

# GEM<sup>®</sup> PREMIER<sup>™</sup> 4000 with IQM<sup>®</sup>

Advanced, simple, and revolutionary.

Automation and innovation  
at the touch of a button.



# GEM<sup>®</sup> PREMIER<sup>™</sup> 4000

## Now, automation is even better.

NEW

Our advanced PLUS technology enables:

- ▶ Faster touch-screen responsiveness
- ▶ Integrated wireless
- ▶ Remote service

**PLUS** 

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.



## 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



MENU	PAK SIZE					Onboard Use-life
	75	150	300	450	600†	
Blood Gas, Hct, tHb, O <sub>2</sub> Hb, HHb, COHb, MetHb, sO <sub>2</sub> , Total Bili*	✓	✓	✓	✓	✓	30 days
Blood Gas, Electrolytes, Hct, tHb, O <sub>2</sub> Hb, HHb, COHb, MetHb, sO <sub>2</sub> , Total Bili*	✓	✓	✓	✓	✓	30 days
Blood Gas, Electrolytes, Glu, Lac, Hct, tHb, O <sub>2</sub> Hb, HHb, COHb, MetHb, sO <sub>2</sub> , Total Bili*	✓	✓	✓	✓	✓	30 days

Menus with: Creat, BUN, and measured tCO<sub>2</sub> are in development.

\* Cartridges available with or without Total Bili.  
 † Onboard use-life is 21 days.

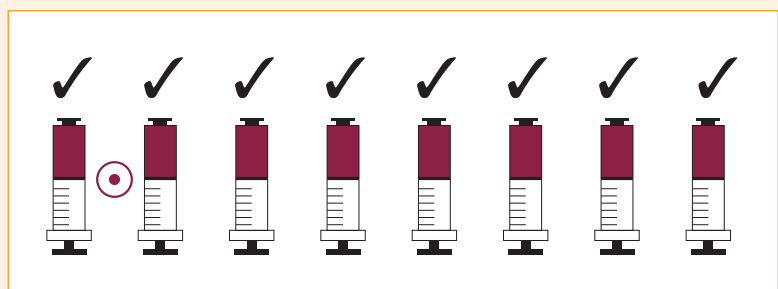
# Automated Quality Assurance

## 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*

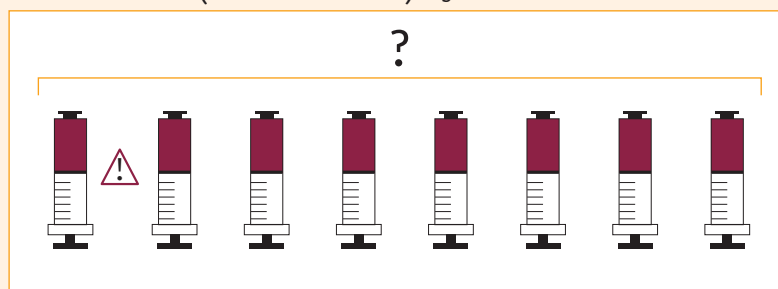


⊙ = Error automatically detected, corrected and documented immediately

✓ = Optimal test results ensured

0 —————> Continuous  
Time

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



⚠ = Error undetected

? = Questionable test results (*all results from eight-hour period require review*)

0 —————> 8 hrs  
QC IN Time QC OUT

Reduces Error Detection Time from Hours to Minutes<sup>1, 2</sup>

	pH	pO <sub>2</sub>	pCO <sub>2</sub>	Na <sup>+</sup>	K <sup>+</sup>	Ca <sup>++</sup>	Glu	Lac	Hct
<b>iQM</b>	3 mins	3 mins	3 mins	17 mins	3 mins	3 mins	11 mins	6 mins	3 mins
<b>Traditional QC</b> (Manual or Auto)	≥8 hrs	≥8 hrs	≥8 hrs	≥8 hrs	≥8 hrs	≥8 hrs	≥8 hrs	≥8 hrs	≥8 hrs

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

“ iQM: a new standard for the future of QC.”

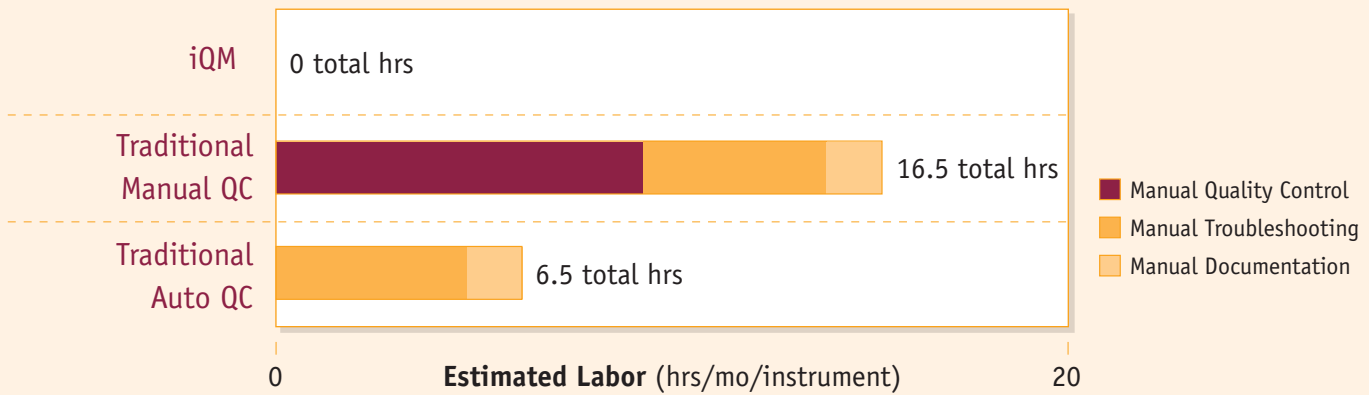
– James Westgard, PhD, developer of the ‘Westgard Rules’

References:

- Westgard JO, Fallon KD, Mansouri S. Validation of iQM Active Process Control Technology. *Point of Care, The Journal of Near-Patient Testing and Technology*, 2003: Vol. 2, No. 1.
- Toffaletti JG, McDonnell EH, Ramanathan LV, Tolnai J, Templin R, Pompa L. Validation of a quality assessment for a blood gas and electrolyte testing. *Clinica Chimica Acta*, 382 (2007) 65–70.

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



▶ 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



IL's patented iQM and all analytical components are included inside a single-component, self-contained PAK.

# Automated Information Management

## GEMweb Plus Custom Connectivity

True web-based, bi-directional management from any networked analyzer or PC, customized for your hospital.

### The ONLY connectivity software to:

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

### AND:

- ▶ 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

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

Integrated wireless for seamless communication to the LIS or HIS.



## GEMweb

### Automated, web-based information management

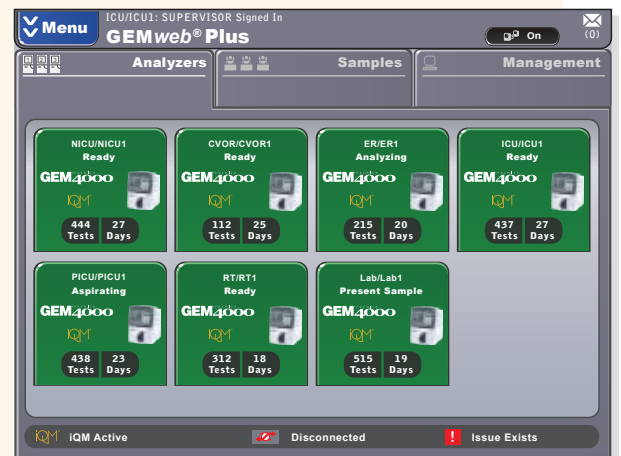
- ▶ Single, graphic user-interface
- ▶ Bi-directional operator management
- ▶ Remote analyzer review and control
- ▶ Remote iQM review
- ▶ Demographic query



## GEMweb Plus 100

### Everything GEMweb offers AND:

- ▶ Remote global/area/analyzer system configuration
- ▶ Consolidated:
  - Analyzer status and control
  - Operator management
  - iQM reports
  - Patient information management
- ▶ System-wide sample lookup database
- ▶ HIS and LIS order receiving and processing



## GEMweb Plus 200

### Everything GEMweb Plus 100 offers AND:

- ▶ Operator competency ensured through automated and customizable certification, including exams
- ▶ Advanced regulatory compliance management
- ▶ Audit log creation



## GEMweb Plus 100 & 200 Customizable Options

### More functionality, more flexibility

- ▶ Receipt of ADT transmissions, including positive patient ID verification
- ▶ Automated and customizable point-of-care order creation (solicited and unsolicited)

# 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  $\mu$ L)\*
- ▶ Ideal for nitric oxide therapy

### 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 assist in smoke-inhalation treatment
- ▶ Advanced GEMweb Plus connectivity—fully integrated, real-time information management



\* BG, Electrolytes, Metabolites, Hct I † Basic Metabolic Panel in development: BUN/Creat and measured tCO<sub>2</sub>

# 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

GEM Premier Analyzers	GEMweb Plus Custom Connectivity	GEM Complementary Products
<ul style="list-style-type: none"><li>▶ GEM Premier 4000</li><li>▶ GEM Premier 3500</li></ul>	<ul style="list-style-type: none"><li>▶ GEMweb Plus 200</li><li>▶ GEMweb Plus 100</li><li>▶ GEMweb Plus Customizable Options</li><li>▶ GEMweb</li></ul>	<ul style="list-style-type: none"><li>▶ GEMdraw</li><li>▶ GEM PCL Plus</li><li>▶ GEM OPL</li></ul>

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: 10 in, D: 8 in, Wt: 8 lbs

## Sample Volume

150 µL BG\*/Hct/Lytes\*\*/Glu/Lac/CO-Ox or any subset of the menu that includes CO-Ox

100 µL CO-Ox/Total Bili only

65 µL BG/Hct/Lytes/Glu/Lac

(micro mode) (capillary only)

\*BG = pH, pCO<sub>2</sub>, pO<sub>2</sub>

\*\*Lytes = Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>

## 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: pO<sub>2</sub>, Glu, Lac, Creat<sup>†</sup>

Potentiometric: pH, pCO<sub>2</sub>, Na<sup>+</sup>, K<sup>+</sup>, Ca<sup>++</sup>, Cl<sup>-</sup>, BUN,<sup>†</sup> measured tCO<sub>2</sub><sup>‡</sup>

Conductivity: Hct

Optical measurement following chemical lysing of the whole blood sample:

CO-Ox, Total Bili

<sup>†</sup> In development. Not currently saleable.

## Interface Protocols

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

## Measured Analytes

Analyte	Unit	Measured Range <sup>‡</sup>
pH	n/a	6.80 – 8.00
pCO <sub>2</sub>	mmHg	6 – 150
pO <sub>2</sub>	mmHg	5 – 800
Na <sup>+</sup>	mmol/L	100 – 200
K <sup>+</sup>	mmol/L	0.2 – 20.0
Ca <sup>++</sup>	mmol/L	0.10 – 5.00
Cl <sup>-</sup>	mmol/L	40 – 170
Glu	mg/dL	4 – 750
Lac	mmol/L	0.3 – 20.0
Hct	%	15 – 75
tHb	g/dL	3.0 – 23.0
O <sub>2</sub> Hb	%	-10.0 – 110.0
COHb	%	-10.0 – 110.0
MetHb	%	-10.0 – 110.0
HHb	%	-10.0 – 110.0
Total Bili	mg/dL	0.3 – 40
BUN <sup>†</sup>		
Creat <sup>†</sup>		
tCO <sub>2</sub> <sup>‡</sup>		

<sup>‡</sup> The measured ranges reflect actual numeric value ranges the system can report.

## Derived (calculated) Parameters

BE(B)	CvO <sub>2</sub>	paO <sub>2</sub> /pAO <sub>2</sub>
BE(ecf)	p <sub>50</sub>	RI
tHb(c)	O <sub>2</sub> cap	CcO <sub>2</sub>
Ca <sup>++</sup> (7.4)	sO <sub>2</sub>	a-vDO <sub>2</sub>
Anion gap	sO <sub>2</sub> (c)	Q <sub>sp</sub> /Q <sub>t</sub> (est)
P/F ratio	HCO <sub>3</sub> <sup>-</sup> std	Q <sub>sp</sub> /Q <sub>t</sub>
pAO <sub>2</sub>	HCO <sub>3</sub> <sup>-</sup> (c)	Hct(c)
CaO <sub>2</sub>	A-aDO <sub>2</sub>	

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