

Reliability analysis of GEM® Premier™ technology: a multicenter study

Francesco Faggiano,¹ Tiziana Franchin,¹
Matteo Ritrovato,¹ Pietro Derrico²

¹Health Technology Assessment and Safety Research Unit, Clinical Technology Innovation Research Area, Bambino Gesù Children's Hospital, IRCCS, Rome;

²Enterprise Risk Management Structure, Clinical Technology Innovation Research Area, Bambino Gesù Children's Hospital, IRCCS, Rome, Italy

Abstract

This paper describes how specific blood gas analyzer characteristics can support the emerging clinical and organizational user's needs while ensuring patient safety. A one-year data set from two Italian hospitals was analyzed from 10 different blood gas analyzers. Performance measurements in terms of mean down time (MDT) were calculated to show how technical characteristics declared by the manufacturer compare to the analyzer availability in real clinical settings. Results show a high level of reliability for the analyzed technology, associated with very low MDT of each sensor integrated in the cartridge. Moreover, results show a high level of efficiency in cartridge usage. Such results are consistent with the specification of the GEM® Premier™ maintenance-free technology and are particularly relevant in the point-of-care testing setting.

Introduction

During the National Meeting of the American Association of Clinical Chemistry (AACC) in 1992, GEM® Premier™ technology was introduced. It was described for the first time as a *system that provides a choice of blood gases and/or electrolytes in a controllable and maintenance-free format for any remote testing need – at costs comparable to previous systems*.¹

At that time, GEM® Premier™ blood gas (and electrolyte) analyzers were already characterized by single, multi-use cartridges containing all the analytical reagents packed inside. The whole fluidic system, *e.g.* sample probes, waste containers, *etc.*, were included in the unique consumable provided. Patented cartridges included both miniaturized sensors and solutions (sealed and gas tonometered) in order to eliminate most of the maintenance-related drawbacks typically associated with a

traditional blood gas analyzer.¹

GEM® Premier™ technology integrated structural characteristics such as self-calibration, self-diagnostics and self-control, which included automatic detection, automatic correction and documentation of errors. These functions were integrated into the system to meet emerging clinical and organizational user needs. The intelligent Quality Management (iQM), is an innovative system for quality control of blood gas analyzers and was cleared by Food and Drug Administration (FDA) in October 2002.²

The iQM system is conceptually consistent with EP23-A, Laboratory Quality Control Based on Risk Management, which was approved and published by the Clinical and Laboratory Standards Institute (CLSI) in October 2011.³⁻⁵ This document provides guidance based on risk management for laboratories to develop quality control plans tailored to the particular combination of measuring system, laboratory setting, and clinical application of the test. Therefore, blood gas analysis is recognized as context-specific (*e.g.* emergency departments, intensive care units, operating rooms, *etc.*) whereby decision-makers are invited to focus on the strategy for quality control plan to prevent incorrect results, which may impact clinical decisions. In a critical care setting, elimination of potential risk and inaccurate patient results is crucial, because there will not be enough time to repeat the analysis.

Technological progress in Laboratory Medicine aims to ensure immediate diagnostic test results as well as patient safety.^{6,7} Over the past 20 years, the rising demand for technological advances has been met through the innovative total management approach of the GEM® Premier™ blood gas analyzer, thereby enhancing simplicity, flexibility, reliability, and inherent availability⁸ of blood gas analysis.

The present study aimed to investigate the above mentioned aspects by collecting and analyzing data sets (cartridge data) of corrective action reports for the period January-December 2011 taken from 10 blood gas analyzers (series 3000 and 4000) installed, respectively, at the Bambino Gesù Children's Hospital, IRCCS, Rome, Italy and Ospedale Valduce in Como, Italy.

Materials and Methods

Several reliability parameters were taken into account to quantitatively measure the functionality of the blood gas analyzers. One of the *classical* indicators is the number of corrective actions which takes into consideration both technical support calls and work reports from the service organization. It is possible to calculate the mean down time (MDT)⁹ to ana-

Correspondence: Matteo Ritrovato, Health Technology Assessment and Safety Research Unit, Clinical Technology Innovation Research Area, Bambino Gesù Children's Hospital, IRCCS, viale Ferdinando Baldelli 41, 00146 Rome, Italy.
Tel: +39.06.68593183 - Fax: +39.06.68593851.
E-mail: matteo.ritrovato@opbg.net

Key words: Reliability; Point-of-care testing; Blood gas analyzer.

Acknowledgements: Medical Laboratory Service of Ospedale Valduce in Como, Italy and Medical Laboratory Service of Bambino Gesù Children's Hospital are thanked for making study-related information available.

Conflict of interest: the authors declare no conflict of interest.

Received for publication: 22 October 2014.

Revision received: 16 July 2015.

Accepted for publication: 16 July 2015.

This work is licensed under a Creative Commons Attribution 3.0 License (by-nc 3.0).

©Copyright F. Faggiano et al., 2015
Licensee PAGEPress, Italy
Emergency Care Journal 2015; 11:4795
doi:10.4081/ecj.2015.4795

lyze maintenance performance. Mean down time is the average total downtime required to restore an asset to its full operational capabilities; it includes time from the reporting of an asset being down to the time the asset is returned to operation.

Given the clinical significance of blood gas analysis relating to urgent care's diagnostic and therapeutic evaluation, MDT was calculated as: *total downtime*, *i.e.* total non-operating hours of cartridge's sensors during the period from 1st January 2011 to 31st December 2011, and *total uptime*, *i.e.* total operating hours of cartridges during the same period. *Total downtime* includes all the times where at least one of the sensors was unavailable, including: cartridge warm-up time, fixing (automatically performed by the analyzer), corrective actions and uninterruptable control checks. Of cartridges, 153 were analyzed.

It is necessary to take into account intrinsic characteristics of GEM® Premier™ blood gas analyzers with respect to data sets of corrective actions performed in response to electronic signals of cartridges. Data mining and data processing were carried out on the basis of considerations in the table below (Table 1). Treatment of data was performed by the Strategic Business Unit of Instrumentation Laboratory, Bedford, MA, USA.

Results and Discussion

In 2011, the 10 blood gas analyzers taken into account were not subject to any technical interventions by the supply company. Equipment was exclusively affected by downtime related to the corrective actions resulting from unacceptable electronic signals of cartridges, as shown by corrective action reports.

With regard to the evaluation of operativeness, Table 2 shows the MDT (in percentage) of GEM® Premier™ blood gas analyzers (series 3000 and 4000): during the year, the mean availability time (in percentage) of the blood gas analyzers, which included all partial or non-operative events, was 98.67%. Table 2 shows how both series of products are characterized by high reliability with a slight improvement for the most recent series. It must be noted that the downtime, as calculated in Table 2 refers both to time when the analyz-

ers could not be operated because completely unavailable (e.g. during warm-up), and to time where the analyzer could still be used, but with at least one of the parameters unavailable.

Figure 1 shows usage percentage of cartridges: 76% of cases concern the best-performing cartridges with a mean usage rate of 85%. There are no evident differences in data sets collected in the hospitals. It must be noted that the cartridges that were not used up to their full use life include those consumables replaced prematurely because of organizational (and not technological) explanations, e.g. cartridges removed by the operator without any technical reason. They account for 6.5% of all cartridges analyzed. By observing the evolution of annual interruptions for the 10 measurement parameters during the use of sensors integrated in the 153 cartridges, as shown in Figure 2, it is clear that there was a MDT of 9 min and 30 seconds/month for each cartridge. Such an unavailability was resolved automati-

cally by iQM without any operator intervention or distraction from ordinary patient care.

Conclusions

Datasets validate the reliability of GEM® Premier™ technology in continuous diagnostics. The MDT (in percentage) of blood gas analyzers is consistent with maintenance-free specifications, self-control and self-correction relating to non-compliances and not operator dependent (all of these functions are guaranteed by iQM). These features are particularly relevant for the point-of-care testing (POCT) context, in which the operator is not specialized in Laboratory Medicine and the main focus is with patient care and their emergency conditions. Ultimately, accuracy, reliability and immediate availability of data is necessary to appropriately diagnose and treat patients.^{10,11}

Table 1. Calculation parameters used to estimate downtime of GEM® Premier™ blood gas analyzers.

General assumptions	Calculation parameters
1. Warm-up for GEM® Premier™ systems=45 min max	1. Lifetime, total time of operations with cartridges (time for cartridge housing)
2. CVP analysis for GEM® Premier™ systems=15 min max	2. Uptime, period when the blood gas analyzer is available relating to simultaneous availability of all sensors
	3. Downtime, period when the blood gas analyzer is unavailable, warm-up time included
	4. MDT=downtime/lifetime
	5. Average operating time=time of operations (this includes both Uptime as defined above and time where the system can be run, but with one or more of the sensors unavailable)
	CVP, central venous pressure MDT, mean down time

CVP, central venous pressure MDT, mean down time.

Table 2. Mean availability time of GEM® Premier™ blood gas analyzers (series 3000 and 4000) in 2011.

	Lifetime (hours)	Downtime (hours)	Mean down time (%)
GEM® Premier™ 3000	42523.79	585.6	1.37
GEM® Premier™ 4000	11987.88	139.1	1.16
Total	54511.67	723.7	1.33

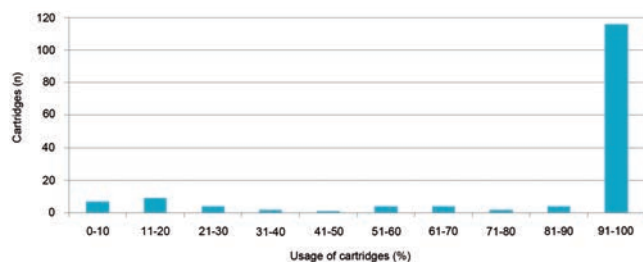


Figure 1. Usage percentage of cartridges with reference to time for housing.

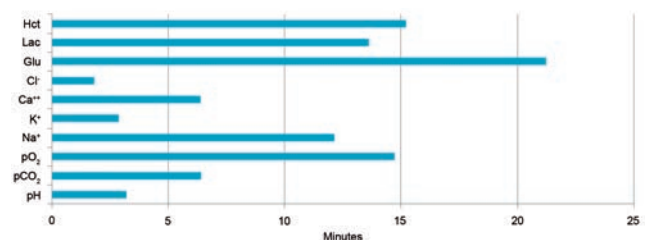


Figure 2. Mean downtime of sensors integrated in cartridges.

Industry commitment in the design of far more *stable and robust* instrumentation has led to highly complex blood gas analyzers equipped with quality and operation control systems to exponentially decrease downtime compared with the previous generations.

It is desirable that industry continues to invest in innovative solutions, which optimize diagnostics (especially for POCT environment), and continue to develop health technology assessment methodologies with multidisciplinary approaches that encompass a broad-spectrum evaluation (*e.g.* patient outcomes, patient safety, economic evaluation, organizational aspects, *etc.*).

References

1. Jacobs E, Nowakowski M, Colman N. Performance of Gem Premier blood gas/electrolyte analyzer evaluated. *Clin Chem* 1993;39:1890-3.
2. FDA. Approval FDA 510 (k) K022158. Available from: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfp/MN/pmn.cfm?ID=K022158>
3. D'Orazio P, Mansouri S. Integrated quality control: implementation and validation of instrument function checks and procedural controls for a cartridge-based point of care system for critical care analysis. *Clin Lab Med* 2013;33:89-109.
4. Westgard JO, Fallon KD, Mansouri S. Validation of iQM active process control technology. *Point of Care* 2003;2:1-7.
5. Toffaletti JG, McDonnell EH, Ramanathan LV, et al. Validation of a quality assessment system for blood gas and electrolyte testing. *Clin Chim Acta* 2007;382:65-70.
6. Ehrmeyer SS, Laessig RH. Point-of-care testing, medical error, and patient safety: a 2007 assessment. *Clin Chem Lab Med* 2007;45:766-73.
7. Rambaldi M, Baranzoni M, Coppolecchia P, et al. Blood gas and patient safety: considerations based on experience developed in accordance with the risk management perspective. *Clin Chem Lab Med* 2007;45: 774-80.
8. O'Connor PDT. *Practical reliability engineering*. 4th ed. Hoboken, NJ, USA: Wiley; 2002.
9. British Standard Institute. *Glossary of international terms*. IEC 50(191):1990. Part 3. Availability, reliability and maintainability terms. *Quality Vocabulary BS4778:1990*. London, UK: British Standard Institute; 1991.
10. Clinical and Laboratory Standards Institute. *Statistical quality control for quantitative measurement. Principles and definition*. CLSI C24-A3-A. Wayne, PA, USA: Clinical and Laboratory Standards Institute; 2006.
11. Clinical and Laboratory Standards Institute. *Quality management: approaches to reducing errors at the point of care*. CLSI POCT 07-A. Wayne, PA, USA: Clinical and Laboratory Standards Institute; 2010.