NSO Pulse Oximeter Information and Requirements

If your Pulse Oximeter was supplied by Newborn Screening:

- The monitor is your property; your responsibility to maintain
- Service and warranty issues are to be managed through the respective vendor and not through Newborn Screening Ontario
- The recommendation is to contact your biomedical department for any equipment issues as an initial step.
- Consumables for screening (probes and wraps) will be provided through Newborn Screening annually on a volume based approach. Please contact NSO at NSOCCHD@cheo.on.ca for more information

If your Pulse Oximeter was NOT supplied from Newborn Screening:

As part of assuring quality for CCHD screening in Ontario, Newborn Screening Ontario has developed a list of standards for pulse oximeters used for CCHD screening. Your biomedical engineering department or vendor will be able to provide you with specifications for your pulse oximeter(s) to ensure that your monitor meets the requirements.

<u>Pulse Oximeter Requirements</u>

1. Pulse oximeters must report functional oxygen saturation (SpO_2).
2. Pulse oximeters must be motion-tolerant.
3. Pulse oximeters must be validated by the manufacturer for use in low perfusion conditions
4. Pulse oximeters must have a documented accuracy range of saturation +/- 3% or less in the 70-100% reading range, and +/- 3% or less in low perfusion conditions
5. Pulse oximeter must have an indicator of signal reliability (e.g. plethysmograph (pleth) line or waveform, audible heartbeat, or signal indicator).
6. Probes must be designed for use for neonatal patients.
7. Pulse oximeters must have built in quality assurance and/or system validation checks.
8. Pulse oximeters must be cleared by Health Canada and/or the U.S Food and Drug Administration for use in newborns and conform to relevant standards (FDA guidance document 1605: Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff).

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