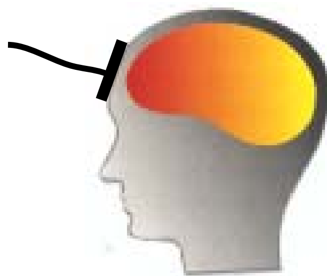
TOS-96 Brain Oximeter
TOSTEC CO., LTD



This purpose of this Web site is to provide an overview of the TOS-96 Brain Oximeter

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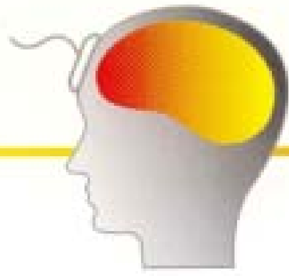


TOS-96

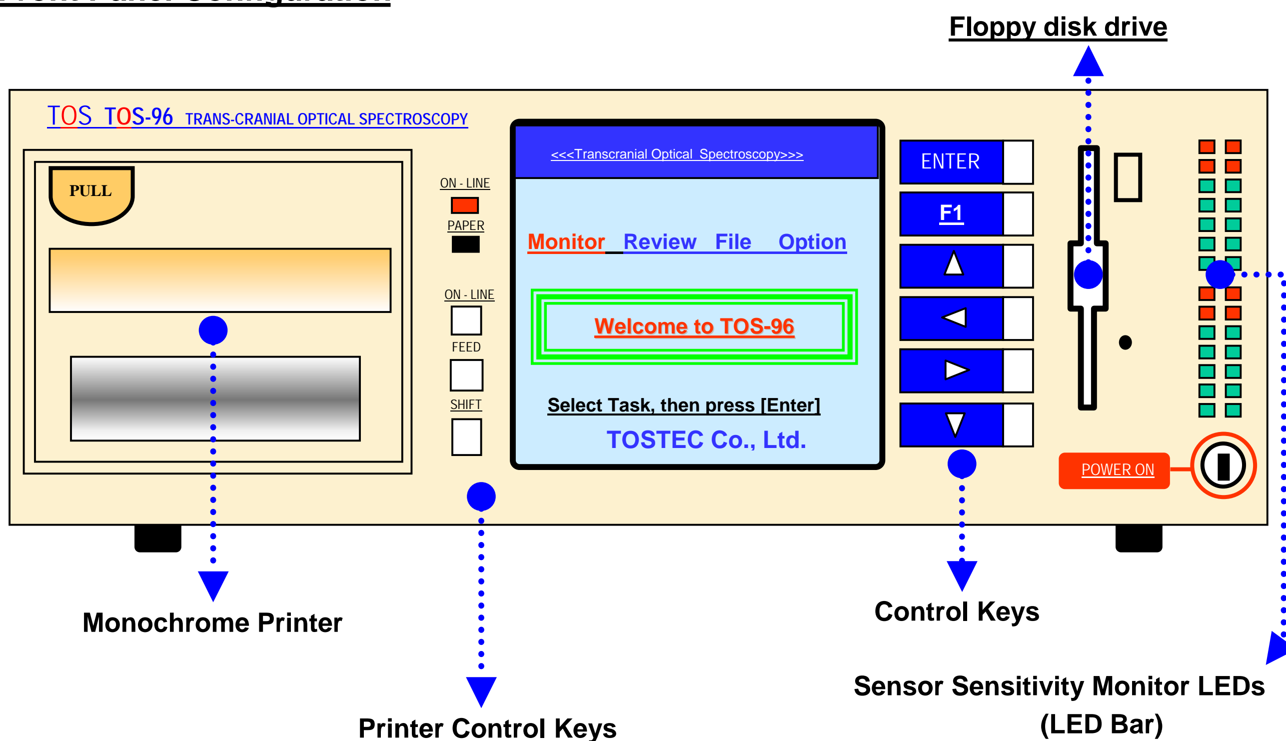
Dual Channel, Non-invasive Microvascular
Cerebral Oxygen Saturation Monitor

Near Infrared is watching a cerebral oxygen condition.

- Dual Channel capabilities enables simultaneous monitoring of both hemisperes.
- Cerebral blood volume index of the brain tissue underneath the sensor is mesurable and displayed in real time.
- Built-in computer with 1.44MB disc drive and 420MB hard disc enables data analysis.
- Integral printer for data print out is installed.
- Re-usable sensor is guaranteed for 750 hours of continuous use.
- Sensor calibration unit is attached.

TOSTEC Tokyo, Japan

TOS96 Front Panel Configuration



Description of TOS-96 Front-Panel Components

Printer :
Monochrome thermal transfer printer that prints monitoring information on- and off-line.
＊ chart speeds : 3cm/10 min.

ON-LINE lamp :
Lit when the internal printer is set to on-line printing.

PAPER :
When lit, indicates that the printer paper should be replaced.

ON-LINE :
Used to turn on-line printing on and off.

FEED :
Used to feed the printer

SHIFT :
Unused on the current model.

Color monitor :
Displays monitoring information.

Enter :
Used to execute the selected function.

F1 :
Used to enter a Yes response.

∆.◁ , ▷ and ∇ :
Move the red window used to select function and numerical values.

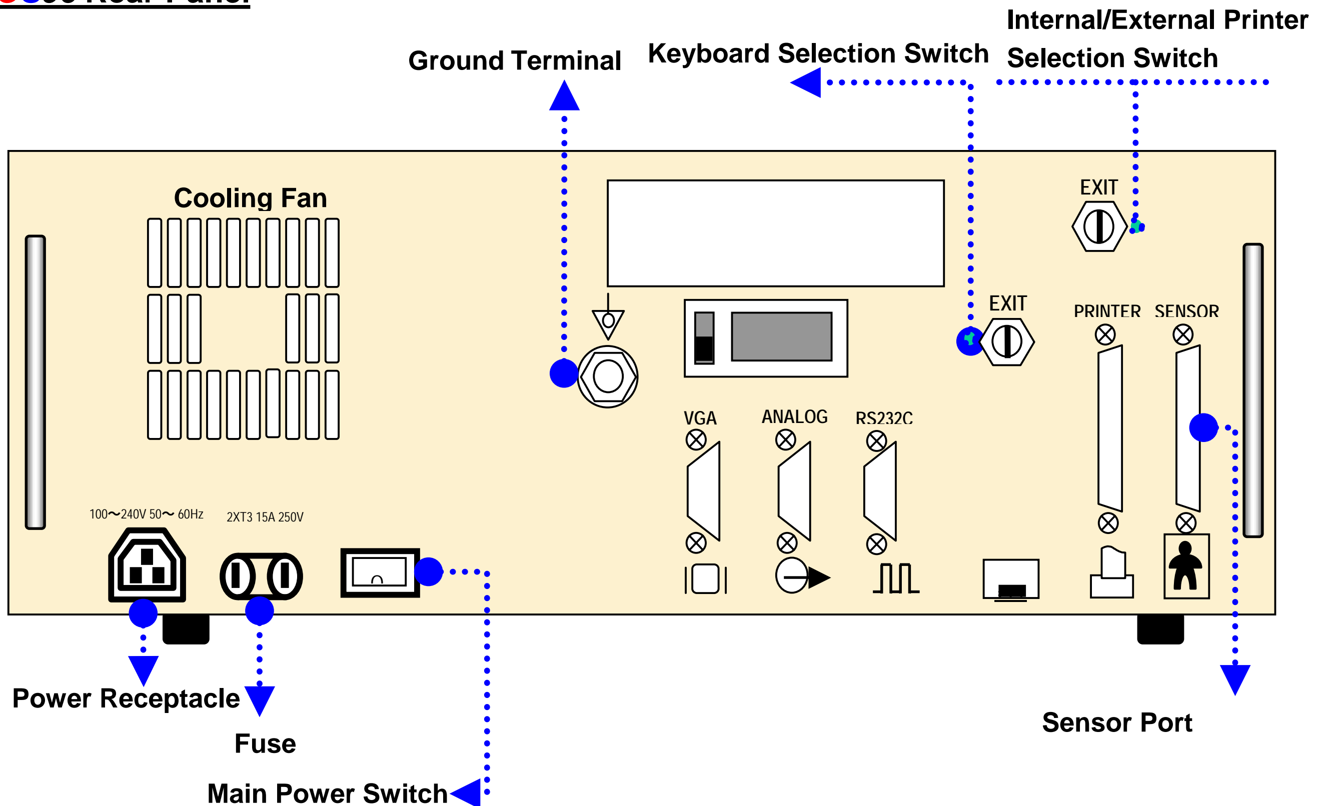
Esc :
Used to stop the execution of a function.

FD Drive unit :
Uses windows (DOS-V)-formatted 3.5-inch, 1.44MB floppy disks.

Sensor sensitivity monitor LEDs (LED bar):
Indicate the operating status of the sensors and the monitor status.

Power :
Used to turn power to the unit on and off.

TOS96 Rear Panel



Description of TOS-96 Front Panel Components :

1 : Cooling fun :

2-1 : Power receptacle : The includes power cable connected here.
Connects to the nearest electrical outlet for medical devices.

2-2 : Fuse : Please do not replace the fuse. Doing so may dangerous.

2-3 : Main power switch : Press "O" to turn the unit on and "I" to turn it off.

3 : Ground terminal : Connect to the nearest ground point.

4 : VGA Port : For connecting an external monitor.

5 : Analog out port : 0-10V/0-100%.

6 : RS232C output port : Port for digital output.

7 : Hour meter (usage timer) : Total the number of hours that power to the unit has been turned on.

8 : Keyboard port : Please do not use without instructions from TOSTEC.

9 : Printer port : For connecting an ESC-type printer.

10 : Sensor cable connector port : For connecting external the included sensor cable and other side port should be connected to the sensor amplifier box.

11 : Printer selection switch : Used when an external printer is used.

12 : Keyboard selection switch : Please set slot se to the vertical position when monitoring is performed.

Non-invasive Direct and Continuous BRAIN OXIMETER *TOS96*

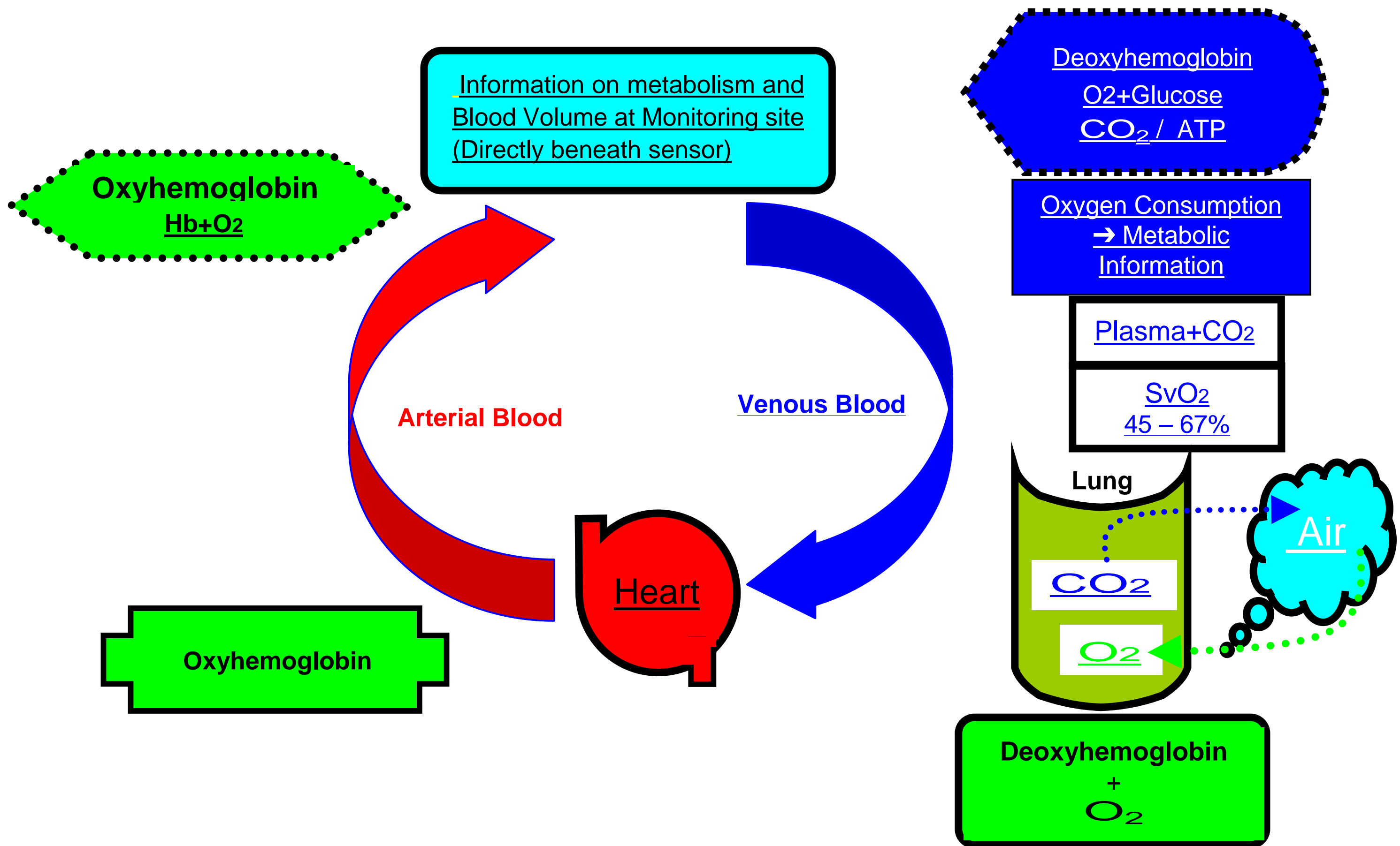
Non-invasive monitoring of Oxygen Saturation in the Brain and muscles : *TOS96*

rSO2：rSO2 (regional oxygen saturation) represents the balance between the oxygen supply to the capillaries directly beneath the sensor (monitoring site) and oxygen consumption at that sit. In other words, it provides information on metabolism at the monitoring site.

Estimated $rSO_2 = (0.25 \times SaO_2) + (0.75 \times SvO_2)$

Substituting the range of normal values for SaO2 (95-100%) and SvO_2 (45-67%) in this equation results in an rSO_2 values of between 57% and 75%.

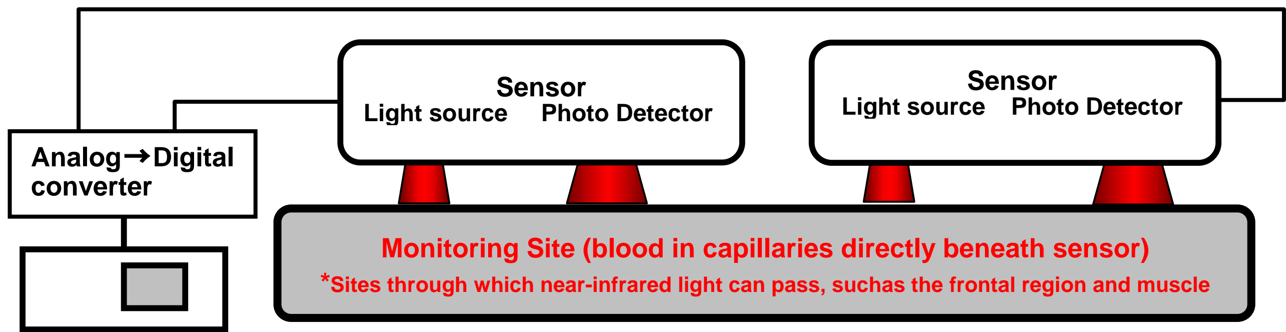
HbI represents the percentage change in blood volume at the monitoring site (this is not an absolute value)



Real-time monitoring of rSO2 (Oxygen saturation)
Real-time monitoring of HbI (percentage change in blood concentration.
Information on left-right differences.
Information on percentage change in oxyhemoglobin level
Information on percentage change in deoxyhemoglobin level

All in one system
Dual-channel monitor
Easy to operate
Reusable sensor
Long-term (24hr or longer), continuous monitoring
LED bar for monitoring sensor operating status
Sensor for adults, children, and muscle

BRAIN OXIMETER *TOS96*

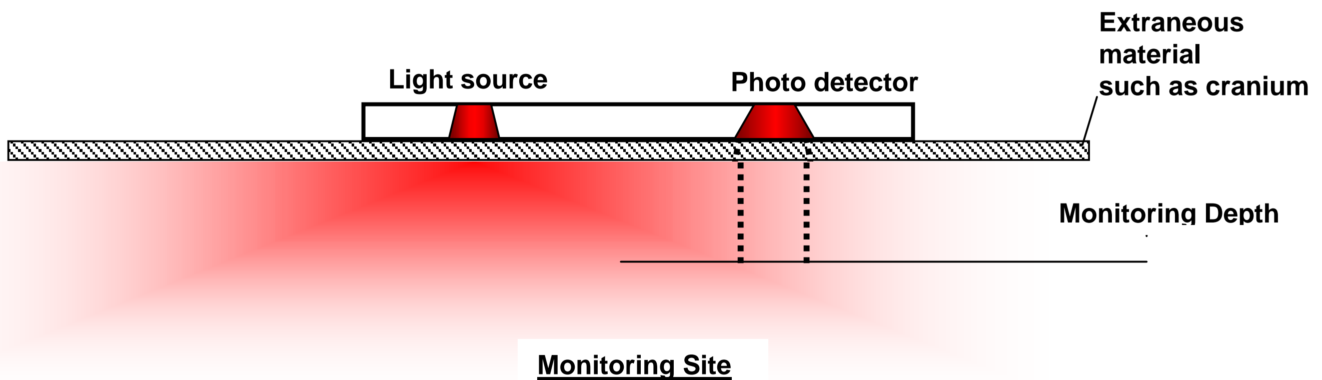


Non-Invasive Monitoring of Oxygen Saturation in the Brain and Muscles : *TOS96*

Measurement Principles of the TOS-96 Brain Oximeter

Near-infrared light at frequencies of 760nm and 850nm, which reacts specifically with deoxyhemoglobin and oxyhemoglobin , is projected onto the monitoring site from the LED light-source component of the sensor, which is attached over the monitoring site. The near-infrared light reacts with the deoxyhemoglobin and oxyhemoglobin at the site. With the light –source LED at its center, the near-infrared light propagates through the monitoring by continuous diffusion and dispersion.

As indicated in the schematic below, the energy of the near-infrared light that reacts with the - deoxyhemoglobin and oxyhemoglobin decreases as its distance from the light source increases. The near-infrared light signal (absorbance) detected by the photo detector component is converted from analog to digital and processed by the processor in the main unit.



Calculating rSO2 (regional oxygen saturation,1.e., in capillaries directly beneath sensor)

The absorbance values at 760nm and 850nm reflect the concentration of deoxyhemoglobin and oxyhemoglobin, respectively (chromophores: luminophores)
The values for deoxyhemoglobin and oxyhemoglobin are calculated based on the absorbance detected by photo detector component of the sensor.

The monitoring depth is determined by the distance between the light source and the photo detector. However, the greater this distance, the weaker the energy of the near-infrared light becomes, preventing its detection by the photo detector. With a separation of 40mm between the light source and photo detector, the monitoring depth is approximately 30mm. Since this depth corresponds to the location of cerebral cortex, it is favorable for monitoring.

Because extraneous material such as skull and muscle -- ,material other than the hemoglobin to be measured – lies between the sensor and the monitoring site, the signal that arrive at the photo detector includes information on this extraneous material. However, because oxygen saturation is calculated as an estimated oxyhemoglobin/(deoxyhemoglobin+ oxyhemoglobin), the effects of the extraneous material are eliminated by the relationship between the numerator and denominator.

$$rSO_2 = \frac{\text{OxyHb} \; \text{Extraneous matters}}{\text{OxyHb} \; \text{Extraneous matters} + \text{DeOxyHb} \; \text{Extraneous matters}}$$

$$= \frac{\text{OxyHb}}{\text{DeOxyHb} + \text{OxyHb}}$$

Description of HbI : another type of data provided by th *TOS-96*

Developed by TOSTEC, HbI (hemoglobin index) is a numerical value that indicates blood concentration. HbI is calculated using the total deoxyhemoglobin and oxyhemoglobin obtained at the start of monitoring, as the base value, or b (oxyhemoglobin b + deoxyhemoglobin b). Supposing, for example, that the value at the start of monitoring, n (oxyhemoglobin n +deoxyhemoglobin n), was 5 and value at an arbitrary time point (oxyhemoglobin n + deoxyhemoglobin n) was 4.9, HbI for that time point would be 4.9/5, or 0.98. If the value at the arbitrary time point was 5.1, HbI would be 5.1/5, or 1.02. Because extraneous material would affect both the numerator and denominator, its effects would be cancelled out. Thus, HbI is hemoglobin information that is unaffected by such material. However, because HbI represents the percentage change as compared with the baseline value at start of monitoring, which is a relative value, it cannot be used to compare individual subjects or to establish a range of normal value. For all subject, monitoring normally starts with HbI at or near 1.

$$HbI = \frac{\text{OxyHb } n \; \text{Extraneous matters} + \text{DeOxyHb } n \; \text{Extraneous matters}}{\text{OxyHb } b \; \text{Extraneous matters} + \text{DeOxyHb } b \; \text{Extraneous matters}}$$

$$= \frac{\text{OxyHb } n + \text{DeOxyHb } n}{\text{OxyHb } b + \text{DeOxyHb } b}$$

Numerator → Value at arbitrary time point after the start of monitoring

Denominator → Value at the start of monitoring

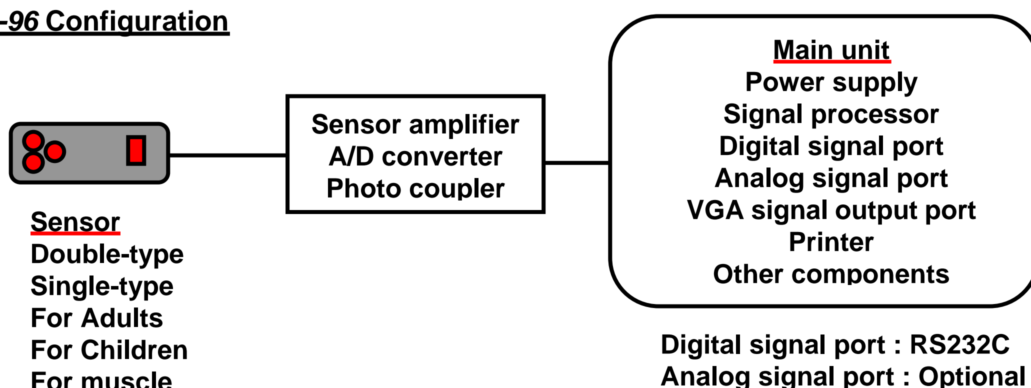
An increase in HbI reflects an increase in total oxyhemoglobin and deoxyhemoglobin at the monitoring site as compared with the start of monitoring, while a decrease in HbI means that total oxyhemoglobin and deoxyhemoglobin at the monitoring site decrease.

Note!!

HbI indicates the percentage change, a relative value. Therefore, it cannot be used for purposes such as determining a range of normal values or comparing individual patients.

TOSTEC is currently developing an index that will permit the normal range to be determined.

TOS-96 Configuration



Digital signal port : RS232C
Analog signal port : Optional

Data Provided by the *TOS96* Brain Oximeter :

rSO_2 :

rSO_2 (regional oxygen saturation) represents the balance between the oxygen supply to the capillaries directly beneath the sensor (monitoring site) and oxygen consumption at that site. In other wards, it provides data on metabolism at the monitoring site.
The monitoring depth depends on the form of sensor used. With a sensor for adults, the monitoring depth is approximately 30mm. The information obtained is expressed as a digital number (%, updated every second) and as a trend graph (updated every 5 second9. The blood at the monitoring site is in the capillaries and is therefore a mixture of arterial and venous blood. Consequently, oxygen saturation at the monitoring site can be estimated by the formula $(0.25 \times SaO_2) + (0.75 \times SvO_2)$. Assuming that the normal range for SaO_2 is 95% 50 100% and that for SaO_2 is 45% to 67%, the normal range for rSO_2 can be estimated to be 57% to 75%.

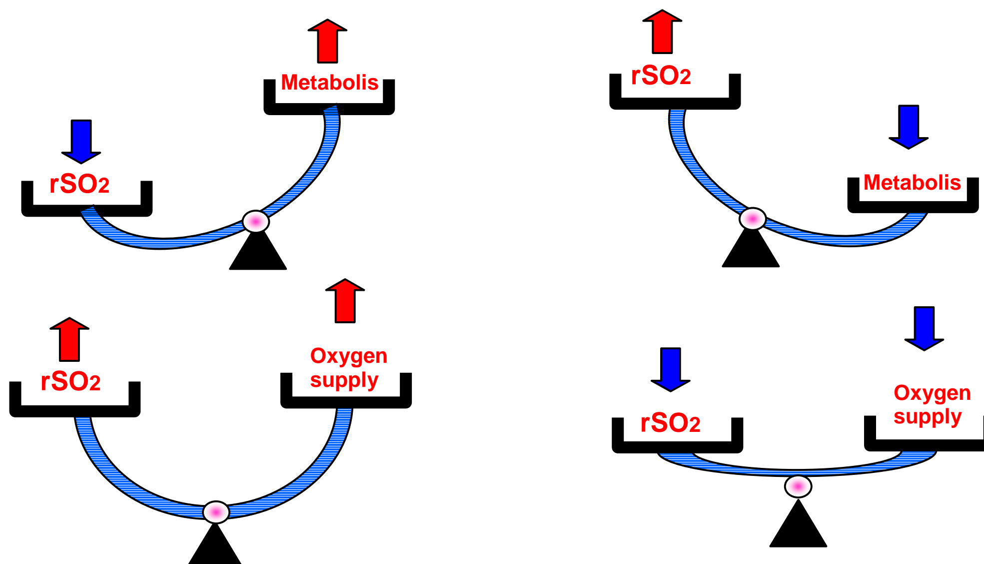
Example of rSO_2 Application :

If there has been no change in the oxygen supply or blood volume at the monitoring site, an increase in rSO_2 would indicate that oxygen consumption at the monitoring site decrease, while a decrease in rSO_2 would indicate that oxygen consumption increased.

If there has been no change in the oxygen consumption (metabolism) at the monitoring site, and increase in rSO_2 would indicate that the oxygen supply to the monitoring site increase, while a decrease in rSO_2 would indicate that the oxygen supply decreased.

Caution should be exercised in identifying the cause of a change in rSO_2 if the oxygen/blood supply changes simultaneously with oxygen demand at the monitoring site.
There appear to be many cases in which the direct cause of the change is related to cardiac function or the vascular system that supplies blood to the monitoring site. rSO_2 changes with blood pressure, pulse rate, stroke volume or the occurrence or elimination of vascular stenosis or occlusion that affects the monitoring site. In other words, it is necessary to determine whether the change in rSO_2 is due to a change at the monitoring site, a change in the functions that supply oxygen to the monitoring site, or a combination of these factors.

	rSO_2	Oxygen consumption	Oxygen supply
No change in oxygen supply or blood volume monitoring site	↑	↓	→
	↓	↑	→
No change in oxygen consumption (metabolism) at monitoring site	↑	→	↑
	↓	→	↓
Change in oxygen/blood supply to monitoring site with simultaneous change in oxygen demand at site	↑	↑ ↓ →	↑ ↓ →
	↓	↑ ↓ →	↑ ↓ →



If information on blood volume at the monitoring site (deoxyhemoglobin + oxyhemoglobin) is available, more accurate information on the oxygen supply and consumption at the monitoring site can be obtained.

If oxyhemoglobin increases, it can be inferred that either the oxygen supply to the monitoring site increased or oxygen demand at the site decreased.

A decrease in oxyhemoglobin indicates that either the oxygen supply to the monitoring site decreased or oxygen demand increased.

If deoxyhemoglobin increases, it can be inferred that either more carbon dioxide was delivered to monitoring site or oxygen consumption at the monitoring site increased, resulting in an increase in the amount of carbon dioxide released.

A decrease in deoxyhemoglobin indicates that either less carbon dioxide was delivered to the monitoring site or oxygen consumption at the monitoring site decreased, resulting in a decrease in the amount of carbon dioxide released.

The total oxyhemoglobin and deoxyhemoglobin provides data on the overall blood volume at the monitoring site. This value, HbI, is described in the next section.

HbI：

This index, which indicates the total oxyhemoglobin and deoxyhemoglobin at the monitoring site, is displayed as a digital number and trend graph.

As was explained in the previous section, HbI is unaffected by extraneous material such as the patient's cranium and provides data on hemoglobin only.

Because HbI is a relative value, the HbI levels of individual patients cannot be compared, and no normal range for HbI can be established. For all patients, monitoring starts with HbI at or near 1.

An increase in HbI means that the blood volume at the monitoring site increased as compared with the start of monitoring, while a decrease in HbI indicates that the blood volume decreased.

Oxyhemoglobin

The percentage change in oxyhemoglobin is displayed in a trend graph. Because it is expressed as a relative value, the oxyhemoglobin value cannot be used to establish a normal range or compare individual patients. An increase in the value indicates that the oxyhemoglobin concentration at the monitoring site increased as compared with the start of monitoring, while a decrease in the value means that the concentration decreased.

Deoxyhemoglobin

The percentage change in deoxyhemoglobin is displayed in a trend graph. Because it is expressed as a relative value, the deoxyhemoglobin value cannot be used to establish a normal range or compare individual patients. An increase in the value indicates that the deoxyhemoglobin concentration at the monitoring site increased as compared with the start of monitoring, while a decrease in the value means that the concentration decreased.

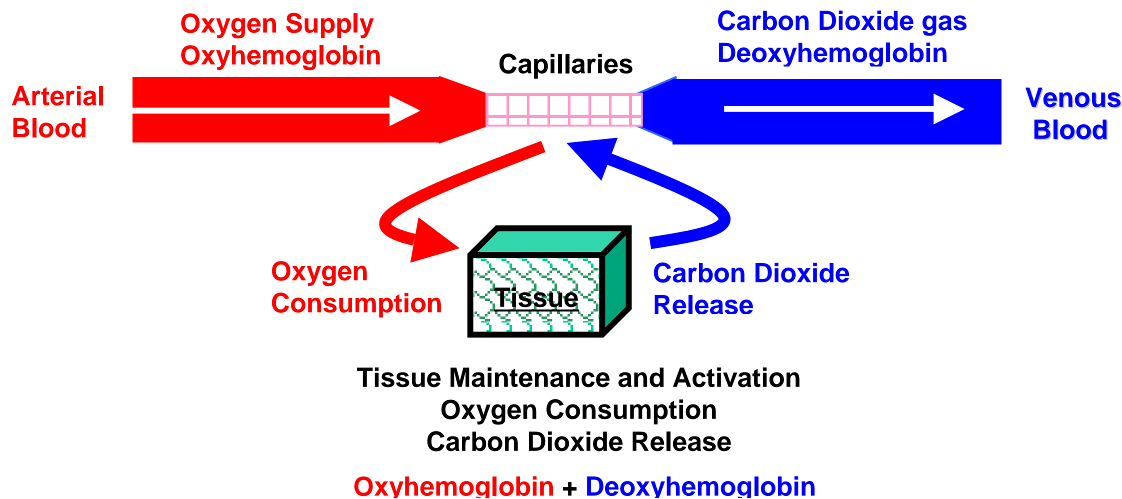
Deoxyhemoglobin can be a product of the patient's metabolism, or it can be produced according to the gas exchange rate. If the patient's gas exchange rate can be assumed to be constant, their metabolic state can be directly inferred from the deoxyhemoglobin value.

Left-Right Difference

Values obtained by subtracting the oxygen saturation obtained with the right sensor from that obtained with the left sensor (left sensor signal – right sensor signal) are displayed in a trend graph. These values can be used to compare a control site with the affected area. With ASA, placing one sensor over a normal site and the other over the affected area allows the condition of the affected area to be observed.

Summary of Data Provided by the *TOS-96*

The data provided by the TOS-96 are described in the following figure.



Arterial blood with an oxygen saturation level of approximately 100% is supplied

In general, metabolism occurs in tissues for tissue maintenance, and during this process oxygen is consumed and carbon dioxide produced.
During normal metabolism, the level of oxygen consumption is constant, and the level of carbon dioxide produced is also constant.
If the level of tissue activation increases, metabolism is enhanced, and more oxygen is consumed and more carbon dioxide produced than during normal metabolism.
A decrease in the level of tissue activation results in a decrease in metabolism, with less oxygen consumed and less carbon dioxide produced than during normal metabolism.

During normal metabolism, the levels of oxygen consumed and carbon dioxide produced are constant. Therefore, rSO_2 remains at a constant level in the normal range. However, it should be noted that rSO_2 also may remain unchanged if an increase in oxygen demand by the tissues is met by a sufficient change in the oxygen supply. With increased tissue activation, metabolism is enhanced, and more oxygen is consumed and more carbon dioxide produced than during normal metabolism. Consequently, rSO_2 will decrease. It also will decrease if the oxygen supply to the tissue decreases.

There may be reservations about using rSO_2 as the only information for determining whether a decrease in rSO_2 is due to enhanced metabolism in the tissue or to decreased oxygen supply to the tissue. In this case, taking HbI, oxyhemoglobin, and deoxyhemoglobin into account allows a more accurate determination.

A decrease in the level of tissue activation results in a decrease in metabolism, with less oxygen consumed and less carbon dioxide produced than during normal metabolism.
Consequently, rSO_2 will increase. Here again, more accurate determination of the cause of the increase may be possible by taking HbI, oxyhemoglobin, and deoxyhemoglobin into account.

Hardware Features

All-in-one system :
Internal color monitor, black-and-white printer, hard disk, and floppy disk drive

2-channel monitor :
Uses sensors for the left and right sides.

Reusable sensors :
Sensors can be used repeatedly. A sensor can be used continuously for at least 750 hr.

Sensors can be sterilized with EO gas (non-thermal, non-liquid sterilization) :
Sensors can be sterilized with ethylene oxide gas or formalin. Sensor surface can be wiped with alcohol gauze.

Allows continuous monitoring for 24 hr or longer :
The energy of the LEDs used in the system is infinitesimal and unlikely to produce red spots or other skin damage.

Sensor operating status monitor :
Constantly monitors the operating status of the sensors and the status of the monitor signal.

Sensors :
Single- and double-type sensors (left-right pair) are available, with versions of each type for adults, children, and muscle monitoring.

Specifications

Data Provided	The following types of data are provided on- and off-line rSO_2: trend graph and numerical values HbI (hemoglobin index): trend graph and numerical values Information on left-right difference: trend graph Oxyhemoglobin and deoxyhemoglobin: trend graph
Accuracy	rSO_2 : 100〜80% ±5% 80〜40% ±3% 40〜 0% ±5%
Data recording medium	Internal hard disk: > 1 GB (holds at least 3 years' worth of data) Floppy disk: 1.44 MB, 3.5-inch disk *Each floppy disk can store approximately 26 hr of data
Display screen	Color TFT-LCD 115.2 x 84.2 mm
CPU	INTEL
Light source	Light-emitting diode
Photo detector	Silicon diode
Internal printer	Black-and-white thermal transfer printer, chart speed : 3cm/10min
Output	Analog output: 0-10V *Available separately Digital output: RS232C VGA output: Printer port: ESC/P type Floppy disk drive: DOS-V, 1.44 MB, 3.5 inch
Operating temperature	+16 – 32℃
Operating humidity	20 – 80% non-condensing
Power supply	100 – 240VAC
Operating power	140VA
Leakage current	< 0.5mA
Dimensions	420W×460D×130H (cm)
Weight	14.5Kg
Other specifications	Japanese pharmaceutical license:20800BZZ00343000 and IEC-601,

*The analog output port is available separately; please note that it is not included with the standard unit.
**These specifications may be improved without prior notification

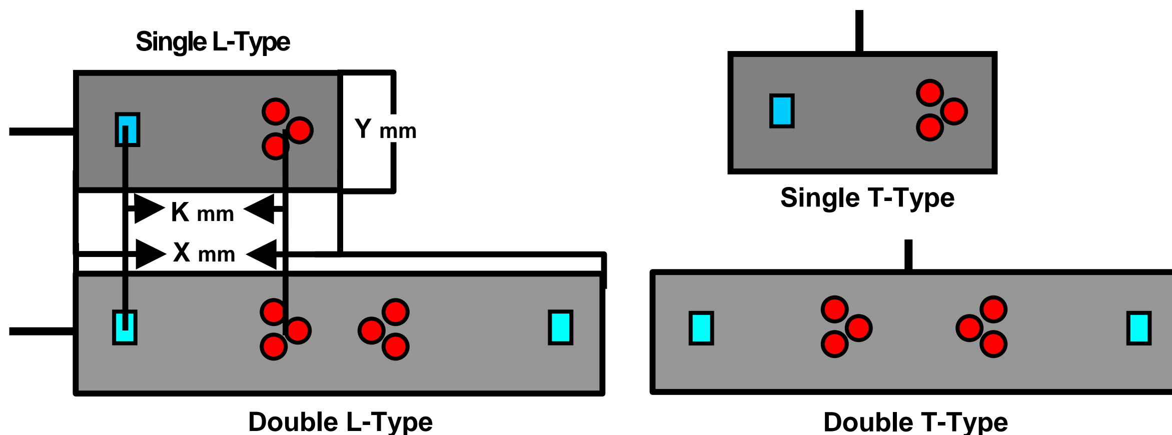
Sensor Types and Monitoring Depth

The following is a description of the TOS sensors.
Each sensor consists of 3 LEDs (light source component) and 1 silicon photodiode (photo detector component). The LEDs of the light source component project near-infrared light on the monitoring site, and the photo detector component detects near-infrared light that has reacted with oxyhemoglobin and deoxyhemoglobin and at their crossover point. The near-infrared light is projected on the monitoring site as 0.2 mSec pulses at an intensity of 12 mW/cm^2 and rate of 50 pulses/sec (total of 150 pulses/sec for the 3 wavelengths).

The photo detector component detects the near-infrared light that is projected from the light source component onto the monitoring site and absorption-attenuated by material such as tissue and hemoglobin. This analog signal is converted to a digital signal by the sensor amplifier box and then sent to the processor of the main unit.

A 1,500 mm sensor cable is the standard cable provided, but cables up to 3,000 mm long are available. The sensors must be stored in a clean and dry condition.

Sensors are available as either the single- or double-type, depending on their shape, and each of these types comes in either the T- or L-type, depending on where the cable attaches.



Monitoring Depth : D±3mm

Sensor type	D mm	K mm	X mm	Y mm
Single L for Adults	28mm	40mm	80mm	40mm
Single T for Adults	28mm	40mm	80mm	40mm
Double L for Adults	28mm	40mm	160mm	40 mm
Double T for Adults	28mm	40mm	160mm	40mm
Single L for Children	20mm	30mm	80mm	40mm
Single T for Children	20mm	30mm	80mm	40mm
Double L for Children	20mm	30mm	140mm	40mm
Double T for Children	20mm	30mm	140mm	40mm
Single T for Children	15mm	20mm	80mm	40mm
Double T for Children	15mm	20mm	120mm	40mm
For Muscle &Tissue	7mm	10mm	40mm	40mm

Comparison with Pules oxynetry and Oxymetry Methods

The differences between the TOS-96 Brain Oximeter, pulse oxymetry, and SjO_2 monitoring are shown below.

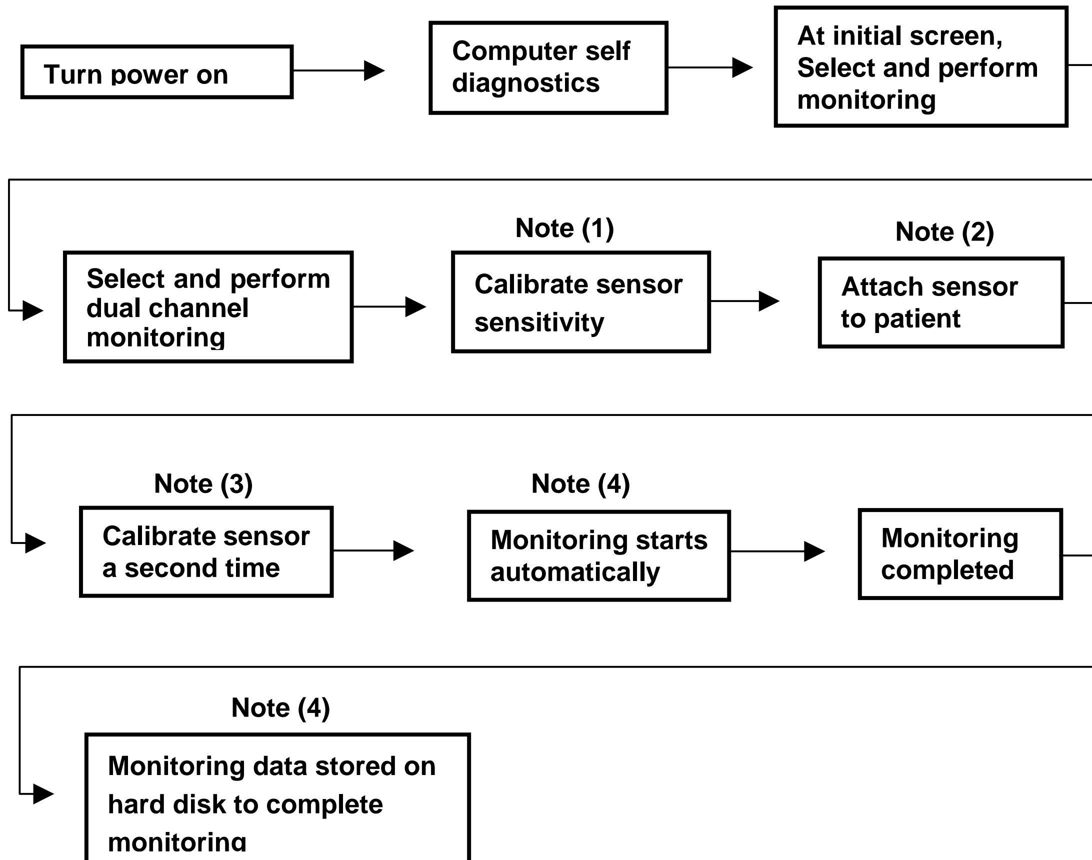
	Brain Oximeter	Pulse Oximeter	SjO2
Sensor location	Sites through which near-infrared light passes: e.g., the frontal region and muscle	Tips of finger, toes	Jugular bulb
Monitoring material	Hb at the monitoring site	Arterial blood in tips of finger, toes	Venous blood in jugular bulb
Type of information provided	Oxygen saturation in capillaries at the monitoring site Change in blood volume at the monitoring site Information on left-right difference Change in oxyhemoglobin and deoxyhemoglobin levels	Oxygen saturation of arterial blood in tips of finger and toes Pulse rate	Oxygen saturation of venous blood in jugular bulb
Condition for use	Can be used in subjects with hypotension and bradycardia Completely non--invasive	Blood pressure and pulse required	highly invasive
Normal values	55% to 75% Monitoring values determined by the balance between oxygen supply and oxygen consumption at the monitoring site.	95% to 100% Monitoring assumes the values for oxygen saturation in arterial blood of tips of fingers and toes are proportional to the pulmonary gas exchange rate.	40% to 67% Monitoring values change depending on the location of the sensor chip. Provides whole-brain information.

Additional note:
Transcranial Doppler ultrasound utilizes the Doppler principle to monitor blood flow velocity beneath areas through which 2 MHz ultrasound can pass. To obtain information on blood flow velocity in the head, such monitoring is performed in the area of the temple where the cranium is thin. The data are expressed in units of cm/sec. Transcranial Doppler permits completely non-invasive monitoring. This type of monitoring requires skill, and data cannot be obtained if the cranium is too thick. Moreover, the blood flow velocity varies depending on the angle at which the ultrasound crosses the blood vessel.

Operating Flowchart

The following describes the flow of operations of the *TOS-96*.
The TOS-96 is operated using the 7-key keypad located on the front panel.

The following describes normal 2-channel monitoring, from start to finish.
Each screen displays the operating procedure to be carried out next.



Note (1)
Sensitivity of light source and photo detector calibrated to the prescribed ratio.
Note (2)
The sensor must be attached tightly to the skin so that external light does not mix with the light detected by the photo detector. The sensor is made from a flexible silicon material and therefore fits closely to the skin. To attach the sensor, first firmly apply 2-sided medical adhesive tape to the monitoring site, and place the sensor over the tape. Press down on the edges of the sensor with your fingers to prevent contamination by external light. An effective way to prevent external light from entering beneath the sensor is hold down the edges of the sensor with tape.
Note (3)
The second sensor calibration is performed to eliminate the absorption and dispersion of the near-infrared light caused by material such as the cranium and muscle tissue, which varies from patient to patient. This calibration takes 20 seconds. When it is complete, monitoring begins automatically.
Note (4)
The monitoring data also can be stored directly on a floppy disk.

Clinical Applications of the *TOS-96*

The *TOS-96* is used primarily in the fields indicated below.
It can be used to obtain sequential information on oxygen saturation, metabolism, blood, and oxyhemoglobin and deoxyhemoglobin in the capillaries of tissues directly beneath the sensor. It can therefore be used in the case of clinical symptoms for which metabolic and blood-related information for the monitoring site is needed.

The *TOS-96* is used in anesthesiology, cardiac surgery, vascular surgery, thoracic surgery, pediatrics, neurosurgery, neuropsychiatry, neurological checkups, emergency medicine, operating rooms, intensive care, neurosurgical intensive care, rehabilitation, health sciences, and sports medicine. Monitoring with the *TOS-96* is used for purposes including circulatory management for cerebroprotection; peripheral circulatory treatment evaluation and postoperative management; measurement evaluation of the effect of drugs and other treatments; and examination and stress testing of the cerebral and peripheral circulation.

The following is an overview of these applications by field.

1) Anesthesia management

Management of cerebral circulation for cerebroprotection:

Prevention of perioperative brain damage due to factors such as position changes, neck torsion pressure, and reduced cerebral perfusion pressure

Under general anesthesia, the sympathetic reflexes are inhibited and cerebral blood volume decreases significantly due to the low position of the head. Autoregulation of cerebral blood flow is lost during anesthesia, but cerebral blood flow can be safely maintained by using the values for rSO_2 and HbI obtained immediately prior to anesthesia induction as reference levels to manage functions such as ventilation and blood pressure from the start of anesthesia until the patient awakens. With intravenous and inhaled anesthetics, the effect on cerebral blood flow varies depending on the anesthetic used. Following anesthesia induction, oxygen saturation can gradually decrease and approach hypoxia. However, by monitoring rSO_2 and HbI and controlling factors such as CO_2, blood pressure, pulse rate, and ventilation, a proper balance between oxygen supply and demand can be maintained. Inadequate management of the patient's physiological functions can cause blood pressure disturbances, and problems such as hyperventilation, ventilatory failure, and hypotension may lead to long-term hypoxia, possibly resulting in postoperative sequelae.

Tips!!

During monitoring, close attention should be paid to the percentage change in HbI, for which a value approximately 1 is displayed at the start of monitoring. An increase in this value means that the concentration of the blood increased as compared with the start of monitoring, while a decrease indicates that the blood concentration decreased. Because HbI indicates total deoxyhemoglobin and oxyhemoglobin, it also can be used as an approximate measure of cerebral blood volume.

In some cases, rSO_2 may remain unchanged even though the oxygen supply to the monitoring site changes. This occurs if the change in the oxygen supply is in a range that is sufficient to meet oxygen demand at the monitoring site. For more rigorous observation of the change in the oxygen supply, it is recommended that the percentage change in oxyhemoglobin and deoxyhemoglobin be observed at the same time as rSO_2.

By displaying the percentage change in oxyhemoglobin and deoxyhemoglobin on the data display screen of the TOS-96 and printing rSO_2 and HbI data to the printer, these 4 types of data can be observed together.

2) Cardiovascular surgery

Management of cerebral circulation for cerebroprotection:

Management and monitoring of cerebral circulation and percutaneous cardiopulmonary support (management of circulatory status with PCPS)

It is estimated that approximately 10% of patients who undergo heart surgery have postoperative brain sequelae (affecting brain function). Examples of applications of the TOS-96 include monitoring of the cerebral circulation to prevent postoperative brain dysfunction resulting from hypoperfusion in procedures such as replacement of the thoracic aorta, aortic arch, thoracic descending aorta, and ascending aorta; coronary artery bypass; revascularization; mitral, aortic, and tricuspid valve replacement; and circulatory arrest during the replacement of a thoracic aortic aneurysm with a synthetic graft. Other examples include monitoring of the cerebral circulation to prevent brain damage due to hypoperfusion during rewarming by extracorporeal circulation, to detect risk for perioperative neurological complications during selective

cerebral perfusion and prevent such complications, and to prevent neurological complications caused by bending of the graft during surgery to replace a blood vessel with a synthetic graft (even with successful revascularization, bending may occur at times such as suture removal, resulting in damage due to inadequate blood flow).

In open-heart surgery, a heart-lung machine is used, and problems may occur during cannulation or withdrawal of this support. Even during pumping, when blood should be flowing to the brain, the blood flow may actually be insufficient (hypoperfusion) due [Page 18]
to bending or pressure on the feeding vessel. Based on the rSO_2 and HbI information, the pump operator, anesthesiologist, and surgeon can detect these abnormalities and safely take measures to prevent an accident.

rSO_2 and HbI also can be observed using a TOS-96 sensor placed on the forehead to allow monitoring for hypoperfusion and abrupt changes in cerebral blood flow and thereby detect cases such as blockage of a cerebral blood vessel that occurs during surgery when thrombus or other material travels down the bloodstream. Although imperfect, such monitoring enables appropriate measures to be undertaken immediately in such cases.

3) Management of cerebral circulation during pediatric heart surgery (e.g., for congenital heart or pulmonary artery malformation) and extracorporeal membrane oxygenation (ECMO) in neonates and premature infants

Management of cerebral and peripheral circulation and assisted circulation for cerebroprotection:
In neonates and infants, slight changes in position or torsion of the neck can impair blood flow. Because the TOS-96 sensors for infants are soft, they can be attached firmly to small heads, allowing stable, long-term monitoring of neonates, premature infants, and other infants during surgery and on the ward. In addition, the energy level of the near-infrared light is miniscule, which is also conducive to long-term monitoring.

4) Neurosurgery

Management of cerebral circulation for cerebroprotection:
Cerebral blood flow must be monitored before and after procedures such as internal carotid endarterectomy, tumorectomy, intravascular thrombolysis, CNS surgery, and the various bypass procedures. It is difficult to obtain blood-flow information about the surgical field itself due to the surface area of the TOS-96 sensor. However, in internal carotid endarterectomy, a sensor can be placed on the side of the forehead ipsilateral to the affected area, allowing the presence or absence of collaterals to be determined and postoperative circulatory improvement to be directly monitored. The TOS-96 is also effective for preventing postoperative hyperemia, hyperperfusion, and cerebral edema.

5) Other surgical procedures

Peripheral hemodynamics can be monitored by placing sensors in the region supplied by the blood vessels of interest.
To monitor ischemia of the lower extremities during surgery for severe lower-extremity ischemia, evaluation and management of peripheral circulatory dynamics following revascularization can be performed by pre-, intra-, and postoperative monitoring of the dorso-ventral muscles and the plantar region. In addition, measurement of cerebral oxygen saturation during procedures in the neck region, such as right thyroid lobectomy and venous ligation as part of a dental procedure, is effective for managing cerebral and peripheral circulation.

6) Emergency medicine

Applications such as evaluation of cerebral oxygen status on hospital arrival and management and evaluation of cerebral and peripheral blood flow during and after emergency surgery:
The TOS-96 can be used to monitor and manage peripheral circulation for the purpose of cardiopulmonary resuscitation (CPR) and cerebroprotection. Such monitoring and management includes the evaluation of cerebral and peripheral blood flow and oxygenation during CPR, management of cerebral and peripheral circulation following treatment for severe head trauma or cerebral or myocardial infarction, and preventive management of vasospasm following treatment for subarachnoid hemorrhage.

7) Long-term, continuous monitoring of cerebral blood flow in the ICU

Monitoring and evaluation of circulatory status following drug administration or other intervention and monitoring during fibrinolytic therapy:
Continuous monitoring is performed to detect hyperemia, congestion, vasospasm, and hypoxia for postoperative management in cardiac and neurological procedures to prevent brain damage during hypothermia therapy and following surgery for head trauma or severe brain injury. With cerebral hypothermia, continuous monitoring for approximately 3 weeks is necessary. Continuous monitoring with devices from other manufacturers is limited to a few days due to concern that the emitted light can result in

low-temperature burns. However there is no such concern with the TOS-96, and long-term monitoring over many days can be performed.

8) Testing and evaluation of peripheral and cerebral blood flow in outpatient neurosurgery, neurological checkups, and other areas of examination

Examinations to evaluate surgery, circulatory status, and peripheral circulatory status:

The TOS-96 permits detection and evaluation of cerebral circulatory abnormalities, such as abnormal vascular reactivity and carotid artery stenosis resulting from balloon occlusion testing, temporary blockage of the internal carotid artery, the orthostatic test, and the hyperventilation test. It is used for evaluation of cerebral and peripheral blood flow and procedure selection in the angiography lab before aneurysmoplasty or carotid endarterectomy (CEA). A decrease in oxygen saturation would indicate that the test affected the region supplied by the blood vessel.

9) Outpatient examination of cerebral blood flow in neurology and psychiatry

Evaluation of drug efficacy and blood-flow reduction resulting from depression and vascular stenosis:

The patient's current condition and the effects of drug administration and treatment can be evaluated on an outpatient basis by performing rSO_2 testing and examining the patient's condition and values for rSO_2 and HbI.

Patients with depression are thought to exhibit reduced blood flow in the frontal region. Thus, the TOS-96 can be used to examine higher-order brain function in psychiatric outpatient care.

***Evaluation is possible by taking measurements before and after administration of a drug or other treatment, since in these cases blood flow increases in the frontal lobe regions used. The efficacy of a drug therapy can be evaluated based on symptomatic improvement and the increase in rSO_2 resulting from increased cerebral blood flow.**

10) Outpatient examination in vascular surgery

Screening to ascertain whether gait disturbance is spinal or caused by intermittent claudication, evaluation of peripheral circulatory status, and evaluation of effects of surgery and the patient's postoperative condition:

With sensors attached to the calves of both legs, the patient is placed on a treadmill and the workload is gradually increased. rSO_2 is measured at the point where the patient complains of pain. If claudication is present, oxygen saturation is greatly reduced. However, with a spinal gait disturbance, pressure exerted on a nerve by the bone produces pain. In this case, there is no decrease in rSO_2, permitting discrimination between gait disturbances resulting from claudication and those with a spinal cause.

The patient's status after lower extremity revascularization is evaluated by measuring the recovery time immediately following stress testing. If the postoperative recovery time is shorter than the preoperative time and there is a smaller rSO_2 decrease postoperatively, blood flow can be evaluated as having improved.

11) Rehabilitation

Evaluation of factors such as improvement in exercise capacity and skeletal muscle blood flow resulting from thermotherapy and various other treatments:

The TOS-96 can be used to evaluate muscle fatigue and metabolism under a load by measuring oxygen saturation in localized muscle tissue. Changes in motor function are associated with changes in blood flow in the muscles, and improvement in blood flow can be evaluated according to the increase in rSO_2, while increases in blood flow are evaluated using HbI. The TOS-96 sensor is waterproof, allowing sites that are immersed in water to be monitored.

***Research on factors such as the relationship between blood flow and recovery of motor function is currently being conducted.**