T-Stat

Advancing Free Flap Monitoring in Reconstructive Microsurgery

Real-time, Continuous, Non-Invasive Tissue Oximetry



Introduction

At Spectros, we are committed to improving outcomes in reconstructive microsurgery through ***cutting-edge monitoring solutions.*** *The T-Stat Tissue Oximeter provides real-time, continuous monitoring of tissue oxygenation, giving surgeons and bedside staff the earliest possible warning of complications. By* ***supporting both healthcare providers and patients,*** *Spectros helps ensure better surgical outcomes and reduced post-operative risks.* ***Our dedication to patient advocacy and education remains a driving force behind our innovation.***

The Need for
EARLY DETECTION

Free tissue flaps are essential in reconstructive surgery, but they come with risks - particularly vascular occlusions that can lead to flap failure. Delayed detection of these complications increases the risk of fat necrosis, scarring, wound healing complications, and the need for revision surgeries. T-Stat provides the earliest warning of vascular compromise, often hours before clinical signs appear. By continuously monitoring StO_2% levels, T-Stat helps prevent complications and improves surgical success rates.



Technology Comparison

White Light Spectroscopy (T-Stat) vs. NIR Technology

- T-Stat provides absolute StO_2% values, while NIR provides only relative estimates.
- T-Stat's sensitivity enables early detection of ischemia and venous complications.
- NIR devices are less accurate for microvascular tissue.

T-Stat vs. Doppler

- Doppler only detects blood flow, not oxygenation.
- T-Stat detects both arterial and venous compromise.
- Continuous monitoring vs. episodic checks.

Feature	**T-Stat** (White Light Spectroscopy)	Clinical Exam	Pencil Doppler	Implantable Coupler Doppler	NIR Technology
Measurement Type	Absolute StO2% and hemoglobin	Visual inspection & palpation	Blood flow presence/velocity (acoustic signal)	Continuous flow patency at anastomosis (acoustic/pressure signal)	Relative oxygenation trend estimates
Detection Capability	Arterial and venous occlusions	Late-stage compromise detection	Detects flow only (no oxygenation)	Detects anastomotic patency only (no oxygenation)	Later detection of venous congestion, trend-based
Monitoring Type	Continuous, real-time	Intermittent, subjective	Episodic, user-dependent probe contact, subjective interpretation	Continuous but localized to coupler site only, alarms vary by system	Continuous
Depth of Measurement	1-2 mm superficial capillary/venous microvasculature	Surface only	2-8+ mm depending on pressure and probe angle (variable), large pressure artifact risk	Local to vessel walls at coupler interface (~sub-mm at anastomosis)	3-12+ mm deeper tissue penetration
Sensitivity to Early Ischemia	Highly sensitive	Low sensitivity	Moderate sensitivity to complete flow loss only	Moderate sensitivity to complete patency disruption only	Moderate sensitivity to ischemia trends only
Color Sensitivity	Color-blind (all skin tones)	Skin-tone bias risk	Not applicable	Not applicable	Affected by skin pigmentation and optical scattering
Remote Monitoring	Yes - cloud or clinician dashboard via OnCall	No	No	No	Yes - some models support remote trend viewing
Cost Efficiency	Can prevent ICU escalation and revisions by early detection	Low cost but delayed compromise leads to high downstream cost	Low device cost but pressure artifact can trigger false assessments and delayed decisions	High device/procedure cost per case, invasive, revision risk remains if ischemia occurs outside coupler site	Higher capital cost, downstream costs if compromise is missed early

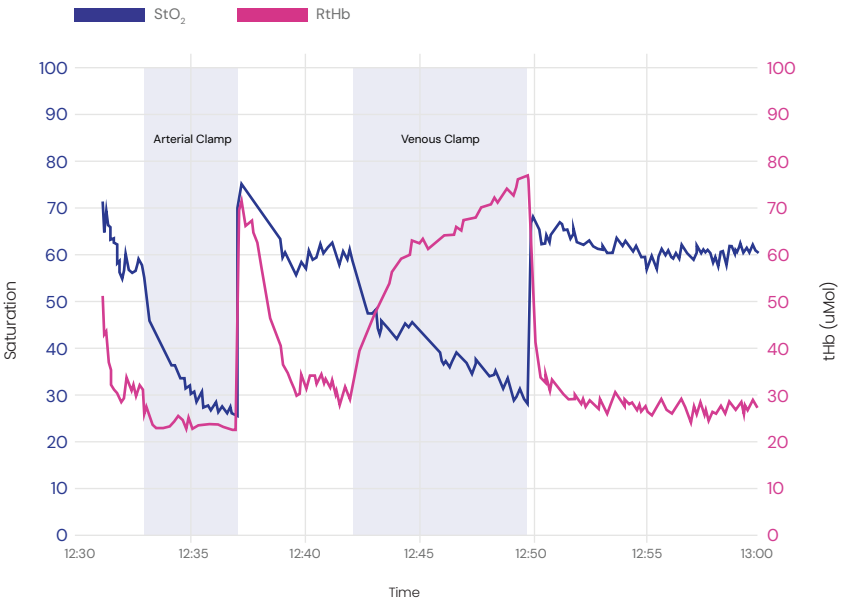
"The Spectros T-Stat™ 2.0 Microvascular Tissue Oximeter is intended for use as an adjunct monitor of the localized hemoglobin oxygen saturation of blood in the microvascular tissue spaces (StO_2%) in infants, children, or adults at risk for reduced-flow and no-flow ischemic states."

Clinical Advantages of T-Stat

T-Stat provides key advantages over traditional monitoring methods:

- **Hemoglobin Monitoring:** Differentiates between arterial and venous occlusion.
- **Non-Invasive, Continuous Monitoring:** Provides real-time trends instead of snapshot readings.
- **OnCall Remote Access:** HIPAA-compliant web platform for real-time monitoring from any location.

Artery and Vein Clamping Study



Dr. John Griffin, San Mateo, CA, 2010

Venous vs. Arterial Detection

- **Arterial Occlusion:** Causes an immediate drop in tissue oxygen saturation (StO_2%) and total hemoglobin levels. This reduction in perfusion results in rapid ischemia, which can be detected within seconds by T-Stat.
- **Venous Occlusion:** Leads to blood pooling and an increase in total hemoglobin while StO_2% drops more gradually. If left untreated, venous congestion can cause increased tissue pressure, ultimately leading to flap failure.
- **T-Stat Differentiation:** Unlike Doppler or visual exams, T-Stat can detect both arterial and venous complications, providing critical data to guide ..... preventing further tissue damage.



Pushing the DIEP envelope with ERAS

Fracol, M., Teven, C. M., Selimos, B., Wier, S., Stockslager, C., Schoenfeldt, J., Connors, P., Monahan, D., Dumanian, G. A., & Howard, M. A. (2023).
Pushing the DIEP envelope with ERAS: 24-hour discharge is safe in appropriately selected patients. Plastic & Reconstructive Surgery-Global Open, 11(6), e5070
Division of Plastic Surgery, Northwestern Medicine, Lake Forest, Ill

The Enhanced Recovery After Surgery (ERAS) protocol prioritizes reduced hospital stays and improved post-operative recovery. T-Stat supports ERAS initiatives by providing continuous monitoring that eliminates the need for ICU admissions. Studies show that T-Stat enables early discharge, reduces hospital resource use, and prevents unnecessary interventions. Beyond these logistical benefits, T-Stat provides significant **peace of mind** for the patient, a crucial factor in recovery. Rest is one of the most important elements of healing after surgery. Unlike traditional monitoring methods that require frequent waking for flap checks, T-Stat allows patients to **sleep undisturbed**, ensuring early rest at the most critical time post-operatively. Sleep aids in tissue repair, immune function, and overall recovery, making it a key component of modern surgical protocols. Additionally, **stress reduction** plays a crucial role in enhanced healing. With continuous monitoring, patients and their care teams can feel more at ease, knowing that real-time data is being collected without invasive interruptions. Patients can focus on recovery rather than worrying about the viability of their flap, leading to **faster healing, improved comfort, and better overall outcomes.**

> ***"In a study conducted at NW, it showed... "With T-Stat, our patients bypass the ICU, reducing cost and resource use."***
>
> Dr. Michael Howard, MD
> *Northwestern, IL*

Surgeon & Patient Testimonials

Real-world experiences highlight the value of T-Stat:

Dr. Michael Howard,
Northwestern, IL: "We have found that ICU-level monitoring is unnecessary with the T-Stat monitor, which had a 100% success rate at picking up early vascular compromise in our cohort of patients. This technology allowed us to salvage 100% of the flap takebacks occurring during hospital stay."

Dr. Minas Chrysopoulo,
PRMA San Antonio, TX: "T-Stat's ability to also monitor the flap's hemoglobin concentration has helped me identify venous outflow issues way before any visible clinical changes, greatly speeding up return to the OR and maximizing the opportunity for flap salvage."

Dr. Jesse C. Selber,
Royal Oak, MI: "T-Stat technology allows for continuous instead of episodic monitoring and is sensitive to venous congestion, both advantages over traditional hand-held Doppler. Early detection of vascular compromise is one of the most critical factors in the success of free flap salvage."

Dr. Chris Hoo,
Belfast Health, IRL : "T-Stat didn't change my practice, it changed my life!"

Dr. Kamakshi Zeidler,
Silicon Valley, CA: "I prefer T-Stat because of its sensitivity to flap compromise compared to other devices. The nurses like the ease of use and that it is an objective and continuous way of assessing a flap. It also enhances communication between surgeons and bedside staff."

Dr. Aldona Spiegel,
Houston, TX: "I love that T-Stat has evolved and has really improved our patient care."

Dr. David Chang,
San Francisco, CA: "The timely recognition of perfusion problems in a flap can mean the difference between success and failure. The T-Stat provides an immediate and objective measurement of flap perfusion that can accurately detect both venous and arterial problems before they may be evident by conventional flap monitoring techniques, including the implantable Doppler."

Dr. Galen S. Wachtman,
Austin, TX: "I think T-Stat represents best-in-class technology for flap monitoring." – Austin, TX

Dr. Richard Santucci,
Austin, TX: "T-Stat really is the gold standard." – TX

Dr. Alexander F. Mericli,
MD Anderson, Houston, TX: "The T-Stat allows for accurate and precise continuous flap monitoring. This translates to earlier detection of flap malperfusion, which equates to a greater likelihood of flap salvage. The device is easy to use and interpret for the nursing staff, and the online interface essentially allows the surgeon to check in on the flap from anywhere in the world, 24 hours a day." – MD Anderson Cancer Center, TX

Patient: Lacey Reid-Terpstra: "Having that device 100% brought me peace of mind going through the surgery. I was even able to see the number before the nurses. It was the greatest thing."

CLINICAL STUDY

White Light Spectroscopy for Free Flap Monitoring

Stanford Hospital, Palo Alto Ca.

Fox et al., Microsurgery (2012)

A clinical study evaluated **visible light spectroscopy (VLS)** using the **Spectros T-Stat system** for post-operative **free flap monitoring.** The study compared T-Stat with **pencil Doppler and clinical exam** to assess its ability to detect early ischemia.

Key Findings:

- Normal **capillary hemoglobin saturation (StO_2%)** ranged from **40–75%**, increasing postoperatively.
- **T-Stat detected flap compromise 50 minutes before clinical signs,** allowing **successful intervention.**

Surface Probe Summary (31-flaps)

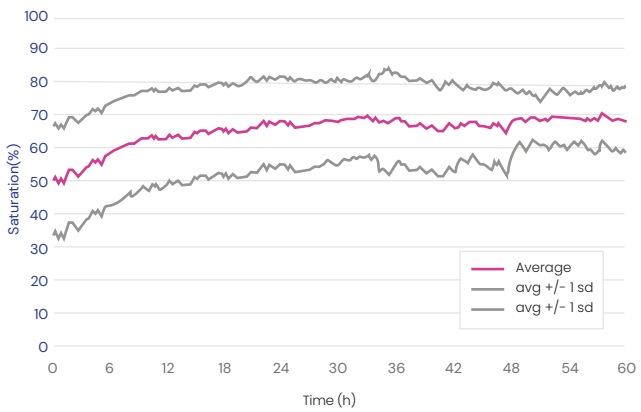


Figure 2. Data collected from monitoring of 31 successful free tis- sue transfers. Time 0 5 time of probe application at conclusion of the case. The black line represents the average StO_2%. The gray lines represent one standard deviation above and below the aver- age value at each time point.

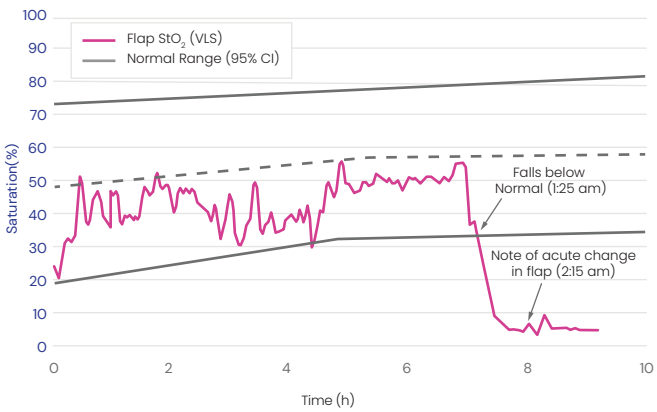


Figure 3. Data collected during monitoring of one free flap used in breast reconstruction that demonstrated flap compromise and required return to the operating room for exploration. The black line is data collected from the compromised flap. The dashed gray line is the mean percent StO_2 in viable flaps and the solid gray lines represent one standard deviation above and below mean percent StO_2 values.

CLINICAL STUDY

Comparing Visible Light Spectroscopy to Handheld Doppler for Free Flap Monitoring

MD Anderson, Houston Tx.

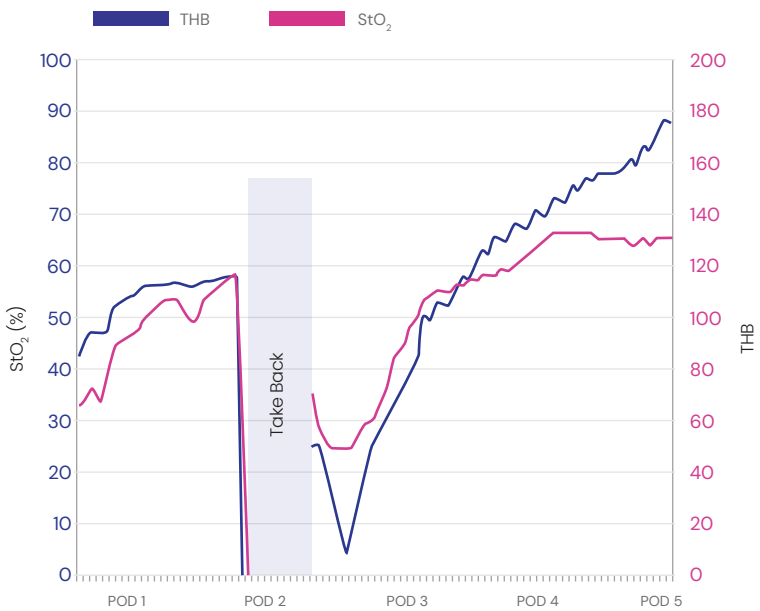
Mericli et al., Plast. Reconstr. Surg. (2017)

A prospective clinical trial compared **Visible Light Spectroscopy (VLS)** using the **T-Stat system** with **handheld Doppler and clinical exam** for detecting free flap compromise. The study assessed **sensitivity, specificity, and accuracy** across **81 free flaps.**

Key Findings:

- **VLS detected all three cases of flap compromise before Doppler or clinical exam, leading to 100% flap salvage.**
- **Sensitivity:** VLS = **100%,** Doppler = **33%,** Clinical Exam = **66%.**
- **VLS provides real-time monitoring of both arterial inflow and venous drainage,** unlike Doppler, which is less sensitive to venous congestion.
- **Continuous monitoring** reduces reliance on intermittent assessments by staff with varying experience levels.

Case 1



OnCall Remote Access: Real-Time Monitoring Anytime, Anywhere

T-Stat's OnCall Remote Access platform revolutionizes free flap monitoring by allowing surgeons and clinicians to access critical tissue oxygenation data from anywhere, anytime.



Key Benefits of OnCall:

- **24/7 Remote Access: View real-time StO_2% and hemoglobin levels through a HIPAA-compliant online portal.**
- **Immediate Alerts: Customizable thresholds ensure that clinicians receive early warnings of vascular compromise, allowing for rapid intervention.**
- **Enhanced Collaboration: Surgeons can consult with hospital staff remotely, making real-time decisions without needing to be physically present.**
- **Secure & Compliant: Data is encrypted and protected, ensuring patient privacy while providing accessibility from any device.**
- **Reduced Need for Bedside Checks: Eliminates unnecessary patient disturbances while still ensuring flap viability is continuously monitored.**

Dr. Summer E. Hanson, MD

University of Chicago

"I really like it. I check it incessantly and then my husband makes fun of me but also noted that pre-T-Stat, I would just hunker down at home when I had a fresh flap and wait for the fellows to call, and now he'll be like, "Wanna go to a movie?" and I'll check my phone and head out. Surgeon quality of life - little side perk of the device."

Spectros Resources & Contact Info

Spectros is committed to supporting healthcare professionals with extensive resources:

- **Clinical Support:** Direct representative support and clinical nurse training.
- **Educational Materials:** Online training videos, quick reference and instructional guides, and research publications.
- **OnCall Remote Access:** Secure online platform for monitoring patient data in real-time.
- **Contact Information:**
  - Email: info@spectros.com
  - Website: www.spectros.com
  - OnCall: www.oncall.spectros.com

T-Stat is more than a device—it's a critical tool in ensuring the success of reconstructive surgery. By providing precise, real-time data, T-Stat empowers surgeons to make informed decisions, ensuring better patient outcomes and reducing complications.





American Society for Reconstructive Microsurgery
The leading organization for complex reconstruction



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