Statistical Analysis Plan for Masimo Study titled "Calibration and Validation of Masimo's O3 Regional Oximetry Device in Neonates, Infants and Children Undergoing Cardiac Catherization"

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Data Analysis

We compute error statistics, including mean bias, precision, standard deviation of bias, and absolute root-mean-squared-error accuracy A_{rms}, accounting for within-subject correlations.

Applicable Analysis Methods

Measurement error or bias for the kth sample $e(k)$ is defined as

$$e(k) = rSO_2(k) - SavO_2(k).$$

Mean bias over N data points is defined as

$$\mu = \frac{1}{N}\sum_{k=1}^{N} e(k)$$

The A_{rms} can be calculated as

$$A_{rms} \approx \sqrt{\mu^2 + s^2}$$

where s is the estimated standard deviation of bias, accounting for within-subject correlation, which is calculated using the Bland and Altman method for repeated measures. The 95% confidence interval of mean bias was calculated as (μ - $2s/\sqrt{N}$, μ + $2s/\sqrt{N}$).