



## ***The Intelligent Analyzer.***

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

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



With the GEM Premier 5000 system:\*

**NEW** iQM2 provides **real-time assurance**

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

In the lab and at the point-of-care

## Real-time quality assurance, everywhere

New iQM2 with IntraSpect<sup>™</sup> 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.

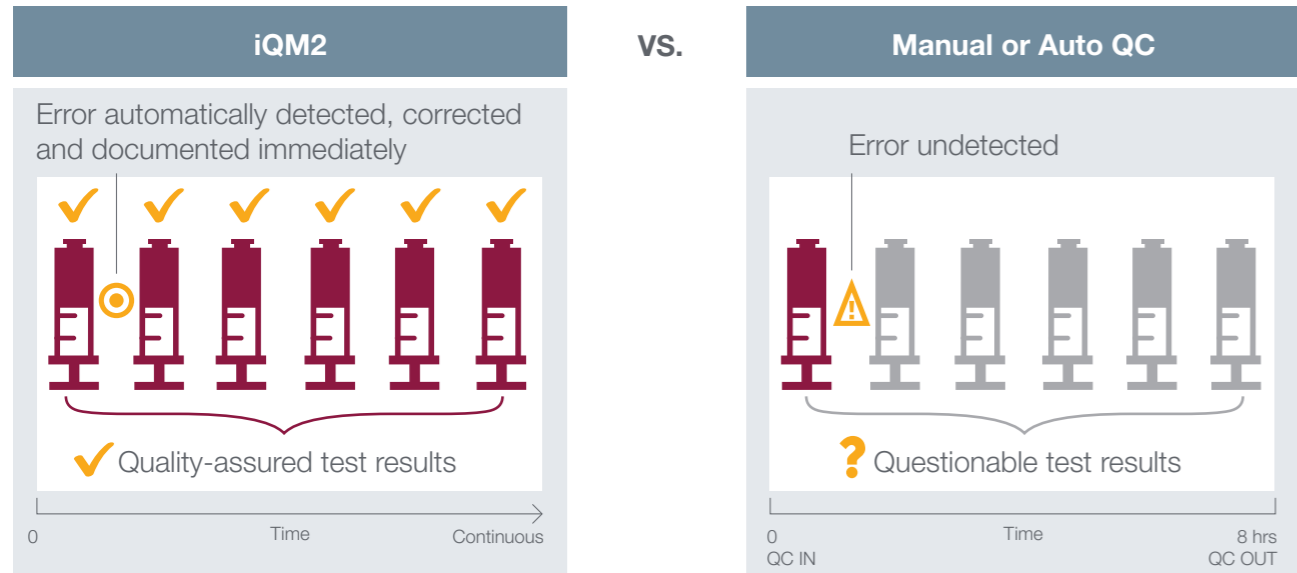


30 different GEM PAK configurations available.

\* Not available in all countries.

## 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<sup>1,2</sup> and detects transient sample-specific errors that traditional QC methods miss**

	pH	pO <sub>2</sub>	pCO <sub>2</sub>	Na <sup>+</sup>	K <sup>+</sup>	Ca <sup>++</sup>	Cl <sup>-</sup>	Glu	Lac	Hct	tHb	tBili
<b>iQM2* (mins)</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>4.1</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>16.8</b>	<b>2</b>	<b>2</b>	<b>2</b>	<b>2</b>
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



*PAK contains all components required for sample testing.*

### 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)

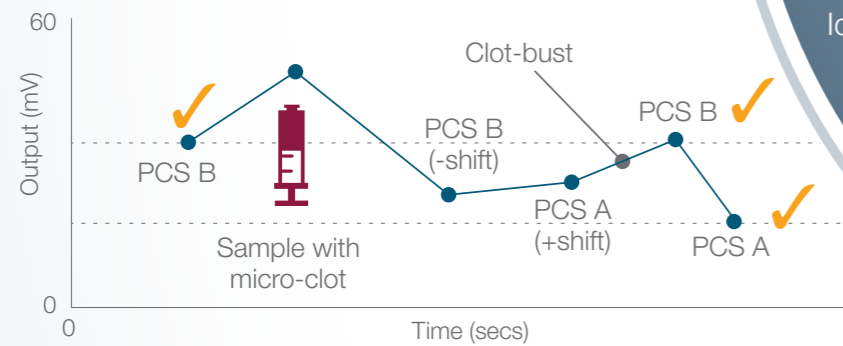
# iQM2: a continuous cycle of 5 quality checks for intelligent analysis

iQM2 runs quality checks for every sample analysis, before, during and after. This ensures accuracy of results, regardless of point-of-care operator, time or place.

## All-in-one PAK for continuous process control



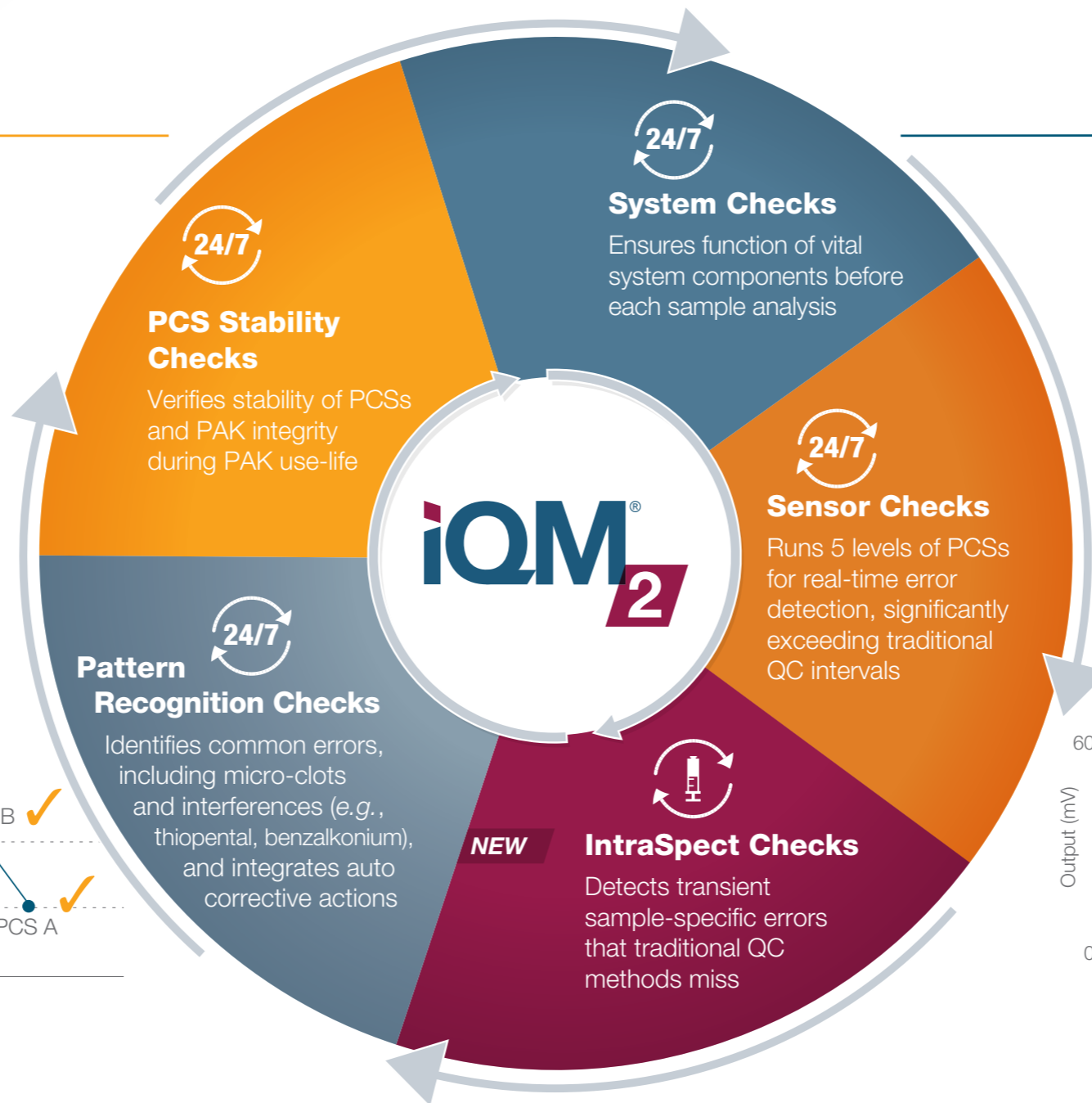
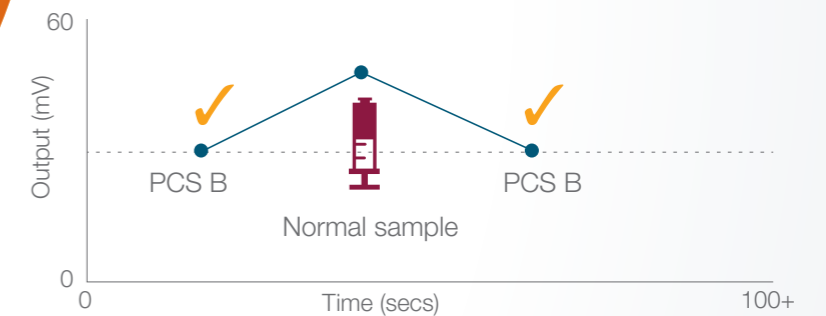
## Pattern sensor signals before, during and after each sample



## Automatic system component checks



## Sensor checks before and after each sample



## IntraSpect: how it works

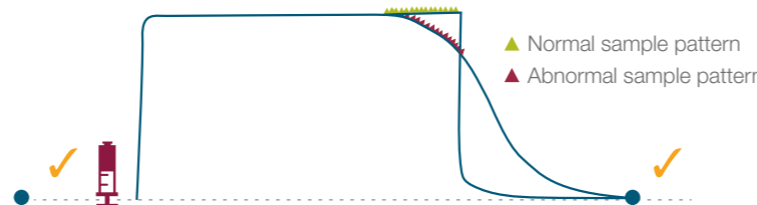
IntraSpect checks can detect abnormal sensor response or residual error **during** the measurement process, which may be caused by:

- 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.

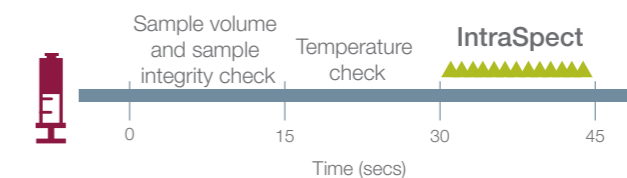
## How IntraSpect detects an abnormal sample

IntraSpect identifies sensor-slope shape and coefficient deviation.



## 15 in 15

15 sensor readings are collected and analyzed in 15 seconds.

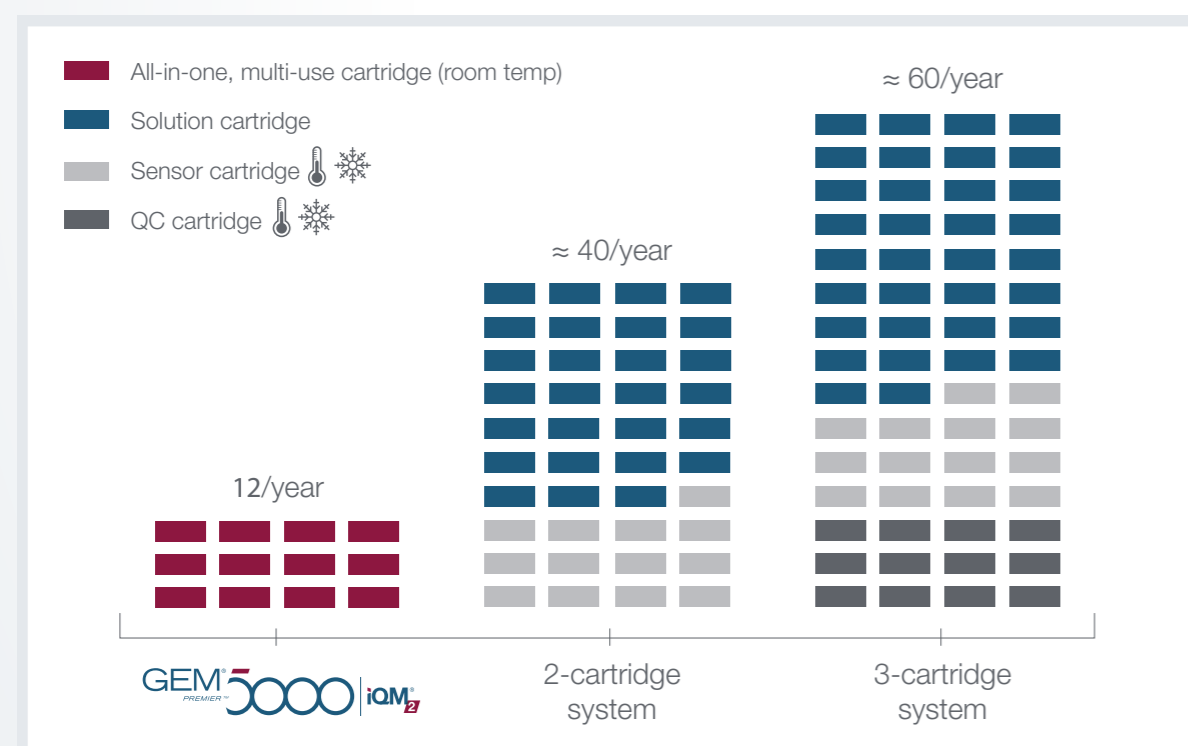


## GEM PAK: advanced simplicity at every point of care

### 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

### Real-Time Assurance *inside*

**iQM<sup>2</sup> with IntraSpect™ technology**  
Provides a complete picture of quality for each sample

**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<sup>®</sup> 5000  
PREMIER™

iQM<sup>®</sup> 2

GEMweb<sup>®</sup> Plus  
CUSTOM CONNECTIVITY

## Technical Specifications

### Quantitative Measured Analytes

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

\* sO<sub>2</sub> = O<sub>2</sub>Hb/O<sub>2</sub>Hb+HHb.

### Derived (Calculated) Parameters

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

### Flexible Customization

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

Menu
Blood Gas, Hct, tHb, O <sub>2</sub> Hb, HHb, COHb, MetHb, sO <sub>2</sub> , tBili†
Blood Gas, Electrolytes, Hct, tHb, O <sub>2</sub> Hb, HHb, COHb, MetHb, sO <sub>2</sub> , tBili†
Blood Gas, Electrolytes, Glu, Lac, Hct, tHb, O <sub>2</sub> Hb, HHb, COHb, MetHb, sO <sub>2</sub> , 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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