Published in final edited form as:

Anesth Analg. 2018 February ; 126(2): 621–628. doi:10.1213/ANE.0000000000002692.

IN VITRO EVALUATION OF A NOVEL IMAGE PROCESSING DEVICE TO ESTIMATE SURGICAL BLOOD LOSS IN SUCTION CANISTERS

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Contribution: This author helped perform data analysis and manuscript preparation.

Attestation: Gerhardt Konig attests to approving the final manuscript and to the integrity of the data analysis reported in this manuscript.

Conflicts of Interest: None

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Contribution: This author helped perform manuscript preparation.

Attestation: Jonathan Waters attests to approving the final manuscript.

Conflicts of Interest: None

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Contribution: This author helped perform study design, data collection and Figure development

Attestation: Eric Hsieh attests to approving the final manuscript.

Conflicts of Interest: Eric Hsieh is an employee of Gauss Surgical, Inc.

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Conflicts of Interest: none

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Conflicts of Interest: none

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Conflicts of Interest: none

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Attestation: Mazyar Javidroozi attests to approving the final manuscript and to the integrity of the statistical analysis reported in this manuscript

Conflicts of Interest: Mazyar Javidroozi is a consultant for Gauss Surgical, Inc.

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Attestation: Griffeth Tully attests to approving the final manuscript and to the integrity of the data analysis reported in this manuscript.

Conflicts of Interest: Griffeth Tully is an employee of Gauss Surgical, Inc.

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Attestation: Gregg Adams attests to approving the final manuscript.

Conflicts of Interest: Gregg Adams is a scientific advisor of Gauss Surgical, Inc.

IRB: This study was approved by the Institutional Review Board of Santa Clara Valley Medical Center (San Jose, CA)

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Abstract

Background—Clinicians are tasked with monitoring surgical blood loss. Unfortunately, there is no reliable method available to assure an accurate result. Most blood lost during surgery ends up on surgical sponges and within suction canisters. A novel FDA-cleared device (Triton system, Gauss Surgical, Inc., Los Altos, CA) to measure the amount of blood present on sponges using computer image analysis has been previously described. This study reports on performance of a complementary FDA-cleared device (Triton Canister System, Gauss Surgical, Inc., Los Altos, CA), that uses similar image analysis to measure the amount of blood in suction canisters.

Methods—Known quantities of expired donated whole blood, packed red blood cells (PRBC), and plasma, in conjunction with various amounts of normal saline, were used to create 207 samples representing a wide range of blood dilutions commonly seen in suction canisters. Each sample was measured by the Triton device under 3 operating room lighting conditions (Bright, Medium and Dark) meant to represent a reasonable range, resulting in a total of 621 measurements. Using the Bland-Altman method the measured hemoglobin mass in each sample was compared to the results obtained using a standard laboratory assay as a reference value. The analysis was performed separately for samples measured under each lighting condition. It was expected that under each separate lighting condition the device would measure the various samples within a pre-specified clinically significant Hb mass range (± 30 g per canister).

Results—The limits of agreement between the device and the reference method for Dark [bias 4.7 g (95% CI: 3.8 g to 5.6 g); LOA -8.1 g (95% CI -9.7 g to -6.6 g) to 17.6 g (95% CI 16.0 g to 19.1 g)], Medium [bias 3.4 g (95% CI: 2.6 g to 4.1 g); LOA -7.4 g (95% CI -8.7 g to -6.1 g) to 14.2 g (95% CI 12.9 g to 15.5 g)], and Bright lighting conditions [bias 4.1 g (95% CI: 3.2 g to 4.9 g); LOA -7.6 g (95% CI -9.0 g to -6.2 g) to 15.7 g (95% CI 14.3 g to 17.1 g)] fell well within the predetermined clinically significant limits of ± 30 g.

Repeated measurements of the samples under the various lighting conditions were highly correlated, with intraclass correlation coefficient (ICC) of 0.995 (95% CI 0.993–0.996, $p < 0.001$) showing that lighting conditions did not have a significant impact on measurements. Hemoglobin mass bias was significantly associated with hemolysis level (Spearman's rho correlation coefficient -0.137 , $p = 0.001$) and total canister volume (Spearman's rho correlation coefficient 0.135 , $p = 0.001$), but not ambient illuminance.

Conclusion—The Triton Canister System was able to measure the Hb mass reliably with clinically acceptable accuracy in reconstituted blood samples representing a wide range of Hb concentrations, dilutions, hemolysis and ambient lighting settings.

BACKGROUND

Accurate assessment of blood loss during surgery is essential in providing appropriate perioperative patient management. The amount and rate of bleeding are among the factors considered in anesthetic management and transfusion decisions.¹ In the absence of reliable and objective measures, clinicians typically rely on visual estimation of blood loss, a subjective method with documented inaccuracy and imprecision.^{2–5}

The bulk of blood lost during surgery is collected on surgical sponges or in suction canisters. An FDA-cleared device that accurately estimates the amount of blood on surgical sponges using computer image analysis has previously been described.^{6,7} Blood loss determined by that method correlates well with the results obtained using an assay standard and provides significantly more accurate information than weighing sponges to determine the amount of blood absorbed.⁶ These results have been confirmed across a range of ambient lighting conditions, sponge saturations and initial blood hemoglobin (Hb) levels. The measurements are not affected by irrigants or other fluids that are absorbed on the sponges.⁷

The primary objective of this study was to evaluate the accuracy of a complementary FDA-cleared device (Triton Canister System, Gauss Surgical, Inc., Los Altos, CA) that uses a similar image-analysis approach to estimate the amount of Hb present in canisters used to collect blood and other fluids from a surgical field under a variety of lighting conditions. Together, these two devices can accurately tally most of the blood lost during surgery, providing clinicians with real-time blood loss measurements to support their clinical decision-making.

METHODS

This study was approved by the Institutional Review Board (IRB) of the Santa Clara Valley Medical Center (San Jose, CA). This was an *in vitro* study performed on expired donated human blood destined for disposal. The Institutional Review Board reviewed the use of these specimens and found that they met the requirements for exemption from written informed consent. This manuscript adheres to the applicable Equator guidelines.

The Triton Canister System is intended to assist clinicians in estimating blood loss in procedures where blood is aspirated into canisters (herein called canister estimated blood loss or EBL). One type of suction canister (Medi-Vac® Guardian Suction System, 3000-mL)

was used in conjunction with two physical attachments (an injection molded insert and a color correction label). The Triton Canister System utilizes the image analysis system known as Feature Extraction Technology whereby cloud-based computer vision servers are connected to a mobile application installed on a computer tablet (iPad). The system uses the iOS app to capture images of the suction canister at a designated spot where the color and thickness of the fluid layer is standardized by the presence of the molded canister insert. The images captured are sent to a remote cloud-based server where a pre-processing module extracts several photographic and geometric features from the image representing blood in the canister, and then uses pixels extracted from the attached color correction label to normalize the blood pixels for variations in ambient lighting. These features are then inputted into a proprietary mathematical model that is calibrated to map image features to Hb concentration values. The Hb concentration of the canister is then multiplied by the user-entered volume of fluid in the container to calculate the Hb mass (g) contained in the canister. Upon division by the patient's most recently measured Hb concentration (g/dL) this yields a volumetric estimate for the blood within the canister. If there has been settling of the fluid in the canister, gentle mixing is required prior to scanning. These images can be captured periodically during a surgical procedure (Figure 1) for real-time assessment of canister blood loss.

Sample Preparation and Measurement

Sample preparation and testing was performed in an empty surgical OR at Santa Clara Valley Medical Center (San Jose, CA) according to standard laboratory and environmental safety practices and guidelines. Expired human whole blood, packed red blood cell (PRBC) and plasma units were obtained from the Stanford Blood Center (Stanford, CA). Hb concentrations of whole blood and PRBC units were prepared and measured per the manufacturer's instructions using Hemocue Hb201+ and Hemocue Plasma/Low Spectrophotometers (HemoCue America, Brea, CA). The whole blood, PRBC and plasma were combined in ratios determined by a random number generator to create blood samples with known Hb concentrations between 6.1 g/dl to 17.3 g/dL., covering range typically encountered in clinical practice.² Additional serial dilutions were prepared by adding normal saline to simulate irrigation fluid often present in the surgical field. To simulate varying levels of hemolysis, aliquots of blood specimens were treated with a blender. Hemolysis was verified and quantified by separating the intracellular (intact) and extracellular (free) Hb using a Premiere XC-2000 centrifuge at 4000 rpm for 5 minutes then measuring the extracellular Hb concentration in the supernatant and calculating the ratio of extracellular to total Hb concentration. Subsequently, various amounts of hemolyzed blood were added to samples to reproduce desired hemolysis levels (expressed in percentage). Reconstituted bloody canister samples, therefore, were highly variable (Figure 2). To achieve sufficient volumes in the canisters, these samples necessarily contained blood and plasma from multiple sources. This was considered reasonable due to the relative consistency of donated human blood between subjects, and because the variables that were known to impact the Triton reading, such as Hgb concentration and degree of hemolysis, were carefully controlled.

Once prepared, the samples were transferred into canisters and the total volume in each canister was manually read and recorded by the operators. Finally, the Hb concentrations of the canisters were measured using Hemocue Hb201+ (HemoCue America, Brea, CA) and Plasma/Low Spectrophotometers (HemoCue America, Brea, CA) per the manufacturer's instructions and designated as reference measurements (herein referred to as Assay measurements) for the comparison against Triton. Due to its greater precision at the low end of the spectrum, the Plasma/Low device was used for samples with Hb concentrations less than 3.0 g/dL. The Hb201+ device was used for samples with Hb concentration greater than 3.0 g/dL. The Hemocue technology was chosen as the reference standard because it offered a validated point-of-care test with accuracy and precision comparable to a standard azide-methemoglobin benchtop assay and, as the closest comparable point-of-care product to the Triton device, it was the most representative technique for the chosen statistical comparison.

The Triton Canister App was then used to capture scans of the canisters. This step was performed in a vacant standard operating room under three different ambient lighting conditions (Bright, Medium, and Dark) meant to represent a reasonable range, modulated by controlled changes in the overhead light levels. The illuminance for the three ambient light settings was selected to mimic standard lighting conditions (Bright), mildly dimmed lighting (Medium) and moderately dimmed lighting (Dark) and were measured using an Extech Lux Meter (Extech Instruments, Nashua, NH) positioned at the face of the canister.

Based on the Hb concentration determined by Triton from the captured image (Triton Hb concentration) and the manually entered canister volume, the Triton device calculated the Hb mass (Triton Hb mass) for each sample. The Triton Hb mass was then compared with the pre-measured Hb mass (Assay Hb mass) of the reconstituted samples. The Assay estimated blood loss (Assay EBL) was calculated using the Assay Hb mass (g) and the pre-measured Assay Hb concentrations of whole blood or packed RBC units.

In this study the clinically significant Hb mass difference between the Triton Hb mass and the Assay Hb mass was set *a priori* at ± 30 g per canister. This difference, which has been applied elsewhere as a clinically relevant limit,^{2,11} corresponds to approximately 5% of the total blood volume of an average adult, and the hemoglobin content of $\frac{1}{2}$ unit of allogeneic whole blood. It was expected that under each separate lighting condition the device would measure the various samples within this pre-specified clinically significant Hb mass range.

Statistical Analysis

Measurements obtained under each lightning condition were analyzed together and data from various lightning conditions were not pooled together to avoid issues related to repeated measures. To assess agreement between the Triton Hb mass and the Assay Hb mass (the primary aim of the study), the approach described by Bland and Altman was used.⁹ Bland and Altman approach emphasizes the fact that correlation is not the same as agreement, and little agreement might exist between two methods despite significant correlation. The bias (mean difference between the two methods of measurement) was calculated and plotted. The limits of agreement, within which 95% of the differences between the two measurements lie, was calculated as the bias $\pm 1.96 \times \text{SD}$ of differences.

According to the Bland-Altman approach,⁹ to declare the two measurements in agreement, the outer 95% confidence intervals (CI) of the upper and lower limits of agreement should fall within the clinically-acceptable range of -30 to +30 g. The bias and limits of agreement for EBL were also calculated and plotted. Furthermore, for Bland-Altman analyses the data from measurements under different light conditions were analyzed separately to avoid repeated measurement of the same samples. For each sample, consistency of Triton measurements across the various ambient light settings was evaluated using Intra-class Correlation Coefficient (ICC) and Coefficient of Variation (CV).

Variables were expressed in mean $\pm$ SD, median/interquartile range (IQR) or count (%) as appropriate. Given the reconstituted nature of samples, the data were not expected to follow a normal distribution (verified with Kolmogorov-Smirnov test) and focus was placed on non-parametric tests. Additional analyses were performed using t-test, Mann-Whitney U-test, or Wilcoxon Signed Ranks Test as appropriate (to compare bias between different lighting settings), and Pearson or Spearman's correlations (assessing the correlation between the measurements performed by the Triton and Assay methods, which as indicated earlier, is not an indicator of agreement between the two). Exploratory linear multiple regressions were performed for measurements performed under each lighting conditions with the Hb Mass bias as the dependent variable and canister volume, hemolysis, Hb concentration of sample and patient Hb concentration as independent variables to assess the combined effect of the predictors. Hemolysis was grouped into quartiles (1st quartile, 1.66–24.75%; 2nd quartile, 25.71–43.16%; 3rd quartile, 50.04–78.40%; and 4th quartile, 82.85–99.50% hemolysis). Residuals were evaluated to ensure normal distribution. Statistical analyses were performed using SPSS (version 13.0, SPSS, Inc).

According to the method described by Bland and Altman a sample size of 100 was determined sufficient to achieve a 95% CI of $\pm 0.34 \times \text{SD}$ around the upper and lower limits of agreement.¹⁰ However, when accounting for the various combinations (whole blood/PRBC/plasma ratios, hemolysis level, saline dilution, overall canister fluid volume, and various Hb concentrations), and to make the reconstituted samples more representative of the broad variety of samples encountered in clinical practice, a total of 207 canister configurations were eventually prepared and scanned under the three ambient light conditions.

RESULTS

The device successfully captured images of the canisters and determined the Triton Hb mass for all 207 samples under 3 lighting conditions. Table 1 provides the calculated bias and limits of agreement (with 95% confidence intervals) for Hb mass (g), Hb concentration (g/dL) and EBL (ml) under 3 lighting conditions measured using the reference (Assay) method and Triton. Hb Mass, concentration and EBL were all highly correlated between the Triton and Assay methods, under each of the three lighting conditions, and the Pearson's coefficient of correlation (and the corresponding lower limit of 95% confidence interval) in all cases were 0.97 or higher. Scatter plots of measurements by the two methods are provided in Figure 3.

The mean $\pm$ standard deviation (SD) of the actual measured illuminance values corresponding to the Bright, Medium, and Dark settings were 506 ± 132 lx, 372 ± 87 lx, and 154 ± 77 lx, respectively. Repeated measurements of the samples under three different lighting settings were highly correlated (data not shown). The ICC for single measures across the three ambient lighting settings was 0.995 (95% CI 0.993–0.996, $p < 0.001$) and the ICC for the average measure was 0.998 (95% CI 0.998–0.999, $p < 0.001$). The CV for measurements performed under three ambient lighting settings was 0.070. Hb mass bias varied significantly in the 3 lighting settings: Median/IQR Hb mass bias in Dark, 3.0/6.1; Medium, 2.0/4.8; Bright, 2.8/4.9 ($p = 0.025$) (Figure 4). When the correlation between bias and actual ambient illuminance was considered, it was not significant for all data points combined (Spearman's rho correlation -0.034 , 95% CI -0.112 to 0.044 , $p = 0.404$), or when only data from the Bright setting were considered. However, this correlation was significant for data from measurements performed under the Dark (Spearman's rho 0.224 , 95% CI 0.091 to 0.349 , $p = 0.001$) and Medium setting (Spearman's rho -0.248 , 95% CI -0.371 to -0.116 , $p < 0.001$). Other factors that were statistically significantly correlated with Hb bias were hemolysis (Spearman's rho correlation coefficient -0.137 , 95% CI -0.213 to -0.059 , $p = 0.001$) and canister volume (Spearman's rho correlation coefficient 0.135 , 95% CI 0.057 to 0.211 , $p = 0.001$). When various lighting settings were considered individually, Hb mass bias was correlated with canister volume under Dark (Spearman's rho correlation coefficient 0.149 , 95% CI 0.013 to 0.279 , $p = 0.032$) and Bright (Spearman's rho correlation coefficient 0.164 , 95% CI 0.029 to 0.293 , $p = 0.018$) settings. Under Medium lighting setting, Hb mass bias was correlated with hemolysis (Spearman's rho correlation coefficient -0.173 , 95% CI -0.302 to -0.038 , $p = 0.013$). Table 2 summarizes the predictors of Hb Mass bias identified by the regression analysis under various lighting conditions. The final models had adjusted R-square values of 0.165, 0.131 and 0.125 under Dark, Medium and Bright lighting conditions, respectively.

DISCUSSION

Monitoring blood loss is fundamental to intraoperative patient management and transfusion decision making. Official recommendations from various surgical and transfusion medicine societies include specific transfusion triggers based on measurement of blood loss.^{12–15} Furthermore, optimizing hemostasis and reducing blood loss are among the central tenets of patient blood management.¹⁶ However, with no reliable, evidence-based method to keep track of the surgical blood loss, clinicians often rely on their best guess to come up with an estimate at any given time. Visual estimates of blood loss based on the number and “bloodiness” of sponges used combined with the volume of the fluid collected in suction canisters is considered to be the best practical option, but this subjective approach has been shown to be unreliable and inaccurate.^{3,4} The arbitrary nature of this method and its potential to misguide clinical decision-making have given rise to calls to abandon visual estimation of blood loss.¹⁷ Others have attempted to develop solutions such as standard cards to reduce the subjectivity of the estimates with limited success.^{18,19} Gravimetric assessment (i.e. weighing) of blood loss is another well described method, however results for this technique are mixed with measurements frequently confounded by recording bias, amniotic fluid/saline corruption, and human error.^{17,21}

As shown in Table 1, the limits of agreement between the device and the reference method for Dark, Medium, and Bright lighting conditions fell well within the predetermined clinically significant limits of ± 30 g. The clinically-acceptable range had been set *a priori* and corresponded to approximately 5% of the total blood volume of an average adult, or the hemoglobin content of $\frac{1}{2}$ of an average unit of whole blood. This threshold for clinical relevance has been used previously by other investigators in similar assessments.^{2,11} Typically only one canister is set up for a procedure. However, given the accuracy demonstrated, the clinically-acceptable range would be met even if multiple canisters were used.

A concern when using image analysis algorithms is the impact of ambient lighting conditions on the image processing. In this study, the image analysis showed a high level of consistency under a range of operating room lighting conditions. Hb mass bias was not correlated with overall ambient illuminance level, but the association became statistically significant in subgroup analyses of the Dark and Medium lighting settings. Hb mass bias was also significantly associated with hemolysis level and canister volume. While these findings were statistically significant, the correlation coefficients and subsequent clinical impact are relatively small. In practice, the system will provide accurate information in all lighting conditions commonly found in operating rooms. If the lighting were to be dimmed, the accuracy would be minimally compromised. More substantial dimming of light is detected by the device and relayed to the user as a “low-lighting” warning.

In terms of study limitations, despite efforts to cover ranges of Hb and asanguinous fluids, this study is limited by the fact that the fluids studied may not be representative of the contents of canisters during actual surgical cases. With large enough sampling, the latter is expected to follow a normal distribution, while the goal here was to create a wide variety of samples to adequately cover all key parameters. As such, representation of various ranges of Hb, hemolysis and volumes in our samples are not necessarily reflective of real world situations. Furthermore, for practicality purposes, study samples contained blood and plasma from multiple sources, which is another potential confounder. Nevertheless, given the similarities of studied variables between blood units, the expected performance of the device should be similar in clinical studies using samples obtained from real surgeries. Further studies are needed to establish this.

Tracking of blood loss during surgical procedures requires consideration of the various routes that shed blood may follow. One major route is that blood suctioned into canisters, although commonly discarded, may, if appropriate, be reinfused back into the patient using a cell salvage system. Furthermore, blood that is contained on surgical sponges can also sometimes be rinsed out and collected for reinfusion using a cell salvage device.²⁰ No matter what the measurement method, the estimated blood loss should be adjusted for any amount of blood reinfused back to the patient. Importantly, clinicians must recognize that the blood infused using a cell salvage system consists entirely of red cells. When considering loss of coagulation factors and other plasma constituents, cell salvage blood should not be deducted from EBL.

While it is theoretically possible to measure the hemoglobin concentration in surgical suction canisters using standard laboratory tests, that is not commonly done due to the difficulty in extracting aliquots of liquid without exposing staff to potentially contaminated fluids, the complexity of and time needed for the task and the delay in obtaining results. The technology studied removes all of those barriers.

In this study, the Triton Canister system was able to estimate the Hb mass and EBL in suction canisters with an average bias of 18.5% versus the reference method (Assay). It has been previously shown that the Triton System is able to accurately estimate the blood on surgical sponges with a mean bias of around 10%.^{6, 7} Together, these two systems complement each other and are able to estimate the bulk of the blood lost during surgery in real time with relatively high accuracy. While the evidence supports the superior performance of these devices compared with visual estimation, the impact of the combined use of Triton and Triton Canister systems in management of surgical patients needs to be addressed in future studies to better understand their role as clinical decision support tools.

Acknowledgments

The authors would like to recognize the following person for their significant contributions to this study: Eunice Tsai, BS; Research Associate, Gauss Surgical Inc.

Funding: This research was supported by a grant from the National Institutes of Health (T32GM075770). Equipment for study was provided by Gauss Surgical, Inc., Los Altos, USA.

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Key Points**Question**

Can the Triton System be used to objectively quantify blood contained in surgical canisters.

Findings

The Triton System was able to measure the Hb mass reliably with clinically acceptable accuracy in reconstituted blood samples representing a wide range of Hb concentrations, dilutions, hemolysis and ambient lighting settings.

Meaning

The Triton Canister System can be used to objectively quantify blood contained in surgical canisters.

Figure 1. Triton Canister System uses an iOS app to enable a user to capture scans of blood bearing containers intraoperatively to estimate the Hb mass loss and estimated blood loss within the container

Figure 2.
Canister blood volume, total volume, Hb mass, and % hemolysis for prepared samples
(n=207)

Figure 3. Scatter plots of Hb mass (g), concentration (g/dl) and EBL (ml) obtained from reference method and Triton System under each of 3 lighting conditions (n=207 for each).

Figure 4.
Box plots of Hb mass bias (g) of the same samples under 3 lighting conditions.

Hb mass, concentration and estimated blood loss in 207 study samples under 3 lighting conditions. The bias represents the mean difference between the Triton and Assay values.

Table 1

Variable	Lighting Condition	Bias (Triton vs. Assay)	Lower Limit of Agreement	Upper Limit of Agreement
Assay Hb Mass (g)	Dark	4.7 (3.8 to 5.6)	-8.1 (-9.7 to -6.6)	17.6 (16.0 to 19.1)
	Medium	3.4 (2.6 to 4.1)	-7.4 (-8.7 to -6.1)	14.2 (12.9 to 15.5)
	Bright	4.1 (3.2 to 4.9)	-7.6 (-9.0 to -6.2)	15.7 (14.3 to 17.1)
Assay Hb Concentration (g/dl)	Dark	0.3 (0.2 to 0.3)	-0.4 (-0.5 to -0.3)	1.0 (0.9 to 1.0)
	Medium	0.2 (0.2 to 0.2)	-0.4 (-0.5 to -0.3)	0.8 (0.7 to 0.9)
	Bright	0.2 (0.2 to 0.3)	-0.4 (-0.5 to -0.3)	0.9 (0.8 to 1.0)
Assay EBL (ml)	Dark	37.8 (29.9 to 43.8)	-62.6 (-74.6 to -50.6)	136.3 (124.3 to 148.3)
	Medium	26.8 (20.9 to 32.8)	-58.7 (-69.0 to -48.4)	112.4 (102.1 to 122.7)
	Bright	32.0 (25.5 to 38.5)	-61.0 (-72.2 to -49.8)	124.9 (113.7 to 136.1)

The limits of agreement for Hb mass fall within the clinically acceptable range of ± 30 g. All values are provided with corresponding 95% confidence intervals.

Table 2

Predictors of Hb Mass bias. A linear regression analysis was run for data under each lighting condition with the Hb Mass bias as the dependent and the variables listed in the table as the independent variables. Slopes are the unstandardized coefficients for each variable, which indicate the change in the dependent variable for every unit change in the respective variable.

Variable	Lighting Conditions	Slope (95% Confidence Intervals)	P Value
Canister Volume (mL)	Dark	0.003 (0.002 to 0.005)	<0.001
	Medium	0.003 (0.001 to 0.004)	<0.001
	Bright	0.003 (0.002 to 0.004)	<0.001
Hemolysis (Quartiles)	Dark	-1.232 (-1.993 to -0.472)	0.002
	Medium	-1.135 (-1.786 to -0.483)	0.001
	Bright	-1.068 (-1.773 to -0.364)	0.003
Measured Hb Concentration of Sample (g/dL)	Dark	1.085 (0.485 to 1.685)	<0.001
	Medium	0.526 (0.013 to 1.040)	0.045
	Bright	0.637 (0.082 to 1.192)	0.025
Patient Hb Concentration (g/dL)	Dark	3.854 (-2.176 to 9.884)	0.209
	Medium	-0.435 (-0.799 to -0.071)	0.020
	Bright	-0.372 (-0.765 to 0.022)	0.064

For example and according to the table, 1 mL increase in the Canister Volume would result in 0.003 g increase in the Hb Mass bias under each of the 3 lighting conditions.