GEM® PREMIER™ 5000

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GEM® PREMIER™ 5000 | iQM2

Instrumentation Laboratory

A Werfen Company

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℞ IVD CE

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Safety and Compliance

This section describes the Safety and Compliance Requirements for the GEM 5000, 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 5000 if and only if:

- Persons authorized by IL carry out assembly operations, extensions, adjustments, modifications or repairs. The GEM 5000 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.

Ambient Environmental Requirements

External Ambient Temperature Limits:	12°C (53.6°F) to 32°C (89.6°F)
Relative Humidity Limits:	15 – 85% RH (non-condensing)
Barometric Pressure Limits:	-30 to 10,000 ft (or 102kPA/762mmHg to 71kPa/534mmHg). Process Control Solution bags have zero headspace for operation over a wide range of atmospheric pressures with no change in dissolved gas concentration.

In accordance with IEC regulations, no breakdown or safety hazard will occur in the temperature ranges between 12 to 32°C (53.6 to 89.6°F).

Ventilation Requirements

The instrument must be positioned so that there is at least 15.2 cm (6 inches) clearance on both sides, back and top for proper air circulation. The instrument should be placed in a position free from dust, fumes, vibrations and excessive variations in temperature.

Do not block the vents on the analyzer.

Audible Noise

GEM Premier 5000 analyzer passed sound power levels of 80 dB (Limit) with a declared level of 68.1 dB. Testing conducted in according to ISO 3774, Second Edition 1994/05/01 and 7779, Third Edition, 2010/09/22.

Storage Requirements

Instrument Storage	May be stored at a temperature of -10 to 38°C (14 to 100.4°F) with a Relative Humidity of 15-85%, non-condensing
GEM Premier 5000 PAK Storage	Store at 15 to 25°C (59.0 to 77.0°F)
GEM Premier 5000 PAK Shelf Life	Expires on the date indicated on the label of each GEM PAK. A GEM PAK may be inserted up to and including the date of expiration. If a GEM PAK is inserted past its indicated expiration date it will be rejected by the system. GEM PAK should be stored in foil pack prior to use.

Shipping Requirements

Instrument	Instrument may be shipped at -20 to 60°C (-4.0 to 140.0°F), at a Relative Humidity of 15 to 85 %, non-condensing.
GEM Premier 5000 PAK	PAK may be shipped at 10 to 38°C (50.0 to 100.4°F), at a Relative Humidity of 15-85%, non-condensing. GEM PAKs may only be exposed to this temperature range for a period of 3 days.

Important Warning Symbols

Throughout this manual you should pay particular attention to paragraphs marked **WARNING**, **CAUTION**, **NOTE** and **BIOHAZARD**. Paragraphs containing these symbols contain important information.

WARNING: General warning, caution, risk of danger.

CAUTION: Caution, risk of electrical shock.

BIOHAZARD: alerts the user of potential biological risks associated with the medical device.

NOTE: Documentation must be consulted in all cases where this symbol is marked.

Warning, hot surface.

Example: Safety sign combined with additional symbol to indicate the type of hazard.

INFORMATION: statements contain helpful user information.

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Marking Labels Description

Instrumentation Laboratory uses some symbols in consumable product and instrument labeling:

The CE label is on the back of the instrument indicates that the GEM Premier 5000 system conforms to the European Directives as stated in IL's Declaration of Conformity.


Accompanying documents must be consulted


Consult instructions for use


Caution, consult accompanying documents. Attention, see instructions for use.

Fragile, handle with care


Temperature limitation


Use by date


Date of manufacture

Batch code or lot number

Catalogue or part number

Serial number

In vitro diagnostic device


Manufacturer

Authorized representative in the European Community


Contains sufficient for <n> tests


Standby


Earth (ground)


Fuse


Alternating current


Output


Modem


Ethernet


USB


Keypad


Serial


Printer


Electrical and electronic equipment waste that requires specific disposable instructions from the manufacturer


This way up

Prescription Use Only

Certifications

CE Certifications

The CE label on the back of the instrument indicates that the GEM Premier 5000 system 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
- RoHS2 Directive 2011/65/EU (Starting with sn# 1606XXXX)

Applicable standards:

EMC Standards:

- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic compatibility – Requirements and tests
- FCC Title 47 Part 15 Sub-part B & Japan EMC VCCI V-3
- Wi-Fi (Wireless) standard ETSI EN 301 489-1 & ETSI EN 301 489-17

Safety standards:

- IEC 61010-1: Safety requirements for electrical equipment for measurement, control, and laboratory Use
- IEC 61010-2-101: *In vitro* Diagnostic (IVD) – Safety requirements

Other Certification

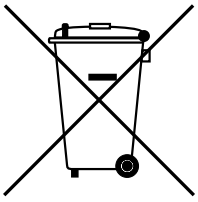
CEI/IEC 61010-1

The GEM Premier 5000 meets CEI/IEC 61010-1 for the following:

- External surface temperature
- Flame resistance
- Internal air flow and temperature
- Audible noise
- Product labeling

The GEM Premier 5000 instrument shipping crate complies with the International Safe Transit Packaging Testing Procedure.

European Union Directive 2002/96/EC on Waste Electrical and Electrical Equipment (WEEE)



Instrumentation Laboratory is committed to meeting or exceeding the conditions of the WEEE Directive and being a good environmental partner. In compliance with the WEEE Directive, beginning with product shipped after August 13, 2005, all instruments are labeled with the symbol.

Disposing of this product correctly helps prevent potential negative consequences for the environment and for human health. Recycling conserves natural resources.

Penalties may be applicable for incorrect disposal of this waste, in accordance with national (European) legislation.

Please call your local Instrumentation Laboratory distributor for information regarding the disposal of any end-of-life instruments.

Power Requirements

The power supply operates from 90 to 264 VAC. The product is rated at 100 to 240 VAC. The instrument cannot be operated during power interruptions.

Volts AC	Amps	Volts/Amp	Watts (Rated)	Frequency
100 VAC	3A	300 VA	300 W	50/60 Hz
115 VAC	3A	345 VA	300 W	50/60 Hz
240 VAC	1.5A	360 VA	300 W	50/60 Hz

The power cord connection is located to the immediate right of the power switch (when facing the front of the analyzer). The power cord provided with the instrument is a certified cord; three-prong, double insulated, grounded (NEMA) receptacle and plug.

This analyzer must be shut down using the Shut Down procedure located in the Menu drop down prior to cleaning. The system must also be shut down if the system is to be moved and it is not connected to an uninterruptible power source (UPS).
Do not connect the analyzer to power before verifying correct voltage setting. The analyzer can be used with a power (main) voltage of 100 to 240 VAC (50/60 Hz). Verify the voltage of the local power (main) to be used. Always plug the analyzer into a grounded outlet.

Electrical Requirements

The instrument has been designed to operate correctly with electrical variations of up to ±10% voltage in an ambient temperature of 12°C to 32°C (53.6°F to 89.6°F) with a relative humidity of 15% to 85% (non-condensing). The instrument has been designed to operate correctly with electrical variations of up to ±10% on the nominal supply and with supply frequencies between 47 and 63 Hz.

The GEM Premier 5000 system is single phase, has current leakage of less than 500 µAmps.

Power Consumption

The GEM Premier 5000 system is rated for a power consumption of 300 Watts. The actual operating power consumption of the analyzer is approximately 150 Watts.

Fuse Rating and Characteristics

There are two (2) fuses that may be replaced by the operator. The fuses are located directly below the power switch and is behind a black cover. The fuses are a 3 Amp, 250 Volt, SLO-BLO, and measures 5 mm x 20 mm. The fuses should only be replaced if after connecting the power cord to the power connector, and pressing the power switch, the system does not respond.

Dispose of the fuses using a container that is approved for glass disposal.

For continued fire hazard protection always replace the fuse with specified type and rating listed above.

1 - General Information

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This section contains an Overview of the GEM Premier 5000, 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.

Overview

The GEM Premier 5000 is a portable critical care system for use by health care professionals to rapidly analyze heparinized whole blood samples at the point of health care delivery in a clinical setting and in a central laboratory. The instrument provides quantitative measurements of pH, pCO_2, pO_2, sodium, potassium, chloride, ionized calcium, glucose, lactate, hematocrit, total bilirubin and CO-Oximetry (tHb, O_2Hb, COHb, MetHb, HHb, sO_{2*}) parameters. These parameters, along with derived parameters, aid in the diagnosis of a patient's acid/base status, electrolyte and metabolite balance and oxygen delivery capacity.

- sO2 = ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin.

The GEM Premier 5000 has two primary components: the analyzer and a disposable, multi-use cartridge. These components are described in the following paragraphs.

GEM Premier 5000 Analyzer

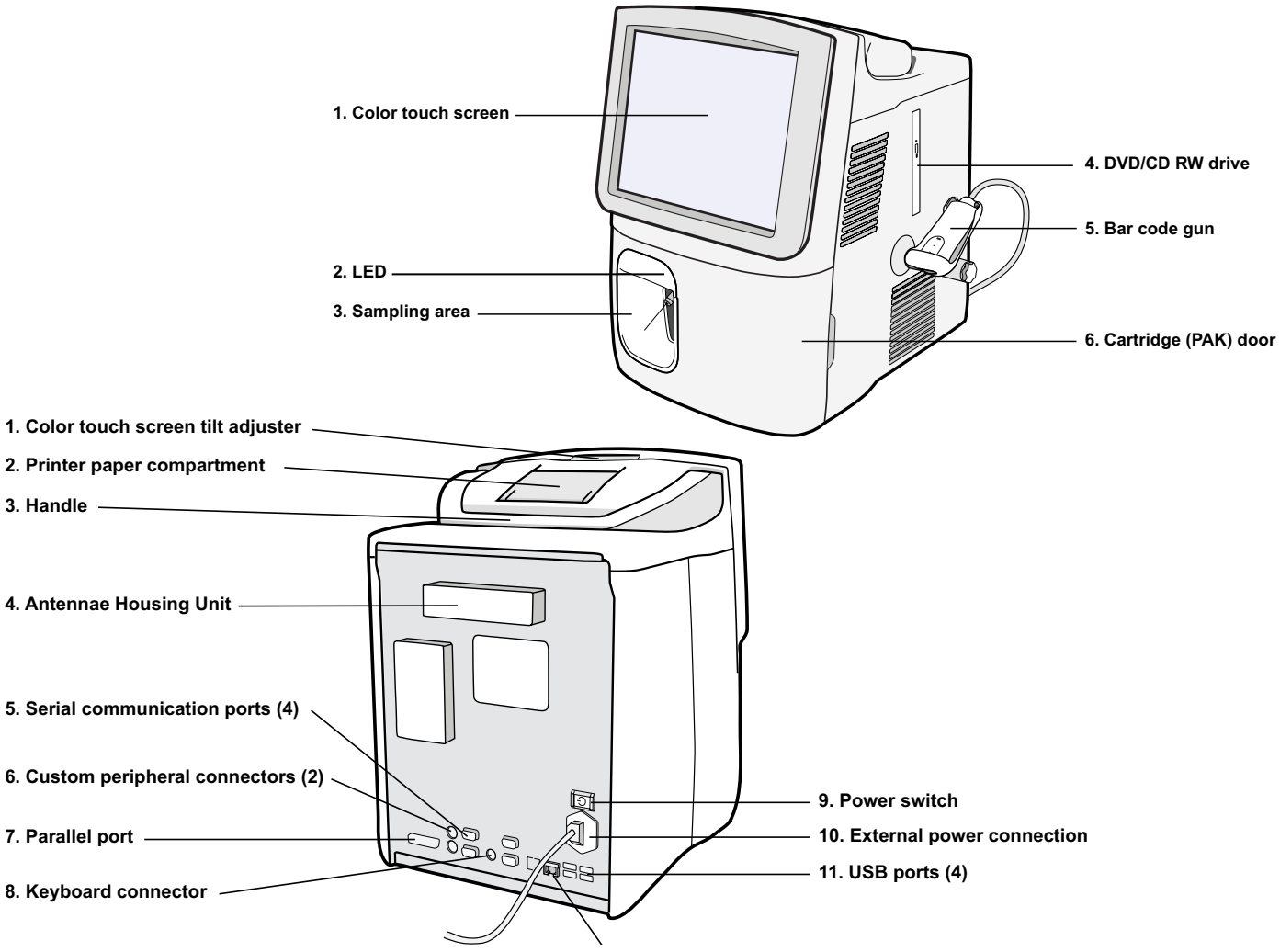
The GEM Premier 5000 analyzer employs a unique color touch screen and a simple set of menus and buttons for user interaction. The instrument guides operators through the sampling process with simple, clear messages and prompts.

Key Components of the GEM Premier 5000 System

The two key components of the GEM Premier 5000 system are:

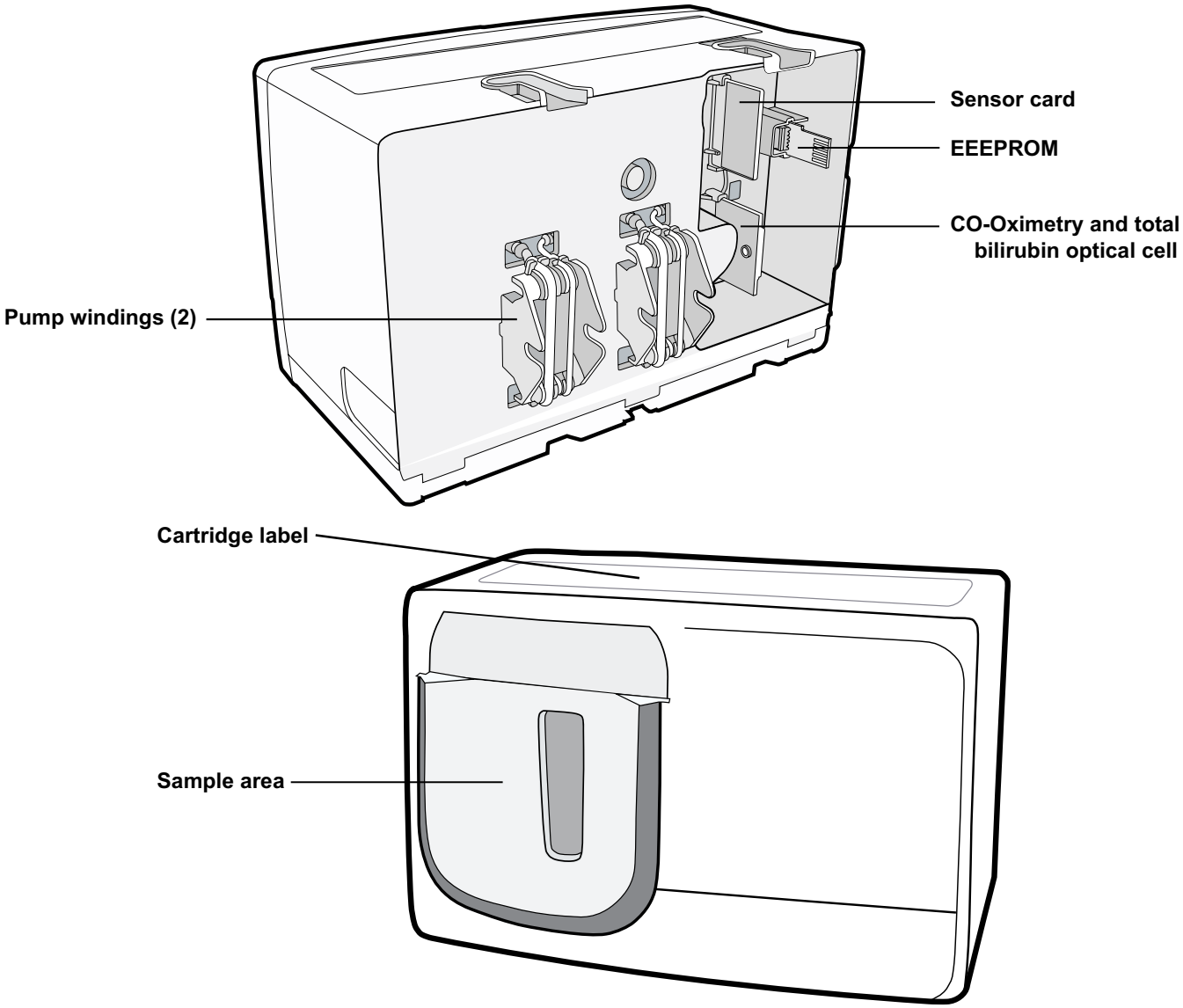
- **The analyzer**, which has the internal logic and processing power necessary to perform analysis.
- **The GEM PAK**, which contains the reagents, sensors, CO-Ox and total bilirubin optical cell, sampler, and waste bag, enable analysis of 75 to 600 samples.

These illustrations highlight important parts and features of the analyzer and cartridge.



GEM Premier 5000 PAK (Cartridge)

The primary component of the GEM Premier 5000 analyzer is the GEM Premier 5000 GEM PAK. The disposable, multi-use GEM PAK houses all components necessary to operate the instrument once the GEM PAK is validated. These components include the sensors, solutions, sampler, CO-Ox/tBili optical cell, and waste bag. GEM Premier 5000 GEM PAK has flexible menus and test volume options to assist facilities in maximizing efficiency.



Optical System Measurements

CO-Oximetry (tHb, O_2Hb, COHb, MetHb HHb and sO_2)

CO-Oximetry is based on an optical absorbance measurement of the sample. An in-line optical cell is integrated in the flow path of the hemolyzed sample to provide a measure of hemoglobin and its derivatives. The optical cell is a flow through channel with two parallel plate optical windows separated by a well-defined path length. The chemical lysing of the sample is implemented to minimize the scattering effect of the blood and to make the spectral measurement more reliable. The optical measurement hardware consisting of a white light-emitting diode (LED) light source, a neon reference and a high resolution spectrometer with a holographic diffraction grating and a charge-coupled device (CCD) array (2048 pixels, 0.15 nm/pixel) are all contained in the analyzer. The optical components are connected through optical fibers into a read head. Only the optical cell is located in the disposable cartridge (GEM PAK) and is aligned with the analyzer optics for spectral measurements following installation of the GEM PAK.

The sample spectrum is measured simultaneously at about 2000 wavelengths between 480 to 650 nm. Multi-component analysis of the sample spectrum leads to its resolution into hemoglobin derivatives and any other optically absorbing components present in the sample. From the spectral values, absorbance is calculated from AbsS = Log10 [IB / IS], where IB and IS are dark corrected spectra for the PCS B and sample respectively.

Absorbance spectra data are collected and stored. The matrix data processing, using the internally stored coefficients, is used for calculating concentration results for hemoglobin derivatives.

Total Bilirubin

Total bilirubin measurement is based on an optical absorbance measurement of the sample. An in-line optical assay is integrated in to the GEM PAK flow path where the hemolyzed whole blood sample provides a measure of total bilirubin and CO-Oximetry. The optical cell is a flow-through channel with two parallel plate optical windows separated by a well-defined path length. The chemical lysing of the sample is implemented to minimize the scattering effect of the blood and to make the spectra measurement more reliable. The optical measurement hardware including a white LED light source, a neon reference and a spectrometer with a holographic diffraction grating and a CCD array are all contained in the analyzer. Only the optical cell is located in the disposable cartridge.

Fiber optic lines direct the light from the LED to the optical cell and from the optical cell to the spectrometer. The sample spectrum is measured simultaneously at about 2000 wavelengths between 480 to 650 nm. Multi-variate analysis of the sample spectrum leads to its resolution into total bilirubin and any other optically absorbing components present in the sample.

The sample spectrum is compared to on-board standards based on Beer Lambert's Law, in order to obtain the measurement value. The analytical principle and calculations are very similar to CO-Oximetry measurements:

$A = \log_{10} (I_0 \bullet I) = \varepsilon C L$, where

A = Absorbance

I_0 = Incident Light Intensity

I = Transmitted Light Intensity

C = Concentration

ε = Extinction Coefficient

L = Path length ε

The GEM Premier 5000 system measures total bilirubin in the sample. Total Bilirubin is the sum of all bilirubin fractions. The bilirubin fractions are:

- Conjugated (Direct) Bilirubin. Conjugation with glucuronic acid makes this bilirubin analog water soluble.
- Unconjugated (Indirect) Bilirubin. Unconjugated bilirubin is water insoluble, and is highly toxic.
- Delta Bilirubin

The ratio of conjugated to unconjugated bilirubin differs depending on the age of the patient. Total bilirubin measurements on the GEM Premier 5000 system are not affected by the ratio of conjugated to unconjugated fractions.

Total bilirubin is reported as a plasma equivalent concentration. When whole blood is analyzed, hematocrit correction is necessary for reporting the plasma equivalent concentration to adjust for the dilution effect from red blood cells. The hematocrit correction is accomplished by applying the formula:

$Bili_p = Bili_b / (1\text{-}Hct)$, where

$Bili_p$ = concentration of total bilirubin in the plasma phase

$Bili_b$ = concentration of total bilirubin in whole blood

Hct = Hematocrit expressed as a fraction, and is determined by multiplying total hemoglobin (g/dL) by 0.03. The constant 0.03 is calculated from using an expression for the average concentration of hemoglobin within the red blood cells.

The optical system and absorbance spectra are depicted on the following page.

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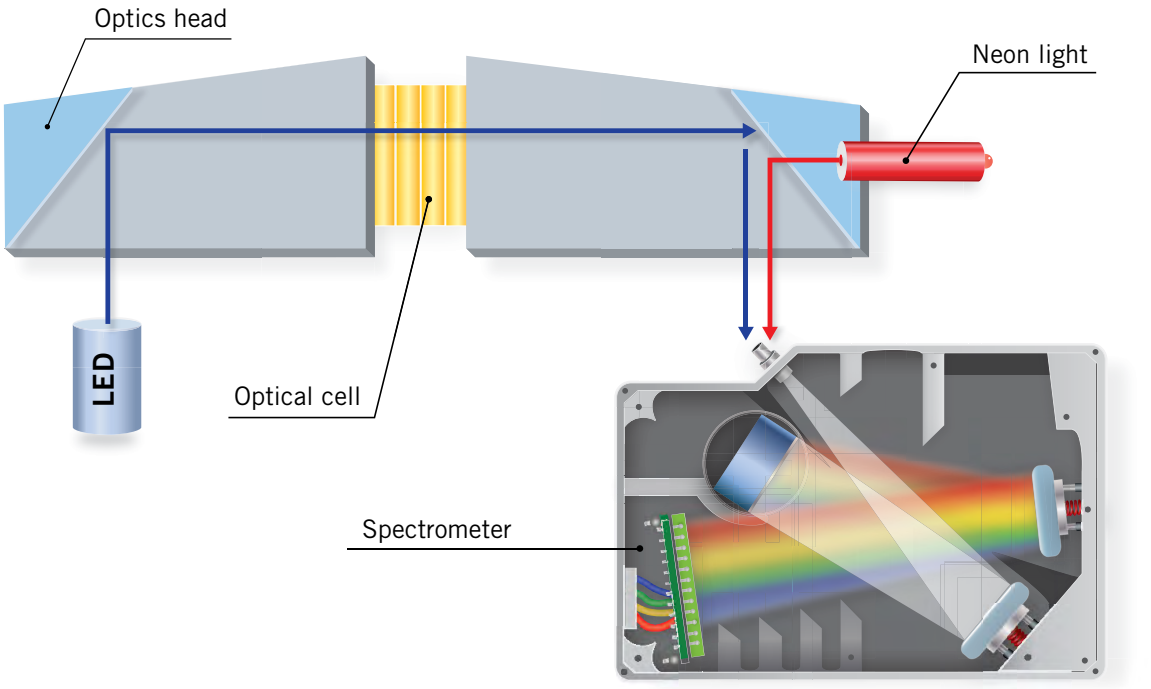
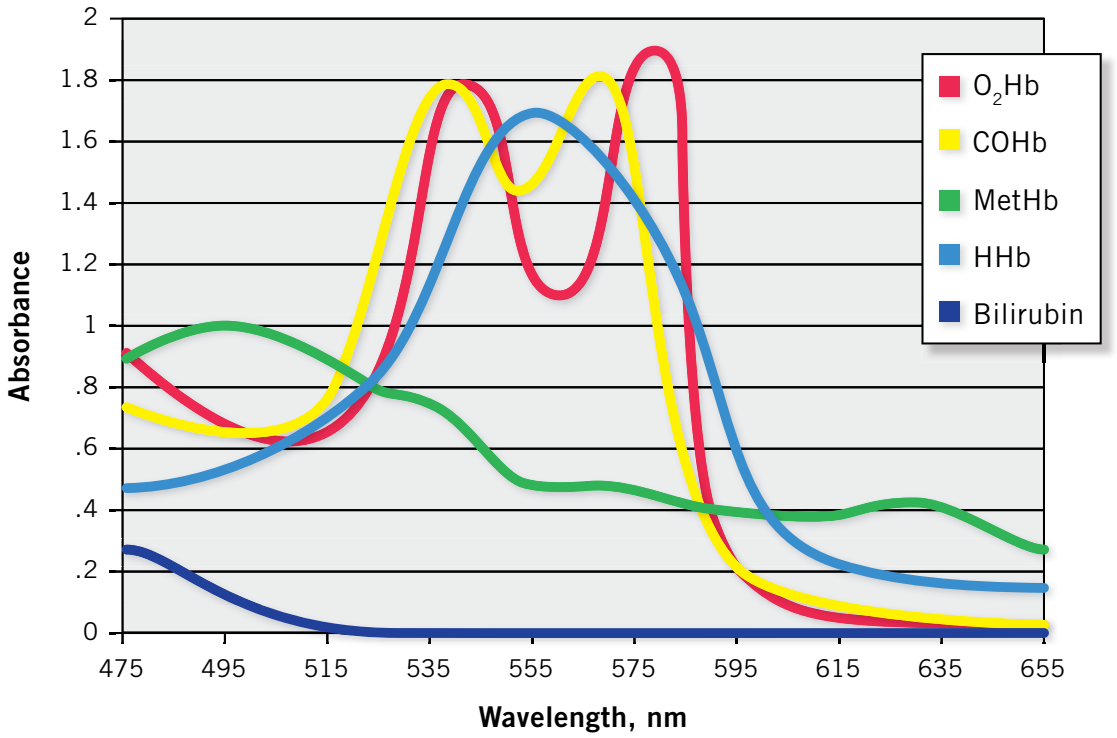
GEM® Premier 5000 Optical System



GEM® CO-Oximetry and Total Bilirubin Absorbance Spectra



Measured Analytes

The GEM Premier 5000 produces the following parameters, depending on the cartridge in use and the configurationof the instrument:

Analyte Name	Abbreviation
Hydrogen ion	pH or cH
Carbon dioxide partial pressure	pCO_2
Oxygen partial pressure	pO_2
Sodium ion	Na^+
Potassium ion	K^+
Chloride	Cl^-
Ionized calcium	Ca^{++}
Glucose	Glu
Lactate	Lac
Hematocrit	Hct
Total hemoglobin	tHb
Oxyhemoglobin	O_2Hb
Carboxyhemoglobin	COHb
Methemoglobin	MetHb
Deoxyhemoglobin or reduced hemoglobin	HHb
Oxygen Saturation	sO_2
Total bilirubin	tBili

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

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Derived Parameters

Derived calculations are represented on the analyzer and throughout the manual by the following symbols or abbreviations.

Derived Parameter	Abbreviation
Total Carbon Dioxide	TCO_2
Base Excess of Extracellular Fluid (In vitro)	BEecf
Base Excess of Blood (In vitro)	BE(B)
Calculated Total Hemoglobin*	tHb(c)
Ionized Calcium normalize to a pH of 7.4	Ca^{++} (7.4)
Anion Gap	AG
Arterial partial pressure/inspired oxygen ratio – (estimate of gas exchange ratio)	P/F Ratio
Alveolar oxygen partial pressure	pAO_2
Arterial oxygen content	CaO_2
Mixed venous oxygen content	CvO_2
Partial pressure of oxygen in a hemoglobin solution having an oxygen saturation of 50%	p_{50}
Arterial sample oxygen capacity	O_2cap
Oxygen Saturation – (calculated from measured CO-Oximetry analytes)	sO_2
Calculated Oxygen Saturation	sO_2 (c)
Standard bicarbonate	HCO_3^- std
Actual bicarbonate	HCO_3^- actual
Alveolar-arterial oxygen gradient	A-aDO_2
Arterial-alveolar oxygen ratio	paO_2/pAO_2
Respiratory index	RI
End pulmonary capillary oxygen content	CcO_2
Arterial-mixed venous oxygen gradient	a-vDO_2
Estimated shunt	$Q_{sp}/Q_{t\ (est)}$
Physiological shunt	Q_{sp}/Q_t
Calculated Hematocrit**	Hct(c)
Oxygen Content	O_2ct

* Utilizes Hct measurement to calculate when CO-Oxinmetry (tHb measured) is unavailable.

** Utilizes tHb measurement to calculate when Hct sensor is unavailable.

2 - Installation

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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 5000. This chapter also guides the IL authorized engineer through the installation process.

Anaylzer Dimensions and Weight

	Metric	English
Crated Instrument Size/Weight Specifications		
Height:	77.8 cm	31 inches
Width:	53.2 cm	21 inches
Depth:	47.8 cm	19 inches
Weight:	34 kg	75 pounds

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 The maximum external dimensions for the GEM 5000 are:

	Metric	English
GEM **Premier 5000 Analyzer**		
Height:	47.2 cm	18.6 inches
Width:	33.0 cm	13.0 inches
Depth:	41.7 cm	16.4 inches
Weight:	20.6 kg	45.4 pounds

NOTE: The GEM 5000 generates approximately 1024 BTU / hour.

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

Power Supply Voltage Values	
Input Voltages	**Output Voltages**
100 - 240VAC 50/60 HZ.	+ 24 V DC
	+ 12 V DC
	+ 5 VDC (DCS Board supply)
	+ 5 VDC (CPU Board supply)

GEM 5000 Electrical Requirements				
Volts AC	**Amps**	**Volts/Amp**	**Watts (Rated)**	**Frequency**
100 VAC	3A	300 VA	300 W	50/60 Hz
115 VAC	3A	345 VA	300 W	50/60 Hz
240 VAC	1.5A	360 VA	300 W	50/60 Hz

For all voltage applications, the Gem 5000 uses a 3-amp glass fuse, located in the power connection module.

The part number of this fuse is 00025002107. 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.

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 3 AMP fuse (part number 00025002107), located in the power entry module, and no changes are required to the fuse for any of the acceptable line voltages.

The GEM 5000 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 front of the instrument). This switch is for the main power supply and controls all power to the instrument. The GEM 5000 has a momentary power switch. When the instrument is in the power off state, the switch is pressed and released and the instrument begins a power on cycle. To power the instrument off, it is necessary to use the shutdown command in the instrument software which is accessed through the MENU selection. If the power switch is pressed and held for 5 seconds or longer, the instrument shuts down. However, this results in an illegal shutdown and the instrument software may not be able to recover.

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

Installation of the Analyzer

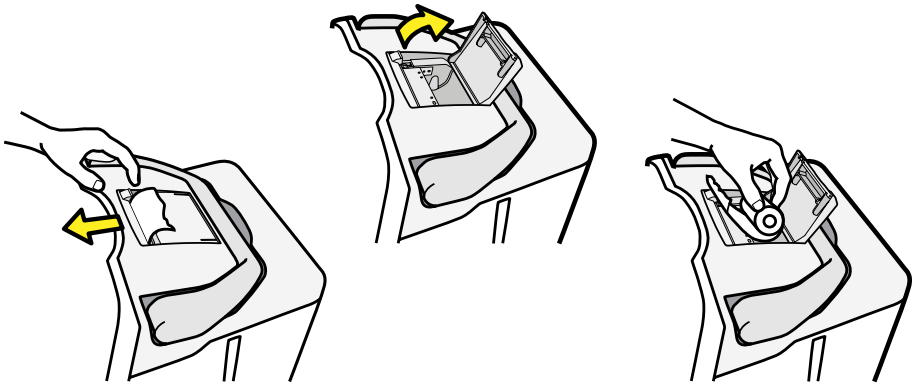
NOTE: The installation of the GEM 5000 should be performed only by an authorized Instrumentation Laboratory representative!

1. Inspect the box for damage. Remove the unit from the shipping box.
2. Place the instrument on a stable surface in a convenient location.
3. Connect the power cord to the power module.
4. Then connect the plug to a grounded electrical supply.
5. Press and release the power switch on the back left side of the instrument to turn it ON. The analyzer enters a self diagnostics mode. When the Ready screen is displayed press Open Door on the touch screen. At the audio prompt, the door releases and opens slightly.
6. Manually move the door all the way to the left.
7. Remove the shipping cartridge by grasping it on both sides and pulling it straight out. Save this cartridge in case the analyzer must be shipped back to IL.
8. Select the Menu button, and press Shut Down. Follow the prompts. Refer to “Shutdown” in Chapter 3 for further details.
9. Remove the power cord from the electrical supply.
10. Remove the shipping bracket by pulling forward and down, from behind the protruding top edge of the bracket. The bracket is to be removed by hand only. Do not use any tools to remove the bracket.
11. Connect the barcode gun to the appropriate custom peripheral port on the back of the analyzer.
12. Reconnect the power cord to the power module and then to a grounded electrical supply.

Installing the Printer Paper

To install the printer paper in the paper area on top of the system:

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



Startup

1. Press and release the power switch on the back left side of the instrument to turn it ON.

   While the diagnostics internal check is being performed, the analyzer shows the self diagnostic screen.

2. Install a cartridge as detailed in “Cartridge Installation” in Chapter 4.

Start Up Kit Contents

1	00014882100	CORD LINE SHIELDED 110V	1
2	00019725500	VDE APPROVED LINE CORD 220V	1
3	00024015859	WAND, BAR CODE	1
4	00024017288	KIT, BAR CODE ACCESSORY	1
5	00024306171	KIT,ANTENNA WITH WIRELESS WARNING LETTER	1
6	00025000500	PAPER PRINTER 5/BOX GEM 4000/3500	1

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 Manual.

General Operation Information

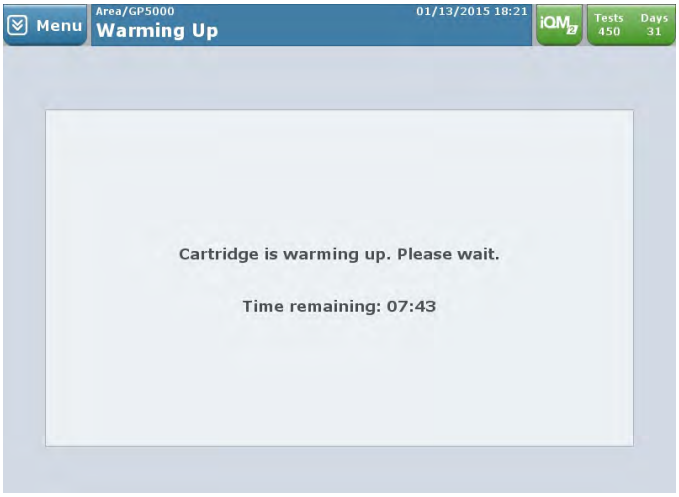
The GEM Premier 5000 system is designed for intuitive use, and provides clear direction when you are operating the system:

Changes in color of the Status bar signals different conditions of the GEM Premier 5000 system:

Green	READY
Yellow	User specific action needed
Red	Analyzer is locked
Blue	Analyzer is performing a function

The Tests/Days button on the status bar help the user determine the status of the current GEM PAK inserted and how soon before a new PAK will need to be changed. This information will help you plan PAK changes at a convenient time.

Operator messages provide clear directions to you for next steps. These instructions are generally in gray boxes with black text.



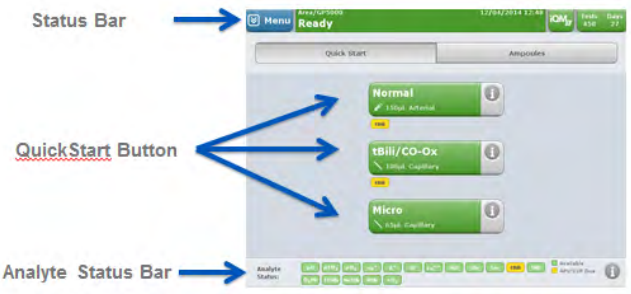
Password protection prevents unauthorized access to key activities. When prompted, enter your password, as provided by your supervisor or other managerial personnel.

Audio prompts also aid use by providing programmed beeps or tones to indicate that an action has occurred or is about to occur.

QuickStart Main Screen

Once Auto PAK Validation and/or CVP5 testing is complete, you will see the QuickStart buttons and analytes buttons in the Analyte Status Bar are green.

The Smart Color Status Bar along the top of the Graphical User Interface (GUI) provides a quick summary of critical analyzer information and capabilities:



- Analyzer Status – indicates overall readiness of analyzer for patient sampling.

Note: Date/Time – system clock runs on 24 hour time.

- iQM2 Button – iQM2 is Instrumentation Laboratory's patented Intelligent Quality Management 2 System, which ensures the integrity of the overall analysis system. When quality testing runs in the background the iQM2 Button will turn yellow.

- Network Status Button – indicates whether the analyzer is connected to a network. Selecting this button provides more detailed information about the network connection (to LIS/HIS/GEMweb Plus).
- Tests/Days Button – displays the number of days/tests remaining before you must change the GEM PAK. When a new GEM PAK is installed, 31 days will be displayed representing the maximum on-board GEM PAK stability along with the number of tests designated by the EEPROM (from 75 to 600 tests).

Note: 600 test GEM PAK have an on-board stability of 21 days.

Note: An expired GEM PAK cannot be used by the analyzer.

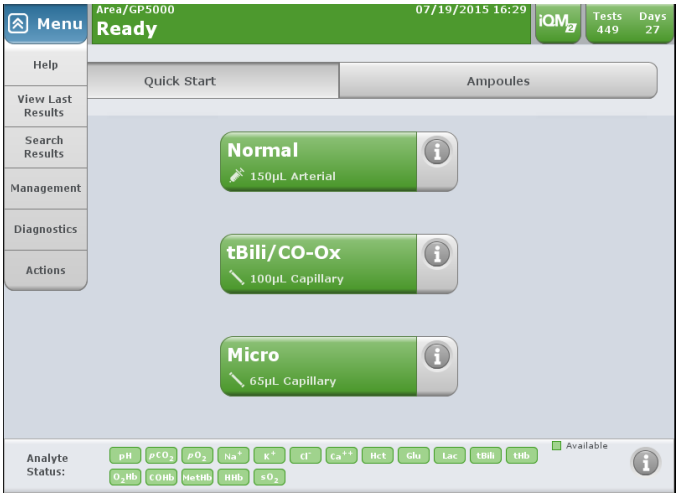
Selecting this button will display the exact day/time the GEM PAK will expire. When either 1 day or 5 tests are remaining, the button background color will turn yellow.

- Mail Button – alerts you to incoming e-mail messages and system error messages. When a new message is received, the Mail Button will turn yellow and the number represents the total mail messages received that have not been acknowledged.

Note: The email feature on the GEM Premier 5000 analyzer may not be available in all countries.

- Menu Button – allows access to additional functions beyond patient sampling.

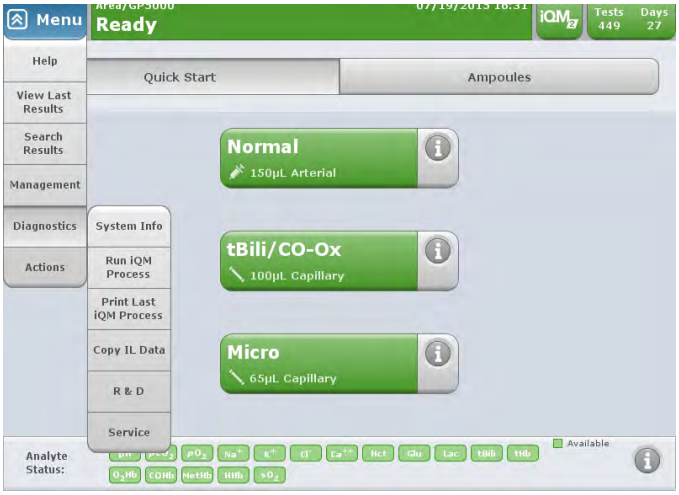
Touching the blue Menu button in the upper left triggers a drop-down menu that provides fast access to additional system functions.



Note: You may be prompted to enter a password to access the Menu Options.

Menu Button drop-down functions:

- Help – provides direct access to topic-based training videos.
- View Last Results – enable you to search last 20 patient results.
- Search Results – enables you to search patient results from the database.
- Management or GEMweb Plus – allows managers or key users access to key system tasks to include configuration and operator management.
- Diagnostics – offers access to a range of tasks related to the status of the GEM Premier 5000 (see Diagnostics Section).
- System Info – provides system information to include SW version.
- Run iQM2 Process – allows user to manually initiate iQM2 process.
- Print Last iQM2 Process.



- Copy IL Data – allows user to copy GEM PAK data onto a CD or USB for investigation purposes.
- Action – enables you to manually remove a GEM PAK, restart the analyzer or shutdown the analyzer (see “Removing the GEM PAK” on page 44).

Shutdown

CAUTION: Once the analyzer has been shut down the cartridge will need to be replaced if power is not restored within 20 minutes. If, when power is restored the cartridge cannot be recovered, the analyzer will alert the operator to remove the cartridge.

Press the blue Menu icon in the upper left of the Main Sampling screen. Select Shut Down from the pulldown menu. The analyzer will prompt to consider the decision. Press No to return to the Main Sampling screen. Press Yes to continue to shut down. The analyzer will shut off on its own. The analyzer has now been correctly shut down.

Momentary Power Switch

The GEM Premier 5000 analyzer has a momentary power switch. To power the instrument off, it is necessary to utilize the shut down command in the instrument software. If the power switch is pressed and held for 5 seconds or longer, the instrument shuts down. However, this will result in an illegal shut down, and the instrument software may not be able to recover.

4 - GEM PAK (Cartridge)

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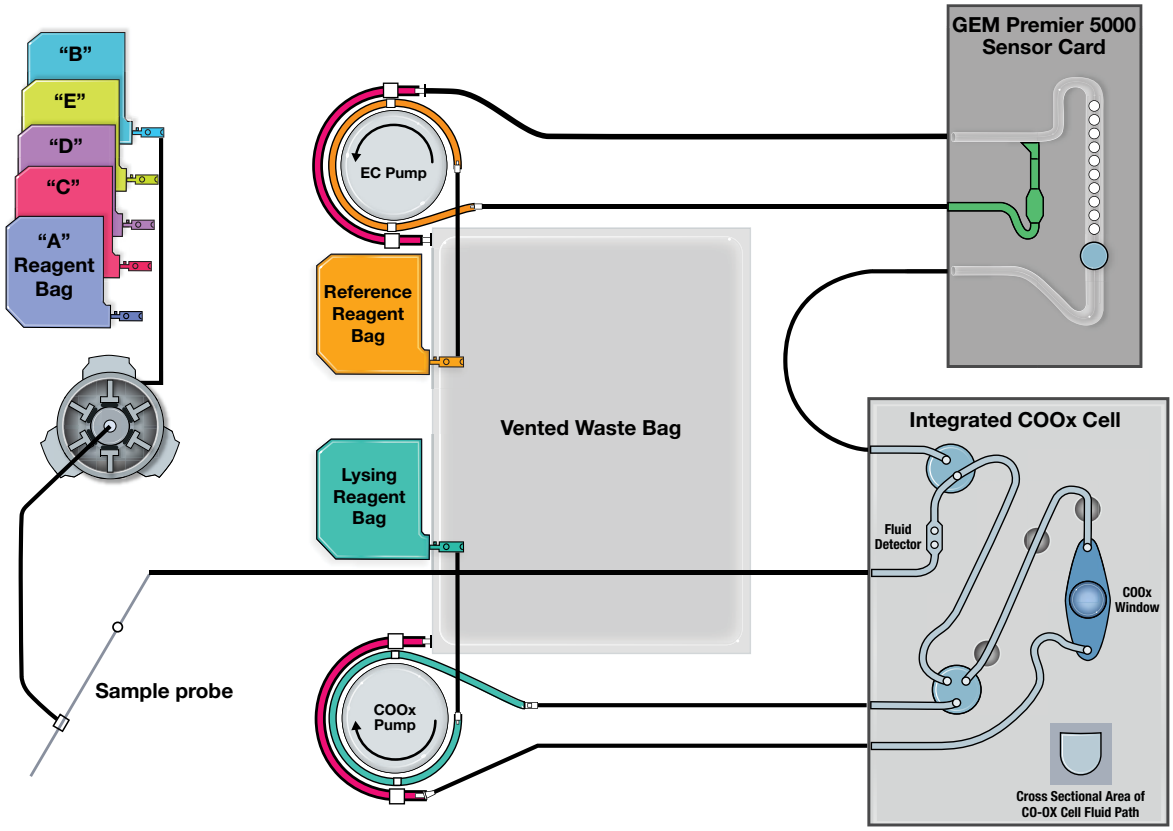
The primary component of the GEM Premier 5000 analyzer is the GEM Premier 5000 GEM PAK. The disposable, multi-use PAK houses all components necessary to operate the instrument once the cartridge is validated. These components include the sensors, solutions, sampler, CO-Ox/tBili optical cell, and waste bag. GEM Premier 5000 PAK has flexible menus and test volume options to assist facilities in maximizing efficiency. The GEM PAK can measure pH, pCO_2, pO_2, Na^+, K^+, iCa, Cl^-, Glucose, Lactate, Total Bilirubin, (tBili) Hematocrit, Total Hemoglobin (tHb), and hemoglobin fractions, including Oxyhemoglobin (O_2Hb), Deoxyhemoglobin (HHb), Carboxyhemoglobin (COHb), Methemoglobin (MetHb), and Oxygen Saturation (sO2).

The following is an overview of the GEM PAK:

- All required components for sample analysis are contained in the GEM PAK, including sensors, optical cell for CO-Oximetry and total bilirubin, sampler, pump tubing, distribution valve, waste container and Process Control Solutions.
- The GEM PAK is a totally closed analytical system. The operator cannot introduce changes to the analytical process before or during the GEM PAK's use-life on board the instrument

GEM Premier 5000 System Fluidic Diagram



- The sensor card contains all of the sensors in a gas-tight chamber.
- The sensors are set to the factory calibrated values and monitored with five Process Control Solutions A, B, C, D and E. The Process Control Solutions (PCSs) are pre-tonometered to specific values of pO_2 and pCO_2, and sealed in gas-impermeable foil laminate. Each PCS contain known quantities of the analytes and dyes tested using NIST - traceable, CLSI or internal standards to establish target values for monitoring medical-decision levels and ensure accuracy of results, where clinical actions are necessary.

- Each PC solution serves a specific function in the iQM2 process. Five PC Solutions (A, B, C, D and E) are performed continuously each day to confirm sensor, CO-Ox and PAK performance:

Process Control Solution	Frequency	Function
A	Every 4 hours	Measures sensitivity, sensor drift and accuracy at medical decision levels* (MDLs) or clinical reference ranges in combination with other PC solutions.
B	Every 30 minutes or after each sample	Measures sensor drift and accuracy across the span of MDLs or clinical reference range. Used as corrective action in high frequency after interference. Remains over sensors and with outputs checked every 30 seconds.
C	Every 24 hours	Measures low level pO_2, pH, pCO_2 for drift. Conditions the interference rejection membrane for glucose/lactate sensor.
D	Every 12 hours	Measures sensor drift and accuracy across the span of MDLs and clinical reference range. Validates calibration (PCS values) and cartridge prior to sample analysis.
E	Every 12 hours	Measures sensor drift and accuracy across the span of MDLs and clinical reference range. Validates calibration (PCS values) and cartridge prior to sample analysis.

* Note: PCS values have been established to monitor all analyte-related MDLs. Many hospital protocols and treatment algorithms employ MDLs (e.g, Sepsis Guidelines for Lactate, ARDSnet and ALVEOLI guidelines for pO_2,). PCS MDLs for the GEM Premier 5000 system are based on Clinical Decision Levels for Laboratory Tests, 2nd Edition, Statland, Bernard, 1987.

- There are two more solutions in the GEM PAK: 1) Reference Electrode Solution that contains silver ion, which is pumped into the reference channel in the sensor card to form the Ag/Ag^+ reference electrode. 2) Lysing Solution, which contains buffered surfactant, is pumped into the mixing chamber of the sensor card to lyse the blood before the blood is brought into the optical cell for CO-Oximetry and total bilirubin measurements.

- The sensor card and the optical cell reside in two thermal blocks, which maintain the temperature at 37°C and provide electrical interface to the sensors and optical interface to the optical cell.

- The peristaltic pumps move various fluids (Sample, Process Control Solutions, Reference Electrode Solution and Lysing Solution) into the sensor card and the optical cell and eventually to the waste container.

GEM PAK Types

Instrumentation Laboratory has a variety of GEM PAK analyte menus and test volumes available to meet the testing needs of all departments. Please refer to the operators manual for PAK options.

Cartridge Installation

The GEM Premier 5000 system requires a GEM Premier 5000 PAK to perform analysis. Only GEM PAKs designed for use with the GEM Premier 5000 system and supplied by Werfen/Instrumentation Laboratory can be used with the analyzer.

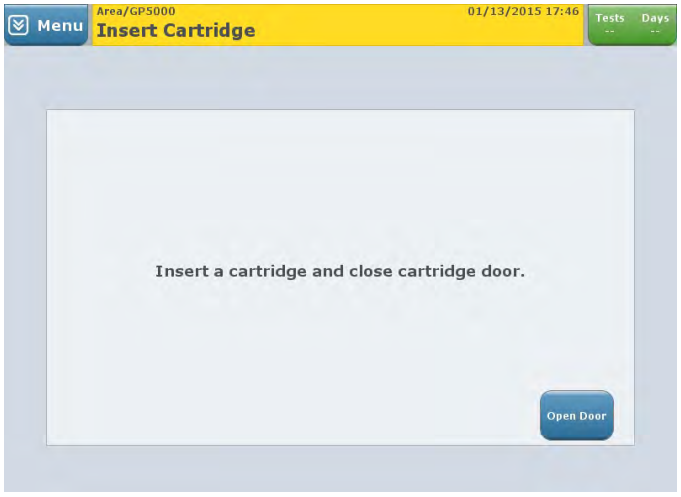
i Refer to the “Installation of the Analyzer” on page 20 Section for information on analyzer setup.

1. If the analyzer power is OFF, press the power switch to turn it ON. The system will automatically begin the power-up cycle.

The analyzer has a momentary power switch (button). Press the button and immediately release it to turn the analyzer on. If the button is pressed and held for 5 seconds or longer, the power is turned off.

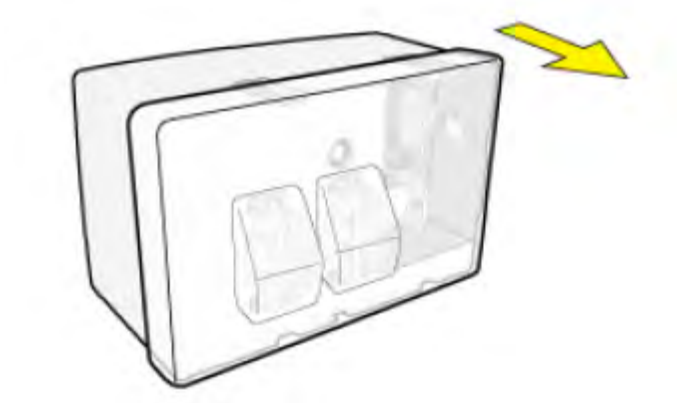
The analyzer should remain powered on unless it is being transported to another source without an uninterruptible power source (UPS).

2. Press Open Door on the touch screen. You will hear an audio prompt, and the door will release and open slightly. Then manually move the door all the way to the left.



3. Unpack the GEM PAK from its protective wrapper. Remove the clear plastic cover and desiccant pouch from the pump winding area.

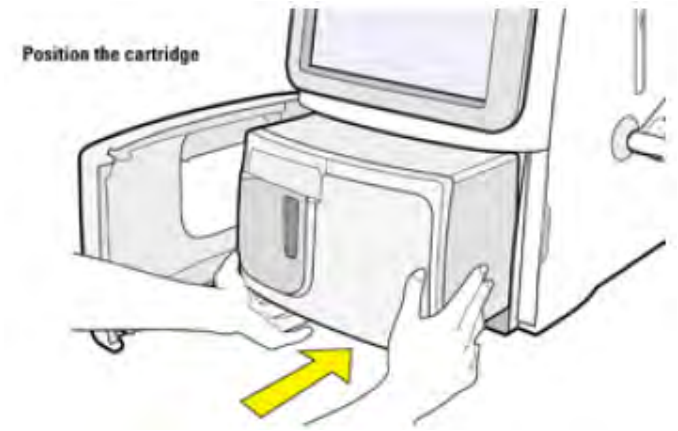
   The GEM PAK must be stored at room temperature (15 to 25° C).



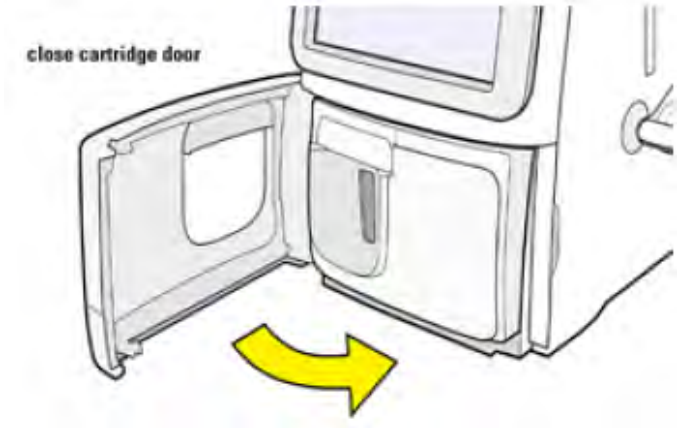
Only IL supplied GEM PAKs may be used with this analyzer. The use of non-IL supplied GEM PAKs will invalidate the analyzer warranty and will release IL from any responsibility for analyzer or PAK performance.

4. Position the GEM PAK with the gray sampling area facing forward. Push the cartridge in until you feel resistance.

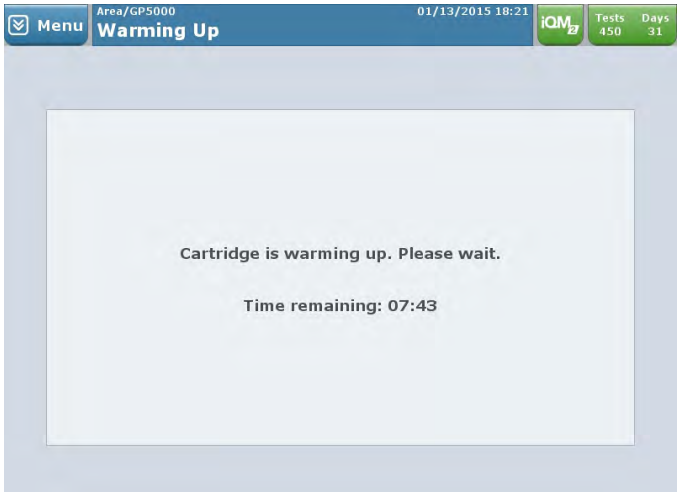
   Please note that approximately one inch of the GEM PAK will extend beyond the front of the analyzer.



5. Guide the analyzer door to the right to close it and move the GEM PAK into its final position.



6. In approximately 20 seconds, the analyzer will inform you that the GEM PAK is warming up. The clock will count down for the next 40 minutes as the GEM PAK warms up. During this time, the sensors will hydrate, and the analyzer will perform internal checks and processes.



7. After the start-up period is complete, the GEM Premier 5000 system will automatically perform calibration validation utilizing two (2) independent NIST-traceable on-board solutions traceable to NIST standards, CLSI procedures or internal standards, called Auto PAK Validation or APV. Only after the APV process is successful can samples be performed on the selected analytes.

Auto PAK Validation (APV)

APV must be acceptable prior to the GEM Premier 5000 analyzer accepting patient samples.

Auto PAK Validation (APV) process is automatically completed after the GEM PAK warm-up: two completely independent NIST-traceable solutions containing two levels of concentration for each analyte (PC Solution D and E), are run by the analyzer to validate the integrity of the PC Solutions and the overall performance of the analytical system (GEM PAK).

Note: GEM PAKs that include the total Bilirubin analyte (tBili) will require the successful performance of CVP5 tBili (Calibration Valuation Product), an external, ampoule-based product prior to performing samples for tBili.

After successfully performance of APV, iQM2 manages the quality control process, replacing the use of external quality controls.

Cartridge EEPROM

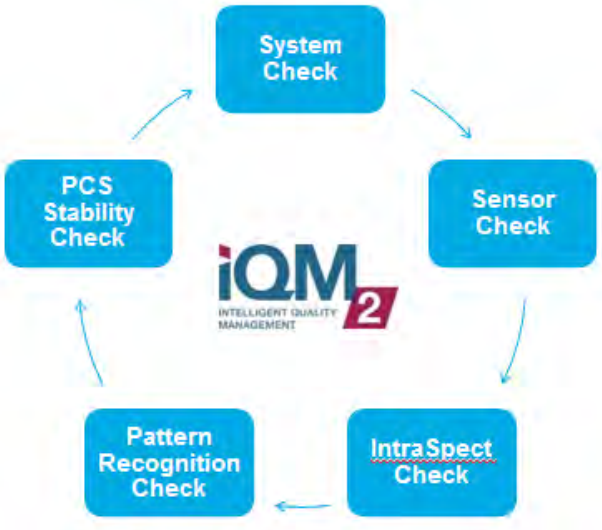
All cartridge data is contained on an EEPROM mounted on the cartridge. When the cartridge is properly inserted, the instrument will read the information from the EEPROM. The instrument will also write to the EEPROM which eliminates the possibility using the cartridge more than one time or utilizing a cartridge past the expiration date.

Intelligent Quality Management 2 (iQM2®)

- Intelligent Quality Management 2 (iQM2) is used as the quality control and assessment system for the GEM Premier 5000 system. iQM2 is an active quality process control program designed to provide continuous monitoring of the analytical process before, *during* and after sample measurement 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 (QC). Facilities should follow local, state and federal regulatory guidelines to ensure that a total quality management system is followed.
- iQM2 is a statistical process control system with well-defined performance characteristics that maximizes probability of error detection, minimizes time to error detection while minimizing probability of false rejection.
- iQM2 performs 5 types of continuous, quality checks to monitor the performance of the GEM PAK, sensors, CO-Ox, and reagents. These checks include System, Sensor, the NEW IntraSpect, Pattern Recognition and Stability Checks to ensure the delivery of quality patient results every time. iQM2 utilizes the various checks along with pattern recognition software to identify errors, initiate corrective actions, and document all steps in the corrective action process to assure regulatory compliance, while significantly reducing the time and cost required for performing traditional quality control.

iQM2 INTELLIGENT QUALITY MANAGEMENT

iQM2 performs continuous 5 specific types of quality checks (Figure below) to continuously monitor performance of the GEM PAKs, reagents, CO-Oximetry and sensors throughout the cartridge use-life.



Components of iQM2

Single, multi-use disposable GEM PAK

The GEM PAK is a completely closed cartridge, to which the user cannot introduce changes either before or during use-life. The GEM PAK contains all materials required to perform analytical testing, including: sensors, solutions, sampler, tubing, and waste bag. A PAK "run" is the period of time during which an analytical system is expected to be stable, and provides a closed environment of known quality (PAK is validated and no changes can be introduced). System changes that may affect the quality of test results are detected by iQM2.

Process Control Solutions (PCSs)

PCSs are internal solutions for the GEM Premier 5000, traceable to National Institute of Standards and Technology (NIST) primary standards or other standards. These solutions are tonometered to specific values of pO_2 and pCO_2 and sealed in gas-impermeable foil laminate. Each PCS serves a specific function in the iQM2 process. Five PCSs (A, B, C, D and E) are performed continuously each day to confirm sensor, CO-Ox and PAK performance. PCS target values were established to monitor medical-decision levels, clinical reference ranges, or normal clinical ranges and ensure accuracy of results, where clinical actions are necessary. Refer to the Operators manual for more information.

Additional features of iQM2 contributing to enhanced efficiency and workflow include:

- Custom QuickStart Graphical User Interface
  - Reduces actions required to initiate testing
  - Reduces potential for errors during sample ordering
- SmartColor Status Bar
  - Provides analyzer status at a glance
  - Provides iQM2 function information
- Illuminated sampling area with universal sample acceptance
  - Assures correct sample presentation/aspiration
  - Accepts tubes, syringes, capillary tubes or ampoules
- Specifications
  - Throughput: 29 samples/hour
  - Time to result: 45 seconds

iQM2 Requirements

1. Closed analytical system
   - All analytical components (sensors, solutions, optical cell, tubing, sample, etc.) are included in the single GEM Premier 5000 disposal PAK figure below).
   - The GEM PAK is a totally closed analytical system that the user can introduce no changes before or during the on-board use-life of the GEM PAK. After initial PAK validation (APV), the quality of the closed system is known and can be monitored.
   - The GEM PAK use-life (up to 31-days) constitutes a “run”, as defined by the Clinical Laboratory Standards Institute (CLSI) C24-A3 – “…period of time during which an analytical system is expected to be stable.”

Figure: GEM Premier 5000 PAK is a closed analytical systems that contains all components required for sample testing.

2. Continuous monitoring of system capable of detecting abnormal changes
   - Process Control (PC) Solutions A, B, C, D and E with analyte values validated using NIST-traceable standards and whose targets and acceptable ranges are encoded in each GEM PAK Electronically Erasable Programmable Read-only Memory (EEPROM) chip.
   - PC Solutions are utilized to monitor and maintain PAK/reagent/CO-Ox quality throughout use-life.
3. Pattern Recognition (PR) software determines patterns (for identification of errors), automatically initiates appropriate corrective actions and confirms successful mitigation of errors
   - Control limits were established to ensure that iQM2 detects any change with the potential to result in a clinically significant error in the analytical system.
   - Microprocessors in the GEM Premier 5000 system record comprehensive PAK information in real-time, including all sensor and CO-Ox module outputs.
   - iQM2 is a statistically-based process control system with well-defined performance characteristics, maximizing probability of error detection, minimizing time to error detection and the probability of false rejection.

- In addition to monitoring GEM PAK and system quality, PR software identifies patterns generated by sample, sensor or PAK errors, including those caused by clots, interferences, insufficient sample, bubbles, etc.
- iQM2 control or “drift” limits are derived from the Total Allowable Error (TEa) criteria established by Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) for proficiency testing. Refer to the Operators manual for more information.

iQM2 Process

Upon manufacture at IL and before sensor cards are assembled into GEM PAKs, every electrochemical sensor is functionally tested using solutions that are NIST-traceable or traceable to other standards. Sensors test results are documented by sensor card serial number and sensors that do not meet specifications are discarded. The unique and proprietary design of the sensor architecture allows for multiple hydration and drying stages without effecting sensor performance. This ensures that the quality of all sensors has been confirmed with NIST-traceable solutions prior to PAK manufacturing and clinical use.

Every lot of PCS is tested and analyte values assigned, using NIST-traceable standards or other standards prior to assembly into GEM PAKs. PCS values are encoded electronically through an EEPROM chip on each PAK. Upon PAK insertion, the GEM Premier 5000 system reads and records all factory-assigned information, including lot number, expiration date, test menu, sample capacity and PCS assigned values and acceptable ranges.

With the iQM2 process the PCSs are exposed to the sensor and CO-Ox along the same fluidic pathway as patient samples, including the full extent of the sampler. iQM2 is thus able to detect any obstructions or malfunctions originating from the sampler through the entire analytical pathway. After insertion of the GEM PAK into the analyzer, the instrument performs an automated PAK start-up during which the sensors are hydrated and a variety of checks occur, all of which take about 40 minutes. PC Solutions are tested and the slope and intercept of the sensors are compared to factory-assigned values on the EEPROM.

After performing PC Solutions checks, the APV (Auto PAK Validation) process is automatically completed: two completely independent solutions traceable to NIST standards, CLSI procedures or internal standards, containing two levels of concentration for each analyte (PC Solution D and E), APV is run by the analyzer to validate the integrity of the PCSs and the overall performance of the analytical system (GEM PAK). APV must be acceptable prior to the GEM Premier 5000 system accepting patient samples.

Note: GEM PAKs that include tBili require the successful performance of CVP 5.

Once the GEM PAK start-up and APV is completed, iQM2 continuously monitors performance of the GEM PAK, reagents, CO-Ox module and sensors throughout the cartridge use-life by five specific quality checks:

- System
- Sensor/CO-Ox
- IntraSpect
- Pattern Recognition (PR)
- PCS Stability

1. **System Checks**: GEM Premier 5000 system routinely conducts functional checks of vital system components, including mechanical sub-assemblies/ electronics and PAK fluidics, to check sample integrity and reagent performance before each sample analysis and at various scheduled times throughout PAK use-life. When errors are identified during system checks, iQM2 alerts the operator, automatically initiates corrective actions, and documents the actions taken. System Checks include:
   a. Mechanical and electronic checks
      i. Sensor milivolt (mV) output thresholds
      ii. Spectrophotometer and optics thresholds
      iii. A/D (analogue/digital) electronic verification
      iv. Processor Communication
      v. Motor checks – valve, sampler, heater-block function
      vi. Light source and spectrophotometer

   b. Fluidic Checks
      i. Sample Volume - ensures proper volume of sample prior to analysis
      ii. Sample Integrity - ensures sample quality for accurate results (e.g., detects bubble in sample)
      iii. Reagent Volume
      iv. Reagent Flow
      v. Pump Verification
2. **Sensor/CO-Ox Checks**: Five PCSs are run automatically to continuously verify sensor, CO-Ox and PAK performance. PCSs are measured and compared to expected values (drift). iQM2 automatically evaluates PCSs, alerts the operator, and initiates corrective actions, if applicable. Sensor/CO-Ox Checks are performed continuously throughout PAK use-life, significantly exceeding the discrete testing schedule of traditional quality control, where QC levels are performed approximately every eight hours.

Note: PC Solutions are performed utilizing the identical analytical pathway as samples and verify performance of the analytical system from the aspiration point through the sample measurement process.

- iQM2 automatically analyzes each PC Solution analyte value, based on established acceptable ranges:
  - If the PC Solution results are within the established control limits (less than TEa), the system is valid for patient testing, as when first validated with APV.
  - If a change beyond the established control limits (drift) is detected for a PC Solution, iQM2 uses PR software to diagnose, initiate corrective actions, and confirm error mitigation and document.
  - Sample results for the affected analyte will be suppressed on the sample report
  - If corrective action is not possible or unsuccessful, iQM2 will automatically disable the affected analyte(s), thus rendering the analyte unavailable for further patient analysis.

PC Solutions are performed continuously each day with each PC Solution frequency designated at a scheduled time throughout each day. In additional, PC Solution B will remain over the sensors with readings performed every 30 seconds when samples are not performed, thus providing hundreds of PC Solution quality checks performed each day to ensure sensor and PAK performance throughout the GEM PAK use-life.

Note: If an error persists in four consecutive PC Solution C, D or E measurements or in seven consecutive PCS A measurements, or in 30 consecutive PCS B measurements, then the affected parameter will be permanently disabled.

- Only after the above steps are successfully completed will iQM2 adjust any drifts to zero, correcting for normal sensor electronic drift.
- iQM2 records all PCS sensor readings. This allows IL to use the information for enhanced understanding of patterns, leading to continuous product improvement.

PCSs are performed continuously each day with the frequency designated at a scheduled time throughout each day (Table below) or after every sample (Figure below). In addition, PCS B will remain over the sensors with readings performed every 30 seconds when samples are not performed, thus providing hundreds of PCS quality checks each day to ensure sensor and performance throughout the GEM PAK use-life.

Process Control Solution	Frequency
A	Every 4 hours
B	Every 30 minutes or after each sample
C	Every 24 hours
D	Every 12 hours
E	Every 12 hours

3. **IntraSpect Technology:** During the sample measurement period, iQM2 software collects 15 sample mV readings in 15 seconds and evaluates sensor performance by abnormal sensor response pattern through slope shape and coefficient values (Figure below). IntraSpect Checks provide continuous sample integrity quality checks throughout the entire measurement process to ensure accuracy of patient results (see figure below).

Note: iQM2 with IntraSpect technology provides complete quality assurance of results throughout the entire sample measurement process.

IntraSpect can detect abnormal sensor response slope or absorbance residual error during the measurement process.

The following events may cause abnormal sensor response or residual absorbance errors during the measurement process:

- Microclots
- Microbubbles
- Interferences

After performing IntraSpect check in a sample, the affected analyte result becomes either incalculable or flagged for sample response errors.

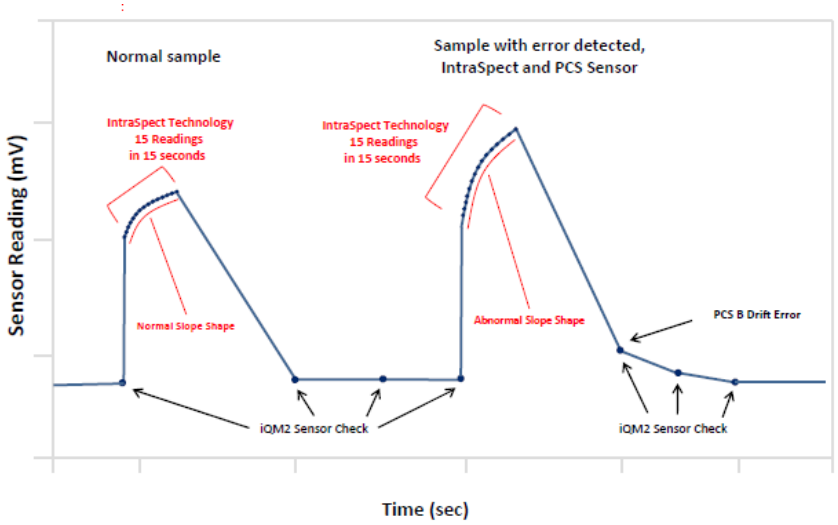


Figure: iQM2 IntraSpect Check is performed during sample measurement. IntraSpect automatically analyzes sample measurement readings and performs corrective actions, if applicable.

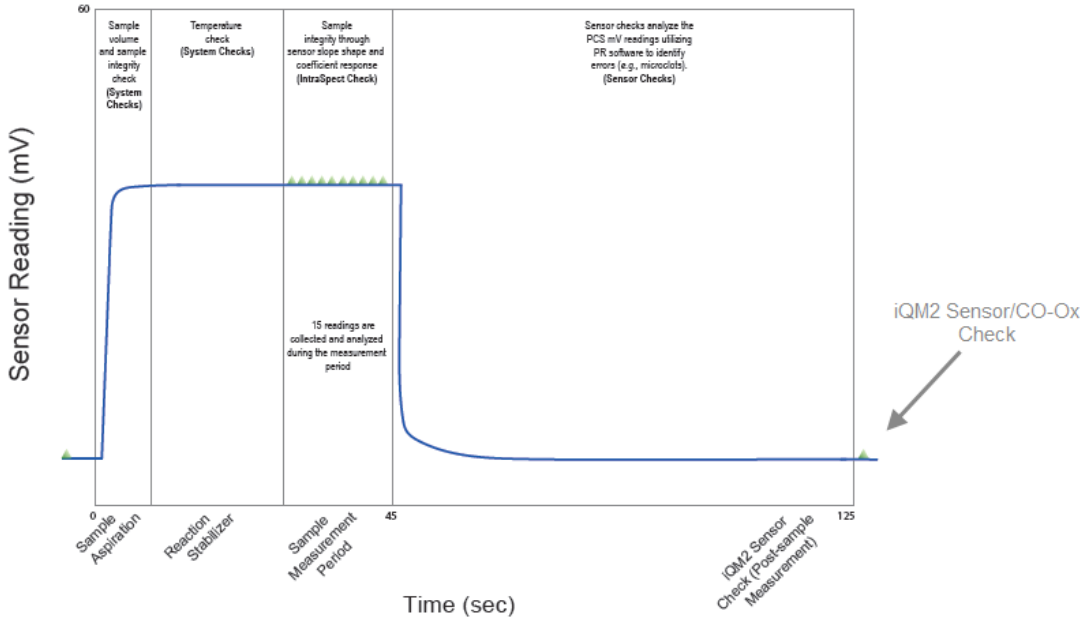


Figure: iQM2 verifies a sample with continuous, real-time quality checks before, during and after sample measurement.

4. **Pattern Recognition (PR)**: Signals from sensors and the CO-Oximeter, generated by samples or PCSs are analyzed by PR software. Patterns (sensor or spectral response) generated by various sample, sensor, CO-Ox and reagent errors can also be recognized. iQM2 initiates intelligent corrective actions based upon the pattern verified, alerts the operator immediately, attempts to automatically correct the problem, then will disable a specific analyte, if recovery is not possible, or reject the GEM PAK, if needed.

   PR software can identify these common errors associated with sample integrity:

   - Micro-clots, which can occur from inadequate anti-coagulant or improper mixing (Figure a).

     Note: Micro-clots are small blood clots or fibrin strands that adhere to the surface of a sensor membrane or CO-Ox cell and induce a change in sensor characteristics, such as sluggish response or sensitivity change or absorbance change in the optical cell. Micro-clot patterns are distinct for various sensors.

     - iQM2 automatically initiates a special rinse cycle upon detecting a micro-clot pattern. When the rinse is complete, the iQM2 software confirms the mitigation of the clot pattern on the affected sensor or will continue corrective actions automatically if the clot pattern remains. Sensors that clots cannot be mitigated will be disabled and unavailable for patient testing.

   - Interferences - Positive and negatively charged lipophilic compounds, such as, Benzalkonium (benzalkonium chloride) or Thiopental.

     - Benzalkonium (benzalkonium chloride), utilized in skin sanitation and intravascular-access devices, is a positive ion that can cause positive bias with Na^{+}, K+, and Ca^{++} (Figure b)

- CO-Ox/TBili spectral errors as a result of turbidity or endogenous/exogenous dyes

- Abnormal sensor slope shape or coefficient (IntraSpect Check) may occur during the measurement process.
- Sensor Malfunction Patterns (pH, pCO_2 and pO_2)
  - A few sensors that require additional pattern checks to detect certain sensor malfunctions. These sensors include pH, pCO_2 and pO_2.
  - Sensor Malfunction Patterns that iQM2 is checking for in these sensors are very rare and very slow in progression. Therefore, the PCS C check that is performed once a day is adequate in detecting these malfunctions. In case of a sensor malfunction pattern, the affected sensor is permanently disabled by iQM2.

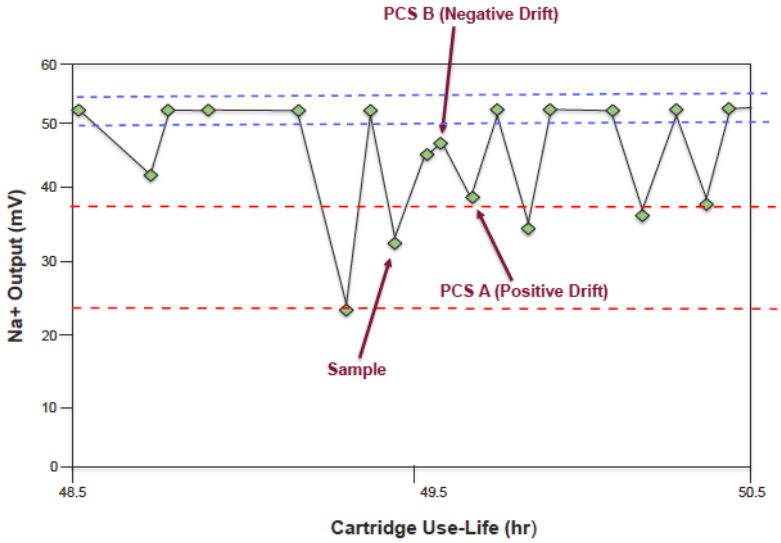


Figure a: Micro-clot detection: Negative PCS B drift followed by positive PCS A drift.

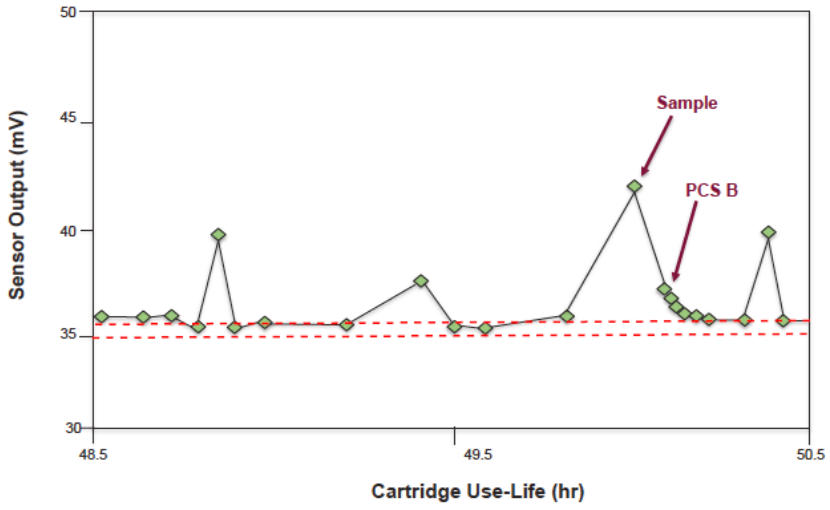


Figure b: Benzalkonium: Positive PCS B drift for Ca^{++} and Na^{+} and no negative drift for K^{+}.

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PR Software will initiate intelligent corrective actions specific for the error verified:

Error Detected	Corrective Action	Confirmation of Error Mitigation
Micro-clot	Perform clot bust rinse to remove micro-clot from sensors	PCS A and B results within acceptable range prior to allowing sample testing
Interference	Increase frequency of PCSB to remove interferent	PCSB readings return to baseline (normal) for the affected sensors.
IntraSpect	Sensor Check utilizing PC Solutions after sample	PCS B results within acceptable range (IntraSpect error notification)
Spectrophotometer Drift	Perform wavelength and accuracy check	Spectrophotometer accuracy is within specifications prior to sample measurement

5. **PCS Stability Checks:** These checks verify PCS stability during PAK use-life. If check fails, the GEM PAK is rejected.
   - pO_2 in PCS A is compared to initial measurement.
   - O_2 is the most sensitive analyte for detecting reagent deterioration.
   - Correct recovery of pO_2 requires all PCSs to be very stable (recover within established limits).

iQM2 Control

iQM2 technology provides active process control that monitors and maintains the stability of calibration during GEM PAK use-life.

- Ongoing monitoring and control of the GEM PAK uses 5 PC Solutions analyzed at different intervals and after every patient sample. Difference between the observed values for PC Solutions and the target values are compared to control limits (drift limits)
- When the observed PC Solution A, B and C values are within established control limits, the active process control technology re-establishes the Target value for PC Solutions A, B or C to maintain the stability of the measurement process.
- Any PC Solution A, B or C value that exceeds the established statistical control limits for an analyte leads to further assessment via PR software which may include corrective actions based upon pattern detection algorithms
- iQM2 control mechanism is predicated on the stability of the PC Solutions, which are monitored via the iQM2 PC Stability Check.

Statistical Evaluation of Drift Limits

Drift limits are used as a trigger for the sensor and PR checks and subsequent iQM2 corrective actions. Working in consultation with James O. Westgard Ph.D., Professor, Department of Pathology and Laboratory Medicine at the University of Wisconsin, (Westgard, JO, et al. Point of Care, 2003, Vol. 2, No. 1, 1-7), a methodology for optimizing the drift limits were developed for high probability of error detection and low probability of false rejection. This section explains how statistical control methods were used for evaluation of the drift limits.

Statistical Method

Drift limits on Process Control Solutions A, B, C, D, and E can be characterized as a single measurement of a control material. Statistical control methods are then used to develop probabilities for error detection and false rejection. This approach allows comparing performance expected for iQM2 with performance of traditional QC procedures.

- Define method performance
  - Method performance in terms of Mean and SD values will be obtained from the data collected from multiple GEM PAKs representing a wide variety of uses from customers in the field and in-house tests.
- Predict QC performance
- Calculate Method Sigma = TEa/SD
- Calculate Control Limit = Drift Limit/SD
- Determine probability of false rejection (Pfr) from normal probability distribution (from tables of areas under normal curve, or z charts)
- Pfr = Prob ($z \geq$Method Sigma)
- Determine probability of error detection with 95% confidence (Ped) from normal probability distribution
- Ped = 1 – Prob ($z \geq$(Method Sigma – Control Limit – 1.65))
- Calculate Average Run Length for rejectable quality
- ARLr = 1/Ped
- Determine average detection time (unit of time for detecting error that can be compared to traditional QC)
- Average detection time = ARLr x sampling time

Sampling time for Process Control Solution A is between 1 to 4 hours, for Process Control Solution B, it is between 0.5 to 2 minutes (2 minutes when there is a sample between B measurements), for Process Control Solution D and E is 12 hours, and for Process Control Solution C, it is 24 hours.

For a given Total Allowable Error (TEa), the drift limits have to provide a high probability of error detection (Ped ≈1) and low probability of false rejection (Pfr ≈0).

Results of the drift limit analysis indicate that the probability of false rejection is close to zero for all parameters in Process Control Solution B. Process Control Solution B is the primary means for error detection because of high measurement frequency. Probability of error detection is high in PCS B. Even for glucose with relatively low Ped values, the average error detection time is within 20 minutes in comparison to a typical quality control program that would require 8 hours.

Software Validation

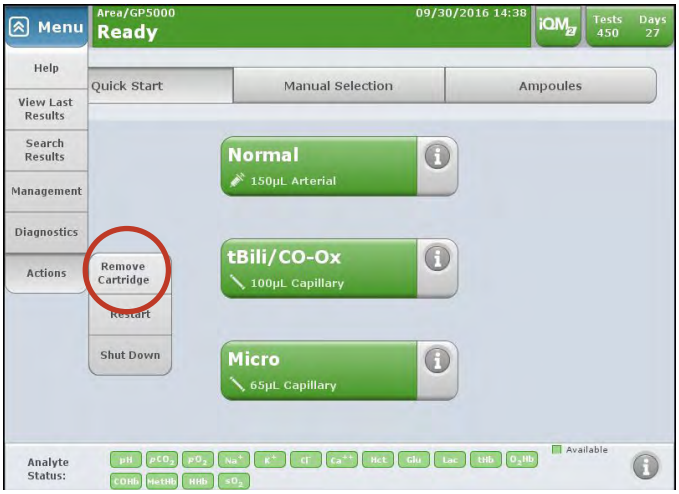
As with any analytical device or computer software, there is always the potential for software failure. However, IL conducts rigorous testing and extensive software validation prior to releasing a software revision. If the user encounters a rare software error code, it should be reported to your local IL Technical Support Representative.

Removing the GEM PAK

Removing the GEM PAK is generally a task that should be performed only when the GEM PAK is completely used and the analyzer indicates that the GEM PAK needs to be replaced. A supervisor may decide to manually remove a GEM PAK when there are a few tests left for convenience (for example, in the operating room PAK changes may not be practical during procedures). GEM Premier 5000 GEM PAKs once removed from the analyzer cannot be reinserted into the analyzer. Be sure to consult your supervisor before performing this task.

If a GEM PAK has reached its maximum onboard use-life or test capacity, the GEM PAK door will automatically open and display a message to the operator to remove the GEM PAK. To remove a GEM PAK prior to its maximum onboard use-life or test capacity, follow the instructions provided below. Removal of the GEM PAK is a simple operation but must be evaluated to avoid underutilizing a GEM PAK.

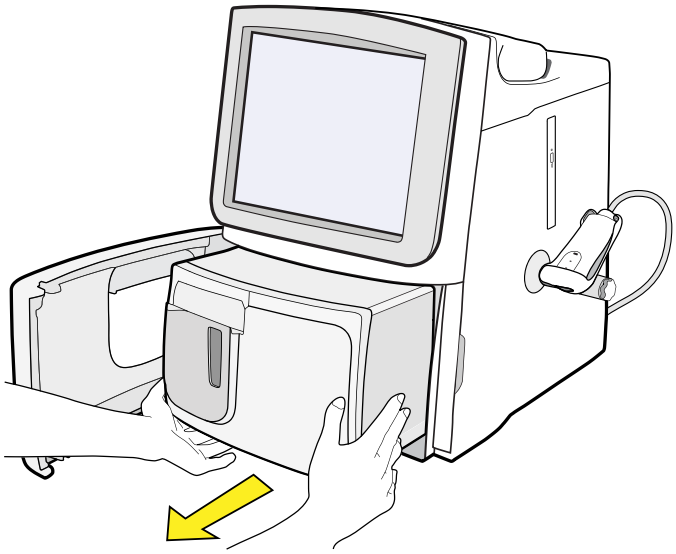
1. Press the **Menu>Action>Remove Cartridge** buttons. If requested, enter your password.



2. As a precaution, the system will ask you whether you want to continue. Press **No** to stop the process and return to the Start New Sample tab. Press **Yes** to continue.

3. Once you press **Yes**, the door will click open slightly. Move the door to the left, grasp the GEM PAK, and pull it gently toward you. Dispose of the GEM PAK in an appropriate biohazard container. The system will now be inactive until you insert a new GEM PAK (see Setting Up the Analyzer).

   Note: GEM PAKs cannot be reused once they have been removed.



CAUTION/BIOHAZARD WARNING: GEM PAKs contains a waste bag that contains blood, a potential biohazard. Use universal precautions as designated by your facility when handling a used GEM PAK. Dispose of it in an appropriate biohazard waste container.

CAUTION: Under no circumstances are cartridges to be opened.

5 - Maintenance

There is limited operator maintenance required on the GEM Premier 5000. 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 (see “Preventive Maintenance (PM)” on page 48).

Cartridge Replacement

Removal of the cartridge is described in “Removal and Disposal” in Chapter 4 insertion of a new cartridge is described in “Cartridge Installation” on page 30.

Loading Paper

Loading of paper is described in “Installing the Printer Paper” on page 21.

Decontamination Procedure

Supplies:

- Disposable latex or rubber gloves
- Laboratory coat or jacket
- Eye protection
- Soft cleaning cloths
- 10% chlorine bleach solution
- Biohazard waste bags
- Non-abrasive, mild cleaning solution

The GEM Premier 5000 analyzer processes patient samples that may be highly infectious. When cleaning the instrument use proper technique and care to avoid contaminating yourself or others.

Put on rubber or latex gloves, eye protection, and a laboratory coat or jacket before handling the instrument.

Prepare a biohazard waste bag for waste disposal.

Decontamination of the GEM Premier 5000 is only required the analyzer needs to be shipped, i.e, to a GEM Service Center.

To decontaminate the touch screen:

1. Remove the GEM PAK from the analyzer as described in the Removing the PAK Section.
2. Discard the GEM PAK in a biohazard container.
3. Shut down the instrument as described in Shutting Down the Analyzer Section.
4. Disconnect the instrument from the AC power supply [AC outlet or uninterruptible power supply (UPS)].
5. Dampen a soft cleaning cloth with a mild cleaning solution.
6. Be sure that the cleaning cloth is only moist, not dripping wet.
7. Carefully wipe the face of the touch screen.

Use only a soft cloth moistened with water or a mild cleaning solution. Do not use an abrasive cleaner or any bleach mixture to clean the touch screen, as this will damage the screen.

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

To disinfect the instrument:

1. Disconnect the power cord from the analyzer and from the AC power source.
2. Using a clean, soft cloth moistened with a 10% chlorine bleach solution and wipe down the exterior of the instrument, except for the touch screen.
3. Wipe down the polyester laminate protective sheet on the bottom of the cartridge bay.
4. Wipe the AC power cord completely from end to end using a soft cloth moistened with cleaning solution.
5. Place any used cloth or paper towel in an appropriate biohazard waste bag. Seal the bag and dispose of it in accordance your institution's procedures for disposing of materials contaminated with biohazard material.

Preventive Maintenance (PM)

Instrumentation Laboratory has determined that preventive maintenance is not required on the GEM Premier Systems for the following reasons:

- The functional performance of the analyzer is determined by the disposable GEM PAK.
- The instrument tests the electronic and software performance of the system. No parts are replaced during a preventive maintenance procedure.
- The GEM Premier 5000 analyzer with iQM2 monitors the analyzer performance. iQM2 has a complete range of diagnostic programs that continuously check the unit's performance and indicates any non-performance to the operator.

Routine Cleaning

The following paragraphs describe how to clean and disinfect the instrument as necessary.

Recommended Supplies:

- Disposable latex or rubber gloves
- Laboratory coat or jacket
- Eye protection
- Soft cleaning cloths
- 10% chlorine bleach solution
- Biohazard waste bags
- Non-abrasive, mild cleaning solution

The GEM Premier 5000 analyzer processes patient samples that may be highly infectious. When cleaning the instrument use proper technique and care to avoid contaminating yourself or others.

Put on rubber or latex gloves, eye protection, and a laboratory coat or jacket before handling the instrument.

Prepare a biohazard waste bag for waste disposal.

Cleaning of the GEM Premier 5000 is only required when a blood spill or drops are visible.

Cleaning the Touch Screen

You do not need to disconnect the GEM Premier 5000 analyzer from AC power when cleaning the touch screen. However, be careful to prevent water or cleaning solution from entering the unit enclosure.

To clean the touch screen:

1. Dampen a soft cleaning cloth with water or mild cleaning solution.
2. Be sure that the cleaning cloth is only moist, not dripping wet.
3. Carefully wipe the face of the touch screen free of fingerprints and other smudges.

Use only a soft cloth moistened with water or a mild cleaning solution. Do not use an abrasive cleaner or any bleach mixture to clean the touch screen, as this will damage the screen.

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

To Clean the Instrument:

1. Remove the GEM PAK from the analyzer as described in **"Removing the** GEM **PAK"**. Discard the GEM PAK in a biohazard container. Once the GEM PAK has been removed, it cannot be reinserted.
2. Shut down the instrument as described in **"Shutting Down the Analyzer"**.
3. Disconnect the instrument from AC power supply [AC outlet or uninterruptible power supply (UPS)].
4. Remove any blood or dust from the outer surface of the case using a clean, soft cloth moistened with the 10% chlorine bleach solution.
5. Inspect the GEM PAK bay area and clean the polyester laminate protective sheet on the bottom of the bay as needed.
6. (Optional) With the AC power cord unplugged from the power source, wipe the AC power cord completely from end to end using a soft cloth moistened with cleaning solution.
7. If necessary, remove the instrument from the work surface, and clean the work surface using a cloth or paper towel moistened with the 10% chlorine bleach solution.
8. Place any used cloth or paper towel in an appropriate biohazard waste bag. Seal the bag and dispose of it in accordance your institution's procedures for disposing of materials contaminated with biohazard material.

9. Reconnect the power cord to a properly grounded and wired AC outlet (AC outlet or UPS).

Make sure the plug and cord are dry before engaging the plug.

10. Turn on the analyzer by briefly pressing the power button on the left side of the back of the analyzer.
11. The GEM Premier 5000 analyzer starts its power-up cycle and then displays the Insert Cartridge screen.
12. Insert a new GEM PAK.

6 - Repair

This section contains instructions for the removal and replacement of components and sub-assemblies of the GEM 5000.

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.

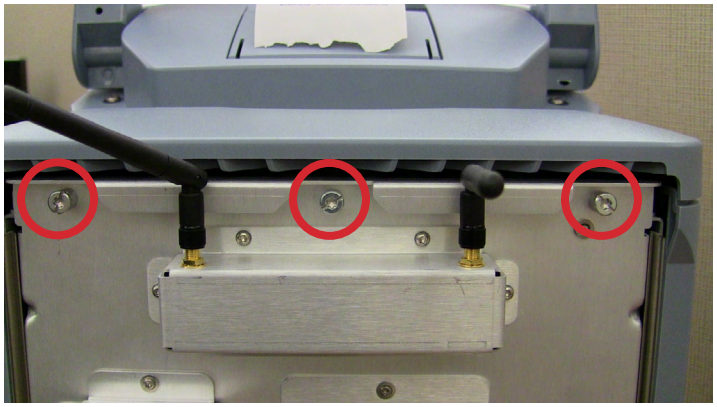
Removal and Replacement

Access to the Instrument

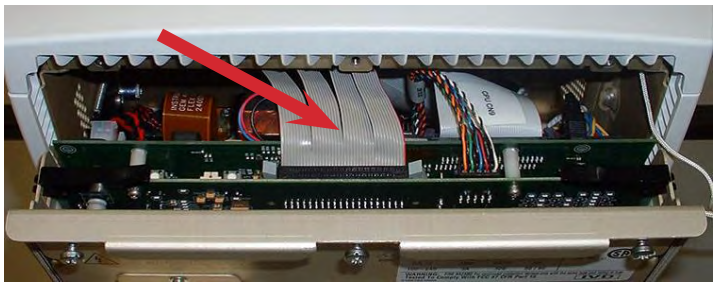
CAUTION: The instrument must be powered down and unplugged before performing this operation.

Components of the Gem Premier 5000 are accessible primarily via the following method:

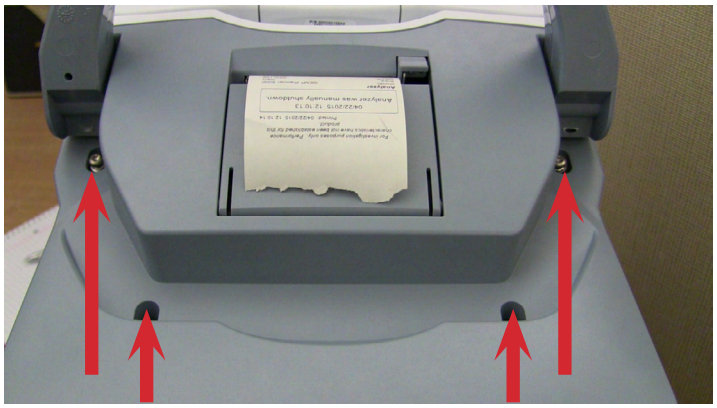
1. Loosen the 3 captive screws at the top of the instrument's rear panel.



2. Disconnect the printer ribbon cable and the CD/DVD ribbon cables.

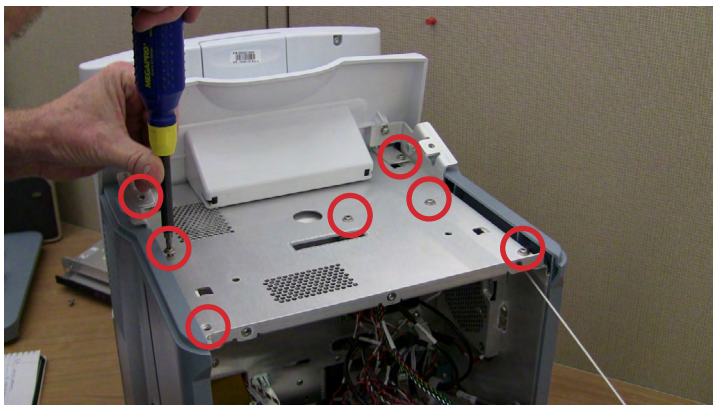


3. Remove the 4 screws on the instrument top cap.

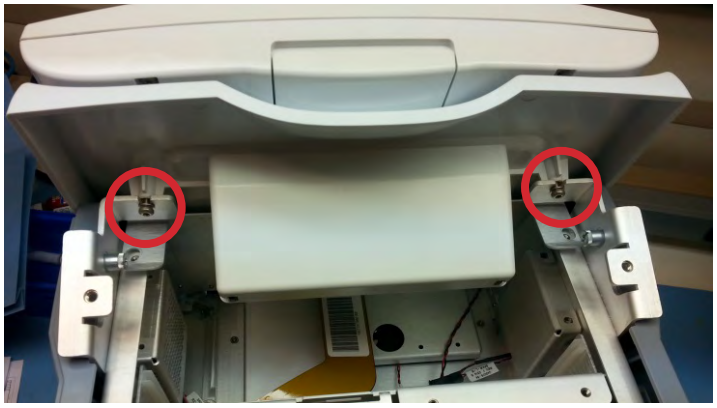


4. Lift cover slightly and pull toward the rear of the unit. Lift the top cap away and carefully feed the printer ribbon cable out of the instrument.

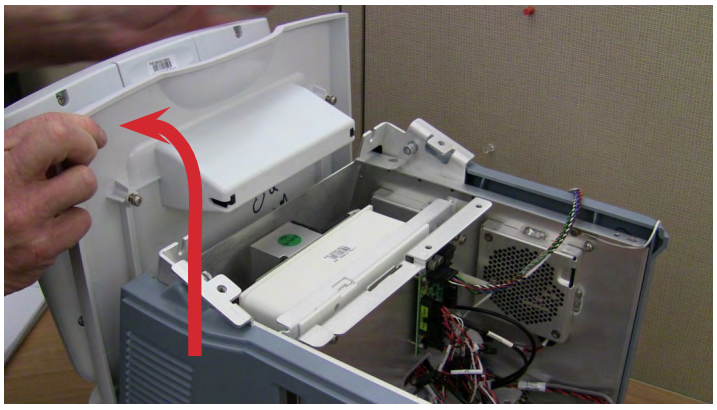
5. Remove the seven screws on the instrument chassis top plate.



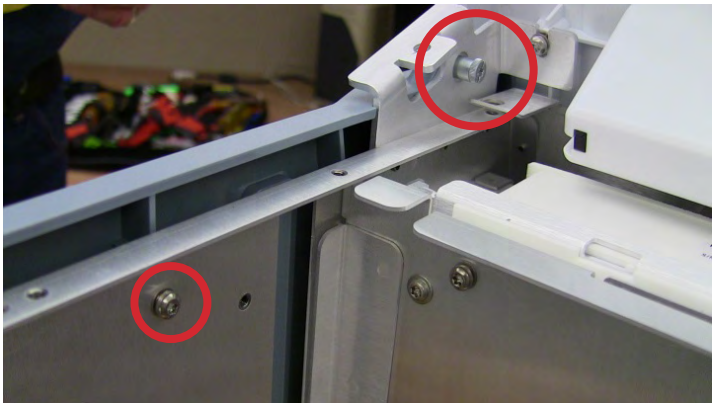
6. Loosen the two screws for the Front Bezel (do not remove these two screws) as indicated.

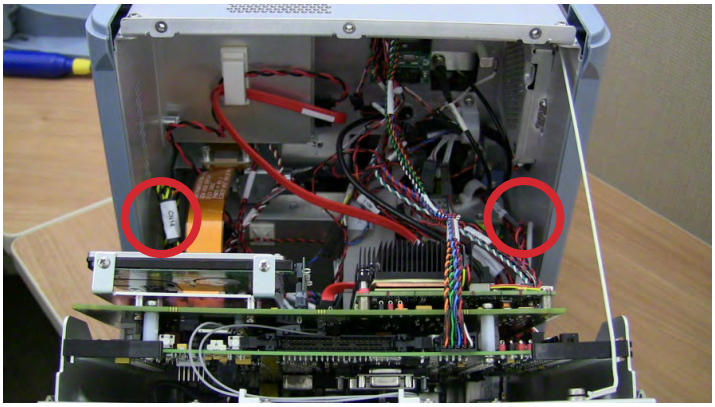


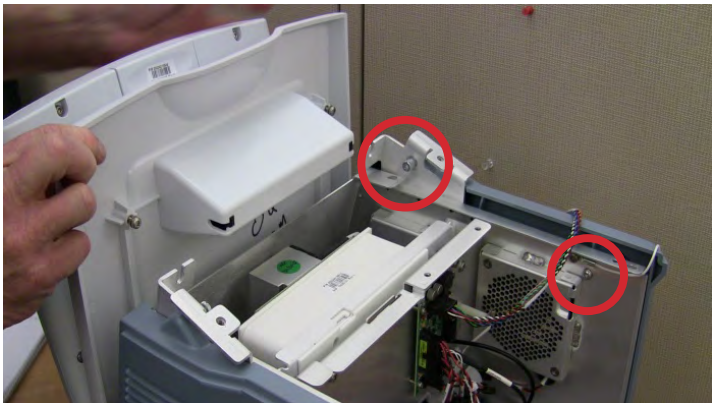
7. Lift the Front Bezel up and push it forward.



8. Five screws secure the side covers, (2 are captive). Remove side covers, loosen the captive screw at the upper front corner, center screw and lower rear captive screw.







9. Remove the two front mounting screws behind the cartridge door.

Perform these steps in reverse order to close the instrument.

Printer Removal/Replacement

1. Follow steps 1 through 4 of “Access to the Instrument” to gain access to the Printer.
2. Turn the cap over to expose the Printer and Printer Board.

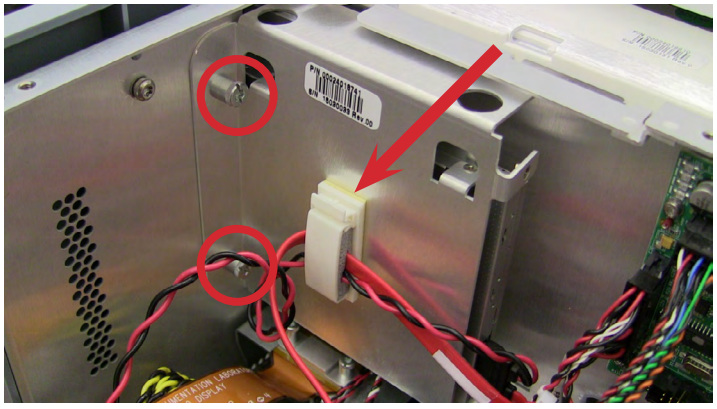
3. Unplug the printer and the two printer board cables.
4. To remove the Printer Board, unscrew the two screws located on the Printer Board Bracket.

   NOTE: The Printer Board may be removed from the bracket by unscrewing the four screws at each corner of the board.
5. To remove the printer, unscrew the two screws located on the Printer Bracket.

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

DVD Drive Removal/Replacement

1. Follow steps 1 through 4 of “Access to the Instrument” to gain access to the DVD drive.
2. Dislodge cable from cable clamp and disconnect cable from DVD.
3. Loosen the 2 captive screws securing the DVD bracket and slide the bracket to the right to remove it.

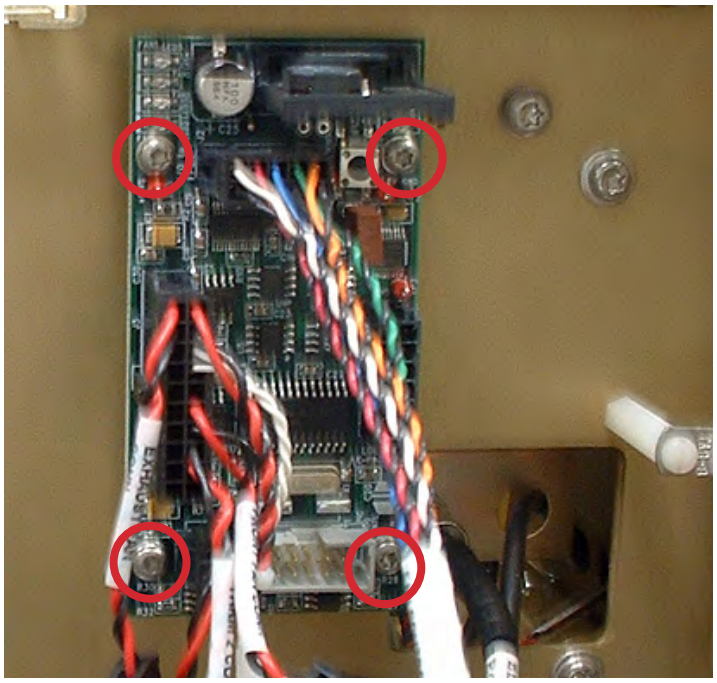


Perform the preceding steps in reverse order to install the DVD Drive.

Fan Controller Board Removal/Replacement

1. Follow steps 1 through 4 of “Access to the Instrument” to gain access to the Fan Controller Board.
2. Disconnect the cable connections to the DCS Board and the four fans.
3. Remove the four torx screws as indicated.

Perform the preceding steps in reverse order to Install the Fan Controller Board.

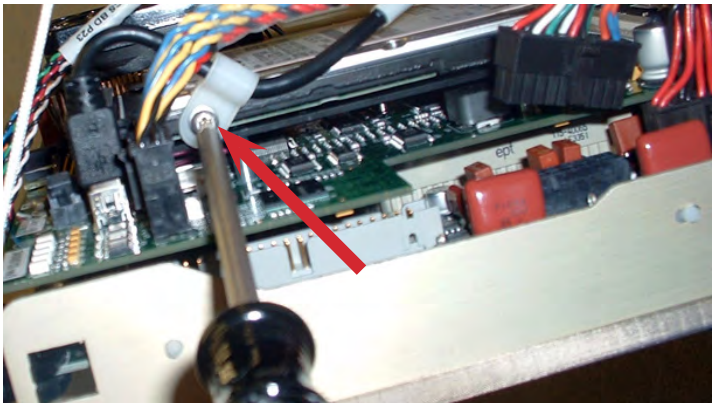


CO-OX Module Removal/Replacement

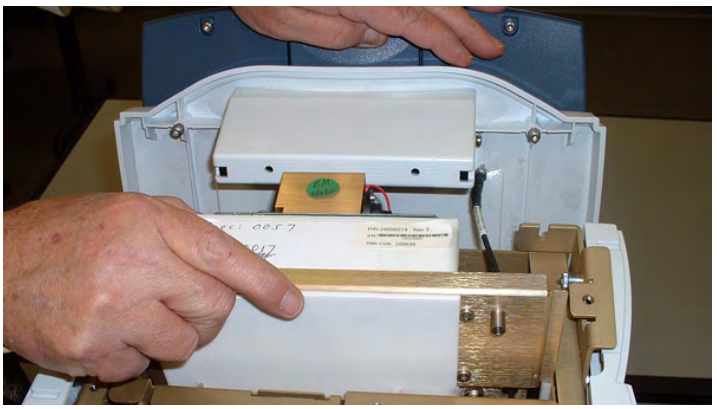
1. Follow steps 1 through 4 of “Access to the Instrument” to gain access to the CO-OX Module and remove the DVD drive assembly.
2. Gently unscrew and remove the Fiber Optic Cable from the CO-OX Module.

   NOTE: DO NOT Bend the Fiber Optic Cable!

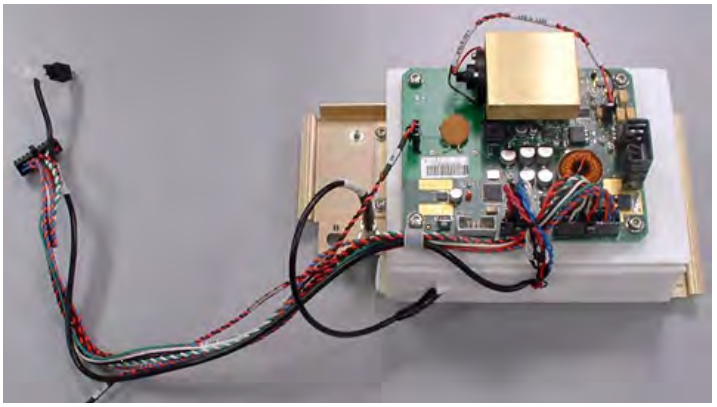
3. Guide the Fiber Optic Cable away from the assembly.
4. Remove the cable clamp that binds the USB Optic Cable to the CPU Board.
5. Unplug the USB connection of the Optic cable from the SBC Board.
6. Disconnect the RED/BLACK cables from the Fan Controller Board.



7. Remove the two coox module mounting screw
8. Push the LCD forward and gently slide the CO-OX Module upward out of the instrument and carefully feed the cables through the Wall.



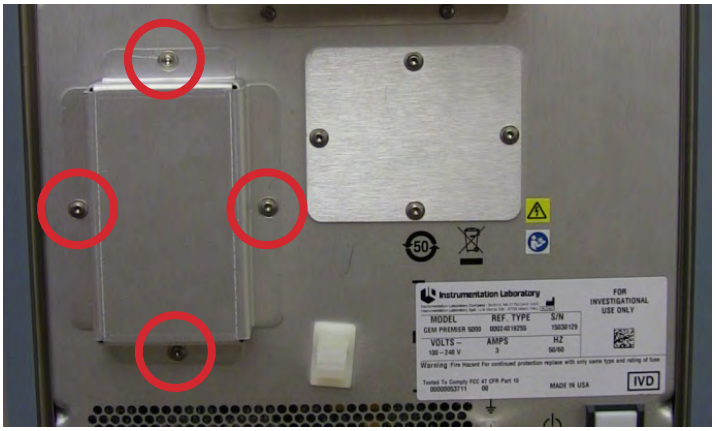
Perform the preceding steps in reverse order to Install the CO-OX Module.



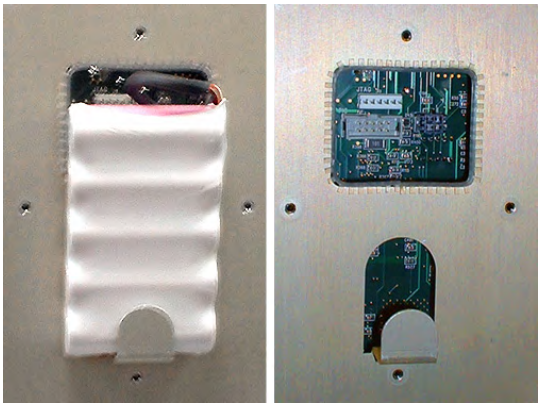
DCS Board Removal/Replacement

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

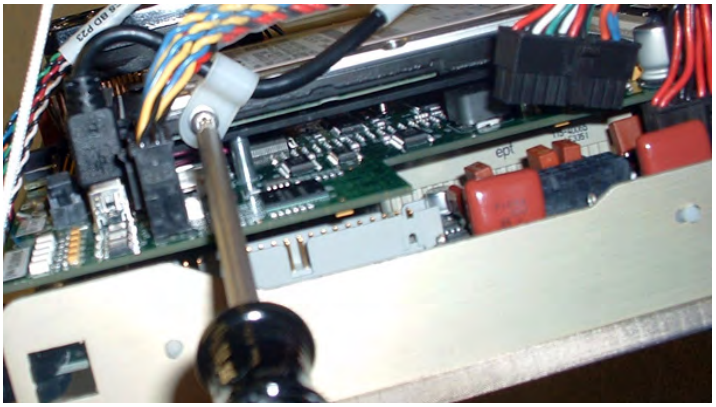
1. Remove the Battery Cover on the back of the instrument by removing its four screws.



2. Lift the battery out of the cradle and disconnect it from the DCS Board.



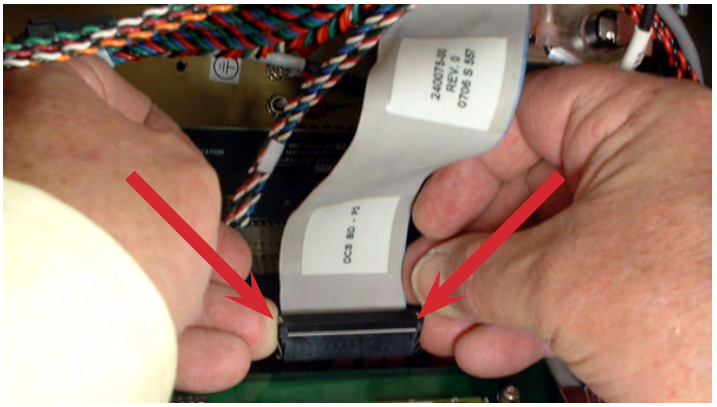
3. Follow the steps described in “Access to the Instrument” to gain access to the DCS Board Assembly.
4. Remove the cable clamp that binds the USB Optic Cable to the Hard Drive and disconnect the USB connection of the Optic cable from the SBC Board.



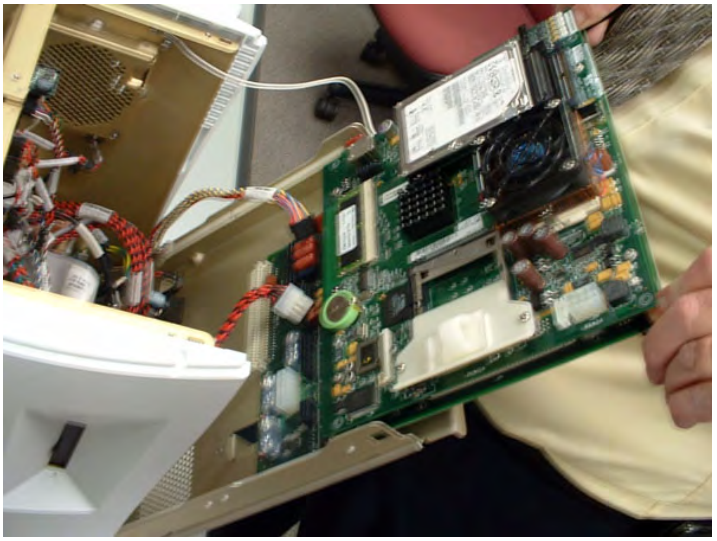
5. Disconnect the two power cables from the SBC Board as shown.

CAUTION: Electrical discharge could occur if the instrument has not been unplugged.

6. Remove the DCS to Analog Board Cable by pushing in the clips on the side of the connector as shown



7. Disconnect the remaining cables from the DCS & SBC Boards.
8. Disengage the clamps at the top of the DCS Board and slide the assembly out of the Backplane board and the instrument as shown.



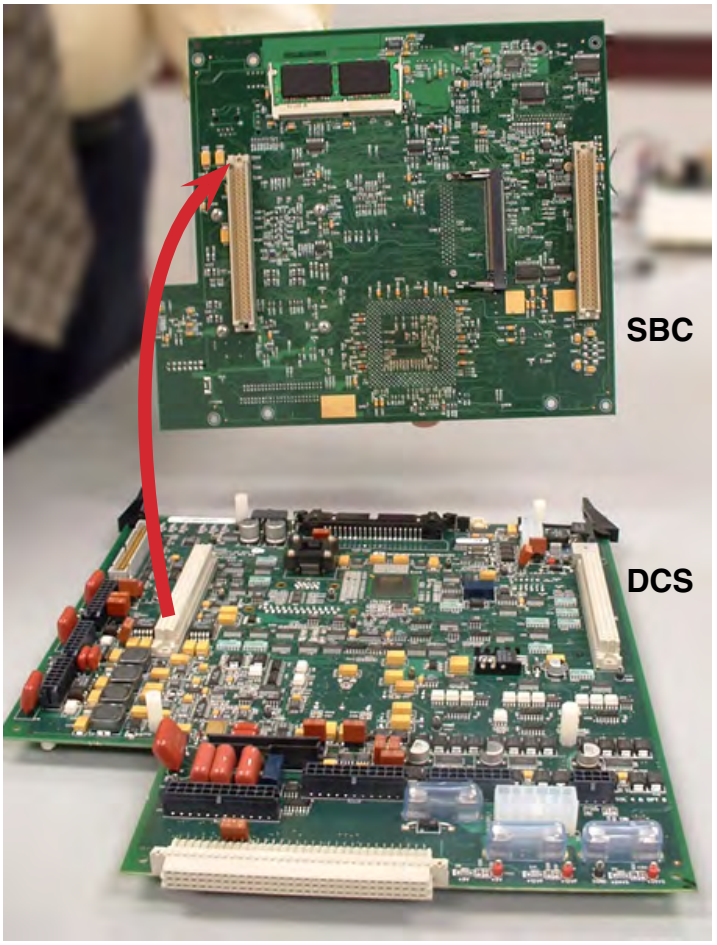
Perform these steps in reverse order to Install the DCS Board Assembly.

9. Remove the four screws at each corner securing the SBC Board to the DCS Board.

NOTE: Be careful to avoid removing the standoff posts.

10. The boards are linked by two connectors. Separate the SBC Board from the DCS board.

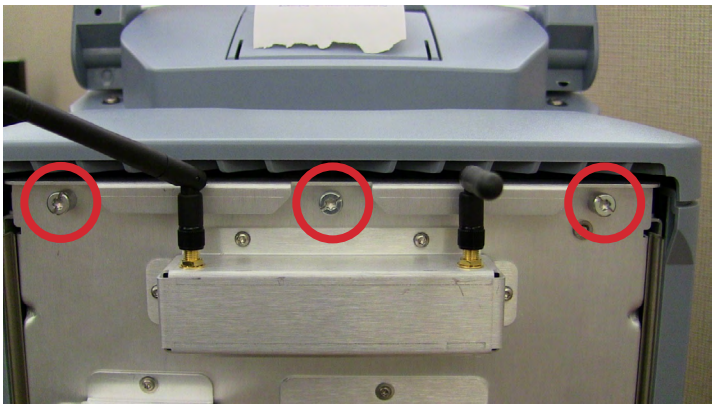
Perform the preceding steps in reverse order to Install the DCS Board.



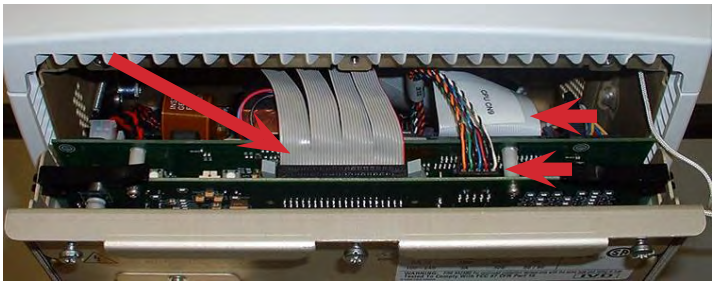
SBC Board Removal/Replacement

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

1. Loosen the 3 captive screws at the top of the instrument's rear panel as shown.



2. Disconnect the printer ribbon cable from the DCS board.

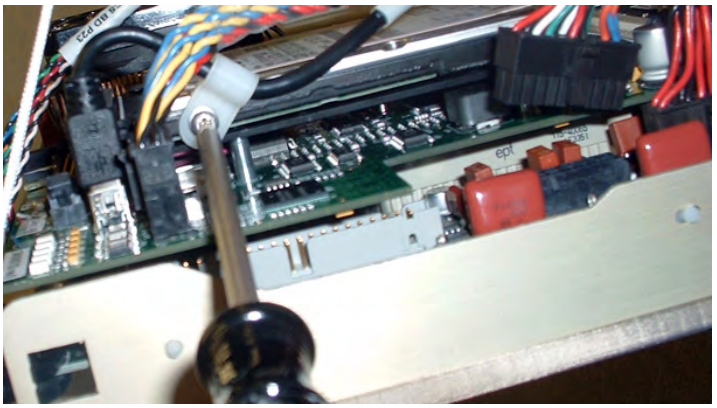


NOTE: It may be helpful to disconnect the Fan Controller Board cable from the DCS Board as well.

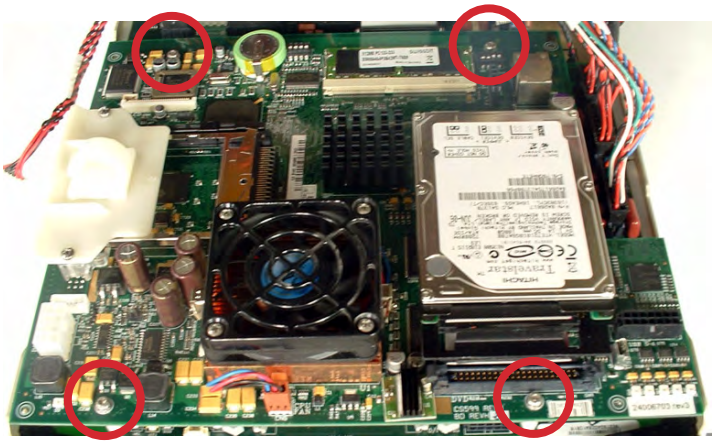
3. Disconnect the two power cables from the SBC Board as shown.

CAUTION: Electrical discharge could occur if the instrument has not been unplugged.

4. Remove the cable clamp that binds the USB Optic Cable to the Hard Drive and disconnect the USB connection of the Optic cable from the SBC Board.



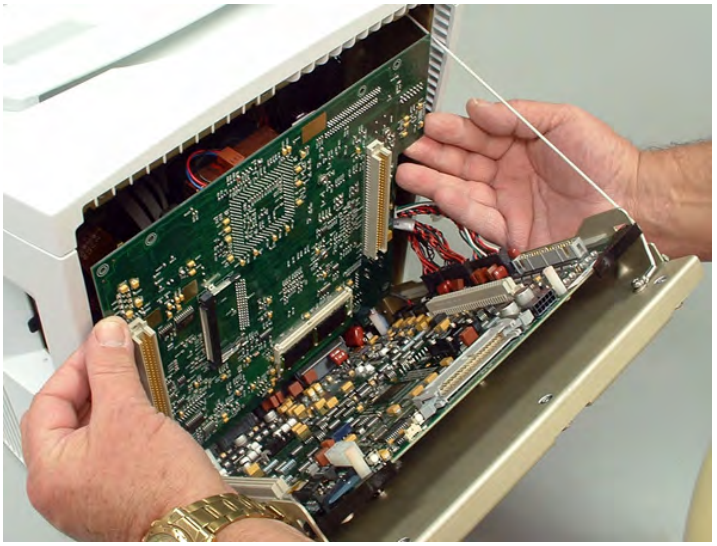
5. Disconnect the remaining cables from the SBC Board.
6. Remove the four screws at each corner securing the SBC Board to the DCS Board.



NOTE: Be careful to avoid removing the standoff posts.

7. The boards are linked by two connectors. Separate the SBC Board from the DCS board.

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

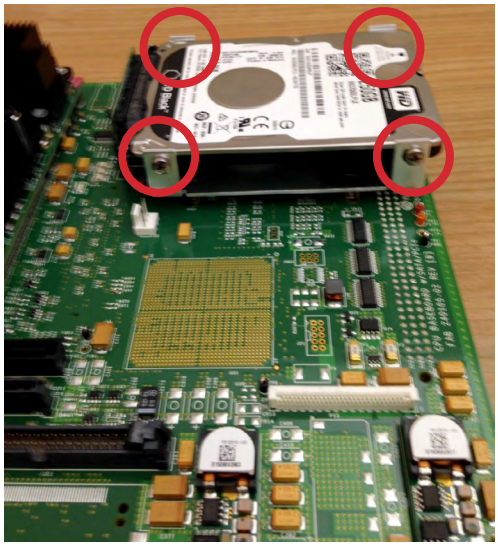


NOTE: After replacing the SBC it is necessary to reload GEM 5000 software and recalibrate the Coox Module.

Hard Drive Removal/Replacement

1. Follow the steps described in “SBC Board Removal/Replacement” to remove the SBC Board.
2. Remove the four screws securing the hard drive to the mounting bracket on the CPU board.
3. Gently slide the hard drive out of the mounting bracket.

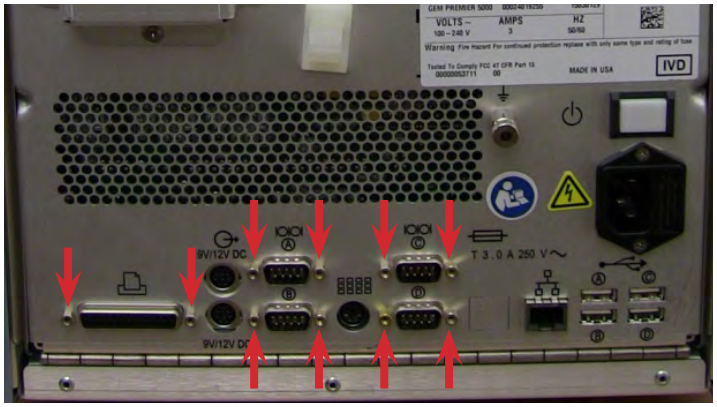
Perform the preceding steps in reverse order to Install the Hard Drive.



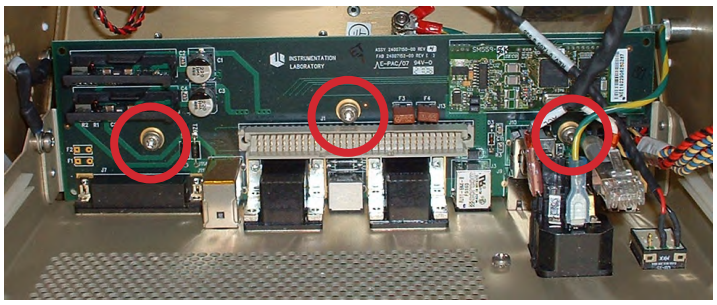
Backplane Board Removal/Replacement

1. Follow the steps described in “DCS Board Removal/Replacement” to remove the DCS Board Assembly.

2. Remove the ten standoff nuts from the back panel.



3. Disconnect all cables from the Backplane Board.
4. Remove the 3 screws from the Backplane Board as shown.



5. Pull the Backplane Board away from the back panel and out of the instrument.

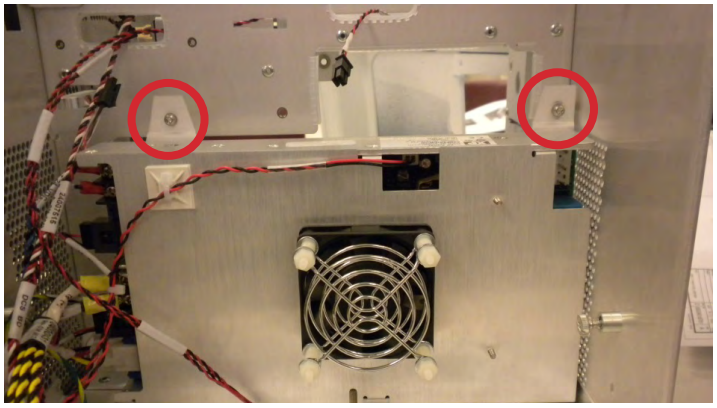
Perform the preceding steps in reverse order to Install the Backplane Board.

Power Supply Removal/Replacement

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.

   NOTE: It may be helpful to remove the CD/DVD Drive as described in “DVD Drive Removal/Replacement” and Door Solenoid as described in “Door Solenoid Removal”.
2. Disconnect all cables from the Power Supply.
3. Loosen the two screws (upper left and upper right corner) as shown.



4. Remove the Ground Lug from the Ground Post.
5. Lift the Power Supply up and out of the instrument.

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

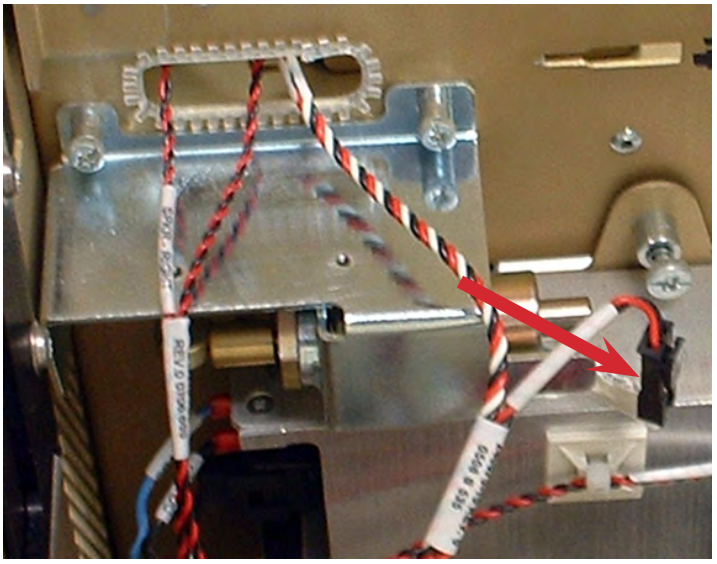
Door Solenoid Removal/Replacement

The Door Solenoid is located under the DVD Drive within the instrument.

1. Follow the steps described in “Access to the Instrument” to gain access to the Door Solenoid.

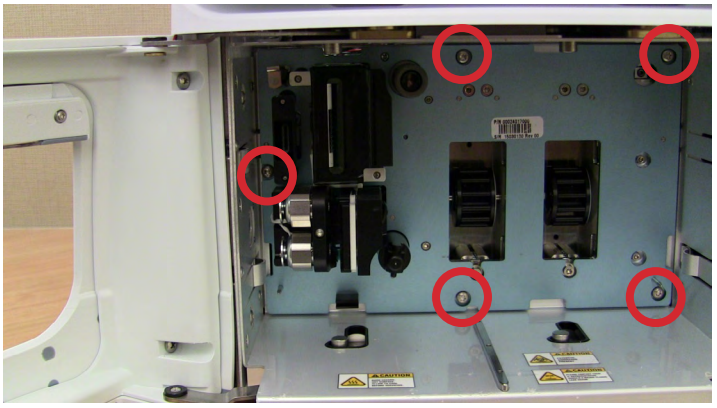
   NOTE: It may be helpful to remove the DVD Drive as described in “DVD Drive Removal/Replacement” .
2. Remove the flex cable bracket from the solenoid and disconnect the Solenoid Cable.
3. Loosen the captive hardware on the Solenoid Bracket and remove the assembly from the instrument

Perform the preceding steps in reverse order to Install the Door Solenoid.

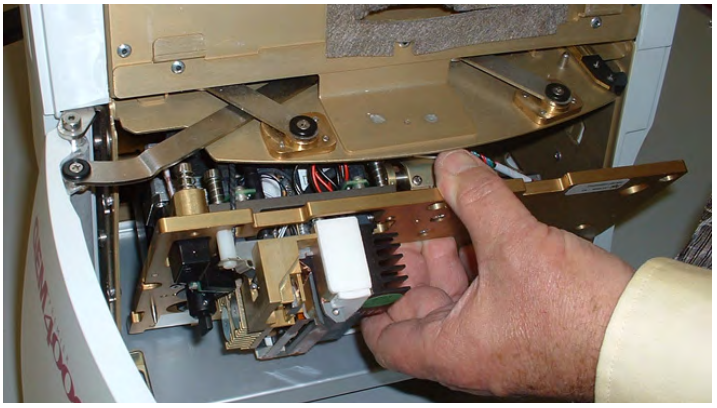


Interface Wall Removal/Replacement

1. Follow the steps described in “Access to the Instrument” .
2. Open the Cartridge Door.
3. Remove the five screws holding the Interface Wall to the Chassis as shown.



4. Disconnect the Interface Wall cable connections to the SBC Board, Fan Controller Board, and the Power Supply.
5. Tilt the Interface Wall forward and guide it out of the instrument.
6. Carefully guide the attached cables out of the instrument.



Perform the preceding steps in reverse order to install the Interface Wall. Take care to avoid trapping any cables behind the Interface Wall.

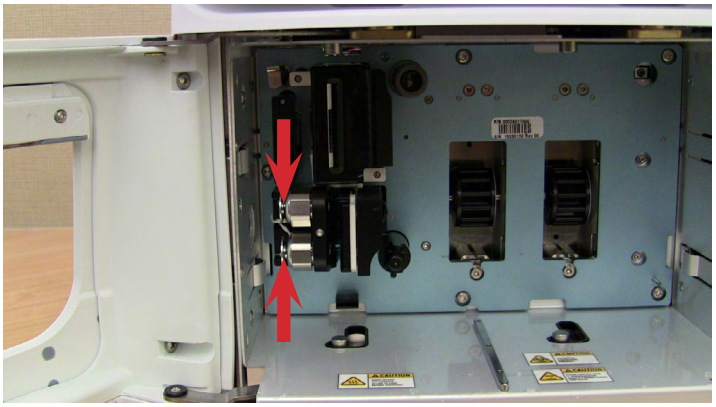
Interface Wall Component Removal/Replacement

Follow the steps described in “Interface Wall Removal/Replacement”.

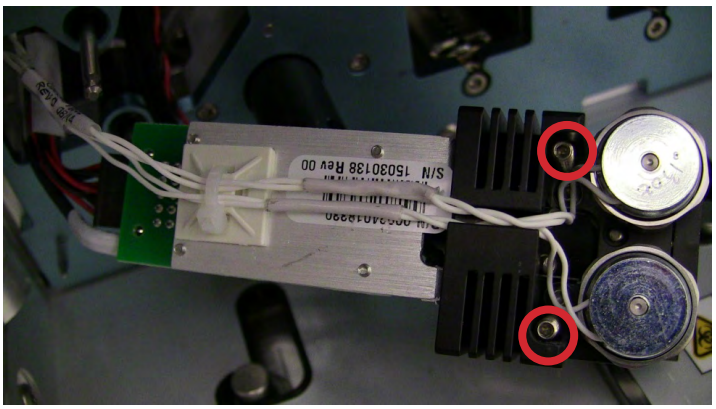
Optical Head Module Removal

1. Loosen the two set screws securing the Optical Head to the mounting posts. Set screws are behind the Diverter and Mixer valves.

   NOTE: Sets screws may be accessed from left side after left side panel is removed.



2. Pull Optical Head forward off of the mounting posts.



3. Disconnect cables from rear of Optical Head Assembly.
4. Slide the Optical Head Module out of the wall opening and thread through Optical Bracket. Use care not to break the wires.

Optical Head Module Installation

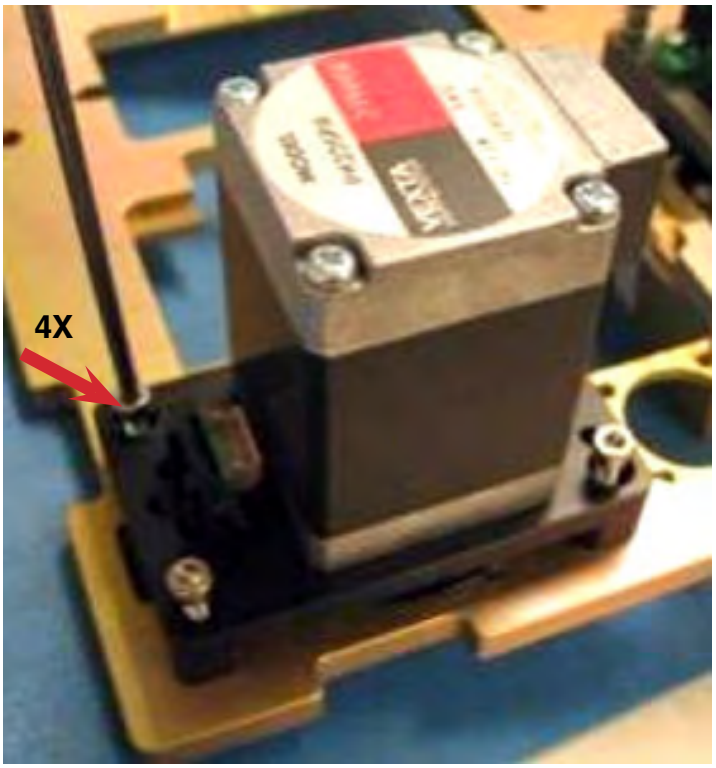
Perform the preceding steps in reverse order to install the Optical Head Assembly.

NOTE: When sliding the Optical Head onto the mounting posts insure the set screws align with the notch on the mounting post.

NOTE: After re-installing Optical Head Assembly verify assembly “floats” on mount assembly.

Rotary Valve Removal

Remove the four screws from the Rotary Valve as shown and remove it from the wall.

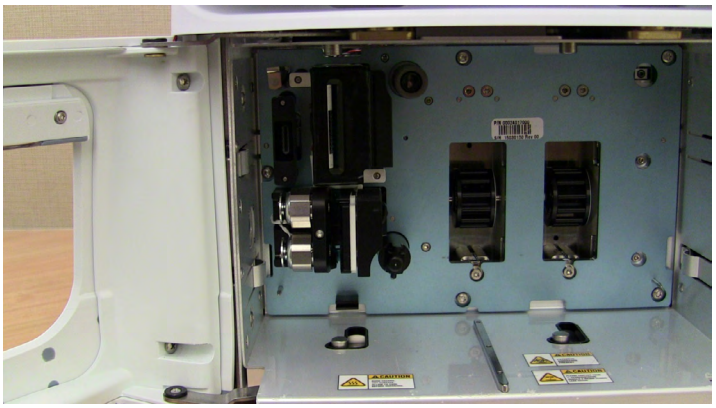


Rotary Valve Installation

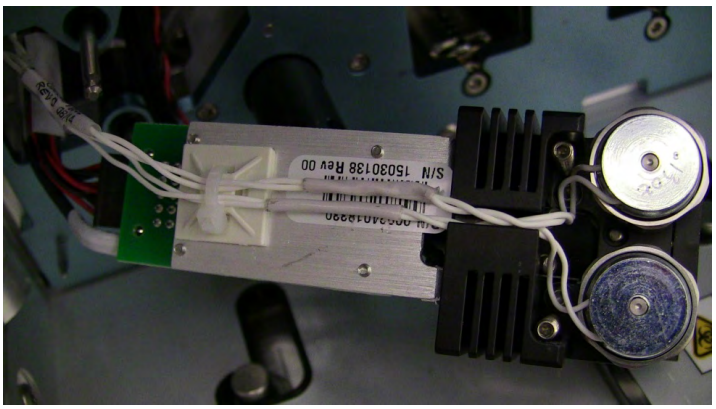
Perform the preceding steps in reverse order to Install the Rotary Valve. Clearance should always be present between the disk and the wall as shown

EEPROM Reader Assy Installation

1. Loosen the two set screws securing the EEPROM Reader to the mounting posts. Set screws are accessed from the left side.



2. Pull EEPROM Reader forward off of the mounting posts.



3. Disconnect cables from rear of EEPROM Reader Assembly.

Perform the preceding steps in reverse order to install the EEPROM Reader Assembly.

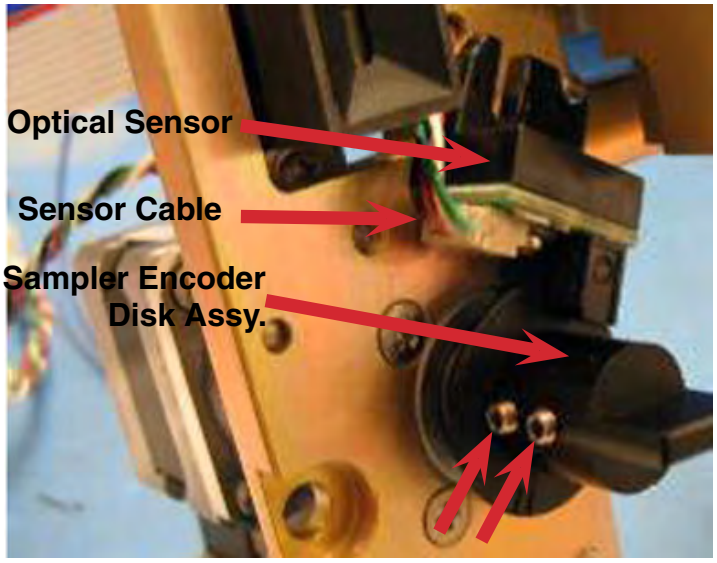
NOTE: When sliding the EEPROM Reader onto the mounting posts insure the set screws align with the notch on the mounting post.

NOTE: After re-installing EEPROM Reader Assembly verify assembly “floats” on mount assembly.

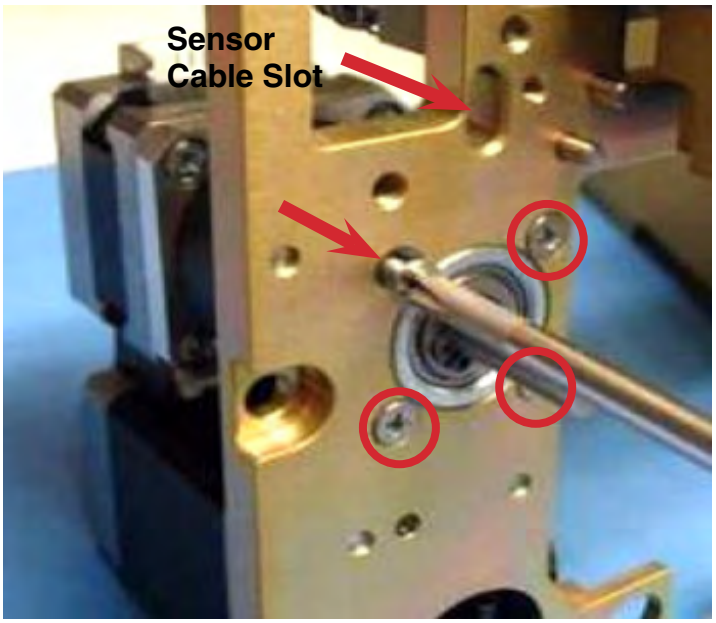
Sampler Valve Motor Assy Removal

1. Unplug the sensor cable.
2. Unscrew and remove the optical sensor.

3. Loosen the two set screws on the Sampler Encoder Disk and remove it.

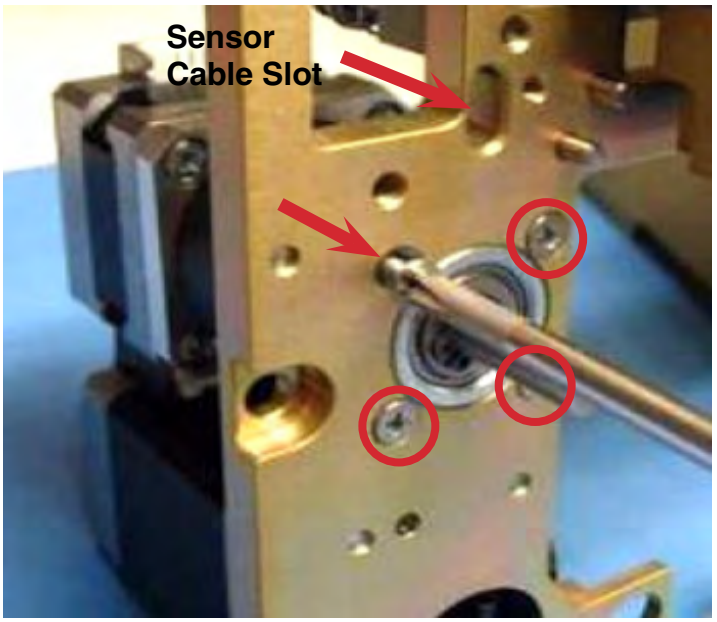


4. Remove the four screws as shown.



Sampler Valve Motor Assy Installation

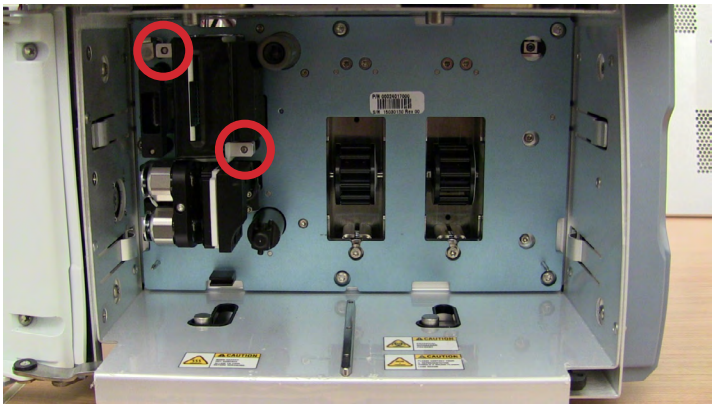
1. Mount Sampler Valve Motor to wall with four screws as shown.
2. Feed Sensor Cable through slot prior to installation of Sampler Encoder Disk Assy.



3. Slide the Sampler Encoder Disk Assy loosely onto motor shaft.
4. Position the Optical Sensor onto the wall while placing the encoder disk into the slot
5. Secure the Optical Sensor with a screw.
6. Center the Encoder Disk in the notch located on the Sensor Board and tighten the two set screws.

Heater Block Removal/Replacement

1. Loosen the 2 set screws securing the heater block to the mounting posts.



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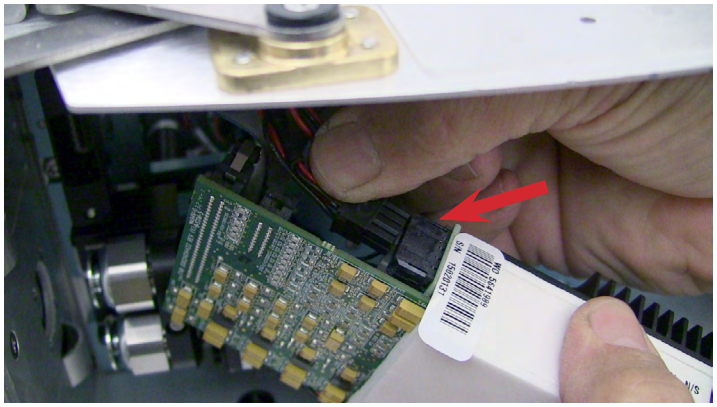
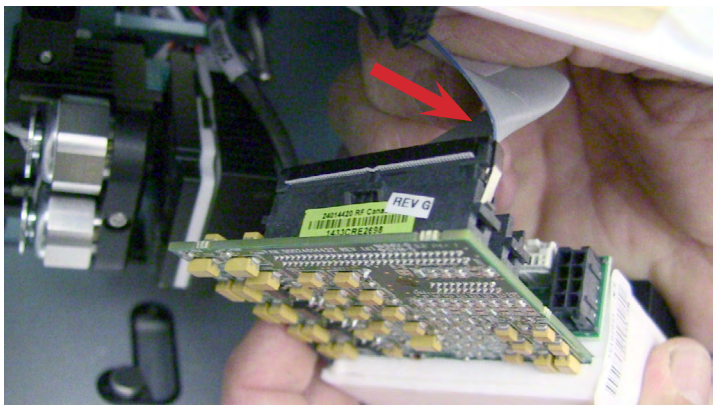
2. Pull heater block forward off of the mounting posts.

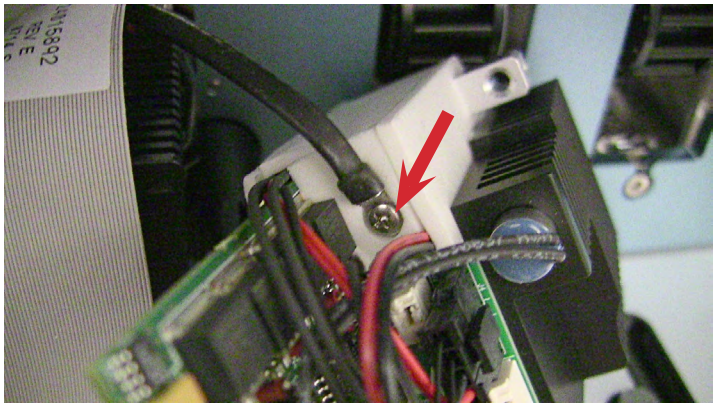


NOTE: When sliding the heater block onto the mounting posts insure the set screws align with the notch on the mounting post.

3. Disconnect the power cable and ribbon cable from the analog board.



4. Remove the screw securing the ground cable.



Perform the preceding steps in reverse order to install the Heater Block.

NOTE: When sliding the heater block onto the mounting posts insure the set screws align with the notch on the mounting post.

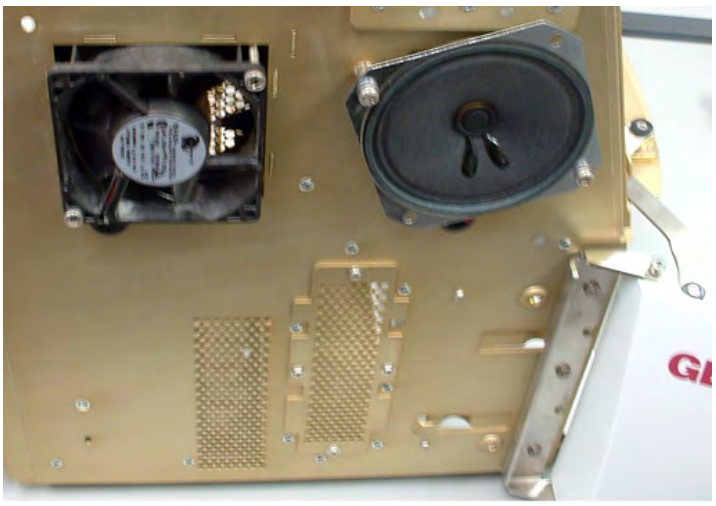
NOTE: After re-installing Heater Block Assembly verify assembly "floats" on mount assembly.

Pivot Pump Removal/Replacement

1. Remove the Pivot Pump adjustment hardware, (shoulder screw, spring, and adjuster flag) and re-assemble.
2. Start with the two screws in the front, and then assemble the shoulder screw, spring, and adjuster flag.

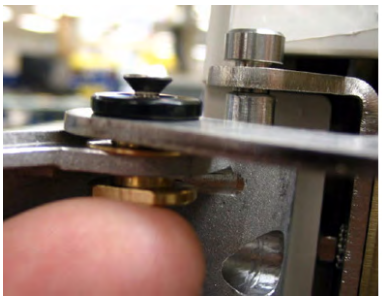
Cartridge Door Removal/Replacement and Adjustment

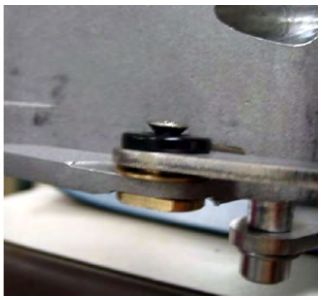
1. Remove the instrument side panel on the hinge side of the door as described in “Access to the Instrument”.



2. Remove the three screws on the inside of the cartridge area as shown.

3. Unscrew the top and bottom door linkages as shown.





Perform the preceding steps in reverse order to Install the Cartridge Door.

Cartridge Door Adjustment

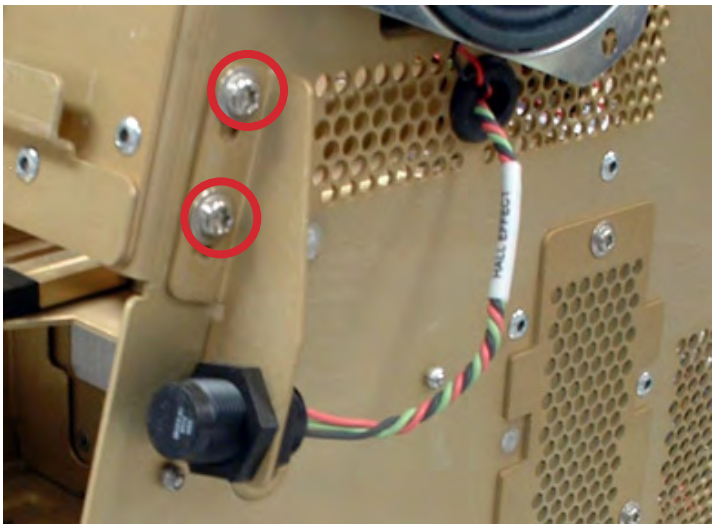
1. Remove the Cartridge Door as described in “Cartridge Door Removal/Replacement and Adjustment”.

2. Add washers as needed between the instrument chassis and the Cartridge Door to adjust the alignment of the door.

Door Proximity Sensor Removal/Replacement

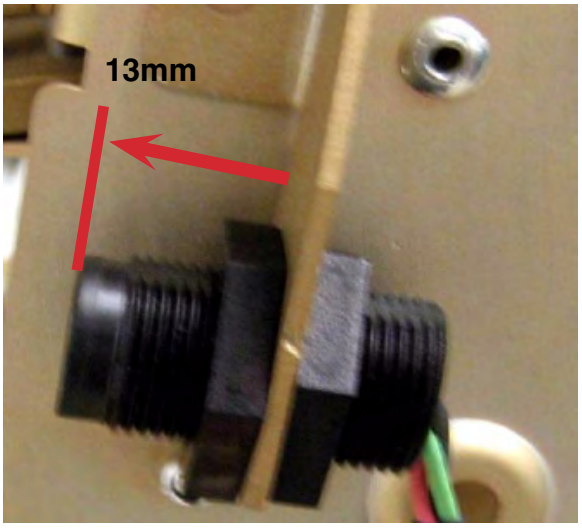
Door Proximity Sensor Removal

1. Remove the right side instrument panel as described in “Access to the Instrument”.
2. Unplug the Proximity Sensor Cable from the Solenoid Cable.
3. Unscrew the two screws on the Proximity Sensor Bracket.



Door Proximity Sensor Installation

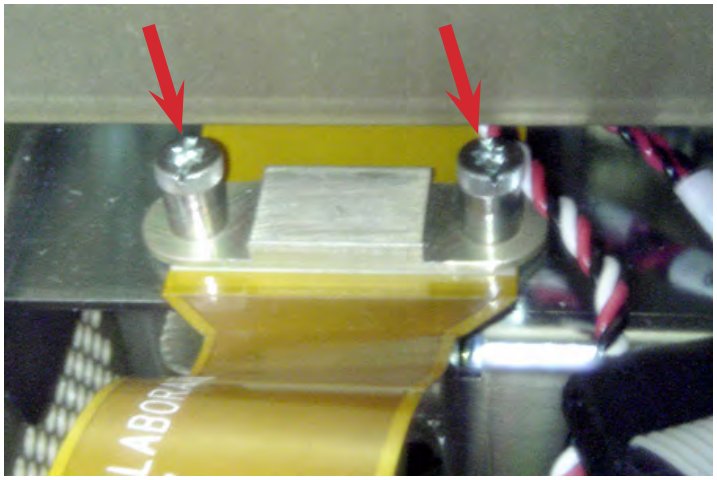
1. Perform the preceding steps in reverse order to Install the Door Proximity Sensor.
2. Set the distance of the Switch at 13mm as shown.



Display Assembly Removal/Replacement

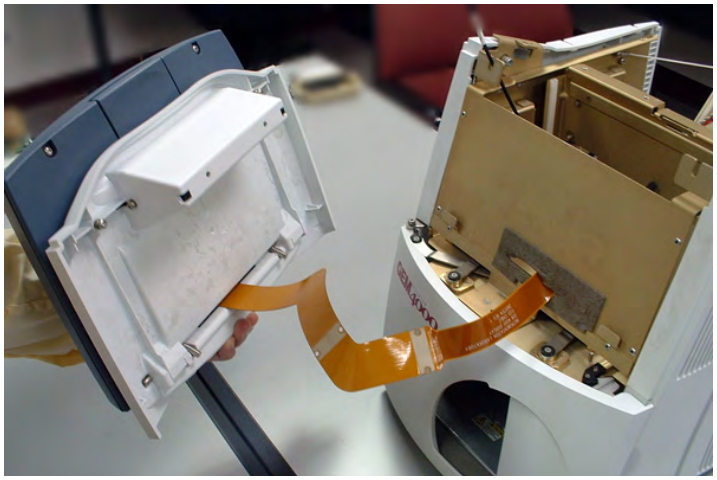
1. Follow the steps described in “Access to the Instrument” to gain access to the Display Flat Cable.
2. Carefully disconnect the Display Flat Cable from the SBC Board.

3. Remove the Display Flat Cable Bracket by loosening the captive hardware.



4. Lift the Display assembly up and away from the instrument and Carefully feed the Display Flat Cable out of the instrument as shown.

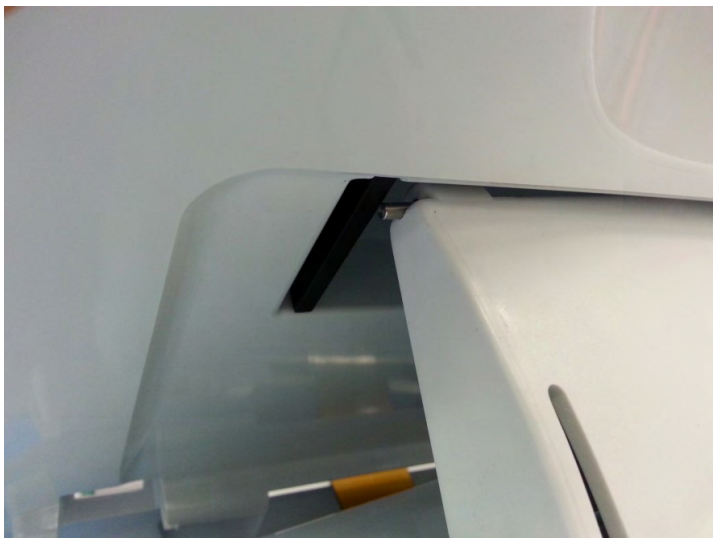
Perform the preceding steps in reverse order to Install the Display Assembly.



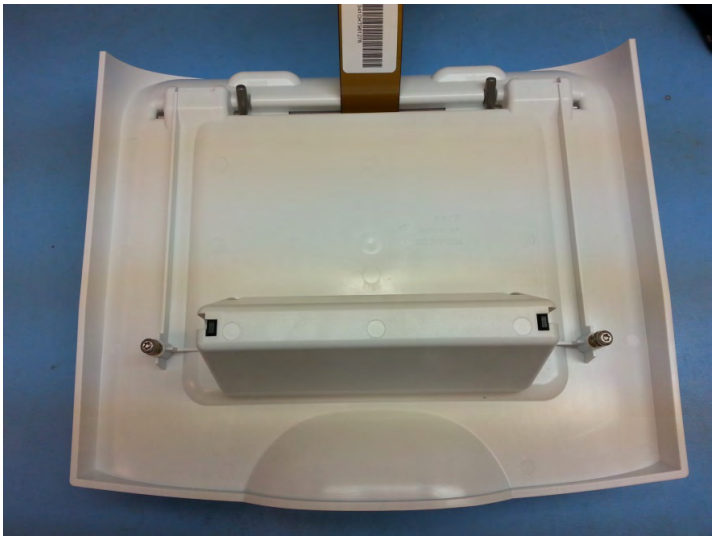
Display Assembly Component Removal/Replacement

1. Remove the Display Assembly as described in “Display Assembly Removal/ Replacement”.

2. Remove the two “L” pivot pins by tilting them up and pulling them out as shown.

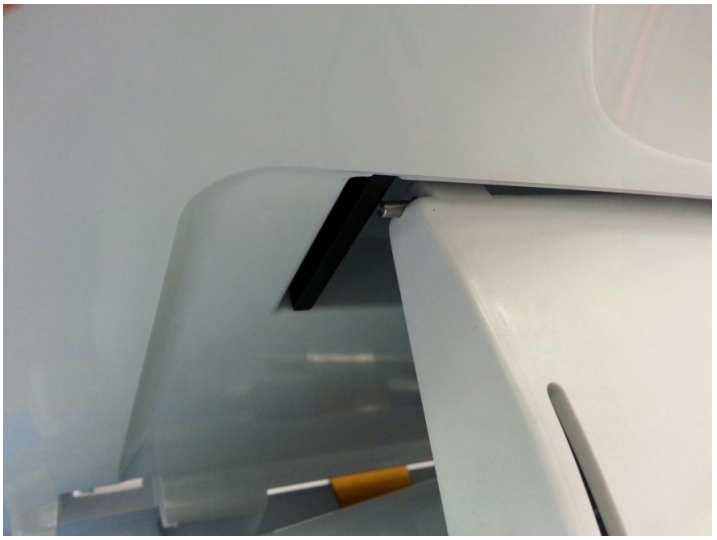


3. Loosen the two screws on the tilt adjuster and unhook both sides of the adjustment pin as shown.

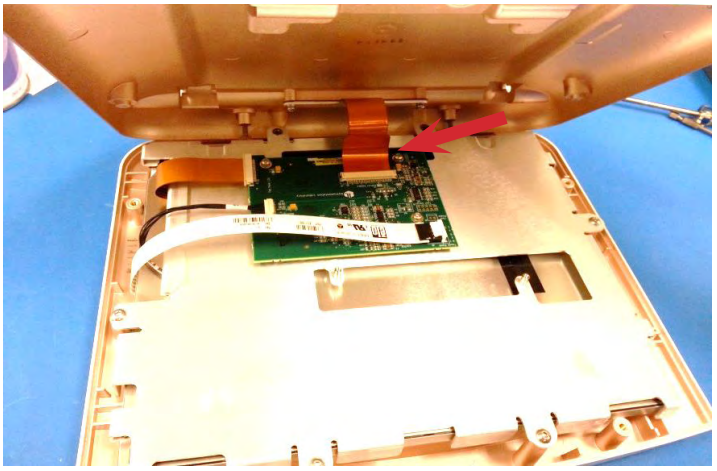


LCD Removal/Replacement

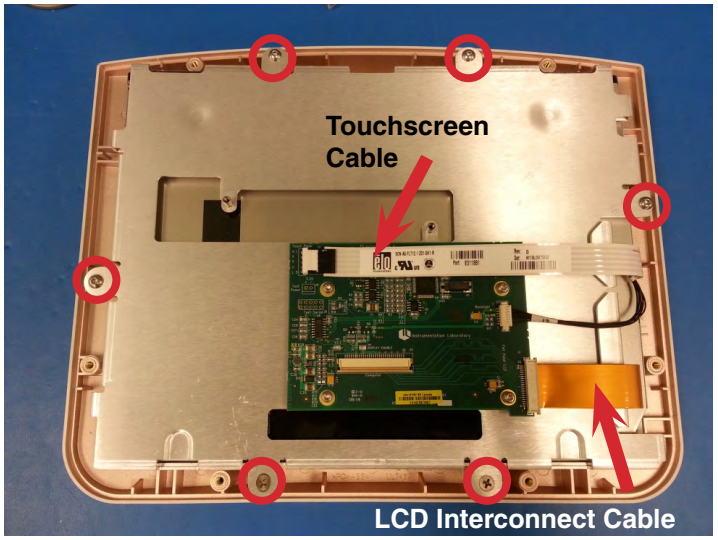
1. Remove the four screws on the back of the LCD Bezel as shown.



2. Disengage the connector lock and disconnect the Video Cable

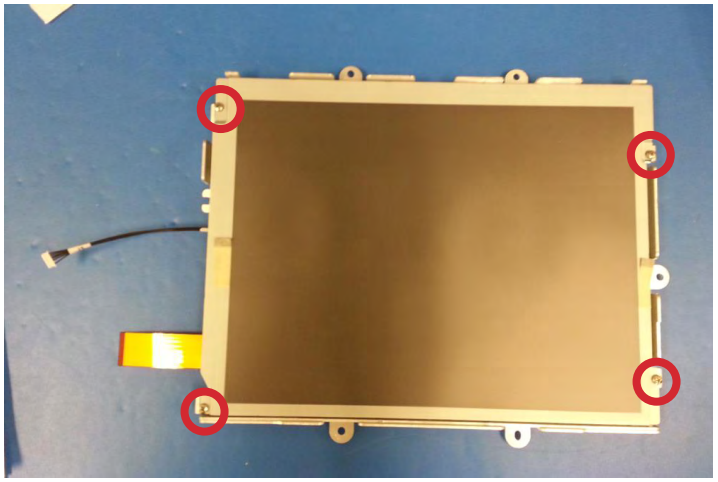


3. Disconnect the Touchscreen Cable.
4. Disconnect the LCD Interconnect Cable.
5. Remove the six screws that mount the LCD Bracket to the Front Bezel as indicated.



6. Turn the LCD and bracket over and remove the four screws located at each corner of the LCD.

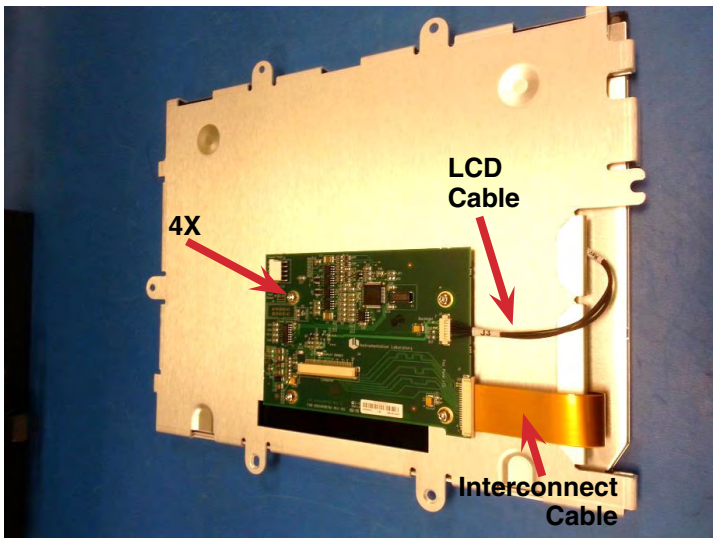
Perform the preceding steps in reverse order to Install the LCD.



Touchscreen Board Removal/Replacement

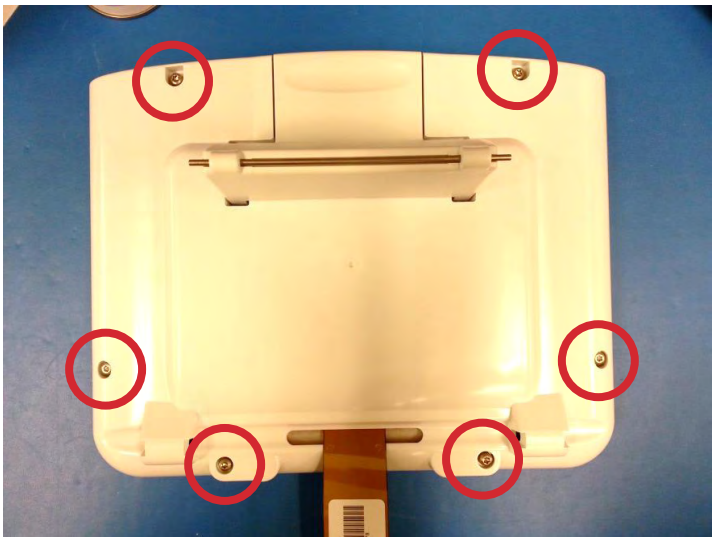
1. Disconnect the Touchscreen, LCD Interconnect, and Inverter Board Cables.
2. Remove the four screws on the Touchscreen Board as shown.

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



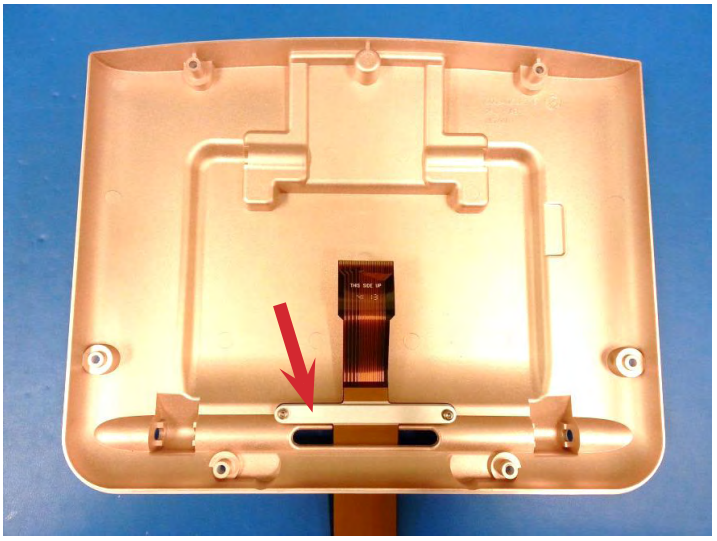
Video Cable Removal/Replacement

1. Remove the six screws on the back of the LCD Bezel as shown



2. Disengage the connector lock and disconnect the Video Cable

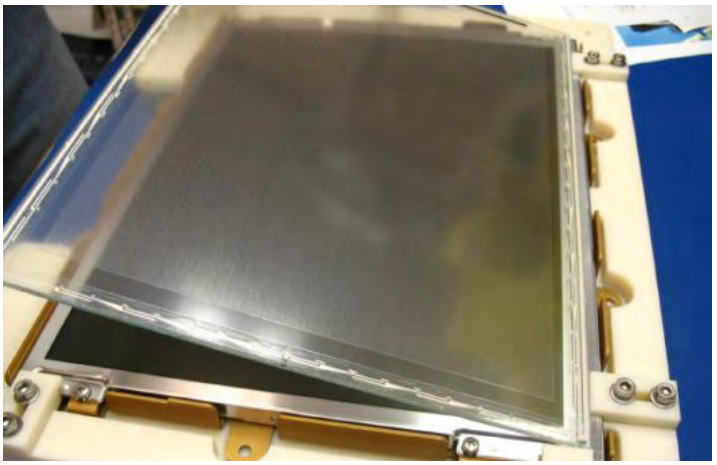
3. Loosen or remove the Video Cable Bracket and carefully remove the bezel.
4. Carefully feed the cable out of the bezel.



Touchscreen Removal

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

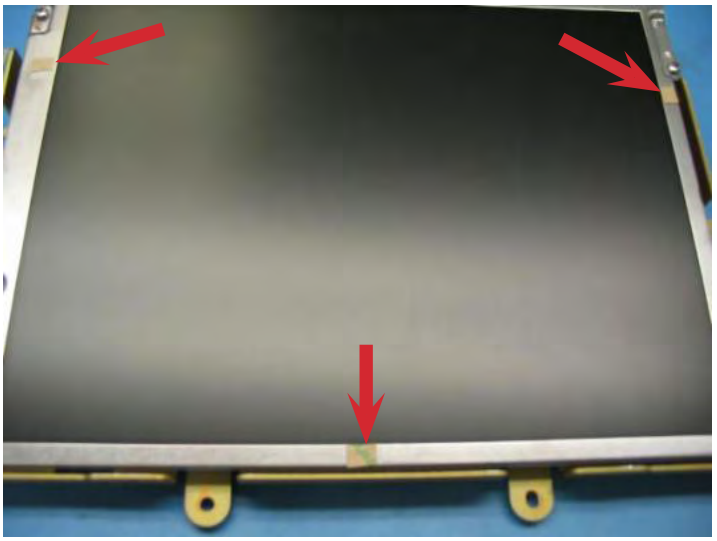
1. Disconnect the Touchscreen Cable.
2. Gently pry the Touchscreen panel away from the LCD.



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.

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



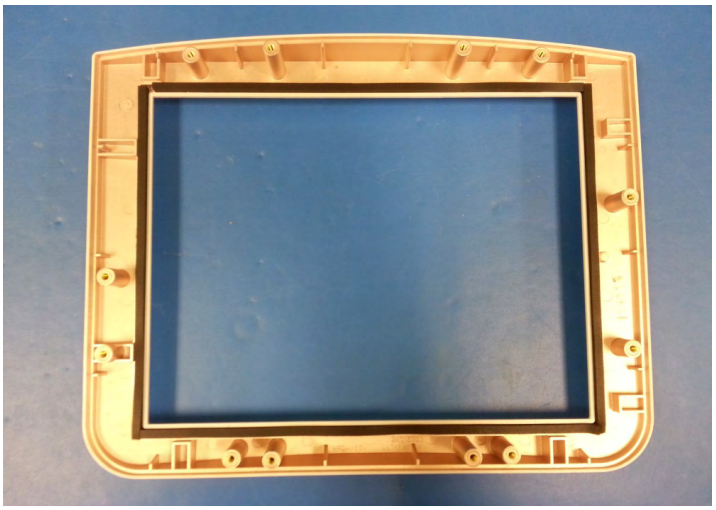
3. Remove the backing from he double--sided tape and carefully center the Touchscreen evenly over the LCD to avoid hash marks from showing when the assembly is completed.

   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.



Touchscreen Seal Installation

Apply four lengths of cut adhesive-backed seal foam as shown above in “Touchscreen Seal Removal”.

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Listing of Cable and Board Connections

SBC Board

J19 -- DVD Power
J17 -- DVD SATA Data
J16 -- Ethernet
CN11 -- Rear Panel I/O Board
CN22 -- Rear Panel I/O Board
CN7 -- Speakers (Left, Right)
J8 -- Power Supply (12 vdc)
CN16 -- Power Switch & Power Supply
J3 -- Display
CN18 -- Wireless Adaptor
CN20 -- Coox Module / Spectrometer
CN9 -- CPU Fan

DCS Board

J13 -- Hall Effect, Door Solenoid
J28 -- Door LED
J9 -- Battery
J11 -- Printer
J8 -- Valve Sensor Board (to P2 00024014998)
J6 -- Stepper Motor 0 Pump
Stepper Motor 1 Valve
Stepper Motor 2 Sampler
EEPROM Board #2
J25 -- Coox Pump Motor
J5 -- Chem Guard Board
J3 -- Analog Board
J7 , J27 -- Optics Head Board, Fan Controller
J23 -- Fan Controller Board
J15 -- Coox Module
J14 -- Power Supply
J4-A1 -- Interface Board

7 - Check Out and Adjustment

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This section contains the instructions for testing and adjusting the GEM Premier 5000. There is specialized test equipment required for several of the tests and adjustments.

Software Installation

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 andejected. 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), full system installation will be assumed and the process continues with the steps outlined in section 3.3 (for the analyzer) or section 3.4 (for the server). 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 I 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 5000 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 - 5000. 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 G5K 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. On the server, an attached keyboard is always assumed. 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 or Server

On the analyzer or server, 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 5000 (or, GEMweb Plus Server)
   - Application Upgrade

   Confirming 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 software compares the “Compatibility Version Number” of the already installed translation file (see 5.4), if one exists, to the translation version number required by the new application software being installed (as shown on the System Info screen).

If they are the same, the installer is prompted: “Applications upgrade from version <y> to version <x>. Continue with the upgrade? <Yes> <No>”. If they are different, the installer is prompted: “Applications upgrade from version <y> to version <x>. Translation file will be deleted. You will have to update your translation and load a new translation file. Continue with the upgrade? <Yes> <No>”.

- If <Yes> is selected the translation file is deleted, if applicable, and the upgrade continues. If <No> is selected, the upgrade aborts: the CD is ejected and reboot continues on the existing software version.
- If the translation file is deleted, the selected langauge is set to English and the langauge selection list is limited to the English choice. Note that if more than one langauge translation file was installed (for example Spanish and French), all will be deleted.

5. 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.
6. The system goes through self-reboot to complete installation of the new applications software.
7. 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.

Software Upgrade of the GWP Networked Members

The networked GWP client analyzer must have compatible software version to that of the server. The server will reject the client connection if the client’s software version is incompatible to the server’s version. See section 5 for how version compatibility is determined, and volume 4a for the message presented when the connection is rejected due to incompatible versions.

When it is mandatory to upgrade all network members for compatibility, it is recommended that all network members be upgraded within a short period of time to minimize interruption of the network operations. It is also recommended that the server be upgraded first, then the clients. This way, the client will be able to reestablish its connection to the server immediately after the client is upgraded.

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 software version number of the DEFAULT PASSWORD CD is identical to the first release of the analyzer System software (A.1.0.0). In the unlikely event that the contents of that CD change in a future version of the analyzer system software, the version number of that CD shall change to match the version number of the analyzer System software.

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.

Testing and Adjustments

The following procedures reference GEM 5000 units running software version 1.0.0 or 1.0.1. which utilizes GEM 5000 ETC version 1.0 or ETC version 2.0.

For GEM 5000 units running software version 1.1.0 and above refer to the Testing and Adjustments procedures beginning on page 114. GEM 5000 software version 1.1.0 and above contain the on board service diagnostics and requires GEM 5000 ETC version 3.0.

WARNING: High voltage is present when instrument is connected. DO NOT TOUCH WHILE TEST IS IN PROGRESS.

EQUIPMENT / TOOLS

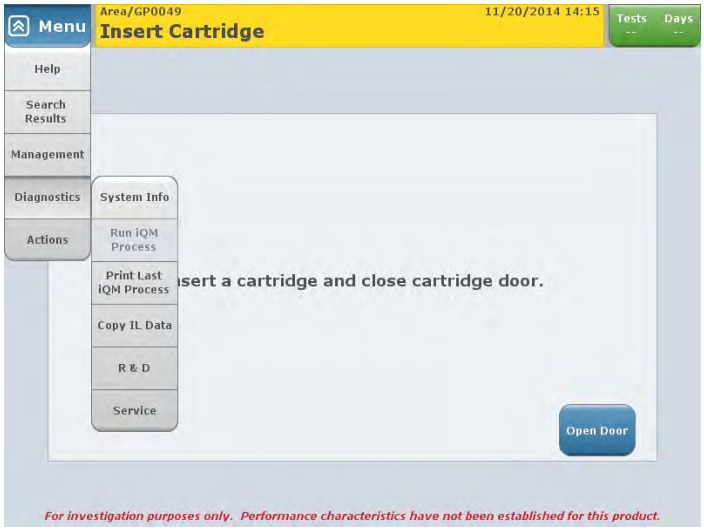
Description	IL Part Number
Personal Computer loaded with VI GTE software	N/A
Digital Torque Watch 100 In-Oz	00024017652
Fixture, Arbor, Sampler Arm Torque	00024017453
Fixture, G5k Solenoid Pinocchio Gauge	00024011540
RS232 Cable	N/A
8Pin Din Cable	N/A
Thermal Printer Paper	00025000500
Connector, loop back RS232	00024001581
Electric Test Cartridge	00024019750
Manufacturing Mode CD	00025002110
Depot Mode CD	00024005702
Aluminum Pump Tension Fixture	00024014520

INSTRUMENT CHECKOUT PROCEDURE

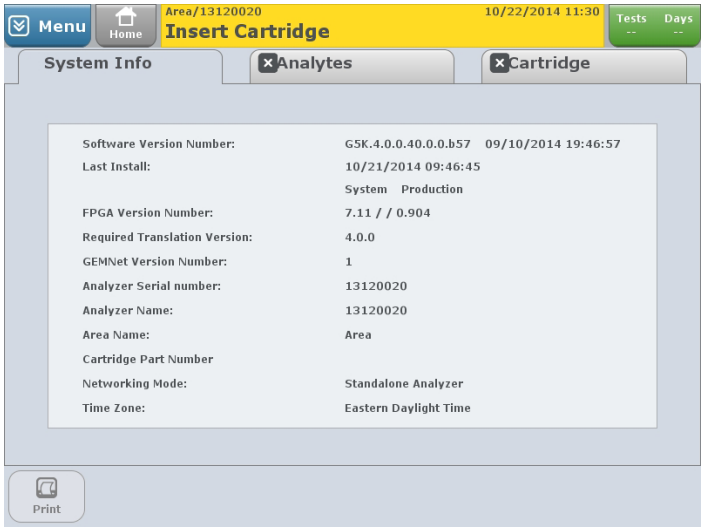
Final Instrument Test

This portion of the test shall be done prior to starting the LabVIEW Final Test program.

1. Verify Software Version. Touch Menu → Diagnostics → System Info



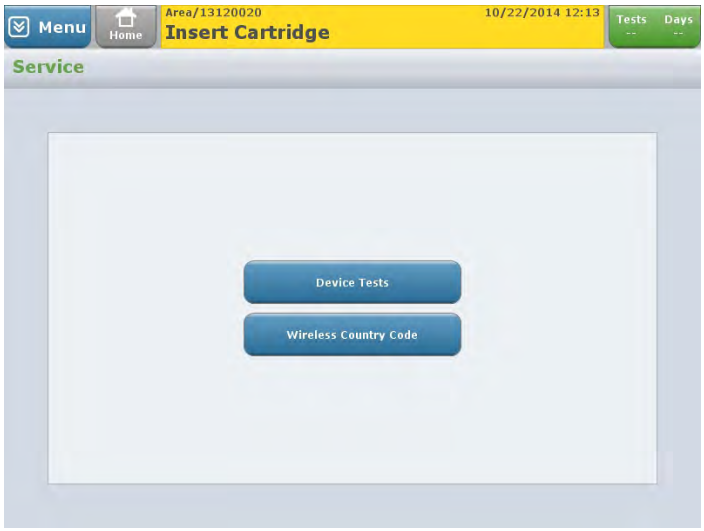
2. The screen in Figure 8 displays. Touch Home.



3. Perform a speaker check. Touch MENU. A beep should sound from both speakers.

Pre-LabVIEW Final Test

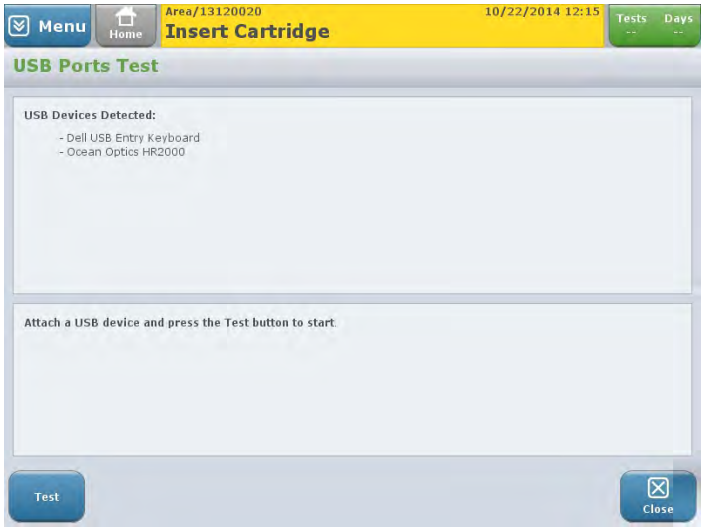
1. This portion of the test shall be done prior to starting the VI Software program.
2. Install Depot Mode disk into the CD drive. Perform an Instrument Shut Down (Menu → Shut Down).Enter Password on the onscreen keyboard display. Touch Enter. Touch Save (Y)
3. Re-install the Depot disk and then turn the instrument back on.
   When the instrument finishes rebooting and running self diagnostics:
   Touch Menu and Diagnostics → Modes → Depot (which displays a panel of tests) Touch OK. The instrument reboots again.
   When instrument finishes rebooting, touch Menu → Diagnostics → Service. If password is requested Key in 123456 and touch Enter.
   Touch DeviceTests.



Communication Test

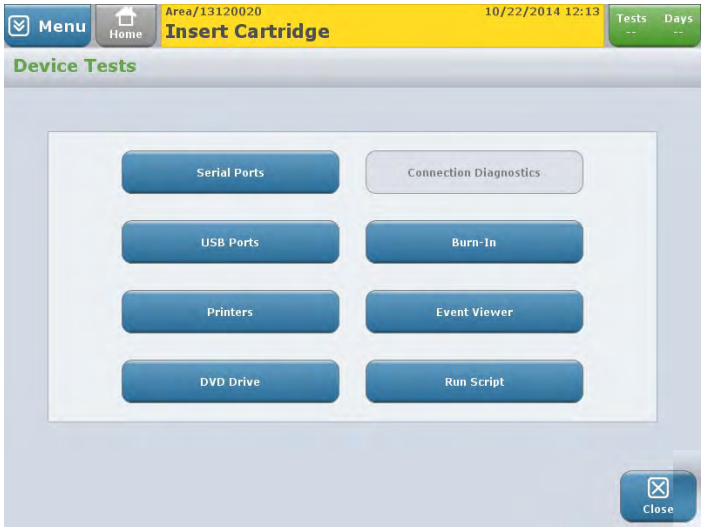
1. The Device Tests screen displays, as shown in Figure 10. Select USB Ports.

2. Insert a USB device (mouse, keyboard, memory stick, Etc.) in the appropriate port 1-4 and select USB. If devices are already connected, a list displays. Verify the screen lists the appropriate devices (the sequence in the list is not important).
3. Install a USB device in Port A (at the back of the machine) and Select Test at bottom left of screen. Repeat test for USB ports B, C, and D.
4. Select Close to exit to Device Tests Menu.



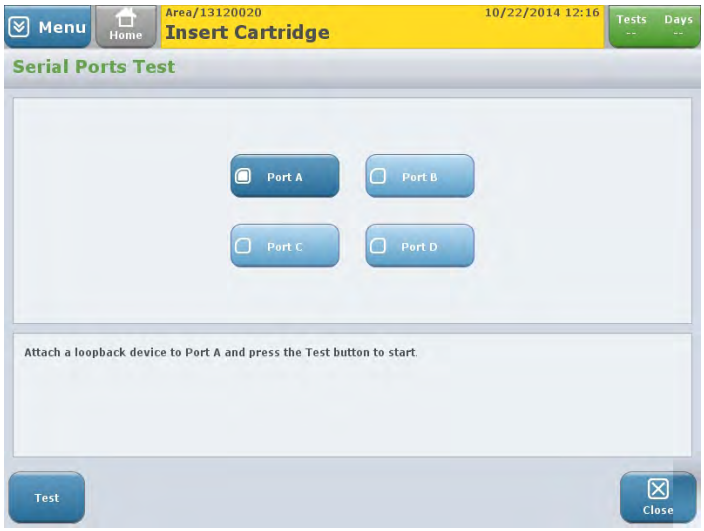
5. Install a USB device in Port A (at the back of the machine) and Select Test at bottom left of screen. Repeat test for USB ports B, C, and D.

6. Next, select Serial Ports.

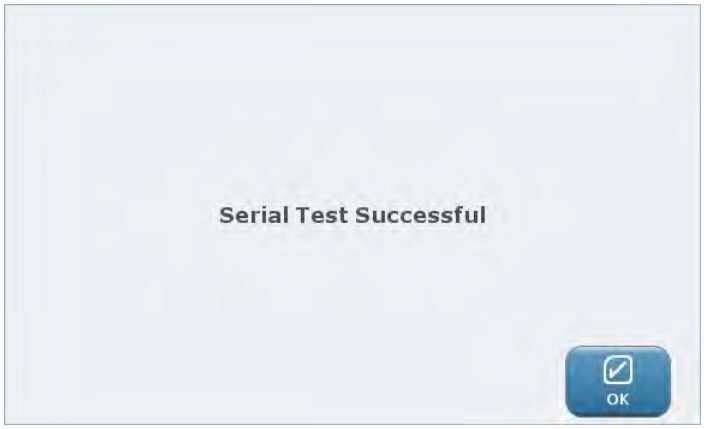


7. Install all (4) Loop back connectors (00024001581) in Ports A - D at the back of the Instrument.

8. Click Port A, and click Test, as shown in Figure 15. Test Port B, Test Port C, Test Port D.
Select Close.



9. The Success window displays.
Select OK.

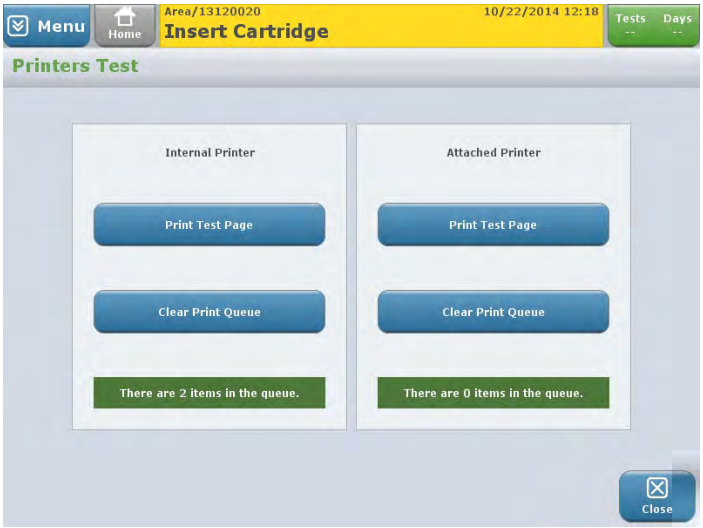


10. Select Close to exit to Device Tests Menu.

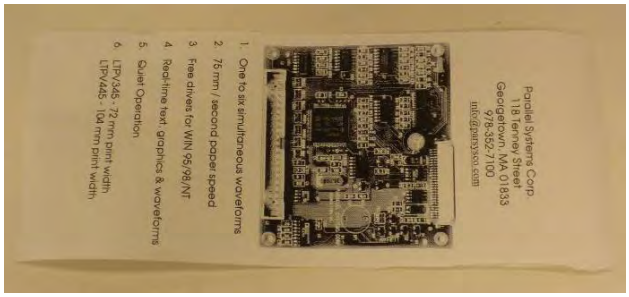
11. The Device Tests screen displays.
Select Printers.

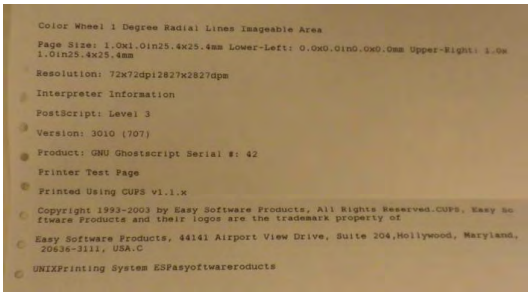
12. Connect the parallel printer to the parallel port on the back of the GEM.

13. Install paper in the unit's internal printer and close the printer door. Select Internal Printer and Print Test Page (Figure 19). After the internal printer has finished printing, select Attached Printer and Print Test Page.



14. Confirm the text on the test page (receipt) is clear and complete.





15. Click Close to exit Printers Test and return to Device Tests Menu.

Sampler LED Test

1. From Device Tests screen select “Run Script”

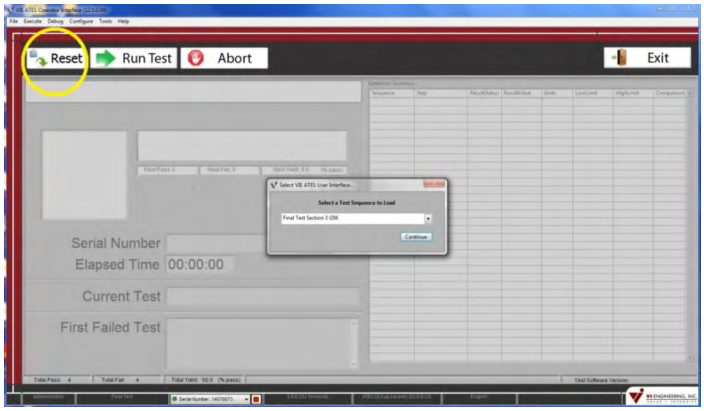
2. Select “SAMP_LED_FLASH” form the script list and press “Run”
3. Verify LED flashes and then remains illuminated.
4. Select “SAMP_LED_OFF form script list and press “Run”
5. Verify LED is turned off
6. Press “Done” to return to Device Tests screen.

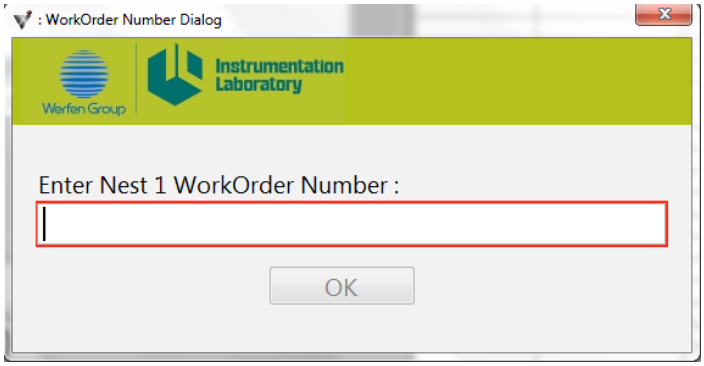
VI Tester Software Section 2 of Final Instrument Test (Co-ox)

Note: VI Tester Software Section 2 is fully automated and only requires the operator to make the necessary connections (between the VI test station and the test unit) called for in the VI Tester Software on screen instructions.

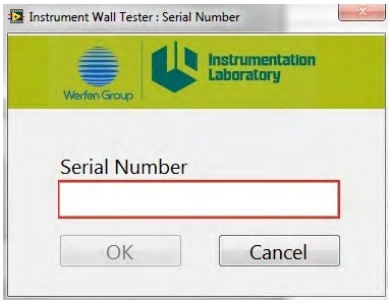
1. Launch the VIE ATES Operator Interface application icon from the PC screen.

2. To start the Section 2 test, from the VI tester software main screen, click “Reset” in the top left corner of the screen. From the drop down menu on the prompt, select “Final Test Section 2 G5K”. Click “Continue” to proceed and then click “Run Test”.

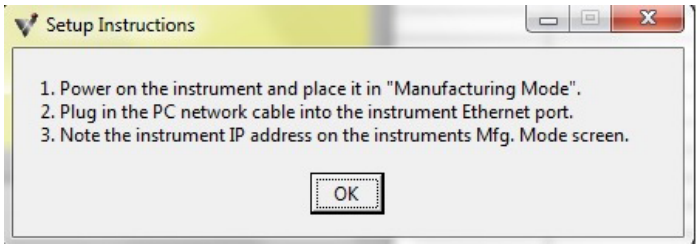




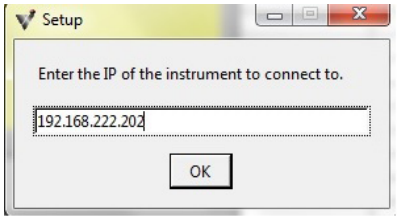
3. The Tester Software will prompt the user to enter the serial number of the unit under test.



4. The Tester Software will then prompt the user to place the instrument under into “Manufacturing Mode and connect the Ethernet cable.



5. Next, enter the IP address of the unit under test, as instructed by the prompt.



Note: The same address set in step 6.6.9 will be used in this step. IP address in Figure 33 is for reference only.

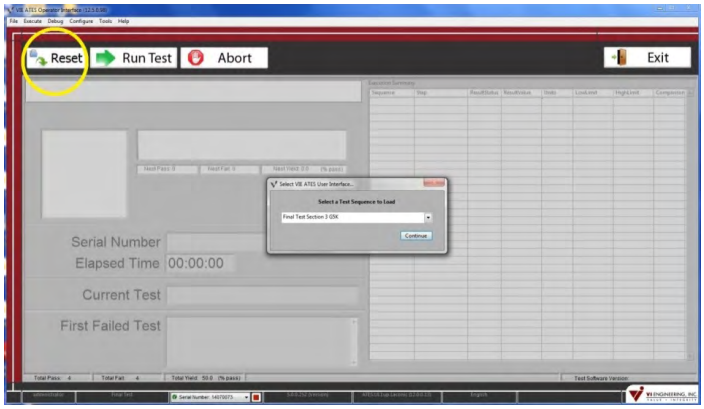
6. The Tester Software will then display a Testing Status. Once completed, the application will display as “Passing” screen, as shown

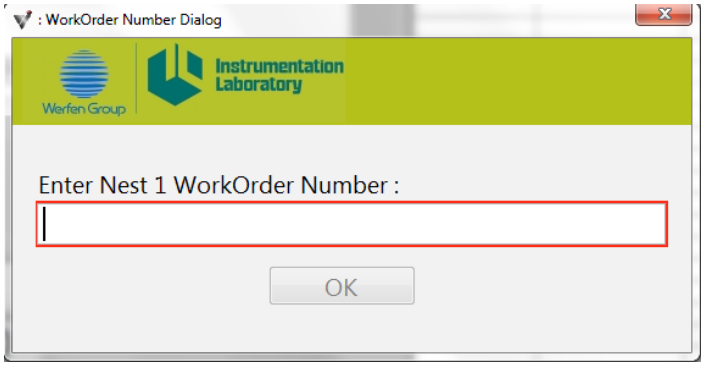
VI Tester Software Section 2B of Final Instrument Test

Note: VI Tester Software Section 2B and Section 3 are interactive and require occasional input and installation of auxiliary fixtures by the tester. The combined tests run approximately 25 minutes.

Note: Follow the VIE on-screen instructions and see the following references for proper ETC attachment.

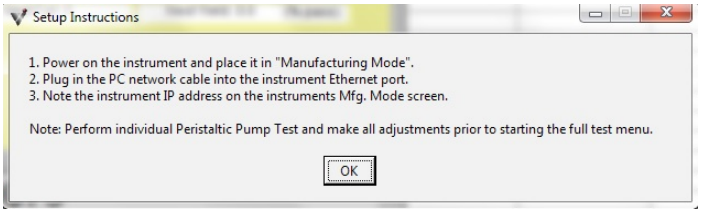
1. Ensure the system under test is in Manufacturing Mode. To start the Section 2B test, from the VI tester software main screen, click “Reset” in the top left corner of the screen. From the drop down menu on the prompt, select “Final Test Section 2B G5K”. Click “Continue” and “Run Test” to proceed.





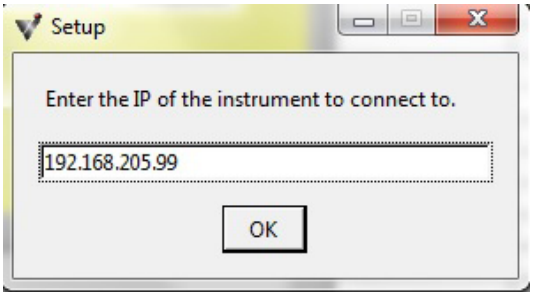
2. The Tester Software will prompt the user to enter the serial number of the unit under test.

3. The next prompt will provide setup instructions. Ensure the Ethernet cable from the test station PC is connected to the instrument under test.

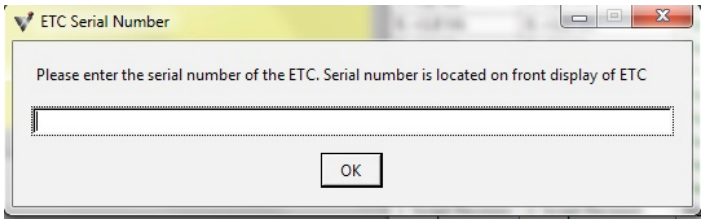


4. The tester software will then prompt the user to enter the Instrument's IP address.

   Note: The same address set in step 6.6.9 will be used in this step. IP address shown is for reference only.

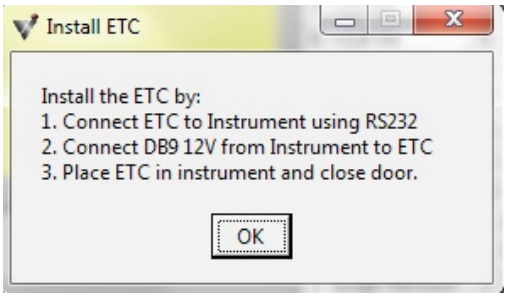


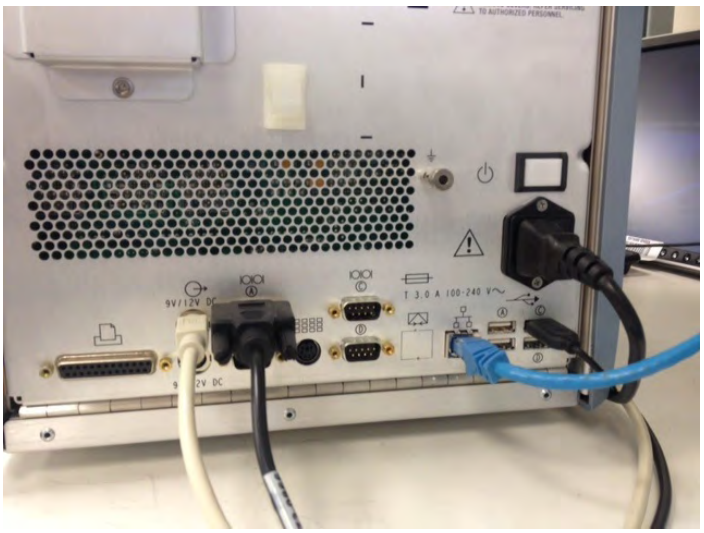
5. Next, the Tester Software will prompt the user to enter the serial number of the ETC being interfaced to the system under test. The serial number is located on the screen on the front of the ETC.

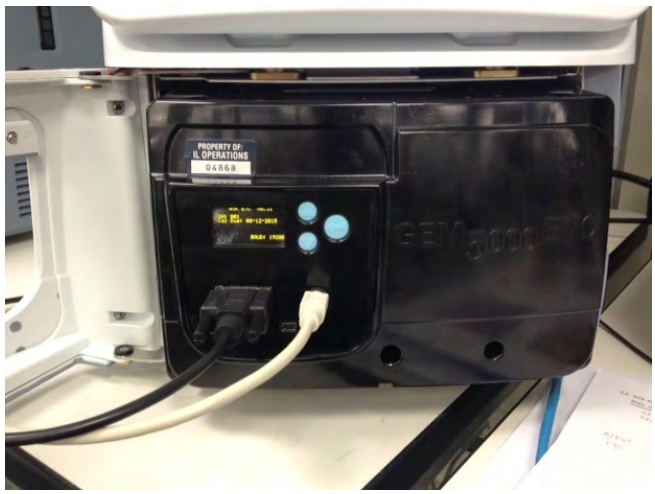


6. After entering the ETC serial number, the next step is installing the ETC in the system under test. Reference Figure for the Tester Software prompt. The RS232 and Mini Din power cable must pass through the open door of the system in order to connect to the ETC. Close the system door before proceeding.

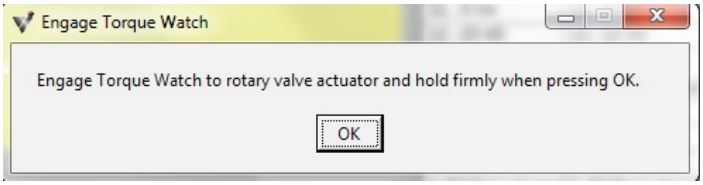
   Note: Plug Mini Din Power Cable last.



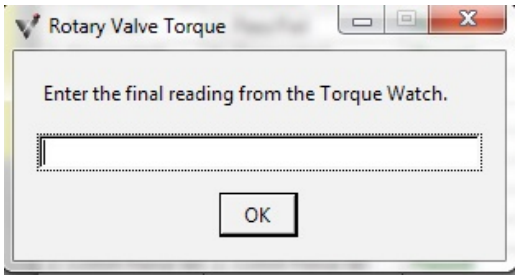




7. Once this section of the test sequence completes, disengage the ETC from the system under test before proceeding.
8. The Tester Software will then prompt the user to engage the Torque Watch to the rotary valve actuator.
9. Lock Fixture, Arbor, Rotary Valve (00024017452) on the Digital Torque Watch 100 In-Oz (00024017652).
10. Set torque gauge to peak counterclockwise operation by pressing the menu “Mode” button until the “PCCW” is displayed.

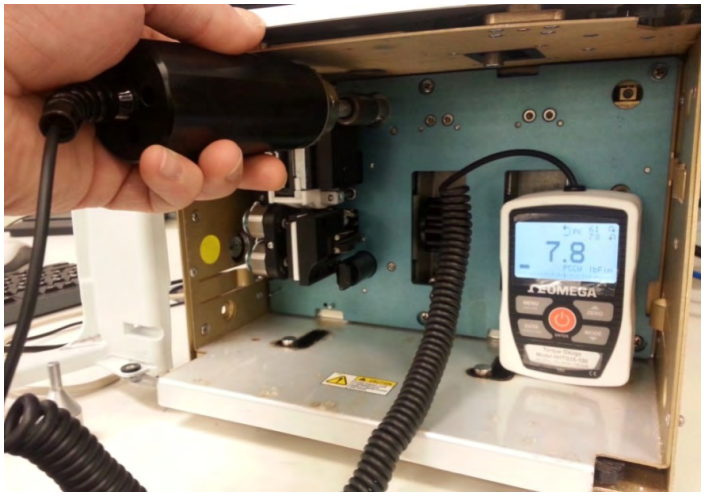


11. The next prompt should then ask the user to enter the final reading from the Digital Torque Watch. This step will repeat three times.

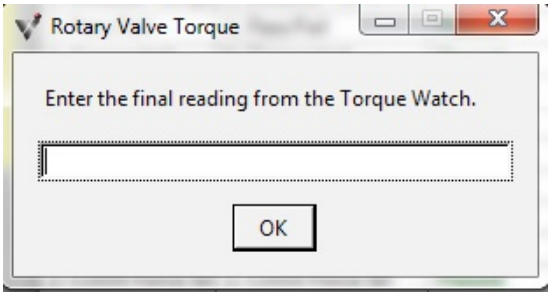


12. The Tester Software will then prompt the user to engage the Torque Watch to the Sampler actuator.
13. Lock Fixture, Arbor, Sampler Arm Torque (00024017453) on the Digital Torque Watch 100 In-Oz (00024017652).

14. Set Digital Torque Watch to peak counterclockwise operation by pressing the menu “Mode” button until the “PCCW” is displayed.

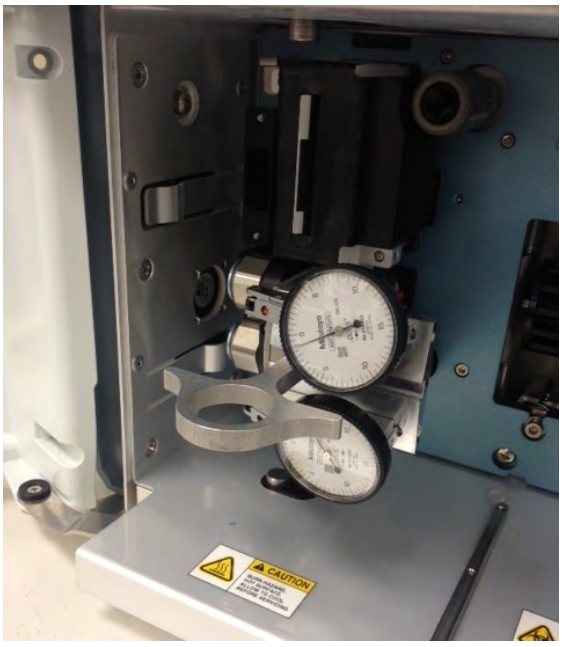


15. The next prompt will also repeat three times, asking the user to enter the final reading from the Torque gauge.



16. The Tester software will then prompt the user to insert the Pinocchio Gauge into the setup block and adjust the dials to zero.

17. The next prompt will ask the user to place the Pinocchio gauge in the Optic Head assembly, as shown.



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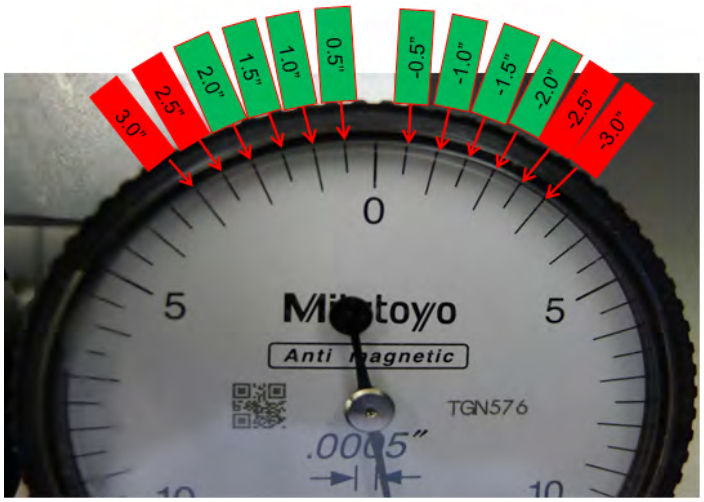
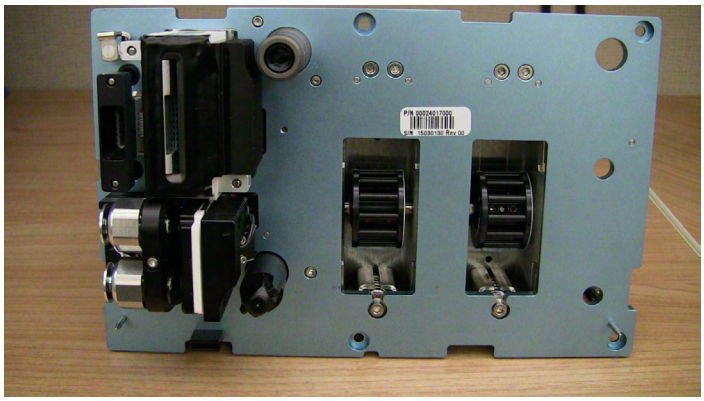
18. The Tester Software will then energize the solenoids before prompting the user to enter the readings from the Pinocchio gauge. Use the template in Figure 51 to determine the appropriate value to enter. Once the system deactivates the solenoids, remove the Pinocchio gauge from the Optic Head assembly and place back in the Setup Block.

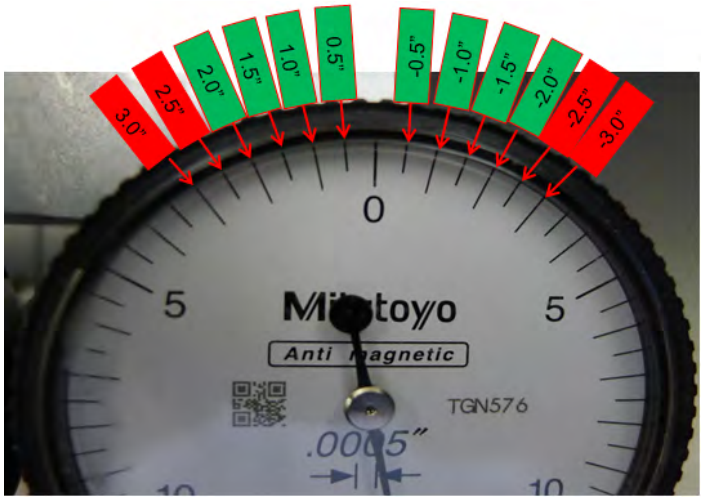


19. If adjustment of the Mixer or Diverter solenoid valve is required loosen the solenoid valve retaining set screw. Loosen the set screw just enough so the solenoid(s) can be adjusted, but not enough that the solenoids spin free.

NOTE: Do not loosen the set screw to an excessive state as both solenoid valves will become loose.



20. Using a wrench adjust the solenoid until the gauge reads 0 +/- 2.0.

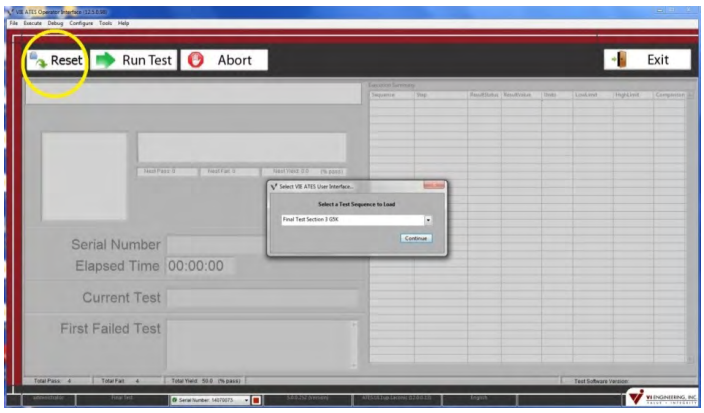


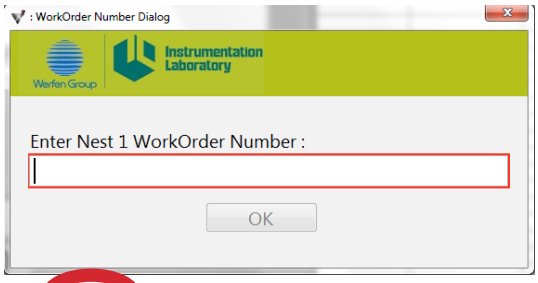
21. Upon completion of adjustment tighten the set screw to secure the solenoid valves.

22. Re-check both Mixer and Diverter valve adjustment (repeat steps 17 – 19).

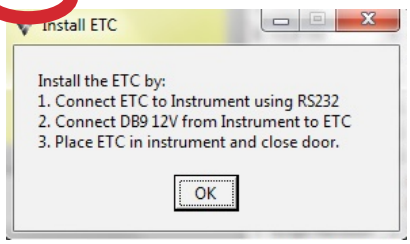
VI Tester Software Section 3 of Final Instrument Test

1. Ensure the system under test is in Manufacturing Mode. To start the Section 3 test, from the VI Tester Software main screen, click “Reset” in the top left corner of the screen. From the drop down menu on the prompt, select “Final Test Section 3 G5K”. Click “Continue” to proceed.



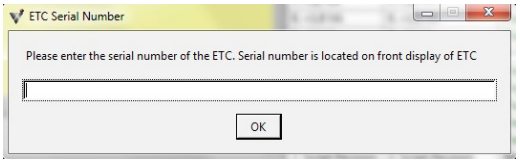


2. The Tester Software will prompt the user to connect the ETC to the system under test. Pass the RS232 and Mini Din power cables through the open door, then connect to the instrument. Close the door of the instrument before proceeding.



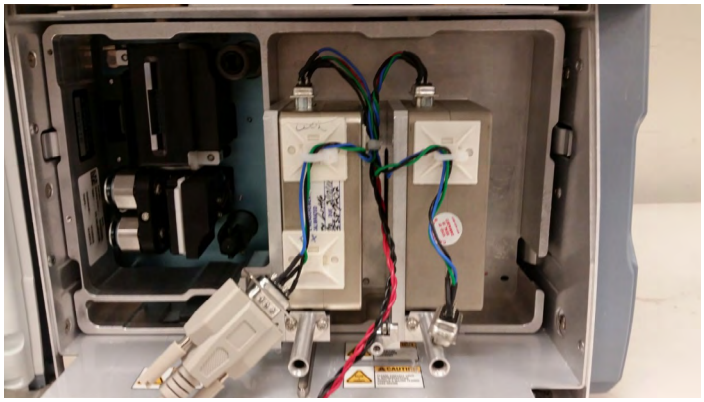
3. At the Tester Software prompt, enter the serial number of the ETC connected to the instrument under test. Click “OK” to continue.

4. After completion of section 3 testing disconnect cables and remove ETC from instrument.



Setting EC and COOX Pump Tension with the Aluminum Fixture

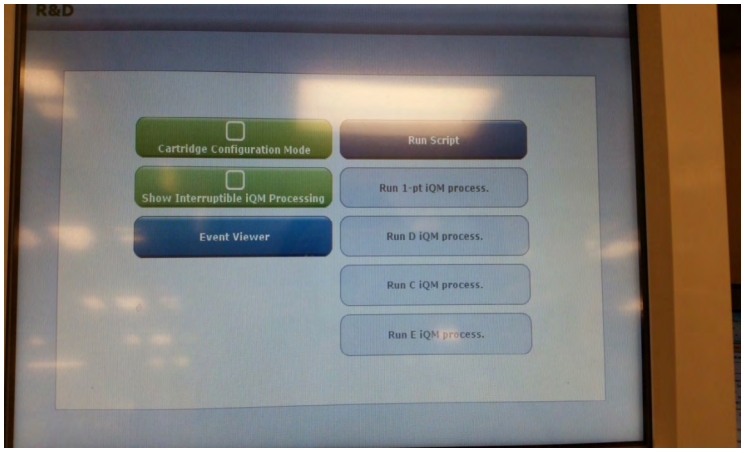
1. Run the script “DOOR_OPEN” from the R&D menu, if the front door is not already in an open state.
2. Remove the front door skin and disconnect LED cable
3. Feeding the cable through the door frame, attach one end of the RS-232 Cable to the CX pump transducer of the Aluminum Pump Tension Fixture.
4. Connect the other end of the RS-232 Cable to COM port ‘B’ in the back of the GEM Premier 5000 instrument



5. Feeding the cable through the door frame, connect one end of the Power Cable to the front of the Aluminum Pump Tension Fixture and the other end to the back of the GEM Premier 5000 instrument.
6. Set instrument under test in production mode
7. Open the dialog window by pressing “CTRL + ALT + F2”.
8. Log in using the user name “root” and password “n0bridge”
9. Enter “la” at the prompt and press Enter.
10. Press “CTRL + ALT + F7” to return to the main screen.

Enter R&D mode from the main menu by going through: Menu>>Diagnostics>>R & D

11. Use the keyboard to enter password “*IL&GEM+” to log in to R&D mode or scan “*IL&GEM+” barcode label.
12. Click “Run script” to enter script menu.



13. Ensure fixture is on the bench with clearance from objects around the platens for purposes of setting null force measurement.
14. On the instrument run the script “PUMP_FORCE_ZERO”.
15. Go to the dialog window by pressing “CTRL + ALT + F2”. Do not issue the next command until this script has ended.
16. Verify that all mean and SD measurements read “0.000.”
17. Return to the main command interface window by pressing: “CTRL + ALT + F7”.

Co-Ox Pump Tension Adjustment

1. Insert the fixture and close door engaging fixture to instrument interface wall.
2. From script menu, run ‘PUMP_FORCE_CX’ Script
3. Go to the dialog window by pressing “CTRL + ALT + F2” to observe the real time force measurement.
4. If values are outside the specified limits below, use the wrench to adjust the pump tension to within the specified limits.

   Note: Clockwise increases and counter-clockwise decreases force measurements.

Pump Tension Adjustment Limits	
Pump ID	**Range (in lbs)**
Co-Ox	**6.5 ±0.1**

5. Manually open door, remove fixture and re-insert, repeating steps 6.11.19.1 through 6.11.19.4 until the pump force settles within the limits and further adjustment is not required, continue to step 7. (End of adjustment)
6. Manually open door, remove fixture, re-insert, and run an additional ‘PUMP_FORCE_CX’ script and confirm that SD value is below 0.1. If SD is higher, instrument must be inspected for defects. (Confirmation of adjustment)

7. Record Aluminum Pump Tension Fixture SN, average force and SD from previous step in SAP.

   Note: Record Pump force average and SD values to three decimal places

EC Pump Tension Adjustment

1. Open instrument door
2. Remove fixture from instrument
3. Disconnect the RS232 communication cable from CX force transducer and connect to EC transducer.
4. With the fixture on the bench and platens cleared from contact with other objects, run the script “PUMP_FORCE_ZERO”.
5. Insert the fixture and close door engaging fixture to instrument interface wall.
6. From script menu, run ‘PUMP_FORCE_EC’ Script
7. Go to the dialog window by pressing “CTRL + ALT + F2” to observe the real time force measurement.
8. If values are outside the specified limits below, use the wrench to adjust the pump tension to within the specified limits.

   Note: Clockwise increases and counter-clockwise decreases force measurements.

Pump Tension Adjustment Limits	
Pump ID	**Range (in lbs)**
EC	**6.3 ±0.1**

9. Repeat steps 6.11.20.5 through 6.11.20.8 until the pump force settles within the limits and further adjustment is not required. (End of adjustment)
10. Run an additional ‘PUMP_FORCE_EC’ script and confirm that SD value is below 0.1. If SD is higher, instrument must be inspected for defects. (Confirmation of adjustment)
11. Record Aluminum Pump Tension Fixture SN, average force and SD from previous step in SAP

    Note: Record Pump force average and SD values to three decimal places

12. Return to the main command interface window by pressing: “CTRL + ALT + F7”.
13. Re-attach front door skin.

GEM 5000 ETC Instructions for On-Board Diagnostics

GEM 5000 ETC (version 3.0) instructions with GEM 5000 software version 1.1.0 or above.

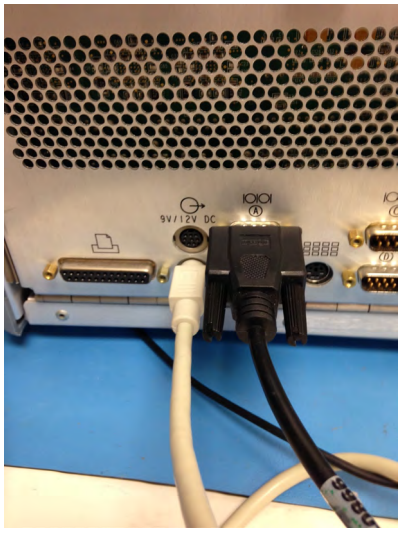
GEM 5000 software version 1.1.0 or above with On-Board Diagnostics and ETC version 3.0

The GEM 5000 software version 1.1.0 and above contains the on-board service diagnostic (service mode). Utilized with software version 1.1.0 and above is the GEM 5000 ETC (version 3.0).

The on-board diagnostic utilizes a pop-up keypad where input of alpha or numeric values is required. In addition, pop-up instructional windows are utilized where specific operator instruction or intervention is required to complete a test script.

NOTE: The GEM 5000 software version 1.1.0 and above is only compatible with the GEM 5000 ETC version 3.0. GEM 5000 ETC version 1.0 and 2.0 are only compatible with GEM 5000 software version 1.0.0 and 1.0.1. Software versions 1.0.0 and 1.0.1 do not contain the on-board service diagnostics and must utilize the external PC with Labview software.

1. To connect the GEM 5000 ETC to the GEM 5000 plug the power cable into the 9/12 v DC power connector on the rear panel of the GEM 5000 and plug the serial communication cable into serial port A on the rear panel of the GEM 5000.



2. On the GEM 5000 ETC plug the power cable into the power connector and the serial communication cable into the serial port on the front of the GEM 5000 ETC. Route the cables through the sample access hole in the GEM 5000 door.

3. To enter the GEM 5000 Service Mode (on-board diagnostics) place the GEM 5000 Service Mode CD (part number 00024019530) into the CD drive and restart the GEM 5000. Upon completion of the boot process the GEM 5000 will display the Service ID # screen.

The Service ID # field is used to identify the service person performing the diagnostic activity. The Service ID # will identify the service rep performing the tests when the Session History is viewed.

To enter an ID touch the value window to activate the pop-up keypad and enter an ID and press the OK button or press the OK button if no ID is entered.

4. The Service Mode home screen (menu) appears. The home screen displays the GEM 5000 unit serial number, software version and date & time. In addition the test buttons and function buttons are displayed.

NOTE: Prior to running test 2, 2B and 3 the GEM 5000 should be powered on for at least 45 minutes to allow temperature stabilization and Coox LED stabilization.

NOTE: When running the On-Board Service mode follow prompts that appear in the pop-up windows for various tests.

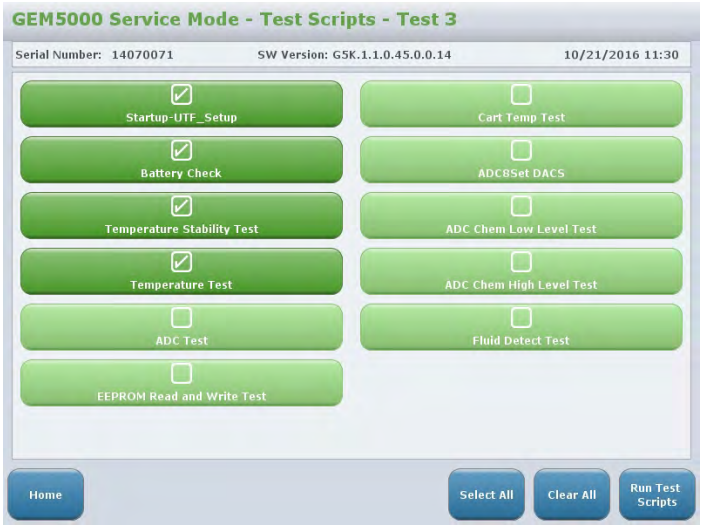
NOTE: To cancel a test in process touch the Cancel button. Some tests may not cancel immediately and will continue to run until an appropriate stopping step is reached.

NOTE: When running test 2B step: Set & Check EC & Coox Peristaltic Pump Tension Test, to make adjustments while the pump is running the front door must be removed to access the adjustment holes in the ETC. Remove the 4 screws from the rear side of the door, disconnect the sample LED cable and remove the door.

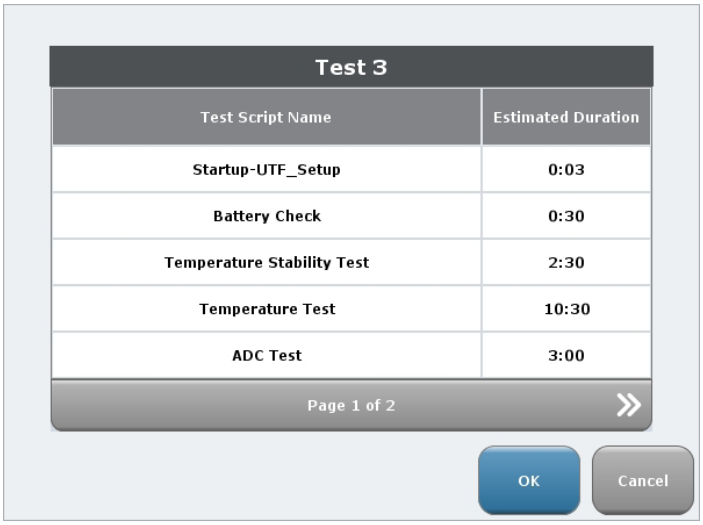
NOTE: When running test 2B and 3 the Start-up-UTF Setup will indicate FAIL with version 1.1.0 software. This is due to the +24 VS range in the diagnostic software being incorrect at 24 min and 25 max. Range should be 22.8 min and 25.2 max. Verify obtained value in the Data column is within the range of 22.8 – 25.2 vdc. This is corrected in version 1.1.1 software release.

NOTE: Test 3 will be used for the following examples. Test 2, 2B and 3 are all run in the same manor.

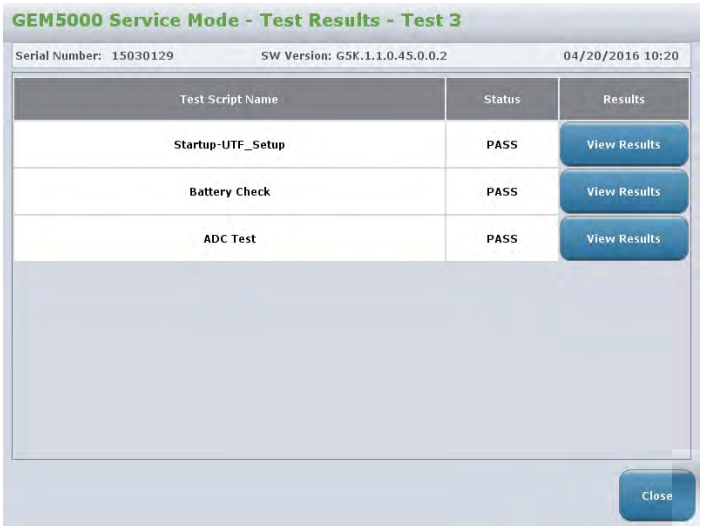
5. To perform a test press the test button from the home screen (menu). The test menu screen appears. Individual scripts may be run by touching the button for the desired script, or all scripts may be run by touching the Select All button, (typical selection). Once scripts are selected touch the Run Test Scripts button.



6. The screen will display the scripts selected with the estimated duration time to perform each script. Press the OK button to start the test. If select all or multiple scripts were selected scroll to page 2 to view the additional scripts and duration.

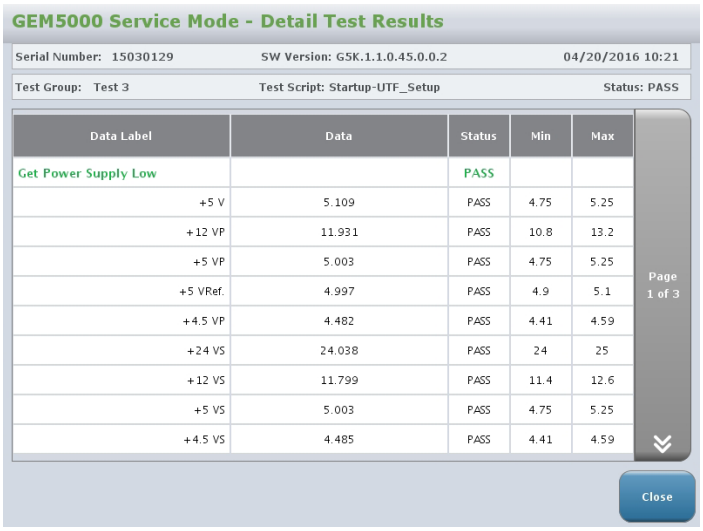


7. As the script completes the test the test status is displayed as Pass or Fail. Pressing the View Results button next to the script status will display test details.



8. Test details include the obtained data (result), status (pass or fail), Min value and Max value (min and max is acceptable range). Use the scroll key to view additional pages.

NOTE: Tests 2, 2B and 3 are all run in the same manner as the previous example.



Diagnostics Button

The Diagnostics function contains pre-defined scripts. The scripts perform specific functions for motors, valves, Sample LED, etc.

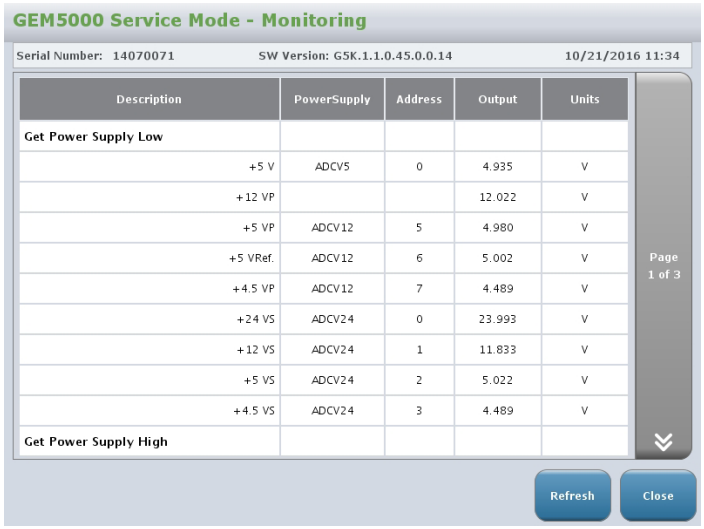
1. After touching the Diagnostics button the pre-defined scripts are displayed. Use the scroll key to view additional pages.
2. To run a script touch the script button to select the script. Touch the Run Test Script button to run the script.

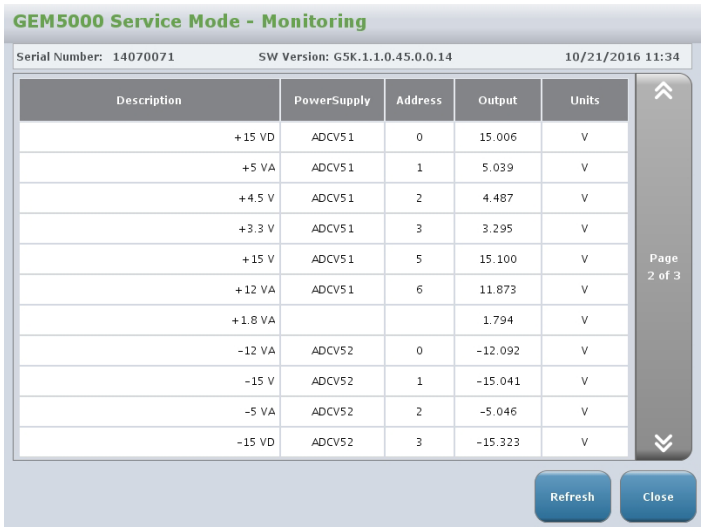
   Only 1 script can be performed at a time. No results are available from Diagnostic scripts, only visual confirmation.

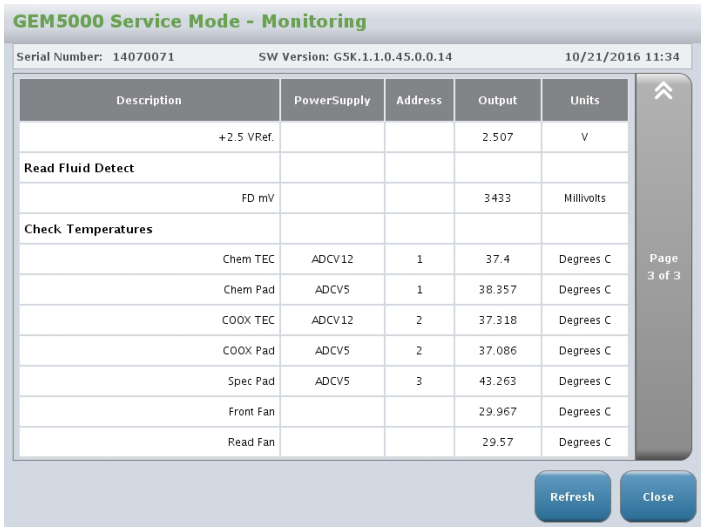
Monitoring Button

1. The Monitoring function allows the operator to view power outputs, temperature outputs, etc. There is no operator interaction with this function

2. After touching the Monitoring button the power and temperature values are displayed. Use the scroll key to view additional pages. Monitored values can be updated by touching the Refresh button.





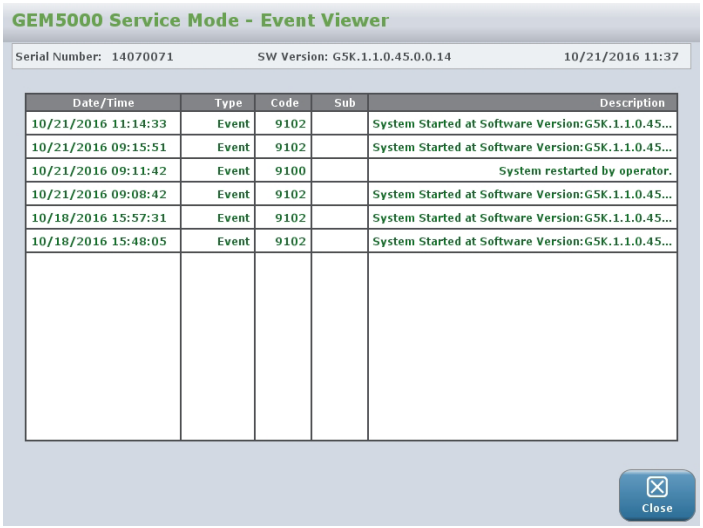


Event Viewer

Touching the Event Viewer button will display the last 100 entries logged into the event viewer. This allows the user to view the latest events without having to exit the service diagnostic mode.

1. Touch the Event Viewer button.

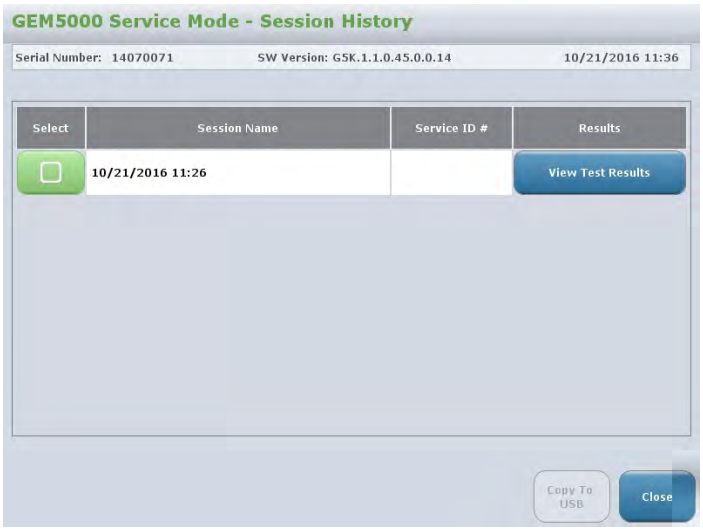
2. The screen displays up to the last 100 entries into the event viewer. Use the scroll key to view additional pages.



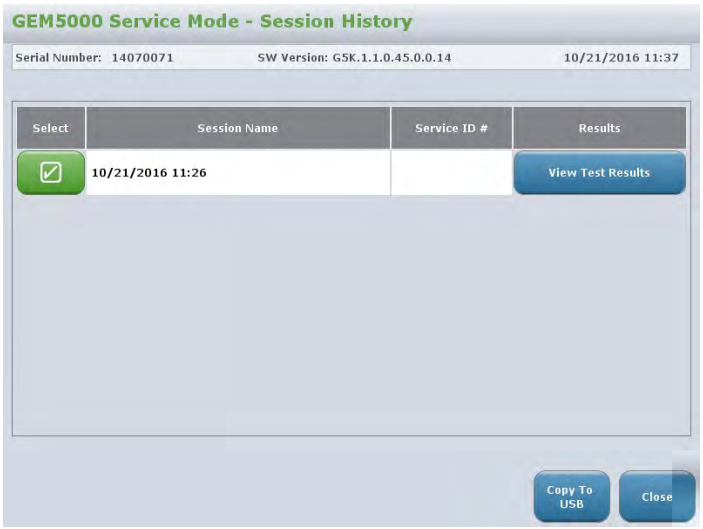
Session History

The Session History provides a record of the current Service Mode activity and previous Service mode activities results. Example shows one service mode activity.

1. To view the results of a Service Mode activity touch the View Test Results button.



2. To copy results of a Service Mode activity touch the green button under the Select column for the activity to be copied.
3. Plug a USB drive into any USB port on the GEM 5000.
4. Touch the Copy to USB button.



The detailed and summary reports will be copied to the USB drive. Reports are titled and saved by date and time (example: December_13_2016_12.58_Detail Report or December_13_2016_12:58_Summary Report). The reports can be viewed and printed from a PC.

Restart

Touching the Restart button will re-Start the GEM 5000 in the Service Mode.

Shutdown

Touching the Shutdown button will power off the GEM 5000. When powered on it will boot up in the Service Mode.

Return to Production Mode

Touching the Return to Production Mode will reboot the GEM 5000 back into the normal operation mode.

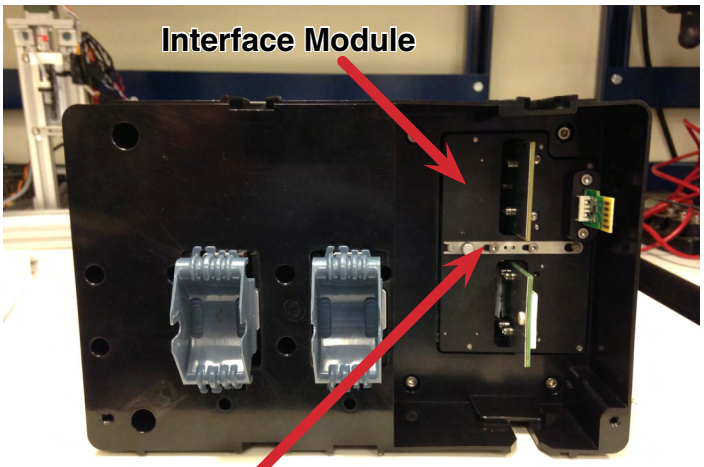
When all service activity is completed touch the Return to Production Mode to exit the service mode.

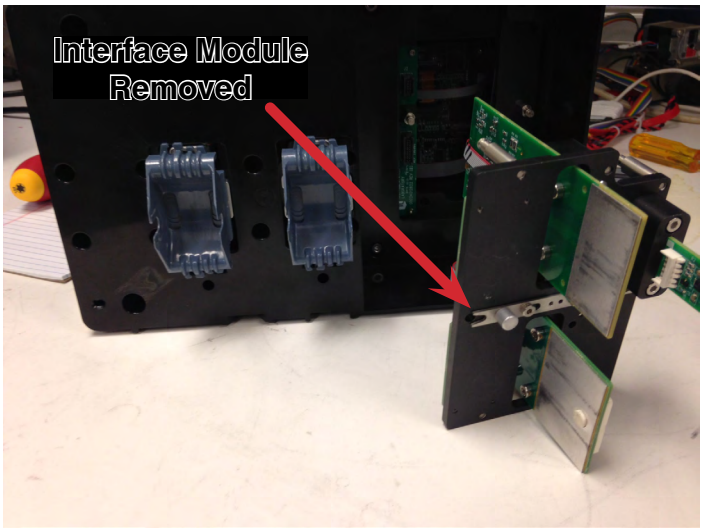
GEM 5000 ETC (Version 3.0)

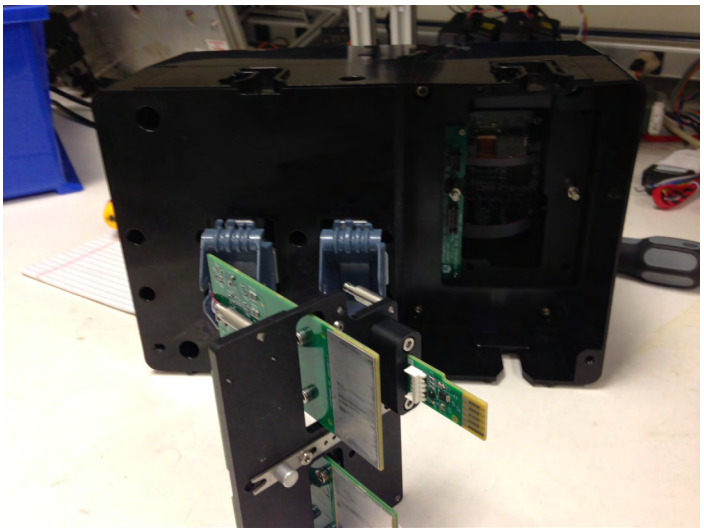
The GEM 5000 ETC is used when performing test 2B and 3.

The GEM 5000 ETC has a removable Interface Module. When performing test 2B, Set & Check EC & COOX Peristaltic Pump Tension Test and Check EC & COOX Peristaltic Pump Tension Test the Interface Module must be removed from the ETC. When the pumps adjustment and pumps tension tests are performed the program will display a prompt to remove the Left Hand Interface Module and install the ETC into the GEM 5000. The Interface Module is removed from the rear of the GEM 5000 ETC by sliding the lock plate to the right and removing (pulling) the Interface Module out of the ETC.

To re-install the Interface Module insert the Interface Module into the rear of the ETC and slide the lock plate to the left.







Pump Tension Adjustment (test 2b)

NOTE: To adjust the pump tensions the GEM 5000 front door must be removed to allow access to the adjustment screw holes in the ETC.

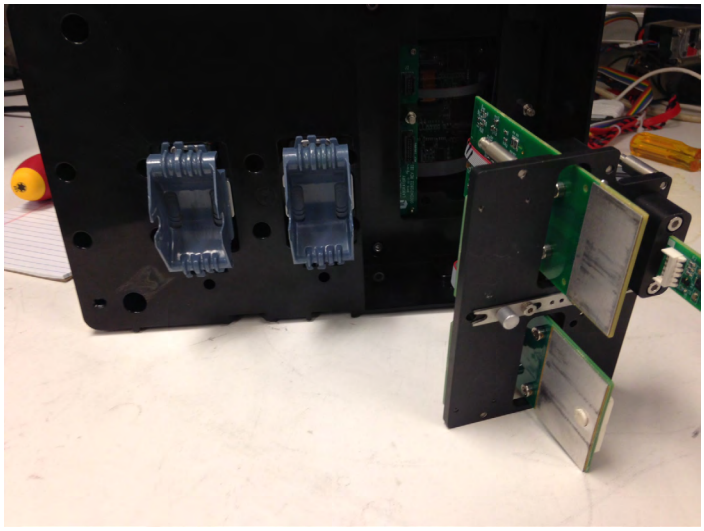
NOTE: The Left Hand Interface Module must be removed from the ETC to perform the pump tension test (follow screen prompts).

The EC pump tension is set to 6.3 +/- 0.2 (range 6.1 to 6.5).

The COOX pump tension is set to 6.5 +/- 0.2 (range 6.3 to 6.7).

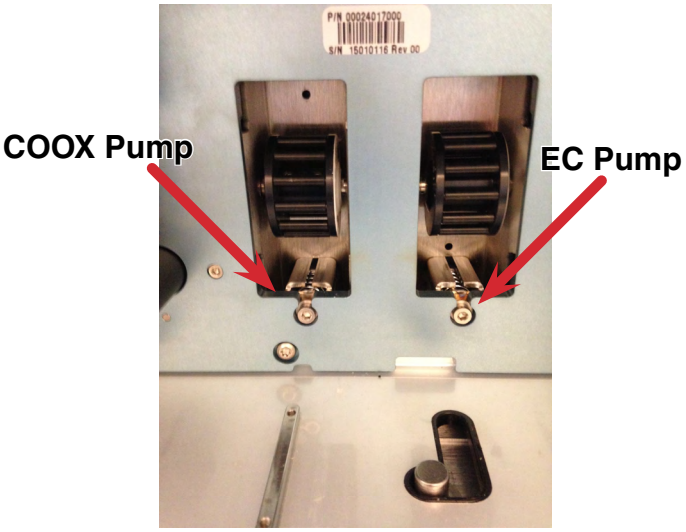
From Test 2B select the “All” button to run all test scripts under Test 2B or select Set & Check EC & COOX Peristaltic Pump Tension Test .

Follow the prompts to remove the Left Hand Interface Module from the ETC.



Insert the ETC into the GEM 5000.

Pump adjustment screws are shown below. (ETC removed for clarity).

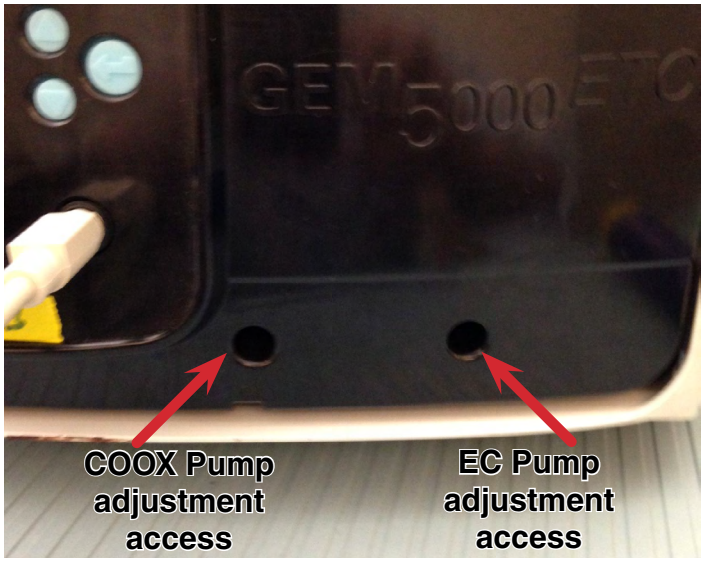


To adjust pump tensions while the script is running insert the 3.0 mm hex driver into the appropriate pump adjustment access hole in the front of the ETC. Adjust pump as necessary. Pump tension values are displayed on the GEM 5000 screen.

Adjust pump tensions to the following values.

The EC pump tension is set to 6.3 +/- 0.2 (range 6.1 to 6.5).

The COOX pump tension is set to 6.5 +/- 0.2 (range 6.3 to 6.7).



Mixer & Diverter Valve Adjustment (test 2b)

From Test 2B Mixer and Diverter Valve check and Adjustment.

1. The Tester software will prompt the user to insert the Pinocchio Gauge into the setup block and adjust the dials to zero.

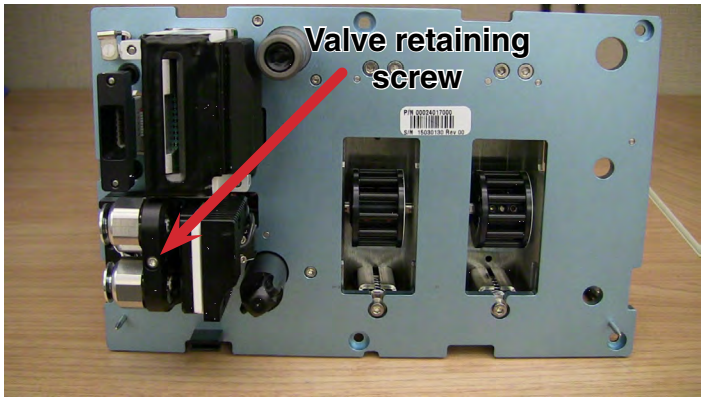
2. The next prompt will ask the user to place the Pinocchio gauge in the Optic Head assembly, as shown.

3. The Tester Software will then energize the solenoids before prompting the user to enter the readings from the Pinocchio gauge. Use the template in Figure 51 to determine the appropriate value to enter. The acceptable range is +/- 2.0.

4. Once the system deactivates the solenoids, remove the Pinocchio gauge from the Optic Head assembly and place back in the Setup Block. Acceptable range is -2.0 to + 2.0. (Green area in photo).

5. If adjustment of the Mixer or Diverter solenoid valve is required loosen the solenoid valve retaining set screw. Loosen the set screw just enough so the solenoid(s) can be adjusted, but not enough that the solenoids spin free.

   NOTE: Do not loosen the set screw to an excessive state as both solenoid valves will become loose



6. Using a wrench adjust the solenoid until the gauge reads 0 +/- 2.0.
7. Upon completion of adjustment tighten the set screw to secure the solenoid valves.
8. Re-check both Mixer and Diverter valve adjustment.

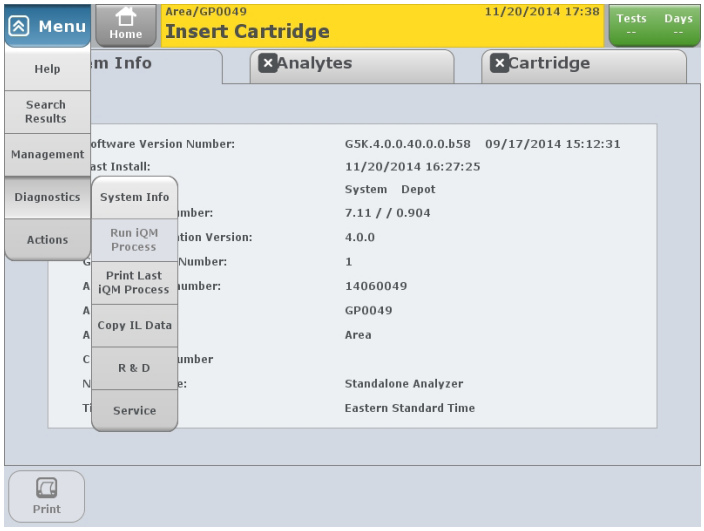
Wireless Testing

The minimal set of parameters to be set in order to enable the wireless network communications are:

- Wireless card IP address
- Wireless Network Name
- Country Code

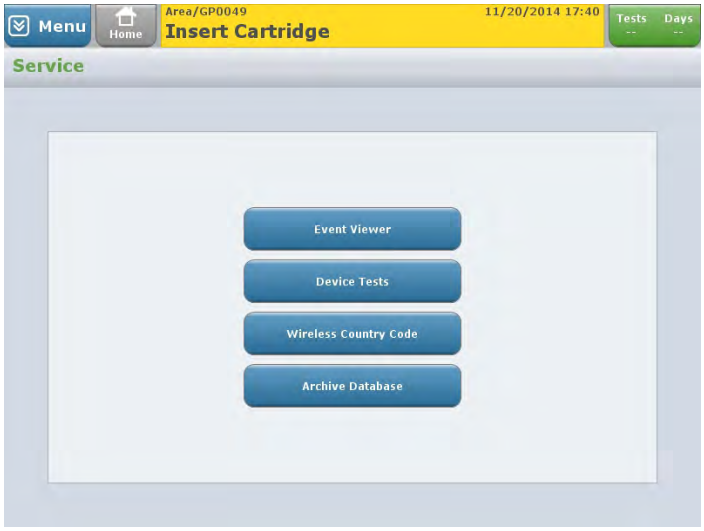
1. Set Instrument under test in depot mode. See sections 6.4.1 and 6.4.2 for detail.

   Touch Menu → Diagnostics → Service



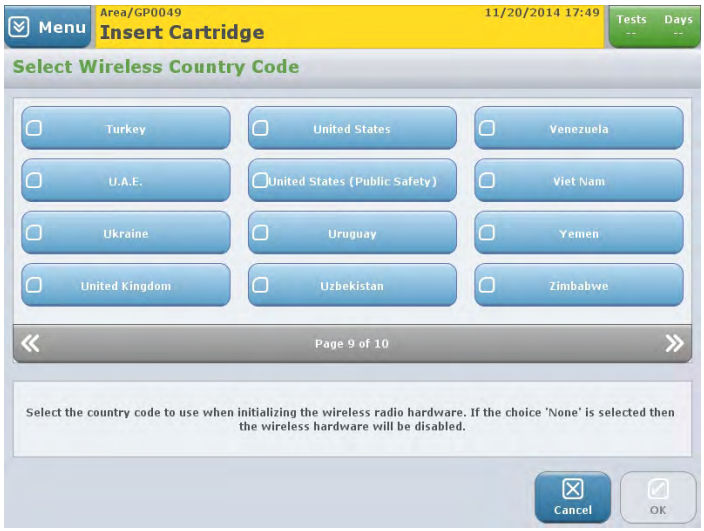
2. Enter *IL&GEM+ on the onscreen keyboard display to sign in.

3. The Select “Wireless Country Code” screen displays



4. Window displays Insert disk. Close drawer and insert wireless country code disk (00024001257) and press OK.

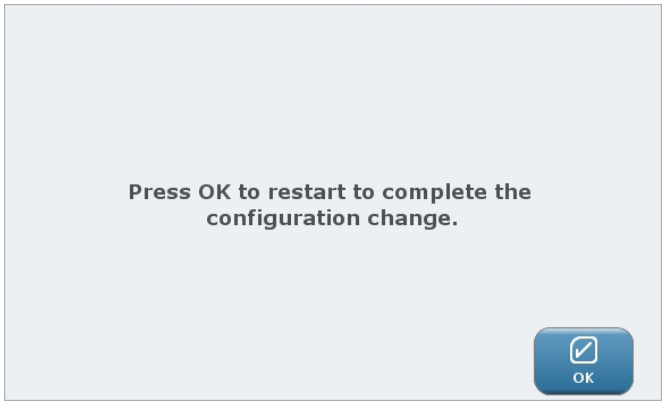
5. Advance through with the double arrows and select the button with the appropriate Country Code for your country. Select OK.



6. Select OK to confirm the selection and restart the Instrument.

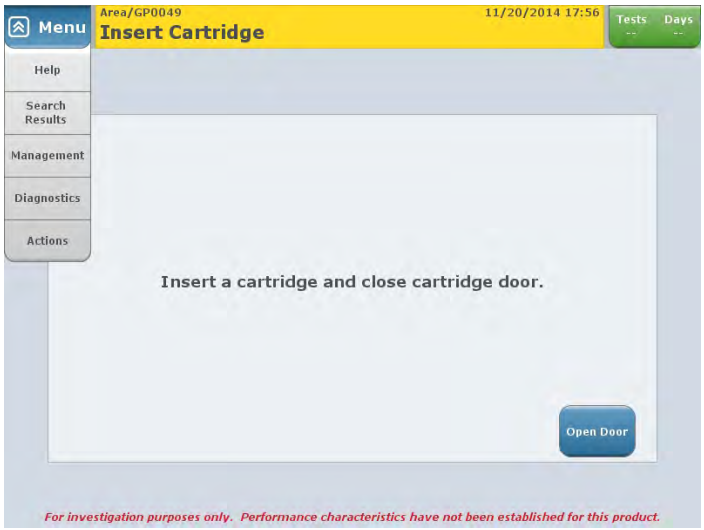
   Note: The restart window displays and then GEM instrument does a self-diagnosis.

7. Wireless feature displays.

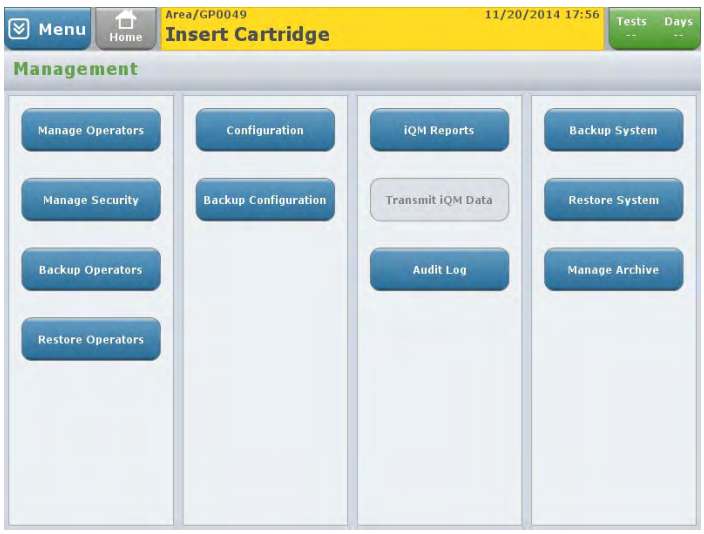


GEM Instrument Wireless Network Setting.

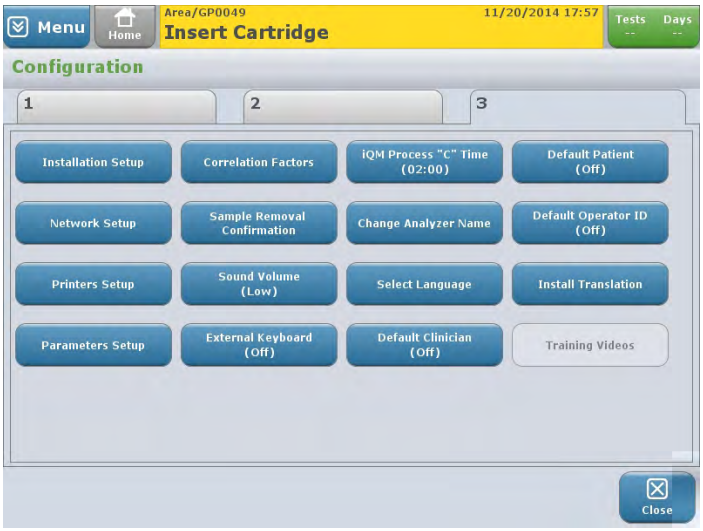
1. Touch Menu → Management.
2. Enter password 123456 in the window that displays. Touch Enter.



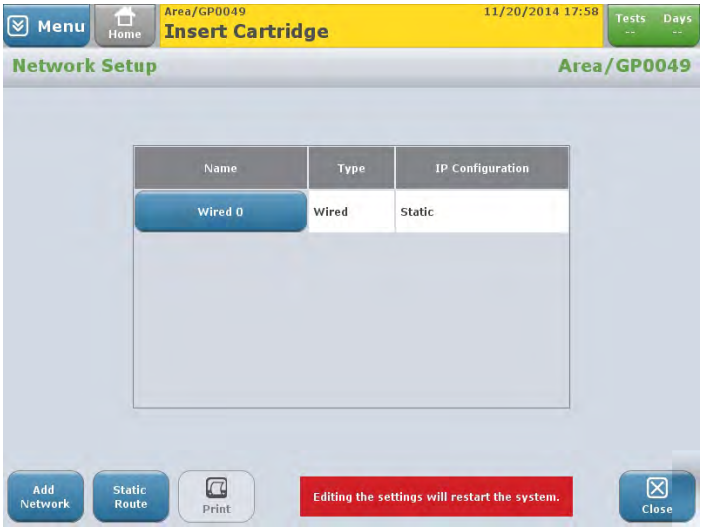
3. Touch Configuration.



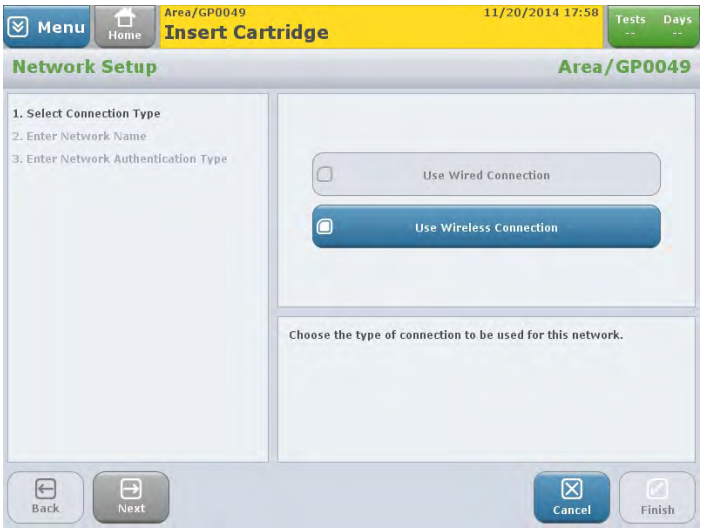
4. Touch Tab 3. On TAB3, touch Network Setup.



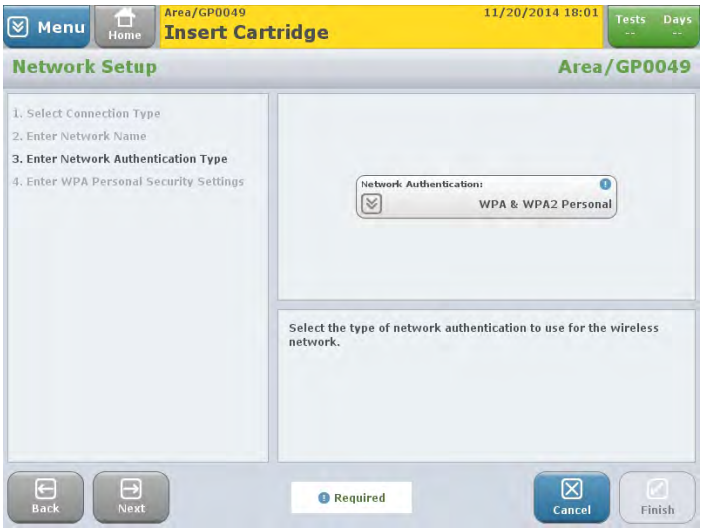
5. Touch Add Network.



6. Touch Use Wireless Connection. Touch Next.

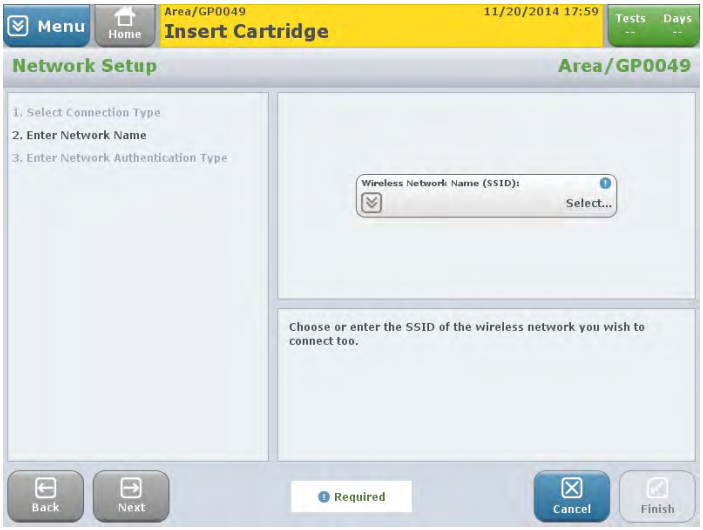


7. The Wireless network Name (SSID) screen displays. Touch Select.



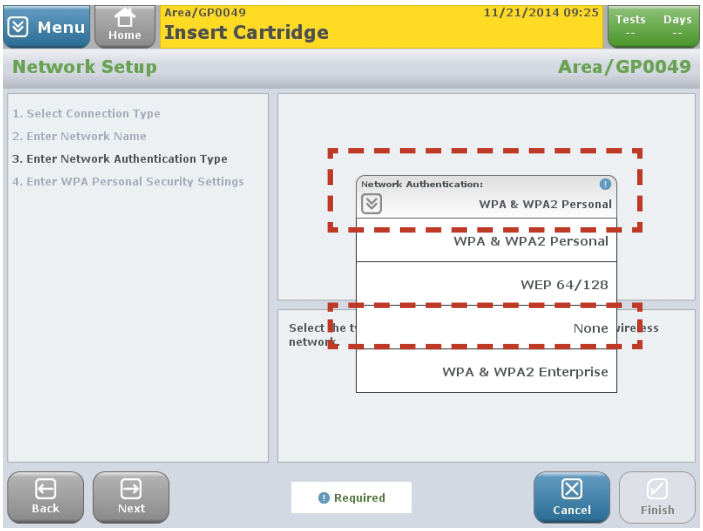
8. From the SSID touch Menu, select gem5000. Touch Next.

9. The Wireless Network Name displays gem5000. Touch Next.

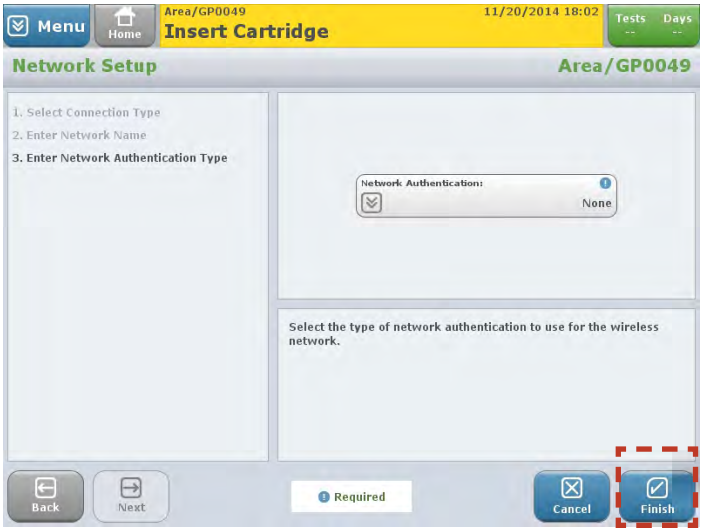


10. The Network Authentication Type screen displays. Touch Network Authentication.

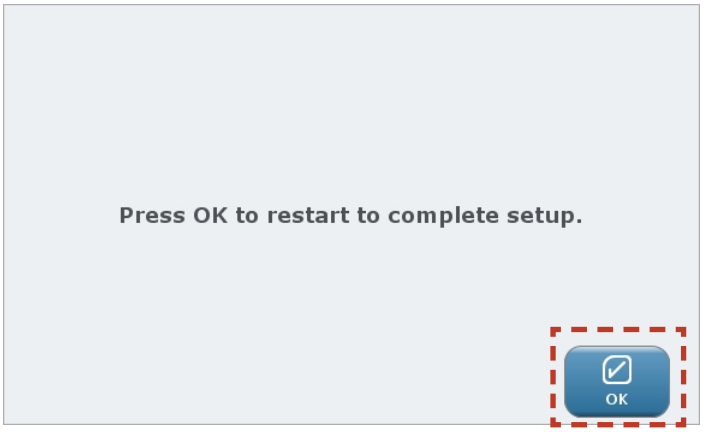
    Touch None.



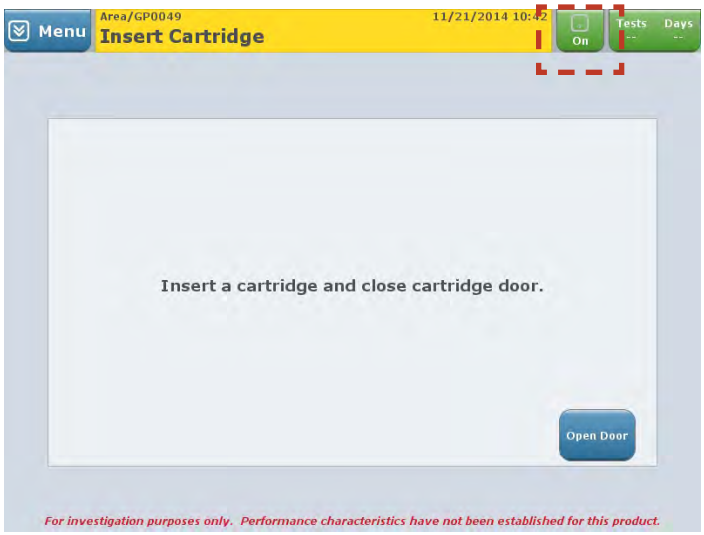
11. Touch Finish.



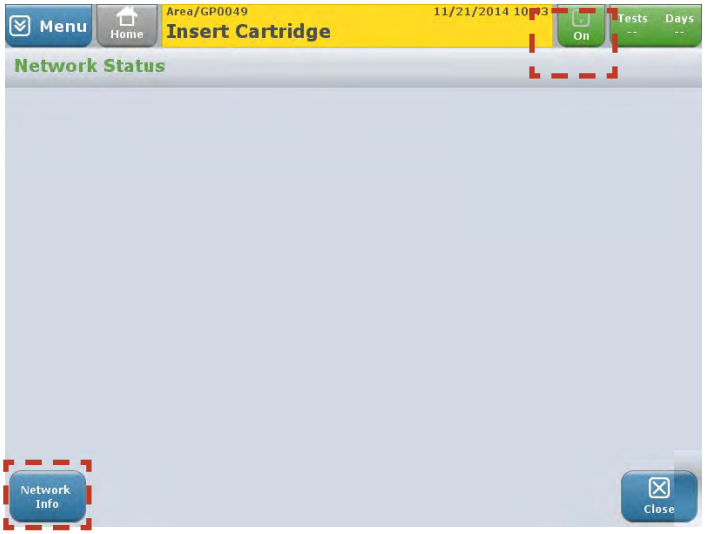
12. The restart window displays. Touch OK. The GEM instrument restarts.



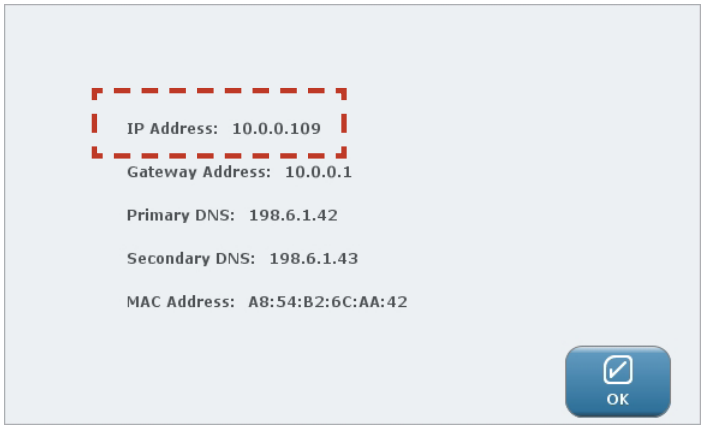
13. After the instrument has restarted unplug the Ethernet cable from the back of the instrument. The screen will display the wireless icon.



14. Touch the wireless icon and then Touch Network info to confirm wireless is active.

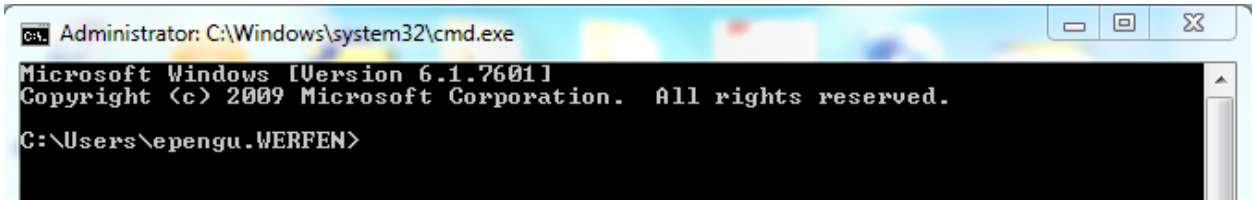


15. The window displaysthe Wireless IP Address. Let it remain on screen.

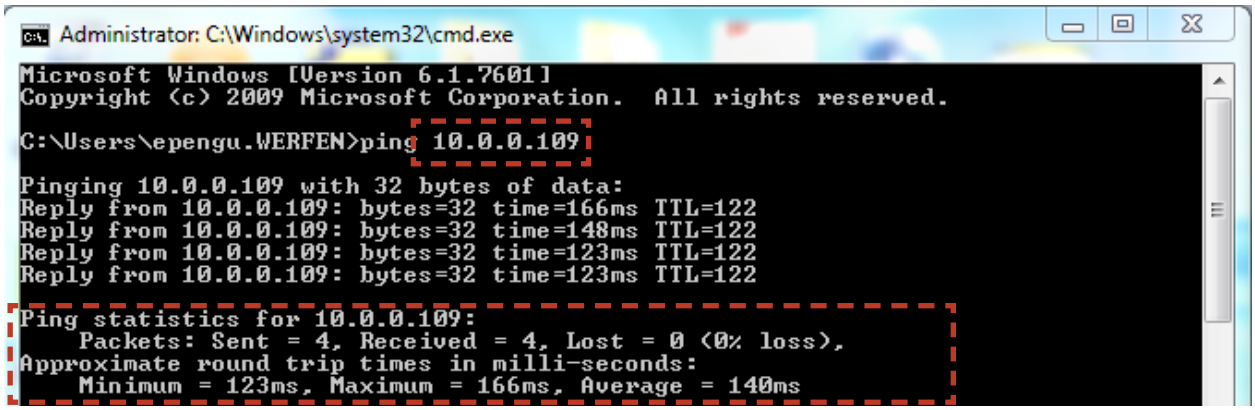


Wireless Communication Test

1. Open a command prompt on the personal computer configured for wireless testing (another test computer).



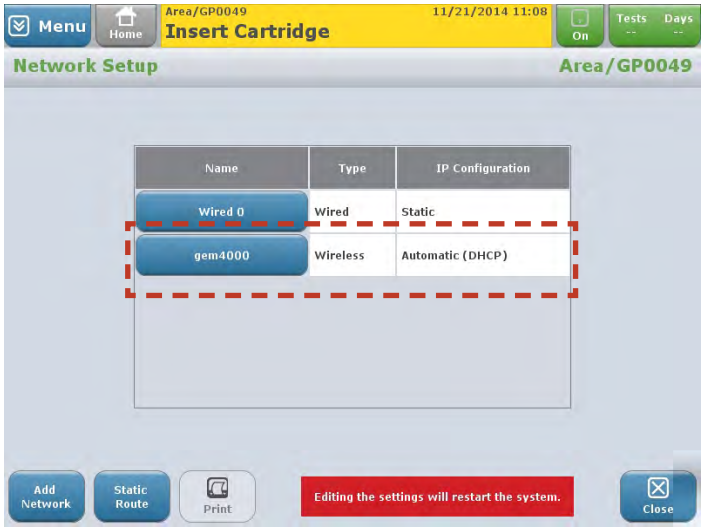
2. Type command ping (IP Address) (where IP Address is a known computer location). Press Enter on keyboard.
3. Confirm that a Pass (0% loss) results.



Disabling Wireless.

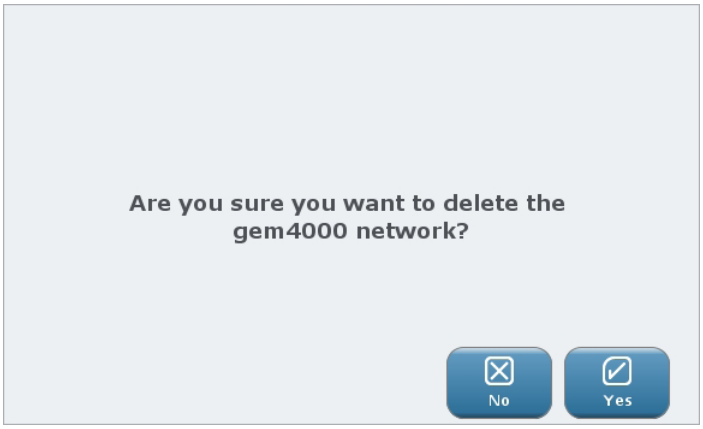
Note: The wireless setting must be set back to the default after wireless testing and for shipping.

1. Touch Menu → Management → Enter 123456 as the password.
2. Touch Configuration → touch third tab → Network Setup.
3. Select wireless gem5000



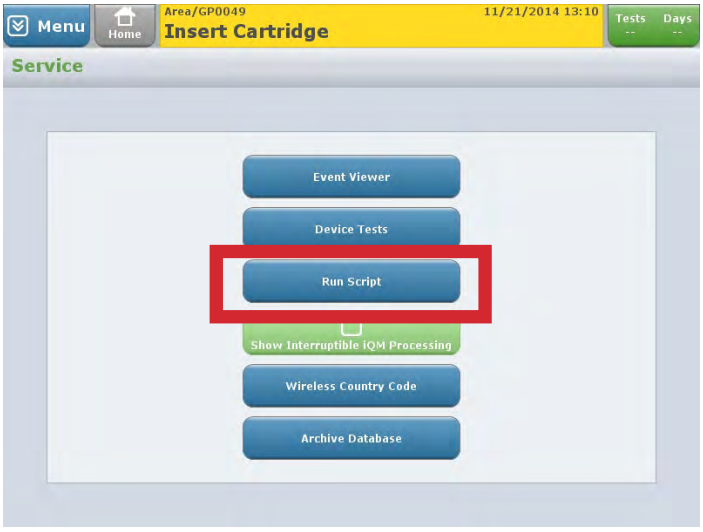
4. Touch Delete

5. When the “Are you sure you want to delete the gem5000 network?” displays Touch “Yes” .
6. The analyzer restarts.
7. Plug the Ethernet cable on the back of the instrument.



Run individual scripts from the R&D menu (optional)

1. Insert Depot Mode CD → Touch Menu → Diagnosticsà Service.
2. A window displays asking for a password. On the onscreen keyboard display, type *IL&GEM+. Touch Enter.
3. The Service screen displays. Individual GEM Scripts for diagnostics troubleshooting can now be run, independent of external VI Tester software.
4. Touch Run Script.



5. A list displays. Choose a test by touching the name on the screen and then touch “Run”. When finished with the tests you wish to run, Touch Done.

8 - Troubleshooting

This section describes the errors reported on the GEM 5000 analyzer and on the GEMweb Plus server to the operator and how they are processed.

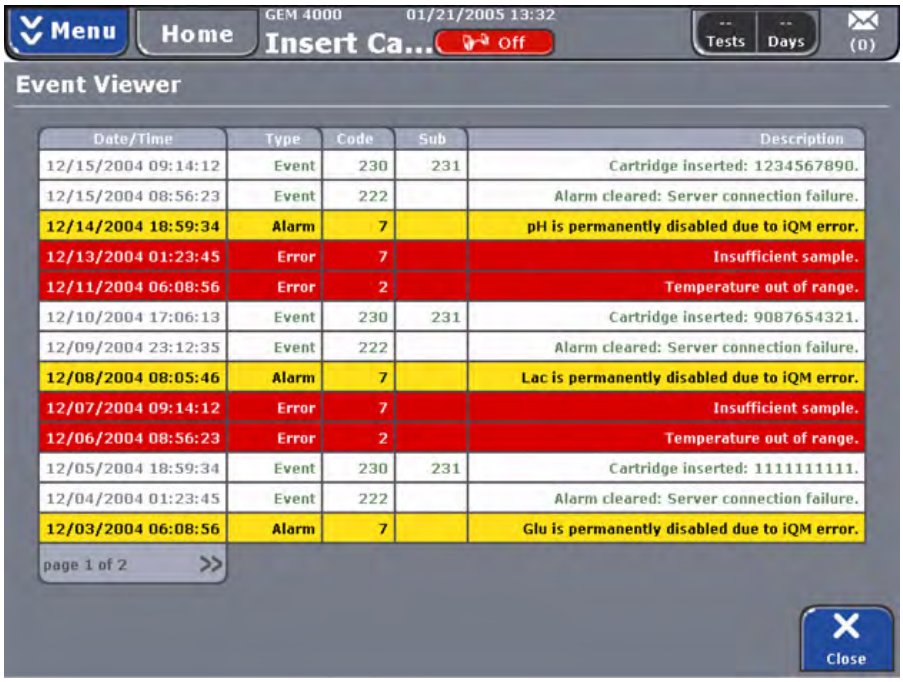
The errors reported are caused by malfunction of the instrument, the cartridge, or the software. Errors may also be caused by the improper use of the analyzer by the operator.

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.

This specification also specifies the events logged in a file called event_log.csv, which is copied to disc when Copy IL Data is run. Events are time-stamped textual messages that are stored in the database. When the Copy IL Data process is run, these events are copied to the file event_log.csv, which is then written to disc. Every error or alarm generates an event entry in this log. Other pre-defined critical events also generate event messages. The event_log.csv file is used for troubleshooting purposes and is intended for use by IL personnel only.

The Event Table

The event table is viewed by selecting Menu/Diagnostics/Service, then selecting the Event Viewer button. The image below shows the contents of the Event Viewer screen. The Event Viewer screen is color-coded using the red background for errors and the yellow background for alarms.



The Error Attributes

An error is defined by 3 attributes: error code, severity level, and an optional error subcode. When the system detects an error, the error is posted to the user interface software by providing these 3 attributes. The user interface software uses this information to determine the message to be displayed to the operator and to define the corrective action to be taken (such as repeat sample analysis or replace the cartridge).

Error Code

The error code uniquely defines the error. For example, LEAD_EDGE_NOT_FOUND is the error code when the process control solution is not detected. The error code defines the error message to display to the operator.

Error Severity Level

The error severity level defines the corrective action to be taken, e.g, remove the cartridge. In most but not all cases, the severity level can be assigned to any error, which in turn defines the corrective action to be taken. The severity levels supported by the GEM 5000 software are defined in Table 1.

Table 1

Severity Level (1=highest)	Severity Level Name	Description
1	SHUTDOWN_NOW	There is no possible recovery from the error. The GEM 5000 analyzer is shut down and powered off immediately and without operator acknowledgment. The instrument requires service by IL personnel.
2	SHUTDOWN_OK	The instrument is shutdown after operator acknowledgement by pressing an <OK> button.
3	INSTR_RESET	The instrument is reset, that is, complete restart of the analyzer applications and operating system software is performed in an attempt to clear the error and recover to a known state. The instrument hardware or software, not the cartridge, is believed to be the cause of the failure.
4	CART_DIAG	The cartridge or the instrument is the cause of the error. The cartridge must be removed but diagnostics must be run before the next cartridge is inserted. The operator is notified of the error and is requested to remove the cartridge and wait for diagnostics to complete before inserting the next cartridge.
5	CART_REMOVE	The cartridge is defective. The operator is notified of the error and is requested to replace the cartridge.
6	OP_RETRY	The error is caused by the introduced sample, for example, insufficient specimen. The user is notified to repeat the test.
7	MESSAGE_OK	When an error is reported with the MESSAGE_OK severity level, a message is presented to the operator with an [OK] confirmation button. The software takes no corrective action beyond notifying the operator of the condition. Once OK is pressed, the message is removed. The presentation of the message does not disturb the current state of the software. For example, if the message is presented during sample analysis, the sample analysis process continues in the background unaffected by the notification message.
8	LOG_EVENT	When an error is reported with the LOG_EVENT severity level an event is entered in the analyzer's database for tracking purposes. No operator notification or corrective action is taken. See the Event Logging section 7). The message text to log depends on the reported error, see the Error List in Section 6.

Error Subcode

The error subcode is an optional identifier that can be used to further characterize the error. The subcode is for the IL analytical staff internal use only. The use and value of the subcode is left to the programmer's discretion and is not specified in this manual.

Error Processing

Overview

This section defines error processing for the severity level OP_RETRY or higher. Processing of the lower severity levels is specified in Table 1.

The following steps outline the error's "life cycle":

1. The operating software or the analytical script detects the error.
2. The operating software or the analytical script logs an event due to the error.
3. The operating software or the analytical script attempts to recover from the error, typically by retrying the failed operation.
4. If the recovery is successful, the operation continues without an explicit operator notification, and error processing ends here.
5. If recovery fails (hard error), the error is reported to the user interface software. The operator is notified of the error and asked to wait till the failed operation ends.
6. The operating software or script performs clean-up work, such as washing out the sample or homing the devices.
7. Optionally, the operating software or the analytical script attempts to troubleshoot the problem to confirm the error severity level.
8. The failed operation ends. The operator is notified of the action to be taken, if any. The corrective action is executed based on the error severity level.

The steps are detailed in the following sections.

Logging the Error Event

The error is logged in the database. See "Event Logging".

Error Recovery

The software or analytical script attempts to recover from the error. Recovery may include retrying the failed action. If recovery succeeds, the current activity proceeds as if no error has occurred. Otherwise, if the error persists, the operating software continues to the error reporting step.

Error Reporting

The error is reported to the user interface software by specifying the error code, the severity level and, optionally, an error subcode. Analytical scripts use the ERROR script command to report the error.

The user interface software reports the following information to the user in a message box in the middle of the screen:

"The message text" (The message text depends on the reported error, see "The Error List".)

"Error n" (Where n is the error number from the error list)

"Please wait…".

The presented error message is accompanied by 3 beeps.

Error Cleanup

During cleanup the instrument is returned to a known state by performing operations such as washing out the sample and homing the devices. Optionally, troubleshooting and hardware diagnostics can be run to further define the underlying cause of the error, as being a cartridge or instrument error. If a further error of greater severity is discovered at this point, the user interface software is notified again.

Severity Levels and Their Corrective Action

Upon completion of cleanup and troubleshooting, the corrective action steps taken depend upon the severity level of the error, as specified in the following subsections.

The SHUTDOWN_NOW Severity Level

1. The message "Analyzer will be shut down. Contact Technical Support." is displayed, replacing "Please wait…" in the message box:
2. All the information in the message box is printed on the on-board printer (under the IL logo and current date and time).
3. Wait for 30 seconds to allow time to read the message and for the report to print.
4. Open the cartridge door
5. Perform a system shutdown

The SHUTDOWN_OK Severity Level

1. The message “Analyzer will be shut down. Contact Technical Support.” is displayed, replacing “Please wait…” in the message box, and an [OK] button is added.
2. All the information in the message box is printed on the on-board printer (under IL logo and current date and time).
3. Open the cartridge door
4. Perform a system shutdown after [OK] is selected.

The INSTR_RESET Severity Level

1. The message “Analyzer will be reset.” is displayed, replacing “Please wait…” in the message box:
2. All the information in the message box is printed on the on-board printer (under IL logo and current date and time).
3. Wait for 30 seconds to allow time to read the message and for the report to print.
4. Perform a system restart.

The GEM 4000 software maintains the number of times it restarts due to an error. If restart occurs for the fourth time in any rolling 24-hour period, the GEM 4000 escalates the error condition to the SHUTDOWN_NOW severity level.

Before the shutdown, the G4K resets the counter to zero so that if the instrument is manually restarted it counts 3 more resets before shutting down again.

The CART_DIAG Severity Level

When an error of this level is reported to the user interface software, remove the cartridge as outlined in the Remove Cartridge State section of Volume 3 . When the cartridge is removed, the software performs diagnostics to determine the cause of the failure being the cartridge or the instrument. If the cause of the failure is the cartridge, the operator is notified to insert a new cartridge. If the cause of the failure is the instrument, the severity level is elevated to SHUTDOWN_OK.

The CART_REMOVE Severity Level

When an error of this level is reported to the user interface software, remove the cartridge as outlined in the Remove Cartridge State section of Volume 3.

The OP_RETRY Severity Level

The message “Repeat test.” is displayed replacing “Please wait…” in the message box, and a [OK] button is added. After [OK] is selected, the dialog box is removed and the operator is returned to the analysis tab to rerun the sample.

The message displayed to the operator depends on the reported error, see “The Error List”.

Error Reporting Examples

Example #1: Solution “A” not detected during an iQM operation.

After detecting the error, the executing script logs the error in the event log by coding the following script command (<command name> <error code> <severity level> <error subcode>):

ERROR LEAD_EDGE_NOT_FOUND LOG_EVENT SOLN_A

The executing script then attempts to recover by performing the appropriate steps to detect the A solution.

If recovery succeeds, the operation continues and error processing ends. If recovery fails, the script notifies the user interface software by issuing the following script command:

ERROR LEAD_EDGE_NOT_FOUND CART_REMOVE SOLN_A

The software displays a message to describe the error and instructs the operator to wait for further instructions:

> Process control solution not detected.
>
> Error 201
>
> Please wait…

The executing script then continues to perform clean-up operations. After the script ends, the software transitions to the Remove Cartridge state, since the severity level is CART_REMOVE. Remove the cartridge.

Example #2: Operator introduced patient sample with insufficient blood for analysis.

After detecting the error, the sample analysis script logs the error in the event log:

ERROR ASP_ERROR LOG_EVENT

Error recovery may not be appropriate in this case. The sample script notifies the operator by issuing the following script command:

ERROR ASP_ERROR OP_RETRY

The software displays a message to describe the error and asks the operator to wait for further instructions:

Insufficient sample.

Error 222

Please wait....

The sample script continues to perform clean-up operations. After the script ends, the user interface modifies

the message to the operator as follows:

> Insufficient sample
>
> Error 222

Repeat test [OK]

After [OK] is selected, and after the rinse that follows the sample is performed, the software transitions to the Ready state to allow the operator to start a new sample.

The Error List

Overview

The tables in the following sections list the errors detected and reported to the GEM 4000 operator. For any error not listed below, the generic message “System error.” is be used. For some errors, Corrective Action Report entries are made as indicated.

Analytical and Hardware Errors

Error code	Sub code	Error	Message displayed to operator	Description	Cause
201		LEAD_EDGE_ NOT_FOUND (Calibration)	“Process control solution not detected.”	Process control solution not detected	Cartridge failure (plumbing, leak or out of solution) or hardware failure (RV, pump, solenoids, electronics, etc.)
203		SAMP_LAS_NOT_ FOUND	“Sample not detected.”	Air slug before sample not detected	Cartridge failure (plumbing or sampler) or hardware failure (Luer motor or encoder.)
		(Sample Analysis)			
204		SAMP_LE_NOT_ FOUND (Sample Analysis)	“Sample not detected.”	Sample not detected	Cartridge failure (plumbing or sampler) or hardware failure (Luer motor or encoder.)
220		LUER_ERROR (Sample Analysis)	“Sample probe error.”	Luer did not move into position during sample analysis	Motor, sensor, encoder disk, cabling, DCS board fuse or circuit failure
	160	LR_READY	“Sample probe error.”	Failed to find home position	Motor, sensor, encoder disk, cabling, DCS board fuse or circuit failure
	162	LR_CAP	“Sample probe error.”	Failed to find capillary position	Motor, sensor, encoder disk, cabling, DCS board fuse or circuit failure
	163	LR_SYR	“Sample probe error.”	Failed to find syringe position	Motor, sensor, encoder disk, cabling, DCS board fuse or circuit failure
222		ASP_ERROR (Sample Analysis)	“Insufficient sample.”	Air detected within sample during aspiration.	Sample handling error or cartridge failure.
224		POST_ASP_ COOX_ERROR (Sample Analysis)	“Air detected within sample. Displayed results questionable.”	Insufficient sample for CO-Ox	Sample handling error or cartridge failure.
228		IDEE_ERROR	“Cartridge ID error.”	An error occurred while reading or writing to the cartridge EEPROM.	Corrupted EEPROM, cabling, DCS board.

Error code	Sub code	Error	Message displayed to operator	Description	Cause
230		TEMP_ERROR (Anytime)	"Temperature out of range."	Block temperature out of valid range	General temperature error: refer to sub codes.
	231	PAD_CHEM	"Temperature out of range."	PAD thermistor for Electrochemistry heater block out of range	Broken or shorted thermistor wire on module or cable, DCS failure.
	232	TEC_CHEM	"Temperature out of range."	TEC thermistor for Electrochemistry heater block out of range	Broken or shorted thermistor wire on module or cable, DCS heating circuit failure, or TEC calibration failure.
	233	TEC_COOX	"Temperature out of range."	TEC thermistor for Co-ox head heater block out of range	Broken or shorted thermistor wire on module or cable, DCS heating circuit failure, or TEC calibration failure.
	234	PAD_COOX	"Temperature out of range."	PAD thermistor for Co-ox head heater block out of range	Broken or shorted thermistor wire on module or cable, DCS failure
	235	PAD_SPEC	"Temperature out of range."	PAD thermistor for Spectrometer out of range	Broken or shorted thermistor wire on module or cable, LED/NEON board failure.
	245	FAN_FRONT	"Temperature out of range."	Front fan thermistor out of range (mounted on interface wall)	Broken or shorted thermistor wire on cable or not connected to fan controller cabling.
	246	FAN_REAR	"Temperature out of range."	Rear fan thermistor out of range (mounted by the fan controller board)	Broken or shorted thermistor wire on cable or not connected to fan controller cabling.
236		PSV_ERROR (Anytime)	"Power supply voltage error."	DCS Board Power supply voltage out of valid range	General power supply error: refer to sub codes.
	237	5V	"Power supply voltage error."	+5V voltage is out of range	Fuse blown on DCS board, voltage not adjusted to correct setting, or cable failure.
	238	12V	"Power supply voltage error."	+12V voltage is out of range	Fuse blown on DCS board, voltage not adjusted to correct setting, or cable failure.
	239	24V	"Power supply voltage error."	+24V voltage is out of range	Fuse blown on DCS board, voltage not adjusted to correct setting, or cable failure.
240		AIR_SLUG_NOT_FOUND (Calibration)	"Process control solution not detected."	No air detected before a calibration solution	Cartridge failure (plumbing, leak or out of solution) or hardware failure (RV, pump, solenoids, electronics, etc.)
241		RV_ERROR (Calibration)	"Rotary valve error."	Rotary valve sensor not found	Motor, sensor, encoder or DCS board fuse or circuit failure

Error code	Sub code	Error	Message displayed to operator	Description	Cause
	193	RV_E	"Rotary valve error."	Rotary valve can't go out of HOME position when moving to E position	Motor, sensor, encoder or DCS board fuse or circuit failure
	194	RV_AIR	"Rotary valve error."	Rotary valve can't go out of HOME position when moving to AIR position	Motor, sensor, encoder or DCS board fuse or circuit failure
	195	RV_READY	"Rotary valve error."	Rotary valve sensor can't find Home position	Motor, sensor, encoder or DCS board fuse or circuit failure
	196	RV_A	"Rotary valve error."	Rotary valve can't go out of HOME position when moving to A position	Motor, sensor, encoder or DCS board fuse or circuit failure
	197	RV_B	"Rotary valve error."	Rotary valve can't go out of home position when moving to B position	Motor, sensor, encoder or DCS board fuse or circuit failure
	198	RV_C	"Rotary valve error."	Rotary valve can't go out of HOME position when moving to C position	Motor, sensor, encoder or DCS board fuse or circuit failure
	199	RV_D	"Rotary valve error."	Rotary valve can't go out of HOME position when moving to D position	Motor, sensor, encoder or DCS board fuse or circuit failure
260		DOOR_ERROR (During cartridge removal)	"Door failure. Door must be opened manually. Contact Technical Support for assistance."	Door sensor stuck close during cartridge removal	Door solenoid, door springs, door skin binding, or door out of adjustment. Note: this error occurs while removing cartridge. The script issues command to open door and then checks the sensor continuously till it reads open. If it doesn't after a given timeout, it posts this error. The operator will have to manually open door with a tool and remove cartridge.
	148	DOOR_CLOSED	"Door failure. Door must be opened manually. Contact Technical Support for assistance."	Door sensor stuck close during cartridge removal	Door solenoid, door springs, door skin binding, or door out of adjustment.
261		PUMPCAL_ ERROR (Anytime)	"Cartridge error."	P ump calibration failed	General Error

Error code	Sub code	Error	Message displayed to operator	Description	Cause
	73	EC_PATH	“Cartridge error.”	PUMPCAL failed during EC path calibration only	Cartridge failure in EC Path (plumbing, leak or out of solution) or hardware failure (RV, pump, solenoids, electronics, etc.)
	-74	COOX_PATH	“Cartridge error.”	PUMPCAL failed during Coox path calibration only	Cartridge failure in Coox path (plumbing, leak or out of solution) or hardware failure (RV, pump, solenoids, electronics, etc.)
	75	ECCOOX_PATH	“Cartridge error.”	PUMPCAL failed both EC path and Coox path calibration	Cartridge failure in the common path of EC and Coox path (plumbing, leak or out of solution) or hardware failure (RV, pump, solenoids, electronics, etc.)
264		SCANIT_ERROR (Anytime)	“CO-Ox hardware failure.”	CO-Ox integration time could not be set	Broken optical fiber(s), LED/NEON board failure, LED bulb failure
265		REF_ERROR (Anytime)	“Reference solution not detected.”	Reference voltage out of range	Cartridge failure or electronics failure (analog or DCS board)
266		DAC_ERROR	“Voltages out of range.”	Sensor polarization voltages out of range during scheduled SETDACS, startup, warm-up, power fail.	DCS board fuses, analog board DAC calibration failure, or cabling
268		HCT_CAL_ ERROR (Calibration)	“Hct calibration failed.”	Hct circuit gain is out of range	DCS board fuses, Hct calibration value out of range
281		SOLDV_ERROR	“Diverter valve error.”	“Diverter valve error.”	Cabling, DCS board circuit failure, failed solenoid possibly due to solution on diverter valve solenoid body.
282		SOMV_ERROR	“Mixer valve error.”	Mixer valve error	Cabling, DCS board circuit failure, failed solenoid possibly due to solution on mixing valve solenoid body.
285		NEON_ERROR (Anytime)	“CO-Ox hardware failure.”	CO-Ox neon light calibration failure	Broken optical fiber (from optics head to Spec.), LED/ NEON board failure, Neon bulb failure, cable.
287		COOX_INIT_ ERROR	“CO-Ox initialization failure.”	CO-Ox error (due to coox file loading error, or other types of errors)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	0	SUBCODE_ MATRIX_0	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 0 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	1	SUBCODE_ MATRIX_1	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 1 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files

Error code	Sub code	Error	Message displayed to operator	Description	Cause
	2	SUBCODE_ MATRIX_2	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 2 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	3	SUBCODE_ MATRIX_3	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 3 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	4	SUBCODE_ MATRIX_4	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 4 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	5	SUBCODE_ MATRIX_5	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 5 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	6	SUBCODE_ MATRIX_6	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 6 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	7	SUBCODE_ MATRIX_7	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 7 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	8	SUBCODE_ MATRIX_8	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 8 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	9	SUBCODE_ MATRIX_9	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 9 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	10	SUBCODE_ MATRIX_10	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 10 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	11	SUBCODE_ MATRIX_11	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 11 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	12	SUBCODE_ MATRIX_12	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 12 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	13	SUBCODE_ MATRIX_13	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Matrix 13 loading failure)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	20	SUBCODE_ NEON_COEFFS	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Neon Coefficients not available)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	21	SUBCODE_ RESIDUAL_FILE	“CO-Ox initialization failure.”	CO_Ox file loading error (Constant Residual File error)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files

Error code	Sub code	Error	Message displayed to operator	Description	Cause
	22	SUBCODE_NL_CAL_FILE	"CO-Ox initialization failure."	CO_Ox file loading error (Constant Missing NL cal file)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	23	SUBCODE_DARK_LIB_FILE	"CO-Ox initialization failure."	CO_Ox file loading error (Constant Missing dark library file)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	20108	MISSING_MATRIX	"CO-Ox initialization failure."	CO_Ox file loading error(Missing CO-Ox matrix file)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	20157	MISSING_NEON_COEFFS	"CO-Ox initialization failure."	CO_Ox file loading error(Missing neon coeffs)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
	20144	MISSING_RESIDUAL	"CO-Ox initialization failure."	CO_Ox file loading error(Missing CO-Ox residual file)	Miss /incomplete/corrupt COOx calibration files due to failed calibration or bad files
288		SPEC_ERROR	CO-Ox hardware failure."	CO-Ox error (due to spectrometer read error, or other types of errors)	USB connection to SECO, USB update not installed, spectrometer failure.
		(Anytime)			
289		PO2_C_THRESHOLD_CHECK_FAILED (During warm-up)	"iQM error for pO2"	pO2 mV is outside threshold when measured during C cal during cartridge warm-up.	Cartridge failure (O2 sensor)
The following codes above 300 are assigned but not implemented in 5K. The present script domain didn't monitor these hardware errors.					
300		SBC_BRD_TEMP_WARNING (Anytime)	"Temperature out of range. Check ambient."	The SBC board and CPU temperature is above 70C.	Seco board heat sink fan, rear fan or fan controller board failure, system ventilation slots blocked
301		SBC_BRD_TEMP_ERR (Anytime)	"Analyzer temperature too high. Shutting down."	The SBC board and CPU temperature is above 90C.	Seco board heat sink fan, rear fan or fan controller board failure, system ventilation slots blocked
302		HD_ERROR (Anytime)	"Hard drive showing excessive errors and may fail soon. Perform backup. Contact Technical Support."	Hard drive showing excessive amount of errors indicating it may fail soon. Operator should perform backup and contact Technical Support.	Hard drive failure.
303		LCD_BACKLIGHT_FAIL (Anytime)	"LCD backlight failed. Contact Technical Support."	One of the LCD backlights failed.	LCD failure in display.
304		BACKPANEL_USB_FAIL (Anytime)	"Disconnect USB device and then reconnect."	One of the 4 USB ports on the back panel failed (overload detected).	This error is detected only if a device is connected to the port is causing overload.

TABLE OF CONTENTS

Error code	Sub code	Error	Message displayed to operator	Description	Cause
305		COOX_USB_ PORT_FAIL (Anytime)	"CO-Ox port failure."	Overload detected on the CO-Ox USB port.	Spectrometer or Seco board failure.
306		MEMORY_ ERROR (Anytime)	"Memory error."	Memory error detected.	Seco board memory failure
The following codes are analytical errors.					
401		AMPROMETRIC_ SPIKE	"Incalculable error for Glu/Lac."	Amprometric spike check on Glu/Lac. In this case the Glu/Lac is reported as incalculable.	Cartridge failed for Glu/Lac.
2010		PC_SOLUTION_ STABILITY_ FAILURE (During iQM operations)	"Process control solutions stability failure"	iQM solution stability check failed.	Cartridge failure.
2012		REFERENCE_ VOLTAGE_ ERROR (Anytime)	"Reference voltage error."	Reference sensor voltage is saturated or out of range.	Cartridge failure or electronics failure (analog or DCS board)
2015		pO2_SENSOR_ ERROR	"pO2 sensor error"	iQM failures for pO2 sensor that is not due to the solution stability	Cartridge failed for pO2 sensor error
2016		GROUND_ VOLTAGE_ ERROR (Anytime)	"Ground voltage error."	Ground voltage is saturated or out of range.	Cartridge failure or Cartridge failure or electronics failure (analog or DCS board)
2017		PATTERN3_ RINSE_FAILED (During special rinse following pattern 3 detection)	"Micro Clot Caused Solution Detect Error After Sample"	Pattern 3: Special rinse failed leading to cartridge removal	Cartridge failure for a clot.
Below lists the codes are software errors. The software errors will be reported to the operator (on analyzer or GWP server).					
3001		FILE_SYS_ERR	"File system check error." System halts upon the detection of this error.	The file system check, performed during startup, failed and could not self correct. The file system check is performed by the Linux utility "fsck".	Seco board or hard drive failure.
3002		FPGA_COMM_ ERR	"FPGA communication error."	The instrument software could not communicate to the FPGA.	DCS board power not connected or FPGA failure

Error code	Sub code	Error	Message displayed to operator	Description	Cause
3003		FPGA_DATA_ERR	“FPGA error.”	Whenever the FPGA sends an unexpected message to the software, or fails to send an expected message, or sends a message with the incorrect contents.	DCS board failure or FPGA corruption.
3004		FPGA_INIT_ERR	“FPGA error.”	FPGA failed to initialize or reset.	DCS board power not connected or FPGA failure
3006		DM_AM_COMM_ ERR	“Internal communications error.”	The DM (Data Management Module) and AM (Analytical Module) could not communicate, or went out of synch.	Software did not install properly.
3007		DB_ERR	“DB error.”	An error during a database operation.	Software error.
3008		FILE_IO_ERR	“File I/O error.”	An error during a file I/O operation.	Software error.
3009		UI_DM_COMM_ ERR	“Internal communications error.”	UI to DM comm. error	Software did not install properly.
3012		SCRIPT_ERR	“Script error.”	An illegal script command or an illegal command argument. The script cannot be executed by the script engine.	Script, software error, or software failure during inst.
3013		TOO_MANY_ RESETS	“Too many resets. Shutting down. Contact Technical Support.”	More than 3 analyzer resets occurred	Repeated resets, system must be shutdown fully before being turned on again otherwise system will reset again.
3203		SERVER_ ACCESS_ERR	“This operation failed. Retry after server is available.”	Problem accessing GWP server	Software error.
3205		OPERATION-FAILED	“The system cannot perform the requested operation.”	The system cannot perform the requested operation.	Software error.
3206		INTERNAL_DM_ SW_FAILURE	“Internal DM software error.”	DM software error	Software error.

Event Logging

Feature Description

Events are stored in a database table as time-stamped messages in the English langauge only. The event data is local only, i.e., not replicated to the server.

When the operator requests the “Copy IL Data” function, the events table is written in chronological order to the file “event_log.csv” which is then written to the CD. Each entry written to the file starts on a new line.

Each event entry is comprised of the fields described below. These fields are separated by a comma character ‘,’ to allow the file to he opened in Excel. These fields are:

1. Date in MM/DD/YYYY format, showing the date when the event occurred.
2. Time in hh:mm:ss format, showing the time the event occurred.
3. Event Type, as “Alarm”, “Error” or “Event”.
4. Code, containing an integer code or ID associated with the event.
5. Event subcode, containing an integer code associated with the event.
6. Message text, containing the message text describing the event. The message is in English, and its length can not exceed 80 characters. The text can not include any escape, tab, new-line, or line feed characters.
7. Cartridge S/N associated with the event, if one was inserted. Not displayed on the viewer.
8. Severity Level (if event type is Error). Not displayed on the viewer.

Example:

01/01/2004, 01:15:35, Error, 230,231,Temperature out of range, 345987, SHUTDOWN_NOW

Event Types

Events that get logged come from these different sources:

- Analytical and Hardware errors as listed in “Analytical and Hardware Errors”. The event type is “Error”. The event code and subcode are as specified when the error was posted. The event message is the error message itself.
- Event caused by posting of an alarm. The event type is “Alarm”. The alarm code is internally generated.
- Other critical system events. These events are listed in the Special Events List section below.

Event Table Size Limit

The event table is sized for a maximum of the most recent 5000 events.

Note: Printer alarms are not be logged to prevent cluttering of the events table.

Critical Events List

The table below lists the GEM 5000 special events logged to the events table.

Event code	Cause	Message logged
CART_INSERTED	A cartridge has been successfully inserted.	“Cartridge inserted: %s” Where %s is the cartridge serial number.
CART_RECOVERY _STARTED	Power failure recovery started on a cartridge	“Cartridge recovery started.”
CART_REMOVED	A cartridge has been removed.	“Cartridge removed: %s” Where %s is the removal code (see IDEE contents).
NEW_DATE_TIME	System date and time changed by operator.	“System date-time changed: from %s to %s” Where %s is the time and date.
SYSTEM_SHUTDOWN	System is shut down by operator or automatically.	“System shut down.”
ALARM_CLEARED	The operator cleared an alarm.	“Alarm cleared: %s.” Where %s is the text of the alarm.
IMPROPER_SHUTDOWN	The last shutdown was not initiated by operator or system (power shut off)	“Improper shutdown.”
REF_CHANNEL_SHIFT	iQM generated	“Reference channel shift.”
CLOT_PATTERN_1	iQM generated	“Clot pattern 1 detected.”
CLOT_PATTERN_2	iQM generated	“Clot pattern 2 detected.”
CLOT_PATTERN_3	iQM generated	“Clot pattern 3 detected.”
CLOT_PATTERN_NO_AIR	iQM generated	“Clot pattern no-air detected.”
CLOT_PATTERN_NO_B	iQM generated	“Clot pattern no-solution detected.”
INTERFER_DETECTED	iQM generated	“Sample interference detected.”
SENSOR_REENABLED_BY_IQM	iQM generated	“<anal> re-enabled by iQM”
SBC_TEMP_SENSOR_FAILURE SBC	temperature sensor reading is at the rail (+ or - 200) indicating sensor failure “SBC temp sensor failure.”	
CPU_FAN_ERROR	The CPU fan speed is monitored. Normal speed is about 5400 rpm. If the speed drops below 3000 rpm this event is posted.	“CPU fan error”
CPU_VOLTAGE_ERROR	The CPU voltages (1.45v, 2.5v, 3.3v, 5v, 12v) are monitored. If any falls out of range, this event is posted.	“CPU voltage error”
HD_TEMP_ERROR HD	temperature exceeded the maximum expected of 55C.	“HD temperature out of range.”
HD_SECTOR_REALLOCATION	Read errors occurred on a sector on the HD and the sector had to be reallocated.	“HD sector reallocated.”

9 - Interfacing

Interface Specifications

Port Descriptions

- Paralell Port - A standard DB-25 female connector provides parallel interface to a printer
- External Power Connection - Provides external power for IL approved low power components.

Each connector has the ability to provide +9VDC and. or 12VDC at 1.2 Amps.

CAUTION: Only IL approved external cables are permitted.

- Serial Communication Ports - Four standard DB-9 male connectors provide a serial data interface to external devices and networks in a RS-232C format
- Keyboard Connector - A 6-pin mini DIN PS/2 low speed serial connection
- Integrated LAN Support - RJ-45 LAN network port is provided for a 10/100 Mbps Base T Ethernet connection
- USB High Speed (Universal Serial Bus) - Four USB compliant connectors are available for data transfer rates of up to 480 Mbps

Paralell Port (25 PIN D-SUB FEMALE at the PC)

Pin	Name	Direction	Description
1	/STROBE	Ë	Strobe
2	D0	Ë	Data Bit 0
3	D1	Ë	Data Bit 1
4	D2	Ë	Data Bit 2
5	D3	Ë	Data Bit 3
6	D4	Ë	Data Bit 4
7	D5	Ë	Data Bit 5
8	D6	Ë	Data Bit 6
9	D7	Ë	Data Bit 7
10	/ACK	Á	Acknowledge
11	BUSY	Á	Busy
12	PE	Á	Paper End
13	SEL	Á	Select
14	/AUTOFD	Ë	Autofeed
15	/ERROR	Á	Error
16	/INIT	Ë	Initialize
17	/SELIN	Ë	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

External Power Connection (J11A)

Pin	Description
1	+9VDC
2	+9VDC
3	GND
4	GND
5	+12VDC
6	+12VDC
7	GND
8	GND

External Power Connection (J11B)

Pin	Description
1	+9VDC
2	+9VDC
3	GND
4	GND
5	+12VDC
6	+12VDC
7	GND
8	GND

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)

Keyboard Connector

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

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

USB Port

Pin	Name	Description
1	VCC	+5 VDC
2	D-	Data -
3	D+	Data +
4	GND	Ground

10 - Parts List

Service Parts

Saleable P/N	Saleable Description
00024019310	SS G5K, PCB Fan PIC Controller
00024019311	SS G5K, Mount Power Supply
00024019312	SS G5K, Cable, GEM 5K Rear Fan
00024019313	SS G5K, Cable, Side Fan
00024019314	SS G5K, DVD Drive
00024019315	SS G5K, Cable, SATA and Power
00024019316	SS G5K, Assy, LCD Tilt
00024019317	SS G5K, PCB Controller Touchscreen
00024019318	SS G5K, Cable , Display Power (LEDBL)
00024019319	SS G5K, Assy Co-Ox Module
00024019320	SS G5K, Assy, Co-Ox PCB
00024019321	SS G5K, Assy, Heater Module
00024019322	SS G5K, Assy, Module Optical Head
00024019323	SS G5K, Assy, Pivot Pump, Right
00024019324	SS G5K, Assy, Pivot Pump, Left
00024019325	SS G5K, Assy, Motor Selector Valve
00024019326	SS G5K, Cable, Optic Head Interface
00024019327	SS G5K, Cable, GEM 5K EEPROM Sensor
00024019328	SS G5K, Cable, Front Thermistor
00024019329	SS G5K, Assy, Sampler Drive
00024019330	SS G5K, Cable, Home & Position Sensor
00024019331	SS G5K, Cable, CHEM H/C2
00024019332	SS G5K, Cable, COOX Pump
00024019333	SS G5K, Assy Solenoid Heatsink
00024019334	SS G5K, Belt, Pump G5K
00024019335	SS G5K, PCB Sampler Sensor
00024019336	SS G5K, Assy, SBC GEM 5000
00024019337	SS G4/G5K, Harddrive SATA,250GB,7200RPM,2.5" WDIDLE
00024019338	SS G5K, PCB Assy, DCS Board, GEM 5000
00024019339	SS G5K, WiFi, PCIe Half-Mini Card
00024019340	SS G5K, Assy, Filtered Pwr Entry & Fuse
00024019341	SS G5K, Assy, Interface Board, G5K
00024019342	SS G5K, Cable, DCS to Analog Board
00024019343	SS G5K, Cable, Stepper Mtr 0,1,2,EEPROM
00024019344	SS G5K, Cable, Internal Printer +Ferrite

Saleable P/N	Saleable Description
00024019345	SS G5K, Bracket / Printer Assy
00024019346	SS G5K, Cable, Sampler LED
00024019347	SS G5K, Cable, Sampler LED Internal
00024019348	SS G5K, Cable, Power Entry
00024015859	Wand, Bar Code Reader GEM 5000
00024018533	GEM 5K System Software V1.0.0
00024019355	S/S GEM 5K Arbor, Rotary Valve, Sampler Arm Adaptor (tool)
00024019356	S/S GEM 5K Digital Torque Watch (tool)
00025002072	Cable Assy Speaker
00025002077	Cable Assy Sol 4, Hall Effect
00025002087	Cable Assy, Fan Controller
00025002088	Door Solenoid
00025002089	Door Sense Assy
00025002091	Cable Assy, Fan Communication
00025002092	Speaker Left, Right
00025002090	Cable Assy, Front Fan
00025002076	Cable Assy LCD
00025002084	Cable Assy LCD Display Interconnect
00025002094	Touch screen
00024002976	LCD Display 12.1# Backlight
00025002119	Cable Assy, Quad USB, GEM 4000
00025002044	Battery, Power backup
00025002069	Cable Assy, Ethernet Shielded
00025002082	Cable Assy, Soft pushbutton
00025002107	Fuse 3Amp/250V Slo- Blo 5X20MM
00024018731	SW ver 1.0.1 GEM 5000
00026002016	Antenna
00024018955	Kit, GEM 5000 Software ver 1.1.0 Upgrade
00024019255	GEM Premier 5000 Analyzer
00024015859	Wand, Bar Code
00024004463	CD, System GEM5000 Ops Manual
00024018533	DVD, System GEM5K Sys SW V1.0.0 (use 00024018731)
00024018731	Disc, System GEM 5000 Software 1.0.1
00024018578	CD, System GEM5000 Service Manual
00024018779	Assy Demo Pak, Finalized
00024018892	Kit, GEMWeb Plus 450 V4.0.0
00014882100	Cord Line Shielded 110 V
00019725500	VDE Approved Line Cord 220 V
00024015859	Wand Barcode

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Saleable P/N	Saleable Description
00024017288	Kit, Barcode Accessory
00024306171	Kit, Antenna with Wireless Warning Letter
00025000500	Printer Paper 5/Box

Service Tools

Part Number	Descrtiption
00024019750	GEM 5000 ETC (version 2.0) (for sw version 1.0.0, 1.0.1 only)
00024019198	GEM 5000 Pinocchio Gauge
00024013720	GEM 5000 ETC (version 3.0) (for sw 1.1.0 and above)
00024013730	Assy, GEM 5000 ETC Kit (ETC version 3.0, cables, service CD) (for sw 1.1.0 and above)
00024019530	System GEM 4K/5K Service Mode CD
00024013732	Assy GEM 5K ETC Cables
00024019309	S/S GEM 5K Sorbothane pad, Pinocchio gauge
00024019355	S/S GEM 5K Arbor, Rotary Valve, Sampler Arm Adaptor (tool)
00024019356	S/S GEM 5K Digital Torque Watch (tool)

11 - Drawings and Schematics

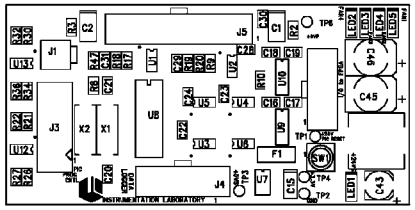
Drawings

Refer to Chapter “11 - Parts List” on page 147 for lists of salable part numbers and their manufacturing part number equivalents.

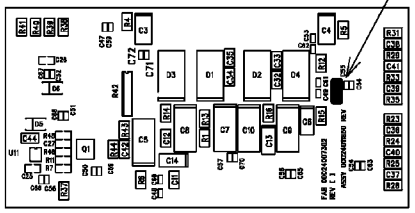
REVISION HISTORY			
REV	DESCRIPTION	DATE	BY
0	RELEASED PER CO 451013	17DEC14	D.COX
1	BOM UPDATE PER CO 453855	14APR15	D.COX

NOTES:

1. REFERENCE DOCUMENTS: SEE BILL OF MATERIAL
2. BOARD MARKING
   A. VENDOR TO PERMANENTLY MARK ASSY REVISION NUMBER IN BLOCK WHERE SHOWN UNLESS A LABEL IS ADDED PER NOTE 2B
   B. IF USED, BOARD WILL BE MARKED WITH AN IDENTIFYING WHITE POLYESTER LABEL MEASURING APPROX 1" X .25" CONTAINING IL PART NUMBER AND REV FOLLOWED BY THE FOLLOWING INFORMATION: DATE OF MANUFACTURE, SUPPLIER ID, AND UNIQUE 4 DIGIT SERIAL NUMBER. INFORMATION TO BE IN 3 OF 9 BARCODE AND IN HUMAN READABLE FORM PER THE FOLLOWING FORMAT: YYWWXXXXSSSS WHERE YY=YEAR, WW=WEEK (DATE OF MANUFACTURE), XXXXX=SUPPLIER ID, AND SSSS=SERIAL NUMBER. LOCATE BAR CODE LABEL IN POSITION SHOWN.
   C. STAMP IN INDELIBLE INK OR OTHERWISE PERMANENTLY MARK BOARD WITH COUNTRY OF ASSEMBLY ORIGIN (EX, MADE IN USA)
3. FINISHED BOARD SHALL SHOW LEVEL OF WORKMANSHIP THAT MEETS OR EXCEEDS IPC-600, IPC-A-610 CLASS 2 AND CONFORM TO THE CURRENT ROHS DIRECTIVE.
4. IF ELECTRICAL TESTING IS REQUIRED, PCB WILL BE STAMPED WITH A TEST STAMP OR A TEST REPORT WILL BE SENT WITH THE BOARD. ALL REPORTS AND FIXTURES USED FOR TESTING MUST MEET CFR11 REQUIREMENTS.
5. CERTIFICATE OF COMPLIANCE: TO BE AVAILABLE UPON REQUEST STATING THAT THE BOARDS WERE BUILT AND TESTED TO IL SPECIFICATIONS, SIGNED AND DATED BY THE PC BOARD HOUSE REPRESENTATIVE. THE C OF C MUST LIST THE SERIAL NUMBERS CONTAINED IN THE LOT, THE LOT NUMBER AND DATE CODE. VENDOR WILL ATTACH ANY DATA PRINTOUTS IF APPLICABLE.
6. CLEANLINESS SPECIFICATION:
   BOARD TO EXHIBIT A SURFACE CONTAMINANT LEVEL (IONIC CLEANLINESS) OF LESS THAN OR EQUAL TO 1.0 MICRO-GRAMS OF NACL PER SQ. CENTIMETER. TEST RESULTS FROM A RANDOM SAMPLE OF 10% OF THE LOT TO BE AVAILABLE UPON REQUEST
7. DO NOT INSTALL X2



FRONT SIDE



REAR SIDE

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
INTERPRET DIM AND TOL PER ASME Y14.5-2009
REMOVE ALL BURRS AND SHARP EDGES
SURFACE FINISH 32
X.X +/- .020
X.XX +/- .010
X.XXX +/-.005
ANGULAR +/0 .5 dEG

CAD FORMAT: PADS
MATERIAL: NA
FINISH: NA
CREATED BY: D.COX DATE: 12AUG14
DRAFTED BY: D.COX DATE: 12AUG14

Instrumentation Laboratory
180 Hartwell Road/Bedford, MA 01730/TEL.781-861-0710

TITLE ASSEMBLY DRAWING,
FAN PIC CONTROLLER BD, GEM 5000

SIZE	DWG NO.	REV
B	00024011850	1

SCALE: NONE | DO NOT SCALE DRAWING | SHEET 1 OF 1

QMDD-40003-26 REV 00

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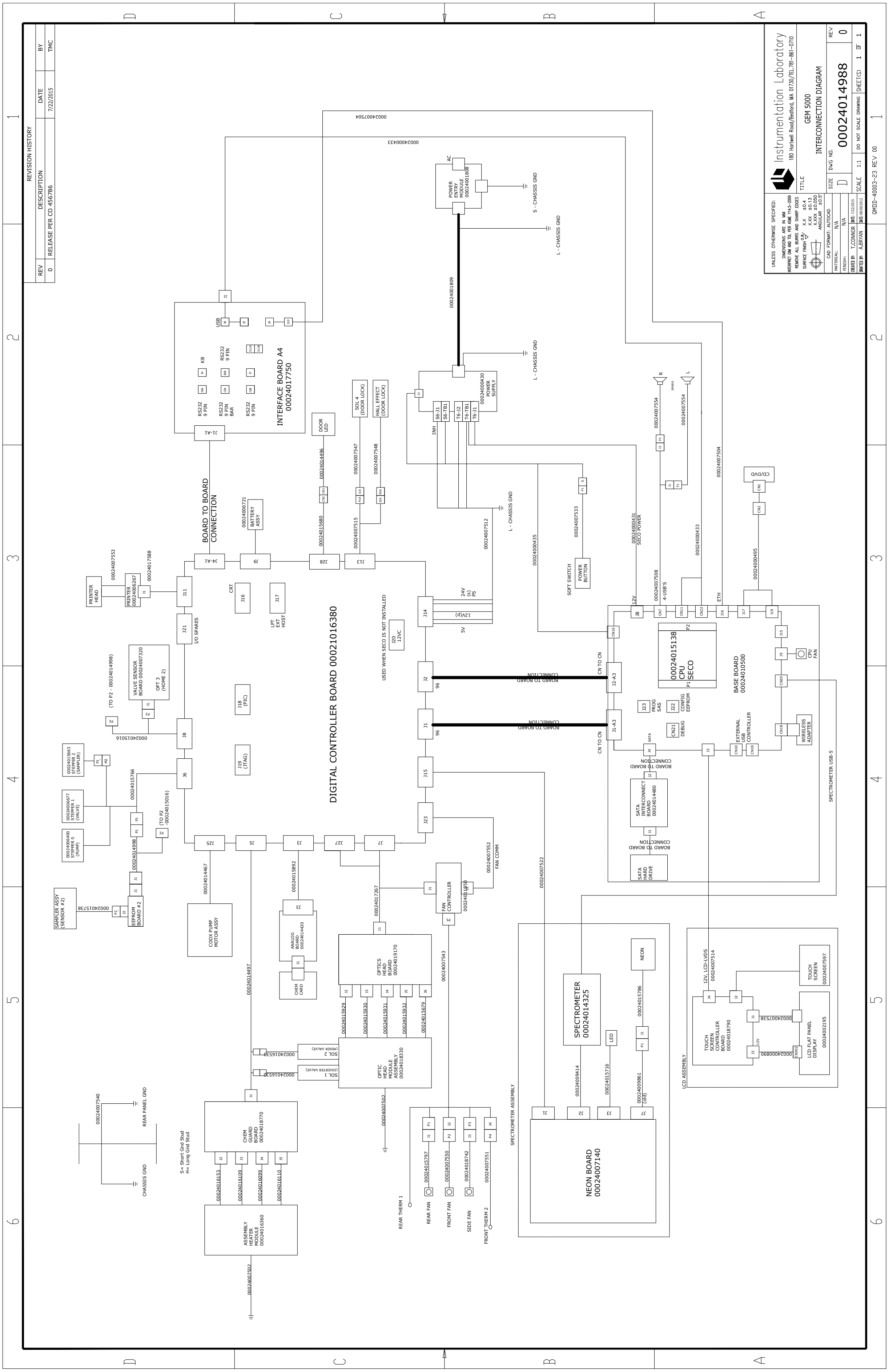
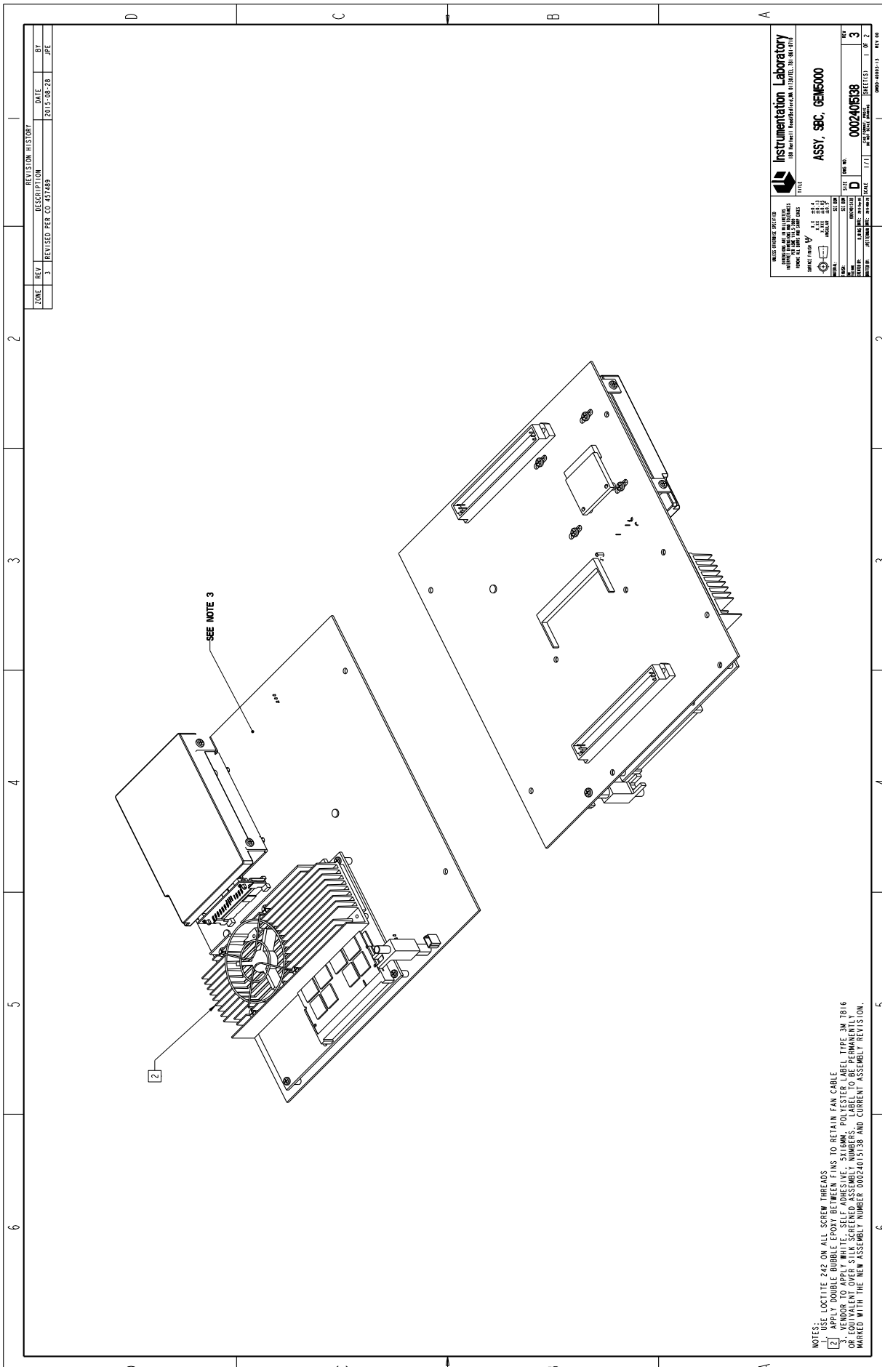
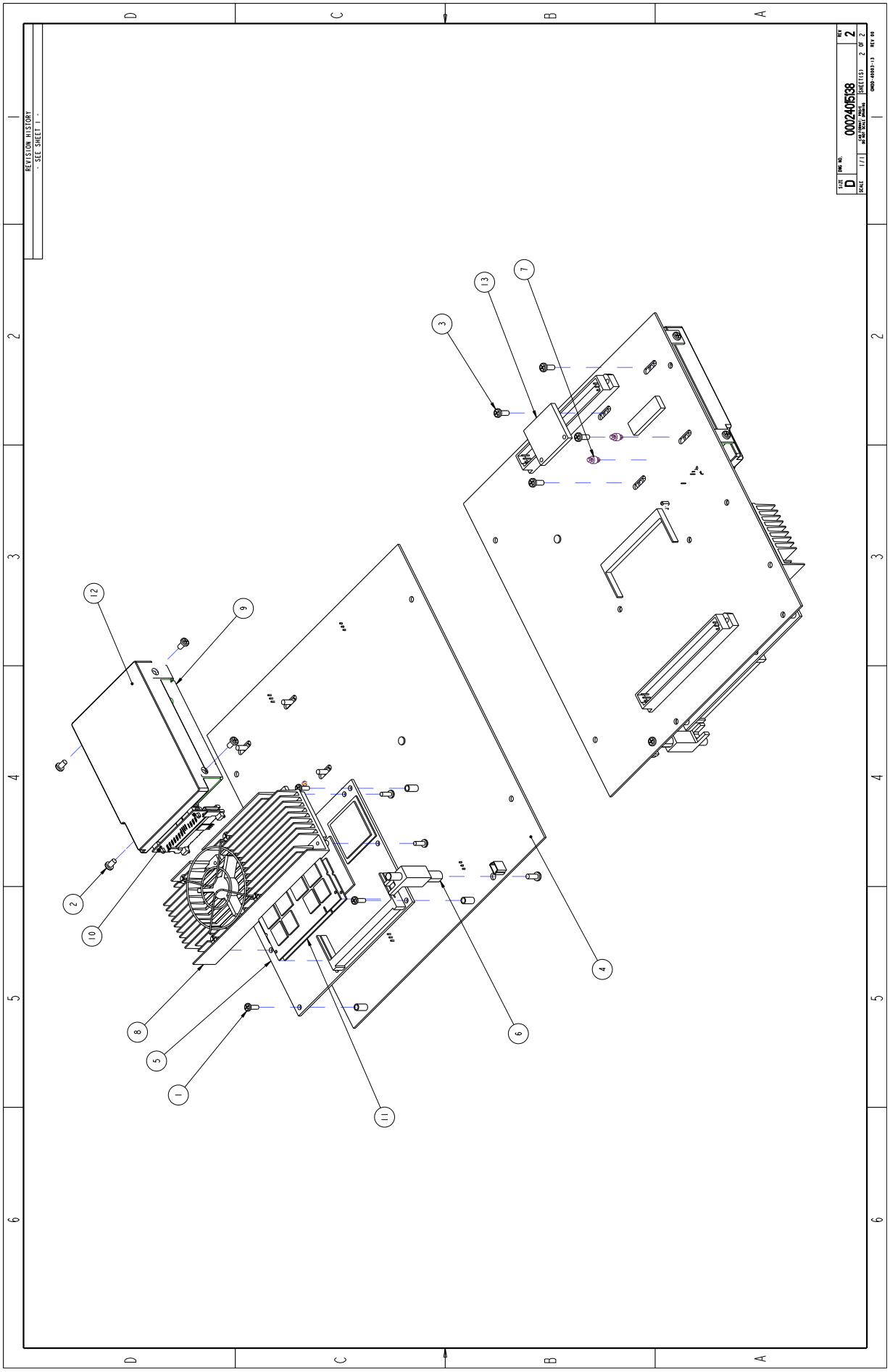



SEE NOTE 3
2
REVISION HISTORY
ZONE REV DESCRIPTION DATE BY
3 REVISED PER CO 451489 2015-08-28 JPE
Instrumentation Laboratory
ASSY, SBC, GEM5000
00024015138
3
NOTES:
1. USE LOCTITE 242 ON ALL SCREW THREADS
2. APPLY DOUBLE BUBBLE EPOXY BETWEEN FINS TO RETAIN FAN CABLE
3. VENDOR TO APPLY WHITE SELF ADHESIVE, SX18MM, POLYESTER LABEL TYPE 3M 7816
OR EQUIVALENT OVER SILKSCREENED AREA. LABEL TO BE PERMANENTLY
MARKED WITH THE NEW ASSEMBLY NUMBER 00024015138 AND CURRENT ASSEMBLY REVISION.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- SEE SHEET 1 -
SIZE D
DWG NO. 00024051538
SCALE 1/1
SHEET 1 OF 2
REV 2
REV 03
1
2
3
4
5
6
7
8
9
10
11
12
13

BOM: 00024015138 Rev: 03
Description: ASSY, SBC, GEM 5000
Plant: AK10 Base Qty: 1.000 - UN
Usage: E Alt: 01

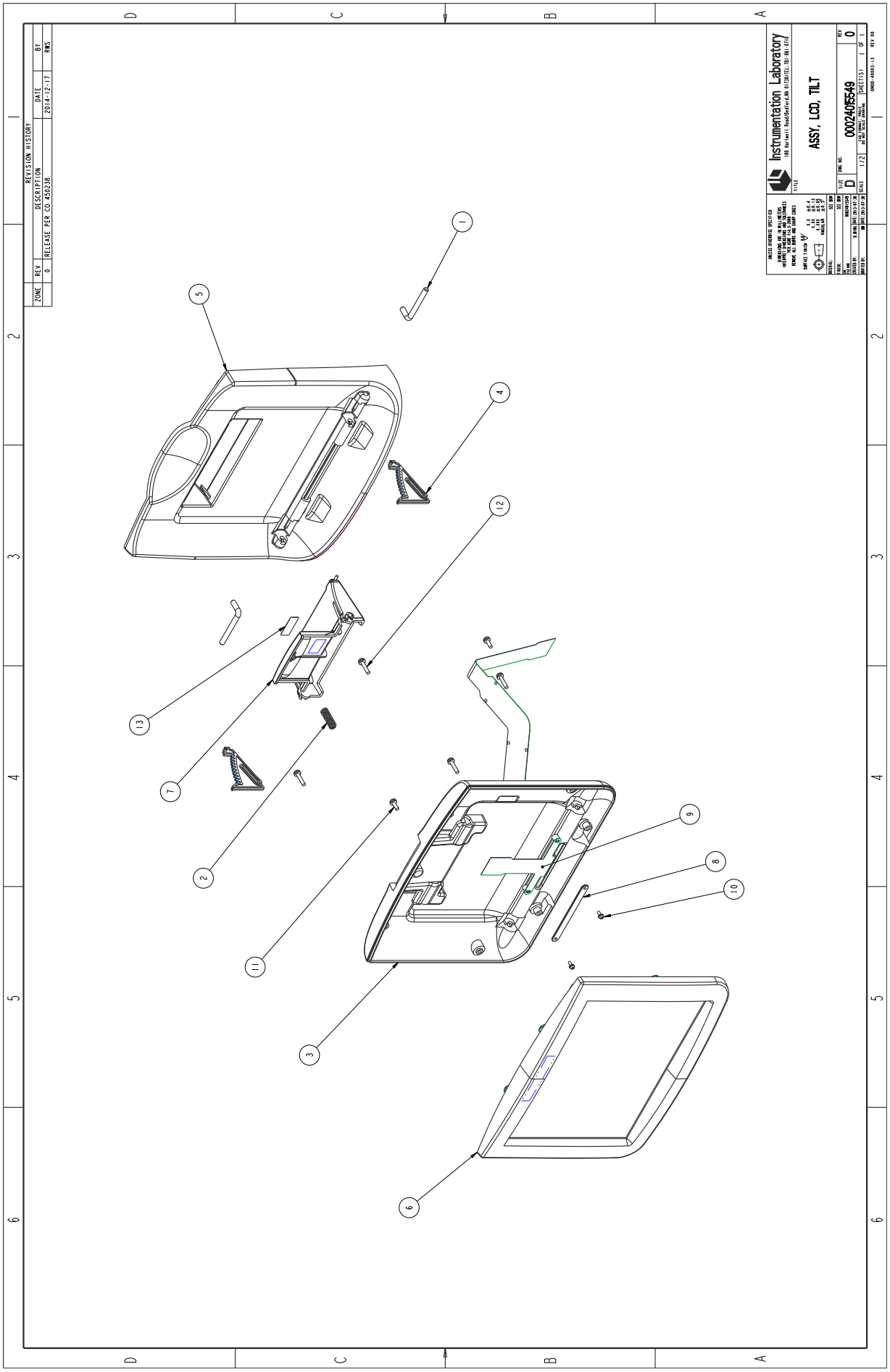
Effectivity Date: 08/28/2015
Procurement: F - 20
Downloaded by: DMILLER
Export Date: 02/01/2017

Documents:

	Document	Description	Rev.	From	To
L01	L0024015138	ASSY, SBC, GEM 5000	03	08/28/2015	12/31/9999

Bill of Material:

Item	Component	Description	Rev	Quantity	UN	ICT	Sloc	From	To	F/V	F.U.
0001	00028901321	SCR PHH PAN, M2.5 X 8.0 LG, SST	01	11.000	UN	N		01/28/2014	12/31/9999	V	
0002	00028901330	SCR PHH PAN, M3 X 5.0 LG, SST	01	4.000	UN	N		01/28/2014	12/31/9999	V	
0003	00028901332	SCR PHH PAN, M3 X 8.0 LG, SST	01	5.000	UN	N		01/28/2014	12/31/9999	V	
0004	00024010500	ASSY, CPU BASEBOARD BOARD wSATA/PCIe, G5	00	1.000	UN	N		01/28/2014	12/31/9999	V	
0005	00024015116	MODULE, CPU SECOMEXP-965,L7500,1.60GHZ	01	1.000	UN	N		01/28/2014	12/31/9999	V	
0006	00024000422	ASSY, USB RESTRAINT	02	1.000	UN	N		01/28/2014	12/31/9999	V	
0007	00024016023	CB SPT DUAL LCK NATURAL 3MM SPC	01	2.000	UN	N		01/28/2014	12/31/9999	V	
0008	00024000484	HEATSINK, COM/E MODULE	01	1.000	UN	N		01/28/2014	12/31/9999	V	
0009	00024015869	BRKT, HARD DRIVE	00	1.000	UN	N		01/28/2014	12/31/9999	V	
0010	00024014480	PCB ASSY, SATA INTERFACE BD	00	1.000	UN	N		01/28/2014	12/31/9999	V	
0011	00024000436	MEMORY, 1GB, DDR2-667, SODIMM	02	2.000	UN	N		01/28/2014	12/31/9999	V	
0012	00024018276	ASSY, HDD SATA 2.5", 250GB, WDIDLE	00	1.000	UN	N		08/28/2015	12/31/9999	V	
0013	00024016928	WIFI, PCLE HALF-MINI CARD, 802.11N	01	1.000	UN	N		08/15/2014	12/31/9999	V	
0014	00007160901	LOCTITE 242	01	0.001	OZ	N		01/28/2014	12/31/9999	V	


REVISION HISTORY
ZONE
REV
DESCRIPTION
DATE
BY
0
RELEASE PER CO 450238
2014-12-17
RMS
Instrumentation Laboratory
ASSY, LCD, TILT
00024005549
D
1/2
1
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BOM: 00024015549 Rev: 00
Description: ASSY, LCD, TILT
Plant: AK10 Base Qty: 1.000 - UN
Usage: 1 Alt: 01

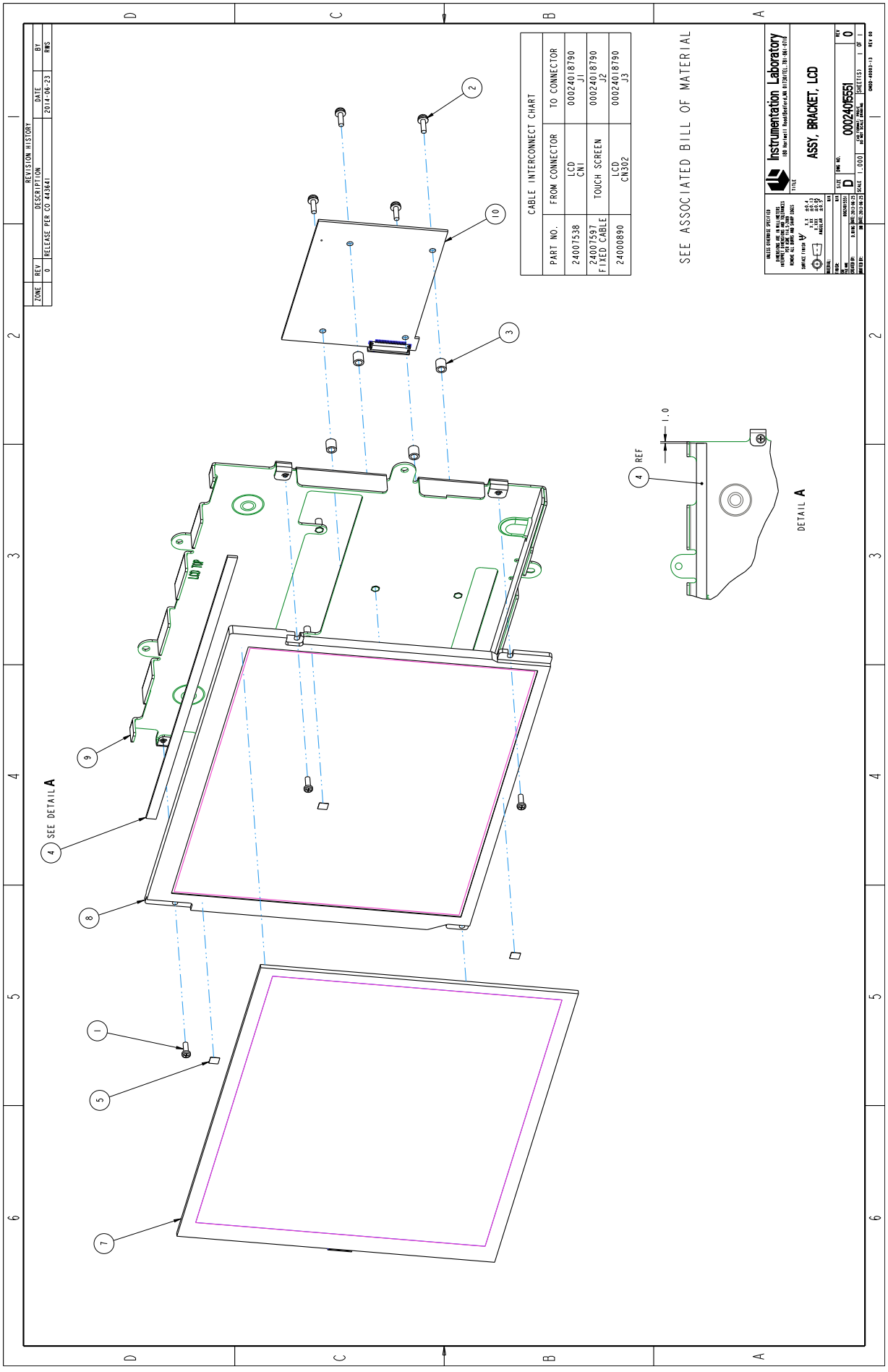
Effectivity Date: 01/19/2015
Procurement: E - 10
Downloaded by: JSANTANA
Export Date: 08/19/2015

Documents:

	Document	Description	Rev.	From	To
DOC	L0024018806	PROC, LCD DISPLAY ASSY	01	03/04/2015	12/31/9999
L01	L0024015549	ASSY, LCD, TILT	00	01/19/2015	12/31/9999

Bill of Material:

Item	Component	Description	Rev	Quantity	UN	ICT	Sloc	From	To	F/V	F.U.
0001	00024006507	PIN, LCD PIVOT	01	2.000	UN	L	01	02/13/2014	12/31/9999	V	
0002	00024006522	SPRING, TILT BRACKET	01	1.000	UN	N		02/13/2014	12/31/9999	V	
0003	00024015323	COVER, DISPLAY, REAR	00	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0004	00024015325	BRKT, DISPLAY, TILT	00	2.000	UN	L	01	02/13/2014	12/31/9999	V	
0005	00024015328	PANEL, FRONT	02	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0006	00024015550	ASSY, BEZEL, LCD	00	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0007	00024015643	ASSY, TILT, DISPLAY	00	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0008	00024018744	STRAIN RELIEF, FLEX CABLE, LCD	00	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0009	00024007514	CABLE ASSY LCD	02	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0010	00028923003	SEMS, TORX HEAD, M3 X 8	00	2.000	UN	N		02/13/2014	12/31/9999	V	
0011	00028923008	SEMS, TORX HEAD, M4 X 12	00	2.000	UN	N		02/13/2014	12/31/9999	V	
0012	00028923015	SEMS, TORX HEAD, M4 X 20	00	4.000	UN	N		02/13/2014	12/31/9999	V	
0013	00000000359	LABEL, SERIAL NUMBER	01	1.000	UN	N		01/19/2015	12/31/9999	V	


CABLE INTERCONNECT CHART
PART NO.
FROM CONNECTOR
TO CONNECTOR
24007538
LCD CN1
00024018790 J1
24007597 FIXED CABLE
TOUCH SCREEN J2
00024018790 J3
24000890
LCD CN302
00024018790 J3
SEE ASSOCIATED BILL OF MATERIAL
REVISION HISTORY
ZONE
REV
DESCRIPTION
DATE
BY
0
RELEASE PER CO 443641
2014-06-23
RWS
Instrumentation Laboratory
ASSY, BRACKET, LCD
00024015551
SEE DETAIL A
DETAIL A
1.0
REF

BOM: 00024015551 Rev: 00
Description: ASSY, BRACKET, LCD
Plant: AK10 Base Qty: 1.000 - UN
Usage: 1 Alt: 01

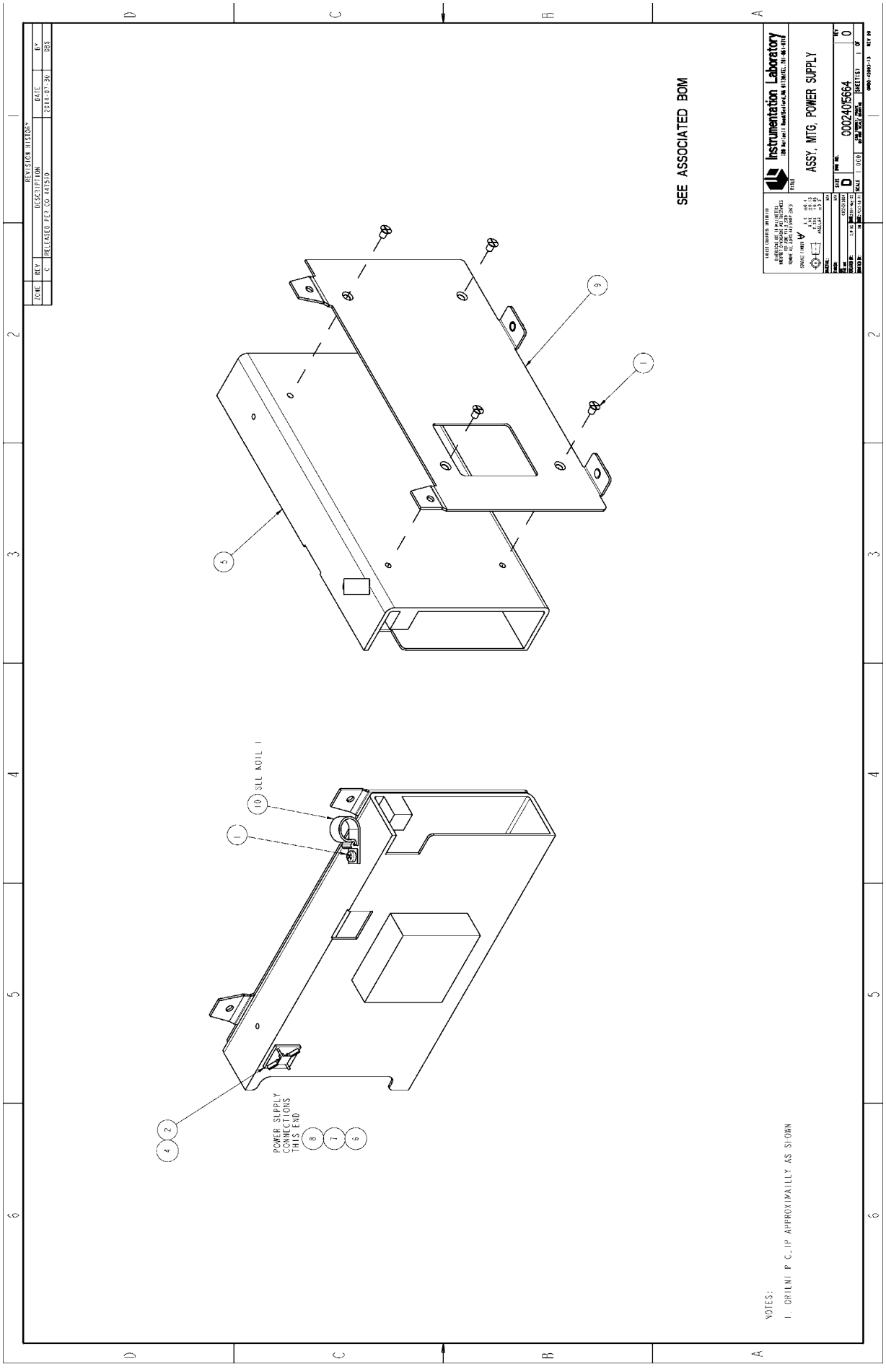
Effectivity Date: 07/25/2014
Procurement: E - 50
Downloaded by: JSANTANA
Export Date: 08/19/2015

Documents:

	Document	Description	Rev.	From	To
L01	L0024015551	ASSY, BRACKET, LCD	00	07/25/2014	12/31/9999

Bill of Material:

Item	Component	Description	Rev	Quantity	UN	ICT	Sloc	From	To	F/V	F.U.
0001	00020462132	SCR PHH PAN M3X6.0 LG SST LITE PATCH	00	4.000	UN	N		02/13/2014	12/31/9999	V	
0002	00028923002	SEMS, TORX HEAD, M3 X 6	00	4.000	UN	N		06/23/2014	12/31/9999	V	
0003	00028936900	SPACER, NYLON	02	4.000	UN	N		02/13/2014	12/31/9999	V	
0004	00024006520	GASKET, TOUCHSCREEN, TOP/BOTTOM	01	1.000	UN	N		02/13/2014	12/31/9999	V	
0005	00024006552	ADHESIVE, LCD	01	3.000	UN	N		02/13/2014	12/31/9999	V	
0006	00024007538	CABLE ASSY, LCD DISPLAY INTERCONNECT	03	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0007	00024007597	TOUCHSCREEN	02	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0008	00024002195	LCD DISPLAY, 12.1”, LED BACKLIGHT	00	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0009	00024015552	BRACKET, LCD	01	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0010	00024018790	PCB ASSY, CONTROLLER TOUCHSCREEN, G5K	01	1.000	UN	L	01	02/13/2014	12/31/9999	V	
0011	00024000890	CABLE ASSY, DISPLAY POWER (LEDBL)	00	1.000	UN	L	01	02/13/2014	12/31/9999	V	


SEE ASSOCIATED BOM
Instrumentation Laboratory
ASSY, MTG, POWER SUPPLY
00024056664
POWER SUPPLY CONNECTIONS THIS END
NOTES:
1. ORIENT PC ZIP APPROXIMATELY AS SHOWN

BOM: 00024015664 Rev: 00
Description: ASSY, MTG, POWER SUPPLY
Plant: AK10 Base Qty: 1.000 - UN
Usage: 1 Alt: 01

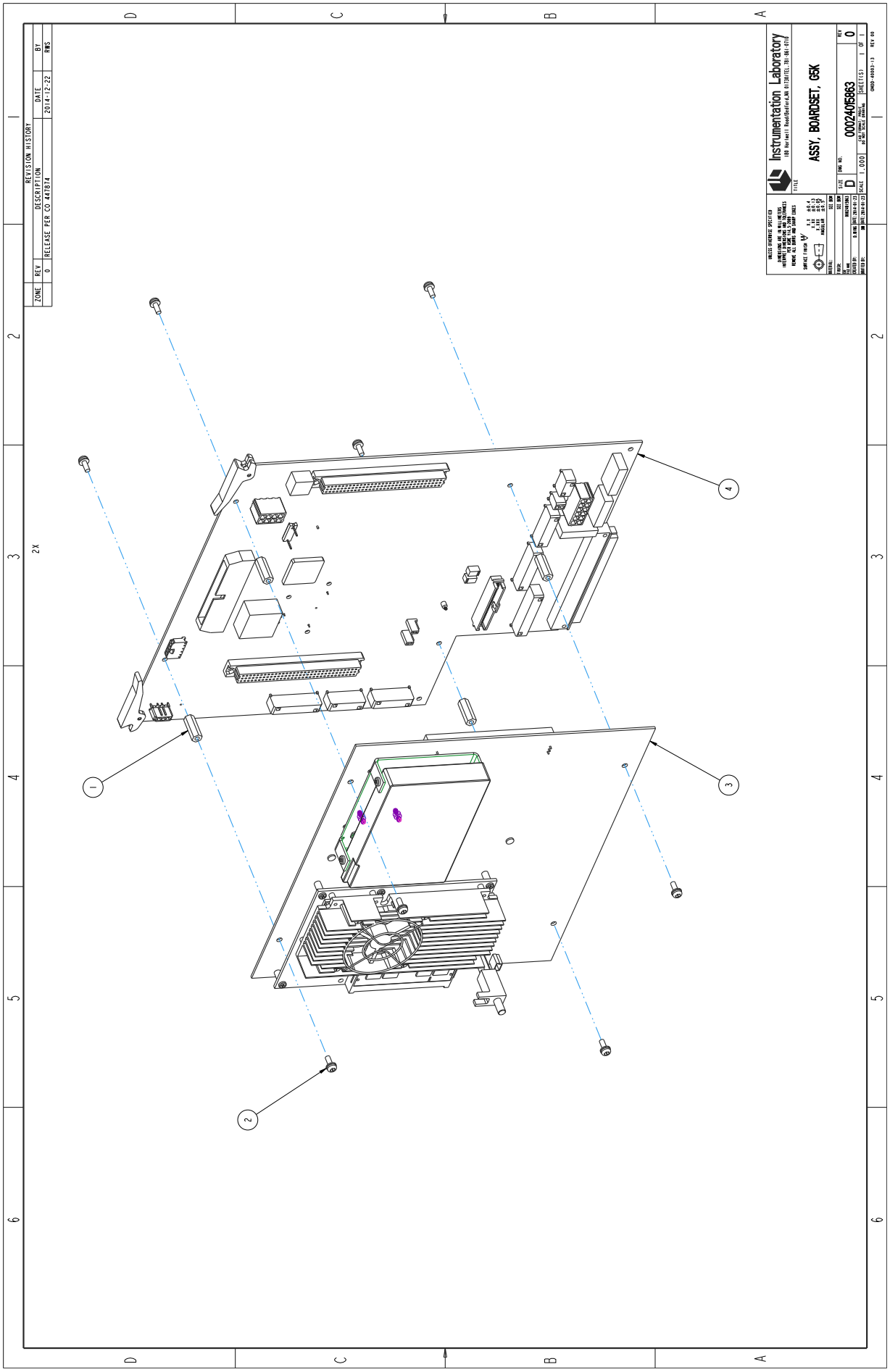
Effectivity Date: 10/25/2014
Procurement: E - 10
Downloaded by: JSANTANA
Export Date: 08/19/2015

Documents:

	Document	Description	Rev.	From	To
DOC	L0024015665	PROC, ASSY POWER SUPPLY, GEM 5000	00	10/25/2014	12/31/9999
L01	L0024015664	ASSY, MTG, POWER SUPPLY	00	10/25/2014	12/31/9999

Bill of Material:

Item	Component	Description	Rev	Quantity	UN	ICT	Sloc	From	To	F/V	F.U.
0001	00020462348	SCR PHH FLT M4X6.0 LG SST LITE PATCH	00	4.000	UN	N		12/19/2013	12/31/9999	V	
0002	00006998220	CLIP, SELF ADHESIVE	01	1.000	UN	N		12/19/2013	12/31/9999	V	
0004	00008977100	TIE, CABLE NYLON 3/4 IN.	02	1.000	UN	N		12/19/2013	12/31/9999	V	
0005	00024000430	PWR SUPPLY, GEM4000, 12V, 5V, 24V	00	1.000	UN	L	01	12/19/2013	12/31/9999	V	
0006	00024000431	CABLE ASSY, SBC POWER, GEM4000	00	1.000	UN	L	01	12/19/2013	12/31/9999	V	
0007	00024000435	CABLE ASSY, STBY SW, GEM4000	03	1.000	UN	L	01	12/19/2013	12/31/9999	V	
0008	00024007512	CABLE ASSY DCS BOARD POWER	02	1.000	UN	L	01	12/19/2013	12/31/9999	V	
0009	00024010114	BRKT, MOUNTING, PWR SUP	01	1.000	UN	L	01	12/19/2013	12/31/9999	V	
0010	00028951202	CLIP EXTRUDED WIRE HARNESS .50	01	1.000	UN	N		05/16/2014	12/31/9999	V	
0011	00028901347	SCR PHH PAN, M4 X 6.0 LG, SST	01	1.000	UN	N		05/16/2014	12/31/9999	V	


REVISION HISTORY
ZONE
REV
DESCRIPTION
DATE
BY
0
RELEASE PER CO 447674
2014-12-22
RWS
Instrumentation Laboratory
ASSY, BOARDSET, G5K
00024005863
2X
1
2
3
4

BOM: 00024015863 Rev: 00
Description: ASSY, BOARDSET, G5K
Plant: AK10 Base Qty: 1.000 - UN
Usage: 1 Alt: 01

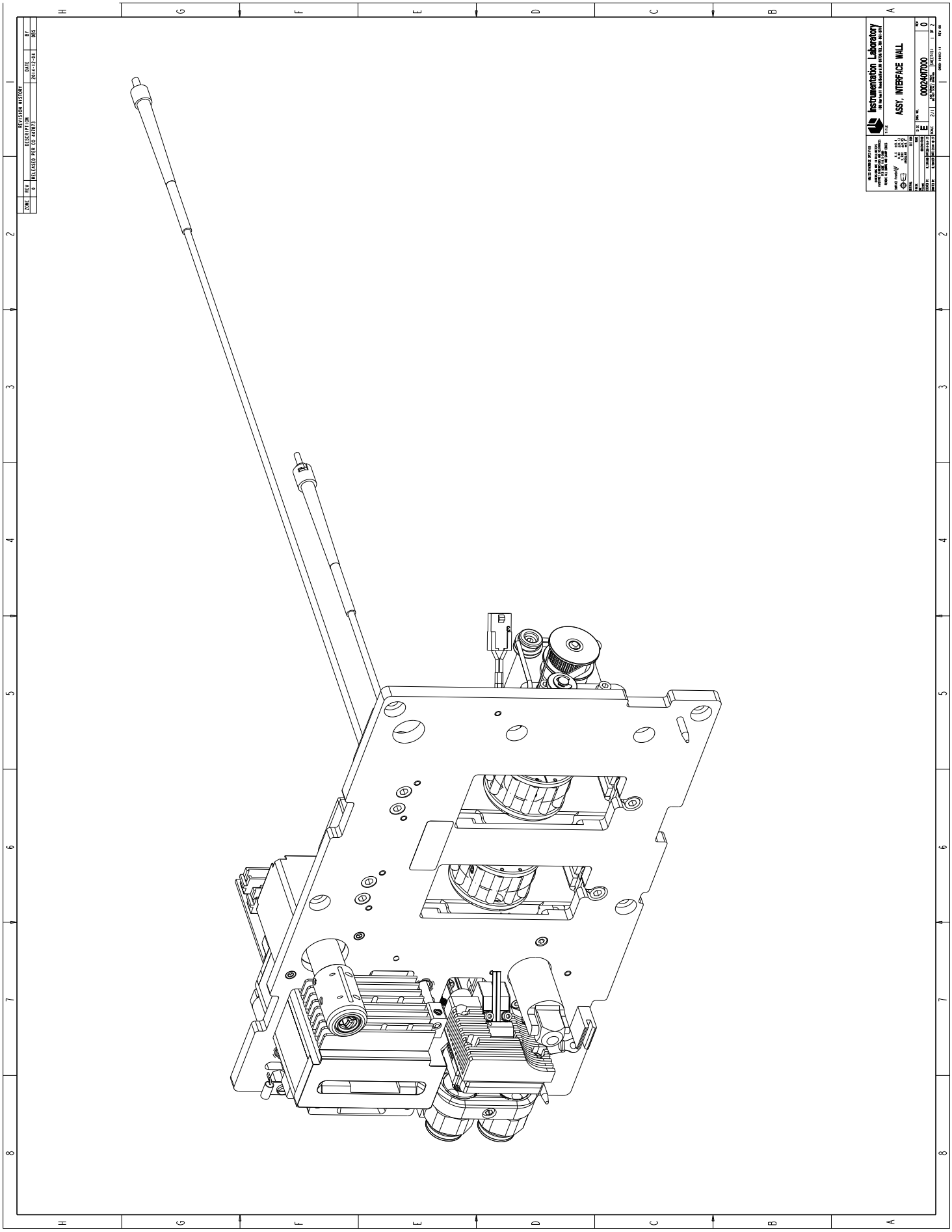
Effectivity Date: 01/23/2015
Procurement: E - 50
Downloaded by: JSANTANA
Export Date: 08/19/2015

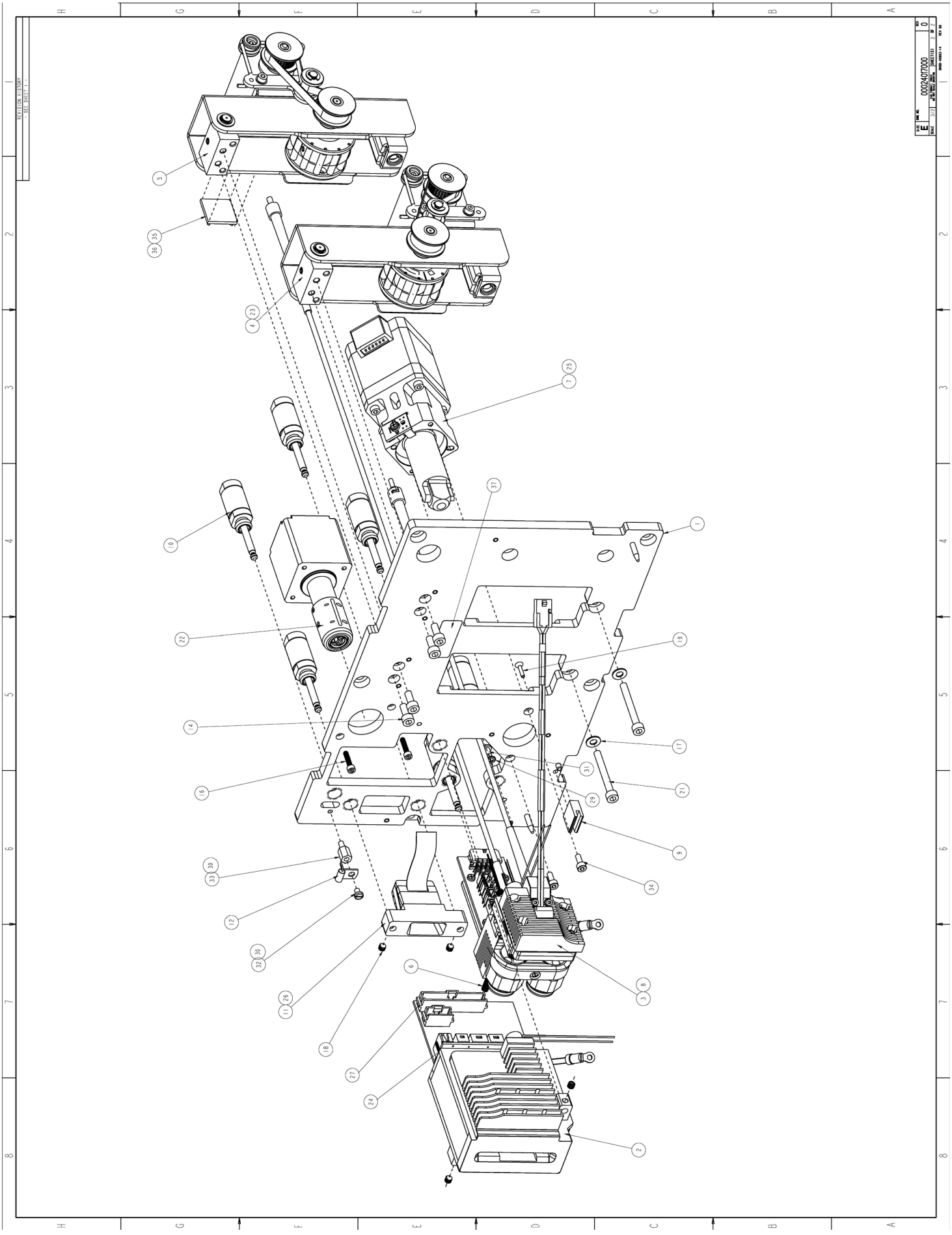
Documents:

	Document	Description	Rev.	From	To
L01	L0024015863	ASSY, BOARDSET, G5K	00	01/23/2015	12/31/9999

Bill of Material:

Item	Component	Description	Rev	Quantity	UN	ICT	Sloc	From	To	F/V	F.U.
0001*	00028901061	STDF, 6.0 HEX F/F, M3 X 17.0 LG, NYLON	00	4.000	UN	N		01/31/2014	12/31/9999	V	
0002*	00028923003	SEMS, TORX HEAD, M3 X 8	00	8.000	UN	N		01/31/2014	12/31/9999	V	
0003*	00024015138	ASSY, SBC, GEM 5000	02	1.000	UN	L	01	01/31/2014	12/31/9999	V	
0004*	00024016380	PCB ASSY, DCS BOARD, GEM 5000	01	1.000	UN	L	01	01/31/2014	12/31/9999	V	
0005*	049C311-0132-001	VIBRA-TITE THD LOCKER	01	0.001	UN	N		01/31/2014	12/31/9999	V	


REVISION HISTORY
ZONE
REV
DESCRIPTION
DATE
BY
0
RELEASED PER CO 441813
2014-12-04
DBS
Instrumentation Laboratory
ASSY, INTERFACE WALL
00024007000
SIZE
A1
REV
0
SHEET 1 OF 2



BOM: 00024017000 Rev: 00
Description: ASSY, INTERFACE WALL
Plant: AK10 Base Qty: 1.000 - UN
Usage: 1 Alt: 01

Effectivity Date: 01/20/2015
Procurement: E - 10
Downloaded by: JSANTANA
Export Date: 08/19/2015

Documents:

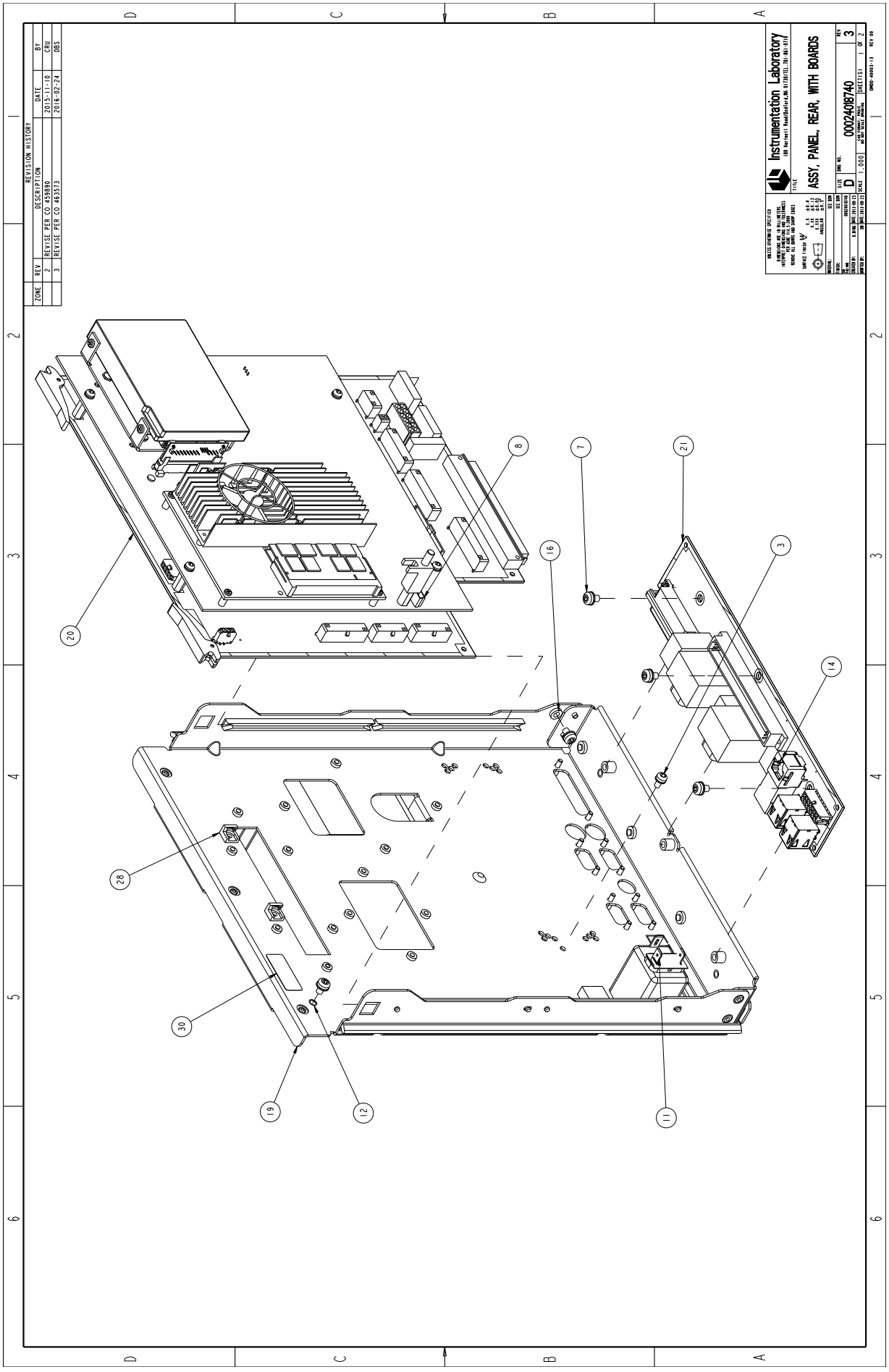
	Document	Description	Rev.	From	To
DOC	L0024016927	PROC, INTERFACE WALL TEST FIXTURE	00	01/20/2015	12/31/9999
DOC	L0024018804	PROC, INTERFACE WALL, G5K	00	01/20/2015	12/31/9999
L01	L0024017000	ASSY, INTERFACE WALL	00	01/20/2015	12/31/9999
L13	L0024016846	DRIVER, FLOATING MOUNT TORQUE	00	01/20/2015	12/31/9999
L13	L0024019745	FIXTURE, INTERFACE WALL TEST, GEM 5000	01	05/01/2015	12/31/9999

Bill of Material:

Item	Component	Description	Rev	Quantity	UN	ICT	Sloc	From	To	F/V	F.U.
0001	00024017710	PANEL, INTERFACE, MACHINED	00	1.000	UN	L	01	01/30/2014	12/31/9999	V	
0002	00024016360	ASSY, HEATER MODULE	01	1.000	UN	L	01	01/30/2014	12/31/9999	V	
0003	00024018330	MODULE OPTICAL HEAD	00	1.000	UN	L	01	01/30/2014	12/31/9999	V	
0004	00024017110	ASSY, PIVOT PUMP, RIGHT	00	1.000	UN	L	01	01/30/2014	12/31/9999	V	
0005	00024017500	ASSY, PIVOT PUMP, LEFT	00	1.000	UN	L	01	01/30/2014	12/31/9999	V	
0006	00024015866	SET SCREW M4 X 25 LONG	00	2.000	UN	N		05/19/2014	12/31/9999	V	
0007	00024016473	ASSY, MOTOR, SELECTOR VALVE	00	1.000	UN	L	01	07/07/2014	12/31/9999	V	
0008	00024017267	CABLE ASSY, OPTIC HEAD INTERFACE	00	1.000	UN	L	01	11/07/2014	12/31/9999	V	
0009	00024015615	ACTUATOR, BAG OPENER	00	1.000	UN	L	01	01/30/2014	12/31/9999	V	
0010	00024018380	ASSY, MOUNT, FLOATING	00	6.000	UN	L	01	01/30/2014	12/31/9999	V	
0011	00024014998	CABLE ASSY, GEM 5K EEPROM-SENSOR	00	1.000	UN	L	01	01/30/2014	12/31/9999	V	
0012	00024007551	CABLE ASSY FRONT THERMISTOR	00	1.000	UN	L	01	01/30/2014	12/31/9999	V	
0014	00028901449	SCR SCH CAP, M4 X 10.0 LG, SST	08	4.000	UN	N		01/30/2014	12/31/9999	V	
0016	00024015624	4-40 X 0.5 LG SHCS SS W/LOCKING PATCH	00	2.000	UN	N		01/30/2014	12/31/9999	V	
0017	00024015820	WSHR FLAT, 4.3 X 1.0 THK, SST	00	2.000	UN	L	01	01/20/2015	12/31/9999	V	
0018	00024017211	SET SCREW, M4, CONE POINT	00	4.000	UN	N		05/19/2014	12/31/9999	V	
0019	00019070805	SCR, SCH FLAT HD, M2.5X10 LG	01	1.000	UN	N		01/30/2014	12/31/9999	V	
0021	00028901457	SCR SCH CAP, M4 X 35.0 LG, SST	08	2.000	UN	N		01/30/2014	12/31/9999	V	
0022	00024015596	ASSY, SAMPLER DRIVE	00	1.000	UN	L	01	03/06/2014	12/31/9999	V	
0023	00024014467	CABLE ASSY, G5K COOX PUMP	00	1.000	UN	L	01	03/06/2014	12/31/9999	V	
0024	00024014497	CABLE ASSY, G5K CHEM H/C2	00	1.000	UN	L	01	03/06/2014	12/31/9999	V	
0025	00024015016	CABLE ASSY, G5K HOME & POSITION SENSORS	00	1.000	UN	L	01	03/06/2014	12/31/9999	V	
0026	00024015766	CABLE ASSY, STEPPER MOTOR 0,1,2,&EEPROM	01	1.000	UN	L	01	03/06/2014	12/31/9999	V	
0027	00024015892	CABLE ASSY, DCS TO ANALOG BOARD	00	1.000	UN	L	01	03/06/2014	12/31/9999	V	
0029	00028911001	WSHR LK STAR, M3 SST	01	2.000	UN	N		03/06/2014	12/31/9999	V	

L = BUY PART/ASSY
N = FLOOR STOCK

0030	049C311-0132-001	VIBRA-TITE THD LOCKER	01	0.001	UN	N		05/19/2014	12/31/9999	V	
0031	00028901330	SCR PHH PAN, M3 X 5.0 LG, SST	01	2.000	UN	N		05/19/2014	12/31/9999	V	
0032	00028922129	SCREW PAN HD SLOTTED M3X4.0 LG NYLON	00	1.000	UN	N		05/19/2014	12/31/9999	V	
0033	00028927802	STANDOFF, M/F, M3 NYLON NTS-8	00	1.000	UN	N		05/19/2014	12/31/9999	V	
0034	00024002157	SCREW,PHILLIPS SOCKET HD M3X8MM POLYLOK	01	2.000	UN	N		07/14/2014	12/31/9999	V	
0035	00006998220	CLIP, SELF ADHESIVE	01	2.000	UN	N		11/07/2014	12/31/9999	V	
0036	00008977100	TIE, CABLE NYLON 3/4 IN.	02	2.000	UN	N		11/07/2014	12/31/9999	V	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ZONE | REV | DESCRIPTION | DATE | BY
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3 | REVISE PER CO 465313 | 2016-02-24 | OBS
Instrumentation Laboratory
ASSY, PANEL, REAR, WITH BOARDS
00024016740
SIZE D
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SCALE 1.000
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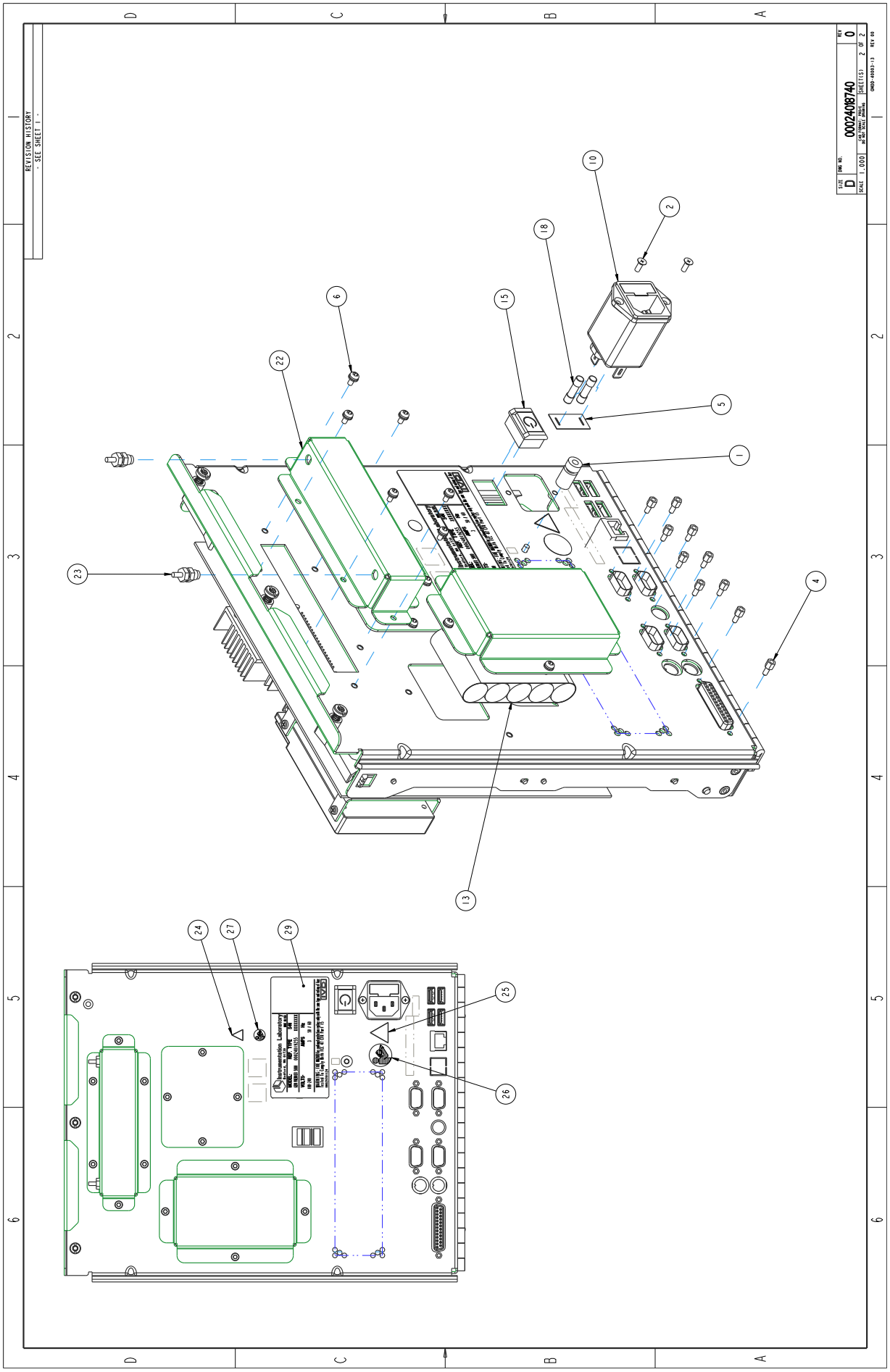
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SCALE 1.000
SHEET 1 OF 2
REV 0
REV 00
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BOM: 00024018740 Rev: 03
Description: ASSY, PANEL, REAR, WITH BOARDS
Plant: AK10 Base Qty: 1.000 - UN
Usage: 1 Alt: 01

Effectivity Date: 02/24/2016
Procurement: E - 10
Downloaded by: DMILLER
Export Date: 02/01/2017

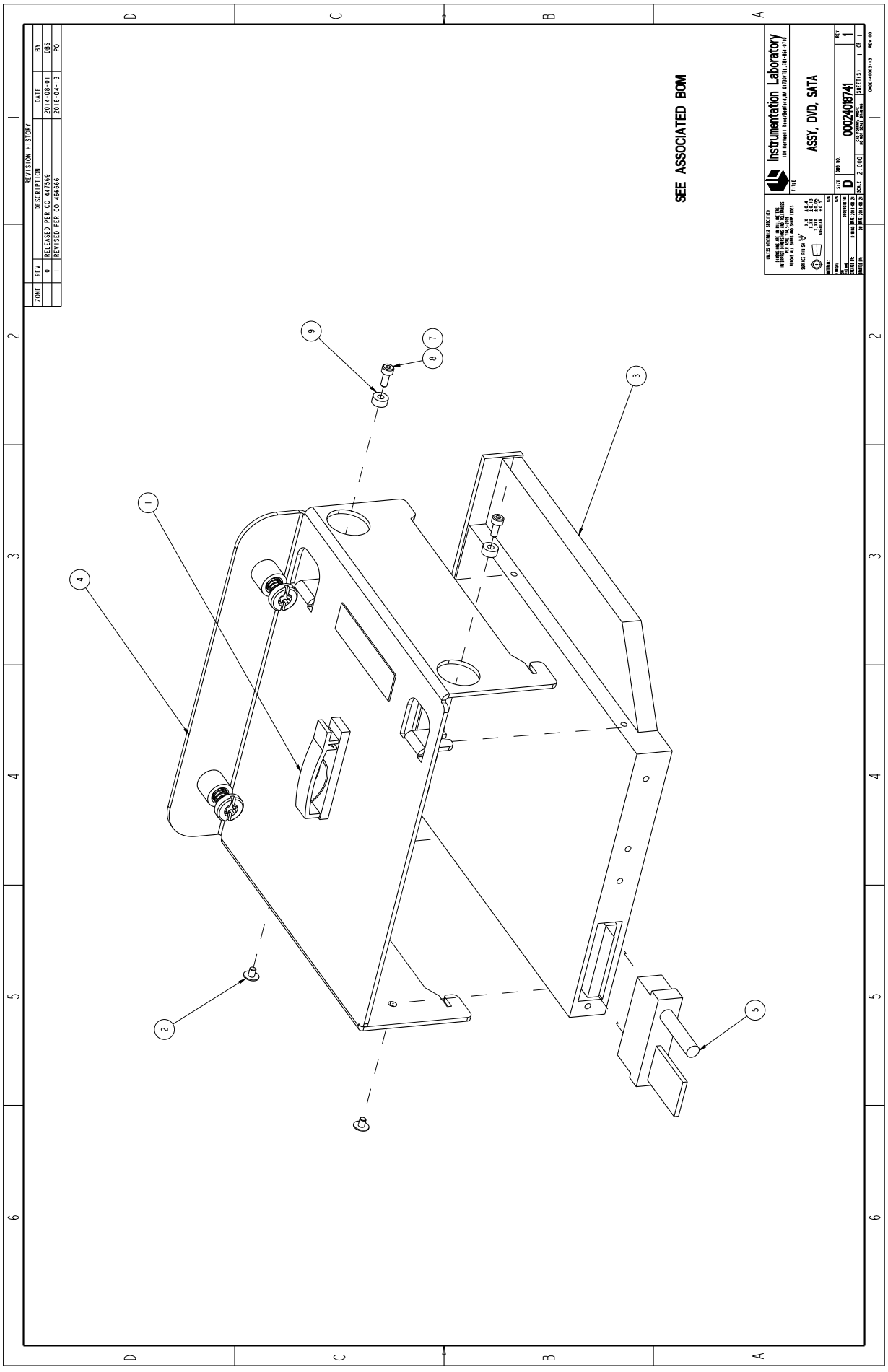
Documents:

	Document	Description	Rev.	From	To
DOC	L0024015681	PROC, REAR PANEL ASSY	02	02/24/2016	12/31/9999
L01	L0024018740	ASSY, PANEL, REAR, WITH BOARDS	03	02/24/2016	12/31/9999

Bill of Material:

Item	Component	Description	Rev	Quantity	UN	ICT	Sloc	From	To	F/V	F.U.
0001*	00005634900	POST BINDING METAL	01	1.000	UN	N		01/31/2014	12/31/9999	V	
0002*	00009960003	SCREW, FLAT HD, X-SLT, M3 X 8, SST	01	2.000	UN	N		01/31/2014	12/31/9999	V	
0003*	00019993708	SCREW, PAN HD SEMS, PHL #6 X .25 LG, SST	00	1.000	UN	N		01/31/2014	12/31/9999	V	
0004*	00020462551	SCREW LOCK FEMALE 4-40 X .250 LITE PATCH	01	10.000	UN	N		01/31/2014	12/31/9999	V	
0005*	00028447600	TERMINAL SHIELD	01	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0006*	00028923002	SEMS, TORX HEAD, M3 X 6	00	6.000	UN	N		01/31/2014	12/31/9999	V	
0007	00028923005	SEMS, TORX HEAD, M4 X 6	00	5.000	UN	N		06/17/2014	12/31/9999	V	
0008*	00024000433	CABLE ASSY, QUAD USB, GEM4000	00	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0010*	00024001808	ASSY, FILTERED PWR ETNRY MOD W/ FUSE HLD	01	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0011*	00024001809	CABLE ASSY, PWR ENTRY MODULE	00	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0012*	00024006490	STRAP, HINGE REAR PANEL	01	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0013*	00024006721	BATTERY, POWER BACKUP	03	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0014*	00024007504	CABLE ASSY ETHERNET SHIELDED	02	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0015*	00024007533	CABLE ASSY SOFT PUSH BUTTON	00	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0016*	00024007540	CABLE ASSY CHASSIS GROUND	00	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0018*	00024009984	FUSE 3A/250V SLO-BLO 5X20MM	01	2.000	UN	N		01/31/2014	12/31/9999	V	
0019*	00024015528	ASSY, REAR PANEL, GHASSIS, GEM 5K	02	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0020*	00024015863	ASSY, BOARDSET, G5K	00	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0021*	00024017750	ASSY, INTERFACE BOARD, G5K	00	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0022*	00024018745	BOX, ANTENNA, GEM	01	1.000	UN	L	01	06/17/2014	12/31/9999	V	
0023*	00024305458	CABLE ASSY, WIRELESS CARD TO ANTENNA	01	2.000	UN	L	01	06/17/2014	12/31/9999	V	
0024*	00099004801	LABEL, ELECTRIC SHOCK, 0.375" X 0.375"	01	1.000	UN	N		06/17/2014	12/31/9999	V	
0025*	00099004802	LABEL, ELECTRIC SHOCK, 0.369" X 0.60"	01	1.000	UN	N		06/17/2014	12/31/9999	V	
0026*	00099004702	LABEL, CONSULT OPERATORS MANUAL, 0.75"	01	1.000	UN	N		06/17/2014	12/31/9999	V	
0027*	00099004701	LABEL, CONSULT OPERATORS MANUAL,	01	1.000	UN	N		06/17/2014	12/31/9999	V	

		0.375"									
0028*	00024306087	CLAMP, WIRE LOCKING	01	2.000	UN	N		07/14/2014	12/31/9999	V	
0029	00000001088	ASSY, PRODUCT SN LABEL, CE/CSA	00	1.000	UN	N		02/24/2016	12/31/9999	V	
0030*	00000000359	LABEL, SERIAL NUMBER	02	1.000	UN	N		01/23/2015	12/31/9999	V	


SEE ASSOCIATED BOM
Instrumentation Laboratory
ASSY, DVD, SATA
00024008741
REVISION HISTORY
DESCRIPTION
RELEASED PER CO 4417569
REVISED PER CO 466666
DATE
2014-08-01
2016-04-13
BY
DBS
PO

BOM: 00024018741 Rev: 01
Description: ASSY, DVD SATA
Plant: AK10 Base Qty: 1.000 - UN
Usage: 1 Alt: 01

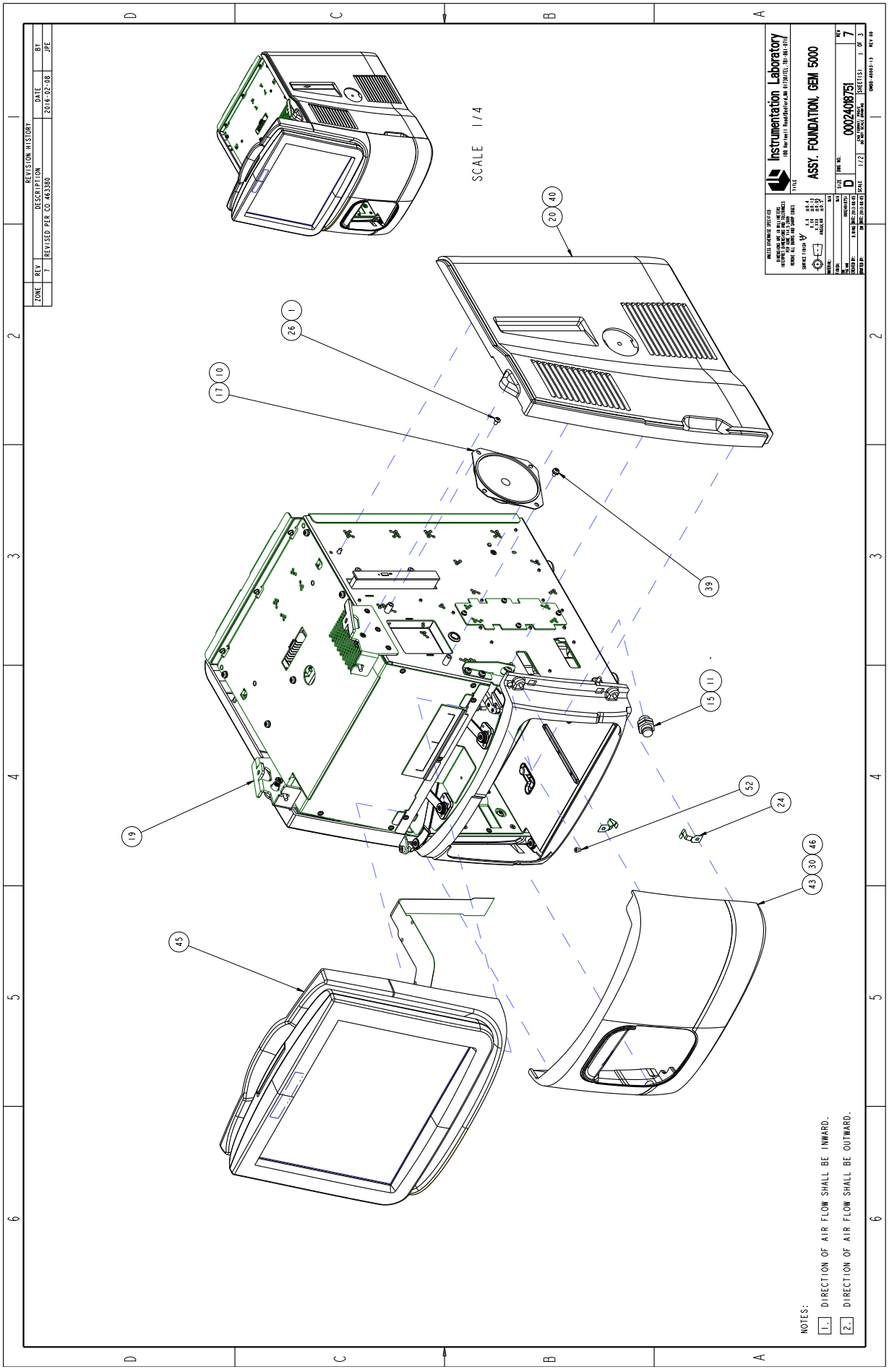
Effectivity Date: 04/25/2016
Procurement: E - 10
Downloaded by: DMILLER
Export Date: 02/01/2017

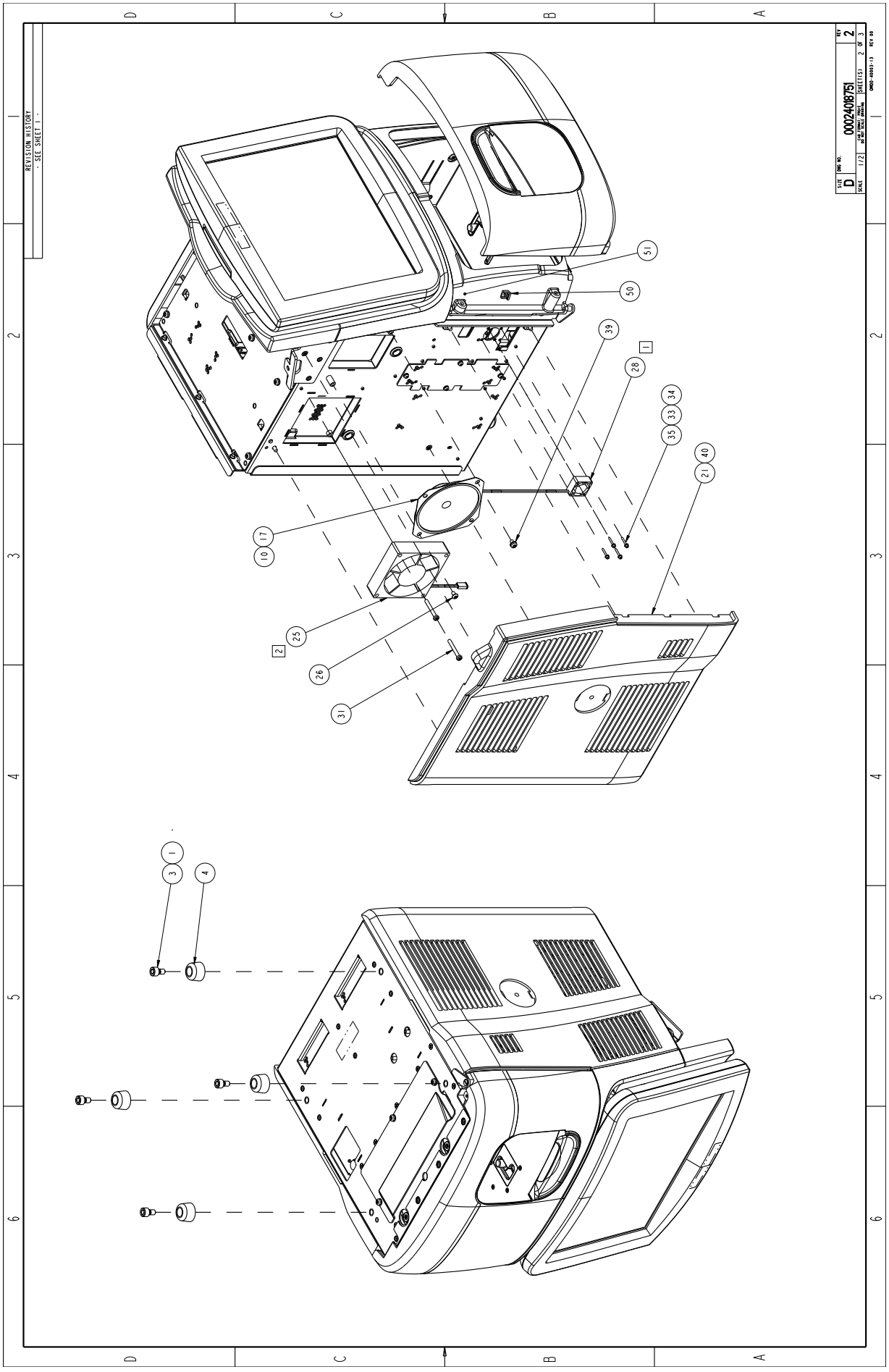
Documents:

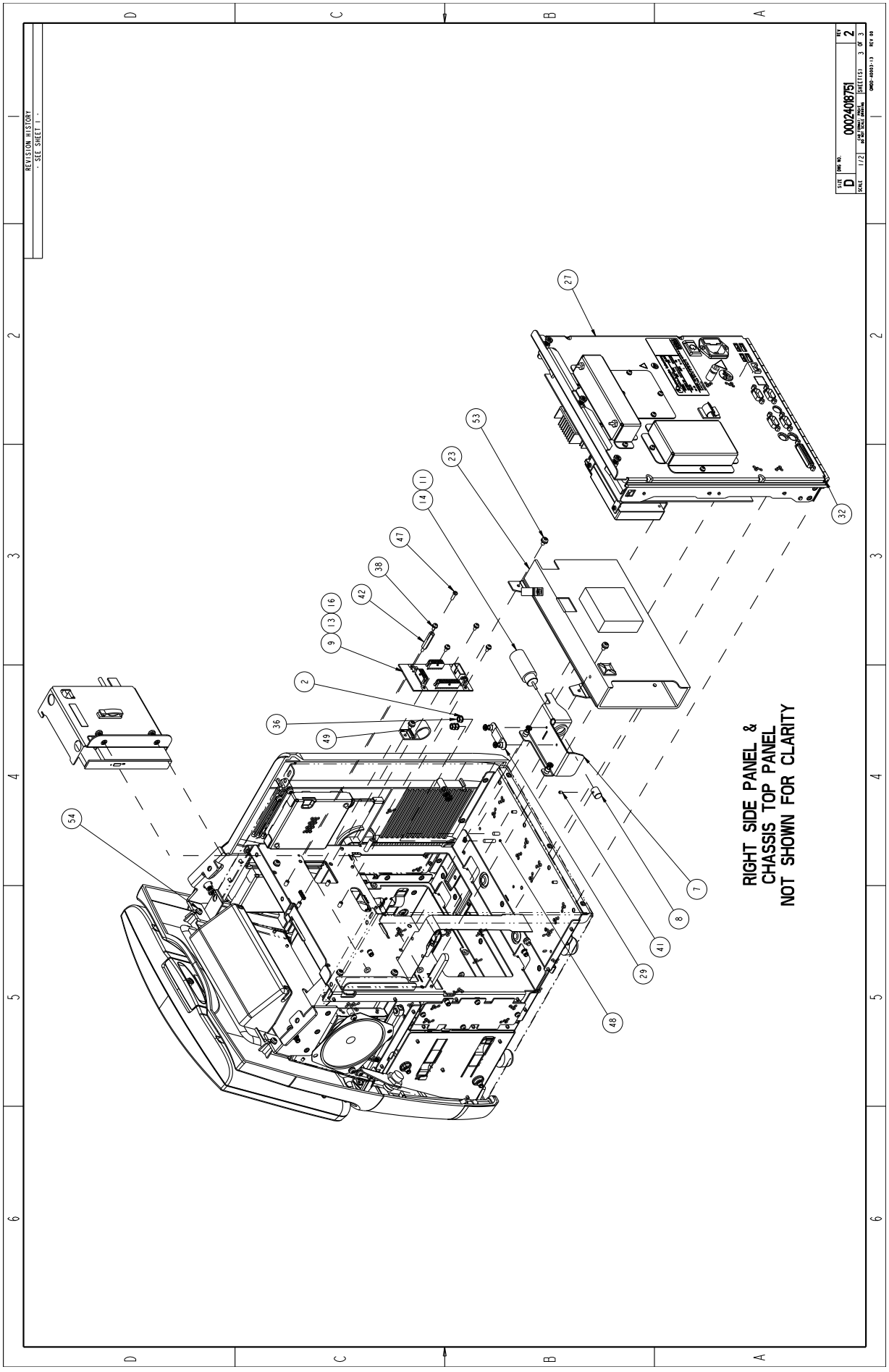
	Document	Description	Rev.	From	To
DOC	L0024018823	PROC, DVD ASSEMBLY	01	04/25/2016	12/31/9999
L01	L0024018741	ASSY, DVD DATA	01	04/25/2016	12/31/9999

Bill of Material:

Item	Component	Description	Rev	Quantity	UN	ICT	Sloc	From	To	F/V	F.U.
0001	00018924201	CABLE CLAMP, 1.25 WIDTH	01	1.000	UN	N		01/09/2014	12/31/9999	V	
0002	00024001095	SCREW WAFER HEAD 2M X 3 WITH LOCKING PAT	00	2.000	UN	N		04/25/2016	12/31/9999	V	
0003	00024000503	DVD DRIVE	02	1.000	UN	L	01	06/18/2014	12/31/9999	V	
0004	00024018743	BRACKET, MOUTING, DVD	01	1.000	UN	L	01	06/18/2014	12/31/9999	V	
0005	00024000495	ASSY, CABLE, SATA AND POWER	01	1.000	UN	L	01	06/18/2014	12/31/9999	V	
0007	000760004	LOCTITE,THREADLOCK,PURPLE,#222	03	0.001	OZ	N		04/25/2016	12/31/9999	V	
0008	00009967803	SCREW SOC HD CAP, M2 X 0.4 X 5 MM L	02	2.000	UN	N		04/25/2016	12/31/9999	V	
0009	00024005436	BOLT SPACER	00	2.000	UN	L	01	04/25/2016	12/31/9999	V	


SCALE 1/4
Instrumentation Laboratory
ASSY. FOUNDATION, GEM 5000
00024087751
NOTES:
1. DIRECTION OF AIR FLOW SHALL BE INWARD.
2. DIRECTION OF AIR FLOW SHALL BE OUTWARD.


REVISION HISTORY
- SEE SHEET 1 -
SIZE D
DWG NO. 00024018751
REV 2
SCALE 1/2
SHEET 2 OF 3
REV A0
51
50
39
28
34
33
35
40
21
17
10
25
26
31
3
4


REVISION HISTORY
- SEE SHEET 1 -
SIZE D
DWG NO. 00024018751
REV 2
SCALE 1/2
SHEET 3 OF 3
REV A0
RIGHT SIDE PANEL &
CHASSIS TOP PANEL
NOT SHOWN FOR CLARITY
27
53
23
11
14
47
38
42
16
13
9
2
36
49
54
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48
32

BOM: 00024018751 Rev: 07
Description: ASSY, FOUNDATION, GEM 5000
Plant: AK10 Base Qty: 1.000 - UN
Usage: 1 Alt: 01

Effectivity Date: 02/16/2016
Procurement: E - 10
Downloaded by: DMILLER
Export Date: 02/01/2017

Documents:

	Document	Description	Rev.	From	To
DOC	L0024016753	PROC, SW INSTALLATION, GEM 5000	00	01/23/2015	12/31/9999
DOC	L0024018805	PROC, FOUNDATION ASSY	01	09/14/2015	12/31/9999
L01	L0024018751	ASSY, FOUNDATION, GEM 5000	07	02/16/2016	12/31/9999
L13	L0024009987	FIXTURE, DOOR SENSOR HGT	00	07/10/2006	12/31/9999
L13	L0024011530	ASSY, FIXTURE, WEIGHTED CARTRIDGE, 5K	00	01/23/2015	12/31/9999

Bill of Material:

Item	Component	Description	Rev	Quantity	UN	ICT	Sloc	From	To	F/V	F.U.
0001	00007160901	LOCTITE 242	01	0.001	OZ	N		02/12/2014	12/31/9999	V	
0002	00009676605	WASHER ID=4.3, OD=8.0, s=0.5	01	3.000	UN	N		02/12/2014	12/31/9999	V	
0003	00024005559	INSERT FOOT	01	4.000	UN	L	01	02/12/2014	12/31/9999	V	
0004	00024006079	FOOT MOUNTING NON MARKING	01	4.000	UN	N		02/12/2014	12/31/9999	V	
0007	00024006647	BRKT MTG SOLENOID LATCH	05	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0008	00024006648	TIP SOLENOID LATCH	02	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0009	00024011850	PCB ASSY, FAN PIC CONTROLLER, G5K	01	1.000	UN	L	01	11/07/2014	12/31/9999	V	
0010	00024007508	CABLE ASSY SPEAKER	01	1.000	UN	L	01	09/09/2015	12/31/9999	V	
0011	00024007515	CABLE ASSY SOL 4. HALL EFFECT 8	00	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0013	00024007543	CABLE ASSY, FAN CONTROLLER	01	1.000	UN	L	01	08/27/2014	12/31/9999	V	
0014	00024007547	DOOR SOLENOID	00	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0015	00024007548	DOOR SENSOR ASSEMBLY	03	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0016	00024007552	CABLE ASSY FAN COMMUNICATIONS	02	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0017	00024007554	SPEAKER LEFT/RIGHT	02	2.000	UN	L	01	02/12/2014	12/31/9999	V	
0019	00024010110	ASSY, CHASSIS, GEM	02	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0020	00024015330	PANEL, RIGHT SIDE, GEM 5K	01	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0021	00024015331	PANEL, LEFT SIDE, GEM 5K	01	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0023	00024015664	ASSY, MTG, POWER SUPPLY	00	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0024	00024015789	CLIP, SPRING, DOOR	00	2.000	UN	L	01	06/23/2014	12/31/9999	V	
0025	00024015797	CABLE ASSY, GEM 5K REAR RAN	00	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0026	00028903120	SCR SCH BUTTON, M4 X 6.0 LG, SST	01	2.000	UN	N		02/12/2014	12/31/9999	V	
0027	00024018740	ASSY, PANEL, REAR, WITH BOARDS	03	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0028	00024018742	CABLE ASSY, SIDE FAN	00	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0029	00024018748	STRAIN RELIEF, FLEX CABLE	00	1.000	UN	L	01	02/12/2014	12/31/9999	V	
0030	00020462149	SCR PHH PAN M4X8.0 LG SST LITE PATCH	00	4.000	UN	N		02/12/2014	12/31/9999	V	
0031	00020462156	SCR PHH PAN M4X25.0 LG SST LITE	00	2.000	UN	N		02/12/2014	12/31/9999	V	

		PATCH									
0032	00020462348	SCR PHH FLT M4X6.0 LG SST LITE PATCH	00	4.000	UN	N		02/12/2014	12/31/9999	V	
0033	00028901102	WSHR, FLAT M2 X 0.3 THK, SST	01	4.000	UN	N		02/12/2014	12/31/9999	V	
0034	00028901202	WASHER LK, M2 SST	00	4.000	UN	N		02/12/2014	12/31/9999	V	
0035	00028901416	SCR SCH CAP, M2 X 14.0 LG, SST	08	4.000	UN	N		02/12/2014	12/31/9999	V	
0036	00028914602	NUT, HEX KEP M4, SST	02	3.000	UN	N		06/23/2014	12/31/9999	V	
0038	00028923002	SEMS, TORX HEAD, M3 X 6	00	4.000	UN	N		03/04/2015	12/31/9999	V	
0039	00028923005	SEMS, TORX HEAD, M4 X 6	00	4.000	UN	N		11/07/2014	12/31/9999	V	
0040	00028923006	SEMS, TORX HEAD, M4 X 8	00	6.000	UN	N		03/04/2015	12/31/9999	V	
0041	00028923702	SOC SET SCR M3X4.0 LG SS/PATCH	00	1.000	UN	N		02/12/2014	12/31/9999	V	
0042	00028927811	STANDOFF, M/F, M3 NYLON NTS-25	00	1.000	UN	N		02/12/2014	12/31/9999	V	
0043	00024016185	ASSY, PANEL, DOOR	00	1.000	UN	L	01	03/20/2014	12/31/9999	V	
0044	00024018741	ASSY, DVD SATA	01	1.000	UN	L	01	03/20/2014	12/31/9999	V	
0045	00024015549	ASSY, LCD, TILT	00	1.000	UN	L	01	03/20/2014	12/31/9999	V	
0046	00024015680	CABLE ASSY, SAMPLER LED INT	00	1.000	UN	L	01	03/20/2014	12/31/9999	V	
0047	00028922133	SCREW PAN HD SLOTTED M3X10.0 LG NYLON	00	1.000	UN	N		06/23/2014	12/31/9999	V	
0048	00018633500	LABEL, PROTECTIVE GND.	03	1.000	UN	N		06/23/2014	12/31/9999	V	
0049	00028951203	CLIP EXTRUDED WIRE HARNESS .75	01	1.000	UN	N		06/23/2014	12/31/9999	V	
0050	00024306087	CLAMP, WIRE LOCKING	01	1.000	UN	N		08/08/2014	12/31/9999	V	
0051	00024005239	TAPE, KAPTON, 0.75 WIDE	01	2.000	UN	N		08/08/2014	12/31/9999	V	
0052	00028901429	SCR SCH CAP, M3 X 4.0 LG, SST	08	1.000	UN	N		08/27/2014	12/31/9999	V	
0053	00020462405	SEMS TORX HD M3X8.0 LG SST LITE PATCH	00	2.000	UN	N		01/29/2015	12/31/9999	V	
0054	00028923008	SEMS, TORX HEAD, M4 X 12	00	2.000	UN	N		03/04/2015	12/31/9999	V	
0055	00024018731	DISC, SYSTEM GEM 5000 SOFTWARE V1.0.1	00	0.001	UN	N		02/16/2016	12/31/9999	V	

GEM® PREMIER™ 5000 | iQM2

Service Manual • P/N 00024019300 • Rev. 01 • February, 2017

Instrumentation Laboratory

A Werfen Company

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Instrumentation Laboratory SpA - V.le Monza 338 - 20128 Milano (Italy) EC REP