

T-Stat® 303

Microvascular Tissue Oximeter

Noninvasive

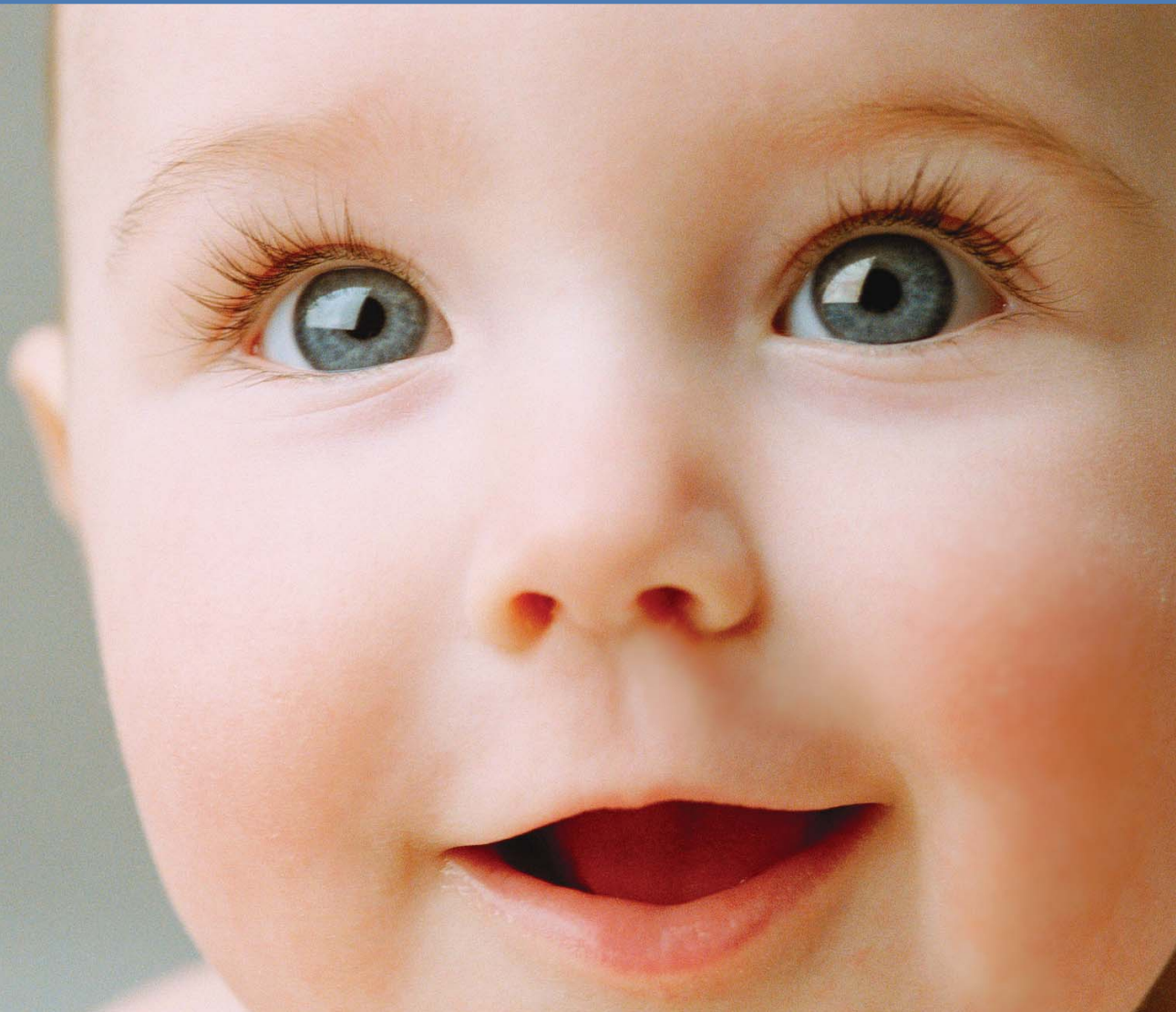
Ischemia

Monitoring System

- *Rapidly placed*
- *Continuous monitoring*
- *Responds in seconds*
- *Correlates with Svo_2*

Manage Ischemia... at last™

Spectros
Corporation



Ischemia: Silent and deadly

Early physical and laboratory signs of ischemia are unreliable. In patients with the required vascular access, venous saturation has been the standard to turn to. Why? Because noninvasive measures such as blood pressure and arterial saturation aren't predictive of outcome, while invasive measures such as lactate are late signs, and cannot be used for real-time management.

You said: "...if only we could monitor Svo₂ in all patients"

Neonatal and Pediatric intensivists already demand venous saturation (Svo₂) in their sickest patients (ECMO, pre- and post-op cardiac surgery patients)... yet Svo₂ requires invasive sampling, and thus may not be available when you need it, nor as often as you want it.

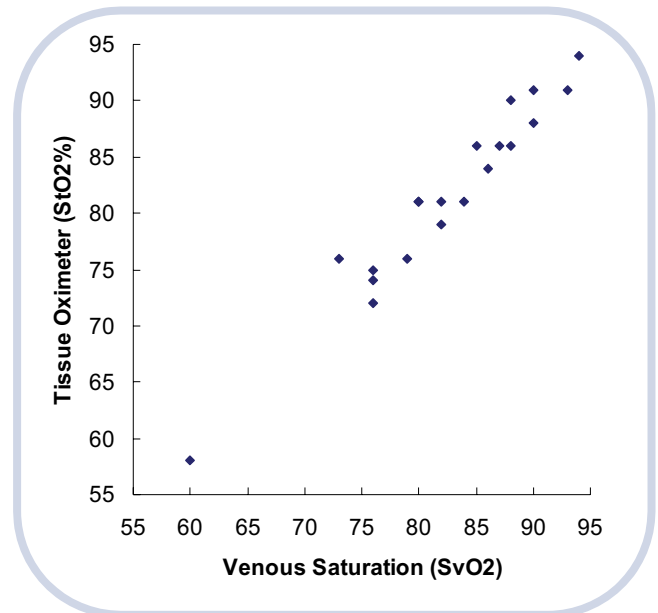
Now, monitor ischemia in any patient, noninvasively, with T-Stat[®]

T-Stat[®] is proven in multiple trials to be sensitive to ischemia (see selected studies, page 5)

T-Stat[®] is correlated to measures of venous saturation ($r^2=0.94$). In the study shown at right, patients undergoing cardiac surgery on cardiopulmonary bypass were studied using noninvasive T-Stat[®] sensors. Despite cardiac arrest during surgery, T-Stat[®] continued to monitor tissue saturation (Sto₂) in all patients. The relationship between Svo₂ and Sto₂ was linear.

So why not use T-Stat[®] as a noninvasive alternative to Svo₂ in all your sick patients?

Noninvasive T-Stat[®] (Visible Light) Sto₂
Correlates with
Swan-Ganz (PAC) Svo₂⁶



"To noninvasively monitor Svo₂ is revolutionary. Ischemia has always been a diagnosis of exclusion... by the time you found it, it was rather late."

Neonatologist, T-Stat[®] Investigator

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

Proven Reliability and Significance

Multiple clinical studies have shown that T-Stat® is reliable – 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, even in cardiac standstill or severe shock. No percutaneous 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. Manage ischemia in your practice... at last.™



Neo/Pedi Oral Clip Sensor



5 mm Spot/Enteric Sensor



1.5 mm Nasal/Endoscope 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.¹
- **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.^{1,2} Why is visible light more accurate? Because visible light senses hemoglobin in tissue 100 times more strongly than infrared,³ substantially reducing noise and measurement error.
- **Visible light correlates with invasive Svo₂, 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 central venous saturation.⁴

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
Range of Normal	✓ Tight (±3%) ¹	Wide (±9%) ^{1,6}	Wide (±9%) ^{1,6}	Wide (±9%) ^{1,6}
Correlated to Svo ₂ ?	✓ Yes ⁶	✓ Yes	No	No
Changes Outcome?	✓ Yes ⁵	✓ Yes	No	No
Site Measured	✓ Mucosal	Cortical	Muscle	Cortical
Range of Probes?	✓ Yes	No	No	No

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

Why measure at the mucosa? ... because “non-invasive tissue saturation over [muscle] does not correlate with Svo₂.”

Pediatric Critical Care Medicine 2005

Patients are more stable with the T-Stat™. Oxygen delivery, drips, drugs, and volume resuscitations can be managed in real time – with second-to-second feedback.

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 blood sampling, reduce risk**

Continuous monitoring reduces excess blood sampling,⁷ all without invasive lines, especially important in critically ill infants and children.

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

Have confidence as to your patient's status.

- **More Stability**

Facilitates management as pharmacological and respiratory interventions can be reduced under continuous monitoring.

- **Real time feedback to interventions**

Watch tissue oxygenation change as settings and drips are changed.

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

Detect deterioration before worsening of acidosis and oxygenation occur.

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

Surgeon, T-Stat® Investigator

Selected Recent Publications Using T-Stat®

- ▶ [Vascular Repair Improved Using T-Stat®](#) (2006). Use of T-Stat® to detect organ ischemia during surgery. *J Surgery Research 2006;in press*.
- ▶ [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)*.
- ▶ [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*.
- ▶ [Design and Operation of the T-Stat®](#) (2005). Design and benchtop validation of T-Stat®. *J Biomed Optics 2005; Jul/Aug 10(4)*.
- ▶ [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*.
- ▶ [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*.
- ▶ [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*.
- ▶ [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)*.
- ▶ [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.

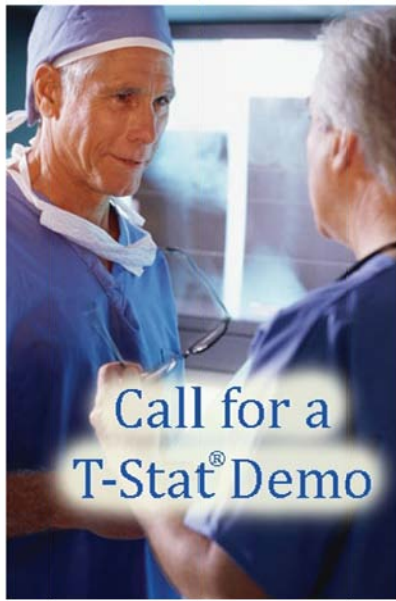
The prospective clinical value of measurements made with the T-Stat® Oximeter has not been demonstrated in disease states. The T-Stat® Oximeter should not be used as the sole basis for diagnosis or therapy.

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] J Surgical Research 2006; in press.
- [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	Pedi/Neo buccal (cheek) clip-on sensor
END-060	5	1.5 mm diameter nasal/endoscope sensor
REC-060	5	5 mm diameter oral/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 Sto₂ – 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 Sto₂ ± 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, or call 1-877-T-Stat-303.

Spectros Corporation

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**Manage Ischemia...
starting now™**