

CCHD Screening with Pulse Oximetry

Reliable, Clinically-Proven Screening for Critical Congenital Heart Disease (CCHD)
with Masimo SET® Pulse Oximetry



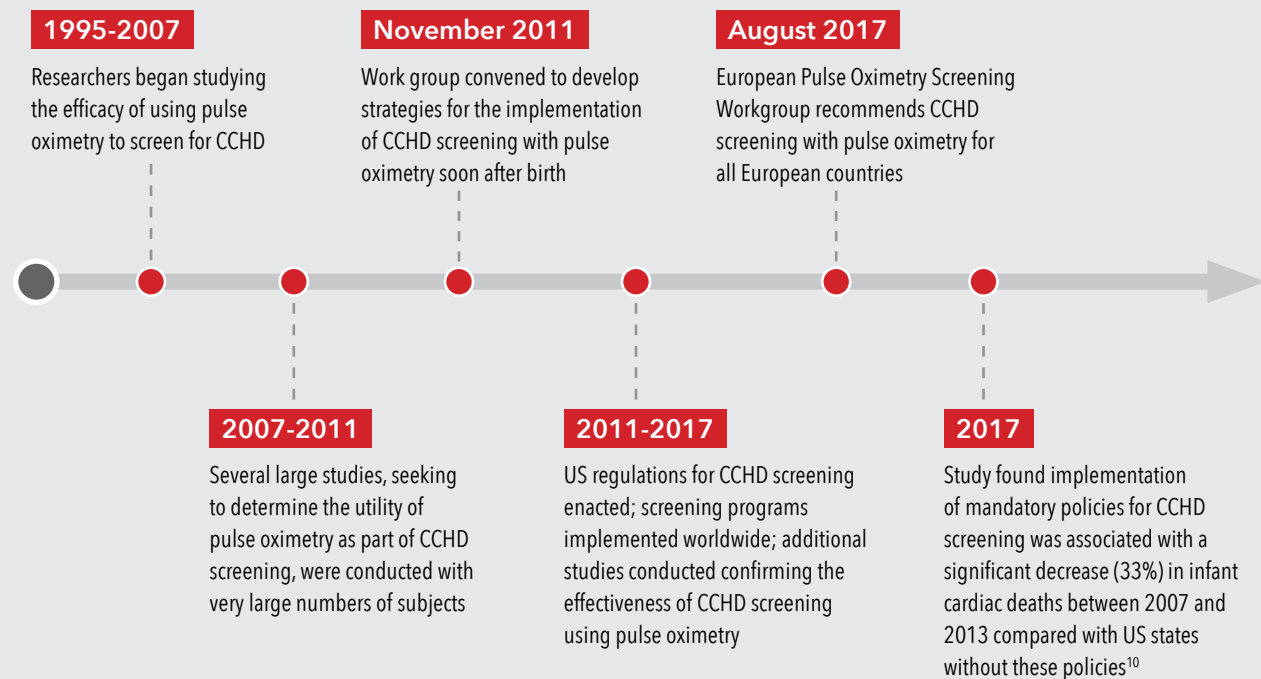
Why Screen for CCHD?

Traditionally, following birth, newborns were observed for evidence of congenital heart defects (CHDs) by physical assessment and monitoring for common symptoms.¹ **Today, studies show that these methods alone can be unreliable and may fail to detect up to 36% of infants with a Critical CHD (CCHD) before discharge.**^{2,3}

Adding screening with pulse oximetry can help diagnose CCHD before an infant becomes symptomatic.⁴ Further, multiple studies have shown that using Masimo SET® Measure-through Motion and Low Perfusion™ pulse oximetry for CCHD screening, in conjunction with clinical assessment, improves screening sensitivity compared to routine physical exam alone.^{2,3,5-8}

The Evolution of CCHD Screening with Pulse Oximetry

In 2011, following numerous studies observing the utility of pulse oximetry in screening for CCHD, a work group was convened to develop strategies for the implementation of safe, effective, and efficient CCHD screening with pulse oximetry.⁹ The work group found sufficient evidence to recommend the use of pulse oximetry to screen for CCHD, and further recommended that screening be performed with motion-tolerant pulse oximeters that report functional oxygen saturation (SpO₂) and have been validated in low-perfusion conditions.⁹



In a recent study, researchers found a **33% decrease in infant cardiac deaths** after US statewide implementation of mandatory policies for CCHD screening, compared with prior periods and states without policies, as well as a **21% decrease in early infant deaths from other cardiac causes.**¹⁰



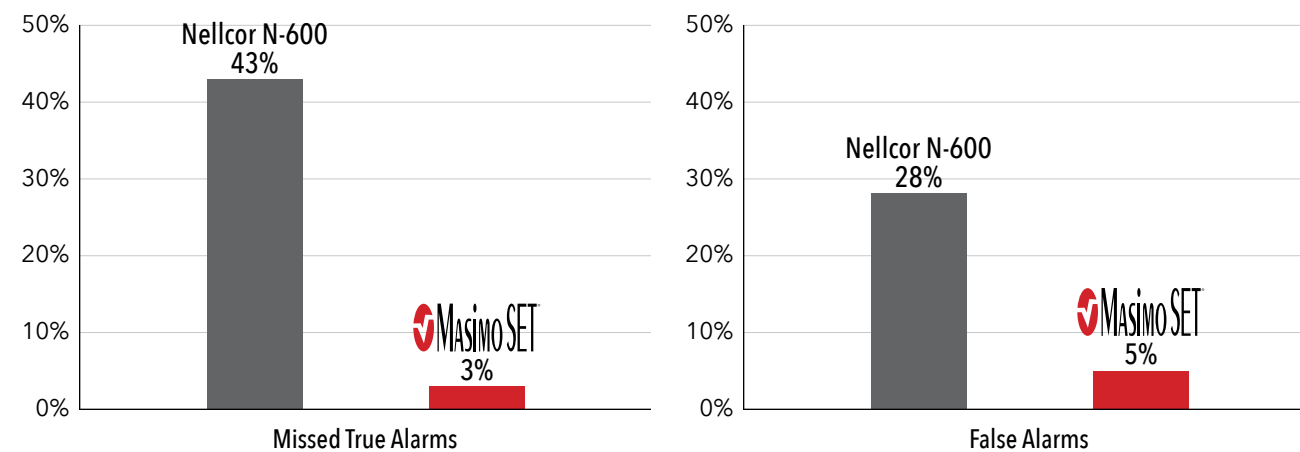
Improving CCHD Screening with Masimo SET® Pulse Oximetry

Masimo SET® Measure-through Motion and Low Perfusion Pulse Oximetry

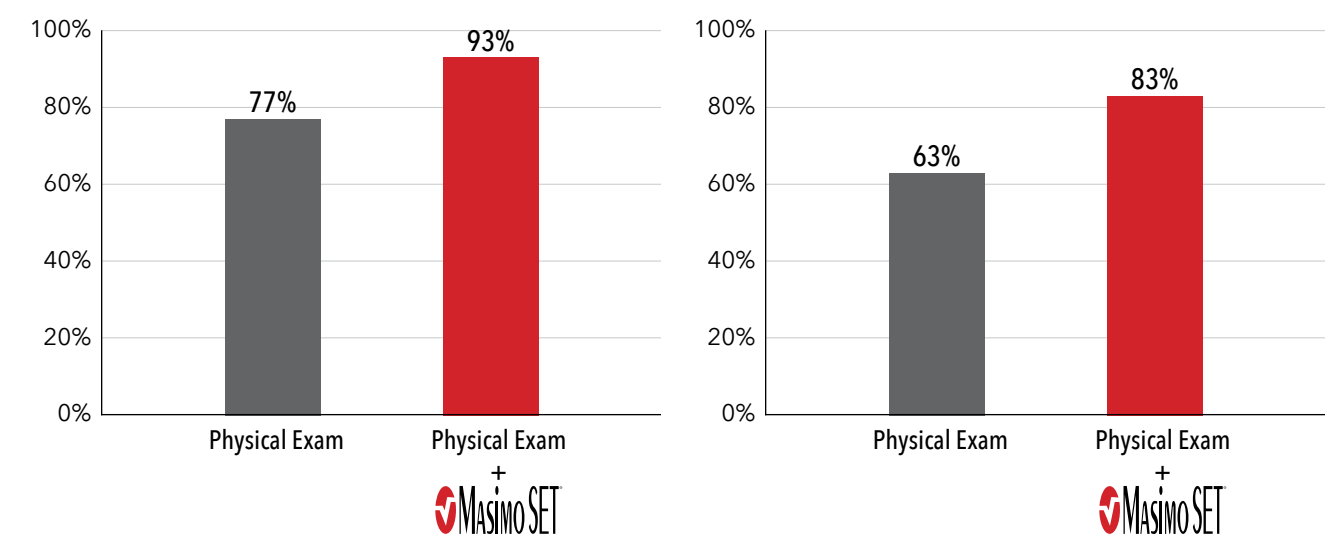
Masimo's breakthrough Signal Extraction Technology® (SET®) overcomes the limitations of conventional pulse oximetry with the ability to **measure through motion and low perfusion**. The ability to measure through motion enables researchers and clinicians to obtain pulse oximetry measurements on active newborns without needing to first calm them or wait for stable plethysmographic waveforms to be displayed.

Over 100 independent and objective studies have shown that Masimo SET® outperforms other pulse oximetry technologies during motion and low perfusion conditions, providing clinicians with increased sensitivity and specificity to help them make critical patient care decisions.¹¹ For example, in a study comparing the ability of three pulse oximetry technologies to detect hypoxic events, Masimo SET® pulse oximetry demonstrated the highest sensitivity and specificity during induced conditions of motion and low perfusion.¹²

Performance During Motion and Low Perfusion¹²



Improved CCHD Screening Detection vs. Physical Exam Alone



In Zhao's study of 122,738 infants – the largest CCHD screening study to date – Masimo SET® improved CCHD screening sensitivity to 93% when combined with clinical assessment. In addition, 46% of babies with false positive screening results needed medical intervention or further monitoring due to other abnormalities including pulmonary hypertension, lung problems, and other CHDs.³

In de-Wahl Granelli's study of 39,821 infants, Masimo SET® improved CCHD screening sensitivity to 83% when combined with clinical assessment. In addition, 45% of babies with false positive screening results had other significant heart malformation, lung problems, or infection.²

Pi

Including Perfusion Index Measurement in CCHD Screening

Incorporating perfusion index into screening has been shown to increase sensitivity to the detection of CCHD in infants with pathologically low perfusion.² In a study of 10,009 infants, when Pi was added to CCHD screening, screening revealed abnormalities in 100% of all newborns who had left heart obstructive disease (LHOD).⁵



Masimo SET® in CCHD Screening Studies

There have been **multiple large published CCHD screening studies that exclusively used Masimo SET® pulse oximeters and sensors**, two of which (59,876 subjects) were the basis for the CCHD workgroup recommendation for CCHD screening protocols.^{2,7,9} Cumulatively, six of these studies represent over **284,800** infants^{2,3,5-8} and include the largest CCHD screening study to date, with over 122,738 subjects.³

- 10,009 Infants: de-Wahl Granelli A et al. *Acta Paediatr.* 2007.
- 20,055 Infants: Ewer A et al. *Lancet.* 2011.
- 50,008 Infants: Meberg A et al. *J of Peds.* 2008.
- 122,738 Infants: Zhao et al. *Lancet.* 2014.
- 39,821 Infants: de-Wahl Granelli A et al. *BMJ.* 2009.
- 42,169 Infants: Schena F et al. *J of Peds.* 2017.

These six notable studies, all using Masimo SET®, concluded that pulse oximetry, in conjunction with clinical assessment, improved screening sensitivity compared to routine physical exam alone.^{2,3,5-8}

Implementing CCHD Screening with Masimo SET® Pulse Oximetry

Portable, Easy-to-use Masimo Pulse CO-Oximeters®

Radical-7® and Rad-97® Pulse CO-Oximeters can be mounted on a portable roll stand to easily move between rooms and include advanced connectivity solutions that enable automated documentation of screening measurements in hospital EMRs. A Rad-5® handheld pulse oximeter is also available, allowing quick screening and easy transport between rooms.

Masimo's roll stand solutions feature wheels that glide smoothly and quietly, as well as a basket to store sensors and other supplies and a bracket for disinfecting wipes.



Multiple Masimo SET® Sensor Options for Gentle, Flexible Application on Newborns

RD SET™ Neo » single-patient-use, wrap-around-style sensors feature a flat, lightweight cable that lies comfortably on the infant's hand or foot



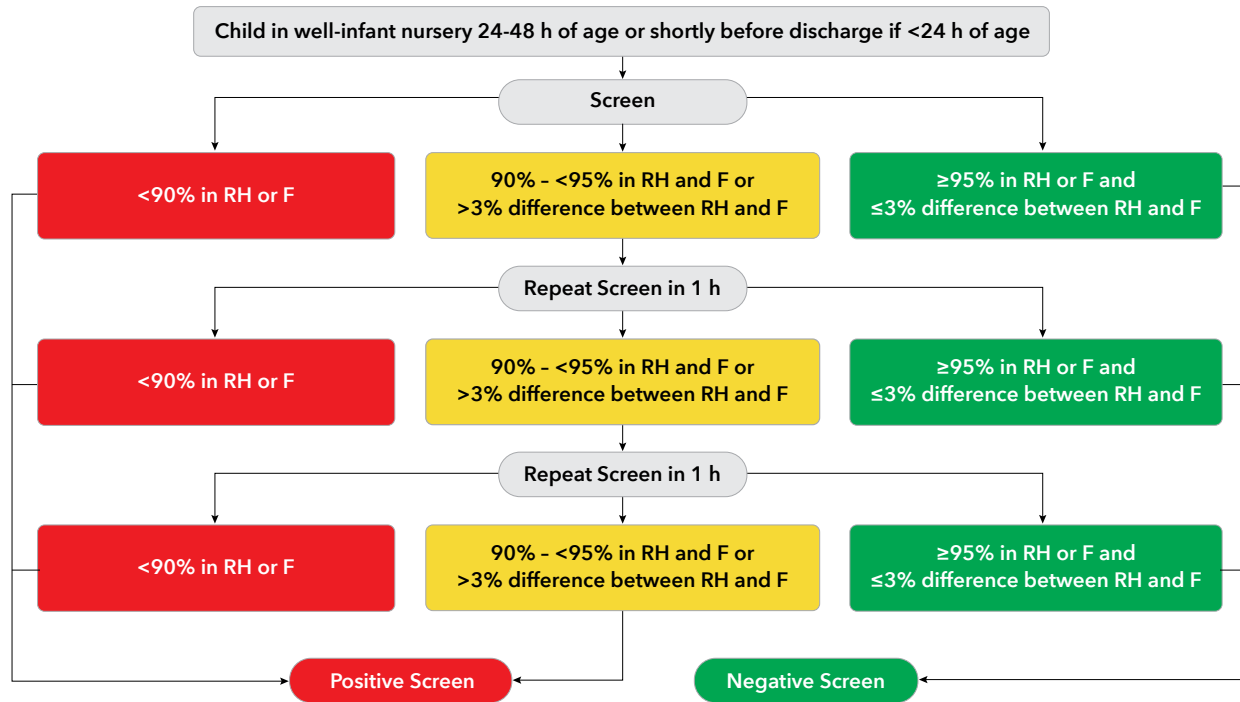
Multisite Y-I reusable sensors with soft foam wraps, which have been used in multiple prominent CCHD screening studies,^{2,3,5-7} enable quick, comfortable application and removal, without disturbing infants.



Work Group's Recommendations for CCHD Screening with Pulse Oximetry

CCHD screening using pulse oximetry can be easily implemented following the 2011 work group's protocol recommendations. Screening is conducted by taking a preductal SpO₂ measurement on the right hand followed by a postductal SpO₂ measurement on either foot. Based on the measurement results, the protocol will identify a positive or negative screening result, or recommend that repeat screening be conducted.⁹

The Work Group's Recommended CCHD Screening Protocol



To improve the early detection of CCHD, the US Secretary of Health and Human Services (HHS) recommended that CCHD screening be added to the uniform newborn screening panel.¹³ One of the well accepted methods for screening newborns for CCHD is a protocol endorsed by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC), American Academy of Pediatrics (AAP), the American College of Cardiology Foundation (ACCF) and the American Heart Association (AHA) and based on pulse oximetry studies by Granelli et al.²⁹ It involves measuring pre-ductal (right hand, RH) and post ductal (foot, F) functional oxygen saturation (SpO₂) levels in newborns after 24 hours of age.

¹Ewer AK, et al. *NIHR Health Technology Assessment Programme: Executive Summaries*. 2012. ²de-Wahl Granelli A et al. *BMJ*. 2009;Jan 8;338. ³Zhao et al. *Lancet*. 2014 Aug 30;384(9945):747-54. ⁴www.thelancet.com/child-adolescent. Published online August 30, 2017 [http://dx.doi.org/10.1016/S2352-4642\(17\)30066-4](http://dx.doi.org/10.1016/S2352-4642(17)30066-4). ⁵de-Wahl Granelli A et al. *Acta Paediatr*. 2007 Oct;96(10):1455-9. ⁶Meberg A et al. *Pediatr*. 2008 Jun;152(6):761-5. ⁷Ewer AK et al. *Lancet*. 2011 Aug 27;378(9793):785-94. ⁸Schena F et al. *J of Peds*. 2017. Volume 183, 74-79. ⁹Kemper AR et al. *Pediatrics*. 2011 Nov;128(5):e1259-67. ¹⁰Rahi Abouk et al. *JAMA*. 2017;318(21):2111-2118. doi:10.1001/jama.2017.17627. ¹¹Published clinical studies on pulse oximetry and the benefit of Masimo SET® can be found on our website at <http://www.masimo.com>. Comparative studies include independent and objective studies which are comprised of abstracts presented at scientific meetings and peer-reviewed journal articles. ¹²Shah N. et al. *J Clin Anesth*. 2012 Aug;24(5):385-91. ¹³Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. HHS Secretary adopts recommendation to add critical congenital heart disease to the Recommended Uniform Screening Panel. September 21, 2011. Washington, DC: US Department of Health and Human Services.

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

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