

# Newborn CCHD Screening: Step-by-Step Instructional Guide<sup>1</sup>

Using an Adhesive Disposable Sensor (Masimo M-LNCS® Neo)<sup>2</sup>

**STEP 1: PREDUCTAL (R HAND)**

Place sensor on the outer lateral aspect of the RIGHT hand under the 4th or 5th finger, wrap the tape around the site ensuring that the emitter (\*) and detector are aligned.

**STEP 3: POSTDUCTAL (L OR R FOOT)**

Place sensor on the outer lateral aspect of either foot under 4th or 5th toe, wrap the tape around the site ensuring that the emitter (\*) and detector are aligned.

**STEP 5: CCHD SCREEN RESULTS**

24-48 hours of age or before discharge:

**Negative Screen (Pass)**  
 $SpO_2 \geq 95\%$  in hand OR foot  
 AND hand-foot difference  $\leq 3\%$

**Positive Screen (Repeat 3 Times to Confirm)**  
 $SpO_2$  90-94% in the hand AND foot  
 OR hand-foot absolute difference is  $> 3\%$   
**Repeat measurement in one hour**

**Positive CCHD Screening Test**  
 $SpO_2 < 90\%$  in hand OR foot,  
 OR 3 repeated positive screens  
**Refer infant for echocardiogram & further medical evaluation**

**STEP 2: RECORD  $SpO_2$  AND PI<sup>3</sup>**

**STEP 4: RECORD  $SpO_2$  AND PI<sup>3</sup>**

<sup>1</sup> This newborn screening protocol is based on the recommendations of a work group selected by SACHDNC, AAP, ACCF and AHA: Kemper et al., *Pediatrics*. 2011; Vol. 128; No. 5; pp e1259-67.

In making this recommendation, the work group referenced the scientific evidence from two large-scale, published CCHD screening studies using Masimo SET Measure-Through Motion and Low Perfusion Pulse Oximetry, which indicated that preductal and postductal  $SpO_2$  measurements can improve screening results for CCHD: Granelli, et al. *British Medical Journal (BMJ)*. January 2009; 338:a3037

Ewer, et al. *The Lancet*. 2011; Vol. 378; No. 9793; pp 785-794

Masimo does not make recommendations on particular screening protocols or cutoffs. The screening values represented are merely replication of the guidance given in the referenced articles. Each hospital should make its own determination as to whether to follow the specific screening values and protocol listed.

<sup>2</sup> Recommended Sensors:  
 $<3kg$  = M-LNCS/LNCS Neo or LNOP Neo-L adhesives.  
 $3-10 kg$  = M-LNCS/LNCS Inf or LNOP Inf-L adhesives. Requires application to great toe or thumb.  
 $>1kg$  = M-LNCS/LNCS or LNOP YI.  
 Refer to Sensor DFU for proper sensor application.

<sup>3</sup> Granelli, et al. also reported that a Perfusion Index (PI) value of  $<0.70$  in at least one limb may indicate a positive screen. The screen should be repeated and the PI values should be reported in addition to the  $SpO_2$  results.

Note: Oxygen saturation thresholds for a positive screening result may vary at high altitude.



# U.S. Health & Human Services (HHS) Makes Critical Congenital Heart Defect (CCHD) Screening Using Motion-Tolerant Pulse Oximetry a Nationwide Newborn Screening Standard

*Implementation Strategy and Protocols Recommended by Federal Advisory Committee of Leading Associations (AAP, ACC, AHA, HHS) Call for Motion-Tolerant Pulse Oximetry Validated in Low Perfusion Conditions*

## The Strategy for a Nationwide Solution—"Motion-Tolerant Pulse Oximetry"

In a letter dated September 21, 2011, HHS Secretary Kathleen Sebelius outlined the decision to adopt expert panel recommendations for universal CCHD screening by pulse oximetry for all newborns into federal Recommended Uniform Screening Panel (RUSP) Guidelines—the national newborn screening system standards and policies. Sebelius directed federal agencies to "proceed expeditiously with implementation."

In August 2011, a panel of pediatric and cardiac experts from the American Academy of Pediatrics (AAP), the American College of Cardiology (ACC), and the American Heart Association (AHA), in conjunction with the HHS Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC), acted on the HHS 2010 recommendation and outlined a strategy for routine screening of newborns to improve detection of CCHD. The 28-page report recommends that newborn screening be done with **"motion-tolerant pulse oximeters that report functional oxygen saturation, have been validated in low perfusion conditions, have been cleared by the FDA for use in newborns, and have a 2% root-mean-square accuracy."** The report also outlined a 5-point implementation strategy and follow-up procedures, which includes screening, diagnostic confirmation, electronic results reporting, primary care follow-up, surveillance and tracking.

Gerard R. Martin, M.D., F.A.A.P., F.A.C.C., Senior Vice President of the Center for Heart, Lung and Kidney Disease at Children's National Medical Center in Washington, D.C., stated, "The excellent results that we can now achieve in correcting critical congenital heart defects make timely diagnosis even more important. This is major win for babies born with congenital heart diseases, as well as the families and providers who care for them."

## Implementing Newborn CCHD Screening—Tools of the Trade

Oximeters	Neonatal/Infant Sensors
 <p>Radical-7™</p>  <p>Rad-57™</p>  <p>Rad-87™</p>	<p><b>ADHESIVE</b></p>  <p>M-LNCS® Neo</p>  <p>LNOP® Neo-L</p>  <p>LNCS® Neo</p>  <p>M-LNCS Inf</p>  <p>LNOP Inf-L</p>  <p>LNCS Inf</p>
 <p>Rad-5™</p>  <p>Rad-8™</p>	<p><b>REUSABLE</b></p>  <p>M-LNCS YI</p>  <p>LNOP YI</p>  <p>LNCS YI</p>

Caution: Federal law restricts this device to sale by or on the order of a physician.

For more information, contact:

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Name

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Phone

**Masimo U.S.**  
Tel: 1 877 4 Masimo  
info-america@masimo.com

**Masimo International**  
Tel: +41 32 720 1111  
info-international@masimo.com

