GEM Premier 5000 (Werfen): analyzer evaluation, risk assessment and practicability

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AIM OF THE STUDY: To evaluate the Gem Premier 5000 (Werfen) a new portable blood gas/CO-oximeter/hematocrit/electrolytes/glucose/lactate/ bilirubin analyzer intended for stat laboratory or point-of-care (POC). The only reagent required is a disposable cartridge which contains all materials required to perform analytical testing including quality controls (Intelligent Quality Management 2, IQM2).

METHODS: Evaluation was made according to the French Society of Clinical Biology (SFBC): within-run precision and between-run precision at 3 levels, accuracy with external quality assessment, comparison of methods with 250 routine patient samples, reportable ranges, and endogenous/exogenous interferences for CO-oximetry. Comparisons analyzers were ABL835 (Radiometer) and DXC800 (Beckman-Coulter) for electrolytes/glucose/bilirubin. Risk assessment was done using Ishikawa diagram and FMECA method. Practicability was evaluated in the laboratory and by POC users.

RESULTS: Within-run and between-day imprecision gave conform CV values for all parameters except for pO2 at low value (25mmHg - no clinical incidence). Accuracy was satisfactory and linearity was within the expected ranges given by Werfen. Method comparisons showed close agreement (with 0.95< r< 1.00). No interferences on CO-Oximetry parameters were found. New features of the GEM 5000 (IQM2 and the IntraSpect check process to identify potential errors) contribute to minimize the risks especially in POC conditions. Users consider the GEM 5000 as a very positive evolution of GEM 4000.

CONCLUSION: Gem Premier 5000 analytical performances are validated for all parameters with the accuracy and the reliability of traditional systems. This blood gas analyzer fulfils the requirements for a POC or a stat laboratory usage and is an improvement in the GEM series.