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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
16 October 2003 (16.10.2003)

PCT

(10) International Publication Number
WO 03/084396 A1

(51) International Patent Classification[7]: A61B 5/0285

(21) International Application Number: PCT/US03/09900

(22) International Filing Date: 1 April 2003 (01.04.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/369,142 1 April 2002 (01.04.2002) US

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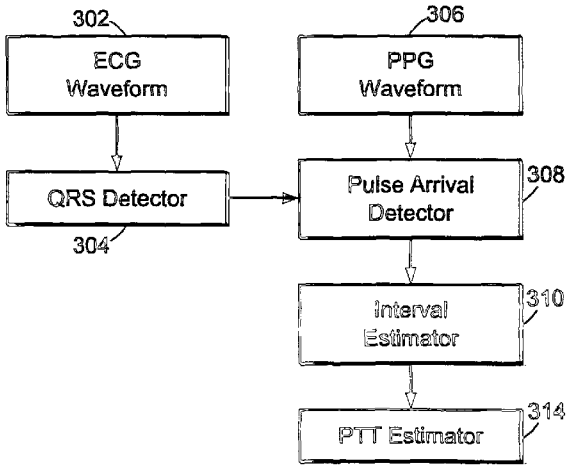
(81) Designated States *(national)*: AU, BR, CA, JP, MX.

(84) Designated States *(regional)*: 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).

Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

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 OF ASSESSMENT OF AROUSAL, PAIN AND STRESS DURING ANESTHESIA AND SEDATION



(57) Abstract: A PTT (Pulse Transit Time) monitoring system for measuring arousal and responses to stress or pain during sedation or anesthesia includes ECG electrodes and a PPG (photo plethysmography) probe connected to a computer via signal conditioning and digitizing hardware. The ECG and PPG waveforms are continuously analyzed to update and display a current estimate of the subject's PPT from heart to hand. For each cardiac cycle, fiducial points are identified to indicate the pulse onset time (via QRS detection in the ECG) and pulse arrival time (via the point of steepest ascent in the PPG). Finally, the current PTT estimate is displayed numerically and the trend of PTT is updated every second. Clinicians may interpret the instantaneous PTT value directly or in context of its recent trend. If there is a rapid decrease in PTT much less than the predetermined baseline value when the patient should be unconscious and free of stress and pain, then supplemental analgesics are administered to bring PTT greater than or equal to such baseline value.

WO 03/084396 A1

SYSTEM AND METHOD OF ASSESSMENT OF AROUSAL, PAIN AND STRESS DURING ANESTHESIA AND SEDATION

Cross Reference to Related Application

This application claims priority from United States Provisional Application Serial No. 60/369,142 filed April 1, 2002.

Field of the Invention

The present invention relates to devices for analyzing autonomic tone in a body, and, more particularly, to devices for measuring arousal, stress and pain during sedation and anesthesia.

Background of the Invention

Management of anesthesia requires titration of medications to achieve adequate states of three clinical endpoints: consciousness (i.e. hypnotic state), analgesia, and muscle relaxation. Commercial devices currently exist to directly measure consciousness (e.g., Bispectral Index, Aspect Medical Systems, MA) and muscle relaxation. To date, clinicians indirectly monitor adequacy of analgesia (i.e., the lack of excessive stress or perceived pain) in unresponsive patients by assessing the autonomic state of their patient, traditionally via heart rate, blood pressure, sweating and/or tearing. During periods of arousal, stress or pain in normal subjects, there is a significant change in the autonomic state: there is an increase in sympathetic tone and a decrease in parasympathetic tone causing an increase in heart rate and arterial constriction (tone) resulting in increased blood pressure. During periods of relaxation, the opposite response typically occurs. Consequently, clinicians typically monitor heart rate and blood pressure as standard practice and note changes in these parameters in context with changes in interventions or stimulation.

This patent describes the novel application of the use of Pulse Wave Velocity (PWV) and Pulse Transit Time (PTT) to assess the autonomic state of the patient during anesthesia or sedation.

"Pulse Wave Velocity" (PWV) is the velocity of the wave front propagating along an arterial tree generated by a bolus of blood ejected from a ventricle. The PWV is inversely proportional to the tension in the arterial wall and moves more rapidly (4-5 m/sec) than the blood flow itself (< 0.5 m/sec). "Pulse Transit Time" is the time for the wave front to travel a fixed distance ("D"), for example, from the root of the aorta to an index finger. The transit time is related to the velocity in the expected way: PTT = D/PWV.

One estimator of Pulse Transit Time is the time difference from initial ventricular contraction (as estimated by the peak of the R-wave within the electrocardiogram (ECG)) to the arrival of the resultant pulse at the periphery (as estimated by the point of steepest ascent of the photoplethysmography signal (PPG) measured at the finger (via a pulse oximetry device, for example.)) Although this estimator is biased (i.e., it is longer than necessary because it contains the period when the heart contracts prior to ejecting blood), this estimator is precise and readily calculated.

Because PTT and PWV are related to arterial tone, changes in these parameters reflect changes in the autonomic control of arterial tone. For example, during periods of increased sympathetic activity (e.g., in response to painful stimulation), arterial tone increases (i.e., arteries stiffen and compliance decreases). Consequently, PWV increases and PTT decreases. Conversely, during periods of decreased sympathetic activity or increased parasympathetic activity (e.g., as subjects fall unconscious), arterial tone decreases. Consequently, PWV decreases and PTT increases.

Because changes in PTT and PWV reflect changes in the autonomic system and in vascular stiffness (i.e., compliance), these parameters have been studied in various applications.

The principal object of the present invention is the use of the PTT to quantify the level of stress, pain and arousal of a subject.

Another object of the present invention to provide a method and device for accurately determining the PTT from the heart to the periphery.

Summary Of The Invention

A PTT monitoring system is described for measuring arousal and responses to stress or pain during sedation or anesthesia. In a preferred embodiment, the PTT monitoring system includes ECG electrodes and a PPG probe connected to a computer via signal conditioning and digitizing hardware. Lead I is typically used as the ECG lead while the PPG probe is typically placed on a finger.

The ECG and PPG waveforms are continuously analyzed to update and display a current estimate of the subject's PPT from heart to hand. For each cardiac cycle, fiducial points are identified to indicate the pulse onset time (via QRS detection in the ECG) and pulse arrival time (via the point of steepest ascent in the PPG). The onset and arrival times for each cardiac cycle are paired, and the time difference is the interval estimate for that beat. An artifact post-processor (e.g., trim-mean filtering) excludes unlikely intervals from entering the averaged, current estimate of PTT. Finally, the current PTT estimate is displayed numerically and the trend of PTT is updated every second. Clinicians may interpret the instantaneous PTT value directly or in context of its recent trend. If there is a rapid decrease in PTT much less than the predetermined baseline value when the patient should be unconscious and free of stress and pain, then supplemental analgesics are administered to bring PTT greater than or equal to such baseline value.

These and other objects and features of the present invention will be more fully understood from the following detailed description which should be read in light of the accompanying drawings in which corresponding reference numerals refer to corresponding parts throughout the several views.

Brief Description of the Drawings

Fig. 1 is an illustration of a human body indicating the preferred ECG electrode and probe placements when using the data acquisition and analysis system of the present invention;

Fig. 2 is a schematic view of the ECG and PPG data acquisition and analysis system constructed according to the present invention;

Fig. 3 is a process flow diagram of the signal analysis method according to the present invention;

Fig. 4 is a schematic view of 3 seconds of ECG and PPG waveforms indicating the fiducial point locations within same.

Fig.5 is a graph of a simultaneous trend of BIS and PPT over the course of a surgical case.

Detailed Description of the Invention

Referring to Figs. 1 and 2, the PTT monitoring device 200 includes of a computer 216 (which includes CPU 208, display 210, printer 212, and input means 214) that analyzes digitized ECG and PPG waveforms extracted from a subject 102 via ECG leads 104 and PPG probe 106. The analog ECG and PPG signals collected from the body are first conditioned by the ECG amplifier/filter 202 and PPG amplifier/filter 204, respectively, prior to sampling by the analog-to-digital converter 206 for analysis by the CPU 208.

In the preferred embodiment, ECG lead 104 is Lead I measured across the patient's chest and the PPG probe 106 is an oximetry probe (e.g., Oxy-Tip+ by Datex-Ohmeda, Finland) placed on the subject's index finger. Pulse wave signals may also be acquired through a tonometer device or an invasive arterial line. In a preferred embodiment, the ECG signal conditioning amplifier/filter 202 is a 4-pole high pass filter with 3-db breakpoint at 0.05 Hz with gain adjusted so that 10mv ECG is scaled to the full input range of the analog-to-digital converter 206. The PPG signal conditioning amplifier/filter is preferably a 4-pole high pass filter with 3-db breakpoint at 0.05 Hz and the gain is adjusted so that 100% SaO2 in the PPG waveform is scaled to the full input range of the analog-to-digital

converter 206. For example, the ECG signal can be collected from the analog output pin #18 of a Datex-Ohmeda CardioCap II system. Likewise, the PPG signal can be collected from the analog output pin #22 of a Datex-Ohmeda Capnomax Ultima sytems.

Analog-to-digital conversion can be performed with any number of commonly available analog-to-digital converter cards installed in a computer or with the A1000 EEG Monitor (Aspect Medical Systems, Inc, Newton MA). The preferred sampling rate is 128 samples per second, and should be no less because of increased jitter in estimation of fidicual point placement.

For each cardiac cycle, the ECG waveform 302 and resulting PPG waveform 306 are analyzed to identify pulse onset and arrival times. QRS detector 304 determines the pulse onset time by detecting the peak of each R-wave using a matched filter with threshold as described below. The pulse arrival detector 308 determines the pulse arrival time by detecting the peak in the first derivative of each pulse response (i.e., the point of steepest ascent in the PPG waveform) using a matched filter with threshold as described below. For each detected R-wave, the interval estimator 310 determines the time interval for a given beat by measuring the difference in the pulse onset and arrival times. If no arrival time is detected within a maximal delay (typically 500msec), then the interval is excluded from further analysis by the interval estimator 310. Finally, the PTT estimator 314 updates the current PTT estimate using the a trim-mean filter (using the central 50% of observations to exclude artifactual intervals) calculated over the preceding user-defined window (30 seconds in the preferred embodiment)

In the preferred embodiment, the peak detectors used for the QRS detector 304 and pulse arrival detector 308 employ matched filters with threshold, a common technique for peak detection. The method used in the preferred embodiment is described in: W.A.H. Engelse and C. Zeelenberg, ``A single scan algorithm for QRS detection and feature extraction", 1979 Computers in Cardiology 6:37-42 the teachings of which are incorporated herein. Software known as "sqrs.c" that implements this algorithm (for data

sampled at 125 samples per second) is available from MIT researchers at http://www.physionet.org/physiotools/wfdb/app/sqrs.c. This method processes the input data stream from the analog-to-digital converter 206 continuously.

The computer display 210 is updated each second with the current numerical value as well as an update of the time course of the PTT (i.e., the PTT trend). Computer printer 212 is available to the user to record hardcopies of the PTT trend 501 shown in Fig. 5 for documenting a particular subject case.

An example of such a system for performing PTT estimation is described in Dahan, Greenwald, Olofsen, Duma, "Pulse Transit Time (PTT) Reflects Changes in Anesthetic State During Sevoflurane/N_2O Anesthesia," Anesthesiology 2002; 96: A544. A study of 42 patients undergoing general anesthesia using sevoflurane/N2O validated the efficacy of PTT to reflect changes in arousal state and perceived surgical stimulation compared to traditional measures including heart rate (HR) and Bispectral Index (BIS) as well as Heart Rate Variability (HRV). ECG and finger SaO2 plethysmograph waveforms were continuously monitored as illustrated in Fig. 5. The method of the present invention was used to calculate the PTT. The average and standard deviation of intra-beat intervals over the preceding 30 seconds were used to estimate heart rate and Heart Rate Variability, respectively.

PTT increased during anesthetic induction (#1) and decreased during recovery (#4) as illustrated in Fig 5 which shows sample patient trends. PTT (mean (SD)) was shorter in light hypnotic levels as measured by BIS > 70 (i.e., 281 (17) msec) than deeper hypnotic levels (i.e., BIS < 70: 306 (20)msec, $p < 0.001$). Inspection of patient trends demonstrated that PTT rapidly decreased in response to painful stimulation (e.g., during intubation (# 2) and patient movement (# 3)). As shown in the Table 1 below, PTT correlated more strongly with an objective measure of consciousness (BIS) (R= -0.52) than did heart rate or heart rate variability. These results demonstrate that PTT reflects changes in arterial tone resulting from changes in consciousness level (i.e., BIS) and

inadequacy of analgesia. Rapid decreases in PTT reflect acute arterial constriction and occur during instances of perceived painful stimulation or recovery from anesthesia.

Table 1. Correlation Between Various Metrics of Consciousness

	BIS	PTT	HRV	HR
BIS	---	-0.52	0.26	0.19
PTT			n.s.	-0.42
HRV				-0.42

Clinicians may interpret the instantaneous PTT value directly or in context of its recent trend. The PTT (measured from the R-wave to the point of steepest ascent in the finger PPG waveform) in awake, normal subjects is typically 250msec. The goal of adequate analgesia is to titrate sufficient analgesics to ensure that PTT is maintained greater than 250msec. If there is a rapid decrease in PTT much less than 250msec when the patient should be unconscious and free of stress and pain, then supplemental analgesics are administered to bring PTT greater than or equal to 250msec.

The forgoing clinical algorithm may be modified to provide patient-specific titration of analgesia by replacing the population normal value of 250msec with a patient specific value calculated during awake baseline monitoring.

Since PWV is linearly related to PTT, this invention includes the monitoring of PWV as a means to quantify level of stress, pain and arousal.

While the foregoing invention has been described with reference to its preferred environments, various alterations and modifications will occur to those skilled in the art. All such alternatives and modifications are intended to fall within the scope of the appended claim.

We claim:

1. A method of noninvasively monitoring and controlling stress, pain or arousal states during sedation or anesthesia comprising the steps of:

acquiring at least one ECG signal from a subject being analyzed;

acquiring an arterial pulse waveform;

processing said at least one ECG signal to identify a pulse initiation fiducial point;

processing said arterial pulse waveform to identify a pulse arrival fidicual point;

calculating the time difference between said pulse initiation fiducial point and said resultant pulse arrival fiducial points of cardiac cycles;

estimating a current PTT from a sequence of said time differences; and

adjusting the administration of analgesia based on clinical interpretation of PTT.

2. The method of claim 1 wherein said arterial pulse waveform is acquired through use of a photoplethysmograph.

3. The method of claim 1 wherein said arterial pulse waveform is acquired through use of a tonometer device.

4. The method of claim 1 wherein said arterial pulse waveform is acquired through use of an invasive arterial line.

5. The method of claim 1 wherein said pulse initiation fiducial point is determined by use of QRS detection.

6. The method of claim 1 wherein said pulse arrival fiducial point is determined by use of Pulse detection.

7. The method of claim 1 wherein the step of calculating the time difference between said pulse initiation fiducial point and said resultant pulse arrival fiducial point of a cardiac cycle further comprises the steps of:

for a pulse initiation fiducial point, identifying a resultant pulse arrival fiducial point within the following predetermined time interval;

if a pairing is identified, calculating the time difference between said initiation fiducial point and said arrival fiducial point; and

if a pairing is not identified, excluding data related to said pulse initiation fiducial point from further processing.

8. The method of claim 1 wherein said step of estimating said current PTT from a sequence of said time differences further comprises using the most recent value.

9. The method of claim 1 wherein said step of estimating said current PTT from a sequence of said time differences further comprises using the X% trim-mean over the last Y seconds, where X is 50% or 75%, and Y is between 5 and 30 seconds.

10. The method of claim 1 wherein said step of estimating said current PTT from a sequence of said time differences further comprises using median filtering over the last Y seconds where Y is between 5 and 30 seconds.

11. The method of claim 1 wherein said step of adjusting the administration of analgesia via clinical interpretation of PTT further comprises the step of:

if PTT decreases to less than a baseline value in response to surgical or procedural stimulation, then administering sufficient analgesia to increase PTT to greater than said baseline value.

12. The method of claim 7 wherein said predetermined time interval is 500 msec.

13. A system for noninvasively monitoring stress, pain or arousal in a subject comprising:

at least one ECG lead connected to a subject for acquiring ECG signals from said subject;

probe connected to a subject for acquiring pulse waveform signal from said subject;

a processor for analyzing said ECG and PPG signals to compute an estimate of said subject's PTT from the heart of said subject to a location on the body of said subject where said PPG probe is attached and for determining whether the administration of analgesia needs to be adjusted based on said PTT.

14. The system for noninvasively monitoring stress, pain or arousal in a subject of claim 13 wherein said probe is a photoplethysmograph.

15. The system for noninvasively monitoring stress, pain or arousal in a subject of claim 13 wherein said probe is a tonometer device.

16. The system for noninvasively monitoring stress, pain or arousal in a subject of claim 13 wherein said probe is a an invasive arterial line.

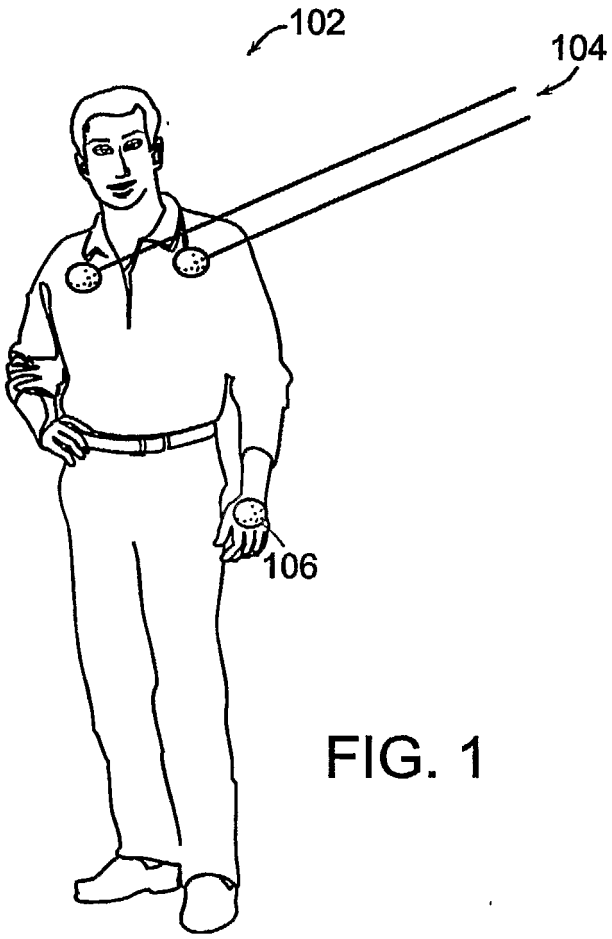

102
104
106

FIG. 1

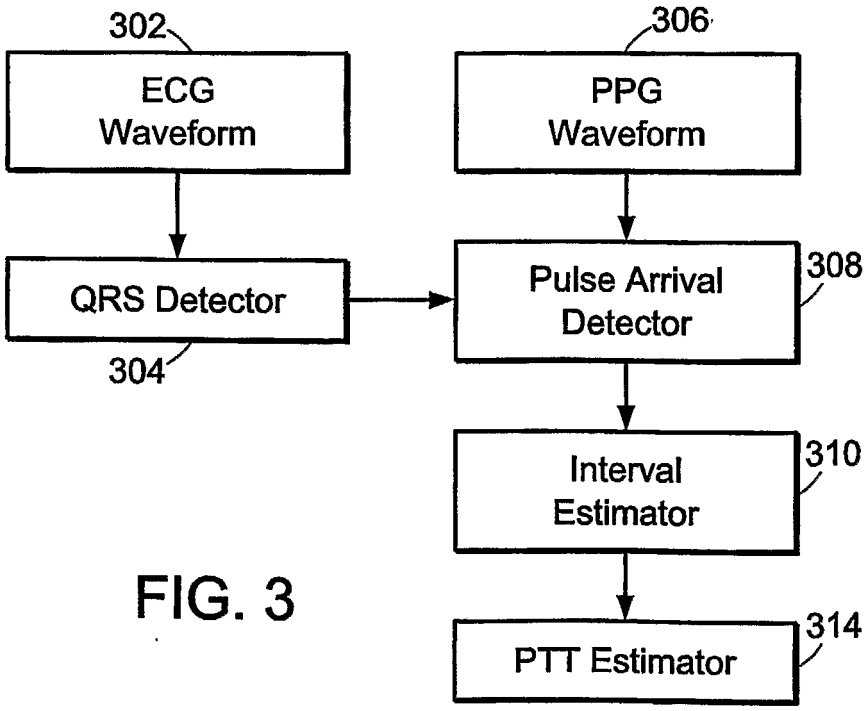

302
ECG Waveform
306
PPG Waveform
QRS Detector
304
Pulse Arrival Detector
308
Interval Estimator
310
PTT Estimator
314

FIG. 3

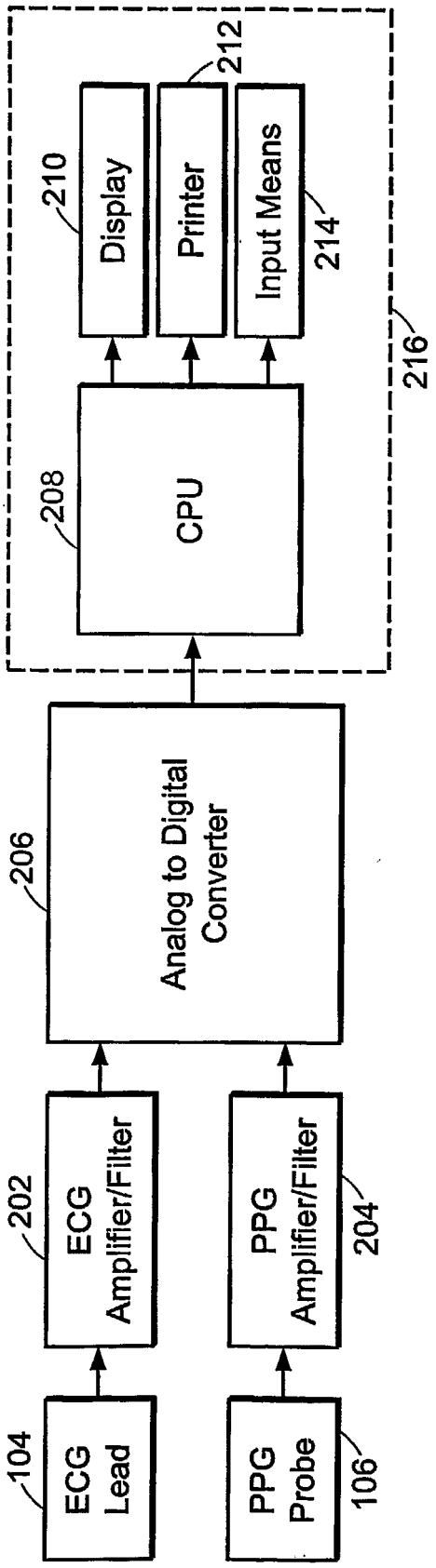

ECG Lead
104
PPG Probe
106
ECG Amplifier/Filter
202
PPG Amplifier/Filter
204
Analog to Digital Converter
206
CPU
208
Display
210
Printer
212
Input Means
214
216

FIG. 2

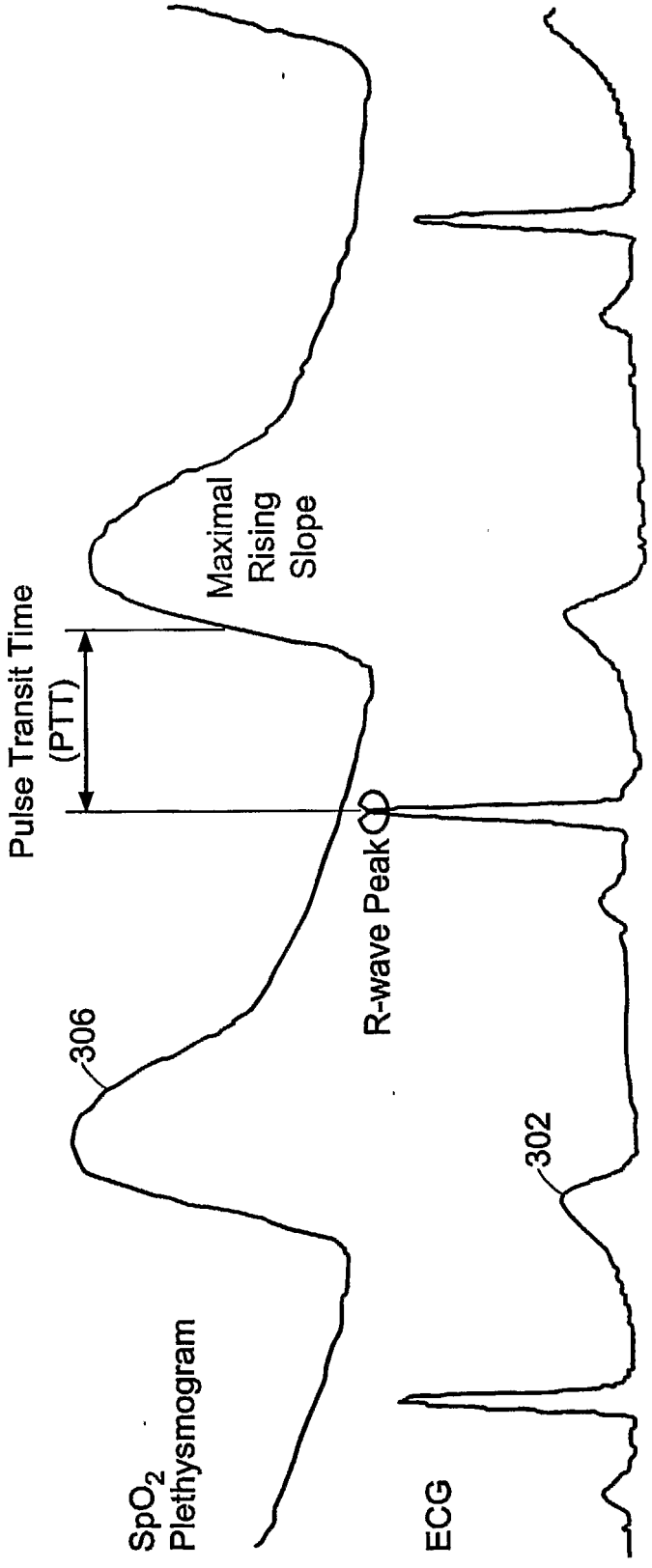

Pulse Transit Time
(PTT)
Maximal
Rising
Slope
R-wave Peak
306
302
SpO_2
Plethysmogram
ECG

FIG. 4

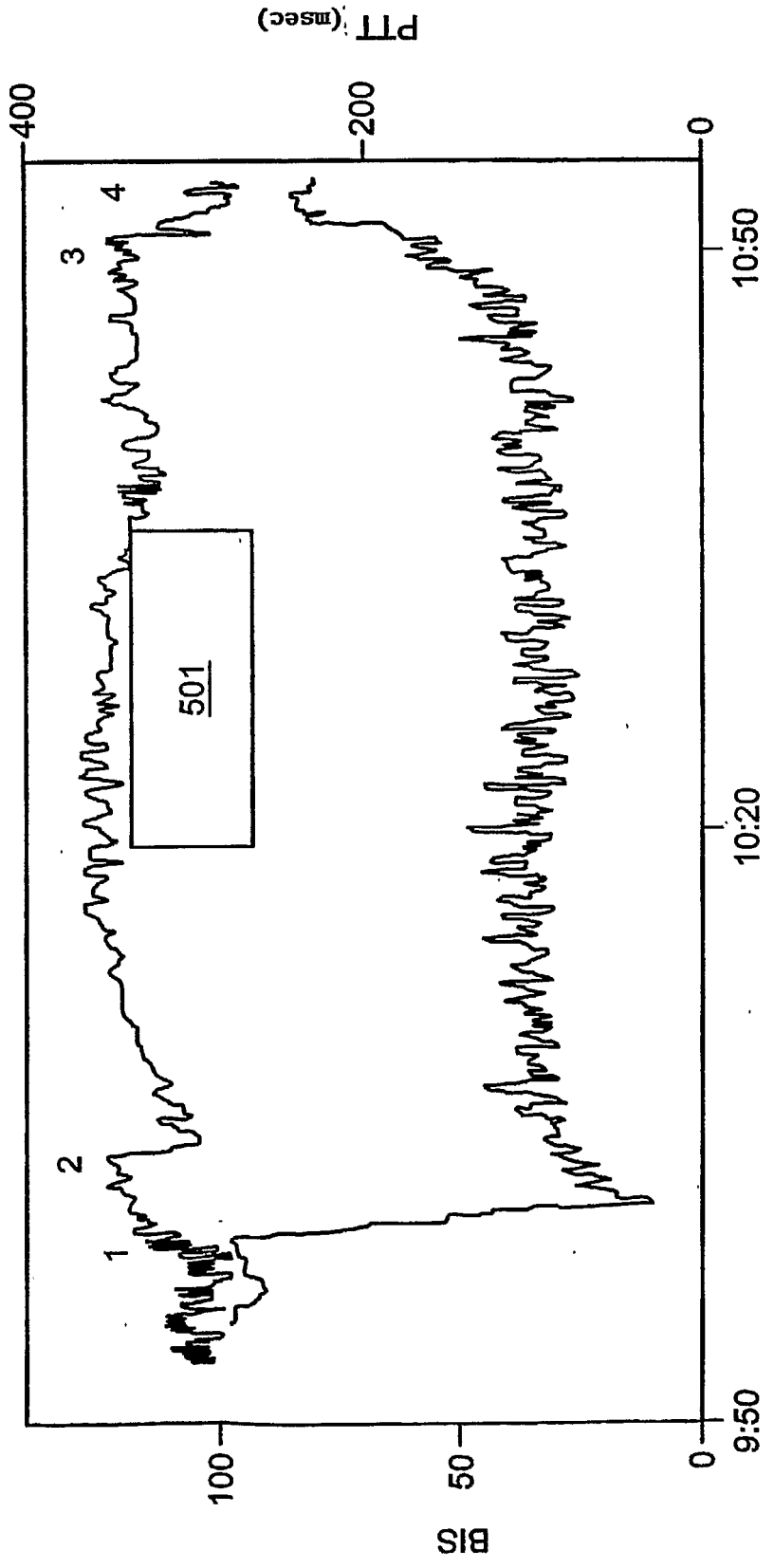


FIG. 5

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/09900

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/0285

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)
IPC 7 A61B

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 practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 02 100267 A (BURTON DAVID ;COMPUMEDICS LTD (AU); ZILBERG EUGENE (AU)) 19 December 2002 (2002-12-19) page 24, line 13 -page 25, line 3 page 42, line 14-28 figures 18,18I-18IV,33,44,48 ---	13-15
A	BUGRAM R ET AL: "EINE METHODE ZUR BESTIMMUNG DER PULSWELLENLAUFZEIT A METHOD FOR DETERMINING PULSE TRANSMISSION TIME" BIOMEDIZINISCHE TECHNIK, FACHVERLAG SCHIELE UND SCHOEN GMBH. BERLIN, DE, vol. 39, no. 3, March 1994 (1994-03), pages 51-56, XP001032163 ISSN: 0013-5585 page 52, item "3.1 Datenaufnahme"; page 54, item "4. Ergbnisse 3" figure 3 --- -/--	13-16

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

"E" earlier document but published on or after the international filing date

"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)

"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

"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

"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

"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.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 July 2003	05/08/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Dhervé, G

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/09900

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	BABCHENKO A ET AL: "INCREASE IN PULSE TRANSIT TIME TO THE FOOT AFTER EPIDURAL ANAESTHESIA TREATMENT" , MEDICAL AND BIOLOGICAL ENGINEERING AND COMPUTING, PETER PEREGRINUS LTD. STEVENAGE, GB, VOL. 38, NR. 6, PAGE(S) 674-679 XP001153411 ISSN: 0140-0118 abstract	13-16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 03/09900

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-12
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy.

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

on on patent family members

International Application No
PCT/US 03/09900

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 02100267 A	19-12-2002	WO 02100267 A1	19-12-2002

专利名称(译)	在麻醉和镇静期间评估觉醒，疼痛和压力的系统和方法		
公开(公告)号	EP1489964A1	公开(公告)日	2004-12-29
申请号	EP2003746093	申请日	2003-04-01
申请(专利权)人(译)	ASPECT医疗系统，INC.		
当前申请(专利权)人(译)	COVIDIEN LP		
[标]发明人	DAHAN ALBERT GREENWALD SCOTT D		
发明人	DAHAN, ALBERT GREENWALD, SCOTT, D.		
IPC分类号	A61B5/0285 A61B5/0402 A61B5/00 A61B5/021 A61B5/024 A61B5/0452 A61B5/0456 A61B5/0472 A61B5/11 A61B5/145 A61B5/1455 A61B5/16 A61M5/00 A61M16/01 A61M21/02		
CPC分类号	A61B5/4821 A61B5/02125 A61B5/02416 A61B5/0285 A61B5/0452 A61B5/0456 A61B5/1106		
优先权	60/369142 2002-04-01 US		
外部链接	Espacenet		

摘要(译)

PTT（脉冲传输时间）监测系统用于测量在镇静或麻醉期间唤醒和对压力或疼痛的响应，包括ECG电极和通过信号调节和数字化硬件连接到计算机的PPG（光电体积描记术）探针。持续分析ECG和PPG波形以更新并显示受试者PPT的当前估计值。对于每个心动周期，识别基准点以指示脉冲开始时间（通过ECG中的QRS检测）和脉冲到达时间（通过PPG中最陡的上升点）。最后，以数字方式显示当前的PTT估计值，并且每秒更新PTT的趋势。临床医生可以直接或在其近期趋势的背景下解释瞬时PTT值。如果当患者失去知觉并且没有压力和疼痛时，PTT的快速下降远小于预定的基线值，则施用补充镇痛药以使PTT大于或等于这样的基线值。