Masimo SET®: Advancing Patient Safety

"I saw and was conquered. I was not able to defeat the Masimo SET® pulse oximeter using all the motion and low pulse tricks I know. This technology is most impressive and should be available in all oximeters."

John Severinghaus, M.D.
Professor of Anesthesiology, Emeritus
University of California, San Francisco

The accuracy and reliability of Masimo SET® pulse oximetry has been studied in challenging conditions.

- Masimo SET® pulse oximeters detected approximately **10 times more** true events than other "Next Generation" pulse oximeters studied.[1,2]
- Researchers showed time to **reliable oxygen saturation readings during neonatal resuscitation** was approximately **50 seconds faster** using Masimo SET® than using other pulse oximetry technologies.[3]
- In a PACU, Masimo SET® had a greater than **50% reduction** in false alarms compared to other pulse oximetry technology.[4]
- In two NICU settings, Masimo SET®, coupled with changes in clinical practice, showed significantly **reduced rates of severe retinopathy of prematurity (ROP)** and decreased the need for **laser treatment to 0%**.[5,6]
- In a study of 39,821 infants, CCHD screening sensitivity increased from **63%** with physical exam alone to **83%** with physical exam and Masimo SET® pulse oximetry.[7]
- In a study of 122,738 infants, critical congenital heart disease (CCHD) screening sensitivity increased from **77% to 93%** with the combined use of Masimo SET® and clinical assessment.[8]
- On a post-surgical unit, rescue calls and ICU transfers were **reduced by 65% and 48%,** respectively, after the implementation of continuous surveillance monitoring with Masimo SET®.[9]

[1] Hay WW. Reliability of conventional and new oximetry in neonatal patients. *J of Perinatol*, 2002;22:360-36. [2] Barker SJ. "Motion-Resistant" Pulse Oximetry: A comparison of new and old models. *Anesth Analg.* 2002;95(4):967-72. [3] Baquero H et al. Avoiding Hyperoxemia during Neonatal Resuscitation: Time to Response of Different SpO_2 Monitors. *Acta Paediatr.* 2011 Apr;100(4):515-8. [4] Malviya S et al. False Alarms and Sensitivity of Conventional Pulse Oximetry Versus the Masimo SET® Technology in the Pediatric Postanesthesia Care Unit. *Anesth Analg* 2000; 90(6):1336-1340. [5] Castillo et al. Prevention of retinopathy of prematurity in preterm infants through changes in clinical practice and SpO_2 Technology. *Acta Paediatr.* 2011 Feb;100(2):188-92. [6] Sola et al. Can changes in clinical practice decrease the incidence of sever retinopathy of prematurity in very low birth weight infants? 2003;111(2):339-345. [7] de-Wahl Granelli A et al. Impact of pulse oximetry screening on the detection of duct dependent congenital hear disease: a Swedish prospective screenign study in 39,821 newborns. *BMJ* 2009;338:a3037. [8] Zhao et al. Pulse oximetry with clinical assessment to screen for congenital heart disease in neonates in China: a prospective study. *Lancet.* 2014 Aug 30;384(9945):747-54. [9] Taenzer AH et al. Impact of pulse oximetry surveillance on rescue events and intensive care unit transfers: a before-and-after concurrence study. *Anesthesiology.*2010:112(2):282-287.

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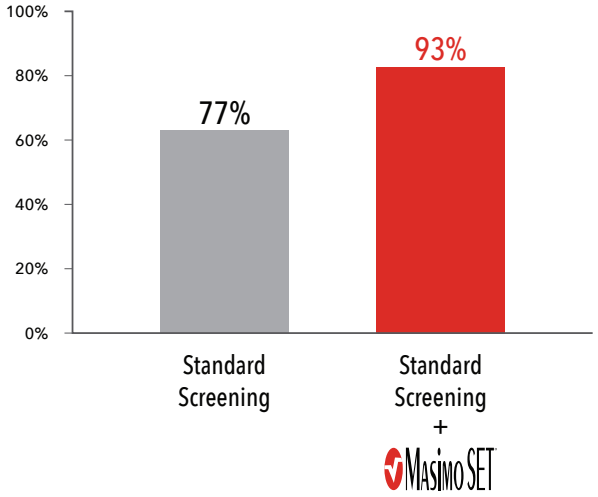
Clinical Studies: The Performance of Masimo SET®

CCHD Screening

> When combined with clinical assessment, Masimo SET® **improved** critical congenital heart disease (CCHD) screening sensitivity to 93%

Improved Critical Congenital Heart Disease Screening Sensitivity vs. Clinical Assessment Alone

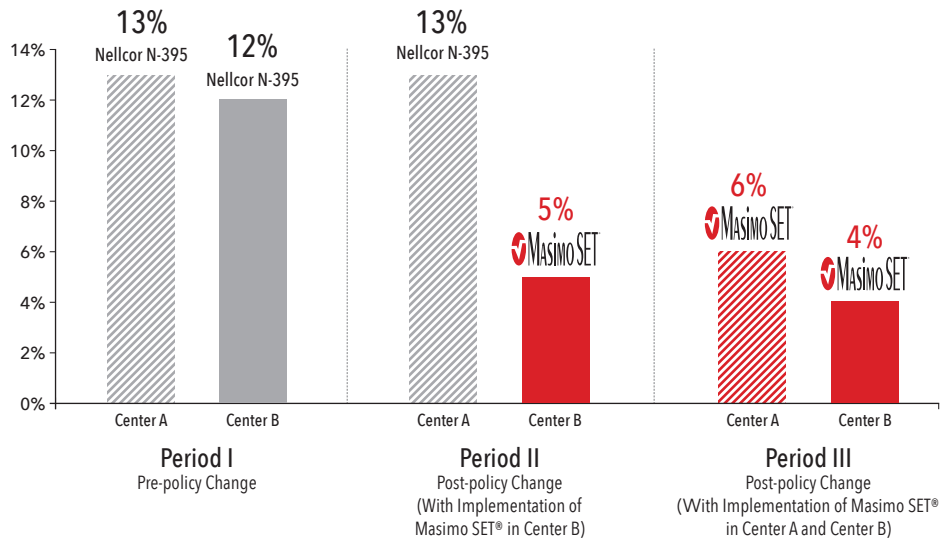


Zhao et al. *Lancet*. 2014 Aug 30;384(9945):747-54.

Retinopathy of Prematurity

> Masimo SET®, coupled with changes in clinical practice, led to a significant **reduction** in rates of severe Retinopathy of Prematurity (ROP)

Severe Retinopathy of Prematurity Rate

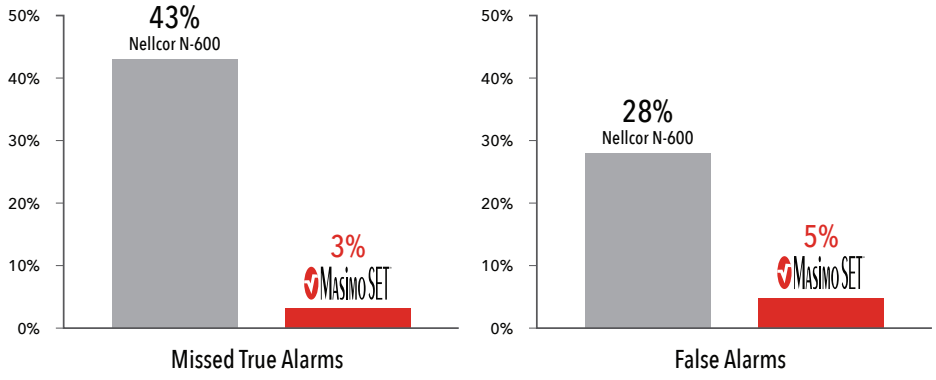


Castillo et al. *Acta Paediatr*. 2011 Feb;100(2):188-92.

Performance During Motion and Low Perfusion

> Masimo SET® had **3% missed true alarms and 5% false alarms** versus 43% and 28%, respectively, using competitor technology

Performance During Motion and Low Perfusion



Shah et al. *J Clin Anesth*. 2012;24(5):385-91.
*Results shown are calculated by combining sensitivity and specificity outcomes of machine-generated and volunteer-generated motion.

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