Technical Specifications

Dimensions and Weight
Analyzer
H: 18 in, W: 12 in, D: 15 in, Wt: 44 lbs

Sample Volume
150 µL (BG, Hct, Lac, °2), 200 µL CO-Ox, or any subset of the menu that includes CO-Ox
100 µL (CO-Ox, Hb, tBili) only
65 µL (BG, Hct, Lac, °2, °2 + Lytes, °2 + Glu, °2 + Lac)

Sample Type
Heparinized whole blood
Heparinized plasma (tBili)

Time to Results
All tests without CO-Ox: 70 seconds from sample introduction
All tests with CO-Ox: 95 seconds from sample introduction
Sample capacity: 75 – 600 tests

Measurement Methodology
Amperometric: pH, O2, Glu, Lac, Creat°
Potentiometric: pCO2, Na+, K+, Ca++, Cl–, pH, °2, °2 + Lytes, °2 + Glu, °2 + Lac
Conductivity: Hct
Optical measurement following chemical lysing of the whole blood sample: CO-Ox, tBili

Interface Protocols
ASTM or HL7 enables data transmission to a laboratory, hospital or third-party information management system.

Sample capacity:
All tests with CO-Ox:

**Lytes**

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Unit</th>
<th>Measured Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>mmol/L</td>
<td>6.80 – 8.00</td>
</tr>
<tr>
<td>pCO2</td>
<td>mmol/L</td>
<td>4 – 750</td>
</tr>
<tr>
<td>Na+</td>
<td>mmol/L</td>
<td>100 – 200</td>
</tr>
<tr>
<td>K+</td>
<td>mmol/L</td>
<td>0.3 – 2.00</td>
</tr>
<tr>
<td>Ca++</td>
<td>mmol/L</td>
<td>0.10 – 5.00</td>
</tr>
<tr>
<td>Cl–</td>
<td>mmol/L</td>
<td>40 – 170</td>
</tr>
<tr>
<td>Glu</td>
<td>mg/dL</td>
<td>5 – 800</td>
</tr>
<tr>
<td>Lac</td>
<td>mg/dL</td>
<td>0.3 – 20.0</td>
</tr>
<tr>
<td>Hct</td>
<td>%</td>
<td>15 – 75</td>
</tr>
<tr>
<td>tHb</td>
<td>g/dL</td>
<td>3.0 – 23.0</td>
</tr>
<tr>
<td>O2Hb</td>
<td>%</td>
<td>10.0 – 110.0</td>
</tr>
<tr>
<td>COHb</td>
<td>%</td>
<td>10.0 – 110.0</td>
</tr>
<tr>
<td>Methb</td>
<td>%</td>
<td>10.0 – 110.0</td>
</tr>
<tr>
<td>HIHb</td>
<td>%</td>
<td>10.0 – 110.0</td>
</tr>
<tr>
<td>tBili</td>
<td>mg/dL</td>
<td>0.3 – 4.0</td>
</tr>
</tbody>
</table>

1. In development; not currently available.

**Derived (Calculated) Parameters**

<table>
<thead>
<tr>
<th>BE(B)</th>
<th>CO2</th>
</tr>
</thead>
<tbody>
<tr>
<td>B+Hb</td>
<td>CO2</td>
</tr>
<tr>
<td>HCO3</td>
<td>CO2</td>
</tr>
<tr>
<td>O2Hb</td>
<td>CO2</td>
</tr>
</tbody>
</table>

Advanced, simple and revolutionary. Automation and innovation at the touch of a button.

For more information, call 1.800.955.9525 or visit instrumentationlaboratory.com.
Now, automation is even better.

Our advanced PLUS technology enables:
• Faster touch-screen responsiveness
• Integrated wireless
• Remote service

Complements other key features:
iQM
Automates quality assurance

GEMweb Plus Custom Connectivity
Automates information management

Multi-use PAK
Automates maintenance

Just press GO!

Automation and quality care go hand in hand.

The GEM Family of Critical Care Testing Solutions

<table>
<thead>
<tr>
<th>GEM Premier Analyzers</th>
<th>GEMweb Plus Custom Connectivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEM Premier 4000</td>
<td>• GEMweb Plus 4000</td>
</tr>
<tr>
<td>GEM Premier 3500</td>
<td>• GEMweb Plus 300</td>
</tr>
<tr>
<td></td>
<td>• GEMweb Plus Customizable Options</td>
</tr>
<tr>
<td></td>
<td>• GEMweb</td>
</tr>
</tbody>
</table>

Every member of the GEM Family delivers fast, accurate results, in the lab or at the point-of-care, for the very best patient care.
Ultimate Flexibility

- Standardized platform for the lab and at the point-of-care
- Full analyte menu and integrated CO-Oximetry
- Accepts a syringe, capillary tube or ampule
- Multiple menu and volume PAK configurations

<table>
<thead>
<tr>
<th>PAK Size</th>
<th>75</th>
<th>150</th>
<th>300</th>
<th>450</th>
<th>600†</th>
<th>Onboard Use-life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Gas, Hct, O₂,Hb, HHb, COHb, MetHb, sO₂, tBili*</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>30 days</td>
</tr>
<tr>
<td>Blood Gas, Electrolytes, Hct, tHb, O₂,Hb, HHb, COHb, MetHb, sO₂, tBili*</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>30 days</td>
</tr>
<tr>
<td>Blood Gas, Electrolytes, Glu, Lac, Hct, tHb, O₂,Hb, HHb, COHb, MetHb, sO₂, tBili*</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>30 days</td>
</tr>
</tbody>
</table>

Menus with: Creatinine, BUN and measured tCO₂ are in development.

* Cartridges available with or without tBili.
† Onboard use-life is 21 days.
iQM: Intelligent Quality Management
Automated Continuous Quality Assurance

How iQM helps to improve patient care
iQM continuously ensures the quality of test results with automatic error detection and correction.
- Prevents the reporting of erroneous results
- Provides rapid, quality-assured test results with every sample, not just every 8 hours
- Identifies and reduces risks associated with testing processes

Continuous quality management vs. traditional QC
iQM automatically performs continuous quality checks with every sample to detect any error patterns and correct them immediately. This reduces error detection time from hours to minutes compared with all other methods.

![Diagram comparing iQM and traditional QC](image)

### iQM assures quality continuously
- Error automatically detected, corrected and documented immediately
- Quality-assured test results

### Traditional QC (Manual or Auto)
- Error undetected
- Questionable test results

### iQM reduces error detection time from hours to minutes.1,2

<table>
<thead>
<tr>
<th>Parameter</th>
<th>iQM</th>
<th>Traditional QC (Manual or Auto)</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>3 mins</td>
<td>≥ 8 hrs</td>
</tr>
<tr>
<td>pO₂</td>
<td>3 mins</td>
<td>≥ 8 hrs</td>
</tr>
<tr>
<td>pCO₂</td>
<td>3 mins</td>
<td>≥ 8 hrs</td>
</tr>
<tr>
<td>Na⁺</td>
<td>17 mins</td>
<td>≥ 8 hrs</td>
</tr>
<tr>
<td>K⁺</td>
<td>3 mins</td>
<td>≥ 8 hrs</td>
</tr>
<tr>
<td>Ca²⁺</td>
<td>3 mins</td>
<td>≥ 8 hrs</td>
</tr>
<tr>
<td>Glu</td>
<td>11 mins</td>
<td>≥ 8 hrs</td>
</tr>
<tr>
<td>Lac</td>
<td>6 mins</td>
<td>≥ 8 hrs</td>
</tr>
<tr>
<td>Hct</td>
<td>3 mins</td>
<td>≥ 8 hrs</td>
</tr>
</tbody>
</table>

Statistical presentation of an average error detection time with 95% confidence.

“iQM: a new standard for the future of QC.”
– James Westgard, PhD, developer of the ‘Westgard Rules’

References:
How iQM saves time and resources

It’s simple. Just insert the self-contained, maintenance-free GEM PAK and iQM does the rest.

• Manages quality in a closed system; everything is self-contained (and no refrigeration necessary)
• Eliminates outside variability
• Eliminates maintenance
• Keeps documentation just a click away

Continuous quality management vs. traditional QC

iQM continuously automates nearly all labor- and skill-intensive processes, giving clinical staff more time at the bedside to care for patients. And, by providing continuous automated quality management with no operator intervention, iQM reduces annual labor costs per instrument compared with traditional quality control.

<table>
<thead>
<tr>
<th>Annual Labor/Instrument*</th>
<th>Annual Cost/Instrument*</th>
</tr>
</thead>
<tbody>
<tr>
<td>iQM</td>
<td>Traditional Auto QC</td>
</tr>
<tr>
<td>0 total hrs</td>
<td>78 total hrs</td>
</tr>
<tr>
<td>$0</td>
<td>$1,950</td>
</tr>
</tbody>
</table>

Positive impact on staff time

Calculate the savings with iQM.
198 hrs/instrument = staff time saved
$4,950/instrument = cost saved

Example in a hospital with 8 GEM Premier instruments:
198 X 8 = 1,584 staff hrs/year and $4,950 X 8 = $39,600/year

Positive impact on hospital costs

Ask your IL representative for a customized time, resources and storage savings calculation.

* Data on file, IL. ** At hourly rate of $25/hr.

FDA-Cleared Intended Use Statement:

iQM is an active quality process control program designed to provide continuous monitoring of the analytical process with real-time, automatic error detection, automatic correction of the system and automatic documentation of all corrective actions, replacing the use of traditional external quality controls.

† Cleared in 2002 for GEM Premier 3000 system and again in 2006 for GEM Premier 4000 system.
†† To ensure adherence to a total quality management system, please follow local, state and federal regulatory guidelines.
Integrated wireless for seamless communication to the LIS or HIS.

Delivers automated quality assurance and regulatory compliance, while significantly reducing staff time.

Provided intuitive, customizable control of instruments and operators—from any GEM Premier 4000 analyzer or PC

The ONLY connectivity software to provide:

- **Single-interface simplicity.** The only solution to feature the same intuitive interface when accessed on an analyzer or a PC
- **Flexible customization.** Fully customizable to individual hospital configurations and needs—by individual GEM Premier analyzer, department or globally
- **Unprecedented control.** System-wide control from any networked PC or GEM Premier, regardless of location

Plus:

- Allows automatic review of analyzer and PAK status
- Alerts operator to replace PAK
- Offers patient history with delta versus previous result with one keystroke
- Consolidates iQM reports, operator competency, audit logs and positive patient ID

GEMweb Plus Custom Connectivity

Automated Information Management

Integrated wireless for seamless communication to the LIS or HIS.
GEMweb

Web-based information management, including:

- Intuitive user interface, accessible from any networked analyzer or PC
- Complete operator management
- Remote access to analyzer status and control
- Remote review of iQM reports

GEMweb Plus 300

Everything GEMweb offers AND:

- System-wide control from any analyzer or PC
- Consolidated:
  - Analyzer/PAK status and control
  - iQM review
  - Patient information management
  - Sample database
  - Operator management
- Remote system configuration
- NEW:
  - Operator download
  - eSignature capability
  - Expanded report menu

GEMweb Plus 400

Everything GEMweb Plus 300 offers AND:

- Automated administration of operator certification exams
- Advanced regulatory audit logs for compliance

GEMweb Customizable Options

Everything made easier

- Receipt of ADT transmissions, including positive patient ID verification
- Automated and customizable point-of-care order creation (solicited and unsolicited) and order download
PAKs contain all components for patient testing and are ideal for high- and low-volume testing.
Point-of-Care Testing
Automation at the Bedside

Brings simplicity to the point-of-care
Standardized lab-quality results and real-time connectivity for immediate decisions anywhere in the hospital.

CVOR
Immediate, precise testing
- CO-Oximetry, the most accurate method to measure Hemoglobin, is fully integrated, offering a complete test menu
- Measured Total Hemoglobin not affected by common operative variables, unlike conductive Hematocrit

ICU
Saves time and enhances patient care
- Provides complete oxygenation status
- Only cartridge-based system to provide Lactate testing in a single sample
- Comprehensive results in a single sample for fast clinical assessments and better outcomes
- Immediately recalls patient information, enhancing safety

NICU
Fast, reliable results for tiny patients
- The only cartridge-based system to offer Total Bilirubin
- Automatic Fetal Hemoglobin detection and correction
- Capillary-tube sampling (65 µL)*
- Ideal for nitric oxide therapy

ED
Rapid, comprehensive testing
- Only cartridge-based system to provide Lactate testing in a single sample
- tHb for triaging trauma-related blood loss
- COHb, MetHb to assist in smoke-inhalation treatment
- Advanced GEMweb Plus Custom Connectivity—intuitive, customized control from any GEM Premier 4000 analyzer or PC

* BG, Electrolytes, Metabolites, Hct
Simple and flexible, it’s the automatic choice for your hospital

The top choice of hospitals worldwide, the GEM Premier 4000 is advanced, simple, revolutionary and is fully automating Critical Care testing.

Automated Continuous Quality Assurance
iQM ensures test quality—24 hours a day, seven days a week, providing continuous error detection and correction.

Automated Information Management
GEMweb Plus Custom Connectivity offers true bi-directional communication anywhere—it automates information management and provides system-wide control from any networked PC or GEM Premier 4000.

Automated Maintenance
GEM PAKs contain all testing components, are replaced every 30 days and require no refrigeration. Combined with automated detection, correction and documentation, the most labor- and skill-intensive processes are eliminated, saving significant time.

Automation at the Bedside
Flexible cartridge test volumes and menu options, including a complete CO-Oximetry panel, and standardized, lab-quality results and real-time connectivity for immediate decisions at the POC.

Just press GO!
The GEM Family of Critical Care Testing Solutions

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Instrumentation Laboratory

Our Passion. Your Results.

Driven by our constant passion for innovation, IL has provided the most comprehensive and valuable diagnostic solutions for decades. From the launch of our first instrument, our integrated solutions continue to revolutionize Critical Care testing with more capabilities, more end-to-end automation and more flexibility.
Technical Specifications

**Dimensions and Weight**
- **Analog**: H: 18 in, W: 12 in, D: 15 in, Wt: 44 lbs
- **PAK**: H: 6.75 in, W: 10 in, D: 8 in, Wt: 8 lbs

**Sample Volume**
- 150 µL: BG ± pH, CO-Ox, CaO2, COHb, MetHb, HHb, tHb, O2, Glu, Lac
- 100 µL: CO-Ox only

**Sample Type**
- Heparinized whole blood
- Heparinized plasma (tBili)

**Time to Results**
- All tests with CO-Ox:
  - Heparinized plasma (tBili): 70 seconds from sample introduction
  - Heparinized whole blood: 95 seconds from sample introduction

**Sample Capacity**
- 65 µL: 200 tests
- 150 µL: 180 tests

**Analyzer Dimensions and Weight**
- PAK: H: 18 in, W: 12 in, D: 15 in, Wt: 44 lbs

**Derived (Calculated) Parameters**
- BE(B): mmol/L
- BE(ecf): mmol/L
- Anion gap: mmol/L
- P/F ratio: n/a

**Measured Analytes**
- Analyte: Unit
- Measured Range:
  - pH: mmol/L
  - pCO2: mmol/L
  - pO2: mmol/L
  - Na+: mmol/L
  - K+: mmol/L
  - Ca2+: mmol/L
  - Cl–: mmol/L
  - Glu: mg/dL
  - Lac: mg/dL
  - O2: 5 – 800
  - Hct: %
  - tHb: g/dL
  - COHb: %
  - MetHb: %
  - HHb: %
  - Hb: mg/dL
  - tBili: mg/dL

**Interface Protocols**
- ASTM or HL7 enables data transmission to a laboratory, hospital or third-party information management system.

Instrumentation Laboratory®

For more information, call 1.800.955.9525 or visit instrumentationlaboratory.com.