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(71) Applicants and

(72) Inventors: **ANGIOLI, Roberto** [IT/IT]; Via Deviti Demarco, 50, I-00191-ROMA (IT). **PORTUESI, Antonio** [IT/IT]; Viale Michelangelo, 1004, I-90145-PALERMO (IT). **PORTUESI, Tonio** [IT/IT]; Viale Michelangelo, 1004, I-90145-PALERMO (IT).

(74) Agent: **PORTUESI, Tonio**; Viale Michelangelo, 1004, I-90145-PALERMO (IT).

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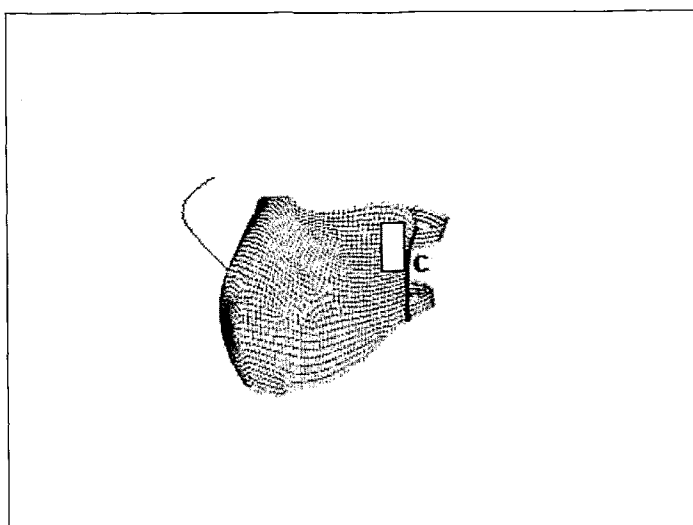
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(54) Title: INTEGRATED PREGNANCY MONITORING UNIT



(57) **Abstract:** The Integrated Pregnancy Monitoring Unit is a system able to monitor and to show, even graphically, those phenomena detectable through physical and chemical parameters (pressure, temperature, humidity, PH, electric voltages, etc.) on the surface of an elastic- plastic, living or inert, body. The system has built to give to the gynaecologist the possibility to follow the various labour steps, to determine the frequency, the intensity and the course of the contractions, and their correspondence with the parameters screening the fetus' health and the woman's weariness. This system emulates, enlarges and makes objective those perceptions which are detectable through an expert medical hand. The system monitors the perceptions in time and space, it shows them in 2D/3D and connects together the values. This instrument can be used for several applications and can assume shapes and dimensions according to the parameters and the body to monitor.

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DESCRIPTION

1 **Integrated Pregnancy Monitoring Unit**

1) TECHNICAL FIELD

The “**Integrated Pregnancy Monitoring Unit**” is a non-invasive maternal- fetal monitoring integrated system, which allows a contemporary detection of uterine contractions, fetal ECG and fetal pulsed oximetry.

This system, mainly directed to diagnostics and to monitoring of the “birth event”, can be used either in several fields of the biomedical engineering environment and for other industrial applications.

With this system, the gynaecologist and the obstetrician can follow, measure and enlarge many parameters, among which those tactile perceptions that they could directly perceive putting their hands on the pregnant abdomen, following the uterine contractions course; they can also detect the fetal hypoxia status, the fetus heart rate and the mother's one, the skin surface temperature and so on.

This is a system that improves the family of instruments used at present for the diagnosis described through images (or clinical imaging) (TAC, Magnetic Resonance, Echography, Thermography, Angiography, etc.).

This unit, with an adapted shape of the sensor/transducer and with similar softwares, is also useful to monitor the biological parameters detectable on a man's calf in a motor rehabilitation

20 2) BACKGROUND ART

Several progress in the modern diagnostic medicine were due to the possibility to examine and to monitor the tissues condition, to detect biological parameters and vital process using diagnosis through images, (or clinical imaging) that in these last decades have developed thanks to the researchers' creativity, to software development and to power of the modern calculators.

Together with this development, there are those instruments of medical diagnosis strictly connected to electronics, optoelectronics and micro and nanoelectronics, which allowed , for example, the endoscopic analysis and the Laparoscopy and Tele surgery, besides many diagnostic and monitoring instruments.

The development of these instruments has made obsolete the medical practice of putting hands on patient's body; for the doctor this practice was an important element to make

diagnosis of some diseases, or to receive relevant perceptions to make a diagnosis.

Meanwhile, from the technological point of view, the sensors of some physical and chemical parameters reached a so high level in sensitivity, thus improving the ability to imitate and to overtake, above all with the nanotechnologies, the sensory cells of the human beings.

The instruments used at present to monitor the last steps of the labour, can be retraced in: Tocographics instruments, to determine the uterine pressure and the kind of contractions: they have the limit to detect the pressure only on a little area of the abdomen and the needed of an elastic bend.

That bend loses its former position because of patient movement, producing a poor quality signal. Besides, those instruments need to be replaced if the shape and the volume of the abdomen change. They also limit the pregnant's movements, are uncomfortable in the natural labour and cannot be used in the waterbirth.

Cardiographs to determine the fetal heart rate: they are based on the use of ultrasounds, reproducing the fetal heart rate, but actually they don't reproduce the real ECG that should allow the fetal hypoxia status identification.

Transvaginal probes (some electrodes put on the fetus scalp needed): they allow the detection of fetal pulsed oximetry. These invasive methods, are really uncomfortable and they can cause internal infections.

In the scientific literature some interesting, but partial solutions, have been suggested, but these are nearly only valid for the scientific research, because they are simple ideas not really applicable in the industry today, such as "the Artificial sensibility based on the use of piezoresistive sensors" (Lund Institute of Technology, Sweden), tested to give the artificial pressure sensibility to fingertips of damaged hands; or the instrument for the labour monitoring presented as a patent proposal n. US5807271 (but this is a theoretical, encumbering, rigid and unreliable instrument that needs, among others, insufflated air in the membrane wrapping all the trunk of the woman in labour); or the patent proposal n. WO0016689, dealing with a tablet with one or more pressure sensors, that needs a second antagonist surface to work properly and that, with the varying of the sensors inside the tablet, it could be used for the monitoring of other physical and chemicals parameters of a surface.

Those solutions are not adaptable to the "birth event" because of several aspects of the sensors, including: their extreme size, their elevated rigidity, they are not ergonomic, they need an antagonist surface for the sensors, they are also not enough reliable, they

are not comfortable for the patient, etc.

3) DISCLOSURE OF INVENTION

The "**Integrated Pregnancy Monitoring Unit**" is a system that allows to perceive different parameters from the abdominal surface of a pregnant woman, to provide
70 objective and measurable parameters shown through very intelligible images, which can be recorded, analyzed and compared with reference models and with other images pre-recorded of the same patient.

Through this unit, the doctor can easily follow the stages of the labour, identifying the frequency, the intensity and the course of the contractions and their relation with the
75 parameters indicating the fetus health and the weariness of the woman in labour.

This device combines in one system the ability to detect numerous predictable parameters of the fetal wealth, it is lightweight and comfortable for the pregnant woman, it is reliable and sensitive, not-invasive, ergonomic, it can be used for the tele-monitoring and for the waterbirth, it unneed antagonist surface or insufflated air, the
80 patient is free in its movements etc.; it combines in one equipment different instruments used at present in the ambulatories, it shows, with simple images, the detected parameters and suggests sample clinical diagnosis and improve the effectiveness of those diagnosis.

This instrument is new, original and innovative. It does not present those disadvantages
85 and those limits mentioned in the previous paragraph, belonging to the systems used at present, or to those experimental instruments proposed to be patented.

The "**Integrated Pregnancy Monitoring Unit**" is primarily composed by two subsystems logically marked: [A] and [B].

1) Subsystem [A], detecting sensor, (Fig. 1) consists of an elastic membrane with a
90 continuous sensitive surface, or of a reticular elastic bend with integrated a set of independent sensor/transducers, placed according to a planned layout. It can be extended as large as the body to be examined and can assume its superficial shape.

The [A] subsystem is built with sterilizable materials which can bear-up temperatures from -10 to $+120$ °C, it is anallergic, it does not stop the perspiration, it is radio electric
95 emission compliant in the medical environment. It is an all-in-one solution that integrates several types of microsensors to detect the temperature values, deformation, pH, infrared radiation, humidity, electric voltage, pressure, fetus and mother heart rate, fetal hypoxia, skin stretching, etc. These data are transmitted through the [C] device to the [B] subsystem. In several points, mainly corresponding to the sensory cells places,

100 the membrane shows some lenticular corps, mechanically located between the sensor and the surface to monitor, that ease and give more accuracy of the measure of parameters.

One of the sensors (D device) is placed on another part of the body to detect a sync signal for a best reliability and precision in the uterine contractions measurement.

105 The [A] subsystem, also, includes a [C] device which electrically feeds the sensors/transducers, elaborats the received data and transmits the results to the [B] subsystem, through wire, or wireless transmission system.

Subsystem [B] (Fig. 2) receives data from the [A] subsystem; it process, records, presents them through images, gives a sample clinical pre-diagnosis and remotely
110 transmits some results of those processed data.

The algorithm of the software process and the analysis and data interpretation, that are embedded in the instrument, allow to represent in alphanumeric and graphic format the detected phenomena, to choose and to put in evidence from time to time one or more parameters simultaneously, to connect, according to the time and space variable, the
115 detected phenomena. It also uses "fuzzy logic" technologies, that allow an "interpretation" and a direct and an immediate representation, through a display or a print or a monitor, of the examined phenomena. The [B] subsystem uses technologies typical used on the Expert Systems and on A.I., it explains some of the detected phenomena and gives probabilistic clinical diagnosis . Some of the so obtained results
120 are encoded to be transmitted to the remote unit of tele-diagnosis. This instrument uses, as computing unit and graphic representation, a standard personal computer with standard de facto operating systems and softwares. Computing, interface data systems and transmission use common microprocessors and widely used electronic standard systems.

125 A model of the [B] subsystem also works as a "Holter" and it is able to engage or transmit "warning" signals to an operator when some parameters values exceed predefined limits, such as parts of the body temperature, of the heart rate, of the frequency and/or the intensity of the uterine contractions, of the fetal hypoxia status. Both the [A] subsystem and the [B] subsystem are radio electric emission compliant in
130 the medical environment, etc.

4) BRIEF DESCRIPTION OF DRAWINGS

Fig. 1 shows the [A] subsystem seeming a common medical elastic reticular bend, with an anatomic shape. It contains the sensory cells and the lenticular corps. Two end fasten

the bend at the back of the patient body. The [D] device is connected to another point
135 and assures a better synchronism with the contraction signals. The [C] devices includes
the power batteries and the microprocessor system that transfers to the [B] subsystem
(Fig. 2) the detected and pre-processed data of the sensory cells.

Subsystem [B] (Fig.2) consists of a unit receiving data from the [A] subsystem; they
are processed, recorded and graphically shown on a display or on a monitor, giving a
140 direction to the user's diagnosis. It transmits to a remote unit [E], or a Holter-like unit
[F] some elaborated results.

5) BEST MODE FOR CARRYING OUT THE INVENTION

The best way to reproduce this device is to use, for the [A] subsystem an anatomic
elastic membrane (Fig. 1) that reproduces, in corresponding pre-definite points, or
145 according to a geometrical matrix, some sensor/transducers (microsensors or
nanosensors) able to detect the parameters that it wants to measure and to compare
themselves. The detected data are directed through wires to an interface [C] which
transfers them, through a wireless system, to the [B] subsystem. Corresponding to the
pressure sensors there is a mechanic lenticular transducer which improves their
150 precision.

To realize the [B] subsystem it can be used a common personal computer with a suitable
processing performance with a wireless input, a graphic interface and a color monitor.
The software can be developed with advanced processing languages, both for the
processing algorithms of the data received by the [A] subsystem, and for those that
155 permit to connect time and space to the phenomena detected by the sensory cells. To a
better reliable data understanding, "fuzzy logic" technologies have to be used, because
they give a contribution to obtain an intuitive and immediate graphic and visual
representation through a display, a print or a monitor. Besides, in the [B] subsystem,
specific processing languages, belonging to special systems and to artificial intelligence
160 are implemented, to understand the phenomena and the suggestions as probabilistic
diagnosis. The obtained data can be transmitted to a tele-diagnosis remote unit, through a
common telecom wire/wireless equipment and to a registration and alert Holter-like
system.

6) INDUSTRIAL APPLICABILITY

165 This instrument has been built and can be directly applied to monitor some biological
and vital parameters of a pregnant woman, of a fetus and of many parts of the human
body. The main competitive advantage of this unit is being lightweight and handy like a

common abdominal sheath, to be an useful device for the obstetrics department to monitor, without any false alarms and untimely interventions, for various steps of the labour and its preparation. A customized version can be used for the waterbirth.

The unit can replace, in a comfortable and non-invasive way, even if with a minor precision, the use of the transvaginal uterine probe, used to evaluate the fetal distress, in order to reduce the number of positive falses on the actual cardiographic methods and techniques.

Furthermore in the bio-medical environment, the [A] subsystem can be easily reproduced by industries with a wide range of parameters to be detected, shape and features, according to the check to make (orthopedical, physiatrical, in the sportive area, etc.); For that specific applications, the [B] subsystem, above described, needs some simple corresponding tuning of the graphic models and of the processing and graphic software.

This instrument can be also used as a monitoring system among industrial sectors in which it is necessary to detect values of one or more physical and/or chemical parameters of an elastic-plastic body, showing superficial variations (temperature, pressure, humidity, electric voltage, superficial currents, superficial deformations, etc.), according to its inner phenomena.

The instrument could be also used in those industrial sectors in which, to build ergonomic items, it is necessary to detect before the different parameters, in order to analyze the reactions on the human body such as, for example, to build an arch support for a personalized shoe, using the data detected during the deambulation, for various purposes or an orthopedic aid or a seat for the optimal posture of a pilot, or to analyze and optimize the movements and the postures of athlete during training, and so on.

Due to its improved performance, compared to conventional method of clinical diagnosis, the Integrated Pregnancy Monitoring Unit could be included as a standalone medical equipment in the mother and child health-related structures.

CLAIMS:

- 1 1. A non-invasive Pregnancy Monitoring Unit that in a single apparatus integrates features associated with different types of diagnostic systems that allows the detection and the showing of the uterine contraction and/or of the fetal ECG and/or of the fetal pulsed oximetry; that unit comprises:
- 5 a). an elastic (sensitive) membrane, or a reticular elastic bend (Fig.1), that fits and covers pregnant woman's abdomen, using sensors and analog and digital transducers;
- b). a trasmission device (Fig. 1-C) connecting the elastic sensitive membrane with a computer system (Subsystem B of the description);
- 10 c). a computer system that elaborates data and electrical signals coming from the membrane transducers (Fig.1-C) and provides, through a monitor, or display or printer, diagnostic images and other data in intuitive, immediate, and user-friendly way for easy understanding.
2. An elastic membrane, or a reticular elastic bend, according to Unit described in claim 1-a), that includes and has integrated a set of sensors/transducers able to sense and
- 15 acquire physical and chemical parameters having absolute or differential measurement;
3. An elastic membrane, or a reticular elastic bend, according to Unit above described in claim 1-a) and in claim 2, wherein the transducers/sensors are integrated, providing electrical analog or digital signals according to sensed physical or chemical parameters including: heartbeats, pH, temperature and temperature flow, pressure and pressure
- 20 flow, humidity, radiant energy and radiant energy flow, blood oxymetry, weight, gauge, stress, and so on, able to sense and acquire physical and chemical parameters having absolute or differential measurements;
4. An elastic membrane, or a reticular elastic bend, according to Unit above described in claim 1 and to any one of the preceding claims, wherein some lenticular bubbles,
- 25 mechanically located between sensors and the surface to be monitored, are used and placed in several places, mainly corresponding to the sensory cells of the membrane, that ease and give more accuracy to the parameters measurement.
5. An elastic membrane, or a reticular elastic bend, according to Unit above described in claim 1 and to any one of the preceding claims, wherein one of the sensors/transducers
- 30 (Fig.1 - D device) is placed on another body part to detect a sync signal for best reliability and precision in the contractions measurement.

6. An elastic membrane, or a reticular elastic bend, according to any one of the preceding claims, that can be enveloped in a sealed bag for substantially covering the pregnant abdomen, or a generic body to be monitored, without losing the ability to
35 acquire near all the data and physical parameters either from the abdomen or other object under monitoring.
7. An elastic membrane, or a reticular elastic bend, according to any one of the preceding claims, wherein two ends for releasable fastening at the back are enough to hold up itself to patient abdomen;
- 40 8. A transmission device (Fig. 1-C) connected to, or integrated in, the elastic sensitive membrane, or in the reticular elastic bend, according to Unit of above claim 1 and any one of the preceding claims, which electrically feeds the sensors/transducers, encodes electrical signal coming from transducers, makes first data processing and transmits outputs to a computer/diagnostic system for data processing (Subsystem [B] - Fig. 2) by
45 wire or wireless transmission system, setting the patient completely free in its movement and in the waterbirth too.
9. A computer/diagnostic system, according to Unit of above claim 1 and to any one of the preceding claims, which elaborates data and electrical signals coming from the membrane transducers devices (Fig.1-C) and provides, through a monitor, or display or
50 printer, diagnostic images (Fig.2) and other data in intuitive, immediate, and user-friendly way for easy understanding.
10. A computer/diagnostic system, according to Unit of above claim 1 and to any one of the preceding claims, wherein several algorithms softwares, a fuzzy logic system and some applications using Expert System and Artificial Intelligence technologies, is able
55 to show images and data through a display/monitor (Fig.2), or a printer, in a very user friendly modemaking the monitored phenomena very understandable, and gives a first sample clinical diagnosis suggestion.

AMENDED CLAIMS

[received by the International Bureau on 5th February 2007 (05.02.07)]

- 1 1. A non-invasive Pregnancy Monitoring Unit that in a single apparatus integrates several features currently associated with different types of diagnostic systems, that allows the detection, in each point of an abdominal surface of: temperature, pressure and pressure surface flow, skin stretching, electrical voltage, pH, etc. and the display of
5 those parameters value and graphic associated with: the waveform of uterine contraction, the fetal ECG and the fetal pulsed oximetry. That unit comprises:
- a). an elasto-plastic membrane (schematized in a reticular discrete array in Fig.1) characterized to be: sensitive in each its point, as light as a cotton elastic cloth, very comfortable for the patient and very handy for medical personnel,
10 manufactured in only one thin layer, transpiring; this membrane needn't to be pressed tightly against the skin of the patient and a second antagonist surface to work properly and can fit and cover pregnant woman's abdomen giving a comfortable sensation of lightly clad;
 - b). a transmission device (Fig. 1-C), that is able to transform and transmit electrical
15 analog and digital signals of parameters detected by sensitive elasto-plastic membrane, connecting this membrane with a computer system (Subsystem B of the description);
 - c). a computer system running custom software application that elaborates data and electrical signals coming from the sensitive membrane (Fig.1-C) and provides,
20 through a colour LCD or CRT monitor, or display or printer, diagnostic images and other relevant clinical data about the phenomenon in an intuitive, immediate, and user-friendly way for easy understanding by clinical personnel; the images, on the LCD or CRT monitor, portray the woman's surface abdomen in which the colours indicate graphically the values of parameters (fig. 2).
- 25 2. An elasto-plastic membrane, as claimed in claim 1a, where the membrane, having a structure continue (or reticular like, as showed in Fig.1), is able to sense by each its point, in continuous mode (point by contiguous point and in a way similar to the 'CCD full frame array sensor').
- 30 3. An elasto-plastic membrane, as claimed in claim 1a and claim 2, wherein the single point provide, as a microsensors/transducer electrical signals according to sensed physical and chemical parameters including: heartbeats, pH, temperature and

temperature flow, pressure and pressure flow, humidity, radiant energy and radiant energy flow, blood oxymetry, weight and skin stretching.

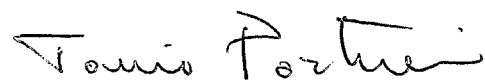
- 35 4. An elasto-plastic sensitive membrane, according to claim 2, wherein some microlenticular idrogel (or rubber, or polymeric) bubbles, located in a array-like frame between the membrane and the surface to be monitored, determine a more accuracy in the measurement of the parameters.
- 40 5. An elasto-plastic membrane, as claimed in claim 2 and claim 3, wherein the single sensor point is able to sense and transmit electrical analog and digital signals according to detected parameter value of the abdominal surface pressure without an antagonist surface;
- 45 6. An elasto-plastic membrane, according to the foregoing claims, that can be enveloped in a sealed bag for substantially covering the pregnant abdomen, or a generic body to be monitored, without losing the ability to acquire all the data and physical parameters referred in claim 3 (except umidity) either from the abdomen or other object under monitoring.
7. (cancelled).
8. (cancelled).
9. (cancelled).
- 50 10. A computer/diagnostic system, according to Unit of claim 1a and to the foregoing claims, in which several software algorithms, a fuzzy logic system and specific developed applications using Expert Systems and Artificial Intelligence technologies, is able to show images and data on a display/monitor (Fig.2), or a printer, in a very user-friendly modemaking the monitored phenomena very understandable, and gives a first
- 55 sample clinical diagnosis suggestion.

Statements under Article 19 .

The claims 1 to 6 and the claim 10 replaced by amended claims bearing the same number; these claims give a description of the features of this “pregnancy monitoring unit” only more accurate and explicative.

The main difference between the ‘unit’ described in this PCT/IT/2006/000454 and others described in the units of the documents reported by the ‘opinion of the Searching Authority’ consist in:

- the sensitive elasto-plastic membrane is a continuous system, light and comfortable, like a ‘technological multi-sensitive kid glove’ (not a system with several sensors in an encumbering or not ergonomic cuirass);
- the LCD, or CRT, monitor restores images of phenomenon under test giving to the clinical personnel the tactile perceptions like, that they could directly perceive putting their expert hands on the pregnant abdomen (not a simple checklist or graphic images of several data values).



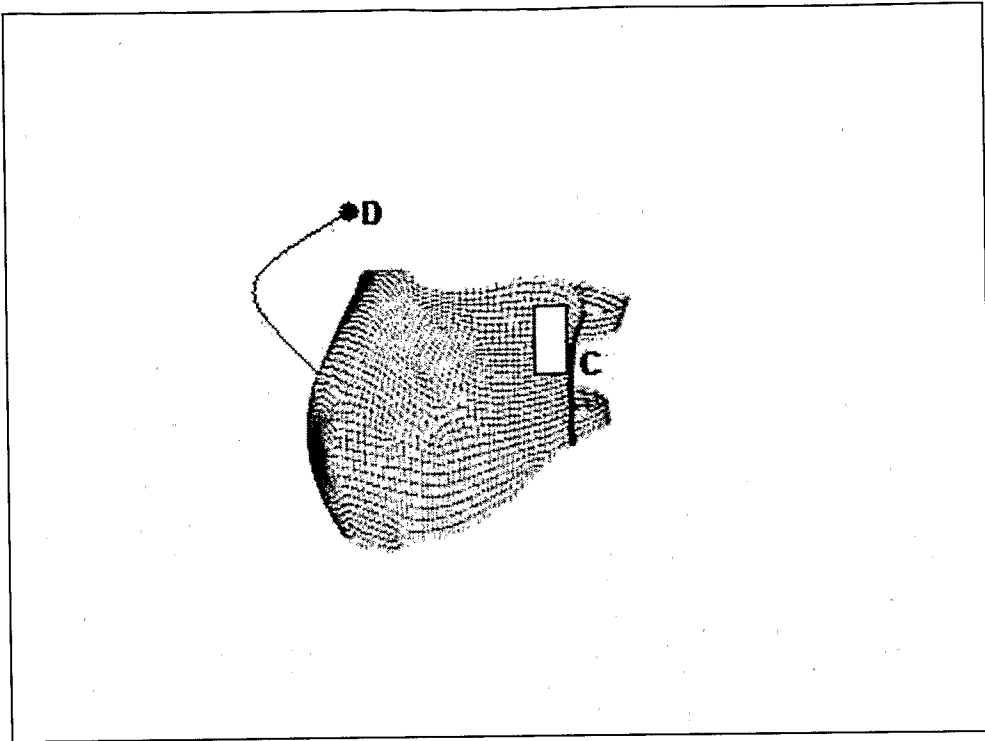


Fig.1

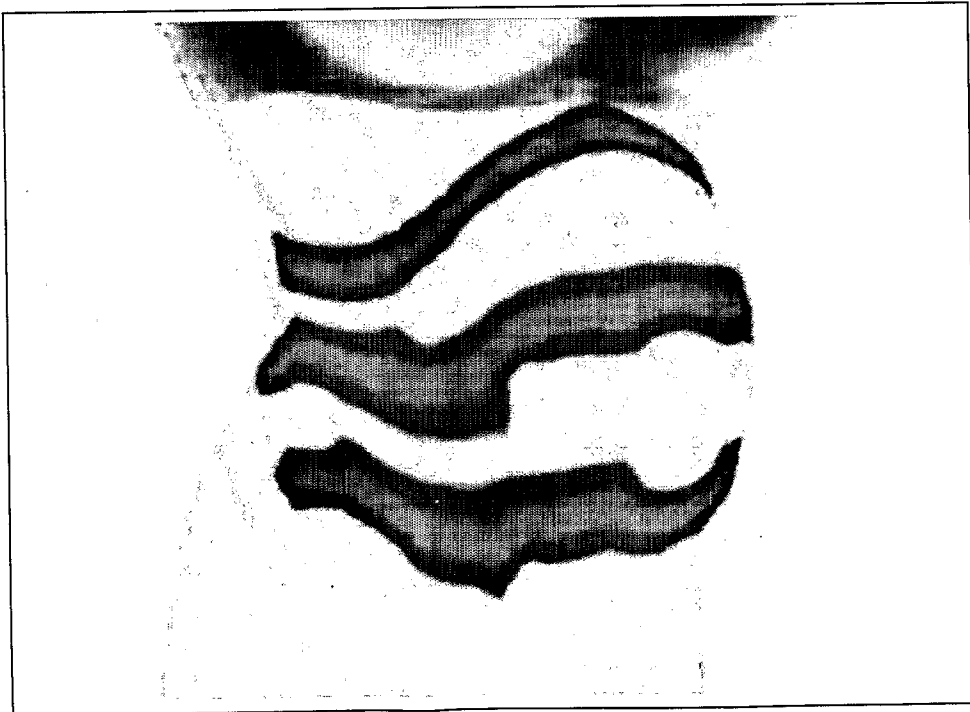


Fig.2

INTERNATIONAL SEARCH REPORT

International application No

PCT/IT2006/000454

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61B5/03 A61B5/024

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)

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)

EP0-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 807 271 A (TAYEBI SEAN [US] ET AL) 15 September 1998 (1998-09-15) cited in the application abstract column 2, line 13 - column 4, line 34 -----	1-4,6-10
X	US 4 781 200 A (BAKER DONALD A [US]) 1 November 1988 (1988-11-01) abstract column 4, line 17 - column 5, line 4 -----	1-10
X	WO 2005/117692 A2 (UNIV FLORIDA [US]; CONVERGENT ENGINEERING INC [US]; MAROSSERO DOROTHEE) 15 December 2005 (2005-12-15) abstract page 9, line 15 - page 18, line 11 ----- -/--	1-4,6-10



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:

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

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

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

27 November 2006

Date of mailing of the international search report

08/12/2006

Name and mailing address of the ISA/

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

Authorized officer

Beck, Ewa

INTERNATIONAL SEARCH REPORT

International application No
PCT/IT2006/000454

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 171 263 B1 (SULLIVAN COLIN EDWARD [AU]) 9 January 2001 (2001-01-09) abstract column 6, line 65 - column 8, line 35 -----	1-3,5-10
X	WO 2004/016163 A (MYSENS LTD [IL]; BABCHENKO ANATOLY [IL]; CHERNYAK VALERI [IL]) 26 February 2004 (2004-02-26) abstract page 5 - page 9 -----	1-3,7-10

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IT2006/000454

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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US 4781200	A	01-11-1988	NONE	
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