

Clinical Studies Quick Guide

CITATION	Johnston ED, Boyle B, Juszczak E, King A, Brocklehurst P, Stenson BJ. Oxygen targeting in preterm infants using the Masimo SET Radical pulse oximeter. <i>Arch Dis Child Fetal Neonatal Ed.</i> 2011;96(6):F429-33.
PRODUCT CATEGORY	Pulse Oximetry
PRODUCT DISCUSSED	Masimo Set® Radical® pulse oximeter

BACKGROUND

The NeOProm (Neonatal Oxygenation Prospective Meta-analysis) Collaboration convened in 2003. This prospective meta-analysis includes five trials (SUPPORT, BOOST II - Australia, BOOST NZ, BOOST II - UK and COT) each targeted to recruit between 300 and 1,300 babies. The aim of these trials is to compare the outcomes of extremely preterm infants who have their pulse oximeter oxygen saturation (SpO₂) maintained in either the range 85% to 89% or 91% to 95% until they reach 36 weeks corrected gestational age. International trials are being conducted with the aim of ending 60 years of uncertainty about oxygen therapy for preterm infants. The trials are using Masimo SET® Radical® pulse oximeters. A pretrial clinical improvement project for the BOOST-II UK trial of oxygen saturation targeting revealed an artifact affecting saturation profiles obtained from the Masimo Set® Radical® pulse oximeter. The first NeOProm publication appeared in the *New England Journal of Medicine* May 2010 issue from the SUPPORT study group based in the U.S. From February 2005 to February 2009, 1,316 infants age 24 weeks to 27 weeks six days gestation were included in this randomized study.¹ The findings suggest lower oxygen targeting significantly reduces severe ROP, but may increase the risk of death.

The SUPPORT trial was completed before the oximeter modifications. No mention of the algorithm problem can be found in the SUPPORT study publication. This study by Johnston et al is a detailed evaluation of the algorithm problem and concludes that this finding has important implications for the interpretation of emerging evidence

in neonatal intensive care. Furthermore, in an editorial published in the *New England Journal of Medicine* April 28, 2011 issue, Dr. Ben Stenson points out the joint safety analysis found a significant difference (P=0.006) in survival when comparing the old vs. new algorithm, resulting in trial closure.² Clinicians should consider when oximeter use occurs as a screening tool to identify borderline saturations in congenital heart disease, “threshold saturations,” a shift upward by about 2% could miss some cases.

METHODS

Prior to starting the BOOST-II UK trial, participating units provided routine care to oxygen-dependent preterm infants using standard unmodified Masimo SET® Radical® oximeters. This study describes a pretrial audit to evaluate and support clinician success in saturation targeting prior to participation in the BOOST II study. Additionally, paired studies comparing Masimo oximeters running the new software algorithm with commercially available oximeters from four other manufacturers were conducted on a series of preterm infants.

- The study looked at 176 oxygen-dependent preterm infants in 35 UK and Irish neonatal units from August 2006 to April 2009
- SpO₂ data was collected from standard, unmodified Masimo SET® Radical® oximeters every 10 seconds for up to two weeks
- SpO₂ data were plotted in the form of frequency histograms of the percentage of SpO₂ readings at each saturation

RESULTS

- Babies: Mean weight 1455 grams (SD 872g); gestational age 31 weeks (SD 4.0 weeks) and postmenstrual age 34 (4) weeks. Nellcor™ nonadhesive neonatal sensors (SoftCare SC-NEO) were used on 16 infants; Nellcor™ adhesive neonatal sensors (Max-N) were used on 24 infants.
- In the range of 87%-90%, the unmodified Masimo pulse oximeter showed values that were elevated by up to 2%. In the same range, Nellcor showed a normal distribution of values.
- Installing revised software (board firmware V4.8 or higher) eliminated the error in the Masimo pulse oximeter values. Only with updated software were the Masimo and Nellcor results were similar.

AUTHORS' CONCLUSIONS

In conclusion, we have shown that the algorithm used by one generation of the Masimo SET®* Radical®* oximeter returns a distribution of saturation values above 87% that is different from other oximeters. This could be important if the device is being used to target saturation values in a narrow range or to evaluate threshold saturation values. This finding has important implications for the interpretation of emerging evidence in neonatal intensive care.

References

1. Stenson, BE, Brocklehurst, PE, Tarnow-Mordi, WI. Increased 36-weeks survival with high oxygen saturation target in extremely preterm infants. *The New England Journal of Medicine*. 2011; 364(17): 1680-1682.
2. Waldemar, C., Finer, N., Walsh, M., et al. Target ranges of oxygen saturation in extremely preterm infants. *The New England Journal of Medicine*. 2010; 362(21): 1959-1969.

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