

Pulse Oximeter Issues for May 13th Meeting

Anesthesiology and Respiratory Therapy Devices Panel

1. Pulse oximeter sensors may be implemented in either a transmittance or reflectance configuration. In both configurations, light is scattered by blood, which has time dependent characteristics, and bone or other tissue structures which are not time dependent. Transmittance sensors are configured in a manner where the emitter outputs light which travels through tissue (e.g. finger, toe, and ear) and is received on the opposite side by the detector. Reflectance sensors are configured with the emitter and detector in the same plane. Emitted light must reach the detector by reflection off a surface which typically results in smaller signal strengths in comparison to transmittance sensors. Please discuss the clinical differences between transmittance and reflectance sensors. In your discussion, please specifically comment on:
 - a. Any differences in performance between the two sensor types.
 - b. Whether the differences in performance would lead you to recommend different pre-market evaluation methods and standards, and, if so, what those would be.
 - c. Whether differences in performance would exclude certain indications for use for one type compared to the other and, if so, what those would be.

2. The agency currently recommends that pulse oximeter sensors are clinically validated to a stated accuracy (e.g. $\pm 2\%$ from 70-100 %) on healthy adults under ideal laboratory conditions. For transmittance sensors intended for use on neonates, a 1% degradation factor is then added to the stated accuracy specification for use on neonates (e.g. $\pm 3\%$) to compensate for uncertainty due to the inability to perform suitable calibration studies and due to the apparent affect of fetal hemoglobin (FHb) on saturation measurements (there is some evidence that co-oximeters, the reference device used to analyze blood, is inaccurate at high concentrations of FHb).
 - a. Please discuss whether you believe the agency should continue to follow this recommendation for validation of transmittance sensors intended for use on neonates and if this same recommendation should also be followed for validation of reflectance sensors intended for use on neonates. If the panel does not feel that this recommendation is appropriate, please provide the agency with suggestions and recommendations as to how the validation of accuracy for neonatal use should be revised.
 - b. Please discuss whether you believe that the labeling for sensors, especially those for neonates, should contain information on how the saturation accuracy specification were developed and validated.

3. To date, the agency has not cleared any pulse oximeters for medical uses as over-the-counter (OTC) devices. Please comment on the risks and benefits of OTC pulse oximeters. Please specifically discuss:
 - a. Under what circumstances, and for what general or specific clinical conditions or indications (asthma, COPD monitoring), if any, should the agency allow the clearance of an OTC pulse oximeter.
 - b. Whether you believe adequate labeling can be written to ensure the safe¹ and effective² use of an OTC pulse oximeter including directions for use, contraindications, warnings, and precautions. If so, please comment on what specific elements or statements should be in such labeling.
 - c. Whether the significant chance for misuse of OTC pulse oximeters exists if cleared or approved by the agency for OTC use and what the potential risks would be.

¹ There is a reasonable assurance that a device is **safe** when it can be determined, based upon valid scientific evidence³, that the probable benefits to health from the use of the device for its intended uses and conditions for use, when accompanied by adequate directions and warnings against unsafe use, outweigh any probable risks. The valid scientific evidence used to determine the safety of the device shall adequately demonstrate the absence of unreasonable risk associated with the use of the device for its intended uses and conditions for use.

² There is a reasonable assurance that a device is **effective** when it can be determined, based upon valid scientific evidence³, that in a significant portion of the target population, the use of the device for its intended uses and conditions of use, when accompanied by adequate directions for use and warnings against unsafe use, will provide clinically significant results.

³ Valid scientific evidence includes:

- Well-Controlled Investigations
- Partially Controlled Studies
- Studies & Objective Trials without Matched Controls
- Well-Documented Case Histories by Qualified Experts
- Reports of Significant Human Experience with a Marketed Device