

FORE-SIGHT[®]

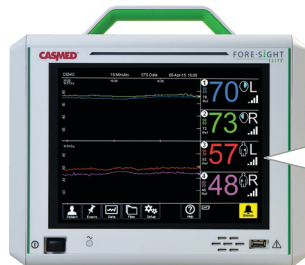
Absolute Tissue Oximetry ELITE[®]



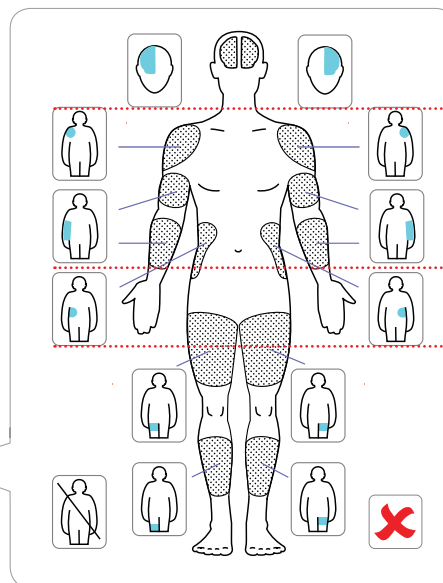
FORE-SIGHT ELITE, which raised the standard of cerebral oximetry, now provides the highest level of actionable and accurate measurements for somatic oximetry.

- The first and only FDA cleared tissue oximeter utilizing a 5th wavelength of near-infrared light
- FORE-SIGHT algorithm is customized to the unique optical properties of each skeletal muscle site.
- Clinical validation of StO₂ for a skeletal muscle site, as referenced to **central venous** and **arterial** blood oxygenation samples.

FORE-SIGHT ELITE allows the user to select specific skeletal muscle locations. Each sensor site uses a specific algorithm that compensates for the effects of the melanin and other tissue properties. This level of customization permits the precise and reliable quantification of the oxygen saturation of the tissue under the sensor.



57% L



Arm:
Deltoid (shoulder)
Biceps (upper arm)
Brachioradialis (forearm)

Flank: Latissimus dorsi
Abdomen: External oblique

Leg:
Quadriceps (upper leg)
Gastrocnemius (calf)
Tibialis (calf)

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Validation of FORE-SIGHT ELITE® StO₂ Measurements from Adult Skeletal Muscle

This study was undertaken to validate the accuracy performance of the FORE-SIGHT ELITE Absolute Tissue Oximeter (CAS Medical Systems, Branford, CT USA) using Large Sensors to measure tissue oxygen saturation (StO₂) of adult skeletal muscle.

Methods

Twenty-four healthy, diverse, adult volunteers (15 Male, 9 Female, 14 African American, 8 Caucasian, 2 Asian, 19–40 years, 51.0–96.5 kg) participated in this IRB-approved study in the Duke University Human Pharmacology Laboratory, after providing written, informed consent. As in previous StO₂ validation studies, the accuracy reference was functional oxygenation of blood samples drawn from intravenous and radial artery catheters.¹ While the intravenous catheter was placed in the jugular bulb for the prior cerebral tissue validation study, the catheter was placed in the vena cava for this study because this position more accurately represents venous flow from other body tissues.² FORE-SIGHT ELITE Large Sensors were positioned over two different musculoskeletal tissue beds: flank and quadriceps, alternating between left and right sides. The design of the FORE-SIGHT ELITE Large Sensor is the same as that used for the cerebral validation: five wavelengths of light (690, 730, 770, 810, and 870 nm) are emitted from an LED light source array and two detectors are placed 15 mm and 50 mm from the light source.¹

The subjects underwent a controlled hypoxia sequence while maintaining isocarbica using a RespirAct™ gas delivery system (Thornhill Research Inc., Toronto, Canada); the targeted peripheral oxygen saturation ranged between 100% and 70% as measured with finger pulse oximetry (S_pO₂). At each step of the sequence, paired blood samples were collected from the arterial (S_aO₂) and central venous catheters (S_vO₂) and were analyzed by a co-oximeter. These functional oxygen blood saturations were used to calculate a weighted arteriovenous reference (REF CX) to represent whole body tissue saturation as derived from Pang's findings²: $REF\ CX = (0.3 \times S_aO_2) + (0.7 \times S_vO_2)$

The REF CX was compared to FORE-SIGHT ELITE measured StO₂ to determine accuracy on all subjects. The study also looked at ethnicity and skin pigmentation to determine if the monitor's accuracy was affected.

Results

The two muscle locations yielded 432 StO₂ data points from 24 subjects. When comparing the results to REF CX, the bias ± precision (1 standard deviation) of the Flank and Quadriceps together was $0.24 \pm 5.17\%$ (Figures 1-2). FORE-SIGHT ELITE StO₂ measurements from the Flank muscle had a bias ± precision of $-0.97 \pm 4.29\%$, while the Quadriceps muscle StO₂ values had a bias ± precision of $1.45 \pm 5.67\%$ (both at 1 standard deviation). No statistically significant differences were found between subjects with light/medium vs dark skin ($P = 0.76$).

Conclusions

FORE-SIGHT ELITE Large Sensors in combination with an algorithm compensating for various tissue properties demonstrated consistent accuracy when monitoring skeletal muscles of adults. These data were provided to FDA in substantiation for the cleared claim for use of Large Sensors to monitor skeletal muscle with the FORE-SIGHT ELITE Absolute Tissue Oximeter (FDA: K133879).

References

- MacLeod D, Ikeda K, Cheng C, Shaw A. Validation of the Next Generation FORE-SIGHT ELITE Tissue Oximeter for Adult Cerebral Tissue Oxygen Saturation. *Anesth Analg*. 2013; 116(SCA Suppl):1-182.
- Pang CCY. Measurement of body venous tone. *J Pharmacol Toxicol Methods*. 2000; 44(2):341-60.

