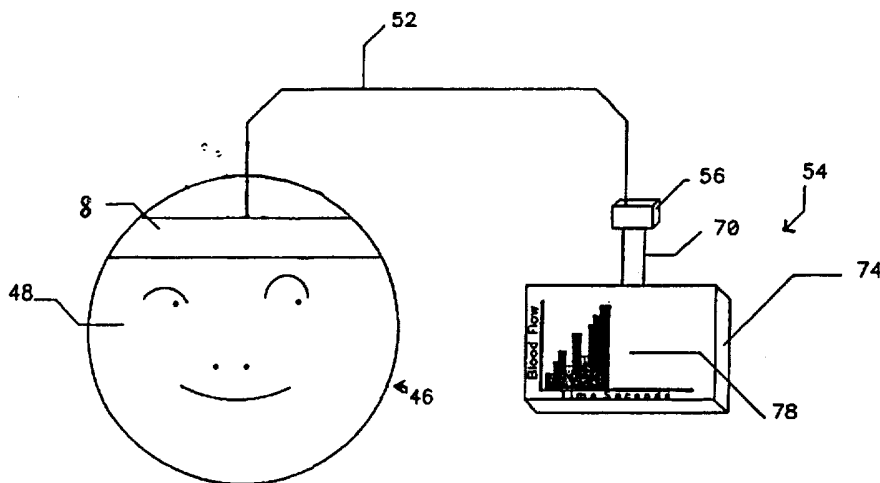




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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**(54) Title:** BIOFEEDBACK OF HUMAN CENTRAL NERVOUS SYSTEM ACTIVITY USING RADIATION DETECTION

**(57) Abstract**

This invention is an apparatus and method for biofeedback of human central nervous system activity using radiation detection. This invention uses radiation from the brain resulting either from an ingested or injected radioactive material or radio frequency excitation or light from an external source (8) impinging on the brain. The radiation is measured by suitable means, and is made available to the subject on which measurement is being made for his voluntary control. The measurement may be metabolic products of brain activity or some quality of the blood, such as its oxygen content. One such system utilizes red and infrared light to illuminate the brain through the translucent skull and scalp (48). Absorption and scattering of incident radiation depends on the degree of oxygen saturation of the blood in the illuminated tissue. The relationship of the returned scattered and absorbed light intensities can be obtained and displayed via a suitable display (74) of sound, graphics or both so that a human being included in the feedback system can attempt to vary the display and thereby control the actual brain blood oxygenation at will. Control of brain blood perfusion is so quickly mastered that most subjects require less than five minutes to gain control.

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DescriptionBiofeedback of Human Central Nervous  
System Activity Using Radiation Detection

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Technical Field

The present invention relates to a method and equipment for biofeedback of alterable characteristics of the brain with the objective of altering blood flow and encouraging vascular growth in a manner conducive to the mental health of a human being.

Background Art

15 With the advent of SPECT, PET and fMRI, blood flow in various brain areas is increasingly being correlated with various brain disorders such as Attention Deficit Disorder (ADD), Schizophrenia, Parkinson's Disease, Dementia, Alzheimers Disease, Endogenous Depression, Oppositional Defiant Disorder, Bipolar Disorder, memory loss, brain trauma, Epilepsy and others.

20

These disorders are, at present, mainly treated with psychoactive drugs and or psychotherapy. Such treatments are marginally effective. The drugs require continuous treatment schedules and have serious side effects such as Tardive Diskinesia, sleep disruption, drowsiness, dullness, skin disorders and digestive interference. Psychotherapy is of limited usefulness in these disorders and is very expensive.

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Previous brain blood flow measurement techniques have required injection of radioactive materials into the blood stream or irradiation of brain tissue with radio frequency power. These are, at present, slow and expensive, requiring minutes to achieve a measurement. Consequently, at present, many important clues to brain operation are completely obscured. See "Interactions Between

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Electrical Activity and Cortical Microcirculation Revealed by Imaging Spectroscopy: Implications for Functional Brain Mapping", Malonek, D. and Grinvad, A., Science, May 26, 1997, pp. 551-554. Continued research and development are making inroads on these obstacles and it is anticipated that the  
5 radioactive tracer and radio frequency irradiation techniques will eventually become useful for biofeedback.

Research has demonstrated that low frequency electrical activity of the brain, as measured by the EEG, is negatively correlated with brain blood flow.  
10 ADD as well as many other brain disorders are characterized by excessive, slow wave activity and below normal blood flow to one or more brain areas. See "Cerebral Glucose Metabolism in Adults with Hyperactivity of Childhood Onset", Zametkin, A.J. et al., New England Journal of Medicine, September 15, 1990, pp. 1361-1366.

15 In recent years Electroencephalographic (EEG) Biofeedback has been used for treating brain disorders with considerable success. A limited course of treatment produces lasting effects. EEG Biofeedback has made great strides in the treatment of some of these problems. Attention Deficit Disorder (ADD) is on  
20 outstanding example. The EEG Biofeedback technique makes non-invasive measurements of brain electrical activity, modifies them to enhance important characteristics and attempts to present the result in a readily understandable form to the patient so that the he can modify the EEG in a healthful direction.

25 EEG Biofeedback is difficult to utilize because of the required multiple electrodes and the required skin preparation for each electrode. See "Muscles Alive", J.V. Basmajian and C.J. Deluca, Williams and Wilkins, Baltimore, pp. 22-23. It is also sensitive to artifacts due to eye and muscle movement. This is especially troublesome near the prefrontal cortex, an important brain area  
30 involved in executive functions, planning, and working memory. The complex electrical signals obtained are ambiguous and represent many simultaneous events. They are difficult for the trainee to interpret and require many sessions

before control is learned. The cost of present day EEG Biofeedback equipment, the skill required to operate it, and the total required treatment time has made this technique so costly that only a small proportion of the estimated eleven million handicapped people in the United States who need access to this technology can  
5 afford it.

Development of a low cost non-invasive brain blood flow monitor represents a great improvement in the field of biofeedback and provides, for the first time, an easily used, safe method of treating many devastating brain disabilities, satisfying  
10 a long felt need of the mental patient and the mental health professional.

#### Disclosure of Invention

This invention uses radiation from the brain resulting from: an ingested or  
15 injected radioactive material, such as is used in the PET, SCAN or SPECT systems; radio frequency excitation, such as used in MRI; or energy from an external source impinging on the brain. The returned radiation is measured by suitable means and is made available to the subject on which the measurement is being made for his voluntary control. The measurement may relate to metabolic  
20 products of brain activity or some quality of the blood such as its oxygen content. Depending on the technique used, the length of path that the radiation travels may or may not be used to localize the subject brain tissue of implementation and need to be compensated. This affects the complexity of calculation that needs to be performed in order to correlate the measured radiation to the metabolic  
25 products or quality of the blood and to present this measurement in a meaningful way.

One such system uses reflected and scattered light from an incident light source to assess the brain blood oxygenation. With this system response is  
30 immediate. It has the advantage of convenience and simplicity: no skin preparation or radio active tracer material injection is required.

This form of the present invention allows simple, non-invasive, low cost measurement and control of brain blood flow. It provides real time information in small fractions of a second and requires only donning of a headband with a light source and a photoelectric amplifier coupled to an electronic sound or visual display. No injection or skin preparation is necessary. This invention uses non-ionizing and non-invasive radiation, traversing the skull and overlying tissues, to illuminate the brain. See "Near Infrared Monitoring of the Cerebral Circulation", Kurth, C.D., Steven, J.M., Benaron, D., Chance B., Journal of Clinical Monitoring, vol. 9, no. 3 (1993). Reflected and scattered radiation, as modified by blood flow in the brain, is sensed at the scalp, interpreted, and presented to the trainee for control.

This form of the present invention utilizes the techniques of oximetry using red and infra-red light to illuminate the brain through the translucent skull and scalp. Absorption and scattering of incident radiation depends on the degree of oxygen saturation of the blood in the illuminated tissue and the wavelength of the illumination. By alternately illuminating the tissue with red and infrared light, the relationship of the returned scattered and absorbed light intensities can be obtained. The relationship can be difference, ratio or any other meaningful calculation, however ratio is preferred. Wavelengths are chosen to maximize the difference in response to oxyhemoglobin and deoxyhemoglobin in the red and in the infrared regions. The ratio is displayed via a suitable display of sound, graphics or both so that a human being included in the feedback system can attempt to vary the display and thereby control the actual brain blood oxygenation at will.

Ratio is, to a first approximation, independent of the depth of penetration of the examined tissue, the brightness of the light and the length of path that the light travels. This is an important consideration in removing interference from the composition and thickness of the scalp, hair, skull and meninges. The system is responsive to the average density of blood in the examined tissue which is

dominated by the capillary system so that arteries and arterioles are of negligible importance to the measurement.

This technique offers great flexibility in optimizing brain blood flow to  
5 selected brain areas and has not been used heretofore in the biofeedback mode  
nor has it been used for voluntary control of brain blood perfusion. Control of  
brain blood perfusion is so quickly mastered that most subjects require less than 5  
minutes to gain control when presented with ongoing measures of brain blood  
flow. This is in great contrast to the difficult task of learning to control the EEG to  
10 optimize brain improvement which requires 6 to 10, 45 minute sessions.

Although alternate illumination with the two radiation wavelengths is  
described above, it is also reasonable to illuminate with both simultaneously and  
to separate the returned light by means of filters or other spectrophotometric  
15 techniques.

An appreciation of the other aims and objectives of the present invention and  
an understanding of it may be achieved by referring to the accompanying  
drawings and description of a preferred embodiment.

20

#### Brief Description of Drawings

Figure 1 illustrates the general principle of this invention.

25 Figure 2 illustrates the preferred irradiation/detection subsystem of this  
invention at its full length, viewed from the inside.

Figure 3 shows a trainee hooked up to the preferred irradiation/detection  
subsystem of this invention, which is connected to an electronic processor and  
30 suitable display.

Figure 4 is a logic flow diagram for the preferred embodiment of this invention.

Figure 5 is a diagram of the electronic circuitry required to drive the alternating light sources and to amplify the returned signal for processing by the display unit of the preferred embodiment of this invention.

Figure 6 shows the relationship between wavelength and light absorption of deoxyhemoglobin and oxyhemoglobin.

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Figure 7 shows the increases in initial brain blood flow in a extremely depressed, suicidal patient at each of 10 half hour treatments using of the preferred embodiment of this invention.

#### 15 Best Mode for Carrying Out Invention

Figure 1 illustrates the general principle of this invention 54. Figure 1 shows an individual 46 wearing a detector 8 attached to his head 48. The detector 8 is responsive to any radiation modified by the particular brain characteristic it is desired to study. Such radiation is produced in response to energy from an energy source. Such an energy source may be:

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25

- 1) radioactive material, selected for a specific brain characteristic, inhaled, ingested, or injected into the individual 46;
- 2) radio frequency excitation tuned to the precession frequency of an atom it is desired to influence; or
- 3) one or more light sources which can illuminate brain tissue with a wavelength or wavelengths chosen for susceptibility to the particular brain characteristic it is desired to influence.

30

On Figure 1 the detector 8 is shown attached directly to the head 48. However, the detector 8 need not be so attached and may be a camera, or other kind of detector 8 responsive to the radiation of interest, at a distance from the

head 48. One cable 52 connects the detector 8 to an electronic processor 56 and a second cable 70 connects the processor 56 to a suitable display module 74. The electronic processor 56 typically includes a computer, which is not separately illustrated. The electronic processor 56 can either be analog or digital. An  
5 analog processor 56 can do the desired calculations continuously. A digital calculator 56 with memory can do the desired calculations serially. Preferably, the display 78 is visual but an audible, audio/visual or tactile display 78 could easily be used. While wires, cables, printed or flexible circuits, and connectors are the most usual methods of connecting electrical components, it will be  
10 recognized by those familiar with the art to which this invention pertains that connection of electrical components can also be done by wireless means, such as infrared or radio-frequency. Furthermore, while use of a processor 56 is preferred, it will be recognized by those familiar with the art to which this invention pertains, that, if the display 78 is sophisticated enough, such as a modern  
15 oscilloscope, this invention may be practiced without the processor 56.

The preferred characteristic is the relationship of oxygenated hemoglobin to deoxygenated hemoglobin. Figure 2 illustrates the preferred irradiation/detection subsystem 10 of this invention, viewed from the inside. This subsystem 10 is  
20 essentially a positioning means for the preferred radiation sources and detectors for carrying out this invention 54. The heart of the preferred subsystem 10 is a subassembly 12 of a dual light source 14, 18 and photo amplifier 22 mounted on a flexible membrane 26. The membrane 26 is a printed flexible circuit for mounting and interconnecting the light sources 14, 18 and the photo detector 22. The light  
25 sources 14, 18 are mounted as close together as possible: orientation is immaterial. While the preferred irradiation/detection subsystem 10 includes two individual light sources 14, 18, it will be recognized by those familiar with the art to which this invention pertains that light energy could be provided by other means such as one or more light pipes. Moreover, the light could be provided  
30 with a broad range of wavelengths and filters to limit the wavelength or wavelengths to that or those of greatest application.

In the preferred subsystem 10, this subassembly 12, in turn, is mounted on a band 30 which can easily mold to the contours of the head 48. The band 30 must be at least partially opaque to external radiation to protect the photo sensor 22 from external light sources. The band 30 can be made of neoprene or similar elastomer adapted to secure around the head 48. A barrier layer, not illustrated, can be placed over the membrane 26 in the interests of cleanliness. If such a barrier layer is used electrodes, not illustrated, are necessary for grounding. The preferred fastening method is strips of hook 34 and loop 38 fastener attached to the ends of the band 30. A connector 42, located on the membrane 26 away from the band 30, enables connection of the dual light source 14, 18 and photo amplifier 22 to external electronics. While wires, cables, printed or flexible circuits, and connectors are the most usual methods of connecting electrical components, it will be recognized by those familiar with the art to which this invention pertains that connection of electrical components can also be done by wireless means, such as infrared or radio-frequency.

The first light source 14 is preferably a red light emitting diode (LED) radiating in the range of 650 to 700 nm with 660 nm being the preferred wavelength. The first light source 14 is a Stanley Electric model BR1102W or equivalent. The BR1102W outputs 3 mW at an excitation current of 20 ma. The second light source 18 is preferably an infrared LED radiating at a wavelength in the range of 800 to 1000 nm with 920 nm being the preferred wavelength. The second light source 18 is a Stanley Electric model AN1102W or equivalent. The AN1102W outputs 3 mW at an excitation current of 20 ma. These wavelengths are chosen to maximize the difference in response to oxyhemoglobin and deoxyhemoglobin in the red, 650 to 700 nm range, and to maximize the difference in response to deoxyhemoglobin and oxyhemoglobin in the infrared, 800 to 1000 nm range.

The photo sensor 22 maximally responds in the limited range of the chosen radiation wavelengths. The photo sensor is a Burr Brown model OPT 101R or

equivalent. It discriminates against other unused wavelengths below 600 nm and above 960 nm by means of built in wavelength filters.

The depth of penetration and intensity of the returned light depends on the separation between the closely spaced light sources 14, 18 and the photo sensor 22 as well as on the available light energy. To insure adequate returned light intensity and to reach the cerebral cortex at a depth of approximately 1.5 cm, the distance between the light sources, using 20 ma excitation current, should be less than 3.5 cm and greater than 2 cm. The preferred separation is 3 cm. The use of laser light sources, when they become available, will allow greater separation and penetration depth. The subsystem 10 can be designed to examine fairly large or extremely small volumes of tissue depending on the portion of the brain in which it is desired to modify blood flow.

There is a limit to the light energy that can be applied to tissue without causing damage. However, higher power light sources 14, 18 can alternatively be used without causing damage, providing the exposure times are very short, e.g. of the order of picoseconds. With such a pulsed light source system, the time of flight to determine position and color of the returned radiation can be measured.

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While Figure 2 illustrates the preferred construction of the subsystem 10, it will be recognized by those familiar with the art to which this invention pertains that alternate subsystems can be conceived and constructed. All that is necessary is that the band 30 be at least partially opaque, fasten securely to the head 48, and carry on its internal surface the two light sources 14, 18 and light detector 22 which must be separated from, yet electrically connected to, each other as described above. Furthermore, it will be recognized that a positioning means for the preferred embodiment of this invention 54 may be an array of radiation sources 14, 18 and detectors 22 adhesively attached to the head 48. Alternatively, the positioning means may be a cap with light pipes for the radiation sources 14, 18 and multiple detectors 22 mounted on its inner surface.

30

Figure 3 shows an individual 46 wearing the headband 10 illustrated in Figure 2 attached to his head 48. While the headband 10 is shown with the light sources 14, 18 and detector 22 adjacent to the forehead 50, it can be worn in any convenient position around the head 48. One cable 52 connects the headband electronics 14, 18, 22 via the connector 42 to an electronic processor 56 and a second cable 70 connects the processor 56 to a suitable display module 74. The electronic processor 56 typically includes a computer, which is not separately illustrated. The electronic processor 56 can either be analog or digital. An analog processor 56 can do the desired calculations continuously. A digital calculator 56 with memory can do the desired calculations serially. The connected parts illustrated on this figure comprise the preferred embodiment of this invention 54. In the preferred embodiment, the display 78 is visual but an audible, audio/visual or tactile display 78 could easily be used. In the preferred embodiment, the processor 56 alternately drives the light sources 14, 18 to illuminate the brain with the selected light wavelengths, interprets the photoelectric intensities returned and presents a display 78 to the trainee 46 to guide his efforts to enhance or decrease his brain blood flow. Alternatively, light from the light sources 14, 18 could be "turned on and off" by Kerr cells, or liquid crystal or equivalent devices. When the headband 10 is attached to the trainee's head 48 as illustrated in Figure 3, the dual light sources 14, 18 are directed at his brain and the light sensitive detector 22 receives reflected and scattered light from his brain.

While Figures 1, 2 and 3 all illustrate an invention 54 having separate components at a distance from each other and being connected together, it should be recognized that the whole invention 54 could be built into one integrated device. For example, the invention 54 could be built into a cap with the display module 74 built into the underside of the visor.

Figure 4 is a logic flow diagram for the preferred embodiment of this invention 54. The processor:

- 5           1)       alternately illuminates the brain of the trainee 46 with two light wavelengths;
- 2)       measures the returned light of each wavelength;
- 3)       compares returned light intensity to determine which is red and which is infrared (infrared is always the larger);
- 10          4)       calculates the red to infrared light intensity ratio R which approximates the oxyhemoglobin to deoxyhemoglobin ratio; and
- 5)       displays the result R with sufficient sensitivity for control by the trainee.

15           In the preferred embodiment, as described above, each light source 14, 18 is alternately illuminated. However, it is conceivable to illuminate both light sources 14, 18 simultaneously and to separate the returned light by means of filters or other spectrophotometric techniques.

Figure 5 is a diagram of the electronic circuitry required to drive light sources 20 14, 18 alternately and to amplify the returned signal for display on the display unit 74. The preferred embodiment of the invention excites the two light sources 14, 18 alternately and a computer program calculates the ratio of the two received intensities for display. The circuit of Figure 5 receives a timing square wave of 17 hz from the host computer on pins 6 and 16 of connector J2. At the transition 25 times of the square wave, the computer reads the output light signal on pin 11 of connector J2. Pins 4 and 8 of connector J1, supply power to the photo amplifier 22 of the headband 10. Pins 5 and 6 of connector J1 supply a square wave of current to the opposing polarity connected light sources 14, 18. Pin 9 of connector J1 carries the photo amplifier 22 output to the buffer amplifier U4C.

30

Pins 1, 2, and 3, of connector J1 collect signals from added photo sensors 22 on the headband (not shown) to achieve multichannel capability. In the

preferred embodiment the red light is always lower in intensity than the infrared light. This characteristic is used by the computer program to sort the returned signals for calculation and display of the oxyhemoglobin to deoxyhemoglobin ratio. This ratio follows the blood requirements of the active brain tissue being  
5 monitored.

An equally viable system excites the two sources 14, 18 simultaneously. It uses a dual photo receiver 22 with red and infrared filters and thereby separates the two wavelengths for calculation of the relationship to be displayed.

10

Figure 6 shows the relationship between wavelength and light absorption of deoxyhemoglobin (Hgb) and of oxyhemoglobin (HgbO<sub>2</sub>). It can be seen that the curves separate from about 600 to 775 nm and above about 825 nm. However, the frequencies where the greatest differences occur are 660 nm and 920 nm.

15 That is why the wavelengths for the light sources 14, 18 are chosen to be 650 to 700 nm with 660 nm being the preferred wavelength and 800 to 1000 nm with 920 nm being the preferred wavelength

### Experimental Results

20

Figure 7, shows the effect of blood flow training. Each succeeding session shows a trend of increasing initial blood flow. With a treatments spaced two days apart, increased vascularity in the tissues of the trainee 46 occurred as a result of the enforced brain exercise and a long lasting effect was achieved. The patient  
25 recovered a sunny disposition toward the end of treatment. She then obtained her first job in 16 years. Similar brain blood flow results have been obtained with a stroke victim and several sufferers of ADD.

The following reference numerals are used on Figures 1 through 4:

- 30           8           Generic detector  
            10          Preferred irradiation/detection subsystem

	12	Electronics subassembly
	14	Red light source
	18	Infrared light source
	22	Photo detector, photo amplifier or photo sensor
5	26	Flexible membrane or circuit
	30	Band
	34	Hook fastener
	38	Loop fastener
	42	Connector
10	46	Individual or trainee
	48	Head
	50	Forehead
	52	First cable
	54	Invention
15	56	Electronic processor
	70	Second cable
	74	Display module
	78	Visual, audible, audio/visual or tactile display

20       An apparatus for biofeedback of human central nervous system activity  
using radiation detection 54 has been described with reference to a several  
embodiments. In the process a method for biofeedback of human central nervous  
system activity using radiation detection has also been described. Other  
modifications and enhancements can be made without departing from the spirit  
25   and scope of the claims that follow.

Claims

What is claimed is:

- 5 1. A biofeedback apparatus for allowing an individual to adjust his own brain blood flow comprising:
  - a. an energy administration means for administering energy to the brain of said individual;
  - 10 b. a detecting means for detecting radiation produced by said brain in response to said energy administration; and
  - c. a display means for presenting said radiation for control by said individual.
- 15 2. A biofeedback apparatus as claimed in claim 1 further comprising a processing means for making said presentation more meaningful.
- 20 3. A biofeedback apparatus as claimed in claim 1 in which said energy is a radioactive material and said energy administration means is selected from the group consisting of inhalation, ingestion and injection.
- 25 4. A biofeedback apparatus as claimed in claim 1 in which said energy is radio frequency excitation.
5. A biofeedback apparatus as claimed in claim 1 in which said energy is light.
- 30 6. A biofeedback method for allowing an individual to adjust his own brain blood flow comprising:
  - a. administering energy to the brain of said individual;
  - b. providing a detecting means for detecting radiation produced by said brain in response to said energy administration;
  - c. providing a display means for presenting said radiation for control by said individual;
  - d. connecting said detecting means to said display means;

- e. detecting said radiation via said detecting means; and
  - f. presenting said radiation on said display means.
7. A biofeedback apparatus as claimed in claim 6 further comprising the steps of:
- a. providing a processing means for making a presentation enhancing calculation based on said detection;
  - b. connecting said processing means between said detecting means and said display means; and
  - c. making said presentation enhancing calculation in said processing means.
8. A biofeedback apparatus for allowing an individual to adjust his own brain blood flow comprising:
- a. a light emitting means for irradiating said individual's brain with light;
  - b. a radiation detection means for detecting radiation reflected and scattered by said individual's brain from said light emitting means;
  - c. a processor means, connected to said radiation detection means for calculating a relationship about radiation detected by said radiation detection means; and
  - d. a display means, connected to said processor means, for displaying said relationship for control by said individual.
9. A biofeedback apparatus as claimed in claim 8 in which said light is pulsed.
10. A biofeedback apparatus as claimed in claim 8 in which said display means is selected from the group consisting of, audio, visual, audiovisual and tactile.

11. A biofeedback method for allowing an individual to adjust his own brain blood flow comprising the steps of:
- a. providing a light source adapted to irradiate said individual's brain with light;
  - 5 b. providing a radiation detector adapted for detecting radiation reflected and scattered by said individual's brain from said light source;
  - c. providing a processor capable of calculating a relationship of the radiation detected by said radiation detector;
  - 10 d. providing a display which can display said relationship for control by said individual;
  - e. interconnecting said light source, said radiation detector, said processor, and said display;
  - f. positioning said light source and said radiation detector about said individual's head so that they will properly operate as designed;
  - 15 g. activating said light source and said radiation detector;
  - h. calculating said relationship in said processor; and
  - i. outputting said relationship to said display.
12. A biofeedback method as claimed in claim 11 further comprising the step of
- 20 pulsing said light source.
13. A biofeedback apparatus for allowing an individual to adjust his own brain blood flow comprising:
- 25 a. a red light emitting means for irradiating said individual's brain with red light;
  - b. an infrared light emitting means for irradiating said individual's brain with infrared light;
  - c. a radiation detection means for detecting light reflected and scattered by said individual's brain from said red and infrared light emitting
  - 30 means;

- d. a processor means, connected to said radiation detection means, for calculating a relationship between red and infrared light detected by said radiation detection means; and
- e. a display means, connected to said processor means, for displaying said relationship for control by said individual.
- 5
14. A biofeedback apparatus as claimed in claim 13 further comprising a circuit means for electrically connecting said red radiation emitting means, said infrared radiation emitting means and said radiation detection means.
- 10
15. A biofeedback apparatus as claimed in claim 14 in which said circuit means includes a wireless connector for permitting connection and disconnection of said processor means to and from said circuit means.
- 15
16. A biofeedback apparatus as claimed in claim 13 in which said lights are pulsed.
17. A biofeedback apparatus as claimed in claim 13 further including an attaching means for attaching said red light emitting means, said infrared light emitting means and said radiation detection means to said individual's head.
- 20
18. A biofeedback apparatus as claimed in claim 17 in which said attaching means additionally excludes ambient light from said radiation detection means.
- 25
19. A biofeedback apparatus as claimed in claim 13 in which said red light emitting means radiates at a wavelength of about 660 to 700 nm, said infrared light emitting means radiates at a wavelength about 800 to 1000 nm, and said distance is from about 2 to 3.5 cm.
- 30

20. A biofeedback apparatus as claimed in claim 13 in which said red light emitting means radiates at a wavelength of 660 nm, said infrared light emitting means radiates at a wavelength 920 nm.
- 5 21. A biofeedback apparatus as claimed in claim 13 in which, in order to calculate said relationship, said processor evaluates said red and infrared light serially by alternately activating said red radiation emitting means and said infrared radiation emitting means.
- 10 22. A biofeedback apparatus as claimed in claim 13 in which, in order to calculate said relationship, said processor evaluates said red and infrared light simultaneously.
23. A biofeedback apparatus as claimed in claim 13 in which said display means  
15 is selected from the group consisting of, audio, visual, audiovisual and tactile.
24. A biofeedback method for allowing an individual to adjust his own brain blood flow comprising the steps of:
- 20 a. providing a red light source adapted to irradiate said individual's brain with red light of a wavelength of about 660 to 700 nm ;
- b. providing an infrared light source adapted to irradiate said individual's brain with infrared light of a wavelength of about 800 to 1000 nm ;
- c. providing a radiation detector adapted for detecting light reflected and  
25 scattered by said individual's brain from said red and infrared light sources;
- d. providing a processor capable of calculating a relationship between red and infrared light detected by said radiation detector;
- e. providing a display which can display said relationship for control by  
30 said individual;
- f. connecting said processor to said display;

- g. positioning said red light source, said infrared light source and said radiation detector around said individual's head so that they will properly operate as designed;
  - h. activating said red light source, said infrared light source and said radiation detector;
  - i. calculating said relationship in said processor; and
  - j. outputting said relationship to said display.
25. A biofeedback method as claimed in claim 24 additionally comprising the step of alternately activating said red light source and said infrared light source.
26. A biofeedback method as claimed in claim 24 further comprising the step of pulsing said light sources.
27. A biofeedback apparatus as claimed in claim 24 further including the steps of:
- a. providing an attaching means for attaching said red light emitting means, said infrared light emitting means and said radiation detection means to said individual's head; and
  - b. attaching said red light emitting means, said infrared light emitting means and said radiation detection means to said individual's head.
28. A biofeedback apparatus for allowing an individual to adjust his own brain blood flow comprising:
- a. a red light emitting means, adjacent to said individual's head, for irradiating said individual's brain with red light;
  - b. an infrared light emitting means, adjacent to said individual's head, immediately adjacent to said red light emitting means, for irradiating said individual's brain with infrared light;

- c. a radiation detection means, adjacent to said individual's head, at a distance from said said red and infrared light emitting means, for detecting light reflected and scattered by said individual's brain from said red and infrared light emitting means;
  - 5 d. a circuit means for electrically connecting said red radiation emitting means, said infrared radiation emitting means and said radiation detection means;
  - e. an attaching means for attaching said red light emitting means, said infrared light emitting means and said radiation detection means to said individual's head and for excluding ambient light from said radiation  
10 detection means;
  - f. a processor means, connected to said circuit means, for calculating a relationship between red and infrared light detected by said radiation detection means; and
  - 15 g. a display means, connected to said processor means, for displaying said relationship for control by said individual.
29. A biofeedback apparatus as claimed in claim 27 in which said circuit means includes a wireless connector for permitting connection and disconnection of  
20 said processor means to and from said circuit means.
30. A biofeedback apparatus as claimed in claim 28 in which said lights are pulsed.
- 25 31. A biofeedback apparatus as claimed in claim 28 in which said red light emitting means radiates at a wavelength of about 660 to 700 nm, said infrared light emitting means radiates at a wavelength about 800 to 1000 nm, and said distance is from about 2 to 3.5 cm.
- 30 32. A biofeedback apparatus as claimed in claim 28 in which said red light emitting means radiates at a wavelength of 660 nm, said infrared light emitting means radiates at a wavelength 920 nm, and said distance is 3 cm.

33. A biofeedback apparatus as claimed in claim 27 in which, in order to calculate said relationship, said processor evaluates said red and infrared light serially by alternately activating said red radiation emitting means and said infrared radiation emitting means.
- 5
34. A biofeedback apparatus as claimed in claim 28 in which, in order to calculate said relationship, said processor evaluates said red and infrared light simultaneously.
- 10 35. A biofeedback apparatus as claimed in claim 28 in which said display means is selected from the group consisting of, audio, visual, audiovisual and tactile.
- 15 36. A biofeedback method for allowing an individual to adjust his own brain blood flow comprising the steps of:
- a. providing a red light source adapted to irradiate said individual's brain with red light of a wavelength of about 660 to 700 nm ;
  - b. providing an infrared light source adapted to irradiate said individual's brain with infrared light of a wavelength of about 800 to 1000 nm ;
  - 20 c. providing a radiation detector adapted for detecting radiation reflected and scattered by said individual's brain from said red and infrared light sources;
  - d. providing a circuit interconnecting said red light source, said infrared light source and said radiation detector;
  - 25 e. providing a processor capable of calculating the relationship between red and infrared light detected by said radiation detector;
  - f. providing a display which can display said relationship for control by said individual;
  - g. connecting said processor to said circuit and said display;

- 5       h.    attaching said red light source, said infrared light source and said radiation detector to said individual's head so that said light sources are adjacent to each other, said radiation detector is 2 to 3.5 cm from said light sources, and ambient light is excluded from said radiation detector;
- i.    activating said red light source, said infrared light source and said radiation detector;
- j.    calculating said relationship; and
- k.    outputting said relationship to said display.

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37.   A biofeedback method as claimed in claim 36 additionally comprising the step of alternately activating said red light source and said infrared light source.

- 15   38.   A biofeedback method as claimed in claim 36 further comprising the step of pulsing said light sources.

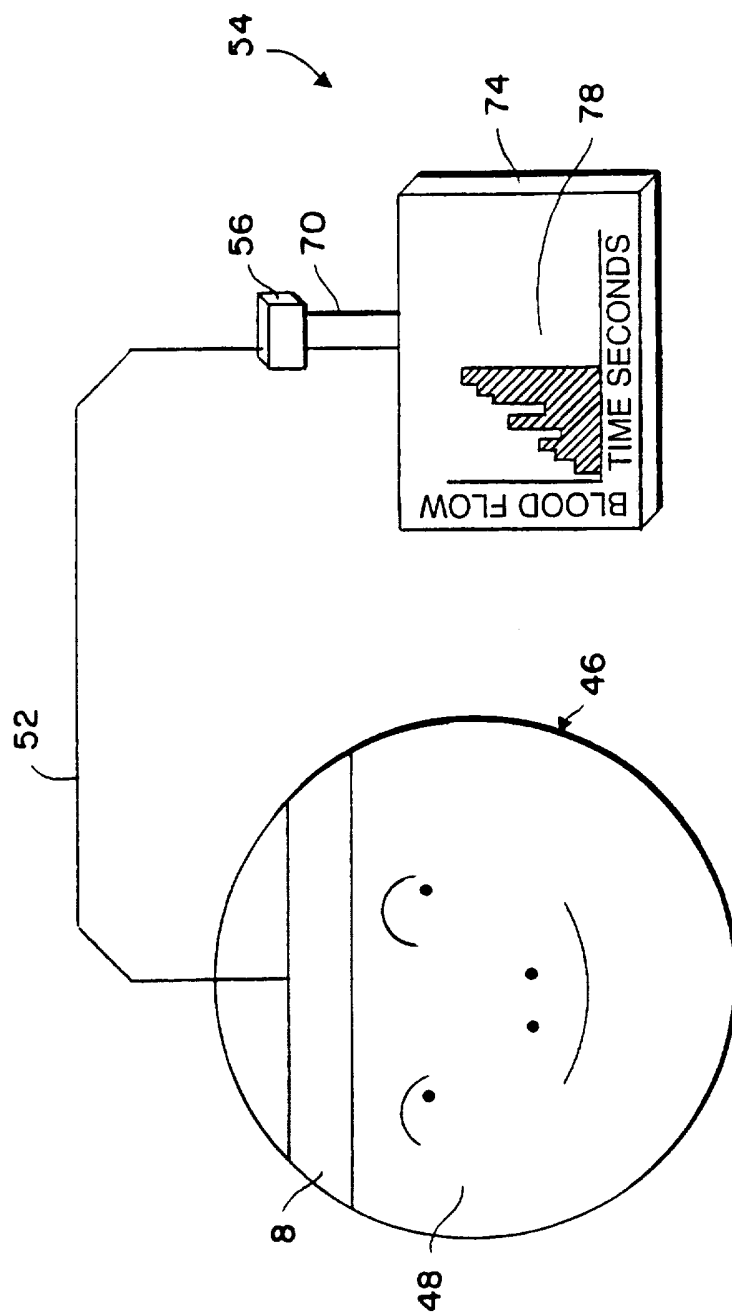


FIG. 1

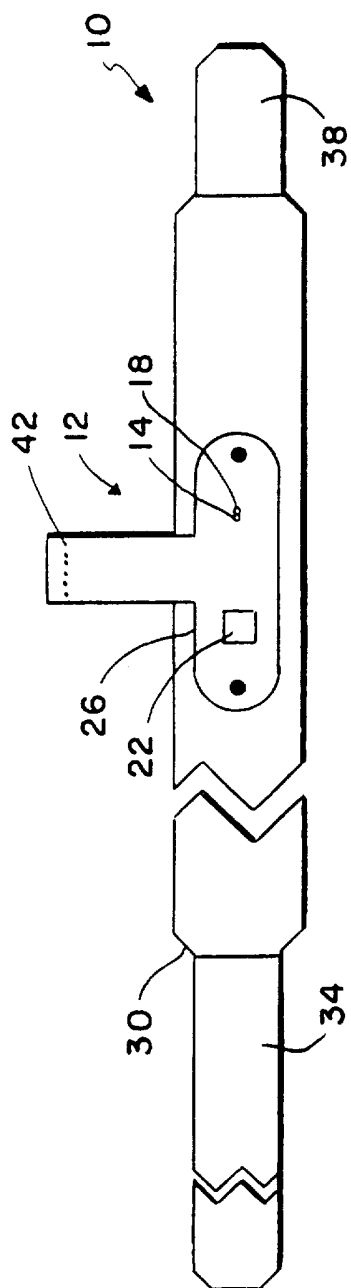


FIG. 2

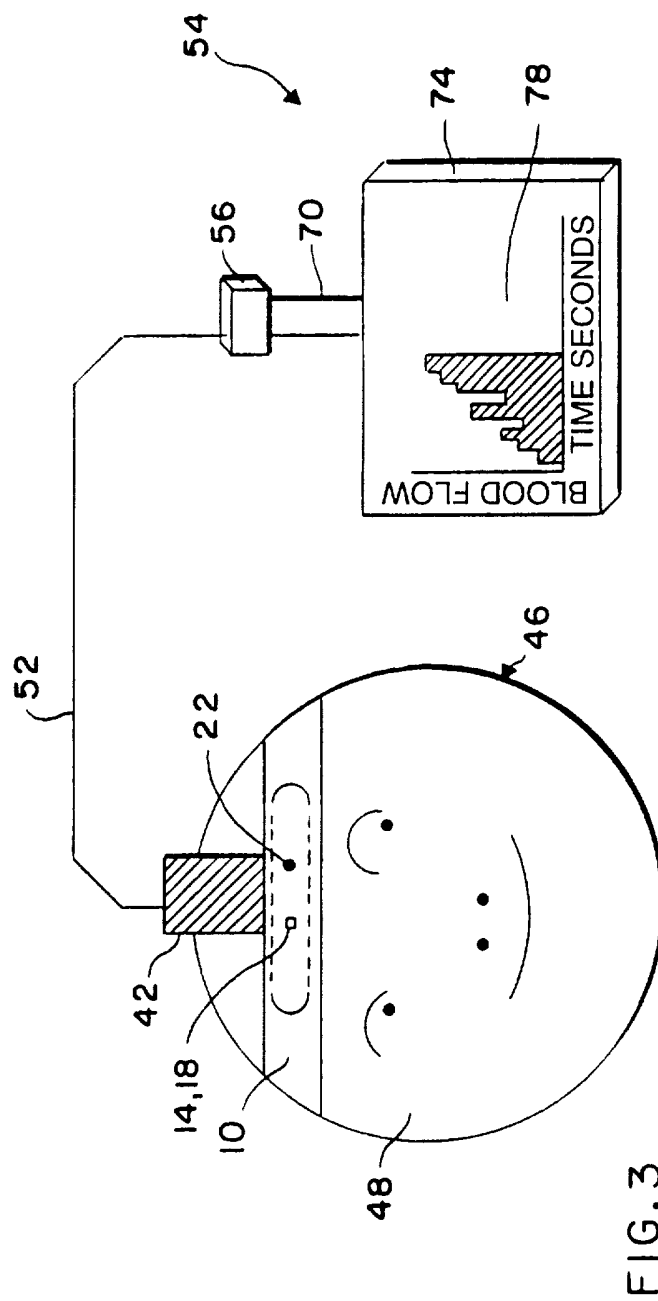


FIG. 3

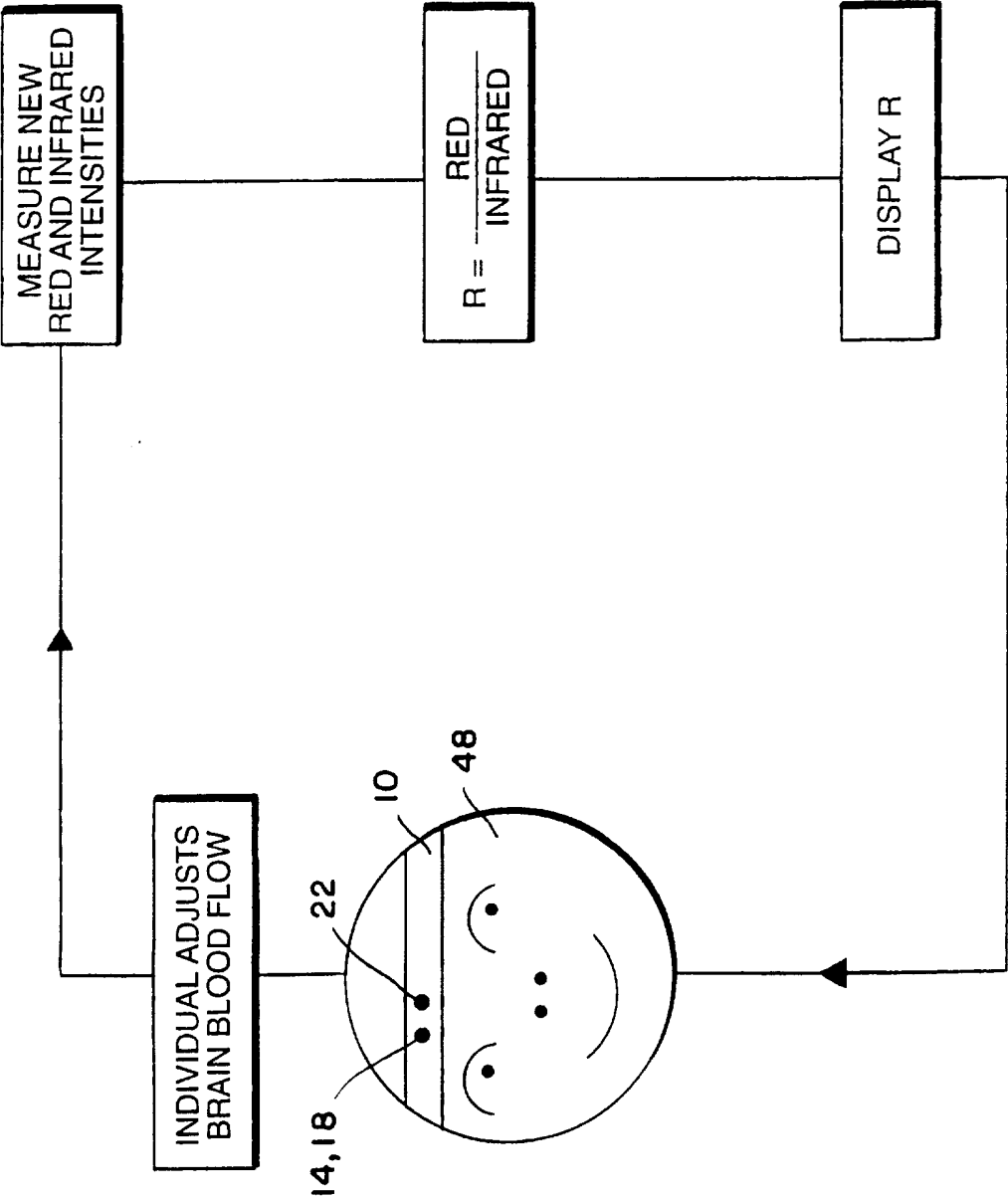


FIG. 4

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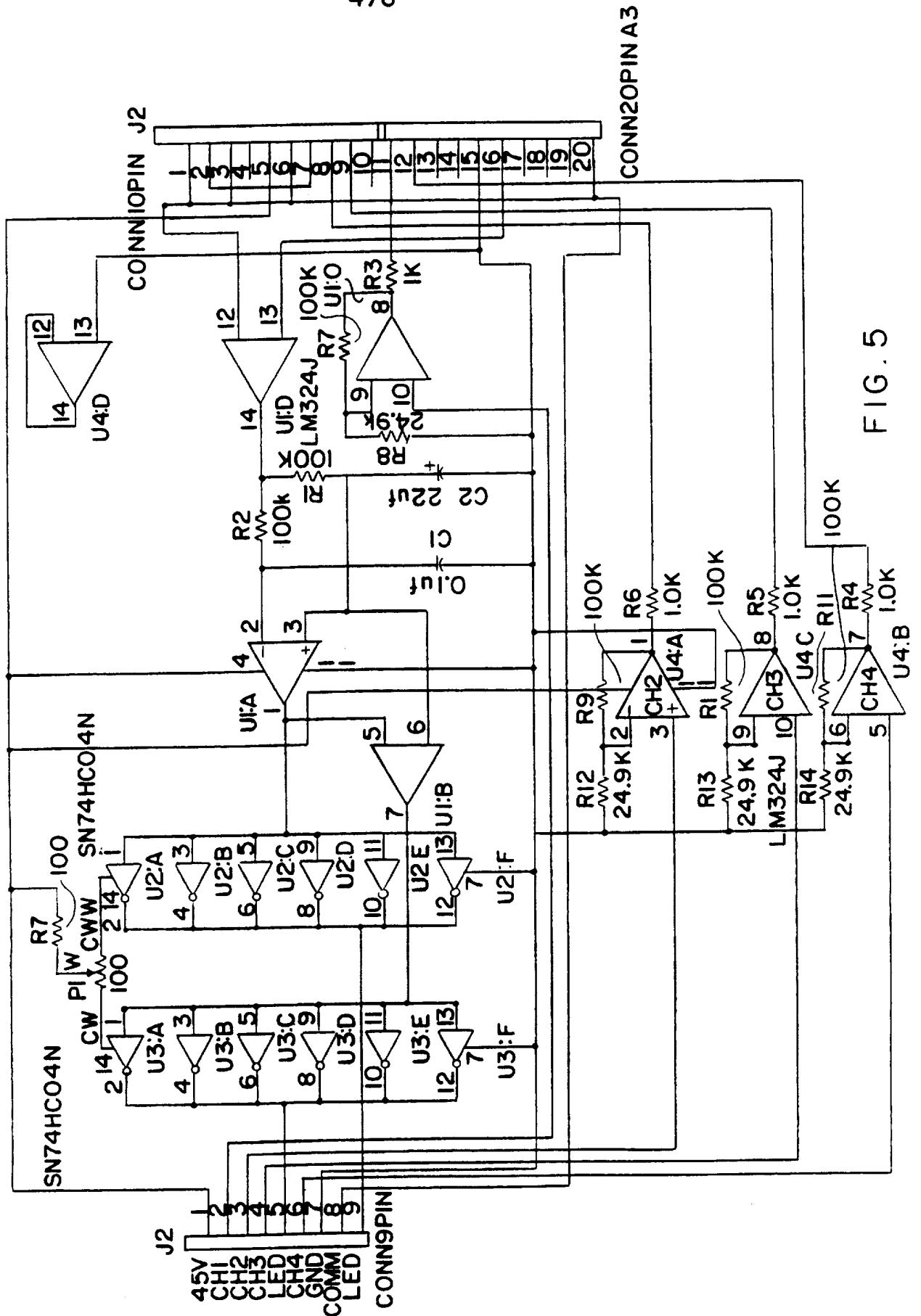


FIG. 5

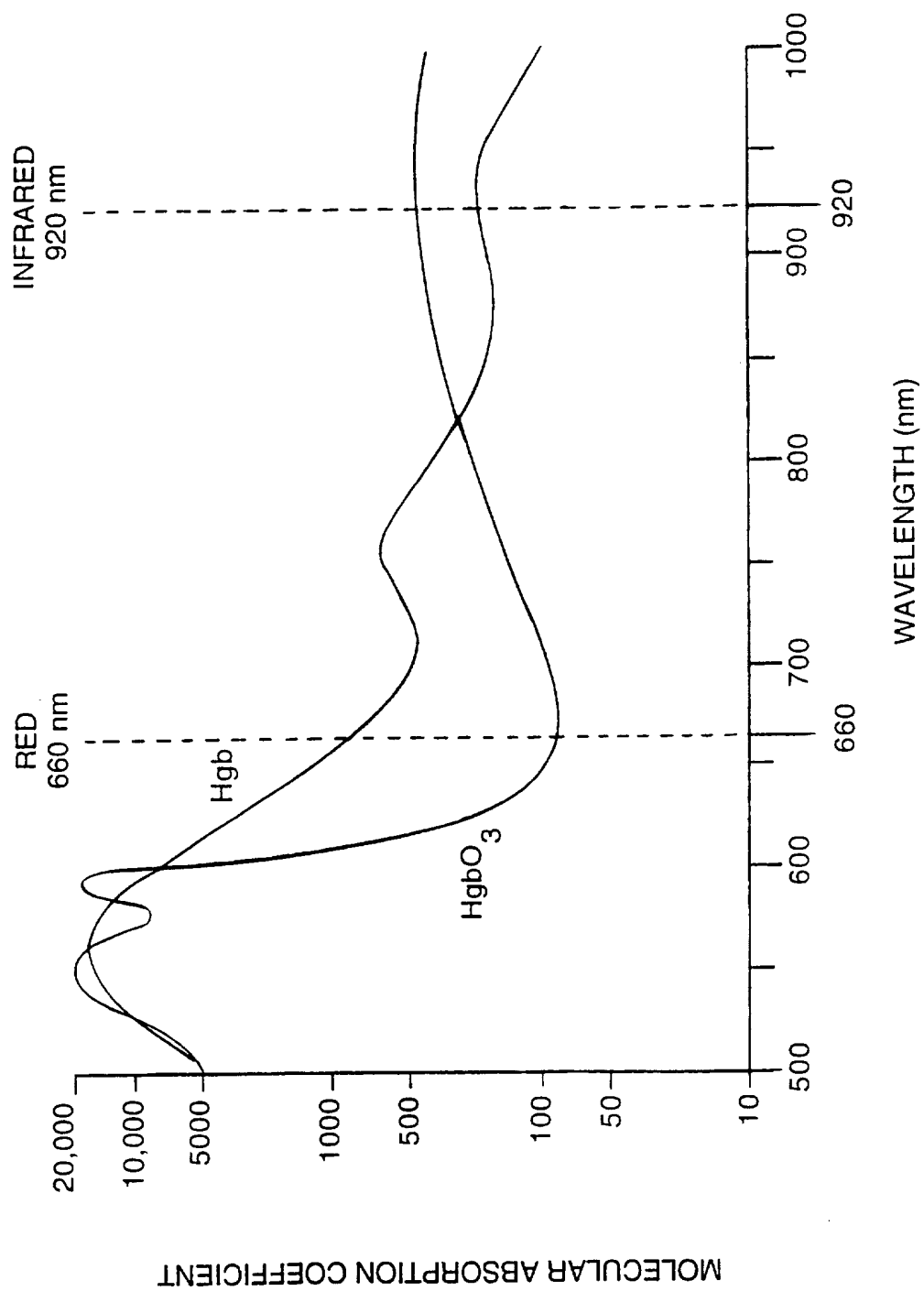


FIG. 6

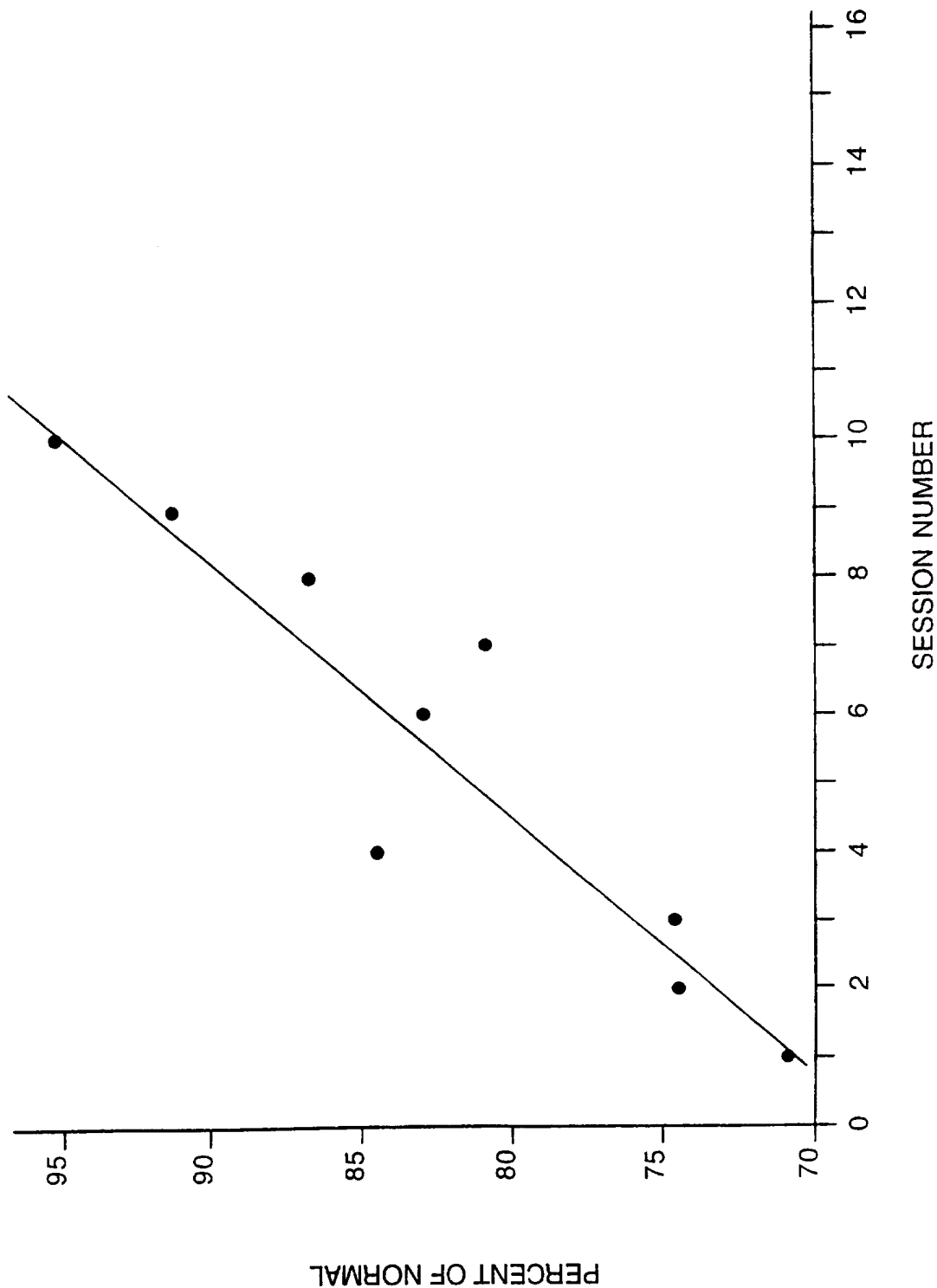


FIG. 7

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/12764

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC(6) :A61B 5/00

US CL :600/407, 476, 477, 479

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/407,476,477,479

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,309,907 A (FANG et al.) 10 May 1994, entire document.	1, 2, 4-11, 14, 17-25, 27, 28, 31-37 ----- 3, 12, 15, 16, 26, 29, 30, 38
Y	US 5,062,431 A (POTTER) 05 November 1991, entire document.	3
X --- Y	US 4,515,165 A (CARROLL) 07 May 1985, entire document.	1, 2, 4-14, 16- 28, 30-38 ----- 3, 15, 29

☒ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

* Special categories of cited documents:	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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"O" document referring to an oral disclosure, use, exhibition or other means	
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

27 OCTOBER 1997

Date of mailing of the international search report

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Facsimile No. (703) 305-3230

Authorized officer

*Calvin Redwell Jr*  
 STEPHEN HUANG

Telephone No. (703) 308-3399

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/12764

## C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,174,298 A (DOLFI et al.) 29 December 1992, entire document.	1, 2, 4-11, 12, 14, 17-25, 27, 28, 31-37 ----- 3, 12, 15, 16, 26, 29, 30, 38