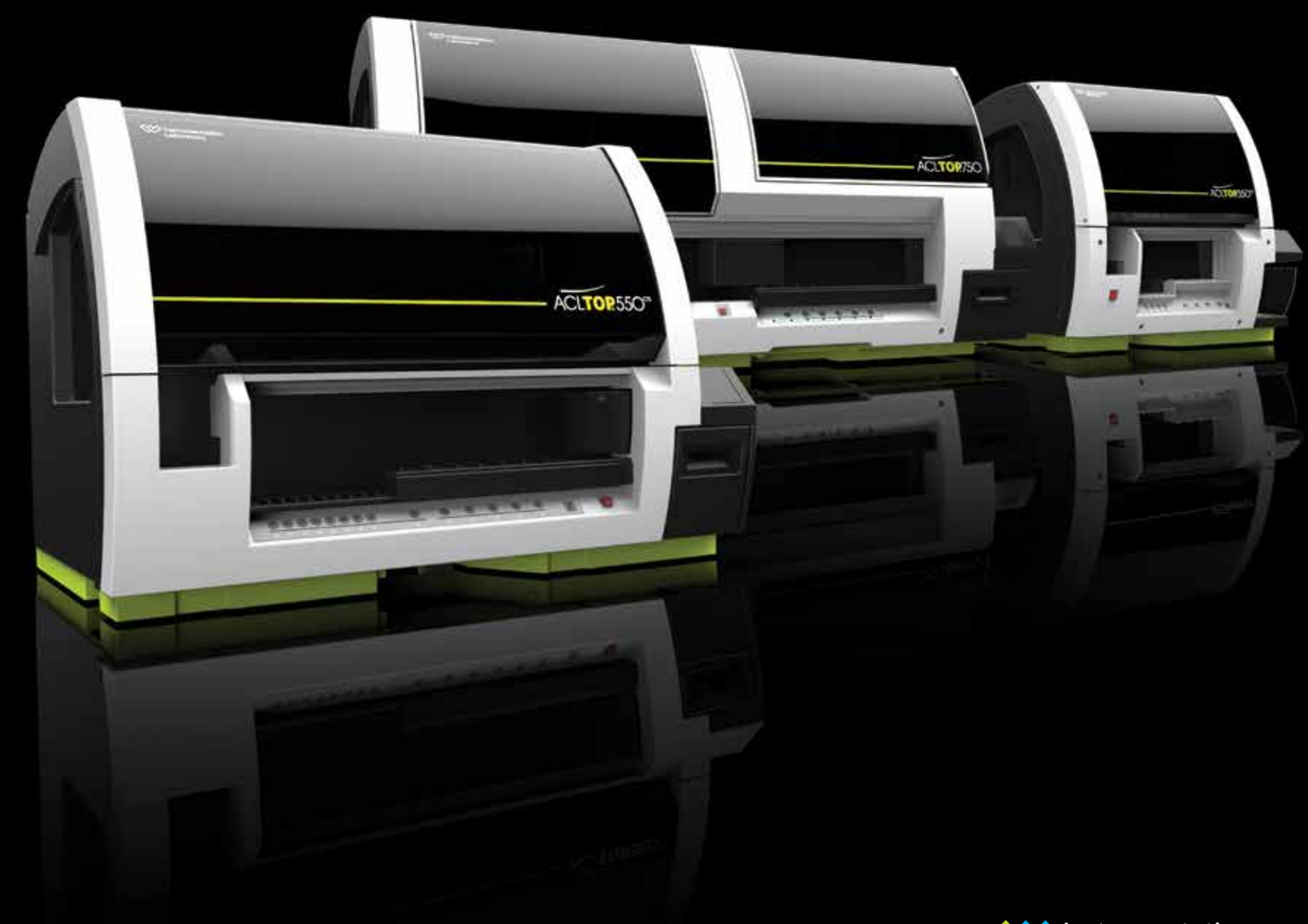
NEW

ACLTOP®
Family 50 series

Introducing
The most advanced systems in Hemostasis testing.



HEMOSTASIS INNOVATION IS HERE.

Instrumentation Laboratory
A Werfen Company

A breakthrough in Hemostasis testing.

New **ACL TOP Family 50 Series**

Offering the most advanced automation and quality management from routine to specialty assays.

Standardized across all ACL TOP systems—for superior performance across your entire testing process

- **Same** quality results
- **Same** comprehensive reagent portfolio
- **Same** powerful and intuitive software
- **Same** features and usability

And now:

- **Same** assay-specific pre-analytical sample checks
- **Same** advanced lab accreditation support
- **Same** advanced quality management

ACL TOP® Family 50 series

The *new* ACL TOP Family 50 Series is designed to **minimize errors** and **enhance quality**.

Completely standardized for advanced automation and quality

Ideal for medium- to high-volume labs, including integrated lab automation systems—routine or specialty testing.

For high-volume labs

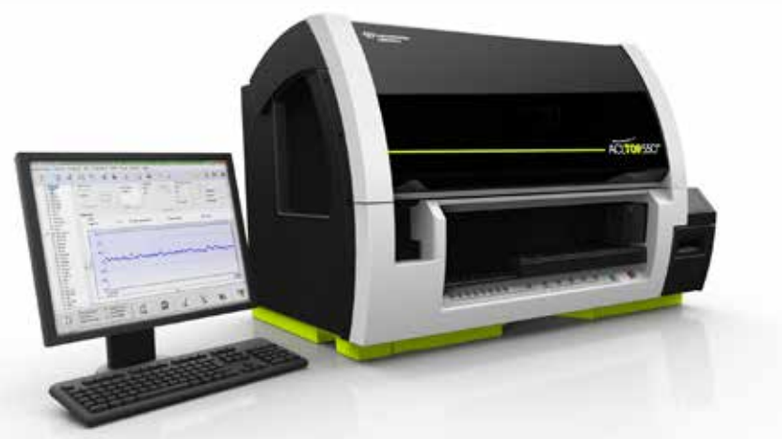
ACL TOP 750
Runs more tests in less time—user-friendly and high-throughput for routine analysis in laboratories with the heaviest workloads.

ACL TOP 750 CTS
Closed-Tube Sampling adds safety in routine, high-volume and specialty labs.

ACL TOP 750 LAS
Connects to laboratory automation tracks for maximum flexibility and efficiency.

	ACL TOP 750	ACL TOP 750 CTS
Throughput (PT/hr)	up to 360	up to 270
Samples onboard	120	120
Reagents onboard	60	60

For medium- to high-volume labs



ACL TOP 550 CTS
For highly automated testing in routine, medium- to high-volume and specialty labs.

Throughput (PT/hr)	up to 240
Samples onboard	80
Reagents onboard	40

For medium-volume labs

ACL TOP 350 CTS
The most compact ACL TOP Family 50 Series system for routine or specialty assays in medium-volume labs. Perfect companion to ACL TOP 750 CTS and 550 CTS systems.

Throughput (PT/hr)	up to 110
Samples onboard	40
Reagents onboard	26

The ACL TOP Family

Analyzer automation

- Barcoded reagents
- Continuous onboard reagent-stability monitoring
- Automatic QC frequency execution
- Rerun and reflex testing capabilities
- Fully automated reporting of factor assays with parallelism
- Auto-verification and uploading of results
- Closed-Tube Sampling via cap-piercing (CTS models only)

Continuous operation

- Continual loading and unloading of samples and reagents via racks with no system interruption
- Uninterrupted cuvette loading and waste disposal

Simple maintenance

- Daily maintenance, ordered by user and performed by system, in < 5 minutes
- “Maintenance overdue” notifications to alert user
- Remote instrument diagnostics and troubleshooting via web in real time* (optional)

Laboratory automation

- Follows CLSI Guidelines (AUTO 1–5) for true “Point-of-Reference” sampling
- Open system compatible with most laboratory automation track systems
- Eliminates need for costly and slow robotic interface

Fast turnaround

- Up to 360 PT/hr
- PT results from standby in approximately 3 minutes
- Samples loaded on any rack, in any position, at any time, including STAT

* Not available in all countries.

Onboard barcode reader allows real-time reagent management.

Closed-Tube Sampling enhances safety in the testing process.

The ACL TOP Family 50 Series

Automated pre-analytical sample integrity checks

- Detects interference from Hemolysis, Bilirubin or Lipemia
  - Values exceeding assay-specific thresholds are flagged
  - Pre-set to validated thresholds with optional customization
- Detects tube-fill height issues
- Flags abnormal sample aspiration, prompting user to check for clots

Advanced quality and accreditation support tools

- Most comprehensive set of audit-trail tools available
- Time, date and operator stamps for all analyzer functions and activity
- Maintenance, QC and calibration logs, and temperature report
- Comprehensive and secure one-click audit reports

Enhanced system security

- Second-level password and electronic signature
- Automatic system log-off
- System-access restriction with user-specific log-in and password
- Automatic password expiration
- Comprehensive 21 CFR Part 11 support tools
- Optional user-access restriction to patient-demographic information

Comprehensive assay menu for disease state management

HemosIL assays

ACL TOP Family 50 Series systems are optimized to operate with a comprehensive panel of HemosIL assays. Together, they are a complete disease-state management solution. Innovative **HemosIL assays**, routine to specialty, help guide pathways for better patient care that can reduce costs associated with hospital length-of-stay and therapeutic management.

True standardization throughout the lab for routine and specialty assays on all ACL TOP systems

General Screening and Anticoagulant Monitoring/ Testing

RecombiPlasTin® 2G
PT-FIB HS Plus
♦ SynthASil
♦ APTT-SP
Fibrinogen-C
Q.F.A. Thrombin
♦ Liquid Anti-Xa
Direct Thrombin Inhibitor*

Heparin-Induced Thrombocytopenia

♦ HIT-Ab$_{(PF4-H)}$*

Antiphospholipid Syndrome

♦ Silica Clotting Time
dRVVT Screen/Confirm

Thrombophilia

♦ Antithrombin
Protein C (Chromogenic)
Protein C (Clotting)
Free Protein S (Antigenic)
Free Protein S (Clotting)
FV Leiden (APC-R V)
Homocysteine
ThromboPath*

D-Dimer

♦ D-Dimer HS 500
D-Dimer HS
D-Dimer 500*
D-Dimer

Coagulation Factors

Intrinsic Factors
Extrinsic Factors
♦ FXIII Antigen

Fibrinolysis

Plasminogen
Plasmin Inhibitor

von Willebrand Disease

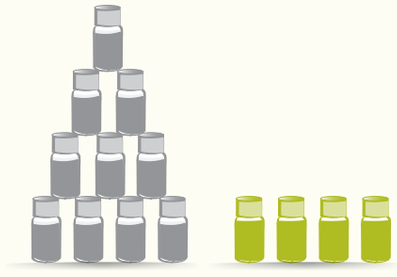
♦ VWF:RCo*
VWF Activity
♦ VWF:Ag
FVIII

* Not FDA cleared. Not saleable in the U.S. | ♦ Liquid, ready-to-use format.

♦ Increased efficiencies with HemosIL liquid, ready-to-use assays

- The great majority of Hemostasis tests performed in laboratories today are comprised of PT and APTT; therefore, their efficient use is essential.
- HemosIL high-sensitivity, liquid, ready-to-use assays are available for PT, APTT, D-Dimer, Anti-Xa and more.
- These assays deliver efficiency by:
  - Eliminating reconstitution errors for more accurate results
  - Eliminating extra pipetting steps for increased efficiency
  - Reducing labor utilization overall

Significant Reduction in Hands-on Tech Time for Vial Reconstitution*



Competitor solution | **HemosIL solution**

Reduced by ≈ 65%**

* Data on file, IL.
** Assumes high-volume, routine testing with PT, APTT, D-Dimer and Fibrinogen assays.

HemosIL® ASSAYS

NEW

ACL TOP Family 50 series

A new breakthrough in Hemostasis testing

ACL TOP Family 50 Series systems are the first in Hemostasis testing to automate and integrate:

- Pre-analytical sample integrity checks
- Advanced quality management
- Lab accreditation tools

ACL TOP Family 50 Series. Advanced automation and quality for lab efficiency and better patient care.

ACL TOP Family 50 Series standardizes the Hemostasis testing process—for flexibility, efficiency and enhanced patient care

Technical Specifications

Test menu		Clotting, chromogenic and immunological assays
System configurations	ACL TOP 750	Open-Tube Sampling
	ACL TOP 750 CTS	Closed-Tube Sampling (cap-piercing)
	ACL TOP 750 LAS	Laboratory Automation System compatibility (offboard sampling)
	ACL TOP 550 CTS	Midsize with Closed-Tube Sampling
	ACL TOP 350 CTS	Compact size with Closed-Tube Sampling
Samples onboard	ACL TOP 750, 750 CTS	120
	ACL TOP 750 LAS	Continuous from LAS track or 90 front-loaded
	ACL TOP 550 CTS	80
	ACL TOP 350 CTS	40
Pre-analytical sample checks	All ACL TOP Family 50 Series systems	Assay-specific HIL sample check and sample aspiration clog check
Reagents onboard	ACL TOP 750, 750 CTS, 750 LAS	60
	ACL TOP 550 CTS	40
	ACL TOP 350 CTS	26
Patient samples results database		20,000 samples (configurable)
Throughput	ACL TOP 750	PT.....up to 360 tests/hr (360 samples/hr)
		APTT.....up to 320 tests/hr (320 samples/hr)
		PT and APTT.....up to 330 tests/hr (165 samples/hr)
	ACL TOP 750 CTS	PT.....up to 270 tests/hr (270 samples/hr)
		APTT.....up to 270 tests/hr (270 samples/hr)
		PT and APTT.....up to 260 tests/hr (130 samples/hr)
	ACL TOP 750 LAS	Throughput from the LAS track is dependent upon factors such as LAS track configuration and settings
	ACL TOP 550 CTS	PT.....up to 240 tests/hr (240 samples/hr)
		APTT.....up to 180 tests/hr (180 samples/hr)
		PT and APTT.....up to 180 tests/hr (90 samples/hr)
	ACL TOP 350 CTS	PT.....up to 110 tests/hr (110 samples/hr)
		APTT.....up to 110 tests/hr (110 samples/hr)
		PT and APTT.....up to 110 tests/hr (55 samples/hr)
Unit dimensions (w x d x h)	ACL TOP 750, 750 CTS	151 x 76 x 73 cm (59 x 30 x 29 in)
	ACL TOP 750 LAS	188 x 87 x 162 cm (74 x 34 x 64 in) (includes integrated table and arm)
	ACL TOP 550 CTS	110 x 82 x 73 cm (43 x 32 x 29 in)
	ACL TOP 350 CTS	81 x 84 x 73 cm (32 x 33 x 29 in)
Weight	ACL TOP 750	162 kg (356 lbs)
	ACL TOP 750 CTS	166 kg (367 lbs)
	ACL TOP 750 LAS	184 kg (406 lbs)
	ACL TOP 550 CTS	147 kg (324 lbs)
	ACL TOP 350 CTS	91 kg (200 lbs)

Werfen
Corporate Headquarters
Plaza de Europa, 21–23
08908 L'Hospitalet de Llobregat
Barcelona, Spain
+34-93-4010101
werfen.com

Instrumentation Laboratory Headquarters
180 Hartwell Road
Bedford, MA 01730 USA
+1-781-861-0710
www.ilww.com

Worldwide Locations

US, Canada, Latin America and South America

Brazil
São Paulo
+55-11-41543337
br.werfen.com

Canada
Richmond Hill, ON
+1-800-552-2025 x6115
www.ilus.com

Colombia
Bogotá
+57(1)-616-7513

Mexico
Col. Granada
+52-55-5262-1760
ildiagnostics.com

Uruguay
Montevideo
+5982-481-81-33

USA
Bedford, MA
+1-781-861-0710
www.ilus.com

Pacific

Australia
Artarmon, Sydney
+61-02-9098-0200

China
Shanghai
+86-21-66308671
Beijing
+86-10-59756055
cn.werfen.com

Hong Kong
Hong Kong
+852-2792-7773
cn.werfen.com

India
New Delhi
+91-490-29-550
in.ilwerfen.com

Japan
Minato-ku, Tokyo
+81-3-5419-1301
jp.werfen.com

Korea
Seoul
+82-2-5719246
kr.werfen.com

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

Europe, Middle East, Africa

Austria
Vienna
+43-1-256-58-000
at.werfen.com

Benelux
Belgium
+32-2-7252052
The Netherlands
+31-76-5480100
benelux.werfen.com

Czech Republic
Prague
+420-246-090-931
cz.werfen.com

France
Le Pré Saint Gervais
+33-182-30-86-00
fr.werfen.com

Germany
Munich
+49-89-909070
de.werfen.com

Hungary
Budapest
+36-1-882-73-10
hu.werfen.com

Italy
Milan
+39-02-25221
it.werfen.com

Lithuania
Kaunas
+370-37-313157
lt.werfen.com

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

Portugal
Carnaxide
+351-214247312
pt.werfen.com

Russia
Moscow
+7-499-124-45-59
ru.ilwerfen.com

Spain
Barcelona
+34-902-20-30-90
es.werfen.com

UK
England
+44-1925-810141
uk.werfen.com

For all other countries visit
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Werfen

CODE

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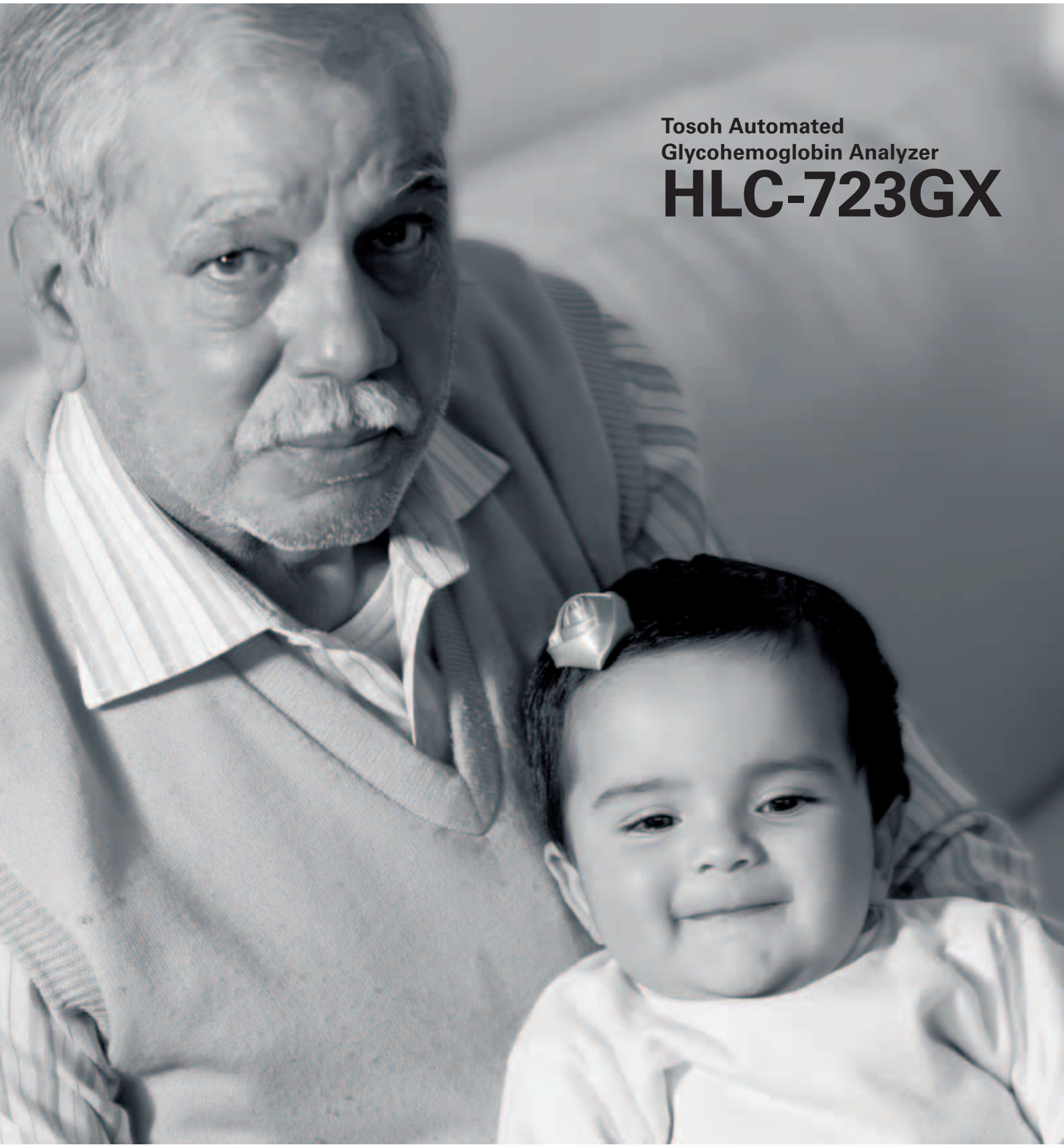
TOSOH



Tosoh Automated
Glycohemoglobin Analyzer

HLC-723GX

TOSOH BIOSCIENCE

The Diabetes Epidemic and the role of HbA_{1c}

Diabetes is recognised worldwide as a disease that is reaching epidemic proportions. [1]

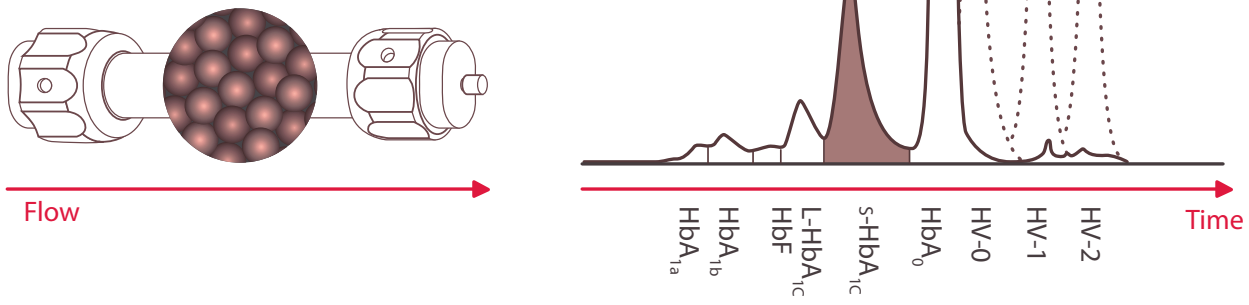
IDF region	Adult Population (20-79) in 1000s	Diabetes cases (20-79) in 1000s	Diabetes national prevalence (%)	Undiagnosed Diabetics in 1000s	Undiagnosed Diabetics %	Diabetes related deaths (20-79)	Mean diabetes-related expenditure per person with diabetes (EURO)
WORLD	4,479,259	371,329	8.29 %	187,087	4.18 %	4,802,747	1,027
EUR	655,983	54,942	8.38 %	21,204	3.23 %	622,114	2,043
MENA	366,249	34,163	9.33 %	18,114	4.95 %	356,586	285
AFR	398,113	14,920	3.75 %	12,148	3.05 %	401,276	135

The significance of HbA_{1c} for the diagnosis and follow-up of diabetes has increased with the continuing rise in the number of patients. This represents a significant workload challenge to many laboratories.

How to measure HbA_{1c}?

One of the reference methods for HbA_{1c} measurement is “High Performance Liquid Chromatography”, better known as “HPLC” (this method was also used in the DCCT and UKPDS trials). With this technique the different haemoglobin fractions are separated based on charge.

When using the Tosoh Automated Glycohemoglobin Analyzer HLC-723GX (GX) separation of the haemoglobin fractions is obtained by use of a negatively charged column and positively charged buffers that compete with the different haemoglobins to bind to the column (= cation exchange). Tosoh offers you over 35 years of world leading HPLC experience.



Why use HPLC?

Besides being the method used during the DCCT and UKPDS trials different arguments are raised in literature.

"The method of choice should measure HbA_{1c} highly precisely; should be economical, automatable and simple to perform; and should yield results that are comparable between different laboratories, ...one should use a method that meets the following conditions: The Hb variant should be recognised; and HbA_{1c}, HbA_0 and Hb variants should be separated and quantified reliably." [2]
"The advantage of HPLC lies in its ability to separate variant haemoglobins and, in doing so, allowing better interpretation of the result!" [3]

The Importance of low CV%

HbA_{1c} can be used for three specific applications*:

1. For identifying risk.
HbA_{1c} could be used as a tool, among other parameters, to identify individuals at risk for developing diabetes. The American Diabetes Association (ADA) suggested 5.7 – 6.4 % (39 – 47 mmol/mol) as the high risk range. [4,5]

2. For Diagnosis.
An international expert committee assembled by the American Diabetes Association (ADA), International Diabetes Federation (IDF), and European Association for the Study of Diabetes (EASD) has recommended the HbA_{1c} assay as the new test for the diagnosis of diabetes. An HbA_{1c} value greater than or equal to 6.5 %, or 48 mmol/mol, is used as cut-off for the diagnosis of diabetes. Diagnosis should be confirmed with a repeat HbA_{1c} test. [4,5]

3. For treatment follow-up.
Lowering HbA_{1c} to below or around 7 %, or 53 mmol/mol, has been shown to reduce micro-vascular and neuropathic complications of type 1 and type 2 diabetes. HbA_{1c} of ≥ 7 %, or 53 mmol/mol, should initiate or change therapy to reach an HbA1c level of < 7 %, or 53 mmol/mol. Relevant changes in serial measurements of HbA_{1c} testing serve as the guide to changes in therapeutic regimes. [6,7]

The Coefficient of Variation (CV) determines the difference between two serial HbA_{1c} measurements.
At a medical decision point of 7 %, or 53 mmol/mol, a healthcare provider should be able to conclude that a significant difference of 0.5 %, or 5 mmol/mol, is caused by a change in glycaemic control of a patient and not by the analytical imprecision. For that reason the CV% of the method should be ≤ 2.4 %. [8]

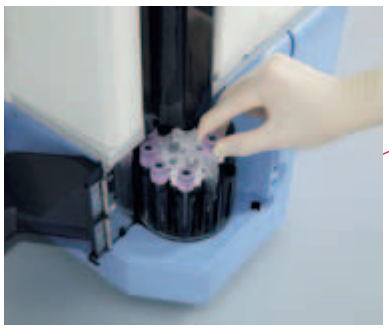
"...95 % of the laboratories using a method from Tosoh were able to meet the criteria of having an analytical CV% of ≤ 2.4 %!" [8]

* Official guidelines on the use of HbA_{1c} may vary from country to country.

Stable HbA_{1c} result with variant detection in **2.2 minutes,**

The GX will deliver:

- Precision
  Direct determination of stable HbA_{1c} with less than 1 % CV.
- Speed
  Stable HbA_{1c} result with variant detection in 2.2 minutes.
  Time to first result is 6.6 minutes.
- Operational Simplicity
  With cap piercing, positive sample identification, automated maintenance, the GX is simplicity itself.
- Absence of Interference
  In the presence of the most common haemoglobin variants, HbF or haemoglobin derivatives such as labile and carbamylated haemoglobin, HbA_{1c} results are unaffected.



with less than **1 % CV.** Time to first result is 6.6 minutes.

Compact
W 370 mm
D 525 mm
H 482 mm
25 kg

The GX provides you exceptional Operational Simplicity...

- Cap piercing capability minimises manual handling.
- Positive sample identification via barcode reader (optional).
- Up to 10 samples per batch.
- Automated daily maintenance.
- A user friendly touch screen enables easy instrument operation.
- Simple finger tight connectors permit quick, convenient and easy replacement of columns and pre-filters.
- Constant visual monitoring of buffer consumption with customisable alarm.
- Integration to Tosoh's data management software (optional) for full data management capabilities including:
  - Patient linked result validation
  - Chromatogram review with overlay and library facility
  - Full QC-package including Levey-Jennings charts
  - Reagent logging and audit trail
  - Data storage and full result archiving

...and an unparalleled level of patient safety.

- Highly developed function for programming user-selectable flags to ensure easy interpretation of results.
- Unique TSKgel column and optimal column temperature control guarantee stable results.

The GX: the perfect solution for reliable diabetic patient monitoring!

- HbA_{1c} results directly determined with less than 1 % CV and reportable to 2 decimal places.
- Results unaffected by the presence of the most common haemoglobin variants or haemoglobin derivatives such as labile HbA_{1c} and carbamylated - or acetylated haemoglobin.
- HbA_{1c} results traceable to the NGSP / DCCT and IFCC.

	Intra-Assay precision			Inter-Assay precision	
N = 30	Mean HbA_{1c} (%)	CV (%)	N = 91	Mean HbA_{1c} (%)	CV (%)
Normal value	4.97	0.41	Normal value	5.28	0.89
Elevated value	9.25	0.29	Elevated value	10.11	0.28

Source: Evaluation de l'automate HLC-723GX Tosoh Bioscience pour le dosage de l'hémoglobine A1c. Protocole EH12-08.
Fonfrède et. al. Laboratoire de biochimie métabolique, Groupe Hospitalier Pitié-Salpêtrière, APHP, Paris, France.

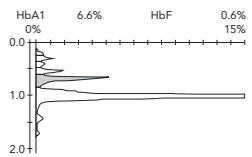
Best-in-class chromatographic separation!

- Separation of labile A_{1c} from stable A_{1c} is achieved without loss of precision or resolution and without manipulating the sample or using mathematical algorithms.

Non-diabetic Patient*

NAME	%	TIME	AREA
FP	0.0	0.00	0.00
A1A	0.4	0.23	6.99
A1B	0.9	0.31	13.52
F	0.6	0.41	9.64
LA1C+	1.4	0.55	22.60
SA1C	5.3	0.67	67.68
A0	92.3	1.02	1447.06
		TOTAL AREA	1567.49

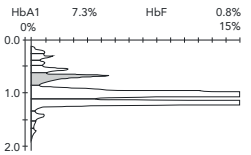
IFCC 35 mmol/mol
HbA1C 5.3%



HbD Patient*

NAME	%	TIME	AREA
FP	0.0	0.00	0.00
A1A	0.7	0.23	10.49
A1B	1.1	0.32	17.54
F	0.8	0.44	12.39
LA1C+	2.0	0.55	32.73
SA1C	5.6	0.68	73.42
A0	89.3	1.02	1434.55
H-V0	18.7	1.20	369.52
		TOTAL AREA	1976.02

IFCC 38 mmol/mol
HbA1C 5.6%



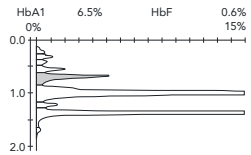
P00	0.9	1.41	14.63
P01	0.3	1.55	5.01
P02	0.4	1.72	5.75

HB-VAR DETECT

HbS Patient*

NAME	%	TIME	AREA
FP	0.0	0.00	0.00
A1A	0.5	0.23	8.06
A1B	0.8	0.32	13.74
F	0.6	0.42	10.08
LA1C+	1.5	0.56	24.47
SA1C	5.2	0.69	69.46
A0	91.1	1.02	1505.38
H-V1	15.5	1.40	303.12
		TOTAL AREA	1956.15

IFCC 33 mmol/mol
HbA1C 5.2%



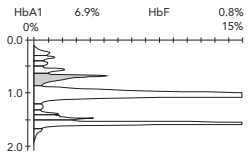
P00	1.0	1.24	16.78
P01	0.3	1.73	5.07

HB-VAR DETECT

HbC Patient*

NAME	%	TIME	AREA
FP	0.0	0.00	0.00
A1A	0.9	0.23	12.98
A1B	0.8	0.32	11.92
F	0.8	0.44	11.23
LA1C+	1.6	0.55	23.19
SA1C	5.3	0.67	62.77
A0	87.7	1.03	1290.06
H-V2	12.2	1.57	204.03
		TOTAL AREA	1674.47

IFCC 34 mmol/mol
HbA1C 5.3%



P00	0.6	1.27	8.25
P01	0.9	1.39	13.38
P02	2.0	1.48	29.36
P03	0.5	1.70	7.29

HB-VAR DETECT

* HbA_{1c} is reportable and in the presence of the most common variants the result is flagged.

Traceability to International Standards

HbA_{1c} results obtained with the G8 are traceable to the "National Glycohemoglobin Standardization Program (NGSP; DCCT-aligned)" and the "International Federation of Clinical Chemistry (IFCC)".

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EC REP **TOSOH EUROPE N.V.**
Transportstraat 4 3980 Tessenderlo - BELGIUM
Tel : +32 (0)13 66 88 30 Fax : +32 (0)13 66 47 49
www.tosohbioscience.eu

TOSOH BIOSCIENCE LTD
The Business Centre, Edward Street, Redditch, Worcestershire. B97 6HA - UK
Tel : +44 (0)1527 592901 Fax : +44 (0)1527 592902
www.tosohbioscience.eu

TOSOH CORPORATION BIOSCIENCE DIVISION
Shiba-Koen First Bldg. 3-8-2, Shiba, Minato-ku, Tokyo 105-8623 - JAPAN
Tel : +81-3-5427-5181 Fax : +81-3-5427-5220
www.tosoh.com

Revision : GX-Variant EN Rev.07112013.01 – 12-2013 www.rosseels.eu

Introducing

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

* Not available in all countries. Not currently 510(k) cleared.

GEM® 5000 PREMIER™ | iQM®2

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**.

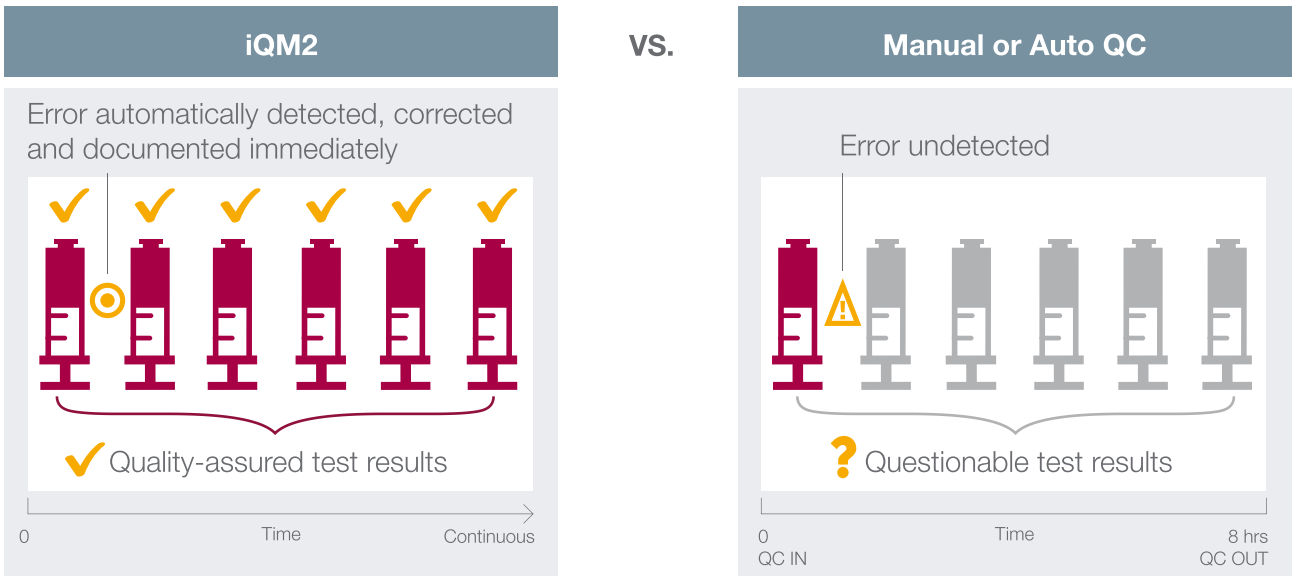
** 21-day onboard use-life for 600-test PAK.

30 different GEM PAK configurations available.

NEW

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 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)

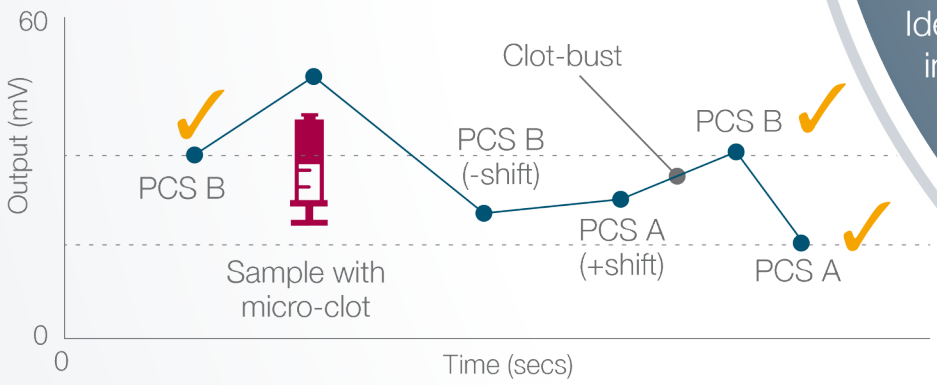
- PCSs are traceable to Clinical & Laboratory Standards Institute (CLSI) and National Institute of Standards and Technology (NIST) primary standards
- Each PCS follows the same pathway as a sample and serves a specific function in the iQM2 process
- Established target values monitor MDLs and ensure accuracy 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)

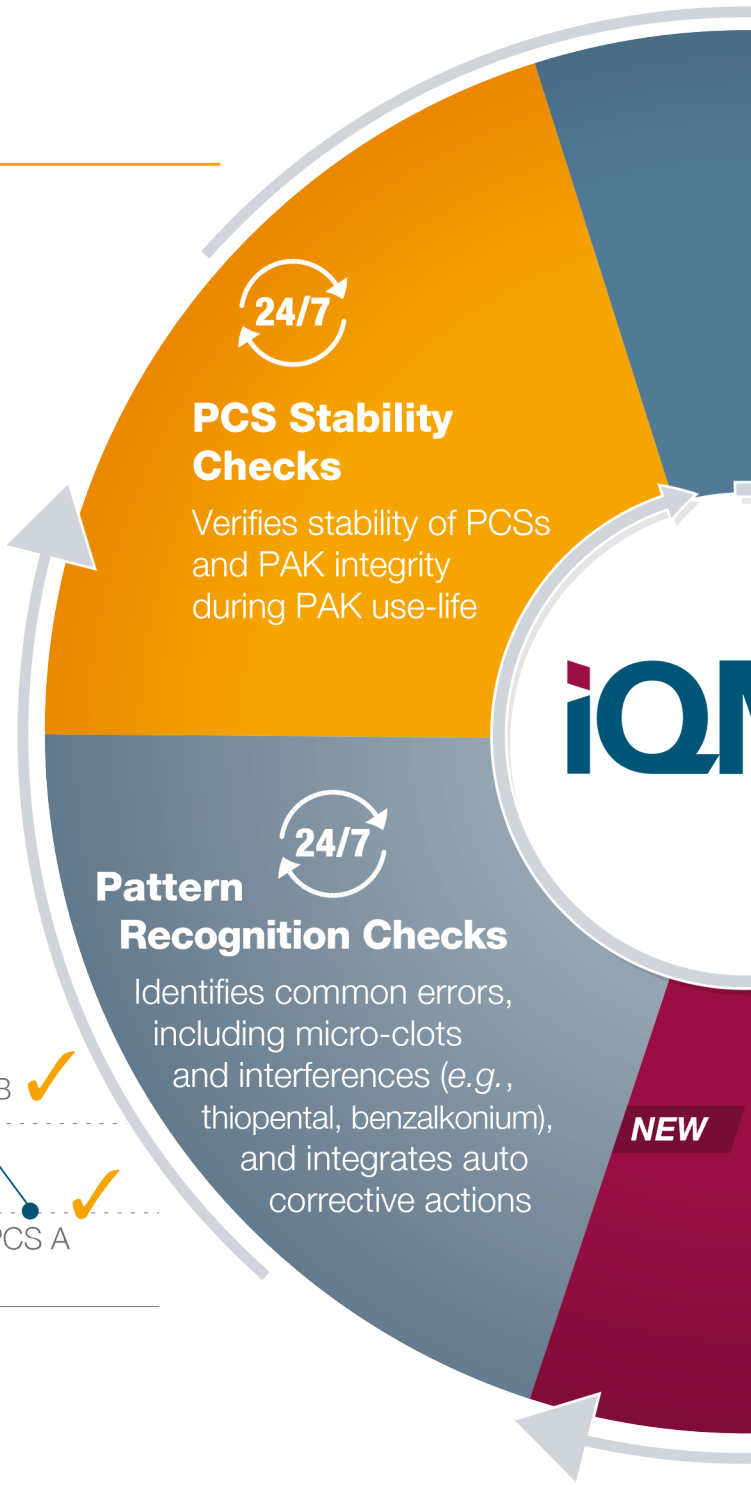
iQM2: a continuous cycle of 5 qua

iQM2 runs quality checks for every sar
This ensures accuracy of results, regardle

All-in-one PAK for continuous process control

Pattern sensor signals before, during and after each sample





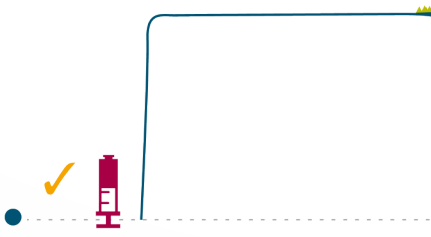
IntraSpect: how it works

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

- Micro-clots
- Micro-bubbles
- Interferences

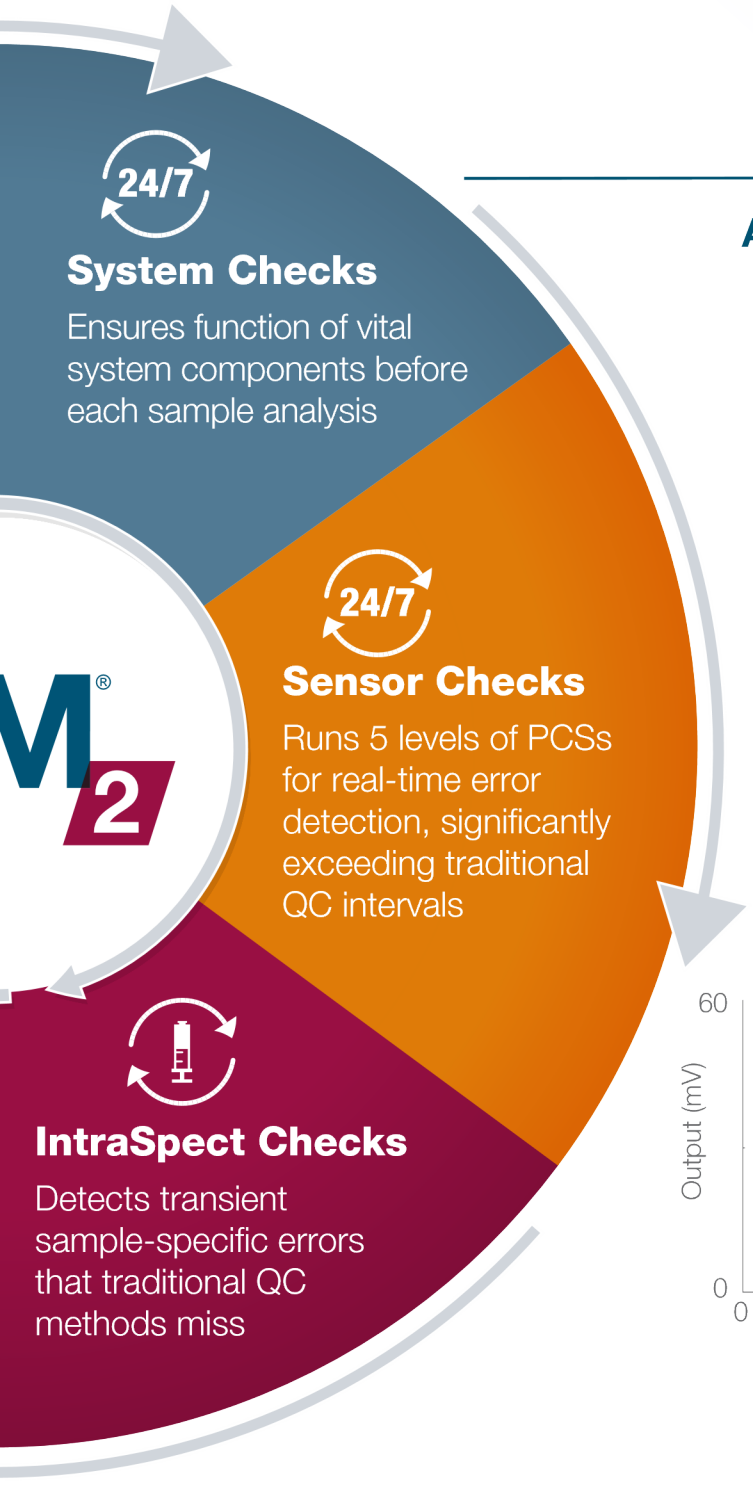
How IntraSpect detect

IntraSpect identifies sensor-slop



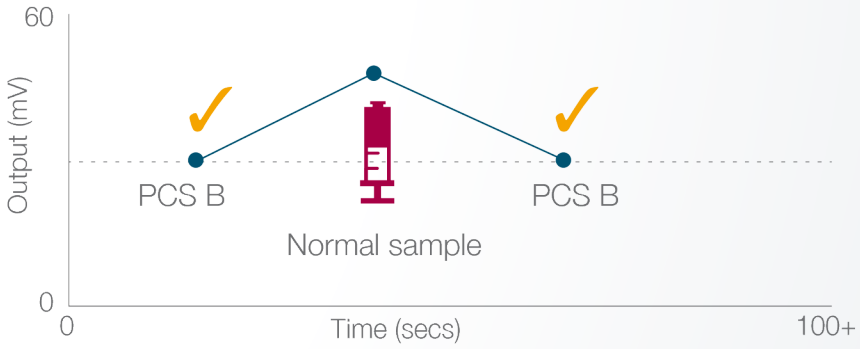
lity checks for intelligent analyzing

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



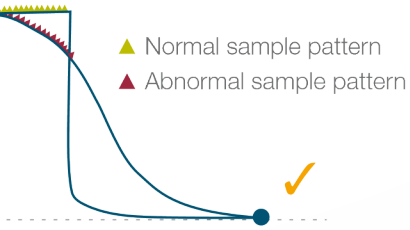
Automatic system component checks

Sensor checks before and after each sample



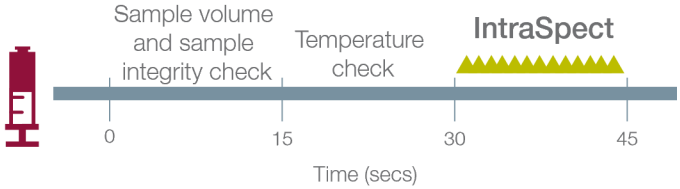
ts an abnormal sample

e shape and coefficient deviation.



15 in 15

15 sensor readings are collected and analyzed in 15 seconds.

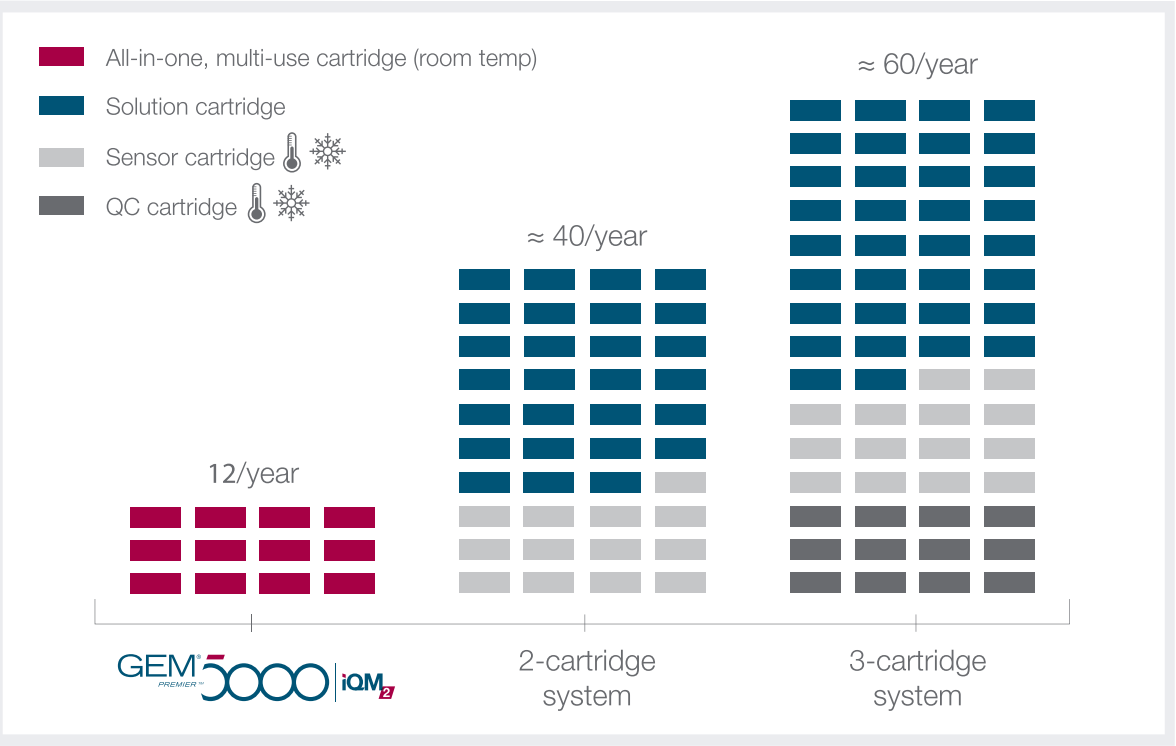


GEM PAK: advanced simplicity at every point of care

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.

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

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

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

A complete solution for improved patient care and efficiency.

GEM® PREMIER™ 5000 | iQM®2 | GEMweb® Plus CUSTOM CONNECTIVITY

GEM® PREMIER™ 5000 | iQM®2

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.

Werfen
Corporate Headquarters
Plaza de Europa, 21–23
08908 L'Hospitalet de Llobregat
Barcelona, Spain
+34-93-4010101
werfen.com

Instrumentation Laboratory Headquarters
180 Hartwell Road
Bedford, MA 01730 USA
+1-781-861-0710
instrumentationlaboratory.com

Worldwide Locations

The Americas

Brazil
São Paulo
+55-11-41543337
br.werfen.com

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

Colombia
Bogotá
+57-15-221-052

Mexico
Mexico City
+52-55-5262-1760
mx.werfen.com

Uruguay
Montevideo
+5982-481-81-33

USA
Bedford, MA
+1-781-861-0710
instrumentationlaboratory.com

Asia-Pacific

Australia
Sydney
+61-02-9098-0200
au.werfen.com

China
Beijing
+86-10-59756055
Hong Kong
+852-2792-7773
Shanghai
+86-21-66308671
cn.werfen.com

India
New Delhi
+91-490-29-550
in.ilwerfen.com

Japan
Tokyo
+81-3-5419-1301
jp.werfen.com

Korea
Seoul
+82-1899-9217
kr.werfen.com

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

Europe

Austria
Vienna
+43-1-256-58-000
at.werfen.com

Belgium
Brussels
+32-2-7252052
benelux.werfen.com

Czech Republic
Prague
+420-246-090-931
cz.werfen.com

France
Paris
+33-182-30-86-00
fr.werfen.com

Germany
Munich
+49-89-909070
de.werfen.com

Hungary
Budapest
+36-1-882-73-10
hu.werfen.com

Italy
Milan
+39-02-25221
it.werfen.com

Lithuania
Kaunas
+370-37-313157
lt.werfen.com

The Netherlands
Breda
+31-76-5480100
benelux.werfen.com

Poland
Warsaw
+48-22-336-18-00
pl.werfen.com

Portugal
Lisbon
+351-214247312
pt.werfen.com

Russia
Moscow
+7-499-124-45-59
ru.ilwerfen.com

Spain
Barcelona
+34-902-20-30-90
es.werfen.com

UK
Warrington, England
+44-1925-810141
uk.werfen.com

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Werfen

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HORIBA
Medical

H550

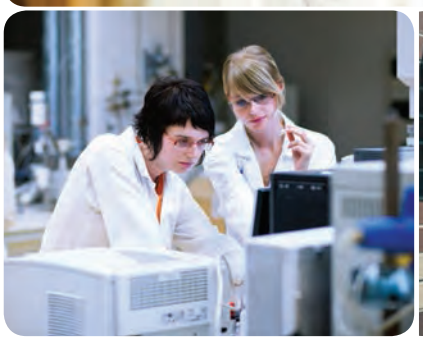
Yumizen
Solutions for Laboratories

«Hematology

Delivering Safe Patient Care to Small-Mid Size Laboratories

Cost Effective Hematology Solution

Tailored for various environments: hospitals, satellite labs, emergency departments, doctors' offices, small independent labs,...



Mrs Catalina ANDONE,
Technical Director of Clinica Sante Lab, Bucharest, Romania

'The Yumizen H550 perfectly fits today's lab requirements : high performance and economical inputs.
The Yumizen H550 is very easy to use and shows excellent correlation with reference hematology systems.'

Everywhere, and Beyond»

Yumizen H550

Providing Walk-away Capability

The Yumizen H550 is designed to provide rapid testing and full hematology diagnosis

The Yumizen H550 is a **compact** hematology system with integrated **sample rack auto loading**.

It provides the operator with a **full walk-away capacity of 40 tubes with continuous loading.**

Based on **proven and innovative technologies**, the Yumizen H550 answers the need for a robust analyzer and requires **no user maintenance**.

Sample Management

In order to ensure a reliable process, the Yumizen H550 allows:

- **Automatic rack mixing**,
- **Positive identification** of tubes.

The 10-tube racks are compatible with Yumizen H1500/2500.

STAT Mode for urgent samples.
Anytime, on **open** and **closed** tubes.
Compatible with various **micro tubes**.
Ideal for **pediatrics** and **critical care**.

Ensuring Safe Diagnosis

Reliable Analysis

The new Yumizen H550 technologies provide added value advantages:

- **Only 3 reagents** : Diluent, Cleaner and Whitediff®,

- **Low consumption** and **ergonomic reagent management,**

- Unique **Whitediff®** is a cyanide free lysis reagent for HGB measurement and WBC counting & differential.

Based on micro-sampling of **20 µL of whole blood**, the Yumizen H550 can run any type of blood sample including pediatrics.

27 parameters with full **WBC 6 Differential** : LYM%#, MON %#, NEU %#, BAS %#, EOS#% and LIC%# (Large Immature Cells).

Specific parameters for Iron Deficiency Anemias diagnosis & PLT disorders: **RDW-CV**, **RDW-SD**, **P-LCC**, **P-LCR**.

Timely Results

User-friendly **touch screen software**.

Comprehensive menus with graphs & flags.

Easy handling with minimal operator training.

Expert alarms system for interpretation guide.

Managing Results & Monitoring Quality

Multi Connection Capacity

Bidirectional communication to LIS or middleware.
ASTM with **query mode**.
HL7 compatible, suitable for POLs connection.

Quality & Traceability

Automatic **reagents management**.
Logs archiving.
Levey Jennings & radar graphs.
Overlapping QC : 6 active control levels.
Accreditation support tools.
Online **Quality Control Program**.

Data Management

10,000 patient results storage.
Patient data export in **PDF** or **Excel** formats.
Customizable Printing Out Format Reports.

HORIBA Medical International Support

Help Line Support
E-Learning Training Program
Worldwide Representation

http://www.horiba.com/medical/contacts

Yumizen H550

PHYSICAL SPECIFICATIONS

Dimensions & Weight:

	Height	Width	Depth	Weight
Analyzer	62 cm	53 cm	67 cm	36 kg
	24 in	20 in	26 in	77 lbs

Printer (optional):
Compatible models with Linux drivers

Throughput:
43 samples/hour

Sample Management:
Autonomy of 40 tubes in 1 hour
Continuous Loading
STAT Mode
Rack Automatic Mixing
Tubes Positive Identification

Sound Level:
54 dBa

Operating Temperature & Humidity:
+15°C (+59°F) to + 30°C (+86°F)
Relative humidity of 30%-80% maximum, without condensation

Specimen Volume:
CBC mode: 20µL
DIF mode: 20µL

Power Requirements:
Power supply: 100 V to 240 V (+ /- 10%), 50 Hz to 60 Hz
Power consumption: 165 VA
Heat output: 403 KJ/h (382 BTU/h)

Reagents:
2 reagents for analysis :
ABX Diluent (10L or 20L)
Whitediff 1L (cyanide free)

1 reagent for daily shutdown :
ABX Cleaner 1L

MEASUREMENT PRINCIPLES

WBC & Differential
Methods:
• Cytometry : Double Hydrodynamic Sequential System 'DHSS'
• Optical Reading : Absorbance
• Impedance Variation

HGB Measurement
Method:
• Spectrophotometry

RBC & PLT Detection
Methods:
• Impedance Variation
• Analogic Digital Conversion

HCT Measurement
Method: analogical integration

SOFTWARE SPECIFICATIONS

• Data Processing
Color LCD touch screen: 12,1 in.
Operating System: Linux™
Connection: RS232, Ethernet, USB
Communication: ASTM & HL7 protocols
Capacity: 10 000 results + graphs
Options: keyboard, mouse and bar code reader

• Quality Control
3 controls levels (low, normal, high)
Target values download (USB)
QC results compatible with HORIBA Medical Quality Control Program (QCP)
Levey-Jennings graphs
Radar graphs
XB on 3 or 9 parameters
Overlapping QC (6 active QC files)

PARAMETERS & PERFORMANCE DATA

27 Parameters:

WBC	RBC	PLT
NEU# & NEU%	HGB	MPV
LYM# & LYM%	HCT	PCT*
MON# & MON%	MCV	PDW*
EOS# & EOS%	MCH	P-LCC*
BAS# & BAS%	MCHC	P-LCR*
LIC# & LIC%*	RDW-CV	RDW-SD*

Linearity:	Linearity Limits	Visible Range	Unit
WBC	0 - 300	300 - 999	10^9/L
RBC	0 - 8	8 - 18	10^{12}/L
HGB	0 - 240	240 - 300	g/L
HCT	0 - 0.67	0.67 - 0.80	L/L
PLT	0 - 2500	2500 - 4000	10^9/L
PLT (concentrate)	0 - 4000	4000 - 5000	10^9/L

Precision (Repeatability):

Parameters	CV (%)	Range	Unit
WBC	<3.0	4 – 100	10^9/L
RBC	<2.0	3.6 – 6.2	10^{12}/L
HGB	<1.5	120 – 180	g/L
HCT	<2.0	0.36 – 0.54	L/L
PLT	<5.0	180 – 500	10^9/L

* RUO parameters (Research Use Only)

CERTIFICATION

98/79/EC (IVD)
EN ISO 13485
EN ISO9001
IEC 61010-1
IEC 61010-2-081
IEC 61010-2-101
EN 61326-1
EN 61326-2-6
IEC 61000-3-2
IEC 61000-3-3
UL 61010-1
CAN/CSA-C22.2 61010-1

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POLAND +48 / 22 30 05 460 - USA +1 / 949 453 0500 - BRAZIL +55 / 11 2923-5439 - THAILAND +66 / 2 861 59 95 - CHINA +86 / 21 3222 1818
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tem®

Redefining Bleeding Control

ROTEM® *sigma*

Proven technology.
Fully automated.

Combining innovation with experience, ROTEM® *sigma* provides rapid haemostasis information in time-critical patient care situations.

ROTEM®

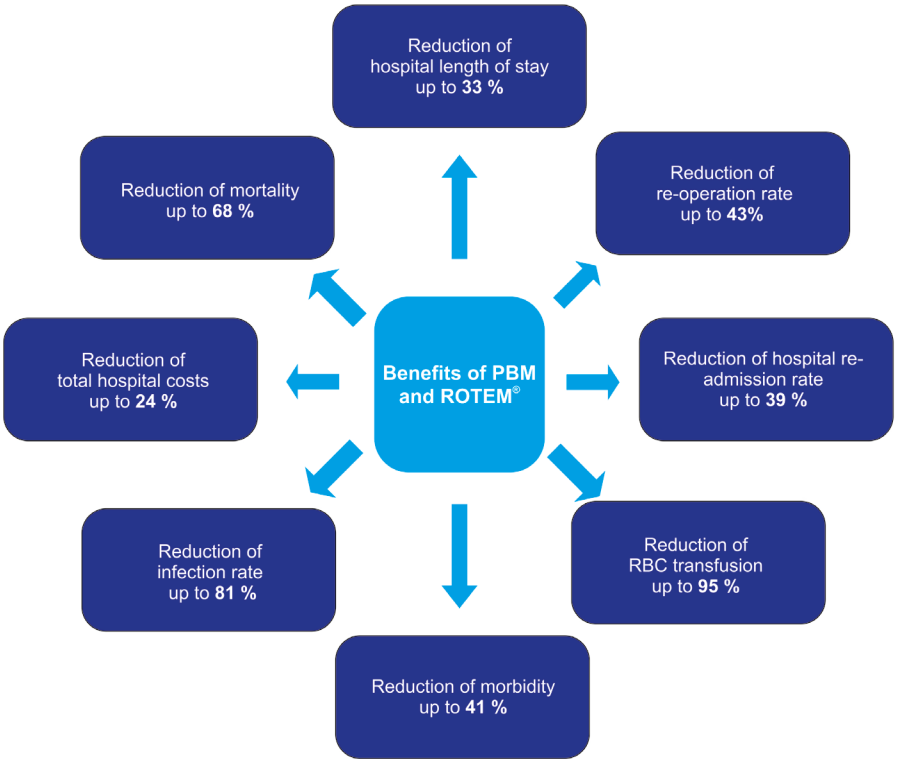
ROTEM® *sigma* in clinical use.

Ensuring both, the quality and the supply of blood products is becoming increasingly difficult. This is leading to a more rational use of the limited resource “blood“ and to a critical view on the need of **blood transfusions**.

Blood loss, anaemia and blood transfusions are independent predictors for worse outcomes and patients´ quality of life. This includes an increase in morbidity and mortality, as well as a prolongation of the average length of hospital stay. In short, transfusions typically lead to **avoidable complications and costs.**

In this context, the **targeted** ROTEM®-based bleeding management is an integral part of **Patient Blood Management** that is predicated on both preemptive and reactive blood-saving measures. In fact, the WHO has encouraged all their 193 member states with the WHA 63.12 to implement the PBM concept in a timely manner.

ROTEM®- based bleeding control



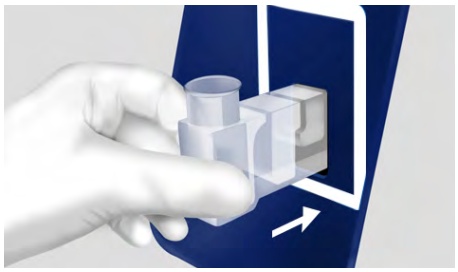
See economic folder for literature references

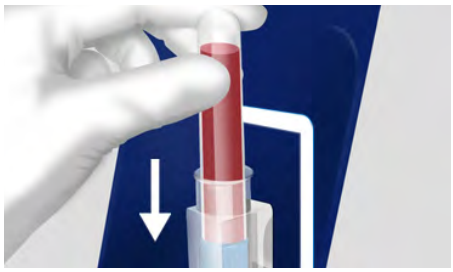
Technology you can trust.

ROTEM® *sigma* offers the cutting-edge combination of innovative automated functionality with generally accepted and proven ROTEM® technology.

The ROTEM® *sigma* is a closed system, easy-to-use:

- **Fully automated** – pipetting and test preparation are not required
- Sample vial fits directly into cartridge to avoid blood handling
- **Simplistic cartridge system** that minimises operator involvement
- Runs automated functionality checks before every measurement
- Shows results easily visible from afar, via large integrated screen
- Provides results with prevailing reference ranges
- Existing **algorithms**, recommendations, guidelines and literature are applicable





The ROTEM® *sigma* haemostasis analyser measures kinetic changes of the clot elasticity of **whole blood samples**. It allows quantitative and qualitative assessment by measuring different parameters of the **clot status** of the blood sample. A comprehensive set of assays permits a **differential diagnosis**.

The differential ROTEM®- analysis can be performed at the patient´s **point of care** and provides information about hyperfibrinolysis, dilutional coagulopathies, the need for substitution of fibrinogen, factors or platelets, as well as the control of heparin or protamine dosage.

Proven technology. Fully automated.

Rapid, accurate test results when time is crucial

Both ROTEM® *sigma* **cartridges**:

- Detect factor deficiency
- Discriminate between thrombocytopenia and fibrinogen deficiency or fibrin polymerization disorders
- Detect hyperfibrinolysis
- Detect direct FX inhibitors and direct thrombin (FIIa) inhibitor effects

ROTEM® *sigma* complete

FIBTEM C | EXTEM C | INTEM C | APTEM C

ROTEM® *sigma* **complete:**

- Discrimination between hyperfibrinolysis and platelet mediated clot retraction/FXIII deficiency
- *In vitro* assessment of the effect of antifibrinolytic drugs

ROTEM® *sigma* complete + hep

FIBTEM C | EXTEM C | INTEM C | HEPTEM C

ROTEM® *sigma* **complete + hep:**

- Detection of heparin and heparin-like substances
- Discrimination between factor deficiency and heparin effect

Thromboelastometry.

The proven ROTEM® technology provides an overview about the coagulation status within 10 minutes.

Contact

www.rotem.de
info@tem-international.de

tem®
Redefining Bleeding Control

Tem International GmbH
Martin-Kollar-Strasse 13-15
D-81829 Munich-Germany
T: +49 (0)89 454295-0
F: +49 (0)89 454295-22