NEW GEM® PREMIER™ 3500 with iQM®

Test Assured in Critical Care Diagnostics.

Werfen Group | Instrumentation Laboratory

Instrumentation Laboratory 50 FIFTY AND FORWARD

Introducing the New GEM Premier 3500:

Fast, reliable whole blood testing for your lab and hospital.

Building on the unprecedented testing simplicity, flexibility and reliability of the GEM Premier 3000, the GEM Premier 3500 offers new capabilities in an enhanced system, adaptable to the needs—and volume—of your hospital and lab.

- **Simple.** Maintenance-free, multi-use, disposable cartridge PAKs and intuitive touchscreen menus are very easy to use.
- **Flexible.** Customized cartridge configurations and a broad test menu meet the needs of any location and any testing capacity, cost-effectively.
- **iQM.** IL's proprietary Intelligent Quality Management provides continuous, real-time quality control for the most accurate results, every time.
- **Total Connectivity.** GEMweb® software allows information management and real-time communication throughout the hospital.

PAKs contain all the components required for patient testing, are replaced every 21 days, and require no refrigeration.

More versatility and flexibility for faster, easier, more efficient critical care testing.

Self-Contained Cartridge PAKs

- Non-refrigerated disposable PAKs include all components for patient testing, and are maintenance-free

Intuitive Touchscreen

- Basic operation learned in minutes—simply press 'Go!' and present sample
- Easy-to-use, touchscreen displays and clear, concise menus simplify selection and customization of parameters, and viewing of results

GEMweb Connectivity, Enhanced with HL-7

- Allows wireless communication to LIS or HIS
- Patient and quality results can be viewed remotely from any networked PC

Enhanced Features

- Larger sampling area with LED light facilitates sampling
- Barcode scanner allows rapid data input

iQM

- Monitors all testing processes and components while providing continuous error detection and correction, 24 hours a day, 7 days a week

Complete Test Menu

- Customized cartridges include blood gases, electrolytes, metabolites, and hemocrit, with optional CO-Oximetry† and coagulation†† modules

Multiple Cartridge Configurations Offer Flexibility and Cost-Efficiency

Analyte Menu	Tests/PAK	Onboard Use Life (weeks)
BG*, Hct	35 75 150 300 450 600	4 4 3 3 3 2
BG, Lytes, Hct**	75 150 300 450 600	4 3 3 3 2
BG, Lytes, Glu, Lac, Hct	75 150 300 450 600	3 3 3 3 2

* BG = pH, pCO_2, pO_2
** Lytes = Na^+, K^+, Ca^{++}

† GEM OPL™ portable CO-Oximeter
†† GEM PCL™ Plus portable coagulation analyzer

iQM—IL's patented, real-time, automated, continuous quality assurance system—helps to ensure optimal test results for enhanced patient care.

Consistent Quality Assurance

- Active, continuous, real-time quality processing—even during use
- Reduces error detection time when compared to traditional QC
- Ensures optimal quality control protocol at all times, regardless of time of day or level of operator training
- Generates reports for regulatory compliance
- Continuously monitors and checks all critical components in real time
  - Sensors
  - Process Control Solutions
  - Failure Pattern Recognition software
  - Process stability

Improved Patient Care

- Automatically and continuously monitors, detects and corrects potential errors
- Assesses functionality and initiates and documents corrective action
- Prevents reporting of results when instrument tolerance limits are exceeded
- Helps ensure the quality and accuracy of each patient result

Reduces Error Detection Time from Hours to Minutes[1,2]

	pH	pO_2	pCO_2	Na^+	K^+	Ca^{++}	Glu	Lac	Hct
iQM*	3 min	3 min	3 min	17 min	3 min	3 min	11 min	6 min	3 min
Traditional/ Auto QC	≥8 hr	≥8 hr	≥8 hr	≥8 hr	≥8 hr	≥8 hr	≥8 hr	≥8 hr	≥8 hr

* Represents average time to error detection during sample processing.

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

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.
2. 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.

"iQM: A new standard for the future of QC."

– James O. Westgard, PhD*

A published study, analyzing 10,550 patient samples, confirms iQM is not only valid in the research environment, but is also proven in the *clinical* setting.[1]

Study Details

Conducted to clinically validate the performance claims of iQM, as reported by Westgard *et al.*[2]

- 10,550 patient samples
- Four major teaching institutions
- Compared iQM-measured QC values to traditional QC results
- Calculated the average error detection time for each measured analyte

Conclusions

Study results were published in the peer-reviewed, laboratory reference journal, *Clinica Chimica Acta*, as follows:

"The findings from our study confirm that (a) iQM precision in a clinical setting is comparable to that found in previous studies done in a research setting, (b) the improved precision of control material in iQM is likely because the internal control fluids are sealed and not susceptible to exposure from handling, and (c) the system detects and often corrects errors in specific samples that might not be reported by traditional analytical systems...iQM provides quality control results comparable to or better than those obtained with traditional QC methods running on the GEM or other benchtop analyzers...Furthermore, the error detection capabilities that function on every sample provide an additional safeguard against reporting erroneous results due to clots or interferences."[1]

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.
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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."

* Professor, Pathology and Laboratory Medicine, University of Wisconsin, and developer of 'Westgard Rules'.

GEMweb facilitates information exchange and remote management: iQM Delta Charts display detection and correction of errors to monitor quality and accuracy—even remotely.

GEMweb connectivity software—integrated information management for complete control...throughout the hospital system. *Now* wireless.

- New wireless configuration option provides mobility and greater flexibility for data management
- Remotely view status for all networked analyzers, in real time
- Search and view patient and quality results on all networked analyzers from any networked PC
- Request patient demographic information from the HIS/LIS
- Connects to HIS/LIS via ASTM or HL-7 protocol

Communicate wirelessly to LIS or HIS with GEMweb connectivity software

GEM Premier 3500
Technical Specifications

Dimensions and Weight
Analyzer
H: 17.5 in, W: 13 in, D: 11.8 in, Wt: 31.2 lbs

PAK
H: 6 in, W: 8.5 in, D: 3 in, Wt: 4.2 lbs

Sample Volume

135µL	BG*, Hct cartridges
135µL	BG, Lytes,** Hct cartridges
145µL	BG, Lytes, Glu, Lac, Hct cartridges (capillary mode)
150µL	BG, Lytes, Glu, Lac, Hct cartridges

*BG = pH, pCO_2, pO_2
**Lytes = Na^+, K^+ and Ca^{++}

Sample Type
Heparinized whole blood

Time to Results
All tests: 85 seconds from sample introduction

Measurement Methodology

Amperometric:	pO_2, Glu, Lac
Potentiometric:	pH, pCO_2, Na^+, K^+, Ca^{++}
Conductivity:	Hct

Power Requirements
Universal power input, 100–240 VAC, 50/60 Hz
60-minute power interrupt allows transport without power.

Temperature Control
Electrode Chamber maintained at 37°C nominal

Data Output Port
3 RS-232 Serial I/O Ports, 1 Parallel Printer Port, 1 Ethernet Port, 4 USB Ports

Product Safety
Complies with IEC 610101, IEC 61326, ISTA, and ASTM 999.

Interface Protocols
ASTM or HL-7 data transmission to a Laboratory, Hospital or third-party Information System via a wired or wireless connection.

Measured Analytes†

Analyte	*Displayed Ranges*	*Resolution*
pH	6.80 to 7.80	0.01
pCO_2	5 to 115 mmHg††	1 mmHg
pO_2	0 to 760 mmHg	1 mmHg
Na^+	100 to 200 mmol/L	1 mmol/L
K^+	0.1 to 20.0 mmol/L	0.1 mmol/L
Ca^{++}	0.10 to 5.00 mmol/L	0.01 mmol/L
Glu	5 to 500 mg/dL	1 mg/dL
Lac	0.2 to 15.0 mmol/L	0.1 mmol/L
Hct	15% to 65%	1%

† See Operator's Manual for complete validated ranges, specifications and performance characteristics
††pCO_2 trending to 150 mmHg available

Derived (calculated) Parameters

Derived Analytes	*Displayed Ranges*	*Resolution*
HCO_3^-	3.0 to 60.0 mmol/L	0.1 mmol/L
HCO_3^- std	3.0 to 60.0 mmol/L	0.1 mmol/L
TCO_2	3.0 to 60.0 mmol/L	0.1 mmol/L
BE(B) *(in vitro)*	–30.0 to 30.0 mmol/L	0.1 mmol/L
BE(ecf) *(in vitro)*	–30.0 to 30.0 mmol/L	0.1 mmol/L
SO_2C	0 to 100%	1%
$Ca^{++}(7.4)$	0.10 to 5.00 mmol/L	0.01 mmol/L

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