Exceeds Low Range of reportable range	Lower limit	Yes
Q	Analyte outside the range established for the QC lot	Yes	Yes

An analyte will be flagged as having failed QC *for a particular lot* when any of the exceptions in the table are encountered for the analyte providing the QC sample was run on an *active* lot and the sample has been *accepted*. The QC failure will be associated with the analyte *and* the particular QC lot that was analyzed.

This QC failure will be cleared for the analyte *and* the QC lot when QC results have passed and been accepted for a QC sample run on the **same** QC lot.

The QC failure will not be cleared for *the analyte* unless the failure is cleared on *all the lots* on which it was originally set. This means that even if an analyte passes QC with a particular QC lot, if there are failures for the analyte associated with another QC lot, the failure will not be cleared.

**Displayed Exceptions (CO-Oximeter QC)**

If an IL CO-Oximeter device is being used and exceptions are present, the CO-Ox exceptions will be displayed in a color coded manner similar to the blood gas results. The codes are described in the following table.

---

		What will be displayed?	
Flag	Exception	Value	Units
	CO-Ox analyte disabled on GEM Premier 3500	Line omitted	
?	Result not received from attached CO-Ox device	Blank	Yes
?	Results received from CO-Ox device with error status	Yes	Yes
Q	Results outside the QC range defined for the lot on the GEM Premier 3500	Yes	Yes

### QC Sample Report

The instrument will automatically print a QC Sample Report (*figure 6.8*) when the **Accept** button is selected. The report's title will indicate the type of QC: QC Sample Report (for native GEM Premier 3500 analytes) or CO-Ox QC Sample Report (for CO-Ox analytes). The report title will be followed by the words "PASS" or "FAIL" to indicate the overall results of the QC.

- Reports for IL 682 QCs will include the CO-Oximeter model (IL 682) and the identification number transmitted from the device.
- Reports for GEM OPL QCs will include the model (GEM OPL) and the serial number transmitted from the device.

The **Print** button can be used to print the report whenever the QC Sample Results screen is displayed. The QC Sample Report can also be printed from the **Database** option during QC sample or All samples recall and review (see Chapter 8).

**Figure 6.8: QC Sample Report (GEM Premier 3500 QC Material)**

QC Ranges		
	Low	High
pH	7.35	7.49
pCO <sub>2</sub>	31	77
pO <sub>2</sub>	80	115
Na <sup>+</sup>	135	145
K <sup>+</sup>	3.7	4.8
Ca <sup>++</sup>	1.04	1.22
Glu	79	103
Lac	0.8	1.6

pH	7.36	
pCO <sub>2</sub>	75	mmHg
pO <sub>2</sub>	83	mmHg
Na <sup>+</sup>	141	mmol/L
K <sup>+</sup>	4.7	mmol/L
Ca <sup>++</sup>	1.10	mmol/L
Glu	90	mg/dL
Lac	1.4	mmol/L

*NOTE: Using transparent tape to affix printed reports for documentation may cause the text in the report to fade. This may cause problems for long-term recordkeeping.*

**Printed Exceptions (GEM Premier 3500 QC Material)**

If exceptions are present in the QC results, the analyte name will be displayed along with an exception flag as indicated in the following chart (see the next page for CO-Ox exceptions). See "Displayed Exceptions (GEM Premier 3500 QC Material)" in this section for a description of the impact of these codes.

<b>What will be printed?</b>			
<b>Flag</b>	<b>Exception</b>	<b>Value</b>	<b>Units</b>
<b>Analyte disabled</b>			<b>Line omitted</b>
?	Slope Error	Overwritten with "Slope Error"	No
?	Drift Error	Overwritten with "Drift Error"	No
?	Result Incalculable	Dashes (----)	No
?	Exceeds High Range of reportable range	> Upper limit	Yes
?	Exceeds Low Range of reportable range	< Lower limit	Yes
*	Analyte outside the range established for the QC lot	Yes	Yes

### Printed Exceptions (CO-Oximeter QC)

If an IL CO-Oximeter device is being used and CO-Ox exceptions are present, the CO-Ox exceptions will be displayed in a similar way, as indicated in the following chart. See “Displayed Exceptions (CO-Oximeter QC)” in this section for a description of the impact of these codes.

What will be printed?				
Flag	Exception	Value	Units	
	CO-Ox analyte disabled in GEM Premier 3500	Line omitted		
?	Results not received from attached CO-Ox device	Dashes (----) “FAILED” will be printed on the report	No	
\	Results received from CO-Ox device with error status	Yes “FAILED” will be printed on the report	Yes	
*	Results outside the QC range defined for the lot on the GEM Premier 3500	Yes “FAILED” will be printed on the report	Yes	

## 7 – Set QC Sample Disposition

The disposition of a sample is set at the QC Sample Results screen as the final step in QC sample processing.

Sample dispositions provide a data management feature that enables the flagging of samples if and when they have been reviewed and the user-entered information optionally edited. Dispositions also provide a way to flag whether samples have been used clinically.

The instrument will provide two dispositions: ACCEPTED or DISCARDED. These dispositions correspond to the **Accept** and **Discard** buttons on the QC Sample Results screen. Any editing of sample information must be completed before a sample is accepted or discarded.

A QC sample that is DISCARDED will not be used for QC blank out assessment and will not be included in the lot statistics.

The following chart shows the relationship between a QC sample's disposition and how the instrument will handle the sample:

---

	Edit?	Auto-Print?	Demand Print?	Auto-Send?	Demand Send?	Copy to Disk?	Add to Statistics?
A	No	Yes	Yes	Yes	Yes	Yes	Yes
D	No	No	Yes	No	No	Yes	No

A = Accepted; D = Discarded

---

 **NOTE:** QC samples marked as *DISCARDED* will not be automatically printed or transmitted to the LIS/DMS. They will not be used to satisfy scheduled QCs or for QC pass/fail assessment (pass or fail will be shown on the results but not used to mark the analyte with the Failed QC status). They will not be used for QC statistics. Once a sample is discarded, it shall not be possible to accept it again nor edit its information.

If the sample has a disposition of PENDING, the **Entered Data** button can be used to review and/or edit the Operator ID and Comment associated with the sample. Otherwise, this button can be used to display the information but will not allow any edits.

 **NOTE:** The Operator ID cannot be edited if **Operator Security** is turned On (see "Security Setup" in Chapter 3).

### Buttons for Setting Sample Disposition on QC Sample Results Screen

#### Accept

The **Accept** button can be used after review of the sample has deemed it as satisfactory and after any user-entered sample information has been edited. No further editing of the sample will be allowed, either at the QC Sample Results screen or if the sample is later recalled from the sample database.

If one or more analytes failed QC and the **Accept** button is pressed, the user will be prompted with the message: *Accepting this QC sample will include its failed results in the QC lot statistics. Do you wish to accept this QC sample?* If **No** is selected, the instrument will remove the dialog box and abort the accept request. If **Yes** is selected, the instrument will accept the QC sample.

When a QC sample is accepted, the instrument will:

- Set the sample's disposition to ACCEPTED and save it to the sample database.
- Print the QC Sample Report, *figure 6.8*. The instrument will automatically print a duplicate report if the **Duplicate Sample Report** configuration option (see “Sample Setup” in Chapter 3) is turned On. The QC Sample Report will include the same information as QC Sample Results screen.
- Send the results to the LIS/DMS, if configured (see “Interface Setup” in Chapter 3).
- Satisfy the QC Schedule. See “QC Scheduling” in Section 6.7.
- Flag any failed analytes as having failed QC for that QC lot if the sample was run on a QC lot marked as ACTIVE. See “Displayed Exceptions (GEM Premier 3500 QC Material)” in this section.
- Return to the Ready screen.

#### Discard

The **Discard** button can be used 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**.

When a QC sample is discarded, the instrument will:

- Prompt to confirm the disposition. If **No** is selected, the instrument will remain at the QC Sample Results screen, and leave the sample's disposition unset. If **Yes** is selected, the instrument will:
- Set the sample's disposition to DISCARDED and save it to the sample database.
- Return to the Ready screen.

Discarded samples must be manually printed. They will always be included with all other samples when the entire sample database is copied (see “Save GEM Premier 3500 PAK Cartridge Data” in Chapter 8).

#### Exit

The **Exit** button will not be available until the QC sample has been accepted or discarded. When the **Exit** button is selected the instrument will:

- Save the QC sample to the sample database.
- Return to the Ready screen.

## 6.4 Responding to a QC Sampling Failure

If a measured value falls outside the expected range for an analyte, the screen displays QC FAIL and highlights any analyte that failed QC. To correct a failure:

1. Repeat the QC with freshly opened QC material from the same QC lot.
2. If the results still indicate a failure:
  - If the QC failure is for native GEM Premier 3500 analytes, initiate a full iQM process, then repeat with freshly opened QC material from the same lot. To initiate a full iQM process, see the instruction in “Manual iQM Process” in Section 6.9.
  - If QC fails for CO-Oximeter analytes, please refer to the CO-Oximeter operator's manual for further assistance.



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

2. If the problem persists:
  - Contact Technical Support at Instrumentation Laboratory.  
OR
  - Continue to use the cartridge, and use the results from only those analytes that passed QC.

## 6.5 Aborted QC Samples

The instrument will abort QC sample processing under the following circumstances:

- If the **Cancel** button is selected at any point in the sampling process.



*NOTE: Do not cancel a sample when an iQM process has been interrupted to analyze the sample.*

- If a prompt is not responded to within a two-minute period.
- If the instrument encounters a fatal processing error, such as insufficient sample volume.
- If results for an IL CO-Ox QC are not received within three minutes.

When the GEM Premier 3500 aborts a sample, it will take the following actions:

- If sample processing was still at the preparation stage (aspiration was not begun), the instrument will not save the sample in the database, and the sample will not be counted toward the total samples available from the cartridge. The instrument will return to the Ready screen.
- If sample processing has progressed beyond the point of aspiration, the instrument will:
  - Save the sample to the database as ABORTED. All results will be marked unavailable, and the reason the sample was aborted will be noted.
  - Count the sample toward the total samples available from the cartridge.
  - Not print or transmit the sample.
  - Return to the Ready screen.

The following chart shows what the instrument will allow operators to do with aborted samples:

Edit?	Auto-Print?	Demand Print?	Auto-Send?	Demand Send?	Copy to Disk?	Add to Statistics?
No	No	No	No	No	Yes	No

## 6.6 Active and Parallel QC Material

The Key Operator may designate QC materials with a status of “Active” or “Parallel”:

Active      QC material marked as “Active” is used for routine QC sampling. The instrument will flag patient results if a QC from an Active lot fails. Active QC material can be included in QC schedules, and the pass/fail ranges that have been defined for the material will be applied to QC results.

Parallel      QC material marked as “Parallel” can be used to help evaluate the performance of new QC material prior to incorporating it into routine QC sampling.

QC material with a “Parallel” status is used and defined in the same way as routine QC material, except Parallel QC material cannot be scheduled. Although pass/fail ranges are defined for Parallel QC material, the criteria will not be applied to the results. The instrument will simply list the results, which can then be compared to the results from similar Active QC material.

The instrument will label and display the results from Parallel QC material with the word *Parallel* at the top, while active QC material will be marked with *Active*.

When satisfactory results are seen with the Parallel QC material, the Key Operator can change its status from Parallel to Active so that the material can be used in scheduled and unscheduled QC analysis.



*NOTE: The status of QC material cannot be changed from Active to Parallel.*

## 6.7 QC Scheduling

The Key Operator can create a QC sampling schedule that the GEM Premier 3500 will either *Request* or *Require*:

- QC samples will be **requested** to be analyzed according to a schedule that has been defined by the Key Operator. In this mode, the GEM Premier 3500 will allow analysis of patient samples when QC samples are due or overdue but will mark those samples with the message "QC is Overdue."
- QC samples can be **required** to be analyzed according to a schedule that has been defined by the Key Operator. In this mode, the GEM Premier 3500 will not allow analysis of patient samples when QC samples are due or overdue.

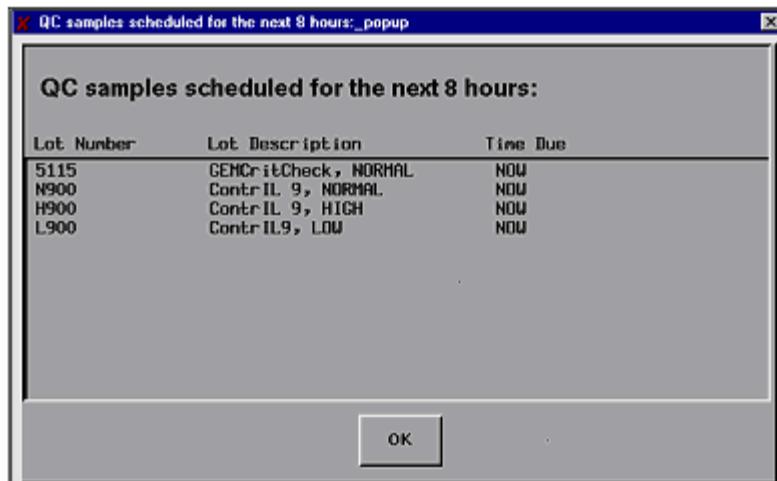
The Key Operator may also specify that separate QC samples be analyzed whenever a new GEM Premier 3500 PAK cartridge is inserted. These new cartridge QCs are the same as routine QCs, except that they are scheduled to be analyzed in a particular order after each new cartridge is inserted.



*NOTE: QC scheduling on the GEM Premier 3500 is driven solely by the schedule developed by the Key Operator. Simply turning on Mandatory QC (see "QC Setup" in Chapter 3) will not automatically implement any preset QC sampling. QC schedules must be defined.*

Any scheduled QC that is due within the next eight hours can be viewed by selecting the **Next QC** button on the Ready screen. The instrument will display the Next QC screen (figure 6.9), which contains a scrollable listing with the currently defined QC schedules, showing the lot number, description, and the time for routine QC or order sequence for new cartridge QC. The QC schedules will be listed by time, with the first one due at the top of the list.

**Figure 6.9: Next QC Screen**



The **Next QC** button will be displayed in yellow when QC is due within one hour. If QC is past due or a new cartridge QC is due, the **Next QC** button will flash, and the time for the QC on the QC List screen will be displayed as NOW.

When a QC sample is analyzed as an active lot and the results have been accepted, any scheduled QC on the QC List screen for the same lot number that is due within the next two hours will be removed. New cartridge QC will be removed if analyzed since cartridge warm-up was completed.

Operators can analyze QC in any order. The GEM Premier 3500 removes from the list each QC that is analyzed, regardless of the pass/fail status of the analysis, when the QC material

has been run and accepted. When all QC that is due has been analyzed, the **Next QC** button's display will return to normal.

Overdue QC is not cumulative. To satisfy a particular QC lot that is overdue, only one QC sample for the lot needs to be analyzed, even if that QC lot was not analyzed for previous schedules. All entries with the same lot number will be removed from the list.

The QC List screen will be empty if **Mandatory QC** (see “QC Setup” in Chapter 3), is turned off, if no QC schedules have been defined (see “QC Setup” in Chapter 3), or if no QC is due within the next eight hours.

## 6.8 QC Statistics

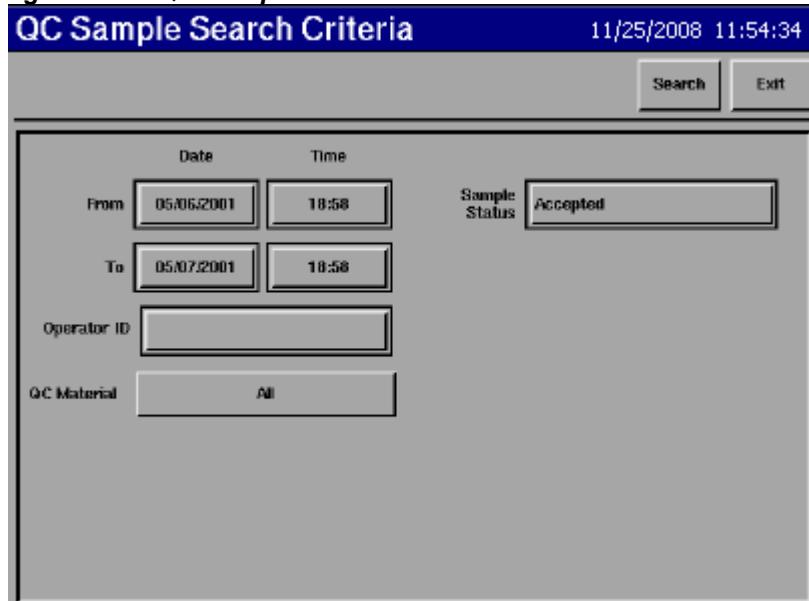
The GEM Premier 3500 automatically calculates QC statistics (ranges and means) for all QC samples analyzed. When recalling QC samples with an ACCEPTED disposition and for a specific QC material, the instrument allows users to review the statistics and optionally apply them to the ranges used for the QC material.

### To View QC Statistics:

1. If necessary, return to the Ready screen.
2. Select QC Samples from the Database menu.

Status: The instrument will display the QC Sample Search Criteria screen (*figure 6.10*).

**Figure 6.10: QC Sample Search Criteria Screen**



3. Touch the QC Material field.

Status: When the QC Material field is selected, a list of available QC material will be displayed, with the lot number, description/level, and lot status. This is the same list used to select QC material when QC samples are analyzed.

4. Select the QC material for which you want to view statistics, then touch OK.

Status: The instrument will redisplay the QC Sample Search Criteria screen.

5. Select "Accepted" from the Sample Status field.

Status: In order to view statistics, the QC material must have a disposition of ACCEPTED.

6. Optionally specify additional search criteria, such as the From/To Date or Time.

**7. Touch Search.**

Status: The GEM Premier 3500 will display the message *Recalling Samples. Please wait.*

- If no samples are found, the instrument will display a message saying so. Touching **OK** will return to the QC Sample Search Criteria screen. Modify the search criteria specified in Steps 3 through 6, then search again.
- If samples are found, the instrument will display the Search Results screen (*figure 6.11*).

**Figure 6.11: Search Results Screen**

Search Results				12/01/2008 08:44:49
				Send All   Print All   View   Exit
Date/Time	Status	Operator ID	Lot	
05/07/2001 19:06	Accepted, Failed	OPERATOR 12	5115 Active GENcritCheck, NORMAL	
05/07/2001 19:05	Accepted, Passed	OPERATOR 12	N900 Active Control 9, NORMAL	
05/07/2001 19:03	Accepted, Passed	OPERATOR 12	N900 Active Control 9, NORMAL	
05/07/2001 10:16	Accepted, Passed	OPERATOR 12	N900 Active Control 9, NORMAL	

1 through 4 : 4

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**8. Touch the Show Statistics button.**

Status: The instrument will display the QC Statistics screen (*figure 6.12*). Note that the example screen shows the native GEM Premier 3500 analytes. If the recalled samples had been CO-Ox QCs, the screen would list CO-Ox analytes.

**Figure 6.12: QC Statistics Screen (native analytes)**

QC Statistics										12/05/2008 08:39:25
										Set Ranges   Print   Exit
Lot Number:	H900									
Lot Description:	Control 9, HIGH									
Lot Status:	Active									
From:	05/06/2001 09:33									
To:	05/08/2001 09:33									
Number of Cartridges:	1									
	pH	pCO2	pO2	Na+	K+	Ca++	Glu	Lac	Hct	
N	4	4	4	4	4	4	4	4	0	
Passed	3	3	3	3	3	3	3	3	3	
Failed	1	1	1	1	1	1	1	1	1	
Mean	7.13	80	87	136	4.9	0.98	95	1.3		
SD	0.005	0.5	1.0	2.0	0.00	0.022	11.0	0.15		
%CV		1	1	1	0	2	12	12		
N = All accepted samples.										

## The QC Statistics Screen

This QC Statistics screen provides powerful features for analyzing and managing a QC program. The following statistical data can be viewed for each analyte in the specified lot:

- number of values in the statistics calculations
- number of values that passed QC
- number of values that failed QC
- mean
- standard deviation (SD)
- coefficient of variation (%CV)



*NOTE: See "Statistical Formulas" in this section for information about how the GEM Premier 3500 calculates these statistics.*

The QC Statistics screen also shows the lot number, lot description, lot status (Active or Parallel), and the from/to dates and times over which the statistics were calculated. The "from" date and time is the analysis time of the oldest sample; the "to" date and time is the analysis time of the most recent sample.

The information on the QC Statistics screen can be printed by touching the [Print] button (*figure 6.13*).

### Setting QC Ranges

The **Set Ranges** button is displayed on the QC Statistics screen only if the number of data points for every individual analyte and number of different cartridges represents the number identified in "QC Statistics – Set Ranges Requirements" under "QC Setup" in Chapter 3 (five cartridges and eight data points is the default setting).

Setting QC ranges, like all other instrument configuration, is limited to the Key Operator. Touching this button displays the prompt for the Key Operator ID.

Setting ranges will automatically print a QC Statistics report.

The GEM Premier 3500 will calculate the QC ranges from the statistical data and replace the current lot ranges with the calculated values. The Set QC Ranges screen (*figure 6.14*) displays the lot number and description of the QC material and the following information for each individual analyte in the lot:

<b>Instrumentation Laboratory</b>	
For Investigational Use Only	
<b>QC STATISTICS</b>	
<hr/>	
Lot Number:	N900
Description:	ContrIL 9, NORMAL
Lot Status:	Active
From:	01/02/2001 06:24
To:	01/08/2001 07:11
Number of Cartridges:	1
<hr/>	
pH	
N:	5
Passed:	4
Failed:	1
Mean:	7.36
SD:	0.006
%CV:	
<hr/>	
... (Additional Analytes)	

**Figure 6.13: QC Statistics Report**

- The mean and standard deviation from the previous (QC Statistics) screen.
- The currently-defined low and high range.
- The Formula selection field, which specifies how the calculated ranges are determined. The options that are available include: No Change, Mean  $\pm$  2SD, Mean  $\pm$  2.5SD, Mean  $\pm$  3SD, Mean  $\pm$  3.5SD, Mean  $\pm$  4SD, Mean  $\pm$  5SD, Mean  $\pm$  6SD, Mean  $\pm$  7SD, Mean  $\pm$  8SD. The initial value is No Change, which means the current ranges will be displayed.
- The calculated ranges are based on the selected formula. The calculated ranges are updated immediately after different formulas are selected.

**Figure 6.14: Set QC Ranges Screen (native analytes)**

**Set QC Ranges**      12/20/2008 08:48:32

	Mean	SD	Formula	Calculated Range Low	Calculated Range High	Current Range Low	Current Range High
pH	7.36	0.006	Mean $\pm$ 2SD	7.35	7.37	7.00	7.69
pCO <sub>2</sub>	75	0.6	No change			21	89
pO <sub>2</sub>	84	1.2	Mean $\pm$ 3.5SD	80	88	50	174
Na <sup>+</sup>	142	1.5	No change			114	160
K <sup>+</sup>	4.6	0.06	Mean $\pm$ 2.5SD	4.5	4.8	2.6	6.3
Ca++	1.08	0.035	No change			0.57	2.30
Glu	99	8.5	Mean $\pm$ 4SD	65	133	54	109
Lac	1.6	0.17	No change			0.9	3.2
Hct			No change				

Touch **Apply** when the ranges displayed in the Calculated Range column are satisfactory. The current ranges will be immediately replaced with the new calculated ranges. The Set QC Ranges report will automatically be printed.

## Statistical Formulas

The GEM Premier 3500 uses the following formulas to calculate the QC statistics:

**Data Points (N)** For every analyte in the QC lot, N is equal to the number of recalled **Accepted** samples minus the number of values:

- that were incalculable
- not measured due to iQM process error
- outside the reportable range
- not reported due to analyte lockout
- not measured due to the analyte not having ranges defined

If N=0 for an analyte, the instrument does not calculate any of the remaining statistical values for that analyte (the values will be blank).

**Passed** The number of data points that were within the QC range

**Failed** The number of data points that were outside the QC range.

**Mean** The arithmetic mean of the data set.

$$\text{Mean} = \sum x/N$$

where x = the value of the individual point in the data set.

**SD** One standard deviation for the data set. For SD to be calculated, N must be greater than or equal to two. Otherwise, the instrument displays N/A.

$$SD = \sqrt{\left[ \left( N \sum x^2 - (\sum x)^2 \right) / (N(N-1)) \right]}$$

**%CV** The coefficient of variation.

$$\%CV = 100 \frac{(SD)}{\text{Mean}}$$

## 6.9 iQM Process

The GEM Premier 3500 automatically performs three types of iQM processes: iQM process “B”, full iQM process, and iQM process “C”. As explained in Chapter 5 – Intelligent Quality Management (iQM), iQM is an automated Quality Assurance system for IL’s GEM Premier 3500 that replaces the use of traditional external Quality Control (QC). iQM is designed to help improve the quality of the test results and thus the quality of patient care.

iQM has different components. One component is the three on-board process control solutions, traceable to NIST primary standards, for the analytes available on the GEM Premier 3500. The solutions are tonometered to specific values of pO<sub>2</sub> and pCO<sub>2</sub> and sealed in gas-impermeable foil laminate bags with zero headspace. Each solution serves a specific function in the iQM process. iQM processes will be performed after each analysis, periodically during idle time, and on demand when needed.

### Manual Full iQM Processes

A manual full iQM process can be initiated to correct previous iQM process errors or as a step to correct QC failures. See “Responding to an iQM process Failure” in this section and “Response to a QC Sampling Failure” in Section 6.4.



*NOTE: A manual full iQM process cannot be initiated during an iQM process “C” or during iQM process “B” or full iQM process retries.*

To initiate a full iQM process manually, select **Full iQM Process** from the **Diagnostics** menu. This command will only be available when the Ready screen is displayed.

The instrument will start the iQM process, displaying a progress indicator in the Status Area at the bottom of the screen. When the iQM process finishes, the instrument will print an iQM process report if one has been configured in **iQM Setup** (see “iQM Setup” in Chapter 3).

### Automatic iQM Process “B”

The GEM Premier 3500 performs iQM process “B” in the background. Operators will not normally see them unless an iQM process error occurs. The exception is for the iQM process “B” that occurs immediately after each sample is analyzed. This iQM process is noted on the Ready screen with a progress indicator and cannot be interrupted.

The GEM Premier 3500 performs iQM process “B” according to the following schedule:

Cartridge life (after warm-up)	iQM Process “B” 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

## Automatic Full iQM Process

During full iQM processes, the instrument will remain at the Ready screen, displaying a progress indicator to indicate when the iQM process will finish. When the full iQM process finishes, the instrument will print an iQM process report if one has been configured in **iQM Setup** (see “iQM Setup” in Chapter 3).

During the first four hours after a cartridge is inserted, a full iQM process cannot be interrupted for patient sample analysis. After four hours, a full iQM process can be interrupted up to three consecutive times. **A full iQM process cannot be interrupted to analyze QC or CVP samples.**

The GEM Premier 3500 performs full iQM processes according to the following schedule.

Cartridge life (after warm-up)	Full iQM process frequency
30 minutes to less than 50 minutes	every 20 minutes
50 minutes to less than 80 minutes	every 30 minutes
80 minutes 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

## Automatic iQM Process “C”

iQM processes “C” are performed once every 24 hours. This iQM process cannot be interrupted by a sample or a full iQM process.

## Interrupting iQM Processes

iQM processes can be interrupted to analyze samples in certain circumstances. If a sample is run when the instrument is performing an iQM process that cannot be interrupted, it will display the message *Calibration in progress* for non-iQM cartridges or *Process Control in progress* for iQM cartridges.

The following iQM processes cannot be interrupted to analyze a patient sample:

- Full iQM processes during the first four hours of cartridge life
- Full iQM processes after the first four hours of cartridge life if the three previous full iQM processes were interrupted for sample analysis
- Any iQM process “C”
- The first iQM process “B” after sample analysis

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

- Any iQM process “C”
- Any full iQM process
- The first iQM process “B” after sample analysis



*NOTE: Do not interrupt iQM processes in progress unless it is absolutely necessary to analyze an urgent sample. If an iQM process is interrupted, always allow the sample analysis to complete.*

## iQM Process Reports

The results of the GEM Premier 3500's iQM processes are documented with iQM process reports. The conditions at the time the reports are printed and the level of detail provided is configured by the Key Operator in **iQM Setup** (see "iQM Setup" in Chapter 3).

A report for the last full iQM process can be printed on demand with the **Print Last iQM Process** command on the **Database** menu.

The iQM Process Report will identify the type of iQM process in its title. For cartridges running with iQM Mode "Off" (iQM disabled), the possible titles are: One-point Calibration, Two-point Calibration, or Low Oxygen Calibration. For cartridges running with iQM Mode "On" (iQM enabled), the report title will be Process Control Report. See *figure 6.15* for sample reports.

The following table describes the reports that the instrument may print. The "Config. Setting" column refers to selection made for the **iQM Process Reports** option in **Configuration**.

<b>Config. Setting</b>	<b>Report will be printed...</b>	<b>Report will contain...</b>
Off (Default)	iQM process reports will not be printed.	
Summary	After all full iQM process and iQM process "C" After iQM process "B" that follow the full iQM process so that reports appear at 30-minute intervals.	Date and time of iQM process. iQM process "B", full iQM process, or iQM process "C". <i>No Errors</i> or an error indicator.
Full	After all full iQM process and iQM process "C" After iQM process "B" that follow the full iQM process so that reports appear at 30-minute intervals.	Date and time of iQM process. iQM Process Type. <i>No Errors</i> or an error indicator. Slope and drift values for all parameters.
Errors (corrective action)	After iQM process "B", full iQM process, and iQM process "C" that contain errors. After the first successful iQM process "B", full iQM process, or iQM process "C" following an error.	Same as "Summary" Report.

**Figure 6.15: Sample iQM Process Reports**

"Full" iQM Process Report	"Summary" iQM Process Reports																																																																																										
 <b>Instrumentation Laboratory</b> <hr/> <p>FULL iQM PROCESS 11/24/2008 08:13:53</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>pH</td><td>Drift Error</td></tr> <tr><td>pCO2</td><td>Slope Error</td></tr> <tr><td>pCO2</td><td>Drift Error</td></tr> </table> <hr/> <p>Instrument S/N: 12004 Cartridge S/N: 778464</p> <hr/> <p>ELECTRODE SLOPES</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>T pH</td><td>60</td><td>mV/dec</td></tr> <tr><td>? pCO2</td><td>63</td><td>mV/dec</td></tr> <tr><td>pO2</td><td>17</td><td>pA/mmHg</td></tr> <tr><td>Na+</td><td>62</td><td>mV/dec</td></tr> <tr><td>K+</td><td>64</td><td>mV/dec</td></tr> <tr><td>Ca++</td><td>29</td><td>mV/dec</td></tr> <tr><td>Glu</td><td>24</td><td>pA/mg/dL</td></tr> <tr><td>Lac</td><td>72</td><td>pA/mg/dL</td></tr> <tr><td>Hct</td><td>92</td><td>mV/mho</td></tr> </table> <hr/> <p>DRIFT A MEAS A</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>pH</td><td>-0.01</td><td>6.09</td></tr> <tr><td>? pCO2</td><td>-----</td><td>mmHg</td></tr> <tr><td>pO2</td><td>0</td><td>121 mmHg</td></tr> <tr><td>Na+</td><td>0</td><td>102 mM/L</td></tr> <tr><td>K+</td><td>0.0</td><td>6.7 mM/L</td></tr> <tr><td>Ca++</td><td>-0.02</td><td>2.57 mM/L</td></tr> <tr><td>Glu</td><td>0</td><td>142 mg/dL</td></tr> <tr><td>Lac</td><td>0.0</td><td>3.2 mg/dL</td></tr> </table> <hr/> <p>DRIFT B MEAS B</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>pH</td><td>0.00</td><td>7.40</td></tr> <tr><td>? pCO2</td><td>-----</td><td>mmHg</td></tr> <tr><td>pO2</td><td>0</td><td>175 mmHg</td></tr> <tr><td>Na+</td><td>0</td><td>145 mM/L</td></tr> <tr><td>K+</td><td>0.0</td><td>3.6 mM/L</td></tr> <tr><td>Ca++</td><td>0.00</td><td>1.14 mM/L</td></tr> <tr><td>Glu</td><td>0</td><td>0 mg/dL</td></tr> <tr><td>Lac</td><td>0.0</td><td>0.0 mg/dL</td></tr> <tr><td>Hct</td><td>0</td><td>11 %</td></tr> </table> <p>? = Review</p>	pH	Drift Error	pCO2	Slope Error	pCO2	Drift Error	T pH	60	mV/dec	? pCO2	63	mV/dec	pO2	17	pA/mmHg	Na+	62	mV/dec	K+	64	mV/dec	Ca++	29	mV/dec	Glu	24	pA/mg/dL	Lac	72	pA/mg/dL	Hct	92	mV/mho	pH	-0.01	6.09	? pCO2	-----	mmHg	pO2	0	121 mmHg	Na+	0	102 mM/L	K+	0.0	6.7 mM/L	Ca++	-0.02	2.57 mM/L	Glu	0	142 mg/dL	Lac	0.0	3.2 mg/dL	pH	0.00	7.40	? pCO2	-----	mmHg	pO2	0	175 mmHg	Na+	0	145 mM/L	K+	0.0	3.6 mM/L	Ca++	0.00	1.14 mM/L	Glu	0	0 mg/dL	Lac	0.0	0.0 mg/dL	Hct	0	11 %	 <b>Instrumentation Laboratory</b> <hr/> <p>FULL iQM PROCESS 11/24/2008 08:13:53</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td>pH</td><td>Drift Error</td></tr> <tr><td>pCO2</td><td>Slope Error</td></tr> <tr><td>pCO2</td><td>Drift Error</td></tr> </table> <hr/> <p>OR</p>  <b>Instrumentation Laboratory</b> <hr/> <p>FULL iQM PROCESS 11/24/2008 08:57:20</p> <hr/> <p>No Errors.</p>	pH	Drift Error	pCO2	Slope Error	pCO2	Drift Error
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pCO2	Slope Error																																																																																										
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## iQM Process Data

The GEM Premier 3500 will save all corrective action and manual iQM process results in the appropriate data files. The results from automatic iQM process will be saved only if no iQM process of the same type has been saved during the last half hour.

The instrument will send the iQM process data through the RS-232 or Ethernet port if it is configured to do so by the Key Operator (see "Port Configuration" under "Interface Setup" in Chapter 3).

The GEM Premier 3500 uses the same report nomenclature for iQM process reports as for printed and displayed patient or QC reports. A "?" character printed to the left of an analyte indicates an issue for review:

Description	Measured Value...
Slope value is outside of valid slope range	Shown
Slope value is outside the reportable slope range or incalculable	not shown
Drift value is outside of the valid drift range	Shown
Drift value is outside of the reportable drift range or incalculable	not shown
Measured analyte value is outside of valid range or incalculable	not shown

If a measured analyte reports with an error or a Review (?) message, then the GEM Premier 3500 will not report any calculated parameters that rely on the measured value. Therefore, if pH,  $pCO_2$  or  $pO_2$  are flagged with a "?," then  $HCO_3^{std}$ ,  $HCO_3^-$ ,  $TCO_2$ , BEecf, BE(B), and/or  $SO_2c$  may report "-----" on both the screen and the printout. The errors will also appear if the sample is temperature corrected.

## Responding to an iQM Process Failure

If an iQM process "B" fails, the GEM Premier 3500 will automatically initiate up to two additional, consecutive iQM processes "B" to recover from the failure. Should the sensor not respond, the instrument will print the appropriate "?" analyte "Drift Error" indicator on the iQM process report.

If a full iQM process or iQM process "C" fails, the GEM Premier 3500 will automatically initiate up to two additional, consecutive full iQM process to recover from the failure. Should the sensor not respond, the instrument prints the appropriate "?" analyte "Error" indicator on the iQM process report.



*Allow all iQM process retries to come to completion. Interruption will cause delays in the instrument recovery from slope or drift errors.*



*NOTE: Repeat iQM processes of sensors that have failed iQM processes are not performed if the sensor in question has been disabled with Analyte Enable/Disable, see "Sample Setup" in Chapter 3.*

The instrument will treat retried iQM processes as independent iQM processes. The results will be printed and transmitted as has been configured for routine iQM processes.

If the GEM Premier 3500 continues to fail iQM processes, the following remedies are available:

- Continue to use the cartridge, and report only the results from the working sensors.
- Initiate another full iQM process manually. See “Manual Full iQM Processes” in Section 6.9.
- Contact Technical Support.

If the iQM process “C” does not pass after two retries, the user will be prompted to remove the cartridge.



NOTE: iQM process “C” retries cannot be initiated manually.

# 7 Shutdown & Transport

## 7.1 Shutdown & Transport

This section describes how to shutdown the GEM® Premier 3500, how to transport the instrument, and how it recovers from power interruptions.



**CAUTION:** Data loss may result if the instrument is turned off or if power is removed without first shutting down the instrument using the information provided in this section. If the GEM Premier 3500 is improperly shut down, the instrument may take up to two hours to check its system.

## 7.2 Instrument Shutdown

In order to turn off the GEM Premier 3500 for storage or transport, the shutdown procedure below must be followed. This allows the system's files to be properly closed. To avoid data loss, you should never turn off or remove power from the instrument without first going through this procedure.

If the instrument is being transported to a new location, the cartridge should not be removed before shutdown.



**CAUTION:** Once a cartridge has been removed, it cannot be reinserted. A new cartridge must be used.

### To Shutdown the Instrument:

**1. Select Shutdown from the Shutdown menu.**

**2. If Operator Security is turned on, (see "Operator Security" under "Security Setup" in Chapter 3), an authorized operator password will need to be entered before proceeding.**

**3. The instrument will confirm the shutdown with one of the following messages:**

- If an iQM Process "C" or an iQM Process "A" is **not** in progress: *You must restore power within 60 minutes or you will have to replace the cartridge. Do you want to shutdown now?*
- If an iQM Process "C" or an iQM Process "A" is in progress: *iQM Process is in progress. You must restore power within 20 minutes or you will have to replace the cartridge. Do you want to shutdown now?*

**4. Touch Yes to confirm the shutdown.**

Status: The shutdown can be aborted by touching **No**. When shutdown is confirmed, the instrument will display the message *The instrument is shutting down. Please wait.* When the instrument has completed its shutdown tasks, it will display the message *It is now safe to turn off the instrument.*

**5. When the instrument prompts that it is safe to turn off the instrument, turn the power switch to OFF.**

Status: If you are moving the instrument to a new location, do not remove the cartridge. You must power ON the instrument within one hour or you will be prompted to remove the cartridge.



**CAUTION:** Turn the instrument's power switch to OFF before unplugging the instrument to avoid harmful power surges.

## 7.3 Instrument Transport

### To Transport the Instrument:

1. Follow the shutdown procedure in the previous section.

Status: The instrument should be turned off.



**CAUTION:** Data loss may result if you turn the instrument off or remove power from the instrument without first selecting Shutdown.

2. If the instrument is cabled to another instrument or a computer via the RS-232 or Ethernet port, disconnect the cable from the instrument.

3. Move the instrument to the new location, and turn it on *within either one hour or 20 minutes*, according to the message that was displayed by the instrument during the shutdown process (see Step 3 in “Instrument Shutdown”, Section 7.2).

4. If the serial port connection is to be re-established at the new location, connect the cable to the instrument *before restoring power*.



**CAUTION:** Connect the serial cable before turning the instrument’s power switch to ON to avoid damage to the instrument’s serial ports.

5. Plug the power cord into a properly grounded and wired receptacle.

6. Turn the power switch to ON.

Status: The GEM Premier 3500 will start its automatic recovery cycle, described in the next section. When it is ready to analyze samples, the instrument will display the Ready screen.

## 7.4 Power Recovery Cycle / Instrument Restart

The GEM Premier 3500 automatically recovers from power interruptions of up to one hour (or 20 minutes if an iQM Process "C", an iQM Process "A", or a Sample was in progress when the instrument shutdown). When power is restored, the instrument will start an automatic recovery cycle that includes an iQM Process "B", a full iQM Process, and an iQM Process "C". The recovery process will take about three to twelve minutes depending upon the recovery status.

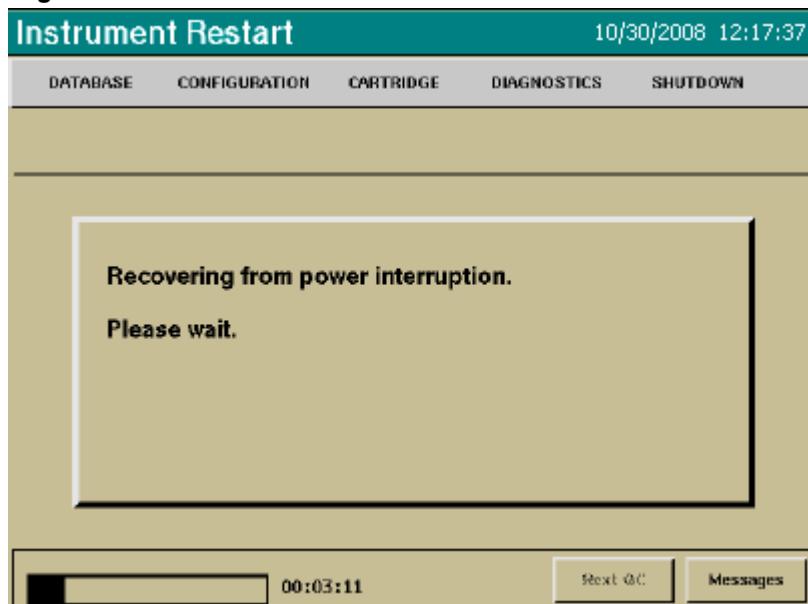
During recovery, the Instrument Restart screen (figure 7.1) is displayed if the instrument is turned on with a cartridge inserted and:

The instrument has been without power for less than one hour while no blood sample, iQM Process "A", or iQM Process "C" solution was on the sensors (analysis was not underway when power was interrupted)

OR

The instrument has been without power for less than 20 minutes while blood, iQM Process "C", or iQM Process "B" solution was on the sensors (analysis underway when power was interrupted).

**Figure 7.1: Instrument Restart Screen**



The GEM Premier 3500 cannot recover from power interruptions if the following conditions exist:

Blood, iQM Process "A" or iQM Process "C" solution has rested on the sensors for more than 20 minutes while the instrument was without power. This might occur if power was interrupted when a sample, iQM Process "A" or iQM Process "C" solution was being analyzed.

The power has been off for more than one hour. Power failure time is included in cartridge life time. The life of a cartridge cannot be extended by unplugging the instrument.

The inserted cartridge has reached its time limit of 504 hours (336 hours for 600-test cartridges).

The inserted cartridge has reached its sample capacity.

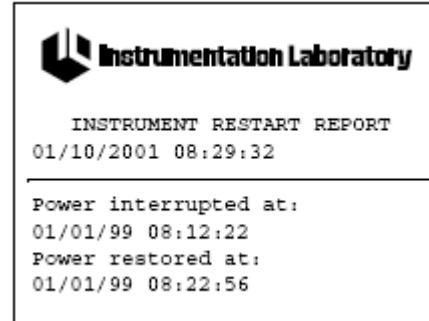
If any of these events occur, the instrument displays the Remove Cartridge screen with a message stating the reason the removal is required. See "Cartridge Removal" in Chapter 4 for more information about removing a cartridge.

The Instrument Restart screen displays a recovery message that tells the time until the GEM Premier 3500 will again be ready to analyze samples.

The **Messages** button will be available for viewing of alarm and text messages. (Alarm messages are described in Chapter 9; text messages in Chapter 11). Many of the commands on the menus are also available during restart.

When the instrument completes the power failure recovery process, it will print an Instrument Restart Report (figure 7.2) and display one of the following screens:

If the recovery was successful, the Ready screen will be displayed.



**Figure 7.2: Instrument Restart Report**

If a cartridge error occurred during recovery, the Remove Cartridge screen, with information about why the cartridge must be removed (see "Cartridge Removal" in Chapter 4 for more information about removing a cartridge).

If cartridge warm-up was interrupted, the Cartridge Warm-up screen will be displayed, and cartridge warm-up will be restarted from the beginning. Cartridge life will also be reset to zero. See "Start Up" in Chapter 2.

# 8 Database Operations

## 8.1 Data Recall

The GEM® Premier 3500 stores the data for the samples run on the current GEM Premier 3500 PAK cartridge as well as the previous cartridges. These samples can be recalled at any time using the options on the **Database** menu.



**NOTE:** The **Database** menu also includes the **Print Last full iQM option** (see “*iQM Process Reports*” under “*iQM Processes*” in Chapter 5) and options for *iQM reports* (see “*iQM Reports*” in Chapter 6).

This section provides information about working with the data stored by the instrument. The GEM Premier 3500 provides a simple yet powerful interface for retrieving previous samples – whether a single, specific sample or a group of samples with a common trait. Instructions are also provided for copying cartridge data to a CD, DVD or USB storage device for archival purposes.



**NOTE:** If **Operator Security** is turned On, a valid password will be required to review samples. See “*Operator Security*” under “*Security Setup*” in Chapter 3 for more information.

## 8.2 Recall and Review Samples

The **Review Last Sample**, **Patient Samples**, **QC Samples**, **CVP Samples**, and **All Samples** commands on the **Database** menu allow the recall of one or more samples. The process is similar regardless of the type of sample to be recalled:

1. Specify search criteria.
2. Initiate the search. Once the desired search criteria has been entered, touch the **Search** button to initiate the search. The instrument will display the message *Recalling Samples*. *Please wait.* If no samples are found, the instrument will display a message saying so. Touch **OK** to return to the Search Criteria screen. If samples are found, the instrument will display the Search Results screen.
3. Review the search results. The Search Results screen provides summary information for each of the samples found in the search. If the search was for accepted QC samples **and** a QC material was specified, the **Show Statistics** button will be available to see statistical information for the recalled samples. This option is not available with CVP samples. See “QC Statistics” in Chapter 5 for more information.
4. Review individual sample results. Individual samples may be selected from the Search Results screen for closer review on the Sample Results screen.

### Search Criteria

The following table shows the search keys that are provided for each sample type (patient, CVP, or QC).

---

#### Search Keys

<b>Last Sample</b>	Recalls the last sample analyzed, regardless of its type (patient, CVP, or QC).
--------------------	---

#### All Samples

From/To Dates and Times	The from/to date and time fields indicate the time period during which the samples to be recalled were analyzed. The “From” fields are initially filled with the current date and time less 24 hours. The “To” fields are initially blank. This search criteria will recall the last 24 hours worth of samples.
----------------------------	---



*NOTE: The format for the date should follow the format established in **Instrument Setup** located on the **Configuration** menu. To see the format configured for your instrument, look at the date displayed on the instrument's screen.*

Operator ID	This field is initially blank. Entry of an operator ID will search the database for all samples by that operator.
-------------	---

Sample Status	Accepted, Pending (patient samples only), Discarded, All; default is Accepted.
---------------	--

### Patient Samples Only

---

Patient ID	Up to 16 alphanumeric characters; initially blank. The patient ID to be searched for may be entered with the barcode gun.
Patient First Name	Up to 16 alphanumeric characters; initially blank.
Patient Last Name	Up to 16 alphanumeric characters; initially blank.

---

### QC and CVP Samples Only

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QC Material/ CVP Material	Indicates a particular QC/CVP material (lot number) to search for. The material is initially blank, which will recall samples regardless of the material used.  When the QC Material/CVP Material field is selected, a list of available material will be displayed, with the lot number, description/level, and lot status (QC only). This is the same list used to select material when QC or CVP samples are analyzed.  One use for specifying a QC material is to obtain statistical information for a material. This option is not available with CVP samples. The statistical information can then be used as the pass/fail criteria for the QC material. The <b>Show Statistics</b> button will be available on the Search Results screen when accepted QC samples and a specific QC material is searched for. See "QC Statistics" in Chapter 5 for more information.
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## 8.3 Review Last Sample Analyzed

The **Last Sample** command on the **Database** menu provides recall of the last sample that was analyzed, regardless of its type (patient, QC, or CVP) or disposition status. Aborted samples will not be recalled.

- If the last sample was a patient sample, it will be displayed on the Patient Sample Results screen (*figure 4.19*).
- If it was a QC sample, it will be displayed on the QC Sample Results screen (*figure 5.7*).
- If it was a CVP sample, it will be displayed on the CVP Sample Results screen (*figure 6.8*).

After a sample has been recalled in this way, the **Next** and **Previous** buttons on the Results screens can be used to view other samples.

## 8.4 Recall Patient Sample Results

When patient samples are recalled, they will be displayed on screens similar to the Results Screen that the instrument displays after a sample is analyzed.

The major difference in the screens is that the disposition buttons may not be displayed if the recalled sample's disposition has already been set, and buttons are provided for recalling other samples and sending the sample to the LIS/DMS.

### To Search for Patient Sample Results:

1. **Return to the Ready screen.**
2. **Select Patient Samples from the Database menu.**

Status: The instrument will display the Patient Samples Search Criteria screen (*figure 8.1*).

*Figure 8.1: Patient Sample Search Criteria Search*

The screenshot shows a search criteria entry form titled "Patient Sample Search Criteria". At the top right, the date and time are displayed as "11/14/2008 11:57:23". Below the title, there are two buttons: "Search" and "Exit". The search criteria are listed in a grid:

	Date	Time	
From	05/07/2001	09:40	Sample Status
To	05/08/2001	09:40	All
Operator ID			
Patient ID	1		
Patient Last Name	SMITH		
Patient First Name			

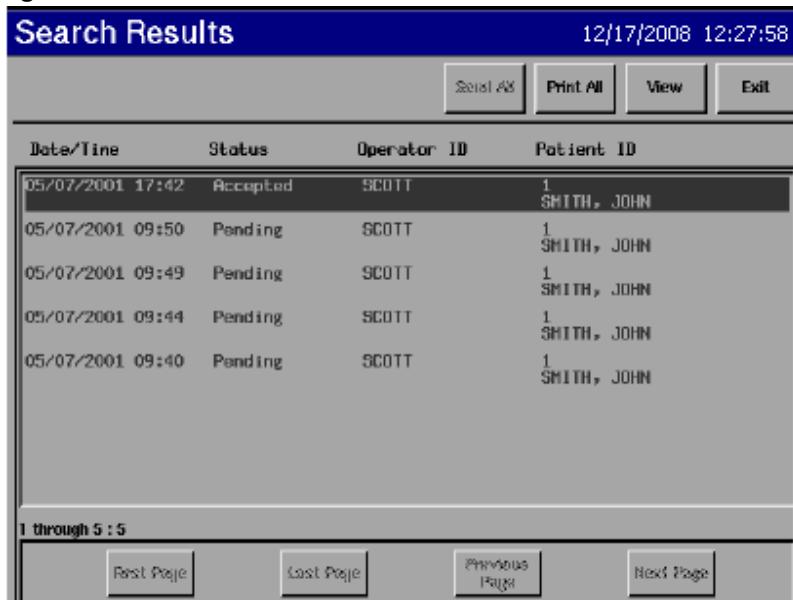
3. **Enter the criteria for the search: From/To Date and/or Time; Operator ID; Patient ID, Last Name, or First Name; or Sample Status.**

#### 4. Touch Search.

Status: The GEM Premier 3500 will display the message *Recalling Samples. Please wait.*

- If no samples are found, the instrument will display a message saying so. Touch **OK** to return to the Patient Sample Search Criteria screen.
- If samples are found, the instrument will display the Search Results screen (*figure 8.2*). This screen shows one sample per line, with the most recent sample at the top of the list. Each line contains the analysis date and time, sample status, and patient ID and name, if available.

**Figure 8.2: Search Results Screen**



Search Results				12/17/2008 12:27:58
				<input type="button" value="Serial All"/> <input type="button" value="Print All"/> <input type="button" value="View"/> <input type="button" value="Exit"/>
Date/Time	Status	Operator ID	Patient ID	
05/07/2001 17:42	Accepted	SCOTT	1 SMITH, JOHN	
05/07/2001 09:50	Pending	SCOTT	1 SMITH, JOHN	
05/07/2001 09:49	Pending	SCOTT	1 SMITH, JOHN	
05/07/2001 09:44	Pending	SCOTT	1 SMITH, JOHN	
05/07/2001 09:40	Pending	SCOTT	1 SMITH, JOHN	

1 through 5 : 5

5. If necessary, use the Next Page, Previous Page, First Page, Last Page buttons to move through the recalled samples.
6. To review a particular sample, highlight the sample in the list by touching the sample, then touch View.

Status: The sample information will be displayed on the Patient Sample Results screen.

- The **Show History** button will be available only if the sample is identified with a patient ID on the Patient Information screen when running a patient sample. This button will show the last seven accepted samples of the same type for the same patient.
- See “Review Patient Sample Results” under “Patient Sample Process” in Chapter 4 for other options provided on the Patient Sample Results screen.
- Touch **Exit** to return to the Search Results screen.

7. To print all samples, touch Print All.

Status: The instrument will display the number of samples to be printed and prompt to confirm that the samples should be printed. The oldest sample in the list will be the first printed. As samples are printed, the instrument will allow exiting from the Search Results screen to analyze samples or perform other instrument tasks.

**8. To send all accepted samples to the LIS/DMS, touch Send All.**



**NOTE:** The **Send All** button will only be displayed if an LIS/DMS has been configured in **Port Configuration** ("Interface Setup" section in Chapter 3).

Status: The instrument will display the number of samples to be transmitted and prompt to confirm that the samples should be sent. The oldest sample in the list will be the first sent. As samples are sent, the instrument allows exiting the Search Results screen to analyze samples or perform other instrument tasks.

**9. Touch Exit.**

Status: The instrument will display the Patient Samples Search Criteria screen.

**10. Touch Exit again.**

Status: The instrument will return to the Ready screen.

## 8.5 Recall QC Sample Results

When QC samples are recalled, they will be displayed on screens similar to the results screen displayed after a QC sample is analyzed.

### To Search for QC Sample Results:

1. If necessary, return to the Ready screen.
2. Select QC Samples from the Database menu.

Status: The instrument will display the QC Sample Search Criteria screen (*figure 8.3*).

**Figure 8.3: QC Sample Search Criteria Screen**

QC Sample Search Criteria 12/08/2008 07:54:23

Date Time

From 05/06/2001 18:58

To 05/07/2001 18:58

Operator ID

QC Material All

Sample Status Accepted

Search Exit

3. Enter the criteria for the search: From/To Date and/or Time, Operator ID, Sample Status, QC Material.

**4. Touch Search.**

Status: The GEM Premier 3500 will display the message *Recalling Samples. Please wait.*

- If no samples are found, the instrument will display a message saying so. Touch **OK** to return to the QC Sample Search Criteria screen.
- If samples are found, the instrument will display the Search Results screen (*figure 8.4*). This screen shows one sample per line, with the most recent sample at the top of the list.

**Figure 8.4: Search Results Screen**

The screenshot shows a search results interface. At the top, a blue header bar displays "Search Results" and the date/time "10/28/2008 12:33:49". Below the header are four buttons: "Send All", "Print All", "View", and "Exit". The main area is a table with four columns: "Date/Time", "Status", "Operator ID", and "Lot". The data rows show the following information:

Date/Time	Status	Operator ID	Lot
05/07/2001 19:06	Accepted, Failed	OPERATOR 12	5115 Active GEMcritCheck, NORMAL
05/07/2001 19:05	Accepted, Passed	OPERATOR 12	N900 Active Control 9, NORMAL
05/07/2001 19:03	Accepted, Passed	OPERATOR 12	N900 Active Control 9, NORMAL
05/07/2001 10:16	Accepted, Passed	OPERATOR 12	N900 Active Control 9, NORMAL

At the bottom of the table, a message indicates "1 through 4 : 4". Below the table are four navigation buttons: "First Page", "Last Page", "Previous Page", and "Next Page".

- 5. If necessary, use the Next Page, Previous Page, First Page, Last Page buttons to move through the recalled samples.**
- 6. To review a particular sample, highlight the sample in the list by touching the sample, then touch View.**

Status: The sample information will be displayed on the QC Sample Results screen.

- See “Review QC Sample Results” under “QC Sampling” in Chapter 5 for options provided on this screen.
- Touch **Exit** to return to the Search Results screen.

**7. To print all samples, touch Print All.**

Status: The instrument will display the number of samples to be printed and prompt to confirm that the samples should be printed. The oldest sample in the list will be the first printed. As samples are printed, the instrument will allow exiting from the Search Results screen to analyze samples or perform other instrument tasks.

**8. To send all accepted samples to the LIS/DMS, touch Send All.**

 **NOTE:** The **Send All** button will only be displayed if an LIS/DMS has been configured in Port Configuration (“Interface Setup” in Chapter 3).

Status: The instrument will display the number of samples to be transmitted and prompt to confirm that the samples should be sent. The oldest sample in the list will be the first sent. As samples are sent, the instrument allows exiting the Search Results screen to analyze samples or perform other instrument tasks.

9. If the recalled samples have all been accepted and used the same QC material, view statistics for the material with the Show Statistics button.

Status: See "QC Statistics" in Chapter 5 for more information about how these statistics can be used.

— Touch **Exit** to return to the Search Results screen.

10. Touch **Exit**.

Status: The instrument will display the QC Samples Search Criteria screen.

11. Touch **Exit again**.

Status: The instrument will return to the Ready screen.

## 8.6 Recall CVP Sample Results

When CVP samples are recalled, they will be displayed on screens similar to the results screen displayed after a CVP sample is analyzed.

### To Search for CVP Sample Results:

1. If necessary, return to the Ready screen.
2. Select CVP Samples from the Database menu.

Status: The instrument will display the CVP Sample Search Criteria screen (*figure 8.5*).

**Figure 8.5 CVP Sample Search Criteria Screen**

Date	Time
From 09/04/2002	13:34
To 09/05/2002	13:34

Sample Status Accepted

Operator ID

Material All

Search Exit

3. Enter the criteria for the search: From/To Date and/or Time, Operator ID, Sample Status, CVP Material.
4. Touch Search.

Status: The GEM Premier 3500 will display the message *Recalling Samples. Please wait.*

- If no samples are found, the instrument will display a message saying so. Touch OK to return to the CVP Sample Search Criteria screen.

- If samples are found, the instrument will display the Search Results screen (*figure 8.6*). This screen shows one sample per line, with the most recent sample at the top of the list.

**Figure 8.6: CVP Search Results Screen**

Search Results				12/07/2008 14:23:19
Date/Time	Status	Operator ID	Lot	
09/05/2002 13:27	Accepted, Passed	1802	GEM CVP 1	Active
09/04/2002 13:09	Accepted, Passed	3803	GEM CVP 3	Active
09/04/2002 13:06	Accepted, Passed	4803	GEM CVP 4	Active
09/04/2002 12:36	Accepted, Passed	2803	GEM CVP 2	Active
09/04/2002 12:23	Accepted, Passed	1802	GEM CVP 1	Active

1 through 5 : 5

**First Page**    **Last Page**    **Previous Page**    **Next Page**

- If necessary, use the Next Page, Previous Page, First Page, Last Page buttons to move through the recalled samples.
- To review a particular sample, highlight the sample in the list by touching the sample, then touch View.

Status: The sample information will be displayed on the CVP Sample Results screen.

- See “Review CVP Sample results” under “CVP Sampling” in Chapter 6 for options provided on this screen.
- Touch Exit to return to the Search Results screen.

- To print all samples, touch Print All.

Status: The instrument will display the number of samples to be printed and prompt to confirm that the samples should be printed. The oldest sample in the list will be the first printed. As samples are printed, the instrument will allow exiting from the Search Results screen to analyze samples or perform other instrument tasks.

- To send all accepted samples to the LIS/DMS, touch Send All.



**NOTE:** The Send All button will only be displayed if an LIS/DMS has been configured in Port Configuration (see “Interface Setup” in Chapter 3).

Status: The instrument will display the number of samples to be transmitted and prompt to confirm that the samples should be sent. The oldest sample in the list will be the first sent. As samples are sent, the instrument allows exiting the Search Results screen to analyze samples or perform other instrument tasks.

- Touch Exit.

Status: The instrument will display the CVP Samples Search Criteria screen.

- Touch Exit again.

Status: The instrument will return to the Ready screen.

## 8.7 Save GEM Premier 3500 PAK Cartridge Data

The GEM Premier 3500 retains the following data for at least 20 and up to 40 GEM Premier 3500 PAK cartridges:

- patient samples
- QC samples
- CVP samples
- iQM process data
- cartridge barcode information
- cartridge insertion date and time
- raw sensor data

Once the database contains 40 cartridges, it is considered “full.” When you try to insert the 41st cartridge, the instrument will prompt you to perform database maintenance:

- If you select **Yes**, the instrument will remove the data for all cartridges except the first 20. The Insert Cartridge screen will then reappear.
- If you select **No**, the Insert Cartridge screen will reappear. When you insert the cartridge, you will again be prompted to perform database maintenance. You will be allowed to insert the cartridge when you select **No** as long as the database contains data for less than 45 cartridges. Once the database reaches the 45 cartridge limit, the instrument will display a “database full” message, and database maintenance will be required before a cartridge can be inserted.

A regular schedule of copying the data from previous cartridges should be developed so that cartridge data is not unintentionally lost.

The data from specific cartridges can be copied to a CD, DVD or USB storage device with the **Copy Cart. Data** command on the **Diagnostics** menu.



*NOTE: The **Copy Cart. Data** command is different from the **Copy IL Data** command. The latter copies diagnostic files for use in troubleshooting instrument problems. See “Copy IL Data” in Chapter 9.*

Each cartridge requires one CD or DVD for storage of its data. Note that you can save multiple cartridges if you use a USB storage device instead. If a CD or DVD that already contains cartridge data is inserted, the instrument will display the cartridge serial number for the previous data and prompt to confirm that the data should be overwritten. This is not the case if you use a USB storage device when using the **Copy Cart. Data** or **Copy IL Data** features. You will be able to copy multiple cartridges without having to remove existing files in the device.

Copying cartridge data to a CD, DVD or USB storage device does not remove it from the instrument. Cartridge data will be removed from the instrument only when the forty-cartridge limit is reached. At that point, the data from the oldest cartridge will be automatically deleted.

## To Save Cartridge Data:

### 1. Select Copy Cart. Data from the Diagnostics menu.

Status: This command will always be available when the menus are displayed (at the Power Failure Recovery, Remove Cartridge, Insert Cartridge, Cartridge Warm-up, and Ready screens).

The instrument will display the Copy Cart. Data screen (*figure 8.7*) with the first cartridge in the list highlighted. The first entry in the list represents the most recent cartridge. Each line will show the cartridge serial number, insertion date/time, and number of samples analyzed on the cartridge. The list will be ordered in reverse chronological order (the most recent at the top).



*NOTE: The number of samples analyzed does not include CO-Ox samples.*

**Figure 8.7: Copy Cartridge Data Screen**

Copy Cart. Data			12/26/2008 14:27:32
Select Cartridge to Copy			<input type="button" value="Copy"/> <input type="button" value="Exit"/>
Cartridge Serial Number	Insert Date/Time	No. of Samples Run	
154970	02/04/2001 13:09	10	
154959	01/13/2001 12:59	300	
154954	12/22/2001 12:55	300	
154946	12/01/2001 12:49	300	

### 2. Select the cartridge to be copied by touching its entry in the listing.

Status: The instrument will highlight the cartridge entry you select.

### 3. Touch Copy.

Status: The instrument will prompt for a CD / DVD Disc or USB storage device (USB) to be inserted.

### 4. Insert a blank CD, DVD or a USB storage device into the disc drive or USB port located on the side of the GEM Premier 3500.

### 5. Touch Disc or USB as appropriate. If Disc is selected, touch OK when instrument prompts for insertion of a blank disc.

Status: The instrument will display the following messages: *Preparing data for copying.*

*Please wait, and then: Writing. Please wait.* After the data is written, the following message will be displayed: *Data has been written.* If an error is encountered during the writing, the following message will be displayed: *Write error. Retry operation.*



*NOTE: The GEM Premier 3500 may take several minutes to copy the data.*

### 6. Remove the CD, DVD or USB storage device, and touch OK.

Status: The GEM Premier 3500 will display the Select Cartridge to Copy screen.

**7. Touch Exit.**

Status: The instrument will display the Ready screen.

**8. Label the CD or DVD with the cartridge serial number and the instrument serial number.**

## 8.8 Save iQM Data

The iQM performance data stored by the instrument can be copied to a CD / DVD Disc or USB storage device (USB) with **Copy iQM Data** on the **Diagnostics** menu.

If a CD or DVD that already contains cartridge data is inserted, the instrument will prompt to confirm that the data should be overwritten. This is not the case if you use a USB storage device when using **Copy iQM Data**. You will be able to copy multiple sets of data without having to remove existing files in the device.

Copying iQM data to a CD, a DVD or an USB storage device does not remove it from the instrument. iQM data will be removed from the instrument only when the data is older than 1 year. At that point, the data from the oldest month will be automatically deleted.

### To Save iQM Data:

1. **Select Copy iQM Data from the Diagnostics menu.**

Status: This command will always be available when the menus are displayed (at the Power Failure Recovery, Remove Cartridge, Insert Cartridge, Cartridge Warm-up, and Ready screens).

The instrument will prompt for a CD, DVD (Disc) or USB storage device (USB) to be inserted.

2. **Insert a blank CD, DVD or a USB storage device into the disc drive or USB port located on the side of the GEM Premier 3500.**
3. **Touch Disc or USB as appropriate. If Disc is selected, touch OK when instrument prompts for insertion of a blank disc.**

Status: The instrument will display the following messages: *Preparing data for copying.*

*Please wait,* and then: *Writing. Please wait.* After the data is written, the following message will be displayed: *Data has been written.* If an error is encountered during the writing, the following message will be displayed: *Write error. Retry operation.*



*NOTE: The GEM Premier 3500 may take several minutes to copy the data.*

4. **Remove the CD, DVD or USB storage device, and touch OK.**

Status: The instrument will display the screen from which the **Copy iQM Data** option was accessed.

5. **Label the CD or DVD with the instrument serial number and date.**

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# 9 Troubleshooting and Cleaning

## 9.1 Troubleshooting & Cleaning

This section describes how to contact Instrumentation Laboratory for help, how to handle system problems, and how to return materials to materials to Instrumentation Laboratory. Instructions are also provided for installing system software and cleaning the instrument.

## 9.2 Preventive Maintenance

Only IL personnel or other person(s) duly authorized by IL will perform preventive maintenance on the GEM Premier 3500.

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

The functional performance of the analyzer is determined by the disposable GEM PAK.

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 service.

The GEM Premier 3500 with Intelligent Quality Management (iQM) monitors the analyzer performance. iQM has a complete range of diagnostic programs that continuously check the unit's performance and indicate any non-performance to the operator.

Instrumentation Laboratory recommends a preventive maintenance during the sixth year of service and every other year thereafter.

## 9.3 Contact Instrumentation Laboratory

Support of the GEM® Premier 3500 is available seven days a week, 24-hours a day. In order for IL Technical Support to serve you efficiently, please have the following information available before you call:

- Operating software version and instrument serial number (from the Diagnostics, System Info screen, described in "Diagnostics Menu" in Section 9.5).
- The error number and/or message the instrument is displaying, if applicable.
- The barcode number of the GEM Premier 3500 PAK cartridge currently installed in the instrument (from the Diagnostics, System Info screen, described in "Diagnostics Menu" in Section 9.5).

Call the following numbers in the USA and Canada for assistance with the GEM Premier 3500 and its components:

Technical Support: (800) 678-0710

Customer Service: (800) 955-9525 (orders only)

The address and phone number for Instrumentation Laboratory's worldwide facilities are listed in Appendix C. The Internet address for Instrumentation Laboratory can be found there as well.

## 9.4 System Problems

If a problem is encountered, the instrument may display screen-printed directions to follow. If the GEM Premier 3500 displays a message not understood, contact Technical Support.

One source of information is the **Messages** button on the Ready and other screens. This button provides a way to view alarm messages, review when the last alarms occurred, and clear the alarms. The **Messages** button is displayed in yellow when an alarm has occurred. For more information, see "Error Messages, Alarms, and Corrective Actions" in Section 9.6.

## 9.5 Diagnostics Menu

The **Diagnostics** menu provides access to diagnostic information related to the GEM Premier 3500 PAK cartridge and the instrument that can aid in troubleshooting. This menu provides the following diagnostic commands:

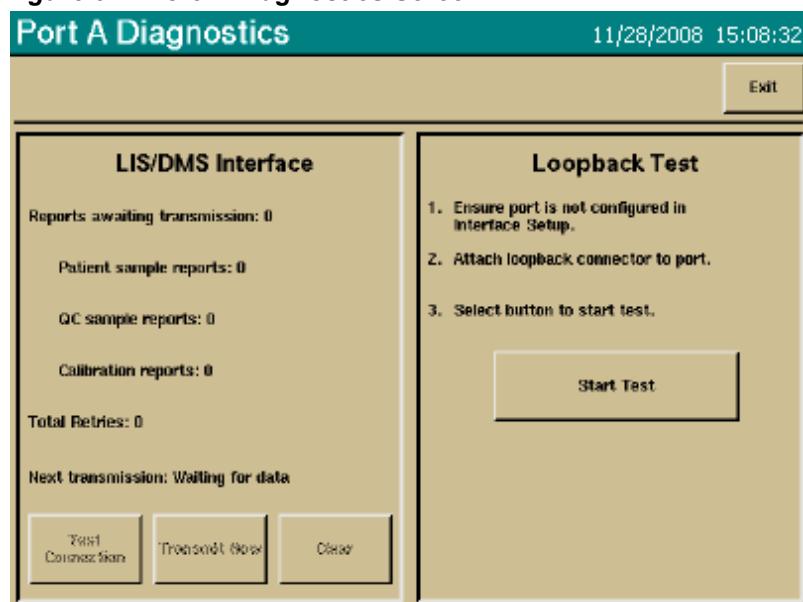
- Ports
- Printers
- System Info
- Copy IL Data
- Full iQM Process – see “Manual Full iQM Process” under “iQM Processes” (Section 6.9).
- Copy Cartridge Data – see “Save GEM Premier 3500 PAK Cartridge Data” in Section 8.7.
- Copy iQM Data – see “Save iQM Data” in Section 8.8.
- Transmit iQM Data.

### Ports

**Ports** on the Diagnostics menu provides access to a menu of the instrument’s four ports (COM A, B, C, and Network). Selecting a port will display the diagnostic screen for that port.

All four diagnostics screens include diagnostics for the external interface to an LIS/DMS as shown on the Port A Diagnostics screen (*figure 9.1*). The “Loopback Test” shown on that screen applies only to COM ports, not the Network port.

*Figure 9.1: Port A Diagnostics Screen*



### LIS/DMS Interface

The GEM Premier 3500 supports transmission of patient, QC, and iQM Process data to Laboratory Information or Data Management Systems (LIS/DMS) connected to one of the instrument's ports. Two types of communications protocols can be utilized to communicate with LIS/DMS: ASTM and HL-7 protocols. There is no support for any other types of data, nor for receiving any remote commands from the LIS/DMS.

To enable automatic transmission of sample and iQM Process data, the port must be set up in Interface Setup (see "Port Configuration" under "Security Setup" in Chapter 3). The instrument will attempt to send the data immediately after it is available. If transmission fails, the instrument will retry every ten minutes.

The Ports Diagnostic screen for each of the four instrument ports provides the following information for the LIS/DMS interface:

- The number of total reports and individual patient sample, QC sample, and iQM process reports that are awaiting transmission. The numbers will be 0 (zero) if transmission has not been configured in "Interface Setup" (Chapter 3).
- The total number of retries since the last time the transmission queue was empty. The number will be 0 (zero) if the port has not been configured in "Interface Setup" (Chapter 3).
- The time at which the instrument will automatically transmit the data. The instrument will display the message *Waiting for data* if queue is empty or the port has not been configured in "Interface Setup" (Chapter 3). It will display *In Progress* if data transmission is underway.

This information will be continuously updated to reflect the current transmission status.

The LIS/DMS area also provides the following buttons:

<b>Clear</b>	Purges all records from the transmit queue. The instrument will prompt to confirm the purge.
<b>Transmit Now</b>	The instrument will attempt to transmit records in the queue immediately instead of waiting for the next scheduled retry.
<b>Test Connection</b>	The instrument will attempt to communicate with the LIS/DMS to test the connection. While the test is underway, the message: <i>Test in progress. Please wait</i> will be displayed. When the test finishes, the instrument will display a <i>Pass</i> or <i>Fail</i> message.

This button will be unavailable if no device is configured to the port.

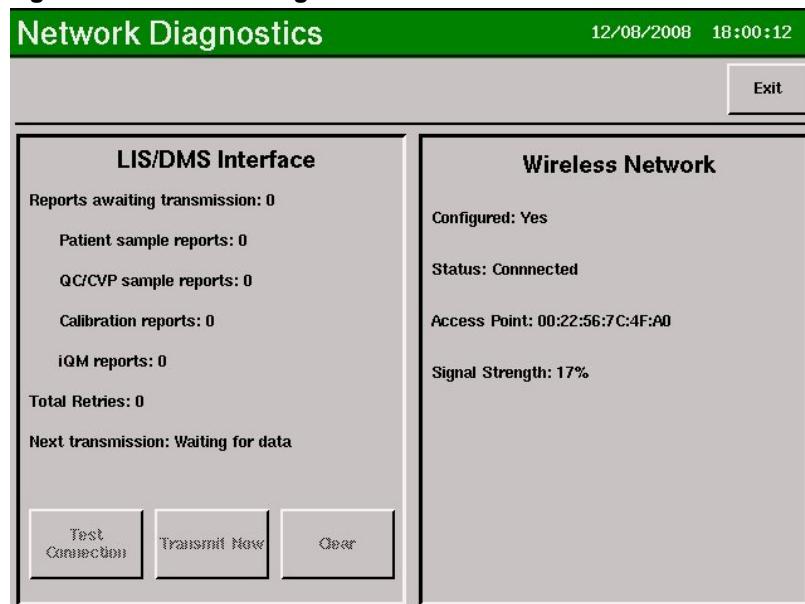
### Loopback Test

The Loopback test on the diagnostics screens for COM ports is used by IL Manufacturing and Depot Repair to verify COM port functioning. If COM port problems are suspected, contact IL Technical Support for assistance.

### Network Diagnostics / Wireless Network

The **Network Diagnostics** screen (see figure 9.2) under **Ports** can be divided in two parts: The first part is the LIS/DMS Interface diagnostics frame. Please refer to LIS/DMS Interface section above for an explanation on how to utilize the LIS/DMS Interface diagnostic tool.

**Figure 9.2 Network Diagnostics Screen**



The second part of the screen is the **Wireless Network** frame. This frame provides information on the wireless network. The Wireless Network frame has four parameters with the following functionality explained below:

Configured: "Yes" will be displayed if the required information has been entered in the Wireless tab under Interface Setup -> Network Setup in the configuration menu. "No" will be displayed otherwise.

Status: "Connected" will be displayed once a successful wireless connection is established. "Not Connected" will be displayed otherwise.

Access Point: The access point parameter will display the MAC address of the access point the analyzer is connected to. Blank will be displayed if the GEM Premier 3500 is not wirelessly connected.

Signal Strength: The signal strength parameter will display the value of the signal strength once the analyzer is connected. The range goes from 0% to 100%. 0% is displayed when no connection has been established. The signal strength parameter will be automatically refreshed every 10 seconds.

## Printers

**Printers** on the **Diagnostics** menu displays the Printer Diagnostics screen (*figure 9.3*). This screen displays status information, print queue information, and diagnostics for the internal (thermal) printer, the attached printer, and the network printer:



**NOTE:** See “Printer Setup” and “Network Setup” under *Interface Setup in Chapter 3* for information about configuring printers for use with the instrument.

**Figure 9.3 Printer Diagnostics Screen**

Printer Diagnostic			12/09/2008 14:45:17
Exit			
Internal Printer	Attached Printer	Network Printer	
Status:	Ready	Ready	Ready
Entries in queue:	0	0	0
Clear queue	<input type="button" value=""/>	<input type="button" value=""/>	<input type="button" value=""/>
Test printer	<input type="button" value=""/>	<input type="button" value=""/>	<input type="button" value=""/>

**Status:** Either *Ready*, or *Not Ready* when there is an “out of paper” or some other printer error. If the printer fails a print test (see below), the Status will change to *Not Ready*.

**Entries in Queue:** If the printer is not accepting print jobs for some reason, print requests from the GEM Premier 3500 will be stored in the instrument’s internal memory.

*Entries in Queue* shows the number of reports in the instrument’s queue. Zero entries does not necessarily mean all reports have been printed, because the report may be waiting in the printer’s own queue.

The instrument will try to print reports in the queue every 30 seconds for up to 10 minutes. After that time, the print job will be deleted. Print jobs will also be deleted when the instrument is restarted

**Clear Queue:** Deletes all jobs in the specified printer’s print queue. The instrument will display a prompt for confirmation before clearing the queue. The **Clear Queue** button also resets the instrument’s internal printer.

**Test Printer:** Tests the specified printer’s operation:

- For internal and attached printers, the instrument will print *PRINTER TEST* centered horizontally, followed by a solid line, the printer’s font set, and then another solid line.
- For network printers, the instrument will attempt to communicate with the printer by issuing a “ping” command; no report will be printed. The instrument will display the message: *Test in progress. Please wait* while

the test is performed. If communication is successful, *Test Passed* will be displayed.

If a printer fails the print test, the instrument will display *Test Failed*, and the printer will be set to *Not Ready* status.

## System Information

**System Info** on the **Diagnostics** menu displays the System Information screen (*figure 9.4*) with information about software versions, software installation date and type, instrument serial number, and the GEM Premier 3500 PAK cartridge to aid in troubleshooting. The cartridge information will be for the currently inserted cartridge. If no cartridge is inserted, the previous cartridge information will be shown. If no cartridge has ever been inserted, the cartridge information will be blank.

The **Print** button can be used to print the system information.

**Figure 9.4: System Information Screen**

System Information		12/09/2008 13:38:14
		<b>Print</b> <b>Exit</b>
Software Version:	7.0.0.B9	12/03/2008 09:00:00
Last Install:	12/04/2008 16:18:49	System Demo
LLP Version:	00/19/2005 14:21:00	
Language Version:	1.0	
Instrument S/N:	12345678	? Daylight Saving Time: On
Cartridge Information:		
Barcode:	6348470559554728332050640354633610576911	
Cartridge S/N:	576911	Cartridge Lot No.: 828566
Insertion date/time:	12/09/2008 12:59	
Expiration date/time:	12/30/2008 12:59	
Shelf life:	180 days	
Age:	59 days	
Use life:	21 days	
Days remaining:	21 days	
Capacity:	450 samples	
Samples remaining:	450 samples	
Analyte	A-Bag	B-Bag
pO1		177.000
pH	6.909	7.405
pCO2	63.000	33.000
pO2		174.760
Na+	102.000	144.000
K+	6.800	3.600
Ca++	2.660	1.150
Glu	146.000	0.000
Lac	29.000	0.000

## Copy IL Data

**Copy IL Data** copies important files to a CD / DVD (Disc) or USB storage device (USB) to assist Instrumentation Laboratory in solving problems that might arise with the instrument. Data for a specified cartridge will also be copied, with the patient ID and patient names blanked out for privacy.



**NOTE:** The **Copy IL Data** command is used to copy files for Instrumentation Laboratory's use in diagnosing system problems. To save sample data for a cartridge, use the **Copy Cart. Data** command. See "Save GEM Premier 3500 PAK Cartridge Data" in Chapter 8.

When **Copy IL Data** is selected, the instrument will prompt for selection of a cartridge to copy. Then touch **Copy** to begin copying the diagnostic information.

The instrument will prompt for insertion of a CD / DVD (Disc) or USB storage device (USB). If a CD, DVD or USB storage device already contains files with the same names, the instrument will prompt to confirm that the files should be overwritten. The original files that are stored in the instrument will remain unchanged (they will *not* be deleted).

## Full iQM Process

See "Manual Full iQM Process" under "iQM Processes" in Chapter 5.

## Copy Cartridge Data

See "Save GEM Premier 3500 PAK Cartridge Data" in Chapter 8.

## Copy iQM Data

See "Save iQM Data" in Chapter 8.

## Transmit iQM Data

The **Transmit iQM Data** screen allows you to send iQM Data (i.e. delta chart reports and corrective action reports) to an LIS or HIS. The Transmit iQM Data screen represents 12 checkboxes corresponding to the 12 months of the year, with the current month on the top of the screen followed by one checkbox per one of the eleven previous months. By default all checkboxes are unchecked. The checkboxes for the months that iQM data is not available will be ghosted.

If no iQM data is present (neither delta chart reports nor corrective action reports for the past twelve months are available), the dialog box *No iQM data to send. OK* will be presented, and the **Transmit iQM Data** screen will disappear when the message is acknowledged.

The **Transmit iQM Data** screen will display two command buttons:

- |       |  |
|-------|--|
| Exit: | The instrument will exit the Transmit iQM Data screen and return to the previous screen (i.e. Ready Screen, Insert Cartridge Screen, etc).   |
| Send: | The instrument will initiate the processing and transmission of the iQM data for the selected month(s). The Send button will be ghosted if no port is configured for LIS/DMS (iQM/CVP) in Interface Setup screen (see Chapter 3 – Interface Setup) or if no month is selected in the Transmit iQM Data screen. |

When the Send button is pressed to transmit iQM data for the selected month(s), the following message will display *Processing. Please wait.* This message will remain on the screen until the data is collected and processed (please note it can take up several seconds), at which point the message will be removed and the following new message will be displayed *Transmitting NNN records*, where NNN is the number of records being queued for transmission. Once the data has been transmitted, the message will disappear and the **Transmit iQM Data** screen will be redisplayed.

## 9.6 Error Messages, Alarms, and Corrective Actions

In certain situations during the operation of the GEM Premier 3500, the instrument may notify the operator of problems with *Alarms* or *Error Messages*.

### Alarms

In general, *Alarms* are less serious and include a specific course of corrective action that can be performed to correct the situation. Alarms will always address either problems with transmitting data or problems with the on-board printer.

The instrument notifies operators of Alarms with the **Messages** button, which is displayed on the Restart, Remove Cartridge, Insert Cartridge, Cartridge Warm-up, and Ready screens.

The **Messages** button will be displayed in yellow when at least one message or alarm is present. The Messages screen (*figure 9.5*) shows the messages and/or alarms and allows them to be cleared. Each alarm entry will show the date and time the alarm occurred and the alarm message. To clear all alarms, touch the **Clear** button. The screen will immediately refresh to remove the alarms.

**Figure 9.5: Message Screen**



The Alarms listed in the following table are types that will require attention.

<b>Alarm Message</b>	<b>Possible Cause</b>	<b>Corrective Action</b>
<i>Printer Out of Paper</i>	The printer is out of paper, or there is paper in the printer but the paper lever is up, or there is a problem with the printer or printer cable.	Install paper in printer, then clear alarm. If alarm occurs again, cycle power on instrument. If alarm continues to occur, contact Technical Support.
<i>Printer Error</i>	There is a hardware problem with the printer or printer cable.	Verify paper in the printer and paper lever is down, then clear alarm. If alarm occurs again, cycle power on instrument. If alarm continues to occur, contact Technical Support.
<i>Transmission Error</i>	Data could not be transmitted to the LIS (Laboratory Information System) successfully. The LIS cable may be faulty or the LIS system configured incorrectly.	Check connections to the RS-232, Ethernet port or to the receiving computer system. Check configuration of LIS system and wireless configuration if applicable. If alarm occurs again, cycle instrument power. If alarm continues, contact Technical Support.

## Error Messages

*Error Messages* are individually numbered to identify the specific type of error. Many of the messages will provide corrective action information to act upon. The remainder of the error messages will refer operators to Technical Support. When contacting Technical Support, record and communicate the particular error number and message the instrument is displaying. This information helps Technical Support resolve the issue as quickly and thoroughly as possible. See page 9.1 for information about contacting Technical Support.

The messages listed in the following table are the types of errors that will require attention.

Error Message	Possible Cause	Corrective Action
<i>Heater block temperature out of range. The instrument has been halted.</i>	The operating environment is outside the expected range, or a hardware failure has occurred.	Check ambient temperature. Contact Technical Support.
<i>Insufficient sample volume. Test cancelled. Please repeat test.</i>	Sample volume was less than the minimum requirement (see “Patient Sampling Process” in Chapter 4).	Aspirate another sample. Ensure greater volume and that end of the sampler is continuously submerged during sampling.
<i>The cartridge shelf life has expired. Please remove the cartridge now and use another cartridge.</i>	The cartridge shelf life read by the instrument or barcode gun has been exceeded.	Select and insert a cartridge that has not exceeded its expiration date. Verify that instrument’s internal clock is set to the current date.

## 9.7 Return Goods to Instrumentation Laboratory

If the GEM Premier 3500 or related components require service, contact Technical Support. If a return is necessary, Instrumentation Laboratory will issue you a Return Goods Authorization (RGA) number.

Prior to packaging the instrument for return, please refer to Section 9.9 for cleaning and disinfecting instructions. Please ensure that the ampoule breaker container has been emptied and the printer paper has been removed prior to shipping the instrument.

Do not attempt to return a product without first receiving a Return Goods Authorization (RGA) number from Instrumentation Laboratory. Reference the Return Goods Authorization number on the shipment packing list. It should be clearly visible on all packages.

In the USA only, ship the products to the following address:

**Instrumentation Laboratory, Inc.**  
Depot Repair  
180 Hartwell Rd.  
Bedford, MA 01730-2443 U.S.A.

The warranty on individual components of the GEM Premier 3500 system may vary. Refer to the warranty statement in Appendix C.

## 9.8 Software Upgrade

From time to time, Instrumentation Laboratory may update the operating software that controls the GEM Premier 3500. The following instructions provide the steps required to upgrade the instrument's operating software, unless special instructions are received with the new software.



*NOTE: To see the version number of the operating software currently in use by the instrument, use the **System Info.** on the **Diagnostics** menu, described in "Diagnostics Menu", Section 9.5.*



*Never load an older version of the software on the GEM Premier 3500. The instrument cannot be downgraded to previous versions of the software.*

### To Upgrade the Software:

1. **Select Shutdown from the Shutdown menu, and power off the instrument.**

Status: Follow the shutdown procedure as described in "Instrument Shutdown", Chapter 7.

2. **Insert the Upgrade CD. Follow the upgrade instructions provided in the upgrade kit.**
3. **If the instrument was previously customized through configuration, save the configuration information as described in "Save Configuration" (Chapter 3).**

Status: Discard any configuration media generated under older versions of the software, as these will not be useable with the new software version.

## 9.9 Disinfecting and Cleaning Procedure

With proper care, the GEM Premier 3500 requires very little cleaning and preventative maintenance. The following paragraphs describe how to clean and disinfect the instrument as necessary.

### Recommended Supplies

The following supplies are recommended for cleaning the GEM Premier 3500:

- Disposable latex or rubber gloves
- Laboratory coat or jacket
- Soft cleaning cloths
- 50/50 mixture of liquid chlorine bleach and water
- Biohazard waste bags
- Non-abrasive, mild cleaning solution



**CAUTION: Make sure the cleaning cloth is only moist, not dripping wet.**

**Avoid letting water or cleaning solution enter the unit enclosure. If cleaning solution enters the enclosure, do not reconnect the instrument to AC power. Instead, contact Technical Support at Instrumentation Laboratory.**

### Preparation for Cleaning



**BIOHAZARD: The GEM Premier 3500 processes patient samples that may be highly infectious. When cleaning the instrument, use proper technique and care to avoid contaminating yourself or others.**

1. Put on rubber or latex gloves and a laboratory coat or jacket before handling the instrument.
2. Prepare a biohazard waste bag for waste disposal.

### Cleaning the Touch Screen

You do not need to disconnect the GEM Premier 3500 from AC power when cleaning the touch screen. However, be careful to prevent water or cleaning solution from entering the unit enclosure.

#### To Clean and Disinfect the Touch Screen:

1. Dampen a soft cleaning cloth with water or mild cleaning solution.

Status: Be sure that the cleaning cloth is only moist, not dripping wet.

2. 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 abrasive cleaner or any bleach mixture to clean the touch screen, as this will damage the screen.**

**To Clean the Instrument:**

1. Shut down the instrument as described in “Instrument Shutdown” in Chapter 7.  
 **CAUTION:** Data loss may result if you turn the instrument off or remove power from the instrument without first selecting Shutdown.
2. Disconnect the instrument from AC power (AC outlet or uninterruptible power supply (UPS)).  
 **NOTE:** If a cartridge is inserted, power must be restored to the instrument within 20 minutes or one hour, depending upon the message displayed during the shutdown process. See Section 7 for information about the instrument’s capability to go without power. See Section 4 for information about removing the cartridge.
3. If the instrument is cabled to another instrument or a computer via the serial port, disconnect this cable from the instrument.
4. Place the unit on a non-porous surface, such as a laboratory counter.  
 **NOTE:** It is generally a good idea to first cover the counter space with a piece of plastic sheeting.
5. Remove any blood or dust from the outer surface of the case using a clean, soft cloth moistened with the 50/50 bleach mixture.
6. Wipe the outer surface of the touch screen clean using a clean soft cloth moistened with cleaning solution.
7. Inspect the gutter area into which the GEM Premier 3500 PAK cartridge is inserted, and clean as necessary.  
 **NOTE:** If moisture is evident, wipe the bottom of the gutter and exit hole using a cotton-tipped swab moistened with cleaning solution.
8. Remove the QC ampoule-breaker storage container, and empty its contents into an appropriate biohazard waste container.
9. Remove QC solution stains on the instrument or in the ampoule storage container using cleaning solution.
10. If necessary, remove the instrument from the work surface, then clean the work surface using a cloth or paper towel moistened with the 50/50 bleach mixture.
11. Place any used cloth or paper towel in an appropriate biohazard waste bag. Seal the bag and dispose of it in accordance with your institution’s procedures for disposing of materials contaminated with blood.
12. (Optional) With the AC power cord unplugged from the power source, wipe the AC power cord completely from end to end using a soft cloth moistened with cleaning solution.
13. Return the instrument to its place of operation.
14. Connect the instrument to a properly grounded and wired AC outlet (AC outlet or UPS).  
 **CAUTION:** Check to make sure the plug and cord are dry before engaging the plug.
15. Set up the instrument as described in “Instrument Setup” in Chapter 2.

Status: The GEM Premier 3500 starts its power-up cycle, then displays the Insert Cartridge screen.

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# 10 Operating Principles and Precautions

## 10.1 Operating Principles and Precautions

Blood gas/electrolyte/metabolite/hematocrit measurements may be performed on arterial, capillary, or venous blood. Proper collection of the blood sample before analysis ensures that the data obtained corresponds directly to the actual state of the blood "in-vivo."

This section describes the principles of operation and operative precautions to be applied in the pre-analytical and analytical phases, as well as limitations and interferences of the GEM Premier 3500, method evaluation protocols, and a bibliography of references.

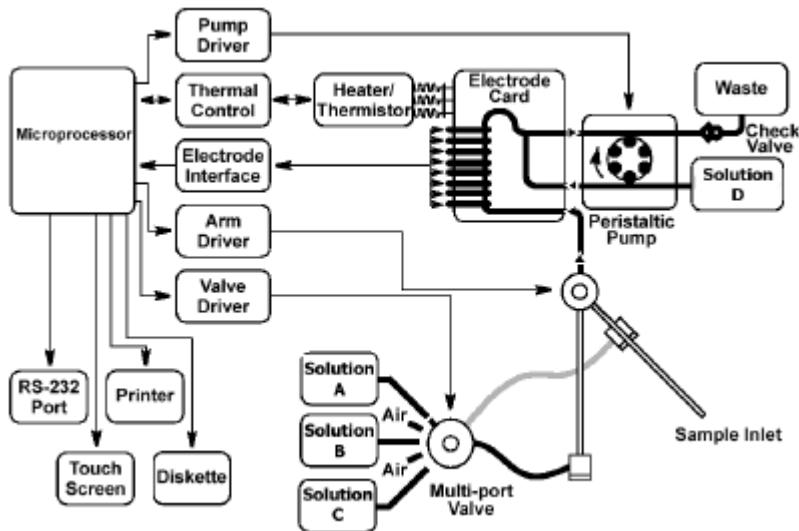


**CAUTION: Use only IL reagents. Use of other than IL reagents may cause harm to the sensors in the instrument.**

## 10.2 Principles of Operation

The central component of the GEM Premier 3500 PAK cartridge is the sensor card, which provides a low volume, gas tight chamber in which the blood sample is presented to the sensors. The pH, PCO<sub>2</sub>, PO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, glucose, lactate, and hematocrit sensors, together with the reference electrode, are integral parts of the chamber, with chemically sensitive membranes permanently bonded to the chamber body. When the cartridge is installed in the instrument, the chamber resides in a thermal block which maintains the sample temperature at 37 ± 0.3°C and provides the electrical interface to the sensors.

**Figure 10.1: GEM Premier 3500 Block Diagram**



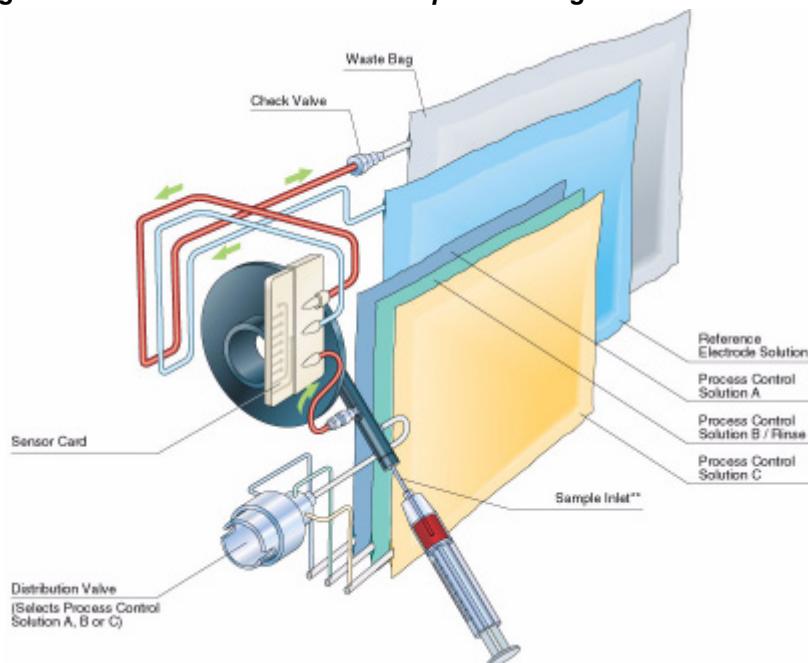
Included in the cartridge are three process control solutions called iQM Process Control "A", iQM Process Control "B", and iQM Process Control "C". These process control solutions allow for iQM process control checks. The iQM Process Control "A" and "B" provide high and low concentrations for all parameters. The iQM Process Control "C" solution is used to test the low oxygen level, as well as additional checks for the pH and pCO<sub>2</sub>. The iQM Process Control "C"

is also used for conditioning the glucose and lactate sensors, removing micro clots, and cleaning the sample path.

The iQM Process Control "A", "B" and "C" are tested as unknown to determine if any change beyond the specific control limits has occurred in the analytical system since it was first validated using the external CVP solutions. If the result is within the established control limits, the system is then as valid as it was when the cartridge was first inserted into the analyzer and validated with CVP. If a change beyond the established control limits is detected, iQM uses the Failure Pattern Recognition software to diagnose, correct, and document the failure and corrective action taken. After the above steps are successfully completed, the system then adjusts any drifts to zero to correct for the normal sensor electronic drift

The three on-board process control solutions "A", "B" and "C", traceable to the NIST primary standards, are tonometered to specific values of pO<sub>2</sub> and pCO<sub>2</sub> and sealed in gas-impermeable foil laminate bags with zero headspace. The lack of head space, or gas bubbles, in the solution allows it to be maintained and used over a range of temperatures and barometric pressures with no change in dissolved gas concentration.

**Figure 10.2: GEM Premier 3500 Component Diagram**

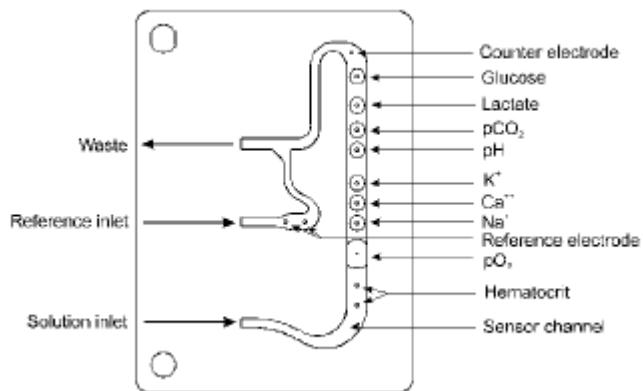


The cartridge also includes a reference solution, distribution valve, pump tubing, sampler, and waste bag. Blood samples that have been analyzed are prevented from flowing back out of the waste bag due to the presence of a one-way check valve in the waste line.

## Electrochemical Sensors

The electrochemical sensors used in the GEM Premier 3500 PAK disposable cartridge are all formed on a common plastic substrate. A schematic of the sensor card is shown in *figure 10.3*. The tube marked "Reference Inlet" supplies a silver nitrate solution to a flowing-junction reference electrode that provides a highly stable reference potential for the system.

**Figure 10.3: Schematic of GEM Premier 3500 Sensor Card**



The individual sensors, with the exception of hematocrit and reference, are formed from layers of polymer films which are bonded to the substrate. A metallic contact under each sensor is brought to the surface of the substrate to form the electrical interface with the instrument.

### pH and Electrolytes ( $\text{Na}^+$ , $\text{K}^+$ , and $\text{Ca}^{++}$ )

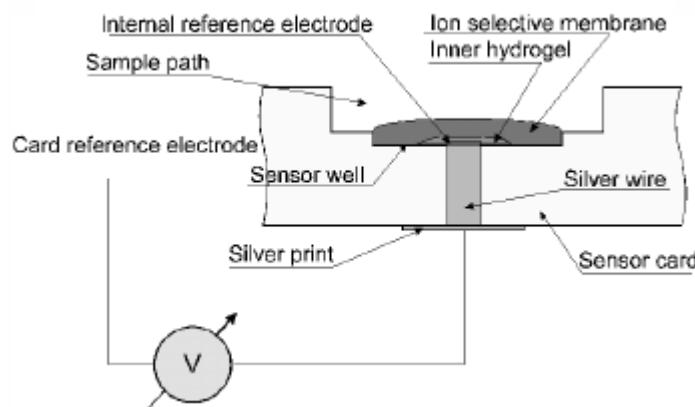
The pH and electrolyte sensors are all based on the principle of ion-selective electrodes; that is, an electrical potential can be established across a membrane which is selectively permeable to a specific ion. The potential can be described by this simplified form of the Nernst equation:

$$E = E' + S \log C$$

where  $E$  is the electrode potential,  $E'$  is the standard potential for that membrane,  $S$  is the sensitivity (slope), and  $C$  is the ion activity.  $E'$  and  $S$  can be determined by the sensor response to the iQM process control solutions, and the equation can be solved for the activity of the ion of interest. For pH, “ $\log C$ ” is replaced by “ $\text{pH}$ ” and the equation solved accordingly.

The pH and electrolyte sensors are polyvinyl chloride (PVC) based ion selective electrodes, consisting of an internal Ag/AgCl reference electrode and an internal salt layer. Their potentials are measured against the card reference electrode. The cutaway view in *figure 10.4* shows the flow of the solution past an ion-selective sensor.

**Figure 10.4: Cutaway of an Ion-Selective Sensor**



If pH reports with an exception, then  $p\text{CO}_2$ ,  $\text{HCO}_3^-$ ,  $\text{TCO}_2$ , BE, and  $\text{SO}_2\text{c}$  will not be reported. If  $\text{Na}^+$  reports with an exception, then Hct will not be reported.

### $\text{Ca}^{++}$ correction to $\text{pH}=7.4$

The following equation is used to calculate the ionized calcium value using a constant pH of 7.4 for each patient sample analysis.

$$\text{Ca}^{++} (\text{corrected}) = (\text{Ca}^{++} (\text{meas}) \times 10^{(-0.178 \times (7.4 - \text{pH}))})$$

### Carbon Dioxide ( $p\text{CO}_2$ mmHg)

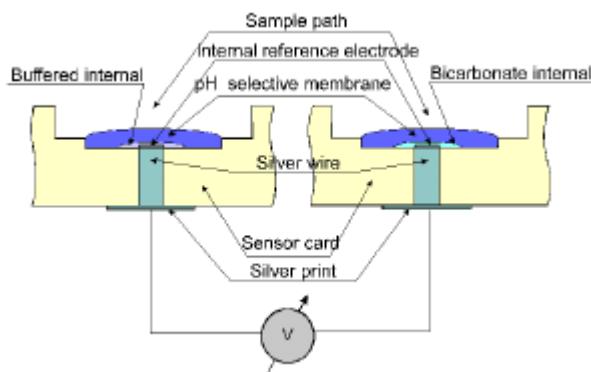
The  $p\text{CO}_2$  sensor is a patented design which relies on a pH selective polymer as a gas permeable outer membrane. The sensor has an internal Ag/AgCl reference electrode and an internal bicarbonate buffer. The  $p\text{CO}_2$  in the internal solution will come to equilibrium with the  $p\text{CO}_2$  of a liquid (e.g. blood) in contact with the outer surface of the membrane. The pH of the internal solution varies with the  $p\text{CO}_2$  in accordance with the Henderson-Hasselbalch equation:

$$\text{pH} = \text{pK}_a + \log \left( \frac{\text{HCO}_3^-}{\text{pCO}_2 \times a} \right)$$

where  $\text{pK}_a$  is an equilibrium constant,  $\text{HCO}_3^-$  is the bicarbonate ion concentration, and "a" is the solubility coefficient of  $\text{CO}_2$  in water. The generated potential versus the pH sensor is related to the logarithm of  $p\text{CO}_2$  content in the sample. Cutaway views of the  $p\text{CO}_2$  and pH sensors are shown in *figure 10.5*.

If  $p\text{CO}_2$  reports with an exception, then  $\text{HCO}_3^-$  and  $\text{TCO}_2$  will not be reported.

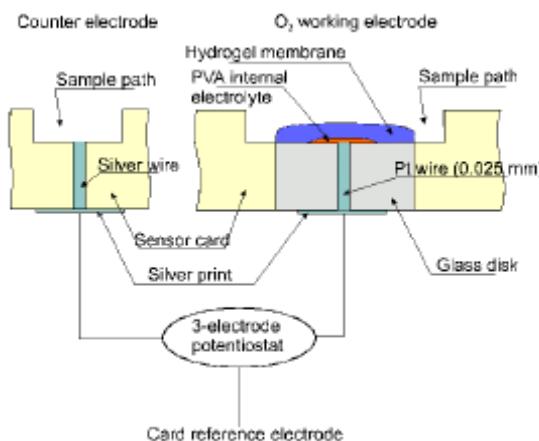
**Figure 10.5: Cutaway View of  $p\text{CO}_2$  and pH Sensors**



### Oxygen ( $pO_2$ , mmHg)

The oxygen sensor is an amperometric electrode consisting of a small platinum electrode poised at a negative potential with respect to the card reference electrode. A gas permeable membrane protects the platinum from protein contamination, prolonging sensor life. A cutaway view of the oxygen sensor is shown in *figure 10.6*.

**Figure 10.6: Cutaway View of Oxygen Sensor**



The current flow between the platinum and the counter electrode is proportional to the oxygen partial pressure.

The current flow between the platinum surface and the ground electrode is proportional to the rate at which oxygen molecules diffuse to the platinum and are reduced, which in turn is directly proportional to the  $pO_2$ . This relationship is described by the equation:

$$I = (S \times pO_2) + IZ$$

where  $I$  is the electrode current,  $S$  is the sensitivity, and  $IZ$  is the zero current. The values of  $S$  and  $IZ$  can be calculated from the iQM Process data for the sensor. The equation can then be solved for  $pO_2$ , where  $I$  becomes the electrode current produced by the blood sample.

If  $pO_2$  reports with an exception, then BE and  $SO_2c$  will not be reported.

### Glucose and Lactate

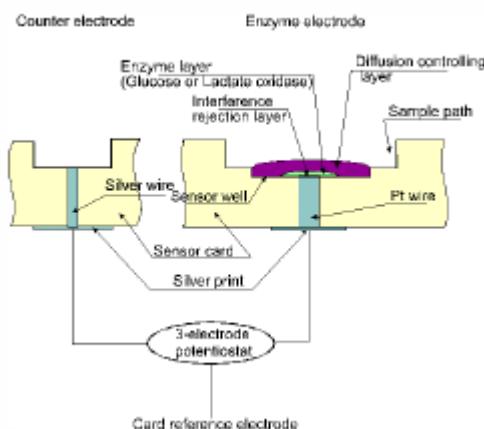
The glucose and lactate sensors are amperometric electrodes consisting of a platinum electrode poised at a positive potential with respect to the card reference electrode. Glucose or lactate determination is accomplished by enzymatic reaction of glucose or lactate with oxygen in the presence of glucose oxidase or lactate oxidase and the detection of the resulting hydrogen peroxide with the platinum electrode. The current flow between the platinum electrode and the ground electrode is proportional to the rate at which hydrogen peroxide molecules diffuse to the platinum and are oxidized, which in turn is directly proportional to the metabolite (glucose or lactate) concentration:

$$I = (S \times \text{metabolite}) + IZ$$

where  $I$  is the electrode current,  $S$  is the sensitivity, and  $IZ$  is the zero current. The value of  $S$  and  $IZ$  can be calculated from the iQM Process data for the sensor. The equation can then be solved for the metabolite concentration, where  $I$  becomes the electrode current produced by the blood sample.

A diagram showing the configuration of the sensor is shown in *figure 10.7*. The sensor is constructed of a three-layer composite membrane consisting of an inner layer for screening out the interferences, the enzyme for oxidation reaction, and the outer layer for controlling the metabolite diffusion in the enzyme layer.

**Figure 10.7: Cutaway View of Glucose and Lactate Sensors**



The current flow between the platinum and the counter electrode is proportional to the analyte concentration.

## Hematocrit

Hematocrit is measured by an electrical conductivity technique. The conductivity technique is based on the principle that because plasma is more conductive than blood cells due to the high resistance of the cell membranes, the resistivity of blood will increase as the concentration of cells increases. This relationship is expressed by the Maxwell-Fricke equation:

$$r = R_p \times (1 + Hct/100) / (1 - Hct/100)$$

where  $r$  is the blood resistivity,  $R_p$  is a constant based on the plasma resistivity, and  $Hct$  is hematocrit.

The electrode chamber contains a miniature conductivity cell. By applying an alternating current through the cell, the resistance of the fluid in the cell can be determined by means of Ohm's Law.

The GEM Premier 3500 performs hematocrit measurements using a conductivity cell method which is dependent on the patient's plasma electrical resistance remaining constant. The plasma resistance can vary due to changes in ionic as well as protein and lipid levels. The contribution of the ionic effect of sodium, the major extracellular cation, is accounted for in the hematocrit algorithm.

The GEM Premier 3500 will use the actual sodium value measured in the blood sample to calculate the hematocrit value. Therefore, if the sodium is deselected or if a slope, drift, or calculation error message has been reported for sodium, results for hematocrit will not be reported until the sodium sensor is activated or functioning properly.

Deviation of protein and lipid away from their expected levels can cause an error in the hematocrit results. A 10 g/L change in the blood protein concentration can cause a one percent change in the hematocrit reading (10 g/L protein increase can cause a 1% increase in the hematocrit and vice-versa). A 1 g/L change in the blood lipid concentration can cause a 0.3% change in the hematocrit reading (a 1 g/L lipid increase can cause 0.3% increase in the hematocrit and vice-versa).

### Card Reference

The card reference consists of a Ag/AgNO<sub>3</sub> electrode with an open liquid junction between the silver electrode and the sensor chamber. Every time a sample is pumped into the sensor chamber, fresh reference solution containing silver nitrate flows into the reference chamber and comes in contact with the sample. This process provides a stable and reliable potential independent of the sample composition.

### Cartridge Warm-Up

These miniaturized sensors are stored dry. When a cartridge is placed in the instrument, an iQM Process Control solution is pumped into the sensor chamber and hydrates the sensors. After hydration the sensors are calibrated and the system becomes ready for use. The hydration and calibration is completed within 30 minutes from cartridge insertion.

## 10.3 Pre-Analytical Phase

For a detailed description of the consideration that should be applied to the pre-analytical phase, refer to CLSI Document C46-A: "Blood Gas and pH Analysis and Related Measurements; Approved Guideline and CLSI Document C31-A2: Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection, and Handling; Approved Guideline.

### Effects of Patient Status on Results

Before obtaining a blood sample, be sure that the patient is in a steady state of ventilation. Anxiety caused by arterial puncture may result in hyperventilation, which can alter blood gas values significantly. Reassurance and the establishing of a good relationship with the patient may be helpful in relaxing him or her. A local anesthetic may also be used to reduce the pain of arterial puncture and patient anxiety.

Patients who are on a ventilator or receiving supplemental oxygen should be given at least 20 minutes following changes in ventilator parameters or %FiO<sub>2</sub> before samples are taken. This time allows the stabilization of the physiological parameters.

All blood samples must be accurately labeled with the patient ID to avoid sample mix-up. Other useful information to be collected with a sample includes time of drawing, location, sampling site, ventilation state, %FiO<sub>2</sub>, hemoglobin value, body temperature, patient activity, infectious diseases present, and physician ID.

### Selecting the Sampling Site

The criteria that should be applied when selecting the arterial sampling site include:

- presence of collateral blood flow
- vessel accessibility
- insensitivity of periarterial tissues

The radial artery at the wrist is the vessel that best meets these criteria and is usually indicated for drawing arterial blood. Other sites utilized in clinical practice are the brachial artery at the elbow and the femoral artery.

Although arterial blood is usually recommended for blood gas studies, capillary blood, if properly collected, is suitable. The capillary sites most frequently used for collection are the heel, the tip of the finger, and the earlobe.



*NOTE: Tissue fluid may affect hematocrit and electrolyte results.*

Venous samples, usually obtained from an antecubital vein, can supply reliable information on pH,  $pCO_2$ , electrolytes, and hematocrit but should not be considered acceptable for oxygenation studies.

Mixed venous blood samples can be collected via catheter from the pulmonary artery. Before sampling, the catheter deadspace volume should be cleared of infusion liquid. During arterial sampling, blood must be withdrawn from the catheter slowly enough to prevent back-mixing of well oxygenated pulmonary capillary blood with the mixed venous blood.

The type of sampling can be specified on the system printout when the sample is introduced (see Chapter 4).

### **Choice of Anticoagulant**

The only acceptable anticoagulant for blood gas, electrolyte, metabolite, and Hct determinations is lithium or sodium heparin at a final concentration of 25 IU/mL of whole blood or lithium heparin balanced with calcium, potassium, and sodium (balanced heparin at a final concentration of approximately 20 to 50 IU/mL of whole blood).

Samples must be mixed immediately upon drawing to ensure adequate mixing of the anticoagulant.

A higher concentration of balanced heparin (50 to 70 IU/mL of whole blood) may be used when sampling with capillary tubes.

The sampling process must be carried out properly, avoiding the aspiration of air bubbles that, if present, must be eliminated immediately. Care should be taken to avoid dilution caused by the anticoagulant solution.



**CAUTION:** Do not use anticoagulants other than lithium or sodium heparin at the proper final concentrations. Anticoagulants such as EDTA, citrate, oxalate, or sodium fluoride may adversely affect sensor performance.

Because of the high gas solubility of paraffin hydrocarbons, avoid the use of grease or mineral oil lubricants.

A high concentration of sodium heparin can lead to elevated sodium readings.

High concentration of lithium and sodium heparin can slightly lower ionized calcium readings.

### **Sample Volume**

Minimum sample requirements for the cartridge in use are as follows:

Sample Volume	Cartridge
150uL	BG/Hct/Lytes/Glu/Lac
145uL (capillary mode)	BG/Hct/Lytes/Glu/Lac
135uL	BG/Hct/Lytes
135uL	BG/Hct



*NOTE: If you have an IL CO-Oximeter attached to the GEM Premier 3500, refer to the CO-Oximeter's operator's manual for recommended CO-Oximeter sample volumes.*

## Plastic Syringes

The majority of plastic syringes used are made of a dense polypropylene. Such plastics are not permeable to gases under low gas tensions, and will not affect  $pCO_2$  and  $pO_2$  values significantly. However, plastic syringes under consideration should be pretested to determine their diffusion effect.

Plastic syringes having a barrel and plunger configuration frequently have tight fitting plungers that do not slide freely after lubrication. The plunger must be pulled back to obtain the sample. This is not recommended, as pressure created in the syringe may affect the gas tensions in the blood sample.

A variety of disposable plastic syringes specifically manufactured to obtain blood samples are currently available. Most of these syringes have overcome the problems associated with normal plastic syringes. Such syringes should be pretested however, to determine their suitability and performance before being routinely used.

## Blood Collection with Glass Syringes

Glass syringes must have a properly matched barrel and plunger to avoid binding. The plunger and glass barrel should be lubricated to assure air tightness and reduce friction. Normally, the heparin used to coat the inner barrel surfaces and fill the needle deadspace will provide sufficient lubrication. Use only enough heparin to wet the internal syringe surfaces and fill the deadspace volume.

After drawing a quantity of heparin into the syringe, slide the plunger up and down the barrel to coat all the inner surfaces, and then eject the excess heparin. Enough heparin will remain in the needle and syringe deadspace to serve as an anticoagulant.

Complete anticoagulation is essential because even microscopic aggregates in a sample can adversely affect a blood gas analysis. Heparin final concentration should not exceed the limits previously stated.

A properly lubricated glass syringe should fill from arterial pressure alone. After the syringe has filled with blood, the sample should be carefully inspected to see if air bubbles are present. If present, they must be ejected immediately.

At the end of the blood sampling, discard the needle appropriately and place a cap over the tip of the syringe. Mix the blood sample with the anticoagulant by gentle inversion and rolling of the syringe, between the hands, for at least 20 seconds.

To avoid infection, always use sterile technique.

## Sample Storage

Whole blood samples for blood gas/electrolyte/glucose/lactate and hematocrit analysis should be analyzed as soon as possible (within 15 minutes of collection for blood gas, electrolytes, and Hct; 5 minutes if glucose/lactate testing is included). If immediate analysis is not possible, the sealed blood syringe must be placed in a bath containing ice and water to slow down the metabolic process. Ice-water stored samples at 1 to 4°C may give reliable results for up to 30 minutes.

## 10.4 Analytical Phase

### Mixing the Blood Sample

Before analyzing the blood sample, it is important that it be mixed properly. Proper mixing is achieved by gently rolling and inversion of the syringe between the hands for at least 30 seconds.



**CAUTION:** During storage, blood cells tend to settle. If complete mixing is not achieved before analysis, results may be significantly different from actual values. All parameters are influenced by incomplete mixing, with hematocrit being the first parameter to be affected.

### Other Precautions

- Do not introduce a blood sample if clotting is evident or if no anticoagulant has been used.
- If an air bubble is trapped within the syringe, it must be eliminated before sampling. The blood report should make note of the fact that an air bubble was present. Most influenced parameters are  $pO_2$  and  $pCO_2$ .
- Patients undergoing open-heart surgery are often times diluted with a substantial volume of non-blood solution (referred to as plasma expanders), which may or may not contain protein. Once this fluid is infused into the patient, the process of equilibrium between the intravascular and extravascular fluid alters both the electrolyte and the protein composition of the blood. This in turn may change the red cell size and/or the plasma protein concentration and may cause errors in the common automated methods for determining hematocrit. For this reason, hematocrit determination by any automated method on whole blood from this type of patient should be verified by the micro-centrifugation method (spun Hct).
- Catheters that are treated with benzalkonium salts should only be used after proper removal of the excess chemical compound, which may have a possible effect on sodium and calcium determinations.

## 10.5 Clinical Interpretation

The following paragraphs describe how results generated by the GEM Premier 3500 might be interpreted in the laboratory.

### pH and Blood Gases

Arterial blood gases are important as an aid in:

- determining the acid base status,
- assessing the efficiency of lungs in exchanging gases,
- diagnosing pulmonary emboli, and
- adjusting oxygen therapy.

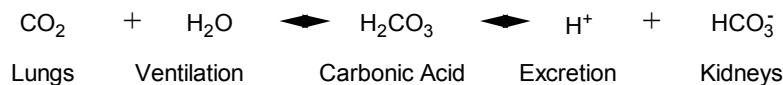
Because large quantities of acid or base can be produced by or administered to an individual, the blood pH has to be properly controlled to minimize major fluctuations. This is usually achieved through the buffer systems in our body, namely the bicarbonate-carbonic acid

system, the hemoglobin-protein system, and the phosphate buffer system. The bicarbonate-carbonic system is by far the most important one.

The Henderson-Hasselbach equation relates pH to blood bicarbonate and carbon dioxide tension.

$$\text{pH} = \text{pK} + \log \left( \frac{\text{HCO}_3^-}{\text{H}_2\text{CO}_3} \right)$$

The regulation of bicarbonate and carbonic acid concentration, thus plays an important role in controlling proper blood pH.



The lungs are a more efficient means of regulating blood pH since CO<sub>2</sub> tension can be altered within minutes by changes in ventilation. On the other hand, it takes many hours for the kidneys to change the amount of bicarbonate being excreted.

Thus, depending on whether the acid-base imbalance is due to metabolic (non-respiratory) or respiratory disturbances, the acid-base disorders can be classified as: metabolic acidosis or alkalosis; respiratory acidosis or alkalosis.

The characteristics of simple acid-base disorders and the accompanied compensatory changes are as follows:

Disorder	pH	HCO <sub>3</sub> <sup>-</sup>	pCO <sub>2</sub>
Metabolic acidosis	L	L <sup>1</sup>	L <sup>2</sup>
Respiratory acidosis	L	H <sup>2</sup>	H <sup>1</sup>
Metabolic alkalosis	H	H <sup>1</sup>	H <sup>2</sup>
Respiratory alkalosis	H	L <sup>2</sup>	L <sup>1</sup>

<sup>1</sup>Primary Changes

<sup>2</sup>Compensatory Changes

L = Low

H = High

Oxygen (O<sub>2</sub>) is the other clinically important blood gas measured. It is carried in the blood in a free form (dissolved gas) and also in a combined form (as oxyhemoglobin). Oxygen is taken up by hemoglobin in the lung and delivered to the tissues. Physiological factors that affect the binding of O<sub>2</sub> to hemoglobin are pH, temperature and 2,3-diphosphoglycerate.

Important clinical conditions that lead to anoxia (without oxygen) and respiratory failure include sedative drug overdose, cerebral edema, spinal cord or peripheral nerve lesions, crushed chest, chronic obstructive lung disease, asthma and pulmonary embolism.

## Sodium

This is the major cation of the extracellular fluid (ECF). Sodium has a renal threshold, so that if the serum level is greater than 110 - 130 mmol/L, sodium is excreted in the urine. If the serum level is less than 110 mmol/L or the  $\text{Na}^+$  intake is 30 mmol/day, the renal tubules reabsorb all the sodium.

Hyponatremia occurs where there is a sodium loss or excess water production. Examples of sodium loss are in diarrhea (where  $\text{Na}^+$  is lost through the stool), nephrosis, Addison's insipidus, and polyuric states. Examples of water excess occur with hypovolemia, inappropriate ADH secretion (Schwartz-Bartler Syndrome - water retention with continuous ADH secretion), in malignancies, inflammatory lung disease, CNS disease, and following drug therapy by anticancer agents and thiazide. Hyperglycemia gives an increased serum osmolarity and the intracellular fluid (ICF) goes to the ECF giving a decreased sodium. If there are high levels of triglyceride, sodium is only in the water phase, not the lipid phase; ultracentrifuge the specimen.

Hypernatremia occurs with water loss such as occurs with profuse sweating, prolonged hyperapnea, diarrhea, renal disease, and polyuric states. High sodium may also be due to lack of water intake, coma, hypothalamic disease, or Cushing's hyperaldosteronism. Severe dehydration, certain types of brain injury, and excessive treatment with sodium salts will give hypernatremia.

## Potassium

This is the major intracellular cation. The kidneys excrete 80 - 90% of the ingested  $\text{K}^+$ , even if there is a serum deficiency, as there is no renal threshold.

Hypokalemia occurs with GI fluid losses (vomiting and diarrhea), renal diseases, diuretic administration, mineral corticosteroid excess (Cushing's hyperaldosteronism) and in alkalemia (alkalosis -  $\text{K}^+$  in ECF exchanged for  $\text{H}^+$ ).

Hyperkalemia occurs with acute and some chronic renal disease, renal tubular acidosis, extensive tissue injury, acidotic states, and renal obstruction. Artifactual hyperkalemia may occur when the platelet count is high, the tourniquet is left on too long (fist is clenched and unclenched) hemolyzed serum ( $\text{K}^+$  in RBC 105 mmol/L) and if serum is not separated from the cells. Both elevated and depressed potassium have an adverse effect on the neuromuscular system (apathy, weakness, and paralysis) and myocardium. If left unattended, it may cause arrhythmia and death.

## Ionized Calcium

Ionized calcium is useful in the evaluation of non-bound calcium, calcium metabolism, physiologically active calcium fraction, hyperparathyroidism and ectopic hyperparathyroidism. Since calcium is bound to albumin (about 40%), patients with low serum albumin invariably have low total calcium levels, but may have normal ionized calcium.

## Glucose

Glucose is the primary energy source and its blood level is maintained within a fairly narrow range. The most common disorder in maintaining blood glucose is due to diabetes mellitus, which can cause hyperglycemia (high blood glucose) and hypoglycemia (low blood glucose).

## Lactate

Lactate is an intermediary product of carbohydrate metabolism and is derived mainly from muscle cells and erythrocytes. Severe oxygen deprivation of tissues due to shock, cardiac decompensation, hematologic disorders, and pulmonary insufficiency leads to "lactic acidosis" and is associated with a significant increase in blood lactate. Liver malfunction may also play an important role in the production of lactate acidosis.

### Hematocrit

The hematocrit measurement gives the red cell fraction of the blood, a vital component in determining its oxygen carrying capacity. Hematocrit levels are useful in evaluating anemia, blood loss, hemolytic anemia and polycythemia.

## 10.6 Bibliography

The following material provides background information on blood gases/electrolytes and hematocrit, sampling considerations, measurement principles and limitations, and clinical applications.

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- 11.Interference Testing in Clinical Chemistry - Proposed Guideline, NCCLS Document EP7-P, Vol 6, No. 13.

# 11 Specifications

## 11.1 Specifications

This section describes the GEM Premier 3500 system requirements, specifications, theory of operation, typical analytical performance, and calculation of derived parameters.



**CAUTION: The GEM Premier 3500 system consists of non-interchangeable components. Use only components supplied by Instrumentation Laboratory.**



**NOTE: For In-Vitro Diagnostic Use; Professional Use Only**

## 11.2 Dimensions

	Metric	English
<b>GEM Premier 3500</b>		
Height:	44.5 cm	17.5 inches
Width:	33.0 cm	13.0 inches
Depth:	30.0 cm	11.8 inches
Weight:	14.2 kg	31.2 pounds
<b>GEM Premier 3500 PAK</b>		
Height:	15.2 cm	6.0 inches
Width:	21.6 cm	8.5 inches
Depth:	7.6 cm	3.0 inches
Weight:	1.9 kg	4.2 pounds

## 11.3 Power Requirements and Product Safety

Power Requirements:	Switching power supply accommodates 100-240 VAC, 1.5 Max Amps at 50/60Hz. Power interrupts of up to 60 minutes are allowed for instrument transport. The instrument cannot be operated during power interruptions.
Product Safety:	CSA International Safety Approved. Complies with IEC 61010-1. The CE label on the back of the instrument indicates that the GEM Premier 3500 conforms to the European Directives as stated in IL's Declaration of Conformity.

## 11.4 Certifications

### CE Certification

IVD – 98/79/EC (27/10/1998) – Annex I and III

Applicable standards:

- CEI/IEC 61326.1:1998 (Class B)
- CEI/IEC 61010-1-04
- CEI/IEC 61010-2-101:2004
- CEI/IEC 61010-2-081:2004

### CSA Certification

The CSA label on the back of the instrument indicates that the Canadian Standards Association (CSA) has certified the GEM Premier 3500 to the applicable standards.

Applicable standards:

- CAN/CSA C22.2 No. 1010.1-92
- CAN/CSA C22.2 61010-2-081:2004
- CAN/CSA C22.2 61010-2-101:2004
- UL Std. No. 61010.1, 2<sup>nd</sup> Edition

### WEEE Directive:

#### European Union Directive 2002/96/EC on Waste Electrical and Electrical Equipment (WEEE)

Instrumentation Laboratory is committed to meeting or exceeding the conditions of the WEEE Directive, and being a good environmental partner. In compliance with the WEEE Directive, beginning with product shipped after August 13, 2005, all instruments will be labeled the symbol indicated above.

Disposing of this product correctly will help to prevent potential negative consequences for the environment and human health, which could otherwise arise from inappropriate waste handling. The recycling of materials will help to conserve natural resources. Penalties may be applicable for incorrect disposal of this waste, in accordance with national (European) legislation.

Please call your local Instrumentation Laboratory distributor for information regarding the disposal of any end-of-life instruments.

### Other

The GEM Premier 3500 meets CEI/IEC 61010-1, 2001 Mod, Second Edition, for the following:

- External Surface Temperature
- Flame Resistance
- Fluid Resistance
- Internal Air Flow and Temperature
- Audible Noise
- Product Labeling

The GEM Premier 3500 shipping package, US or overseas, complies with the International Safe Transit Packaging Procedure 1A (June, 1999) and AST 999.

The GEM Premier 3500 has an International Protection Rating (IP) of IP20.

Audible noise: The GEM Premier 3500 passes safety agency tests IEC 61010.1 and ISO 7779 for Acoustic noise measurements.

## 11.5 External Ground

The Mechanical ground point on the back of the instrument is for test purposes only. This is not the primary ground to the instrument.

## 11.6 Ambient Environmental Requirements

External Ambient Temperature Limits:	15°C (59°F) to 35°C (95°F)
Relative Humidity Limits:	5% to 90%
Barometric Pressure Limits:	None applicable. Process control bags have zero head space for operation over a wide range of atmospheric pressures with no change in dissolved gas concentration.



*NOTE: In accordance with IEC regulations, no breakdown or safety hazard will occur in the temperature ranges between 5 to 40°C (41 to 104°F).*

## 11.7 Storage Requirements

Instrument Storage:	Store in original packaging.
GEM Premier 300 PAK Storage:	15 to 25°C (59 to 77°F).
GEM Premier 3500 PAK Shelf Life:	Expires on the date indicated on the label of each cartridge. A cartridge may be inserted up to and including the date of expiration. Do not insert a cartridge past its indicated expiration date.

## 11.8 Sampling/Measurements



**WARNING: Use only Sodium Heparin or Lithium Heparin anticoagulant.**

**Sample Volume:**

150uL	BG/Hct/Lytes/Glu/Lac cartridges
145uL (capillary mode)	BG/Hct/Lytes/Glu/Lac cartridges
135uL	BG/Hct/Lytes cartridges
135uL	BG/Hct cartridges
Sample Type:	Whole blood with addition of 25 IU/mL Sodium Heparin or Lithium Heparin only.
Time To Results:	85 seconds from sample introduction.

**Sample Capacity**

Test Menu	iQM	Capacity Use-Life	
Blood gases, Hct	26403584	35	4 weeks
	26407584	75	4 weeks
	26315084	150	3 weeks
	26330084	300	3 weeks
	26345084	450	3 weeks
	26360084	600	2 weeks
Blood gases, Hct, electrolytes	26407587	75	4 weeks
	26315087	150	3 weeks
	26330087	300	3 weeks
	26345087	450	3 weeks
	26360087	600	2 weeks
Blood gases, Hct, electrolytes, glucose, lactate	26307589	75	3 weeks
	26315089	150	3 weeks
	26330089	300	3 weeks
	26345089	450	3 weeks
	26360089	600	2 weeks

**Measurement Methodology**

Amperometric:	pO <sub>2</sub> , glucose, lactate
Potentiometric:	pH, pCO <sub>2</sub> , Na <sup>+</sup> , K <sup>+</sup> , Ca <sup>++</sup>
Conductivity:	Hct
Internal Temp. Control:	Electrode chamber maintained at 37°C (98.6°F) nominal

## 11.9 Limitations

Samples Contaminated 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 immediately after drawing or prior to measurement.
Changes to Manufacturer's Instructions or Method Verification Protocols	Data obtained may be compromised.
Improper Installation	The instrument must be installed per the manufacturer's instructions. Prior to initiating any method evaluation protocol, acceptable cartridge performance must be demonstrated. All levels of CVP must be run and within acceptable ranges for iQM cartridges.
Under-Heparinized Sample	Blood clot can form in the sensor chamber causing various sensor failures if sample is not properly heparinized.

## 11.10 Interferences

The following substances can potentially interfere with sample analysis:

- Severely abnormal plasma osmolarities or abnormal levels of proteins or lipids.
- Hematocrit values produced by the GEM Premier 3500 may differ significantly from the values produced by a cell counter. In general, abnormally high protein or lipid values may cause higher hematocrit values, and vice-versa.
- Benzalkonium Chloride (see “Note 1” in this section): Arterial lines and sampling devices coated with Benzalkonium Chloride may interfere with sodium and ionized calcium determinations, causing falsely elevated sodium and ionized calcium readings.
  - Benzalkonium Heparin (see “Note 1” in this section): Arterial lines and sampling devices coated with Benzalkonium Heparin may interfere with sodium and ionized calcium determinations, causing falsely elevated sodium and ionized calcium readings.
  - Thiopental sodium (see “Note 2” in this section): May interfere with the sodium, potassium,  $pCO_2$  and ionized calcium readings (see “Note 3” in this section).
  - The anesthetic halothane may produce unreliable  $pO_2$  results due to interferences with  $pO_2$  sensor.
  - 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	$\geq 2$ mg/dL	1.4 mg/dL
Ethanol	$\geq 350$ mg/dL	100 mg/dL (toxic)

\*See reference 11 in “Bibliography”, Chapter 10.

- 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

\*See reference 11 in "Bibliography", Chapter 10.

- 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

\*See reference 11 in "Bibliography", Chapter 10.

## Notes

- iQM cartridges employ Failure Pattern Recognition (FPR) checks. One of the FPR checks that the GEM Premier 3500 recognizes is for the positively charged lipophilic compound Benzalkonium. 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*

The GEM Premier 3500 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 (see "Flag Patient Results for Interference and Micro Clots" under "Sample Setup" in Chapter 3), 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 clots*

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*

2. Another FPR check that the GEM Premier 3500 recognizes is for negatively charged lipophilic compounds, such as Thiopental Sodium. Thiopental Sodium is also known by other names, including: thiomebumal sodium, pentiobarbital sodium, thiopentone sodium, thionembutatal, pentothal sodium, nesdonal sodium, intraval sodium, traoanal, and thiothal sodium.

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 xxxx on last sample* (where xxxx is the analyte or analytes affected)

The GEM Premier 3500 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. If flagging of patient results for an interference is enabled (see “Flag Patient Results for Interference and Micro Clots” under “Sample Setup” in Chapter 3), 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 clots*

This message will remain displayed until the Process Control Solution B analysis is complete. If the associated 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 xxxx on last sample* (where xxxx is the analyte or analytes affected)

## 11.11 Measured Analytes

Measured Analyte	Reportable Range	Resolution
pH	6.80 to 7.80	0.01
$p\text{CO}_2$	5 to 115 mmHg	1 mmHg
$p\text{O}_2$	0 to 760 mmHg	1 mmHg
$\text{Na}^+$	100 to 200 mmol/L	1 mmol/L
$\text{K}^+$	0.1 to 20.0 mmol/L	0.1 mmol/L
$\text{Ca}^{++}$	0.10 to 5.00 mmol/L	0.01 mmol/L
Glu	5 to 500 mg/dL	1 mg/dL
Lac	0.2 to 15.0 mmol/L	0.1 mmol/L
NOTE: Due to the instability of Lactate in whole blood, samples used to establish the 0.2 mmol/L concentration were stabilized through repeated washing and icing <i>in vitro</i> for testing.		
Hct	15 to 65%	1%
*THb		
* $\text{O}_2\text{Hb}$		
*COHb	Refer to your CO-Oximeter Operator's manual for reportable ranges.	
*MetHb		
*HHb		
* $\text{SO}_2$		
*These analytes will be measured only if an IL CO-Oximeter device has been configured in instrument setup.		

## 11.12 Calculated Analytes

Derived Parameter	Reportable Range	Resolution
HCO <sub>3</sub> std	3.0 to 60.0 mmol/L	0.1 mmol/L
HCO <sub>3</sub> <sup>-</sup>	3.0 to 60.0 mmol/L	0.1 mmol/L
TCO <sub>2</sub>	3.0 to 60.0 mmol/L	0.1 mmol/L
BEecf	-30.0 to +30.0 mmol/L	0.1 mmol/L
BE(B)	-30.0 to +30.0 mmol/L	0.1 mmol/L
SO <sub>2</sub> c	0 to 100%	1%
Ca <sup>++</sup> (7.4)	0.10 to 5.00 mmol/L	0.01 mmol/L
THbc	Defined by Input Parameters	0.1 g/dL
*O <sub>2</sub> ct	Refer to your CO-Oximeter Operator's manual for reportable ranges.	
*O <sub>2</sub> cap		
A-aDO <sub>2</sub>	**	1 mmHg
pAO <sub>2</sub>	**	1 mmHg
paO <sub>2</sub> /pAO <sub>2</sub>	**	0.01
RI	**	0.1
CaO <sub>2</sub>	**	0.1 mL/dL
CvO <sub>2</sub>	**	0.1 mL/dL
CcO <sub>2</sub>	**	0.1 mL/dL
a-vDO <sub>2</sub>	**	0.1 mL/dL
Q <sub>sp</sub> /Q <sub>t</sub>	**	0.1
Q <sub>sp</sub> /Q <sub>t(est)</sub>	**	0.1
P <sub>50</sub>	**	1 mmHg

\*O<sub>2</sub>ct and O<sub>2</sub>cap are derived on an attached IL CO-Oximeter device and then transmitted to the GEM Premier 3000.

\*\*Depends on the reportable range of the measured analytes used to calculate the parameter.

## 11.13 User-Entered Analytes

Entered Analyte	Reportable Range
Temperature	15°C to 45°C (59°F to 113°F)
*Glu	0 to 999 mg/dL
*Lac	0 to 30 mmol/L
**THb	2 g/dL to 25 g/dL
**SO2	0% to 100%
**O2Hb	0% to 100%
**COHb	0% to 100%
**MetHb	0% to 30%
**HHb	0% to 60%
APTT-P	0.0 to 999.9 seconds
PT-P	0.0 to 999.9 seconds
PT INR	0.0 to 99.9 seconds
ACT	0.0 to 9999 seconds
ACT-LR	0.0 to 999 seconds
*Only available when BG/Hct or BG/Hct/Lytes cartridge is inserted.	
**If an IL CO-Oximeter device has been configured in instrument setup, these analytes will be available as measured analytes.	

**User-Entered O<sub>2</sub> and Vent Settings**

Entered Analyte	Reportable Range
O <sub>2</sub>	0.0 to 99.0 L/min
FiO <sub>2</sub>	20% to 100%
V <sub>T</sub>	0 to 9999 mL
Mode	N/A
Mech Rate	0 to 9999 bpm
Spon Rate	0 to 9999 bpm
Peak Press	0.0 to 999.9 cm H <sub>2</sub> O
Itime (sec)	0.0 to 99.9 sec
Itime (%)	0 to 99 %
MAP	0.0 to 999.9 cm H <sub>2</sub> O
PEEP	0.0 to 99.9 cm H <sub>2</sub> O
CPAP	0.0 to 99.9 cm H <sub>2</sub> O
BIPAP (I)	0.0 to 99.9 cm H <sub>2</sub> O
BIPAP (E)	0.0 to 99.9 cm H <sub>2</sub> O

## 11.14 Input Parameters

Input Parameter	Maximum Length/Amount
Patient ID	16 alphanumeric characters
Patient Last Name	16 alphanumeric characters
Patient First Name	16 alphanumeric characters
Operator ID	16 alphanumeric characters
Operator Password	10 alphanumeric characters
Accession Number	16 alphanumeric characters
Sample Comment	48 alphanumeric characters
User Measurement Panels	1 default panel; 9 user-defined panels
Panel Name	16 alphanumeric characters
Report Title	6 lines, 24 alphanumeric characters each
QC Lot Number	10 alphanumeric characters
QC Description	20 alphanumeric characters
Definable QC Solutions	20
Routine QC Schedules	250
New Cartridge QC Schedules	10
CVP Lot Number	10 alphanumeric characters
CVP Description	20 alphanumeric characters
Definable CVP Solutions	20

## 11.15 CVP, PVP, and Quality Control Solutions

Product	Description
GEM CVP:	For verification of GEM Premier 3500 iQM cartridges prior to use with patient samples
P/N 24001587	Multipak, 20 ampules x 2.5 mL x 4 levels
GEM PVP:	For periodic use, as designated by some regulatory agencies. For use with any cartridge type.
P/N 24001515	PVP set, multipak, 4 x 5 levels
P/N 24001516	PVP Crit set, multipak, 4 x 4 levels
Quality Control Products:	
ContrIL 7:	For blood gas and electrolyte quality control
P/N 24001380	Multipak, 30 ampules x 2mL x 3 levels
P/N 24001381	Level 1, 30 ampules x 2mL
P/N 24001382	Level 2, 30 ampules x 2 mL
P/N 24001383	Level 3, 30 ampules x 2 mL
ContrIL 9:	For blood gas, electrolyte, glucose, and lactate quality control
P/N 24001418	Multipak, 30 ampules x 2mL x 3 levels
P/N 24001419	Level 1, 30 ampules x 2mL
P/N 24001420	Level 2, 30 ampules x 2mL
P/N 24001421	Level 3, 30 ampules x 2mL
GEM critCheck:	For hematocrit quality control
P/N 002309	Low and High, 15 ampules x 5mL x 2 levels



*NOTE: If you are using an IL CO-Oximeter device with the GEM Premier 3500, refer to the operator's manual for the CO-Oximeter for information about QC solutions for use with the device.*

## 11.16 iQM Process Schedules

### iQM Process B

Cartridge life (after warm-up)	iQM Process "B" 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 iQM Process B's, all sensor outputs are being monitored every 30 seconds and an automatic iQM Process B's will be initiated if excessive drift in any channel is detected.

### Full iQM Process

Cartridge life (after warm-up)	Full iQM Process frequency
30 minutes to less than 50 minutes	every 20 minutes
50 minutes to less than 80 minutes	every 30 minutes
80 minutes 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.

### iQM Process C

iQM Process C occur once every 24 hours throughout cartridge life (after warmup). Following the iQM Process C, the instrument will perform iQM Process "B" every three minutes for 15 minutes, then return to the previous schedule. The exact time of the day for performing the iQM Process C is determined by the user.

### Instrument Restart

During the recovery following instrument restart, the instrument will perform an iQM Process B and a Full iQM Process as needed before the Ready screen is displayed, then the iQM Process frequency will be according to the previous schedules.

## 11.17 Input/Output Ports

**Figure 11.1: GEM Premier 3500 Back Panel**




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Port	Description		
Serial A, Serial B, and Serial C ports:	Standard DB-9 male connectors provide serial data interface to external devices and networks in RS-232C format. The serial ports conform to the PC standard and have pins defined as below. Serial B port is used for the GEM PCL (and PCL Plus) interface.		
Pins:	1 dcd	4 dtr	7 rts
	2 rxd	5 gnd	8 cts
	3 txd	6 dsr	9 ri

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Parallel port: Standard DB-25 female connector provides a parallel data interface intended to be connected with an external printing device. The Parallel port conforms to the PC standard and has the pins defined as below. The Parallel port is used to interface to an external parallel printer.

Pins:	1 -strobe	8 data 6	14 -autofeed	20 gnd
	2 data 0	9 data 7	15 -error	21 gnd
	3 data 1	10 -ack	16 -reset	22 gnd
	4 data 2	11 busy	17 sel in	23 gnd
	5 data 3	12 paper out	18 gnd	24 gnd
	6 data 4	13 sel out	19 gnd	25 gnd
	7 data 5			

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Ethernet port: Standard RJ-45 female connector provides for connection to either 10Mbps Ethernet or 100Mbps fast Ethernet networks.

USB ports:	Accepts USB devices, such as the barcode gun that is supplied with the instrument, a supported printer, and a supported storage medium. The connectors are standard USB.
Barcodes Standards:	Recognizes standard barcode types 39 and 128, subcodes A, B, and C. Code 128C will not recognize an ID with a leading zero. See section 1.6 for additional information about GEM Premier 3500 PAK barcodes.
9V Power port:	Intends to provide power to the base of an optional wireless barcode gun.

## 11.18 Typical Analytical Performance

Performance characteristics reflect the typical imprecision and inaccuracy expected from a GEM Premier 3500 that is operated according to specifications, instructions for use and specific method evaluation procedure. Actual performance may vary due to variation in method characteristics (lot-to-lot consistency, instrumental differences) and environmental conditions.

### Definitions

#### Bias

The difference between the mean of the test results and an accepted reference value obtained from a specific method evaluation procedure.

#### Calibration

The process of testing and adjusting values obtained from the instrument to provide a known relationship between the response measurement and the value of the analyte measured by the procedure.

#### Coefficient of Variation (%CV)

Gives a measure of precision expressed as a percentage of the standard deviation (SD) to the Mean. %CV facilitates the comparison of precision between different levels. Rule of thumb: A %CV <5.0 is generally indicative of an acceptable level of variation from a well functioning analyzer at the 95% confidence level.

$$\%CV = \frac{SD \times 100\%}{X}$$

#### Correlation

The comparison of results between the test (new) and the reference (old) method.

#### Evaluation data

Evaluation data are the statistical summaries of the results that have been obtained from a specific method evaluation procedure.

#### Inaccuracy

Numerical difference between the mean of a set of replicate measurement and the true value obtained from a specific method evaluation procedure.

#### Imprecision

Any of a number of expressions of quantitative measures of random dispersion of a set of replicate measurements (i.e., standard deviation, coefficient of variation, etc.) obtained from a specific method evaluation procedure. The presence of random error, variability, or inconsistency.

#### Mean (X)

The average of the numerical results obtained from a series of analyses. The average of all acceptable test values for each parameter.

$$X = \frac{\Sigma X}{n}$$

**Performance Limits**

The maximum error that users should achieve from a specific method evaluation procedure.

**Point Estimate**

The point estimate is a convenient means of describing evaluation results as a single value.

**Reportable Range**

The range of results from a GEM Premier 3500 system over which the performance characteristics are expected to be achieved.

**Standard Deviation**

A measure of the distribution of test values around the mean. In a normal distribution, 68% of all values fall within a 1 SD range, 95.5% within a 2 SD range and 99.7% within a 3 SD range.

$$SD = \sqrt{\frac{\sum(X - \bar{X})^2}{n-1}}$$

**Verification**

A procedure used to determine, with a high degree of confidence, that a test system or device performs as claimed when used by the persons who routinely perform patient testing.

**Performance Characteristics Summary****Introduction**

The following analytical data were collected during evaluation studies at Instrumentation Laboratory's facilities and at an external field site. These studies demonstrate the typical performance characteristics of the GEM Premier 3500.

**Quality Control Material Precision**

Blood gas precision data were generated by using three aqueous control levels of Controll 9 for pH,  $pCO_2$ ,  $pO_2$ ,  $Na^+$ ,  $K^+$ ,  $Ca^{++}$ , glucose, lactate and two control levels of GEM critCheck for hematocrit. Based on NCCLS guidelines, control levels were run in replicates of two once a day for 14 days (twice on Day one) for a total of 30 replicates on each of seven different instruments ( $N=210$ ). The following table lists the combined results of the seven instruments.



*NOTE: SD is used for pH since differences are so small that %CV would be misleading.*

**Combined Precision Data for Controll 9 or GEM critCheck****Level 1**

Parameter	Mean	Within Run %CV (or SD)	Day to Day %CV (or SD)	Total %CV (or SD)
pH	7.15	0.008 (SD)	0.005 (SD)	0.009 (SD)
$pCO_2$ (mmHg)	67	2.69	0.48	2.74
$pO_2$ (mmHg)	72	1.25	2.3	2.63
$Na^+$ (mmol/L)	159	0.50	0.71	0.86
$K^+$ (mmol/L)	5.8	0.60	0.40	0.71
$Ca^{++}$ (mmol/L)	1.59	0.76	1.56	1.74
Glucose (mg/dL)	274	2.04	0.70	2.16
Lactate (mmol/L)	5.1	2.13	1.13	2.41
Hematocrit (%)	24	0.91	1.20	1.50

**Level 2**

Parameter	Mean	Within Run %CV (or SD)	Day to Day %CV (or SD)	Total %CV (or SD)
pH	7.46	0.004 (SD)	0.002 (SD)	0.005 (SD)
$pCO_2$ (mmHg)	35	1.59	0.21	1.60
$pO_2$ (mmHg)	106	0.87	1.27	1.48
$Na^+$ (mmol/L)	140	0.55	0.47	0.73
$K^+$ (mmol/L)	4.0	0.99	0.59	1.11
$Ca^{++}$ (mmol/L)	1.13	1.03	0.56	1.17
Glucose (mg/dL)	91	2.21	0.93	2.39
Lactate (mmol/L)	1.0	4.11	0.87	4.23
Hematocrit (%)	42	0.75	0.76	1.07

**Level 3**

Parameter	Mean	Within Run %CV (or SD)	Day to Day %CV (or SD)	Total %CV (or SD)
pH	7.66	0.004 (SD)	0.003 (SD)	0.005 (SD)
pCO <sub>2</sub> (mmHg)	17	2.28	1.70	2.78
pO <sub>2</sub> (mmHg)	163	0.63	0.31	0.70
Na <sup>+</sup> (mmol/L)	120	0.32	1.04	1.09
K <sup>+</sup> (mmol/L)	2.8	0.94	1.30	1.69
Ca <sup>++</sup> (mmol/L)	0.65	0.72	2.11	2.23
Glucose (mg/dL)	63	1.71	2.24	2.95
Lactate (mmol/L)	2.8	1.46	2.70	3.02
Hematocrit (%)	NA	NA	NA	NA

**GEM CVP Precision – iQM Cartridges**

Precision data were generated at Instrumentation Laboratory using GEM CVP (Calibration Validation Product): two levels for pH, blood gases, electrolytes and metabolites, and two levels for hematocrit. Based on NCCLS guidelines, the verification material levels were run in singlet once a day for 14 days (twice on Day 1) for a total of 15 replicates on each of 9 different instruments (N=135). The table below lists the combined results of the 9 instruments.



*NOTE: SD is used for pH since differences are so small that %CV would be misleading.*

**GEM CVP Level 1**

Parameter	Mean	Day-to-Day %CV (or SD)	Total %CV (or SD)
pH	7.200	0.005 (SD)	0.007 (SD)
pCO <sub>2</sub> (mmHg)	70.8	1.39	1.63
pO <sub>2</sub> (mmHg)	54.5	4.97	5.16
Na <sup>+</sup> (mmol/L)	129.3	0.46	0.55
K <sup>+</sup> (mmol/L)	2.90	0.25	0.70
Ca <sup>++</sup> (mmol/L)	1.493	0.95	1.26
Glucose (mg/dL)	46.1	2.23	2.99
Lactate (mmol/L)	0.93	4.73	4.87

**GEM CVP Level 2**

Parameter	Mean	Day-to-Day %CV (or SD)	Total %CV (or SD)
pH	7.640	0.002 (SD)	0.003 (SD)
pCO <sub>2</sub> (mmHg)	29.9	1.78	1.91
pO <sub>2</sub> (mmHg)	148.2	1.33	1.93
Na <sup>+</sup> (mmol/L)	158.7	0.44	0.56
K <sup>+</sup> (mmol/L)	6.46	0.75	0.98
Ca <sup>++</sup> (mmol/L)	0.486	1.15	2.06
Glucose (mg/dL)	192.8	1.67	1.78
Lactate (mmol/L)	5.54	1.85	2.19

**GEM CVP Level 3**

Parameter	Mean	Day-to-Day %CV (or SD)	Total %CV (or SD)
Hematocrit (%)	23.4	2.14	2.11

**GEM CVP Level 4**

Parameter	Mean	Day-to-Day %CV (or SD)	Total %CV (or SD)
Hematocrit (%)	43.8	1.21	1.23

**Whole Blood Precision**

Whole blood precision testing was performed, spanning the three-week cartridge use life. Six levels (for pH, gases, and glucose), five levels (for lactate), and seven levels (for electrolytes and hematocrit) were evaluated using whole blood from healthy adult volunteers. Samples were altered with various levels of analytes (salts, gases or plasma) to span the claimed measuring range and tested in four replicates per run. Glucose was tested once per week for three weeks while pH, gases, electrolytes and hematocrit were tested in weeks one and three on seven different instruments. Lactate was tested once in week two on 9 different instruments. Shown in the following tables are the within-run standard deviations and %CV pooled to determine the average imprecision per level.



*NOTE: Because of various factors, not all levels of analytes had the same number of replicates. Some data points were eliminated because of hemolysis or missing reference values. For each analyte level, the number of replicates is shown in the table (N = between 32 and 84).*

**Combined Within Run Precision Data for Whole Blood****pH Whole Blood Precision**

N per Level	Mean	SD	%CV
55	7.153	0.012	0.17
56	7.175	0.007	0.10
49	7.280	0.011	0.14
56	7.381	0.007	0.09
56	7.504	0.006	0.08
56	7.682	0.009	0.11

**pCO<sub>2</sub> Whole Blood Precision**

N per Level	Mean (mmHg)	SD	%CV
56	8.3	0.47	5.63
56	22.9	0.40	1.75
56	39.8	0.57	1.43
49	61.2	1.53	2.50
56	92.2	2.33	2.53
55	105.3	2.97	2.82

**pO<sub>2</sub> Whole Blood Precision**

N per Level	Mean (mmHg)	SD	%CV
55	29.4	0.79	2.67
56	51.2	1.42	2.77
49	103.9	2.07	1.99
42	211.5	3.46	1.67
42	401.8	5.80	1.46
42	683.7	8.51	1.25

**Na<sup>+</sup> Whole Blood Precision**

N per Level	Mean (mmol/L)	SD	%CV
54	110.4	0.50	0.46
54	121.3	0.89	0.74
53	132.0	1.53	1.16
55	138.0	0.84	0.61
56	155.9	0.77	0.50
56	169.3	1.58	0.93
56	187.0	1.70	0.91

**K<sup>+</sup> Whole Blood Precision**

N per Level	Mean (mmol/L)	SD	%CV
56	2.36	0.083	3.53
54	3.47	0.116	3.34
54	4.59	0.080	1.74
54	5.58	0.160	2.86
56	7.24	0.057	0.79
56	9.48	0.107	1.13
54	17.0	0.253	1.48

**Ca<sup>++</sup> Whole Blood Precision**

N per Level	Mean (mmol/L)	SD	%CV
56	0.62	0.018	2.83
56	0.99	0.016	1.65
49	1.50	0.026	1.74
26	1.62	0.021	1.28
54	2.71	0.102	3.75
56	3.44	0.081	2.36
32	4.96	0.121	2.44

**Glucose Whole Blood Precision**

<b>N per Level</b>	<b>Mean (mg/dL)</b>	<b>SD</b>	<b>%CV</b>
84	30.0	1.50	5.00
84	53.1	2.08	3.92
84	97.6	3.02	3.10
84	177.4	6.93	3.91
84	348.5	14.9	4.28
84	441.0	21.1	4.78

**Lactate Whole Blood Precision**

<b>N per Level</b>	<b>Mean (mmol/L)</b>	<b>SD</b>	<b>%CV</b>
33	1.15	0.07	6.26
36	3.09	0.06	1.94
36	6.29	0.09	1.47
36	11.58	0.36	3.09
36	15.54	0.21	1.35

**Hematocrit Whole Blood Precision**

<b>N per Level</b>	<b>Mean (%)</b>	<b>SD</b>	<b>%CV</b>
55	16.0	0.58	3.64
47	22.1	0.56	3.39
55	22.1	0.22	2.14
49	28.3	0.54	2.59
53	35.1	0.85	2.62
56	44.5	0.40	1.42
53	61.6	1.03	1.65

## Whole Blood Inaccuracy

The data from the whole blood precision study were used in the following inaccuracy calculations. Tonometry was used as the reference for  $pCO_2$  and  $pO_2$ , and manual spun hematocrit was used as the reference for hematocrit. A traditional laboratory blood gas and electrolyte system was used to obtain reference values for pH,  $Na^+$ ,  $K^+$ ,  $Ca^{++}$ , glucose and lactate. The bias results were calculated using the pooled instrument results and subtracting the reference (target) test results. The bias for each parameter at each level was then compared to the acceptance criteria as shown in the table below and on the next page. All parameter levels passed specification\*.



*\*NOTE: Specification (Ea) is the allowable error established from CLIA 88 or from internal specification claims (bias at upper 95% confidence limit).*

### pH Whole Blood Inaccuracy

N per Level	Mean (pH Units)	Target (pH Units)	Bias	Specification (Ea) (pH Units)
55	7.153	7.136	0.017	$\pm 0.04$
56	7.175	7.160	0.015	$\pm 0.04$
49	7.280	7.267	0.014	$\pm 0.04$
56	7.381	7.373	0.008	$\pm 0.04$
56	7.504	7.501	0.003	$\pm 0.04$
56	7.682	7.681	0.001	$\pm 0.04$

### $pCO_2$ Whole Blood Inaccuracy

N per Level	Mean (mmHg)	Target (mmHg)	Bias	Specification (Ea) (mmHg)
56	8.3	10.8	-2.49	$\pm 5.0$
56	22.9	25.2	-2.28	$\pm 5.0$
56	39.8	41.5	-1.70	$\pm 5.0$
49	61.2	62.4	-1.19	$\pm 5.0$
56	92.2	93.6	-1.37	$\pm 7.5$
55	105.3	109.4	-4.06	$\pm 8.8$

**pO<sub>2</sub> Whole Blood Inaccuracy**

N per Level	Mean (mmHg)	Target (mmHg)	Bias	Specification (Ea) (mmHg)
55	29.4	31.1	-1.70	± 7.8
56	51.2	52.4	-1.20	± 10.5
49	103.9	104.3	-0.40	± 10.4
42	211.5	207.1	4.4	± 20.7
42	401.8	417.3	-15.5	± 41.7
42	683.7	708.7	-25.0	± 70.9

**Na<sup>+</sup> Whole Blood Inaccuracy**

N per Level	Mean (mmol/L)	Target (mmol/L)	Bias	Specification (Ea) (mmol/L)
54	110.4	109.8	0.6	± 4.0
54	121.3	121.3	0.0	± 4.0
53	132.0	131.9	0.1	± 4.0
55	138.0	136.5	1.5	± 4.0
56	155.9	155.6	0.3	± 4.0
56	169.3	169.0	0.3	± 4.0
56	187.0	187.0	0.0	± 4.0

**K<sup>+</sup> Whole Blood Inaccuracy**

N per Level	Mean (mmol/L)	Target (mmol/L)	Bias	Specification (Ea) (mmol/L)
56	2.36	2.36	0.00	± 0.5
54	3.47	3.35	0.12	± 0.5
54	4.59	4.58	0.01	± 0.5
54	5.58	5.56	0.02	± 0.5
56	7.24	7.39	-0.15	± 0.5
56	9.48	9.90	-0.42	± 1.0
54	17.02	17.59	-0.57	± 1.8

**Ca<sup>++</sup> Whole Blood Inaccuracy**

N per Level	Mean (mmol/L)	Target (mmol/L)	Bias	Specification (Ea) (mmol/L)
56	0.62	0.69	-0.07	± 0.10
56	0.99	1.02	-0.03	± 0.10
49	1.50	1.52	-0.02	± 0.10
26	1.62	1.67	-0.05	± 0.10
54	2.71	2.67	-0.04	± 0.27
56	3.44	3.58	-0.14	± 0.43
32	4.96	4.65	0.31	± 0.70

**Glucose Whole Blood Inaccuracy**

N per Level	Mean (mg/dL)	Target (mg/dL)	Bias	Specification (Ea) (mg/dL)
84	30.0	30.2	-0.2	± 9.1
84	53.1	53.3	-0.2	± 5.3
84	97.6	97.8	-0.2	± 9.8
84	177.4	175.5	1.9	± 17.6
84	348.5	342.9	5.6	± 34.3
84	441.0	432.1	8.9	± 43.2

**Lactate Whole Blood Inaccuracy**

N per Level	Mean (mmol/L)	Target (mmol/L)	Bias	± Bias Spec. (mmol/L)
33	1.15	1.22	-0.07	± 0.20
36	3.09	3.11	-0.02	± 0.22
36	6.29	6.33	-0.04	± 0.38
36	11.58	11.58	0.00	± 0.85
36	15.54	14.95	0.59	± 1.10

## Hematocrit Whole Blood Inaccuracy

N per Level	Mean (%)	Target (%)	Bias	Specification (Ea) (%)
55	16.0	17.6	-1.6	± 3.0
47	22.1	19.9	2.2	± 3.0
55	22.1	24.0	-1.9	± 4.0
49	28.3	27.9	0.4	± 4.0
53	35.1	34.0	1.1	± 4.0
56	44.5	43.8	0.7	± 4.0
53	61.6	60.5	1.1	± 4.0

## Linearity

The data from the whole blood precision study (see previous section) was used in the following linearity calculations.

The data are presented in the following table and graphs.

Parameter	N per Level	Slope	Intercept	R2
pH	49 to 56	0.970	0.231	0.997
pCO <sub>2</sub> (mmHg)	49 to 56	1.020	-2.65	0.996
pO <sub>2</sub> (mmHg)	42 to 56	0.961	3.395	0.999
Na <sup>+</sup> (mmol/L)	53 to 56	0.995	1.177	0.997
K <sup>+</sup> (mmol/L)	54 to 56	0.954	0.192	0.999
Ca <sup>++</sup> (mmol/L)	26 to 56	1.043	-0.106	0.990
Glucose (mg/dL)	30 to 32	1.012	-1.369	0.997
Lactate (mmol/L)	32 to 33	1.031	-0.028	0.999
Hct (%)	47 to 56	1.039	-1.035	0.989

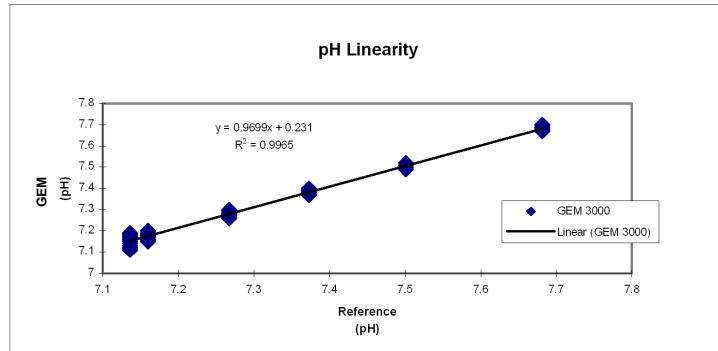


Figure 11.2: pH Linearity

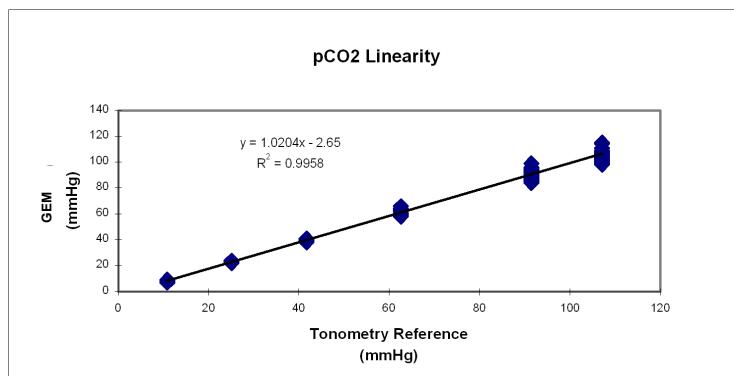


Figure 11.3: pCO<sub>2</sub> Linearity

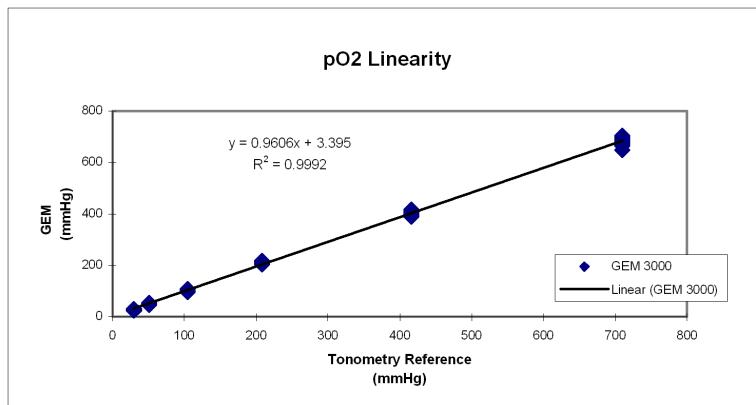
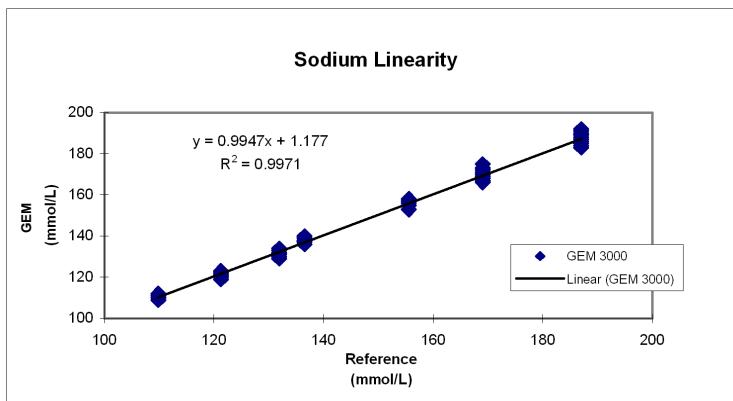
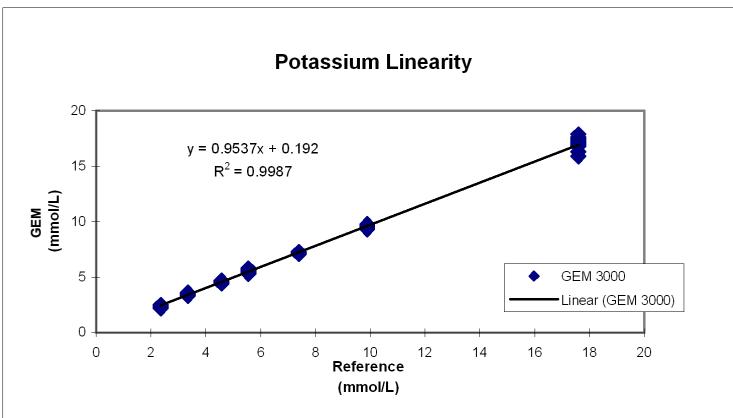
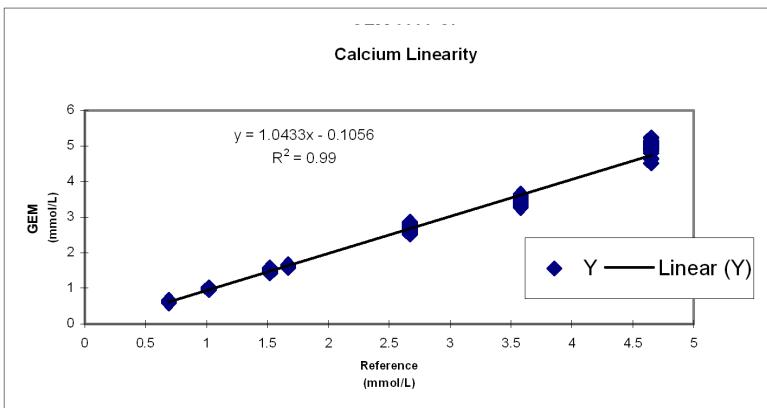
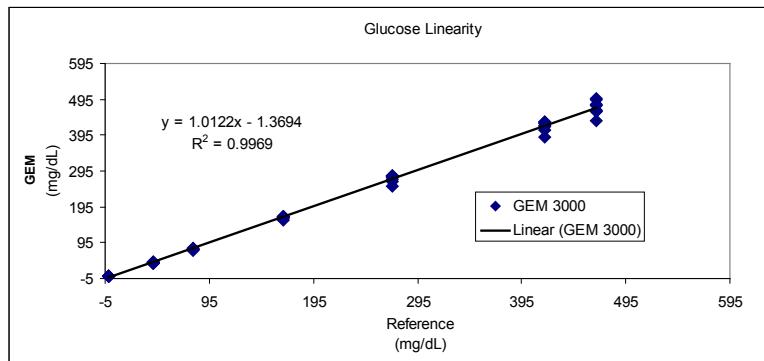
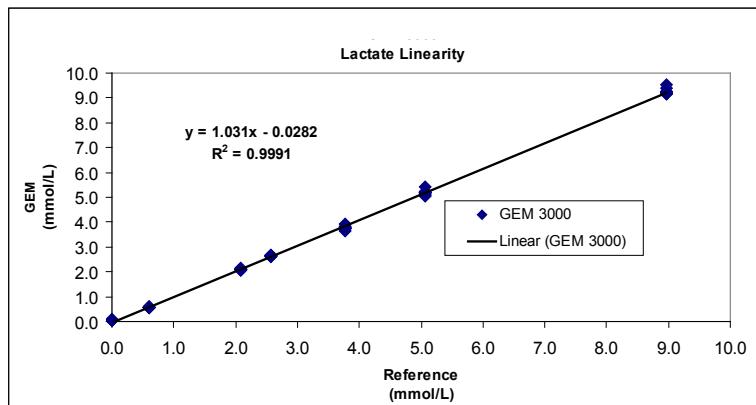


Figure 11.4: pO<sub>2</sub> Linearity

Figure 11.5:  $\text{Na}^+$  LinearityFigure 11.6  $\text{K}^+$  LinearityFigure 11.7:  $\text{Ca}^{++}$  Linearity



54



55

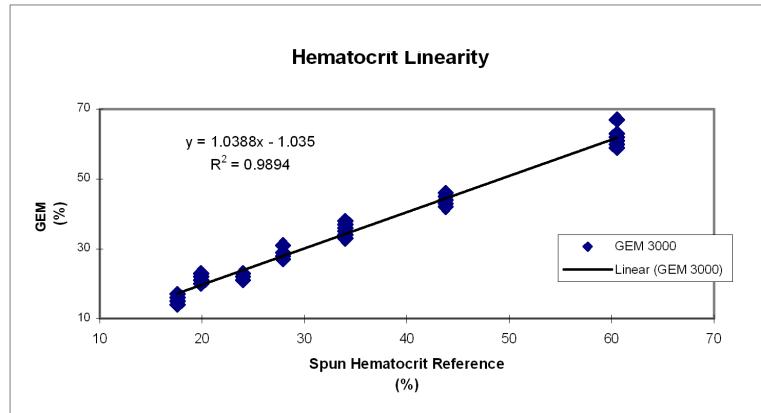


Figure 11.10 Hematocrit Linearity

## Method Comparison

Arterial, venous, heart bypass and liver transplant blood samples were obtained from patients using heparinized syringes, and tested by health care professionals. The table and graphs below show that the instrument using iQM cartridge is statistically similar in performance to the reference analyzer.

Analyte	N	Slope	Intercept	r	Sample Range
pH	281	1.0802	-0.581	0.9917	7.129-7.559
pCO <sub>2</sub> (mmHg)	282	1.0674	-2.380	0.9839	25.3-87.5
pO <sub>2</sub> (mmHg)	282	0.9715	6.990	0.9988	26-489
Na <sup>+</sup> (mmol/L)	271	0.9801	2.926	0.9584	119-148
K <sup>+</sup> (mmol/L)	271	0.9743	-0.061	0.9871	3.2-7.4
Ca <sup>++</sup> (mmol/L)	271	0.9196	0.127	0.9590	0.82-1.40
Glucose (mg/dL)	283	1.0111	8.868	0.9860	66-389
Lactate (mmol/L)	279	0.9382	0.163	0.9957	0.49-15.07
Hct (%)	284	0.9983	-0.800	0.9600	17-56

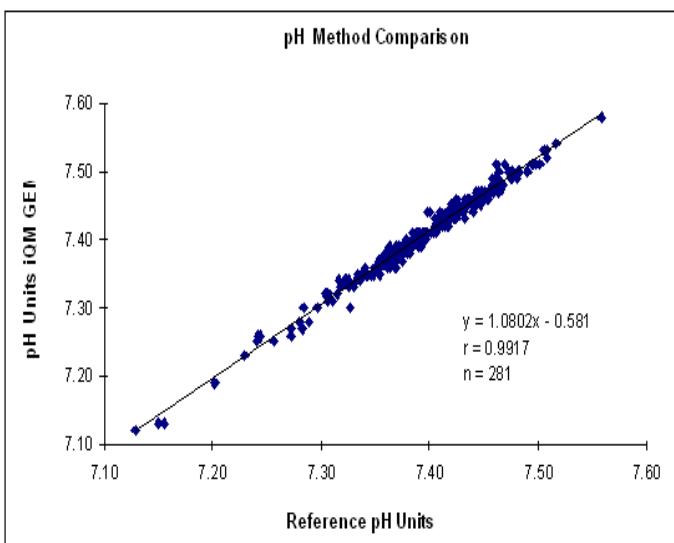


Figure 11.11: pH Method Comparison

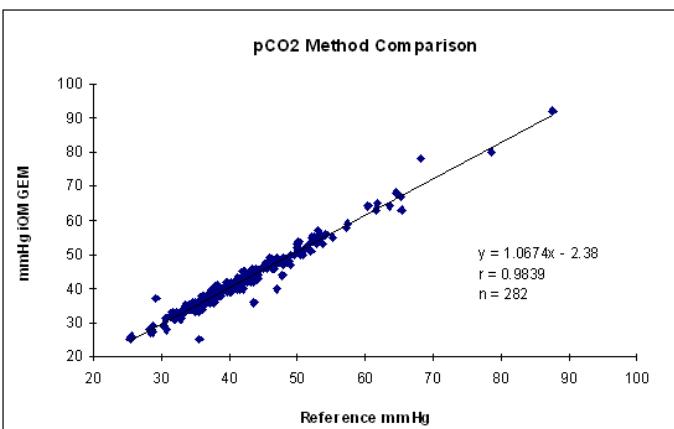


Figure 11.12: pCO<sub>2</sub> Method Comparison

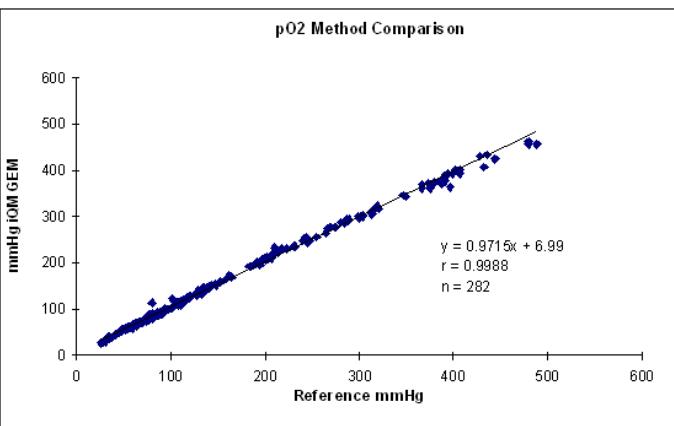


Figure 11.13: pO<sub>2</sub> Method Comparison

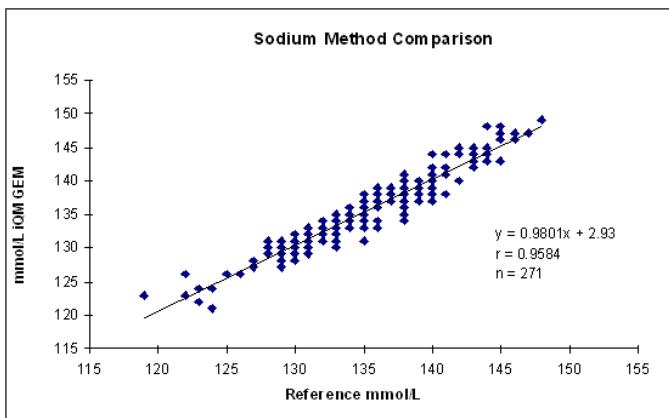


Figure 11.14:  $\text{Na}^+$  Method Comparison

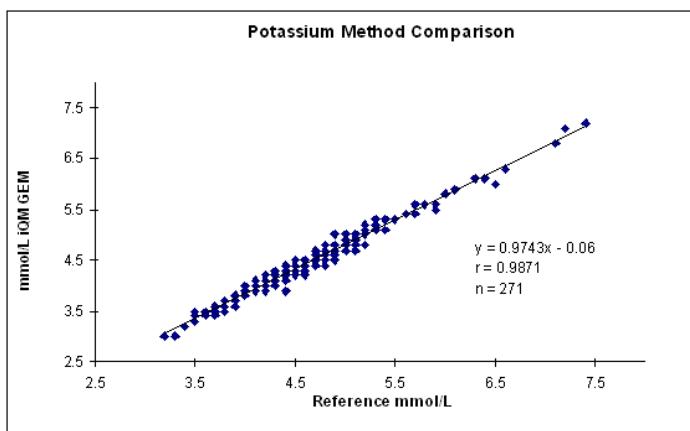


Figure 11.15:  $\text{K}^+$  Method Comparison

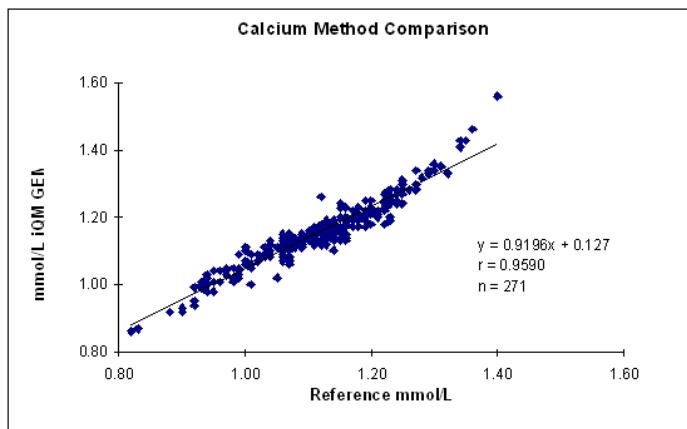


Figure 11.16:  $\text{Ca}^{++}$  Method Comparison

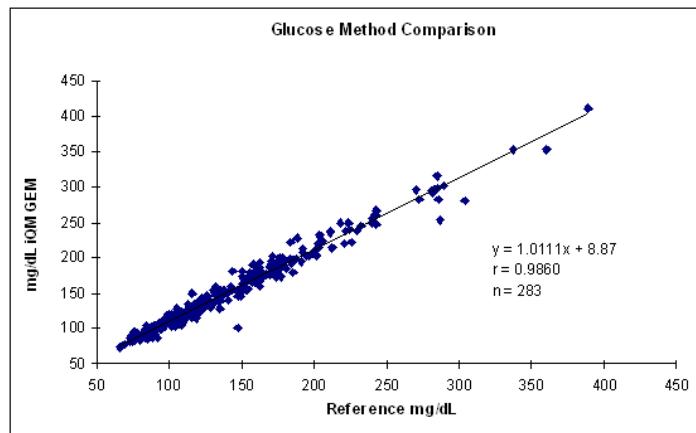


Figure 11.17: Glucose Method Comparison

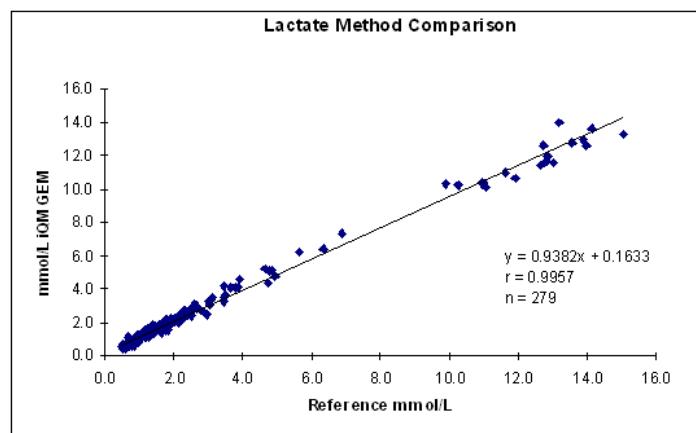


Figure 11.18: Lactate Method Comparison

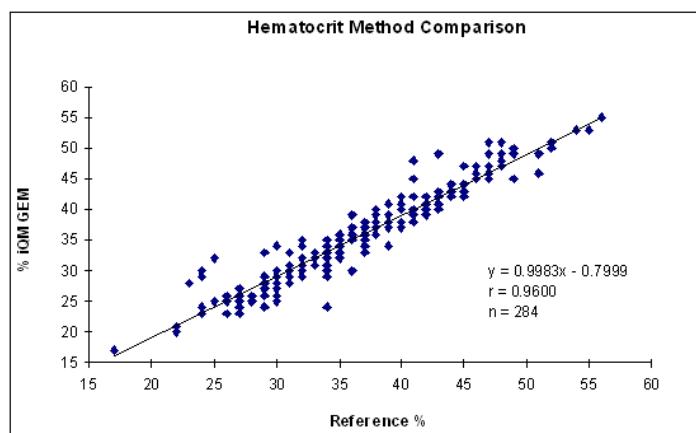


Figure 11.19: Hematocrit Method Comparison

## 11.19 Intelligent Quality Management (iQM) Evaluation

### Evaluation of Cartridge Malfunction Detection

Data from 79 Instruments cartridges that demonstrated a QC failure during their cartridge use life were extensively analyzed. The Failure Pattern Recognition (FPR) checks were applied to these data to determine if iQM could detect any malfunction.

The Failure Pattern Recognition (FPR) checks were able to detect malfunction in 74 out of 79 reported QC failures. In most cases, iQM would have flagged the failure immediately after the sample that caused the malfunction, while with conventional external controls, the user would only be aware of a problem when the external control was run again, which may be up to hours after the event occurred. Furthermore, no false positive flags were generated by the FPR checks in any of the 79 investigated cartridges.

### Resolution of 5 Unflagged QC Failures

For the 5 reported QC failures that iQM did not detect, there was no identifiable cartridge malfunction. All system parameters were within specifications. There were no error flags and no failure patterns. There were no unusual blood values for the parameter with reported QC failure, and the customer did not report any concern about blood results. In all five cases, the reported QC failures were marginal and at one level only. It was concluded that the reported QC failures in these five cartridges could not represent a serious cartridge malfunction. The failures could be considered as a false positive QC failure.

### Field Evaluation: External QC vs. iQM

During an external field evaluation at a U.S. hospital, a side-by-side comparison was performed on a GEM instrument using iQM versus two reference instruments, IL Synthesis and another GEM instrument without iQM and using traditional external quality controls. This study was conducted over a 3-week period with the external quality controls run during each day's shift: ContrIL 9 on all three analyzers and GEM critCheck on the GEM analyzers only. Each GEM instrument used a single 450 sample capacity cartridge (1 instrument with iQM and 1 instrument without iQM). A total number of 304 blood samples were tested.

During this field evaluation, there were no instances of external quality control failure on any instrument. However, the instruments experienced transient drift failures caused by interference as noted below:

- There were 4 instances of Benzalkonium exposure, which caused analyte failures on all three instruments.
- There were 8 instances of Thiopental Sodium\* exposure, which caused analyte failures on both the GEM instruments, with and without iQM.

\*The IL Synthesis is not affected by Thiopental Sodium.

In all of the above cases, the GEM instrument using iQM successfully detected and flagged the failed analytes and identified the cause as an interference. All three systems self-corrected by the next sample run and therefore, the interference went undetected by external quality controls.

## 11.20 Calculation of Derived Parameters

The following paragraphs describe how the GEM Premier 3500 calculates derived parameters.

### Bicarbonate

#### Actual Bicarbonate ( $\text{HCO}_3^-$ )

$$\text{HCO}_3^- = 10^{(\text{pH} + \log(p\text{CO}_2) - 7.608)}$$

Most of the carbon dioxide of the blood is present in the form of bicarbonate ions. The ratio of  $\text{HCO}_3^-$  to  $p\text{CO}_2$  in the blood sample depends upon the acid-base balance, and in conjunction with other data, is useful in assessing the type of acid-base disturbances that exist in a given patient.

#### Standard Bicarbonate ( $\text{HCO}_3^- \text{ std}$ )

Standard bicarbonate is the bicarbonate concentration from blood that has been equilibrated at 37°C with a  $p\text{CO}_2$  of 40 mmHg and a  $p\text{O}_2$  to produce full oxygen saturation.

$$\text{HCO}_3^- \text{ std} = 25 + 0.78 \times \text{BE(B)} + 0.002 \times \text{Hgb} \times (\text{M} - 100)$$

Where:

$\text{BE(B)}$  = Base Excess in mmol/L

$\text{Hgb}$  = THb from attached IL CO-Oximeter in g/dL or

0.31 x Hct if no CO-Oximeter is attached;

Hct = 40% if Hct is unavailable

$\text{M}$  =  $\text{O}_2\text{Hb}$  from attached IL CO-Oximeter in % or  $\text{SO}_2\text{c}$

If no CO-Oximeter is attached

### Oxygen Saturation ( $\text{SO}_2\text{c}$ )

$$\text{SO}_2\text{O} = 100 \left[ 1 + \frac{23400}{(p\text{O}_2\text{pp})^3 + 150 \times p\text{O}_2\text{pp}} \right]$$

where  $p\text{O}_2\text{pp}$  is partial pressure of oxygen in blood at pH=7.4 and T=37°C and is calculated from (Severinghaus, J.W., American Physiological Society, 1979, page 599-602.).

$$p\text{O}_2\text{pp} = p\text{O}_2 \times e^{((p\text{O}_2/26.7)^{0.184}) + 0.003 \times \text{BE(B)} - 2.2 \times (7.4 - \text{pH})}$$

where  $e = 2.718$  and  $\text{BE(B)}$  is in-vitro base excess and is calculated from the formula described by Siggaard-Anderson:

$$\text{BE(B)} = (1 - 0.014 \times \text{Hgb}) \times [\text{HCO}_3^- - 24 + (1.63 \times \text{Hgb} + 9.5) \times (\text{pH} - 7.4)]$$

$$\text{Hgb} = 0.31 \times \text{Hct}$$

Oxygen saturation is a ratio, expressed as a percentage of the volume of oxygen carried to the maximum volume which the blood could carry. Knowing the SO<sub>2</sub> is useful for predicting the amount of oxygen available for tissue perfusion.

### Total Carbon Dioxide (TCO<sub>2</sub>)

Concentration of free and bound CO<sub>2</sub> in plasma.

$$\text{TCO}_2 = \text{HCO}_3^- + (0.0307 \times p\text{CO}_2)$$

where HCO<sub>3</sub><sup>-</sup> is actual bicarbonate.

### In-vivo Base Excess BE(ecf)

Base excess of extracellular fluid is a term that approximates the amount of acid or base that would be needed to titrate one liter of *extracellular fluid* to a pH of 7.40 with a pCO<sub>2</sub> of 40 mmHg at 37°C.

Also called standard base excess, in-vivo base excess reflects the metabolic, nonrespiratory component of pH disturbances.

- IL equation:

$$\text{BE}(\text{ecf}) = (1 - 0.004 \times \text{Hgb}) \times (\text{HCO}_3^- - 24) + (9 + 0.03 \times \text{Hgb}) \times (\text{pH} - 7.4) - (0.03 \times \text{Hgb}) \times (100 - \text{SO}_2)/100$$

Reference: Dell RB, Winters RW. *Am J. Physiol* 1970;219:37-44 and Dell RB, Lee CE, Winters RW. *Pediatr Res* 1971;5:523-538.

- NCCLS equation:

$$\text{BE}(\text{ecf}) = \text{HCO}_3^- - 24.8 + 16.2 \times (\text{pH} - 7.4)$$

Reference: NCCLS document C46-P, NCCLS, Wayne, PA 2001, p.4.

### In-vitro Base Excess BE(B)

Base excess is a term that approximates the amount of acid or base that would be needed to titrate one liter of *blood* back to a normal pH of 7.40. This quantity is also called "in-vitro base excess."

- IL equation:

$$\text{BE}(\text{B}) = (1 - 0.014 \times \text{Hgb}) \times [\text{HCO}_3^- - 24 + (1.63 \times \text{Hgb} + 9.5) \times (\text{pH} - 7.4)]$$

Reference: Siggaard-Andersen O, *The Acid-Base Status of the Blood*. 4th ed. Baltimore: Williams and Wilkins;1974:51,116.

- NCCLS equation:

$$\text{BE}(\text{B}) = (1 - 0.014 \times \text{Hgb}) \times [\text{HCO}_3^- - 24.8 + (7.7 + 1.43 \times \text{Hgb}) \times (\text{pH} - 7.4)]$$

Reference: NCCLS document C46-P, NCCLS, Wayne, PA, 2001, p.5.

Where:

Hgb	THb from attached IL CO-Oximeter in g/dL or 0.31 × Hct if no CO-Oximeter is attached; Hct = 40% if Hct is unavailable
-----	---

HCO <sub>3</sub> -	Actual bicarbonate derived from the sample
pH	pH result from the sample

**O<sub>2</sub>ct**

O<sub>2</sub>ct, oxygen content, is calculated externally on the attached IL 682 or GEM OPL CO-Oximeter. The GEM Premier 3500 will report the result as received without performing any limit checks on the value. If the current sample is blood gas only, this parameter is not reported (omitted from the report, as if disabled in setup).

The GEM Premier 3500 reports O<sub>2</sub>ct as it is received from the CO-Oximeter, without performing a reportable range check.

**O<sub>2</sub>cap**

O<sub>2</sub>cap, oxygen capacity, is calculated externally on the attached IL 682 or GEM OPL CO-Oximeter. The GEM Premier 3500 will report the result as received without performing any limit checks on the value. If the current sample is blood gas only, this parameter is not reported (omitted from the report, as if disabled in setup).

The GEM Premier 3500 reports O<sub>2</sub>cap as it is received from the CO-Oximeter, without performing a reportable range check.

**A-aDO<sub>2</sub>**

The alveolar-arterial oxygen gradient, A-aDO<sub>2</sub>, is calculated using the following equation:

$$A-aDO_2 = pAO_2 - paO_2(T)$$

Where:

pAO<sub>2</sub> Alveolar oxygen partial pressure, corrected for patient temperature

paO<sub>2</sub>(T) pO<sub>2</sub> for the current arterial sample, corrected for patient temperature. Use non-temperature corrected value if pO<sub>2</sub>(T) is unavailable.

If the antecedent analytes are reported, the calculated parameter will be reported too.

**pAO<sub>2</sub>**

The alveolar oxygen partial pressure, pAO<sub>2</sub>, gives a general indication of the efficiency of the oxygen exchange process in the alveolar-capillary unit. The following equation is used:

$$pAO_2 = FiO_2 \times (BP - 47 \times paCO_2(T))$$

Where:

FiO<sub>2</sub> Fraction of inspired oxygen (operator entered %FiO<sub>2</sub>/100)

BP Operator entered barometric pressure in mmHg

T Operator entered patient temperature in Celsius (use 37°C if not entered)

paCO<sub>2</sub>(T) pCO<sub>2</sub> for the current arterial sample, corrected for patient temperature. Use non-temperature corrected value if pCO<sub>2</sub>(T) is not available.

References: *Intensive Care and Clinical Biochemistry*, Gosling, Marshall, and Clapham, ABC Venture Publication, London, 1994 p.17.; *Practical Math for Respiratory Care*, Sibberson, Mosby, 1996.

**paO<sub>2</sub>/pAO<sub>2</sub>**

The arterial-alveolar oxygen ratio, paO<sub>2</sub>/pAO<sub>2</sub>, is calculated by dividing:

paO<sub>2</sub>(T)       $pO_2$  for the current arterial sample, corrected for patient temperature. Use non-temperature corrected value if the temperature was not entered.

by:

pAO<sub>2</sub>      Alveolar oxygen partial pressure, in mmHg (see previous equation).

If the antecedent analytes are reported, the calculated parameter will be reported too.

**RI**

The respiratory index, RI, is calculated with the following equation:

$$RI = A-aDO_2/paO_2(T)$$

Where:

A-aDO<sub>2</sub>      Alveolar-arterial oxygen gradient in mmHg (see previous equation)

paO<sub>2</sub>(T)       $pO_2$  for the current arterial sample, corrected for patient temperature. Use non-temperature corrected value of  $pO_2(T)$  if it is not available.

If the antecedent analytes are reported, the calculated parameter will be reported too.

**CaO<sub>2</sub>**

CaO<sub>2</sub> is the arterial oxygen content. If CaO<sub>2</sub> is reported for the current sample (and not incalculable), O<sub>2</sub>ct (from an attached IL CO-Oximeter) will not be reported (omitted from the report, as if it is disabled in setup). The following equation will be used:

$$CaO_2 = (0.0139 \times THb \times O_2Hb) + (0.0031 \times paO_2(T))$$

Where:

THb      Received from the external IL CO-Oximeter for current arterial sample, in g/dL

O<sub>2</sub>Hb      Received from the external IL CO-Oximeter for current arterial sample, %

paO<sub>2</sub>(T)       $pO_2$  (mmHg) for the current arterial sample, corrected for patient temperature. Use non-temperature corrected value if  $pO_2(T)$  is not available.

Reference: NCCLS Document C46-P, NCCLS, Wayne, PA, 2001, p.8.

If the antecedent analytes are reported, the calculated parameter will be reported too.

**CvO<sub>2</sub>**

CvO<sub>2</sub> is the mixed venous oxygen content. If CvO<sub>2</sub> is reported for the current sample (and not incalculable), O<sub>2</sub>ct from an attached IL CO-Oximeter will not be reported (omitted from the report, as if it is disabled in setup). The following equation will be used:

$$\text{CvO}_2 = (0.0139 \times \text{THb} \times \text{O}_2\text{Hb}) + (0.0031 \times p\text{O}_2(\text{T}))$$

Where:

THb Received from the external IL CO-Oximeter for current venous sample, in g/dL

O<sub>2</sub>Hb Received from the external IL CO-Oximeter for current venous sample, %

pO<sub>2</sub>(T) pO<sub>2</sub> (mmHg) for the current venous sample, corrected for patient temperature. Use non-temperature corrected value if pO<sub>2</sub>(T) is not available.

Reference: NCCLS Document C46-P, NCCLS, Wayne, PA, 2001, p.8.

If the antecedent analytes are reported, the calculated parameter will be reported too.

**CcO<sub>2</sub>**

The end pulmonary capillary oxygen content, CcO<sub>2</sub>, is calculated using the following equation:

$$\text{CcO}_2 = (1.39 \times \text{THb} \times \alpha) + (0.0031 \times p\text{AO}_2)$$

$$\alpha = (1 - \text{COHb}/100) - C$$

C = 0 if pAO<sub>2</sub> is greater than 150

C = 0.01 if pAO<sub>2</sub> is greater than 125 and less than or equal to 150

C = 0.02 if pAO<sub>2</sub> less than or equal to 125

Where:

THb Received from the external IL CO-Oximeter for the current arterial sample, in g/dL

COHb Received from the external IL CO-Oximeter for current arterial sample, %

pAO<sub>2</sub> Alveolar oxygen partial pressure for the current arterial sample, mmHg, as calculated in an earlier section.

Reference: R.D. Cane, et. al., *Crit Care Med*, 8, 294-297, 1980.

If the antecedent analytes are reported, the calculated parameter will be reported too.

**a-vDO<sub>2</sub> Calculation**

The arterial-mixed venous oxygen gradient, a-vDO<sub>2</sub>, is calculated only for venous samples using the following equation:

$$\text{a-vDO}_2 = \text{CaO}_2 - \text{CvO}_2$$

Where:

CaO<sub>2</sub> Arterial oxygen content, mL/dL, from the last arterial sample analyzed for the same patient within the previous 30 minutes. If no patient ID was

entered for the current venous sample, or if no matching arterial sample is found, or if the matching arterial was not an accepted sample, a-vDO<sub>2</sub> will not be calculated for the current venous sample (the line will be omitted from report, as if it is disabled in setup).

CvO<sub>2</sub>                  Venous oxygen content for the current venous sample, mL/dL

If the antecedent analytes are reported, the calculated parameter will be reported too.

### **Qsp/Qt**

The physiological shunt, Qsp/Qt, is calculated only for venous samples using the following equation:

$$\text{Qsp/Qt} = 100 \times (\text{CcO}_2 - \text{CaO}_2) / (\text{CcO}_2 - \text{CvO}_2)\%$$

Where:

CcO<sub>2</sub>, CaO<sub>2</sub>        End pulmonary capillary oxygen content and Arterial oxygen content (mL/dL), from the last arterial sample analyzed for the same patient within the previous 30 minutes. If no patient ID was entered for the current venous sample, or if no matching arterial sample is found, or if the matching arterial was not an accepted sample, Qsp/Qt will not be calculated for the current venous sample (line omitted from report, as if disabled in setup)

CvO<sub>2</sub>                  Venous oxygen content from the current venous sample, mL/dL, as calculated earlier.

Reference: *Intensive Care and Clinical Biochemistry*. Gosling P, Marshall WJ, Clapham MC, eds. ABC Venture Publications, London, 1994, p.20.

If the antecedent analytes are reported, the calculated parameter will be reported too.

### **Qsp/Qt(est)**

The estimated physiologic shunt, Qsp/Qt(est), is an alternative method for reflecting changes in the physiologic shunt using the following equation:

$$\text{Qsp/Qt(est)} = 100 \times (\text{CcO}_2 - \text{CaO}_2) / 3.5 + (\text{CcO}_2 - \text{CaO}_2)\%$$

Where:

CcO<sub>2</sub>, CaO<sub>2</sub>        End pulmonary capillary oxygen content and Arterial oxygen content (mL/dL), from the arterial sample analyzed.

3.5                      Assumed value for C(a-v)O<sub>2</sub>

*Note: Alternative methods for calculating the physiologic shunt can be applied only to patients with good cardiovascular function and stable metabolic rate.*

Reference: *Clinical Application of Blood Gases*. Shapiro BA, Peruzzi T, Kozelowski-Templin R. Mosby, St. Louis Fifth Edition, p.99.

If the antecedent analytes are reported, the calculated parameter will be reported too.

**P50**

The partial pressure of O<sub>2</sub> in a hemoglobin solution having an oxygen saturation of 50%, P50, is calculated only for venous samples. The following equation will be used:

$$P50 = 10^{-(Q / 2.7)}$$

$$Q = \log (R / (100 - R)) - 2.7 * \log (pvO_2(T))$$

R = O<sub>2</sub>Hb or SO<sub>2</sub>, as selected in configuration

Where:

pvO<sub>2</sub>(T)      pO<sub>2</sub> (mmHg) for the current venous sample, corrected for patient temperature. Use non-temperature corrected value if pO<sub>2</sub>(T) is not available.

O<sub>2</sub>Hb      Received from external CO-Ox for current venous sample, %. If O<sub>2</sub>Hb is not in the range 30 - 75%, P50 becomes incalculable.

SO<sub>2</sub>      O<sub>2</sub> saturation as received from the external IL CO-Oximeter for current venous sample, %. If SO<sub>2</sub> is not in the range 30 - 75%, P50 becomes incalculable.

Reference: Wimberley PD, et.al., *Scand J Clin Lab Invest* 1990;50,Suppl.203:227-234.

If the antecedent analytes are reported, the calculated parameter will be reported too.

**Total Hemoglobin (THbc)**

The estimated total hemoglobin (THbc) in the sample is obtained from the measured hematocrit. The system estimates total hemoglobin as follows:

$$THbc = [THbc/Hct Ratio] \times Hct$$

Where:

THbc/Hct Ratio      Selectable ratio between 0.31 and 0.37 in increments of 0.01. Default value is 0.31.

Hct      Reported Hct value in %.



*NOTE: THbc will not be calculated if measured THbc is reported from an attached IL CO-Oximeter.*

## 11.21 Temperature Correction

The following equations are used to calculate the temperature corrected blood gas parameters. All temperature corrections are done to the standard default unit of measure, in this case Celsius, and then converted to Fahrenheit if requested. Also, all temperature-correction equations are based on a standard temperature of 37°C (Kelman and Nunn) as can be seen by the constants used in the equations.

The measured value to be temperature-corrected must be rounded to the display resolution before it is used in these equations.

These computations are discussed by E.R. Ashwood, G. Kost, and M. Kenny, Clin. Chemistry, 1983, page 1877-1885.

### pH Temperature Correction

IL equation:

$$pH(T) = pH - 0.015 \times (TEMP - 37)$$

NCCLS equation:

$$pH(T) = pH + (TEMP - 37) \times [-0.0147 + 0.0065 \times (7.4 - pH)]$$

where pH = pH measured at 37°C, TEMP = patient temperature to be corrected to, and pH(T) = temperature-corrected pH.

### pCO<sub>2</sub> Temperature Correction

IL equation:

$$pCO_2(T) = pCO_2 \times 10^{0.021 \times (TEMP - 37)}$$

NCCLS equation:

$$pCO_2(T) = pCO_2 \times 10^{0.019 \times (TEMP - 37)}$$

where pCO<sub>2</sub> = pCO<sub>2</sub> measured at 37°C, TEMP = patient temperature to be corrected to, and pCO<sub>2</sub>(T) = temperature-corrected pCO<sub>2</sub>.

### pO<sub>2</sub> Temperature Correction

IL equation:

$$pO_2(T) = pO_2 \times 10^{[C \times (TEMP - 37)]}$$

Where:

$$C = 0.0052 + 0.0268 \times (1 - e^{[-0.3 \times (100 - SO_2)]})$$

NCCLS equation:

$$C = (5.49 \times 10^{-11} \times pO_2^{3.88} + 0.071) / (9.72 \times 10^{-9} \times pO_2^{3.88} + 2.3)$$

where pO<sub>2</sub> = pO<sub>2</sub> measured at 37°C, TEMP = patient temperature to be corrected to, pO<sub>2</sub>(T) = temperature-corrected pO<sub>2</sub>, e = 2.718, C = temporary, subordinate calculation, and SO<sub>2</sub> = oxygen saturation value from attached IL CO-Oximeter or the calculated saturation (SO<sub>2</sub>c) if measured SO<sub>2</sub> is unavailable.

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# 12 GEMweb

## 12.1 GEMweb Overview

The GEM Premier 3500 system software includes an integrated web capability called "GEMweb." GEMweb allows you to use a standard web browser on a computer on your facility's computer network to securely access the instrument.

With GEMweb, remote users can:

- View a snapshot of what is currently displayed on the instrument's screen
- Review patient, QC, and CVP sample results
- E-mail accepted patient, QC, and CVP sample results
- Send an e-mail of instrument diagnostics data to a pre-configured recipient
- Access the Instrumentation Laboratory corporate web site
- View instrument status information
- Perform remote control activity (available to the Key Operator)
- Send messages to the instrument
- View and print iQM reports.

The GEM Premier 3500 is configured with a static IP address. When it is configured properly, the instrument provides security so that users outside of your institution's network cannot access the instrument and its data. Furthermore, network access privileges for users within your institution's network are granted only to those individuals authorized by the Key Operator.

The GEM Premier 3500 can be configured to forward e-mail requests to your mail server and out to pre-configured recipients at any valid Internet e-mail address. Only authorized network users can initiate such e-mail requests.

Currently, cartridge failure diagnostics data can be e-mailed. The e-mail address of the Technical Support staff at IL is configured as the default destination address, but the Key Operator, if desired, can change this address. The Technical Support staff at IL will use the diagnostics information for complaint investigation.

To assure privacy of sample results, patient identification information is removed (blanked out) from the diagnostics data before it is e-mailed outside your institution.

The GEM Premier 3500 provides secure transfer of information across the network. Encryption is used, so the data cannot be viewed without deciphering. The software uses 128-bit cipher-strength encryption, and will back down to 40 if the client requires the 40-bit cipher strength. The SSL (Secure Socket Layer, developed by Netscape) encryption system is used to secure transactions across the web.

## 12.2 GEMweb Configuration

Only the Key Operator can perform GEMweb configuration.

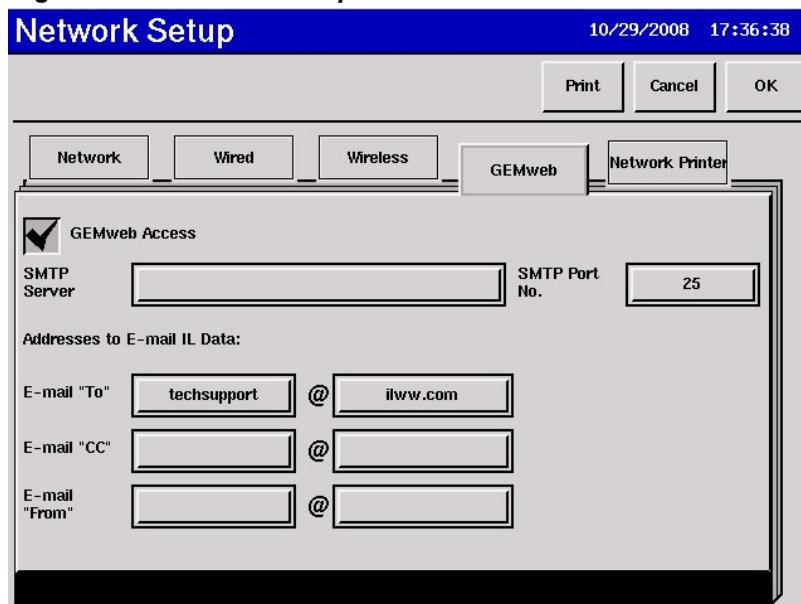
### 1. Connect the GEM Premier 3500 to the network.

Status: Connect the network port on the back of the instrument to an Ethernet-TCP/IP network access port in your facility (RJ-45, 10baseT or 100baseT).

### 2. Configure the instrument in the GEMweb area of Network Setup.

Status: The GEMweb tab of the Network Setup screen (*figure 12.1*) provides a checkbox for enabling or disabling remote access as well as fields for entering networking parameters. See “GEMweb Tab” under “Interface Setup” in Chapter 3 for information. Your facility’s network administrator will have to provide some of the required network setup parameters.

**Figure 12.1: Network Setup Screen – GEMweb Tab**



**NOTE:** The GEMweb Access checkbox on the Network Setup screen serves as a switch for turning all GEMweb access on and off. Turning Off GEMweb access will disable all remote access to the instrument; however, the network parameters you have entered will be saved for use if you later turn GEMweb access back On.

### 3. Define authorized network users.

Status: Network users are defined from the instrument’s list of authorized operators.

Operators may be allowed network access by selecting an option in the instrument’s authorized operator setup. See “Authorized Operators Setup” under “Security Setup” in Chapter 3.

**NOTE:** Operators are not allowed network access by default. You must enable network access before operators will be allowed remote access to the instrument.

## 12.3 GEMweb Operation

After you have configured GEMweb, an authorized network operator may remotely log into the GEM Premier 3500 from a supported web browser on the local network. The following browsers are supported:

- Internet Explorer version 5.x or 6.0

### The Login Page

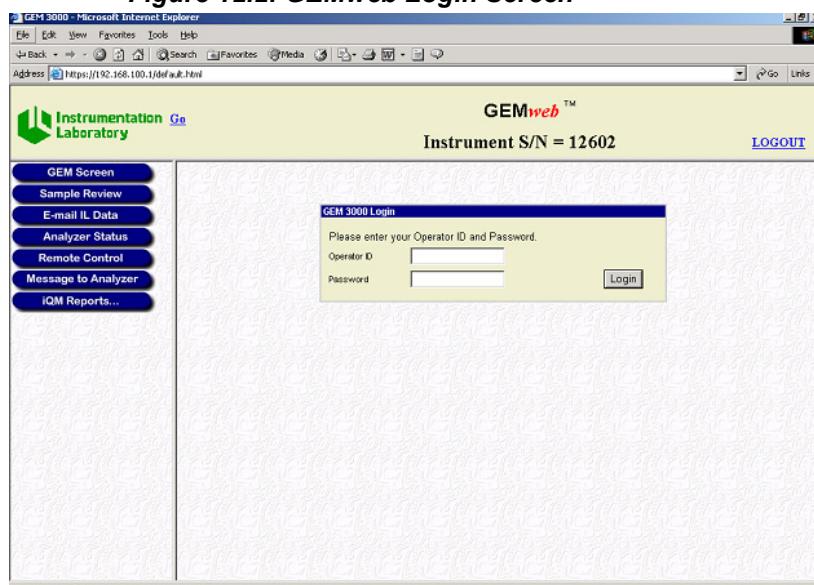
Type the URL of the instrument in the address area of the browser. You may use the IP address or host name assigned to the GEM Premier 3500. Both are configured on the Network Setup screen, GEMweb tab. For example:

`http://192.168.100.85/ OR http://hostname/`

In order to ensure the highest level of security for patient data with the GEM Premier 3500, the instrument uses a security method called Secure Socket Layer (SSL). This is the same security method that many people use to do on-line banking, shopping, etc. This method has proven to work well and is flexible. A Site Certificate that holds an encryption key used to encode and decode the data being accessed is used. When prompted by the system, view and install the certificate.

The Login screen (*figure 12.2*) will appear showing the serial number of the instrument (12602 in *figure 12.2*).

**Figure 12.2: GEMweb Login Screen**



To log into the instrument, you must enter a valid operator ID and password as defined in the instrument. The operator ID and password are both case sensitive; that is, they must be entered in the same case as defined on the Authorized Operators Setup screen (*figure 3.36*) on the GEM Premier 3500.

The login request will be denied if:

- the GEMweb Access checkbox is set to Off (unchecked)
- the specific operator is not authorized for network access
- the operator is not defined at all.

If the browser is left idle for 15 minutes or more, the operator is automatically logged out.

After a successful login, the GEMweb Home screen is displayed (*figure 12.3*).

**Figure 12.3: GEMweb Home Screen**



The Home screen contains buttons along the left side and a snapshot of the screen currently displayed on the instrument's touch screen. Clicking on the **GEM Screen** button will refresh the snapshot to reflect the screen currently displayed on the instrument. The Home screen shown in *figure 12.3* was taken while the instrument had the Ready screen displayed.

## Instrumentation Laboratory Logo

The green Instrumentation Laboratory logo at the upper left-hand corner of the screen is a link to IL's corporate web site ([ilww.com](http://ilww.com)). To access the site, click on the underlined **GO** link. You may use this link for information about IL products and supplies as well as for technical support and customer service.

## Sample Review

Click on the **Sample Review** button to display the Sample Review screen (*figure 12.4*). In the example below, the form is filled to view samples of all types that have a status of ACCEPTED and were analyzed between September 10, 2002 and September 11, 2002.

**Figure 12.4: Sample Review Screen**

This query form allows you to select or enter the following query parameters:

Query Parameter	Valid Range or Choices and Format
Sample Type	All, Patient, QC, CVP
Sample status	All, Accepted, Pending, Discarded
From Date	Pull-down menus for day, month, and year.
To Date	Pull-down menus for day, month, and year.
From Time	hh:mm:ss
To Time	hh:mm:ss
Operator ID (optional)	Free text, case sensitive
Patient ID (optional)	Free text, case sensitive
Patient First Name (optional)	Free text, case sensitive
Patient Last Name (optional)	Free text, case sensitive
QC or CVP Lot No. (optional)	Free text, case sensitive

After you have entered the parameters, click on the **Search** button to send a query to the instrument's database.

The results are presented in a summary format. Each sample record matching the query criteria is presented on a single line, as shown in *figure 12.5*.

**Figure 12.5: Query Results Screen**

A screenshot of a Microsoft Internet Explorer window displaying the GEMweb™ software interface. The title bar reads "GEM 3000 - Microsoft Internet Explorer". The main content area shows a table titled "All Samples Search Results" with 12 rows of data. The columns are "Date/Time", "Status", "Operator ID", and "Type". Each row contains a "View" link followed by the timestamp, status, operator ID, and type. The "View" links are highlighted in blue. The table has a dark header row and light-colored body rows. The left sidebar contains navigation links: "GEM Screen", "Sample Review", "E-mail IL Data", "Analyzer Status", "Remote Control", "Message to Analyzer", and "iQM Reports...". The top right corner shows "Instrument S/N = 12602" and a "LOGOUT" link. The bottom right corner shows the "Internet" icon.

All Samples Search Results			
Number of Matching Records: 12			
Date/Time	Status	Operator ID	Type
<a href="#">View</a> 09/13/2002 17:34:34	Accepted		Patient
<a href="#">View</a> 09/13/2002 17:33:12	Accepted		Patient
<a href="#">View</a> 09/13/2002 17:31:51	Accepted		Patient
<a href="#">View</a> 09/13/2002 17:30:23	Accepted		Patient
<a href="#">View</a> 09/13/2002 17:24:23	Accepted		CVF
<a href="#">View</a> 09/13/2002 17:22:18	Accepted		CVF
<a href="#">View</a> 09/12/2002 17:20:23	Accepted		CVF
<a href="#">View</a> 09/12/2002 17:18:52	Accepted		CVF
<a href="#">View</a> 09/12/2002 16:14:24	Accepted		CVF
<a href="#">View</a> 09/12/2002 16:12:25	Accepted		CVF
<a href="#">View</a> 09/12/2002 16:10:58	Accepted		CVF
<a href="#">View</a> 09/12/2002 16:09:39	Accepted		CVF

Next to each line, a **View** link is provided to bring up the results details of the selected sample. See *figure 12.6* for the detailed results of one of the QC samples as it appears in the browser.

**Figure 12.6: Results Screen**

A screenshot of a Microsoft Internet Explorer window displaying the GEMweb™ software interface. The title bar reads "GEM 3000 - Microsoft Internet Explorer". The main content area shows a table titled "Patient Sample Results" with various patient and sample information. The left sidebar contains navigation links: "GEM Screen", "Sample Review", "E-mail IL Data", "Analyzer Status", "Remote Control", "Message to Analyzer", and "iQM Reports...". The top right corner shows "Instrument S/N = 12602" and a "LOGOUT" link. The bottom right corner shows the "Internet" icon.

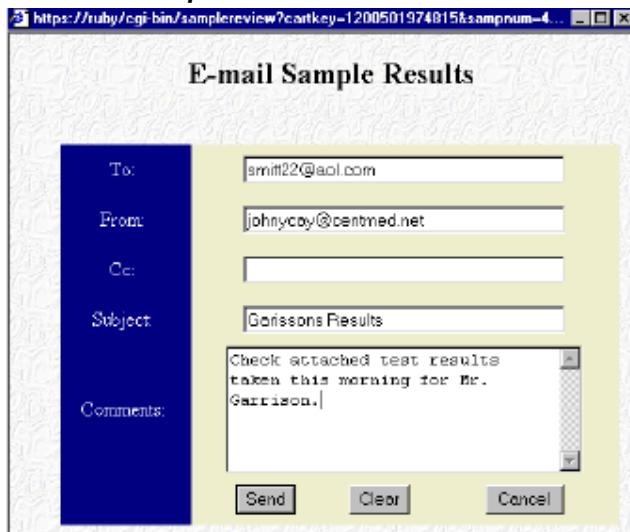
Patient Sample Results			
Patient ID	8246	Patient Name	WALSH, PATRICIA
Accession No.	84321	Operator ID	1
Date/Time	09/11/2002 12:16:52	Sample Type	Arterial
<b>Measured (37.0°C)</b>		<b>Derived Parameters</b>	
pH	7.36	HCO3-	34 mmol/L
pCO2	41 mmHg	TCO2	36.5 mmol/L
pO2	94 mmHg	BE(B)	16.6 mmol/L
Na+	141 mmol/L	SO2c	96 %
K+	↑ 4.7 mmol/L	THbc	7.4 g/dL
Ca++	↓ 1.11 mmol/L	A-aDO2	mmHg
Glu	98 mg/dL	pAO2	mmHg
Lac	1.5 mmol/L	paO2/pAO2	
Hct	↓ 24 %	RI	
C = Incalculable			

The Query Results screen also contains a **Modify Query** link that allows you to modify the previous query. The **New Query** link redisplays the Sample Review screen with the parameters set to default values.

## E-mail Accepted Sample Results

If Enable E-mail Sample Results is enabled in configuration (see "Security Setup" in Chapter 3), the **E-Mail** button can be used to send the results to a valid Internet e-mail address. Touching the **E-mail** button will display a screen for entering the e-mail address and message (figure 12.7).

**Figure 12.7: E-Mail Sample Results Screen**



## E-mail IL Data

The **E-mail IL Data** button displays the E-mail IL Data screen (figure 12.8). Cartridge diagnostic data that is available for sending is listed at the top of the screen. You may select a single cartridge per e-mail.

Space is provided for entering your name and a description of the problem. Both are required. Problem descriptions are used to explain the reason for sending the diagnostics data. Click on the **Send E-Mail** button to gather the data and send the e-mail to the recipients specified in the E-mail "To" and "CC" fields on the Network Setup screen (figure 12.1).

**Figure 12.8: E-Mail IL Data Screen**

The screenshot shows the "Select Cartridge To Send" page of the GEMweb™ software. It lists cartridges with their serial numbers, insertion dates/times, and sample counts. A radio button next to cartridge 623101 is selected. Below the list are fields for "Your Name (Required)" (Sam Jones) and "Problem Description (Required)" (Micro-Clot was detected by the analyzer, but the analyzer was unable to self-correct.).

Cartridge Serial Number	Insert Date/Time	No. of Samples Run
C 635159	09/11/2002 11:26:10	0
C 635086	09/11/2002 10:25	8
C 631509	09/09/2002 08:44	17
C 626386	09/06/2002 09:35	3
C 625074	09/05/2002 15:22	2
R 623101	09/04/2002 12:01	24
C 623085	09/04/2002 11:44	0
C 611379	08/28/2002 17:09	4

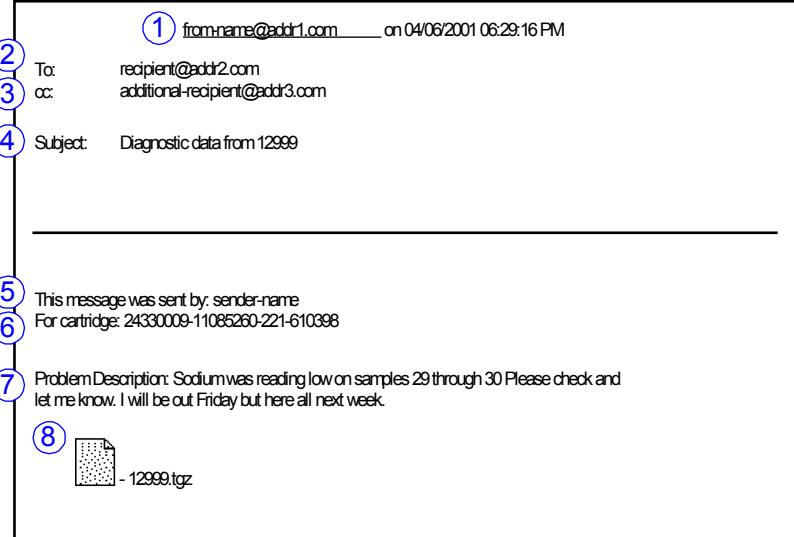
## Format of E-mail Messages

The e-mail message received at the destination will have the format shown in *figure 12.9*.



*NOTE: E-mail message format can vary depending on the e-mail program that you use.*

**Figure 12.9: Typical E-Mail Message Format**



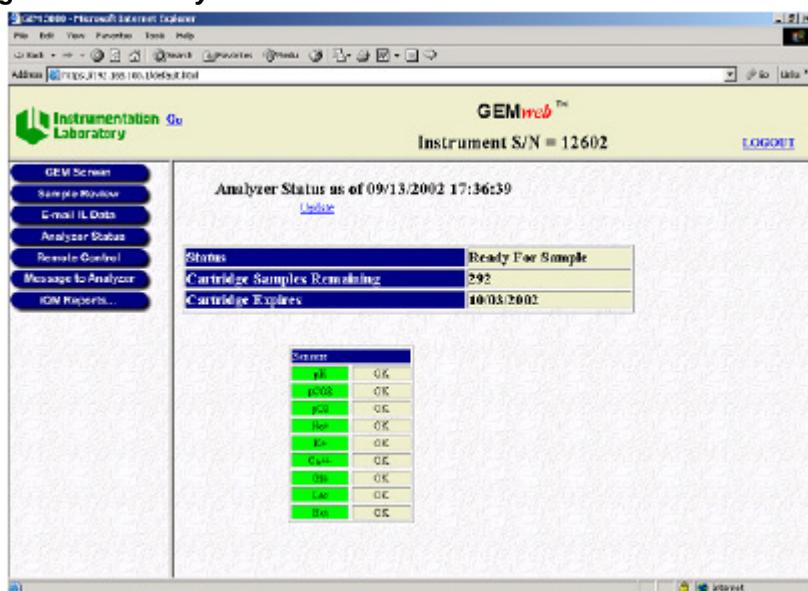
Description of E-mail message contents:

- ① E-mail “From” name as entered on Network Setup (*figure 12.1*) and the date and time the message was sent.
- ② E-mail “To” name as entered on Network Setup (*figure 12.1*). The default is set to Techsupport@ilww.com.
- ③ E-mail “CC” name as entered on Network Setup (*figure 12.1*)
- ④ Subject: will always read “Cartridge data from G3K SN “nnnnn” where “nnnnn” is the GEM Premier 3500 serial number.
- ⑤ Will always read: “This message was sent by:” followed by the sender name as entered in the “Your Name” field on the E-Mail Request screen (*figure 12.8*)
- ⑥ “For cartridge:” The groups of numbers between the hyphens correspond to the following for the selected cartridge: Cartridge Part Number, Cartridge Lot Number, Number Of Tests Run, and Card Serial Number.
- ⑦ “Problem Description:” Text of problem description as entered in the “Problem Description” field of the E-Mail Request screen (*figure 12.8*)
- ⑧ Attached file of GEM Premier 3500 cartridge data. These files are the same ones that are copied with the instrument’s **Copy IL Data** and **Copy iQM Data** menu options. The file name will be in the format “nnnnn.tgz,” where “nnnnn” is the instrument’s serial number. This file is a compressed file that must be uncompressed with a utility like WinZip.

## Analyzer Status

The **Analyzer Status** button displays the Analyzer Status screen (*figure 12.10*).

**Figure 12.10 Analyzer Status Screen**



This screen contains the following information:

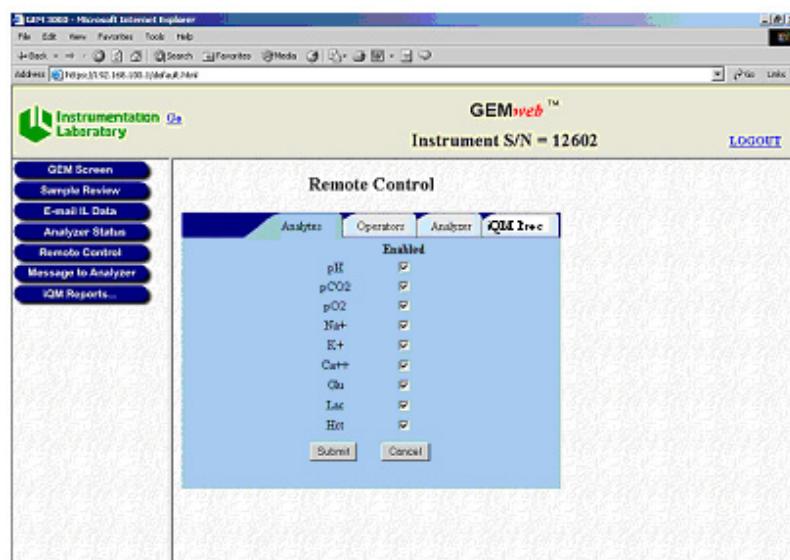
- The Page Title shows the date and time that the instrument's status was read. The **Update** link can be used to update the status information at any time. The format for the date is the same as the format chosen on the instrument being viewed.
- The Instrument Name is the same as the name entered for the instrument in Instrument Setup.
- Status shows the current status of the instrument:
  - Waiting for Cartridge
  - Warming Up
  - Ready for Sample
  - Analyzing Sample
  - Restarting
  - Locked
- The Sensors area\* shows the status of measured GEM Premier 3500 analytes as shown on the Ready screen. Each analyte's status may be OK, Failed iQM Process, Failed QC, Disabled, or Incalculable. CO-Ox analytes, if enabled, will not be included on this screen.
- Scheduled QC\* will show one of the following:
  - Overdue, which means the **Next QC** button is flashing on the instrument
  - Due, which means the **Next QC** button is yellow on the instrument but not flashing
  - No schedule, which means no QC schedules have been defined on the instrument
  - Done, which means none of the above apply
- The Cartridge area\* shows the number of samples remaining on the current cartridge and the date that the cartridge expires.

\*The Sensor, Scheduled QC, and Cartridge information will not be shown if the status of the instrument is Waiting for Cartridge, Warming Up, or Restarting. Scheduled QC is shown for when iQM Mode is Off only.

## Remote Control

Remote control of a GEM Premier 3500 is available only to Key Operators. The **Remote Control** button displays the Remote Control screen (*figure 12.11*).

**Figure 12.11: Remote Control Screen, Analytes Tab**

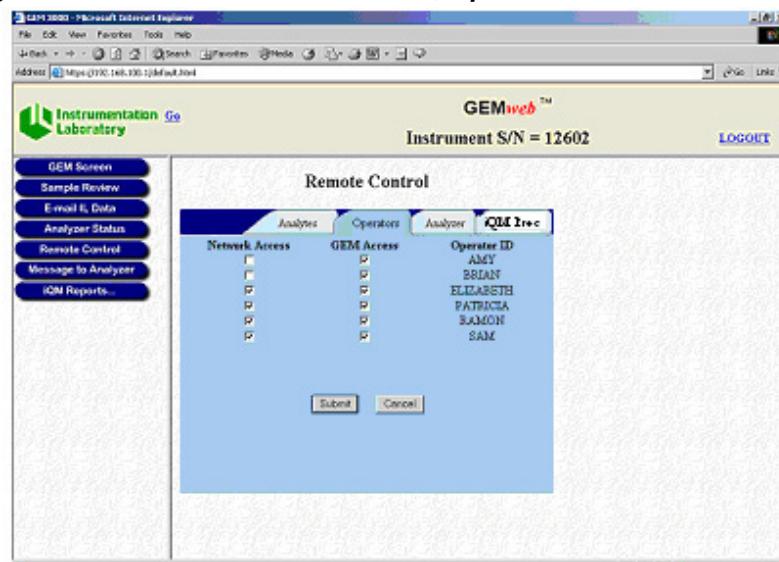


This screen provides four different areas of information, each presented on a different tab:

- **Analytes** (*figure 12.11*): Lists the native GEM Premier 3500 analytes for the current cartridge and allows each analyte to be enabled or disabled. A filled checkbox indicates an enabled analytes. Operation is identical to Analyte Enable/Disable in instrument configuration (see “Sample Setup” in Chapter 3). The **Submit** button sends the settings to the instrument. The **Cancel** button returns the checkboxes to their original settings.

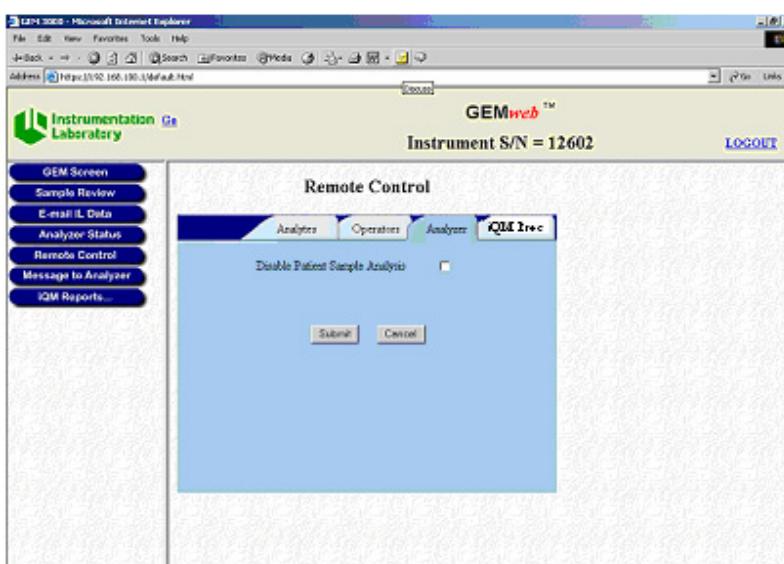
- Operators (*figure 12.12*): Lists the authorized operators currently defined on the instrument, with checkboxes to enable or disable remote and GEM access. Operation is identical to Authorized Operator Setup in instrument configuration (see “Security Setup” in Chapter 3). The **Submit** button sends the settings to the instrument. The **Cancel** button returns the checkboxes to their original settings.

**Figure 12.12: Remote Control Screen, Operators Tab**

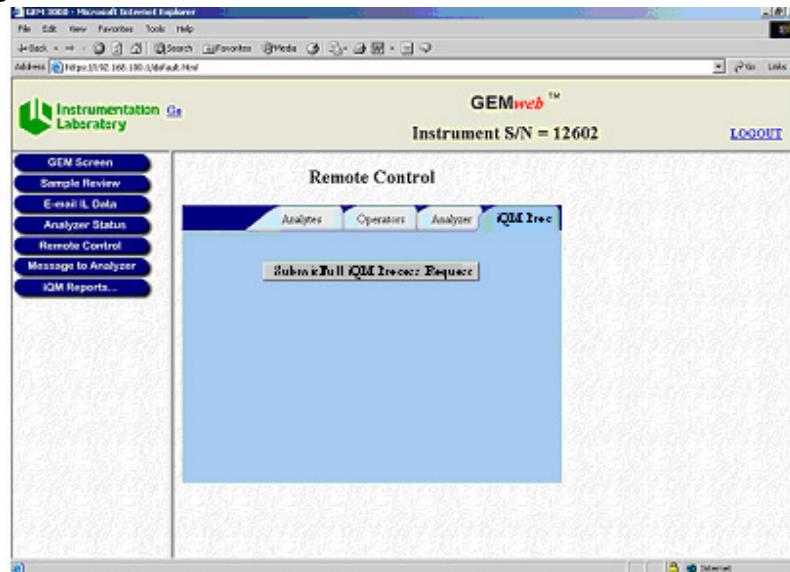


- Analyzer (*figure 12.13*): Provides remote locking of the instrument. When the Disable patient sample analysis checkbox is filled, samples cannot be run on the instrument. Operation is identical to Disable Patient Sample Analysis in instrument configuration (see “Security Setup” in Chapter 3). The **Submit** button sends the setting to the instrument. The **Cancel** button returns the checkbox to its original setting.

**Figure 12.13: Remote Control Screen, Analyzer Tab**

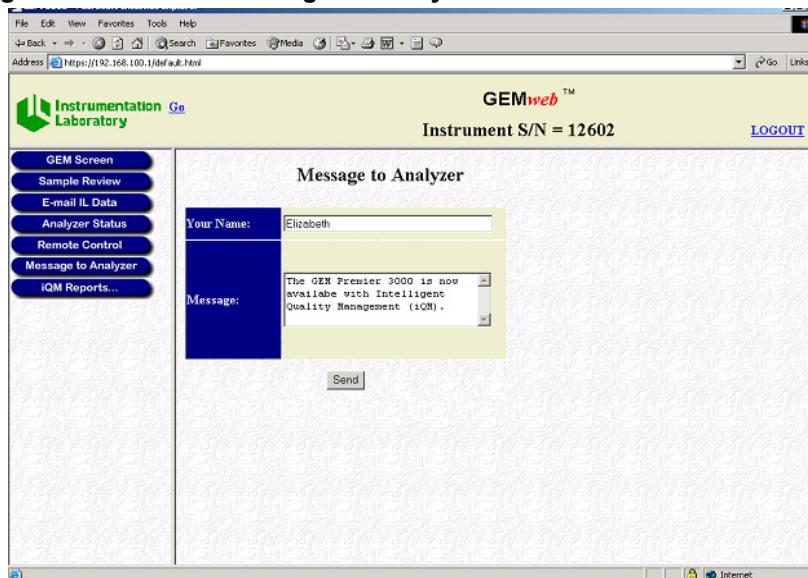


- iQM Process (*figure 12.14*): Provides a single button used to schedule an immediate Full iQM Process on the instrument. If the current state of the instrument does not allow for an iQM Process, the message *Your request cannot be processed at this time. Please try again* later will be displayed.

**Figure 12.14: Remote Control Screen, Calibration Tab**

### Message to Analyzer

The **Message to Analyzer** button displays the Send Message to Analyzer screen (*figure 12.15*).

**Figure 12.15: Send Message to Analyzer Screen**

This screen provides space for entering your name and a short message. The message may be up to 80 characters long. The **Send** button sends the message to the instrument and displays a confirmation message. Blank messages cannot be sent.

GEM Premier 3500 operators will be notified of received messages through the **Messages** button in the Status area of the screen. The button will be yellow when messages are waiting to be viewed on the Messages screen.

## iQM Reports

The **iQM Reports** button will display a menu listing the 3 types of iQM reports (iQM Delta Chart, iQM Corrective Action Report, and CVP Report). The report selection mechanism and displayed information is the same as for iQM reports on the GEM Premier 3500 (see “iQM Reports” in Chapter 6). Printing one of the iQM Reports from GEMweb will direct the report to the printer configured for the browser and will only print the report being viewed.



## LOGOUT

The **Logout** button logs out the current operator and redisplays the Login screen (*figure 12.2*). If the browser is left idle for 15 minutes or more, the operator is automatically logged out.

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# Appendix A. CO-Oximetry

## A.1 Working with an IL CO-Oximeter

An IL 682 or GEM OPL CO-Oximeter can be connected to one of the GEM Premier 3500 COM ports. Blood samples (for same patient) can then be run on both instruments within a three-minute time window. The GEM Premier 3500 will combine the results of both analyzers into one patient report. CO-Ox-only samples and CO-Ox QCs can also be analyzed from the GEM Premier 3500.

The GEM Premier 3500 will accept CO-Ox results only when it is at the Ready screen. If no cartridge is inserted, the cartridge is warming up, etc., any CO-Ox results sent to the instrument will be ignored.

To connect the instruments, a RS-232 cable is run from port A, B, or C on the GEM Premier 3500 (as configured in instrument setup) to the serial port 1 or 2 (as configured on the IL 682), or to the only RS-232 port on the GEM OPL.

For an IL CO-Ox sample to be accepted by the GEM Premier 3500, it must:

- Arrive to the GEM Premier 3500 within three minutes after the operator was prompted to introduce the CO-Ox sample. If CO-Ox results are received before or after the three-minute time period, the GEM Premier 3500 will discard the results.
- Correspond to the device configured in GEM Premier 3500 setup. If an IL 682 is configured as connected to one of the GEM Premier 3500 COM ports, the received record must identify the model as "IL 682." If a GEM OPL is configured to one of the COM ports, the received record must identify the model as "GEM OPL."

### CO-Oximeter Configuration

The serial port on the IL 682 should be configured as follows:

- Connected to "DMS"
- Data format = standard, BAUD rate = 9600, Parity = none, Data bits = 8, Stop bits = 1, Ack/Nack = Off, Xon/Xoff = off, Send Cal data = off, Send QC data = On, Instrument ID = (as determined by operator), Start char = STX, Header selection = On.

The GEM OPL should have the following settings when connected to the GEM Premier 3500 (if not mentioned below, the setting is entirely up to the OPL operator):

- Data Transfer: ON
- Auto Trans.: ON
- Printer Parameters: default values of 9600 baud rate and no parity

### Transmitted Data

For the IL 682, the CO-Ox parameters transmitted to the GEM Premier 3500 are THb, O<sub>2</sub>Hb, COHb, MetHb, HHb, SO<sub>2</sub>, O<sub>2</sub>ct, and O<sub>2</sub>cap. For GEM OPL, the same parameters are transmitted except HHb. For the OPL, the GEM Premier 3500 will calculate HHb from the other OPL CO-Ox derivatives provided that these derivatives were all sent without exception flags.

If the CO-Ox result is not received by the GEM Premier 3500, but was expected because it is part of the panel, it will be blanked out and flagged with "? = Review."

If the IL 682 sends a CO-Ox value with an error status other than 6, the GEM Premier 3500 will flag the result with "? = Review." An error flag of 6 (QC out of range) from the IL 682 will be ignored by the GEM Premier 3500. The GEM OPL does not send any error flag with the result.

The IL 682 instrument ID is transmitted to the GEM Premier 3500 and is included on the sample report on the GEM Premier 3500.

The GEM OPL serial number is transmitted to the GEM Premier 3500 and is included on the sample report generated by the GEM Premier 3500.

Fetal correction is performed on the GEM Premier 3500 and not on the CO-Oximeter. The operator should disable Fetal Mode on the IL 682, but enable the entry of FetHb on the GEM Premier 3500. The GEM OPL is not capable of performing fetal correction.

Only Patient and QC samples are processed by the GEM Premier 3500. Calibration data transmitted from the IL 682 will be ignored.

### **Patient and Operator ID**

Patient ID and Operator ID should be entered on the GEM Premier 3500. If they are entered on the CO-Ox device, they will be ignored.

### **CO-Oximeter QC**

CO-Ox QC material must be defined on the GEM Premier 3500 to allow initiating CO-Ox QC from the GEM Premier 3500. Defining CO-Ox QC material on the CO-Oximeter is optional. If the material is not defined on the CO-Oximeter, QC samples must be run as patient samples on the CO-Oximeter. After the CO-Ox results are received by the GEM Premier 3500, they are treated as QC results (since the GEM Premier 3500 is expecting QC results).

The user may optionally schedule CO-Ox QC runs using the GEM Premier 3500 scheduling feature. If the mandatory mode is ON and QC becomes overdue, sample analysis on the GEM Premier 3500 will be blocked regardless of the type of QC (CO-Ox or blood gas).

If the GEM Premier 3500 is expecting patient results and QC results are received from the CO-Oximeter, the results will be discarded.

The GEM Premier 3500 evaluates CO-Ox QC results based on the lot ranges entered on the GEM Premier 3500.

Cuvette lot number transmitted from the GEM OPL for liquid QC will be ignored by the GEM Premier 3500.

### **Reporting and Data Storage**

The GEM Premier 3500 reports CO-Ox parameters based on the units and format selected on the GEM Premier 3500, not the one defined on the transmitting CO-Oximeter.

The GEM Premier 3500 reports CO-Ox parameters in a fixed nomenclature, not the nomenclature selected on the IL 682.

CO-Ox-only patient samples (and CO-Ox QC samples) are stored on the GEM Premier 3500 with the GEM samples of the cartridge that is inserted at the time the CO-Ox sample was received. If the cartridge data is copied, these CO-Ox samples will be copied with it. The number of cartridge samples, however, excludes these samples (i.e. the reported number of samples remaining, or number of samples run for the cartridge, does not include CO-Ox-only samples).

The GEM Premier 3500 does not provide correlation factor correction to the CO-Ox analytes after they are received from the CO-Oximeter.

If saturation format on the IL 682 is in fraction format, it will be converted on the GEM Premier 3500 to percent format.

# Appendix B. Draft Standard Operating Procedure

A Draft Standard Operating Procedure (SOP) template has been provided with the GEM Premier 3500 for review and modification to assist individual facilities in efforts to document regulatory compliance. This template is provided on the CD located in the back of this manual. For your convenience, the SOP is provided in Microsoft® Word 2003.

This SOP document is provided as an example only and merely a foundation upon which to construct an SOP specific for individual institutions. Users must review and modify this document to conform with local practices and procedures. This document should contain or reference individual institutions' local safety policy.

The SOP template is written in the CLSI GP2-A4 format. The SOP includes instructions throughout the sections advising where modification of the document is necessary to reflect practices at individual institutions.

Questions or requests for further information should be directed to Technical Support at Instrumentation Laboratory.

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# Appendix C. Warranty

## C.1 Warranty

IL declares to the original purchaser that each instrument manufactured and sold by IL or sold by an authorized IL distributor shall be free from defects in material and workmanship and, under normal and proper use conditions, should read "warrants it for a period of five years from installation.

IL's obligation is limited to repairing, replacing, or modifying (at IL's undisputed judgment) at IL's factory, or elsewhere, the material whose defects have been verified, on condition that the purchaser has informed IL of any defects found within 8 days from receipt or of discovery in case of defects which may not be identified in the normal inspection. Damages caused by or connected to transport are excluded.

Transport to and from IL facility will be in any case at purchaser's charge and risk, and shall also be prepaid for reshipment.

These replacements, repairs, or alterations will in no case determine extension to the above specified warranty period.

The warranty does not cover those parts which deteriorate or which are in any case considered consumables or those parts or "items" which by their nature are normally required to be replaced periodically consistent with normal maintenance.

It is also understood that, following the purchase and delivery of the instrument, the purchaser shall be deemed liable for any losses, damages, or complaints concerning persons or things incurred by the use or misuse of the instrument on behalf of the purchaser, its employees, co-operators, or others.

IL does not assume any obligation or warranty engagement concerning precision and/or accuracy of the measurements as well as for any damage to the instrument directly or indirectly resulting from the use of reagents and/or consumables different from those produced by IL specifically for its own instruments and for the same properly tested.

Warranty will not apply to those defective instruments or materials showing defects or damage arising from the following causes:

1. Insufficient or negligent care by the purchaser.
2. Insufficient or negligent maintenance by the purchaser in relation to the instructions contained in the manuals prepared by IL for this purpose, tampering or alterations of the instruments or in any case interventions or repairs made by any person not duly authorized by IL.
3. Misuse due to carelessness, negligence, or inexperience.
4. Employment of materials under heavier conditions than those for which they have been designed and manufactured and use of the same in combination with incompatible or dangerous products.
5. Non-observance of the regulations relevant to installation, power supply, and operation of the instruments (with particular regard to the regulations for accident prevention).

THIS WARRANTY IS GIVEN EXPRESSLY AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED. PURCHASER AGREES THAT THERE IS NO WARRANTY OR MERCHANTABILITY AND THAT THERE ARE NO OTHER REMEDIES OR WARRANTIES, EXPRESS OR IMPLIED, WHICH EXTEND BEYOND THE CONTENTS OF THIS AGREEMENT.

No agent or employee of IL is authorized to extend any other warranty or to assume for IL any liability except as above set forth.

## **C.2 IL Worldwide Locations**

Please go to [www.ilww.com](http://www.ilww.com) for contact information on all IL worldwide locations.