Spectros

Real Time Perfusion Monitors

T-Stat 303

non-invasive Ischemia monitoring system

innovative. proven. trusted.

Spectros markets and licenses advanced molecular sensing devices that shed light on life-threatening diseases, including ischemia and cancer.

Our medical devices build upon state-of-the-art optical molecular technologies to speed diagnosis, reduce complications, and lower costs.

Spectros

T-Stat 303

The T-Stat 303 provides a continuous, non-invasive and localized measurement, sensitive to regional and global ischemia. T-Stat reports a capillary-weighted oxygen saturation which is closely related to a local venous saturation measure.

T-Stat is the first medical device to be labeled by the FDA as "sensitive to ischemia" and has been proven in multiple trials as an easy-to-use and reliable tool for assessing the adequacy of oxygen delivery to tissue.

T-Stat represents the newest and most advanced generation of optical critical care devices.

- T-Stat is proven sensitive to ischemic injury, as it happens.
- T-Stat makes patient management more effective because the narrow range of normal ensures that changes in a patient's baseline are detected earlier. Why is visible light more accurate? Because visible light senses hemoglobin in tissue 100 times more strongly than infrared, substantially reducing noise and measurement error.
- T-Stat is unlike other optical devices that measure skin or muscle saturation – as these measures do not correlate with vascular outcome.

Detection of ischemia

T-Stat uses visible light spectroscopy (VLS) to measure the oxygen content of hemoglobin at a micro-vascular level. By analyzing the reflected white light from the tissue the T-Stat is able to assess the adequacy of oxygen delivery (blood flow) to specific tissues and organs. The T-Stat provides a continuous, non-invase and localized measurement, sensitive to regional and global ischemia.

T-Stat Overview

The complete Spectros monitoring system consists of the T-Stat 303 monitor and any of 5 single use probes designed for specific applications and measurement sites.

Each probe contains a visible white light source for illuminating the tissue and a fiber optic bundle that transmits directly back to the monitor for real-time results.

T-Stat will alert clinicians earlier, since St02 values will change immediately, if tissue oxygen supply is not meeting the tissue oxygen demand

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Buccal probe

The buccal probe (available in multiple sizes: neonatal, pediatric and adult), is designed to fit in the mouth to monitor the saturation of the buccal mucosa as a surrogate for GI perfusion.

Endoscopic catheter

The 1.5mm (Endoscopic) catheter is designed to be used in the instrument channel of an endoscope for assessing local perfusion in the large and small bowel.

5mm catheter

The 5mm catheter is designed to be placed in the esophagus or rectum for continuous GI saturation monitoring. This probe can also be used through a trocar for spot organ measurements during laproscopic surgery.

Surface probe

The Surface probe is a side-looking probe designed for skin monitoring applications.

Using T-Stat in Neonatology

non-invasive caring

Eliminate the risks of invasive monitoring…

What should I normally see?

For healthy neonates, T-Stat normally reads 61-69%

T-Stat normals are very DIFFERENT than pulse oximeter normals. This is because the tissues of healthy patients normally remove enough oxygen from arterial blood to drop T-Stat levels to 25-35% below the pulse oximeter. Even a well-perfused child with a cardiac mixing lesion (and a low pulse oximeter reading of 70-85%) will still have a T-Stat reading 25-35% below the pulse oximeter, or a T-Stat reading of about 40-55%.

What is abnormal, and what do these readings mean?

There are 2 important ways to think about abnormal T-Stat readings at the bedside. First, consider the T-Stat reading. T-Stat readings below 55% are rarely normal, and indicate an increased risk of inadequate oxygen delivery.

T-Stat values below 35% in children lead to metabolic acidosis by lactic acid production. If left untreated, T-Stat values below 30% may rapidly lead to ultimate failure.

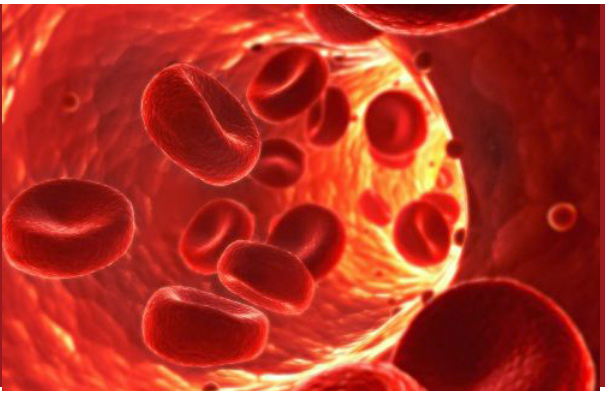
Second, consider the gap between T-Stat and the Pulse Oximeter. The gap between tissue and pulse oximeter readings grows with impaired oxygen delivery.

A difference of 38% or more between T-Stat and Pulse Oximeter suggests an impaired delivery of oxygen to tissue.

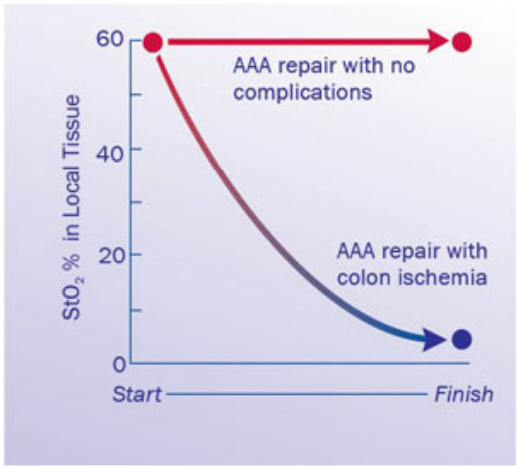
Low T-Stat readings and widened Pulse-Tissue gaps may be caused by:

- Decreased systemic blood flow (hypovolemia, shock, heart dysfunction)
- Increased left-to-right shunts (intracardiac, open ductus)
- Anemia
- Increased metabolism (fever, stress, sepsis)
- Changes in drips, medications, or ventilator settings that worsen perfusion

Using T-Stat in Vascular Surgery



reliable



Avoid added stress to your critically ill patients...

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.

Venous saturation is well correlated with clinical outcome, ...yet until now, Svo2 could not be locally measured at specific end-organs, and thus was not available for assessment during vascular procedures.

At multiple centers, the use of tissue oximeters has been shown to reduce the incidence of organ failure and death due to low or impaired delivery of oxygen to tissues and organs. Continuous monitoring reduces progression to infarction and allows real-time assessment of embolization, stent placement and cardiac surgery in multiple studies. You can watch tissue oxygenation change as stents, staples and sutures are placed and detect deterioration before irreversible injuries occur.

What do tissue saturation readings mean?

T-Stat values below 40% in adults have been shown to lead to metabolic acidosis via lactic acid production. If left untreated, T-Stat values below 30% may rapidly lead to tissue death.

T-Stat has been routinely used in AAA, TAAA and EVAR repair where these procedures pose a risk of post operative colon ischemia.

Using the 5mm T-Stat catheter, placed rectally, the tissue saturation of colonic mucosa can be monitored in real-time during the procedure in order to detect any circulatory compromise during the procedure, when perfusion can be restored before the tissue becomes irreversibly damaged.

In multi-center studies, it has been demonstrated that patients who develop interoperative colon ischemia that is detected by the T-Stat and repaired, go on to normal recoveries, and avoid the 55% mortality rate typically associated with colon ischemia detected post-operatively.

Measuring St02 will give you an early indication of change...

Using T-Stat in Gastro-Intestinal Applications

predictive

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 may not change significantly in cases of regional ischemia. Venous saturation is well correlated with clinical outcome, ... yet until now, Svo2 could not be locally measured at specific end-organs, and thus was not available for assessment during endoscopic procedures.

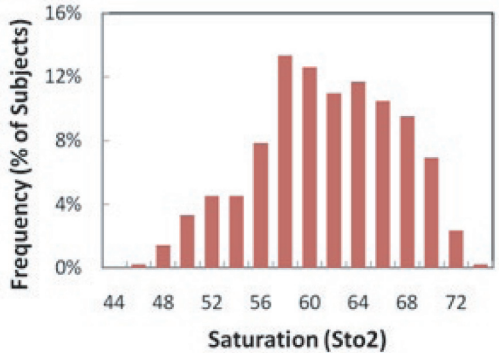
What do tissue saturation readings mean?

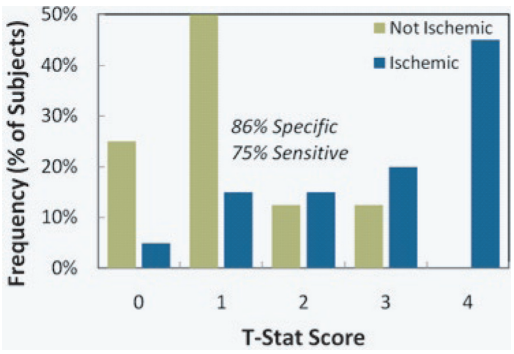
Normal mucosa has been found to have a capillary hemoglobin oxygen saturation of 60-80% in the esophagus, stomach, small intestine, colon and rectum.

Significant decreases in capillary oxygen saturation were observed in patients with chronic mesenteric ischemia, with capillary saturations of 20-40% in severe cases. Capillary oxygen saturation was also found to be significantly lower than normal in ischemic colitis and in advanced gastrointestinal neoplasms. In contrast, capillary oxygen saturation was found to be normal in most cases of chronic radiation proctopathy and peptic ulcer.

In cases of low capillary saturations due to mesenteric ischemia, capillary saturation has been shown to normalize following percutaneous stenting of the affected arteries.

The T-Stat 1.5 mm catheter can be used through the instrument channel of most endoscopes – including double-balloon endoscopes – and has been shown to have a high specificity for the diagnosis of mesenteric ischemia.





In a study conducted to determine diagnostic thresholds of the T-Stat during endoscopy to identify chronic mesenteric ischemia, VLS saturation levels and clinical diagnosis were compared. The T-stat proved to have a high specificity for the diagnosis of mesenteric ischemia and may also detect mesenteric ischemia that is otherwise clinically misdiagnosed.

T-Stat Prescribing Information

The sensitivity and specificity of the St02 values provide vital perfusion information to customize treatment plans, quickly detect evolving problems and implement interventions that are most appropriate for each patients situation.

{ 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.

{ Clinical Studies }

In peer-reviewed studies of T-Stat:

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 tissue oxygenation (StO_2%) determined using VLS was unbiased in comparison to StO_2% determined using NIRS predicates (StO_2% Bias = –1%±5%, p=N.S.), but VLS demonstrated significantly tighter ranges of normal (VLS normal range 62-75% vs. NIRS reported at 48-88%, $p<0.001$) [1].

{ 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 the 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.

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