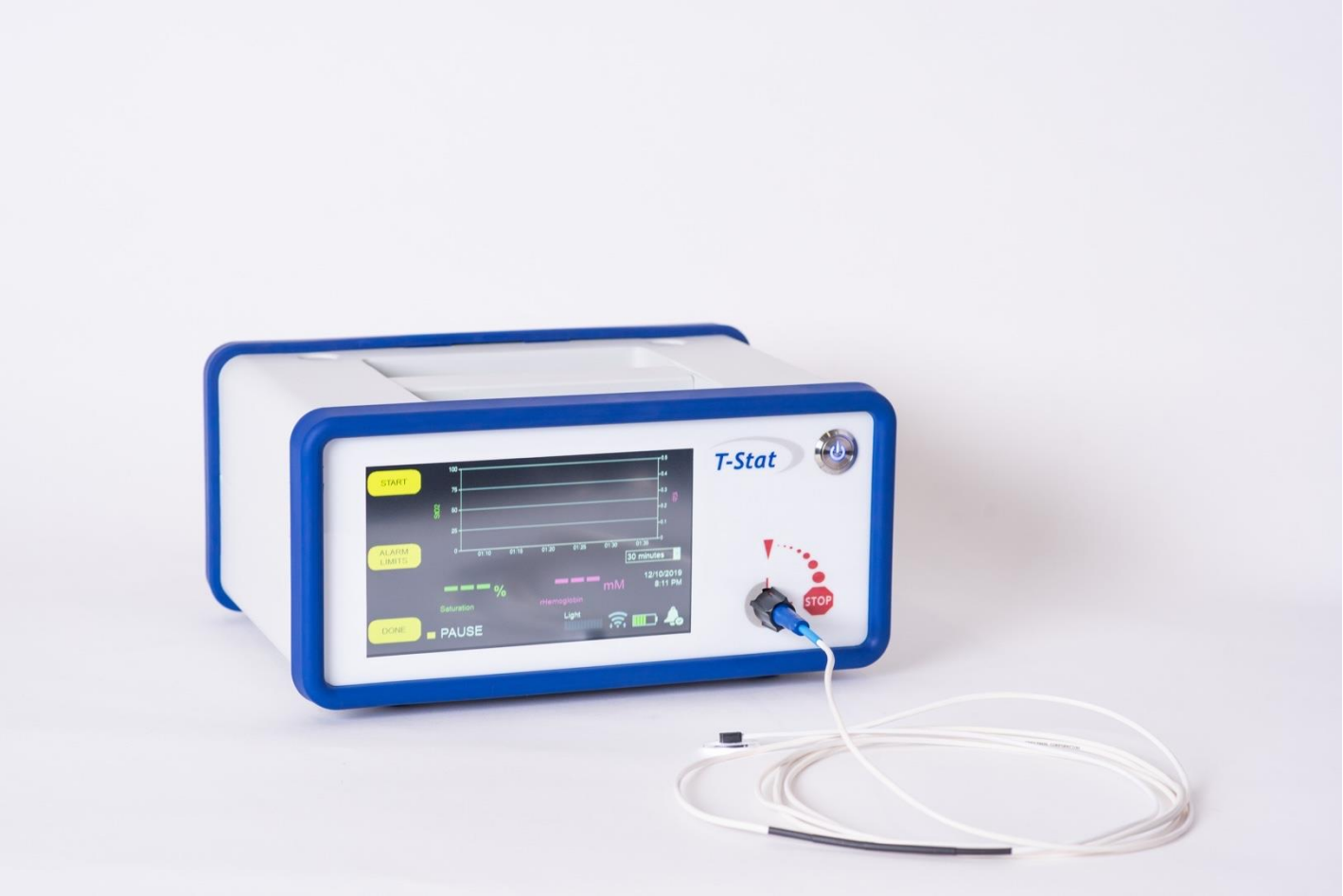
T-Stat 2.0
User Manual



CE 2797

T-Stat 2 Be Sure 2.0

T-Stat 2.0
Microvascular Tissue Oximeter
User Manual

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T-Stat monitor and sensors are protected by the following patents issued:
US6711426; US7062306; US7427165

For Prescription Use Only

Table of Contents

Contents

A. Safety Information 4
B. Table of Symbols 6
C. About the Spectros T-Stat® Tissue Oximeter 7
D. Indications for Use 8
E. Principle of Operation 9
F. Understanding T-Stat® Readings 9
G. Cautions and Notes 11
H. Feature Layout 12
I. Operation 13
- Monitoring Oxygenation 13
- Monitor Set-up and Oxygenation Measurement 13
- Placement and Use of the Oral Sensor 15
- Placement and Use of the Endoscopic Sensors 16
- Placement and use of the 1 cm Surface Sensor 17
- Placement and use of the 2.5 cm Surface Sensor 18
- Changing the Alarm Settings 19
- Saving Data to Internal Disk 19
- Data File Naming Convention: 19
- Moving Stored Data 20
- Changing Date and Time 21
- Checking Software Version Numbers 21
- Instructions for Use of On-Call via Wi-Fi 22
- Instructions for Use of On-Call via Verizon or ATT 25
- Verizon Access: 25
- AT&T Access: 26

J. Care and Maintenance 27
- Cleaning 27
- Storage and Transport 27

K. Messages 28
Appendix A: Measured Values 29
Appendix B: Sensor Specifications 32
Appendix C: Self-Test and Errors 35
Appendix D: T-Stat® 2.0 Specifications 36
Appendix E: EMC Information 38
Appendix F: Warranty Information 41
Appendix G: Service and Disposal Information 43
References: 44

A. Safety Information

NOTE: Federal Regulations in the United States restrict the sale of this device to or on the order of licensed medical practitioners.

Warnings

WARNING: Explosion hazard. Do not operate the monitor in the presence of flammable gases or anesthetics, such as high concentrations of oxygen or nitrous oxide.

WARNING: Electric shock hazard. The monitor's cover is to be removed only by qualified service personnel. There are no user-serviceable parts inside.

WARNING: Use only the medical-grade AC power cord provided by the manufacturer. If in doubt about the integrity of the mains supply connection, cease the operation of the monitor.

WARNING: Do not look directly into light source for extended periods of time.

WARNING: T-Stat sensors are designed for single use only and may not be re-used. Do not autoclave or gas-sterilize any of the T-Stat sensors.

WARNING: Use only T-Stat sensors in conjunction with the T-Stat monitor. Connecting other sensors may result in damage to the T-Stat monitor, or compromise its safety or performance.

WARNING: Do not autoclave, gas-sterilize, or immerse the T-Stat® monitor. This may create an electric shock hazard, or damage internal components.

WARNING: Do not connect any accessories to the USB port on the rear panel of the monitor when the system is in use on a patient other than the approved AT&T or Verizon modems.

WARNING: When monitoring on neonates or infants, check site every 4 hours for pressure necrosis and change site every 24 hours.

WARNING: Reuse of Sterile Sensors can result in infection due to cross contamination.

WARNING: Sensors are designed for single use. Reuse can result in intermittent operation due to contamination of the receiving connection in the T-Stat.

WARNING: When monitoring on adults, check site every 12 hours for pressure necrosis and change site every 24 hours.

WARNING: Lithium Battery: Replacement by inadequately trained personnel could result in a HAZARD (such as excessive temperatures, fire or explosion).

Precautions

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. While normal StO_2% ranges have been established, and tissue oximetry has a demonstrated sensitivity to both hypoxemia and low-flow and no-flow ischemic states, the prospective clinical value of StO_2% measurements have not been established in disease states.

The T-Stat® Oximeter measures regional StO2% and may not reflect changes in oxygenation that occur in regions outside of that monitored by the T-Stat® sensor.

The T-Stat® Oximeter, used alone at a single site, cannot differentiate between local and global conditions.

Use of the 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(R) to detect tissue hypoxia is unknown.

Normal values, as read by the T-Stat® Tissue Oximeter, for liver and the small intestine have not yet been established, as these readings are affected by organ pigments, and surface bile (respectively).

B. Table of Symbols

Caution: Consult this manual for a complete explanation

Electrical Shock Hazard

(AC). **Alternating Current**

Type BF Equipment

RX ONLY: US Federal regulations restrict the sale of this device to, or on the order of licensed medical practitioners

Off/On

Audible Alarm Sounding

Do not re-use

No Latex

Battery Indicating Charge Level

Battery Exhausted- Shutdown will begin soon.

Battery Charging

C. About the Spectros T-Stat® Tissue Oximeter

The T-Stat® Microvascular Tissue Oximeter provides a continuous, noninvasive, and localized measurement of the microvascular hemoglobin oxygen saturation, sensitive to regional and global reduced-flow or no-flow ischemia, as demonstrated in peer- reviewed human clinical studies.

The complete system consists of:

(a) a durable, reusable monitor; and,

(b) a sterile, disposable patient sensor.

The monitor is a software-driven spectrophotometer, embedded CPU analyzer, isolated, switching, AC-to-DC power supply, and touch-screen-based graphic user interface (GUI) running under Windows 10 Embedded. A photograph of the monitor is shown below:

Figure 1 Photo of T-Stat® 2.0

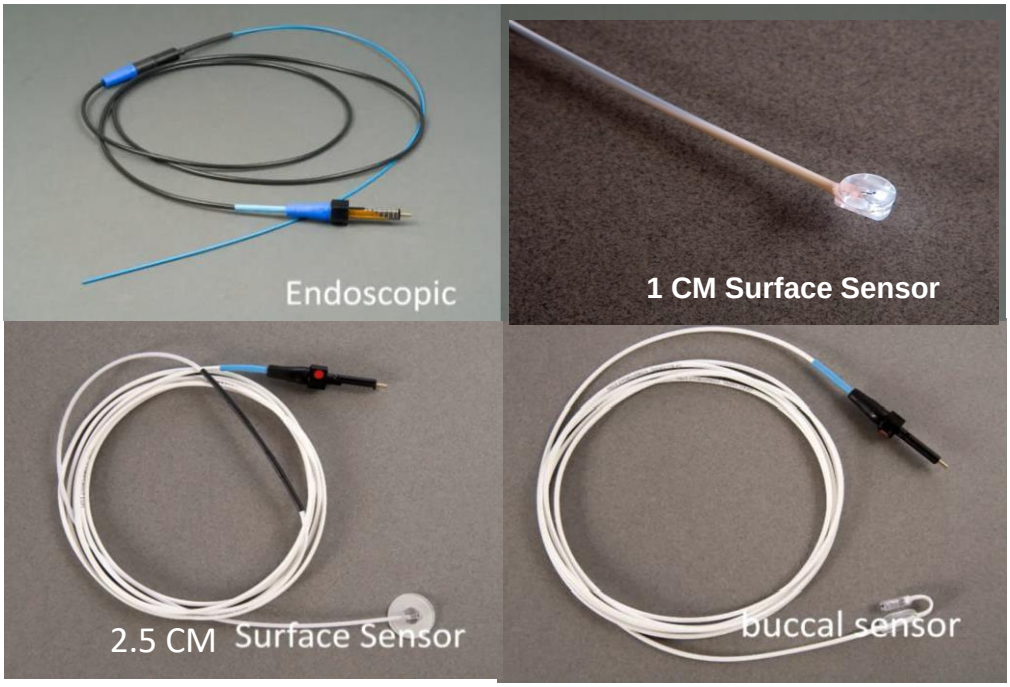
Each single-use patient sensor contains a visible light source for illuminating the tissue, and glass optical fibers for transmitting light remitted from tissue, along the sensor fiber, and back to the monitor.

There are five different T-Stat® sensor sensors available. The clinical choice of sensor is determined by the target site of monitoring, either oral (buccal), endoscopic (via endoscopy), or surface (Skin- 2 sizes).

Monitoring is achieved by attaching the connector end of the selected sensor to the monitor and placing the patient end of the selected sensor near, on, or into the target tissue to be studied, depending upon the site selected.

A view of the patient end of each sensor is shown below:

Figure 2 Photographs of T-Stat® 2.0 Sensors



D. Indications for Use

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.

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 diagnosis or therapy.

For prescription use only.

E. Principle of Operation

The basis for operation for the T-Stat® 2.0 Tissue Oximeter is that hemoglobin in its various forms (oxy-, deoxy-, met-, carboxy-) has unique spectroscopic properties that allow StO2% to be determined based on measurements of the spectral characteristics of the reflectance of light from tissue. The Spectros T-Stat® uses broadband, multi-wavelength illumination and monitoring to determine the relative amount of oxygenated and deoxygenated hemoglobin in the microvascular tissue spaces. StO2% is then defined as the percentage of hemoglobin in the oxygenated form as compared to the total hemoglobin in both oxygenated and deoxygenated forms. The broadband spectral approach also allows for measurement of tissue characteristics, ie lipid and water concentration. These characteristics can be used to make a determination that the site or region where the sensor is placed is in fact looking at components that comprise normal tissue. The software provides a displayed warning of "no tissue" when it detects spectral parameters outside normal tissue ranges in order to alert the doctor to verify the sensor placement.

F. Understanding T-Stat® Readings

The T-Stat® Tissue Oximeter measurements differ from conventional pulse oximetry in several important ways:

Capillary-weighted

Hemoglobin oxygen saturation of blood in the microvascular tissue, is typically lower than pulse oximetry saturation (SpO_2%) and arterial saturation (SaO_2%). 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).

Non-pulsatile

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 (StO_2%) typically runs much closer to venous saturation (SvO_2%) than to arterial saturation (SaO_2%). Tissue oxygen saturation StO_2% 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 StO_2% for many tissues are typically 71% +/- 3%, or a 95% confidence interval of 65% - 77% (see Table 1, below).

Table 1 Normal Range of Oxygenation Values for pulse oximetry, central venous sampling, and VLS tissue oximetry

Value	Normal Range	Description
SaO_2%	95-100%[i,ii]	Arterial hemoglobin saturation. Commonly estimated by Pulse Oximetry.
SvO_2%	65-75%[iii,iv]	Venous hemoglobin saturation. Commonly estimated by Central Venous Catheter sampling.
StO_2%	65-77%*	Tissue optical hemoglobin saturation. A capillary-weighted value that is typically much closer to venous saturation than to arterial saturation.

*Normal values, as read by the T-Stat ® Tissue Oximeter, for liver and the small intestine have not yet been established, as these readings are affected by organ pigments, and surface bile (respectively).

Sensitive to Hypoxemia

During hypoxemia (low arterial saturation), when oxygen delivery to the tissue is reduced, both pulse oximetry and tissue optical oximetry report low values.

Sensitive to low-flow or no-flow Ischemia

Reduced blood flow ischemic states are detected by tissue oxygen saturation (StO_2%) but are not detected by pulse oximetry. During reduced blood flow ischemia (such as from tissue ablation, thrombosis, or cardiac failure), the arterial saturation remains unchanged, but the reduced blood flow results in a lowered tissue oxygenation due to a higher fractional extraction of delivered oxygen to the capillaries.

Estimates Blood Content

T-Stat® estimates and displays the relative hemoglobin of the tissue (rHemoglobin) in µmol/L. Pulse oximetry is insensitive to this value, registering only the changes in blood content during arterial pressure changes between systole and asystole rather than the total blood signal. This signal may vary with depth of the measurement, and therefore is dependent upon the sensor used, as well as has a high noise induced by scattering. rHemoglobin values are +/- 20% and include total hemoglobin plus myoglobin.

G. Cautions and Notes

1. Capillary-weighted tissue oxygenation **differs from arterial oxygenation** as measured by pulse oximetry. Tissue oxygenation (StO_2%) is influenced by arterial blood oxygenation (SaO_2%), as well as by blood flow and blood hemoglobin content, and does not require a pulse in order to obtain a measurement.

2. Measured values are **affected by blood in direct contact with air**. Care must be taken to ensure the measured surface is devoid of free, extravasated hemoglobin, such as introduced by trauma or surgery. Thin mucosa, such as the intestinal wall, can also absorb oxygen directly through the mucosa, and read as more highly oxygenated, during open surgical procedures.

3. Tissue oxygenation is **affected by tissue compression**, which locally reduces blood flow and produces local ischemia. Care must be taken that local tissues are not made artificially ischemic by direct pressure from the sensor.

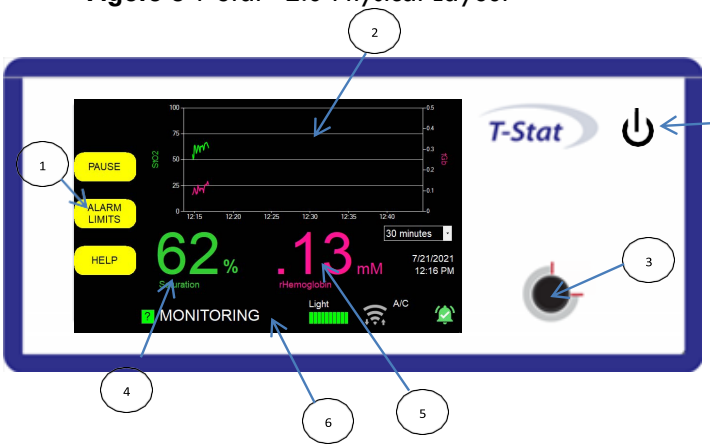
4. T-Stat® sensors are designed for single human use only. **Do Not Re-sterilize** and **Do Not Reuse** sensors in human subjects.

5. Normal values, as read by the T-Stat® Tissue Oximeter, for **the liver and the small intestine** have not yet been established, as these readings are affected by organ pigments, and surface bile (respectively).

H. Feature Layout

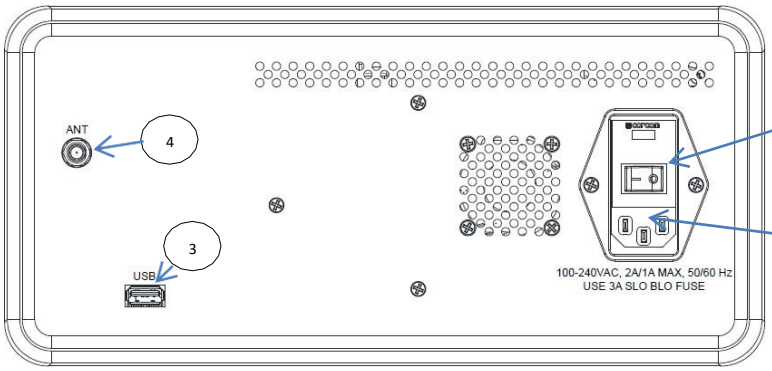
The T-Stat® Tissue Oximeter parts and features are illustrated below:

Figure 3 T-Stat® 2.0 Physical Layout



Menu buttons

1. Alarm Limits page
2. Graph (StO2%,rHb)
3. Sensor Probe Socket
4. Saturation
5. Relative Hemoglobin (rHb)
6. Color Status "?" and Message
7. On/Off Button



1. Power Switch
2. Electrical Supply
3. USB Port
4. Wi-Fi Antenna Port

I. Operation

Monitoring Oxygenation

In order to use the T-Stat® Tissue Oximeter, the monitor is placed 2meters or less from the bedside (limited only by the length of the sensor cable, not by any fundamental limitation of transmission). A disposable sensor is then placed at the target tissue site, either oral (buccal), skin, or through an endoscope. These procedures are described below.

Monitor Set-up and Oxygenation Measurement

1. Plug-in and turn the T-Stat® monitor unit on (make sure the rear panel power switch is turned to the "on" position).

2. The monitor automatically performs a self-test that requires about 1 minute to complete.

3. Remove the T-Stat® sensor from its sterile packaging, using either clean or sterile technique as required given the site of measurement.

4. Sensor can be plugged in at any time. Attach the connector on the sensor to the connection port on the monitor, located to the lower right of the monitor display. Align the red line on the sensor connector with the red arrow on the front panel (12:00), insert the connector into the connection port until it hits a hard stop and rotate ¼- turn clockwise to lock in place (3:00). Sensor identification and calibration will begin automatically when sensor is plugged in.

5. When the T-Stat completes its self-test and senses a sensor it reads the calibration data from the sensor and goes to the start screen.

6. Place T-Stat® sensor on desired location for patient monitoring (see the following section for the procedures for placement of each of the three different sensor types).

7. Push **START** to collect and display data, Then indicate whether this is a new patient.

8. Push PAUSE to temporarily stop monitoring (data will be retained on the existing screen.)

9. Chart display range can be changed by pressing the pull-down menu to the lower right of the chart. Ranges available are 20min, 1hr, 12hr, 1 day, 2 day, 3 day, 4 day and 5 day.

10. Measurement can be started and stopped as needed by pressing **PAUSE.**

11. When finished monitoring, press **PAUSE** then **DONE** Selecting DONE will close the

current data file, store it in the internal memory and no longer display this file on the visual screen chart.

12. When finished monitoring remove from the patient and discard sensor.

13. Make sure to turn the power off from the front of the monitor. If you wish to keep the monitor charging, make sure it is plugged in, the back power switch is on and the front power button is off.

Placement and Use of the Oral Sensor

The oral sensor is placed in the following steps:

Caution: If pouch integrity is compromised prior to removal, discard sensor. Possibility of contamination presents risk to patient

1. The sensor is connected to the monitor, and then the cable is routed to comfortably place the sensor alongside either the left or right cheek.

2. The patient's mouth is opened, and the illuminated portion of the sensor is placed inside the mouth, with the cable portion placed on the outside of the cheek.

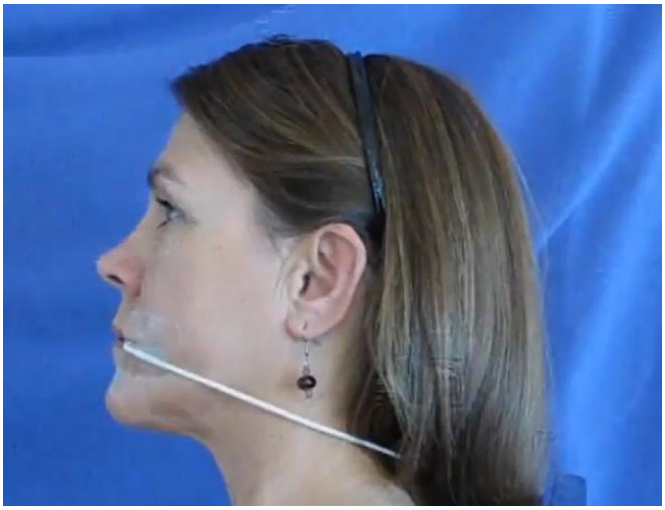
Caution:

- **Ensure that the illuminated portion of the sensor is not in contact with the cheek. Excess pressure on the inner cheek at the sensor site can alter local blood flow and result in lower measured local saturation.**

- **Ensure that the inner cheek surface is free of surface blood. Free blood becomes well oxygenated upon exposure to air and result in a higher measured saturation. A monitor warning of "Excess Blood" or a saturation above 95% suggests this condition**.

3. The sensor cord is positioned along the angle of the jaw, near or behind the ear. The sensor cord may be taped to the skin, near the angle of the jaw or behind the ear if desired, to stabilize the sensor.

Figure 4: Placement of the Oral Sensor in an Adult



The sensor can be placed against either cheek, left or right. Note that the sensor end is located against the inner oral mucosa.

Placement and Use of the Endoscopic Sensors

The endoscopic sensor is placed during an endoscopy procedure in the following steps:

Caution: If pouch integrity is compromised prior to removal, discard sensor. Possibility of contamination presents risk to patient

1. The connector end of the endoscopic sensor is connected to the monitor, and the cable is routed to where the endoscopist is located.

2. The patient end of the endoscopic sensor is inserted into a 2 mm minimum diameter endoscope accessory channel, and advanced until visualized by the endoscopist through the viewing channel of the endoscope.

3. The endoscopic sensor is brought into proximity of the tissue to be measured. A white VLS spot is seen on the tissue, for confirmation purposes. The endoscopic VLS sensor is a non-contact sensor. All that is required for measurement is a view of the mucosal tissue to be monitored.

Caution:

- **Ensure that the illuminated portion of the endoscopic sensor is not in contact with the mucosal tissue. Excess pressure on mucosal tissue at the sensor site can alter local blood flow and result in lower measured local saturation. A visual confirmation of sensor positioning during measurement will avoid this condition.**

- **Ensure that the mucosal surface is free of surface blood. Free blood becomes well oxygenated upon exposure to air and will cause a higher measured saturation. A monitor warning of "Excess Blood" or a saturation above 95% suggests this condition.**

The placement of the endoscopic sensor is illustrated in the following figure:

Figure 6 Placement of the Endoscopic Sensor

Placement and use of the 1 cm Surface Sensor

Preparation

- Assure skin area to be measured is clean and free of blood.
- Do not apply to open wound.

Placement

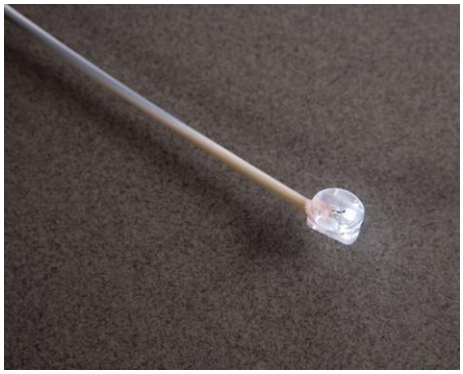
1. Remove T-Stat® Surface Sensor from Sterile Package

Caution: If pouch integrity is compromised prior to removal, discard sensor. Possibility of contamination presents risk to patient

2. Insert the connector end of the sensor into the T-Stat VLS Monitor, aligning the red line on the sensor connector nut and the red arrow at 12:00 on the monitor, then rotating one quarter turn clockwise after insertion (to the locked position.). When locked into position, the white light sensor will illuminate and will automatically go through recognition and calibration. If this does not happen, this step is incomplete.
3. Hold sensor flat on skin surface being careful not to apply pressure, so as to cause local ischemia.

Caution:
Local pressure may cause local ischemia.
Move sensor to new site every 12 hours

FIGURE 7 - 1 cm surface sensor



Placement and use of the 2.5 cm Surface Sensor

Preparation

- Assure skin area to be measured is clean and free of blood.
- Do not apply to open wound.

Placement

Remove T-Stat® Surface Sensor from Sterile Package.

Caution: If pouch integrity is compromised prior to removal, discard Sensor. Possibility of contamination presents risk to patient

1. Insert the connector end of the sensor into the T-Stat VLS Monitor, aligning the red line on the sensor connector nut and the red arrow at 12:00 on the monitor, then rotating one quarter turn clockwise after insertion (to the locked position.). When locked into position, the white light sensor will illuminate and will automatically go through recognition and calibration. If this does not happen, this step is incomplete. Remove the white sticker tape from the face of the surface sensor disk.
2. Place sensor flat on skin surface being careful not to apply too much pressure so as to not cause local ischemia.
3. Surgical tape or Tegaderm can be used to help make sure the sensor stays in place.

Caution: Local pressure may cause local ischemia. Move sensor to new site every 12 hours

FIGURE 8. Placement of 2.5 cm Surface Sensor

Changing the Alarm Settings

A flashing alarm can be set to display on the screen if saturation rises above or falls below a set value. This can be done on the main menu, which appears after power up, before plugging in the sensor, or can be reached by pausing the measurement and pressing "Done Monitoring"

1. The alarm limit screen is selected by pressing **ALARM Limits** .

2. Change the saturation limits using the +/- buttons until the desired limits are shown. The default is set to 20% low and 90% high.

3. Both 2 and 5 minute alarm silencing options will display on the sidebar when the device is alarming.

4. Auditable alarms can be silenced permanently by pressing **DISABLE ALARM**

5. When done press **HIDE ALARM SCREEN**
   When setting the alarms, the real-time values measured continue to be displayed at the bottom of the screen.

Saving Data to Internal Disk

1. From the main screen, select

2. To save/discard future displayed results select "Save Patient Results"

3. To save/discard future raw data select/deselect "Save RAW DATA"

4. To save/discard future intermediate calculations select/deselect "Keep Calculations"

5. When done select **OPTION DONE**

Data File Naming Convention:

Files are automatically named using the date and monitor serial number, as follows:
YYYY_MM_DD_SerialNumber_####.

For example, the second study on January 25, 2002 would be saved under the name:
2002_01_25_TS2.0D1000A_0002

In the example above, the T-Stat® device serial number is: TS2.0D1000A.

File Folders:

T-Stat® files are transferred to two folders: Data and Results.

Data Files:

T-Stat® produces 3 types of output files in Windows PC format:

Type:	Save As:	Where
Data Files:	ID files (*.tid)	Spectros\Data
Saved:	TIR files (*.tir)	Spectros\Results
Results Files:	TII files (*.tii)	Spectros\Results
Intermediate Files:		

File Format:

For export, files are saved as text, and can be opened using Word, WordPad, NotePad or Excel on a PC running under Windows.

Moving Stored Data

When data are stored (see above), they are saved to an internal T-Stat® Oximeter disk. Moving stored data copies the data to a disk and erases the data stored in the T-Stat® system. Stored data can be transferred to a Zip™ or other USB Storage Device as follows:

1. Connect storage device to the USB data port (on rear panel of monitor).

2. From the main screen, select **OPTIONS**

3. Select **TRANSFER DATA** There will be a brief pause before copying data is complete

4. Wait until copying is done and "OK to Remove Disk." is displayed before removing the disk. Press **DONE WITH OPTIONS** to complete. If the disk becomes full, copying will stop and a message will be displayed describing the number of files copied and the number remaining to be copied. The remaining files can be copied by inserting another memory device and repeating the steps above.

Changing Date and Time

1. From the main screen, press **OPTIONS.**
2. Press **SELECT TIME**
3. Use the arrows to change the time, date, and time units (12h vs. 24h, AM or PM).
4. Press **SAVE** or **DO NOT SAVE**

Checking Software Version Numbers

You may view the software versions and view the results of a system integrity check using the Versions screen, as follows:

1. From the main screen, select **ABOUT**
2. When finished viewing, press **DONE**

Instructions for Use of On-Call via Wi-Fi

CAUTION: Do not touch or move antenna while the unit is transmitting or receiving

CAUTION: Do not operate the radio or attempt to transmit data unless the antenna is connected; this behavior may cause damage to the radio.

WARNING: Do not engage Wi-Fi or use cell modems in areas where emissions could interfere with critical wireless monitors. Follow hospital policy.

To set up On-Call access using Wi-Fi connections available in the vicinity, follow the instructions provided below:

1. Power up the T2 and wait for the self-test to finish its checklist.

2. At the back of the machine, there will be a terminator attached to the body of the T2. Unscrew the terminator and connect the antenna provided with the T2. (Refer to image below)

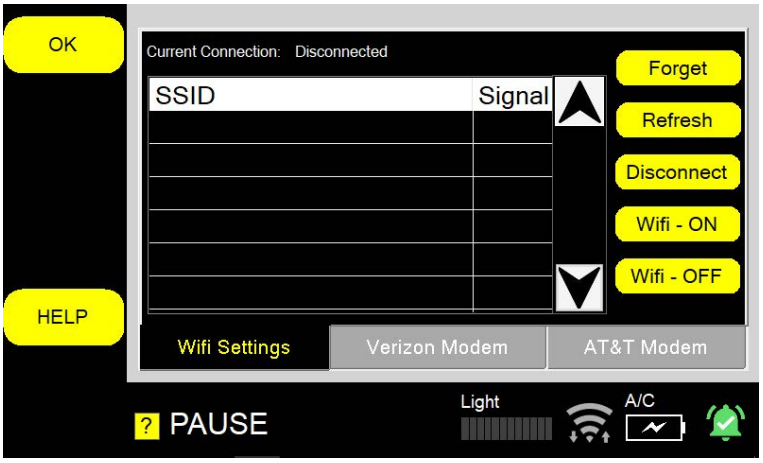
3. Turn the antenna until it is pointing upwards.

4. On the home screen, click on **OPTIONS** In the following page, there will be a number of options on the left panel.

5. Click on the button that says **ONCALL ACCESS** This will be the 4th from the top.

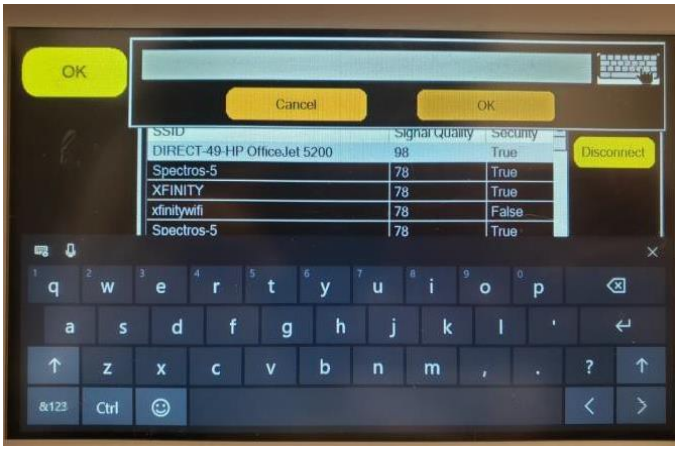
6. Click on the **WiFi** Settings Tab.

7. Click on the button labelled **Wifi - ON**. This will give you a list of Wi-Fi networks available in the vicinity. If you do not see a list, hit the Refresh button on the top right.



8. Once a list of network appears, click on the desired network.

9. On clicking the network name, an on-screen keyboard will appear along with a section to type in the password.



5. Enter the password using the on-screen keyboard and click on **"OK"** when done.

6. Click on the "x" located on the on-screen keyboard to close the keyboard.

7. The connection should now be established. The name of the network will now appear right next to "Current Connection" on the top of the page. If the connection has failed, try re-typing the password or connect to a different network.

8. To verify that the connection has been established, click on **DONE** at the bottom left corner of the page and navigate to the home page. The Wi-Fi symbol on the bottom of the page should be green if there is an active internet connection, and grey if it isn't connected.

9. Once the connection has been established, the device is ready to transmit.

10. To turn off the wifi connection, navigate to OnCall Access in the **OPTIONS** menu and click on **Wifi - OFF**.

Note: The Wi-Fi menu is now available anytime except active monitoring by pressing the Wi-Fi icon on the bottom of the screen.

Instructions for Use of On-Call via Verizon or ATT

WARNING: Do not engage Wi-Fi or use cell modems in areas where emissions could interfere with critical wireless monitors. Follow hospital policy.

1. Power up the T2 and wait for the self-test to finish its checklist.

2. On the home screen, click on "**Options**". In the following page, there will be a number of options on the left panel. (Can also press Wi-Fi Icon)

3. Click on the button that says "**Oncall Access**". This will be the 4th from the top.

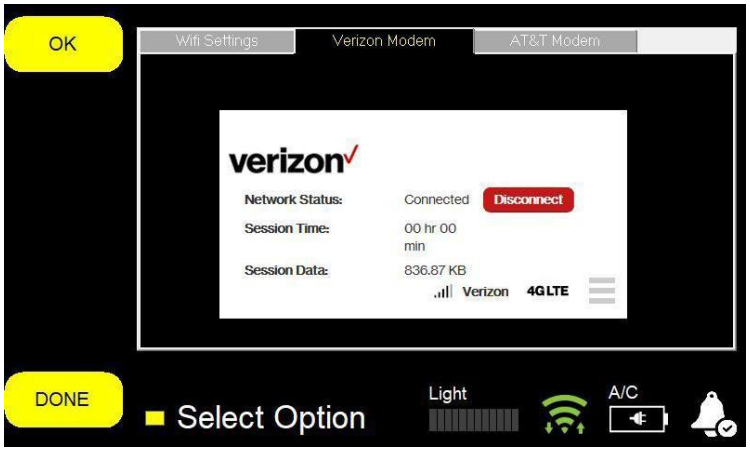
4. On the page that appears, there will be 3 options to choose from: **Wi-Fi Settings**, **Verizon Modem** and **AT&T Modem**. Follow instructions given below to setup your connection.

Verizon Access:

1. Connect the Verizon Modem to the USB port at the back of T2 and wait for the Status button to turn into a solid green light.

2. When the light is solid, click on the "**Verizon Modem**" tab on top of the page.

3. Wait for a few seconds while Verizon establishes a connection. The following page will appear when the modem is ready to transmit.



4. To verify, check the internet connection icon at the bottom of the page. It should be green if there is an active connection, and grey when the connection is lost.

5. Once the connection is established, the device is ready for transmission. To disconnect, navigate to the connection page above and click on the "Disconnect" button.

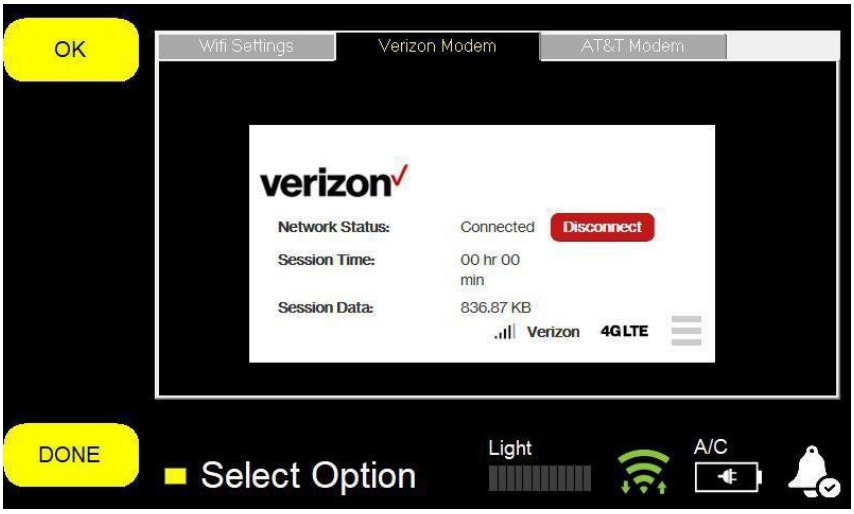
NOTE: If the LED on the modem doesn't become a solid green for a prolonged period of time, try moving the device to a more open area with better cellular reception.

AT&T Access:

1. Connect the AT&T Modem to the USB port at the back of T2 and wait for the LED to turn a solid green color.

2. When the light is solid, click on the "**AT&T Modem**" tab on the OnCall Access page.

3. When the connection has been established, the following page will appear.



4. To verify, check the internet connection symbol at the bottom of the page. It should be green if the connection is active, and grey when it is inactive.

5. Once the connection has been established, the device is ready to transmit.

To disconnect, navigate to the connection page above and click on "**Off**" and then "**Apply**".

NOTE: If the LED on the modem doesn't become a solid green for a prolonged period of time, try moving the device to a more open area with better cellular reception.

J. Care and Maintenance

Cleaning

CAUTION: Disconnect the T-STAT® system from AC power prior to

WARNING: Do not autoclave, gas-sterilize, or immerse the T-STAT® system.

- Disconnect the power cord before cleaning
- Use a soft cloth and mild, non-abrasive cleaners on the touch screen display. Scratches on the display screen may impair proper operation.
- Do not immerse.
- Do not allow fluid to enter the connection port on the front of the monitor. Fluids and dried substances will impair light collection, and may impart color to the returning light, which may result in inaccuracies.
- Allow unit to dry completely prior to re-connecting AC power

Storage and Transport

- Do not drop.
- Do not store in humid condensing or wet environments.
- Short term exposure to -20C to +60C 5-95% RH is permissible
- For sensors storage we recommend the WHO recommendation of 15-25C Ambient.

K. Messages

Table 2 T-Stat® Messages

T-Stat® Message:	**Possible cause and course of action:**
Message: No Sensor	Insure that probe is connected to monitor. Insure that probe connector is rotated clockwise to its full extent. Insure that sensor is a T-Stat® sensor.
Message: Monitoring	All is well and T-stat is reading patient data.
Message: Acquiring	Monitor is loading in sensor calibration data
Message: Probe Expired	DO NOT USE SENSOR. The sensor has expired.
Message: Pause	Monitor is ready to capture and display incoming data.
Message: Check Sensor	Sensor may be improperly placed. Re-position sensor. Sensor may be picking up excess light from an external light source. Re-position sensor, external light source, or cover sensor to shadow it from room light. Tip of sensor may be obscured by blood. Remove sensor and clean tip.
Message: Check Contact	Sensor is not pointing toward tissue or the surface of tissue may be obscured by other matter between the sensor and the tissue. Re-position sensor. Surface of tissue may be bloody, reposition sensor.
Message: Contact Technical Support 1(346) 398-7828	Monitor condition sensed that requires Technical Support.

Appendix A: Measured Values

1. Normal Values

Tissue optical saturation has been measured in a number of clinical studies. However, the validity and significance of these normal ranges of values for human use has not been established.

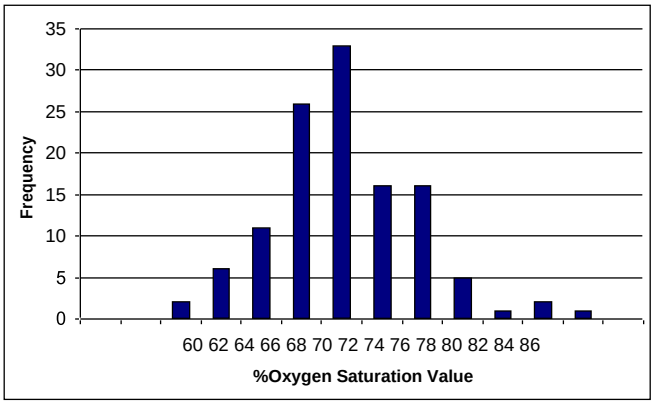
Healthy patients undergoing endoscopic exam have been studied under informed consent and IRB supervision. Patients were excluded if they were referred for suspected colonic ischemia or active colitis, or were hypotensive (systolic blood pressure below 90 mmHg). A total of 786 measurements in oral and GI system tissues were performed in 111 healthy patients. Normal values are as follows:

Table A.1 T-Stat® mucosal oxygenation values measured in healthy patients

Region	**Oxygenation** (Mean +/- SD)	**Number of Subjects** (n)	**95% C.I.**	**Reference**
Buccal Mucosa	77% +/- 3%	(n=21)	71-83%	6
Colon	69% +/- 4%	(n=40)	61-77%	6
Small Intestine	71% +/- 3%	(n=10)	65-77%	6
Stomach	70% +/- 4%	(n=5)	62-78%	6
Esophagus	68% +/- 4%	(n=10)	60-76%	6

These values are normally distributed, as shown for the values measured in the colon[6]

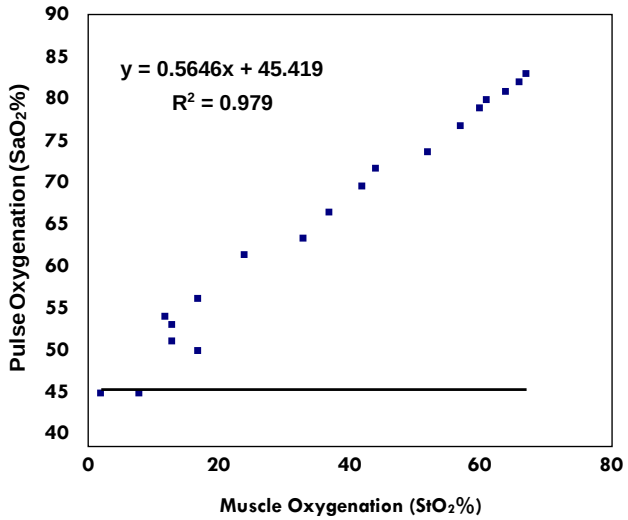
Figure A.1 Distribution of T-Stat® measurements of mucosal tissue saturation is normal



2. T-Stat® Values During Hypoxemic Hypoxia (Low saturation):

During hypoxemia induced by mixture of room air with nitrogen (breathe down study) in a pig, the relationship between arterial blood oxygen saturation as measured by pulse oximetry (SaO_2%) and tissue oxygenation as measured by the T-Stat® tissue oximeter (StO_2%) in muscle is shown in Figure A.2. The relationship between pulse oximetry and tissue oxygenation during acute hypoxemia is linear.[6]

Figure A.2 Tissue oximetry versus pulse oximetry in a porcine hypoxemia model, measured in leg muscle



Note that during hypoxemia, the difference between SaO_2% and StO_2% in muscle is typically less than 35%, though this rises to as high as 50% during severe hypoxemia, likely due to myocardial dysfunction which leads to a mixed ischemic/hypoxemic condition.

3. T-Stat® Values During Ischemic Hypoxia (Low blood flow):

During local ischemia in human colon polyps, induced by either epinephrine injection or suture ligation, the following values have been measured.[5]

Table A.2. Human Colon Polyp Tissue Oxygenation During Ischemia

Polyp Intervention	**Oxygenation** (Mean +/- SD)	**No. of Tests** (n)
Normal	70% +/- 5%	(n=26)
Vascular Tie-Off	15% +/- 6%	(n=14)
Epinephrine Injection	13% +/- 5%	(n=16)
Control (Saline Injection)	75% +/- 4%	(n=5)

Note that during hypoxemia, with a normal pulse oximetry reading of 90-94%, the difference between SaO_2% and StO_2% in muscle raises to as high as 77% (well above the hypoxemia range of 15-35%). Thus, the difference between the pulse oximetry estimate of SaO2% and the tissue oximetry measure of StO2% may allow for discrimination of ischemia from pure hypoxemia.

4. Discriminating Between Ischemia, Hypoxemia, or mixed Hypoxia-Ischemia:

The predictive value of this feature has not been tested in prospective clinical trials. In animal and human studies, a difference between the pulse oximeter saturation (SaO2%) and tissue oximeter (StO2%) of <30% suggests hypoxemia, while a difference >35% suggests ischemia or mixed hypoxemia-ischemia.

Appendix B: Sensor Specifications

The T-Stat® was designed to operate with multiple interchangeable T-Stat sensors, including surface sensors, endoscopic sensors,

T-Stat® sensors undergo 100% testing at manufacture. This testing produces an internal certification file (registration file) that is stored on an internal EEPROM memory chip located in the connector of each tissue oximeter sensor.

Operating instructions for each of the sensors are provided in Section G of this manual. User-reparable errors are identified and displayed by the monitor system during measurement, including testing for sensor placement (proper total hemoglobin seen, light level appropriate), sensor movement (unstable total hemoglobin or unstable light levels), sensor failure (no or insufficient returning light), and insufficient or excess returning light.

Important:

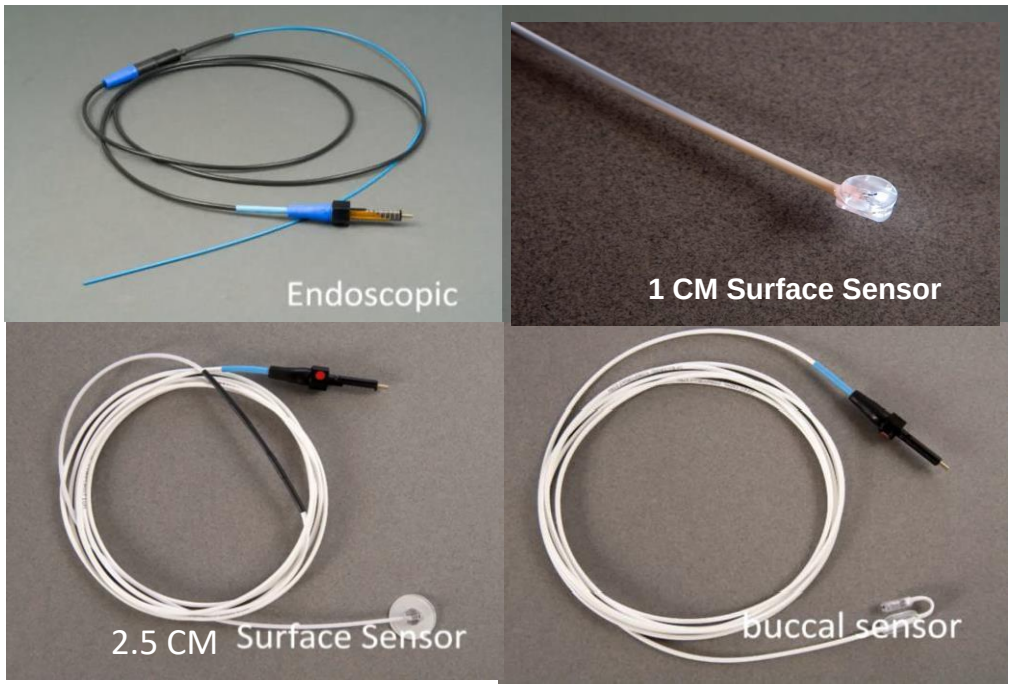
- There should be no pressure on the tissue at the placement site, as this may alter local blood flow and result in lower measured local saturation.
- The inner cheek surface should be free of blood. Free blood will be well oxygenated upon exposure to air, and result in a higher measured saturation.

The following sensors are available and have been approved by the FDA for human use.

Table 3 T-Stat® Sensor Types.

Sensor Number	Sensor Description
CTH-060-ORA M	Oral Sensor
CTH-060-SUR 2.5	2.5 cm Surface Sensor
CTH-060-SUR 1	1 cm Surface Sensor
CTH-060-END 2M	Endoscopic T-Stat® 2 m Catheter

Figure B.1 Four Basic Sensors



T-Stat® Sensor Specifications applicable to all sensors

1. Physical Specifications

Length:	3 m Long
Weight:	2 oz (60 g)

2. Optical Specifications:

Connector Output:	Fiber optic return line
Connector Input:	Internally-current-limited electrically-isolated 5v electrical source
Connector:	Male, Type 1 Spectros Light-Jack Connector
Light Output:	Non-laser broadband LED source Visible wavelength range (420-700) nm Luminous Intensity 12.9 cd TYP

3. Electrical/Emissions Specifications:

Input Voltage:	5V DC Electrically isolated
Power Required:	500 mVA (typical)
Battery:	Back-Up
Fuse:	None
Patient/Operator Protection:	Isolated 5V DC supply to sensor socket Dual current limit resistor (socket and sensor)
Memory	Internal EEPROM 1kB memory, with the following information: – Lot Number – Serial Number – Mfg Date – Sensor Name – Sensor Type – Compatibility Version – Expiration Date – Expiration Flag – Reuse Flags – Concentration and/or wavelength calibration factor
Approvals:	Tested with T-Stat 2.0 to the following specifications: UL 2601-1 ; EN60601-1(2005) Class 1, Type BF, continuous operation ; IEC 60601-1-2 (2007),

4. Operating Specifications:

Environment:	Intended for Indoor Hospital Use 5-35 degrees Celsius 5%-95% humidity (non-condensing)
Start-Up	Warm-up and self test requires up to 2 minutes

5. Sensor Specifications:

Sterile	Sensors supplied sterile for single use.

6. Storage Specifications:

Temperature/humidity range – not to exceed	-20-60 degrees C 5-95% RH
Storage	We recommend WHO recommendation of 15-25C Ambient. Temperature can vary up to the -20 to +60C limits so long as long-term average is 25C or less.

Appendix C: Self-Test and Errors

The T-Stat® Tissue Oximeter performs comprehensive self-test upon power-up. This test consists of a verification of constancy of the program software, standards, algorithm, and support files, validation of the algorithm software using a known set of testing standards, and operation and functionality of the hardware. An error in any of these tests will produce a FATAL ERROR message at power-up.

After the internal operating system is loaded (Windows 10 Embedded), the following tests are performed:

- Software Versions.

  The version of each routine is checked for consistency with the initial installation and/or software updates.

- Software Integrity

  A bit by bit comparison is performed to ensure that each software, script, and database component has not been altered since installation.

- Algorithm Integrity

  A full test of the data handling and calculation using an internal database to ensure calculation is accurate.

- Storage Maintenance

  A self-cleaning utility for data saved (if storage option has been selected)

- Hardware Integrity

  Test of hardware communications and operation. A full functional testing of the optical hardware is deferred until "Calibration" stage of monitoring.

- Ongoing Error Trapping

  Testing for errors is performed at all stages of operation, and errors are trapped and handled, with display to the user of any cause for failure from which the system cannot recover.

Appendix D: T-Stat® 2.0 Specifications

T-Stat® 2.0 Specifications

1. Physical Specifications

1.1 Size:	11" Wide x 5.5" High x 8.5" Deep
1.2 Weight:	6 lbs. (2.7 kg)
1.3 Color:	Light Grey Case
1.4 Front Panel:	HDMI TFT Module w/ USB-HID Resistive Touch Type SPEC-1 Female Sensor Socket
1.5 Rear Panel:	Power switch Power socket and fuse access USB (Type II) data port Wi Fi antenna connection
1.6 Top:	Recessed Carrying Handel

2. Value and Accuracy Specifications:

2.1 Values Displayed

StO2%
rHemoglobin (relative hemoglobin)
Signal intensity
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) ± 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. Informational Warning Specifications

Warning levels	
Low StO2%:	User settable, 0-99% (preset Low 40%)
High StO2%:	User settable, 0-99% (preset High 95%)
Low Heme:	rHemoglobin < 5 uM (analysis suppressed, "no tissue" error)
High Heme:	rHemoglobin >100 uM ("bloody tissue" error)
Too Dim:	Signal < 500 counts in 500 ms
Too Bright:	Signal > 4000 counts in 5 ms
Unstable:	Signal strength changes >20% between sample
Result Blanking:	Invalid data x 6 seconds
(blanks to "- - -")	Out of range data x 6 seconds No tissue seen x 6 seconds
Warning Indicator:	Red/Yellow/Green Status Indicator White error message on flashing red background Audible alarm (silenceable)
Audio Warning Silencing:	Audible alarm silenced x 2 min or 5 min 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 Visual display of self-test progress Validation of software versions Validation of software integrity Validation of algorithm successful operation Test of optical spectrometer Test of optical socket reader Test of memory storage space Test of microprocessor system Red/Green self-test success indicators Halt at Start up if errors in self-test

4. Microprocessor Specifications:

Operating System:	Windows 10 64-bit and Visual Studio [VB.Net] 201
Internal Memory:	4 GB
CPU:	Intel Celeron N3350
Oximetry Software:	T-Stat® operating software 1.05.022.00 (clinical release CR4) or later

5. Optical Specifications:

Sensor Input:	150 uM fiber return line
Sensor 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 Electrically isolated US/Canada: Green-dot (hospital grade) 3 m grounded cord
Power Required:	70 VA (typical)
Battery:	11.25V 6400mAh 72.0Wh Lithium Ion Rechargeable Smart Battery Pack
Fuse:	T3A/250V
Patient/Operator Protection:	Medical-grade Isolated power supply Isolated DC supply to sensor socket Dual-Fuse Power Supply (external (user-replaceable), and internal fuse) Dual current limit resistor (limit resistor in socket AND limit resistor in each sensor)
Approvals:	UL 2601-1, IEC 60601-1-2:2014Ed 4, IEC 60601-1 :2012 Class1, FCC 47CFR PT 15 SPT B, Rated IPX1

7. Operating Specifications:

Environment:	Intended for Indoor Hospital Use 5-40 degrees Celsius 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 Optional data export to external disk via USB port Optional analysis scripting for user-specific analysis

9. Compatible sensors:

Sterile	T-Stat sensors are ETO sterilized for single use.
Sensor Types:	CTH-060-REC --- 5mm T-Stat® sensor CTH-060-END .5M--- Endoscopic T-Stat® Catheter CTH-060-ORA --- Oral T-Stat® Sensor CTH-060-SUR 1 & 2.5 CM – Surface Sensor

Appendix E: EMC Information

Warning: MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following tables.

Warning: The use of ACCESSORIES, transducers and cables other than those provided by Spectros and specified, in this manual, may result in increased EMISSIONS or decreased IMMUNITY of the T-Stat® 2.0 system.

The following tables apply to all T-Stat® 2.0 sensors offered by Spectros

Table 1

Guidance and manufacturer's declaration – electromagnetic emissions		
The T-Stat®2.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the T-Stat® 2.0 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The T-Stat® 2.0 uses RF energy for its internal function and optional Wi Fi or cell modem. Therefore, its RF emissions without the RF options are very low and are not likely to cause any interference in nearby electronic equipment. Likewise, the emissions outside the Wi Fi or Cell modem bands are very low when these options are available.
RF emissions CISPR 11	Class b	The T-Stat® 2.0 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The T-Stat® 2.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the T-Stat®2.0 should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the T-Stat®2.0 requires continued operation during power mains interruptions, it is recommended that the T-Stat® 2.0 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity

The T-Stat® 2.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the T-Stat®2.0 should assure that it is used in such an environment.

IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the T-Stat®2.0, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $D=1.2xP^{.5}$ $D=1.2xP^{.5}$ 80 MHz to 800 MHz $D=2.3P^{.5}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as deter-mined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the is used exceeds the applicable RF compliance level above, the T- Stat® 2.0 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the T-Stat® 2.0.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Appendix F: Warranty Information

The Spectros T-Stat [2.0] system is warranted free of manufactured defects for one year from the date of delivery to the customer. Spectros MDI warrants the Product to be free of defects in material or workmanship resulting in the Product's failure to meet Spectros MDI's published specifications at the time of delivery.

The customer's sole and exclusive remedy with respect to this warranty shall be to repair or, at Spectros' sole discretion, replace the units that prove to be defective in material or workmanship.

If Spectros determines that the Product is defective and that the claim was made within the warranty period, Spectros shall satisfy its obligations under this warranty by repairing or replacing the Product and returning it to the Customer at Spectros' expense. If Spectros determines that the Product is not defective, or that the claim was not made within the warranty period, the Customer shall be responsible for all fees related to shipping, and Spectros' handling, diagnostics, and repair of the system.

Limited Warranty.

(a) THE T-STAT® SHALL BE DELIVERED FREE FROM MANUFACTURING DEFECTS, AND SPECTROS MDI WILL REPAIR OR REPLACE ANY PART IDENTIFIED AS DEFECTIVE TO SPECTROS BY THE CUSTOMER FOR THE FIRST YEAR FOLLOWING DELIVERY OF THE T-STAT®.

(b) SPECTROS SHALL NOT BE RESPONSIBLE FOR ANY FAILURE OF THE T-STAT® SYSTEM THAT IS DUE TO NEGLECT, MISUSE, OR ABUSE.

(c) TO THE KNOWLEDGE OF SPECTROS MDI, THE T-STAT® TECHNOLOGY DOES NOT INFRINGE OR MISAPPROPRIATE THE PATENT RIGHTS OR CONFIDENTIAL INFORMATION RIGHTS OF ANY THIRD PARTY. SUPPLIER MAKES NO OTHER REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, AGAINST INFRINGEMENT OR MISAPPROPRIATION OF ANY THIRD PARTY PATENT OR CONFIDENTIAL INFORMATION RIGHTS, NOR UNDERTAKES ANY INDEMNITY OBLIGATION IN RESPECT THEREOF.

(d) EXCEPT FOR THE LIMITED WARRANTIES PROVIDED IN THIS SECTION THE T-STAT® IS PROVIDED WITHOUT WARRANTY. SPECTROS EXPRESSLY DISCLAIMS ALL IMPLIED WARRANTIES, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Indemnity.

THE CUSTOMER AGREES TO INDEMNIFY AND HOLD THE SUPPLIER HARMLESS AGAINST ALL CLAIMS OF THIRD PARTIES AND RELATED LOSSES, LIABILITIES AND EXPENSES (INCLUDING ATTORNEYS' FEES AND DISBURSEMENTS) ARISING FROM THE CUSTOMER'S USE OF THE T-STAT® SYSTEM.

Limitation of Liability.

(a) NOTWITHSTANDING ANY OTHER PROVISION CONTAINED HEREIN, THE MAXIMUM LIABILITY OF SPECTROS TO THE CUSTOMER, ANY AGENT OR CUSTOMER, THE CUSTOMER'S CUSTOMERS, OR ANY OTHER PERSON FOR DAMAGES ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE USE OF THE T-STAT® SYSTEM, WHETHER SUCH LIABILITY ARISES FROM ANY CLAIM BASED UPON CONTRACT, WARRANTY, TORT OR OTHERWISE, SHALL IN NO EVENT EXCEED IN THE AGGREGATE, THE TOTAL AMOUNT PAID BY THE CUSTOMER TO SPECTROS HEREUNDER.

(b) IN NO EVENT SHALL SUPPLIER BE LIABLE FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, OR PUNITIVE DAMAGES OF ANY KIND OR FOR THE LOSS OF REVENUE, LOSS OF BUSINESS OR OTHER FINANCIAL LOSS OR THE COST OF SUBSTITUTE GOODS OR SERVICES HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY ARISING OUT OF THIS AGREEMENT. THESE LIMITATIONS SHALL APPLY NOTWITHSTANDING THE FAILURE OF ANY LIMITED REMEDY PROVIDED HEREIN.

Purpose of Product.

This Limited Warranty is given on the basis that Spectros MDI's T-STAT® system is designed and intended solely for the purpose of providing patients and physicians with information concerning regional changes in oxygenation. Spectros MDI makes no claim or warranty express or implied, related to the use of the Spectros T- STAT® system as a test for a patient's overall condition or any specific disease.

Appendix G: Service and Disposal Information

Obtaining Service for your T-Stat® system.

For authorized service of your T-Stat® system, contact:

Customer Service Department
Spectros Medical Devices Inc.
2211 Norfolk St #1110
Houston, Texas 77098
Phone: (650) 851-4040

Email: customerservice@spectros.com
Website: www.spectros.com

When returning a T-Stat® system, ship it prepaid in the original packing materials. It is important to use the original container and packing material to prevent damage to the unit during shipping. Spectros will not assume responsibility for damage caused in shipment if the customer does not use original shipping materials. Shipping materials can be obtained by contacting Spectros' Customer Service Department.

Before shipping, call Spectros' Customer Service Department and obtain a Return Materials Authorization (RMA) number. When returning a system, include the following information:

Description of problem
RMA number
Contact information for person to contact at your facility
Return address

Unauthorized Repair

There are no user-serviceable components inside the T-Stat® monitor. Do not attempt to perform any service or tamper with the warranty seal unless you have been authorized to do so in writing by Spectros MDI. Performing unauthorized service or repairs during the warranty period will void the product's warranty.

Disposal

Sensors should be disposed of as medical waste per local regulations
Monitors can be returned to Spectros or Distributor for appropriate disposal unless local regulations allow for alternate method

References:

1. Levesque BM, Pollack P, Griffin BE, Nielsen HC. Pulse oximetry: what's normal in the newborn nursery? Pediatr Pulmonol. 2000 Nov;30(5):406-12.

2. Gries RE, Brooks LJ. Normal oxyhemoglobin saturation during sleep. How low does it go? Chest. 1996 Dec;110(6):1489-1492.

3. Ladakis C, Myrianthefs P, Karabinis A, Karatzas G, Dosios T, Fildissis G, Gogas J, Baltopoulos G. Central venous and mixed venous oxygen saturation in critically ill patients. Respiration. 2001;68(3):279-285.

4. Macmillan CS, Andrews PJ. Cerebrovenous oxygen saturation monitoring: practical considerations and clinical relevance. Intensive Care Med. 2000 Aug;26(8):1028-1036.

5. Friedland S, Benaron DA, Parachikov I, Soetikno R. Measurement of mucosal capillary hemoglobin oxygen saturation in the colon by reflectance spectrophotometry. Gastrointenstinal Endoscopy. 2003;57(4):492-497

6. Benaron DA, et Al. Continuous, noninvasive, and localized microvascular tissue oximetry using visible light spectroscopy. Anesthesiology. 2004 (In Press)

[End of Manual]