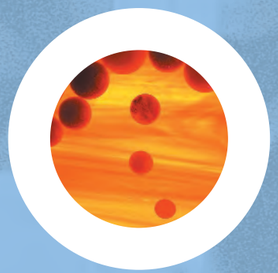
oxiplexTS™

Near Infrared,

Non-Invasive,

Tissue Spectrometer

A non-invasive, real-time monitor of precise tissue oxygenation and hemoglobin concentration



The ISS OxiplexTS is a non-invasive, real-time monitor of blood oxygen saturation and hemoglobin concentration in tissue and in the brain. A measuring sensor, delivering a low power level of infrared light, is placed on the tissue under examination and the physiological parameters are displayed in real time on the computer screen. Several sensors are available to the research physician, making the OxiplexTS suitable for a wide range of clinical research applications. Using the dual channel option, measurements can be acquired simultaneously from two different regions of the body. The optical fibers can be as long as ten meters, making the ISS OxiplexTS useable in a variety of environments: as a bedside monitor in the recovery room; as an instrument in the intensive care unit or in the operating room; or, simply, as a control tool in the vascular laboratory, in the hyperbaric chamber, or in the sports medicine clinic.

The ISS OxiplexTS is unique and novel for its capability to determine the absolute level of oxygenation in the tissue, rather than relative changes in the level of oxygenation, as provided by other available near infrared oximeters. Moreover, OxiplexTS complements the pulse oximeter in several applications and addresses its limitations whenever information about the tissue oxygenation and perfusion is required. Since its readings are independent of the arterial blood pressure, unlike the pulse oximeter, OxiplexTS works even in the case of cardiac arrest, poor tissue perfusion and hypothermia. Likewise, flickering room light does not affect its measurements.

OxiplexTS is versatile and easy to use by the laboratory technician and the research nurse. The instrument can be interfaced to other devices for synchronous logging of data received from up to four independent instruments; data provided by the external devices are then displayed and plotted with the data generated by the tissue oximeter. Data are displayed in either numerical mode or graphical mode and are stored in the computer under the subject's personal file. Files can be retrieved at a later time, and custom reports can be generated for the researcher's examination.

absolute measure

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OxiplexTS Operating Principle

Near-Infrared Spectroscopy (NIRS) , a non invasive diagnostic tool, offers ideal features for the assessment and monitoring of oxygenation in tissues such as brain and muscle.

Near-Infrared ligh penetrates several centimeters into tissues, passing through bony structures . NIRS enables continuous real time measurements of changes in the hemoglobin oxygenation state and blood volume, thus providing information on tissue oxygenation and hemodynamics.

The ISS OxiplexTS uses near infrared light at two different wavelengths (690 nm and 830 nm) selected to maximize the absorption contribution of oxygenated and deoxygenated hemoglobin while minimizing the absorption contribution of other compounds.

The modulated light intensity at the two wavelengths is carried from the instrument to the measuring sensor by fiber optics; a collector fiber carries back to the instrument a portion of the light that traversed the tissue back to the instrument.The emitter fibers delivering light to the tissue are positioned on the sensor at multiple distances(usually four) from the collector fiber.

Figure 1

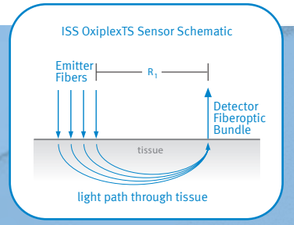
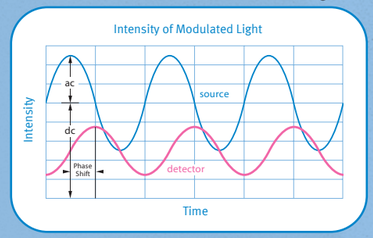


Figure 1 shows the schematic of the OxiplexTS sensors. Emitter fibers deliver light to the tissue. As a result of scattering, some of the light travels through the tissue along the paths shown and is collected by the detector fiberoptic bundle. R1 is the emitter-detector distance from emitter fiber 1 to the detector fiber bundle. Typically, eight emitter fibers are used, (four for each wavelength), but only four are shown here for simplicity.

Figure 2 shows the measured parameters of a modulated light beam. AC is the amplitude of the modulation. DC is the average intensity. The phase shift between the two signals is also shown. The blue line represents the light entering the tissue; the red line represents the light which traversed the tissue.

Figure 2



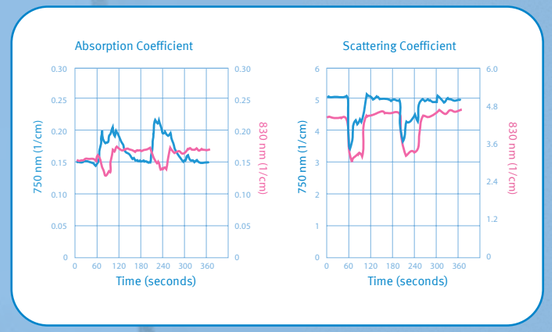


Figure 3

Applying the Theory of Photon Migration, the absorption and scattering coefficients are determined from the measured intensity (AC or DC) and phase shift. The ISS patented technology measures the absolute level of absorption and scattering coefficients of tissues (see **Figure 3**).

As a result, the OxiplexTS provides absolute values of tissue hemoglobin saturation in real time. Thus, the instrument provides other important physiological quantities, such as total hemoglobin concentration, and the individual concentration of oxy- and deoxy-hemoglobin, which form the basis for the measurement of tissue hemodynamics.

The unique ability to separate scattering from absorption places the ISS OxiplexTS above all other NIRS oximetry technologies.

Tissue Oximetry: Absolute Versus Relative

There are several commercial tissue oximeters available in the market place today. With the OxiplexTS, ISS has surpassed other available technologies by developing a device that is capable of determining the absolute values of hemoglobin concentrations as opposed to changes in concentration, which remain relative to a zero line. The operational differences between the ISS OxiplexTS and other tissue oximeters are summarized in the table.

	ISS OxiplexTS	Other Tissue Oximeters
Method of Operation	Uses modulated light beam probing the tissue and frequency-domain technique	Use continuous-wave light beam probing the tissue
Scattering Coefficient	Measured	Assumed
Absorption Coefficient	Measured	Measures changes
Deoxygenated Hemoglobin	Measured	Measures changes
Oxygenated Hemoglobin	Measured	Measures changes
Total Hemoglobin	Measured	Measures changes
Tissue Hemoglobin Oxygen Saturation (SO2)	Measured	Measures changes

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Research Applications

Peripheral Vascular Disease

In its most common form, Peripheral Vascular Disease (PVD) is a narrowing of the vessels carrying blood to the muscles in the legs and arms. Most patients report experiences of pain in the extremities (usually lower limbs), which is relieved with rest. The pain is a manifestation of inadequate blood flow and oxygen delivery to the exercising muscle due to vascular luminal narrowing and blockage. OxiplexTS, by monitoring the tissue oxygenation, provides the research physician with unique information about the perfusion of the muscle, information that is not obtainable using other techniques such as the pulse oximeter. In fact, the pulse oximeter probes the arterial oxygenation level, which can still be at acceptable levels in patients suffering from PVD.

Early diagnosis of PVD significantly improves a patient's quality of life. Through monitored treatment and the introduction of a few changes in lifestyle, such as exercise and following special dietary guidelines, the patient is able to control the effects of the disease. OxiplexTS provides indispensable information during the observation phase in monitoring and assessing the patient's improvements.

Peripheral Vascular Disease research was conducted at the Dallas VA Medical Center. The clinical study involved conducting measurements on calf muscles during rest and exercise to determine early presence of vascular insufficiency. Patients participated in exercise stress tests to note the changes in their physiology prior to exercise, during exercise, and post exercise.

Figure 4 compares the percentage of Hemoglobin Oxygen Saturation between a healthy subject and a patient with PVD. The sensor was applied on a calf muscle and data were collected before, during, and after a stationary bicycle exercise. The shaded areas indicate periods of exercise.

Figure 4

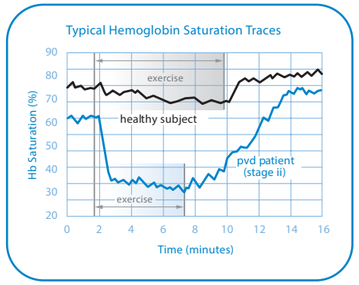


Figure 5

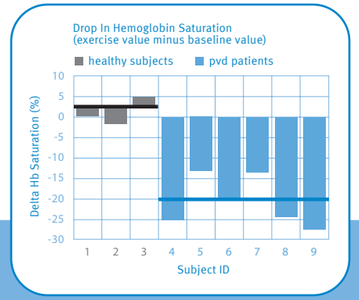
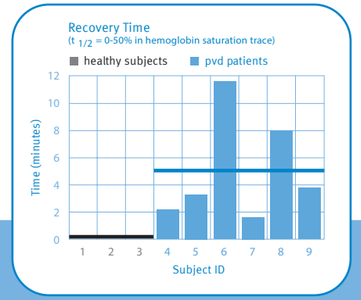


Figure 6



In Figures 5 and 6, the results show a drop in the Hb saturation caused by exercise and a significantly larger recovery time in the PVD patient compared to the healthy subject. The horizontal lines indicate the average values.

Brain Oxygenation

With 20% of oxygen consumption occurring in the human brain, any deficiency in oxygen supply may result in injury. While the causes leading to hypoxic or ischemic conditions in the brain may differ (high altitudes, sleep apnea, difficult childbirth, heart attack, etc.), adequate brain oxygenation levels are necessary for brain homeostasis.

Sports Medicine

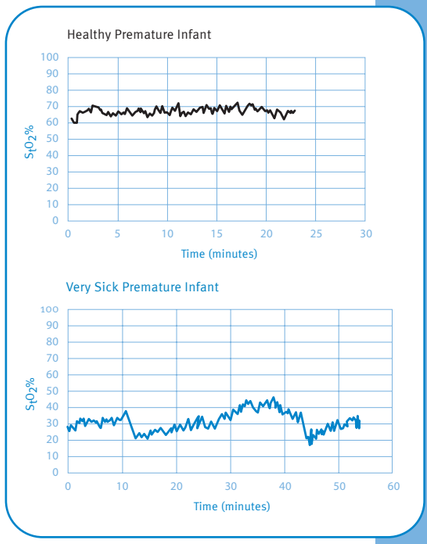
The ability to characterize the muscular performance of athlete's before, during, and after exercise leads to vital information in the field of sports medicine. These measurements may monitor the muscle tissue oxygenation and hemodynamics and assist in determining an athlete's exercise capacity, assessing the efficacy and validity of training programs, and tracking an athlete's progress while in rehabilitative conditioning.

Other Exploratory Areas

Several areas may benefit from the monitoring of the absolute values of tissue oxygenation, especially when pulse oximetry is not applicable because of the irregularity, or the lack of, the heartbeat, and in all the cases where the tissue oxygenation, and not the arterial oxygen saturation, is the parameter of interest.

- Anesthesiology
- Cardiothoracic Surgery
- Vascular Surgery
- Neurosurgery
- Monitoring Brain Oxygenation in OR/ER
- Women's Health
- Obstetrics
- Neonatal Care
- Sleep Apnea
- Attention Deficit Disorder
- Tumor Oxygenation
- High Altitude Physiology
- Tissue Oxygenation in Hyperbaric Chambers
- Ergonomics

Figure 7



Measurements of neonatal cerebral hemodynamics were conducted at Stanford University Medical Center. The clinical conditions of the infants ranged from healthy/stable to critically ill. Cerebral saturation for the healthiest infant was high and stable while the saturation for the sickest infant was low and unstable. Figure 7 shows Cerebral Tissue Oxygen Saturation (StO2%) versus time (minutes) for a healthy infant and an ill infant. The variability in saturation for the sick infant indicates an unstable struggle among oxygen supply, demand, and blood flow. The comparative stability for the healthy infant indicates a stable and adequately oxygenated brain. OxiplexTS is pivotal in providing brain hemodynamic data even in the most critical cases, where the pulse oximeter may not function properly due to irregularities in the pulse rate of the baby.

OxiplexTS and Accessories

Oxiplex TS

The OxiplexTS is available as either a single-channel or a dual-channel system. The dual-channel system can be used for simultaneously acquiring measurement on two different locations. Each probing channel is equipped with 8 infrared light sources (four emitting at 690 nm and four emitting at 830 nm; other wavelengths are available upon request) and one detection channel including a selected light detector (photomultiplier tube) with related optics and electronics. Various optical probes can be coupled to the oximeter for specific medical research applications.

Interface Module

Up to four analog signals generated by external devices (pulse oximeter, blood pressure monitor, breathing rate monitor, inspired gas mixture monitor) may be sent to OxiplexTS and displayed along with oximetry measurements. This allows for the correlation of tissue oximetry data with a wide array of other measurements.

Sensors

There are several sensors available for the OxiplexTS. Custom designed sensors are available upon request for special applications.

Standard Rigid Sensor

Made of a lightweight plastic material for durability and easy maintenance, the sensor is equipped with eight emitters and a detector for data collection. It features four emitter positions with user-selected emitter-detector distances. Velcro ®straps are attachable to the sensor for use during motion measurements.

Suggested Applications:
Muscle oxygenation

Flexible Low-Profile Sensor

Featuring a flexible rubber molded construction, the low-profile sensor is designed for measurements on curved surfaces such as the head. The sensor has four emitter positions (eight emitters) with emitter-detector distances ranging from 1.5 cm to 5.0 cm. The sensor may be held in place by either Velcro® straps or double-sided adhesive pads. Right hand and left hand versions are available for simultaneously monitoring two nearby positions.

Suggested Applications:
Brain Oxygenation,
Sleep Apnea,
Cerebral Hematoma

Flexible Low-Profile Mini Sensor

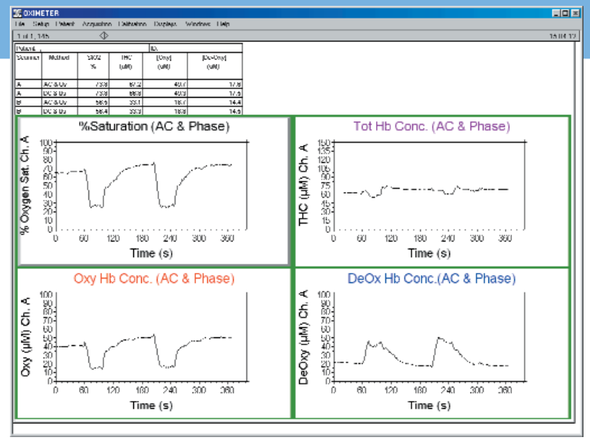
The low-profile, flexible mini sensor has been optimized for infant studies. The probe has four emitter positions (eight emitters) with emitter-detector distances ranging from 1.5 cm to 4.0 cm. Right hand and left hand versions are available for simultaneously monitoring two positions.

Suggested Applications:
Neonatal Care,
Cerebral Hematoma

Software

OxiTS Software Package

OxiTS, the data acquisition and processing software package powering the instrument, features a flexible and modular design suitable for both the researcher looking at variations in the tissue optical parameters and the routine practitioner who acquires data for a clinical study using a custom protocol. The software allows the user to visualize, in real time onlythe measured quantities of interest which span from the optical properties of the tisssue under examination to he hemodynamics parameters. OxiTS is built for the Window environment, plots displaying several parameters can be opened simultaneously and the user can switch beteen the pages. OxiTS includes feedback visual alarm signaling the user for an improper use of the instrument.



OxiTS in Graph Display Mode

Software Features

Quantities Measured

- Oxy- and Deoxy-hemoglobin concentrations
- Total hemoglobin concentration
- Oxygen saturation
- Absorption and scattering coefficients at each wavelength
- Intensity and phase shift values for each emitter

Data Acquisition

- Data Point Acquisition Rate:
  User selectable, adjustable rate, from milliseconds to minutes
- Duration of data recording session:
  Up to days
- Marker Button:
  Places a marker in the data log and on the graphs

Patient Information File and Record Storage

- All data collected is stored in files which may be replayed for review, or re-analyzed.
- The software includes conversion to ASCII format for export into spreadsheet software or other data analysis software.
- OxiTS includes patient and patient ID fields; patient notes and comments can be added; these notes are added to the data file for subsequent review/change.

Available Displays

Graph Display

Data are displayed either in numerical table format or in a convenient Graph Mode, where real time graphs of the hemodynamic parameters selected by the user from channel A and/or B are displayed. Up to four graphs per page, with three data traces per graph can be displayed. Multiple pages can be opened simultaneously. The axis scales and colors are user configurable.The user can create custom graphic pages to display. any data, induding data provided by other instruments for comparison with the data collected by OxiplexTS. For instance, the OxiplexTS data can be displayed in real time along with data provided by a pulse oximeter, a blood pressure monitor, an inspired gas mixture monitor, or a breathing and heart rate monitor.

Feedback Graph Display

Improper contact of the sensor with the tissue is signaled to the user by the Feedback Graph Display plot. This plot may also indicate a lack of uniformity within the tissue being measured.

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CAUTION: Investigational device. Limited by Federal (or United States) law to investigational use. The ISS OxiplexTS is presently used for research only.

Information furnished by ISS is believed to be reliable. However, no responsibility is assumed for possible inaccuracies or emissions. ISS reserves the right to change the design, specifications, etc., of the product at any time without notice.

OxiplexTS is covered by US Patents numbers: 5,212,386; 5,492,118; 5,497,769; 5,772,587; 6,078,833, 6,192,261 B1. Other US and foreign patents pending.