Acute Care Diagnostics

GEM® PREMIER™ 3500 with iQM®

Test assured at the point of care

werfen

Fast, reliable whole blood testing for your lab and hospital

With unprecedented simplicity, flexibility, and reliability, the GEM Premier 3500 offers an enhanced system, adaptable to the needs—and volume—of your hospital and lab.

- **Simple.** Maintenance-free, multi-use, disposable GEM PAKs, and intuitive touchscreen menus are 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.** Werfen's proprietary Intelligent Quality Management (iQM) provides continuous, real-time quality assurance for the most accurate results, every time
- **Total connectivity.** GEMweb® Plus 500 Custom Connectivity software allows information management and real-time communication throughout the hospital

GEM® PREMIER™ 3500 with iQM®

More versatility and flexibility for faster, easier, more efficient blood gas testing

Self-contained GEM PAK cartridges

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

Intuitive touchscreen

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

HIS/LIS connectivity, enhanced with HL-7

- Allows wireless communication to HIS/LIS
- 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

HIS = Hospital Information System
LIS = Laboratory Information System

iQM

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

Complete test menu

- Customized cartridges include blood gases, electrolytes, metabolites, and hematocrit

Multiple cartridge configurations

Analyte Menu	Tests/PAK	Onboard Use-Life (weeks)
BG, Hct	75 150 300 450 600	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++
Hct = Hematocrit
Glu = Glucose
Lac = Lactatez

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

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

Consistent quality assurance

- Performs active, continuous, real-time quality processing—even during use
- Reduces error detection time when compared with traditional (auto or manual) quality control (QC)
- Ensures optimal QC protocol at all times, regardless of time of day or level of operator training
- Generates reports for accreditation compliance
- Continuously monitors and checks all critical components in real time
  - Sensors
  - Process Control Solutions
  - 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 statistical presentation of average time to error detection during sample processing with 95% confidence.

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

– James O. Westgard, PhD*

A published study, analyzing more than 10,000 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 validate the performance claims of iQM, in a clinical setting as reported by Westgard, et al. and published in the peer-reviewed laboratory reference journal *Clinica Chimica Acta*.[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

"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 QC 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]

What is iQM?†

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."

†Cleared for GEM Premier 4000.

††To ensure that a total quality management system is adhered to, local, state and federal regulatory guidelines should be followed.

Management and compliance simplified

GEMweb Plus 500 provides customizable connectivity and automated functionality for comprehensive management of systems and data oversight.

Simple, intuitive dashboard, accessible from any PC or tablet.

Simplify POCT

- Simple web access from any browser
- Optimized interface for access from any PC and tablet devices
- Easy at-a-glance dashboard, with color-coded system status and actionable information highlighted

Centralize POCT

- Single, unified database provides access to patient results
- Centralized access to iQM data on GEM Premier 3500/4000 and GEM Premier ChemSTAT® systems
- Centralized access to iQM2 data on GEM Premier 5000 systems*
- Customizable to multiple connection types, including patient monitors, HIS/LIS and ADT
- Open connectivity, including select non-Werfen systems

ADT = Admission, Discharge, Transfer • POCT = Point-of-Care Testing

*Not available in all countries.

‡Contact your local representative for information on non-Werfen device connectivity and availability.

Technical specifications

Dimensions and Weight

System

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

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

Sample Type

Heparinized whole blood (sodium or lithium only)

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 61010-1 and 61010-2-101 IVD, 61326-1 and 61326-2-6 IVD, ISTA

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

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. *Clin Chim Acta*. 2007; 328:65-70.
2. Westgard JO, Fallon KD, Mansouri S. Validation of iQM active process control technology. *Point Care*. 2003;2(1):1-7.

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