Screening for CCHD:

Equipment for Screening

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CCHD Interest Call
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Screening Basics

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Screening Basics

Supplies You Will Need

- Pulse Oximeters
  - At least one pulse oximeter to be used for screening
  - One pulse oximeter for back-up
- Infant Disposable or Reusable Pulse Ox Sensors
  - If using disposable sensors, one disposable sensor for every infant screened
  - If using reusable sensors, one reusable sensor for each pulse oximeter. Also consider additional reusable sensors for back-up
    - Disinfecting agent recommended by pulse oximetry equipment manufacturer
- Rolling Cart for Supplies
- Data Collection Forms
  - One for every infant screened
- Dedicated individual to perform screening
- Red Heart-Shaped Stickers
  - One red heart-shaped sticker for every infant who has been screened
- Blankets for warming the infant and blocking extraneous light
- A parent for comforting infant

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Screening Basics

1. Pair screening with other standard-of-care newborn screening performed following 24 hours of age (prior to DC).

2. Movement, shivering and crying **may** affect the accuracy of the pulse ox reading. Ensure that the infant is calm and warm during the reading. Swaddle the infant and encourage family involvement to promote comfort while obtaining the reading. If possible conduct screening while the infant is awake.

3. Nail polish dyes and substances with dark pigmentation (such as dried blood) can affect the pulse ox reading. Assure that the skin is clean and dry before placing the sensor on the infant. Skin color and jaundice do not affect the pulse ox reading.

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Screening Basics

4. Wrap the sensor around the thinnest part of the outer aspect of hand/foot or around the great toe/thumb.
5. Place the light emitter on the top of the foot/hand/digit, with the photodetector directly opposite on the fleshy portion of the foot/hand/digit.
6. If using reusable sensors, use disposable wrap to secure sensor to the infant.

When placing the sensor on the infant's skin, there should not be gaps between the sensor and the infant's skin. The sides of the sensor should be **directly opposite** of each other.

CAUTION

Never use your hand or tape to secure sensor to site.

Do not use adult clips on infant patients

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Screening Basics

Right Hand

Foot

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Screening Basics

Application with Disposable Sensor

"Star to the Sky"

Application with Reusable Sensor

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"Raise the (Red) Bar"

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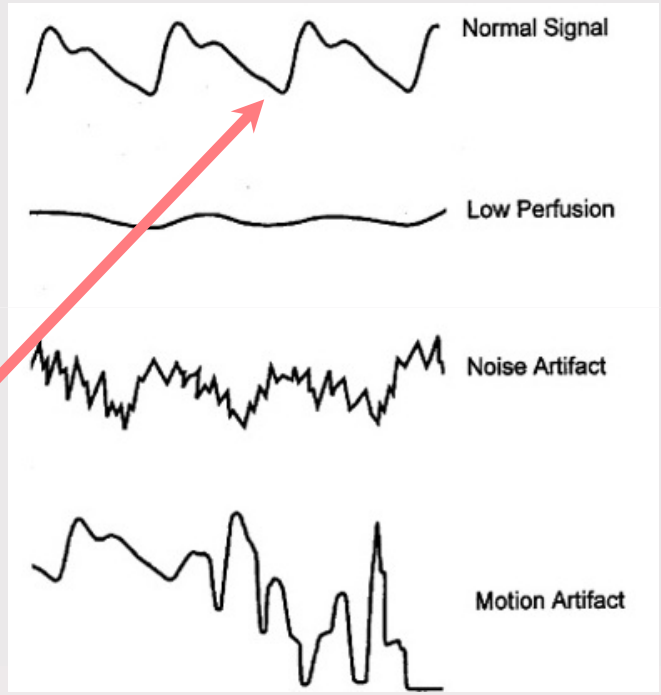
Is Your Reading Accurate?

Considerations for conventional oximeters:

- Heart rate displayed and correlates with what is expected for an infant (100-160 BPM)

- Ensure that pleth wave (arterial pulse) is stable, indicating perfusion to the site being monitored and with no motion artifact



Troubleshooting: Motion, Sensor placement

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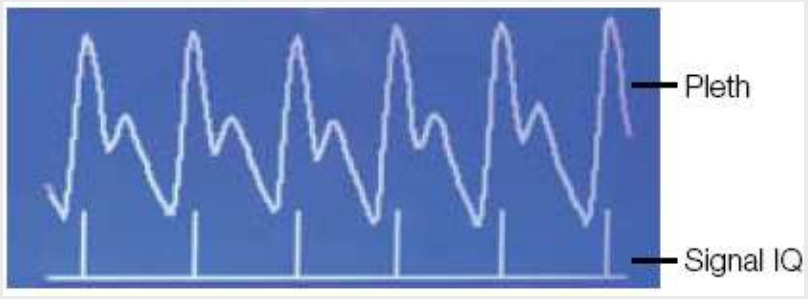
Is Your Reading Accurate?

Consider the following if using Signal Extraction Technology:

- Motion is not a limiting factor, therefore do not depend on pleth wave

Peripheral Perfusion Index (PPI) – An assessment of the pulse strength at the monitoring site and can range from 0.02 (weak pulse strength) -20 (strong pulse strength). Most newborns should have a PPI of >1.0.



- Troubleshooting: Sensor Placement (opposite and min space between probes), Clean sensor, Ambient Light, **CCHD?**

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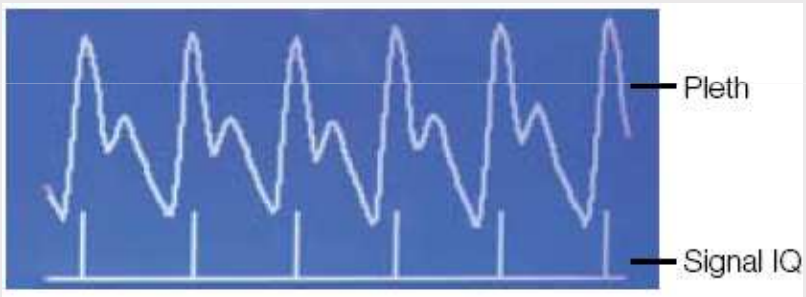
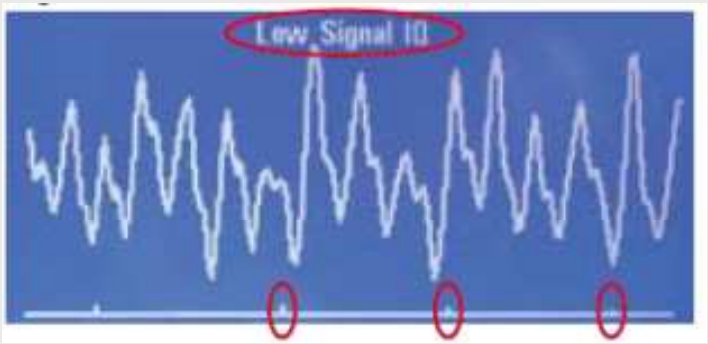
Is Your Reading Accurate?

- **Signal Identification and Quality Indicator (Signal IQ)**
  An indicator of the system's confidence level in the strength of the arterial pulse and oximetry measurements



Strong Signal IQ



Weak Signal IQ

- Troubleshooting: Sensor placement, Interruption in blood flow to site - BP cuff ?, Legs Crossed?, Diaper Change?

Screening Basics

Ahmadi Hospital; Kuwait

9. If using disposable probes, dispose of used probe. If using reusable probes, dispose of disposable wrap and clean reusable probe with alcohol pad.

10. Document readings and proceed per nursery protocol.

If you are using disposable pulse ox sensors, use a new, clean sensor for each infant. If you are using reusable pulse ox sensors, clean the sensor with recommended disinfectant solution between each infant. Dirty sensors can decrease the accuracy of your reading and can transmit infection. A disposable wrap should be used to secure the sensor to the site.

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Equipment Overview

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Equipment Overview: Covidien (Nellcor)

NELLCOR™ N-600X PULSE OXIMETER WITH OXIMAX™ TECHNOLOGY AND ALARM MANAGEMENT SYSTEM†

Features and Specifications

PERFORMANCE

MEASUREMENT RANGE

SpO_2: 1% to 100%

Pulse rate: 20 to 250 beats per minute (bpm)

Perfusion range: 0.03% to 20%

ACCURACY††

Saturation (% SpO_2 ± 1 SD)

70% to 100% ± 2 digits

60% to 80% ± 3 digits

Low perfusion: 70% to 100% ± 2 digits

Pulse rate: 20 to 250 bpm ± 3 digits

Low perfusion: 20 to 250 bpm ± 3 digits

† Refer to the Nellcor™ N-600x pulse oximeter operator's manual for complete descriptions, instructions, warnings, cautions and specifications. Specifications are subject to change without notice.

NELLCOR™ N-560 PULSE OXIMETER WITH OXIMAX™ TECHNOLOGY†

Features and Specifications

PERFORMANCE

MEASUREMENT RANGE

SpO_2: 1% to 100%

Pulse rate: 20 to 250 beats per minute (bpm)

Perfusion range: 0.03% to 20%

ACCURACY††

Saturation (% SpO_2 ± 1 SD)

70% to 100% ± 2 digits

60% to 80% ± 3 digits

Low perfusion: 70% to 100% ± 2 digits

Pulse rate: 20 to 250 bpm ± 3 digits

Low perfusion: 20 to 250 bpm ± 3 digits

† Refer to the Nellcor™ N-560 pulse oximeter operator's manual for complete descriptions, instructions, warnings, cautions and specifications. Specifications are subject to change without notice.

NELLCOR™ N-65 HAND-HELD PULSE OXIMETER WITH OXIMAX™ TECHNOLOGY†

Features and Specifications

PERFORMANCE

DISPLAY RANGE

SpO_2: 0% to 100%

Pulse rate: 20 to 250 beats per minute (bpm)

ACCURACY††

Saturation (% SpO_2 ± 1 SD)

70% to 100% ± 2 digits

60% to 80% ± 3 digits

Low perfusion: 70% to 100% ± 2 digits

Pulse rate: 20 to 250 bpm ± 3 digits

Low perfusion: 20 to 250 bpm ± 3 digits

http://www.covidien.com/rms/pages.aspx?page=OurProducts/Oximetry/Monitors&product=3

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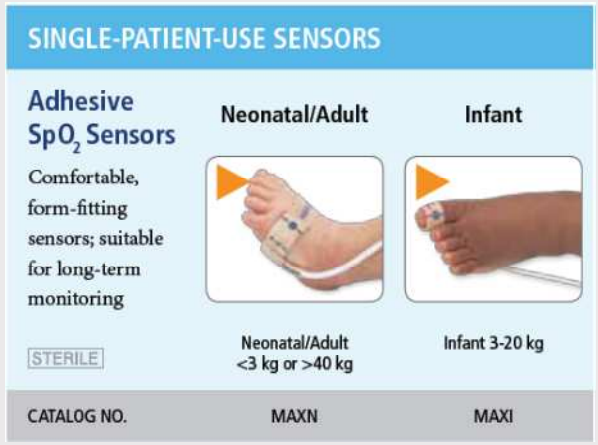
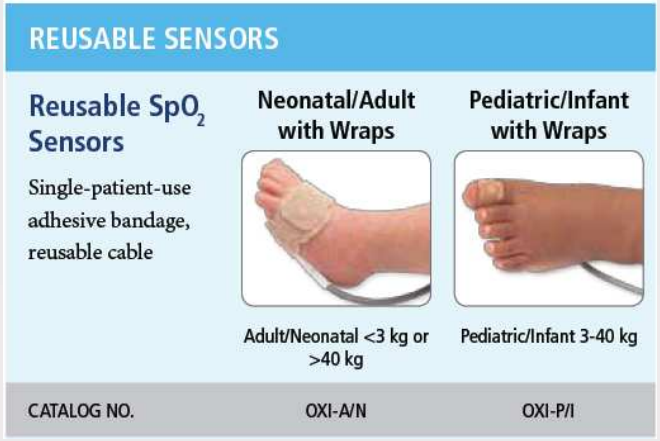
Equipment Overview: Covidien (Nellcor)

NELLCOR™ SENSOR ACCURACY CHART IN NEONATES		
Model	70%-100% SpO_2 Range	LoSat 60%-80% SpO_2 Range
MAXN*	±2	±3
MAXI	±2	±3
SC-NEO**	±2	
SC-PR**	±2	
N	±3.5	
I	±2.5	
OXI-A/N	±4	
OXI-P/I	±3	
D-YS	±4	



▶ Sensors with low saturation expanded accuracy range.



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Equipment Overview: Masimo

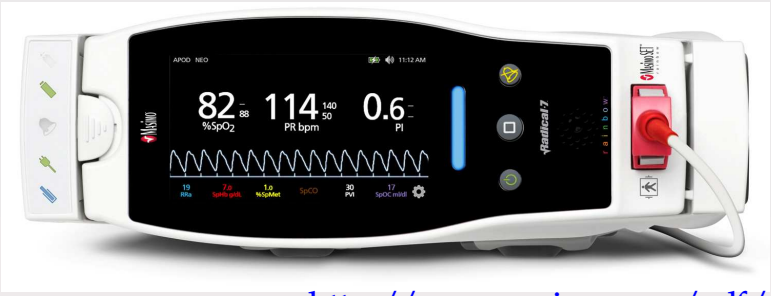
Rad 7

MEASUREMENT RANGE

SpO_2	0 – 100%
SpMet	0 – 99.9%
SpCO	0 – 99%
SpHb	0 – 25 g/dL
SpOC	0 – 35ml of O_2/dL of blood
Pulse Rate	25 – 240 bpm
Perfusion Index	0.02 – 20%
PVI	0 – 100%
RRa	4 – 70 breaths per minute

OXYGEN SATURATION ACCURACY (%SpO_2)[1]

Saturation	60 – 80%
No Motion	
Adults/Infants/Pediatrics	± 3%
Saturation	70 – 100%
No Motion	
Adults/Infants/Pediatrics	± 2%
Neonates	± 3%
Motion	
Adults/Infants/Pediatrics/Neonates	± 3%
Low Perfusion	
Adults/Infants/Pediatrics/Neonates	± 2%



Rad 5

PERFORMANCE
MEASUREMENT RANGE

SpO_2	1 – 100%
Pulse Rate	25 – 240 (bpm)
Perfusion	0.02% – 20%

SATURATION ACCURACY

Saturation	70% to 100%
No Motion	
Adults, Pediatrics	±3 digits
Neonates	±3 digits
Motion	
Adults, Pediatrics	±2 digits
Neonates	±3 digits
Low Perfusion	
Adults, Pediatrics	±2 digits
Neonates	±3 digits

http://www.masimo.com/pdf/radical-7/LAB4540E_radical-7_brochure.pdf
http://www.masimo.com/pdf/rad-5/LAB3388N_Sell%20Sheet,%20Rad-5.pdf

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Adhesive Sensors: Neonates < 3 kg = Neo sensor

Foot Application:

- Apply the sensor to either foot using the thinnest part of the foot – this is the lateral aspect
- The detector can be on either the sole of the foot or the top of the foot
- Ensure the emitter and detector are aligned.
- Wrap the tape around the foot.

Hand Application:

- Apply the sensor to the right hand using the thinnest part of the palm – this is the lateral aspect
- The detector should be on the fleshy part of the hand, this may be the back of the hand – dorsal aspect
- Ensure the emitter and detector are aligned.
- Wrap the tape around the hand.

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LNCS Inf Infant Sensor

Great Toe or Thumb Application
Patient Weighing 3 - 10 kg

Great Toe Application

Thumb Application

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Multisite YI with Foam Wrap: Neonates > 1 kg

Foot Application

Hand Application

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Applications of YI Wraps

Clean Shield®
Multisite Wrap

Standard
Wrap

Foam
Wrap

Body Weight	Clean Shield® Multisite Wrap	Standard Wrap	Foam Wrap
1 kg ~ 3 kg	■	■	■
3 kg ~ 10 kg	■	■	■
10 kg ~ 30 kg			■
10 kg ~ 50 kg			■
> 30 kg	■	■	■

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Equipment Overview: Masimo Pricing

** Estimates Only

Oximeters:

Rad 5 (handheld) - $500

Rad 7 (stand alone) - $1700

Sensors:

Adhesive Sensors:

Neonates < 3 kg,	($10-$12 each sensor), sold in boxes of 20
Infants 3-10kg ,	($10-$12 each sensor), sold in boxes of 20

Reusable Sensor:

Multisite YI, ($116-$175), 1 sensor

Warranty for 6months

Wraps for YI; one used for each newborn screened:

Foam Wrap	($1.50 per wrap) sold in packs of 12
Clean Shield Wrap	($1.77-$1.92 per wrap) sold in boxes of 100
Standard Wrap	($0.72-$0.78 per wrap) sold in boxes of 100

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PalmSat® 2500 Series: Product Highlights

- Reliable: Proven Nonin Technology
  - 2% root-mean-square accuracy
  - Regulatory clearance for neonates, infant, pediatric and adult patients
  - Claims for accuracy under conditions of motion and low perfusion
- Versatile: Broad assortment of sensors available
- Pulse rate monitoring range of 18-300 bpm
- Durable: Backed by industry leading 3-year warranty & tested to assure performance in challenging conditions, such as drops & liquid ingress. Granted US Army/Air Force Aeromedical Certification.
- Dependable Long Battery life: 80 hours with 4AA alkaline batteries or 40 hours with Nonin rechargeable battery pack
- Made in the U.S.A.

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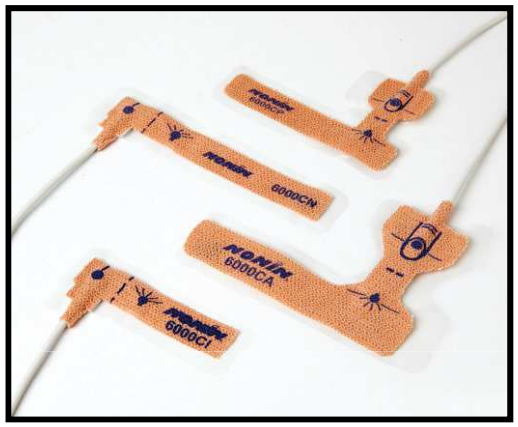
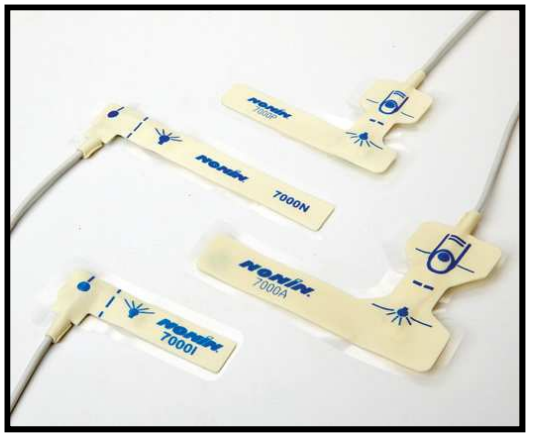
NONIN Single-use-sensors
6000 Cloth and 7000 Micro foam

- 2 material choices
  - Cloth
  - Micro-foam
  - Pressure-sensitive adhesive
- Latex free
- Sensors for neonates, infants, pediatric and adult sizes
- Accuracy of +/- 2 in motion and low perfusion





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7000 Flexi-Form III sensor single-patient-use

- **Maximum comfort –** The cushioned, adhesive micro-foam material allows for maximum patient comfort during extended monitoring.
- **Optimal fit –** New, smoother backing for a comfortable fit.

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FDA Discussion

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