

FORE-SIGHT[®]

Absolute Tissue Oximetry



Actionable Accuracy

using Near Infrared Spectroscopy (NIRS) to assess cerebral and tissue oxygen saturation

Continuous and Consistent

real-time data with spot-check capability

Precise Measurements

in adults, children, and babies

Patient-tailored Algorithm

accounts for individual differences including age, weight, and skin pigmentation



Absolute Accuracy

Improving the Precision of Patient Care

- **Absolute Measurements**

Clearly indicate a patient's tissue oxygen saturation, eliminating the need for a pre-induction baseline. This permits clinicians to establish an exact StO₂ threshold to guide interventions.

- **Patented Algorithm**

Determines the precise absorption coefficients of Hb and HbO₂ and compensates for individual patient characteristics such as age, weight, and skin pigmentation. It is the only algorithm designed to account for human growth factors: skull curvature, scalp, and brain gray matter thickness.

- **Unique Sensor Design**

Maximizes interrogation depth and optical volume for all sensors. Large, Medium, and Small sensors are available to monitor StO₂ in adults, children, and babies.

- **LASER-SIGHT[®] Technology**

Generates four precise wavelengths to accurately determine the concentration of Hb and HbO₂ to provide precise measurements of cerebral and skeletal muscle tissue oxygen saturation.

When Precision and Confidence Matter Most



FORE-SIGHT Applications

Cardiac Surgery

- Coronary Artery Bypass Graft (CABG)
- Aortic Arch Surgery
- Deep Hypothermic Circulatory Arrest (DHCA)
- Carotid Endarterectomy (CEA)
- Valve Replacement/Repair
- Single Lung Ventilation

EP/Cath Lab

Emergency Room

Neurosurgery

Orthopedic Surgery

- Shoulder – Beach Chair
- Spine
- Hip Replacement

ICU

- Hemodynamic instability
- ECMO
- VAD
- Single Lung Ventilation

FORE-SIGHT®

Absolute Tissue Oximeter

- Easy-to-read, color LCD monitor
- Two channels of StO₂
- Absolute accuracy for all patient populations
- Repeatable, reliable readings every two seconds
- No baseline reading required
- Tissue Perfusion Index (TPI) aids in optimal placement of sensor
- Spot-check and continuous monitoring
- Time under Threshold: Real-time tracking of elapsed time under user-defined thresholds
- Database summary screen for input into STS Database
- Data analysis and charting tool is available as a Microsoft® Excel® "Add-In" Software



Monitor Dimensions

Height:	20.3 cm/8"
Width:	20.3 cm/8"
Depth:	33.0 cm/13"
Monitor Cable:	3 m/9.8'
Patient Cable/Sensor:	
Large, Medium and Small Sensors	1 m/3.3'
Small Non-Adhesive Sensor	1.5 m/5.0'

Vital Signs Monitoring Functions

Absolute Cerebral Tissue Oxygen Saturation (%StO₂):	
Range of StO₂:	0-99%
Refresh Rate:	every 2 seconds
Diagnostics:	Auto self-test
Cerebral Tissue Accuracy:	
Large Sensors:	45% to 95%: ±3.7% 1 SD ¹
Medium Sensors:	50% to 99%: ±4.9% 1 SD ²
Small Sensors:	50% to 99%: ±5.0% 1 SD ³
Skeletal Muscle Tissue Accuracy:	
Medium Sensors:	60% to 95%: ±5.2% 1 SD ⁴

Environmental Conditions

Operating Temperatures:	10° C to 40° C
Operating Humidity:	30% - 75%, non-condensing
Atmospheric Pressure:	860-1060 HPa, derived from altitude
Storage Temperature:	-20° C to 60° C
Storage Humidity:	95% RH @ 50° C to 15% RH @ 0° C

Alarms

Low and High limit violations
Equipment status messages
Left / Right differential alarm

Power

Battery (run time):	12 VDC (1.5 hours)
Input Voltage:	100-240 VAC, 50-60 Hz
Power input:	1.5 RMS (max) at 115 VAC

Calibration

Factory calibrated
No user calibration required

Digital Output

Three dedicated, bi-directional RS-232 interfaces
USB data storage

Safety

Class 1 laser output with internal laser safety interlock system
Defibrillator-proof BF type patient applied parts

Device Connectivity

Patient Monitor: Philips IntelliVue
Data Management Systems: Philips CompuRecord, Dräger Innovian®, Terumo T-Link™, Sorin DMS, Maquet JoCap XL, iMDsoft MetaVision, Spectrum Medical VIPER, Capsule Technologies, Cerner CareAware.

Regulatory Standards

FORE-SIGHT complies with the following U.S. and international regulatory standards for medical equipment:
UL 60601-1, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60825-1, IEC 60601-1-4, IEC 60601-1-8
93/42/EEC Medical Device Directive
ISO 10993-1

Warranty

1 year warranty on FORE-SIGHT monitor
1 year warranty on optional batteries
90 day warranty on reusable monitor cables
Extended Care Plans available

References:

- ¹ MacLeod DB, et al. Validation of the CAS adult cerebral oximeter during hypoxia in healthy volunteers. *Anesth Analg* 2006;102(IARS Suppl); 1-330:S-162.
- ² Kussman BD, Laussen PC, Benni PB, McElhinney DB, McGowan FX. Validation of the FORE-SIGHT pediatric NIRS cerebral oximeter. Presented at American Society of Anesthesiologists Annual Meeting 2009. A685.
- ³ Rais-Bahrami K, Rivera O, Short BL. Validation of a noninvasive neonatal optical cerebral oximeter in veno-venous ECMO patients with a cephalad catheter. *J Perinatol* Oct 2006; 26(10):628-35
- ⁴ Kussman B, Laussen P, Benni P, McElhinney D, McGowan F. Validation of the FORE-SIGHT® Tissue Oximeter for measurement of somatic oxygenation in children. Presented at American Society of Anesthesiologists Annual Meeting 2011.

Large Sensor

Part Number (Dual Sensor 10 kits/Ctn):
01-07-2007

Sensor intended use and patient weight range Cerebral Tissue Oximetry: ≥40 kg

Medium Sensor

Part Number (Dual Sensor 10 kits/Ctn):
01-07-2005

Sensor intended use and patient weight range Cerebral Tissue Oximetry: 4-60 kg
Skeletal Muscle Tissue Oximetry: 5-50 kg

Small Non-Adhesive Sensor

Part Number (Single Sensor (NAS) 10 kits/Ctn):
01-07-2000

Sensor intended use and patient weight range Cerebral Tissue Oximetry: ≤8 kg

Small Sensor

Part Number (Dual Sensor 10 kits/Ctn):
01-07-2003

Sensor intended use and patient weight range Cerebral Tissue Oximetry: ≤8 kg

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U.S. Patents 6,456,862; 7,047,054; 7,072,701; 7,313,427. U. S. Patents Pending.



Product is Marked

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CASMED®

CAS Medical Systems, Inc.

44 East Industrial Road, Branford, CT 06405 USA
Telephone: 203.488.6056 | Toll Free: 800.227.4414
www.casmed.com