Neonatal Sensor Clinical Validation

In contrast to the volunteer study with adult subjects (page 1), a validation for the HP M1193A neonatal sensor had to be done with neonates in a clinical environment. Because blood sampling is very critical for sick neonates, only when an arterial line was already in place for therapy could we get blood sample values. Fig. 1 shows the regression line for 290 data points from 20 subjects. The correlation ($R^2 = 0.91$) is good considering that neonates often have oxygen saturation states that are unstable and changing rapidly. To eliminate these uncertainties, SpO_2 values with big differences before and after blood sampling ($\Delta SpO_2 > 5\%$) and with poor signal quality (perfusion index < 0.2) were not included. Fig. 2 shows that the specified accuracy of 3% SpO_2 standard deviation for the range $70\% < SpO_2 < 100\%$ has been reached for the HP M1193A sensor based on the clinical data from neonates.

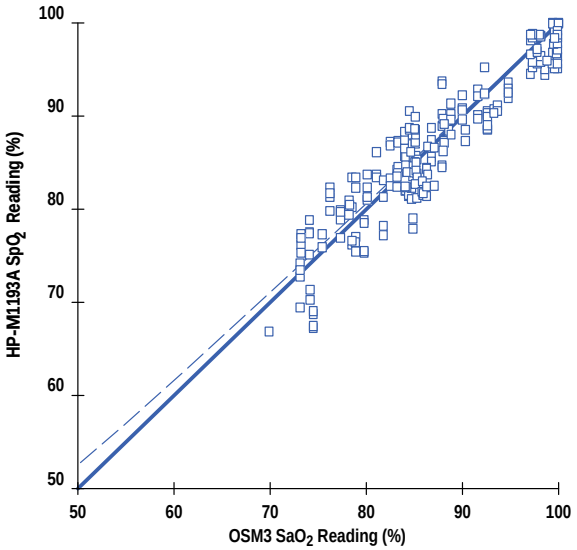

Fig. 1. *Regression analysis with data from clinical trials with the HP M1193A neonatal sensor. The 290 data points are derived from 20 subjects who already had an arterial line for blood sampling. The arterial SaO_2 values were measured by an OSM3 oximeter.*

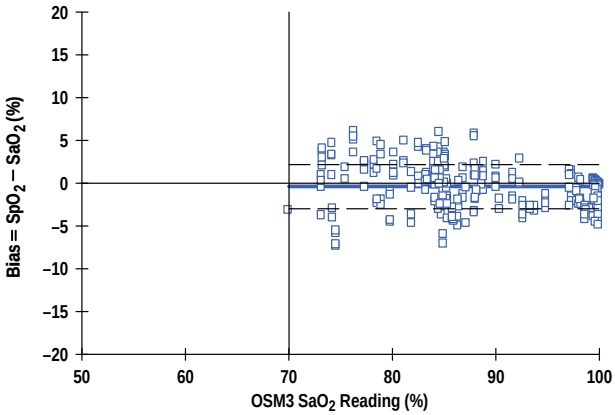

Fig. 2. *Bias and standard deviation for the HP M1193A neonatal sensor within the specification range of $70\% < SpO_2 < 100\%$, based on data from 20 neonates.*

▶ Return to Article 7

▶ Go to Next Article

▶ Go to Journal Home Page