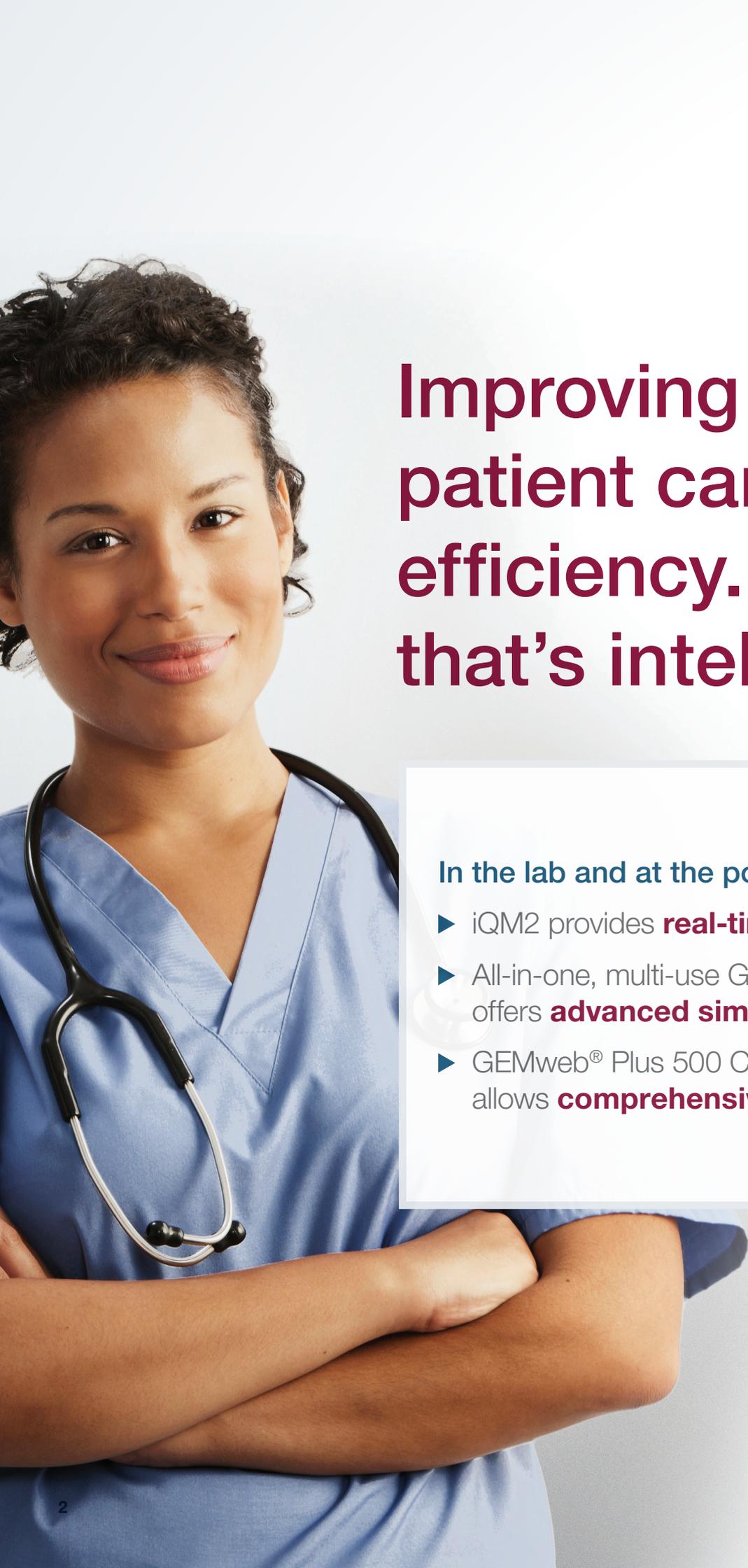


The Intelligent Analyzer



Now with
new features





Improving patient care and efficiency. Now that's intelligent.

In the lab and at the point of care:

- ▶ iQM2 provides **real-time assurance**
- ▶ All-in-one, multi-use GEM PAK cartridge offers **advanced simplicity**
- ▶ GEMweb® Plus 500 Custom Connectivity allows **comprehensive management**

Real-time quality assurance, everywhere

iQM2 with IntraSpect™ technology provides intelligent analyzing—automated quality assurance with every sample, continuously and in real time, unlike traditional (auto or manual) quality control (QC) offerings.

Real-time detection

Performs continuous checks—**before**, **during** and **after** every sample.

Immediate, automatic correction

Automatic documentation

Advanced simplicity, anywhere

GEM PAK cartridges

- Self-contained and multi-use
- Available in a variety of menu and test-volume configurations, allowing ultimate flexibility for the specific needs of units (e.g., ICU, NICU, CVOR, ED)
- **31-day[†]** use-life and **no refrigeration** required

[†]21-day onboard use-life for 600-test GEM PAK.

Simplified connectivity, compliance and control

GEMweb Plus 500 Custom Connectivity provides customizable connectivity and automated functionality for management of systems, operators and data oversight

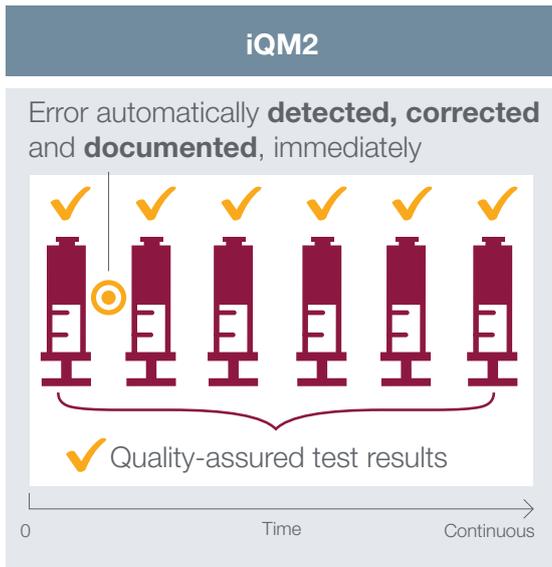
- Easy web access from any browser
- Intuitive, at-a-glance dashboard
- Real-time remote management of system configuration



New features deliver advanced cybersecurity, enhanced Wi-Fi and remote support.

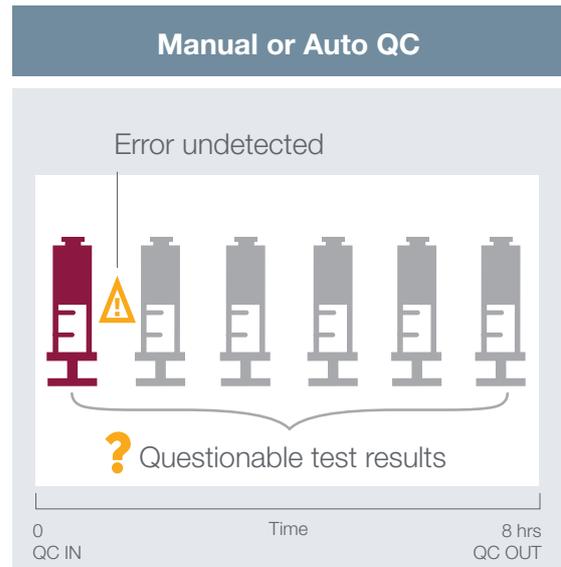
iQM2: Real-time detection, correction and documentation

- A complete picture of quality for each and every sample
- Designed to mitigate risks in all phases of testing, from pre-analytical through post-analytical



iQM2 assures quality continuously

VS.



ALL results from 8-hour period require review

Reduces error detection time from hours to minutes^{1,2} and detects transient sample-specific errors that traditional QC methods could miss.

	pH	pO ₂	pCO ₂	Na ⁺	K ⁺	Ca ⁺⁺	Cl ⁻	Glu	Lac	Hct	tHb	tBili
iQM2* (mins)	2	2	2	4.1	2	2	2	16.8	2	2	2	2
Traditional QC (manual or auto)	← ≥8 hrs →											

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

Automated, real-time assurance helps ensure accurate results with every sample.

- Fast and quality-assured test results allow for immediate patient management decisions
- Eliminates unnecessary retesting, for higher patient and staff satisfaction
- Allows more time for patient care

*Together with J. Westgard, PhD, a methodology for optimizing high probability of error detection and low probability of false rejection of drift limits was established. Method performance (mean and Standard Deviation), of measured Process Control Solution (PCS) values were obtained from the data of 276 GEM PAK cartridges used in Proof-of-Performance and external studies for the GEM Premier 5000 system.

How is it possible?

- **iQM2 functions within a stable, closed analytical system**
 - Eliminates outside variables
 - Ensures errors are known and limited
- **Identifies errors through patented Pattern Recognition software**
 - Pattern Recognition is at the heart of iQM2 functionality
 - Possible only with a stable, closed analytical system to which users cannot introduce change
- **Analyzes 5 levels of Process Control Solutions (PCSs) continuously to confirm sensor and PAK performance**

All-in-one, multi-use GEM PAK



Continuous monitoring through 5 PCSs across Medical Decision Levels (MDLs)

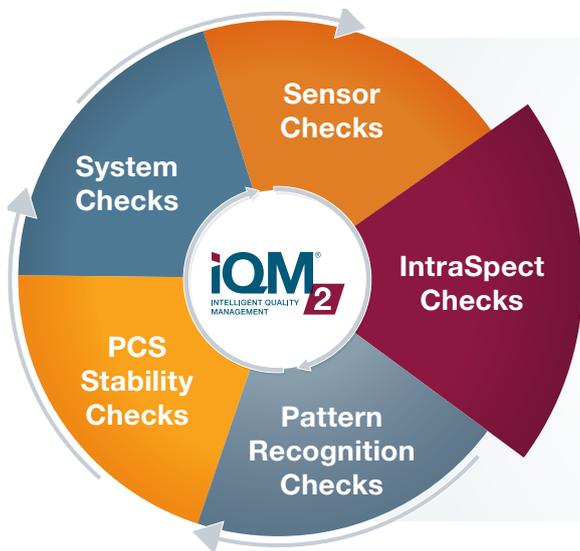
- PCSs are traceable to Clinical & Laboratory Standards Institute (CLSI) procedures, National Institute of Standards and Technology (NIST) standards or other internal standards
- Each PCS follows the same pathway as a patient sample and serves a specific function in the iQM2 process
- Established target values monitor MDLs and ensure accuracy of results
- Monitoring MDLs is essential to ensure accuracy in clinical decisions, particularly in critically ill patients (e.g., lactate MDLs align with recommended values for treatment of sepsis)

Only iQM2 ensures the integrity of every sample

Exclusive to the GEM Premier 5000 system, iQM2 provides continuous quality management with integrity checks before, during and after every sample analysis.

- Features patented Pattern Recognition technology in a stable, single-cartridge, closed system, to enable detection of errors originating from the pre-analytical phase
- IntraSpect auto-detects sample-specific, transient errors during sample analysis other QC methods could miss
- Auto-documents all errors and corrections
- Generates operator-specific and sample-quality-specific reports for quality improvement initiatives*

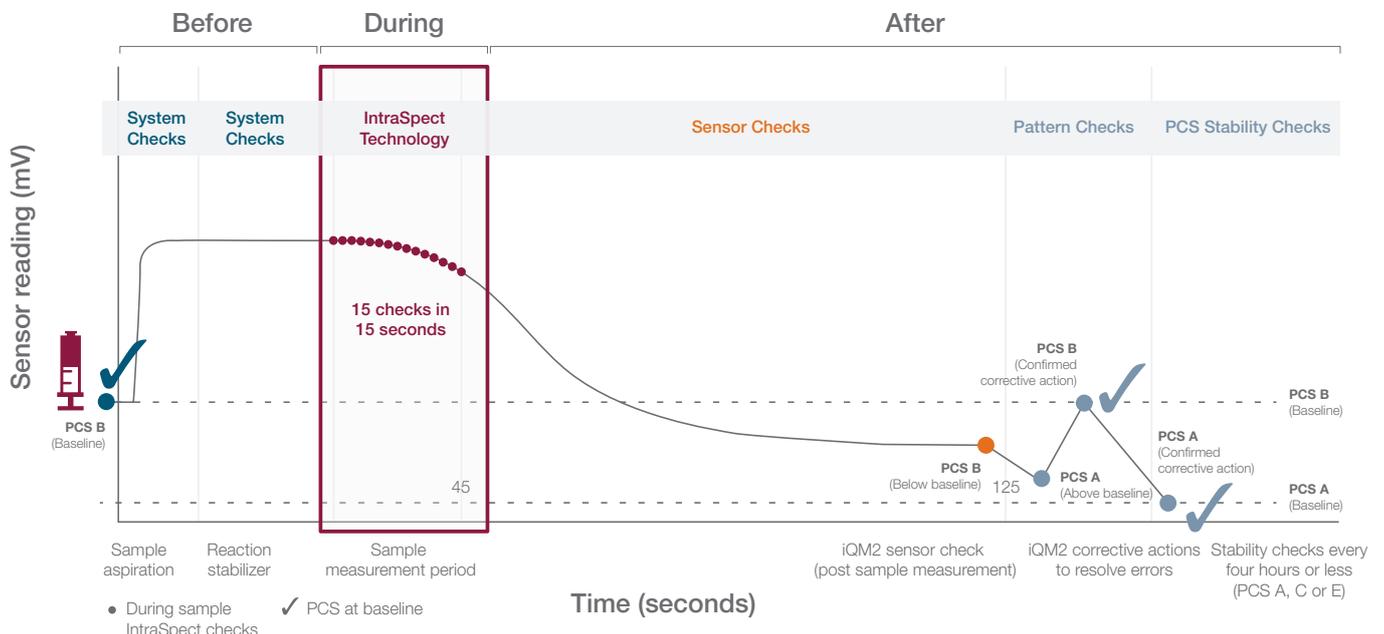
*Available through GEMweb Plus 500 Custom Connectivity.



Continuous cycle of 5 quality checks—more than any other blood gas system. And, only iQM2 has IntraSpect technology.

Traditional QC methods can miss sample-specific, transient errors (e.g., micro-clots, micro-bubbles, and interferences), potentially impacting current or future sample integrity.

Checks before, during and after every sample for a complete picture of quality.



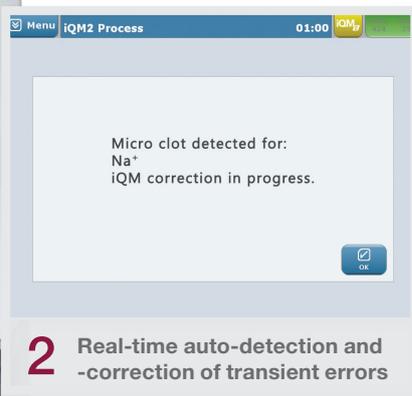
Only iQM2 offers complete automation of quality management

Performs auto-detection, -correction and -documentation, and creates sample-handling reports, tailored training programs and certification—uniquely improving quality and management.*

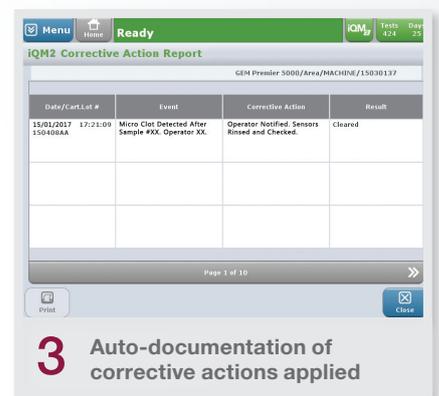
*Reports available through GEMweb Plus 500 Custom Connectivity.



1 Real-time error detection



2 Real-time auto-detection and -correction of transient errors



3 Auto-documentation of corrective actions applied

Operator ID	210		
Last Name, First Name	Bachelder, Vanesa		
Event Rate	4 events for 224 samples (1.78%)		
Event	Analysis Date/Time	Area	Analyzer
Micro Clot Detected	06/25/2019 14:47:30	CVOR 1	G5000 1
	06/25/2019 14:13:32	CVOR 1	G5000 1
Absorbance Error	06/26/2019 14:37:11	OR 2	AAAC-5
	06/13/2019 14:37:46	OR 2	AAAC-5
Operator ID	z34		
Last Name, First Name	Wadleigh, Oleta		
Event Rate	4 events for 228 samples (1.75%)		
Event	Analysis Date/Time	Area	Analyzer
Micro Clot Detected	06/28/2019 14:38:06	CVOR 1	G5000 1
	06/28/2019 13:46:36	CVOR 1	G5000 1
	06/28/2019 13:42:32	CVOR 1	G5000 1
	06/28/2019 13:38:54	CVOR 1	G5000 1

4 Sample-handling reports, traceable to operator or clinical setting (from GEMweb Plus 500 Custom Connectivity)

“iQM2 manages the quality control process, replacing external quality control.”

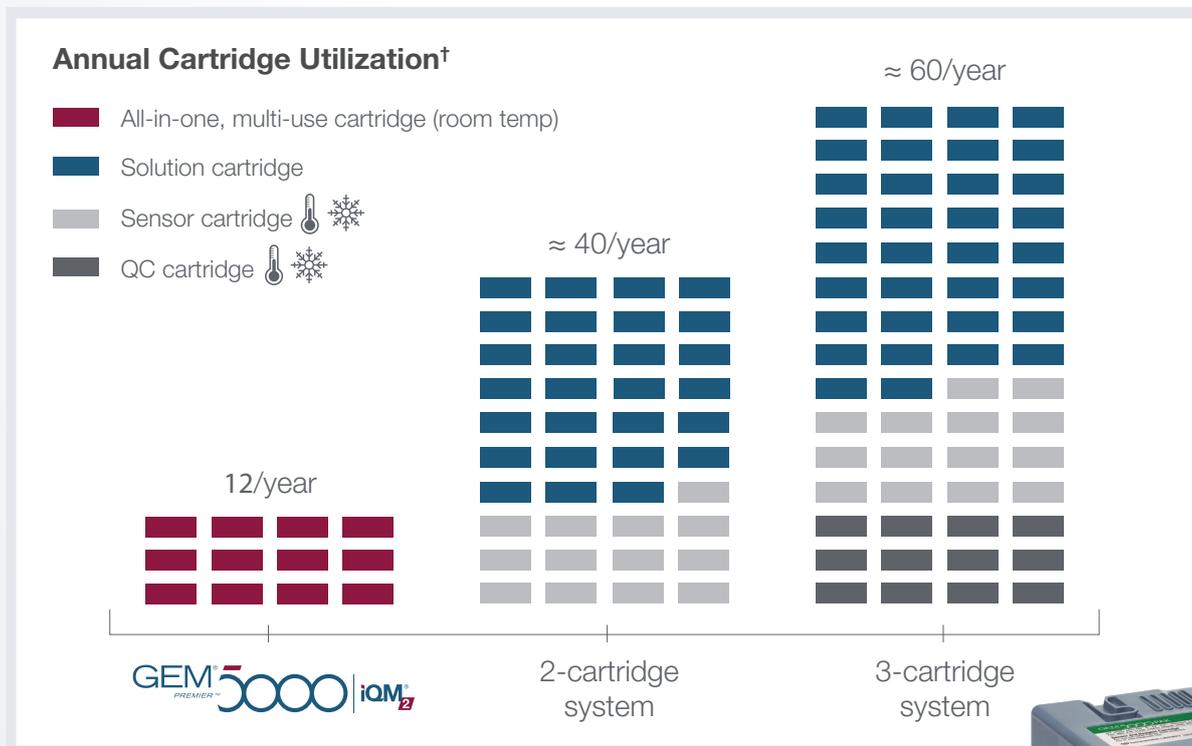
— US Food and Drug Administration

GEM PAK: Advanced simplicity at every point of care

Automates the most labor- and skill-intensive processes.

- Zero maintenance—just replace the disposable, all-in-one, multi-use GEM PAK cartridge monthly; no additional cartridge-handling required**
 - Includes all testing components: sensors, CO-Ox optical cell, lysing solution, PCSs, tubing, waste bag and sampler
 - Only 1 PAK to inventory and manage
 - No hands-on troubleshooting or corrective actions required
- Ensures patient and operator safety**
 - All components are self-contained, limiting operator biohazard exposure
 - No blood enters the instrument, limiting infection exposure for patient and operator
- Ultimate simplicity—no special requirements**
 - Easy front-loading
 - Room-temperature storage; no refrigeration required
 - Replaced every 31 days—only 12 GEM PAKs per year*
 - Ideal for high- and low-volume testing

Significantly fewer cartridges used vs other systems



GEM PAK contains all analytical and quality control components.



*Assumes constant test volume of 450 samples/month or less.

† Based on 1 instrument with annual sample volume ≈ 4,800 and QC requirement of 3 times/day. Data on file.

‡ Requires refrigeration.

Management and compliance simplified

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



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

Simplify POCT

- Simple web access from any browser
- Optimized interface for access from instrument and tablet devices
- Easy at-a-glance dashboard
- Real-time remote management of system configuration without testing interruption
- Total automated management of operators with multi-level authorization and traceability of users, actions and competence

Centralize POCT

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

*Not available in all countries.

LIS = Laboratory Information System • HIS = Hospital Information System • ADT = Admission, Discharge, Transfer • POCT = Point-of-Care Testing

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



New advanced features ensure optimum cybersecurity and efficiency

Powerful cybersecurity protects system from malware threats and unauthorized access through continual monitoring and proactive prevention

- Offers more robust protection with whitelisting, a proactive approach to safeguarding from security threats
- Continuous vigilance with security-by-design, ongoing vulnerability testing, and rapid patching, with Linux Long-Term Support
- Delivers firewall protection

Enhanced integrated Wi-Fi simplifies and streamlines processes

- Enables system portability between patient rooms and departments with continuous connection, maximizing system uptime and optimizing POCT flexibility

Remote support

- Enables remote screen sharing with Technical Support

A system designed for enhanced efficiency and patient care

Efficiency

- Automate system and operator management
- Manage quality in self-contained GEM PAKs
- Eliminate outside variability
- Eliminate maintenance
- Customize GEM PAK menu and volume for specific clinical unit needs
- Allow system-wide control from any instrument or PC
- Easily access documentation

Patient care

- Ensure rapid, quality-assured test results with every sample, not just every 8 hours
- Identify and reduce risks associated with testing processes before, during and after every sample
- Mitigate erroneous result reporting
- Eliminate maintenance and troubleshooting at POC, allowing more time for patient care

References

1. Westgard JO, Fallon KD, Mansouri S. Validation of iQM active process control technology. *Point Care*. 2003;2:1–7.
2. Toffaletti JG, McDonnell EH, Ramanathan LV, Tolnai J, Templin R, Pompa L, et al. Validation of a quality assessment of blood gas and electrolyte testing. *Clin Chim Acta*. 2007;382:65–70.



What's unique about the GEM Premier 5000 system?

Advanced Simplicity

NEW
Cybersecurity for optimum protection

NEW
Enhanced integrated Wi-Fi for maximal flexibility in POCT

NEW
Seamless connectivity to remote Technical Support

Smartcolor status bar
Analyzer status at a glance

iQM² with IntraSpec technology
Provides a complete picture of quality for each sample

Custom Quick Start sampling
Programmed shortcuts expedite testing

Fast time to result
45 seconds including quality checks

Illuminated sampling area
Ensures proper capillary or syringe insertion

i-button for iQM2
Conveys real-time iQM2 status

Universal sampling
Accepts tubes, syringes or capillaries

Motion-detection barcode reader
Enables one-hand use

Real-Time Assurance

AutoPAK validation
Standardizes time-to-ready state



Integrative solutions at the speed of life

The GEM Premier 5000 system is part of our broad Acute Care Diagnostics portfolio. From the ED to the ICU, acute care requires timely, decisive action, based on accurate diagnostic assessment. That's why thousands of hospitals trust Acute Care Diagnostics solutions from Werfen. Our Whole Blood Hemostasis and Blood Gas products deliver quality results, quickly and simply, for utmost efficiency and enhanced patient care.

Technical Specifications

Measured Analytes

	Unit
pH	n/a
pCO ₂	mmHg
pO ₂	mmHg
Na ⁺	mmol/L
K ⁺	mmol/L
Ca ⁺⁺	mmol/L
Cl ⁻	mmol/L
Glu	mg/dL
Lac	mmol/L
Hct	%
tHb	g/dL
O ₂ Hb	%
COHb	%
MetHb	%
HHb	%
tBili	mg/dL
sO ₂ *	%

*sO₂ = O₂Hb/O₂Hb+HHb.

Derived (Calculated) Parameters

BE(B)	pAO ₂	O ₂ ct	RI
BE(ecf)	CaO ₂	HCO ₃ ⁻ std	CcO ₂
tHb(c)	CvO ₂	TCO ₂	a-vDO ₂
Ca ⁺⁺ (7.4)	p ₅₀	HCO ₃ ⁻ (c)	Q _{sp} /Q _t (est)
Anion gap (AG)	O ₂ cap	A-aDO ₂	Q _{sp} /Q _t
P/F ratio	sO ₂ (c)	paO ₂ /pAO ₂	Hct(c)
Osm	OI		

Flexible Customization

Test volumes: 75, 150, 300, 450, 600[†]

Menu

Blood Gas, Hct, tHb, O₂Hb, HHb, COHb, MetHb, sO₂, tBili[‡]

Blood Gas, Electrolytes, Hct, tHb, O₂Hb, HHb, COHb, MetHb, sO₂, tBili[‡]

Blood Gas, Electrolytes, Glu, Lac, Hct, tHb, O₂Hb, HHb, COHb, MetHb, sO₂, tBili[‡]

[†]Onboard use-life is 31-days, except 600-test PAK (21-days).

[‡]PAKs available with or without tBili.

Corporate Headquarters

Plaza de Europa, 21-23
08908 L'Hospitalet de Llobregat
Barcelona, Spain
+34-93-4010101

Headquarters and Technology Center, Hemostasis and Acute Care Diagnostics

180 Hartwell Road
Bedford, MA 01730-2443
USA
+1-781-861-0710

Worldwide Locations

The Americas

Brazil
São Paulo
+55-11-46227878

Canada
Richmond Hill, ON
+1-800-552-2025 x6115

Colombia
Bogotá
+57-15-221-052

Mexico
Mexico City
+52-55-5262-1760

Uruguay
Montevideo
+5982-481-81-33

USA
Bedford, MA
+1-781-861-0710

Asia-Pacific

Australia
Sydney
+61-02-9098-0200

China
Beijing
+86-10-59756055

Hong Kong
+852-2792-7773
Shanghai
+86-21-66308671

India
New Delhi
+91-490-29-550

Japan
Tokyo
+81-3-5419-1301

Korea
Seoul
+82-1899-9217

Thailand
Bangkok
+66-271-226-28/9

Europe

Austria
Vienna
+43-1-256-58-000

Belgium
Brussels
+32-2-7252052

Czech Republic
Prague
+420-246-090-931

France
Paris
+33-182-30-86-00

Germany
Munich
+49-89-909070

Hungary
Budapest
+36-1-882-73-10

Italy
Milan
+39-02-25221

Lithuania

Kaunas
+370-37-313157

The Netherlands
Breda
+31-76-5480100

Poland
Warsaw
+48-22-336-18-00

Portugal
Lisbon
+351-214247312

Russia
Moscow
+7-499-124-45-59

Spain
Barcelona
+34-902-20-30-90

UK
Warrington, England
+44-1925-810141

werfen.com

For more information, contact your local Werfen sales representative or distributor.

GEM, Premier, GEM Premier ChemSTAT, ChemSTAT, GEMweb, IQM, Hemochron, VerifyNow, Avoximeter and ROTEM are trademarks of Instrumentation Laboratory Company and/or one of its subsidiaries or parent companies and may be registered in the United States Patent and Trademark Office and in other jurisdictions. The Werfen logo is a trademark of Werfen and may be registered in the Patent and Trademark Offices of jurisdictions throughout the world. All other product names, company names, marks, logos and symbols are trademarks of their respective owners.

©2021 Instrumentation Laboratory. All rights reserved.