# *Abbott iSTAT* for Blood Gas Analysis: The Halifax Perfusion Experience

**Roger Stanzel[1,2] and Mark Henderson[1].**
**[1]Nova Scotia Health Authority, [2] Dalhousie University, Dept of Surgery**

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**Introduction:**

In 2015, our department developed and committed to a quality assurance initiative. This initiative necessitated regularly monitoring the perfusion market for new equipment, such that if/when the need arose to replace our current equipment, we would be prepared. Importantly, the initiative also meant that currently utilized equipment would be clinically evaluated on an ongoing basis to ensure that the level of care we expected did not change over time.

For example, when the oxygenator we had been using was approaching the end of its production cycle, we designed and executed a clinical evaluation of all new-generation, *Health-Canada* approved products. The evaluation we designed for this purpose included the collection of data on functional prime volumes, oxygen and carbon dioxide transfer, pressure gradients, blood cell counts (pre-Cardiopulmonary bypass (CPB) and post-cross clamp) and blood transfusion rates.

While cost was taken into consideration, clinical evaluation played a significant part in the products we chose to use.

The second part of this initiative was the establishment of a baseline of our current practice via ~~i~~nitial and ongoing clinical evaluations. For example, we will be conducting an oxygenator evaluation this year to compare with our initial evaluation to examine the hypothesis that we are providing the same level of care that we did when we conducted the initial oxygenator evaluation.

We have used a similar approach to identify a new activated clotting time (ACT) analyzer, the *Abbott iSTAT*®. A benefit of this ACT device was that this platform could be used for analysis of blood gases, electrolytes, hemoglobin/hemoglobin saturation, etc. by using different evaluation cassettes. With the current contract for our blood gas analysis device coming to an end, we chose to do a clinical evaluation of the *iSTAT*® as a potential replacement point-of-care (POC) device.

For this evaluation, we ran a blood sample on our current device (*Instrumentation Laboratories*

*GEM4000®*) then on the *iSTAT* using **CG4**+ and **CG8+** cassettes and compared*: pH, partial pressure of oxygen ($pO_2$), partial pressure of carbon dioxide ($pCO_2$), bicarbonate ($HCO_3$), oxygen saturation ($sO_2$), sodium (Na), potassium (K), ionized calcium ($_iCa$), glucose, hemoglobin (HgB), and lactate* values. Our hypothesis was that there were no significant differences in these values when the same sample was evaluated on the different platforms.

**Methods:**

We obtained ethics approval for this clinical evaluation as a '*quality assurance'* initiative through the *Research Ethics Board* of the *Nova Scotia Health Authority* as there was no change in the level of care provided, no patient identifiers were collected, and no additional blood was required.

*Abbot* provided two boxes of **CG4+** and **CG8+** for this evaluation, permitting analysis of 50 blood samples.

The **CG4+** cassette measures: pH, $pO_2$, $pCO_2$, $TCO_2$, $HCO_3$, BE, $sO_2$ and lactate.

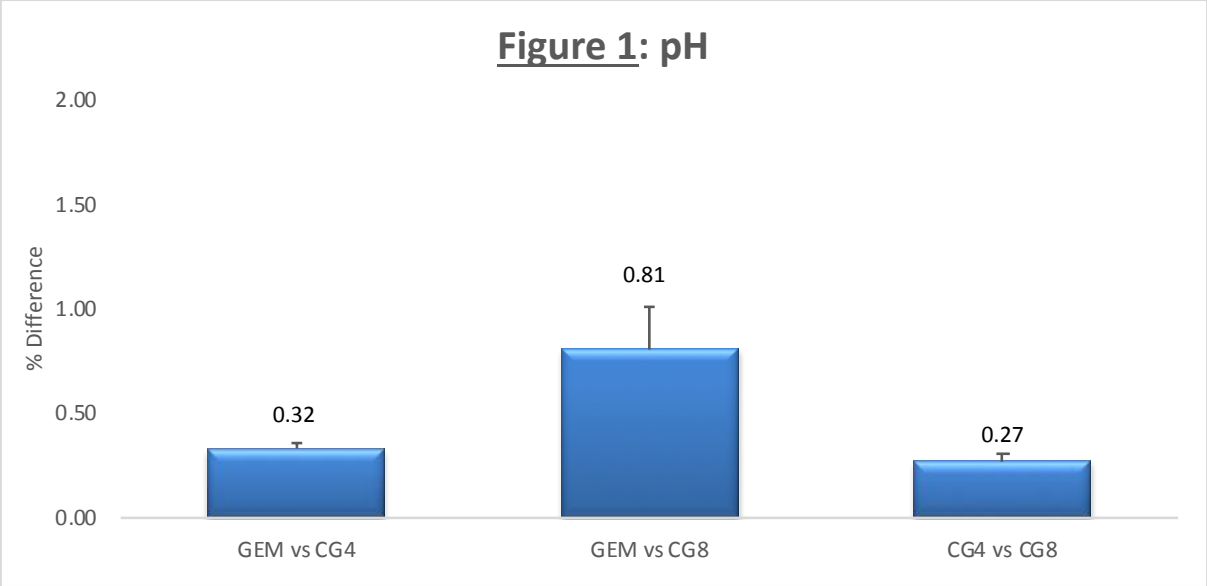
The **CG8+** measures: glucose, Na, K, $_{i}Ca$, Hct, HgB, pH, $pO_2$, $pCO_2$, $TCO_2$, $HCO_3$, BE, $sO_2$.

Blood used for this evaluation was obtained from cardiac surgery patients. Over a one-week period, blood analyzed for ACT and blood gases were analyzed at the same time with the **CG4+** and **CG8+** cassettes. Paired analyte values from the *GEM4000* and *iSTAT* (**CG4+**/**CG8+**) were recorded manually and entered into *Microsoft Excel®*. Once all of the **CG4+** and **CG8+** cassettes were used, data were analyzed by expressing the relevant **CG4+** and **CG8+** values as '*percent difference*' to the corresponding *GEM4000*, **CG4+** or **CG8+** values. Since the **CG4+** and **CG8+** cassette have overlapping analytes, they were also compared against each other.

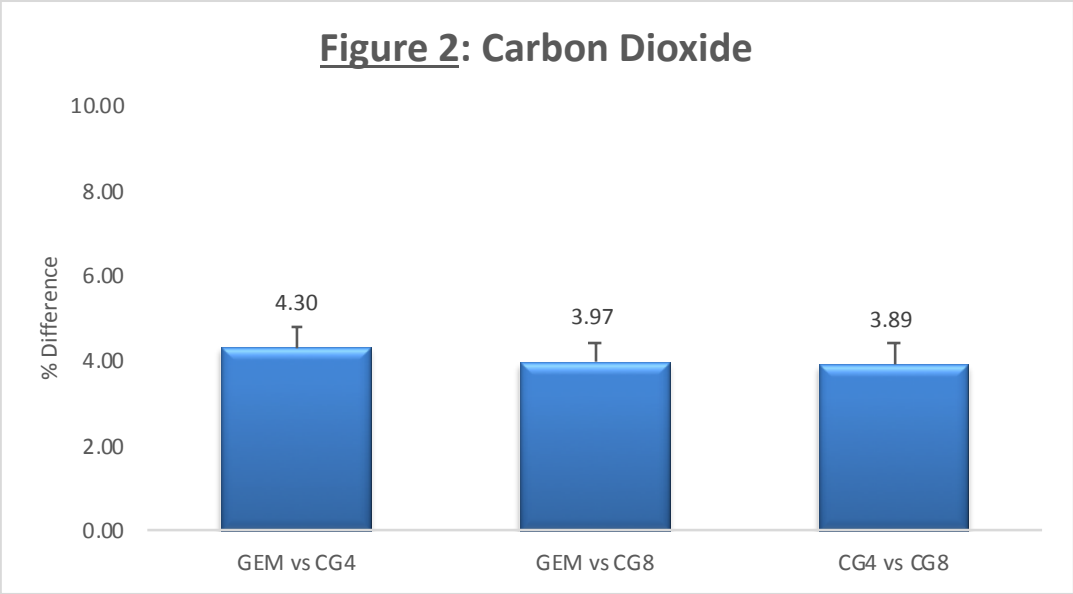
Graphs represent mean $\pm$ standard deviation. Statistical analysis conducted using *Microsoft Excel®*, t-Test two sample assuming equal variances with a p-value less than 0.05 considered to be significant.

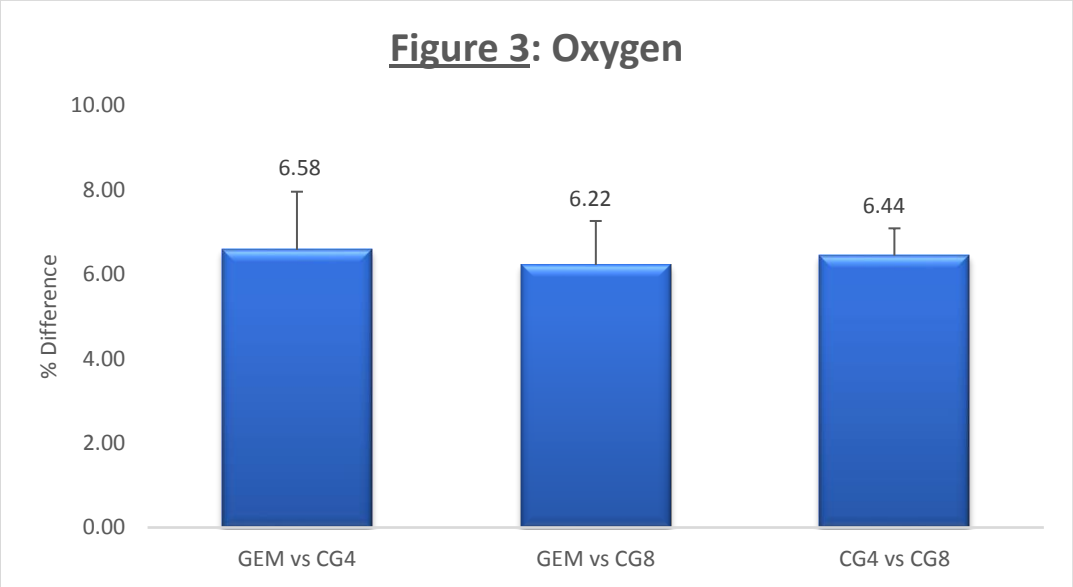
**Results:**

pH was analyzed by both **CG4+** and **CG8+** cassettes and when paired analysis was conducted, the pH values, were less than a percent different (GEM vs CG4+, GEM vs CG8+ and CG4+ vs CG8+ were 0.32, 0.81 and 0.27 % different, $p > 0.05$).

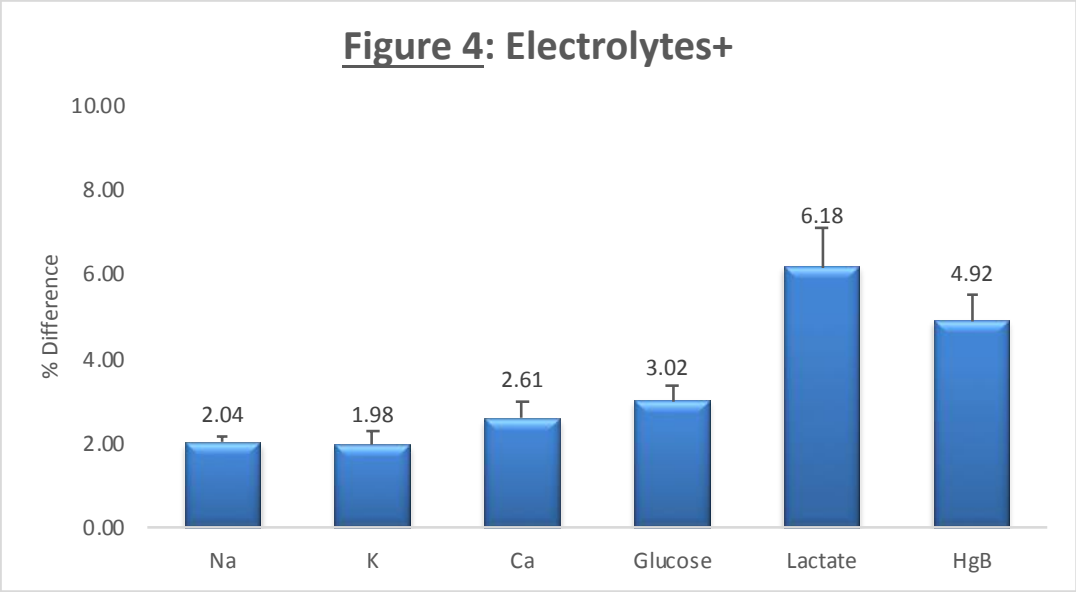



$pCO_2$ and $pO_2$ varied to a greater extent (GEM vs CG4+, GEM vs CG8+ and CG4+ vs CG8+ were 4.3, 9.97 and 3.89 % different for $pCO_2$ and 6.58, 6.22 and 6.44 % different for $pO_2$). There were no significant differences ($p > 0.05$).

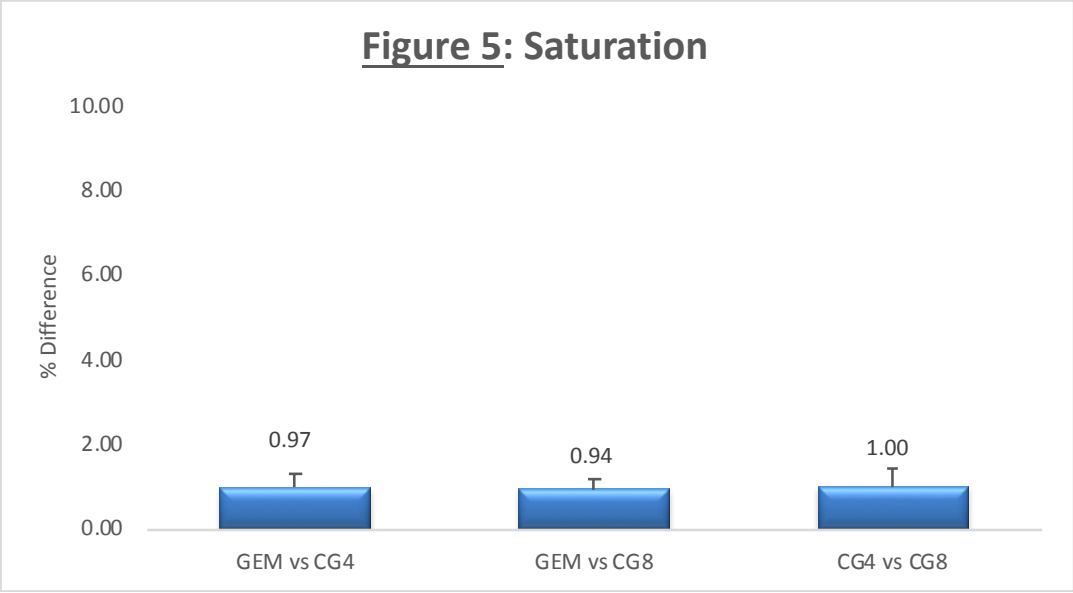



In terms of electrolytes and HgB, the **CG4+** cassette measured lactate, while the **CG8+** cassette measured Na, K, Ca, glucose and both measured HgB. There was little demonstrated variation in these values with Na, K, *i*Ca, glucose, lactate and HgB having 2.04, 1.98, 2.61, 3.02, 6.18 and 4.92 % difference to *GEM4000* values, respectively. As both *iSTAT* cassettes analyzed HgB and were nearly identical ($p < 0.001$, data not shown), the averaged HgB value was compared to *GEM4000* values. There were no significant differences ($p > 0.05$).




Oxygen saturation values were comparable (**GEM** vs **CG4+**, **GEM** vs **CG8+** and **CG4+** vs **CG8+** were 0.97, 0.94 and 1% different), while $HCO_3$ had more variation (**GEM** vs **CG4+**, **GEM** vs **CG8+** and **CG4+** vs **CG8+** were 7.64, 4.99 and 5.91 % different). **GEM** vs **CG4+**, $p < 0.05$, otherwise, there were no significant differences.



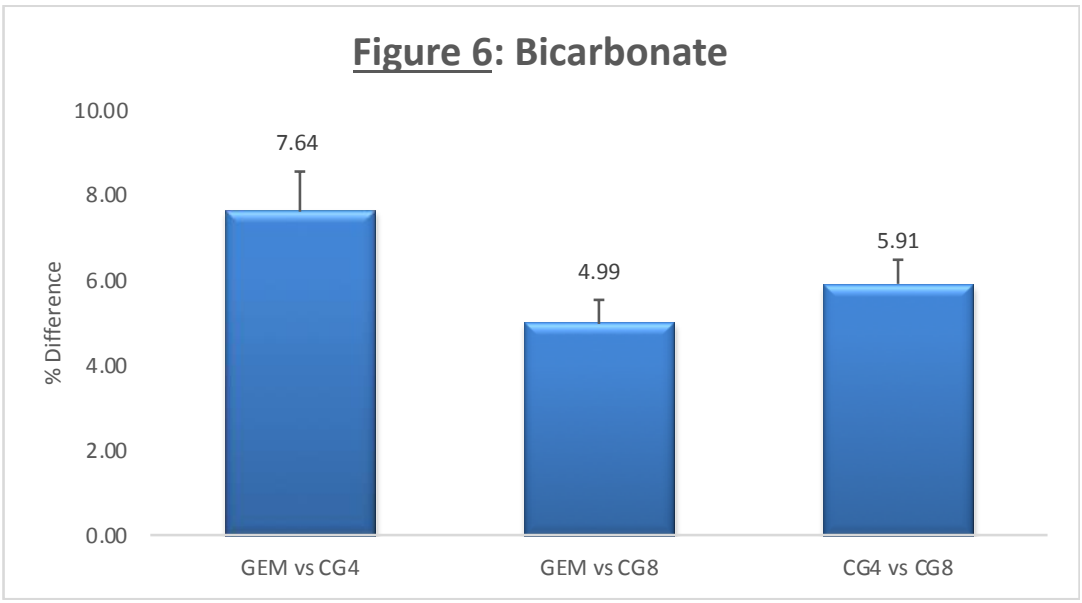


Figure 6: Bicarbonate
10.00
8.00
6.00
4.00
2.00
0.00
% Difference
7.64
4.99
5.91
GEM vs CG4
GEM vs CG8
CG4 vs CG8

**Discussion:**

With impending completion of our contract for blood gas analysis, we activated our *quality assurance initiative* to evaluate another device on the market. Since we currently use the *iSTAT* for our ACT analysis, this was a natural first choice of device to evaluate for blood gas analysis as it only requires different cassettes and not an entire platform.

Overall, we were satisfied with the fidelity of this device for blood gas analysis given the low variation among key analytes. However, any decision would require significant input from the Laboratory Services team, as well as financial considerations.

We noted other positives for the *iSTAT* for blood gas analysis including the ease of use, only a drop of blood is required (we typically draw 2-3 ml for the *GEM4000* to ensure the probe is immersed) for analysis and quality control (QC) is conducted on each cassette prior to analysis. Analysis can be uploaded to the patient's electronic record.

With the QC performed on each *iSTAT* cartridge prior to analysis, each evaluation requires 2 minutes to complete in comparison with 80 seconds for the *GEM4000*, which then needs an additional 80 seconds to process. Unlike the *GEM4000*, the *iSTAT* does not require the 80 second processing time post sample prior to subsequent analysis. The *GEM4000* also requires an initial QC that requires 45 minutes to 'warm up' the *GEM* cartridge plus two *calibration valuation product* (*CVP)* samples from *Instrumentation Laboratories* need to be run on the analyzer to confirm electrolyte values are in appropriate ranges. Typically, this entire process requires 60 minutes to complete and if the *CVP* samples do not pass after multiple 'lots' tested, the cartridge needs to be replaced and the process repeated. Based on the presentation on the soon-to-be available *GEM5000* at the *2017 CSCP AGM*, this initial 45-60 minute start-up quality control will not be required with this device. Overall, there is likely little difference in time required for sample analysis.

The *iSTAT* is also portable, which we found to be invaluable during a catheterization laboratory TAVI emergency case when there was no access to a *GEM4000* and no one available to transport samples to the operating room where we maintain the *GEM4000* units. The perfusionist grabbed the *iSTAT* and the remaining **CG4+/CG8+** that *Abbott* provided when we purchased the devices for us to trial.

In comparison with the *GEM4000*, we noted the reduction in wastage. With the *iSTAT*, cassettes can be maintained in the fridge for 3 months and once at room temperature are stable for 2 weeks meaning zero wastage can be realized in our practice. However, with the *GEM4000* platform, the internal cartridges last for one month or a set number of tests (different sizes available). Currently, we waste approximately 100 tests in our two-high volume (12-hour room) cardiac operating rooms and 300-400 tests in our low volume (8-hour room) cardiac operating room. However, the *GEM4000* cost less per test. Hence, we suggest that centers consider doing a cost analysis as part of their overall assessment of the two devices for their sites.

The *iSTAT* has considerable versatility with 19 different cassettes available (with some overlap) that can quantify 24 different clinical parameters including creatinine, urea nitrogen, prothrombin time/international normalized ratio (PT/INR), cardiac-specific troponin I (cTni), creatine kinase-myocardial band isoenzyme (CK-MB), brain natriuretic peptide (BNP) and D-Dimer in addition to the standard values reported herein. This increases the utility of this device in other areas of the hospital including the emergency room, catheterization laboratory and intensive care units as results are available in minutes rather than tens of minutes when blood samples are sent to the core laboratory.

We also noted some disadvantages of using this device for blood gas analysis in addition to the extra time required for the individual QC evaluation. As our standard of care is to monitor lactate levels on cardiopulmonary bypass, we needed to use two different cassettes to achieve all the analytes we normally do on the *GEM4000*, which would add time to the analysis. Having said that, lactate levels do not normally rise on CPB with some exceptions (long pump times, septic patients, beta-agonist usage, etc.), meaning that the **CG4+** cassette would not be required for all blood gases.

Several factors need to be considered when choosing a new blood analyzer in addition to accuracy and reliability including cost, ease of use and departmental preferences.
While we do not need to start the procurement process of blood gas monitoring at the current time, the fact that we have utilized our quality assurance initiative to evaluate one of the options for a replacement (should we chose not to continue with the *GEM4000*) means that we are able to make a more educated decision.

## Conclusion:

As part of our department's *quality assurance initiative*, we evaluated the *Abbott iSTAT* for point of-care blood analysis in conjunction with our standard-of-care, *GEM4000*. Except for bicarbonate analysis with the **CG4+** but not **CG8+** cassette, no significant difference in analyte levels was observed. While the initial QC of each *iSTAT* cassette appeared to increase the time required for analysis, the ability to do subsequent cassettes without processing and the hour long initial set-up required for the *GEM4000* likely negates any time difference between devices. Given the array of cassettes available with the *iSTAT* to quantify several analytes, its portability and the ability to achieve zero wastage, this device appears to be a reasonable POC blood analysis device for the perfusionist.