

**CDRH Anesthesiology and Respiratory Therapy Devices
Panel of the Medical Devices Advisory Committee –
Pulse Oximetry**

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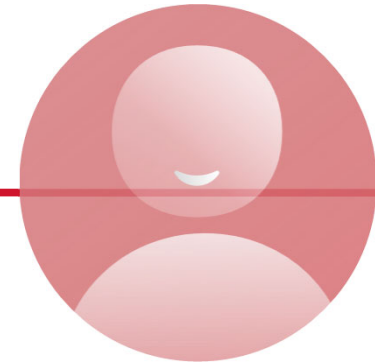
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2024-02-02

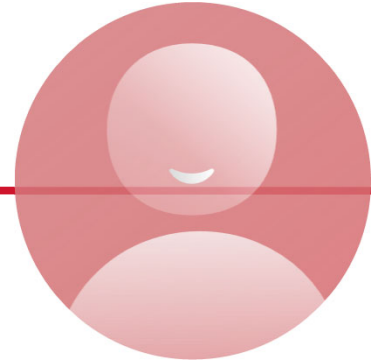
Disclosure: Dr. Barker is a part-time employee of Masimo Corporation.

Industry Perspective on the FDA Discussion Paper



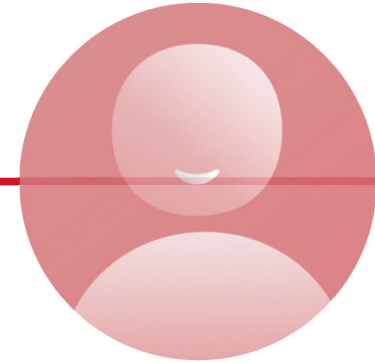
- FDA and Industry are aligned in the importance of equity in medical device performance.
- We applaud the FDA for addressing the importance of Pulse Oximetry. FDA's discussion paper on Pulse Oximeters and Skin Pigmentation shows careful thought and extensive research.
- The discussion paper takes a significant step in accounting for race and ethnicity accuracy issues.

FDA Feedback Request



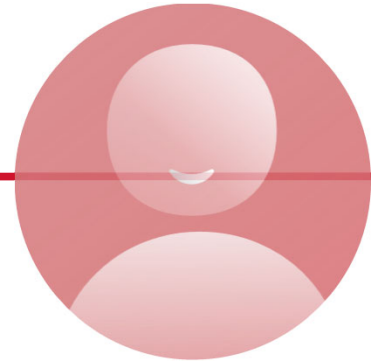
- FDA requested feedback on 7 questions.
- 4 - Questions are on the use of the Monk Skin Tone (MST) Scale and Individual Typology Angle (ITA) assessments to address different skin pigments within the US Population.
- 1 - Question requests feedback on the performance criteria among varying skin pigments.
- 2 - Questions ask for additional measures the Agency can take to address diversity of skin pigments.

Feedback on MST and ITA



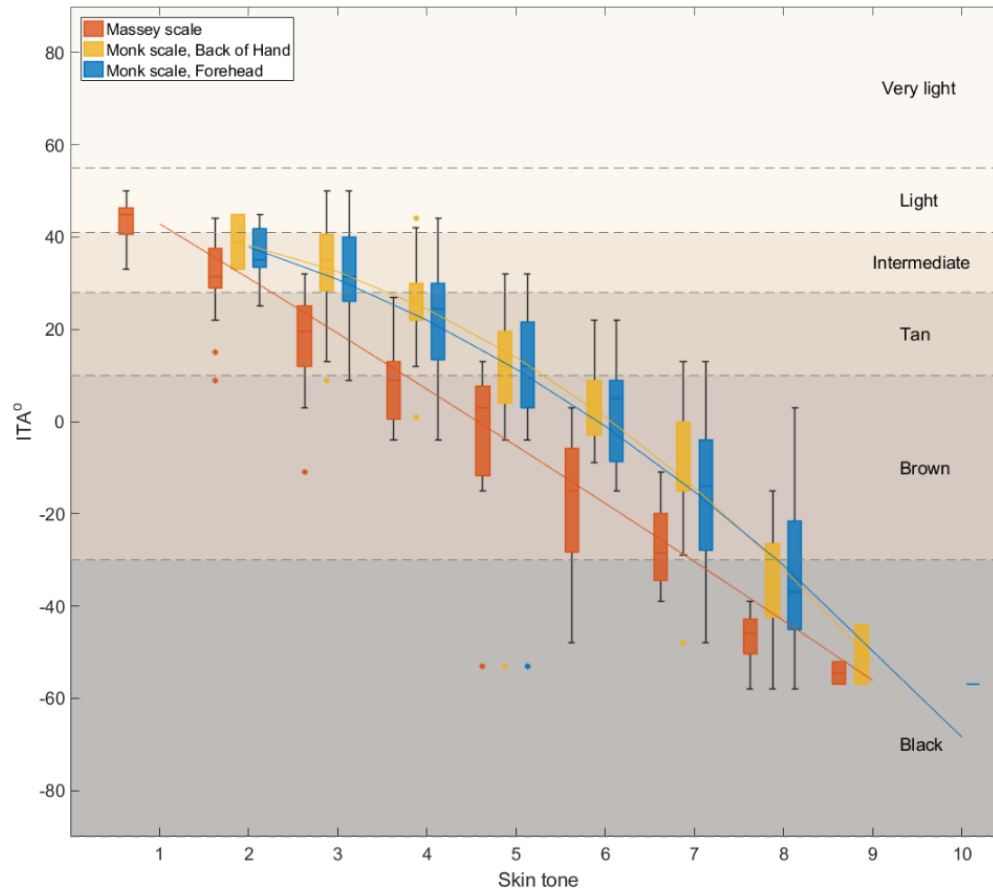
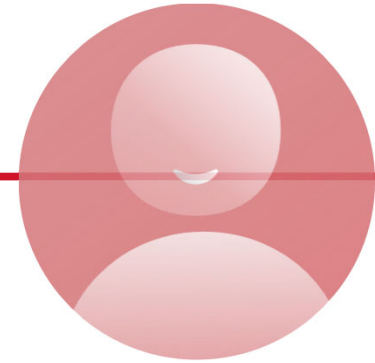
- The use of Monk Skin Tone (MST) scale for initial assessment of skin pigmentation, followed by an objective measure using Individual Typology Angle (ITA) assessment is satisfactory.
- MST provides good resolution and range to skin tones from very light to very dark.
- The ITA provides an objective measure to detect subjective bias in the assessment of skin tone.

Recommendations for use of MST and ITA



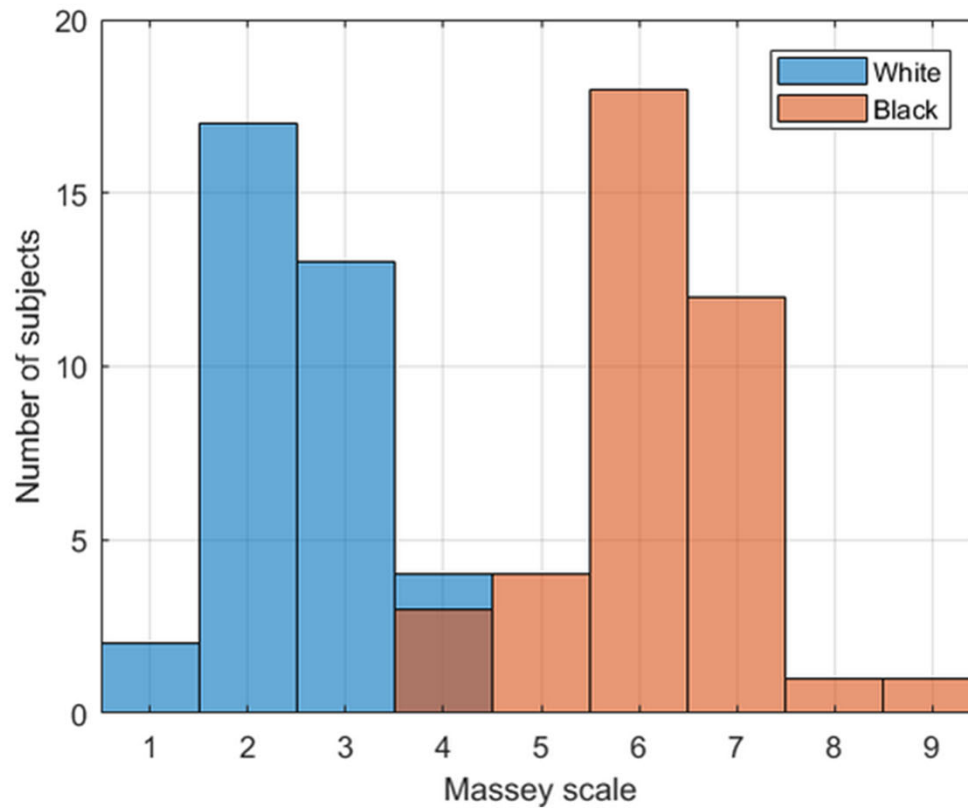
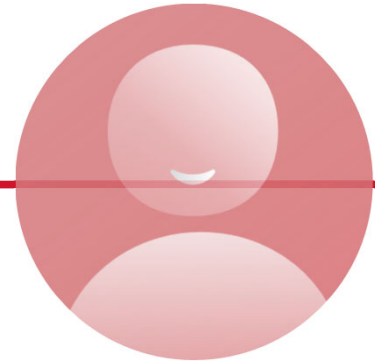
- Provide more specific guidance regarding the location for obtaining ITA measurements.
- Identify preferential assessment sites as forehead or back of hand. The nail beds have large variability, and measurement at the finger sensor site may be more challenging than the forehead or hand.
- Require three ITA samples at the designated target area, to decrease error from a single measurement.

Comparison of ITA to Skin Pigment Scales



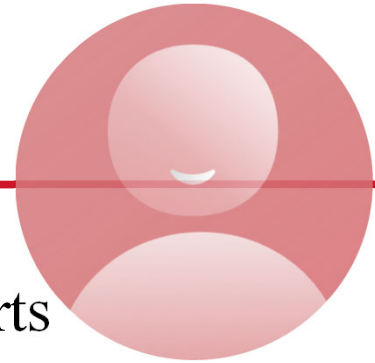
Skin pigment data measured in 81 subjects by Masimo Corp.

Skin Pigment Distributions



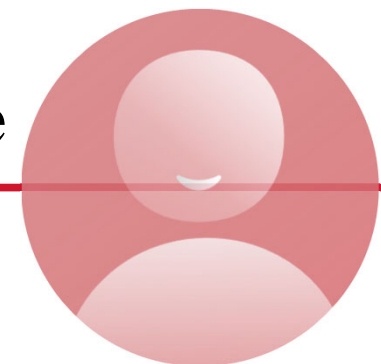
Barker S, Wilson W: *“Racial effects on Masimo pulse oximetry: a laboratory study”*
Journal of Clinical Monitoring and Computing; <https://doi.org/10.1007/s10877-022-00927-w>

Recommendations for use of MST and ITA (Cont'd)



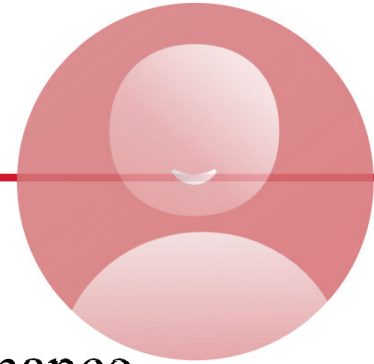
- Move forward with stratifying skin pigments into 3 MST cohorts (1-4, 5-7, 8-10). These cohorts can detect performance difference trends with skin pigment.
- We agree that at least 25% of participants come from each MST cohort (1-4, 5-7, 8-10). Balancing cohorts will help avoid under- or over-weighting of a particular cohort.
- Require at least one subject with MST values of 2 and 9. Inclusions of MST 2 and 9 assure diverse subject enrollments and help avoid recruitment constraints due to lack of available subjects.

Feedback on Criteria for Non-Disparate Performance



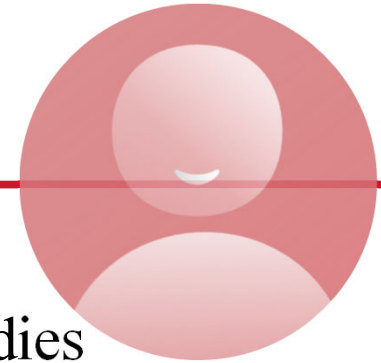
- The proposed bias requirement for non-disparate performance of $\pm 1.5\%$ for $\text{SaO}_2 > 85\%$ is acceptable, but the definition at the lower SaO_2 range $70\% < \text{SaO}_2 \leq 85\%$ of $\pm 3.5\%$ raises clinical concerns.
- SaO_2 values below 85% present more significant hypoxia risks than values above 85% . The disparate results in this SaO_2 range are also what has been identified as “occult hypoxemia” in recent publications.

Recommendations on Criteria for Non-Disparate Performance



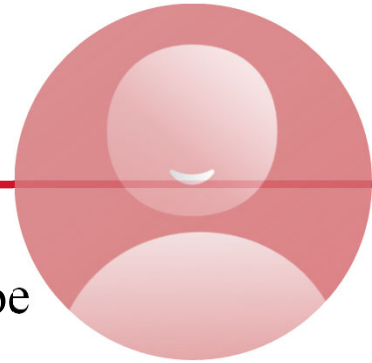
- Use the MST for the main assessment of non-disparate performance. The use of two different skin pigment measures will be unnecessarily complicated.
- Define non-disparate performance for maximum bias difference in the range $70\% < \text{SaO}_2 \leq 85\%$ as $\pm 2\%$, rather than the proposed $\pm 3\%$.
- The $\pm 2\%$ threshold is similar to the $\text{SaO}_2 > 85\%$ of $\pm 1.5\%$, while accounting for the potentially greater bias that exists at lower SaO_2 values.

Proposals for Further FDA Actions



- Tighten the accuracy requirements of laboratory validation studies from 3% Arms to 2% Arms. Reducing the error will lessen clinical impact of disparate performance due to skin pigmentation.
- Apply new requirements to reprocessed sensors. Reprocessed sensors are significant modifications of FDA-cleared disposable sensors. The impact of the reprocessing should be assessed for disparate performance due to skin pigmentation.
- Track the 510(k) submission and clearance rates over the next two years to assess the adherence to the requirements.

Summary



- We agree with the proposed use of MST and ITA to quantify the skin pigmentation diversity of the US population. Preferred locations should be forehead and back of the hand.
- Require subjects in the range of MST 2 and 9 and require $\geq 25\%$ of participants from each MST cohort (1-4, 5-7, 8-10).
- Criterion for non-disparate performance is recommended to be a bias $\pm 1.5\%$ for $\text{SaO}_2 > 85\%$ and $\pm 2\%$ for $70\% < \text{SaO}_2 \leq 85\%$.
- Tighten the SpO_2 accuracy requirement from 3% Arms to 2% Arms.
- Apply new requirements to reprocessed sensors.
- Follow-up after 2 years to assess the consistent adherence to these requirements and the burden to manufacturers.

Thank You

