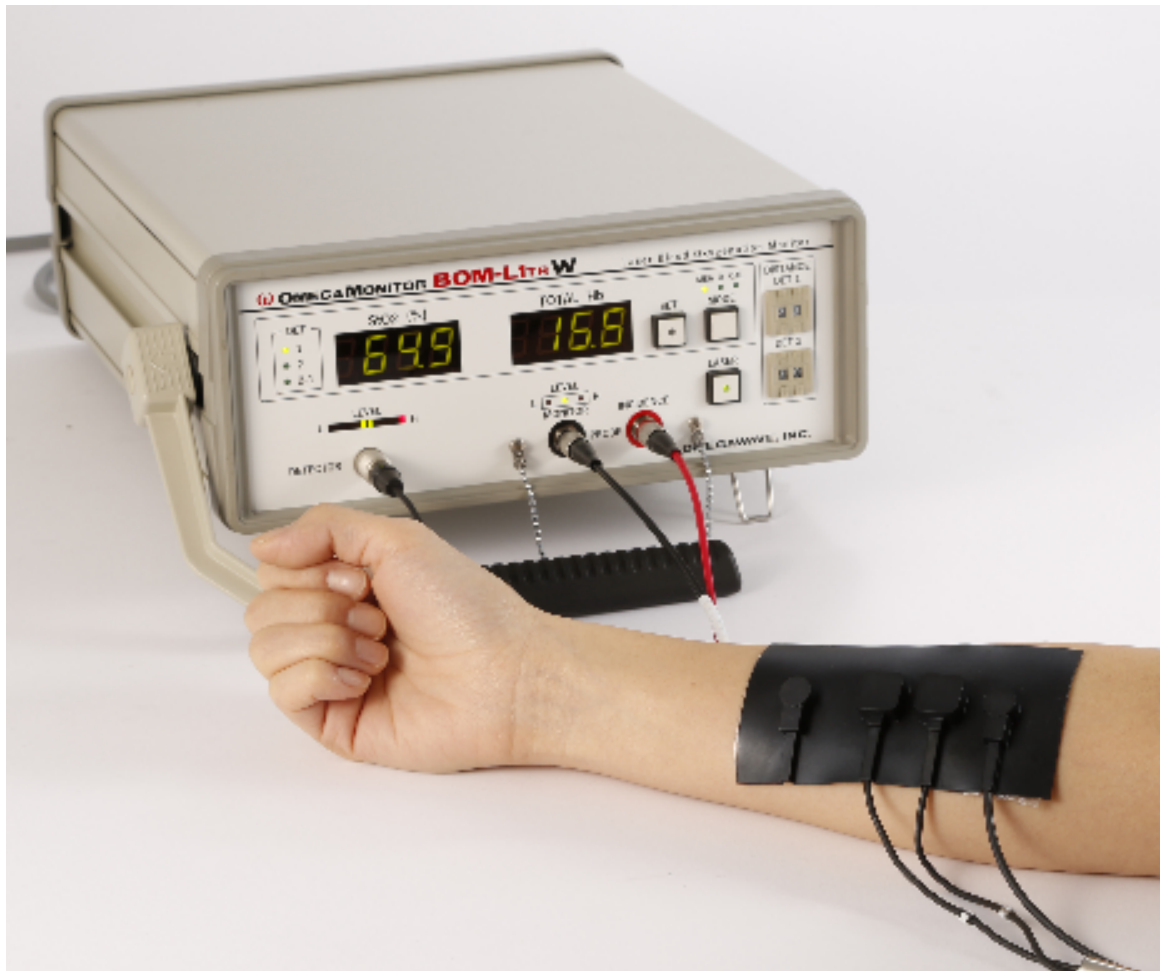


OMEGAMONITOR

BOM-L1 TR W

USER'S MANUAL



CONTENTS

	Page
1. Summary	2
2. Part names and Function	3
3. Connection to Recorder and Operation	9
4. Theory	13
5. Handling and Cautions	16
6. Specifications	19
7. Guarantee	20

1. Summary

This laser tissue blood oxygenation monitor, OMEGAMONITOR BOM-L1TRW, is an useful instrument for measuring tissue blood volume and its oxygenation in muscle, brain and internal organs. BOM-L1TRW can measure the hemodynamics continuously and non-invasively, and is used in fundamental research and in clinical applications.

BOM-L1TRW has two detection system. One is for measuring the shallow part from the surface and the other is for measuring the deeper part from the surface of tissue. The differential of these two outputs can tell the hemodynamics only in the deep part.

The measurement depth is relational to the distance between the incidence and receiving point, and it is almost same as the distance.

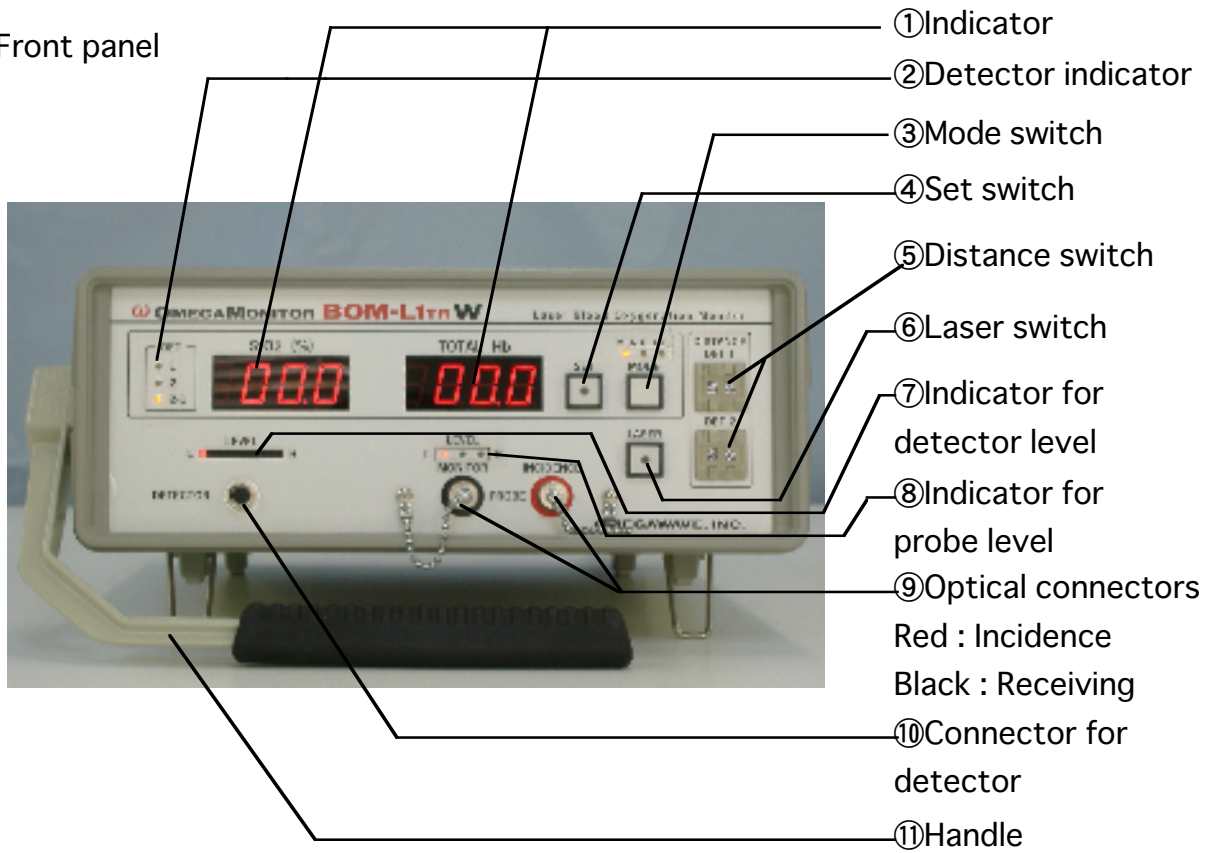
BOM-L1TRW uses three semiconductor laser diodes, and their narrow bandwidth of spectrum enables high S/N ratio measurement.

BOM-L1TRW outputs oxygenated hemoglobin volume, deoxygenated hemoglobin volume, total hemoglobin volume and its oxygenation continuously, then the detail of hemodynamics under study can be observed.

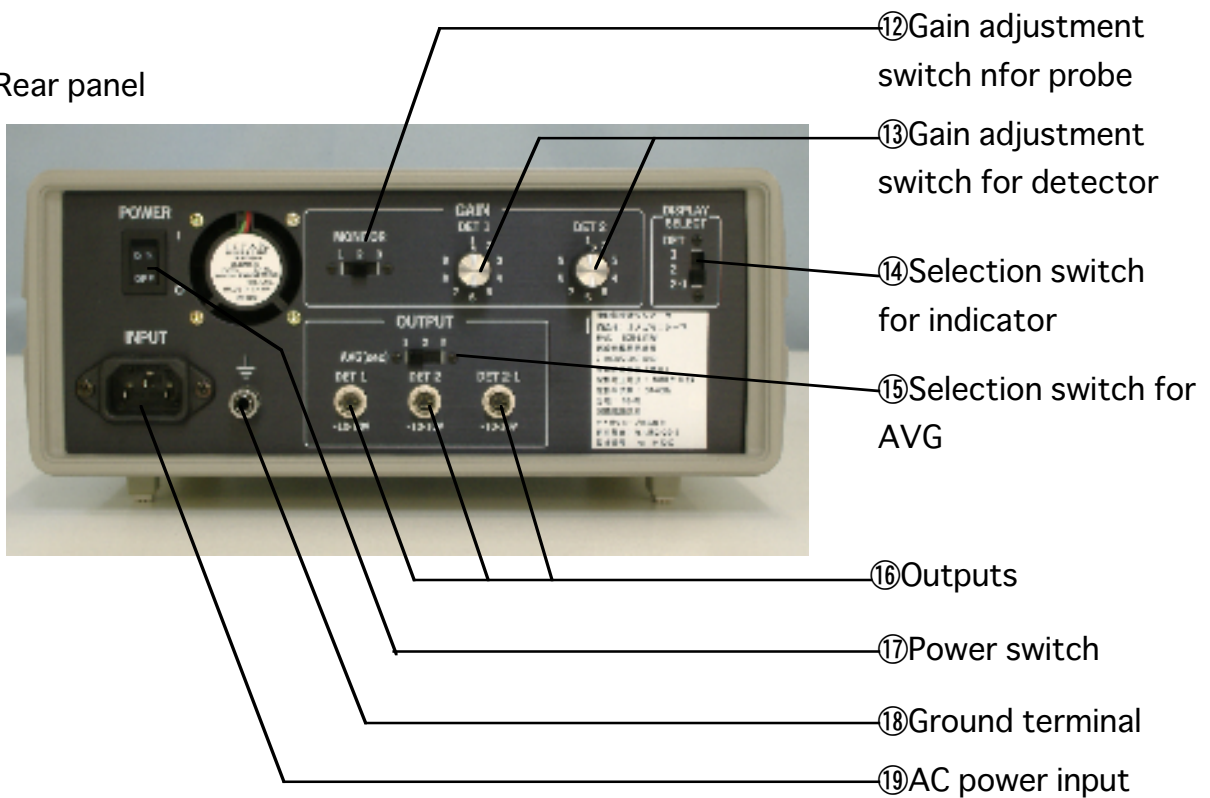
2. Part names and Functions

1) Part names

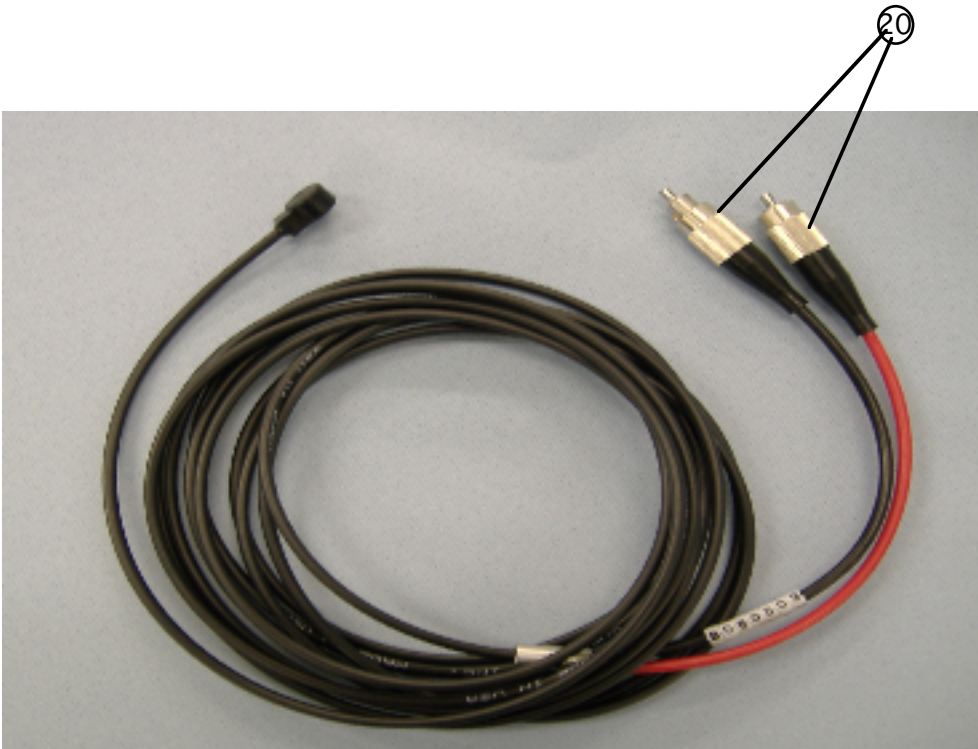
Front panel



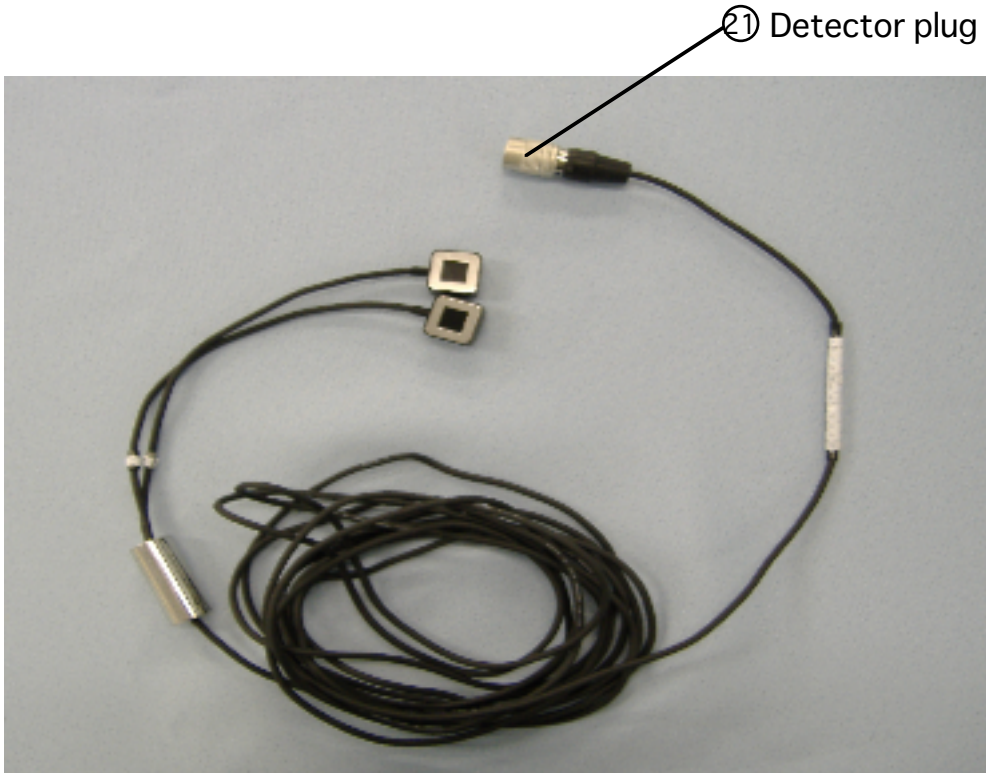
Rear panel



Probe



Detector



2) Functions

① Indicator

This indicator shows the measurement value of tissue blood oxygenation ratio and total Hb volume.

The tissue blood oxygenation ratio, StO₂, is showed as percentage, and total Hb volume, TOTAL Hb, is showed as 0~100.0.

The oxy-Hb volume, OXY HB, and deoxy-Hb volume, DEDOXY Hb, are not showed in this indicator, but all of StO₂, Total Hb, OXY Hb and DEOXY Hb are obtained from the output on the rear panel.

Output mode has three modes. "MEA" mode is for measurement, "0" mode shows 0 (zero) on this indicator and sets the output to 0 (V), and "CAL" mode shows calibration value and outputs its voltage. The calibration value of

StO₂ on the indicator is 10.0 and the value of TOTAL Hb is 20.0. The calibration voltage of the output of OXY Hb, DEOXY HB and StO₂ are 1.0 (V) respectively, and the voltage of TOTAL HB is 2.0(V).

$$\text{TOTAL Hb} = \text{OXY Hb} + \text{DEOXY Hb}$$

② Detector indicator :

This indicator shows the detector number selected by Selection switch for indicator.

The Indicator shows the values of the detector shown on this Detector indicator.

③ Mode switch

The output mode of "MEA", "0" and "CAL" is selected by this switch.

④ Set switch

This switch is used for measuring the value of change from a point. When this switch is pushed, OXY-Hb, DEOXY-HB and TOTAL-Hb become zero. Then just the volume change is obtained. However, StO₂ is not affected by this switch. The red light shows "ON".

This switch is controlled when Mode switch shows "MEA", Laser switch is "ON", Detector level shows green light and Probe level shows green light.

⑤ Distance switch

This switch is for normalizing the distance between Probe and Detector on tissue. Input the distance as the unit of "mm".

⑥ Laser switch

Laser power is operated by this switch. Press this switch for ON and the red light glows.

⑦ Indicator for detector level

This indicator shows the level of detected light intensity detected by the detector. The hemodynamic values are obtained when this indicator shows green. When it shows red at L or H level, adjust the detection level using "⑫Gain adjusting switch for detector" to become green. L level means low detected light intensity, and H level does high intensity for processing the signal.

The larger number of switch means higher gain.

⑧ Indicator for probe level

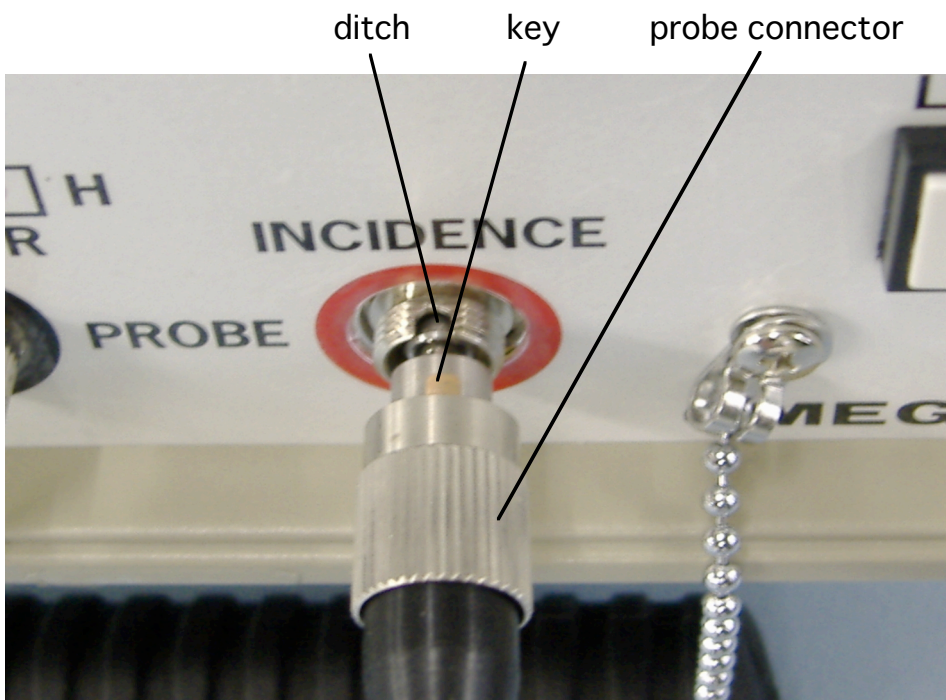
This indicator shows the level of detected light intensity detected by the probe. This light intensity is used to compensate the output laser power on tissue and absorption by pigment in the tissue. The hemodynamic values are obtained when this indicator shows green. When it shows red at L or H level, adjust the detection level using "⑪Gain adjusting switch for probe" to become green. L level means low detected light intensity, and H level does high intensity for processing the signal.

The larger number of switch means higher gain.

⑨ Optical connectors

Optical connectors to connect the probe. The plugs of standard probes are specified by RED and BLACK. Match the key of the plug of the probe with the ditch of the connector, and push and screw the plug.

TOP VIEW



⑩ Connector for detector

Put the plug of the detector into this connector.

⑪ Handle

Use this handle for carrying BOM-L1TRW.

⑫ Gain adjustment switch for probe

This selection switch is used to adjust the detected light intensity level of the probe.

Usually the position of "2" is widely used for many tissue. When dark tissue is measured and the indicator for probe level shows red at L, set to "3".

When white tissue is measured and the indicator for probe level shows red at H, set to "1".

⑬ Gain adjustment switch for detector

This selection switch is used to adjust the detected light intensity level of the detector.

The detected light intensity is affected by the distance between the probe and the detector.

When the indicator for detector level shows red at L, turn this switch to higher number.

When the indicator for detector level shows red at H, turn this switch to lower number.

⑭ Selection switch for indicator

This switch is for selecting which detector's value is shown on Indicator. The outputs are not affected by this switch.

⑮ Selection switch for AVG

The average of the output voltage can be set by this switch. The averaging time is 1, 2 or 5 sec.

⑯ Outputs

The three connectors output OXY Hb, DEOXY Hb and TOTAL Hb for each DET1, DET2 and DET2-1.

DET1 : This outputs the signal from the shallow part of a tissue from the surface.

DET2 : This outputs the signal from the deeper part of a tissue from the surface.

DET2-1 : This outputs the differential value after calculating each Hb values.

This DET2-1 is calculated as

$$\text{DET2-1} = \{(\text{DET2} \times \text{L2}) - (\text{DET1} \times \text{L1})\} / (\text{L2}-\text{L1}).$$

L2 and L1 : Distance between the incidence and receiving set by ⑤ Distance switch.

The range of the voltage is 0~10(V). When the set switch shows "ON", the range is -10~+10(V).

0 (zero) (V) is generated on each parameter on "0" mode.

1(V) is obtained for OXY Hb and DEOXY Hb on "CAL" mode.

2(V) is obtained for TOTAL Hb on "CAL" mode.

⑰ Power switch

This switch is used for "ON-OFF".

⑱ Ground terminal

To connect another instrument to make the ground level same.

①⑨ AC power input

Insert 3P power cord.

②⑩ Probe plug

This is connected to the optical connector on BOM-L1TRW.

Match the key of the plug of the probe with the ditch of the connector, and push and screw the plug.

(21)Detector plug

This is connected to the detector connector on BOM-L1TRW.

3. Connection to Recorder and Operation

1) Connection to a recorder

(1) Connect the output of BOM-L1TRW to the inputs of a recorder using the signal cable having three black and red banana jacks. Black banana jacks are grounds and red ones are signals for each hemodynamics parameters.

(2) Put the power source cord into the "AC power input" of BOM-L1TRW and connect to a power source.

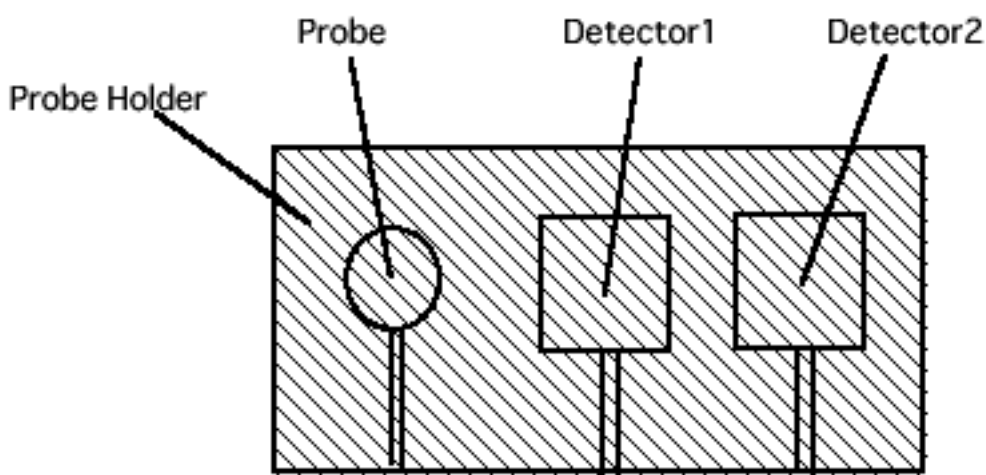
2) Operation

(1) Insert the plugs of a probe into the optical connectors of BOM-L1TRW and screw the coupling of the plugs to the right by one hand holding the black rubber boots not to turn by the other. Insert the plugs slowly and in a straight line. Do not insert the plugs slantwise by force.

BOM-L1TRW has laser incidence and receiving optical connectors. Insert the red plug of the probe into the red mark connector, and the black plug into the black connector. The probe not being colored has no side. Both plugs of the probe can be inserted into either side of the optical connectors.

(2) Insert the plug of the detector into the connector for the detector.

(3) Put the probe and the detector on the tissue under study. To avoid the light from outside, put the optional probe holder, a black rubber sheet or venal tape over them.

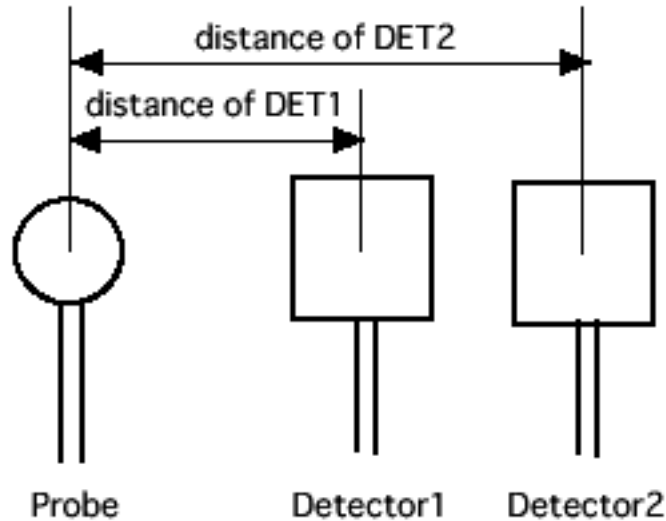


(4) Input the distance between the probe and detector in the distance switch. The unit is "mm". Use the small switches over and under these digital switches to input the numbers.

The distance between the probe and the detector 1 should be shorter than that between the probe and the detector 2.

Input the distance between the probe and the detector 1 for DET1.

Input the distance between the probe and the detector 2 for DET2.



(5) Turn on BOM-L1TRW and the recorder by each power switch.

(6) Turn "LASER" switch on. The red lamp is lighted. Confirm the green light on both the detector level and probe level. When they shows red, adjust the gain adjustment switch for the detector and probe on the rear panel.

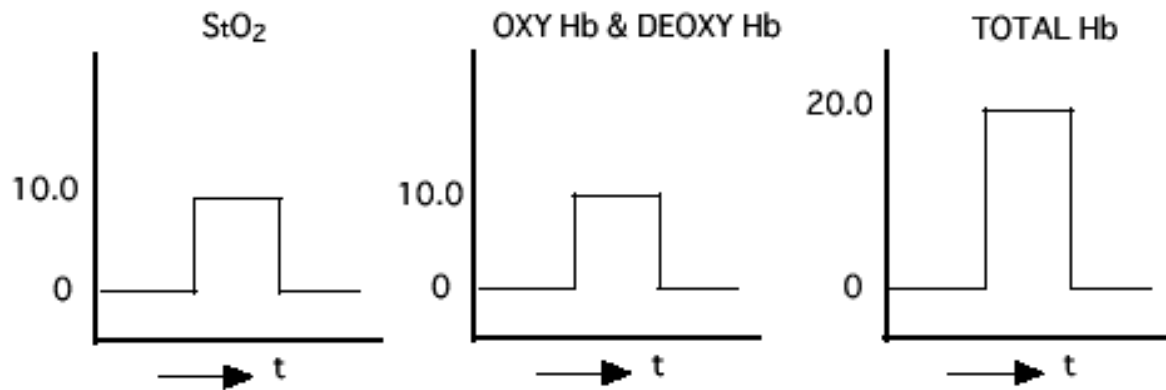
(7) Calibration

- ① Set the full scale of a recorder at 10 (V) using the range dial of the recorder.
- ② Press "MODE" switch and set at "0".
- ③ Set the pen of the recorder at zero line using the zero null dial of the recorder.
- ④ Press "MODE" switch again and set at "CAL".

OXY Hb : 10.0 , DEOXY Hb : 10.0 , TOTAL Hb : 20.0, StO₂ : 10.0 are obtained from the out put of BOM-L1 TR. The each voltage is 1 (V) for OXY Hb, DEOXY Hb and StO₂, and 2(V) for TOTAL Hb.

Set the pen of the recorder at an adequate point.

⑤ Run the chart paper and make the calibration form showed below operating ① to ④ again.



(7) Press "MODE" switch to set at "MEA" . Measurement starts.

(8) Raise the gain of the recorder if the measuring wave is too small.

(9) Chose the AVG switch on the rear panel. To obtain averaged measuring wave, choose longer time-constant.

Once the recorder is adjusted, this "Calibration" section will not be needed.

3) Stop Operating

(1) Stop the chart of the recorder, and turn off "LASER" switch.

(2) Turn off the power switch of BOM-L1TRW.

(3) Remove the probe from BOM-L1TRW slowly. Do not pull the plugs out slantwise by force.

(4) Cap the optical connectors.

(5) Cap the plugs of the probe and keep it in the probe case.

4. Theory

1) NIRS (Near InfraRed Spectroscopy)

The absorption spectrum of light by oxygenated hemoglobin and deoxygenated hemoglobin are different. Three kinds of laser lights illuminate tissue and the scattered light is detected at the point separated 30-50 mm from the incident point. As tissues are highly scattering materials in the wavelength range between 500 and 900 nm, photons are scattered many times in tissue, and some of them are absorbed by hemoglobin in erythrocytes. The absorption coefficient of hemoglobin depends on wavelength, and the detected light intensity can be expressed as

$$I = \eta I_0 \exp [(-\alpha V_o - \beta V_d - \mu) L]. \quad (1)$$

Here,

I : detected light intensity

I_0 : incident light intensity

η : the coefficient of measurement system

α : absorption coefficient of oxy-hemoglobin

β : absorption coefficient of deoxy- hemoglobin

V_o : volume fraction of oxygenated blood(hemoglobin) in tissue

V_d : volume fraction of deoxygenated blood(hemoglobin) in tissue

μ : attenuation(scattering + absorption) coefficient of tissue

L : optode, the distance between the incident point and the detected point.

Using three laser lights, we can obtain the volume fraction of oxygenated and deoxygenated blood in the tissue as

$$V_o \cdot L = A \cdot [\ln (I_1/I_{10}) - \ln (I_2/I_{20})] + B \cdot [\ln (I_2/I_{20}) - \ln (I_3/I_{30})] \quad (2)$$

$$V_d \cdot L = C \cdot [\ln (I_1/I_{10}) - \ln (I_2/I_{20})] + D \cdot [\ln (I_2/I_{20}) - \ln (I_3/I_{30})]. \quad (3)$$

Here,

I_1 , I_2 and I_3 are the detected light intensity of the three laser wavelengths

1, 2, and 3 respectively,

I_{10} , I_{20} and I_{30} are the incident light intensity of the three laser light,
 A, B, C and D are the coefficients obtained from α_1 , α_2 , α_3 , β_1 , β_2 , and β_3 ,
 α_1 , α_2 and α_3 are the absorption coefficient of oxy- hemoglobin at the
 three laser wavelengths, and
 β_1 , β_2 , and β_3 are the absorption coefficients of deoxy-hemoglobin at the three laser
 wavelengths.

Usually, the assumption that the scattering coefficient of tissue itself are the same for
 each wavelength if the wavelengths are close enough to each other.

The oxygenation of the blood, StO_2 , is calculated as

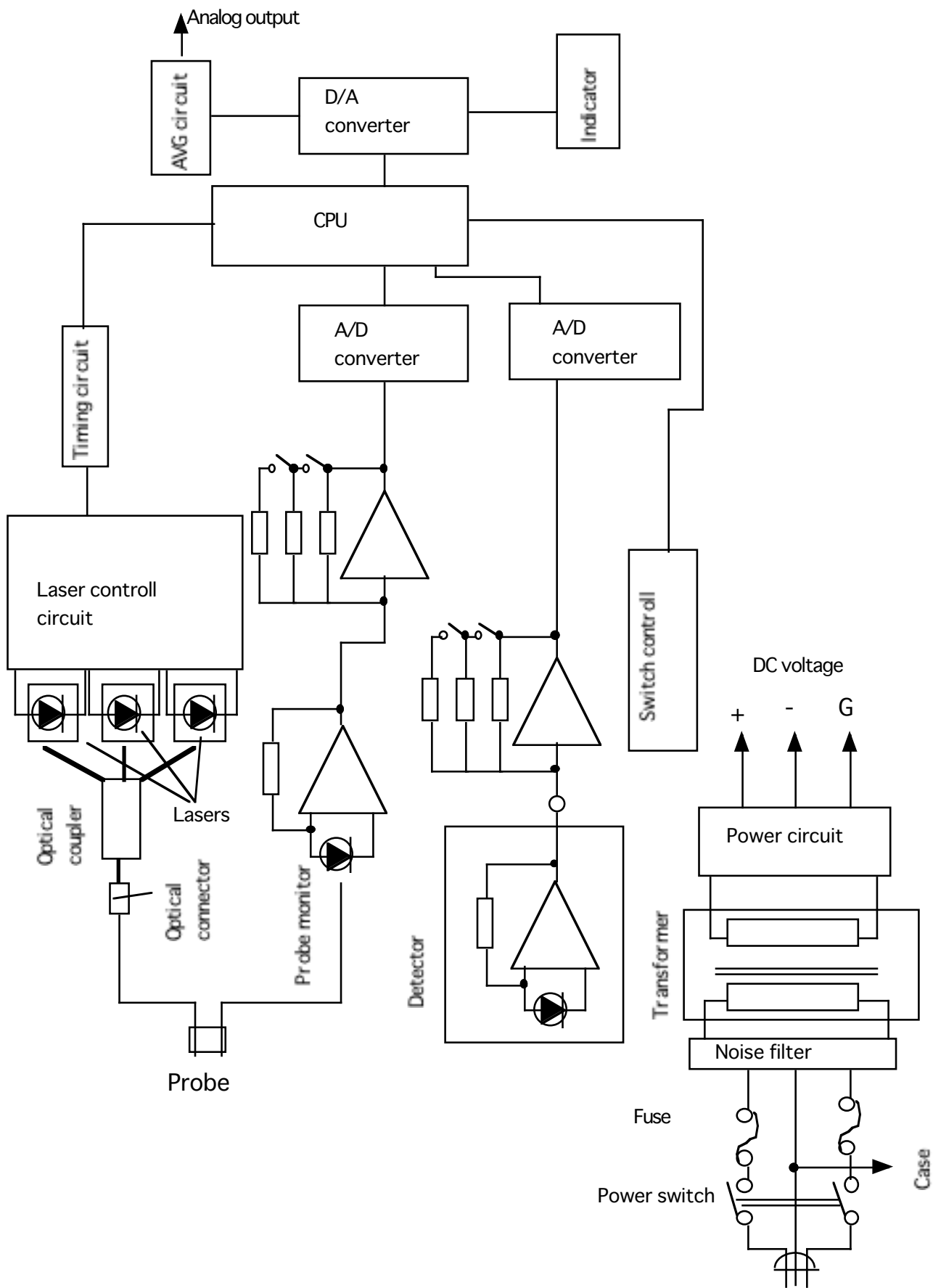
$$StO_2 = V_o / (V_o + V_d). \quad (4)$$

2) Unit and Indication

The indication of 1.0 and output of 0.1(V) for OXY Hb, DEOXY Hb and TOTAL Hb is
 equivalent to about 1×10^4 [N/mm³] of the density of erythrocyte in tissue in the condition
 that the actual optical pass length in tissue is assumed 4 times of the distance between
 the probe and detector.

The laser light is basically absorbed by hemoglobin. However, in a living tissue,
 hemoglobins are contained in red blood cells, and hemoglobin does not exist in blood
 alone. Also, the light is absorbed and scattered by red blood cells actually. Therefore,
 BOM-L1TRW indicates the blood volume as the number of red blood cells in a unit volume
 of tissue.

As the volume of hemoglobin, $1[\mu\text{mol}/100\text{mL}] \cong 2.2 \times 10^4$ [N/mm³].



Block diagram

5. Handling and Cautions

1) Pay attention to the next matters.

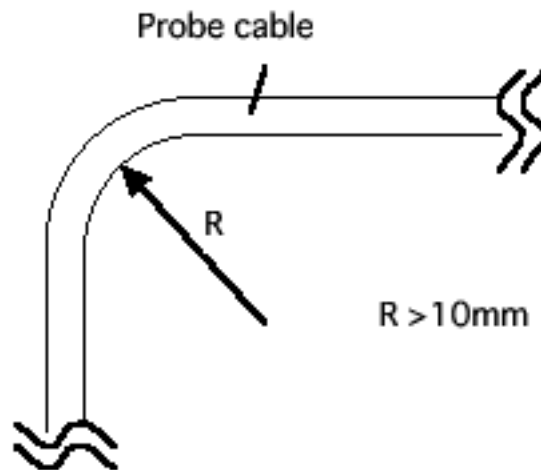
- (1) Keep BOM-L1TRW out of water.
- (2) Set BOM-L1TRW on the place where air pressure, temperature, humidity, wind, sunlight, dust, and air containing salt and sulfur do not cause bad condition.
- (3) Pay attention to inclination, vibration and shock.
- (4) Keep BOM-L1TRW out of a storeroom of chemicals and the place where gas generates.
- (5) Pay attention to the voltage, frequency and power of the power source which BOM-L1TRW is connected to.
- (6) Connect the ground correctly.

2) Pay attention to the next matters before using BOM-L1TRW.

- (1) Examine switch workings and meters, and confirm BOM-L1TRW working.
- (2) Confirm the ground being completely connected.
- (3) Confirm all the cables being connected correctly and completely.
- (4) Pay attention to using another instruments together.

3) Pay attention to the next matters in use of BOM-L1TRW.

- (1) Do not use over the time for diagnosis and medical treatment.
- (2) Always keep watch on BOM-L1TRW and a patient being not unusual.
- (3) Take proper measures, like turning of BOM-L1TRW, if something is unusual on BOM-L1TRW and a patient
- (4) Keep patients out from BOM-L1TRW.
- (5) Do not look at the laser light generated from BOM-L1TRW directly and through a lens .
- (6) Probes are made from glass fibers, and they are hardly repaired. Pay attention to the next matters for probes.
 - ① Do not scrub the tip of probe and detectors.
 - ② Do not bend into a circle of under 10 mm radius.



- ③ Do not step on probes.
- ④ Keep the tip and plugs clean.
- ⑤ Do not insert and pull the plugs slantwise by force.
- ⑥ Use under 60°C sterilization.

4) Pay attention to the next matters after using BOM-L1TRW

(1) Turn off the power switch after restoring the condition of before using BOM-L1TRW along the process.

(2) Do not pull the cables by force.

(3) Pay attention to keeping.

① Keep BOM-L1TRW out of water.

② Set BOM-L1TRW on the place where air pressure, temperature, humidity, wind, sunlight, dust, and air containing salt and sulfur do not cause bad condition.

③ Pay attention to inclination, vibration and shock.

④ Keep BOM-L1TRW out of a storeroom of chemicals and the place where gas generates.

(4) Put belongings, cables and probes in order after cleaning.

(5) Clean BOM-L1TRW for the next using.

5) When BOM-L1TRW is out of order, do not handle. Leave it to a specialist.

6) Do not remodel BOM-L1TRW.

7) Maintenance

(1) Inspect BOM-L1TRW regularly.

(2) Confirm BOM-L1TRW being in order before using it having not used for a long time.

6. Specifications

Laser for Measurement : Semiconductor lasers、

Wavelength : 780nm, 810nm and 830nm

Under 7mW at the probe end

Probe : Optical fiber

Detector : Silicon photo-diode

Measuring parameters

1)Tissue oxygenated blood volume(OXY Hb) :0~+100.0

2)Tissue deoxygenated blood volume(DEOXY Hb) :0~+100.0

3)Tissue total blood volume(TOTAL Hb) :0~+100.0

4) Oxygenation ratio (StO₂) : 0 ~ 100.0 %

Indicator : StO₂ and TOTAL Hb

Analog output

1)OXY Hb : 0~10V

2)DEOXY Hb : 0~10V

3)TOTAL Hb : 0~10V

4)StO₂ : 0~10V

AVG : 1, 2 and 5 sec

Power source : AC110±10V, 50/60Hz, 20VA

Weight: 5.5kg

Size : W257、 H100、 D322 (mm) without the handle

Operation circumstance

Temperature : 5-40°C

7. Guarantee

1) BOM-L1TRW

Repair is free within one year after the purchase of BOM-L1TRW except the next cases.

- (1) Malfunction and damage due to incorrect using and inattention.
- (2) Malfunction and damage due to a nature calamity and a fire.

2) Probes and Detectors

Repair is according to the table below at the first time.

<u>after purchase</u>	<u>cost of repair</u>
within 6 months	under 50% of the list price
within one year	under 70% of the list price
after one year	not provided

OMEGAWAVE, INC
2-20-3 KATAMACHI
FUCHU, TOKYO, JAPAN

No.