CRITICAL CONGENITAL HEART DEFECTS (CCHD) AND PULSE OXIMETRY SCREENING

Medtronic
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PULSE OXIMETRY SCREENING

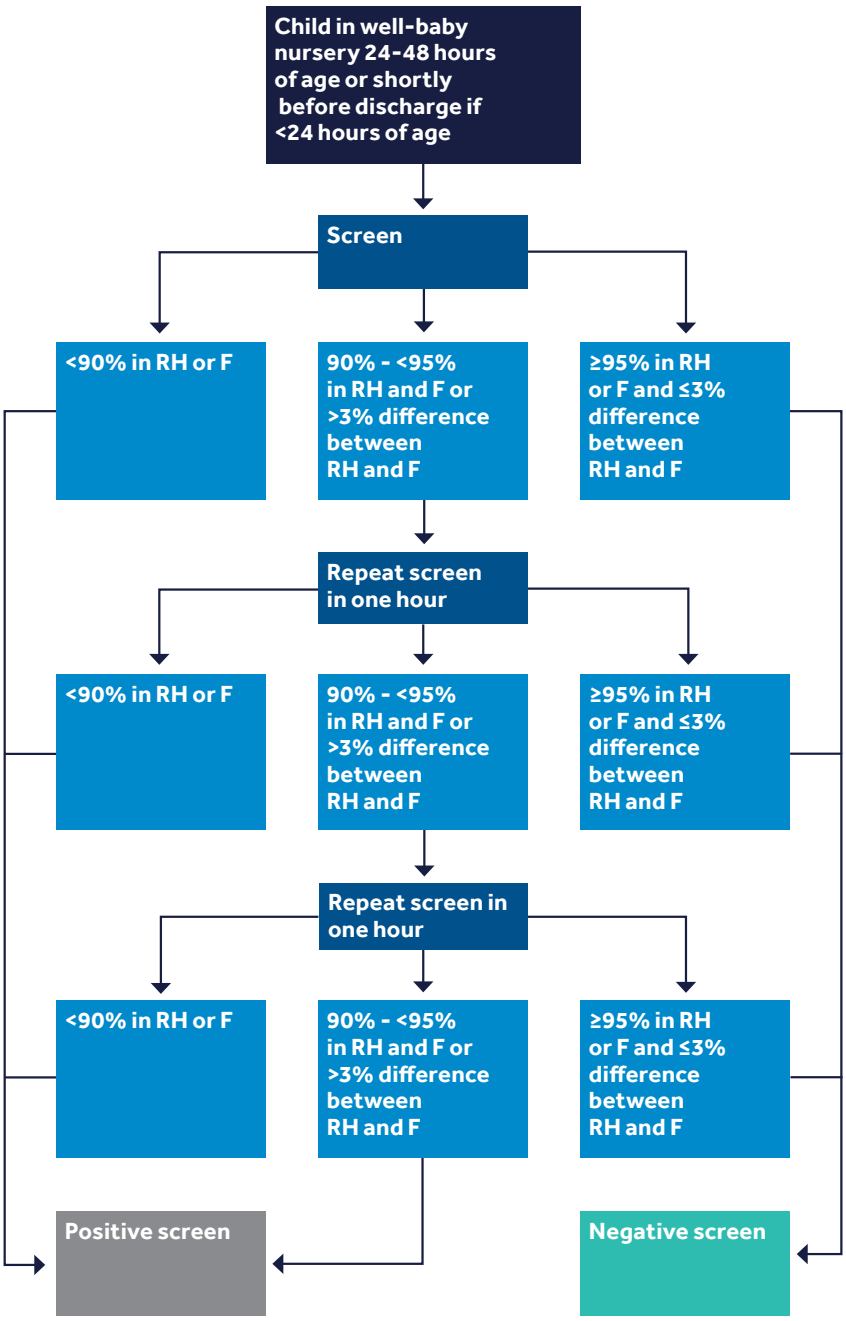
At 24 to 48 hours of age, or just prior to discharge if less than 24 hours of age, a series of pulse oximetry readings are taken to determine the amount of oxygen in a baby's blood and the baby's pulse rate. Low levels of oxygen in the blood can be a sign of a CCHD.[1]

Kemper Recommended Screening[7]:

- **SpO_2 readings from the right hand and either foot (in parallel or in sequence)**
- **Protocol:**
  - <90% is an automatic positive screen
  - 90% to <95% in both extremities on three measurements, separated by one hour = positive screen
  - >3% difference in SpO_2 between right hand and foot on three measurements, separated by one hour = positive screen
  - ≥95% in right hand or foot and ≤3% difference between right hand or foot is an automatic negative screen

PULSE OXIMETRY SCREENING RESULTS

Both health care providers and families must understand the rationale for and limitations of pulse oximetry monitoring to detect CCHD, including the important understanding that a negative screening result does not exclude the possibility of CCHD or other congenital heart disease. If the results are positive, it means that the baby's test results showed low levels of oxygen in the blood, which can be a sign of a CCHD, and further testing is needed.



*Pulse oximetry screening can be an effective tool in identifying CCHDs, but there still could be instances of false positives and negatives.

"Any 'hospital-grade' pulse oximeter that is cleared by the FDA for use in neonates is suitable for CCHD screening. It is important that the entire system is designed and cleared to work together, from the sensors that are designed for use in the neonate population, to the pulse oximeter. Reusable pulse oximetry sensors are also a viable solution, as long as the proper cleaning protocols are practiced."

Alex R. Kemper, *MD, MPH, MS, Duke University Medical Center*

NELLCOR™ PULSE OXIMETRY

For more than 25 years, clinicians have been using Nellcor pulse oximetry technology. We have a full offering of pulse oximetry sensors and monitoring platforms, which can be used as tools for CCHD screening. Our technology features SpO_2 and pulse rate. accuracy during low perfusion and motion conditions[12], as well as unsurpassed LoSat expanded accuracy claims. With LoSat functionality, you can accurately monitor your patients in lower saturation ranges unlike other pulse oximeters.

Nellcor™ Bedside Respiratory Patient Monitoring System*Ω

PM1000N

Measurement range

SpO_2
1% to 100%

Pulse rate
20 to 250 beats per minute (bpm)

Pulse amplitude
0.03% to 20%

Accuracy**

Saturation
Adult: 70 to 100% ±2 digits
Adult and Neonate Low Sat: 60 to 80% ±3 digits
Neonate: 70 to 100% ±2 digits
Low Perfusion: 70 to 100% ±2 digits
Adult and Neonate with Motion: 70 to 100% ±3 digits

Pulse Rate
Adult and Neonate: 20 to 250 bpm ±3 digits
Low Perfusion: 20 to 250 bpm ±3 digits
Adult and Neonate with Motion: 48 to 127 bpm ±5 digits

Nellcor™ Bedside SpO_2 Patient Monitoring System*†Ω

PM100N

Measurement range

SpO_2
1% to 100%

Pulse rate
20 to 250 beats per minute (bpm)

Pulse amplitude
0.03% to 20%

Accuracy**

Saturation
Adult: 70% to 100% ±2 digits
Adult and Neonate Low Sat: 60 to 80% ±3 digits
Neonate: 70 to 100% ±2 digits
Low Perfusion: 70 to 100% ±2 digits
Adult and Neonate with Motion: 70 to 100% ±3 digits

Pulse Rate
Adult and Neonate: 20 to 250 bpm ±3 digits
Low Perfusion: 20 to 250 bpm ±3 digits
Adult and Neonate with Motion: 20 to 250 bpm ±5 digits

Nellcor™ Portable SpO_2 Patient Monitoring System*†Ω

PM10N

Measurement range

SpO_2
1% to 100%

Pulse rate
20 to 250 beats per minute (bpm)

Perfusion range
0.03% to 20%

Accuracy**

Saturation
Adult: 70% to 100% ±2 digits
Adult and Neonate Low Sat: 60 to 80% ±3 digits
Neonate: 70 to 100% ±2 digits
Low Perfusion: 70 to 100% ±2 digits
Adult and Neonate with Motion: 70 to 100% ±3 digits

Pulse Rate
Adult and Neonate: 20 to 250 bpm ±3 digits
Low Perfusion: 20 to 250 bpm ±3 digits
Adult and Neonate with Motion: 20 to 250 bpm ±5 digits

Ω Refer to the Nellcor™ Bedside SpO_2 Patient Monitoring System operator's manual for complete descriptions, instructions, warnings, cautions and specifications. Specifications are subject to change without notice.
† The PM100N and PM10N are indicated for both home care and in-hospital use.
* FDA-cleared indication for use during conditions of motion and no motion.
** Adult and neonate specifications are shown for the Nellcor™ MAX-A and MAX-N sensors with OxiMax™ technology. Saturation accuracy will vary by sensor type. Refer to Nellcor Sensor Accuracy Grid Card for details.

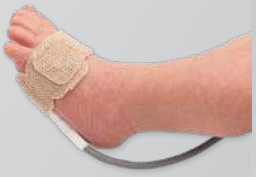
Single-Patient-Use Sensors

Adhesive SpO_2 Sensors Comfortable, form-fitting sensors; suitable for long-term monitoring	Sensors with low saturation expanded accuracy range.	
	Neonatal/Adult	**Infant**
		
Sterile	Neonatal/Adult <3 kg or >40 kg	Infant 3–20 kg
Catalog No.	**MAX-N-I**	**MAX-I-I**
Case/24		

Specialty sensors

Adult/Neonatal SpO_2 Sensor, Non-adhesive For patients with fragile skin; suitable for long-term monitoring	Neonatal	Preemie
		
Sterile	Neonatal 1.5-5 kg	Preterm Infant <1,5 kg
Catalog No.	**SC-NEO-I**	**SC-PR-I**
Case/24		

Reusable Sensors

Reusable SpO_2 Sensors Single-patient-use adhesive bandage, reusable cable	Neonatal/Adult with Wraps	Pediatric/Infant with Wraps
		
	Adult/Neonatal <3 kg or >40 kg	Pediatric/Infant 3–40 kg
Catalog No.	**OXI-A/N**	**OXI-P/I**
Case/24 Sensors, 1/PKG Cable		

Nellcor™ Sensor Accuracy Chart In Neonates

Model	70%–100% SpO_2 Range	LoSat 60%–80% SpO_2 Range
MAX-N-I*	±2	±3
MAX-I-I	±2	±3
SC-NEO-I**	±2	
SC-PR-I**	±2	
OXI-A/N	±4	
OXI-P/I	±3	

* MAX-N clinical functionality has been demonstrated on a population of hospitalized neonate patients. The observed SpO_2 accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 63 observations made spanning a range of 85 to 99% SaO_2.

** SC-PR and SC-NEO clinical functionality has been demonstrated on a population of hospitalized neonate and infant patients. The observed SpO_2 accuracy was 3.0% in a study of 57 patients with ages of 24 weeks, weight from 710 to 5,000 grams, and the 185 observations made spanning a range of 63 to 100% SaO_2.

IN THE UNITED STATES, **ABOUT 7200 (OR 18 PER 10.000)** BABIES ARE BORN EVERY YEAR WITH **CRITICAL CONGENITAL HEART DEFECTS (CCHDs).**[1]

CCHD AND PULSE OXIMETRY

In September 2011, the United States Department of Health and Human Services approved adding screening for critical congenital heart defects (CCHDs) with pulse oximetry to the Recommended Uniform Screening Panel.

In the United States, about 7200 (or 18 per 10.000) babies are born every year with CCHDs. These babies are at significant risk if this condition goes undiagnosed.[1] Since 1993, Nellcor™ pulse oximetry technology has been utilized on more than 33,000 newborns spanning five separate clinical studies evaluating the use of pulse oximetry for critical congenital heart disease screening.[2-6] Using Nellcor pulse oximetry has been shown to be a simple and economical tool to aid healthcare providers in CCHD screening.[6]

The seven classifications for CCHDs are:

1. Hypoplastic left heart syndrome
2. Pulmonary atresia (with intact septum)
3. Tetralogy of Fallot
4. Total anomalous pulmonary venous return
5. Transposition of the great arteries
6. Tricuspid atresia
7. Truncus arteriosus

GLOSSARY

Hypoplastic left heart syndrome
A birth defect that affects normal blood flow through the heart. As the baby develops during gestation, the left side of the heart does not form correctly.[1]

Pulmonary atresia
A congenital heart disease where the pulmonary valve does not form properly. As a result, blood from the right side of the heart cannot go to the lungs to pick up oxygen.[8]

Tetralogy of Fallot
A birth defect that affects normal blood flow through the heart. It is made up of the following four defects of the heart and its blood vessels[1]:

1. A hole in the wall between the two lower chambers—or ventricles—of the heart. This condition also is called a *ventricular septal defect*.
2. A narrowing of the pulmonary valve and main pulmonary artery. This condition also is called *pulmonary stenosis*.
3. The aortic valve, which opens to the aorta, is enlarged and seems to open from both ventricles, rather than from the left ventricle only, as in a normal heart. In this defect, the aortic valve sits directly on top of the ventricular septal defect.
4. The muscular wall of the lower right chamber of the heart (right ventricle) is thicker than normal. This also is called *ventricular hypertrophy*.

Total anomalous pulmonary venous return (TAPVR)
In TAPVR, oxygenated blood returns from the lungs back to the right atrium or a vein flowing into the right atrium and not to the left side of heart. Blood circles to and from the lungs and never gets out to the body.[9]

Transposition of the great arteries (TGA)
TGA occurs when the two main arteries going out of the heart—the pulmonary artery and the aorta—are switched in position, or "transposed."[1]

Tricuspid atresia
Normally, blood flows from the body into the right atrium, then through the tricuspid valve to the right ventricle and on to the lungs. If the tricuspid valve does not open, the blood cannot flow from the right atrium to the right ventricle. Blood ultimately cannot enter the lungs, where it must go to pick up oxygen (become oxygenated).[10]

Truncus arteriosus
Truncus arteriosus is a rare type of congenital heart disease in which a single blood vessel (truncus arteriosus) comes out of the right and left ventricles, instead of the normal two (pulmonary artery and aorta).[11]

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12. 510(k) K123581

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medtronic.eu/product-catalog

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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