



The Intelligent Analyzer.

Assuring quality before, during and after sample analysis—for improved patient care.



Improving patient Now that's intellig

With the GEM Premier 5000 system:*

NEW

iQM2 provides **real-time assurance**

- ▶ All-in-one, multi-use GEM PAK offers **advanced simplicity**
- ▶ GEMweb® Plus 500 Custom Connectivity allows **complete control**

In the lab and at the point-of-care



care and efficiency. ent.

Real-time quality assurance, everywhere

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

Real-time detection

iQM2 performs continuous checks—**before, during** and **after** every sample.

Immediate, automatic correction

Automatic documentation

Advanced simplicity, anywhere

- Self-contained GEM PAKs
- Available in different menu and test-volume configurations
- Allow ultimate flexibility for the needs of specific units (e.g., ICU, NICU, CVOR, ED)
- **31-days**** use-life and **require no refrigeration**

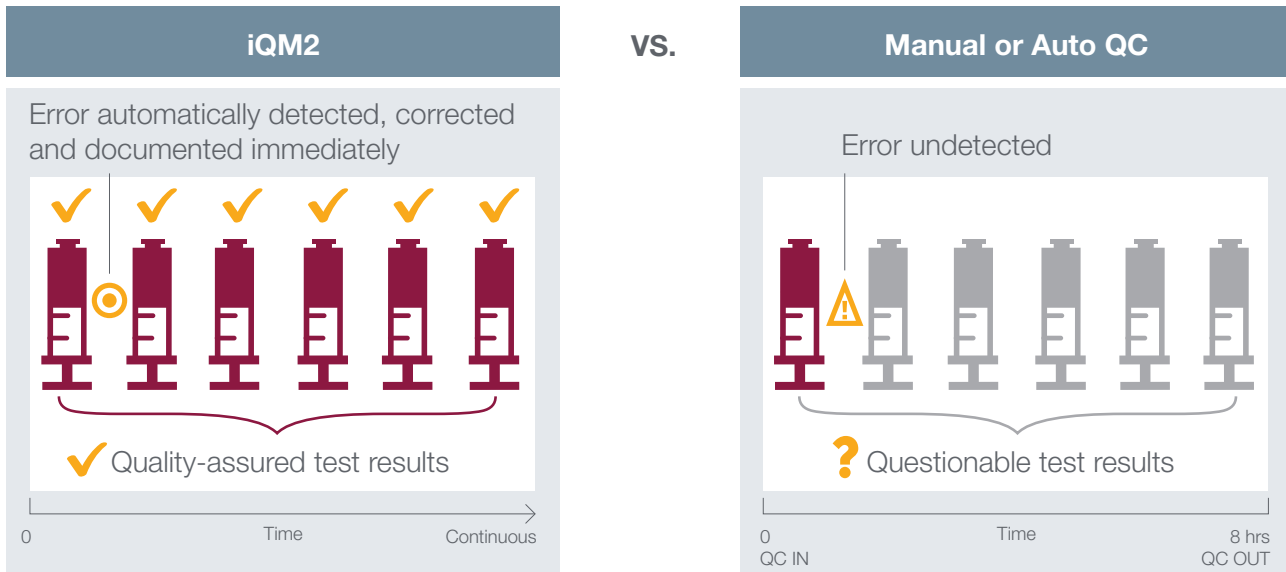
** 21-day onboard use-life for 600-test PAK.



30 different GEM PAK configurations available.

iQM2: real-time detection, correction and documentation

- Error detection reduced from hours to minutes
- 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

All results from 8-hour period require review

iQM2 reduces error detection time from hours to minutes^{1,2} and detects transient sample-specific errors that traditional QC methods 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 with iQM2 enhances patient care and comfort

- Provides caregivers more time at the bedside
- Fast and quality-assured test results allow for immediate patient management decisions
- Eliminates unnecessary retesting for higher patient and staff satisfaction

*Together with James Westgard, PhD, IL established the methodology for optimizing high probability of error detection and low probability of false rejection of drift limits. Method performance, in terms of mean and Standard Deviation, of measured PCS values were obtained from the data of 276 GEM PAK cartridges used in Proof-of-Performance and beta trials for the GEM Premier 5000 analyzer.

How is it possible?

- **iQM2 functions within a stable, closed analytical system**
 - Eliminates outside variables
 - Ensures errors are known and limited
 - Predicts errors through Patented Pattern Recognition software
- **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 at Medical Decision Levels (MDLs)

- PCSs are traceable to Clinical & Laboratory Standards Institute (CLSI) and National Institute of Standards and Technology (NIST) primary standards
- Each PCS follows the same pathway as a 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 ensuring accuracy in clinical decisions, particularly in critically ill patients (e.g., Lactate MDLs align with recommended values for treatment of sepsis)

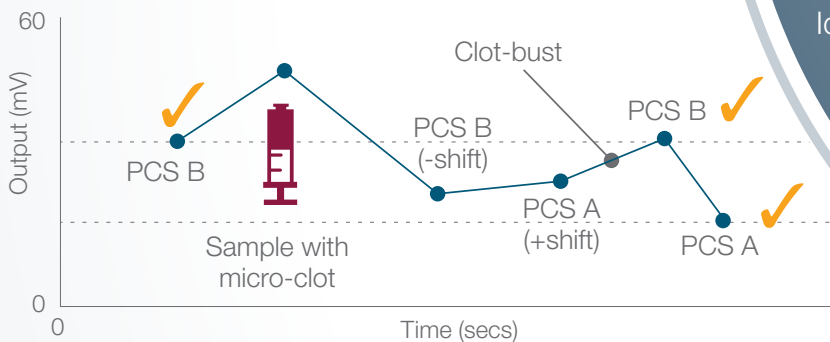
iQM2: a continuous cycle of 5 quality checks

iQM2 runs quality checks for every sample. This ensures accuracy of results, regardless of the sample.

All-in-one PAK for continuous process control



Pattern sensor signals before, during and after each sample



IntraSpect: how it works

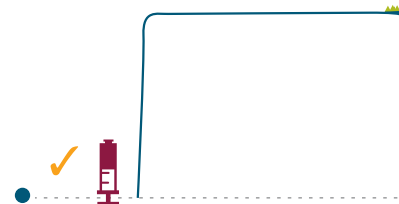
IntraSpect checks can detect abnormal sensor response or residual error **during** the measurement process, which may be caused by:

- Micro-clots*
- Micro-bubbles
- Interferences

These errors may be transient, with no residual error remaining after analyzer rinse. Thus traditional QC methods could leave errors undetected during sample analysis, adversely affecting test results.

How IntraSpect detects errors

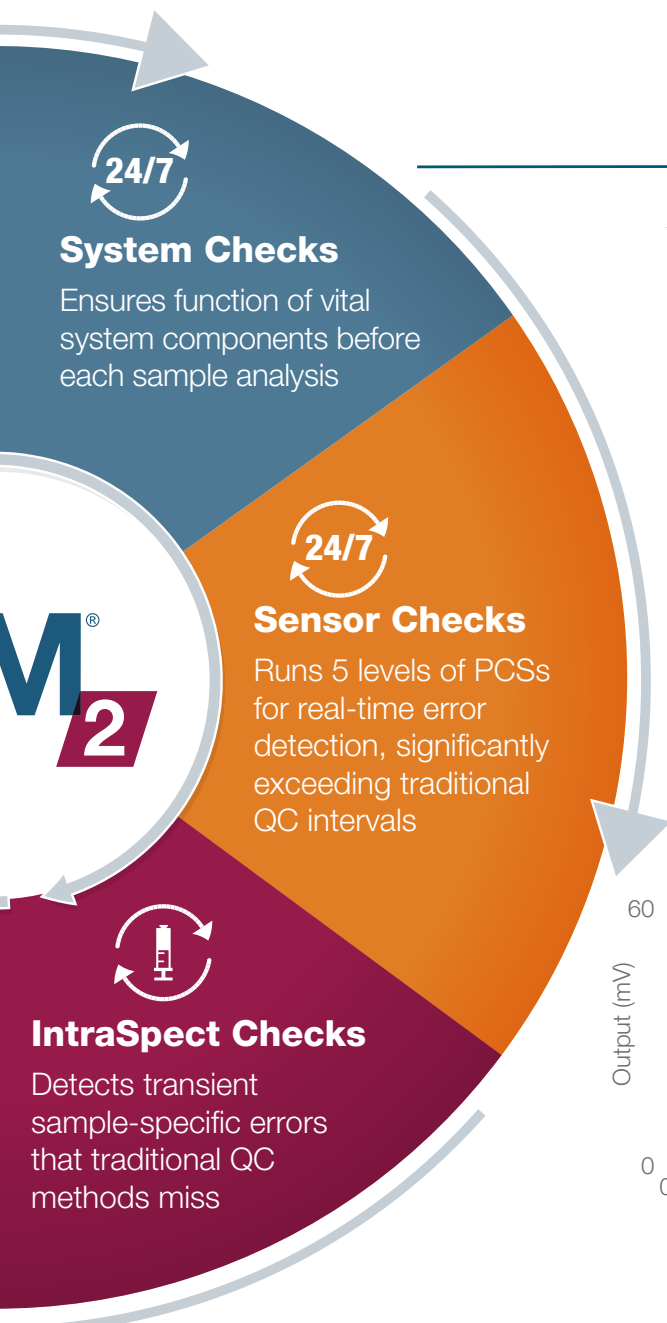
IntraSpect identifies sensor-slope



*Micro-clots are small blood clots or fibrin strands that adhere to a sensor and induce a change in sensor characteristics.

Quality checks for intelligent analysis

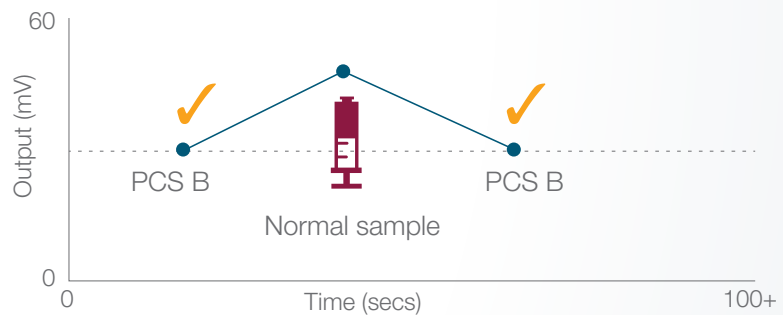
Simple analysis, before, during and after.
 Less of point-of-care operator, time or place.



Automatic system component checks

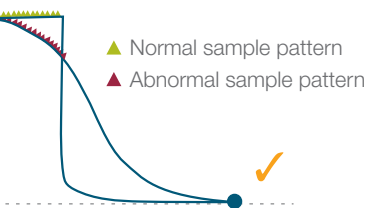


Sensor checks before and after each sample



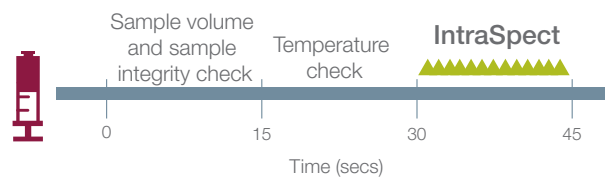
Detects an abnormal sample

Identifies the shape and coefficient deviation.



15 in 15

15 sensor readings are collected and analyzed in 15 seconds.

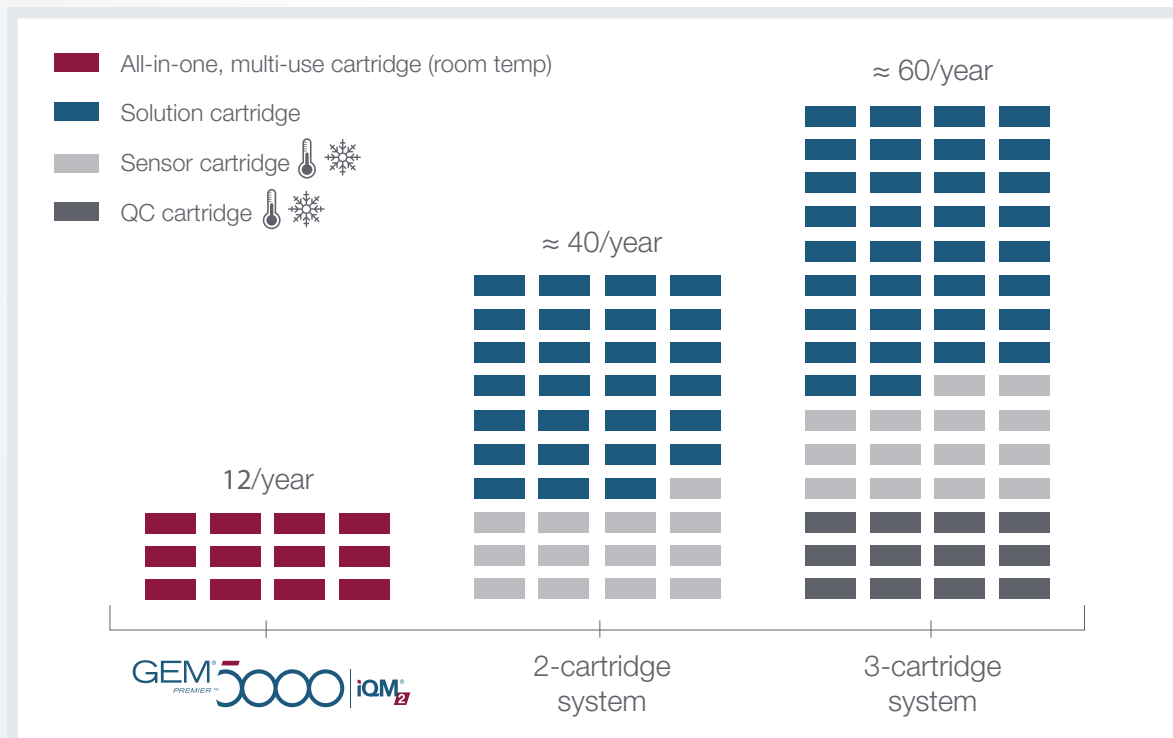


GEM PAK: advanced simplicity at every point of care

Automates the most labor- and skill-intensive processes

- **Zero maintenance—just replace the disposable, all-in-one, multi-use PAK 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, including all solutions, sensors and quality control
 - No hands-on troubleshooting or corrective actions required
- **Ensures patient and operator safety**
 - All components are self-contained, limiting biohazard exposure for operator
 - No blood enters the analyzer, 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 PAKs per year*
 - Ideal for high- and low-volume testing

Annual Cartridge Utilization Comparison†



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

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

❄️ Requires refrigeration.

GEM PAK contains all analytical and quality control components.



Management and compliance simplified

GEMweb Plus 500 Custom Connectivity provides customizable connectivity and automated functionality for complete control of analyzers, operators and data oversight.



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

Simplify POCT

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

Centralize POCT

- Single unified database to access patient samples and historical results
- Data connection to iQM on GEM Premier 3500 and 4000 systems
- Data connection to iQM2 on GEM Premier 5000 systems
- Customizable to multiple connection types, including patient monitors, EHR and ADT
- Open connectivity, including analyzers from non-IL manufacturers

What's new about the GEM Premier 5000 system?

Advanced Simplicity *outside*



Custom Quick Start sampling

Programmed shortcuts expedite testing

Illuminated sampling area

Ensures proper capillary or syringe insertion

Universal sampling

Accepts tubes, syringes or capillaries

Smartcolor status bar

Analyzer status at a glance

Fast time to result

45 seconds including quality checks

i-button for iQM2

Conveys real-time iQM2 status

Motion-detection barcode reader

Enables one-hand use

iQM² with IntraSpect™ technology

Provides a complete picture of quality for each sample

Real-Time Assurance

inside



AutoPAK Validation

Standardizes time-to-ready state

Improve patient care *and* efficiency

Improved patient care

- Rapid, quality-assured test results with every sample, not just every 8 hours
- Identifies and reduces risks associated with testing processes before, during and after every sample
- Prevents the reporting of erroneous results
- Enables staff to spend more time at the patient's bedside



Ask your IL representative for a customized time, resource and storage calculation.

Improved efficiency

- Automates analyzer and operator management
- Manages quality in self-contained GEM PAKs
- Eliminates outside variability
- Eliminates maintenance
- Menu- and volume-specific GEM PAKs allow analyzer customization tailored to unit needs
- Allows system-wide control from any analyzer or PC
- Keeps documentation just a click away

A complete solution for improved patient care and efficiency.



GEM[®] 5000
PREMIER™

iQM[®]
2

GEMweb[®] Plus
CUSTOM CONNECTIVITY

Technical Specifications

Quantitative Measured Analytes

Analyte	Unit
pH	n/a
$p\text{CO}_2$	mmHg
$p\text{O}_2$	mmHg
Na^+	mmol/L
K^+	mmol/L
Ca^{++}	mmol/L
Cl^-	mmol/L
Glu	mg/dL
Lac	mmol/L
Hct	%
tHb	g/dL
O_2Hb	%
COHb	%
MetHb	%
HHb	%
tBili	mg/dL
sO_2^*	%

* $\text{sO}_2 = \text{O}_2\text{Hb}/\text{O}_2\text{Hb}+\text{HHb}$.

Derived (Calculated) Parameters

BE(B)	$p\text{AO}_2$	O_2ct	RI
BE(ecf)	CaO_2	$\text{HCO}_3^- \text{ std}$	CcO_2
tHb(c)	CvO_2	TCO_2	a- vDO_2
Ca^{++} (7.4)	p_{50}	$\text{HCO}_3^- \text{ (c)}$	$Q_{sp}/Q_t \text{ (est)}$
Anion gap (AG)	O_2cap	A-a DO_2	Q_{sp}/Q_t
P/F ratio	$\text{sO}_2\text{(c)}$	$p\text{aO}_2/p\text{AO}_2$	Hct(c)

Flexible Customization

Test volumes: 75, 150, 300, 450, 600**

Menu

Blood Gas, Hct, tHb, O_2Hb , HHb, COHb, MetHb, sO_2 , tBili†

Blood Gas, Electrolytes, Hct, tHb, O_2Hb , HHb, COHb, MetHb, sO_2 , tBili†

Blood Gas, Electrolytes, Glu, Lac, Hct, tHb, O_2Hb , HHb, COHb, MetHb, sO_2 , tBili†

**Onboard use-life is 31-days, except 600-test PAK, which is 21-days.

† PAKs available with or without tBili.

Real-time assurance and advanced simplicity. Now that's intelligent.

1. Westgard JO, *et al.* Validation of iQM active process control technology. *Point of Care, The Journal of Near-Patient Testing and Technology*. 2003:Vol. 2, No. 1.
2. Toffaletti JG, *et al.* Validation of a quality assessment of blood gas and electrolyte testing. *Clinica Chimica Acta*. 2007:382:65–70.

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