### (19) World Intellectual Property Organization

International Bureau





(43) International Publication Date 5 February 2004 (05.02.2004)

**PCT** 

# (10) International Publication Number WO 2004/010844 A3

(51) International Patent Classification<sup>7</sup>:

A61B 5/00

(21) International Application Number:

PCT/US2003/022999

(22) International Filing Date: 24 July 2003 (24.07.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/398,937 26 July 2002 (26.07.2002) US 60/407,277 30 August 2002 (30.08.2002) US

- (71) Applicant: CAS MEDICAL SYSTEMS, INC. [US/US]; 44 East Industrial Road, Branford, CT 06405 (US).
- (72) Inventors: CHEN, Bo; 18 Strang Road, Derby, CT 06418 (US). BENNI, Paul, B.; Apt. N301, 1450 Washington Boulevard, Stamford, CT 06902 (US).

- (74) Agents: GETZ, Richard, D. et al.; McCormick, Paulding & Huber LLP, CityPlace II, 185 Asylum Street, Hartford, CT 06103-3402 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: METHOD FOR SPECTROPHOTOMETRIC BLOOD OXYGENATION MONITORING

Transmit Light Signal into Tissue at First Intensity (i.e., a "First Light Signal Intensity") along at least a First, a Second, and a Third Predetermined Wavelengths Using a NIRS Sensor

Sensing a First Intensity and a Second Intensity of the Light Signal After the Light Signal Travels Through the Subject at a First Predetermined Distance and a Second Predetermined Distance

Determine Attenuation of the Light Signal along the Predetermined Wavelengths Using the First and Second Light Signal Intensities

Determine the Difference in Attenuation as a function of Wavelength: i.e., between the First and the Second Predetermined Wavelengths, and between the First and the Third Predetermined Wavelengths

Empirically Determine Venous Blood Oxygen Saturation Level and Arterial Blood Oxygen Saturation Level Within the Tissue

Determine Calibration Constants  $\Psi_{\text{Hb02}}$  and  $\Psi_{\text{Hb}}$  Using the Empirically Determined Venous and Arterial Blood Oxygen Saturation Levels, Light Signal Attenuation and Statistical Analysis

Calibrate the NIRS Sensor

(57) Abstract: A method and apparatus for non-invasively determining the blood oxygen saturation level within a subject's tissue is provided that utilizes a near infrared spectrophotometric (NIBS) sensor capable of transmitting a light signal into the tissue of a subject and sensing the light signal once it has passed through the tissue via transmittance or reflectance. The method includes the steps of: (1) transmitting a light signal into the subject's tissue, wherein the transmitted light signal includes a first wavelength, a second wavelength, and a third wavelength; (2) sensing a first intensity and a second intensity of the light signal, along the first, second, and third wavelengths after the light signal travels through the subject at a first and second predetermined distance; (3) determining an attenuation of the light signal for each of the first, second, and third wavelengths using the sensed first intensity and sensed second intensity of the first, second, and third wavelengths; (4) determining a difference in attenuation of the light signal between the first wavelength and the second wavelength, and between the first wavelength and the third wavelength; and (5) determining the blood oxygen saturation level within the subject's tissue using the difference in attenuation between the first wavelength and the second wavelength, and the difference in attenuation between the first wavelength and the third wavelength.

## WO 2004/010844 A3



#### Published:

with international search report

(88) Date of publication of the international search report:  $$10\ \mathrm{June}\ 2004$ 

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/22999

		101.0000,2200	
A. CLASSIFICATION OF SUBJECT MATTER			
IPC(7) : A61B 5/00	•		
US CL : 600/331; 250/341.5		TD 0	
According to International Patent Classification (IPC) or to both na	tional classification and	IPC	
B. FIELDS SEARCHED			
Minimum documentation searched (classification system followed l	by classification symbols	s)	
U.S.: 600/331, 323, 336; 250/341.5, 330.09, 341.1; 356/41,	319		
			in the Caldernania d
Documentation searched other than minimum documentation to the	extent that such docum	ents are included	in the fields searched
Electronic data base consulted during the international search (nam	e of data base and whe	re practicable ses	arch terms used)
been one data base constitled during the mechational scarch (name	c of data base and, when	re practicable, sea	ich ternis useu)
C. DOCUMENTS CONSIDERED TO BE RELEVANT			
Category * Citation of document, with indication, where a	Citation of document, with indication, where appropriate, of the relevant passages		
A US 4,805,623 A (JOBSIS) 21 February 1989 (21.02	US 4,805,623 A (JOBSIS) 21 February 1989 (21.02.1989), see the entire document.		
A US 5,729,333 A (OSTEN et al) 17 March 1998 (17)	US 5,729,333 A (OSTEN et al) 17 March 1998 (17.03.1998), see the entire document.		
A US 6,192,260 B1 (CHANCE) 20 February 2001 (20	US 6,192,260 B1 (CHANCE) 20 February 2001 (20.02.2001), see the entire document.		
			İ
			l
			1
			**
		The state of the s	<u> </u>
Further documents are listed in the continuation of Box C.	See notent f	omilu onnov	
		amily annex.	
Special categories of cited documents:			ternational filing date or priority
'A" document defining the general state of the art which is not considered to be		eory underlying the in	ication but cited to understand the
of particular relevance	•	cory underrying the in	vention
(THE DESCRIPTION OF THE PROPERTY OF THE PROPER			e claimed invention cannot be
'E" earlier application or patent published on or after the international filing date		vel or cannot be consident ment is taken alone	lered to involve an inventive step
'L" document which may throw doubts on priority claim(s) or which is cited to	when the doct	ment is taken atone	
establish the publication date of another citation or other special reason (as	"Y" document of particular relevance; the claimed invention cannot be		
specified)			ep when the document is ch documents, such combination
'O" document referring to an oral disclosure, use, exhibition or other means		to a person skilled in	•
(D) decreased published union to the interesting of Stine day but the standard		•	
'P" document published prior to the international filing date but later than the priority date claimed	"&" document mer	nber of the same paten	t ramily
	Data of modiling of st	. i	noh noment of the
Date of the actual completion of the international search	Date of mailing of the	international sea	ach terony with
06 November 2003 (06.11.2003)	//	V	01111
Name and mailing address of the ISA/US	Authorized officer	<del></del>	$\rightarrow$ ( ) $$
Mail Stop PCT, Attn: ISA/US		die 110	ale
Commissioner for Patents	Eric F Winakur	<b>V</b> -	<del>-</del>
P.O. Box 1450	Tolomber N. Good	000 0050	
Alexandria, Virginia 22313-1450	Telephone No. 703/3	8C8U-6U	
Facsimile No. (703)305-3230			
orm PCT/ISA/210 (second sheet) (July 1998)			