

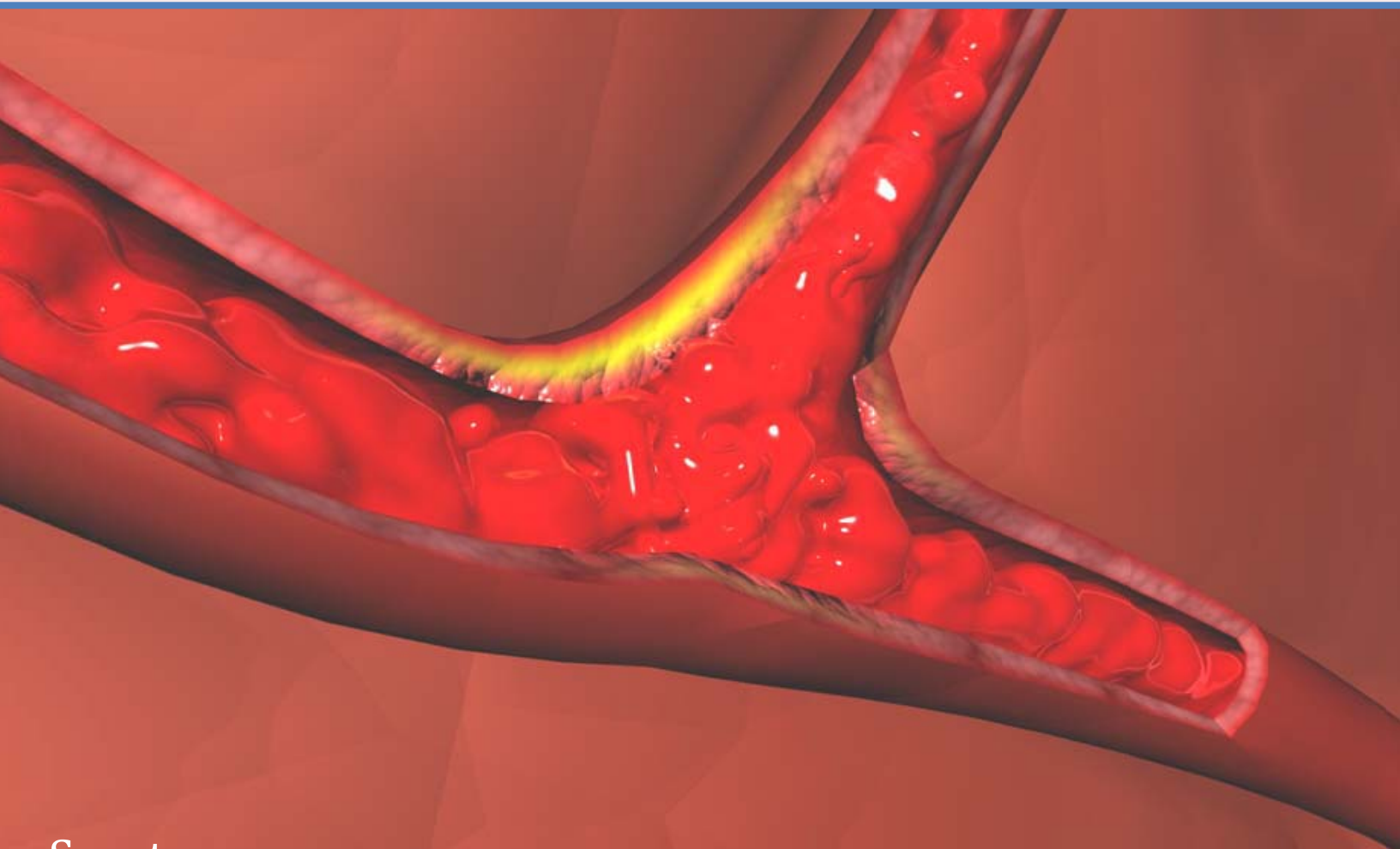
Noninvasive

T-Stat<sup>®</sup> 303  
Microvascular Tissue Oximeter

# Vascular/Surgical Ischemia Monitoring System

- *Intraoperative feedback*
- *Continuous monitoring*
- *Responds in seconds*
- *Correlates with outcome*

*Manage Ischemia... at last™*



## Ischemia: Silent and deadly

Early visual signs of ischemia are unreliable. Noninvasive measures such as Doppler flow, pulsatility, and capillary refill are imperfect predictors of outcome, while invasive tests (such as lactate) respond slowly and cannot be used for real-time management.

## You said: "...if only we could detect ischemia, locally"

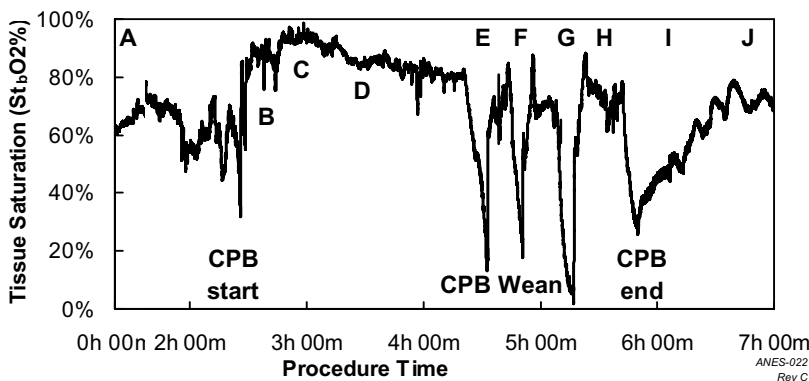
Intensivists already demand venous saturation (Svo<sub>2</sub>) in their sickest patients. Why? Because venous saturation is well correlated with clinical outcome, ... yet until now, Svo<sub>2</sub> could not be locally measured, and thus was not available for assessment during vascular procedures.

## Now, detect ischemia rapidly in any patient, with T-Stat<sup>®</sup>

T-Stat<sup>®</sup> is proven in multiple vascular, cardiac, and surgical trials to be sensitive to ischemia (see selected studies, page 5) – and is the *first* device labeled by the FDA as “sensitive to ischemia.”

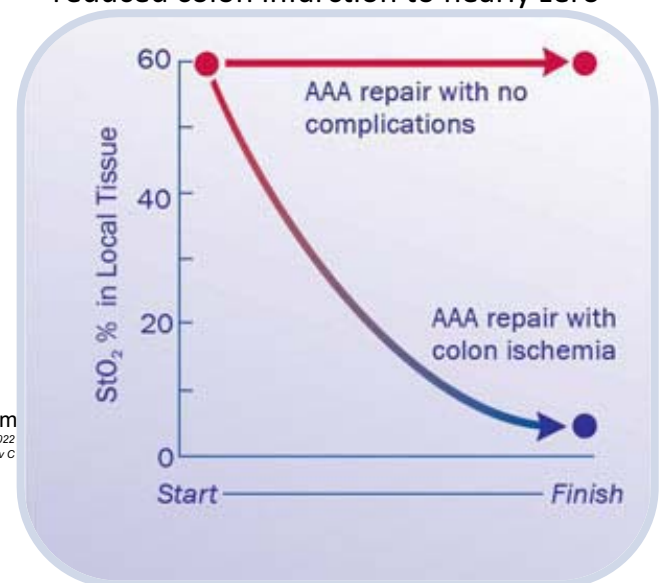
### Rapid Response to Cardiac Output After Bypass

T-Stat<sup>®</sup> Sto<sub>2</sub> detects reduced cardiac function faster than NIRS, and more continuously than thermodilution or TEE.



### Changes AAA Stenting Outcome

Noninvasive T-Stat<sup>®</sup> Sto<sub>2</sub> Detected Reductions in Colon Perfusion During AAA Stenting – and reduced colon infarction to nearly zero <sup>6</sup>



So why not use T-Stat<sup>®</sup> as a noninvasive alternative to Svo<sub>2</sub> in all your patients ischemia?

**“To noninvasively detect and monitor ischemia in real time is revolutionary. Ischemia has always been a diagnosis of exclusion... by the time you find it, it’s too late.”**

... Stay one step ahead of ischemia with T-Stat®

## Proven Reliability During Stenting, Cardiac Surgery, and Anastomosis

Multiple studies have shown T-Stat® is reliable during stenting, embolization, and G.I. anastomosis – even during cardiac surgery (see studies, page 5). The  $Sto_2$  display is clear and legible from a distance, while the trend line helps spot changes over time.



**T-Stat® 303 Monitor**

## Fast, Simple Placement

T-Stat® noninvasive sensor probes are simple to place to get you up and running fast. No calibration or vascular access is required. Sensor probes can be placed on any mucosal surface – in the cheek, nose, pharynx, esophagus, G.I. tract, or colon – wherever ease of access is maximized. Now, you can manage ischemia in your practice... at last.™



**Clip Sensor**



**5 mm Spot/  
Enteric Sensor**



**1.5 mm Endoscopic /  
Enteric Sensor**

**“The reproducible and narrow  $Sto_2$  normal range for oral/ enteric mucosa supports use of this site as an accessible and reliable reference point.”**

**Anesthesiology 2004**

## T-Stat® *is* Different

**T-Stat® represents the newest and most advanced generation of optical critical care devices.** In the 1980's, pulse oximetry and near-infrared (NIRS) became available, Now, Spectros introduces the first critical care system based on visible light spectroscopy (VLS). Why visible light?

- **Visible light is sensitive to ischemia, unlike pulse oximetry**  
*T-Stat® is proven sensitive to ischemic injury, as it happens.<sup>1</sup>*
- **Visible light has tight range of normal, unlike Near-Infrared Spectroscopy (NIRS)**  
*T-Stat® makes patient management more effective because the narrow range of normal ensures that changes in a patient's baseline are detected earlier.<sup>1,2</sup> Why is visible light more accurate? Because visible light senses hemoglobin in tissue 100 times more strongly than infrared,<sup>3</sup> substantially reducing noise and measurement error.*
- **Visible light correlates with invasive Svo<sub>2</sub>, unlike skin or muscle-based systems**  
*T-Stat® is unlike other optical devices that measure skin or muscle saturation – as these measures do not correlate with vascular outcome.<sup>4</sup>*

## Compare T-Stat®

Device	Spectros T-Stat®	Somanetics Invos®	Hutchinson InSpectra®	CAS Medical Fore-Sight®
Device Type	✓ Visible Light	Near-Infrared	Near-Infrared	Near-Infrared
Labeled for Ischemia Detection	✓ Yes	✓ Yes	No	No
Range of Normal	✓ Tight (±3%) <sup>1</sup>	Wide (±9%) <sup>1,6</sup>	Wide (±9%) <sup>1,6</sup>	Wide (±9%) <sup>1,6</sup>
Changes Outcome?	✓ Yes <sup>5</sup>	✓ Yes	No	No
Site Measured	✓ Mucosal	Brain	Muscle	Brain
Range of Probes?	✓ Yes	No	No	No

**The difference between NIRS and VLS is the difference between night and day**

**Mucosal saturation is correlated with outcome in vascular surgery. Why measure at the mucosa? ... because “non-invasive tissue saturation over [muscle] does not correlate with Svo<sub>2</sub>.”**

***P Critical Care Medicine 2005***

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**Vascular interventions can be tested in real-time... such as testing Iliac embolization effect on the colon, or watching for changes in perfusion during stent release.– with second-to-second feedback.**

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## Bring the Benefits of T-Stat® to Your Practice

Don't operate in the dark using invisible Near-Infrared... use T-Stat® Visible Light for a difference you can see. Compare T-Stat® to other optical systems:

- **Sensitive to Ischemia**

*The first device labeled sensitive to ischemia, with the advantages of visible light.*

- **Reduce risk**

*Continuous monitoring reduces progression to infarction and allows real-time assessment of embolization, stent placement, cardiac surgery, and G.I. anastomosis in multiple studies.*

- **Know, don't guess, at ischemia**

*Have confidence as to your patient's perfusion status.*

- **More Stability**

*Facilitates real-time management as intervention is quickly initiated and performed under continuous feedback monitoring.*

- **Real time feedback to interventions**

*Watch tissue oxygenation change as stents, staples, and sutures are placed.*

- **Gain an edge over stealthy ischemia illnesses**

*Detect deterioration before irreversible injuries occur.*

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**“I have used T-Stat®, and in as many as 3 of the first 50 patients, T-Stat® probably saved lives.”**

**Vascular Surgeon, T-Stat® Investigator**

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## Selected Recent Publications Using T-Stat®

### Vascular and Mesenteric Ischemia

- ▶ [Diagnosis of Chronic Mesenteric Ischemia Using T-Stat®](#) (2007). T-Stat detects mesenteric ischemia and guides therapy. *Gastrointestinal Endoscopy* 2007;65(2):294-300.
- ▶ [Intraoperative colon mucosal oxygen saturation during aortic surgery](#) (2006). *J Surg Res* 2006 Nov;136(1):19-24
- ▶ [Aortic Repair Improved Using T-Stat®](#) (2005). Use of T-Stat® to detect organ ischemia during AAA repair led to reduced death rates and length of ICU stays. *Anesthesiology* 2005;103:A349 (abstract).
- ▶ [Chronic Mesenteric Ischemia Diagnosable Endoscopically Using T-Stat®](#) (2005). Use of T-Stat® to detect and monitor treatment of chronic mesenteric ischemia. *DDW 2005* (abstract).
- ▶ [T-Stat® Prospectively Detects Ischemia During Vascular Surgery](#) (2004). Prospective human clinical study demonstrating T-Stat® detects ischemia during vascular surgery. *Soc Interventional Radiol* 2004 (abstract)
- ▶ [Detection of Gut Ischemia Using T-Stat® During Endoscopy](#) (2004). Use of T-Stat® to detect gastrointestinal ischemia during endoscopy. *Gast Endo Clin N Am* 2004;14(3):539-553.

### Cardiac Surgery

- ▶ [T-Stat® reflects flow-related changes in brain oxygenation during regional low-flow perfusion and DHCA](#) (2006). *J Thorac Cardiovasc Surg* 2006;132(6):1307-1313.
- ▶ [Esophageal saturation during antegrade cerebral perfusion: monitoring with T-Stat®](#) (2006). *Paediatr Anaesth* 2006 Nov;16(11):1133-1137.
- ▶ [T-Stat® Prospectively Detects Tissue and Organ Ischemia During Cardiac Bypass](#) (2004). Animal study demonstrating T-Stat® predicts cerebral ischemia during cardiac surgery on cardiopulmonary bypass. *Amer Soc Anesthesiology* 2004 (abstract).
- ▶ [T-Stat® Prospectively Detects Ischemia During Vascular Surgery](#) (2004). Prospective human clinical study demonstrating T-Stat® detects ischemia during vascular surgery. *Soc Interventional Radiol* 2004 (abstract)
- ▶ [T-Stat® Experience During Cardiac Bypass Surgery](#) (2003). First experiences using T-Stat® During Cardiopulmonary Bypass During Cardiac Surgery. *Anesthesiology* 2003;99:A558 (abstract).

### Anastomotic Ischemia

- ▶ [T-Stat During in Esophageal Anastomosis – a feasibility study](#) (under review).

### Other Studies

- ▶ [Design and Operation of the T-Stat®](#) (2005). Design and benchtop validation of T-Stat®. *J Biomed Optics* 2005; Jul/Aug 10(4).
- ▶ [Validation of the T-Stat® Platform for the in vivo Detection of Ischemia](#) (2004). Validation of the T-Stat® during normoxia, hypoxemia, and ischemia. *Anesthesiol* 2004 Jun;100(6):1469-1475.
- ▶ [Tumors Detectable Endoscopically Using T-Stat®](#) (2005). VLS tissue oximetry can distinguish neoplastic tissue from normal tissue with a high specificity, potentially aiding endoscopic detection of gastrointestinal tumors. *Technol Canc Res Treat* 2005 Jun;4(3):227-234.
- ▶ [Monitoring RF Tumor Ablation in vivo](#) (2005). Use of T-Stat® to detect ablation in tumors. *J Vasc and Interven Radiol* 2005;16:1473-1478.
- ▶ [Detection of Tumor Ischemia During Electroporation of Tpz Chemotherapy Using T-Stat®](#) (2004). Use of T-Stat® to detect changes in tumor oxygenation during electrical delivery of chemotherapy. *Radiation Res* 2004 Jul;162:185-193.
- ▶ [T-Stat® During Plastic Surgery Detects Ischemia](#) (2003). Monitoring oxygenation of the skin flaps during plastic surgery allowed detection of skin regions later going on to develop ischemia using T-Stat®. *Amer Derm Surg Assoc* 2003 (abstract).
- ▶ [T-Stat® During GI Endoscopy Detects Ischemia](#) (2003). Human gastrointestinal tract oxygenation can be monitored using T-Stat®. Tissue hypoxia, can be detected, whether from hypoxemia or ischemia. *Gastro Endosc* 2003 Apr;57(4):492-497.

## **General Description:**

T-Stat® 303 Ischemia Detection System is a broadband, multi-wavelength, Visible Light Spectroscopy (VLS) ischemia detection system, sensitive in real time to the presence of local ischemia.

A complete T-Stat® 303 system consists of a single-use disposable catheter connected to a monitor. Illumination of the tissue is provided by a light source within the catheter. Reflected light from mucosal tissue is captured and returned to the monitor. Tissue ischemia is detected by estimating the microvascular hemoglobin oxygen saturation using differential optical diffuse reflectance spectroscopy and fitting for background scattering over a range of reflected visible wavelengths.

Single-use catheters are available for oral, catheter, nasal/endoscopic, hand-held spot-check use.

## **Clinical Studies:**

In peer-reviewed studies of T-Stat® submitted to the FDA for pre-approval review:

- T-Stat® was sensitive to reduced-flow and no-flow ischemic states ( $p < 0.001$ ) [1,2].
- T-Stat® provided readings in low-flow and no-flow ischemic states [1,2].
- T-Stat® VLS measures ( $Sto_2$ ) are unbiased in comparison to NIRS measures ( $Sto_2\%$  Bias =  $-1\% \pm 5\%$ ,  $p = N.S.$ )
- T-Stat® VLS demonstrated significantly tighter ranges of normal than NIRS (VLS  $\pm 3\%$  vs. NIRS  $\pm 9\%$ ,  $p < 0.001$ ) [1].

## **Indications for Use:**

The Spectros T-Stat® 303 Microvascular Tissue Oximeter is intended for use as an adjunct monitor of the localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces ( $Sto_2$ ) in infants, children, or adults at risk for reduced-flow and no-flow ischemic states.

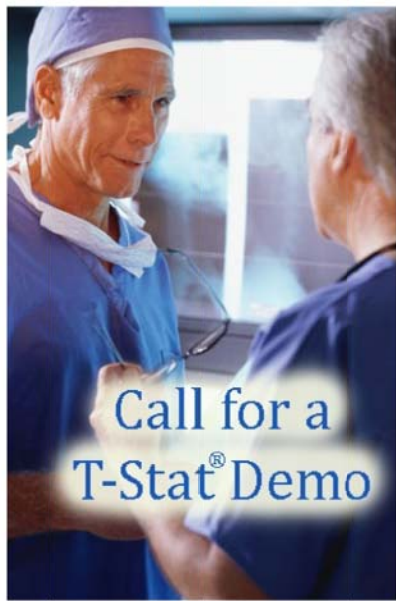
The prospective clinical value of measurements made with the T-Stat® Oximeter has not been demonstrated in disease states. The T-Stat® Oximeter should not be used as the sole basis for diagnosis or therapy.

## **Precautions:**

- T-Stat® measures locally, and may not reflect changes in oxygenation that occur in regions outside of that monitored by the T-Stat® catheter.
- T-Stat® used alone at a single site cannot differentiate between local and global ischemic conditions.
- Use of T-Stat® during high-output shock states such as sepsis has not been evaluated. During these conditions, central venous saturation may be normal or elevated, and the ability of T-Stat® to detect tissue hypoxia is unknown.
- Normal T-Stat® values in liver and the small intestine have not yet been established, as these readings are affected by organ pigments and surface bile (respectively).
- Catheters are supplied sterile for single use. Do not reuse.

## **References:**

- [1] Anesthesiology. 2004 Jun;100(6):1469-75.
- [2] Gastrointest Endosc Clin N Am. 2004 Jul;14(3):539-53, ix-x.
- [3] J Biomed Optics 2005; Jul/Aug 10(4).
- [4] Pediatric Crit Care Med 2005;6(6):671-675.
- [5] Intraoperative colon mucosal oxygen saturation during aortic surgery (2006). J Surg Res. 2006 Nov;136(1):19-24
- [6] Data on file.
- [7] Continuous monitoring reduced blood sampling in indwelling  $Svo_2$  studies.



## Ordering Information

To order, or to set up a visit or demonstration in your hospital, please call 1-877-T-Stat-303 (1-877-878-2830). Outside of the U.S., please contact our distributor in the E.U. (Netherlands +31 (0) 65.42.78.646).

Item	Quantity	Description
TSM-303	1	T-Stat® 303 Monitor
ORA-061	5	Clip-on sensor
ORA-060	5	Mini-clip sensor
END-060	5	1.5 mm diam. enteric/endoscope sensor
REC-060	5	5 mm diam. Hand-held/enteric sensor
MAN-303	1	T-Stat® 303 Manual

## Technical Specifications

**Power** 90-240 VAC only  
48-60 Hz

**Physical** 5 kg  
11" x 8" x 6"

**Values Displayed** St<sub>o2</sub> – Tissue Saturation  
rtHb – Local total hemoglobin

**Approvals**  Approved for marketing in the U.S. and the E.U. Not for sale in Canada or Australia.

**Accuracy** St<sub>o2</sub> ± 2 percentage units  
rtHb ± 10% of total value

## About the Company

Spectros is the world-leader in real-time noninvasive molecular detection. T-Stat®, a molecular Ischemia Detection System, was the *first* device labeled for sale by the U.S. FDA as sensitive to ischemia. FirstScan®, a molecularly targeted cancer diagnostic product, is under Phase III clinical study. For more company info, please see the web site at [spectros.com](http://spectros.com), or call 1-877-T-Stat-303.

## Spectros Corporation

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**Manage Ischemia...  
starting now™**