Neonatal Sensor Clinical Validation

In contrast to the volunteer study with adult subjects (page 1), a validation for the HP M 1193A 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 M 1193A sensor based on the clinical data from neonates.

Fig. 1. Regression analysis with data from clinical trials with the HP M 1193A 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 OSM 3 oximeter.

Fig. 2. Bias and standard deviation for the HP M 1193A neonatal sensor within the specification range of 70\% < SpO$_2$ < 100\%, based on data from 20 neonates.