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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 2

HITACHI

HITACHI MEDICAL CORPORATION
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

510(k) Summary

K042501

Submitter Information

Submitter: Hitachi Medical Corporation
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

Contact: Douglas J. Thistlethwaite
ph: (330) 425-1313
fax: (330) 425-1410

Date: September 13, 2004

Device Name

Device Name: Optical Topography System
Trade/Proprietary Name: ETG-4000 Optical Topography System
Common Name: Oximeter
Classification Name: Oximeter
Classification Number: Sec. 870.2700

Predicate Device

Predicate Device: Hitachi ETG-100, K011320

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Description

Function

The ETG-4000 is a device that measures relative changes in tissue concentration of oxy-hemoglobin and deoxy-hemoglobin and total hemoglobin (proportional to the level of blood) in the surface area of the cerebral cortex by beaming near-infrared light (670-1300nm) that can penetrate the body efficiently, and is absorbed by the hemoglobin in the blood.

The ETG-4000 displays the changes of overall Hemoglobin concentration in time- course graphs, 2D topography images and 3D topography images (motion images and still images) based on the data from multiple point measurements.

This is a non-invasive test that is done by contacting an array of small optical fiber tips on the surface of the scalp.

The ETG-4000 beams frequency modulated near-infrared light into the surface of the brain through several of the optical fibers. The light passes through the scalp, skull and upper layer of the cerebral cortex. The light is absorbed by the hemoglobin in the blood and is reflected back and is collected by optical fibers.

The ETG-4000 measures relative changes in tissue concentration of oxy-hemoglobin and deoxy-hemoglobin in the blood of the cerebral cortex at multiple points on the head simultaneously by utilizing the changes of light absorption.

The ETG-4000 provides data that show the activity status of the cerebral cortex by displaying the blood volume changes, hemodynamics in the brain surface, and the metabolic and circulatory status of the cerebral cortex in a time-course graphic representation of oxy-hemoglobin, deoxy-hemoglobin and total hemoglobin, 2D dynamic images and 3D dynamic images.

Device Intended Use

The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

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Device Technological Characteristics

The characteristics of the ETG-4000 Optical Topography System compare substantially to the ETG-100 predicate device in materials used, technology applied, and functional methodology. Differences do not affect safety and effectiveness of the device, intended use, or application methods. The ETG-4000 operates in a manner that is substantially equivalent to the cleared predicate device and represents an enhancement of the technology of the predicate.

Safety

The ETG-4000 is a non-invasive device with no moving parts. It has been designed to comply with all applicable safety standards.

Conclusions

The ETG-4000 system has been developed and validated in accordance with design controls and applicable standards. Testing has proven that the system is safe and effective for the indicated use. Risk and hazard analysis shows that there are no new safety issues associated with this system as compared with the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2004

Hitachi Medical Corporation
c/o Mr. Douglas J. Thistlethwaite
Manager of Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44087

Re: K042501
Trade/Device Name: ETG-4000 Optical Topography System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 13, 2004
Received: September 14, 2004

Dear Mr. Thistlethwaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Number (if known): K042501

Device Name: ETG-4000 Optical Topography System

Indications for Use:

The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042501

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K042501 / A

HITACHI

HITACHI MEDICAL CORPORATION, INC.
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

Please Add to

September 29, 2004

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

K5021

Re: Special 510(k) Device Modification (K042.
Hitachi ETG-4000 Optical Topography Sys

To Whom It May Concern:

The attached documents are provided to answer discrepancies noted by the 510(k) reviewer. Please contact me if there are further questions or concerns.

Refer to page 2 for the list of documents and comments.

Sincerely,

Doug Thistlethwaite
Official Correspondent, Hitachi Medical Corporation
(330)-425-1313 x3720
thistlethwaited@hitachi.com

Stc 4

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Change Request	Description/Comments
Truth and Accurate Statement	Attachment 1. See revised T&A statement using standard form.
Device Name in 510(k) Summary	Attachment 2. Corrected to read "ETG-4000 Optical Topography System".
Intended use	Attachment 3. Revised using standard form.
User Manual Corrections	Attachment 4. Changed sterilization references to cleaning. See pages 1-4 and 3-5, included.
Technical Paper references 4, 5, 6	Attachment 5. Item 5 - Note that the title reference for item 5 was incorrect in the algorithm evaluation document. The included document is the correct reference. Item 6 – The listed item was published in Japanese. The included document is an English version on the same topic.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 1

PREMARKET NOTIFICATION
TRUTH AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Official Correspondent of Hitachi Medical Corporation, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Douglas Thistlethwaite

(Name)

9/29/04

(Date)

510(k) Number: K042501

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment 2

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510(k) Number (if known): K042501

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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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1.7 Cautions in Handling the System

1.7.1 Handling optical fiber cable

The optical fiber cables are important parts that transmit irradiation light to the patient and receive reflected light to conduct it to the detectors. Observe the following cautions so as not to damage it by careless handling.

(1) Do not bend the optical fiber cable by curvature radius of 30mm or less.

(2) Do not pull the optical fiber cable or place any heavy article on it.

(3) Do not hit the fiber cable with any hard object or drop it.

(4) Use gauze soaked with alcohol to clean the tip of fiber socket and probe holder before starting measurement.

(5) Full care should be taken not to damage the tip of fiber socket.

(6) When not using the optical fiber cable, set it to the phantom in the system.

(7) When attaching and detaching the optical fiber cable to/from the system, be sure to make contact with our sales or service personnel

1.7.2 Connecting external devices

Use "BNC cable" and "RS-232C cable" attached to the system for connecting the external devices.

< CAUTION >

- Use the external devices outside the patient environment.
- The external devices used should be products approved in response to the IEC safety standard.

1.7.3 Cautions in operating and using the system

(1) When any abnormality occurred in the system, immediately stop using and shut off the power, and then make contact with our service or sales personnel.

(2) When not using the system for a long period of time, be sure to disconnect the power cable from the power outlet.

(3) Never remodel the system (both hardware and software) and optical fiber cables.

The personal computer used in this system is for measurement control, data acquisition, data processing and data display. Mounting any general computer on the system can cause malfunction. Do not mount such computer.

(4) Items described in this instruction manual are subject to change without notice for improvement.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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3.1.4 Attaching the probe holder and fiber sockets

(1) To protect infection, clean the probe holder and so on before using for the patient.

When cleaning, wipe it with gauze or the like soaked with ethanol.

Do not carry out cleaning or disinfection using chemicals or heating other than ethanol.

(2) Hook the optical fiber cable protection hose to the hanger while using it.

If the tip of fiber socket contact with scalp moves during measurement is pulled by the optical fiber cable due to body movement and so on, measurement data is affected and a wrong result may be produced. Adjust the hanger so that all optical fiber cables are bundled together at the optical fiber cable protection hose.

Attach the probe holder suitable for the objective mode to the patient.

Fig. 3.8 Attaching the Probe Holder

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Attachment 5

Wavelength dependence of the precision of noninvasive optical measurement of oxy-, deoxy-, and total-hemoglobin concentration

Yuichi Yamashita,[a] Atsushi Maki, and Hideaki Koizumi
Hitachi, Ltd., Advanced Research Laboratory, Hatoyama, Saitama, 350-0395, Japan

(Received 18 October 2000; accepted for publication 21 March 2001)

The precision of noninvasive optical measurement of the concentration changes in oxy-, deoxy-, and total-hemoglobin depends on wavelength. For estimating the precision, we calculated the noise level of the concentration changes as the uncertainty in measurements using several wavelength pairs of light. Seven laser diodes (664–848 nm) were used simultaneously for spectroscopic measurement of brain activity during finger motor stimulation. We also used the analysis of error propagation from the uncertainty in direct measurements of absorbance changes to estimate indirectly the uncertainty of concentration changes. The measurement of the concentration changes made using an 830/664-nm pair are two times (oxy-Hb) and six times (deoxy-Hb) more precise than those made using an 830/782-nm pair. © *2001 American Association of Physicists in Medicine.* [DOI: 10.1118/1.1373401]

Key words: noninvasive optical measurement, hemoglobin, wavelength, precision, brain activity

I. INTRODUCTION

Near-infrared spectroscopy (NIRS) is a method for noninvasive measurement of tissue metabolism,[1] cerebral hemorrhage,[2,3] and brain activity.[4–7] In particular, the measurement of brain activity has recently become of interest not only to neuroscience but also to clinical medicine because of the development of several measurement techniques such as fMRI,[8] PET,[9] and MEG.[10] The advantages of NIRS compared with those techniques are portability, real-time measurement, and decreased sensitivity to subject movement. Thus NIRS is expected to become a widely useful method for measurement of brain activity.

The origin of noninvasive optical measurement including NIRS is the oximeter, which measures the oxygen saturation of hemoglobin[11] by using hemoglobin absorption spectra.[12,13] Following the development of the oximeter, NIRS has also been used to detect the concentration changes in oxy-, deoxy-, and total-hemoglobin due to metabolic changes, cerebral hemorrhage, and brain activity. Using NIRS, several studies have developed a new methodology for noninvasive topographic imaging of brain activity[14–17] and measurement systems for this imaging.[18,19]

For spectroscopic measurement of hemoglobin, wide wavelength regions from visible to near-infrared are used. The light within the wavelength region of 500–600 nm is used for optical recording of an exposed brain[20] because of a large absorption band of hemoglobin. The oximeter uses the wavelength range of 600–700 nm for the measurement of hemoglobin in the earlobe or fingertip.[11] On the other hand, the light within the near-infrared region (around 800 nm) is suitable for the noninvasive measurement of the brain because of the greater penetration through the scalp and skull. The molar absorption coefficients of oxy- and deoxy-hemoglobin[13] in the near-infrared region are shown in Fig. 1. The absorption coefficients are based on natural logarithms.

For the noninvasive optical measurement of hemoglobin, several researchers have developed multiwavelength measurement in the near-infrared region.[21] For example, four wavelengths (778, 813, 867, and 904 nm) are used for measuring hemoglobin and cytochrome aa_3.[22] Another method uses three wavelengths (780, 805, and 830 nm) for the cancellation of tissue scattering change that obstructs hemoglobin measurement.[23] Moreover, two wavelengths provide a simple method for measuring concentration changes in oxy-, deoxy-, and total-hemoglobin.[5,14–18,24–26] The light within the wavelength region 750–850 nm is widely used for the noninvasive measurement of hemoglobin by two wavelengths because the oxy- and deoxy-hemoglobin spectra are crossed at an isosbestic point around the wavelength of 805 nm.[12,13] In general, a more sensitive and precise measurement is expected when there is a large difference in the absorption coefficients between two wavelengths. Thus we can expect better precision by the use of wavelengths under 700 nm because the absorption coefficient of deoxy-hemoglobin at 670 nm is four times larger than that at the 830-nm wavelength as shown in Fig. 1.

Laser diodes have recently become commercially available not only for near-infrared light (750–830 nm) but also for red light (650–700 nm). However, there is little research to estimate the effectiveness of such red light in noninvasive measurement of brain activity. Moreover, few studies have shown a wavelength dependence of measurement precision except for a theoretical study for the measurement of hemoglobin oxygenation saturation in retinal blood vessels.[27]

In the current study we estimated the dependence of measurement precision of the concentration changes in hemoglobin on wavelength in a two-wavelength analysis. We experimentally developed a simultaneous measurement system using seven laser diodes from red to near-infrared light (664–848 nm). The system uses modulation and lock-in detection for highly sensitive spectroscopic measurement of brain activity. We used the theoretical analysis of error

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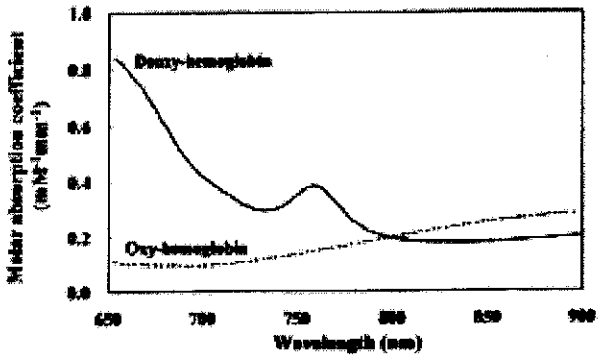

FIG. 1. Absorption spectra of oxy- and deoxy-hemoglobin (data from Ref. 13).

propagation for the indirect measurement of the precision of the concentration changes.

II. THEORY

The two-wavelength analysis of hemoglobin concentration is explained as follows. When the distance between the incident and detection points on the scalp is about 30 mm, the detected light has reached the cerebral cortex, passing through the scalp and the skull.[3,28] The absorbance $A_{\mathrm{rest}(\lambda 1)}$ for wavelength $\lambda 1$ during rest state is thus approximately,[14,15]

$$A_{\mathrm{rest}(\lambda 1)} = -\ln\left(\frac{I_{\mathrm{rest}(\lambda 1)}}{I_{0(\lambda 1)}}\right) = \varepsilon_{\mathrm{oxy}(\lambda 1)} C_{\mathrm{oxy(rest)}} d + \varepsilon_{\mathrm{deoxy}(\lambda 1)} C_{\mathrm{deoxy(rest)}} d + a_{\mathrm{rest}(\lambda 1)} + s_{(\lambda 1)}, \quad (1)$$

where $I_{\mathrm{rest}(\lambda 1)}$ is the detected light intensity during the rest state, $I_{0(\lambda 1)}$ is the incident light intensity, $\varepsilon_{\mathrm{oxy}(\lambda 1)}$ and $\varepsilon_{\mathrm{deoxy}(\lambda 1)}$ are the molar absorption coefficients of oxy- and deoxy- hemoglobin at wavelength $\lambda 1$,[13] $C_{\mathrm{oxy(rest)}}$ and $C_{\mathrm{deoxy(rest)}}$ are the concentrations of oxy- and deoxy-hemoglobin during the rest state, d is the effective path length in tissue, $a_{(\lambda 1)}$ is the attenuation due to absorption (for example, cytochrome aa_3) except for that by hemoglobin, and $s_{(\lambda 1)}$ is the attenuation due to scattering in tissue. During stimulation, the oxygenation of the hemoglobin is changed, and absorbance $A_{\mathrm{sti}(\lambda 1)}$ is given as

$$A_{\mathrm{sti}(\lambda 1)} = -\ln\left(\frac{I_{\mathrm{sti}(\lambda 1)}}{I_{0(\lambda 1)}}\right) = \varepsilon_{\mathrm{oxy}(\lambda 1)} C_{\mathrm{oxy(sti)}} d + \varepsilon_{\mathrm{deoxy}(\lambda 1)} C_{\mathrm{deoxy(sti)}} d + a_{\mathrm{sti}(\lambda 1)} + s_{(\lambda 1)}, \quad (2)$$

where sti means the values during stimulation. Because the absorbance due to hemoglobin is about ten times larger than that due to cytochrome aa_3 [the main term of $a_{(\lambda 1)}$] in tissue in the near-infrared region,[29] we neglect the change in $a_{(\lambda 1)}$ and assume $a_{\mathrm{rest}(\lambda 1)} = a_{\mathrm{sti}(\lambda 1)}$. Subtracting Eq. (1) from Eq. (2) gives the absorbance change $\Delta A_{\lambda 1}$ due to brain activity (or tissue metabolism) as follows,

$$\Delta A_{(\lambda 1)} = -\ln\left(\frac{I_{\mathrm{sti}(\lambda 1)}}{I_{\mathrm{rest}(\lambda 1)}}\right) = \varepsilon_{\mathrm{oxy}(\lambda 1)} \Delta C_{\mathrm{oxy}} + \varepsilon_{\mathrm{deoxy}(\lambda 1)} \Delta C_{\mathrm{deoxy}}, \quad (3)$$

where

$$\Delta C_{\mathrm{oxy}} = (C_{\mathrm{oxy(sti)}} - C_{\mathrm{oxy(rest)}}) d, \quad (4)$$

$$\Delta C_{\mathrm{deoxy}} = (C_{\mathrm{deoxy(sti)}} - C_{\mathrm{deoxy(rest)}}) d, \quad (5)$$

and

$$\Delta C_{\mathrm{total}} = \Delta C_{\mathrm{oxy}} + \Delta C_{\mathrm{deoxy}}. \quad (6)$$

In Eq. (6) $\Delta C_{\mathrm{total}}$ means change in total-hemoglobin concentration, which corresponds approximately to the change in blood volume. Because it is difficult to determine the effective path length d inside the cerebral cortex, we show the relative concentration changes, ΔC_{oxy}, $\Delta C_{\mathrm{deoxy}}$, and $\Delta C_{\mathrm{total}}$, in units of millimolar-millimeter. By using two different wavelengths, $\lambda 1$ and $\lambda 2$, we can obtain the concentration changes by solving Eq. (3) as follows,

$$\Delta C_{\mathrm{oxy}} = \frac{-\varepsilon_{\mathrm{deoxy}(\lambda 2)} \Delta A_{(\lambda 1)} + \varepsilon_{\mathrm{deoxy}(\lambda 1)} \Delta A_{(\lambda 2)}}{E}, \quad (7)$$

$$\Delta C_{\mathrm{deoxy}} = \frac{\varepsilon_{\mathrm{oxy}(\lambda 2)} \Delta A_{(\lambda 1)} - \varepsilon_{\mathrm{oxy}(\lambda 1)} \Delta A_{(\lambda 2)}}{E}, \quad (8)$$

$$\Delta C_{\mathrm{total}} = \Delta C_{\mathrm{oxy}} + \Delta C_{\mathrm{deoxy}} = \frac{(\varepsilon_{\mathrm{oxy}(\lambda 2)} - \varepsilon_{\mathrm{deoxy}(\lambda 2)}) \Delta A_{(\lambda 1)} + (\varepsilon_{\mathrm{deoxy}(\lambda 1)} - \varepsilon_{\mathrm{oxy}(\lambda 1)}) \Delta A_{(\lambda 2)}}{E}, \quad (9)$$

where

$$E = \varepsilon_{\mathrm{deoxy}(\lambda 1)} \varepsilon_{\mathrm{oxy}(\lambda 2)} - \varepsilon_{\mathrm{deoxy}(\lambda 2)} \varepsilon_{\mathrm{oxy}(\lambda 1)}. \quad (10)$$

Equations (7)–(10) show that the concentration changes in hemoglobin are indirect measurements calculated from the direct measurement of the absorbance changes $\Delta A_{(\lambda 1)}$ and $\Delta A_{(\lambda 2)}$. The effective path length inside tissue (brain) depends on wavelength strictly because the tissue scattering coefficient depends on wavelength slightly.[30] Although the wavelength dependence of the path length may cause the uncertainty in ΔC_{oxy}, $\Delta C_{\mathrm{deoxy}}$, and $\Delta C_{\mathrm{total}}$, there is little information on the wavelength dependence of the scattering coefficients of scalp, skull, and brain *in vivo*. In this analysis we assume that the effective path length is independent of wavelength.

If the two wavelengths are fixed, the concentration

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changes are considered to be a function of the absorbance changes. In general, error propagation in indirect measurement is explained as follows. The indirect measurement z is described by a general function f of the direct measurements x and y:

$$z=f(x,y). \tag{11}$$

If the direct measurement uncertainties of δx and δy are random and independent each other, the uncertainty of the indirect measurement δz is approximately shown by the partial differential of Eq. (11) as follows,

$$(\delta z)^2=\left(\frac{\partial f(x,y)}{\partial x}\right)^2(\delta x)^2+\left(\frac{\partial f(x,y)}{\partial y}\right)^2(\delta y)^2. \tag{12}$$

Assuming that the uncertainties of the absorbance changes for two wavelengths are random and independent, we apply Eqs. (7)–(9) to Eq. (12) and obtain the following equations;

$$(\delta\Delta C_{oxy})^2=\left(\frac{-\varepsilon_{deoxy(\lambda 2)}}{E}\right)^2(\delta\Delta A_{(\lambda 1)})^2+\left(\frac{\varepsilon_{deoxy(\lambda 1)}}{E}\right)^2(\delta\Delta A_{(\lambda 2)})^2, \tag{13}$$

$$(\delta\Delta C_{deoxy})^2=\left(\frac{\varepsilon_{oxy(\lambda 2)}}{E}\right)^2(\delta\Delta A_{(\lambda 1)})^2+\left(\frac{-\varepsilon_{oxy(\lambda 1)}}{E}\right)^2(\delta\Delta A_{(\lambda 2)})^2, \tag{14}$$

and

$$(\delta\Delta C_{total})^2=\left(\frac{\varepsilon_{oxy(\lambda 2)}-\varepsilon_{deoxy(\lambda 2)}}{E}\right)^2(\delta\Delta A_{(\lambda 1)})^2+\left(\frac{\varepsilon_{deoxy(\lambda 1)}-\varepsilon_{oxy(\lambda 1)}}{E}\right)^2(\delta\Delta A_{(\lambda 2)})^2, \tag{15}$$

where $\delta\Delta A_{(\lambda 1)}$ and $\delta\Delta A_{(\lambda 2)}$ are the direct measurement uncertainties of the absorbance changes, and $\delta\Delta C_{oxy}$, $\delta\Delta C_{deoxy}$, and $\delta\Delta C_{total}$ mean the indirect measurement uncertainties of the concentration changes in hemoglobin. According to Eqs. (13)–(15), the uncertainties in the concentration changes depend on not only the uncertainties in absorbance changes but also on the molar absorption coefficients. These equations thus indicate that $\delta\Delta C_{oxy}$, $\delta\Delta C_{deoxy}$, and $\delta\Delta C_{total}$ depend on the wavelength pair of $\lambda 1$ and $\lambda 2$.

III. MEASUREMENT SYSTEM

A block diagram of the measurement system is shown in Fig. 2. The basic design of the modulation and the lock-in detection is the same as a previous topographic imaging system[19] that has two wavelengths of 780 and 830 nm. The current system uses seven-laser diodes with wavelengths of 664, 692, 752, 782, 799, 830, and 848 nm and each has a power of 0.2 mW. Their intensities are modulated sinusoidally at frequencies ranging from 1.2 to 3.3 kHz. The modulation frequencies are chosen to avoid any overlap in their harmonic frequencies. The light from each laser diode can be

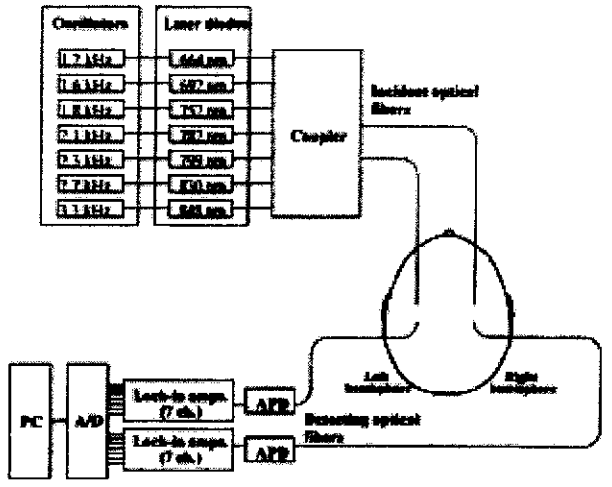

FIG. 2. Block diagram of the measurement system: APD, avalanche photodiode.

uniquely identified by the modulation frequency. After coupling each diode by an optical fiber coupler (Mitsubishi Gas Chemical CG5-S8), the seven-wavelength light is split to two incident optical fibers (1-mm diameter) arranged at the left and right hemispheres. The reflected light from each hemisphere is received by a detecting optical fiber (1-mm diameter) next to each incident fiber and connected to one of two avalanche photodiodes (Hamamatsu C5460-01). The distance between the incident and detecting optical fibers is 30 mm on each hemisphere. This arrangement allows the simultaneous measurement of the brain activities of the left and right hemispheres. The noise equivalent power of the avalanche photodiode is 20 fW/$\sqrt{\text{Hz}}$. Each avalanche photodiode output is separated into seven modulated signals, one for each wavelength, by seven lock-in amplifiers. To simultaneously measure both hemispheres and seven wavelengths, we used a total of 14 lock-in amplifiers. Each lock-in amplifier consists of an IC module that acts as a phase sensitive detector (NF Corporation CD-505R2). The input equivalent noise voltage of the lock-in amplifiers is 30 nV/$\sqrt{\text{Hz}}$. Because the noise voltage of the avalanche photodiode output after current-to-voltage amplifier is 2 μV/$\sqrt{\text{Hz}}$, the sensitivity of the lock-in amplifier is enough. The time constant of the lock-in amplifiers is 125 ms (the corresponding stabilizing time is about 500 ms). The 14 output signals of the lock-in amplifiers are sent to a computer via a multichannel analog-to-digital converter (Keithley MetraByte DAS-1801HC) with a sampling rate of 500 ms. Through the modulation and lock-in detection of all detected light, we simultaneously obtain spectroscopic measurements from each laser diode with high sensitively against stray light, virtually no crosstalk between the signals (less than −50 dB), no optical loss (no optical filter or diffraction grating), and no time loss (no switch).

IV. MEASUREMENT OF BRAIN ACTIVITY

The purpose of this measurement is not to clarify brain activity itself but to estimate the wavelength dependence on

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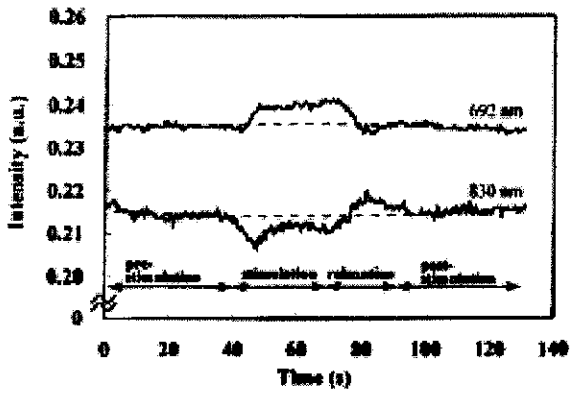

FIG. 3. Time courses of detected light intensity for left-hand stimulation at the right hemisphere (692 and 830 nm). Solid curves are measured intensities. Broken curves are the fitting curves obtained from the period of pre- and post-stimulation.

uncertainty. Thus we used a simple and well-known finger motor stimulation. The subject was a 55-year-old, right-handed, healthy male volunteer. Informed consent was obtained from the subject before the investigation. The subject was settled in a relaxed condition, a supine position, and kept his eyes closed throughout the measurement. As the stimulation, he tapped his fingers, the digits II–V, in random order against his thumb, first for the right hand and then for the left hand for 30 s. The measurements of the brain activity resulting from this stimulation were integrated 13 times for each hand.

The measurement position is the midpoint between the incident and detecting positions, because concentration changes in hemoglobin inside the cerebral cortex are usually obtained from just below these midpoints.[31] The measurement positions for each hemisphere were anatomically identified as finger motor areas by MRI.[14–16]

V. RESULTS AND DISCUSSION

A. Absorbance change

The time courses of the detected light intensities at 692 and 830 nm integrated 13 times are shown in Fig. 3 for left-hand stimulation at the right hemisphere. The detected light intensities fluctuate by about 0.01 Hz, which probably reflects natural tissue metabolism.[14,15] To extract the exact intensity changes due to brain activity from the fluctuation, we show the fluctuation as fitting curves by using the least-squares method for a third-order polynomial.[14,15] For the fitting, we used two nonstimulation (rest) periods: one just before stimulation and another after 20-s relaxation (pre- and post-stimulation periods in Fig. 3). Since the whole analyzing period (130 s) in Fig. 3 and the fluctuation period (about 100 s) are close, the third-order polynomial fitting is an empirical method to describe the fluctuation.

The intensity changes corresponding to the wavelength of 692 and 830 nm during the stimulation are positive and negative, alternatively. According to the spectra in Fig. 1, deoxy-hemoglobin is more sensitive to the 692-nm light; on

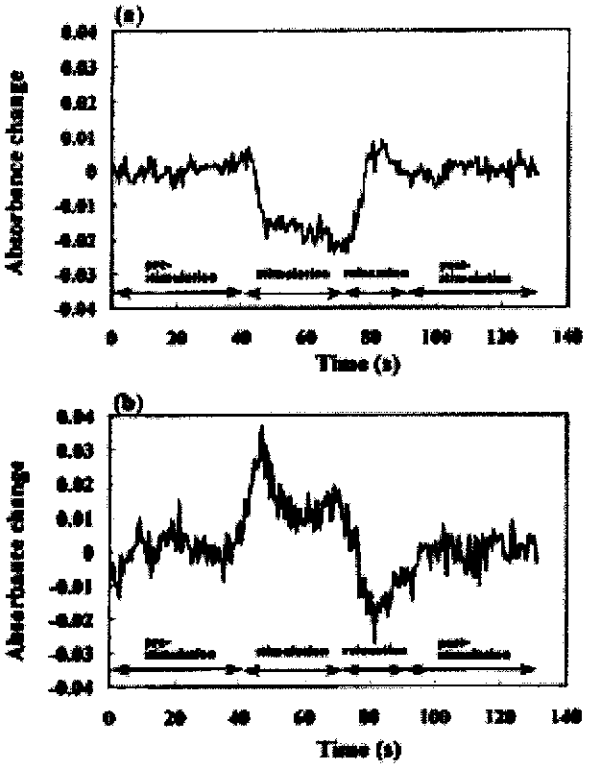

FIG. 4. Time courses of absorbance change for left-hand stimulation at the right hemisphere [(a) 692 nm and (b) 830 nm].

the other hand, oxy-hemoglobin is more sensitive to the 830-nm light. Thus the time courses in Fig. 3 probably reflect oxy-hemoglobin (830 nm) and deoxy-hemoglobin (692 nm). We use the fitting curves as I_{rest} and the measurement intensities as I_{st} in Eq. (3) to obtain absorbance changes for each detected time. The time courses of the absorbance changes in ΔA_{692} and ΔA_{830} are shown in Fig. 4. To estimate theoretically the uncertainty in the hemoglobin concentration from the analysis of error propagation, we calculate the uncertainty in the measured absorbance change ($\delta\Delta A$) as the standard deviation of the measured absorbance change during the prestimulation period. The uncertainties in the measured absorbance changes at all wavelengths are listed in Table I. These uncertainties are fairly similar for all wavelengths.

TABLE I. Experimental uncertainties of absorbance change.

	Uncertainty of absorbance change ($\delta\Delta A$)	
Wavelength (nm)	Right-hand stimulation at left hemisphere	Left-hand stimulation at right hemisphere
664	0.006 48	0.003 65
692	0.005 57	0.002 28
752	0.004 98	0.004 12
782	0.004 95	0.006 29
799	0.004 21	0.004 16
830	0.005 16	0.005 00
848	0.006 99	0.004 60

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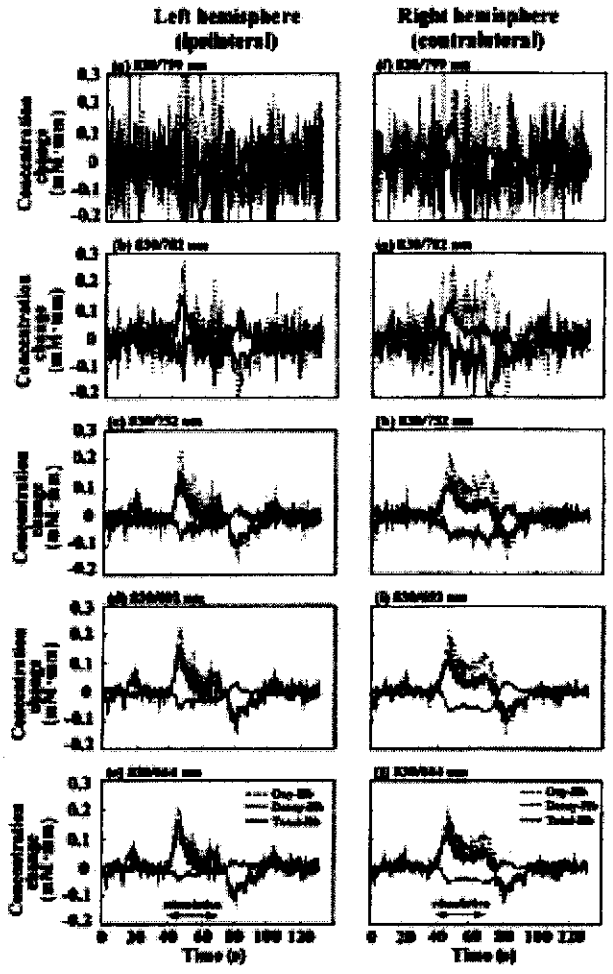

FIG. 5. Changes in concentration of oxy- (dotted curves), deoxy- (solid curves), and total- (bold curves) hemoglobin for left-hand stimulation at [(a)–(e)] the left hemisphere (ipsilateral) and [(f)–(j)] the right hemisphere (contralateral): (a) and (f) 830/799-nm pair; (b) and (g) 830/782-nm pair; (c) and (h) 830/752-nm pair; (d) and (i) 830/692-nm pair; and (e) and (j) 830/664-nm pair.

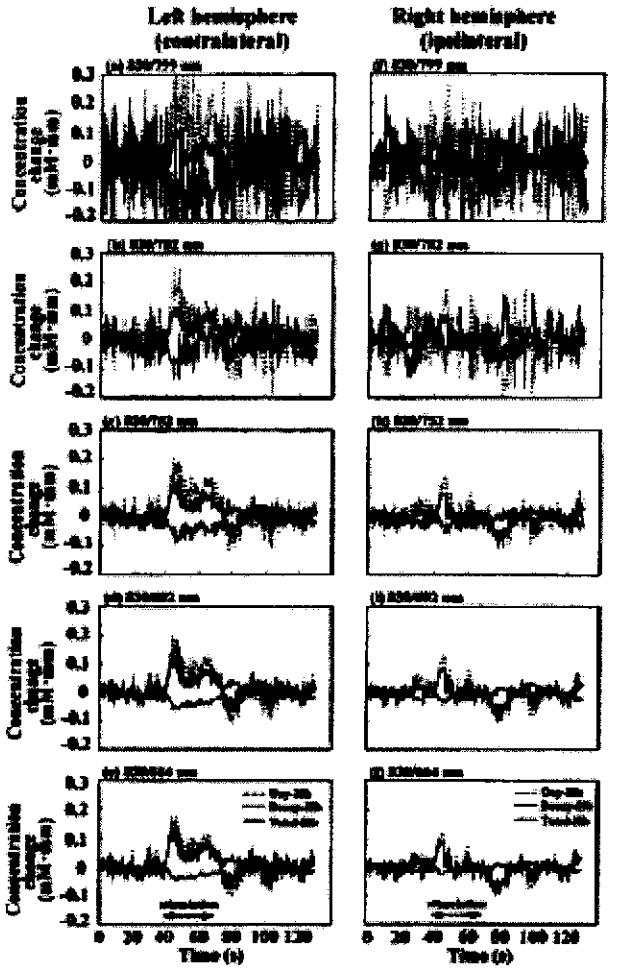

FIG. 6. Changes in concentration of oxy- (dotted curves), deoxy- (solid curves), and total- (bold curves) hemoglobin for right-hand stimulation at [(a)–(e)] the left hemisphere (contralateral) and [(f)–(j)] the right hemisphere (ipsilateral): (a) and (f) 830/799-nm pair; (b) and (g) 830/782-nm pair; (c) and (h) 830/752-nm pair; (d) and (i) 830/692-nm pair; and (e) and (j) 830/664-nm pair.

B. Concentration change in hemoglobin

Substituting the absorbance changes into Eq. (3), for arbitrary wavelength pair, we obtained the concentration changes in oxy-, deoxy-, and total-hemoglobin. In Fig. 5 (left-hand stimulation) and Fig. 6 (right-hand stimulation) we fixed $\lambda 1$ as 830 nm and showed that the measurement precision of the concentration changes depended on the second wavelength. We can clearly see that the uncertainty (noise) is reduced as $\lambda 2$ is reduced. These time courses show that oxy-hemoglobin concentration increases and deoxy-hemoglobin concentration slightly decreases in contralateral hemisphere. These time courses are typical responses to the motor stimulation.[14,15,32] For ipsilateral hemisphere, oxy- and total-hemoglobin concentration increase at the start of stimulation but decay rapidly. When the 830/799-nm pair is used, it is difficult to measure the concentration changes except for measuring total-hemoglobin. However, we can find clearly the structure of the time courses corresponding to the 830/692-nm pair.

To estimate the precision in the measurement of concentration changes in hemoglobin experimentally, we calculated the experimental uncertainty in hemoglobin concentration measurement as the standard deviation during the prestimulation period. This calculation is similar to that of the absorbance change mentioned in part A above. We also calculated theoretical estimation of the uncertainty by using the values of $\delta\Delta A$ in Table I and the hemoglobin absorption coefficient. We then put these values into Eqs. (13)–(15) to determine the uncertainty in the concentration change. The experimental and theoretical uncertainties are compared in Table II and show good agreement. The measurement of the concentration changes by using the 830/664-nm pair are two times (oxy-Hb) and six times (deoxy-Hb) more precise than those by using the 830/782-nm pair. On the other hand, the

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TABLE II. Uncertainties of concentration changes in oxy-, deoxy-, and total-hemoglobin in two-wavelength analysis with 830 nm.

	Uncertainty of concentration change in hemoglobin [$\times 10^{-2}$(mM mm)]											
	Right-hand stimulation at left hemisphere						Left-hand stimulation at right hemisphere					
	Oxy-Hb		Deoxy-Hb		Total-Hb		Oxy-Hb		Deoxy-Hb		Total-Hb	
Wavelength (nm)	Theory	Expt.	Theory	Expt.	Theory	Expt.	Theory	Expt.	Theory	Expt.	Theory	Expt.
664	2.57	2.58	1.00	1.11	2.17	2.16	2.44	2.43	0.63	0.62	2.08	2.09
692	2.69	2.84	1.41	1.48	2.17	2.13	2.61	2.59	0.78	0.76	2.04	2.04
752	3.12	3.51	2.01	2.31	2.11	1.99	3.18	3.31	1.89	2.00	1.96	1.92
782	4.73	6.06	4.42	5.74	2.07	1.75	5.29	6.53	5.57	6.68	2.19	1.89
799	9.70	12.8	10.7	14.4	2.21	2.28	8.57	12.5	9.46	14.1	2.17	2.26

measurement of total-hemoglobin concentration is only slightly dependent on wavelength. Moreover, the value of the concentration change in total-hemoglobin is independent of the wavelength pairs (Figs. 5 and 6). This suggests experimentally that the effective path length in the brain does not depend on the wavelength (664–830 nm). The Monte Carlo simulation of the photon propagation in the head shows that the structure of the head (skin, skull, cerebrospinal fluid, and brain) strongly affects the distribution of the photon path.[33] More study is needed on the photon path in the head.

C. Estimation of optimal wavelength pair

The first wavelength λ1 was fixed as 830 nm and the second wavelength dependence of the precision was estimated (Fig. 7). For the theoretical estimation we use $\delta\Delta A_{(\lambda 1)}$ of 830-nm light as 0.005 16 and the $\delta\Delta A_{(\lambda 2)}$ of second wavelength is 0.005 24, which is the mean value of $\delta\Delta A$ from 664 to 799 nm (left hemisphere; right-hand stimulation). According to Fig. 7 the agreement between experiment and theory is very good. The uncertainty in total-hemoglobin concentration is less sensitive to this wavelength region; on the other hand, the uncertainties in oxy- and deoxy-hemoglobin concentration sharply drop around 800 nm and have a minimum at 760 nm, which corresponds to an absorption peak of deoxy-hemoglobin at this wavelength. Below 730 nm, the uncertainties gradually drop and become stable. The most precise measurement is for deoxy-hemoglobin under 700 nm as the second wavelength.

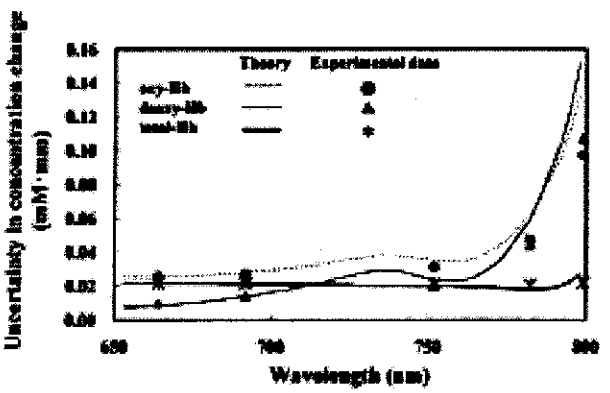

FIG. 7. Uncertainties of concentration change against wavelength in two-wavelength analysis with 830 nm and a second wavelength (right-hand stimulation at left hemisphere). Uncertainties in oxy- (dotted curve), deoxy- (solid curve), and total- (bold curve) hemoglobin are shown theoretically. Experimentally measured uncertainties are also shown [oxy- (closed circle), deoxy- (closed triangle), and total- (asterisk) hemoglobin].

We also used a wavelength of 848 nm as λ1 in the analysis of the wavelength dependence of measurement precision. This wavelength produces very similar results to those with 830 nm as λ1. Although the precision in the measurement of motor activation is good when using the 830/664-nm pair, more study is needed on other activation, such as visual, auditory, and language. Moreover, the kind of uncertainty estimation studied here can be applied to three-, four-, and multi-wavelength analysis as well.

VI. CONCLUSION

We estimated the wavelength dependence of the measurement uncertainties (concentration changes in oxy-, deoxy-, and total-hemoglobin). Using two-wavelength analysis when one wavelength is fixed at 830 nm, we showed theoretically and experimentally that the uncertainties are dependent on the wavelength pair in oxy- and deoxy-hemoglobin measurements. Moreover, measurement of the concentration changes by using the 830/664-nm pair are two times (oxy-Hb) and six times (deoxy-Hb) more precise than those by using the 830/782-nm pair. On the other hand, the measurement of total-hemoglobin concentration is only slightly dependent on the wavelength pair.

ACKNOWLEDGMENTS

We would like to thank Dr. Iwao Kanno (Akita Research Institute of Brain and Blood Vessels) for his fruitful discussions. This research was supported by Japan Science and Technology Corporation.

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Wavelength Dependence of Sensitivity in NIRS for Measurements of Different Brain Areas

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Introduction

Concentration changes in hemoglobin (Hb) caused by neural activity can be measured in cerebral cortices using near-infrared spectroscopy (NIRS) [1-3]. We proposed NIR topography in 1995 as a new noninvasive imaging modality [4] and have developed the system since then. The system called 'Optical Topography' (OT) is commercially available (ETG-100; Hitachi Medical Corporation). It has 10 laser diodes of two wavelengths at 780 and 830 nm and measures relative concentration changes in oxy-Hb (ΔC_{oxy}) and those in deoxy-Hb (ΔC_{deoxy}). These values of ΔC_{oxy} and ΔC_{deoxy} are derived from the differences in absorption coefficients of oxy-Hb (ε_{oxy}) and deoxy-Hb (ε_{deoxy}) between two wavelengths.

The wavelength dependence of the measurement sensitivity has lately been evaluated using the error propagation law [5]. The study suggested that the measurement uncertainties are dependent on the differences in ε_{oxy} and ε_{deoxy} between two wavelengths in indirect measurements. Yamashita and colleagues also conducted an experiment to investigate the validity of wavelength dependence and found results supporting the prediction that a more sensitive measurement would be achieved if we use two wavelengths that have larger differences in ε_{oxy} and ε_{deoxy} between two wavelengths. That is, wavelengths shorter than 780 nm paired with 830 nm should provide more sensitive measurements of ΔC_{oxy} and ΔC_{deoxy}.

However, the experimental confirmation in the previous study seemed to be insufficient for practical use because a structural variance in tissue is expected in different areas of the head while they measured only motor function in the parietal lobe for one subject. Therefore, we examine which wavelength allows more sensitive measurements among various areas of the brain and subjects. Wavelengths of 678, 692, and 780 nm were tested as a wavelength paired with 830 nm among various lobes in 6 subjects.

Methods

We used a system with 4 laser diodes of wavelengths at 678, 692, 780, and 830 nm. The 4 waves were guided into an optical fiber to irradiate the same point simultaneously. Each power of waves was 1.0 mW (intensity average: 1.06 mW, standard deviation: 0.10). The mixed light was irradiated to the head-skin, and reflected lights from tissues were obtained using another optical-fiber at a distance of 30 mm from an irradiation fiber. The amplitude of each wave was modulated at different frequency (1.0 ~ 2.7 kHz) to separate the detected

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signal into individual light sources using lock-in amplifiers. The reflected lights were detected every 500 ms using an avalanche photodiode. Four lobes (frontal, temporal, occipital, and parietal) for 6 subjects (4 males and 2 females) were measured in 120-s periods with no task.

The time-courses of reflected light in randomly selected periods of 30-s were analyzed in each condition. After concentration changes in Hb were calculated using three wavelength-pairs (678/830 nm, 692/830 nm, and 780/830 nm), the standard deviations of ΔC_{oxy} and ΔC_{deoxy} were used as the noise-level to compare the sensitivity of measurements. The paired wavelength was fixed at 830 nm because a longer wavelength such as 848 nm had no advantages [5].

Results and Discussion

The differences in noise-levels among wavelength pairs were examined in each measurement area. The pairs of 678/830 nm and 692/830 nm showed smaller noise-levels than the pair of 780/830 nm in all lobes, as were expected. Although the noise-level in the pair of 678/830 nm was smaller than that in the pair of 692/830 nm in only the frontal lobe, the pair of 692/830 nm showed less noise-level than the pair of 678/830 nm in other lobes. The inconsistency with the previous study [5], which had shown that a shorter wavelength such as 664 nm could achieve a lower noise-level in the parietal lobe, could be due to the great variance of noise-level among areas and subjects. In general, the pair of 692/830 nm achieved a stable improvement in sensitivity across all lobes and subjects.

In addition, we examined the noise-level of the reflected light at each wavelength and found that the level at 678 nm was occasionally larger than those in other wavelengths. This result suggests that the attenuation of reflected light at 678 nm is sometimes too strong to measure cortical activation accurately compared with other wavelengths.

We conclude that the pair of 692/830 nm provides more sensitive NIRS measurements in all brain lobes, making it ideal for practical use, while shorter wavelengths such as 678 nm appear to be less suitable because of dependency on the measurement area.

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Practicality of wavelength selection to improve signal-to-noise ratio in near-infrared spectroscopy

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Received 8 August 2003; revised 9 December 2003; accepted 9 December 2003

Near-infrared spectroscopy (NIRS), which can be used to detect changes in the concentration of oxygenated hemoglobin (oxy-Hb) and deoxygenated hemoglobin (deoxy-Hb) in tissue by using illumination at two different wavelengths, is often applied to noninvasive measurements of human brain functions. It is common to use two wavelengths that are on opposite sides of the point where the optical absorptions of oxy- and deoxy-Hb are equal (about 800 nm) but an optimal wavelength pair has not yet been determined. In this study, we conducted simultaneous recordings at five wavelengths (678, 692, 750, 782, and 830 nm) to determine the best wavelength for pairing with 830 nm. A theory suggests that pairing a shorter wavelength with 830 nm can provide more sensitivity because of the larger difference in absorption coefficients of hemoglobin between two wavelengths. The changes measured in four cortical areas (frontal, occipital, parietal, and temporal) showed that the noise level when the 678-, 692-, and 750-nm wavelengths were paired with 830 nm was usually lower than when the 782-nm wavelength was paired with 830 nm, which is consistent with theoretical prediction. Moreover, the signal-to-noise ratios (S/Ns) and wavelength dependencies of the power detected in all areas and subjects together suggest that the 692-nm pairing had the highest S/N. This suggests that the optimal wavelengths depend on not only the difference in the absorption coefficients of hemoglobin but also on the optical properties in the measurement area, which affect the strength of the attenuation data. The 692-nm wavelength is thus a more optimal choice than wavelengths around 780 nm for pairing with 830 nm to measure Hb changes induced by cortical activation. The improved S/N enables more sensitive statistical analysis, which is essential to functional mapping with NIRS.
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Keywords: Near-infrared spectroscopy; Wavelength; Hemoglobin; Cortical activation; Sensitivity

Introduction

Near-infrared spectroscopy (NIRS) has been used for measurements of biological metabolism such as concentration changes in hemoglobin (Hb) species (Jobsis, 1977; Jobsis et al., 1988; Wray et al., 1988). Particularly important has been the application of NIRS to noninvasive measurements of concentration changes in oxygenated hemoglobin (oxy-Hb) and deoxygenated hemoglobin (deoxy-Hb) related to brain functions (Chance et al., 1993; Hoshi and Tamura, 1993; Kato et al., 1993; Villringer et al., 1993). Since near-infrared (NIR) topography with multiple measurement positions was introduced as a noninvasive imaging modality (Maki et al., 1995; Yamashita et al., 1996a,b), many cognitive studies using NIR topography have been reported in various fields (Kennan et al., 2002a,b; Minagawa-Kawai et al., 2002; Noguchi et al., 2002; Obata et al., 2003; Pena et al., 2003; Sato et al., 1999; Taga et al., 2000; Watanabe et al., 1998). In this method, the changes in the concentration of oxy-Hb and deoxy-Hb in the cerebral cortex are simultaneously recorded at multiple positions by using light at two different wavelengths (780 and 830 nm). Noninvasive NIR topography, which has advantages such as applicability to infants, is expected to provide novel information on brain function (Koizumi et al., 1999, 2003).

The current NIR system has both future potential and current limitations (Koizumi et al., 2003). One limitation is the signal-to-noise ratio (S/N)—the data must be averaged to detect small activation signals such as event-related responses (Kennan et al., 2002b; Noguchi et al., 2002). Improving S/N sensitivity is thus one improvement needed to make NIR topography more useful. We have investigated wavelength selection for improving the S/N in practical NIR measurements.

In dual-wavelength analysis, equations based on the modified Beer–Lambert law are used (Cope and Delpy, 1988; Delpy et al., 1988):

$$L \cdot \Delta C_{\mathrm{oxy}} = \Delta C'_{\mathrm{oxy}\ (\lambda 1,\ \lambda 2)} = \frac{-\varepsilon_{\mathrm{deoxy}\ (\lambda 2)} \cdot \Delta A_{(\lambda 1)} + \varepsilon_{\mathrm{deoxy}\ (\lambda 1)} \cdot \Delta A_{(\lambda 2)}}{E}, \quad (1)$$

$$L \cdot \Delta C_{\mathrm{deoxy}} = \Delta C'_{\mathrm{deoxy}\ (\lambda 1,\ \lambda 2)} = \frac{\varepsilon_{\mathrm{oxy}\ (\lambda 2)} \cdot \Delta A_{(\lambda 1)} - \varepsilon_{\mathrm{oxy}\ (\lambda 1)} \cdot \Delta A_{(\lambda 2)}}{E}, \quad (2)$$

where

$$E = \varepsilon_{\mathrm{deoxy}\ (\lambda 1)} \cdot \varepsilon_{\mathrm{oxy}\ (\lambda 2)} - \varepsilon_{\mathrm{deoxy}\ (\lambda 2)} \cdot \varepsilon_{\mathrm{oxy}\ (\lambda 1)}. \quad (3)$$

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doi:10.1016/j.neuroimage.2003.12.017

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The relative concentration changes ($\Delta C'_{oxy\ (\lambda 1,\ \lambda 2)}$ and $\Delta C'_{deoxy\ (\lambda 1,\ \lambda 2)}$) are expressed as the concentration changes (ΔC_{oxy} and ΔC_{deoxy}) multiplied by the indefinite optical path-length in the activation region (L), where ΔA, ε_{oxy}, and ε_{deoxy} indicate the logarithm of the intensity changes, the absorption coefficient of oxy-Hb, and that of deoxy-Hb, respectively, for two wavelengths ($\lambda 1$, $\lambda 2$). Note that we have to assume that the path-length (L) is equal for every wavelength because accurate estimation of L is almost impossible with this technique. Although the wavelength dependence of L can be predicted and can make independent measurements for multiple chromophores difficult (cross-talk), the cross-talk effect is negligible when measuring changes only in oxy- and deoxy-Hb (Uludag et al., 2002).

Wavelengths that are symmetric about the point where the optical absorptions of oxy- and deoxy-Hb are equal (about 800 nm) are usually used as $\lambda 1$ and $\lambda 2$ (e.g., 780 and 830 nm), but optimal wavelengths have not yet been determined. The present study aims to improve the S/N for hemoglobin changes expressing cortical activation by selecting an appropriate wavelength pair for practical use.

According to the general error-propagation law, the noise levels in the Hb changes depend on the differences in the Hb absorption coefficients between the two wavelengths (Yamashita et al., 2001). The theoretical noise levels in $\Delta C'_{oxy}$ and $\Delta C'_{deoxy}$ depend on the wavelengths and can be expressed as

$$(\delta\Delta C'_{oxy\ (\lambda 1,\ \lambda 2)})^2 = \left(\frac{-\varepsilon_{deoxy\ (\lambda 2)}}{E}\right)^2 (\delta\Delta A_{\ (\lambda 1)})^2 + \left(\frac{\varepsilon_{deoxy\ (\lambda 1)}}{E}\right)^2 (\delta\Delta A_{\ (\lambda 2)})^2, \quad (4)$$

$$(\delta\Delta C'_{deoxy\ (\lambda 1,\lambda 2)})^2 = \left(\frac{\varepsilon_{oxy\ (\lambda 2)}}{E}\right)^2 (\delta\Delta A_{\ (\lambda 1)})^2 + \left(\frac{-\varepsilon_{oxy\ (\lambda 1)}}{E}\right)^2 (\delta\Delta A_{\ (\lambda 2)})^2, \quad (5)$$

where $\delta\Delta C'_{oxy\ (\lambda 1,\ \lambda 2)}$ and $\delta\Delta C'_{deoxy\ (\lambda 1,\ \lambda 2)}$ are the indirectly measured noise levels of $\Delta C'_{oxy\ (\lambda 1,\lambda 2)}$ and $\Delta C'_{deoxy\ (\lambda 1,\lambda 2)}$, and $\delta\Delta A_{\ (\lambda 1)}$ $\delta\Delta A_{\ (\lambda 1)}$ and $\delta\Delta A_{\ (\lambda 2)}$ are the directly measured noise levels of $\Delta A_{\ (\lambda 1)}$ and $\Delta A_{\ (\lambda 2)}$. Assuming that $\delta\Delta A_{\ (\lambda 1)}$ and $\delta\Delta A_{\ (\lambda 2)}$ are random and independent, we can calculate $\delta\Delta C'_{oxy\ (\lambda 1,\ \lambda 2)}$ and $\delta\Delta C'_{deoxy\ (\lambda 1,\ \lambda 2)}$ using Eqs. (4) and (5). On the assumption that $\delta\Delta A_{\ (\lambda 1)}$ and $\delta\Delta A_{\ (\lambda 2)}$ are the same, using a wavelength pair having a larger difference in the hemoglobin absorption between the two wavelengths should provide more sensitivity. For example, wavelengths shorter than 780 nm paired with 830 nm should provide less noise in measurements of $\Delta C'_{oxy}$ and $\Delta C'_{deoxy}$ (Koizumi et al., 2003; Yamashita et al., 2001). Another study using a similar theory suggests that the 780- and 830-nm pairings are not optimal for oxygen saturation-related measurements (Strangman et al., 2003).

However, the optimal range of wavelengths has not been determined and the effectiveness of these wavelengths for practical use is still unclear. A previous study (Yamashita et al., 2001) measured only motor function in the parietal lobe of one subject although optical properties are predicted to depend on the anatomical variances among subjects and areas. Although the results supported the theoretical prediction that using two wavelengths having larger differences in the absorption coefficients of hemoglobin reduces measurement noise, they did not clarify the method's practicality. On the other hand, another study (Strangman et al., 2003) conducted simultaneous measurements with multiple wavelengths of 675, 691, 752, 780, 788, 830, and 840 nm. The study, however, did not compare actual noise levels among wavelength pairs although it concluded that pairing 690 or 760 nm with 830 nm is better than pairing 780 with 830 nm for measuring oxygenation changes.

We think experimental examination of the Hb changes resulting from the use of an optimal wavelength (approximately 650–750 nm) paired with 830 nm is necessary to determine the practicality of this method because simulation studies cannot verify every possible model. In particular, the practicality of each wavelength should be investigated by measuring the variation in the detected light power, which depends on the transparency of the wavelength in tissue. Moreover, the dependencies of the activation-signal profile and S/N on the wavelengths should be examined to verify that these wavelengths measure the Hb changes induced by the same cortical activation.

In this study, we measured cortical activations in four areas (frontal, occipital, parietal, and temporal) with simultaneous recording using five wavelengths (678, 692, 750, 782, and 830 nm) to find a way to improve the sensitivity of NIRS measurements.

Materials and methods

Subjects and measurement paradigm

Four subjects (two men, two women; ages 25–45) gave informed consent to participate in this study. All subjects showed right-handedness by the Edinburgh inventory (Oldfield, 1971).

Four stimulation paradigms were given to each subject for measurement of the four cortical areas. To measure frontal cortex activation, mental arithmetic tasks were used. A number from 1 to 9 was randomly presented every 1500 ms. The subjects were instructed to calculate the running total in their head and to whisper with minimum jaw movement the answer at the end of each string of 10 numbers. For the occipital cortex measurements, rectangular black-and-red checkerboard stimuli with the squares reversing between black and red at a frequency of 8 Hz were presented. The subjects were instructed to focus their attention on the fixation cross at the center. The parietal cortices were activated using a finger-tapping task—the fingers of the left hand were placed on the tip of the thumb in serial order (forefinger–second finger–third finger–little finger–third finger–second finger–forefinger). The subjects were asked to repeat the tapping sequence as rapidly as possible during the time 'Tapping' was presented on a CRT monitor. Auditory-language stimuli were used for the temporal area measurements. The subject wore headphones and was instructed to carefully listen to a Japanese story presented through the headphones while looking at the fixation cross on the monitor. In each measurement paradigm, a 15-s stimulation period and a 30-s rest period were alternated 10 times after a 30-s rest period. All the visual stimuli were displayed on a CRT monitor placed 70 cm from the subject's eyes in a dark room. During the measurements, the subject sat in a chair and was instructed to fix his or her gaze on the cross at the center of monitor and to concentrate on each task.

The measurement positions were determined for each subject based on the preliminary experiments using multichannel NIR topography (Optical Topography®, ETG-100: Hitachi Medical Corporation, Japan) using the 780- and 830-nm pairings. The positions showing significant activation in the frontal areas were around the middle of the F_{P2}, F_4, and F_8 locations in the international 10-20 system (American Electroencephalographic

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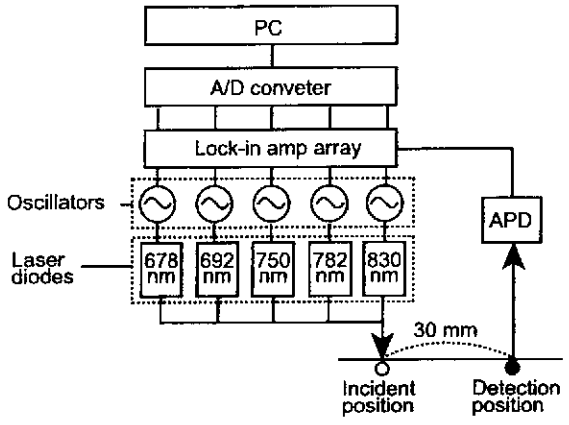

Fig. 1. Diagram of measurement system. APD: avalanche photodiode.

Society, 1994). The measurement positions in the occipital, parietal, and temporal areas were determined to be around the O_1, C_4, and T_3 locations, respectively. In general, the locations in the international 10-20 system have an appropriate relationship with cortical anatomy (Towel et al., 1993).

NIRS measurement

A measurement system with five laser diodes operating at different wavelengths (678, 692, 750, 782, and 830 nm) was used (Fig. 1). The five waves were guided into an optical fiber to irradiate the same point simultaneously. The continuous mixed-light was irradiated on the subjects' head, and the reflected light was detected every 100 ms using an avalanche photodiode (APD) located 30 mm from the incident position. Optical fibers (diameter of 1 mm) were used for both the irradiating and detecting lights. The average power of each light source was 0.93 mW, and each source was modulated at a different frequency (1.0–2.7 kHz) to enable separation using a lock-in amplifier after detection.

Data analysis

Hb time course

The detected temporal data for the attenuation change at each wavelength were separated into blocks consisting of a 5-s prestimulation period during the resting state, a 15-s stimulation period during the stimulation, and a 25-s poststimulation period during the rest state. The data were baseline-corrected using the data for the 5-s prestimulation period and the data for the final 10 s of the poststimulation period. After eliminating the blocks with artifacts caused by obvious motions such as a cough or sneeze, we were left with more than eight blocks for each area and subject. Using the modified Beer–Lambert law, we derived the concentration changes in oxy- and deoxy-Hb [$\Delta C'_{\mathrm{oxy}\,(\lambda 1,\,\lambda 2)}$ and $\Delta C'_{\mathrm{deoxy}\,(\lambda 1,\,\lambda 2)}$] from the attenuation data of two wavelengths [$\Delta A_{(\lambda 1)}$ and $\Delta A_{(\lambda 2)}$], one of which was fixed at 830 nm and paired with one of the four other wavelengths (e.g., Maki et al., 1995). We compared the Hb time course for the 782- and 830-nm pairs (the 782-nm pairing) with that for the 678-, 692-, and 750-nm pairings in each area.

Activation-signal amplitude

Activation signals were statistically assessed and selected. Assuming that the hemodynamic changes induced by the stimuli were delayed 6 s from the stimuli onset, the shifted period of the stimulation was defined as the activation period. The mean Hb changes during the prestimulation period and those during the activation period were calculated for each block. Based on the t value (paired t test) between the mean Hb changes in the prestimulation periods and those in the activation periods, data with significant t values ($P < 0.1$) were selected for further analysis using the activation signal. After the selection, the mean Hb changes in the activation periods were used to examine the signal amplitude and signal-to-noise ratio (S/N). We calculated the signal-to-noise ratio by dividing the signal amplitude by the noise amplitude.

Noise levels in Hb changes

The noise amplitude in the Hb changes was determined using attenuation data for the first prestimulation period of 20 s before the original data was separated into blocks. The concentration changes in the oxy- and deoxy-Hb were derived from the data after it was baseline-corrected using a line. The noise amplitude was defined as the standard deviation in the Hb changes after applying a high-pass 1.5-Hz filter. A filtering threshold was set so as to extract the pure system noise, eliminating the effect of spontaneous low-frequency fluctuations and physiological signals such as respiration and pulse signals.

Results and discussion

Detected power of reflected light

The detected power of the original reflected light (830 nm) is shown in Fig. 2 for each cortical area. The power detected in the frontal area differed greatly from those in the other areas, probably because the subjects had no hair covering the frontal area. The power detected in the temporal area was higher than in the occipital and parietal areas, possibly due to differences in the root-of-hair density and cranium thickness.

As shown in Fig. 3, the relative detected power was weaker the shorter the wavelength, except for the frontal area. Compared with the detected power for 830 nm, those for 678, 692, and 750 nm were 36%, 44%, and 59% on average, respectively. The power detected in each area differed depended on the wavelength, suggesting the need for spectroscopic study of human hair.

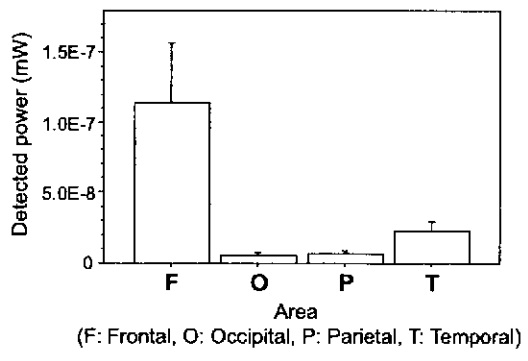

Fig. 2. Mean detected power (830 nm) in four cortical areas calculated using recorded voltage and corrected for detector's wavelength sensitivity and amplifier gain. Error bars indicate standard error.

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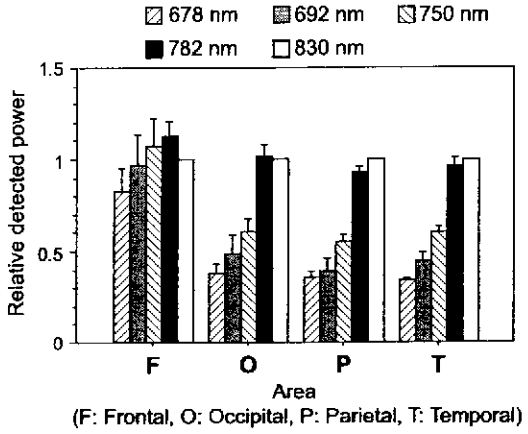

Fig. 3. Relative detected power of five wavelengths for each area corrected for detector's wavelength sensitivity and amplifier gain, and normalized by data for 830 nm. Error bars indicate standard error.

Hb time course

Using the attenuation data for each wavelength, we calculated the Hb time courses. The block-averaged results for each cortical area for each wavelength pair for a representative subject are shown in Fig. 4. The shapes of the time courses obtained with the different wavelength pairs were similar for each area. As in previous studies (e.g., Sato et al., 1999), the concentration of oxy-Hb increased and that of deoxy-Hb decreased during the task period in the occipital, parietal, and temporal areas. However, increases in both oxy- and deoxy-Hb were found in the frontal area. The variation in the deoxy-Hb could be related to variations in the vascular system, as suggested by another study (Yamamoto and Kato, 2002), in which similar results were found in Broca's area. Further studies focusing on the relationship among neural activity, the fMRI signal, and the NIRS signal are needed for better understanding of the physiological mechanism.

The t tests for all subjects except one indicated significant activation for both oxy- and deoxy-Hb in every cortical area. The exceptional subject showed insignificant deoxy-Hb changes only in the parietal and occipital areas. One reason for the exception might be the possibility of variation in the deoxy-Hb changes (Yamamoto and Kato, 2002). Another possibility is a poor S/N for deoxy-Hb in both areas (Table 1). The activation-signal amplitudes for deoxy-Hb are usually less than half those for oxy-Hb (Maki et al., 1996).

After low-pass 0.8-Hz filtering, the profiles obtained from the four wavelength-pairs were compared. The low-pass filtering eliminated the effects of high-frequency system noise. The correlation coefficients (Pearson's product-moment correlation coefficient) are listed in Table 2. Every comparison shows a significant positive correlation ($P < 0.0001$) for all subjects, indicating that every wavelength pair measured almost the same cortical area.

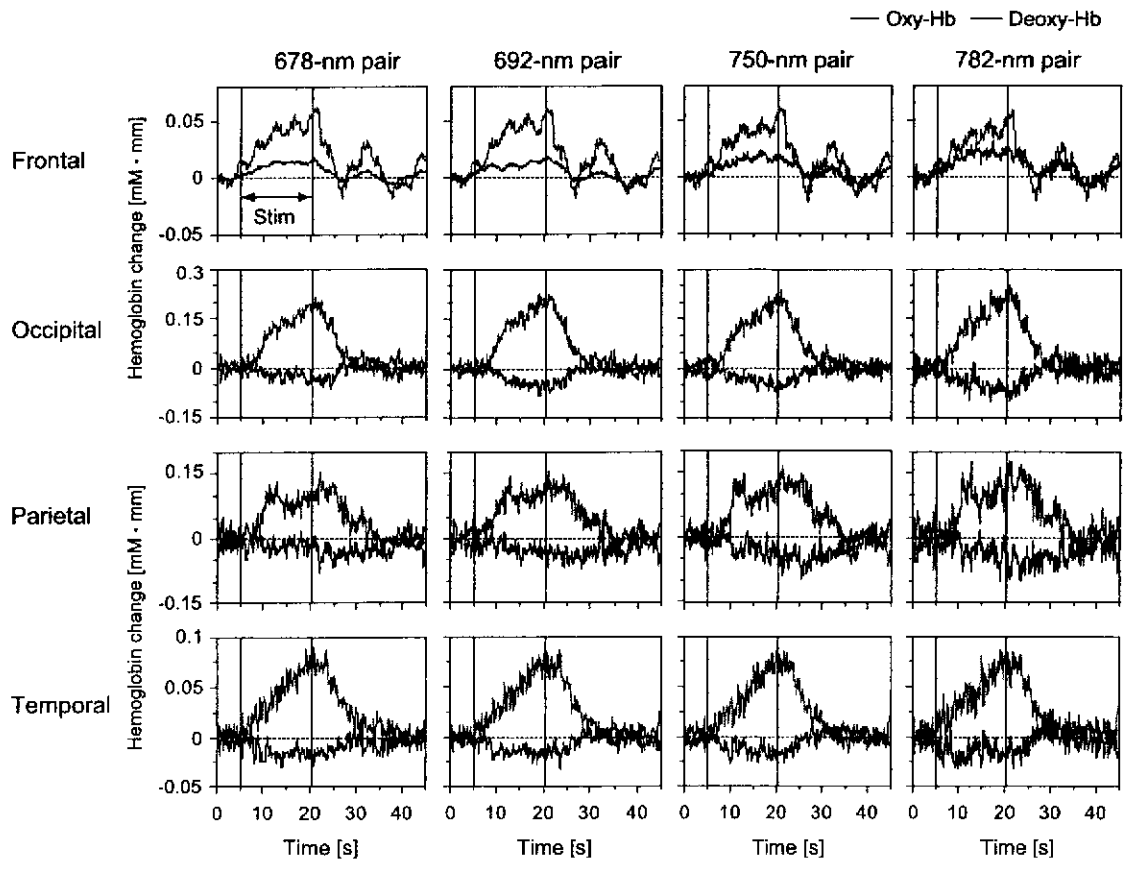

Fig. 4. Block-averaged hemodynamics in each cortical area for each wavelength pair for a representative subject. All wavelength pairs were simultaneously measured in each area. In the 'stim' period, a stimulus was given to the subject.

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Table 1
Relative signal-to-noise ratios (S/Ns) for four areas for 782-nm pairing calculated by dividing signal (amplitude of Hb change in activation periods) by noise level (standard deviation during pre-activation period)

Hb species	Area	Relative S/N (mean ± SE)
Oxy-Hb	frontal	1.00
	occipital	0.57 ± 0.11
	parietal	0.46 ± 0.05
	temporal	0.62 ± 0.04
Deoxy-Hb	frontal	0.64 ± 0.04
	occipital	0.31 ± 0.13
	parietal	0.20 ± 0.08
	temporal	0.37 ± 0.10

They were normalized using Oxy-Hb data for frontal area.
SE = standard error.

The correlation coefficients for deoxy-Hb for all areas except for the frontal area were relatively low because of the lower S/N in those areas. The mean S/Ns for deoxy-Hb in the occipital, parietal, and temporal areas were about 31%, 20%, and 37% relative to the S/N for oxy-Hb in the frontal area, respectively (Table 1). The lower correlate coefficients for deoxy-Hb may have resulted from the area dependence of the detected power (Fig. 2) and a lower S/N.

Activation-signal amplitude

The activation-signal amplitudes normalized using the data for the 782-nm pairing are shown in Fig. 5. The amplitudes were lower for the shorter wavelengths in most cases. An analysis of variance (ANOVA) (wavelength pairs × areas) indicated significant effect of wavelength pairs for deoxy-Hb [$F(3,40) = 3.65$, $P < 0.05$] although no significant effect for oxy-Hb [$F(3,48) = 0.97$, $P > 0.1$] was found. According to Eqs. (1)–(3), the Hb changes ($\Delta C'_{oxy}$ and $\Delta C'_{deoxy}$) do not depend on the wavelength pair, but it is possible that the activation-signal amplitudes were affected by a difference in optical path-lengths (L's) among the wavelengths.

Although the path-length (L) should be the same for different wavelengths according to Eqs. (1)–(3), it changes depending on the optical properties of the biological tissue. We defined L as the partial path-length, which is the average path-length of light traveling through a focal region of absorber changes (Hiraoka et al., 1993). To estimate the wavelength dependence of the activation-signal amplitude, we calculated the relative path-length (L') for each wavelength, on the assumption that the path-lengths of 782 and 830 nm are the same:

$$L'(\lambda 1) = \frac{\Delta A_{(\lambda 1)}}{\varepsilon_{oxy\,(\lambda 1)} \times \Delta C'_{oxy\,(782,\,830)} + \varepsilon_{deoxy\,(\lambda 1)} \times \Delta C'_{deoxy(782,\,830)}}, \quad (6)$$

where the concentration changes for the 782-nm pairing were used as the standard changes [$\Delta C'_{oxy\,(782,\,830)}$ and $\Delta C'_{deoxy\,(782,\,830)}$] for every wavelength to isolate the difference in amplitude of $\Delta C'_{oxy}$ and $\Delta C'_{deoxy}$ for the 678-, 692-, and 750-nm pairings due to the variance in optical path-length (L) from that for the 782-nm pairing. Recent reports suggest that the partial path-length is more appropriate than the differential path-length for compensating for the difference in NIRS sensitivity (Okada and Delpy, 2003a,b).

The relative path-lengths (L') calculated for each area are shown in Fig. 6. The average path-lengths for 678, 692, and 750 nm were shorter than those for 782 and 830 nm although there were large intersubject variances. These results indicate that the variances in the signal amplitude might be explained by the effect of the varying path-lengths. The large variances for 678, 692, and 750 nm would greatly affect the deoxy-Hb signal because shorter wavelengths have a higher absorption coefficient in deoxy-Hb.

The wavelength dependence of the optical path-length might raise concern about the cross-talk effect (Uludag et al., 2002). Although we could not determine which wavelength pair actually resulted in the minimum cross-talk since the L's were calculated on the assumption that the path-lengths of 782 and 830 nm are the same, it is important that the direction of the signal (positive or negative) was consistent among the wavelength pairs in each hemoglobin and subject. This suggests that the wavelength dependence of cross-talk was small enough not to cause a different activation pattern and that the signal amplitude can be corrected using the relative path-length when the signal amplitudes in the 782-nm pair are fixed as the standard.

Table 2
Correlation coefficients of Hb time courses in wavelength-pairs comparison

Wavelength-pairs comparison	Frontal (mean ± SE)	Occipital (mean ± SE)	Parietal (mean ± SE)	Temporal (mean ± SE)
Oxy-Hb				
678–830/692–830	0.998 ± 0.001	0.934 ± 0.028	0.967 ± 0.021	0.983 ± 0.013
678–830/750–830	0.998 ± 0.001	0.937 ± 0.029	0.959 ± 0.029	0.986 ± 0.004
678–830/782–830	0.989 ± 0.003	0.909 ± 0.031	0.891 ± 0.045	0.977 ± 0.006
692–830/750–830	0.998 ± 0.001	0.918 ± 0.039	0.948 ± 0.038	0.985 ± 0.004
692–830/782–830	0.992 ± 0.002	0.902 ± 0.042	0.884 ± 0.049	0.981 ± 0.006
750–830/782–830	0.993 ± 0.002	0.909 ± 0.031	0.887 ± 0.050	0.980 ± 0.005
Deoxy-Hb				
678–830/692–830	0.979 ± 0.014	0.803 ± 0.081	0.730 ± 0.091	0.795 ± 0.075
678–830/750–830	0.978 ± 0.006	0.824 ± 0.058	0.810 ± 0.070	0.782 ± 0.088
678–830/782–830	0.970 ± 0.013	0.782 ± 0.059	0.575 ± 0.058	0.760 ± 0.090
692–830/750–830	0.972 ± 0.019	0.845 ± 0.052	0.760 ± 0.070	0.779 ± 0.101
692–830/782–830	0.970 ± 0.017	0.825 ± 0.047	0.598 ± 0.084	0.829 ± 0.054
750–830/782–830	0.981 ± 0.008	0.824 ± 0.049	0.641 ± 0.076	0.801 ± 0.076

Profiles after low-pass 0.8-Hz filtering were compared.
SE = standard error.

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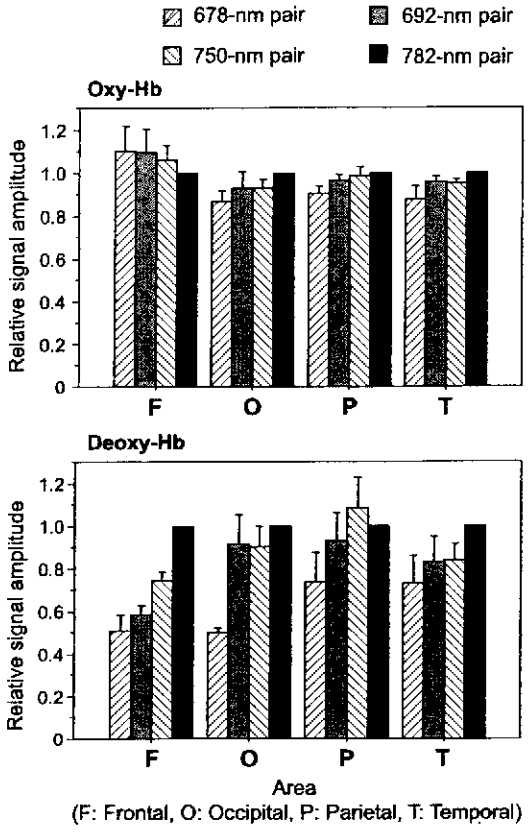

Fig. 5. Relative mean hemoglobin changes in activation periods normalized using data in 782-nm pairing. Each sample was intrasubject averaged data from 6 s after onset of stimulation to end of stimulation. Error bars indicate standard error.

The wavelength dependence of the optical path-length also suggests that the measurement area differs among wavelengths. Significantly, the relative path-lengths were (1) the partial path-length in the activation area and (2) the calculated path-length when the concentration change for the 782-nm pair was fixed as the standard. It was not possible to determine whether each optical path passed through the same tissue because the optical path depends on absorption and scattering not only in the cerebral cortex but also in the skin, muscle, skull, and so on. However, the similar shape time courses shown in Fig. 4 and Table 2 demonstrate that every wavelength could be used to measure the same area and that differences in the signal amplitude are due to differences in the path-length. A simulation study examining the dependence of the optical path on the wavelength is necessary for further discussion.

A previous study (Yamashita et al., 2001) suggested that there is no difference in signal amplitude and a similar tendency is seen in their graphs. Another study (Strangman et al., 2003) did not mention any dependence of signal amplitude on wavelength pair.

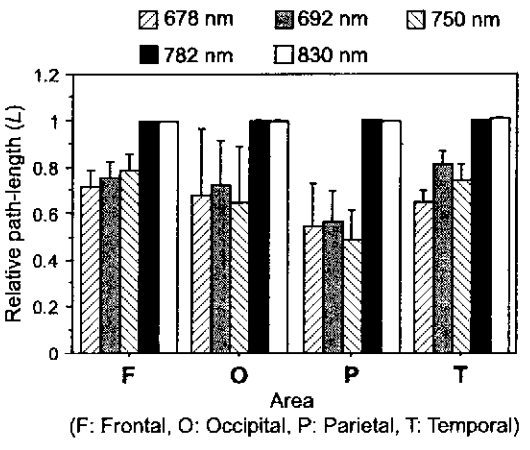

Fig. 6. Relative optical path-length (L) calculated for each block for each subject and area and then averaged for each area. Error bars indicate standard error.

Noise levels in Hb change

The noise levels normalized by the noise amplitude in the 782-nm pairing are shown in Fig. 7 for the four wavelength pairs and four areas. The wavelength pairs using 678, 692, and 750 nm generally produced less noise for both oxy- and deoxy-Hb in every area. An analysis of variance (ANOVA, wavelength pairs × areas) was used to test the dependence of the wavelength pairs on Hb noise. It showed a significant main effect of wavelength pairs [oxy-Hb: $F(3,48) = 3.36$, $P < 0.05$, deoxy-Hb: $F(3,48) = 21.90$, $P < 0.0001$]. Post hoc tests (Fisher's PLSD) revealed differences between the 678- and the 782-nm pairings (oxy-Hb: $P < 0.01$, deoxy-Hb: $P < 0.01$) and between the 692- and 782-nm pairings (oxy-Hb: $P <$

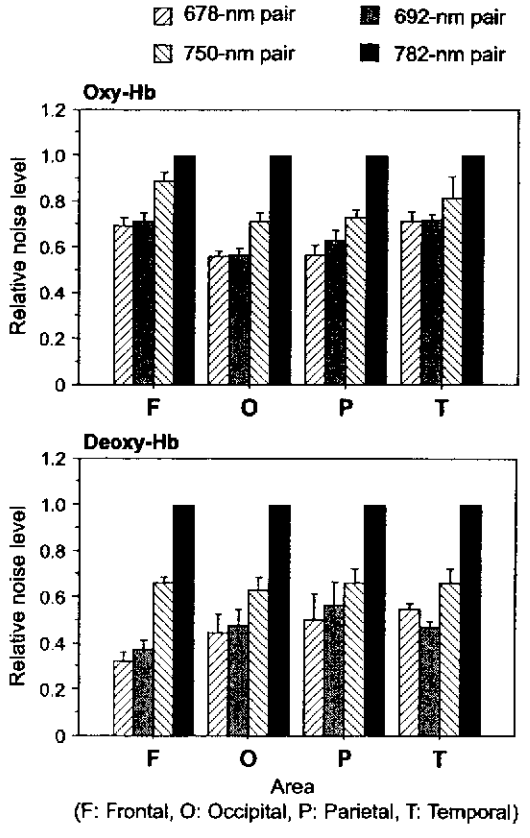

Fig. 7. Relative noise level of oxy- and deoxy-Hb. Noise level was standard deviation in rest period normalized by standard deviation in 782-nm pairing. Levels were calculated for each subject, then averaged among subjects. Error bars indicate standard error.

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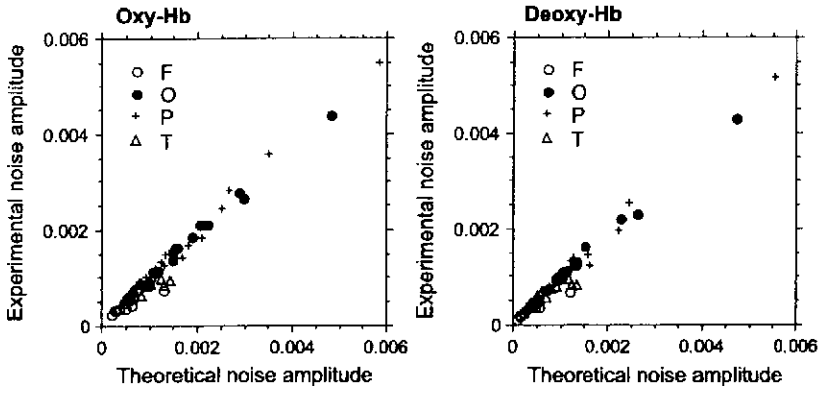

Fig. 8. Scattering diagram of theoretical noise amplitude (horizontal axis) and experimental noise amplitude (vertical axis). F = frontal area, O = occipital area, P = parietal area, and T = temporal area.

0.05, deoxy-Hb: $P < 0.01$). Although a significant main effect of area was shown in the ANOVA [oxy-Hb: $F(3,48) = 17.00$, $P < 0.001$, deoxy-Hb: $F(3,48) = 2.80$, $P < 0.05$], the interaction between wavelength pair and area was not significant. These results suggest that the noise levels in the 678- and 692-nm pairings were lower than those in the 782-nm pairing regardless of area and subject. The dependence of the noise level on the area was probably due to the difference in transparency between areas, as previously mentioned.

The experimentally obtained noise levels corresponded to those derived from theory (Eqs. (4) and (5)), as shown in Fig. 8.

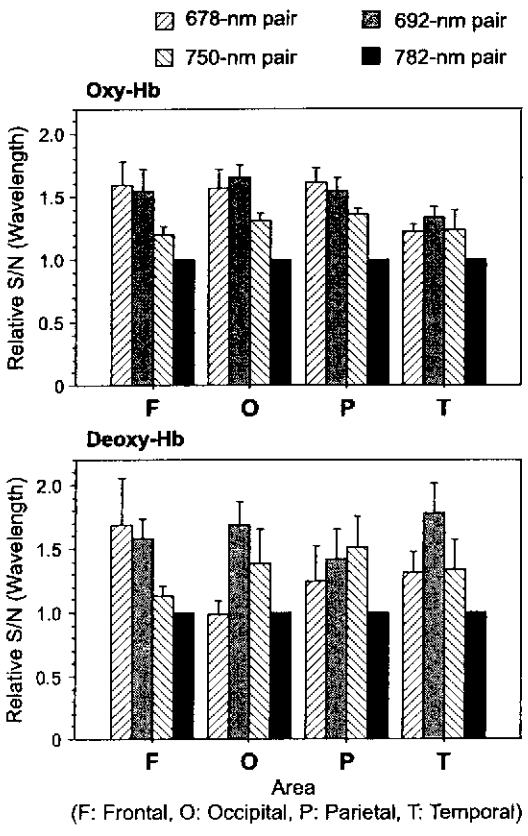

Fig. 9. Relative signal-to-noise ratio for wavelength pairs normalized using data in 782-nm pairing. Error bars indicate standard error.

The experimental and theoretical noise levels showed significantly high correlation coefficients (oxy-Hb: 0.99, $P < 0.0001$, deoxy-Hb: 0.99, $P < 0.0001$), indicating that the noise levels were properly assessed. Consequently, these results suggest that using a shorter wavelength reduces noise levels in most Hb measurements.

Signal-to-noise ratio

The relative S/N levels normalized using those in the 780-nm pairing are shown in Fig. 9. In most areas, using 678 or 692 nm with 830 nm produced the highest S/N. An ANOVA (wavelength-pairs × areas) revealed a significant main effect of wavelength pairs both for oxy-Hb [$F(3,48) = 21.90$, $P < 0.001$] and for deoxy-Hb [$F(3,40) = 6.27$, $P < 0.005$]. For oxy-Hb, post-hoc tests (Fisher's PLSD) indicated a difference for every comparison ($P < 0.005$) except for that between the 678- and the 692-nm pairings, suggesting that the most sensitive measurement is achieved using the 678- or the 692-nm pairing. In contrast, post hoc tests (Fisher's PLSD) for deoxy-Hb revealed a difference between the 678- and the 692-nm parings ($P < 0.05$). A difference for every comparison ($P < 0.05$) except for that between the 678- and the 750-nm pairings was demonstrated in this analysis. Therefore, it can be concluded that the 692-nm pairing provides the highest S/N for deoxy-Hb measurements in this system.

The S/Ns for the 692-nm pairing for oxy-Hb and deoxy-Hb were approximately 1.52 and 1.63 times higher than those for the 782-nm pairing. Thus, the 692-nm pairing provided the highest S/N for both oxy-Hb and deoxy-Hb in our system although the error-propagation law predicts a higher S/N when using shorter wavelength such as 678 nm. This suggests that the optimal wavelength cannot be determined only by the wavelength (absorption-coefficient of Hb species)—the optical properties of the measurement area must be considered. Note that the optimal wavelength also depends on the system properties, such as the irradiated light intensity and detection device. Our results demonstrate the practicality of using around 690 nm to improve NIR measurements for brain functional study.

Conclusion

Wavelengths of 678, 692, 750, and 782 nm were examined for pairing with 830 nm to improve the S/N of NIRS for measuring

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cortical activation. Noise levels in Hb changes decreased when using wavelengths shorter than 782 nm, as predicted by the error-propagation law, and the S/N was improved in most cases. Although it has been suggested that activation-signal amplitudes are affected by a difference in the optical path-lengths, the Hb time courses measured using all wavelength pairs agreed well in each cortical area. This suggests that this wavelength range can be used to measure the same cortical area. The 692-nm pairing generally provided the highest S/N both for oxy- and deoxy-Hb in this system. Although the detected power of the transparent light at 678 and 692 nm did weaken in most cases, the effects of the absorption coefficients surpassed those of the decreasing transparent light on noise reduction for the Hb measurements. Consequently, around 690 nm is a more optimal choice than around 780 nm for pairing with 830 nm to measure Hb changes induced by cortical activation. The improved S/N enables more sensitive statistical analysis, which is essential to functional mapping with NIR topography.

Acknowledgments

We thank Mr. Tatsuya Takeuchi and Dr. Kuniyoshi L. Sakai for their assistance with a pilot experiment; Ms. Akiko Obata, Mr. Ryosuke Hirosaka, and Ms. Ayako Fujii for their technical assistance; Mr. Yuichi Yamashita, Dr. Naoki Tanaka, Ms. Yukari Yamamoto, Dr. Tsuyoshi Yamamoto, and Mr. Takushige Katsura for their helpful discussions; and Dr. Hideo Kawaguchi and Dr. Hideaki Koizumi for their general support.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 12 2004

Hitachi Medical Corporation
c/o Mr. Douglas J. Thistlethwaite
Manager of Regulatory Affairs
Hitachi Medical Systems America, Inc.
1959 Summit Commerce Park
Twinsburg, Ohio 44087

Re: K042501
Trade/Device Name: ETG-4000 Optical Topography System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: September 13, 2004
Received: September 14, 2004

Dear Mr. Thistlethwaite:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Number (if known): K042501

Device Name: ETG-4000 Optical Topography System

Indications for Use:

The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042501

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

September 15, 2004

HITACHI MEDICAL CORP.
C/O HITACHI MEDICAL SYSTEMS AMERICA
1959 SUMMIT COMMERCE PARK
TWINSBURG, OH 44087
ATTN: DOUG THISTLEWAITE

510(k) Number: K042501
Received: 14-SEP-2004
Product: ETG-4000 OPTICAL TOPOGRAPHY SYSTEM

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at http://www.fda.gov/cdrh/mdufma/guidance/1219.html.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the regulatory requirements for medical device available at Device Advice http://www.fda.gov/cdrh/devadvice/". If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K042501

Form Approved:OMB No. 0910-0511 Expiration Date: (b) (4) [redacted]

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBE
Write the Payment Identification Numb

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: In no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

HITACHI MEDICAL CORPORATION
1-1-14 UCHI-KANDA, CHIYODA-KU
TOKYO, 101-0047
JAPAN

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
DOUG THISTLETHWAITE

2.1 E-MAIL ADDRESS
thistlethwaited@hitachimed.com

2.2 TELEPHONE NUMBER (Include Area Code)
330-425-1313

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
330-425-1410

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:

- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologics License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:

- ☑ Original Application

Supplement Types:

- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- ☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE **EXCEPTIONS**? IF SO, CHECK THE APPLICABLE EXCEPTION.

- ☐ This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms
- ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).)

☐ YES ☑ NO

(b) (4) [redacted] ENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

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Questions? Contact CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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HITACHI

HITACHI MEDICAL CORPORATION
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

SPECIAL 510(k)
Device Modification

Hitachi ETG-4000 Optical Topography System

Submitted September 13, 2004 by:

Hitachi Medical Corporation
1-1-14 Uchi-kanda, Chiyoda-ku
Tokyo 101-0047, Japan
Phone: 81-3-3294-3851
Fax: 81-3-3294-3860

For inquiries, contact:

Doug Thistlethwaite
Official Correspondent
Email: ThistlethwaiteD@hitachimed.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ETG-4000 System 510(k) Table of Contents

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Product Labeling Includes: Operator's Manuals Marketing Literature	7

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

HITACHI

HITACHI MEDICAL CORPORATION, INC.
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

September 13, 2004

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: Special 510(k) Device Modification
Hitachi ETG-4000 Optical Topography System

To Whom It May Concern:

Pursuant to the requirements of Section 510(k) of the Food, Drug, and Cosmetic Act and in conformance with 21 CFR 807, this pre-market notification is submitted in duplicate by Hitachi Medical Systems America, Inc. (HMSA).

The following information is supplied in accordance with 21 CFR 807.87 and FDA Device Advice guidance on the content of a 510(k):

Item	**Description**
Device Name	Oximeter 870.2700
Trade/Proprietary Name	ETG-4000 Optical Topography System
Common Name	Oximeter
Establishment Registration	Hitachi Medical Corporation, Inc. #8030405
Classification	II ✓
Classification panel	Anesthesiology
Classification Name	Sec. 870.2700 Oximeter
Product Codes	DQA
Applicable Performance Standards/Special Controls	Laser performance standards outlined in 21 CFR 1040.10-11.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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CDRH SUBMISSION COVER SHEET

Date of Submission: September 13, 2004

FDA Document Number:

Section A Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☑ Original submission: ☐ Traditional ☑ Special ☐ Abbreviated ☐ Additional information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B Applicant or Sponsor

Company / Institution name: Hitachi Medical Corporation	Establishment registration number: 8030405
Division name (if applicable):	Phone number (include area code): ( )
Street address: 1-1-14 Uchi-Kanda, Chiyoda-ku	FAX number (include area code): ( )
City: Tokyo 101-0047 State / Province	Country: Japan
Contact name:	
Contact title:	Contact e-mail address:

Section C Submission correspondent (if different from above)

Company / Institution name: Hitachi Medical Systems America, Inc.	Establishment registration number: 1528028
Division name (if applicable):	Phone number (include area code): (330) 425-1313
Street address: 1959 Summit Commerce Park	FAX number (include area code): (330)425-1410
City: Twinsburg State / Province: OH 44087	Country: USA
Contact name: Doug Thistlethwaite	
Contact title: Manager of Regulatory Affairs	Contact e-mail address: thistlethwaited@hitachimed.com

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Section D1 — Reason for Submission — PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Process change
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other (specify below)
- ☐ Response to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Other reason (specify):
- ☐ Change in design, component, or specification:
  - ☐ Software
- ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
- ☐ Other (specify below)
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
- ☐ Shelf life
- ☐ Trade name
- ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Report submission:
  - ☐ Annual or periodic
  - ☐ Post-approval study
  - ☐ Adverse reaction
- ☐ Device defect
- ☐ Amendment
- ☐ Change in ownership
  - ☐ Change in correspondent

Section D2 — Reason for Submission — IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Other reason (specify):
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol – feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ Final
- ☐ Response to FDA letter concerning:
  - ☐ Conditional approval
  - ☐ Deemed approved
  - ☐ Deficient final report
  - ☐ Deficient progress report
  - ☐ Deficient investigator report
  - ☐ Disapproval
  - ☐ Request extension of time to respond to FDA
  - ☐ Request meeting

Section D3 — Reason for Submission — 510(k)

- ☐ New device
- ☐ Additional or expanded indications
- ☐ Other reason (specify):
- ☐ Change in technology
- ☑ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

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Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:

1 DQA	2	3	4
5	6	7	8

Summary of, or statement concerning, safety and effectiveness data:
☑ 510(k) summary attached
☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K011320	1 ETG-100 Optical Topography System	1 Hitachi Medical Corporation
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

Section F Product Information — Applicable to All Applications

Common or usual name or classification name:
Oximeter

Trade or proprietary or model name	Model number
1 ETG-4000	1
2	2
3	3
4	4
5	5

FDA document numbers of all prior related submissions (regardless of outcome):

1	2	3	4	5	6
7	8	9	10	11	12

Data included in submission: ☑ Laboratory testing ☐ Animal trials ☐ Human trials

Section G Product Classification — Applicable to All Applications

Product code DQA | C.F.R. Section: 870.2700

Device class:
☐ Class I ☑ Class II
☐ Class III ☐ Unclassified

Classification panel: Anesthesiology

Indications (from labeling):

The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

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Item	Description
Labeling	Refer to Section 7.
Substantial Equivalence	We believe that the Hitachi ETG-4000 system is substantially equivalent to the ETG-100 Optical Topography system, identified in K011320. The ETG-100 is currently in commercial distribution in the U.S. We have selected this system as the primary predicate devices for our claim of substantial equivalence. Refer to Section 6 for comparisons to the predicate device.
510(k) Summary	Refer to Section 2.
Address Of Manufacturing Facility/Facilities	Hitachi Medical Corporation 1-1-14 Uchi-Kanda, Chiyoda-ku Tokyo, Japan
List Of Attachments	
Section	Description
2	510(k) Summary of Safety and Effectiveness
3	Statement of Intended Use
4	Device Description
5	Declaration of Conformity with Design Controls
6	Comparison to Predicate Devices
7	Product Labeling
8	Software Information
9	Safety Information
10	Performance Information

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Truth And Accuracy Statement

We believe this document and the reference attachments demonstrate the substantial equivalence of the Hitachi ETG-4000 to the predicate device, and will be sufficient for the Food and Drug Administration to reach a decision on this submission.

I certify that, in my capacity as Official Correspondent for Hitachi Medical Corporation, I believe that, to the best of my knowledge, all data and information submitted in this pre-market notification are truthful and accurate and that no material fact has been omitted.

I can be contacted as follows, if necessary. Thank you for your consideration of this submission.

Contact Information

Phone: (330) 425-1313
Fax: (330) 425-1410
Email: thistlethwaited@hitachimed.com

Sincerely,

Doug Thistlethwaite
Manager, Regulatory Affairs
Hitachi Medical Systems America, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number:

Section H Manufacturing / Packaging / Sterilization Sites Relating to a Submission

☑ Original ☐ Add ☐ Delete	FDA establishment registration number: 8030405	☑ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name: Hitachi Medical Corporation		Establishment registration number: 8030405	
Division name (if applicable):		Phone number (include area code): (81) 3-3294-3851	
Street address: 1-1-14 Uchi-Kanda, Chiyoda-ku		FAX number (include area code): (81) 3-3294-3860	
City: Tokyo 101-0047	State / Province:		Country: Japan
Contact name:			
Contact title:		Contact e-mail address:	
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:		Country:
Contact name:			
Contact title:		Contact e-mail address:	
☐ Original ☐ Add ☐ Delete	FDA establishment registration number:	☐ Manufacturer ☐ Contract manufacturer	☐ Contract sterilizer ☐ Repackager / relabeler
Company / Institution name:		Establishment registration number:	
Division name (if applicable):		Phone number (include area code): ( )	
Street address:		FAX number (include area code): ( )	
City:	State / Province:		Country:
Contact name:			
Contact title:		Contact e-mail address:	

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Section 2

510(k) Summary

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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HITACHI

HITACHI MEDICAL CORPORATION
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

510(k) Summary

Submitter Information

Submitter: Hitachi Medical Corporation
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

Contact: Douglas J. Thistlethwaite
ph: (330) 425-1313
fax: (330) 425-1410

Date: September 13, 2004

Device Name

Device Name: Optical Topography System
Trade/Proprietary Name: ETG-4000 Optical Topography System
Common Name: Oximeter
Classification Name: Oximeter
Classification Number: Sec. 870.2700

Predicate Device

Predicate Device: Hitachi ETG-100, K011320

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Description

Function

The ETG-4000 is a device that measures relative changes in tissue concentration of oxy-hemoglobin and deoxy-hemoglobin and total hemoglobin (proportional to the level of blood) in the surface area of the cerebral cortex by beaming near-infrared light (670-1300nm) that can penetrate the body efficiently, and is absorbed by the hemoglobin in the blood.

The ETG-4000 displays the changes of overall Hemoglobin concentration in time- course graphs, 2D topography images and 3D topography images (motion images and still images) based on the data from multiple point measurements.

This is a non-invasive test that is done by contacting an array of small optical fiber tips on the surface of the scalp.

The ETG-4000 beams frequency modulated near-infrared light into the surface of the brain through several of the optical fibers. The light passes through the scalp, skull and upper layer of the cerebral cortex. The light is absorbed by the hemoglobin in the blood and is reflected back and is collected by optical fibers.

The ETG-4000 measures relative changes in tissue concentration of oxy-hemoglobin and deoxy-hemoglobin in the blood of the cerebral cortex at multiple points on the head simultaneously by utilizing the changes of light absorption.

The ETG-4000 provides data that show the activity status of the cerebral cortex by displaying the blood volume changes, hemodynamics in the brain surface, and the metabolic and circulatory status of the cerebral cortex in a time-course graphic representation of oxy-hemoglobin, deoxy-hemoglobin and total hemoglobin, 2D dynamic images and 3D dynamic images.

Device Intended Use

The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Technological Characteristics

The characteristics of the ETG-4000 Optical Topography System compare substantially to the ETG-100 predicate device in materials used, technology applied, and functional methodology. Differences do not affect safety and effectiveness of the device, intended use, or application methods. The ETG-4000 operates in a manner that is substantially equivalent to the cleared predicate device and represents an enhancement of the technology of the predicate.

Safety

The ETG-4000 is a non-invasive device with no moving parts. It has been designed to comply with all applicable safety standards.

Conclusions

The ETG-4000 system has been developed and validated in accordance with design controls and applicable standards. Testing has proven that the system is safe and effective for the indicated use. Risk and hazard analysis shows that there are no new safety issues associated with this system as compared with the predicate device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 3

Indications for Use

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

510(k) Number (if known): _____

Device Name: ETG-4000 Optical Topography System

Indications for Use:

The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use _____

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 4

Device Description

Section Contents:

ETG-4000 SYSTEM DESCRIPTION 2

ETG-4000 PRODUCT SPECIFICATION 5

Hitachi regards the following as trade secrets and confidential in nature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ETG-4000 System Description

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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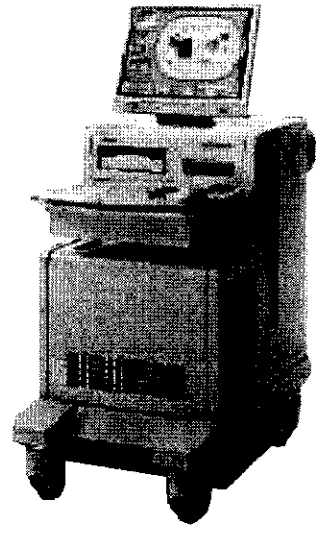
ETG-4000 System Description



The ETG-4000 is a device that measures relative changes in tissue concentration of oxy-hemoglobin and deoxy-hemoglobin and total hemoglobin (proportional to the level of blood) in the surface area of the cerebral cortex by beaming near-infrared light (670-1300nm) that can penetrate the body efficiently, and is absorbed by the hemoglobin in the blood.

The ETG-4000 displays the changes of overall Hemoglobin concentration in time- course graphs, 2D topography images and 3D topography images (motion images and still images) based on the data from multiple point measurements.

This is a non-invasive test that is done by contacting an array of small optical fiber tips on the surface of the scalp.

The ETG-4000 beams frequency modulated near-infrared light into the surface of the brain through several of the optical fibers. The light passes through the scalp, skull and upper layer of the cerebral cortex. The light is absorbed by the hemoglobin in the blood and is reflected back and is collected by optical fibers.

The ETG-4000 measures relative changes in tissue concentration of oxy-hemoglobin and deoxy-hemoglobin in the blood of the cerebral cortex at multiple points on the head simultaneously by utilizing the changes of light absorption.

The ETG-4000 provides data that show the activity status of the cerebral cortex by displaying the blood volume changes, hemodynamics in the brain surface, and the metabolic and circulatory status of the cerebral cortex in a time-course graphic representation of oxy-hemoglobin, deoxy-hemoglobin and total hemoglobin, 2D dynamic images and 3D dynamic images.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Features of the System

1. It will display the changes of oxygenated Hemoglobin, deoxygenated Hemoglobin, and overall Hemoglobin concentration in a time-course graphic representation of Hemoglobin, 2D dynamic images and 3D dynamic images.
   (3D wire frame Topographic image is standard, 3D Probe positioning system and 3D MRI Composite display system are option)
2. The examiner can use it safely and repeatedly, as it is a non-invasive measurement.
3. The subject will experience no load because it is a relatively restraint-free test that gives the examiner greater freedom of choice of the tasking or stimulation to be used.
4. It is small and transportable. It can be wheeled anywhere, reducing environmental requirements like a shield room. Its compact design allows optical topography measurement to be taken at bedside.

Available Options

1. 3D MRI Composite Topographic image display system superimposing a optical topography image on a 3-dimentional MRI image. (Optical Topography 3-dimensional Display System, 3D Topographic image display system)
2. Synchronous replay of video-recorded scenes of measurement
   Video-recorded data can be synchronously replayed on the analysis screen to show how the examinee behaved or responded to load stimuli during the test. (Interface for the video recording system)
3. Various forms of Child's probes that can fit any subject and any region of the head. (holders and optical fibers)

With the ETG-4000 you can choose a single probe (simultaneous 24-channels maximum measurement) or two probes (simultaneous 52-channels maximum measurement).
A system can be upgraded from the single-probe system to the two-probe system as an option.

System Specifications: Refer to the following pages.

Safety Parameters: Please refer to section 9.

Software: Please refer to section 8.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ETG-4000 Product Specification

Note to Reviewer:
The following specification is translated from the original Japanese language version.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ETG-4000 Product Specification

1) Measurement Portion

(1) Measured Items

Oxygenated Hemoglobin concentration change
De-oxygenated Hemoglobin concentration change
Total Hemoglobin concentration change

(2) Light source

Semiconductor Laser

2 Wavelengths (695nm±20nm. 830nm±20nm)
Each Wavelength 18 (2 probes)
Each Wavelength 10(1probe)

Radiated Power 2.0±0.4mW(695nm)
2.0±0.4mW(830nm)

(3) Detector

Avalanche Photodiode 16 (2 probes)
8 (1 probe)

(4) Probe

A Maximum of 52 channels simultaneous measurement is possible with two probes on the head. A Maximum of 24 channels simultaneous measurement is also possible with a single probe.
When used in combinations, a wide array of probes expands the range of applications as listed below.

Table. Combined use of probes

System Specifications	No.of Measurement Points	No.of Holders			
		4×4	3×5	3×3	3×11
Two probe	48	2			
	46	1	1		
	48	1		1	
	44		2		
	46		1	1	
	52				1
A single probe	24	1			
	22		1		
	24			1	

Optical fiber: 2 probes (18 lines for transmission, 16 lines for reception)
1 probe (10 lines for transmission, 8 lines for reception)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(5) Data Collection and Display

Data Collection from 0.1sec Optional set is possible.

(Sampling 10points/s)

Display

- Hemoglobin time-course graph
  Displays a graphic representation of changes in oxyhemoglobin,deoxyhemoglobin and total hemoglobin separately
- Hemoglobin Time-course mapped graph
- Hemoglobin Time-course mapped graph(over a figure of a scalp)
- 2D Topography display
- 2D Topography display(over a figure of a scalp)
- 3D wire frame Topography display
- 3D MRI Composite display(option)

*) Motion images and still images are available for Topography display

2) Probe Portion

(1) 3×3 holder
(2) 4×4 holder
(3) 3×5 holder
(4) 3×11holder(2probe exclusively)
(5) Optical Fiber

3) Computer

(1) Main Unit (CPU) CPU:Intel^{R}Pentium^{R}4 processor 1.5GHz or greater
256MB or greater RAM, 30GB or greater HD
(2) Operating System Microsoft^R Windows^{R}2000 SP3 or later edition
(3) Application Software Optical Topography system software
(4) Magneto- Optical disk drive (MO disk) Compatible with 2.3GB media
(5) Color Printer

When using the computer, read the instruction manual pertaining to the computer

4) Measurement Mode

Two Mode Selections are possible based upon application

	Mode 1 4×4	Mode 2 3×5	Mode 3 3×3	Mode 4 3×11
No.of Measurement Points	24	22	24	52
No.of Light Sources	8	8	10	17
No.of Detectors	8	7	8	16

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5) Data Output for analysis and backup
   (1) Hemoglobin Time-course graph
      Text (txt) format: information about the subjects, Measurement Conditions, Measurement data, Marker, external input information
   (2) Topography Images still image: bmp format, motion image: avi format
   (3) Video Images (option): mpeg format
   (4) File for backup data: individual format

6) External channels

External analog signal input (BNC)	2 channels (input range : 0-+5V)
External digital signal input (BNC)	4 channels (L : OV ; H:+5V)
Digital signal output (BNC)	4 channels (L:OV ; H :+5)
Serial communication (RS232C)	2 channels
Network (LAN)	1 line (not operational during optical topography measurement)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 5

Declaration of Conformity with Design Controls

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Summary of Design Control Activities

Validation/Verification Activities

The design validation/verification tests that were performed as a result of the risk analysis assessment are listed below:

Design Change	Test Performed	Acceptance Criteria
Laser Diodes	Laser safety	IEC – 60825-1
Software modification	See Section 8	See Section 8
Probe holder material change	Biocompatibility	See Section 9

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Declaration of Conformity with Design Controls

Verification and Validation Activities

To the best of my knowledge, the verification and validation activities for the device design modification, as required by the risk analysis, were performed by the designated individual(s) and the results demonstrated that pre-determined acceptance criteria were met.

(b) (6), (b) (4) [redacted]

Title (b) (6), (b) (4) [redacted]

Date

Manufacturing Facility

The Hitachi Medical Corporation manufacturing facility is in conformance with the design control requirements specified in 21 CFR 820.30 and the records are available for review.

Name: (b) (6), (b) (4) [redacted]

Signature:

Title: (b) (6), (b) (4) [redacted]

Date:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 6

Comparison to Predicate Device

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ETG-4000 Comparison to Predicate Device

Physical Characteristics: The Hitachi ETG-4000 system is similar to the predicate device in that it combines the same basic design.

The similarities and differences between the two devices are listed in the table below. The most significant difference noted is the number of available channels.

Table 1: Specification Comparison

	Hitachi ETG-4000	Hitachi ETG-100
Channels		
Number of channels	24, 48 (52) channel configuration	24 channels
Measurement Items		
	Same	Change in oxyhemoglobin concentration
	Same	Change in deoxyhemoglobin concentration
	Same	Change in total hemoglobin concentration
Light Source		
Light source	Same	Semiconductor laser
Wavelength	695, 830nm	780, 830nm
Modulation system	Same	Frequency modulation, rock-in-amp system
Measurement rate	Same	100ms
Number of sources	20 (2 wavelengths X 10), 36 (2 X 18)	20 (2 wavelengths X 10)
Laser Safety Class (IEC)	1M	3A
Photodetector		
Type	Same	Avalanche Diode
Number of detectors	8, 16	8
Measurement		
Measurement face	1,2	1
Arrangement	Choose one (4x4, 3x5, 3x3), Choose two (4x4, 3x5, 3x3, 3x11)	Choose one (4x4, 3x5, 3x3)
Detected light level adjustment	Same	Automatic
Number of channels	24, 48 (52 with 3x11)	24
Display		
3D image	Same	Probe positioning unit, 3D Composite unit, Wire frame display
Hb Time-course display	Time-course display, Mapped display, Topography display	Time-course display, Topography display
Data Output		
Data types	Measurement, Voltage, Hemoglobin, Topographic image (still), Topographic image (motion)	Measurement, Voltage, Hemoglobin, Topographic image (still)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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	Hitachi ETG-4000	Hitachi ETG-100
Probe		
Fiber diameter	Same	Incident light 1mm, Detected light 1.5mm
Tip material	Plastic	Stainless steel
Tip configuration/ structure	Angle, spring installed structure	Straight, angle spring installed structure
Neonate type	Available	Available
Mechanical, Electrical		
External dimensions	526x933x1470	570x1110x1310
Mass	Approximately 130kg	Approximately 130kg
Power source	AC 120V, 500VA or less	AC 120V, 500VA or less
Electrical Safety		
Electrical Safety Test Standards Applied[1]	IEC 60601-1, IEC 60601-1-1, IEC 60825-1	IEC 60601-1, IEC 60601-1-1, IEC 60825-1
Safety Class (IEC 60601-1)	I	I
Waterproof	No	No
Explosion proof	No	No
Labeling		
User's Manuals	Instruction Manual	Instruction Manual

Clinical Characteristics: The ETG-4000 and the predicate device are substantially equivalent in clinical use. We are not aware of any significant clinical difference.

[1] See Section 9 for details.

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Predicate Literature

Note to reviewer:

No predicate literature was included because it would duplicate data contained in 510(k) K011320.

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Section 7

Product Labeling
Operator's Manuals and Marketing Literature

Manual No.	Title	Page
	Operator's Manuals	
Q1E-FS0242-1	System Instruction Manual	3
	Site Planning Guide	
N/A	None required[1]	
	Marketing Literature	
Not assigned	ETG-4000 Product Brochure	210
	Product Labels	
N/A	IEC Test Report excerpt	215

[1] The ETG-4000 is portable and requires no special room environment.

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Operator's Manual

Note to Reviewer:

The Operator's Manual is the initial draft for the product. It will be edited, reviewed and released prior to the first commercial shipment of the product.

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Optical Topography System

Model ETG-4000

INSTRUCTION MANUAL

(Ver 1.0)

HITACHI MEDICAL CORPORATION

Tokyo, Japan

Q1E-FS0242-1

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Introduction

Thank you very much for purchasing Hitachi Optical Topography System ETG-4000.

To use the system safely and correctly and also to keep functions normal for a long period of time, it is essential to fully understand functions, operations and maintenance of the system. Carefully read this instruction manual before use.

As for handling the personal computer and printer, read relevant instruction manuals attached to respective devices.

Cautions in using the system safely

To use this system safely and for a long period of time, observe the following items.

(1) Be sure to supply the power to the optional position measurement unit used together with this system from the optical topography system. At this time, be sure not to use the adaptor plug or the like but the cable (3-core plug).

(2) Do not remove covers of the system.

(3) Do not remodel the system.

(4) Observe the following conditions in using the system:

Working temperature range: +5~+35°C

Working relative humidity: 30~85% (no condensation, no freezing)

Working atmospheric pressure: 700~1060hPa

Do not install at any location excessively humid.

Do not install where the system is exposed to steam.

Do not install where the system is exposed to water drop.

Do not install in a dusty or sandy place.

Do not install where excessive oil vapor exists.

Do not install where the system is exposed to saline air.

Do not install where explosive gas exists.

Do not install where the system is subject to excessive vibration or shock.

Do not install in any place inclined more than 5°.

Do not install where mains voltage drops or rises excessively.

Do not install where the system is exposed to direct sun light.

When the system is to be electrically or mechanically connected with any devices of other company, be sure to make contact with our appointed agent or us.

The personal computer main unit is exclusive for ETG-4000. Do not install any other software.

CAUTION

When any abnormality occurred in the system, immediately shut off the power.

Make contact with our appointed agent or us for the abnormality to the extent you may find. We will dispatch our service personnel for investigation and repair.

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Section 1 Getting Started

1.1 General

ETG-4000 utilizes absorption of near-infrared light by hemoglobin (Hb) to measure variation of blood volume in the vicinity of cerebral surface, and displays it as a 2-D image. Only touching the scalp with the tip of optical fiber cable allows for measurement without invasion and burden on the patient

The optical topography system applies amplitude modulation to near-infrared light and irradiates the surface of living body. It measures concentration variation of oxygenated hemoglobin and deoxygenated hemoglobin in blood within the brain at multiple points (maximum 52 channels) simultaneously, and reconstructs an image and cinematically displays distribution of blood volume variation and the state of metabolism and circulation in the brain as a two-dimensional topographic image providing data that indicates brain activity.

1.2 Features

(1) ETG-4000 has maximum 52 channels of measurement points (when utilizing an option).

(2) It displays variation of concentration of oxygenated hemoglobin, deoxygenated hemoglobin and whole hemoglobin at the surface of cerebrum as two-dimensional topographic cine images.

(3) Measurement is non-invasive and no burden on the patient.

(4) The patient is less restricted in measurement, and stimulation can be selected relatively free.

(5) The system is compact so that it can be moved for measurement.

(6) Type of protection against electrical shock is Class I (JIS T1001).

(7) Degree of protection against electrical chock is BF type device (JIS T1001).

1.3 Purpose of Use

ETG-4000 allows you to keep track of cerebral activation by measuring variation of oxygenated hemoglobin and deoxygenated hemoglobin in blood at the surface of cerebrum at multiple points simultaneously based on variation of light absorption. Therefore, ETG-4000 provides useful data for a wide rang of diagnosis such as estimating location of epilepsy focus, monitoring language and kinetic functions, monitoring rehabilitation and so on. Also, it is a mobile type allowing for bedside measurement.

Please read descriptions to use the system safely before use.

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1.4 Environmental Conditions

To use the system safely, observe the following environmental conditions.

(1) Working environmental conditions

- Ambient temperature +5 ~ +35°C
- Relative humidity 30 ~ 85% (no condensation, no freezing)
- Atmospheric pressure 700 ~ 1060hPa

(2) Storing conditions

- Ambient temperature −10 ~ +40°C
- Relative humidity 10 ~ 90% (no condensation, no freezing)
- Atmospheric pressure 700 ~ 1060hPa

1.5 Power Supply

Power supply necessary for this system is as follows. Never use it outside this range. Or otherwise, the system can be damaged.

(1) Voltage AC 100V±10%

Variation of the power supply of this system should be within ±10% of the rated voltage. If using it outside the range specified, performance of the device may not be fully utilized.

(2) Phase Single phase

(3) Frequency 50/60Hz

(4) Capacity 500VA or less

(5) Connecting of power cable

The power cable attached to this system is a 3-core type including the protective grounding wire. To prevent electrical shock, the power cable of this system should be directly connected with the 3-core type outlet including the medical grounding terminal (grounding resistance is 10 Ω or less). Never use the power outlet including no medical grounding terminal.

(6) Replacing fuses

When any fuse is blown or the circuit breaker is turned off, any serious trouble is suspected. Stop using the system, disconnect the power cable and make contact with our service staff.

Fuses used are compatible with those shown in the table below.

Any fuse other than rated ones may cause a trouble. Never use such fuses.

Table 1.1 Fuse used

Fuse No.	Rating
F1, F2	5A/250V
F3, F4	8A/250V
F5, F6	2A/250V
F7, F8	1A/250V
F9, F10	5A/250V

Fuses used are rush resistant.

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1.6 Installation

When installing this system, observe the following conditions to secure the patient and operator and to keep normal operation of the system.

(1) Environmental conditions

Use this system within the range of environmental conditions described in [1.4 Environmental Conditions].

<WARNING>

This system is not explosion proof. Never use it where explosive gas or inflammable gas such as oil vapor exists.

<WARNING>

This system is not specified as water drop proof, watertight or environmental resistant. Avoid use in the following environment. Or otherwise, a trouble may result.

- Where it is exposed to direct sun light
- Where close to heating appliances being used such as a heater and humidifier
- Where it is subject to water drop
- Dusty place

(2) Power facilities

Use this system within the range of power supply requirements described in [1.5 Power Supply].

(3) Site for installing the system

- Be sure to install the system on a horizontal surface.
- If installing it on a surface having inclination over 5°, it can fall.
- At location for installation, securely lock all of the stoppers of four wheels.
- Push the release lever (gray) located on the wheel to release the lock.

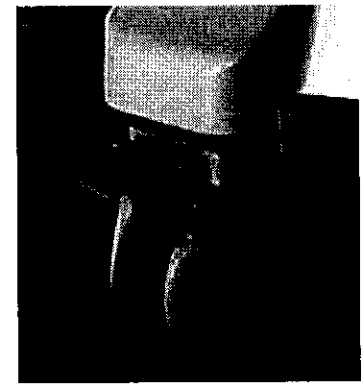

Fig. 1.1 Stopper

(4) Space necessary for use

- The main unit should not be appressed against the wall or the like. Keep more than 10cm free around it.
- Select environment with less noise and vibration and less comings and goings of persons.

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1.7 Cautions in Handling the System

1.7.1 Handling optical fiber cable

The optical fiber cables are important parts that transmit irradiation light to the patient and receive reflected light to conduct it to the detectors. Observe the following cautions so as not to damage it by careless handling.

(1) Do not bend the optical fiber cable by curvature radius of 30mm or less.

(2) Do not pull the optical fiber cable or place any heavy article on it.

(3) Do not hit the fiber cable with any hard object or drop it.

(4) Use gauze soaked with alcohol to sterilize the tip of fiber socket and probe holder before starting measurement.

(5) Full care should be taken not to damage the tip of fiber socket.

(6) When not using the optical fiber cable, set it to the phantom in the system.

(7) When attaching and detaching the optical fiber cable to/from the system, be sure to make contact with our sales or service personnel

1.7.2 Connecting external devices

Use "BNC cable" and "RS-232C cable" attached to the system for connecting the external devices.

< CAUTION >

- Use the external devices outside the patient environment.
- The external devices used should be products approved in response to the IEC safety standard.

1.7.3 Cautions in operating and using the system

(1) When any abnormality occurred in the system, immediately stop using and shut off the power, and then make contact with our service or sales personnel.

(2) When not using the system for a long period of time, be sure to disconnect the power cable from the power outlet.

(3) Never remodel the system (both hardware and software) and optical fiber cables.

The personal computer used in this system is for measurement control, data acquisition, data processing and data display. Mounting any general computer on the system can cause malfunction. Do not mount such computer.

(4) Items described in this instruction manual are subject to change without notice for improvement.

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1.7.4 Interaction

Never use any device emitting radio wave such as "cellular telephone", "transceiver", "portable radio", "radio-controlled toys" and so on near this system.

Also, when carrying around any of them without use, be sure to shut off the power.

Radio wave emitted from any device may cause malfunction of the system or adversely affect images.

1.7.5 Others

The personal computer main unit is exclusive for ETG-4000. Do not install any other software.

1.8 Cautions in Relation to Laser Output

Optical intensity of laser used in the optical topography system is small enough and measurement by this system is considered to have almost no effect on living body; however, observe the following items.

> This system is a laser product classified to Class 1M (IEC60825-1) in the safety standards IEC60825.
>
> Any special control is not required; however, handle it while following to <CAUTION> and <Cautions in Using the System>.

< CAUTION >

> Laser beam is emitted from the tip of irradiation probe. Do not look into the beam.
>
> Also, do not directly look the beam with an optical instrument. Order us for operation related to laser such as replacing the optical fiber cable.

1.9 Cautions in Using the System

(1) Any person other than those certified should not use this system.

(2) When installing the system, pay attention to the following items:

- Do not install the system where it is splashed with water.
- Install the system where it can operate stably while paying attention to environmental conditions such as temperature and humidity.
- Care should be taken not to give vibration, shock (including transportation) and so on.
- Do not install the system where any gas due to chemicals, especially flammable gas, is generated.
- Check if frequency, voltage and capacity of the power supply conform to specification of the connecting device.

(3) Before using the system, observe the following items:

- Check if the ground connection is complete.
- Check if all cable connection is correct and complete.

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- Pay full attention to that sharing or connecting with any other device can cause an erroneous result or hazard.
- Check if no abnormality is found in the probes and cables.

(4) Care should be taken for the following items while using the system.

- Constantly monitor to check if no abnormality is found in the system and patient.
- When any abnormality is found in the system and patient, take an appropriate action such as turning the system power off to stop operation.
- Care should be taken for the patient not to touch the system.
- The probe can be damaged by shock. Care should be taken not to give shock or hurt.

(5) Pay attention to the following items after using the system.

- Turn the system power off and disconnect the power plug.
- Pay attention to the following items for storing site:
  1) Keep the system where it is not splashed with water.
  2) Do not store it in any site where environmental condition such as temperature and humidity is poor or air includes salt or sulfa.
  3) Do not store it in any site where gas due to chemicals is generated.
  4) Pay attention to the state of stability such as vibration and shock (including transportation).

(6) If any trouble occurred, immediately make contact with our service office and entrust the service personnel for repair.

(7) Do not remodel the system.

(8) Maintenance inspection

- Be sure to conduct periodical inspection for the system and probe. Order our service personnel for periodical inspection.
- When using the system not used for some period of time, be sure to check if it works correctly and stably.

(9) Others

Follow the instruction manual to perform correct operation.

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1.10 Warning Labels and Caution Labels and Their Location

The warning labels and caution labels displayed on the surface of system and their positions are shown below

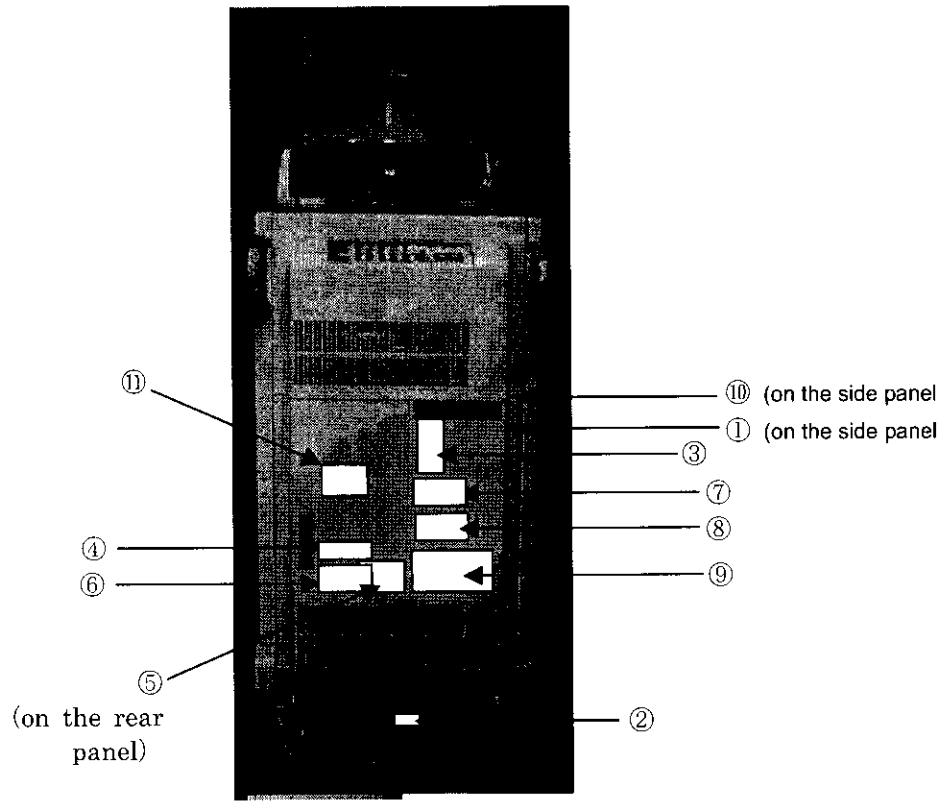
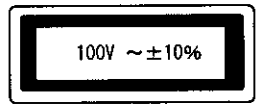


Fig. 1.2 Positions of System Labels

①

②



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③

⚠ 危　険

爆発注意 引火性ガスの	可燃性および引火性ガスのある場所では絶対に使用しないでください。

⚠ 注　意

故障注意 故障のおそれあり	この装置は防滴、防水的ではありません
転倒注意 装置が転倒または動く可能性あり	5° を超える傾斜に設置しないでください。また移動中以外は車輪のストッパを確実にかけてください。
破損注意 ファイバーが破損するおそれあり	ファイバの取り扱いに注意してください。 1．曲率半径30mm以下にまげないでください。 2．無理に引張らないでください。 3．踏んだりしないでください。

④

型式 TYPE			
製造番号 SERIAL NUMBER		据付年月日 DATE	

⑤

REVISION

TYPE ETG-4000

1	ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz
2	ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz
3	ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz
4	ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz
5	ABCDEFGHIJKLMNOPQRSTUVWXYZ abcdefghijklmnopqrstuvwxyz

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⑥

光トポグラフィ装置

医療用具認定番号

形式 TYPE: ETG-4000

VOLT: 100V～

FREQ. 50/60H z ,RATING 500 VA

SERIAL No.

株式会社日立メディコ
東京都千代田区内神田一丁目一番十四号
Hitachi Medical Corporation
1-1-14 Uchi-Kanda Chiyoda-Ku, Tokyo Japan

⑦

注 意
ファイバケーブルを外した場合
機器内光源のレーザ安全クラス３B

⑧

修理が必要な場合は、
弊社、或いは、認可された
代理店に依頼願います。

⑨

不可視レーザ光： 安全クラス 1M
レーザ光は、ファイバ先端から出力
されます。直接、または何らかの光学機器を用いて
レーザ光をみないでください。
レーザ安全クラス 1M
全出力：4mW
パルス長：連続波
波長：695nm, 830nm
IEC60825-1 Ed.1.2/2001-08

⑩

⑪

注意
ここを開き、セーフティインターロックを
解除すると、レーザ光が出力されます。

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1.11 Cautions in Applying to the Patient

1.11.1 Assistance person

When measuring a patient who has difficulty on physical strength such as grip and so on, engage in the study with the patient assisted.

1.11.2 Application to newborn baby and infant

(2) When applying to a newborn baby or so, carefully conduct the study under instructions by the doctor.

(3) For the study of an infant, engage in the study with it assisted.

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Section 2 System Composition

2.1 Composition

(Items may differ according to configuration of the system delivered.)

(1) Main unit of optical topography system 1 set

- Optical transmitter/receiver
- Data processing unit (PC: Pentium-4, 1.5MHz, 256MB RAM, 30GB HDD or higher)
  (OS: Windows 2000 SP3 or higher, MO (2.3GB) mounted)
- Display (18.1" LCD)

(2) Probe set

- Probe holder Max 3 sets
- Optical fiber cable (1mm ϕ, 3m, with plug) Max 2 sets

(2) Ink-jet color printer 1 set

(3) Accessories

- Hair keeper 2
- Check phantom 1 (built-in)
- Instruction manual (Main unit) 1 set
- Instruction manual (PC and so on), others 1 set

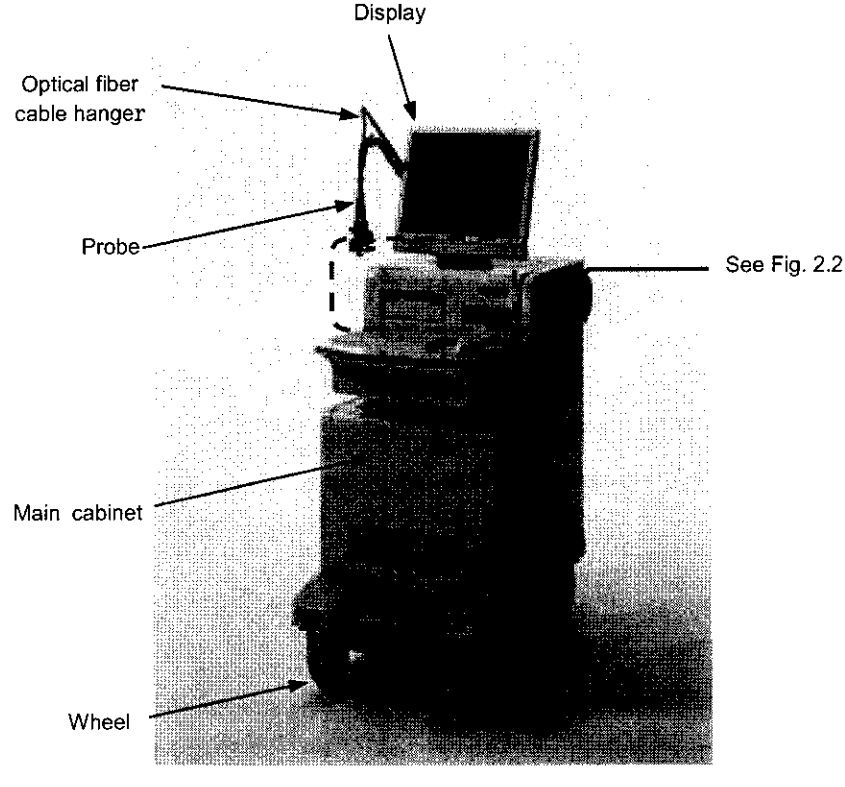

Fig. 2.1 Appearance of the System

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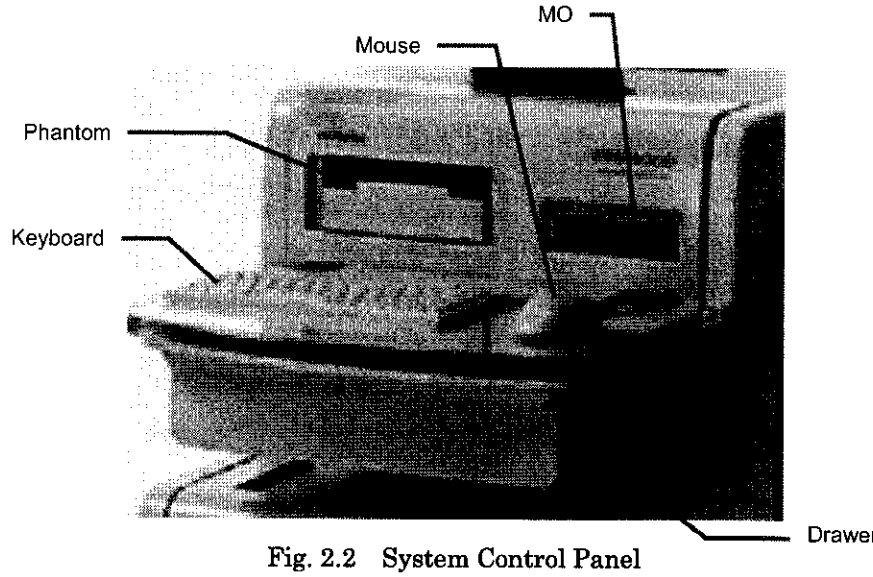

Fig. 2.2 System Control Panel

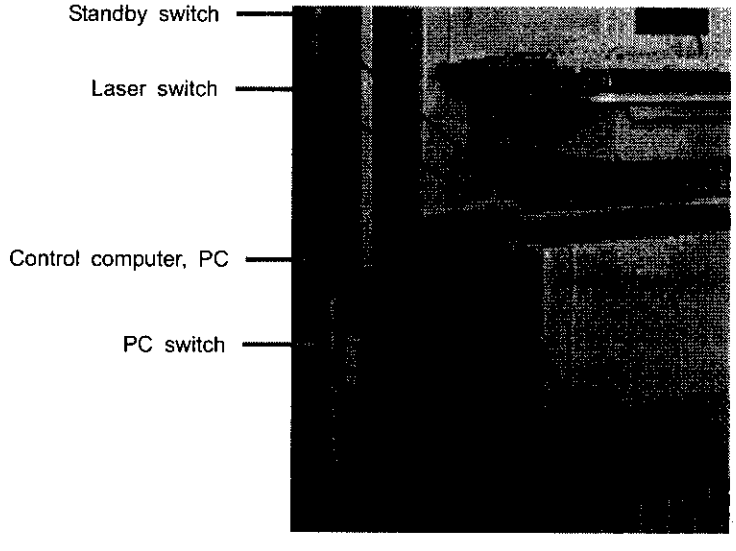

Fig. 2.3 System Left Side View

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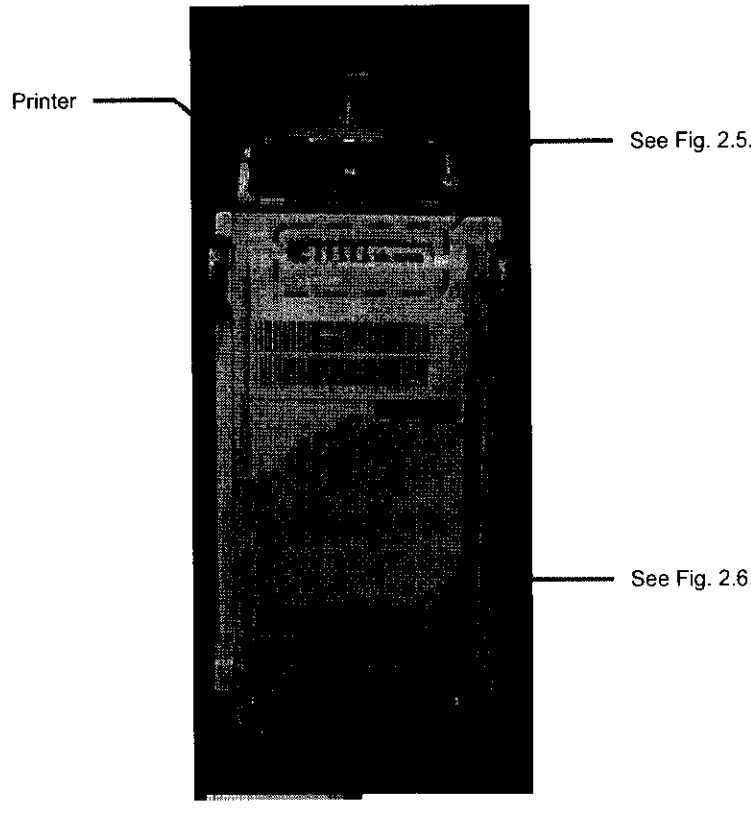

Fig. 2.4 System Rear View

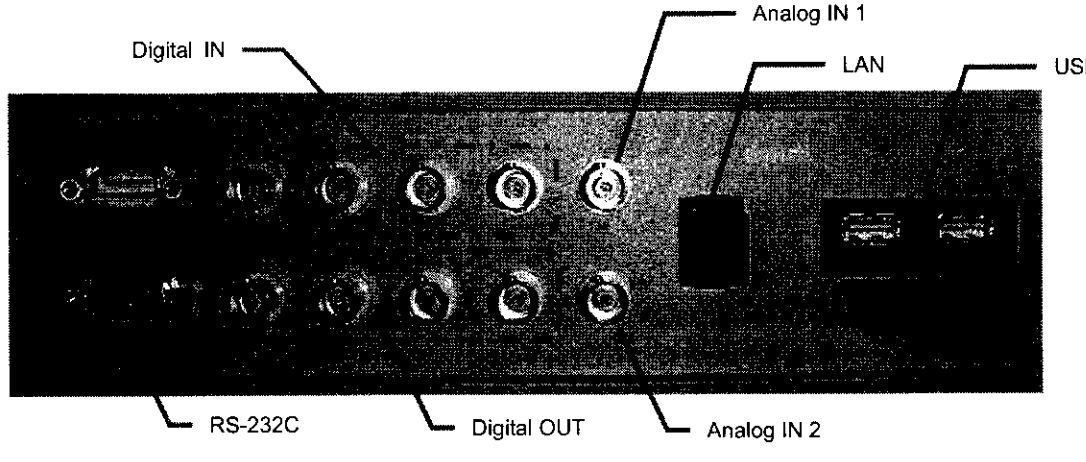

Fig. 2.5 External Output Terminal

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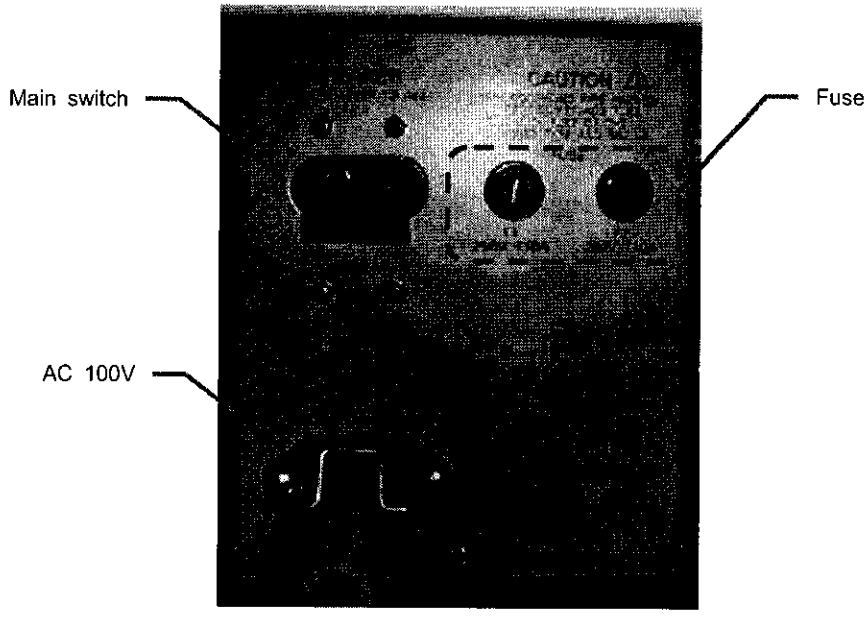

Fig. 2.6 System Bottom View (Power BOX)

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Section 3 Preparation before Use

3.1 Power Operation

3.1.1 Power ON

(1) Check if the Standby switch (See Fig. 2.3) located at the center of front panel of main unit is set to the [OFF] side, and set the breaker switch [Main Switch] (see Fig. 2.6) at the rear panel of main unit to the [ON] side.

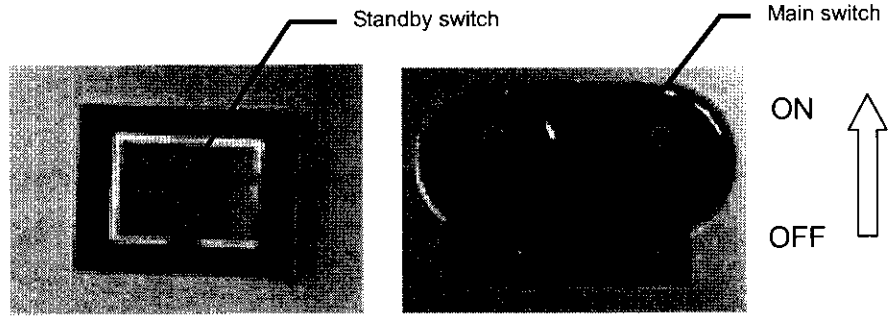

Fig. 3.1 Power Switches

(2) Press the Standby switch on the front panel of main unit and check if the power lamp is lit.

< CAUTION >

- When the Standby switch lamp is not lit even if pressing the Standby switch, check the power cable and breaker switch [Main Switch] again.
- If the power cable is correctly connected and the breaker switch [Main Switch] is set to the [ON] side and the Standby switch is still unlit, set the breaker switch [Main switch] of main unit to the [OFF] side and make contact with out service or sales personnel with the power cable disconnected.

(3) Press the PC power switch to turn it [ON]. It is located at the bottom of left side panel viewing from the main unit console (See Fig. 2.3).

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(4) The startup window appears on the PC screen.

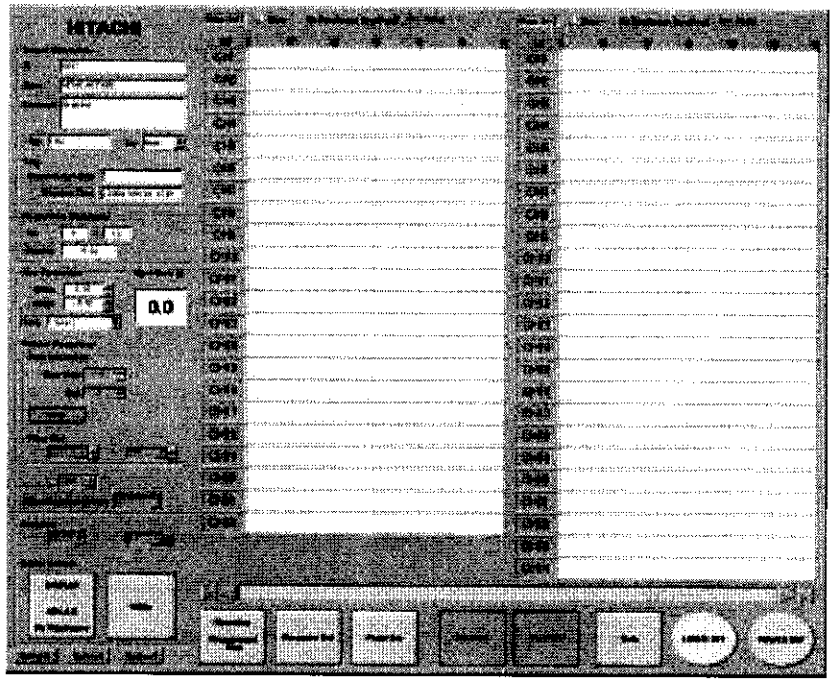

Fig. 3.2 Startup Window

3.1.2 Power OFF

* Be sure to follow the steps below to shut off the power. Or otherwise, the system performance can be degraded.

(1) Click the [POWER OFF] button at the lower right corner of window.

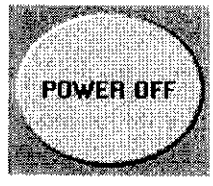

Fig. 3.3 [POWER OFF] Button

(2) If the shut down message is displayed on the screen, click the [OK] button. PC power is automatically shut off. The power to electronic circuits and printer is not shut off.

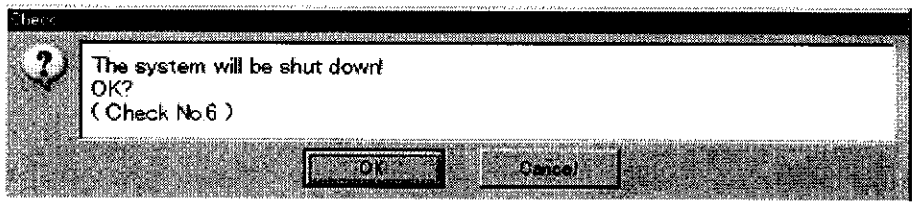

Fig. 3.4 Shut Down Message

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(3) Press the Standby switch (See Fig. 2.3) at the center of front panel of main unit to shut off the entire power. Set the breaker switch (See Fig. 2.6) at the rear panel of main unit to the [OFF] side as necessary.

3.1.3 Checking signals

Use the phantom to check if measurement operation is normal.

(1) Mount the fiber socket with correct color and number to the accessory phantom.

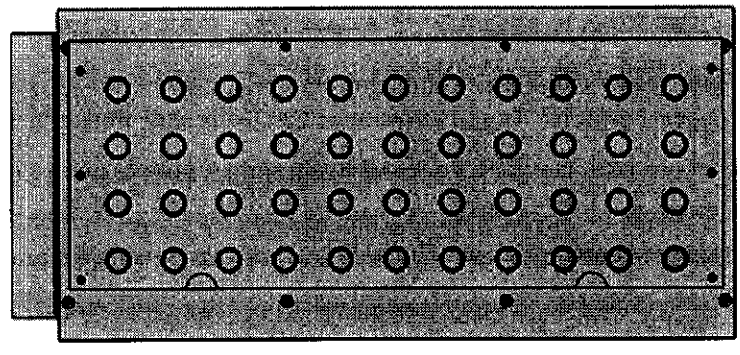

Fig. 3.5 Phantom Appearance 1

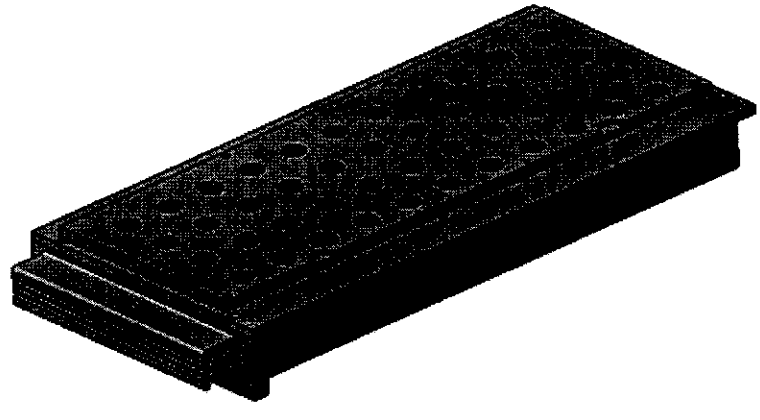

Fig. 3.6 Phantom Appearance 2

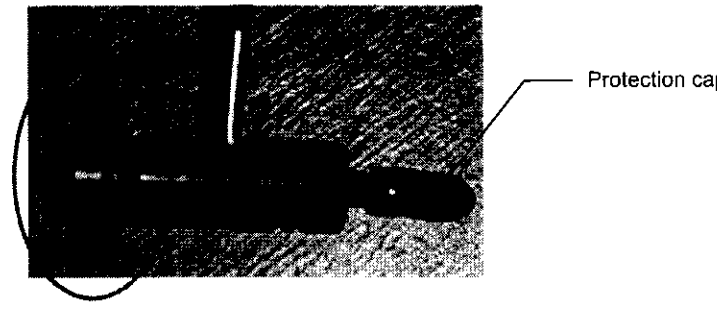

Fig. 3.7 Fiber Socket

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NOTE: 1) When pulling out/inserting the fiber cable from/into the phantom, be sure to hold the ◯ part.

2) When pulling out, do not hold the optical fiber cable.

(2) Remove the protection cap, and make the fiber socket securely contact with the phantom surface.

(3) Click the [Probe Set] button to display the Probe Set window.

(Operation needs to be set to Measurement.)

For the Probe Set window, see [6.3 Description on Probe Set window].

(4) Then, after checking orientation and quantity of the probes, click the [Single] or [Repeat] button. It will take about 12~18 seconds until the result is displayed.

(Process time may differ depending on the number of probes.)

According to intensity of the signal detected by the probe, red (Over Gain), green (Normal Gain) or yellow (Under Gain) appears at each channel position.

(5) Green indicates appropriate signal intensity. Red indicates signal intensity over and yellow signal intensity under (both are not appropriate). The signal intensity allows you to expect or judge whether sufficient accuracy could be obtained or not in the subsequent measurement.

Appropriate or not appropriate is an estimate, so judgment may not be applied if condition varies during actual measurement. Also, signal intensity over cannot hurt the measurement system.

(6) When the result color of each channel is not green but yellow or red, reset the fiber socket and click the [Single] button. Also, check again if the fiber socket is correctly located and the mode is correct. Even if not all channels are green after clicking the [Single] button several times, you can use the [Exit] button to exit the gain adjustment and start measurement if you judge that there is no problem since poor locations are out of the object to be studied. In such case, some sort of trouble is suspected. Please make contact with our service or sales personnel.

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3.1.4 Attaching the probe holder and fiber sockets

(1) To protect infection, sterilize the probe holder and so on before using for the patient.

When sterilizing, wipe it with gauze or the like soaked with ethanol.

Do not carry out sterilization or disinfection using chemicals or heating other than ethanol.

(2) Hook the optical fiber cable protection hose to the hanger while using it.

If the tip of fiber socket contact with scalp moves during measurement is pulled by the optical fiber cable due to body movement and so on, measurement data is affected and a wrong result may be produced. Adjust the hanger so that all optical fiber cables are bundled together at the optical fiber cable protection hose.

Attach the probe holder suitable for the objective mode to the patient.

Fig. 3.8 Attaching the Probe Holder

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Follow the procedure shown below for attaching the probe holder.

(1) Attach the fiber socket to the holder socket which number is agreed.

(2) Put on the probe holder. While adjusting balance by moving the probe holder lightly, attach it.

At this time, press the Probe Set button to check if a signal of which channel is not acquired. (For Probe Set, see [4.4 Probe Set Operation]).

- If there is a channel of which signal is not acquired:

  Check the related fiber and use the hair pusher to push hairs in the socket aside to expose scalp.

  Fix the fiber cable with the tip of fiber probe touched with the scalp (skin).

  Execute Auto Gain again.

  The tip of fiber socket has a slide mechanism using a spring to be pushed to the scalp. If pushing strength is too much, the patient can feel pain at the touched portion as time elapsed, so do not push too hard. As a standard, the tip of fiber socket returns 1~3 mm from its free state.

* Even if pushing the fiber socket hard, transmission of light will not become better. To improve transmission, the accessory hair pusher needs to be used to push hair aside completely and set the fiber socket.

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Section 4 Measurement Operation

This section describes procedures of measurement operation.

Before starting the first measurement, perform [Section 3 Preparation before Use].

4.1 Preparation to Measurement

4.1.1 Mounting probe holder and fiber sockets

(See [3.1.4 Attaching the probe holder and fiber sockets].)

4.1.2 Entering patient information

(See [6.1.1 Information display area] for details of entering patient information.)

(1) Enter patient information (name, age, ID, etc.) to the "Patient Information" field located at the upper left of window. In entering information, Set IME to "direct entry" and use alphanumeric characters only (including period and comma).

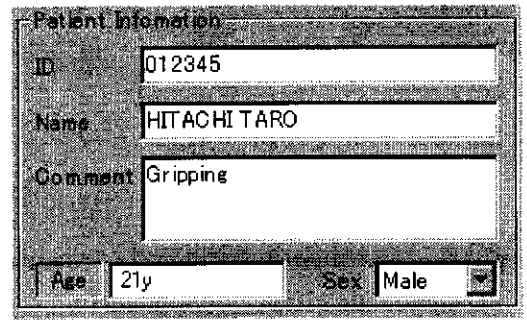

Fig. 4.1 Entering Patient Information

(2) Patient information is controlled by ID.

See [4.6 Saving Measurement Data] for details.

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4.1.3 Selecting measurement mode

(1) If Analysis is displayed on the [Operation] button, click the [Operation] button and select Measurement.

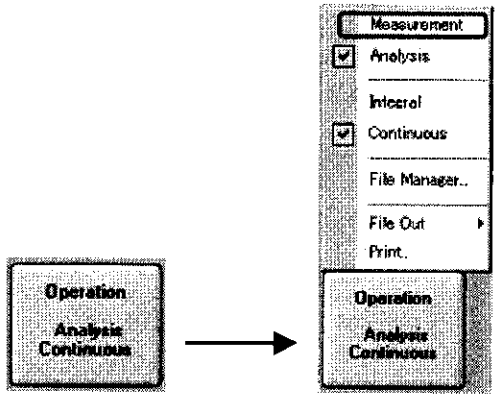

Fig. 4.2 [Operation] Button

(2) Click the [Operation] button and select Stim or Event measurement.

(See the following page for Stim and Event measurement.)

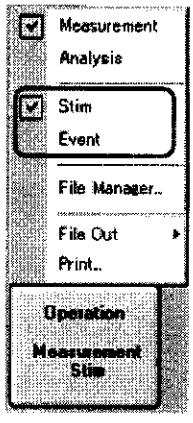

Fig. 4.3 [Operation] Button

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Stim measurement (Stimulation measurement)

① Intended use

It is used to analyze reaction against repeated load stimulation such as language stimulation and kinetic stimulation.

Averaging allows you to obtain waveform with reduced noise component.

② Outline of measurement method

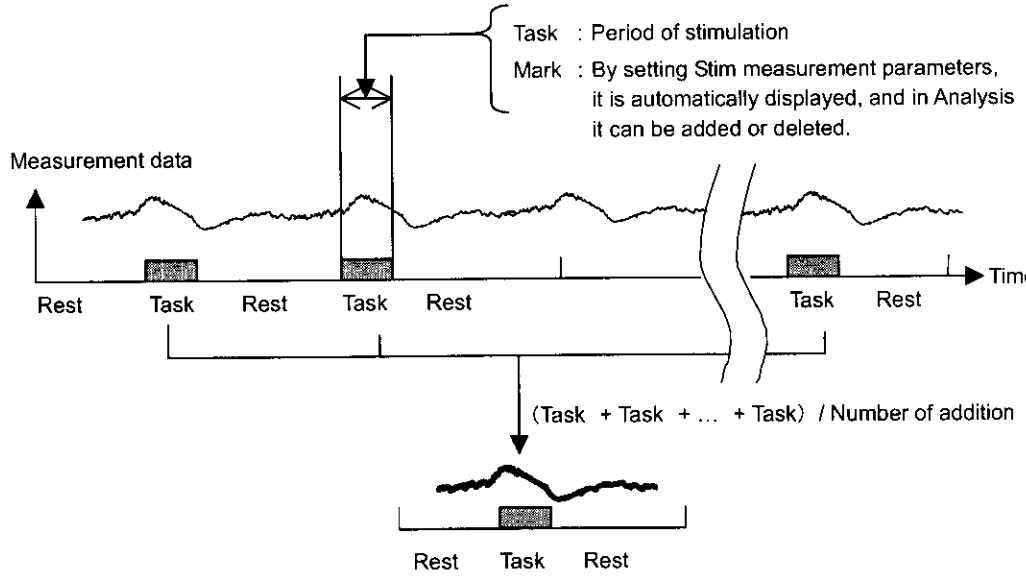

Fig. 4.4 Outline of Stim Measurement

Event measurement (Event variation)

① Intended use

It is used for monitoring during operation or of self-seizure. By entering Event when any information arises such as administration of pharmaceutical or movement of the patient, meaning of signals can be recognized in analysis giving hint.

② Outline of measurement method

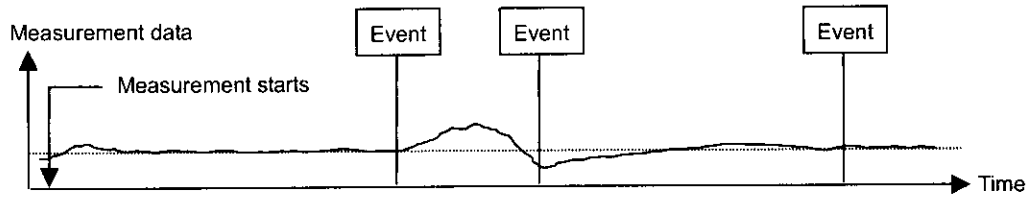

Fig. 4.5 Outline of Event Measurement

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4.2 Setting Parameters

4.2.1 Setting Stim measurement parameters

(For details, see [6.2.1 Stim measurement parameters].)

Click the [Parameter Set] button of main screen to display the Parameter Set window.

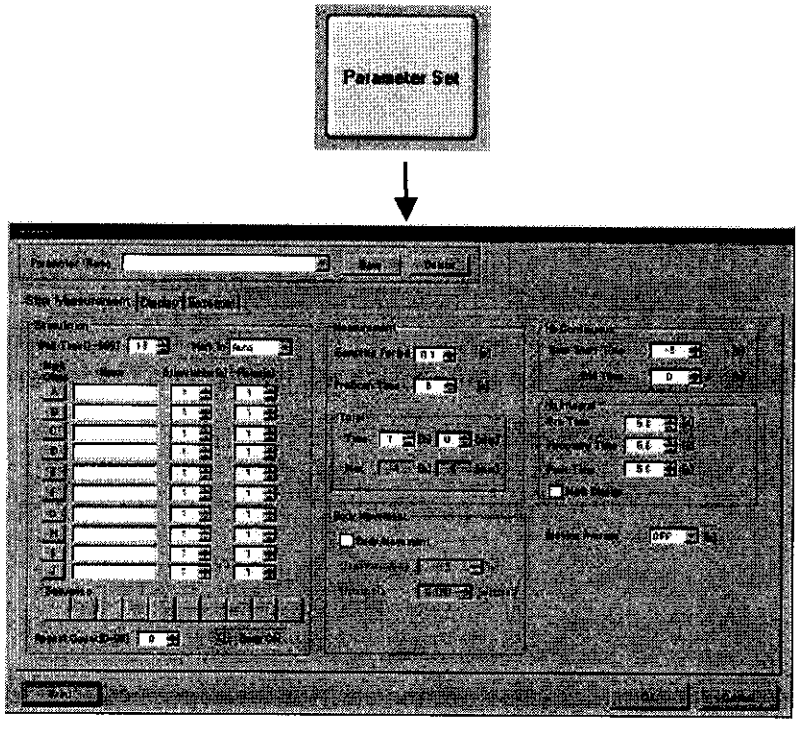

Fig. 4.6 Stim Parameter Set Window

(1) Set the default measurement time to acquire measurement data and interval of acquisition.

(2) Set the waiting time to starting measurement and the total measurement time.

(3) Set methods of entering stimulation mark, type, stimulation time, interval between stimulations.

(4) Set the stimulation sequence and repetition time.

* These parameter settings can be saved and loaded.

(For details, see [6.2.1 Stim measurement parameters]).

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4.2.2 Setting Event measurement parameters

(For details, see [6.2.2 Event measurement parameters].)

Click the [Parameter Set] button on the main screen to display the Parameter Set window.

Then select the Event Measurement tab and set parameters for Event measurement.

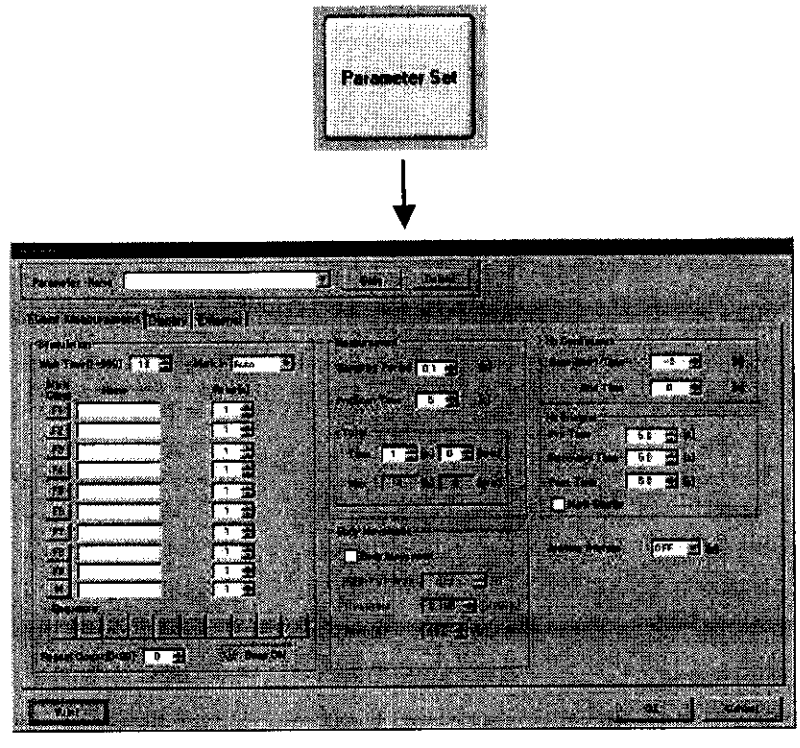

Fig. 4.7 Event Parameter Set Window

(1) Set the default measurement time to acquire measurement data and interval of acquisition.

(2) Set the waiting time to starting measurement and total measurement time.

(3) Set methods of entering stimulation mark, type, stimulation time, interval between stimulations.

(4) Set the stimulation sequence and repetition time.

* These parameter settings can be saved and loaded.

(For details, see [6.2.2 Event measurement parameters].)

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4.3 Setting Display Parameters

Set display parameters for measurement data to be displayed during measurement.

(1) [Display] button (For details, see [6.1.4 Display related operation area].)

(a) Select the Hb type to be displayed.

(b) Select each data to be displayed.

(c) The status of measurement channel signal can be displayed on a separate window.

NOTE: During measurement, only "AD Status" can be selected (See [6.5.6].)

While executing measurement, the AD Status window cannot be moved and the size of window cannot be changed.

(d) On the separate window, Realtime Integral processed data can be displayed. (For details, see [6.6].)

(During Analysis, the Realtime Integral is not displayed.)

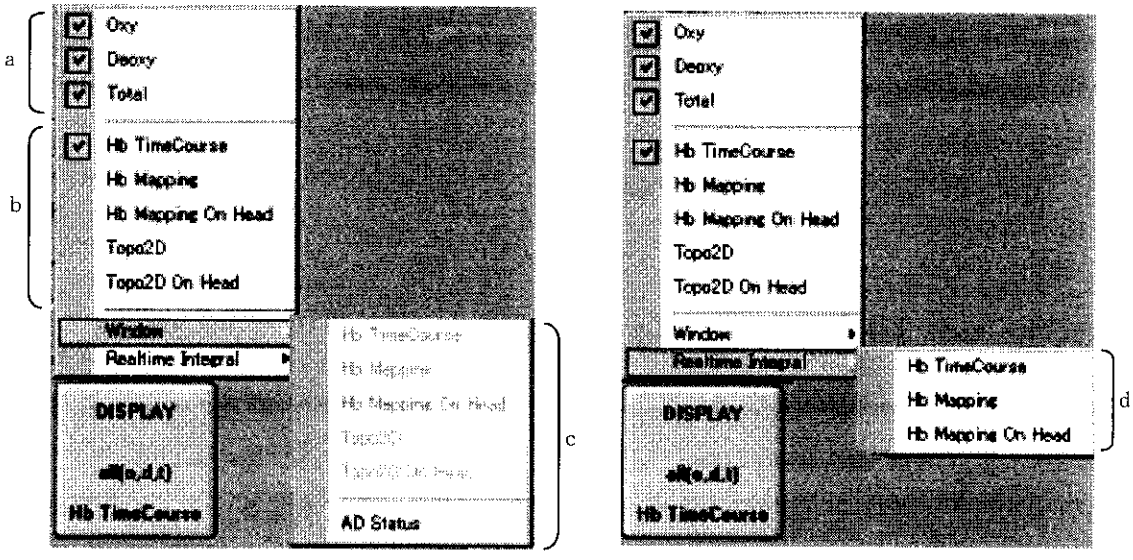

Fig. 4.8 DISP Button

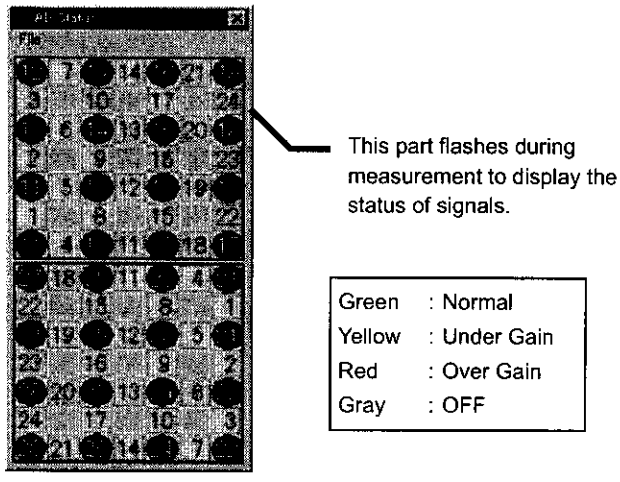

Fig. 4.9 AD Status Window

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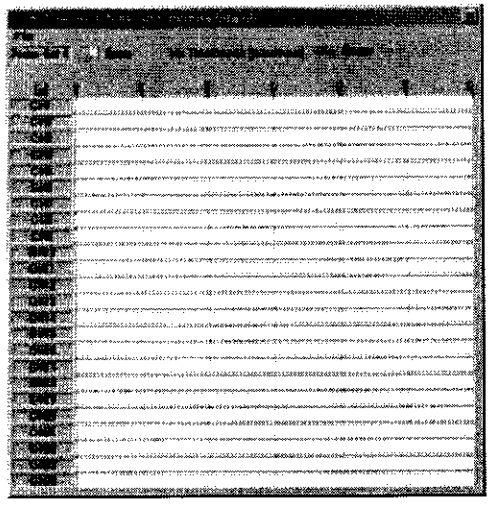
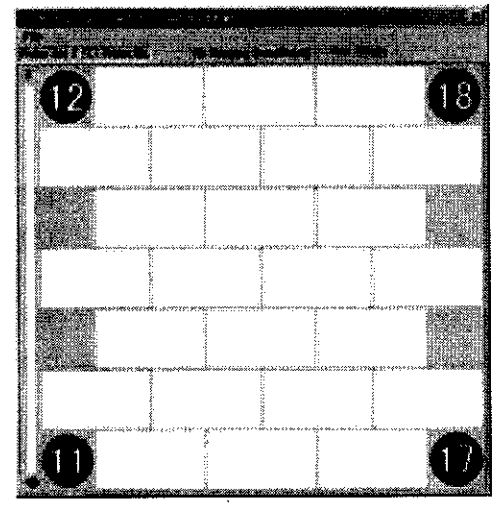
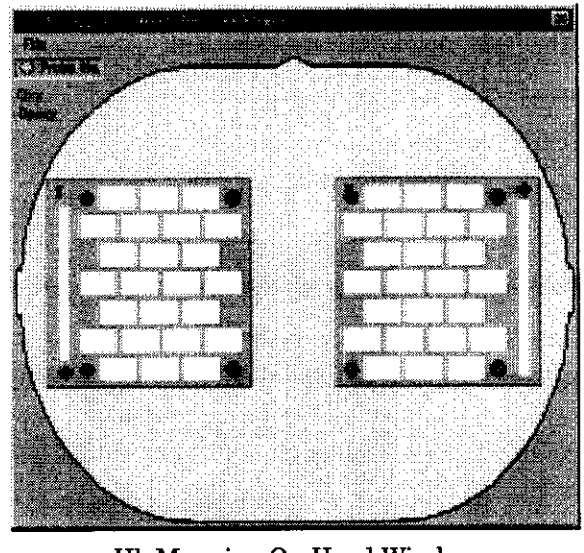


Hb Time Course Window



Hb Mapping Window



Hb Mapping On Head Window

Fig. 4.10 Realtime Integral Window

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(2) Selecting time unit (displayed on the left side of main screen)

(For details, see [6.1.1 Information display area].)

(a) Select the time unit to be displayed. [s], [min], [h:min:s], [time].

Time unit can be changed even during measurement.

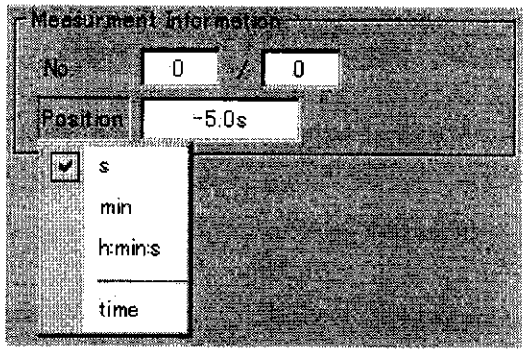

Fig. 4.11 Setting Time Unit

(3) Selecting time axis (displayed on the left side of main screen)

(For details, see [6.1.1 Information display area].)

(a) Set the time axis to be displayed.

This cannot be changed during measurement.

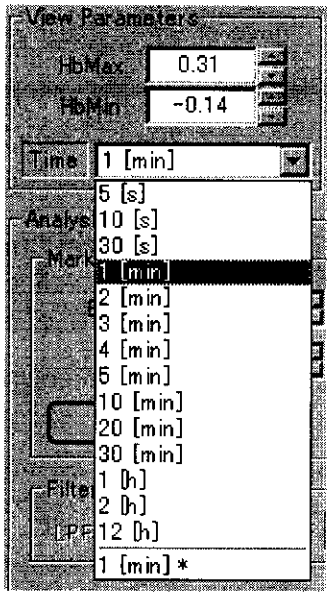

Fig. 4.12 Setting Time Axis

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4.4 Probe Set Operation

(For details of the probe set window, see [6.3 Description on Probe Set window].)

Click the [Probe Set] button of the main screen to display the probe set window.

Set the number, layout and orientation of the probe unit here.

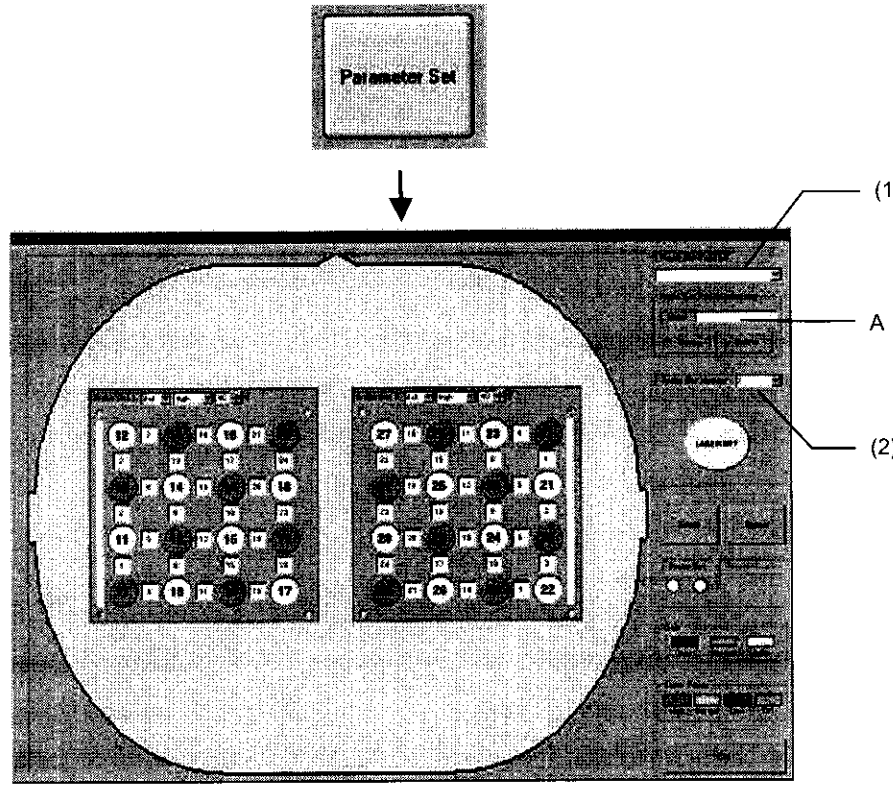

Fig. 4.13 Probe Set Window

(1) One of probe unit settings already registered can be selected.

* If it is saved after completing probe unit setting, data is only loaded next time for convenience.

Enter the name in the field A and click the [Save] button to register the setting. Maximum number of settings that can be saved is 10.

(2) Set the number of probe units to be used.

When data has been saved in (1), proceed to the next step.

(3) Use the mouse drag to set position of the probe unit.

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(4) Adjust Auto Gain and confirm it.

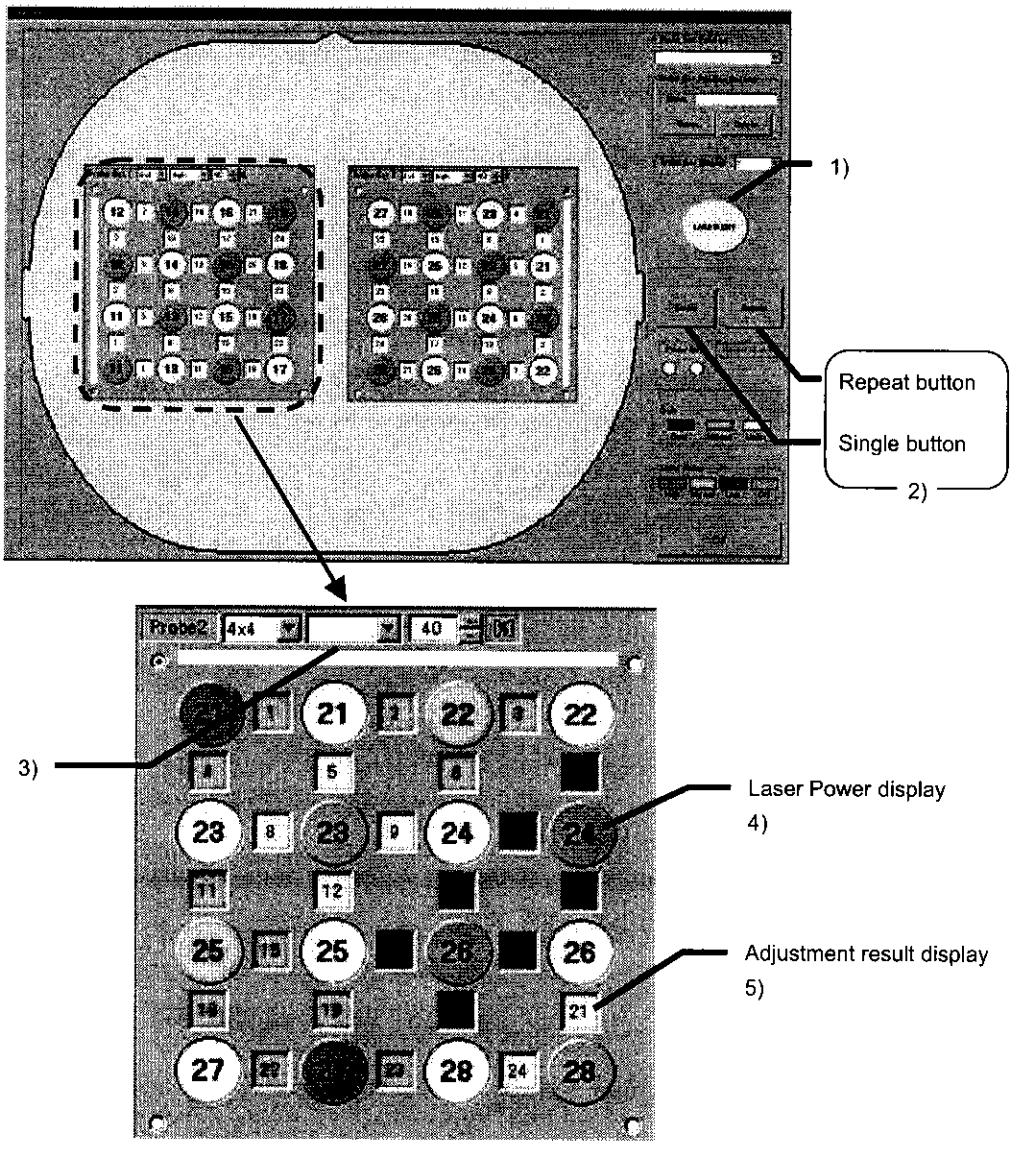

Fig. 4.14 Probe Set Window

1) Set Laser ON/OFF. When performing the Auto Gain process, set Laser ON.

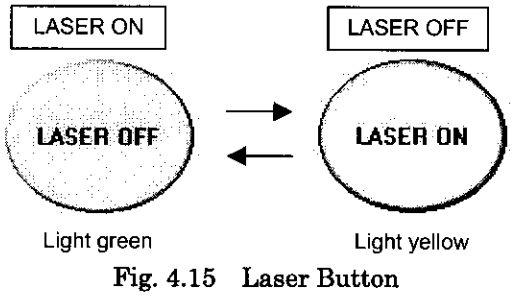

Fig. 4.15 Laser Button

2) The Auto Gain process can be performed once ([Single] button) or repeated ([Repeat] button).

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Confirm that the Auto Gain of all probe units has been completed.

- Use the [Single] button usually for one time Auto Gain.
- The [Repeat] button repeats execution of the Auto Gain and adjustment result display until clicking the [Stop] button. Use this button for repeated check when adjusting mount of the fiber sockets.

  Stopping measurement is only allowed when judging the Auto Gain is completed. Stop is disabled during measurement.

3) Set the target value of laser output intensity and Auto Gain of detected optical amplifier for each probe holder.

Select from Off, Low, Normal and High.

- Default of laser output intensity is [High].

  When there are many "Over", set laser output to [Normal] or [Low].

  When using for an infant, set laser output to [Low] or [Normal].

- Use Threshold to change gain when detecting laser light.

  Default is 40%.

  For Over Gain : Raise Threshold.
  For Under Gain : Lower Threshold.

* This adjustment changes only Threshold and signal level is not changed.

4) Set laser output intensity for each channel.

Every time clicking the channel number, output intensity varies.

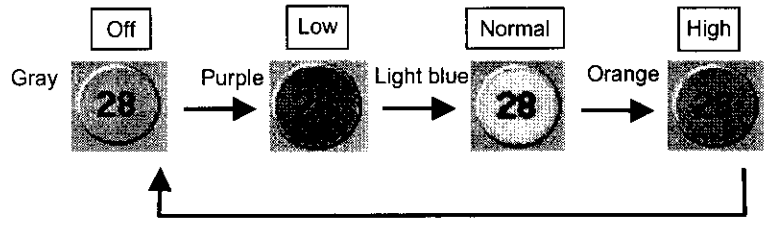

Fig. 4.16 Setting Laser Intensity

5) Auto Gain result is displayed in colors.

Green: Normal, red: over gain, yellow: under gain

(Confirm that gain adjustment result of all probe holders is normal (green)).

Measurement can be performed even if some of values are not optimum, but all optimum values may produce better result.

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4.5 Measurement Operation

4.5.1 Executing Stim measurement

Click the [READY] button to display a message of measurement ready. As soon as becoming ready, the [READY] button turns to the [START] button.

Then click the [START] button to start Stim measurement. Measurement data is displayed on the main screen.

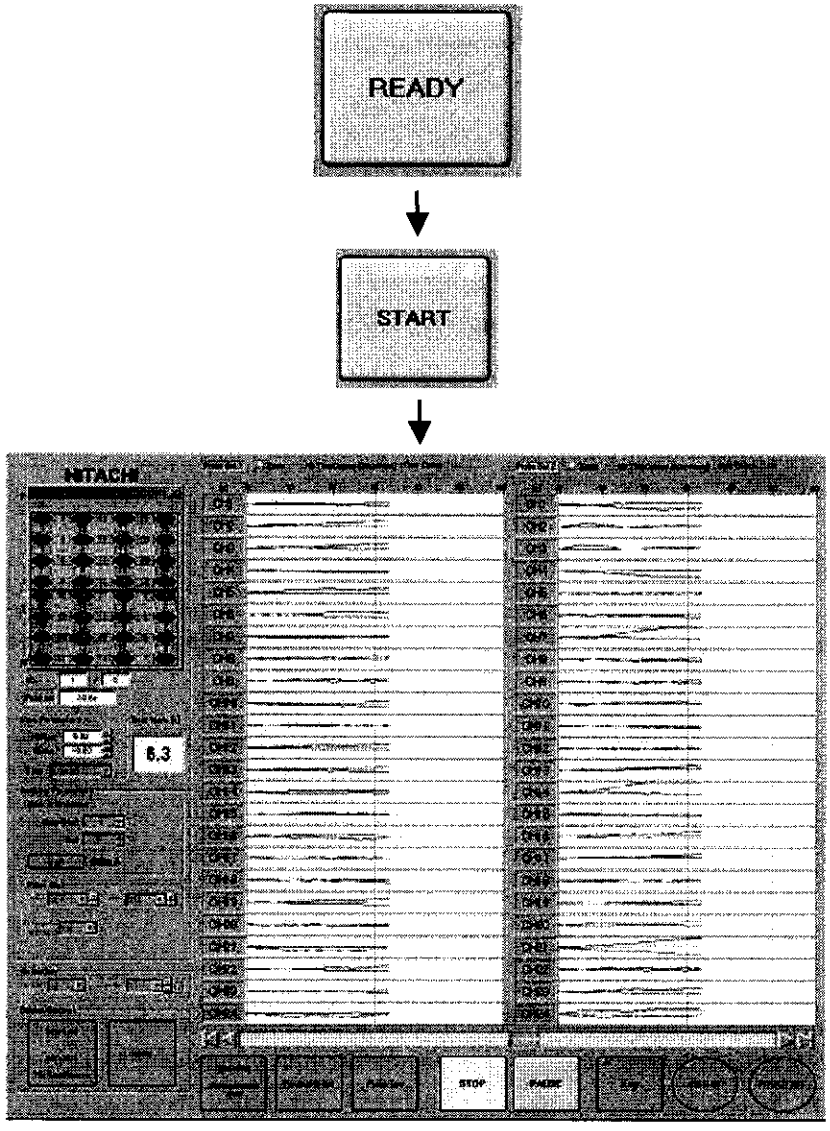

Fig. 4.17 Example Display of Main Screen

AD Status window can be placed on any location.

NOTE: However, this window cannot be moved or changed in its size while executing measurement.

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(1) Stimulation marking during measurement

(a) When marking automatically (stimulation entry is {Auto} and more than one mark class have been selected in the Sequence field on the Parameter Setting window)

After Wait Time, stimulation sequence is executed.

Only when marking automatically, the following Next Mark is activated.

This counts down the time to the next mark.

Utilize it for informing the patient of timing of the next mark.

Fig. 4.18 Next Mark Display

(b) When marking manually (stimulation entry is {Manual} on the Parameter Set window.

- In Stim measurement, marking is inevitably a pair, so click the [Mark] button when starting stimulation and click the [Mark] button again when completing stimulation.
- Type and order of marking depend on entry set in the Parameter Set window.

(Stim time and Relaxation time depend on interval of clicking the [Mark] button.)

(For details of manual marking, see [6.2.1 Stim measurement parameters].)

(c) When marking via serial communication (stimulation entry is {Serial} in the Parameter Set window)

- Marks can be entered remotely during measurement by using the RS-232C cable from any other PC or the like. The RS-232C port is located at the rear panel (Fig. 2.5).
- Mark entry order depends on communication timing from the serial command A to J. (For details of serial communication, see [4.7 Description on External Input (Serial, External)].)

(d) When marking by the external input signal (stimulation entry is {External} in the Parameter Set window.

- Marking is performed based on the external input signal.

  The external input port is located on the rear panel (Fig. 2.5).

(For details of external input, see [4.7 Description on External Input (Serial, External)].)

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(2) Click the [PAUSE] button to suspend measurement. Name of the button turns to [UnPAUSE]. Clicking again starts the Probe Set window and conducts Auto Gain again.

As soon as completing Auto Gain, measurement resumes automatically.

(For details of Auto Gain, see [6.3 Description on Probe Set Window].)

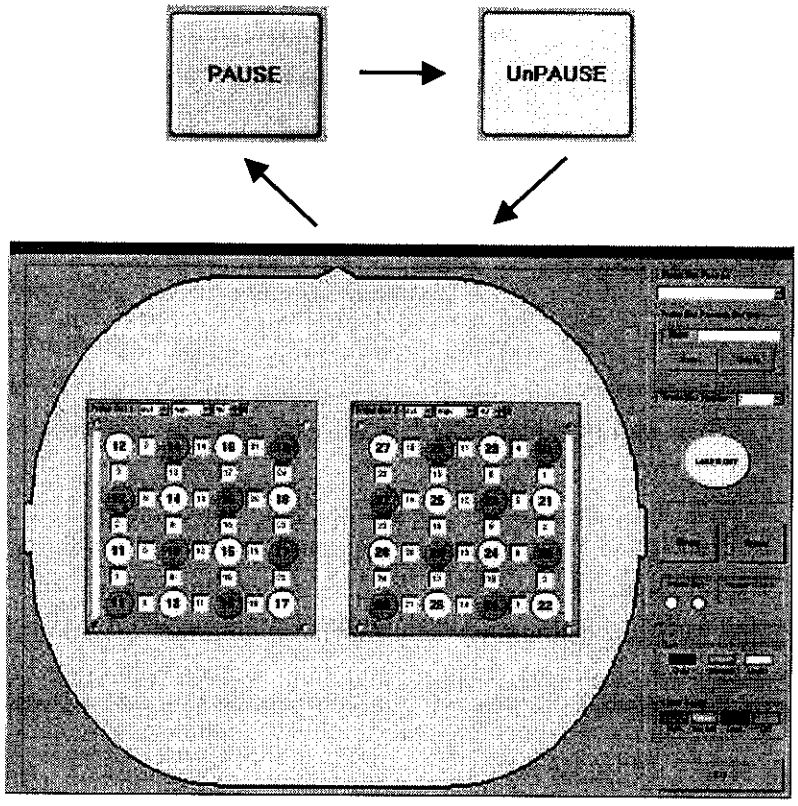

Fig. 4.19 When Measurement is Suspended

(3) In the following cases, measurement stops.

(a) Clicking the [STOP] button during measurement forces measurement to stop.

(b) When the set measurement time (Total Time) has elapsed, measurement stops automatically.

(c) When marking automatically, measurement stops automatically if repetition time of stimulation is completed.

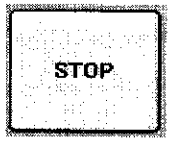

Fig. 4.20 STOP Button

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(4) As soon as completing measurement, the [STOP] button flashes. Click the [STOP] button. This boots the File Manger window.

Note that measurement data is not saved automatically here.

Click the [Save] or [Save As] button to save data.

To save data, check if patient information entry (see 4.1.2) is correct. If any correction is needed, click [EXIT] to close the [File Manager] window and reenter patient information. Then click the [Save] or [Save As] button on [File Manager] of [Operation].

(For details of file handling, see [6.4 File Related Operation].

If the measurement data (for test and so on) needs no saving, click [Exit] to close the window. Measurement data at this time is not saved.

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4.5.2 Running Event measurement

Clicking the [READY] button displays a message for measurement preparation. As soon as completing preparation, the [[READY] button turns to [START] button.

Then, clicking the [START] button starts Event measurement and displays measurement data on the main screen.

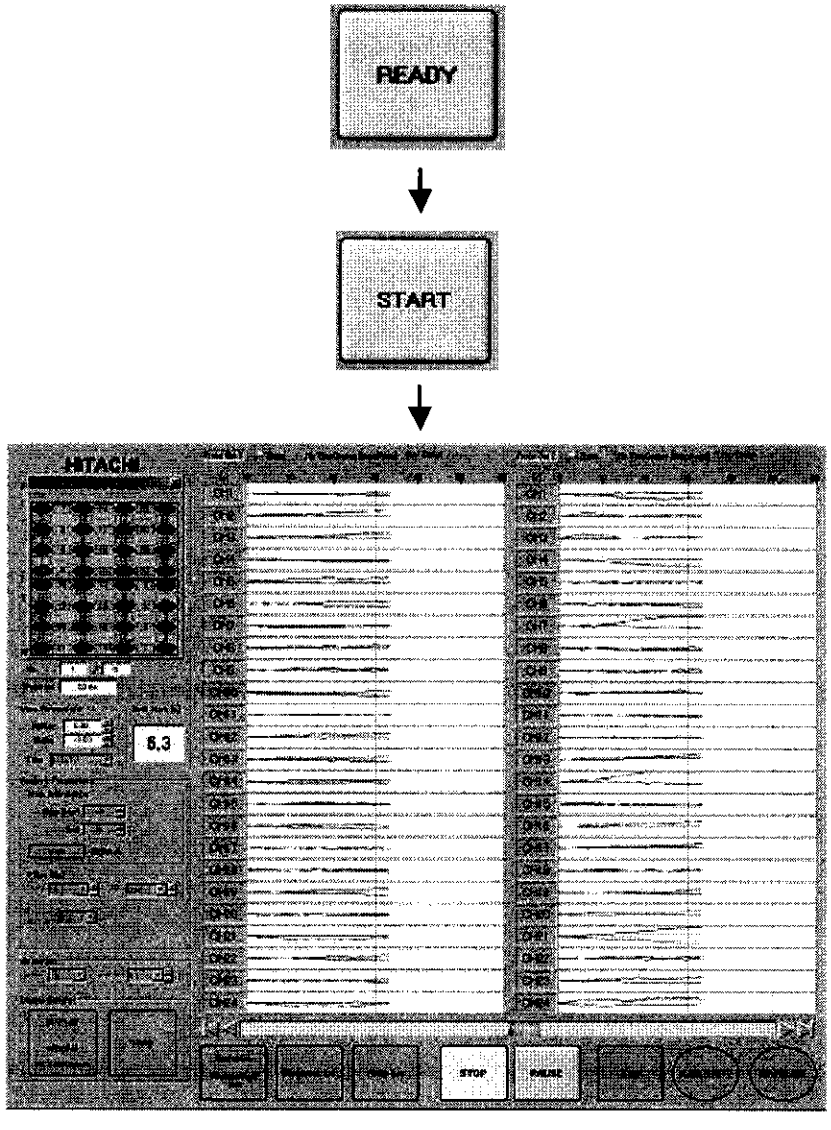

Fig. 4.21 Example Display of Main Screen

Window layout may be freely determined according to setting.

NOTE: However, the window cannot be moved and changed in size while executing measurement.

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(1) Stimulation marking during measurement

(a) When marking automatically (stimulation entry is {Auto} on the Parameter Set window and more than one mark class have been selected in the Sequence field)

After Wait Time, the stimulation sequence is automatically executed.

(b) When marking manually (Mark In {Stimulation entry} is [Manual] in the Parameter Set window)

Marking is independent of one by one, and pressing any function key (F1~F9) in the timing when stimulation occurs allows the position where stimulation occurred to be marked.

(For details of manual marking, see [6.2.2 Event measurement parameters].)

(c) When marking via serial communication (Stimulation entry is {Serial} in the Parameter Set window)

- Marks can be remotely entered by using the RS-232C cable from any other PC during measurement. The RS-232C port is located at the rear of cabinet (Fig. 2.5).
- Order to enter marks follows timing of the serial communication command A to J.

(For details of serial communication, see [4.7 Description on External Input (Serial, External)].)

(d) When marking by the external input signal (Stimulation entry is {External} in the Parameter Set window)

- Marking is performed based on the external input signal.

  The external input port is located at the rear of cabinet (Fig. 2.5).

(For details of external input, see [4.7 Description on External Input (Serial, External)].)

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(2) Clicking the [PAUSE] button suspends measurement and the button name turns to [UnPAUSE].

Clicking once more starts the Probe Set window and measures Auto Gain again.

As soon as completing Auto Gain, measurement resumes automatically.

(For details of Auto Gain, see [6.3 Description on Probe Set Window.)

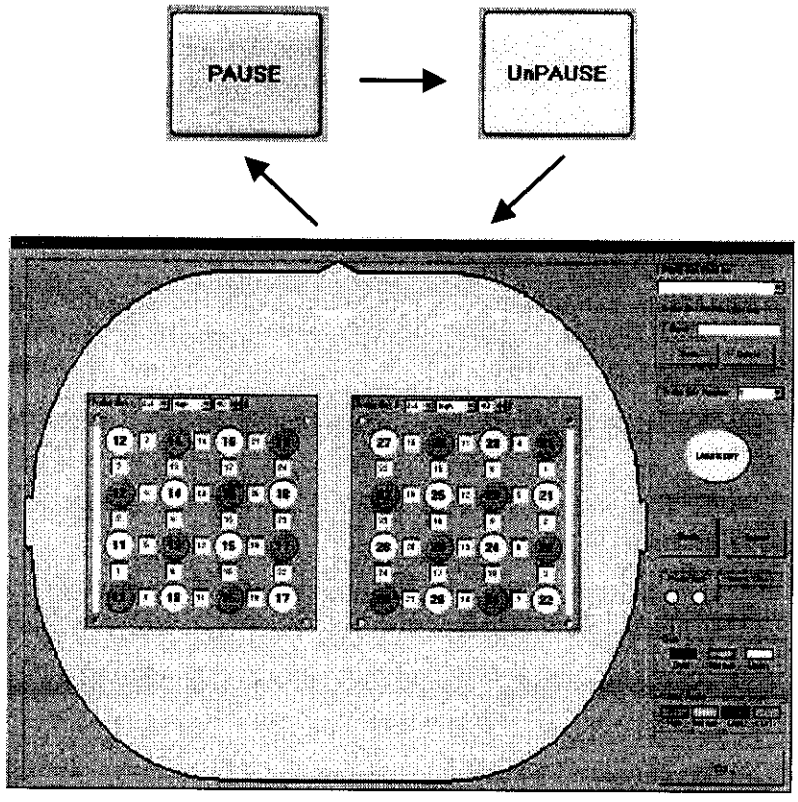

Fig. 4.22 When Pausing Measurement

(3) Measurement stops in the following cases.

(a) Clicking the [STOP] button forces measurement to stop.

(b) If the set measurement time (Total Time) elapses, measurement stops automatically.

(c) When marking automatically, measurement stops automatically if the stimulation repetition time is completed.

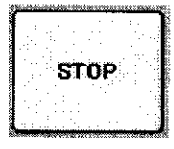

Fig. 4.23 STOP Button

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(4) When measurement is completed, the [STOP] button flashes. Click the [STOP] button.

This boots the [File Manager] window automatically.

Note that measurement data is not saved automatically here.

Click the [Save] or [Save As] button to save data.

Before saving data, check if entries of patient information are correct (see 4.1.2).

If any correction is needed, use [EXIT] to close the [File Manager] window and reenter patient information. Then click the [Save] or [Save As] button from [File Manager] of [Operation] to save data.

(For details of file handling, see [6.4 File Related Operation].)

If the measurement data (for test and so on) needs no saving, click [Exit] to close the window. Measurement data at this time is not saved.

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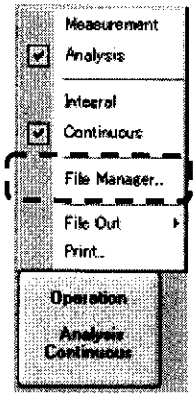
4.6 Saving Measurement Data

(For details of file handling, see [6.4 File Related Operation].)

Select [File Manager] from menu of the [Operation] button to display the File Manager window.

* **When completing measurement, [File Manage] appears automatically. Measurement data is not saved automatically, so follow the steps below.**

(However, if the measurement data (for test and so on) needs no saving, click [Exit] to close the window. Measurement data at this time is not saved. When loading another data or perform another measurement, confirmation message appears.)



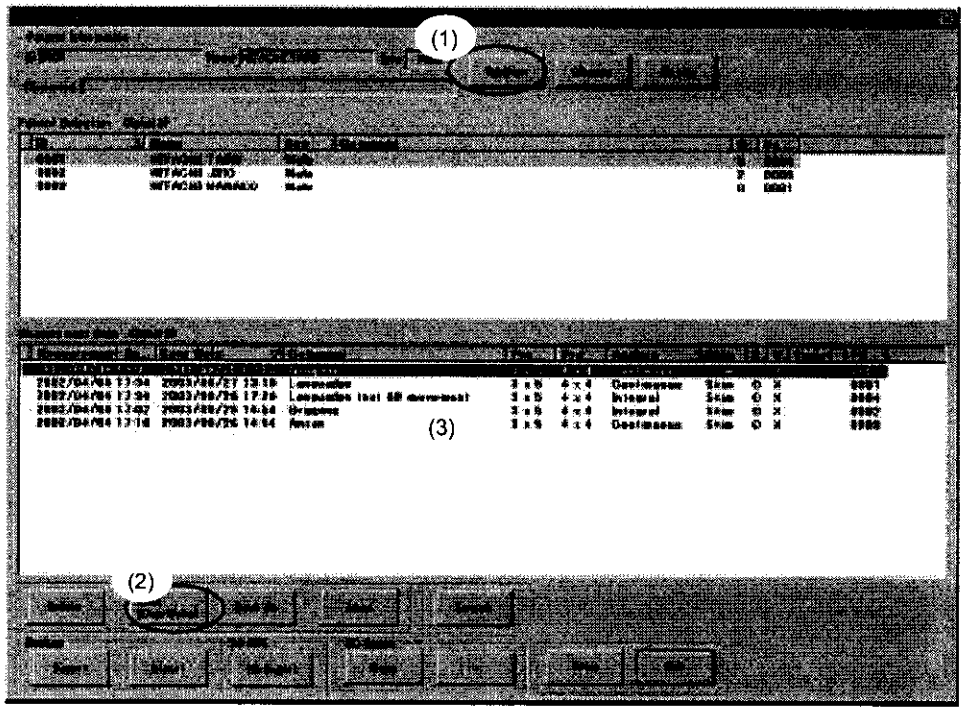


Fig. 4.24 File Manager Window

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(1) When the following warning message is displayed, click the [Addition] button to register patient data.

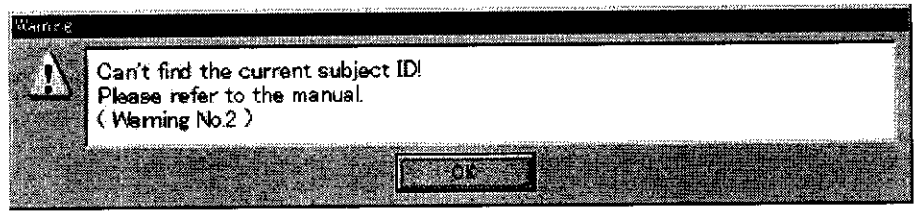

Fig. 4.25 Warning for Unregistered ID

If patient ID has not been entered, the [Addition] button is disabled. In such case, exit the File Manager once and then enter patient information (name, age, ID, etc.) into "Patient Information" at the upper left of main screen. After entering patient information, select [File Manager] from menu of [Operation] button.

(2) If patient ID is registered, the [Save] button is enabled.

Clicking the [Save] button displays the data save confirmation window.

(When saving without overwrite, press the [Save As] button.)

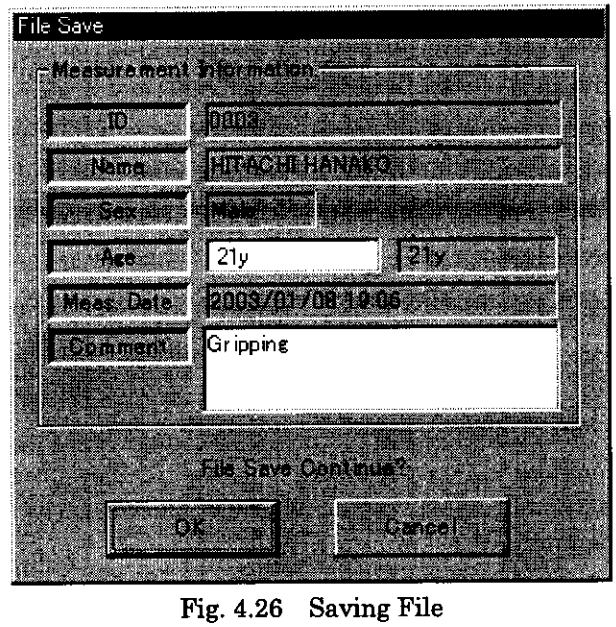

Fig. 4.26 Saving File

(a) Age of the patient when measured can be changed.

(b) Comment for measurement can be changed.

(c) When saving data, click the [OK] button.

(d) When canceling data saving, click the [Cancel] button.

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(3) When completing saving, the following appears and information on measurement data saved is displayed. Correctness of data information saved can be checked.

① Measurement	② Save Date	③ Comment	④ Pro.	⑤ Pro.	⑥ Analyze	⑦ Stim	⑧ 3D	⑨ V	⑩ Export	⑪ FILE
2003/01/08 18:39	2003/01/08 18:41	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0001
2003/01/08 18:43	2003/01/08 18:44	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0002
2003/01/08 18:45	2003/01/08 18:47	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0003
2003/01/08 18:56	2003/01/08 18:59	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0004
2003/01/08 19:06	2003/01/08 19:09	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0005
2003/01/08 19:06	2003/01/14 11:40	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0006
2003/01/08 19:06	2003/01/14 11:40	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0007
2003/01/08 19:06	2003/01/16 13:35	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0008
2003/01/08 19:06	2003/01/27 09:35	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0009
2003/01/08 19:06	2003/03/03 10:33	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0010
2003/01/08 19:06	2003/03/03 10:33	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0011

Fig. 4.27 Measurement Data

① Displays date and time when measured.

② Displays date and time when saving measurement and analysis.

③ Displays comment.

④ Displays the shape of probe 1 (Shape of probe: 3×3, 4×4, 3×5)

⑤ Displays the shape of probe 2 (Shape of probe: 4×4, 3×5) * Only for 48CH case.

⑥ Displays type of analysis (Continuous, Integral)

⑦ Displays type of stimulation (Stim, Event)

⑧ Displays presence of 3D Space (optional) data by ○×.

⑨ Displays presence of Video Capture (optional) data by ○×.

⑩ For measurement data exported, displays the folder to which data was exported.

⑪ Displays file No.

NOTE: Patient data is controlled by ID. Since ID and NAME are those of the same patient in principle (one to one correspondence), the measurement data list (Fig. 4.25) has no NAME column. (However, data can be saved with the other NAME designated by the same ID.)

Therefore, when arranging a series of measurement as the same ID data, discriminating variation for each measurement by difference of NAME is inappropriate.

Use COMMENT to discriminate plural patients with the same ID.

Example (1) The same patient

ID	NAME	COMMENT	DATE
TARO	TARO	TASK1	03/07/20
TARO	TARO	TASK2	03/07/20
TARO	TARO	TASK1	03/07/21
TARO	TARO	TASK3	03/07/23

(2) Plural patients (sorted by date)

ID	NAME	COMMENT	DATE
03/07/20	—	TARO TASK1	03/07/20
03/07/20	—	JIRO TASK1	03/07/20
03/07/20	—	HANAKO TASK1	03/07/20
03/07/20	—	TARO TASK2	03/07/20

(DATE is entered automatically.)

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4.6.1 Changing ID, Name, Sex and so on

When saving data, ID, Name, Comment, Age and Sex information can be changed.

(1) After completing measurement, click the flashing [STOP] button to start the [File Manager] window automatically.

(2) If ID, Name, Comment, Age and Sex are to be changed after the [File Manager] window started, click the [Exit] button to close the window.

(3) Enter ID, Name Comment, Age and Sex to be saved to the upper left of main screen (Patient Information) on the main screen.

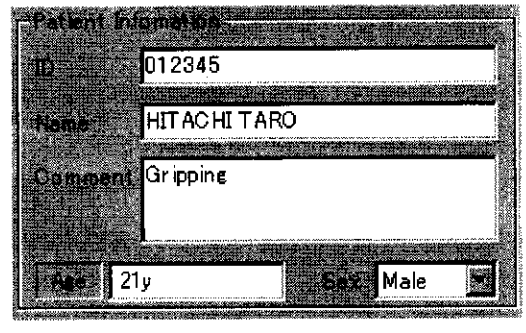

Fig. 4.28 Changing Name

(4) After completing [Patient Information] entry, select [File Manger] from menu of the [Operation] button.

When starting File Manager, the following warning appears. Click the [OK] button. If any ID exists in the File Manager, this window does not appear.

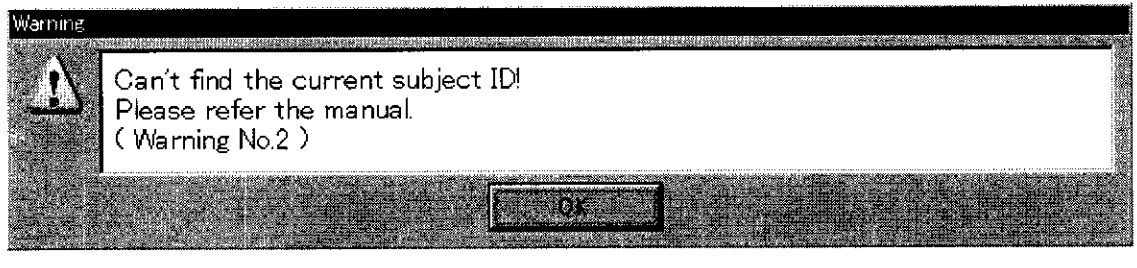

Fig. 4.29 Warning for Unregistered ID

(5) If the same ID has not been registered, click the [Addition] button to register ID.

If ID exists in the File Manager, this operation is not needed.

Fig. 4.30 Addition Button

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(6) When completing ID registration, click the [Save] button to save data.

At this time, the following window appears. Check ID, Name, Comment, Age and Sex.

Click the [OK] button to save data.

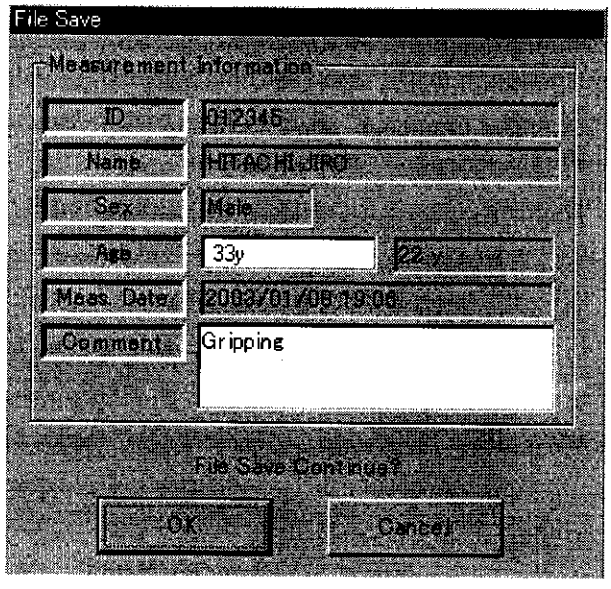

Fig. 4.31 Saving File

With the status as it is the next measurement (4.1) or new data analysis (5.1) can be performed.

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4.7 Description on External Input (Serial, External)

The RS-232C cable can be used to import signals from an external PC or the lick into ETG-4000. This allows you to remotely control ETG-4000 to start/stop measurement and enter marks.

4.7.1 Setting environment

To import signals via serial communication, be sure to perform this setting and check connectivity.

(1) Use the RS-232C cable to connect ETG-4000 and an external PC.

Connect both ETG-4000 and external PC with COM1.

At this time check if all powers are shut off.

(2) Turn on the power to ETG-4000 and the external PC.

(3) Setting environment of the external PC

(a) From the task bar, select [Start] → [Program] → [Accessories] → [Communication] → [Hyper Terminal] to start the hyper terminal.

When the hyper terminal is started, the following window appears. Enter appropriate name and click the [OK] button. (Any icon may be selected.)

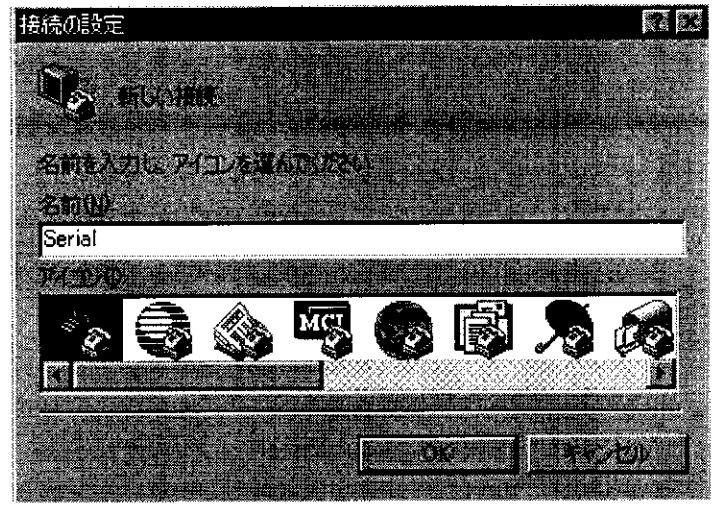

Fig. 4.32 Connection Set Window (Entering Name)

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(b) The following window appears. Select COM1 for the connecting method and click [OK].

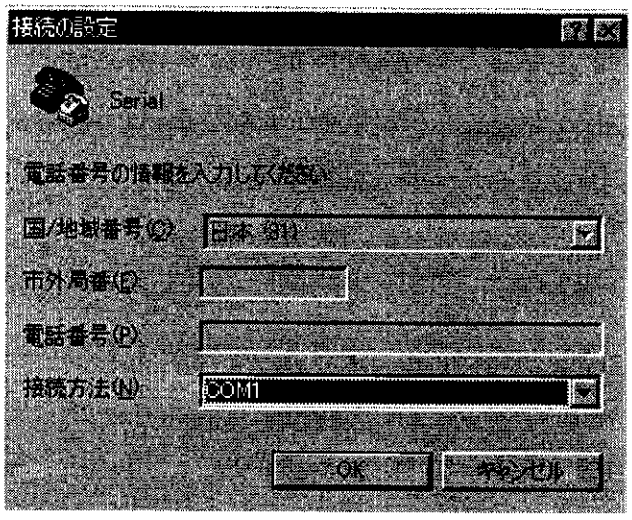
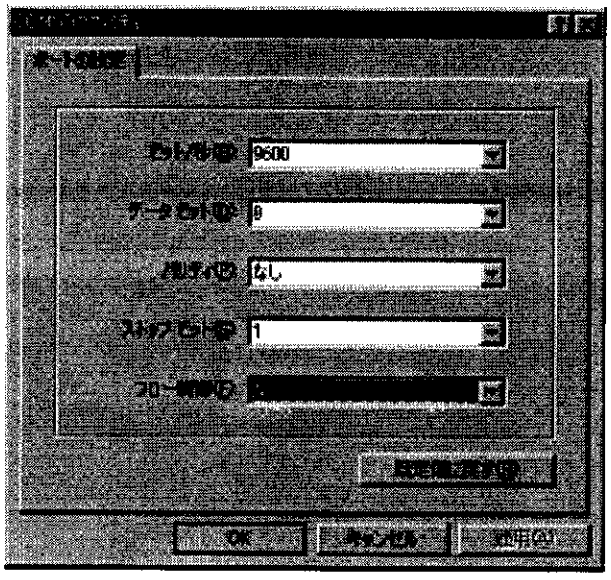


Fig. 4.33 Connection Set Window (Selecting connection method)

(c) Then the following window appears. Set as shown below and click [OK].



Bit/s	:	9600
Data bit	:	8
Parity	:	None
Stop bit	:	1
Flow control	:	None

Fig. 4.34 COM1 Set Window

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(d) The following window appears. Click Property from the [File] button.

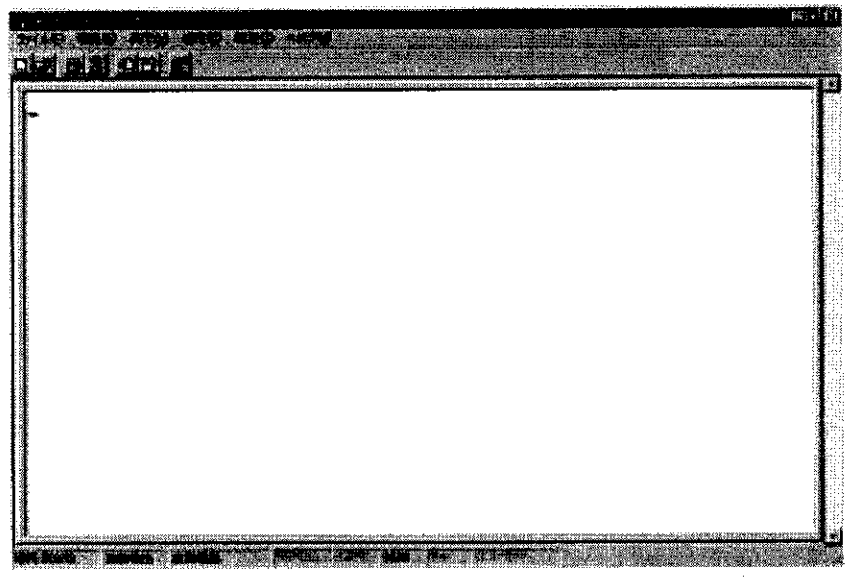

Fig. 4.35 Hyper Terminal Main screen

(e) The Property window appears. Set emulation to "VT100". Click [ASCII setting] button.

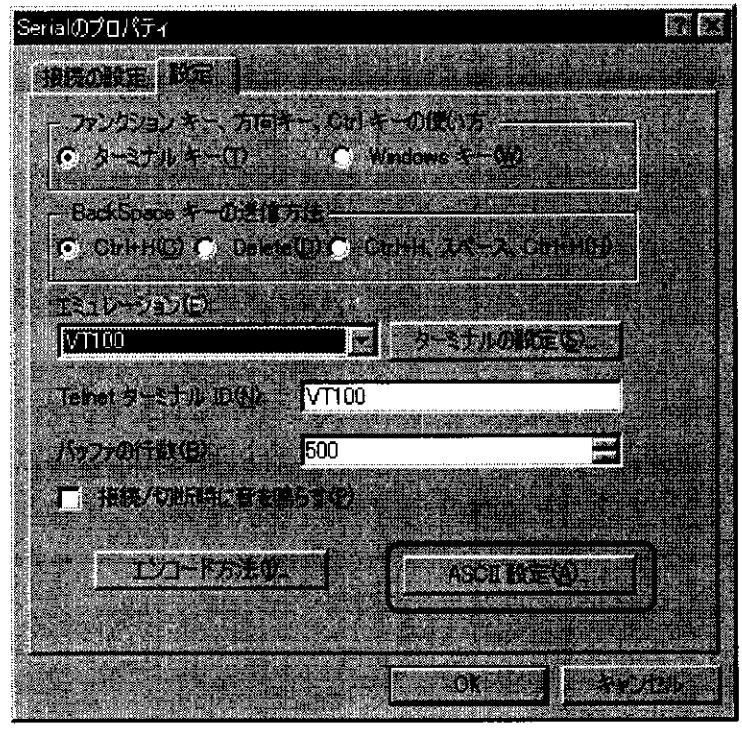

Fig. 4.36 Property Window

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(f) The ASCII Setting window appears. Mark the check box of "Local echo" only and click the [OK] button.

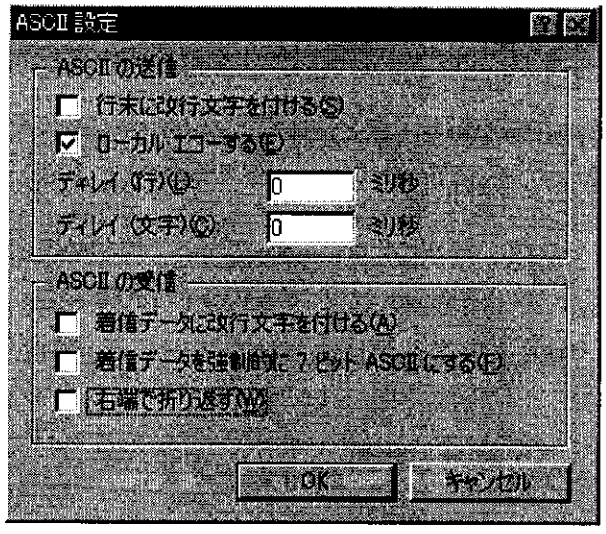

Fig. 4.37 ASCII Set Window

(4) Setting environment for ETG-4000

Environment setting of PC built in ETG-4000 is the same as that in (3) (when shipped). If it cannot be connected, check the setting of PC built in ETG-4000.

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4.7.2 Setting parameters of Serial measurement

Set parameters before starting measurement utilizing serial communication.

(1) Clicking the [Parameter Set] button in main screen displays the Parameter set window.

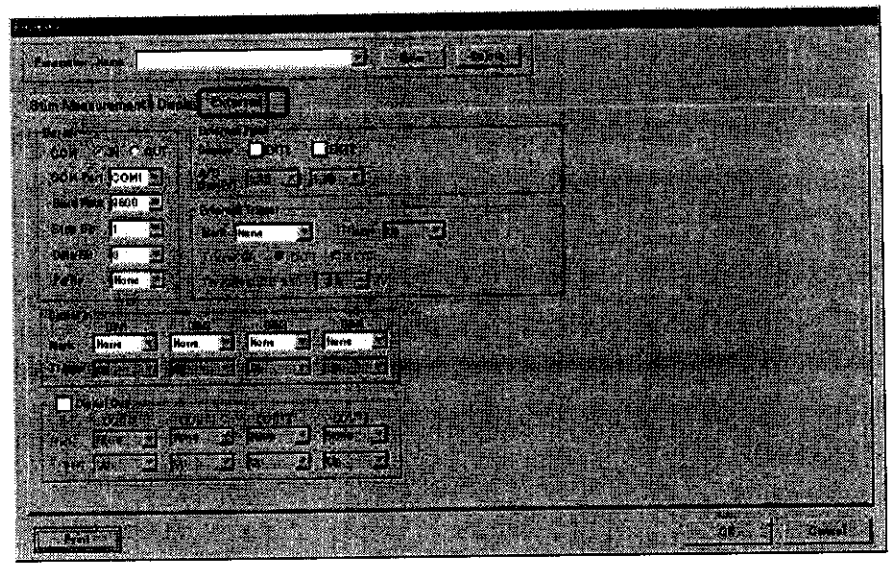

Fig. 4.38 Parameter Window (External)

(2) Select Serial settings as shown below.

COM IN : Select when inputting external signals for control.
COM OUT : Select when outputting signals from this system

} Every time clicking, display changes.

COM Port : COM1
Baud Rate : 9600
Stop Bit : 1
Data Bit : 8
Parity : None

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(3) Then click Stim measurement and change mark input method. For Event measurement, click the Event measurement tab.

Change Mark In (shown below) to "Serial".

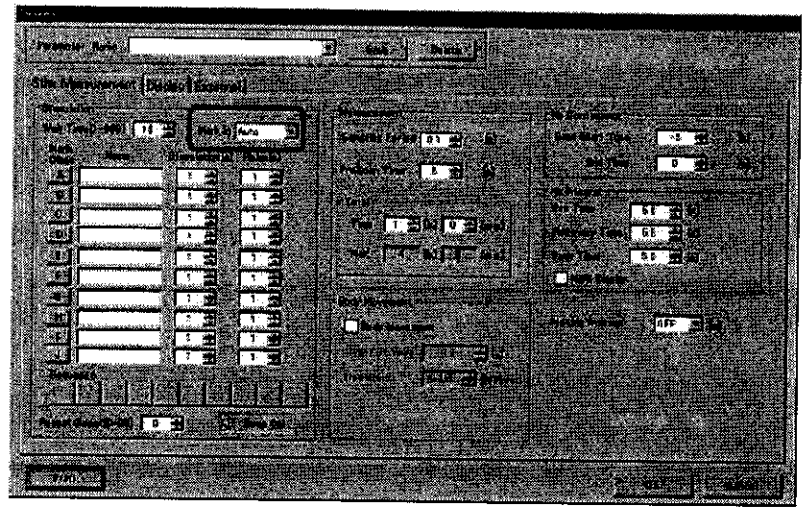

Fig. 4.39 Parameter Window (Stim Measurement)

4.7.3 Using serial communication (RS-232C)

RS-232C allows measurement commands to be transmitted and received via serial communication. Measurement command is 3-byte fixed length (command 2 bytes + CR code) allowing the following commands to be transmitted and received. Any command should be composed of capital letters. Transmission and reception of commands are performed using the serial line (COM port).

Measurement can be controlled by entering the following commands on the main screen of hyper terminal.

Table 4.1 Commands for Serial Communication

Command name	Command	Receiving by ETG-4000	Transmitting from ETG-4000
Start	ST	Starts measurement.	Informs start of measurement
Stop	ED	Stops measurement.	Informs stop of measurement
Stimulation Mark (Stim Measure)	One of characters "A"~"J" + Space	Inserts stimulation mark.	Informs insertion of stimulation mark
Stimulation Mark (Event Measure)	One of characters "A"~"J" + Space	Inserts and displays stimulation mark "A + Space" displays "F1" "B + Space" displays "F2" 〉 "J + Space" displays "F10"	Informs insertion of stimulation mark

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4.7.4 Setting parameters of External measurement

Set parameters before conducting measurement utilizing External signal.

(1) Click the [Parameter Set] button of main screen to display the Parameter Set window.

After displayed, click the External tab.

For details of setting, see [6.2.4 External parameters].

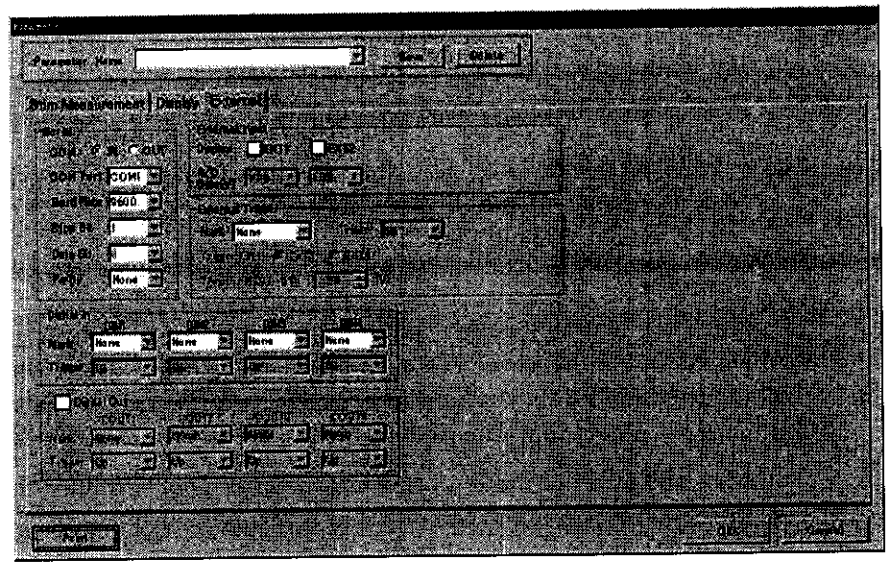

Fig. 4.40 Parameter Window

(2) Select External Input setting as shown below:

(a) Display

Select whether External Input signal flag is displayed or not.

If selected, EXT (external input signal flag) is displayed at the bottom of Hb Time Course window.

(b) A/D Gain

Select the display range [V] of external input signal flag from the following:

1.25, 2.5, 5.0

NOTE: Sampling rate of the external input signal depends on the setting of Sampling Period (6.2.2).

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(3) Select External Trigger setting as shown below:

(a) Mark

Select valid/invalid of Stimulation setting of external input signal.

- *None*

  Mark input by external input signal trigger is not valid.

- *J, M*

  Mark can be freely inputted following the trigger edge setting of external input signal of (4).

  For analog signal

  J is assigned for Stim measurement and M for Event measurement without fail.

  For digital signal

  A~J is assigned for Stim measurement and F1~F9 and M for Event measurement without fail.

- *Sequence*

  Mark can be freely inputted following the trigger edge setting of external input signal of (4); however, Stim measurement does not accept external signal inputted within the set time of StimTime + RelaxTime and Event measurement does not accept that inputted within the set time of RelaxTime.

  Also, the order of input at this time follows Sequence (order of mark input) of the Stim measurement tab or Event measurement tab.

(b) Trigger channel

Select either channel to be a trigger of stimulation mark input from the following:

EXT1, EXT2

(c) Threshold

Directly enter trigger threshold [V] of stimulation mark input or select a button. Input range should be 0.0~5.0 [V].

Increment/decrement of the up/down button is 0.1.

(d) Trigger

Select orientation of the edge of stimulation mark trigger. Items to be selected are as follows:

- Up Mark is inputted when the signal value exceeds the threshold upward at the continuous sampling points.
- Down Mark is inputted when the signal value exceeds the threshold downward at the continuous sampling points.

(4) Digital In

Set a response to digital signal input. For details, see [6.2.4 (4) Digital In].

(5) Digital Out

Set a digital output for setting operation. For details, see [6.2.4 (5) Digital Out].

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4.8 Example of Using Mark Input

4.8.1 When repeating one type stimulation (Stim measurement)

(For two types of stimulation input, see [4.8.3 Applying two types of stimulation alternately].)

NOTE: Stim measurement does not accept any external signal inputted within the set time of StimTime + RelaxTime, and Event measurement does not accept that of RelaxTime.

(1) Mark input by parameter setting

Select the "Stim Measurement" tab of Parameter Set window.

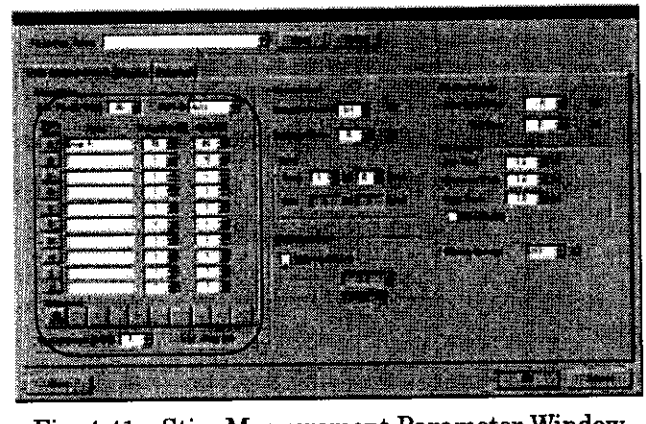

Fig. 4.41 Stim Measurement Parameter Window

① Select a method of mark input [Auto] from Mark In.

② Set Wait Time to 10 [s].

③ Click the [A] button of Mark Class to set it to "Sequence" shown below.

④ Enter "Stim_A" to Name as a name of stimulation class.

⑤ Set Stimulation (stimulation periodl) to 20 [s].

⑥ Set Relax time to 30 [s].

⑦ Set Repeat Count (repeating time of Sequence) to 3.

If completing entries above, marks are inputted three times in measurement.

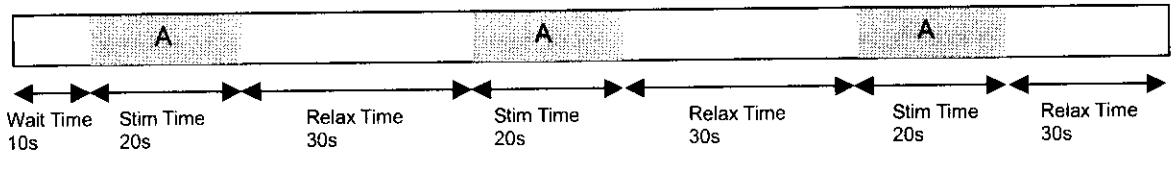

Fig. 4.42 Mark Input Timing

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(2) External input – mark input by serial communication

① Follow [4.7.2 Setting parameters Serial measurement] for setting.

- Select "Serial" for Mark In.
- Set the Serial communication as shown below:

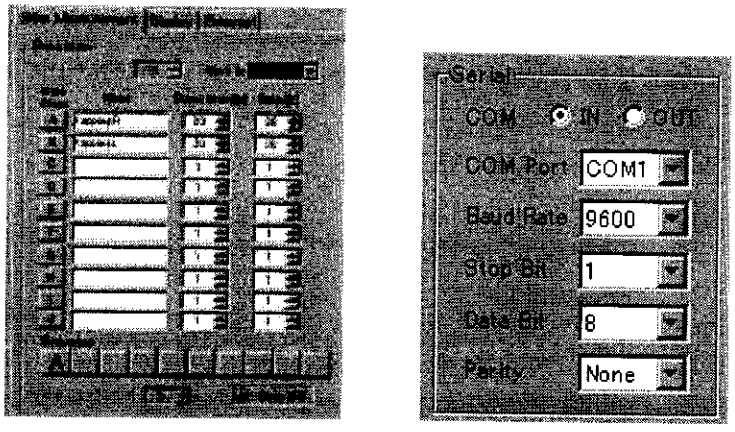

Fig. 4.43 Setting Serial Parameters

② Start the hyper terminal set in [4.7.1 Setting environment] from PC connected with ETG-4000.

③ Enter ["A" + Space + Return] on the main screen of hyper terminal.

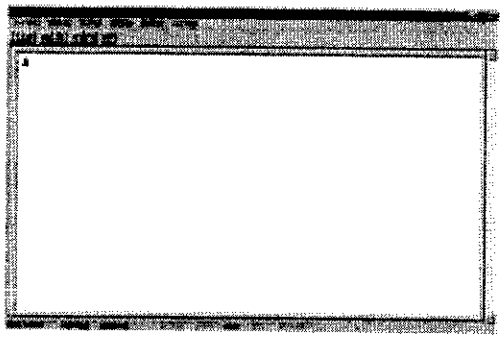

Fig. 4.44 Hyper Terminal Window

④ Enter ③ again to end Stimulation (Odd: Start of stimulation, Even: End of stimulation)

⑤ When marks are to be inputted further, repeat ③ and ④.

If completing entries above, marks are inputted three times in measurement.

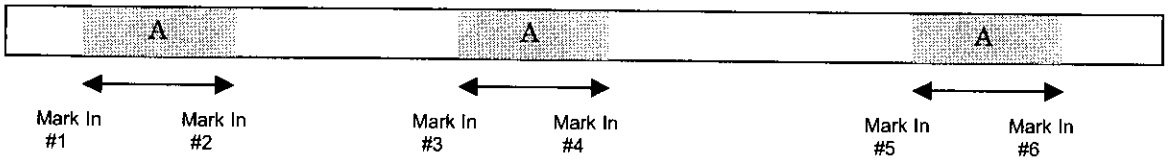

Fig. 4.45 Mark Input Timing

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(3) External input – mark input by External Input

① Follow [4.7.4 Setting parameters of External measurement].

- Select "External" for Mark In.
- Set "J" for Mark.
- Set "UP" for Trigger.
- Set "EXT1" for Trigger Ch.
- Set 2 [V] for Threshold.
- Set 5 [V] for A/D Gain.

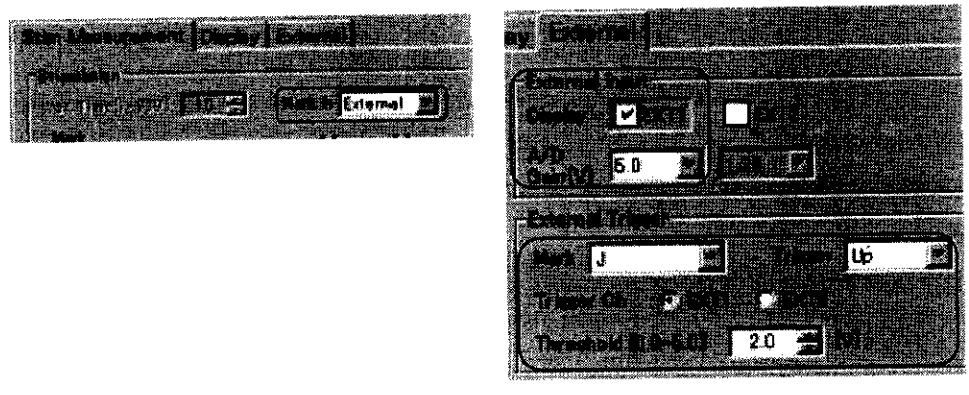

Fig. 4.46 Setting External Parameters

With setting above, if input voltage to EXT1 becomes over 2 [V], the mark "J" is inputted in measurement.
(Odd: Start of stimulation, Even: End of stimulation)

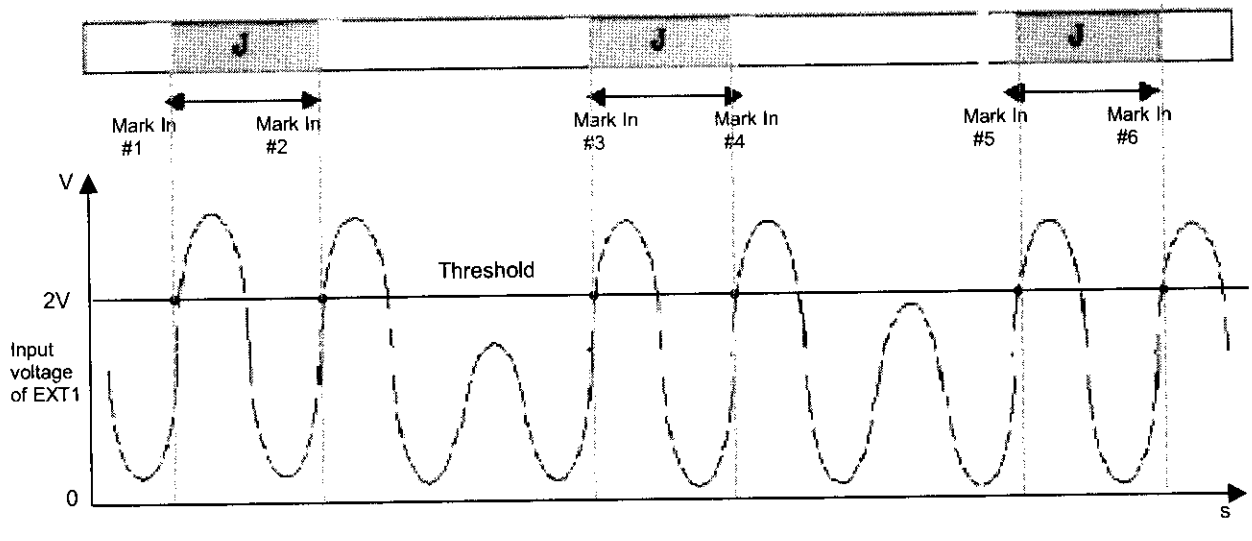

Fig. 4.47 Mark Input Timing

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(4) External input – mark input by Digital In

① Follow [4.7.4 Setting parameters of External measurement].

- Select "External" for Mark In.
- Set "A" for DIN1 of Digital In.
- Set "UP" for Trigger of DIN1 of Digital In.

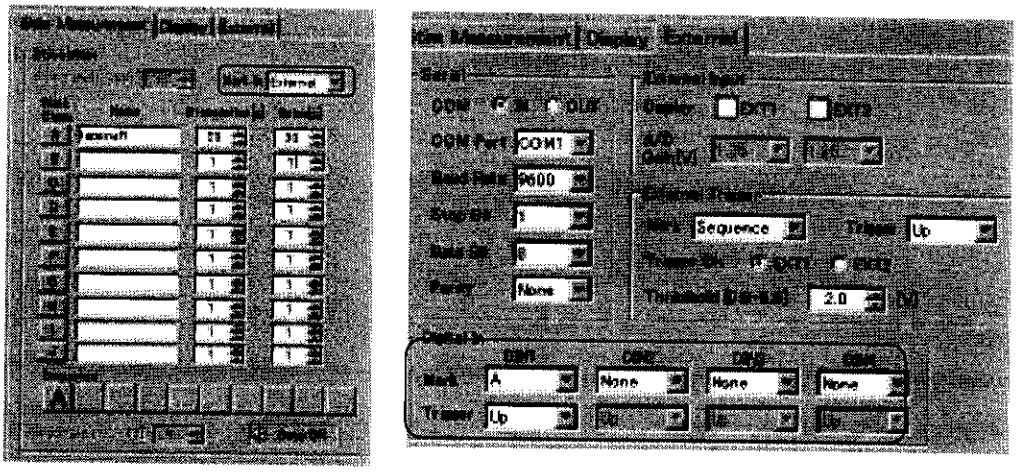

Fig. 4.48 Setting Digital In Parameters

If there is input voltage to DIN1 with setting above, a mark "A" is inputted in measurement.

(Off: Start of stimulation, Even: End of stimulation)

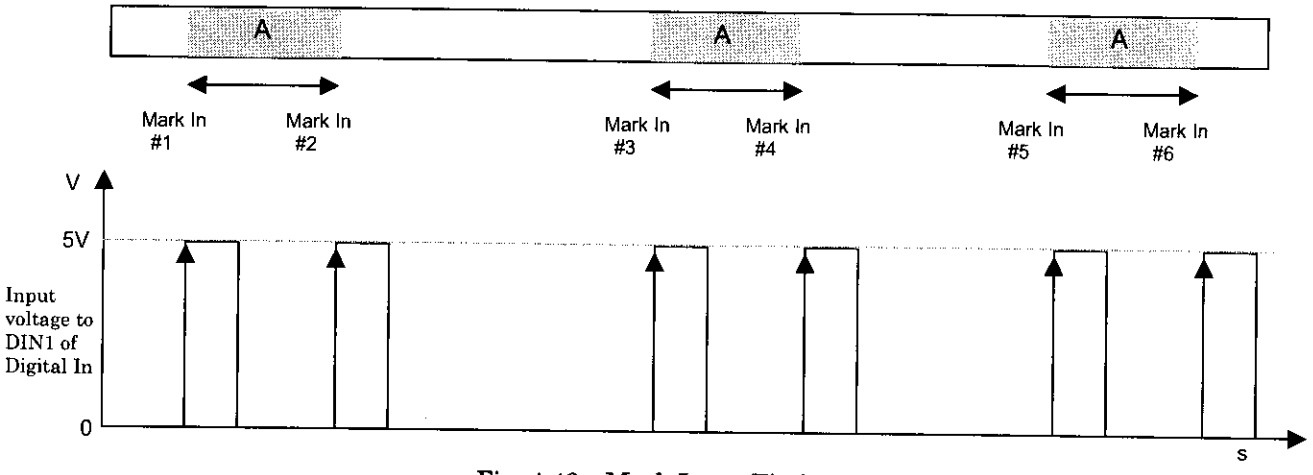

Fig. 4.49 Mark Input Timing

NOTE: 1) Input pulse width needs 100ms or more.

2) Interval from the end of mark to the input of next mark needs 100ms or more.

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4.8.2 When repeating one type stimulation (Event measurement)

(1) When marking from the system

Select "Event Measurement" tab of Parameter Set window.

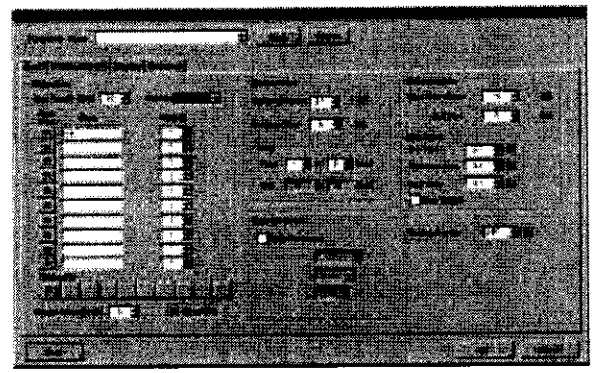

Fig. 4.50 Parameter Set Window

① Select "Auto" for Mark In.
② Set 10 [s] for Wait Time.
③ Click the
④ "A" button of Mark Class to set it to Sequence at the bottom.
⑤ Enter "Stim_A" into Name for the stimulation class.
⑥ Set 50 [s] for Relax time.
⑦ Set 3 for Repeat Count (sequence repeating time).

With setting above, F1 is entered three times in measurement.

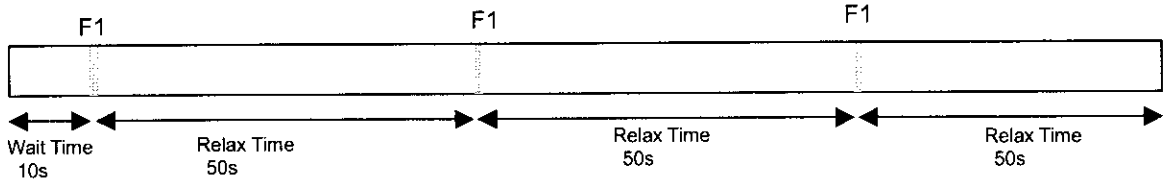

Fig. 4.51 Mark Input Timing

(2) External input: when marking via serial communication

① Follow [4.7.2 Setting parameters of Serial measurement].

- Select "Serial" for Mark In.
- Set Serial as shown below.

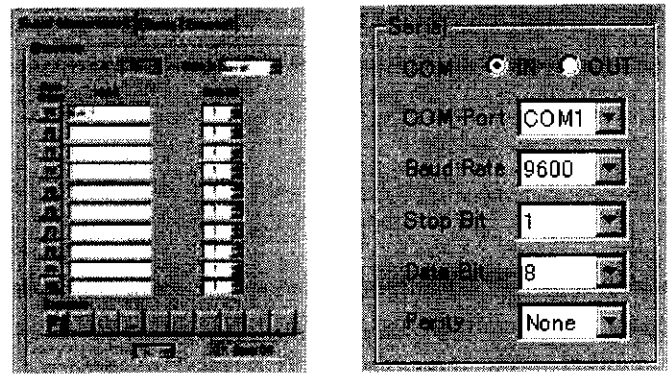

Fig. 4.52 Parameter Set Window

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② Start the hyper terminal set in [4.7.1 Setting environment] from PC connected with ETG-4000.

③ Enter "A" + Space + Return in the main screen of hyper terminal.

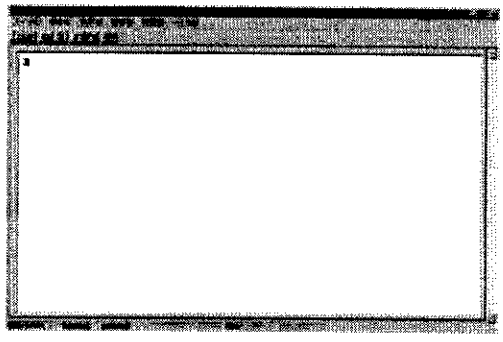

Fig. 4.53 Hyper Terminal Window

④ If marks are to be inputted further, repeat ③.

With setting above, the mark "A" is inputted in measurement.

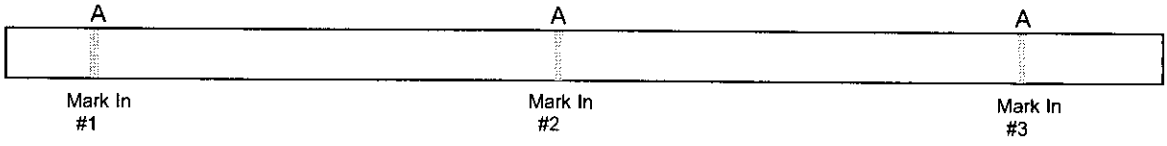

Fig. 4.54 Mark Input Timing

(3) External input: when marking with External Input

① Follow [4.7.4 Setting parameters of External measurement].

- Select "External" for Mark In.
- Set "M" for Mark.
- Set "UP" for Trigger.
- Set "EXT1" for Trigger Ch.
- Set 2 [V] for Threshold.
- Set 5 [V] for A/D Gain.

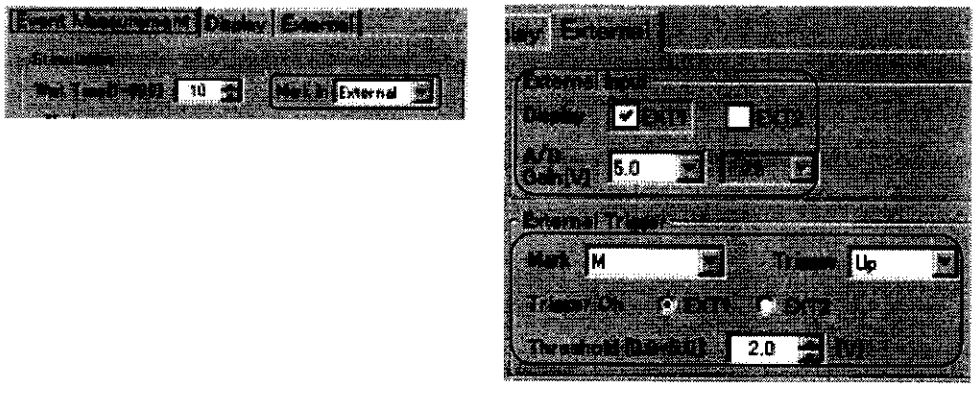

Fig. 4.55 Setting External Parameters

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If input voltage to EXT1 becomes 2 [V] or more with setting above, the mark "M" is inputted in measurement.

(Odd #: Start of stimulation, Even #: End of stimulation)

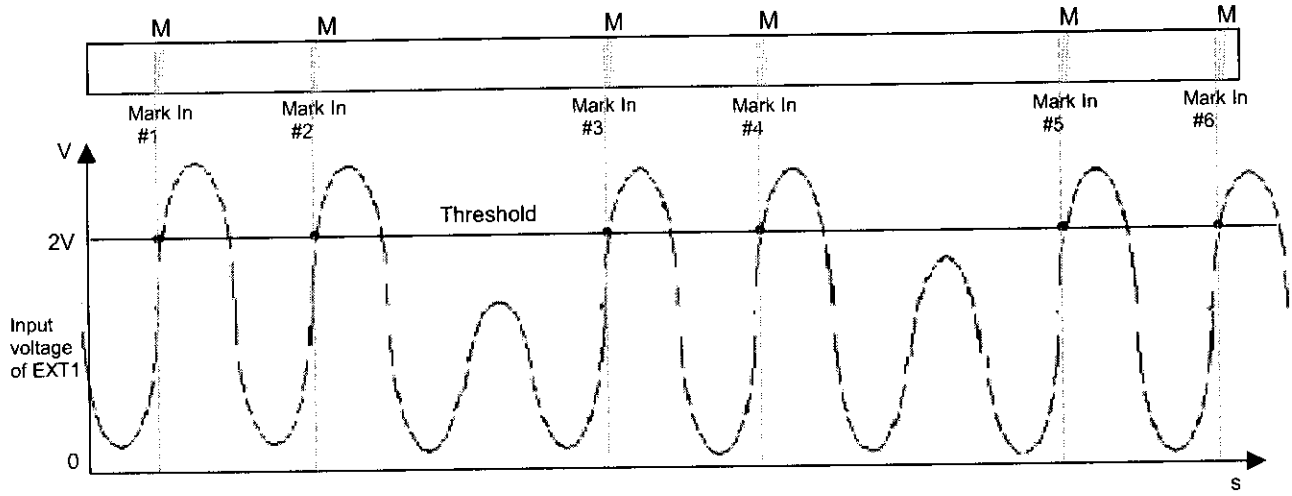

Fig. 4.56 Mark Input Timing

(4) External input: when marking with Digital In

① Follow [4.7.4 Setting parameters of External measurement].

- Select "External" for Mark In.
- Set "F1" for Digital In.
- Set "UP" for Trigger.

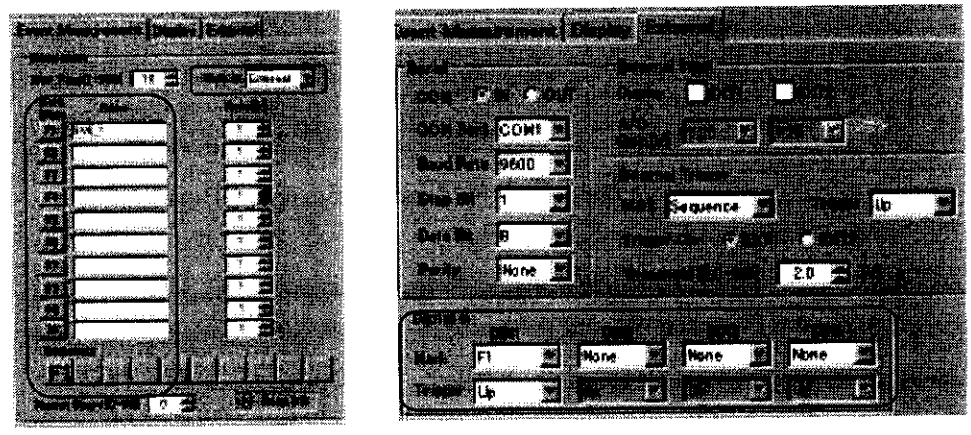

Fig. 4.57 Setting External Parameters

If there is input voltage to DIN1 with setting above, the mark "F1" is inputted in measurement.

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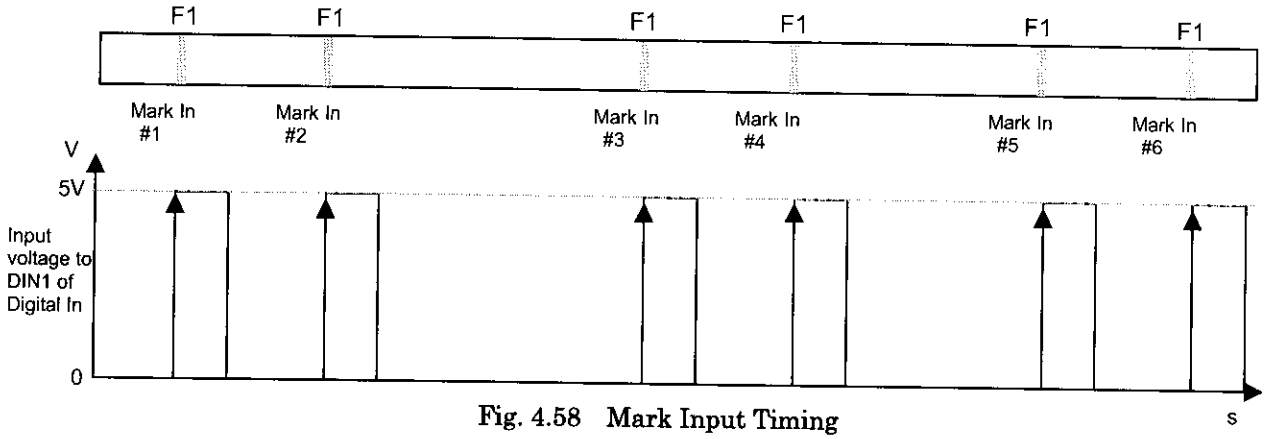

Fig. 4.58 Mark Input Timing

NOTE: 1) Input pulse width needs 100ms or more.

2) Interval from the end of mark to the input of next mark needs 100ms or more.

4.8.3 When repeating two types of stimulation alternately

(1) Mark input from the system

Select "Stim Measurement" tab of parameter setting window.

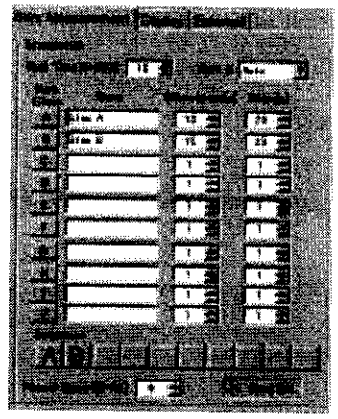

Fig. 4.59 Setting Stim Measurement Parameters

① Select "Auto" for Mark In.

② Set 10 [s] for Wait Time.

③ Click the "A" and "B" buttons of Mark Class and set "Sequence" at the bottom.

④ Enter "Stim_A" and "Stim_B" respectively to Name as stimulation class names.

⑤ Set Stimulation (interval of stimulation) to A = 10 [s] and B = 15 [s].

⑥ Set Relax time to A = 20 [s] and B = 30 [s].

⑦ Set Repeat Count (the number of times to repeat Sequence) to 2.

With setting above, "A" and "B" are inputted twice respectively in measurement.

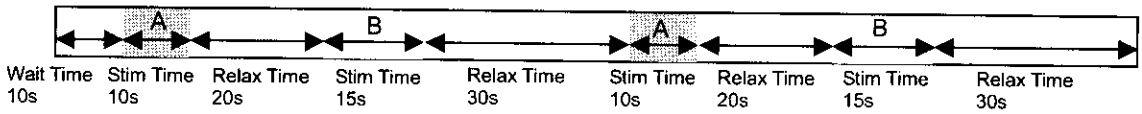

Fig. 4.60 Mark Input Timing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(2) External input: Mark input using serial communication only

① Follow [4.7.2 Setting parameters of Serial measurement].

- Select "Serial" for Mark In.
- Set Serial communication as shown below:

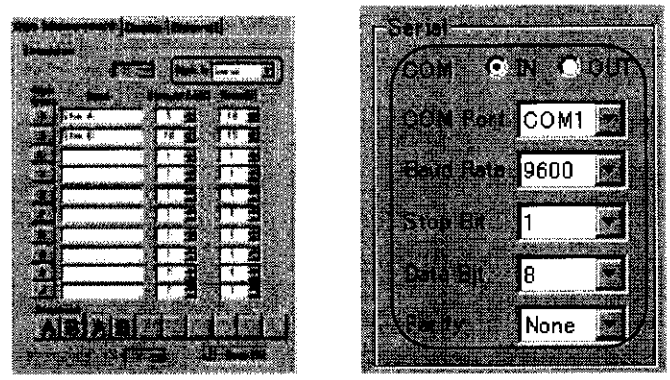

Fig. 4.61 Setting Serial Parameters

② Start the hyper terminal set in [4.7.1 Setting environment] from PC connected with ETG-4000.

③ In the main screen of hyper terminal, enter "A" + Space + Return, "A" + Space + Return, "B" + Space + Return, "B" + Space + Return, "A" + Space + Return, A" + Space + Return.

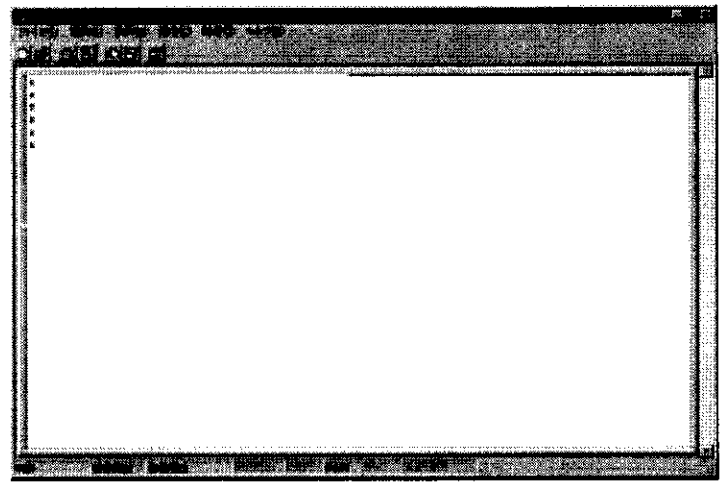

Fig. 4.62 Hyper Terminal Window

④ Repeat command entries if marks are to be inputted further.

With the above, marks "A", "B", "A" are inputted in measurement.

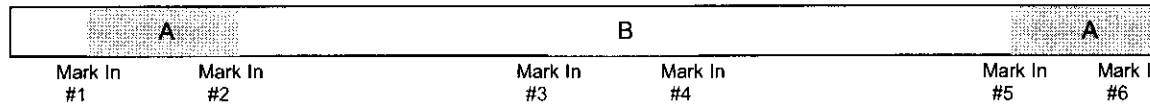

Fig. 4.63 Mark Input Timing

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(3) External input: Mark input using External Input only

① Follow [4.7.4 Setting parameters of External measurement].

- Select "External" for Mark In.
- Set "Sequence" for Mark.
- Set "UP" for Trigger.
- Set "EXT1" for Trigger Ch.
- Set 2 [V] for Threshold

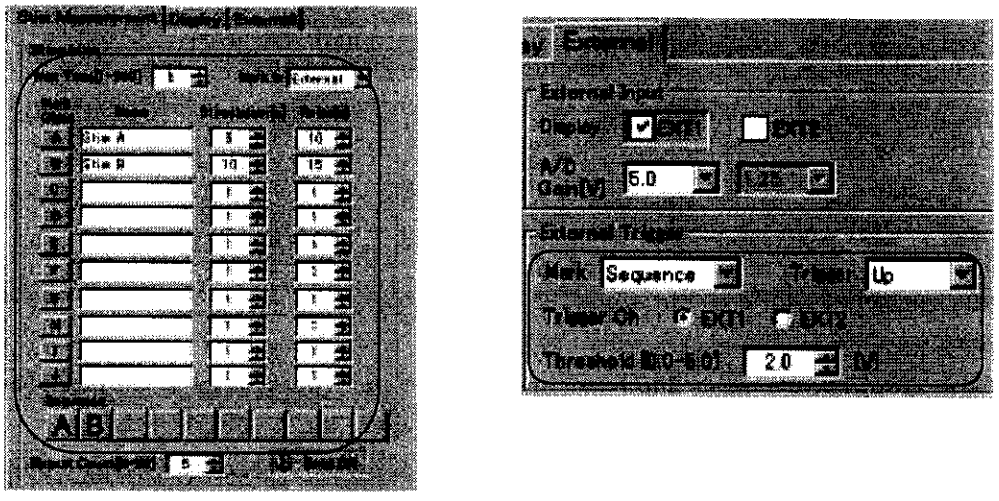

Fig. 4.64 Setting External Parameters

If input voltage to EXT1 exceeds 2 [V] with setting above, marks "A" and "B" are inputted in measurement.

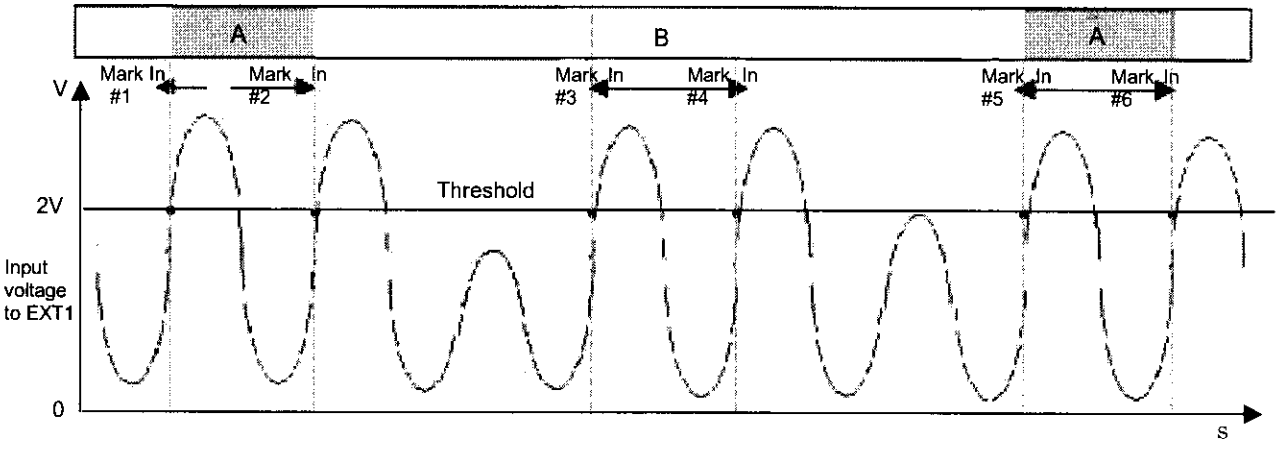

Fig. 4.65 Mark Input Timing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(4) External input: Mark input using Digital In only

① Follow [4.7.4 Setting parameters of External measurement].

- Select "External" of Mark In.
- Set "A" to DIN1 of Digital In.
- Set "B" to DIN2 of Digital In.
- Set "UP" to Trigger.

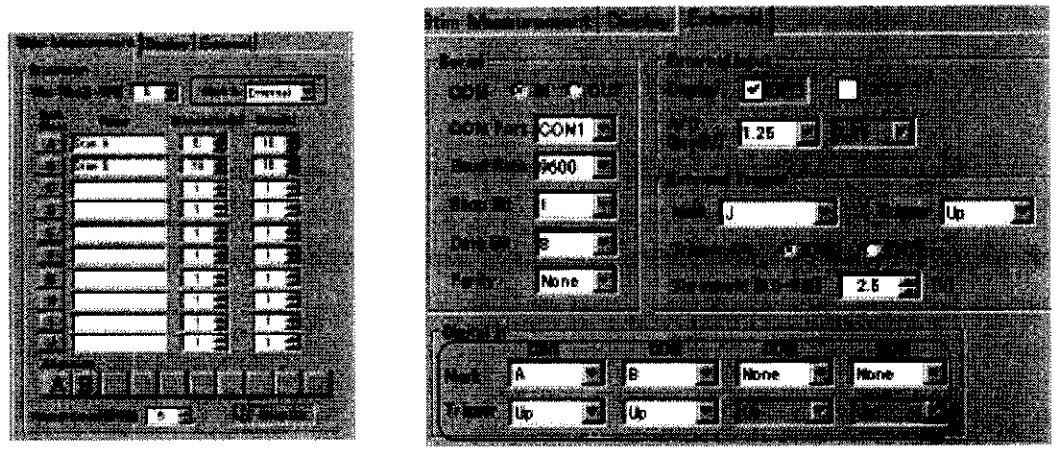

Fig. 4.66 Setting External Parameters

If input voltage appears on DIN1 with the setting above, mark "A" is inputted, while if appearing on DIN2, mark "B" is inputted.

NOTE: Both marks cannot be inputted at the same time.

(Odd: Start of stimulation, Even: End of stimulation)

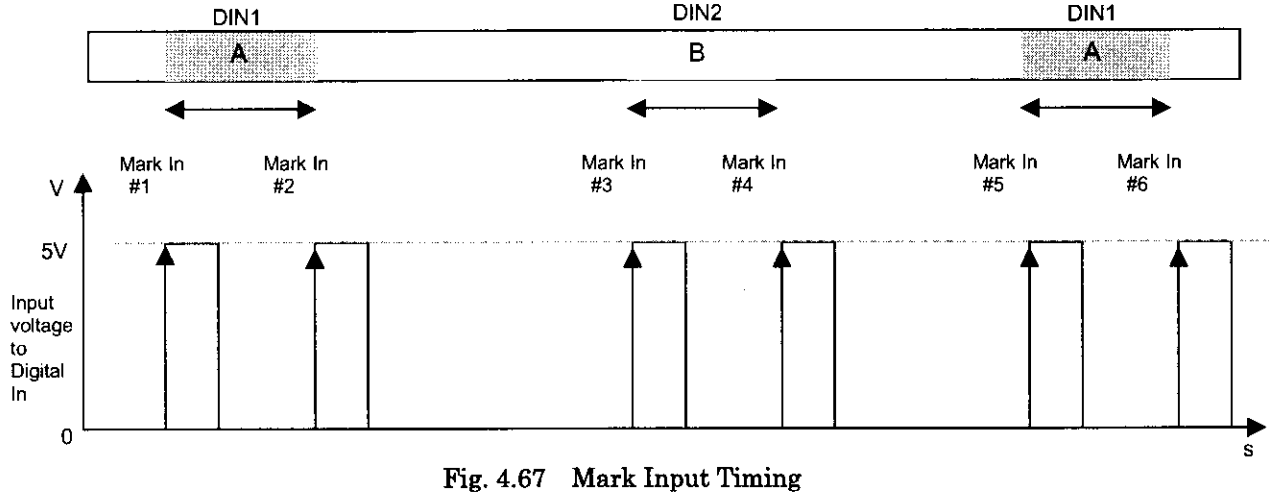

Fig. 4.67 Mark Input Timing

NOTE: 1) Input pulse width needs 100ms or more.

2) Interval from the end of mark to the input of next mark needs 100ms or more.

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4.9 External Output

4.9.1 Checking external output

Using the DIGITAL Out terminal of ETG-4000 allows signals to be outputted to an external PC and so on.

(1) Before enabling external digital output, set parameters.

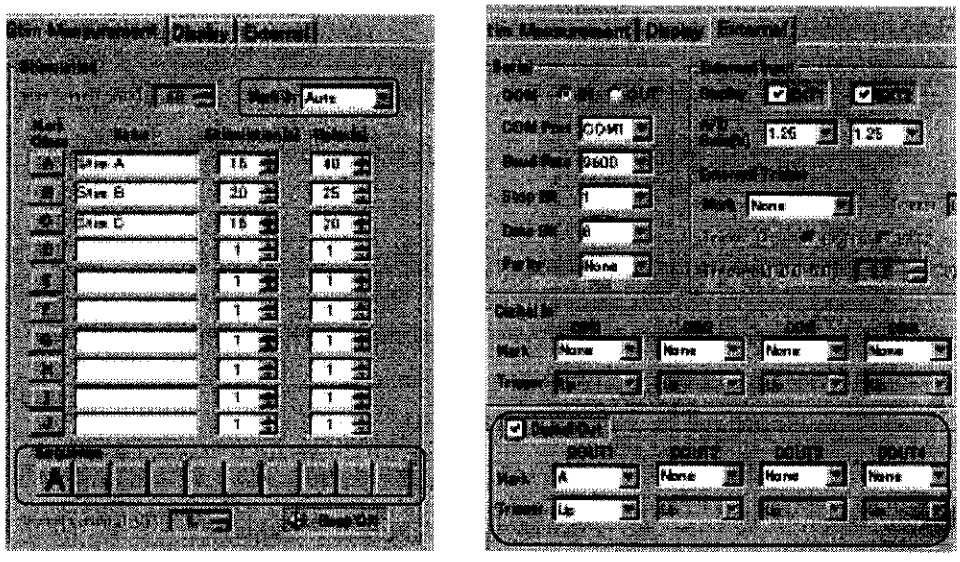

Fig. 4.68 Setting External Parameters

Clicking the [Parameter Set] button of the main screen displays the Parameter Set window.

Click the External tab.

For details of setting, see [6.2.4 External parameters].

(2) Select setting of External Out as shown below (when connecting with DOUT1).

- Set Mark to "A".
- Set Trigger to "Up".

As soon as inputting the mark A, a signal comes out to the external PC and so on.

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Section 5 Analysis Procedure

This section describes analysis procedure.

5.1 Preparation to Analysis

5.1.1 Preparation of measurement data

Click the [Operation] button on the main screen and select [File Manager].

Measurement data to be analyzed can be loaded from the file here.

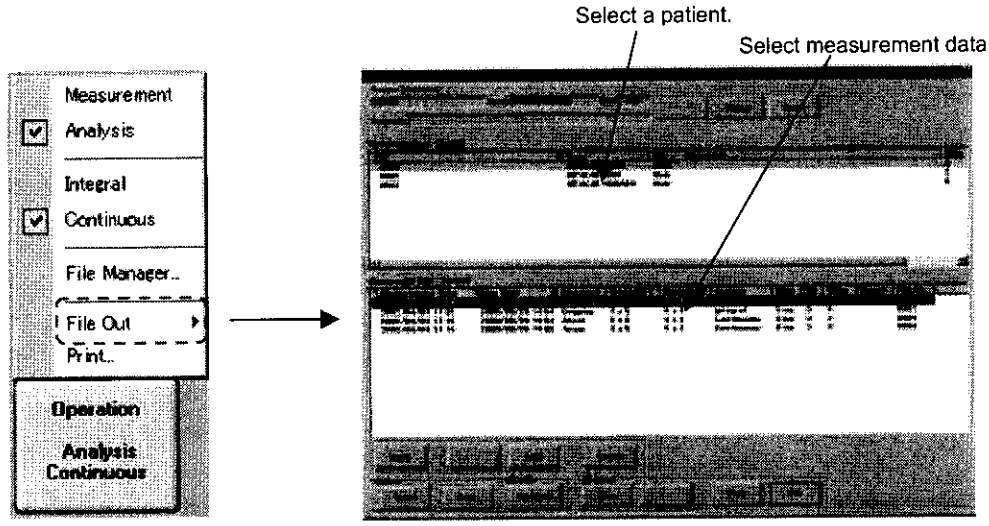

Fig. 5.1 File Manager Window

(1) Select any Patient ID from the [Patient Selection] list.

(2) Select measurement data from the [Measurement Data] list.

(3) Double click on the measurement data list or click the [Load] button to load the measurement data and analyze automatically.

(Layout of the main screen is recalculated and displayed in the state of data frame when saved.)

For details of [File Manager], see [6.4 File Related Operation].

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5.1.2 Selecting window display

Set display parameters of analysis data to be displayed on the main screen.

(1) [DISPLAY] button

(a) Select any Hb type to be displayed (Select more than one).

(b) Select various data to be displayed (Select more than one).

(For details of the display window, see [6.1.4 Display related operation area].)

(c) Select various data to be displayed individually.

(For details of the window, see [6.5 Description on Window Display].)

While executing analysis, the window can be moved and changed in its size.

Also, Realtime Integral display options are not displayed.

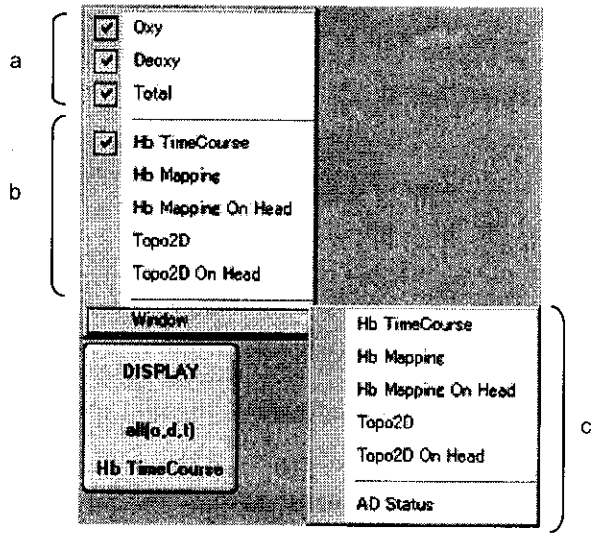

Fig. 5.2 DISPLAY Button

Even if changing settings such as parameters on the main screen and switching over the display window, recalculation is not carried out. Press the [Reanalyze] button to carry out recalculation and redisplay.

(When changing settings by Parameter Set, the Reanalyze button needs not to be pressed.)

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5.2 Hemoglobin Continuous Analysis

5.2.1 Setting analysis parameters

(1) Set the base start time and base end time of Continuous analysis.

* These parameters can be set at the left center of main screen.
* During replay, operation is disabled. Operation is available only before replay and when suspended by the [PAUSE] button.

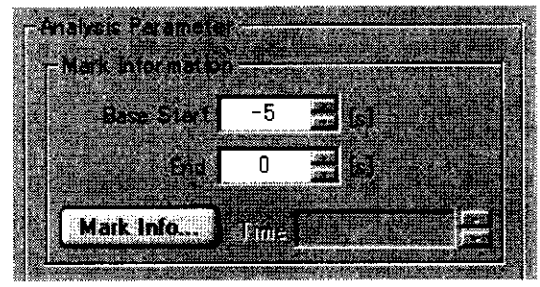

Fig. 5.3 Setting Mark Information

(2) Clicking the [Mark Info] button displays the Mark Information window.

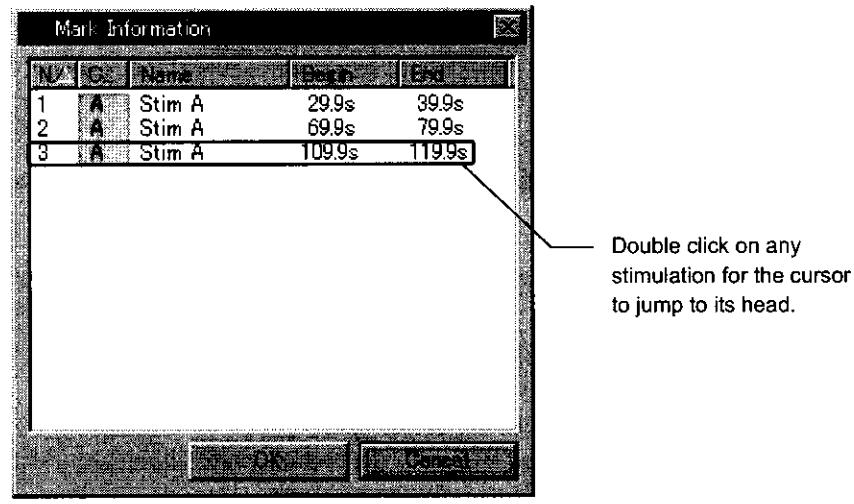

Fig. 5.4 Mark Information Window

(3) Filter can be set.

Only necessary frequency components can be extracted and displayed with data passed through the filter.

* Filter can be set at the lower left of the main screen.
* During analysis, operation is disabled. Operation is available only before executing analysis and when suspended by the [PAUSE] button.

Fig. 5.5 Setting Filter

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(4) Set time to get Moving Average

Select ant setting from OFF, 0.5, 1, 6, 10, 30 and 60 [s].

Fig. 5.6 Setting Moving Average

Data is averaged by the moving average method.

This process obtains an average from data at each time in the analysis range and in the vicinity of it (for the time designated) and replaces data at each time with it.

This allows data to be displayed with noise suppressed.

In case of the Hb Time Course window or Topography window during Event measurement, averaging operation is applied to data at each time and that before it.

Effect of moving average is visible when {Moving Average}≧{Sampling Period}×2.

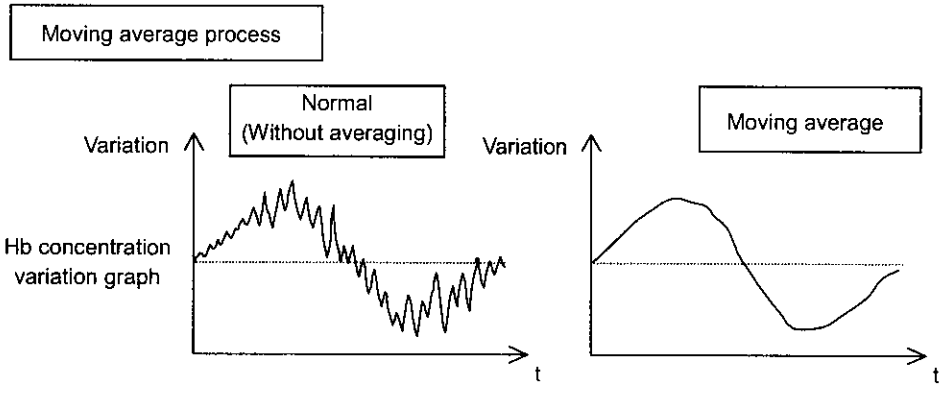

Fig. 5.7 Overview of Moving Average Process

* It can be set by Parameter Set.

* During analysis, operation is disabled. Operation is available only before executing analysis and when suspended by the [PAUSE] button

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(5) When setup on the main screen is completed, click the [Reanalyze] button to update analysis settings.

Fig. 5.8 [ReAnalyze] Button

(6) Setup same as that of the main screen and further detailed setup can be carried out on the Parameter Set window.

(Fore detailed description, see [6.2.1 Stim measurement parameters].)

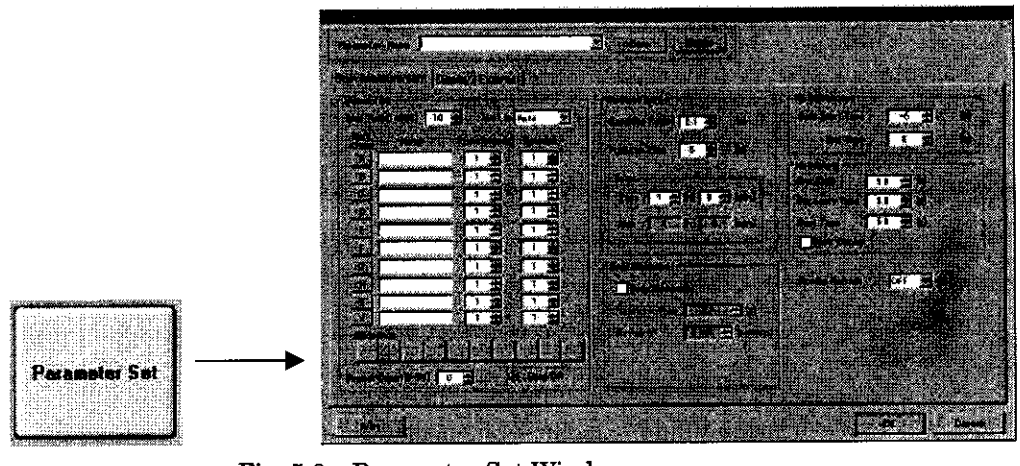

Fig. 5.9 Parameter Set Window

- Clicking the [OK] button updates Continuous analysis automatically.

  The [ReAnalyze] button needs not to be clicked after operation of the Parameter Set window.

Settings only available on the Parameter Set window
• Mark input method • Sampling Period • PreScan Time • Total Time • Body Movement (For details, see [6.2 Description on Parameter Set Window].)

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5.2.2 Executing Continuous analysis

(2) Clicking the [START] button replays the result of Continuous analysis in the cine mode on the main screen.

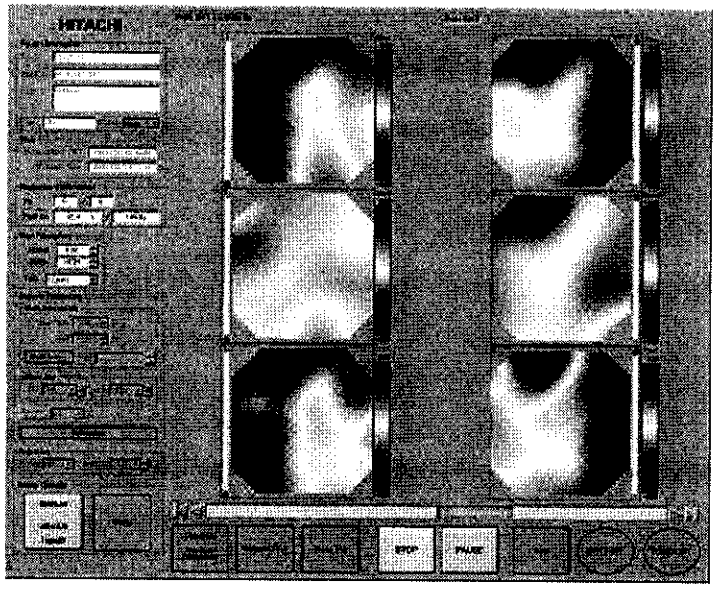

Fig. 5.10 Replay Screen

(1) Clicking the [Pause] button suspends and resumes analysis.

Every time clicking the button, PAUSE and UnPAUSE are replaced alternately

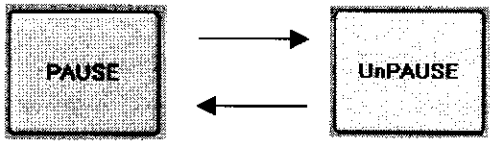

Fig. 5.11 [PAUSE] Button

(2) Clicking the [STOP] button stops analysis.

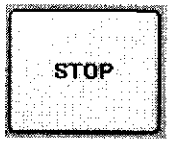

Fig. 5.12 [STOP] Button

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(3) Setting display parameters

(a) Select Time Scale and Range to display results (at the left center of main screen)

HbMax, HbMin: Set the vertical range of Hb graph.

Time: Select the horizontal range of Hb graph.

(For details, [6.1.1 Information display area].)

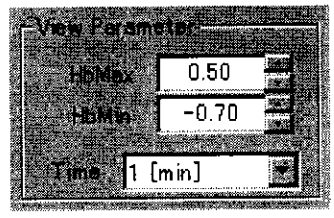
(b) Select Display Speed and Interval (at the lower left of main screen)

Speed: Set display speed.

Interval: Set interval to thin.

(For details, see [6.1.1 Information display area].)

* [View Parameter] can be operated, but [Animation] cannot be operated during execution of analysis. It is operable only before execution of analysis and while suspended by the [PAUSE] button.



(a)

(b)

Fig. 5.13 Setting Graph Display

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5.3 Hemoglobin Integral Analysis

5.3.1 Setting analysis parameters

(1) Set the rest time before stimulation (Pre time), stimulation time (Stimulation time), recovery time after stimulation (Recovery time) and rest time after stimulation (Post time).

* These parameters can be set at the left center of main screen.

* Operation is not available during replay. It is available only before replay and while suspended by the [PAUSE] button.

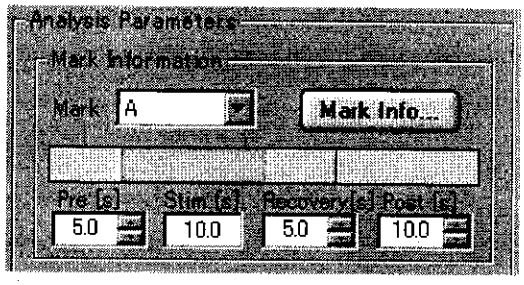

Fig. 5.14 Setting Mark Information

(2) Clicking the [Mark Info] button displays the Mark Information window.

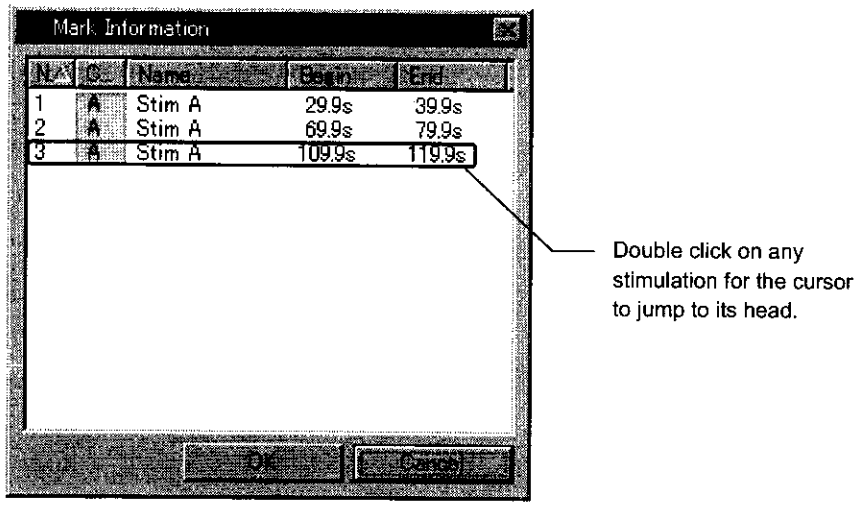

Fig. 5.15 Mark Information Window

(3) Filter can be set. (For details, see [5.2.1 (3)].)

(4) Set Moving Average ([s]).

(For details of moving average, see [5.2.1 (4)].)

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(5) Upon completing setup on the main screen, click the [ReAnalyze] button to update analysis setup.

* If this operation is omitted, analysis setup changed is not reflected.

(6) Setup same as that of the main screen and further detailed setup can be carried out on the Parameter Set window.

(For details, see [6.2.1 Stim measurement parameters].)

Clicking the [Parameter Set] button on the main screen displays the Parameter Set window.

Then select the Stim Measurement or Event Measurement tab to set analysis parameters.

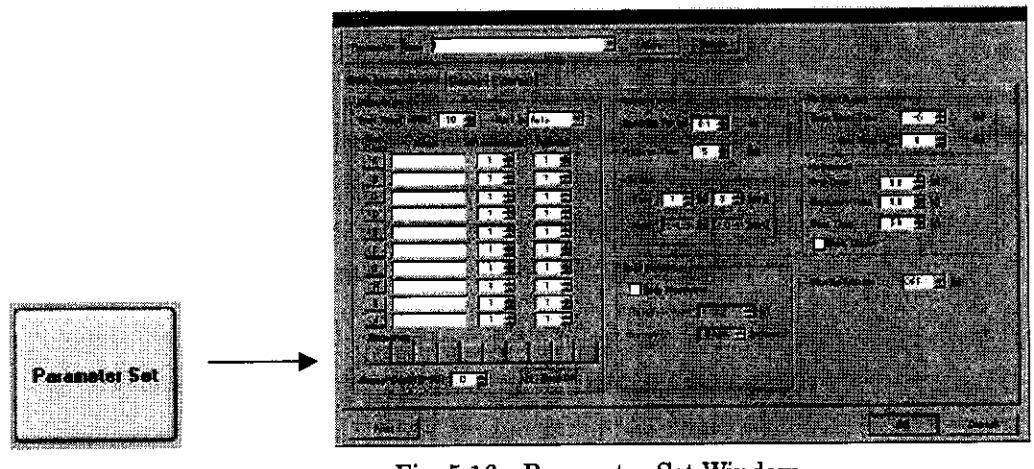

Fig. 5.16 Parameter Set Window

- Clicking the [OK] button carries out Integral analysis automatically.
  The [ReAnalyze] button needs not to be clicked.

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5.3.2 Executing Integral analysis

(4) Click the [START] button to replay the result of Integral analysis in the cine mode on the main screen.

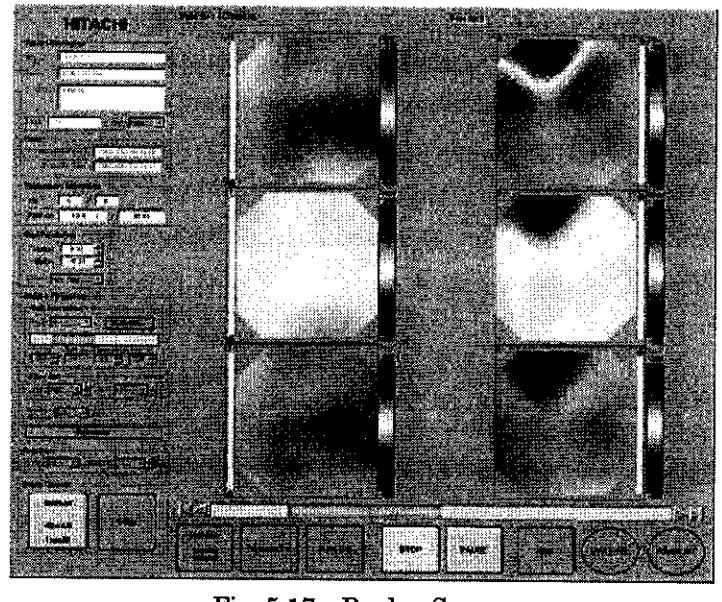

Fig. 5.17 Replay Screen

(2) Clicking the [Pause] button suspends and resumes analysis.

Every time clicking the button, PAUSE and UnPAUSE are replaced alternately.

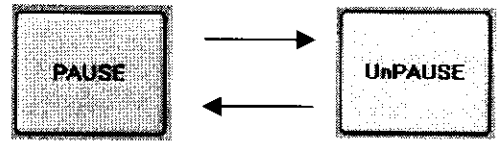

Fig. 5.18 [PAUSE] Button

(3) Clicking the [STOP] button stops analysis.

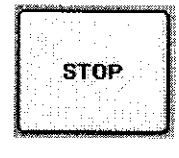

Fig. 5.19 [STOP] Button

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(4) Display setup

(a) Select Time Scale and Range to display results (at the left center of main screen)

HbMax, HbMin: Set the vertical range of Hb graph.

Time: Select the horizontal range of Hb graph.

(For details, [6.1.1 Information display area].

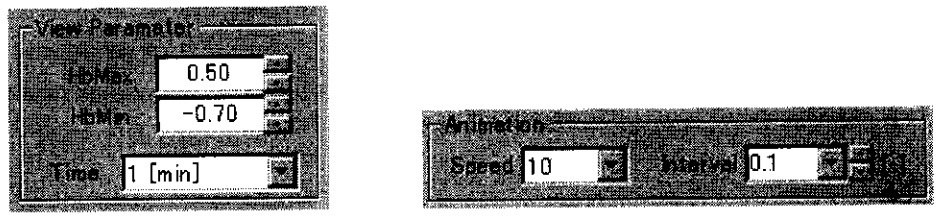
(b) Select Display Speed and Interval (at the lower left of main screen)

Speed: Set display speed.

Interval: Set interval to thin.

(For details, see [6.1.1 Information display area].)

* [View parameter] can be operated, but [Animation] cannot be operated during execution of analysis. It is operable only before execution of analysis and while suspended by the [PAUSE] button.



(a) (b)

Fig. 5.20 Setting Graph Display

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5.4 Mark Edit Analysis

For analysis, stimulation marking can be freely edited (moved, inserted and deleted).

In the following cases, edit marking.

(a) When marking has been set by mistake.

(b) When data of any section needs to be deleted from Integral analysis since body movement or any other noise occurred.

(c) When unnecessary last mark needs to be deleted, since measurement has been terminated in the halfway.

5.4.1 Table of mouse right button click menu

The mouse button right click menu when editing marking are shown in the table below.

- Position to click on with the mouse right button and menu

Table 5.1 Mouse Right Button Click Menu

Frame	Menu in graph	Remarks
Hb Time Course	Mark Edit Mode Data Cut Mode Time Adjust Mode	In the measurement mode and Integral analysis, "Mark Edit Mode", "Data Cut Mode" and "Time Adjust Mode" are made invalid.
Hb Mapping	—	—
Hb Mapping On Head	—	—
Topo 2D	—	—
Topo 2D On Head	—	—
AD Status	—	—

When no measurement data exits, "Mark Edit Mode", "Data Cut Mode" and "Time Adjust Mode" are invalid.

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5.4.2 Editing marks

(1) Starting edit mode

In Continuous analysis, place the pointer on the graph in Hb Time Course screen and right click to display the menu. Select Mark Edit Mode. "Mark Edit Mode" is displayed at the left center of window (In Integral analysis, mark edit is unavailable).

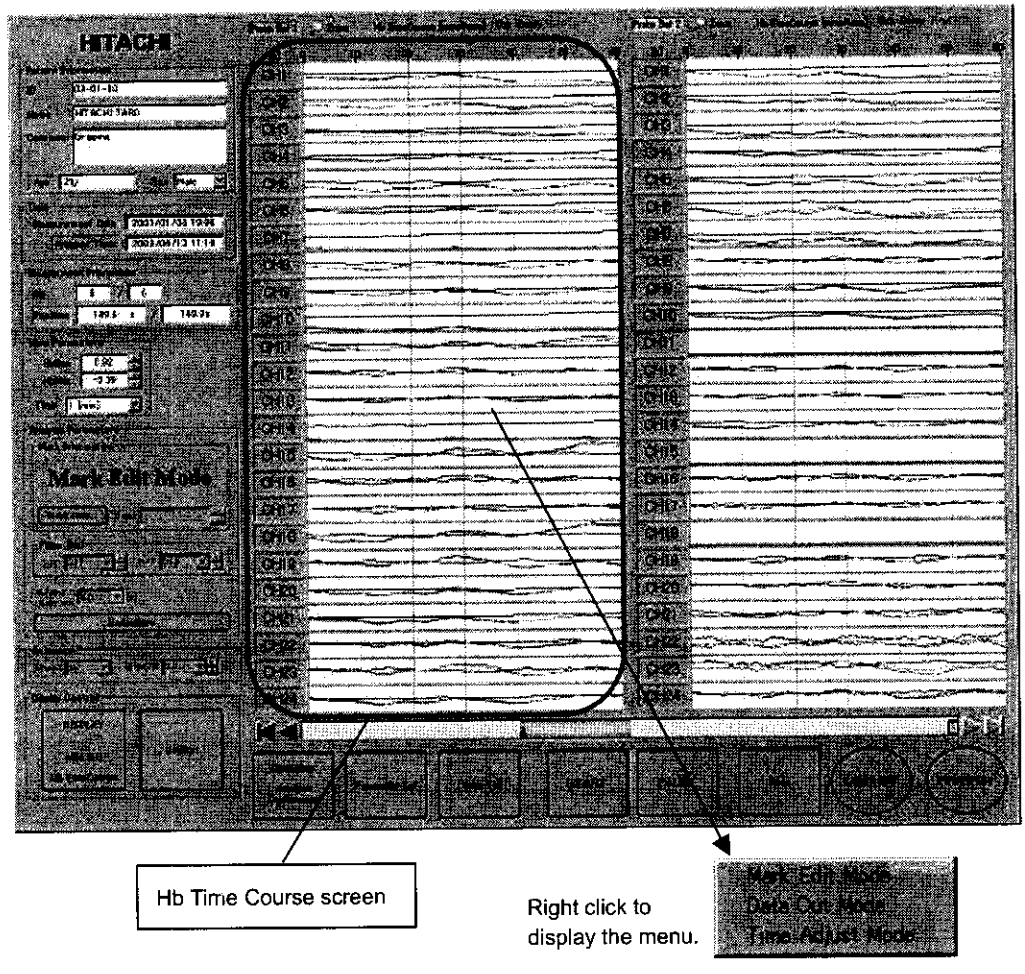

Fig. 5.21 Mark Edit Mode

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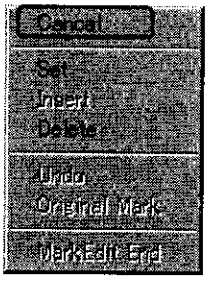
(2) Marking

Marking operation in the Mark Edit Mode is shown below.

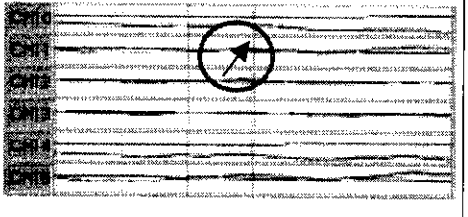
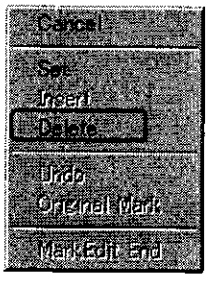
(a) Selecting a mark to be edited

Step	Entry operation	Screen display	Remarks
1	Use the pointer to select a mark and left click on it.	Color of the mark selected turns to red.	

(b) Deselecting a mark

Step	Entry operation	Screen display	Remarks
1	From the right click menu, select Cancel.		This is valid when the mark is being selected.

(c) Deleting a mark

Step	Entry operation	Screen display	Remarks
1	Use the pointer to select the mark to be deleted, and then left click on it.	Color of the mark selected turns to red. 	
2	Select Delete from the right click menu.		

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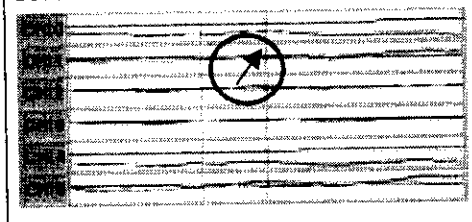
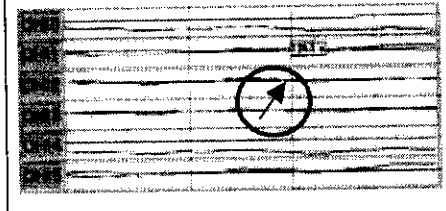
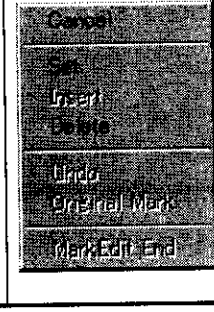
(d) Moving a mark

Step	Entry operation	Screen display	Remarks
1	Use the pointer to select a mark to be moved.	Color of the mark selected turns to red. 	
2	Determine the position to which the mark is to be moved and left click on it.	A red mark appears at the position to which the mark is to be moved. 	Time is displayed.
3	Select Set from the right click menu.		

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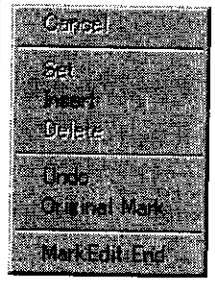
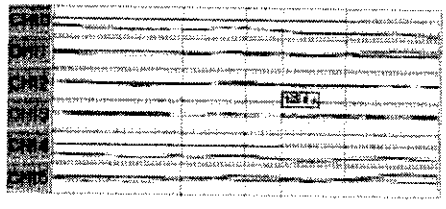
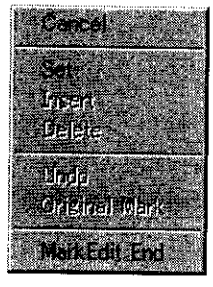
(e) Inserting a mark

Step	Entry operation	Screen display	Remarks
1	Select Insert from the right click menu.		
2	Determine the position to which the mark is to be inserted.	An insert mark is displayed in red. 	Two marks are inserted automatically. Move the marks for adjustment.
3	Select Set from the right click menu.		

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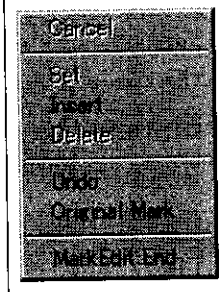
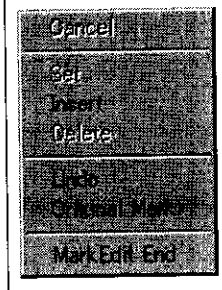
(f) Canceling edit operation

Cancels edit operation and returns to the previous state.

Step	Entry operation	Screen display	Remarks
1	Select Undo from the right click menu.		Returns to the previous edit operation.

(g) Initializing the state of mark

Restores the state of marking in measurement.

Step	Entry operation	Screen display	Remarks
1	Select Original Mark from the right click menu.		

(3) Ending Mark Edit Mode

To end the Mark Edit Mode, Select Mark Edit End from the right click menu.

Upon ending the Mark Edit Mode, analysis is carried out according to the stimulation marks edited.

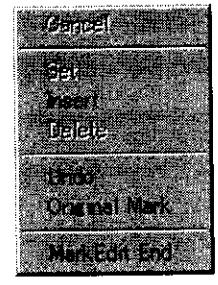


Fig. 5.22 Edit Mode End Menu

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5.4.3 Executing analysis with edited marks

(1) Click the [START] button to replay analysis results on the main screen depending on stimulation marks edited.

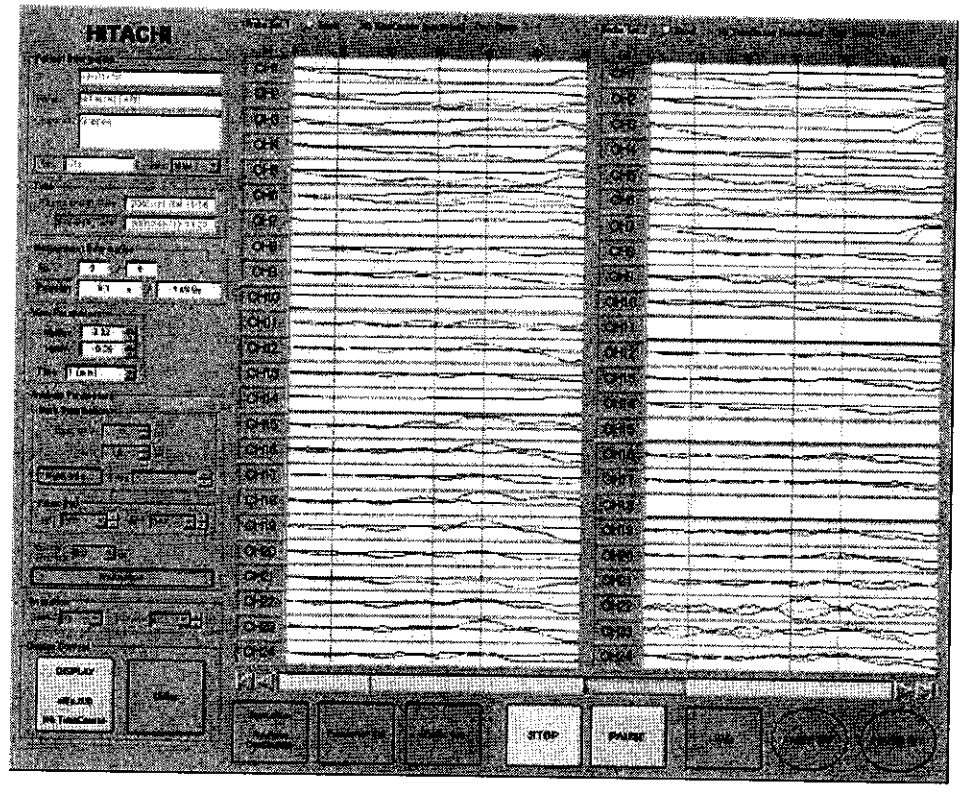

Fig. 5.23 Replay Screen

(2) Clicking the [PAUSE] button suspends and resumes replay in the cine mode.

Every time clicking the button, PAUSE and UnPAUSE is replaced alternatively.

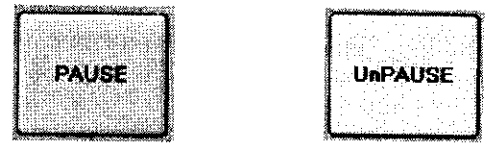

Fig. 5.24 [PAUSE] Button

(3) Clicking the [STOP] button ends replay of analysis.

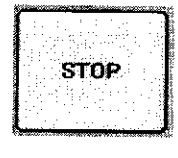

Fig. 5.25 [STOP] Button

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5.4.4 Real time display function

(1) Operation of real time display

In Continuous analysis, left clicking on the graph in the Hb Time Course screen, Hb Mapping screen and Hb Mapping On Head screen allows for real time display and moving the time bar.

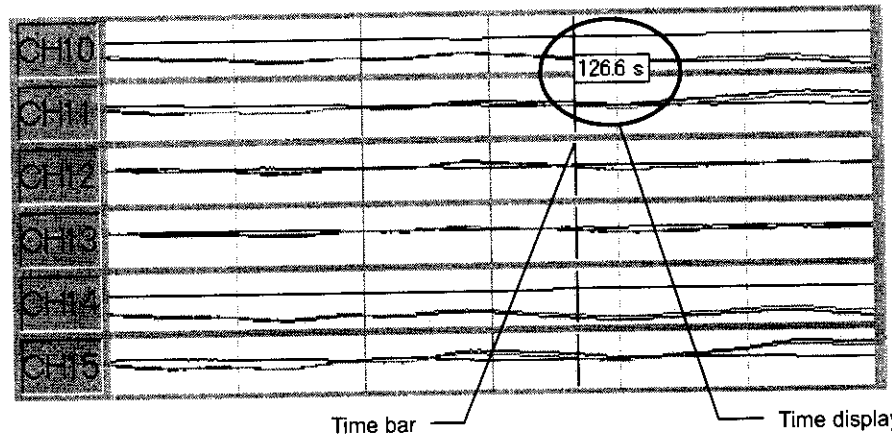

Fig. 5.26 Realtime Display

(2) Changing time display

Time display can be changed by clicking the [DISPLAY] button of Measurement Information at the left of screen.

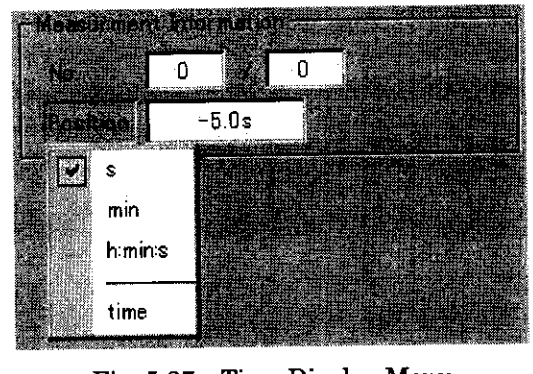

Fig. 5.27 Time Display Menu

* In Integral analysis, real time display from the Integral analysis start position is not available. Only relative time display is available with start of the Pretime period as zero.

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5.4.5 Real time display adjust function

Real time to be displayed can be adjusted.

(1) Starting Adjust mode

In the Continuous analysis, right clicking on the Hb Time Course screen displays a menu to select "Time Adjust Mode".

At the left center of window, "Time Adjust Mode" is displayed.

(In the Integral analysis, real time cannot be adjusted.)

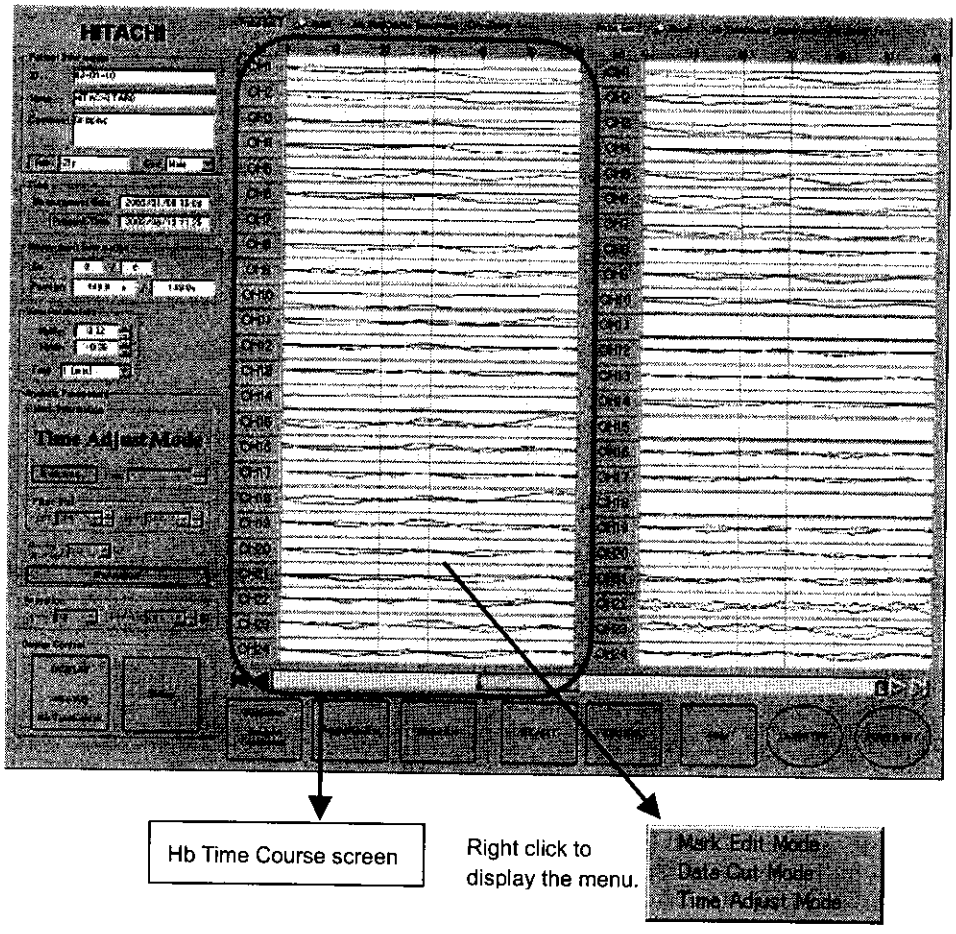

Fig. 5.28 Mark Edit Mode

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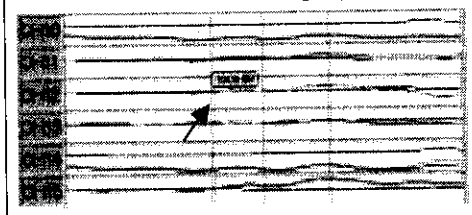
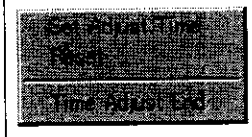
(2) Time adjust operation

The following shows operation in the Time Adjust Mode.

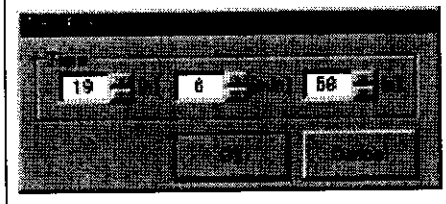
(a) Selecting a position to be edited

Step	Entry operation	Screen display	Remarks
1	Use the pointer to left click on the graph to be changed.	The mark selected is displayed in red. 	

(b) Selecting Set Adjust Time

Step	Entry operation	Screen display	Remarks
1	Select Set Adjust Time from the right click menu.		Valid when the mark is selected.

(b) Entering time

Step	Entry operation	Screen display	Remarks
1	Enter any time to be changed and click the [OK] button.		

(c) Initializing input time

Step	Entry operation	Screen display	Remarks
1	Select Reset from the right click menu. When prompted, click the [OK] button		Initialized with the time changed.

(3) Ending Adjust operation

Select Time Adjust End from the right click menu to end operation.

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5.4.6 Data cut function

Any time zone of Hb data can be cut out.

(1) Starting the Edit mode

In the Continuous analysis, right clicking on the graph in the Hb Time Course screen or Hb Graph screen displays a menu for selecting the Data Cut Mode. The "Data Cut Mod" is displayed at the left center of window.

(In the Integral analysis, no data cut is allowed.)

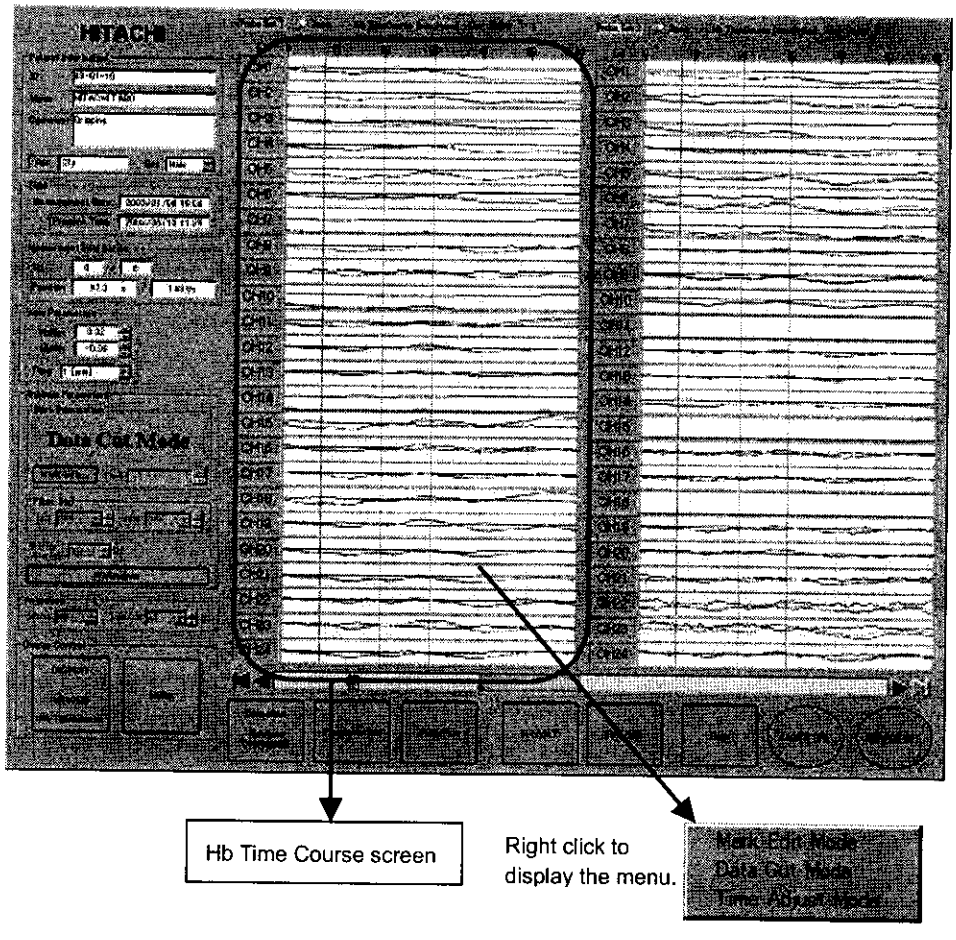

Fig. 5.29 Data Cut Mode

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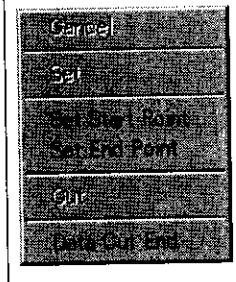
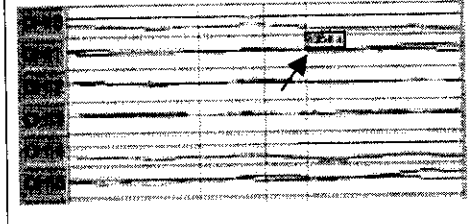
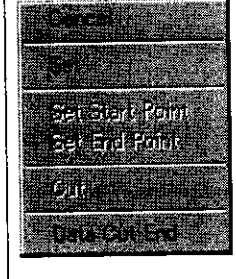
(2) Cut out operation

Edit operation in Data Cut Mode is shown below:

(a) Selecting start position

Step	Entry operation	Screen display	Remarks
1	Right click on the graph and select Set Start Point.		
2	Use the pointer to select the cut start point and left click it. This is operable any number of times.	The mark selected is displayed in red dotted line. 	
3	Right click on the graph and select Set.		Determining the cut start position.

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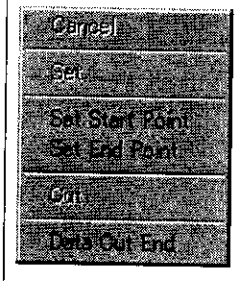
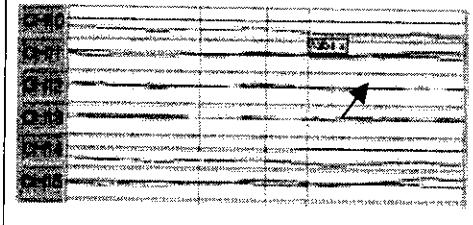
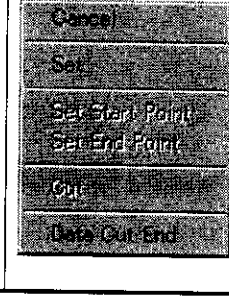
(b) Selecting end position

Step	Entry operation	Screen display	Remarks
1	Right click on the graph and select Set End Point.		
2	Use the pointer to select the cut end point and left click it. It is operable any number of times.	The mark selected is displayed in red dotted line. 	Set the end point at the right of the start point.
3	Right click on the graph and select Set.		Determining the cut end position.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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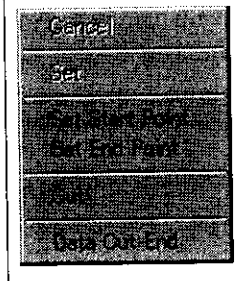
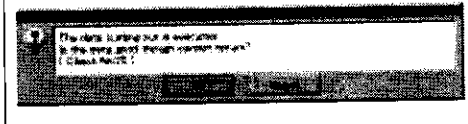
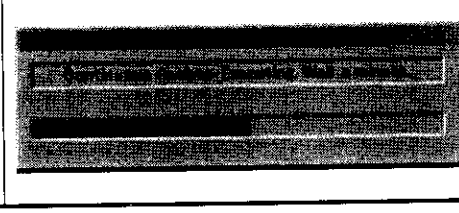
(c) Data cut

Step	Entry operation	Screen display	Remarks
1	Right click on the graph and select Cut.		
2	When prompted for final confirmation, click the [OK] button.		
3	When the gauge reached the end, cut process is completed.		Executing the cut process.

(3) Ending change operation

Right click to select Data Cut End for ending operation.

(4) Saving data

Use Save to save data having been edited.

(For details, see [5.5 Saving Analysis Data].)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5.5 Saving Analysis Data

(For detailed description on the File Manager, see [6.4 File Related Operation].)

Selecting "File Manager" from the [Operation] button menu displays the File Manager window.

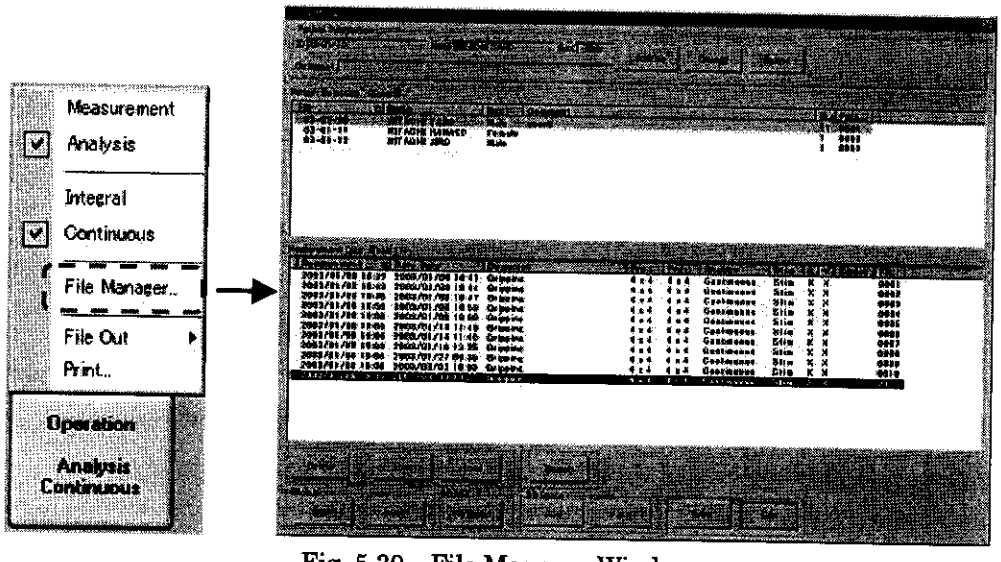

Fig. 5.30 File Manager Window

(1) Clicking the [Save] button displays the data save confirmation dialog.

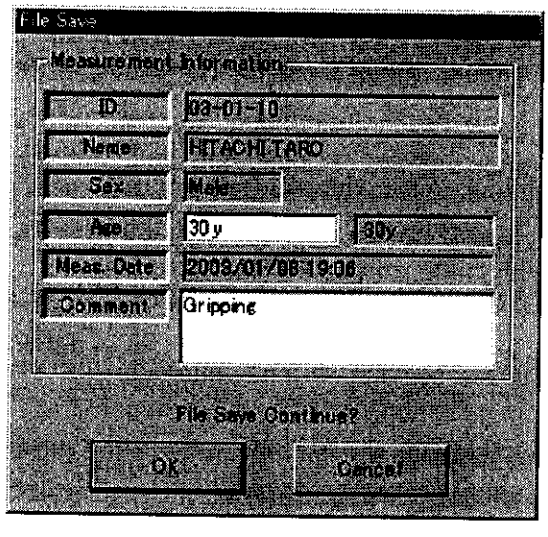

Fig. 5.31 Data Save Confirmation Window

(a) Age of the patient when measured can be modified.

(b) Measurement comment can be modified.

(c) To save data, click the [OK] button.

(d) To cancel saving data, click the [Cancel] button.

To modify ID, Name and Sex and save again, press [Cancel] and modify any on the main screen. Then, in the "File Manager", perform data saving process.

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(2) Upon completing save, the following appears.

① Measurement	② Save Date	③ Comment	④ Pro.	⑤ Pro.	⑥ Analyze	⑦ Stim	⑧ 3D	⑨ V.	⑩ Export	⑪ File
2003/01/08 18:39	2003/01/08 18:41	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0001
2003/01/08 18:43	2003/01/08 18:44	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0002
2003/01/08 18:45	2003/01/08 18:47	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0003
2003/01/08 18:56	2003/01/08 18:59	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0004
2003/01/08 19:06	2003/01/08 19:09	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0005
2003/01/08 19:06	2003/01/14 11:40	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0006
2003/01/08 19:06	2003/01/14 11:40	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0007
2003/01/08 19:06	2003/01/16 13:35	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0008
2003/01/08 19:06	2003/01/27 09:36	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0009
2003/01/08 19:06	2003/03/03 10:33	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0010
2003/01/08 19:06	2003/03/03 10:33	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0011

Fig. 5.32 Measurement Data

① Displays date and time when measured.

② Displays date and time when saving measurement or analysis.

③ Displays description of comment.

④ Displays the shape of Probe 1.

⑤ Displays the shape of Probe 2.

⑥ Displays the type of analysis (Continuous, Integral)

⑦ Displays the type of stimulation (Stim, Event)

⑧ Displays whether the 3D Space (optional) data is present or not.

⑨ Displays whether Video Capture (optional) data is present or not.

⑩ Displayed the destination folder when measurement data was exported.

⑪ Displays file No.

When loading any data having been saved, analysis and display settings when data was saved will be valid.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section.6 Description on Main Screen

6.1 Description on Main Screen

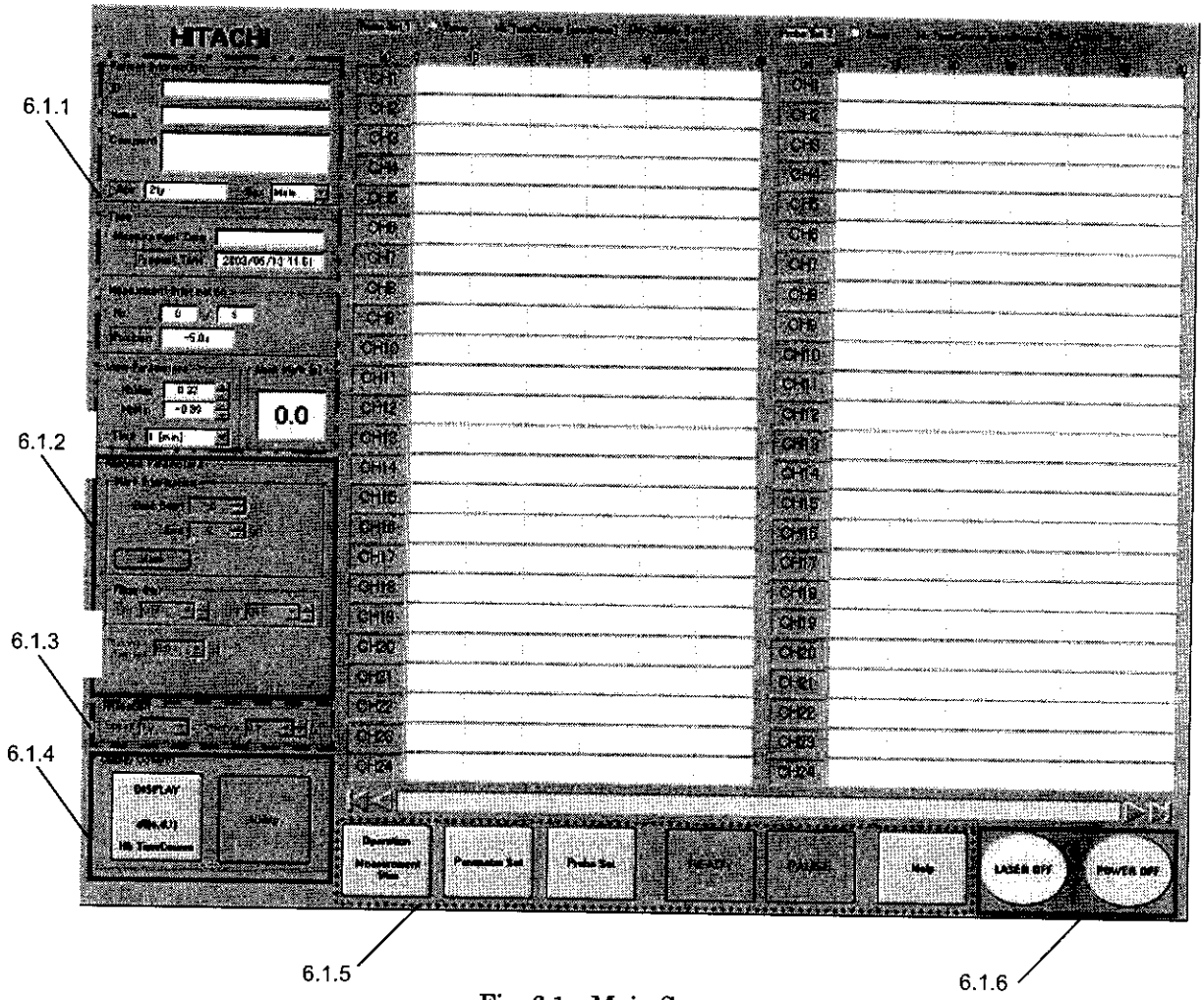

Fig. 6.1 Main Screen

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6.1.1 Information display area

(1) Patient Information

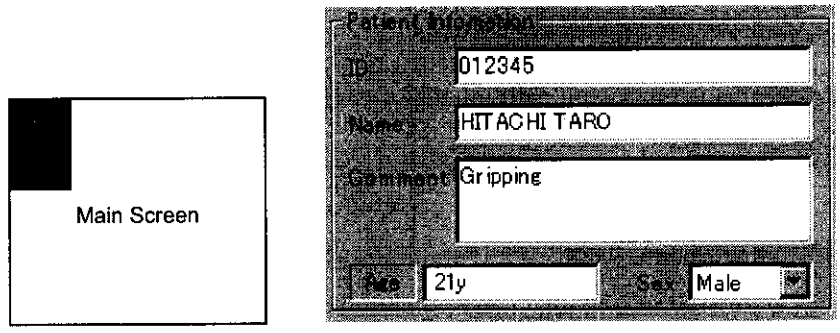

Fig. 6.2 Patient Information

1) ID

Enter patient ID.

2) Name

Enter the patient name.

3) Comment

Enter any comment on measurement data. Maximum three lines

4) Age

Clicking on it displays the following menu. Select any item for the patient age to be entered (Month, Week and Day are used for the age of patient such as an infant.

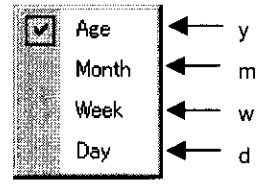

Fig. 6.3 Age Menu

5) Patient age

Enter patient age according to items designated in 4) Age.

6) Sex

Select patient sex.

- Male
- Female

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(2) Time

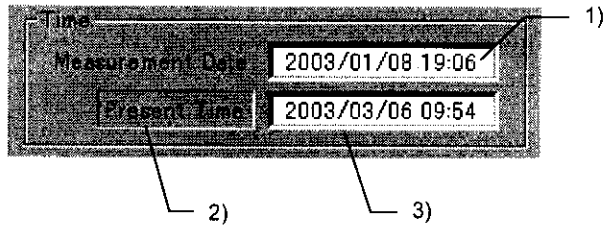

Fig. 6.4 Time

1) Measurement Date

Date and time when clicking the [Start] button in measurement are displayed.

2) Present Time (Title)

Clicking on this displays the following dialog for changing system time.

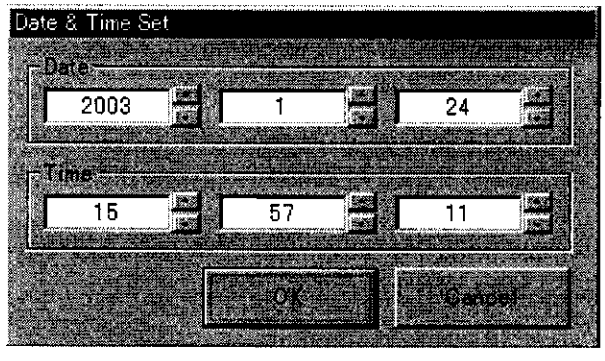

Fig. 6.5 Time Change Window

3) Present Time (Display)

Current time is displayed.

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(3) Measurement Information

• Measurement mode

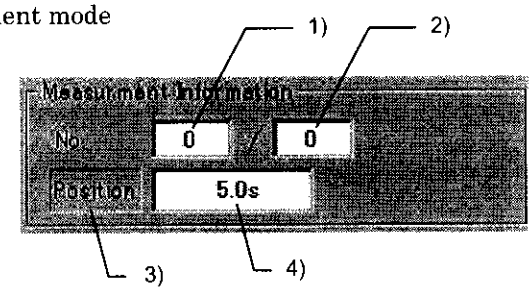

Fig. 6.6 Measurement Information (Measurement)

• Analysis mode

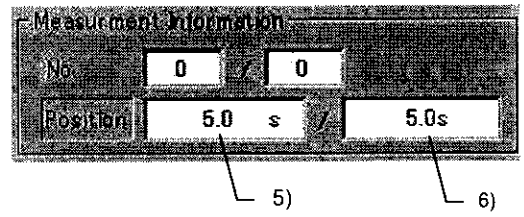

Fig. 6.7 Measurement Information (Analysis)

1) No. (number of times)

Displays the number of mark inserting times during measurement

2) No. (Total)

Displays the number of mark inserting times only when Mark In is Auto

3) Position (Title)

Clicking on it displays the following menu for selecting time display format

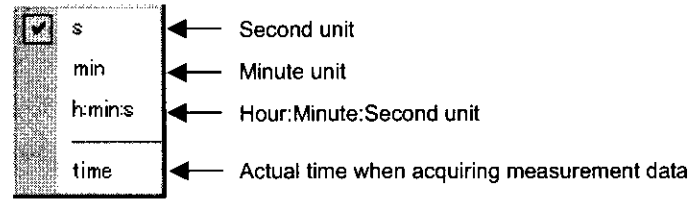

Fig. 6.8 Time Display Format Menu

4) Position (Time display in measurement 1)

Present measurement time with PreScan end time (Wait time start) as 0.0s.

5) Position (Time display in analysis)

Displays time where the time bar is located.

The time bar can be moved by entering time. Up or down of the cursor key allows the value to be increased or decreased.

When pressing the Enter key or moving to any other focus, the time bar moves.

6) Position (Time display in measurement 2)

Displays total time of analysis data excluding PreScan

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(4) View Parameter

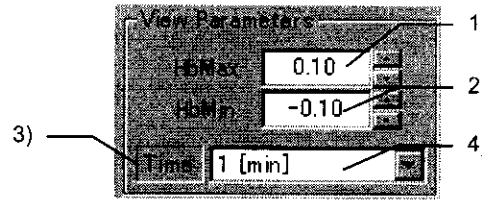

Fig. 6.9 View Parameter Screen

1) HbMax

2) HbMin

- When Hb Range is Auto [Peak to Peak] - ALL

  The maximum values in plus and minus directions are obtained among all Hb data of all measurement channels to make them Max and Min values (range) of all measurement channels.

- When Hb Range is Auto [Peak to Peak] - Each

  The maximum values in plus and minus directions are obtained by measurement channel to make them respective Max and Min values (range). For topographic images, these values are to be Max and Min values (range) of respective topographic image.

- When Hb Range is Auto [+/−Max] - Each

  The maximum of absolute values is obtained among all Hb data of all measurement channels to make it Max and Min (range) of all measurement channels as both sides (±) of zero.

- When Hb Range is Auto [+/−Max] - ALL

  The maximum of absolute values is obtained by measurement channels to make it respective Max and Min (range) as both sides (±) of zero. For topographic images, these are Max and Min (range) of respective topographic image.

- When Hb Range is Manual

  Max and Min values are entered to make them Max and Min values (range) of all measurement channels. Entry range is −999.99~999.99 [mmol*mm]. Increment/decrement value of the up/down button is 0.1.

3) Time (Title)

Clicking on it displays the following menu and set the horizontal axis range of graph freely. Default is 1 [min].

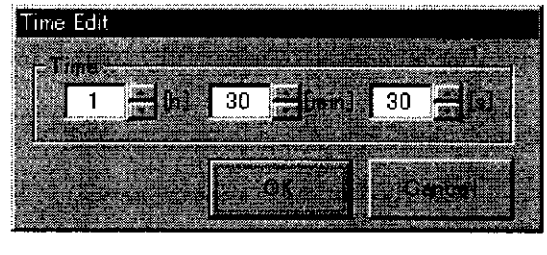

Fig. 6.10 Free Setting Horizontal Range of Graph

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(a) Indexing of Hb Time Course and AD Time Course

- When set time is 1 hour and over, it is displayed in the [h] unit.

  (Ex.) When setting with 1[h] 30[min]

- When set time is 1 minute and over and under 1 hour, it is displayed in the [min] unit.

  (Ex.) When setting with 0[h] 30[min] 30[s]

- When set time is below 1 minute, it is displayed in the [s] unit.

  (Ex.) When setting with 0[h] 0[min] 30[s]

- When attempting to display in respective unit, 6 scales if the maximum of scale can be divided by 5, or 7 scales in other cases are displayed.

  (Ex.) When the maximum scale can be divided by 5

4) Time (Display)

Select a horizontal width range of Hb graph.

Options are shown below:

- 5[s], 10[s], 30[s], 1[min], 2[min], 3[min], 4[min], 5[min], 10[min], 20[min], 30[min], 1[h], 2[h], 12[h], free horizontal range, (Full Time).

  Full Time is available only in the Integral analysis.

  (Range of Full Time = Pre time + Stim time + Recovery time + Post time)

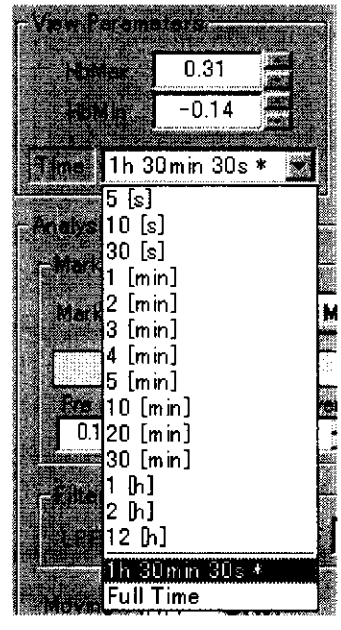

Fig. 6.11 Selecting Horizontal Range of Graph

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5) Next Mark

This is displayed only in measurement. It is activated only when Mark is Auto, and it counts down the time [s] to inserting the next mark.

Fig. 6.12 Next Mark

※ Scroll bar

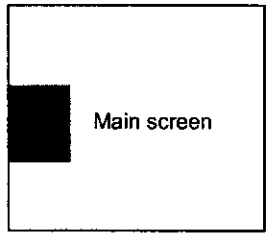
- Left page scroll button
  This displays a range that current display range − (TimeScale +1) point.
- Right page scroll button
  This displays a range that current display range + (TimeScale +1) point.
- Left scroll button
  This displays a range that current display range − 1 point. **Pressing the mouse right button** (while pressing the left button) displays a range that current display range − (TimeScale ÷10) point.
- Right scroll button
  This displays a range that current display range + 1 point. **Pressing the mouse right button** (while pressing the left button) displays a range that current display range + (TimeScale ÷10) point.

Fig. 6.13 Scroll Bar

6.1.2 Analysis parameter area

According to contents set in the Parameter window, values of each item are displayed. When the [ReAnalyze] button is pressed, analysis process is executed and displayed while reflecting the value changed in the analysis parameter entry field to parameters of the shared memory.

Fig. 6.14 ReAnalyze Button



(1) Mark Information

○ In the measurement mode

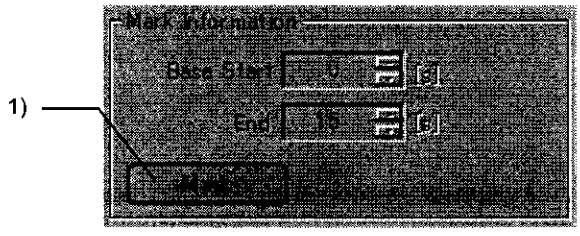


Fig. 6.15 Mark Information (Measurement)

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○ Continuous analysis mode

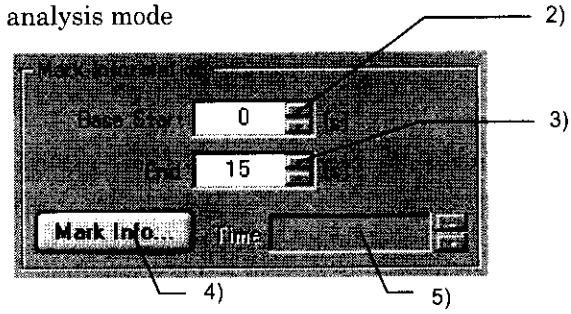

Fig. 6.16 Mark Information (Continuous analysis)

○ Integral analysis mode

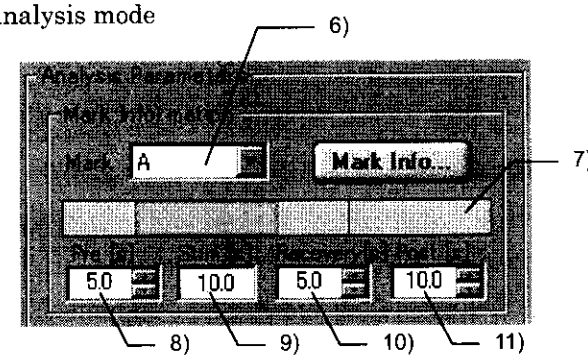

Fig. 6.17 Mark Information (Integral analysis)

1) Mark button

This is activated only when Mark is Manual in the Stim measurement. Clicking on it inserts a mark in turn following to the Sequence setting..

(For Sequence, see [6.2.1 Stim measurement parameter].)

2) Base start

Set the time [s] to start base line calculation. Entry range is −32766~32767[s].

However, restriction is provided so that any value that is lower than Base End Time and of which sign is reversed does not become higher than PreScan Time. Increment/decrement of the up/down button is 1.

3) Base End

Set the end time [s] for base line calculation. Entry range is −32766~32767[s]. However, a restriction is provided so that it becomes higher than Base Start Time. Increment/decrement of the up/down button is 1.

4) Mark Info

Mark information is listed as shown on the next page.

Clicking the title starts sorting. When list item is selected, the time bar is moved to the mark start time (or Event time). Clicking the [OK] button or double clicking any list item closes the list display. The [Cancel] button closes the list display while returning the time bar to the position before closing the dialog (the X button at the upper right of window acts the same.

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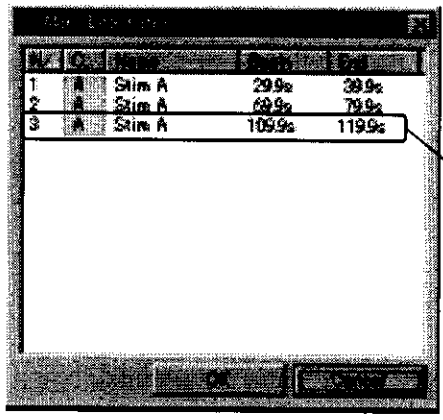
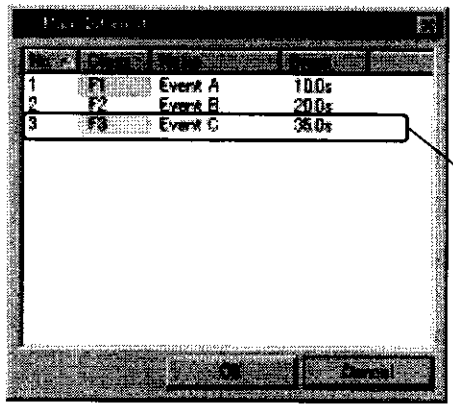
○ Stimulation measurement



Double clicking any line enables the cursor to jump to the head of stimulation clicked.

Fig. 6.18 Mark Information (Stimulation measurement)

○ Even measurement



Double clicking any line enables the cursor to jump to the head of stimulation clicked.

Fig. 6.19 Mark Information (Event measurement)

No. column : Displays the order to insert marks.

Class column : Displays stimulation marks. Background color is determined by stimulation.

Name column : Displays stimulation name.

Begin column : Displays stimulation start time. Display format follows that of Position of Measurement Information in [5.4.4 (2)].

End column : Displays stimulation end time. Display format follows that of Position of Measurement Information in [5.4.4 (2)].

Event column : Displays event occurrence time. Display format follows that of Position of Measurement Information in [5.4.4 (2)].

5) Time

Displays current time of the mark selected in Mark Edit Mode. Also, the spin button may be used to perform fine adjustment in 0.1 [s] unit.

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6) Mark

Select a mark subject to the Integral analysis.

- Stim measurement: A~J
- Even measurement: F1~F9, M

7) Integral analysis status display

Stimulation range is painted out in stimulation color. Also, depict the boundary between Recovery and Post (Vertical line).

8) Pre

Set pre-stimulation time. Entry range is Sampling Period ~ 999.9 [s]. Increment/decrement of the up/down button is the setting of Sampling Period.

9) Stim

Displays stimulation time in the Stim measurement.

10) Recovery

Set the recovery time [s]. Entry range is Sampling Period ~ 999.9 [s]. Increment /decrement of the up/down button are the setting of Sampling Period.

11) Post

Set the post-stimulation time [s]. Entry range is Sampling Period ~ 999.9[s]. Increment/decrement of the up/down button is the setting of Sampling Period.

(2) Filter

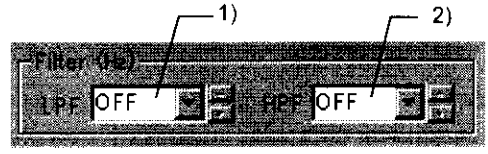

Fig. 6.20 Filter

1) LPF (Low pass filter, cut-off)

Set frequency [Hz] of LPF. Entry range is 0.001~4.999 [Hz] and increment /decrement of the up/down button is 0.001.

Also, predetermined values may be selected. Options are as follows:

- OFF, 0.5, 1.0. 2.5

2) HPF (High pass filter, cut-off)

Set frequency [Hz] of HPF. Entry range is 0.001~4.999 [Hz] and increment /decrement of the up/down button is 0.001.

Also, predetermined values may be selected. Options are as follows:

- OFF, 0.001, 0.01, 0.1

(3) Moving Average

Fig. 6.21 Moving Average

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Set moving average [s]. Options are as shown below:

- OFF
- Sampling Period * 5
- Sampling Period * 10
- Sampling Period * 50
- Sampling Period * 100
- Sampling Period * 300
- Sampling Period * 600

Data is averaged by the moving average method.

In OFF, seconds for sampled data are displayed as they are.

This process obtains an average from data of each time and its vicinity data (for designated time) in the analysis range and replaces data of each time with it.

This allows data with suppressed noise to be displayed.

In case of Hb Time Course screen or topography display in the Event measurement, averaging is applied to data of each time and those for designated time before that.

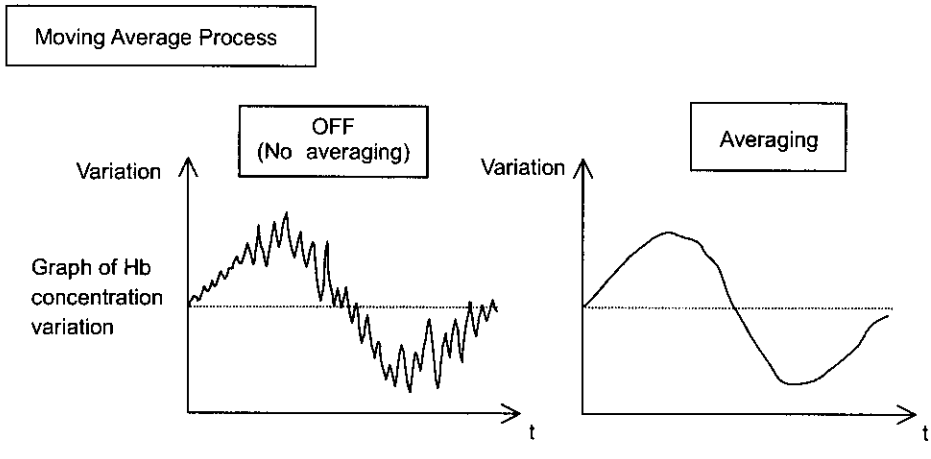

Fig. 6.22 Overview of Moving Average

(4) Realtime Integral

Set marks to perform the real-time Integral analysis.

It is valid when the real-time Integral window is displayed.

Fig. 6.23 Setting Marks for Real-time Integral Analysis

(This cannot be set in the Parameter Set window.)

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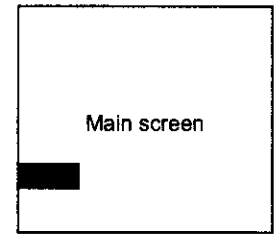
6.1.3 Continuous display parameter area

(1) Animation display parameters

Set parameters of continuous cine display in analysis.

Fig. 6.24 Animation Parameters



1) Speed

Select the following values as a standard of replay speed.

- 1/10, 1/5, 1/2, 1, 2, 5, 10

2) Interval

Set interval [s] of animation for thinned-out replay. Entry range is Sampling Period ~ total time [s] of analysis data, and increment/decrement of the up/down button is Sampling Period [s].

Also, predetermined values may be selected. Options are shown below:

- 1×Sampling Period [s]
- 2×Sampling Period [s]
- 5×Sampling Period [s]
- 10×Sampling Period [s]
- 20×Sampling Period [s]
- 50×Sampling Period [s]
- 100×Sampling Period [s]

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6.1.4 Display related operation area

(1) [DISPLAY] button

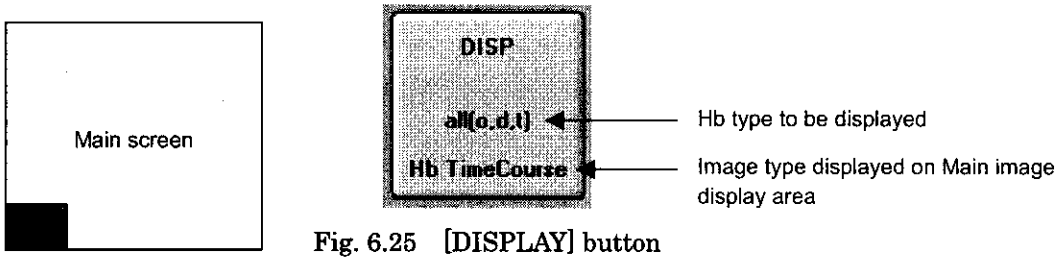

Fig. 6.25 [DISPLAY] button

When clicked, the following menu appears.

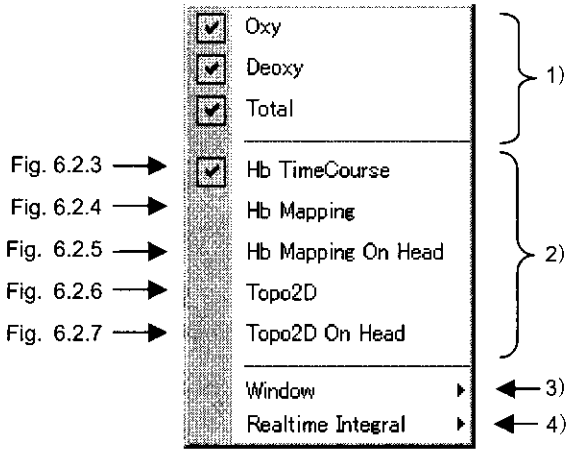

Fig. 6.26 [DISPLAY] Menu

1) Display Hb type

Select any Hb type to be displayed. One or more out of three may be selected.

2) Image type to be displayed on the main image display area

Select any image type to be displayed on the main image display area. If selection is changed, the main image is switched over.

(See Fig. 6.23 ~ Fig. 6.27.)

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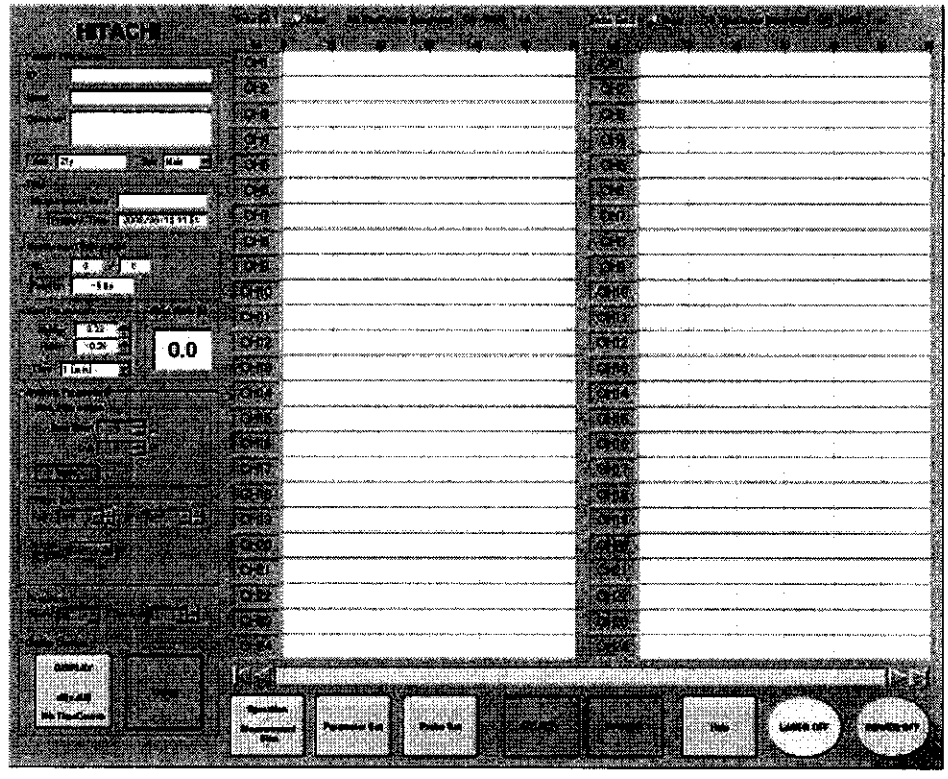

Fig. 6.27 Hb Time Course Screen

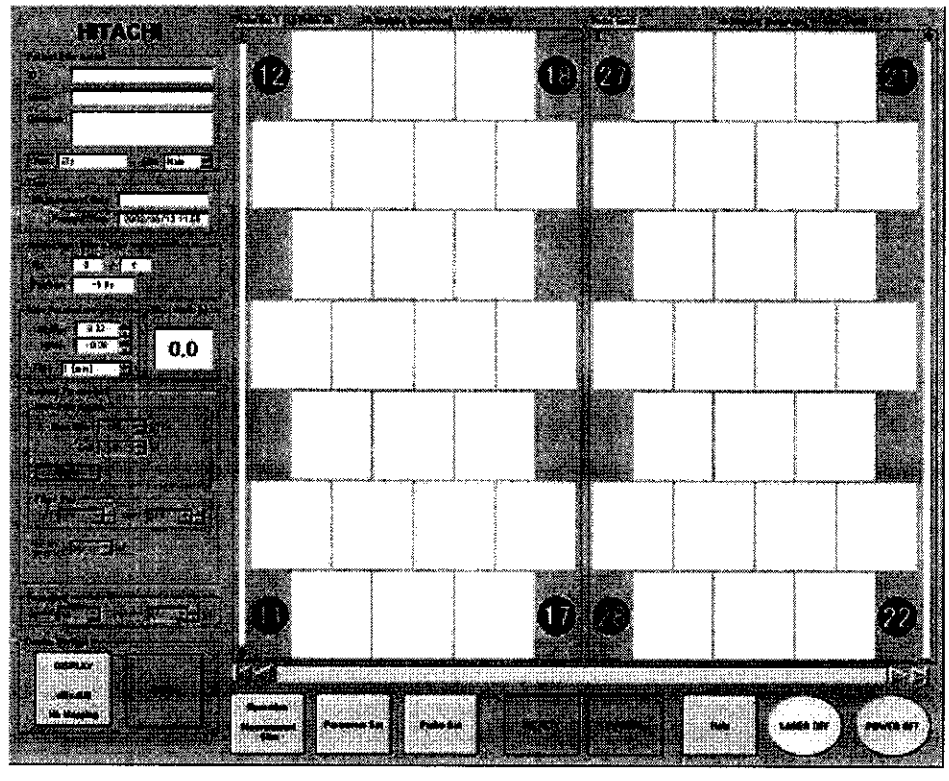

Fig. 6.28 Hb Mapping Screen

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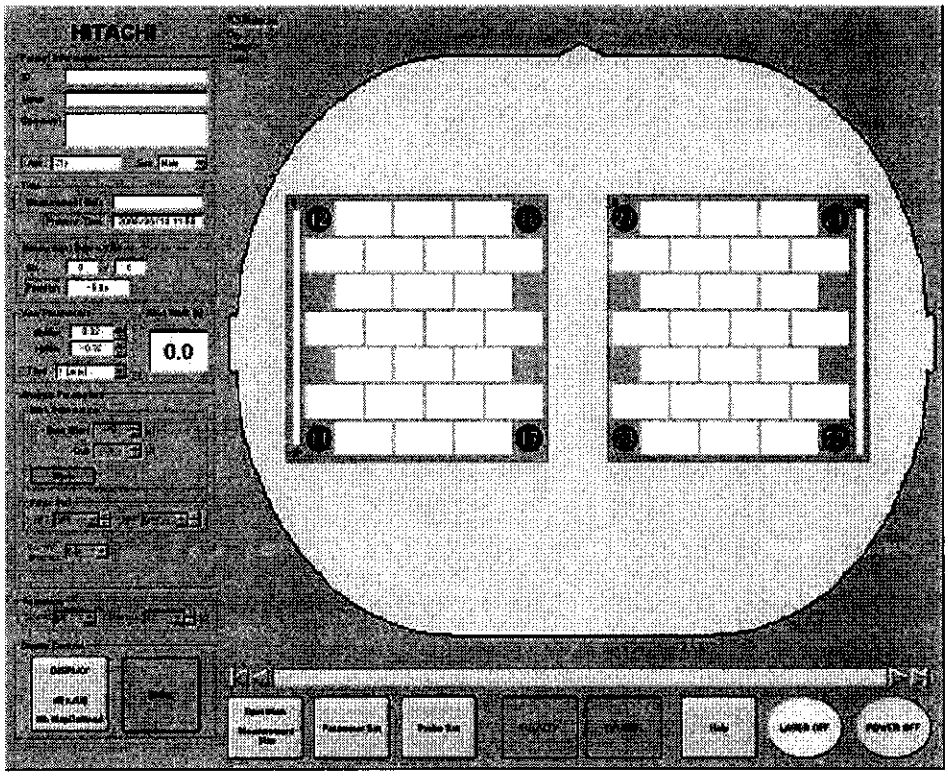

Fig. 6.29 Hb Mapping On Head Screen

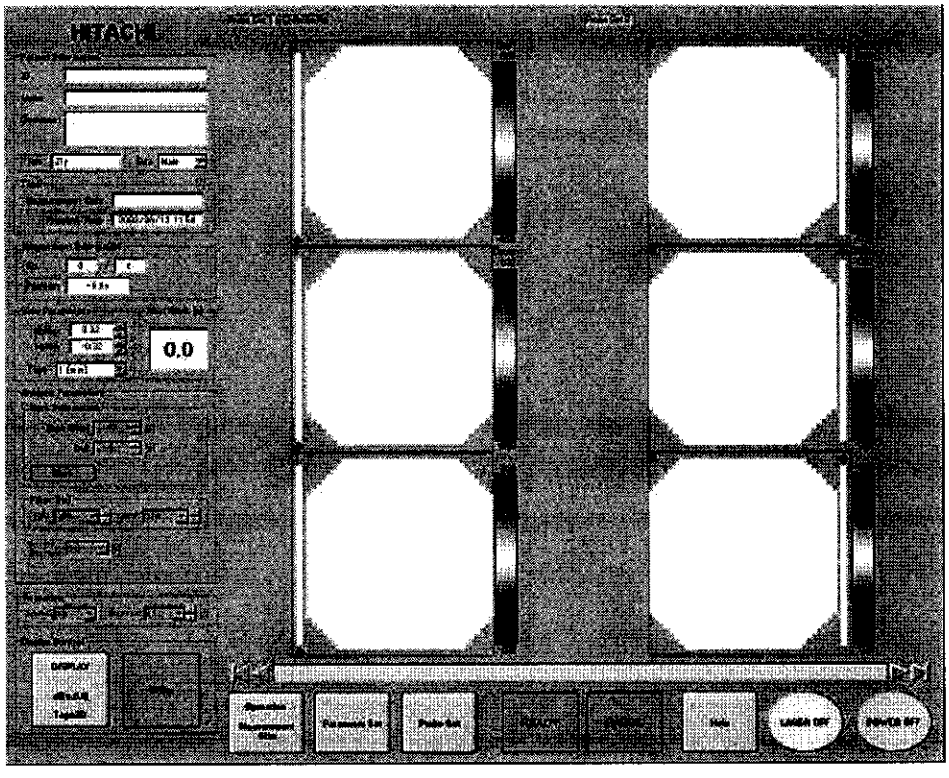

Fig. 6.30 Topo 2D Screen

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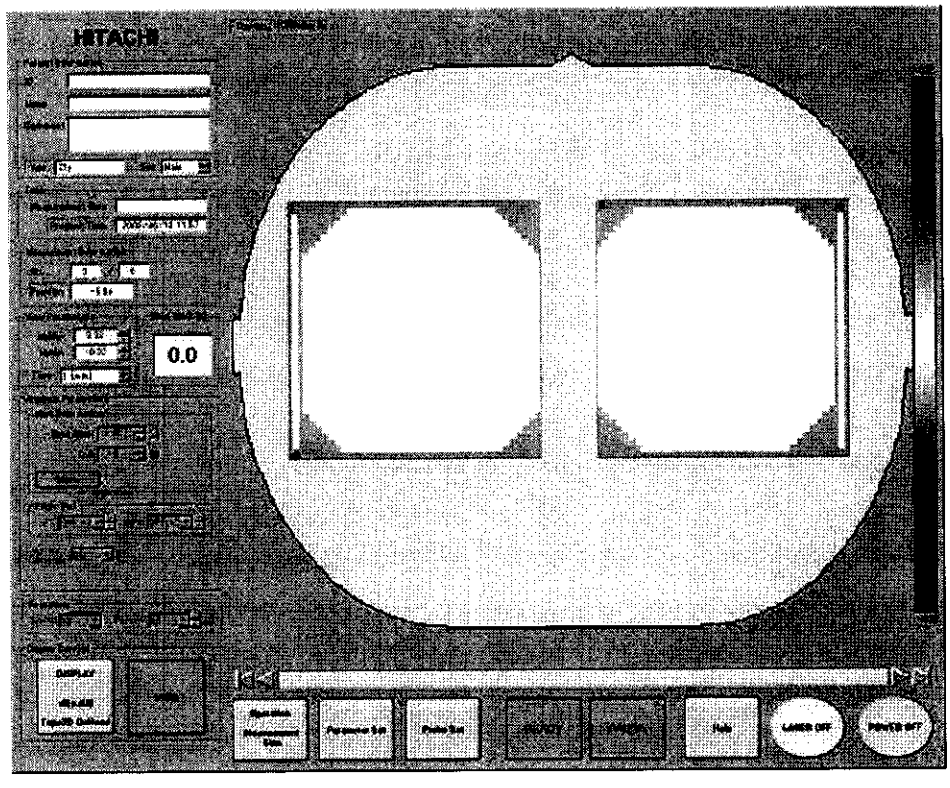

Fig. 6.31 Topo 2D On Head Screen

3) Window display options

The menu is shown below:

(For details, see [6.5 Description on Window Display].)

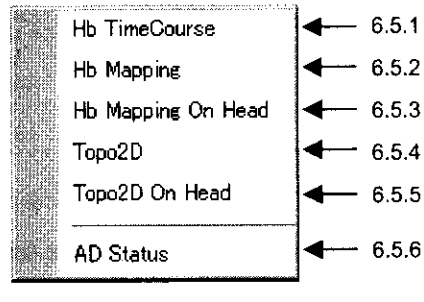

Fig. 6.32 Window Display Options

4) Realtime Integral display options

The menu is shown below:

(For details, see [6.6 Description on Realtime Integral Display].)

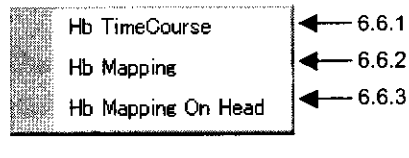

Fig. 6.33 Window Display Options

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(2) [Utility] button

Use the [Utility] button only when purchasing the 3D Space (optional).

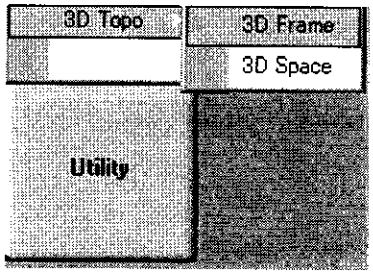

Fig. 6.34 [Utility] Button

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.1.5 Measurement and analysis related operation area

(1) Operation button

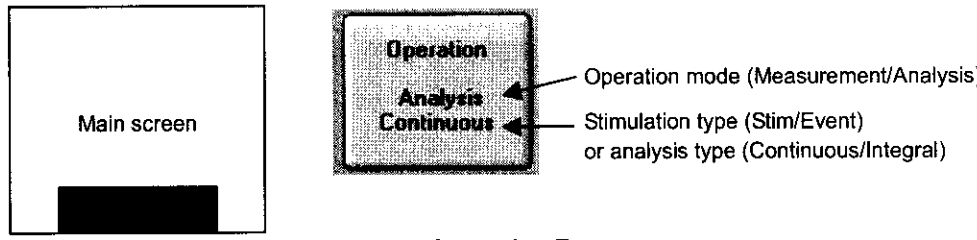

Fig. 6.35 Operation Button

When clicked, the following menu is displayed.

○ Measurement mode

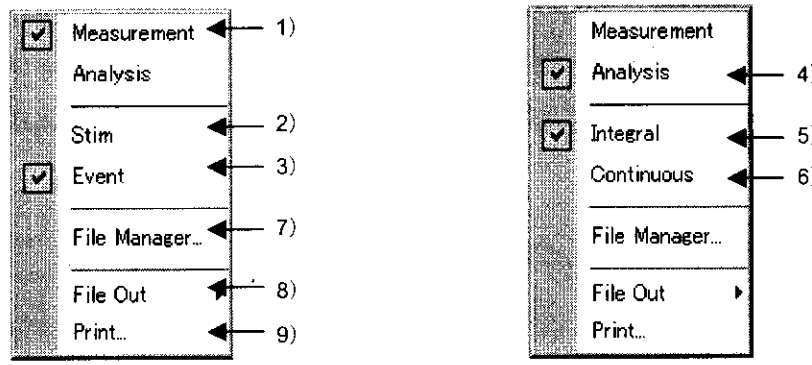

Fig. 6.36 Operation Button Menu

1) Measurement

Moves to the measurement mode.

2) Stim

Moves to the Stim mode.

3) Event

Moves to the Event mode.

4) Analysis

Moves to the Analysis mode. Updates the state of each item on the main screen.

5) Integral

Executes Integral analysis and moves to the Integral mode.

6) Continuous

Executes Continuous analysis and moves to the Continuous mode.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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7) File Manager

Displays the following dialog and performs file management of ETG-4000 data.

(For details, see [6.4 File Related Operation].)

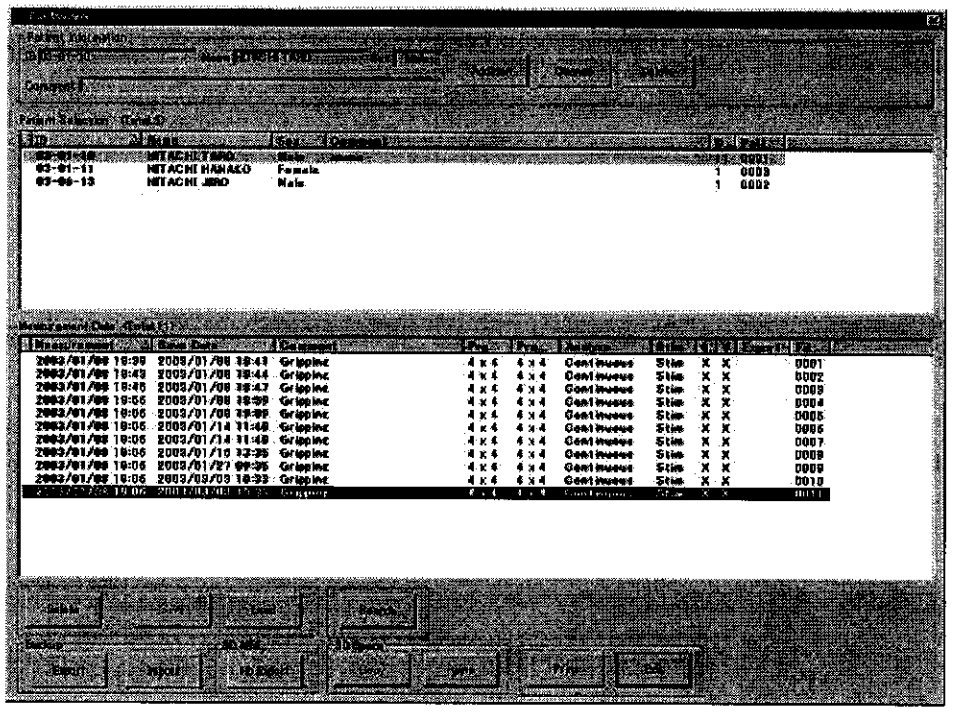

Fig. 6.37 File Manager Window

8) File Out

The following menu is displayed. Text File Out and Animation File Out will be active when no measurement data exists.

(For details, see each section.)

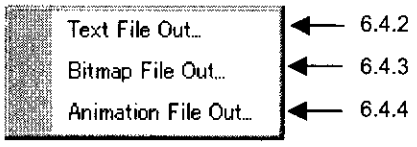

Fig. 6.38 File Out Menu

9) Print

The whole main screen is printed out.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 185

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(2) Parameter Set button

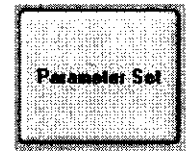

Fig. 6.39 [Parameter Set] Button

When clicked, the following dialog is displayed for parameter setting.

(For details, see each section number described in Fig. 6.36.)

○ Whole view

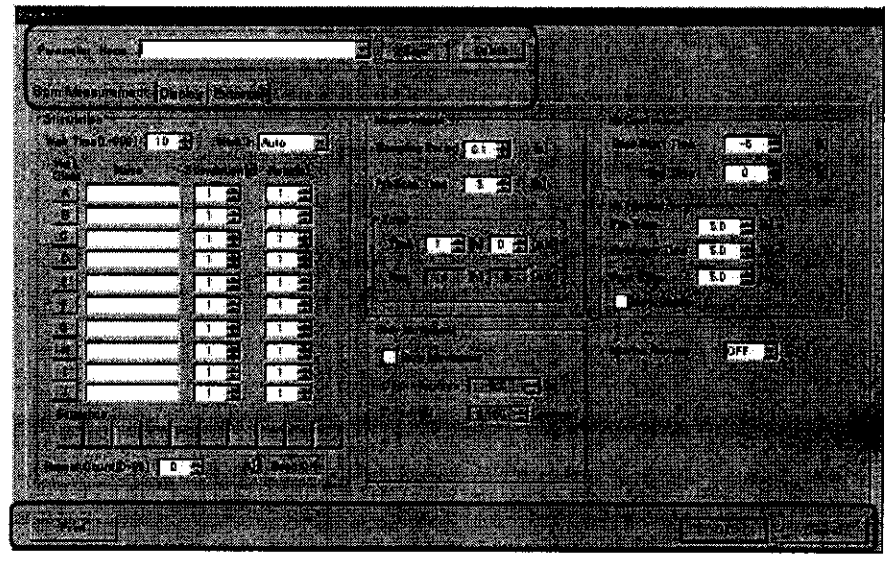

Fig. 6.40 Parameter Window (Whole view)

○ Upper section

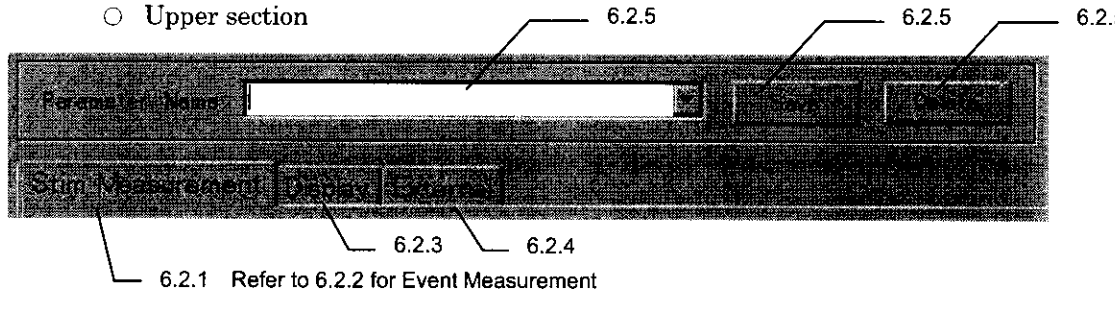

Fig. 6.41 Parameter Window and References (Upper section)

○ Lower section

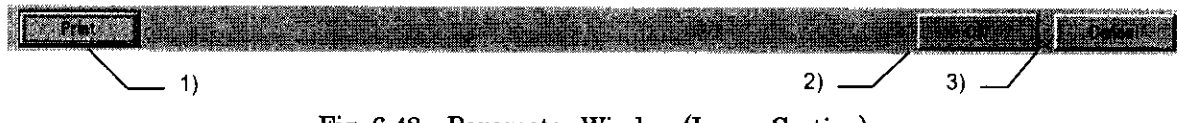

Fig. 6.42 Parameter Window (Lower Section)

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1) Print

Prints the parameter dialog box.

2) OK

Makes the parameter having been set valid and exits the process.

3) Cancel

Makes the parameter having been set invalid and exits the process.

(3) Probe Set button

Fig. 6.43 [Probe Set] Button

Clicking the [Probe Set] button above displays the following probe set window.

(Fro details, see [6.3 Description on Probe Set Window].)

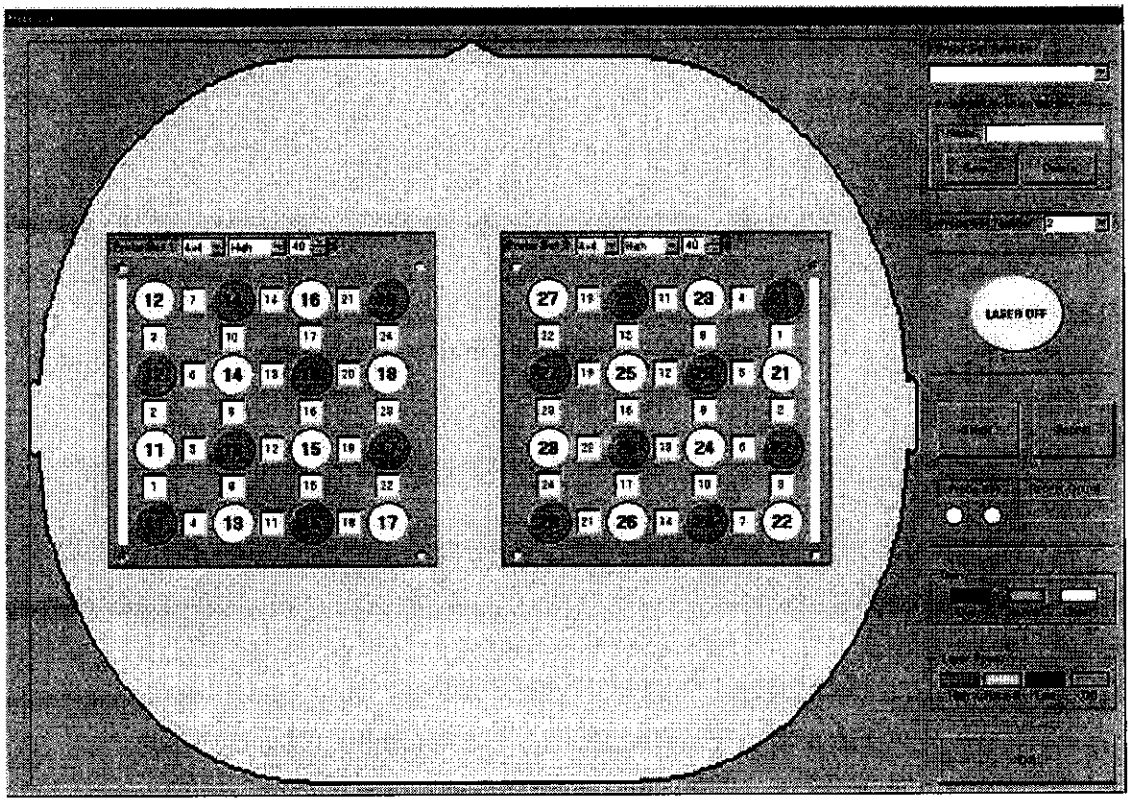

Fig. 6.44 Probe Set Window

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(4) READY, START and STOP buttons

1) [READY] button

Clicking the [READY] button prepares measurement.

When ready, this button is displayed as the [START] button shown in Fig. 6.47.

① Before executing Probe Set

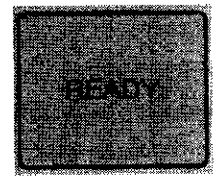

Fig. 6.45 [READY] Button (Inactive)

② After executing Probe Set, or after measurement (active to perform measurement continuously)

Fig. 6.46 [READY] Button (Active)

2) [START] button

Clicking the [START] button starts measurement and analysis.

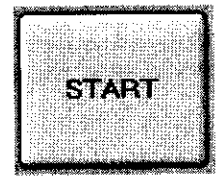

Fig. 6.47 [START] Button

3) [STOP] button

Clicking the [STOP] button stops measurement and analysis.

The [STOP] button is displayed during measurement or analysis.

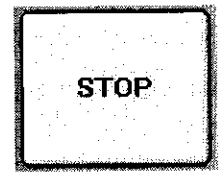

Fig. 6.48 [STOP] Button

4) [PAUSE] button

Clicking the [PAUSE] button suspends measurement and analysis.

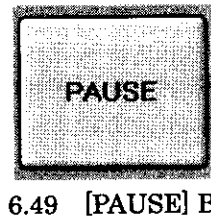

Fig. 6.49 [PAUSE] Button

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5) [UnPAUSE] button

Clicking the [UnPAUSE] button resumes measurement and analysis.

At this time, if while measurement, the Probe Set window starts and re-measure Auto Gain. When completed, measurement resumes automatically.

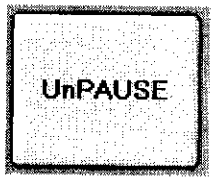

Fig. 6.50 [UnPAUSE] Button

6) [Help] button

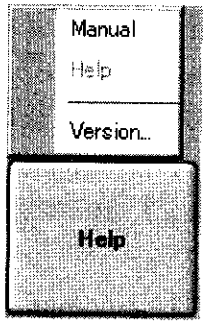

Fig. 6.51 [Help] Button

① Manual

Clicking Manual displays this instruction manual in the window.

② Help

Since the [Help] button is not used at present, it is always inactive.

③ Version

Clicking Version displays the version information dialog.

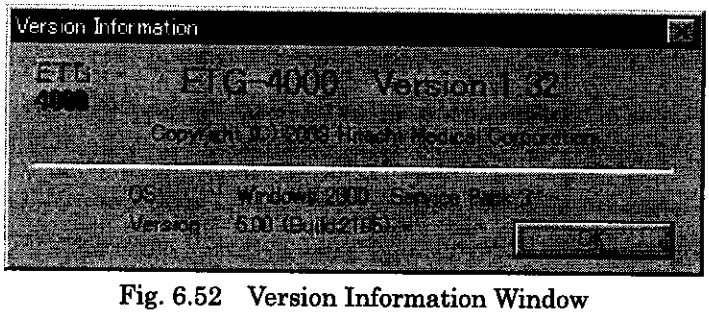

Fig. 6.52 Version Information Window

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6.1.6 Hardware control area

(1) LASER ON/OFF button

Turns the laser output ON/OFF.

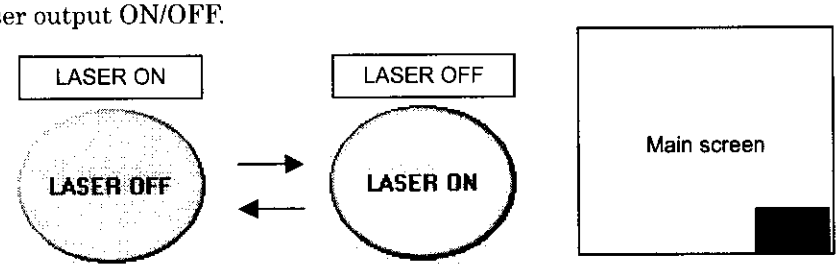

Fig. 6.53 LASER ON/OFF Button

(2) POWER OFF button

Click to end using the system.

This shuts off the power to PC automatically.

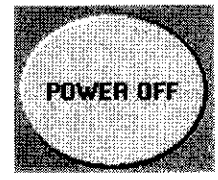

Fig. 6.54 POWER OFF Button

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6.2 Description on Parameter Set Window

The following describes each parameter set section.

6.2.1 Stim Measurement parameters

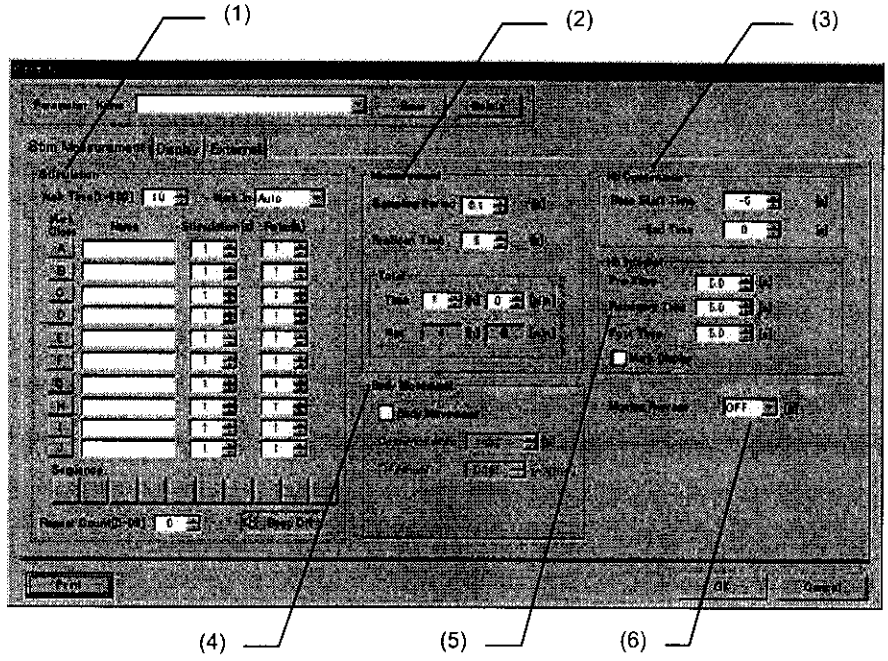

Fig. 6.55 Stim Measurement Parameter Window

(1) Stimulation

Mainly set methods to enter marks.

1) Wait Time

Set stimulation start time. Entry range is 1~999 [s].

2) Mark In

Select any type of stimulation mark. Options are as follows:

- Auto : Automatically performs marking following the setting of stimulation mark and mark input order.
- Manual : Use the [Mark] button to enter any type of stimulation set by A to J of Mark Class in any timing.

  At this time, the order of mark input follows the setting of 3) Mark input order
- Serial : Marking is carried out via serial communication.

  At this time, the order of mark input follows timing of the serial communication command A to J.
- External : Marking is carried out via the external input signal.

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3) Mark Class

Stimulation mark identification buttons of A to J. Clicking each button adds the mark to Sequence.

4) Name

Enter any stimulation name of A to J.

5) Stimulation

Set stimulation time [s] of A to J. Entry range is 1~999 [s].

Increment/decrement by the up/down buttons is 1.

6) Relaxation

Set interval time between stimulations of A to J. Entry range is 1~999 [s].

Increment/decrement by the up/down buttons is 1.

7) Sequence

These buttons display the order of inserting marks (10). Clicking each button cancels the mark from Sequence.

8) Repeat Count

Set repetition time of stimulation input. Entry range is 0~99.

Increment/decrement by the up/down buttons is 1.

9) Beep ON/Beep OFF

Select the beep tone to be sounded or not when inserting a mark.

(2) Measurement

Set measurement time.

1) Sampling Period

Set measurement period [s]. When changing the value, display of maximum measurement time is updated.

Entry range is 0.1~10.0 [s].

Increment/decrement by the up/down buttons is 1.

2) PreScan Time

Set initial measurement time [s]. Entry range is 5~32767 [s].

Increment/decrement by the up/down buttons is 1.

3) Total Time

Set total measurement time (hh:mm). Entry range is 0[h]1[min]~Total Max.

Increment/decrement by the up/down buttons is 1 for both [h] and [min].

4) Total Max

Set the maximum measurement time (hh:mm). Its value is Sampling Period × 10 × 240 [min].

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(3) Hb Continuous

Set parameters of Continuous analysis.

1) Base Start Time

Set start time [s] for base line calculation. Entry range is −32767~32766 [s].

However, restriction should be provided so that it is lower than Base End Time and its absolute value is not higher than PreScan Time. Increment/decrement value by the up/down buttons is 1.

2) Base End Time

Set end time [s] for base line calculation. Entry range is −32767~32766 [s].

However, restriction should be provided so that it is higher than Base Start Time. Increment/decrement value by the up/down buttons is 1.

(4) Body Movement

- When spike signal such as body movement component occurs during measurement, measurement is continued until stable (no body movement) data is obtained without increasing the mark count in the stimulation period.
- Body movement signal means that currently acquired measurement signal [V] varies larger than (over threshold designated) the measurement signal acquired before (average in the designated period).

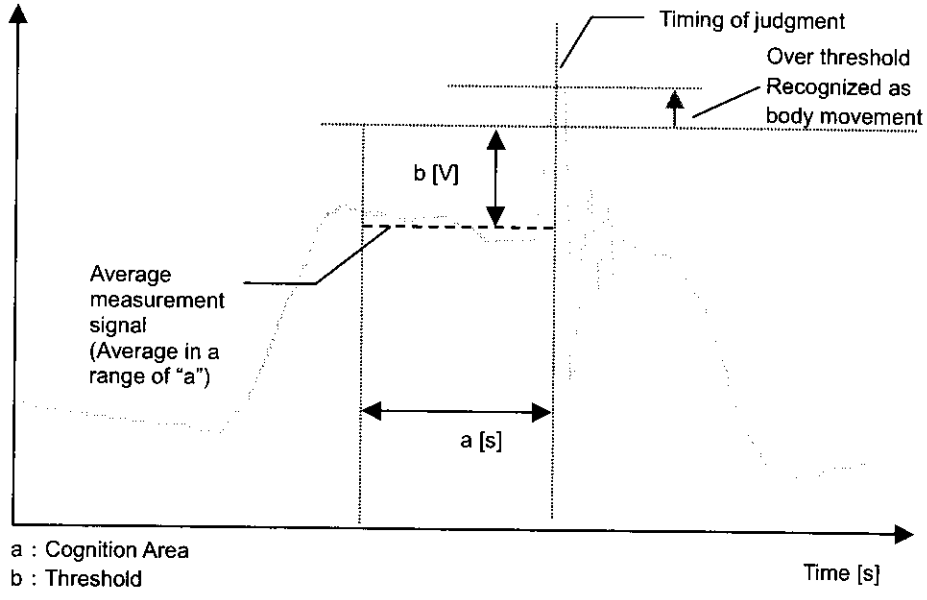

Fig. 6.56 When Body Movement Occurred

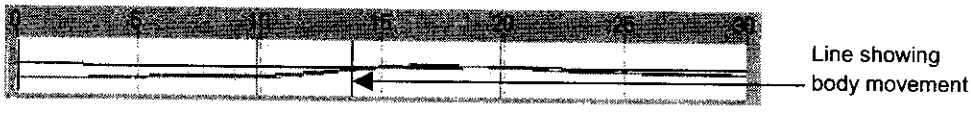

Fig. 6.57 Graph Display When Body Movement Occurred

Fig. 6.58 Mark Display When Body Movement Occurred (Lattice display)

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1) Body Movement

Select presence of action against body movement.

2) Cognition Area

Set cognition area [s] for body movement. When Sampling Period is changed, a relevant value is redisplayed. Entry range is 2×Sampling Period ~ 999×Sampling Period.

Default is 2×Sampling Period [s].

3) Threshold

Set the threshold of body movement [mMmm]. Entry range is 0.01~10.00.

Increment/decrement of the up/down button is 0.01.

Detailed description

1) Judgment of body movement in measurement

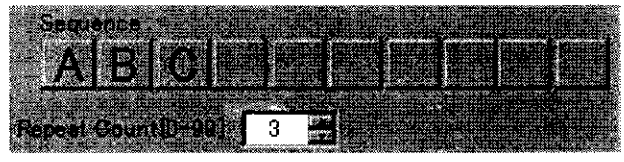
(a) Judging body movement

In all probes and all channels, the latest Hb data is compared with data for the time set in "Cognition Area" to calculate its absolute value. If over "Threshold", it is judged as "body movement".

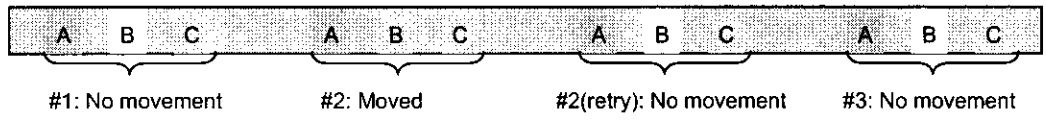
(b) Retrying Sequence

If "body movement" has occurred even once in the Sequence area at the time when a series of Sequences are completed, retry the Sequence from the beginning.

(Ex.) Measurement is conducted by setting that Sequence "A, B, C" is to be repeated three times.



Measurement flow chart (it is supposed that "body movement" occurred in the second Sequence.)



2) Judgment of body movement in Continuous analysis

In all probes and all channels, each Hb data of all measurement points is compared with data before the time set in "Cognition Area" to calculate its absolute value. If over "Threshold", it is judged as "Body movement". Also in each mark, if "body movement" occurred in the Pre time + marking period + Recovery time + Post time, this marking period is displayed latticed.

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3) Judgment of body movement in Integral analysis

Data is processed as well as judging body movement in Continuous analysis and averaged excluding the marking period judged as "body movement". The marking period judged as "body movement" is that displayed latticed in Continuous analysis.

(5) Hb Integral

Perform setting in Integral analysis.

1) Pre Time

Set time before applying stimulation [s]. When sampling period is changed, the relevant value is redisplayed. Entry range is Sampling Period ~ 999.9 [s].

Increment/decrement of the up/down button is Sampling Period.

2) Recovery Time

Set the recovery time [s]. When Sampling Period is changed, the relevant value is redisplayed. Entry range is Sampling Period ~ 999.9 [s].

Increment/decrement of the up/down button is Sampling Period.

3) Post Time

Set the time after applying stimulation [s]. When sampling period is changed, the relevant value is redisplayed. Entry range is Sampling Period ~ 999.9 [s].

Increment/decrement of the up/down button is Sampling Period.

4) Mark Display

Select whether a border line is to be drawn or not between Relax Time and Post Time.

(6) Moving Average

Perform setup in Hb conversion

① Moving average

Set moving average time [s]. Options are as shown below:

- OFF
- Sampling Period × 5 [s]
- Sampling Period × 10 [s]
- Sampling Period × 50 [s]
- Sampling Period × 100 [s]
- Sampling Period × 300 [s]
- Sampling Period × 600 [s]

Data is averaged in the moving average process.

This process obtains average from data at each time in the analysis range and in the vicinity of data (for designated time) and replaces data at each time with it.

This allows data suppressed with noise to be displayed.

For the Hb Time Course screen or Topography screen during Event measurement, averaging is applied to data at each time and that before it.

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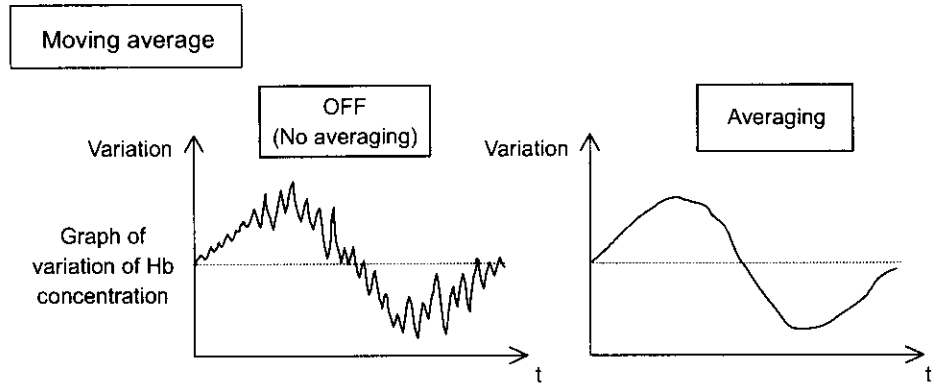

Fig. 6.59 Outline of Moving Averaging

6.2.2 Event Measurement parameters

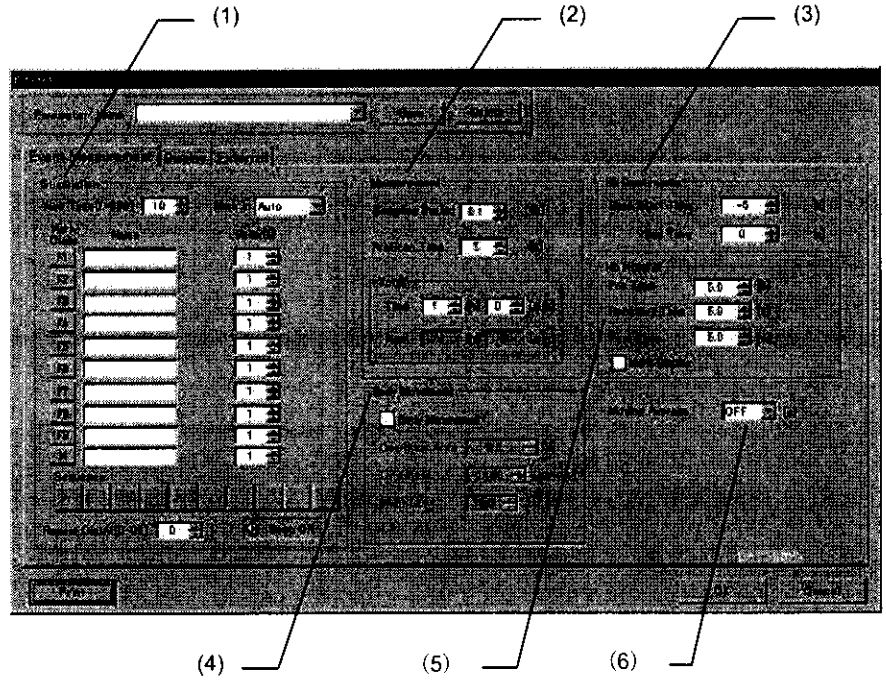

Fig. 6.60 Even Measurement Parameter Window

(1) Stimulation

Operation is same as the tab of [6.2.1 Stim measurement parameters] except no field to set Stim time [s].

(2) Measurement

Operation is same as tab of [6.2.1 Stim measurement parameters].

(3) Hb Continuous

Operation is same as the tab of [6.2.1 Stim measurement parameters].

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(4) Body Movement

1) Body Movement

2) Cognition Area

3) Threshold

Operation is same as the tab of [6.2.1 Stim measurement parameters].

4) Width

Set the period for cognizing body movement [s] (for Event). When Sampling Period is changed, the relevant value is redisplayed. Entry range is 1 × Sampling Period ~ 1000 × Sampling Period.

Increment/decrement of the up/down button is Sampling Period.

Default is 100 × Sampling Period [s].

Detailed description

1) Judgment of body movement in measurement

(a) Judging body movement

In all probes and all channels, the latest Hb data is compared with data for the time set in "Cognition Area" to calculate its absolute value. If over "Threshold", it is judged as "body movement". Also, all marks existing from the position of "body movement" data to that ahead by "Width" are displayed latticed.

(b) Retrying Sequence

Operation is same as the tab of [6.2.1 Stim measurement parameters].

2) Judgment of body movement in Continuous analysis

In all probes and all channels, each Hb data of all measurement points is compared with data before the time set in "Cognition Area" to calculate its absolute value. If over "Threshold", it is judged as "Body movement". Also in each mark, if "body movement" occurred in the Pre time + marking period + Recovery time + Post time, this marking period is displayed latticed..

3) Judgment of body movement in Integral analysis

Data is processed as well as judging body movement in Continuous analysis and averaged excluding the marking period judged as "body movement". The marking period judged as "body movement" is that displayed latticed in Continuous analysis.

(5) Hb Integral

Operation is same as the tab of [6.2.1 Stim measurement parameters].

(6) Others

Operation is same as the tab of [6.2.1 Stim measurement parameters].

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6.2.3 Display parameters

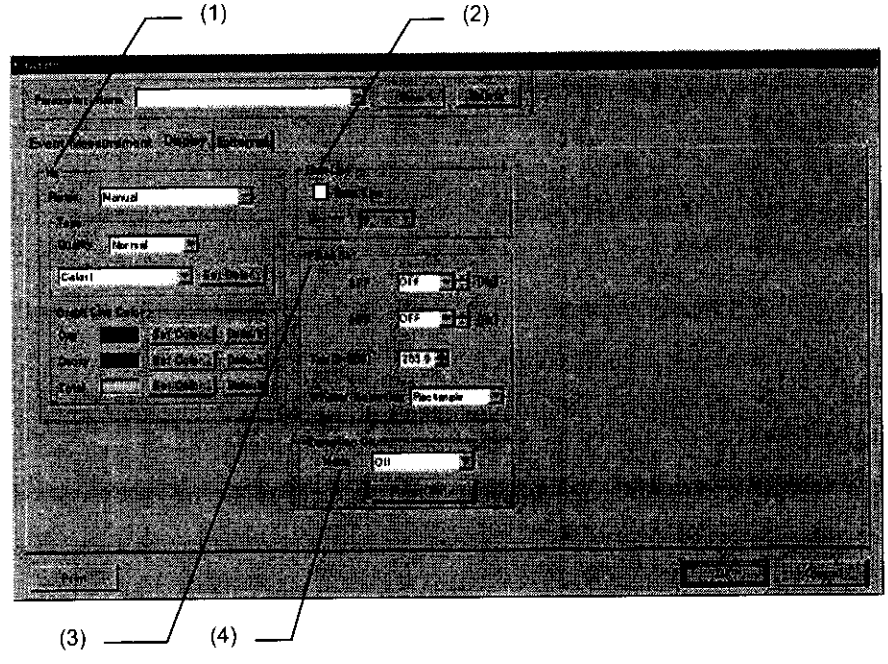

Fig. 6.61 Display Parameter Window

(1) Hb

Perform setup related to displaying the Hb graph.

1) Range

Select how to determine the vertical axis range of Hb graph and topographic image range. Options are as shown below:

- *Auto [Peak to Peak] - All*

  Maximum values in the plus and minus directions are obtained among all Hb data of all measurement channels for Max and Min values (range) of all measurement channels.

- *Auto [Peak to Peak] - Each*

  Maximum values in the plus and minus directions are obtained by measurement channel for Max and Min for each channel (range). For topographic images, these are Max and Min values (range) of each topographic image.

- *Auto [+/–Max] - All*

  Maximum of absolute values is obtained among all Hb data of all measurement channels for Max and Min values (range) of all measurement channel with them as both sides (±) of 0.

- *Auto [+/–Max] - Each*

  Maximum of absolute values is obtained by measurement channel for Max and Min values (range) of each measurement channel with them as both sides (±) of 0.

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For topographic images, these are Max and Min values (range) of each topographic image.

- *Manual*

  Enter Max and Min values for Max and Min values (range) of all measurement channels.

2) Quality

Select resolution of topographic image. Options are as shown below:

- Fine
- Normal
- Coarse

3) Selecting display colors

Select colors to be used for topographic image. Options are as shown below:

- Color 1 (Red, blue)
- Color 2 (Orange, green)
- Color 3 (White, black)
- Color 4 (Black, white)

4) Set Color (Topo)

Set the color balance of topographic images.

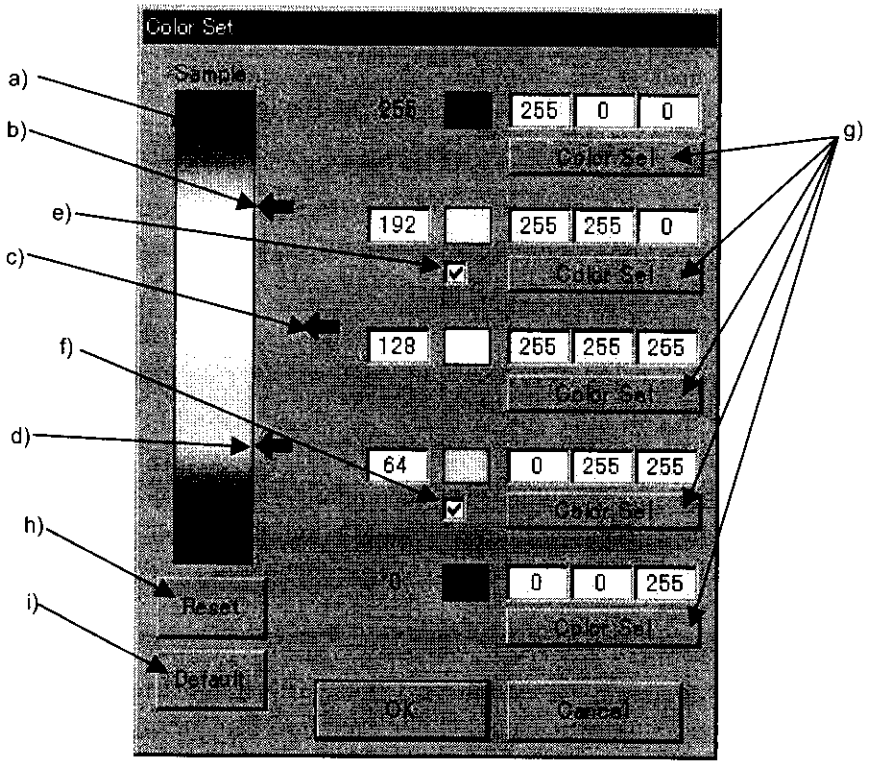

Fig. 6.62 Color Balance Set Window

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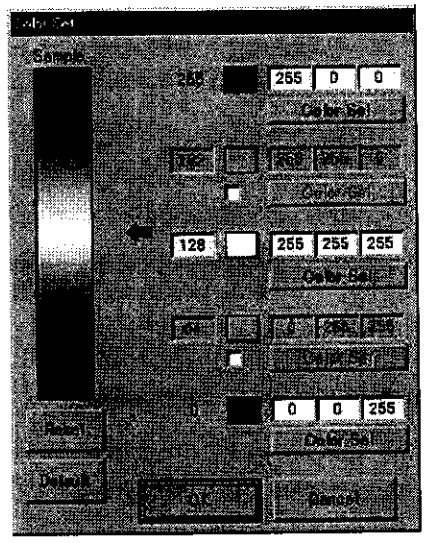
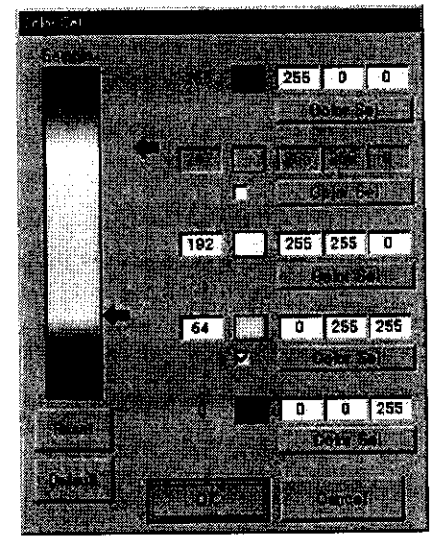
a) Displays color balance currently set.
b) Set boundary 1 of color balance (Drag)
c) Set boundary 2 of color balance (Drag)
d) Set boundary 3 of color balance (Drag)
e) Make the boundary 1 valid.
f) Make the boundary 3 valid.
g) Displays a dialog to select colors of each boundary.
h) Returns the setting of color balance to that when starting this window.
i) Returns the setting of color balance to the when shipping the product.

(Default setting when the product was shipped)

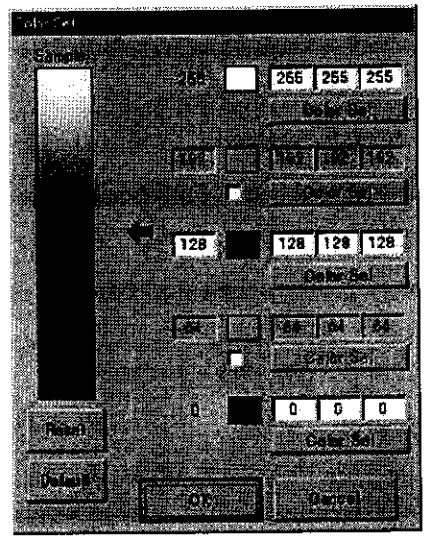
Color 1



Color 2



Color 3



Color 4

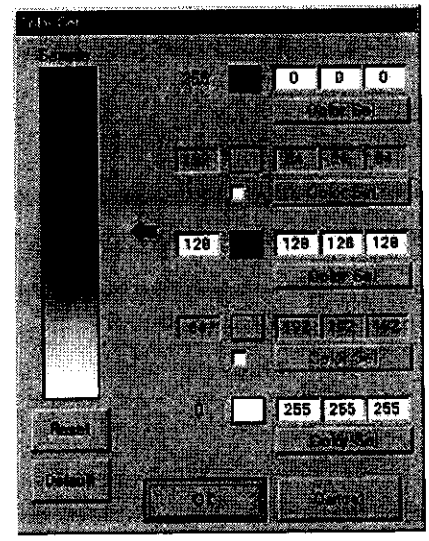


Fig. 6.63 Color Sample

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4) Graph Line Color

Change line color of Oxy, Deoxy and Total displayed on the Hb graph.

[Set Color] button

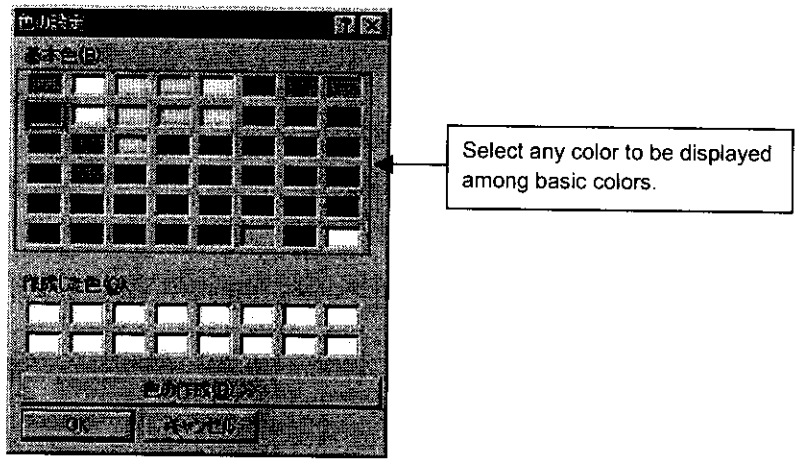

Fig. 6.64 Color Set Window (1)

Clicking the [Blend color (D)] button changes the window as shown below. Enter any value in items of Color shade(E), Sharpness(S), Luminosity(L), Red(R), Green(G) and Blue(B) to create a color. Clicking the [Add Color(A)] button

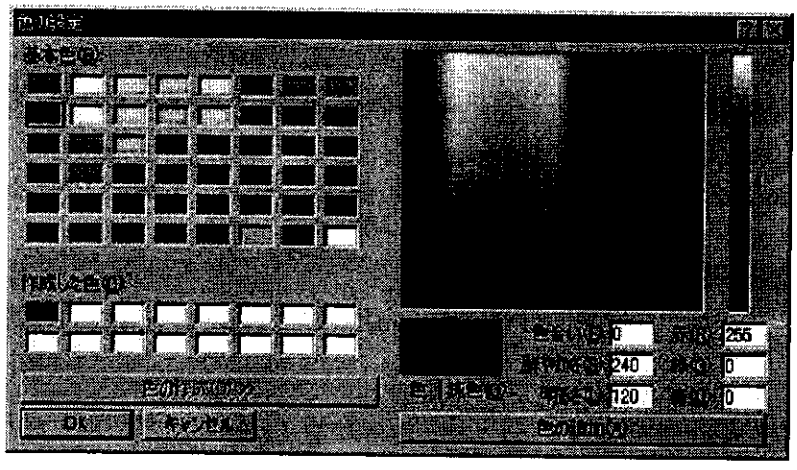

Fig. 6.65 Color Set Window (2)

[Default] button

This returns the colors to those when the product was shipped.

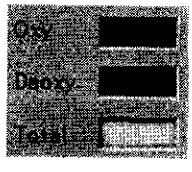

Fig. 6.66 Default Color When Shipped

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(2) Base Line

Perform setup of base line subtraction.

1) Base Line

Set whether the base line subtraction is applied or not.

2) Degree

Set the order of function fitting in the base line subtraction.

Options are as shown below:

- 0, 1, 2, 3, 4, 5

(3) Filter Set

Perform setup of filters

1) LPF (Cutoff of low pass filter)

Set LPF frequency [kHz]. Entry range is 0.001~4.999 [Hz]. Increment /decrement of the up/down button are 0.001. Also, it can be selected in the combo box. Options are as shown below:

- Off, 0.5, 1.0, 2.5

2) HPF (Cutoff of high pas filter)

Set HPF frequency [kHz]. Entry range is 0.001~4.999 [Hz]. Increment /decrement of the up/down button are 0.001. Also, it can be selected in the combo box. Options are as shown below:

- Off, 0.001, 0.01, 0.1

3) Tap

Set the window width at the left and right with data when each filter was set as a center. Entry range is odd values of 3~255. Increment /decrement of the up/down button are 2.

4) Window Selection

Select any window function to cut signal when each filter was set.

Options are as shown below:

- Rectangle, Hanning, Hamming

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(4) Exception Ch

When S/N of measurement channel signal is low, the channel is excluded. Background color of the graph of excluded channel becomes dark gray in order to discriminate it from the other display. Also, the topographic image is created with Hb value of measurement channel excluded as 0 [mmol*mm] and displayed

■ Supplement

- Measurement channel excluded is not a subject of judging body movement.
- When any damaged LD is detected on the Probe Set window, relevant measurement channel is automatically excluded.
- When Hb Range is Auto [Peak to Peak] - ALL or Auto [+/−Max] - ALL, excluded measurement channel is not a subject of retrieving Max and Min.

1) Mode

Select the low S/N signal exception mode. Options are as shown below:

- Off (default)

  The low S/N signal exception is not executed.
- Auto

  In Probe Set, "Over" and "Under" channels are automatically excluded.
- Manual

  Any channel may be excluded. When completing Probe Set, "Over" and "Under" channels are automatically excluded.

2) Manual Set

This is active only when Mode is Manual. Clicking on it displays the following dialog:

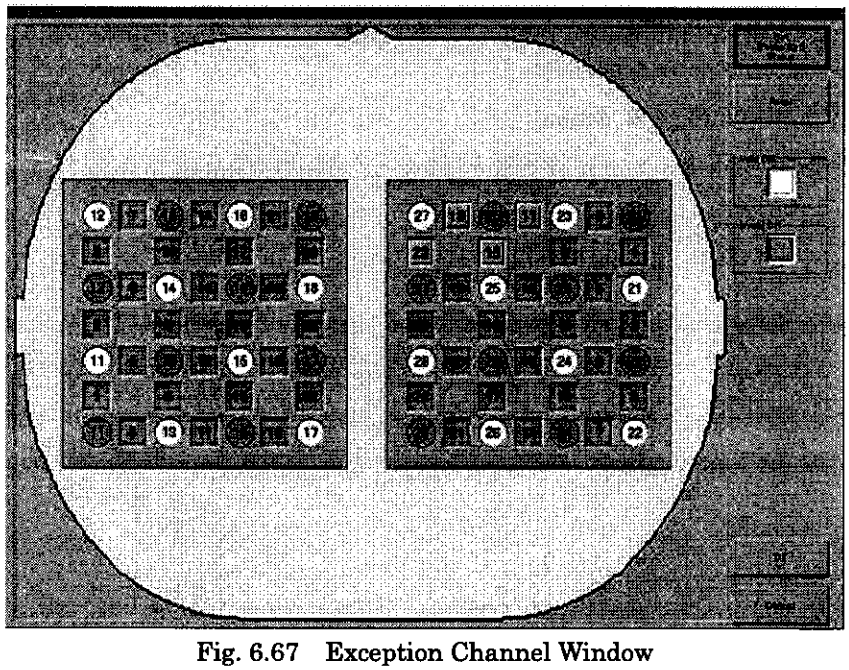

Fig. 6.67 Exception Channel Window

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Each channel button : Select exclude or not exclude. Depending on the result of executing Probe Set, colors of buttons and its border will be green (Normal Gain), red (Over Gain) or yellow (Under Gain). When color of any button is gray, it indicates unselected (excluded), while other cases indicate selected (not excluded).

[Reset] button : Contents currently set are canceled, and all channels are selected (not excluded).

[Get Probe Set Status] button : Depending on the result of executing previous Probe Set, each channel button is selected or unselected. "Over Gain" and "Under Gain" channels when executing Probe Set are unselected (excluded). Any "Normal Gain" channels are selected (not excluded).

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6.2.4 External parameters

Set parameters related to external input and output.

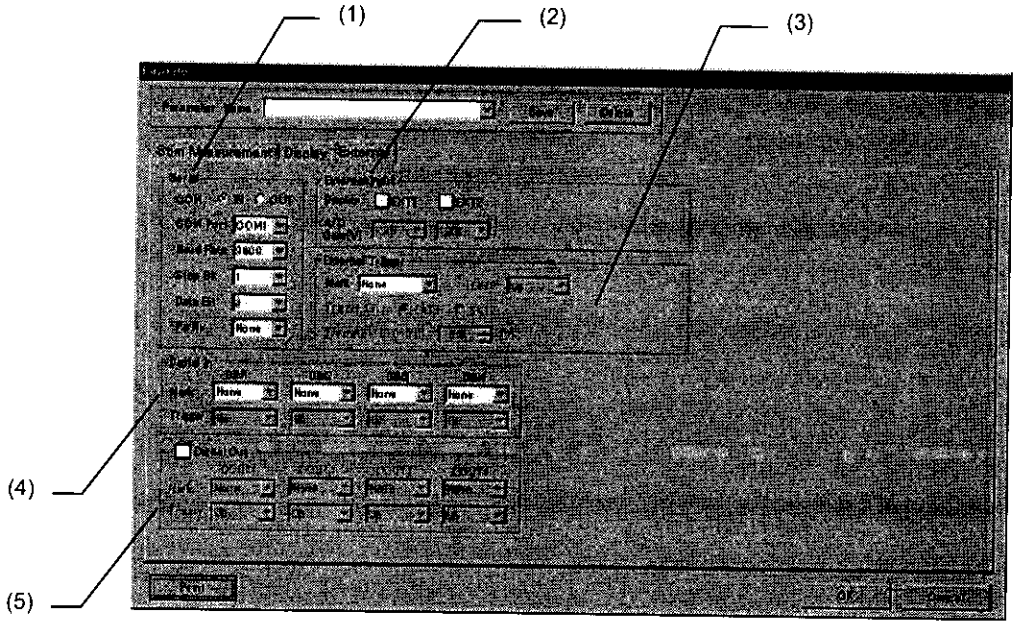

Fig. 6.68 External Parameter Window

(1) RS-232C

Carry out setup related to RS-23C communication.

For relevant commands, see [4.7.3 Using serial communication (RS-232C)].

1) COM IN/OUT

Select direction of command transmission and reception. Options are as shown below:

- IN (Select if signals such as external mark input are to be received.)
- OUT (Select if signals such as external mark output are to be transmitted.)

2) COM Port

Select the port number. Options are as shown below:

- COM1 (Default)
- COM2

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3) Baud rate

Select the baud rate. Options are as follows:

- 2400
- 4800
- 9600 (Default)
- 19200

4) Stop Bit

Select stop bit. Options are as follows:

- 1 (Default)
- 2

5) Data Bit

Select the number of data bits. Options are as follows:

- 7
- 8 (Default)

6) Parity

Select the parity bit. Options are as shown below:

- Odd
- Even
- None (Default)

(2) External Type

Carry out setup related to external input signal

1) Display

Select whether the external input signal graph is to be displayed or not.

EXT (external input signal flag) selected is displayed at the bottom of Hb Time Course screen.)

2) A/D Gain

Select display the range [V] of external input signal graph. Options are as follows:

- 1.25, 2.5, 5.0

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(3) External Trigger

Carry out setup related to external input signal trigger

1) Mark

Select valid/invalid of Stimulation setting of external input signal.

- *None*

  No mark input by external input signal trigger

- *J, M*

  ① Any mark can be inputted following the setting of external input signal trigger edge.

  At this time, types of input stimulation are:

  For analog signal

  J is assigned definitely for the Stim measurement, while M for the Event measurement.

  For digital signal

  A~J is assigned definitely for the Stim measurement, while F1~F9 and M for the Event measurement.

- *Sequence*

  ② Any mark can be inputted following the setting of external input signal trigger edge.

  However, external signal inputted within the set time of StimTime + RalaxTime is not accepted in the Stim measurement, while RelaxTime in the Event measurement.

  Also, the order of mark input at this time follows the setting of Sequence (Mark input order) in the Stim Measurement tab or Event Measurement tab.

2) Trigger Ch

Select either channel to be the trigger of stimulation mark input. Options are as follows:

EXT1, EXT2

3) Threshold

Set the threshold [V] of trigger of stimulation mark input. Entry range is 0.0~5.0 [V]. Increment/decrement of the up/down button is 0.1.

4) Trigger

Select either edge direction of stimulation mark input trigger. Options are as follows:

- *Up*

  Mark is inputted when signal exceeds the threshold upward.

- *Down*

  Mark is inputted when signal exceeds the threshold downward.

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(4) Digital In

When Mark In is External, mark insert type by digital input can be selected. Utilize terminals provided at the rear of equipment for (DIN1~4).

(See Fig. 2.5.)

1) Mark

Mark type selection

Common items

- None (Mark input by digital signal is not performed. No Trigger is available for selection.)
- START (Measurement by digital signal can be started.)
- STOP (Measurement by digital signal can be stopped.)

Items by measurement type

Stim measurement	Event measurement
· A	· F1
· B	· F2
· C	· F3
· D	· F4
· E	· F5
· F	· F6
· G	· F7
· H	· F8
· I	· F9
· J	· M

2) Trigger

Method to receive digital signals can be selected.

- Up (Mark is inserted at rise-up. Low→High)
- Down (Mark is inserted at rise-down. High→Low)

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(5) Digital Out

Output of digital signal when the mark designated is inserted can be selected.

Type of Mark In has no meaning at this time.

(For DOUT1~4, utilize the terminals provided at the rear of equipment.)

1) Mark

Mark type selection

- None (Digital signal output by mark input is not available. Trigger cannot be selected.)
- START (Digital signal is outputted at measurement start.)
- STOP (Digital signal is outputted at measurement stop.)

Items by measurement type

Stim measurement	Event measurement
· A	· F1
· B	· F2
· C	· F3
· D	· F4
· E	· F5
· F	· F6
· G	· F7
· H	· F8
· I	· F9
· J	· M

2) Trigger

Method of sending digital output signals can be selected.

- Up (Rise-up, Low→High)
- Down (Rise-down, High→Low)

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6.2.5 Saving parameter setting

Parameter setting can be saved and loaded.

○ Overall view

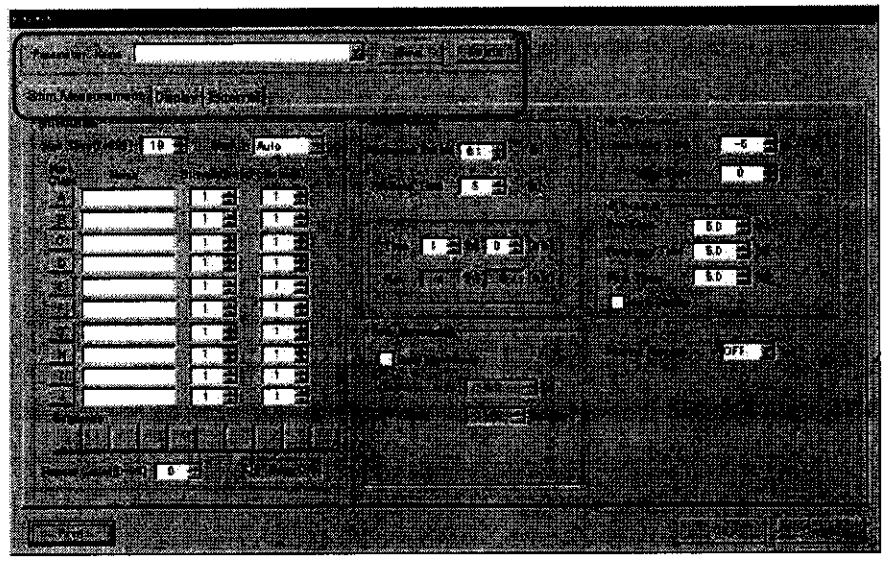

Fig. 6.69 Parameter Window (Overall view)

○ Upper section view

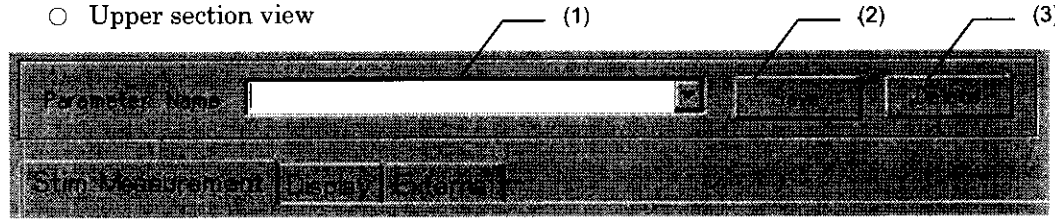

Fig. 6.70 Parameter Window (Upper section view)

(1) Parameter Name

A list of parameters saved in (2) is displayed in a combo box.

When a parameter is selected, the parameter file is loaded and reflected to the window. However, when current measurement data is not saved, a message of Check No. 11 (confirming deletion of measurement data) is displayed and loaded if it is OK.

(2) Save

Current parameters are saved as "parameter name.ini" designated in (1). When the same name exists, a message of Check No. 14 (confirming overwrite) is displayed and saved if it is OK.

(3) Delete

A message of Check No. 15 (confirming deletion) is displayed. If it is OK, parameter selected in (1) is deleted.

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6.3 Description on Probe Set Window

Clicking the [Probe Set] button] on the main screen displays the Probe Set window.
In this window, set the number, type, position and orientation of probe unit.
Setting in this window is reflected to any other data display window.
Also, setting of this window may be saved in (2) Probe Position Setting.

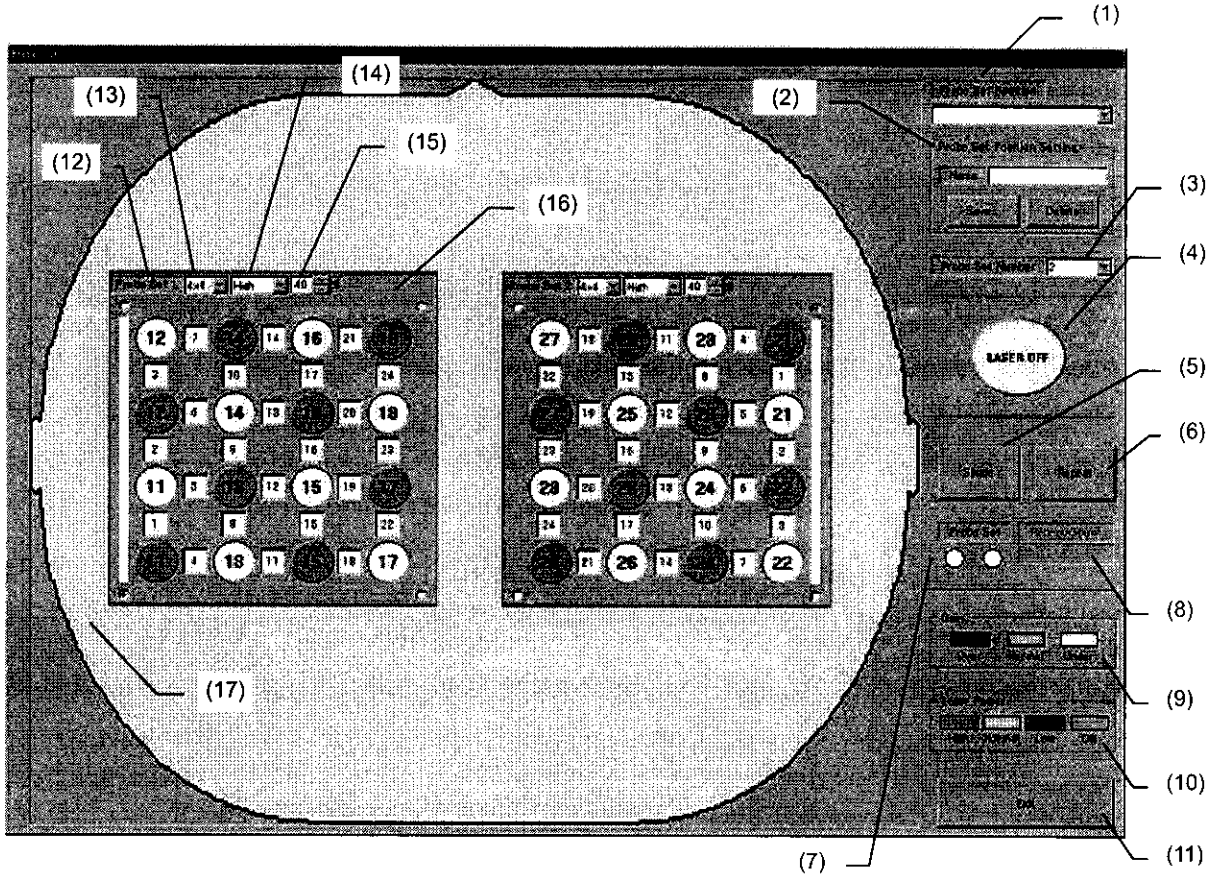

Fig. 6.71 Probe Set Window

(1) Probe Position

Probe position information registered is loaded and reflected.

(2) Probe Position Setting

Name	:	Designate the name with which current probe position information is to be saved.
Save	:	Save the current probe position information. Maximum number of registration is 10.
Delete	:	Delete probe position information being saved.

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(3) Probe Number

Select the number of proves to be used.

(4) Laser Power ON/OFF

Turn the laser power ON/OFF.

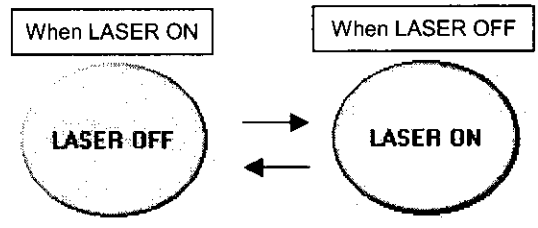

Fig. 6.72 Laser ON/OFF

(5) Single button

Performs Auto Gain once.

- Use the [Single] button for the normal one-time process.

(6) Repeat button

Repeats Auto Gain.

- The [Repeat] button repeats execution of Auto Gain adjustment and display of adjustment result until clicking the [Stop] button.

  Use this button for adjusting the optical fiber cable mounting or repeating checks.

(7) Probe

Informs that Auto Gain of each probe has been completed.

(8) Repeat Count

Displays the number of repeating times in Repeat.

(9) Gain

Displays the meaning of Auto Gain result colors

Red : Over gain
Yellow : Under gain
Green : Correct value
(Green: Measurement may be available even if it is not correct, but executing measurement in a correct state is preferable.)

(10) Laser Power

Displays the meaning of laser power colors.

(11) Exit button

Exits the Auto Gain process.

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(12) Probe1

Displays the probe number.

(13) 4×4

Displays the measurement mode.

Select from (4×4, 3×5, 3×3×2 and 3×11).

(14) Laser Power setting

Set laser power by probe unit.

Select from (High, Normal and Low, OFF).

- Default of power intensity is [High]. When there are many Over indications in the Auto Gain result, it is recommended to set it to [Low].

  [Low] is suitable for new born babies.

(15) Threshold

Set the threshold.

- Threshold (%) can increase/decrease laser intensity as well.

  It is adjustable in a range of 1~100. Default is 40%.

(16) Probe unit frame

Drag & drop the probe unit frame to move the probe unit to any position on top of the head.

(17) Probe orientation setting check box

Clicking the check boxes at four corners of probe unit allows probe No. to be rotated by 90° for setting orientation.

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6.4 File Related Operation

6.4.1 File Manager window

Selecting [File Manger] from the [Operation] button menu of main secreen displays the File Manager window. The size of File Manager window may be changed.

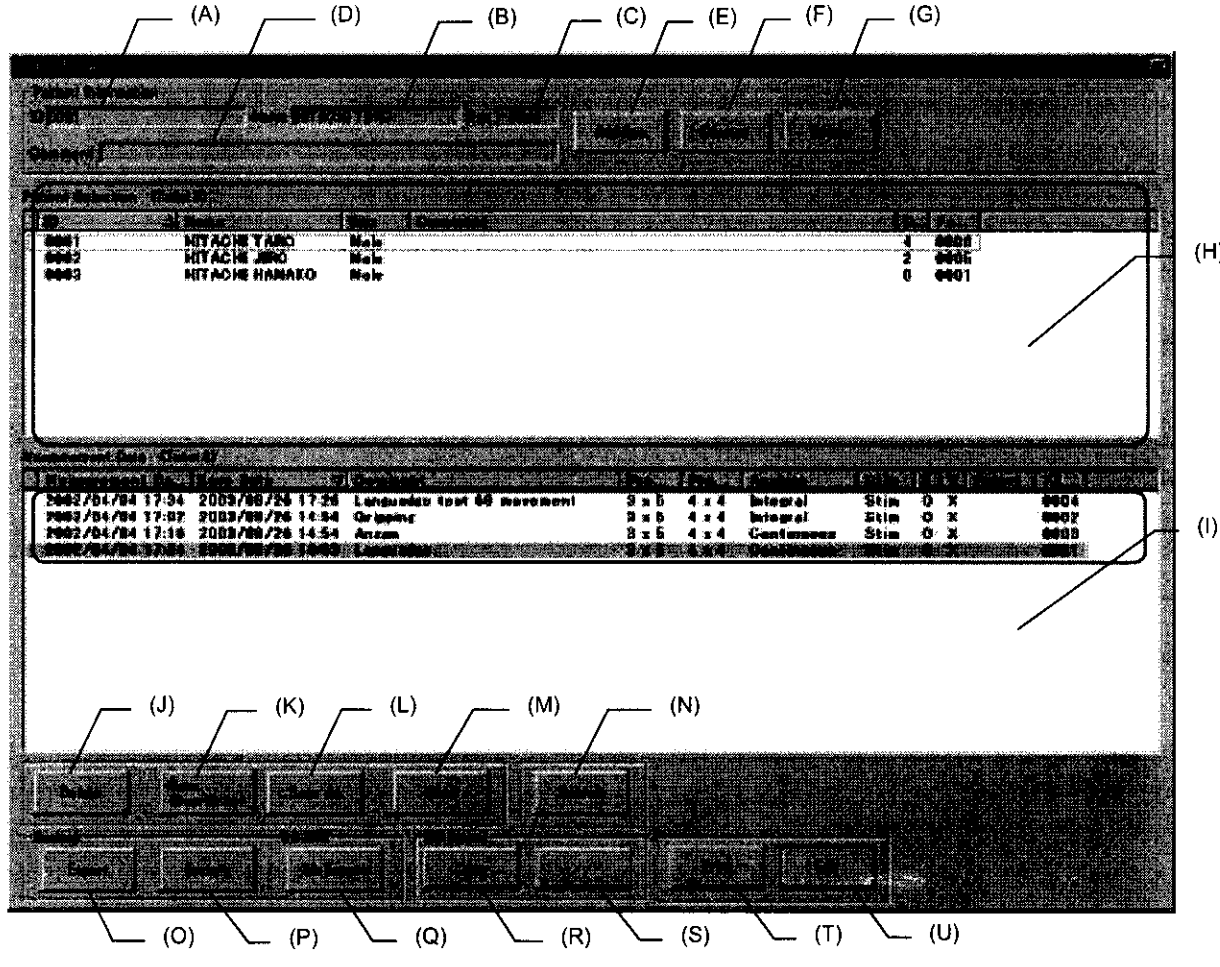

Fig. 6.73 File Manager Window

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(A) ID

Displays patient ID set in the patient information area (4.1.2) of main screen.

(B) Name

Displays patient name set in the patient information area of main screen.

Double clicking (A) ID and (B) Name field displays the following dialog to change contents respectively.

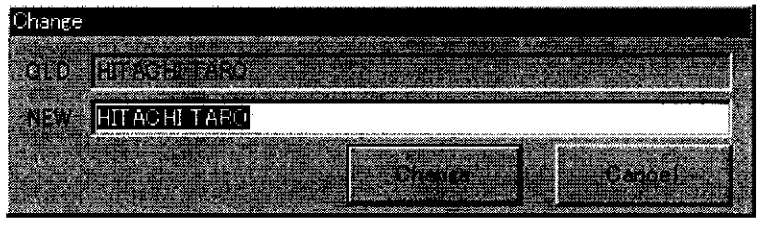

Fig. 6.74 Name Change Dialog

(C) Sex

Displays patient sex set in the patient information area of main screen.

(D) Comment

Displays a comment.

(E) Addition

This is used to newly add patient ID information.

When the same ID already exists in the [Patient Select], it cannot be clicked.

(F) Change

Displays a dialog to check patient information of data selected.

Fig. 6.75 Patient Information Change Dialog

(G) Delete

Entirely deletes patient information being selected and measurement data of the patient.

(H) Patient Selection

Displays a list of patient information. Clicking a title sorts the list with each item as a key. The figure below is sorted with ID as a key in the ascending order (△: ascending order, ▽: descending order). Also, dragging the border between titles changes display width of each item.

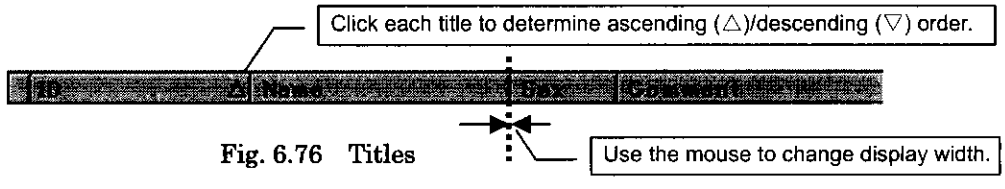

Fig. 6.76 Titles

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① ID	② Name	③ Sex	④ Comment	⑤ D.	⑥ Pat.
03-01-10	HITACHI TARO	Male		11	0001
03-01-11	HITACHI HANAKO	Female		1	0003
03-06-13	HITACHI JIRO	Male		1	0002

Fig. 6.77 Patient Data

① Displays the patient ID.

② Displays the patient name.

③ Displays patient sex.

④ Displays comment.

⑤ Displays the number of measurement data set

⑥ Displays patient No. (automatically attached by the system)

(I) Measurement Data

A list of measurement data information of the patient being selected is displayed. Clicking any title allows for sorting the list with each item as a key. The following figure is sorted with Measurement Date as a key (△: ascending order, ▽: descending order). Also, dragging the border between titles changes display width of each item.

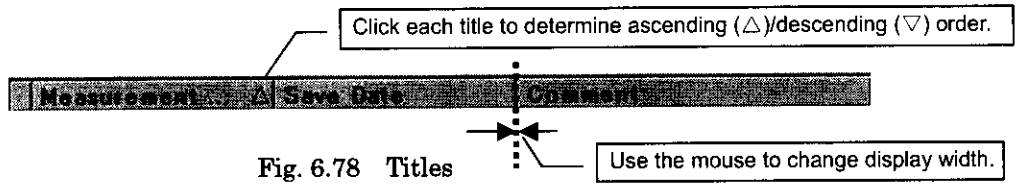

Fig. 6.78 Titles

① Measurement	② Save Date	③ Comment	④ Pro.	⑤ Pro.	⑥ Analyze	⑦ Stim	⑧ 3	⑨ 4	⑩ Error	⑪ File
2003/01/08 18:39	2003/01/08 18:41	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0001
2003/01/08 18:43	2003/01/08 18:44	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0002
2003/01/08 18:45	2003/01/08 18:47	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0003
2003/01/08 18:56	2003/01/08 18:59	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0004
2003/01/08 19:06	2003/01/08 19:09	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0005
2003/01/08 19:06	2003/01/14 11:40	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0006
2003/01/08 19:06	2003/01/14 11:40	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0007
2003/01/08 19:06	2003/01/16 13:35	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0008
2003/01/08 19:06	2003/01/27 09:35	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0009
2003/01/08 19:06	2003/03/03 10:33	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0010
2003/01/08 19:06	2003/03/03 10:33	Gripping	4 x 4	4 x 4	Continuous	Stim	X	X		0011

Fig. 6.79 Measurement Data

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① Display date and time of measurement.
② Displays data and time of saving measurement and analysis.
③ Displays comment.
④ Displays the shape of probe 1.
⑤ Displays the shape of probe 2.
⑥ Displays results of analysis (Continuous, Integral)
⑦ Displays type of stimulation (Stim, Event).
⑧ Displays presence of 3D Space (optional) data.
⑨ Displays presence of Video Capture (optional) data.
⑩ When measurement data is exported, this displays the destination folder.
⑪ Displays file No. (attached automatically by the system).

(J) Delete

Saved data being selected can be deleted.

(K) Save (Over Write)

Clicking the [Save] button displays the following dialog.

Data is saved overwriting the old data.

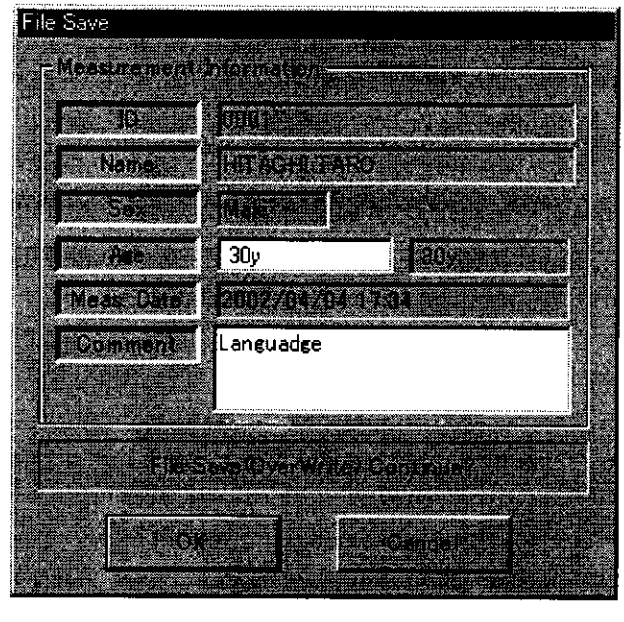

Fig. 6.80 File Save Dialog

- Patient age when measured can be changed.
- Comment for measurement can be changed.

Click the [OK] button to save data.

Click the [Cancel] button to return to the File Manager window without saving data.

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(L) Save As

Clicking the [Save As] button displays the following dialog.

This saves data without overwriting.

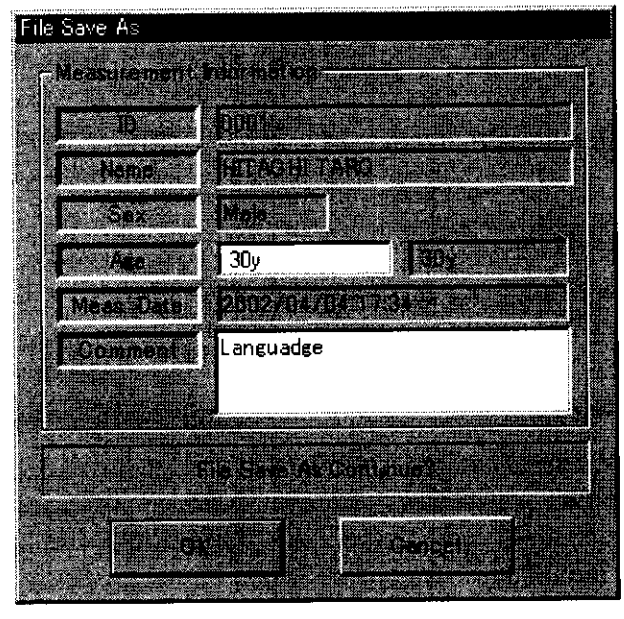


Fig. 6.81 File Save Dialog

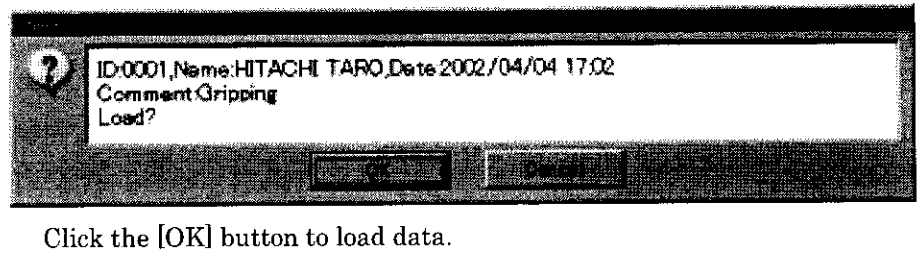
- Patient age when measured can be changed.
- Comment for measurement can be changed.

Click the [OK] button to save data.

Click the [Cancel] button to return to the File Manager window without saving data.

(M) Load

Click the [Load] button to display the following dialog.



Click the [OK] button to load data.

Click the [Cancel] button to return to the File Manager window without loading data.

(N) Search

Click the [Search] button to display the following dialog. Even if this dialog is displayed, operation of the File Manager window is available.

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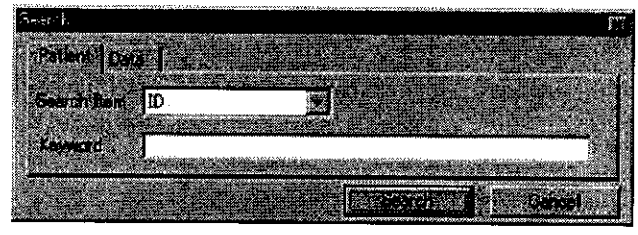

Fig. 6.82 Search Dialog

① Tab control (Patient/Data)

Select either of Patient or Data for searching.

② Search Item

Select any item to be searched. According to the search item, search type is switched over to text entry or options.

- Patient tab

Search item	Search type
ID	Text entry
Name	Text entry
Sex	Options: Male, Female
Comment	Text entry
Data Num	Text entry
Patient No	Text entry

- Data tab

Search item	Search type
Measurement Date	Text entry
Save Date	Text entry
Comment	Text entry
ProbeSet1	Options: 3×3, 4×4, 3×5, 3×11
ProbeSet2	Options: 4×4, 3×5
Analyze	Options: Measurement, Continuous, Integral
Stim	Options: Stim, Event
3D	Options: O, X
Video	Options: O, X
Export	Text entry
File No	Text entry

③ Search button

Starts search. Identified data are highlighted.

For text entry type, upper and lower cases are not sorted.

(O) Export

Outputs measurement data to any external device.

* Exported data is for backup, so it can be reloaded by the Import function. (Binary data is included.)

① Select any drive to which data is to be exported.

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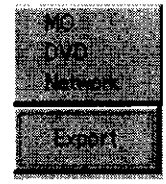

Fig. 6.83 Export Button

Selecting a drive displays the directory tree of destination. Select the folder to which data is to be exported.

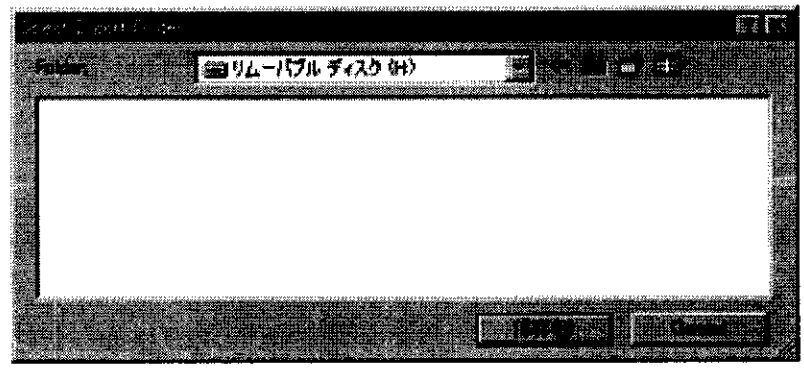

Fig. 6.84 Destination Folder Selection Window

② Measurement data selected for export on the File Manager window is listed with it highlighted.

- When any export data of the same ID exists in the destination folder, the data is not highlighted in the list.
- When any export data of the different ID in the destination folder, a message of WAR0034 appears and returns to ①.
- When any Hb Export data already exists in the destination folder, a message of WAR0040 appears and returns to ①.

Click the [OK] button to archive the data.

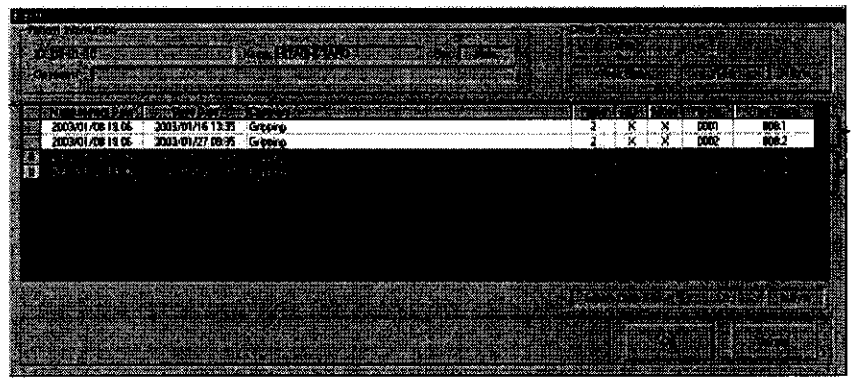

Fig. 6.85 List of Data to be Exported

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(P) Import

Exported data is registered to the database.

* Note that the Text File Out data cannot be reloaded.

① Select any drive in which an exported data exists.

Fig. 6.86 Import Data Selection

② Selecting a drive displays the directory tree of destination. Select a folder from which data is to be imported.

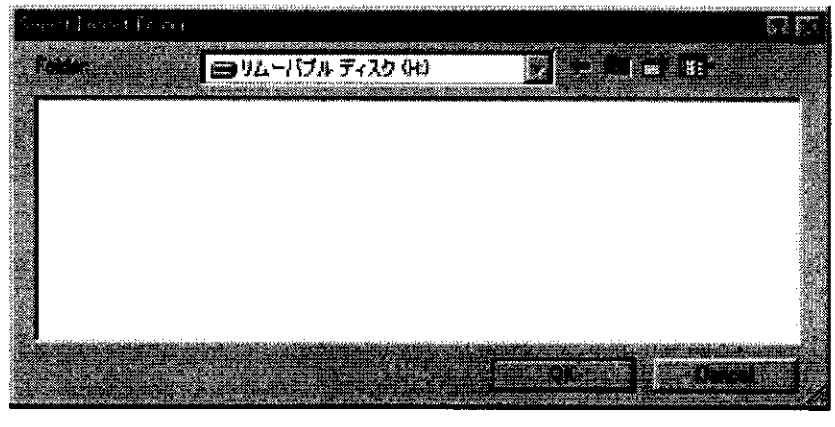

Fig. 6.87 Exported Data Selection Window

③ List up the exported data and select any data to be imported.

Pressing the [All Select] button selects all Exported data.

Press the [OK] button to import the data.

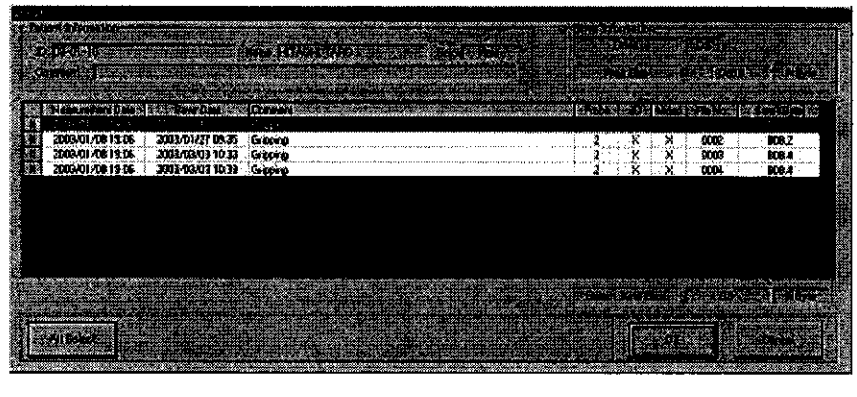

Fig. 6.88 List of Data to be Selected for Import

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(Q) Hb Export

Hb data can be exported to any external device.

Data exported by Hb Export may be imported by 3DMRI of optional functions.

① Select any drive to which data is to be exported.

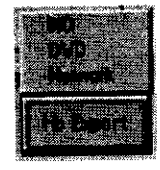

Fig. 6.89 Hb Export Data Selection

② When selecting the drive, the directory tree of destination folder is displayed. Select any output folder.

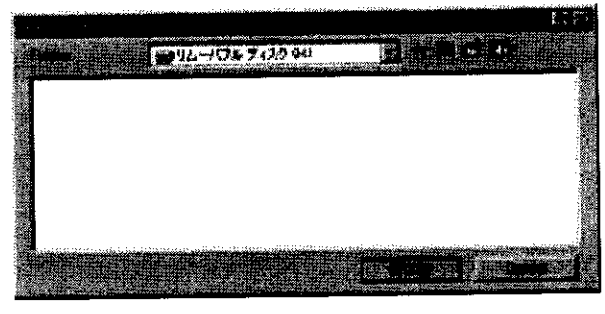

Fig. 6.90 Destination Selection Window

③ Measurement data selected on the File Manager window for Hb Export is listed with it highlighted.

- When Hb Export data of the same ID already exists in the destination folder, it is listed with it not highlighted.
- When Hb Export data of different ID already exists in the destination folder, a message of WAR0034 appears and returns to ①.
- When any Export data exists in the destination folder, a message of WAR0040 appears and returns to ①.

Click the [OK] button to archive the data.

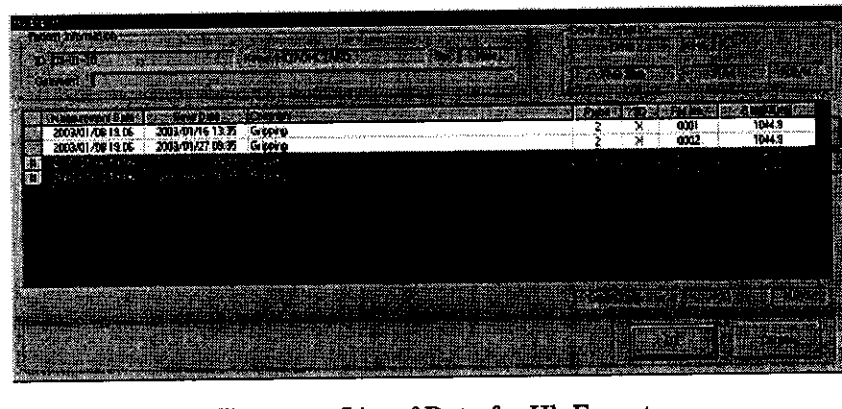

Fig. 6.91 List of Data for Hb Export

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(R) Copy button

If clicking this button to copy the 2D position information file, relevant measurement data number is saved in the memory. Actual file copy is performed by the (S) [Paste] button.

(S) Paste button

Pastes the 3D position information file.

(T) Print

Prints the File Manager window.

(U) Exit

Exit the File Manger.

6.4.2 Text File Out

If selecting [Text File Out] from the [Operation] button menu of main screen, the File Out window appears.

* This is of Excel format: therefore, the Import function cannot reload it.

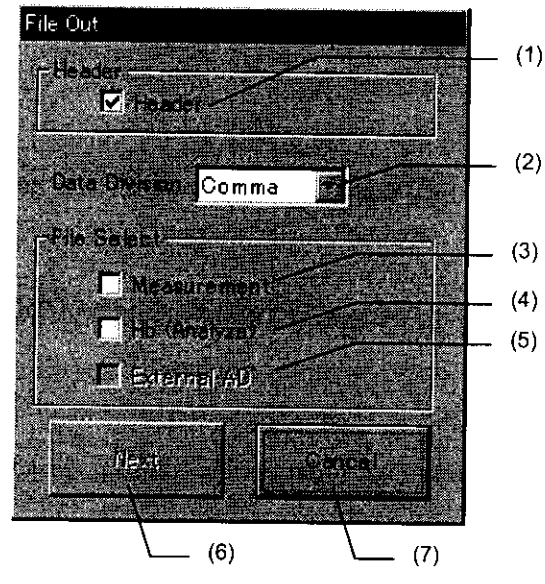

Fig. 6.92 File Out Window

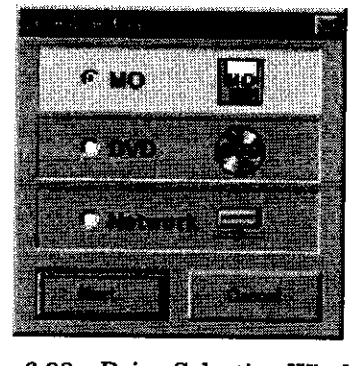

Fig. 6.93 Drive Selection Window

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If selecting any output drive and clicking [Next...], the Text File Out window appears.

Select any destination directory, enter file name and click the [Save] button.

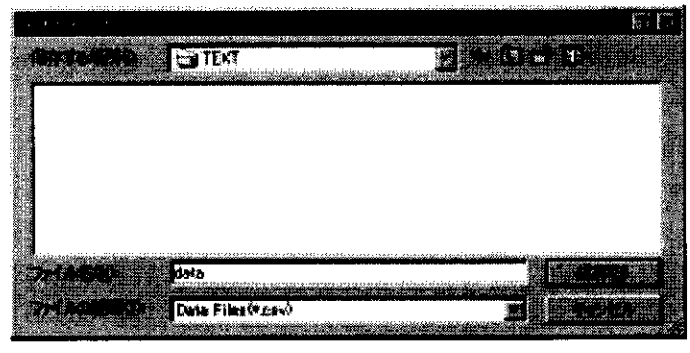

Fig. 6.94 Drive Selection Window

Outputted data is that selected and displayed before File Out.

(1) Header

Select whether header information is to be attached or not to the output file.

(2) Data Division

Select any letter for separation between output data. Options are as follows:

- Comma, Space, Tab, Semicolon

(3) Measurement

Select whether AD data is to be outputted or not.

(4) Hb

Select whether Hb data is to be outputted or not. "Hb (Measurement) is displayed for measurement mode, while "Hb (Analyze)" for analysis mode.

(5) External AD

Select whether external AD data is to be outputted or not.

However, only measurement data that external input signal was imported can be selected.

(6) Next

Displays the File Destination Selection dialog and exports the file to it.

(7) Cancel

Closes the dialog.

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6.4.3 Text File Out format

(1) Output file name

Output file is automatically named from the file name designated and the number of probe units.

The following table shows details.

(Ex.) File name designated : 00
The number of probe units : N

Table 6.1 Output File Name

Data type	File name	Data contents
Measurement	00_MES_Probe1.csv : : 00_MES_ProbeN.csv	Measurement data of probe unit 1 : : Measurement data of probe unit N
Hb	00_HBA_Probe1_Oxy.csv 00_HBA_Probe1_Deoxy.csv 00_HBA_Probe1_Total.csv : : 00_HBA_ProbeN_Oxy.csv 00_HBA_ProbeN_Deoxy.csv 00_HBA_ProbeN_Total.csv (_HBM_ for measurement mode, _HBA_ for analysis mode)	Hb-Oxy data of probe unit 1 Hb-Deoxy data of probe unit 1 Hb-Total data of probe unit 1 : : Hb-Oxy data of probe unit N Hb-Deoxy data of probe unit N Hb-Total data of probe unit N
External AD	00_EXT.csv	External input analog data

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(2) Header output format

A file outputted with a header is added with patient information and measurement information.

The header section is common to all data types and 39 lines from the head of file.

The table below shows details:

Table 6.2 Header Output Format

Line No.	Output format	Description
1	Header	Header section
2	File Version	File version
3	Patient Information	Patient information
4	ID	Patient specific ID number
5	Name	Patient name
6	Comment	Comment on data
7	Age	Patient age
8	Sex	Patient sex (Male/Female)
9	Analyze Information	Information on analysis
10	Analyze Mode	Analysis mode (Continuous/Integral)
11	Pre Time[s]	Pre stimulation time [s]
12	Post Time[s]	Rest time post stimulation [s]
13	Recovery Time[s]	Recovery time after stimulation [s]
14	Base Time[s]	Time to calculation base line [s]
15	Fitting Degree	Degree of fitting curve
16	HPF[Hz]	HPF frequency [Hz]. No Filter when filter is not provided.
17	LPF[Hz]	LPF frequency [Hz]. No Filter when filter is not provided.
18	Moving Average[s]	Moving average [s]
19	Measure Information	Measurement information
20	Date	Date when measurement was performed
21	Mode	Probe type (3x3/4x4/3x5/3x11). ※ Nothing for External AD output
22	Wave[nm]	Wavelength [nm]
23	Wave Length, CH1(695.0),CH1(830.0),… CHN(695.0),CHN(830.0),	Detailed wavelength of each channel [nm]
24	Analog Gain, 1,…,N	Analog gain of each channel
25	Digital Gain, 1,…,N	Trimming gain of each channel
26	Sampling Period[s]	Sampling period of measurement data [s]
27	Stim Type	Stimulation type (STIM/EVENT)
28	Stim Time[s]	Stimulation time [s]
29	A,…J, または F1,…M	Stimulation time of each stimulation sequence [s]
30	Repeat Count	The repeating number of stimulation
31～39	Return	Spare area

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(3) Measurement output format

AD data (original) is outputted from PreScan.

File name is (File name designated)_MES_Probe (Probe unit number).csv.

Table 6.3 Measurement Output Format

Line No.	Output format	Description
1	Data	Data section No this line for the data without header
2	Probe, CH1(695.0),CH1(830.0) ...CHN(695.0),CHN(830.0), Mark, Time, BodyMovement, RemovalMark, PreScan	Title Probe unit number is outputted for the Probe number. N (the number of channels) of CHN is different depending on the probe unit. 3×5: N=24, 4×4: N=24, 3×5: N=22, 3×11: N=52.
3 : :	Item number, CH1(695.0),CH1(830.0), ... CHN(695.0),CHN(830.0), Mark, Time, BodyMovement, RemovalMark, PreScan	CH1~N (695): Measurement signal of laser light of which wavelength is 695 [nm]. Unit is [V]. CH1~N (830): Measurement signal of laser light of which wavelength is 830 [nm]. Unit is [V]. Mark: Stimulation mark letter (see the table below for outputted letter). Stimulation mark letters are outputted at the start point and end point in the Stim measurement, while at the point where an event occurred in the Event measurement. '0' is outputted for other cases. Time: Actual time measured (hh:mm:ss.s) is outputted. BodyMovement: Body movement position (1) or not (0) is displayed. RemovalMark: Removal mark (1) or not (0) is displayed. PreScan: Data in PreScan (1) or not (0) is displayed.

List of stimulation marks

Stimulation mark letters of '1'~'10' are outputted.

Table 6.4 Stimulation Mark Letters

Stimulation mark letter	1	2	3	4	5	6	7	8	9	10
Stim measurement	A	B	C	D	E	F	G	H	I	J
Event measurement	F1	F2	F3	F4	F5	F6	F7	F8	F9	M

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(4) Hb Output format

Hb data is outputted.

In the Continuous analysis, data after completing PreScan is outputted.

However, file name is (file name designated)_HBA_Probe(Probe unit number)_(Hb type).csv.

However, "_HMA_" is _HBM_ in the measurement mode and _HMA_ in the analysis mode.

Table 6.5 Hb Output Format

Line No.	Output format	Description
1	Data	Data section. No this line for data without header.
2	Probe No. (Hb type), CH1~CHN, Mark, Time	Title Probe unit number is outputted for Probe number. Oxy, Deoxy or Total is outputted for probe type. N (number of channels) of CHN differs depending on each probe unit. 3×5: N=24, 4×4: N=24, 3×5: N=22, 3×11: N=52
3 : :	Item No., CH1,~CHN, Mark, Time, BodyMovement, RemovalMark, PreScan	CH1~N: Hb data, unit is [mmol*mm] Mark: Stimulation mark letter Stimulation mark letters are outputted at the start point and end point in the Stim measurement, while at the point where an event occurred in the Event measurement. '0' is outputted for other cases. Time: actual measured time (hh:mm:ss.s) is outputted in the Continuous analysis, while relative time starting from 0.0 [s] is outputted in the Integral analysis. BodyMovement: Body movement position (1) or not (0). RemovalMark: Removal mark (1) or not (0). PreScan: Data in PreScan (1) or not (0)

(5) External AD output format

External AD data is outputted. Data from PreScan is outputted.

File name is (file name designated)_EXT.csv.

Table 6.6 External AD Output Format

Line No.	Output format	Description
1	Data	Data section, no this line for data without header
2	EXT_AD, CH1, CH2, Mark, Time	Title CH1 and CH are outputted when EXT1 (CH1) or EXT2 (CH2) is checked to ON.
3 : :	Item No., CH1, CH2, Mark, Time, BodyMovement, RemovalMark, PreScan	CH1, CH2: External input analog data. Unit is [V]. Mark: Stimulation mark letter. Stimulation mark letters are outputted at the start point and end point in the Stimulation measurement, but at the point where an event occurred in the Event measurement. In other cases, '0' is outputted. Time: Measured actual time is outputted (hh:mm:ss.s) BodyMovement: Body movement (1) or not (0) RemovalMark: Removal mark (1) or not (0) PreScan: Data in PreScan (1) or not (0)

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6.4.4 Bitmap File Out

Selecting [Bitmap File Out] from the [Operation] button menu of main screen displays the following window.

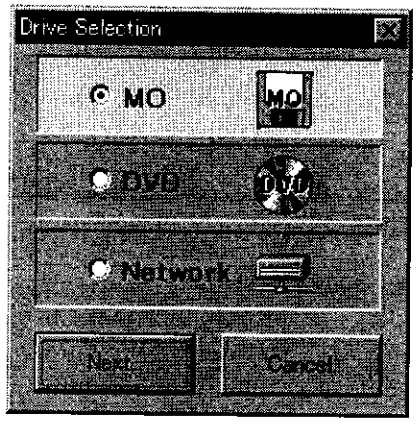

Fig. 6.95 Drive Selection Window

Select any output drive and click [Next...] to display the Bitmap File Out window. Select destination directory, enter file name and click the [Save] button.

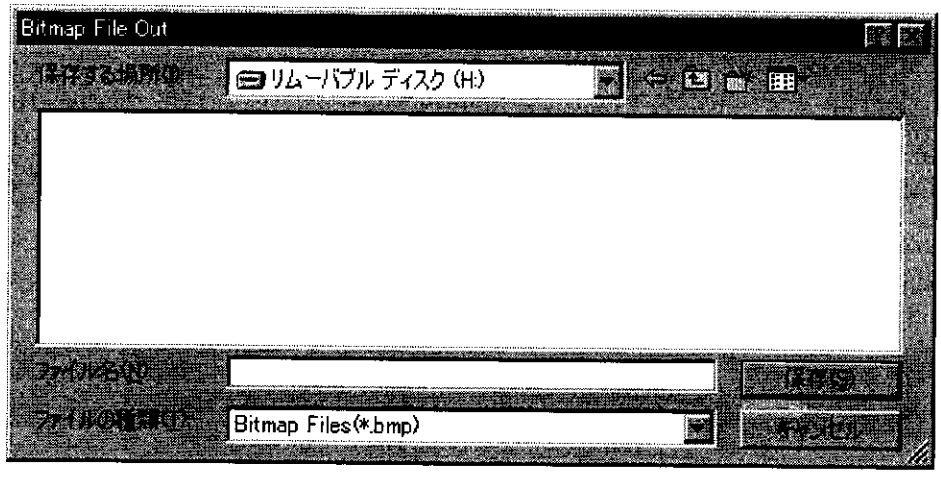

Fig. 6.96 Saving Destination Selection Window

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6.4.5 Animation File Out

If selecting [Animation File Out] from the [Operation] button menu of main screen, the following window is displayed.

Results continuously displayed in analysis are outputted in a cine file (AVI). Also, bitmap file can be outputted frame by frame.

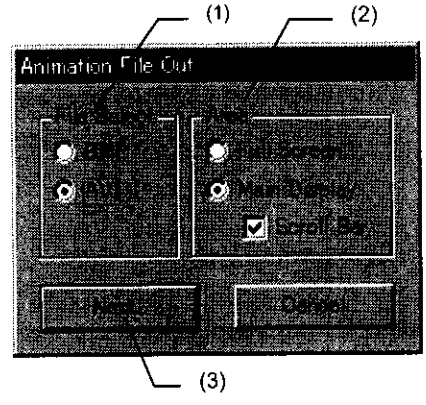

Fig. 6.97 Detailed Output Setting

(1) File Select

Select output file type.

- BMP, AVI

(2) Area

Select any area to display images to be outputted.

- Full Screen : Full main screen
- Main Display : Image display area of main screen
- Scroll Bar : Select whether the scroll bar is to be included or not. Selectable only when selecting Main Display

(3) Next (when selecting BMP file)

1) Displaying the drive selection window

Select any output drive and click [Next...].

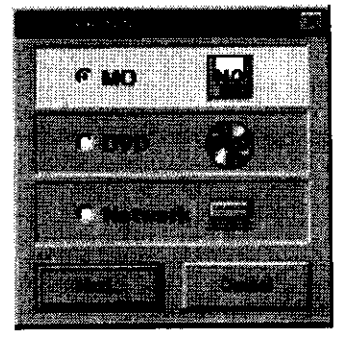

Fig. 6.98 Drive Selection Window

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2) Entering file name

Enter the file name into the following dialog to save it.

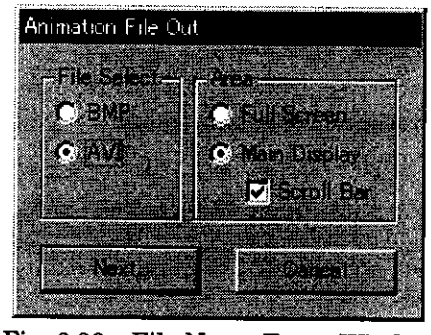

Fig. 6.99 File Name Entry Window

3) Setting output start/stop time

The [START] button varies to the following to set output start/stop time. Positions of output start/stop are depicted on the scroll bar as lines.

Fig. 6.100 Picture Scroll Bar

④ Output start time

Click the picture scroll bar to determine the start position.

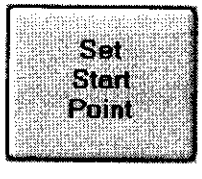

Fig. 6.101 Output Start Time

⑤ Output stop time

Click the picture scroll bar to determine the end position.

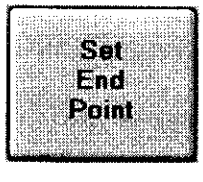

Fig. 6.102 Output Stop Time

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⑥ [START] button flickers

Click on it to continuously replay for the time designated.

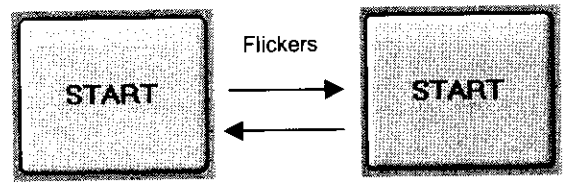

Fig. 6.103 [START] Button Flickers

⑦ [STOP] button flickers

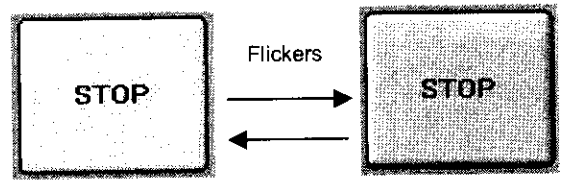

Fig. 6.104 [STOP] Button Flickers

After completing continuous replay, the [STOP] button flickers.

Click on it to return to the normal main screen operation.

(4) Next (When selecting AVI file)

1) Designate any compression method and click the [OK] button if acceptable. To stop selection, click the [Cancel] button.

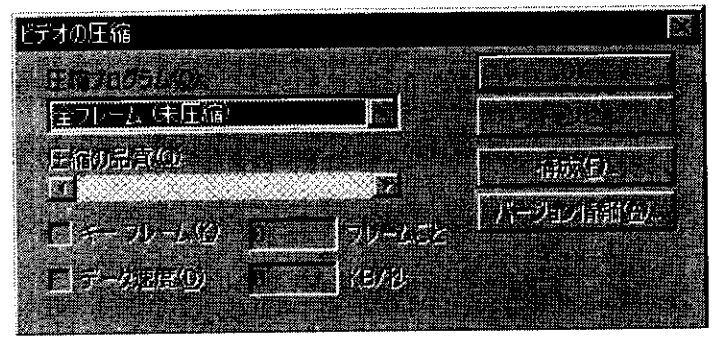

Fig. 6.105 Compression Method Selection Window

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2) Select any output drive and click [Next...].

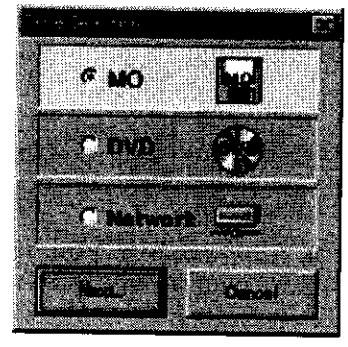

Fig. 6.106 Drive Selection Window

3) Entering file name

Enter the file name into the following dialog to save it.

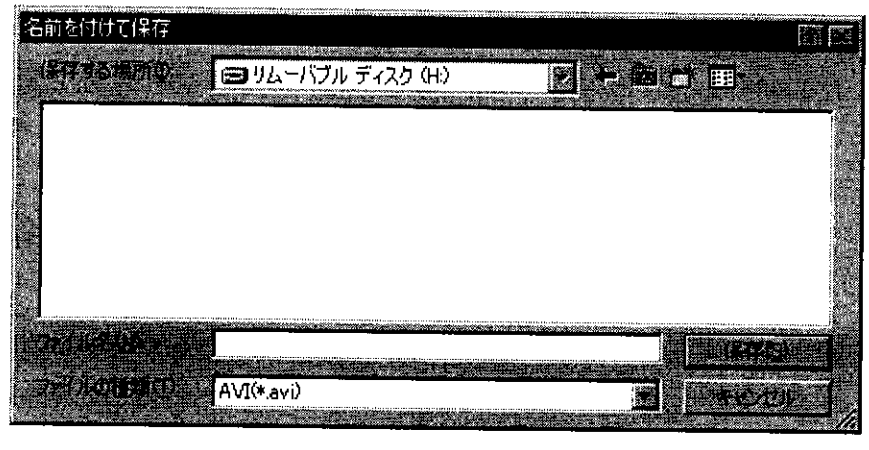

Fig. 6.107 File Name Entry Window

4) Setting output start/stop time

The [START] button varies to the following to set output start/stop time. Positions of output start/stop are depicted on the scroll bar as lines.

Fig. 6.108 Picture Scroll Bar

① Output start time

Click the picture scroll bar to determine the start position.

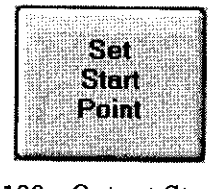

Fig. 6.109 Output Start Time

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② Output stop time

Click the picture scroll bar to determine the stop position.

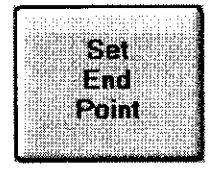

Fig. 6.110 [START] Button Flickers

③ [START] button flickers

Click on it to continuously replay for the time designated.

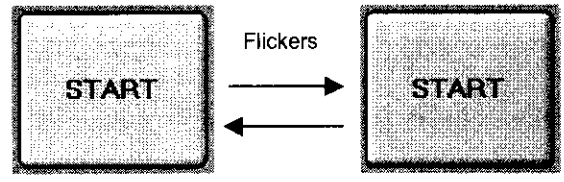

Fig. 6.111 [START] Button Flickers

④ [STOP] button flickers.

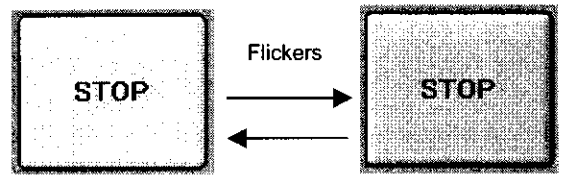

Fig. 6.112 [STOP] Button Flickers

After completing continuous replay, the [STOP] button flickers.

Click on it to return to the normal main screen operation.

6.4.6 Print

Selecting [Print] from the [Operation] button menu of main screen prints a hard copy of the screen being displayed in color or in black and white.

- To save printer ink, background colors of buttons and windows are printed in white.
- For operation of the print dialog window, see the instruction manual of printer.
- For operating the printer and replenishing it with paper and ink, see the instruction manual of printer.

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6.5 Description of Window Display

6.5.1 Hemoglobin time course graph display [Hb Time Course]

Select [Window] → [Hb Time Course] from the [DISPLAY] button menu of main screen to display the following window.

Hb time courses are displayed for probes provided. The window can be changed in its size and moved.

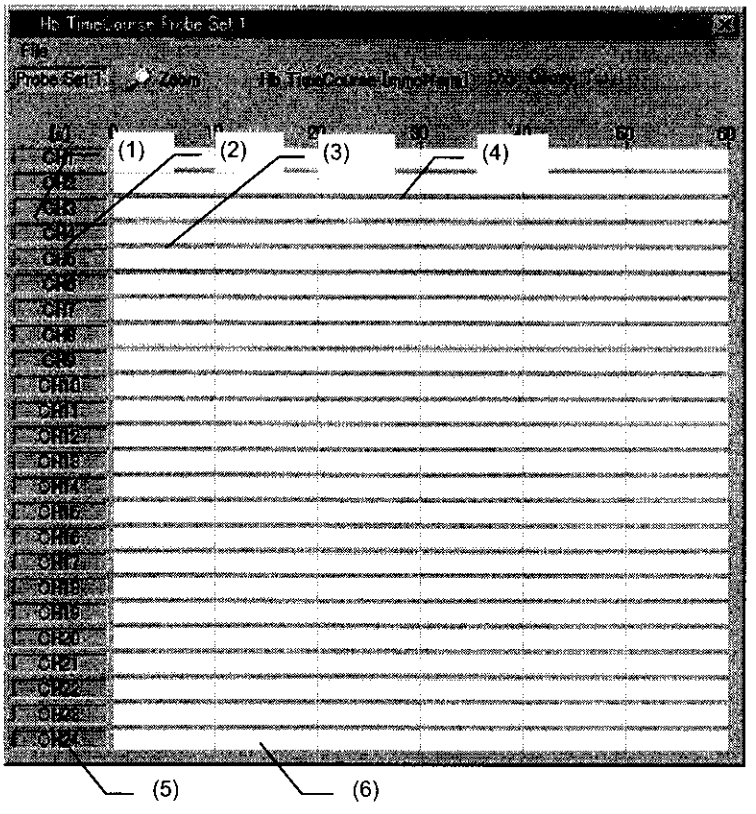
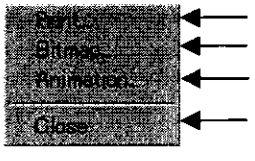


Fig. 6.113 Hb Time Course Window

(1) File menu



- Prints this window. (See [6.5.8].)
- Saves a bitmap file of this window. (See [6.5.9 (1)].)
- Outputs an AVI file. (See [6.5.10].)
- Closes the window. Window size and position are saved, and the same window will be displayed next time.

Fig. 6.114 File Menu

(2) Probe Set

Probe number is displayed.

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(3) Zoom

The channel selected in (5) is zoomed. Pressing the Zoom button while displaying enlarged returns display normal.

(4) Title bar

Title bars are displayed in different colors for Probe 1 and 2.

Fig. 6.115 Title Bars

(5) Channel selection

Select any channel to be zoomed.

(6) Graph display area

Hb graphs of each channel are displayed.

- For 3×3 probe, Hb graph is displayed in an area for 25 channels (rows) with a separator channel provided between 12 and 13 channels.
- When clicking on the graph, the time bar moves to the X-axis position clicked.
- When double clicking on the graph, the channel double clicked is enlarged.

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6.5.2 Hemoglobin mapping display [Hb Mapping]

Select [Window] → [Hb Mapping] from the [DISPLAY] button menu of main screen displays the following window.

Hb mapping graphs are displayed for probes provided. The window can be changed in its size and moved.

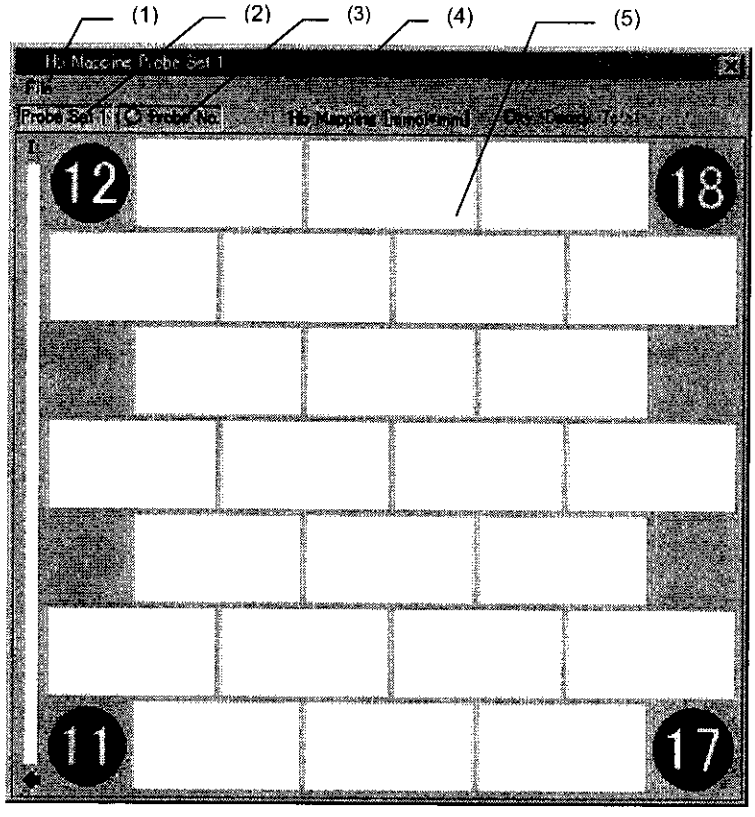
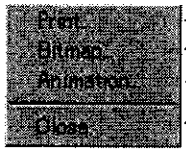


Fig. 6.116 Hb Mapping Window

(1) File menu



Prints this window. (See [6.5.8].)

Saves a bitmap file of this window. (See [6.5.9 (1)].)

Outputs an AVI file. (See [6.5.10].)

Closes the window. Window size and position are saved, and the same window will be displayed next time.

Fig. 6.117 File Menu

(2) Probe Set

Displays probe number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(3) Probe No

Displays probe number.

Set the Probe No. to ON/OFF.

- When ON

Probe No. : ■, ■

Probe orientation : ◆, ◆, ◆, ◆

Probe orientation bar: [ ]

(4) Title bar

Title bars are displayed in different colors for Probe 1 and 2.

Hb Mapping Probe1

Hb Mapping Probe2

Fig. 6.118 Title Bars

(5) Graph display area

Hb graphs of each channel are displayed according to actual channel layout.

- Relevant optical fiber cable numbers are displayed at four corners
- The sources are displayed in red and detectors in white number in a blue circle.
- If clicking on the graph, the time bar moves to the X-axis position clicked.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.5.3 Hemoglobin mapping graph display [Hb Mapping On Head]

Select [Window] → [Hb Mapping On Head] from the [DISPLAY] button menu of main screen to display the following window.

Whole hemoglobin mapping graphs are displayed for the probes provided.

Window can be changed in its size and moved.

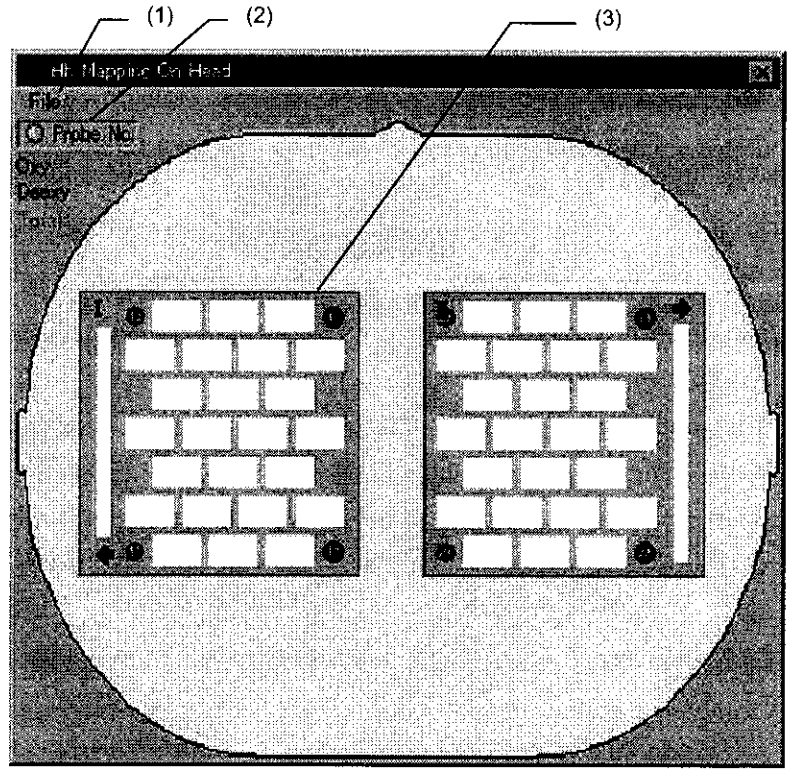

Fig. 6.119 Hb Mapping On Head Window

(1) File menu

- Prints this window. (See [6.5.8].)
- Saves a bitmap file of this window. (See [6.5.9 (1)].)
- Outputs an AVI file. (See [6.5.10].)
- Closes the window. Window size and position are saved, and the same window will be displayed next time.

Fig. 6.120 File Manu

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(2) Probe No

Probe number is displayed

Set the Probe No. to ON/OFF.

- When ON

Probe No. : [redacted], [redacted]

Probe orientation : [redacted], [redacted], [redacted], [redacted]

Probe orientation bar: [redacted]

(3) Graph display area

Hb graphs of each channel are displayed according to actual channel layout.

- Relevant optical fiber cable numbers are displayed at four corners
- The sources are displayed in red and detectors in white number in a blue circle.
- If clicking on the graph, the time bar moves to the X-axis position clicked.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6.5.4 2D topographic image display [Topo2D]

Selecting [Window] → [Topo2D] from the [DIPAY] button menu of main screen displays the following window.

2D topographic images are displayed for the probes provided.

The window can be changed in its size and moved.

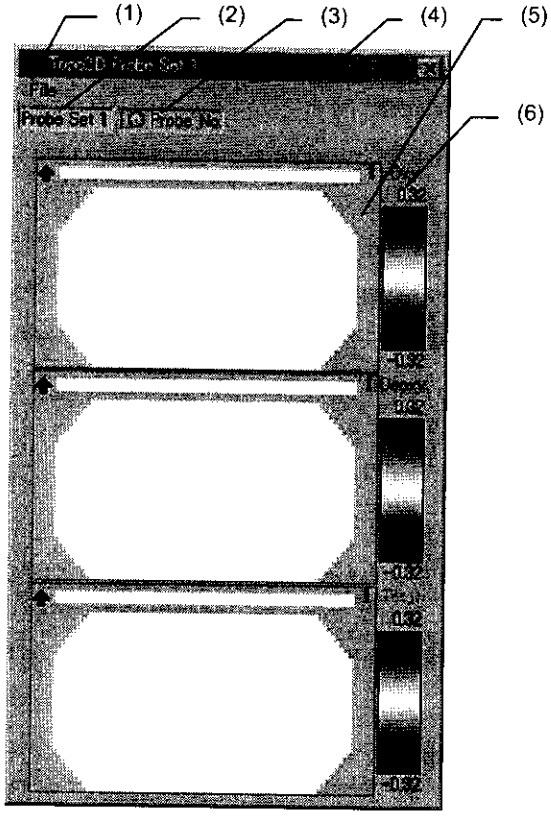

Fig. 6.121 Vertical Layout of Topo2D Images

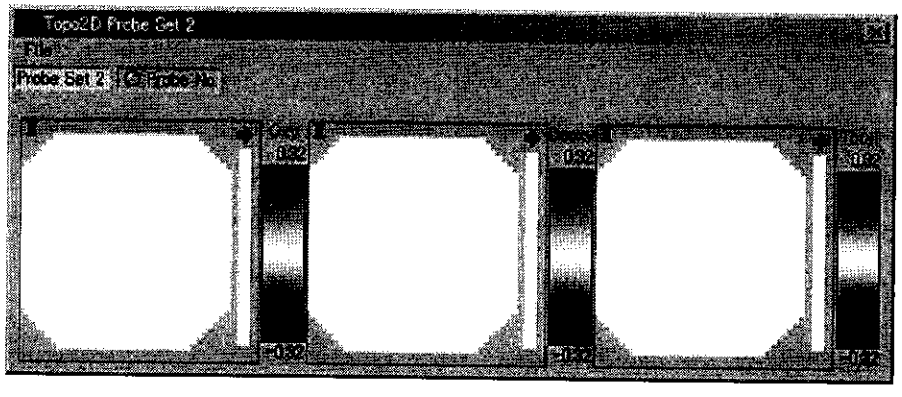

Fig. 6.122 Horizontal layout of Top2D Images

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(1) File menu

Prints this window. (See [6.5.8].)
Saves a bitmap file of this window. (See [6.5.9 (1)].)
Outputs an AVI file. (See [6.5.10).)
Closes the window. Window size and position are saved, and the same window will be displayed next time.

Fig. 6.123 File Menu

(2) Probe Set

Probe number is displayed.

(3) Probe No

Probe number is displayed

Set the Probe No. to ON or OFF.

- When ON

Probe No. : [redacted]
Probe orientation : [redacted]
Probe orientation bar: [redacted]

(4) Title bars

Title bars are displayed in different colors for Probe 1 and 2.

Fig. 6.124 Title Bars

(5) Topographic image display area

Displays topographic images

- Use the [DISPLAY] button to switch over Oxy, Deoxy and Total displays.
- For 3×3 probe, both A and B probes are displayed side by side in the horizontal layout, while they are displayed up and down in the vertical layout.

(6) Color bar

The color bar and Max and Min range of topographic image are displayed.

For 3×3 probe, only one color bar is displayed for both A and B probes.

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6.5.5 2D topographic image overall display [Topo2F On Had]

Selecting [Window] → [Topo2D On Had] from the [DISPLAY] button menu of main screen displays the following window.

The 2D topographic images are displayed for the probes provided.

The window can be changed in its size and moved.

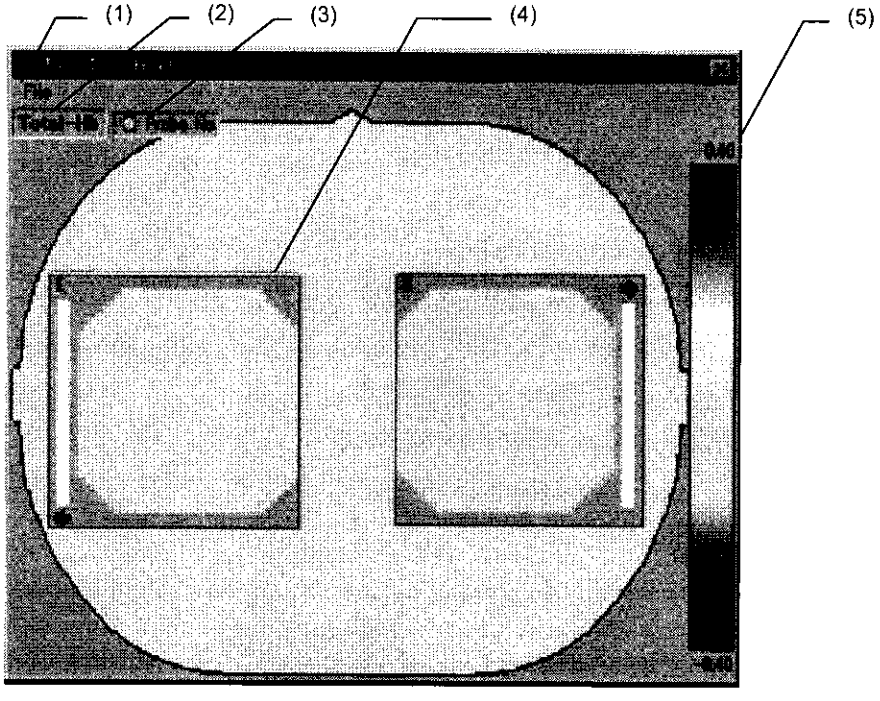
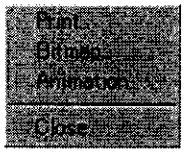


Fig. 6.125 Topo2D On Head Window

(1) File menu



Prints this window. (See [6.5.8].)

Saves a bitmap file of this window. (See [6.5.9 (1)].)

Outputs an AVI file. (See [6.5.10].)

Closes the window. Window size and position are saved, and the same window will be displayed next time.

Fig. 6.126 File Menu

(2) Displayed Hb type

Options are Oxy-Hb, Deoxy-Hb and Total-Hb.

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(3) Probe No

Probe number is displayed

Set the Probe No. to ON/OFF.

- When ON

Probe No. : [redacted], [redacted]

Probe orientation : [redacted], [redacted], [redacted], [redacted]

Probe orientation bar: [redacted]

(4) Topographic image display area

Topographic images are displayed.

- Clicking on the topographic image displays Hb value [mmol*mm] at the position clicked.

(5) Color bar

The color bar and Max and Min range of topographic image are displayed.

However, Max and Min range is not displayed if Hb Range is Each.

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6.5.6 Displaying signal status of measurement channel [AD Status]

Clicking [Window] → [AD Status] from the [DISPLAY] button menu of main screen displayed the following window.

- The window can be changed in its size and moved.
  However, it cannot be changed in its size and moved during measurement.
- In case of 2-Probe display, they are arranged vertically.
- Depending on SN, status is displayed in the following color:

Table 6.7 SN and Display Color

SN	Display color
Normal	Green
Under	Yellow
Over	Red
(Clear)	Gray

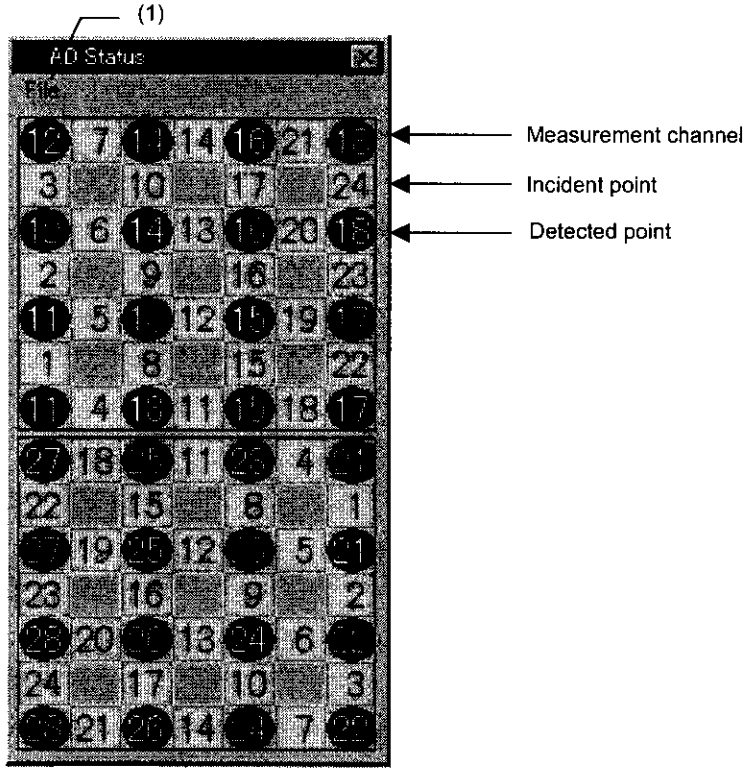

Fig. 6.127 AD Status

(6) File menu

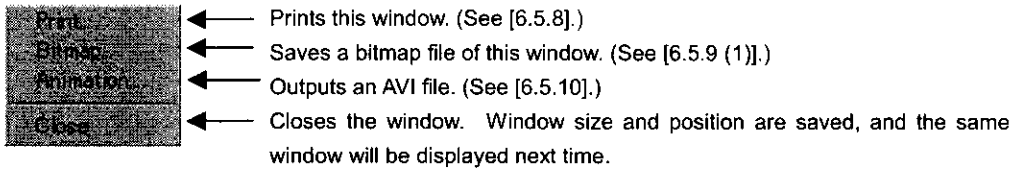

Fig. 6.128 File Menu

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6.5.7 Print of window display

Hardcopy of the window is printed in color or black and white.

- To save printer ink, background colors of buttons and windows are printed in white.
- For operation of the print dialog window, see the instruction manual of printer.
- For operating the printer and replenishing it with paper and ink, see the instruction manual of printer.

6.5.8 Bitmap File Out of window display

(1) For normal window

The following window appears. Select any destination and enter the file name.

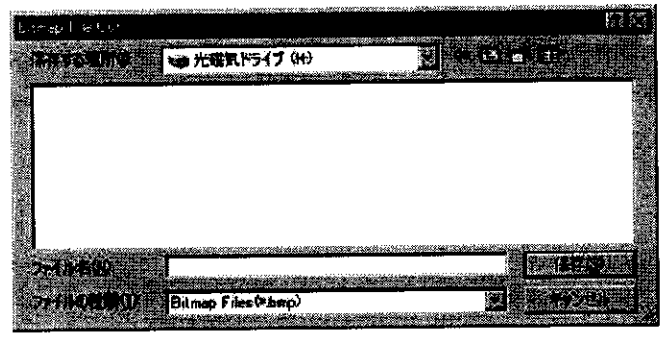

Fig. 6.129 Destination Selection Window

(2) For 2D topographic image display [Topo2D]

The following window appears. Select an output type (Hb Select), select the destination and enter the file name. When Hb Select is All, a BMP image of the whole window display area is outputted. In other cases, only Hb types selected are outputted in the BMP format.

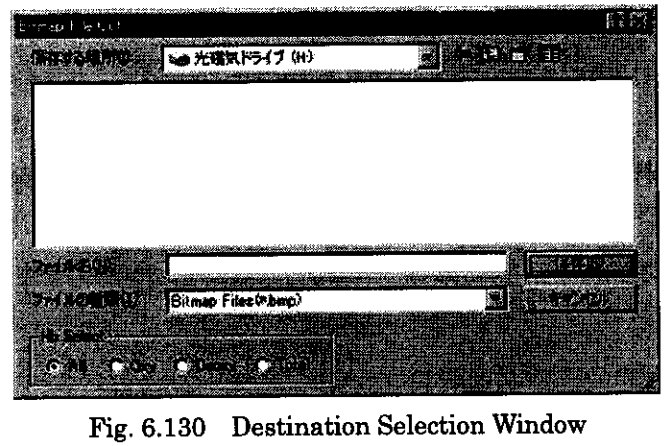

Fig. 6.130 Destination Selection Window

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6.5.9 Animation File Out of window display

The following window appears. The results continuously displayed in analysis are outputted in a cine file (AVI). Also, bitmap file (BMP) output is available frame by frame.

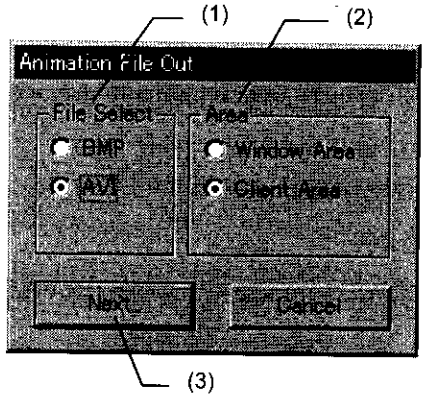

Fig. 6.131 Detailed Output Setting

(1) File Select

Select either output file format.

- BMP, AVI

(2) Area

Select either display area for output.

- Window Area : Entire window display area
- Client Area : Area with the title bar and outer frame excluded

(3) Next

See (3) Next (BMP file selected) of [6.4.5 Animation File Out] or (4) Next (AVI file selected) of [6.4.5 Animation File Out].

※ The window cannot be changed in its size and moved during output.

6.6 Description on Realtime Integral Display

Realtime Integral process displays an average for marks inputted during measurement.

(1) Press the [Parameter Set] button to display the [Parameter] dialog and set parameters.

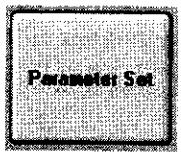

Fig. 6.132 [Parameter Set] Button

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Setting of [Stimulation], [Hb Integral], [Moving Average], [Body Movement] is reflected to display. Set these before starting measurement.

(For details, see [6.2.1].)

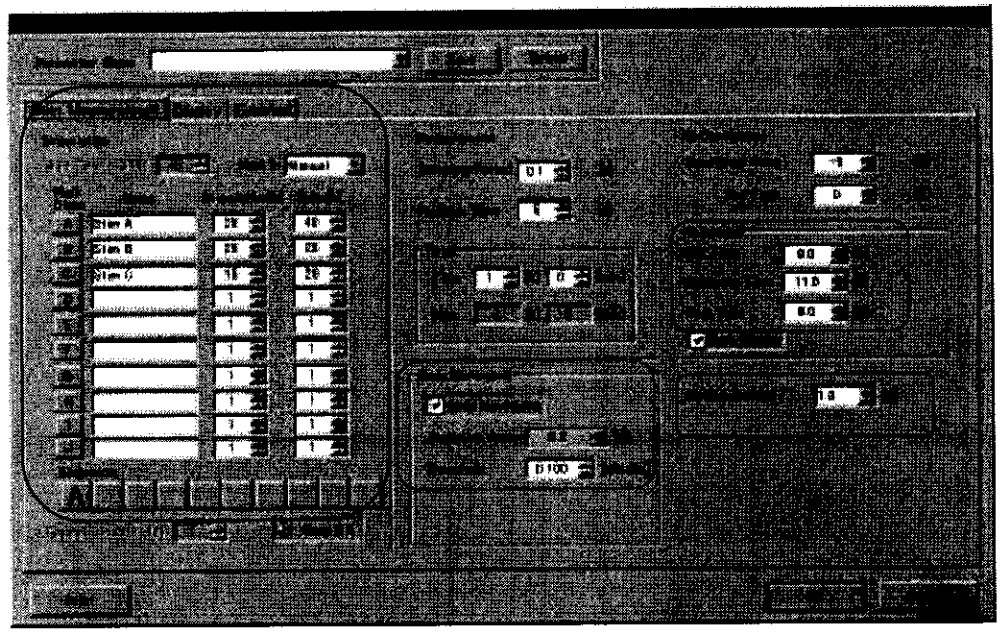

Fig. 6.133 Parameter Window

(2) To set [Moving Average] of the main screen, use [Moving Average] of the parameter window.

Fig. 6.134 Moving Average Setting

(3) Use [Realtime Integral] Mark to select a mark to perform Integral analysis. (Select any one of A~J having been set in Mark In.)

It becomes valid when displaying the Realtime Integral window

Stim measurement Event measurement

Fig. 6.135 Realtime Integral Analysis Mark Setting

(This cannot be set in the parameter window.)

(4) Open the result display window of Realtime Integral process before starting measurement.

Hb Time Course
Hb Mapping
Hb Mapping On Head
] Select any one of three.

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6.6.1 Hemoglobin time course graph [Hb Time Course]

Selecting [Realtime Integral] → [Hb Time Course] from the [DISPLAY] button menu of main screen displays data applied with the Realtime Integral process in the following window.

When selecting each menu item of Realtime Integral, a relevant daughter window is displayed. When any other realtime integral menu item is selected, current daughter window is automatically closed and selected daughter window is displayed

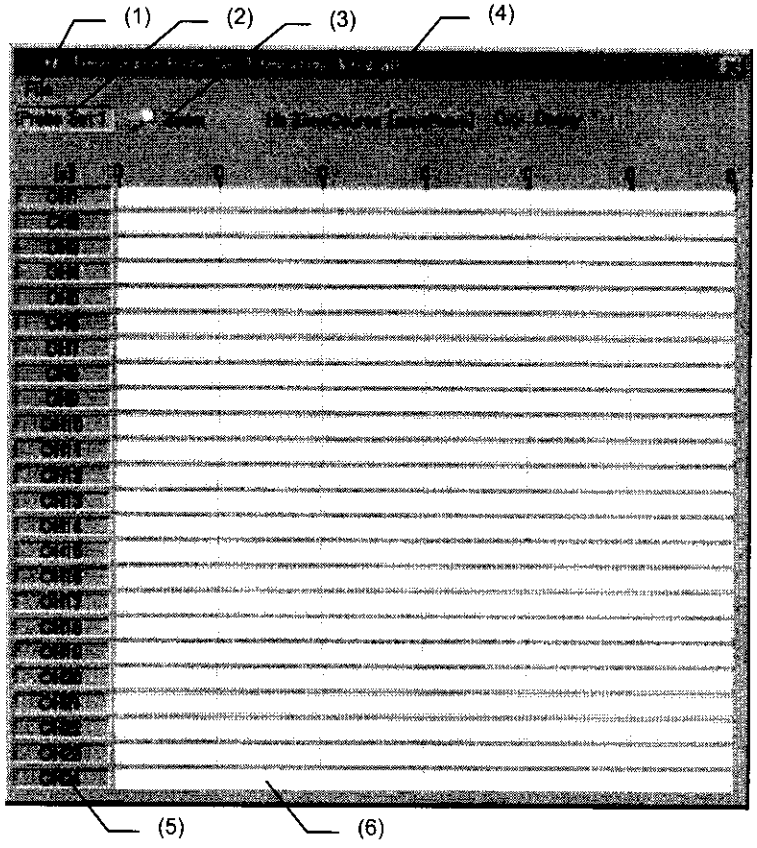
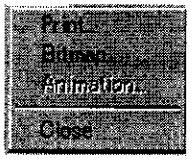


Fig. 6.136 Hb Time Course Window

(1) File menu



Prints this window. (See [6.5.8].)

Saves a bitmap file of this window. (See [6.5.9 (1)].)

Closes the window. Window size and position are saved, and the same window will be displayed next time.

Fig. 6.137 File Menu

(2) Probe Set

Displays probe number.

(3) Zoom

Channel selected in (5) is displayed enlarged. Pressing the Zoom button during zoomed display returns to normal display.

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(4) Title bars

Title bars are displayed in different colors for Probe 1 and 2.

Fig. 6.138 Title Bars

(5) Channel selection

Select any channel to be enlarged.

Select at least one.

(6) Graph display area

Displays Hb graphs of each channel.

- Clicking on the graph moves the time bar to the X-axis position clicked.
- Double clicking on the graph enlarges the channel clicked.

6.6.2 Hemoglobin mapping graph display [Hb Mapping]

Selecting [Realtime Integral] → [Hb Mapping] from the [DISPLAY] button menu of main screen displays data applied with Realtime Integral process in the following window.

The Hb mapping graphs are displayed for the probes provided. The window can be changed in its size and moved.

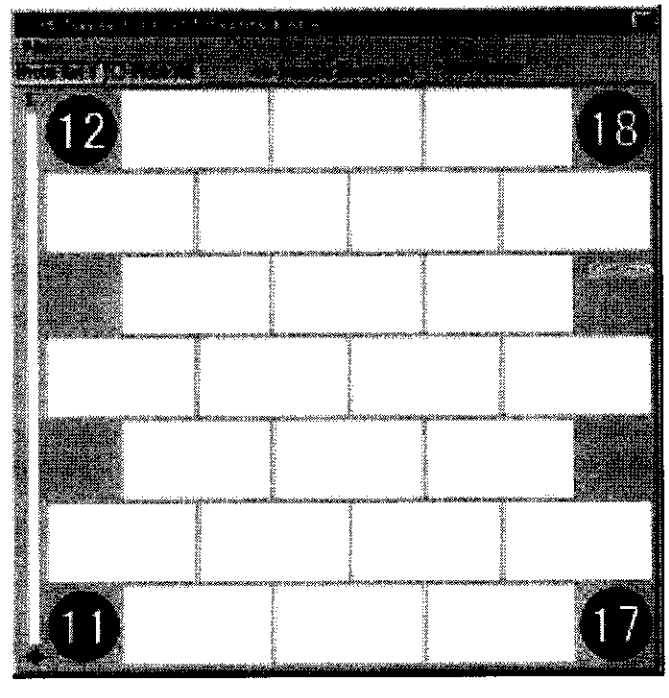

Fig. 6.139 Hb Mapping Window

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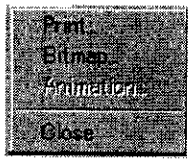
(1) File menu



Prints this window. (See [6.5.8].)

Saves a bitmap file of this window. (See [6.5.9 (1)].)

Closes the window. Window size and position are saved, and the same window will be displayed next time.

Fig. 6.140 File Menu

(2) Probe Set

Displays probe number.

(3) Probe No

Probe number is displayed

Set the Probe No. to ON/OFF.

- When ON

  Probe No. : [redacted]

  Probe orientation : [redacted]

  Probe orientation bar: [redacted]

(4) Title bars

Title bars are displayed in different colors for Probe 1 and 2.

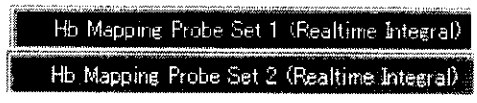


Fig. 6.141 Title Bars

(5) Graph display area

Hb graphs of each channel are displayed according to actual channel layout.

- Relevant optical fiber cable numbers are displayed at four corners
- The sources are displayed in red and detectors in white number in a blue circle.
- If clicking on the graph, the time bar moves to the X-axis position clicked.

6.6.3 Displaying whole hemoglobin mapping graphs [Hb Mapping On Head]

Selecting [Realtime Integral] → [Hb Mapping On Head] from the [DISPLAY] button menu of main screen displays data applied with the Realtime Integral process in the following window.

Whole hemoglobin integral mapping graphs are displayed for the probed provided.

The window can be changed in its size and moved.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118 251

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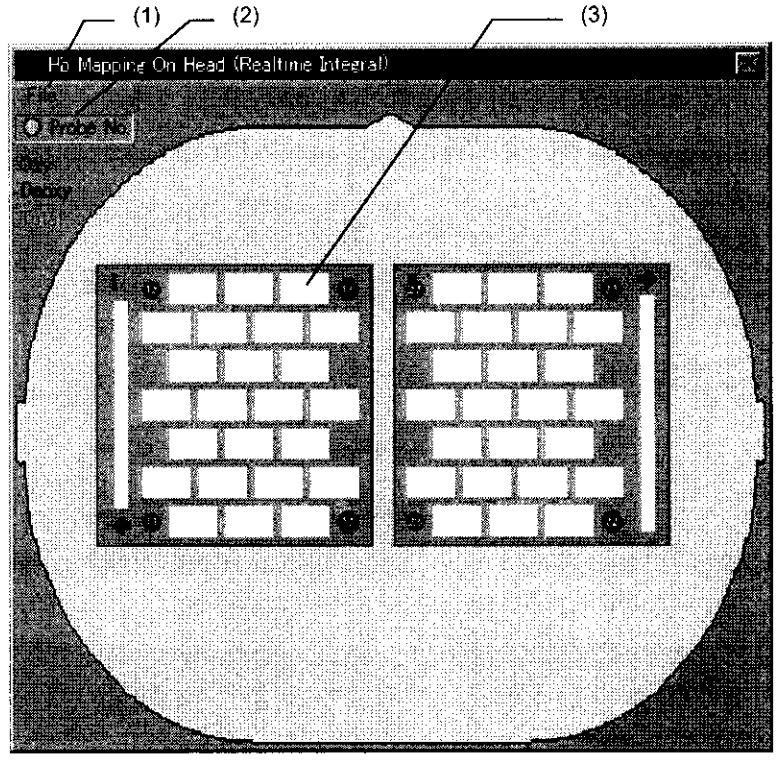
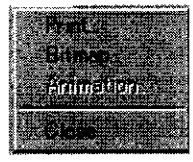


Fig. 6.142 Hb Mapping On Head Window

(1) File menu



Prints this window. (See [6.5.8].)

Saves a bitmap file of this window. (See [6.5.9 (1)].)

Closes the window. Window size and position are saved, and the same window will be displayed next time.

Fig. 6.143 File Menu

(2) Probe No

Probe number is displayed

Set the Probe No. to ON or OFF.

- When ON

  Probe No. : ■, ■

  Probe orientation : ●, ●, ●, ●

  Probe orientation bar: [ ]

(3) Graph display area

Hb graphs of each channel are displayed according to actual channel layout.

- Relevant optical fiber cable numbers are displayed at four corners
- The sources are displayed in red and detectors in white number in a blue circle.
- If clicking on the graph, the time bar moves to the X-axis position clicked.

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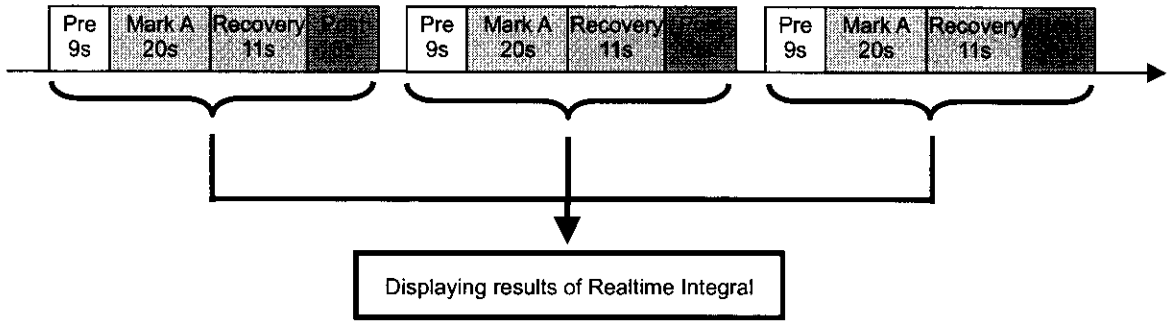
6.6.4 Example operation

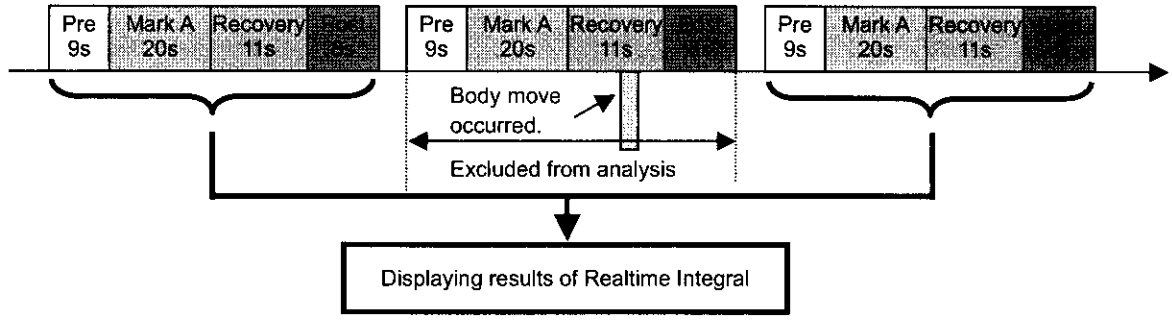
6.1.1.1 Stim measurement

Example operation shows a case in which Mark A is selected for display.

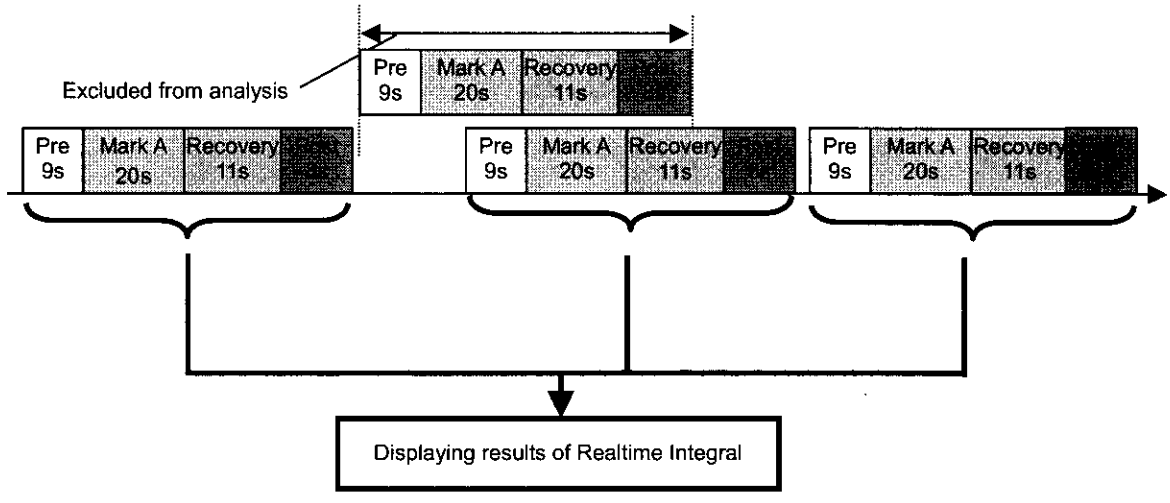
1) Time of Stim period uses that of Stim period of the mark firstly selected.



2) When using the body movement removal function, any mark period judged as body movement exists is not included in the average.



3) When analysis periods are overlapped, any mark period came first is not included in the average.



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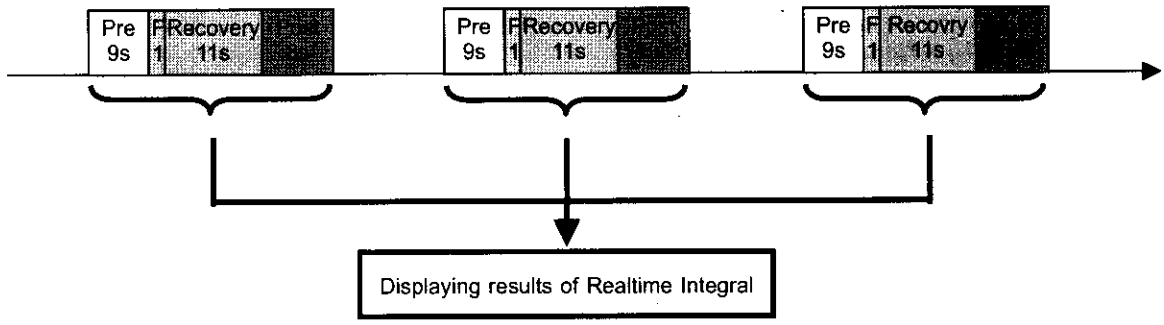
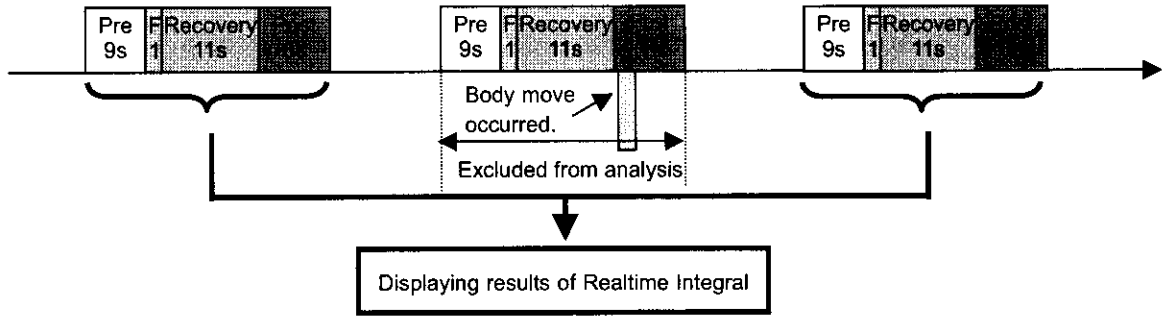
6.1.1.2 Event measurement

Example operation shows a case in which F1 is selected for display.

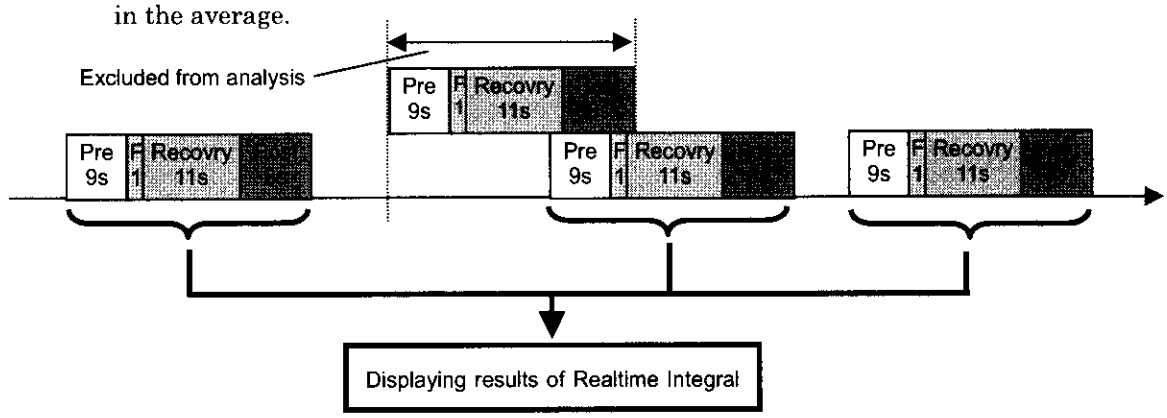
1) Time of Event period uses that of Event period of the mark firstly selected.



2) When using the body movement removal function, any mark period judged as body movement exists is not included in the average.



3) When analysis periods are overlapped, any mark period came first is not included in the average.



※ Analysis period

- Time of Stim period uses that of Stim period of the mark selected first
- Considering that periods of the 2nd mark and after differ from that of the 1st mark, when judging whether the 2nd mark and after is to be removed or not, the period between "the mark start point minus Pre time" and "mark start point plus Stim time + Relax time + Post time" is used.

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Section 7 Measurement Data Handling

This section describes relationship among [4.6 Saving Measurement Data], [5.6 Saving Analysis Data] and [6.4 File Related Operations], and provides additional information.

7.1 Structure of Data Files

See below. This chart describes components of the optical topography system and a flow of information among these components. The topography system in measurement has functions to display data on the monitor after calculating that acquired by the data acquisition system as well as save data to the database.

Data saved in the database is available for loading with a file selected, analysis, display, print and file out in the text format.

As for database related operations besides above, data may be deleted with one or more files selected, data may be exported for backup, as well as the data may be imported again to the database.

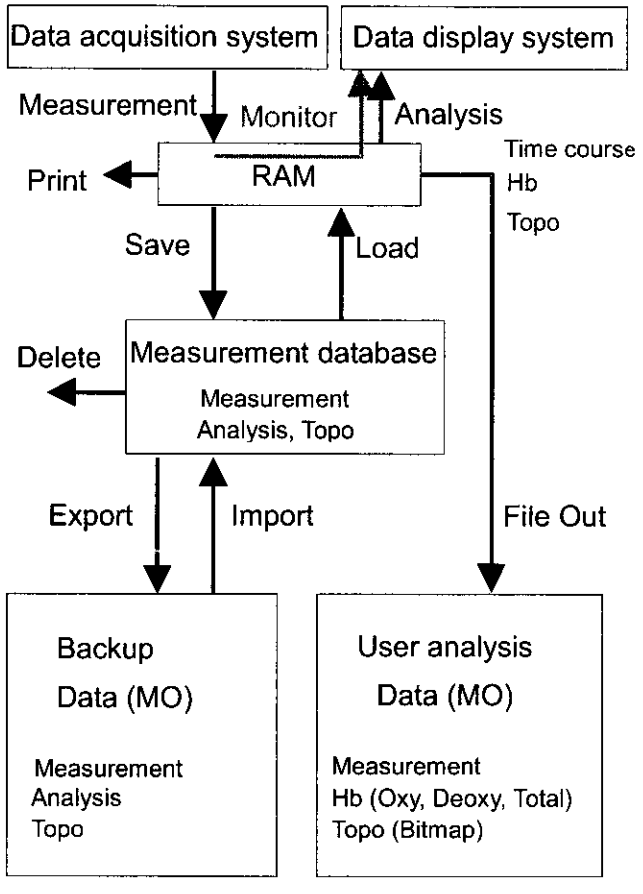

Fig. 7.1 Data File Structure

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For Measurement, Analysis and Print use the exclusive buttons located on the measurement analysis window for operation.

For Save, Load, Delete, Import and Export, select [File Manager] from the [Operation] button menu of main screen for operation.

(For operation, see [6.4 File Related Operations].)

For File Out, select [File Out] from the [Operation] button menu as well.

(For operations, see [6.4.2, 6.4.3 and 6.4.4.].)

7.2 Export and Import

This section describes operations of Export and Import.

7.2.1 Export

This outputs data being selected to any external device. Multiple data sets may be selected.

(1) Clicking the [Export] button displays a window asking the destination drive.

(2) Selecting the drive displays a window asking the destination folder. A new folder may be created and designated.

(3) Press the [OK] button to save data to the designated folder.

(For detailed operations, see [6.4.1 (N) Export].)

7.2.2 Import

(1) Clicking the [Import] button displays a window asking a destination driver. Designate a folder.

(2) Selecting the drive displays a window asking the directory in which the data is saved. Designate the folder.

(3) If content of the folder is Export data of optical topography system, click the [OK] button. This displays a list window. Click on the necessary data. Multiple selections are acceptable.

(4) Clicking the [OK] button adds the designated data to the database.

(For details, see [6.4.1 (O) Import].)

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Section 8 Message List / Troubleshooting

8.1 Category of Dialog Display

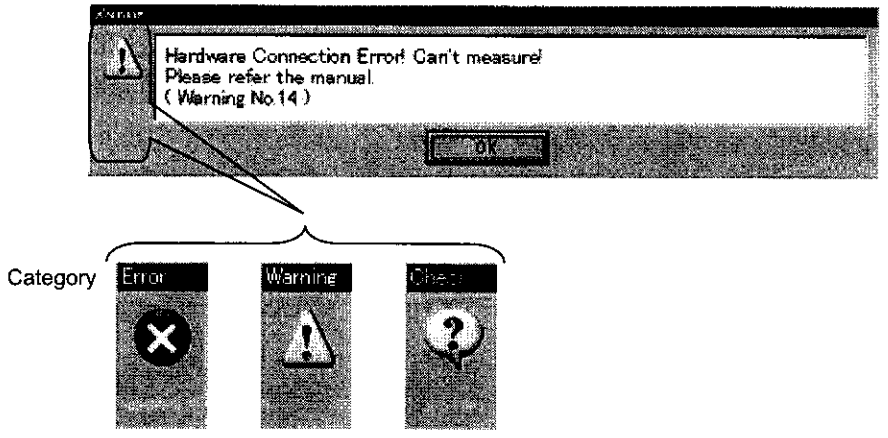

Fig. 8.1 Dialog Display

8.2 Error Messages

Table 8.1 List of Error Messages

Class	No.	Message	Description	Action to be taken
⊗	1	**Can't delete the folder!** **Please refer to the manual.** (Error No.1)	When deleting patient information, deleting the folder that saves measurement data of the patient has not been completed.	The process can be continued since there is no problem even if the folder remains.
⊗	2	Can't delete the files in the Specified folder! Please refer the manual. (Error No.2)	When deleting patient information, deleting files in the folder that saves measurement data of the patient has not been completed.	The process can be continued since the file is forced to be overwritten.
⊗	3	Can't print out the screen! Please connect the printer. (Error No.3)	Hardcopy of each screen has not been completed.	Check connection with the printer.
⊗	4	**Hard disk is full!** **Please delete unneeded data.** (Error No.4)	Judgment when starting measurement tells that the number of data files is too much or the data file is too big.	Check free space of the hard disk. Or delete unnecessary files.
⊗	5	Connection time out error occurred! Please refer to the manual. (Error No.5)	When sending a command to the DLA or DRV board or receiving data, no response was received from the board so communication has been canceled.	Check the DLA, DRV board and backboard. Make contact with the service personnel.
⊗	6	Hardware control failed! Please refer to the manual. (Error No.6)	An error other than communication timeout occurred.	Check the DLA, DRV board and backboard. Make contact with the service personnel.
⊗	7	Can't communicate with the DLA-PCB! Please refer to the manual. (Error No.7)	In the adjustment process, an error occurred in data communication with the DLA board.	Check the DLA, DRV board and backboard. Make contact with the service personnel.

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Class	No.	Message	Description	Action to be taken
⊗	8	Can't save the data! Please refer to the manual. (Error No.8)	With the file name designated, the file could not be opened.	Retry saving with another file name. Or, if retrying is unsuccessful, reboot the system. Make contact with the service personnel.
⊗	9	Can't save the parameter data! Please refer to the manual. (Error No.9)	With the designated parameter name, the parameter file could not be opened.	Retry saving with another name. Or, if unsuccessful, reboot the system. Make contact with the service personnel.
⊗	10	Can't read the parameter data! Please refer to the manual. (Error No.10)	With the designated parameter name, the parameter file could not be opened, or content is broken.	The file is broken or file itself may not exist. Make contact with the service personnel.
⊗	11	Can't discard the page for the tab! Please reboot the system. (Error No.11)	Resource leaks.	Reboot the system. If it is still displayed after rebooting the system, make contact with the service personnel.
⊗	12	Can't create the data file for the measurement! Please set the measurement time shorter. (Error No.12)	When preparing measurement start, the process failed to make sure of measurement data area.	Clean up the disk to make sure of free space. Reduce measurement time so as to reduce the number of measurement data, or widen sampling interval.
⊗	13	Can't save the preset data! Please choose another name for the preset data. (Error No.13)	When registering position of the probe, probe unit position information could not be registered.	With another file name, retry saving process. If it is still displayed, make contact with the service personnel.
⊗	14	Can't save the data! Please refer to the manual. (Error No.14)	In the data file saving process, the data could not be saved.	With another file name, retry the saving process. If it is still displayed, make contact with the service personnel.
⊗	15	Can't read the data! Please refer to the manual. (Error No.15)	In saving a data file, format of data saved is abnormal or no file exists.	Retry the loading process. If it is still displayed, make contact with the service personnel.
⊗	16	Auto Gain Time out! Please refer to the manual. (Error No.16)	Auto Gain is timed out.	Retry the Auto Gain process.
⊗	17	Can't copy Export files. (Error No.17)	Export data cannot be copied.	Check if the destination drive is not write-protected, or there is ample free space.
⊗	18	Can't execute 3D Space program.(Error No.18)	3D Space cannot be executed.	Make contact with the service personnel.
⊗	19	Can't read the file [3DSpaceTempFile.etd] Please refer to the manual. (Error No.19)	The file [3DSpaceTempFile.etd] cannot be loaded.	Retry 3D position measurement.
⊗	20	(Non) Can't create the data file for the measurement! Please refer to the manual. (Error No.20)	Measurement data cannot be created.	Make sure of free space for the hard disk. Or delete unnecessary files.
⊗	21	Failed in cutting out the measurement data. (Error No.21)	The process failed to cut measurement data.	Retry the cut process. If it is still displayed, make contact with the service personnel.
⊗	22	Can't execute the program. (Error No.22)	The program cannot run.	Make contact with the service personnel.
⊗	23	Bitmap File Out Error. (Error No.23)	The process failed to extract the bitmap file.	Reboot the system. If it is still displayed after rebooting, make contact with the service personnel.
⊗	24	Bitmap file Memory Error. (Error No.24)	Bitmap file memory has a trouble.	Reboot the system. If it is still displayed after rebooting, make contact with the service personnel.

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Class	No.	Message	Description	Action to be taken
⊗	25	Bitmap file Create Error. (Error No.25)	Bitmap file creation failed.	Reboot the system. If it is still displayed after rebooting, make contact with the service personnel.
⊗	26	Bitmap file Open Error. (Error No.26)	Bitmap file open failed.	Make sure of free space for the hard disk. Or delete unnecessary files.
⊗	27	AVI file Initialize Error. (Error No.27)	AVI file initialization failed.	Reboot the system. If it is still displayed after rebooting, make contact with the service personnel.
⊗	28	AVI file Write Error. (Error No.28)	AVI file write failed.	Make sure of free space for the hard disk. Or delete unnecessary files.
⊗	29	LAN Connect Control Error. (Error No.29)	LAN connector control has a trouble.	If it is displayed several times, reboot the system.

8.3 Warning Messages

Table 8.2 List of Warning Messages

Class	No.	Message	Description	Action to be taken
⚠	1	Wrong file format! Please choose the right format file. (Warning No.1)	3D position data file format is not correct.	Reselect a correct file.
⚠	2	Can't find the current subject ID! Please refer to the manual. (Warning No.2)	File manager window is opened with unregistered ID or wrong ID.	Register a new patient. Change ID.
⚠	3	The patient ID is empty! Please set the patient ID. (Warning No.3)	Edit box to set patient ID is void.	Set patient ID.
⚠	4	The output file is not set! Please select the output file. (Warning No.4)	In the File Out, file to be outputted is not designated	Designate an output file.
⚠	5	Can't find the analyzed data! Please set the adequate analyzing parameters. (Warning No.5)	The [START] button is clicked when no analysis data exists due to failed analysis process.	Change parameters and so on so that the analysis process normally ends.
⚠	6	Wrong value is set! Set the right value. (Warning No.6)	In the dialog for calculating standard variation (Maintenance mode), the setting is not correct.	Enter a normal setting.
⚠	7	Can't change ID! Please choose the other ID. (Warning No.7)	When changing patient ID, the same ID has already exist.	Change it to another ID.
⚠	8	The name for the frame position set is not defined! Please define the name. (Warning No.8)	When saving the frame position, the name to be saved has not been set.	Set a name to be saved.
⚠	9	The head shape can't be displayed! Please refer to the manual. (Warning No.9)	The head shape basic data file cannot be loaded.	In 3D topo, the shape of head is not displayed. It is displayed when the file is deleted, so make contact with the service personnel.
⚠	10	**A time greater than the total time is selected! Please select a time less than the total measurement time.** (Warning No.10)	The position to which the mark is to be moved is set behind the end position.	Change it to a position that can be set.

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Class	No.	Message	Description	Action to be taken
⚠	11	**A time before the start time is selected! Please select a time after the measurement start time.** (Warning No.11)	The position to which the mark is to be moved is set ahead the start position.	Change it to a position that can be set.
⚠	12	**Mark position is at the same time as another mark! Please choose a position that has no other mark.** (Warning No.12)	Position to which mark is to be moved is duplicated with another mark.	Change it to a position that can be set.
⚠	13	Can't analyze! Check the analyzing parameter. (Warning No.13)	When changing analysis parameters, the process cannot proceed to the analysis process.	Set parameters to those with which data can be analyzed.
⚠	14	Hardware Connection Error! Can't measure! Please refer to the manual. (Warning No.14)	When booting the system, hardware is not connected or powered.	Check if the hardware is powered. Or check connection with hardware.
⚠	15	Initialization error with RS-232C! Please refer to the manual. (Warning No.15)	Initialization of RS-232C serial port failed.	Reboot the system since the setting has been rewritten to an abnormal value or PC is abnormal. If it is still displayed after rebooting, make contact with the service personnel.
⚠	16	Interpolation for 3D visualization failed! Please refer to the manual. (Warning No.16)	In the 3D spline, interpolation failed.	Since it occurs when measurement channel is wrong, retry to measure 3D position data.
⚠	17	Interpolation for 3D visualization failed. Please refer to the manual. (Warning No.17)	In the 3D 3rd cycle spline, interpolation failed.	Retry to acquire 3D position information.
⚠	18	**Save Count Over! Set the number less than 10.** (Warning No.18)	When registering probe set position, the number of probe set exceeds the limit.	Maximum positions must be below 10. Register below 10.
⚠	19	The name for the probe position is empty! Please define the name for the probe position set. (Warning No.19)	When registering or deleting probe set position, probe set position registration name has not been entered.	Enter probe position name.
⚠	20	The specified name of the probe position set doesn't exist. Choose the existing name of the probe position set. (Warning No.20)	When deleting a probe set position, the name designated does not exist.	Designate a probe position name that exists.
⚠	21	Please set the time under [m]. (Warning No.21)	Set the time under message time.	Set the time under message time.
⚠	22	The name for the definition of the parameter is empty. Please input the name. (Warning No.22)	When registering and deleting a parameter set, the parameter set registration name is not entered.	Designate the parameter set name.
⚠	23	**The specified name does not exist. Please choose an existing name.** (Warning No.23)	In judgment when deleting a parameter set, the parameter set name for deletion is not entered.	Designate the parameter set name.
⚠	24	**Tap cannot be even. Tap will automatically be set to an odd number.** (Warning No.24)	The number of filter taps must be odd.	Set an odd number.

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Class	No.	Message	Description	Action to be taken
⚠	25	The set value is out of the limits. The appropriate value is automatically set. (Warning No.25)	Set value is out of the limit, so it is automatically corrected.	
⚠	26	Probe Set has not been done! Please execute Probe Set before the measurement. (Warning No.26)	Probe Set has not been completed.	Execute Probe Set before measurement.
⚠	27	Preset has not been done! Please execute Preset before the measurement. (Warning No.27)	Probe Set has not been completed.	Execute Probe Set before measurement.
⚠	28	Patient Information is different. (Warning No.28)	Patient information differs.	Select correct patient information.
⚠	29	(NG) It is short of size of the export point. (Warning No.29)	Extraction point is too short.	Take the extraction point longer.
⚠	30	Can't find Export TBL file. (Warning No.30)	Export TBL file can not be found.	Designate the folder exported.
⚠	31	**There is not enough disk space to perform this function.** (Warning No31)	There is no sufficient free space in the destination medium.	Make sure of free space of the destination hard disk. Or delete unnecessary files.
⚠	32	The PreSet data is not corresponding to 3D-Position data. Please refer to the manual. (Warning No.32)		
⚠	33	**The Integral Analysis could not be done using the Body Movement processing.** **Check the parameters.** (Warning No.33)	Analysis was not executed due to body movement.	Re-set Integral analysis parameters.
⚠	34	Export type is different. (Warning No.34)	Export data type is wrong.	Correctly designate files Hb Exported or Exported.
⚠	35	**The Integral Analysis could not be done.** **Check the parameter.** (Warning No.35)	No analysis has been executed.	Re-set Integral analysis parameters.
⚠	36	**Pre, Recovery, and Post times overlap.** (Warning No.36)	Pre, Relax and Post time overlap.	Set values so that Pre, Relax and Post time do not overlap each other.
⚠	37	Setting is illegal. (Warning No.37)	Setting is wrong.	Retry extracting data.
⚠	38	The privilege of Windows 2000 was not able to be changed. (Warning No.38)	The privilege of Windows2000 could not be changed.	Make contact with the service personnel.
⚠	39	A set location overlaps with PreScan data. Please select the position which does not overlap. (Warning No.39)	A set position overlaps with PreScan data.	Designate any section other than PreScan.
⚠	40	The set value is out of the limits. (Warning No.40)		
⚠	41	Failed in the copy of the 3D position data. (Warning No.41)	3D position data copy failed.	Make sure of free space of hard disk. Or delete unnecessary files.
⚠	42	**Probe information is different. The file cannot be copied.** (Warning No.42)	The file could not be copied due to different probe information.	Select correct information file.

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Class	No.	Message	Description	Action to be taken
⚠	43	Start Point cannot be set in the PreScan section. (Warning No.43)	The start point cannot be set in the PreScan section.	Designate any section other than PreScan.
⚠	44	End Point cannot be set in the PreScan section. (Warning No.44)	The end point cannot be set in the PreScan section.	Designate any section other than PreScan.
⚠	45	**Measurement time is too long. Please select a shorter time.** (Warning No.45)	Measurement time is too long.	Set shorter measurement time.
⚠	46	Parameter Name is illegal. Please change Parameter Name. (Warning No.46)	Parameter name is not correct.	Enter another name.
⚠	47	The specified Mark Class does not exist. Please set the Mark Class again. (Warning No.47)	Designated mark class does not exist.	Select any mark class that exists.
⚠	48	Too many windows. (Warning No.48)	Too many windows are displayed.	Close windows.

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8.4 Check Messages

Table 8.3 Check Messages

Class	No.	Message	Description	Action to be taken
?	1	Didn't save the measurement data! Load the other data? (Check No.1)	Displayed when attempting to load data without saving it after measurement.	OK: Disposes the current measurement data and loads selected data. Cancel: Returns to its original state.
?	2	Didn't save the measurement data! Continue the Probe Set? (Check No.2)	Displayed when attempting to execute Probe Set without saving it after measurement.	OK: Disposes the current measurement data and executes Probe Set. Cancel: Returns to its original state.
?	3	Didn't save the measurement data! Start the measurement? (Check No.3)	Displayed when attempting measurement without saving it after measurement.	OK: Disposes the current measurement data and prepares measurement. Cancel: Returns to its original state.
?	4	Didn't save the measurement data! Change the type of stimulus? (Check No.4)	Displayed when attempting to change stimulation mode without saving it after measurement.	OK: Disposes the current measurement data and changes stimulation type. Cancel: Returns to its original state.
?	5	Didn't save the measurement data! Finish the program? (Check No.5)	Displayed when attempting to exit this software without saving it after measurement.	OK: Disposes the current measurement data and terminates this software. Cancel: Returns to its original state.
?	6	The system will be shut down! OK? (Check No.6)	Displayed when attempting to exit this software.	OK: Terminates this software. Cancel: Returns to its original state.
?	7	The same name already exists! Change the name? (Check No.7)	Displayed if the same name has been already registered when attempting to change patient name in the patient information.	OK: Changes the patient name. Cancel: Returns to its original state.
?	8	The existing file will be overwritten. OK? (Check No.8)	Displayed when confirming overwrite.	OK: Overwrites. Cancel: Returns to its original state.
?	9	The selected item will be deleted. OK? (Check No.9)	Displayed when confirming deletion.	OK: Deletes. Cancel: Returns to its original state.
?	10	The default value will be set. OK? (Check No.10)	Displayed when confirming the setting to be returned to the default value.	OK: Returns the setting to the default value. Cancel: Returns to its original state.
?	11	Didn't save the measurement data! Change the parameter? (Check No.11)	Displayed when attempting to change a parameter without saving it after measurement.	OK: Disposes the current measurement data and changes parameters. Cancel: Returns to its original state.
?	12	The parameter will be overwritten. OK? (Check No.12)	Displayed when confirming overwrite of parameters.	OK: Overwrites. Cancel: Returns to its original state.
?	13	The parameter will be deleted! OK? (Check No.13)	Displayed when confirming deletion of parameters.	OK: Deletes. Cancel: Returns to its original state.
?	14	The 3D Space data will be deleted! OK? (Check No.14)	3D Space data will be deleted.	OK: Deletes. Cancel: Returns to its original state.
?	15	The 3D Space data is changed. Load the 3D Space data? (Check No.15)	3D Space data has been changed. Do you wish to load 3D Space data?	OK: Disposes the current data and loads a new data. Cancel: Returns to its original state.
?	16	Didn't save the measurement data! Continue the Hb Export? (Check No.16)	Measurement data cannot be saved. Do you wish to continue Hb Export?	OK: Disposes the current data and loads a new data. Cancel: Returns to its original state.

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Class	No.	Message	Description	Action to be taken
?	17	This File name already exists. Overwrite? (Check No.17)	A file of which name is the same exists. Do you wish to overwrite?	OK: Overwrites. Cancel: Returns to its original state.
?	18	The probe position is changed. OK? (Check No.18)	Probe position has been changed.	OK: Disposes the current data and exits. Cancel: Returns to its original state.
?	19	The parameter is changed. OK? (Check No.19)	The parameter has been changed.	OK: Disposes the current data and exits. Cancel: Returns to its original state.
?	20	Change the type of stimulus? (Check No.20)	Stimulation type has been changed.	OK: Disposes the current data and exits. Cancel: Returns to its original state.
?	21	The program will end! OK? (Check No.21)	The program will end.	OK: Exits. Cancel: Returns to its original state.
?	22	Time Adjust Reset! OK? (Check No.22)	Time Adjust will be reset.	OK: Resets Time Adjust. Cancel: Returns to its original state.
?	23	Delete Probe Position Name? (Check No.23)	Probe Position Name will be deleted.	OK: Deletes. Cancel: Returns to its original state.
?	24	Pre, Relax, Post time overlaps. Start the Analyze? (Check No.24)	Pre, Relax and Post time overlaps with the analysis start point.	Set values so that Pre, Relax and Post time do not overlap.
?	25	The cut data will be removed. OK? (Check No.25)	Data cut will be executed. Data cannot be recovered. OK?	OK: Executes data cut. Cancel: Returns to its original state.
?	26	The 3D Space data already exists. Overwrite? (Check No.26)	3D Space data with the same name exists. May it be overwritten?	OK: Overwrites. Cancel: Returns to its original state.
?	27	Do you wish to copy the 3D Space data? (Check No.27)	Do you wish to copy the 3D Space data?	OK: Copies the 3D Space data. Cancel: Returns to its original state.
?	28	The last measurement will be cancelled. Load the new measurement data? (Check No.28)	The last measurement failed. Do you wish to load a new data?	OK: Disposes the current measurement data and loads a new measurement data. Cancel: Returns to its original state.
?	29	Selected file will be deleted. Continue? (Check No.29)	Data selected has been deleted. Do you wish to continue?	OK: Continues. Cancel: Returns to its original state.
?	30	Already exists. Overwrite? (Check No.30)	It has already existed. Do you wish to overwrite?	OK: Overwrites. Cancel: Returns to its original state.
?	31	The system will shutdown. Please restart the system. (Check No.31)	The system will shut down. Reboot the system.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8.5 Probe Set Messages

Table 8.4 List of Probe Set Messages

Class	No.	Message	Description	Action to be taken
⊗	1	Can't read the DLA & DRV setup data. Please refer to the manual. (Probe Set Error No.1)	Can't read the DLA & DRV setup data.	Reboot the system. If it is still displayed after rebooting, make contact with the service personnel.
⊗	2	Can't communicate with the DLA-PCB! Please refer to the manual. (Probe Set Error No.2)	Can't communicate with the DLA-PCB.	Reboot the system. If it is still displayed after rebooting, make contact with the service personnel.
⊗	3	Auto Gain time out! Please refer to the manual. (Probe Set Error No.3)	Auto Gain is timed out.	Execute Auto Gain again.
⚠	1	The name to save information is not set. Please set the name. (Probe Set Warning No.1)	The name to save information is not set.	Enter the name.
⚠	2	The number of maximum registration is exceeded. Please delete another item when registering. (Probe Set Warning No.2)	The number of maximum registration is exceeded. Delete other registration data.	
⚠	3	There is no specified name. Please set the name. (Probe Set Warning No.3)	Designated name does not exist. Register the name.	
⚠	4	LD broke down. <<Please call the service person>> (Probe Set Warning No.4)	LD is broken.	Make contact with the service personnel.
?	1	The existing file will be overwritten. OK? (Probe Set Check No.1)	May this file be overwritten?	OK: Overwrites. Cancel: Returns to its original state.
?	2	The selected item will be deleted. OK? (Probe Set Check No.2)	May the file selected be deleted?	OK: Deletes. Cancel: Returns to its original state.
?	3	The probe position is changed. Continue? (Probe Set Check No.3)	Probe position has changed. Do you wish to continue?	OK: Disposes the current probe position and continues. Cancel: Returns to its original state.
?	4	LD broke down. Continue? <<Please call the service person>> (Probe Set Check No.4)	LD is broken. Do you wish to continue?	OK: Continues. Cancel: Returns to its original state. Make contact with the service personnel.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Section 9 Cautions in Moving Equipment

To move equipment safely, observe the following items.

9.1 Moving Equipment

9.1.1 Preparation before moving

(1) Check if there is no obstacle on the transportation route. Remove any item to be an obstacle against transportation in advance.

(2) Turn off the power to the main unit and PC, and disconnect the power cable.

(3) Hook the optical fiber cables to the optical fiber cable support so that they are not stepped or caught by wheels.

(4) Put the mouse on a place and secure so that it does not fall down. Check if the printer is secured. Do not place the instruction manual and the like on equipment, and bring them separately.

9.1.2 Cautions in moving equipment

(1) Release the lock of wheel stoppers at four locations when moving equipment. Press the wide gray lever. The lock of caster swing is released as well.

(2) When passing through a narrow space, let the wheels swing for easier operation. For longer travel, lock swing of the wheels to be back for easier operation. According to the situation, press the green lever to stop swing. However, lock is effective only when the wheels are oriented in the front/back direction.

(3) Be sure to move equipment by two persons. Moving by one person is hazardous since equipment needs to be pulled backward in some cases and front view is poor due to equipment itself.

(4) Pay full attention to the feet not to be caught by the wheels. Do not hit any item while moving (transporting) equipment or give vibration.

(5) Especially pay attention to the optical fiber cables so as not to catch any person or article or not to be caught.

(6) Do not tilt equipment over 10°. Do not attempt to pass by any tilted place.

(7) When passing by any place with a step such as the elevator entrance or fire door, handle with care so as not to give vibration.

(8) After moving equipment, lock the wheel stoppers (for both rotation and swing).

9.2 Transporting Equipment

When transporting equipment using a car, special care for transportation needs to be taken besides description in [9.1 Moving Equipment]. Be sure to order us for transportation. Responsibility belongs to the persons who transport equipment.

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Section 10 Maintenance Check and Cleaning

In using this system, perform pre-work, in-use and periodical checks and cleaning.

10.1 Pre-work Check

Every day	Weekly	Monthly	Others

Before turning on the power, check the following:

(1) Check if the sheath of system power cable is not broken or does not fall off.

If using equipment with the defect as it is, electrical shock may result.

(2) Check if the sheath of optical fiber cables is not broken or does not fall off.

If any abnormality is found, make contact with us.

10.2 Check in Using Equipment

Every day	Weekly	Monthly	Others

After turning on the power, check the following items:

(1) Check if there is no abnormal sound or burning smell. If any abnormality is found, immediately disconnect the power cable and make contact with us.

(2) Set the fiber socket to the phantom to carry out Gain check. When CH signal display is yellow in Gain adjustment by the [Probe Set] button, re-set the probe and retry check. When it is still yellow even if repeating check, laser trouble may be suspected. Make contact with us.

CAUTION: Never look into the laser beam.

10.3 Using Equipment after Long Storage

When using equipment not used for some period of time (a month or more), check if the system works normally before using it.

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10.4 Periodical Check

Every day	Weekly	Monthly	Others

Carry out the following checks at least once every month.

- There is no fault on the optical fiber cables.
- There is no fault on the power cable and other cables.
- The stopper attached to wheels works normally.

When any fault is found or the system malfunctions, stop using equipment, turn off the power and disconnect the power cable, and then make contact with us.

10.5 Cleaning Equipment

Turn off the system power and disconnect the power cable from the power outlet before starting checks.

Use cloth soaked with mild detergent and squeezed hard to wipe off dirt, and then rub with dry soft cloth.

CAUTION: Never use organic solvent such as thinner.

Do not apply liquid such as detergent directly to equipment.

10.6 Backup of Measurement Data

If the hard disk mounted on the main unit is damaged by any chance, saved measurement data, analysis data and so on vanish.

At lease once a month, make a backup copy of measurement data.

For backup of measurement data, see the instruction manual.

10.7 Keeping Performance

To keep system performance, periodical maintenance is mandatory.

Please ask our service personnel who has special knowledge for periodical maintenance.

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Section 11 Repair, Readjustment and Disposition

(1) Responsibility on repair

When the system needs to be repaired or readjusted, ask us for it.

Responsibility belongs to the person(s) who repair(s) and readjust(s).

(2) Order for repair

When any abnormality occurred in the system, immediately shut down the power and disconnect the power cable from the power outlet, and then ask us for repair. We will dispatch the service personnel for investigation and repair.

Inform us of the state of abnormality and circumstance as far as you can find.

(3) Disposition of equipment

When disposing this system, it must be treated as an industrial waste. Be sure to obtain permission according to bylaws and regulations of local authority and ask the industrial waste processor for disposition.

At this time, if disposing the main unit and accessories, make contact with us.

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Section 12 Specification

12.1 Measurement Section

(1) Measurement items

- Oxygenated hemoglobin concentration change
- Deoxygenated hemoglobin concentration change
- Total hemoglobin concentration change

(2) Light source

- Semiconductor laser — 2 wavelength (695±20nm, 830±20nm)
  Max: 18 channels each, Total 36 channels
- Optical intensity — 2.0mW (per wavelength)

(3) Detector

- Avalanche diode — Max: 16

(4) Topographic image measurement

- Max 52 channels — Concurrent measurement available

The number of probes (measurement channels) can be selected as shown below:
(This can be increased later.)

	Number of measurement channels	Number of holders			
		4×4	3×5	3×3×2	(3×11)
1-probe specification	52				1
2-probe specification	48	2			
2-probe specification	46	1	1		
2-probe specification	44		2		
3-probe specification	48	1		1	
3-probe specification	46		1	1	

(3×11 is optional)

(5) Data acquisition and display

- Data acquisition time (velocity) — Settable from max 0.1s
- Accuracy of data acquisition time — ±10ms or less
- Display — ① Hb Time Course reception, Hb display
  ② 2D topographic cine images
  ③ 3D topographic cine images (optional)

12.2 Probe Holder Section

(1) 3×3 holder

(2) 4×4 holder

(3) 3×5 holder

(4) 3×11 holder (optional)

(5) Optical fiber cables: max 34 cables

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12.3 Computer

(1)	Main unit	CPU: Pentium4, 1.5Ghz, RAM:256MB, HDD:30GB
(2)	OS	Windows2000 SP3 or higher
(3)	Application software	Optical topography software
(4)	MO	2.3GB

For handling the computer, see the instruction manual attached to the computer.

12.4 Measurement Mode

According to use, maximum two modes can be combined.

		Mode 1 4×4	Mode 2 3×5	Mode 3 3×3×2	Mode 4 3×11
Number of measurement points		24	22	24	52
Number of light sources		8	8	10	17
Number of detectors		8	7	8	16
Display	Hb Time Course	○	○	○	○
	Topographic image	○	○	○	○

(Measurement mode 4 (3×11) is optional.)

12.5 Data Output

(1) Measurement voltage Time Course data

Text format: Patient ID, measurement parameters, measurement data, marker information, etc.

(2) Calculation Hb Time Course data

Text format: Patient ID, measurement parameters, measurement data, marker information, etc.

(3) Topographic image

Bitmap (BMP) format
Cine (AVI) format

12.6 Power Requirement

(1)	Voltage	AC 100V±10%
(2)	Frequency	50 / 60Hz
(3)	Power consumption	500VA or less
(4)	Power outlet	3-core outlet with grounding terminal (Grounding resistance: 10Ω or less)

12.7 Environment Condition

(1)	Temperature	+5 ~ +35°C
(2)	Relative humidity	30 ~ 85%
(3)	Atmospheric pressure	700 ~ 1060hPa

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12.8 Outside Dimensions

526(W)×933(D)×1,470(H)

12.9 Weight

About 130kg

12.10 Available Period

Standard available period of this system (based on our standard of legal useful life)

(1) Main unit: 6 years (if specified maintenance check is implemented)

(2) Laser diode: 3 years

(3) Commercially available components
(Refer to the useful life recommended by the manufacturer.)

The system includes commercially available components. Service parts may not be supplied even in its useful life due to discontinuation because of model change and so on.

In such case, you are provided with information in advance for actions to be taken.

12.11 Warranty

One year after delivery.

However, for the product delivered based on this specification, any defect caused by our design or manufacture fault will be repaired without charge. Any trouble caused by unreasonable handling, any trouble out of warranty or any cost incurred as a result of additional specification will be charged.

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Marketing Literature

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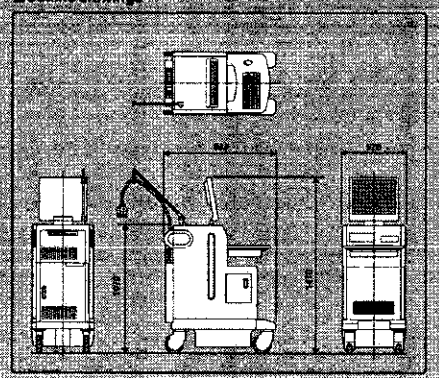
HITACHI

Non-invasive Measurement of the Activation of the Cerebral Cortex

The Optical Topography® System

ETG-4000

■Outline drawings



■Specifications

	16-channel configuration	24-channel configuration
Measuring item	Change in oxyhemoglobin concentration	
	Change in deoxyhemoglobin concentration	
	Change in total hemoglobin concentration	
Light source	Multi-wavelength laser 2 wavelengths (830 nm & 690 nm)	
	Laser class 1M (IEC60825-1)	
	10 mW	10 mW
Photodiode	16 units	8 units
Simultaneous measurement channel	16 points (32 points when optional 3x11 probe used)	24 points
Probes	Optical fiber: 16 lines for emission, 16 lines for detection	Optical fiber: 16 lines for emission, 8 lines for detection
	Holder: 3x3 (1 set), 3x5 (2), 4x4 (1)	Holder: 3x3 (1 set), 3x5 (1), 4x4 (1)
	Holder: 3x11 (optional)	—
External analog signal input (BNC)	2 channels input range: 0 ~ ±5V	
External digital signal input (BNC)	4 channels (L: 0V, H: +5V)	
Digital signal output (BNC)	4 channels (L: 0V, H: +5V)	
Serial communication (RS232C)	2 channels	
Network (LAN)	1 line (not operational during optical topography measurement)	
External devices	2 channels	
Data sampling rate	10 samples/sec. or less	
Data output	Hemoglobin time course graph in text file format	
	Topographic image data (raw) in bmp format	
	Topographic image data (marked) in jpg format	
Magneto-optical disc drive	Compatible with 2.3 GB media	
Service environment	Service temperature range: +4~+35℃	
	Service humidity range: 30~85% RH	
Power source	100VAC, single-phase, 50/60Hz	
Power consumption	500VA or less	
External dimensions	520 (W) x 850 (D) x 1120 (H) mm	
Mass	Approx. 140kg	

Hitachi Medical Corporation, Medical division (Iwai plant Tokyo), is certified as complying with the International Standard Management System (ISO 13485).

● Specifications and appearance of this product are subject to change for improvement without notice.
● For proper use of the system, be sure to read the operating manual prior to handling it for safety.

Please contact us or nearest distributor or agent to:

Hitachi Medical Corp.
Hitachi Kamakura-bashi Bldg., 1-1-14, Uchi-kanda, Chiyoda-ku, Tokyo, Japan
International Division
Hitachi Hagoromo Bldg., 1-2-10, Uchi-kanda, Chiyoda-ku, Tokyo, Japan
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CU-20308
Printed in Japan ZH-X (DMC)

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New Light Shed on the Brain

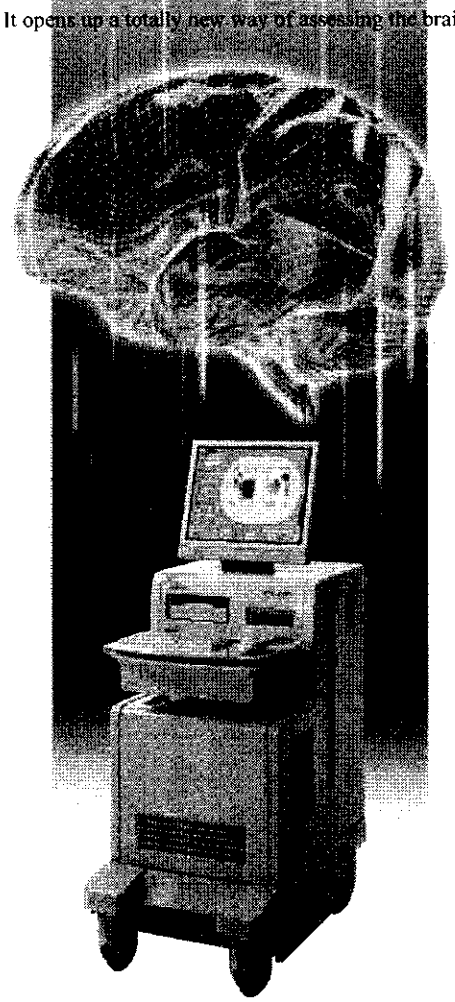
Every healthcare professional would say: "I wish I could see how the human brain is working in vivo."

Hitachi's Optical Topography® system has made this dream come true.

It measures and images dynamically the hemoglobin levels in the brain during functional activity.

The system beams near-infrared light into the patient's head, and picks up the reflected light penetrating through the cerebral cortex.

It opens up a totally new way of assessing the brain.



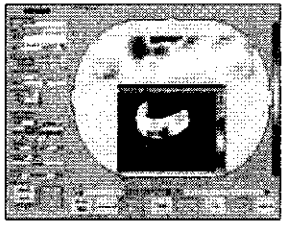
Real-time, non-invasive measurement with less patient-restraint

Just place the tip of the optical fiber on the scalp, and Optical Topography measures and provides real-time images of changing brain activity. What's more, it's non-invasive, and relatively restraint-free and convenient for the patient being tested.

3×5 (22-channel) probes on the head

Simultaneous multi-channel measurement

With two probes on the head, you can take simultaneous data through 48 channels (52 channels maximum when optional 3×11 probes are used). Simultaneous 24-channel measurement is also possible with a single probe. So, the system can be used in the field of cognitive neuroscience.



3×11 (52-channel) probe and 3D display function are optional.

Compact, Mobile, User-friendly

The technology is encased in a compact and light unit that can be easily wheeled anywhere in the facility; so you can take measurements at the bedside. What's more, the incorporated short wavelength light source generates low levels of interfering noise during measurement. It has the capacity for rapid and accurate testing with straightforward on-screen operability; for example, parameters can be set on the main screen panel.In short, this system can be handled in the same way as other portable devices being used in the hospitals or clinics.

Novel Insightful Technology

http://www.hitachi-medical.co.jp/opt/

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Multipurpose Probes and Various Display Methods

Combined use of probes is possible according to the site you want to examine.

Changes in hemoglobin concentration due to cerebral activation can be displayed in the forms of time-course graph, time-course mapped graph, and 2D topographic images.

3×5 (22 channels×2)

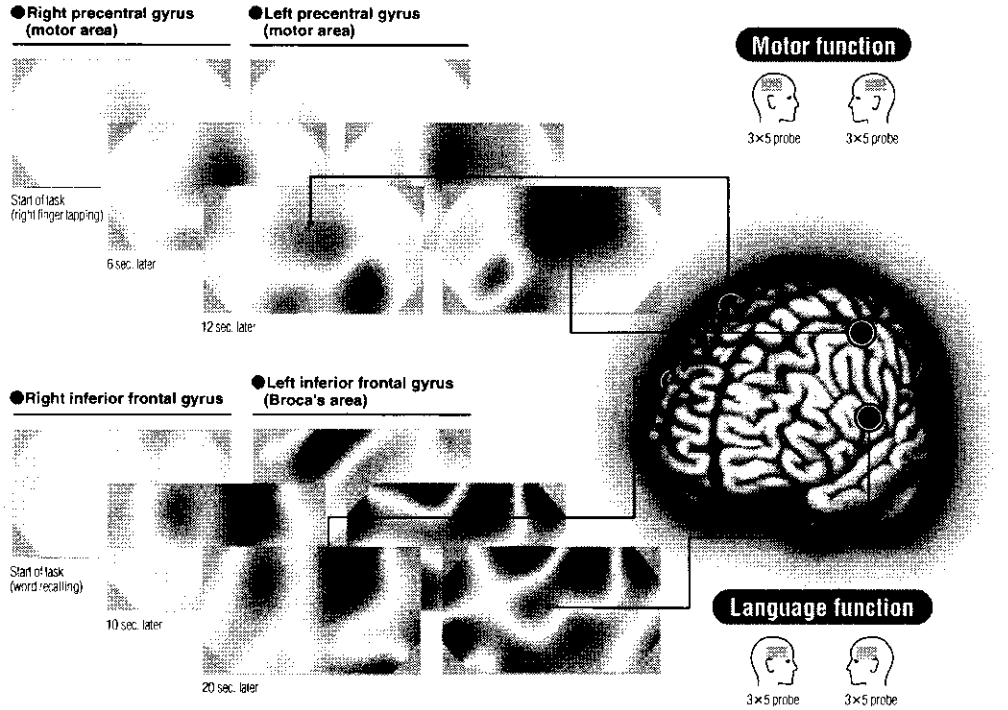
• Two probe holders used at the same time for right-left difference analysis

3×3 + 4×4 (12 channels × 2+ 24 channels)

• Two or more sites at the same time

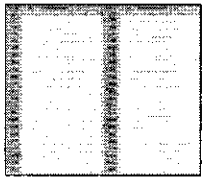
3×11 (52 channels) (optional)

• "Blanket" measurement over a wide area

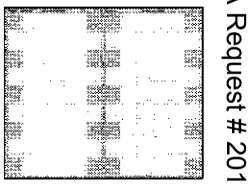


In Topo Data, red means the increase of Total-Hemoglobin and blue means the decrease of Total-Hemoglobin.

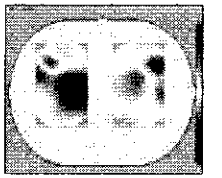
●Time-course graph display
Gives a graphic representation of changes in oxyhemoglobin, deoxyhemoglobin and total hemoglobin, separately.



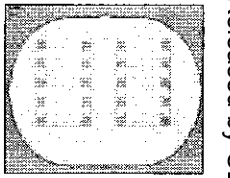
●Time-course mapped graph display
Graphs for measurement channels appear on the screen.



●2D Topography display
Hemoglobin data appears as a two-dimensional dynamic image over a figure of a scalp.

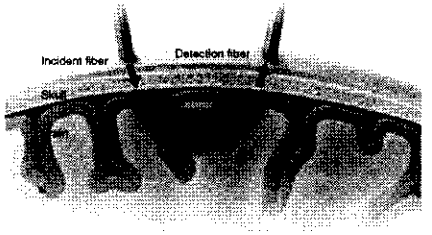


●Time-course mapped display
Changing hemoglobin concentrations at measurement channels are displayed over a figure of a scalp.

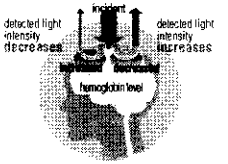


Near-Infrared Light Is Shed to Measure Hemoglobin Levels in the Cerebral Cortex.

Located at a depth of some 20 mm from the scalp, the cerebral cortex controls high-order brain functions such as muscular movements, recognition, language, and thinking. The Optical Topography system beams near-infrared light into the head to measure the activation of the cortex.

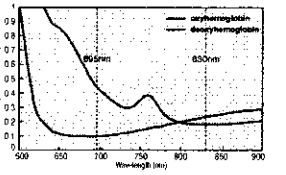


Changes in the light detected are an indicator of hemoglobin concentration.
The cerebral cortex abounds in capillary vessels in which blood flows. The hemoglobin in the blood efficiently absorbs near-infrared light. Therefore, by beaming near-infrared rays into the brain and monitoring their reflections on the scalp, you can know the relative level of blood the cortex contains, or how actively a region of the brain is working.



Relationship between hemoglobin concentration and reflected light.

The system uses near-infrared light of two different wavelengths (695nm and 830nm) to monitor changes in the levels of oxyhemoglobin, deoxyhemoglobin, and total hemoglobin. Thanks to the use of a shorter wavelength light source, the system provides a multi-faceted means of measurement with low levels of interfering noise.



Light absorption spectra of hemoglobin.

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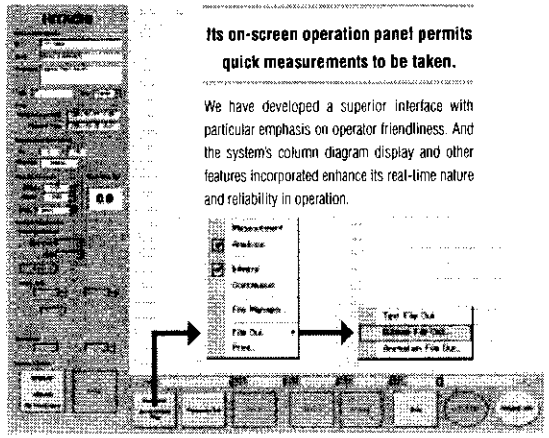
An Operator – friendly System with a Full Array of Options

The ETG-4000 has been engineered with emphasis on ease of use in clinical and research settings.
With this system, you will find it easy to do a series of jobs
such as measurement, analysis, data reduction, and data sharing.

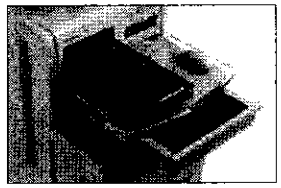


Its on-screen operation panel permits quick measurements to be taken.

We have developed a superior interface with particular emphasis on operator friendliness. And the system's column diagram display and other features incorporated enhance its real-time nature and reliability in operation.

The built-in phantom shortens pre-check time.

The incorporated slide-out phantom facilitates preliminarily checkout procedure before measurement, ensuring smooth startup of the measurement operation.

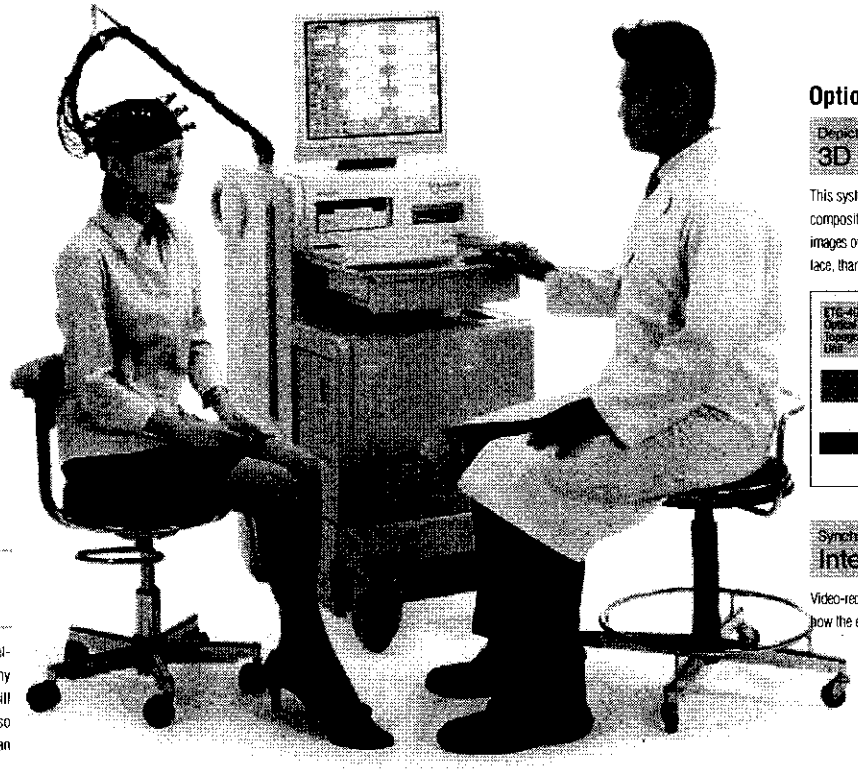


Measurement data in standard formats

Time-course graph data can be output as Excel-compatible or text-file data, while 2D topography images are available in bmp format for still images and in avi format for motion images; so you can easily reduce data or publish them at an academic conference or presentation meeting.

LAN Compatible

The ETG-4000 can be connected to a LAN communication system in a facility to have the data shared.

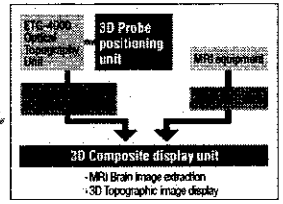


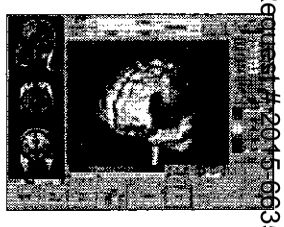
Options

Depiction of blood volume changes over the cerebral surface

3D Topographic image display system

This system consists of a three-dimensional positioning unit that measures probe positions, and a 3D composite display unit that gives a three-dimensional representation of two-dimensional topographic images over the surface of a brain. Topographic images can be accurately displayed over the brain surface, thanks to the magnetic sensors provided for probe position measurement.

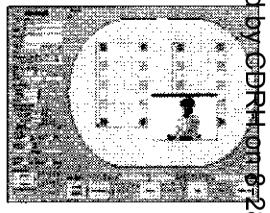




Synchronous replay of video-recorded scenes of measurement

Interface for the video recording system

Video-recorded data can be synchronously replayed on the analysis screen(for up to four hours) to show how the examinee behaved or responded to load stimuli during the test.



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Product Labels

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Section 8

Software Documentation

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ETG-4000 Software Hazard Analysis 66

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General Information

Software Version Number: ETG-4000 Software Version 1.41e Date: July 15, 2004

Operational Environment:

Hardware platform: Pentium IV, 1.5Ghz or greater

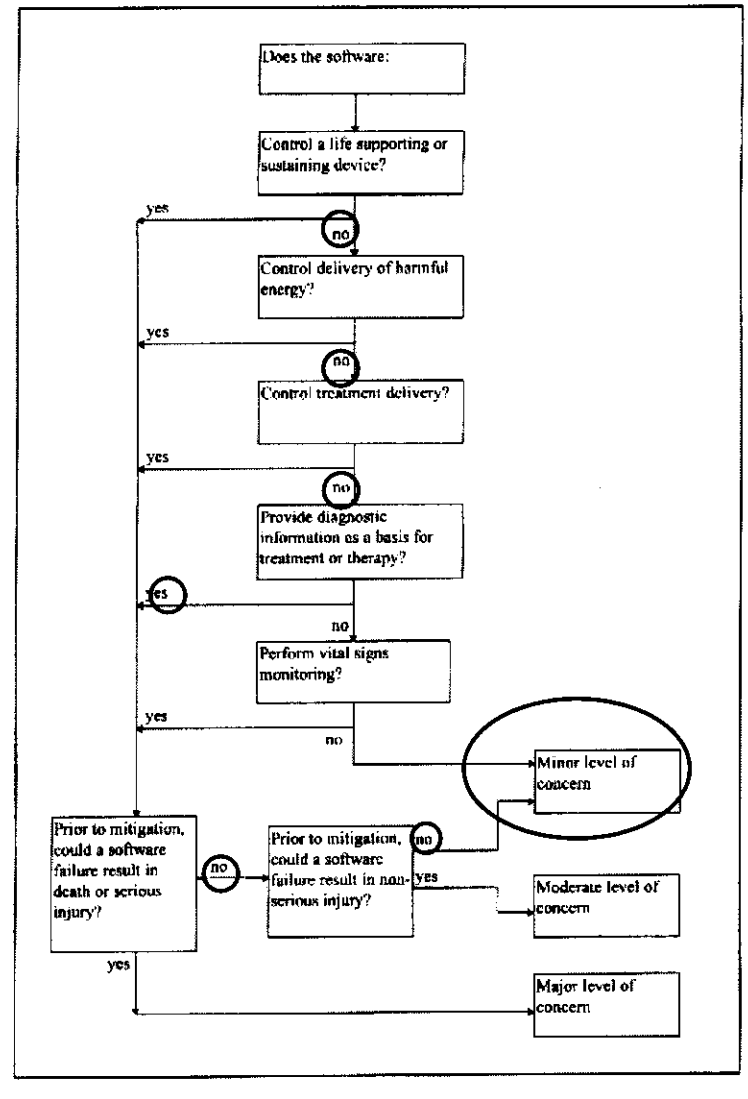
Operating system: Windows 2000 SP3 or later

Software Level of Concern:

The software level of concern was determined using the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices* (5/29/98).

The flowchart (included) from that guidance was used to determine the level of concern. The ETG-4000 does not provide life support or have the capacity to deliver harmful energy levels. It does not control treatment or provide a diagnosis. The device is an adjunctive tool intended to be used by a competent professional or physician who exercises good judgment to interpret the information presented.

Based on these factors and a formal risk analysis, we believe that the ETG-4000 software falls under the category of minor concern. Therefore, the following information is provided, based on Table 1 in the guidance document referenced above.



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ETG-4000 Software Algorithm Evaluation

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Technical Report

Evaluation of calculation algorism of Hemoglobin (Hb) concentration change using blood Phantom

Hitachi, Ltd, Advanced Research Laboratory

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Abstract

We investigated the calculation algorism of the hemoglobin(Hb) concentration change through phantom experiment using human blood in the optical topography system. We simulated hemoglobin concentration change with the light scattering nature of living tissue and brain activation by dropping blood into phantom filled with a Intralipid solution that has a light scattering nature. When hemoglobin concentration changes , the strength of the reflected light that penetrates the phantom changes. We calculated hemoglobin concentration change by measuring such change. It was found that the calculated hemoglobin concentration change and the actual hemoglobin concentration change are highly linear with a Determination coefficient over 0.98.

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Methods, Results, Conclusions of Technical Reports (b) (4)

Methods, Results, Conclusions of Technical Reports (b) (4)

Methods, Results, Conclusions of Technical Reports (b) (4)

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ETG-4000 Software Requirements

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Optical Topography System

Software Requirements

ETG-4000

(b) (4)

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Revision Control Table

(b) (4)

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1.0	Initial revision	(b) (4)

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Title	Name	Signature	Date
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Software Requirements (b) (4)

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ETG-4000 Software Design and Development, Quality Plan

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4. SOFTWARE DESIGN AND DEVELOPMENT

4.1 Modularization Criteria and Software Architecture

Software will be divided into modules according to the basic design and functional design.

(1) Modularization criteria

Module division in the basic design will be based on the following criteria:

(a) It will be divided into the basic software common to the entire system and the application software.

(b) The application software will be divided by functions.

(c) For application modules, it will be divided by events such as key input.

(2) Software Architecture

The architecture of the software will obtain by the basic design is shown in Fig.2.

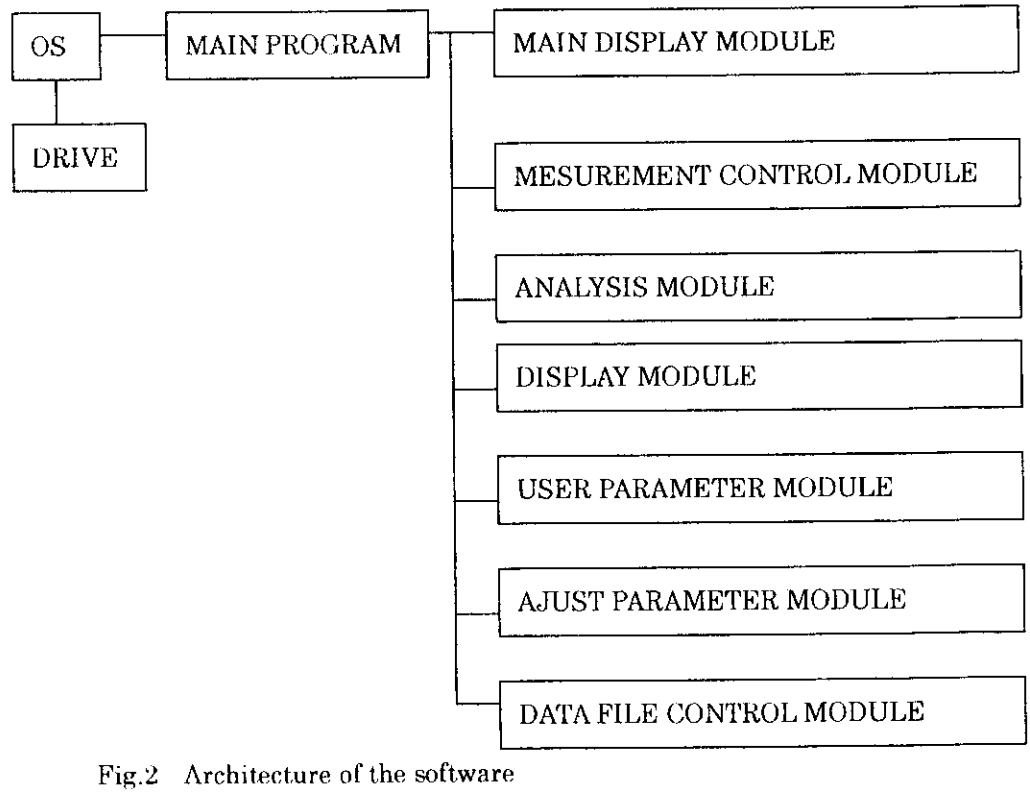

Fig.2 Architecture of the software

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(3) Program functions

(a) Operating system program(OS);

The kernel of the software, and generally will control the tasks, Interrupts, etc.

Microsoft Windows 2000 will be used as OS.

(b) Drivers;

Drives the panel controller, transmitter·receiver controller, display of Image and characters on the screen, option devices,etc.

(c) Main display module;

It will be for data entry, control switch setting and execution process.

(d) Measurement control module;

It will be for controlling the measuring parameter setting, setting gain automatically, measuring of data and storing measured data.

(e) Analysis module;

It will be for performing data analysis, storage of analyzed data, topography generation and still topographic image storing process.

(f) Display module;

It will be for performing main image display, time course display, Topography display ,fitting curve display, hemoglobin display and Real time topography display process.

(g) User parameter module;

It will be for controlling user parameter screen, user parameter renewal, user parameter storage and color setting process.

(h) Adjust module;

It will be for controlling adjusting user parameter screen, adjusting parameter renewal, adjusting parameter storage and Tune up setting process.

(i) Data file control module

It will be for controlling data file managing screen, file save, file load, file copy, file elimination, file search and file sorting process.

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(4) Flowchart of program

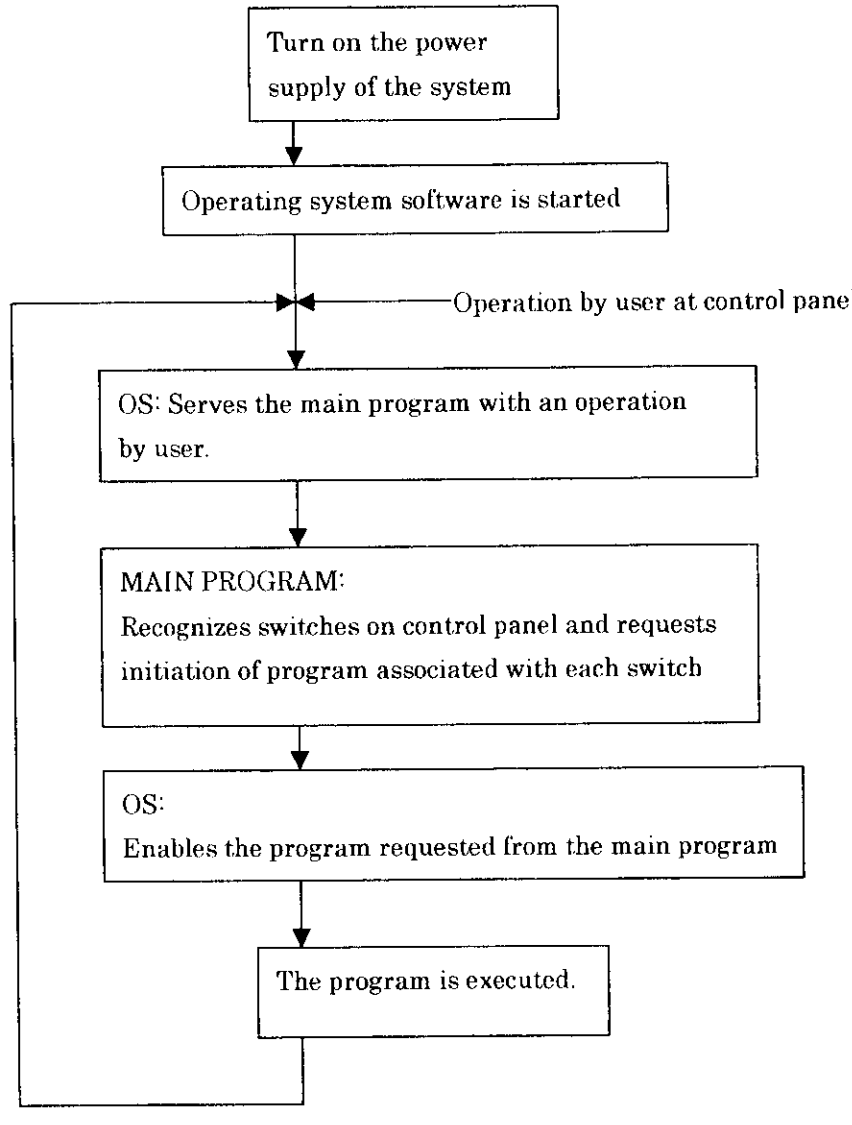

Fig. 3 Flow chart of program

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Optical Topography System

Software Quality Plan

ETG-4000

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(b) (4) [redacted]

Contents
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(b) (4) [redacted]

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Title	Name	Signature	Date
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1. Introduction

This Software Quality Plan provides the plan of Development Validation in the development process of the ETG-4000 (b) (4) [redacted]
The following documents including Software Quality Plan have been created based on "The documents generation standard for software validation in the design standard of Applied System Development Office" which is required under HMC's Quality system.

(1) Software Requirements
(2) Software Validation Specification
(3) Software Quality Plan
(4) Test Plan
(5) Test Procedure
(6) Validation Report

Development Validation is to validate whether or not the product meets its user's requirements.
The important things are to ensure the incorporation of user's requirements into development in the development process and to realize traceablity.
To realize the "Development Validation", the plan aims to:
(1) Reduce the number of user's requirements that failed to be realized
(2) Detect defects by testing

2. Quality Plan

2.1 Software Design Development Procedure

2.1.1 Preparation based on user's requirements

The ETG-4000 (b) (4) [redacted] Software Requirements will be created after collating and analyzing user's requirements. [redacted]

2.1.2 Creation of the development plan

The ETG-4000 (b) (4) [redacted] development plan will be created based on ETG-4000 (b) (4) [redacted] Software Requirements. A list of user's requirements will be created.
The preparation method of the development plan is prescribed in the research and development regulation (HMK C0011), the research and development specification regulation (HMK C4004).

2.1.3 Creation of the basic specifications

The ETG-4000 (b) (4) [redacted] basic specifications will be created to realize user's requirements, based on the ETG-4000 [redacted] Software Requirements and the ETG-4000 (b) (4) [redacted] Development Plan.
The preparati [redacted] of the basic specifications is prescribed in the basic specifications regulation (HMK C4004) [redacted]

2.1.4 Creation of the functional specifications

ETG-4000 (b) (4) unctional specifications will be created to describe functions, input/output data for each module divided by functions based on the contents of the ETG-4000 (b) (4) Software Requirements, the ETG-4000 (b) (4) development plan and the ETG-4000 (b) (4) basic specifications.

The preparation method of the functional specifications is prescribed in the functional specifications regulation (HMK C4005).

2.1.5 Manufacture

The program will be created based on the ETG-4000 (b) (4) Software Requirements, the ETG-(b) (4) development plan, the ETG-4000(b) (4) basic specifications and the ETG-4000(b) (4) inctional specifications.

The preparation method of the cording is prescribed in the Coding Standard (CDM-S002B).

2.2 Verification and Validation

2.2.1 Test

Tests will be conducted following the ETG-4000 (b) (4) Plan. The details are described in the ETG-4000(b) (4) Plan.

The test results are described in the ETG-4000 (b) (4) Test Procedure. The preparation method of the Test Procedure is prescribed in the Test Procedure standard (CDM-S005).

2.2.2 Analysis of Test Results

When defects are detected in tests, the design department must analyze the reason(s) why defects occurred and try to prevent a recurrence of defects after all tests are conducted.

The development plan, the basic specifications, the functional specifications will be reviewed if necessary.

2.2.3 Validation

Validation in developing the ETG-4000 (b) (4) be described in the ETG-4000 (b) (4) Validation Report.

SOftware Design and Development Process (b) (4)

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ETG-4000 Software Validation

This section contains:

- Validation Specification
- Test Plan
- Test Procedure
- Validation Report

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Optical Topography System

Software Validation Specification

ETG-4000

(b) (4)

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1.0	(b) (4), (b) (6) [redacted]		

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Module Analysis and Display (b) (4)

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Optical Topography System

Test Plan

ETG-4000

(b) (4)

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Optical Topography System

Test Procedure

ETG-4000

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Optical Topography System

Validation Report

ETG-4000

(b) (4)

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(b) (4), (b) (6) [redacted]		nitial revision	(b) (4), (b) (6) [redacted]

Design department

Title	(b) (4), (b) (6) [redacted]	Check No	(b) (4), (b) (6) [redacted]	
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Checker				
Tester		No1, 2,3,4,5,6,7,8,9		
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QA department

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System Software Outline (b) (4)

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ETG-4000 Software Risk Analysis

Note to Reviewer:

Software hazard analysis is included in the overall risk analysis document. Please refer to Section 9, Safety for the document.

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Section 9

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Test Reports

Note to Reviewer:

The reports included in this section cover:

IEC 60601-1: Medical Electrical Equipment – General Requirements for Safety
IEC 60825-1: Safety of Laser Products – Part 1; Equipment Classification, Requirements, and User's Guide.

Test report attachments are not included for the sake of brevity.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

TÜV RHEINLAND
Product Safety GmbH
Am Grauen Stein
D-51105 Köln

TÜV

TEST REPORT

12005692 001

IEC 60601-1:1988 + A1:1991 + A2:1995
EN60601-1:1990+A1:1993+A2:1995+A13:1996
IEC 60601-1-1:2000 / EN 60601-1-1:2001

Optical Topography System

ETG-4000

Hitachi Medical Corporation

TÜV
Authorized Copy

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

TEST REPORT

IEC 60601-1, -1-1

Medical electric equipment
General and particular requirements for safety

TÜV

Report

Reference No. ..... : 12005692 001

Compiled by (+ signature) ..... : M. Mattes

Approved by (+ signature) ..... : M. Strege

Date of issue ..... : 2003-09-10

Contents ..... : 48 pages

This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator (see below).

Authorized Copy

Testing laboratory

Name ..... : **TÜV Rheinland Japan Ltd.**, Yokohama Laboratory

Address ..... : 1-26-10, Hayabuchi, Tsuzuki-ku, Yokohama 224-0025, Japan

Testing location ..... : as above

Client

Name ..... : Hitachi Medical Corporation

Address ..... : 2-1, Shintoyofuta, Kashiwa-shi, Chiba-ken, 277-0804, Japan

Test specification

Standard ..... : IEC 60601-1:1988 + A1:1991 + A2:1995
EN 60601-1:1990 + A1:1993 + A2:1995+ A13:1996
IEC 60601-1-1:2000 / EN 60601-1-1:2001

Test procedure ..... : TUV Test Report

Procedure deviation ..... : N.A.

Non-standard test method ..... : N.A.

Test Report Form/blank test report

Test Report Form No. ..... : I601-1_C/97-07 / I601-1-1_A

TRF originator ..... : UL

Master TRF ..... : dated 97-04

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Test item

Description ..... : Optical Topography System

Trademark ..... : Hitachi

Model and/or type reference ..... : ETG-4000

Manufacturer ..... : Same as client

Factory ..... : Same as client

Rating(s) ..... : 230V~, 50/60Hz, 700VA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

Particulars: test item vs. test requirements

Classification of installation and use ..... : ~~transportable~~ / ~~portable~~ / ~~stationary~~ / mobile / ~~fixed~~ / ~~permanently installed~~ / ~~hand-held~~

Supply connection ..... : ~~internally powered~~ / ~~permanently installed~~ / appliance coupler / ~~non-detachable cord~~

Test case verdicts

Test case does not apply to the test object..... : N(.A.)

Test item does meet the requirement ..... : P(ass)

Test item does not meet the requirement..... : F(ail)

Testing

Date of receipt of test item ..... : 2003-03-11

Date(s) of performance of test..... : 2003-08-26 - 2003-09-03

General remarks

This test report shall not be reproduced except in full without the written approval of the testing laboratory.
The test results presented in this report relate only to the item tested.
"(see remark #)" refers to a remark appended to the report.
"(see appended table)" refers to a table appended to the report.
Throughout this report a comma is used as the decimal separator.

Brief description of device under test

This medical equipment is for measuring the oxidization in the blood on the cerebrum surface. Additionally, it measures the amount of reduction hemoglobin at many points from change of the amount of absorption of light. In this way it can grasp a cerebral activation state. Therefore, it is a semiconductor laser, incorporating a class 3b laser, used. The System consists of a movable (casters) base rack. A metal box underneath incorporates a AC power supply (linear transformer) and 4 switching power supplies. The equipment main unit consits of a laser unit, a PC workstation, CRT-monitor, keyboard and mouse.
Fiber cables leading from the main unit to the patient applied parts for the measurement operations.
Accessories such as printer, have not been subject to the system safety evaluation.
The following components were part of the device under test:

- CRT-Monitor: Eizo Co.,
- Keyboard: Dell Co.,
- Mouse: Dell Co.,
- Workstation with CD ROM/Floppy: Dell Co.

For EN 60601-1, the Amendment A13:1996 has been listed. However, since the described requirements are not applicable, no further reporting is deemed necessary.

Attachments

Attachment 1:	Rating label / Transport/Storage label / Laser safety markings / Label Overview	15 pages
Attachment 2:	Insulation Diagram / Block Circuit Diagram	7 pages
Attachment 3:	Measurement Equipment List	1 page
Attachment 4:	Photo Documentation	7 pages

Copy of marking plate

Refer to Attachment 1

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TÜV RHEINLAND
Product Safety GmbH
Am Grauen Stein
D-51105 Köln

TÜV

TEST REPORT

12004909 001

IEC 60825-1:2001, Edition 1.2
EN 60825-1:1994+A11:1996+A2:2001
Safety of laser products – Part 1. Equipment classification, requirements and user's guide

Optical Encephalography System

ETG-4000

Hitachi Medical Corporation

41D

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

Prüfbericht - Nr.: *Test Report No.*	**12004909 001**		Seite 1 von 14 *Page 1 of 14*
Auftraggeber: *Client:*	**Hitachi Medical Corporation** 2-1 Shintoyofuta, Kashiwa-shi, Chiba 277-0804, Japan		
Gegenstand der Prüfung: *Test item:*	Optical Encephalography System		
Bezeichnung: *Identification:*	**ETG-4000**	**Serien-Nr.:** *Serial No.*	Engineering Sample
Wareneingangs-Nr.: *Receipt No.:*	**3028121**	**Eingangsdatum:** *Date of receipt:*	11.03.2003
Prüfort: *Testing location:*	**TÜV Rheinland Japan Ltd.**, Yokohama Laboratory 1-26-10, Hayabuchi, Tsuzuki-ku, Yokohama 224-0025, Japan		
Prüfgrundlage: *Test specification:*	IEC 60825-1:2001, Edition 1.2 EN 60825-1:1994+A11:1996+A2:2001 Safety of laser products – Part 1. Equipment classification, requirements and user's guide		
Prüfergebnis: *Test Result*	**Der vorstehend beschriebene Prüfgegenstand wurde geprüft und entspricht oben genannter Prüfgrundlage.** The a. m. test item passed.		

Prüflaboratorium/Testing Laboratory **kontrolliert/*checked by***

geprüft/*tested by:*

Datum *Date*	Name *Name*	Unterschrift *Signature*	Datum *Date*	Name *Name*	Unterschrift *Signature*
27.06.2003	E. Riechert	E. Riechert	27.06.2003	U. Bast	

Sonstiges/*Other Aspects:*

A standard update according to IEC 60825-1:2001, Edition 1.2 was performed.
The equipment was tested as delivered, assembled and set by the manufacturer.
Deviations from the set parameters and fault conditions have not been applied for.
The tested parameters and settings represent the normal operation conditions as adjusted by the manufacturer.

Attachments:
Attachment 1: Labeling instruction
Attachment 2: Description of safety interlock system
Attachment 3: Photo documentation

Abkürzungen:			*Abbreviations:*		
ok / P	=	*entspricht Prüfgrundlage*	*ok / P*	=	*passed*
fail / F	=	*entspricht nicht Prüfgrundlage*	*fail / F*	=	*failed*
n.a. / N	=	*nicht anwendbar*	*n.a. / N*	=	*not applicable*

Dieser Prüfbericht bezieht sich nur auf den o.g. Prüfgegenstand und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden.
This test report relates to the a. m. test item. Without permission of the test center this test report is not permitted to be duplicated in extracts.

TÜV Rheinland Product Safety GmbH · Am Grauen Stein · D - 51105 Köln · Phone: +49 221 806-1371 · Fax: +49 221 806-3995
Mail: trps-certification@tuv.com · Web: www.tuv.com

H:\PSO\GROUPS\GF 303\Projects_Testing\HITACHI\Hitachi Medical\3028121\12004909 001.doc

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

Reference No. ..... :	**12004909 001**
Compiled by (+ signature)..... :	see cover page
Approved by (+ signature)..... :	see cover page
Date of issue ..... :	see cover page
Testing laboratory	
Name ..... :	**TÜV Rheinland Japan Ltd.**, Yokohama Laboratory
Address ..... :	1-26-10, Hayabuchi, Tsuzuki-ku, Yokohama 224-0025, Japan
Testing location ..... :	as above
Applicant	
Name ..... :	**Hitachi Medical Corporation**
Address ..... :	2-1 Shintoyofuta, Kashiwa-shi, Chiba 277-0804, Japan
Test specification	
Standard ..... :	IEC 60825-1:2001, Edition 1.2
Test procedure	N.A.
Procedure deviation	N.A.
Non-standard test method	N.A.
Test item	
Description..... :	Optical Encephalography System
Trademark ..... :	HITACHI
Model and/or type reference ..... :	ETG-4000
Manufacturer ..... :	same as applicant
Factory..... :	same as applicant
Rating ..... :	230V~ 50/60Hz 500VA
Copy of marking plate	
engineering sample, no marking provided	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

Biocompatibility Statement

The patient contact surfaces of the ETG-4000 use common materials that have been previously tested for biocompatibility. Hitachi has the test results on file and is not aware of any new factors that would affect the biocompatibility of the device in question.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Risk Analysis

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Risk Assessment Report 1 (Scope of object for securing product safety)
(Clarification of qualitative and quantitative characteristics)

Approval [redacted] (b) (4) ,Checked: , Prepared:

Product name : Optical Topography System	
Name of person performed risk analysis,	Electric : [redacted] Software [redacted] Mechani[redacted]

Item No.	Scope of object for securing product safety (Clarification of qualitative and quantitative characteristics of product)	
	Requirement	Description
a	What is intended application of the equipment and how it is used ? Application User Environment Installing person Assistance Matter to be taking into consideration for special patients	Head; It measures changes in cerebrocortical blood volume Physicians, Qualified person like examination technician and Researchers Hospitals (in general diagnostic room, ward and operating room) and Research Field service person of HMC and distributor No None
b	Is the equipment intended to contact with the patient and other patients ?	Probe (optical fiber); Head
c	What kinds of material/parts are used in the equipment ?	Material of probe surface : Biocompatible material Material of holder : Biocompatible material Hazardous material : Battery and solder Risky material
d	Is the equipment to give any kind of energy to the patient and/or to take the energy out of patient ?	Yes (LASER)
e	Is there any material to administer to the patient and/or to take out of patient ?	No
f	Is any biological material which is processed by the equipment for reuse ?	No
g	Is the equipment supplied after sterilization or is it required to sterilize by the user or is another microbe control regulation applied ?	NO
h	Is the equipment intended to modify patient environment ?	No
I	Is the equipment used for any measurement ?	It measures quantitative change of Hemoglobin (blood).
j	Is the equipment provided with a function to interpret the measurement result ?	No
k	Is the equipment intended to be interactive with other equipment or drugs, or to control other equipment or drugs ?	No
l	Does the equipment exhaust any undesirable energy or material ?	Energy; Laser power, EMI and leak current , Meterial;
m	Is the equipment easily affected by environment ?	Temperature, humidity, sterilizing process, immunity and pressure from outside to package during transportation
n	Is there indispensable consumptive goods and accessories to the equipment ?	Consumptive goods; Printer ink
o	Are maintenance and/or calibration required ?	Maintenance; Dust filter , Calibration; Not required
p	Is software installed in the equipment ?	Yes
q	Is there any limit of storing period of equipment ?	No
r	Is the operation of equipment affected if it has been stored for long period or if it is used for long time ?	Operation after long storing; No problem , Long time operation; No problem
s	To what kind of mechanical power is the equipment related ?	No
t	What dose decide the life of the equipment ?	Laser
u	Is the equipment intended for the operation of only one time or intended the repeated operation ?	Main unit and probe are intended for repetitive operation.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Risk Assessment Standard

Table -1 Risk Severity

Class	Level	Injury	Definition
Ⅳ	Catastrophic	Deaths Total Breakdown of System	- Deaths - Physical or mental serious injuries (Care is necessary.) - System or Facility burned down.
Ⅲ	Critical	Serious Injuries Serious Occupational Disease Serious System Trouble	- Physical or mental injuries which influence daily life - Facility catches fire.
Ⅱ	Marginal	Slight Injuries Occupational Disease Slight System Trouble	- Physical or mental injuries which don't influence daily life - Necessary to cure by medical facility - System catches fire, not repairable
Ⅰ	Negligible	Slight Injuries Occupational Disease Slighter than System Trouble	- Slight injury and slight pain, no scar - Smoke from system, repairable

Table -2 Risk Likelihood

Level	Likelihood	Probability (/year) (for reference)
5	Frequent	1
4	Probable	$1 \sim 10^{-1}$
3	Occasional	$\sim 10^{-3}$
2	Improbable	$\sim 10^{-5}$
1	Incredible	$\sim 10^{-6}$

Table -3 Risk Level

Likelihood				
5	A	A	A	A
4	B	A	A	A
3	B	B	A	A
2	C	B	B	A
1	C	C	B	A
	Ⅰ	Ⅱ	Ⅲ	Ⅳ Severity

Table -4 Risk Criteria

	Acceptable region	Criteria
A	Intolerable region	- Risk is serious and intolerable. Risk shall be reduced.
B	As Low as Reasonably Practicable region	- Risk shall be reduced as low as possible. - Risk shall be reduced as low as reasonably practicable considering Risk reducing benefit and expense.
C	Broadly Acceptable region	- System isn't necessary to change.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Risk Assessment Report (b) (4)

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Section 10

Performance

Contents:

Sample Data Output 2

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sample Data Output

Hitachi regards the following as trade secrets and confidential in nature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

The ETG-4000 system Sample data

Task: Right Hand Tapping

Hb Time course graph

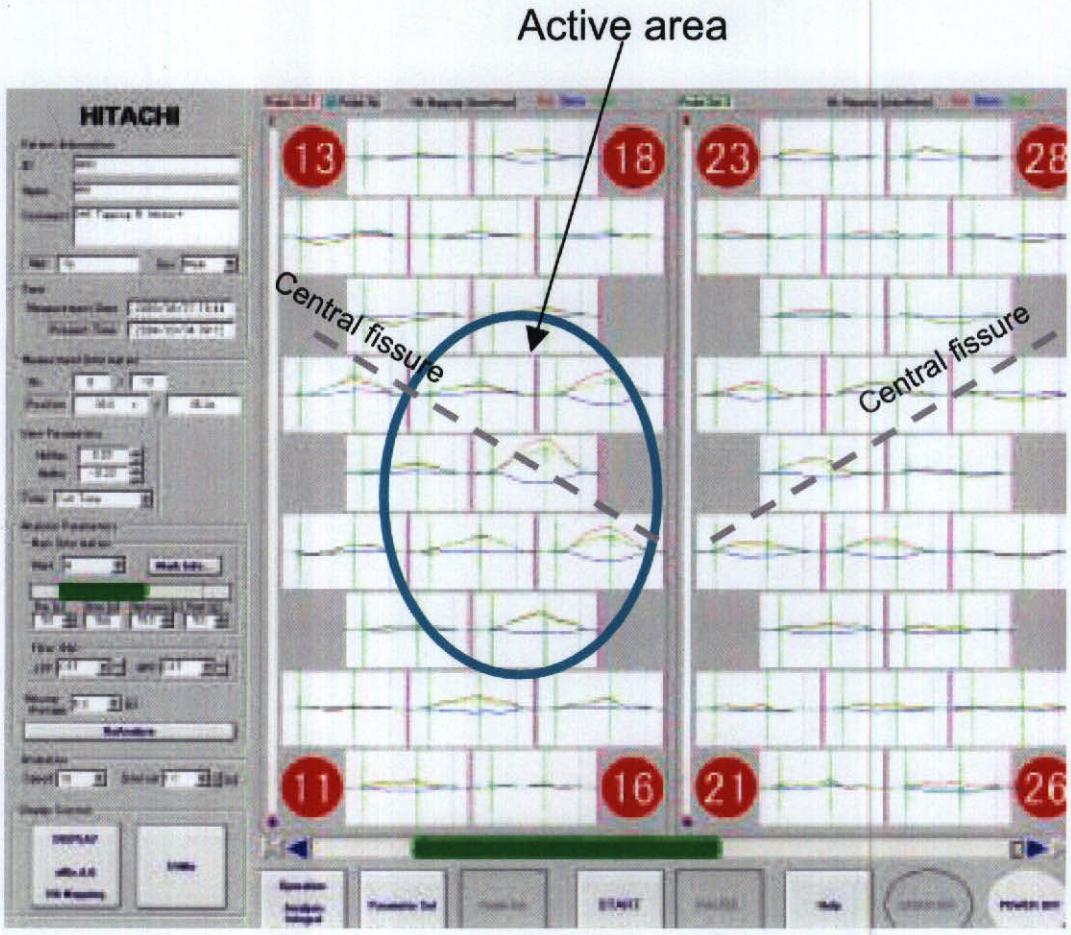
5 task Data is averaged arithmetically. The increase of Oxy-Hb and Total-Hb is observed around the central fissure.

Large increases are observed in the left area, the opposite side to the right hand which did the task. This suggests that the Left motor field activity is dominant. An increase in the Oxy-hemoglobin level spreading around central fissure means that both the motor area and the somatosensory area are activating.

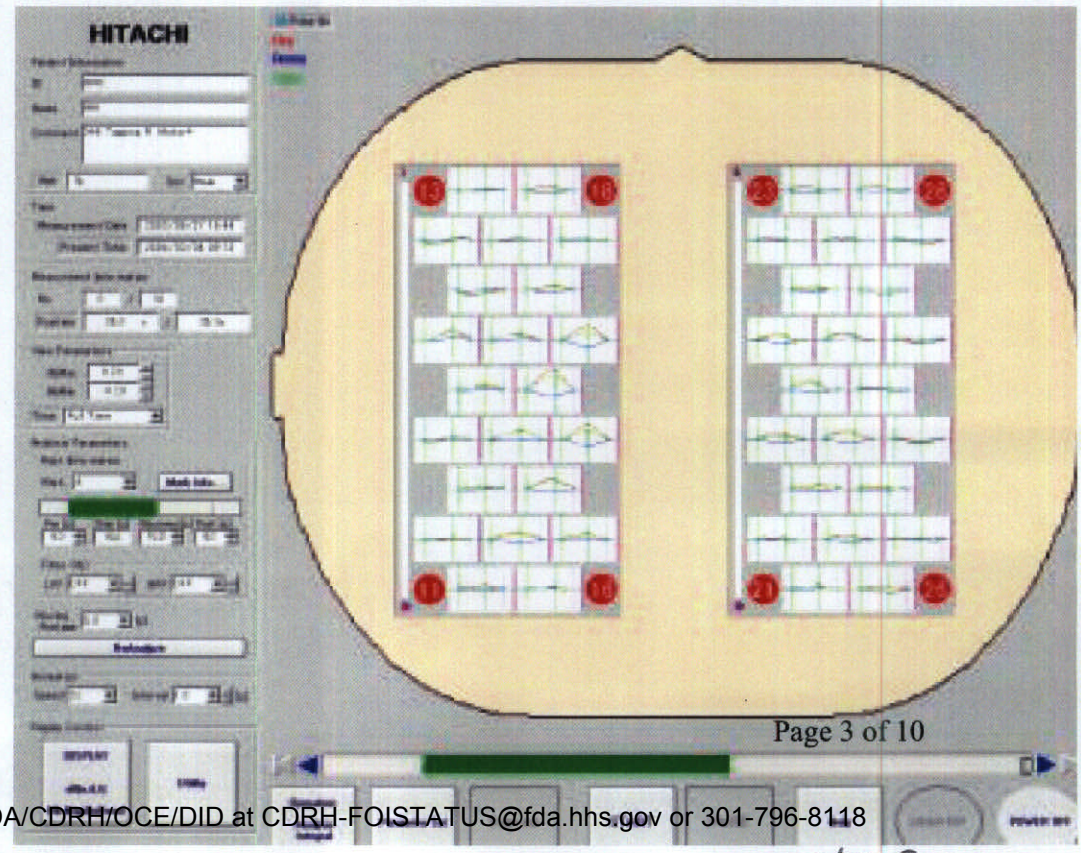
This OT graph shows;

About 2-3sec after the task started, the amount of Total-Hb started to increase. After about 15sec, the signal reached a peak. After the peak,the signal returns to normal gradually.

Compared with Oxy-Hb and Total-Hb, Deoxy-Hb change is small. The amount of signal change depends on task speed or on the extent of a subject's concentration during the task term.



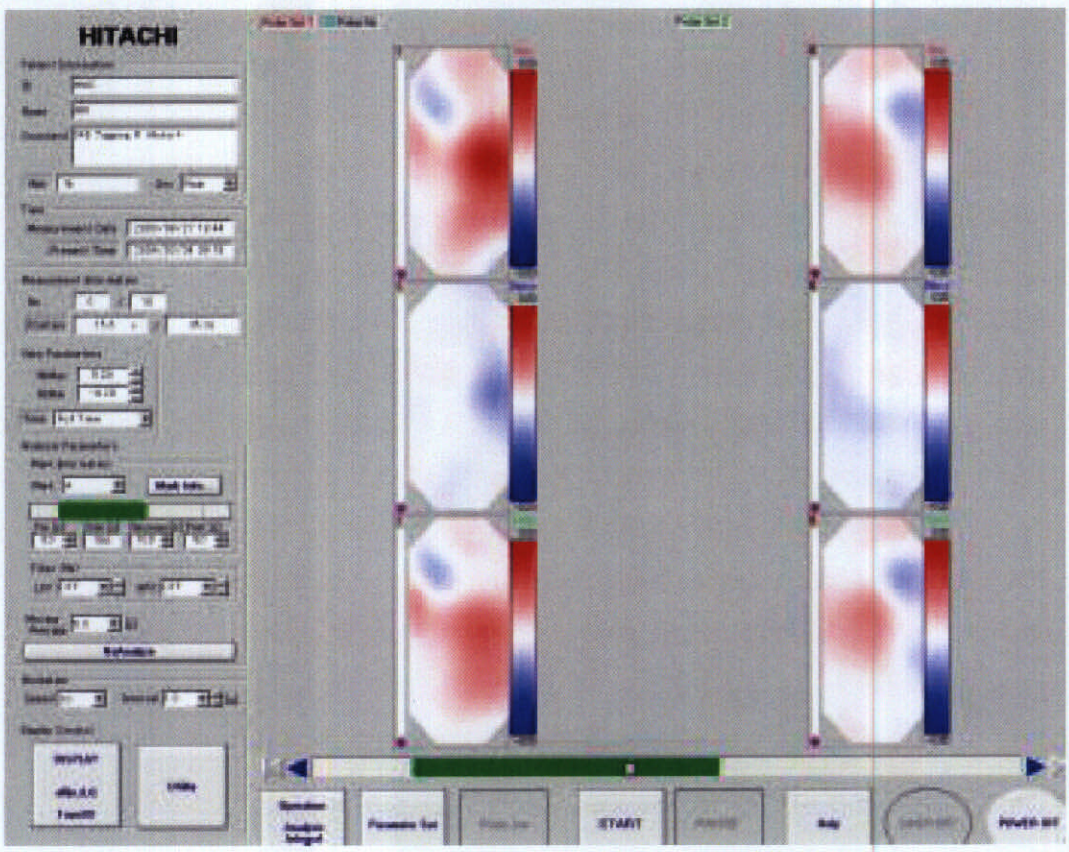
Hb Time course graph on the head



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

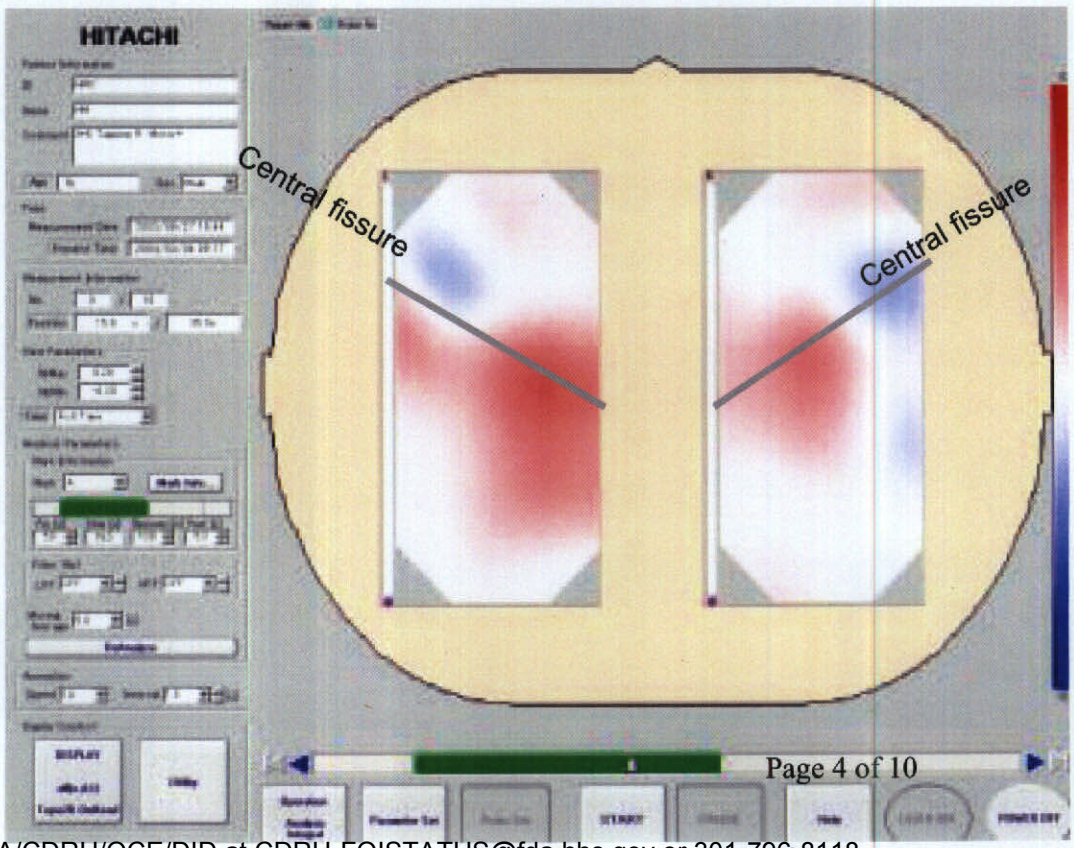
2D Topo graph

In Topo Data, red means the increase of blood and blue means the decrease of blood. According to this data, it can be observed that Oxy-Hb and Total-Hb around the central fissure increase.
The opposite area (left area) to the right hand which did the task shows deep red. It means there are large increases.
Just after the start of the task, Oxy-Hb and Total-Hb had no remarkable change. After 15sec, the largest concentration of deep red appeared. After the end of the task, the red gradually goes pale and the 2D Topo graph returns to its original state before the task started.



2D Topo graph on the head

Select: Total Hb



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The ETG-4000 system Sample data

Task: Calculation

Active area

Hb Time course graph

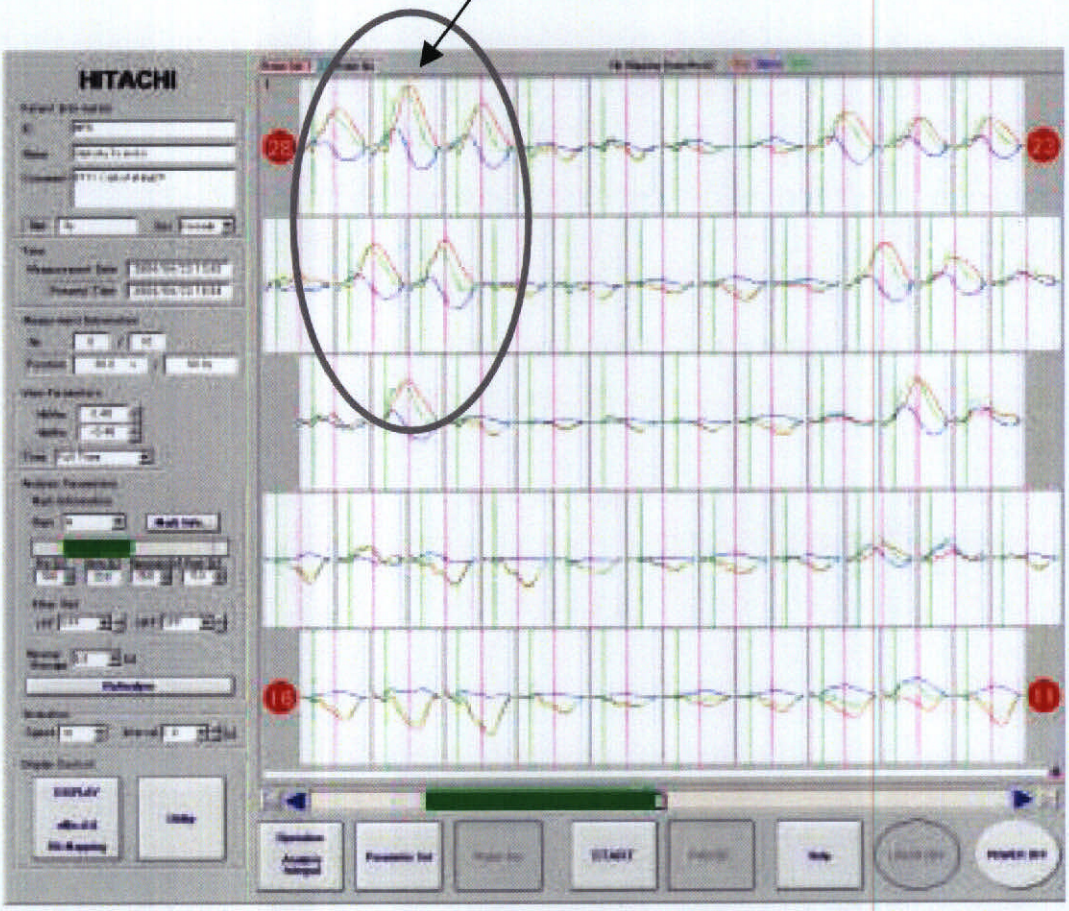
5 task Data is averaged arithmetically. The increase of Oxy-Hb and Total-Hb is observed in the frontal region.

Large increases are observed in the Broca area, the working memory area and the thinking area. The data also suggests that the Left frontal field activity is dominant. An increase in the Oxy-hemoglobin level spreading around the Broca area, the working memory area and the thinking area means that the Broca area, the working memory area and the thinking area are activating.

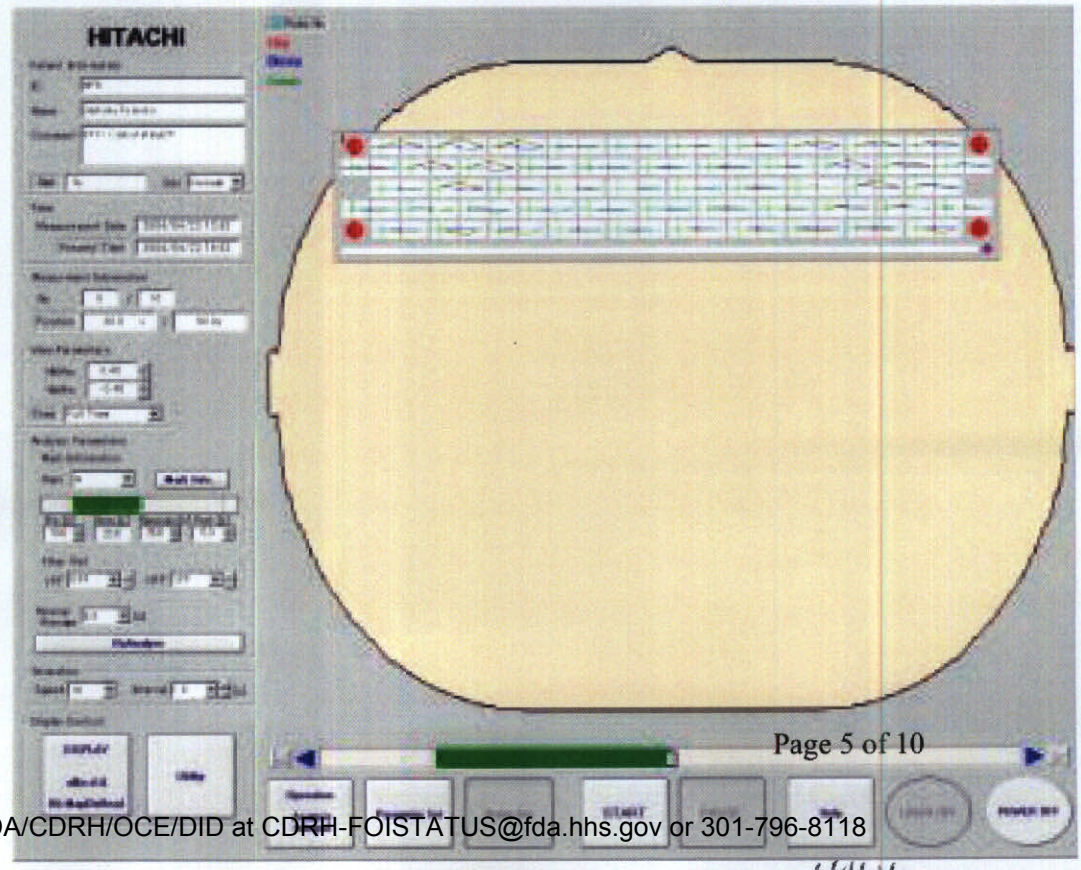
This OT graph shows;

About 2-3sec after the task started, the amount of Total-Hb started to increase. After about 20sec, the signal reached a peak. After the peak,the signal returns to normal gradually.

Compared with Oxy-Hb and Total-Hb, Deoxy-Hb change is small. The amount of signal change depends on task speed or on the extent of a subject's concentration during the task term.



Hb Time course graph on the head



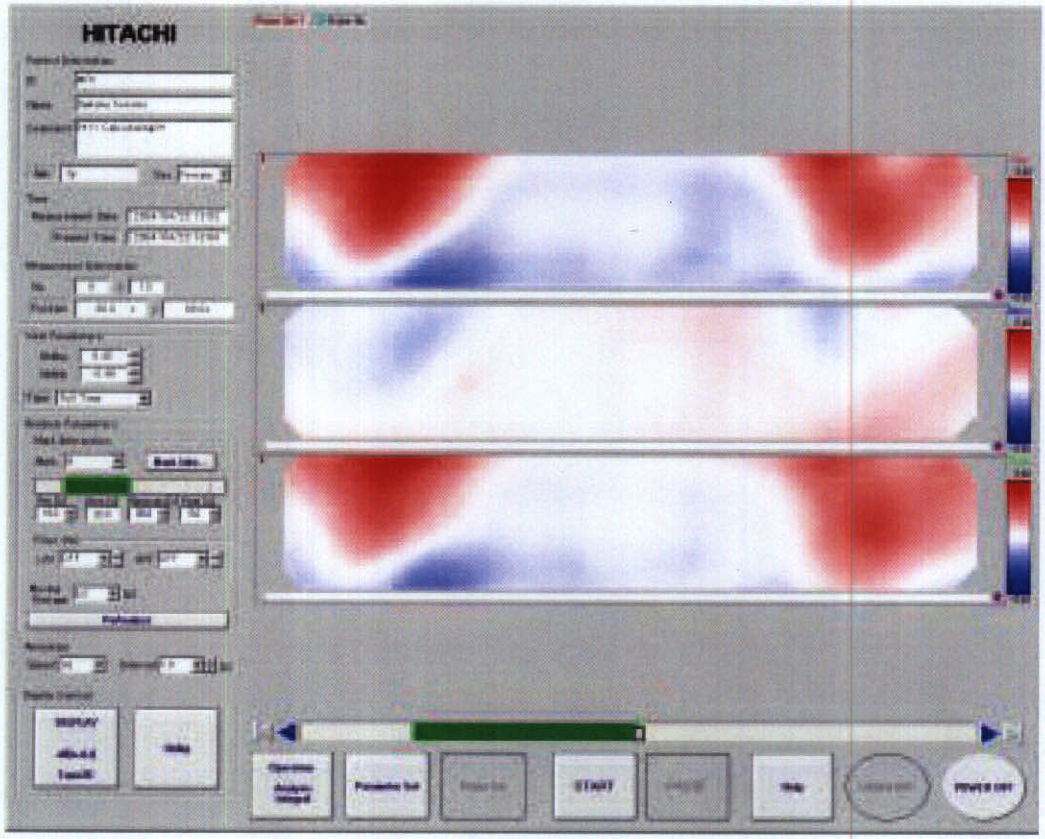
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

2D Topo graph

In Topo Data, red means the increase of blood and blue means the decrease of blood. According to this data, it can be observed that Oxy-Hb and Total-Hb in the frontal region increase.

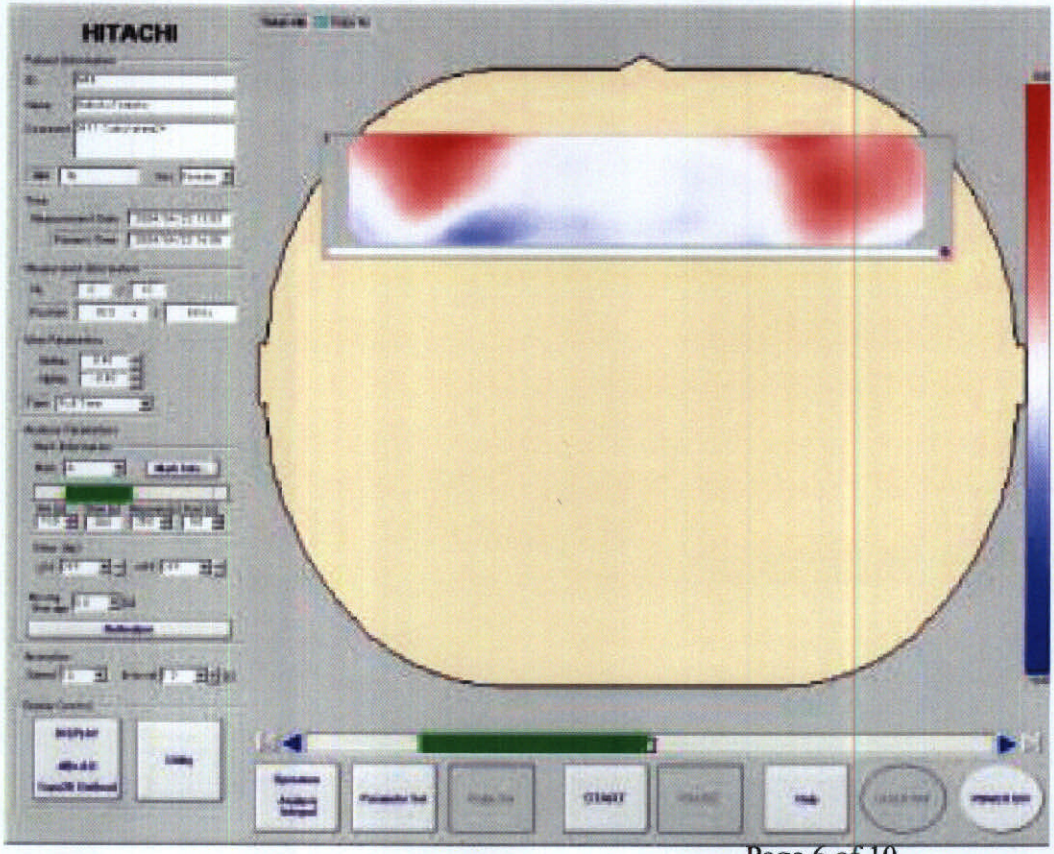
The Broca area, the working memory area and the thinking area in the frontal region show deep red. It means there are large increases.

Just after the start of the task, Oxy-Hb and Total-Hb had no remarkable change. After 20sec, the largest concentration of deep red appeared. After the end of the task, the red gradually goes pale and the 2D Topo graph returns to its original state before the task started.



2D Topo graph on the head

Select: Total Hb



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Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

The ETG-4000 system Sample data

Task: Name Listing

Active area

Hb Time course graph

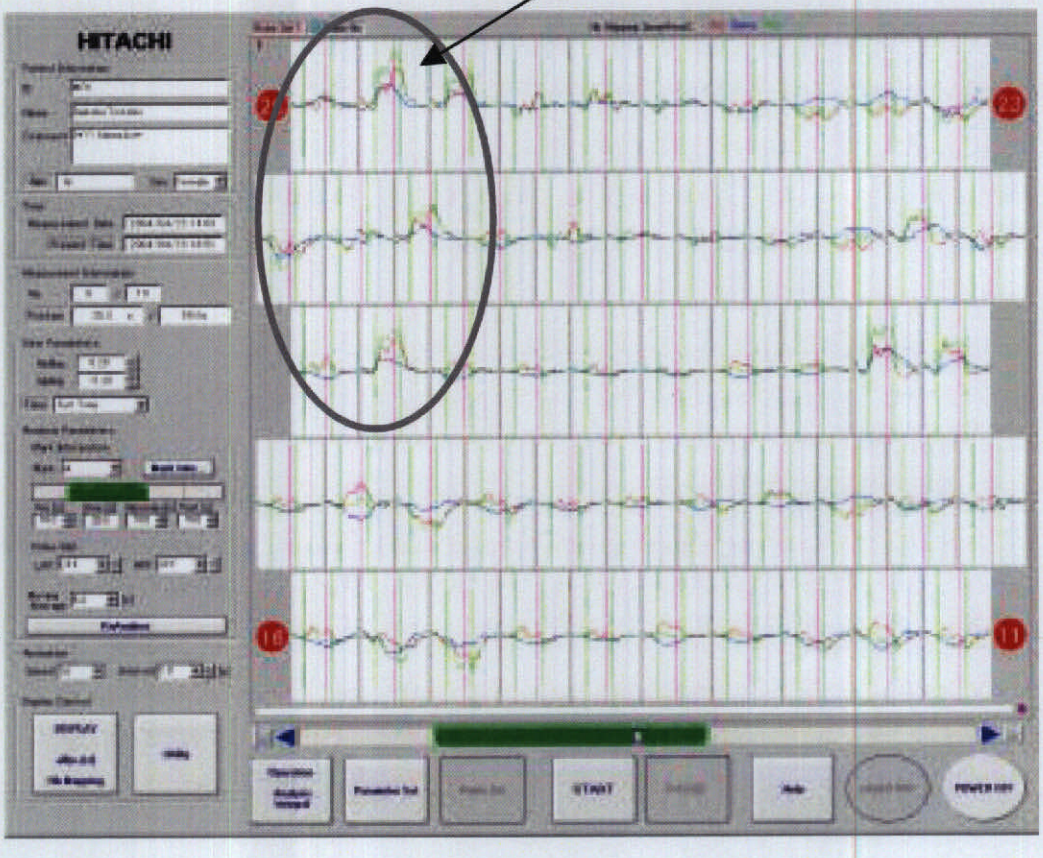
5 task Data is averaged arithmetically. The increase of Oxy-Hb and Total-Hb is observed in the frontal region.

Large increases are observed in the Broca area, the working memory area and the thinking area. The data also suggests that the left frontal field activity is sperior. An increase in the Oxy-hemoglobin level spreading around the Broca area, the working memory area and the thinking area means that the Broca area, the working memory area and the thinking area are activating.

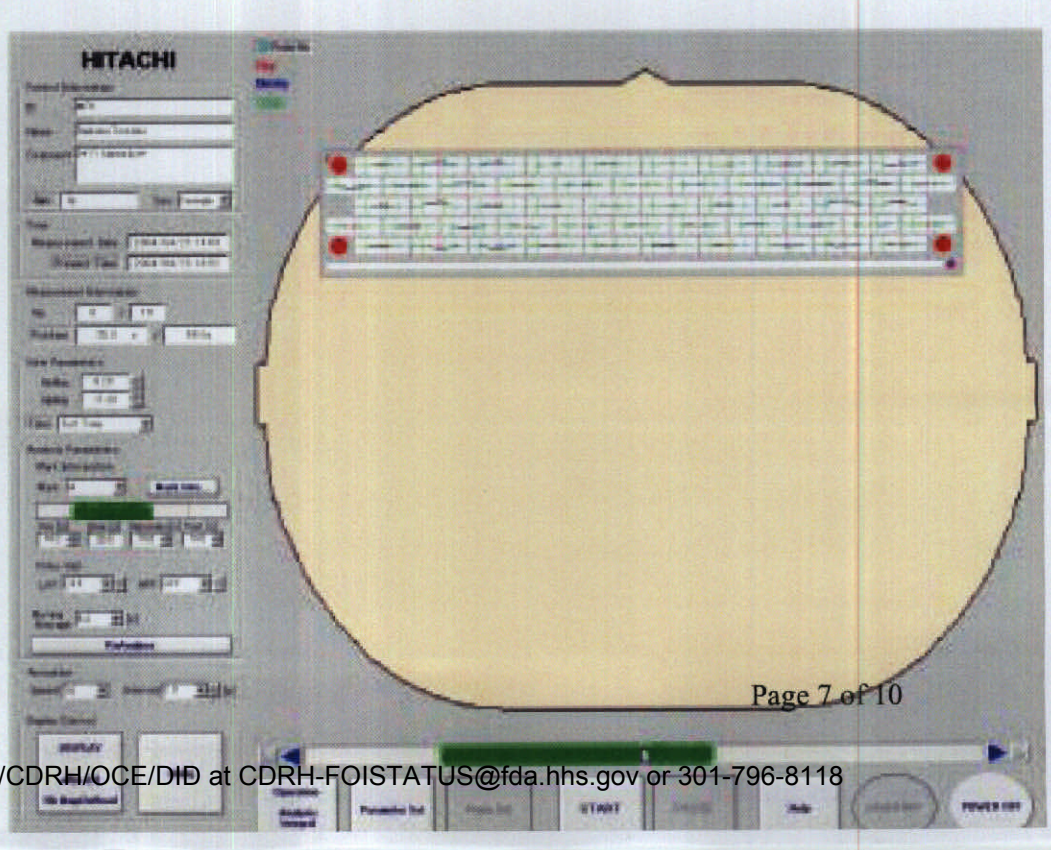
This OT graph shows;

Just after the task started, the amount of Total-Hb started to increase. After about 16sec, the signal reached a peak. After the peak,the signal returns to normal gradually.

Compared with Oxy-Hb and Total-Hb, Deoxy-Hb change is small. The amount of signal change depends on task speed or on the extent of a subject's concentration during the task term.



Hb Time course graph on the head



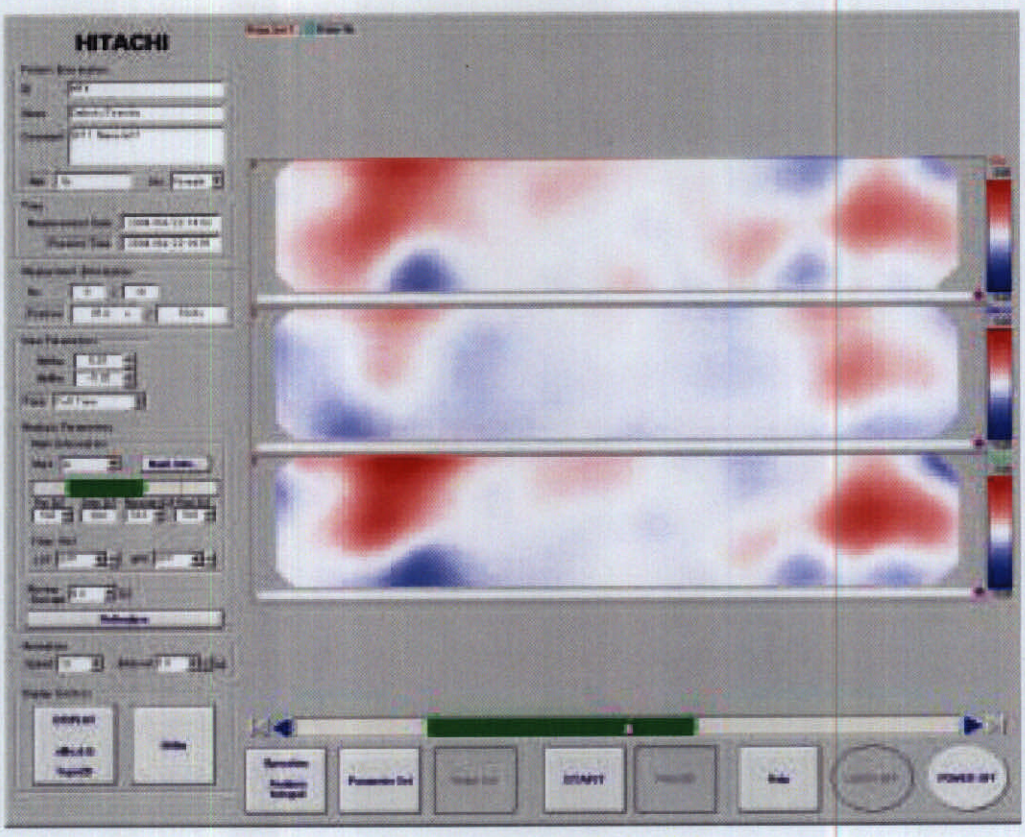
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

2D Topo graph

In Topo Data, red means the increase of blood and blue means the decrease of blood. According to this data, it can be observed that Oxy-Hb and Total-Hb in the frontal region increase.

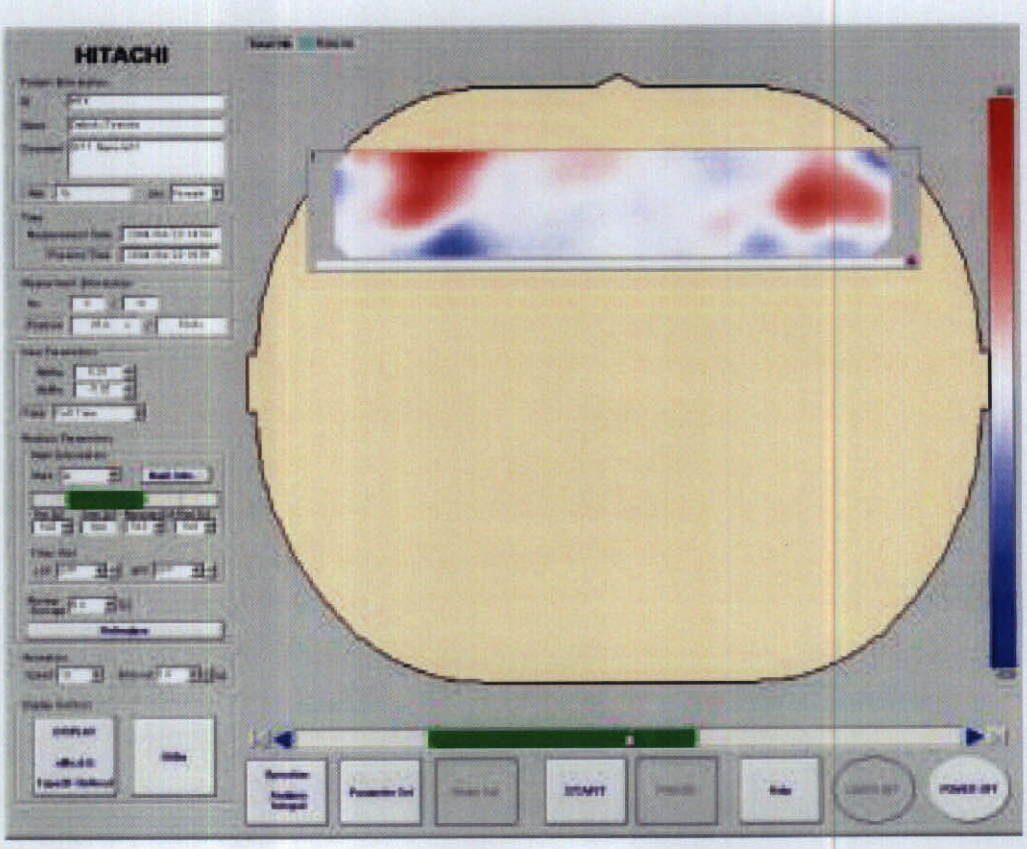
The Broca area, the working memory area and the thinking area show deep red. It means there are large increases.

Just after the start of the task, the amount of Oxy-Hb and Total-Hb started to increase . After 16sec, the largest concentration of deep red appeared. After the end of the task, the red gradually goes pale and the 2D Topo graph returns to its original state before the task started.



2D Topo graph on the head

Select: Total Hb



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records Processed under FOIA Request # 2015-6635; Released by CDRH on 8-28-2015

The ETG-4000 system Sample data

Task: Visual Stimulus (Checkerboard pattern reversal)

Active area

Hb Time course graph

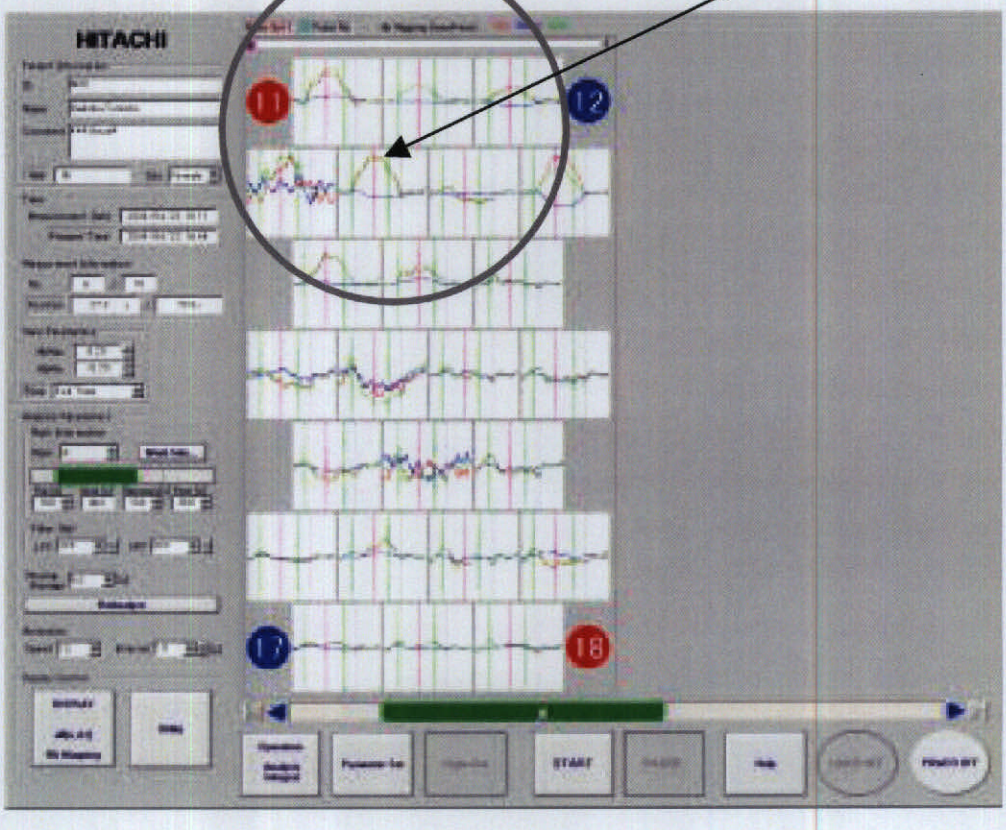
5 task Data is averaged arithmetically. The increase of Oxy-Hb and Total-Hb is observed in the occipital region.

Large increases are observed in both the right and left visual areas when a visual stimulus (checkerboard pattern reversal) is given. An increase in the Oxy-hemoglobin level spreading around the primary visual field means that both the right and left visual areas are activating.

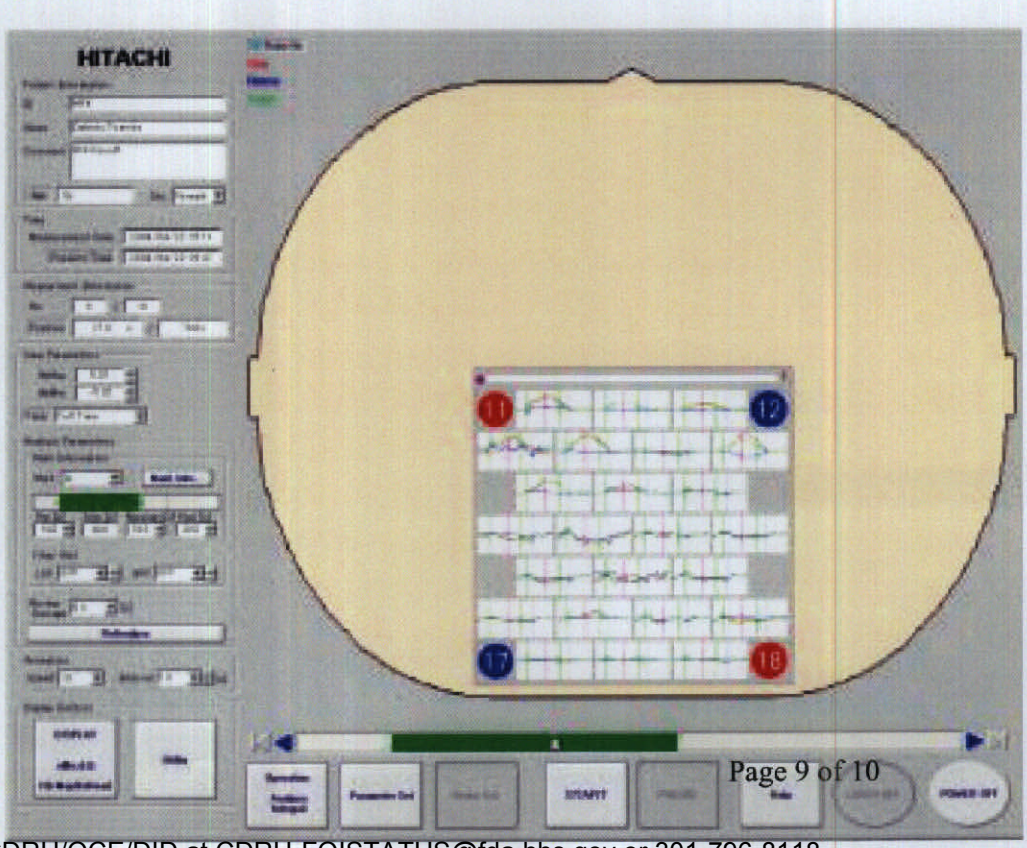
This OT graph shows;

Just after the task started, the amount of Total-Hb started to increase. After about 15sec, the signal reached a peak and the peak lasted 8sec. After the peak,the signal returns to normal gradually.

Compared with Oxy-Hb and Total-Hb, Deoxy-Hb change is small. The amount of signal change depends on task speed or on the extent of a subject's concentration during the task term.



Hb Time course graph on the head



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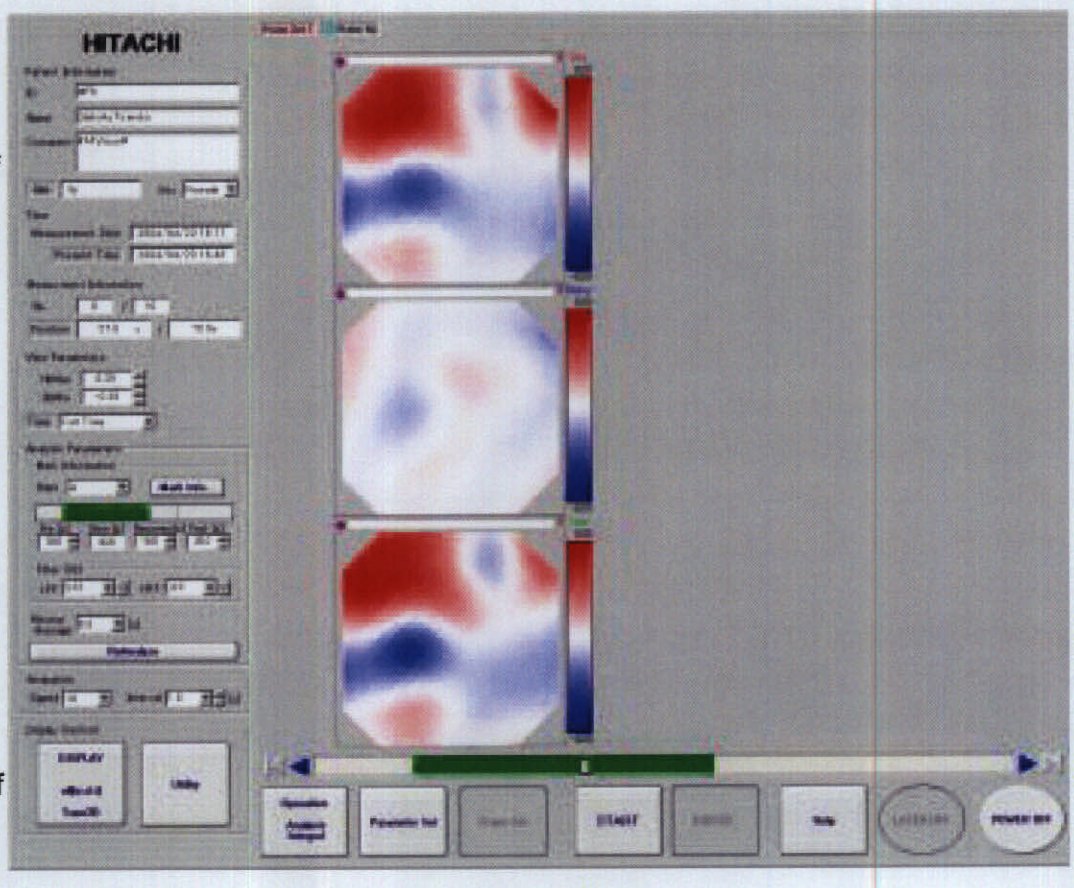
2D Topo graph

In Topo Data, red means the increase of blood and blue means the decrease of blood. According to this data, it can be observed that Oxy-Hb and Total-Hb in the occipital region increase.

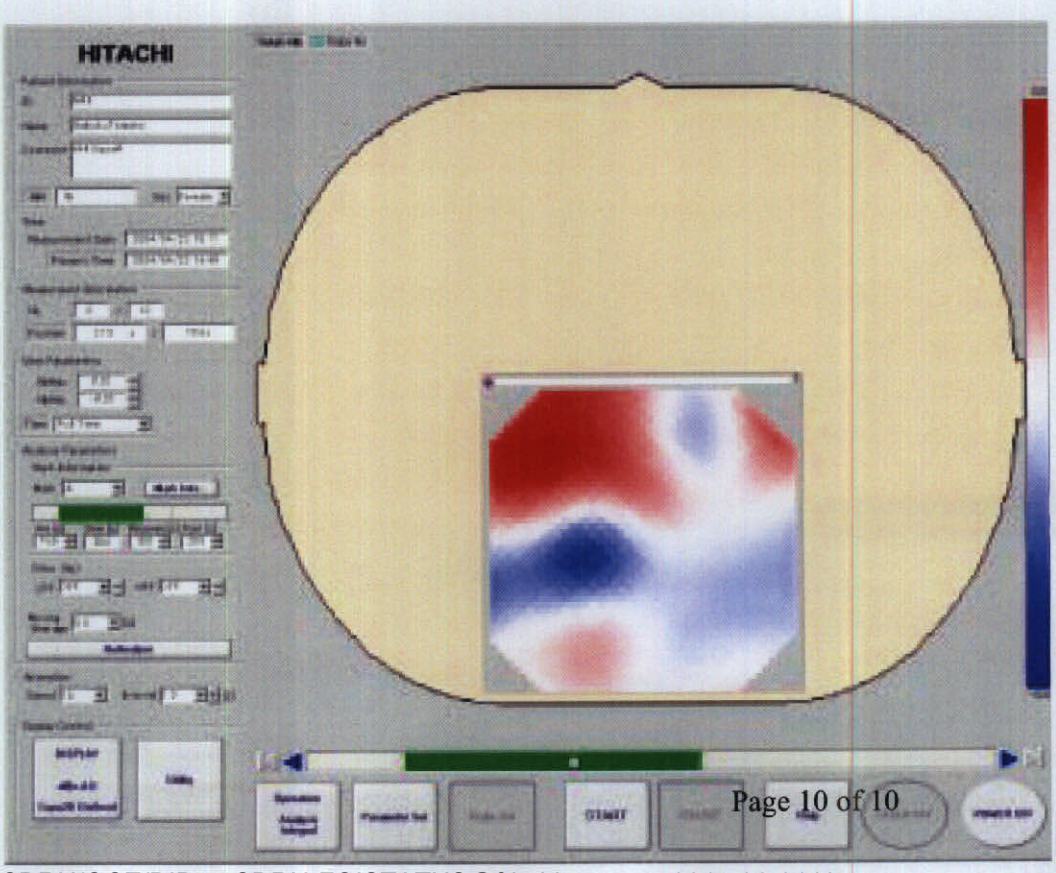
The right and left visual areas show deep red. It means there are large increases.

Just after the start of the task, the amount of Oxy-Hb and Total-Hb started to increase. After 15sec, the largest concentration of deep red appeared and it lasted 8sec. After the end of the task, the red gradually goes pale and the 2D Topo graph returns to its original state before the task started.



2D Topo graph on the head

Select: Total Hb



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HITACHI

HITACHI MEDICAL SYSTEMS AMERICA, INC.

Fax Transmission

DATE: 9/29/04

Page 1 of 8

TO: Michel Janda

COMPANY: FDA

Fax: 301-827-4350

cc:

FROM: Doug Thistlethwaite

Telephone: 330.425.1313
Fax: 330.425.1410

SUBJECT: 510(k) K042501 Responses

REF#:

The documents accompanying this telecopy transmission contain confidential information belonging to the sender which is legally privileged. The information is intended only for the use of the individual or entity named above. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or the taking of any action in reliance on the contents of this telecopy's information is strictly prohibited. If you have received this telecopy in error, please immediately notify us by telephone to arrange for return of the original documents to us.

Dear Mr. Janda,

The revised documents that you requested are included, except the technical paper references. Those will be emailed to preserve readability.

The full package will be mailed separately as you requested.

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HITACHI

HITACHI MEDICAL CORPORATION, INC.
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

September 29, 2004

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Re: Special 510(k) Device Modification (K042501)
Hitachi ETG-4000 Optical Topography System

To Whom It May Concern:

The attached documents are provided to answer discrepancies noted by the 510(k) reviewer. Please contact me if there are further questions or concerns.

Refer to page 2 for the list of documents and comments.

Sincerely,

Doug Thistlethwaite
Official Correspondent, Hitachi Medical Corporation
(330)-425-1313 x3720
thistlethwaited@hitachi.com

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Change Request	Description/Comments
Truth and Accurate Statement	Attachment 1. See revised T&A statement using standard form.
Device Name in 510(k) Summary	Attachment 2. Corrected to read "ETG-4000 Optical Topography System".
Intended use	Attachment 3. Revised using standard form.
User Manual Corrections	Attachment 4. Changed sterilization references to cleaning. See pages 1-4 and 3-5, included.
Technical Paper references 4, 5, 6	Attachment 5. Item 5 - Note that the title reference for item 5 was incorrect in the algorithm evaluation document. The included document is the correct reference. Item 6 – The listed item was published in Japanese. The included document is an English version on the same topic.

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Attachment 2

HITACHI

HITACHI MEDICAL CORPORATION
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

510(k) Summary

K042501

Submitter Information

Submitter: Hitachi Medical Corporation
1-1-14 Uchi-Kanda, Chiyoda-ku
Tokyo 101-0047, Japan

Contact: Douglas J. Thistlethwaite
ph: (330) 425-1313
fax: (330) 425-1410

Date: September 13, 2004

Device Name

Device Name: Optical Topography System
Trade/Proprietary Name: ETG-4000 Optical Topography System
Common Name: Oximeter
Classification Name: Oximeter
Classification Number: Sec. 870.2700

Predicate Device

Predicate Device: Hitachi ETG-100, K011320

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Attachment 1

PREMARKET NOTIFICATION TRUTH AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Official Correspondent of Hitachi Medical Corporation, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.

(Signature)

Douglas Thistlethwaite
(Name)

9/29/04
(Date)

510(k) Number: K042501

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510(k) Number (if known): K042501

Device Name: ETG-4000 Optical Topography System

Indications for Use:

The intended use of the ETG-4000 is the measurement of relative levels of cerebral deoxy-hemoglobin and oxyhemoglobin.

Prescription Use X AND/OR Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Attachment 4

1.7 Cautions in Handling the System

1.7.1 Handling optical fiber cable

The optical fiber cables are important parts that transmit irradiation light to the patient and receive reflected light to conduct it to the detectors. Observe the following cautions so as not to damage it by careless handling.

(1) Do not bend the optical fiber cable by curvature radius of 30mm or less.

(2) Do not pull the optical fiber cable or place any heavy article on it.

(3) Do not hit the fiber cable with any hard object or drop it.

(4) Use gauze soaked with alcohol to clean the tip of fiber socket and probe holder before starting measurement.

(5) Full care should be taken not to damage the tip of fiber socket.

(6) When not using the optical fiber cable, set it to the phantom in the system.

(7) When attaching and detaching the optical fiber cable to/from the system, be sure to make contact with our sales or service personnel

1.7.2 Connecting external devices

Use "BNC cable" and "RS-232C cable" attached to the system for connecting the external devices.

< CAUTION >

- Use the external devices outside the patient environment.
- The external devices used should be products approved in response to the IEC safety standard.

1.7.3 Cautions in operating and using the system

(1) When any abnormality occurred in the system, immediately stop using and shut off the power, and then make contact with our service or sales personnel.

(2) When not using the system for a long period of time, be sure to disconnect the power cable from the power outlet.

(3) Never remodel the system (both hardware and software) and optical fiber cables.

The personal computer used in this system is for measurement control, data acquisition, data processing and data display. Mounting any general computer on the system can cause malfunction. Do not mount such computer.

(4) Items described in this instruction manual are subject to change without notice for improvement.

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3.1.4 Attaching the probe holder and fiber sockets

(1) To protect infection, clean the probe holder and so on before using for the patient.

When cleaning, wipe it with gauze or the like soaked with ethanol.

Do not carry out cleaning or disinfection using chemicals or heating other than ethanol.

(2) Hook the optical fiber cable protection hose to the hanger while using it.

If the tip of fiber socket contact with scalp moves during measurement is pulled by the optical fiber cable due to body movement and so on, measurement data is affected and a wrong result may be produced. Adjust the hanger so that all optical fiber cables are bundled together at the optical fiber cable protection hose.

Attach the probe holder suitable for the objective mode to the patient.

Fig. 3.8 Attaching the Probe Holder

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Wavelength dependence of the precision of noninvasive optical measurement of oxy-, deoxy-, and total-hemoglobin concentration

Yuichi Yamashita,[a] Atsushi Maki, and Hideaki Koizumi
Hitachi, Ltd., Advanced Research Laboratory, Hatoyama, Saitama, 350-0395, Japan

(Received 18 October 2000; accepted for publication 21 March 2001)

The precision of noninvasive optical measurement of the concentration changes in oxy-, deoxy-, and total-hemoglobin depends on wavelength. For estimating the precision, we calculated the noise level of the concentration changes as the uncertainty in measurements using several wavelength pairs of light. Seven laser diodes (664–848 nm) were used simultaneously for spectroscopic measurement of brain activity during finger motor stimulation. We also used the analysis of error propagation from the uncertainty in direct measurements of absorbance changes to estimate indirectly the uncertainty of concentration changes. The measurement of the concentration changes made using an 830/664-nm pair are two times (oxy-Hb) and six times (deoxy-Hb) more precise than those made using an 830/782-nm pair. © *2001 American Association of Physicists in Medicine.* [DOI: 10.1118/1.1373401]

Key words: noninvasive optical measurement, hemoglobin, wavelength, precision, brain activity

I. INTRODUCTION

Near-infrared spectroscopy (NIRS) is a method for noninvasive measurement of tissue metabolism,[1] cerebral hemorrhage,[2,3] and brain activity.[4–7] In particular, the measurement of brain activity has recently become of interest not only to neuroscience but also to clinical medicine because of the development of several measurement techniques such as fMRI,[8] PET,[9] and MEG.[10] The advantages of NIRS compared with those techniques are portability, real-time measurement, and decreased sensitivity to subject movement. Thus NIRS is expected to become a widely useful method for measurement of brain activity.

The origin of noninvasive optical measurement including NIRS is the oximeter, which measures the oxygen saturation of hemoglobin[11] by using hemoglobin absorption spectra.[12,13] Following the development of the oximeter, NIRS has also been used to detect the concentration changes in oxy-, deoxy-, and total-hemoglobin due to metabolic changes, cerebral hemorrhage, and brain activity. Using NIRS, several studies have developed a new methodology for noninvasive topographic imaging of brain activity[14–17] and measurement systems for this imaging.[18,19]

For spectroscopic measurement of hemoglobin, wide wavelength regions from visible to near-infrared are used. The light within the wavelength region of 500–600 nm is used for optical recording of an exposed brain[20] because of a large absorption band of hemoglobin. The oximeter uses the wavelength range of 600–700 nm for the measurement of hemoglobin in the earlobe or fingertip.[11] On the other hand, the light within the near-infrared region (around 800 nm) is suitable for the noninvasive measurement of the brain because of the greater penetration through the scalp and skull. The molar absorption coefficients of oxy- and deoxy-hemoglobin[13] in the near-infrared region are shown in Fig. 1. The absorption coefficients are based on natural logarithms.

For the noninvasive optical measurement of hemoglobin, several researchers have developed multiwavelength measurement in the near-infrared region.[21] For example, four wavelengths (778, 813, 867, and 904 nm) are used for measuring hemoglobin and cytochrome aa_3.[22] Another method uses three wavelengths (780, 805, and 830 nm) for the cancellation of tissue scattering change that obstructs hemoglobin measurement.[23] Moreover, two wavelengths provide a simple method for measuring concentration changes in oxy-, deoxy-, and total-hemoglobin.[5,14–16,24–26] The light within the wavelength region 750–850 nm is widely used for the noninvasive measurement of hemoglobin by two wavelengths because the oxy- and deoxy-hemoglobin spectra are crossed at an isosbestic point around the wavelength of 805 nm.[12,13] In general, a more sensitive and precise measurement is expected when there is a large difference in the absorption coefficients between two wavelengths. Thus we can expect better precision by the use of wavelengths under 700 nm because the absorption coefficient of deoxy-hemoglobin at 670 nm is four times larger than that at the 830-nm wavelength as shown in Fig. 1.

Laser diodes have recently become commercially available not only for near-infrared light (750–830 nm) but also for red light (650–700 nm). However, there is little research to estimate the effectiveness of such red light in noninvasive measurement of brain activity. Moreover, few studies have shown a wavelength dependence of measurement precision except for a theoretical study for the measurement of hemoglobin oxygenation saturation in retinal blood vessels.[27]

In the current study we estimated the dependence of measurement precision of the concentration changes in hemoglobin on wavelength in a two-wavelength analysis. We experimentally developed a simultaneous measurement system using seven laser diodes from red to near-infrared light (664–848 nm). The system uses modulation and lock-in detection for highly sensitive spectroscopic measurement of brain activity. We used the theoretical analysis of error

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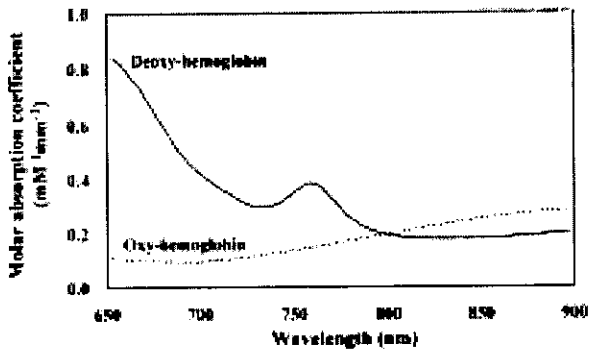

FIG. 1. Absorption spectra of oxy- and deoxy-hemoglobin (data from Ref. 13)

propagation for the indirect measurement of the precision of the concentration changes.

II. THEORY

The two-wavelength analysis of hemoglobin concentration is explained as follows. When the distance between the incident and detection points on the scalp is about 30 mm, the detected light has reached the cerebral cortex, passing through the scalp and the skull.[3,28] The absorbance $A_{\mathrm{rest}(\lambda 1)}$ for wavelength λ1 during rest state is thus approximately,[14,15]

$$A_{\mathrm{rest}(\lambda 1)} = -\ln\left|\frac{I_{\mathrm{rest}(\lambda 1)}}{I_{0(\lambda 1)}}\right| = \varepsilon_{\mathrm{oxy}(\lambda 1)} C_{\mathrm{oxy(rest)}} d + \varepsilon_{\mathrm{deoxy}(\lambda 1)} C_{\mathrm{deoxy(rest)}} d + a_{\mathrm{rest}(\lambda 1)} + s_{(\lambda 1)}, \tag{1}$$

where $I_{\mathrm{rest}(\lambda 1)}$ is the detected light intensity during the rest state, $I_{0(\lambda 1)}$ is the incident light intensity, $\varepsilon_{\mathrm{oxy}(\lambda 1)}$ and $\varepsilon_{\mathrm{deoxy}(\lambda 1)}$ are the molar absorption coefficients of oxy- and deoxy- hemoglobin at wavelength λ1,[13] $C_{\mathrm{oxy(rest)}}$ and $C_{\mathrm{deoxy(rest)}}$ are the concentrations of oxy- and deoxy-hemoglobin during the rest state, d is the effective path length in tissue, $a_{(\lambda 1)}$ is the attenuation due to absorption (for example, cytochrome aa_3) except for that by hemoglobin, and $s_{(\lambda 1)}$ is the attenuation due to scattering in tissue. During stimulation, the oxygenation of the hemoglobin is changed, and absorbance $A_{\mathrm{sti}(\lambda 1)}$ is given as

$$A_{\mathrm{sti}(\lambda 1)} = -\ln\left|\frac{I_{\mathrm{sti}(\lambda 1)}}{I_{0(\lambda 1)}}\right| = \varepsilon_{\mathrm{oxy}(\lambda 1)} C_{\mathrm{oxy(sti)}} d + \varepsilon_{\mathrm{deoxy}(\lambda 1)} C_{\mathrm{deoxy(sti)}} d + a_{\mathrm{sti}(\lambda 1)} + s_{(\lambda 1)}, \tag{2}$$

where sti means the values during stimulation. Because the absorbance due to hemoglobin is about ten times larger than that due to cytochrome aa_3 [the main term of $a_{(\lambda 1)}$] in tissue in the near-infrared region,[29] we neglect the change in $a_{(\lambda 1)}$ and assume $a_{\mathrm{rest}(\lambda 1)} = a_{\mathrm{sti}(\lambda 1)}$. Subtracting Eq. (1) from Eq. (2) gives the absorbance change $\Delta A_{\lambda 1}$ due to brain activity (or tissue metabolism) as follows,

$$\Delta A_{(\lambda 1)} = -\ln\left|\frac{I_{\mathrm{sti}(\lambda 1)}}{I_{\mathrm{rest}(\lambda 1)}}\right| = \varepsilon_{\mathrm{oxy}(\lambda 1)} \Delta C_{\mathrm{oxy}} + \varepsilon_{\mathrm{deoxy}(\lambda 1)} \Delta C_{\mathrm{deoxy}}, \tag{3}$$

where

$$\Delta C_{\mathrm{oxy}} = (C_{\mathrm{oxy(sti)}} - C_{\mathrm{oxy(rest)}}) d, \tag{4}$$

$$\Delta C_{\mathrm{deoxy}} = (C_{\mathrm{deoxy(sti)}} - C_{\mathrm{deoxy(rest)}}) d, \tag{5}$$

and

$$\Delta C_{\mathrm{total}} = \Delta C_{\mathrm{oxy}} + \Delta C_{\mathrm{deoxy}}. \tag{6}$$

In Eq. (6) $\Delta C_{\mathrm{total}}$ means change in total-hemoglobin concentration, which corresponds approximately to the change in blood volume. Because it is difficult to determine the effective path length d inside the cerebral cortex, we show the relative concentration changes, ΔC_{oxy}, $\Delta C_{\mathrm{deoxy}}$, and $\Delta C_{\mathrm{total}}$, in units of millimolar-millimeter. By using two different wavelengths, λ1 and λ2, we can obtain the concentration changes by solving Eq. (3) as follows,

$$\Delta C_{\mathrm{oxy}} = \frac{-\varepsilon_{\mathrm{deoxy}(\lambda 2)} \Delta A_{(\lambda 1)} + \varepsilon_{\mathrm{deoxy}(\lambda 1)} \Delta A_{(\lambda 2)}}{E}, \tag{7}$$

$$\Delta C_{\mathrm{deoxy}} = \frac{\varepsilon_{\mathrm{oxy}(\lambda 2)} \Delta A_{(\lambda 1)} - \varepsilon_{\mathrm{oxy}(\lambda 1)} \Delta A_{(\lambda 2)}}{E}, \tag{8}$$

$$\Delta C_{\mathrm{total}} = \Delta C_{\mathrm{oxy}} + \Delta C_{\mathrm{deoxy}} = \frac{(\varepsilon_{\mathrm{oxy}(\lambda 2)} - \varepsilon_{\mathrm{deoxy}(\lambda 2)}) \Delta A_{(\lambda 1)} + (\varepsilon_{\mathrm{deoxy}(\lambda 1)} - \varepsilon_{\mathrm{oxy}(\lambda 1)}) \Delta A_{(\lambda 2)}}{E}, \tag{9}$$

where

$$E = \varepsilon_{\mathrm{deoxy}(\lambda 1)} \varepsilon_{\mathrm{oxy}(\lambda 2)} - \varepsilon_{\mathrm{deoxy}(\lambda 2)} \varepsilon_{\mathrm{oxy}(\lambda 1)}. \tag{10}$$

Equations (7)–(10) show that the concentration changes in hemoglobin are indirect measurements calculated from the direct measurement of the absorbance changes $\Delta A_{(\lambda 1)}$ and $\Delta A_{(\lambda 2)}$. The effective path length inside tissue (brain) depends on wavelength strictly because the tissue scattering coefficient depends on wavelength slightly.[30] Although the wavelength dependence of the path length may cause the uncertainty in ΔC_{oxy}, $\Delta C_{\mathrm{deoxy}}$, and $\Delta C_{\mathrm{total}}$, there is little information on the wavelength dependence of the scattering coefficients of scalp, skull, and brain *in vivo*. In this analysis we assume that the effective path length is independent of wavelength.

If the two wavelengths are fixed, the concentration

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changes are considered to be a function of the absorbance changes. In general, error propagation in indirect measurement is explained as follows. The indirect measurement z is described by a general function f of the direct measurements x and y:

$$z = f(x,y). \tag{11}$$

If the direct measurement uncertainties of δx and δy are random and independent each other, the uncertainty of the indirect measurement δz is approximately shown by the partial differential of Eq. (11) as follows,

$$(\delta z)^2 = \left|\frac{\partial f(x,y)}{\partial x}\right|^2 (\delta x)^2 + \left|\frac{\partial f(x,y)}{\partial y}\right|^2 (\delta y)^2. \tag{12}$$

Assuming that the uncertainties of the absorbance changes for two wavelengths are random and independent, we apply Eqs. (7)–(9) to Eq. (12) and obtain the following equations;

$$(\delta\Delta C_{oxy})^2 = \left|\frac{-\varepsilon_{deoxy(\lambda 2)}}{E}\right|^2 (\delta\Delta A_{(\lambda 1)})^2 + \left|\frac{\varepsilon_{deoxy(\lambda 1)}}{E}\right|^2 (\delta\Delta A_{(\lambda 2)})^2, \tag{13}$$

$$(\delta\Delta C_{deoxy})^2 = \left|\frac{\varepsilon_{oxy(\lambda 2)}}{E}\right|^2 (\delta\Delta A_{(\lambda 1)})^2 + \left|\frac{-\varepsilon_{oxy(\lambda 1)}}{E}\right|^2 (\delta\Delta A_{(\lambda 2)})^2, \tag{14}$$

and

$$(\delta\Delta C_{total})^2 = \left|\frac{\varepsilon_{oxy(\lambda 2)} - \varepsilon_{deoxy(\lambda 2)}}{E}\right|^2 (\delta\Delta A_{(\lambda 1)})^2 + \left|\frac{\varepsilon_{deoxy(\lambda 1)} - \varepsilon_{oxy(\lambda 1)}}{E}\right|^2 (\delta\Delta A_{(\lambda 2)})^2, \tag{15}$$

where $\delta\Delta A_{(\lambda 1)}$ and $\delta\Delta A_{(\lambda 2)}$ are the direct measurement uncertainties of the absorbance changes, and $\delta\Delta C_{oxy}$, $\delta\Delta C_{deoxy}$, and $\delta\Delta C_{total}$ mean the indirect measurement uncertainties of the concentration changes in hemoglobin. According to Eqs. (13)–(15), the uncertainties in the concentration changes depend on not only the uncertainties in absorbance changes but also on the molar absorption coefficients. These equations thus indicate that $\delta\Delta C_{oxy}$, $\delta\Delta C_{deoxy}$, and $\delta\Delta C_{total}$ depend on the wavelength pair of λ1 and λ2.

III. MEASUREMENT SYSTEM

A block diagram of the measurement system is shown in Fig. 2. The basic design of the modulation and the lock-in detection is the same as a previous topographic imaging system[19] that has two wavelengths of 780 and 830 nm. The current system uses seven-laser diodes with wavelengths of 664, 692, 752, 782, 799, 830, and 848 nm and each has a power of 0.2 mW. Their intensities are modulated sinusoidally at frequencies ranging from 1.2 to 3.3 kHz. The modulation frequencies are chosen to avoid any overlap in their harmonic frequencies. The light from each laser diode can be

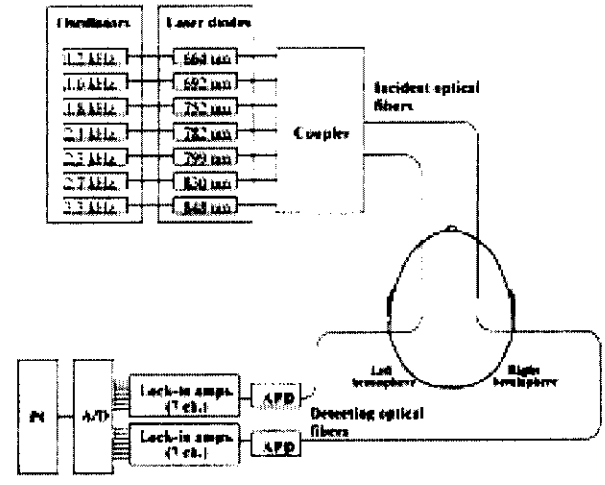

FIG. 2. Block diagram of the measurement system: APD, avalanche photodiode.

uniquely identified by the modulation frequency. After coupling each diode by an optical fiber coupler (Mitsubishi Gas Chemical CG5-S8), the seven-wavelength light is split to two incident optical fibers (1-mm diameter) arranged at the left and right hemispheres. The reflected light from each hemisphere is received by a detecting optical fiber (1-mm diameter) next to each incident fiber and connected to one of two avalanche photodiodes (Hamamatsu C5460-01). The distance between the incident and detecting optical fibers is 30 mm on each hemisphere. This arrangement allows the simultaneous measurement of the brain activities of the left and right hemispheres. The noise equivalent power of the avalanche photodiode is 20 fW/$\sqrt{\text{Hz}}$. Each avalanche photodiode output is separated into seven modulated signals, one for each wavelength, by seven lock-in amplifiers. To simultaneously measure both hemispheres and seven wavelengths, we used a total of 14 lock-in amplifiers. Each lock-in amplifier consists of an IC module that acts as a phase sensitive detector (NF Corporation CD-505R2). The input equivalent noise voltage of the lock-in amplifiers is 30 nV/$\sqrt{\text{Hz}}$. Because the noise voltage of the avalanche photodiode output after current-to-voltage amplifier is 2 μV/$\sqrt{\text{Hz}}$, the sensitivity of the lock-in amplifier is enough. The time constant of the lock-in amplifiers is 125 ms (the corresponding stabilizing time is about 500 ms). The 14 output signals of the lock-in amplifiers are sent to a computer via a multichannel analog-to-digital converter (Keithley MetraByte DAS-1801HC) with a sampling rate of 500 ms. Through the modulation and lock-in detection of all detected light, we simultaneously obtain spectroscopic measurements from each laser diode with high sensitively against stray light, virtually no crosstalk between the signals (less than −50 dB), no optical loss (no optical filter or diffraction grating), and no time loss (no switch).

IV. MEASUREMENT OF BRAIN ACTIVITY

The purpose of this measurement is not to clarify brain activity itself but to estimate the wavelength dependence on

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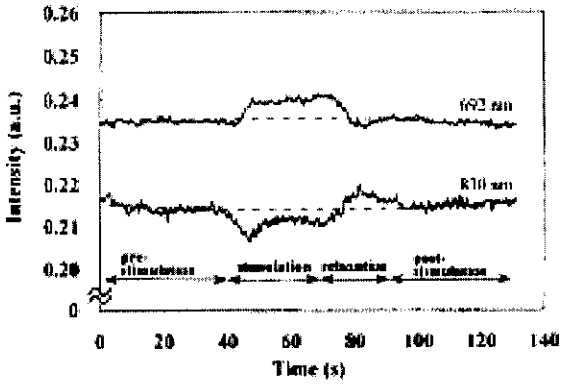

FIG. 3. Time courses of detected light intensity for left-hand stimulation at the right hemisphere (692 and 830 nm). Solid curves are measured intensities. Broken curves are the fitting curves obtained from the period of pre- and post-stimulation.

uncertainty. Thus we used a simple and well-known finger motor stimulation. The subject was a 55-year-old, right-handed, healthy male volunteer. Informed consent was obtained from the subject before the investigation. The subject was settled in a relaxed condition, a supine position, and kept his eyes closed throughout the measurement. As the stimulation, he tapped his fingers, the digits II–V, in random order against his thumb, first for the right hand and then for the left hand for 30 s. The measurements of the brain activity resulting from this stimulation were integrated 13 times for each hand.

The measurement position is the midpoint between the incident and detecting positions, because concentration changes in hemoglobin inside the cerebral cortex are usually obtained from just below these midpoints.[31] The measurement positions for each hemisphere were anatomically identified as finger motor areas by MRI.[14–16]

V. RESULTS AND DISCUSSION

A. Absorbance change

The time courses of the detected light intensities at 692 and 830 nm integrated 13 times are shown in Fig. 3 for left-hand stimulation at the right hemisphere. The detected light intensities fluctuate by about 0.01 Hz, which probably reflects natural tissue metabolism.[14,15] To extract the exact intensity changes due to brain activity from the fluctuation, we show the fluctuation as fitting curves by using the least-squares method for a third-order polynomial.[14,15] For the fitting, we used two nonstimulation (rest) periods: one just before stimulation and another after 20-s relaxation (pre- and post-stimulation periods in Fig. 3). Since the whole analyzing period (130 s) in Fig. 3 and the fluctuation period (about 100 s) are close, the third-order polynomial fitting is an empirical method to describe the fluctuation.

The intensity changes corresponding to the wavelength of 692 and 830 nm during the stimulation are positive and negative, alternatively. According to the spectra in Fig. 1, deoxy-hemoglobin is more sensitive to the 692-nm light; on

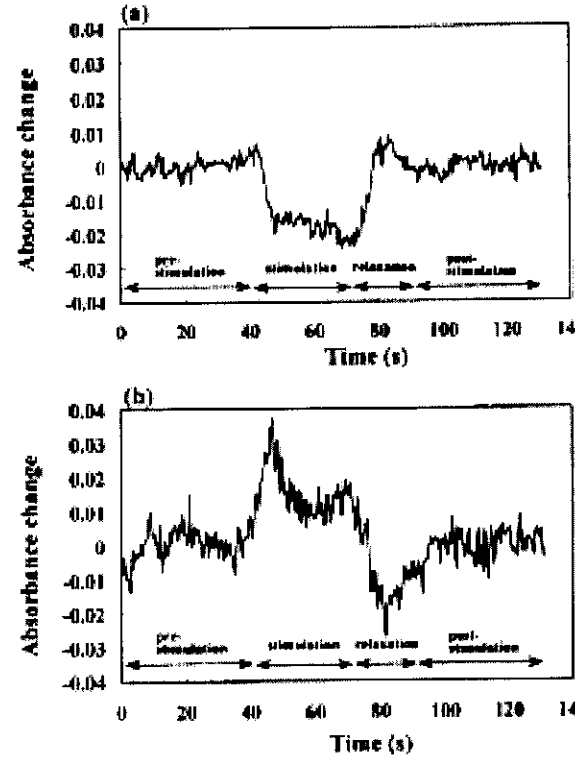

FIG. 4. Time courses of absorbance change for left-hand stimulation at the right hemisphere [(a) 692 nm and (b) 830 nm].

the other hand, oxy-hemoglobin is more sensitive to the 830-nm light. Thus the time courses in Fig. 3 probably reflect oxy-hemoglobin (830 nm) and deoxy-hemoglobin (692 nm). We use the fitting curves as I_{rest} and the measurement intensities as I_{st} in Eq. (3) to obtain absorbance changes for each detected time. The time courses of the absorbance changes in ΔA_{692} and ΔA_{830} are shown in Fig. 4. To estimate theoretically the uncertainty in the hemoglobin concentration from the analysis of error propagation, we calculate the uncertainty in the measured absorbance change ($\delta\Delta A$) as the standard deviation of the measured absorbance change during the prestimulation period. The uncertainties in the measured absorbance changes at all wavelengths are listed in Table I. These uncertainties are fairly similar for all wavelengths.

TABLE I. Experimental uncertainties of absorbance change.

	Uncertainty of absorbance change ($\delta\Delta A$)	
Wavelength (nm)	Right-hand stimulation at left hemisphere	Left-hand stimulation at right hemisphere
664	0.006 48	0.003 65
692	0.005 57	0.002 28
752	0.004 98	0.004 12
782	0.004 95	0.006 29
799	0.004 21	0.004 16
830	0.005 16	0.005 00
848	0.006 99	0.004 60

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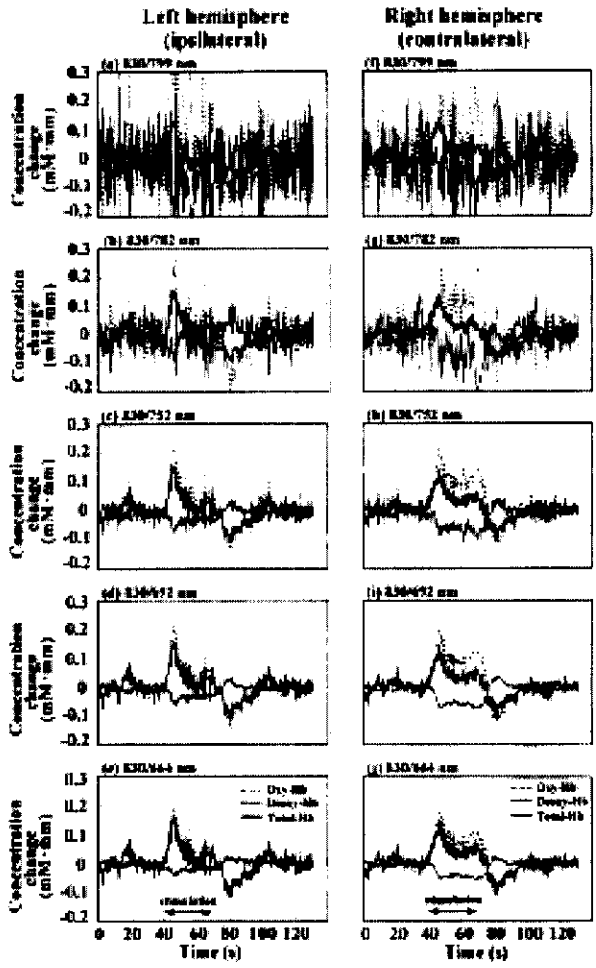

FIG. 5. Changes in concentration of oxy- (dotted curves), deoxy- (solid curves), and total- (bold curves) hemoglobin for left-hand stimulation at [(a)–(e)] the left hemisphere (ipsilateral) and [(f)–(j)] the right hemisphere (contralateral): (a) and (f) 830/799-nm pair, (b) and (g) 830/782-nm pair, (c) and (h) 830/752-nm pair; (d) and (i) 830/692-nm pair; and (e) and (j) 830/664-nm pair.

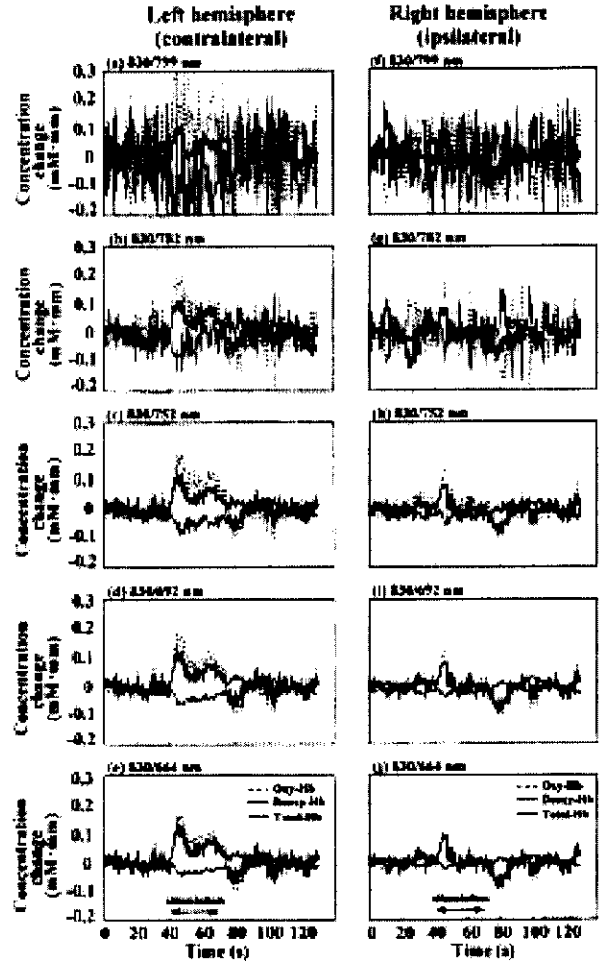

FIG. 6. Changes in concentration of oxy- (dotted curves), deoxy- (solid curves), and total- (bold curves) hemoglobin for right-hand stimulation at [(a)–(e)] the left hemisphere (contralateral) and [(f)–(j)] the right hemisphere (ipsilateral): (a) and (f) 830/799-nm pair; (b) and (g) 830/782-nm pair; (c) and (h) 830/752-nm pair; (d) and (i) 830/692-nm pair; and (e) and (j) 830/664-nm pair.

B. Concentration change in hemoglobin

Substituting the absorbance changes into Eq. (3), for arbitrary wavelength pair, we obtained the concentration changes in oxy-, deoxy-, and total-hemoglobin. In Fig. 5 (left-hand stimulation) and Fig. 6 (right-hand stimulation) we fixed $\lambda 1$ as 830 nm and showed that the measurement precision of the concentration changes depended on the second wavelength. We can clearly see that the uncertainty (noise) is reduced as $\lambda 2$ is reduced. These time courses show that oxy-hemoglobin concentration increases and deoxy-hemoglobin concentration slightly decreases in contralateral hemisphere. These time courses are typical responses to the motor stimulation.[14,15,32] For ipsilateral hemisphere, oxy- and total-hemoglobin concentration increase at the start of stimulation but decay rapidly. When the 830/799-nm pair is used, it is difficult to measure the concentration changes except for measuring total-hemoglobin. However, we can find clearly the structure of the time courses corresponding to the 830/692-nm pair.

To estimate the precision in the measurement of concentration changes in hemoglobin experimentally, we calculated the experimental uncertainty in hemoglobin concentration measurement as the standard deviation during the prestimulation period. This calculation is similar to that of the absorbance change mentioned in part A above. We also calculated theoretical estimation of the uncertainty by using the values of $\delta\Delta A$ in Table I and the hemoglobin absorption coefficient. We then put these values into Eqs. (13)–(15) to determine the uncertainty in the concentration change. The experimental and theoretical uncertainties are compared in Table II and show good agreement. The measurement of the concentration changes by using the 830/664-nm pair are two times (oxy-Hb) and six times (deoxy-Hb) more precise than those by using the 830/782-nm pair. On the other hand, the

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TABLE II. Uncertainties of concentration changes in oxy-, deoxy-, and total hemoglobin in two-wavelength analysis with 830 nm.

	Uncertainty of concentration change in hemoglobin [$\times 10^{-2}$(mM mm)$^{-1}$]											
	Right-hand stimulation at left hemisphere						Left hand stimulation at right hemisphere					
	Oxy-Hb		Deoxy-Hb		Total-Hb		Oxy-Hb		Deoxy-Hb		Total-Hb	
Wavelength (nm)	Theory	Expt.	Theory	Expt.	Theory	Expt.	Theory	Expt.	Theory	Expt.	Theory	Expt.
664	2.57	2.58	1.00	1.11	2.17	2.16	2.44	2.43	0.63	0.62	2.08	2.09
692	2.69	2.84	1.31	1.48	2.17	2.13	2.61	2.59	0.78	0.76	2.04	2.04
752	3.12	3.53	2.01	2.31	2.11	1.99	3.18	3.31	1.89	2.00	1.96	1.92
782	4.73	6.06	4.42	5.74	2.07	1.75	5.29	6.53	5.57	6.68	2.19	1.89
799	9.70	12.8	10.7	14.4	2.21	2.28	8.57	12.5	9.46	14.1	2.17	2.26

measurement of total-hemoglobin concentration is only slightly dependent on wavelength. Moreover, the value of the concentration change in total-hemoglobin is independent of the wavelength pairs (Figs. 5 and 6). This suggests experimentally that the effective path length in the brain does not depend on the wavelength (664–830 nm). The Monte Carlo simulation of the photon propagation in the head shows that the structure of the head (skin, skull, cerebrospinal fluid, and brain) strongly affects the distribution of the photon path.[33] More study is needed on the photon path in the head.

C. Estimation of optimal wavelength pair

The first wavelength λ1 was fixed as 830 nm and the second wavelength dependence of the precision was estimated (Fig. 7). For the theoretical estimation we use $\delta\Delta A_{(\lambda 1)}$ of 830-nm light as 0.005 16 and the $\delta\Delta A_{(\lambda 2)}$ of second wavelength as 0.005 24, which is the mean value of $\delta\Delta A$ from 664 to 799 nm (left hemisphere; right-hand stimulation). According to Fig. 7 the agreement between experiment and theory is very good. The uncertainty in total-hemoglobin concentration is less sensitive to this wavelength region; on the other hand, the uncertainties in oxy- and deoxy-hemoglobin concentration sharply drop around 800 nm and have a minimum at 760 nm, which corresponds to an absorption peak of deoxy-hemoglobin at this wavelength. Below 730 nm, the uncertainties gradually drop and become stable. The most precise measurement is for deoxy-hemoglobin under 700 nm as the second wavelength.

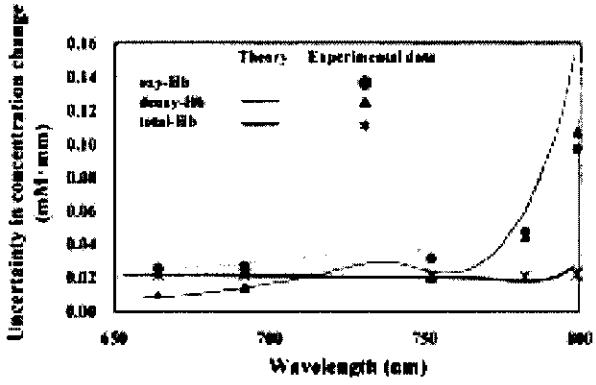

FIG. 7. Uncertainties of concentration change against wavelength in two-wavelength analysis with 830 nm and a second wavelength (right-hand stimulation at left hemisphere). Uncertainties in oxy- (dotted curve), deoxy- (solid curve), and total- (bold curve) hemoglobin are shown theoretically. Experimentally measured uncertainties are also shown [oxy- (closed circle), deoxy- (closed triangle), and total- (asterisk) hemoglobin].

We also used a wavelength of 848 nm as λ1 in the analysis of the wavelength dependence of measurement precision. This wavelength produces very similar results to those with 830 nm as λ1. Although the precision in the measurement of motor activation is good when using the 830/664-nm pair, more study is needed on other activation, such as visual, auditory, and language. Moreover, the kind of uncertainty estimation studied here can be applied to three-, four-, and multi-wavelength analysis as well.

VI. CONCLUSION

We estimated the wavelength dependence of the measurement uncertainties (concentration changes in oxy-, deoxy-, and total-hemoglobin). Using two-wavelength analysis when one wavelength is fixed at 830 nm, we showed theoretically and experimentally that the uncertainties are dependent on the wavelength pair in oxy- and deoxy-hemoglobin measurements. Moreover, measurement of the concentration changes by using the 830/664-nm pair are two times (oxy-Hb) and six times (deoxy-Hb) more precise than those by using the 830/782-nm pair. On the other hand, the measurement of total-hemoglobin concentration is only slightly dependent on the wavelength pair.

ACKNOWLEDGMENTS

We would like to thank Dr. Iwao Kanno (Akita Research Institute of Brain and Blood Vessels) for his fruitful discussions. This research was supported by Japan Science and Technology Corporation.

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Wavelength Dependence of Sensitivity in NIRS for Measurements of Different Brain Areas

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Introduction

Concentration changes in hemoglobin (Hb) caused by neural activity can be measured in cerebral cortices using near-infrared spectroscopy (NIRS) [1-3]. We proposed NIR topography in 1995 as a new noninvasive imaging modality [4] and have developed the system since then. The system called 'Optical Topography' (OT) is commercially available (ETG-100; Hitachi Medical Corporation). It has 10 laser diodes of two wavelengths at 780 and 830 nm and measures relative concentration changes in oxy-Hb (ΔC_{oxy}) and those in deoxy-Hb (ΔC_{deoxy}). These values of ΔC_{oxy} and ΔC_{deoxy} are derived from the differences in absorption coefficients of oxy-Hb (ε_{oxy}) and deoxy-Hb (ε_{deoxy}) between two wavelengths.

The wavelength dependence of the measurement sensitivity has lately been evaluated using the error propagation law [5]. The study suggested that the measurement uncertainties are dependent on the differences in ε_{oxy} and ε_{deoxy} between two wavelengths in indirect measurements. Yamashita and colleagues also conducted an experiment to investigate the validity of wavelength dependence and found results supporting the prediction that a more sensitive measurement would be achieved if we use two wavelengths that have larger differences in ε_{oxy} and ε_{deoxy} between two wavelengths. That is, wavelengths shorter than 780 nm paired with 830 nm should provide more sensitive measurements of ΔC_{oxy} and ΔC_{deoxy}.

However, the experimental confirmation in the previous study seemed to be insufficient for practical use because a structural variance in tissue is expected in different areas of the head while they measured only motor function in the parietal lobe for one subject. Therefore, we examine which wavelength allows more sensitive measurements among various areas of the brain and subjects. Wavelengths of 678, 692, and 780 nm were tested as a wavelength paired with 830 nm among various lobes in 6 subjects.

Methods

We used a system with 4 laser diodes of wavelengths at 678, 692, 780, and 830 nm. The 4 waves were guided into an optical fiber to irradiate the same point simultaneously. Each power of waves was 1.0 mW (intensity average: 1.06 mW, standard deviation: 0.10). The mixed light was irradiated to the head-skin, and reflected lights from tissues were obtained using another optical-fiber at a distance of 30 mm from an irradiation fiber. The amplitude of each wave was modulated at different frequency (1.0 ~ 2.7 kHz) to separate the detected

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signal into individual light sources using lock-in amplifiers. The reflected lights were detected every 500 ms using an avalanche photodiode. Four lobes (frontal, temporal, occipital, and parietal) for 6 subjects (4 males and 2 females) were measured in 120-s periods with no task.

The time-courses of reflected light in randomly selected periods of 30-s were analyzed in each condition. After concentration changes in Hb were calculated using three wavelength-pairs (678/830 nm, 692/830 nm, and 780/830 nm), the standard deviations of ΔC_{oxy} and ΔC_{deoxy} were used as the noise-level to compare the sensitivity of measurements. The paired wavelength was fixed at 830 nm because a longer wavelength such as 848 nm had no advantages [5].

Results and Discussion

The differences in noise-levels among wavelength pairs were examined in each measurement area. The pairs of 678/830 nm and 692/830 nm showed smaller noise-levels than the pair of 780/830 nm in all lobes, as were expected. Although the noise-level in the pair of 678/830 nm was smaller than that in the pair of 692/830 nm in only the frontal lobe, the pair of 692/830 nm showed less noise-level than the pair of 678/830 nm in other lobes. The inconsistency with the previous study [5], which had shown that a shorter wavelength such as 664 nm could achieve a lower noise-level in the parietal lobe, could be due to the great variance of noise-level among areas and subjects. In general, the pair of 692/830 nm achieved a stable improvement in sensitivity across all lobes and subjects.

In addition, we examined the noise-level of the reflected light at each wavelength and found that the level at 678 nm was occasionally larger than those in other wavelengths. This result suggests that the attenuation of reflected light at 678 nm is sometimes too strong to measure cortical activation accurately compared with other wavelengths.

We conclude that the pair of 692/830 nm provides more sensitive NIRS measurements in all brain lobes, making it ideal for practical use, while shorter wavelengths such as 678 nm appear to be less suitable because of dependency on the measurement area.

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Practicality of wavelength selection to improve signal-to-noise ratio in near-infrared spectroscopy

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Received 8 August 2003; revised 9 December 2003; accepted 9 December 2003

Near-infrared spectroscopy (NIRS), which can be used to detect changes in the concentration of oxygenated hemoglobin (oxy-Hb) and deoxygenated hemoglobin (deoxy-Hb) in tissue by using illumination at two different wavelengths, is often applied to noninvasive measurements of human brain functions. It is common to use two wavelengths that are on opposite sides of the point where the optical absorptions of oxy- and deoxy-Hb are equal (about 800 nm) but an optimal wavelength pair has not yet been determined. In this study, we conducted simultaneous recordings at five wavelengths (678, 692, 750, 782, and 830 nm) to determine the best wavelength for pairing with 830 nm. A theory suggests that pairing a shorter wavelength with 830 nm can provide more sensitivity because of the larger difference in absorption coefficients of hemoglobin between two wavelengths. The changes measured in four cortical areas (frontal, occipital, parietal, and temporal) showed that the noise level when the 678-, 692-, and 750-nm wavelengths were paired with 830 nm was usually lower than when the 782-nm wavelength was paired with 830 nm, which is consistent with theoretical prediction. Moreover, the signal-to-noise ratios (S/Ns) and wavelength dependencies of the power detected in all areas and subjects together suggest that the 692-nm pairing had the highest S/N. This suggests that the optimal wavelengths depend on not only the difference in the absorption coefficients of hemoglobin but also on the optical properties in the measurement area, which affect the strength of the attenuation data. The 692-nm wavelength is thus a more optimal choice than wavelengths around 780 nm for pairing with 830 nm to measure Hb changes induced by cortical activation. The improved S/N enables more sensitive statistical analysis, which is essential to functional mapping with NIRS.
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Keywords: Near-infrared spectroscopy; Wavelength; Hemoglobin; Cortical activation; Sensitivity

Introduction

Near-infrared spectroscopy (NIRS) has been used for measurements of biological metabolism such as concentration changes in hemoglobin (Hb) species (Jobsis, 1977; Jobsis et al., 1988; Wray et al., 1988). Particularly important has been the application of NIRS to noninvasive measurements of concentration changes in oxygenated hemoglobin (oxy-Hb) and deoxygenated hemoglobin (deoxy-Hb) related to brain functions (Chance et al., 1993; Hoshi and Tamura, 1993; Kato et al., 1993; Villringer et al., 1993). Since near-infrared (NIR) topography with multiple measurement positions was introduced as a noninvasive imaging modality (Maki et al., 1995; Yamashita et al., 1996a,b), many cognitive studies using NIR topography have been reported in various fields (Kennan et al., 2002a,b; Minagawa-Kawai et al., 2002; Noguchi et al., 2002; Obata et al., 2003; Pena et al., 2003; Sato et al., 1999; Taga et al., 2000; Watanabe et al., 1998). In this method, the changes in the concentration of oxy-Hb and deoxy-Hb in the cerebral cortex are simultaneously recorded at multiple positions by using light at two different wavelengths (780 and 830 nm). Noninvasive NIR topography, which has advantages such as applicability to infants, is expected to provide novel information on brain function (Koizumi et al., 1999, 2003).

The current NIR system has both future potential and current limitations (Koizumi et al., 2003). One limitation is the signal-to-noise ratio (S/N)—the data must be averaged to detect small activation signals such as event-related responses (Kennan et al., 2002b; Noguchi et al., 2002). Improving S/N sensitivity is thus one improvement needed to make NIR topography more useful. We have investigated wavelength selection for improving the S/N in practical NIR measurements.

In dual-wavelength analysis, equations based on the modified Beer–Lambert law are used (Cope and Delpy, 1988; Delpy et al., 1988):

$$L \cdot \Delta C_{\text{oxy}} = \Delta C'_{\text{oxy}\ (\lambda 1,\ \lambda 2)} = \frac{-\varepsilon_{\text{deoxy}\ (\lambda 2)} \cdot \Delta A_{(\lambda 1)} + \varepsilon_{\text{deoxy}\ (\lambda 1)} \cdot \Delta A_{(\lambda 2)}}{E}, \quad (1)$$

$$L \cdot \Delta C_{\text{deoxy}} = \Delta C'_{\text{deoxy}\ (\lambda 1,\ \lambda 2)} = \frac{\varepsilon_{\text{oxy}\ (\lambda 2)} \cdot \Delta A_{(\lambda 1)} - \varepsilon_{\text{oxy}\ (\lambda 1)} \cdot \Delta A_{(\lambda 2)}}{E}, \quad (2)$$

where

$$E = \varepsilon_{\text{deoxy}\ (\lambda 1)} \cdot \varepsilon_{\text{oxy}\ (\lambda 2)} - \varepsilon_{\text{deoxy}\ (\lambda 2)} \cdot \varepsilon_{\text{oxy}\ (\lambda 1)}. \quad (3)$$

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doi:10.1016/j.neuroimage.2003.12.017

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The relative concentration changes ($\Delta C'_{oxy\ (\lambda 1,\ \lambda 2)}$ and $\Delta C'_{deoxy\ (\lambda 1,\ \lambda 2)}$) are expressed as the concentration changes (ΔC_{oxy} and ΔC_{deoxy}) multiplied by the indefinite optical path-length in the activation region (L), where ΔA, ε_{oxy}, and ε_{deoxy} indicate the logarithm of the intensity changes, the absorption coefficient of oxy-Hb, and that of deoxy-Hb, respectively, for two wavelengths ($\lambda 1$, $\lambda 2$). Note that we have to assume that the path-length (L) is equal for every wavelength because accurate estimation of L is almost impossible with this technique. Although the wavelength dependence of L can be predicted and can make independent measurements for multiple chromophores difficult (cross-talk), the cross-talk effect is negligible when measuring changes only in oxy- and deoxy-Hb (Uludag et al., 2002).

Wavelengths that are symmetric about the point where the optical absorptions of oxy- and deoxy-Hb are equal (about 800 nm) are usually used as $\lambda 1$ and $\lambda 2$ (e.g., 780 and 830 nm), but optimal wavelengths have not yet been determined. The present study aims to improve the S/N for hemoglobin changes expressing cortical activation by selecting an appropriate wavelength pair for practical use.

According to the general error-propagation law, the noise levels in the Hb changes depend on the differences in the Hb absorption coefficients between the two wavelengths (Yamashita et al., 2001). The theoretical noise levels in $\Delta C'_{oxy}$ and $\Delta C'_{deoxy}$ depend on the wavelengths and can be expressed as

$$(\delta\Delta C'_{oxy\ (\lambda 1,\ \lambda 2)})^2 = \left(\frac{-\varepsilon_{deoxy\ (\lambda 2)}}{E}\right)^2 (\delta\Delta A_{\ (\lambda 1)})^2 + \left(\frac{\varepsilon_{deoxy\ (\lambda 1)}}{E}\right)^2 (\delta\Delta A_{\ (\lambda 2)})^2, \quad (4)$$

$$(\delta\Delta C'_{deoxy\ (\lambda 1,\lambda 2)})^2 = \left(\frac{\varepsilon_{oxy\ (\lambda 2)}}{E}\right)^2 (\delta\Delta A_{\ (\lambda 1)})^2 + \left(\frac{-\varepsilon_{oxy\ (\lambda 1)}}{E}\right)^2 (\delta\Delta A_{\ (\lambda 2)})^2, \quad (5)$$

where $\delta\Delta C'_{oxy\ (\lambda 1,\ \lambda 2)}$ and $\delta\Delta C'_{deoxy\ (\lambda 1,\ \lambda 2)}$ are the indirectly measured noise levels of $\Delta C'_{oxy\ (\lambda 1,\lambda 2)}$ and $\Delta C'_{deoxy\ (\lambda 1,\lambda 2)}$, and $\delta\Delta A_{\ (\lambda 1)}$ $\delta\Delta A_{\ (\lambda 1)}$ and $\delta\Delta A_{\ (\lambda 2)}$ are the directly measured noise levels of $\Delta A_{\ (\lambda 1)}$ and $\Delta A_{\ (\lambda 2)}$. Assuming that $\delta\Delta A_{\ (\lambda 1)}$ and $\delta\Delta A_{\ (\lambda 2)}$ are random and independent, we can calculate $\delta\Delta C'_{oxy\ (\lambda 1,\ \lambda 2)}$ and $\delta\Delta C'_{deoxy\ (\lambda 1,\ \lambda 2)}$ using Eqs. (4) and (5). On the assumption that $\delta\Delta A_{\ (\lambda 1)}$ and $\delta\Delta A_{\ (\lambda 2)}$ are the same, using a wavelength pair having a larger difference in the hemoglobin absorption between the two wavelengths should provide more sensitivity. For example, wavelengths shorter than 780 nm paired with 830 nm should provide less noise in measurements of $\Delta C'_{oxy}$ and $\Delta C'_{deoxy}$ (Koizumi et al., 2003; Yamashita et al., 2001). Another study using a similar theory suggests that the 780- and 830-nm pairings are not optimal for oxygen saturation-related measurements (Strangman et al., 2003).

However, the optimal range of wavelengths has not been determined and the effectiveness of these wavelengths for practical use is still unclear. A previous study (Yamashita et al., 2001) measured only motor function in the parietal lobe of one subject although optical properties are predicted to depend on the anatomical variances among subjects and areas. Although the results supported the theoretical prediction that using two wavelengths having larger differences in the absorption coefficients of hemoglobin reduces measurement noise, they did not clarify the method's practicality. On the other hand, another study (Strangman et al., 2003) conducted simultaneous measurements with multiple wavelengths of 675, 691, 752, 780, 788, 830, and 840 nm. The study, however, did not compare actual noise levels among wavelength pairs although it concluded that pairing 690 or 760 nm with 830 nm is better than pairing 780 with 830 nm for measuring oxygenation changes.

We think experimental examination of the Hb changes resulting from the use of an optimal wavelength (approximately 650–750 nm) paired with 830 nm is necessary to determine the practicality of this method because simulation studies cannot verify every possible model. In particular, the practicality of each wavelength should be investigated by measuring the variation in the detected light power, which depends on the transparency of the wavelength in tissue. Moreover, the dependencies of the activation-signal profile and S/N on the wavelengths should be examined to verify that these wavelengths measure the Hb changes induced by the same cortical activation.

In this study, we measured cortical activations in four areas (frontal, occipital, parietal, and temporal) with simultaneous recording using five wavelengths (678, 692, 750, 782, and 830 nm) to find a way to improve the sensitivity of NIRS measurements.

Materials and methods

Subjects and measurement paradigm

Four subjects (two men, two women; ages 25–45) gave informed consent to participate in this study. All subjects showed right-handedness by the Edinburgh inventory (Oldfield, 1971).

Four stimulation paradigms were given to each subject for measurement of the four cortical areas. To measure frontal cortex activation, mental arithmetic tasks were used. A number from 1 to 9 was randomly presented every 1500 ms. The subjects were instructed to calculate the running total in their head and to whisper with minimum jaw movement the answer at the end of each string of 10 numbers. For the occipital cortex measurements, rectangular black-and-red checkerboard stimuli with the squares reversing between black and red at a frequency of 8 Hz were presented. The subjects were instructed to focus their attention on the fixation cross at the center. The parietal cortices were activated using a finger-tapping task—the fingers of the left hand were placed on the tip of the thumb in serial order (forefinger–second finger–third finger–little finger–third finger–second finger–forefinger). The subjects were asked to repeat the tapping sequence as rapidly as possible during the time 'Tapping' was presented on a CRT monitor. Auditory-language stimuli were used for the temporal area measurements. The subject wore headphones and was instructed to carefully listen to a Japanese story presented through the headphones while looking at the fixation cross on the monitor. In each measurement paradigm, a 15-s stimulation period and a 30-s rest period were alternated 10 times after a 30-s rest period. All the visual stimuli were displayed on a CRT monitor placed 70 cm from the subject's eyes in a dark room. During the measurements, the subject sat in a chair and was instructed to fix his or her gaze on the cross at the center of monitor and to concentrate on each task.

The measurement positions were determined for each subject based on the preliminary experiments using multichannel NIR topography (Optical Topography®, ETG-100: Hitachi Medical Corporation, Japan) using the 780- and 830-nm pairings. The positions showing significant activation in the frontal areas were around the middle of the F_{P2}, F_4, and F_8 locations in the international 10-20 system (American Electroencephalographic

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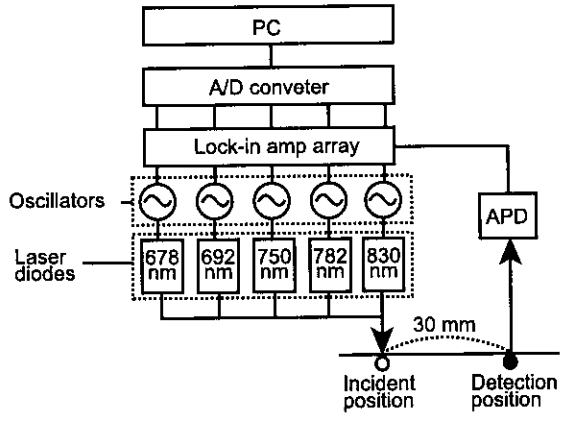

Fig. 1. Diagram of measurement system. APD: avalanche photodiode.

Society, 1994). The measurement positions in the occipital, parietal, and temporal areas were determined to be around the O_1, C_4, and T_3 locations, respectively. In general, the locations in the international 10-20 system have an appropriate relationship with cortical anatomy (Towel et al., 1993).

NIRS measurement

A measurement system with five laser diodes operating at different wavelengths (678, 692, 750, 782, and 830 nm) was used (Fig. 1). The five waves were guided into an optical fiber to irradiate the same point simultaneously. The continuous mixed-light was irradiated on the subjects' head, and the reflected light was detected every 100 ms using an avalanche photodiode (APD) located 30 mm from the incident position. Optical fibers (diameter of 1 mm) were used for both the irradiating and detecting lights. The average power of each light source was 0.93 mW, and each source was modulated at a different frequency (1.0–2.7 kHz) to enable separation using a lock-in amplifier after detection.

Data analysis

Hb time course

The detected temporal data for the attenuation change at each wavelength were separated into blocks consisting of a 5-s prestimulation period during the resting state, a 15-s stimulation period during the stimulation, and a 25-s poststimulation period during the rest state. The data were baseline-corrected using the data for the 5-s prestimulation period and the data for the final 10 s of the poststimulation period. After eliminating the blocks with artifacts caused by obvious motions such as a cough or sneeze, we were left with more than eight blocks for each area and subject. Using the modified Beer–Lambert law, we derived the concentration changes in oxy- and deoxy-Hb [$\Delta C'_{oxy\ (\lambda 1,\ \lambda 2)}$ and $\Delta C'_{deoxy\ (\lambda 1,\ \lambda 2)}$] from the attenuation data of two wavelengths [$\Delta A_{(\lambda 1)}$ and $\Delta A_{(\lambda 2)}$], one of which was fixed at 830 nm and paired with one of the four other wavelengths (e.g., Maki et al., 1995). We compared the Hb time course for the 782- and 830-nm pairs (the 782-nm pairing) with that for the 678-, 692-, and 750-nm pairings in each area.

Activation-signal amplitude

Activation signals were statistically assessed and selected. Assuming that the hemodynamic changes induced by the stimuli were delayed 6 s from the stimuli onset, the shifted period of the stimulation was defined as the activation period. The mean Hb changes during the prestimulation period and those during the activation period were calculated for each block. Based on the t value (paired t test) between the mean Hb changes in the prestimulation periods and those in the activation periods, data with significant t values ($P < 0.1$) were selected for further analysis using the activation signal. After the selection, the mean Hb changes in the activation periods were used to examine the signal amplitude and signal-to-noise ratio (S/N). We calculated the signal-to-noise ratio by dividing the signal amplitude by the noise amplitude.

Noise levels in Hb changes

The noise amplitude in the Hb changes was determined using attenuation data for the first prestimulation period of 20 s before the original data was separated into blocks. The concentration changes in the oxy- and deoxy-Hb were derived from the data after it was baseline-corrected using a line. The noise amplitude was defined as the standard deviation in the Hb changes after applying a high-pass 1.5-Hz filter. A filtering threshold was set so as to extract the pure system noise, eliminating the effect of spontaneous low-frequency fluctuations and physiological signals such as respiration and pulse signals.

Results and discussion

Detected power of reflected light

The detected power of the original reflected light (830 nm) is shown in Fig. 2 for each cortical area. The power detected in the frontal area differed greatly from those in the other areas, probably because the subjects had no hair covering the frontal area. The power detected in the temporal area was higher than in the occipital and parietal areas, possibly due to differences in the root-of-hair density and cranium thickness.

As shown in Fig. 3, the relative detected power was weaker the shorter the wavelength, except for the frontal area. Compared with the detected power for 830 nm, those for 678, 692, and 750 nm were 36%, 44%, and 59% on average, respectively. The power detected in each area differed depended on the wavelength, suggesting the need for spectroscopic study of human hair.

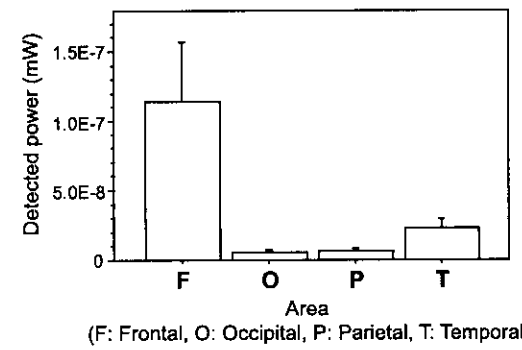

Fig. 2. Mean detected power (830 nm) in four cortical areas calculated using recorded voltage and corrected for detector's wavelength sensitivity and amplifier gain. Error bars indicate standard error.

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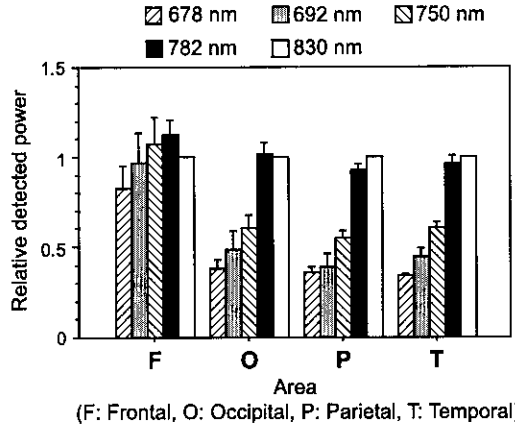

Fig. 3. Relative detected power of five wavelengths for each area corrected for detector's wavelength sensitivity and amplifier gain, and normalized by data for 830 nm. Error bars indicate standard error.

Hb time course

Using the attenuation data for each wavelength, we calculated the Hb time courses. The block-averaged results for each cortical area for each wavelength pair for a representative subject are shown in Fig. 4. The shapes of the time courses obtained with the different wavelength pairs were similar for each area. As in previous studies (e.g., Sato et al., 1999), the concentration of oxy-Hb increased and that of deoxy-Hb decreased during the task period in the occipital, parietal, and temporal areas. However, increases in both oxy- and deoxy-Hb were found in the frontal area. The variation in the deoxy-Hb could be related to variations in the vascular system, as suggested by another study (Yamamoto and Kato, 2002), in which similar results were found in Broca's area. Further studies focusing on the relationship among neural activity, the fMRI signal, and the NIRS signal are needed for better understanding of the physiological mechanism.

The t tests for all subjects except one indicated significant activation for both oxy- and deoxy-Hb in every cortical area. The exceptional subject showed insignificant deoxy-Hb changes only in the parietal and occipital areas. One reason for the exception might be the possibility of variation in the deoxy-Hb changes (Yamamoto and Kato, 2002). Another possibility is a poor S/N for deoxy-Hb in both areas (Table 1). The activation-signal amplitudes for deoxy-Hb are usually less than half those for oxy-Hb (Maki et al., 1996).

After low-pass 0.8-Hz filtering, the profiles obtained from the four wavelength-pairs were compared. The low-pass filtering eliminated the effects of high-frequency system noise. The correlation coefficients (Pearson's product-moment correlation coefficient) are listed in Table 2. Every comparison shows a significant positive correlation ($P < 0.0001$) for all subjects, indicating that every wavelength pair measured almost the same cortical area.

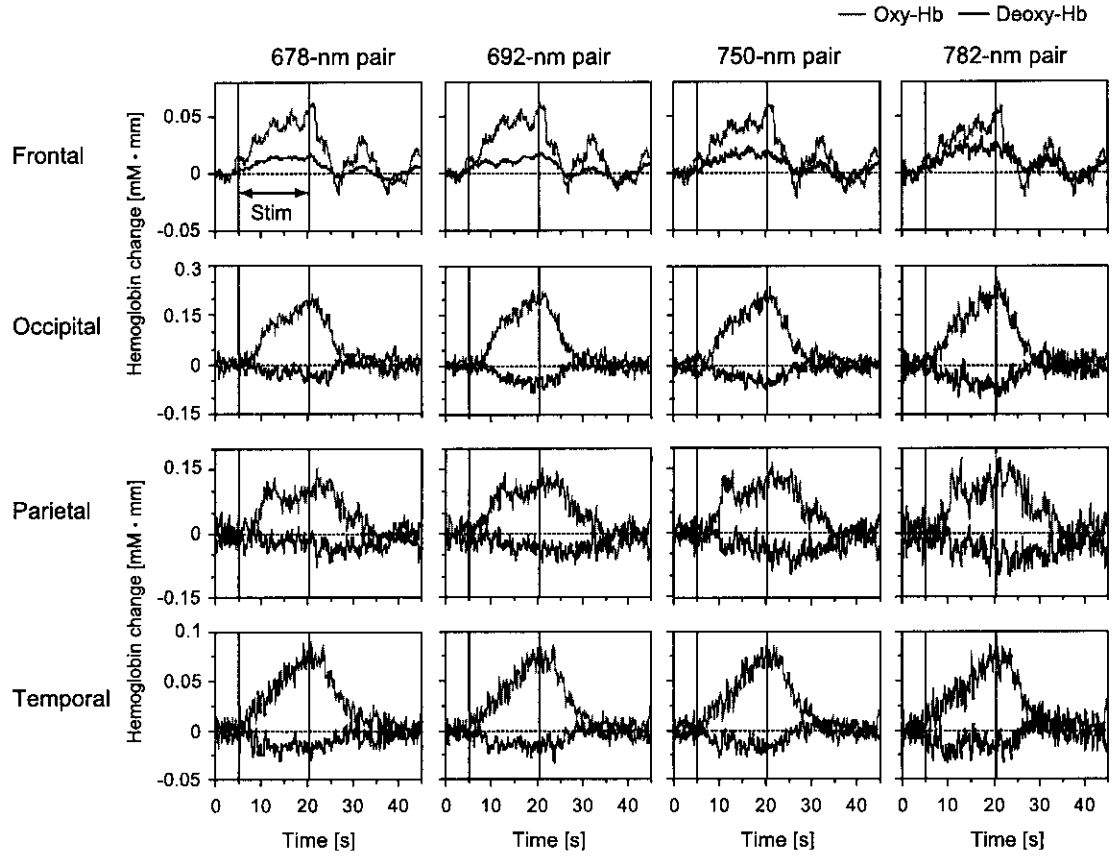

Fig. 4. Block-averaged hemodynamics in each cortical area for each wavelength pair for a representative subject. All wavelength pairs were simultaneously measured in each area. In the 'stim' period, a stimulus was given to the subject.

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Table 1
Relative signal-to-noise ratios (S/Ns) for four areas for 782-nm pairing calculated by dividing signal (amplitude of Hb change in activation periods) by noise level (standard deviation during pre-activation period)

Hb species	Area	Relative S/N (mean ± SE)
Oxy-Hb	frontal	1.00
	occipital	0.57 ± 0.11
	parietal	0.46 ± 0.05
	temporal	0.62 ± 0.04
Deoxy-Hb	frontal	0.64 ± 0.04
	occipital	0.31 ± 0.13
	parietal	0.20 ± 0.08
	temporal	0.37 ± 0.10

They were normalized using Oxy-Hb data for frontal area.
SE = standard error.

The correlation coefficients for deoxy-Hb for all areas except for the frontal area were relatively low because of the lower S/N in those areas. The mean S/Ns for deoxy-Hb in the occipital, parietal, and temporal areas were about 31%, 20%, and 37% relative to the S/N for oxy-Hb in the frontal area, respectively (Table 1). The lower correlate coefficients for deoxy-Hb may have resulted from the area dependence of the detected power (Fig. 2) and a lower S/N.

Activation-signal amplitude

The activation-signal amplitudes normalized using the data for the 782-nm pairing are shown in Fig. 5. The amplitudes were lower for the shorter wavelengths in most cases. An analysis of variance (ANOVA) (wavelength pairs × areas) indicated significant effect of wavelength pairs for deoxy-Hb [$F(3,40) = 3.65$, $P < 0.05$] although no significant effect for oxy-Hb [$F(3,48) = 0.97$, $P > 0.1$] was found. According to Eqs. (1)–(3), the Hb changes ($\Delta C'_{oxy}$ and $\Delta C'_{deoxy}$) do not depend on the wavelength pair, but it is possible that the activation-signal amplitudes were affected by a difference in optical path-lengths (L's) among the wavelengths.

Although the path-length (L) should be the same for different wavelengths according to Eqs. (1)–(3), it changes depending on the optical properties of the biological tissue. We defined L as the partial path-length, which is the average path-length of light traveling through a focal region of absorber changes (Hiraoka et al., 1993). To estimate the wavelength dependence of the activation-signal amplitude, we calculated the relative path-length (L') for each wavelength, on the assumption that the path-lengths of 782 and 830 nm are the same:

$$L'(\lambda 1) = \frac{\Delta A_{(\lambda 1)}}{\varepsilon_{oxy\,(\lambda 1)} \times \Delta C'_{oxy\,(782,\,830)} + \varepsilon_{deoxy\,(\lambda 1)} \times \Delta C'_{deoxy(782,\,830)}}, \quad (6)$$

where the concentration changes for the 782-nm pairing were used as the standard changes [$\Delta C'_{oxy\,(782,\,830)}$ and $\Delta C'_{deoxy\,(782,\,830)}$] for every wavelength to isolate the difference in amplitude of $\Delta C'_{oxy}$ and $\Delta C'_{deoxy}$ for the 678-, 692-, and 750-nm pairings due to the variance in optical path-length (L) from that for the 782-nm pairing. Recent reports suggest that the partial path-length is more appropriate than the differential path-length for compensating for the difference in NIRS sensitivity (Okada and Delpy, 2003a,b).

The relative path-lengths (L') calculated for each area are shown in Fig. 6. The average path-lengths for 678, 692, and 750 nm were shorter than those for 782 and 830 nm although there were large intersubject variances. These results indicate that the variances in the signal amplitude might be explained by the effect of the varying path-lengths. The large variances for 678, 692, and 750 nm would greatly affect the deoxy-Hb signal because shorter wavelengths have a higher absorption coefficient in deoxy-Hb.

The wavelength dependence of the optical path-length might raise concern about the cross-talk effect (Uludag et al., 2002). Although we could not determine which wavelength pair actually resulted in the minimum cross-talk since the L's were calculated on the assumption that the path-lengths of 782 and 830 nm are the same, it is important that the direction of the signal (positive or negative) was consistent among the wavelength pairs in each hemoglobin and subject. This suggests that the wavelength dependence of cross-talk was small enough not to cause a different activation pattern and that the signal amplitude can be corrected using the relative path-length when the signal amplitudes in the 782-nm pair are fixed as the standard.

Table 2
Correlation coefficients of Hb time courses in wavelength-pairs comparison

Wavelength-pairs comparison	Frontal (mean ± SE)	Occipital (mean ± SE)	Parietal (mean ± SE)	Temporal (mean ± SE)
Oxy-Hb				
678–830/692–830	0.998 ± 0.001	0.934 ± 0.028	0.967 ± 0.021	0.983 ± 0.013
678–830/750–830	0.998 ± 0.001	0.937 ± 0.029	0.959 ± 0.029	0.986 ± 0.004
678–830/782–830	0.989 ± 0.003	0.909 ± 0.031	0.891 ± 0.045	0.977 ± 0.006
692–830/750–830	0.998 ± 0.001	0.918 ± 0.039	0.948 ± 0.038	0.985 ± 0.004
692–830/782–830	0.992 ± 0.002	0.902 ± 0.042	0.884 ± 0.049	0.981 ± 0.006
750–830/782–830	0.993 ± 0.002	0.909 ± 0.031	0.887 ± 0.050	0.980 ± 0.005
Deoxy-Hb				
678–830/692–830	0.979 ± 0.014	0.803 ± 0.081	0.730 ± 0.091	0.795 ± 0.075
678–830/750–830	0.978 ± 0.006	0.824 ± 0.058	0.810 ± 0.070	0.782 ± 0.088
678–830/782–830	0.970 ± 0.013	0.782 ± 0.059	0.575 ± 0.058	0.760 ± 0.090
692–830/750–830	0.972 ± 0.019	0.845 ± 0.052	0.760 ± 0.070	0.779 ± 0.101
692–830/782–830	0.970 ± 0.017	0.825 ± 0.047	0.598 ± 0.084	0.829 ± 0.054
750–830/782–830	0.981 ± 0.008	0.824 ± 0.049	0.641 ± 0.076	0.801 ± 0.076

Profiles after low-pass 0.8-Hz filtering were compared.
SE = standard error.

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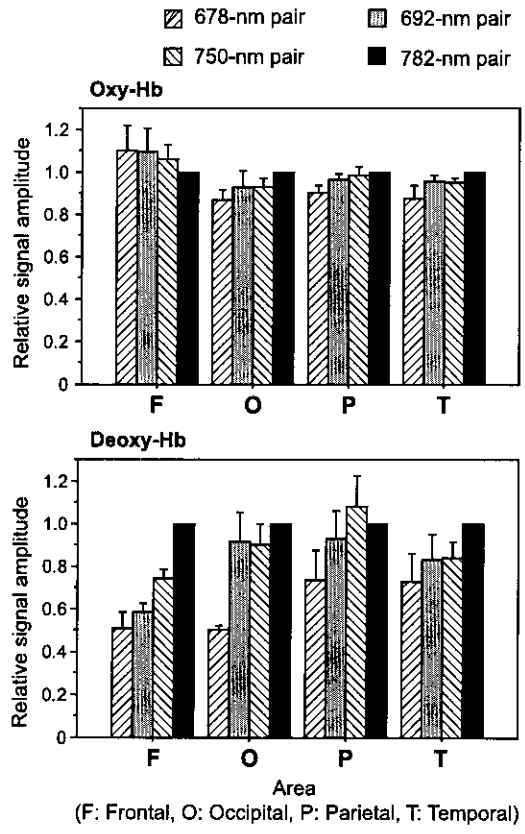

Fig. 5. Relative mean hemoglobin changes in activation periods normalized using data in 782-nm pairing. Each sample was intrasubject averaged data from 6 s after onset of stimulation to end of stimulation. Error bars indicate standard error.

The wavelength dependence of the optical path-length also suggests that the measurement area differs among wavelengths. Significantly, the relative path-lengths were (1) the partial path-length in the activation area and (2) the calculated path-length when the concentration change for the 782-nm pair was fixed as the standard. It was not possible to determine whether each optical path passed through the same tissue because the optical path depends on absorption and scattering not only in the cerebral cortex but also in the skin, muscle, skull, and so on. However, the similar shape time courses shown in Fig. 4 and Table 2 demonstrate that every wavelength could be used to measure the same area and that differences in the signal amplitude are due to differences in the path-length. A simulation study examining the dependence of the optical path on the wavelength is necessary for further discussion.

A previous study (Yamashita et al., 2001) suggested that there is no difference in signal amplitude and a similar tendency is seen in their graphs. Another study (Strangman et al., 2003) did not mention any dependence of signal amplitude on wavelength pair.

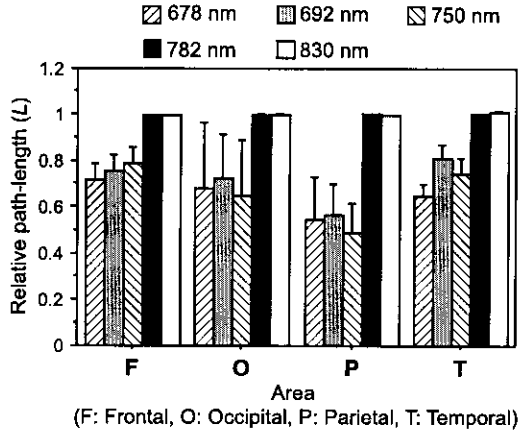

Fig. 6. Relative optical path-length (L) calculated for each block for each subject and area and then averaged for each area. Error bars indicate standard error.

Noise levels in Hb change

The noise levels normalized by the noise amplitude in the 782-nm pairing are shown in Fig. 7 for the four wavelength pairs and four areas. The wavelength pairs using 678, 692, and 750 nm generally produced less noise for both oxy- and deoxy-Hb in every area. An analysis of variance (ANOVA, wavelength pairs × areas) was used to test the dependence of the wavelength pairs on Hb noise. It showed a significant main effect of wavelength pairs [oxy-Hb: $F(3,48) = 3.36$, $P < 0.05$, deoxy-Hb: $F(3,48) = 21.90$, $P < 0.0001$]. Post hoc tests (Fisher's PLSD) revealed differences between the 678- and the 782-nm pairings (oxy-Hb: $P < 0.01$, deoxy-Hb: $P < 0.01$) and between the 692- and 782-nm pairings (oxy-Hb: $P <$

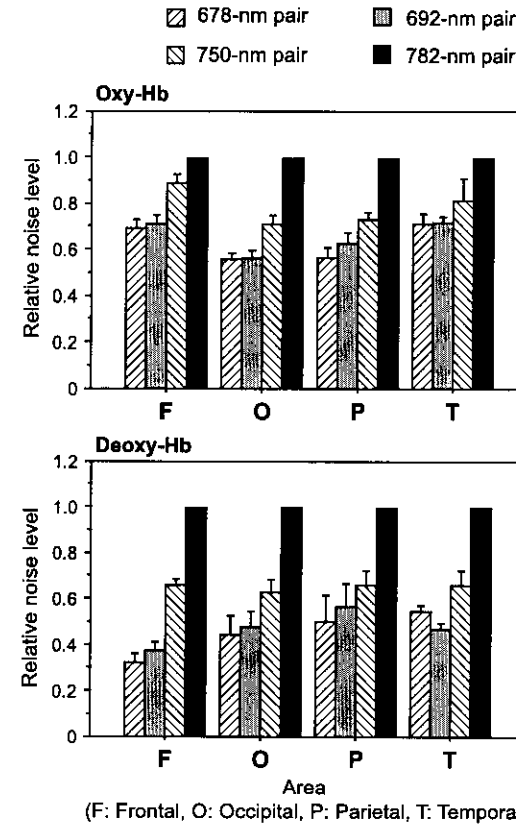

Fig. 7. Relative noise level of oxy- and deoxy-Hb. Noise level was standard deviation in rest period normalized by standard deviation in 782-nm pairing. Levels were calculated for each subject, then averaged among subjects. Error bars indicate standard error.

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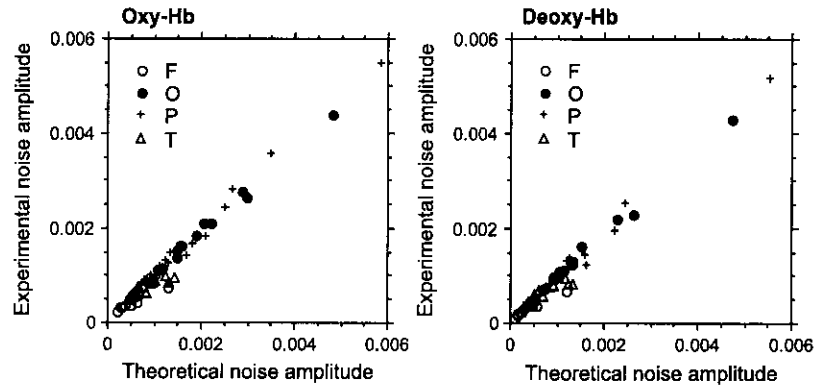

Fig. 8. Scattering diagram of theoretical noise amplitude (horizontal axis) and experimental noise amplitude (vertical axis). F = frontal area, O = occipital area, P = parietal area, and T = temporal area.

0.05, deoxy-Hb: $P < 0.01$). Although a significant main effect of area was shown in the ANOVA [oxy-Hb: $F(3,48) = 17.00$, $P < 0.001$, deoxy-Hb: $F(3,48) = 2.80$, $P < 0.05$], the interaction between wavelength pair and area was not significant. These results suggest that the noise levels in the 678- and 692-nm pairings were lower than those in the 782-nm pairing regardless of area and subject. The dependence of the noise level on the area was probably due to the difference in transparency between areas, as previously mentioned.

The experimentally obtained noise levels corresponded to those derived from theory (Eqs. (4) and (5)), as shown in Fig. 8.

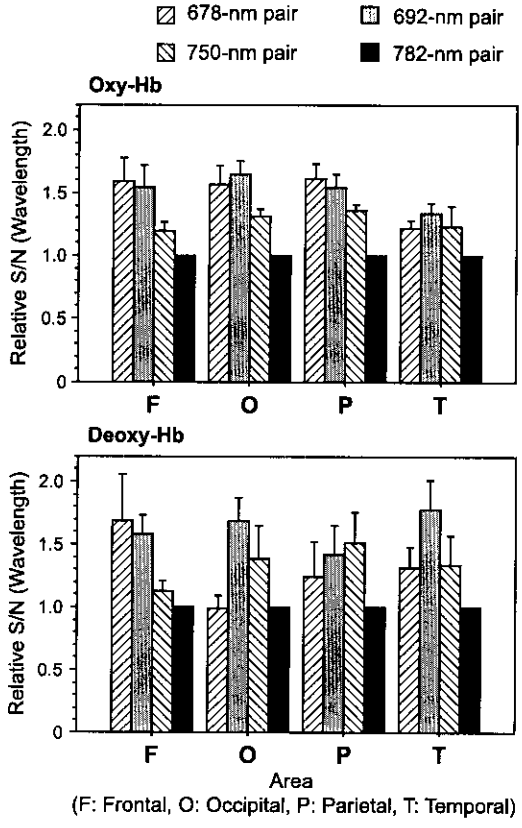

Fig. 9. Relative signal-to-noise ratio for wavelength pairs normalized using data in 782-nm pairing. Error bars indicate standard error.

The experimental and theoretical noise levels showed significantly high correlation coefficients (oxy-Hb: 0.99, $P < 0.0001$, deoxy-Hb: 0.99, $P < 0.0001$), indicating that the noise levels were properly assessed. Consequently, these results suggest that using a shorter wavelength reduces noise levels in most Hb measurements.

Signal-to-noise ratio

The relative S/N levels normalized using those in the 780-nm pairing are shown in Fig. 9. In most areas, using 678 or 692 nm with 830 nm produced the highest S/N. An ANOVA (wavelength-pairs × areas) revealed a significant main effect of wavelength pairs both for oxy-Hb [$F(3,48) = 21.90$, $P < 0.001$] and for deoxy-Hb [$F(3,40) = 6.27$, $P < 0.005$]. For oxy-Hb, post-hoc tests (Fisher's PLSD) indicated a difference for every comparison ($P < 0.005$) except for that between the 678- and the 692-nm pairings, suggesting that the most sensitive measurement is achieved using the 678- or the 692-nm pairing. In contrast, post hoc tests (Fisher's PLSD) for deoxy-Hb revealed a difference between the 678- and the 692-nm parings ($P < 0.05$). A difference for every comparison ($P < 0.05$) except for that between the 678- and the 750-nm pairings was demonstrated in this analysis. Therefore, it can be concluded that the 692-nm pairing provides the highest S/N for deoxy-Hb measurements in this system.

The S/Ns for the 692-nm pairing for oxy-Hb and deoxy-Hb were approximately 1.52 and 1.63 times higher than those for the 782-nm pairing. Thus, the 692-nm pairing provided the highest S/N for both oxy-Hb and deoxy-Hb in our system although the error-propagation law predicts a higher S/N when using shorter wavelength such as 678 nm. This suggests that the optimal wavelength cannot be determined only by the wavelength (absorption-coefficient of Hb species)—the optical properties of the measurement area must be considered. Note that the optimal wavelength also depends on the system properties, such as the irradiated light intensity and detection device. Our results demonstrate the practicality of using around 690 nm to improve NIR measurements for brain functional study.

Conclusion

Wavelengths of 678, 692, 750, and 782 nm were examined for pairing with 830 nm to improve the S/N of NIRS for measuring

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cortical activation. Noise levels in Hb changes decreased when using wavelengths shorter than 782 nm, as predicted by the error-propagation law, and the S/N was improved in most cases. Although it has been suggested that activation-signal amplitudes are affected by a difference in the optical path-lengths, the Hb time courses measured using all wavelength pairs agreed well in each cortical area. This suggests that this wavelength range can be used to measure the same cortical area. The 692-nm pairing generally provided the highest S/N both for oxy- and deoxy-Hb in this system. Although the detected power of the transparent light at 678 and 692 nm did weaken in most cases, the effects of the absorption coefficients surpassed those of the decreasing transparent light on noise reduction for the Hb measurements. Consequently, around 690 nm is a more optimal choice than around 780 nm for pairing with 830 nm to measure Hb changes induced by cortical activation. The improved S/N enables more sensitive statistical analysis, which is essential to functional mapping with NIR topography.

Acknowledgments

We thank Mr. Tatsuya Takeuchi and Dr. Kuniyoshi L. Sakai for their assistance with a pilot experiment; Ms. Akiko Obata, Mr. Ryosuke Hirosaka, and Ms. Ayako Fujii for their technical assistance; Mr. Yuichi Yamashita, Dr. Naoki Tanaka, Ms. Yukari Yamamoto, Dr. Tsuyoshi Yamamoto, and Mr. Takushige Katsura for their helpful discussions; and Dr. Hideo Kawaguchi and Dr. Hideaki Koizumi for their general support.

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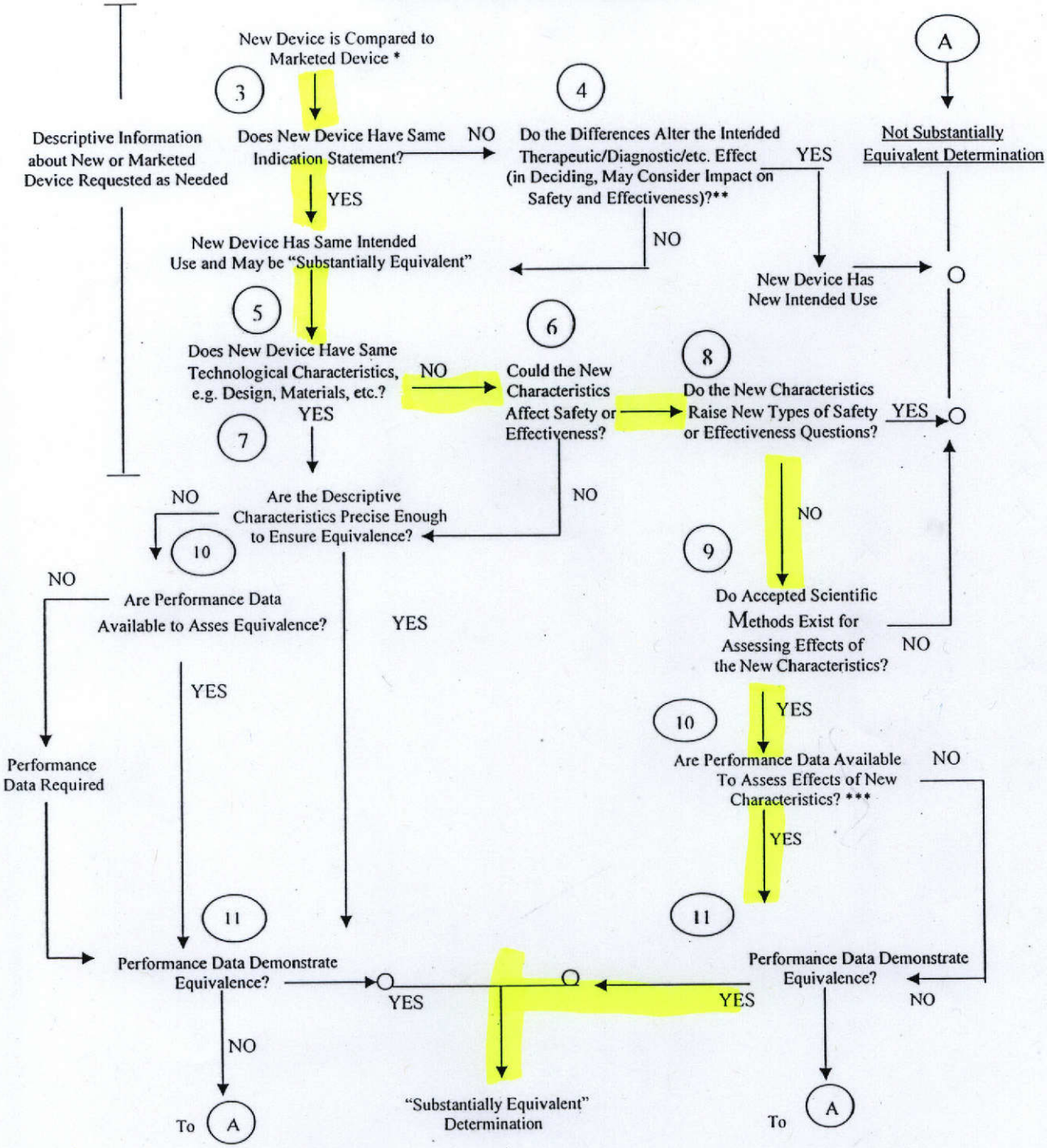
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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