Advanced, simple, and revolutionary.

Fully automated at the touch of a button.

GO!
GEM Premier 4000

Brings complete automation to critical care testing—at the touch of a button.

Simply press GO!

- **iQM:** Automates quality assurance
- **GEMweb Plus Custom Connectivity:**
  Automates information management
- **Multi-use PAK:** Automates maintenance

Automation and quality care go hand in hand.

Fully automated maintenance, quality control and information management help to ensure patient safety and enhance 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

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**PAK Size**

<table>
<thead>
<tr>
<th>MENU</th>
<th>75</th>
<th>150</th>
<th>300</th>
<th>450</th>
<th>600†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Gas, Hct, THb, O₂Hb, HHb, MetHb, sO₂, Total Bili*</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Blood Gas, Electrolytes, Hct, THb, O₂Hb, HHb, MetHb, sO₂, Total Bili*</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Blood Gas, Electrolytes, Glu, Lac, Hct, THb, O₂Hb, HHb, MetHb, sO₂, Total Bili*</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

* Menus with: Creat, BUN, measured tCO₂ are in development.

† Onboard use-life is 21 days.
Automated Quality Assurance

iQM: Intelligent Quality Management

The most accurate results, every time, for maximum efficiency and enhanced patient care.

Automatically monitors all components. Provides continuous error detection and correction.

### iQM Continuous Model

- Error automatically detected, corrected and documented immediately
- Optimal test results ensured

### Traditional QC (Manual or Auto) Eight-hour Model

- Error undetected
- Questionable test results (all results from eight-hour period require review)

### Reduces Error Detection Time from Hours to Minutes

<table>
<thead>
<tr>
<th>Component</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:
IL’s patented iQM and all analytical components are included inside a single-component, self-contained PAK.

FDA-cleared in 2002 for GEM Premier 3000, and again in 2006 for GEM Premier 4000, iQM is the only quality management system designed to provide continuous monitoring of the analytical process with real-time, automatic error detection, correction and documentation of all corrective actions, replacing the use of traditional external quality controls.

Positive Impact on Staff Time

<table>
<thead>
<tr>
<th></th>
<th>iQM</th>
<th>Traditional Manual QC</th>
<th>Traditional Auto QC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0 total hrs</td>
<td>16.5 total hrs</td>
<td>6.5 total hrs</td>
</tr>
</tbody>
</table>

- Over 16 hours saved monthly
- Over 190 hours saved annually

**This means:**
In a hospital with 8 GEM Premier 4000 analyzers, iQM can save over 1,500 hours annually.
Automated Information Management
GEMweb Plus Custom Connectivity

System-wide control from any networked analyzer or PC, customized for your hospital.

The ONLY connectivity software to:

- Provide a single user-interface
- Allow system-wide control from any networked PC or GEM Premier 4000
- Automate and customize operator certification and management

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

True web-based, bi-directional communication, anywhere.
GEMweb
Automated, web-based information management
- Single, graphic user-interface
- Bi-directional operator management
- Remote analyzer review and control
- Remote iQM review
- Demographic query

GEMweb Plus 100
Everything GEMweb offers AND:
- Remote global/area/analyzer system configuration
- Consolidated:
  - Analyzer status and control
  - Operator management
  - iQM review
  - Patient information management
- System-wide sample lookup database
- HIS and LIS order receiving and processing

GEMweb Plus 200
Everything GEMweb Plus 100 offers AND:
- Automated and customizable operator certification, including exams
- Advanced regulatory compliance management

GEMweb Plus 100 & 200 Customizable Options
More functionality, more flexibility
- Receipt of ADT transmissions
- Automated point-of-care order creation
Automated Maintenance

Saves significant staff time and reduces training and documentation requirements.

GEM PAK – The only single-component, multi-use cartridge on the market.

- Self-contained; includes all testing components: sensors, CO-Ox optical cell, lysing solution, Process Control Solutions, tubing, waste container and sampler
- Stored at room temperature
- Easy front-loading
- Replaced every 30 days

Automates the most labor- and skill-intensive processes.

- Zero maintenance—just replace the disposable PAK monthly; no additional cartridge handling required
- Only one PAK to inventory and manage, including all solutions, sensors and quality control
- Immediately detects errors—no hands-on troubleshooting required
- Immediately corrects errors—no hands-on corrective actions required
- Regulatory compliance reports generated automatically

PAKs contain all components for patient testing and are ideal for high- and low-volume testing.
# Automation at the Bedside

**Bringing 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; no interference from use of Methylene Blue

## ED

**Rapid, comprehensive testing**

- Only cartridge-based system to provide Lactate testing in a single sample—key to rapid implementation of sepsis protocol
- tHb for triaging trauma-related blood loss
- COHb, MetHb to manage smoke inhalation treatment
- Advanced GEMweb Plus connectivity—fully integrated, real-time information management

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* BG, Electrolytes, Metabolites, Hct | ** Basic Metabolic Panel in development: BUN/Creat and measured tCO2,
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 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

<table>
<thead>
<tr>
<th>GEM Premier Analyzers</th>
<th>GEMweb Plus Custom Connectivity</th>
<th>GEM Complementary Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>GEM Premier 4000</td>
<td>GEMweb Plus 200</td>
<td>GEMdraw</td>
</tr>
<tr>
<td>GEM Premier 3500</td>
<td>GEMweb Plus 100</td>
<td>GEM PCL Plus</td>
</tr>
<tr>
<td></td>
<td>GEMweb Plus Customizable Options</td>
<td>GEM OPL</td>
</tr>
<tr>
<td></td>
<td>GEMweb</td>
<td></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.

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
Analyzer
H: 18 in, W: 12 in, D: 15 in, Wt: 44 lbs
PAK
H: 6.75 in, W: 8 in, D: 8 in, Wt: 8 lbs

Sample Volume
150 µL BG*/Hct/Lytes*/Gluc/Lac/CD-Ox or any subset of the menu that includes CD-Ox
100 µL CO-Ox/Total Bili only
65 µL BG/Hct/Lytes/Gluc/Lac

Sample Type
Heparinized whole blood
Heparinized Plasma (Total Bili)

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: pO2, Gluc, Lac, Creat*
Conductivity: Hct
Optical measurement following chemical lysis of the whole blood sample: CO-Ox, Total Bili

In development. Not currently salable.

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

Measured Analytes

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Unit</th>
<th>Measured Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH</td>
<td>n/a</td>
<td>6.80 – 8.00</td>
</tr>
<tr>
<td>pO2</td>
<td>mmHg</td>
<td>6 – 350</td>
</tr>
<tr>
<td>pO2</td>
<td>mmHg</td>
<td>5 – 800</td>
</tr>
<tr>
<td>Na</td>
<td>mmol/L</td>
<td>100 – 200</td>
</tr>
<tr>
<td>K+</td>
<td>mmol/L</td>
<td>0.2 – 20.0</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>Gluc</td>
<td>mmol/L</td>
<td>4 – 750</td>
</tr>
<tr>
<td>Lac</td>
<td>mmol/L</td>
<td>0.3 – 20.0</td>
</tr>
<tr>
<td>Hct</td>
<td>%</td>
<td>15 – 75</td>
</tr>
<tr>
<td>Hb</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>Total Bili</td>
<td>mg/dL</td>
<td>0.3 – 40</td>
</tr>
<tr>
<td>BUN*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Creat†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>tCO2†</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* The measured ranges reflect actual numeric value ranges the system can report.

Derived (calculated) Parameters

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Equation</th>
</tr>
</thead>
<tbody>
<tr>
<td>BE(B)</td>
<td>CvO2</td>
</tr>
<tr>
<td>BE(ecf)</td>
<td>pO2(pH)</td>
</tr>
<tr>
<td>tHb(c)</td>
<td>O2cap</td>
</tr>
<tr>
<td>Ca++(7.4)</td>
<td>sO2(c)</td>
</tr>
<tr>
<td>Antion gap</td>
<td>sO2(c)</td>
</tr>
<tr>
<td>P/F Ratio</td>
<td>HCO3(standard)</td>
</tr>
<tr>
<td>pAO2</td>
<td>Q(1)/Q(2)</td>
</tr>
<tr>
<td>Qsp/Qt</td>
<td></td>
</tr>
<tr>
<td>Hct(c)</td>
<td></td>
</tr>
<tr>
<td>CaO2*</td>
<td>A-aO2</td>
</tr>
</tbody>
</table>

For more information, call 1.800.955.9525 or visit www.ilus.com.

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