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\(^\text{®}\) Measure-through Motion and Low Perfusion\(^\text{™}\) pulse oximetry for CCHD screening, in conjunction with clinical assessment, improves screening sensitivity compared to routine physical exam alone.\(^5-8\)

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 (SpO\(_2\)) 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. 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.

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. Cumulatively, six of these studies represent over 284,800 infants and include the largest CCHD screening study to date, with over 122,738 subjects.


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.

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.

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.

Incorporating perfusion index into screening has been shown to increase sensitivity to the detection of CCHD in infants with pathologically low perfusion. 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).
Solutions for CCHD Screening with Masimo SET® Pulse Oximetry

Eve® Newborn Screening Application

Eve combines Masimo SET® Measure-through Motion and Low Perfusion pulse oximetry with step-by-step instructions to assist clinicians in screening for CCHD.

Portable, Easy-to-use Pulse CO-Oximeters® and Flexible Sensor Options for CCHD Screening

Radical-7® and Rad-97® Pulse CO-Oximeters, available with Eve Newborn Screening Application, 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.
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 $SpO_2$ measurement on the right hand followed by a postductal $SpO_2$ 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.¹

The Work Group’s Recommended CCHD Screening Protocol

Children in well-infant nursery 24-48 h of age or shortly before discharge if <24 h of age

− Positive Screen
− Negative Screen

<table>
<thead>
<tr>
<th>Screen</th>
<th>Repeat Screen in 1 h</th>
<th>Repeat Screen in 1 h</th>
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<tbody>
<tr>
<td>&lt;90% in RH or F</td>
<td>90% – &lt;95% in RH and F or &gt;3% difference between RH and F</td>
<td>≥95% in RH or F and ≤3% difference between RH and F</td>
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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.²³ It involves measuring pre-ductal (right hand, RH) and post ductal (foot, F) functional oxygen saturation ($SpO_2$) levels in newborns after 24 hours of age.