Adult ForeSight Tissue Oximetry System: The right monitor makes a difference – for all of your patients' differences

Background
Patients vary in age, size, gender, race, physical characteristics, as well as urgency of needed care. Multiple publications have noted racial disparity in both pulse oximetry (SpO_2) and near infrared spectroscopy (NIRS) tissue oximetry (StO_2 or rSO_2) technologies,[1-6] which has brought public attention to this matter. A related concern of erroneous oximetry values is they may confuse interpretation and lead to incorrect clinical intervention.[2-4,7,8] ForeSight NIRS tissue oximetry technology continues to perform well, while other technologies may falter.[6,7]

Specific examples of where performance of other NIRS technologies may be challenged include:

- Darker skin pigmentation
- When cranial scalp-to-cortex depth >1.76 cm
- Required baseline values - which may conflict with a realistic clinical environment

2-Wavelength NIRS and darker skin pigmentation
NIRS technology was introduced to the medical device market by Somanetics in 1996 with a 2-wavelength device for deriving rSO_2 values. This 2-wavelength approach continues in the latest INVOS platform, where any "additional wavelengths are only used for the sensor on/off detection algorithm."[9]

Sun et al. found in a study with the INVOS 2 wavelength system on 3,282 Caucasian (Cauc) and African American (AA) patients, "steady-state (preoperative) mean rSO_2 values were lower in the AA group than in the Cauc group by ~12%."[5] (see Figure 1) Notably, this potential offset is corroborated in the INVOS operator's manual as, "poor performance" may be seen in patients with "dark skin pigment".[10]

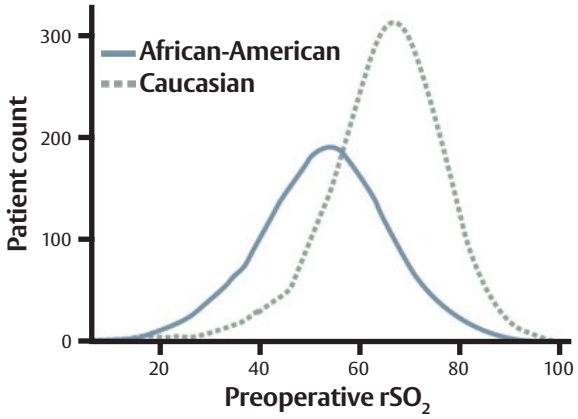


Figure 1: INVOS 2-Wavelength system performance. Preoperative rSO_2 by ethnic group. The number of patients associated with each level of rSO_2 is depicted. Notice the normal distribution of the data in each ethnic group with that in African Americans being systematically lower.[5]

Stannard et al. used the ForeSight system to measure cerebral StO_2 on 4,267 patients of self-identified racial cohorts, the author stated, "These findings in a large institutional case series support the utility of rSO_2 readings as a metric for assessing cerebral perfusion during cardiac surgery across a diverse patient population."[6] (see Figure 2) Note: rSO_2 was the term used for ForeSight sensor tissue oxygenation values in the publication.

Edwards

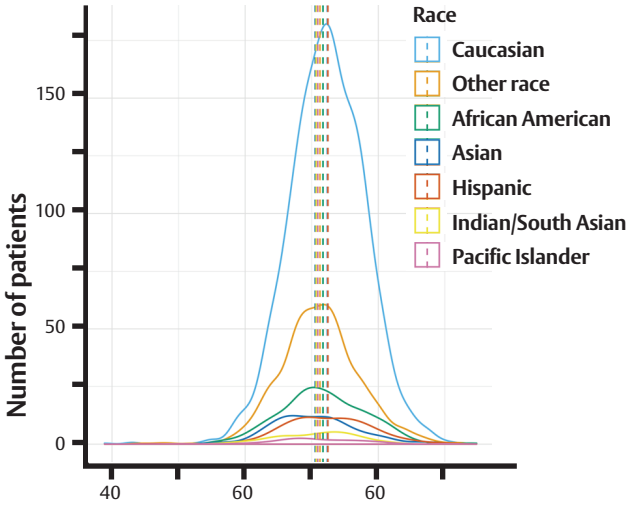


Figure 2: "The distribution of mean pre-bypass rSO_2 level for each racial group is depicted. The "interaction variable between rSO_2 and race was not statistically significant."[6]

5 specific wavelengths

To ensure accurate readings on patients of different skin complexions, the ForeSight sensor contains specific wavelengths to detect and compensate for the melanin present in the skin. Incorporating five different wavelengths of NIRS light, analyzes the tissue at the points where oxygenated and deoxygenated hemoglobin are well distinguished.[15] Utilizing the absorption curves of oxygenated and deoxygenated hemoglobin and other chromophores (such as melanin), enables ForeSight system technology to provide reliable and consistent readings regardless of skin color (see Figure 3).

ForeSight system wavelengths

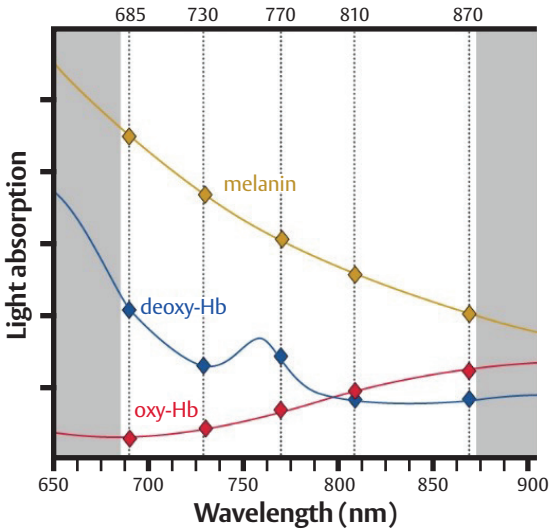


Figure 3: Relationship of light absorption by three chromophores (melanin, deoxy- and oxy-hemoglobin) to light wavelengths between 650 and 900 nm. Note: the selection of five specific wavelengths and spacing between them follows the curvilinear characteristics of deoxygenated hemoglobin.

Additionally, hyperbilirubinemia (i.e., jaundice) also changes skin color, which can match melanin pigmentation.[11] It was found in a comparison of the 2-wavelength NIRS device to ForeSight system technology, hyperbilirubinemia "significantly reduces cerebral and somatic rSO_2 readings by INVOS 5100 C through 'competitive' absorbance of transmitted light".[12] The investigators found that the ForeSight device overcame interference from hyperbilirubinemia, for both cerebral and somatic StO_2 body sites.

Scalp-to-Cortex Distance

The Scalp-to-Cortex Distance (SCD) varies among individuals and can include multiple factors, e.g., skull thickness, cerebral spinal fluid (CSF) and brain atrophy.[13] NIRS penetration that is too shallow in patients with deeper SCD may contaminate signals and result in erroneous readings.[7] (see Figures 4 and 5)

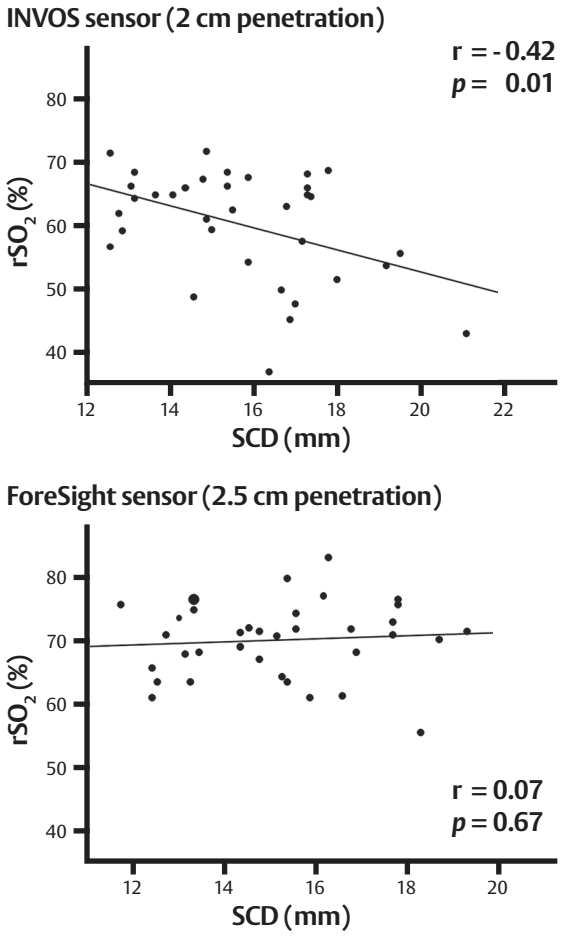


Figure 4: "There is a significant negative correlation between mean rSO_2 value and scalp–cortex distance (SCD) in group I (i.e., INVOS sensor plot). In group F (i.e., ForeSight sensor plot), measured mean rSO_2 value is not affected by SCD."[7] Note: rSO_2 is the tissue oxygenation term used by the authors for both sensor manufacturer groups.

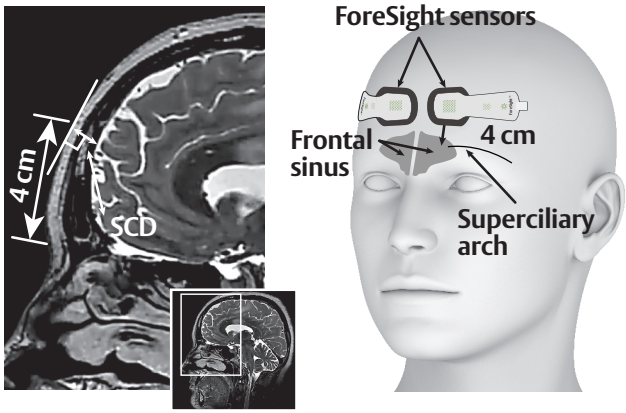


Figure 5: "Scalp–cortex distance (SCD) was defined as the distance between the scalp surface of the forehead at 4 cm from the superciliary arch and the frontal cerebral cortex in reference to a midsagittal plane of a T1-weighted magnetic resonance image."[8]

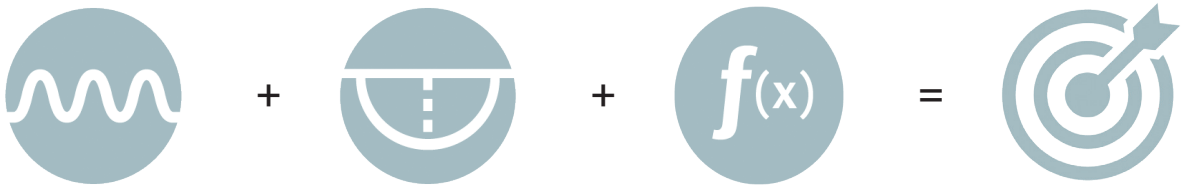
Studies which used a 2 cm depth of penetration technology during cardiac surgery, found apparent erroneous rSO_2 values (<40%) with SCD greater than 1.76 cm.[7-8] These authors found the erroneous values resulted in the clinician performing excessive interventions (including significantly higher CPB pump flow and transfusion rates).[7]

Baselines required

NIRS system which can only trend and cannot provide absolute tissue oximetry readings, require a baseline reading while the patient is stable and awake.[10] This is not always realistic in a fast-paced environment. The 2021 ISO standard recognized a concern with use of trend-based cerebral NIRS, "For some clinical applications, trend performance can be insufficient. For emergency care, and whenever the first cerebral tissue oxygenation reading is obtained in a diseased state, the value that is obtained needs to be trustworthy and operators need to be able to interpret this value in a context of 'normality' and of risk of brain injury or neurological damage."[14] The ForeSight system technology has the option of obtaining a baseline value but is not required.

Three facets of ForeSight system performance

ForeSight system's performance results from the number and selection of NIRS wavelengths, sensor design, and algorithms.

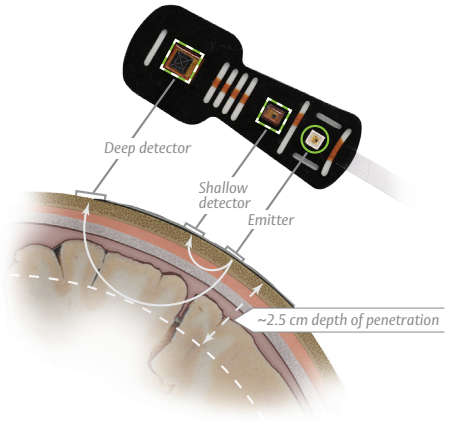


5-wavelengths | **Sensor design** | **Site-specific algorithms** | **Trusted performance**

Unique 2.5 cm penetration sensor design

Near infrared light readily penetrates scalp and skull, which is the basis for providing a signal to assess cerebral oxygenation.[16] Experts consider the depth of light penetration to be approximately half the distance between the light emitter and detector.[17] ForeSight sensor's deep detector is separated from the emitter by 5 cm making the depth of penetration 2.5 cm. (see Figure 6) This is 25% deeper than the other major suppliers of most major commercially available NIRS sensors. This deeper penetration mitigates contamination, which is problematic in 2 cm depth systems.[7,8]

Figure 6: ForeSight large sensor component separation allows for a penetration of ~2.5 cm



Refined algorithms
ForeSight system uses site specific algorithms, which have been refined over time to matching cerebral or somatic locations. Cerebral StO_2 is calibrated and validated to venous blood from the jugular bulb, and for Somatic StO_2 to locations within designated vena caval sampling sites.[18] Most major commercially available NIRS technologies do not claim non-cerebral site specific algorithms and are solely venous referenced to jugular blood.

Enhanced performance when timing matters to urgency of care
With the ForeSight system NIRS technology, all three facets come together to bring absolute tissue oximetry values you can count on from patient to patient, regardless of the skin color[18] (see Figure 7). Note: cerebral NIRS StO_2 closely and uniformly follows CO-oximetry blood SO_2 analysis throughout the range of values. Moreover, absolute StO_2 allows for initiating NIRS monitoring at any time, making baselines optional so that it is never too late to initiate ForeSight system and obtain an accurate status of tissue oxygenation.

Validation of ForeSight system cerebral NIRS

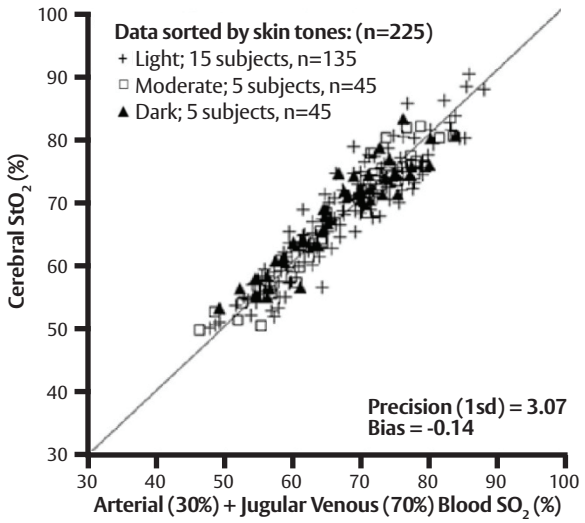


Figure 7: The distribution of paired cerebral StO_2 values to CO-oximeter blood analysis of a mixed skin pigmentation cohort of desaturated volunteers.[18]

Conclusions
2-wavelength NIRS systems may not compensate for darker skin pigmentation, and thereby can display erroneously StO_2 values. Separately or in addition, NIRS systems which only penetrate to 2 cm may be contaminated in patients with a deeper cerebral cortex, also leading to erroneous StO_2 readings. Incorrect oximetry values may confuse interpretation and lead to unnecessary clinical intervention.

ForeSight sensor uses 5-wavelengths of NIRS, allowing it to compensate for varying skin pigmentation. In addition, the ForeSight sensor penetrates 25% deeper than the other major suppliers of commercially available NIRS sensors, mitigating cranial contamination from superficial tissues. All these factors come together (5 specific wavelengths, unique sensor design, and refined algorithms) to bring you accurate and actionable tissue oximetry, where baselines are optional, and it is "never too late" to initiate.

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