

# GEM® PREMIER™ GEM3500

## SERVICE MANUAL



**Instrumentation Laboratory**

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# Safety and Compliance

This section describes the Safety and Compliance Requirements for the GEM 3500, including Environmental Requirements, Reagent Specifications, Limitations, Important Symbols, and Certifications.

## Limited Warranty

Instrumentation Laboratory is responsible for the safety and electrical performance of the GEM 3500 if and only if:

- Persons authorized by IL carry out assembly operations, extensions, adjustments, modifications or repairs. The GEM 3500 is only to be repaired by authorized personnel at an IL Depot Repair facility.
- The electrical installation of the room complies with the local, state, or national requirements (including power supply circuit with independent grounding).
- The equipment is used in accordance with these instructions for use.
- IL brand products are used. Non-IL brands are not covered.

## Sound Power Level

Meets CEI/IEC 61010.1

## Environmental Conditions

The instrument will function correctly in an ambient temperature of 15°C to 32°C (53.6°F to 89°F) with a relative humidity of 15% to 85% (non-condensing).

In accordance with the IEC regulations, no instrument failures will occur in the presence of short-term ambient temperatures as low as 5°C or as high as 40°C.

The instrument has been tested per Mil Spec to 2000 meters and functioned per the specification. The GEM 3500 should not be used at an altitude greater than 2000 meters.

The audible noise emission passes the safety requirements for electrical and laboratory equipment, EN61010.1.

# Reagent Specifications

Reagent specifications for the GEM 3500 are published separately and distributed in the reagent packaging.

## Non-IL Reagents

The use of non-IL brand reagents or supplies for testing may cause a clinically significant degradation of performance and results. IL does not assume any obligation or warranty engagement concerning precision and/or accuracy of the measurements nor for any damage to the instrument directly or indirectly resulting from the use of reagent, consumables and/or expendable supplies other than those produced by IL. **GEM 3500 Limitations**

Instrumentation Laboratory, Co. (IL) is responsible for the safety and electrical performance of this equipment ***if and 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 the local, state or national requirements (including a power supply circuit with independent grounding).
- The equipment is used in accordance with these instructions for use.

IL does not assume any obligation or warranty engagement concerning precision and/or accuracy of the measurements or for any damage to the instrument directly or indirectly resulting from the use of reagents and/or consumables other than those produced by IL.

THIS WARRANTY IS GIVEN EXPRESSLY AND IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED. PURCHASER AGREES THAT THERE IS NO WARRANTY OR MERCHANTABILITY AND THAT THERE ARE NO OTHER REMEDIES OR WARRANTIES, EXPRESSED 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.

# Document Symbols

Only trained operators following the procedures described in this manual should use the GEM 3500. IL declines any responsibility otherwise.

Good laboratory practices dictate that biohazard precautions are taken while operating the GEM 3500 and when handling patient samples, controls, calibrators, or similar materials.

Throughout this manual, you should pay particular attention to paragraphs marked "WARNING", "CAUTION", "NOTE", and "BIOHAZARD." These paragraphs are labeled with the following symbols and contain important information:



**WARNING** Warning statements provide information about electrical hazards.



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



**NOTE** Note statements contain important user information.



**BIOHAZARD** Biohazard statements alert you to potentially biohazardous conditions.

# Label Symbols

The following symbols appear on the labels of GEM 3500 components.

Symbol	Description
	CE Mark
	Temperature Limitation
	Use by
	Manufacturer
	Batch Code
	Biological Risk
	Attention: See Instructions for Use
	Caution: Risk of Electric Shock
	Note: Important User Information
	Attention: Consult Documents
	Catalog Number



Serial Number



In Vitro Diagnostic Device



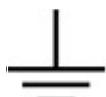
Authorized Representative



Contents sufficient for &lt;n&gt; tests



Protective Conductor Terminal - Earth



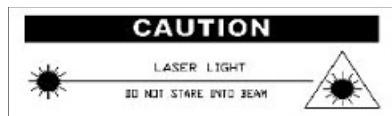
Earth Ground



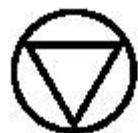
Off (supply)



On (supply)



Bar Code Reader Hazard



Stop Action – Instrument will stop all moving parts immediately

# Certification

## **CE Certification:**

The CE label on the back of the instrument indicates that the GEM 3500 conforms to the European Directives as stated in IL's Declaration of Conformity.

## **EU Directive:**

IVD - 98/79/EC (27/10/1998) – Annex I and III

## **EMC Standard:**

- CEI/IEC 61326-1: 1998 (Class B)

## **Safety Standards:**

- CEI/IEC 61010-2-04 Safety requirements for electrical equipment for measurement, control and laboratory use
- EN 61010-2-101 Part 2 Particular requirements for in-vitro diagnostic medical equipment
- EN 61010-2-081 Particular requirements for semi-automatic and automatic laboratory equipment

## **CSA Certification:**

The CSA label on the back of the instrument indicates that the Canadian Standards Association (CSA) has certified the GEM 3500 to the applicable standards.

## **Applicable standards:**

- CAN/CSA C22.2 No. 1010.1-92
- UL Std. No. 61010-1, 2nd Edition

## **LOPD (Data Protection Organic Law):**

Directive 95/46/CE of the European Parliament and the Council Directive of October 24th, 1995.

European regulation on data protection, concerning:

§ Luxembourg	§ Ireland	§ Greece
§ United Kingdom	§ Belgium	§ Portugal
§ Austria	§ Germany	§ Italy
§ Denmark	§ France	§ Netherlands
§ Sweden	§ Finland	§ Spain

European parliament and council directives and regulations on data protection

Spanish Constitution of 1978

Organic Law 15 of December 13th, 1999, on Personal Data Protection (LOPD)

Royal Decree 994/1999 on Security Measures. Royal Decree 1332/1994

Regulation of the Computerized Processing of Personal Data

Spanish Data Protection Agency instructions

#### Other Certification:

The GEM 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 3500 shipping package, US or overseas, complies with the International Safe Transit Packaging Testing Procedure ISTA 1B (June, 1999) and ASTM 999.



***CAUTION: Only authorized service personnel should perform field service on the instrument. The instrument contains potentially hazardous electrical voltages and many mechanical parts.***

## Electrical Requirements

The instrument has been designed to operate correctly with electrical variations of up to  $\pm 10\%$  in an ambient temperature of 15°C to 32°C (59°F to 89°F) with a relative humidity of 5%-90% (non-condensing). The instrument should be placed in a position free from dust, fumes, vibrations and excessive variations in temperature. Using this instrument at an altitude greater than 2000 meters is not recommended.

The GEM 3500 is single phase, has current leakage of less than 500  $\mu$ Amps, and produces 1024 BTU's per hour.

In accordance with IEC 61010-2-04 safety standard, paragraph 1.4, there is no safety hazard in the temperature range 5-40° C.

The instrument has been designed to operate correctly with electrical variations of up to  $\pm 10\%$  on the nominal supply and with supply frequencies between 47 and 63 Hz.

**Table 1-1 GEM 3500 Electrical Requirements**

Volts AC	Amps	Volts/Amp	Watts	Frequency
100 VAC	3A	300 VA	300 W	50/60Hz
115VAC	3A	345 VA	300 W	50/60Hz
240VAC	3A	360 VA	300 W	50/60 Hz

For all voltage applications, the Gem 3500 uses a 3-amp glass fuse, located in the power connection module. The part number of this fuse is 00000024009984. Prior to replacing the fuse, the power must be turned off and the power cord disconnected. For further details, contact IL.

The protective earth is located inside the instrument on the bottom of the chassis and is the primary ground point for the instrument.

# Chapter 1 – General Information

This section contains an Overview of the GEM Premier 3500, a list of the measured and calculated parameters, a description of the front components of the instrument, and a description of the rear components of the instrument.



**BIOHAZARD:** *Avoid touching, with bare hands, any parts of the system which may have come in contact with potentially infectious fluids. ALWAYS wear gloves when performing any type of Maintenance/Service action on these areas.*

## 1-1 Overview

The GEM Premier 3500 is a portable system for use by health care professionals to 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 be interfaced to an external IL CO-Oximeter, the IL 682™ or the GEM OPL®, with the CO-Ox results integrated into the GEM Premier 3500 results.

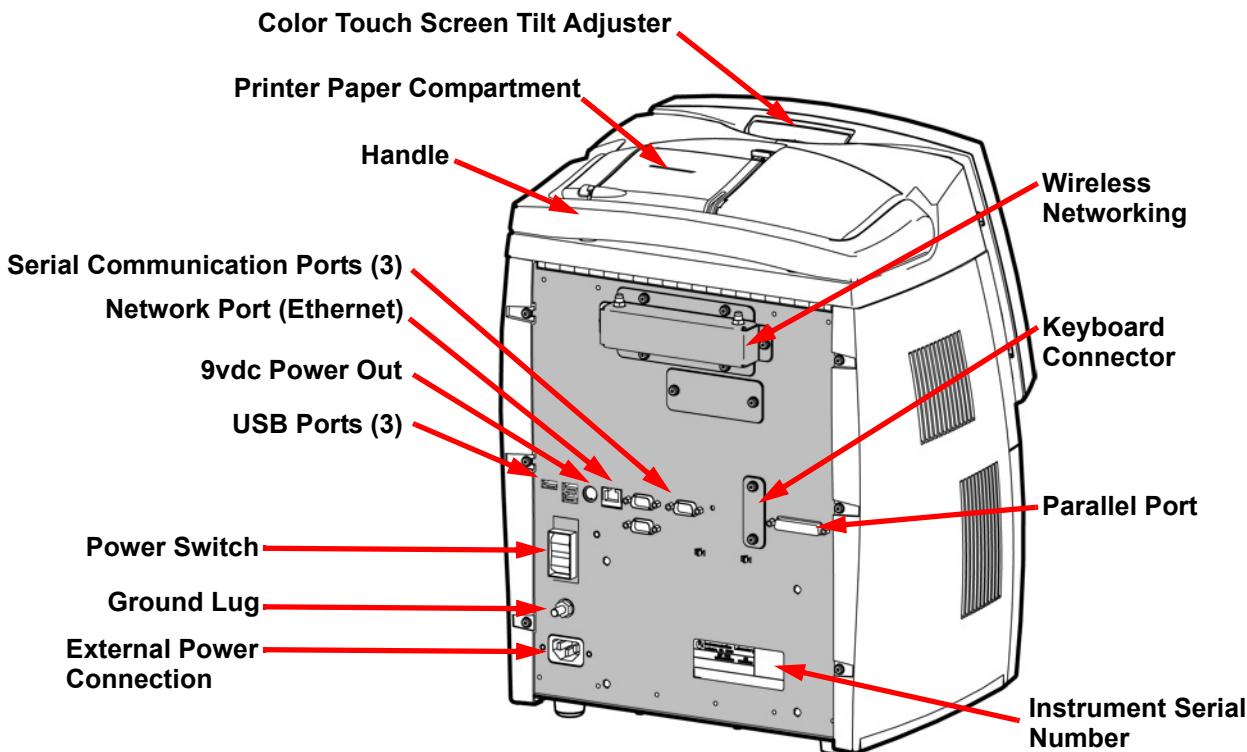
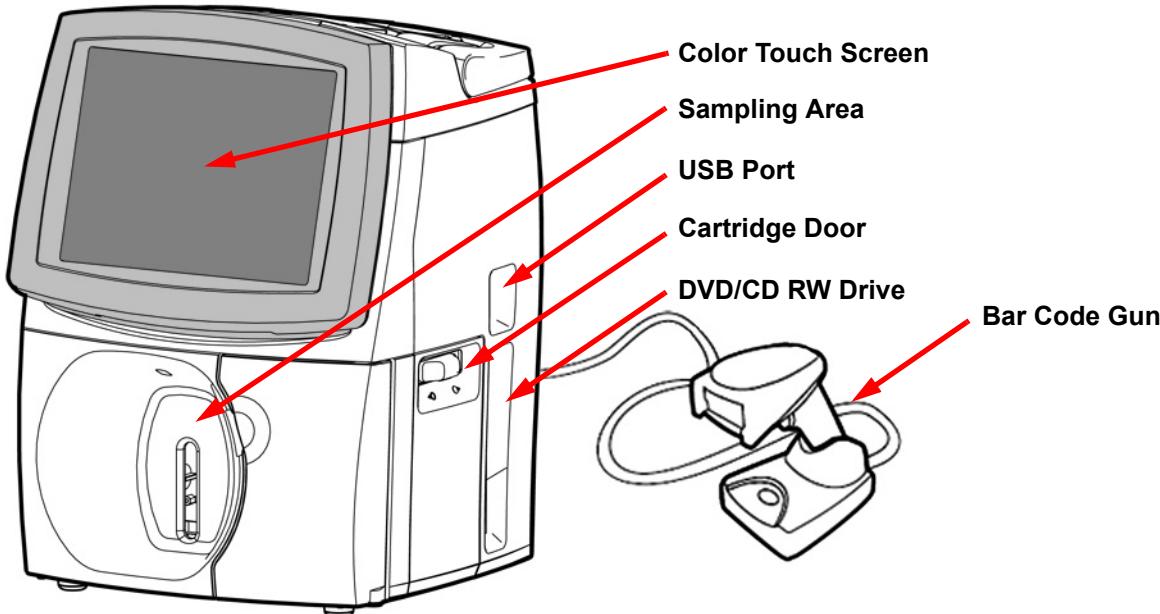
The GEM Premier 3500 system is comprised of the instrument and the cartridge. The cartridge is a self contained, disposable package that includes all of the Process Control Solutions, sensors, and the entire sample pathway, including the pumps, valves, and waste bag. The instrument controls the cartridge to perform all the necessary functions for heating, calibration, probe movement, pumping, and sample aspiration. The instrument accepts all of the sensor data from the cartridge and processes this data to perform and verify the calibrations and to present the data for the analyses. The instrument will display, store, print, and transmit the data.

The GEM Premier 3500 can use a wide variety of cartridges, from a 35 test, 4-week cartridge to a 600-test 2-week cartridge. In addition, the instrument and cartridges can be configured to use intelligent Quality Management (iQM) or traditional, external QC.

## GEM Premier 3500 Analyzer

The GEM Premier 3500 analyzer 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.

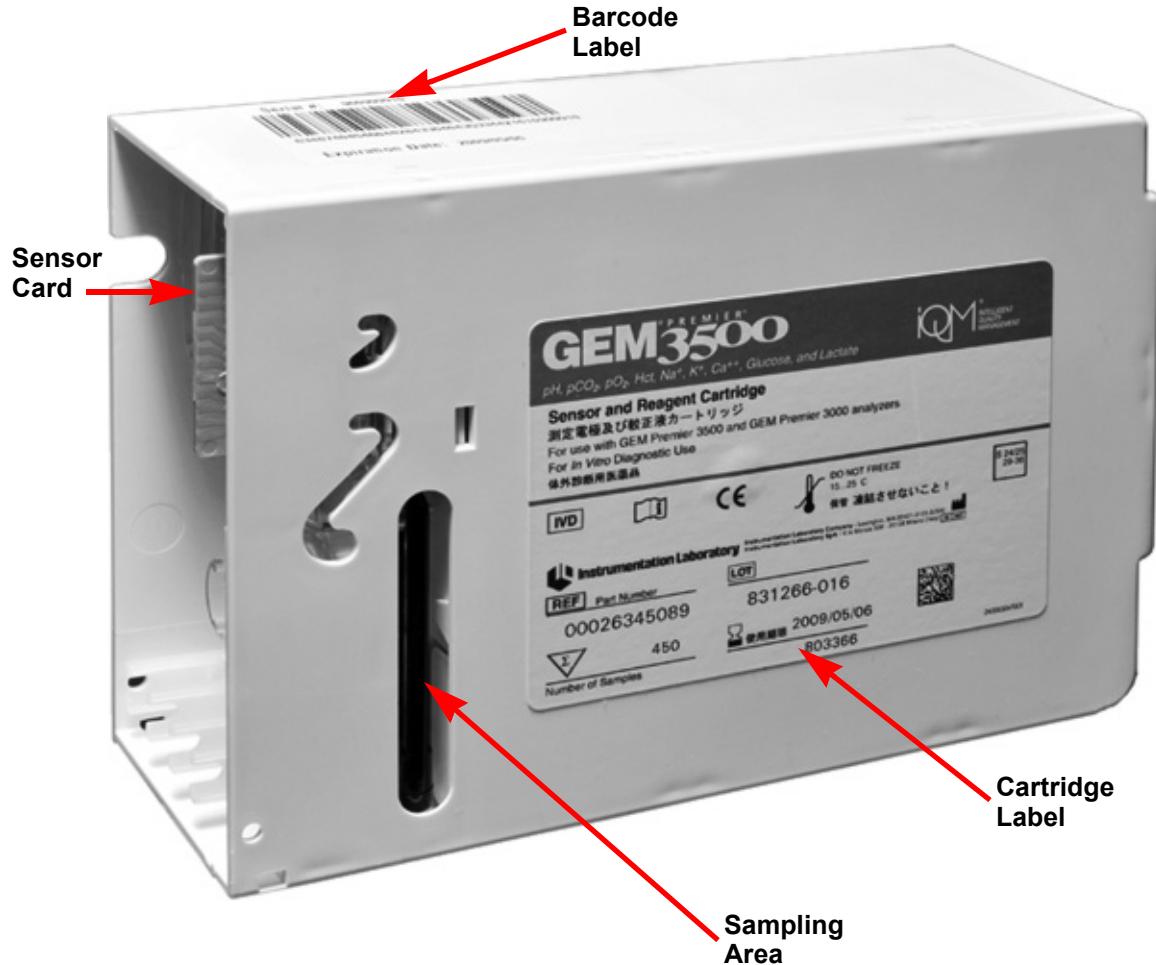
**Figure 1-1 GEM Premier 3500 Analyzer**



## GEM Premier 3500 PAK Cartridge

The primary component of the GEM Premier 3500 is the GEM Premier 3500 PAK cartridge. The disposable, multi-use PAK houses all components necessary to operate the instrument once the cartridge calibration is validated. These components include the sensors, solutions, sampler and waste bag. A variety of cartridge menus and test volumes are available.

**Figure 1-2 GEM Premier 3500 PAK Cartridge**



## 1-2 Measured Parameters

The GEM Premier 3500 produces the following parameters, depending on the cartridge in use and the configuration of the instrument:

- pH Hydrogen ion activity
- pCO<sub>2</sub> Partial pressure of Carbon Dioxide
- pO<sub>2</sub> Partial pressure of Oxygen
- Na<sup>+</sup> Sodium ion concentration
- K<sup>+</sup> Potassium ion concentration
- Ca<sup>++</sup> Calcium ion concentration
- Glu Glucose
- Lac Lactate
- Hct Hematocrit

Refer to the Operators Manual for more information on these parameters.

## 1-3 Derived Parameters

The GEM Premier 3500 produces the following derived parameters, depending on the cartridge in use and the configuration of the instrument:

- $\text{TCO}_2$  Total Carbon Dioxide
- $\text{BE}_{\text{ecf}}$  Base excess of extracellular fluid
- $\text{BE(B)}$  Base excess of blood
- $\text{tHbc}$  Calculated total Hemoglobin
- $\text{Ca}^{++} (7.4)$  Ionized Calcium standardized to pH 7.4
- $\text{pAO}_2$  Alveolar Oxygen partial pressure
- $\text{CaO}_2$  Arterial Oxygen content
- $\text{CvO}_2$  Mixed venous Oxygen content
- $P_{50}$  Partial pressure of Oxygen at 50% saturation
- $s\text{O}_2\text{c}$  Oxygen saturation (calculated)
- $\text{HCO}_3^{\text{std}}$  Standard Bicarbonate
- $\text{HCO}_3^-$  Actual Bicarbonate
- $\text{A-aDO}_2$  Alveolar-arterial oxygen gradient
- $\text{paO}_2/\text{pAO}_2$  Arterial-alveolar oxygen ratio
- RI Respiratory Index
- $\text{CcO}_2$  End pulmonary capillary oxygen content
- $\text{a-vDO}_2$  Arterial-mixed venous oxygen gradient
- $Q_{\text{sp}}/Q_t$  Physiologic shunt

Refer to the Operators Manual for more information on these parameters, and for information on User-entered analytes/parameters.

## 1-4 Intelligent Quality Management (iQM™)

Intelligent Quality Management (iQM™) is used as the quality control and assessment system for the GEM Premier 3500 analyzer. iQM™ is an active quality process control program designed to provide continuous monitoring of the analytical process with real-time, automatic error detection, automatic correction of the system and automatic documentation of all corrective actions, replacing the use of traditional external quality controls. As part of this program, GEM CVP (Calibration Valuation Product) with CO-Ox and GEM CVP Hematocrit are external solutions intended to complete the calibration process and final accuracy assessment of the iQM cartridge calibration following warm-up. The reported values for the four levels of GEM CVP (two levels for pH, blood gases, electrolytes, metabolites and CO-Oximetry; two levels for hematocrit) must meet specifications before the iQM cartridge can be used for patient sample measurements. Once the cartridge calibration is verified, the internal iQM program monitors the status of the system during the cartridge use life.

# Chapter 2 – Installation

## 2-1 Overview

This chapter guides the IL authorized engineer through the process of ensuring the facility can accommodate and is ready for the installation of the GEM 3500. This chapter also guides the IL authorized engineer through the installation process.

The physical dimensions for the shipping box are as follows:

**Table 2-1** Crated Instrument Size/Weight Specifications

Height	70 cm - 27.5 inches)
Width	37 cm - 14.5 inches)
Depth	44 cm - 17.25 inches)
Weight (approximate)	17 Kg - 37 lbs)

## Working Area / Environment

The physical dimensions of the system are as follows:

The instrument must be positioned so there is at least 15.2 cm (6 inches) clearance on all sides, back and top for proper air circulation.

Position the GEM Premier 3500 in a location where it is secure and not in danger of falling or being accidentally knocked off of a counter. Ensure that the instrument is not directly in the path of cooling air or heated air and avoid direct sunlight.

The maximum external dimensions for the **GEM 3500** are:

**Table 2-2 Instrument Size/Weight Specifications**

Height	44.5 cm (17.5 inches)
Width	33 cm (13 inches)
Depth	30 cm (11.8 inches)
Weight (approximate)	14.13 kg (31.15 lbs.)

## Ambient Conditions:

The GEM Premier 3500 must be operated at an ambient temperature between 15°C (59 F) and 32 C (95 F), and a relative humidity between 15% and 90%. The instrument is intended for indoor use only.

The instrument operates independent of Barometric Pressure. The process control Solution bags have zero headspace and there is no affect on the dissolved gas concentration over a wide range of atmospheric pressures.

The rear of the instrument requires adequate clearance to allow for any connections (Ethernet, RS 232, USB, Parallel port, bar code reader) without putting stress on the cables (6 inches minimum). The right side of the instrument requires a minimum of 12 inches of clearance to allow insertion and removal of the cartridge and CD/DVD.

## Electrical Power Requirements

The GEM Premier 3500 requires a grounded electrical supply. The switching power supply accommodates 90 to 264 VAC, 50 or 60 HZ. The power consumption of the GEM Premier 3500 is less than 120 watts. The instrument is protected with a 1.5 amp circuit breaker integral to the power switch. The GEM Premier 3500 has electrical filters to protect against line noise. In locations where significant voltage or current fluctuations frequently occur, the use of a line conditioner or an uninterruptible power supply (UPS) is recommended.

The GEM 3500 is designed to recover from a power interruption of less than one hour (or within 20 minutes if a low oxygen, or "A" calibration is in progress, or blood is resting on the sensor). If routine power failures are anticipated, a UPS can be used.

A 60-minute power interrupt feature allows instrument transport. The instrument cannot be operated during power interruptions, unless connected to a UPS.

**NOTE:** Check that the supply voltage in the laboratory is compatible with the label on the rear of the instrument as shown in the following table:

**Table 2-3 Power Supply Voltage Values**

Input Voltages	Output Voltages
100 - 240VAC	+ 24 V DC
50/60 HZ.	+ 12 VDC
	+ 5 VDC

**Table 2-4 GEM 3500 Electrical Requirements**

Volts AC	Amps	Volts/Amp	Watts	Frequency
100 VAC	1A	100 VA	100 W	50/60 Hz
115 VAC	1A	100 VA	100 W	50/60 Hz
240 VAC	0.5A	100 VA	100 W	50/60 Hz

## Power Connection

The instrument is to be connected to power using the 3 wire detachable line cord supplied (part number 00014882100 - 115 VAC and 00019725500 - 220 VAC). The power supply is auto sensing and no changes to the instrument are required for any acceptable voltages or frequencies. The instrument is protected by a 1.5 Amp circuit breaker, integral to the power switch, and no changes are required to the power switch for any of the acceptable line voltages.

The GEM 3500 power switch is located on the rear panel of the instrument, adjacent to the power cord connection on the lower left portion of the rear panel (viewed from the rear of the instrument). This switch is for the main power supply and controls all power to the instrument



***CAUTION: This switch must be turned off and the power cord must be disconnected off prior to servicing or moving the instrument.***

## 2-2 Installation



**NOTE:** The installation of the GEM 3500 should be performed only by an authorized Instrumentation Laboratory representative!

### Unpacking and Inspection

An authorized IL representative should remove the GEM Premier 3500 from its carton. Check that the instrument and its accessories have not been damaged during transport. If damage is noted, initiate the proper procedures to file any claims and obtain a replacement instrument, if required.

The GEM Premier 3500 will be packaged in a plastic bag, with two desiccant packs. There will be a separate box with the instrument accessories in it.

### Applying Power

Verify that the line power is within the limits required (see "[Electrical Power Requirements](#)"). Verify that the power switch on the GEM Premier 3500 is in the off position (bottom of switch pushed in). Using the detachable line cord with the appropriate power connections, plug the cord into the receptacle on the back of the GEM and to the power source. Turn the power on by pushing the top half of the switch all the way in.

### Start Up

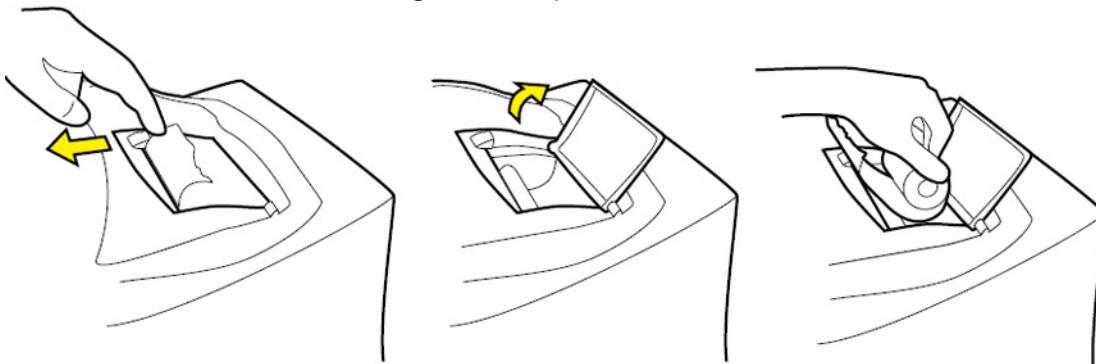
When power is first applied, the fan will turn on and the motors will home themselves. The screen will then show a light colored bloom, followed by a very brief logon display. It will then display "loading GEM 3500 software for several seconds. After that the screen will display the normal startup screen with "The instrument is performing self diagnostics. Please wait." After several minutes, the screen will blank out, the motors will find home again and the display will come on in the "Insert Cartridge" screen.

## Loading Paper

Install the printer paper in the paper area on top of the system.

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

**Figure 2-1** Paper Installation



## Inserting Cartridge

Prior to inserting cartridge, verify the date and time are correct. No changes can be made to the date or time after the cartridge is inserted. Using the proper date and time is essential for the proper performance of the PO2 channel. The Date format can be selected by pressing “Configuration” and “Instrument Setup”. The possible selections are:

MM/DD/YYYY

DD/MM/YYYY

YYYY/MM/DD

To change the Date and/or Time, press “Configuration” and “Set Date and Time”. Any changes made in this screen will require restarting the instrument.

If the Daylight Saving Time feature is selected, the instrument will automatically move the time forward one hour on the second Sunday in March, and it will move the time back one hour on the first Sunday in November for the USA. For Europe, the clock changes according to the schedule defined by the European Union. If this is changed, it will require restarting the instrument.

If the daylight Savings Time feature is not desired, it must be turned off by pressing “Configuration”, Set Date and Time” and deselecting “Enable Daylight Saving Time”. Prior to inserting cartridge, verify that the desired setting for iQM is entered. Press “configuration” and “iQM Setup”. If the cartridge is an iQM cartridge, verify that the “iQM Mode” is selected.

1. Remove cartridge from foil pouch, ensure inside of foil pouch is dry
2. Open door for cartridge
3. Remove dust cover – this activates the cartridge
4. Insert the cartridge into the GEM Premier 3500. Slide the cartridge in with a smooth, continuous motion.

5. Follow prompt answering “Yes” or “No” to “Is instrument date/time correct?”
6. If “Yes”, follow prompt – CLOSE DOOR, LOCK. (CAUTION! Door will unlock if instrument is unplugged to be moved)
7. If “No”, follow prompt – REMOVE CARTRIDGE, (correct for date/time), restart process
8. Allow 30 minutes for cartridge to complete warm up cycle

For complete details on insertion of cartridge, and use of CVP/QC to validate the cartridge, refer to the GEM Premier 3500 Operators Manual.

## 2-3 Configuration

The GEM 3500 provides a significant amount of flexibility in the configuration menu. Section 3 of the Operators Manual provides details on each of the selections available. In the Configuration Menu, selections are available for :

- Sample Setup
- QC Setup
- IQM Setup
- Calibration Setup
- Instrument Setup
- Interface Setup
- Security Setup

In addition, there are choices to save the configuration to a CD/DVD, and to restore the configuration from this disk. The configuration can be saved with a cartridge in use, but once a cartridge is inserted, the configuration disk cannot be used to load a specific configuration onto an instrument.. This Save and Restore feature can be very useful when installing multiple instruments in the same facility. If one instrument is configured to suit the user’s requirements, the configuration can be loaded onto the other instruments with the disk, saving a significant amount of time.

The Configuration Menu also has a selection to “Restore KOPW” (Key Operator Password). A Restore KOPW disk is provided with each instrument, in the back of the Operators Manual. When this is selected, the Key Operator Password will be restored to 1 2 3 4. The Date and Time can also be selected (as detailed in ["Inserting Cartridge"](#)).



**NOTE:** The key Operator Password is required to access all selections on the Configuration Menu, except Restore KOPW.

## 2-4 Instrument Shutdown

The GEM can be shutdown for short periods of time to move the instrument, or to load a software upgrade, or video disks, with a cartridge inserted. If the instrument is shutdown with a cartridge, a popup screen will appear, indicating that power must be restored within 60 minutes or the cartridge must be replaced. In some instances, if the instrument is performing a 2 point cal, a C solution cal or if there is blood on the sensors, power must be restored within 20 minutes.

If the instrument is to be shut down for an extended period of time, the cartridge should be removed prior to shutdown.

Select “Shutdown” from the ready screen, press shutdown and confirm that the instrument is to be turned off. There will be a prompt to wait while the instrument is shutting down, followed by “It is now safe to turn off the instrument.” Turning power off before this message is displayed can cause corruption of the operating software, and will cause a delay in restarting the instrument when power is restored.

## 2-5 Start Up Kit Contents

**Table 2-5 00025001000 GEM PREMIER 3500 INSTRUMENT STARTUP KIT**

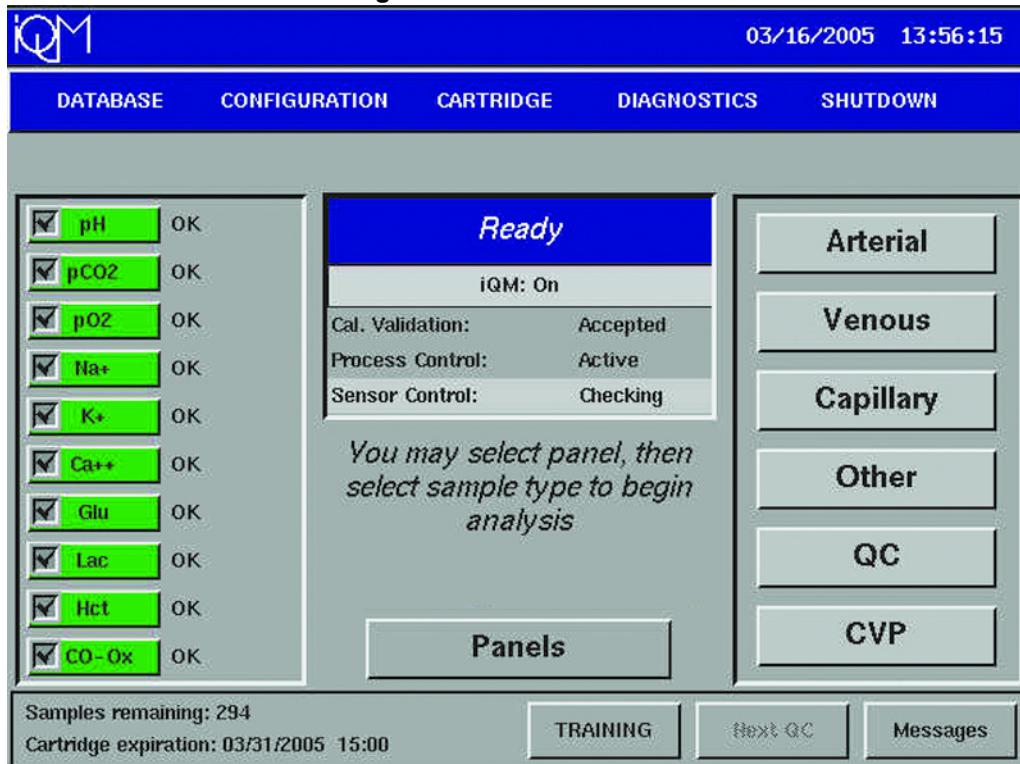
Item	Component	Description	Qty.
1	25000310	GEM 4000 OPERATOR'S GUIDE	1
2	25000210	CD MANUAL OPERATOR GEM PREMIER 4000	1
3	25000320	GEM 4000 DATA MANAGEMENT GUIDE	1
4	25000330	GEM 4000 REFERENCE GUIDE	1
5	25000340	CONFIGURATION GUIDE	1
6	25000350	GEM 4000 TRAINING GUIDE	1
7	25000260	CD TRAINING GUIDE GEM PREMIER 4000	1
8	25000270	CD, RESTORE SUPERVISOR V1.0.1	1
9	25000280	CD SOP TEMPLATE GEM PREMIER 4000	1
10	25000400	BARCODE GUN 2D BLUE TOOTH	1
11	25000450	AMPOULE BREAKER GEM PREMIER 4000	1
12	25000500	PAPER PRINTER 5/BOX GEM PREMIER 4000	1
13	24008992	CARTON, STARTUP KIT, GEM 4000	1
14	24008993	DIVIDER, STARTUP KIT	1
25	14882100	CORD LINE SHIELDED 110V	1
26	19725500	VDE APPROVED LINE CORD 220V	1

# Chapter 3 – Operating Programs

This section contains a brief overview of the available menu choices. Significant detail about each of these choices is available in the Operators Guide.

## 3-1 Main Screen

**Figure 3-1 The Main Screen**

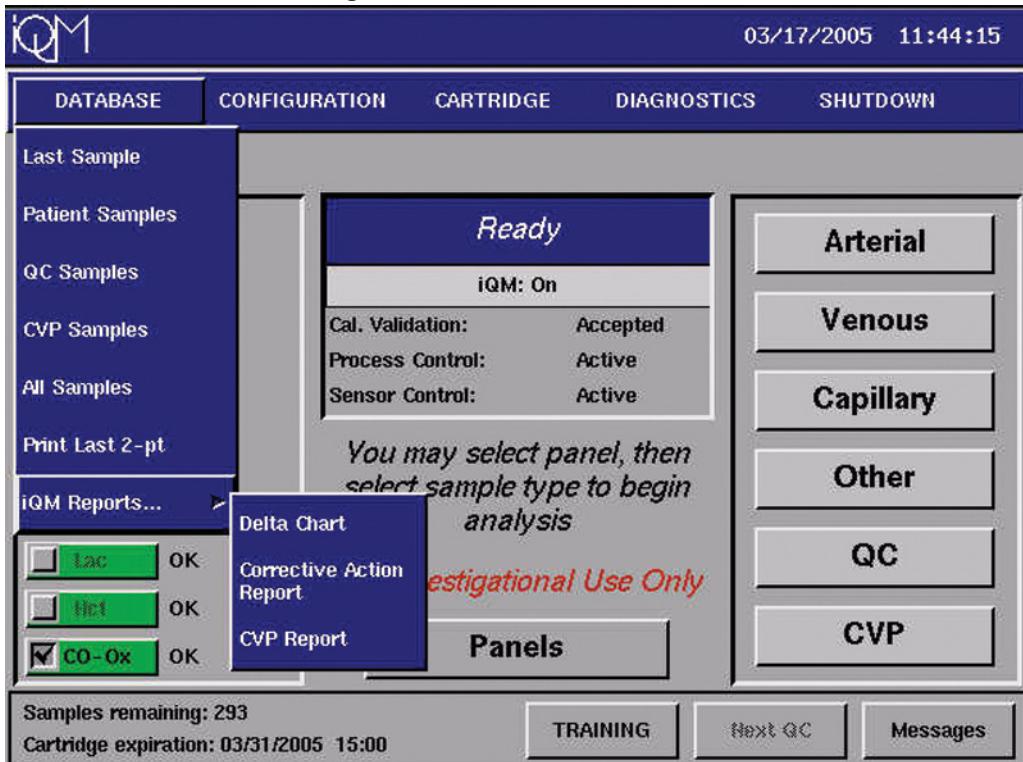


The Status Bar along the top of the Main Sampling screen provides quick access to critical information and capabilities.

- A. iQM status. IQM on if displayed
- B. Instrument date and Time
- C. Drop down menu selections
- D. Ready and iQM status
- E. Available sample types
- F. Analyte status
- G. Panel selection
- H. Current cartridge status

## 3-2 Database

Figure 3-2 The Database Screen



- A. Allows viewing, printing and transmitting previous samples, starting with most recent.
- B. Access to entering search criteria for patient samples in database
- C. Access to entering search criteria for QC samples in database
- D. Access to entering search criteria for CVP samples in database
- E. Access to entering search criteria for all samples in database
- F. Initiates printout of most recent 2-pt calibration results
- G. Opens drop down menu for iQM specific reports

### Delta chart

Displays screen to enter criteria for selection of specific charts. Charts can be viewed and printed. Printing is limited to parallel or network printer.

### Corrective Action Report (CAR)

Displays CAR for current month for viewing and printing. Printing is limited to parallel or network printer. Selection of previous months data available

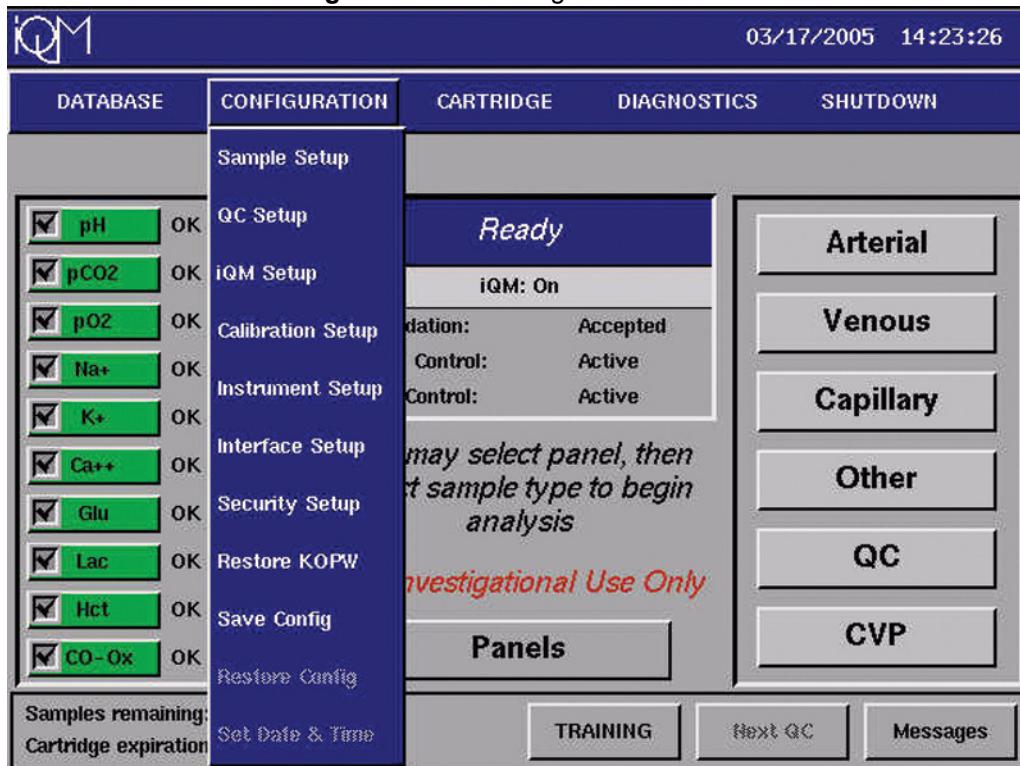
## CVP Report

Displays screen to enter month of CVP report to be printed. Report is not displayed and printing is limited to parallel or network printer.

All iQM Reports are available for 12 months, then are overwritten.

## 3-3 Configuration

Figure 3-3 The Configuration Screen



- A. Accesses a screen with choices for; Analyte Enable/Disable, Panel Setup, Demographics, Units of Measure Sample Print Options, Correlation Factors Patient Ranges, Print Ranges, Auto Accept, Flag Interference and Clots, and Report PCO2 when above 115 mmHg.
- B. Accesses a screen with choices for; Mandatory QC, QC Failure and Patient Results, QC Material setup, CO-Ox QC Material Setup, Routine QC Schedule Setup, New Cartridge QC Schedule Setup, and Range requirements for QC Statistics.
- C. Set up of CVP material ranges
- D. Allows for configuration of the Calibration Report printout and for setting the Low Oxygen calibration time.
- E. Choices for Time and date format, Language, Instrument Name, Touch screen volume and Screen color scheme. Any changes in this menu will require rebooting the instrument.

- F. Choices for selecting output or input to Com Ports A, B, C, and Ethernet Port. Accesses Network Setup, including GEMweb, and Printer Setup, internal, parallel or network printer. Changes made in this menu may require rebooting the instrument.
- G. Accesses a screen with choices for; Disable Patient Analysis, Enable Email Sample Results, Operator Security, Default Operator, Authorized Operator Setup, Save Authorized Operators, Restore Authorized Operators and Change Key Operator Password.
- H. Displays a prompt to insert KOPW disk
- I. Displays a prompt to insert a blank disk to save the configuration for use on another instrument, or on the same instrument at a later date.
- J. This menu choice is only accessible when no cartridge is inserted. Prompts to insert the disk created in Save Config.
- K. This menu choice is only accessible when no cartridge is inserted. Allows change of date and time and selection of Daylight saving Time.

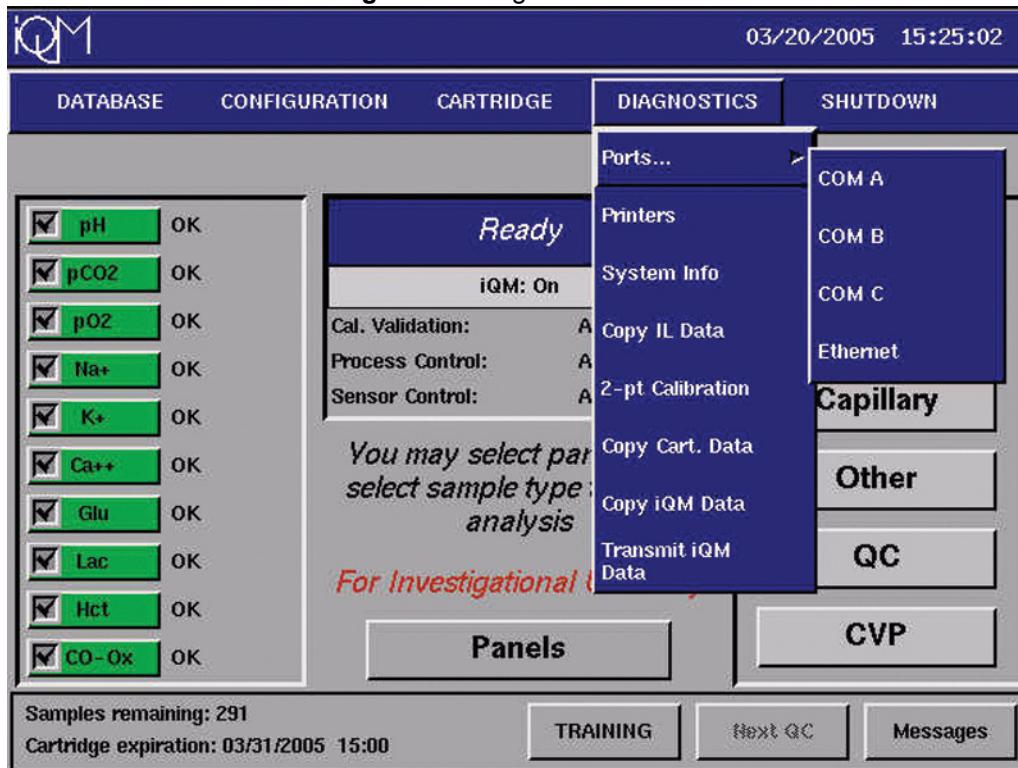
**With the exception of “Restore KOPW”, access to any of these menus requires the use of the Key Operator Password.**

## 3-4 Cartridge

This menu has only one selection; “Remove Cartridge”. When this choice is selected, it must be verified, then the cartridge may be removed.

## 3-5 Diagnostics

Figure 3-4 Diagnostics Screen



- A. Provides screens for status and testing of Com Port A, B, C and the Ethernet port.
- B. Provides screen for status and testing of the internal printer, parallel printer and network printer.
- C. Provides specific information about software version, instrument serial number and hardware, and cartridge information.
- D. Provides a screen to select specific cartridges for copying IL Data to a disk. IL Data contains no patient information.
- E. Initiates a 2-pt calibration.
- F. Provides a screen to select specific cartridges for copying data to disk. Data will contain patient information.
- G. provides a screen to select a month for which iQM data can be transmitted via the selected COM Port.

## 3-6 Shutdown

This menu has only one selection “Shutdown”. When this is selected, it must be verified, then the instrument will prepare for shutdown.

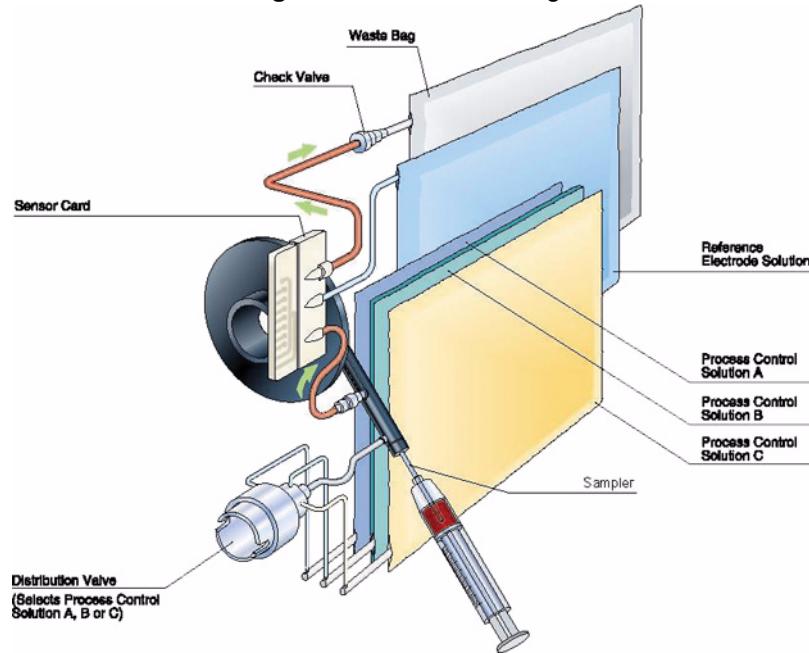
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# Chapter 4 – Fluidic Cartridge

The GEM Premier 3500 uses a cartridge to perform all measurements. The cartridge contains all of the fluidic components and sensors of the instrument. The sensors are contained on a card that interfaces with the Heater Block for temperature control, and with the analog PCB to provide the output voltages to the processor.

The Process Control solutions are contained in three airtight bags, with no headspace. This eliminates any changes in values due to changes in Barometric pressure or temperature, a key requirement for iQM.

**Figure 4-1 Fluidic Cartridge**



## 4-1 Cartridge Types

Cartridges are available in multiple configurations, based on Menu (BG + Hct, BG/Lytes + Hct, and BG/Lytes/Glucose Lactate + Hct) sample volume (75 to 600 tests), and use life (2, 3, or 4 weeks). In addition, each cartridge is available as iQM or non-iQM. The chart below shows all of the available cartridges.

**Table 4-1** Cartridges

Test Menu	Capacity	Use-Life
Blood Gases, Hct	75	4 weeks
	75	3 weeks
	150	3 weeks
	300	3 weeks
	450	3 weeks
Blood gases, Hct, Electrolytes	75	3 weeks
	150	3 weeks
	300	3 weeks
	450	3 weeks
	600	2 weeks
Blood gases, Hct, Electrolytes, Glucose, Lactate	75	3 weeks
	150	3 weeks
	300	3 weeks
	450	3 weeks
	600	2 weeks

## 4-2 Storage and Shelf Life

The requirements for storage of the cartridges are ambient temperature 15 to 25° C (59 to 77° F). It cannot be frozen. The shelf life of the cartridge is 6 months from the date of manufacture. The cartridge is marked with an expiration date (YYYY/MM/DD). The cartridge can be used as long as it is inserted before midnight of the day following the expiration date.

## 4-3 Preparation for Use

There is a small notch in the edge of the foil pouch. The pouch can be opened by hand by tearing at this notch. Remove the cartridge from the foil pouch. Inspect the cartridge for leaks, and inspect the inside of the pouch to ensure that it is dry. There is a clear plastic cover over the end of the cartridge, with a tab at the top of the cartridge. Pull on this tab to remove this cover. Removing the cover will open the four valves and allow the proper flow of the internal solutions.

The cartridge can now be inserted into the instrument, larger bar code label up.

## 4-4 Calibration Frequency

**Table 4-2 Calibration Frequency**

<b>Cartridge life (after warm-up) Frequency</b>	<b>One-point Calibration</b>
0.5 to < 3 hours	every 2 minutes
3 hours to < 6 hours	every 4 minutes
6 hours to < 10 hours	every 6 minutes
10 hours to < 20 hours	every 10 minutes
20 hours to < 40 hours	every 15 minutes
40 hours to < 80 hours	every 20 minutes
80 hours to 504 hours	every 30 minutes
<b>Cartridge life (after warm-up) Frequency</b>	<b>Two-point Calibration</b>
30 minutes to < 50 minutes	every 20 minutes
50 minutes to < 80 minutes	every 30 minutes
80 minutes to < 2 hours	every 40 minutes
2 hours to < 8 hours	every hour
8 hours to < 20 hours	every 2 hours
20 hours to < 40 hours	every 3 hours
40 hours to 504 hours	every 4 hours
<b>Cartridge life (after warm-up) Frequency</b>	<b>Two-point Calibration</b>
0 hours to 504 hours	once every 24 hours

(The exact time of the day for performing Low Oxygen calibration is user selectable, default is 0200)

## Calibration evaluation

The calibration results will be reported (no errors or an error indicated) according to the Calibration Report settings configured by the Key Operator

If a calibration fails, results for the analyte(s) involved will not be reported, however, results for analytes that passed calibration will continue to be reported

Slope (two-point calibration) and drift (one and two point calibration) errors must be corrected prior to reporting results for the failed analyte(s)

## Corrective action – calibration failure

Following a calibration failure, corrective two-point calibrations will be performed automatically up to three times. **Allow the instrument to complete this self-diagnostics!**

If desired, continue to use the cartridge and only report results from working sensors Additional two-point calibrations may be manually initiated

## Calibration interruption

During the first 4 hours after cartridge insertion, a two-point calibration cannot be interrupted for sample analysis

- Four hours after cartridge insertion, a two-point calibration can be interrupted up to 3 consecutive times only for patient sample analysis. Calibrations cannot be interrupted for QC samples
- The first one-point calibration after sample analysis cannot be interrupted

Low O<sub>2</sub> calibration cannot be interrupted.

## 4-5 Removal and Disposal



**BIOHAZARD: Avoid touching, with bare hands, any parts of the system which may have come in contact with potentially GEM Premier 3500 Service Manual infectious fluids. ALWAYS wear gloves when performing any type of Maintenance/Service action on this area.**

The cartridge must be removed for the following:

The cartridge has reached its time limit of 504 hours for a 3 week cartridge, 336 hours for a 2 week cartridge or 672 hours for a 4 week cartridge.

The cartridge has reached its sample capacity.

Blood or process control solution C has rested on the sensors for more than 20 minutes.

The power has been interrupted for greater than one hour.

The cartridge encounters a fatal error.

In these cases, the instrument will prompt to “Remove and Discard cartridge”. In addition, the cartridge can be removed at any time by pressing “Cartridge” on the main screen and then pressing “Remove Cartridge” on the drop down menu. If security is on, an authorized operator password must be entered to proceed. After confirmation, the “Remove and Discard Cartridge” screen will be displayed. Open the cartridge door by sliding the lock on the cartridge door forward and opening the door. The cartridge can be removed and discarded at this time.

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# Chapter 5 – Maintenance

There is limited operator maintenance required on the GEM Premier 3500. The only necessary maintenance is; changing printer paper, changing cartridge, emptying ampoule breaker, and cleaning exposed surfaces. In addition, there is a Preventive Maintenance (PM) procedure to be performed by an authorized IL service technician.

## 5-1 Cartridge Replacement

Removal of the cartridge is described in “[Removal and Disposal](#)” in Chapter 4 insertion of a new cartridge is described in “[Preparation for Use](#)” in Chapter 4.

## 5-2 Loading Paper

Loading of paper is described in “[Loading Paper](#)” in Chapter 2.

## 5-3 Emptying Ampoule Breaker

Remove the ampoule breaker by pulling straight out on the tab at the bottom of the breaker. The top will open by lifting up from the back. The ampoule breaker can then be emptied and cleaned before replacing.



***CAUTION: Use caution, contains broken glass. Dispose of properly.***

## 5-4 Cleaning

The instrument surfaces can be wiped clean according to the laboratory protocols. The painted surfaces can be sprayed with a mild (10%) bleach solution, or any approved commercially available decontaminant. To clean the LCD, spray the decontaminant onto the wiping material, then wipe the LCD surface. Do not use excess liquid when cleaning the LCD.

## 5-5 PM Procedure

Instrumentation Laboratory currently recommends a PM after the first five years and every other year thereafter.

### Preliminary

If necessary, decontaminate instrument. Copy configuration to disk using “Save Config” selection in Configuration Menu.

### Tools

- Key Operator ID Disk
- Pump Spring Tension Force Gauge
- Loopback Test Connector
- Ethernet Test Cable

### Preventive Maintenance Procedure

**Remove cover:** Visually inspect the following areas and repair if needed:

**Perform Pump Spring Tension Test:** Adjust pump tension to 6.2 +/- 0.1lbs if necessary. Record pump tension as received and after setting.

**Clean dust out of the card rack.**

**CD/DVD Ejection Test:** Insert a disk into the drive. Press the ejection button to eject the disk. Repeat the test three times.

**Line cord:** Inspect the line cord for nicks, breaks, or cuts.

**General loose screw inspection:** Verify that the hardware is secured on the following assemblies and in the following areas:

- Pump motor
- Handle screws
- Actuators
- Cartridge compartment
- Heater Block

**Sensor flex cable:** Visually inspect the sensor flex cable for fluid leak.

#### Display Assembly:

Check for faulty latch, loose hardware, and loose connections to the display.

- Adjust the display to the upright position, and then push on the display to tilt the unit; the latch should not slip.
- Verify that display is uniformly bright, and that brightness is adequate.

## System Performance Tests

The instrument performance should be verified. The method of verifying the performance is by using “live” cartridge. After the cartridge warm-up is complete, all levels of CVP must be run, with acceptable results.

### Bar Code Reader Tests

When inserting the cartridge, verify that the cartridge bar code reader correctly reads the cartridge barcode. Use the Bar code wand to enter either the CVP or the QC ranges. Verify that the wand reads correctly. Use the ampoule spinner to read the CVP or the QC material. Verify that the ampoule spinner bar code reader reads the ampoules correctly.

### Loopback Test

Perform RS232 Loopback test

### Ethernet Test:

Perform Ethernet “Ping” test.

### Instrument Information

View the System Information screen and record the serial number and software revision.

### Restore Customer Configuration Back to System

Insert the “Copy Customer Configuration Disk” that was used in Preliminary Check. Verify the copying status on the screen.

### Final Verification:

Verify that the GEM Premier 3000 Test Record is complete.

**Incident Report** - verify that the Incident Report form is complete.

**Printouts** - verify that the calibration printouts are present.

**No missing screws** - verify that there are no missing screws.

**Paper is removed** - verify that the printer paper is removed.

**Time and date are set** - verify that time and date are set correctly to the customer’s geographic area.

**Software version** - verify that the software version is the same as recorded on the Preventive Maintenance Test Record “Preliminary Check-in.” The software version is located in the upper left corner of the display screen.

**Instrument cosmetics** - the outside of the instrument should be cleaned.

## 5-6 PM Checklist

The following checklist can be used to record results and document the work performed during the PM. Procedure.

**ACCOUNT NAME** \_\_\_\_\_

S/N \_\_\_\_\_ Call # \_\_\_\_\_

**PM**

Operation	Yes	N/A
Clean dust out of card rack		
Check connections on line filter/power switch wires		
Check ejection of floppy disk drive		
Inspect line cord for nicks, breaks or cuts		
General loose screw inspections (pump motor, handle screws actuators, cartridge compartment)		
Checks for fluid on sensor flex cable (LEAK)		
Display assembly		
Latch, hardware, connections, all screws tight		
Latch slip test		
Uniform and adequate brightness		
Serial number correct		
Record software revision		

Pump Spring Tension Test 6.2 LB. +/- .1LB

Adjusted Yes \_\_\_\_\_ No \_\_\_\_\_

Initial \_\_\_\_\_ lb. Final \_\_\_\_\_ lb.

Comments

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Tech \_\_\_\_\_ Date \_\_\_\_\_

### System Performance Test

Test used : CVP \_\_\_\_\_ QC \_\_\_\_\_ All Parameters passed \_\_\_\_\_

Barcode readers operational

Cartridge \_\_\_\_\_ Wand \_\_\_\_\_ Spinner \_\_\_\_\_

RS 232 Loopback test

Port A \_\_\_\_\_ Port B \_\_\_\_\_ Port C \_\_\_\_\_

Ethernet Ping test Pass \_\_\_\_\_

Tech \_\_\_\_\_ Date \_\_\_\_\_

Restore System Configuration

Customer Configuration Files (Copy Disk) \_\_\_\_\_

Tech \_\_\_\_\_ Date \_\_\_\_\_

### **Final Verification**

Verify all items checked \_\_\_\_\_

Verify TIME and DATE \_\_\_\_\_

Printouts are present and correct \_\_\_\_\_

Verify software level is correct \_\_\_\_\_

S/W Rev Level \_\_\_\_\_

Verify all screws are installed \_\_\_\_\_

Inspect instrument cosmetics \_\_\_\_\_

Verify serial number installed \_\_\_\_\_

Tech \_\_\_\_\_ Date \_\_\_\_\_

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# Chapter 6 – Instrument Repair

This section contains instructions for the removal and replacement of components and sub-assemblies of the GEM Premier 3500.



**BIOHAZARD:** *Avoid touching, with bare hands, any parts of the system which may have come in contact with potentially infectious fluids. ALWAYS wear gloves when performing any type of Maintenance/Service action on these areas.*

## 6-1 Removal and Replacement

### Access to the Instrument



**CAUTION:** *The instrument must be powered down and unplugged before performing this operation.*

Components of the Gem Premier 3500 are accessible primarily via the following method:

1. Lift the instrument handle and unscrew the four top cap mounting screws (see [Figure 6-1 "Top Cap Mounting Screws"](#)).

**Figure 6-1** Top Cap Mounting Screws



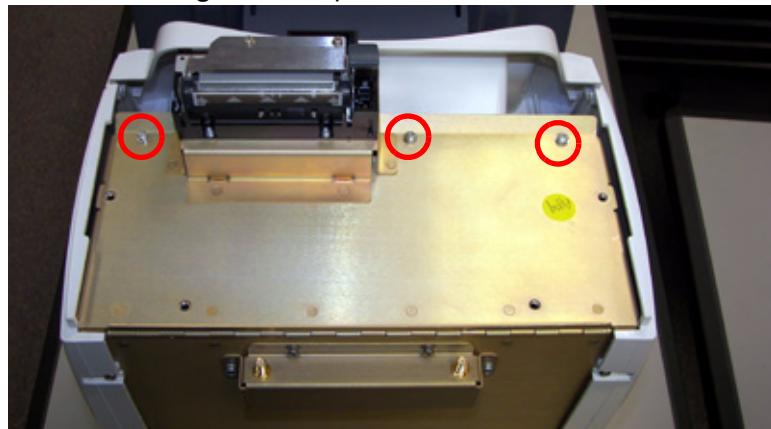
2. Open the printer door and lift the top cap off of the instrument (see [Figure 6-2 "Printer Door"](#)).

**Figure 6-2 Printer Door**



3. Remove three screws as shown in [Figure 6-3 "Top Access Panel Screws"](#).

**Figure 6-3 Top Access Panel Screws**



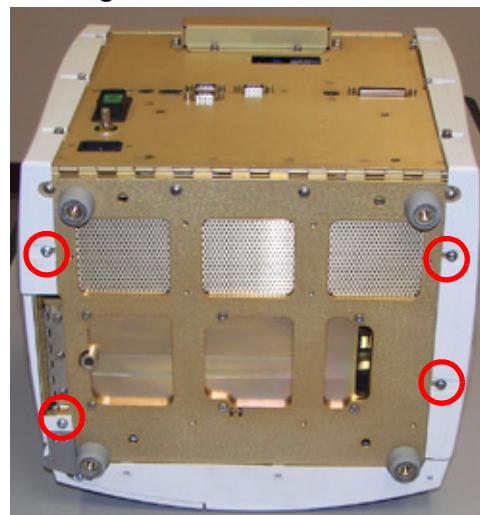
4. Loosen or remove the six screws on the back of the instrument (see [Figure 6-4 "Instrument Rear"](#)).

**Figure 6-4** Instrument Rear



5. Loosen or remove the four screws on the bottom of the instrument and remove the side panels (see [Figure 6-5 "Instrument Bottom"](#)).

**Figure 6-5** Instrument Bottom



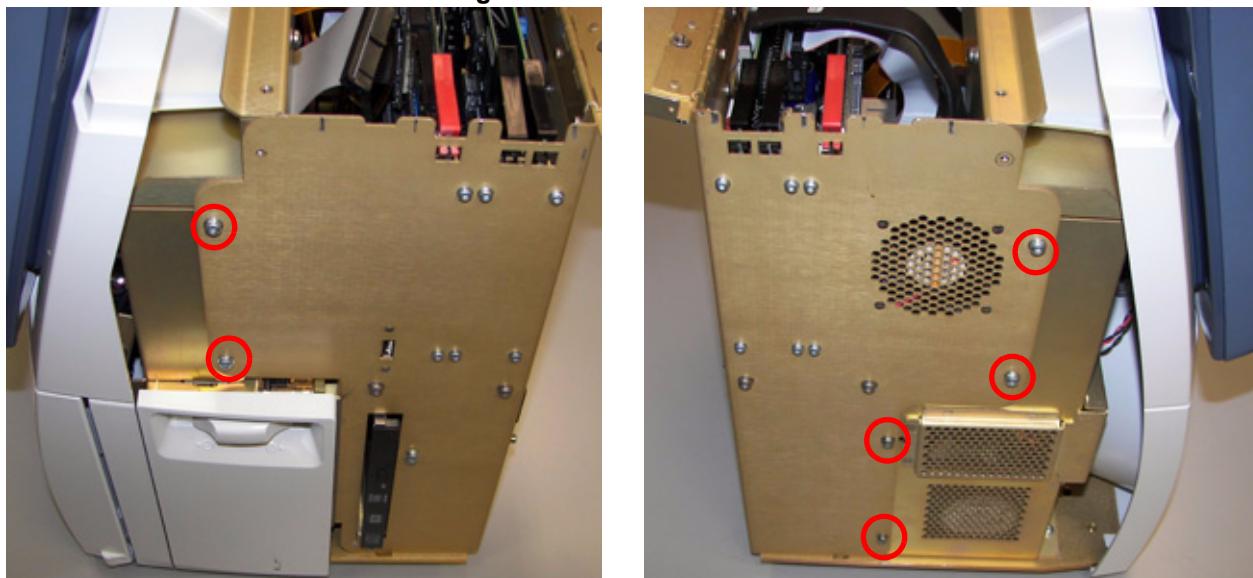
6. Open the top access panel and disconnect the printer cable (see [Figure 6-6 "Printer Cable"](#)).

**Figure 6-6 Printer Cable**



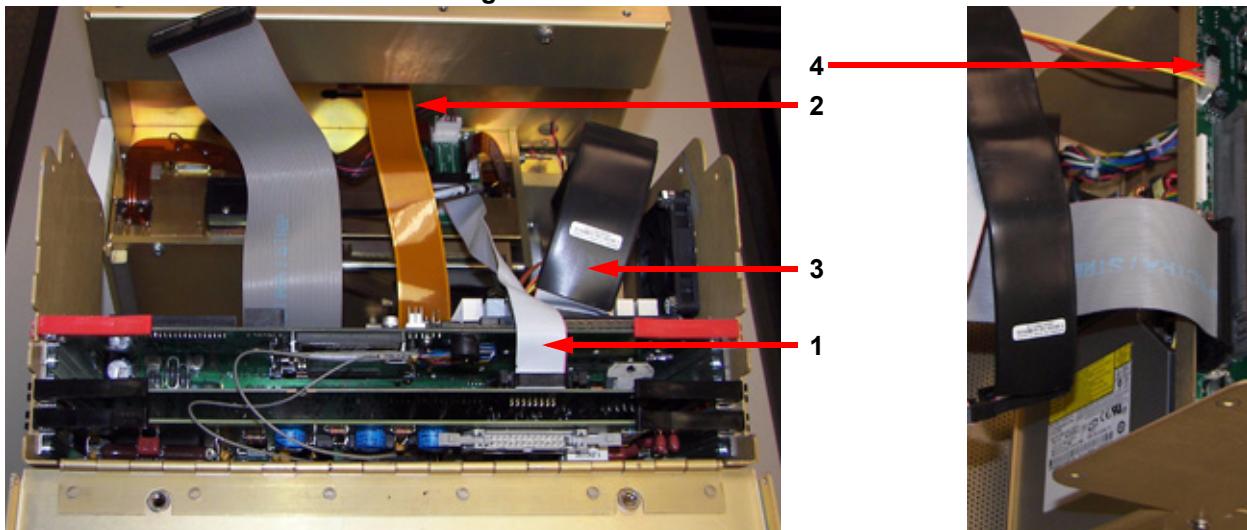
7. Remove two screws from the right side and four screws from the left side of the instrument chassis as shown in [Figure 6-7 "Instrument Chassis"](#).

**Figure 6-7 Instrument Chassis**



8. Tilt the rear of the instrument back and disconnect the Analog Board Cable (1), Video Cable (2), DCS Board Cable (3) and the Stepper Motor Cable (4) as shown in [Figure 6-8 "Instrument Cables"](#) and open the instrument (see [Figure 6-9 "Open Instrument"](#)).

**Figure 6-8 Instrument Cables**



**Figure 6-9 Open Instrument**

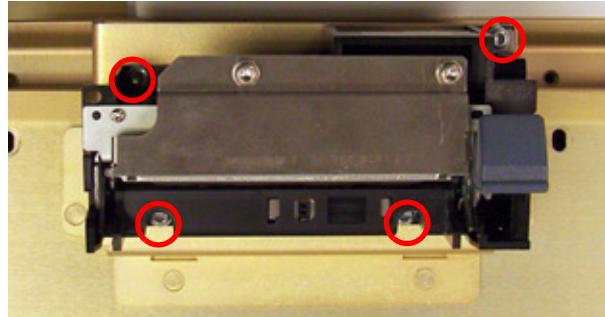


## Printer Removal/Replacement

### Printer Removal

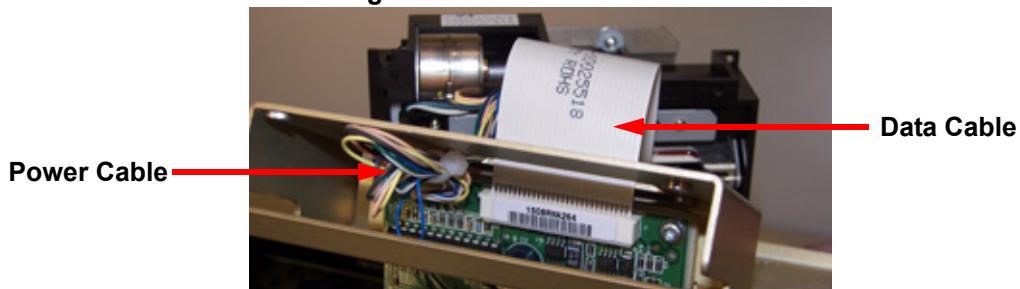
1. Follow steps 1 through 4 of "Access to the Instrument" to gain access to the Printer.
2. Unscrew the four printer mounting screws as shown in **Figure 6-10 "Printer"**.

**Figure 6-10 Printer**



3. Unplug the two printer board cables (see **Figure 6-11 "Printer Board Cables"**).

**Figure 6-11 Printer Board Cables**



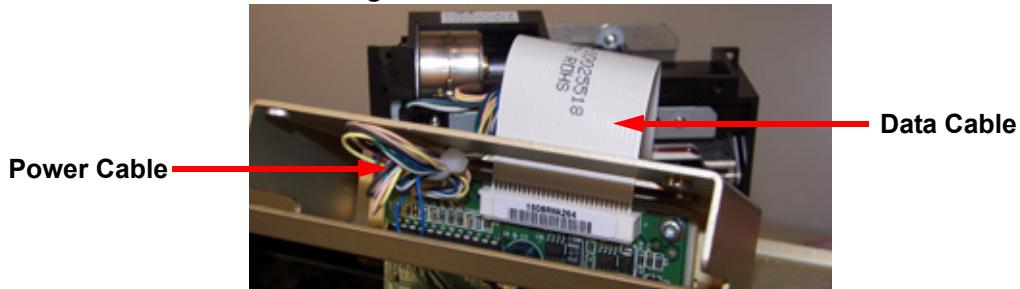
### Printer Installation

Perform the preceding steps in reverse order to install the Printer.

### Printer PCB Removal/Replacement

1. Follow steps 1 through 4 of "Access to the Instrument" to gain access to the Printer.
2. Unplug the power and data cables (see **Figure 6-11 "Printer Board Cables"**).

**Figure 6-12 Printer Board Cables**



3. Remove the four screws at each corner of the Printer PCB.

## Printer PCB Installation

Perform the preceding steps in reverse order to install the Printer PCB.

## CD/DVD Drive Removal/Replacement

### CD/DVD Drive Removal

1. Follow the steps described in "[Access to the Instrument](#)" to gain access to the CD/DVD drive.
2. Disconnect the power and data cables.
3. Unfasten the two screws on the outside of the CD/DVD drive and remove the assembly from the instrument (see [Figure 6-13 "CD/DVD Drive Removal"](#)).

**Figure 6-13** CD/DVD Drive Removal



### CD/DVD Drive Installation

Perform preceding steps in reverse order to Install the CD/DVD Drive.

## DCS Board Removal/Replacement

### DCS Board Removal

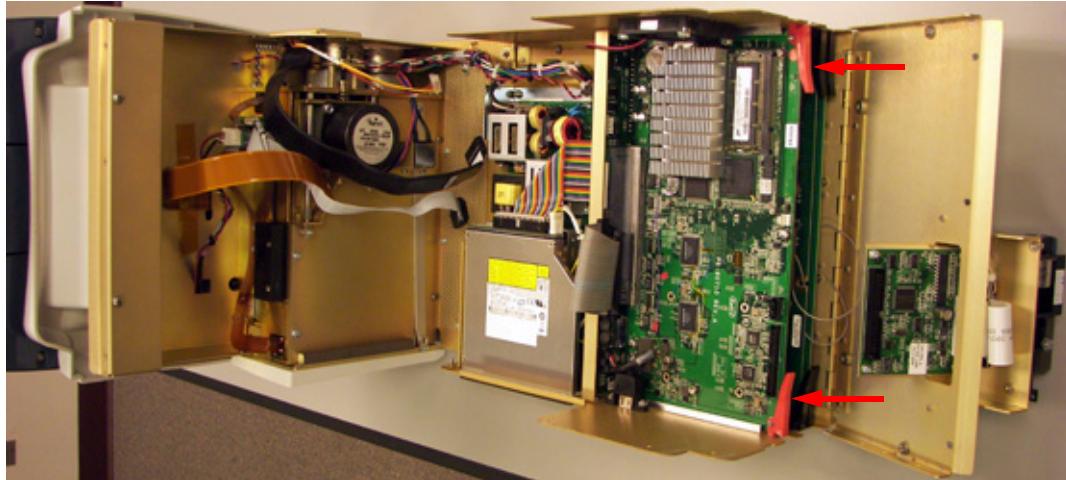


**CAUTION:** The instrument must be powered down and unplugged before performing this operation.

1. Follow steps 1-5 and 8-11 in "[Access to the Instrument](#)" to gain access to the DCS Board Assembly.

2. Disengage the clamps at the top of the DCS Board and slide the assembly out of the Backplane board and the instrument as shown in [Figure 6-14 "PCB Assembly Removal"](#).

**Figure 6-14 PCB Assembly Removal**



## **DCS Board Installation**

Perform the preceding steps in reverse order to Install the DCS Board Assembly.

## **SBC Board Removal/Replacement**

### **SBC Board Removal**

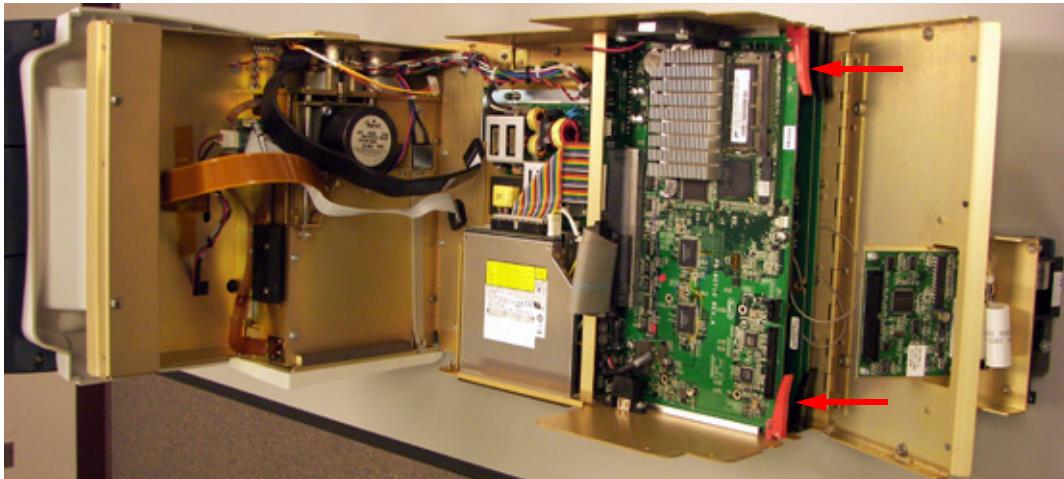


**CAUTION: The instrument must be powered down and unplugged before performing this operation.**

1. Follow steps 1-5 and 8-11 in ["Access to the Instrument"](#) to gain access to the SBC Board Assembly.

2. Disengage the clamps at the top of the SBC Board and slide the assembly out of the Backplane board and the instrument as shown in [Figure 6-14 "PCB Assembly Removal"](#).

**Figure 6-15 PCB Assembly Removal**



## SBC Board Installation

Perform the preceding steps in reverse order to Install the SBC Board.

## SD Memory Removal/Replacement

### SD Memory Removal



**CAUTION: The instrument must be powered down and unplugged before performing this operation.**

1. Follow steps 1-3 in ["Access to the Instrument"](#) to gain access to the SD Memory card.
2. Pull the SD Memory card out of its socket (see ).

**Figure 6-16 SD Memory Card**



## SD Memory Installation

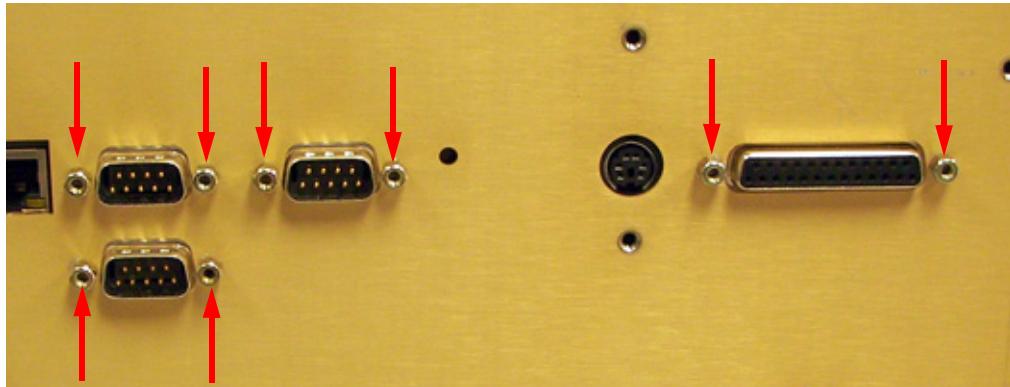
Perform the preceding steps in reverse order to Install the SD Memory card.

## Backplane Board Removal/Replacement

### Backplane Board Removal

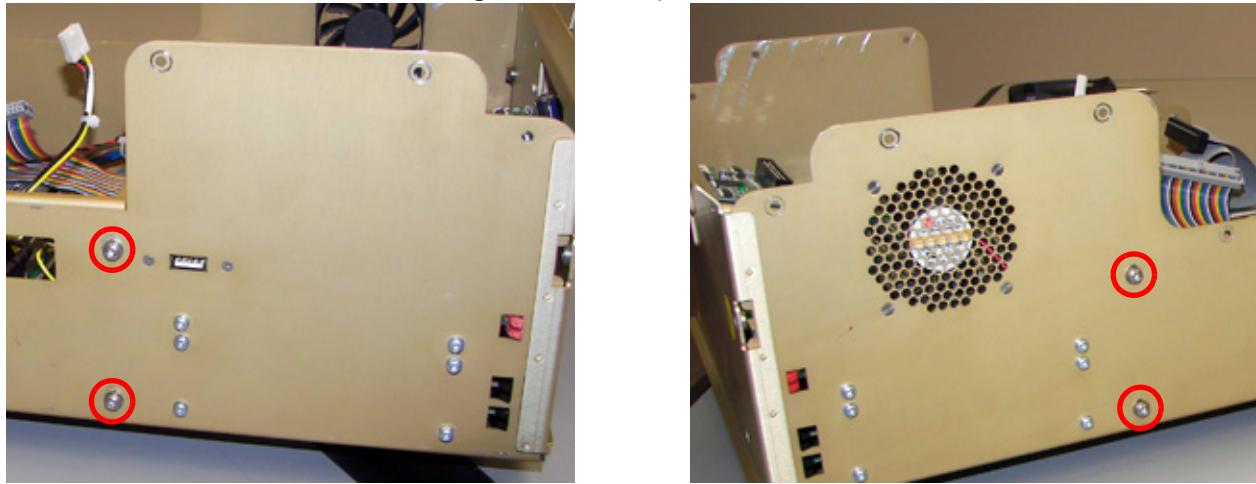
1. Remove the DCS Board, SBC Board and Motherboard Assemblies.
2. Remove the eight standoff nuts from the back panel (see [Figure 6-17 "Standoff Nuts"](#)).

**Figure 6-17 Standoff Nuts**



3. Disconnect all cables from the Backplane Board.
4. Remove the four screws from each side of the chassis as shown in [Figure 6-18 "Backplane Bracket"](#) and remove the Backplane Board and bracket.

**Figure 6-18 Backplane Bracket**



5. Remove the four screws on the Backplane Board to remove it from the bracket.

### Backplane Board Installation

Perform the preceding steps in reverse order to Install the Backplane Board.

## Power Supply Removal/Replacement

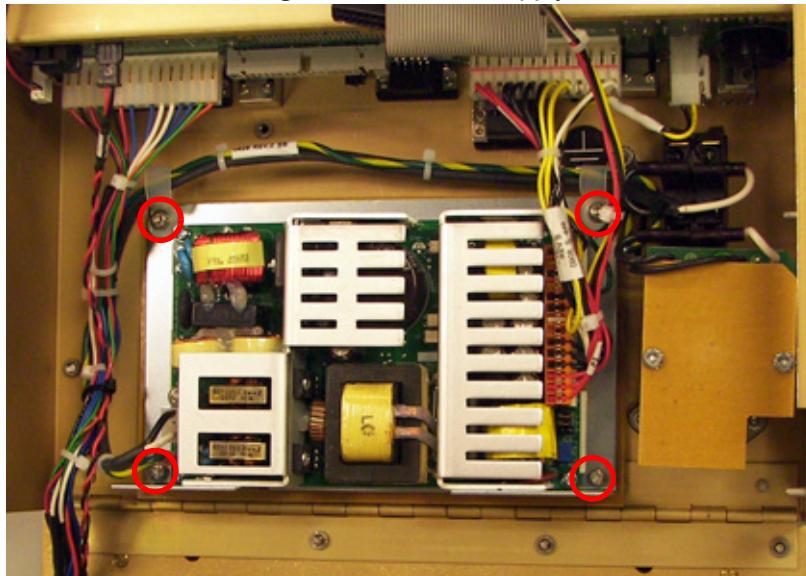
### Power Supply Removal



**CAUTION:** The instrument must be powered down and unplugged before performing this operation.

1. Follow the steps described in "[Access to the Instrument](#)" to gain access to the Power Supply.
2. Disconnect all cables from the Power Supply.
3. Remove the four screws as shown in **Figure 6-19** Power Supply.

**Figure 6-19** Power Supply



4. Lift the Power Supply up and out of the instrument.

### Power Supply Installation

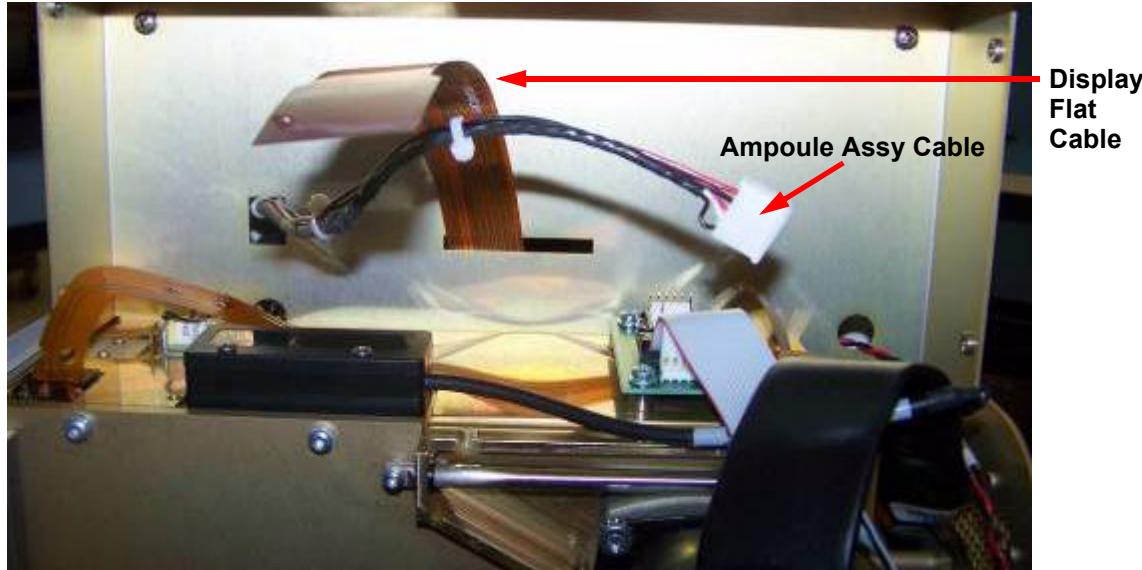
Perform the preceding steps in reverse order to Install the Power Supply.

## Front Panel Removal/Replacement

### Front Panel Removal

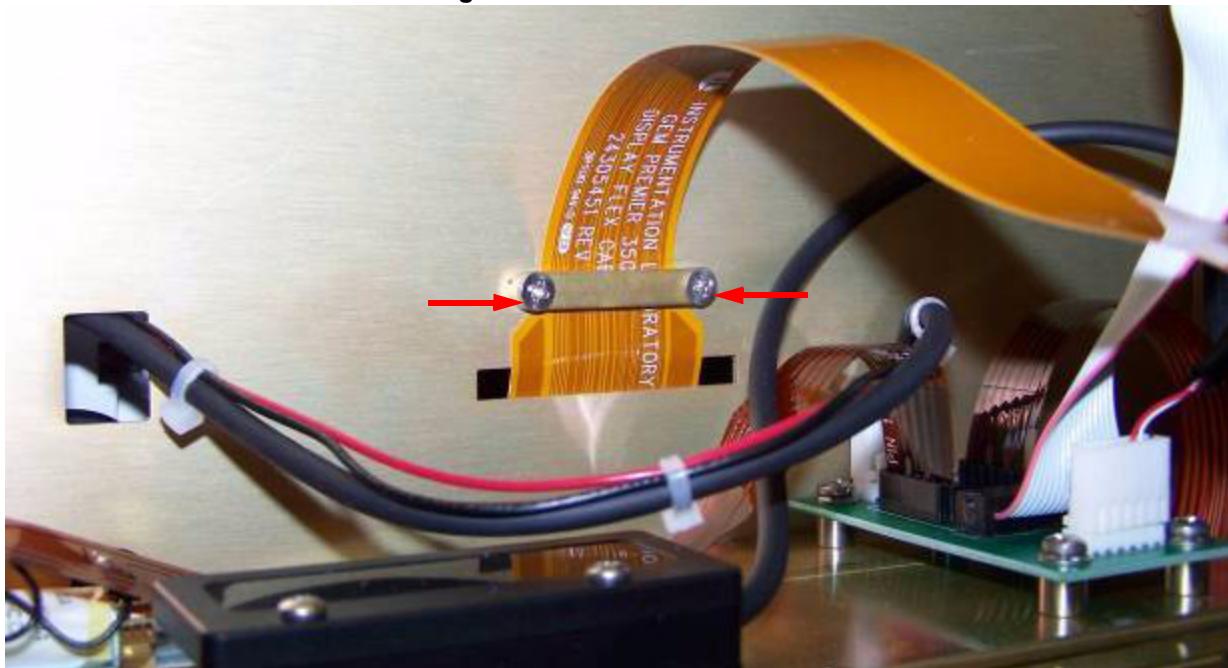
1. Follow the steps described in "[Access to the Instrument](#)" to disconnect and gain access to the Display Flat Cable (see [Figure 6-20 "Display Flat Cable"](#)).

**Figure 6-20 Display Flat Cable**



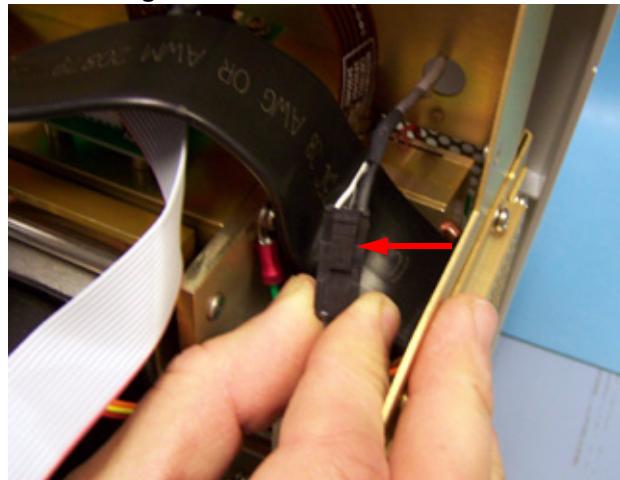
2. Disconnect the Ampoule Assy. Cable as shown above in [Figure 6-20 "Display Flat Cable"](#).
3. Remove the Display Flat Cable Bracket by loosening the captive hardware as shown in [Figure 6-21 "Flat Cable Bracket"](#).

**Figure 6-21 Flat Cable Bracket**



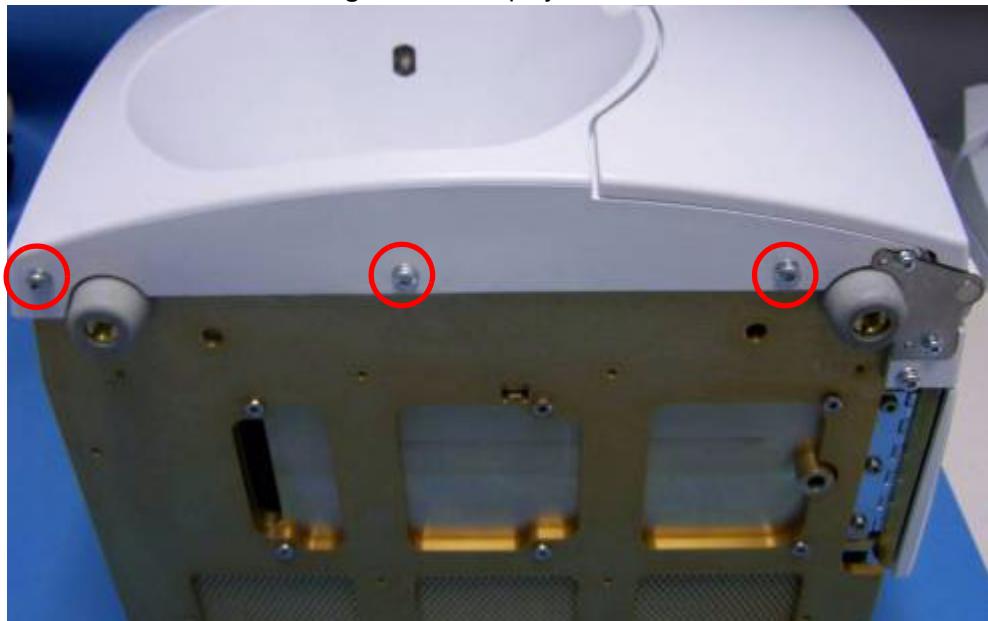
4. Disconnect the LED Extension Cable as shown in [Figure 6-22 "LED Extension Cable"](#).

**Figure 6-22** LED Extension Cable



5. Remove the three screws from the bottom of the front cover Carefully feed the Display Flat Cable out of the instrument as shown in [Figure 6-22 "Display Removal"](#) and pull the Front Panel Assy away from the instrument.

**Figure 6-23** Display Removal



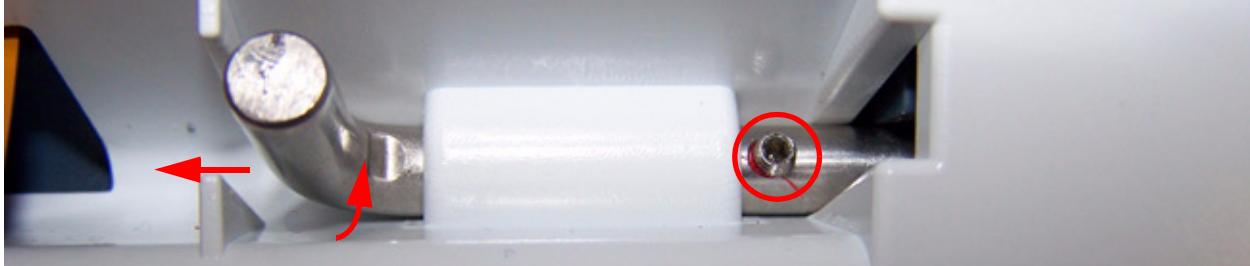
## Front Panel Installation

Perform the preceding steps in reverse order to Install the Display Assembly.

## Display Assembly Removal/Replacement

1. Remove the Front Panel Assembly as described in "[Front Panel Removal/Replacement](#)".
2. Remove the two "L" pivot pins by first loosening the set screws and then tilting the pins up and pulling them out as shown in [Figure 6-23 "Display Pivot Pins"](#).

**Figure 6-24 Display Pivot Pins**



3. Apply pressure to the Tilt Display Brackets as shown in [Figure 6-24 "Tilt Display Brackets"](#) to disengage them from the front panel.

**Figure 6-25 Tilt Display Brackets**



4. Carefully turn the assembly over and pull the display assembly out of the Front Panel (see [Figure 6-25 "Display Assy. Removal"](#)). Carefully guide the video cable out of the front panel.

**Figure 6-26 Display Assy. Removal**



## Front Panel Installation

Perform the preceding steps in reverse order to Install the Display Assembly.

## LCD Removal/Replacement

### LCD Removal

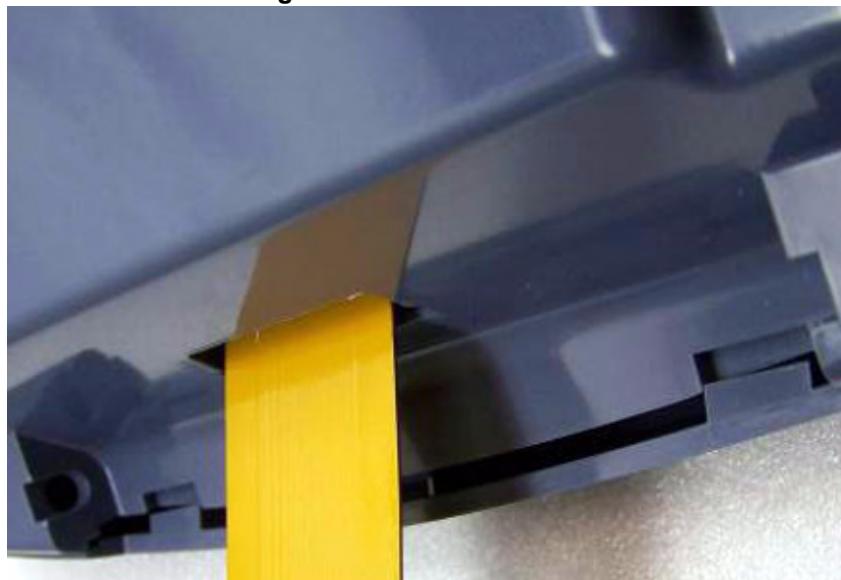
1. Remove the four screws on the back of the LCD Bezel as shown in [Figure 6-26 "LCD Rear Bezel"](#).

**Figure 6-27 LCD Rear Bezel**



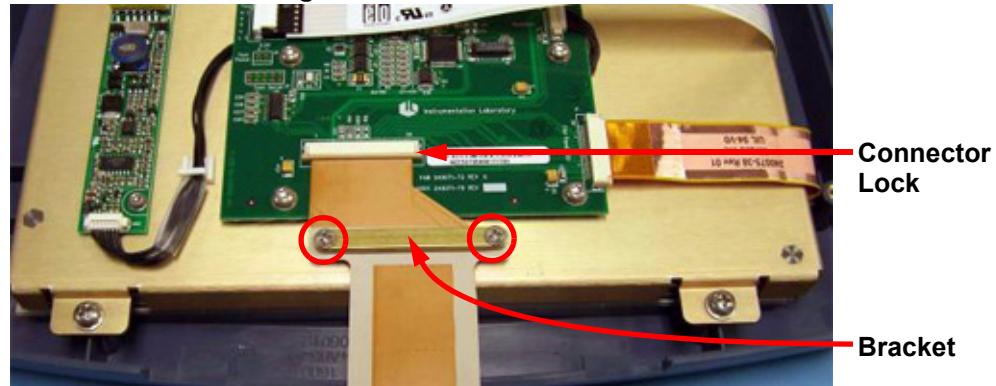
2. Tilt the rear panel of the display back to disengage it from the tabs on the front bezel (see [Figure 6-27 "Front Bezel Tabs"](#)).

**Figure 6-28 Front Bezel Tabs**



3. Remove the two screws on the video cable strain relief bracket and disengage the connector lock and disconnect the Video Cable (see [Figure 6-29 "LCD Cables"](#)).

**Figure 6-29** Video Cable



4. Disconnect the Touchscreen Cable (see [Figure 6-29 "LCD Cables"](#)).
5. Disconnect the LCD Interconnect Cable (see [Figure 6-29 "LCD Cables"](#)).
6. Remove the four screws that mount the LCD Bracket to the Front Bezel as indicated in [Figure 6-29 "LCD Cables"](#).

**Figure 6-30** LCD Cables



- Turn the LCD and bracket over and remove the four screws located at each corner of the LCD (see [Figure 6-30 "LCD Mounting Screw Location"](#)).

**Figure 6-31 LCD Mounting Screw Location**



## LCD Installation

Perform the preceding steps in reverse order to Install the LCD.

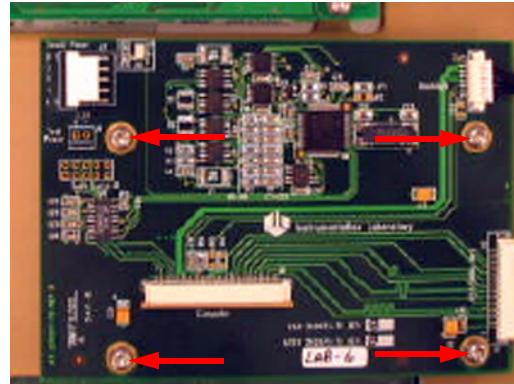
## Touchscreen Board Removal

- Disconnect the Touchscreen, LCD Interconnect, and Inverter Board Cables (see [Figure 6-31 "Video Cables"](#)).

**Figure 6-32 Video Cables**



- Remove the four screws on the Touchscreen Board as shown in [Figure 6-32 "Touchscreen Board"](#).

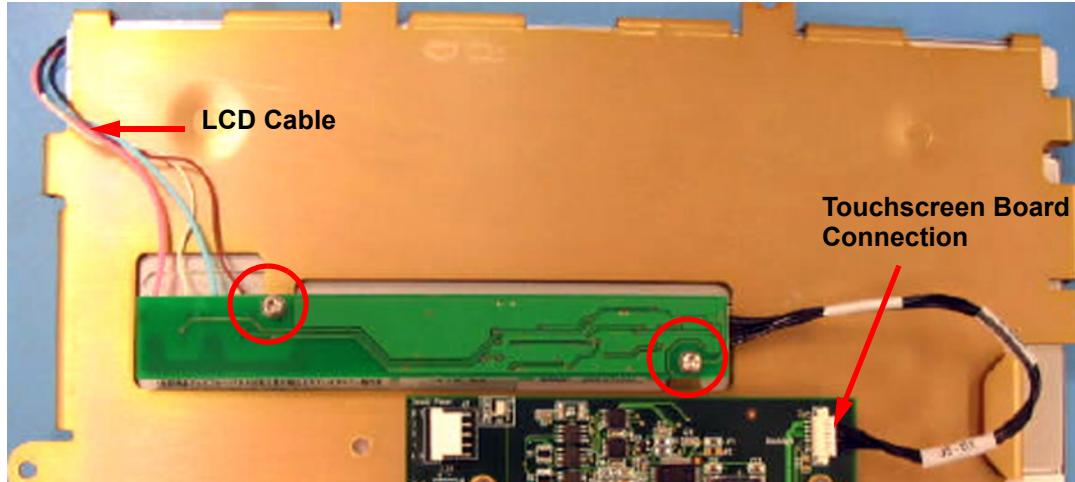
**Figure 6-33 Touchscreen Board**

### Touchscreen Board Installation

Perform the preceding steps in reverse order to Install the Touchscreen Board.

### Inverter Board Removal

1. Disconnect the LCD Cable and the Touchscreen Board Connection (see [Figure 6-33 "Inverter Board"](#)).
2. Remove the two screws as shown in [Figure 6-33 "Inverter Board"](#).

**Figure 6-34 Inverter Board**

### Inverter Board Installation

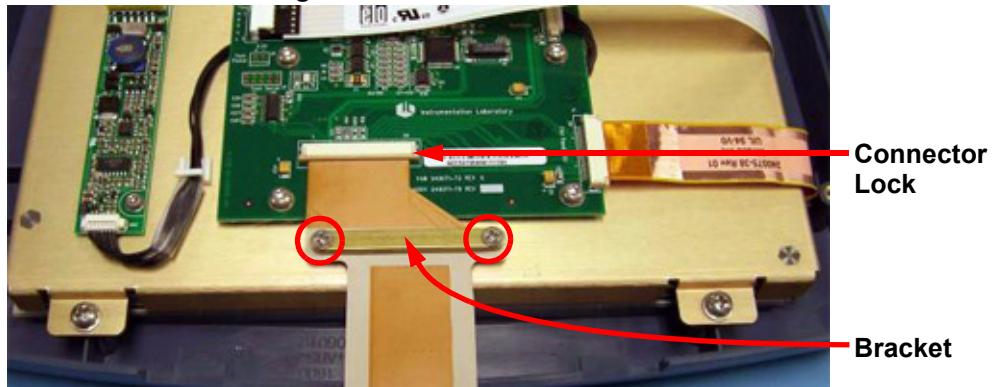
Perform the preceding steps in reverse order to Install the Inverter Board.

### Video Cable Removal

1. Remove the four screws on the back of the LCD Bezel as shown in [Figure 6-26 "LCD Rear Bezel"](#).

**Figure 6-35 LCD Rear Bezel**

2. Disengage the connector lock and disconnect the Video Cable (see [Figure 6-36 "Video Cable"](#)).

**Figure 6-36 Video Cable**

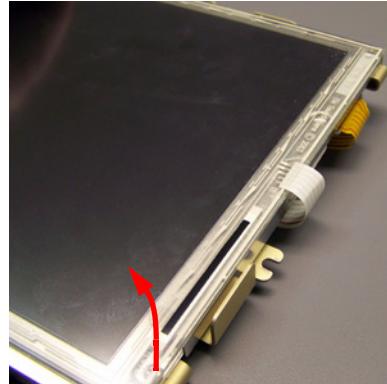
3. Loosen or remove the Video Cable Bracket and carefully remove the bezel.
4. Carefully feed the cable out of the bezel.

## Touchscreen Removal

The Touchscreen panel is attached to the LCD by three pieces of double-sided tape located at the upper-left, upper right, and lower center of the metal frame on the LCD.

1. Disconnect the Touchscreen Cable
2. Gently pry the Touchscreen panel away from the LCD (see [Figure 6-37 "Touchscreen Panel"](#)).

**Figure 6-37 Touchscreen Panel**

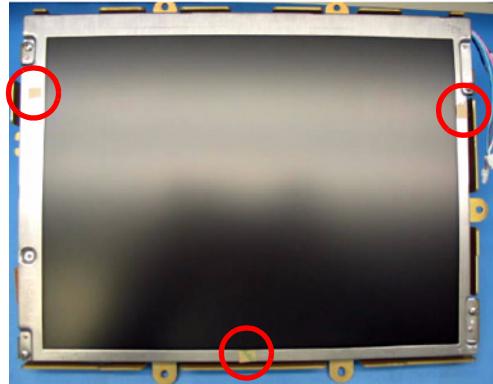


## Touchscreen Installation

1. Remove the old double-sided tape from the LCD and/or the Touchscreen panel.
2. Apply new double sided tape as shown in [Figure 6-38 "Double-sided Tape Location"](#).

**NOTE:** Make sure screen is clean before removing backing from double sided tape.

**Figure 6-38 Double-sided Tape Location**



3. Remove the backing from the double-sided tape and carefully center the Touchscreen evenly over the LCD to avoid hash marks from showing when the assembly is completed.

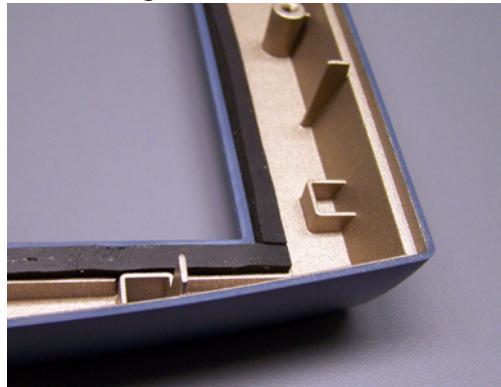
**NOTE:** The removable protective sheet on the Touchscreen faces outward.

4. Apply pressure to the Touchscreen over the double-sided tape to secure it in place.

## Touchscreen Seal Removal

1. Follow steps 1-5 of "[LCD Removal](#)".
2. Peel away the foam seal from the inside edge of the Front LCD Bezel (see [Figure 6-39 "Foam Seal"](#)).

**Figure 6-39** Foam Seal



## Touchscreen Seal Installation

Apply four lengths of cut adhesive-backed seal foam as shown above in [Figure 6-39 "Foam Seal"](#).

# Chapter 7 – Check Out and Adjustment

This section contains the instructions for testing and adjusting the GEM Premier 3500. There is specialized test equipment required for several of the tests and adjustments

## 7-1 Software Installation

This section provides instructions for loading the System software using a System Disk. When software is loaded with a system disk, all information on the Hard Drive will be lost.

### Starting the Software Installation

1. Insert the applicable (analyzer or server) System CD in the CD drive and reboot the system. If the wrong CD is inserted, the software ejects it during the restart process.

**Note:** During restart, the system (analyzer or server) recognizes specific CD types and takes actions according to the recognized type. These recognized types are specified in this specification volume. Any unrecognizable CD found in the drive during reboot is simply ignored by the software and ejected. If a server system CD is detected on an analyzer, on an analyzer system CD on the server, the disc will be still ignored and ejected.

2. The system detects the presence of the system CD in the drive while starting up. If there is no pre-existing software version installed (typically on a newly manufactured analyzer, or a newly purchased server), a full installation is required. The BIOS must be changed to "boot from CD". If a software version is already installed, the user is prompted to make a choice of either full system installation or an application upgrade, as follows:
  - Perform application upgrade (default choice)
  - Perform full system installation
    - <Cancel> <OK>

If application upgrade <OK> is selected, application upgrade is performed as outlined in section 3.5.

If full system installation <OK> is selected, the process continues with the steps outlined in section 3.3 (for the analyzer) or section 3.4 (for the server).

If <Cancel> is selected, the message: "Are you sure you want to exit software installation? <Yes> <No>" is presented. If Yes is selected, the system CD is ejected and the system restarts on the old (existing) software version. If No is selected, the warning message box is removed and the software waits for user selection.

### Full System Install Procedure on the Analyzer

1. The installer is prompted: "Full install of version x. All information on the hard drive will be overwritten. Continue with the install? <Yes> <No>".

- If <No> is selected, installation exits, the CD is ejected, and the system restarts with the existing software. The process ends here.
  - If <Yes> is selected, system installation continues according to the following steps.
2. The following message is presented, with a progress bar: "Installing the GEM 3500 Analyzer Operating System and Applications".
  3. System installation reformats the internal hard drive and copies the required files from the CD to the hard drive. This operation takes approximately 5 minutes. When completed, the CD is ejected.
  4. The system self reboots. During the reboot, the following message is presented, with a progress bar: "The analyzer is performing self diagnostics. Please wait."
  5. Wait for the prompt to enter the serial number. Entry of the serial number is mandatory. "Enter the analyzer serial number (between 1 and 999999999) <OK>". If the entered serial number is not in the requested range, the message "nnnnn is invalid. Enter 1 through 999999999. <OK>" is presented. Enter the serial number and press OK.
  6. The installer is prompted to confirm the entered serial number with the message: "Setting the serial number to nnnnn <Yes> <No>". If No is selected, we return to the previous dialog to re-enter the serial number. If <Yes> is selected the entered serial number is accepted and saved.
  7. The system continues with installation for approximately 2 more minutes. During that time, a message is presented: "Please wait to calibrate the touch screen."
  8. The software prompts the installer to calibrate the touch screen. With the tip of a pointed object (such as a pencil), the installer touches the 4 corners of the screen between the arms of the small fork. Ensure that you touch the corner of the screen only once. The software validates the screen coordinates to be within the following limits: minimum position in the range 200 - 550, maximum position in the range 3000 - 3500. If validation fails, the user is prompted with the message: "Coordinates out of range. Press any key to recalibrate.". After any keyboard key is pressed, the calibration screen is presented again. If validation passes, the coordinates are shown and the operator is prompted to answer "Y" or "N" to confirm and end calibration. If "Y" is selected, the process continues. If "N" is selected, the coordinates are reset to allow the operator to recalibrate.
  9. The system runs an LCD test, during which the LCD color changes to red, green, blue, then white, for 3 seconds each. Confirm each color is solid (no streaks or vertical bars). If not solid colors, the LCD is defective.
  10. The software completes the installation by presenting the message "Completing Installation", with progress bar. This lasts for 2 additional minutes.
  11. After installation is complete, the analyzer Installation Setup Wizard is presented (see volume 4b).

## Application Upgrade

### Feature Description

Application upgrade refers to installing the application software by replacing the existing applications with a newer version. Application upgrade is supported on the GEM Premier 3500 analyzer and on the GWP server. The application software is upgraded from the same System CD that is used for the system software installation. The end user can perform application upgrade when a newer version of the released software is made available. Installing the applications does not require a keyboard when performed on the analyzer. The application upgrade retains the existing database and user configuration information. The database of the old version is "migrated" to the new database if the new version includes changes to the database schemas.

## Application Upgrade Procedure on the Analyzer

On the analyzer, the upgrade software verifies that the system is already installed with a version to be upgraded. When upgrading an analyzer the upgrade can be performed with or without an inserted cartridge. The following steps complete the application upgrade process after the user had selected that option.

1. The top of the screen shall display the message box:
  - GEM Premier 3500
  - Application UpgradeConfirming to the operator the start of the application upgrade process.
2. If the software on the CD can only be system-installed, as is typically the case when a new o/s version is on the CD, the operator is prompted with the message: "Currently installed version is not upgradable <OK>". Pressing OK ejects the CD and the unit starts up on the old version.
3. If the CD contains an older version of the software, the installer will be prompted "Incompatible software versions. New: <x> Old: <y> <OK>". Once <OK> is selected, the CD will be ejected, and the system will continue restarting on the old software version. Note: to install an earlier version of the software, you must perform a system install of that version.
4. The application upgrade takes approximately 10 minutes, during which database migration is performed if required (see section 3.5.3). During the installation, the message "Application upgrade in progress. Please wait." is displayed. When completed, the System CD will be ejected.
5. The system goes through self-reboot to complete installation of the new applications software.
6. On the analyzer, the Insert Cartridge screen is presented (if no cartridge is inserted), or the Recovering screen (if a cartridge is inserted). On the server, the GWP home screen is presented.

## Application Upgrade Rollback

If the application upgrade prematurely terminates, for example due to failure of the media or the CD drive or due to power interruption at the middle of the upgrade, then on the next reboot, the software shall check for presence of the System CD in the drive. If it is present, the software upgrade process shall restart. If the System CD is not in the drive, the software shall recognize that the previous upgrade has been interrupted and revert to the original software version that existed prior to the interrupted upgrade.

## Restore Default Password Software Version Number

The Configuration Menu has a selection to “Restore KOPW” (Key Operator Password). A Restore KOPW disk is provided with each instrument, in the back of the Operators Manual. When this is selected, the Key Operator Password will be restored to 1 2 3 4. The Date and Time can also be selected.

## The Full System Install Procedure

1. Connect a standard PC keyboard to the keyboard connector on the back panel (or to the USB port).
2. Remove the cartridge by following the proper cartridge removal procedure, if present.
3. Extend the CD drive drawer and power off the instrument.
4. Insert the system disk in the CD drive and switch the power on.

5. The system continues with the install procedure if it detects a system disk in the CD drive while starting up.
6. The system verifies that the instrument model is 3500 (identified by Win Enterprises SBC model MB-60710, with wireless board) and verifies that the software version number on the system disk is 7.X.X before continuing. If this is not the case, the disk is ejected and this procedure ends.
7. If there is no pre-existing software version installed (typically on a newly manufactured instrument), full system installation is assumed and the process continues with the next step. If a software version is already installed, the user is prompted to make a choice to perform either full system installation or an application upgrade. Three buttons shall be presented: [Full Install], [Upgrade], and [Cancel].
  - If [Full Install] is selected, the process continues to the next step.
  - If [Upgrade] is selected, application upgrade is performed as described in chapter 5.
  - If [Cancel] is selected, the message: "Are you sure you want to exit software installation? <Yes> <No>" shall be presented. If Yes is selected, the system disk is ejected and the system restarts on the old (existing) software version. If No is selected, the warning message is removed and the software waits for user selection.
8. The user is prompted: "Full install of version "x". All information on the internal disk will be overwritten. Continue with the install? <Yes> <No>", where "x" is the version number to be installed as read from the inserted system disk.
  - a. If <No> is selected, installation exits, the disk is ejected, and the system restarts with the existing software. The process ends here.
  - b. If <Yes> is selected, system installation continues with the next step.
9. The install software performs checksum integrity check on the system disk. During the test, the message: "Checking install media. This will take a few minutes." is displayed. If the test passes, installation continues with the next step. If the test fails, the message: "Install media test failed. Installation aborted." is displayed and the disk is ejected. The message remains on the screen until the user recycles power.
10. The system reformats the internal flash disk and copies the required files from the release media. During the install, the following message is presented: "Installing the GEM 3500 system software. Please wait.", along with file loading messages. This operation takes approximately 5 minutes. After it is completed, the system disk is ejected.
11. The system self reboots. After the reboot, the following message is presented: "The instrument is performing self diagnostics. Please wait."
12. The following prompt is presented to enter the serial number. Entry of the serial number is mandatory. "Enter an 8-digit instrument serial number. <OK>". The installer enters the serial number and presses OK. If the entered serial number is not 8 digits, the message "Enter an 8-digit serial number. <OK>" is presented.
13. The installer is prompted to confirm the entered serial number with the message: "Setting the serial number to nnnnnnnn <Yes> <No>". If No is selected, the software returns to the previous dialog to re-enter the serial number. If <Yes> is selected the entered serial number is accepted and saved.
14. The software prompts the installer to calibrate the touch screen. With the tip of a pointed object (such as a pencil), the installer touches the 4 corners of the screen between the arms of the small fork. Ensure that you touch the corner of the screen only once. The software validates the screen coordinates to be within the following limits: minimum position in the range 200 - 600, maximum position in the range 3000 - 4000. If validation fails, the user is prompted with the message: "Coordinates out of range. Press any key to recalibrate.". After any keyboard key is pressed, the calibration screen is presented again. If validation passes, the coordinates are shown on the corners of the screen and the operator is prompted

to answer “Y” or “N” to confirm and end calibration. If “Y” is selected, the process continues to the next step. If “N” is selected, the coordinates are reset to allow the operator to recalibrate.

15. The system runs an LCD test during which the LCD color changes to red, green, blue, white, then black, for 3 seconds each. The installer confirms that each color is solid (no streaks or vertical bars). If not solid colors, the LCD can be defective.
16. The software completes the installation by presenting the message “Completing Installation. Please wait.”. This lasts for 2 additional minutes.
17. After installation is complete the instrument comes up in the production mode and the Insert Cartridge screen is presented.

## Modes Software Version Number

The software version number of the Modes CD (Demo or Depot) is identical to the first release of the analyzer System software (A.1.0.0). In the unlikely event that the contents of the modes CD change in a future version of the analyzer system software, the version number of the modes CD shall change to match the version number of the analyzer System software.

## 7-2 Testing and Adjustments

This section covers the testing and adjustments required for the GEM 3500. The testing is performed using GTE software on a PC or a laptop connected to the GEM 3500. For a portion of the testing, an ETC is required, in addition to the GTE software

### Pump Spring Tension Fixture

Adjustment of the pump spring tension requires a 2-part fixture, consisting of a “dummy” cartridge, containing a calibrated force gage and an indicator that signals when the proper force is applied. These parts are IL specific and are designated with IL Part Numbers

000995356 Test Cartridge

000995390 Indicator

### Electronic Test cartridge (ETC)

The ETC is used to test the instrument prior to shipment and can be used to verify repairs. Repairs can also be verified by use of a “live” cartridge and CVP or liquid QC material.

There are several other parts required to utilize the ETC for testing. All of the required parts are:

ETC 00024005050

ETC Test Harness 000995410

ETC Power Supply 000995100

ETC Adapter Board 00024005162

Premtest Disk 00024005534

Skipwarm Disk 00024306129

PC or Laptop with 9-pin serial connection and Premtest disk loaded.

## Loopback Tester

A Loopback test connector is available to test the three serial ports on the GEM.

Loopback Connector 00024001581

The instructions to perform the Loopback test are displayed on the instrument when “Diagnostics”, “Ports”, and “COM A, COM B, or COM C” are selected. The test can be performed at any time. To avoid any potential problems with future transmissions, any reports in the queue should be cleared after the Loopback tests are completed.

## Testing with the ETC

The test that can be performed with the ETC is the Cartridge Simulation Test, using the PC. The cartridge simulation test will allow the analysis of a simulated sample, to verify the results fall within range.

## Cartridge Simulation Test

1. Connect ETC harness to ETC power Supply, Plug Power Supply into outlet.
2. Remove access cover from back panel of instrument to expose connector on Analog PCB (see [Figure 7-1 "Access Panel"](#)).

**Figure 7-1 Access Panel**



3. Plug adapter Board, with ETC harness connected, into connector on Analog PCB. The handle on the adapter board must be at the top (see [Figure 7-2 "Adapter Board"](#)).

**Figure 7-2 Adapter Board**



4. Plug ETC harness into appropriate COM port on the PC.
5. Turn power OFF, inset skipwarm disk into instrument and turn power ON. Select “Skipwarm” and “OK” on screen, then press “OK” again when prompted.
6. Instrument will restart and eject skipwarm disk.
7. Verify that the two actuators on the ETC are in the vertical position, with the marked ends up. When the instrument displays the “Insert cartridge” screen, insert the ETC.
8. Close, but **DO NOT LATCH** the cartridge door. Plug the ETC harness into the connector inside the sample probe port (see [Figure 7-3 "ETC Harness"](#)).

**Figure 7-3 ETC Harness**



9. Latch the cartridge door after the connection is made. The warm up will start automatically. The warm up will take approximately 7 minutes.
10. When the warm up is completed, the instrument will display the READY screen, and the PC will display the voltages and the temperature, along with other information.

The acceptable ranges for the voltages at are:

+11.25 to +12.75 VDC

-11.25 to -12.75 VDC

+4.75 to +5.25VDC

-4.75 to -5.25 VDC

The acceptable range for the temperature is:

36.4 to 37.6 °C

The other results displayed should read “PASS”. (The valve may display “Not aligned”. This is acceptable, as it will be tested in the Manual Premtest.)

11. To simulate a sample, initiate a 2-pt Calibration from the Diagnostics drop down menu on the instrument. When the calibration is completed, press “arterial” and “OK”.

The instrument will simulate a sample and display the results. The acceptable ranges for these results are:

PH 7.06 to 7.08

PCO<sub>2</sub> 60 to 63 mmHg

PO<sub>2</sub> 24 to 27 mmHg

Na 138.7 to 141.0 mmol/L

K 2.79 to 2.83 mmol/L

Ca 0.56 to 0.58 mmol/L

Glu 93 to 105 mg/dL

Lac 1.4 to 1.6 mmol/L

Hct 39 to 42 %

12. If any values are out of range, initiate a second 2-pt calibration and repeat the test.

This completes the Cartridge Simulation Test.

13. Insert skipwarm disk and turn the instrument power on, press and hold the “delete” key while the instrument is starting. The instrument will display the BIOS setup screen.

14. Highlight the “Reset CMOS to Factory Default” screen using the arrows on the keyboard and press enter. Press “Y” to confirm.

The instrument will reboot, and display screen with selection for production or skipwarm.

15. Press skipwarm and OK. Press OK again when prompted.

The instrument will return to “Insert cartridge” screen.

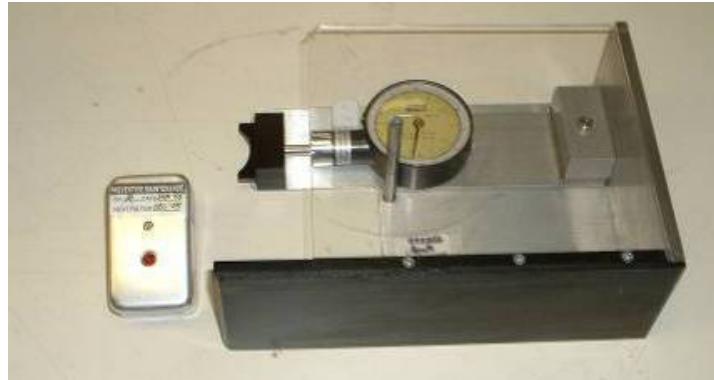
16. Reset the time and date if necessary, and disconnect the keyboard.

## Adjusting Pump Spring Tension

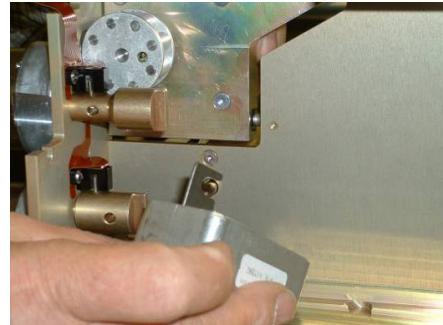
This section details the pump spring tension measurement and adjustment. The pump spring tension is critical for the correct pumping, and pump rate, of the pump windings in the cartridges. The pump spring tension must be at 6.2 +/- 0.1 lbs, and requires a specific fixture to measure and/or adjust.

The pump spring tension should be checked each time the left side cover is removed, for any reason. The purpose of checking the tension at this time is to verify that there is no interference with the pump slides when the cover is replaced, caused by movement of cables and harnesses.

The test is to be performed with power off.

**Figure 7-4 Test Cartridge and Indicator****Tension measurement (covers on)**

1. Mount the indicator inside the cartridge compartment on the lower slide of the pump assembly. To mount the indicator, slide the pump all the way to the left by pushing on the rollers with one hand. With the other hand, place the hook on the indicator over the exposed lower slide, and release the pump assembly (see [Figure 7-5 "Indicator Mounting \(Front\)"](#) and [Figure 7-6 "Indicator Mounting \(Back\)"](#)).

**Figure 7-5 Indicator Mounting (Front)****Figure 7-6 Indicator Mounting (Back)**

**NOTE:** These pictures were taken to clarify the mounting, without any covers, and without the printer or heater block mounted.

2. After mounting the indicator, verify that the LED on the indicator is “ON”, by looking through the sample probe port (see [Figure 7-7 "LED Indicator"](#)).

**Figure 7-7 LED Indicator**



3. On the test cartridge, reset the gage to 0, and insert the cartridge into the instrument slowly. Do not insert the cartridge completely. Leave approximately  $\frac{1}{4}$  inch exposed.
4. Slowly raise the cartridge door while observing the LED. Immediately when the LED extinguishes, lower the cartridge door and remove the test cartridge (see [Figure 7-8 "Remove the Test Cartridge"](#)). Observe the reading of the gage.

**Figure 7-8 Remove the Test Cartridge**



**NOTE:** This figure above shows the cartridge door position at the point the LED typically extinguishes.

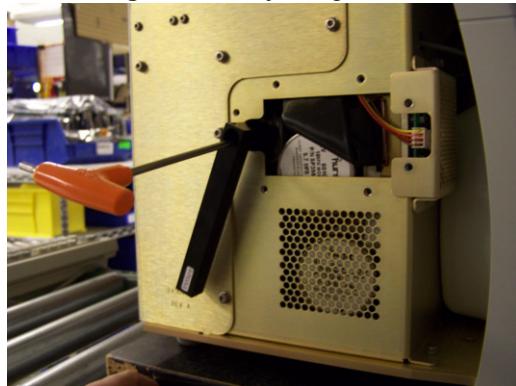
5. Reset the Gage and repeat the test two more times. Taking 3 readings will provide a more accurate result.
6. If the results are within the range of 6.1 to 6.3, the tension is acceptable, and does not require adjustment.

## Tension Adjustment

Adjustment of the pump spring tension requires removal of the left side cover of the instrument (section 6.2 – Gaining Access).

Insert the guide and loosen the lock nut and turn the adjustment screw clockwise to increase the tension, counterclockwise to decrease the tension (2 turns = approximately 1 lb.) as shown in [Figure 7-9 "Adjusting Screw"](#). After adjusting the tension, tighten the lock nut and perform the measurement to verify the proper result. After replacing the side cover, perform the measurement to ensure that there is no interference with the slides.

**Figure 7-9 Adjusting Screw**



## Calibrating the Touchscreen

When loading the System disk, the Touchscreen must be calibrated as part of the procedure (see "[Software Installation](#)"). If the Touchscreen requires calibration, without loading the system disk, the following procedure may be used.

At the command line type the underlined texts then press <Enter>

Type lower case texts only and observe the spacing in the command lines 5,6 & 8.

- \*5 1 space between 't' and '3'
- \*6 1 spaces between 'm' and '-' and 1 space between the 'f' and '/'
- \*8 1 space between 't' and '5'

(1) The password does not display on the screen, just type it then press <Enter>

(2) Command line prompt may not be the same ..Eg. [root@TLH-OR /root]#

0) !! The 'Ready' or 'Insert Cartridge' screen must be displayed !!

1) Attach the keyboard to the rear of the unit.

2) On the keyboard Press: Ctrl Alt F1

The screen blanks out then displays:

[Command line Prompt] [Type]

3) '\_ ' root <Enter>

4) Password: n0bridge <Enter>

?a=Zero

5) \* [root@(none) /root]# init..3 <Enter>

6) \* [root@(none) /root]# rm..-f../etc/gem/elo.cal <Enter>

7) [root@(none) /root]# gemtouchcal <Enter>

**The Gem unit should display the XYZ setup screen.**

To Exit

8) \*[root@(none) /root]# init..5 <Enter>

# Chapter 8 – Troubleshooting

## 8-1 Overview

This section describes the errors reported on the GEM 3500 analyzer to the operator and how they are processed.

The errors reported are caused by malfunction of the instrument, the cartridge, or the software. Errors may also be caused by the improper use of the analyzer by the operator.

Errors occur mostly during the instrument analytical operations, such as iQM processing or sample analysis. In most cases, the analytical "script" that manages the operation detects the error and attempts to recover from the error. If the problem is corrected, the analytical operation continues. If the error persists, the software reports the error to the operator and the analytical operation performs "cleanup" steps to gracefully exit the failed operation. The operator is notified of the corrective action to take, such as re-analyzing the sample, or replacing the cartridge. The operating software external to the analytical script may also report errors.

## 8-2 Errors and Alarms

Below is a list of the types of GEM 3500 errors that can occur. The range of error numbers used is included with the description of each type of error.

**Table 8-1 Error Types**  
**Table 8-2**

Type	Description	Number Range
Alarms	Errors that must be resolved by operator intervention.	0.01 - 0.99
Cartridge Errors	Errors that can occur due to a faulty cartridge inserted in the GEM 3500 instrument.	1.01 - 1.99
Hardware Errors	Errors that can occur due to a problem with the GEM 3500 instrument hardware.	2.01 - 2.99
Software Errors	Errors that can occur due to a problem with the GEM 3500 operating software.	3.01 - 3.99
Events	Events, such as cartridge insertion and removal, that occur.	9.01 - 9.99 0.00 - -0.99

Errors are handled by the GEM 3500 operating software in one of the following ways:

- Alarm notification, with error message written to alarm log file and system log file.
- User dialog box, with error message written to system log file.
- LLP (Low Level Processor) reset, with error message written to system log file.
- System reset, with error message written to system log file.
- System log file.

Each of these types of error handling is described below. Note that all types of error handling include writing a message to the operating software's system log file that uniquely identifies and describes the error that occurred.

## Alarm Notification

For alarms that require operator intervention to resolve, such as the printer is out of paper, the GEM 3500 operating software presents an alarm on the screen.

## User Dialog Box

For error handling that requires immediate operator action, the operating software displays a user dialog box, with an <OK> button, that describes the error that has occurred and instructs the operator on what to do next. For example:

*Error 1.06*

*No sample detected.*

*Test canceled.*

*Please repeat test*

## LLP Reset

The GEM 3500 HLP (High Level Processor) software commands the GEM 3500 LLP (Low Level Processor) to perform a hardware reset when certain error conditions occur (for example, when the LLP reports a failure to calibrate the A/D converter at the start of a sample or calibration). When the LLP resets, it restarts at the beginning of its code, initializes all of the LLP hardware, calibrates the A/D converter, and verifies that the valve and arm actuators can be moved to their home positions.

When the LLP is reset due to an error that occurred while attempting to perform a particular procedure (such as attempting to detect calibration solution), the desired procedure is performed a second time. If an error occurs again, the LLP is reset a second time, and the procedure is performed a third time. If an error occurs during the third attempt, the operating software either displays a user dialog box that explains what has happened, or the operating software performs a system reset.

## System reset

When the GEM 3500 operating software is about to perform a system reset, a display is presented with the following message:

<type of error> X.XX

*This instrument will reset in 30 seconds.*

*If the problem persists, contact Technical Service.*

Where X.XX is the number of the error that occurred (for example, 3.01) and <type of error> is one of the following lines of text:

*Cartridge error*

*Hardware error*

*Software error*

Then, the GEM 3500 system resets itself, which includes resetting both its HLP (High Level Processor) and LLP (Low Level Processor).

After the instrument is reset, the following message is printed:

**SYSTEM RESET**

04/07/2000 15:25:00

<type of error> X.XX

*If the problem persists, contact Technical Service.*

The GEM 3500 operating software maintains the number of times it resets itself, due to an error, in a persistent data file on its internal disk. This persistent data file is cleared during the daily log rotation. If a system reset occurs because of an error (any error) four times between log rotations, the GEM 3500 performs a system halt. While the system is halting, a display is presented with the following message:

<type of error> X.XX

*The instrument will be halted.*

*Please wait.*

and the following message is printed:

**SYSTEM BEING HALTED**

04/07/2000 15:25:00

<type of error> X.XX

*If the problem persists, contact Technical Service.*

When the system has halted, a display is presented with the following message:

<type of error> X.XX

*The instrument has been halted.*

*Contact Technical Service.*

## System Log File

For all alarms and errors a message will be written to a system error log file called syslog.dat. Each message logged will contain the date and time the error occurred, the error type, the error code, and the error text. Examples:

MM/DD/YYYY hh:mm:ss Alarm 0.03 Transmission error

MM/DD/YYYY hh:mm:ss Cartridge Error 1.05 Insufficient sample solution detected

The software will also log to syslog.dat system events that occur [see Section Error! Reference source not found.]. For example, in order to associate the errors with the installed cartridge, cartridge installation and removal events, along with the cartridge barcode, will be logged to syslog.dat as follows:

MM/DD/YYYY hh:mm:ss Event 9.01 Cartridge inserted:

nnnnnnnnnnnn

MM/DD/YYYY hh:mm:ss Event 9.04 Cartridge removed:

nnnnnnnnnnnn

In addition, the software will log to syslog.dat when alarms are cleared. For example:

MM/DD/YYYY hh:mm:ss Alarm -0.03 Transmission error corrected

**syslog.dat** is stored on the instrument's internal disk in ASCII text format to allow easy viewing after it is copied to disk. syslog.dat will be designed as a circular file to contain about the last 256 messages and to limit the file size to about 10KB.

Syslog.dat is copied to diskette by selecting "Copy IL Data" on the Diagnostics pull down menu.

## 8-3 Alarm List

### Alarms (0.01 - 0.99)

This section describes the GEM 3500 operating software alarm conditions that can occur.

#### 0.01 Internal printer out of paper

Label	ERR_NO_PAPER_INT
Alarm Message	Message Internal printer out of paper
When	Whenever the operating software is attempting to print, such as when the results are ready to report during a sample or calibration.
Cause	The printer is out of paper.
Handling	Alarm notification for each failed attempt to write to the printer if an alarm is not already posted for this error condition.
Remedy	Install paper in the printer and clear the alarm. If the alarm occurs again, turn the printer off, then on, in configuration. If the alarm still occurs, cycle power on the instrument. If the alarm continues to occur, contact Technical Service.

#### 0.02 Internal printer failure

Label	ERR_PRINTER_FAILURE_INT
Alarm Message	Internal printer error
When	Whenever the operating software is attempting to print, such as when the results are ready to report during a sample or calibration.
Cause	There is a hardware problem with the printer or printer cable, or the paper lever is up.
Handling	Alarm notification for each failed attempt to write to the printer if an alarm is not already posted for this error condition.
Remedy	Install paper in the printer and clear the alarm. If the alarm occurs again, turn the printer off, then on,

in configuration. If the alarm still occurs, cycle power on the instrument.

### 0.03 External communication error

Label	ERR_LIS_COMM
Alarm Message	Transmission error
When	Whenever the operating software is attempting to transmit data, such as when the results are ready to report during a sample or calibration and the system has been configured to transmit sample or calibration data to port A.
Cause	Data could not be transmitted to the LIS (Laboratory Information System) system successfully. The LIS cable may be faulty or the LIS system configured incorrectly.
Handling	Alarm notification for each failed attempt to transmit data to the LIS if an alarm is not already posted for this error condition.
Remedy	Check the connection with the LIS system and the configuration of the LIS system then clear the alarm. If the alarm occurs again, cycle power on the instrument.

### 0.04 Parallel printer failure

Label	ERR_PRINTER_FAILURE_EXT
Alarm Message	Parallel printer error
When	Whenever the operating software is attempting to print to the parallel printer.
Cause	There is a hardware problem with the printer or printer cable.
Handling	Alarm notification for each failed attempt to write to the printer if an alarm is not already posted for this error condition.
Remedy	Check parallel printer connections then reset printer queue and try again. Cycle power to the printer if necessary.

### 0.05 Parallel printer out of paper

Label	ERR_NO_PAPER_EXT
Alarm Message	Parallel printer out of paper
When	Whenever the operating software is attempting to print to the parallel printer.
Cause	The printer is out of paper.
Handling	Alarm notification for each failed attempt to write to the printer if an alarm is not already posted for this error condition.
Remedy	Install paper in the printer and clear the alarm. Reset the printer queue. Cycle power to the printer if necessary.

### 0.06 Network printer failure

Label	ERR_PRINTER_FAILURE_NT
Alarm Message	Network printer error
When	Whenever the operating software is attempting to print to the network printer.
Cause	Communication error to the network printer, or network printer returning an error.
Handling	Alarm notification for each failed attempt to write to the printer if an alarm is not already posted for this error condition.
Remedy	Check network printer connections then reset printer queue and try again. Cycle power to the printer if necessary.

### 0.07 Improper instrument shutdown

Label	ERR_IMPROPER_SHUTDOWN
Alarm Message	Improper instrument shutdown

When	When the instrument restarts after it was improperly shutdown.
Cause	The “Shutdown” button was not used to shut down the instrument before the instrument was powered off. This can be due to an unexpected power outage or operator error.
Handling	The Alarm Message is logged in the system error log file “syslog.dat”. The alarm is not displayed on the “Alarms” screen.
Remedy	Users/customers must be reminded to use proper shutdown procedure from the Shutdown pull-down menu.

## 0.11 iQM Disabled pH Sensor

Label	ERR_IQM_PH
Alarm Message	pH is permanently disabled due to iQM error
When	After iQM corrective action failed to correct the iQM error triggered following A, B, or C calibration.
Cause	Sensor and/or calibration solution error.
Handling	Alarm notification whenever a sensor is permanently disabled due to unrecoverable iQM error.
Remedy	Replace cartridge if failed sensor is essential to the continued operation of the instrument

## 0.12 iQM Disabled pCO2 Sensor

Label	ERR_IQM_PCO2
Alarm Message	pCO2 is permanently disabled due to iQM error
When	After iQM corrective action failed to correct the iQM error triggered following A, B, or C calibration.
Cause	Sensor and/or calibration solution error.
Handling	Alarm notification whenever a sensor is permanently disabled due to unrecoverable iQM error.
Remedy	Replace cartridge if failed sensor is essential to the continued operation of the instrument

## 0.13 iQM Disabled pO2 Sensor

Label	ERR_IQM_PO2
Alarm Message	pO2 is permanently disabled due to iQM error.
When	After iQM corrective action failed to correct the iQM error triggered following A, B, or C calibration.
Cause	Sensor and/or calibration solution error.
Handling	Alarm notification whenever a sensor is permanently disabled due to unrecoverable iQM error.
Remedy	Replace cartridge if failed sensor is essential to the continued operation of the instrument.

## 0.14 iQM Disabled Na+ Sensor

Label	ERR_IQM_NA
Alarm Message	Na+ is permanently disabled due to iQM error.
When	After iQM corrective action failed to correct the iQM error triggered following A or B calibration.
Cause	Sensor and/or calibration solution error.
Handling	Alarm notification whenever a sensor is permanently disabled due to unrecoverable iQM error.
Remedy	Replace cartridge if failed sensor is essential to the continued operation of the instrument.

## 0.15 iQM Disabled K+ Sensor

Label	ERR_IQM_K
Alarm Message	K+ is permanently disabled due to iQM error
When	After iQM corrective action failed to correct the iQM error triggered following A or B calibration.
Cause	Sensor and/or calibration solution error.
Handling	Alarm notification whenever a sensor is permanently disabled due to unrecoverable iQM error.
Remedy	Replace cartridge if failed sensor is essential to the continued operation of the instrument.

## 0.16 iQM Disabled Ca++ Sensor

Label	ERR_IQM_CA
Alarm Message	Ca++ is permanently disabled due to iQM error
When	After iQM corrective action failed to correct the iQM error triggered following A or B calibration.
Cause	Sensor and/or calibration solution error.
Handling	Alarm notification whenever a sensor is permanently disabled due to unrecoverable iQM error.
Remedy	Replace cartridge if failed sensor is essential to the continued operation of the instrument

## 0.17 iQM Disabled Hct Sensor

Label	ERR_IQM_HCT
Alarm Message	Hct is permanently disabled due to iQM error
When	After iQM corrective action failed to correct the iQM error triggered following A or B calibration.
Cause	Sensor and/or calibration solution error.
Handling	Alarm notification whenever a sensor is permanently disabled due to unrecoverable iQM error.
Remedy	Replace cartridge if failed sensor is essential to the continued operation of the instrument.

## 0.18 iQM Disabled Glu Sensor

Label	ERR_IQM_GLU
Alarm Message	Glu is permanently disabled due to iQM error
When	After iQM corrective action failed to correct the iQM error triggered following A or B calibration.
Cause	Sensor and/or calibration solution error.
Handling	Alarm notification whenever a sensor is permanently disabled due to unrecoverable iQM error.
Remedy	Replace cartridge if failed sensor is essential to the continued operation of the instrument.

## 0.19 iQM Disabled Lac Sensor

Label	ERR_IQM_LAC
Alarm Message	Lac is permanently disabled due to iQM error
When	After iQM corrective action failed to correct the iQM error triggered following A or B calibration.
Cause	Sensor and/or calibration solution error.
Handling	Alarm notification whenever a sensor is permanently disabled due to unrecoverable iQM error.
Remedy	Replace cartridge if failed sensor is essential to the continued operation of the instrument.

## Cartridge Errors (1.01-1.99)

This section describes the GEM 3500 cartridge errors that can occur. The remedy for a persistent cartridge error is to replace the cartridge inserted in the instrument with a new cartridge.

### 1.01 Cartridge error

Message	Calibration solution could not be detected.
Label	ERR_NO_A_SOLN
Log Message	No A calibration solution detected
When	While A solution is being pumped from the cartridge during an A calibration.
Cause	Either the A solution has been depleted or there is a hardware problem with the analog circuitry (A/D converter out of calibration, faulty hematocrit sensor, etc.), the pump or valve driver, or the cartridge (plugged tubing, arm not fully homed, etc.).
Handling	Up to three attempts to detect solution are made. With each attempt, a set of sensor A/D readings is taken and saved to the sensor data file with a no solution detected error status. After each of the first

two attempts, an LLP reset is performed. If the third attempt is unsuccessful, the operating software displays the *Remove Cartridge* screen with the error type, number, and message shown above. No calibration report is printed, saved to the database, or transmitted.

## 1.02 Cartridge error

Message	Calibration solution could not be detected.
Label	ERR_NO_B_SOLN
Log Message	No B calibration solution detected
When	While B solution is being pumped from the cartridge during a B calibration or cartridge warm up.
Cause	Either the B solution has been depleted or there is a hardware problem with the analog circuitry (A/D converter out of calibration, faulty hematocrit sensor, etc.) the pump or valve driver, or the cartridge (plugged tubing, arm not fully homed, etc.).
Handling	See Cartridge error 1.01

## 1.03 Cartridge error

Message	Calibration solution could not be detected.
Label	ERR_NO_AIR_BEFORE_A
Log Message	No air before A calibration solution detected
When	While A solution is being pumped from the cartridge during an A calibration.
Cause	Air is pumped between each solution (so the new solution can be positively detected). No air being detected can be caused by a bad pump, valve, tubing, or analog circuitry. Failed solid-state relays can cause a valve to stick in the A or B position.
Handling	Up to three attempts to detect solution are made. With each attempt, a set of sensor A/D readings is taken and saved to the sensor data file with a no air detected before solution error status. After each of the first two attempts, an LLP reset is performed. If the third attempt is unsuccessful, the operating software displays the <i>Remove Cartridge</i> screen with the error type, number, and message shown above. No calibration report is printed, saved to the database, or transmitted.

## 1.04 Cartridge error

Message	Calibration solution could not be detected.
Label	ERR_NO_AIR_BEFORE_B
Log Message	No air before B calibration solution detected
When	While B solution is being pumped from the cartridge during a B calibration or cartridge warm up.
Cause	Air is pumped between each solution (so the new solution can be positively detected). No air being detected can be caused by a bad pump, valve, tubing, or analog circuitry. Failed solid-state relays can cause a valve to stick in the A or B position.
Handling	See Cartridge error 1.03.

## 1.05 Cartridge error

Message	Insufficient sample volume. Test canceled. Please repeat test.
Label	ERR_INSUFF_SAMPLE
Log Message	Insufficient sample solution detected
When	During sample aspiration.
Cause	Most likely, incorrect operator technique in introducing the sample. Anything that could cause bubbles in the sample slug (most likely bad tubing or a faulty arm septum) could cause this to be a persistent problem.
Handling	The sample is aborted and a user dialog box, that contains an <i>Ok</i> button, is displayed with the error number, type, and message shown above. When the <i>Ok</i> button is pressed, the <i>Ready</i> screen appears. The operator may then attempt to process the sample again. The sensor A/D readings that

were taken for the sample are saved to the sensor data file with an air in sample detected error status. An aborted sample report is saved to the database, but no sample report is displayed, printed, or transmitted.

## 1.06 Cartridge error

Message	No sample detected. Test canceled. Please repeat test.
Label	ERR_NO_SAMPLE
Log Message	No sample solution detected
When	During sample aspiration.
Cause	Most likely, incorrect operator technique in introducing the sample, obstructed tubing, or a bad valve or pump.
Handling	The sample is aborted and a user dialog box, that contains an <i>Ok</i> button, is displayed with the error number, type, and message shown above. When the <i>Ok</i> button is pressed, the <i>Ready</i> screen appears. The operator may then attempt to process the sample again. The sensor A/D readings that were taken for the sample are saved to the sensor data file with a no solution detected error status. An aborted sample report is saved to the database, but no sample report is displayed, printed, or transmitted.

## 1.07 Cartridge error

Message	No sample detected. Test canceled. Please repeat test.
Label	ERR_NO_AIR_BEFORE_SAMPLE
Log Message	No air before sample solution detected
When	During sample aspiration.
Cause	Most likely, incorrect operator technique in introducing the sample, obstructed tubing, or a bad valve or pump.
Handling	The sample is aborted and a user dialog box, that contains an <i>Ok</i> button, is displayed with the error number, type, and message shown above. When the <i>Ok</i> button is pressed, the <i>Ready</i> screen appears. The operator may then attempt to process the sample again. The sensor A/D readings that were taken for the sample are saved to the sensor data file with a no air detected before solution error status. An aborted sample report is saved to the database, but no sample report is displayed, printed, or transmitted.

## 1.08 Cartridge error

Label	ERR_BAD_SENSOR_VALS
Log Message	Na, K, Ca, pH at A/D rail for B cal
When	During B calibration measurement.
Cause	Any 3 of the Na, K, Ca, or pH sensor readings are at the A/D rail and any 3 of those sensor readings were at the A/D rail for the previous B calibration. This is probably due to reference failure going to rail due to air bubble on reference wire.
Handling	The sensor A/D readings that were taken for the calibration are saved to the sensor data file. Then, a system reset is performed. No calibration report is printed, saved to the database, or transmitted.

## 1.09 Cartridge error

Message	No C solution detected
Label	ERR_NO_C_SOLN
Log Message	No C solution detected
When	While C solution is being pumped from the cartridge during low oxygen calibration.

Cause	Either the C solution has been depleted or there is a hardware problem with the analog circuitry (A/D converter out of calibration, faulty hematocrit sensor, etc.), the pump or valve driver, or the cartridge (plugged tubing, arm not fully homed, etc.).
Handling	Up to three attempts to detect solution are made. With each attempt, a set of sensor A/D readings is taken and saved to the sensor data file with a no solution detected error status. After each of the first two attempts, an LLP reset is performed. If the third attempt is unsuccessful, the operating software displays the <i>Remove Cartridge</i> screen with the error type, number, and message shown above. No calibration report is printed, saved to the database, or transmitted.

## 1.10 Cartridge error

Message	No C solution detected
Label	ERR_NO_AIR_BEFORE_C
Log Message	No air before C solution detected
When	While C solution is being pumped from the cartridge during low oxygen calibration.
Cause	Air is pumped between each solution (so the new solution can be positively detected). No air being detected can be caused by a bad pump, valve, tubing, or analog circuitry. Failed solid-state relays can cause a valve to stick in the A or B position.
Handling	Up to three attempts to detect solution are made. With each attempt, a set of sensor A/D readings is taken and saved to the sensor data file with a no air detected before solution error status. After each of the first two attempts, an LLP reset is performed. If the third attempt is unsuccessful, the operating software displays the <i>Remove Cartridge</i> screen with the error type, number, and message shown above. No calibration report is printed, saved to the database, or transmitted.

## 1.11 Cartridge error

Message	Low oxygen calibration failure
Label	ERR_LOW_O2_CAL_FAILURE
Log Message	Low oxygen calibration failure
When	During low oxygen calibration.
Cause	Low oxygen calibration failure that could not be corrected by the 2 retries.
Handling	After the third attempt to correct the calibration failure is unsuccessful, the operating software displays the <i>Remove Cartridge</i> screen with the error type, number, and message shown above. All 3 calibration reports are printed to show the cause of failure.

## 1.12 Cartridge error

Message	Process control solutions stability failure.
Label	ERR_PC_STABILITY_FAILURE
Log Message	Process control solutions stability failure
When	During A calibration.
Cause	pO2 threshold check failure during A calibration.
Handling	The operating software displays the <i>Remove Cartridge</i> screen with the error type, number, and message shown above.

## Hardware Errors (2.01-2.99)

This section describes the GEM 3500 hardware errors that can occur (2.01-2.99). And be displayed. The first attempt at a remedy for a persistent hardware error is to cycle the instrument power.

### 2.01 Hardware error

Message	Cartridge error: 2.01
---------	-----------------------

Label	A cartridge error has occurred.
Log Message	ERR_TEMP_NOT_AT_TARGET
When	Target temperature not reached during cartridge warm up
Cause	During cartridge warm up.
Cause	The GEM 3500 operating software timed out waiting for the heater block to reach the cartridge warm up target temperature.
Handling	The operating software displays the <i>Remove Cartridge</i> screen with the message shown above.

## 2.02 Hardware error

Label	ERR_HBLK_WARM_UP_TOUT
Log Message	Power Fail Recovery temperature error
When	During power fail recovery.
Cause	The GEM 3500 operating software timed out waiting for the heater block to reach a temperature of 37.0 degrees C.
Handling	System reset is performed.

## 2.03 Hardware error

Label	ERR_BAD_CAL_GND
Log Message	Calibration ground error
When	During calibration measurement.
Cause	The ground A/D reading is not within +/- five bits of the expected value.
Handling	The sensor A/D readings, including ground, that were taken for the calibration are saved to the sensor data file with a bad ground error status. Then, a system reset is performed. No calibration report is printed, saved to the database, or transmitted.

## 2.04 Hardware error

Message	An unexpected system error has occurred preventing normal software behavior. Test canceled. Please repeat test.
Label	ERR_BAD_SAMPLE_GND
Log Message	Sample ground error
When	During sample measurement.
Cause	The ground A/D reading is not within +/- five bits of the expected value.
Handling	The sample is aborted and a user dialog box, that contains an <i>Ok</i> button, is displayed with the error number, type, and message shown above. When the <i>Ok</i> button is pressed, the <i>Ready</i> screen appears. The operator may then attempt to process the sample again. The sensor A/D readings, including ground, that were taken for the sample are saved to the sensor data file with a bad ground error status. An aborted sample report is saved to the database, but no sample report is displayed, printed, or transmitted.

## 2.05 Hardware error

Label	ERR_BAD_CAL_TEMP
Log Message	Calibration temperature error
When	During calibration measurement.
Cause	The temperature A/D reading is not 37.0 degrees C.
Handling	The sensor A/D readings, including temperature, that were taken for the calibration are saved to the sensor data file with a bad temperature error status. Then, a system reset is performed. No calibration report is printed, saved to the database, or transmitted.

## 2.06 Hardware error

Message	Sample Temperature Error. Test canceled. Please repeat test.
Label	ERR_BAD_SAMPLE_TEMP
Log Message	Sample temperature error
When	During sample measurement.
Cause	The temperature A/D reading is not 37.0 degrees C.
Handling	The sample is aborted and a user dialog box, that contains an <i>Ok</i> button, is displayed with the error number, type, and message shown above. When the <i>Ok</i> button is pressed, the <i>Ready</i> screen appears. The operator may then attempt to process the sample again. The sensor A/D readings, including temperature, that were taken for the sample are saved to the sensor data file (see <i>Volume 6 - Files and Formats</i> ) with a bad temperature error status. An aborted sample report is saved to the database, but no sample report is displayed, printed, or transmitted.

## 2.07 Hardware error

Label	ERR_A2D_CAL
Log Message	A/D converter calibration error
When	During sample or calibration preparation.
Cause	The A/D converter was unable to obtain valid (+/- 5 bits) readings from the ground and/or voltage reference channels following calibration of the A/D converter.
Handling	Up to three attempts are made to calibrate the A/D converter. After each of the first two attempts, an LLP reset is performed. If the third attempt is unsuccessful, a system reset is performed. No sample or calibration report is displayed, printed, saved to the database, or transmitted.

## 2.08 Hardware error

Label	ERR_A2D_READ
Log Message	A/D converter read error
When	Whenever the LLP requests an A/D reading(s) from the LLP, such as during sample or calibration measurement.
Cause	An error was detected and signaled by the LLP (Low Level Processor) when it attempted to read the A/D converter or the multiplexer using the synchronous serial bus.
Handling	System reset is performed.

## 2.09 Hardware error

Label	ERR_D2A_WRITE
Log Message	D/A converter write error
When	During LLP initialization.
Cause	An error was detected and signaled by the LLP (Low Level Processor) when it attempted to write to a D/A converter using the synchronous serial bus.
Handling	System reset is performed.

## 2.10 Hardware error

Label	ERR_ARM_HOMING
Log Message	Sample arm homing error
When	During sample preparation or LLP initialization.
Cause	The sample arm could not be returned to the home position, or the sample arm homing sensor could not detect the homing pin.
Handling	System reset is performed.

## 2.11 Hardware error

Label	ERR_VALVE_HOMING
Log Message	Valve homing error
When	During sample or calibration preparation, or LLP initialization.
Cause	The valve could not be returned to the home position, or the valve homing sensor could not detect the homing pin.
Handling	System reset is performed.

## 2.12 Hardware error

Label	ERR_NO_INST_SERIAL_NUM
Log Message	Uninitialized instrument serial number
When	During system start up.
Cause	No instrument serial number was found in the instrument's non-volatile memory.
Handling	System is halted.

## 2.13 Hardware error

Label	ERR_FSCK_FAILED
Log Message	File system check/repair failed
When	During system start up.
Cause	The file system check, performed when the GEM 3500 operating system software starts up, failed. This file system check is performed by the Linux operating system utility "fsck".
Handling	System is halted.

## 2.14 Hardware error

Message	Cartridge error: 2.14
A cartridge error has occurred.	
Label	ERR_TEMP_OUT_OF_RANGE
Log Message	Temperature out of range during cartridge warm up
When	During cartridge warm up.
Cause	The heater block temperature is outside the specified range of $37\pm0.5^{\circ}\text{C}$ .
Handling	The operating software displays the <i>Remove Cartridge</i> screen with the message shown above.

## 2.15 Hardware error

Message	Cartridge error: 2.15
A cartridge error has occurred.	
Label	ERR_REF_OUT_OF_RANGE
Log Message	Reference out of range during cartridge warm up
When	During cartridge warm up.
Cause	The reference voltage is outside the specified range of $\pm2.0\text{V}$ .
Handling	The operating software displays the <i>Remove Cartridge</i> screen with the message shown above.

## Software Errors (3.01-3.99)

This section describes the GEM 3500 software errors that can occur. The remedy for a persistent software error is to reinstall the GEM 3500 application software.

For any of the software errors, the message displayed by the instrument will be:

<type of error> X.XX

*This instrument will reset in 30 seconds.*

*If the problem persists, contact Technical Service.*

### 3.01 Software error

Label	ERR_BAD_TIME_DATE
Log Message	Unknown cartridge age
When	During cartridge warm up or power fail recovery.
Cause	The amount of time that power was off or the age of the cartridge could not be determined. That is, the last time saved is negative or greater than the system time. This may indicate corruption of the persistent data file that contains the last time saved.
Handling	System reset is performed.
Remedy	Confirm that the system time is correct. If the error occurs following the system reset, remove the cartridge, copy the cartridge data to a diskette, then reinstall the GEM 3500 application software.

### 3.02 Software error

Label	ERR_LL_P_HDR_READ
Log Message	No header in message from LLP
When	Whenever the HLP is communicating with the LLP, such as during a sample or calibration.
Cause	The GEM 3500 HLP (High Level Processor) did not find a header in the message it received from the LLP (Low Level Processor). The HLP needs the header to determine the type of data contained in the message.
Handling	System reset is performed.

### 3.03 Software error

Label	ERR_LL_P_HDR_MISMATCH
Log Message	Unexpected header in message from LLP
When	Whenever the HLP is communicating with the LLP, such as during a sample or calibration.
Cause	The GEM 3500 HLP (High Level Processor) did not find the header it expected in the message it received from the LLP (Low Level Processor). The HLP needs the header to determine the type of data contained in the message.
Handling	System reset is performed.

### 3.04 Software error

Label	ERR_LL_P_DATA_READ
Log Message	No data in message from LLP
When	Whenever the HLP is communicating with the LLP, such as during a sample or calibration.
Cause	The GEM 3500 HLP (High Level Processor) found only a header in the message it received from the LLP (Low Level Processor) but did not find any data in the message.
Handling	System reset is performed.

### 3.05 Software error

Label	ERR_STS_MSG_HDR
Log Message	No status message from LLP
When	Whenever the HLP sends the status command to the LLP, such as when the HLP polls the LLP to determine if a cartridge has been inserted or removed, or when the HLP sends the status command to the LLP a few seconds after sending a reset command to the LLP.

Cause	The GEM 3500 HLP (High Level Processor) was waiting to receive a status message from the LLP (Low Level Processor), but the message that the HLP received did not contain a status message header.
Handling	System reset is performed.

### 3.06 Software error

Label	ERR_CMP_MSG_HDR
Log Message	No batch complete message from LLP
When	Whenever the HLP sends a batch of commands to the LLP, such as during a sample, calibration, or LLP initialization.
Cause	The GEM 3500 HLP (High Level Processor) was waiting to receive a batch complete message (which indicates that a set of commands has been processed by the LLP) from the LLP (Low Level Processor), but the message that the HLP received did not contain a batch complete message header.
Handling	System reset is performed.

### 3.07 Software error

Label	ERR_AD_MSG_HDR
Log Message	No sensor reading message from LLP
When	During sample or calibration measurement, or while waiting for the heater block to reach a particular temperature during cartridge warm up or power fail recovery.
Cause	The GEM 3500 HLP (High Level Processor) was waiting to receive a single channel sensor reading message from the LLP (Low Level Processor), but the message that the HLP received did not contain a single channel sensor reading message header.
Handling	System reset is performed.

### 3.08 Software error

Label	ERR_AS_MSG_HDR
Log Message	No sensor readings message from LLP
When	During sample or calibration measurement.
Cause	The GEM 3500 HLP (High Level Processor) was waiting to receive a signal channels (analyte channels, temperature, ground, reference) sensor reading message from the LLP (Low Level Processor), but the message that the HLP received did not contain a signal channels sensor reading message header.
Handling	System reset is performed

### 3.09 Software error

Label	ERR_SOLN_MSG_HDR
Log Message	No solution type message from LLP
When	During sample aspiration or when solution is pumped from the cartridge during a calibration.
Cause	The GEM 3500 HLP (High Level Processor) was waiting to receive a solution type message from the LLP (Low Level Processor), but the message that the HLP received did not contain a solution type message header.
Handling	System reset is performed.

### 3.10 Software error

Label	ERR_REV_MSG_HDR
Log Message	No revision message from LLP

When	Whenever the HLP sends the revision command to the LLP, such as during system initialization.
Cause	The GEM 3500 HLP (High Level Processor) was waiting to receive a revision message from the LLP (Low Level Processor), but the message that the HLP received did not contain a revision message header.
Handling	System reset is performed.

### 3.11 Software error

Label	ERR_INIT_LL_P
Log Message	LLP initialization failed
When	During LLP initialization.
Cause	The GEM 3500 HLP (High Level Processor) received an unexpected error message from the LLP (Low Level Processor) during LLP initialization.
Handling	System reset is performed.

### 3.12 Software error

Label	ERR_B_CAL_BAD_SOLN
Log Message	No B solution message from LLP
When	While B solution is being pumped from the cartridge during a B calibration.
Cause	The GEM 3500 HLP (High Level Processor) received an incorrect solution message from the LLP (Low Level Processor) during a B calibration. The HLP was expecting a B solution message.
Handling	System reset is performed.

### 3.13 Software error

Label	ERR_A_CAL_BAD_SOLN
Log Message	No A solution message from LLP
When	While A solution is being pumped from the cartridge during an A calibration.
Cause	The GEM 3500 HLP (High Level Processor) received an incorrect solution message from the LLP (Low Level Processor) during an A calibration. The HLP was expecting an A solution message.
Handling	System reset is performed.

### 3.14 Software error

Label	ERR_SAMP_BAD_SOLN
Log Message	No sample solution message from LLP
When	During sample aspiration.
Cause	The GEM 3500 HLP (High Level Processor) received an incorrect solution message from the LLP (Low Level Processor) during sample processing. The HLP was expecting a sample solution message.
Handling	System reset is performed.

### 3.15 Software error

Label	ERR_UNEXP_LL_P_MSG
Log Message	Unexpected message from LLP
When	Whenever the HLP is communicating with the LLP, such as during a sample or calibration.
Cause	The GEM 3500 HLP (High Level Processor) received an unexpected message from the LLP (Low Level Processor).
Handling	System reset is performed.

### 3.16 Software error

Label	ERR_LLPD_MAX_RESENGS
Log Message	HLP to LLP maximum message resends
When	Whenever the HLP is communicating with the LLP, such as during a sample or calibration.
Cause	The GEM 3500 LLP (Low Level Processor) is not acknowledging (by responding with an ASCII ACK or NAK character) a command sent from the HLP (High Level Processor). Or, the GEM 3500 LLP has requested the HLP to resend a command the maximum number of times.
Handling	System reset is performed.

### 3.17 Software error

Label	ERR_CARTD_TIMEOUT
Log Message	Cartridge daemon timeout
When	When the GEM 3500 HLP (High Level Processor) is waiting for the LLP (Low Level Processor) to complete a cartridge function, such as positioning the valve or moving the sample arm.
Cause	The GEM 3500 HLP (High Level Processor) waited the maximum amount of time for the LLP (Low Level Processor) to complete a cartridge function.
Handling	System reset is performed.

### 3.18 Software error

Label	ERR_CARTD_UNEXP_EVENT
Log Message	Unexpected cartridge daemon event
When	When the GEM 3500 HLP (High Level Processor) is waiting for the LLP (Low Level Processor) to complete a cartridge function, such as positioning the valve or moving the sample arm.
Cause	Communication between the GEM 3500 HLP (High Level Processor) and LLP (Low Level Processor) is not synchronized because the HLP cannot successfully reset the LLP. Failure to reset the LLP may be due to an instrument failure, such as an unrecoverable valve error when the LLP starts up. Failure to reset the LLP may also be due to a problem with the signal line that the HLP uses to reset the LLP.
Handling	System reset is performed.

### 3.19 Software error

Label	ERR_UNEXP_MSG_FROM_CARTD
Log Message	Frontend and cartridge out of sync
When	When a GEM 3500 front end process, such as Ready, receives an unexpected message from the cartridge daemon (for example, during sample aspiration).
Cause	Communication between a GEM 3500 front end process and the cartridge daemon is not synchronized. The communication failure may be due to an error detected by the cartridge daemon and for which the system is about to reset (for example, an unrecoverable A/D calibration error).
Handling	System reset is performed.

### 3.20 Software error

Label	ERR_TIMEOUT_FROM_CARTD
Log Message	Frontend timed out on cartridge response
When	When a GEM 3500 front end process, such as Ready, times out waiting to receive a message from the cartridge daemon (for example, during sample aspiration).
Cause	Communication between a GEM 3500 front end process and the cartridge daemon is not synchronized. The communication failure may be due to an error detected by the cartridge daemon and for which the system is about to reset (for example, an unrecoverable A/D calibration error).
Handling	System reset is performed.

### 3.21 Software error

Label	ERR_DB_ERROR
Log Message	Database error: %s (where %s is the database name)
When	Whenever a database operation is performed.
Cause	A database operation has failed.
Handling	System reset is performed.

### 3.22 Software error

Label	ERR_FILE_IO
Log Message	File I/O error: %s (where %s is the database name)
When	Whenever a file I/O operation is performed.
Cause	A file I/O operation has failed.
Handling	System reset is performed.

### 3.23 Software error

Label	ERR_IPC_ERROR
Log Message	Inter Process Communication error: %s (where %s is the process name)
When	Whenever communication between two processes occurs.
Cause	Communication between two processes has failed.
Handling	System reset is performed.

### 3.24 Software error

Label	ERR_FSCK_ERROR
Log Message	File system check detected error
When	During system start up.
Cause	The file system check, performed when the GEM 3500 operating system software starts up, detected an error. This may indicate that the instrument's internal disk is starting to fail. The file system check is performed by the Linux operating system utility "fsck". When an error is detected, "fsck" attempts to fix the area of the file system that caused the error.
Handling	The log message is logged in the system error log file "syslog.dat".

### 3.25 Software error

Label	ERR_ABORT LLP
Log Message	No abort message from LLP
When	When the HLP sends an abort command to the LLP, which causes the LLP to stop execution of any command it is currently performing and clear its command queue.
Cause	The GEM 3500 HLP (High Level Processor) was waiting to receive an abort message from the LLP (Low Level Processor) in response to the abort command, but the message that the HLP received did not contain an abort message header.
Handling	System reset is performed.

### 3.26 Software error

Label	ERR_A0_CAL_BAD_SOLN
Log Message	No A0 solution message from LLP

When	While A0 solution is being pumped from the cartridge during an A0 calibration.
Cause	The GEM 3500 HLP (High Level Processor) received an incorrect solution message from the LLP (Low Level Processor) during an A0 calibration. The HLP was expecting an A0 solution message.
Handling	System reset is performed.

## Event Logging (9.01-9.99, 0.00-0.99)

This section describes the GEM 3500 events that are logged in the system error log file “syslog.dat”.

### 9.01 Event

Label	EVENT_INSERT_CART
Log Message	Cartridge inserted: %s (where %s is the cartridge barcode)
When	When a cartridge is inserted into the instrument.

### 9.02 Event

Label	EVENT_POWFAIL_STATE
Log Message	Cartridge power fail recovery state
When	When the instrument is restarted with a cartridge inserted.

### 9.03 Event

Label	EVENT_REMOVE_CART
Log Message	Remove cartridge state: %s (where %s is the reason the cartridge is to be removed)
When	When the instrument goes to the remove cartridge state.

### 9.04 Event

Label	EVENT_REMOVED_CART
Log Message	Cartridge removed: %s (where %s is the cartridge barcode)
When	When a cartridge is removed from the instrument.

### 9.05 Event

Label	EVENT_CHANGE_TIME_DATE
Log Message	Time/date changed: %s (where %s is the time and date)
When	When time and date is changed on the instrument.

### 9.06 Event

Label	EVENT_CHANGE_COLOR
Log Message	Color palette changed: %s (where %s is the color palette)
When	When the color palette is changed on the instrument.

**9.07 Event**

Label            EVENT\_SYS\_RESTART  
 Log Message    Instrument restart  
 When            When the instrument is restarted.

**9.08 Event**

Label            EVENT\_SYS\_SHUTDOWN  
 Log Message    Instrument shutdown  
 When            When the instrument is shut down.

**9.09 Event**

Label            EVENT\_REF\_SHIF  
 Log Message    Reference channel shifted during cal A or B  
 When            When the instrument detects a shift in Reference sensor during A or B calibration.

**9.10 Event**

Label            EVENT\_BLOOD\_CLOT\_PATTERN1  
 Log Message    Blood clot pattern 1 detected.  
 When            When the instrument detects the iQM clot pattern 1 in B calibration following patient sample.

**9.11 Event**

Label            EVENT\_BLOOD\_CLOT\_PATTERN2  
 Log Message    Blood clot pattern 2 detected.  
 When            When the instrument detects the iQM clot pattern 2 in A calibration sometime after a patient sample.

**9.12 Event**

Label            EVENT\_BLOOD\_PATTERN3  
 Log Message    Pattern 3 pO2 malfunction detected.  
 When            When the instrument detects the iQM pattern 3 when measuring pO2 in B calibration.

**9.13 Event**

Label            EVENT\_NOAIR\_DETECT  
 Log Message    Clot Pattern No-Air in B after sample detected.  
 When            When the instrument encounters Air detection failure during the B calibration cycle immediately following a patient sample.

**9.14 Event**

Label            EVENT\_NOSOLU\_DETECT  
 Log Message    Clot Pattern No-Solu in B after sample detected.  
 When            When the instrument encounters calibration solution detection failure during the B calibration cycle immediately following a patient sample.

## 9.15 Event

Label EVENT\_INTERFERENCE  
Log Message Sample interference detected.  
When When the instrument detects Thiopental or Benzalkonium sample interference pattern in the B calibration immediately following a patient sample.

## 0.00 Event

Label CLEAR\_ERR\_ALL  
Log Message All alarms cleared  
When When all the alarms [see "[Alarms \(0.01 - 0.99\)](#)"] have been cleared.  
0.07 Improper instrument shutdown  
Label ERR\_IMPROPER\_SHUTDOWN  
Log Message Improper instrument shutdown  
When When the instrument restarts after it was improperly shutdown.

## 0.11 iQM Disabled pH Sensor

Label ERR\_IQM\_PH  
Log Message pH is permanently disabled due to iQM error  
When Sensor fails calibration A, B, or C calibration.

## 0.12 iQM Disabled pCO2 Sensor

Label ERR\_IQM\_PCO2  
Log Message pCO2 is permanently disabled due to iQM error  
When Sensor fails calibration A, B, or C calibration.

## 0.13 iQM Disabled pO2 Sensor

Label ERR\_IQM\_PO2  
Log Message pO2 is permanently disabled due to iQM error  
When Sensor fails calibration A, B, or C calibration.

## 0.14 iQM Disabled Na+ Sensor

Label ERR\_IQM\_NA  
Log Message Na+ is permanently disabled due to iQM error  
When Sensor fails calibration A or B calibration.

## 0.15 iQM Disabled K+ Sensor

Label ERR\_IQM\_K  
Log Message K+ is permanently disabled due to iQM error  
When Sensor fails calibration A or B calibration.

## 0.16 iQM Disabled Ca++ Sensor

Label ERR\_IQM\_CA

Log Message    Ca++ is permanently disabled due to iQM error  
When              Sensor fails calibration A or B calibration.

### 0.17 iQM Disabled Hct Sensor

Label            ERR\_IQM\_HCT  
Log Message    Hct is permanently disabled due to iQM error  
When            Sensor fails calibration A or B calibration.

### 0.18 iQM Disabled Glu Sensor

Label            ERR\_IQM\_GLU  
Log Message    Glu is permanently disabled due to iQM error GEM Premier 3500 Service Manual  
When            Sensor fails calibration A or B calibration.

### 0.19 iQM Disabled Lac Sensor

Label            ERR\_IQM\_LAC  
Log Message    Lac is permanently disabled due to iQM error  
When            Sensor fails calibration A or B

# Chapter 9 – Interfacing

## 9-1 Overview

### Port Descriptions



**NOTE:** Refer to "[Interface Specification](#)" for complete interface specifications.

## Pin Descriptions

**Table 9-1 Paralell Port (25 PIN D-SUB FEMALE at the PC)**

Pin	Name	Direction	Description
1	/STROBE	—	Strobe
2	D0	—	Data Bit 0
3	D1	—	Data Bit 1
4	D2	—	Data Bit 2
5	D3	—	Data Bit 3
6	D4	—	Data Bit 4
7	D5	—	Data Bit 5
8	D6	—	Data Bit 6
9	D7	—	Data Bit 7
10	/ACK	—	Acknowledge
11	BUSY	—	Busy
12	PE	—	Paper End
13	SEL	—	Select
14	/AUTOFD	—	Autofeed
15	/ERROR	—	Error
16	/INIT	—	Initialize
17	/SELIN	—	Select In
18	GND	±	Signal Ground
19	GDN	±	Signal Ground
20	GND	±	Signal Ground
21	GND	±	Signal Ground
22	GND	±	Signal Ground
23	GND	±	Signal Ground
24	GND	±	Signal Ground
25	GND	±	Signal Ground

**Table 9-2 Serial Communications Ports**

Pin	Function
1	DCD (Data Carrier Detect)
2	RX (Receive Data)
3	TX (Transmit Data)
4	DTR (Data Terminal Ready)
5	GND (Signal Ground)
6	DSR (Data Set Ready)
7	RTS (Ready to Send)
8	CTS (Clear to Send)
9	RI (Ring Indicator)

**Table 9-3 Keyboard Connector**

Pin	Name	Direction	Description
1	DATA	↔	Key Data
2	n/c		Not Connected
3	GND	⊖	Ground
4	VCC	↔	Power, +5VDC
5	CLK	↔	Clock
6	n/c		Not Connected

**Table 9-4 Integrated LAN Support**

Pin	Name	Description
1	TX+	Tranceive Data +
2	Tx-	Tranceive Data -
3	Rx+	Receive Data +
4	n/c	Not Connected
5	n/c	Not Connected
7	RX-	Receive Data -
8	n/c	Not Connected
9	n/c	Not Connected

**Table 9-5 USB Port**

Pin	Name	Description
1	VCC	+5 VDC
2	D-	Data -

3	D+	Data +
4	GND	Ground

## 9-2 Interfacing

### Interfacing a CO-Oximeter

The Gem 3500 can be interfaced to either the IL682 or the ILOPL, to have the CO-Oximeter data transferred to the GEM. The CO-Oximeter data will be used to perform calculations for derived parameters, and it will be printed, transmitted from and stored on the GEM. If a CO-Ox only sample is analyzed and transmitted to the GEM, it will not affect the number of tests available on the cartridge.

To interface either a 682 or an OPL, the same interface cable (00018420238) is used.

### Interfacing to the IL682

1. Connect one end of the interface cable to Serial/COM port A, B, or C on the back of the GEM.
2. In the “Configuration”, “Interface Setup” menu, place a checkmark in the “IL682” box for the same COM Port.
3. Shutdown the GEM, then power it up again.
4. Enable the desired CO-Ox parameters in the “Configuration”, “Sample Setup”, “Analyte Enable/Disable” menu, using both the “Measured” and “Derived” tabs. If Fetal Hb corrections are to be performed, use the “Entered” tab.
5. Connect the other end of the serial cable to the “Serial 2” port on the back of the instrument.
6. Press “Menu”, “4 Utility”, “2 configuration”, “1 Interfaces”, “3 serial Port 2”, and “1 DMS”. Configure the port as:
  - Standard
  - Baud rate – 9600
  - Data Bits – 8
  - Parity – None
  - Stop Bits – 1
  - Ack/Nack – OFF
  - XON/XOFF – OFF
  - Send Cal Data – OFF
  - Send QC Data – ON or OFF (as required)
  - Start Char – STX
  - Header – ON
  - Instrument ID – 1

7. Disable the Fetal Mode on the 682 (Menu 4,2,3,3,2,2) as the GEM will perform the calculations if the Fetal % is entered. If the 682 performs the calculation also, the data can be affected.

Instructions for sampling are found in the GEM Premier 3500 Operators Manual.

## Interfacing to the ILOPL

1. Connect one end of the interface cable to Serial/COM port A, B, or C on the back of the GEM.
2. In the “Configuration”, “Interface Setup” menu, place a checkmark in the “ILOPL” box for the same COM Port.
3. Shutdown the GEM, then power it up again.
4. Enable the desired CO-Ox parameters in the “Configuration”, “Sample Setup”, “Analyte Enable/Disable” menu, using both the “Measured” and “Derived” tabs. If Fetal Hb corrections are to be performed, use the “Entered” tab.
5. Connect other end of the cable to the RS-232 Serial Port on the back of the OPL
6. Activate “Data Transfer” on the OPL. Press “Computer”, “#1 Data Management”, “#1 Data Transfer On/Off” and select “#2 ON”. Press enter after each selection and press cancel to return to the ready screen.
7. Activate “Auto Transfer” on the OPL. Press “Main Menu”, “#3 Stored Data”, “#3 Transfer”, “#3 Auto Transfer”, and select “#2ON”. Press enter after each selection and press cancel to return to the ready screen.
8. Confirm the OPL interface configuration. Press “Main Menu”, “#2 Printer Mode”, “#3 Printer Parameters”. Confirm that the Baud Rate is 9600 and Parity is NONE. These are the only configurable settings. If a setting needs to be changed, use the YES+ or NO- keys until the appropriate setting is displayed. Press enter after each selection and press cancel to return to the ready screen

Instructions for sampling are found in the GEM Premier 3500 Operators Manual.

## 9-3 Interface Specification



# Chapter 10 – Parts List

## 10-1 Service Parts

### Manufacturing Part Number to Salable Part Number List

Part No. (MFG)	Description	Salable Part No.
00085011	Card guide grounding left	00085011
000500039	Line filter PCB	000500039
000500057	C.I. to DCS PC assy	000500057
000560031	Roller pump	000560031
000630065	Screw socket pump spring	000630065
000630066	Standoff, shaft	000630066
000630068	Arm Driver Kit	000630068
000630069	Valve Driver Kit	000630069
000630075	Pull bar bracket	000630075
000630079	Slide cover guide	000630079
000630086	C.I. door hinge	000630086
000695148	Motor pulley	000695148
000750010	Motor, 5000 RPM DC	000750010
000810007	Photomicrosensor reflective	000810007
000850012	Card guide grounding right	000850012
000930037	Switch PCB 0.1 A 125 V	000930037
00020405100	Power input cable	00020405100
00020491700	Kit solenoid cartridge	00020491700
00024000228	PCB Adapter	00024000228
00024002052	Door solenoid latch kit	00024002052
00024005000	Heater Block	00024005000
00024005044	Touchscreen	00024005044
00024005118	LCD cable bracket, short	00024005118
00024005119	LCD cable bracket, long	00024005119
00024005126	Reader block	00024005126
00024005172	PCB ASSY DCS 2 GEM 3	00024005172
00024005269	Fan, 12V, 16.6 CFM	00024005269

<b>Part No. (MFG)</b>	<b>Description</b>	<b>Salable Part No.</b>
00024005291	Ampule wheel	00024005291
00024005541	Switch power/Ckt Bkr	00024005541
00024305380	Backplane	00026002001
00024305450	Inverter cable	00026002002
00024305451	LCD flex cable	00026002003
00024305456	Power output cable	00026002004
00024305457	Cable, side USB	00026002005
00024305458	Cable assy wireless card to antenna	00026002006
00024305459	Cable 3500 LED	00026002007
00024305461	Flex cable cartridge top	00026002008
00024305463	Assy cart motors flex cable	00026002009
00024305464	Flex cable motor	00026002010
00024305466	Ampule reader assy	00026002011
00024305467	Cable assy barcode reader	00026002012
00024305471	DVD cable	00026002013
00024305472	Cable assy front LED extension	00026002014
00024305480	Wireless card	00026002015
00024305481	Wireless Antenna, Rubber Duck	00026002016
00024305482	LCD screen 10.4 LVDS	00026002017
00024305483	PWR supply GEM3500 5V, 12V, 12V, 24V	00026002018
00024305484	SBC 3X00	00026002019
00024305488	Motor GEM3500 valve	00026002020
00024305489	Motor GEM3500 pump	00026002021
00024305490	Motor GEM 3500 arm	00026002022
00024305610	Analog Bd	00026002023
00024306001	Panel side left	00026002024
00024306003	Cartridge door	00026002025
00024306005	Door front	00026002026
00024306006	Door ampule reader	00026002027
00024306008	Door cartridge	00026002028
00024306011	Slide cartridge door	00026002029
00024306012	Bezel monitor front	00026002030
00024306013	Bezel display rear	00026002031
00024306014	Panel top	00026002032
00024306015	Handle	00026002033

Part No. (MFG)	Description	Salable Part No.
00024306016	Door printer	00026002034
00024306022	Base plate	00026002035
00024306023	cartridge interface wall left	00026002036
00024306039	Display ratchet	00026002037
00024306047	Cartridge interface top	00026002038
00024306048	LED holder	00026002039
00024306051	Support handle left	00026002040
00024306053	Box, antenna	00026002042
00024306055	LCD bracket	00026002043
00024306057	Ampule door back	00026002044
00024306058	Door front bracket	00026002045
00024306059	Support handle right	00026002041
00024306065	Keyboard cover	00026002046
00024306067	Disk drive bracket	00026002047
00024306073	Support, paper	00026002048
00024306077	Ampule beaker	00026002049
00024306078	Access panel	00026002050
00024306082	Gasket, Fan	00026002051
00024306084	Clearance box	00026002052
00024306085	Shelf bracket	00026002053
00024306086	Handle Bushing	00026002054
00024306088	Clamp, flat cable	00026002055
00024306095	Pump motor bracket	00026002056
00024306096	Pin, LCD, Pivot	00026002057
00024306097	Spacer GND, Display	00026002058
00024306098	DVD drive	00026002059
00024306105	Printer	00026002060
00024306107	Printer platen	00026002061
00025002021	RELEASE BUTTON	00025002021
00025002034	Tilt bracket	00025002034
00025002061	Touchscreen to LCD interface Bd	00025002061
00025002084	LCD interconnect cable	00025002084
00025002111	Inverter PCB	00025002111
00063630102	Pump motor bracket	00063630102

## Service Tools

Part No.	Description
000995100	ETC Power Supply
000995356	Pump Tension Test Cartridge
000995390	Pump Tension Indicator
000995410	ETC Harness
00024001581	Loopback Connector
00024005050	Electronic Test cartridge (ETC)
00024005162	ETC Adapter Board
00024005534	Premtest Disk V4.12
00024306129	Skipwarm Disk

## 10-2 Customer Parts and Supplies

### Cartridges

Test Menu	iQM	Capacity	Use-Life
<b>Blood Gases, Hct</b>	00026407584	75	4 weeks
	00026307584	75	3 weeks
	00026315084	150	3 weeks
	00026330084	300	3 weeks
	00026345084	450	3 weeks
<b>Blood gases, Hct, Electrolytes</b>	00026307587	75	3 weeks
	00026315087	150	3 weeks
	00026330087	300	3 weeks
	00026345087	450	3 weeks
	00026360087	600	2 weeks
<b>Blood Gases, Hct, Electrolytes, Glucose, Lactate</b>	00026307589	75	3 weeks
	00026315089	150	3 weeks
	00026330089	300	3 weeks
	00026345089	450	3 weeks
	00026360089	600	2 weeks

### Supplies and Accessories

Part No.	Description
00018420238	Interface cable GEM to CO-Ox
00024001170	Kit safety draw plastic capillary 1000pk
00025000500	Print Paper, 5 rolls

### CVP

Part No.	Description
00024001587	MULTIPAK, 20 AMPOULES X 2.5 ML X 4 LEVELS
00024001811	CVP 1, 20 AMPOULES X 2.5 ML
00024001812	CVP 2, 20 AMPOULES X 2.5 ML
00024001813	CVP 3, 20 AMPOULES X 2.5 ML
00024001814	CVP 4, 20 AMPOULES X 2.5 ML

## ContrIL 7

Part No.	Description
00024001380	MULTIPAK, 30 AMPOULES X 2ML X 3 LEVELS
00024001381	LEVEL 1, 30 AMPOULES X 2ML
00024001382	LEVEL 2, 30 AMPOULES X 2 ML
00024001383	LEVEL 3, 30 AMPOULES X 2 ML

## ContrIL 9

Part No.	Description
00024001418	MULTIPAK, 30 AMPOULES X 2ML X 3 LEVELS
00024001419	LEVEL 1, 30 AMPOULES X 2ML
00024001420	LEVEL 2, 30 AMPOULES X 2ML
00024001421	LEVEL 3, 30 AMPOULES X 2ML

# Chapter 11 – Drawings and Schematics

## 11-1 Drawings

Refer to [Chapter 10 “Parts List”](#) for lists of salable part numbers and their manufacturing part number equivalents.

[Figure 11-1 "00063006901 VALVE DRIVER"](#)

[Figure 11-2 "00063006801 ARM DRIVER"](#)

[Figure 11-3 "00024005000 HEATER BLOCK ASSY"](#)

[Figure 11-4 "00024305380 GEM 3500 BACKPLANE BOARD"](#)

[Figure 11-5 "00024305466 GEM 3X00 AMPOULE SPINNER"](#)

[Figure 11-6 "00024305481 WIRELESS ANTENNA, RUBBER DUCK"](#)

[Figure 11-7 "00024305484 GEM 3X00 CPU ASSY"](#)

[Figure 11-8 "00024305610 GEM 3X00 ANALOG BOARD"](#)

[Figure 11-9 "00024306105 GEM 3500 PRINTER"](#)

[Figure 11-10 "00026000000 GEM 3500 INSTRUMENT"](#)

Figure 11-1 000630006901 VALVE DRIVER

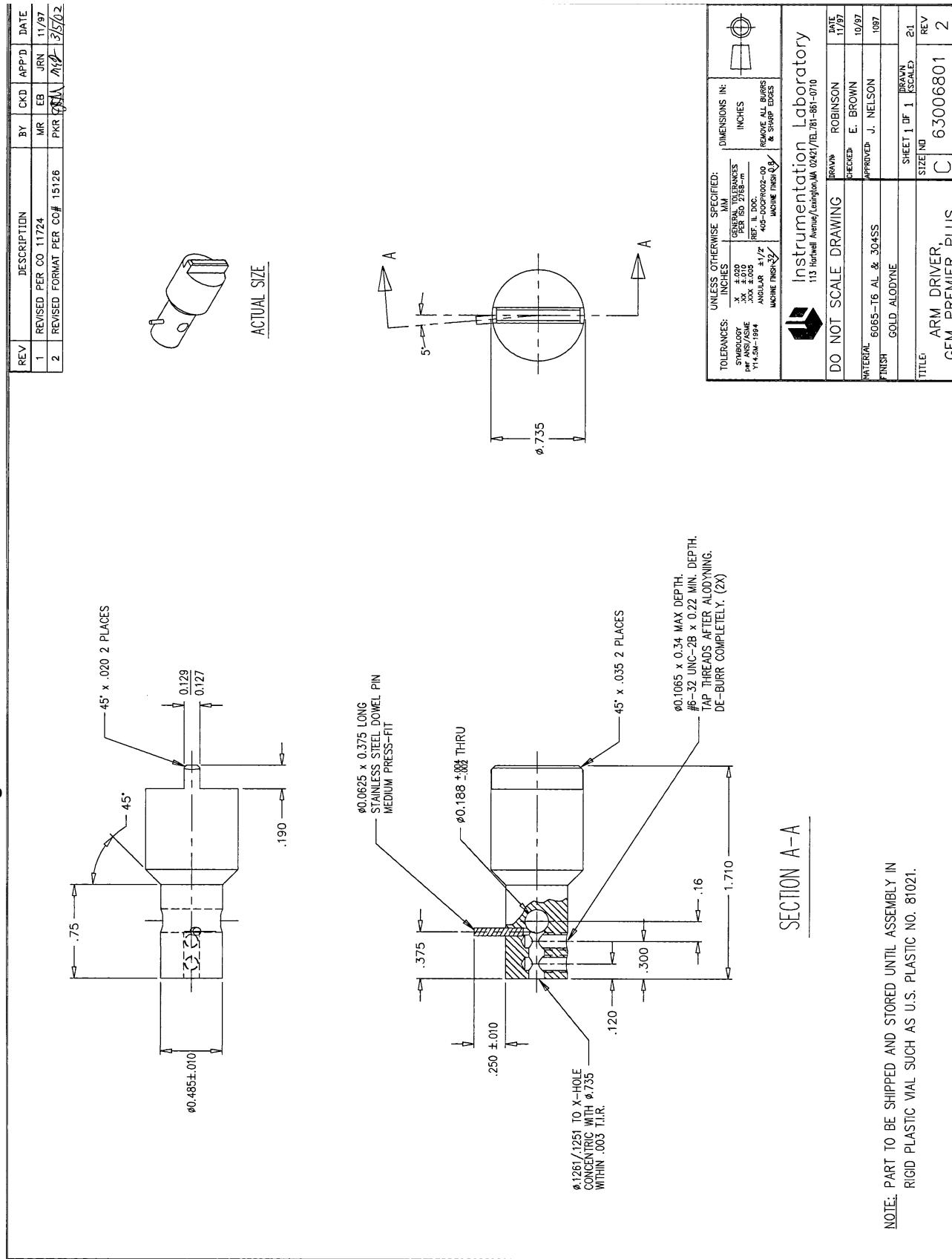


Figure 11-2 0000630006801 ARM DRIVER

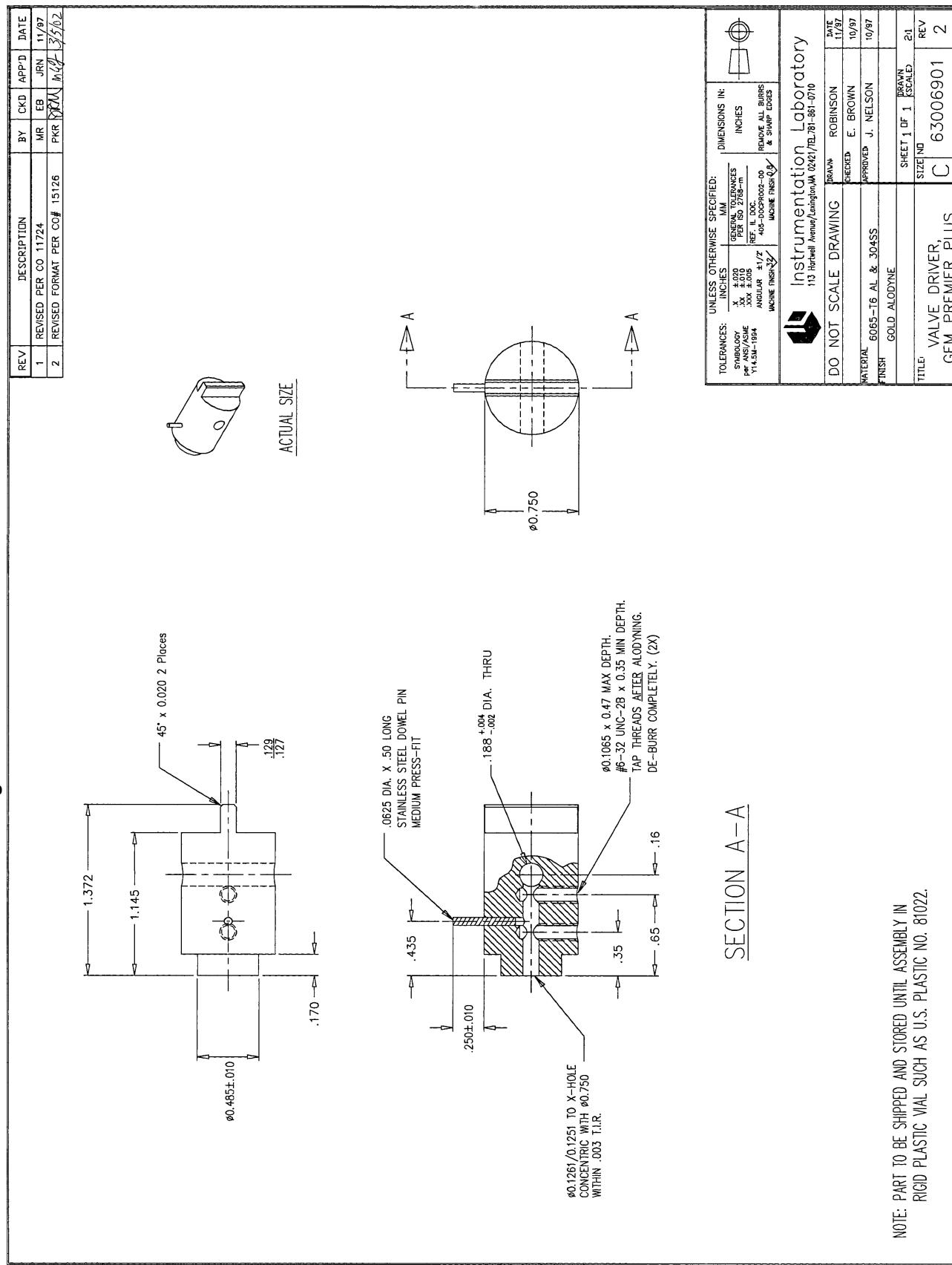


Figure 11-3 00024005000 HEATER BLOCK ASSY

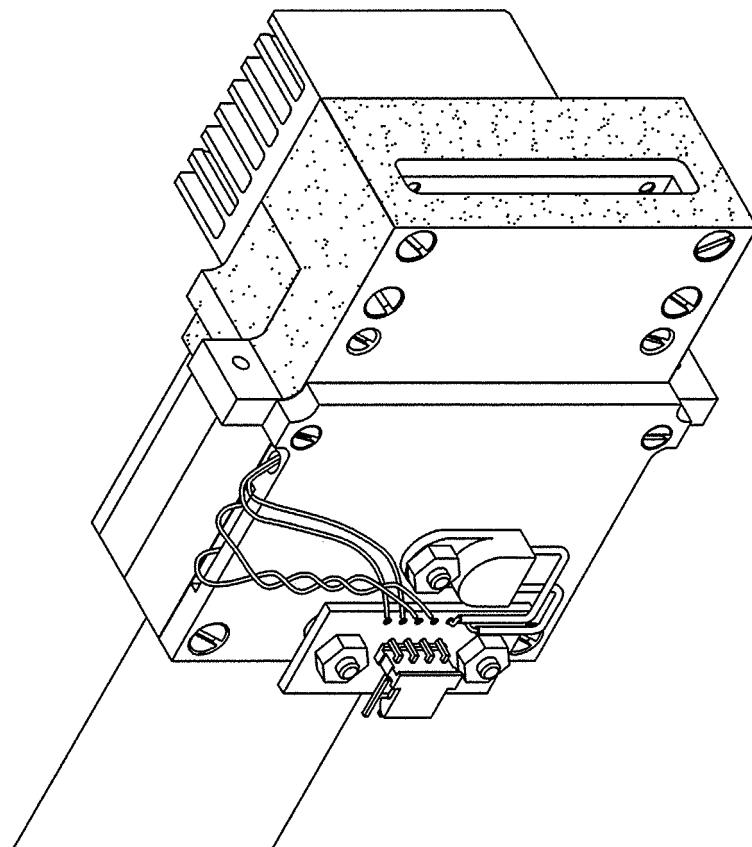


Figure 11-4 00024305380 GEM 3500 BACKPLANE BOARD

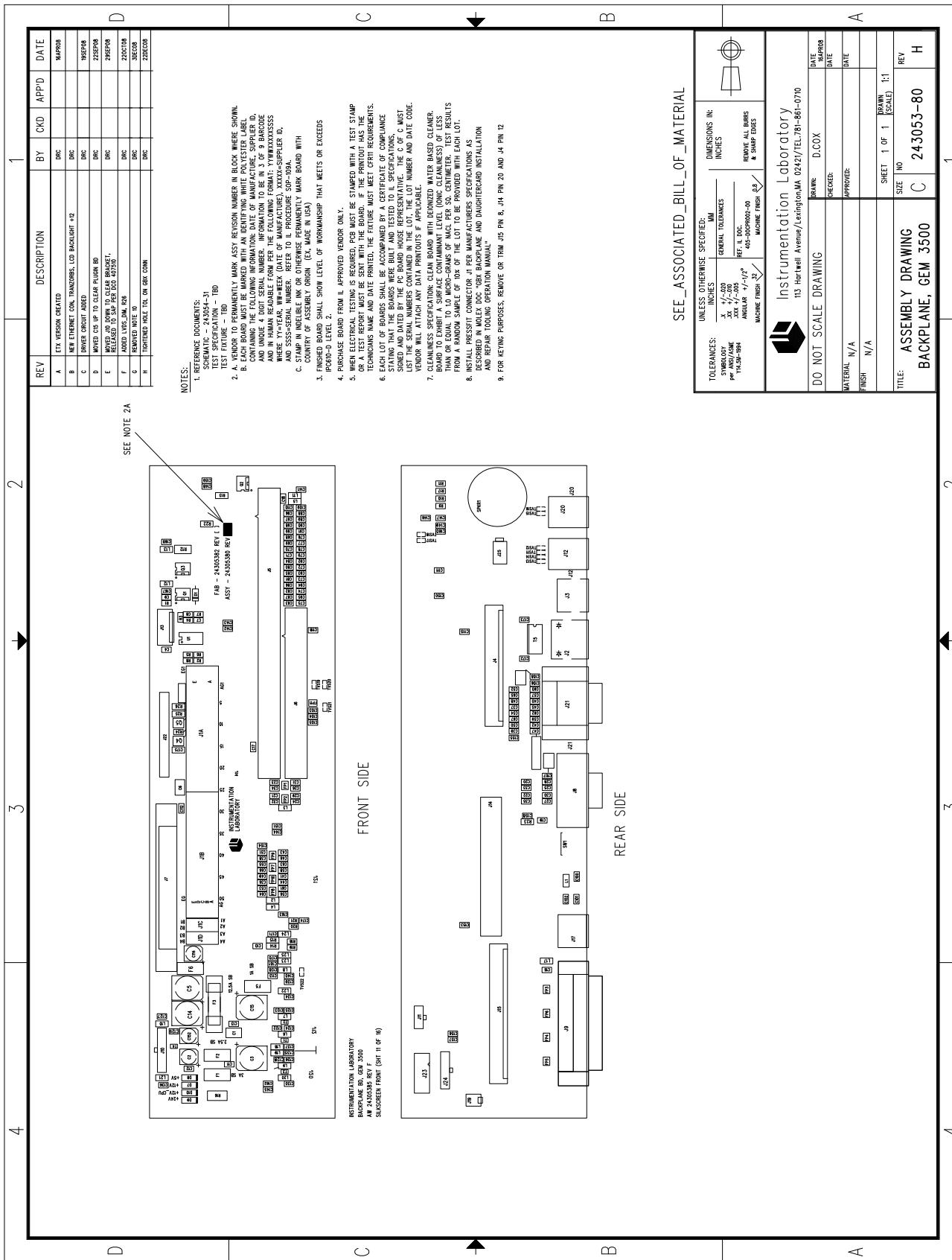
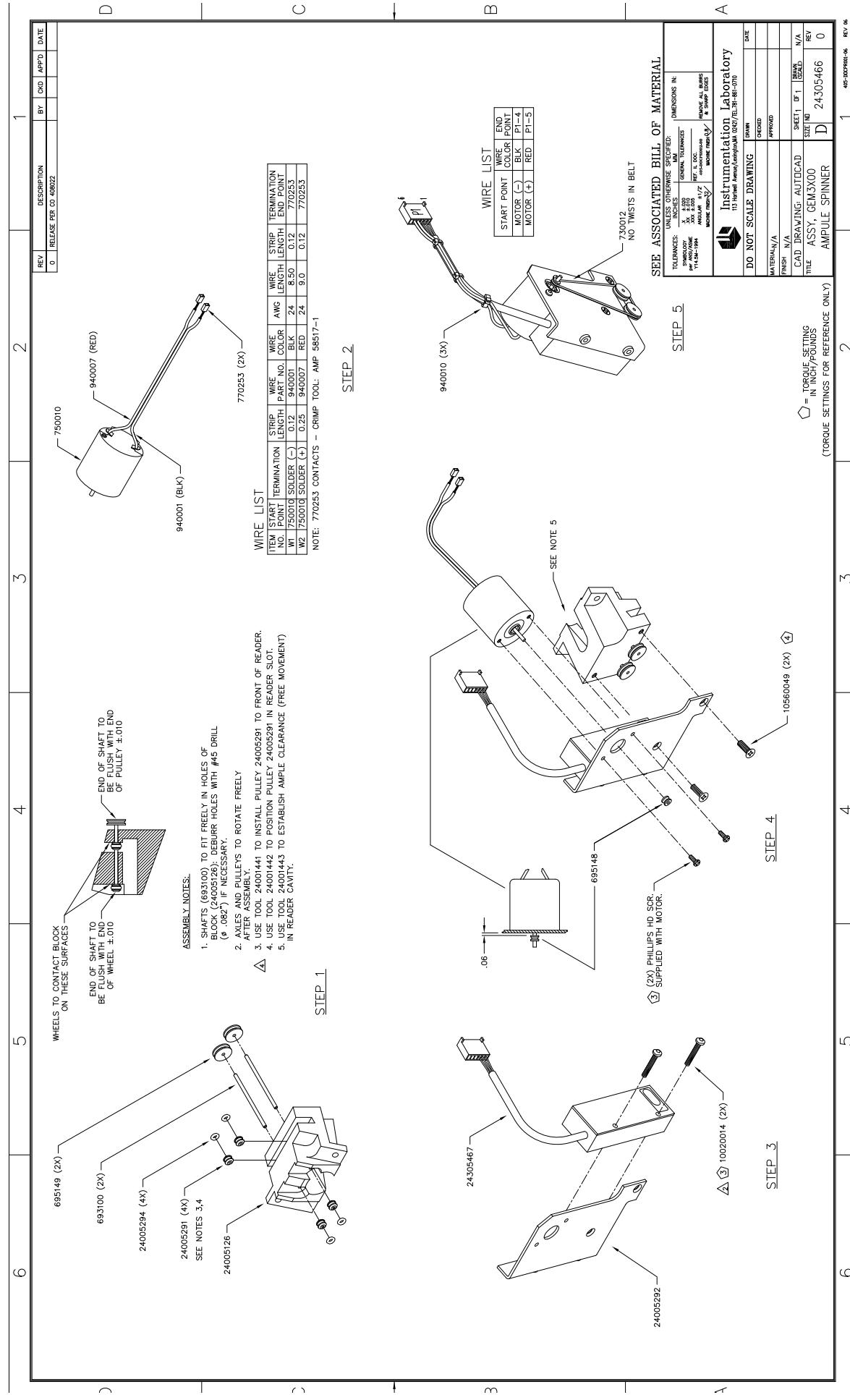


Figure 11-5 00024305466 GEM 3X00 AMPOULE SPINNER



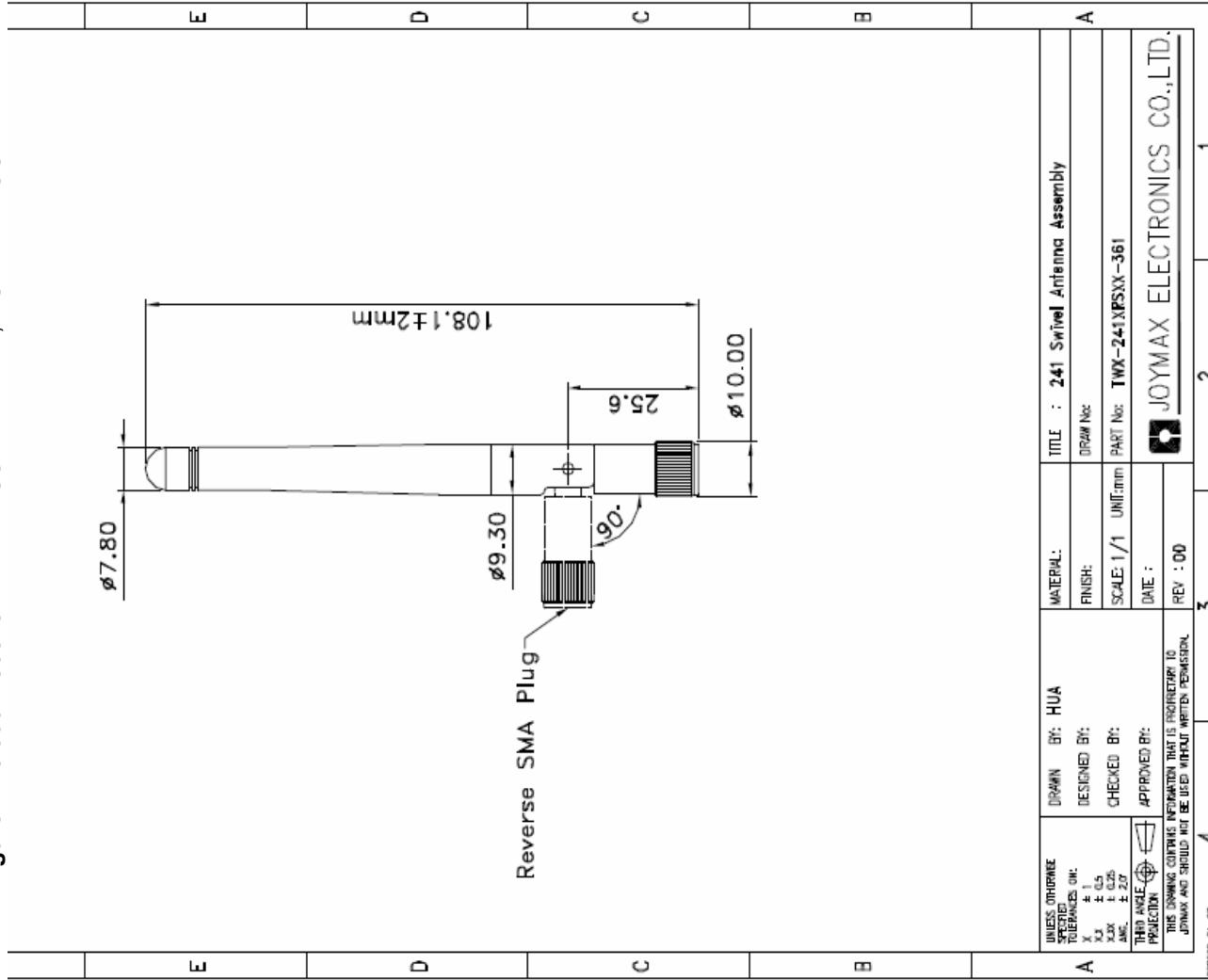
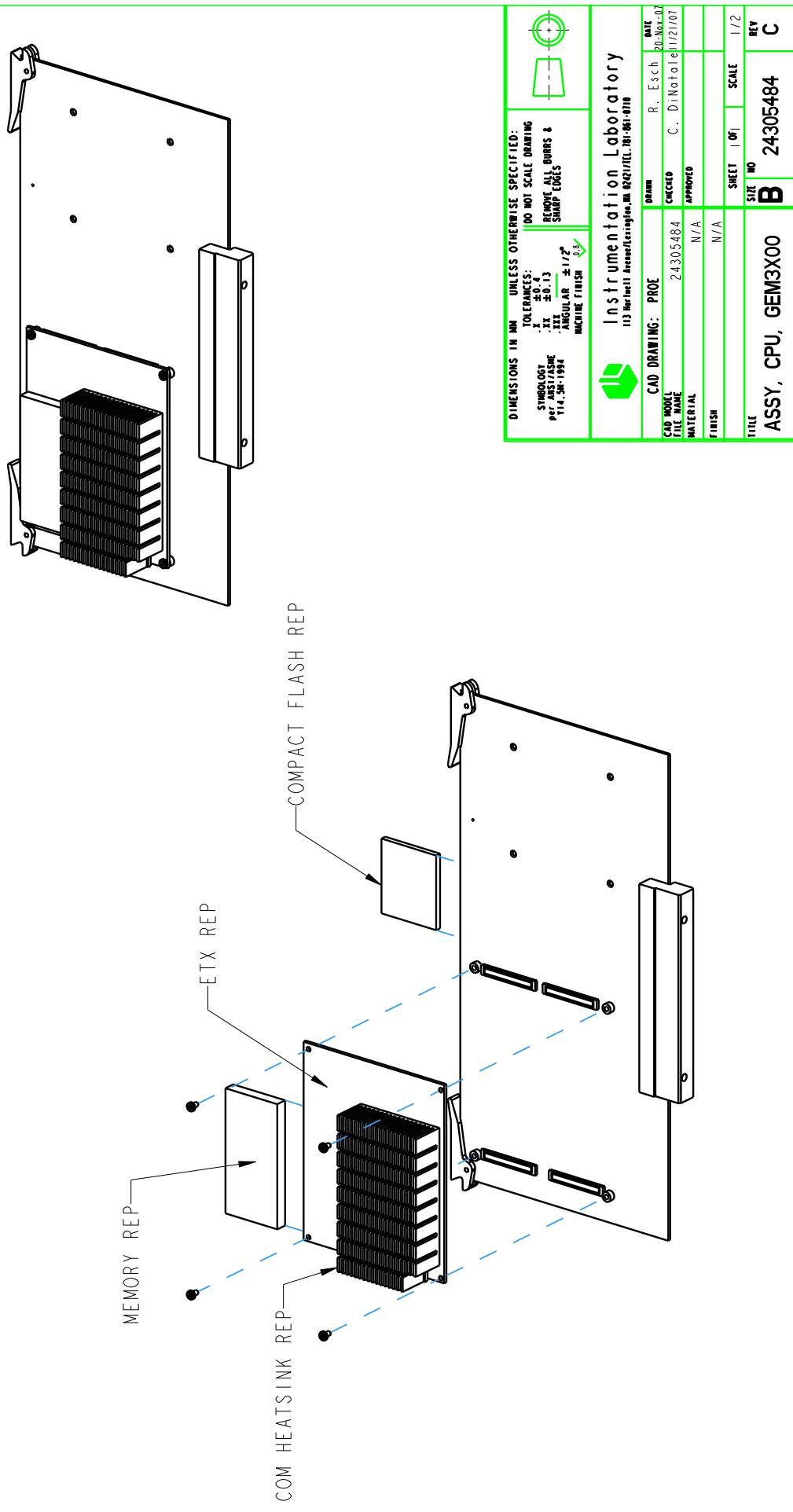
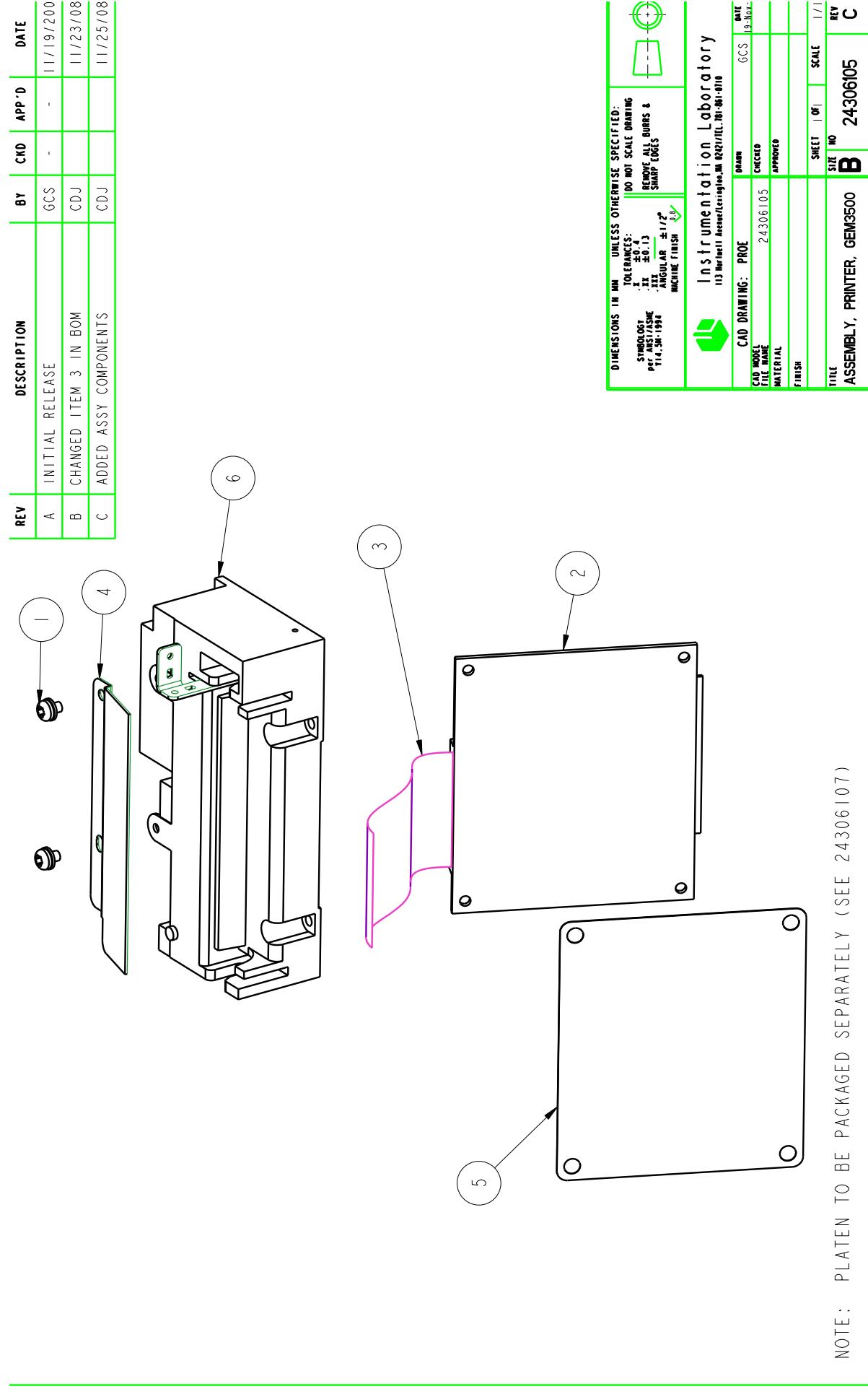
**Figure 11-6 00024305481 WIRELESS ANTENNA, RUBBER DUCK**

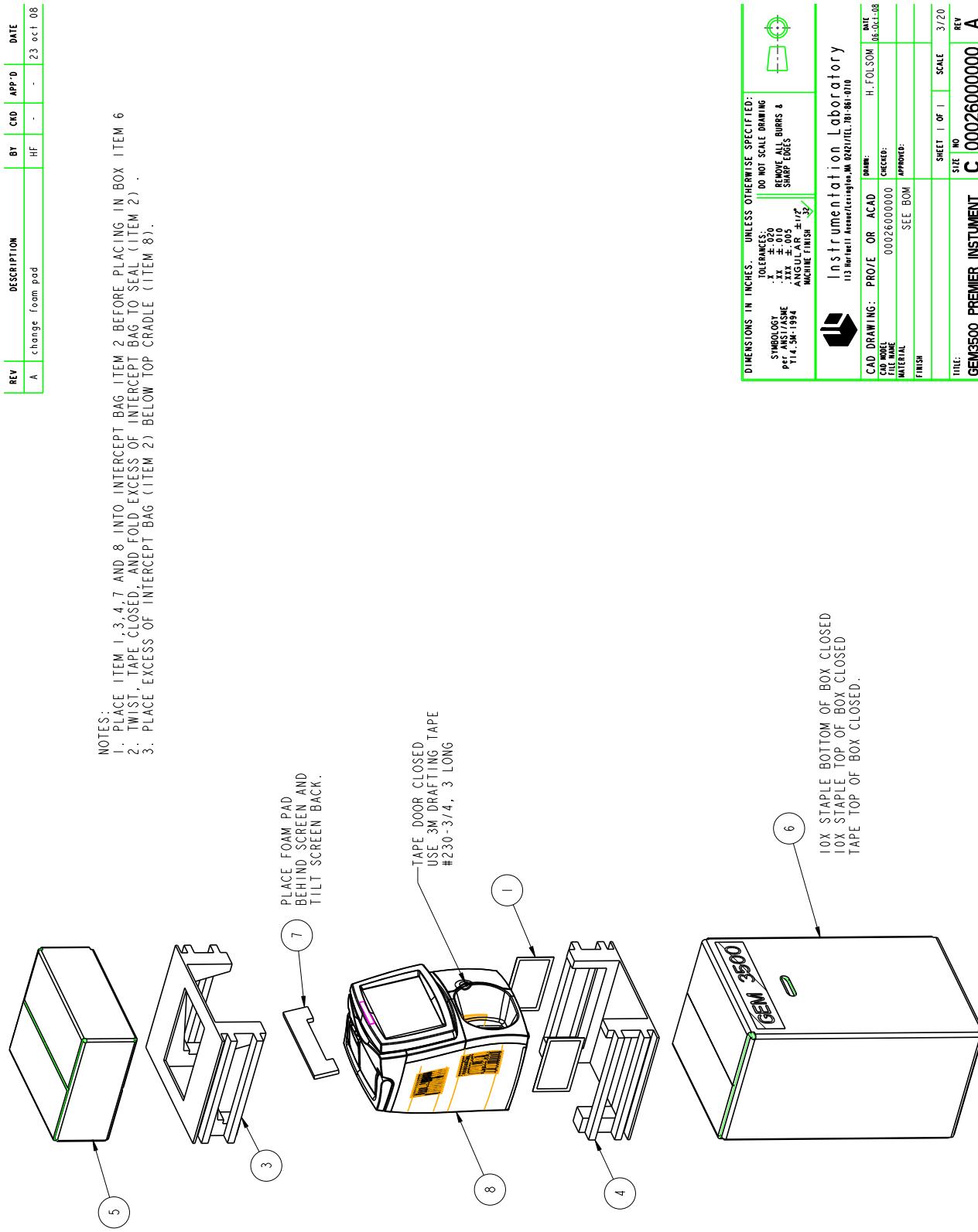
Figure 11-7 00024305484 GEM 3X00 CPU ASSY



**Figure 11-8 000024305610 GEM 3X00 ANALOG BOARD**

Figure 11-9 00024306105 GEM 3500 PRINTER



**Figure 11-10 00026000000 GEM 3500 INSTRUMENT**

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# Appendix A – Interface Protocols

Last Save Date:	Part Number:
<b>December 22, 2008</b>	<b>24305657</b>
Document Revision:	Software Version:
<b>1.10</b>	<b>7.0</b>

## Functional Specification GEM 3500 Operating Software

## Volume 7 Interface Protocols

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<b>December 22, 2008</b>	<b>24305657</b>
Document Revision:	Software Version:
<b>1.10</b>	<b>7.0</b>

## **Functional Specification**

### **GEM 3500 Operating Software**

## **Volume 7**

### **Interface Protocols**

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## 1. Document Summary

This document describes how data is transferred between a GEM and a receiving system, such as a Laboratory Information System (LIS), via TCP/IP and the serial (RS-232) data port on the rear panel of the GEM.

WARNING: To add the requirements for the HL7 protocol we had to leave the layout of the previous version of the document unchanged because of hardcoded references (i.e. "See section 3.9.1").

The data transfer protocol specified in this document is implemented according to the following protocols:

- ASTM (American Society for Testing and Materials) E1394-91 and E1381-91 high and low level clinical data transfer protocols. The documentation for ASTM E1394-91 and E1381-91 should also serve as reference material.
- HL7 (Health Level Seven) v2.4.

High level protocol: Observation Reporting Interface. A high level messaging protocol of NCCLS POCT1-A standard for connection between a data manager and the host HIS/LIS/CIS system. ORI is based on HL7 v2.4.

Low level protocol: HL7 Hybrid Lower Layer Protoc

## 2. Document Control

### 2.1 Document History

The following table summarizes the revision history of this document:

<b>SW Version/ Doc Revision</b>	<b>Author</b>	<b>Date</b>	<b>Reason for Change</b>
V7.0/1.1	U. De Ros	4/30/08	Base line version based on GEM 3000 v5.6.1
V7.0/1.2	U. De Ros	5/1/08	CR #41: Added language codes for Portuguese, Danish, Finnish, Norwegian languages in section "Manufacturer Record". Replaced language list with reference to Volume 3. Done to match GEM 3000 v5.6.2
V7.0/1.3	U. De Ros	5/2/08	CR #43: Set instrument name to host to GEM 3500
V7.0/1.4	U. De Ros	5/7/08	CR # 48: Added HL7 Protocol section () Replaced "GEM 3000" with "GEM" whenever possible.
V7.0/1.5	U. De Ros	5/8/08	Added tables section for HL7
V7.0/1.6	U. De Ros	5/13/08	Removed test order management from HL7 section
V7.0/1.7	U. De Ros	9/10/08	Fixed language codes for Portuguese, Finnish, Danish, Norwegian
V7.0/1.8	A. Azer	9/12/08	<ul style="list-style-type: none"> <li>° Updated documents part numbers and corrected title.</li> <li>° Highlighted text pertinent to the GEM 3500 changes vs. the GEM 3000.</li> <li>° Changed GEM 3000 to GEM 3500 (Header Record (ASTM Level 0 Record), Comment Record, Application Data Message Examples, Request Information Record)</li> </ul>
V7.0/1.9	U. De Ros	9/23/08	Updated section 4 (HL7) before review
V7.0/1.10	U. De Ros	9/25/08	<ul style="list-style-type: none"> <li>· HL7: added truncation of patient name coming from host</li> <li>· HL7: Added proposal for QC result upload</li> </ul>
V7.0/1.11	U. De Ros	10/10/08	Renamed document to vol7-g35.doc
V7.0/1.3	U. De Ros	10/27/08	Updated sections related to the HL7 protocol after review.
V7.0/1.4	U. De Ros	10/27/08	<ul style="list-style-type: none"> <li>· Updated sections related to HL7 protocol:</li> <li>· Update calibration types table</li> <li>· Added references to the HL7 configuration screen in Volume 3</li> </ul>
V7.0/1.5	U. De Ros	10/27/08	<ul style="list-style-type: none"> <li>· Updated sections related to uploading of QC results with HL7 protocol:</li> <li>· Defined the sample role character (SAC segment, field 6)</li> <li>· Defined values for the Substance Identifier Segment</li> <li>· Updated the reporting of sample exceptions for patient samples, CVP and QC samples.</li> </ul>
V7.0/1.6	U. De Ros	11/21/08	<ul style="list-style-type: none"> <li>· Updated sections related to uploading of sample results with HL7 protocol:</li> <li>· Redefined the analyte names (replaced analyte names table with reference the section related to the ASTM result record)</li> </ul>
V7.0/1.7	U. De Ros	12/08/08	<ul style="list-style-type: none"> <li>· Updated HL7 section.</li> <li>· Fixed inconsistencies found by the SQA team;</li> <li>· Added support for Patient Accession Number (See CR#98)</li> <li>· Replaced old examples (from Gem4K) with new examples generated by a Gem3500 instrument.</li> </ul>

V7.0/1.8	U. De Ros	12/08/08	<p>Updated HL7 sections related to accession number and order number:</p> <ul style="list-style-type: none"> <li>· Section 4.5.1: Patient sample results are reported using ORU_R32 message if the Accession Number is defined and ORU_R31 otherwise</li> <li>· Section 4.5.1.1.4: Updated description of ORC segment when the Accession Number is available.</li> </ul>
V7.0/1.9	U. De Ros	12/15/08	<p>Updated HL7 sections related to accession number (See defect #8866):</p> <ul style="list-style-type: none"> <li>· Section 4.5.1: Patient sample results are reported using ORU_R32 message if the Accession Number is defined and ORU_R31 otherwise</li> <li>· Section 4.5.1.1.4: Updated description of ORC segment when the Accession Number is available.</li> </ul> <p>Removed redundant entries in the Calibration Record tables for HL7 protocol (Defect #8868)</p> <p>Updated HL7 sections related to the reporting of sample exceptions (See CR#99)</p>
V7.0/1.10	U. De Ros	12/22/08	Section 3.5.4: added missing language code for Chinese language

## 2.2 Cross References

This document is one of eight volumes that comprise the functional specification for the GEM 3500 software:

Specification Title	Part Number	Description
<i>Volume 1 – User Interface Standard</i>	24305651	Describes the generic features of the user interface not related to any one specific feature of the operating software, including features that enable operator interaction and report information back to the operator. Also includes a description of screen elements.
<i>Volume 2 – Cartridge Internal Operations</i>	24305652	Describes the internal operations of the instrument during warm-up, restart, and sample analysis.
<i>Volume 3 - Operational Characteristics</i>	24305653	Describes specific functionality and features of the software.
<i>Volume 4 - Algorithms and Parameters</i>	24305654	Describes the calculations made by the operating software and defines any constant values used in the calculations.
<i>Volume 5 - Errors and Alarms</i>	24305655	Describes alarm conditions and reported errors, possible causes, and remedies.
<i>Volume 6 - Files and File Formats</i>	24305656	Describes the files and file formats associated with the operating software.
<i>Volume 7 - Interface Protocols</i>	24305657	Describes protocols to interface to external LIS or DMS devices
<i>Volume 8 - Software Installation</i>	24305658	Describes the installation of the operating software.

## 3. GEM Data ASTM Transfer Protocol

### 3.1 Overview

This document specifies how data is transferred between a GEM and a receiving system, such as a Laboratory Information System (LIS), via an RS-232 serial connection or an Ethernet connection. The GEM 3500 data transfer protocol is implemented according to the ASTM (American Society for Testing and Materials) E1394-91 and E1381-91 high and low level clinical data transfer protocols. GEM 3500 instruments support also the HL7 protocol (v2.4). These protocols provide an established standard for transferring clinical data between an LIS system and a medical instrument.

While this volume is a complete specification of the GEM data transfer protocol, documentation for the ASTM protocol standards should also serve as reference material.

### 3.2 TCP/IP Implementation

The GEM will allow only one connection at a time for data transfer.

#### 3.2.1 ASTM over TCP/IP (GEM as Server)

The GEM shall be considered the server (master) and the receiving system shall be the client (slave). The GEM opens a port and listens for a connection request. Once the request has been accepted, the GEM shall be able to transmit the full ASTM1381 data reports to the receiving system. These data reports contain the sample in the ASTM1394 format. If the receiving system closes the connection, GEM will wait for another connection before attempting another transmission.

#### 3.2.2 HL7 over TCP/IP (GEM as Server)

The HL7 protocol shall be available on GEM 3500 instruments.

The GEM shall be considered the server (master) and the receiving system shall be the client (slave). The GEM opens a port and listens for a connection request. Once the request has been accepted, the GEM shall be able to transmit the full HL7 Hybrid Low Level data reports to the receiving system. These data reports contain the sample in the ORI (HL7 v2.4) format. If the receiving system closes the connection, GEM will wait for another connection before attempting another transmission.

### 3.3 [ASTM] Types of Data Reports Transmitted by GEM

Below is a list of the types of data reports the GEM transmits. For each report type, a list of the data items transmitted for that report type is included. See section [ASTM] Application Data Transfer Layer for a detailed description of the format of each type of report.

#### 3.3.1 Patient Sample Report

The following data is transmitted for a patient sample report:

- Instrument Model
- Operating Software Version
- Instrument Serial Number
- Instrument Name
- Cartridge Serial Number
- GEM Data Format Version
- Date/Time Report Queued for Transmission
- Patient ID, Name, Birth Date, and Sex.
- Accession Number
- Sample Number
- Sample Type
- Date/Time Sample Processed
- Sample draw date and time
- Operator ID
- Parameter Values (including Parameter Name and Result Status)
- Sample Comments

### **3.3.2 QC Sample Report**

The following data is transmitted for a QC sample report:

- Instrument Model
- Operating Software Version
- Instrument Serial Number
- Instrument Name
- Cartridge Serial Number
- GEM Data Format Version
- Date/Time Report Queued for Transmission
- Sample Number
- Sample Type
- QC Lot Number and Description
- Date/Time Sample Processed
- Operator ID
- Parameter Values (including Parameter Name, Result Status, and QC Min and Max Range Values)
- Sample Comments

### 3.3.3 Calibration Report

The following data is transmitted for a calibration report:

- Instrument Model
- Operating Software Version
- Instrument Serial Number
- Instrument Name
- Cartridge Serial Number
- GEM Data Format Version
- Date/Time Report Queued for Transmission
- Calibration Type (One, Two Point or Low Oxygen)
- Date/Time Calibration Processed
- Parameter Values (including Parameter Name and Result Status)
- 

### 3.3.4 iQM Report-Monthly Delta Chart

The following data is transmitted for an iQM Delta Chart report:

- Instrument Model
- Operating Software Version
- Instrument Serial Number
- Instrument Name
- GEM Data Format Version
- Date/Time iQM Report
- Month/Year of report
- The lot number of cartridges inserted during the month
- Cartridge insertion days during the month
- Parameter/Sensor
- Process Control Solution (A, B, or C)
- Nominal Target Value
- Delta Chart Data (as it appears in Delta Chart file produced by “Copy iQM Data”. See Volume 6).
- 
- Note that a given iQM delta chart report for a given month may get fairly large in size. This report is transmitted using a single ASTM 1394 message. It is recommended that the **receiving module allocates buffer space of 32K bytes** in order to be able to receive and process the entire message.

### 3.3.5 iQM Report-Corrective Action Report

The following data is transmitted for an iQM Corrective Action report:

- Instrument Model
- Operating Software Version
- Instrument Serial Number
- Instrument Name
- GEM Data Format Version
- Date/Time iQM Report
- Month/Year of report
- Corrective Action Report Data with embedded HTML tags in either English or the selected foreign language on GEM. See the section on Foreign Language Support.
- Note that iQM corrective action report for a given month may get fairly large in size. This report is transmitted using a single ASTM 1394 message. It is recommended that the **receiving module allocates buffer space of 32K bytes** in order to be able to receive and process the entire message.

### **3.4 [ASTM] Features Not Included in The Data Transfer Implementation**

An LIS system cannot query the GEM for sample data. The ASTM E1394-91 standard defines a request information record for the purpose of requesting data, such as sample results for a range of patient IDs. However, this feature is not presently implemented for the GEM.

#### **3.4.1 RS-232 Exceptions to the Standard**

The following features are not a part of the GEM RS-232 data transfer specification:

- The serial connection between the GEM and a receiving system must be set according to the specifications in Section Physical Transfer Layer. The ASTM E1381-91 standard allows for configurable baud rate, parity, data bits, and stop bits. However, these parameters are not currently configurable on the GEM.
- RTS/CTS or XON/XOFF flow control is not currently implemented.

#### **3.4.2 TCP/IP Exceptions**

The following features are not a part of the GEM TCP/IP data transfer specification:

- As of the writing of this document, the ASTM1381 over TCP/IP has not been released. It is assumed that the instrument will be ASTM1381 compliant until the standard is released and the software is reviewed.

### **3.5 [ASTM] Application Data Transfer Layer**

The *Application Data Transfer Layer* defines the structure and content of the *application data messages* exchanged between the GEM and a receiving system. The application data transfer layer is implemented according to the ASTM E1394-91 standard.

This section defines the structure of the application data message (Section Application Data Message Structure), provides general syntax for the message content (Section General Message Syntax), describes each of the records that comprise a message (Sections Header Record (ASTM

Level 0 Record) through Message Terminator Record), lists restricted ASCII characters (Section Restricted Characters), and shows examples of application data messages for a patient sample, a QC sample, a one point calibration, a two point calibration and a low oxygen calibration. (Section Application Data Message Examples).

### 3.5.1 Application Data Message Structure

An application data message contains the results of a patient sample, a QC sample, a one point calibration, or a two point calibration, including information that identifies the sample or calibration. The message consists of a set of records that are hierarchically organized as follows:

*HEADER RECORD.* Contains information that indicates the start of a message. See Section Header Record (ASTM Level 0 Record).

*PATIENT INFORMATION RECORD.* Contains patient identifying information for a patient sample. See Section Manufacturer Record (ASTM Level 1 Record).

*TEST ORDER RECORD.* Contains sample or calibration identifying information, such as sample or calibration type. See Section Test Order Record.

*COMMENT RECORD 1.* Contains a comment that is associated with the sample or calibration identified in the Test Order record that precedes the Comment record(s). See Section Comment Record.

*COMMENT RECORD 2.*

*COMMENT RECORD n.*

*RESULT RECORD 1.* Contains the numeric result for one parameter of the sample or calibration. See Section Result Record.

*RESULT RECORD 2.*

*RESULT RECORD n.*

*MESSAGE TERMINATOR RECORD.* Contains information that indicates the end of a message. See Section Message Terminator Record.

For an A-V pair patient sample, an application data message contains the results of both the arterial part of the sample and the venous part of the sample. The set of records that make up an A-V pair patient sample message are hierarchically organized as follows:

*HEADER RECORD.* Contains information that indicates the start of a message. See Section Header Record (ASTM Level 0 Record).

*PATIENT INFORMATION RECORD.* Contains patient identifying information for a patient sample. See Section Manufacturer Record (ASTM Level 1 Record).

*TEST ORDER RECORD 1.* Contains sample information, such as sample type A for Arterial sample. See Section Test Order Record.

*COMMENT RECORD 1.* Contains a comment that is associated with the sample identified in the Test Order record that precedes the Comment record(s). See Section Comment Record.

*COMMENT RECORD 2.*

.

.

.

*COMMENT RECORD n.*

*RESULT RECORD 1.* Contains the numeric result for one parameter of the sample. See Section Result Record.

*RESULT RECORD 2.*

.

.

.

*RESULT RECORD n.*

*TEST ORDER RECORD 2.* Contains sample information, such as sample type V for Venous sample. See Section Test Order Record.

*COMMENT RECORD 1.* Contains a comment that is associated with the sample identified in the Test Order record that precedes the Comment record(s). See Section Comment Record.

*COMMENT RECORD 2.*

.

.

.

*COMMENT RECORD n.*

*RESULT RECORD 1.* Contains the numeric result for one parameter of the sample. See Section Result Record.

*RESULT RECORD 2.*

*RESULT RECORD n.*

*MESSAGE TERMINATOR RECORD.* Contains information that indicates the end of a message. See Section Message Terminator Record.

*iQM Delta Chart and Corrective Action Data Report:*

*MANUFACTURER RECORD.* Contains information describing the iQM report type (Delta Chart or Corrective Action).

*COMMENT RECORD 1 thru n:* Contains data content of iQM files; once comment record per line in file.

*MESSAGE TERMINATOR RECORD.* Contains information that indicates the end of a message.

### 3.5.2 General Message Syntax

#### Allowable Characters

Data in an application data message must be represented by eight bit values. The following ASCII characters represented by decimal values as defined by the ANSI standard X3.4-1986 can be contained in an application data message:

7, 9, 11-13, 32-126

The ASTM E1394-91 standard also allows decimal values 128-254 to appear in an application data message. However, the GEM does not currently define any characters for decimal values 128-254. Therefore, the application data message cannot contain the decimal values 128-254.

## Message Delimiters

Each record in a message is terminated with the ASCII carriage return character <CR>, decimal value 13.

Fields within a record are separated by the ASCII vertical bar character “|”, decimal value 124. A field in a record contains a single item of information, such as the patient ID or a numeric test result, or may be null.

Repeat fields within a record are separated by the ASCII backslash character “\”, decimal value 92. A repeat field contains a single data element that expresses a duplication of the field definition it is repeating. Currently, the GEM does not use repeat fields. However, the ASTM E1394-91 standard requires that a repeat delimiter be defined for the header record.

Components within a field are separated by the ASCII caret character “^”, decimal value 94. Components break up information within a field; for example, the components of the specimen descriptor field for a QC sample include the QC sample type and the QC lot number.

The escape delimiter is the ASCII ampersand character “&”, decimal value 38. An escape delimiter is used to signal special characteristics of portions of a text field, such as embedded delimiters. The GEM inserts the escape delimiter character just before and after each field, repeat, component, or escape delimiter character found in any instrument name, patient ID, patient name, accession number, or operator ID it transmits.

## Unused Fields in a Record and Unused Components in a Field

The GEM does not use all fields defined by the ASTM E1394-91 standard for a record. Unused fields that occur before or between used fields are null. A <CR>, the record delimiter, immediately follows the last used field of a record.

Similarly, the GEM may not use all components in a field. Unused components that occur before or between used components are null. A vertical bar “|” (the field delimiter) immediately follows the last used component of a field.

### 3.5.3 Header Record (ASTM Level 0 Record)

The Header record contains information that indicates the start of a message.

#### Syntax

Record type ID|Delimiter definitions|||Instrument model^Operating software version^Instrument serial number^User-assigned instrument name^Cartridge serial number^GEM 3000 3500 data

format version|||||||Date and time message queued for transmission<CR>

## Field Descriptions

The GEM uses fields 1, 2, 5, and 14 in the Header record:

H1                   Header field 1 is the record type ID. Always the character H.

H2                   Header field 2 contains the delimiter definitions, in the following order:

- | field delimiter
- \ repeat delimiter
- ^ component delimiter
- & escape delimiter

All four delimiters must be included in this field, even if they are not used in the message.

H5                   Header field 5 contains six instrument identification components in the following order:

- C1 Instrument model, which is “GEM 3000 3500”
- C2 Operating software version. Set to the current GEM operating software version number.
- C3 Instrument serial number stored in the instrument’s non-volatile memory.
- C4 User-assigned instrument name. Set to null if the instrument name is not customized. Set to the instrument name, a maximum string of 13 characters, if the instrument name is customized (see *Volume 3 - Operational Characteristics*). The GEM inserts the escape delimiter character just before and after each field, repeat, component, or escape delimiter character found in any instrument name it transmits.
- C5 Cartridge serial number derived from the cartridge barcode. Six characters maximum.
- C6 GEM data format version. Set to the current GEM data format version number. The data format version number does not change every

time the operating software version number, contained in component C2, changes. (=2.3 for sw version 5.2)(=2.4 for sw version 5.4)

H14

Header field 14 contains the date and time at which the message was queued for transmission. Consists of 14 characters in the following format:

YYYYMMDDHHMMSS

where

YYYYMMDD is year, month, day

HHMMSS is hour, minute, second

## Examples

```
H|^\&|||GEM 3500^V4.0r2^8040^OR3^123456^1.00|||||||  
|19980922072320<CR>
```

H	Field 1: record type ID
\^&	Field 2: delimiter definitions
GEM 3500	Field 5, component 1: instrument model
V7.0	Field 5, component 2: operating software version
80140	Field 5, component 3: instrument serial number
OR3	Field 5, component 4: instrument name
123456	Field 5, component 5: cartridge serial number
1.00	Field 5, component 6: GEM data format version
19980922072320	Field 14: date and time message queued for transmission

### 3.5.4 Manufacturer Record (ASTM Level 1 Record)

The Manufacturer record contains GEM custom iQM report information. This record is sent as a level 1 ASTM record with iQM Delta Chart and iQM Corrective Action reports.

#### Syntax

iQM Delta Chart:

```
Record type ID|Record sequence number|iQM Report  
Descriptor|Year^Month|Sensor Name^Process Control Solution  
Name<CR>
```

iQM Corrective Action Report:

Record type ID|Record sequence number|iQM Corrective Action Report Descriptor|Year^Month<CR>

## Field Descriptions

The GEM uses fields 1, 2, 3, 4, and 5 in the Manufacturer Information record:

- M1                    Manufacturer Record field 1 is the record type ID. Always the character M.
- M2                    Manufacturer Record field 2 contains the record sequence number. This field always contains 1 because the GEM always transmits one iQM report in an ASTM message.
- M3                    Manufacturer Record field 3 contains a character string as the iQM report type/descriptor. Valid values for this component are “**iQM-MDC**”, or “**iQM-MCA**” for iQM Delta charts or iQM Corrective Action.
- M4                    Manufacturer Record field 4 is comprised of two components. The first component is a 4 digit string for the year of iQM report, and the second component is a 2 digit string (01 thru 12) for the month of iQM report.
- M5                    Manufacturer Record field 5 for iQM Delta Chart is comprised of two components. The first component contains a character string for the Sensor Name. The second component contains a single character for the Process Control Solution Name. The supported sensor names are pH, pCO<sub>2</sub>, pO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Glu, Lac, and Hct. NOTE that the pH sensor will NOT be reported as cH when one of cH units of measure is configured on GEM. The Process Control Solution ID component contains the name of PC solution ‘A’, ‘B’, or ‘C’. This field for iQM Corrective action report will contain a 2 to 3 character string for language code for the language in which the report is transmitted. The language code is based on standard defined in the [ISO 639.2](#) specification.

## Examples

### IQM Delta Chart:

M | 1 | iQM-MDC | 2003^01 | pH^A<CR>

M	Field 1: record type ID
1	Field 2: record sequence number
iQM-MDC	Field 3: iQM Delta Chart report descriptor
2003^01	Field 4: first component is year 2003, and second component is month 01 (for January)
pH^A	Field 5: first component is sensor name (pH), and second component is PC Solution ‘A’.

### IQM Corrective Action Report:

M | 1 | iQM-MCA | 2003^01 | en<CR>

M	Field 1: record type ID
1	Field 2: record sequence number
iQM-MCA	Field 3, iQM Corrective Action report descriptor
2003^01	Field 4: first component is year 2003, and second component is month 01 (for January)
en	Field 5: <a href="#">ISO 639.2</a> language code for the English language in which iQM report is transmitted.

It is recommended that the receiving module removes ASTM1394 from data stream, and save the rest of data as is in an appropriate HTML file for the year, month, and language. The file can then be viewed using a browser software product.

### ***IQM Corrective Action Reports – Foreign Language Support:***

- 
- In addition to the English language, the GEM software supports a set of foreign languages defined in Volume 3, section “Supported languages”. If the GEM instrument is configured in one of the supported foreign languages, those iQM events that have been logged since the foreign language selection was made will be transmitted in the selected foreign language. It is recommended that

the receiving module will provide flexibility for support of additional languages as more foreign languages may be supported in future GEM software releases. The GEM software uses the standard specified in [ISO 639.2](#) for language encoding. This standard defines 2 to 3 character strings for language codes. These codes for the supported languages in GEM software version V5.4 are:

- 
- “en” For English
- “fr” For French
- “de” For German (Allemand)
- “it” For Italian
- “es” For Spanish
- “sv” For Swedish
- “pl” For Polish
- “ja” For Japanese
- “pt” For Portuguese[CR #41]
- “da” For Danish [CR #41]
- “fi” For Finnish [CR #41]
- “no” For Norwegian[CR #41]
- “zh” For Chinese
- 
- 
- See [ISO 639.2](#) for a complete list of language codes.
- 
- Note that the HTML report will contain the character encoding in which the report text is transmitted and can be viewed from a browser software. This will enable proper display of report in the specified character encoding, if the Auto-Detect or Auto-Select character encoding feature is enabled in the browser software. Otherwise, the user must manually select the proper encoding from the browser's View menu. The supported character encodings in GEM software version V5.4 are:
- 
- ISO-8859-1 For Western European Languages
- ISO-8859-2 For Polish
- EUCJIS For Japanese
- 

### **3.5.5 Patient Information Record**

The Patient Information record contains patient identifying information for a patient sample. This record is sent as a level 1 ASTM record with patient sample, QC sample, and calibration reports.

## Syntax

Patient Sample:

Record type ID|Record sequence number||Patient ID||^Patient last name^Patient first name<CR>

QC Sample:

Record type ID|Record sequence number<CR>

One , Two Point or Low Oxygen Calibration:

Record type ID|Record sequence number<CR>

## Field Descriptions

The GEM uses fields 1, 2, 4, 6, 8 and 9 in the Patient Information record:

- |    |  |
|----|--|
| P1 | Patient Information field 1 is the record type ID.<br>Always the character P.  |
| P2 | Patient Information field 2 contains the record sequence number. This field always contains 1 because the GEM always transmits data for only one patient in a message.   |
| P4 | Patient Information field 4 contains the patient ID. Sixteen characters maximum. This field is only used for patient samples with an operator-entered patient ID (see <i>Volume 3 - Operational Characteristics</i> ). The GEM inserts the escape delimiter character just before and after each field, repeat, component, or escape delimiter character found in any patient ID it transmits. Patient Information field 4 is not used for messages containing QC sample or calibration data.  |
| P6 | Patient Information field 6 contains the patient's name. The GEM uses <del>the second and third components of this field, which are the last name and first name, respectively</del> the first, second, and third components of this field, which contain the last name, first name, and middle initial, respectively. All other components of this field are null. The patient's last and first name can be a maximum of 16 characters each, and the patient's middle initial is only 1 character long. The GEM inserts the escape delimiter character just before and after each field, repeat, component, or escape delimiter character |

found in any patient name it transmits. Patient Information field 6 is not used for messages containing QC sample or calibration data.

- P8                   Patient Information field 8 contains the patient's Birth Date, in the format YYYYMMDD. This field is not used for messages containing a QC sample or calibration data.
- P9                   Patient Information field 9 contains the patient's Sex. The contents of this field will be "M", "F", or "U". This field is not used for messages containing a QC sample or calibration data.

## Examples

### Patient Sample:

```
P | 1 || 1234567812345678 | |BLAKE^LINDSEY| |19610922 | F<CR>
```

P	Field 1: record type ID
1	Field 2: record sequence number
1234567812345678	Field 4: patient ID
BLAKE	Field 6, component 2: patient last name
LINDSEY	Field 6, component 3: patient first name
19610922	Field 8: patient Birth Date Sept 22, 1961
F	Field 9: patient Sex female

### QC Sample:

```
P | 1<CR>
```

P	Field 1: record type ID
1	Field 2: record sequence number

### One or Two Point Calibration:

```
P | 1<CR>
```

P	Field 1: record type ID
1	Field 2: record sequence number

### 3.5.6 Test Order Record

The Test Order record contains sample or calibration identifying information, such as sample or calibration type.

#### Syntax

Patient Sample:

Record type ID|Record sequence number|Accession  
number|Sample number|||||||Sample type and qualifiers<CR>

QC Sample:

Record type ID|Record sequence number||Sample  
number|||||||Sample type and qualifiers^QC lot number^QC lot  
description<CR>

One, Two Point or Low Oxygen Calibration:

Record type ID|Record sequence number|||||||Calibration  
type<CR>

#### Field Descriptions

The GEM uses fields 1, 2, 3, 4, 8 and 16 in the Test Order record:

- |    |   |
|----|---|
| O1 | Test Order field 1 is the record type ID. Always the character O.   |
| O2 | Test Order field 2 contains the record sequence number. For patient samples that are not A-V pair patient samples, QC samples, and calibrations, this field is always 1 because the GEM transmits data for only one sample or calibration in a message. For A-V pair patient samples, Test Order field 2 contains 1 when Test Order field 16 contains A for Arterial sample and contains 2 when Test Order field 16 contains V for Venous sample. |
| O3 | Test Order field 3 contains the accession number, also known as the specimen ID or test order number. Sixteen characters maximum. The GEM inserts the escape delimiter character just before and after each field, repeat, component, or escape delimiter character found in any accession number it transmits. Test Order field 3 is not used for messages containing QC sample or calibration data.   |
| O4 | Test Order field 4 contains the sample number for patient and QC samples. Ten numeric characters  |

maximum. This field is not used for messages containing calibration data.

O8            Test order field 8 contains the sample draw date and time, also known as specimen collection date and time, in the format YYYYMMDDHHMMSS. This field is not used for messages containing a QC sample or calibration data.

O16            Test Order field 16 is the specimen descriptor field.

### **Patient, QC , and CVP Samples**

Six basic sample types are indicated by the first character of this field:

- A Arterial sample
- V Venous sample
- C Capillary sample
- I QC sample
- Q Parallel QC sample
- O Other sample

ABArterial bypass sample

VBBVenous bypass sample

CBCCapillary bypass sample

OBOther bypass sample

### **PiQM Calibration Validation Protocol sample**

The following additional 4 types are reserved for future use:

A1 Arterial sample, first half of an A-V sample pair

VP Venous sample, second half of an A-V sample pair

V1 Venous sample, first half of an A-V sample pair

AP Arterial sample, second half of an A-V sample pair

For QC samples, Test Order field 16 contains up to four components to indicate the sample type. The first component is a character code, consisting of one or more characters as listed above. The second component is the QC lot number, a maximum of ten characters (see *Volume 4/GL - Algorithms and Parameters*). The third component is the QC lot description, a maximum of 20 characters. The fourth component is the QC level, a maximum of two characters.

Note to the GEM programmer: use the following lookup table to determine the lot level:

Lot Description	Lot Number(*)	Lot Level
GEMCritCheck, LOW	4xxx	1
GEMCritCheck, NOR-MAL	5xxx	2
ContrIL 7, LOW	L7xx	1
ContrIL 7, NORMAL	N7xx	2
ContrIL 7, HIGH	H7xx	3
ContrIL 9, LOW	L9xx	1
ContrIL 9, NORMAL	N9xx	2
ContrIL 9, HIGH	H9xx	3
IL Multi-4 Level 1	As given on package. No specific convention.	1
IL Multi-4 Level 2		2
IL Multi-4 Level 3		3
IL Multi-4 Level 4		4
GEM OPL Yellow		4
GEM OPL Orange		5
PCL TQC	As given on package. No specific convention.	1
PCL E-QC 1		1
PCL E-QC 2		2
PCL QC NORMAL		1
PCL QC ABNORMAL		2
PVP L1	01xx	1
PVP L2	02xx	2
PVP L3	03xx	3
PVP L4	04xx	4
PVP L5	05xx	5
CRITPVP L1	46xx	1
CRITPVP L2	47xx	2
CRITPVP L3	48xx	3
CRITPVP L4	49xx	4
None of the above		Level = first digit of lot number

(\*) Lot number given for information only. Not used for level determination.

For CVP samples, Test Order field 16 contains three components to describe the CVP sample completely. The first component is a character string “P” to identify sample as CVP sample. The second component is a character string containing the CVP lot number, a maximum of ten characters (see *Volume 4/GL - Algorithms and Parameters*). The third component is a character string containing the CVP lot description, a maximum of 20 characters. NOTE that the CVP lot level is not included in the report.

### **Calibrations**

Test Order field 16 contains one of the following character strings to indicate the calibration type:

- LOCalLow oxygen calibration
- 1PtCalOne point calibration
- 2PtCalTwo point calibration

### **Examples**

#### Patient Samples:

```
O|1|88888|123||||20020207080900|||||||A<CR>
```

```
O|1|99999|200|||||||||A1<CR>
```

O	Field 1: record type ID
1	Field 2: record sequence number
88888, 99999	Field 3: accession number
123, 200	Field 4: sample number
20020207080900	Field 8: sample draw date and time
A, A1	Field 16: specimen descriptor field (A = arterial sample; A1 = arterial sample, first half of A-V pair)

#### QC Sample:

O|1||4|||||||||I^N900^ContrIL 9, NORMAL^2<CR>

O	Field 1: record type ID
1	Field 2: record sequence number
null	Field 3: accession number
4	Field 4: sample number
I	Field 16, component 1: specimen descriptor (I = QC sample)
N900	Field 16, component 2: QC lot number
ContrIL 9, NORMAL	Field 16, component 3: QC lot description
2	Field 16, component 4: QC level

Calibration:

O|1|||||||||1PtCal<CR>

O	Field 1: record type ID
1	Field 2: record sequence number
null	Field 3: accession number
null	Field 4: sample number
1PtCal	Field 16: specimen descriptor (1PtCal = one point calibration)

### 3.5.7 Comment Record

The Comment record is used in two types of reports; sample reports and iQM reports. In sample reports the Comment record contains a comment that is associated with the sample identified in the Test Order record that precedes the Comment record. The comment text can be up to 48 characters long.

In iQM reports (Monthly Delta Chart and Monthly Corrective Action reports) the Comment record is used as a vehicle to transfer the data content of iQM files compiled for the respective reports. One Comment record is used per line of data in file. NOTE that the combination of Manufacturer record and Comment record is designed to enable receiver of iQM reports to reconstruct the data in the same way and format as it appears on GEM instrument. See Volume 6 for format of iQM files.

### Operational Discussion (iQM Data Reports)

The instrument software will automatically (if iQM Data Transfer is enabled on instrument) transmit the monthly iQM Delta Chart and iQM corrective action files/reports once per day. This usually occurs around 02:00 A.M. when the scheduled “C” calibration occurs, during which the

instrument will be unavailable for about 8 minutes for sample analysis. Additionally, the instrument will provide on-demand iQM Data transmit capability. During a given transmit session of iQM data up to 22 reports (21 delta chart report and one corrective action report) are transmitted. NOTE that these reports will not always be transmitted synchronously. Sample and calibration reports, and patient verification requests will preempt transmission of iQM reports. However, once the transmission of an iQM report is started it will not get preempted for any other types of reports. Additionally, the following rules shall be followed by instrument software when transmitting iQM data.

- Every iQM report will contain the data for the entire month. Under this approach the majority of data in each report is redundant data that has most likely been transmitted already. To filter out transmission of redundant data will require a fairly significant amount of additional software intelligence from the instrument side as well as the receiving side, which makes the feature a lot more complex than desired. This is the easiest and simplest approach to implement. The time delay caused by transmission of redundant data is fairly small (around two minutes) and it does not hinder instrument in its normal operation.
- Automatic transmit of iQM data (around 02:00 A.M.) will transfer the iQM report up to and including the time of transmit if it is within same month. If the transmit time falls in a new month, only the data for the previous month is transmitted. The data for the new month is usually transmitted on the second day of month.
- The automatic full transmission of iQM data (22 files/reports) will continue even if user switches from iQM full-menu cartridge to iQM BG/HCT cartridge or even non-iQM cartridge. This is the only way to ensure that the full iQM data for the month is transmitted.
- When instrument is configured for one of the supported foreign languages the English and the foreign language copies of corrective action reports will be transmitted. Note that the foreign language copy of report will contain those reports that have been logged since the foreign language selection was made.

#### Syntax:

Sample, iQM Delta Chart, iQM Corrective Action:

Record type ID|Record sequence number|Comment source|Comment text|Comment type<CR>

### **Field Descriptions:**

The GEM uses fields 1, 2, 3, 4, and 5 in the Comment record:

- C1                      Comment field 1 is the record type ID. Always the character C.
- C2                      Comment field 2 contains the record sequence number. This field contains 1 for the first Comment record that follows the Test Order record, 2 for the second, and so on.
- C3                      Comment field 3 contains a character code that indicates the source of the comment. This field always contains the character I, which indicates that the comment originates from a clinical instrument system.
- C4                      For sample report the Comment field 4 contains the text of the comment; 0 – 48 characters. The GEM inserts the escape delimiter character just before and after each field, repeat, component, or escape delimiter character found in any comment text it transmits.  
  
For iQM reports (Delta Chart and Corrective Action) the Comment field 4 contains the ASCII data contained in a single line from the respective iQM file. This field may contain data up to 128 characters in length. Special ASTM characters contained in data will be escaped in the report by GEM software.
- C5                      Comment field 5 contains a character code that indicates the comment type. This field always contains the character G, which indicates that this is a generic/free text comment.

### **Examples**

Sample:

C | 1 | I | CORRECTIVE ACTION | G<CR>

C                   Field 1: record type ID  
1                   Field 2: record sequence number  
I                   Field 3: comment source

**CORRECTIVE ACTION**

Field 4: comment text  
G                   Field 5: comment type

IQM Delta Chart:

C|1|I|Header:|G<CR>  
 Or  
 C|1|I|Device, GEM 3500, 12345,|G<CR>  
 Or  
 C|1|I|Month, Mar, 2003|G<CR>  
 Or  
 C|1|I|Cartridge insertion days, 11, 19, 27|G<CR>  
 Or  
 C|1|I|Cartridge lot, 301176, 301976, 302776|G<CR>  
 Or  
 C|1|I|Parameter, pH,|G<CR>  
 Or  
 C|1|I|Nominal target value, 6.9|G<CR>  
 Or  
 C|1|I|Material, A|G<CR>  
 Or  
 C|1|I|Mean, 0|G<CR>  
 Or  
 C|1|I|Low, -0.020000|G<CR>  
 Or  
 C|1|I|High, 0.020000|G<CR>  
 Or  
 C|1|I|Precision, 2|G<CR>  
 Or  
 C|1|I|Interval, 1, 31|G<CR>  
 Or  
 C|1|I|Data:|G<CR>  
 Or  
 C|1|I|01/01/2003, 6, 0.000000, 0.000000, 0.000000,  
 0.000000|G<CR>

C	Field 1: record type ID
1	Field 2: record sequence number
I	Field 3: comment source
Generic iQM data	Field 4:ASCII data as appears in iQM Delta

Chart Report file. Different examples show a variety of data recorded for a given sensor (pH) in PC solution type A. Included is the comment record, which shows the tabulated data points for 01/01/2003. The receiver of report shall extract data contained in this field and store it in the same order as it appears in report (when multiple comment records appear in report) in local database/file.

G

Field 5: comment type

IQM Corrective Action:

C|1|I|&lt;html&gt; &lt;head&gt;|G&lt;CR&gt;

Or

C|1|I|<meta HTTP-EQUIV="content-type" CONTENT="text/html;  
charset=ISO-8859-1">|G<CR>

Or

C|1|I|&lt;/head&gt; &lt;body&gt; &lt;br&gt;|G&lt;CR&gt;

Or

C|1|I|2003/03/20 13:54:28 Cartridge Lot No.:  
301976<br>|G<CR>

Or

C|1|I|Cartridge Removed. <br>Samples Remaining = 594.<br>No.  
of Solution B Adjustments = 0<br><pre> </pre>|G<CR>

Or

C|1|I|&lt;/body&gt; &lt;/html&gt;|G&lt;CR&gt;

C

Field 1: record type ID

1

Field 2: record sequence number

I

Field 3: comment source

Generic IQM data

Field 4: ASCII data embedded in HTML  
 directives as appears in the IQM Corrective Action Report file. The receiver of report shall extract data contained in this field and store it in the same order

as it appears in report (when multiple comment records appear in report) in local database/file.

G

Field 5: comment type

### 3.5.8 Result Record

Each Result record contains the numeric result for one reported parameter of the sample or calibration. Each application data message will therefore contain a total number of Result records equal to the number of reported parameters for the particular sample or calibration.

#### Syntax

##### Patient Sample:

First Result Record:

Record type ID|Record sequence number|^Parameter name|Parameter value|Parameter units|Patient low and high ranges|Abnormal result flag||||Operator ID||Date and time results were processed|Instrument identification<CR>

Second and Subsequent Result Records:

Record type ID|Record sequence number|^Parameter name|Parameter value|Parameter units|Patient low and high ranges|Abnormal result flag|||||Instrument identification<CR>

##### QC Sample:

First Result Record:

Record type ID|Record sequence number|^Parameter name|Parameter value|Parameter units|QC low and high ranges|Abnormal result flag||||Operator ID||Date and time results were processed<CR>

Second and Subsequent Result Records:

Record type ID|Record sequence number|^Parameter name|Parameter value|Parameter units|QC low and high ranges|Abnormal result flag<CR>

##### Calibration:

First Result Record:

Record type ID|Record sequence number|^Parameter name|Parameter value|Parameter units||Abnormal result flag||||Operator ID||Date and time results were processed<CR>

### Second and Subsequent Result Records:

Record type ID|Record sequence number|^|^Parameter name|Parameter value|Parameter units||Abnormal result flag<CR>

### Discussion

For a patient sample, a Result record is transmitted for a parameter if the parameter is part of the test panel selected for the sample. If the parameter is not part of the test panel that was selected for the sample, no Result record will be transmitted for that parameter.

For a QC sample, a Result record is transmitted for a parameter if the parameter is defined in the QC material lot data selected for the sample. If the parameter is not defined in the QC material lot data that was selected for the sample, no Result record will be transmitted for that parameter.

Note that the ASTM E1394-91 standard does not specify that Result records be transmitted in a particular order.

The following is a list of parameters that may appear in Result records for a patient or QC sample:

pH	pH value at 37.0 degrees C (98.6 degrees F).
cH	cH value at 37.0 degrees C (98.6 degrees F).
pCO2	pCO2 value at 37.0 degrees C (98.6 degrees F).
pO2	pO2 value at 37.0 degrees C (98.6 degrees F).
Temp	Temperature value entered for temperature correction.
pH(T)	Temperature corrected pH value.
cH(T)	Temperature corrected cH value.
pCO2(T)	Temperature corrected pCO2 value.
pO2(T)	Temperature corrected pO2 value.
Na+	Na+ value at 37.0 degrees C (98.6 degrees F).
K+	K+ value at 37.0 degrees C (98.6 degrees F).
Ca++	Ca++ value at 37.0 degrees C (98.6 degrees F).
Hct	Hematocrit value.
Ca++(7.4)	Ca++ value corrected to pH=7.4.
HCO3-	Derived value of normal HCO3.
HCO3std	Derived value of standard HCO3.

TCO2	Derived value of total CO2.
BEecf	Derived value of invivo BE.
BE(B)	Derived value of invitro BE.
SO2c	Derived O2 saturation value.
THbc	Derived total hemoglobin value.
%FiO2	Percent inspired oxygen.
Glu	Glucose value.
Lac	Lactate value.
THb	Actual total hemoglobin value.
SO2	Actual O2 saturated value.
O2Hb	Oxyhemoglobin value.
COHb	Carboxyhemoglobin value.
MetHb	Methemoglobin value.
HHb	Deoxyhemoglobin value.
APTT-P	Activated partial thromboplastin time.
PT-P	Prothrombin time.
PT INR	Patient to Normal PT ratio
ACT	Activated clotting time.
ACT-LR	Activated clotting time - low range.
O2ct	Calculated Oxygen Content
O2cap	Calculated Oxygen Capacity
A-aDO2	Alveolar-arterial oxygen gradient
pAO2	Alveolar oxygen partial pressure
paO2/pAO2	Arterial-Alveolar oxygen ratio
RI	Respiratory Index
CaO2	Arterial oxygen content
CvO2	Venous oxygen content
CcO2	End pulmonary capillary oxygen content
a-vDO2	Arterial-mixed venous oxygen gradient
Qsp/Qt	Physiological shunt

Qsp/Qt(est)	Estimated Shunt
P50	Partial pressure of O <sub>2</sub> in a hemoglobin solution having an oxygen saturation of 50%
FetHb	Fetal hemoglobin percent
O <sub>2</sub>	L/min Oxygen for vent settings
VT	Tidal Volume (vent setting)
Mode	Mode (vent setting)
Mech Rate	Mechanical Rate (vent setting)
Spon Rate	Spontaneous Rate (vent setting)
Peak Press	Peak Pressure (vent setting)
Itime(sec)	Inspiratory time in seconds (vent setting)
Itime(%)	Inspiratory time in percent (vent setting)
MAP	Mean Airway Pressure (vent setting)
PEEP	Positive End Expiratory Pressure (vent setting)
CPAP	Continuous Positive Airway Pressure (vent setting)
BIPAP(I)	Bi-level Positive Airway Pressure (Inspiratory) (vent setting)
BIPAP(E)	Bi-level Positive Airway Pressure (Expiratory) (vent setting)

The following is a list of parameters that may appear in Result records for a calibration:

pHSlope	pH slope value for a two point calibration.
pCO2Slope	pCO <sub>2</sub> slope value for a two point calibration.
pO2Slope	pO <sub>2</sub> slope value for a two point calibration.
Na <sup>+</sup> Slope	Na <sup>+</sup> slope value for a two point calibration.
K <sup>+</sup> Slope	K <sup>+</sup> slope value for a two point calibration.
Ca <sup>++</sup> Slope	Ca <sup>++</sup> slope value for a two point calibration.
GluSlope	Glu slope value for a two point calibration.
LacSlope	Lac slope value for a two point calibration.
HctSlope	Hematocrit slope value for a two point calibration.

pHDriftA	pH drift value for solution A for a two point calibration.
pCO2DriftA	pCO2 drift value for solution A for a two point calibration.
pO2DriftA	pO2 drift value for solution A for a two point calibration.
Na+DriftA	Na <sup>+</sup> drift value for solution A for a two point calibration.
K+DriftA	K <sup>+</sup> drift value for solution A for a two point calibration.
Ca++DriftA	Ca <sup>++</sup> drift value for solution A for a two point calibration.
GluDriftA	Glu drift value for solution A for a two point calibration.
LacDriftA	Lac drift value for solution A for a two point calibration.
HctDriftA	Hct drift value for solution A for a two point calibration.
pHMeasuredA	Measured pH value for solution A for a two point calibration.
pCO2MeasuredA	Measured pCO2 value for solution A for a two point calibration.
pO2MeasuredA	Measured pO2 value for solution A for a two point calibration.
Na+MeasuredA	Measured Na <sup>+</sup> value for solution A for a two point calibration.
K+MeasuredA	Measured K <sup>+</sup> value for solution A for a two point calibration.
Ca++MeasuredA	Measured Ca <sup>++</sup> value for solution A for a two point calibration.
GluMeasuredA	Measured Glu value for solution A for a two point calibration.
LacMeasuredA	Measured Lac value for solution A for a two point calibration.
HctMeasuredA	Measured Hct value for solution A for a two point calibration.

pHDriftB	pH drift value for solution B for a one or two point calibration.
pCO2DriftB	pCO2 drift value for solution B for a one or two point calibration.
pO2DriftB	pO2 drift value for solution B for a one or two point calibration.
Na+DriftB	Na <sup>+</sup> drift value for solution B for a one or two point calibration.
K+DriftB	K <sup>+</sup> drift value for solution B for a one or two point calibration.
Ca++DriftB	Ca <sup>++</sup> drift value for solution B for a one or two point calibration.
GluDriftB	Glu drift value for solution B for a one or two point calibration.
LacDriftB	Lac drift value for solution B for a one or two point calibration.
HctDriftB	Hematocrit drift value for solution B for a one or two point calibration.
pHMeasuredB	Measured pH value for solution B for a one or two point calibration.
pCO2MeasuredB	Measured pCO2 value for solution B for a one or two point calibration.
pO2MeasuredB	Measured pO2 value for solution B for a one or two point calibration.
Na+MeasuredB	Measured Na <sup>+</sup> value for solution B for a one or two point calibration.
K+MeasuredB	Measured K <sup>+</sup> value for solution B for a one or two point calibration.
Ca++MeasuredB	Measured Ca <sup>++</sup> value for solution B for a one or two point calibration.
GluMeasuredB	Measured Glu value for solution B for a one or two point calibration.
LacMeasuredB	Measured Lac value for solution B for a one or two point calibration.
HctMeasuredB	Measured hematocrit value for solution B for a one or two point calibration.

pHDriftC	pH drift value for solution C during low oxygen calibration.
pHMeasuredC	Measured pH value for solution C during low oxygen calibration.
pCO2DriftC	pCO <sub>2</sub> drift value for solution C during low oxygen calibration.
pCO2MeasuredC	Measured pCO <sub>2</sub> value for solution C during low oxygen calibration.
pO2DriftC	pO <sub>2</sub> drift value for solution C during low oxygen calibration.
pO2MeasuredC	Measured pO <sub>2</sub> value for solution C during low oxygen calibration.

## Field Descriptions

The GEM uses fields 1, 2, 3, 4, 5, 6, 7, 11, 13, and 14 in the Result record:

R1              Result field 1 is the record type ID. Always the character R.

R2              Result field 2 contains the record sequence number. Contains 1 for the Result record for the first parameter, 2 for the second, and so on through the total number of parameters reported for the sample or calibration identified in the Test Order record.

R3              Result field 3 is the universal test ID field. The ASTM E1394-91 standard requires that this field consist of four components. Presently, the GEM uses only the fourth component; thus the first three component entries are null.

For a patient or QC sample, the fourth component contains one of the parameter names listed above under “Discussion”.

For a one point, two point or low oxygen calibration, the fourth component contains one of the following parameter names:

pHSlope  
pCO<sub>2</sub>Slope  
pO<sub>2</sub>Slope  
Na<sup>+</sup>Slope

K+Slope  
Ca++Slope  
GluSlope  
LacSlope  
HctSlope  
pHDriftA  
pHMeasuredA  
pCO2DriftA pCO2MeasuredA  
pO2DriftA  
pO2MeasuredA  
Na+DriftA  
Na+MeasuredA  
K+DriftA  
K+MeasuredA  
Ca++DriftA Ca++MeasuredA  
GluDriftA  
GlumeasuredA  
LacDriftA  
LacmeasuredA  
HctDriftA  
HctmeasuredA  
pHDriftB  
pHMeasuredB  
pCO2DriftB pCO2MeasuredB  
pO2DriftB  
pO2MeasuredB  
Na+DriftB  
Na+MeasuredB  
K+DriftB  
K+MeasuredB  
Ca++DriftB  
Ca++MeasuredB  
GluDriftB  
GluMeasuredB

LacDriftB  
 LacMeasuredB  
 HctDriftB  
 HctMeasuredB  
 pHDriftC  
 pHMeasuredC  
 pCO2DriftC pCO2MeasuredC  
 pO2DriftC  
 pO2MeasuredC

R4

Result field 4 is the analyte value field in ASCII text.

### Patient and QC Samples

Result field 4 will be null for a measured or derived parameter if the abnormal flag (see R7) indicates that the parameter could not be reported.

For measured or derived parameters, result field 4 will contain the parameter maximum reportable range value if the parameter value is greater than its upper reportable range limit (R7 = “H >”), or the parameter minimum range value if the parameter value is less than its lower reportable range limit (R7 = “L <”).

Result field 4 will be null for an external device analyte if the value is not received from the external device.

Result field 4 will be null for a user enterable analyte if the value was not entered by the operator.

### Calibrations

Result field 4 will be null for a calibration parameter if the value of that parameter is incalculable.

R5

Result field 5 contains the units, in ASCII text, that the parameter's value in Result field 4 is being reported in.

R6

Result field 6 contains the low and high range for an analyte. The low range value in ASCII text

appears first in the field, followed by a blank, followed by the high range value in ASCII text.

For QC samples, the range is the QC lot range.

For patient samples, the range is the reference range if the abnormal flag is set to N, or the critical limits if the flag is set to P. Otherwise the range is null. If the user defines only one range value (Low or High), then only that value is transmitted. In such case, the position of the blank separator determines if the transmitted value is the low or the high value.

This field will be null for calibrations.

R7

Result field 7 contains the abnormal result flag. If the parameter's value results in an error, this field contains a character indicating the type of error. If the parameter's value does not indicate an error, this field will be null.

### Patient and QC Samples

Valid character codes are, in order of precedence:

- S Slope failure
- D Drift failure
- C Incalculable
- B (Patient only) Uncorrected QC failure and QC blankout was On (to hide result) when the sample was processed.
- H >Upper reportable range limit exceeded
- L <Lower reportable range limit exceeded
- F Uncorrected QC failure for a patient sample (result tagged); or QC failure for a QC sample
- I (Patient only) Interference detected while sampling.
- T (Patient only) Blood clot detected while sampling.
- M (Patient only) measurement error due to reference electrode shift.

- P (Patient only) Result is outside panic range (critical limits).
- N (Patient only) Result is outside patient normal (reference) range.
- X CO-Ox Exception
- A (Patient only) Measured/Calculated reported result is above linearity range. This flag is used only if pCO<sub>2</sub> Trending Mode is enabled on GEM instrument.

### **Calibrations**

Result field 7 will contain the following character code if a calibration parameter's value results in an error:

- F Calibration failure

R11

Result field 11 contains the operator ID if Result field 2 contains 1; otherwise, Result field 11 is null. The operator ID is 16 characters maximum. The GEM inserts the escape delimiter character just before and after each field, repeat, component, or escape delimiter character found in any operator ID it transmits. For patient or QC samples, Result field 11 is only used when an operator ID has been entered for the sample (see *Volume III - Operational Characteristics*). If an operator ID has not been entered, the field is null. Result field 11 is not used for messages containing calibration data.

R13

Result field 13 contains the date and time the sample or calibration results were processed if Result field 2 contains 1; otherwise, Result field 13 is null. The date and time the results were processed consists of 14 characters in the following format:

YYYYMMDDHHMMSS

where

YYYYMMDD is year, month, day

HHMMSS is hour, minute, second

R14

Result field 14 contains an alphanumeric string of characters that identify the instrument from which

the parameter's value was obtained if the parameter's value comes from an external device attached to the GEM. The GEM inserts the escape delimiter character just before and after each field, repeat, component, or escape delimiter character found in any instrument identification string it transmits. Possible contents:

§“IL682 dd”, where dd is the 2-char ID of the attached IL682 instrument.

§“GEM OPL sssss”, where sssss is the 5-char serial number of the attached GEM OPL instrument.

§“GEM PCL ssssss”, where ssssss is the 6-char serial number of the attached GEM PCL instrument.

## Examples

### Patient Sample:

```
R|1|^^^pH|7.22||||||1234567890||19980922142357<CR>
```

```
R|2|^^^Hct|65|%||><CR>
```

```
R|3|^^^ACT-LR|175|seconds|||||||GEM PCL 000086<CR>
```

```
.
```

```
.
```

```
.
```

R	Field 1: record type ID
1, 2, 3	Field 2: record sequence number
pH, Hct, ACT-LR	Field 3, component 4: universal test ID (3 null components, parameter name)
7.22, 65, 175	Field 4: data or measurement value
null, %, seconds	Field 5: units
null,>, null	Field 7: abnormal result flag
1234567890, null, null	Field 11: operator ID
19980922142357,	
null, null	Field 13: date and time results were processed
null, null, GEM PCL	Field 14: external instrument identification

## QC Sample:

R|1|^\_\_pH|7.00||6.8 7.8|||||19980922072319&lt;CR&gt;

R|2|^\_\_pCO2|83|mmHg|5.0 200.0&lt;CR&gt;

.

.

.

R	Field 1: record type ID
1, 2	Field 2: record sequence number
pH, pCO2	Field 3, component 4: universal test ID (3 null components, parameter name)
7.00, 83	Field 4: data or measurement value
null, mmHg	Field 5: units
6.8 7.8,5.0 200.0	Field 6: QC low and high ranges
null, null	Field 7: abnormal result flag
null, null	Field 11: operator ID
19980922072319, null	Field 13: date and time results were processed

## One Point Calibration:

R|1|^\_\_pHdriftB|0.00|||||19980825140636&lt;CR&gt;

R|2|^\_\_Ca++driftB|0.25|mmol/L||F&lt;CR&gt;

.

.

.

R	Field 1: record type ID
1, 2	Field 2: record sequence number
pHdriftB, Ca++driftB	Field 3, component 4: universal test ID (3 null components, parameter name)
0.00, 0.25	Field 4: data or measurement value
null, mmol/L	Field 5: units
null, F	Field 7: abnormal result flag
null	Field 11: operator ID
19980825140636, null	Field 13: date and time results were processed

### Two Point Calibration:

```
R|1|^^^pHslope|    62|mV/dec|||||||19980825133636<CR>
R|2|^^^pCO2slope|   54|mV/dec<CR>
.
.
.
R           Field 1: record type ID
1, 2        Field 2: record sequence number
pHslope, pCO2slope Field 3, component 4: universal test ID
                      (3 null components, parameter name)
62, 54       Field 4: data or measurement value
mV/dec, mV/dec Field 5: units
null          Field 7: abnormal result flag
null          Field 11: operator ID
19980825133636, null Field 13: date and time results were processed
```

### 3.5.9 Message Terminator Record

The Message Terminator record contains information that indicates the end of a message.

#### Syntax

Record type ID|Record sequence number<CR>

#### Field Descriptions

The GEM uses fields 1 and 2 in the Message Terminator record:

L1	Message Terminator field 1 is the record type ID. Always the character L.
L2	Message Terminator field 2 contains the record sequence number. Always contains 1.

#### Example

L 1<CR>	
L	Field 1: record type ID
1	Field 2: record sequence number

### 3.5.10 Restricted Characters

The ASCII characters listed below with their respective decimal values cannot appear in the text of a message:

ASCII Character	Decimal Value
<SOH>	1
<STX>	2
<ETX>	3
<EOT>	4
<ENQ>	5
<ACK>	6
<LF>	10
<DLE>	16
<DC1>	17
<DC2>	18
<DC3>	19
<DC4>	20
<NAK>	21
<SYN>	22
<ETB>	23

### 3.5.11 Application Data Message Examples

This section contains examples of a patient sample data message, a QC sample data message, a one point calibration data message, and a two point calibration data message. In these examples, the different types of records have been labeled.

Refer to Section Application Data Message Structure for message structure and Section General Message Syntax for message syntax, including allowable characters, delimiters, and unused fields and components.

#### *Example of a Patient Sample Data Message*

Record	Patient Sample Data Message
Header Record:	H   \^&      GEM 3500^V4.0r2^7040^999^123456^1.00

```

|||||19980922142358<CR>
Patient Information Record: P|1|||1234567812345678||^BLAKE^LINDSEY<CR>
Test Order Record: O|1|99999|123|||||||||A<CR>
Parameter 1 Result Record: R|1|^^^pH|7.22|||||123456789||19980922142357<CR>
Parameter 2 Result Record: R|2|^^^pCO2|62|mmHg<CR>
Parameter 3 Result Record: R|3|^^^pO2| 81|mmHg<CR>
Parameter 4 Result Record: R|4|^^^Na+|131.1|mmol/L<CR>
Parameter 5 Result Record: R|5|^^^K+|5.14|mmol/L<CR>
Parameter 6 Result Record: R|6|^^^Ca++|1.14|mmol/L<CR>
Parameter 7 Result Record: R|7|^^^Hct|65|%|><CR>
Parameter 8 Result Record: R|8|^^^Ca++ (7.4)|1.14|mmol/L<CR>
Parameter 9 Result Record: R|9|^^^HCO3-|25.3|mmol/L<CR>
Parameter 10 Result Record: R|10|^^^HCO3std|25.3|mmol/L<CR>
Parameter 11 Result Record: R|11|^^^TCO2|27.2|mmol/L<CR>
Parameter 12 Result Record: R|12|^^^BEecf||||C<CR>
Parameter 13 Result Record: R|13|^^^BE (B)|||C<CR>
Parameter 14 Result Record: R|14|^^^SO2c|||C<CR>
Parameter 15 Result Record: R|15|^^^%FiO2|100|%<CR>
Message Terminator Record: L|1<CR>

```

### ***Example of a QC Sample Data Message***

#### **Record**

Header Record:

#### **QC Sample Data Message**

H|\^&|||GEM 3500^V4.0r2^7040^1234567812345678^123

456^1.00|||||||19980922072320<CR>

Patient Information Record: P|1<CR>

Test Order Record: O|1||123|||||||I^N030^NORMAL QC LEVEL<CR>

Comment Record: C|1|I|CORRECTIVE ACTION QC|G<CR>

Parameter 1 Result Record: R|1|^pH|7.00||6.8 7.8||||123456789||19980922072319<CR>

Parameter 2 Result Record: R|2|^pCO2|83|mmHg|5.0 200.0<CR>

Parameter 3 Result Record: R|3|^pO2| 62|mmHg|0.0 760.0<CR>

Parameter 4 Result Record: R|4|^Na+|124.4|mmol/L|100.0 200.0<CR>

Parameter 5 Result Record: R|5|^K+|2.52|mmol/L|0.1 20.0<CR>

Parameter 6 Result Record: R|6|^Ca++|0.76|mmol/L|0.1 5.0<CR>

Message Terminator Record: I|1<CR>

### ***Example of a One Point Calibration Data Message***

<b>Record</b>	<b>One Point Calibration Data Message</b>
Header Record:	H ^&   GEM 3500^V4.0r2^7040^ICU #1^123456^1.00          19980825144500<CR>
Patient Information Record:	P 1<CR>
Test Order Record:	O 1       1PtCal<CR>
Parameter 1 Result Record:	R 1 ^pHdriftB 0.00     19980825140636<CR>
Parameter 2 Result Record:	R 2 ^pCO2driftB  0 mmHg<CR>
Parameter 3 Result Record:	R 3 ^pO2driftB  0 mmHg<CR>
Parameter 4 Result Record:	R 4 ^Na+driftB  0.0 mmol/L<CR>
Parameter 5 Result Record:	R 5 ^K+driftB 0.00 mmol/L<CR>
Parameter 6 Result Record:	R 6 ^Ca++driftB 0.25 mmol/L  F<CR>
Parameter 7 Result Record:	R 7 ^HctdriftB  0 %<CR>
Parameter 8 Result Record:	R 8 ^pHmeasuredB 7.41<CR>
Parameter 9 Result Record:	R 9 ^pCO2measuredB 35 mmHg<CR>
Parameter 10 Result Record:	R 10 ^pO2measuredB 199 mmHg<CR>
Parameter 11 Result Record:	R 11 ^Na+measuredB 136.0 mmol/L<CR>
Parameter 12 Result Record:	R 12 ^K+measuredB 6.00 mmol/L<CR>
Parameter 13 Result Record:	R 13 ^Ca++measuredB 2.07 mmol/L<CR>

Parameter 14 Result Record: R|14|^^^HctmeasuredB|11|%<CR>

Message Terminator Record: L|1<CR>

### ***Example of a Two Point Calibration Data Message***

<b>Record</b>	<b>Two Point Calibration Data Message</b>	
Header Record:	H \^&   GEM 3500^V4.0r2^7040^ICU #1^123456^1.00	19980825144500<CR>
Patient Information Record:	P 1<CR>	
Test Order Record:	O 1         2PtCal<CR>	
Parameter 1 Result Record:	R 1 ^^^pHslope	62 mV/dec     19980825133636<CR>
Parameter 2 Result Record:	R 2 ^^^pCO2slope	54 mV/dec<CR>
Parameter 3 Result Record:	R 3 ^^^pO2slope	8 mV/dec<CR>
Parameter 4 Result Record:	R 4 ^^^Na+slope	64 mV/dec<CR>
Parameter 5 Result Record:	R 5 ^^^K+slope	58 mV/dec<CR>
Parameter 6 Result Record:	R 6 ^^^Ca++slope	24 mV/dec<CR>
Parameter 7 Result Record:	R 7 ^^^Hctslope	38 mV/mho<CR>
Parameter 8 Result Record:	R 8 ^^^pHdriftA 0.01<CR>	
Parameter 9 Result Record:	R 9 ^^^pCO2driftA	0 mmHg<CR>
Parameter 10 Result Record:	R 10 ^^^pO2driftA	0 mmHg<CR>
Parameter 11 Result Record:	R 11 ^^^Na+driftA	0.01 mmol/L<CR>
Parameter 12 Result Record:	R 12 ^^^K+driftA	-0.01 mmol/L<CR>
Parameter 13 Result Record:	R 13 ^^^Ca++driftA 0.25   F	mmol/L<CR>
Parameter 14 Result Record:	R 14 ^^^pHmeasuredA	6.93<CR>
Parameter 15 Result Record:	R 15 ^^^pCO2measuredA	63 mmHg<CR>
Parameter 16 Result Record:	R 16 ^^^pO2measuredA	0 mmHg<CR>
Parameter 17 Result Record:	R 17 ^^^Na+measuredA	154.0 mmol/L<CR>
Parameter 18 Result Record:	R 18 ^^^K+measuredA	1.89 mmol/L<CR>
Parameter 19 Result Record:	R 19 ^^^Ca++measuredA	0.19 mmol/L<CR>
Parameter 20 Result Record:	R 20 ^^^pHdriftB 0.00<CR>	
Parameter 21 Result Record:	R 21 ^^^pCO2driftB	0 mmHg<CR>
Parameter 22 Result Record:	R 22 ^^^pO2driftB	0 mmHg<CR>

Parameter 23 Result Record: R|23|^\_\_Na+driftB| 0.0|mmol/L<CR>

Parameter 24 Result Record: R|24|^\_\_K+driftB|0.00|mmol/L<CR>

Parameter 25 Result Record: R|25|^\_\_Ca++driftB|0.00|mmol/L<CR>

Parameter 26 Result Record: R|26|^\_\_HctdriftB| 0| %<CR>

Parameter 27 Result Record: R|27|^\_\_pHmeasuredB| 7.41<CR>

Parameter 28 Result Record: R|28|^\_\_pCO2measuredB| 35|mmHg<CR>

Parameter 29 Result Record: R|29|^\_\_pO2measuredB|199|mmHg<CR>

Parameter 30 Result Record: R|30|^\_\_Na+measuredB|136.0|mmol/L<CR>

Parameter 31 Result Record: R|31|^\_\_K+measuredB| 6.00|mmol/L<CR>

Parameter 32 Result Record: R|32|^\_\_Ca++measuredB|2.07|mmol/L<CR>

Parameter 33 Result Record: R|33|^\_\_HctmeasuredB|11| %<CR>

Message Terminator Record:L|1<CR>

***Example of CVP Sample Data Message***

<b>Record</b>	<b>CVP Sample Data Message</b>
Header Record:	H   \^&      GEM 3500^5.4.0 ^14002^OR-1^123456^2.4        20030407110606<CR> P   1<CR> O   1   1                 P^1800^GEM CVP 1<CR> R   1   ^^^Ca++ 1.51 mmol/L 1.40 1.60     20030327094426 <CR> R   2   ^^^Glu 21 mg/dL 19 31<CR> R   3   ^^^K+ 3.1 mmol/L 2.4 3.4<CR> R   4   ^^^Lac 1.0 mmol/L 0.7 1.1<CR> R   5   ^^^Na+ 131 mmol/L 127 135<CR> R   6   ^^^pCO2 65 mmHg 61 79<CR> R   7   ^^^pH 7.21  7.16 7.24<CR> R   8   ^^^pO2 50 mmHg 47 59<CR> L   1

***Example of an iQM Delta Chart Data Message***

<b>Record</b>	<b>iQM Delta Chart Data Message</b>
Header Record:	H ^\&   GEM 3500^5.4.0 ^14002^OR-1^123456^2.4           20030103020010<CR>
Manufacturer record:	M 1 iQM-MDC 2003^01 pH^A<CR>
Comment records	C 1 I Header: G<CR>
Containing iQM data:	C 2 I Device, GEM 3500, 12345,  G<CR> C 3 I Month, Mar, 2003 G<CR> C 4 I Cartridge insertion days, 11, 19, 27 G<CR> C 5 I Cartridge lot, 301176, 301976, 302776 G<CR> C 6 I Parameter, pH,  G<CR> C 7 I Nominal target value, 6.9 G<CR> C 8 I Material, A G<CR> C 9 I Mean, 0 G<CR> C 10 I Low, -0.020000 G<CR> C 11 I High, 0.020000 G<CR> C 12 I Precision, 2 G<CR> C 13 I Interval, 1, 31 G<CR> C 14 I Data: G<CR> C 15 I 01/01/2003, 10, 0.000000, 0.010000, 0.002000, 0.020000 G<CR> C 16 I 01/02/2003, 6, -0.010000, 0.010000, -0.001997, 0.010000  G<CR>
Message Terminator Record:	L 1<CR>

### **Example of an iQM Corrective Action Data Message**

<b>Record</b>	<b>iQM Corrective Action Data Message</b>
Header Record:	H ^\^&   GEM 3500^7.0.0       ^14002^OR-1^123456^2.4           20030103020010<CR>
Manufacturer record:	M 1 iQM-MCA 2003^01 en<CR>
Comment records	C 1 I <html> <head> G<CR> C 2 I <meta HTTP-EQUIV="content-type" CONTENT="text/html; charset=ISO-8859-1"> G<CR> C 3 I </head> <body>   G<CR>
containing iQM data:	C 4 I 2003/03/20 13:54:28 Cartridge Lot No.: 301976  G<CR> C 5 I Cartridge Removed.  Samples Remaining = 594. No. of Solution B Adjustments = 0 <pre> </pre> G<CR> C 6 I </body> </html> G<CR>

Message Terminator Record:L|1<CR>

### **[ASTM] Low Level Message Transfer Layer**

The *Low Level Message Transfer Layer* defines how application data messages are framed, or packaged, and then transferred between the GEM and a receiving system. A primary function of this communication layer is to prevent loss of data between the GEM and the receiving system. The low level message transfer layer is implemented according to the ASTM E1381-91 standard.

This communication layer is identical for both RS-232 and TCP/IP. TCP/IP emulates all frames and phases of the RS-232 protocol by wrapping all frames and data inside the TCP/IP packets.

#### **3.5.12 Message Frame Structure and Content**

Only one application data message is transmitted in a frame. Messages whose length is greater than 240 characters must be sent in more than one frame, with not more than 240 characters of the message in each frame transmitted. The first part of the message is sent in an Intermediate frame, while the final part of the message is sent in an End frame. These frames have the following forms:

Intermediate frame	<STX> FN text <ETB> C1 C2 <CR> <LF>
End frame	<STX> FN text <ETX> C1 C2 <CR> <LF>
	where
	<STX> ASCII start of text transmission control character, decimal value 2.
FN	Single, ASCII numeric character “0” through “7”, decimal values 48 through 55, representing the frame number (modulo 8). The frame number begins at 1 with the first frame of the transfer phase and is incremented by 1 for every new frame transmitted. The frame number rolls over to 0 after 7.
text	Text of a single application data message. Cannot exceed 240 characters in a frame.
<ETB>	ASCII end of text block transmission control character, decimal value 23.
<ETX>	ASCII end of text transmission control character, decimal value 3.
C1 C2	Most and least significant hex characters of the message checksum, ASCII characters “0” - “9” and “A” - “F”, decimal values 48 - 57 and 65 - 70. The checksum is computed by adding the binary values of FN, text, and <ETB> or <ETX>, and keeping the least significant 8 bits of the result. Note that the checksum does not include <STX>, the checksum characters C1 and C2, or the trailing <CR> and <LF> characters.
<CR>	ASCII carriage return character, decimal value 13.
<LF>	ASCII line feed character, decimal value 10.

If an application data message is not more than 240 characters, it is transmitted in an End frame. Otherwise, Intermediate frames are used to send 240 character segments of the message, with the final part of the message sent in an End frame.

### 3.5.13 Transmission Phases

According to the ASTM E1381-91 standard, either the GEM or an LIS system can send a message frame. In the current implementation of the RS-232 data transfer protocol, however, only the GEM sends message frames.

A stop-and-wait protocol is used to transmit message frames between the GEM and an LIS system. That is, information only flows in one direction at a time. Replies occur after information is sent, never at the same time.

There are three phases involved in the transmission of message frames:

1. **Establishment phase**, in which the link connection is made between the GEM and receiving system.
2. **Transfer phase**, in which the GEM transmits message frames.
3. **Termination phase**, in which the link is released.

#### 1. Establishment Phase

The Establishment phase is initiated by the GEM transmitting the ASCII <ENQ> transmission control character, decimal value 5. If the receiving system is ready to accept messages, it responds with the ASCII <ACK> transmission control character, decimal value 6, and the link connection is established.

If the receiving system is not ready to receive, it responds with the ASCII <NAK> transmission control character, decimal value 21. Upon receiving the <NAK>, the GEM waits at least ten seconds before transmitting another <ENQ>.

If both the GEM and the receiving system wish to send information, the GEM has sending priority over the receiving system. Therefore, when the receiving system receives an <ENQ> in response to the <ENQ> it has just sent, and receives another <ENQ> from the GEM, it must respond with an <ACK> or <NAK>, depending on its readiness to receive. If the receiving system does not receive the subsequent <ENQ> within twenty seconds, it will regard the line to be in the neutral state. See “3. Termination Phase” for additional information.

If, after sending an <ENQ>, the GEM does not receive an <ACK>, <NAK>, or <ENQ> within fifteen seconds, the GEM enters the Termination phase. If the GEM receives a <NAK> or <ENQ>, it waits an additional ten seconds before sending another <ENQ>. The GEM resends <ENQ> in response to receiving a <NAK> or <ENQ> up to six times to establish a link connection with a receiving system. After six attempts, the GEM enters the Termination phase.

#### 2. Transfer Phase

The Transfer phase is entered once a link connection has been established between the GEM and receiving system. During this phase, the GEM transmits message frames to the receiving system. The last frame transmitted must be an End frame.

Upon entering the Transfer phase, the GEM sets the frame number, FN, to 1 and increments it, modulo 8, for every new frame it transmits. After transmitting a frame, the GEM waits to receive one of the following replies from the receiving system:

<ACK>      Indicates the receiving system successfully received the frame and is ready to accept another.

<NAK>      Indicates the receiving system did not successfully receive the last frame sent and is prepared to receive the frame again. The receiving system will <NAK> a frame for one of the following reasons:

- A character error was detected, such as an overrun, parity, or framing error.
- The checksum contained in the frame does not equal the checksum computed for the received frame.
- The frame number is not the next one in sequence or it is not the same as the frame number in the last accepted frame.

<EOT>      ASCII end of transmission control character, decimal value 4, which indicates that the receiving system successfully received the last frame sent and is requesting to end the transmission.

The GEM waits up to fifteen seconds for a reply from the receiving system and, depending on the reply or lack of reply, takes one of the following actions:

- If an <ACK> is received, the GEM increments the frame number (modulo 8) and sends the next frame. If all frames have been sent, the GEM initiates the Termination phase.
- If a <NAK> is received, the same frame is sent again. The GEM retransmits a frame up to six times. If a <NAK> is received in response to the sixth resend, the sender aborts the message transmission and initiates the Termination phase.
- If an <EOT> is received, the sender aborts the message transmission and initiates the Termination phase. In addition, the GEM waits fifteen seconds before attempting to enter the Establishment phase again.
- If no <ACK>, <NAK>, or <EOT> is received within fifteen seconds, the GEM aborts the message transmission and initiates the Termination phase.

If the receiving system does not receive a frame or <EOT> from the GEM within thirty seconds, it regards the line to be in the neutral state. See “3. Termination Phase” for additional information.

### **3. Termination Phase**

The Termination phase releases the link connection by returning the line to the neutral state. The GEM initiates or enters the Termination phase by transmitting an <EOT> and then

regards the line to be in the neutral state. When the receiving system receives the <EOT>, the receiving system then also regards the line to be in the neutral state.

## 3.6 Physical Transfer Layer

### 3.6.1 RS-232

The *Physical Transfer Layer* defines the serial transmission connection between the GEM and an LIS system.

#### Connector Pin-Out

The GEM's serial port connector (labeled SERIAL A on the back of the instrument) is a standard, male DB-9 connector with the following pin connections:

**PinDescription**

- 2Receive data
- 3Transmit data
- 5Signal ground

#### Serial Port Specifications

The ASTM E1381-91 standard specifies configurable baud rate, parity, data bits, and stop bits for serial communications. These parameters are not currently configurable on the GEM.

The GEM's serial port is configured as follows:

- Baud rate:9600
- Parity: none
- Start bits:1
- Data bits:8
- Stop bits:1

### 3.6.2 TCP/IP

The TCP/IP *Physical Transfer Layer* defines the network transmission connection between the GEM and an LIS system. The GEM's Ethernet port is a standard RJ-45 network connector.

Port: 1182

### 3.7 [ASTM] Testing Connection to Remote Computer

The operator can request the GEM to test its connection to a remote computer (see *Volume 3 - Operational Characteristics*). If a request to test the connection to a remote computer is made while the GEM is currently transmitting data, the connection test is not performed.

To test the connection, the GEM transmits the ASCII <ENQ> transmission control character, decimal value 5. If the receiving system responds within fifteen seconds with one of the following:

- the ASCII <ACK> transmission control character, decimal value 6,
- the ASCII <NAK> transmission control character, decimal value 21, or
- <ENQ>,

The GEM enters the Termination phase (Section Transmission Phases) and the result of the connection test is success. If the GEM does not receive one of the above responses within 15 seconds, the GEM enters the Termination phase and the result of the connection test is failure. See *Volume 3 - Operational Characteristics* for a description of how the operator is notified of the success or failure of the connection test.

### 3.8 [ASTM] Requesting data from LIS or DMS

The GEM requests data from the LIS or DMS by sending a “Request Information Message”. The GEM sends a Request Information Message to request the test order and patient demographics for a specific patient ID. As a reply to the Request Information Message, the LIS or DMS returns the “Test Order Message”.

The Request Information Message is composed of a Message Header Record, a Request Information Record and a Message Terminator Record. See section Request Information Record for information on the Request Information Record. See sections 3.5.3 and 3.5.10 for details on the Message Header Record and Message Terminator Record, respectively. See an example of a Request Information Message on section Request Information Record.

The Test Order Message is composed of a Message Header Record, a Patient Information Record followed by one or more Test Order Records and a Message Terminator Record. See section 3.5.5 for information on the Test Order Record and sections 3.5.3, 3.5.4 and 3.5.10 for details on the Message Header Record, Message Patient Information Record and Message Terminator Record, respectively. See an example of a Test Order Message in section 3.9.2.

After the GEM requests data, it will wait for the LIS/DMS response. The wait time will not exceed a configurable timeout (default = 15 seconds). If the data arrives after the GEM times out, the data will be discarded.

#### 3.8.1 Request Information Record

The Request Information record is used by the GEM to request information from the LIS or DMS.

##### Syntax

Record type ID|Record sequence number|Starting Range ID  
Number|||||||Request Information Status Codes<CR>

## Field Descriptions

The GEM uses fields 1, 2, 3, 13, in the Request Information record:

- Q1                      Request Information field 1 is the record type ID.  
Always the character Q.
- Q2                      Request Information field 2 contains the record sequence number. This field always contains 1 because the GEM always request data for only one patient in a message.
- Q3                      Request Information field 3 contains the starting range ID number. This field can have up to three components but the GEM will only use the first component. It contains the patient identification.
- Q13                    Request Information field 13 contains the request information status codes. The GEM inserts either “D”, which specifies to the LIS or DMS that the GEM is only interested in receiving patient demographics information, or “O” (capital o, not zero) to request both test order and patient demographics.

## Examples

Example 1 (Request only patient demographics):

- ```
Q|1|001122334455|||||||D<CR>
Q                      Field 1: record type ID
1                      Field 2: record sequence number
001122334455        Field 3: patient id = 001122334455
D                      Field 13: requesting demographics only
```

Example 2 (Request both demographics and test order information):

- ```
Q|1|9988-1122|||||||O<CR>
Q                      Field 1: record type ID
1                      Field 2: record sequence number
9988-1122            Field 3: patient id = 9988-1122
O                      Field 13: requesting test order information and
                          demographics
```

## **Example of a Request Information Message**

Record	Request Information Message
Header Record:	H ^\&   GEM 3500^5.2.0 ^12345^^353604^2.3         20020401162606<CR>
Request Information Record:	Q 1 112233998877       O<CR>
Terminator Record:	L 1<CR>

### **3.8.2 Test Order Message**

The Test Order Message is composed of a Message Header Record, a Patient Information Record, zero or more Test Order Records, and a Message Terminator Record. See section 3.5.5 for information on the Test Order Record. See sections 3.5.3, 3.5.4 and 3.5.10 for details on the Header Record, Patient Information Record and Terminator Record, respectively.

The GEM is only interested in getting from LIS or DMS the following fields in the Test Order Message:

1. Patient First Name
  2. Patient Last Name
  3. Patient Birth Date
  4. Patient Sex
  5. Accession Number (one or more, if available)
  6. Patient ID (returned for verification of requested data)

## **Example of a Test Order Message**

Record	Test Order Message
Header Record:	H ^&   Harvard Hospital Host       20021023120023<CR>
Patient Information Record:	P 1  112233998877  BLAKE^LINDSEY  19740722 F<CR>
Parameter 1 Test Order Record:	O 1 33745677         A<CR>
Parameter 2 Test Order Record:	O 2 33745678         A<CR>
Parameter 3 Test Order Record:	O 3 33745703         V<CR>
Parameter 4 Test Order Record:	O 4 33745704         V<CR>
Parameter 5 Test Order Record:	O 5 33745705         V<CR>
Parameter 6 Test Order Record:	O 6 33745722         O<CR>
Terminator Record:	L 1<CR>

### 6.0.3 LIS / DMS Rejection Message

LIS / DMS can reject the GEM query by sending a rejection message. A rejection message is composed of a Message Header Record, a Request Information Record, and a Message Terminator Record.

A LIS/DMS rejection message can be identified by the presence of a 'X' in the Request Information Status Code (field 13) in the Request Information Record.

#### Example of a LIS / DMS Rejection Message

Record	LIS / DMS Rejection Message
--------	-----------------------------

Header Record: H | \^& || | Cambridge Hospital|||||||20021023120023<CR>

Request Information Record: Q | 1 | | | | | | | | X<CR>

Terminator Record: L | 1<CR>

## 4. HL7 PROTOCOL

### 4.1 HL7 over TCP/IP (GEM as Server)

The HL7 protocol shall be available on GEM 3500 instruments; it shall not be available on GEM 3000 instruments.

The GEM shall be considered the server (master) and the receiving system shall be the client (slave). The GEM opens a port and listens for a connection request. Once the request has been accepted, the GEM shall be able to transmit the full HL7 Hybrid Low Level data reports to the receiving system. These data reports contain the sample in the ORI (HL7 v2.4) format. If the receiving system closes the connection, GEM will wait for another connection before attempting another transmission.

## 4.2 HL7 HYBRID LOWER LAYER PROTOCOL

### 4.2.1 Overview

This Lower Level Protocol is intended for those environments where communications primarily occur over LANs. These environments usually have much lower bit error rate and flow control is already available from the network. Therefore, this protocol avoids implementing controls that are already provided by the network.

The mode of operation is a one-way transfer of information, from the sender to the receiver. The receiver shall reply once all the information block has been received or an error was identified.

### 4.2.2 Frame definition

Frame or Blocks in HL7 Hybrid Low Level Protocol can be of type data or NAK. All frames will have the same structure regardless the kind of message they are:

```
<SB>tvv<CR>ddddccccxxx<EB><CR>
```

Frames consist of the following fields:

- <SB> : Start frame ASCII character (1 byte). <VT> ASCII character code is used.
- t : Frame type (1 byte). It will be 'D' for data frames and 'N' for NAK frames.
- vv : Protocol id (2 bytes). HL7 version being used by the GEM 3500. For instance "24" as for HL7 2.4.
- <CR> : Carriage return ASCII character (1 byte).
- dddd : Data (variable number of bytes). In a data type frame this will be the content of the frame.  
**Note that the GEM 3500 does not support <CR> stuffing in data frames.**

In NAK type frames it will contain a 1-byte reason code as follows:

- 'C': character count wrong in previous data block received.
- 'X': checksum wrong in previous data block received.
- 'B': data too long for input buffer in previous block received.
- 'G': Error not covered elsewhere.
  
- ccccc: Frame size (5 bytes). Character count of all characters so far in the data block up to and including the last data character.
- xxx: Checksum (3 bytes). Exclusive-OR checksum of all characters in the block up to and including the last data character. The checksum is expressed as a decimal number in three ASCII digits.
- <EB>: End block character (1 byte). <FS> ASCII character code is used.
- <CR>: Carriage return (1 byte).

### 4.2.3 Communication flow

The communication flow with this protocol is very simple. In the usual way, the initiating system sends an initiate message to the receiver and the responding system sends back a response message.

#### 4.2.3.1 *Communication parameters*

See the list below for the communication parameters assumed in GEM 3500:

- **Receive message timeout:** 10 seconds. It is the amount of time GEM 3500 will wait for a reply after sending a message.
- **Number of retries to resend a message:** 5 times. It is the number of times GEM 3500 will resend a message due to either a receive timeout or any error in the received message.

#### 4.2.3.2 *GEM 3500 acting as the sender*

These are the steps the GEM 3500 will perform (send a message and receive a response) when behaving as message sender:

1. Build frame with message contents.
2. Send the data frame that contains the message.
3. Receive the response from the responding system.
  - If a complete frame is not received before the receive timeout the original frame will be resent.
  - Ignore all incoming characters until a Start Frame is received. Any time another Start Frame is received before the end of the frame, all previous characters will be ignored. Receive characters until <EB><CR> is recognized. This is the end of the block.
  - If a frame is received with an error in the frame structure or control data (checksum, etc), resend the original frame.

- If the frame is acceptable and is a NAK the original frame will be resent.
- If the frame is acceptable and is a data frame, the data will be processed.

### ***3.0.0.3 GEM 3500 acting as the receiver***

These are the steps the GEM 3500 will perform when acting as a responding system (receive a message and send back response):

1. Receive the frame that contains the initial message.
  - Ignore all incoming characters until the Start Frame character is received. Any time another Start Frame character is received before the end of a block, ignore all previous characters. Receive characters until <EB><CR> is recognized. This is the end of the Frame.
  - If an incorrect frame is received, build a NAK frame message with appropriate rejection reason and send it back to the sender.
  - If the received frame message is correct, continue with next step.
2. Process message
3. Create response to the received message. Response frame is created.
4. Send response back to sender.

### ***4.0.0.4 Connection Test***

There is no good way to test if a connection is established by using this Low Level Protocol. As a result, HL7 connection test is implemented by using the High Level Protocol. Please, see section 7.11 for details.

## **4.3 HL7 MINIMAL LOWER LAYER PROTOCOL**

### **4.3.1 Frame definition**

Frame or Blocks in HL7 Minimal Low Level Protocol can only be of data type. ACK/NAK frames are not supported.

All frames will have the same structure regardless the kind of message they are:

<SB> dddd<EB><CR>

Frames consist of the following fields:

- <SB> : Start frame ASCII character (1 byte). <VT> ASCII character code is used.

- dddd : Data (variable number of bytes). This is the content of the frame. **Note that the GEM 3500 does not support <CR> stuffing in data frames.**
- <EB>: End block character (1 byte). <FS> ASCII character code is used.
- <CR>: Carriage return (1 byte).

### 4.3.2 Communication flow

The communication flow with this protocol is trivial. Each single frame is sent or received without any acknowledge activity.

No retry or timeout mechanisms are required.

#### 4.3.2.1 GEM 3500 acting as the sender

These are the steps the GEM 3500 will perform (send a message) when behaving as message sender:

1. Build frame with message contents.
2. Send the data frame that contains the message.
3. Be ready to send (or receive) the next frame.

#### 3.0.0.2 GEM 3500 acting as the receiver

These are the steps the GEM 3500 will perform when acting as a responding system (receive a message):

1. Receive the frame that contains the initial message.
2. Ignore all incoming characters until the Start Frame character is received. Any time another Start Frame character is received before the end of a block, ignore all previous characters. Receive characters until <EB><CR> is recognized. This is the end of the Frame.
3. If an incorrect frame is received, ignore it.
4. If the received frame message is correct, continue with next step.
5. Process message and be ready to receive (or send) the next frame.

#### 5.0.0.3 Connection Test

There is no good way to test if a connection is established by using this Low Level Protocol. As a result, HL7 connection test is implementing by using the High Level Protocol. Please, see section 7.11 for details.

## 5.4 High Level Protocol - ORI (HL7 v2.4)

HL7 Protocol shall be available on GEM 3500 instruments and it shall not be available on GEM 3000 instruments.

### 4.4.1 Background and conventions [INFO]

This section defines the HL7 implementation used by the GEM. This specification handles the communication of test result and ordering information between the GEM and the HIS/LIS/CIS.

This implementation is compliant with **version 2.4 of the Health Level Seven (HL7) Standard**.

The reporting of patient sample results to the HIS/LIS/CIS is compliant with the POCT1-A Standard (as well as with HL7 v2.4):

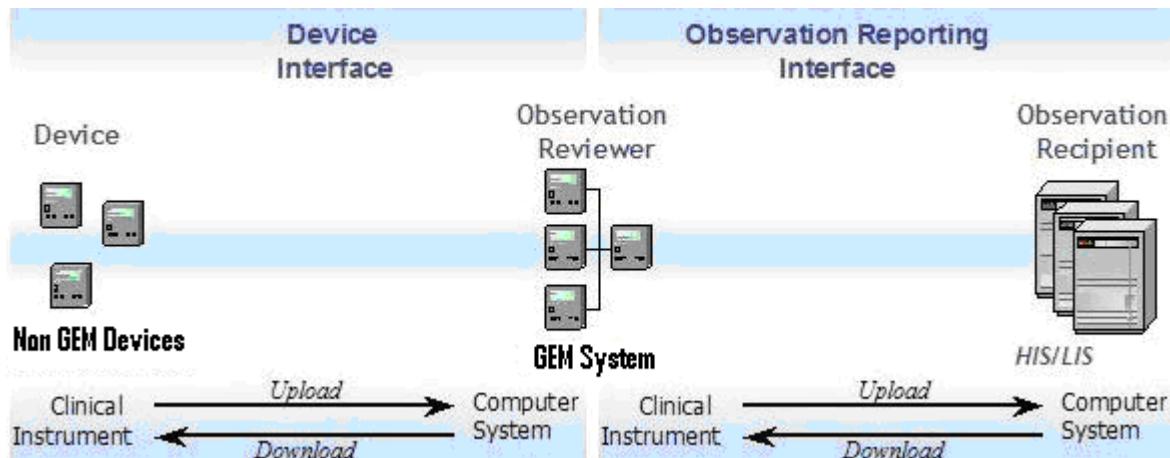
***Point-Of-Care Connectivity; Approved Standard. NCCLS Document POCT1.A (ISBN 1-56238-450-3)***  
Appendix C: Observation Reporting Interface.

According to the POCT1-A Standard, the interface described in this chapter is the Observation Reporting Interface (Figure 1: The POCT1-A Observation Reporting Interface), where the GEM system plays the role of Observation Reviewer and the HIS/LIS/CIS plays the role of Observation Recipient.

Data transmitted from the HIS/LIS/CIS to GEM is called *download*.

Data transmitted from the GEM to HIS/LIS/CIS is called *upload*.

FIGURE 1: THE POCT1-A OBSERVATION REPORTING INTERFACE



When describing the syntax of the protocol, the following conventions shall be used:

<b>Convention</b>	<b>Meaning</b>
X	1 Element X is required and can only appear once
{X}	1...* Element X is required and can appear more than once
[X]	0, 1 Element X is not required and can only appear once
[{X}]={ [X] }	0...* Element X is not required and can appear more than once
+	And
	Or

#### 4.4.2 Message Structure and contents

This section defines the components of messages and provides the methodology for defining abstract messages that are used in later sections. A message is the atomic unit of data transferred between systems. It is comprised of a group of segments in a defined sequence. Each message has a message type that defines its purpose. For example the ADT Message type is used to transmit portions of a patient's Patient Administration (ADT) data from one system to another. A three-character code contained within each message identifies its type. Messages used by the GEM are listed in Table 1: HL7 Messages used by the GEM1.

TABLE 1: HL7 MESSAGES USED BY THE GEM

<b>Message</b>	<b>Description</b>
ACK	General acknowledgement Message
ORU	Observation Result Unsolicited Message
OUL	Unsolicited Laboratory Observation Message

The real-world event that initiates an exchange of messages is called a trigger event. These events (a three letter code) represent values such as "A patient is admitted" or "An order event occurred". There is a one-to-many relationship between message types and trigger event codes. The same trigger event code may not be associated with more than one message type; however a message type may be associated with more than one trigger event. Triggers used by the GEM are listed in Table 2: HL7 Triggers used by the GEM2.

TABLE 2: HL7 TRIGGERS USED BY THE GEM

<b>Trigger</b>	<b>Description</b>	<b>Initiated by</b>
ORU^R31	New Observation. Search for an Order	GEM
ORU^R32	Preordered Observation	GEM
ACK^R33	Acknowledgement of ORU^R30/31/32,	HIS/LIS/CIS
OUL^R21	Update calibrations, QCs and CVP	GEM

#### 4.4.2.1 Segments

A **segment** is a logical grouping of **data fields**. Segments of a message may be required or optional. They may occur only once in a message or they may be allowed to repeat. Each segment is given a name. For example, the ADT message may contain the following segments: Message Header (MSH), Event Type (EVN), Patient ID (PID), and Patient Visit (PV1).

Each segment is identified by a unique three-character code known as the Segment ID. Segments used by the GEM are listed in Table 3: HL7 Segments used by the GEM3:

TABLE 3: HL7 SEGMENTS USED BY THE GEM

<b>Segment</b>	<b>Description</b>
MSA	Message Acknowledgment Segment
MSH	Message Header Segment
NTE	Notes and Comments Segment
OBR	Observation Request Segment
OBX	Observation Segment
ORC	Common Order Segment
PID	Patient identification Segment
SAC	Specimen and Container Detail Segment

#### 4.4.2.2 Fields

Definition: A field is a string of characters.

HL7 does not care how systems actually store data within an application. When fields are transmitted, they are sent as character strings. Except where noted, HL7 data fields may take on the null value. Sending the null value, which is transmitted as two double quote marks (""), is different from omitting an optional data field. The difference appears when the contents of a message will be used to update a record in a database rather than create a new one. If no value is sent, (i.e., it is omitted) the old value should remain unchanged. If the null value is sent, the old value should be changed to null.

The various sections in §High Level Protocol: ORI Messages (HL7 v4.2) contain segment attribute tables. These tables list and describe the data fields in the segment and characteristics of their usage. In defining a segment, the following information is specified about each field:

- **Field, Field Name and Description.** HL7 definitions for the field.
- **Comp.:** If the field has only one component, is empty. If the field has only one repeat, it indicates the component (1, 2, 3...). If it has more than one repeat, indicates repeat and component (1.1, 1.2, 1.3, 2.1, 2.2...).
- **Max. Len.:** A dash indicates that length is implicit in the field or has no maximum.
- **Req.:**
  - o R: Required.
  - o RE: Required may be empty.
  - o O: Optional.
  - o X: Unused.
- **Values Formats and Comments:**

- o Quoted text shall appear exactly like this.
- o Elements in italics refer to the GEM database fields.

#### 4.4.2.3 Character Codes

All data shall be represented as 8-bit, single-byte, coded graphic character values as defined in ISO 8859-1:1987.

The allowed and disallowed characters are as follows:

<b>Code</b>	<b>Status</b>	<b>Comments</b>
0-31	<b>Disallowed</b>	NUL (Null char.) SOH (Start of Header) STX (Start of Text) ETX (End of Text) EOT (End of Transmission) ENQ (Enquiry) ACK (Acknowledgment) BEL (Bell) BS (Backspace) HT (Horizontal Tab) LF (Line Feed) VT (Vertical Tab) FF (Form Feed) CR (Carriage Return) SO (Shift Out) SI (Shift In) DLE (Data Link Escape) DC1 (XON) (Device Control 1) DC2 (Device Control 2) DC3 (XOFF) (Device Control 3) DC4 (Device Control 4) NAK (Negative Acknowledgement) SYN (Synchronous Idle) ETB (End of Trans. Block) CAN (Cancel) EM (End of Medium) SUB (Substitute) ESC (Escape) FS (File Separator) GS (Group Separator) RS (Request to Send)(Record Separator) US (Unit Separator)
32-126	<b>Allowed</b>	<b>Space</b> ! " # \$ % & ' ( ) * + , - . / 0 1 2 3 4 5 6 7 8 9 : ; < = > ? @ A B C D E F G H I J K L M N O P Q R S T U V W X Y Z [ \ ] ^ ~ a b c d e f g h i j k l m n o p q r s t u v w x y z {   } ~
127	<b>Disallowed</b>	DEL (Delete)
128-254	<b>Allowed</b>	ISO-8859-1 (Latin-1) extended character set.
255	<b>Disallowed</b>	

GEM shall use the ISO-8859-1 (Latin-1) extended character set.

If a disallowed character is received in a field, the GEM shall process the field, ignoring the disallowed character (ex: "S<BEL>mith" shall be processed as "Smith").

The following predefined escape sequences **shall** be used by the GEM (being "\")the escape delimiter):

- \F\Imbedded field delimiter character
- \S\Imbedded component field delimiter character
- \R\Imbedded repeat field delimiter character
- \T\Imbedded subcomponent delimiter character
- \E\Imbedded escape delimiter character

The following predefined escape sequences **shall** be ignored by the GEM.

- \H\Start highlighting text (ignored by GEM).
- \N\ Normal text (end highlighting) (ignored by GEM).

#### **4.4.2.4 Delimiters**

In constructing a message, certain special characters are used. They are the segment terminator, the field separator, the component separator, subcomponent separator, repetition separator, and escape character.

The segment terminator is always a carriage return (in ASCII, a hex 0D). The other delimiters are defined in the MSH segment, with the field delimiter in the 4th character position, and the other delimiters occurring as in the field called Encoding Characters, which is the first field after the segment ID. The delimiter values used in the MSH segment are the delimiter values used throughout the entire message.

GEM **shall** always use the suggested values by HL7, found in Table 4: HL7 Separators4.

TABLE 4: HL7 SEPARATORS

Delimiter	Suggested Value	Usage
Segment Terminator	<cr> (0x0D)	Terminates a segment record.
Field Separator		Separates two adjacent data fields within a segment. It also separates the segment ID from the first data field in each segment.
Component Separator	^	Separates adjacent components of data fields where allowed.
Subcomponent Separator	&	Separates adjacent subcomponents of data fields where allowed. If there are no subcomponents, this character may be omitted.
Repetition Separator	~	Separates multiple occurrences of a field where allowed.
Escape Character	\	Escape character for use with any field represented by an ST, TX or FT data type, or for use with the data (fourth) component of the ED data type. If no escape characters are used in a message, this character may be omitted. However, it must be present if subcomponents are used in the message.

#### 4.4.2.5 Message Construction Rules

**Step 1:** Construct the segments in the order defined for the message. Each message is constructed as follows:

- a) The first three characters are the segment ID code.
- b) Each data field in sequence is inserted in the segment in the following manner:
  - 1) A field separator is placed in the segment.
  - 2) If the value is not present, no further characters are required.
  - 3) If the value is present, but null, the characters "" (two consecutive double quotation marks) are placed in the field.
  - 4) Otherwise, place the characters of the value in the segment. As many characters can be included as the maximum defined for the data field. It is not necessary, and is undesirable, to pad fields to fixed lengths. Padding to fixed lengths is permitted.
  - 5) If the field definition calls for a field to be broken into components, the following rules are used:
    - i. If more than one component is included they are separated by the component separator.
    - ii. Components that are present but null are represented by the characters "".
    - iii. Components that are not present are treated by including no characters in the component.
    - iv. Components that are not present at the end of a field need not be represented by component separators. For example, the two data fields are equivalent:  
|ABC^DEF^^| and |ABC^DEF|.
  - 6) If the component definition calls for a component to be broken into subcomponents, the following rules are used:
    - i. If more than one subcomponent is included they are separated by the subcomponent separator.
    - ii. Subcomponents that are present but null are represented by the characters "".
    - iii. Subcomponents that are not present are treated by including no characters in the subcomponent.
    - iv. Subcomponents that are not present at the end of a component need not be represented by subcomponent separators. For example, the two data components are equivalent:  
^XXX&YYY&&^ and ^XXX&YYY^.
  - 7) If the field definition permits repetition of a field, the repetition separator is used only if more than one occurrence is transmitted. In such a case, the repetition separator is placed between occurrences. If three occurrences are transmitted, two repetition separators are used.)

In the example below, two occurrences of telephone number are being sent:

|234-7120~599-1288B1234|

- c) Repeat Step 1b while there are any fields present to be sent. If all the data fields remaining in the segment definition are not present there is no requirement to include any more delimiters.
- d) End each segment with an ASCII carriage return character.

**Step 2:** Repeat Step 1 until all segments have been generated.

#### 4.0.0.6 Message Processing Rules

The following rules apply to receiving HL7 messages and converting their contents to data values:

- a) Ignore segments, fields, components, subcomponents, and extra repetitions of a field that are present but were not expected.
- b) Treat segments that were expected but are not present as consisting entirely of fields that are not present.

- c) Treat fields and components that are expected but were not included in a segment as not present.

### 3.0.3 Message Transmission Control

Because the protocol describes an exchange of messages, it is described in terms of two entities, the initiating and responding systems. The GEM can play both roles.

Each is both a sender and receiver of messages. The initiating system sends first and then receives, while the responding system receives and then sends.

The HL7 protocols prescribes two kinds of acknowledge, original and enhanced. The GEM **shall** support the original as well as the enhanced acknowledgement mode.

In overview this exchange proceeds as described in the following sections.

#### 4.4.3.1 Initiation

The initiating application creates a message with data values according to the rules described in §Message Structure and contents.

The Message Header Segment (MSH) contain several fields that control the later message flow

- MSH-10 contains a unique identifier for the message. Acknowledgements shall refer to this ID.
- MSH-15 is set to AL, meaning that the message requires an accept acknowledgement
- MSH-16, depending on the nature of the message, can be set to
  - o AL: The message requires an application acknowledgement
  - o NE: The message does not require an application acknowledgement.

#### 4.4.3.2 Response

The responding system returns a general acknowledgment message (ACK) with:

- 1) A commit accept (CA) in *MSA-1-acknowledgment code* if the message can be accepted for processing.
- 2) A commit reject (CR) in *MSA-1-acknowledgment code* if the one of the values of *MSH-9-message type*, *MSH-12-version ID* or *MSH-11-processing ID* is not acceptable to the receiving application.
- 3) A commit error (CE) in *MSA-1-acknowledgment code* if the message cannot be accepted for any other reason (e.g., sequence number error or a required field is not present).

The ACK message contain a NE in fields MSH-5 and MSH-6.

If the message header segment indicates that the initiating system also requires an application acknowledgment, this will be returned as the initial message of a later exchange.

For this message, the receiving system acts as the initiator. Since the message it sends is application-specific, the layouts of these application-level response messages are defined in the relevant application-specific chapter. If needed, this application acknowledgment message can itself require (in *MSH-15-accept acknowledgement type*) an accept acknowledgement message (MSA). *MSH-16-application acknowledgement type*, however, is always null, since the protocol does not allow the application acknowledgment message to have an application acknowledgment.

At this point, the application acknowledgment portion of this message exchange is considered complete.

### 3.0.0.3 Error Recovery

#### 4.4.3.3.1 Resend timeout

When GEM acting as the initiator, if the accept acknowledgement is not received in 60 seconds, the GEM shall resend the message until any of the following conditions occurs:

1. The acknowledgement is received.
2. the transmission queue is cleared.
3. The same message has already been sent to the host three times.

In this case, the GEM shall report an alarm [TBD] and discard the outgoing message.

#### 3.0.0.2 Non-expected message received

If the message does not require accept acknowledge, the SW shall take no action

If the message requires accept acknowledge, the SW shall reply with a message having the structure defined in Table 5: ORI.HL7. Upload ACK of a Non Expected Message5.

TABLE 5: ORI.HL7. UPLOAD ACK OF A NON EXPECTED MESSAGE

<i>Message</i>	<i>Comments</i>
MSH	See Table 6: ORI. HL7. Upload ACK of a NON-EXPECTED Message. MSH6
MSA	See Table 7: ORI. HL7. Upload ACK of a NON-EXPECTED Message. MSA7

TABLE 6: ORI. HL7. UPLOAD ACK OF A NON-EXPECTED MESSAGE. MSH

<i>Field</i>	<i>Field Name</i>	<i>Description /INFO</i>	<i>Count</i>	<i>Length</i>	<i>Reqd</i>	<i>Values, formats and comments</i>
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)	1	18	RE	"IL"
			2	0		"GEM Premier 3500"
						"1.0" (Data Format version)
4	Sending Facility		1	18	RE	<i>Area Name</i>
			2	0		<i>Analyzer Name</i>
			3			<i>Analyzer Model</i>
			4			<i>Analyzer Serial Number</i>
			5			<i>Analyzer Cartridge Serial Number</i>
			6			<i>Analyzer SW Version Number</i>
5	Receiving Application			18	RE	Null
				0		

6	Receiving Facility		18 0	RE	Null
7	Date/Time Of Message	Date time the message was generated (HL7/ASTM format).	26	R	YYYYMMDDHHMMSS
8	Security		40	X	
9	Message Type	ORU^R30, ORU^R31, ORU^R32, ACK^R33.	7	R	"ACK"
10	Message Control ID	Unique identifier for the message (32 bits PK).	20	R	0 - 4294967295
11	Processing ID	"T/D/P": Training/Debug/Production	3	R	"P"
12	Version ID		8	R	"2.4"
13	Sequence Number		15	X	
14	Continuation Pointer		18 0	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"	2	R	"NE"
16	Application Acknowledgement Type	All ORU messages will specify "AL"	2	R	"NE"
17	Country Code	Not used by GEM	2	RE	Null

TABLE 7: ORI. HL7. UPLOAD ACK OF A NON-EXPECTED MESSAGE. MSA

Field	Field Name	Description [INFO]	Co mp	Le n	Re q	Values, formats and comments
1	Acknowledgement Code	"CA," "CE," "CR," "AA," "AE," "AR"		2	R	"CR"
2	Message Control ID	From MSH-10 of the non expecte message		20	R	0 - 4294967295
3	Text Message Note (2)			80	O	"Non Expected Message"
4	Expected Sequence Number			15	X	
5	Delayed Acknowledgement Type			1	X	
6	Error Condition	Coded Error		10 0	O	Null

### 3.5 High Level Protocol: ORI Messages (HL7 v4.2)

The HL7 v2.4 protocol details stated in §High Level Protocol - ORI (HL7 v2.4) shall apply.

#### 4.5.1 Upload Patient Sample Results to HIS/LIS/CIS

This specification is compliant with HL7 v2.4 and NCCLS POCT1-A

Point-of-care workflow for measurement and ordering is quite complex, dynamic, and flexible. However, most scenarios may be reduced to three use cases:

1. A test is performed without an order and the Observation Recipient should place an order.
2. A test is performed which may or may not have an order previously placed.
3. A test is performed that was previously ordered.

These three use cases all rely on the **ORU** message to communicate the appropriate mix of result and order information. Currently, the **ORU** message has no trigger event appropriate for the common POC Use Cases. Four new trigger events are required to distinguish between the **ORU**

messages that support these three use cases. The HL7 organization has issued an Authoritative Use Statement permitting the use of the new triggers: **R30**, **R31** and **R32**, in advance of being balloted by HL7 for a future version of the standard.

The GEM 3500 shall report patient sample results as follows:

- Use case 2 (ORU-R31), if the Accession Number is not available.
- Use case 3 (ORU-R32), if the Accession Number is available.

The message flow of use case 2 is described in Figure 2: Upload Patient Sample Results to HIS/LIS/CIS.2.

The following sections describe these triggers and their use in more detail.

FIGURE 2: UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS.



#### ***4.5.1.1 Message 1: ORU^R31 / ORU^R32 (uploading)***

This message shall be an uploading message.

Shall have the structure defined in one of the following tables.

TABLE 8: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. SAMPLE INFORMATION REPORTED BY NTE SEGMENTS. MESSAGE 1

<b>Message</b>	<b>Comments</b>
MSH	See §Message Header Segment – MSH: Message Header Segment – MSH.
PID	See §Patient Identification Segment – PID: Patient Identification Segment – PID.
[NTE]	Custom Patient information – NTE (MSG) [TBD]
ORC	See §Common Order Segment – ORC: Common Order Segment – ORC.
OBR	See §Observation Request Segment – OBR: Observation Request Segment – OBR.
[NTE]	See §Operator Comment (related to message) – NTE (MSG) : Operator Comment (related to message) – NTE (MSG) . [TBD]
{	
OBX	See §Observation Result Segment – OBX: Observation Result Segment – OBX.
[NTE]	See §Notes and Comment Segment (related to Observation) – NTE (OBX): Notes and Comment Segment (related to Observation) – NTE (OBX).
}	

#### 4.5.1.1.1 Message Header Segment – MSH

TABLE 9: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. MSH

<b>Field Id</b>	<b>Field Name</b>	<b>Description /INFO/</b>	<b>Com</b>	<b>Len</b>	<b>Req</b>	<b>Values, formats and comments</b>
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)	1 2 3 4 5 6	18 0 18 0 5 6	RE RE RE RE RE	"IL" "GEM Premier 3500" "1.0" (Data Format version) Area Name Analyzer Name Analyzer Model Analyzer Serial Number Analyzer Cartridge Serial Number Analyzer SW Version Number Null
4	Sending Facility					
5	Receiving Application			18 0	RE	Null
6	Receiving Facility			18 0	RE	Null
7	Date/Time Of Message	Date time the message was generated (HL7/ ASTM format).		26	R	YYYYMMDDHHMMSS
8	Security			40	X	
9	Message Type	ORU^R30, ORU^R31, ORU^R32, ACK^R33.		7	R	ORU^R32/ORU^R31: See note below
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 - 4294967295
11	Processing ID	"T/D/P": Training/Debug/Production		3	R	"P"
12	Version ID			8	R	"2.4"
13	Sequence Number			15	X	
14	Continuation Pointer			18 0	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"		2	R	"AL"

16	Application Acknowledgement Type	All ORU messages will specify "AL"		2	R	"AL"
17	Country Code	Not used by GEM		2	RE	Null

Notes:

**MSH-4:** Items that appear in MSH-4 **shall** refer to those of the analyzer that ran the sample at analysis date time (i.e, cartridge serial number at that time, not current inserted cartridge).

**MSH-9:** Possible values **shall** be:

- ORU^R31: indicates that this is a ORU^R31 trigger ("search for an order"), the use case #2 in the POCT1-A standard.
- ORU^R32: indicates that this is a ORU^R32 trigger ("preordered observation"), the use case #3 in the POCT1-A standard.

Comments (informative only):

- MSH-15 is set to "AL" (always), so the message requires acknowledge at accept level (which is message 2).
- MSH-16 is set to "AL" (always), so the message requires acknowledge at application level (which is message 4).

#### 4.5.1.1.2 Patient Identification Segment – PID

TABLE 10: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. PID

Field Id	Field Name	Description /INFO/	Comp	Len	Req	Values, formats and comments
1	Set ID - Patient ID Optional. Set ID Sequence Number.			4	O	"1"
2	Patient ID			20	X	
3	Patient Identifier List Use Case #1, #2 Patient ID required.	GEM <b>shall</b> always consider this fields as optional.		20	O	<i>Patient ID</i>
4	Alternate Patient ID – PID			20	X	
5	Patient Name	Extension to the standard	1 2 3 48	25 0 0 X	O O O	<i>Patient Last Name</i> <i>Patient First Name</i> <i>Patient Middle Initial</i>
6	Mother's Maiden Name					
7	Date/Time of Birth	Extension to the standard		26	O	<i>Patient Birth Date (YYYYMMDDHHMMSS)</i>
8	Administrative Sex	Extension to the standard		1	O	"M"/"F"/"U"/""
9	Patient Alias			48	X	
10	Race			1	X	
11	Patient Address			10 6	X	
12	Country Code Empty for USA.			4	RE	Null
13	Phone Number – Home			40	X	
14	Phone Number – Business			40	X	

15	Primary Language		60	X
16	Marital Status		1	X
17	Religion		3	X
18	Patient Account Number	Account number, if available.	20	X
19	SSN Number – Patient		16	X
20	Driver's License Number - Patient		25	X
21	Mother's Identifier		25 0	X
22	Ethnic Group		25 0	X
23	Birth Place		25 0	X
24	Multiple Birth Indicator		1	X
25	Birth Order		2	X
26	Citizenship		25 0	X
27	Veterans Military Status		25 0	X
28	Nationality		25 0	X
29	Patient Death Date and Time		26	X
30	Patient Death Indicator		1	X
31	Identity Unknown Indicator		1	X
32	Identity Reliability Code		20	X
33	Last Update Date/Time		26	X
34	Last Update Facility		40	X
35	Species Code		25 0	X
36	Breed Code		25 0	X
37	Strain		80	X
38	Production Class Code		25 0	X

#### Notes about field 5:

- The GEM 3500 supports only 16 characters patient first and last name.
- The GEM 3500 does not support patient mid initials, so the third component shall be left empty.

#### Note about field 7:

- The GEM 3500 does not support patient birth time. The digits related to the birth time (HHMMSS) shall be set to "000000"

#### Comments (informative only):

- PID-2 and PID-4 are deprecated fields.
- PID-5, PIC-7 and PID-8 are HL7 valid extensions to the POCT1-A standard.

#### 4.5.1.1.3 Custom Patient information – NTE (MSG)

Custom patient information shall be sent on this NTE segment only if configured on the ECM HL7 connection setup.

The only custom patient information supported by the GEM 3500 is the patient age.

TABLE 11: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. NTE (MSG)

<i>Field Id</i>	<i>Field Name</i>	<i>Description [/INFO]</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Set ID – NTE			4	R	As only one NTE record is sent in HL7, it will have always value “1”
2	Source of Comment			8	X	
3	Comment			64 k	RE	See below.

The comment field shall contain a comma separated string containing one or more the following values:

- “FIELD”, “Patient Age”, The numerical value of the patient age

(The only comment field currently supported by GEM3500 instruments is the patient age)

The unit of measure of the patient name value (Units for age are described in \$Age Units)

The only unit of measure for age values supported GEM3500 is years.

Example: “FIELD, Patient Age, 99, YR”

#### 4.5.1.1.4 Common Order Segment – ORC

TABLE 12: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. ORC

<i>Field Id</i>	<i>Field Name</i>	<i>Description [/INFO]</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Order Control	Use Case #1, #2: “NW.” Use Case #3: “RE.”		2	R	(See Note about the Accession Number:)
2	Placer Order Number.	Use Case #3 Only: Order Number		22	X/ R	(See Note about the Accession Number:)
3	Filler Order Number	External identifier for these results in the Observation Reviewer.		22	O	Sample Number
4	Placer Group Number			22	X	
5	Order Status			2	X	
6	Response Flag			1	X	
7	Quantity/Timing			20 0	X	
8	Parent			20 0	X	
9	Date/Time of Transaction			26	X	
10	Entered By			12 0	X	
11	Verified By			12 0	X	

12	Ordering Provider		12 0	X
13	Enterer's Location		80	X
14	Call Back Phone Number		40	X
15	Order Effective Date/Time		26	X
16	Order Control Code Reason		20 0	X
17	Entering Organization		60	X
18	Entering Device		60	X

Note about the Accession Number:

If the Accession Number is available, the first two fields shall be set as follows:

- **ORC-1:** "RE" (Preordered Observation)
- **ORC-2:** Accession Number (As entered by the user).

If the Accession Number is not available, the first two fields shall be set as follows:

- **ORC-1:** "NW" (Search for an order)
- **ORC-2:** Empty

#### 4.5.1.1.5 Observation Request Segment – OBR

TABLE 13: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. OBR

<i>Field Id</i>	<i>Field Name</i>	<i>Description /INFO</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Set ID – OBR Optional. Set ID Sequence Number			4	R	1
2	Placer Order Number See ORC-2			75	X	
3	Filler Order Number See ORC-3			75	X	
4	Universal Service ID		1 2	25 0	R R	Sample panel. LOINC Number. See Table 68: Loinc Codes (first column) Sample panel. Component/Analyte. See Table 68: Loinc Codes (second column).
5	Priority			2	X	
6	Requested Date/Time			26	X	
7	Observation Date/Time			26	X	
8	Observation End Date/Time			26	X	
9	Collection Volume		1	20	X	
10	Collector Identifier			60	X	
11	Specimen Action Code	"O" (Specimen obtained by service other than Lab)		1	R	"O"
12	Danger Code			60	X	
13	Relevant Clinical Info.			30 0	X	
14	Specimen Received Date/Time			26	X	

15	Specimen Source. e.g., BLDA^^LLFA^^P (Patient test from arterial blood taken from left lower forearm). Optional in the spec	The specimen source name	1	30	R	Patient Sample types are described in table "PATIENT SAMPLE TYPES" in section Tables
		Free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable.	2	0	X	
		Free text component describing the method of collection	3		R	Sample size and container. See below.
		Body site from which the specimen was obtained.	4		X	
		Site modifier. For example, the site could be antecubital fossa, and the site modifier "right."	5		X	
		Indicates whether the specimen is frozen as part of the collection method. If the component is blank, the specimen is assumed to be at room temperature.	6		X	
16	Ordering Provider e.g., Smith^John^J^Dr Order Callback Phone Number	Sample Role.	7	80	R	"P"
				0	O	<i>Ordering Clinician ID</i>
				40	X	
18	Placer Field 1			60	X	
19	Placer Field 2			60	X	
20	Filler Field 1			60	X	
21	Filler Field 2			60	X	
22	Results Rpt/Status Chng – Date/Time			26	X	
23	Charge to Practice			40	X	
24	Diagnostic Serv Sect ID			10	X	
25	Result Status			1	X	
26	Parent Result			40	X	
27	Quantity/Timing			0	X	
28	Result Copies To			20	X	
29	Parent			0	X	
30	Transportation Mode			15	X	
31	Reason for Study			0	X	
32	Principal Result Interpreter			20	X	
33	Assistant Result Interpreter			0	X	
34	Technician			20	X	
35	Transcriptionist			0	X	
36	Scheduled Date/Time			26	X	

**OBR-15.3:** This component shall contain

- Sample size: "N" (Gem3500 instruments support only normal sample size).
- A dash ("–").
- Container used: "U" (Gem3500 instruments do not manage the sample container size.).

Example: "N-U"

#### 4.5.1.1.6 Operator Comment (related to message) – NTE (MSG)

The operator comment shall be sent on this NTE segment only if the “Sample segment information” is configured as “Notes and Comments (NTE)” (See Volume 3, High Level Protocol Setup).

TABLE 14: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. NTE (MSG)

<i>File Id</i>	<i>Field Name</i>	<i>Description [INFO]</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Set ID – NTE			4	R	As only one NTE record is sent in HL7, it will have always value “1”
2	Source of Comment			8	X	
3	Comment			64 k	RE	See below.

Format is as follows:

<i>Compo- nent</i>	<i>Length</i>	<i>Require d</i>	<i>Contents</i>
1	7	R	“COMMENT”
2	14	R	Date Time the comment was performed, in YYYYMMDDHHMMSS format.
3	24	O	Operator ID.
4	255	O	Comment Text

Example: “COMMENT,20053112173456,ggalilei,Eppur si muove”

#### 4.5.1.1.7 Observation Result Segment – OBX

TABLE 15: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. OBX

<i>File Id</i>	<i>Field Name</i>	<i>Description [INFO]</i>	<i>Co mp</i>	<i>Len</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Set ID Optional.	Provided by some Devices.		10	R	Sequence number 1,2, 3...
2	Value Type	All POCT1 values are “ST” (string).		2	R	“ST”
3	Observation Identifier		1	590	X	
			2		X	
			3		X	
			4		R	Parameter Name See description below
			5		X	
			6		X	
			20		X	
4	Observation Sub-ID					
5	Observation Value	E.g., “150,” “<50,” “HI,” “LO”	6553	RE		Parameter Value. See description below
6	Units “mg/dL” or similar		6	60	RE	Parameter Units. See description below
7	References Range	70^mg/dl-105^mg/dl	60	O		See note below.

8	Abnormal Flags.		40	RE	See note below.
9	Probability		5	X	
10	Nature of Abnormal Test		2	X	
11	Result Status		1	R	"F" (valid result) or "X" (result has an error)
12	Date Last Observed Normal Values		26	X	
13	User Defined Access Checks		20	X	
14	Date/Time of the Observation	Format is CCYYMMDDHHMMSS	26	O	Date and time the instrument completed the test.
15	Producer's ID		60	X	
16	Responsible Observer POC User ID^optional Last^First name	Operator who performed the analysis	1	80	O <i>Operator Run ID</i> (only the first result)
			2		O <i>Operator Run Last Name</i> (only the first result) (note: for future use)
			3		O <i>Operator Run First Name</i> (only the first result) (note: for future use)
			4		O <i>Operator Run Middle Initial</i> (only the first result) (note: for future use)
			60		O <i>Null</i>
17	Observation Method				
18	Equipment Instance Identifier IEEE EUI-64 format.		22	O	Serial number of the instrument that performed the test or the calculation. Only needed in the first result
19	Date/Time of Analysis	The timestamp when the Device performed the test. Format is CCYYMMDDHHMMSS	26	O	Date and time the instrument completed the test. Only needed in the first result

A Result record **shall** be transmitted for a parameter if the parameter is part of the test panel selected for the sample. If the parameter is not part of the test panel that was selected for the sample, no Result record will be transmitted for that parameter.

Results **shall** always be sent using the format defined in Volume 3.

Decimal separator **shall** be always the default (1234.56).

Note that the standard does not specify that Result records be transmitted in a particular order.

**OBX-3:** Field OBX-3.4 contains one of the parameter names listed in the section related to the ASTM result record (see page 37).

**OBX-6:** Parameter units (OBX-6) **shall** be sent in the display units configured in the system.

Available units are described in Volume 3.

**OBX-7:** The reference range values (OBX-7) **shall** be encoded using the following scheme:

- If both lower (lo) and upper (hi) limit are known:  
`lo_value^lo_units-hi_value^hi_units` (e.g., 70^mg/dl-105^mg/dl)
  - If only the lower limit is known:  
`>lo_value^lo_units` (e.g., >70^mg/dl)
  - If only the upper limit is known:  
`<hi_value^hi_units` (e.g., <105^mg/dl)
- (note: POCT1-A specs specify a length of 10, which is not enough even for the examples).

The range to be reported shall be:

- Reference (normal) range, if the patient normal range is defined for this observation
- critical range, if the patient normal range is not defined and the critical range is defined

**OBX-8:** Possible values are:

- Null: Reference ranges are unknown or result value not available (see Table 16: ORI. HL7. Upload Patient Sample Results to HIS/LIS/CIS. Message 1. OBX. Exception Handling16 below)
- "LL": Below lower critical ranges.
- "L": Below low reference (normal) ranges.
- "N": Inside reference ranges.
- "H": Above high reference (normal) ranges.
- "HH": Above upper critical ranges.

Exceptions are handled according Table 16: ORI. HL7. Upload Patient Sample Results to HIS/LIS/CIS. Message 1. OBX. Exception Handling16:

TABLE 16: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1.  
OBX. EXCEPTION HANDLING

Exception	Field contents			
	OBX-5	OBX-7, OBX-8	OBX-11	NTE-3
(no exception)	Actual Value	Yes, when available	"F"	(no NTE segment)
Slope Failure	Null	No	"X"	Y^""
Drift Failure	Null	No	"X"	Y^""
Incalculable	Null	No	"X"	C^""
QC Blankout	Null	No	"X"	E^""
Below reportable range	Low reportable range	Yes, when available	"X"	<^""
Above reportable range	High reportable range	Yes, when available	"X"	>^""
Uncorrected QC error	Actual Value	Yes, when available	"X"	F^""
Below patient critical range	Actual Value	Yes, when available	"X"	(no NTE segment)
Above patient critical range	Actual Value	Yes, when available	"X"	(no NTE segment)
Below patient normal range	Actual Value	Yes, when available	"X"	(no NTE segment)
Above patient normal range	Actual Value	Yes, when available	"X"	(no NTE segment)
External Error	Actual Value	Yes, when available	"X"	X^""
External Timeout	Null	No	"X"	X^""
CVP Pending	Null	No	"X"	F^""
CVP Error	Null	No	"X"	F^""
Interference	Actual Value	Yes, when available	"X"	I^""
Blood clot detected	Actual Value	Yes, when available	"X"	T^""
Reference Shift	Actual Value	Yes, when available	"X"	M^""
Above linearity Range	Actual Value	Yes, when available	"X"	A^""

Note: Error X is reserved for external instruments.

#### 4.5.1.1.7.1 Special fields sent in the OBX segment.

Sample related information different than Sample results **shall** be sent on the OBX segment only if “Sample segment information” is configured as “Observation Result (OBX)” (See Volume 3, High Level Protocol Setup).

The OBX segment shall be used to send other Sample related information, different than Sample results, that needs to be processed by the LIS vendor drivers. These new records **shall** be appended

at the end of the regular Observation results. As a result of that, all the Sample related information specified below **shall** have the following fields values in common:

- **OBX-1**: They **shall** continue the incremental sequential value defined by the regular OBX data.
- **OBX-2**: They **shall** have the same value as in the regular OBX information. This is a fixed value of 'ST'.
- **OBX-11**: They **shall** have a fixed value of 'F'. Therefore all Sample related field values shall be considered valid results.

The concrete Sample related fields sent in the OBX segment **shall** be:

1. Patient Age. If there is not Patient Age information, no Patient Age record shall be sent:

<b>Compo- nent</b>	<b>Length</b>	<b>Require d</b>	<b>OBX Record</b>	<b>Contents</b>	<b>Description</b>
Patient age tag	11	R	OBX-3	"Patient Age"	
Patient age	3	R	OBX-5	Patient Age	
Units	2	R	OBX-6	Units. Units for age are described in §Age Units	

2. Operator comments to the sample. Only one comment per sample is supported. If there are no comments related to the Sample being sent, no Comment records shall be sent:

<b>Compo- nent</b>	<b>Length</b>	<b>Required</b>	<b>OBX Record</b>	<b>Contents</b>	<b>Description</b>
Comment tag	7	R	OBX-3	"COMMENT"	
Comment sequence	20	R	OBX-4	Sequence number to identify the comment position in the comment list scope. It will start from value 1.	Since only one comment per sample is supported, this field shall always contain 1
Comment text	255	O	OBX-5	Comment text	
Datetime	14	R	OBX-14	Date Time the comment was performed, in YYYYMMDDHHMMSS format.	
Operador id	24	O	OBX-16 (1)	Operator ID.	
Operador lastname	24	O	OBX-16 (2)	Operator Last Name (note: for future use)	
Operator firstname	24	O	OBX-16 (3)	Operator First Name (note: for future use)	
Operator Middle initial	1	O	OBX-16 (4)	Operator Middle Initial (note: for future use)	

*(Note: Sample drawn date, sample drawn time, User-defined patient and sample demographics fields, edited fields information, Operator's notification of the sample results to a clinician fields are not supported by the GEM 3500)*

Please, note that the defined length, requirement and value constraints defined in the tables listed above do not contradict the general OBX segment requirements defined in *Table 18*. This is to keep consistency with HL7 protocol and POCT1-A standard.

This specific OBX records will not have NTE related records.

#### 2.0.0.0.8 Notes and Comment Segment (related to Observation) – NTE (OBX)

TABLE 17: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. NTE (MSG)

<i>Field Id</i>	<i>Field Name</i>	<i>Description /INFO/</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Set ID – NTE			4	R	As only one NTE record is sent in HL7, it will have always value “1”
2	Source of Comment			8	X	
3	Comment			64 k	RE	See Below.

The comment field shall be set as defined in Table 16: ORI. HL7. Upload Patient Sample Results to HIS/LIS/CIS. Message 1. OBX. Exception Handling16.

Example: " NTE | 1 | F^""<CR>"

#### 2.0.0.2 Message 2: ACK (downloading)

This message shall be a downloading message.

Shall have the structure defined in the following table.

TABLE 18: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 2

<i>Message</i>	<i>Comments</i>
MSH	See §Message Header Segment – MSH: Message Header Segment – MSH

MSA

See §General Acknowledgement Segment – MSA: General Acknowledgement Segment – MSA

#### 4.5.1.2.1 Message Header Segment – MSH

TABLE 19: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 2. MSH

<b>File Id</b>	<b>Field Name</b>	<b>Description [INFO]</b>	<b>Co mp</b>	<b>Le n</b>	<b>Re q</b>	<b>Values, formats and comments</b>
1	Field Separator			1	R	"   "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)		18 0	RE	Ignored by the GEM
4	Sending Facility			18 0	RE	Ignored by the GEM
5	Receiving Application			18 0	RE	Ignored by the GEM
6	Receiving Facility			18 0	RE	Ignored by the GEM
7	Date/Time Of Message	Date time the message was generated (HL7/ ASTM format).		26	R	YYYYMMDDHHMMSS
8	Security			40	X	
9	Message Type			7	R	"ACK"
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 – 4294967295
11	Processing ID	"T/D/P": Training/Debug/Production		3	R	"P". Ignored by the GEM
12	Version ID			8	R	"2.4". Ignored by the GEM
13	Sequence Number			15	X	
14	Continuation Pointer			18 0	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"		2	R	"NE"
16	Application Acknowledgement Type	All ORU messages will specify "AL"		2	R	"NE"
17	Country Code	Not used by GEM		2	RE	Ignored by the GEM

#### 4.5.1.2.2 General Acknowledgement Segment – MSA

TABLE 20: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 2. MSA

<b>File Id</b>	<b>Field Name</b>	<b>Description [INFO]</b>	<b>Co mp</b>	<b>Le n</b>	<b>Re q</b>	<b>Values, formats and comments</b>
1	Acknowledgement Code	"CA," "CE," "CR," "AA," "AE," "AR"		2	R	"CA" / "CE" / "CR"
2	Message Control ID	From MSH-10 of associated message		20	R	0 – 4294967295
3	Text Message			80	O	Text description. Empty if "CA"
4	Expected Sequence Number			15	X	
5	Delayed Acknowledgement Type			1	X	

6	Error Condition	Coded Error		10 0	O	Coded Error
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Notes:

**MSA-1:** Possible values are:

- “CA”: Message accepted.
- “CE”: Error (message not accepted).
- “CR”: Rejection (message not accepted).

Upon reception of the message, the GEM shall remove the record from the transmission queue

If the message has not been accepted, the SW the event shall be traced indicating the contents of MSA-3 and MSA-6.

#### 4.5.1.3 Message 3/3E: ACK^R33 (downloading)

This message shall be a downloading message.

Once the HIS/LIS/CIS has processed the message, it returns the result of the processing using this message.

Shall have the structure defined in the following table.

TABLE 21: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 2

Message	Comments
MSH	See §Message Header Segment – MSH: Message Header Segment – MSH
MSA	See §General Acknowledgement Segment – MSA: General Acknowledgement Segment – MSA

##### 4.5.1.3.1 Message Header Segment – MSH

TABLE 22: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 3. MSH

File Id	Field Name	Description [INFO]	Co mp	Le n	Re q	Values, formats and comments
1	Field Separator			1	R	“ ”
2	Encoding Characters			4	R	“^~\&”
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)		18 0	RE	Ignored by the GEM
4	Sending Facility			18 0	RE	Ignored by the GEM
5	Receiving Application			18 0	RE	Ignored by the GEM
6	Receiving Facility			18 0	RE	Ignored by the GEM
7	Date/Time Of Message	Date time the message was generated (HL7/ ASTM format).		26	R	YYYYMMDDHHMMSS
8	Security			40	X	
9	Message Type	ORU^R30, ORU^R31, ORU^R32, ACK^R33.		7	R	“ACK^R33”

10	Message Control ID	Unique identifier for the message (32 bits PK).	20	R	0 – 4294967295
11	Processing ID	“T/D/P”: Training/Debug/Production	3	R	“P”. Ignored by the GEM
12	Version ID		8	R	“2 . 4”. Ignored by the GEM
13	Sequence Number		15	X	
14	Continuation Pointer		18 0	X	
15	Accept Acknowledgement Type	All source messages should specify “AL”	2	R	“AL” (always)
16	Application Acknowledgement Type	All ORU messages will specify “AL”	2	R	“NE” (never)
17	Country Code	Not used by GEM	2	RE	Ignored by the GEM

#### 4.5.1.3.2 General Acknowledgement Segment – MSA

TABLE 23: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 3. MSA

<i>File Id</i>	<i>Field Name</i>	<i>Description /INFO/</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Acknowledgement Code	“CA,” “CE,” “CR,” “AA,” “AE,” “AR”		2	R	“AA” / “AE” / “AR”
2	Message Control ID	From MSH-10 of associated message		20	R	0 – 4294967295
3	Text Message Note (2)			80	O	Text description
4	Expected Sequence Number			15	X	
5	Delayed Acknowledgement Type			1	X	
6	Error Condition	Coded Error		10 0	O	Coded Error

Notes:

**MSA-1:** Possible values are:

- “AA”: Message accepted.
- “AE”: Error (message not accepted).
- “AR”: Rejection (message not accepted).

If the message has not been accepted, the SW event shall be traced indicating the contents of MSA-3 and MSA-6.

Note (Informative only): This message will be used in the future to receive “returned orders”.

#### 4.5.1.4 Message 4/4E: ACK (uploading)

This message **shall** be an uploading message.

**Shall** have the structure defined in the following table.

TABLE 24: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS.

<i>Message</i>	<i>Comments</i>
MSH	See §Message Header Segment – MSH: Message Header Segment – MSH
MSA	See §General Acknowledgement Segment – MSA: General Acknowledgement Segment – MSA

#### 4.5.1.4.1 Message Header Segment – MSH

TABLE 25: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 4. MSH

<i>Field Id</i>	<i>Field Name</i>	<i>Description /INFO]</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Field Separator			1	R	"   "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)	1 2 3 4 5 6	18 0 18 0 18 0	RE RE RE RE RE	"IL" "GEM Premier 3500" "1.0" (Data Format version) Area Name Analyzer Name Analyzer Model Analyzer Serial Number Cartridge Serial Number Analyzer SW Version Number Null
4	Sending Facility					
5	Receiving Application					
6	Receiving Facility			18 0	RE	Null
7	Date/Time Of Message	Date time the message was generated (HL7/ ASTM format).		26	R	YYYYMMDDHHMMSS
8	Security			40	X	
9	Message Type	ORU^R30, ORU^R31, ORU^R32, ACK^R33.		7	R	"ACK"
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 - 4294967295
11	Processing ID	"T/D/P": Training/Debug/Production		3	R	"P"
12	Version ID			8	R	"2.4"
13	Sequence Number			15	X	
14	Continuation Pointer			18 0	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"		2	R	"NE"
16	Application Acknowledgement Type	All ORU messages will specify "AL"		2	R	"NE"
17	Country Code	Not used by GEM		2	RE	Null

#### 4.5.1.4.2 General Acknowledgement Segment – MSA

TABLE 26: ORI. HL7. UPLOAD PATIENT SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 4. MSA

<i>Field Id</i>	<i>Field Name</i>	<i>Description /INFO]</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Acknowledgement Code	"CA," "CE," "CR," "AA," "AE," "AR"		2	R	"CA"
2	Message Control ID	From MSH-10 of associated message		20	R	0 - 4294967295
3	Text Message Note (2)			80	O	Null

4	Expected Sequence Number		15	X	
5	Delayed Acknowledgement Type		1	X	
6	Error Condition	Coded Error	10 0	O	Null

#### 4.5.1.5 Transmission examples

##### 4.5.1.5.1 Successful upload

###### Message 1 (GEM):

```

MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^^7.0.0.B11
|||20081218121404||ORU^R32|1|P|2.4|||AL|AL|<CR>
PID|1||PAT-345||SMITH^JOHN^||19251218000000|M||||""<CR>
NTE|1||FIELD, Patient Age, 83, YR<CR>
ORC|RE|1234|3<CR>
OBR|1|||24338-6^GAS PANEL||||||O||||BLDA^^N-U^^^^P<CR>
NTE|1||COMMENT, 20081218120605, OPERATOR-123, HELLO<CR>
OBX|1|ST|^^^Ca++||1.11|mmol/L|0.80^mmol/L-0.90^mmol/L|HH|||X|||20081218120605||OPERATOR-
123^^^"||08110003|20081218120605<CR>
OBX|2|ST|^^^Glu||95|mg/dL|80^mg/dL-120^mg/dL|N|||F|||20081218120605|||""||<CR>
OBX|3|ST|^^^Hct||%"||%"|||X|||20081218120605|||""||<CR>
NTE|1||F^<CR>
OBX|4|ST|^^^K+||%"||mmol/L||%"|||X|||20081218120605|||""||<CR>
NTE|1||Y^<CR>
OBX|5|ST|^^^Lac||1.4|mmol/L|1.0^mmol/L-2.0^mmol/L|N|||F|||20081218120605|||""||<CR>
OBX|6|ST|^^^Na+||140|mmol/L|120^mmol/L-130^mmol/L|H|||X|||20081218120605|||""||<CR>
OBX|7|ST|^^^pCO2||77|mmHg|85^mmHg-95^mmHg|LL|||X|||20081218120605|||""||<CR>
OBX|8|ST|^^^pH||7.36||7.30-7.40|N|||F|||20081218120605|||""||<CR>
OBX|9|ST|^^^pO2||81|mmHg|90^mmHg-100^mmHg|L|||X|||20081218120605|||""||<CR>

```

###### Message 2 (HIS/LIS/CIS):

```

MSH|^~\&|Simulator^1.0||||20081218121237||ACK|24|P|2.4|||NE|NE<CR>
MSA|CA|1||||<CR>

```

###### Message 3 (HIS/LIS/CIS):

```

MSH|^~\&|Simulator^1.0||||20081218121237||ACK^R33|25|P|2.4|||AL|NE<CR>
MSA|AA|1||||<CR>

```

###### Message 4 (GEM):

```

MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^^7.0.0.B11
|||20081218121405||ACK|3|P|2.4|||AL|NE|<CR>
MSA|CA|3|||""|||<CR>

```

##### 4.5.1.5.2 HILS/LIS rejects GEM message

###### Message 1 (GEM):

```

MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^^7.0.0.B11
|||20081218121508||ORU^R32|2|P|2.4|||AL|AL|<CR>
PID|1||PAT-345||SMITH^JOHN^||19251218000000|M||||""<CR>
NTE|1||FIELD, Patient Age, 83, YR<CR>
ORC|RE|1234|3<CR>
OBR|1|||24338-6^GAS PANEL||||||O||||BLDA^^N-U^^^^P<CR>

```

```

NTE|1||COMMENT,20081218120605,OPERATOR-123,HELLO<CR>
OBX|1|ST|^^^Ca++||1.11|mmol/L|0.80^mmol/L-0.90^mmol/L|HH|||X|||20081218120605||OPERATOR-
123^^^||"08110003|20081218120605<CR>
OBX|2|ST|^^^Glu||95|mg/dL|80^mg/dL|N|||F|||20081218120605|||""||<CR>
OBX|3|ST|^^^Hct||%"||%||"|||X|||20081218120605|||""||<CR>
NTE|1||F^<CR>
OBX|4|ST|^^^K+||""|mmol/L||"|||X|||20081218120605|||""||<CR>
NTE|1||Y^<CR>
OBX|5|ST|^^^Lac||1.4|mmol/L|1.0^mmol/L-2.0^mmol/L|N|||F|||20081218120605|||""||<CR>
OBX|6|ST|^^^Na+||140|mmol/L|120^mmol/L-130^mmol/L|H|||X|||20081218120605|||""||<CR>
OBX|7|ST|^^^pCO2||77|mmHg|85^mmHg-95^mmHg|LL|||X|||20081218120605|||""||<CR>
OBX|8|ST|^^^pH||7.36||7.30-7.40|N|||F|||20081218120605|||""||<CR>
OBX|9|ST|^^^pO2||81|mmHg|90^mmHg-100^mmHg|L|||X|||20081218120605|||""||<CR>

```

**Message 2 (HIS/LIS/CIS):**

```

MSH|^~\&|Simulator^1.0|||20081218121340||ACK|26|P|2.4|||NE|NE<CR>
MSA|CA|2|||<CR>

```

**Message 3 (HIS/LIS/CIS):**

```

MSH|^~\&|Simulator^1.0|||20081218121341||ACK^R33|27|P|2.4|||AL|NE<CR>
MSA|AR|2|General purpose app reject Message|||<CR>

```

**Message 4 (GEM):**

```

MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^^7.0.0.B11
|||20081218121508||ACK|4|P|2.4|||AL|NE|<CR>
MSA|CA|4|||""|||<CR>

```

**4.5.1.5.3 HIS/LIS/CIS fails to process transmission****Message 1 (GEM):**

```

MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^^7.0.0.B11
|||20081218123237||ORU^R31|2|P|2.4|||AL|AL|<CR>
PID|1|||||^||U|||""||<CR>
ORC|NW||"||4<CR>
OBR|1|||24338-6^GAS PANEL||||||O||||BLDA^^N-U^^^^P<CR>
OBX|1|ST|^^^Ca++||1.11|mmol/L|0.80^mmol/L-0.90^mmol/
L|HH|||X|||20081218121725|||""||08110003|20081218121725<CR>
OBX|2|ST|^^^Glu||95|mg/dL|80^mg/dL|N|||F|||20081218121725|||""||<CR>
OBX|3|ST|^^^Hct||%"||%||"|||X|||20081218121725|||""||<CR>
NTE|1||F^<CR>
OBX|4|ST|^^^K+||""|mmol/L||"|||X|||20081218121725|||""||<CR>
NTE|1||Y^<CR>
OBX|5|ST|^^^Lac||1.4|mmol/L|1.0^mmol/L-2.0^mmol/L|N|||F|||20081218121725|||""||<CR>
OBX|6|ST|^^^Na+||140|mmol/L|120^mmol/L-130^mmol/L|H|||X|||20081218121725|||""||<CR>
OBX|7|ST|^^^pCO2||77|mmHg|85^mmHg-95^mmHg|LL|||X|||20081218121725|||""||<CR>
OBX|8|ST|^^^pH||7.36||7.30-7.40|N|||F|||20081218121725|||""||<CR>
OBX|9|ST|^^^pO2||81|mmHg|90^mmHg-100^mmHg|L|||X|||20081218121725|||""||<CR>

```

**Message 2 (HIS/LIS/CIS):**

```

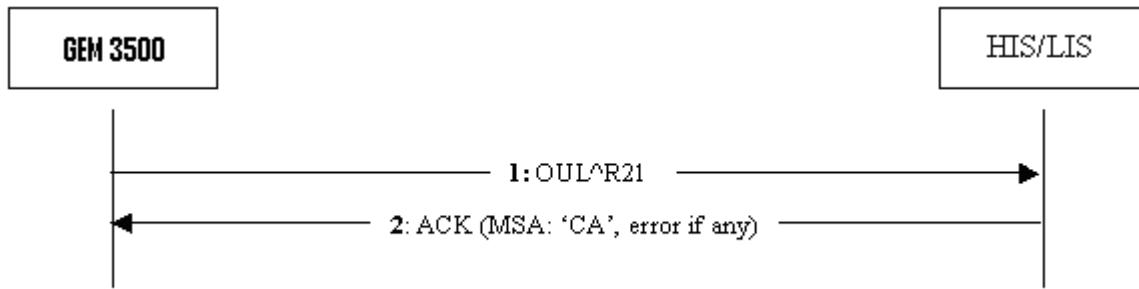
MSH|^~\&|Simulator^1.0|||20081218123110||ACK|37|P|2.4|||NE|NE<CR>
MSA|CE|2|General purpose commit error message|||<CR>

```

**4.5.2 Upload Calibration Results to HIS/LIS/CIS**

The message flow is described in Figure 3: Upload Calibration Results to HIS/LIS/CIS.3.

FIGURE 3: UPLOAD CALIBRATION RESULTS TO HIS/LIS/CIS.



#### 4.5.2.1 Message 1: OUL^R21 (uploading)

This message shall be an uploading message.

Shall have the structure defined in the following table.

TABLE 27: ORI. HL7. UPLOAD CALIBRATION RESULTS TO HIS/LIS/CIS. MESSAGE 1

Message	Comments
MSH	See §Message Header Segment – MSH: Message Header Segment – MSH
SAC	See §Specimen and Container Detail Segment – SAC: Specimen and Container Detail Segment – SAC.
OBR	See §Observation Request Segment – OBR: Observation Request Segment – OBR.
{OBX}	See §Observation Result Segment – OBX: Observation Result Segment – OBX

Note (informative only): This spec follows HL7 v2.4, section 13.5, about QC usage.

Use the 7th component of *OBR-15-specimen source* or *SAC-6-specimen source* to indicate that this is a control specimen. Use *SAC-3-container identifier* for the identification of a control specimen container. The SID segment appended to this SAC segment specifies the manufacturer, lot identifiers, etc. for the control specimen.

The identification of the instrument performing the QC measurement, should be transferred with the *OBX-18-equipment instance identifier*, the measurement data/time with the *OBX-19 date/time of the analysis*.

```

MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY |OUL^R21|MSG00001|P|2.4<cr>
SAC||Q092321^LAS|||SER^^^^^Q|19980620080037|R^PROCESS COMPLETED<cr>
SID|01230^Na|ABCDE-01234567890||04^RD<cr>
ORC|RE|5212498721A|||||^~~~~R<CR>
OBR|1|5212498721A||2951-2^SODIUM^LN||199807240826|||||SER^^^^^Q<CR>
OBX|1|NM|2951-2^SODIUM^LN||24.3|ug/g||N<CR>
  
```

##### 4.5.2.1.1 Message Header Segment – MSH

TABLE 28: ORI. HL7 . UPLOAD CALIBRATION RESULTS TO HIS/LIS/CIS. MESSAGE 1. MSH

Field Id	Field Name	Description /INFO/	Count	Length	Repetition	Values, formats and comments
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"^~\&"

3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)	1	18	RE	"IL"
4	Sending Facility		2	0		"GEM Premier 3500"
			3			"1.0" (Data Format version)
			1	18	RE	<i>Area Name</i>
			2	0		<i>Analyzer Name</i>
			3			<i>Analyzer Model</i>
			4			<i>Analyzer Serial Number</i>
			5			<i>Analyzer Cartridge Serial Number</i>
			6			<i>Analyzer SW Version Number</i>
5	Receiving Application		18	0	RE	Null
6	Receiving Facility		18	0	RE	Null
7	Date/Time Of Message	Date time the message was generated (HL7/ASTM format).	26	R		YYYYMMDDHHMMSS
8	Security		40	X		
9	Message Type		7	R		OUL^R21
10	Message Control ID	Unique identifier for the message (32 bits PK).	20	R		0 - 4294967295
11	Processing ID	"T/D/P": Training/Debug/Production	3	R		"P"
12	Version ID		8	R		"2.4"
13	Sequence Number		15	X		
14	Continuation Pointer		18	0	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"	2	R		"AL"
16	Application Acknowledgement Type		2	R		"NE"
17	Country Code	Not used by GEM	2	RE		Null

**MSH-4:** Items that appear in MSH-4 **shall** refer to those of the analyzer that ran the sample at analysis date time (i.e. cartridge serial number at that time, not current inserted cartridge).

Comments (informative only):

- MSH-15 is set to "AL" (always), so the message requires acknowledge at accept level (which is message 2).
- MSH-16 is set to "NE" (never), so the message does not require acknowledge at application level.

#### 4.5.2.1.2 Specimen and Container Detail Segment – SAC

TABLE 29: ORI. HL7 . UPLOAD CALIBRATION RESULTS TO HIS/LIS/CIS. MESSAGE 1. SAC

<i>Field Id</i>	<i>Field Name</i>	<i>Description [INFO]</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	External Accession Identifier			80	X	
2	Accession Identifier			80	X	
3	Container Identifier			80	X	
4	Primary (parent) Container Identifier			80	X	
5	Equipment Container Identifier			80	X	

6	Specimen Source. e.g., BLDA^^LLFA^^P (Patient test from arterial blood taken from left lower forearm). Optional in the spec	The specimen source name Free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable. Free text component describing the method of collection Body site from which the specimen was obtained. Site modifier. For example, the site could be antecubital fossa, and the site modifier "right." Indicates whether the specimen is frozen as part of the collection method. If the component is blank, the specimen is assumed to be at room temperature.	1 2 3 4 5 6	30 0	X X X X X X
7	Registration Date/Time	Sample Role.	7	26	R "C" X
8	Container Status			25 0	X
9	Carrier Type			25 0	X
10	Carrier Identifier			80	X
11	Position in Carrier			80	X
12	Tray Type - SAC			25 0	X
13	Tray Identifier			80	X
14	Position in Tray			80	X
15	Location			25 0	X
16	Container Height			20	X
17	Container Diameter			20	X
18	Barrier Delta			20	X
19	Bottom Delta			20	X
20	Container Height/Diameter/Delta Units			25 0	X
21	Container Volume			20	X
22	Available Volume			20	X
23	Initial Specimen Volume			20	X
24	Volume Units			25 0	X
25	Separator Type			25 0	X
26	Cap Type			25 0	X
27	Additive			25 0	X
28	Specimen Component			25 0	X
29	Dilution Factor			20	X
30	Treatment			25 0	X
31	Temperature			20	X
32	Hemolysis Index			20	X
33	Hemolysis Index Units			25 0	X
34	Lipemia Index			20	X
35	Lipemia Index Units			25 0	X
36	Icterus Index			20	X
37	Icterus Index Units			25 0	X

38	Fibrin Index		20	X
39	Fibrin Index Units		25 0	X
40	System Induced Contaminants		25 0	X
41	Drug Interference		25 0	X
42	Artificial Blood		25 0	X
43	Special Handling Considerations		25 0	X
44	Other Environmental Factors		25 0	X

#### 4.5.2.1.3 Observation Request Segment – OBR

TABLE 30: ORI. HL7. UPLOAD CALIBRATION RESULTS TO HIS/LIS/CIS. MESSAGE 1. OBR

<i>Field Id</i>	<i>Field Name</i>	<i>Description [INFO]</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Set ID – OBR Optional. Set ID Sequence Number			4	R	1
2	Placer Order Number See ORC-2			75	X	
3	Filler Order Number See ORC-3			75	X	
4	Universal Service ID		1	25 0	X	Calibration Type. See Table 70: Calibration Types70: Calibration Types)
			2		X	
			3		X	
			4		X	
			5		X	
			6		X	
5	Priority			2	X	
6	Requested Date/Time			26	X	
7	Observation Date/Time			26	X	
8	Observation End Date/Time			26	X	
9	Collection Volume			20	X	
10	Collector Identifier			60	X	
11	Specimen Action Code			1	X	
12	Danger Code			60	X	
13	Relevant Clinical Info.			30 0	X	
14	Specimen Received Date/Time			26	X	

15	Specimen Source.	The specimen source name	1	30 0	X	
		Free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable.	2		X	
		Free text component describing the method of collection	3		X	
		Body site from which the specimen was obtained.	4		X	
		Site modifier. For example, the site could be antecubital fossa, and the site modifier "right."	5		X	
		Indicates whether the specimen is frozen as part of the collection method. If the component is blank, the specimen is assumed to be at room temperature.	6		X	
		Sample Role.	7		R	"C"
16	Ordering Provider			80	X	
17	Order Callback Phone Number			40	X	
18	Placer Field 1			60	X	
19	Placer Field 2			60	X	
20	Filler Field 1			60	X	
21	Filler Field 2			60	X	
22	Results Rpt/Status Chng – Date/ Time			26	X	
23	Charge to Practice			40	X	
24	Diagnostic Serv Sect ID			10	X	
25	Result Status			1	X	
26	Parent Result			40 0	X	
27	Quantity/Timing			20 0	X	
28	Result Copies To			15 0	X	
29	Parent			15 0	X	
30	Transportation Mode			20	X	
31	Reason for Study			30 0	X	
32	Principal Result Interpreter			20 0	X	
33	Assistant Result Interpreter			20 0	X	
34	Technician			20 0	X	
35	Transcriptionist			20 0	X	
36	Scheduled Date/Time			26	X	

#### 4.5.2.1.4 Observation Result Segment – OBX

TABLE 31: ORI HL7. UPLOAD CALIBRATION RESULTS TO HIS/LIS/CIS. MESSAGE 1. OBX

<b>Field Id</b>	<b>Field Name</b>	<b>Description /INFO/</b>	<b>Co mp</b>	<b>Len</b>	<b>Re q</b>	<b>Values, formats and comments</b>
1	Set ID Optional.	Provided by some Devices.		10	R	Sequence number 1,2, 3...
2	Value Type	All POCT1 values are "ST" (string).		2	R	"ST"
3	Observation Identifier e.g., ^^^AaDpO2,T&E - a mnemonic identifying the parameter along with a subcomponent specifying the type of observation, in this case [E]stimated).		1	590	X	
			2		X	
			3		X	
			4		R	One of the calibration records. See note at the end of this table.
			5		X	
			6		X	
4	Observation Sub-ID			20	X	
5	Observation Value		6553	RE		Calibration result. Null if incalculable
6	Units "mg/dL" or similar		6	60	RE	Calibration Units. See below.
7	References Range	70^mg/dl-105^mg/dl		10	X	
8	Abnormal Flags.			40	X	
9	Probability			5	X	
10	Nature of Abnormal Test			2	X	
11	Result Status			1	R	"F" (valid result) or "X" (calibration failure)
12	Date Last Observed Normal Values			26	X	
13	User Defined Access Checks			20	X	
14	Date/Time of the Observation	Format is CCYYMMDDHHMMSS		26	O	Date and time the instrument completed the calibration
15	Producer's ID			60	X	
16	Responsible Observer POC User ID^optional Last^First name			80	X	
17	Observation Method			60	X	
18	Equipment Instance Identifier IEEE EUI-64 format.			22	O	Serial number of the instrument that performed the calibration. Only needed in the first result.
19	Date/Time of Analysis	The timestamp when the Device performed the test. Format is CCYYMMDDHHMMSS		26	O	Date and time the instrument completed the calibration. Only needed in the first result.

Calibration records (Field 3 – component 4) are defined in the following tables:

- Table 71: Upload Calibration Results to HIS/LIS/CIS. Uploading Message. Calibration records (table 1 / 2)  
**71: Upload Calibration Results to HIS/LIS/CIS. Uploading Message. Calibration records (table 1 / 2)**
- Table 72: Upload Calibration Results to HIS/LIS/CIS. Uploading Message. Calibration records (table 2 / 2)  
**72: Upload Calibration Results to HIS/LIS/CIS. Uploading Message. Calibration records (table 2 / 2)**

A Result record **shall** be transmitted if the record is reported for a calibration. Otherwise, no record shall be transmitted for that parameter

Note that the standard does not specify that Result records be transmitted in a particular order.

Results **shall** always be sent using the format defined in Volume 3.

Decimal separator **shall** be always the default (1234.56).

Parameter units **shall** be sent in the default units. Default units are described in Volume 3.

#### 4.5.2.2 Message 2: ACK (downloading)

This section is identical to §Message 2: ACK (downloading)

#### 4.5.2.3 Transmission examples

##### 4.5.2.3.1B calibration

###### Message 1 (GEM):

```
SH|~~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^^7.0.0.B9
|||20081209121434||OUL^R21|1|P|2.4|||AL|NE|<CR>
SAC|||||^~~~~~C<CR>
OBR|1|ST|^^^BCal|||||||^~~~~~C<CR>
OBX|1|ST|^^^Ca++MeasuredB||1.13|mmol/L||||F|||20081209121431|||08110003|20081209121431<CR>
OBX|2|ST|^^^Ca++DriftB||0.00|mmol/L||||F|||20081209121431|||<CR>
OBX|3|ST|^^^GluMeasuredB||0|mg/dL||||F|||20081209121431|||<CR>
OBX|4|ST|^^^GluDriftB||0|mg/dL||||F|||20081209121431|||<CR>
OBX|5|ST|^^^HctMeasuredB||11|%||||F|||20081209121431|||<CR>
OBX|6|ST|^^^HctDriftB||0|%||||F|||20081209121431|||<CR>
OBX|7|ST|^^^LacMeasuredB||0.0|mmol/L||||F|||20081209121431|||<CR>
OBX|8|ST|^^^LacDriftB||0.0|mmol/L||||F|||20081209121431|||<CR>
OBX|9|ST|^^^Na+MeasuredB||143|mmol/L||||F|||20081209121431|||<CR>
OBX|10|ST|^^^Na+DriftB||0|mmol/L||||F|||20081209121431|||<CR>
OBX|11|ST|^^^pCO2MeasuredB||33|mmHg||||F|||20081209121431|||<CR>
OBX|12|ST|^^^pCO2DriftB||0|mmHg||||F|||20081209121431|||<CR>
OBX|13|ST|^^^pHMeasuredB||7.41|||||F|||20081209121431|||<CR>
OBX|14|ST|^^^pHDriftB||0.00|||||F|||20081209121431|||<CR>
OBX|15|ST|^^^pO2MeasuredB||172|mmHg||||F|||20081209121431|||<CR>
OBX|16|ST|^^^pO2DriftB||0|mmHg||||F|||20081209121431|||<CR>
```

###### Message 2 (HIS/LIS/CIS):

```
MSH|~~\&|Simulator^1.0|||20081209121306||ACK|24|P|2.4|||NE|NE<CR>
MSA|CA|1||||<CR>
```

##### 4.5.2.3.2 Two point Calibration

###### Message 1 (GEM):

```
MSH|~~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^^7.0.0.B9
|||20081209121607||OUL^R21|3|P|2.4|||AL|NE|<CR>
SAC|||||^~~~~~C<CR>
OBR|1|ST|^^^2PtCal|||||||^~~~~~C<CR>
OBX|1|ST|^^^Ca++Slope||28|mV/dec||||F|||20081209121559|||08110003|20081209121559<CR>
OBX|2|ST|^^^Ca++DriftA||0.00|mmol/L||||F|||20081209121559|||<CR>
OBX|3|ST|^^^Ca++MeasuredA||2.62|mmol/L||||F|||20081209121559|||<CR>
OBX|4|ST|^^^Ca++DriftB||0.00|mmol/L||||F|||20081209121559|||<CR>
OBX|5|ST|^^^Ca++MeasuredB||1.13|mmol/L||||F|||20081209121559|||<CR>
```

```

OBX|6|ST|^^^GluSlope||24|pA/mg/dL||||F|||20081209121559||||<CR>
OBX|7|ST|^^^GluDriftA||0|mg/dL||||F|||20081209121559||||<CR>
OBX|8|ST|^^^GluMeasuredA||144|mg/dL||||F|||20081209121559||||<CR>
OBX|9|ST|^^^GluDriftB||0|mg/dL||||F|||20081209121559||||<CR>
OBX|10|ST|^^^GluMeasuredB||0|mg/dL||||F|||20081209121559||||<CR>
OBX|11|ST|^^^HctSlope||92|mV/mho||||F|||20081209121559||||<CR>
OBX|12|ST|^^^HctDriftA||0|%||||F|||20081209121559||||<CR>
OBX|13|ST|^^^HctMeasuredA||22|%||||F|||20081209121559||||<CR>
OBX|14|ST|^^^HctDriftB||0|%||||F|||20081209121559||||<CR>
OBX|15|ST|^^^HctMeasuredB||11|%||||F|||20081209121559||||<CR>
OBX|16|ST|^^^LacSlope||75|pA/mg/dL||||F|||20081209121559||||<CR>
OBX|17|ST|^^^LacDriftA||0.0|mmol/L||||F|||20081209121559||||<CR>
OBX|18|ST|^^^LacMeasuredA||3.1|mmol/L||||F|||20081209121559||||<CR>
OBX|19|ST|^^^LacDriftB||0.0|mmol/L||||F|||20081209121559||||<CR>
OBX|20|ST|^^^LacMeasuredB||0.0|mmol/L||||F|||20081209121559||||<CR>
OBX|21|ST|^^^Na+|Slope||58|mV/dec||||F|||20081209121559||||<CR>
OBX|22|ST|^^^Na+|DriftA||0|mmol/L||||F|||20081209121559||||<CR>
OBX|23|ST|^^^Na+|MeasuredA||102|mmol/L||||F|||20081209121559||||<CR>
OBX|24|ST|^^^Na+|DriftB||0|mmol/L||||F|||20081209121559||||<CR>
OBX|25|ST|^^^Na+|MeasuredB||143|mmol/L||||F|||20081209121559||||<CR>
OBX|26|ST|^^^pCO2Slope||49|mV/dec||||F|||20081209121559||||<CR>
OBX|27|ST|^^^pCO2DriftA||0|mmHg||||F|||20081209121559||||<CR>
OBX|28|ST|^^^pCO2MeasuredA||63|mmHg||||F|||20081209121559||||<CR>
OBX|29|ST|^^^pCO2DriftB||0|mmHg||||F|||20081209121559||||<CR>
OBX|30|ST|^^^pCO2MeasuredB||33|mmHg||||F|||20081209121559||||<CR>
OBX|31|ST|^^^pHSlope||59|mV/dec||||F|||20081209121559||||<CR>
OBX|32|ST|^^^pHDriftA||-0.00||||F|||20081209121559||||<CR>
OBX|33|ST|^^^pHMeasuredA||6.91||||F|||20081209121559||||<CR>
OBX|34|ST|^^^pHDriftB||0.00||||F|||20081209121559||||<CR>
OBX|35|ST|^^^pHMeasuredB||7.41||||F|||20081209121559||||<CR>
OBX|36|ST|^^^pO2Slope||18|pA/mmHg||||F|||20081209121559||||<CR>
OBX|37|ST|^^^pO2DriftA||0|mmHg||||F|||20081209121559||||<CR>
OBX|38|ST|^^^pO2MeasuredA||118|mmHg||||F|||20081209121559||||<CR>
OBX|39|ST|^^^pO2DriftB||0|mmHg||||F|||20081209121559||||<CR>
OBX|40|ST|^^^pO2MeasuredB||172|mmHg||||F|||20081209121559||||<CR>

```

#### **Message 2 (HIS/LIS/CIS):**

```

MSH|^~\&|Simulator^1.0||||20081209121438||ACK|26|P|2.4|||NE|NE<CR>
MSA|CA|3||||<CR>

```

#### **4.5.2.3.3C Calibration**

##### **Message 1 (GEM):**

```

MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^7.0.0.B9
|||20081209122206||OUL^R21|7|P|2.4|||AL|NE<CR>
SAC|||||^^^^^C<CR>
OBR|1|||||^CCal|||||^^^^^C<CR>
OBX|1|ST|^^^pCO2MeasuredC||42|mmHg||||F|||20081209122204|||08110003|20081209122204<CR>
OBX|2|ST|^^^pCO2DriftC||0|mmHg||||F|||20081209122204||||<CR>
OBX|3|ST|^^^pHMeasuredC||7.36||||F|||20081209122204||||<CR>
OBX|4|ST|^^^pHDriftC||0.00||||F|||20081209122204||||<CR>
OBX|5|ST|^^^pO2MeasuredC||1|mmHg||||F|||20081209122204||||<CR>
OBX|6|ST|^^^pO2DriftC||0|mmHg||||F|||20081209122204||||<CR>

```

##### **Message 2 (HIS/LIS/CIS):**

```

MSH|^~\&|Simulator^1.0||||20081209122037||ACK|30|P|2.4|||NE|NE<CR>

```

MSA | CA | 7 | | | &lt;CR&gt;

### 4.5.3 Upload iQM-CVP Results to HIS/LIS/CIS

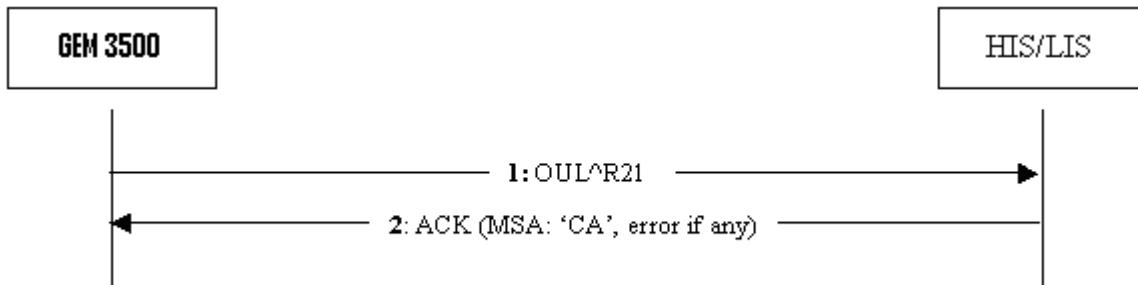
#### 4.5.3.1 When CVP Results are Transmitted

CVP sample results are transmitted to the interface whenever a CVP sample is run and accepted by the operator. For the sample to be transmitted, one of the analyzer's interfaces must be configured for sending of the iQM data. The receiving computer generates the iQM CVP Monthly Report from the individual CVP results received during that month.

#### 4.5.3.2 CVP Sample Results Message Flow

The message flow is described in the following figure.

FIGURE 4: UPLOAD CVP RESULTS TO HIS/LIS/CIS.



#### 4.5.3.3 Message 1: OUL^R21 (uploading)

This message shall be an uploading message.

Shall have the structure defined in the following table.

TABLE 32: ORI. HL7. UPLOAD CVP SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1

<b>Message</b>	<b>Comments</b>
MSH	See §Message Header Segment – MSH: Message Header Segment – MSH
SAC	See §Specimen and Container Detail Segment – SAC: Specimen and Container Detail Segment – SAC
SID	See §Substance Identifier Segment – SID: Substance Identifier Segment – SID
[NTE]	See §Notes and Comment Segment – NTE: Notes and Comment Segment – NTE
OBR	See §Observation Request Segment – OBR: Observation Request Segment – OBR
{	
OBX	See §Observation Result Segment – OBX: Observation Result Segment – OBX
[NTE]	See §Notes and Comment Segment (related to Observation) – NTE (OBX): Notes and Comment Segment (related to Observation) – NTE (OBX)
}	

Note (informative only): This spec follows HL7 v2.4, section 13.5, about QC usage.

Use the 7th component of *OBR-15-specimen source* or *SAC-6 -specimen source* to indicate that this is a control specimen. Use *SAC-3-container identifier* for the identification of a control specimen container. The SID segment appended to this SAC segment specifies the manufacturer, lot identifiers, etc. for the control specimen.

The identification of the instrument performing the QC measurement, should be transferred with the *OBX-18-equipment instance identifier*, the measurement data/time with the *OBX-19 date/time of the analysis*.

```
MSH|^~\&|INSTPROG|AUTINST|LASPROG|LASSYS|19980630080040|SECURITY |OUL^R21|MSG00001|P|2.4|<cr>
SAC|||Q092321^LAS|||SER~~~~~Q|19980620080037|R^PROCESS COMPLETED<cr>
SID|01230^Na|ABCDE-01234567890||04^RD<cr>
ORC|RE|5212498721A|||||^~\>R<CR>
OBR|1|5212498721A||2951-2^SODIUM^LN|||199807240826|||||SER~~~~~Q<CR>
OBX|1|NM|2951-2^SODIUM^LN||24.3|ug/g||N<CR>
```

#### 4.5.3.3.1 Message Header Segment – MSH

This section is identical to §Message Header Segment – MSH (Upload Calibrations, ORI HL7).

#### 4.5.3.3.2 Specimen and Container Detail Segment – SAC

TABLE 33: ORI\_HL7\_UPLOAD\_CVP\_RESULTS\_TO\_HIS/LIS/CIS. MESSAGE 1. SAC

<i>File Id</i>	<i>Field Name</i>	<i>Description /INFO/</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	External Accession Identifier			80	X	
2	Accession Identifier			80	X	
3	Container Identifier			80	X	
4	Primary (parent) Container Identifier			80	X	
5	Equipment Container Identifier			80	X	
6	Specimen Source. e.g., BLDA^LLFA^P (Patient test from arterial blood taken from left lower forearm). Optional in the spec	The specimen source name	1	30	X	
		Free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable.	2	0	X	
		Free text component describing the method of collection	3		X	
		Body site from which the specimen was obtained.	4		X	
		Site modifier. For example, the site could be antecubital fossa, and the site modifier "right."	5		X	
		Indicates whether the specimen is frozen as part of the collection method. If the component is blank, the specimen is assumed to be at room temperature.	6		X	
		Sample Role.	7		R	"Q"
7	Registration Date/Time			26	X	

8	Container Status		25 0	X	
9	Carrier Type		25 0	X	
10	Carrier Identifier		80	X	
11	Position in Carrier		80	X	
12	Tray Type – SAC		25 0	X	
13	Tray Identifier		80	X	
14	Position in Tray		80	X	
15	Location		25 0	X	
16	Container Height		20	X	
17	Container Diameter		20	X	
18	Barrier Delta		20	X	
19	Bottom Delta		20	X	
20	Container Height/Diameter/Delta Units		25 0	X	
21	Container Volume		20	X	
22	Available Volume		20	X	
23	Initial Specimen Volume		20	X	
24	Volume Units		25 0	X	
25	Separator Type		25 0	X	
26	Cap Type		25 0	X	
27	Additive		25 0	X	
28	Specimen Component		25 0	X	
29	Dilution Factor		20	X	
30	Treatment		25 0	X	
31	Temperature		20	X	
32	Hemolysis Index		20	X	
33	Hemolysis Index Units		25 0	X	
34	Lipemia Index		20	X	
35	Lipemia Index Units		25 0	X	
36	Icterus Index		20	X	
37	Icterus Index Units		25 0	X	
38	Fibrin Index		20	X	
39	Fibrin Index Units		25 0	X	
40	System Induced Contaminants		25 0	X	
41	Drug Interference		25 0	X	
42	Artificial Blood		25 0	X	
43	Special Handling Considerations		25 0	X	
44	Other Environmental Factors		25 0	X	

#### 4.5.3.3.3 Substance Identifier Segment – SID

TABLE 34: ORI. HL7. UPLOAD CVP RESULTS TO HIS/LIS/CIS. MESSAGE 1. SID

<b>Field</b>	<b>Field Name</b>	<b>Description /INFO/</b>	<b>Co mp</b>	<b>Le n</b>	<b>Re q</b>	<b>Values, formats and comments</b>
1	Application / Method Identifier		1	25 0	X	
			2		X	
			3		X	
			4		R	“CVP ” +CVP Lot Level (ex “CVP 1”)
			5		R	CVP Lot Description
2	Substance Lot Number			20	R	CVP Lot Number
3	Substance Container Identifier				X	
4	Substance Manufacturer Identifier			25 0	R	“IL”

#### 4.5.3.3.4 Notes and Comment Segment – NTE

TABLE 35: ORI. HL7. UPLOAD CVP SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. NTE (MSG)

<b>File Id</b>	<b>Field Name</b>	<b>Description /INFO/</b>	<b>Co mp</b>	<b>Le n</b>	<b>Re q</b>	<b>Values, formats and comments</b>
1	Set ID – NTE			4	R	As only one NTE record is sent in HL7, it will have always value “1”
2	Source of Comment			8	X	
3	Comment			64 k	RE	See below.

See section Notes and Comment Segment (related to Observation) – NTE (OBX) (Notes and Comment Segment (related to Observation) – NTE (OBX))

#### 4.5.3.3.5 Observation Request Segment – OBR

TABLE 36: ORI. HL7. UPLOAD CVP RESULTS TO HIS/LIS/CIS. MESSAGE 1. OBR

<b>File Id</b>	<b>Field Name</b>	<b>Description /INFO/</b>	<b>Co mp</b>	<b>Le n</b>	<b>Re q</b>	<b>Values, formats and comments</b>
1	Set ID – OBR Optional. Set ID Sequence Number			4	R	1
2	Placer Order Number See ORC-2			75	X	
3	Filler Order Number See ORC-3			75	X	
4	Universal Service ID		1	25 0	R	CVP panel. (See note after the table)
			2		R	CVP panel. Component/Analyte. (See note after the table)
			3		X	
			4		X	
			5		X	
			6		X	
5	Priority			2	X	
6	Requested Date/Time			26	X	
7	Observation Date/Time			26	X	

8	Observation End Date/Time		26	X	
9	Collection Volume		20	X	
10	Collector Identifier		60	X	
11	Specimen Action Code		1	X	
12	Danger Code		60	X	
13	Relevant Clinical Info.		30 0	X	
14	Specimen Received Date/Time		26	X	
15	Specimen Source.	The specimen source name	1	30	X
		Free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable.	2	0	X
		Free text component describing the method of collection	3		X
		Body site from which the specimen was obtained.	4		X
		Site modifier. For example, the site could be antecubital fossa, and the site modifier "right."	5		X
		Indicates whether the specimen is frozen as part of the collection method. If the component is blank, the specimen is assumed to be at room temperature.	6		X
		Sample Role.	7		R "Q"
16	Ordering Provider		80	X	
17	Order Callback Phone Number		40	X	
18	Placer Field 1		60	X	
19	Placer Field 2		60	X	
20	Filler Field 1		60	X	
21	Filler Field 2		60	X	
22	Results Rpt/Status Chng – Date/Time		26	X	
23	Charge to Practice		40	X	
24	Diagnostic Serv Sect ID		10	X	
25	Result Status		1	X	
26	Parent Result		40 0	X	
27	Quantity/Timing		20 0	X	
28	Result Copies To		15 0	X	
29	Parent		15 0	X	
30	Transportation Mode		20	X	
31	Reason for Study		30 0	X	
32	Principal Result Interpreter		20 0	X	
33	Assistant Result Interpreter		20 0	X	
34	Technician		20 0	X	
35	Transcriptionist		20 0	X	
36	Scheduled Date/Time		26	X	

**Note about field 4:** To be compatible with the GEM4000 SW, the components of field 4 shall be set as follows:

- Component 1: 5
- Component 2:**CVP PANEL**

#### 4.5.3.3.6 Observation Result Segment – OBX

TABLE 37: ORI. HL7. UPLOAD CVP RESULTS TO HIS/LIS/CIS. MESSAGE 1. OBX

<i>Field Id</i>	<i>Field Name</i>	<i>Description /INFO/</i>	<i>Comp</i>	<i>Len</i>	<i>Req</i>	<i>Values, formats and comments</i>
1	Set ID Optional.	Provided by some Devices.		10	R	Sequence number 1,2, 3...
2	Value Type	All POCT1 values are "ST" (string).		2	R	"ST"
3	Observation Identifier e.g., ^^AaDpO2,T&E - a mnemonic identifying the parameter along with a subcomponent specifying the type of observation, in this case [E]stimated).		1	590	X	
			2		X	
			3		X	
			4		R	One of the CVP parameter names. See below
			5		X	
			6		X	
			20		X	
4	Observation Sub-ID					
5	Observation Value		6553	CE		CVP result.
6	Units "mg/dL" or similar		6	CE		CVP Units. See description below
7	References Range	70^mg/dl-105^mg/dl		R		lo_value^lo_units-hi_value^hi_units. See below
8	Abnormal Flags.		40	X		
9	Probability		5	X		
10	Nature of Abnormal Test		2	X		
11	Result Status		1	R		"F" (valid result) or "X" (error)
12	Date Last Observed Normal Values		26	X		
13	User Defined Access Checks		20	X		
14	Date/Time of the Observation	Format is CCYYMMDDHHMMSS	26	O		Date and time the instrument completed the CVP
15	Producer's ID		60	X		
16	Responsible Observer POC User ID^optional Last^First name		80	X		
17	Observation Method		60	X		
18	Equipment Instance Identifier IEEE EUI-64 format.		22	O		Serial number of the instrument that performed the CVP. Only needed in the first result.
19	Date/Time of Analysis	The timestamp when the Device performed the test. Format is CCYYMMDDHHMMSS	26	O		Date and time the instrument completed the CVP. Only needed in the first result.

A Result record **shall** be transmitted if the record is reported for a CVP. Otherwise, no record shall be transmitted for that parameter

Note that the standard does not specify that Result records be transmitted in a particular order.

Results **shall** always be sent using the format defined in Volume 3.

Decimal separator **shall** be always the default (1234.56).

Parameter units **shall** be sent in the display units.

**OBX-3:** Field OBX-3.4 contains one of the parameter names listed in table “FACTORY DEFAULT ANALYTE NAMES” (See section Tables), in the GEM column.

**OBX-6:** Parameter units (OBX-6) **shall** be sent in the display units configured in the system.

Available units are described in Volume 2a.

**OBX-7:** The reference range values (OBX-7) **shall** be encoded using the following scheme:

lo\_value^lo\_units-hi\_value^hi\_units (e.g., 70^mg/dl-105^mg/dl)

Units **shall** be the display units.

#### 4.5.3.3.7 Notes and Comment Segment (related to Observation) – NTE (OBX)

Exceptions are handled according to the following tables:

TABLE 38: ORI. HL7. UPLOAD CVP SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. NTE (MSG)

Field Id	Field Name	Description /INFO/	Com	Len	Req	Values, formats and comments
1	Set ID – NTE			4	R	As only one NTE record is sent in HL7, it will have always value “1”
2	Source of Comment			8	X	
3	Comment			64k	RE	See Table 39: ORI. HL7. Upload CVP Sample Results to HIS/LIS/CIS. Message 1. OBX. Exception Handling39: ORI. HL7. Upload CVP Sample Results to HIS/LIS/CIS. Message 1. OBX. Exception Handling.

TABLE 39: ORI. HL7. UPLOAD CVP SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1.

OBX. EXCEPTION HANDLING

Exception	Field contents		
	OBX-5	OBX-11	NTE-3
(no exception)	Actual Value	“F”	(no NTE segment)
Slope Failure	Null	“X”	Y^“”
Drift Failure	Null	“X”	Y^“”
Incalculable	Null	“X”	C^“”
Below reportable range	Low reportable range	“X”	<^“”
Above reportable range	High reportable range	“X”	>^“”
CVP/QC Failure	Actual Value	“X”	F^“”
External Error	Actual Value	“X”	X^“”
External Timeout	Null	“X”	X^“”

#### 4.5.3.4 Message 2: ACK (downloading)

This section is identical to §Message 2: ACK (downloading)

#### 4.5.3.5 Transmission examples

##### Message 1 (GEM):

```
MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^7.0.0.B11
|||20081218120241||OUL^R21|1|P|2.4|||AL|NE|<CR>
SAC|||||^^^^^Q<CR>
SID|^^^CVP 1^GEM CVP 1|1812||IL<CR>
NTE|1||COMMENT^""^OPERATOR-123^^^^HELLO<CR>
OBR|1|||5^CVP PANEL|||||||||^^^^^Q<CR>
OBX|1|ST|^^^Ca++||1.48|mmol/L|1.48^mmol/L-1.68^mmol/
L||||F|||20081218120209|||08110003|20081218120209<CR>
OBX|2|ST|^^^Glu||40|mg/dL|37^mg/dL-53^mg/dL||||F|||20081218120209|||<CR>
OBX|3|ST|^^^K+||""|mmol/L||||X|||20081218120209|||<CR>
NTE|1||Y^<CR>
OBX|4|ST|^^^Lac||1.0|mmol/L|0.7^mmol/L-1.1^mmol/L||||F|||20081218120209|||<CR>
OBX|5|ST|^^^Na+||129|mmol/L|124^mmol/L-134^mmol/L||||F|||20081218120209|||<CR>
OBX|6|ST|^^^pCO2||65|mmHg|65^mmHg-77^mmHg|||F|||20081218120209|||<CR>
OBX|7|ST|^^^pH||7.21||7.17-7.23||||F|||20081218120209|||<CR>
OBX|8|ST|^^^pO2||48|mmHg|46^mmHg-64^mmHg|||F|||20081218120209|||<CR>
```

##### Message 2 (HIS/LIS/CIS):

```
MSH|^~\&|Simulator^1.0||||20081218120114||ACK|18|P|2.4|||NE|NE|<CR>
MSA|CA|1|||<CR>
```

#### 4.5.4 Upload QC Results to HIS/LIS/CIS [GEM3500 Only]

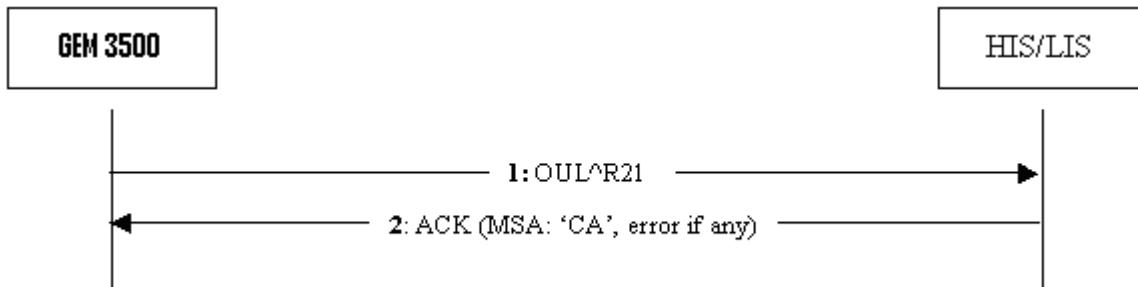
##### 4.5.4.1 When QC Results are Transmitted

QC sample results are transmitted to the interface whenever a QC sample is run and accepted by the operator. For the sample to be transmitted, one of the analyzer's interfaces must be configured for sending of the QC data.

##### QC Sample Results Message Flow

The message flow is described in the following figure.

FIGURE 5: UPLOAD QC RESULTS TO HIS/LIS/CIS.



#### 4.5.4.2 Message 1: OUL<sup>R</sup>21 (uploading)

This message shall be an uploading message.

Shall have the structure defined in the following table.

TABLE 40: ORI HL7. UPLOAD QC SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1

<b>Message</b>	<b>Comments</b>
MSH	See §Message Header Segment – MSH: Message Header Segment – MSH
SAC	See §Specimen and Container Detail Segment – SAC: Specimen and Container Detail Segment – SAC
SID	See §Substance Identifier Segment – SID: Substance Identifier Segment – SID
[NTE]	See §Notes and Comment Segment – NTE: Notes and Comment Segment – NTE
OBR	See §Observation Request Segment – OBR: Observation Request Segment – OBR
{	
OBX	See §Observation Result Segment – OBX: Observation Result Segment – OBX
[NTE]	See §Notes and Comment Segment (related to Observation) – NTE (OBX): Notes and Comment Segment (related to Observation) – NTE (OBX)
}	

##### 4.5.4.2.1 Message Header Segment – MSH

This section is identical to §Message Header Segment – MSH (Upload Calibrations, ORI HL7).

##### 4.5.4.2.2 Specimen and Container Detail Segment – SAC

TABLE 41: ORI\_HL7 . UPLOAD CVP RESULTS TO HIS/LIS/CIS. MESSAGE 1. SAC

<i>File Id</i>	<i>Field Name</i>	<i>Description [INFO]</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	External Accession Identifier			80	X	
2	Accession Identifier			80	X	
3	Container Identifier			80	X	
4	Primary (parent) Container Identifier			80	X	
5	Equipment Container Identifier			80	X	
6	Specimen Source. e.g., BLDA^^LLFA^^P (Patient test from arterial blood taken from left lower forearm). Optional in the spec	The specimen source name	1	30	X	
		Free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable.	2	0	X	
		Free text component describing the method of collection	3		X	
		Body site from which the specimen was obtained.	4		X	
		Site modifier. For example, the site could be antecubital fossa, and the site modifier "right."	5		X	
		Indicates whether the specimen is frozen as part of the collection method. If the component is blank, the specimen is assumed to be at room temperature.	6		X	
7	Registration Date/Time	Sample Role.	7		R	"X"
			26		X	
8	Container Status		25	X		
9	Carrier Type		0	25	X	
10	Carrier Identifier			0	80	X
11	Position in Carrier				80	X
12	Tray Type – SAC				25	X
13	Tray Identifier				0	X
14	Position in Tray				80	X
15	Location				25	X
16	Container Height				0	X
17	Container Diameter				20	X
18	Barrier Delta				20	X
19	Bottom Delta				20	X
20	Container Height/Diameter/Delta Units				25	X
21	Container Volume				0	X
22	Available Volume				20	X
23	Initial Specimen Volume				20	X
24	Volume Units				25	X
25	Separator Type				0	X
26	Cap Type				25	X
27	Additive				0	X
28	Specimen Component				25	X
29	Dilution Factor				0	X

30	Treatment		25 0	X	
31	Temperature		20	X	
32	Hemolysis Index		20	X	
33	Hemolysis Index Units		25 0	X	
34	Lipemia Index		20	X	
35	Lipemia Index Units		25 0	X	
36	Icterus Index		20	X	
37	Icterus Index Units		25 0	X	
38	Fibrin Index		20	X	
39	Fibrin Index Units		25 0	X	
40	System Induced Contaminants		25 0	X	
41	Drug Interference		25 0	X	
42	Artificial Blood		25 0	X	
43	Special Handling Considerations		25 0	X	
44	Other Environmental Factors		25 0	X	

#### 4.5.4.2.3 Substance Identifier Segment – SID

TABLE 42: ORI. HL7. UPLOAD CVP RESULTS TO HIS/LIS/CIS. MESSAGE 1. SID

Field	Field Name	Description /INFO/	Co mp	Le n	Re q	Values, formats and comments
1	Application / Method Identifier		1	25 0	X	
			2		X	
			3		X	
			4		R	"QC" + QC Lot Level
			5		R	QC Lot Description
2	Substance Lot Number			20	R	QC Lot Number
3	Substance Container Identifier				X	
4	Substance Manufacturer Identifier			25 0	R	"IL"

#### 4.5.4.2.4 Notes and Comment Segment – NTE

TABLE 43: ORI. HL7. UPLOAD CVP SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. NTE (MSG)

File Id	Field Name	Description /INFO/	Co mp	Le n	Re q	Values, formats and comments
1	Set ID – NTE			4	R	As only one NTE record is sent in HL7, it will have always value "1"
2	Source of Comment			8	X	
3	Comment			64 k	RE	See below.

The comment record shall be used to send several comments, separated by the repeat character: Format for each comment is as follows:

<b>Component</b>	<b>Requirement</b>	<b>Contents</b>
1	R	"COMMENT"
2	R	Date Time the comment was performed, in YYYYMMDDHHMMSS format.
3	R	Operator Id
4	O	Operator Last Name (note: for future use)
5	O	Operator First Name (note: for future use)
6	O	Operator Middle Initial (note: for future use)
/	R	Comment Text

Example: "COMMENT^20053112173456^ggalilei^^^Eppur si muove"

#### 4.5.4.2.5 Observation Request Segment – OBR

TABLE 44: ORI. HL7. UPLOAD CVP RESULTS TO HIS/LIS/CIS. MESSAGE 1. OBR

<b>Field Id</b>	<b>Field Name</b>	<b>Description /INFO/</b>	<b>Component</b>	<b>Length</b>	<b>Repeat</b>	<b>Values, formats and comments</b>
1	Set ID – OBR Optional. Set ID Sequence Number			4	R	1
2	Placer Order Number See ORC-2			75	X	
3	Filler Order Number See ORC-3			75	X	
4	Universal Service ID		1	25	R	CVP panel: (See below)
			2	0	R	CVP panel. Component/Analyte. (See Below)
			3		X	
			4		X	
			5		X	
			6		X	
5	Priority			2	X	
6	Requested Date/Time			26	X	
7	Observation Date/Time			26	X	
8	Observation End Date/Time			26	X	
9	Collection Volume			20	X	
10	Collector Identifier			60	X	
11	Specimen Action Code			1	X	
12	Danger Code			60	X	
13	Relevant Clinical Info.			30	X	
14	Specimen Received Date/Time			26	X	

15	Specimen Source.	The specimen source name Free text additives to the specimen such as Heparin, EDTA, or Oxlate, when applicable. Free text component describing the method of collection Body site from which the specimen was obtained. Site modifier. For example, the site could be antecubital fossa, and the site modifier "right." Indicates whether the specimen is frozen as part of the collection method. If the component is blank, the specimen is assumed to be at room temperature. Sample Role.	1 2 3 4 5 6 7	30 0	X X X X X X R	"X"
16	Ordering Provider			80	X	
17	Order Callback Phone Number			40	X	
18	Placer Field 1			60	X	
19	Placer Field 2			60	X	
20	Filler Field 1			60	X	
21	Filler Field 2			60	X	
22	Results Rpt/Status Chng – Date/Time			26	X	
23	Charge to Practice			40	X	
24	Diagnostic Serv Sect ID			10	X	
25	Result Status			1	X	
26	Parent Result			40 0	X	
27	Quantity/Timing			20 0	X	
28	Result Copies To			15 0	X	
29	Parent			15 0	X	
30	Transportation Mode			20	X	
31	Reason for Study			30 0	X	
32	Principal Result Interpreter			20 0	X	
33	Assistant Result Interpreter			20 0	X	
34	Technician			20 0	X	
35	Transcriptionist			20 0	X	
36	Scheduled Date/Time			26	X	

**Note about field 4:** The components of field 4 shall be set as follows:

- Component 1: 9
- Component 2:QC PANEL

#### 4.5.4.2.6 Observation Result Segment – OBX

TABLE 45: ORI. HL7. UPLOAD CVP RESULTS TO HIS/LIS/CIS. MESSAGE 1. OBX

<b>Field Id</b>	<b>Field Name</b>	<b>Description [INFO]</b>	<b>Comp</b>	<b>Len</b>	<b>Req</b>	<b>Values, formats and comments</b>
1	Set ID Optional.	Provided by some Devices.		10	R	Sequence number 1,2, 3...
2	Value Type	All POCT1 values are "ST" (string).		2	R	"ST"
3	Observation Identifier e.g., ^^^AaDpO2,T&E - a mnemonic identifying the parameter along with a subcomponent specifying the type of observation, in this case [E]stimated).		1 2 3 4 5 6	590 X X R X X	X X X R X X	One of the QC parameter names. See below
4	Observation Sub-ID			20	X	
5	Observation Value			6553 6	CE	QC result.
6	Units "mg/dL" or similar			60	CE	QC Units. See description below
7	References Range	70^mg/dl-105^mg/dl			R	lo_value^lo_units-hi_value^hi_units. See below
8	Abnormal Flags.			40	X	
9	Probability			5	X	
10	Nature of Abnormal Test			2	X	
11	Result Status			1	R	"F" (valid result) or "X" (error)
12	Date Last Observed Normal Values			26	X	
13	User Defined Access Checks			20	X	
14	Date/Time of the Observation	Format is CCYYMMDDHHMMSS		26	O	Date and time the instrument completed the test
15	Producer's ID			60	X	
16	Responsible Observer POC User ID^optional Last^First name			80	X	
17	Observation Method			60	X	
18	Equipment Instance Identifier IEEE EUI-64 format.			22	O	Serial number of the instrument that performed the QC. Only needed in the first result.
19	Date/Time of Analysis	The timestamp when the Device performed the test. Format is CCYYMMDDHHMMSS		26	O	Date and time the instrument completed the test. Only needed in the first result.

A Result record **shall** be transmitted if the record is reported for a QC. Otherwise, no record shall be transmitted for that parameter

Note that the standard does not specify that Result records be transmitted in a particular order.

Results **shall** always be sent using the format defined in Volume 3.

Decimal separator **shall** be always the default (1234.56).

Parameter units **shall** be sent in the display units.

**OBX-3:** Field OBX-3.4 contains one of the parameter names listed in table "FACTORY DEFAULT ANALYTE NAMES" (See section Tables), in the GEM column.

**OBX-6:** Parameter units (OBX-6) **shall** be sent in the display units configured in the system.

Available units are described in Volume 2a.

**OBX-7:** The reference range values (OBX-7) **shall** be encoded using the following scheme:  
 lo\_value^lo\_units-hi\_value^hi\_units (e.g., 70^mg/dl-105^mg/dl)  
 Units **shall** be the display units.

#### 4.5.4.2.7 Notes and Comment Segment (related to Observation) – NTE (OBX)

Exceptions are handled according to the following tables:

TABLE 46: ORI. HL7. UPLOAD CVP SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. NTE (MSG)

Field Id	Field Name	Description [INFO]	Com	Len	Req	Values, formats and comments
1	Set ID – NTE			4	R	As only one NTE record is sent in HL7, it will have always value “1”
2	Source of Comment			8	X	
3	Comment			64 k	RE	See Table 47: ORI. HL7. Upload QC Sample Results to HIS/LIS/CIS. Message 1. OBX. Exception Handling47: ORI. HL7. Upload QC Sample Results to HIS/LIS/CIS. Message 1. OBX. Exception Handling

TABLE 47: ORI. HL7. UPLOAD QC SAMPLE RESULTS TO HIS/LIS/CIS. MESSAGE 1. OBX. EXCEPTION HANDLING

Exception	Field contents		
	OBX-5	OBX-11	NTE-3
(no exception)	Actual Value	"F"	(no NTE segment)
Slope Failure	Null	"X"	Y^""
Drift Failure	Null	"X"	Y^""
Incalculable	Null	"X"	C^""
Below reportable range	Low reportable range	"X"	<^""
Above reportable range	High reportable range	"X"	>^""
CVP/QC Failure	Actual Value	"X"	F^""
External Error	Actual Value	"X"	X^""
External Timeout	Null	"X"	X^""

#### 4.5.4.3 Message 2: ACK (downloading)

This section is identical to §Message 2: ACK (downloading)

#### 4.5.4.4 Transmission examples

##### Message 1 (GEM):

```
MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^7.0.0.B11
|||20081218123115||OUL^R21|1|P|2.4|||AL|NE|<CR>
SAC|||||^~~~~~X<CR>
SID|^~~QC 2^ContrIL 9, NORMAL|N917||IL<CR>
```

```

NTE|1||COMMENT""^OPERATOR-123^^^Comment text<CR>
OBR|1|||9^QC PANEL|||||||||^^^^^^X<CR>
OBX|1|ST|^^^Ca++||1.11|mmol/L|1.11^mmol/L-1.29^mmol/
L||||F|||20081218123044|||08110003|20081218123044<CR>
OBX|2|ST|^^^Glu||95|mg/dL|83^mg/dL|||F|||20081218123044|||<CR>
OBX|3|ST|^^^Lac||1.4|mmol/L|0.7^mmol/L-1.1^mmol/L|||X|||20081218123044|||<CR>
NTE|1||F^<CR>
OBX|4|ST|^^^Na+||140|mmol/L|135^mmol/L-145^mmol/L|||F|||20081218123044|||<CR>
OBX|5|ST|^^^pCO2||77|mmHg|33^mmHg-41^mmHg|||X|||20081218123044|||<CR>
NTE|1||F^<CR>
OBX|6|ST|^^^pH||7.36||7.41-7.47|||X|||20081218123044|||<CR>
NTE|1||F^<CR>
OBX|7|ST|^^^pO2||81|mmHg|93^mmHg-113^mmHg|||X|||20081218123044|||<CR>
NTE|1||F^<CR>

```

#### **Message 2 (HIS/LIS/CIS):**

```

MSH|^~\&|Simulator^1.0|||20081218122947||ACK|36|P|2.4|||NE|NE<CR>
MSA|CA|1|||<CR>

```

### **4.5.5 Upload iQM CAR Reports to HIS/LIS/CIS**

#### **4.5.5.1 When Corrective Action Report (CAR) Data Are Transmitted**

The CAR data are transmitted to the interface once a day at the time configured for the C calibration to run. For the CAR to be transmitted, one of the analyzer's interfaces must be configured for sending of the iQM data. Each daily transmission of the CAR information contains all the current month-to-date CAR events.

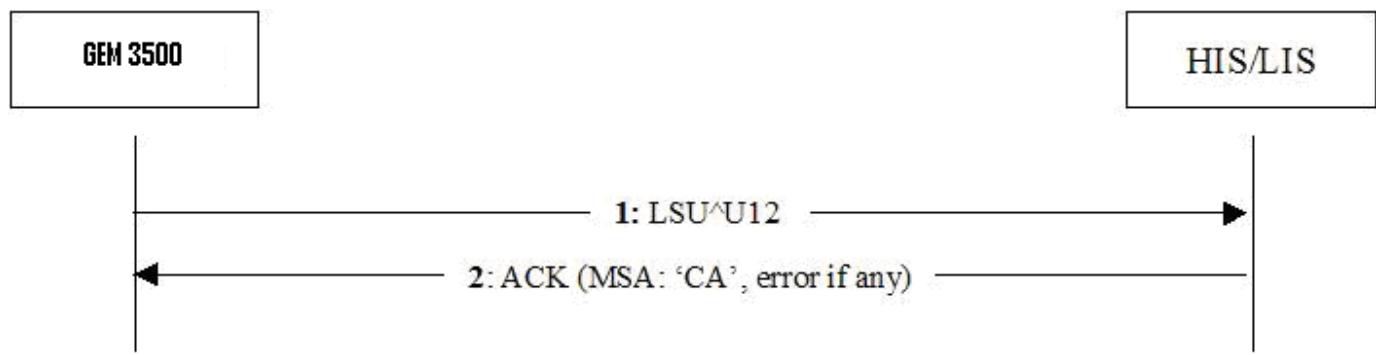
The same CAR data can be transmitted on demand by selecting "Transmit iQM Data" on the Management screen.

The receiving computer generates the iQM CAR Monthly Report from the transmitted CAR information. The format of that report is specified in software specification volume 4a (Data Management).

#### **4.5.5.2 CAR Message Flow**

The message flow is described in the following figure

FIGURE 6: UPLOAD CAR TO HIS/LIS/CIS.



#### **4.5.5.3 Message 1: LSU^U12 (uploading)**

This message shall be an uploading message.

Shall have the structure defined in the following table.

TABLE 48: ORI. HL7. UPLOAD iQM CAR TO HIS/LIS/CIS. MESSAGE 1

<b>Message</b>	<b>Comments</b>
MSH	See §Message Header Segment – MSH Message Header Segment - MSH
EQU	See §Equipment Instance Identifier – EQU: Equipment Instance Identifier – EQU
{ EQP }	See §Equipment Log/Service Segment – EQP: Equipment Log/Service Segment – EQP

#### 4.5.5.3.1 Message Header Segment – MSH

TABLE 49: ORI. HL7 . UPLOAD CAR TO HIS/LIS/CIS. MESSAGE 1. MSH

<b>Field Id</b>	<b>Field Name</b>	<b>Description /INFO/</b>	<b>Com</b>	<b>Len</b>	<b>Req</b>	<b>Values, formats and comments</b>
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)		1	18	RE
				0	0	"IL"
				2		"GEM Premier 3500"
				3		"1.0" (Data Format version)
				1	18	RE
				2	0	Area Name
				3		Analyzer Name
				4		Analyzer Model
				5		Analyzer Serial Number
				6	18	RE
4	Sending Facility			0	0	Cartridge Serial Number(not used)
				1		Analyzer SW Version Number
5	Receiving Application			2	18	RE
				0	0	Null
6	Receiving Facility			18	0	RE Null
7	Date/Time Of Message	Date time the message was generated (HL7/ASTM format).		26	R	YYYYMMDDHHMMSS
8	Security			40	X	
9	Message Type			7	R	LSU^U12
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 – 4294967295
11	Processing ID	"T/D/P": Training/Debug/Production		3	R	"P"
12	Version ID			8	R	"2.4"
13	Sequence Number			15	X	
14	Continuation Pointer			18	0	X
15	Accept Acknowledgement Type	All source messages should specify "AL"		2	R	"AL"
16	Application Acknowledgement Type			2	R	"NE"
17	Country Code	Not used by GEM		2	RE	Null
18	Character set ID			18	0	X
19	Principal language of message	Language		25	0	R nn, being the ISO 639.2 language code for which the iQM report is transmitted. The language code is based on standard defined in the <a href="#">ISO 639.2</a> specification (See language codes defined for ASTM protocol at page 37)

Comments (informative only):

- MSH-15 is set to “AL” (always), so the message requires acknowledge at accept level (which is message 2).

MSH-16 is set to “NE” (never), so the message does not require acknowledge at application level.

#### 4.5.5.3.2 Equipment Instance Identifier – EQU

TABLE 50: ORI, HL7, UPLOAD CAR OR DELTA CHART TO HIS/LIS/CIS, MESSAGE 1, EQU

<i>File Id</i>	<i>Field Name</i>	<i>Description /INFO/</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Equipment Instance Identifier		1	22	R	Analyzer Serial Number
			2		R	“IL”
			3		X	
			4		R	“L” (local namespace)
2	Event Date/Time			26	R	YYYYMM, year and month of the CAR or delta chart
3	Equipment State		25	0	X	
4	Local/Remote Control State		25	0	X	
5	Alert Level		25	0	X	

#### 4.5.5.3.3 Equipment Log/Service Segment – EQP

Each event of the Corrective Action Report shall be reported in an EQP record.

TABLE 51: ORI, HL7, UPLOAD CAR TO HIS/LIS/CIS, MESSAGE 1, EQP

<i>File Id</i>	<i>Field Name</i>	<i>Description /INFO/</i>	<i>Co mp</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Event type			25	R	“LOG”
2	File Name				X	
3	Start Date/Time			14	R	YYYYMMDDHHMMSS date time of the event
4	End Date/Time				X	
5	Transaction Data		1	64	R	“iQM-MCA”
			2		R	Cartridge Lot Number
			3		R	Detected Event Description (in the language of the analyzer)
			4		R	Corrective Action Description (in the language of the analyzer)
			5		R	Corrective Action Result (in the language of the analyzer)

#### 4.5.5.4 Message 2: ACK (downloading)

This section is identical to § Message 2: ACK (downloading)

#### 4.5.5.5 Transmission examples

**Message 1 (GEM):**

```
MSH|^~\&|IL^GEM Premier 3500^1.0||^GEM 3500^08110003^^7.0.0.B9
|||20081209124938||LSU^U12|4|P|2.4|||AL|NE|||en<CR>
EQU|08110003^IL^^L|200111<CR>
EQP|LOG||20011105010003||iQM-MCA^213966^Cartridge Removed. ^Samples Remaining = 0. ^No. of
Solution B Adjustments = 6<CR>
EQP|LOG||20011110070039||iQM-MCA^213966^Interference Detected After Sample# 38.^Operator John
Smith Operator Notified. Sensor Output Adjusted. ^Cleared<CR>
EQP|LOG||20011122012940||iQM-MCA^213966^Cartridge Removed. ^Samples Remaining = 10. ^No. of
Solution B Adjustments = 11<CR>
EQP|LOG||20011123091741||iQM-MCA^213266^Micro Clot Caused Solution Detect Error After Sample #
9^Operator John Smith Operator Notified. Fluidics Checked. ^Corrected<CR>
```

**Message 2 (HIS/LIS/CIS):**

```
MSH|^~\&|Simulator^1.0||||20081209124823||ACK|56|P|2.4|||NE|NE<CR>
MSA|CA|4||||<CR>
```

#### 4.5.6 Upload iQM Delta Chart Data to HIS/LIS/CIS

##### 4.5.6.1 When iQM Delta Chart Data Are Transmitted

The iQM delta chart data are transmitted to the interface once a day at the time configured for the C calibration to run. For the delta chart data to be transmitted one of the analyzer's interfaces must be configured for sending of the iQM data. Each daily transmission of the delta chart data contains all the current month daily data through the previous day, for all the relevant analyte/process control solution combinations. If the transmission is occurring on the first day of the month, it will contain all the previous month daily data.

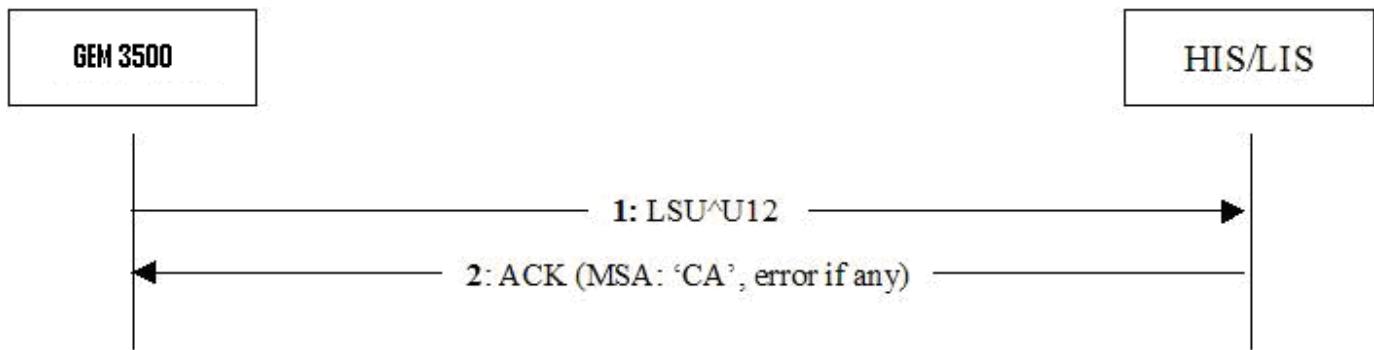
The same delta chart data can be transmitted on demand by selecting "Transmit iQM Data" on the Management screen.

The receiving computer generates the iQM Monthly Delta Chart Report from the transmitted information. The format of that report is specified in software specification volume 4a (Data Management).

##### 4.5.6.2 Delta Chart Data Message Flow

The message flow is described in the following figure

FIGURE 7: UPLOAD DC TO HIS/LIS/CIS.



#### 4.5.6.3 Message 1: LSU^U12 (uploading)

This message shall be an uploading message.

Shall have the structure defined in the following table.

TABLE 52: ORI. HL7. UPLOAD IQM DELTA CHART DATA TO HIS/LIS/CIS. MESSAGE 1

<b>Message</b>	<b>Comments</b>
MSH	See §Message Header Segment – MSH: Message Header Segment – MSH
EQU	See §Equipment Instance Identifier – EQU: Equipment Instance Identifier – EQU
{ EQP }	See §Equipment Log/Service Segment – EQP: Equipment Log/Service Segment – EQP

##### 4.5.6.3.1 Message Header Segment – MSH

This section is identical to §Message Header Segment – MSH (Upload CAR, ORI HL7).

##### 4.5.6.3.2 Equipment Instance Identifier – EQU

This section is identical to §Equipment Instance Identifier – EQU (Upload iQM-CAR, ORI HL7).

##### 4.5.6.3.3 Equipment Log/Service Segment – EQP

This segment shall contain the contents of a delta chart file. There will be a segment for each delta chart sent (i.e. each parameter/process control combination),

TABLE 53: ORI. HL7. UPLOAD IQM DELTA CHART DATA TO HIS/LIS/CIS. MESSAGE 1. EQP

<b>File Id</b>	<b>Field Name</b>	<b>Description /INFO/</b>	<b>Comp</b>	<b>Length</b>	<b>Reqd</b>	<b>Values, formats and comments</b>
1	Event type			25 0	R	"LOG"
3	File Name				X	
3	Start Date/Time			14	R	YYYYMM Year and month of the chart
4	End Date/Time				X	

5	Transaction Data		1	64 k	R	"iQM-MDC"
			2		R	Parameter Name
			3		R	PC Solution "A B C D"
			4.1-4.48		R	Each subcomponent of the field contains one of the lines described in Table 54: Contents of a Delta Chart File

The iQM delta chart files contents are given in the following table.

TABLE 54: CONTENTS OF A DELTA CHART FILE

Line	Contents	Description [INFO]	Example
1	Header:	Marks the start of the header section of the file.	
2	Device, mmm, SSS, nnn	Defines the analyzer name. Mmm is the model name. SSSS is the serial number. Nnn is the instrument name	GEM 3500, 08110003, GemUnit2
3	Month, mmm, yyyy	Defines the month of the data	Month, Jul, 2002
4	Cartridge insertion days, aa, bb...	Defines the dates during the month when cartridges were inserted	Cartridge insertion days, 2, 23
5	Cartridge lot, aaaaaa, bbbbbb, ...	Defines the lot numbers of the inserted cartridges	Cartridge lot, 359870, 359871
6	Parameter, pppp, uuuuuu	Defines the analyte being charted and display units	Parameter, Na+, mmol/L
7	Nominal target value, value, nnn	Defines the nominal value of the analyte for the inserted cartridges	Nominal target value, 144
8	Material, X	Defines the PC solution, where X is A, B, C or D.	Material, B
9	Mean, 0	Defines the y-axis center value, always zero.	
10	Low, nnnn	Defines the y-axis lower range value	Low, -3.00
11	High, nnnn	Defines the y-axis upper range value	High, 3.00
12	Precision, x	Defines the resolution (number of decimal points) of the y-axis values	Precision, 2
13	Interval, m, nn	Defines the x-axis daily range values for the charted month	Interval, 1, 31
14	Data:	Defines the start of the data section	
15	Date, no. of data points, low, high, mean, sum	Defines the first set of daily points to plot, in the selected units	07/01/2002, 5, 0.00, 1.00, 0.60, 3.00
16-48		Define the remaining set of daily points to plot for the month (note: the plot may begin/end at any day of the month, and some days may contain blank data)	

#### 4.5.6.4 Message 2: ACK (downloading)

This section is identical to §Message 2: ACK (downloading)

#### 4.5.6.5 Delta Chart Transmission examples

##### Message 1 (GEM):

```
MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^^7.0.0.B9
|||20081209125051||LSU^U12|5|P|2.4|||AL|NE|<CR>
EQU|08110003^IL^L|200812<CR>
EQP|LOG||200812||iQM-MDC^pH^A^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec,
2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, pH, &Nominal target value,
6.9&Material, A&Mean, 0&Low, -0.030000&High, 0.030000&Precision, 2&Interval, 1, 31&Data:&12/08/
```

2008, 4, 0.000000, 0.000000, 0.000000, 0.000000&12/09/2008, 7, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^pH^B^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, pH, &Nominal target value, 7.4&Material, B&Mean, 0&Low, -0.030000&High, 0.030000&Precision, 2&Interval, 1, 31&Data:&12/08/2008, 41, 0.000000, 0.000000, 0.000000&12/09/2008, 95, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^pH^C^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, pH, &Nominal target value, 8.0&Material, C&Mean, 0&Low, -0.030000&High, 0.030000&Precision, 2&Interval, 1, 31&Data:&12/09/2008, 1, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^pCO2^A^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, pCO2, mmHg&Nominal target value, 64&Material, A&Mean, 0&Low, -4.000000&High, 4.000000&Precision, 0&Interval, 1, 31&Data:&12/08/2008, 4, 0.000000, 0.000000, 0.000000&12/09/2008, 7, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^pCO2^B^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, pCO2, mmHg&Nominal target value, 34&Material, B&Mean, 0&Low, -3.000000&High, 3.000000&Precision, 0&Interval, 1, 31&Data:&12/08/2008, 41, 0.000000, 0.000000, 0.000000, 0.000000&12/09/2008, 95, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^pCO2^C^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, pCO2, mmHg&Nominal target value, 34&Material, C&Mean, 0&Low, -3.000000&High, 3.000000&Precision, 0&Interval, 1, 31&Data:&12/09/2008, 1, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^pO2^A^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, pO2, mmHg&Nominal target value, 120&Material, A&Mean, 0&Low, -6.000000&High, 6.000000&Precision, 0&Interval, 1, 31&Data:&12/08/2008, 4, 0.000000, 0.000000, 0.000000, 0.000000&12/09/2008, 7, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^pO2^B^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, pO2, mmHg&Nominal target value, 175&Material, B&Mean, 0&Low, -10.000000&High, 10.000000&Precision, 0&Interval, 1, 31&Data:&12/08/2008, 41, 0.000000, 0.000000, 0.000000, 0.000000&12/09/2008, 95, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^pO2^C^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, pO2, mmHg&Nominal target value, 3&Material, C&Mean, 0&Low, -4.000000&High, 4.000000&Precision, 0&Interval, 1, 31&Data:&12/09/2008, 1, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^Na+^A^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, Na+, mmol/L&Nominal target value, 100&Material, A&Mean, 0&Low, -3.000000&High, 3.000000&Precision, 0&Interval, 1, 31&Data:&12/08/2008, 4, 0.000000, 0.000000, 0.000000, 0.000000&12/09/2008, 7, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^Na+^B^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, Na+, mmol/L&Nominal target value, 144&Material, B&Mean, 0&Low, -3.000000&High, 3.000000&Precision, 0&Interval, 1, 31&Data:&12/08/2008, 41, 0.000000, 0.000000, 0.000000, 0.000000&12/09/2008, 95, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^K+^A^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, K+, mmol/L&Nominal target value, 6.8&Material, A&Mean, 0&Low, -0.300000&High, 0.300000&Precision, 1&Interval, 1, 31&Data:&12/08/2008, 4, 0.000000, 0.000000, 0.000000, 0.000000&12/09/2008, 7, 0.000000, 0.000000, 0.000000, 0.000000<CR>

EQP|LOG||200812||iQM-MDC^K+^B^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec, 2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, K+, mmol/L&Nominal target value, 3.6&Material, B&Mean, 0&Low, -0.300000&High, 0.300000&Precision, 1&Interval, 1, 31&Data:&12/08/2008, 41, 0.000000, 0.000000, 0.000000, 0.000000&12/09/2008, 95, 0.000000, 0.000000, 0.000000, 0.000000<CR>

```

EQP|LOG||200812||iQM-MDC^Ca++^A^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec,
2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, Ca++, mmol/L&Nominal target
value, 2.7&Material, A&Mean, 0&Low, -0.150000&High, 0.150000&Precision, 2&Interval, 1,
31&Data:&12/08/2008, 4, 0.000000, 0.000000, 0.000000&12/09/2008, 7, 0.000000, 0.000000,
0.000000, 0.000000<CR>
EQP|LOG||200812||iQM-MDC^Ca++B^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec,
2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, Ca++, mmol/L&Nominal target
value, 1.2&Material, B&Mean, 0&Low, -0.060000&High, 0.060000&Precision, 2&Interval, 1,
31&Data:&12/08/2008, 41, 0.000000, 0.000000, 0.000000&12/09/2008, 95, 0.000000,
0.000000, 0.000000<CR>
EQP|LOG||200812||iQM-MDC^Glu^A^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec,
2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, Glu, mg/dL&Nominal target
value, 145&Material, A&Mean, 0&Low, -14.000000&High, 14.000000&Precision, 0&Interval, 1,
31&Data:&12/08/2008, 4, 0.000000, 0.000000, 0.000000&12/09/2008, 7, 0.000000, 0.000000,
0.000000, 0.000000<CR>
EQP|LOG||200812||iQM-MDC^Glu^B^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec,
2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, Glu, mg/dL&Nominal target
value, 0&Material, B&Mean, 0&Low, -10.000000&High, 10.000000&Precision, 0&Interval, 1,
31&Data:&12/08/2008, 41, 0.000000, 0.000000, 0.000000&12/09/2008, 95, 0.000000,
0.000000, 0.000000<CR>
EQP|LOG||200812||iQM-MDC^Lac^A^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec,
2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, Lac, mmol/L&Nominal target
value, 3&Material, A&Mean, 0&Low, -0.300000&High, 0.300000&Precision, 1&Interval, 1, 31&Data:&12/
08/2008, 4, 0.000000, 0.000000, 0.000000&12/09/2008, 7, 0.000000, 0.000000, 0.000000,
0.000000<CR>
EQP|LOG||200812||iQM-MDC^Lac^B^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec,
2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, Lac, mmol/L&Nominal target
value, 0&Material, B&Mean, 0&Low, -0.300000&High, 0.300000&Precision, 1&Interval, 1, 31&Data:&12/
08/2008, 41, 0.000000, 0.000000, 0.000000&12/09/2008, 95, 0.000000, 0.000000, 0.000000,
0.000000<CR>
EQP|LOG||200812||iQM-MDC^Hct^A^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec,
2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, Hct, %&Nominal target value,
25&Material, A&Mean, 0&Low, -2.000000&High, 2.000000&Precision, 0&Interval, 1, 31&Data:&12/08/
2008, 4, 0.000000, 0.000000, 0.000000&12/09/2008, 7, 0.000000, 0.000000, 0.000000,
0.000000<CR>
EQP|LOG||200812||iQM-MDC^Hct^B^Header:&Device, GEM 3500, 08110008, IL Demo unit&Month, Dec,
2008&Cartridge insertion days, 08&Cartridge lot, 828466&Parameter, Hct, %&Nominal target value,
11&Material, B&Mean, 0&Low, -1.000000&High, 1.000000&Precision, 0&Interval, 1, 31&Data:&12/08/
2008, 41, 0.000000, 0.000000, 0.000000&12/09/2008, 95, 0.000000, 0.000000, 0.000000,
0.000000<CR>

```

**Message 2 (HIS/LIS/CIS):**

MSH|^~\&|Simulator^1.0||||20081209124922||ACK|57|P|2.4||||NE|NE<CR>

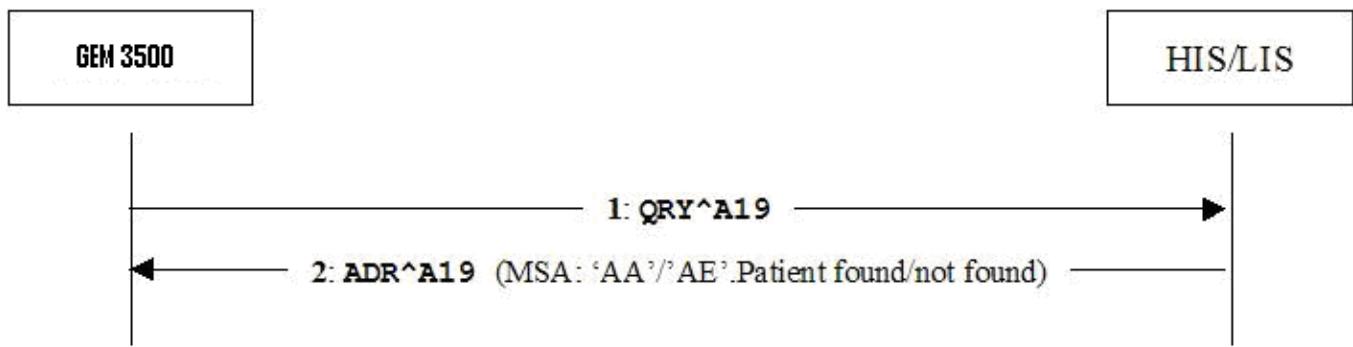
MSA|CA|5||||<CR>

#### 4.5.7 Fetch Demographics from HIS/LIS/CIS (query by Patient ID)

This trigger event is served by QRY (a query from another system) and ADR (a response from an Patient Administration system.)

The message flow is described in the following figure

FIGURE 8: FETCH DEMOGRAPHICS FROM HIS/LIS/CIS.



#### 4.5.7.1 Message 1: QRY^A19 (uploading)

This message shall be an uploading message.

Shall have the structure defined in the following table.

TABLE 55: ORI. HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS. MESSAGE 1

<b>Message</b>	<b>Comments</b>
MSH	
QRD	

##### 4.5.7.1.1 Message Header Segment – MSH

TABLE 56: ORI. HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS (QUERY BY PATIENT ID). MESSAGE 1. MSH

<b>File Id</b>	<b>Field Name</b>	<b>Description /INFO/</b>	<b>Co mp</b>	<b>Le n</b>	<b>Re q</b>	<b>Values, formats and comments</b>
1	Field Separator			1	R	" "
2	Encoding Characters			4	R	"^~\&"
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)	1 2 3	18 0	RE	"IL" "GEM Premier 3500" "1.0" (Data Format version)
4	Sending Facility		1 2 3 4 5 6	0	RE RE RE RE RE	Area Name Analyzer Name Analyzer Model Analyzer Serial Number Cartridge Serial Number Analyzer SW Version Number
5	Receiving Application			18 0	RE	Null
6	Receiving Facility			18 0	RE	Null
7	Date/Time Of Message	Date time the message was generated (HL7/ASTM format).		26	R	YYYYMMDDHHMMSS
8	Security			40	X	
9	Message Type	ORU^R30, ORU^R31, ORU^R32, ACK^R33.		7	R	QRY^A19
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 - 4294967295

11	Processing ID	"T/D/P": Training/Debug/Production	3	R	"P"
12	Version ID		8	R	"2.4"
13	Sequence Number		15	X	
14	Continuation Pointer		18 0	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"	2	X	
16	Application Acknowledgement Type	All ORU messages will specify "AL"	2	X	
17	Country Code	Not used by GEM	2	RE	Null

#### 4.5.7.1.2 Query Definition Segment – QRD

TABLE 57: **ORI. HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS (QUERY BY PATIENT ID). MESSAGE 1. QRD**

<i>Field Id</i>	<i>Field Name</i>	<i>Description /INFO/</i>	<i>Co mpx</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Query Date/Time	Contains the date the query was generated by the application program.		26	R	YYYYMMDDHHMMSS
2	Query Format Code	D/R/T		1	R	"R" – Response is in record-oriented format
3	Query Priority	Contains the time frame in which the response is expected		1	R	"I" – Immediate
4	Query ID	Contains a unique identifier for the query. Assigned by the querying application. Returned intact by the responding application		10	R	0 – 4294967295(32 bits UID)
5	Deferred Response Type			1	X	
6	Deferred Response Date/Time			26	X	
7	Quantity Limited Request	Contains the maximum length of the response that can be accepted by the requesting system. Valid responses are numerical values (in the first component) given in the units specified in the second component		10	R	"1^RD" (one record)
8	Who Subject Filter	Identifies the subject, or who the inquiry is about.		25 0	R	<i>Patient ID</i>
9	What Subject Filter	Describes the kind of information that is required to satisfy the request. Valid values define the type of transaction inquiry and may be extended locally during implementation.		25 0	R	"DEM"
10	What Department Data Code	This field should not have been a required field. However, for backwards compatibility it remains a required field. There are some queries in the standard that have not required this field.		25 0	R	Not Used.
11	What Data Code Value Qual.			20	X	
12	Query Results Level			1	X	

#### 4.5.7.2 Message 2: ADR^A19 (downloading)

This message shall be a downloading message.

If patient is found, shall have the structure defined in the following table.

TABLE 58: ORI. HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS. MESSAGE 2. PATIENT FOUND

<b>Message</b>	<b>Comments</b>
MSH	
MSA	Message contains an application acknowledge “AA”
QRD	Copy of the query sent in the uploading message
PID	Record containing the requested patient demographics
PV1	Dummy record, needed to HL7 compliant

If patient is not found, shall have the structure defined in the following table.

TABLE 59: ORI. HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS. MESSAGE 2. PATIENT NOT FOUND

<b>Message</b>	<b>Comments</b>
MSH	
MSA	Message contains an application error “AE”

##### 4.5.7.2.1 Message Header Segment – MSH

TABLE 60: ORI. HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS (QUERY BY PATIENT ID). MESSAGE 2. MSH

<b>Field</b>	<b>Field Name</b>	<b>Description [INFO]</b>	<b>Count</b>	<b>Length</b>	<b>Repetition</b>	<b>Values, formats and comments</b>
1	Field Separator			1	R	“ ”
2	Encoding Characters			4	R	“^~\&”
3	Sending Application	Identifies the application (company, pg 273 of the specs, application and version)		18 0	RE	Ignored by the GEM
4	Sending Facility			18 0	RE	Ignored by the GEM
5	Receiving Application			18 0	RE	Ignored by the GEM
6	Receiving Facility			18 0	RE	Ignored by the GEM
7	Date/Time Of Message	Date time the message was generated (HL7/ ASTM format).		26	R	YYYYMMDDHHMMSS
8	Security			40	X	
9	Message Type			7	R	“ADR^A19”
10	Message Control ID	Unique identifier for the message (32 bits PK).		20	R	0 – 4294967295
11	Processing ID	“T/D/P”: Training/Debug/Production		3	R	“P”. Ignored by the GEM
12	Version ID			8	R	“2.4”. Ignored by the GEM
13	Sequence Number			15	X	

14	Continuation Pointer		18 0	X	
15	Accept Acknowledgement Type	All source messages should specify "AL"	2	X	
16	Application Acknowledgement Type	All ORU messages will specify "AL"	2	X	
17	Country Code	Not used by GEM	2	RE	Ignored by the GEM

#### 4.5.7.2.2 General Acknowledgement Segment – MSA

TABLE 61: ORI. HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS (QUERY BY PATIENT ID). MESSAGE 2. MSA. PATIENT FOUND

<i>Field Id</i>	<i>Field Name</i>	<i>Description /INFO/</i>	<i>Co mپ</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Acknowledgement Code	"CA," "CE," "CR," "AA," "AE," "AR"		2	R	"AA"
2	Message Control ID	From MSH-10 of associated message		20	R	0 – 4294967295
3	Text Message			80	O	Empty
4	Expected Sequence Number			15	X	
5	Delayed Acknowledgement Type			1	X	
6	Error Condition	Coded Error		10 0	O	Empty

TABLE 62: ORI. HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS (QUERY BY PATIENT ID). MESSAGE 2. MSA. PATIENT NOT FOUND

<i>Field Id</i>	<i>Field Name</i>	<i>Description /INFO/</i>	<i>Co mپ</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Acknowledgement Code	"CA," "CE," "CR," "AA," "AE," "AR"		2	R	"AE"
2	Message Control ID	From MSH-10 of associated message		20	R	0 – 4294967295
3	Text Message			80	O	Any text, ignored by the GEM
4	Expected Sequence Number			15	X	
5	Delayed Acknowledgement Type			1	X	
6	Error Condition	Coded Error		10 0	O	Any text, ignored by the GEM

#### 4.5.7.2.3 Query Definition Segment – QRD

TABLE 63: ORI. HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS (QUERY BY PATIENT ID). MESSAGE 2. QRD

<i>Field Id</i>	<i>Field Name</i>	<i>Description /INFO/</i>	<i>Co mپ</i>	<i>Le n</i>	<i>Re q</i>	<i>Values, formats and comments</i>
1	Query Date/Time	Contains the date the query was generated by the application program.		26	R	YYYYMMDDHHMMSS
2	Query Format Code	D/R/T		1	R	"R" – Response is in record-oriented format
3	Query Priority	Contains the time frame in which the response is expected		1	R	"I" – Immediate
4	Query ID	Contains a unique identifier for the query. Assigned by the querying application. Returned intact by the responding application		10	R	0 – 4294967295(32 bits UID)

5	Deferred Response Type		1	X	
6	Deferred Response Date/Time		26	X	
7	Quantity Limited Request	Contains the maximum length of the response that can be accepted by the requesting system. Valid responses are numerical values (in the first component) given in the units specified in the second component	10	R	"1^RD" (one record)
8	Who Subject Filter	Identifies the subject, or who the inquiry is about.	25 0	R	Patient ID
9	What Subject Filter	Describes the kind of information that is required to satisfy the request. Valid values define the type of transaction inquiry and may be extended locally during implementation.	25 0	R	"DEM"
10	What Department Data Code	This field should not have been a required field. However, for backwards compatibility it remains a required field. There are some queries in the standard that have not required this field.	25 0	R	Not Used
11	What Data Code Value Qual.		20	X	
12	Query Results Level		1	X	

#### 4.5.7.2.4 Patient Identification Segment – PID

TABLE 64: ORI. HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS (QUERY BY PATIENT ID). MESSAGE 1. PID

Field Id	Field Name	Description /INFO/	Comp	Len	Reqd	Values, formats and comments
1	Set ID - Patient ID Optional. Set ID Sequence Number.			4	O	"1"
2	Patient ID			20	X	
3	Patient Identifier List Use Case #1, #2 Patient ID required.	GEM shall always consider this fields as optional.		24	R	Patient ID
4	Alternate Patient ID – PID			20	X	
5	Patient Name	Extension to the standard	1	24	O	Patient Last Name (See note at the end of the table)
6	Mother's Maiden Name		2	24	O	Patient First Name (See note at the end of the table)
			3	1	O	Patient Middle Initial
				48	X	
7	Date/Time of Birth	Extension to the standard		26	O	Patient Birth Date (YYYYMMDDHHMMSS)
8	Administrative Sex	Extension to the standard		1	R RE	"M"/"F"/"U" or Null
9	Patient Alias			48	X	

10	Race		1	X	
11	Patient Address		10 6	X	
12	Country Code Empty for USA.		4	RE	Null
13	Phone Number – Home		40	X	
14	Phone Number – Business		40	X	
15	Primary Language		60	X	
16	Marital Status		1	X	
17	Religion		3	X	
18	Patient Account Number	Account number, if available.	20	X	
19	SSN Number – Patient		16	X	
20	Driver's License Number - Patient		25	X	
21	Mother's Identifier		25 0	X	
22	Ethnic Group		25 0	X	
23	Birth Place		25 0	X	
24	Multiple Birth Indicator		1	X	
25	Birth Order		2	X	
26	Citizenship		25 0	X	
27	Veterans Military Status		25 0	X	
28	Nationality		25 0	X	
29	Patient Death Date and Time		26	X	
30	Patient Death Indicator		1	X	
31	Identity Unknown Indicator		1	X	
32	Identity Reliability Code		20	X	
33	Last Update Date/Time		26	X	
34	Last Update Facility		40	X	
35	Species Code		25 0	X	
36	Breed Code		25 0	X	
37	Strain		80	X	
38	Production Class Code		25 0	X	

### Notes about field 5

- The max length of the patient first name and patient last name (see field 5) are reported by the host is 24 characters. Since the GEM 3500 supports only 16 characters patient names, the characters 17..24 of the patient name reported by the host shall be ignored.

### Notes about field 7:

- The GEM3500 doesn't support the patient birth time. The digits "HHMMSS" shall be ignored by the GEM3500 software.

#### 4.5.7.2.5 Patient Visit Segment – PV1

TABLE 65: ORI, HL7. QUERY PATIENT DEMOGRAPHICS TO HIS/LIS/CIS (QUERY BY PATIENT ID). MESSAGE 1. PID

<i>Field Id</i>	<i>Field Name</i>	<i>Description [INFO]</i>	<i>Comp</i>	<i>Len</i>	<i>Req</i>	<i>Values, formats and comments</i>
2	Patient Class	This field is used by systems to categorize patients by site. It does not have a consistent industry-wide definition. It is subject to site-specific variations. It is required		1	R	"U" – Unknown

#### 4.5.7.3 Transmission examples

##### 4.5.7.3.1 Patient exists

###### Message 1 (GEM):

```
MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^7.0.0.B9
|||20081209123218||QRY^A19|1|P|2.4||||<CR>
QRD|20081209123218|R|I|1228862641|||1^RD|PID-1234|DEM|<CR>
```

###### Message 2 (HIS/LIS/CIS):

```
MH|^~\&|Simulator^1.0||||20081209123049||ADR^A19|35|P|2.4|||<CR>
MSA|AA|9||||<CR>
QRD|20081209123049|R|I|1228862641|||1^RD|PID-1234|DEM<CR>
PID|1||PID-1234||Smith^John^M.|19250102000000|M||||||||<CR>
PV1|1|U<CR>
```

##### 4.5.7.3.2 Patient does not exist

###### Message 1 (GEM):

```
MSH|^~\&|IL^GEM Premier 3500^1.0|^GEM 3500^08110003^7.0.0.B9
|||20081209123326||QRY^A19|2|P|2.4||||<CR>
QRD|20081209123326|R|I|1228862642|||1^RD|PID-567|DEM|<CR>
```

###### Message 2 (HIS/LIS/CIS):

```
MSH|^~\&|Simulator^1.0||||20081209123157||ADR^A19|37|P|2.4|||<CR>
MSA|AE|10||||<CR>
```

## 4.6 Tables

### 4.6.1 Patient sample types

TABLE 66: PATIENT SAMPLE TYPES

<i>Sample Type</i>	<i>HL7</i>
Arterial	<b>BLDA</b>
Venous	<b>BLDV</b>
Capillary	<b>BLDC</b>
Other	<b>BLDO</b>

Notes on POCT1-A:

- “Other” is not defined in HL7, so a new code (*BLDO*) has been created
- Sample size is reported in fields OBR-9 and OBR-15.3.

### 4.6.2 Age Units

The units for age shall use the HL7 convention, described in Table 67: Units for age67.

Gem3500 instruments report the patient age always using Years as unit of measure.

TABLE 67: UNITS FOR AGE

<i>HL7 Name</i>	<i>Description</i>
YR	Years

### 4.6.3 Sample Panels

The sample panels use the LOINC codes described in Table 68: Loinc Codes68.

TABLE 68: LOINC CODES

<i>LOINC Number</i>	<i>Component/Analyte</i>	<i>Description</i>
24343-6	GAS & CO PANEL	Blood gas and COOX sample.
24338-6	GAS PANEL	Blood gas only sample.
24343-6	GAS & CO PANEL	COOX only sample.

### 4.6.4 CVP Panels

The CVP panels codes are described in Table 69: CVP Codes69.

TABLE 69: CVP CODES

<b>CODE #</b>	<b>Component/Analyte</b>	<b>Description</b>
5	CVP PANEL	CVP sample.

#### 4.6.5 Calibration types

Test Order field 16 contains one of the following character strings to indicate the calibration type:

TABLE 70: CALIBRATION TYPES

<b>Character String</b>	<b>Description</b>
CCal	C Calibration (A0 calibration)
BCal	B Calibration (One point calibration)
2PtCal	Two point Calibration (New – GEM3500 Only)

#### 4.6.6 Calibration Records

TABLE 71: UPLOAD CALIBRATION RESULTS TO HIS/LIS/CIS. UPLOADING MESSAGE.

CALIBRATION RECORDS (TABLE 1 / 2)

<b>Analyte</b>	<b>Slope</b>	<b>DriftA</b>	<b>MeasuredA</b>	<b>DriftB</b>	<b>MeasuredB</b>	<b>DriftC</b>
pH	pHSlope	pHDriftA	pHMeasuredA	pHDriftB	pHMeasuredB	pHDriftC
pCO2	pCO2Slope	pCO2DriftA	pCO2MeasuredA	pCO2DriftB	pCO2MeasuredB	pCO2DriftC
pO2	pO2Slope	pO2DriftA	pO2MeasuredA	pO2DriftB	pO2MeasuredB	pO2DriftC
Na+	Na+Slope	Na+DriftA	Na+MeasuredA	Na+DriftB	Na+MeasuredB	
K+	K+Slope	K+DriftA	K+MeasuredA	K+DriftB	K+MeasuredB	
Ca++	Ca++Slope	Ca++DriftA	Ca++MeasuredA	Ca++DriftB	Ca++MeasuredB	
Hct	HctSlope	HctDriftA	HctMeasuredA	HctDriftB	HctMeasuredB	
Glu	GluSlope	GluDriftA	GluMeasuredA	GluDriftB	GluMeasuredB	
Lac	LacSlope	LacDriftA	LacMeasuredA	LacDriftB	LacMeasuredB	

TABLE 72: UPLOAD CALIBRATION RESULTS TO HIS/LIS/CIS. UPLOADING MESSAGE.

CALIBRATION RECORDS (TABLE 2 / 2)

<b>Analyte</b>	<b>MeasuredC</b>
pH	pHMeasuredC
pCO2	pCO2MeasuredC
pO2	pO2MeasuredC

