

## **Reliability and Validity of a Smartphone-Paired Pulse Oximeter for Screening of Critical Congenital Heart Defects in Newborns.**

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**BACKGROUND:** Barriers to widespread implementation of pulse oximetry screening of critical congenital heart defects (CCHD) in newborns include increasing trends of out-of-hospital births and cost of equipment. In recent years, smartphone-compatible pulse oximeters have appeared on the market, but the validity of such devices in the setting of CCHD screening has not been evaluated.

**OBJECTIVES:** To compare the performance in CCHD screening of a smartphone-paired pulse oximeter (Masimo iSpO2-Rx™) and a hospital-grade pulse oximeter (Masimo Radical-7™).

**METHODS:** Preductal (right hand) and postductal (either foot) saturations were determined in a population of 201 term newborns by 2 independent teams, one using the Radical-7 and the other using the iSpO2-Rx. Bland-Altman analysis was applied to calculate mean bias and 95% limits of agreement between the 2 pulse oximeters.

**RESULTS:** For the preductal oxygen saturation, the mean bias (Radical-7 minus iSpO2-Rx) was -0.08 (SD 1.76) and the lower and upper limits of agreement were -3.52 and 3.36, respectively. For the postductal oxygen saturation, the mean bias was -0.11 (SD 1.68) and the lower and upper limits of agreement were -3.49 and 3.18, respectively. In addition, the iSpO2-Rx provided reliable measurements of saturations below 95% in a group of 12 infants admitted to the neonatal intensive care unit.

**CONCLUSIONS:** Our data suggest that CCHD screening with the Masimo iSpO2-Rx is feasible and accurate. The use of reliable smartphone-paired pulse oximeters may contribute to the extension of CCHD screening to home births and low resource settings.