Newborn CCHD Screening: Step-by-Step Instructional Guide

Using an Adhesive Disposable Sensor (Masimo M-LNCS® Neo)

**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 (4) and detector are aligned.

**STEP 2: RECORD SPO2 AND PI**

24-48 hours of age or before discharge:

- **Negative Screen (Pass)**
  - Spo2 ≥ 95% in hand OR foot
  - AND hand-foot difference ≤ 3%

- **Positive Screen (Repeat 3 Times to Confirm)**
  - Spo2: 90-94% in the hand AND foot
  - OR hand-foot absolute difference is > 3%
  - Repeat measurement in one hour

- **Positive CCHD Screening Test**
  - Spo2 < 90% in hand OR foot,
  - OR 3 repeated positive screens
  - Refer infant for echocardiogram & further medical evaluation

**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 (4) and detector are aligned.

**STEP 4: RECORD SPO2 AND PI**

- **Recommended Sensors:**
  - <3kg = M-LNCS/LNCS Neo or LNOP Neo-L adhesives.
  - 3-10 kg = M-LNCS/LNCS Inf or LNOP Inf-L adhesives.
  - >1kg = M-LNCS/LNCS or LNOP YI.
  - Refer to Sensor DFU for proper sensor application.

- **Granelli, et al.** also reported that a Perfusion Index (PI) value of <0.70 in at least one limb may indicate a positive screen.

**STEP 5: CCHD SCREEN RESULTS**

- **Granelli, et al.** also reported that a Perfusion Index (PI) value of <0.70 in at least one limb may indicate a positive screen.

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

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

For more information, contact: