




Instrumentation Laboratory 

Intelligent Quality Management (iQM™) and Active Process Control


“Let the System do the Work for You”



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1: Current Quality Control Procedures – pre iQM



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Instrumentation Laboratory *The market: current QC Offers*

Traditional external (liquid) Quality Control material
Requires labor and material (QC) costs
Time and experience are requested for the interpretation of QC data
In case of cartridge system, reduces the total number of tests declared


EQC (Electronic QC)
Checks only the electronics of the analyzer. (This generates frequent recalls)

Auto QC (on board)
QC solutions or vials are on-board the analyzer (adding mechanical complexity to the system)
The systems are monitored only at scheduled frequency (min every 8 hours)
No corrective actions or documentation are carried out in real time

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2: the “IL Proposal”: iQM



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Instrumentation Laboratory *The IL Proposal: iQM*

DEFINITION

The Intelligent Quality Management (iQM) is an active, statistical, quality-process-control program designed to provide continuous monitoring of the analytical process, with real-time automatic error detection, automatic correction of the system failures, automatic documentation of all corrective actions and quality control reports *

* IL submission claim approved by FDA in Sept. 2002

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Instrumentation Laboratory *The iQM Objective*

iQM was developed by IL R&D with the support of the expert in Statistics and Quality Controls Management (Dr. James Westgard).

iQM was born to replace the use of any conventional QC system (external, auto, electronic) and “to create a new standard of reference for the future QC”

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Instrumentation Laboratory *The iQM Functions*

The iQM, is a combination of

- Software,
- Calibration Validation Product (CVP)
- Process Control Solutions (PC)

for the “management of the entire testing process”

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Instrumentation Laboratory *No Maintenance*



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Instrumentation Laboratory *How iQM Starts and Works*

FIRST: System Validation

After initial iQM cartridge warm-up and iQM activation four ampoules of external Calibration Validation Product (CVP) must be analyzed to verify cartridge calibration (2 for Hct & 2 for BG/Lytes/Metabolites) and validate the whole system

Correct CVP recovery = Certification of valid calibration

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SECOND: runs QC and Active Control

Once cartridge accuracy is validated, iQM automatically:

- runs a continuous and exhaustive QC program
- "actively" monitors the status of the analyzer and the cartridge operations during its whole life

The iQM "Total Management" is:

Active Control for

- System Checks
Fluidics, valves, temperature block, electronics
- Sensor Checks
Solutions A, B and C solutions - drift and slope
- Stability Checks
Solutions A, B and C solutions
- Failure Pattern Recognition
Clot detection and automatic removal

AUTOMATIC DOCUMENTATION

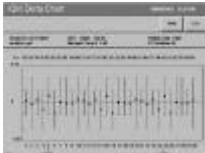
iQM Cartridge has three internal Process Control (PC) Solutions
Solutions have known values traceable to reference standards and are analysed like patient samples

Frequency of PC checks

- Solution B Measured every 30' or after every sample "B" remains on sensors and is monitored every 30'. Drift is checked.
- Solution A Measured every 4 hrs. Drift and slope are checked.
- Solution C Measured every 24 hrs. Drift is checked.

QC Documentation:
Delta Chart

The PC measurements are stored, subjected to statistical analysis and plotted on the GEM 3000 database as "iQM Delta Chart".



Active Control: Drifts

Drifts Limits as "decisional parameters"

Drift limits of the PC solutions (measured values vs references) are the mechanism of the active control process

The limits were chosen using methods of statistical control optimized with the support of Dr. Westgard in order to Obtain the highest probability of error detection and the Lowest probability of false rejection

Active Control Documentation:
Actions Report

All corrective action are documented in the GEM 3000 database in the "Corrective Action Report"

iQM Corrective Action Report

Date	GEM Premier 3000 - Serial: 81250	Corrective action	Result
12/11/14	Process control failure	Drift in solution B	Failed
12/11/14	Process control failure	Drift in solution C	Failed
12/11/14	Process control failure	Drift in solution A	Failed
12/11/14	Process control failure	Drift in solution B	Failed
12/11/14	Process control failure	Drift in solution C	Failed
12/11/14	Process control failure	Drift in solution A	Failed
12/11/14	Process control failure	Drift in solution B	Failed
12/11/14	Process control failure	Drift in solution C	Failed
12/11/14	Process control failure	Drift in solution A	Failed
12/11/14	Process control failure	Drift in solution B	Failed
12/11/14	Process control failure	Drift in solution C	Failed
12/11/14	Process control failure	Drift in solution A	Failed
12/11/14	Process control failure	Drift in solution B	Failed
12/11/14	Process control failure	Drift in solution C	Failed
12/11/14	Process control failure	Drift in solution A	Failed
12/11/14	Process control failure	Drift in solution B	Failed
12/11/14	Process control failure	Drift in solution C	Failed
12/11/14	Process control failure	Drift in solution A	Failed
12/11/14	Process control failure	Drift in solution B	Failed
12/11/14	Process control failure	Drift in solution C	Failed
12/11/14	Process control failure	Drift in solution A	Failed
12/11/14	Process control failure	Drift in solution B	Failed
12/11/14	Process control failure	Drift in solution C	Failed
12/11/14	Process control failure	Drift in solution A	Failed
12/11/14	Process control failure	Drift in solution B	Failed
12/11/14	Process control failure	Drift in solution C	Failed

3: The Science Behind iQM



1: Why iQM is feasible on GEM

- ❖ All analytical components are included in a self-contained cartridge (Pak).
- ❖ Critical Pak components are factory tested
- ❖ No changes can be introduced to the Pak during its three-week use-life. GEM is a "closed system"
- ❖ The system is immediately validated with CVP before accepting any samples
- ❖ The Pak is a "stable system" during its use-life.

This time constitutes a "run" per NCCLS definition

* for purposes of quality control, an analytical run is an interval (i.e., a period of time or series of measurements) within which the accuracy and precision of the measuring system is expected to be stable

4: Key Benefits of iQM



- ❖ iQM & Active Process Control is an active, continuous, real-time quality process of the analyzer's performance
- ❖ Optimal quality control protocol is followed at all times, completely automated and regardless the time of day or operator training
- ❖ All manual processes associated with traditional quality control are eliminated
- ❖ Errors are detected sooner than running external QC
- ❖ Corrective actions are immediate and automatic
- ❖ iQM produces the reports required by regulatory agencies (as CLIA, CAP, JCAOH...)

- | | |
|--------------------|---|
| ❖ High performance | Precision & Accuracy |
| ❖ Automated | No operator/no labor costs |
| ❖ Continuous | 24 hours/day per 21 (14) days |
| ❖ Real time | Immediate answers. Reduction of the time of error detection from hours to minutes |
| ❖ Active | Corrective Actions |
| ❖ Certified | Documentation always available |
| ❖ Cost Saving | No reduction in cartridges' tests |

Better quality control can be provided without any increased effort by analyst and operators, without any further laboratory investment in the education and training and with complete automation and documentation

"Improvements of the Quality in Patient Care"