GEM® PREMIER™ 5000 | iQM®2

The Intelligent Analyzer.

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

Instrumentation Laboratory
A Werfen Company

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 Custom Connectivity
allows **complete control**

In the lab and at the point-of-care

care and efficiency.
ent.

Real-time 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 are available in different menu and test-volume configurations to allow ultimate flexibility for the needs of specific units (*e.g.*, ICU, NICU, CVOR, ED). All PAKs have a use-life of **31 days**** and **require no refrigeration**.
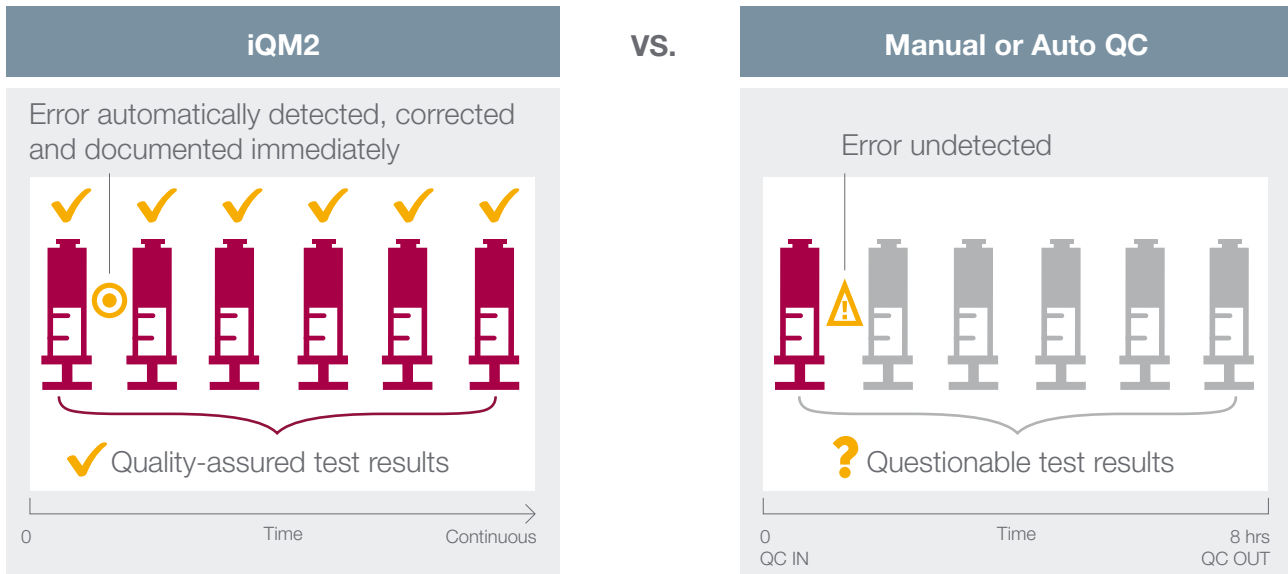
** 21-day onboard use-life for 600-test PAK.

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	VS.	Manual or Auto QC

Error automatically detected, corrected and documented immediately

✓ Quality-assured test results

0   Time   Continuous

Error undetected

? Questionable test results

0
QC IN   Time   8 hrs
QC OUT

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 Pattern Recognition

- **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 are very similar to recommended values for Sepsis diagnosis treatment)
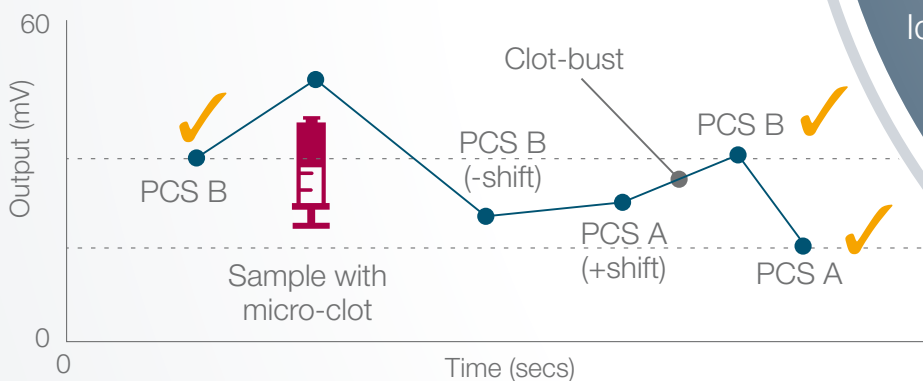
All-in-one PAK for continuous process control

Pattern sensor signals before, during and after each sample

24/7

PCS Stability Checks

Verifies stability of PCSs and PAK integrity during PAK use-life

24/7

Pattern Recognition Checks

Identifies common errors, including micro-clots and interferences (*e.g.*, thiopental, benzalkonium), and integrates auto corrective actions

NEW

Clot-bust

PCS B

PCS B (-shift)

PCS B ✔

PCS A (+shift)

PCS A ✔

PCS A

Sample with micro-clot
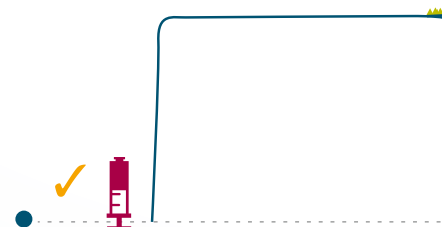
Output (mV)

60

0

0

Time (secs)

iQM

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
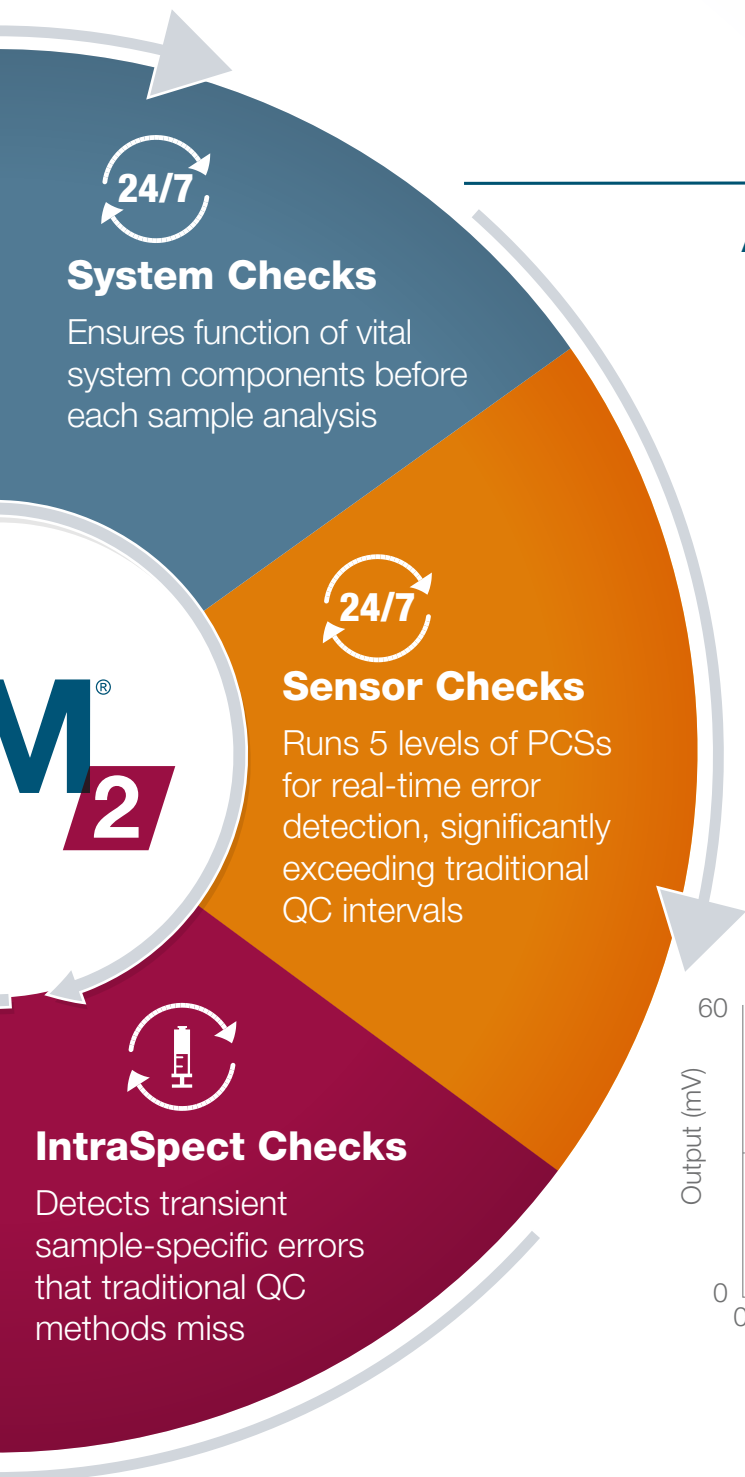- Micro-bubbles
- Interferences

How IntraSpect detect

IntraSpect identifies sensor-slop
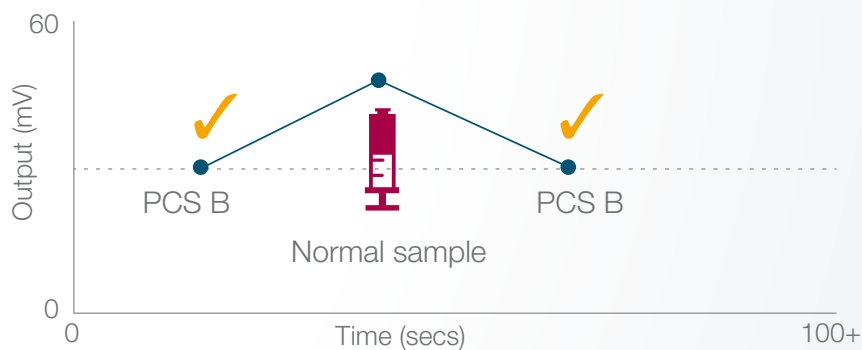
lity checks for intelligent analyzing

mple analysis, before, during and after.
ess of point-of-care operator, time or place.

24/7 System Checks

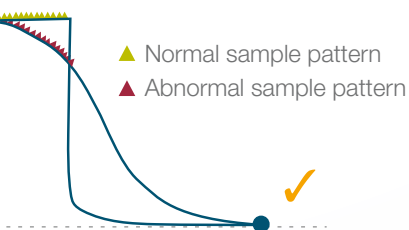Ensures function of vital system components before each sample analysis

24/7 Sensor Checks

Runs 5 levels of PCSs for real-time error detection, significantly exceeding traditional QC intervals

IntraSpect Checks

Detects transient sample-specific errors that traditional QC methods miss

Automatic system component checks

Sensor checks before and after each sample

Output (mV)

60

✓   ✓

PCS B   PCS B

Normal sample

0

0   Time (secs)   100+

ts an abnormal sample

e shape and coefficient deviation.

▲ Normal sample pattern
▲ Abnormal sample pattern

✓

15 in 15

15 sensor readings are collected and analyzed in 15 seconds.

Sample volume and sample integrity check   Temperature check   **IntraSpect**

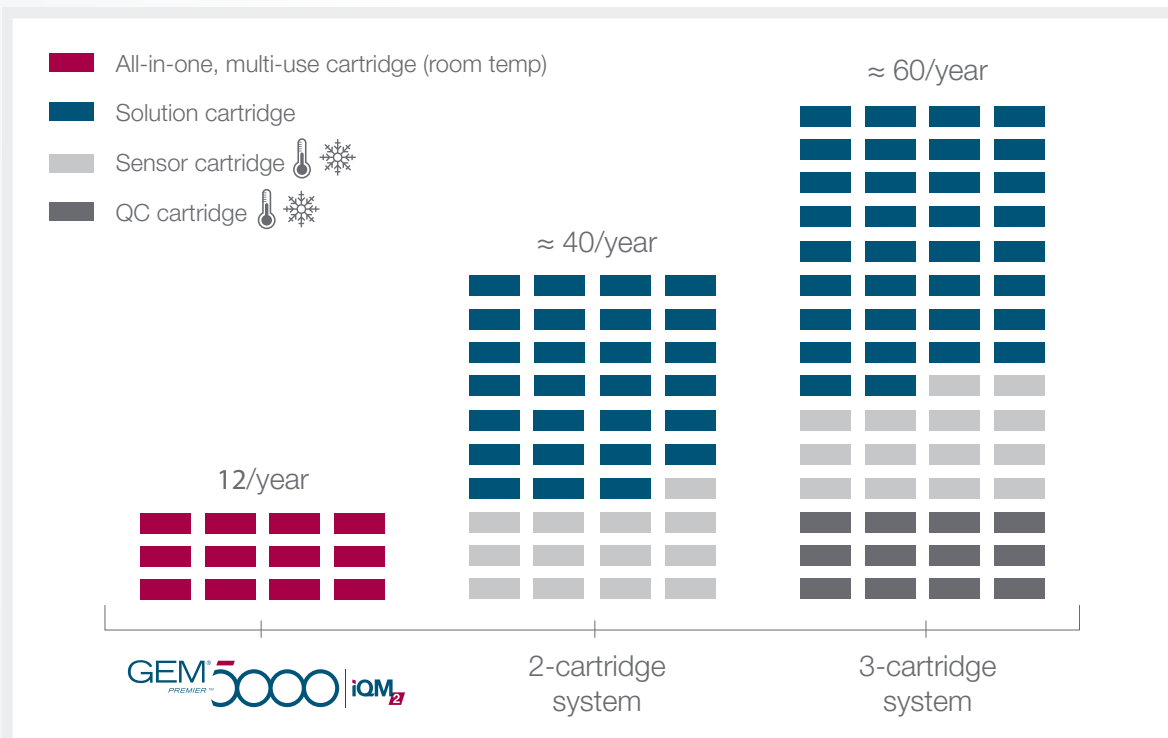0   15   30   45

Time (secs)
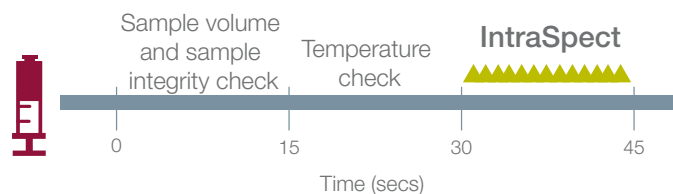
GEM PAK: advanced simplicity at every point of care

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†

Legend:
- All-in-one, multi-use cartridge (room temp)
- Solution cartridge
- Sensor cartridge ❄
- QC cartridge ❄

≈ 60/year — 3-cartridge system

≈ 40/year — 2-cartridge system

12/year — GEM PREMIER 5000 iQM2

* 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.

GEMweb Plus Custom Connectivity: complete control anytime, anywhere

Automates quality assurance, ensures regulatory compliance and reduces staff time.

The ONLY connectivity software to provide:

- **Single-interface simplicity**
  - Same intuitive interface when accessed on any GEM Premier analyzer or a PC

- **Flexible customization**
  - Fully customizable to individual hospital configurations and needs—by individual GEM Premier analyzer,* by department or globally

- **Unprecedented control**
  - System-wide control of instruments and operators from any networked GEM Premier system* or PC, regardless of location

Integrated wireless for seamless real-time communication to the LIS or HIS.

Provides customizable control from any networked GEM Premier analyzer or PC.

* GEM Premier 4000 and 5000 systems only.

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

i-button for iQM2
Conveys real-time iQM2 status

Real-Time Assurance
inside

iQM₂® 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® PREMIER™ 5000   iQM®2   GEMweb® Plus CUSTOM CONNECTIVITY

Technical Specifications

Quantitative Measured Analytes

Analyte	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_2Hb	%
COHb	%
MetHb	%
HHb	%
tBili	mg/dL
sO_2*	%

* $sO_2 = O_2Hb/O_2Hb+HHb$.

Derived (Calculated) Parameters

BE(B)	pAO_2	O_2ct	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_2cap	A-aDO_2	Q_{sp}/Q_t
P/F ratio	sO_2(c)	paO_2/pAO_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**

** 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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