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Letter to the Editor

Response to James Reagor and Colleagues' Article "Spectrum Medical Quantum or Terumo CDI 500: Which Device Measures Hemoglobin and Oxygen Saturation Most Accurately When Compared to a Benchtop Blood Analyzer?"

We would like to thank Mr. Reagor and colleagues for their follow-up study comparing the hemoglobin and oxygen saturation measured with the Terumo® CDI® Blood Parameter Monitoring System 500 (System 500) continuous blood gas monitor (Terumo Cardiovascular Systems Corporation, Ann Arbor, MI) and Spectrum Medical Quantum (Spectrum Medical, Fort Mill, SC). Having thoroughly reviewed the article, we would like to clarify two claims made by the authors: one regarding gas calibration for the CDI System 500 and the second regarding the rate of measurement for hematocrit and hemoglobin. Also, of concern, is a flaw in the methodology used in venous and arterial sampling to compare the two devices has been noted.

In the discussion portion of the paper, the authors make the following statement: "*the quantum device does not require gas calibration before use as is recommended for the CDI 500 representing both a preparation time and cost savings* (1)." This statement is misleading and may be due to misreading the CDI System 500's Instructions for Use. Gas calibration is for the System 500's shunt sensor only and does not apply to the hematocrit/saturation (H/S) cuvette. If a user is using only the H/S cuvette, as in this study, no gas calibration is required.

The focus of the authors' research was a comparison of hemoglobin and oxygen saturation between the two devices. The authors used the CDI H/S cuvette on the venous line of a perfusion circuit to measure venous hemoglobin, hematocrit, and saturations to compare those same indices measured on the Quantum. The CDI System 500 incorporates optical reflectance technology in its H/S probe. This probe completes a self-test that checks for optical drift in the H/S module (2). Further validation is accomplished through the performance of an in vivo calibration completed once cardiopulmonary bypass has begun and the circuit has stabilized before sampling is obtained.

Some clinicians only use the optical reflectance technology to measure hematocrit, hemoglobin, and saturation. Thus, they do not need to complete a gas calibration because they are not using the shunt sensor.

Note: Additional parameters of pH, pO_2, pCO_2, and potassium are measured using a shunt sensor that incorporates optical fluorescence technology. Shunt sensors are recommended to be gas calibrated before each use (2). To achieve the full benefit of continuous monitoring with the CDI System 500, it is recommended to use both the shunt sensor(s) and the HSAT cuvettes to continuously monitor arterial and or venous pH, pO_2, pCO_2, potassium, hematocrit, hemoglobin, and oxygen saturation.

An additional point of clarification is the rate of measurement for the hematocrit and hemoglobin for the CDI System 500. In their paper, the authors stated "*Data generated by the Quantum was collected every second. Data produced by the CDI 500 was collected every 6 seconds, the limit of the device* (1)." The CDI 500 measures hemoglobin and oxyhemoglobin every 18 milliseconds and averages those results to accommodate a screen refresh rate of 6 seconds (3).

Finally, questions regarding the methodology used to compare both monitors exist. It appears, by the author's own disclaimer, that they had concerns over the limitation of their study: "*One limitation to this study was the comparison of venous hemoglobin measurements from the CDI 500 to arterial hemoglobin measurements from the Quantum* (1)." Does this mean that venous samples for hematocrit, hemoglobin, and saturation from the CDI System 500 were compared to arterial samples for the Quantum? And what type of samples were measured on the ABL 90 as the reference device? It is commonly recognized that there are differences in measured hemoglobin and hematocrits between venous and arterial samples and that these differences may be amplified by adding volume to a perfusion circuit while on cardiopulmonary bypass (4).

We look forward to a response from Mr. Reagor and his colleagues to help us better understand the methodology

used to compare the CDI System 500 continuous blood gas monitor to the Spectrum Medical Quantum.

Sincerely,

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In Response

I would like to thank representatives from Terumo Cardiovascular for reading and bringing further attention to our publication. I appreciate the opportunity to discuss concerns and improve the readers experience and understanding of topics important to our practice.

The concern around our statement, "the quantum device does not require gas calibration before use as is recommended for the CDI 500 representing both a preparation time and cost savings" (1), is valid and I am grateful for the clarification. Gas calibration of the CDI System 500 is not necessary for isolated use of the hematocrit/saturation (H/S) cuvette. I agree with the statement "To achieve the full benefit of continuous monitoring with the CDI System 500, it is recommended to use both the shunt sensor(s) and the HSAT cuvettes to continuously monitor arterial and or venous pH, pO2, pCO2, potassium, hematocrit, hemoglobin, and oxygen saturation" (2), yet as you mentioned, some clinicians only use the H/S cuvette. The per case cost savings described only applies to the elimination of the H/S cuvette. The elimination of the gas calibration would only be applicable with the complete abandonment of the CDI System 500 in favor of the Quantum. A recommendation we did not make.

To address the data collection question, we would like to again thank you for providing more information for our readers. It was important for the reader to understand the reporting differences between the devices as related to the data collected for this study and how the data was averaged to produce a minute value for comparison between the three devices. The rate of measurement was not addressed. The CDI System 500 and Quantum devices each update values for observation and data collection at various rates. The Quantum provides values for electronic data collection each second. The CDI 500 provides data for electronic collection every six seconds (3). As a result, and as stated in the methods section of the original publication, "60 measurements from the Quantum and 10 from the CDI 500 were averaged over one minute to provide a single value for the minute" (1).

Finally, regarding your claim of flawed methodology, I respectfully disagree. As the point of this discussion is to ensure the reader has the best opportunity to make an informed decision, I should point out that with the statement: 'It is commonly recognized that there are differences in measured hemoglobin and hematocrits between venous and arterial samples and that these differences may be amplified by adding volume to a perfusion circuit while on cardiopulmonary bypass.' a publication is cited which examines physiological differences between arterial and venous hemoglobin samples. While this publication found a 1.8% difference in arterial vs. venous hemoglobin (14.1 ± 1.4 vs. 14.3 ± 1.2, respectively – mean ± SD), they found no statistical difference ($p = .08$), nor does this publication address cardiopulmonary bypass circuits (4). Additionally, Yang, et al. postulate this difference is due to exudation of 2–3% of plasma in the arterial blood remaining to from tissue fluid resulting in an increase in venous hemoglobin (4). This does not occur between the venous and arterial lines of a cardiopulmonary bypass circuit. The concern around the addition of volume is addressed below.

To the question, "Does this mean that venous samples for hematocrit, hemoglobin, and saturation from the CDI System 500 were compared to arterial samples for the Quantum?", the answer is no, yes, and no. We did not analyze hematocrit. Venous saturation values from the CDI System 500 were compared to venous saturation values from the Quantum. Regarding hemoglobin,