

## Validation of the Masimo O3™ regional oximetry device in pediatric patients undergoing cardiac surgery

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We assessed the accuracy of Masimo O3™ regional cerebral oxygen saturation (rSO2) readings by comparing them with reference values and evaluated the relationship between rSO2 and somatic tissue oxygen saturation (StO2) in children undergoing cardiac surgery. After anesthesia induction, pediatric sensors were applied to the forehead and foot sole, and rSO2 and StO2 values were monitored continuously. Before cardiopulmonary bypass (CPB), FIO2 was set to 0.2, 0.5, and 0.8 serially every 15 min. After CPB, FIO2 was reversed. The reference values (SavO2) were calculated by combining arterial (SaO2) and central venous oxygen saturation (SvO2) readings from the arterial and central lines, respectively ( $0.7 [\text{Formula: see text}] \text{SvO2} + 0.3 [\text{Formula: see text}] \text{SaO2}$ ). In total, 265 pairs of rSO2/StO2 and SavO2 from 49 patients were analyzed. The bias, standard deviation (SD), standard error (SE), and root mean squared error (RMSE) of rSO2 were 2.6%, 4.5%, 0.3%, and 4.3%, respectively. The limits of agreement ranged from -6.3% to 11.6%. Trend accuracy analysis yielded a relative mean error of -1.4%, with an SD of 4.3%, SE of 0.2%, and RMSE of 3.9%. According to multiple linear regression analysis, the application of CPB, FIO2, Hb level, and tip location of the central venous catheter influenced the bias (all  $P < 0.05$ ). Furthermore, the correlation between rSO2 and StO2 was weak ( $r = 0.254$ ). rSO2 readings by the Masimo O3™ device and pediatric sensor had good absolute and trending accuracies with respect to the calculated reference values in children undergoing cardiac surgery. rSO2 and StO2 cannot be used interchangeably. Clinical trial registration <http://clinicaltrials.gov> (number: NCT04208906).