GEM® PREMIER™ 5000

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GEM® PREMIER™ 5000 | iQM2

Instrumentation Laboratory

A Werfen Company

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℞ IVD

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Limited Warranty

Manufacturer responsibility for safety and performance

Instrumentation Laboratory (IL) is responsible for the safety and electrical performance of this equipment if and only if:

- Persons authorized by IL carry out assembly operations, extensions, adjustments, modifications, or repairs.
- The GEM Premier 5000 system is repaired by authorized IL personnel or persons authorized by IL.
- 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 the instructions for use contained in this manual.
- IL brand products are used; non-IL brands are not covered.

Warranty information

The following language applies to all warranties listed in this manual.

Excluded from all warranties are any defects caused by misuse, accidental damage, or unauthorized repair of the product. Those parts which deteriorate or which are in any case considered consumables or those parts or “items” which by their nature are normally required to be replaced periodically consistent with normal maintenance are not covered by the analyzer warranty. The warranty is limited to the replacement, at no cost to the purchaser, of any component or accessory found to be defective during the period in which the warranty is in effect, except for cartridges, for which a pro rata credit for the unused portion of the cartridge may be provided. Product functionality must be determined per the manufacturer’s instructions prior to reporting patient results.

The warranty is expressly in lieu of all other warranties, expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose. It is the responsibility of the purchaser to determine the suitability of this product for any particular application, and to take any necessary actions to determine the fitness of the product at time of use.

The purchaser agrees that any liability against IL for a breach of a warranty shall be limited to the replacement of any defective part, or for cartridges, credit on a pro rata basis as determined by IL. No other remedy including, but not limited to, incidental or consequential damages or lost profits, lost sales, injury to person or property, or any other incidental or consequential loss shall be available to the purchaser.

No agent or employee of IL is authorized to extend any other warranty or to assume for IL any liability except as above set forth.

Exceptions to any of the warranties listed in this manual must be generated by an Instrumentation Laboratory corporate office or authorized distributor corporate office.

GEM Premier 5000 PAK Warranty

GEM Premier 5000 system GEM PAKs are warrantied against defects in materials and workmanship up to the expiration date stamped on the product. Damages caused by or connected to transport are excluded. A defect is defined as follows: visible leakage or mechanical defect as noted at the time the protective wrapper is removed; a sensor failure as indicated by an error code and message displayed or printed by the analyzer at the time of initial cartridge insertion and start-up, or a disabled sensor during cartridge use life that is a result of an internal defect. A sensor disabled as a result of introducing samples that contain clots or interfering substances is not considered a defect.

The purchaser must notify IL within 30 days of the occurrence of any defect. The cartridge information must be returned to IL or its authorized distributor on CD, DVD or via email for warranty adjustment. Cartridges may be requested to be returned to IL. A return authorization number or incident number must be obtained from IL prior to returning the cartridge information or cartridge. IL may issue credit for the partially used cartridges on a pro rata basis at IL's discretion. Please note the "Copy IL Data" feature on the analyzer removes all patient demographic information.

GEM Premier 5000 Analyzer Warranty

IL declares to the original purchaser that each GEM Premier 5000 system manufactured and sold by IL or sold by an authorized IL distributor shall be free from defects in material and workmanship and, under normal and proper use conditions, warrants it for a period of one year from installation and no more than 13 months from the shipping date, except as otherwise provided in writing.

IL's obligation is limited to repairing, replacing, or modifying (at IL's undisputed judgment) at IL's factory, or elsewhere as designated by IL, the material whose defects have been verified, on condition that the purchaser has informed IL of any defects found within 10 days from receipt, or 10 days of discovery in case of defects which may not be identified in the normal inspection. Damages caused by or connected to transport are excluded.

Transport to an IL facility or authorized IL distributor will be at purchaser's charge and risk. Replacements, repairs, or alterations will in no case determine extension to the warranty period.

The warranty does not cover those parts which deteriorate or which are in any case considered consumables or those parts or "items" which by their nature are normally required to be replaced periodically consistent with normal maintenance. It is also understood that following the purchase and delivery of the instrument, the purchaser shall be deemed liable for any losses, damages, or complaints concerning persons or things incurred by the use or misuse of the instrument on behalf of the purchaser, its employees, co-operators, or others.

IL does not assume any obligation or warranty engagement concerning precision and/or accuracy of the measurements as well as for any damage to the instrument directly or indirectly resulting from the use of reagents and/or consumables different from those produced by IL specifically for its own instruments and for the same properly tested.

Warranty will not apply to those defective instruments or materials showing defects or damage arising from the following causes:

1. Insufficient or negligent care by the purchaser.
2. Insufficient or negligent maintenance by the purchaser in relation to the instructions contained in the manuals prepared by IL for this purpose; tampering or alterations of the instruments or in any case interventions or repairs made by any person not duly authorized by IL.
3. Misuse due to carelessness, negligence, or inexperience.
4. Employment of materials under heavier conditions than those for which they have been designed and manufactured and use of the same in combination with incompatible or dangerous products.
5. Non-observance of the regulations relevant to installation, power supply, and operation of the instruments.

1 - USING THIS MANUAL

Understanding labels and symbols

This manual contains the procedures necessary to operate and maintain the IL GEM Premier 5000 system. Personnel responsible for operating and maintaining the analyzer should read and understand the included material prior to use.

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

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:

CE — 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

LOT — Batch code or lot number

REF — Catalog or part number

SN — Serial number

IVD — *In vitro* diagnostic device

 Manufacturer

EC REP — 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

2 - The GEM Premier 5000 Analyzer

Product Intended Use

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 from arterial, venous or capillary heparinized whole blood. 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.

*sO_2 = ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin.

- pH, pCO_2, and pO_2 measurements in whole blood are used in the diagnosis and treatment of life-threatening acid-base disturbances.
- Electrolytes in the human body have multiple roles. Nearly all metabolic processes depend on or vary with electrolytes:
  - Sodium (Na^+) measurements are used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, inappropriate antidiuretic secretion, or other diseases involving electrolyte imbalance.
  - Potassium (K^+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high blood potassium levels.
  - Ionized calcium (Ca^{++}) measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.
  - Chloride (Cl^-) measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders, such as cystic fibrosis and diabetic acidosis.
- Hematocrit (Hct) measurements in whole blood of the packed red cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red cells).
- Glucose (Glu) measurement is used in the diagnosis, monitoring and treatment of carbohydrate metabolism disturbances including diabetes mellitus, neonatal hypoglycemia, idiopathic hypoglycemia, and pancreatic islet cell carcinoma.
- Lactate (Lac) measurement is used:
  - to evaluate the acid-base status of patients suspected of having lactic acidosis;
  - to monitor tissue hypoxia and strenuous physical exertion;
  - in the diagnosis of hyperlactatemia.

- Total Bilirubin (tBili) measurement is used to aid in assessing the risk of kernicterus and hyperbilirubinemia in neonates.
- CO-Oximetry (tHb, COHb, MetHb, O_2Hb, HHb, and sO_2) evaluates the ability of the blood to carry oxygen by measuring total hemoglobin and determining the percentage of functional and dysfunctional hemoglobin species.
  - Total Hemoglobin (tHb): Total hemoglobin measurements are used to measure the hemoglobin content of whole blood for the detection of anemia.
  - COHb: Carboxyhemoglobin measurements are used to determine the carboxyhemoglobin content of human blood as an aid in the diagnosis of carbon monoxide poisoning.
  - MetHb: Methemoglobin measurements are used to determine different conditions of methemoglobinemia.
  - HHb: Deoxyhemoglobin, as a fraction of total hemoglobin, is used in combination with oxyhemoglobin to measure oxygen status.
  - O_2Hb: Oxyhemoglobin, as a fraction of total hemoglobin, is used in combination with deoxyhemoglobin to measure oxygen status.
  - sO_2: Oxygen saturation, more specifically the ratio between the concentration of oxyhemoglobin and oxyhemoglobin plus deoxyhemoglobin, is used to measure oxygen status.

Device Description

The GEM Premier 5000 system provides fast, accurate, quantitative measurements of heparinized whole blood pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, glucose, lactate, Hct, total bilirubin and CO-Oximetry (tHb, O_2Hb, COHb, MetHb, HHb, sO_2) from arterial, venous or capillary samples.

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.

The GEM Premier 5000 system makes use of potentiometric sensors to measure pCO_2, pH, Na^+, K^+, Cl^-, and Ca^{++}. It uses amperometric sensors to measure pO_2, glucose, and lactate concentrations. Blood conductivity is the method used to measure hematocrit. CO-Oximetry and total bilirubin measurements involve chemically lysing the whole blood sample and then utilizing a broad spectrum spectrophotometer to evaluate the sample at a variety of wavelengths.

Refer to the "Measurement Methodology" chapter for additional information on analyte methodologies.

The GEM Premier 5000 system consists of non-interchangeable components. Use only components supplied by Instrumentation Laboratory.

Abbreviations

Measured Analytes

The measured analytes are represented on the analyzer and throughout the manual by the following symbols or abbreviations.

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

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 vivo*)	BEecf
Base Excess of Blood (*In vitro*)	BE(B)
Calculated Total Hemoglobin*	tHb(c)

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Derived Parameter	Abbreviation
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}
Osmolarity	mOsm
Oxygenation Index	OI
Arterial sample oxygen capacity	O_2cap
Calculated Oxygen Saturation	$sO_2(c)$
Standard bicarbonate	HCO_3^- std
Actual bicarbonate	HCO_3^- actual
Alveolar-arterial oxygen gradient	$A\text{-}aDO_2^-$
Arterial-alveolar oxygen ratio	paO_2/pAO_2
Respiratory index	RI
End pulmonary capillary oxygen content	CcO_2
Arterial-mixed venous oxygen gradient	$a\text{-}vDO_2$
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.

User-Entered Parameters

The analyzer provides space for entering the following parameters, which operators must measure, calculate, or obtain elsewhere:

Actual patient temperature (Temp)

The default temperature is 37°C. This temperature will be used to calculate pH, pCO_2 and pO_2 unless a different entry is made by the operator. The measured and corrected temperature results, if applicable, are displayed on the View Results screen and on the printout.

Barometric Pressure (BP)

The default Barometric Pressure is 760 mmHg. This BP will be used unless a different entry is made by the operator. The GEM Premier 5000 system does not need daily entry of Barometric Pressure for sample analysis, as the solutions are sealed in gas impermeable bags with no headspace. However, Barometric Pressure is used in various calculated parameter equations, alveolar oxygen partial pressure (pAO_2) for example.

Therefore, if a BP other than 760 mmHg is desired for use in the calculated parameter equations the operator must enter it when the Enter Information tab is presented. The entered value will be displayed on the screen and shown on the printed report.

In addition, more user-entered parameters and O_2/vent settings can be defined by the facility in Configuration.

Ventilator Modes
A/C
A/C PC
APRV
BiPAP
HFOV
MMV
PCIRV
PCVAPS
SIMV
SIMV/PC
SIMV/PS
VCIRV
VDR
CPAP

O_2 Device Names
Aerosol Mask
Aerosol Tee
Ambu
Cannula
Heli OX (20-80)
Heli OX (30-70)
High flow Cannula
Non Rebreather
Oxy Hood
Oxymizer
Partial Rebreather
Simple Mask
Tracheal Collar
Venti Mask
Face Mask

O_2 or Vent Parameter	Abbreviation
Mode #1	Not Applicable
Mode #2	Not Applicable
O_2 Device #1	Not Applicable
O_2 Device #2	Not Applicable
Oxygen flow	O_2
Percent inspired oxygen	FIO_2
Mechanical Tidal Volume	Mech V_T
Spontaneous Tidal Volume	Spont V_T
Set Minute Volume	Set Minute Vol
Total Minute Volume	Total Minute Vol
Mechanical Rate in bpm	Mech Rate(bpm)
Mechanical Rate in Hz	Mech Rate(Hz)
Spontaneous Rate in bpm	Spont Rate(bpm)
Spontaneous Rate in Hz	Spont Rate(Hz)
Peak Inspiratory Pressure	PIP
Mean Airway Pressure	MAP
Inspiratory time	Itime(sec)
Inspiratory time	Itime(%)
Positive End Expiratory Pressure	PEEP
Continuous Positive Airway Pressure	CPAP
Bi-level Positive Airway Pressure (Inspiratory)	BIPAP(I)
Bi-level Positive Airway Pressure (Expiratory)	BIPAP(E)
Pressure Support	PS
Pressure Control	PC
Pulse Oximeter	Pulse Ox
Flow	Not Applicable
Amplitude	Not Applicable
Delta P	Not Applicable
High Positive End Expiratory Pressure	High PEEP
Low Positive End Expiratory Pressure	Low PEEP
Inspiratory Positive Airway Pressure	IPAP
Expiratory Positive Airway Pressure	EPAP
Adaptive Support Ventilation	ASV
Proportional Assist Ventilation	PAV
Nitric Oxide	Not Applicable

Sample Type/Volume Requirements

Use only Lithium (Li^+) Heparin anticoagulant. Refer to the "Sample Device and Collection Procedures" in Section 4 of this manual for important information on anticoagulants.

Analytes	Sample Volume (µL)
pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct, tHb, O_2Hb, COHb, MetHb, HHb, sO_2, tBili or any combination of Electrochemical* analytes and CO^-Oximetry** and/or tBili	150
tHb, O_2Hb, COHb, MetHb, HHb, sO_2, tBili	100
pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct	65 (Capillary Only)

* Electrochemical analytes = pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct,

** CO^-Oximetry = tHb, O_2Hb, COHb, MetHb, HHb, sO_2

Sample Type:	Whole blood with addition of an appropriate concentration of lithium heparin anticoagulant.
Time To Results:	45 seconds from sample aspiration
Sample Capacity:	75 tests to 600 tests
Throughput	29 samples/hour

Measurement Methodology	
Amperometric:	pO_2, Glucose, Lactate
Potentiometric:	pH, pCO_2, Na^+, K^+, Ca^{++}, Cl^-
Conductivity:	Hct
Optical Measurement following chemical lysing and mixing of the whole blood sample:	CO-Oximetry, tBili

Refer to Section 6., "Measurement Methodology" for further information on methodologies.

Internal Temperature Control: Electrode chamber maintained at 37°C (98.6°F) nominal.

Measured Analytes

Measured Analyte	Units	Measurable Range*	Reportable Range**	Resolution
pH	pH scale	6.80 to 7.92	7.00 to 7.92	0.01
cH	nmol/L	158.5 to 12.0	100.0 to 12.0	0.1
cH	nEq/L	158.5 to 12.0	100.0 to 12.0	0.1
pCO_2	mmHg	6 to 150	6 to 125	1
pCO_2	kPa	0.8 to 20.0	0.8 to 16.7	0.1
pO_2	mmHg	6 to 756	6 to 690	1
pO_2	kPa	0.8 to 100.5	0.8 to 92.0	0.1
Na^+	mmol/L	100 to 200	100 to 180	1
Na^+	mEq/L	100 to 200	100 to 180	1
K^+	mmol/L	1.0 to 20.0	1.0 to 19.0	0.1
K^+	mEq/L	1.0 to 20.0	1.0 to 19.0	0.1
Ca^{++}	mmol/L	0.11 to 5.00	0.11 to 4.25	0.01
Ca^{++}	mEq/L	0.22 to 10.0	0.22 to 8.50	0.01
Ca^{++}	mg/dL	0.44 to 20.0	0.44 to 17.00	0.01
Cl^-	mmol/L	40 to 170	40 to 158	1
Cl^-	mEq/L	40 to 170	40 to 158	1
Glu	mg/dL	4 to 750	4 to 685	1
Glu	mmol/L	0.22 to 41.6	0.22 to 38.0	0.1
Lac	mmol/L	0.3 to 20.0	0.3 to 17.0	0.1
Lac	mg/dL	3 to 180	3 to 153	1
Hct	%	15 to 75	15 to 72	1
tHb	g/dL	3.0 to 23.0	3.0 to 23.0	0.1
tHb	g/L	30 to 230	30 to 230	1
tHb	mmol/L	1.8 to 14.3	1.8 to 14.3	0.1
O_2Hb	%	0.0 to 100.0	0.7 to 100.0	0.1
COHb	%	0.0 to 75.0	0.3 to 75.0	0.1
MetHb	%	0.0 to 30.0	0.7 to 30.0	0.1
HHb	%	0.0 to 100.0	1.0 to 100.0	0.1
sO_2	%	0.0 to 100.0	0.7 to 100.0	0.1
tBili	mg/dL	2.0 to 40.0	2.0 to 40.0	0.1
tBili	µmol/L	34 to 684	34 to 684	1

* The Measuring Range for a parameter is the analyzer electronics capability range translated into analyte measurement units.

** The Reportable Range for a parameter is the range where performance claims are verified and validated in the default units.

Notes: Analytes with measured values outside the Reportable Range are reported with a > or < symbol. Incalculable will be displayed for results that are outside the measuring capability of the analyzer.

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Derived (Calculated) Analytes

Derived Parameter	Unit of Measure	Resoution
TCO_2	mmol/L	0.1
BEecf (In vivo)	mmol/L	0.1
BE(B) (*In vitro*)	mmol/L	0.1
tHb(c)	g/dL	0.1
tHb(c)	g/L	1
tHb(c)	mmol/L	0.1
OI	%	0.1
mOsm	mmol/L	0.1
Ca^{++} (7.4)	mmol/L	0.01
Ca^{++} (7.4)	mEq/L	0.01
Ca^{++} (7.4)	mg/dL	0.01
Anion Gap	mmol/L	1
Anion Gap	mEq/L	1
P/F Ratio	mmHg	1
P/F Ratio	kPa	0.1
pAO_2	mmHg	1
pAO_2	kPa	0.1
CaO_2	mL/dL	0.1
CvO_2	mL/dL	0.1
P_{50}	mmHg	1
P_{50}	kPa	0.1
O_2cap	mL/dL	0.1
O_2cap	mL/L	1
O_2cap	mmol/L	0.1
O_2cap	Vol%	0.1
sO_2(c)	%	0.1
HCO_3^- std	mmol/L	0.1
HCO_3^- (c)	mmol/L	0.1
A-aDO_2	mmHg	1
A-aDO_2	pKa	0.1
paO_2/pAO_2	Not Applicable	0.01
RI	Not Applicable	0.1
CcO_2	mL/dL	0.1
CcO_2	mL/L	1
CcO_2	mmol/L	0.1
CcO_2	Vol%	0.1
a-vDO_2	mL/dL	0.1
a-vDO_2	mL/L	1
a-vDO_2	mmol/L	0.1
a-vDO_2	Vol%	0.1
Q_{sp}/Q_t (est)	%	0.1
Q_{sp}/Q_t	%	0.1
Hct(c)	%	1

Analyte Conversion Chart

Analyte	Default Unit	SI or Alternate Units Conversion Equation
pH	pH Units	$cH\ (nmol/L) = 10^{(-pH)} * 10^9$
		$cH\ (nEq/L) = 10^{(-pH)} * 10^9$
pCO_2	mmHg	$pCO_2\ (kPa) = pCO_2\ (mmHg) \div 7.5$
pO_2	mmHg	$pO_2\ (kPa) = pO_2\ (mmHg) \div 7.5$
Na^+	mmol/L	$Na^+(mEq/L) = Na^+\ (mmol/L)$
K^+	mmol/L	$Cl^-(mEq/L) = Cl^-\ (mmol/L)$
Cl^-	mmol/L	$K^+\ (mEq/L) = K^+\ (mmol/L)$
Ca^{++}	mmol/L	$Ca^{++}\ (mEq/L) = 2.0 * Ca^{++}\ (mmol/L)$
		$Ca^{++}\ (mg/dL) = 4.008 * Ca^{++}\ (mmol/L)$
Glucose	mg/dL	Glu (mmol/L) = Glu (mg/dL) * 0.05555
Lactate	mmol/L	Lac (mg/dL) = 9.0 * Lac (mmol/L)
tHb	g/dL	tHb (g/L) = 10 * tHb (g/dL)
		tHb (mmol/L) = 0.621 * tHb (g/dL)
tBili	mg/dL	tBili (µmol/L)= 17.1 * tBili (mg/dL)

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GEM Premier 5000 Analyzer Reference Ranges

The following general reference ranges for arterial adult blood (unless noted) have been obtained from the sources listed at the end of the tables. Reference ranges are guidelines for the clinician, but they should not be considered as the sole indicator of health and disease. Reference ranges can be dependent on a number of factors, such as age, gender, and the patient's normal physiological condition. Each facility may define gender and age specific reference ranges that are applicable to their patient populations.

Parameter	Reference Range [1, 2, 3, 4, 5, 6, 7, 8, 9]	Unit
pH [2] cH cH pH	7.35 to 7.45 35.5 to 44.7 35.5 to 44.7 7.32 to 7.43 (venous)	pH nmol/L nEq/L pH
pCO_2 [2]	Arterial blood: 35 to 48 (male) and 32 to 45 (female) Arterial blood: 4.6 to 6.4 (male) and 4.3 to 6.0 (female) venous blood (right atrium) - 6-7 mmHg (0.80-0.93 kPa) higher than arterial pCO_2	mmHg kPa
pO_2 [2]	83 to 108 11.0 to 14.4	mmHg kPa
Na^+ [2]	136 to 145 136 to 145	mmol/L mEq/L
K^+ [2]	3.5 to 5.1 3.5 to 5.1	mmol/L mEq/L
Cl^- [2]	98 to 107 98 to 107	mmol/L mEq/L
Ca^{++} [2]	1.15 to 1.33 2.30 to 2.66 4.60 to 5.32 1.16 to 1.32 (venous) 4.64 to 5.28 (venous)	mmol/L mEq/L mg/dL mmol/L mEq/L
Hct [7]	40-50 (male) and 37-47 (female)	%
Gluc [2]	65 to 95 3.6 to 5.3	mg/dL mmol/L
Lac [2]	0.36 to 0.75 (arterial at rest) 3 to 7 (arterial at rest) 0.56 to 1.39 (venous at rest) 5 to 12 (venous at rest)	mmol/L mg/dL mmol/L mg/dL
tHb [7]	12.6 - 17.4 (male) and 11.7 - 16.1 (female) 126 - 174 (male) and 117 - 161 (female) 7.8 - 10.8 (male) and 7.3 - 10.0 (female)	g/dL g/L mmol/L
O_2Hb [8]	90.0 to 95.0	%
COHb [4, 5, 6]	<3.0 (nonsmoker) <10.0 (smokers)	%
MetHb [3]	0.0 to 1.5	%
HHb [9]	1.0 to 5.0	%
sO_2 [7]	94.0 to 98.0	%
TCO_2 [1]	19.0 to 24.0 22.0 to 26.0 (Venous)	mmol/L
BE[1]	-2.0 to 3.0	mmol/L
HCO_3^- [1]	21 to 28 21 to 28 22 to 29 (venous) 22 to 29 (venous)	mmol/L mEq/L mmol/L mEq/L
Anion Gap[1]	10 to 20 $(Na^+ + K^+) - (Cl^- + HCO_3^-)$ 10 to 20 $(Na^+ + K^+) - (Cl^- + HCO_3^-)$	mEq/L mmol/L

Parameter Notes:

[1] TCO_2, HCO_3-, Anion Gap and BE (Base Excess) are derived parameters

Reference Range References:

General Normal Ranges:

[2] Burtis, Carl and David Bruns, Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, Elsevier Saunders, 7th edition, 2015, pp 952-982

CO-Oximetry Normal Ranges:

[3] Burtis, Carl and David Bruns, Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 7th edition, 2015, pp 952-982

[4] Hampson, NB, et al. Practice Recommendations in the Diagnosis, Management and Prevention of Carbon Monoxide Poisoning, Am J Respir Crit Care Med, 2012:186:1095-1101

[5] Piantadosi, C.A, Carbon Monoxide Poisoning, New England Journal of Medicine (2002), 347 (14): 1054-1055

[6] Radford, EP, Blood Carbon Monoxide Levels in Person 3-74 Years of Age: United States, 1976-1980. National Center for Health Statistics, 1982.

[7] Wu, A., Tietz Clinical Guide to Laboratory Tests, W.B. Saunders Co., St. Louis MO, 4th Edition, 2006: 514, 524, and 798

[8] Haymond, S., Oxygen Saturation, A Guide to Laboratory Assessment, Clinical Laboratory News, February 2006, pages 10-12.

[9] American Environmental Laboratory: The Laboratory Assessment of Oxygenation. Robert F. Morgan, 1993, 5(4), p. 170-182.

Parameter	Source	Reference Range	Unit
tBili	Premature Infant 0 – 1 day	<8.0	mg/dL
	Premature Infant 0 – 1 day	<137	µmol/L
	Premature Infant 1 – 2 days	<12.0	mg/dL
	Premature Infant 1 – 2 days	<205	µmol/L
	Premature Infant 3 – 5 days	<16.0	mg/dL
	Premature Infant 3 – 5 days	<274	µmol/L
	Full-term Infant 0 – 1 day	1.4 – 8.7	mg/dL
	Full-term Infant 0 – 1 day	24 – 149	µmol/L
	Full-term Infant 1 – 2 days	3.4 – 11.5	mg/dL
	Full-term Infant 1 – 2 days	58 – 197	µmol/L
	Full-term Infant 3 – 5 days	1.5 – 12.0	mg/dL
	Full-term Infant 3 – 5 days	26 – 205	µmol/L
	>5 days to < 60 years	0.3 – 1.2	mg/dL
	>5 days to < 60 years	5 – 21	µmol/L

Reference:

Wu, A., Tietz Clinical Guide to Laboratory Tests, W.B. Saunders Co., St. Louis MO, 4th Edition, 2006

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GEM Premier 5000 Analyzer Critical Ranges

The following table of critical values has been obtained from the reference listed at the end of the table. Unless otherwise noted, the values are for arterial whole blood samples. These are only suggested critical limits. Each facility may define gender and age specific critical limits that are applicable for their institutions.

Parameter	Lower Limit	Upper Limit	Unit
pH cH cH	7.20 63.1 63.1	7.60 25.1 25.1	pH nmol/L nEq/L
pCO_2	20 2.6	70 9.3	mmHg kPa
pO_2	40 6	- -	mmHg kPa
Na^+	120 120	160 160	mmol/L mEq/L
K^+	2.8 2.8	7.8 7.8	mmol/L mEq/L
Cl^-	80	120	mmol/L
HCO_3^-	10.0 10.0	40.0 40.0	mmol/L mEq/L
Ca^{++}	0.75 1.50 3.00	1.60 3.20 6.40	mmol/L mEq/L mg/dL
Hct	18	60	%
Glu	40 2.2	450 25.0	mg/dL mmol/L
Lac * B + C	-	3.4	mmol/L
tHb	7	20	g/dL
tBili (newborn)	-	15	mg/dL

*Note: Hyperlactemia is an indicator commonly used to detect tissue hypofusion, particularly in the case of sepsis, but also in trauma and surgical settings.

References:

A) Tietz, N.W., Fundamentals of Clinical Chemistry, W.B. Saunders Co., Philadelphia, 5th Edition, 2001.

B) Dellinger R. P. et al, “Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2012”, Critical Care Medicine, 41 (2): 580-637, 2013

C) Levraut J, Ichai C, Petit I, Ciebiera JP, Perus O, Grimaud D. “Low Exogenous Lactate Clearance As An Early Predictor of Mortality in Normolactatemic Critically Ill Septic Patients”, Critical Care Medicine 2003; 31 (3): 705-710.

GEM Premier 5000 Medical Decision Levels (MDLs)

The following table of medical decision levels (MDLs) has been obtained from the references listed at the end of the table. Unless otherwise noted, the values are for arterial whole blood samples. These are only suggested medical decision levels. Each facility may define institute specific MDLs that are applicable for their patient population.

Parameter	MDL1	MDL2	MDL3	MDL4	Unit
pH	7.30	7.35	7.45	-	pH
pCO_2	35	50	70	-	mmHg
pO_2	30	45	60	-	mmHg
Na^+	115	135	150	-	mmol/L
K^+	3.0	5.8	7.5	-	mmol/L
Cl^-	90	112	N/A	-	mmol/L
Ca^{++}	0.37	0.82	1.58	-	mmol/L
Hct	21	33	56 (male)	53 (female)	%
Glu	45	120	180	350	mg/dL
Lac	2.0	5.0	-	-	mmol/L
tHb	7.0	10.5	18 (male)	17 (female)	g/dL
tBili	3.0 - 6.0	14.0	20.0	-	mg/dL
O_2Hb	90.0	-	-	-	%
HHb	6.0	-	-	-	%
COHb	3	10	15	-	%
MetHb	5	10	-	-	%
sO_2	90	-	-	-	%

References:

1 Burtis, Carl and David Bruns, Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, Elsevier Saunders, 7th edition, 2015, pp 952-982

2 Statland, Bernard E., Clinical Decision Levels for Lab Tests, 2nd edition. Medical Economics Company Inc. New Jersey. 1987.

3 Kost, G.J, Table of Critical Limits, Clinical Laboratory Reference, 2013-2014, pp 6-7.

User-Entered Values

Entered Parameter	Unit of Measure	Allowable Range Entry
Temperature (Temp)	°C	15.0 to 45.0
Temperature (Temp)	°F	59.0 to 113.0
Barometric Pressure (BP)	mmHg	500 to 999 (default 760)
Barometric Pressure (BP)	kPa	66.7 to 133.2 (default 101.3)

The default temperature is 37°C. This temperature will be used to calculate pH, pCO_2, pO_2, unless a different entry is made by the operator. The measured and corrected temperatures, if applicable, are displayed on the View Results screen and on the printout.

The default Barometric Pressure (BP) is 760 mmHg. This BP will be used unless a different entry is made by the operator. Barometric Pressure is used in various calculated parameter equations, alveolar oxygen partial pressure (pAO_2) for example. Therefore, if a BP other than 760 mmHg is desired for use in the calculated parameter equations the operator must enter it when the Enter Information tab is presented. The entered value will be displayed on the screen and shown on the printed report.

Input Parameters

Input Parameter	Limitations/Format
Patient ID	24 alphanumeric characters
Patient Last Name	24 alphanumeric characters
Patient First Name	24 alphanumeric characters
Patient Middle Initial	1 alphanumeric character
Patient Birth Date	Date format selected in Configuration
Patient Gender	Combo (Pick) List – Choices are Female, Male, Unknown
Operator ID	24 alphanumeric characters
Operator Password	6 to 16 alphanumeric characters
Sample Number	24 alphanumeric characters
Order Number	24 alphanumeric characters
Clinician	24 alphanumeric characters
Draw Time	24 Hour Clock HH:MM
Draw Date	Date format selected in Configuration
User Defined Demographics	24 alphanumeric characters
User Defined Parameters	12 alphanumeric characters
Sample Comment	255 alphanumeric characters per comment
User-Defined Measurement Panels	1 default panel; unlimited user-defined panels
Panel Name	16 alphanumeric characters
Report Title	6 lines, 24 alphanumeric characters per line
CVP Lot Number	10 alphanumeric characters
CVP Description	20 alphanumeric characters

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Entered O_2 and Vent Entries

Ventilator Modes
A/C
A/C PC
APRV
BiPAP
CPAP
HFOV
MMV
PCIRV
PCVAPS
SIMV
SIMV/PC
SIMV/PS
VCIRV
VDR

O_2 Device Names
Aerosol Mask
Aerosol Tee
Ambu
Cannula
Face Mask
Heli OX (20-80)
Heli OX (30-70)
High flow Cannula
Non Rebreather
Oxy Hood
Oxymizer
Partial Rebreather
Simple Mask
Tracheal Collar
Venti Mask

Parameter	Description	Unit of Measure	Resolution or Format	Entry Range
Mode #1	Pull-down list is provided at analysis time with the configured and enabled ventilator modes, plus <Key Entry> to allow typing in of a different ventilator mode.	Not Applicable	Alpha-numeric	Not Applicable
Mode #2	Pull-down list is provided at analysis time with the configured and enabled ventilator modes, plus <Key Entry> to allow typing in of a different ventilator mode.	Not Applicable	Alpha-numeric	Not Applicable
O_2 Device #1	Pull-down list is provided at analysis time with the configured and enabled O_2 device names, plus <Key Entry> to allow typing in of a different device name.	Not Applicable	Alpha-numeric	Not Applicable
O_2 Device #2	Pull-down list is provided at analysis time with the configured and enabled O_2 device names, plus <Key Entry> to allow typing in of a different device name.	Not Applicable	Alpha-numeric	Not Applicable
O_2	Oxygen flow	LPM	0.1	0.0 – 99.0
FIO_2	Percent inspired oxygen	%	0.1	10.0 – 100.0
Mech VT	Mechanical Tidal Volume	mL	1	0 - 4000
Spont VT	Spontaneous Tidal Volume	mL	1	0 - 4000
Set Minute Vol	Set Minute Volume	L	0.1	0.0-99.9
Total Minute Vol	Total Minute Volume	L	0.1	0.0-200.0
Mech Rate(bpm)	Mechanical Rate in bpm	bpm	1	0 - 999
Mech Rate(Hz)	Mechanical Rate in Hz	Hz	1	0 - 999
Spont Rate(bpm)	Spontaneous Rate in bpm	bpm	1	0 - 999
PIP	Peak Inspiratory Pressure	cm H_2O	0.1	0.0 – 100.0
MAP	Mean Airway Pressure	cm H_2O	1	0 – 999
Itime (sec)	Inspiratory time	sec	1	0 – 10
Itime (%)	Inspiratory time	%	1	0 – 99
PEEP	Positive End Expiratory Pressure	cm H_2O	1	0 – 99
CPAP	Continuous Positive Airway Pressure	cm H_2O	1	0 – 99
BIPAP(I)	Bi-level Positive Airway Pressure (Inspiratory)	cm H_2O	1	0 – 99
BIPAP(E)	Bi-level Positive Airway Pressure (Expiratory)	cm H_2O	1	0 – 99
PS	Pressure Support	cm H_2O	1	0 – 99
PC	Pressure Control	cm H_2O	1	0 – 99
Pulse Ox	Pulse Oximeter	%	1	0 – 100
Flow	Flow	LPM	1	0 – 999
Amplitude	Amplitude	cm H_2O	1	0 – 100
Delta P	Delta P	cm H20	1	0 – 100
High PEEP	High Positive End Expiratory Pressure	cm H_2O	1	0-99
Low PEEP	Low Positive End Expiratory Pressure	cm H_2O	1	0-99
IPAP	Inspiratory Positive Airway Pressure	cm H_2O	1	0-99
EPAP	Expiratory Positive Airway Pressure	cm H_2O	1	0-99
ASV	Adaptive Support Ventilation	% Support	1	0-99
PAV	Proportional Assist Ventilation	% Support	1	0-99
Nitric Oxide	Nitric Oxide	ppm	1	0-80

System Components and Features

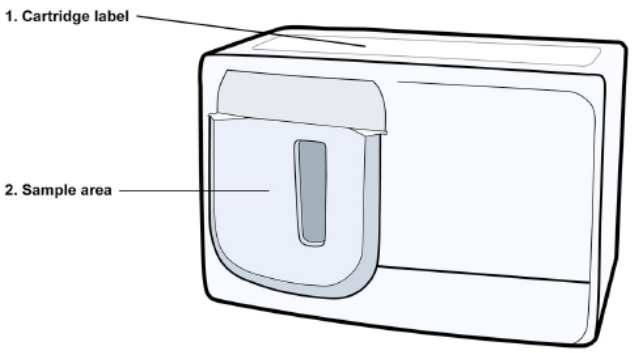
The GEM Premier 5000 system has two primary components: the GEM Premier 5000 analyzer and a disposable, multi-use GEM PAK. These components are described in the following paragraphs.

GEM Premier 5000 Analyzer

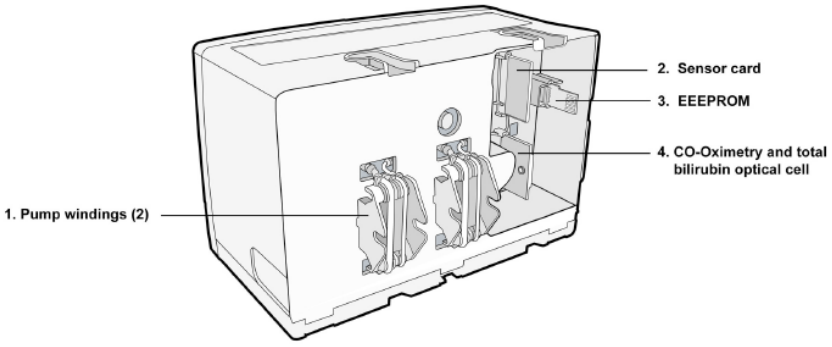
The GEM Premier 5000 system employs a unique color touch screen and a simple set of menus and buttons for user interaction. The analyzer guides operators through the sampling process with simple, clear messages and prompts.

GEM Premier 5000 GEM PAK

The primary component of the GEM Premier 5000 system is the GEM Premier 5000 PAK (or GEM PAK). The disposable, multi-use 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 PAK has flexible menus and test volume options to assist facilities in maximizing efficiency.



The values of all solutions are read from the GEM PAK EEPROM. The components and processes used to manufacture the solutions in the GEM PAK are traceable to NIST standards whenever possible. For those analytes where NIST materials are not available, primary analytical procedures are used, such as, CLSI. Safety Data Sheets (SDS) for GEM PAKs can be requested through Customer Support at Instrumentation Laboratory.



The setup of the instrument consists of inserting the GEM PAK into the instrument. The instrument will perform an automated PAK start-up during which the following is performed: warm-up (15 minutes), sensor conditioning (10 minutes), PCS performance (15 minutes), all of which take about 40 minutes. During start-up, the instrument requires no user intervention.

After GEM PAK start-up, Auto PAK Validation (APV) 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), are run by the analyzer to validate the integrity of the Process Control (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 CVP 5 tBili (Calibration Valuation Product), an external, ampoule-based product prior to measuring samples for tBili.

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

The GEM Premier 5000 automatically notifies operators when it is time to remove the GEM PAK; when sample capacity has been reached, or when GEM PAK use life expires. The internal waste bag, which collects used blood and solutions throughout GEM PAK life, reduces biohazard exposure.

The Instrumentation Laboratory GEM Premier 5000 system may be used with a variety of GEM Premier 5000 GEM PAKs of various menu and size configurations. The screens that are pictured in this manual are appropriate for the full menu of test capabilities. If other GEM PAKs are used, the options on the screens will be relative to the GEM PAK installed. Specifically, the QuickStart buttons and Patient Results screens will reflect only those tests that the installed GEM PAK is able to perform. Basic operation of the analyzer is the same for all GEM PAKs, and the information in this manual applies to operation with all GEM PAKs.

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3 - GEM Premier 5000 System Overview

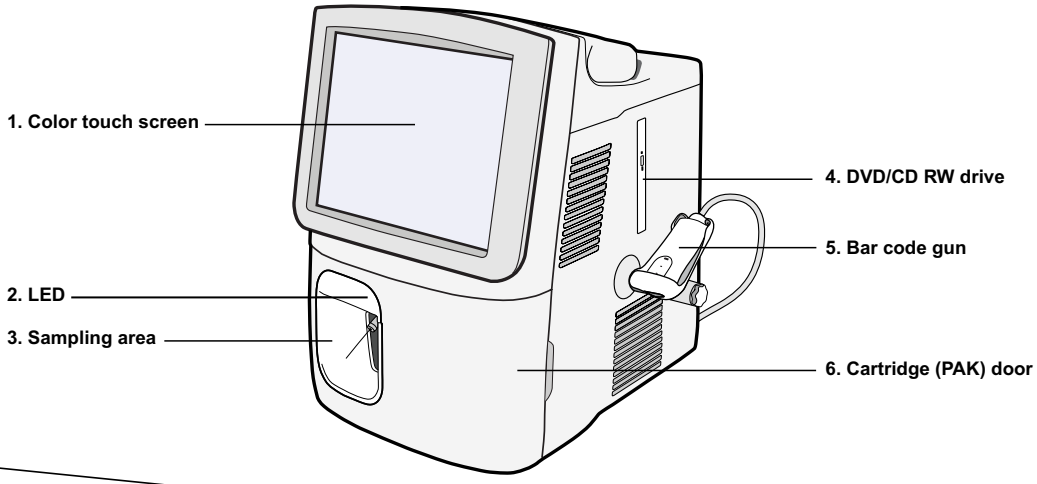
The Instrumentation Laboratory GEM Premier 5000 system with Intelligent Quality Management 2 (iQM2) is an advanced, critical care system used by health care professionals to analyze heparinized whole blood samples in centralized or point-of-care clinical settings. It provides measured results for pH, pCO_2, pO_2, hematocrit, sodium, potassium, ionized calcium, chloride, glucose, lactate, total bilirubin and CO-Oximetry, enabling you to perform critical types of testing from one sample.

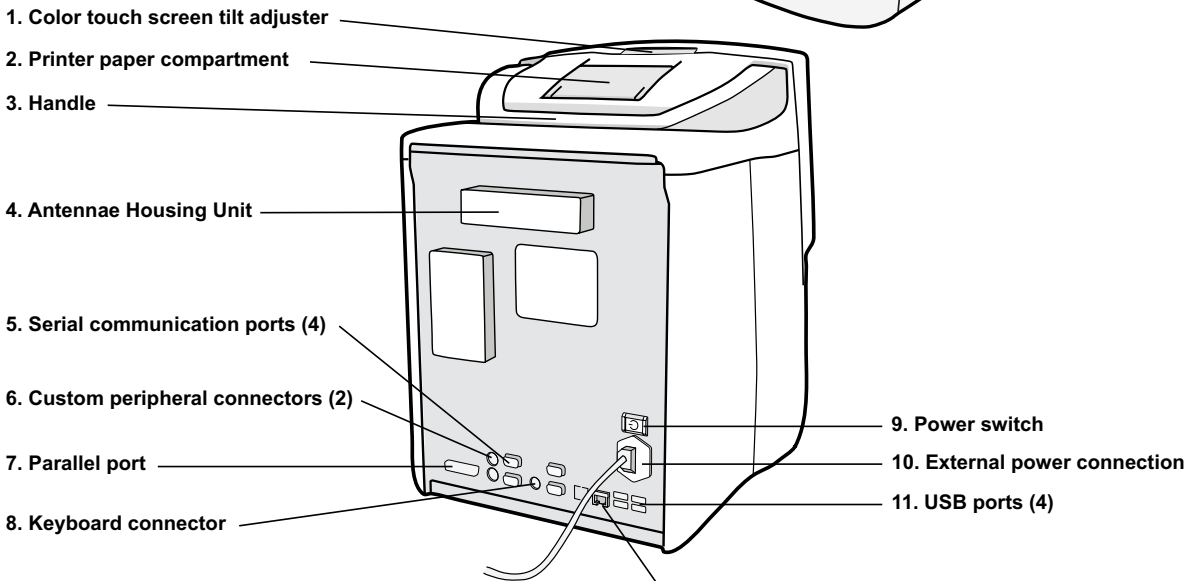
Key Components of the GEM Premier 5000 System

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.





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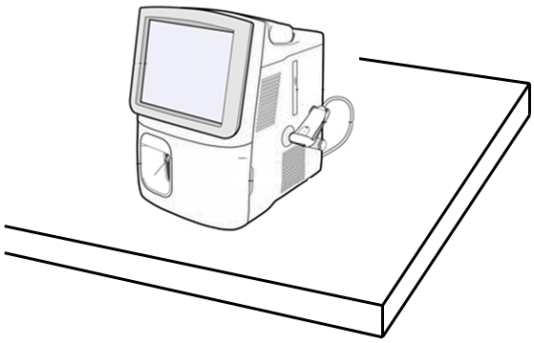
Installing the GEM Premier 5000 Analyzer

Preparing the analyzer for use



The GEM Premier 5000 system is designed for reliable operation in centralized laboratory and patient care settings. It can be used on a horizontal workbench or desktop and on a cart for use in multiple settings.

Place the instrument on a stable surface in a convenient location. Connect the power cord to the power module. Then connect the plug to a grounded electrical supply. Briefly press and release the power switch on the back left side of the instrument to turn it ON.

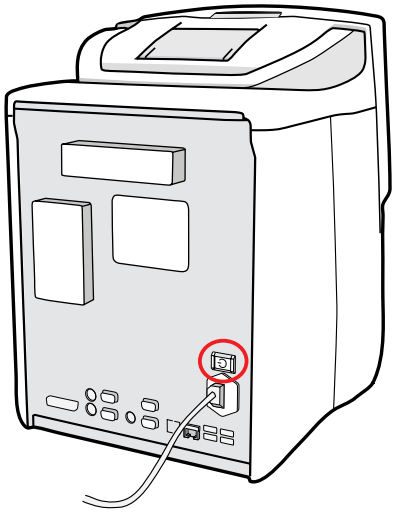
NOTE: The instrument is to be connected to power using the 3-wire detachable line cord supplied (part number 00014882100 for 115 VAC and part number 00019725500 for 220 VAC). The power supply will automatically sense the voltage when plugged in.

The instrument is protected by a 3 Amp fuse located in the power entry module, and no changes are required to the fuse for any of the acceptable line voltages.

The analyzer has a momentary power switch. When the instrument is in the power off state and the switch is pressed and released, the instrument will begin a power on cycle.

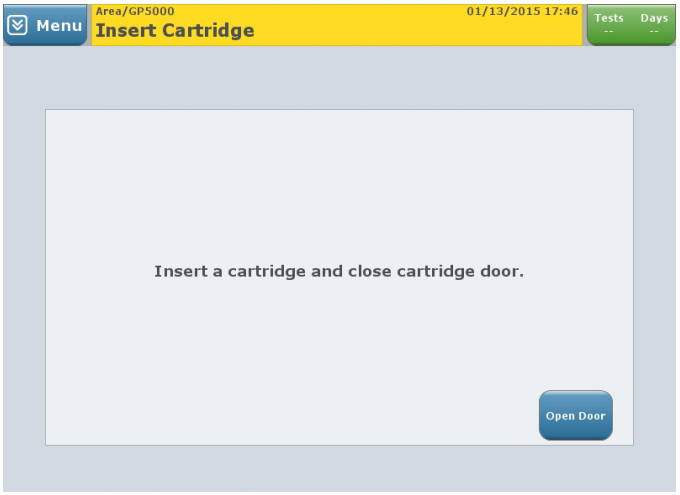
Setting Up the Analyzer

1. 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.

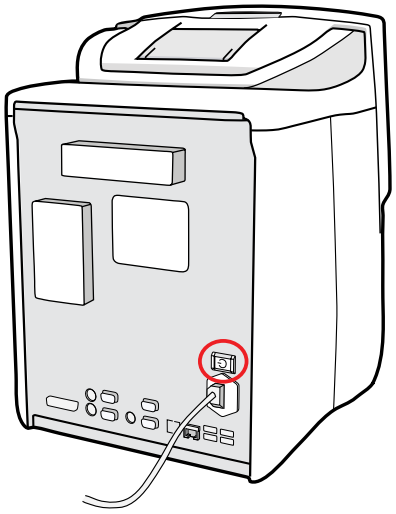


2. The analyzer will enter a self-diagnostic mode.

3. When self-diagnostic mode is completed the Insert Cartridge screen is displayed.
4. Press “Open Door”.



5. Remove the shipping cartridge by grasping it on both sides and pulling it straight out of the analyzer. Save this cartridge in case the analyzer must be shipped back to IL.
6. If barcode gun has been connected previously, skip to configuring the GEM Premier 5000 Analyzer section below. Select the Menu button, and press Shut Down. Remove the power cord.
7. Connect the barcode gun to the appropriate custom peripheral port on the back of the analyzer.
8. Reconnect the power cord to the power module. Then connect the plug to a grounded electrical supply. Press the power switch to turn it ON. The system will automatically begin the power-up cycle.



Configuring the GEM Premier 5000 Analyzer

The GEM Premier 5000 Configuration function is launched automatically the first time you start up the analyzer or server. You may also return to the Configuration settings at any time during the operation of your system.

Contact your facility's IT support personnel or IL representative to help you determine the appropriate configuration for your analyzer or network.

Installation Set-Up

Out-of-box Configuration for GEM Premier 5000 system

The Installation Setup wizard is used to configure an out-of-the-box GEM Premier 5000 system as a standalone analyzer, or, if a GEMweb Plus network is to be setup, as a client-analyzer. Setup can also be used to configure a GEMweb Plus server.

Note: Installation setup requires that a cartridge is not inserted into the instrument.

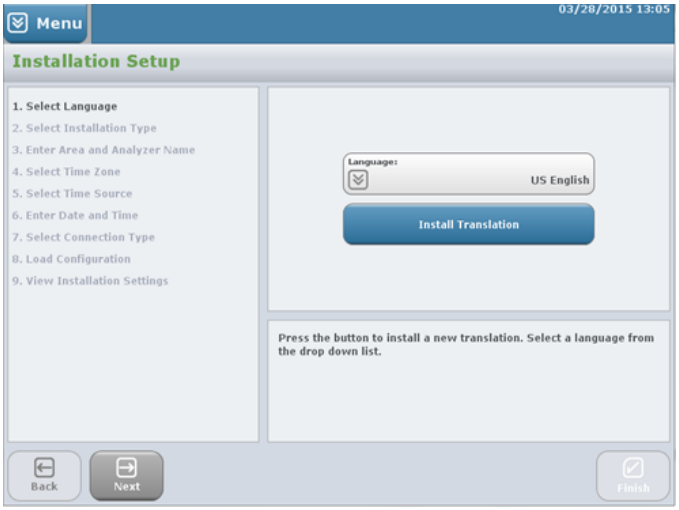
When setting up a GEMweb Plus network consisting of several instruments, the sequence of installation is as follows:

1. Install the server completely before connecting any client analyzers.
2. Install the client analyzers and connect them to the server one at a time.
3. If you are replacing an existing client-analyzer, disconnect and delete it from the server before installing the replacement analyzer.

Note: The Installation Setup wizard will appear on screen the first time you power up your GEM Premier 5000 system. The left-hand side of the screen shows the steps necessary for configuration, and help text is provided in the box in the lower right-hand side. You can also access the Installation Setup wizard at any time through the Menu by selecting Management (or GEMweb Plus) > Configuration > Tab 3 (or Analyzer) > Installation Setup.

Configuration Steps

1. Select your language from the drop-down menu. If your language is not shown in the drop-down, select the Install Translation button instead. Press Next to continue.



2. Select the type of installation you wish to perform: Standalone Analyzer, GEMweb Plus Client Analyzer, or Replace an Existing GEMweb Plus Client Analyzer. Press Next to continue.
3. Analyzers can be organized into areas, which can be set up to represent different departments of the hospital (ICU, CCU, ED, etc.).
   a. Select Area and enter an area name using either the on-screen keypad or the external keyboard (if attached). Press Enter when finished.
   b. Select Analyzer and enter an analyzer name. Press Enter when finished.
   c. When names have been entered for the area and analyzer, press Next to continue.
4. Select the time zone in which the analyzer will be used.
   a. Select the region from the Region drop-down menu.
   b. Select the district from the District drop-down menu.
   c. Press Next to continue. Regional settings cannot be changed unless the Installation Setup process is repeated. The system will automatically adjust for daylight savings time.

   Note: This function allows you to set whether or not to use an external time server to update the clock on the analyzer.
5. Select Use External NTP Time Server to enable this function.
6. If using an external time source enter either the Host Name or IP address of the time server.
7. Set the date and time.
   a. Select Date and key-in the current date using the on-screen keypad or external keyboard; press Enter.
   b. Select Time and key-in the current time; press Enter.
   c. Press Next to continue. Set the date and time is available when 'Do Not Use External NTP Service' is selected. Any changes made to the time or date will not take effect until the analyzer is restarted.
8. Set the connection type; there are three options:
   - The Analyzer Will Not Be Connected to the Network
   - Use Wired Connection
   - Use Wireless Connection
9. **Load Configuration**
   This step allows you to use an instrument configuration copied from a "reference" instrument to other standalone instruments. This eliminates having to enter

configuration parameters on each standalone instrument being installed. If you chose to Load Configuration you will be prompted to insert you configuration disc or USB device after you press **Finish**.

10. **View Installation Settings**
    This step allows you to review all of the settings before pressing Finish. If any entries are in error you can use the Back button to change the incorrect entry.

11. Press Finish to complete the installation. When you press Finish, a dialog box will appear showing "Press OK to restart to complete setup." You must restart the analyzer to activate any changes that were made to the configuration. Press Cancel only if you wish to make additional changes before restarting.

Configuration Set-Up

Making Adjustments to configuration of GEM Premier 5000 system

In most cases, Configuration will be restricted to Supervisor level accesses, and it is also important to keep in mind that changes to Configuration settings may require you to restart your analyzer or server.

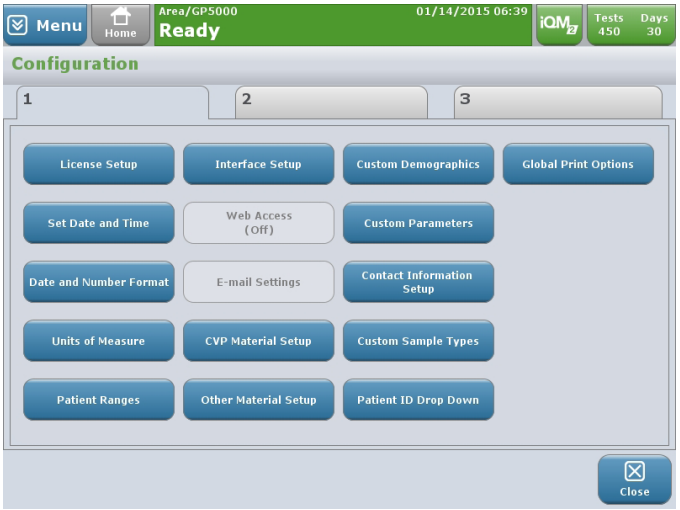
Configuration can be accessed via the following paths, depending on how your system is set up.

- For standalone analyzers: Menu > Management > Configuration
- For networked analyzers: Menu > GEMweb Plus > Management tab > Configuration or Menu > Management > Analyzer > Configuration
- For servers, from the GEMweb Plus Home screen: Management tab > Configuration Refer to the GEMweb Plus Operator's Manual for additional navigation pathways

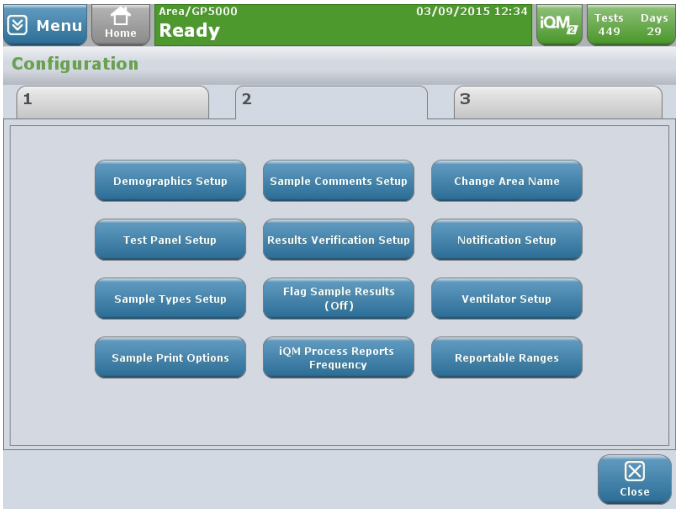
The Configuration screen has three tabs.

- For standalone analyzers, they are denoted Tab 1, Tab 2, and Tab 3;
- For networked analyzers, they are denoted Global, Area, and Analyzer.

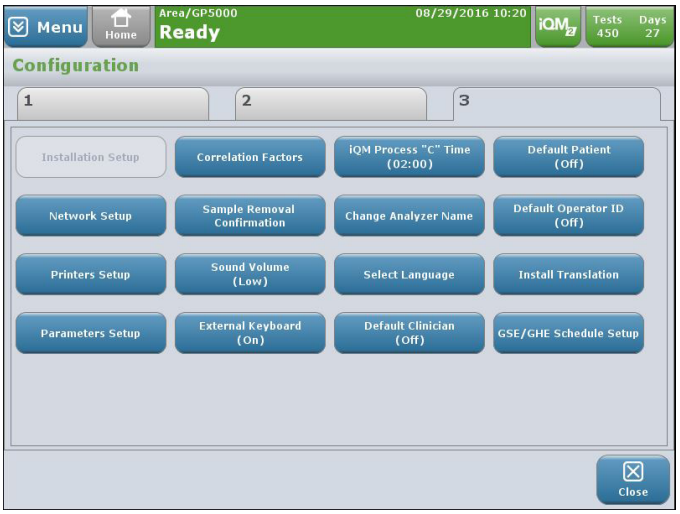
The Tab 1 (Global tab) affects settings that apply to the entire GEMweb Plus network.



The Tab 2 (Area tab) affects settings that can be applied to specific areas.



The Tab 3 (Analyzer tab) affects local settings for individual analyzers.

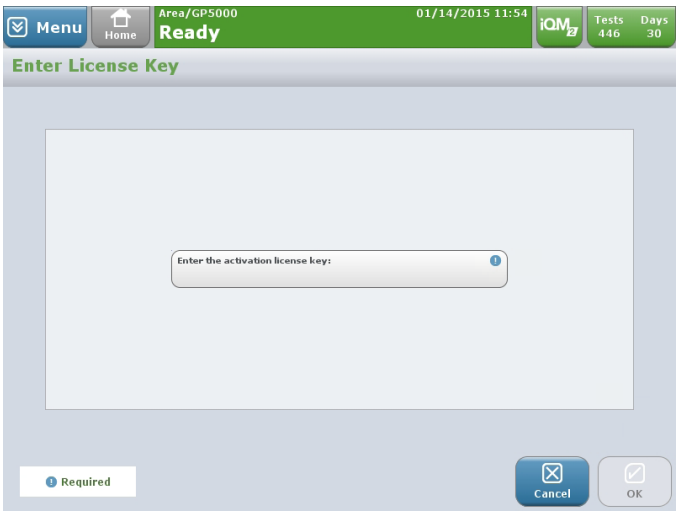


A. Making Adjustments to Tab 1 (Global Tab)

Some configurations/settings will apply only to standalone analyzers or networked analyzers.

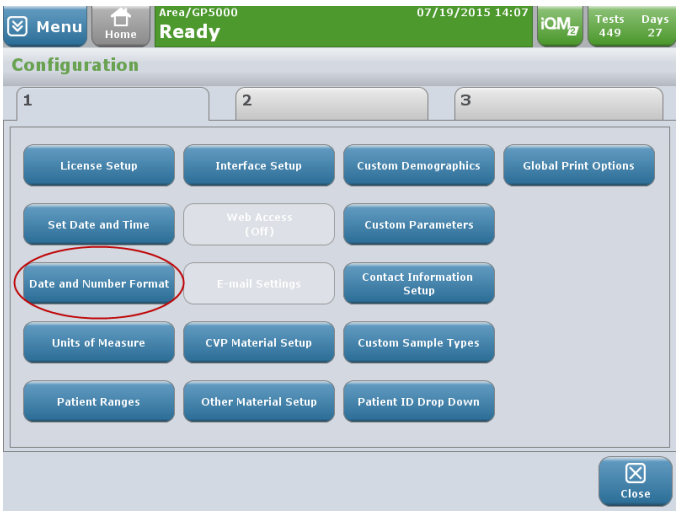
1. **Manage Areas** (GEMweb Plus Only)
   - a. Select Manage Areas
   - b. Select Add Area and enter name for new Area
   - c. Press OK.

2. **License Setup**
   - a. Select License Setup
   - b. License key from IL is required to activate the following:
     - GEMweb for GEM Premier 5000 standalone analyzer
     - GEMweb Plus
     - Number of Instrument connections to GEMweb Plus
   - c. After entering License press OK.

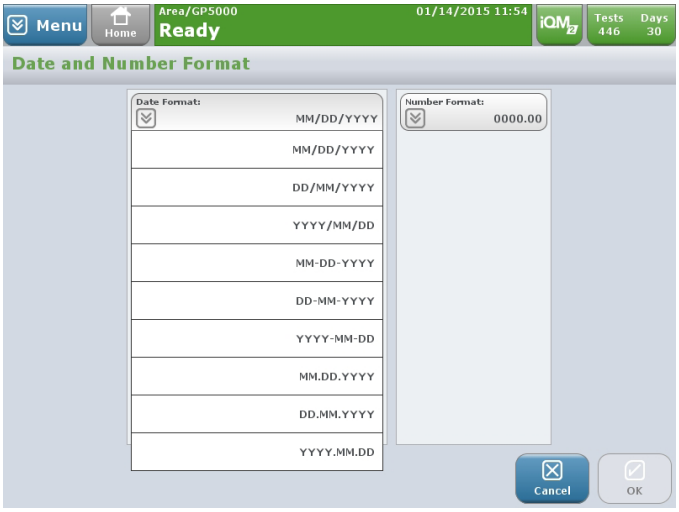


3. **Date and Numbers Format Setup** (standalone analyzers or GEMweb Plus Server)

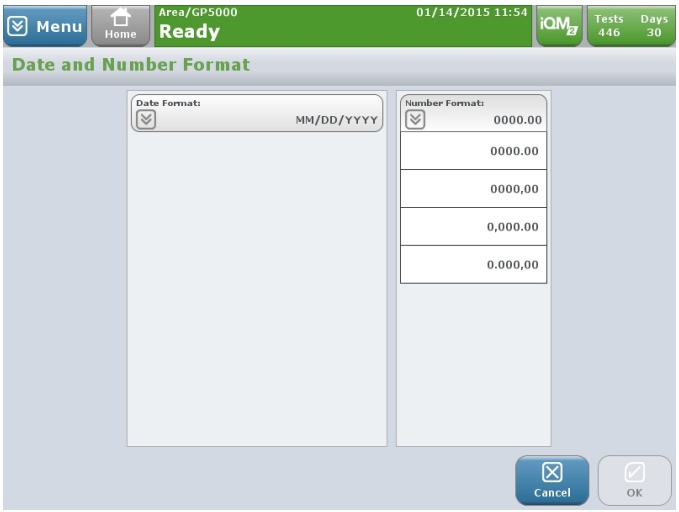
   a. Select Date and Number Format



   b. Select Date Format from pull-down menu

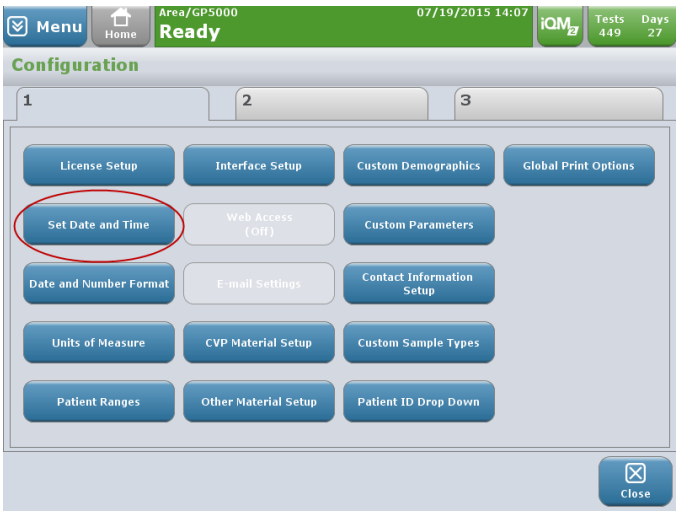


   c. Select Number Format from pull-down menu. Press OK when complete.

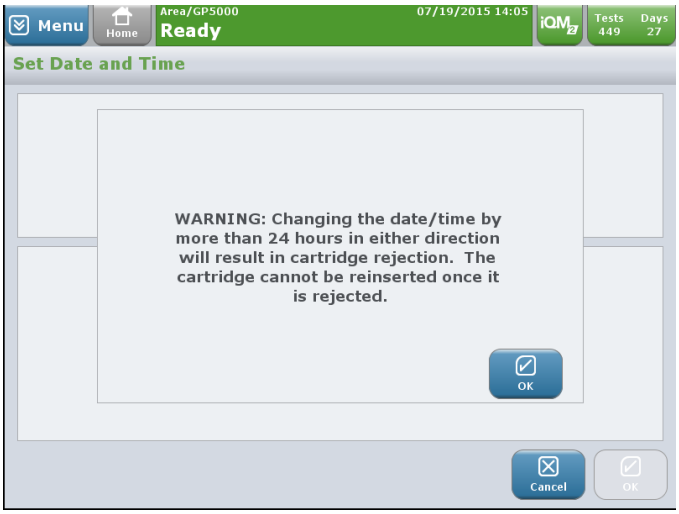


4. Set Date and Time Setup

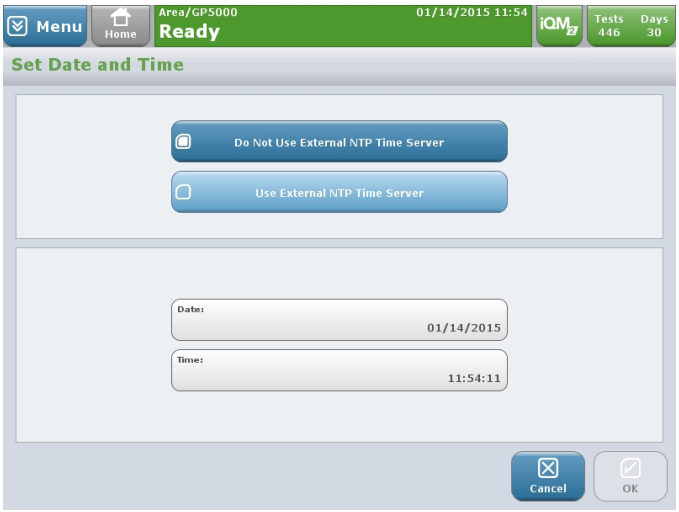
a. Select Date and Time



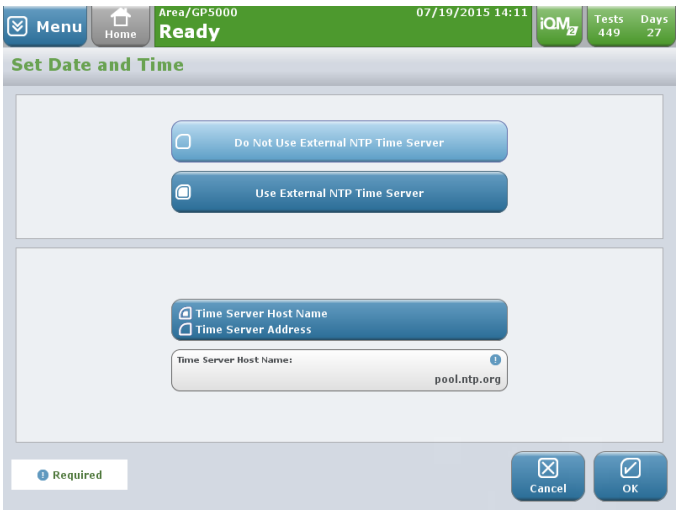
b. Warning message will appear about the effect of changing date/time and possible cartridge rejection. Select OK.



c. The default selection is “Do Not Use External NTP Time Server”. If this is acceptable go to Date and enter the correct date and time. Press OK when Finished.

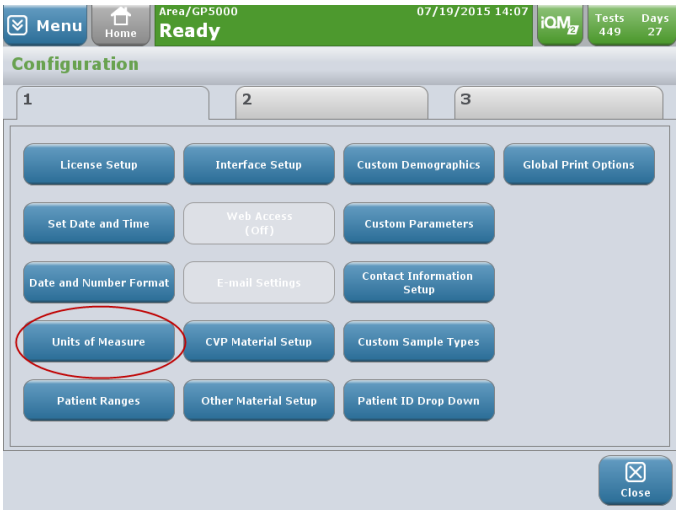


d. If “Use External NTP Time Server” is chosen enter the Time Server Host Name or the Time Server IP Address. The default Time Server Host Name is: pool.ntp.org. This can be changed to the source utilized by the institution. The Date format can be configured using the Date and Number Format setting in the Tab.



5. Units of Measure Setup

a. Select Units of Measure



b. Select Parameter Group from the listing on the left side of screen.

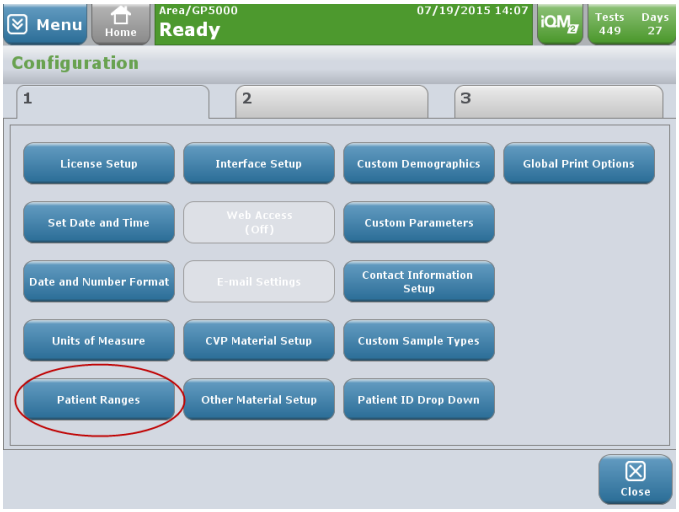
c. Select the units from the pull-down menu on the right side of the screen.

d. Select OK.

6. Patient Ranges Setup

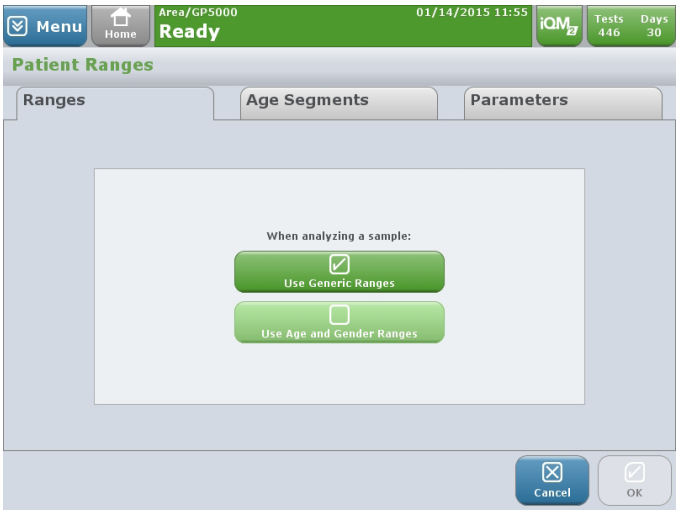
The Patient Ranges function allows you to set the reference and critical range limits for sample data based on either a generic range or an age and gender based range. Sample results will be checked against an age and gender based range only if a range has been configured and if both the patient age and gender have been entered into the system. Otherwise, sample results will be checked against a generic range, if one has been configured. If no range has been configured, the sample results will not be checked against a range.

a. Select Patient Ranges



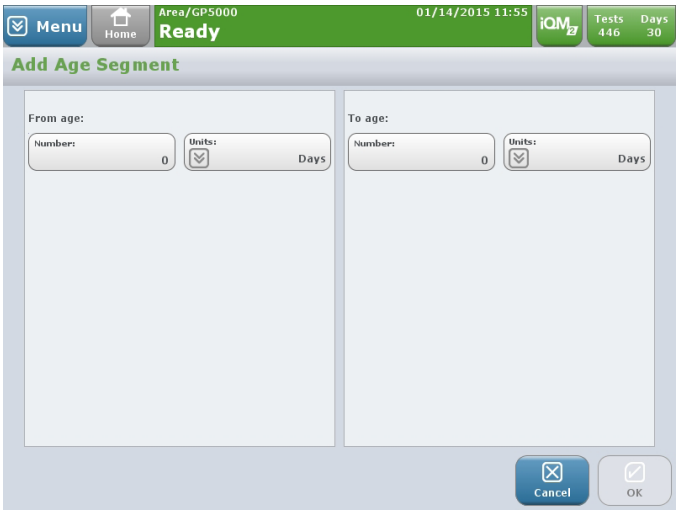
b. In the Ranges tab, select the ranges to be configured:

- Use Generic Ranges
- Use Age and Gender Ranges
- You may choose either, both, or neither. If the third option, Print Ranges with Results, is selected; applicable ranges will be printed at the end of patient sample reports.



c. Age Tab In the Age Segments tab, you may add an age segment, edit existing segments, or delete a segment.

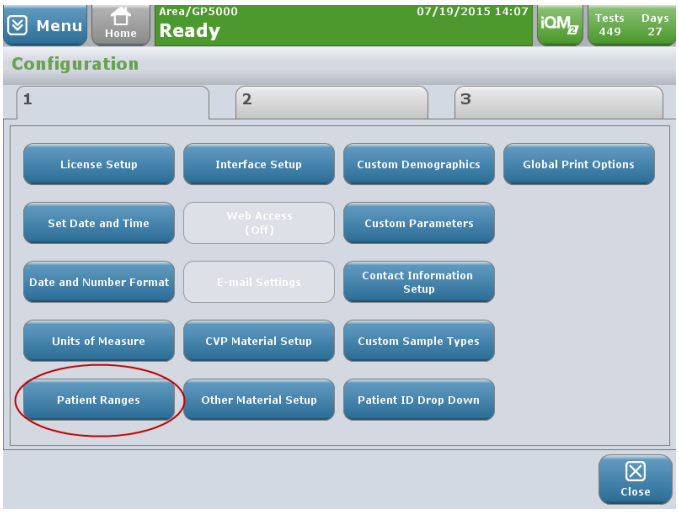
- Select Add Age Segment and you will be prompted to enter a number and units for both the From Age and the To Age
- Press to select the number field, enter age (digits).
- Select the units from the pull-down menu.
- Press OK.



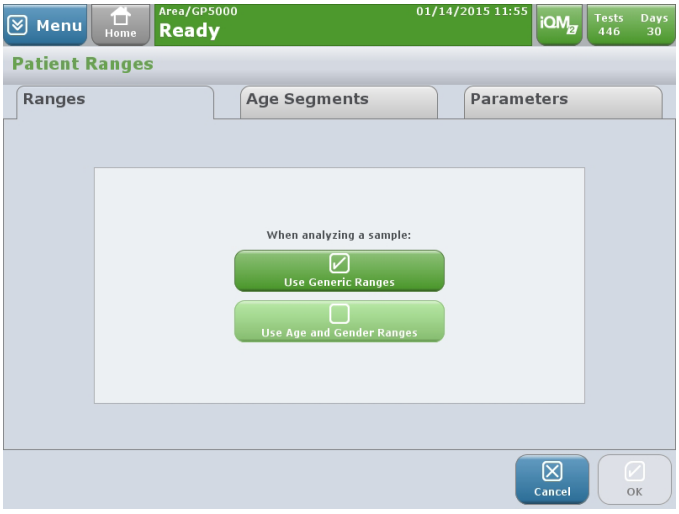
Note: Entered Age Segments can be edited or deleted.

d. Editing Measured Ranges

1.) Select Patient Ranges



2.) Select Parameter tab.



3.) Select Range Type, Age Segment, and Sample Type from the corresponding drop-down menus on the left of the screen.

4.) Enter critical and reference limits by selected a numerical field and then entering in value of the limit.

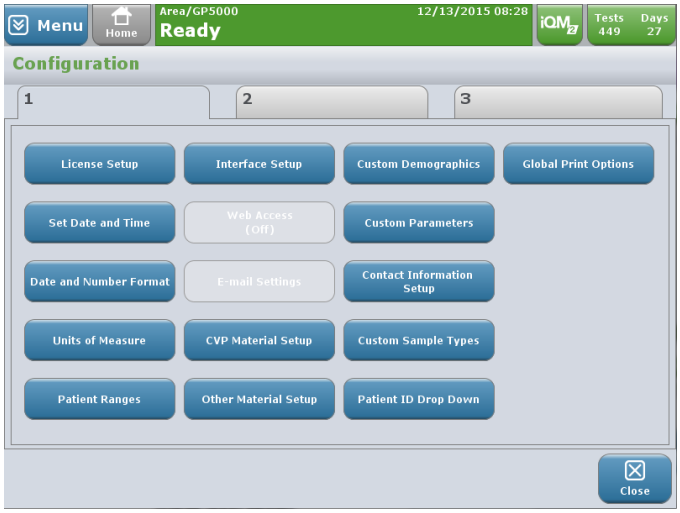
5.) Press OK.

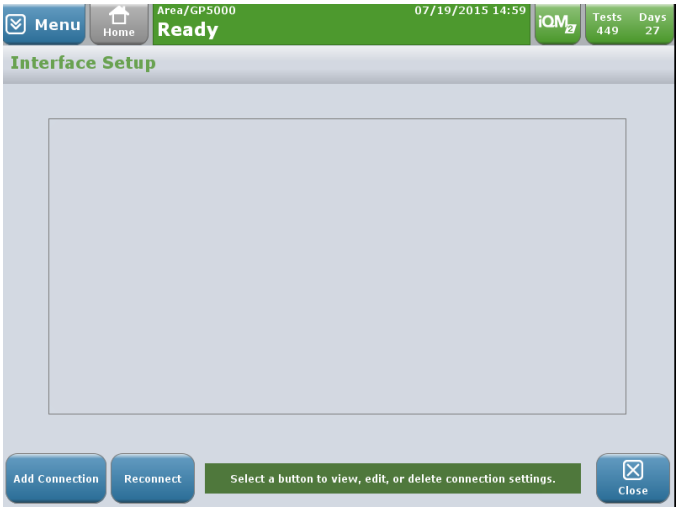
Note: Ranges for derived parameters are edited in the Parameter tab too. Derived parameters are calculated using equations applied to one or more measured analytes.

7. Interface Setup

The Interface Setup function allows you to set up and configure the analyzer or server's connections to external devices (such as DMS or HIS/LIS systems). Press Add Connection to create a new connection. This will launch a wizard to guide you through the setup process. The steps for adding a connection differ based on the type of connection that is selected: Serial or TC P/IP.

a. Select Interface Setup

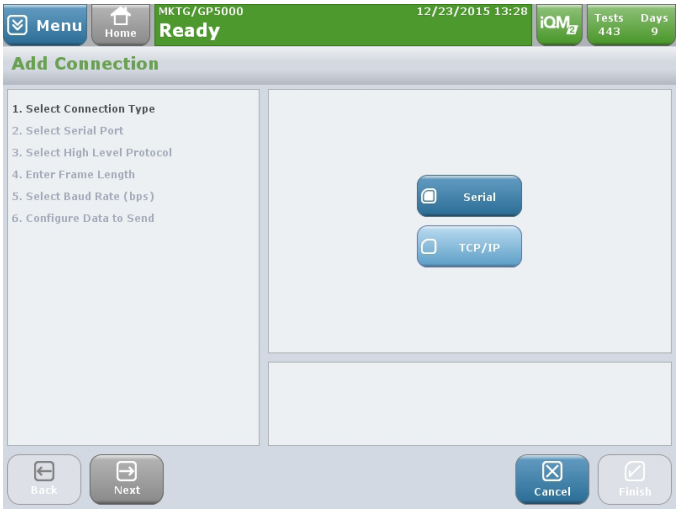


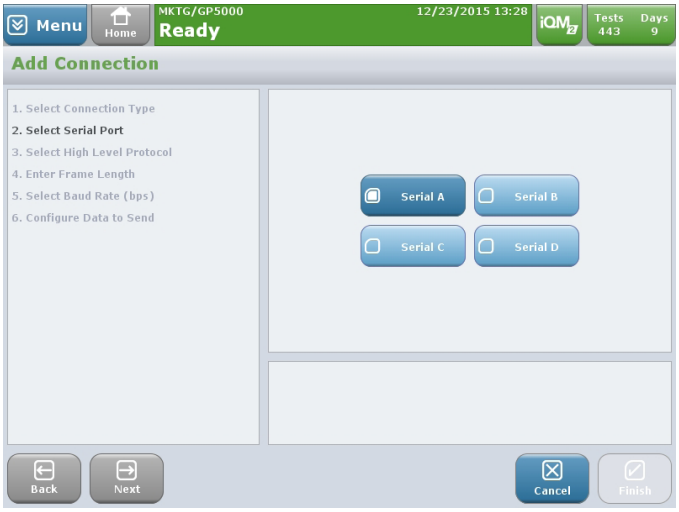


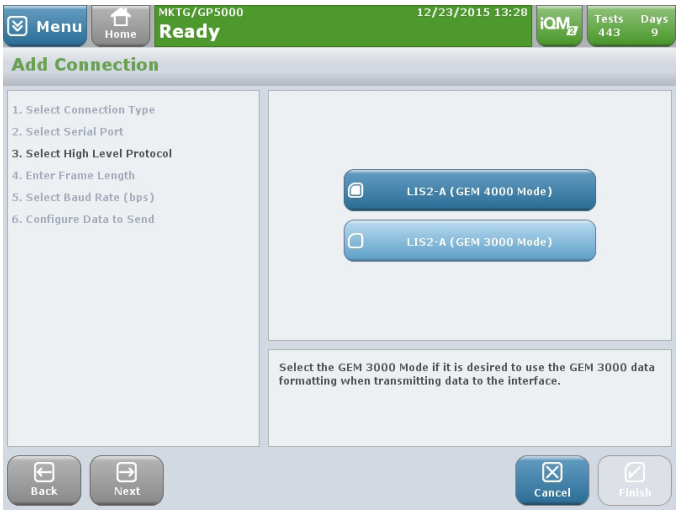
Refer to the desired connection type below.

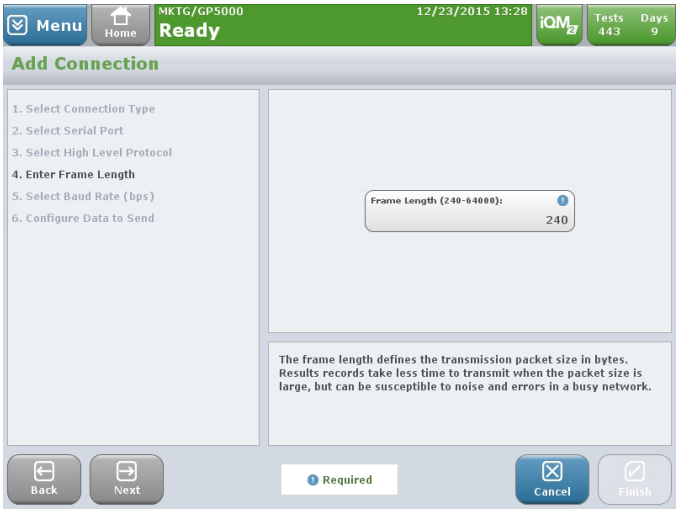
b. Configure a Serial Connection, only if configured as a standalone analyzer.

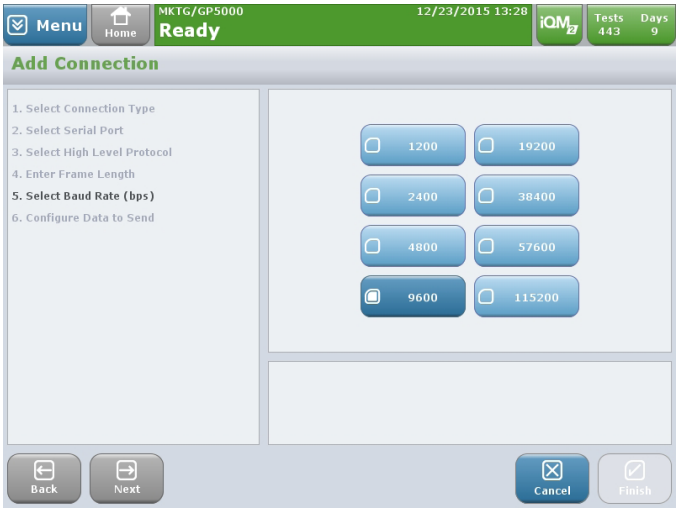
- Select Serial Connection
- Select one of the four serial ports (A, B, C or D)
- Select a high-level protocol, LIS2-A (GEM 4000 Mode), or LIS2-A (GEM 3000 Mode)
- Select the frame length from the drop-down menu
- Select the appropriate baud rate.
- Select the type of data to be transmitted.
- Select Finish.

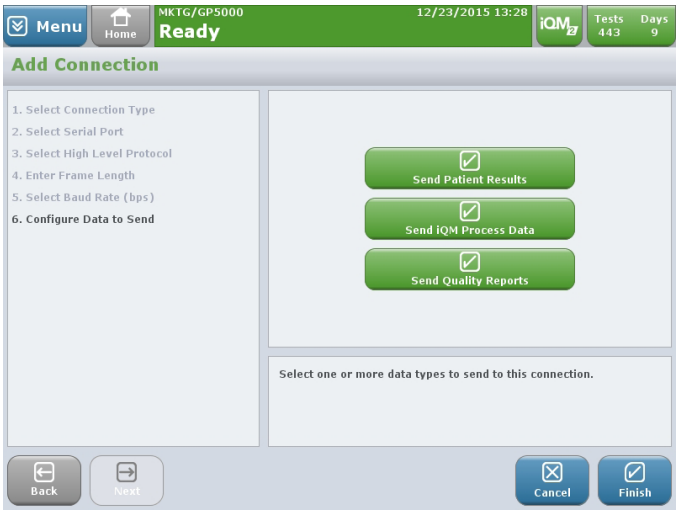






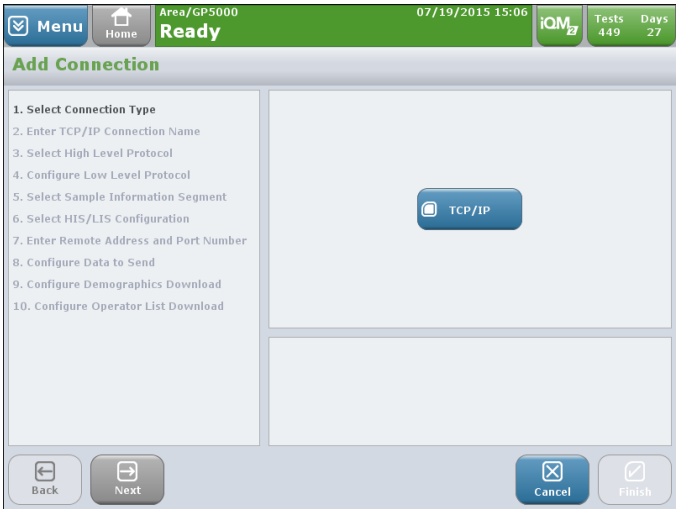

Menu
Home
MKTG/GP5000
Ready
12/23/2015 13:28
iQM2
Tests 443
Days 9
Add Connection
1. Select Connection Type
2. Select Serial Port
3. Select High Level Protocol
4. Enter Frame Length
5. Select Baud Rate (bps)
6. Configure Data to Send
Frame Length (240-64000):
240
The frame length defines the transmission packet size in bytes. Results records take less time to transmit when the packet size is large, but can be susceptible to noise and errors in a busy network.
Back
Next
Required
Cancel
Finish


Menu
Home
MKTG/GP5000
Ready
12/23/2015 13:28
iQM2
Tests 443
Days 9
Add Connection
1. Select Connection Type
2. Select Serial Port
3. Select High Level Protocol
4. Enter Frame Length
5. Select Baud Rate (bps)
6. Configure Data to Send
1200
19200
2400
38400
4800
57600
9600
115200
Back
Next
Cancel
Finish


Menu
Home
MKTG/GP5000
Ready
12/23/2015 13:28
iQM2
Tests 443
Days 9
Add Connection
1. Select Connection Type
2. Select Serial Port
3. Select High Level Protocol
4. Enter Frame Length
5. Select Baud Rate (bps)
6. Configure Data to Send
Send Patient Results
Send iQM Process Data
Send Quality Reports
Select one or more data types to send to this connection.
Back
Next
Cancel
Finish

C. Configure a TCP/IP Connection

- Select TCP/IP connection.
- Enter name for the connection
- Select High Level Protocol to set instrument to use the ORI (HL-7 v2.4) or LIS2-A to use ASTM communication protocol



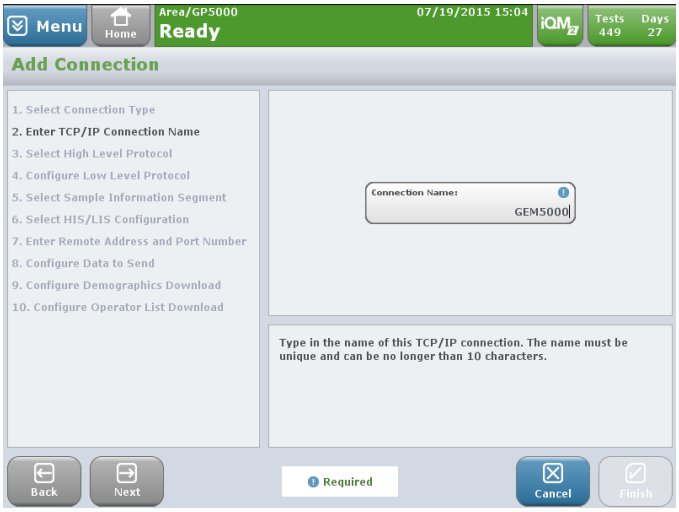
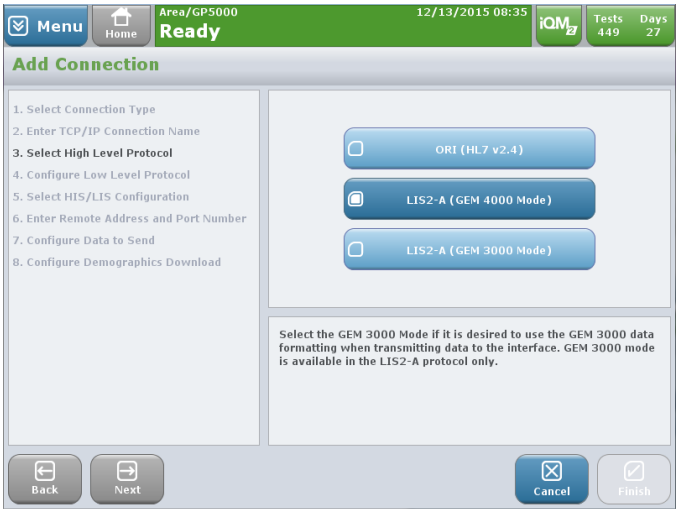
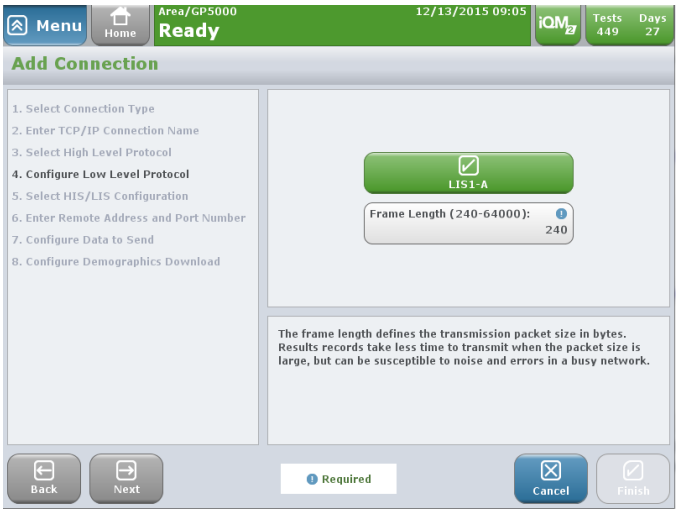


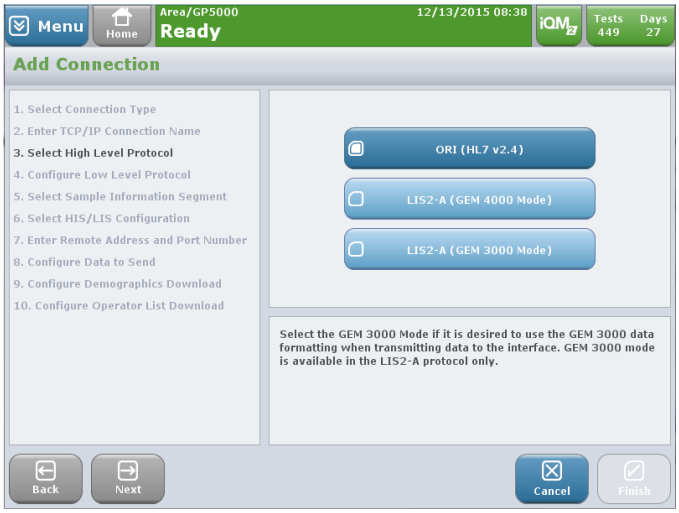
TABLE OF CONTENTS

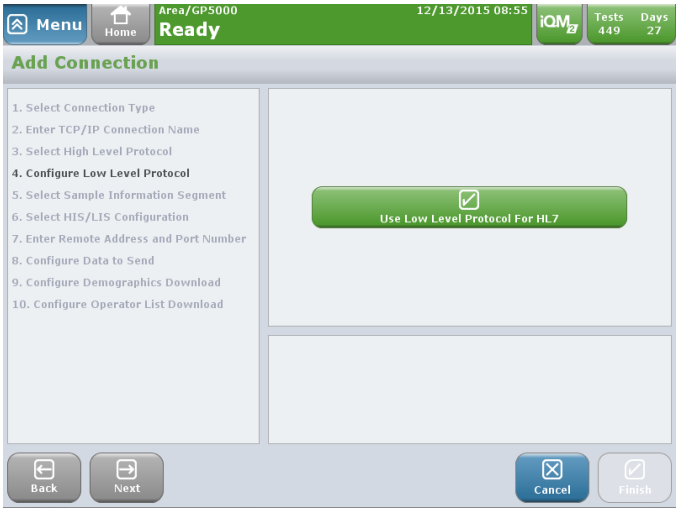
1.) If you selected LIS2-A Protocol (GEM 4000 Mode or GEM 3000 Mode), Configure Low Level Protocol and Frame Length to be used in transmitting data to the LIS/HIS.





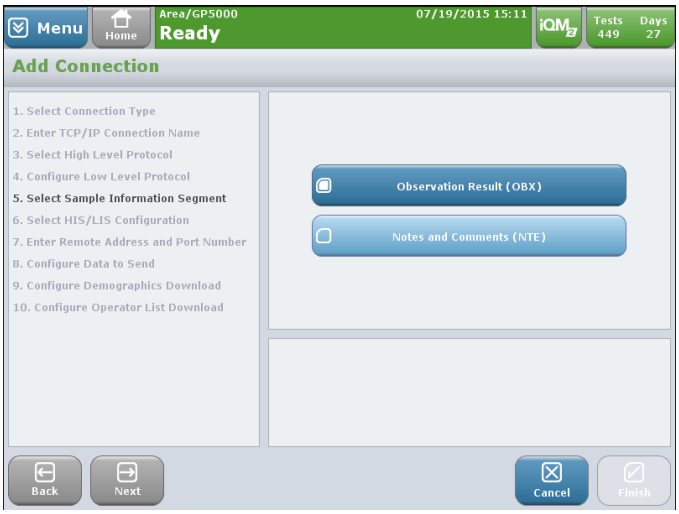
2.) If you selected ORI (HL-7 v2.4) Protocol, you have to enable Low Level Protocol depending on the requirements of your LIS/HIS.



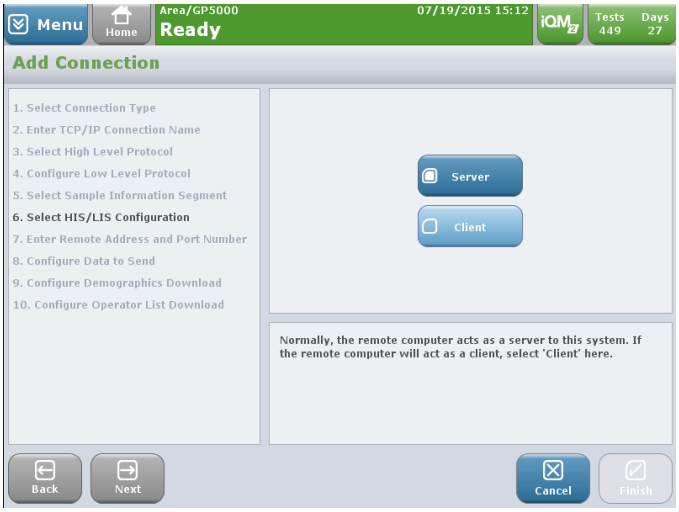


- Select Sample Information Segment

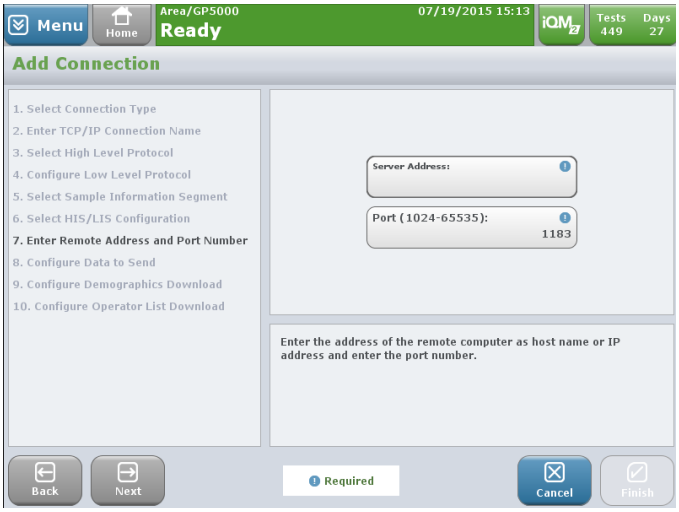
Note: This is dependent on your LIS/HIS requirements.



- Select HIS/LIS Configuration
- Select whether the HIS/LIS acts as a server or client to this connection.

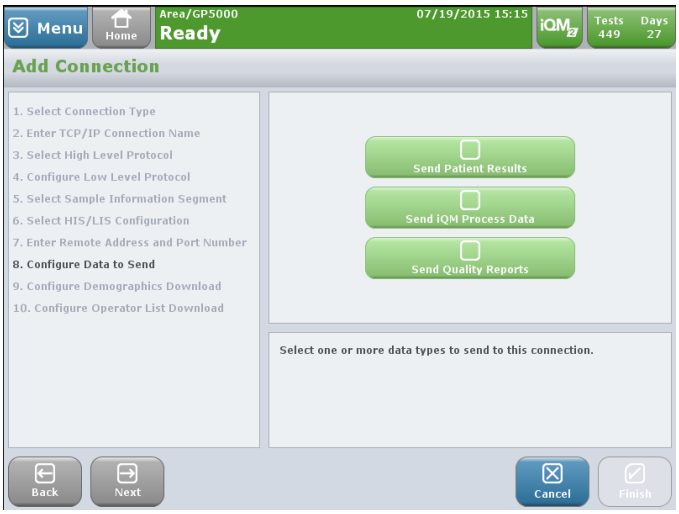


- Enter Remote Address and Port Number
- If you have a server, enter the IP Address of the LIS/HIS. The default port number is 1183 but may be changed if required.



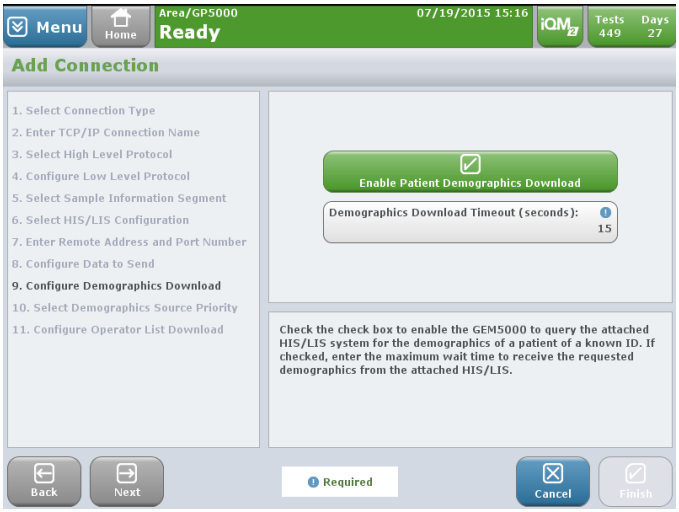
- Configure Data to Send

  Configure which type of information is required to be sent to the LIS/HIS.



- Configure Demographics Download

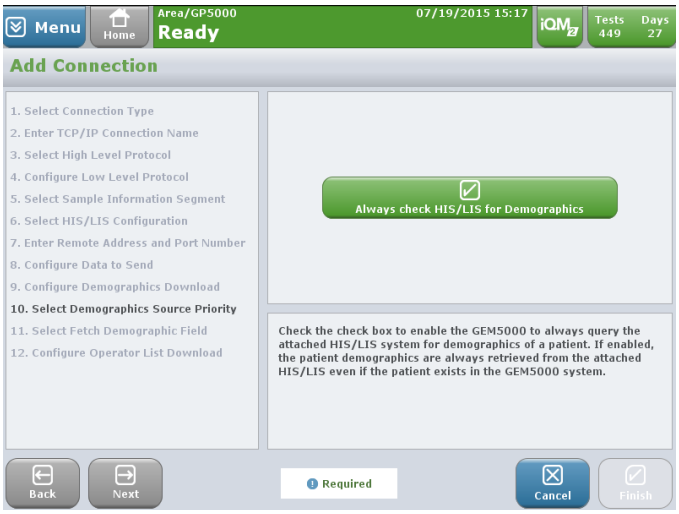
  This enables the GEM Premier 5000 analyzer to perform a query for patient demographic from the HIS/LIS.



Note: This function is available for only one TCP/IP connection, so it will be skipped if this feature has been enabled for another connection.

- Demographics Source Priority

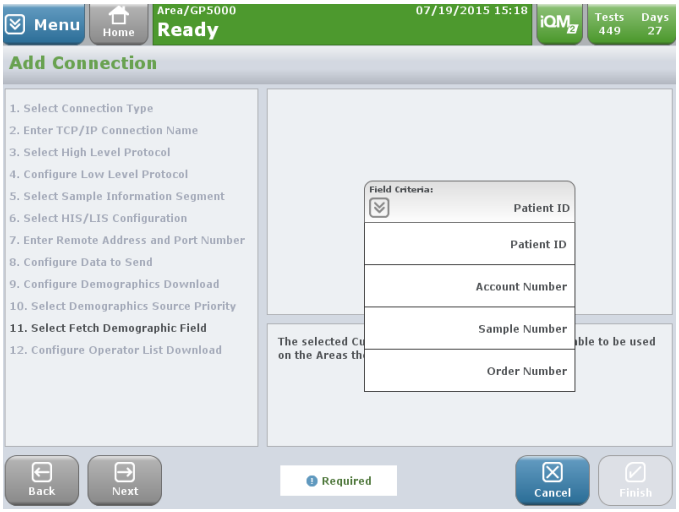
  This feature enables the GEM Premier 5000 system to always query the LIS/HIS for demographics of a patient.



Note: Query will occur if enabled on all patients even if patient data is present in the GEM Premier 5000 system.

- Select Fetch Demographic Field

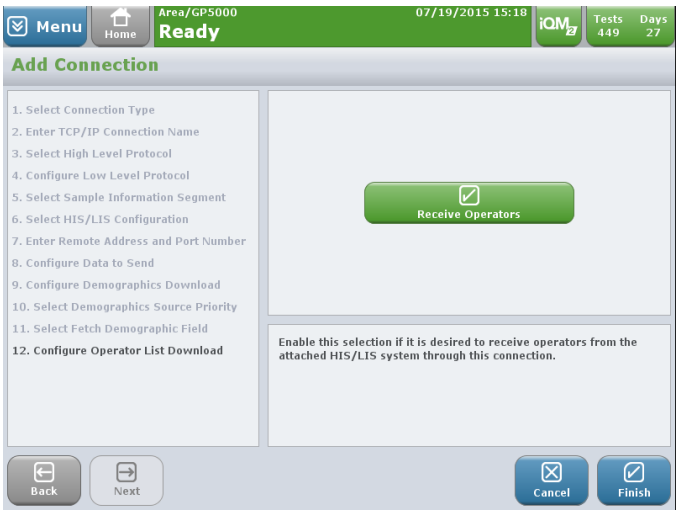
  The selected Custom Demographic Field from the drop-down list will only be able to be used on the Areas the demographic field is enable



- Configure Operator List Download

  Enable the receipt of operators from the HIS/LIS system

Note: Connections can be edited or deleted.



8. Web Access Setup

This feature is for networked analyzers only. Select Enable web access to allow operators to access network information through a standard web browser (such as Internet Explorer v7.0 and above).

9. Email Settings

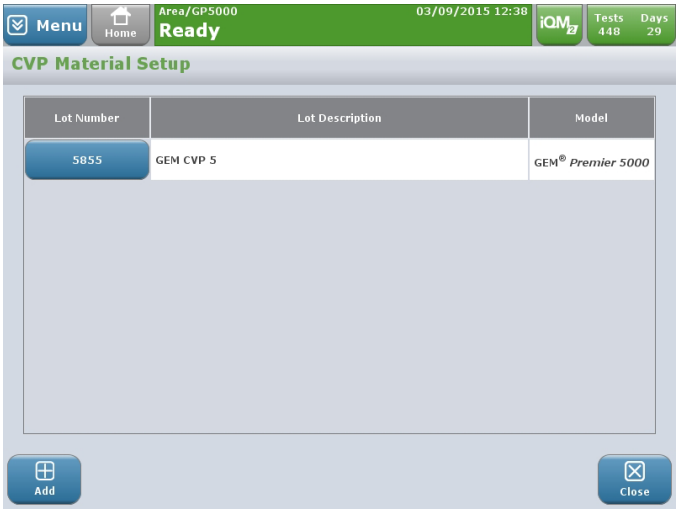
The email settings screen allows operators to add, modify or delete email configuration settings.

10. CVP 5 Material Setup

The CVP Material Setup is utilized to add new lots of CVP 5. When analyzers are networked, CVP 5 lots that are configured will be available on all networked analyzers. Each box of CVP 5 contains a package insert that includes a 2D barcode which defines the attributes of the material. CVP 5 material data will be entered by scanning this 2D barcode.

- Select Add from the CVP Material Setup Screen.

Note: To review an existing CVP 5 lot, select the desired lot by pressing the Lot Number button.



- Scan the 2D barcode when the CVP 5 Material Information screen appears

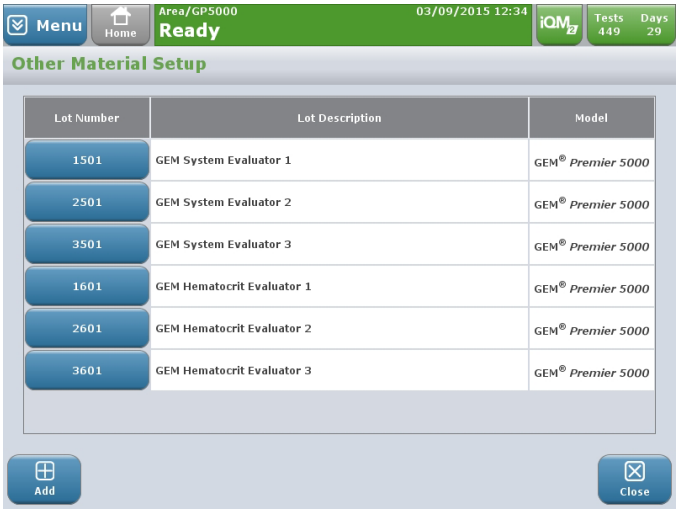
The data fields will reflect the values provided on the barcode. Press OK when complete.

11. Other Material Setup

The Other Material Setup is utilized to add new lots of GEM System Evaluator (GSE) and GEM Hematocrit Evaluator (GHE). When analyzers are networked, GSE/GHE lots that are configured will be available on all networked analyzers. Each box of GSE/GHE contain a package insert that includes a 2D barcode which defines the attributes of the material.

- Select Add from the Other Material Setup Screen.

Note: To review existing GSE/ GHE lots, select the desired lot by pressing the Lot Number button.



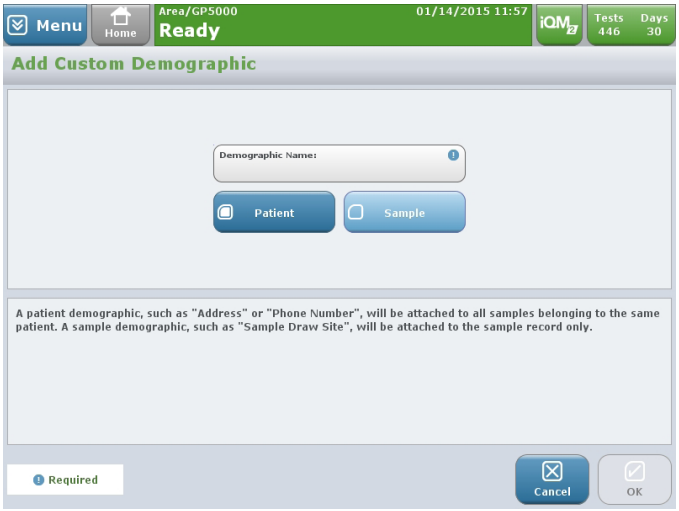
- Scan the 2D barcode when the GSE/GHE Material Information screen appears

- The data fields will reflect the values provided on the barcode. Press OK when complete.

12. Custom Demographics

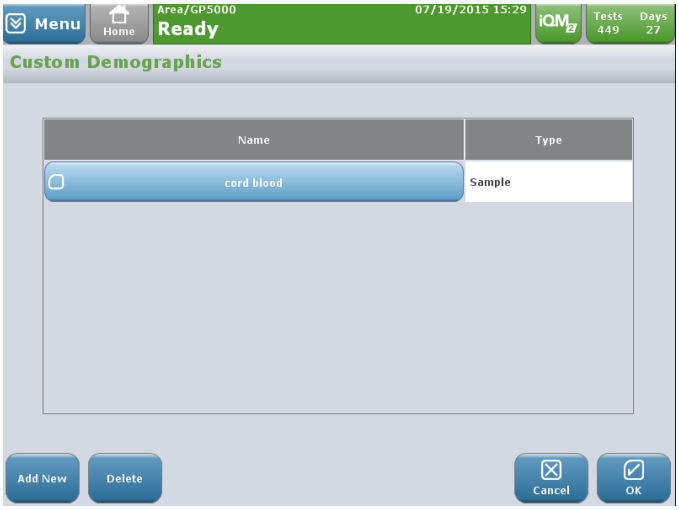
The Custom Demographics function allows you to define new patient or sample demographic fields to be filled in when samples are taken. Individual demographics may be turned on and off by pressing the corresponding radio button.

- Select Add Line in the Custom Demographics screen.
- Enter name for Demographic Name field
- Select demographic type: Patient or Sample.



- Press OK.
- A configured custom demographic can be enabled by selecting and Press OK.

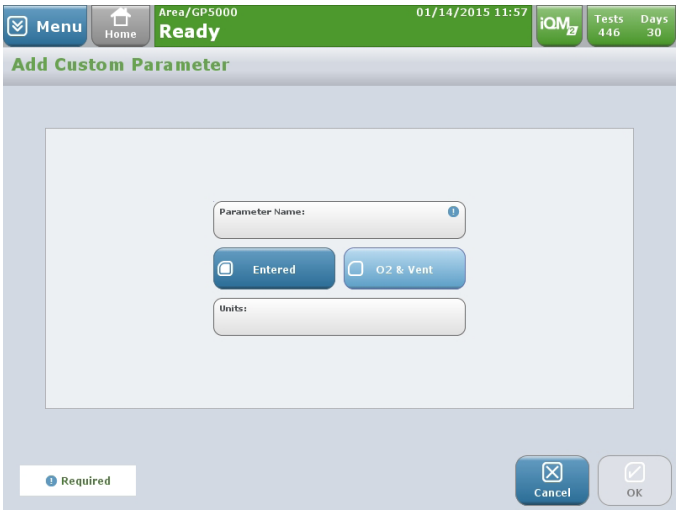
Note: Custom demographics can be deleted from the customer demographics list screen.



13. Custom Parameters

The Custom Parameters function allows you to define new parameter fields to be included with sample information. Values for custom parameters must be entered manually by the operator when the sample is taken.

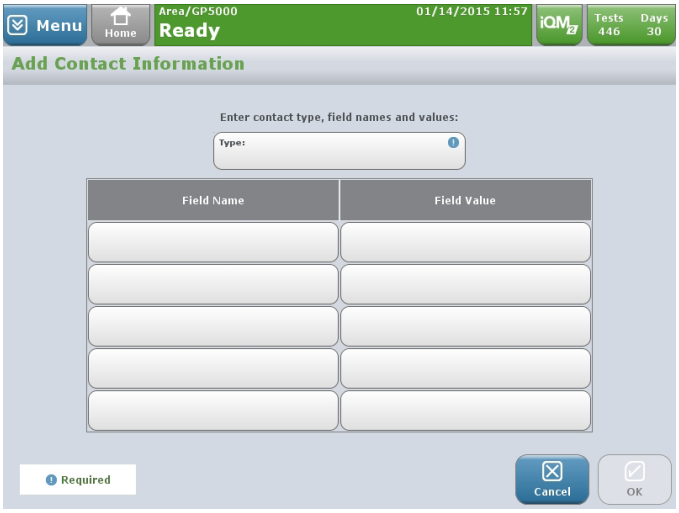
- Select Add New in the Custom Parameters screen.
- Enter a name for the parameter in the Parameter Name Field (e.g. Patient Temperature, Ventilator Settings, etc.)
- Select the parameter type: Entered or O_2 & Vent
- Press OK.



14. Contact Information Setup

Contact Information function allows the entry of name and phone number of IL personnel/departments.

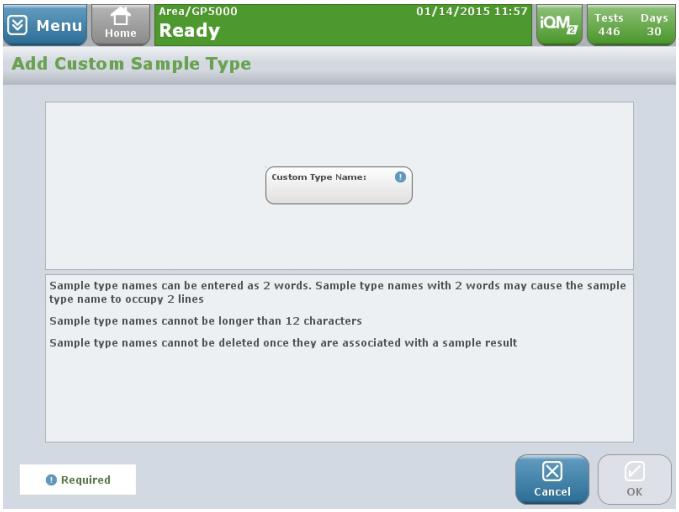
- Select Add in the Contact Information Setup screen.
- Enter the “type of contact” (e.g. Customer Service)
- Enter “Field Name” or individual
- Enter “Field Value” or phone number/email address
- Press OK.



15. Custom Sample Type

For standalone analyzers or GEMweb Plus client-analyzers connected to an LIS/HIS, the customer sample types you define will be transmitted to the LIS/HIS as a sample type “Other”. The custom sample type allows you to define unique sample names for sample types that are not provided as one of the default entries.

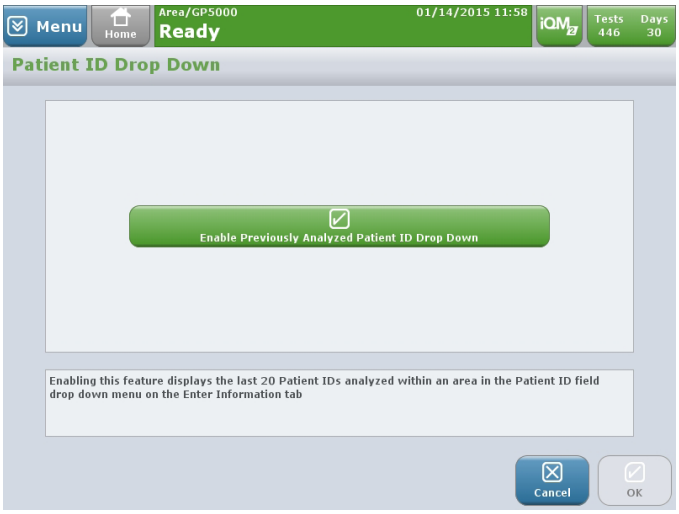
- Select Add Custom Sample Type.
- Enter the sample name
- Custom Sample Types are disabled by default.
- Customer Sample Types cannot be edited or deleted once a custom sample type is run.



16. Patient ID Drop Down

The Patient ID Drop Down function controls whether or not patient ID’s are shown on a drop down list within the “Enter Information” tab.

- Select Patient ID Drop Down
- Enable the “Enable the Previously Analyzed Patient Drop Down”
- Drop Down list will display the last 20 patient IDs performed in an Area

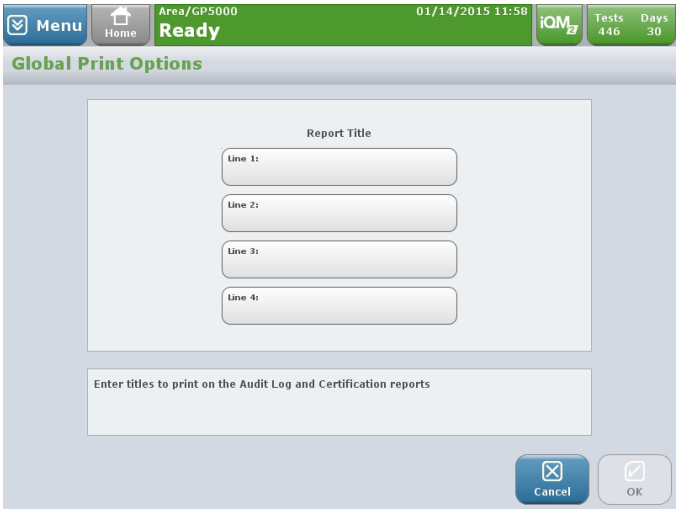


17. Global Print Options

The Global Print Option function allows the setup of report titles for the Audit Log reports and, if enabled, Certification reports.

- Select Global Print Options

Enter up to four (4) lines of information to be displayed in for the Audit Log and Certification reports.

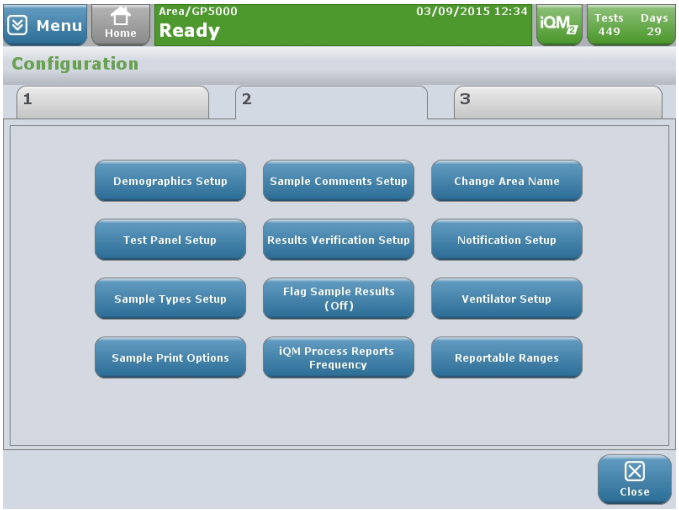


B. Making Adjustments to Tab 2 (Area Tab)

Some configurations/settings will apply only to standalone analyzers or networked analyzers.

Many of the Area Configuration functions screens contain the Copy to Area button, which is enabled when the network has multiple areas. This feature allows you to apply the settings for one area to any other area on the network. To copy the settings from one area to others, select the areas' checkboxes in the copy to area screen.

Note: For GEMweb Plus networked analyzers you will need to use the Area drop-down menu and select the Area you wish to configure.



1. Demographics Setup

- Select Demographic Setup
- Select Tab Enable Demographic Field
- Select each demographic field that you wish to enable.
- Select Define Field Format
- Define prefix for patient ID, Account number or sample number fields which may include minimum or maximum field length.

2. Test Panel Setup

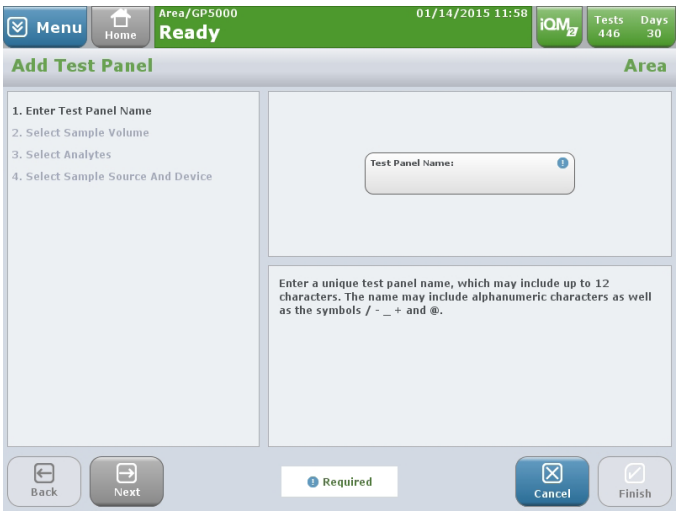
The Test Panel Setup feature allows for the configuration of the QuickStart buttons. QuickStart buttons allows the user to select a single button to run a full panel of analytes from a single sample aspiration. QuickStart buttons are configured to include sample volume and sample type/device.

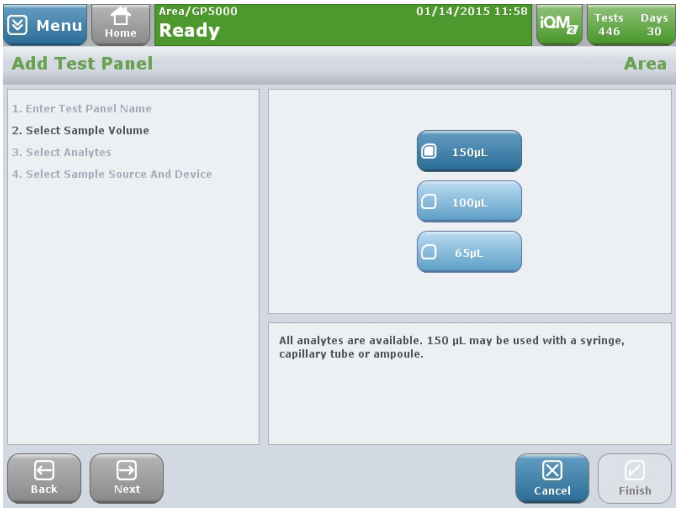
- Select Test Panel Setup

Note: Select Panel Name to view, edit or delete a Test Panel from the list

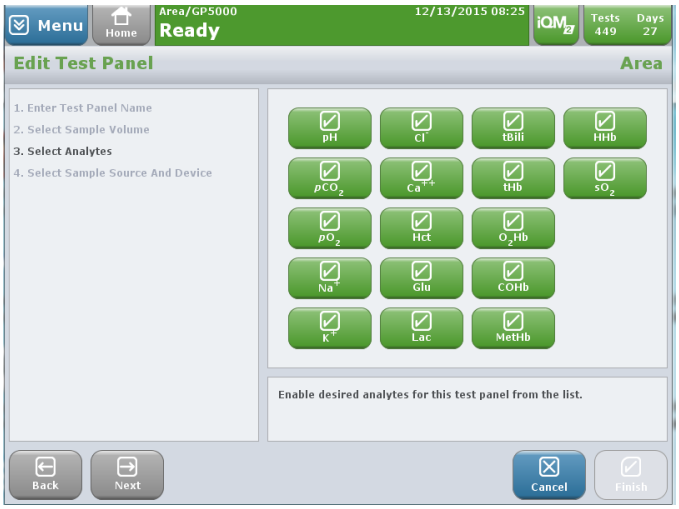
Note: Test Panel order can be sorted from the Test Panel listing

- Select Add Test Panel
- Enter Test Panel name

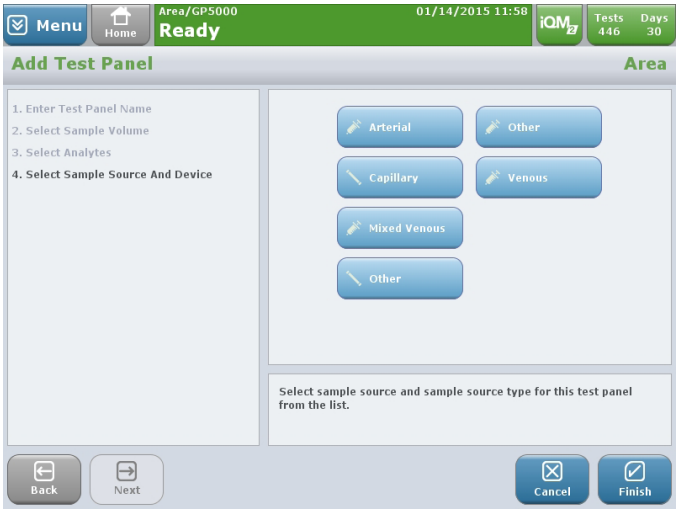




- Select Sample Volume
- Select Analytes



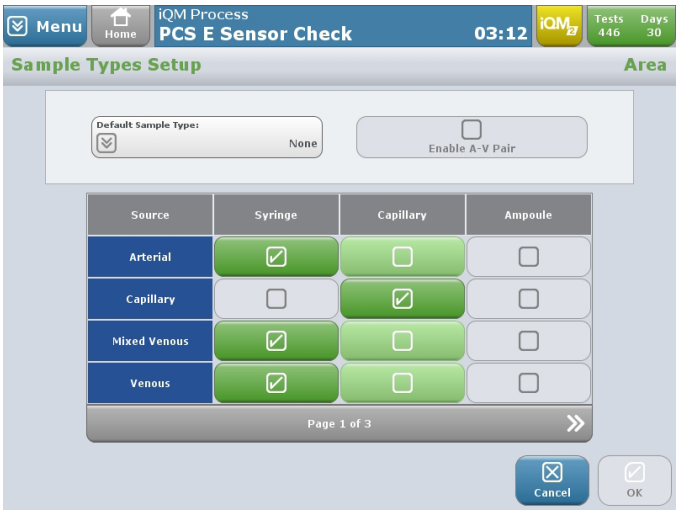
- Select Sample Source and Device
- Press OK.



3. Sample Types Setup

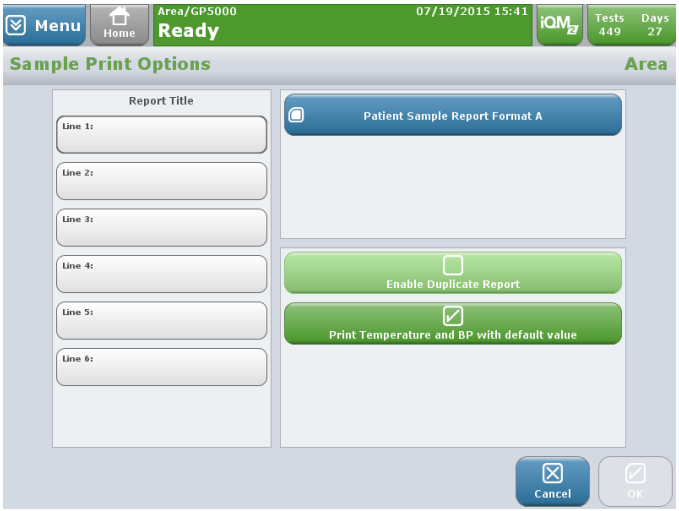
The Sample Types Setup feature allows for the definition of sample source – sample container combinations that are available for testing.

- Select Sample Types Setup
- Use the check boxes to enable or disable containers for specific sources
- Default Sample Type drop-down allows you to choose a sample type that will be set as the default value on the sample
- A-V Pair Tab when enabled allows to report Arterial-Venous Paired Samples (**Note: A-V Pair testing requires FiO_2 parameter enabled**)



4. Sample Print Options

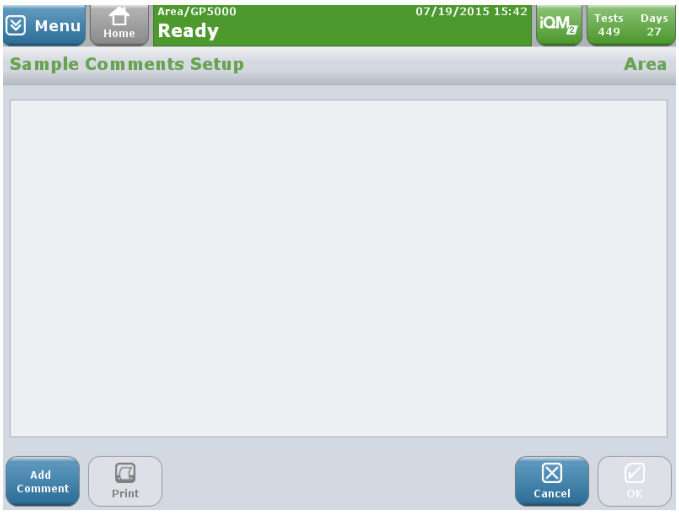
The Sample Print Options feature allows for the customization of the printouts for Sample Reports.



- Select Sample Print Options
- Enter up to six lines of text in the Report Title (will be included in Sample Reports and Patient History Reports)
- Enable Patient Sample Report Format A if this will be the default report printed from the external printer
- Enable Duplicate Report to configure a duplicate report to automatically be printed when sample is accepted
- Enable Print Temperature and BP with Default Value to configure reports to show the default of 37°C for patient temperature and BP of 760 mmHg

5. Sample Comments Setup

The Sample Comments Setup feature allows for the configuration of pre-defined comments that can be added to a sample.

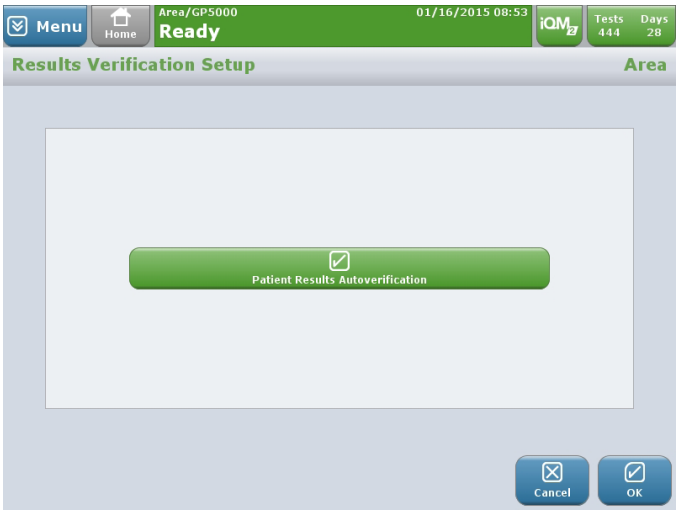


- Select Add Comment
- Type the desired text in the comment text field using an external keyboard or by touching the text field to bring up the on-screen keypad
- A comment may contain up to 255 characters
- Press OK.
- A list of all comments can be printed by pressing the Print button.
- Previously entered comments can be edited or deleted.

6. Results Verification Setup

All analyzers (standalone or GEMweb Plus client-analyzers) interfaced to a LIS/HIS can be configured for Result Verification, where sample results will be automatically accepted and transmitted to the LIS/HIS without any operator intervention.

- Select Results Verification Setup
- Enable Patient Results Autoverification
- Press OK.

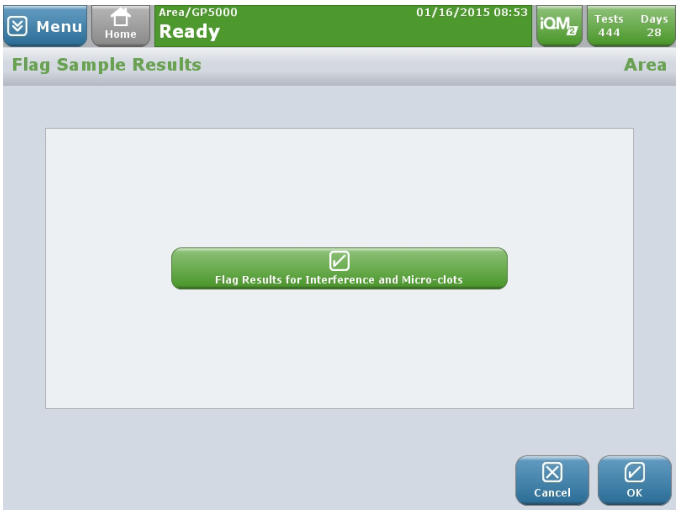


Note: With GEMweb Plus client-analyzers Results Verification all or one of the sample criteria can be configured. Sample information will be checked against the enabled criteria. Samples outside the criteria will require operator manual acceptance.

7. Flag Sample Results

- Select Flag Sample Results
- Enable sample flagging ON

Note: Sampling flagging feature allows users to visually identify analyte/sample-specific flags on a sample report (both on-screen or printed)



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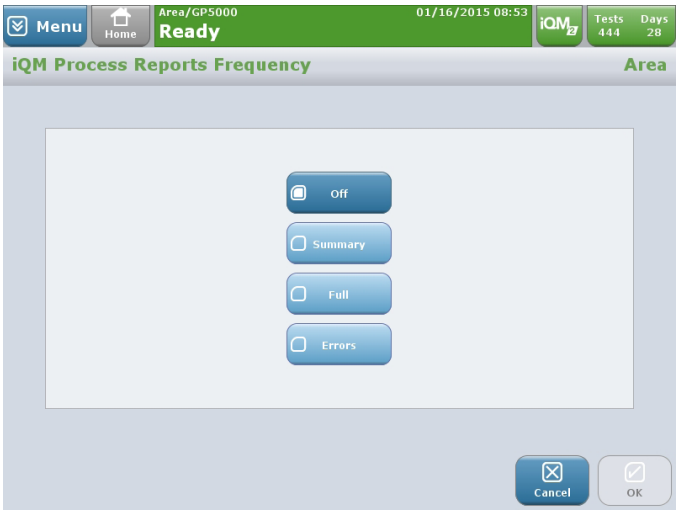
8. iQM2 Process Reports Frequency

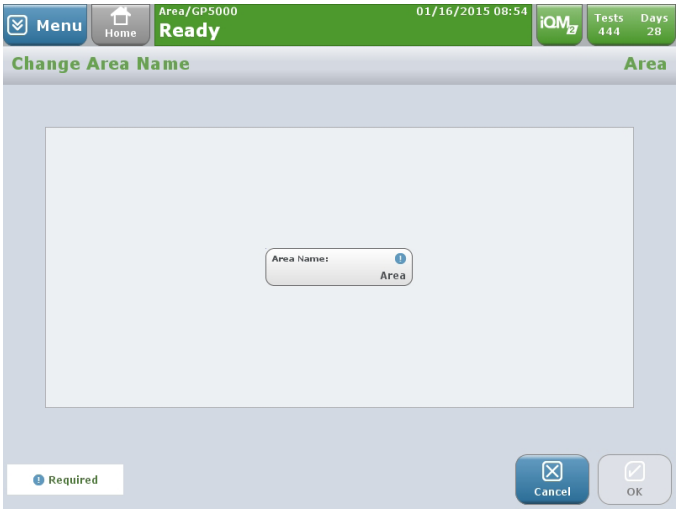
This feature determines what types of iQM2 process report records are printed and/or sent to the LIS.

- Select iQM2 Process Reports Frequency
- Select one of four iQM2 report options:
  - Off – no reports printed/sent
  - Summary – only a summary report
  - Full – full report printed or sent
  - Errors – report with iQM2 errors only sent/printer
- Press OK.



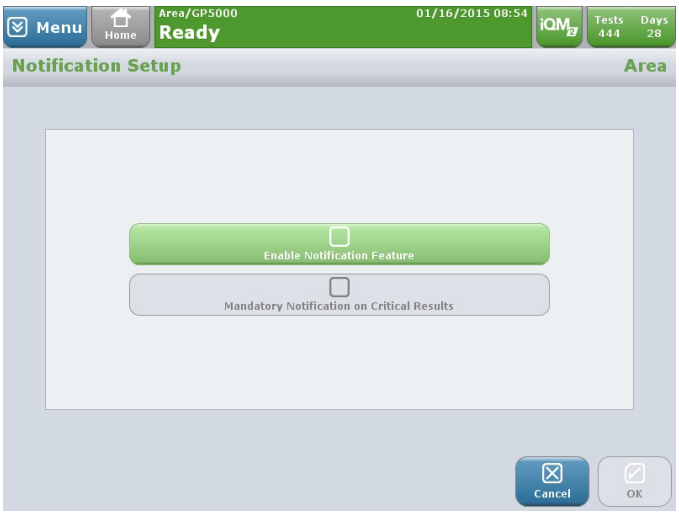
9. Change Area Name

- This feature provides a way to rename an existing Area.



10. Notification Setup

- Select Notification Setup
- Enable Notification Feature and Mandatory Notification if desired.
- When mandatory notification is enabled, operators are instructed to send a notification of critical results to the ordering physician.
- If mandatory notification is enabled, sample results cannot be accepted until notification has been documented via entry in the notification.



Note: Patient ranges must be loaded to provide critical value flag to trigger mandatory notification function. Result Verification (auto-accept) will be disabled if the mandatory notification is enabled.

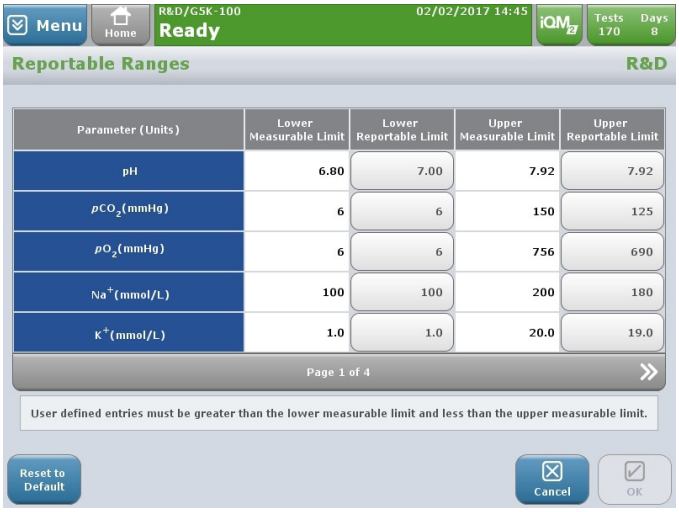
11. Ventilator Setup

The Ventilator Modes function allows the configuration of various ventilator modes.

- Select Ventilator Setup
- Select Ventilator Modes Tab and enable modes desired. Additional ventilator modes can be added.
- Select O_2 Device Names Tab and enable devices desired. Additional devices can be added.
- Press OK.

Note: Reportable range limits are set to the default levels outlined in "Measured Analytes" on page 15. Follow local, state, federal or accrediting agency requirements with respect to reportable ranges.

12. Reportable Ranges



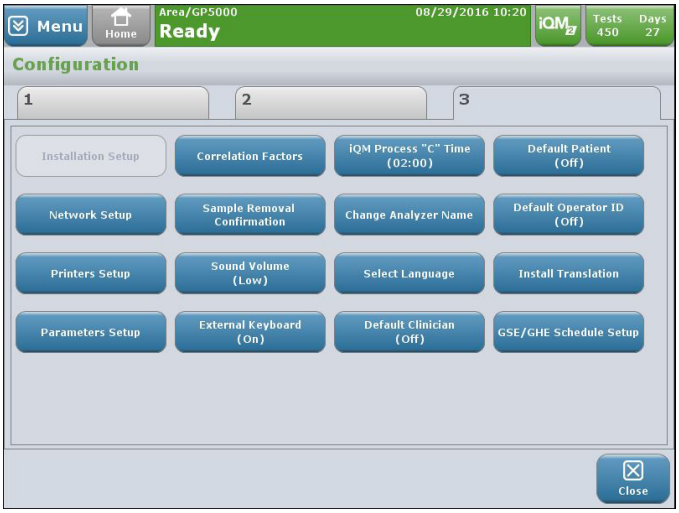
- Select Reportable Ranges
- Enter reportable range for each analyte. Press OK.
- Select Reset to Default to reset to factory settings.

Adding Area:

It is important to realize that no explicit Add Area function exists in the GEM Premier 5000 system. New areas can be created when a new analyzer is added. When you add the analyzer, you will be able to enter a new area name, which will "create" that area. Similarly, areas cannot be explicitly deleted, but when all analyzers in an area have been deleted, the area shall be treated as "deleted." Deleted areas can be reactivated if the name is used for a new area. The configuration settings for a reactivated area will be restored.

C. Making Adjustments to Tab 3 (Analyzer Tab)

Some settings apply only to the current unit, and others may not be applicable on certain instruments or in certain situations. Tab 3 allows you to make adjustments to the local settings for a selected analyzer.



Note: GEMweb Plus provides the capability of configuring certain Analyzer settings remotely. However, some must be configured locally on a specific analyzer.

Note: With GEMweb Plus user must select the analyzer desired to configure from the analyzer drop-down list prior to changes.

To Delete an Analyzer

- Select Delete Analyzer button
- A warning box will appear: Are you sure you want to delete… Select Yes.

Note: A client-analyzer can only be deleted if it is disconnected from GEMweb Plus.

Installation Setup

Note: Installation Setup allows you to restore factory settings or change the deployment of an analyzer (e.g. standalone to client). Installation Setup requires that a cartridge is not inserted into the instrument.

a. For a standalone analyzer, the following warning will be displayed:

Reset the database to factory settings – The database will be set to the factory defaults and the sample records will be deleted. The analyzer will restart and launch the Installation Setup wizard.

To save sample records before resetting factory defaults, use the export function.

b. For a client analyzer, the client-analyzer must be disconnected from the netowork prior to Installation Setup and following warning will be displayed:

Reset the database to factory settings – The database will be set to the factory defaults and the sample records will be deleted. The analyzer will restart and launch the Installation Setup.

The sample records will be maintained in the GEMweb Plus server.

c. For a dedicated server, requires the database to be reset to factory defaults. Perform a server database before proceeding.

Note: To run Installation Setup Wizard on a server, analyzers must be first disconnected and deleted.

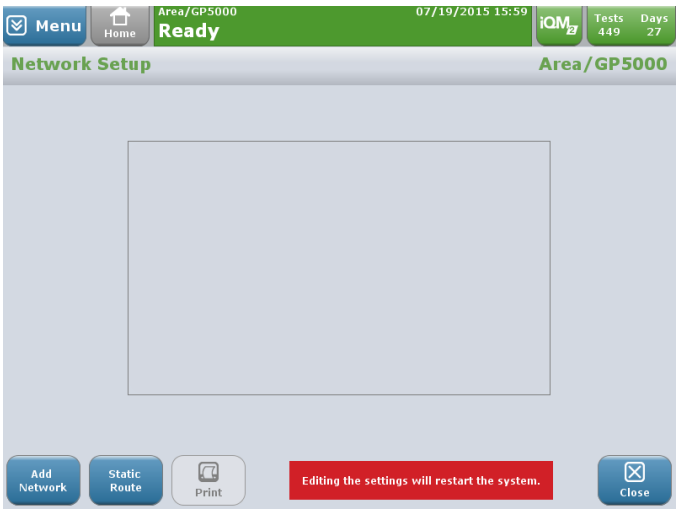
Installation Setup Wizard Procedure

1. Select Interface Setup
   a. Select Installation Type
      - Create a standalone analyzer
      - Create a GEMweb Plus client-analyzer
      - Replace existing client analyzers
   b. Enter Area and Analyzer Name
   c. Select Time Zone
   d. Select Time Source
      - Use External NTP Time Server
      - Do Not Use External NTP Time Server
   e. Enter Date and Time
   f. Select Connection Type (if analyzer is networked)
   g. Local Configuration
      - Function allows to copy configuration from a reference analyzer
      - You will be prompted to insert a disc or usb drive after you select Finish.
2. Network Setup

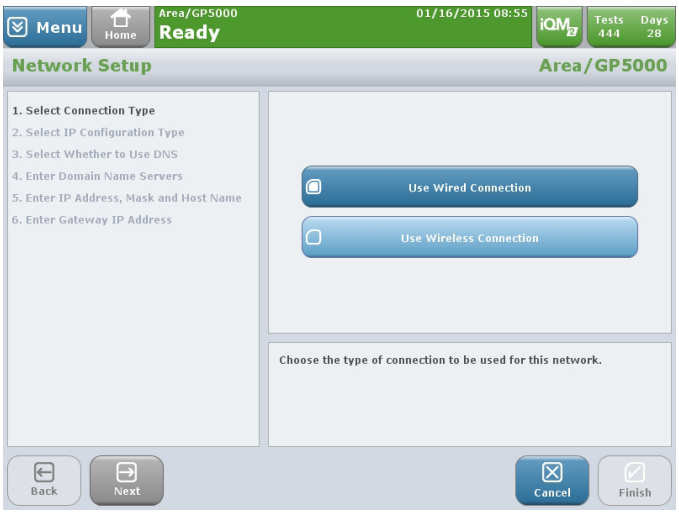
   Allows for first time network setup of a standalone analyzer

- Select Network Setup
- Select Add Network.

NOTE: Ensure the analyzer is connected to a secure network when performing installation and setup.

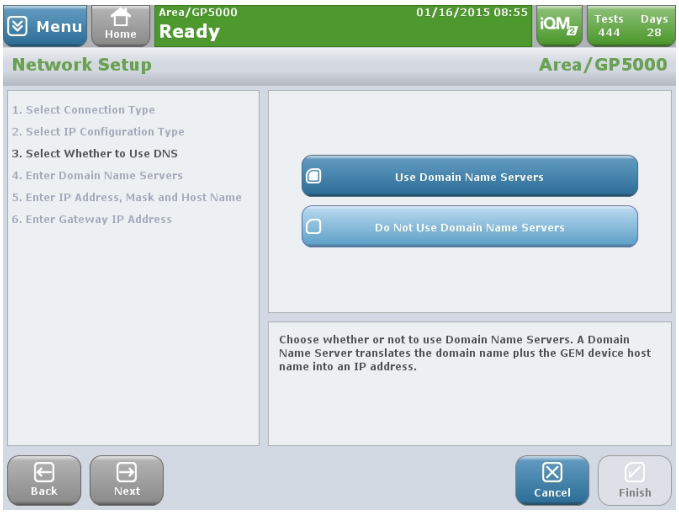


- Select Connection Type
  - Wired
  - Wireless



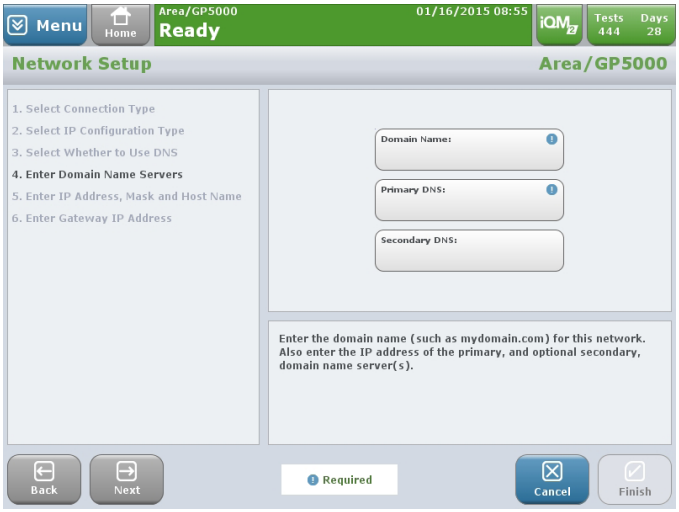
For wired connection:

- Select IP Configuration Type
  - Use Static IP Address
  - Obtain an IP Address Automatically (DHCP)
- Select Whether to Use DNS



- Enter Domain Name Server
- Enter IP Address, Mask and Host Name
- Enter Gateway Address

For wireless connection: Follow on screen network setup options.



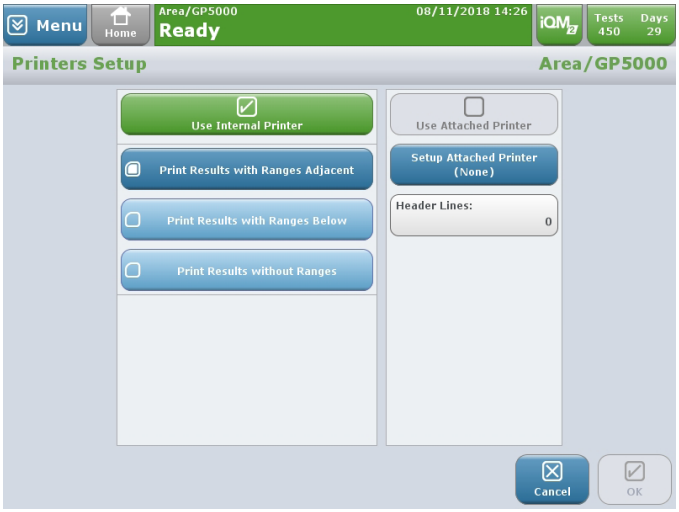
Note: Networks can be edited in the Network Setup function. The IP Address of the GEMweb Plus server can be changed from the Network Setup screen.

3. Printers Setup

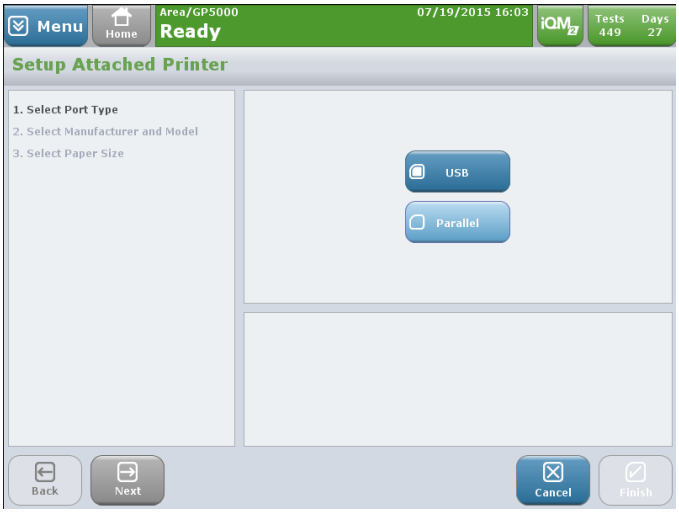
The Printers Setup function allows you to define the printer on which reports will be printed: internal printer, attached printer (directly connected) or a networked printer.

- Select Printers Setup

- Enable Internal Printer (to have reports printed off analyzer internal printer)
- With software 1.4.0 and above, reference ranges are configurable on internal computer print-outs. The analyzer may be configured to:
  - Print Results with Ranges Adjacent: reference ranges are printed next to the sample result
  - Print Results with Ranges Below: reference ranges are printed below the sample result
  - Print Results without Ranges: reference ranges will not be printed



- To setup an external printer connection, select Setup Attached Printer
  - Select Port Type (USB or Parallel)
  - Select Manufacturer and Model
  - Select Paper Size
  - Select Finish



Note: In the Header Box enter the number of lines to be skipped before printing (0-14).

- Select Networked Printer (GEMweb Plus networked analyzers only)
  - Select the default printer from the list
  - Select Network Printer at Print Time (enable if user will need to select printer to use each time)
  - Enable the network printer

Note: In the Header Box enter the number of lines to be skipped before printing (0-14).

Note: Printers can be edited or deleted from the Printers Setup screen.

4. Parameters Setup

The Parameters Setup function is used to enable or disable parameters measured, calculated, or entered when samples are run.

a. Measured Analytes Tab

Use check boxes to enable or disable measured analytes.

If tHb is disabled, the other 5 CO-Oximetry derivatives will be automatically disabled.

b. Derived Analytes Tab

Use check boxes to enable or disable derived parameters. When a sample is run, these parameters will be automatically calculated if enabled.

Note: Some parameters have an equation or calculation option; their labels are shown as buttons. To set the equation or calculation option, press the parameter's label button. A dialog box will appear. Select the desired option and press OK to return to the Derived Parameters tab.

c. Entered and O_2 & Vent Parameters Tabs

Use check boxes to enable or disable the Entered and O_2 & Vent parameters.

The parameter lists may consist of both fixed (system defined) parameters as well as those defined by the operator.

5. Correlation Factors

Correlation Factors function is used to assist facilities with standardizing assay methods.

a. Press Correlation Factors in the Analyzer tab.

b. Use the check box buttons to set how correlation factors are applied:

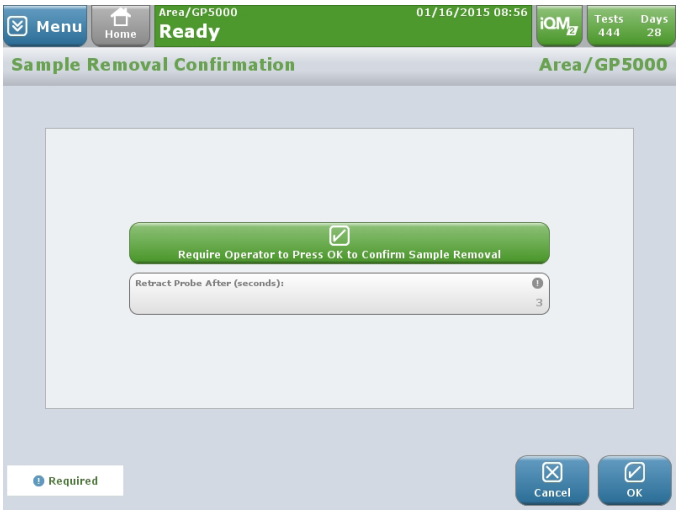
- Apply to all except “Other” and Custom
- Apply to “Other” and Custom

c. Set the correlation factors by selecting a numerical field and then keying in the value of the slope and offset.

d. Press OK.

6. Sample Removal Confirmation

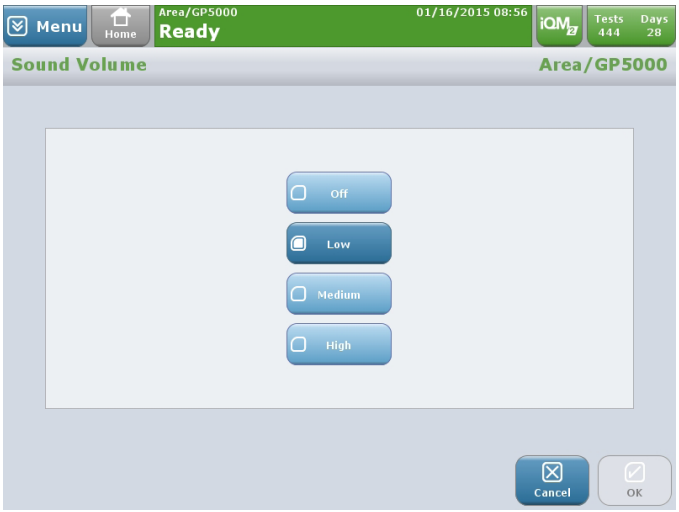
The Sample Removal Confirmation function presents two options for retracting the probe after a sample has been aspirated:



- If Require Operator to Press OK to Confirm Sample Removal is selected, a dialog box will appear at the completion of sample aspiration. A dialogue box will request that the operator confirm the sample has been removed from the probe before the probe will retract. When the operator presses OK, the probe will retract.
- If Require Operator to Press OK to Confirm Sample Removal is deselected, the operator can enter a number between 2 and 10 seconds in the Retract Probe After field. The probe will automatically be retracted after the specified number of seconds has elapsed.

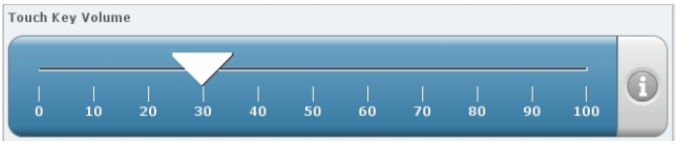
7. Sound Volume

Beginning with software 1.4.0 and above, the analyzer's touch key volume and beep volume may be configured under the **Configuration** tab.



Touch Key Volume

The touch key sound plays whenever the operator presses one of the touch key buttons. There are 11 touch key volume options with 0 muting the volume entirely and 100 playing the loudest volume. To set the touch key volume, select the desired level by pressing and dragging the volume button; then press OK. The touch key volume will be set to 30 by default.



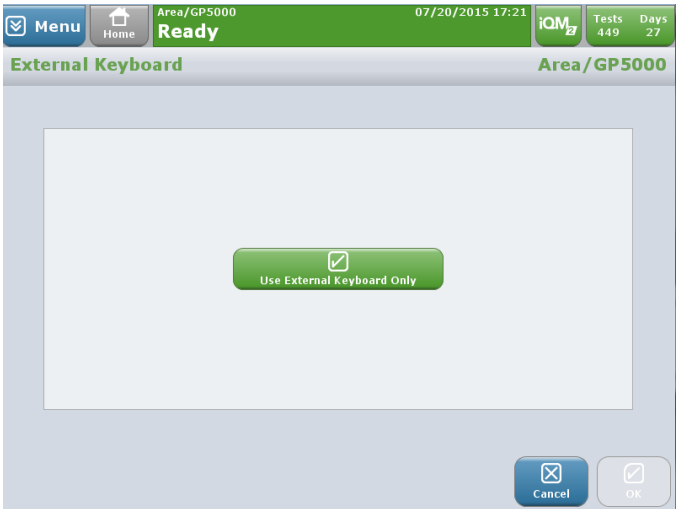
Beep Volume

The beep volume is an audio prompt to indicate than an action has occurred or is about to occur, such as when it is time to remove the sample from the sample probe area. There are 5 beep volume options ranging from Low to High. Note that unlike the touch key volume, the beep volume may not be muted. To set the analyzer's beep volume, select the desired level by pressing and dragging the volume button, then press OK. The beep volume will be set to Medium by default.

Note that for analyzers with SW 1.3.1 and below, the touch key volume only may be configured to: **Off > Low > Medium > High;** the default touch key volume will be Low.

8. External Keyboard

This feature allows you to choose the default means of text data entry. Select Use External Keyboard Only check box if you do not want the on-screen keypad to appear for text-entry boxes. Then press OK.



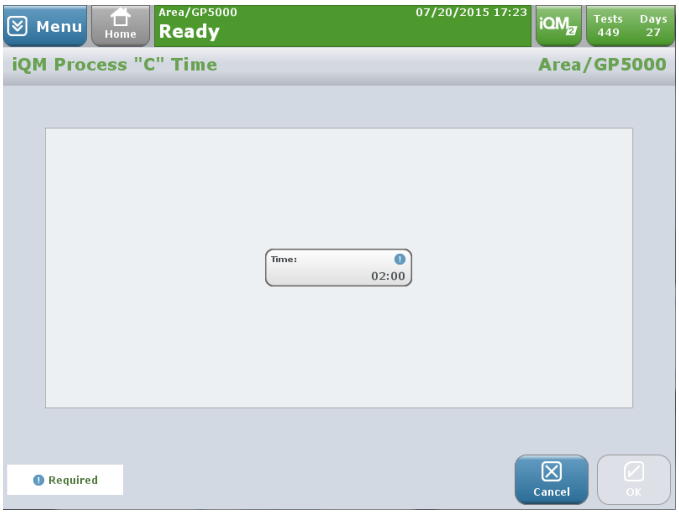
9. iQM Process "C" Time

   a. Press iQM Process "C" Time in the Analyzer tab (Tab 3).

   b. Select the Time field and enter the desired time (using the 24 hour clock) for the daily C calibration. The default value is 2:00 AM

   c. Press OK.

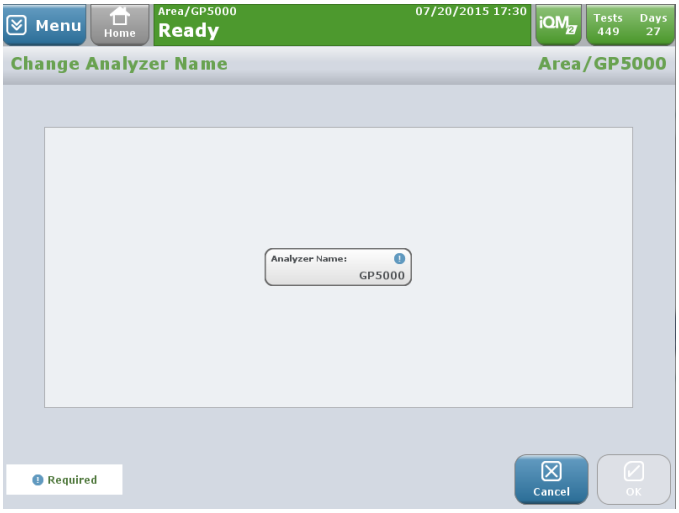
Note: Process Control Solution D and E will be performed 2 hours prior to the scheduled iQM Process "C" Time.



10. Change Analyzer Name

You may change the name of a standalone analyzer or a GEMweb Plus client-analyzer. When the screen is accessed it will show the existing analyzer name.

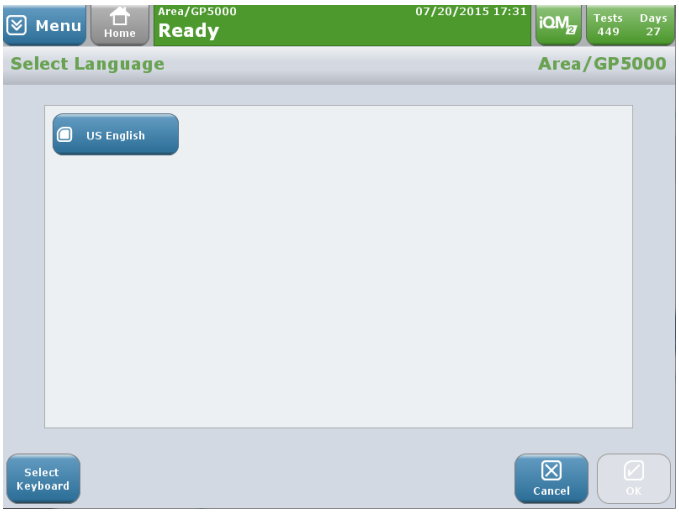
If you are accessing GEMweb Plus client-analyzers from a web browser you can change the name of any attached client-analyzer.



11. Select Language

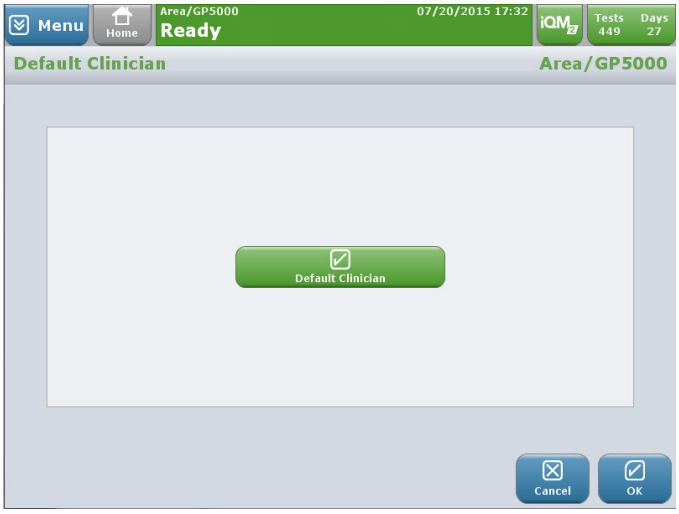
a. The Select Language function allows you to select the language to be displayed on the instrument. The default is U.S. English. Only those languages that have been installed on an instrument will be shown.

b. The Select Keyboard function associates the proper touch screen keyboard on the analyzer to the language translation in use.



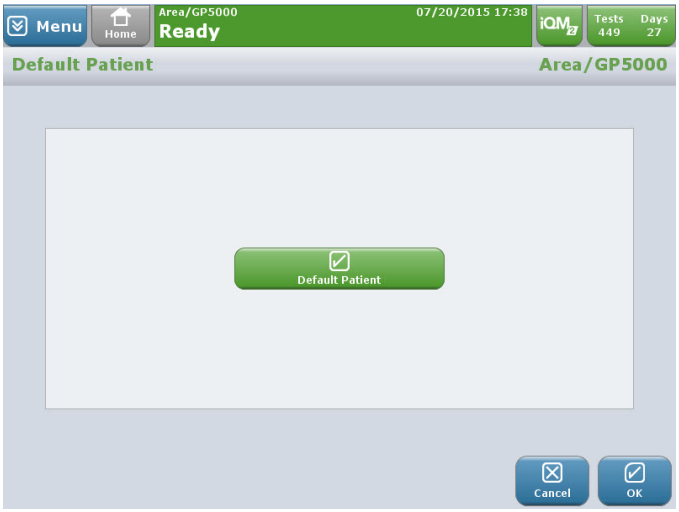
12. Default Clinician

When the Default Clinician function is enabled, the clinician field in the Enter Information tab of the Home screen will be pre-filled with the clinician from the previous sample. To enable or disable this function, press the check box button; then press OK.



13. Default Patient

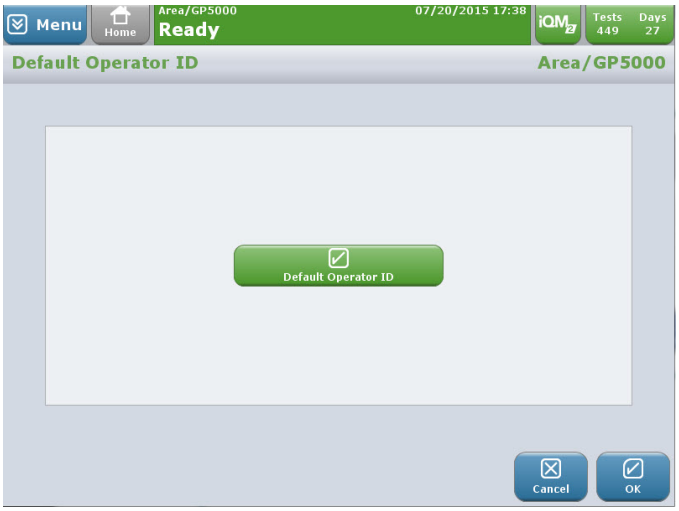
When the Default Patient function is enabled, the Patient ID field in the Enter Information tab of the Home screen will be pre-filled with the patient ID from the previous sample. To enable or disable this function, press the check box button; then press OK.



14. Default Operator ID

When the Default Operator ID function is enabled, the operator ID field in the Enter Information tab of the Home screen will be pre-filled with the operator ID from the previous sample. To enable or disable this function, press the check box button; then press OK.

If sample analysis is configured to require a password, Default Operator ID will be disabled.



15. Install Translation

The Install Translation function allows you to install a language translation onto an analyzer or a GEMweb Plus server. After pressing Install Translation you will be prompted through the necessary steps.

16. Patient Verification

The Patient Verification feature is introduced in software version 1.5.0. This feature enables you to confirm the accuracy of patient demographic information before accepting the patient's results and releasing them to the permanent record. The Patient Verification feature is automatically enabled in SW version 1.5.0, but it may be

disabled within the Configuration menu. If the Patient Verification feature is disabled while the Results Verification option is enabled, the system automatically accepts patient results without allowing you to visually verify the patient's demographics.

To enable the Results Verification option, go to **Management > Configuration > Tab 2** and select Results Verification Setup. Click the Patient Results Autoverification box and press OK.

Accepting Sample Results with Patient Verification Enabled

When the Patient Verification feature is enabled while the Results Verification option is disabled, you will be prompted to confirm the patient's demographic information after accepting the sample results on the View Results screen.

a. Press **Accept** on the View Results screen.

b. Review patient demographic information on the pop-up dialogue screen.

c. If the patient's demographic information is correct, press Confirm to release the results to the permanent record.

If the patient's demographic information is incorrect, select **Cancel** and return to the Enter Information screen to modify the patient's demographic information. After verifying the information, you may select **Accept** in the View Results screen and then select **Confirm** to release the results to the permanent record.

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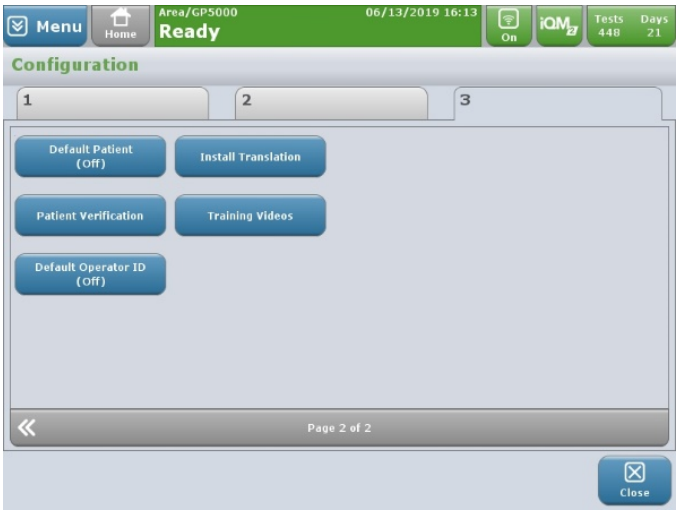
Disabling Patient Verification Feature

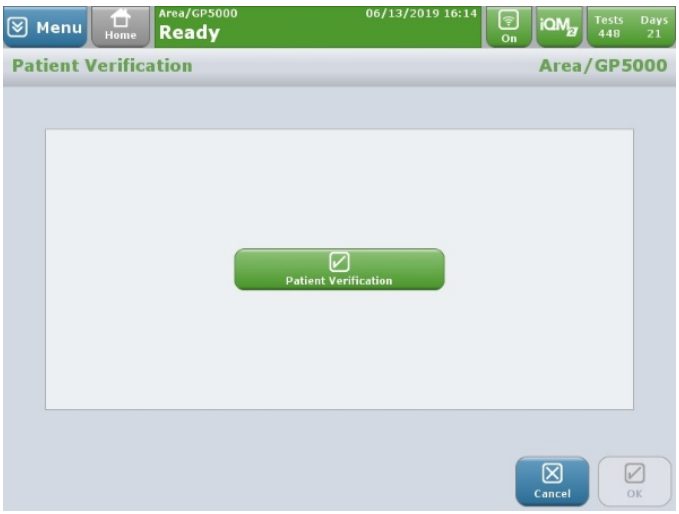
a. To disable the Patient Verification feature, use the following instructions:

- For standalone analyzers: **Menu > Management > Configuration > Tab 3 > Patient Verification**
- For networked analyzers: **Menu > Management > Analyzer > Configuration > Patient Verification**



b. Uncheck the patient verification box.

c. Select **OK**.



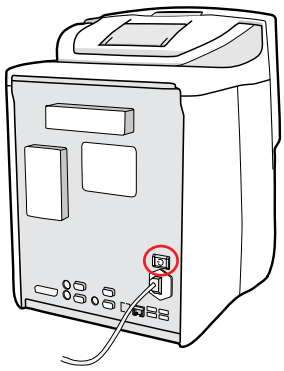
The Patient Verification feature must be disabled for the system to automatically accept patient results. If Results Verification and Patient Verification are both enabled, a pop-up message that states, “A Patient Verification feature has been enabled. When Patient Verification is enabled, patient samples will no longer be auto-accepted. Please confirm and select your Patient and Results Verification settings in the Configuration Menu on this analyzer” will be displayed each time the analyzer restarts

Running the Analyzer

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.

Refer to the “Installing the GEM Premier 5000 Analyzer” 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.



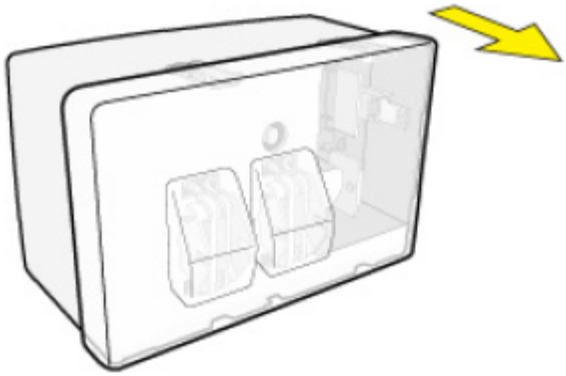
The analyzer has a momentary power switch (button). Press the button and immediately release it to turn the analyzer on. If the button is pressed and held for 5 seconds or longer, the power is turned off.

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.

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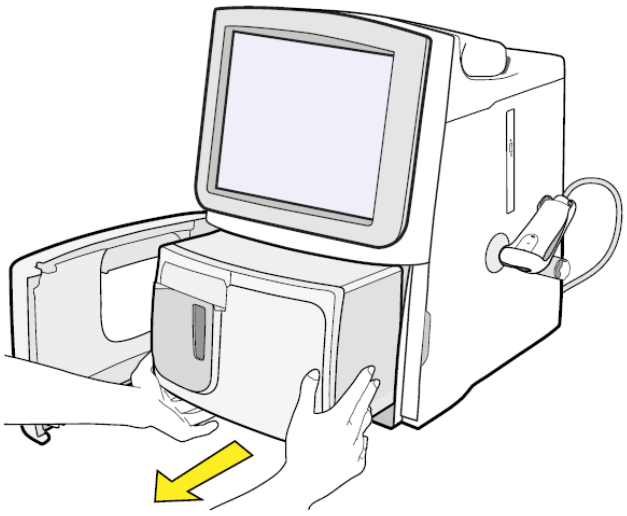
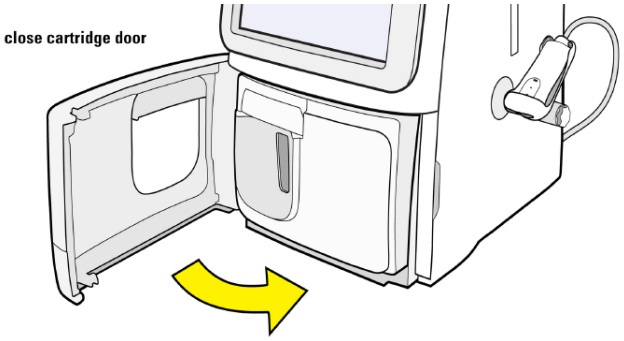
4. Position the GEM PAK with the gray sampling area facing forward. Push the cartridge in until you feel resistance.

   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.

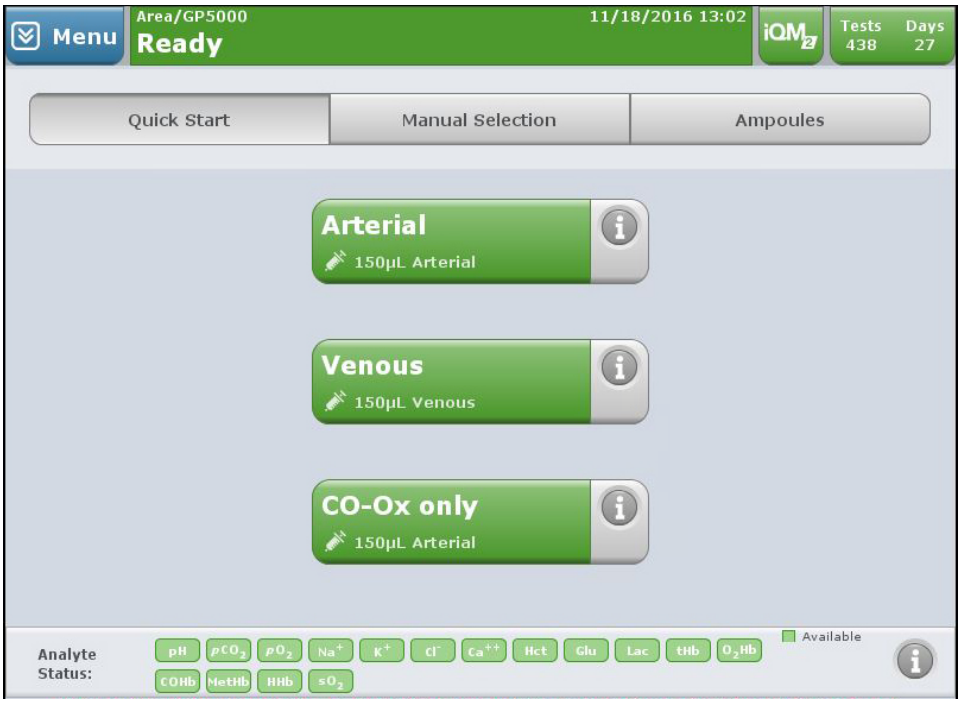


6. In approximately 20 seconds, the analyzer will inform you that the GEM PAK is warming up. The clock will count down for the next 40 minutes as the GEM PAK starts up. During this time, the sensors will hydrate, and the analyzer will perform internal checks and processes.

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.

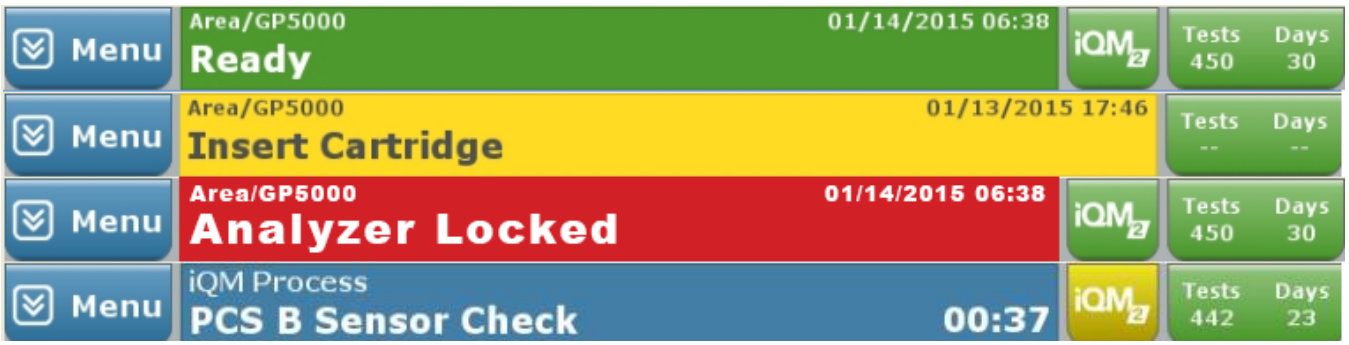
General Operation Information

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.

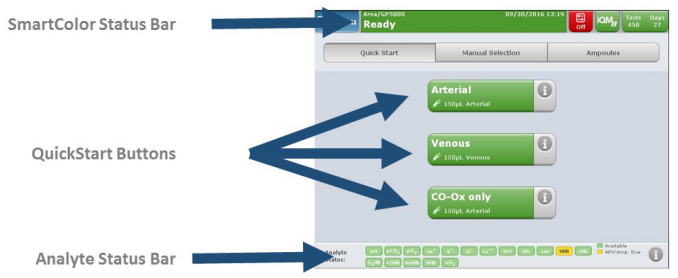
Password protection prevents unauthorized access to key activities. When prompted, enter your password, as provided by your supervisor or other managerial personnel.

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 CVP 5 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 Drop-Down Function

- 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.

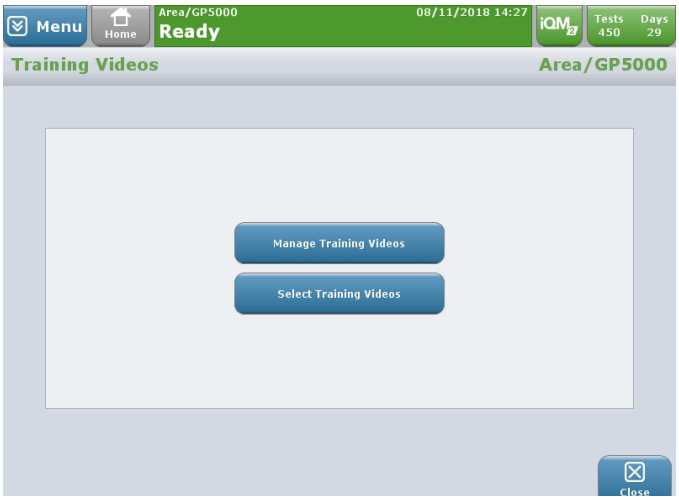
- Copy IL Data – allows user to copy GEM PAK data onto a CD or USB for investigation purposes.
- Action – enables you to manually remove a GEM PAK, restart the analyzer or shutdown the analyzer (see “Removing the GEM PAK” on page 117).

Training Videos

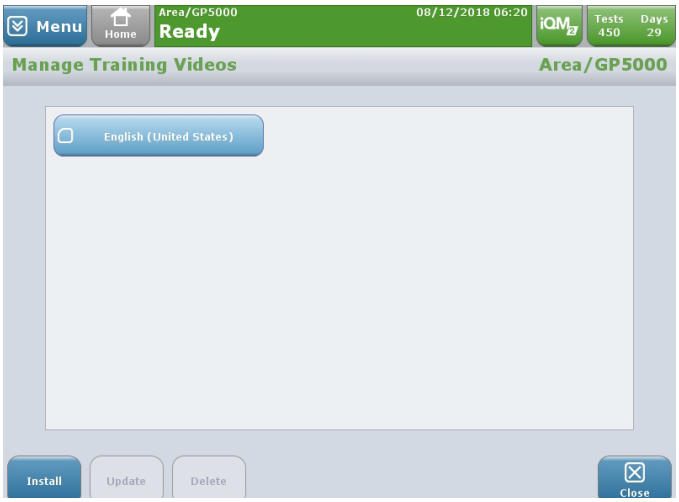
Training topics can be viewed on an analyzer with software 1.4.0 or higher after the training videos disc has been installed.

Installing the GEM Premier 5000 Training Videos

1. Before installing GEM Premier 5000 training videos, ensure that the analyzer is running on software 1.4.0 or higher by selecting **Menu > Diagnostics > System Info** and viewing the Software Version Number.



To install the GEM Premier 5000 training videos for standalone instruments select **Menu > Management > Configuration** and select **Training Videos** located under **Tab 3**. Select **Manage Training Videos** and then select **Ok**. Select the **Manage Training Videos** panel and select Install and insert the GEM Premier 5000 training videos disc. Press **Ok**. The training videos will take a couple of minutes to install. A popup screen with the message "The training videos have been successfully installed" will appear when complete. Press **Ok** to eject the disc. Press Close to complete the installation process.

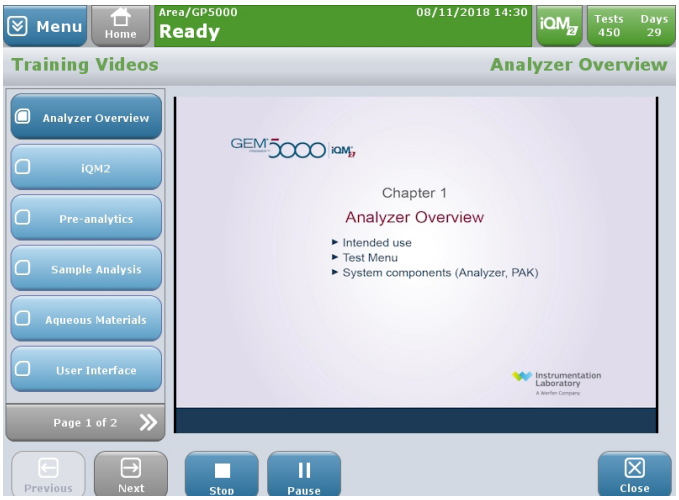


For instruments in client mode, select **Management > Analyzer > Configuration** and select **Training Videos**. Select **Manage Training Videos** and select the **Manage Training Videos panel**. Press **Install** and insert the GEM Premier 5000 training videos disc. To complete the installation, press **Ok**.

Viewing Training Videos

1. To view the training videos, first ensure the correct language is selected under **Manage Training Videos**. To view the training videos, Select **Menu > Help > Training Videos**
2. To view a topic, select the desired topic and press play from the Action buttons located along the bottom of the screen.

Training topics are organized into 12 chapters:



- Chapter 1: Analyzer Overview
- Chapter 2: Intelligent Quality Management 2 (iQM2)
- Chapter 3: Pre-analytical Phase of Testing
- Chapter 4: Sample Analysis
- Chapter 5: Aqueous Materials
- Chapter 6: Graphical User Interface
- Chapter 7: GEM PAK Management
- Chapter 8: Orders from an Information System
- Chapter 9: Database Searches
- Chapter 10: Diagnostic Menu Functions
- Chapter 11: Replacement Components
- Chapter 12: Installation and Shipping Information

Note: The onboard training videos include subtitles only; videos do not contain voiceover.

4 - Sampling

CVP 5 (Calibration Valuation Product 5) SAMPLING

Each time you insert a new GEM PAK that contains total Bilirubin (tBili), the GEM Premier 5000 system will prompt you to run CVP 5 testing.

This process of performing CVP 5 validates the tBili performance of the GEM PAK prior to performing patient samples for tBili. Patient results for tBili cannot be reported until CVP 5 is within acceptable ranges.

Analyzing CVP 5 involves testing one ampoule of solution, which is available only by Instrumentation Laboratory. GEM CVP 5 must be purchased separately.

1. The GEM Premier 5000 system will inform you that CVP 5 testing is due via the Analyte Status Bar at the bottom of the screen and under each QuickStart button which is configured with tBili.

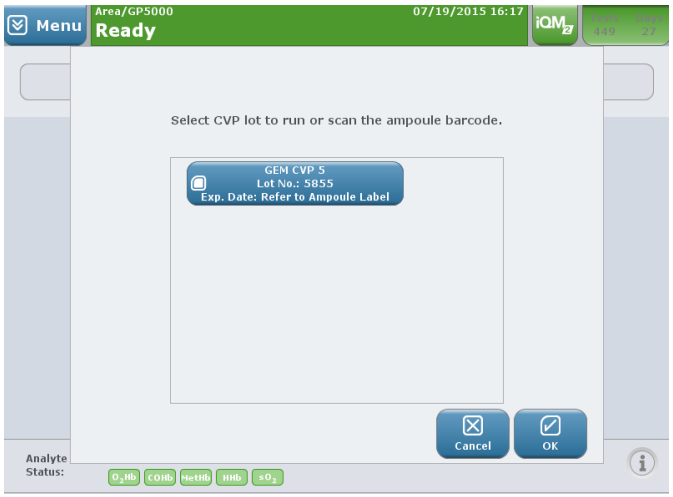
Note: CVP 5 ampoules are stored refrigerated 2-8°C. GEM CVP 5 tBili must be analyzed immediately after removal from the refrigerator. The ampoule material should be deep red in color when received and remain so until the expiration date. Change of color to brown and/or inability to achieve listed values can be an indication of deterioration.

GEM CVP 5 tBili contains human source material, which tested non-reactive for HIV antibody, Hepatitis B Surface Antigen and anti-HCV at the donor stage. This product, as with all human based specimens, should be handled with proper safety procedures to minimize the risk of transmission of infectious disease.

2. Select Ampoule Screen.

3. Press CVP button.

4. Select an ampoule from the choices on the screen or scan the 2D barcode on the ampoule label using the barcode gun. Press OK to begin CVP testing.



Note: Refer to "CVP 5 Material Setup" on page 48 if a new lot number of CVP must be added.

5. GEM CVP 5 should be utilized immediately from refrigerated storage (2-8°C).

   Immediately prior to use, hold the ampoule by the top above the break line and shake the ampoule then gently tap to release bubbles.

Note: Hold the ampoule only above the break line. Holding the ampoule in your hand will cause the aqueous solution to exceed the recommended testing temperature and can adversely affect CVP results.

6. Gently tap the ampoule so the liquid settles back to the bottom.

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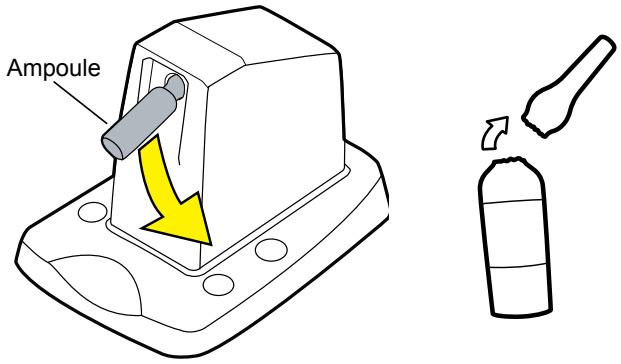
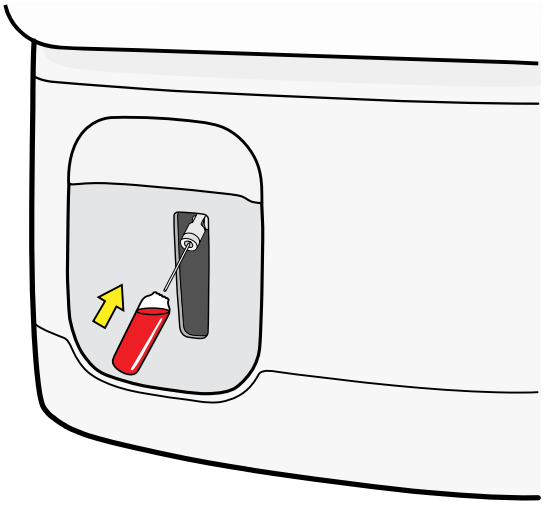
7. IL offers an ampoule breaker as an optional item to assist users in opening ampoule products in their facility.

   Carefully snap open the utilizing the ampoule breaker. Insert the tip of the ampoule into the ampoule breaker and gently pull down on the ampoule until the neck snaps. Be sure to keep a firm grip on the ampoule with one hand and on the top of the ampoule breaker with the other hand.



8. Present the CVP 5 ampoule to the sampler, which will emerge from the gray sampling area at the front of the analyzer. Hold the ampoule so the end of the sampler does not touch the bottom. Press OK to begin aspiration. The analyzer will issue an audio prompt when it has aspirated enough of the CVP 5 solution. Remove the ampoule immediately upon hearing the audio prompt.



9. The analyzer will show you the results of the CVP 5 testing. tBili results within range will be indicated in green text with a white background; out-of-range in white text on a red background. If the tBili result is within range, press Accept. In the unlikely event of an out-of-range CVP 5 result, exclude the sample. The tBili analyte button on the Analyte Status Bar will turn green after a successful CVP 5 result and acceptance, indicating that tBili analyte is available for sample testing

CVP Exception Symbol	CVP Exception Symbol Description
	Outside CVP Range - High
	Outside CVP Range - Low

When CVP 5 does not pass the acceptable range, the operator is prompted to run an iQM2 Process prior to repeating the analysis with a new vial. An iQM2 Process is initiated by selecting Menu > Diagnostics > Run iQM2 Process. When the iQM2 Process is complete, run the new CVP 5 vial. If CVP 5 fails the acceptable range two more times, either perform samples without tBili analyte or replace the GEM PAK. Contact your local IL technical support department to document the failure. (In the US or Canada call 1-800-678-0710.) If the insertion of a new GEM PAK is selected, start again with CVP 5.

10. CVP results can be viewed on demand via the analyzer or GEMweb Plus.

Patient Sampling

The GEM Premier 5000 system is designed to make it simple and efficient for you to analyze patient blood samples. Below is a description on how to prepare samples for analysis, and the key steps you need to take when performing patient sampling, the primary task that you will perform with the analyzer.

Treat all samples as a potential biohazard. Use universal precautions as designated by your facility.

Sampling Considerations

Your facility should have written policies in place to ensure that accurate results are obtained by maintaining positive patient identification and specimen integrity from the time of specimen collection to reporting of results.

Patient Assessment

Urgent measurements of blood gases require immediate specimen collection. To determine the effect of ventilator changes a steady state of ventilation should be achieved before obtaining arterial blood samples. Twenty to thirty minutes of stable ventilatory status are desired for spontaneously breathing patients. Other patients may require more than 30 minutes to equilibrate following ventilatory changes. Less time may elapse for specific applications, such as obtaining confirmation that a change in ventilator settings is having the desired effect, without waiting for complete equilibration.

Preparing the Sample

Types of patient sample sources accepted by the GEM Premier 5000 system include:

- arterial
- capillary
- mixed venous
- venous
- arterial-mixed venous pairs

Note: Custom sample sources can be defined in Configuration.

Types of sampling devices accepted include:

- syringe
- capillary tube
- opened ampoules
- uncapped collection tubes using the syringe or ampoule sampling position

Pre-defined non patient sample sources accepted include:

- Proficiency
- GEM System Evaluator (GSE)

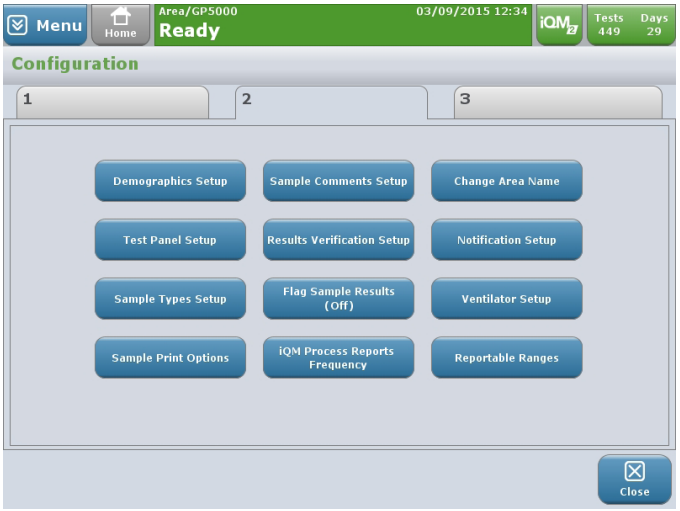
Note: GEM System Evaluator are products that are available from IL to GEM Premier customers, in order to meet individual local, state or country requirements. However, these products are not required by Instrumentation Laboratory to be analyzed on the GEM Premier 5000 system. Contact your local representative for information on these products, and availability in your area.

Sample Source Configuration

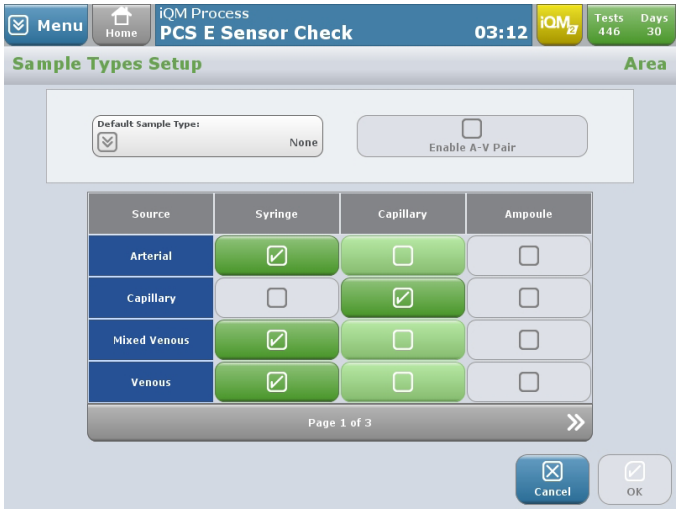
Note: Sample sources and devices must be configured prior to sample running.

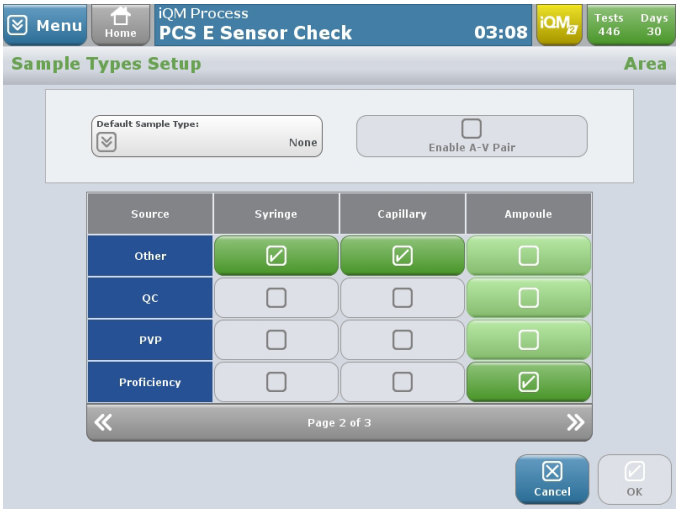
1. Select the Menu Button
2. Select Management or GEMweb Plus Button
3. Enter password if required

4. Go to Configuration>Tab 2>Sample Types Setup



5. Under each Sample Source, select the appropriate sample device that will be utilized.





Sample Device and Collection Procedures

Sample device

Typically, arterial blood gases should be collected using a 1-3mL plastic, disposable blood gas syringe, pre-filled with the appropriate concentration of lithium heparin. Contact your IL representative for recommendations on syringe devices appropriate for blood gas and electrolyte analysis in your market.

Note: Due to the permeable nature of plastic syringes, it is recommended that syringes be kept at room temperature as long as the blood is analyzed within 30 minutes of collection. Plastic syringes should not be iced.

WARNING: Arterial Blood Gas (ABG) sampling devices with auto-venting designs may contain carboxymethyl cellulose (CMC) in the porous vent of the syringe. CMC is intended to provide a fluidic seal for the syringes and is not designed to enter and contaminate the blood sample matrix. Sample contamination with CMC has been observed in specific ABG syringe models. If CMC contaminates the sample, the GEM Premier 5000 may increase iQM2 corrective actions and quality processes to remove the CMC contamination and ensure quality results. Facilities should evaluate their collection devices prior to clinical use. Contact your local Werfen/IL representative for recommendations on this matter.

Arterial Samples

Collection of arterial samples is typically obtained by needle puncture or from in-dwelling catheters. Arterial blood gases are measured for the purpose of evaluating the gas exchange function of the lungs as well as for the assessment of metabolic acid base disorders and electrolytes. CLSI[1] guidelines recommend that arterial line samples have an appropriate dead space flush waste volume collected to avoid sample contamination from intravenous solution prior to sample collection and use of high-pressure flush devices to avoid flush solutions embolus.

Syringe samples must be mixed thoroughly immediately after sample collection. Follow your institutions protocols for the directions for mixing requirements. In the absence of instructions, mix the sample for >30 by quick inversion of 1-2 inversions per second.

Note: Key for a thorough mixing is the quick and fast inversion of the syringe.

Note: Vigorous shaking can cause falsely elevated K+ results.

Note: Samples should be mixed for >30 seconds prior to sample analysis. Insufficient mixing can cause erroneous Hct/tHb/tBili results.

Capillary samples

Peripheral capillary samples may be collected in the event that arterial blood cannot be obtained; however, caution is advised when interpreting results as this only approximates blood gas measurement. Other difficulties associated with capillary sampling include inadequate sample volume and air bubbles.

The ideal collection device for capillary or "arterialized samples is a non-glass capillary tube in order to prevent the possible biohazard that a glass tube may present if it should break. The capillary tube should be coated with lithium heparin, calcium-titrated heparin or electrolyte-balanced heparin. Warming the skin to approximately 42° C will mimic arterialization of the blood sample. The sample collection is obtained by making a single, puncture of 2.0 mm or less, allowing a droplet to form and collecting the blood from the center of the droplet. Avoid "milking" the puncture site as this may cause hemolysis. Wipe away first drop to remove extracellular fluid that may interfere with results. Collect sample with capillary tube. Capillary samples should be run within 10 minutes of collection. It is essential to properly dissolve heparin immediately after collecting the capillary sample to prevent clotting. This can be achieved by various methods, for example by capping and rolling the capillary tube between finger tips (> 30 seconds or > 20 times), the use of metal mixing bars/fleas (> 10 times end-to-end), or other recommended procedures according to the capillary manufacturer.

Note: For accurate tHb and Hct results on capillary samples, proper mixing is critical. This may include the use of metal mixing bars/fleas (> 10 times end-to-end) or other recommended procedures according to the capillary manufacturer.

Note: Warming of the collection site may increase blood flow and improve capillary sample collection. This may be accomplished through the use of warming packs or other recommended procedures.

WARNING: A bias on certain analytes with capillary samples was observed with RAM Scientific Capillary Tubes (p/n 06 0186) and Fleas (p/n 07 9503). Therefore, do not use RAM Scientific Capillary Tubes (p/n 06 0186) and Fleas (p/n 07 9503) with the GEM Premier 5000. Facilities should evaluate their collection devices prior to clinical use.

Venous Sample

Venous blood is suitable for analyzing pH, pCO_2, electrolytes, glucose, lactate, total bilirubin, total hemoglobin, hematocrit, carboxyhemoglobin and methemoglobin. Venous blood is not a suitable substitute for arterial blood gas analysis. Mixing strategy recommended for arterial samples should be applied to venous samples.

WARNING: Venous blood collected in heparinized vacuum tubes with gel separators (all volumes) and non-gel vacuum tubes (2 mL only) are not suitable to measure COHb. This is a result of gamma irradiation of vacuum tube material during sterilization which generates carbon monoxide in the tube head space resulting in non-physiologic COHb elevation.

Mixed Venous Sample

Mixed venous blood is obtained from the pulmonary artery via a pulmonary artery catheter and is used to measure and evaluate oxygen uptake and cardiac output. It may also be used to assess the degree of intrapulmonary shunting. Mixing strategy recommended for arterial samples should be applied to mixed venous samples.

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Anticoagulants

The GEM Premier 5000 system requires the use of properly heparinized syringes. Blood samples that have not been mixed correctly or without anticoagulant will result in clots and fluidic errors. Lyophilized lithium heparin is the anticoagulant of choice for analyzing whole blood specimens on the GEM Premier 5000 system. In addition, the type of anticoagulant used must have little to no effect on all the analytes measured. A final heparin concentration of no more than 20 IU/mL of blood is the recommendation made by CLSI[1] guidelines.

Lyophilized anticoagulants eliminate the dilution issue associated with aqueous heparin preparations. However, dried heparin preparations may not dissolve adequately or quickly if the sample is not thoroughly mixed immediately after sample collection. Therefore, IL recommends that specimens obtained in syringes containing lyophilized lithium heparin be thoroughly mixed for >30 seconds by repeatedly inverting the device immediately following collection.

Capillary samples should be run within 10 minutes of collection. It is essential to properly dissolve heparin immediately after collecting the capillary sample to prevent clotting. This can be achieved by various methods, for example by capping and rolling the capillary tube between finger tips (> 30 seconds or > 20 times), the use of metal mixing bars/fleas (> 10 times end-to-end), or other recommended procedures according to the capillary manufacturer.

Note: For accurate tHb and Hct results on capillary samples, proper mixing is critical. This may include the use of metal mixing bars/fleas (> 10 times end-to-end) or other recommended procedures according to the capillary manufacturer.

Note: Vigorous shaking can cause falsely elevated K^+ results.

Note: Key for a thorough mixing is the quick and fast inversion of the syringe.

Note: Samples should be mixed for >30 seconds prior to sample analysis. Insufficient mixing can cause erroneous Hct/tHb/tBili results.

CAUTION: The use of Citrate, EDTA, oxalate or sodium fluoride anticoagulant may adversely affect sensor performance.

Transportation and Handling of Samples

Effects on Sample When Exposed to Air

Atmospheric air can significantly affect blood gases, in particular pH, pCO_2, O_2Hb, HHb, sO_2, and pO_2. However, exposure to air can also affect ionized calcium and consequently the pH in the sample (which can also alter magnesium).

Therefore, IL highly recommends and emphasizes the importance of expelling all air bubbles from sample prior to analysis.

Sample Transport

Hand carrying a blood gas sample appears to have minimal effect on the blood gas and pH results. Therefore, whenever practical, it is preferable to hand carry blood gas specimens without any vigorous movement to the location where they will be analyzed.

A blood sample is very rapidly accelerated and decelerated during pneumatic tube transport, which can robustly agitate the blood in a syringe. If even small air bubbles are present in the blood specimen, pneumatic transport can equilibrate these air bubbles with the blood and have a noticeable effect on pO_2. Therefore, it is important to continually emphasize the importance of removing all air bubbles from a blood gas syringe prior to pneumatic transportation.

Note: It is recommended to analyze samples within 15 minutes from draw to optimize sample quality.

Note: It is recommended that syringes not be iced; if analysis is delayed by more than 30 minutes, storage in icy slurry may be considered but this may impact gases and electrolyte results (particularly K^+). For samples that are delayed by more than 30 minutes, thorough mixing necessary for ensuring the accuracy of Hct, tHb and tBili results.

Hemolysis

Potassium measurements can be significantly altered through inducing trauma to the sample during the collection (vigorous shaking) and transportation (pneumatic tube) phase. IL recommends hand carrying of blood gas samples where possible without any vigorous movement.

Note: Despite the recommendations made in this guide, each facility should establish their own appropriate specimen management protocols.

Sample Volumes Required for Analysis

Analytes	Sample Volume (µl)
pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct, tHb, O_2Hb, COHb, MetHb, HHb, sO_2, tBili or any combination of Electrochemical* analytes and CO^-Oximetry** and/or tBili	150
tHb, O_2Hb, COHb, MetHb, HHb, sO_2, tBili	100
pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct	65 (Capillary Only)

* Electrochemical analytes = pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct

** CO-Oximetry = tHb, O_2Hb, COHb, MetHb, HHb, and sO_2

Sample Preparation Prior to Analysis

Prior to analysis, it is essential that air bubbles are expelled and the sample be thoroughly mixed. Hematocrit, total hemoglobin, hemoglobin derivatives, total bilirubin and oxygen content are particularly affected when samples are not well mixed. Improper mixing may also produce erroneous results for other analytes. A uniform distribution of red blood cells and plasma prior to sample aspiration is mandatory for reliable results.

IL recommends the following procedure for proper mixing;

For syringe samples:

- Expel all air.
- Mix the sample thoroughly.
- Use quick inversion to mix sample for ≥30 seconds.
- Push out a few drops of the sample onto a gauze pad to ensure there is no clot in the syringe tip.

For capillary samples:

- Cap tube and mix immediately with quick inversion by rolling capillary tube between finger tips for ≥30 seconds or > 20 times.
- If metal flea bar is used for mixing (>10 times end-to-end), uncap the capillary and remove the metal mixing bar prior to sample aspiration.
- Remove blood and debris from the outside of the capillary tube prior to placing it in the analyzer sampling port.

Instrumentation Laboratory offers a complete Pre-Analytical Training Package which details correct collection practices and procedures:

- Quick Reference Guides for Capillary, Arterial Line and Arterial Puncture Sample Handling
- ILluminations Webinars
- Graded Knowledge-Assessment Quizzes

Contact your local IL representative for additional information or visit ce.us.instrumentationlaboratory.com to access the Continuing Education portal content.

Notes:

1. Extra care must be taken when mixing capillary tube samples. Samples should be remixed if more than 5 minutes have elapsed since collection. Sample homogeneity is essential for accurate and reliable tBili measurements.
2. Transferring blood samples between devices, for example from a syringe to a capillary tube, is not recommended. Transfer of a sample between devices may introduce air contamination into the blood sample and/or cause an increase in the final heparin concentration that may lead to interferences with analytes, such as Sodium and Ionized Calcium.
3. Each facility must establish appropriate mixing procedures for each type of device.
4. Heparin acts as an anticoagulant because it catalyzes the activation of antithrombin III. Due to heparin's activity as a catalyst, very little is needed, but it must be rapidly dissolved in the blood specimen to inhibit coagulation. Once the coagulation process begins, heparin cannot reverse the process. Therefore, it is essential that the sample be mixed thoroughly immediately after collection.
5. Therapeutic heparin used for systemic anticoagulation should not be used as an anticoagulant for blood gas specimens. It has a very high concentration, which may alter ionized calcium and pH measurements.
6. Fluoride and Oxalate are not suitable anticoagulants for use with the GEM Premier 5000 system. Refer to the Interference Section for specific information on the effect of these substances on GEM Premier 5000 analytes.
7. Collection devices should be filled to required volume specifications to ensure proper heparin concentrations. Sample devices that are under filled have a higher final concentration of heparin which can interfere with certain assays, such as sodium and ionized Calcium.[2]
8. Capillary devices are manufactured to provide a relatively high final heparin concentration due to high frequency of clotting events relative to pediatric sample type. Proper filling of capillary devices with required sample volume eliminates heparin interference due to high heparin concentration.[2]

Footnotes:

1 CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guidelines – Second Edition. CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.

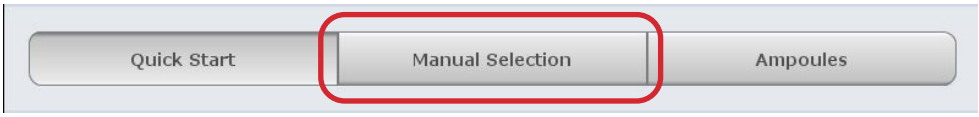
2 Yip, P.M et al. Heparin Interference in Whole Blood Sodium Measurements in a Pediatric Setting. Clinical Biochemistry 39 (2006) 391-395.

Analyzing Patient Samples

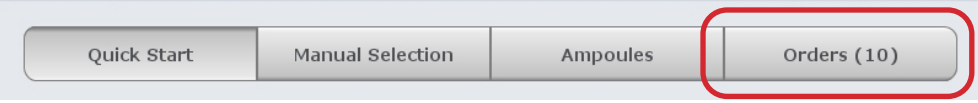
The GEM Premier 5000 with iQM2 features three home screens for analyzing patient samples:

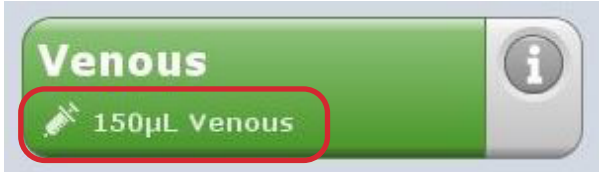
- **Quick Start**

- **Manual Selection**



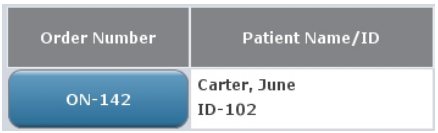
- **Orders**





The default home screen presented on the analyzer is **Quick Start**. The Quick Start screen streamlines the sample analysis process by enabling the configuration of unique test panel buttons customizable to the needs of a given location in the hospital. Quick Start buttons are configured with unique test panel names, parameter selections, sample source and test volumes.

The **Manual Selection** screen allows users to choose parameters, sample source and test volume for samples in a simple 3-4 step workflow that do not fit within a pre-defined Quick Start panel.



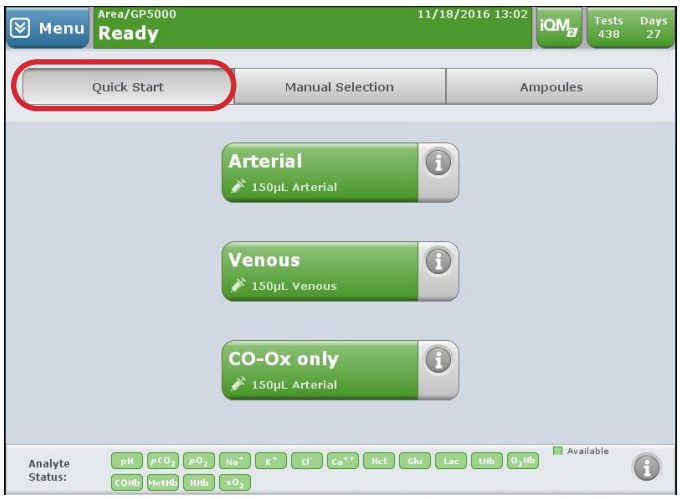
The **Orders** screen provides the ability to execute a test order downloaded from an HIS/LIS. This feature is only available on systems running as a client analyzer on a GEMweb Plus network that is configured to accept orders from a HIS/LIS. Review the GEMweb Plus Data Management Guide for details on how to configure this feature.

The availability of all three screens maximizes flexibility and enables customization to the unique needs of the testing location.

Analyzing samples from the Quick Start screen

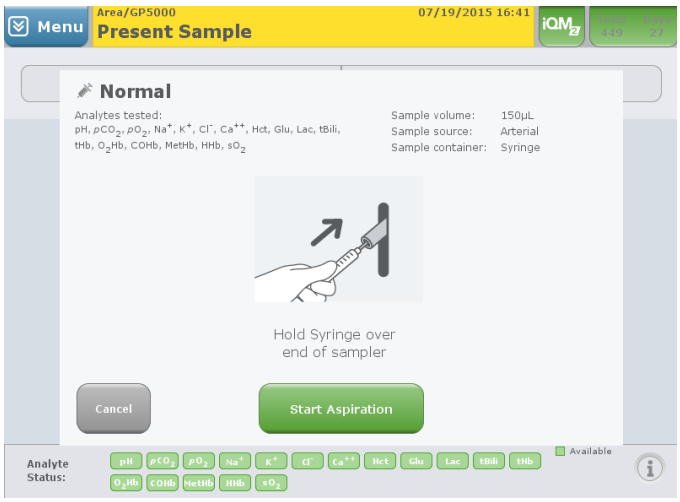
1. Select the desired Quick Start Button. The Quick Start Button outlines customized panel name, sample device, and sample volume.

   Note: Quick Start buttons are configurable to meet the requirements of your facilities (see "Configuration Set-Up" on page 32).



2. The sampler will emerge from its home position.

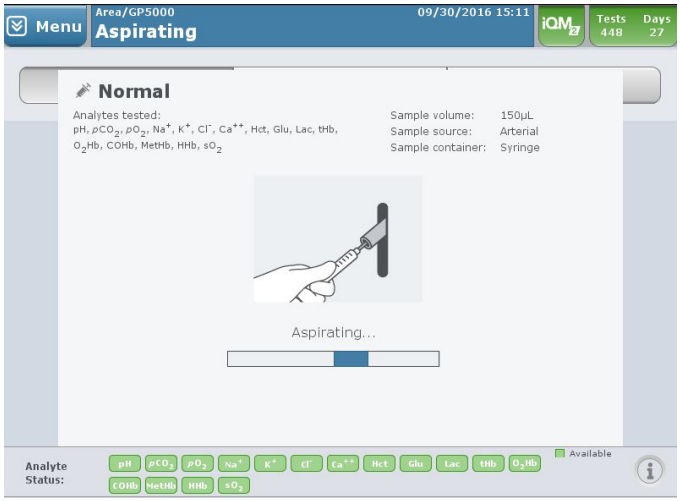
   Syringe or ampoule sampling – The sampler will extend from the luer and move approximately 30 degrees from its home position. Present the syringe or ampoule by placing it over the end of the sampler. *The sampler should be inserted far enough into the container to allow aspiration but not so far that the sampler touches the bottom of the device.*



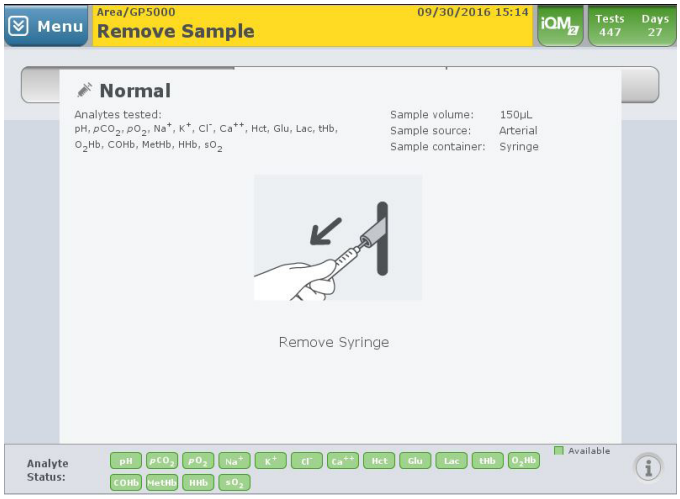
   Capillary tube sampling –The luer will present at the top of the home area at a 90 degree angle with the sampler extended. Remove the end caps. If used, remove the metal mixing bar. Tilt the tube slightly until the blood is flush with the end of the capillary tube. If there is blood or debris on the outside of the capillary tube, wipe the end prior to placing on the sample probe. Place the capillary tube onto the exposed end of the sampler. **Do not use excessive force**.

   Hold the exposed end of the tube and press **Start Analysis** to aspirate. Do not block the exposed end of the capillary tube during aspiration.

3. The system will aspirate the sample and provide audio and visual prompts when aspiration is complete. Remove the container promptly. The sampler will retract into the system. Dispose of the remaining sample as you would medical waste.

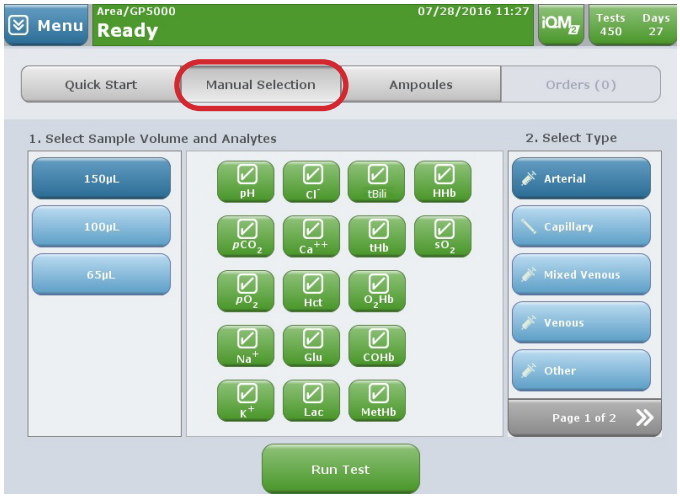


Note: Your analyzer may be configured to have a "Sample Removal Confirmation". If this is enabled, the user must press OK to confirm removal of the device. The sampler will still automatically retract if OK is not selected within 15 seconds of completing aspiration. A count down timer will be displayed.



Analyzing samples from the Manual Selection screen

1. Select the desired sample panel by selecting the radio button on the left.
   - 150 µL mode offers full menu testing for syringe, and tube devices.
   - 100 µL mode offers CO-Ox/tBili only.



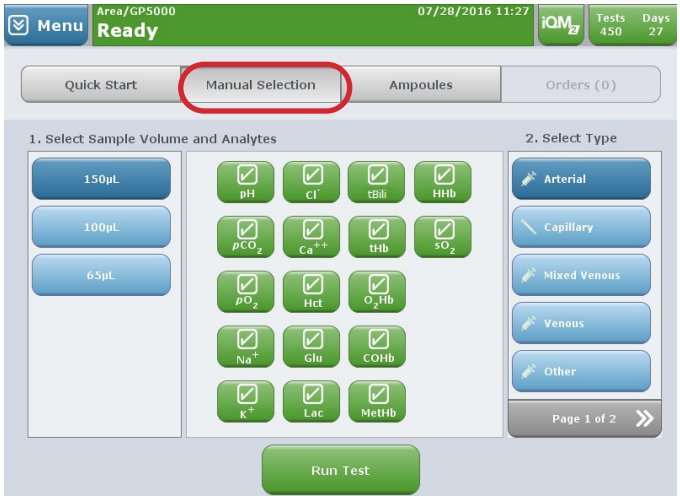
2. Select or deselect available analytes by pressing the green analyte buttons. A check indicates that the analyte will be included in the test.

   Note: Analytes that are not available for testing will be identified with a grey, red or yellow flag (see "Viewing Results" on page 104 for analyte status).

3. Select the sample type/ container under if it is not already selected.

4. Press Run Test

5. The sampler will emerge from its home position. When ready, press Start Analysis.



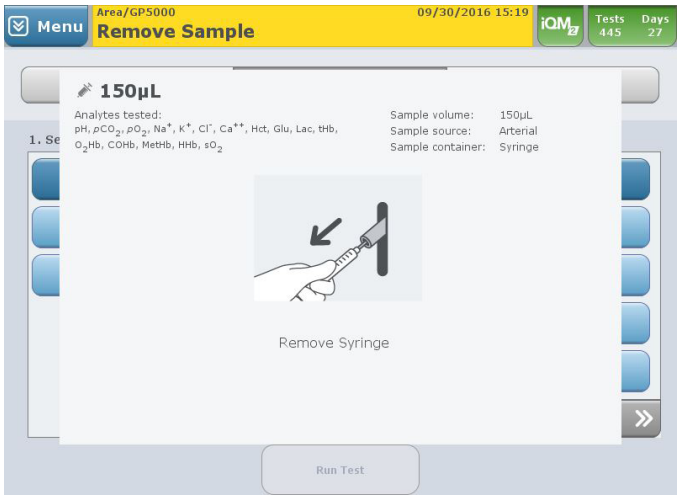
   Syringe or ampoule sampling – The sampler will extend from the luer and move approximately 30 degrees from its home position. Present the syringe or ampoule by placing it over the end of the sampler. The sampler should be inserted far enough into the container to allow aspiration but not so far that the sampler touches the bottom of the device.

   Capillary tube sampling – The luer will present at the top of the home area at a 90 degree angle with the sampler extended. Remove the end caps. If used, remove the metal mixing bar. Tilt the tube slightly until the blood is flush with the end of the capillary tube. If there is blood or debris on the outside of the capillary tube, wipe the end prior to placing on the sample probe. *Place the capillary tube onto the exposed end of the sampler. **Do not** use excessive force.*

   Hold the exposed end of the tube and press **Start Analysis** to aspirate. Do not block the exposed end of the capillary tube during aspiration.

6. The system will aspirate the sample and provide audio and visual prompts when aspiration is complete. Remove the container promptly. The sampler will retract into the system. Dispose of the remaining sample as you would medical waste.

Note: Your analyzer may be configured to have a "Sample Removal Confirmation". If this is enabled, the user must press OK to confirm removal of the device. The sampler will still automatically retract if OK is not selected within 15 seconds of completing aspiration. A count down timer will be displayed.



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Entering patient information during sample analysis

Whether you are using **Quick Start, Manual Selection or Orders** sample processing, the analyzer will provide the user with the **Required and Optional Information** screen where data related to the patient, operator, order and other customized information fields can be scanned, manually entered, or downloaded from a HIS/LIS.

1. The system will perform analysis while you enter patient information using the alphanumeric keypad (the keypad becomes accessible when you press a button requiring data entry), barcode gun, or via pre-populated fields imported from the HIS or LIS. Required fields are indicated with an asterisk (*) and conveniently located in the left column marked “Required”.

   Note: When required fields are configured, View Results cannot be accessed until all required fields are completed.

2. Comments may be entered on the Enter Information screen. Comments may be free-text entries or selected from pre-defined entries.

3. After all required information is completed, user can move to result screen by selecting View Results Button. If required information is completed, the analyzer will migrate to result screen automatically.

4. Results are presented as follows:

- Measured values – pH, blood gas, electrolyte, and metabolite analyte levels measured during patient sample analysis
- Temperature corrected values – displayed only if a patient temperature has been entered in the Required and Optional Information screen
- CO-Oximetry values – displayed only if one or more CO-Oximetry analytes are selected for measurement
- Derived values – calculated using equations applied to one or more measured analytes

If patient reference ranges and critical value limits have been configured, results within the reference range are displayed in green text on a white background. A result outside the reference range, but not above or below a critical limit is displayed in black text on a yellow background. If a result is at, above or below a critical limit it is displayed in white text on a red background. Results in white text on a gray background indicate that no reference range or critical limits have been configured for that analyte.

5. The GEM Premier 5000 system can be configured to automatically release patient results to the HIS/LIS (“Autoverification”) or via manual release. Press Accept to release sample results manually to the HIS/LIS and the permanent record.

   Pressing Exclude will not release results to the HIS/LIS and the permanent record. Although excluded, the results will be kept in the analyzer database and can be retrieved on-demand.

   Note: If user does not select Accept or Exclude, results will remain in the analyzer database but will not transmit to the HIS/LIS.

   Sample results will print automatically if configured to do so. The system will return to the Home screen within one minute. To return to the Home screen manually after results are displayed, press the Home button.

   The Notify button allows the operator to record any notification made to the clinician. This feature must be enabled, refer to “Notification Setup” on page 59 for instructions.

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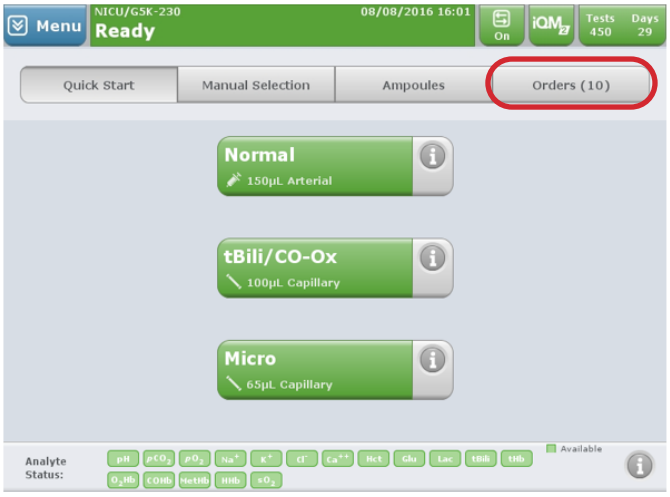
6. Viewing Patient History

To view patient result trending, press the Patient History button located at the lower right part of the screen when current patient result is being displayed. The analyzer will display the most recent five test results of the same sample type for the current patient. Samples older than one month will not be shown. The delta (Δ) value represents the difference between the current sample and the one prior to it.

Analyzing samples from the Orders screen

Note: Receiving and processing Orders generated by the HIS/LIS is available only on a GEM Premier 5000 running as a client analyzer on a GEMweb Plus network. The Order Processing feature must be enabled during the Configuration of the GEMweb Plus server.

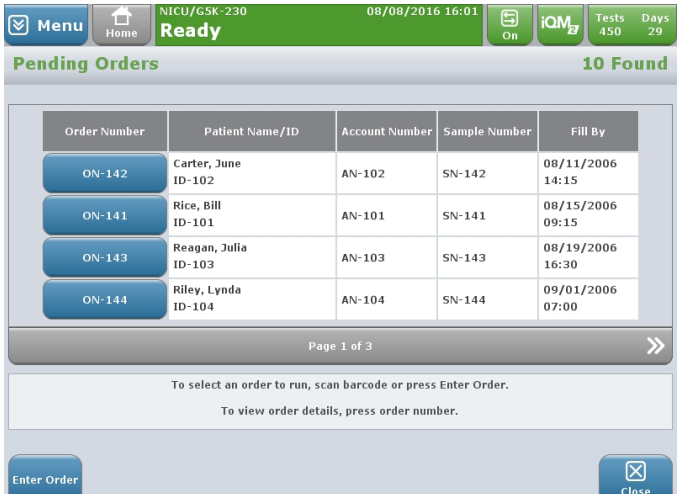
1. If Order Processing is enabled, an action button labeled **Orders** will be presented on the home screen of the analyzer. The button will appear directly to the right of the **Ampoules** toggle button along the top of the screen. The **Orders** button will show the number of pending orders received from the HIS/LIS. Orders are downloaded from the HIS/LIS into an orders database that can be selected when samples are available. The number displayed next to **Orders** will increment as new orders are received and decrement as orders are fulfilled.

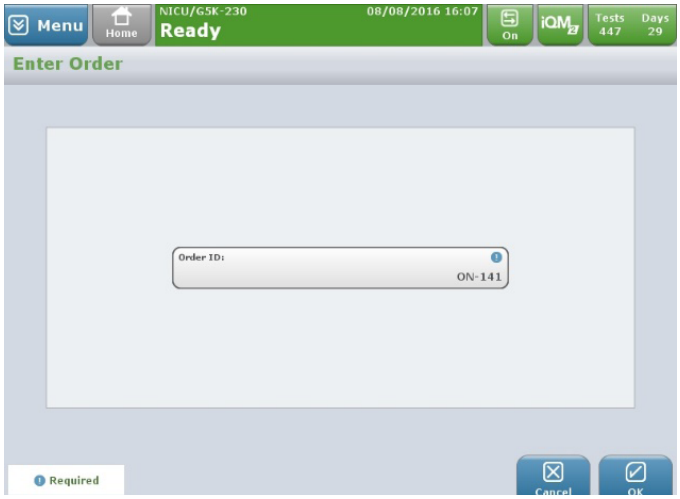


2. There are two ways to search for a test order. All search methods will match the search criteria to the following fields, in order of priority: Order Number, Patient ID, Account Number, Sample Number, Sample ID and Patient Last Name. To search, the following methods can be used:

   a. From the Pending Orders screen, scan the barcode label on the sample

   b. From the Pending Orders screen, select Enter Order and enter the search criteria





Finally, a test order can be initiated from the **Pending Orders** screen by selecting an order from the list.

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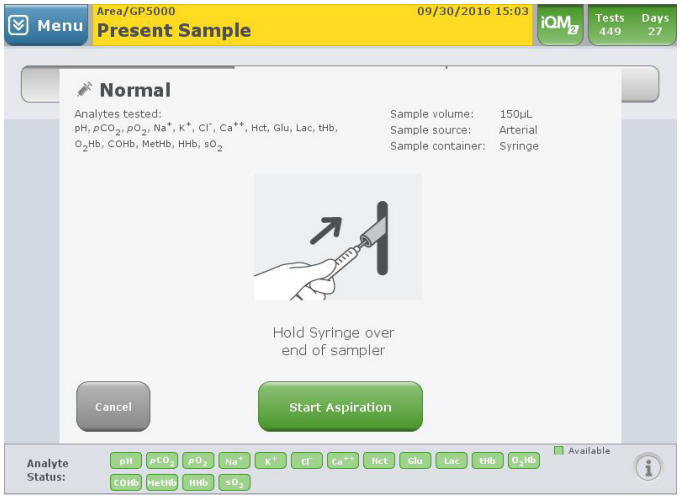
3. Once a sample is matched to an order by any method above, the Order Details screen will be presented. This screen provides details of the order as sent by the HIS/LIS. The order will define what analytes are to be reported for the sample, and may also specify the sample type and volume.

   If the sample type and volume are not available in the test order, they must be selected from an additional pop-up screen prior to running the order.

4. Once the operator is satisfied the sample matches the order, press Start Aspiration to initiate sample processing.

   Patient samples that have no corresponding Orders can be processed on the analyzer using Quick Start or Manual Selection screens.



Viewing Results

Flag Sample Results (or Exception Flags):

The GEM Premier 5000 system can provide sample flagging on patient reports following the completion of the iQM2 quality checks, post-sample analysis.

Sample flagging provides the operator with a notification of a possible sample error that could affect analytes results. Situations that could produce exception flags are microclots or interferences. Please refer to the table located on the next page for a complete listing of exception flags available on the GEM Premier 5000 system.

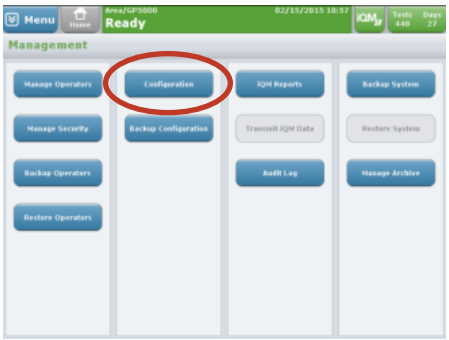
If a sample exception is identified by iQM2 quality checks, the operator will be alerted immediately with a dialogue pop-up screen on the analyzer. The operator will be required to acknowledge the dialogue alert to continue utilizing the analyzer functions. In addition, all affected patient results will be displayed with an exception symbol next to the affected analyte on both on the screen and printout.

Options for "Flag Sample Results":

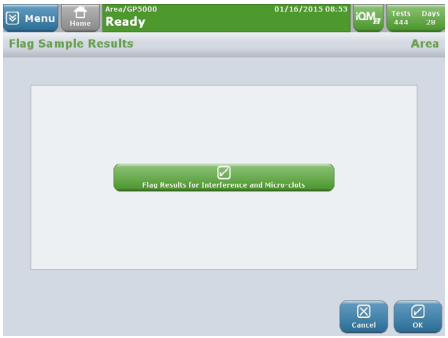
Option 1 – If "Flag Sample Results" is configured "ON", sample results will not be displayed until the completion of post sample iQM2 checks. The final sample report will display exception flags and the user will be immediately notified of possible sample exceptions.

Steps to Turn Sample Flagging "ON":

1. Select the **Menu Button**
2. Select **Management** or GEMweb **Plus Button**
3. Enter password if required
4. Select **Configuration>Tab 2>Flag Sample Results**



5. Select **Flag Results for Interference and Microclots** option (checkmark will appear when selected)
6. Select **OK**



Option 2 - If "Flag Sample Results" is configured "OFF", sample results will be displayed prior to the iQM2 check post sample analysis. The final display and printout of patient results will not include exception flags. A dialogue pop-up will be the only alert which can be dismissed by the user only after acknowledging the alert on the screen. This acknowledgement is required to continue using the analyzer.

CAUTION: If Option 2, "Flag Sample Results OFF ", is configured, a pop-up window appears after the results are displayed to alert the user. However, once the pop-up is acknowledged, sample results will not be flagged in the initial display, database or through electronic transfer.

The following exceptions or flags may be displayed along with the sample results.

Exception Symbol	Exception Symbol Description
	Outside Reference Range - High
	Outside Reference Range - Low
	Outside Critical Limit - High
	Outside Critical Limit - Low
	Outside Reportable Range – Greater Than
	Outside Reportable Range – Less Than
	Result Incalculable
	Absorbance Error
	Sulfhemoglobin Interference Detected
	High Turbidity Detected
	Interference Detected
	Micro Clot Detected
	Temporary Sensor Error
	High Methemoglobin Warning
	Sulfhemoglobin and High Methemoglobin Warning
	Corrected for Sulfhemoglobin
	iQM2 IntraSpect

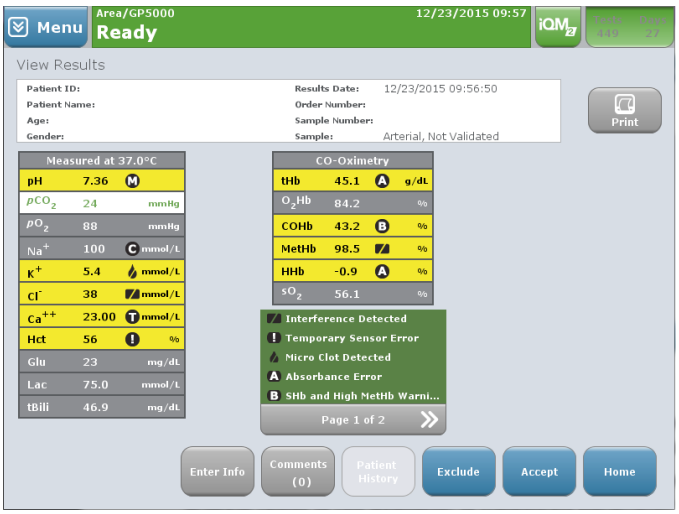
A flagged analyte result should be interpreted with caution, and should be repeated when:

- The result is flagged with an exception symbol when the Flag Results for Interference and Micro Clots is enabled, or
- The result is immediately followed by a message to the operator indicating that any condition exists, which is referenced in the Exception Table above.

Flag Results for Interference and Micro Clots

When this option is enabled in Configuration, reporting of patient results will be displayed after the post-sample sensor check is completed. The GEM Premier 5000 system will flag analytes if an interference or micro clot is detected through the IntraSpect or Sensor Checks, utilizing the Pattern Recognition Check to determine error cause. When this option is disabled, patient results will be displayed immediately after completion of measurement, and results will not display flags unless an error is detected by IntraSpect check during sample analysis. However, the operator will be presented with a pop-up dialogue message when an interference or clot is detected in the previous sample by the post-sample sensor and pattern recognition checks. The dialogue pop-up message will be displayed until dismissed by the operator.

Note: Each facility should determine the need based upon workflow, staff, patient need, etc. prior to configuring sample flagging.



Result Incalculable

When the Incalculable flag (Incalc) is presented for measured analytes it indicates that the required measurement criteria were not met during sample analysis.

The Incalculable flag is displayed by a derived parameter when a required measured analyte result is not available. A measured parameter with an Incalculable flag or a measured parameter outside of the reportable range is an example of when a measured analyte will not be available for use in a calculation. If an entered value required for the calculation is not supplied Incalculable will also be displayed. In addition, an error detected by IntraSpect will display an Incalc or IntraSpect flag and suppress results of affected analyte(s).

Absorbance Error

An absorbance error is an indicator of a residual spectrum inaccuracy during the sample analysis. Residual spectrum is estimated by calculating the difference between the measured spectrum and predicted spectrum based on the CO-Oximetry calculation for that sample. The presence of unknown interfering substances, clots or other foreign matter within the blood sample that alters the optical spectrum will result in higher levels of residual spectrum. A sample with an absorbance error should not be reported and the sample should be repeated, as results can be outside specification claims.

Sulfhemoglobin Interference Detected

This flag is displayed when Sulfhemoglobin is equal to or greater than 10 percent. Sample results may be outside specification claims.

High Turbidity Detected

A turbidity flag is presented when measured turbidity is equal to or greater than five percent (5%), created by 10% Intralipid fat emulsion with a final concentration of 0.5%, is detected. Sample results may be outside specification claims.

Interference Detected

General spectral interference for CO-Oximetry or total bilirubin, or interference from an interfering chemical and/or drugs. Sample results may be outside specification claims. Please refer to the “Limitations and Interference Testing” on page 224 for information on interfering substances.

Temporary Sensor Error

A temporary sensor error reflects when the Process Control solution B post analysis sensor check is outside acceptable ranges. Sample results may be outside specification claims.

High Methemoglobin Warning

Methemoglobin detection is equal to or greater than 30 percent. Sample results may be outside claimed specifications.

Sulfhemoglobin and High Methemoglobin Warning

The sulfhemoglobin detection is equal to or greater than 0.3 percent and the methemoglobin detection is equal to or greater than 30 percent. Sample results may be outside specification claims.

Corrected for Sulfhemoglobin

This flag indicates that Sulfhemoglobin less than 10 percent has been detected in the sample. The appropriate correction algorithm is applied to eliminate the impact of Sulfhemoglobin on other hemoglobin fractions. The sample results are within the claimed specification.

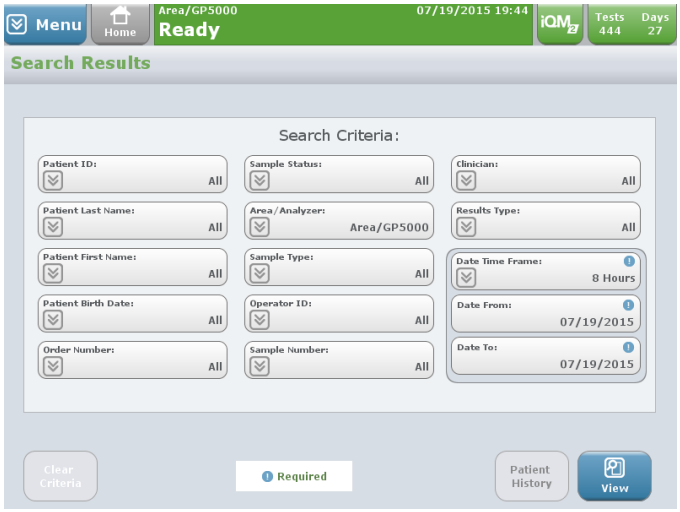
Search Results

The GEM Premier 5000 system's powerful Data Management system allows you to search for information on your standalone analyzer or across the entire GEMweb Plus network, making it easy to pinpoint desired patient and sample data.

To search for sample and patient data, launch the Search Criteria screen:

- Networked analyzers – After signing in to GEMweb Plus, select the Samples tab.
- Standalone or Networked analyzers – Choose Search Results from the drop-down Menu in the upper left corner of the screen. You may need to enter your password to access this feature.

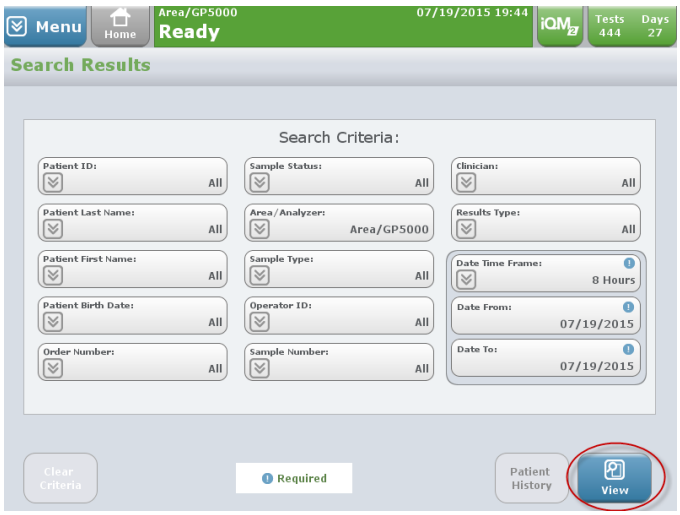
1. Enter the search criteria in the Search Criteria area. These function as data entry fields or drop-down menus (example shown here is from a standalone analyzer).



Notes:

- **If no text is entered in a field, the default is value is "All".**
- **Date and time frame criteria (right column) are required for all searches. The date range will be defaulted to current date for both Date From: and Date To: criteria.**
- **For the Area/Analyzer criterion, if All is selected while the analyzer is networked, the search will be performed on all analyzers in the network (included those that have been deleted). When the analyzer is disconnected or standalone, only information stored on the current analyzer will be searched**

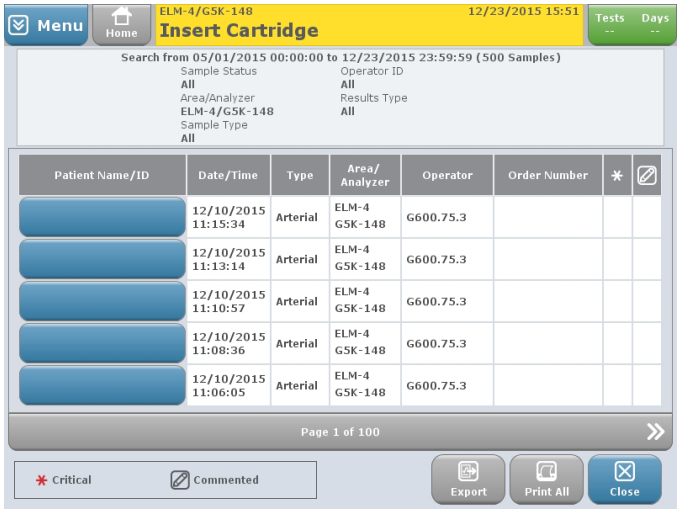
2. To view the samples that meet the selected criteria, press the View button at the bottom of the screen. All samples meeting the search criteria will be displayed on screen.



Note: If the search criteria will result in more than 500 records, a message will appear instructing you to narrow the entered criteria.

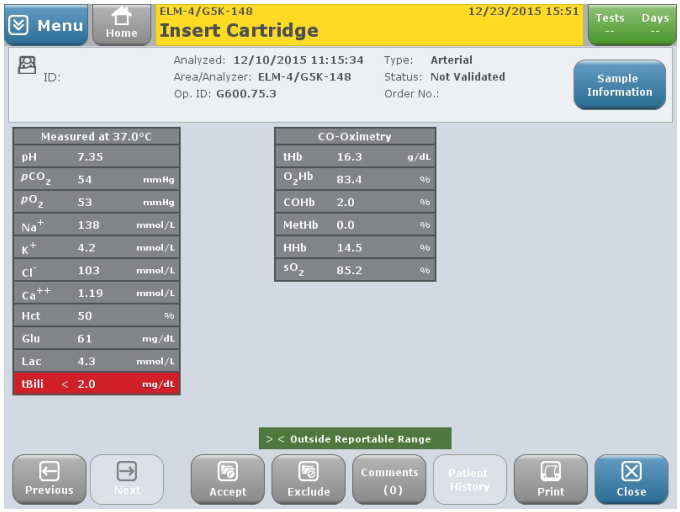
Note: To clear the search criteria, press the Clear Criteria button

3. Results are displayed in list format, along with the criteria used in the search. All samples that meet the criteria selected by the operator will be displayed. The following actions can be performed on the search results:



- Export – creates a Microsoft Excel compatible file that can be saved on a network or written to a CD/DVD or USB memory device.
- Send – for standalone instruments (not connected to GEMweb Plus), allows you to resend any records that have been amended and reaccepted or any previously unvalidated samples that have been reviewed and accepted to the Laboratory or Hospital Information system. This button is presented if there is at least one connection configured to send patient results.
- Print All – prints one copy of each sample record resulting from the search.

4. Details of a specific sample can be accessed by pressing one of the patient name buttons from the sample list; this launches the Sample Results screen, which displays patient demographic information as well as the sample results.



You will have the option to Accept or Exclude samples (if your system is configured to manually accept results), Send Accepted or Amended data to the LIS/HIS or other configured connection (if your system is configured for this function), view Patient History (five most recent samples run within a one month time frame), Print the record, select **Notify** to document a communication regarding the patient's results (if your system is configured for the notification function), or view the Next or Previous record.

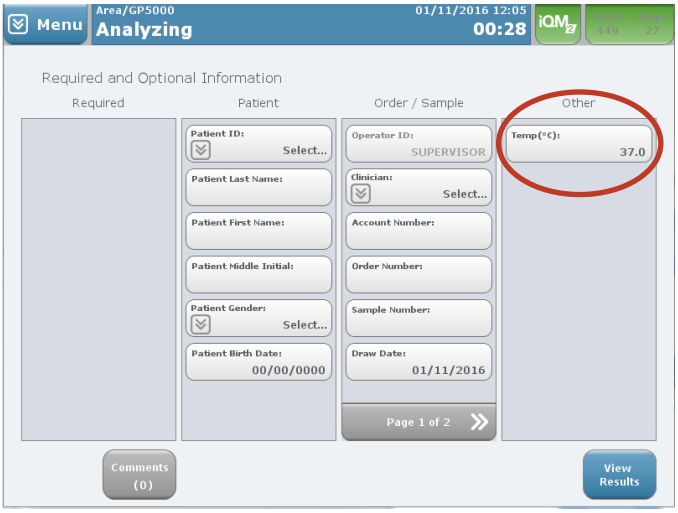
Note: the GEM Premier 5000 system is capable of storing at least 35,000 samples.

5. **Patient History**

   If a valid patient ID and sample type are entered, the Patient History button becomes available. Pressing this button will launch a Patient History screen showing the five most recent samples run in the last month for that patient.

6. Sample Information

If you are authorized to do so, patient temperature and patient demographic information may be amended by selecting the blue Sample Information button, located in the upper right corner of the Sample Details screen. Use the text fields and drop-down menus to amend the sample information. Additional comments may also be added. However, comments already committed may not be amended or deleted.

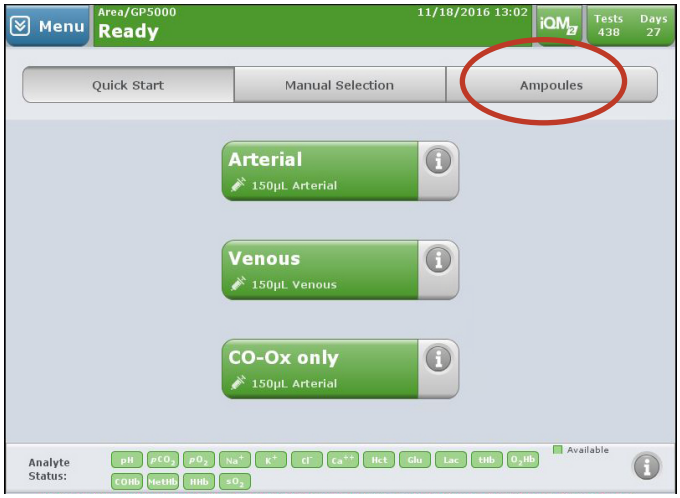


Note: Patient results can never be amended. Whenever the patient's temperature or demographic information has been amended, a new report will be generated and marked as an Amended sample. An amended report will also be generated when additional comments are added. The report will be sent automatically to the LIS/HIS or a Data Management System if your analyzer is configured in this manner.

GEM System Evaluator (GSE) and GEM Hematocrit Evaluator (GHE) Sampling

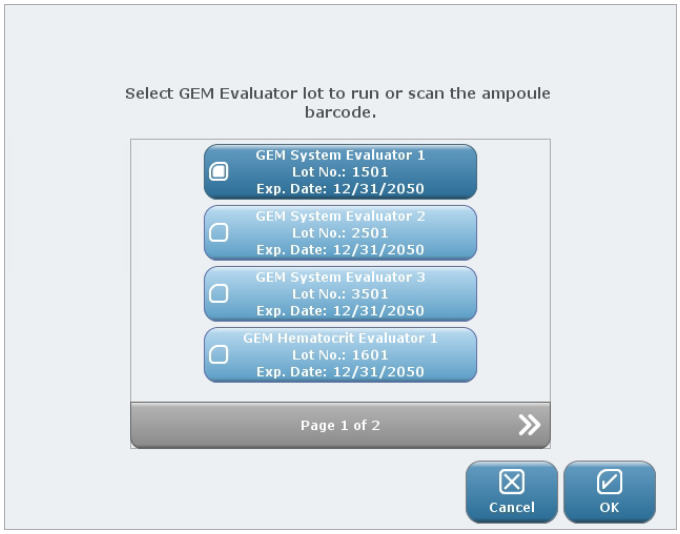
The GEM Premier 5000 system is designed to allow facilities to configure and perform external quality control materials if desired. Facilities should evaluate all local, state, federal, and accreditation guidelines prior to configuring this feature. The steps to perform GSE/GHE are as follows:

1. Select form the QuickStart screen (Home screen) the **Ampoules** mode button.



2. Select GEM Evaluator button

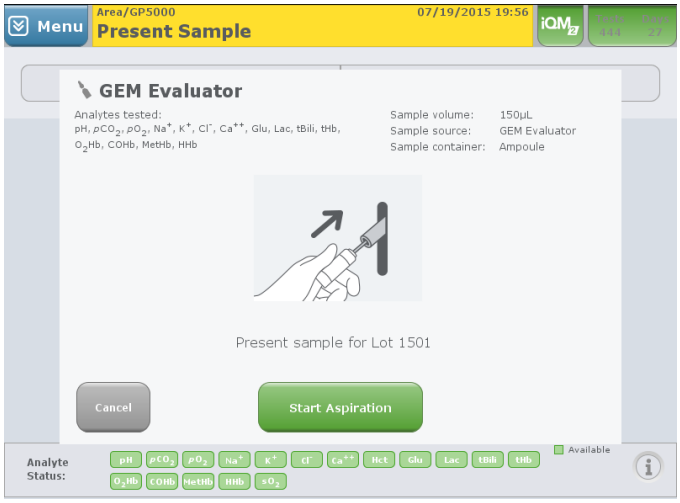
3. Select GSE/GHE material and lot number that you will be performing.



Note: When the Select Button for a specific GSE/GHE material is active, the Select Button will be darker in color and will display a filled in circle.

Note: If GSE lot is not configured, refer to "Other Material Setup" on page 49.

4. The GEM Premier 5000 system will present the sampler to the user for GSE/GHE aspiration. User should present the ampoule by placing it over the end of the sampler



Note: Refer to GSE/GHE package insert for ampoule storage and preparation instructions. GSE/GHE should be equilibrated to room temperature (22+1°C) for at least 8 hours prior to use. Prior to use, hold the ampoule by the top above the break line and shake the ampoule with gentle tapping.

Note: Hold the ampoule only above the break line. Holding the ampoule in your hand will cause the aqueous solution to exceed the recommended testing temperature and can adversely affect GSE results.

5. Gently tap the ampoule so the liquid settles back to the bottom.

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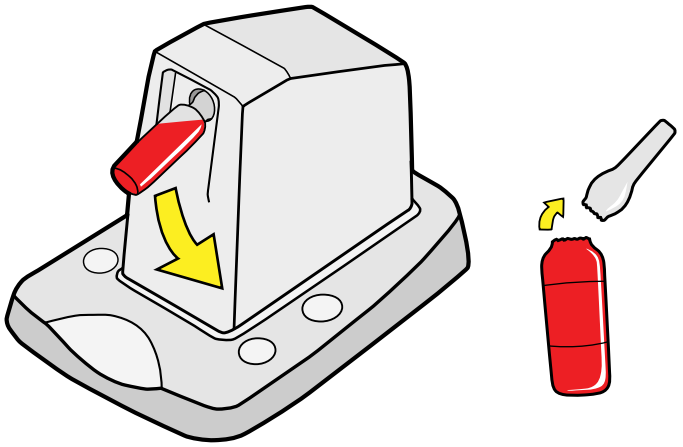
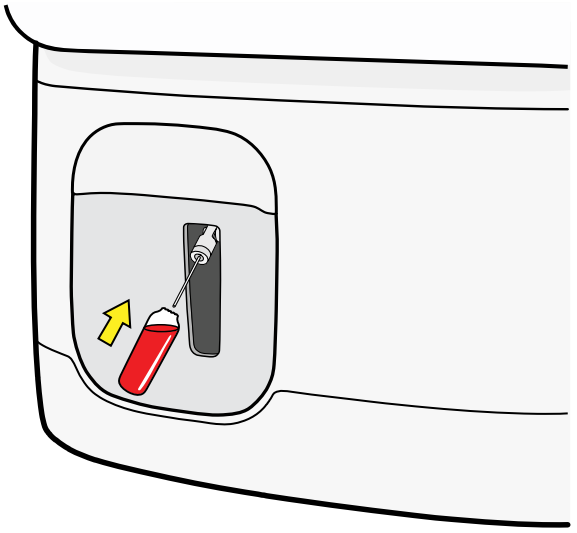
6. IL offers an ampoule breaker as an optional item to assist users in opening ampoule products in their facility.

   Carefully snap open the ampoule utilizing the ampoule breaker. Insert the tip of the ampoule into the ampoule breaker and gently pull down on the ampoule until the neck snaps. Be sure to keep a firm grip on the ampoule with one hand and on the top of the ampoule breaker with the other hand.



7. Present the GSE/GHE ampoule to the sampler, which will emerge from the gray sampling area at the front of the analyzer. Hold the ampoule so the end of the sampler does not touch the bottom. Select the Start Aspiration Button. Continue to hold ampoule during the aspiration process. Press OK to begin aspiration.



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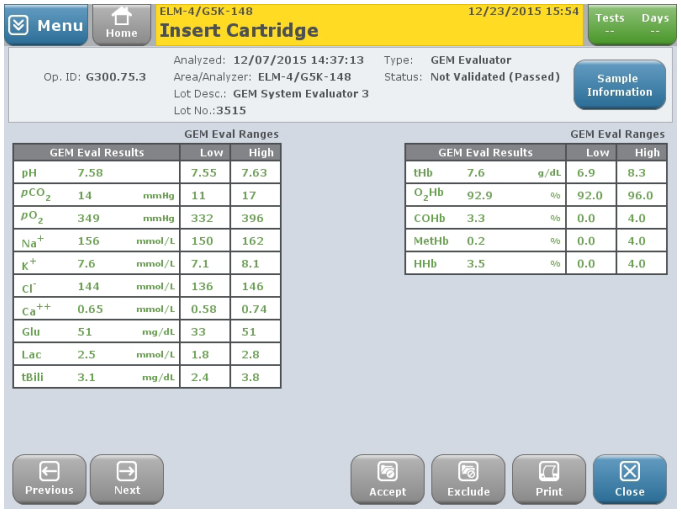
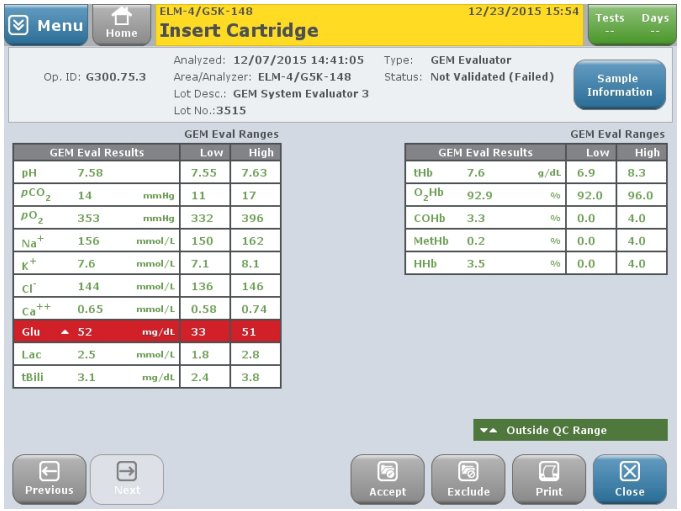
8. The analyzer will issue an audible and visual prompt when the aspiration process is complete. Remove the ampoule immediately upon hearing the audible prompt.

   The analyzer will show the results of the GSE/GHE testing automatically upon completion of the measurement process. All GSE/GHE results within package insert range will be indicated in green text with a white background; out-of-range GSE/GHE results will display in white text on a red background. If all results are within range, press Accept. In the unlikely event of an out-of-range GSE/GHE result, you may accept or exclude the sample.





The GSE/GHE results will be displayed with the following information:

- Measured analyte values
- Low and High acceptable values
- Result exception symbology

GSE/GHE Exception Symbol	GSE/GHE Exception Symbol Description
▲	Outside Reference Range - High
▼	Outside Reference Range - Low

9. GSE/GHE results can be viewed on demand via the analyzer or GEMweb Plus.

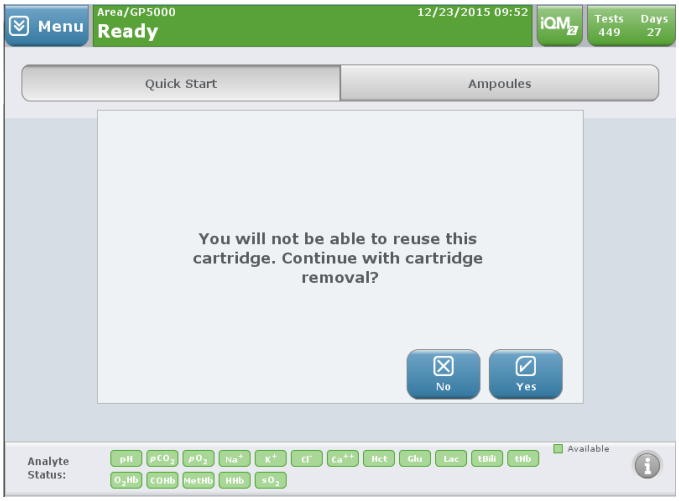
Removing the GEM PAK

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.

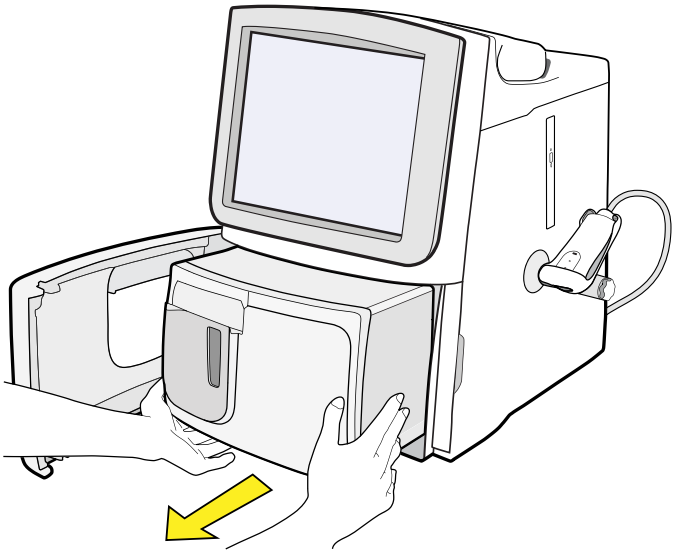
1. Press the **Menu>Action>Remove Cartridge** buttons. If requested, enter your password.

2. As a precaution, the system will ask you whether you want to continue. Press **No** to stop the process and return to the QuickStart 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.

Shutting Down the Analyzer

Shutting down the analyzer is an important step that requires careful consideration before completing. Once the analyzer is shut down you will need to replace the GEM PAK if power is not restored within 60 minutes.

Note: Power must be restored within 60 minutes. If, when power is restored the GEM PAK cannot be recovered, the analyzer will alert the operator to remove the GEM PAK.

1. Press **Menu>Actions>Shutdown** from the pull-down menu.

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

The GEM Premier 5000 system has a momentary power switch. To power the instrument off, it is necessary to utilize the Shut Down command in the instrument software, which is accessed through the drop-down Menu. If the power switch is pressed and held for 5 seconds or longer, the instrument will shut down. However, this causes illegal software shut down, and the depending on the event terminated by the illegal shutdown may shorten the restore power requirement to 20 minutes or reject the installed GEM PAK.

Performing a System Backup

Protecting data

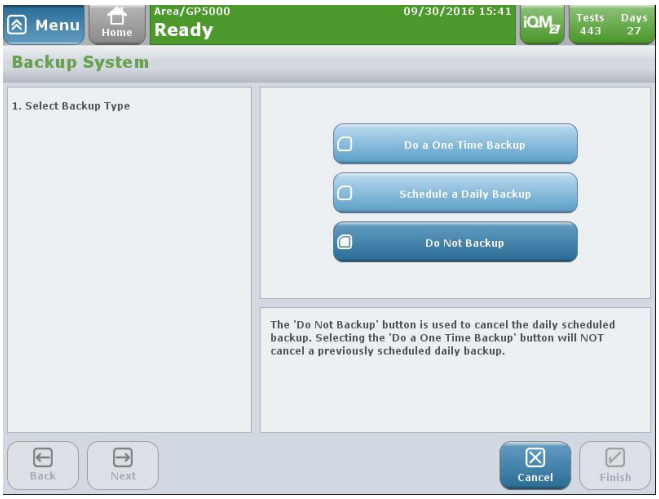
In order to protect data stored on the GEM Premier 5000 system, periodic backups should be performed. These backups can be used to restore data in the event of a malfunction.

The Backup function is accessed from the fourth column of the Management tab.

Data can be backed up to a disc, USB or a network directory. You will have the option to **Do a One Time Backup, Schedule a Daily Backup,** or **Do Not Backup.** Each of these options is described in detail below.

Do Not Backup

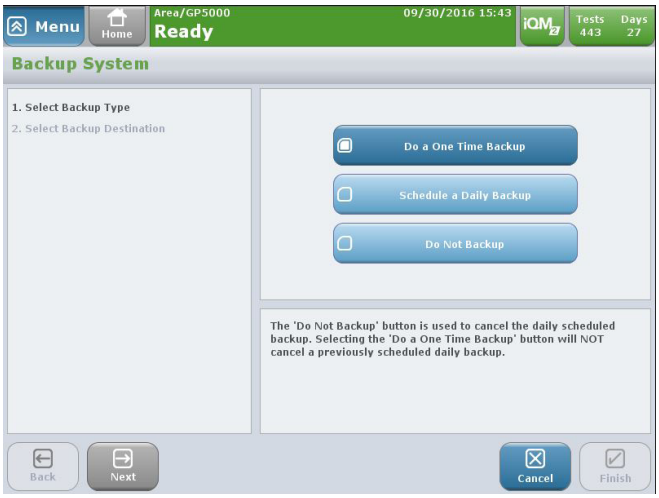
The default selection is Do Not Backup



Do a One Time Backup

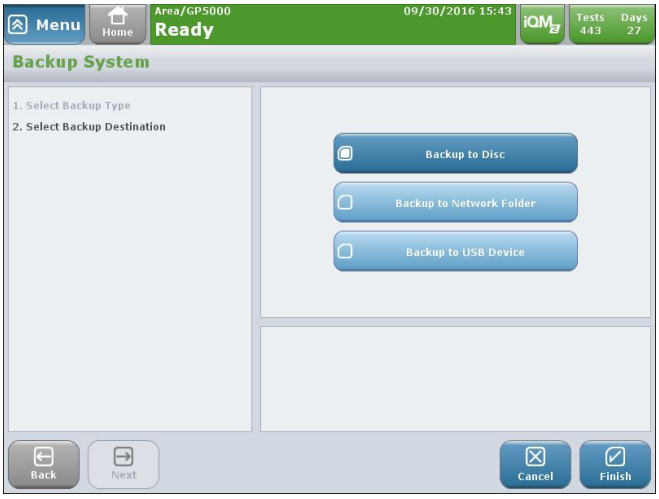
1. Select Backup System from the GEM*web* Plus Management tab. Backup System is available only from the GEM*web* Plus Server. On a GEM Premier 5000 standalone instrument, Backup System may be found in the Management tab.

2. Select **Do a One Time Backup**.



3. Select the backup destination: disc, USB device or network folder.

   Backup to Disc is shown here. For an example on backup to a network folder, see **Schedule a Daily Backup**, below



4. Press **Finish**.

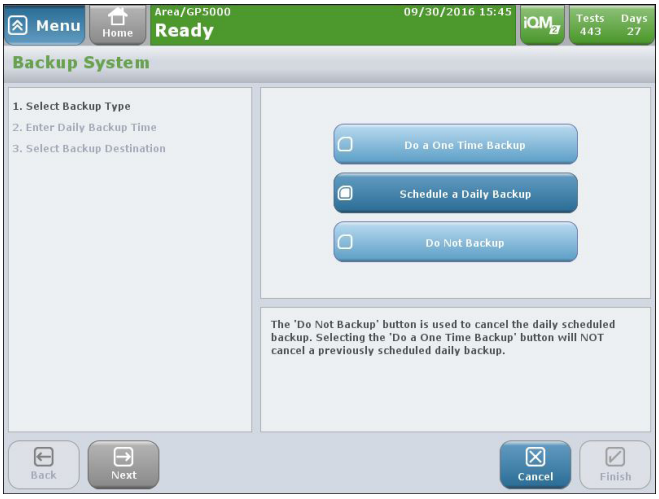
5. You will be prompted to insert a disc or USB device into the Analyzer. Insert the disc or USB device and press **OK**. Data will be backed up.

Multiple CDs or USB devices may be needed for a full backup if the facility is not backing up to a network directory.

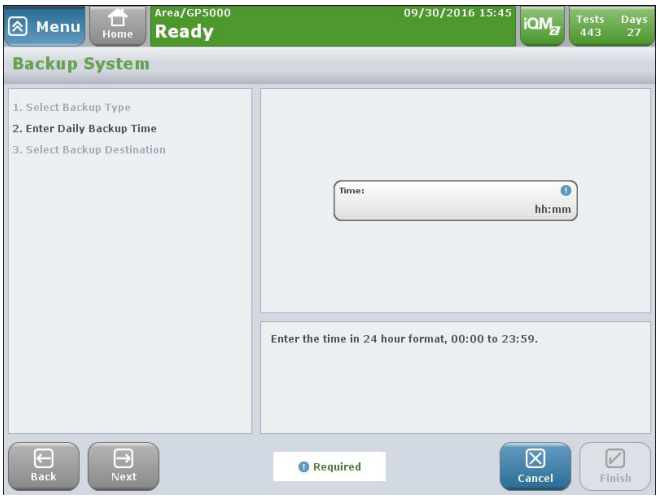
Schedule a Daily Backup

1. Select **Backup System** from the GEM*web* Plus Management tab or from the Management tab for stand alone GEM Premier 5000 instruments.

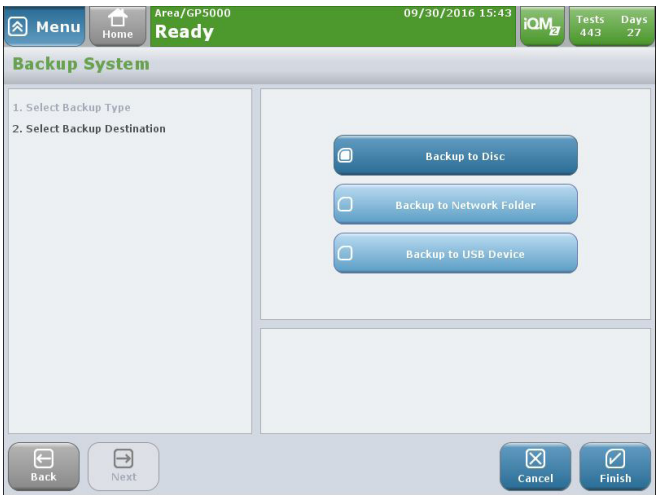
2. Select **Schedule a Daily Backup**.



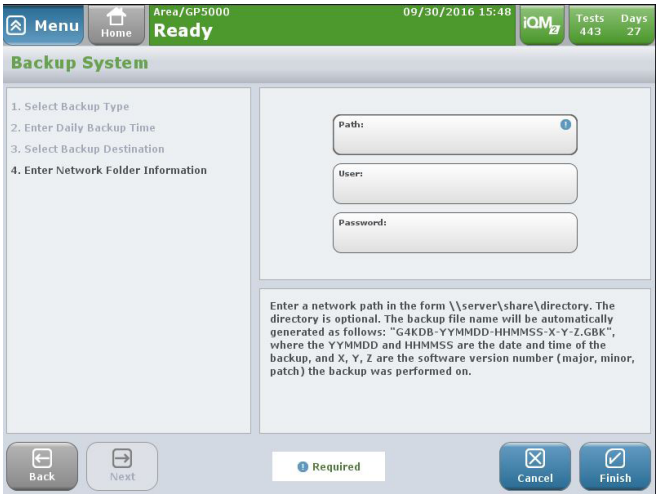
3. Enter the daily backup time.



4. Select the backup destination: disc, USB device or network folder. **Backup to Network Folder** is shown here. For an example on backup to a disc, see **Do a One Time Backup**, above.



5. Enter the Network Folder Information: path, username, and password (if required).



6. Press Finish. Data will be backed up to the network folder.

Performing a System Restore

Restoring backed-up data to the system

In the event of a system malfunction or loss of data from the analyzer or server, data can be restored from a back-up disc, USB device or a network folder.

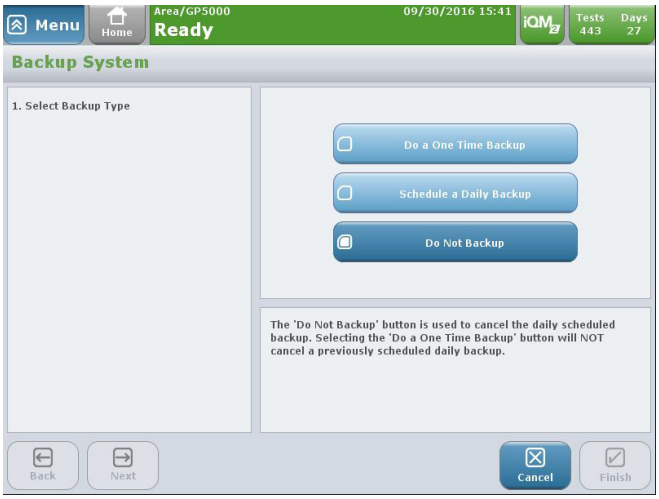
The Restore function is accessed from the fourth column of Management (Tab 3).

The Restore function can only be accessed from the GEMweb Plus server or a stand alone GEM Premier 5000 instrument.

Data can be restored from a disc, USB device or a network directory. Each of these options is described in detail below.

Restore from Disc or USB device

1. Select Restore System from the Management tab (Tab 3).
2. Select **Restore from Disc** or **Restore from USB Device**. Press **Next**.



3. You will be prompted to insert a disc or USB device. After inserting the disc and closing the DVD drive drawer, press **OK**.
4. Select the file to be restored. Press **Finish**.
5. The system will warn you that you are about to overwrite any existing data. Press **OK** to complete the restore process.

Restore from Network Folder

1. Select **Restore System** from the GEMweb Plus Management tab or the Management tab for stand alone GEM Premier 5000 instruments.
2. Select **Restore from Network Folder**. Press **Next**.
3. Enter Network Folder Information: path, username, and password (if required). Press **Next**.
4. Select the file to be restored. Press **Finish**.
5. The system will warn you that you are about to overwrite any existing data. Press **OK** to complete the restore process.

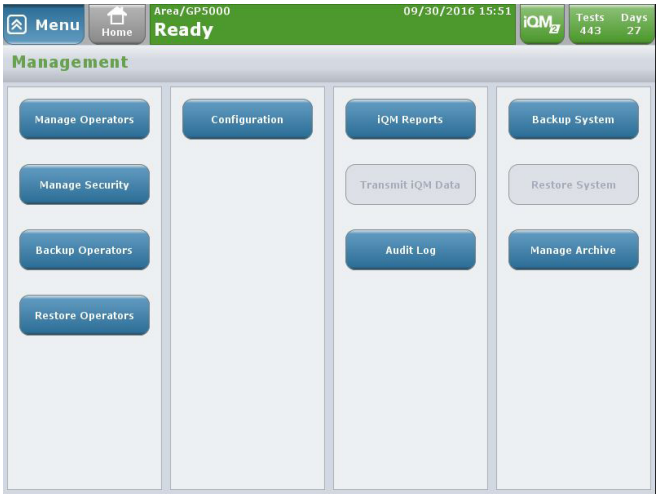
Performing Operator Backup and Restore

Restoring backed-up operator data to the system

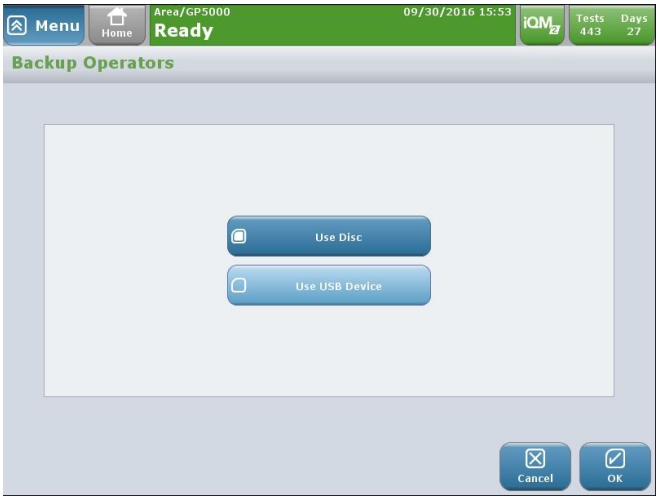
Backup Operators

1. The system will warn you that you are about to overwrite any existing data. Press **OK** to complete the restore process.

Stand-alone GEM Premier 5000 only.



2. You will be prompted to either **Use Disc** or **Use USB Device**.

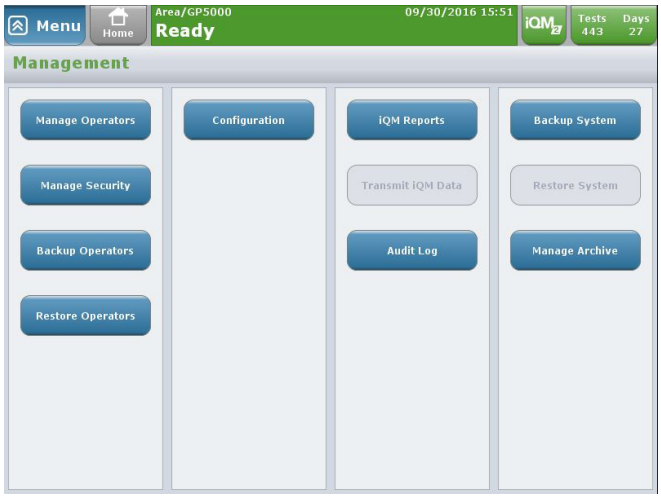


3. Insert the USB device or CD/DVD. The system will proceed through the backup process

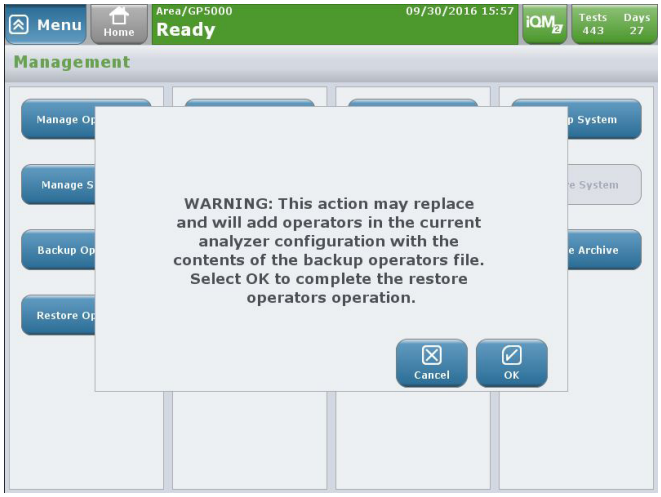
Restore Operators

The Restore Operators function allows you to restore operator record information in the event of a data loss as well as a means to copy operator records from one stand alone GEM Premier 5000 to another one.

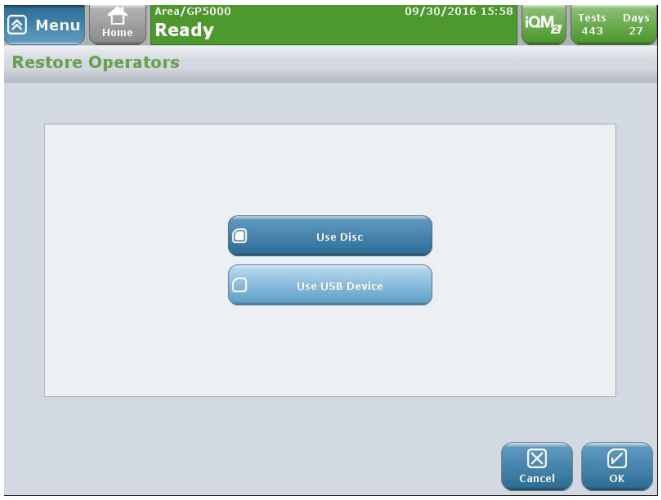
Stand alone GEM Premier 5000 only.



When **Restore Operators** is selected the system will present a warning to notify the operator that the existing operator database will be replaced by the one being restored.



Insert the USB device or CD/DVD that contains the operator backup file. The system will restore the operator records.



5 - DIAGNOSTICS

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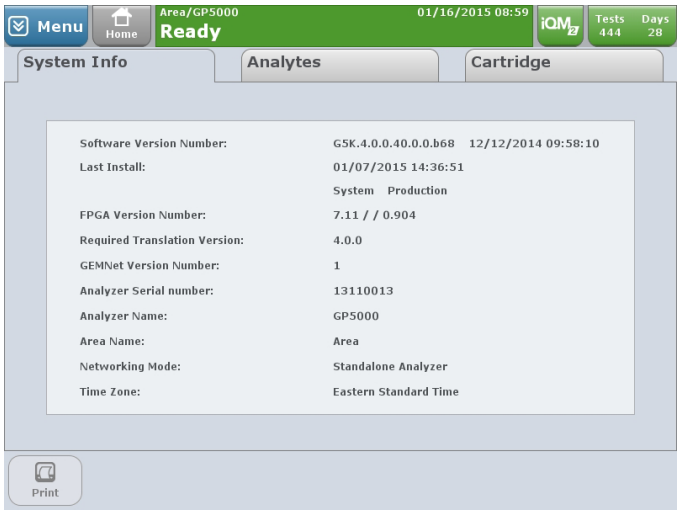
In general, operators will not need to access the Diagnostics area of the analyzer, which includes a range of tasks relevant to the overall status of the GEM Premier 5000 system. This section highlights the key diagnostics tasks available on the analyzer, which are of primary interest to technical personnel.

The Diagnostics function is available via the blue **Menu** button and provides an entry point to perform various diagnostic activities with the analyzer.

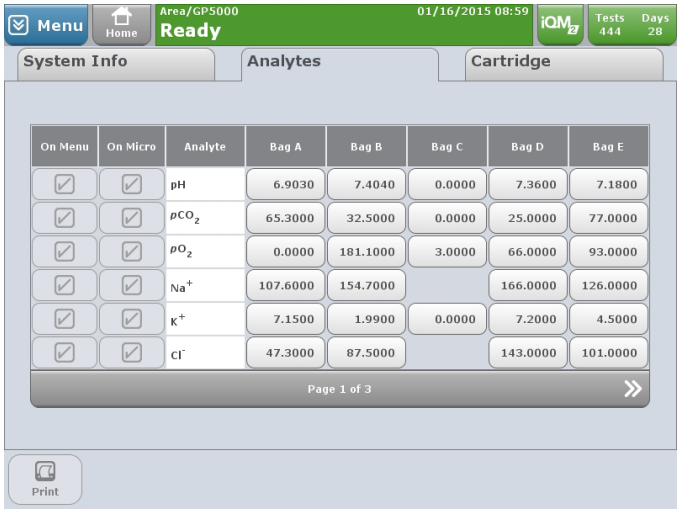
1. Press the blue **Menu** button in the upper left corner of the Start New Sample tab. Select **Diagnostics**. You will see the diagnostic tasks available to you. If prompted, enter your password.

   Select the area you would like to access

2. **System Info** - Provides a snapshot of the system and its operation; it is used primarily by customer support personnel. The software version and analyzer serial number are located here.



- **Analytes** – lists the analyte concentrations in the reagent bags for the selected GEM PAK.

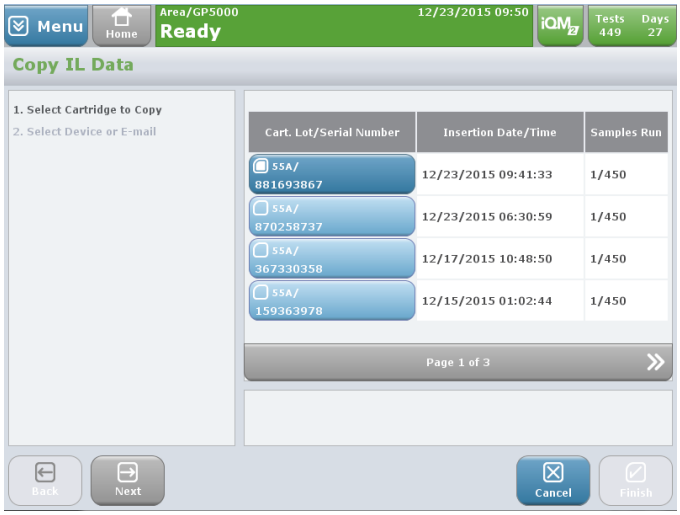


3. **Run iQM2 Process.** – The GEM Premier 5000 system performs iQM2 processes automatically. If you receive a prompt to run an iQM2 process, do so through this menu. For example, if tBili does not pass a CVP 5 specified range, the operator is instructed to run an iQM2 process prior to analyzing a new vial.

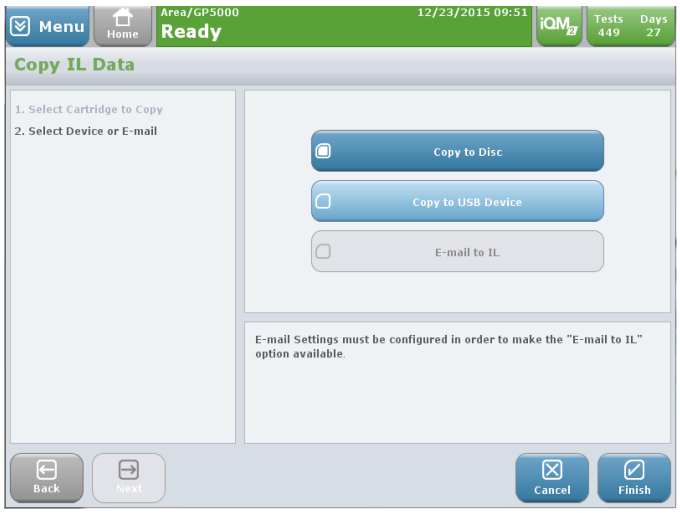
4. **Print Last iQM2 Process**– prints the last complete iQM2 process.

5. **Copy IL Data** – Enables you to copy GEM PAK data onto a CD, DVD, or USB device.

   Select the GEM PAK to be copied. The default selection is the last inserted GEM PAK.



Copy IL Data - Select Device or E-Mail IL - GEM PAK data may be copied to a disc or to a USB device. After making your choice follow the instructions presented on the screen.



6. **Service -** The Service function is for use by authorized service personnel. Access is password protected.

6 - Measurement Methodology

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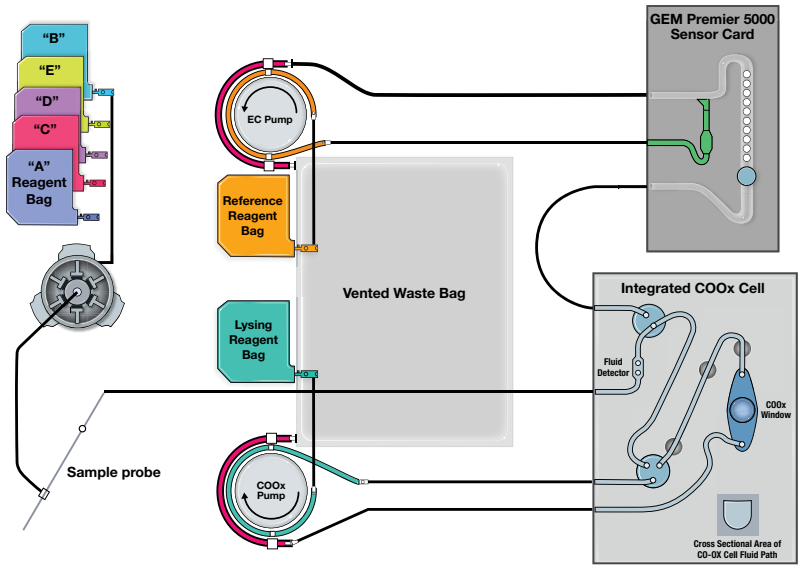
Overview

The GEM Premier 5000 system is comprised of two components, the instrument and a disposable cartridge (GEM PAK). The GEM PAK can measure pH, pO_2, pCO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, Lactate, Hematocrit, total bilirubin (tBili), total hemoglobin (tHb), and hemoglobin fractions including Oxyhemoglobin (O_2Hb), Deoxyhemogobin (HHb), oxygen saturation (sO_2), Carboxyhemoglobin (COHb), and Methemogobin (MetHb). All required components for sample analysis are contained in the GEM PAK, including reagents, sensors, optical cell for CO-Oximetry and tBili, sampler, pump tubing, distribution valve, and waste container. The GEM PAK components and fluidic path are schematically shown in the figure below.

GEM Premier 5000 Fluidic Diagram



The central components of the GEM PAK are the sensor card and CO-Ox cell, which provides a low volume, gas tight chambers in which the blood sample is presented to the sensors for electrochemical and optical measurements. The pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate, and hematocrit sensors, together with the reference electrode, are integral parts of the sensor chamber, with chemically sensitive membranes permanently bonded to the chamber body. The flow of the sample and reagents are controlled by two peristaltic pumps, CO-Ox and EC, and associated valves. These two pumps and associated valves work in concert to control the flow of reagents, sample or air slugs, in the desired fluidic pathway. Solenoid actuated plungers control the operation of these valves.

The two pumps push the lysing and the reference solutions into the sensor card or CO-Ox cell and pulls the sample into the waste container. The reference electrode solution is drawn into the reference electrode junction of the sensor card and merges with the fluid in the main channel. This solution contains silver ion to form the Ag/Ag+ reference electrode.

The lysing solution, contains buffered surfactant, is dispensed into the mixing chamber of the CO-Ox cell, and mixed with the sample in a pre-determined ratio. The movement of sample-lysing solution through three sequential mixing chambers mixes the lysing and the sample solutions, producing a complete hemolysis of the sample. The sensor card and the optical cell reside in two thermal blocks, which maintain the temperature at 37°C, and provide an electrical interface to the sensors and an optical interface to the optical cell

The analyte parameters are monitored with five Process Control Solutions (PCS), designated as A, B, C, D and E . These solutions are pre-tonometered to specific levels of pO_2 and pCO_2, and contain known quantities of the analytes and dyes tested using NIST traceable reference standards when applicable. The solutions are sealed in gas impermeable bags with no head space, allowing their use over a wide range of ambient temperatures and atmospheric pressures. Process Control Solution B is also used for rinse processes. Process Control Solutions A and B are used to set the values of all parameters except for hematocrit and oxygen. Hematocrit uses PCS B, and oxygen utilizes PCS B and PCS C. For CO-Oximetry and total bilirubin, PCS B which is a colorless solution provides a reference for zero concentration. The Process Control Solutions A, D and E contain well-defined concentrations of dyes and their spectral data are used to evaluate, check and qualify the CO-Oximetry and total bilirubin performance.

Electrochemical Sensors

The electrochemical sensors used in the GEM Premier 5000 disposable PAK are all formed on a common plastic substrate. A reference inlet supplies a silver nitrate solution to a flowing junction reference electrode that provides a highly stable reference potential for the system.

The individual sensors, with the exception of hematocrit and reference are formed from layers of polymer films, which are bonded to the substrate. A metallic contact under each sensor is brought to the surface of the substrate to form the electrical interface with the instrument.

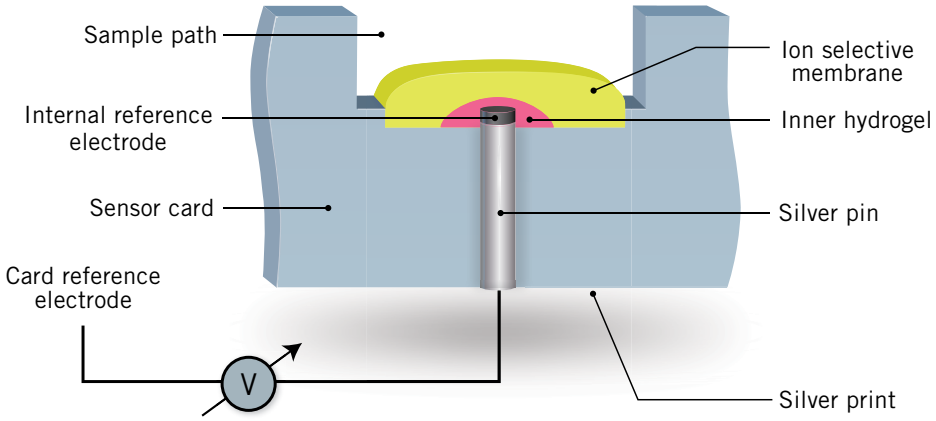
pH and Electrolytes (Na^+, K^+, Cl^- and Ca^{++})

The pH and electrolyte sensors (Na^+, K^+, Cl^-, and Ca^{++}) are based on the principle of ion-selective electrodes in which electrical potential can be established across a membrane resulting from chemical selectivity of the membrane to a specific ion. The potential can be described by this simplified form of the Nernst equation E=E' +(S x Log C), where E is the electrode potential, E' is the standard potential for that membrane, S is the sensitivity (slope), and C is the ion activity. E' and S can be determined by the sensor response to the Process Control Solutions, and the equation can be solved for the activity of the ion of interest. For pH, "log C" is replaced by "pH" and the equation solved accordingly.

The pH and electrolyte sensors are polyvinyl chloride (PVC) based ion selective electrodes, consisting of an internal Ag/AgCl reference electrode and an internal electrolyte layer. Their potentials are measured against the card reference electrode (Ag/ Ag^+). The cross-section view in the figure below shows the flow of the solution past an ion-selective sensor.

GEM® Potentiometric Ion-Selective Sensor

pH, Sodium, Potassium, Chloride, Ionized Calcium



CROSS-SECTION VIEW

NOTES:

- **If pH reports with an exception, then results for pCO_2, $sO_{2(c)}$ and any derived parameter dependent on pH will not be reported.**
- **If sodium reports with an exception, then a Hematocrit value will not be reported.**

pCO_2

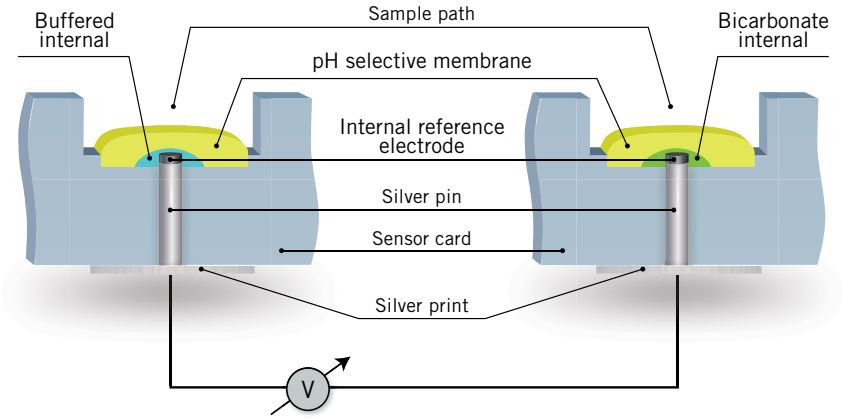
The *p*CO_2 sensor is a patented design which relies on a pH selective polymer as a gas permeable outer membrane. The sensor has an internal Ag/AgCl reference electrode and an internal bicarbonate buffer. The *p*CO_2 in the internal solution will come to equilibrium with the *p*CO_2 of a liquid (e.g. blood) in contact with the outer surface of the membrane. The pH of the internal solution varies with the *p*CO_2 in accordance with the Henderson-Hasselbalch equation:

$pH = pKa + \log [HCO_3^- / (pCO_2 \times a)]$

Where pKa is equilibrium constant, HCO_3^- is the bicarbonate ion concentration, and "a" is the solubility coefficient of CO_2 in water. The generated potential versus the pH sensor is related to the logarithm of pCO_2 content in the sample. A cutaway view of the pCO_2 and pH sensors is shown in the following figure.

Note: If pCO_2 reports with an exception, then HCO_3^- and TCO_2 will not be reported.

GEM® pCO_2 Sensor

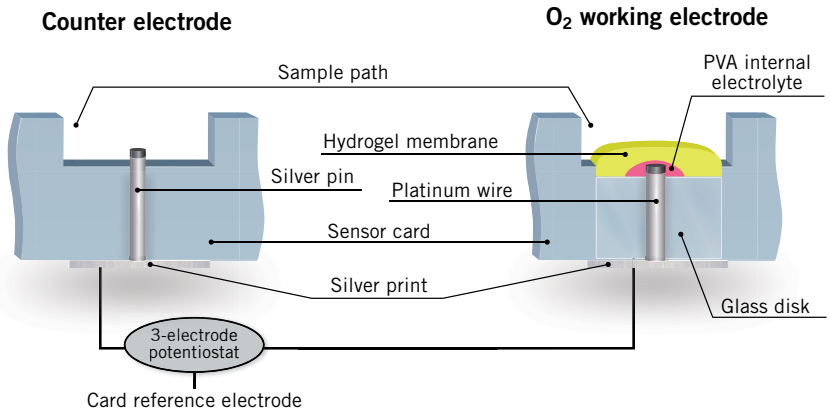


CROSS-SECTION VIEW

pO_2

The oxygen sensor is an amperometric electrode consisting of a small platinum electrode poised at a negative potential with respect to the card reference electrode. A gas permeable membrane protects the platinum from protein contamination, prolonging sensor life. A cross-section view of the oxygen sensor is shown below.

GEM® pO_2 Amperometric Sensor



CROSS-SECTION VIEW

The current flow between the platinum surface and the ground electrode is proportional to the rate at which oxygen molecules diffuse to the platinum and are electrochemically reduced, which in turn is directly proportional to the pO_2 level in the sample. This relationship is described by the equation $I = (S \times pO_2) + IZ$, where "I" is the electrode

current, “S” is the sensitivity, and IZ is the zero current. The values of S and IZ can be calculated from the Process Control Solution data for the sensor. The equation can then be solved for pO_2, where “I” becomes the electrode current produced by the blood sample.

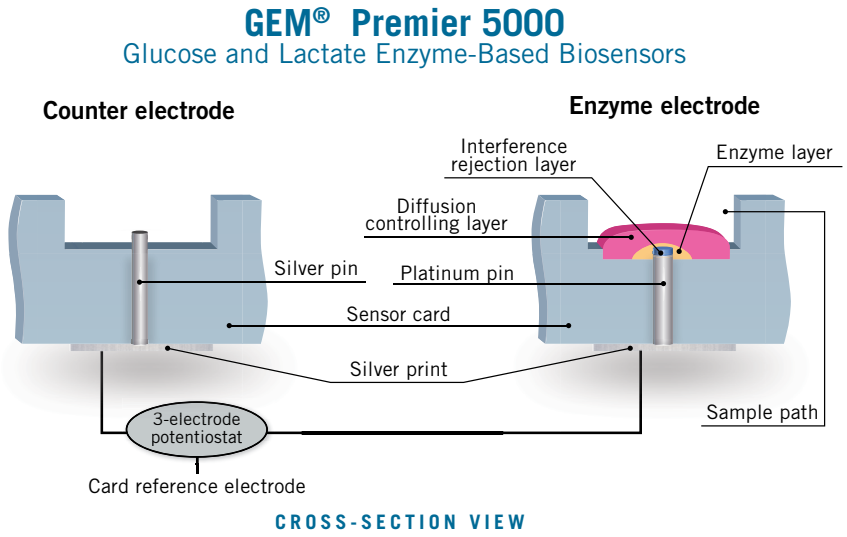
Note: If pO_2 reports with an exception, then results for sO_2 (c) and any derived parameter dependent on pO_2 will not be reported.

Glucose and Lactate

The glucose and lactate sensors are amperometric biosensors consisting of a platinum electrode poised at a positive potential with respect to the card reference electrode.

Glucose or lactate determination is accomplished by enzymatic reaction of glucose or lactate with oxygen in the presence of glucose oxidase or lactate oxidase and the electrochemical oxidation of the resulting hydrogen peroxide at the platinum electrode. The current flow between the platinum electrode and the ground electrode is proportional to the rate at which hydrogen peroxide molecules diffuse to the platinum and are oxidized, which in turn is directly proportional to the metabolite (glucose or lactate) concentration. I = (S x metabolite) + IZ, where “I” is the electrode current, “S” is the sensitivity, and IZ is the zero current. The value of S and IZ can be calculated from the Process Control Solution data for the sensor.

The equation can then be solved for the metabolite concentration, where “I” becomes the electrode current produced by the blood sample.



The diagram above shows the configuration of the sensor. The sensor is constructed of a three layer composite membrane consisting of an inner layer for screening out the interferences, the enzyme for glucose and lactate reaction, and the outer layer for controlling the metabolite diffusion to the enzyme layer. The glucose and lactate sensors measure the analytes in the aqueous portion of the sample. The outer membrane is impermeable to red blood cells.

Hematocrit

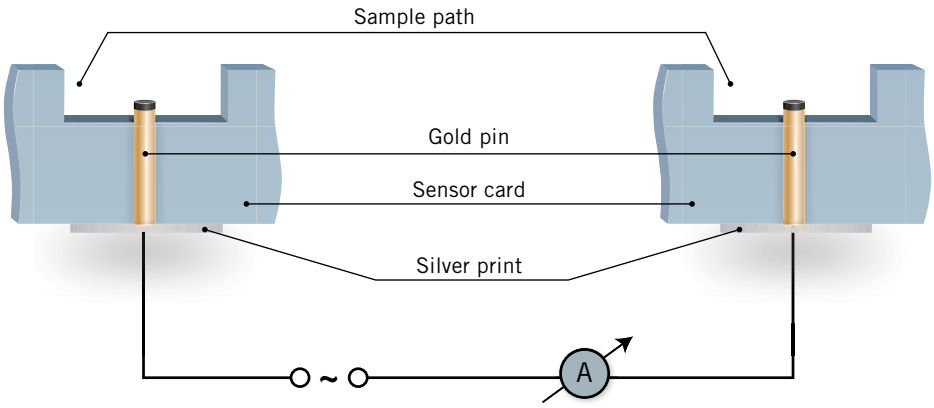
Hematocrit is measured by an electrical conductivity technique. The conductivity technique is based on the principle that because plasma is more conductive than blood cells due to the high resistance of the cell membranes, the resistivity of blood will increase as the concentration of cells increases.

This relationship is expressed by the Maxwell-Fricke equation, r = Rp x (1 + Hct/100)/(1-Hct/100), where r is the blood resistivity, Rp is a constant based on the plasma resistivity, and Hct is hematocrit. The electrode chamber contains a miniature conductivity cell. By applying an alternating potential through the cell, the resistance of the fluid in the cell can be determined by means of Ohm's Law.

The GEM Premier 5000 system performs hematocrit measurements using a conductivity cell method, which is dependent on the patient's plasma electrical resistance remaining constant. The plasma resistance can vary due to changes in ionic as well as protein and lipid levels. The contribution of the ionic effect of sodium, the major extracellular cation, is accounted for in the hematocrit algorithm. The GEM Premier 5000 system uses the actual sodium value measured in the blood sample to correct the hematocrit value.

Therefore, if the sodium is disabled or if a slope, drift, or calculation error message has been reported for sodium, results for hematocrit will not be reported until the sodium sensor is activated or functioning properly.

GEM® Hematocrit Conductivity Sensor



Deviation of protein and lipid concentrations away from their normal levels can cause an error in the hematocrit results. A 10 g/L change in the blood protein concentration can cause a one percent change in the hematocrit reading. A 1 g/L change in the blood lipid concentration can cause a 0.3% change in the hematocrit reading.

Sensor Card Reference

The card reference consists of an Ag/Ag^+ electrode with an open liquid junction between the silver electrode and the sensor chamber. Every time a sample is pumped into the sensor chamber, fresh reference solution containing silver nitrate flows into the reference chamber and comes in contact with the sample. This process provides a stable and reliable liquid junction potential independent of the sample composition.

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 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 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 intensity spectra for the PCS B and sample respectively.

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

Oxygen Saturation (sO_2)

Oxygen saturation is a ratio, expressed as a percentage of the volume of oxygen carried, to the maximum volume which the blood could carry. Knowing the sO_2 is useful for predicting the amount of oxygen available for tissue perfusion. The equation is:
$sO_2 = 100 \times [O_2Hb/(O_2Hb + HHb)]\%$

Where:

O_2Hb = Oxyhemoglobin result obtained from the GEM Premier 5000 system's CO-Oximetry measurement

HHb = Deoxyhemoglobin result obtained from the GEM Premier 5000 system's CO-Oximetry measurement

Reference: CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guidelines – Second Edition. CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

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 light emitting diode (LED) light source, a neon reference and a spectrometer with a holographic diffraction grating and a charged-coupled device (CCD) array are all contained in the analyzer. 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.

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

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 fraction 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

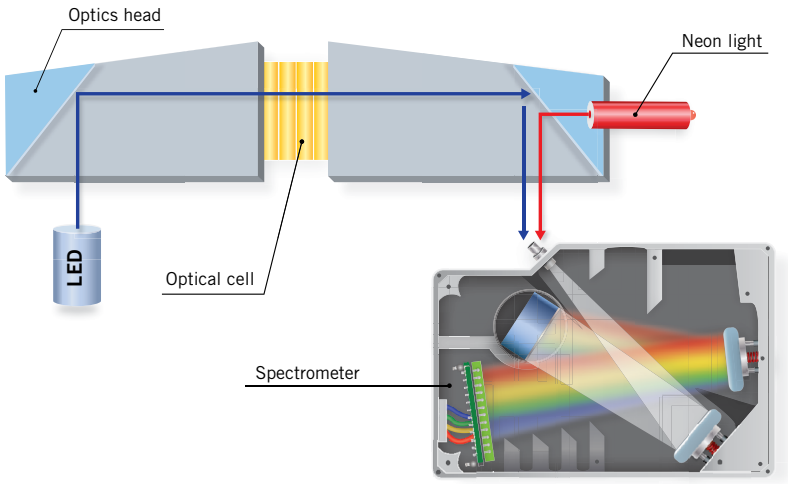
$Bili_p$ = concentration of total bilirubin in the plasma phase

$Bili_b$ = concentration of total bilirubin in whole blood

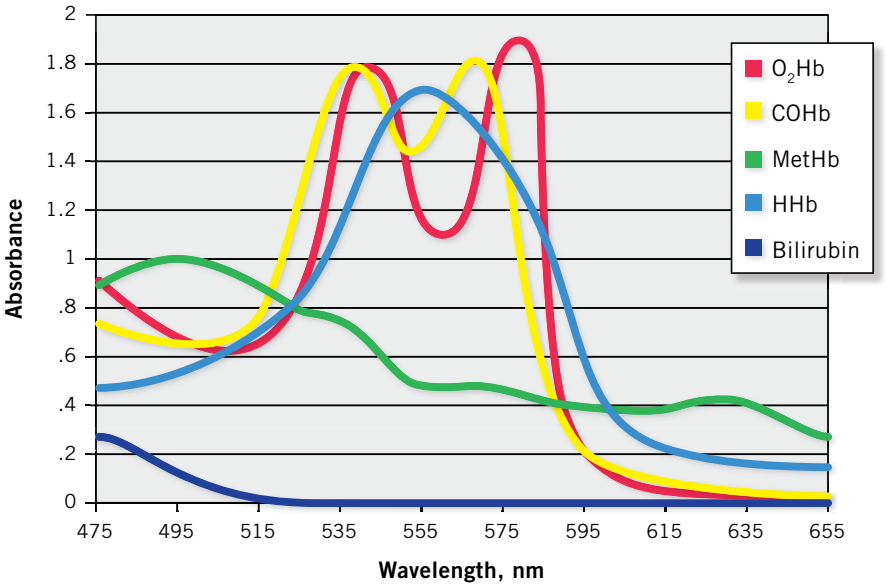
Hct = Hematocrit expressed as a fraction, and is determined by multiplying total hemoglobin (g/dL) by 0.03. The constant 0.03 is based on the average concentration calculated from using an expression for the average concentration of hemoglobin within the red blood cells.

The optical system and absorbance spectra are depicted in the following figures.

GEM® Premier 5000 Optical System



GEM® CO-Oximetry and Total Bilirubin Absorbance Spectra



Calculation of Derived Parameters

The following paragraphs describe how the GEM Premier 5000 system calculates derived parameters.

Standard Bicarbonate

Standard bicarbonate is the bicarbonate concentration from blood that has been equilibrated at 37°C with a pCO_2 of 40 mmHg and a pO_2 to produce full oxygen saturation. The equation is:

HCO_3^- std = 25 + 0.78 x BE(B) + 0.002 x tHb x (O_2Hb -100) mmol/L

Where:

tHb = Measured total hemoglobin, in g/dL, for current sample. Calculated tHb [tHb(c)] is used if measured tHb is not available

O_2Hb = O_2Hb measured locally for current arterial sample, in %. Calculated sO_2 [sO_2(c)] is used if measured O_2Hb is not available.

BE(B) = Base excess approximates the amount of acid or base that would be needed to titrate one liter of blood back to a normal pH of 7.40. This quantity is also called “in-vitro base excess”. The GEM Premier 5000 provides two formulae options to choose from in Configuration. See Base Excess section for more information.

HCO_3-(c) Actual Calculation

Actual Bicarbonate is derived using the CLSI equation as follows:

$HCO_3^-(c) = 10^{(pH + \log(pCO_2) - 7.608)}$

Where:

HCO_3^-(c) = Actual derived bicarbonate concentration in the plasma

pH = Results from current patient sample

pCO_2 = Results from current patient sample

Reference: CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guidelines – Second Edition. CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

Oxygen Saturation ($sO_2(c)$)

The following equation does not utilize measured CO-Oximetry parameters in its calculation.

Oxygen saturation is a ratio, expressed as a percentage of the volume of oxygen carried, to the maximum volume which the blood could carry. Knowing the sO_2 is useful for predicting the amount of oxygen available to tissue perfusion. The equation is:

$sO_2(c) = 100 / [1 + (23400 / (pO_{2pp}^3 + 150 \times pO_{2pp}))]$ %

Where:

pO_{2pp} is partial pressure of oxygen in blood at pH of 7.4 and a temperature of 37°C, and is calculated from:

$pO_{2pp} = pO_2 \times e^{(C + 0.003 \times BE(B) - 2.2) \times (7.4 - pH)}$ (%), where:

e = 2.718 and

$C = (pO_2 / 26.7)^{0.184}$

BE(B) is *In vitro* base excess and is calculated from the formula described by Siggaard Anderson:

$BE(B) = (1 - 0.014 \times tHb) \times [HCO_3^- - 24.8 + (1.43 \times tHb + 7.7) \times (pH - 7.4)]$

Reference: Severinghaus, J.W., American Physiological Society, 1979, page 599-602

Total Carbon Dioxide (TCO_2)

Total Carbon Dioxide (TCO_2) is the concentration of free and bound CO_2 in plasma. The equation is:

TCO_2 mmol/L = $HCO_3^- + 0.0307 \times pCO_2$

Where:

HCO_3^- = Calculated bicarbonate.

pCO_2 = pCO_2 measured from the current sample.

Reference: CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guidelines – Second Edition. CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

Base Excess of Extracellular Fluid [BE(ecf)]

Also called In-vivo Base Excess

Base excess of extracellular fluid is a term that approximates the amount of acid or base that would be needed to titrate a model of extracellular fluid to a pH of 7.40 with a pCO_2 of 40 mmHg at 37°C. Also called standard base excess, in-vivo base excess reflects the metabolic, nonrespiratory component of pH disturbances. The equation to determine BE(ecf) in mmol/L is:

BE(ecf) = HCO_3^- - 24.8 + 16.2 x (pH - 7.4)

Where:

HCO_3^- = Calculated bicarbonate.

pH = pH measured from the current sample.

Reference: CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guidelines – Second Edition. CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

Base Excess of Blood [BE(B)]

Also called In-vitro Base Excess

Base excess is a term that approximates the amount of acid or base that would be needed to titrate one liter of blood back to a normal pH of 7.40. This quantity is also called "in-vitro base excess." The GEM Premier 5000 system provides two formula options to choose from during configuration, which are described next.

CLSI Equation:

BE(B) mmol/L = (1 - 0.014 x tHb) x [HCO_3^- - 24.8 + (1.43 x tHb + 7.7) x (pH - 7.4)]

Where:

tHb = Measured total hemoglobin, in g/dL, for current sample. Calculated tHb is used if measured tHb is not available.

HCO_3^- = Calculated bicarbonate for current sample

pH = pH measured from the current sample

Reference: CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guidelines – Second Edition*. CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

Rolf Zander Equation:

BE(B) in mmol/L = (1- 0.0143 x tHb) x ((0.0304 x pCO_2 x $10^{(pH\ -6.1)}$ - 24.26) + (9.5 + 1.63 x tHb) x (pH - 7.4)) - 0.2 x tHb x (100 – SAT)/100

Where:

tHb =	Measured total hemoglobin, in g/dL, for current sample. Calculated tHb is used if measured tHb is not available.
HCO_3^- =	Calculated bicarbonate for current sample
pH =	pH measured from the current sample
pCO_2 =	pCO_2 measured from the current sample
pO_2 =	pO_2 measured from the current sample
SAT =	O_2 saturation, in %, measured from the current sample. If the measured sO_2 is not available, then SAT is calculated using the following equation:

SAT = 100 / [1 + (23400 / [pO_{2pp}^3 + 150 x pO_{2pp}])] (%)
pO_{2pp} = pO_2 x $e^{(C + 0.003 \times X - 2.2) \times (7.4 - pH)\ (\%)}$
C = (pO_2 / 26.7) 0.184
X = (1 - 0.014 x tHb) x [HCO_3^- - 24 + (1.63 x tHb + 9.5) x (pH - 7.4)]

Reference: Lang, W. and Rolf Zander, The Accuracy of Calculated Base Excess in Blood, Clinical Chemistry Laboratory Medicine 2002; 40 (4) 404-410

Total Hemoglobin (tHb(c))

The estimated total hemoglobin (tHb(c)) in the sample is obtained from the measured hematocrit.The system estimates total hemoglobin as follows:

tHb(c) =	a x Hct

Where:

a =	Multiplier constant of 0.34

Reference: Bauer JD. “Numerical Evaluation of Formed Elements in Blood”, Section 36 in Sonnenwirth A, Jarett LD, eds. Gradwohl’s clinical laboratory methods and diagnosis, St. Louis, CV Mosby, 1980: 785-808.

Ca^{++} (7.4)

Ionized calcium can be normalized and reported as an acid/base value with respect to pH = 7.4. The equation is:

Ca^{++} (7.4) mmol/L = Ca^{++} x $10^{[-0.178 \times (7.4 - pH)]}$

Where:

Ca^{++} =	Ca^{++} measured from the current sample
pH =	pH measured from the current sample

Reference: Thode, J. Adjusted Ionoized Calcium (at pH 7.4) and Actual Ionized Calcium (at Actual pH) in Capillary Blood for Clinical Evaluation of Patients with Disorders of Calcium Metabolism, Clinical Chemistry 36/3, 541-544 (1990)

Anion Gap

Anion Gap (AG) is derived from the measured Na^+, K^+, Cl^-, and the calculated HCO_3^-. The equation is:

AG mmol/L = $(Na^+ + K^+) - (Cl^- + \text{Calculated } HCO_3^-)$

Reference: Tietz Textbook of Clinical Chemistry 2nd ed., Edited by C. A. Burtis and E. R. Ashwood, W.B. Saunders Company, Philadelphia, 1994, p. 1440.

P/F Ratio

P/F Ratio is derived from the measured pO_2 and the user-entered FIO_2. The equation is:

P/F Ratio = $p\,aO_2 / FIO_2$ mmHg

Where:

paO_2 = pO_2 for the arterial sample in mmHg

FIO_2 = The entered FIO_2 in fraction (percent/100)

Reference: Clinical Blood Gases: Application and Noninvasive Alternatives. by, Malley, William J., W.B. Saunders Company, Philadelphia, 1990, p. 171.

pAO_2

The alveolar oxygen partial pressure, pAO_2, gives a general indication of the efficiency of the oxygen exchange process in the alveolar-capillary unit. The equation is:

pAO_2 mmHg = $FIO_2 \times (BP - 47) - 1.25 \times paCO_2(T)$

Where:

FIO_2 = Fraction of inspired oxygen entered by the operator %

BP = Barometric pressure in mmHg entered by the operator

$paCO_2(T)$ = Patient Temp-corrected pCO_2 for the current arterial sample Non temp-corrected value is used if pCO_2 (T) is not available

References: (1) Intensive Care and Clinical Biochemistry, Gosling, Marshall, and Clapham, ABC Venture Publications, London, 1994. p.17. (2) Practical Math for Respiratory Care, by Raymond Sibberson, Mosby, 1996.

CaO_2

CaO_2 is the arterial oxygen content. The equation is:

CaO_2 mL/dL = $0.0139 \times tHb \times O_2Hb + 0.0031 \times paO_2(T)$

Where:

tHb = tHb measured locally for current arterial sample, in g/dL

O_2Hb = O_2Hb measured locally for current arterial sample, in %

$paO_2(T)$ = Patient Temp-corrected pO_2 for the current arterial sample in mmHg. Non-temperature corrected value is used if $pO_2(T)$ is not available

Reference: CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guidelines – Second Edition*. CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

O_2ct

Oxygen content, the concentration of total Oxygen of blood, is the sum of the substance concentration of the oxygen bound to hemoglobin as O_2Hb, plus the amount dissolved in blood. It is calculated using the following equation:

O_2ct (mL/dL) = $(0.0139 \times tHb \times O_2Hb) + 0.00314 \times pO_2(T)$

Where:

tHb = Total hemoglobin as measured for the current sample, in g/dL. If tHb is not requested or available then 0.34 x Hct is used.

O_2Hb = Oxyhemoglobin as measured for current sample, in %. If O_2Hb is not requested or available, then $sO_2(c)$ is used.

$pO_2(T)$ = Patient temperature corrected pO_2 for the current sample. Non-temperature corrected value will be used if default temperature (37°C) is not changed.

0.0139 = Oxygen binding capacity of one gram of hemoglobin

0.00314 = Concentration solubility coefficient of oxygen in blood plasma

O_2ct will be reported if enabled in configuration for any sample source (e.g., arterial, mixed venous, venous).

Reference: CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guidelines – Second Edition*. CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

CvO_2

CvO_2 is the oxygen content in the mixed venous sample. The equation is:

CvO_2 mL/dL = $0.0139 \times tHb \times O_2Hb + 0.0031 \times pvO_2(T)$

Where:

tHb = tHb measured locally for current mixed venous sample in g/dL

O_2Hb = O_2Hb measured locally for current mixed venous sample in %

$pvO_2(T)$ = Patient Temp-corrected pO_2 for the current mixed venous sample in mmHg Non- temp-corrected value is used if $pO_2(T)$ is not available

Reference: CLSI document C46-A2. Blood Gas and pH Analysis and Related Measurements, Approved Guidelines - Second Edition.Wayne, PA: Clinical and Laboratory Standards Institute; 2009

P50

P50 is the partial pressure of O_2 in a hemoglobin solution having an oxygen saturation of 50%. The P50 calculation is available using the following sample sources: mixed venous, venous and arterial. P50 results are only reported for samples in the range of 30-75% for O_2Hb or sO_2. The equation is:

P50 mmHg = $10^{-(Q / 2.7)}$

Where:

Q = Log [R / (100 – R)] – 2.7 x log (pvO_2(T))

R = O_2Hb or sO_2 as selected in configuration

pvO_2(T) = Patient temp-corrected pO_2 for the current mixed venous sample in mmHg. Non temp-corrected value is used if pO_2(T) is not available

O_2Hb or sO_2 = Measured value for the current sample, in %. If result is not in the range of 30 – 75%, P50 becomes incalculable

Reference: Wimberley PD, et.al., Scand J Clin Lab Invest 1990; 50, Suppl. 203:227,234.

O_2cap

O_2cap is the arterial sample oxygen capacity. The equation is:

O_2cap mL/dL = (tHb - tHb x (100-O_2Hb% -HHb%)) x 1.39

Reference: CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

A-aDO_2

A-aDO_2 is the alveolar-arterial oxygen gradient. The equation is:

A-aDO_2 mmHg = pAO_2 – paO_2 (T)

Where:

pAO_2 = Alveolar oxygen partial pressure, corrected for patient temperature. See next section on pAO_2 for calculation

paO_2(T) = pO_2 for the current arterial sample, corrected for patient temperature. Non-temperature corrected value is used if pO_2(T) is not available

paO_2/pAO_2

paO_2/pAO_2 is the arterial-alveolar oxygen ratio. The equation is:

paO_2 / pAO_2

Where:

paO_2(T)= pO_2 for the current arterial sample, corrected for patient temperature. Non temp-corrected value is used if pO_2(T) is not available

pAO_2 = Alveolar oxygen partial pressure in mmHg (see equation described in pAO_2 section).

RI

The respiratory index, RI, is calculated using the following equation:

RI = $A\text{-}aDO_2 / paO_2(T)$

Where:

$A\text{-}aDO_2$ = Alveolar-arterial oxygen gradient, mmHg (refer to section on $A\text{-}aDO_2$)

$paO_2(T)$ = pO_2 for the current arterial sample, corrected for patient temperature. Non-temperature corrected value is used if $pO_2(T)$ is not available

CcO_2

The end pulmonary capillary oxygen content, CcO_2 is calculated using the following equation.

CcO_2 mL/dL= (1.39 x tHb x alpha) +0.00314 x pAO_2

Where:

alpha = (1 - COHb/100) – C, and

C = 0, if pAO_2 is > 150

C = 0.01, if pAO_2 is > 125, but ≤150

C = 0.02, if pAO_2 is ≤ 125

and:

tHb = tHb measured locally for current arterial sample, in g/dL

COHb = COHb measured locally for current arterial sample, in %

pAO_2 = Alveolar oxygen partial pressure for the current arterial sample, in mmHg, as calculated in an earlier section

Reference: R.D. Cane, et. al., Minimizing Errors in Intrapulmonary Shunt Calculations, Crit Care Med, 8, 294-297, 1980

$a\text{-}vDO_2$

The arterial-mixed venous oxygen gradient, $a\text{-}vDO_2$ is calculated and reported for A-V pair samples using the following equation:

$a\text{-}vDO_2$ mL/dL = $CaO_2 – CvO_2$

Where:

CaO_2 = Arterial oxygen content, in mL/dL, for the arterial sample of the A-V pair

CvO_2 = Oxygen content, in mL/dL, for the mixed venous sample of the A-V pair

Qsp/Qt(est)

The estimated shunt, Qsp/Qt(est), is calculated for arterial samples only, and requires the availability of CO-Oximetry parameters. The following equation will be used:

Qsp/Qt (est) % = $100 \times (CcO_2 - CaO_2) / (3.5 + CcO_2 - CaO_2)$

Where:

CcO_2 = End pulmonary capillary oxygen content, in mL/dL, calculated for current sample

CaO_2 = Oxygen content, in mL/dL, calculated for current arterial sample

Reference: Clinical Application of Blood Gases, Fifth Edition, Barry A. Shapiro, M.D. and William T. Peruzzi, M.D., Mosby, 1993:99

Qsp/Qt

The physiological shunt, Qsp/Qt, is calculated for Arterial-Venous (A–V) pair samples using the following equation:

Qsp/Qt %= $100 \times (CcO_2 - CaO_2) / (CcO_2 - CvO_2)$

Where:

CcO_2 = End pulmonary capillary oxygen content calculated for current sample

CaO_2 = Oxygen content, in mL/dL, calculated for current arterial sample of the A-V pair

CvO_2 = Oxygen content, in mL/dL, for the mixed venous sample of the A-V pair

Reference: Intensive Care and Clinical Biochemistry. Gosling P, Marshall WJ, Clapham MC, eds. ABC Venture Publications, London, 1994, p.20

OI

A measure of ventilatory and oxygen support requirements for critically ill patients. Lower value indicates potential for better outcome. The following equation will be used:

$OI = (FiO_2 \times MAP) / paO_2$

Where:

FiO_2= Fracture of inspired oxygen

MAP= Mean Airway Pressure

paO_2= Partial pressure of oxygen in arterial blood

Reference: Evidence-Based Clinical Practice Guideline: Inhaled Ntric Oxide for Neonates with Acute Hypoxic Respiratory Failure DiBlasi R.M., Myers T.R. and Hess D.R. PhD. AARC Clinical Practice Guideline. Respiratory Care, 2010: Vol. 55 No 12.

mOsm

A measure of solute concentration, expressed in mmol/L by using the following equation:

$mOsm = (2 \times Na^+) + Glu$

Reference: Burton DR. Clinical physiology of acid-base and electrolyte disorders. 4th ed. New York: McGraw-Hill, 1994

Hct(c)

Derived hematocrit is calculated from the measured total hemoglobin, and is determined by using the following equation:

Hct(c) % = 3.0 x tHb

Where:

tHb = tHb measured for the current sample, in g/dL

Reference: Bauer JD. “Numerical Evaluation of Formed Elements in Blood”, Section 36 in Sonnenwirth A, Jarett LD, eds. Gradwohl’s clinical laboratory methods and diagnosis, St. Louis, CV Mosby, 1980: 785-808.

Temperature Correction

The following equations are used to calculate the temperature corrected parameters pH, pCO_2 and pO_2.

pH(T) = pH + (T - 37) x [-0.0147 + 0.0065 x (7.4 – pH)]

$pCO_2(T)$ = $pCO_2 \times 10^{[0.019 \times (T - 37)]}$

$pO_2(T)$ = $pO_2 \times 10^{[K \times (T - 37)]}$

Where:

T = Temperature entered by the operator for the sample

K = Temporary subordinate calculation

Reference: CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guidelines – Second Edition*. CLSI document C46-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2009

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7 - Requirements

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 is one (1) fuse that may be replaced by the operator. The fuse is located directly below the power connector and is behind a black cover. The fuse is a 3 Amp, 250 Volt, SLO-BLO fuse, and measures 5 mm x 20 mm. The fuse 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 fuse 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.

Ambient Environmental Requirements

External Ambient Temperature Limits:	12°C (53.6°F) to 32°C (89.6°F)
Relative Humidity Limits:	15 to 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

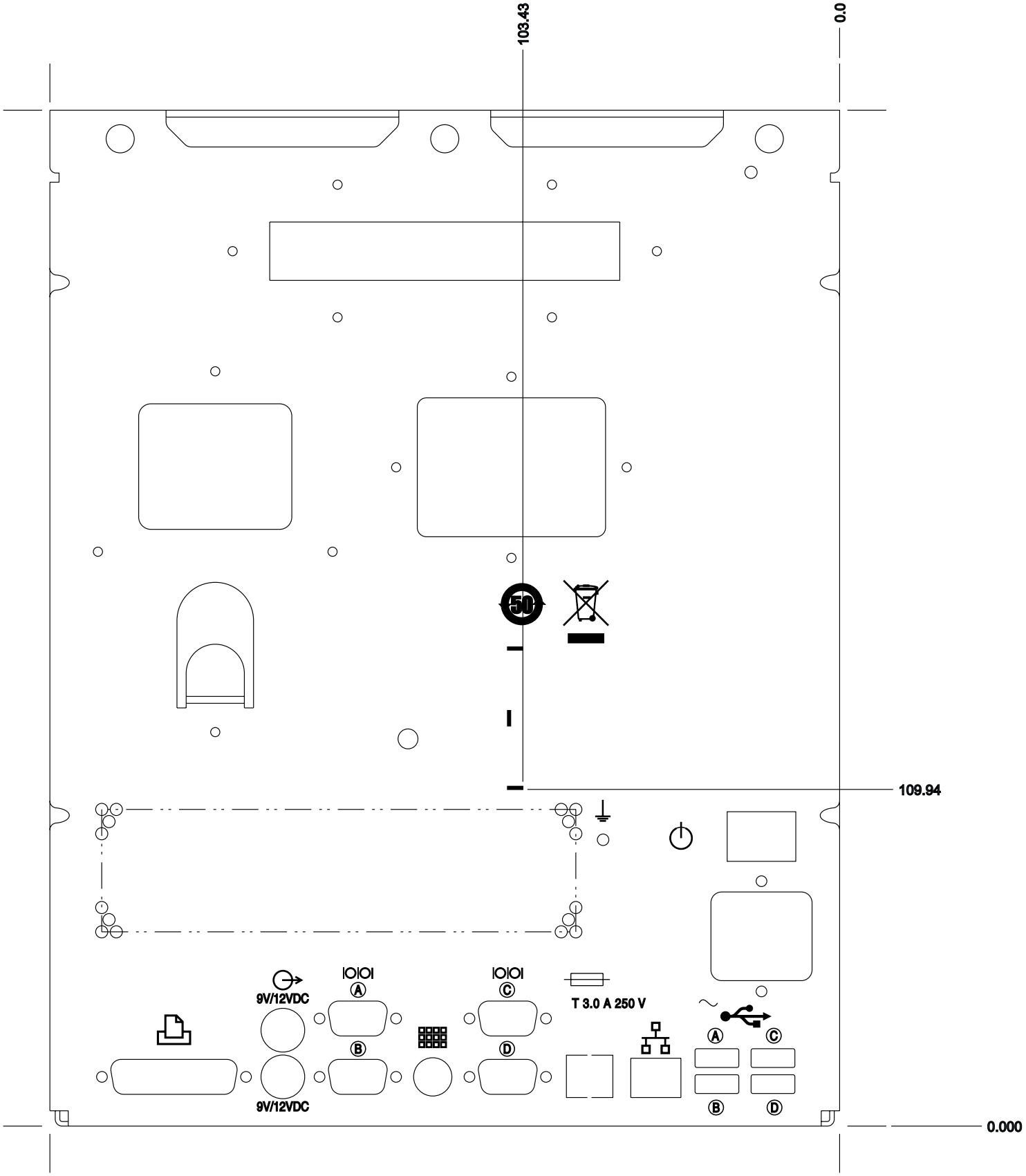
Instrument Storage	May be stored at a temperature of -10 to 38°C (14 to 100.4°F) with a Relative Humidity of 15 to 85%, non-condensing.
GEM Premier 5000 PAK Storage	Store at 15 to 25°C (59.0 to 77.0°F)
GEM Premier 5000 PAK Shelf Life	Expires on the date indicated on the label of each GEM PAK. A GEM PAK 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 up to 3 days.

Input/Output Ports

Rear Panel Schematic



Port	Description
Parallel 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.
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 Port	RJ-45 LAN network port is provided for a 10/100 Mbps Base T Ethernet connection
USB High Speed (Universal Serial Bus)	Four USB 2.0 compliant connectors are available for data transfer rates of up to 480 Mbps

Only IL approved external cables are permitted.

Parallel Port 25 PIN D-SUB FEMALE at the PC

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

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)

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Keyboard Connector

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

Integrated LAN Port

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

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8 - Error Codes and Operator Messages

The GEM Premier 5000 system is designed for simple, trouble-free operation. However, should you encounter any system errors or other issues, this information will help you understand the code or message displayed. Instrumentation Laboratory also provides extensive customer support.

Error Codes Associated With System Malfunctions

Error Code	Description of Error	Operator Message
201	Process Control solution not detected	Process control solution not detected.
203	Air slug before sample not detected	Sample not detected.
204	Sample not detected	Sample not detected.
220	Sampler luer did not move into position	Sample probe error.
222	Air detected within sample during aspiration	Insufficient sample.
223	Air detected within sample during post aspiration	Air detected within sample.
224	Insufficient sample volume for CO-Ox	Insufficient sample for CO-Ox.
228	An error occurred while reading or writing to the cartridge EEPROM	Cartridge ID error.
230	Block temperature out of valid range	Temperature out of range.
236	Power supply voltage out of valid range	Power supply voltage error.
240	No air detected before a Process Control solution	Process control solution not detected.
241	Rotary valve sensor not found	Rotary valve error.
260	Door sensor stuck closed	Door failure. Door must be opened manually. Contact Technical Support for assistance.
261	Pump mechanism calibration failed	Cartridge error.
264	CO-Ox integration time could not be set	CO-Ox hardware failure.
265	Reference voltage out of range	Reference solution not detected.
266	Sensor polarization voltages out of range	Voltages out of range.
267	Pump mechanism error	Cartridge error.
268	Hct circuit gain is out of range	Hct calibration failed.
269	Ground relay failure	Ground relay error.
270	Analytical component leak	Cartridge error.
280	Diverter and/or mixing solenoid error	Sample interference detected.
281	Diverter valve error	Diverter valve error.
282	Mixer valve error	Mixer valve error.
285	CO-Ox neon light calibration failure	CO-Ox hardware failure.

Error Code	Description of Error	Operator Message
286	CO-Ox error due to missing or corrupt coox files	CO-Ox integrity failure. Contact Technical Support. Cartridges will be rejected.
287	CO-Ox Initialization failure	CO-Ox initialization failure. Analyzer will be shut down. Contact technical support
288	CO-Ox error (due to spectrometer read error, or other types of errors)	CO-Ox hardware failure.
289	pO_2 mV is outside threshold when measured during Process Control solution C measurement during cartridge start-up	iQM2 error for pO_2.
300	The SBC board and CPU temperature is monitored. If the temperature rises to 70ºC, a warning is isused. The operator should check the analyzer environment such as blocked ventilation, excessive ambient temperature, etc.	Temperature out of range. Check ambient.
301	The SBC board and CPU temperature is monitored. If the temperature rises to 90ºC, the analyzer is shut down.	Analyzer temperature too high. Shutting down.
302	Hard drive showing excessive amount of errors indicating it may fail soon. Operator should perform backup and contact Technical Support.	Hard drive showing excessive errors and may fail soon. Perform backup. Contact Technical Support.
401	Amprometric spike check on Glu/Lac.	Incalculable error for Glu/Lac.
2010	iQM2 solution stability check failed	Process control solutions stability failure.
2012	Reference sensor voltage is saturated or out of range	Reference voltage error.
2014	An error occurred while reading or writing to the cartridge EEPROM	Unsupported cartridge type.
2015	iQM failures for pO2 sensor that is not due to the solution stability	pO_2 sensor error.
2016	Ground voltage is saturated or out of range	Ground voltage error.
2017	Special rinse failed leading to cartridge removal	Micro clot caused solution detect error.

Error Codes Associated With Software Malfunctions

Error Code	Error Can Occur On: Analyzer, Server or Both	Cause of Error	Operator Message
3001	Analyzer	The file system check, performed during startup, failed and could not self correct.	File system check error.

Error Code	Error Can Occur On: Analyzer, Server or Both	Cause of Error	Operator Message
3002	Analyzer	The instrument software could not communicate to the FPGA (hardware).	FPGA communication error.
3003	Analyzer	Whenever the FPGA sends an unexpected message to the software.	FPGA Error.
3004	Analyzer	FPGA (hardware) failed to initialize or reset.	FPGA error. Analyzer will be reset.
3005	Analyzer	Analyzer or server software out of memory, possibly due to memory leak.	Out of memory error.
3006	Analyzer	The DM (Data Management Module) and AM (Analytical Module) could not communicate, or went out of synch.	Internal communications error. Analyzer will be reset.
3007	Both	An error during a database operation.	DB error. Analyzer will be reset.
3008	Both	An error during a file I/O operation.	File I/O error. Analyzer will be reset.
3009	Both	User interface to Data Management Module communication error.	Internal communications error. Analyzer will be reset
3012	Analyzer	An illegal script command or an illegal command argument. The script cannot be executed by the script engine.	Script error. Analyzer will be reset.
3013	Analyzer	More than 3 analyzer resets occurred.	Too many resets. Shutting down. Contact Technical Support.
3203	Analyzer	Problem accessing GEMweb Plus server.	This operation failed. Retry after server is available.
3205	Both	The system cannot perform the requested operation.	The system cannot perform the requested operation.
3206	Both	DM (Data Management) software error.	Internal DM software error. Analyzer will be reset.
3207	Analyzer	Problem accessing GWP server during installation setup of the client analyzer.	Cannot access server. Analyzer will be reset.

Contacting IL Technical Support

In the US or Canada you may call 1-800-678-0710 for technical support 24 hours per day, 7 days per week. Outside of the US, please contact your local Instrumentation Laboratory office or Instrumentation Laboratory distributor for technical support.

9 - Maintenance

Analyzer Repair

1. In the unlikely event that the GEM Premier 5000 system requires repair; the analyzer may have to be sent to your local Instrumentation Laboratory or Werfen/IL distributor GEM Service Center. The following steps must be followed prior to sending the analyzer to the GEM Service Center.
2. Contact your local IL technical support department in order to determine if the unit requires repair. (In the US or Canada call 1–800–678–0710, 24 hours per day, 7 days per week.)
3. If your unit needs to be returned, you will be provided with a Return Authorization (RA) number and instructions on how and where to ship the instrument.
4. If your analyzer is out of the warranty period, or a service agreement is not in place, a Purchase Order will be required in order to receive a RA number.
5. If you do not have your original instrument packaging, a new box will be sent to you.
6. Your analyzer must be decontaminated prior to returning it to IL. Please refer to the decontamination procedure at the end of this section.
7. Remove the GEM PAK and printer paper prior to shipping.
8. Insert the Shipping Cartridge, which was provided with the analyzer. (Refer to the Configuration Guide or the Installation and Shipping Training Video.)
9. Once the proper packaging is available, pack the analyzer and return it to your GEM Service Center. It is very important to include your RA number on the outside of the package.
10. You will be notified when the instrument has been received at the GEM Service Center (U.S. only).
11. You will also be notified when the instrument has been repaired and has been shipped back to your facility (U.S. only).

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Decontamination Procedure

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

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 system 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, or Personal Protective Equipment (PPE) as defined by your institution's policy before handling the instrument.

Prepare a biohazard waste bag for waste disposal.

To decontaminate the touch screen:

1. Remove the GEM PAK from the analyzer as described in the Removing the GEM 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 system 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.

As Needed Cleaning

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

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

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 system 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 the Touch Screen

You do not need to disconnect the GEM Premier 5000 system 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" on page 117**. 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" on page 119**.
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 system starts its power-up cycle and then displays the Insert Cartridge screen.

12. Insert a new GEM PAK.

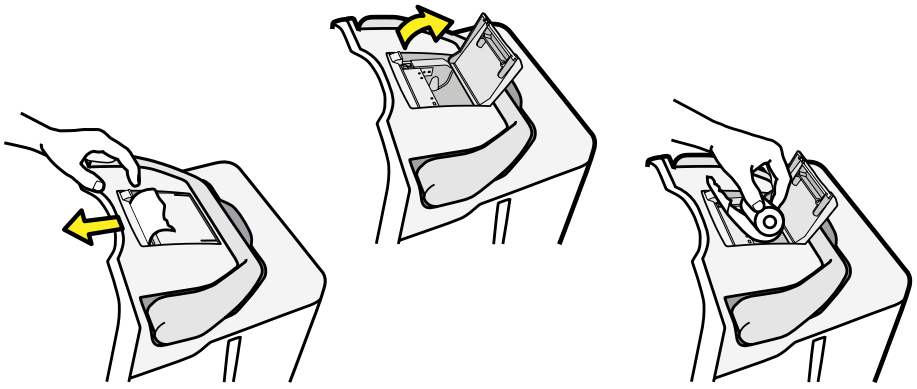
Installing the Printer Paper

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.

Disposing of the Ampoule Breaker

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

Replacing the Fuse

There is one fuse that may be replaced by the operator. The fuse is located directly below the power connector and is behind a black cover. The fuse is a 3 Amp, 250 Volt, SLO-BLO fuse, and measures 5 mm x 20 mm. The fuse should be replaced only if, after the power cord is connected to the power source and the power switch is pressed, the analyzer does not respond.

To replace the fuse:

1. Disconnect the instrument from AC power [AC outlet or uninterruptible power supply (UPS)].
2. Remove the black cover using the tabs.
3. Remove the old fuse.
4. Dispose of the old fuse in a container suitable for glass.
5. Insert the new fuse.

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

6. Replace the cover.
7. Reconnect the instrument to a properly grounded and wired AC outlet (AC outlet or UPS).
8. Turn on the analyzer by briefly pressing the power button on the left side of the back of the analyzer.
9. The GEM Premier 5000 system starts its power-up cycle and then displays the Insert Cartridge screen.
10. Insert a new GEM PAK.

10 - INTELLIGENT QUALITY MANAGEMENT 2 (iQM2)

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System Components and Features

The GEM Premier 5000 system has two primary components: the analyzer and a disposable, multi-use PAK.

GEM Premier 5000 Analyzer

The GEM Premier 5000 system 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.

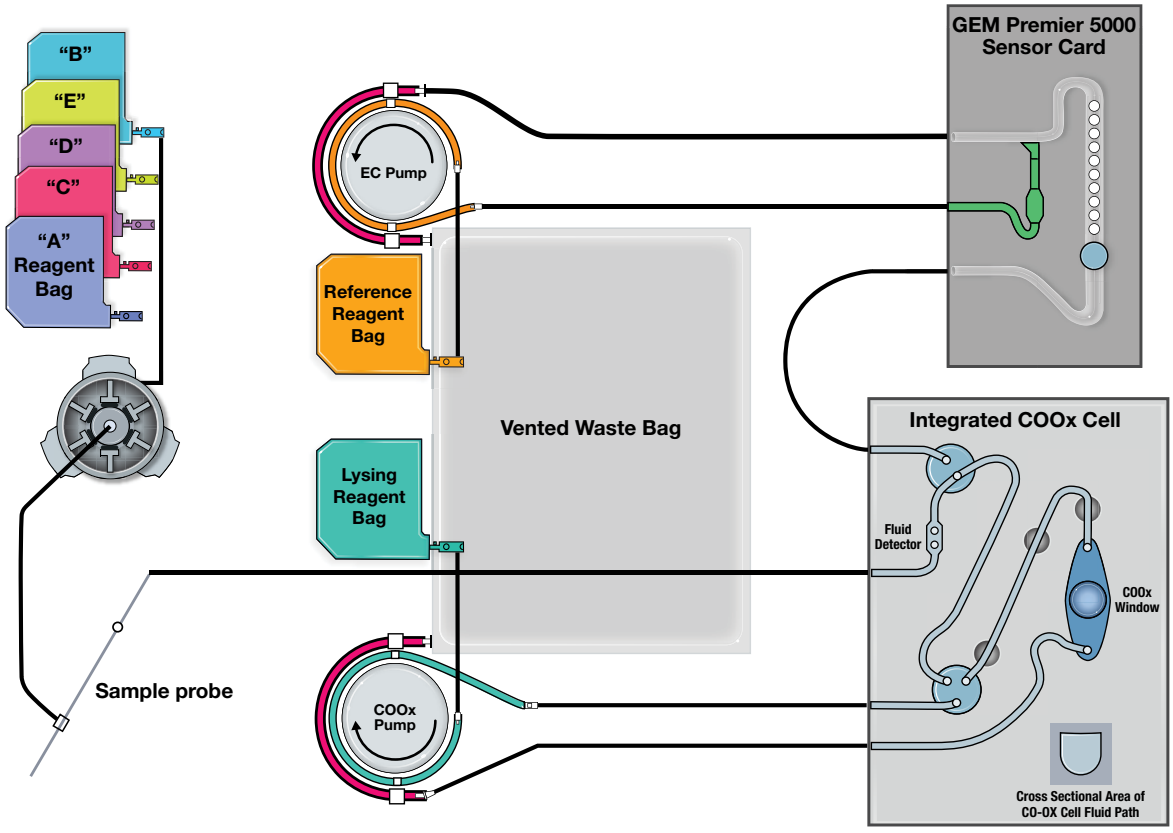
GEM Premier 5000 GEM PAK

The primary component of the GEM Premier 5000 system 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), oxygen saturation (sO_2), Carboxyhemoglobin (COHb) and Methemoglobin (MetHb).

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 an entirely 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 monitored with five Process Control Solutions A, B, C, D and E. The Process Control Solutions (PCSs) are pre-tonometered to specific levels 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 across the span of 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 ranges in combination with other PC Solutions. 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 ranges in combination with other PC Solutions. 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 ranges in combination with other PC Solutions. 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 pump moves 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.

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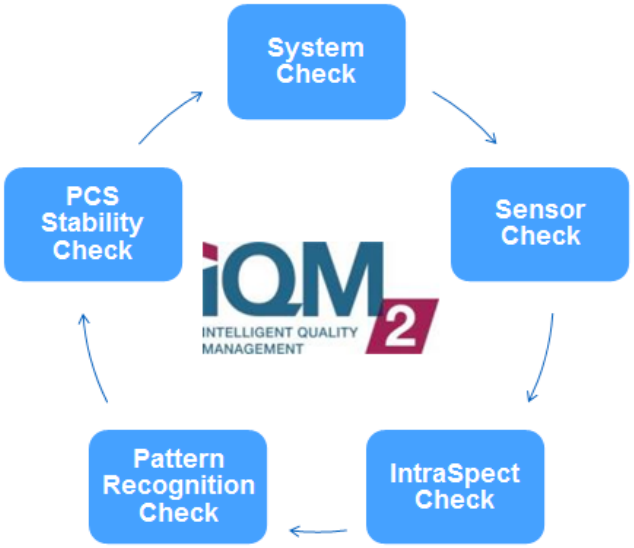
Intelligent Quality Management 2 (iQM2®)

- 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 performs 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 (table below).

Analyte	Units	A	B	C	D	E
pH		6.91	7.40	8.16	7.36	7.22
pCO_2	mmHg	65	33	33	25	67
pO_2	mmHg	120	181	3	52	95
Na^+	mmol/L	105	155	N/A	166	129
K^+	mmol/L	7.1	1.9	N/A	7.2	4.5
Cl^-	mmol/L	49	88	N/A	141	101
Ca^{++}	mmol/L	1.77	0.79	N/A	1.18	0.59
Glu	mg/dL	144	0	N/A	350	70
Lac	mmol/L	3.3	0	N/A	8.1	1.6
Hct	%	28	16	N/A	26	38
tHb	g/dL	14.2	0	N/A	7.3	16.5
O_2Hb	%	94.0	N/A	N/A	80.0	50.9
HHb	%	3.0	N/A	N/A	12.0	30.0
COHb	%	1.5	N/A	N/A	4.0	12.0
MetHb	%	1.5	N/A	N/A	4.0	8.0
tBili	mg/dL	20	0	N/A	10.0	20.0

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 an entirely 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 or other 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 (see table).

Analyte	Total Allowable Error (TEa)*
pH	+/- 0.04
pCO_2	+/- 5 mmHg or 8%, whichever is greater
pO_2	+/- 9 mmHg or 10%, whichever is greater
Na^+	+/- 4 mmol/L for Na^+ 120-160 mmol/L, 5 mmol/L for Na^+ <120 or >160 mmol/L
K^+	+/- 0.5 mmol/L or 7%, whichever is greater
Cl^-	+/- 4 mmol/L or 5%, whichever is greater
iCa	+/- 0.10 mmol/L or 10%, whichever is greater
Glucose	+/- 6 mg/dL or 10%, whichever is greater
Lactate	+/- 0.4 mmol/L or 15%, whichever is greater
Hct	+/- 4% absolute
tHb	+/- 0.7 g/dL for tHb < 18 g/dL and 1.0 g/dL for tHb ≥ 18 g/dL
O_2Hb	+/- 3% absolute
COHb	+/- 2% absolute
MetHb	+/- 2% absolute or 10% relative, whichever is greater
HHb	+/- 3% absolute
sO_2	+/- 3% absolute
tBili	+/- 0.8 mg/dL or 20%, whichever is greater

*Note: TEa is equal to bias + 1.96 x SD or CV%.

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), are 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

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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 millivolt (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

   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 PC Solutions are run automatically to continuously verify sensor, CO-Ox and PAK performance. PC Solutions are measured and compared to expected values (drift). iQM2 automatically evaluates PC Solutions, 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 any measurement or slope value is outside the allowable limits, the following corrective actions will take place:
  - Sample results for the affected analyte will be suppressed on the sample report.
  - 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.
  - If the failure is not associated with any recognizable pattern, then a fresh solution will be brought into the sensor card and re-measured.
  - 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 addition, 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 PC Solution A measurements, or in 30 consecutive PC Solution 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 PC Solution sensor readings. This allows IL to use the information for enhanced understanding of patterns, leading to continuous product improvement.

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 a). IntraSpect Checks provide continuous sample integrity quality checks throughout the entire measurement process to ensure accuracy of patient results (Figure b).

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.

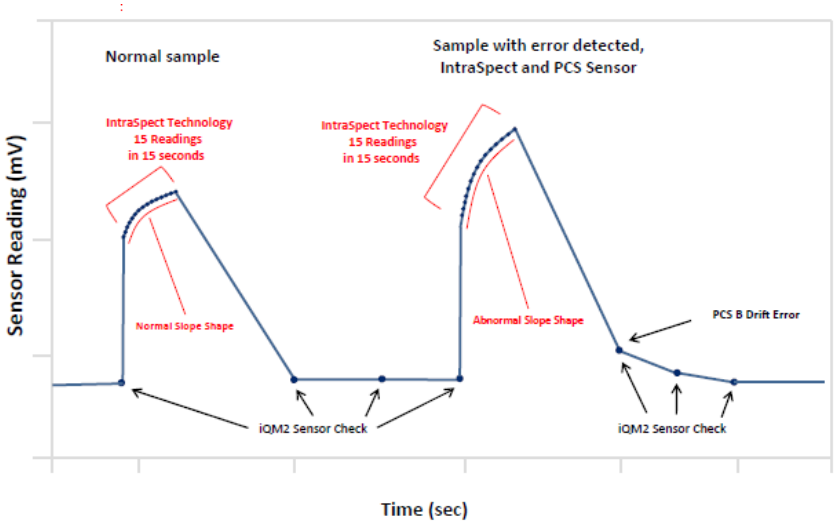

Figure a: iQM2 IntraSpect Check is performed during sample measurement. IntraSpect automatically analyzes sample measurement readings and performs corrective actions, if applicable.

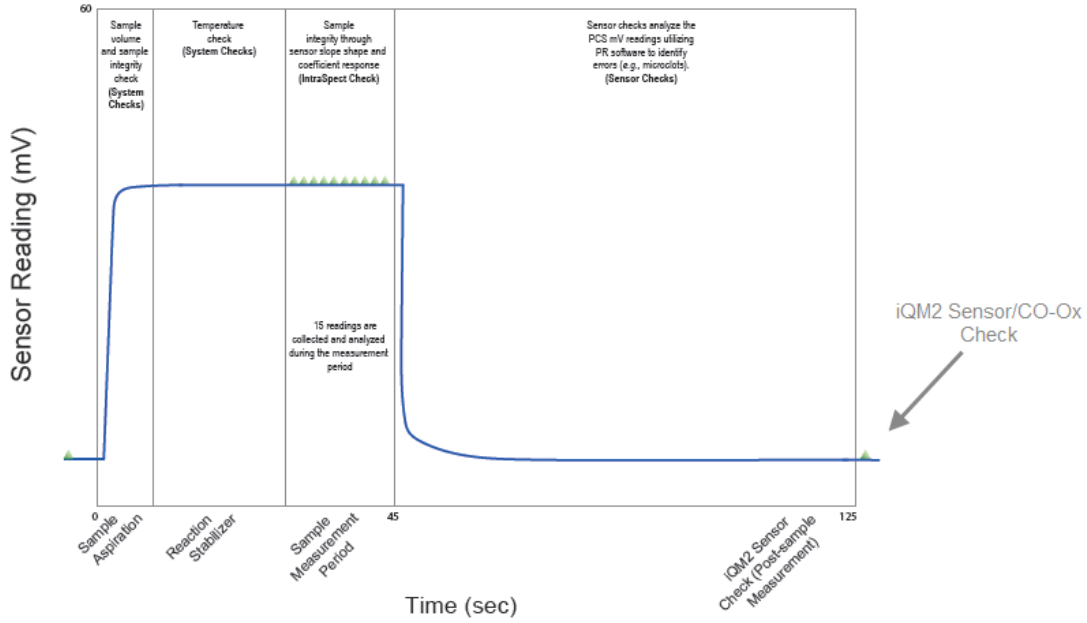

Figure b: iQM2 verifies a sample with continuous, real-time quality checks before, during and after sample measurement.

4. **Pattern Recognition (PR)**: Signals from sensors and the CO-Oximeter, generated by samples or PCSs are analyzed by Pattern Recognition (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 c).

     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 d)

     - Exogenous dyes, sulfhemoglobin, cyanomethemoglobin or excessive turbidity that can interfere with tBili and CO-Oximetry measurement.

- 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 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.

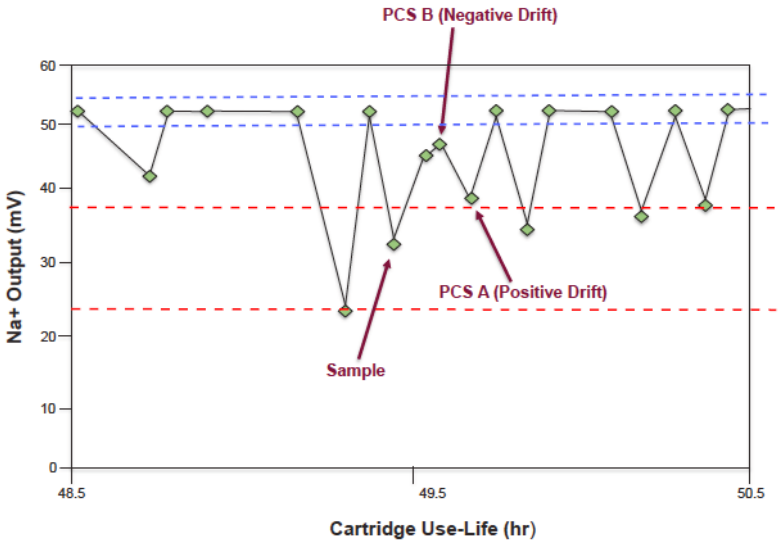

Figure c: Micro-clot detection: Negative PCS B drift followed by positive PCS A drift.

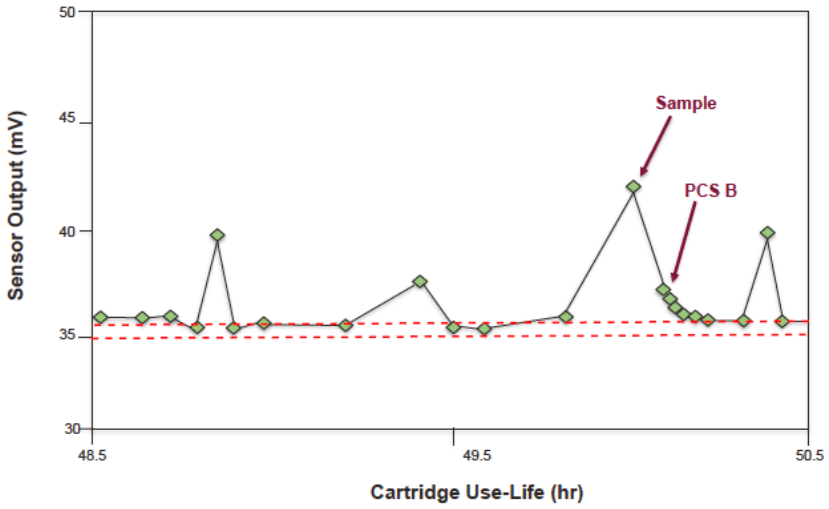

Figure d: Benzalkonium: Positive PCS B drift for Ca^{++} and Na^{+} and no negative drift for K^{+}.

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 PCS B to remove interferent	PCS B 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. This check is performed at least every 4 hours. The measured oxygen in Process Control Solution A during use-life.

   - pO_2 in PCS A is compared to initial measured A during cartridge validation by GEM APV. The delta has to be within allowable limits.
   - The pO_2 in Process Control Solution A is used for the process stability check for the following reasons:
     - Oxygen is considered the most sensitive parameter for detecting deterioration in the Process Control Solutions since there is no oxygen buffering in these solutions.
     - Process of measuring oxygen in Process Control Solutions A utilizes Process Control Solutions B and C. Therefore, deterioration in any of these Process Control Solutions will be detected by this check.
     - Persistent oxygen reading outside of drift limits for Process Control Solutions D and E is also considered failure in Process Stability check.

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 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 Pattern Recognition (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.

The method is as follows:

- Define the quality requirement in terms of total allowable error (TEa) refer to specific ranges outlined in “iQM2 Requirements” on page 171.
- 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 defects. 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.

11 - Performance Characteristics

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Performance Characteristics Summary

Introduction

The following analytical data was collected during evaluation studies at Instrumentation Laboratory's facilities and at external field sites. These studies demonstrate the typical performance characteristics of the GEM Premier 5000 system.

Precision Study - Aqueous Controls

In accordance with CLSI EP05-A3, "Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition, 2014," an internal 20-day precision study was performed on the GEM Premier 5000, with GEM System Evaluator 1, 2 and 3, GEM Hematocrit 1, 2 and 3 and CVP 5 tBili. GEM Evaluators (GSE or GHE), 3 level products, are external aqueous buffer based controls for the measurement of pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, Lactate, Hct, tBili, tHb, O_2Hb, COHb, MetHb, sO_2, and HHb. CVP 5 tBili is an external Calibration Valuation Product (CVP) containing purified human hemoglobin for the measurement of total Bilirubin.

Each of the control levels was run on three (3) GEM Premier 5000 analyzers for twenty (20) days, with two (2) runs per day and one (1) replicate measured per run per level (n=120). The mean, within-analyzer standard deviation (SD), and within-analyzer coefficient of variation (% CV) were calculated across all analyzers. All results were within specification.

GEM System Evaluator Level 1					
Analyte	**Mean**	**N**	**Within Analyzer SD**	**Within Analyzer %CV**	**Specification (SD or %CV)**
pH	7.14	120	0.008	0.1%	0.02
pCO_2 (mmHg)	87	120	2.3	2.7%	4%
pO_2 (mmHg)	31	120	1.9	6.1%	5
Na^+ (mmol/L)	124	120	0.7	0.6%	2
K^+ (mmol/L)	2.4	120	0.02	0.7%	0.25
Cl^- (mmol/L)	85	120	0.6	0.7%	2.5%
Ca^{++} (mmol/L)	1.56	120	0.013	0.8%	5%
Glucose (mg/dL)	378	120	10.9	2.9%	5%
Lactate (mmol/L)	7.3	120	0.06	0.9%	7.5%
tHb (g/dL)	20.8	120	0.14	0.7%	0.5
O_2Hb (%)	37.3	120	0.00	0.0%	1.5
COHb (%)	31.7	120	0.03	0.1%	1.0
MetHb (%)	8.3	120	0.05	0.6%	1.0
HHb (%)	22.6	120	0.05	0.2%	1.5
sO_2 (%)	62.2	120	0.05	0.1%	1.5
tBili (mg/dL)	33.8	120	0.14	0.4%	10%

GEM System Evaluator Level 2					
Analyte	**Mean**	**N**	**Within Analyzer SD**	**Within Analyzer %CV**	**Specification (SD or %CV)**
pH	7.38	120	0.004	0.1%	0.02
pCO_2 (mmHg)	35	120	0.7	1.9%	2.5
pO_2 (mmHg)	88	120	1.2	1.4%	5
Na^+ (mmol/L)	141	120	0.5	0.4%	2
K^+ (mmol/L)	4.7	120	0.04	0.9%	0.25
Cl^- (mmol/L)	108	120	0.5	0.4%	2.5%
Ca^{++} (mmol/L)	1.16	120	0.006	0.5%	5%
Glucose (mg/dL)	104	120	1.6	1.6%	5%
Lactate (mmol/L)	0.8	120	0.03	3.7%	0.2
tHb (g/dL)	14.6	120	0.13	0.9%	0.35
O_2Hb (%)	73.7	120	0.04	0.1%	1.5
COHb (%)	16.8	120	0.05	0.3%	1.0
MetHb (%)	2.6	120	0.06	2.5%	1.0
HHb (%)	6.9	120	0.05	0.7%	1.5
sO_2 (%)	91.4	120	0.06	0.1%	1.5
tBili (mg/dL)	17.7	120	0.13	0.8%	10%

GEM System Evaluator Level 3					
Analyte	**Mean**	**N**	**Within Analyzer SD**	**Within Analyzer %CV**	**Specification (SD or %CV)**
pH	7.57	120	0.003	0.0%	0.02
pCO_2 (mmHg)	14	120	0.3	2.2%	2.5
pO_2 (mmHg)	370	120	4.8	1.3%	5%
Na^+ (mmol/L)	156	120	0.7	0.5%	2
K^+ (mmol/L)	7.7	120	0.04	0.5%	3.5%
Cl^- (mmol/L)	141	120	1.0	0.7%	2.5%
Ca^{++} (mmol/L)	0.64	120	0.006	1.0%	0.05
Glucose (mg/dL)	46	120	1.3	2.7%	3
Lactate (mmol/L)	2.5	120	0.04	1.8%	0.2
tHb (g/dL)	7.8	120	0.13	1.7%	0.35
O_2Hb (%)	93.0	120	0.04	0.0%	1.5
COHb (%)	3.1	120	0.07	2.3%	1.0
HHb (%)	3.3	120	0.09	2.6%	1.5
sO_2 (%)	96.6	120	0.09	0.1%	1.5
tBili (mg/dL)	3.3	120	0.13	4.0%	0.4

GEM Hematocrit Evaluator Level 1					
Analyte	**Mean**	**N**	**Within Analyzer SD**	**Within Analyzer %CV**	**Specification (SD or %CV)**
Hct (%)	21	120	0.2	1.2%	2

GEM Hematocrit Evaluator Level 2					
Analyte	**Mean**	**N**	**Within Analyzer SD**	**Within Analyzer %CV**	**Specification (SD or %CV)**
Hct (%)	41	120	0.2	0.6%	2

GEM Hematocrit Evaluator Level 3					
Analyte	**Mean**	**N**	**Within Analyzer SD**	**Within Analyzer %CV**	**Specification (SD or %CV)**
Hct (%)	65	120	0.4	0.6%	2

CVP 5 tBili					
Analyte	**Mean**	**N**	**Within Analyzer SD**	**Within Analyzer %CV**	**Specification (SD or %CV)**
tBili (mg/dL)	4.8	120	0.13	2.6%	10%

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Precision Study - GEM PAK (Cartridge) Process Control Solution D and E

In accordance with CLSI EP05-A3, an internal 20-day precision study was performed with the GEM PAK (cartridge) Process Control Solutions (PCS) D and E run automatically as a part of the iQM2 process on three (3) GEM Premier 5000 analyzers for twenty (20) days, with two (2) runs per day and one (1) replicate measured per run per level (N=120 per analyte/per level). The mean, within-analyzer standard deviation (SD), and within-analyzer coefficient of variation (% CV) were calculated across all analyzers. All results were within specification.

Process Control Solution D					
Analyte	**Mean**	**N**	**Within Analyzer SD**	**Within Analyzer %CV**	**Specification (SD or %CV)**
pH	7.35	120	0.001	0.0%	0.02
pCO_2 (mmHg)	25	120	0.1	0.4%	2.5
pO_2 (mmHg)	55	120	1.1	1.9%	6
Na^+ (mmol/L)	167	120	0.4	0.3%	2.5
K^+ (mmol/L)	7.3	120	0.02	0.2%	3.5%
Cl^- (mmol/L)	144	120	0.7	0.5%	2.5%
Ca^{++} (mmol/L)	1.21	120	0.004	0.3%	5%
Glucose (mg/dL)	347	120	1.7	0.5%	5%
Lactate (mmol/L)	8.0	120	0.11	1.3%	7.5%
Hct (%)	27	120	0.2	0.6%	2
tHb (g/dL)	7.4	120	0.05	0.6%	0.35
O_2Hb (%)	79.9	120	0.13	0.2%	1.5
COHb (%)	4.0	120	0.11	2.7%	1.0
MetHb (%)	3.9	120	0.12	3.0%	1.0
HHb (%)	12.2	120	0.35	2.9%	1.5
sO_2 (%)	86.8	120	0.35	0.4%	1.5
tBili (mg/dL)	10.4	120	0.05	0.4%	10%

Process Control Solution E					
Analyte	**Mean**	**N**	**Within Analyzer SD**	**Within Analyzer %CV**	**Specification (SD or %CV)**
pH	7.21	120	0.001	0.0%	0.02
pCO_2 (mmHg)	68	120	0.3	0.5%	4%
pO_2 (mmHg)	98	120	1.1	1.1%	5
Na^+ (mmol/L)	128	120	0.2	0.2%	2
K^+ (mmol/L)	4.5	120	0.01	0.3%	0.25
Cl^- (mmol/L)	102	120	0.3	0.3%	2.5%
Ca^{++} (mmol/L)	0.56	120	0.007	1.3%	0.05
Glucose (mg/dL)	71	120	0.6	0.8%	5%
Lactate (mmol/L)	1.6	120	0.02	1.3%	0.2
Hct (%)	37	120	0.0	0.1%	2
tHb (g/dL)	16.5	120	0.04	0.2%	0.35
O_2Hb (%)	49.8	120	0.06	0.1%	1.5
COHb (%)	10.1	120	0.04	0.4%	1.0
MetHb (%)	8.0	120	0.05	0.6%	1.0
HHb (%)	32.1	120	0.14	0.4%	1.5
sO_2 (%)	60.8	120	0.13	0.2%	1.5
tBili (mg/dL)	20.0	120	0.04	0.2%	10%

Precision Study - Whole Blood

In accordance with CLSI EP05-A3, an internal precision study was performed using four or five (4 or 5) different concentrations of whole blood per analyte, spanning the claimed measuring ranges. Each level was run on three (3) GEM Premier 5000 analyzers per sample mode for five (5) days, with one (1) run per day and eight (8) replicates measured per run per level (N=120 per analyte/per sample mode). The mean, within-run standard deviation (SD), and within-run coefficient of variation (% CV) were calculated across all analyzers.

Sample Modes and Volumes:

- Normal Mode 150 µL
- Micro Mode 65 µL
- tBili/CO-Ox Mode 100 µL

These studies demonstrate the typical performance characteristics of the GEM Premier 5000 analyzer. Within run SD or %CV are compared against analyzer precision specification listed below (SD or %CV = ½ Total Allowable Error listed in iQM2 section). All results were within specification.

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pH					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD)**
Normal Mode	120	7.11	0.004	0.1%	0.02
	120	7.33	0.007	0.1%	
	120	7.35	0.004	0.1%	
	120	7.42	0.005	0.1%	
	120	7.68	0.012	0.1%	
Micro Mode	120	7.10	0.006	0.1%	
	120	7.32	0.004	0.1%	
	120	7.35	0.004	0.1%	
	120	7.41	0.005	0.1%	
	120	7.67	0.013	0.2%	

***p*CO_2, mmHg**					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD or %CV)**
Normal Mode	120	112	2.7	2.4%	2.5 mmHg or 4%, whichever is greater
	120	70	1.1	1.5%	
	120	50	0.6	1.2%	
	120	36	0.5	1.3%	
	120	10	0.5	4.6%	

***p*O_2, mmHg**					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD or %CV)**
Normal Mode	120	32	0.4	1.2%	4.5 mmHg or 5%, whichever is greater
	120	62	0.7	1.1%	
	120	204	2.3	1.1%	
	120	415	8.6	2.1%	
	120	722	18.6	2.6%	
Micro Mode	120	31	0.9	3.0%	
	120	62	0.7	1.1%	
	120	204	4.3	2.1%	
	120	402	15.3	3.8%	
	120	693	26.5	3.8%	

Sodium (Na^+), mmol/L					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD or %CV)**
Normal Mode	120	104	0.5	0.5%	2 mmol/L for Na+ 120-160 mmol/L 2.5 mmol/L for Na+ <120 or >160 mmol/L
	120	114	0.4	0.4%	
	120	132	0.4	0.3%	
	120	148	0.6	0.4%	
	120	187	1.1	0.6%	
Micro Mode	120	104	0.4	0.3%	
	120	114	0.3	0.3%	
	120	131	0.3	0.2%	
	120	147	0.4	0.3%	
	120	186	0.6	0.3%	

Potassium (K^+), mmol/L					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD or %CV)**
Normal Mode	120	1.6	0.04	2.5%	0.25 mmol/L or 3.5%, whichever is greater
	120	2.9	0.05	1.7%	
	120	5.5	0.05	0.9%	
	120	7.5	0.14	1.9%	
	120	17.0	0.32	1.9%	

Calcium (Ca^{++}), mmol/L					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD or %CV)**
Normal Mode	120	0.23	0.009	3.9%	0.05 mmol/L or 5%, whichever is greater
	120	0.37	0.006	1.7%	
	120	0.86	0.005	0.6%	
	120	1.54	0.020	1.3%	
	120	4.26	0.074	1.7%	
Micro Mode	120	0.22	0.005	2.4%	
	120	0.35	0.004	1.1%	
	120	0.83	0.004	0.5%	
	120	1.51	0.015	1.0%	
	120	4.20	0.057	1.3%	

Chloride (Cl^-), mmol/L					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD or %CV)**
Normal Mode	120	52	0.4	0.8%	2 mmol/L or 2.5%, whichever is greater
	120	71	0.3	0.5%	
	120	90	0.4	0.4%	
	120	115	0.7	0.6%	
	120	167	1.4	0.9%	

Glucose, mg/dL					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD or %CV)**
Normal Mode	120	24	0.8	3.3%	3 mg/dL or 5%, whichever is greater
	120	42	0.8	2.0%	
	120	120	1.7	1.4%	
	120	179	3.1	1.7%	
	120	729	13.1	1.8%	
Micro Mode	120	26	0.7	2.8%	
	120	44	0.8	1.8%	
	120	118	2.5	2.1%	
	120	176	2.9	1.7%	
	120	761	11.6	1.5%	

Lactate, mmol/L					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD or %CV)**
Normal Mode	120	0.5	0.05	9.4%	0.2 mmol/L or 7.5%, whichever is greater
	120	1.8	0.06	3.3%	
	120	4.9	0.09	1.7%	
	120	7.8	0.17	2.1%	
	120	17.9	0.40	2.2%	
Micro Mode	120	0.5	0.04	7.5%	
	120	1.9	0.05	2.9%	
	120	4.9	0.14	2.9%	
	120	7.8	0.13	1.6%	
	120	18.2	0.31	1.7%	

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Hematocrit (Hct), % (absolute)					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD)**
Normal Mode	120	18	0.3	1.9%	2% (absolute units)
	120	33	0.3	1.0%	
	120	45	0.5	1.0%	
	120	57	0.6	1.1%	
	120	65	0.7	1.1%	

Total Hemoglobin (tHb), g/dL					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD)**
Normal Mode	120	6.2	0.04	0.6%	0.35 g/dL (for tHb <18 g/dL) 0.5 g/dL (for tHb ≥ 18 g/dL)
	120	11.2	0.04	0.4%	
	120	15.1	0.05	0.3%	
	120	18.8	0.06	0.3%	
	120	21.7	0.08	0.4%	

Oxyhemoglobin (O_2Hb), % (absolute)					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD)**
Normal Mode	120	9.1	0.21	2.4%	1.5% (absolute units)
	120	38.4	0.26	0.7%	
	120	77.0	0.20	0.3%	
	120	90.6	0.21	0.2%	
	120	96.4	0.18	0.2%	
tBili/CO-Ox Mode	120	8.7	0.20	2.3%	
	120	38.0	0.27	0.7%	
	120	76.5	0.23	0.3%	
	120	90.2	0.22	0.2%	
	120	96.0	0.21	0.2%	

Carboxyhemoglobin (COHb), % (absolute)					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD)**
Normal Mode	120	1.6	0.14	8.6%	1% (absolute units)
	120	5.6	0.16	2.9%	
	120	15.3	0.17	1.1%	
	120	30.3	0.21	0.7%	
	120	64.3	0.26	0.4%	
tBili/CO-Ox Mode	120	1.8	0.18	9.9%	
	120	5.8	0.16	2.7%	
	120	15.4	0.20	1.3%	
	120	30.4	0.23	0.8%	
	120	64.3	0.31	0.5%	

Methemoglobin (MetHb), % (absolute)					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD or %CV)**
Normal Mode	120	5.0	0.17	3.4%	1% (absolute) or 5% (relative), whichever is greater
	120	9.9	0.19	1.9%	
	120	14.5	0.27	1.9%	
	120	25.5	0.28	1.1%	
tBili/CO-Ox Mode	120	5.1	0.16	3.2%	
	120	10.0	0.21	2.1%	
	120	14.8	0.34	2.3%	
	120	25.6	0.21	0.8%	

Deoxyhemoglobin (HHb), % (absolute)					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD)**
Normal Mode	120	6.6	0.23	3.5%	1.5% (absolute units)
	120	20.5	0.24	1.2%	
	120	59.9	0.29	0.5%	
	120	90.0	0.22	0.2%	
tBili/CO-Ox Mode	120	6.8	0.26	3.8%	
	120	20.9	0.25	1.2%	
	120	60.2	0.29	0.5%	
	120	90.1	0.23	0.3%	

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Oxygen Saturation (sO_2), % (absolute)					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD)**
Normal Mode	120	9.2	0.21	2.3%	1.5% (absolute units)
	120	39.0	0.27	0.7%	
	120	79.0	0.23	0.3%	
	120	93.2	0.24	0.3%	
	120	98.7	0.25	0.2%	
tBili/CO-Ox Mode	120	8.8	0.19	2.2%	
	120	38.7	0.27	0.7%	
	120	78.6	0.24	0.3%	
	120	92.9	0.26	0.3%	
	120	98.5	0.27	0.3%	

Total Bilirubin (tBili), mg/dL					
Mode	**N**	**Mean**	**Within Run SD**	**Within Run %CV**	**Specification (SD or %CV)**
Normal Mode	120	3.3	0.12	3.5%	0.4 mg/dL or 10%, whichever is greater
	120	6.2	0.12	1.8%	
	120	14.1	0.13	0.9%	
	120	19.7	0.17	0.9%	
	120	29.6	0.18	0.6%	
tBili/CO-Ox Mode	120	3.3	0.10	2.9%	
	120	6.3	0.13	2.0%	
	120	14.0	0.14	1.0%	
	120	19.6	0.17	0.9%	
	120	29.4	0.16	0.5%	

Reproducibility Study with Aqueous Controls - Point-of-Care Setting

In accordance with CLSI EP05-A3, a reproducibility study was performed at three (3) external clinical point-of-care (POC) sites. The studies were run by a total of nine (9) different operators on three (3) different GEM Premier 5000 instruments, using a single lot of GEM Premier 5000 PAKs (cartridges). Each site used the same lots of GEM System Evaluator (GSE) 1, 2 and 3, GEM Hematocrit (GHE) 1, 2 and 3 and CVP 5 tBili, running each control level in triplicate, twice a day for 5 days, for a total of 30 replicates per level (N=90 pooled). The mean, repeatability (SD and %CV), and reproducibility (SD and % CV) were calculated. All results were within specification.

GEM System Evaluator Level 1							
Analyte	**Mean**	**N**	**Repeatability**		**Reproducibility**		**Specification (SD or %CV)**
			SD	**%CV**	**SD**	**%CV**	
pH	7.14	90	0.002	0.0%	0.002	0.0%	0.02
pCO_2 (mmHg)	87	90	0.4	0.5%	1.1	1.2%	4%
pO_2 (mmHg)	28	90	0.7	2.3%	1.9	6.7%	5
Na^+ (mmol/L)	125	90	0.4	0.3%	0.5	0.4%	2
K^+ (mmol/L)	2.4	90	0.00	0.0%	0.00	0.0%	0.25
Cl^- (mmol/L)	85	90	0.3	0.4%	0.4	0.4%	2.5%
Ca^{++} (mmol/L)	1.58	90	0.007	0.4%	0.009	0.6%	5%
Glucose (mg/dL)	381	90	2.1	0.5%	4.7	1.2%	5%
Lactate (mmol/L)	7.2	90	0.06	0.8%	0.09	1.3%	7.5%
tHb (g/dL)	20.7	90	0.14	0.7%	0.16	0.8%	0.5
O_2Hb (%)	37.3	90	0.01	0.0%	0.01	0.0%	1.5
COHb (%)	31.7	90	0.04	0.1%	0.05	0.2%	1.0
MetHb (%)	8.3	90	0.05	0.6%	0.06	0.7%	1.0
HHb (%)	22.6	90	0.04	0.2%	0.06	0.2%	1.5
sO_2 (%)	62.2	90	0.04	0.1%	0.06	0.1%	1.5
tBili (%)	33.7	90	0.14	0.4%	0.16	0.5%	10%

GEM System Evaluator Level 2							
Analyte	**Mean**	**N**	**Repeatability**		**Reproducibility**		**Specification (SD or %CV)**
			SD	**%CV**	**SD**	**%CV**	
pH	7.39	90	0.007	0.1%	0.008	0.1%	0.02
pCO_2 (mmHg)	34	90	0.9	2.5%	0.9	2.7%	2.5
pO_2 (mmHg)	87	90	1.4	1.7%	1.9	2.2%	5
Na^+ (mmol/L)	141	90	0.3	0.2%	0.5	0.4%	2
K^+ (mmol/L)	4.7	90	0.03	0.6%	0.04	0.8%	0.25
Cl^- (mmol/L)	108	90	0.2	0.2%	0.3	0.3%	2.5%
Ca^{++} (mmol/L)	1.16	90	0.005	0.4%	0.007	0.6%	5%
Glucose (mg/dL)	102	90	0.5	0.5%	0.8	0.8%	5%
Lactate (mmol/L)	0.8	90	0.02	2.3%	0.02	2.5%	0.2
tHb (g/dL)	14.5	90	0.10	0.7%	0.13	0.9%	0.35
O_2Hb (%)	73.7	90	0.04	0.0%	0.05	0.1%	1.5
COHb (%)	16.8	90	0.04	0.2%	0.04	0.3%	1.0
MetHb (%)	2.5	90	0.04	1.7%	0.06	2.4%	1.0
HHb (%)	6.9	90	0.05	0.7%	0.06	0.8%	1.5
sO_2 (%)	91.4	90	0.05	0.1%	0.07	0.1%	1.5
tBili (%)	17.6	90	0.10	0.5%	0.13	0.7%	10%

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GEM System Evaluator Level 3							
Analyte	**Mean**	**N**	**Repeatability**		**Reproducibility**		**Specification (SD or %CV)**
			SD	**%CV**	**SD**	**%CV**	
pH	7.57	90	0.002	0.0%	0.003	0.0%	0.02
pCO_2 (mmHg)	13	90	0.4	3.3%	0.5	3.5%	2.5
pO_2 (mmHg)	357	90	7.9	2.2%	9.3	2.6%	5%
Na^+ (mmol/L)	155	90	0.3	0.2%	0.4	0.2%	2
K^+ (mmol/L)	7.7	90	0.02	0.3%	0.03	0.4%	3.5%
Cl^- (mmol/L)	142	90	0.4	0.3%	0.6	0.4%	2.5%
Ca^{++} (mmol/L)	0.64	90	0.003	0.5%	0.005	0.8%	0.05
Glucose (mg/dL)	45	90	0.5	1.2%	0.6	1.4%	3
Lactate (mmol/L)	2.4	90	0.02	0.7%	0.06	2.3%	0.2
tHb (g/dL)	7.7	90	0.10	1.3%	0.10	1.4%	0.35
O_2Hb (%)	93.0	90	0.03	0.0%	0.04	0.0%	1.5
COHb (%)	3.2	90	0.06	1.9%	0.07	2.1%	1.0
HHb (%)	3.4	90	0.06	1.9%	0.08	2.3%	1.5
sO_2 (%)	96.5	90	0.06	0.1%	0.08	0.1%	1.5
tBili (%)	3.2	90	0.10	3.0%	0.10	3.3%	0.4

GEM Hematocrit Evaluator Level 1							
Analyte	**Mean**	**N**	**Repeatability**		**Reproducibility**		**Specification (SD or %CV)**
			SD	**%CV**	**SD**	**%CV**	
Hct (%)	21	90	0.0	0.0%	0.0	0.0%	2

GEM Hematocrit Evaluator Level 2							
Analyte	**Mean**	**N**	**Repeatability**		**Reproducibility**		**Specification (SD or %CV)**
			SD	**%CV**	**SD**	**%CV**	
Hct (%)	41	90	0.0	0.0%	0.0	0.0%	2

GEM Hematocrit Evaluator Level 3							
Analyte	**Mean**	**N**	**Repeatability**		**Reproducibility**		**Specification (SD or %CV)**
			SD	**%CV**	**SD**	**%CV**	
Hct (%)	66	90	0.3	0.4%	0.6	0.9%	2

CVP 5 tBili							
Analyte	Mean	N	Repeatability		Reproducibility		Specification (SD or %CV)
			SD	%CV	SD	%CV	
tBili (mg/dL)	4.9	90	0.11	2.2%	0.17	3.5%	10%

Linearity

In accordance with CLSI EP06-A, "Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline, 2003," eight (8) or nine (9) levels per analyte were prepared by tonometry, spiking or diluting whole blood to challenge the claimed measuring range for each parameter. Each blood level was analyzed in triplicate on three (3) GEM Premier 5000 test analyzers and results compared to reference analyzers or standard reference procedures (i.e. tonometry for gases and CNMetHb procedure for tHb per CLSI H15-A3, "Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; Approved Standard - Third Edition, 2000").

NOTE: Combined data from limit of quantitation (LOQ) and linearity studies were used to support lower limit of the claimed measuring range.

Analyte	# of Levels	N per Level	Slope	Intercept	r^2	Tested Range	Reportable Range
pH	8	9	0.972	0.191	0.998	6.67 to 7.97	7.00 to 7.92
pCO_2 (mmHg)	8	9	1.045	-2.027	0.998	1 to 149	6 to 125
pO_2 (mmHg)	9	9	1.028	-4.069	0.995	5 to 723	6 to 690
Na^+ (mmol/L)	9	9	0.972	5.377	0.999	85 to 214	100 to 180
K^+ (mmol/L)	9	9	0.993	-0.072	0.999	0.7 to 21.9	1.0 to 19.0
Cl^- (mmol/L)	9	9	0.964	2.805	1.000	35 to 189	40 to 158
Ca^{++} (mmol/L)	10	9	0.999	0.011	0.999	0.10 to 5.05	0.11 to 4.25
Glucose (mg/dL)	9	9	0.982	-12.489	0.995	1 to 777	4 to 685
Lactate (mmol/L)	9	9	1.037	-0.131	0.998	0.2 to 25.5	0.3 to 17.0
Hct (%)	9	9	0.970	1.904	0.998	7 to 82	15 to 72
tHb (g/dL)	9	9	1.015	0.130	0.999	2.1 to 27.0	3.0 to 23.0
O_2Hb (%)	8	9	1.002	0.918	1.000	-0.3 to 99.3	0.7 to 100.0
COHb (%)*	7	9	1.016	1.532	1.000	7.4 to 98.5	0.3 to 75.0
	5	120	1.004	-0.109	1.000	-0.1 to 10.2	
MetHb (%)*	8	9	1.035	0.029	1.000	3.5 to 38.9	0.7 to 30.0
	5	120	1.006	-0.254	1.000	0.3 to 9.9	
HHb (%)	8	9	1.004	-0.384	1.000	-0.01 to 99.6	1.0 to 100.0
tBili (mg/dL)	9	9	1.040	0.227	0.998	1.4 to 43.7	2.0 to 40.0

* Additional results at the low-end against the GEM Premier 4000

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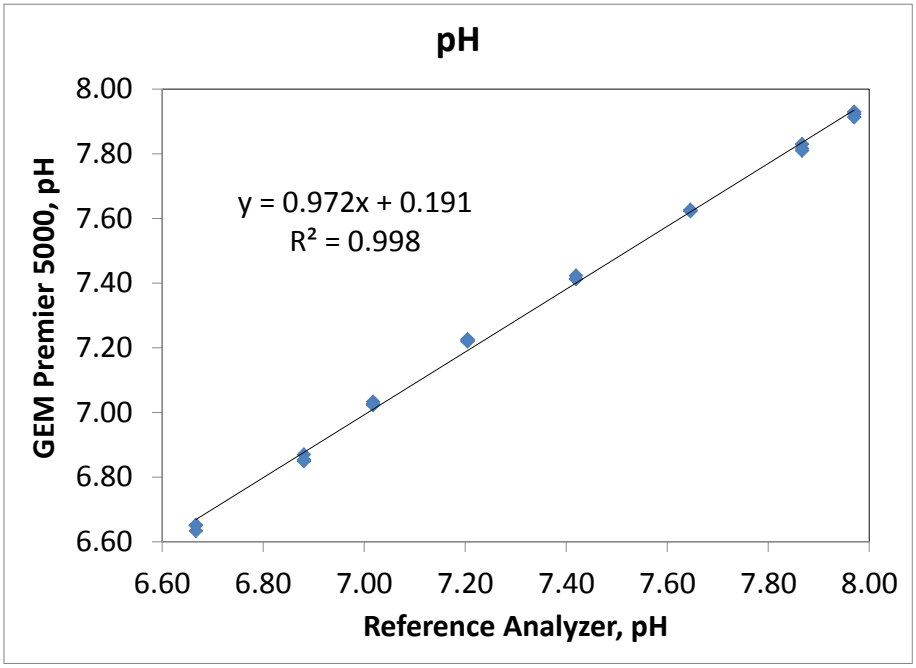
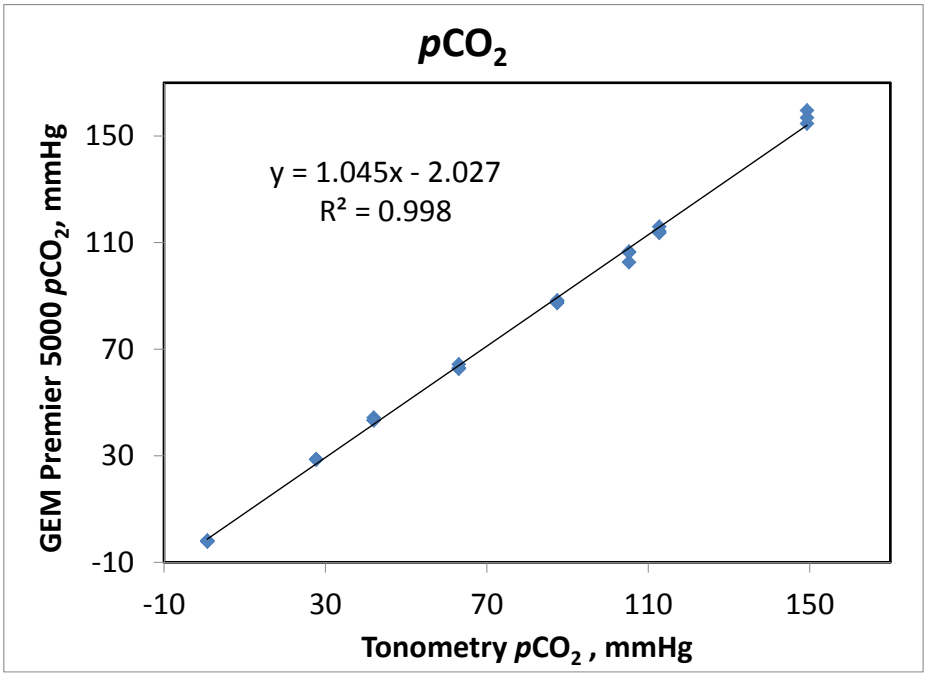
pH (pH Units):



pCO_2 (mmHg):



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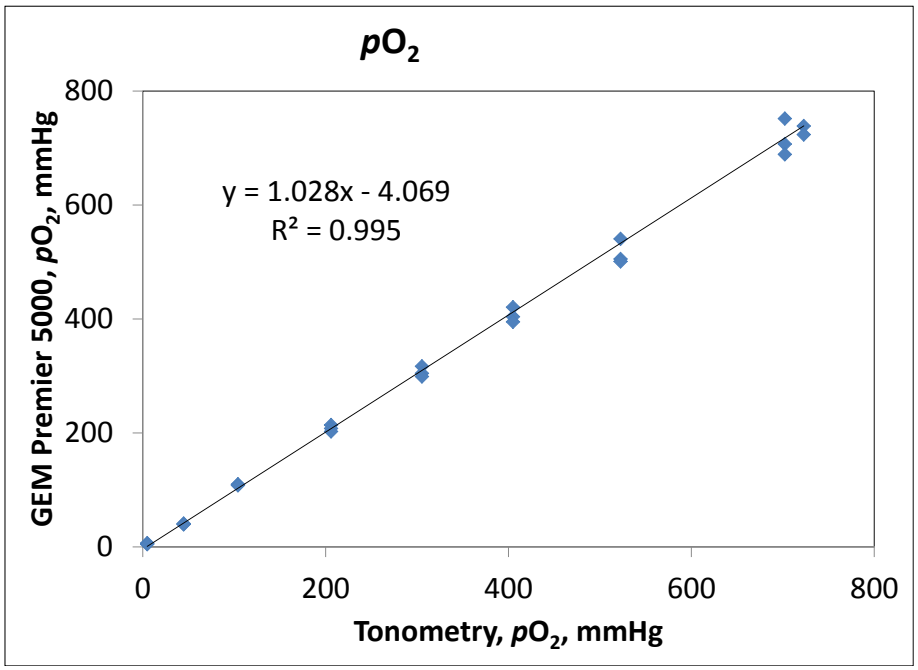
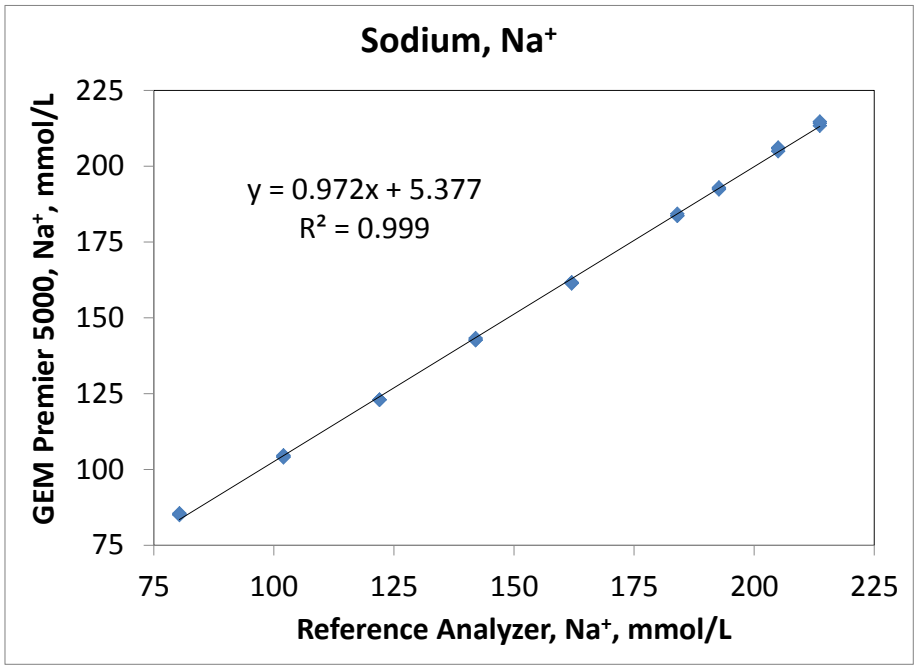
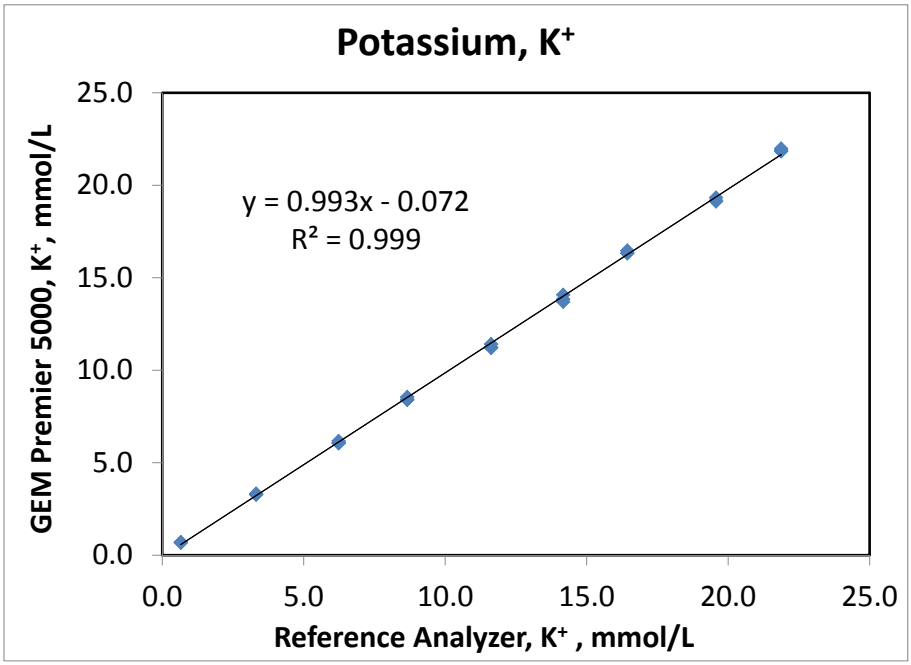
pO_2 (mmHg):



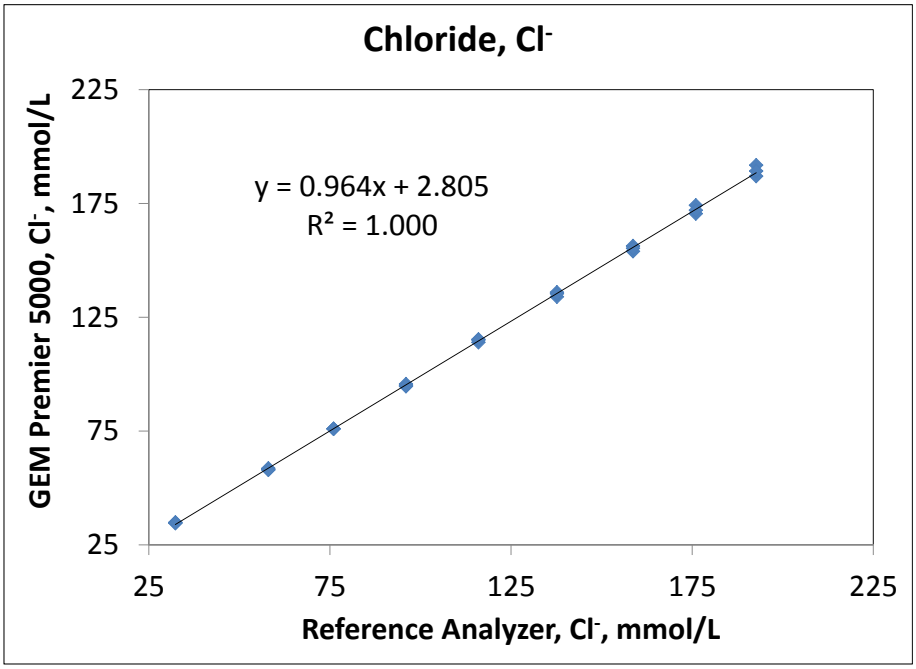
Na^+ (mmol/L):



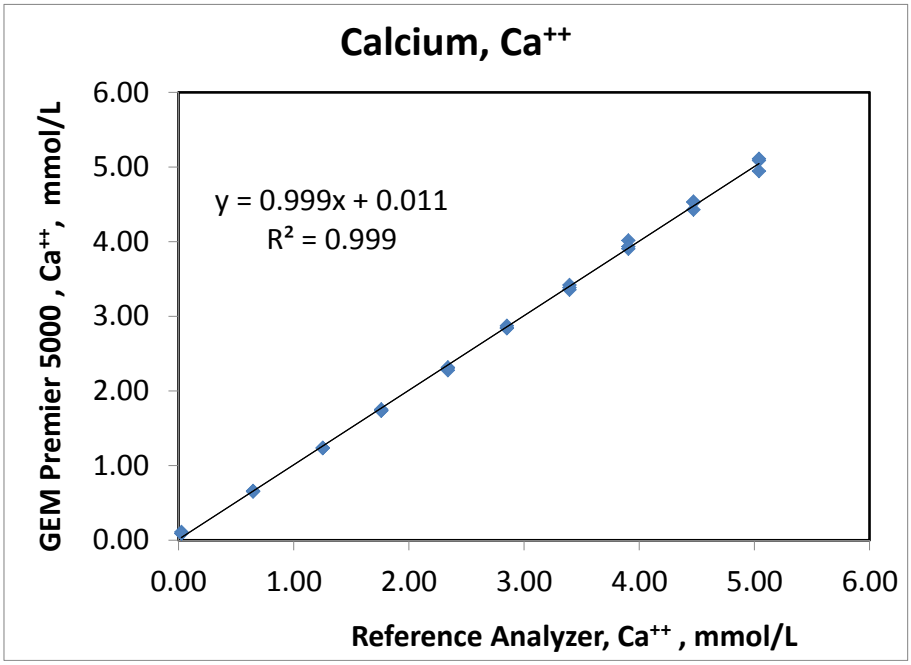
K^+ (mmol/L):



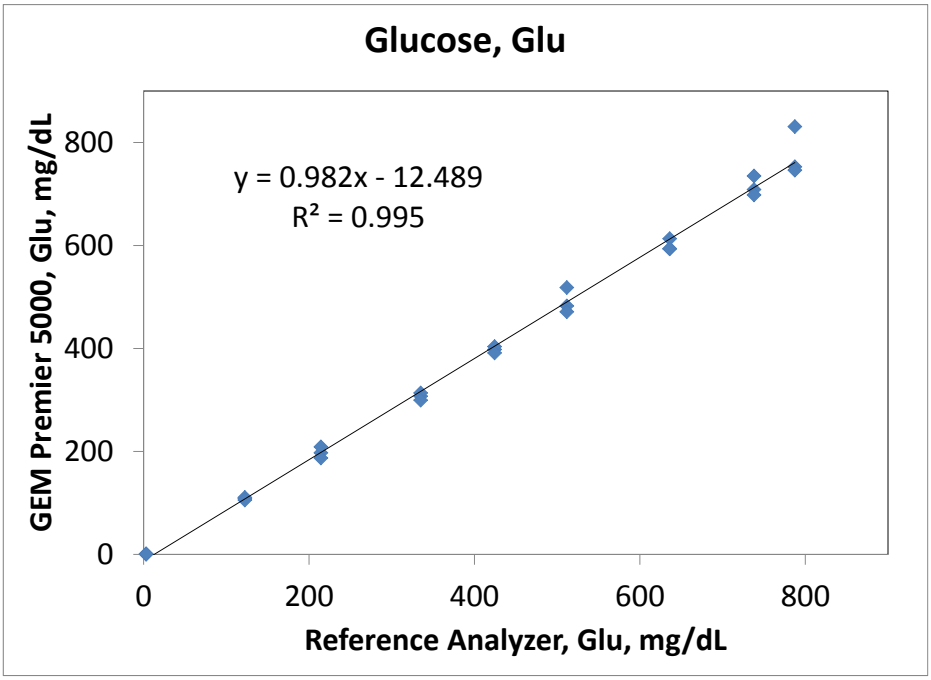
Cl^- (mmol/L):



Ca^{++} (mmol/L):



Glucose (mg/dL):



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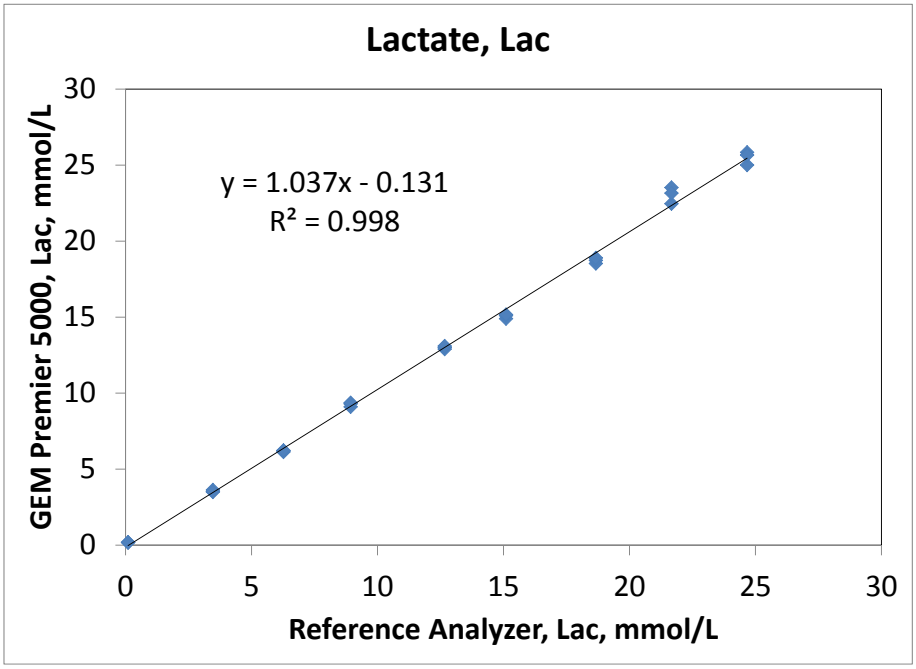
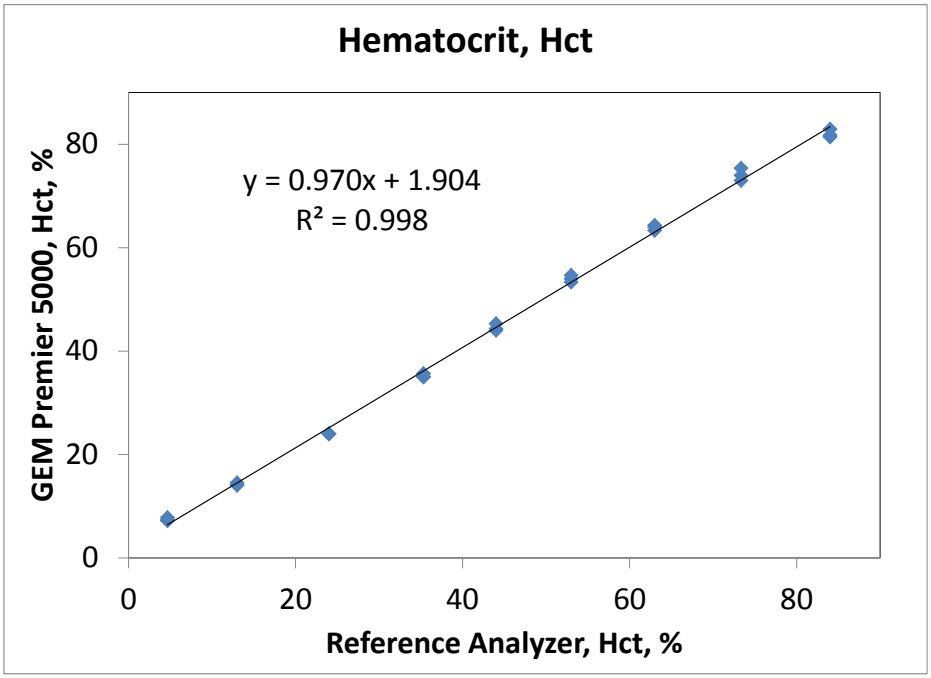
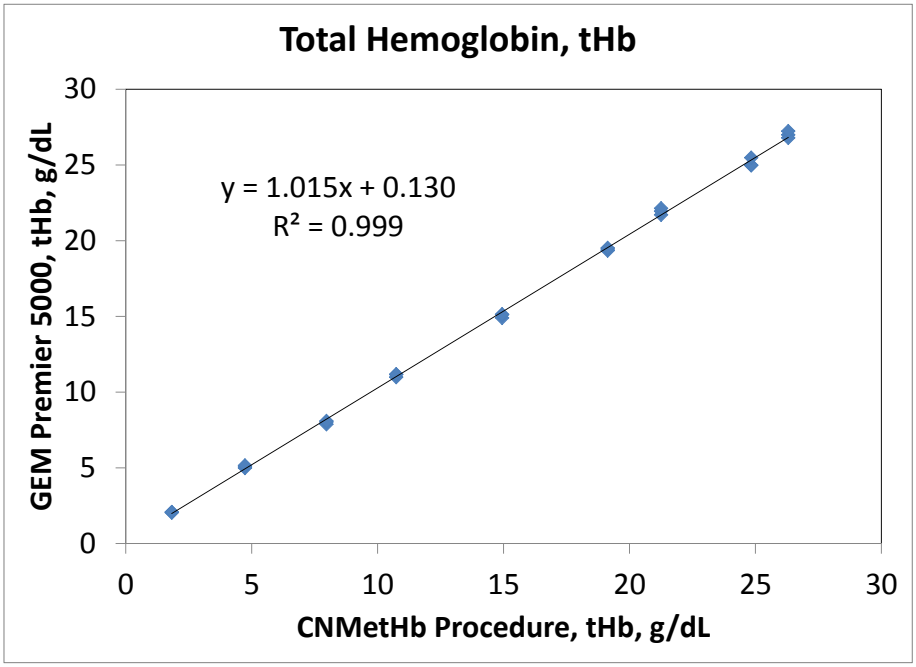
Lactate (mmol/L):



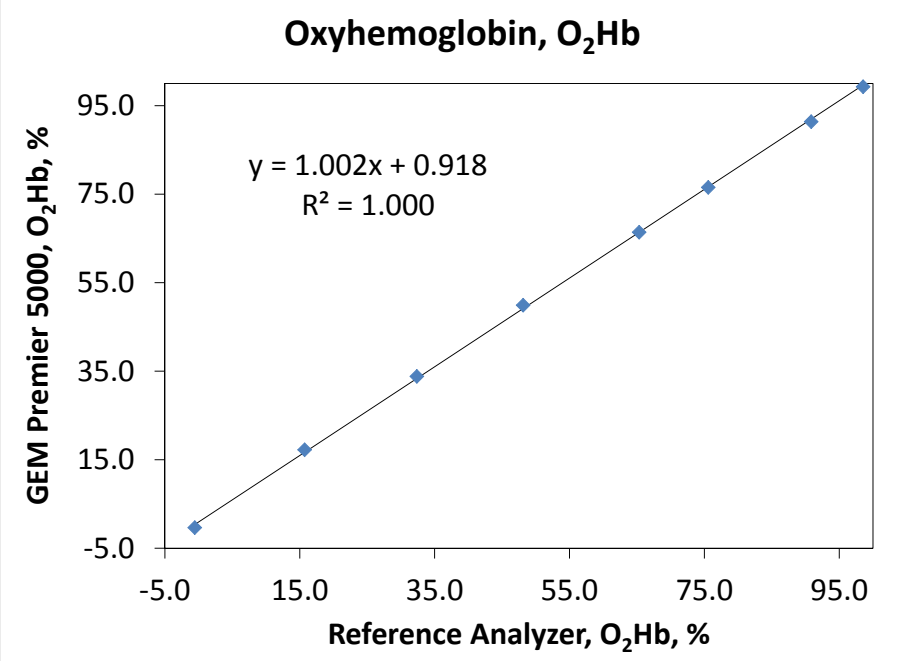
Hct (%):



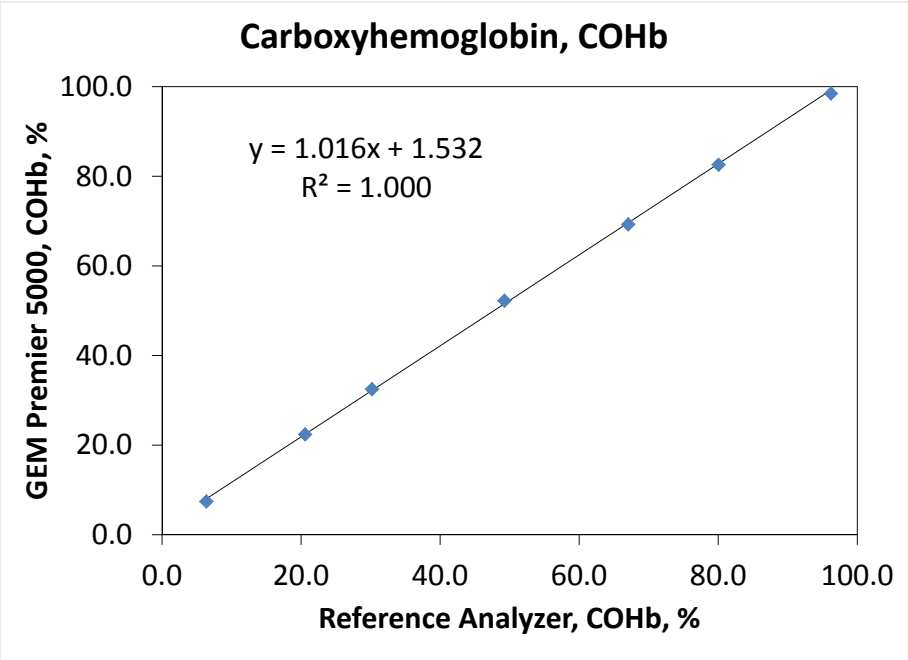
tHb (g/dL):

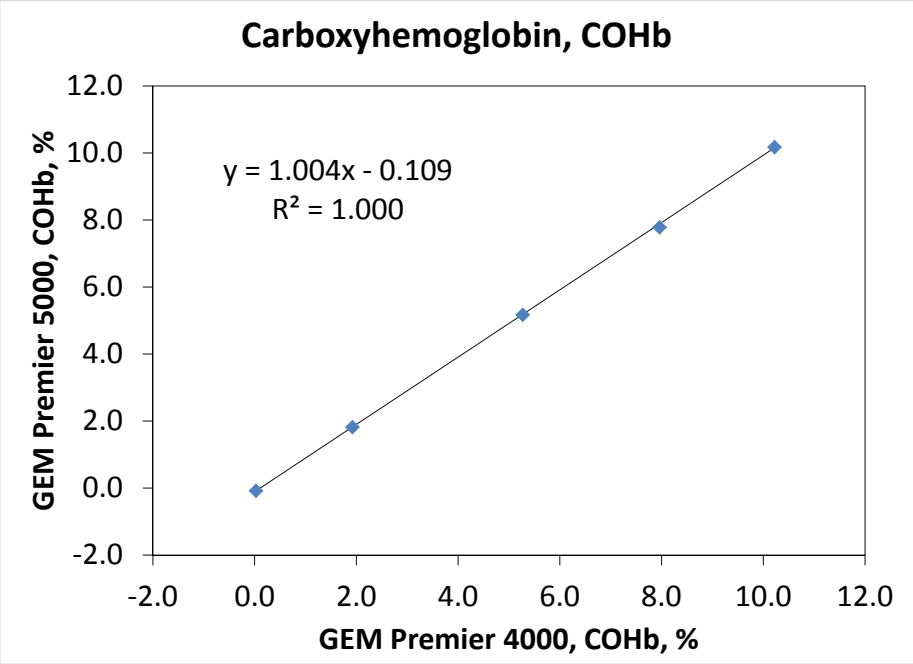

Total Hemoglobin, tHb
y = 1.015x + 0.130
R² = 0.999
GEM Premier 5000, tHb, g/dL
CNMetHb Procedure, tHb, g/dL
0
5
10
15
20
25
30

O_2Hb (%):

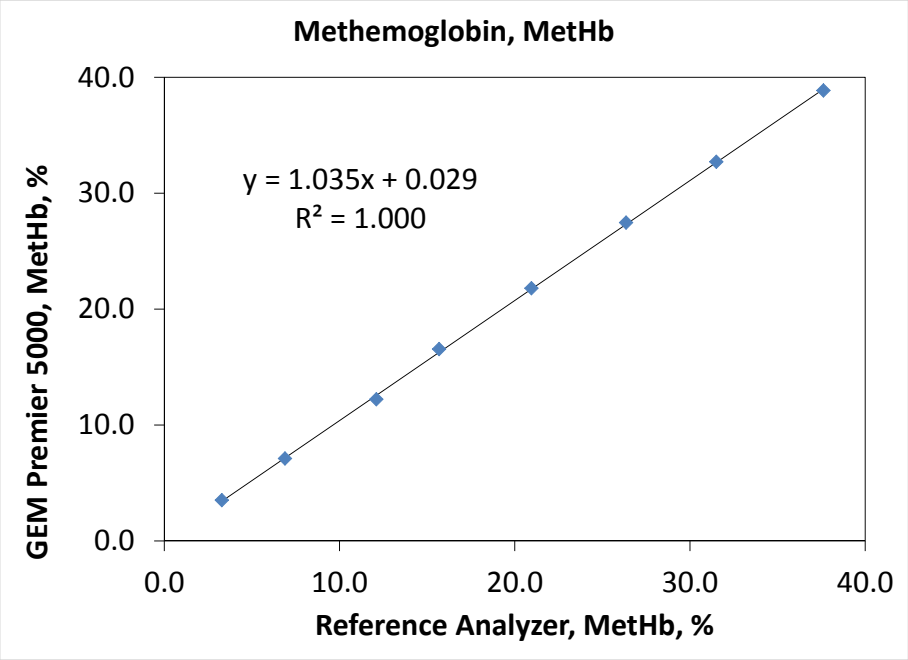

Oxyhemoglobin, O2Hb
y = 1.002x + 0.918
R² = 1.000
GEM Premier 5000, O2Hb, %
Reference Analyzer, O2Hb, %
-5.0
15.0
35.0
55.0
75.0
95.0

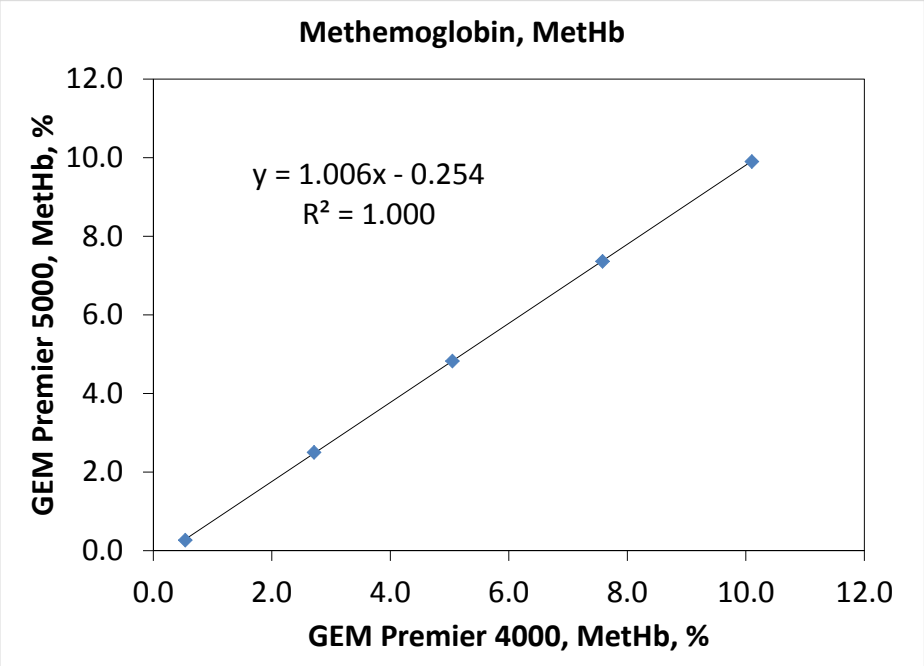
COHb (%):


Carboxyhemoglobin, COHb
y = 1.016x + 1.532
R² = 1.000
GEM Premier 5000, COHb, %
Reference Analyzer, COHb, %
0.0
20.0
40.0
60.0
80.0
100.0

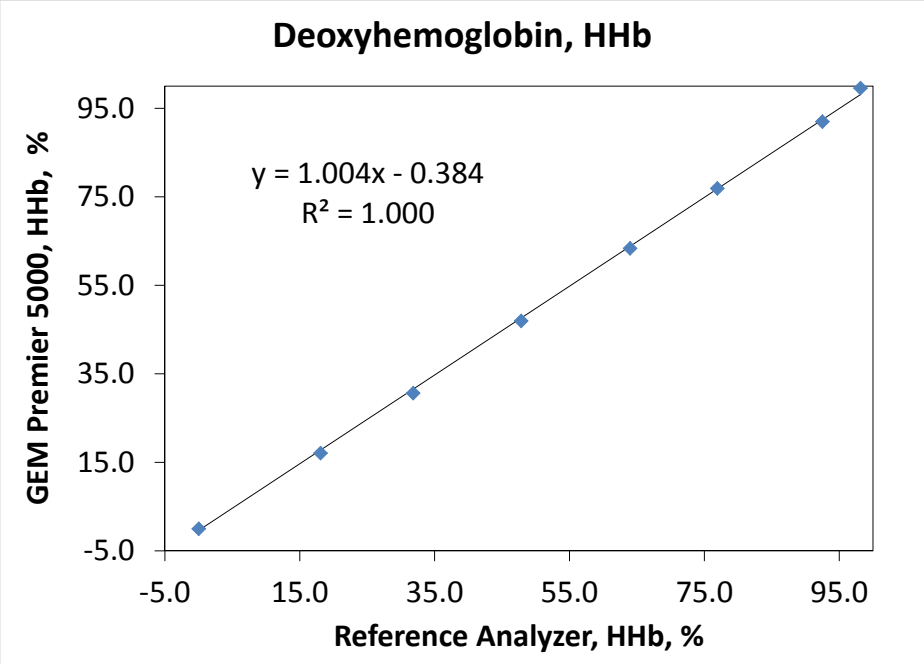

Carboxyhemoglobin, COHb
y = 1.004x - 0.109
R² = 1.000
GEM Premier 5000, COHb, %
GEM Premier 4000, COHb, %
-2.0
0.0
2.0
4.0
6.0
8.0
10.0
12.0

MetHb (%):

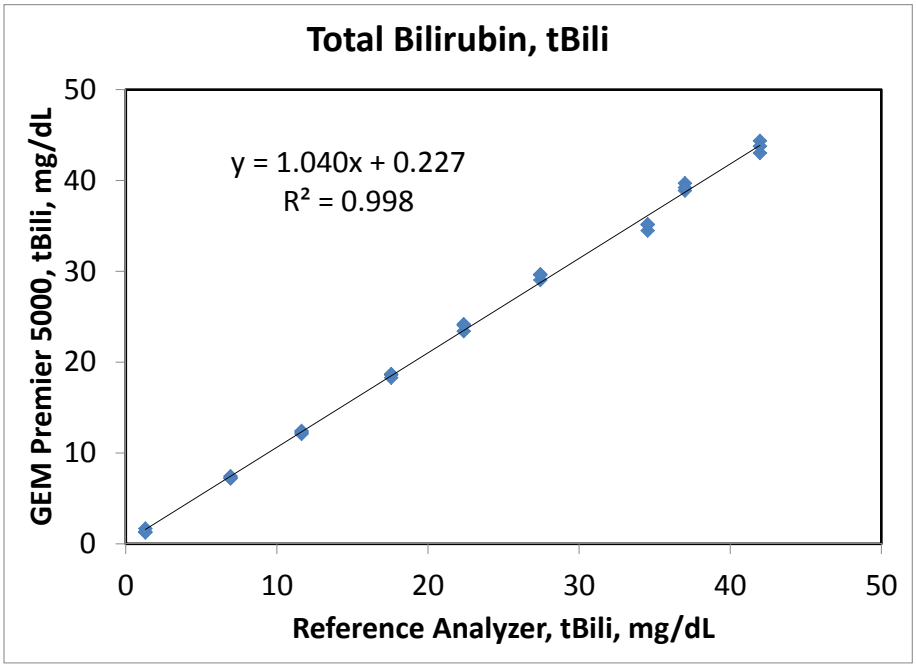

Methemoglobin, MetHb
y = 1.035x + 0.029
R² = 1.000
GEM Premier 5000, MetHb, %
Reference Analyzer, MetHb, %
0.0
10.0
20.0
30.0
40.0


Methemoglobin, MetHb
y = 1.006x - 0.254
R² = 1.000
GEM Premier 5000, MetHb, %
GEM Premier 4000, MetHb, %
0.0
2.0
4.0
6.0
8.0
10.0
12.0

HHb (%):



tBili (mg/dL):



Method Comparison

An in-house whole blood method comparison study was used for bias estimation. Testing was conducted according to EP09-A3, "Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline - Third Edition, 2013." Linear regression factors were generated for each analyte and in different sample modes by comparison GEM Premier 5000 results against its predicate. The bias for each analyte at medical decision levels (MDLs) was then calculated and compared to the specification as shown in the table below. All parameter levels passed specification. GEM Premier 4000 served as predicate for all analytes except pO_2, pCO_2, and tBili. Tonometry was used for pO_2 and pCO_2, and for tBili a commercially available whole blood analyzer was used.

Normal Mode						
Analyte	**N**	**Slope**	**Intercept**	**R^2**	**Medical Decision Level**	**Bias at Medical Decision Level**
pH	373	0.953	0.344	0.993	7.30	0.001
					7.35	-0.001
					7.45	-0.006
pCO_2 (mmHg)	150	1.026	-0.991	0.997	35	-0.1
					50	0.3
					70	1.2%
pO_2 (mmHg)	148	1.027	-1.266	0.999	30	-0.5
					45	0.0
					60	0.4
Na^+ (mmol/L)	373	1.021	-2.577	0.995	115	-0.2
					135	0.2
					150	0.5
K^+ (mmol/L)	373	1.034	-0.066	0.999	3.0	0.04
					5.8	0.13
					7.5	2.5%
Cl^- (mmol/L)	373	1.000	0.500	0.998	90	0.6%
					112	0.4%
Ca^{++} (mmol/L)	373	1.031	-0.033	0.999	0.37	-0.021
					0.82	-0.007
					1.58	1.0%
Hct (%)	376	1.013	-0.651	0.998	21	-0.4
					33	-0.2
					56	0.1
Glucose (mg/dL)	373	0.985	3.746	0.997	45	3.1
					120	1.6%
					180	0.6%
					350	-0.4%

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Normal Mode						
Analyte	**N**	**Slope**	**Intercept**	**R^2**	**Medical Decision Level**	**Bias at Medical Decision Level**
Lactate (mmol/L)	373	1.000	-0.050	0.998	2.0	-0.05
					5.0	-1.0%
tHb (g/dL)	376	1.040	-0.144	0.998	7.0	0.14
					10.5	0.28
					18.0	0.58
O_2Hb (%)	373	0.998	0.700	1.000	90.0	0.54
COHb (%)	374	0.997	-0.349	1.000	3.0	-0.36
					10.0	-0.38
MetHb (%)	270	1.000	0.200	0.998	5.0	0.20
					10.0	0.20
HHb (%)	195	1.000	-0.426	0.999	6.0	-0.43
sO_2 (%)	373	0.995	0.783	0.999	90.0	0.31
tBili (mg/dL)	163	0.977	0.384	0.998	3.0	0.31
					6.0	4.1%
					14.0	0.4%
					20.0	-0.4%

Micro Mode						
Analyte	**N**	**Slope**	**Intercept**	**R^2**	**Medical Decision Level**	**Bias at Medical Decision Level**
pH	387	0.954	0.342	0.989	7.30	0.006
					7.35	0.004
					7.45	0.000
pO_2 (mmHg)	148	1.010	0.994	0.998	30	1.3
					45	1.4
					60	1.6
Na^+ (mmol/L)	388	1.025	-3.724	0.994	115	-0.9
					135	-0.4
					150	0.0
Ca^{++} (mmol/L)	388	1.013	-0.043	0.999	0.37	-0.038
					0.82	-0.033
					1.58	-1.5%
Glucose (mg/dL)	388	0.952	3.831	0.998	45	1.7
					120	-1.6%
					180	-2.7%
					350	-3.7%
Lactate (mmol/L)	387	1.000	-0.050	0.998	2.0	-0.05
					5.0	-1.0%

tBili/CO-Ox Mode						
Analyte	**N**	**Slope**	**Intercept**	**R^2**	**Medical Decision Level**	**Bias at Medical Decision Level**
O_2Hb (%)	385	1.009	0.001	0.999	90.0	0.84
COHb (%)	392	1.000	-0.360	1.000	3.0	-0.36
					10.0	-0.36
MetHb (%)	115	0.973	-0.044	1.000	5.0	-0.18
					10.0	-0.32
HHb (%)	229	1.006	-0.076	0.998	6.0	-0.04
sO_2 (%)	385	1.000	0.132	0.999	90.0	0.16
tBili (mg/dL)	151	0.971	0.404	0.998	3.0	0.32
					6.0	3.8%
					14.0	0.0%
					20.0	-0.9%

Whole Blood Performance at Medical Decision Levels

The data from internal method comparison and precision studies were combined to assess the performance of each sample mode at medical decision levels. Total Error was computed based on the following equation and the results were compared to GEM Premier 5000 Total Error Specifications:

Total Error = Bias + 2 * SD (or %CV)

Note: Previously shown bias and precision data were used in Total Error computations below. The Total Error specification for GEM Premier 5000 is expressed in fixed units or in percentage units depending the analyte concentration levels.

Normal Mode					
Analyte	**Medical Decision Level**	**Absolute Value of Bias at Medical Decision Level**	**2*(SD or CV%)**	**Total error Bias + 2SD (or CV%)**	**Total Error (specification)**
pH	7.30	0.001	0.013	0.014	0.04
	7.35	0.001	0.008	0.009	0.04
	7.45	0.006	0.010	0.016	0.04
pCO_2 (mmHg)	35	0.1	0.9	1.0	5
	50	0.3	1.2	1.5	5
	70	1.2%	3.0%	4.2%	8%
pO_2 (mmHg)	30	0.5	0.7	1.2	9
	45	0.0	1.4	1.4	9
	60	0.4	1.4	1.8	9

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Normal Mode					
Analyte	**Medical Decision Level**	**Absolute Value of Bias at Medical Decision Level**	**2*(SD or CV%)**	**Total error Bias + 2SD (or CV%)**	**Total Error (specification)**
Na^+ (mmol/L)	115	0.2	0.8	1.0	5
	135	0.2	0.7	0.9	4
	150	0.5	1.1	1.6	4
K^+ (mmol/L)	3.0	0.04	0.10	0.14	0.5
	5.8	0.13	0.10	0.23	0.5
	7.5	2.5%	3.7%	6.2%	7%
Cl^- (mmol/L)	90	0.6%	0.8%	1.4%	5%
	112	0.4%	1.2%	1.6%	5%
Ca^{++} (mmol/L)	0.37	0.021	0.012	0.033	0.10
	0.82	0.007	0.010	0.017	0.10
	1.58	1.0%	2.6%	3.6%	10%
Hct (%)	21	0.4	0.7	1.1	4
	33	0.2	0.7	0.9	4
	56	0.1	1.2	1.3	4
Glucose (mg/dL)	45	3.1	1.7	4.8	6
	120	1.6%	2.9%	4.5%	10%
	180	0.6%	3.5%	4.1%	10%
	350	0.4%	3.6%	4.0%	10%
Lactate (mmol/L)	2.0	0.05	0.12	0.017	0.4
	5.0	1.0%	3.5%	4.5%	15%
tHb (g/dL)	7.0	0.14	0.08	0.22	0.7
	10.5	0.28	0.08	0.36	0.7
	18.0	0.58	0.12	0.70	1.0
O_2Hb (%)	90.0	0.54	0.42	0.96	3.0
COHb (%)	3.0	0.36	0.28	0.64	2.0
	10.0	0.38	0.34	0.72	2.0
MetHb (%)	5.0	0.20	0.34	0.54	2.0
	10.0	0.20	0.38	0.58	2.0
HHb (%)	6.0	0.43	0.46	0.89	3.0
sO_2 (%)	90.0	0.31	0.48	0.79	3.0
tBili (mg/dL)	3.0	0.31	0.24	0.55	0.8
	6.0	4.1%	3.7%	7.8%	20%
	14.0	0.4%	1.8%	2.2%	20%
	20.0	0.4%	1.7%	2.1%	20%

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Micro Mode					
Analyte	**Medical Decision Level**	**Absolute Value of Bias at Medical Decision Level**	**2*(SD or CV%)**	**Total error Bias + 2SD (or CV%)**	**Total Error (specification)**
pH	7.30	0.006	0.008	0.014	0.04
	7.35	0.004	0.008	0.012	0.04
	7.40	0.000	0.011	0.011	0.04
pO_2 (mmHg)	30	1.3	1.9	3.2	9
	45	1.4	1.4	2.8	9
	60	1.6	1.4	3.0	9
Na^+ (mmol/L)	115	0.9	0.6	1.5	5
	130	0.4	0.6	1.0	4
	150	0.0	0.9	0.9	4
Ca^{++} (mmol/L)	0.37	0.038	0.008	0.046	0.10
	0.82	0.033	0.008	0.041	0.10
	1.58	1.5%	2.0%	3.5%	10%
Glucose (mg/dL)	45	1.7	1.6	3.3	6
	120	1.6%	4.3%	5.9%	10%
	180	2.7%	3.3%	6.0%	10%
	350	3.7%	3.3%	7.0%	10%
Lactate (mmol/L)	2.0	0.05	0.10	0.15	0.4
	5.0	1.0%	5.7%	6.7%	15%

tBili/CO-Ox Mode					
Analyte	**Medical Decision Level**	**Absolute Value of Bias at Medical Decision Level**	**2*(SD or CV%)**	**Total error Bias + 2SD (or CV%)**	**Total Error (specification)**
O_2Hb (%)	90.0	0.84	0.44	1.28	3.0
COHb (%)	3.0	0.36	0.36	0.72	2.0
	10.0	0.36	0.40	0.76	2.0
MetHb (%)	5.0	0.18	0.32	0.50	2.0
	10.0	0.32	0.42	0.74	2.0
HHb (%)	6.0	0.04	0.52	0.56	3.0
sO_2 (%)	90.0	0.16	0.52	0.68	3.0
tBili (mg/dL)	3.0	0.32	0.20	0.52	0.8
	6.0	3.8%	4.0%	7.8%	20%
	14.0	0.0%	2.0%	2.0%	20%
	20.0	0.9%	1.7%	2.6%	20%

Method Comparison - Clinical Site Evaluations

In accordance with EP09-A3, a method comparison study was conducted on the GEM Premier 5000 in the following settings using whole blood patient samples from the intended use population:

- Point-of-Care for all analytes ***except tBili***: Sites included four (4) point-of-care settings with different intended users, covering the reportable ranges and intended sample devices and sample types.
- Point-of-Care for tBili: Total Bilirubin was tested on neonate samples at three (3) external point-of care settings with different intended users, using adult samples and spiked samples to cover the measurable range.

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In each setting, the performance of the GEM Premier 5000 was compared to the GEM Premier 4000, **except** for tBili testing, which used the commercially available chemistry analyzer in use at each facility.

The regression results are presented in the following tables by sample mode. The subsequent graphs show the POC results in Normal (Syringe) Mode pooled across all sites. Normal (Syringe) Mode results for tBili are shown in two graphs, pooling sites where the same reference analyzer was used. The whole blood correlation data indicate that GEM Premier 5000 is statistically similar in performance to its predicate analyzer.

Pooled Point-of-Care - Normal Mode (Syringe)					
Analyte	**N**	**Slope**	**Intercept**	**r**	**Sample Range**
pH	479	0.941	0.427	0.991	7.01 to 7.92
pCO_2 (mmHg)	492	0.955	3.545	0.991	11 to 117
pO_2 (mmHg)	506	0.992	5.093	0.996	6 to 685
Na^+ (mmol/L)	486	0.991	1.184	0.991	103 to 180
K^+ (mmol/L)	491	1.000	0.100	0.998	1.0 to 15.7
Cl^- (mmol/L)	485	1.000	1.000	0.990	40 to 157
Ca^{++} (mmol/L)	491	1.010	0.008	0.998	0.14 to 4.21
Glucose (mg/dL)	489	0.973	3.622	0.998	12 to 619
Lactate (mmol/L)	488	1.000	0.000	0.996	0.5 to 15
Hct (%)	490	1.003	-0.016	0.997	15 to 70
tHb (g/dL)	496	1.021	-0.055	0.998	3.1 to 22.8
O_2Hb (%)	496	1.003	0.337	0.999	12.2 to 99.0
COHb (%)	485	1.000	-0.198	0.998	0.3 to 73.8
MetHb (%)	297	1.000	-0.100	0.997	0.7 to 29.9
HHb (%)	258	1.007	-0.303	0.999	1.0 to 98.7
sO_2 (%)	494	0.998	0.355	0.999	12.3 to 100.0
tBili (mg/dL) vs Reference Analyzer #1	53	1.062	0.630	0.996	3.1 to 39.7
tBili (mg/dL) vs Reference Analyzer #2	76	1.076	-0.099	0.996	2.0 to 39.7

Pooled Point-of-Care - Micro Mode					
Analyte	**N**	**Slope**	**Intercept**	**r**	**Sample Range**
pH	291	0.921	0.578	0.995	7.06 to 7.89
pO_2 (mmHg)	316	1.017	3.500	0.997	26 to 686
Na^+ (mmol/L)	298	0.998	-0.121	0.994	103 to 180
Ca^{++} (mmol/L)	300	1.000	-0.020	0.999	0.13 to 4.22
Glucose (mg/dL)	293	0.957	4.348	0.997	15 to 433
Lactate (mmol/L)	297	1.000	0.000	0.998	0.6 to 16.6

Pooled Point-of-Care - tBili/CO-Ox Mode					
Analyte	**N**	**Slope**	**Intercept**	**r**	**Sample Range**
O_2Hb (%)	300	1.007	-0.224	0.999	10.5 to 98.9
COHb (%)	295	0.998	-0.174	0.999	0.4 to 74.3
MetHb (%)	156	1.000	0.000	0.997	0.7 to 30.0
HHb (%)	197	1.011	-0.171	1.000	1.0 to 98.8
sO_2 (%)	298	1.005	-0.342	0.999	10.6 to 100.0
tBili (mg/dL) vs Reference Analyzer #1	53	1.068	0.404	0.996	2.0 to 39.7
tBili (mg/dL) vs Reference Analyzer #2	77	1.076	-0.163	0.995	2.0 to 39.2

Pooled Point-of-Care - Normal Mode (Capillary)					
Analyte	**N**	**Slope**	**Intercept**	**r**	**Sample Range**
pH	287	0.924	0.558	0.994	7.01 to 7.89
pO_2 (mmHg)	321	1.000	5.000	0.997	6 to 676
Na^+ (mmol/L)	300	0.998	0.113	0.992	103 to 180
Ca^{++} (mmol/L)	304	1.000	0.010	0.999	0.14 to 4.25
Glucose (mg/dL)	296	0.976	3.923	0.998	12 to 637
Lactate (mmol/L)	298	1.000	0.000	0.997	0.6 to 16.4
O_2Hb (%)	300	0.996	1.057	0.999	13.7 to 98.6
COHb (%)	294	0.995	-0.153	0.999	0.4 to 73.7
MetHb (%)	180	1.000	0.000	0.997	0.7 to 29.7
HHb (%)	195	1.006	-0.671	0.999	1.0 to 98.5
sO_2 (%)	298	0.992	1.133	0.999	13.9 to 100.0
tBili (mg/dL) vs Reference Analyzer #1	58	1.051	0.533	0.996	3.9 to 39.9
tBili (mg/dL) vs Reference Analyzer #2	77	1.072	-0.255	0.996	2.1 to 39.4

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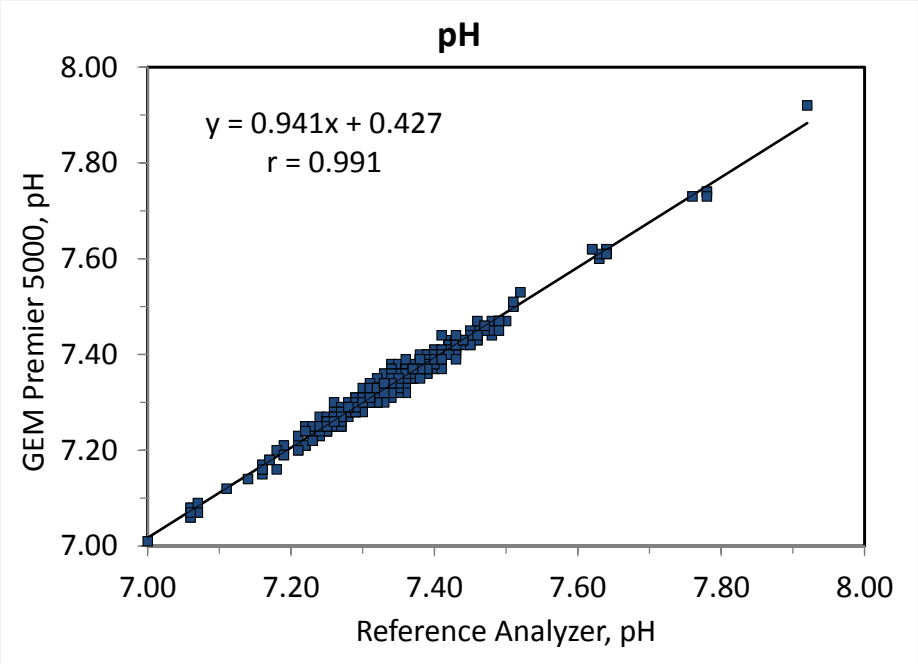
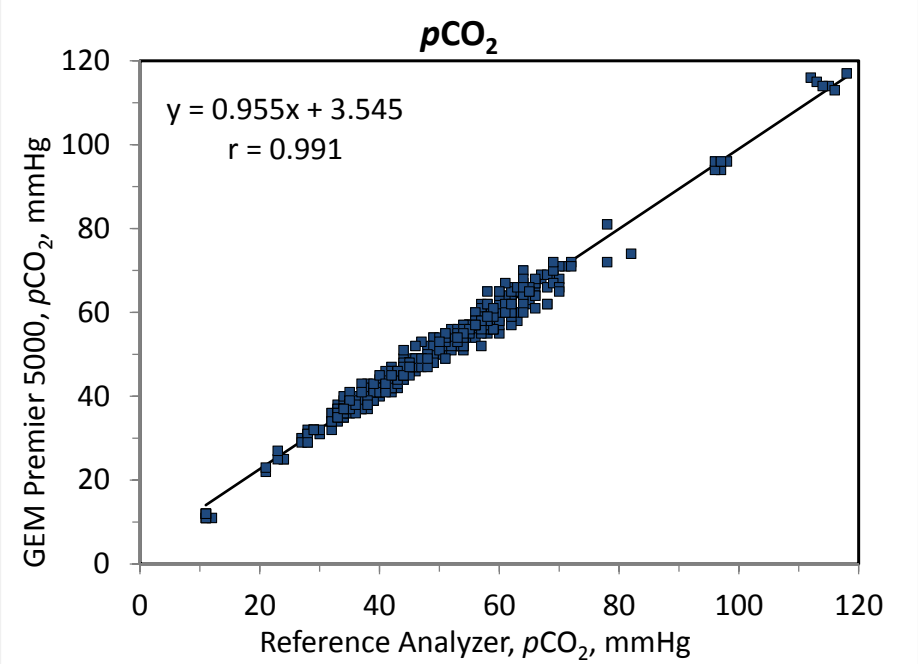
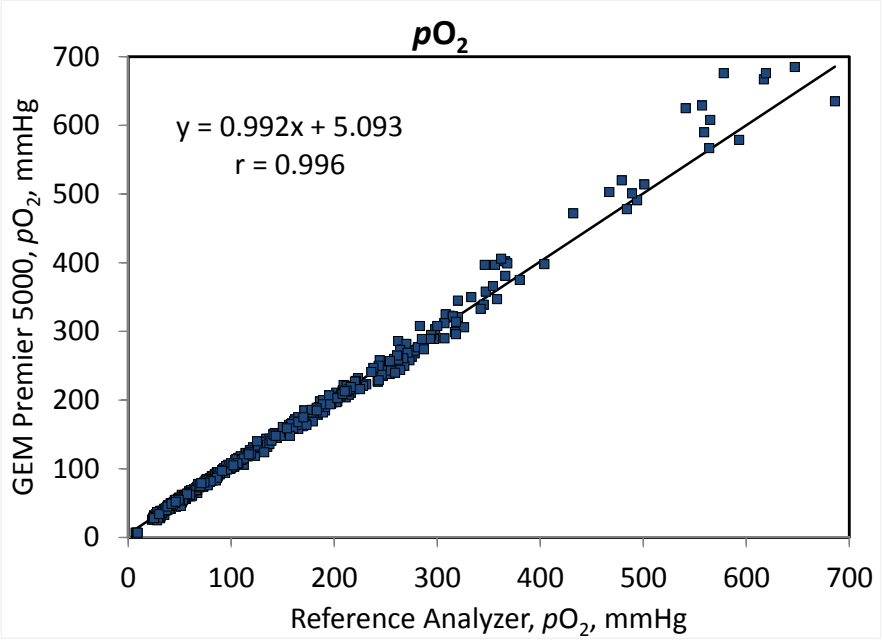
pH (pH Units):



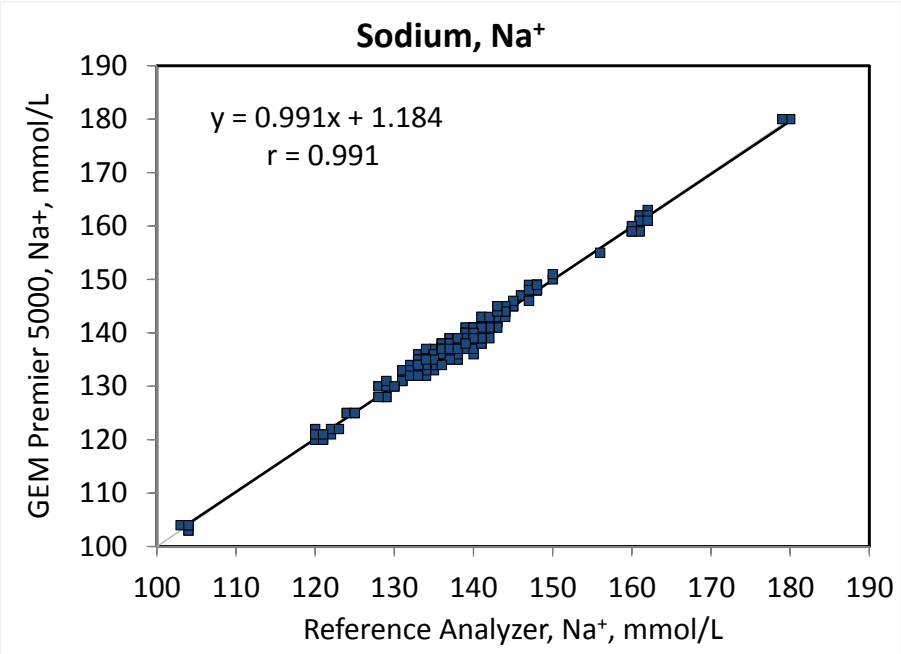
pCO_2 (mmHg):



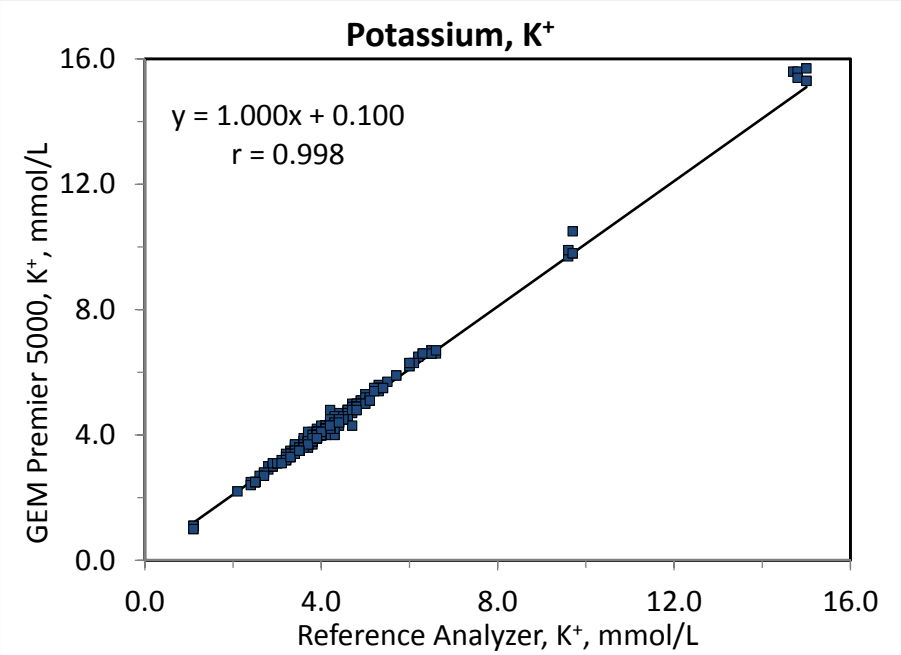
pO_2 (mmHg):



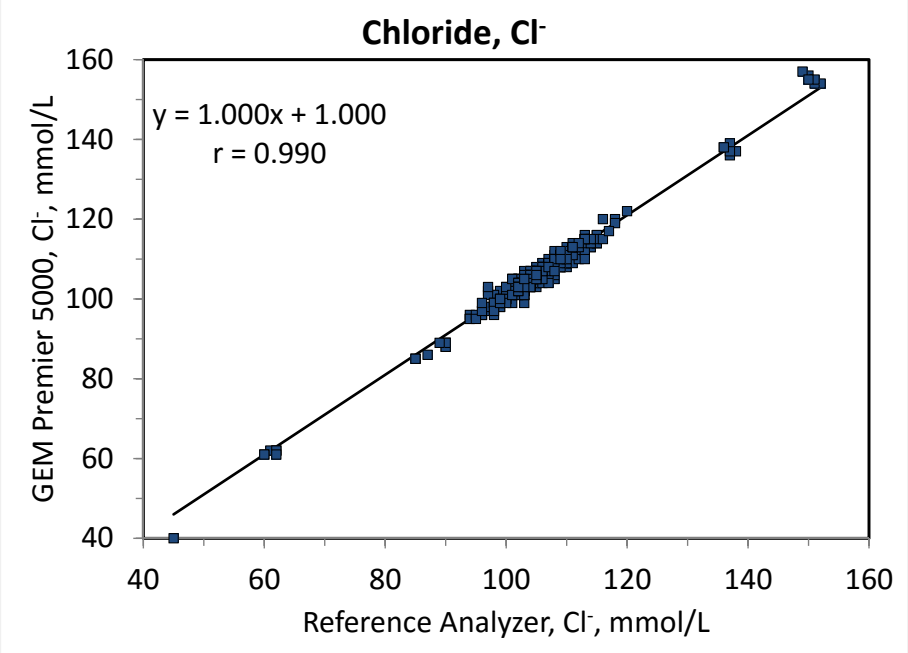
Na^+ (mmol/L):



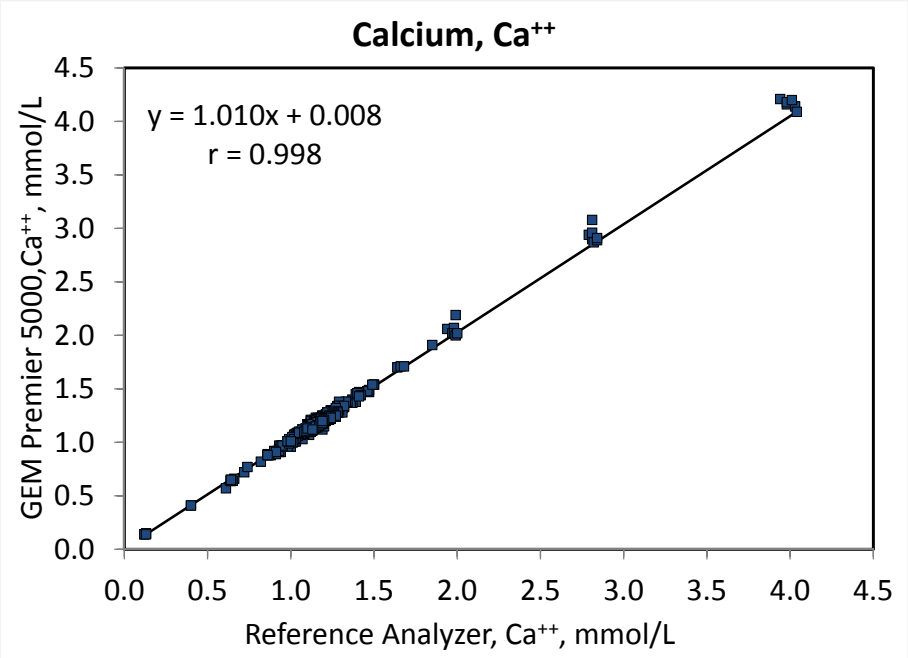
K^+ (mmol/L):



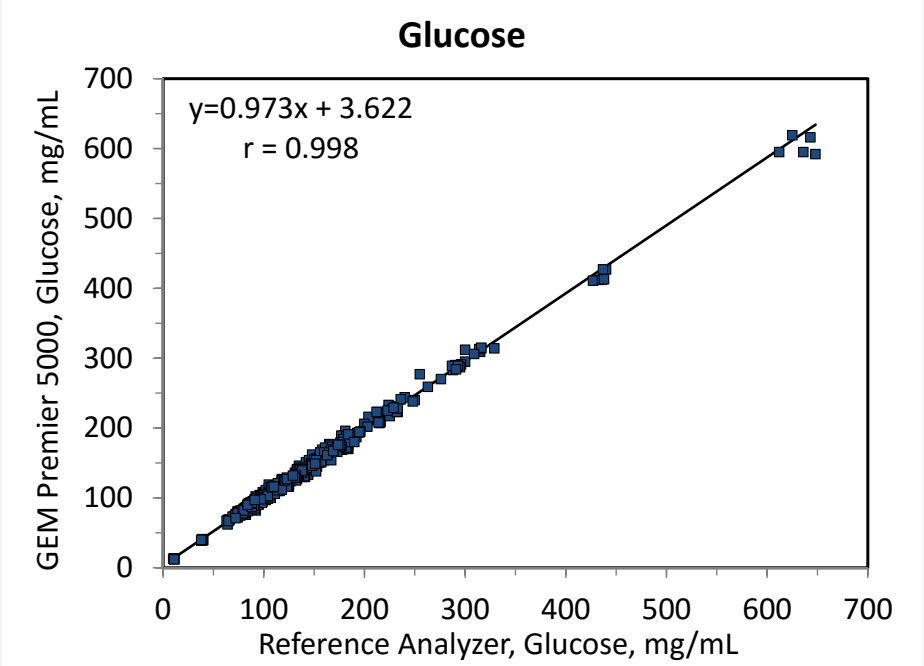
Cl^- (mmol/L):



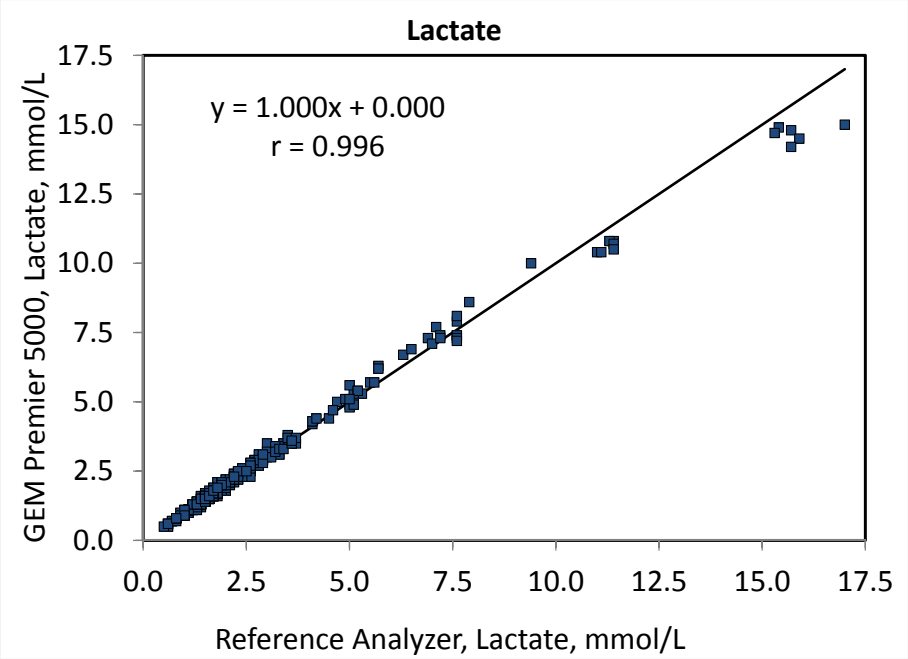
Ca^{++} (mmol/L):



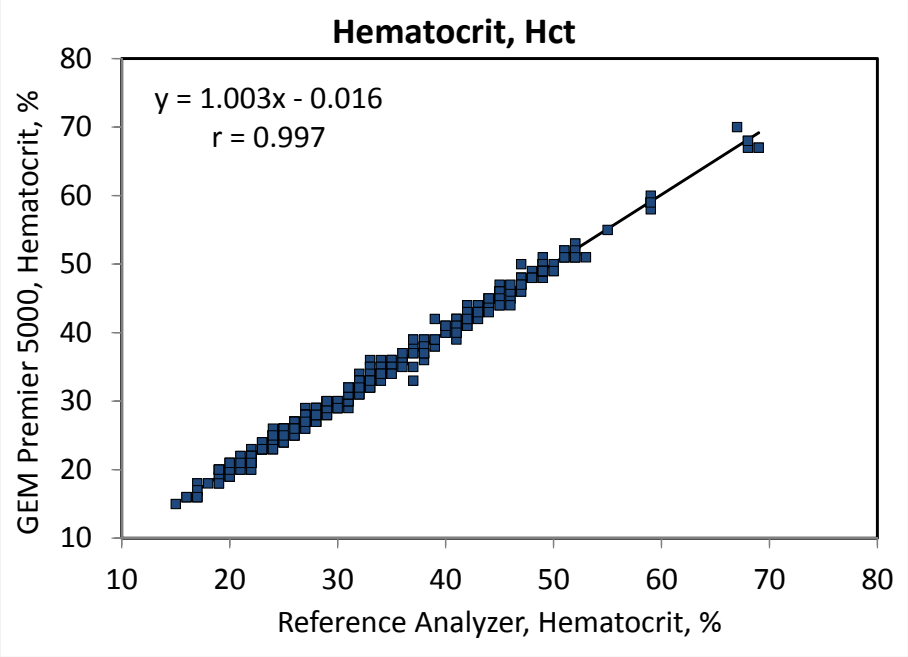
Glucose (mg/dL):



Lactate (mmol/L):



Hct (%):



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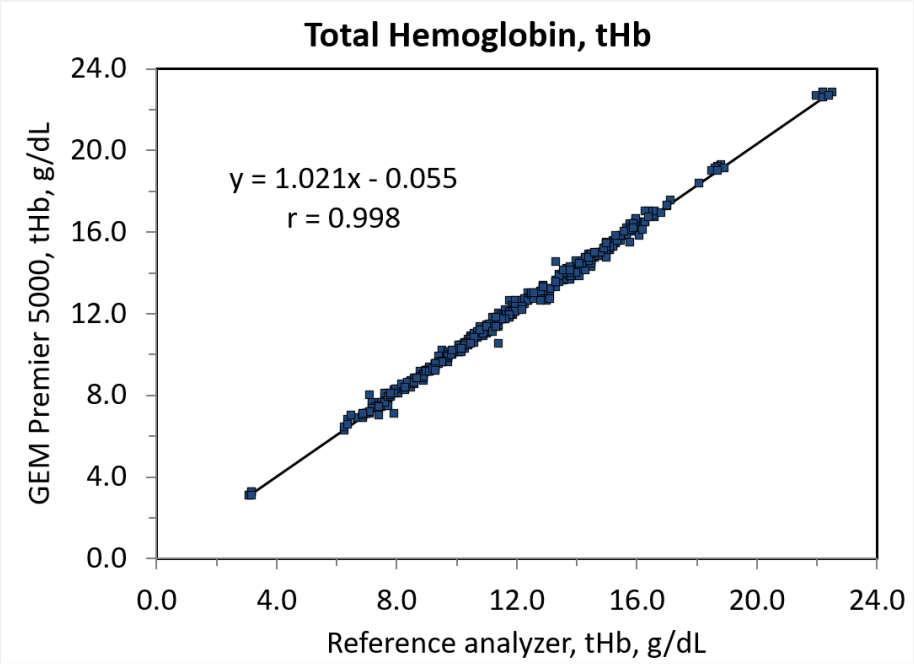
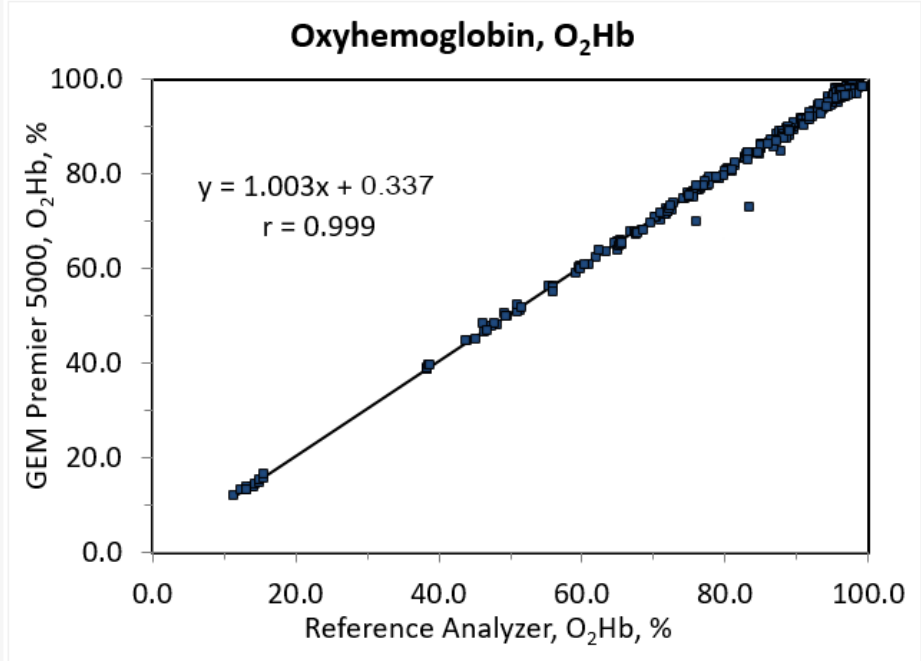
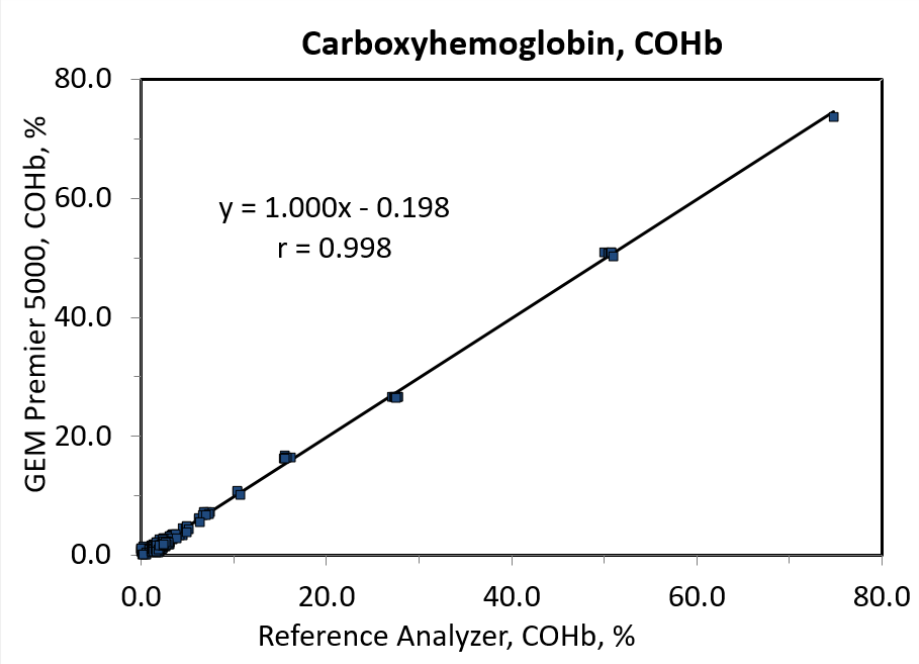
tHb (g/dL):



O_2Hb (%):



COHb (%):


Carboxyhemoglobin, COHb
y = 1.000x - 0.198
r = 0.998
GEM Premier 5000, COHb, %
Reference Analyzer, COHb, %
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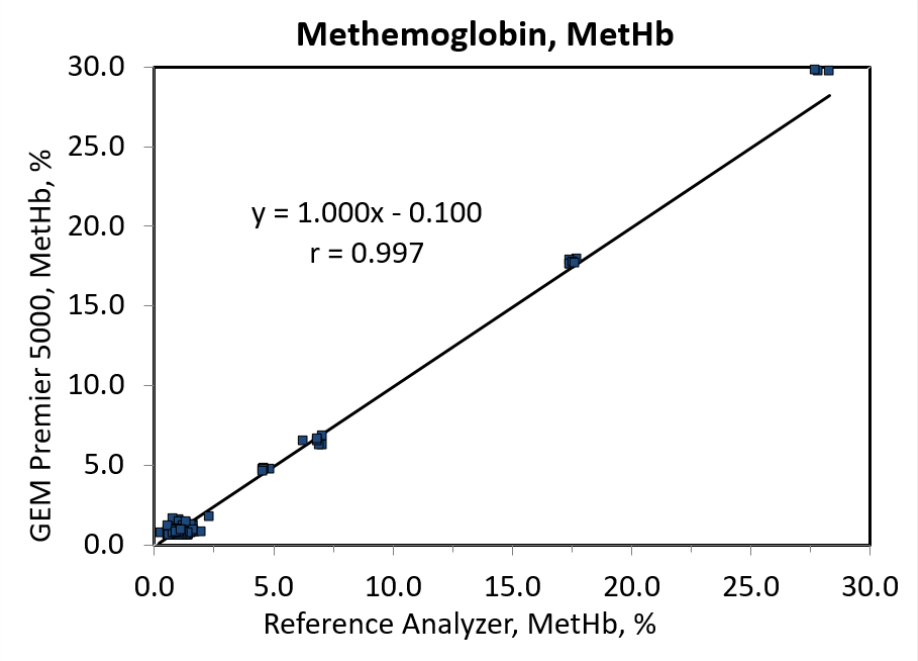
20.0
40.0
60.0
80.0

MetHb (%):


Methemoglobin, MetHb
y = 1.000x - 0.100
r = 0.997
GEM Premier 5000, MetHb, %
Reference Analyzer, MetHb, %
0.0
5.0
10.0
15.0
20.0
25.0
30.0

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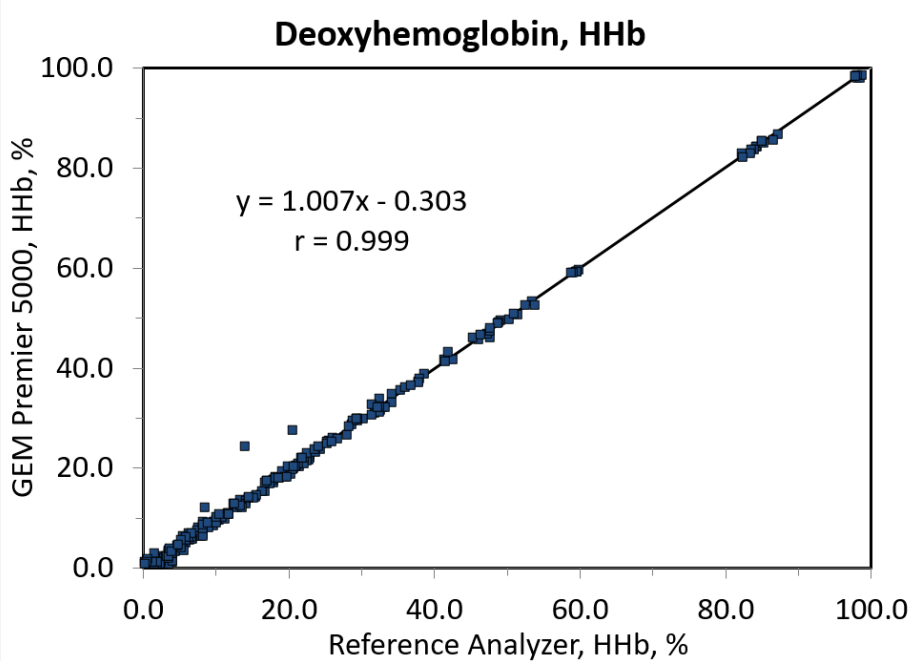
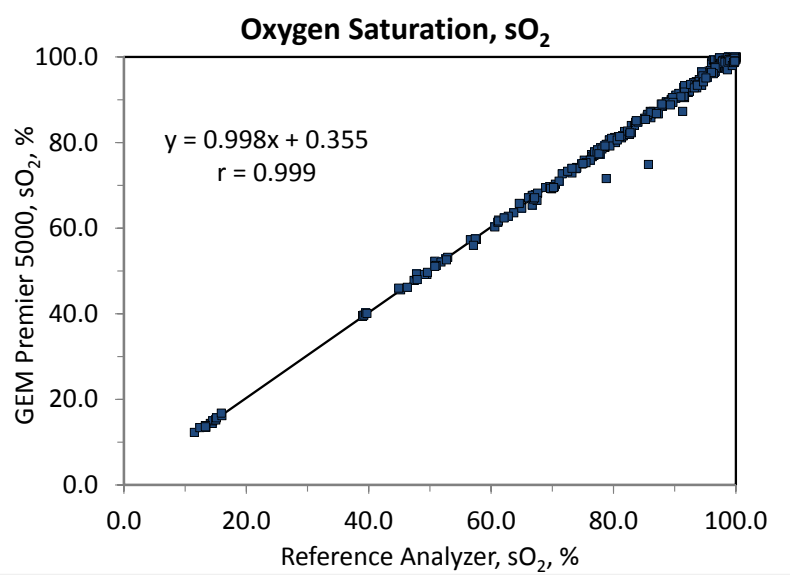
HHb (%):



sO_2 (%):



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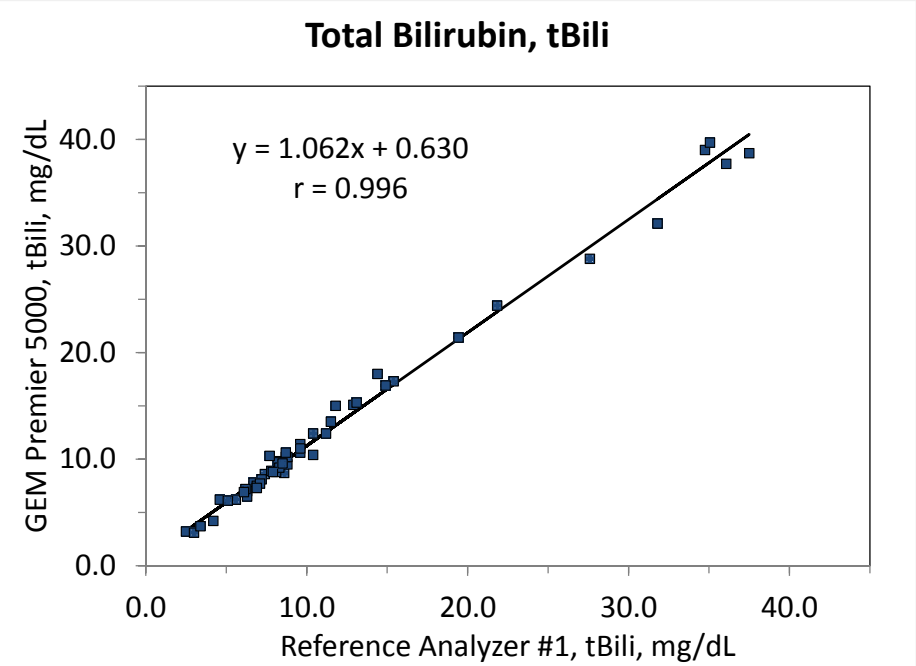
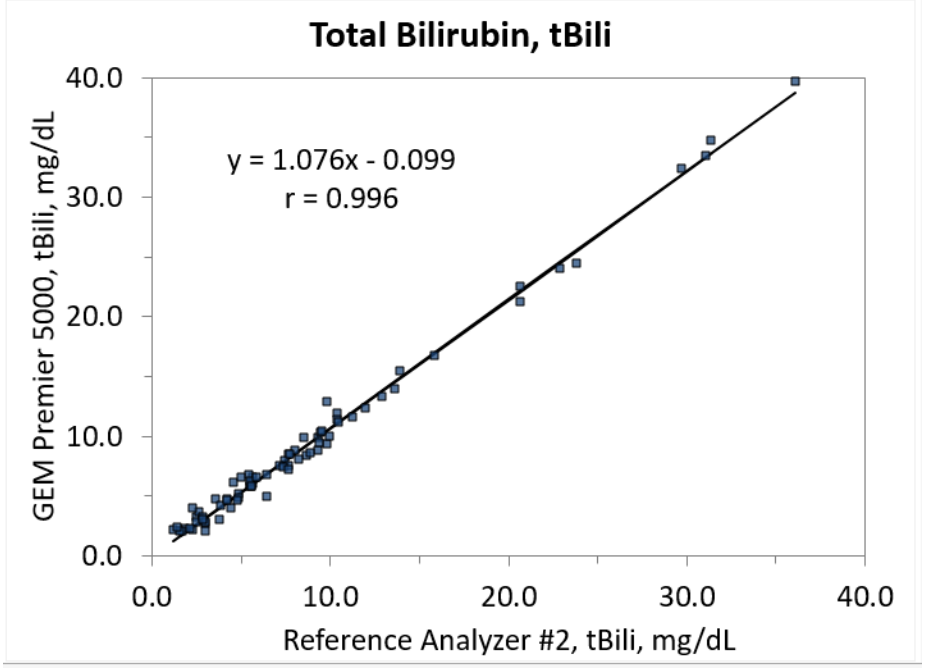
tBili (mg/dL) Reference Analyzer #1:



tBili (mg/dL) Reference Analyzer #2:



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Method Comparison - Contrived and Native Capillary Sample Results

Native capillary samples (finger-stick samples) and the contrived transfer capillary samples results were combined and and analyzed.

Pooled Point-of-Care Site and CSL Data with Additional Contrived Capillary Results					
Analyte	**N**	**Slope**	**Intercept**	**r**	**Sample Range**
pH	189	0.935	0.494	0.975	7.07 to 7.89
pCO_2 (mmHg)	139	1.000	1.000	0.980	11 to 87
pO_2 (mmHg)	218	1.008	2.545	0.996	6 to 676
Na^+ (mmol/L)	201	1.015	-1.750	0.981	103 to 180
K^+ (mmol/L)	140	1.000	0.100	0.995	1.5 to 17.6
Cl^- (mmol/L)	141	1.000	-1.000	0.995	45 to 149
Ca^{++} (mmol/L)	205	1.050	-0.016	0.998	0.14 to 4.25
Glucose (mg/dL)	197	0.966	4.775	0.997	12 to 637
Lactate (mmol/L)	201	1.000	0.000	0.995	0.4 to 16.4
Hct (%)	136	1.003	-0.407	0.987	15 to 64
tHb (g/dL)	137	1.028	-0.470	0.994	4.5 to 20.5
O_2Hb (%)	182	1.000	0.802	0.997	13.7 to 98.6
COHb (%)	180	0.988	-0.269	0.999	0.3 to 73.8
MetHb (%)	98	1.000	-0.100	0.998	0.7 to 29.7
HHb (%)	181	1.001	-0.279	0.998	1.3 to 98.5
sO_2 (%)	180	0.994	0.930	0.997	13.9 to 100.0

Limitations and Interference Testing

Limitations

Condition	Result
Room Air Contamination	Samples having a very low or high pO_2 content or high HHb levels are especially sensitive to room air contamination. Similarly, pCO_2 may be affected and subsequently pH and Ca^{++} results as well.
Metabolic Changes Due to a Delay in Sampling	Errors can occur due to metabolic changes if there is a delay in the measurement of the samples.
Elevated White Blood Cells or Reticulocyte Counts	Samples will deteriorate more rapidly, even when kept in ice water.
Improper Mixing	Errors will be introduced for measurement of hematocrit, total bilirubin and CO-Ox parameters if the sample is not properly mixed prior to measurement.
Not following Manufacturer's Instructions or Method Verification Protocols	Results obtained may be compromised.
Improper Installation	The instrument must be installed per the manufacturer's instructions. Failure to do so invalidates any warranty, explicit or implied.
Under-Heparinized Sample Due to Using Non-Heparinized Sampling Devices or Inadequate Mixing with Heparinized Devices.	Blood clot can form in the sensor chamber causing various sensor failures if sample is not properly heparinized.
Hemolysis	Hemolyzed samples may result in falsely elevated potassium levels.
Over-Heparinized Sample Due to under filling Heparinized Sampling Device or Transferring Heparinized Sample to a Second Heparinized Sampling Device	Over Heparinization can cause bias in Na^+, iCa and Hct results.
Drug/Chemicals	Drugs/Chemicals may change analyte concentration, e.g. Citrate.
Vacutainer tubes with Gel separator	Gel separator can significantly elevate COHb levels.
Using capillary samples collected in RAM Scientific Capillary Tubes (p/n 06 0186) and Fleas (p/n 07 9503)	A bias on certain analytes with capillary samples was observed with RAM Scientific Capillary Tubes (p/n 06 0186) and Fleas (p/n 07 9503). Therefore, do not use RAM Scientific Capillary Tubes (p/n 06 0186) and Fleas (p/n 07 9503) with the GEM Premier 5000. Facilities should evaluate their collection devices prior to clinical use.

Interference Testing Results

All Interference testing followed CLSI EP-7A2, “Interference Testing in Clinical Chemistry, Approved Guideline”.

Table 1, Substances for which no interference was observed on EC or CO-Oximetry analytes

The substances listed in the Table 1 did not show noticeable interference with gases, electrolytes and metabolites measured using electrochemical methods or total hemoglobin, hemoglobin derivatives or tBili measured using CO-Oximetry on the GEM Premier 5000 system when tested at the concentrations listed as per CLSI. Interference was tested on three different lots of GEM Premier 5000 GEM PAKs on 3 GEM Premier 5000 instruments.

Substance	Concentration	Tested analytes where interference was not observed
Acetaminophen	1324 µmol/L	Glucose, Lactate, pH, pCO_2, pO_2, tBili
Acetoacetate	2 mmol/L	Glucose, Lactate
N-acetylcysteine	10.2 mmol/L	Glucose, Lactate
Albumin (Human)	60 g/L	pH, pCO_2, pO_2
Ammonium (Chloride)	107 µmol/L	Sodium, Potassium, Calcium
Amoxicillin	206 µmol/L	pH, pCO_2, pO_2, tBili
Aprotinin	50 mg/L	pH, pCO_2, pO_2
Ascorbic acid	342 µmol/L	Glucose, Lactate, tBili
Atracurium	50 mg/L	pH, pCO_2, pO_2
Benzalkonium (Chloride)	5 mg/L	Sodium, Potassium, Calcium, pH, pCO_2, pO_2, tBili
Bilirubin	20 mg/dL	tHb/Hb fractions/sO_2, pH, pCO_2, pO_2, tBili
Biliverdin	4 mg/dL	tHb/Hb fractions/sO_2, tBili
(Sodium) Bromide	37.5 mmol/L	Potassium, Calcium
Calcium (Chloride)	2.5 mmol/L	Sodium, Potassium
Ceftriaxone	1460 µmol/L	pH, pCO_2, pO_2, tBili
Chlorpromazine	6.3 µmol/L	Glucose, Lactate
Ciprofloxin	30.2 µmol/L	pH, pCO_2, pO_2, tBili
(Sodium) Citrate	12 mmol/L	Potassium, Calcium, Glucose, Lactate
Creatinine	5 mg/dL	Glucose, Lactate
Diazepam	18 µmol/L	pH, pCO_2, pO_2, tBili
Dobutamine	2 mg/dL	Glucose, Lactate
Dopamine	5.87 µmol/L	Glucose, Lactate
Epinephrine	0.5 µmol/L	pH, pCO_2, pO_2, tBili
Ethanol	86.8 mmol/L	Sodium, Potassium, Calcium, Chloride, pH, pCO_2, pO_2, Glucose, Lactate
Etomidate	50 mg/L	pH, pCO_2, pO_2
Evans Blue	10 mg/L	tHb/Hb fractions/sO_2, tBili
Fetal Hemoglobin	78%	tHb/Hb fractions/sO_2
	75%	tBili
Fentanyl	0.02 µg/ml	pH, pCO_2, pO_2

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Substance	Concentration	Tested analytes where interference was not observed
Flaxedil (Gallamine triethiodide)	5 mg/dL	Glucose, Lactate
(Sodium) Fluoride	105 µmol/L	Potassium, Calcium, Chloride, Glucose, Lactate
Fructose	1 mmol/L	Glucose, Lactate
Galactose	0.84 mmol/L	Glucose, Lactate
Gentamycin	21 µmol/L	pH, pCO_2, pO_2, tBili
Glucose	1000 mg/dL	Lactate
Glycolic acid	1 mmol/L	Glucose
Halothane	759 µmol/L	pH, pCO_2, pO_2
Hematocrit	25%	Glucose, pH, pCO_2, pO_2
	75%	Glucose, pH, pCO_2, pO_2
Hemogobin (Hemolysis)	2 g/dL (20%)	pH, pCO_2, pO_2
Hemoglobin	20 g/dL	tBili
Heparin	100,000 U/L	Sodium, Potassium, Calcium, Chloride, Glucose, Lactate
ß-hydroxybutyrate	2 mmol/L	Glucose, Lactate
Ibuprofen	2425 µmol/L	Sodium, Potassium, Calcium, Chloride, Glucose, Lactate
Icodextrin	20 mg/dL	Glucose, Lactate
Indocyanine Green	10 mg/L	tHb/Hb fractions/sO_2, tBili
(Sodium) Iodide	3 mmol/L	Potassium, Calcium
Ipratropium bromide	0.08 mg/L	Sodium, Potassium, Calcium, Chloride
Isoniazide	292 µmol/L	Glucose, Lactate
Lactate	6.6 mmol/L	Glucose
Leflunomide	100 µg/mL	Sodium, Potassium, Chloride, Calcium
Leukocytes	44.43 x 10^3/µl	Hematocrit
Lithium (Chloride)	3.2 mmol/L	Sodium, Potassium, Calcium, pH, pCO_2, pO_2, tBili
Magnesium (Chloride)	15 mmol/L	Sodium, Potassium
Maltose	200 mg/dL	Glucose, Lactate
Mannose	20 mg/dL	Glucose, Lactate
Methadone	6.46 µmol/L	pH, pCO_2, pO_2, tBili
Methylene Blue	20 mg/L	tHb/Hb fractions/sO_2
Midazolam	0.5 µg/mL	pH, pCO_2, pO_2
Morphine	1.75 µmol/L	pH, pCO_2, pO_2, tBili
Omeprazole	17.4 µmol/L	pH, pCO_2, pO_2, tBili
(Sodium) Oxalate	500 mg/dL	Potassium, Calcium, Chloride, Glucose, Lactate
(Sodium) Perchlorate	20 mg/dL	Potassium, Chloride, Calcium
pH (with HCl)	6.8	Sodium, Potassium, Calcium
Phenobarbital	431 µmol/L	pH, pCO_2, pO_2
Platelets	785.0 x 10^3/µl	Hematocrit
pO_2	30 mmHg	Glucose, Lactate
Pralidoxime iodide	40 µg/mL	Glucose, Lactate
Propofol	0.05 mg/mL	pH, pCO_2, pO_2, tBili

Substance	Concentration	Tested analytes where interference was not observed
Pyruvate	309 µmol/L	Glucose, Lactate
(Sodium) Salicylate	4.34 mmol/L	Potassium, Calcium, Chloride
Sodium (Chloride)	180 mmol/L	Potassium, Calcium
Sulfhemoglobin	10%	tHb/Hb fractions/sO_2, tBili
Suxamethonium	68 µmol/L	pH, pCO_2, pO_2, tBili
(Sodium) Thiocyanate	6880 µmol/L	Potassium, Calcium, Glucose, Lactate
Thiopental	248 µmol/L	Sodium, Potassium, Calcium, Chloride, pH, pCO_2, pO_2, tBili
(Sodium) Thiosulfate	20 mmol/L	Potassium, Calcium, Chloride
Teriflunomide	100 µg/mL	Sodium, Potassium, Chloride, Calcium
Thyroxine	1.29 µmol/L	pH, pCO_2, pO_2, tBili
Triglycerides (Intralipid)	2% or 4012 mg/dL	Sodium, Calcium, Chloride, pH, pCO_2, pO_2
Turbidity (Intralipid)	1% or 2006 mg/dL	Hematocrit, tHb/Hb fractions/sO_2
Urea	42.9 mmol/L	Glucose, Lactate
Uric acid	1.4 mmol/L	Glucose, Lactate
Xylose	20 mg/dL	Glucose, Lactate

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Table 2, Interferences observed on gases, electrolytes, metabolites, Hct and tBili

The substances listed in Table 2 showed an interference with electrolytes, Hct, and metabolites measured using electrochemical methods and tBili using CO-Oximetry causing a clinically significant error (> TEa). Interference was tested on three different lots of GEM Premier 5000 GEM PAKs on 3 GEM Premier 5000 instruments.

Interfering Substance	Affected Analyte	Analyte Concentration	Interfering Concentration Tested	Bias Observed (Mean)	Lowest Interfering Concentration with Analyte Impact	Bias Observed at the Lowest Concentration
Albumin	Hematocrit	30%	45.00 g/L	4%	43.92 g/L	4%
		62%	60.00 g/L	5%	49.90 g/L	4%
Bromide (Sodium)	Chloride	90 mmol/L	9.375 mmol/L	31%	1.346 mmol/L	5%
		108 mmol/L	9.375 mmol/L	25%	1.880 mmol/L	5%
Citrate (Sodium)	Chloride	88 mmol/L	6.000 mmol/L	-7%	4.083 mmol/L	-5%
		111 mmol/L	6.000 mmol/L	-5%	5.344 mmol/L	-5%
Cyanocobalamin	tBili	4.8 mg/dL	0.18 g/L	-11%	0.16 g/L	-10%
		13.3 mg/dL	0.53 g/L	-10%	0.47 g/L	-10%
Cyanomethemoglobin	tBili	5.2 mg/dL	1.00%	18%	0.50%	10%
		15.1 mg/dL	3.00%	15%	2.10%	10%
Glycolic Acid	Lactate	1.0 mmol/L	0.250 mmol/L	+0.4 mmol/L	0.237 mmol/L	+0.4 mmol/L
		2.9 mmol/L	0.250 mmol/L	+0.4 mmol/L	0.241 mmol/L	+0.4 mmol/L
Hydroxocobalamin	tBili	5.0 mg/dL	0.18 g/L	-14%	0.12 g/L	-10%
		14.7 mg/dL	0.35 g/L	-13%	0.27 g/L	-10%
Hydroxyurea	Glucose	86 mg/dL	0.60 mg/dL	15%	0.41 mg/dL	10%
		115 mg/dL	0.60 mg/dL	11%	0.57 mg/dL	10%
Hydroxyurea	Lactate	1.0 mmol/L	0.40 mg/dL	0.4 mmol/L	0.37 mg/dL	+0.4 mmol/L
		2.8 mmol/L	0.40 mg/dL	0.5 mmol/L	0.35 mg/dL	+0.4 mmol/L
Iodide (Sodium)	Chloride	88 mmol/L	0.750 mmol/L	6%	0.700 mmol/L	5%
		106 mmol/L	1.500 mmol/L	9%	0.810 mmol/L	5%
Ionized Magnesium (Chloride)	Calcium	1.02 mmol/L	3.938 mmol/L	13%	3.128 mmol/L	10%
		2.00 mmol/L	7.875 mmo/L	11%	6.862 mmol/L	10%
Methylene Blue	tBili	5.0 mg/dL	10 mg/L	-25%	4.6 mg/L	-10%
		14.2 mg/dL	15 mg/L	-11%	12.9 mg/L	-10%
Thiocyanate (Sodium)	Chloride	87 mmol/L	1720 µmol/L	31%	388.3 µmol/L	5%
		109 mmol/L	1720 µmol/L	27%	407.5 µmol/L	5%
Triglycerides (Intralipid)	Potassium	3.2 mmol/L	1003 mg/dL	14%	522 mg/dL	7%
		5.1 mmol/L	1003 mg/dL	11%	662 mg/dL	7%
Turbidity (Intralipid)	tBili	4.8 mg/dL	1505 mg/dL*	-11%	1143 mg/dL*	-10%
		14.0 mg/dL	2006 mg/dL*	No Interference Observed		

* 1% Intralipid is equal to 2006 mg/dL of triglycerides.

Note: The GEM Premier 5000 system with iQM2 employs failure pattern recognition checks. These checks include detecting the presence of positively charged lipophilic compounds (e.g., benzalkonium) and negatively lipophilic compounds (e.g., thiopental). The GEM Premier 5000 system offers the facility the ability to enable flagging of patient results if interference patterns for these compounds are detected by iQM2 at the time of result reporting. Even if the flagging option is not enabled, following the post analysis check, the operator is informed of the event. The operator must acknowledge the message before it will be removed from the screen.

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Table 3, Interferences observed on CO-Oximetry

The substances listed in Table 4 showed an interference with CO-Oximetry/tBili analytes causing a clinically significant error (> TEa). Interference was tested on three different lots of GEM Premier 5000 GEM PAKs on 3 GEM Premier 5000 instruments.

Interferences observed on CO-Oximetry						
Interfering Substance	**Affected Analyte**	**Analyte Concentration**	**Interfering Concentration Tested**	**Bias Observed (Mean)**	**Lowest Interfering Concentration with Analyte Impact**	**Bias Observed at the Lowest Concentration**
Cyanocobalamin	tHb	10.2 g/dL	0.53 g/L*	+0.7 g/dL	0.45 g/L	<|0.7| g/dL
	O_2Hb	84.80%		-4.1%		-3.00%
	COHb	9.60%		-2.00%		<|2.0|%
	MetHb	5.00%		-2.00%		<|2.0|%
	HHb	<1.0%		<|3.0|%		<|3.0|%
	sO_2	99.30%		<|3.0|%		<|3.0|%
	tHb	19.0 g/dL	0.7 g/L*	No Interference Observed		
	O_2Hb	97.20%				
	COHb	1.50%				
	MetHb	<0.7%				
	HHb	<1.0%				
	sO_2	99.20%				
Cyano-methemoglobin	tHb	10.2 g/dL	4.0%*	<|0.7| g/dL	3.80%	<|0.7| g/dL
	O_2Hb	97.30%		<|3.0|%		<|3.0|%
	COHb	1.30%		<|2.0|%		<|2.0|%
	MetHb	0.70%		<|2.0|%		<|2.0|%
	HHb	<1.0%		3.50%		3.00%
	sO_2	99.30%		-3.10%		<|3.0|%
	tHb	20.1 g/dL	4.0%*	No Interference Observed		
	O_2Hb	97.50%				
	COHb	1.80%				
	MetHb	<0.7%				
	HHb	<1.0%				
	sO_2	99.90%				
Hydroxocobalamin	tHb	9.5 g/dL	0.50 g/L*	+0.7 g/dL	0.34 g/L	<|0.7| g/dL
	O_2Hb	84.80%		-5.2%		<|3.0|%
	COHb	10.00%		<|2.0|%		-2.00%
	MetHb	4.50%		2.60%		<|2.0|%
	HHb	<1.0%		-3.90%		<|3.0|%
	sO_2	99.30%		3.50%		<|3.0|%
	tHb	19.6 g/dL	1.00 g/L*	+0.8 g/dL	0.83 g/L	+0.7 g/dL
	O_2Hb	97.60%		-3.4%		<|3.0|%
	COHb	1.50%		<|2.0|%		<|2.0|%
	MetHb	<0.7%		<|2.0|%		<|2.0|%
	HHb	<1.0%		<|3.0|%		<|3.0|%
	sO_2	99.90%		<|3.0|%		<|3.0|%

*Results are flagged by iQM2 at the concentrations noted.
Note: For CO-Oximetry fractions, all biases are expressed in absolute % (i.e. measured units, not CV%)

Carryover testing

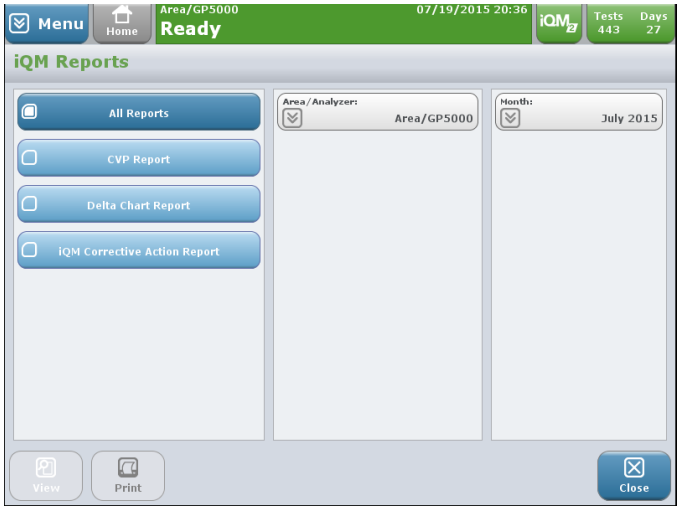
An in-house study was performed to determine the impact of sample carryover on the GEM Premier 5000. Testing included low and high analyte concentrations with minimal delay between levels to determine whether sample carryover has any effect on the accuracy of results reported by GEM Premier 5000. For each level, the bias was calculated between replicate 1 and the average of subsequent replicates. All testing was performed in accordance to CLSI EP10-A3-AMD. Preliminary Evaluation of Quantitative Clinical Laboratory Measurement Procedures; Approved Guideline (May 2014, Third Edition). Results for all parameters (pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct%, and tHb) did not exceed TEa, indicating no carryover effect.

Appendix

iQM2® REPORTS

iQM2 is Instrumentation Laboratory's patented Intelligent Quality Management software, which ensures the integrity of the overall analysis system. Quality testing runs automatically in the background. Running iQM2 reports allows supervisors to monitor the iQM2 functionality.

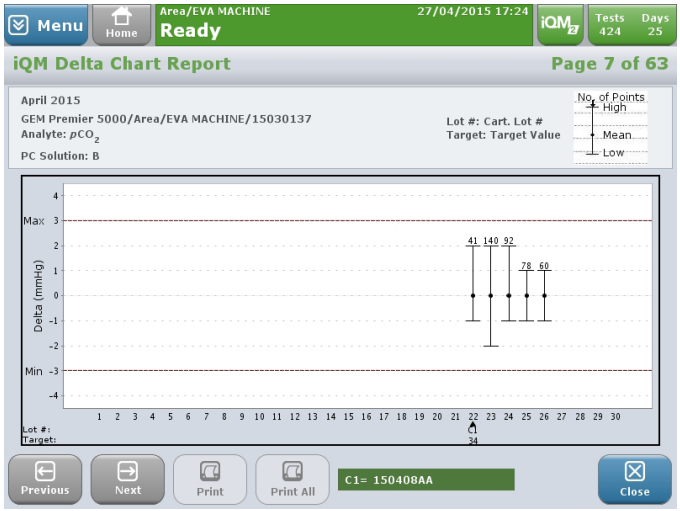
In the **iQM2 Reports** screen (accessed from the Management tab) you can view, print, or export three types of reports:



iQM2 Delta Chart

Delta charts show daily minimum, maximum, and mean delta values for individual process control solutions. Delta values represent the measured result minus the expected value.

1. The top informational area contains:
   - Month
   - Analyzer model, area analyzer name, and analyzer serial number
   - Analyte name
   - Process Control (PC) solution identification
   - A static legend icon is shown on the right-hand side



2. The x-axis of the chart shows:
   - Days of the months (1-28, 29, 30, or 31 as applicable)
   - Date of GEM PAK insertion, marked on the chart with an up arrow (Δ)
   - Target value of the analyte shown in the units selected during configuration, except that pH remains in the default units
   - GEM PAK lot number displayed below the chart

   If more than one GEM PAK was inserted on the same day, the last GEM PAK information is shown.

3. The y-axis of the chart displays:

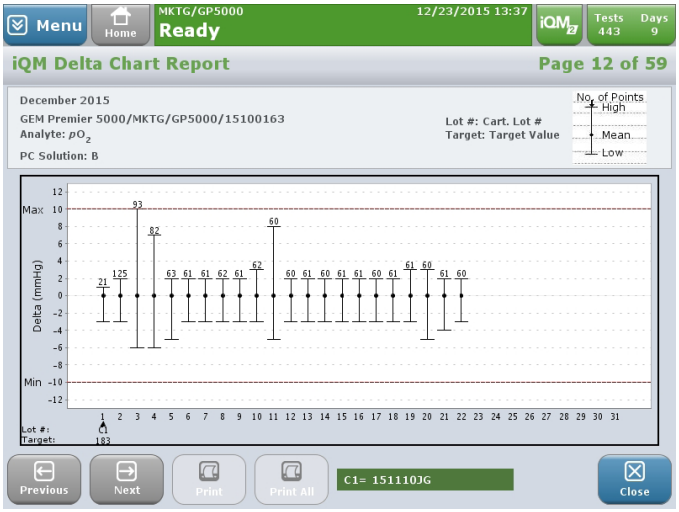
   The delta value, which is the measured result minus the expected value. The delta is used instead of the actual value to allow for different GEM PAK lots, which may have slightly different target values, to be plotted on the same chart. The delta units will be in the format of the units selected in configuration, except for pH, which will remain in pH units. The height of the chart will be the same for all analyte-solution combinations in order to fill the screen and provide viewing consistency.

4. The chart components include:
   - Two red dotted lines, which extend the entire chart area, and indicate the acceptable range established by Instrumentation Laboratory for each analyte and Process Control solution. These acceptable limits cannot be changed.
   - The number of times the solution was measured for the 24-hour period is displayed.
   - The daily mean delta value for that particular Process Control solution is displayed as a round bolded dot.
   - The minimum and maximum delta values for a day are indicated with a short horizontal line. These two horizontal lines are connected with a vertical line.
   - If a value falls outside the acceptable limit an asterisk is posted above the number of points measured for that day. Also, below the bottom red dashed limit line, the following message will be displayed, “*See event on the Corrective Action Report.” Because the chart is static in size, delta values outside the limit are not plotted. Instead, the event is logged on the iQM2 Corrective Action Report (CAR).

   The iQM2 Delta Chart(s) can be printed only on an attached external or network printer. Therefore, the **Print** button on the display screen will be enabled only if an attached external or network printer is selected during configuration. The report can only be printed as a PDF file, and the printed information will be the same as that shown on the displayed chart. The report will be titled iQM2 Delta Chart.

   If for the selected month there are no data points to display for all days of the month for the requested iQM2 Delta Chart, the message “No data points to display. <OK>” will be presented. If there are no data points to display on an iQM2 Delta Chart that

is part of a group of charts being displayed, the iQM2 Delta Chart will be displayed without data (empty), and no message will be displayed to the operator. If the iQM2 Delta Chart is for the current month, the days will be plotted through the previous day.



5. It is possible to have the minimum and maximum delta values coincide with one another and the mean delta result. This occurs when:

   - The same delta value is obtained for an analyte each time a Process Control solution is measured
   - Only one delta value is obtained for an analyte through the course of day, which is expected for some of the solutions that are analyzed once per day

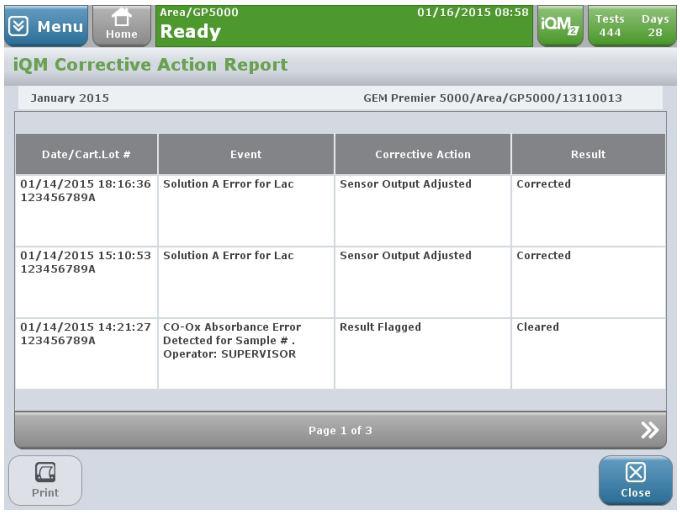
6. A minimum or maximum delta result, represented by a horizontal line, may coincide with a daily mean delta result. An example of this occurring is:

   - pCO_2 is measured in PC Solution B 61 times on one day (day 14 on the chart above)
   - Values for day 15 were between +1 mmHg and -1 mmHg.

In this case, the mean and minimum delta values will be the same, namely zero. The horizontal line representing the minimum delta value will intersect the round bolded dot, which represents the mean value. Furthermore, because the minimum delta value is zero, the horizontal line representing the minimum delta result will coincide with the zero horizontal line on the chart.

Corrective Action Report

The Corrective Action Report (CAR) contains information for all significant events that occur during the GEM PAK on-board use life along with associated corrective actions taken and the results of the corrective action.



1. The top informational area contains:
   - Report month and year
   - Analyzer model, area, analyzer name, and analyzer serial number
2. The body of the report contains:
   - The first column, which displays the date and time of the event as well as the GEM PAK lot number
   - A second column that describes the event, including sample number and operator ID, if applicable
   - The third column, which explains the corrective action automatically initiated for the event
   - A fourth column that lists the result of the corrective action initiated

   If there are more events than can be displayed on the screen, below the body of the report, the number of pages in the format page x of y is shown on the left side. Arrows on the right side indicate that selecting this area will advance the information so it can be viewed.
3. The Corrective Action Report can be printed only on an attached external or network printer. Therefore, the Print button on the display screen will be enabled only if an attached external or network printer is selected during configuration. The report can be printed only as a PDF file, and the printed information will be the same as that shown on the displayed chart.

Calibration Valuation Product

A Calibration Valuation Process (CVP) report contains results for all Auto PAK Validation solutions analyzed, in chronological order, within the specified month and year for the specified analyzer. If no CVP reports exist for the month/year selected the message “No samples found. <OK>” is presented.

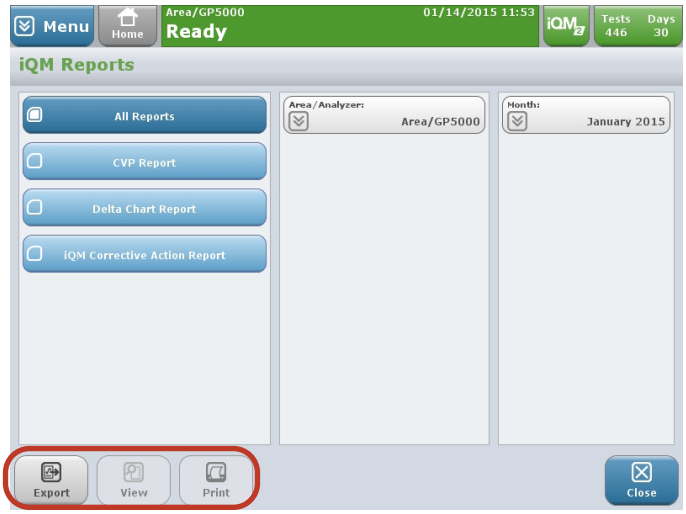
1. The title bar contains:
   - The iQM2 CVP Report heading
   - The number of CVP samples the report contains
2. An informational area contains:
   - Report month and year
   - Analyzer model, area if applicable, analyzer name if configured, and analyzer serial number
   - Operator ID entered, if applicable, of the person analyzing the CVP sample. For APV, these will be listed as XXXX
   - Level description (1, 2, or CVP 5*) and lot analyzed
   - Status of the CVP sample, Accepted (Passed) or Accepted (Failed). APV results are automatically accepted.
   - Date and time the sample was analyzed
3. CVP sample results. The **Next / Previous** buttons will navigate to the rest of the samples. The CVP Report can be printed only on an attached external or network printer. Therefore, the **Print** button on the display screen will be enabled only if an attached external or network printer is selected during configuration. The report can be printed only as a PDF. The printed CVP report will contain one sample per page, with the pages numbered in the format page x of y.

***Note: tBili analyte requires CVP 5 prior to patient analysis for tBili.**

Printing iQM2 Reports

To generate a report, select the report type and the criteria from the IQM2 Reports screen. Then select the desired output type: Export PDF files to a disc or USB device, View on screen, or Print to an external printer.

For a standalone analyzer, the Transmit iQM2 button is provided in case a manual transmission of Delta chart or CAR reports is needed.



Analyzing Proficiency Materials

If your facility is required to analyze proficiency materials, enable the Proficiency sample type in **Configuration>Sample Type**. Using the Proficiency sample type allows proficiency samples to be identified as such in the GEM Premier 5000 database. Additionally, if your analyzer is on Software version 1.2.0 (or higher) materials run in Proficiency Mode will automatically be sent to the HIS/LIS in the same manner as a patient sample. Contact your local IL/Werfen representative for configuration and upgrade details.

The Proficiency sample type minimizes the effect of CO-Oximetry and total bilirubin proficiency materials may have on the electrochemical sensors. The matrix of the material, and the preservatives required for CO-Oximetry and total bilirubin proficiency materials may not be compatible with the electrochemical sensors. This incompatibility may result in the system entering an extended fixing cycle, in order to restore the baseline of the electrochemical sensors following exposure to these proficiency materials. The Proficiency mode for CO-Oximetry and total bilirubin does not alter the measurement mode for those analytes, but does move the sample into the CO-Ox/tBili measurement area faster, in order to expose the electrochemical sensors to the material for a short period of time. Therefore, utilizing the Proficiency sample mode does analyze the proficiency material in the same manner as a patient sample, and meets a Regulatory body's requirement to analyze the proficiency material in the same manner as a patient sample.

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Performing Proficiency Sample:

1. Select Proficiency under sample type
2. After selecting Proficiency sample mode, a Proficiency Test Panel selection screen will appear. User will select the analytes that are to be performed from Proficiency challenge/sample.
3. Present proficiency ampoule and select OK.

Samples analyzed in the Proficiency sample mode are not transmitted to the LIS/HIS unless on SW 1.2.0 or higher.

Ordering Information

Analyzer and Startup Kit

Description	Part Number
GEM Premier 5000 Analyzer	00024019255

Consumables

Description	Part Number
Printer Paper, 5 rolls per Box[2]	00025000500
Replacement Fuse, 5 per Pack	00025002107

CVP (Calibration Valuation Product)

Description	Part Number
GEM CVP 5 tBili, 10 ampoules x 1.8 mL	00025000145

Additional Items

Description	Part Number
GEM Mobile Cart	00024001200
Wand, Bar Code	00024015859
Wireless Barcode Scanner, 2D	00025000420
UPS, Tripp Lite Model SMART1200XLHG, Medical Grade[1]	00025002112
CD, System GEM5000 Ops Manual	00024004463
Ampoule Breaker, 1 per Box	00025000450
Shipping Cartridge[3]	00024019216
GEM Safety Draw Kit, Plastic Capillary Tubes (1,000 pack)	00024001170*
Capillary Cap Adapters (200 pack)	00007071200*
Capillary Tube Adapters (100 pack)	00024001177*

[1]Vendor and model subject to change without notice

[2]Included in GEM Premier 5000 Startup Kit

[3]Shipped with the GEM Premier 5000 Analyzer

* May not be available in all countries

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GEM PAK (Cartridge)

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 chart below for PAK options.

GEM PAK Analyte Menu	Number of Tests	Onboard Stability	Part Number
pH, pCO_2, pO_2, Hct, tHb, O_2Hb, COHB, HHB, MetHb, sO_2	75	31 days	00055407504
	150	31 days	00055415004
	300	31 days	00055430004
	450	31 days	00055445004
	600	21 days	00055360004
pH, pCO_2, pO_2, Hct, tHb, tBili, O_2Hb, COHB, HHB, MetHb, sO_2	75	31 days	00055407505
	150	31 days	00055415005
	300	31 days	00055430005
	450	31 days	00055445005
	600	21 days	00055360005
pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct, tHb, O_2Hb, COHB, HHB, MetHb, sO_2	75	31 days	00055407508
	150	31 days	00055415008
	300	31 days	00055430008
	450	31 days	00055445008
	600	21 days	00055360008
pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Hct, tHb, tBili, O_2Hb, COHB, HHB, MetHb, sO_2	75	31 days	00055407509
	150	31 days	00055415009
	300	31 days	00055430009
	450	31 days	00055445009
	600	21 days	00055360009
pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, Lactate, Hct, tHb, O_2Hb, COHB, HHB, MetHb, sO_2	75	31 days	00055407510
	150	31 days	00055415010
	300	31 days	00055430010
	450	31 days	00055445010
	600	21 days	00055360010
pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, Lactate, Hct, tHb, tBili, O_2Hb, COHB, HHB, MetHb, sO_2	75	31 days	00055407511
	150	31 days	00055415011
	300	31 days	00055430011
	450	31 days	00055445011
	600	21 days	00055360011

Other Ampoule Products[4]

Description	Part Number
GEM System Evaluator 1, 10 ampoules x 1.8 mL	00025000101
GEM System Evaluator 2, 10 ampoules x 1.8 mL	00025000102
GEM System Evaluator 3, 10 ampoules x 1.8 mL	00025000103
GEM Hematocrit Evaluator 1, 10 ampoules x 1.8 mL	00025000104
GEM Hematocrit Evaluator 2, 10 ampoules x 1.8 mL	00025000105
GEM Hematocrit Evaluator 3, 10 ampoules x 1.8 mL	00025000106

[4] These ampoule products are not required by Instrumentation Laboratory to be analyzed on the GEM Premier 5000 system. They are available assist our customers in meeting regulatory requirements. These ampoules may not be available in your country. Contact your local representative for availability.

Anaylzer and GEM PAK (Cartridge) Dimensions and Weight

	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
GEM Premier 5000 PAK		
Height:	15.2 cm	6.75 inches
Width:	21.6 cm	10 inches
Depth:	7.6 cm	8 inches
Weight:	3.7 kg	8.1 pounds

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

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

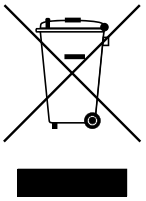
CEI/IEC 61010-1

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.

Patents

The GEM PAK is protected by one or more of the following US Patents.

- 5,132,345
- 5,286,364
- 5,540,828
- 6,652,720
- 6,872,297
- 6,960,466
- 7,022,219
- 8,560,251
- 9,113,833

Instrumentation Laboratory Locations

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Worldwide Internet Address:

www.instrumentationlaboratory.com

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