



# MIDWIVES & CCHD PULSE OXIMETRY SCREENING

## What is Critical Congenital Heart Disease (CCHD)?

CCHD refers to conditions where structural complications exist in the heart and great vessels around the heart. These conditions are called **critical** because affected newborns require surgery or catheter intervention in the first year of life to ensure their survival. CCHDs that can be screened for with pulse oximetry include: hypoplastic left heart syndrome, pulmonary atresia (with intact septum), tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia and truncus arteriosus.

## What is the incidence of CCHD?

Approximately 3 per 1000 babies will have CCHD.

## Why should we offer clients pulse oximetry screening for CCHD?

Pulse oximetry is a simple, non-invasive screening test that measures the level of oxygenation in the arterial blood of newborns, and is a recommended standard of care. Pulse oximetry screening is the best approach to identify asymptomatic newborns with invisible hypoxia. Approximately 50% of newborns with CCHD will be diagnosed by ultrasound in pregnancy, and another 20-30% will be identified during physical examination of the newborn by the following signs and symptoms: heart murmur, cyanosis, tachycardia, tachypnea, feeding difficulties, delayed weight gain, excessive sweating, pale, cool or clammy skin and lethargy.

It is important, however, to note that compensatory cardiac measures can allow a newborn with CCHD to appear well and the condition can be missed in the early days. Newborns have largely fetal hemoglobin at birth, which has higher oxygen affinity, and their oxygen saturation (SpO<sub>2</sub>) levels can decrease to 75-80% before cyanosis becomes visible to the eye. Pulse oximetry testing can detect low oxygen saturation before physical assessment findings are apparent. With the addition of pulse oximetry screening for CCHD, earlier detection and improved outcomes can be expected for about 50-100 babies each year in Ontario.

### Visible Cyanosis and Oxygenation Level (1)

Oxygenation Level	~ <80%	80-94%	>95%
Skin colour	Visible cyanosis	Invisible hypoxia	Well-oxygenated

## How accurate is pulse oximetry screening for CCHD?

The sensitivity of pulse oximetry screening, the proportion of people with the disease who have a positive result, is moderate at 76.5% and the specificity, the proportion of people without the disease who have a negative result, is very high at 99.9% for detection of CCHD. The false positive rate for detection of CCHD is significantly lower when screening occurs at or after 24 hours, with no difference in sensitivity. (2)

## When is the best time to perform pulse oximetry screening for CCHD, and why is this the best timing?

Evidence supports pulse oximetry screening of newborns between 24 and 48 hours of age, with an optimal window of 24-36 hours of age.

In the first 24 hours of life, as newborns transition from fetal to newborn circulation, the ductus arteriosus may remain patent causing transiently low SpO<sub>2</sub> and higher false positive results of 0.5%. **Screening after 24 hours** allows sufficient time for the ductus arteriosus to close, significantly lowering false-positive results to 0.05%. Delaying screening beyond 48 hours increases the risk of a rare undiagnosed newborn with CCHD to rapidly deteriorate, increasing the risk of organ damage and life threatening complications. (2)

Pulse oximetry CCHD screening false positive rate < 24 hours of age: 0.5%  
Pulse oximetry CCHD screening false positive rate ≥ 24 hours of age: 0.05%

## If a screen is done within the first 24 hours of life and results in a screen positive/REFER, can we wait and retest in the recommended window (24 – 48 hours) and respond to those results instead (ignoring the < 24 hour screen since we know there are higher false positives in that window)?

No. Health Care Providers must respond to screening results as they arise whenever the screen is done. A positive screen in the first 24 hours is a positive screen and the newborn requires immediate consultation with a physician. To reduce the likelihood of false positive results, it is recommended to screen within 24 – 48 hours.

## Who performs pulse oximetry screening for CCHD? Where is it done?

It is likely that CCHD screening for most midwifery clients will occur in the community setting and screening will be done by the midwife or midwifery student; however, if the client is in the hospital at 24-36 hours, CCHD screening may be conducted by a nurse.

## The current CMO Postpartum/Newborn Visits Standard, strongly recommends a postpartum visit within 24 hours of birth. Does this mean I have to add a postpartum visit for CCHD pulse oximetry screening at 24-48 hours to my usual postpartum visits?

The CMO is working towards rescinding the [Postpartum/Newborn Visits Standard](#) by the end of 2017. It will not be replaced by a new standard that specifies when and how often midwives conduct postpartum visits. In the meantime, the answer to this question depends on a number of factors including your routine postpartum practice, the particular needs of each client and newborn, and your clinical judgement.

The CMO expects midwives to use their clinical judgement to determine appropriate scheduling of postpartum visits as long as any deviation from the Postpartum/Newborn Visits Standard is clinically indicated and the indication and rationale are well documented. Therefore, in the absence of other considerations which may prompt the midwife to conduct a visit within the first 24 hours of birth, the first postpartum visit can occur at 24-48 hours with the ideal visit occurring between 24-36 hours, to accommodate best practices for CCHD pulse oximetry screening. Until the Postpartum/Newborn Visits Standard is rescinded, midwives should document the reason for the timing of the first postpartum visit in the client's chart if it occurs after 24 hours of birth.

To address potential knowledge gaps left by the rescinding of the Postpartum/Newborn Visits Standard, the AOM will be conducting a review of evidence on postpartum visits focusing on research involving home settings, midwifery care and continuity of care models. The evidence reviewed will be used to develop a document that will provide midwives with evidence-based information to make decisions about timing of postpartum visits. This evidence review about timing of postpartum visits will be made available to midwives in 2018.

## How long does it take to screen a newborn for CCHD?

The CCHD screen takes approximately 5 minutes to perform and the results of the screen are available right away. The vast majority of pulse oximetry screening results will be a screen negative "PASS". Midwives may choose to prioritize screening at the beginning of the postpartum visit, so a second screen can be done 1 hour later if the initial screen result is "REPEAT".

## How do I perform pulse oximetry screening?

Screening is best done when the infant is awake, in a quiet, non-fussing state prior to any disruptive care activities (e.g. bloodwork), and can be conducted while chest or breastfeeding. CCHD screening should be offered as part of an informed choice discussion. It is not a mandatory screening; all parents have the right to decline.

The following newborns do not require CCHD screening: those already diagnosed by prenatal ultrasound or by physical assessment within the first 24 hours of life, or any newborn in the NICU/SCN/PICU with cardio-respiratory instability and an expected length of hospital stay longer than 7 days - all who are receiving appropriate monitoring and treatment.

The following [NSO resources](#) are comprehensive and informative:

- [NSO CCHD screening protocol](#) outlines how to screen and interpret results
- [NSO's video](#) demonstrates CCHD pulse oximetry screening in the community
- [NSO algorithms](#) estimate approximately 300 infants will screen positive per year in Ontario requiring follow-up
- Midwifery Practice Groups are encouraged to contact [NSOCCHD@cheo.on.ca](mailto:NSOCCHD@cheo.on.ca) when ready to implement screening. NSO will provide MPGs with a Launch Kit (includes lanyard-sized NSO screening algorithms and charts).

## Where do I document CCHD pulse oximetry screening results?

The NSO Blood Spot form has been modified to include a detachable CCHD page within the form, with matching bar codes. This CCHD sheet can be removed and conducted at a different time from the dried blood spot screening if necessary. Document the date and time of screen, pre- and post-ductal result, as well as the interpretation of the result (PASS/REPEAT/REFER) and forward as usual to NSO. If the parents decline pulse oximetry screening, document relevant information on the newborn postpartum records as well as both sides of the NSO CCHD screening results sheet and forward to NSO.

NSO is currently working on creating a secure app that will eventually allow health care providers to manually document the results in the app, which will directly link to NSO.

## What is a screen negative or "PASS"?

Any screen with  $SpO_2 \geq 95\%$  in the right hand or either foot with a  $\leq 3\%$  absolute difference is considered a negative screen "PASS".

Receiving a negative screen or "PASS" for CCHD is reassuring, however, the newborn's parents should be aware that the screen does not detect all CCHDs. Optimal management includes routine physical examination of the infant, teaching about signs and symptoms of the unwell baby, and when to page the midwife if they develop, in addition to pulse oximetry screening to detect potential concerns.

## What is a screen positive or "REFER"?

1. Any  $SpO_2$  measure  $< 90\%$  (in the initial screen or in repeat screens)
2.  $SpO_2 < 95\%$  in the right hand and either foot on two (community setting) or three (hospital setting) measures\*, each separated by one hour, or
3. A  $> 3\%$  absolute difference in  $SpO_2$  between the right hand and either foot on two (community) or three (hospital) measures\*, each separated by an hour

In the community setting, a midwife may move into hospital after initial and second screen indicate "REPEAT". This is addressed further in upcoming questions.

Receiving a positive CCHD screen or “REFER” does not necessarily mean that the newborn has a CCHD. The false positive rate for “REFER” results is 0.05% when performed  $\geq 24$  hours.

For ease in the community, midwives may wish to use the following mobile app, developed by Children’s Healthcare of Atlanta: [PulseOxTool](#). This app uses the same screening algorithm as NSO, however, please note midwives in Ontario may choose to move into hospital after two “REFER” screens, instead of the three “REFER” screens as prompted by this algorithm in the PulseOxTool.

## Why wait an hour between screens in the event of a REPEAT result? And why monitor SpO<sub>2</sub> for 30 seconds during screening?

The optimal timing between screening and frequency of rescreening has not been studied; however, studies with rescreening have most commonly used a one hour interval to provide more time for the transitional circulation to adapt and decrease false positive results. NSO has adopted this standardization of screening times, including 30 seconds of monitoring per screen to allow for a comprehensive look at the newborns’ saturation values over time.

## How likely is it that the newborn will need a second (or third) screen?

It appears the need for repeat CCHD screening is infrequent from the limited research found on this topic (rates varied from 0.9-1.8% repeat tests performed). In one U.S. quality evaluation (3) of 7828 CCHD screens performed in hospital using the same hospital screening algorithm recommended by NSO:

- 99.1% of newborns received a negative screen or “PASS”
- 0.9% of newborns required a second screen or “REPEAT” result, of these:
  - » 79% received a negative 2nd screen or “PASS”
  - » 21% received a 2nd “REPEAT” result
- 0.2% of newborns required a 3rd screen, of these:
  - » 100% received a “REFER” result or a screen positive
- 1 newborn of 7828 newborns screened was diagnosed with a CCHD (less than the typical incidence of approximately 3 per 1000 babies who will have a CCHD)

In one small observational study (N=440), Wisconsin midwives performed CCHD screening in the out-of-hospital setting, where 39% of newborns tested were from Amish or Mennonite communities. (4) In this study 1.8% of infants should have had a repeat test performed:

- 432/440 98% of newborn received a negative screen or “PASS”
- 5/440 newborns had misinterpreted screening results
- 3/440 received a “REFER” or screen positive result, of these:
  - » 2 infants were treated for sepsis
  - » 1 had a CCHD
  - » 1/440 had a false negative result (coarctation of the aorta)

## In the community setting, if a newborn's initial screen and second screen both indicate "REPEAT", must I stay another hour to do the third screen or can I expedite a physician assessment for the newborn?

A midwife may choose to arrange for a third screen and physician assessment in hospital, and not perform the third screen in the community setting. The rationale for this is twofold. First, it is highly unlikely a third screen will result in a "PASS" after two "REPEAT" screens, and second, time required to arrange for a consultation and to move into hospital for a physician assessment delays potential treatment for the newborn. Arrangements for a referral with a physician will vary depending on access to referral services (e.g. distance to hospital, time of day and availability of physician).

NSO's out-of-hospital screening protocol, "Critical Congenital Heart Disease Pulse Oximetry Screening – Community Screening Protocol (Non-Hospital Setting)" will be available shortly. This protocol was developed collaboratively with input from midwives and has undergone review by the CCHD Midwifery Task Force, CCHD Hospital Advisory Group, and the CCHD Disease Specific Working Group, and will soon be available for midwives to use when discussing consultation processes with their local hospitals.

## In the community setting, if a newborn screens "REFER" or has more than one "REPEAT" result, how do we arrange an immediate consultation with a physician for assessment?

It is recommended midwifery practice groups (MPGs) roll out CCHD screening implementation at the same time as their local hospitals, to optimize the coordination of potential consultations. To ensure a smooth process, prior to or during CCHD implementation, each MPG will need to make arrangements with their hospital to determine how immediate newborn assessments by physicians will occur.

Consultation processes differ by community. Some midwifery practices may page pediatrics on call or the emergency room physician for a telephone consultation, and send the newborn (with NSO CCHD results sheet and consult note) to the hospital for immediate assessment. Immediate assessment is understood to be within 2 hours of screening (although this may not be possible in rural or remote communities).

Depending on the larger clinical picture with a screen positive (more than one "REPEAT" result or a "REFER" result), midwives may call ahead and send the baby in with parents by car (if close to hospital, and baby appears well); or call EMS for urgent transport if baby appears unwell (cyanosis, tachycardia, tachypnea, feeding difficulties, delayed weight gain, excessive sweating, lethargy, pale cool or clammy skin).

## How can I prepare my client for next steps, in the event of a positive screen (more than one “REPEAT” or a “REFER” result)?

An immediate consultation with a physician should occur to evaluate for causes of hypoxemia. This evaluation will include a comprehensive assessment involving the following: four limb BP, femoral pulses, full vital signs and pre- and post-ductal saturations. Additional diagnostic tests such as electrocardiogram, chest X-Ray and/or other tests to rule out other non-cardiac causes of cyanosis may be ordered. If the most likely cause remains cardiac or is unclear, consultation with paediatric cardiology and an echocardiogram is warranted to rule out CCHD.

## What are the implications of false positive and false negative results?

A false positive screening result occurs when a healthy individual is incorrectly given a positive screening result.

False positive screens will result in the newborn and parent(s) going to the hospital and having an assessment by a physician, which may also include a fetal echocardiogram or possibly in other interventions. There may, however, be value in false positives: false positive screening may detect other conditions such as infections or pulmonary/respiratory disorders such as pulmonary hypertension.

A false negative screening result occurs when an individual with a CCHD incorrectly receives a negative “PASS” screening result.

The moderate sensitivity rate of pulse oximetry screening for CCHD means that approximately 23% of newborns with a CCHD or other congenital heart defect will not be detected with pulse oximetry screening alone. Missed CCHD screens are associated with multiple congenital malformations, low birth weight, prematurity, intrauterine growth restriction and critical congenital heart defects associated with obstruction of the aorta (coarctation) and interruption of the aortic arch.

## How do I know if my current pulse oximeter is appropriate for CCHD screening?

Currently, the majority of midwives use either an Edan H100B or Biolight M700 pulse oximeter, both of which meet NSO’s current requirements for CCHD pulse oximetry screening. If you have a model other than Edan or Biolight, refer to the [NSO Pulse Oximeter Requirements](#) to determine the adequacy of your model for pulse oximetry screening.

NSO’s longer term plan, however, is to work towards standardization of pulse oximeters used for CCHD screening, and recommends all healthcare providers who are performing CCHD screening use one of the following two models--Medtronic/Covidien PM10N or Masimo Rad-5--for pulse oximetry monitoring. NSO recommends replacement of pulse oximeters so that all healthcare providers offering CCHD screening are using the Covidien or Masimo models by the end of March 2018.

NSO is working with Covidien and Masimo to allow users of Medtronic/Covidien PM10N or Masimo Rad-5 pulse oximeters to automatically upload screen results to NSO. The ability to

automatically upload screening to NSO using these pulse oximeters is not currently an option. However, once the ability to upload screening data using the Medtronic/Covidien PM10N or Masimo Rad-5 pulse oximeters becomes an option, the hard copy results sheet may still be used to send in results to NSO.

## Will there be funding to pay for new pulse oximeters in the future, or now if mine is not adequate?

NSO has secured funding from the Ministry of Health to purchase Covidien pulse oximeters for midwives. This funding will be adequate for all General Registrants and Aboriginal Midwives to obtain a new pulse oximeter.

Midwifery practices should contact NSO at [NSOCCHD@cheo.on.ca](mailto:NSOCCHD@cheo.on.ca) to obtain a code to order replacement devices at no cost. NSO will confirm the number of pulse oximeters MPGs are entitled to, and provide a code for MPGs to use when ordering pulse oximeters from Stevens. Practice groups are encouraged to place an order for all midwives at once; oximeters will be delivered to the practice. NSO will also provide single-use accessories (i.e., probes, wraps, cable) at no cost on an on-going basis.

**New Registrants** are encouraged to purchase a pulse oximeter endorsed by NSO (Covidien or Masimo) with their equipment funding. New Registrants can also contact NSO at [NSOCCHD@cheo.on.ca](mailto:NSOCCHD@cheo.on.ca) to obtain a code for a discounted price through NSO's bulk purchasing contract.

The AOM is investigating opportunities for midwives to dispose of or reallocate their pulse oximeters in accordance with [HIROC's best practices for disposal of health equipment](#). Alternatively, some midwives may choose to keep their current pulse oximeter in their birth bag (for use during neonatal resuscitation), and the new device in their postpartum bag (for CCHD screening).

## Why has NSO recently changed the recommended timing of the newborn screen (dried blood spot screening), to 24-48 hours after birth?

The recommended timing has changed based on a literature review conducted by NSO suggesting that earlier screening will be life-saving for 5-10% of infants diagnosed using the dried blood spot screen.

NSO's report on their systematic review will be available on the NSO website later this month.

## Are there additional AOM resources?

- Refer to the AOM's [Normal Newborn Behaviour](#) document for clients (for signs of an unwell baby)
- See the AOM's [Pulse Oximeter Cleaning and Maintenance Instructions](#)



## References

1. Andrea J. Implications of Using Pulse Oximetry to Screen for Critical Congenital Heart Disease in Newborns. *Nurs Womens Health*. 2015;19(4):314–23.
2. Thangaratinam S, Brown K, Zamora J, Khan KS, Ewer AK. Pulse oximetry screening for critical congenital heart defects in asymptomatic newborn babies: a systematic review and meta-analysis. *Lancet (London, England)*. Elsevier Ltd; 2012 Jun 30;379(9835):2459–64.
3. Pflugeisen BM, Amoroso PJ, Zook D, Welke KF, Reedy A, Park M V. Quality improvement measures in pulse-oximetry newborn heart screening: a time series analysis. *Pediatrics*. 2015 Feb;135(2):e531–9.
4. Lhost JJ, Goetz EM, Belling JD, van Roojen WM, Spicer G, Hokanson JS. Pulse oximetry screening for critical congenital heart disease in planned out-of-hospital births. *J Pediatr*. 2014 Sep;165(3):485–9.



# PULSE OXIMETER

## MAINTENANCE and CLEANING INSTRUCTIONS

Through its Critical Congenital Heart Disease (CCHD) screening program, Newborn Screening Ontario (NSO) aims to achieve consistency for Critical Congenital Heart Disease screening across the province. To do so, the pulse oximeters used for screening need to meet [NSO's Pulse Oximeter Requirements](#). Pulse oximeters commonly used by midwives (i.e., Edan (H100B) and Biolight (M700)) meet the requirements, however, NSO is recommending Medtronic/Covidien (PM10N) or Masimo (Rad-5) because those manufacturers are developing the functionality to automatically send data to NSO, which would improve data transfer.

The table below is provided as information only. Please consult manufacturer's instructions for your specific device. If the instructions are unclear or conflict with best practices guidelines (see the Provincial Infectious Diseases Advisory Committee's Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings), contact the manufacturer directly. If a device cannot be cleaned effectively according to the manufacturer's cleaning instructions, consider using an alternate device or single-use accessories (SpO<sub>2</sub> sensor and cable) in situations where the equipment could become soiled and difficult to clean (e.g., neonatal resuscitation).

	Medtronic/Covidien PM10N	Masimo Rad-5	Edan H100B	Biolight M700
<b>Power on self-test. Do not use if "error/fail"</b>	Performed when on/off button is held for 1 second	Automatically performed when turned on.		
<b>Recommended calibration</b>	None	None; a tester can be purchased if desired.	None	
<b>Recommended servicing (check with vendor or manufacturer)</b>	Every 24 months, qualified service technician checks: <ul style="list-style-type: none"> <li>Battery</li> <li>Signs of damage</li> <li>Legibility of safety labels</li> <li>Normal functioning</li> </ul>	No preventive maintenance required by manufacturer.	Before 1st use and every 24 months, qualified service technician checks: <ul style="list-style-type: none"> <li>Signs of damage</li> <li>Legibility of safety labels</li> <li>Normal functioning</li> </ul>	Every 12 months, qualified service technician checks: <ul style="list-style-type: none"> <li>Signs of damage</li> <li>Legibility of safety labels</li> <li>Normal functioning</li> </ul>
<b>Cleaning of oximeter and reusable accessories (SpO<sub>2</sub> sensor and cables) after each use</b>	Use a soft cloth with <ul style="list-style-type: none"> <li>commercial, nonabrasive cleaner;</li> <li>quaternary ammonium compounds;</li> <li>quaternary ammonium compounds in combination with polyhexanide;</li> <li>alcohol (i.e., 70% isopropyl alcohol);</li> <li>glucoprotamin;</li> <li>10% chlorine bleach solution; or</li> <li>PDI Sani-System.</li> </ul>	Disconnect sensor and cable before wiping. Wipe accessories and display panel with 70% isopropyl alcohol. Use of other solvents may cause corrosion or weakened plastic, voiding the warranty. Clean outer surface with mild soap and water using a soft cloth. Air dry thoroughly before use.	Switch off the oximeter and remove batteries. Using a soft cloth, wipe exterior, screen, sensor and cable with <ul style="list-style-type: none"> <li>75 % ethanol; or</li> <li>70% isopropyl alcohol.</li> </ul> Wipe off the cleaning solution with a dry cloth. Allow sensor to air dry to ensure no residual moisture remains.	Use commonly used hospital cleaning agents and non-corrosive detergents. Avoid alcohol-based, amido- or acetone-based detergents when cleaning the oximeter. To clean the sensor and cable, wipe with 70% isopropyl alcohol or 3% hydrogen peroxide.
<b>Cleaning caution</b>	Gently wipe with a soft, non-abrasive cloth. Ensure liquids do not enter the interior of the device.			
<b>Note</b>	Oximeter accessories are sold as reusable, single-use or a combination of reusable/disposable (i.e., reusable cables/disposable wrap). The above pulse oximeter accessory cleaning instructions pertain to reusable accessories. All single-use accessories should be disposed after each use.			