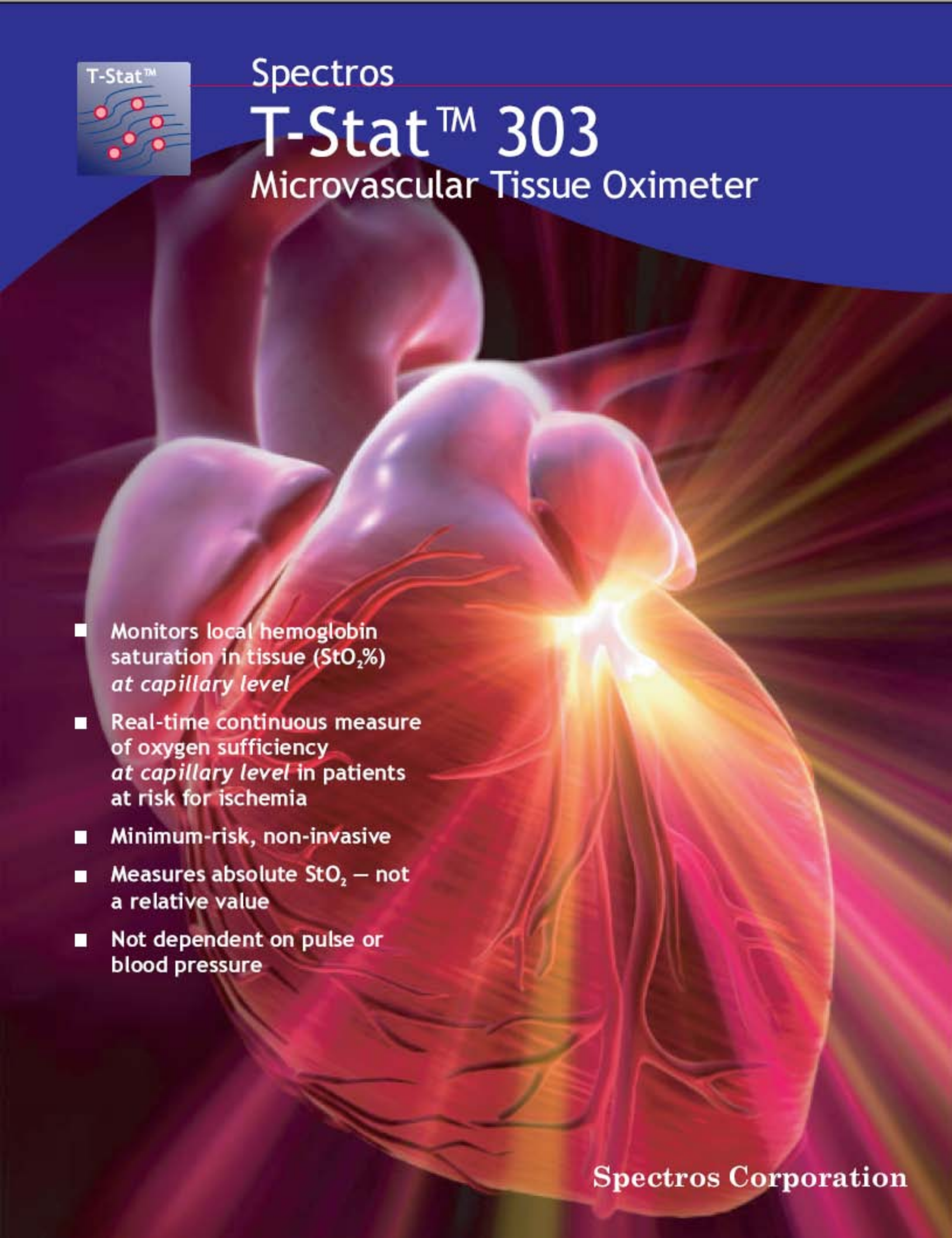


Spectros

T-Stat™ 303

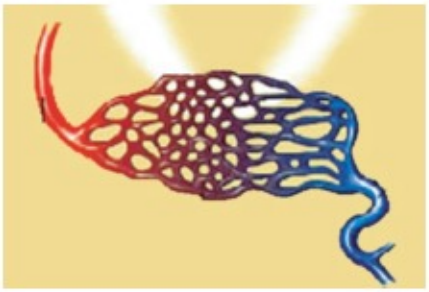
Microvascular Tissue Oximeter

- Monitors local hemoglobin saturation in tissue (StO_2%) *at capillary level*
- Real-time continuous measure of oxygen sufficiency *at capillary level* in patients at risk for ischemia
- Minimum-risk, non-invasive
- Measures absolute StO_2 — not a relative value
- Not dependent on pulse or blood pressure

Spectros Corporation

Detects Ischemia at the Source

The T-Stat™ monitor works without reference to the patient's pulse. Instead it uses the color of the blood in the capillaries — *not* the arteries — to calculate oxygen saturation. Low-power white light shines from the probe through the mucosa (such as the inside of the cheek) to a depth of about 2 mm and diffuses into the tissue. It then re-emerges, colored by the structures through which it has passed — most notably by the oxygen-carrying blood protein hemoglobin. The light emerging from the tissue carries the spectral fingerprint of the oxygenation level of the hemoglobin in the capillaries.[1]



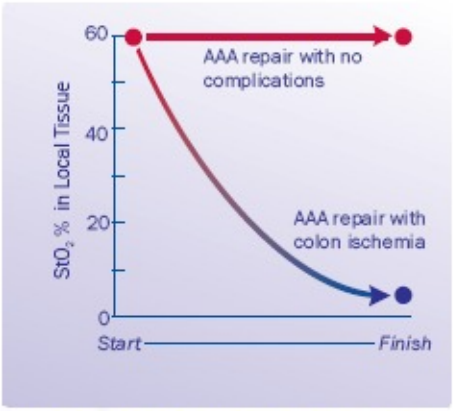
Quick, Simple Placement When Seconds Count

The T-Stat™ probe is rapidly placed — orally, rectally or endoscopically. Each sensor probe self-calibrates. After the physician has verified the placement of the probe, the T-Stat™ oxymeter is ready for use within seconds.

Placement of buccal sensor probe

The Only Device that Detects Local Ischemia during Vascular Surgery

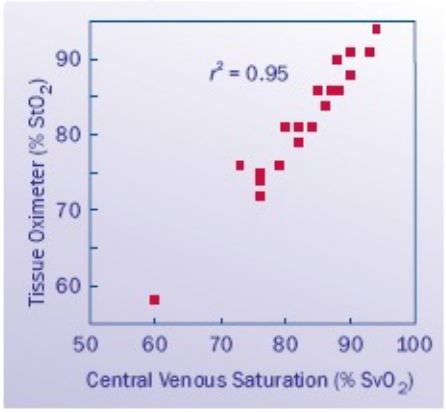
In a study of 50 patients undergoing open or endovascular surgery for abdominal aortic aneurysm repair, the T-Stat™ monitor was used to measure oxygenation levels in colon tissue for the purpose of detecting ischemia that might result from compromised circulation to the colon. In three of the 50 patients colon ischemia was detected in the operating room, and blood supply to the colon was restored through re-vascularization. None of the 50 patients went on to experience complications associated with colon ischemia.[2]



Hemoglobin Saturation in Local Tissue during Surgery for Abdominal Aortic Aneurysm

Sensitive to Global Ischemia

In a peer-reviewed clinical study of 27 patients undergoing cardio-vascular surgery, measurements of StO_2 made by the T-Stat™ monitor were shown to be *directly correlated* to measurements of central venous oxygenation (SvO_2) made on blood samples drawn from a pulmonary arterial catheter.[3]



A Direct Correlation between StO_2 and SvO_2

Responds to Developing Ischemia in Seconds

The T-Stat™ makes a measurement every 50 ms, whether or not there is a pulse. When ventricular fibrillation occurs, local oxygen saturation begins to fall immediately. Measurements made during surgery showed a significant drop in oxygenation after only six seconds.[1]

Narrow Normal Range Leads to Improved Patient Management

Recent studies have shown that close management of patients undergoing cardiovascular surgery with techniques based on central venous saturation leads to better patient outcomes and reduced costs.[4] The data provided by the T-Stat™ allows physicians to make adjustments in managing and controlling oxygen saturation. In healthy patients, the normal range of StO_2 in the buccal mucosa is between 71% and 83%, and in the enteric mucosa it is between 60% and 76%. This narrow normal range, coupled with the T-Stat's ability to monitor patients continuously and non-invasively — even those with a weak or irregular pulse (or no pulse) — makes the T-Stat™ a valuable tool that allows more timely interventions and superior patient management.

1. *Anesthesiology* 2004 Jun; 100(6): 1469-1475.
2. *Journal of Vascular Interventional Surgery* (accepted).
3. *Amer Soc Anesthesiologists* 2004; Abstract 652712.
4. Presented at Outcomes 2004: The Key West Meeting, May 19-23, 2004.

Prescribing Information (Rx Only)

Indications

The Spectros T-Stat™ Microvascular Tissue Oximeter is intended for use as an adjunct monitor of localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces (StO_2) in infants, children or adults at risk for ischemia.

Cautions

Tissue oxygenation is sensitive to local perfusion. Care should be taken not to apply pressure at the measurement site, as this may create local ischemia and result in readings that are falsely low.

The T-Stat™ is sensitive to free blood outside the microvascular space. Values should be interpreted cautiously when free or surface blood is present.

Contraindications

None.

System Specifications

1 Physical Specifications

Size	9 in. wide x 6 in. high x 12 in. deep
Weight	13.5 lbs (6.1 kg)
Display	Back-illuminated, color touch-screen

2 Value and Accuracy Specifications

Values Displayed	StO_2 % (per cent tissue hemoglobin saturation)
	Range: 0 - 99 %
	Resolution: 1 %
	rHemoglobin (relative hemoglobin)
	Range: 0 - 99 M
	Resolution: 0.1 M
	Signal intensity
	Optional trend graph

3 Alarm/Warning Specifications

Alarms	*Low StO_2 %*	User settable, 0-99% (preset low 40%)
	High StO_2 %	User settable, 0-99% (preset high 95%)
	Low heme	rHemoglobin < 5 M (analysis suppressed, "no tissue" error)
	High heme	rHemoglobin >100 M ("bloody tissue" error)
	Unstable	Signal strength changes >20% between samples
Alarm Indicators	Red/yellow/green status indicator	
	White error message on flashing red background	
	Audible alarm (silenceable)	
Alarm Silencing	Audible alarm silenced x 120 sec	

Self-Diagnostics	Automatic self-test at power-on
	Visual display of self-test progress
	Validation of software versions
	Validation of software integrity
	Validation of algorithm successful operation
	Test of optical spectrometer
	Test of optical socket reader
	Test of memory storage space
	Test of microprocessor system
	Red/green self-test success indicators
	Halt at start up if errors in self-test

4 Operating Specifications

Power	90-240 V 50-60 Hz
	Electrically isolated
	US/Canada: Green-dot (hospital grade) 3-m
Environment	Intended for indoor hospital use
	5-40 degrees Celsius
	5%-95% humidity (non-condensing)

5 Optional Software

*Research Options**	Optional data collection to internal flash
	Optional data export to external disk via USB port
	Optional analysis scripting for user-specific analysis

** Not for clinical use*

6 Probes

Probe Types	CTH-060-REC—Rectal T-Stat™ probe
	CTH-060-END—Endoscopic T-Stat™ Catheter
	CTH-060-ORA—Oral Buccal T-Stat™ Probe
Sterile Probes	Single-use sterile probes available (for use on humans)

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