DET 011411

60

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

SOMANETICS CORPORATION,

Plaintiff,

v.

CAS MEDICAL SYSTEMS, INC.,

Defendant.

_____/

COMPLAINT

For its Complaint, Plaintiff Somanetics Corporation, by and through its undersigned counsel, makes the following allegations:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1, et seq., for false advertising arising under 15 U.S.C. § 1125(a)(1)(B), and for unfair competition and libel arising under Michigan law.

PARTIES

2. Plaintiff Somanetics Corporation ("Plaintiff") is a corporation organized and existing under the laws of Michigan with its principal place of business at 1653 East Maple Road, Troy, Michigan 48083.

3. Upon information and belief, Defendant CAS Medical Systems, Inc. ("Defendant") is a corporation organized and existing under the laws of Delaware with its principal place of business at 44 East Industrial Road, Branford, Connecticut 06405. Defendant

has appointed The Corporation Trust Company, 1209 Orange Street, Wilmington, Delaware 19801, as its agent for service of process.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over Plaintiff's patent infringement claims pursuant to 28 U.S.C. §§ 1331 and 1338(a). This Court has subject matter jurisdiction over Plaintiff's false advertising claim pursuant to 15 U.S.C. § 1121 and 28 U.S.C. § 1331. This Court has subject matter jurisdiction over Plaintiff's unfair competition and libel claims pursuant to 28 U.S.C. § 1367, because Plaintiff's state law claims are based on the same operative facts as Plaintiff's federal law claims.

5. This Court has personal jurisdiction over Defendant due at least to Defendant's substantial business in this judicial district, including: (i) committing acts of patent infringement, false advertising, unfair competition, and/or libel, as alleged herein, in this judicial district; and (ii) regularly doing or soliciting business, engaging in other persistent courses of conduct, and/or deriving substantial revenue from goods and services provided to individuals in Michigan and in this judicial district.

6. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b), (c) and 1400(b).

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 5,482,034

7. Plaintiff is the owner by assignment of all rights, title, and interest in U.S. Patent No. 5,482,034 ("the '034 patent") entitled "Method and Apparatus for Spectrophotometric Cerebral Oximetry and the Like." The '034 patent was duly and legally issued by the United

States Patent and Trademark Office ("USPTO") on January 9, 1996. The '034 patent is valid and enforceable. A true and correct copy of the '034 patent is attached as Exhibit A.

8. Upon information and belief, Defendant has been and currently is infringing the '034 patent in violation of 35 U.S.C. § 271, by making, using, offering to sell, or selling within the United States or importing into the United States products that are covered by one or more claims of the '034 patent either literally or under the doctrine of equivalents, including but not limited to Defendant's FORE-SIGHT Absolute Cerebral Oximeter.

9. Upon information and belief, Defendant has been and currently is contributing to and/or inducing infringement of the '034 patent by others in violation of 35 U.S.C. § 271, by offering to sell or selling products that are covered by one or more claims of the '034 patent either literally or under the doctrine of equivalents, including but not limited to Defendant's FORE-SIGHT Absolute Cerebral Oximeter.

10. Plaintiff has not authorized Defendant to make, use, sell, or offer to sell within the United States or import into the United States products that are covered by one or more claims of the '034 patent.

11. Upon information and belief, Defendant has had actual knowledge of the '034 patent.

12. Upon information and belief, Defendant has been and currently is willfully infringing the '034 patent.

13. Upon information and belief, Defendant will continue to infringe the '034 patent unless enjoined.

14. Defendant's infringement of the '034 patent has caused Plaintiff to suffer damages in an amount to be determined at trial. Plaintiff is entitled to recover damages pursuant to 35 U.S.C. § 284.

15. Defendant's infringement of the '034 patent has caused Plaintiff to suffer irreparable harm for which it has no adequate remedy at law. Plaintiff is entitled to a permanent injunction pursuant to 35 U.S.C. § 283.

16. This case is exceptional. Plaintiff is entitled to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 5,902,235

17. Plaintiff is the owner by assignment of all rights, title, and interest in U.S. Patent No. 5,902,235 ("the '235 patent") entitled "Optical Cerebral Oximeter." The '235 patent was duly and legally issued by the USPTO on May 11, 1999. The '235 patent is valid and enforceable. A true and correct copy of the '235 patent is attached as Exhibit B.

18. Upon information and belief, Defendant has infringed the '235 patent in violation of 35 U.S.C. § 271, by making, using, offering to sell, or selling within the United States or importing into the United States products that are covered by one or more claims of the '235 patent either literally or under the doctrine of equivalents, including but not limited to Defendant's FORE-SIGHT Absolute Cerebral Oximeter.

19. Upon information and belief, Defendant has contributed to and/or induced infringement of the '235 patent by others in violation of 35 U.S.C. § 271, by offering to sell or selling products that are covered by one or more claims of the '235 patent either literally or

under the doctrine of equivalents, including but not limited to Defendant's FORE-SIGHT Absolute Cerebral Oximeter.

20. Plaintiff has not authorized Defendant to make, use, sell, or offer to sell within the United States or import into the United States products that are covered by one or more claims of the '235 patent.

21. Upon information and belief, Defendant has had actual knowledge of the '235 patent.

22. Upon information and belief, Defendant has willfully infringed the '235 patent.

23. Defendant's infringement of the '235 patent has caused Plaintiff to suffer damages in an amount to be determined at trial. Plaintiff is entitled to recover damages pursuant to 35 U.S.C. § 284.

24. This case is exceptional. Plaintiff is entitled to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. 6,615,065

25. Plaintiff is the owner by assignment of all rights, title, and interest in U.S. Patent No. 6,615,065 ("the '065 patent") entitled "Multi-Channel Non-Invasive Tissue Oximeter." The '065 patent was duly and legally issued by the U.S. Patent and Trademark Office ("USPTO") on September 2, 2003. The '065 patent is valid and enforceable. A true and correct copy of the '065 patent is attached as Exhibit C.

26. The '065 patent is the subject of a pending reissue proceeding before the USPTO, which was filed on September 2, 2005, as Serial No. 11/219,298, and a pending reexamination proceeding before the USPTO, which was filed on March 31, 2008, as Serial No. 90/010,128.

27. Upon information and belief, Defendant has been and currently is infringing the '065 patent in violation of 35 U.S.C. § 271, by making, using, offering to sell, or selling within the United States or importing into the United States products that are covered by one or more claims of the '065 patent either literally or under the doctrine of equivalents, including but not limited to Defendant's FORE-SIGHT Absolute Cerebral Oximeter.

28. Upon information and belief, Defendant has been and currently is contributing to and/or inducing infringement of the '065 patent by others in violation of 35 U.S.C. § 271, by offering to sell or selling products that are covered by one or more claims of the '065 patent either literally or under the doctrine of equivalents, including but not limited to Defendant's FORE-SIGHT Absolute Cerebral Oximeter.

29. Plaintiff has not authorized Defendant to make, use, sell, or offer to sell within the United States or import into the United States products that are covered by one or more claims of the '065 patent.

30. Upon information and belief, Defendant has had actual knowledge of the '065 patent since at least December 31, 2003.

31. Upon information and belief, Defendant has been and currently is willfully infringing the '065 patent.

32. Upon information and belief, Defendant will continue to infringe the '065 patent unless enjoined.

33. Defendant's infringement of the '065 patent has caused Plaintiff to suffer damages in an amount to be determined at trial. Plaintiff is entitled to recover damages pursuant to 35 U.S.C. § 284.

34. Defendant's infringement of the '065 patent has caused Plaintiff to suffer irreparable harm for which it has no adequate remedy at law. Plaintiff is entitled to a permanent injunction pursuant to 35 U.S.C. § 283.

35. This case is exceptional. Plaintiff is entitled to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

COUNT IV

FEDERAL FALSE ADVERTISING 15 U.S.C. § 1125(A)(1)(B)

36. At least since February 2008, Defendant has been making false and/or misleading statements regarding its own products and/or false, misleading and/or libelous statements regarding Plaintiff's products.

37. For example, Defendant stated in an April 21, 2009 press release that a recent study "indicated that FORE-SIGHT absolute cerebral tissue oxygen saturation measurements are three times more accurate than INVOS;" and in an advertisement that appeared in "Neonatal Intensive Care," Vol. 22 No. 4, July-August 2009 touting FORE-SIGHT's use in connection with infants, that FORE-SIGHT is "3x more accurate than competitor in absolute terms." These statements are false and/or misleading; the "study" which purports to support the statement is inherently unreliable, and certainly would not support any claims vis a vis the products' use in connection with infants as the "study" was conducted on a mere nine healthy adults.

38. Also, in a product comparison chart in its customer presentation materials, Defendant has indicated the "number on the screen" (e.g. the cerebral blood oxygen read out) has "value" for its own product, Fore-Sight, but that the "number on the screen" for Plaintiff's INVOS 5100B and 5100C does not have "value". This statement is false. Indeed, the INVOS

System is the clinical reference standard in cerebral/somatic oximetry, with more than 700 references showing clinical value.

39. Defendant has, on or in connection with its goods and/or services, used in commerce a false or misleading description of fact and/or a false or misleading representation of fact, which, in commercial advertising or promotion introduced into interstate commerce, misrepresent the nature, characteristics, or qualities of Defendant's goods and/or services and the nature, characteristics, or qualities of Plaintiff's goods and/or services, and that such false or misleading descriptions of fact, and/or false or misleading representations of fact are likely to be material to consumers' purchasing decisions.

40. Defendant's acts have been committed with bad faith and the intent to cause confusion, or to cause mistake and/or to deceive purchasers and/or potential purchasers, and Defendant's acts actually caused confusion, or caused mistake and/or deceived, and/or had the capacity to cause confusion, or to cause mistake and/or to deceive purchasers and/or potential purchasers.

41. Plaintiff has suffered, and, if Defendant is not enjoined from its wrongful acts of making false or misleading descriptions of fact and/or false or misleading representations of fact as described herein, Plaintiff will continue to suffer, great and irreparable injury, loss, and damage to its rights for which it has no adequate remedy at law.

42. As a result of Defendant's wrongful acts, Plaintiff has suffered and will continue to suffer substantial and irreparable losses, including loss of valuable business reputation, and, if not enjoined, Defendant will have unfairly derived and will continue to unfairly derive income, profits and business opportunities as a result of its act of false advertising.

43. In view of the foregoing, and as Plaintiff has no adequate remedy at law, under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), Plaintiff is entitled to injunctive relief, corrective advertising and other remedies provided by 15 U.S.C. §§ 1116, 1117 and 1118.

COUNT V

COMMON LAW UNFAIR COMPETITION

44. Plaintiff incorporates paragraphs 1 through 43 of the Complaint as if fully set forth herein.

45. In press releases, on its website, and in statements to customers or potential customers Defendant has, on or in connection with its goods and/or services, used in commerce a false or misleading description of fact and/or a false or misleading representation of fact, which, in commercial advertising or promotion, misrepresent the nature, characteristics, or qualities of Defendant's goods and/or services and the nature, characteristics, or qualities of Plaintiff's goods and/or services, and such false or misleading descriptions of fact, and/or false or misleading representations of fact are likely to be material to consumers' purchasing decisions.

46. Defendant's acts have been committed with bad faith and the intent to cause confusion, or to cause mistake and/or to deceive purchasers and/or potential purchasers, and Defendant's acts actually caused confusion, or caused mistake and/or deceived, and/or had the capacity to cause confusion, or to cause mistake and/or to deceive purchasers and/or potential purchasers.

47. Plaintiff has suffered, and, if Defendant is not enjoined from its wrongful acts of making false or misleading descriptions of fact and/or false or misleading representations of fact as described herein, Plaintiff will continue to suffer, great and irreparable injury, loss, and damage to its rights for which it has no adequate remedy at law.

48. As a result of Defendant's wrongful acts, Plaintiff has suffered and will continue to suffer substantial and irreparable losses, including loss of valuable business reputation, and, if not enjoined, Defendant will have unfairly derived and will continue to unfairly derive income, profits and business opportunities as a result of its act of false advertising.

49. In view of the foregoing, Plaintiff is entitled to injunctive relief, corrective advertising and damages under Michigan common law of unfair competition.

COUNT VI

TRADE LIBEL

50. Plaintiff incorporates paragraphs 1 through 49 of the Complaint as if fully set forth herein.

51. Defendant published false and/or defamatory statements in communications to third parties regarding Plaintiff that tend to prejudice Plaintiff in the conduct of its business or to deter others from dealing with it.

52. Defendant made these false and/or defamatory statements with a degree of fault amounting to at least negligence in that Defendant knew or should have known that the statements would cause economic and other damages to Plaintiff.

53. Defendant's false and/or defamatory statements affected Plaintiff's business reputation and/or its ability to do business. Plaintiff has been injured in its good name, credit and/or in its reputation and its business, and/or has been deprived of an unknown number of business opportunities which otherwise might and/or would have accrued to Plaintiff in its said business.

54. In view of the foregoing, Plaintiff is entitled to compensatory damages under Michigan law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

(a) Enter a judgment that Defendant has infringed the '034 patent, the '235 patent, and the '065 patent;

(b) Enter a judgment that Defendant's infringement of the '034 patent, the '235 patent, and the '065 patent was willful;

(c) Enter a judgment awarding Plaintiff damages for Defendant's infringement of the '034 patent, the '235 patent, and the '065 patent, pursuant to 35 U.S.C. § 284;

(d) Enter a judgment awarding Plaintiff treble damages for Defendant's willful infringement of the '034 patent, the '235 patent, and the '065 patent, pursuant to 35 U.S.C. § 284;

(e) Enter a permanent injunction enjoining Defendant and its officers, directors, agents, employees, attorneys, servants, affiliates, divisions, branches, parents, subsidiaries, and all others acting in active concert therewith from directly or indirectly infringing the '034 patent and the '065 patent, pursuant to 35 U.S.C. § 283;

(f) Enter a judgment deeming this an exceptional case and awarding Plaintiff its reasonable attorneys' fees, pursuant to 35 U.S.C. § 285;

(g) Enter a judgment awarding Plaintiff costs, pre-judgment interest, and post-judgment interest;

(h) Enter a judgment that Defendant is liable for false advertising;

(i) Enter a judgment that Defendant account for all damages on account of its false advertising;

(j) Enter an injunction requiring Defendant to remove the false and misleading statements from its advertising and promotional materials and disseminate effective corrective advertising and promotional information;

(k) Enter a judgment awarding Plaintiff damages, treble and attorney's fees pursuant to 15 U.S.C. §§ 1116, 1117 and 1118;

(l) Enter a judgment awarding Plaintiff compensatory damages as a result of Defendant's libelous statements; and

(m) Enter any and all other relief that the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby requests a trial by jury of all issues so triable in this action, pursuant to Fed. R. Civ. P. 38.

Respectfully submitted,

HOGAN & HARTSON LLP

By: _____
Celine J. Crawson
Columbia Square
555 Thirteenth Street NW
Washington, DC 20004
(202) 637-5600
CJCrawson@hhlaw.com

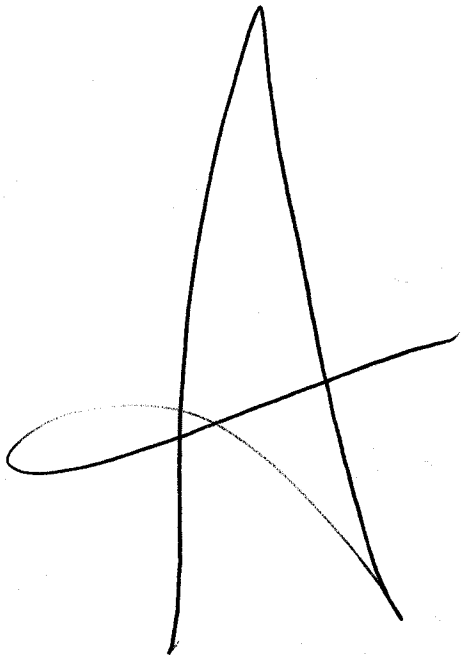
- and -

Jeffrey A. Sadowski (P28163)
Howard and Howard Attorneys PLLC
450 West Fourth Street
Royal Oak, MI 48067
(248) 645-1483
jas2@h2law.com

Dated: August 7, 2009

INDEX OF EXHIBITS

Exhibit A	U.S. Patent No, 5,482,034
Exhibit B	U.S. Patent No. 5,902,235
Exhibit C	U.S. Patent No. 6,615,065



US005482034A

United States Patent [19]

Lewis et al.

[11] Patent Number: 5,482,034

[45] Date of Patent: Jan. 9, 1996

[54] **METHOD AND APPARATUS FOR SPECTROPHOTOMETRIC CEREBRAL OXIMETRY AND THE LIKE**

[75] Inventors: **Gary D. Lewis**, Grosse Pointe Farms, Mich.; **Hugh F. Stoddart**, Groton, Mass.

[73] Assignee: **Somanetics Corporation**, Troy, Mich.

[21] Appl. No.: **297,425**

[22] Filed: **Aug. 29, 1994**

Related U.S. Application Data

[63] Continuation of Ser. No. 69,096, May 28, 1993, abandoned.

[51] **Int. Cl.**[6] **A61B 5/00**

[52] **U.S. Cl.** **128/633**; 128/664; 356/41

[58] **Field of Search** 128/633.4, 664–667; 356/35–41

[56] **References Cited**

U.S. PATENT DOCUMENTS

2,790,438	4/1957	Paplin et al.	28/633
3,230,951	1/1966	Teschner	128/666
3,602,213	8/1971	Howell et al.	128/633
3,769,974	11/1973	Smart et al. .	
3,810,460	6/1974	Van Nie	128/666
3,814,081	6/1974	Mori	128/2 L
3,822,695	7/1974	Takayama	128/2 L
3,910,701	10/1975	Henderson et al.	128/625
4,013,067	3/1977	Kresse et al. .	
4,015,595	4/1977	Benjamin, Jr.	128/2.05 V
4,063,551	12/1977	Sweeney .	
4,091,803	5/1978	Pinder	128/2.05 P
4,109,643	8/1978	Bond et al.	128/2 L
4,163,447	8/1979	Orr	128/666
4,223,680	9/1980	Jobsis	128/633
4,249,540	2/1981	Koyama et al.	128/666
4,259,963	4/1984	Huch	128/635
4,267,844	5/1981	Yamanishi	128/633
4,281,645	8/1981	Jobsis	128/633
4,321,930	3/1982	Jobsis et al.	128/633
4,332,258	6/1982	Arai et al.	128/666
4,336,809	6/1982	Clark	128/665
4,344,438	8/1982	Schultz	128/634

(List continued on next page.)

FOREIGN PATENT DOCUMENTS

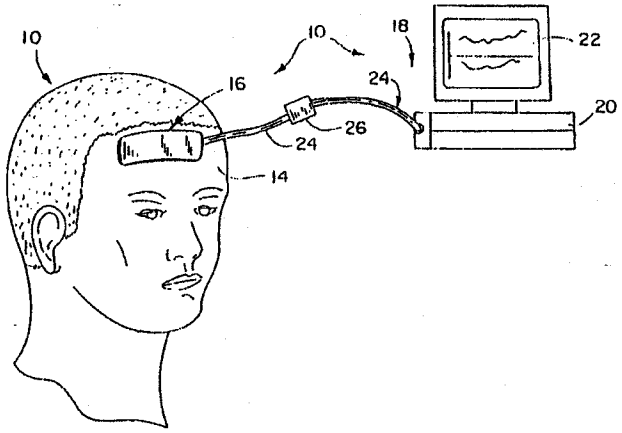
2517129	6/1976	Germany	356/32
2076963A	12/1981	United Kingdom	128/2 L
WO8909566	10/1989	WIPO .	

Primary Examiner—Angela D. Sykes
Assistant Examiner—Robert L. Nasser, Jr.
Attorney, Agent, or Firm—Price, Heneveld, Cooper, DeWitt & Litton

[57] **ABSTRACT**

Spectrophotometric apparatus and related methodology, including a sensor having a source and at least two receivers of electromagnetic radiation such as red and/or near-infrared light, which is applied non-invasively to the outer periphery of a patient or other animate test subject to examine a particular internal region to which is disposed beyond a peripheral extremity of specifically indeterminant thickness lying immediately inwardly of the outer periphery of the test subject. The location of the source and detectors test are selected to be at points spaced from one another by unequal first and second distances defining first and second mean optical paths of specifically differing length, with the second such path defining a primary internal area containing the particular region to be examined, the first optical path generally defining a second internal area located in the primary internal area but substantially separate from the particular internal region to be examined, and the first such optical path including the full thickness of a predetermined typical such peripheral extremity plus at least a small portion of the physiological substance immediately therebeyond. Signals are produced which are representative of the radiation detected by the first and second receivers, and such signals are processed to obtain data which particularly characterizes selected attributes of the substance within the particular internal region, substantially without effects attributable to the secondary internal volume, The second receiver is preferably disposed about thirty to forty millimeters from the source, and the first receiver positioned not closer than about twenty millimeters therefrom.

21 Claims, 3 Drawing Sheets



U.S. PATENT DOCUMENTS

4,350,163	9/1982	Ford, Jr. et al.	128/633
4,380,240	4/1983	Jobsis et al.	128/633
4,510,938	4/1985	Jobsis et al.	128/633
4,515,165	5/1985	Carroll	128/664
4,570,638	2/1986	Stoddart et al.	128/665
4,685,464	3/1987	Goldberger et al.	128/633
4,770,179	10/1988	New, Jr. et al.	128/633
4,805,623	2/1989	Jobsis	128/633
4,819,752	4/1989	Zelin	128/633
4,825,872	5/1989	Tan et al.	128/633
4,825,879	5/1989	Tan et al.	128/633
4,830,014	5/1989	Goodman et al.	128/665
4,840,179	6/1989	Ullrich	128/633
4,865,038	9/1989	Rich et al.	128/633
4,867,557	9/1989	Takatani et al.	356/41
4,880,304	11/1989	Jaeb et al.	356/41
4,928,691	5/1990	Nicolson et al.	128/633
4,938,218	7/1990	Goodman et al.	128/633
4,964,408	10/1990	Hink et al.	128/633
5,057,695	10/1991	Hirao et al.	128/633 X
5,080,098	1/1992	Willett	128/633
5,094,240	3/1992	Muz	128/633
5,111,817	5/1992	Clark et al.	128/633
5,139,025	8/1992	Lewis et al.	128/665
5,140,989	8/1992	Lewis et al.	128/633
5,217,013	6/1993	Lewis et al.	128/633
5,285,784	2/1994	Seeker	128/633

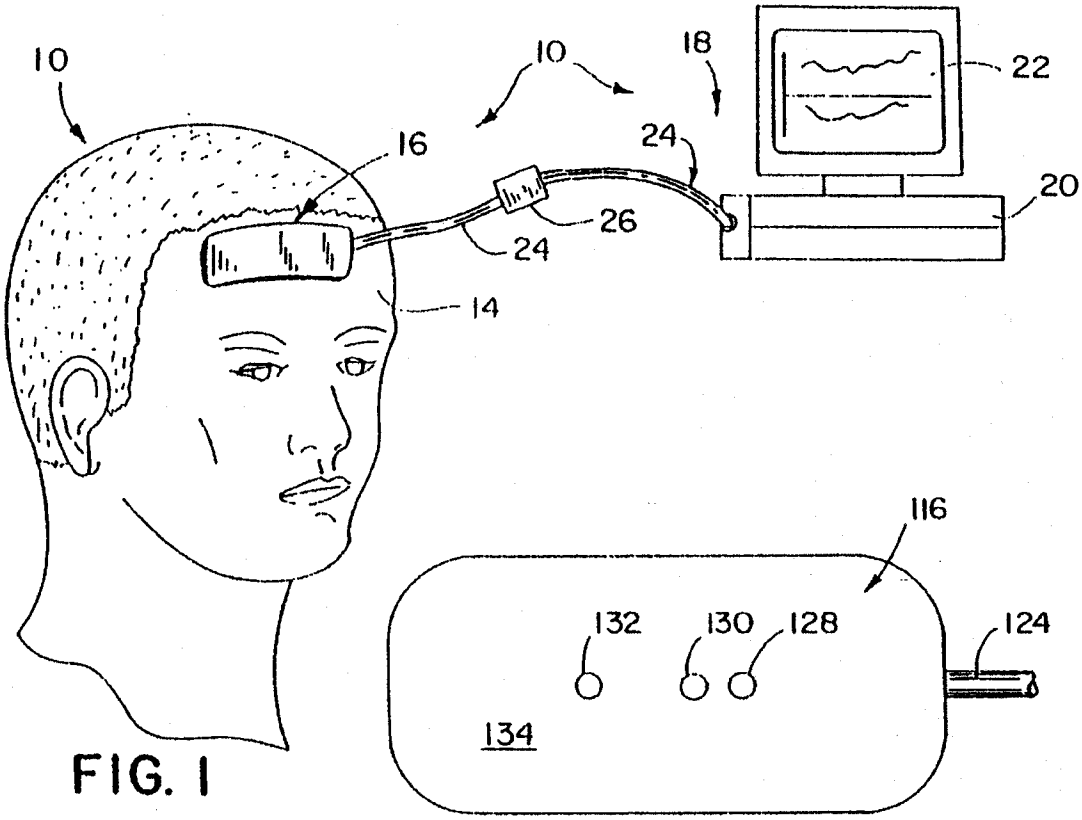


FIG. 1

FIG. 2

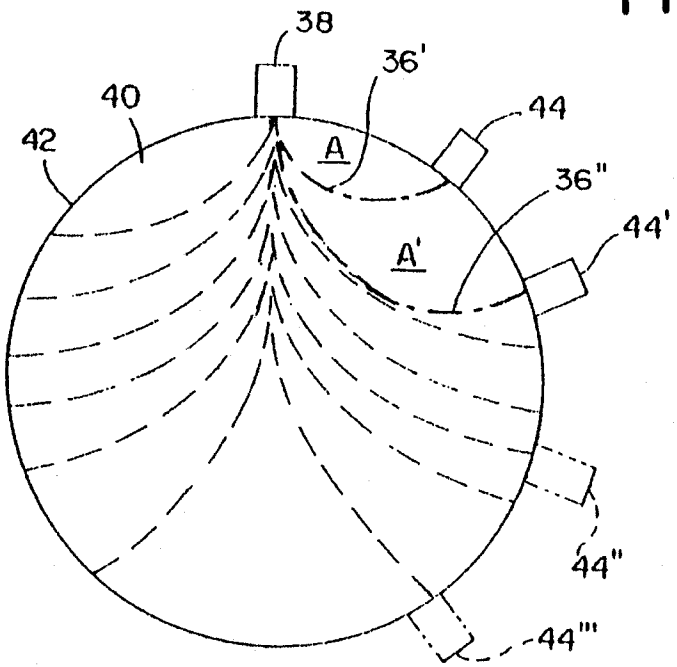


FIG. 3

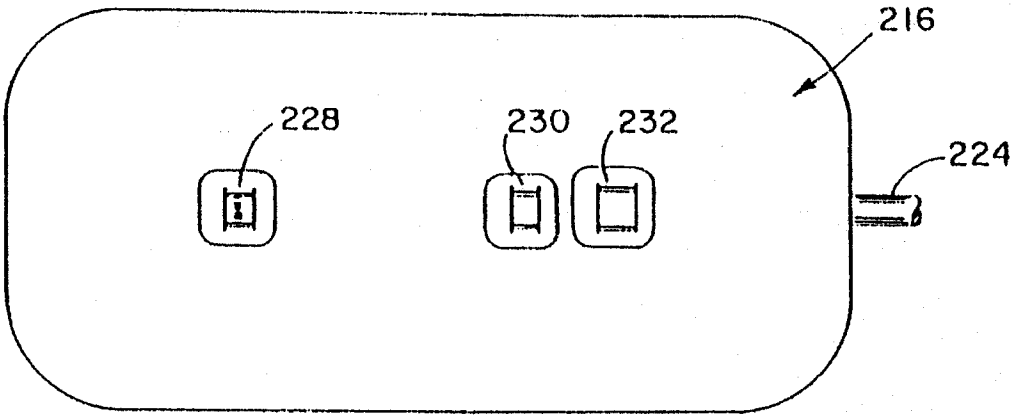


FIG. 4

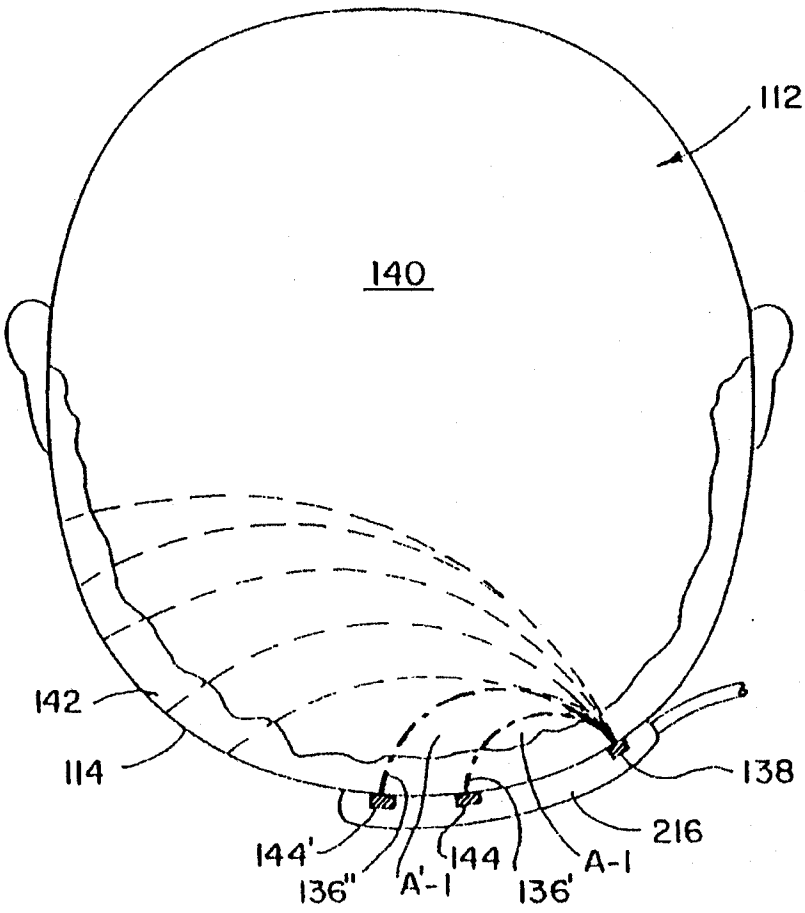
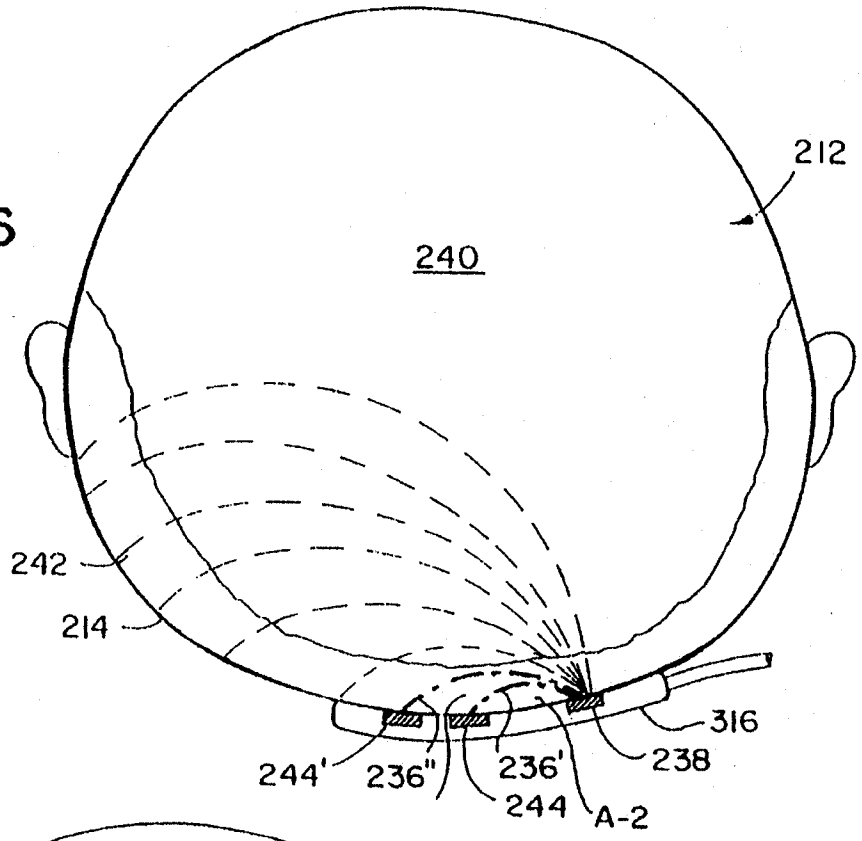


FIG. 5

FIG. 6


212
240
242
214
316
238
244'
236"
236'
244
A-2

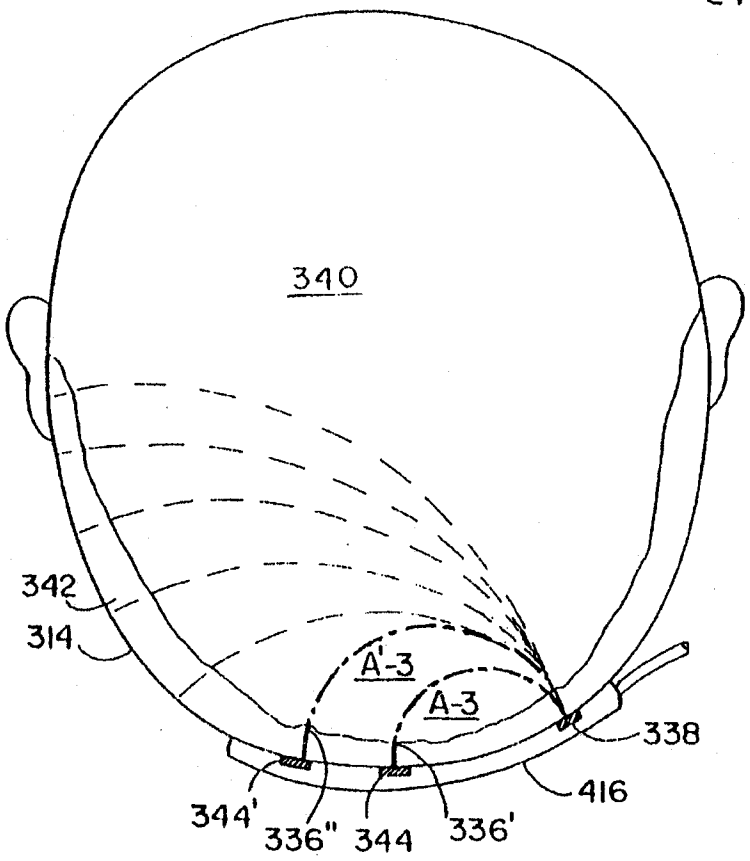

340
342
314
A'-3
A-3
338
416
344'
336"
344
336'

FIG. 7

METHOD AND APPARATUS FOR SPECTROPHOTOMETRIC CEREBRAL OXIMETRY AND THE LIKE

This is a continuation of application Ser. No. 08/069,096 filed on May 28, 1993, abandoned.

FIELD OF THE INVENTION

This invention relates generally to bioelectronic medical examination apparatus, and more particularly to the type of such apparatus which operates on spectrophotometric principles, particularly by use of electromagnetic energy in the visible and near infrared range. Still more particularly, the invention relates to apparatus of the foregoing kind which is used to obtain clinical examination data from the brain, particularly the human brain, by means of an electro-optical sensor placed on the forehead of the patient, and especially to the determination of cerebral hemoglobin oxygen saturation in this manner.

BACKGROUND

In our earlier U.S. Pat. No. 5,139,025, and in subsequent U.S. Pat. No. 5,217,013, assigned to the same assignee, various sensor configurations and structures are disclosed for use in spectrophotometric clinical examination apparatus, particularly the cerebral oxygen saturation monitor developed by Somanetics Corporation, of Troy, Mich., which uses electro-optical components mounted in such a sensor to emit light energy of selected wavelengths and project the same through brain tissue located behind the forehead by transmissivity through the epidermal layers and underlying bone of the frontal skull, and to detect resultant light energy at certain locations spaced laterally from the point of light introduction by certain predetermined distances. In the first such patent, a relatively rigid "hard" sensor configuration is disclosed which is principally suitable for use on generally flat or very soft, compliant surfaces and media, while in the second such patent a flexible, compliant sensor is disclosed which is suitable for use on various curved surfaces, to which it may be manually conformed, such as for example the human forehead.

As indicated above, the lateral distance between the light source and detectors used in such sensors is of considerable importance, since such distances in effect determine the depth to which the interrogating light spectra will penetrate the underlying physiological tissue, at least to the extent that sufficient resultant light is detectable by the sensors to allow for processing and analysis which will yield meaningful data as to the state, condition, or other such attributes of the internal tissue sought to be analyzed. Prior patentees have also referred to this principle, or effect, at least in one way or another; for example, F. Jobsis refers to this in his earlier U.S. Pat. No. 4,223,680, although he appears to primarily attribute the underlying principle or rationale to the belief (not shared by the present inventors) that the interrogating light spectra will traverse the scalp, skull, and "gray matter" of the brain immediately underlying the skull along a rectilinear path, but will be abruptly reflected along another such path by the "white matter" of the brain, with a small amount of the light being directed back to the source but most of it being deflected orthogonally and passing back out of the head through the skull and scalp, etc. a particular distance away from the source. In point of fact, Jobsis categorically asserts in one or more of his patents that an absolute minimum separation distance of 4.25 centimeters

exists in all such cases, which must be observed if the "gray matter" is to be traversed by the examining spectra, and which will thus control the operation of all such devices.

As indicated, the present inventors do not share the opinion just stated, and on the contrary have demonstrated that other factors and principles are involved, and that the transmission of light energy of selected spectra through the brain will essentially exhibit the characteristics of transmission through a highly scattering and partially absorptive media, through which an essentially infinite number of randomly varying transmission paths will occur, all of which, as a general matter, defining a theoretical mean optical path which is arcuately curved, and in the simplest case, essentially a circular arc, between the source and any given detection location, with an exponential decrease in the intensity of the light as a function of the length of the path it has followed to any given point spaced laterally from the point of origin.

Further, the present inventors have previously disclosed the advantages of using two different detectors, or detector groupings, located at mutually different distances from the source of light energy, one being considered a "near" detector and the other a "far" detector, so that the optical response data produced by each could be comparatively analyzed and the effects upon the dam produced by the "far" detector (which samples light that has penetrated more deeply into the subject) can be conditioned so as to in effect eliminate from it tile optical response data which is attributable to the skin, bone, and related skeletal tissue and vascularity, etc., thereby producing data which effectively characterizes only the internal (e.g., brain) tissue. For the most part, however, it was previously thought that the "near" detector should be located in very close proximity to the source, for a variety of reasons. This view is also reflected in the aforementioned patents of Jobsis, at least certain of which also show the use of both a "near" and "far" detector in the same sensor, although the specific reasons for doing so are not considered to be very well, or clearly explained in these patents.

SUMMARY OF THE INVENTION

The present invention reassesses the highly important aspect of source-receiver positioning and relative separation in light of more comprehensive assessment of human anatomical variations at the particular area where the spectrophotometric procedures involved in determining cerebral oxygen saturation are to be employed, i.e., the human forehead area, including the skin and other adjacent dermal layers, skull thicknesses, and variations in forehead geometry, i.e., the extent, nature, and relative location of curvature, together with the nature and presence of tissue and biological substance (e.g., vasculature, pooled blood volumes, other liquids, membranes, etc.) which do or may directly underlie the skin and skull in the forehead region under any and all possible conditions, including injury, trauma, etc. On these bases, the invention provides particular new source-receiver positioning for the sensor which serves as the patient-machine interface, in order to best accommodate the aforementioned considerations.

In a particular and preferred embodiment, the invention provides an improved methodology and sensor component geometry for use in examination of the human brain and determination of the prevalent conditional state of human brain tissue within a relatively defined internal volume of such tissue (i.e., on a regional basis), by use of the com-

pletely non-invasive and innocuous procedures made available by spectrophotometric-type apparatus.

More particularly, the present invention provides novel improvements in methodology and apparatus for a cerebral spectrophotometric sensor as referred to above by which the resulting optical response data is assured of representing purely intrinsic brain tissue, i.e., without the effects which result from passage of the interrogating light spectra through the structure and substances disposed outwardly of the brain itself, i.e., the skin, skull, etc., as noted above. In a broader sense, the novel concepts underlying the invention may be applicable to anatomical areas other than the brain, as should be borne in mind in considering both the foregoing and the ensuing comments relative to and descriptive of the invention.

Accordingly, one characterization of the novel method and apparatus provided by the invention is as follows. Light of selected wavelengths is introduced into the subject from a source location on the outside of its periphery, and first and second light-detection locations are selected on the outer periphery at points spaced from one another and spaced from the source location by unequal, but preferably comparable and not greatly disproportionate, first and second distances, to thereby define unequal first and second mean optical paths extending between the source and the first and second detection locations. By so doing, one such path may be considered as generally defining an overall internal area which contains the particular internal region to be accessed and examined, while the other such path may be considered as defining a secondary internal area which is located generally within the overall such area but which does not include such particular internal region (notwithstanding the fact that in reality some lesser percentage of photons received at the particular detection location involved will no doubt have actually traversed a certain amount of the tissue within such particular region, each "mean optical path" merely representing the idealized path of the predominant number of photons received at the corresponding detector location). In particular, the last-mentioned ("other") such path is selected so that the said secondary internal area includes not only the full thickness of the overlying tissue, etc. disposed between the outer surface and the interior subject or body to be examined, but also at least a small portion of the physiological substance disposed therebeyond, i.e., within the said particular internal volume. By then detecting light at such first and second detection locations resulting from that introduced at the source and producing signals representative of the light detected at both such locations, the signals so produced may be processed to obtain optical response data which particularly characterizes only the tissue of the particular internal region or volume, substantially without effects attributable to any of the tissue and biological substance located between that internal volume and the outside peripheral surface.

In a still more specific sense, the invention provides methodology and apparatus for the indicated spectrophotometric-type clinical examination equipment in which particular distance and positioning parameters are provided for the light source and detectors which will accommodate substantially all known variations in human anatomical size and shape and all or most likely conditions encountered in trauma centers, operating rooms, etc., while consistently providing data which is representative of only the desired internal tissue volume, and not of the overlying tissue and substances disposed nearer the perimeter or making up the peripheral boundaries of the subject. In one particular preferred embodiment, specific relative source-detector separation distances and geometry are provided for the aforementioned cerebral oximeter and directly related apparatus.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a pictorial view illustrating the general environment and structure involved in a preferred embodiment of the invention;

FIG. **2** is a front view of exemplary sensor typifying those previously an used in such applications;

FIG. **3** is a pictorial plan view generally illustrating mean optical path distribution extending from a source to various sensor positions on the perimeter of an idealized highly scattering medium;

FIG. **4** is an enlarged front elevational view of a sensor in accordance with the present invention;

FIG. **5** is a first pictorial sectional view representing the human head and showing a first source-detector position arrangement illustrating certain aspects of the invention;

FIG. **6** is a second pictorial sectional view representing the human head and showing a second source-detector position arrangement illustrating certain aspects of the invention; and

FIG. **7** is a third pictorial sectional view representing the human head and showing a third source-detector position arrangement illustrating certain aspects of the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Referring now to FIG. **1**, an illustrative system **10** for practice of the invention includes a subject **12**, which in this preferred example is a human being upon whose forehead **14** is disposed a sensor **16** that includes an electro-optical source to provide the desired examination wavelengths and various receivers to detect resultant light after the same has passed through the patient's forehead and ;portions of the brain. The corresponding electrical signals for operating the sensor **16** are supplied by and coupled to a spectrophotometric apparatus **18** which, in the preferred embodiment, is configured as the aforementioned cerebral oximeter, referred to and described generally in co-pending U.S. patent application Ser. No. 08/006,705, filed Jan. 21, 1993, and in a more particular sense as exemplified by the Model 3100 cerebral oximeter developed by Somanetics Corporation, of Troy, Mich. As will be apparent, the apparatus **18** essentially comprises an appropriately-programmed microcomputer or "personal computer" **20** having a monitor or visual display **22**, there being an electrical cable **24** extending from the sensor to the apparatus **20** which preferably includes a small amplifier **26** disposed at a predetermined distance from the subject **12** to provide for both optimal safety considerations and detection signal strength for enhanced processing capability.

An exemplary earlier form of the sensor **16** is illustrated in FIG. **2**, wherein it is designated by the numeral **116**. Basically, this device may be considered to be essentially the same as that illustrated and described in patent application Ser. No. 711,452, filed Jun. 6, 1991, (now U.S. Pat. No. 5,217,013) which in essence operates generally in accordance with prior U.S. Pat. No. 5,139,025, both of which are assigned to the assignee of this application. As such, the sensor **116** includes a source **128**, a first or "near" detector **130**, and a second or "far" detector **132**, all mounted in a convenient body **134** that is preferably sufficiently flexible and compliant as to be conformable to the actual forehead

shape of each particular patient by light manual pressure. It is to be noted that the "near" detector **130** shown in the embodiment of FIG. **2** is in fact positioned very near sensor **128**, and in accordance with the aforementioned co-pending application Ser. No. 711,452, the optimum such distance for this separation is described as being in the range of about 8 millimeters. In that configuration, the "far" detector **132** is described as preferably being approximately 23 millimeters from source **128**.

As noted previously, FIG. **3** illustrates in a generalized, pictorial sense the distribution of different mean optical paths **36** of light from a source **38** introduced into a highly scattering medium **40** disposed within a perimeter **42**. As generally depicted in this figure, each of the mean optical paths **36** is arcuately-shaped, and may be considered as a generally circularly-shaped segment in an idealized, illustrative sense, although more generally being described as "banana-shaped" or "canoe-shaped" in technical literature. Consequently, receivers **44, 44'** located at different positions along the perimeter **42** will receive the introduced light spectra along differently-located and differently-curved mean optical paths **36', 36"**, and it will be apparent that each such path in effect defines a different area (designated A, A' inside perimeter **42**, area A being within the totality of area A' but distinguishable therefrom). In a three-dimensional subject, the mean optical paths **36', 36"** would in fact constitute a family of mutually adjacent such arcuate segments, and the areas A, A' would in fact constitute internal volumes with arcuately-shaped, somewhat spherical, ovoid sides. Of course, other particular sensor placements, as shown in phantom at **44"** and **44'"**, would have correspondingly longer mean optical paths disposed between them and source **38** defining other and progressively larger such internal areas and corresponding volumes.

With reference now to FIGS. **5, 6** and **7**, the analogy to the example shown in FIG. **3** will be more apparent, and its significance more readily appreciated. More particularly, each of these three figures represents a cross-section of a simplified human cranium, taken along a plane passing through the forehead **14**. In each case, certain variations are shown in a pictorial schematic sense that occur randomly in various human populations, including differing sizes and degrees of roundness or circularity in the forehead region, and differing thicknesses of skin, skull, and underlying tissue, which are collectively represented by the thickness of the irregular arcuate wall denoted by the numeral **142, 242, 342** in FIGS. **5, 6** and **7**, respectively, and referred to collectively herein as the "peripheral wall" (in the case of the brain and similarly-situated organs) or "overlying tissue structure" (in the case of other internal organs) or, in either case, simply the peripheral extremity. Thus, while shown simplistically as a single area in these figures, but in fact representing a plurality of complex biological structures are in fact represented, as mentioned at various points hereinabove.

More particularly, the head **112** shown in FIG. **5** (representing a typical case) has a somewhat broadly rounded forehead **114** and a "peripheral wall" **142** of a nominal thickness. With an electro-optical sensor **216** applied to the forehead area, a pair of circularly-shaped mean optical paths **136'** and **136"** are produced, which may be analogized to the generally corresponding paths **36'** and **36"** of FIG. **3**, discussed above. As a result, a first internal area **A-1** is produced between the source **138** and the "near" detector **144**, a second such area **A'-1** being similarly produced between the source and the "far" detector **144'**. As may be observed, the "near" area **A-1** does include a moderate amount of the internal (brain) tissue, designated by the numeral **140**, although not as much as the area **A'-1**.

Considering FIGS. **6** and **7**, it may be noted that the head **212** in FIG. **6** is larger and much more broadly rounded than that of skull **112** shown in FIG. **5**, with a flatter forehead **214**. On the other hand, the skull **312** of FIG. **7** is smaller and more elliptical, with a more sharply curved forehead area **314** than the corresponding examples shown in FIGS. **5** and **6**. In addition, the sensor **416** shown in FIG. **7** is somewhat more elongated than the sensors **216** and **3 14** shown in FIGS. **5** and **6**. As a result, the shorter mean optical path **236'** of FIG. **6** does not in fact enter the brain tissue **240** at all, and even the longer mean optical path **236"** hardly enters the brain tissue. Therefore, the volume **A-2** sampled by the near detector **244** is disposed entirely within the "peripheral wall" **242**, and indeed even the larger volume **A'-2** sampled by the far detector **244'** primarily consists of the peripheral wall constituents rather than brain tissue **240**. Basically, a somewhat opposite condition is illustrated in FIG. **7**, in which both of the mean optical paths **336', 336"** extend substantially into the brain tissue **340**, and the sampled volumes **A-3, A'-3** both include substantial amounts of the brain tissue **340**, particularly the volume **A'-3**.

In the preferred processing of output signals from the electro-optical detectors of the sensor, referred to in more detail in earlier U.S. Pat. No. 5,139,025 and co-pending application Ser. No. 08/006,705, filed Jan. 22, 1993, the characteristics of the tissue within the smaller internal area defined by the output signals from the "near" detector are in effect subtracted from the characteristics of the larger internal volume defined by the output from the "far" detector, thereby producing resultant data which is characteristic of a particular internal volume disposed well beyond the peripheral wall, particularly where the "peripheral wall" or "overlying tissue structure" is essentially the same in thickness and characteristic tissue in the area immediately adjacent both such detectors, which is an important consideration within the purview of the invention. That is, with the extensive variations in particular anatomical structure actually encountered between humans of different ethnicity, size, skull thickness, age, vascular structure, etc., variations in the "peripheral wall" or "overlying tissue structure" will certainly occur, not only from one patient to the next, but even in the same patient. Also, as indicated above, significant differences in the degree and type of forehead curvature, etc. are to be expected, rather than the opposite.

Accordingly, as such differences are considered in further detail and explored further, it ultimately becomes clear that the "near" detector should more properly be located closer to the "far" detector than to the source, particularly in the case of spectrophotometric examination of brain tissue, e.g., as applied to a cerebral oximeter as mentioned above, notwithstanding the fact that this is to a considerable extent contrary to prior thinking in this regard. That is, the only way to make certain that the resultant data ultimately obtained does in fact characterize primarily or exclusively internal brain tissue rather than peripheral, epidermal or intervening anatomical substances or structures is to try to make certain that the smaller of the two internal volumes sampled (i.e., that resulting from the "near" receiver output) includes at least the entire thickness of the skin, skull, etc. constituting the "peripheral wall" or boundary, throughout all of the anticipated anatomical variations which may be encountered in peoples from around the world, and in addition, includes at least a minimal amount (and preferably a significant amount) of internal brain tissue within the smaller of the two volumes so sampled.

In point of fact, the present invention recognizes that it is very desirable to have the smaller such internal volume be relatively large in relation to the other such volume, i.e., be almost as large as the other such volume, so that both mean optical paths lie relatively close to one another. By so doing, it becomes much more likely that the thickness and composition of the intervening adjacent biological structure (i.e., the "peripheral wall" or "overlying tissue structure") traversed by photons received at both the "near" and "far" detectors will be the same, or substantially so, and as stated above this is an important factor in achieving accurate results.

At the same time, it is also important to have the "far" detector located at a sufficient distance from the "near" detector to ensure that a significantly different internal volume is sampled by that detector, so that the difference will represent and characterize a meaningfully distinct internal volume, and thereby reliably represent strictly internal tissue situated well within the brain itself. Nonetheless, it must be recognized that the farther either such detector is placed from the source, the more difficult it is to detect sufficient resultant light energy to afford reliable and meaningful processing, bearing in mind that the selected examination wavelengths provided by the source must be accurately representative of those whose selective absorption by reduced and oxygenated hemoglobin is accurately known, and that the amount of power used to generate the resultant light must be maintained at safe and relatively low levels.

With all of the foregoing factors in mind, studies and testing have led to the final conclusion that, for human brain examination, and particularly for cerebral oxygen determination, the "near" detector should be located at least about 20–25 millimeters away from the source, and preferably somewhat further than that, i.e., about 30 millimeters. At the same time, the "far" detector should be positioned at least about 5 to 10 millimeters distant from the "near" detector to guarantee that a distinguishable and different internal tissue volume is in fact sampled by the second such detector, while also assuring that significant detection signal strength will be present. Thus, while a certain range of preferred such positions is potentially present, a specific example of a most preferred such arrangement places the "near" detector at a point 30 millimeters distant from the source, with the "far" detector positioned 10 millimeters beyond, i.e., at a point 40 millimeters away from the source (which is presently considered the maximum such distance which is useful as a practical matter, with commercially available and economically feasible components). This relationship is illustrated in FIG. **4**, wherein an enlarged sensor **216** is shown which has its "near" detector **230** disposed at a point which is clearly much further away from its source **228** than is true of the relationship shown in FIG. **2**, wherein the "near" detector **130** is clearly much closer to source **128**. In point of fact, the "near" detector **230** in the sensor **216** of FIG. **4** is located at a point analogous to the location of the "far" detector **132** of previous sensor **116** shown in FIG. **2**, while the "far" detector **232** of sensor **216** in accordance with the invention is actually disposed even further away from its corresponding source than the "far" detector **132** of earlier sensor **116**.

In view of the aforementioned particular factors and their corresponding significance, the most preferred embodiment of the present invention utilizes a larger detector (photodiode) for the "far" position than that used at the "near" position, so as to increase the likely amount of photon reception by the "far" detector. Of course, within commercially available components there are at least a certain number of different sizes of photodetectors available, notwithstanding cost variations, and whereas prior sensors were implemented by use of photodiodes having an effective surface area of 7.5 square millimeters for both the near and far detector, in accordance with the present invention the far detector is preferably implemented by use of a component essentially twice the size of that previously used at this location, i.e., a 15 square millimeter photodiode. In other respects, the physical structure of the preferred sensor configuration **216** in accordance with the invention is in accordance with that disclosed and claimed in co-pending application Ser. No. 08/065,140 filed May 20, 1993), commonly owned herewith, since that structure provides significant advantages over others used heretofore. Of course, the particular examination spectra emitted by the source remains the same (i.e., approximately 760 nm and 803 nm), and the source should therefore be implemented in the same manner as that referred to in prior patents and/or applications commonly owned herewith, i.e., by wavelength-specific light-emitting diodes.

It is believed that the significant advantages provided by the present invention will be apparent to and appreciated by those skilled in the art upon consideration of the foregoing disclosure, and it is to be noted once again that an underlying concept is advanced which is specifically different from those addressed by the prior state of the art, notwithstanding the superficially similar attributes. It is to be understood that the foregoing detailed description is merely that of certain exemplary preferred embodiments of the invention, and that numerous changes, alterations and variations may be made without departing from the underlying concepts and broader aspects of the invention as set forth in the appended claims, which are to be interpreted in accordance with the established principles of patent law, including the doctrine of equivalents.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A method of non-invasively examining by optical response a physiological substance located within a particular internal region inside an animate test subject having a peripheral extremity of specifically indeterminate thickness disposed generally between said internal region and the outer periphery of the subject, comprising the steps:

introducing light of selected wavelengths into said subject from a source location outside said peripheral extremity;

selecting at least first and second light-detection locations on said outer periphery at points spaced from one another and spaced from said source by unequal first and second distances to thereby define a first mean optical path extending between said source and said first detection location and a second mean optical path of a length different than that of said first mean optical path and extending between the source and said second detection location;

selecting said second path to generally define a primary internal area which contains said particular internal region and selecting said first optical path to generally define a secondary internal area which is located generally within said primary internal area but which is substantially separate from said particular internal region, and particularly selecting said first path to include the full thickness of a predetermined typical such peripheral extremity plus at least a small portion of the said physiological substance therebeyond;

detecting the light resulting from said introduced light at said first and second detection locations, producing

signals representative of such detected light, and processing said signals to obtain optical response data which particularly characterizes selected attributes of said physiological substance within said particular internal region substantially without effects attributable to said secondary internal volume.

2. The method of claim **1**, wherein said physiological substance comprises a highly scattering and partially absorptive media and said mean optical paths comprise arcuate curves.

3. The method of claim **1**, including selecting said second optical path to traverse a generally predetermined internal brain area.

4. The method of claim **1**, in which said step of selecting said first detection location comprises locating a detector not less than about twenty millimeters from the place at which said light is introduced into said subject from said source.

5. The method of claim **1**, in which said step of selecting said second detection location includes locating a detector not less than about thirty millimeters from the place at which said light is introduced into said subject from said source.

6. The method of claim **5**, in which said step of selecting said first detection location comprises locating a detector not less than about twenty millimeters from the place at which said light is introduced into said subject from said source.

7. The method of claim **1**, in which said step of selecting said first detection location comprises locating a detector at about twenty-five to thirty millimeters from the place at which said light is introduced into said subject from said source.

8. The method of claim **1**, in which said step of selecting said second detection location includes locating a detector at about thirty to forty millimeters from the place at which said light is introduced into said subject from said source.

9. The method of claim **8**, in which said step of selecting said first detection location comprises locating a detector at about twenty-five to thirty millimeters from the place at which said light is introduced into said subject from said source.

10. In a method of appraising the internal structure of selected organic bodies and materials, wherein electromagnetic energy is used as an investigative media by passing it through both internal portions of said bodies and materials and overlying tissue structures and quantitative data is produced from such energy which characterizes the composition, condition and/or physiology of a particular area of said internal structure, and wherein a source and at least two receivers are used to send electromagnetic energy of selected wavelengths into and through the selected body or material and receive such energy at at least two separate and mutually-spaced external locations including a first location disposed at least somewhat nearer to said source than a second location, and the resulting energy so received is quantified to obtain characteristic response data values, the improvement comprising:

using as one of said locations a point at which the said energy there received and its corresponding data values characterize primarily said particular area of internal structure, and using as the other of said locations a point at which the energy there received and its corresponding data values characterize both said overlying tissue structure and at least a minimal amount of said internal structure which is located inwardly of said overlying structure, whereby quantified response data valuations are obtained which are assured of characterizing the internal structure at said particular area within said body or material on a generally intrinsic basis and which are independent of characteristics attributable to said overlying tissue structure.

11. The improvement according to claim **10**, in which said step of using a source and at least two receivers is carried out by physically carrying said source and receivers on a single sensor member with said source and receivers disposed at measured distances from one another.

12. The improvement according to claim **10**, in which said bodies and materials are the human head and brain, respectively, and said step of receiving energy at said first location includes disposing both of said receivers at points on the forehead located at least about twenty millimeters from another such point at which said energy is introduced into said head and brain.

13. The improvement according to claim **10**, in which said bodies and materials are the human head and brain, respectively, and said step of receiving energy at said first location includes disposing at least one of said receivers at a point on the forehead located at about twenty-five to thirty millimeters from another such point at which said energy is introduced into said head and brain.

14. The improvement according to claim **13**, in which said step of using a source and at least two receivers is carried out by physically carrying said source and receivers on a single sensor member with said source and receivers disposed at measured distances from one another.

15. Apparatus for obtaining optical response data from discrete organic bodies which is exclusively representative of internal tissue located inside the boundaries of such bodies, comprising in combination:

at least one optical sensor including a source and at least two receivers adapted for placement in optically coupled relation with selected areas on said body and adapted to pass light of selected wavelengths from said source to said receivers through such body;

means for holding said source and receivers in predetermined spatial relation while optically coupled to said selected areas of said body;

said at least two receivers including a first receiver for receiving such light from said source at a first position with respect to s;aid light source as well as a second receiver for receiving such light at a second position located at least somewhat further away from said source than said first position, and for producing corresponding signals representative of data values for each such position which are correlated with said selected wavelengths, both said first and second positions being located so that the light received at each has traversed substantially similar portions of said boundaries and a certain amount of said internal tissue but said second position being located so that the light received there has traversed more of said internal tissue that the light received at said first location; and

means for receiving said signals and producing data values therefrom which characterize the light received at one such position as a function of corresponding light received at the other such position, such that the resulting data values comprise representations of intrinsic characteristics of said internal tissue and are free of optical effects resulting from factors attributable to passages of said light through said boundaries, said first receiver being positioned at a location which is not closer than about twenty millimeters from the location of said source.

16. Apparatus for obtaining optical response data from discrete organic bodies which is exclusively representative of internal tissue located inside the boundaries of such bodies, comprising in combination:

at least one optical sensor including a source and at least two receivers adapted for placement in optically coupled relation with selected areas on said body and adapted to pass light of selected wavelengths from said source to said receivers through such body;

means for holding said source and receivers in predetermined spatial relation while optically coupled to said selected areas of said body;

said at least two receivers including a first receiver for receiving such light from said source at a first position with respect to said light source as well as a second receiver for receiving such light at a second position located at least somewhat further away from said source than said first position, and for producing corresponding signals representative of dam values for each such position which are correlated with said selected wavelengths, both said first and second positions being located so that the light received at each has traversed substantially similar portions of said boundaries and a certain amount of said internal tissue but said second position being located so that the light received there has traversed more of said internal tissue than the light received at said first location; and

means for receiving said signals and producing data values therefrom which characterize the light received at one such position as a function of corresponding light received at the other such position, such that the resulting data values comprise representations of intrinsic characteristics of said internal tissue and are free of optical effects resulting from factors attributable to passages of said light through said boundaries, said second receiver being positioned at a location which is about thirty to forty millimeters from the location of said source.

17. Apparatus according to claim **16**, in which said first receiver is positioned at a location which is not closer than about twenty millimeters from the location of said source.

18. In a method of conducting non-invasive clinical patient examinations of brain tissue by in vivo spectrometry, wherein selected wavelengths of electromagnetic energy are introduced into the brain through the scalp and skull at a first location and resultant amounts of such energy are received at a predetermined number of second locations after transmission back out through the scalp and skull, the improvement in obtaining resultant data which characterizes only brain tissue, comprising:

determining the approximate position for one of said second locations where the resultant energy received will have traversed the scalp, skull and at least a minimal amount of said brain tissue in passing from said first location to said one second location;

determining the approximate position for another of said second locations where the resultant energy received will have traversed the scalp, skull and an amount of said brain tissue greater than said at least minimal amount of brain tissue;

quantifying said resultant amounts of energy received at both said one and said other second locations; and

conditioning the said quantifications of resultant energy received at said one and said other locations by contrasting one with the other such that resultant data is obtained which generally characterizes the difference between said at least minimal amount of brain tissue and said greater amount of brain tissue.

19. The method improvement defined in claim **18**, wherein said steps of determining position for said second locations includes using a representative measure of skull thickness and skull curvature at a predetermined area of the skull.

20. The method improvement defined in claim **19**, wherein said predetermined area of the skull is the forehead.

21. The method improvement defined in claim **20**, wherein said one and said other second locations are determined to be more closely adjacent one another than either is to said first location.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,482,034
DATED : January 9, 1996
INVENTOR(S) : Lewis et al.

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, line 33
"torehead" should be --forehead--.

Column 4, line 10
After "previously" delete "an".

Column 4, line 38
";portions" should be --portions--.

Column 5, line 4
Delete "co-pending".

Column 6, line 10
"3 14" should be --314--.

Column 10, line 41
"s;aid" should be --said--.

Column 10, line 53
"that" should be --than--.

Column 10, line 60
"passages" should be --passage--.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : **5,482,034**
DATED : **January 9, 1996**
INVENTOR(S) : **Lewis et al.**

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

Column 11, line 15
"dam" should be –data–.

Column 11, line 31
"passages" should be –passage–.

Abstract, line 26
"volume," should be –volume.–.

Signed and Sealed this

Seventeenth Day of September, 1996

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,482,034
DATED : January 9, 1996
INVENTOR(S) : Lewis et al.

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

Column 1, line 33
"torehead" should be –forehead–.

Column 4, line 10
After "previously" delete "an".

Column 4, line 38
";portions" should be –portions–.

Column 5, line 4
Delete "co-pending".

Column 6, line 10
"3 14" should be –314–.

Column 10, line 41
"s;aid" should be –said–.

Column 10, line 53
"that" should be –than–.

Column 10, line 60
"passages" should be –passage–.

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : **5,482,034**
DATED : **January 9, 1996**
INVENTOR(S) : **Lewis et al.**

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

Column 11, line 15
"dam" should be –data–.

Column 11, line 31
"passages" should be –passage–.

Abstract, line 26
"volume," should be –volume.–.

Signed and Sealed this

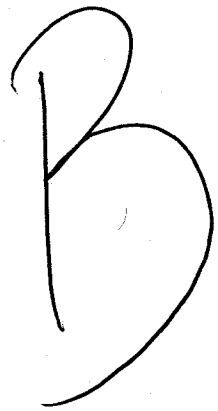
Seventeenth Day of September, 1996

Attest:

BRUCE LEHMAN

Attesting Officer

Commissioner of Patents and Trademarks



US005902235A

United States Patent [19]

Lewis et al.

[11] Patent Number: 5,902,235

[45] Date of Patent: May 11, 1999

[54] OPTICAL CEREBRAL OXIMETER

[75] Inventors: **Gary D. Lewis**, St. Clair Shores; **Wayne P. Messing**, Troy; **Melville C. Stewart, II**, Ann Arbor, all of Mich.

[73] Assignee: **Somanetics Corporation**, Troy, Mich.

[21] Appl. No.: **08/584,147**

[22] Filed: **Jan. 8, 1996**

Related U.S. Application Data

[63] Continuation of application No. 08/361,180, Dec. 21, 1994, abandoned, which is a continuation of application No. 08/161,502, Dec. 2, 1993, abandoned, which is a continuation of application No. 08/006,705, Jan. 21, 1993, abandoned, which is a continuation of application No. 07/711,147, Jun. 6, 1991, abandoned, which is a continuation-in-part of application No. 07/329,945, Mar. 29, 1989, Pat. No. 5,139,025.

[51] **Int. Cl.**[6] **A61B 5/00**

[52] **U.S. Cl.** **600/323**; 600/324; 600/473; 600/476

[58] **Field of Search** 128/633, 664–5; 356/41; 600/310–322, 320, 473–478

[56] **References Cited**

U.S. PATENT DOCUMENTS

3,638,640	2/1972	Shaw .	
4,223,680	9/1980	Jöbsis	128/633
4,281,645	8/1981	Jöbsis	128/633
4,321,930	3/1982	Jöbsis	128/633
4,380,240	4/1983	Jöbsis	128/633
4,485,820	12/1984	Flower .	
4,510,938	4/1985	Jöbsis	128/633
4,570,638	2/1986	Stoddart et al.	128/665
4,807,631	2/1989	Hersh et al.	356/41
4,901,238	2/1990	Suzuki	128/633
4,907,876	3/1990	Suzuki	128/633
4,908,762	3/1990	Suzuki	128/633
5,419,321	5/1995	Evans .	
5,524,617	6/1996	Mannheimer	600/323

FOREIGN PATENT DOCUMENTS

A30286142	10/1988	European Pat. Off. .	
0290278	11/1988	European Pat. Off.	128/633
A10290279	11/1988	European Pat. Off. .	

OTHER PUBLICATIONS

Noninvasive measurement of Regional Cerebrovascular oxygen saturation in humans using optical spectroscopy By Patrick W. McCormick, Melville Stewart, Gary Lewis.

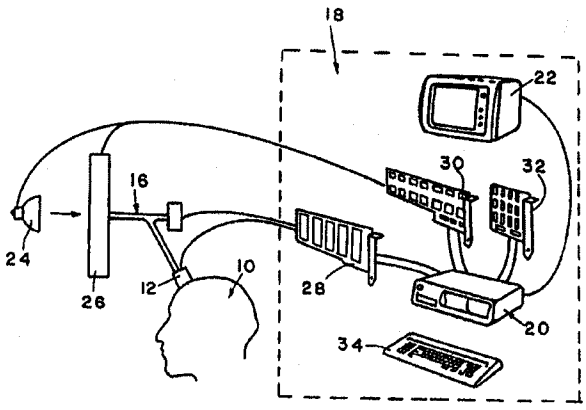
Primary Examiner—Robert L. Nasser

Attorney, Agent, or Firm—Price, Heneveld, Cooper, DeWitt & Litton

[57] **ABSTRACT**

A spectrophotometric instrument for conducting in vivo patient examinations has a sensor which is applied to the patient target area, e.g. the forehead, which includes a source for emitting electromagnetic energy e.g. selected wavelengths in the near infrared range, such that the energy passes through the underlying tissue and is emitted at other locations spaced from the point of entry. The sensor also includes detectors for receiving the resulting light energy at two or more such other locations and sending corresponding signals to a processor for analysis, by which characteristics of the tissue transmissed by the examination wavelengths may be determined. Processing of such signals includes the contrasting of detected intensity levels corresponding to a reference wavelength received at one detection location with intensity signals representative of an investigative wavelength also received at such location to determine a first resultant signal, repeating the process for the same wavelengths at another detection location, to thus determine another resultant signal, and the contrasting of such two resultant signals. In a particular application, the instrument is used to determine regional cerebral blood oxygenation by processing the detection signals to obtain a first resultant having a value proportional to the ratio of deoxygenated hemoglobin with respect to oxygenated hemoglobin and then using the value of such resultant to compute a further resultant having a value proportional to the ratio of oxygenated hemoglobin with respect to the sum of oxygenated hemoglobin and deoxygenated hemoglobin.

19 Claims, 5 Drawing Sheets



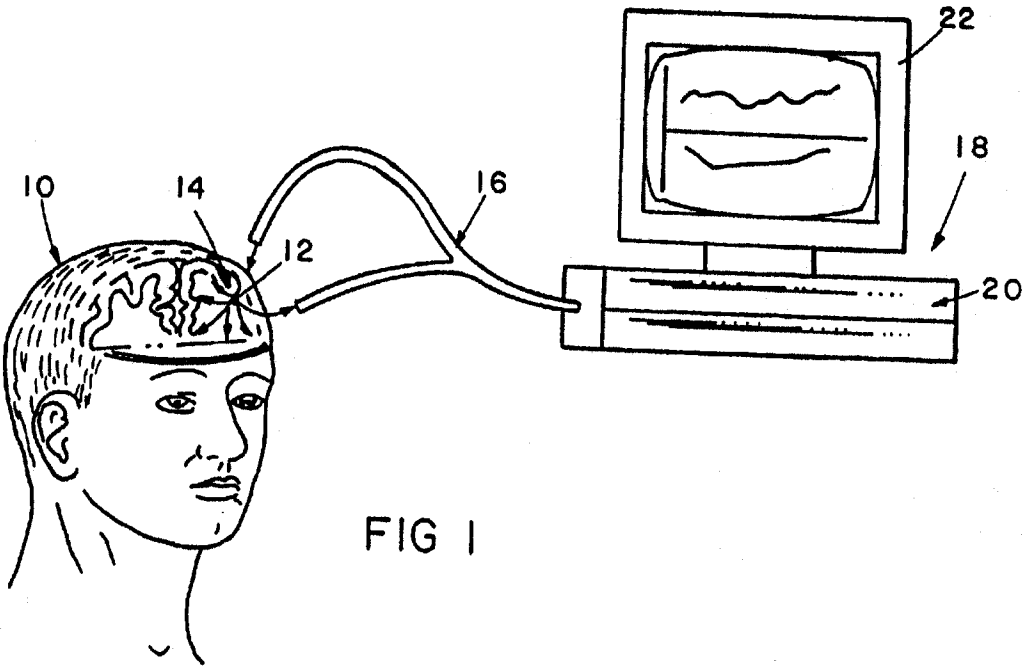


FIG 1

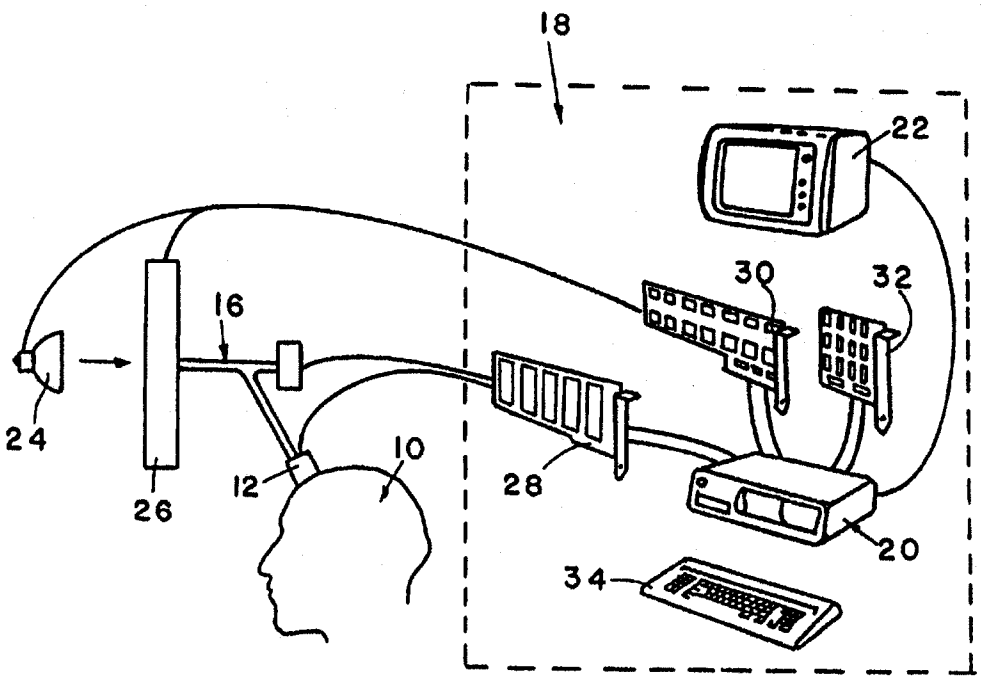


FIG 2

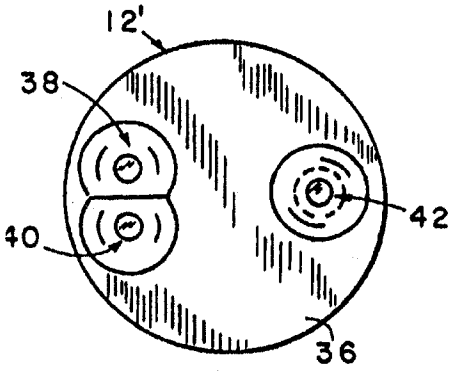


FIG 3

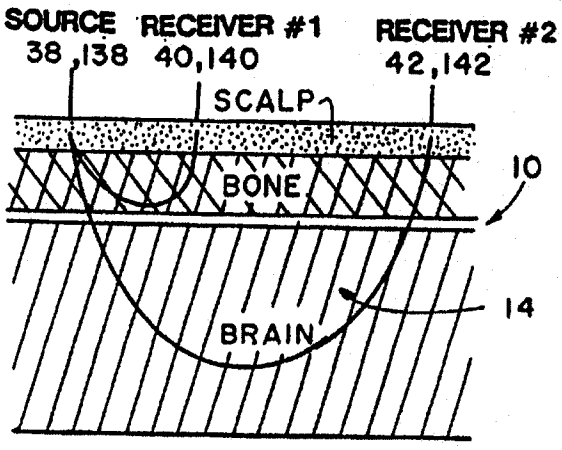


FIG 5

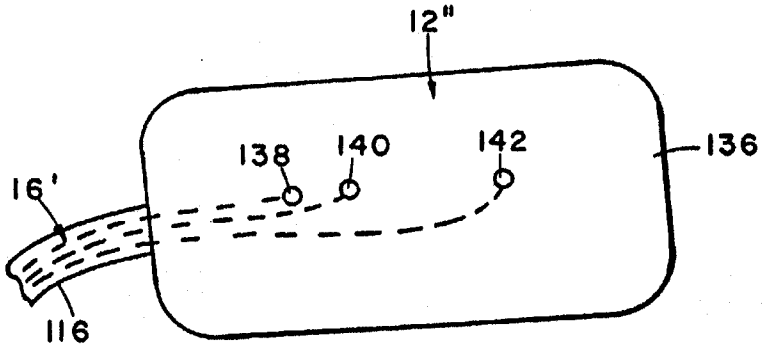


FIG 4

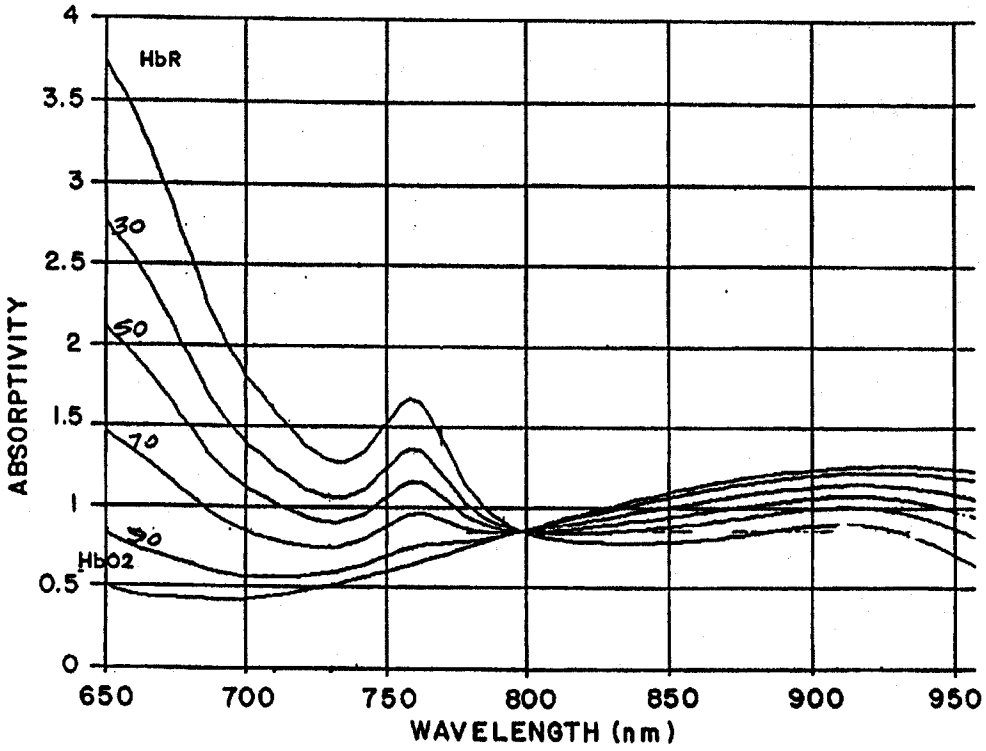

HbR
30
50
70
90
HbO2
ABSORPTIVITY
WAVELENGTH (nm)
4
3.5
3
2.5
2
1.5
1
0.5
0
650
700
750
800
850
900
950

FIG 6

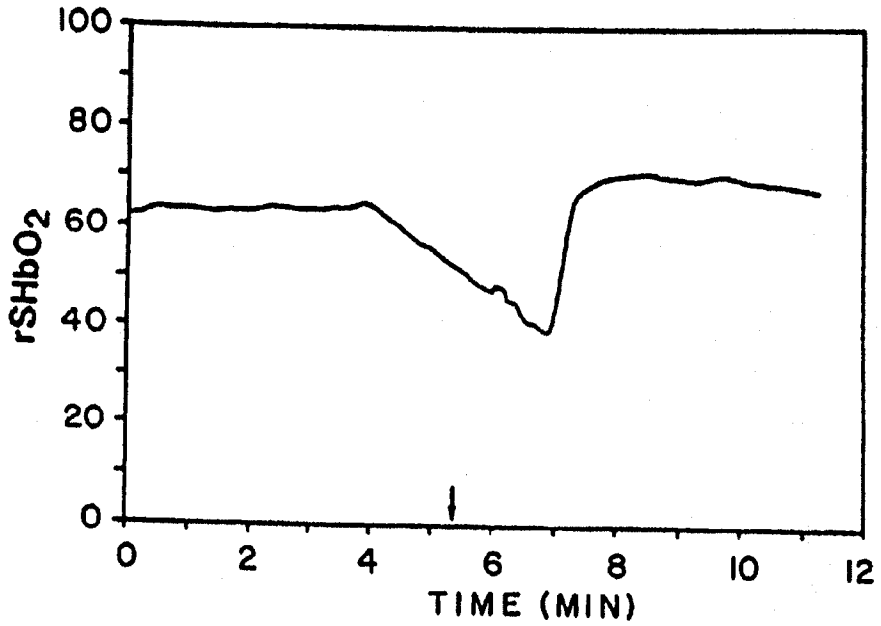

100
80
60
40
20
0
rSHbO2
0
2
4
6
8
10
12
TIME (MIN)

FIG 7

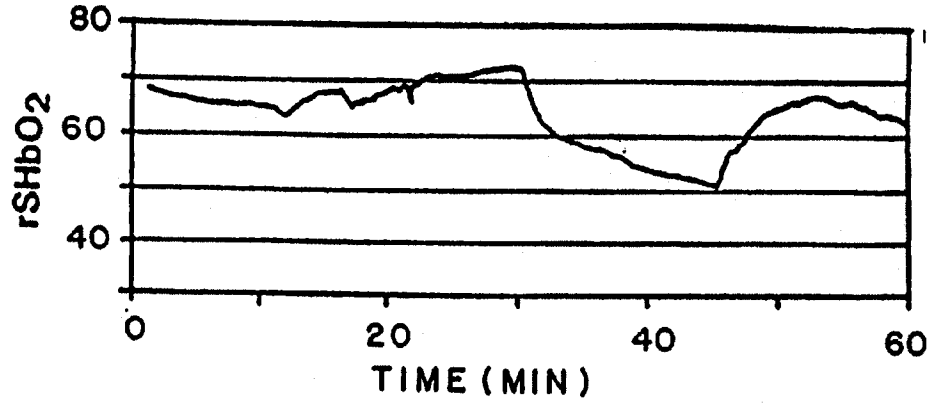

80
60
40
rSHbO2
0
20
40
60
TIME (MIN)

FIG 8

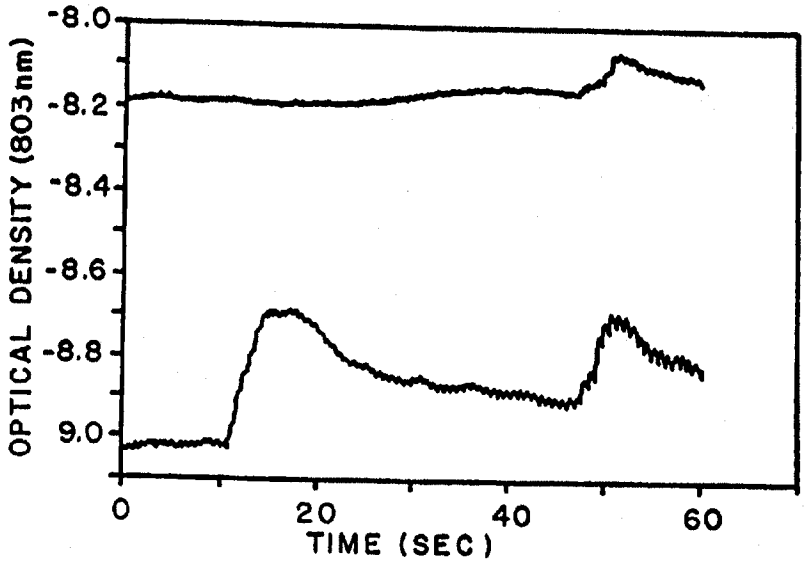

-8.0
-8.2
-8.4
-8.6
-8.8
9.0
OPTICAL DENSITY (803nm)
0
20
40
60
TIME (SEC)

FIG 9

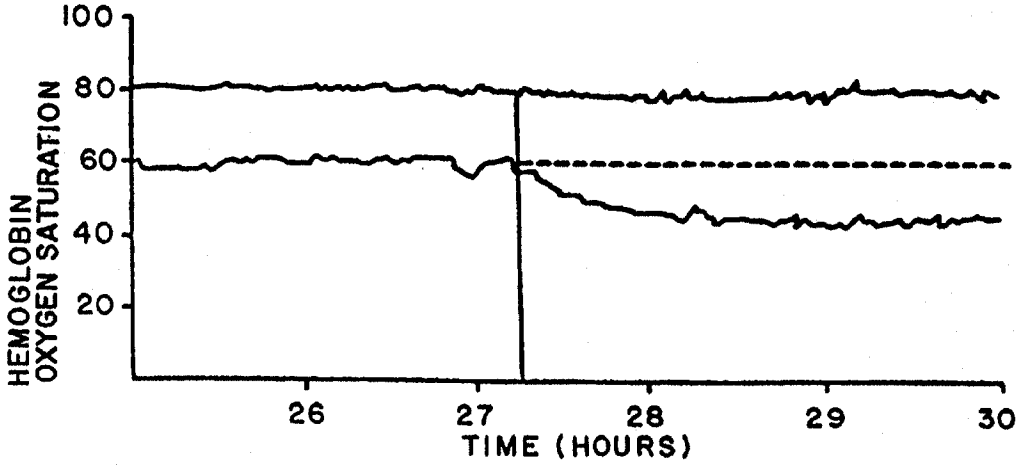

100
80
60
40
20
HEMOGLOBIN OXYGEN SATURATION
26
27
28
29
30
TIME (HOURS)

FIG 10

OPTICAL CEREBRAL OXIMETER

CONTINUING AND RELATED DATA

This application is a continuation of U.S. application Ser. No. 08/361,180, filed Dec. 21, 1994, now abandoned, which is a continuation of U.S. application Ser. No. 08/161,502, filed Dec. 2, 1993, now abandoned, which is a continuation of U.S. application Ser. No. 08/006,705, filed Jan. 21, 1993, now abandoned, which is a continuation of U.S. application Ser. No. 07/711,147, filed Jun. 6, 1991, now abandoned, which is related to and is a continuation-in-part of U.S. application Ser. No. 07/329,945, filed Mar. 29, 1989, now U.S. Pat. No. 5,139,025. This application is also related to U.S. application Ser. Nos. 07/830,567, filed Feb. 18, 1986, now U.S. Pat. No. 4,768,516, and is related to U.S. application Ser. No. 06/830,578, filed Feb. 18, 1986, now U.S. Pat. No. 4,817,623, and is related to U.S. application Ser. No. 06/827,526, filed Feb. 10, 1986, now U.S. Pat. No. 5,140,989, and is related to U.S. application Ser. No. 06/542,022, filed Oct. 14, 1993, now U.S. Pat. No. 4,570,638, the disclosures of which are each incorporated by reference herein.

TECHNICAL FIELD

This invention relates generally to in vivo spectrophotometric methods and apparatus, for examining and/or monitoring biological tissue, substances and/or conditions in living subjects, in particular humans. More particularly, the invention relates to the novel application of such in vivo methods and apparatus to provide a new form of biomedical device for non-invasively monitoring oxidative metabolism in mammalian (e.g. human) subjects on an in vivo basis, a specific and preferred embodiment of which comprises means for so-monitoring regional oxygen saturation in the brain, and for providing a quantitative readout thereof in terms familiar to medical practitioners, i.e., percent oxygen saturation.

BACKGROUND

Spectrophotometry has, of course, long been used as a valuable investigative tool in various scientific fields, particularly biological and medical research, and various applications of the underlying principles utilizing selected wavelengths of light in the near infrared range (often referred to as N.I.R. spectrophotometry) have for quite some time been utilized for certain in vivo procedures and/or investigation on human beings. For example, a frequently-encountered such device is the pulse oximeter conventionally used in hospitals and other medical facilities to provide a direct indication of arterial oxygen saturation by means of a clip or the like which fastens to an appendage such as the ear or finger of the patient. As has been noted by a small but growing field of investigators, the potentially useful applications of N.I.R. in vivo spectrophotometry are considerably broader and more diverse than this, however, due to the interesting and useful characteristic of N.I.R. wavelengths in being able to pass through ("transmiss") biological substance such as human skin, bone, and tissue for at least a length of several centimeters, and a useful brief description and commentary as to this is set forth in the above-referenced prior applications and/or patents attributable in at least part to the present inventor (see for example U.S. Pat. No. 4,570,638), as well as in the various references of record therein. In the latter regard, particular reference is made to the patents issued to Jobsis et al, e.g. U.S. Pat. Nos. 4,281,645, 4,223,680 and 4,321,930.

While previous developments in the general field of N.I.R. in vivo spectrophotometry, as noted above, have no doubt provided interesting and at least potentially useful insights and information heretofore, many important further developments and applications no doubt remain to be made, and certain of these are likely to be of considerable importance to medical practitioners. For example, accurate, meaningful, non-intrusive monitoring of brain status and viability is a most important need which prior technology has not sufficiently satisfied. As is well known and widely appreciated, the brain is a delicate and easily-damaged portion of human anatomy, while at the same time being the epicenter of neurological and physiological function. Brain damage through injury or cerebral vascular disease is responsible for numerous deaths and serious illnesses each year, involving on the order of at least 100,000 surgical procedures annually in recent years. Brain vitality is primarily a function of oxidative metabolism, and the predominant cause of neurological dysfunction and malfunction relates to the lack of sufficient brain oxidation, typically as a result of obstruction or otherwise insufficient arterial blood flow to the brain. Of course, this can occur even during surgery, and it has been estimated that at least 2,000 patients die each year in the United States alone due to anesthetic accidents, while numerous other such incidents result in brain damage of some degree; at the same time, certain major and complex surgical procedures, particularly of a neurological, cardiac or vascular nature, may require induced low blood flow or pressure conditions, which inevitably involves the potential of insufficient oxygen delivery to the brain. At the same time, the brain is the human organ which is most intolerant of oxygen deprivation, and brain cells will die within a few minutes if not sufficiently oxygenated. Moreover, such cells are not replaced, and thus involve irreversible brain damage which may potentially result in paralysis, disability, or even death.

Accordingly, the availability of immediate and accurate information concerning the state of brain oxygen saturation is of critical importance to anesthesiologists and surgeons, as well as other involved medical practitioners, particularly since the patients involved are typically in an unconscious state and thus unable to provide information by ordinary physical response. Up until the present time, however, the instrumentalities available for use, including such things as electroencephalograph ("EEG"), arterial pulse oximeter and blood pressure monitors, etc., and even invasive catheter monitoring of blood oxygen content, acidity, etc. by penetration of the jugular bulb (jugular vein) do not provide accurate, ongoing, timely (instantaneous) information as to cerebral (brain) blood oxygenation state, particularly since the brain blood supply is extensive, diffuse, pervasive, and largely venous in nature rather then arterial. Of course, it is also thus devoid of conventional pulsative characteristics essential to the operation of conventional oximeters.

Accordingly, such devices are not appropriate for cerebral usage, and of course they are typically made to be applied only to peripheral tissue or appendages in any event, i.e., a finger or an ear lobe, and are not utilized in conjunction with venous blood. Of course, jugular bulb catheters are highly invasive and relatively traumatic; at the same time, they merely provide blood samples which are removed and analyzed in another location, at a subsequent point in time, and thus only address the state of venous blood after it has left the brain.

BRIEF SUMMARY OF INVENTION

In a specific and particular sense, the present invention provides a spectrophotometric cerebral oximeter, which

non-invasively and harmlessly provides accurate and continuous real-time information as to the oxygenation state of the human brain, on an in vivo basis, without attendant patient stress or discomfort of any nature. More broadly considered, the present invention provides in vivo spectrophotometric methods and apparatus adaptable to other relatively analogous biomedical procedures and functions, for monitoring oxidative metabolism and/or other physiologic function, condition, or state.

In the particular preferred embodiment disclosed, the invention provides an in vivo, spectrophotometric cerebral oximeter which will non-invasively provide continuous monitoring of cerebral oxidation, and will do so in a form and format of a nature immediately understandable and familiar to physicians, i.e., percent oxygen saturation. Further, the cerebral oximeter so provided operates by examining (sampling) the cerebral blood supply throughout the complete vascularization (arterial, venous, and capillary systems) within the area of investigation, and the particular region investigated is or may be selectively accessed in accordance with the invention, i.e., the tissue volume examined is regional in nature and of a generally predetermined extent and location, constituting less than the entire brain or other area. Still further, the apparatus and methodology in accordance with the invention includes the provision of a convenient and readily-usable sensor which may for example be used in a number of different locations, and/or moved from one location to another, for comparative consideration of the regions selectively accessed and examined, whether cranial or otherwise.

Accordingly, the cerebral oximeter in accordance with the invention examines, and measures, blood oxygen saturation (and thus, oxidative metabolism) in the entire array of blood vessels present in the cranial region being monitored, which in the brain may generally be considered as comprising (by volume) approximately 75 percent venous, 20 percent arterial, and 5 percent capillary. Thus, the cerebral oximeter provided in accordance with the invention addresses not only oxygen delivery via hemoglobin molecules moved arterially, but in addition addresses the general, overall state of cerebral oxygen consumption, which is of course directly related to brain vitality and state, and indicative of continued viability. As already indicated, the invention provides such information on an instantaneous real-time basis, and as a result provides critical immediate information capable of clearly and quantitatively indicating the need for urgent measures to provide increased or decreased cerebral oxygen supply or consumption (metabolic activity), momentary responses to which may well prevent serious neurological or other trauma or injury.

In addition, the cerebral oximeter or other such apparatus provided in accordance with the invention is convenient to use, non-invasive and non-traumatic, produces no attendant side effects, and provides specific, quantified information of a type not previously available. At the same time, such apparatus is compact and relatively portable in nature, may provide direct visible monitoring via CRT or other visual display, and provides digitally storable data which may readily be maintained for future review or comparison or printed out in hard copy, plotted, etc., and/or periodically accessed to provide ongoing trend data, for displaying or analyzing changes which occur over selected periods of time. As such, the apparatus may be used in such diverse circumstances as emergency or trauma conditions, whether in the field (at the scene of accidents, etc. for example) or in emergency medical centers, intensive care units, surgical operating rooms, hospital trauma centers, or at bedside, etc. In particular, however, use during ongoing surgical procedures is clearly anticipated as satisfying an existing and important medical need, particularly during such procedures as brain surgery, open heart, organ or other transplant surgery, or that involving major blood vessels, for example, carotid endarterectomy; or other bypass surgery, etc., where blood flow is maintained through heart-lung machines and there is no arterial pulse present at all in the brain or body.

The foregoing major objectives, advantages and considerations of the invention, together with and including others, will become more apparent following consideration of the ensuing specification, particularly taken in conjunction with the appended drawings, briefly described hereinafter. Once again it is pointed out that the apparatus and methodology principally described hereinafter constitutes merely a preferred embodiment of the underlying invention, and does not specifically address other and further aspects thereof which will or may become further appreciated by those skilled in the art after consideration of the overall disclosure herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a pictorial schematic representation simplistically showing the basic application and utilization of apparatus in accordance with the invention;

FIG. **2** is a further pictorial schematic representation somewhat similar to FIG. **1** showing additional aspects of the subject matter disclosed;

FIG. **3** is an end view of a first optical sensor assembly for use in conjunction with the invention;

FIG. **4** is a pictorial side view representation of a different form of optical sensor, of a more preferred nature;

FIG. **5** is a schematic representation depicting the regional examination of the head and brain in accordance with the invention;

FIG. **6** is a graphical representation illustrating the spectral absorption characteristics of hemoglobin;

FIG. **7** is a graphical representation showing measured cerebral hemoglobin oxygen saturation in accordance with the invention in a first test subject;

FIG. **8** is a graphical representation showing measured cerebral hemoglobin oxygen saturation in accordance with the invention in a second test subject;

FIG. **9** is a graphical representation showing cerebral vascular oxygenation activity contrasted with extracerebral oxygenation of the scalp and skull, as measured by the near and far detectors provided in the sensor assembly utilized by the invention; and

FIG. **10** is a further graphical representation showing cerebral oximetry measurements in accordance with the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS

Oxygen is supplied to the brain by hemoglobin molecules contained in the blood supply, to which the oxygen molecules become bonded during the oxygenation process which occurs in the lungs as the blood is pumped by the heart through arteries and capillaries to the brain. As previously stated, the brain extracts oxygen from the hemoglobin by oxidative metabolism, and resulting carbon dioxide molecules are carried away through the capillaries and veins to the lungs for reoxygenation. Generally speaking, the optical spectrophotometry utilized by the invention is based upon the selective attenuation of particular light spectra in the

near infrared range which is exhibited by oxygenated hemoglobin as compared to reduced (deoxygenated) hemoglobin contained in the blood present within the cerebral region under examination. FIGS. **1** and **2** pictorially and schematically show the overall or general application of the apparatus and methodology of the invention to the human cerebrum. Thus, FIGS. **1** and **2** show a human subject **10** upon whom apparatus in accordance with the invention is being utilized, such apparatus comprising a sensor means **12** for applying and receiving selected light spectra to a particular region **14** of the brain through or via conductors **16** (which, as subsequently noted, may be electrical or optical in nature), from or in conjunction with an infrared spectrophotometry unit **18** which includes in part a small digital computer **20** having a monitor **22** on which various forms of readout information may be presented. As generally shown in a pictorial and schematic manner by FIG. **2**, the sensor assembly **12** applies selected light wavelengths which may emanate from a broadband source **24** (e.g., an incandescent lamp) and be selectively determined by narrow-bandwidth (monochromatic) filters **26**, although as subsequently noted a preferred embodiment utilizes dedicated light-emitting diodes ("L.E.D.s") which produce the selected light spectra, and the computer **20** generally includes an A/D converter section **28**, control circuitry **30** (depicted as a circuit board configured to mount in the expansion slots of computer **20**), together with requisite computer memory **32** and an operator control in the form of a keyboard **34**.

The sensor assembly **12** may as a general matter be in accordance with the above-referenced copending application Ser. No. 329,945 (the disclosure of which is incorporated herein by reference), one embodiment of which is shown for example in FIG. **3**. Since described at length in the referenced copending application, it is neither necessary nor desirable to repeat such detailed description herein; however, it may be noted that, as shown in FIG. **3**, such a sensor assembly **12'** generally comprises a housing or other support **36** which carries a light-emitting element **38**, a first light-detector or receiver **40** (i.e., the "near" receiver) and a second such detector or receiver **42** (the "far" receiver) which is disposed a predetermined and particular distance away from the source **38** and the "near" receiver **40**. In the more preferred form generally depicted in FIG. **4** (and particularly disclosed and claimed in copending application Ser. No. 07/711,452, filed Jun. 6, 1991, incorporated herein by reference), the sensor assembly **12"** is more elongated in overall shape and preferably has a somewhat flexible support **136** which carries the light source **138** and the near and far receivers **140**, **142**, respectively, all arranged in a longitudinal array, disposed along a common linear axis.

As noted, a complete and particular description of a sensor assembly corresponding to that shown at **12"** is provided in the referenced copending and incorporated application; however, it may be noted that in this preferred form the source **138** comprises a pair of separate (but commonly-mounted) light-emitted diodes which provide at least two particularly-selected wavelengths (described in more detail subsequently herein), and the receivers **140** and **142** comprise photodiodes. As a result, the entire sensor assembly **12"** is relatively small and compact, lightweight, and thin, as well as being at least modestly flexible; of course in this form the conductor array **16'** comprises electrical conductors, since the operative elements are electro-optical emitters and detectors. Of course, such components operate with very low levels of electrical excitation, and the actual conductors **16'** are each insulated from one another and carried within an insulating outer sheath **116**.

Regardless of the particular form of sensor assembly **12** which is utilized, the inclusion and relative spacing of the source **38**, **138**, near receiver **40**, **140**, and far receiver **42**, **142** are of great importance to the proper function and performance of apparatus in accordance with the invention, for the reasons set forth at length in the above-referenced and incorporated copending application Ser. No. 329,945. In general, however, the near receiver **(40, 140)** is close to but spaced a particular distance from the source **(38, 138)** so that the photons (light energy) which it detects in response to the emission of selected light spectra by the source will traverse primarily only the skin (scalp) and bone (skull) of the subject **10**, whereas the "far" receiver **(42, 142)** is disposed a particular further distance from the source whereby the light energy (photons) which it receives samples a deeper tissue volume comprising primarily brain tissue. This selected brain tissue volume which is sampled, as generally delineated by the curving line designated **114** which illustratively depicts the mean optical path of the photons received at the far receiver **42, 142**, constitutes the selected region **14** noted previously (FIG. **1**), and it will be observed that such region constitutes a particular internal volume within the overall brain content whose location is determined by the relative disposition and separation of the source **38**, **138**, near receiver **40**, **140**, and far receiver **42**, **142**, together with the relative placement and location of the sensor assembly **12** upon the head of the subject **10**.

Of course, there are practical limits to the maximum distance at which the far receiver **(40, 140)** may be disposed relative to the source **(38, 138)**, since the level of light energy used must be less than that which would be harmful, while at the same time there must be more than merely trivial amounts of light energy received at the far receiver, in order to obtain meaningful data from the spectral modulation or attenuation of the light by the substance transmissed. As presently envisioned, it is probably not effective or useful to dispose the far receiver directly opposite (across the entire skull width) from the source, by which the complete width or diameter of the brain is transmissed, and it will be noted that in the configurations discussed above and depicted in the drawings, both the near and far receivers operate more in a "reflectance" mode than a "transmission" mode as those terms are conventionally used (i.e., they are disposed along mean optical paths which are curved, and are relatively close to the source). Of course, as already indicated, this is directly consistent with monitoring regional brain function, which represents the preferred embodiment of the invention. By way of example, in a particular such preferred embodiment the distance between the source and near receiver is approximately 0.3 inches, while the distance between the source and far receiver is approximately 1.0 inches; once again, however, reference is made to copending application Ser. Nos. 329,945 and 07/711,452, which are more directly related to this subject matter and contain more detailed disclosure.

Generally speaking, some of the basic principles underlying the invention may be appreciated by reference to FIG. **6**, which shows the known absorbtivity of hemoglobin to selected N.I.R. light wavelengths. As there illustrated, the spectral absorption characteristics of oxygenated hemoglobin describe a family of curves which intersect, and reverse, at a wavelength of approximately 800 nanometers ("nm"), which constitutes the isobestic point (typically considered to be at 815 nm). As illustrated, the absorbtivity of reduced (deoxygenated) hemoglobin rises progressively at lower wavelengths as a function of the relative absence of oxygen, the highest such curve thus representing fully deoxygenated

hemoglobin and the lowermost such curve representing fully oxygen-saturated hemoglobin. As shown, these curves describe a peak in the general range of about 760 nm, as well as a valley or dip at approximately 730–740 nm. Accordingly, as is already known, by monitoring the optical response at selected wavelengths, i.e., by comparing intensity of light received at wavelengths less than the isobestic point with that received at the latter, and making appropriate computations, the oxygen content of sampled hemoglobin may be determined. In accordance with the invention, such sampling is preferably carried out at wavelengths representing points of most gradual change, rather than points representing steepest slopes; accordingly, a first sampling wavelength may be in the range of about 735 nm, and another may be at approximately 760 nm. Since the specific point at which isobestic conditions exist may vary somewhat as a result of a number of factors, the reference wavelength is preferably selected to be at approximately 805 nm.

In view of the foregoing, it will be appreciated that the primary focus of this description of preferred embodiments is based upon N.I.R. spectrophotometric procedures directed toward measurement of oxyhemoglobin and deoxyhemoglobin, in order to provide a cerebral oximeter as noted above, i.e., an apparatus for providing quantified information as to regional oxygen saturation in the composite vasculature of the brain, and the following further description sets forth mathematical descriptions and characterizations of the underlying rationale and procedure for such a device. It should be expressly noted, however, that the underlying invention is not necessarily limited to this specific application, and indeed is believed to have direct or meaningful application to other in vivo procedures which are or may be primarily attributed to or defined in meaningful part by other well-characterized chromophores, particularly (but not necessarily) in other somewhat analogous regional areas or domains, where information relative to biological processes in such a reasonably defined and distinctive area is important, and it is necessary or useful that such information be free of distortions attributable to hemoglobin or other attributes characterizing the skin, bone, and dura which is superficial to the more deeply-located region to be investigated.

With further and continuing reference to the particular preferred embodiment under discussion, it will be appreciated that the methodology of the invention utilizes diffused near-infrared spectroscopic procedures of a generally transmission-mode character for quantitative evaluation of tissue which is highly scattering and partially absorptive in nature, utilizing spatial resolution for region definition. Since wavelength-specific attenuation of light propagated through such tissue is a function of the chromophores, their extinction coefficients, their concentrations, and the distance photons travel in the tissue, the basic relationship may be analogized too, and expressed in accordance with, the Beer-Lambert relationship as set forth below, even though this is in fact deemed specifically descriptive of homogeneous non-scattering media:

$$I_{(w)}=I_{(w)0}e^{-sCa}$$

In the foregoing expression, the quantity $I_{(w)}$ represents intensity of transmitted light at wavelength w, the term $I_{(w)0}$ represents the intensity of the incident light at wavelength w, the term a represents the molar extinction coefficient of the light-absorbing molecule (chromophore), the term C represents the content of such chromophore in the tissue under examination, and the term s represents the photon pathlength in the tissue of interest. By use of this relationship, a fundamental approximation is obtained for interpreting the N.I.R. spectra utilized; since there are at least three significant chromophores present in brain tissue, each with separate extinction coefficients and concentrations, the above-noted relationship may be modified and expressed as follows;

$$\ln I_{(w)} / I_{(w)0} = \sum_{j=1}^{N} a_{(w,j)} C_{(j)} s$$

The measurements made at the selected examination wavelengths may be usefully referenced by subtracting them from reference measurements made at second selected wavelength i.e., the isobestic point of hemoglobin noted above in connection with FIG. 6. Since the above relationship refers to absorption at wavelength w, absorption at a second wavelength w' is subtracted from that at the first wavelength, w, yielding the following expression:

$$\ln I_{(w)} / I_{(w)0} + \ln I_{(w')} / I_{(w')0} = \sum_{j=1}^{N} (a_{[w,j]} - a_{[w',j]}) C_{(j)} s$$

The foregoing expression may be simplified by use of arbitrary definitions; i.e., everything directly measured may be defined by the variable M. Since the difference in extinction coefficient is also a known, it may be defined by the term d. Accordingly:

$$M_{(w)}=-\ln I_{(w)}/I_{(w)0}+\ln I_{(w')}/I_{(w')0}$$

$$d_{(w,j)}=a_{(w,j)}-a_{(w',j)}$$

Thus, the expression describing absorption at a second wavelength w' subtracted from that at a first wavelength w may be reduced to the following simpler notation:

$$M_{(w)} = \sum_{j=1}^{N} d_{(w,j)} C_{(j)} s$$

Consideration of the simplified relationship just expressed reveals that the variable of interest, chromophore concentration, may be quantified for oxyhemoglobin and deoxyhemoglobin if such expression is solved by making (N+1) measurements of M to solve for $c_{(j)}s$ (oxyhemogolbin) and $c_{(j)}s$ (deoxyhemogolbin) independently. These values are proportional to chromophore content. The value s is a constant, and by calculating the ratio of deoxy- to oxyhemoglobin, this constant cancels out of the expression. If this is assumed to be constant, the number of unknowns does not increase subsequent measurements, and this assumption appears to be well-supported. Thus:

$$C_{(j')}s/C_{(j)}s=C_{(j')}/C_{(j)}=Hr$$

In the foregoing expression, the variable Hr represents the hemoglobin ratio of deoxy- to oxyhemoglobin, which may then be used to solve for the regional saturation of hemoglobin designated $rSHgbo_2$ below:

$$1/(1+Hr)=Hbo_2/(Hgb+Hbo_2)=rSHgbo_2$$

It will therefore be seen that the term "$rSHgbo_2$", defined as "regional saturation of hemoglobin", constitutes the ratio

of oxygenated hemoglobin to total hemoglobin in the sampled field (defined region) of the brain under investigation. As previously stated, this region will contain both arterial and venous blood, as well as a small capillary content, but the venous blood will heavily outweigh the arterial blood because the great majority (on the order of 70–80 percent) of the cerebral blood is in the venous compartment.

It will be appreciated that the foregoing relationship may be usefully implemented in computer software by appropriate algorithm, particularly in view of the comments and discussion set forth previously herein in conjunction with FIGS. **1–6** inclusive. In this regard, however, it is to be emphasized once again that the invention is preferably implemented by way of the preferred embodiments noted and the accompanying commentary; in particular, the transmitted light of wavelengths w, w', etc. is preferably sequentially applied in short bursts (pulses) by use of a suitable number of repetitions which alternate application of the selected wavelengths. Detection of resulting light for each such burst thus occurs at both the near and far locations essentially simultaneously, and is preferably obtained on a time-gated basis corresponding to the occurrence of the pulsed incident light wavelengths, providing synchronous detection/demodulation techniques. Of course, the detected light burst intensities at the selected wavelengths constitute an analog quantity as detected, and these are preferably converted to digital form for subsequent processing. The computer **20** noted in connection with FIGS. **1** and **2** is preferably utilized to control all time-based functions, as well as for the processing of digitized data in accordance with the aforementioned algorithm.

It should be expressly noted that differential processing (in essence, subtraction) of the near-far detection measurements is considered to be of the essence in order to define the selected internal region which is to be examined, and in particular to exclude the effects of the sampled near field from the measurements of the desired far field, thereby eliminating not only boundary (initial impingement and peripheral penetration) effects but also those attributable to transmission through the skin, bone and dura by the selected examination spectra. This processing may be carried out incrementally, prior to each iterative spectrophotometric transmission and detection sequence, since the digitized data may readily be stored on an increment-by-increment basis and used for further processing (or storage) as desired. It is believed useful, however, to accumulate an average for each particular type of measurement over a given number of cycles (i.e., bursts of investigative light at a common wavelength, received at a particular sensor), and then subtractively process the resulting averages in the manner just noted above.

It will be appreciated from the foregoing that the end result thus obtained will provide a quantified value for regional oxygen saturation of hemoglobin in the brain on an essentially instantaneous, real-time basis, which may be presented in various forms (e.g., as a numeric display on the computer monitor, updated at selected intervals or in accordance with other such parameters), or in a variety of other forms such as graphs, charts, etc. As an example of such formats, and to further illustrate the nature and value of information obtainable in accordance with the invention, reference is made to FIGS. **7–10**, together with the following commentary pertaining thereto.

FIG. **7** presents a graphical-form chart showing measured regional cerebral hemoglobin saturation with respect to time, obtained by actual clinical measurement of a human subject undergoing progressive cerebral hypoxia. As will be readily observed, a rapid shift from baseline to abnormal values (less than 55 percent) is clearly indicated, commencing at about the four minute point, as a result of the progressive hypoxia, as is the very rapid return to baseline (and in fact slightly elevated initial level exceeding baseline) following corrective patient respiration on one-hundred percent oxygen. Particular reference should be given to the arrow indicated on the abscissa scale, which indicates the point in time at which an analog EEG, retrospectively evaluated by a clinician on a "blind" basis, first indicated abnormal theta-delta activity. As may readily be seen from this, the clear indications of serious abnormality provided in accordance with the invention occurred well over a full minute before the earliest such EEG indication, and of course this occurs through ongoing, real-time quantified measurement in terms of percent oxygenation, whereas the EEG chart is retrospectively studied.

FIG. **8** comprises a chart somewhat analogous to that presented in FIG. **7** and described above, but showing a longer-duration procedure during which the monitored patient underwent elective hypothermic cardiac standstill during surgical repair of a giant intracranial aneurysm. As will readily be noted, a clearly-perceptible decline from a baseline value in the range of 60–70 percent saturation commences at approximately 30 minutes, and extends to approximately 45 minutes, during which time the patient was completely off bypass and had no cerebral blood flow, and thus no oxygen delivery (under the aforementioned hypothermic conditions). Following reperfusion at approximately the 45 minute point, brain oxygen saturation is shown to rapidly return toward baseline, and may clearly be monitored during the highly important ensuing period.

FIG. **9** comprises a different form of chart, presenting "optical density" (i.e., attenuative effect) at the reference wavelength over a period of time, in seconds, as evidenced by the detected light intensity information received separately at the near and far detector locations following introduction of a bolus of infrared tracer material. This chart thus shows transit of the tracer through the cerebral vasculature; that is, selective introduction of the tracer in the internal carotid artery results in initial presence thereof only in the deep tissue; thus, ipsilateral spectroscopic measurements made in accordance with the invention show (bottom trace) relatively immediate detection of the tracer at the "far" receiver monitoring the deeper brain tissue, without any attendant indication at the "near" receiver (upper trace) which monitors superficial tissue, etc., until substantially later, after the tracer has recirculated through the heart and entered the external carotid system, at approximately fifty seconds after the initial introduction of the tracer. In this regard, it will be noted that the far receiver also shows recirculation of the bolus at this second point in time, as well as graphically displaying the declining persistence of the tracer within the deep tissue over this interval.

FIG. **10** constitutes a further graphical showing illustrative of the versatility, usefulness and value of information provided in accordance with the invention, by way of a pair of comparative traces showing (lower trace) continuous regional cerebral oxygen saturation (characterizing "deep", i.e., brain, tissue) as compared to that characterizing only the superficial tissue, i.e., scalp and skull (upper trace), an actual trauma patient who suffered a serious closed-head injury and was continuously monitored. As may readily be observed by noting the change occurring at the vertical line disposed at a point representing approximately 27.25 hours after the onset of monitoring, progressive cerebral desaturation com-

mences notwithstanding the fact that the superficial blood supply remains fully oxygenated. It is to be noted that the first clinical manifestation of brain desaturation in this patient occurred more than two hours later, at approximately 29.5 hours.

From the foregoing, the significance and value of information provided in accordance with the invention is believed readily apparent, corroborating expectations based upon appreciation of the fact that cerebral venous oxygen saturation should constitute an excellent indicator of the adequacy of cerebral oxygen delivery and/or cerebral oxygen extraction, and thus of brain vitality as a general matter. That is, cerebral oxygen extraction causes rapid changes in cerebral venous oxygen saturation when cerebral oxygen delivery decreases for any reason, as for example the presence of systemic hypoxia, cerebral oligemia, systemic anemia, etc., even though cerebral oxygen consumption may remain normal. In this regard, the very advantageous results obtained through the spatial resolution techniques noted, providing for specific and independent monitoring of information from deep vascular beds or tissue, provides for desirable organ-specific or area-specific determinations made well below the skin. Further, although the specific accuracy and sensitivity of oximetry measurements in accordance with the invention in heterogeneous tissue such as the scalp and adjacent or near underlying area remain to be seen, and potentially further defined, the usefulness of the resulting information is clearly demonstrated by examples such as those presented in FIGS. **9** and **10**, as discussed above.

As for specific accuracy of regional oxygen saturation determinations pursuant to the mathematical paradigm set forth above, comparative evaluation may readily be accomplished for any specific implementation, and has in fact been done by use of in vitro human blood which was suitably warmed and artificially oxygenated to various saturations, and then subjected to comparative testing with a standard lab cooximeter (using a customized cuvette with immersible light guides for access by apparatus in accordance with the invention). By utilizing linear regression analysis, highly significant correlation is shown which supports the underlying soundness of the mathematical approach discussed above. Of course, appropriate scale factors may be determined in this general manner for any desired specific application of the methodology disclosed herein, and used to calibrate or correlate the actual output of the implemented apparatus, for example by conventional computer data-processing techniques such as embodying the scale factors in appropriate look-up tables, for example. It may be noted that such procedures may also provide a desirable or useful calibration technique in any event.

It should be further pointed out that since the quantified values of regional hemoglobin oxygen saturation provided in accordance with the invention constitute field values, i.e., represent hemoglobin contained in three separate vascular compartments (arterial, venous and microcirculatory), these quantified values represent the weighted average of the three different vascular compartments. While hydraulic analysis of the cerebral vascular system, as evidenced by published information, supports a cerebral blood volume distribution that is in accordance with that set forth above, it may be noted that the specific relative size of each such blood volume compartment is in fact dynamic in a given patient depending upon the ratio of oxygen supply to and demand during conditions of physiologic stress, anatomic location, and in numerous other factors; consequently, an ideal reference methodology would simultaneously measure the actual relative blood volume of these three different compartments, preferably on a regional basis. Nonetheless, employment of assigned weighting values in the mathematical paradigm used, pursuant to the published hydraulic or other analytic information available, is quite sufficient for purposes of providing useful clinical instrumentation. Of course, the presence of extravascular cerebral blood collection, for example in the subarachnoid, subdural, or intraparenchymal tissue compartments, could or may potentially interfere with the strict accuracy of the quantifications provided, even though relative or trend data based thereon would seemingly still be of considerable importance; further, the spatial resolution capabilities of the invention may in fact provide a way to comparatively assess such anomalies, particularly if they are reasonably well defined. At the same time, the paradigms set forth above, being primarily designed to measure and account for extraparenchymal conditions, have the potential to overcome such problems.

Accordingly, it is believed that a highly useful and novel methodology is provided by the invention, particularly, but certainly not exclusively, as applied in the preferred embodiment discussed herein above, as well as in other related or analogous applications. It is to be understood that the foregoing description of a preferred embodiment of the invention is provided for purposes of description and illustration, and not as a measure of the invention, whose scope is to be defined solely by reference to the ensuing claims. Thus, while those skilled in the art may devise embodiments of the particular concepts presented in the foregoing illustrative disclosure which differ somewhat from the particular embodiment shown and described in detail herein, or may make various changes in structural details to the illustrated embodiment, all such alternative or modified embodiments which utilize the concepts of the invention and clearly incorporate the spirit thereof are to be considered as within the scope of the claims appended herebelow, unless such claims by their language specifically state otherwise.

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A spectrophotometric cerebral instrument suitable for conducting in vivo clinical examinations, comprising in combination:

means for applying selected spectra in the near infrared range to the head of a patient at a first location so that they transmiss at least selected portions of the brain after entry through the scalp and skull, said spectra including at least one reference wavelength and at least one investigative wavelength;

means for receiving light energy resulting from said applied spectra at second and third selected locations on the outside of said skull after said applied spectra have passed through said selected brain portions, said second and third locations being spaced from said first location by different distances;

means for producing corresponding and representative signals from the light energy received at said second and third locations;

and means for processing said signals by contrasting certain of said signals representative of light energy corresponding to said reference wavelength and received at said second location with signals representative of light energy corresponding to said investigative wavelength received at said second location to obtain a first resultant signal, contrasting certain of said signals representative of light energy corresponding to said reference wavelength received at said third loca-

tion with signals representative of light energy corresponding to said investigative wavelength received at said third location to obtain a second resultant signal, and then contrasting said first and second resultant signals, to produce an output which is directly indicative of a predetermined regional cerebral pathology condition in said portion of said brain.

2. A spectrophotometric instrument according to claim **1**, including means for producing a visual readout from said output which is indicative of cerebral blood oxygenation.

3. A spectrophotometric instrument according to claim **2**, wherein said readout is in terms of hemoglobin oxygen saturation.

4. A spectrophotometric instrument according to claim **2**, wherein said means for processing said signals operates to contrast certain of such signals by subtracting certain of said logarithm equivalents from one another.

5. A spectrophotometric instrument according to claim **1**, including means for processing said signals by producing logarithm equivalents of the signals received at said second and third locations prior to said contrasting of signals.

6. A spectrophotometric instrument according to claim **1**, wherein said means for applying, receiving and processing function cooperatively such that said readout characterizes the blood oxygen content of a selected region of said brain.

7. A spectrophotometric instrument according to claim **6**, wherein said output comprises a calculated composite indicator representative of the oxygen content of each of the different types of blood within said region.

8. A method of determining cerebral blood oxygenation by in vivo optical spectrophotometry comprising the steps of: applying selected light spectra in the near infrared range to the head of a patient at a first location so as to transmiss portions of the brain through the scalp and skull; receiving light energy resulting from and corresponding to said applied spectra at second and third selected locations on the outside of said skull, each spaced from one another and from said first location; producing corresponding signals representative of the light received at both said second and third locations; and processing said signals to produce therefrom a readout which is indicative of cerebral blood oxygen saturation in at least portions of said brain transmissed by said light spectra; said processing including the steps of contrasting certain of said signals representative of light energy corresponding to a selected wavelength received at said second location with signals representative of light energy corresponding to another selected wavelength received at said third location to obtain a first resultant signal having a value which is proportional to the ratio of deoxygenated hemoglobin with respect to oxygenated hemoglobin in at least said portions of said brain, and then using the value of said resultant signal to compute a further resultant signal having a value which is proportional to the ratio of oxygenated hemoglobin with respect to the sum of oxygenated hemoglobin and deoxygenated hemoglobin, said further resultant signal being indicative of cerebral blood oxygen saturation in said at least portions of said brain transmissed by said light spectra.

9. The method according to claim **8**, wherein said signal-processing step is carried out by producing logarithmic equivalents of said signals representative of light received at said second and third locations prior to performing at least some of said signal-contrasting steps, whereby said contrasting steps are carried out by using said logarithmic equivalents.

10. The method according to claim **9**, wherein at least some of said signal-contrasting steps in said signal-processing comprise subtracting certain of said logarithmic equivalents from one another.

11. The method according to claim **8**, including the steps of selecting said first location as one where the scalp and skull overlie a plurality of said differently oxygenated types of blood, applying said selected spectra to transmiss each of said blood types, and processing said signals produce a readout which characterizes a selected composite of said differently oxygenated types of blood.

12. The method according to claim **8**, including the step of processing said signals to produce a readout which characterizes a defined region of said brain.

13. The method according to claim **8**, including the step of producing said readout as a visible display.

14. The method according to claim **13**, including the step of producing said readout as a numeric display.

15. The method according to claim **13**, including the step of producing said readout as a graph-form display.

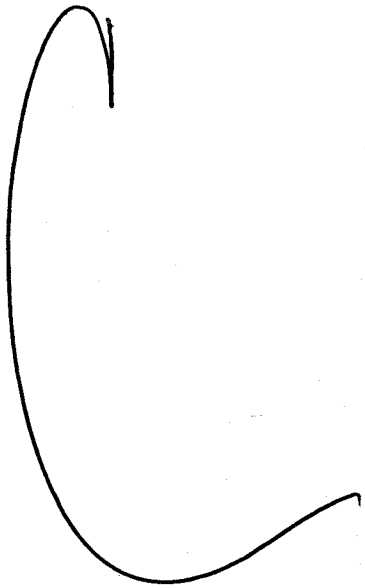
16. The method according to claim **15**, wherein one axis of said graph-form display is a time representation, whereby said display shows trend data.

17. The method accordingly to claim **8**, including the step of producing said readout in terms of cerebral blood oxygen saturation.

18. The method according to claim **17**, including the step of producing said readout in terms of percent hemoglobin oxygen saturation.

19. A method of determining cerebral blood oxygenation by in vivo optical spectrotometry comprising the steps of: applying selected light spectra in the near infrared range to the head of a patient so as to transmiss portions of the brain through the scalp and skull and to transmiss the overall vasculature present within said brain portions, including each of the various types of blood supply present within at least said brain portions, whether arterial, venous or capillary in nature; receiving light energy resulting from and corresponding to said applied spectra at selected locations on the outside of said skull, and producing corresponding and representative signals therefrom; and processing said signals in a manner to produce a readout which is indicative of the oxygen content of a composite of the total blood supply in said overall vasculature by calculating an average representative of the oxygen content present in all of said types of blood supply present within said brain portions and calculating a weighted average based upon said representative average and upon an assumed relative blood volume present for each of said different types of blood supply present within said brain portions.

* * * * *



US006615065B1

(12) **United States Patent**
Barrett et al.

(10) **Patent No.: US 6,615,065 B1**
(45) **Date of Patent: Sep. 2, 2003**

(54) **MULTI-CHANNEL NON-INVASIVE TISSUE OXIMETER**

(75) Inventors: **Bruce J. Barrett**, Birmingham, MI (US); **Oleg Gonopolsky**, West Bloomfield, MI (US); **Richard S. Scheuing**, Rochester Hills, MI (US)

(73) Assignee: **Somanetics Corporation**, Troy, MI (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/807,676**

(22) PCT Filed: **Oct. 13, 1999**

(86) PCT No.: **PCT/US99/22940**

§ 371 (c)(1),
(2), (4) Date: **Jul. 12, 2001**

(87) PCT Pub. No.: **WO00/21435**

PCT Pub. Date: **Apr. 20, 2000**

Related U.S. Application Data

(60) Provisional application No. 60/103,985, filed on Oct. 13, 1998.

(51) **Int. Cl.**[7] **A61B 5/00**
(52) **U.S. Cl.** **600/340**; 600/323
(58) **Field of Search** 600/310, 322, 600/323, 340

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,570,638	A		2/1986	Stoddart et al.
4,725,147	A		2/1988	Stoddart
4,768,516	A		9/1988	Stoddart et al.
4,817,623	A		4/1989	Stoddart et al.
4,910,404	A		3/1990	Cho et al.
5,088,493	A		2/1992	Giannini et al.
5,139,025	A		8/1992	Lewis et al.
5,140,989	A		8/1992	Lewis et al.
5,190,039	A		3/1993	Takeuchi et al.
5,465,714	A		11/1995	Scheuing
5,477,853	A		12/1995	Farkas et al.
5,482,034	A		1/1996	Lewis et al.
5,542,421	A	*	8/1996	Erdman 600/477
5,697,367	A		12/1997	Lewis et al.
5,787,887	A		8/1998	Klingenbeck-Regn
5,803,909	A		9/1998	Maki et al.
5,853,370	A		12/1998	Chance et al.
5,902,235	A		5/1999	Lewis et al.
5,974,337	A		10/1999	Kaffka et al.
5,987,351	A	*	11/1999	Chance 600/473
6,334,065	B1	*	12/2001	Al-Ali et al. 600/323

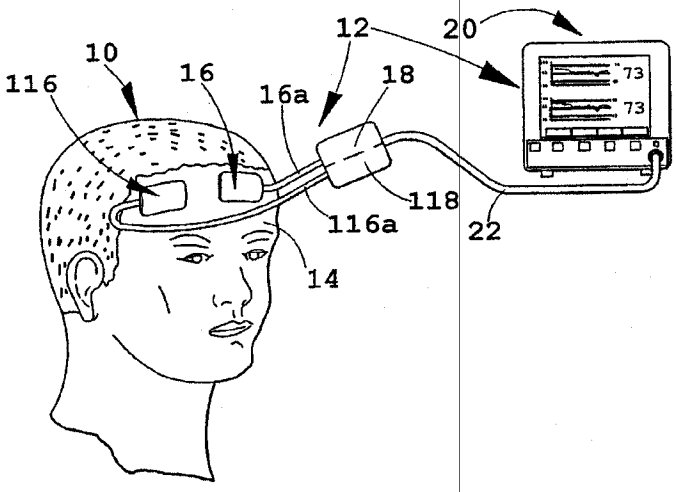
* cited by examiner

Primary Examiner—Eric F. Winakur
(74) *Attorney, Agent, or Firm*—Price Heneveld Cooper DeWitt & Litton

(57) **ABSTRACT**

A method and apparatus for spectrophotometric in vivo monitoring of blood metabolites such as hemoglobin oxygen concentration at a plurality of different areas or regions on the same organ or test site on an ongoing basis, by applying a plurality of spectrophotometric sensors to a test subject at each of a corresponding plurality of testing sites and coupling each such sensor to a control and processing station, operating each of said sensors to spectrophotometrically irradiate a particular region within the test subject; detecting and receiving the light energy resulting from said spectrophotometric irradiation for each such region and conveying corresponding signals to said control and processing station, analyzing said conveyed signals to determine preselected blood metabolite data, and visually displaying the data so determined for each of a plurality of said areas or regions in a comparative manner.

49 Claims, 5 Drawing Sheets



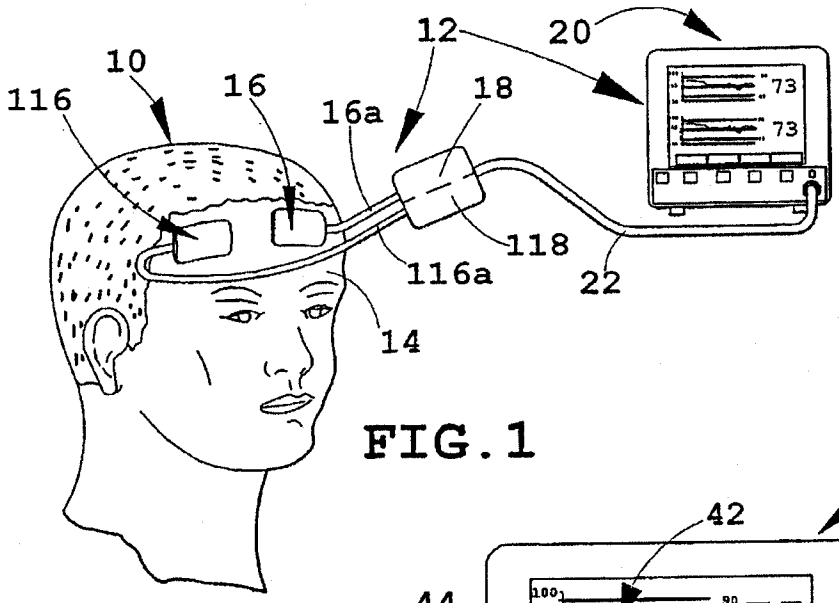


FIG. 1

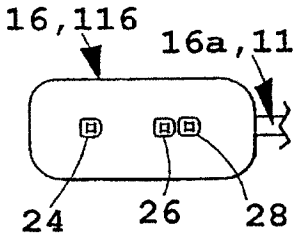


FIG. 2

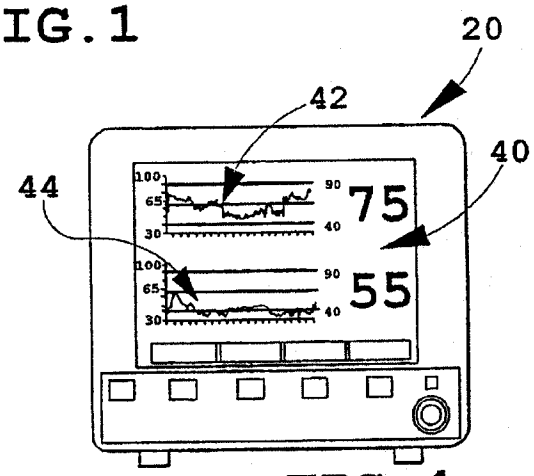


FIG. 4

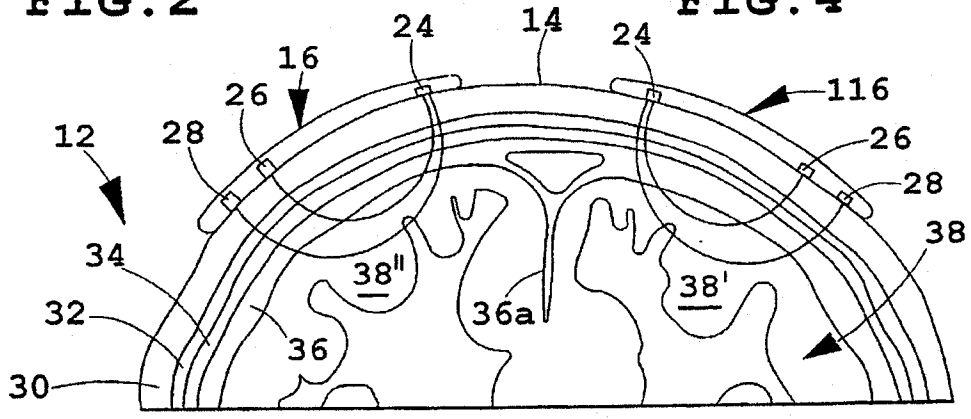


FIG. 3

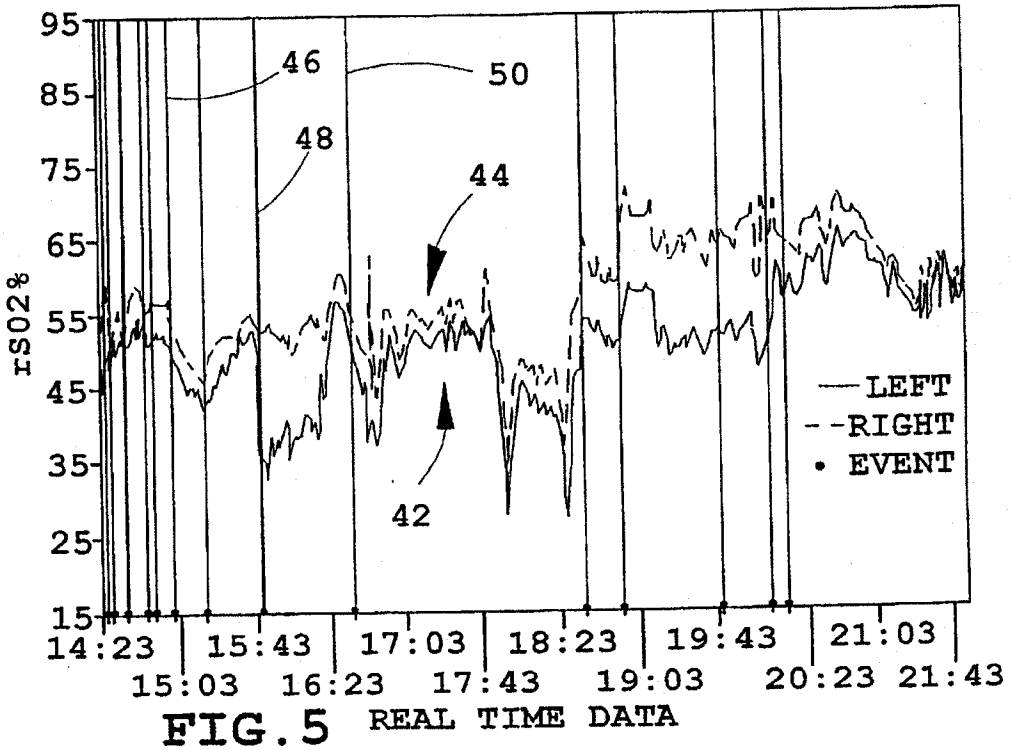

95
85
75
65
55
45
35
25
15
rSO2%
46
50
48
44
42
LEFT
RIGHT
EVENT
14:23
15:03
15:43
16:23
17:03
17:43
18:23
19:03
19:43
20:23
21:03
21:43
REAL TIME DATA

FIG. 5

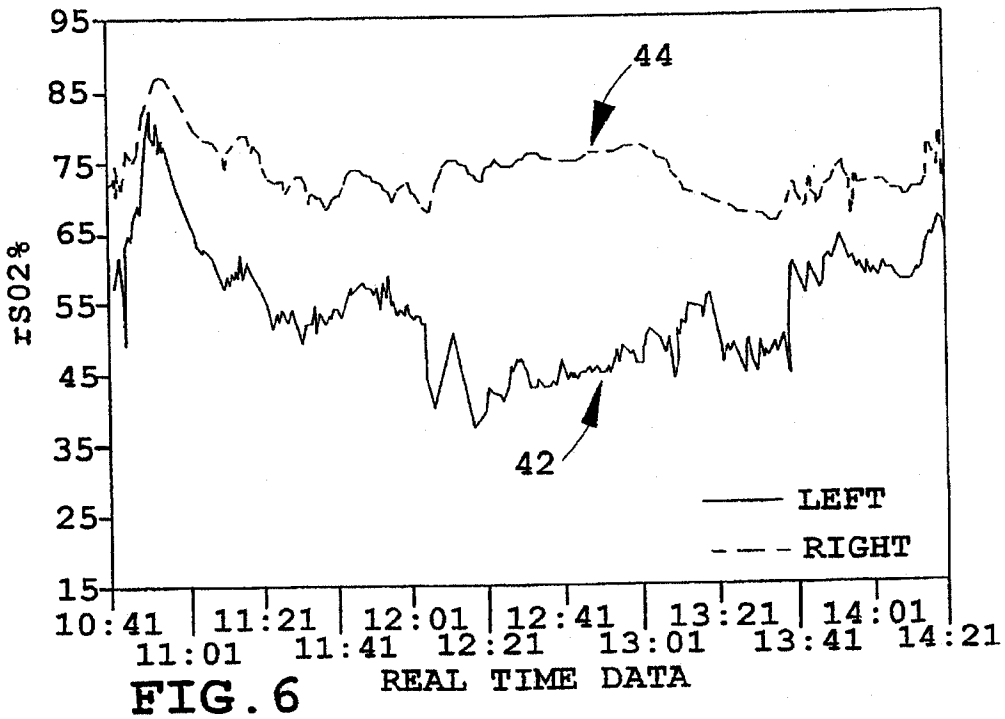

95
85
75
65
55
45
35
25
15
rSO2%
44
42
LEFT
RIGHT
10:41
11:01
11:21
11:41
12:01
12:21
12:41
13:01
13:21
13:41
14:01
14:21
REAL TIME DATA

FIG. 6

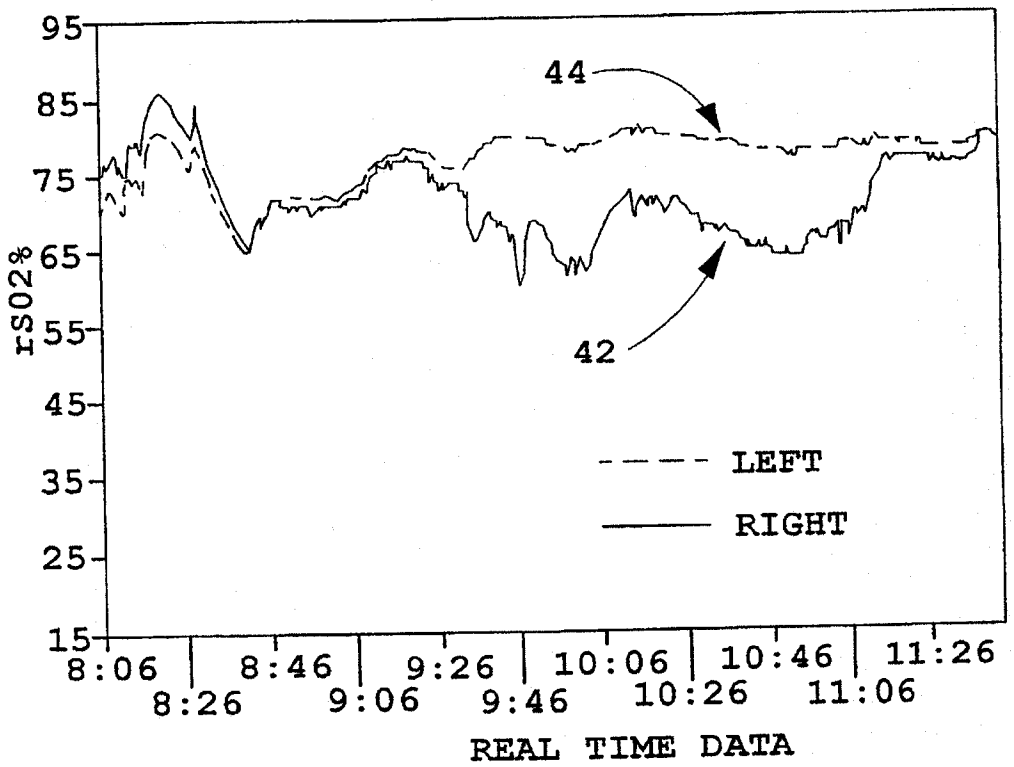

95
85
75
65
55
45
35
25
15
rSO2%
44
42
LEFT
RIGHT
8:06
8:26
8:46
9:06
9:26
9:46
10:06
10:26
10:46
11:06
11:26
REAL TIME DATA

FIG. 7

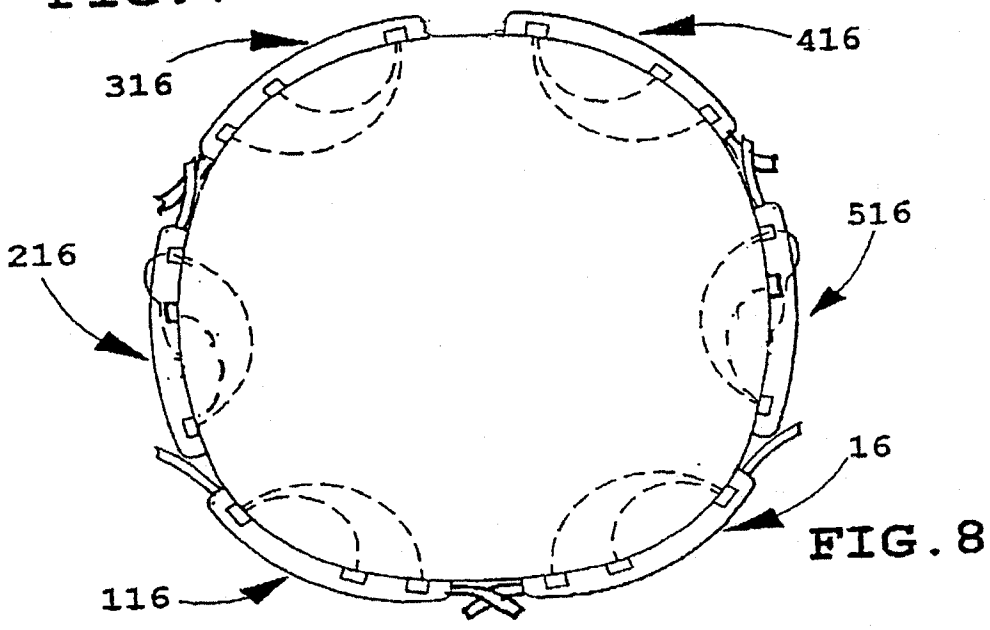

316
416
216
516
16
116

FIG. 8

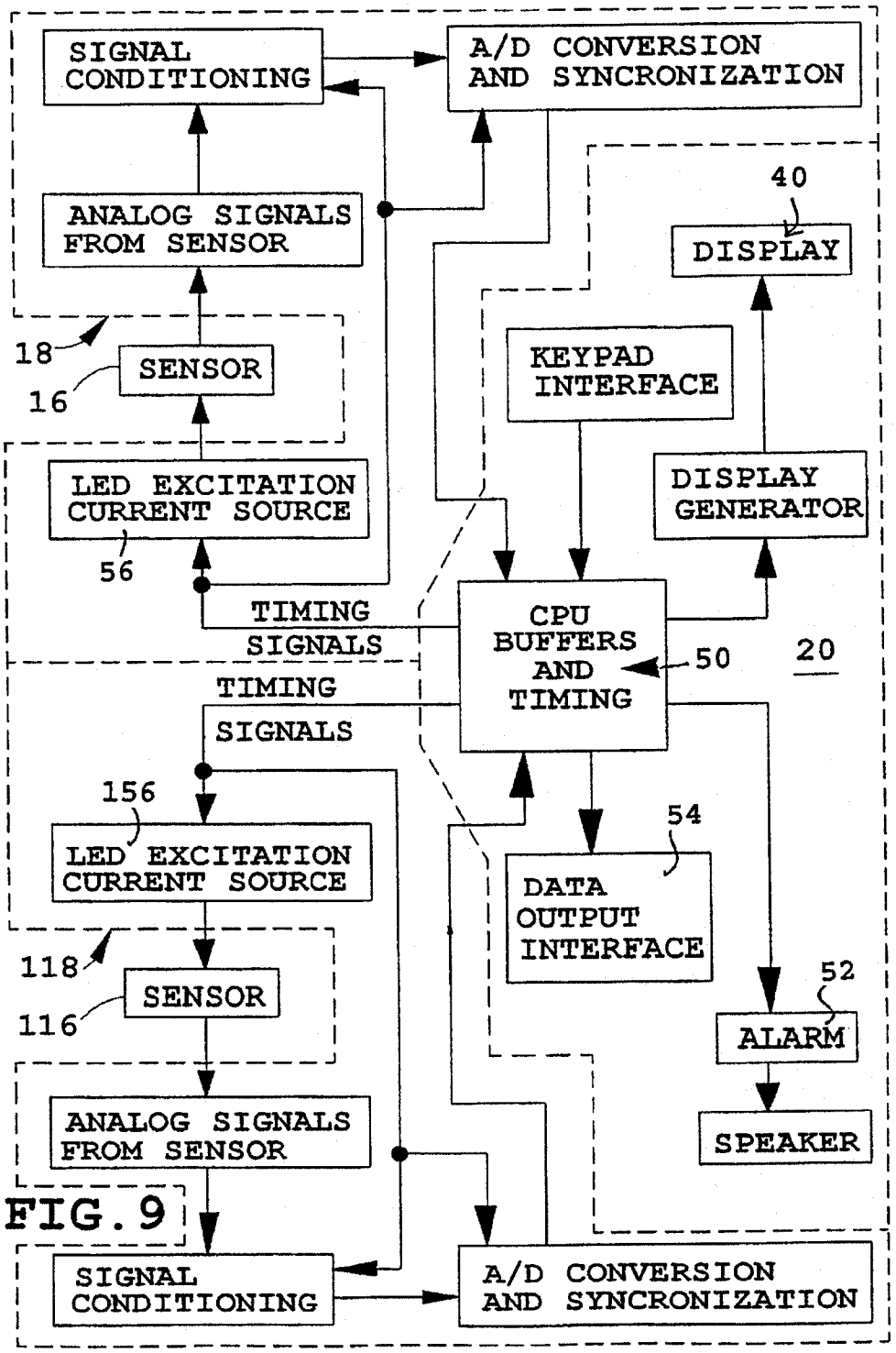

SIGNAL CONDITIONING
A/D CONVERSION AND SYNCRONIZATION
ANALOG SIGNALS FROM SENSOR
40
DISPLAY
18
SENSOR
16
KEYPAD INTERFACE
LED EXCITATION CURRENT SOURCE
56
DISPLAY GENERATOR
TIMING SIGNALS
CPU BUFFERS AND TIMING
50
20
TIMING SIGNALS
156
LED EXCITATION CURRENT SOURCE
54
DATA OUTPUT INTERFACE
118
SENSOR
116
52
ALARM
ANALOG SIGNALS FROM SENSOR
SPEAKER
SIGNAL CONDITIONING
A/D CONVERSION AND SYNCRONIZATION

FIG. 9

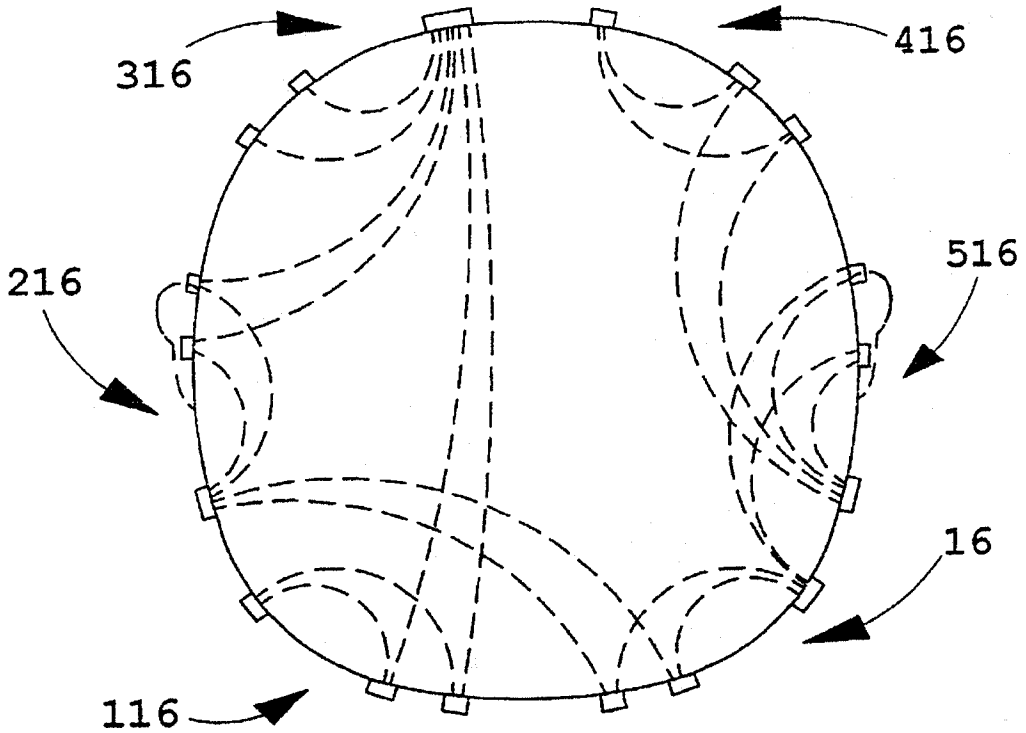


FIG. 10