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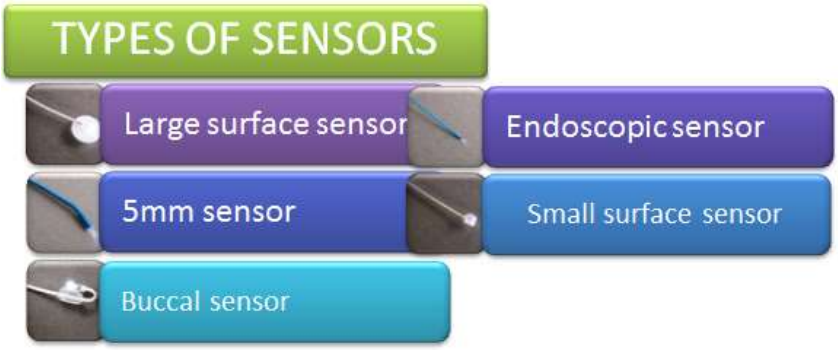
# T-STAT Tissue Oximeter

T-Stat is the first device to be labeled 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. The T-Stat VLS Tissue Oximeter 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.

**Buccal Sensor:** It is designed to fit in the mouth to monitor the saturation of the buccal mucosa as a surrogate for GI perfusion.




**Endoscopic Sensor:** The 1.5mm (Endoscopic) sensor is designed to be used in the (5Fr) instrument channel for an endoscope for assessing local perfusion in the large and small bowel.

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

**Surface Sensors:** The easy to place surface sensor is ideal for any skinn surface monitoring and is available in two sizes, depending on the size of the skin paddle.

## 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%)[1] | Wide (±9%)[1,6] | Wide (±9%)[1,6] | Wide (±9%)[1,6] |
| Changes Outcome | Yes | Yes | No | No |
| Site Measured | Mucosal | Brain | Muscle | Brain |
| Range of Sensors | Yes | No | No | No |

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## The T-Stat Tissue Oximeter measurements differ from conventional pulse oximetry in the following ways:

### Capillary-weighted

Hemoglobin oxygen saturation of blood in the microvascular tissue space, is typically lower than pulse oximetry saturation (SpO2%) and arterial saturation (SaO2%). Whereas pulse oximetry measures arterial saturation, tissue oxygenation is capillary-weighted, and estimates the hemoglobin oxygen saturation at the site of tissue oxygen extraction. Tissue optical saturation is thus responsive to changes in oxygenation of the tissue itself, whether caused by changes in arterial oxygenation (hypoxemia) or by changes in blood flow (reduced-flow or no-flow ischemia).

### Nonpulsatile

Unlike pulse oximetry, a pulse is not required for the measurement to be made. Therefore, the T-Stat® Tissue Oximeter continues to measure during low-perfusion, hypotension, or asystole.

### Normal Values Differ

Hemoglobin oxygen saturation of blood in the microvascular tissue spaces (StO2%) typically runs much closer to venous saturation (SvO2%) than to arterial saturation (SaO2%). Tissue oxygen saturation StO2% for some tissues has been established. While reference ranges for human use have not been recognized in health and disease, measured and published values of StO2% for many tissues are typically 71% +/- 3%, or a 95% confidence interval of 65% - 77%.

## USAGE:

- ***During Plastic Surgery:*** The most important need of successful and reliable surgery is to monitor skin flap perfusion after microsvascular, reconstructive procedures.
- **In Critical Care:** It is used to monitor 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. Use of tissue oximeters in critical care has been shown to lower the risk and incidence of multi-organ failure and death due from low or impaired delivery of oxygen to tissues and organs.
- ***Diagnosis of Chronic Mesenteric Ischemia***
- ***In Vascular Surgery***

## TECHNICAL SPECIFICATIONS:

| T-Stat® VLS Tissue Oximeter Specifications | |
|---|---|
| | |
| **1. Physical Specifications** | |
| 1.1 Size: | 11” Wide x 7 ” High x 9.5” Deep |
| 1.2 Weight: | 11 lbs (5 kg) |
| 1.3 Color: | Light Blue Case<br>Ivory Front and Rear Panels |
| 1.4 Front Panel: | Back-Illuminated touch-screen VGA display screen<br>Type SPEC-1 Female Sensor socket |
| 1.5 Rear Panel: | Power switch |

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| | |
|---|---|
| | Power socket and fuse access<br>USB (Type II) data port |
| 1.6 Top: | Flexible carrying handle |
| 1.7 Bottom: | Folding tilt-up stand |
| **2. Value and Accuracy Specifications:** | |
| 2.1 Values Displayed | |
| | StO2%<br>rHemoglobin (relative hemoglobin)<br>Signal intensity<br>Optional trend graph |
| | |
| 2.2 Tissue Hemoglobin Saturation (StO2%) | |
| *a. range:* | 0-99% |
| b. *resolution:* | 1% |
| *c. reproducibility:* | ± 2% (SD, single site, x 5 over 1 minute, ex vivo) |
| d. *stability:* | ± 2% (SD, single site x 1 day, ex vivo) |
| e. *accuracy:* | ± 2% (SD @ 100% at 100uM, ex vivo)<br>± 2% (SD@ 0%, in vivo |
| | |
| 2.3 Relative Hemoglobin (rHemoglobin) | |
| *a. range:* | 0-0.99 mM |
| b. *resolution:* | 0.01 mM |
| *c. reproducibility:* | ± 5 uM (SD, single site, x 5 over 1 min, ex vivo) |
| d. *stability:* | ± 5 uM (SD, single site x 1 day, ex vivo) |
| e. *accuracy:* | ± 5 uM (SD @ 100% at 100uM, ex vivo) |
| **3. Alarm/Warning Specifications** | |
| Alarms<br>Low StO2%: | User settable, 0-99% (preset Low 40%) |
| High StO2%:<br>Low Heme:<br>High Heme:<br>Too Dim:<br>Too Bright:<br>Unstable: | User settable, 0-99% (preset High 95%)<br>rHemoglobin < 5 uM (analysis suppressed, “no tissue” error)<br>rHemoglobin >100 uM (“bloody tissue” error)<br>Signal < 500 counts in 500 ms<br>Signal > 4000 counts in 5 ms<br>Signal strength changes >20% between sample |
| Result Blanking:<br>(blanks to “- - -“) | Invalid data x 6 seconds<br>Out of range data x 6 seconds<br>No tissue seen x 6 seconds |
| Alarm Indicator: | Red/Yellow/Green Status Indicator<br>White error message on flashing red background<br>Audible alarm (silenceable) |
| Alarm Silencing: | Audible alarm silenced x 2 min<br>Visual alarm cannot be turned off |
| System Collecting: | Sequential illuminated squares when data collecting |
| Good Data Indicator: | Green status indicator when data good |
| Self-Diagnostics: | Automatic Self-Test at Power on<br>Visual display of self-test progress<br>Validation of software versions<br>Validation of software integrity<br>Validation of algorithm successful operation<br>Test of optical spectrometer<br>Test of optical socket reader<br>Test of memory storage space<br>Test of microprocessor system<br>Red/Green self-test success indicators<br>Halt at Start up if errors in self-test |
| **4. Microprocessor Specifications:** | |

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| | |
|---|---|
| Operating System: | Windows Embedded XP SP1 |
| Internal Memory: | 64 Mb (minimum) |
| CPU: | 1GHz P3 (minimum) |
| Oximetry Software: | T-Stat® operating software 1.05.022.00 (clinical release CR4) or later |
| **5. Optical Specifications:** | |
| Probe Input: | 150 uM fiber return line |
| Probe Output: | Current-limited 5V output source |
| Connector: | Female, Type 1 Spectros Light-Jack Connector |
| **6. Electrical/Emissions Specifications**: | |
| | |
| Input Voltage: | 100-240 V~, 50-60Hz<br>Electrically isolated<br>US/Canada: Green-dot (hospital grade) 3 m grounded cord |
| Power Required: | 100 VA (typical) |
| Battery: | None |
| Fuse: | T3A/250V |
| Patient/Operator Protection: | Medical-grade Isolated power supply<br>Isolated DC supply to probe socket<br>Dual-Fuse Power Supply<br>(external (user-replaceable), and internal fuse)<br>Dual current limit resistor<br>(limit resistor in socket AND limit resistor in each probe) |
| Approvals: | UL 2601-1, EN60601-1-2:2001, CE, FC, EMC 89/336/EEC, Medical Directive 93/42/EEC |
| **7. Operating Specifications**: | |
| Environment: | Intended for Indoor Hospital Use<br>5-40 degrees Celsius<br>5%-95% humidity (non-condensing) |
| Start-Up | Warm-up and self test requires up to 2 minutes |
| Shut Down | Power off using switch; no shutdown time required |
| **8. Optional Software**: | |
| | |
| Research Options (not for clinical use) | Optional data collection to internal flash<br>Optional data export to external disk via USB port<br>Optional analysis scripting for user-specific analysis |
| **9. Probe Specifications**: | |
| | |
| Sterile | Human probes are available sterile for single use. |
| Sensor Types: | CTH-060-REC --- Rectal T-Stat® Sensor<br>CTH-060-END 2M & .5M--- Endoscopic T-Stat® Sensor<br>CTH-060-ORA & ORA/MINI --- Oral Buccal T-Stat® Sensor |

## 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 liver and the small intestine have not yet been established, as these readings are affected by organ pigments and surface bile (respectively).
- Sensors are supplied sterile for single use. Do not reuse.

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## References

[1] Anesthesiology. 2004 Jun;100(6):1469-75
[2] Gastrointest Endosc Clin N Am. 2004 Jul;14(3):539-53, ix-x.