

(19) World Intellectual Property Organization  
International Bureau



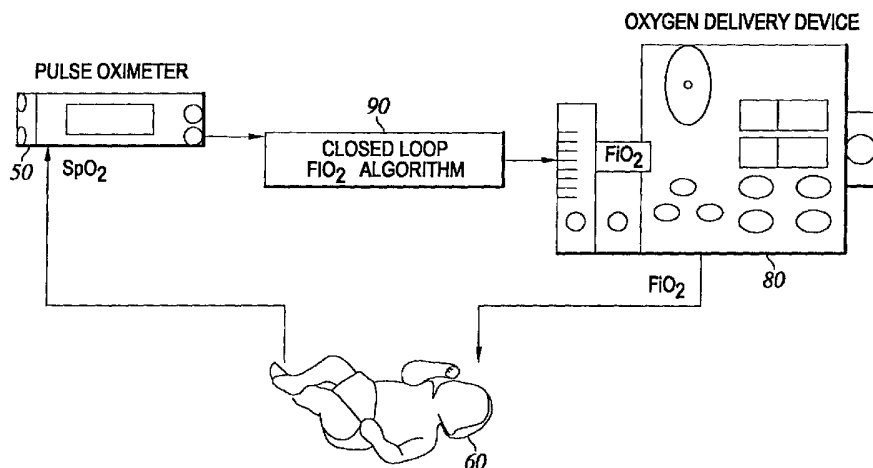
(43) International Publication Date  
20 June 2002 (20.06.2002)

PCT

(10) International Publication Number  
WO 02/047741 A3

- (51) International Patent Classification<sup>7</sup>: A61B 5/00 (74) Agent: STETINA BRUNDA GARRED & BRUCKER;  
75 Enterprise, Suite 250, Aliso Viejo, CA 92656 (US).
- (21) International Application Number: PCT/US01/45135 (81) Designated States (national): AU, CA, JP, KR.
- (22) International Filing Date: 24 October 2001 (24.10.2001) (84) Designated States (regional): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).
- (25) Filing Language: English (84) Designated States (regional): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR).
- (26) Publication Language: English
- (30) Priority Data: 09/735,319 12 December 2000 (12.12.2000) US Published: — with international search report
- (71) Applicant: UNIVERSITY OF MIAMI [US/US]; P.O. Box 016960, Miami, FL 33101 (US). (88) Date of publication of the international search report: 7 November 2002
- (72) Inventors: CLAURE, Nelson, R.; 11731 SW 122nd Avenue, Miami, FL 33186 (US). BANCALARI, Eduardo, H.; 1925 Brickell Avenue, Apt. D 808, Miami, FL 33129 (US). 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.

(54) Title: SYSTEM AND METHOD FOR CLOSED LOOP CONTROLLED INSPIRED OXYGEN CONCENTRATION



(57) Abstract: A system and method for delivering fractionally inspired oxygen (FiO<sub>2</sub>) to a patient in response to receiving an arterial hemoglobin oxygen saturation signal (SpO<sub>2</sub>) are disclosed. The SpO<sub>2</sub> is measured, for example, by using a pulse oximeter. An algorithm receives a signal indicating the SpO<sub>2</sub>. The algorithm determines whether the SpO<sub>2</sub> is in the normoxemia range, hypoxemia range or hyperoxemia range. The algorithm also determines trends by calculating a slope of second-to-second changes in the SpO<sub>2</sub>. Based on the current SpO<sub>2</sub> and the trend, the algorithm determines the appropriate FiO<sub>2</sub> for the patient and instructs a device, such as a mechanical ventilator or an air oxygen mixer as to the appropriate FiO<sub>2</sub> to be delivered to the patient. The system initializes various parameters with default values, but a user (e.g., a nurse) can also update the settings at any time. The system also provides alerts for various conditions, for example, standard pulse oximeter alarms, as well as notification when an episode of hyperoxemia or hypoxemia occurs, when it lasts for more than a specified period of time (e.g., two minutes) in spite of FiO<sub>2</sub> adjustments and when the adjustments set the FiO<sub>2</sub> at certain levels. The user is also alerted when SpO<sub>2</sub> signal is lost.



WO 02/047741 A3

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/45135

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 5/00  
US CL : 600/323

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

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/323, 322, 326, 328; 128/204.22, 204.23, 204.11

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

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

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	P.E. MOROZOFF & R.W. EVANS. "Closed-loop Control of SaO2 in the Neonate". Biomedical Instrumentation & Technology, vol. 26, pp. 113-123, Mar-Apr 1992.	1-6, 10 and 12-17 ----- 7-9, 11 and 13
X --- Y	EAST et al. "Can Pulse Oximetry be used to Reliably Predict Arterial Oxygenation". Pulmonary Division, LDS. Poster presentation for Society of Critical Care Medicine, pp. 1-23, Jan-Feb 1995.	1-6, 10 and 13-17 ----- 7-9, 11 and 12
Y	US 6,148,814 A (CLEMMER et al.) 21 November 2000 (21.11.2000), entire document.	1-17
Y	BHUTANI et al. "Adaptive Control in Inspired Oxygen Delivery to the Neonate". Pediatric Pulmonology, vol. 14, pp. 110-117, Oct. 1992.	1-17
Y	RUDOWSKI et al. "Lung Function Analysis and Optimization during Artificial Ventilation. A Personal Computer-based System". Computer Methods and Programs in Biomedicine, vol. 31, pp. 33-42, Jan. 1990.	1 and 17
Y	US 5,365,922 A (RAEMER) 22 November 1994 (22.11.1994), entire document.	1-17

Further documents are listed in the continuation of Box C.

See patent family annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"E" earlier application or patent published on or after the international filing date

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"&" document member of the same patent family

Date of the actual completion of the international search

Date of mailing of the international search report

25 June 2002 (25.06.2002)

20 AUG 2002

Name and mailing address of the ISA/US

Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703)305-3230

Authorized officer

Gregory Huson

Telephone No. (703) 308-1113

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/45135

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

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,192,260 B1 (CHANCE) 20 February 2001 (20.02.2001), entire document.	1-17

**INTERNATIONAL SEARCH REPORT**

International application No.

PCT/US01/45135

**Continuation of B. FIELDS SEARCHED Item 3:**

PLUS SEARCH, NPL, MEDLINE, EAST BRS, OCR

Key words: fractionally inspired oxygen (FiO<sub>2</sub>), SpO<sub>2</sub>, hemoglobin oxygen saturation, algorithm, automatic closed loop, hypoxemic, hyperoxemic, normoxemic, infant, mechanical ventilation.