Comparison of Coulter Counter and CO-Oximeter (pHOx) Measurements for Hemoglobin.

Introduction
Technology for total hemoglobin (tHb) measurement has rapidly advanced with many different techniques for measuring total hemoglobin (tHb), which result in variances in accuracy ranges and absolute values of tHb. Procedural variations such as the use of liquid heparin in syringes increase variability and reduce accuracy of tHb measurements in point of care devices and CO-Oximeters. In addition to variations seen between different devices and techniques, variations have also been observed between the same models of devices with bias and precision which can vary greatly from -0.8 to 0.4 g/dL and 0.1 to 0.9 g/dL, respectively. The purpose of this study was to compare tHb measurements made with two different devices that use different principles of operation.

Methods
471 paired arterial blood samples were obtained from 33 patients undergoing liver transplantation. After 10 ml waste, a 10 ml sample was analyzed for tHb by the COULTER® AcT diff2 analyzer (Beckman Coulter Inc., Miami, FL, USA). Immediately after, a 2 ml sample was taken for tHb measurement by the pHOx CO-Oximeter (Nova Biomedical, Waltham, MA, USA). Both devices were maintained according to manufacturer's recommendations and calibrated before each case. Accuracy was determined by calculating bias, precision and root mean square of the differences (ARMS) between test (Coulter analyzer) and control (CO-Oximeter) values. Bias was calculated as the mean of the differences and precision was calculated as the standard deviation of the mean of the differences between the devices. Statistical software (SigmaPlot, San Jose, CA) was used to perform the statistical calculations. Statistical differences were assessed by t test after confirming normality of the data.

Results
33 liver transplant patients, 25 males and 8 females, (mean age of 56 ± 10 years, range 23 to 73 years) had an average of 14 paired blood samples taken. Mean surgery time was 4.3 ± 1.4 hours per case, with a range of 3 to 57 packed red blood cell transfusions (mean = 14 ± 12). The mean tHb measured by the Coulter counter was 1.0 g/dL lower than the CO-Oximeter measurements ($P < 0.001$). Figure 1 shows the Scatterplot of tHb readings and Figure 2 shows the Bland-Altman plot highlighting the bias, precision and ARMS for the two devices. The limits of agreement ($±2SD$) for the mean of the differences range from 0.24 to -2.26 g/dL.

Conclusion
The tHb measurements by both devices were highly correlated over the entire range of 5.1 to 14.8 g/dL. The Coulter measurements were biased about 1 g/dL lower than the CO-Oximeter values. This study shows that different devices using different principles of operation can produce consistent differences in the absolute values of measurement.
Figure 1

Correlation = 0.93
P < 0.0001
N = 471

Figure 2

Bland-Altman Plot (N=471)

Bias = -0.97
Prec = 0.58
A_{RMS} = 1.13