

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.

REFERENCES

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2. Operating Manual. Blood Parameter Monitoring System 500, 236603J ed. Ann Arbor, MI: Terumo Cardiovascular Systems Corp; 2015.
3. Technical Compendium. CDI® Blood Parameter Monitoring System 500. Ann Arbor, MI: Terumo Cardiovascular Systems Corporation; 2016.
4. Yang ZW, Yang SW, Chen L, et al. Comparison of blood counts in venous, fingertip and arterial blood and their measurement variation. *Clin Lab Haematol.* 2001;23:155–9.

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 \pm 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,

as you indicated we stated, “One limitation to this study was the comparison of venous hemoglobin measurements from the CDI 500 to arterial hemoglobin measurements from the Quantum” (1). As recommended in the CDI 500 instructions for use and as part of normal practice, a stabilized circuit is recommended for best comparison with laboratory devices (3), as such, volume was not administered in close temporal proximity with sample collection. Additionally, we demonstrated and stated in the discussion the difference, per Bland-Altman analysis, between the venous (CDI System 500) and arterial (Quantum) hemoglobin measurements of the devices as 0.194 g/dL from zero. While due the sheer magnitude of data collected for this study the value is statistically significant ($p < .001$), it may not be clinically significant. This limitation was outlined in full disclosure to be completely transparent about the methods. The methodology was peer-reviewed and accepted for publication.

Thank you, again for the opportunity to help you and our readers better understand our methodology. Collaboration with our industry partners is always beneficial

and I thank Terumo for continuing to elevate conversations important to the community.

Sincerely,

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1. Reagor JA, Gao Z, Tweddell JS. Spectrum Medical Quantum or Terumo CDI 500: Which device measures hemoglobin and oxygen saturation most accurately when compared to a benchtop blood analyzer? *J Extra Corpor Technol.* 2021;53:181–5.
2. Osborne S, Pregulman, S. Letter to the editor. *J Extra Corpor Technol.* 2022;54:161–3.
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