



## *NSO Pulse Oximeter Requirements*

Here is a list of standards outlined by NSO for pulse oximeter use for CCHD screening. Your biomedical engineering department or vendor will be able to provide you with specifications for your pulse oximeters to ensure that your monitor meets the requirements.

### **Pulse oximeter requirements**

1. Pulse oximeters must report functional oxygen saturation (SpO<sub>2</sub>).
2. Pulse oximeters must be motion-tolerant.
3. Pulse oximeters must be validated by the manufacturer for use in low perfusion conditions.
4. Pulse oximeter must have an indicator of signal reliability (e.g. plethysmograph (pleth) line or waveform, audible heartbeat, or signal indicator).
5. Probes must be designed for use for neonatal patients.
6. Pulse oximeters must have built in quality assurance and/or system validation checks.
7. 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).

