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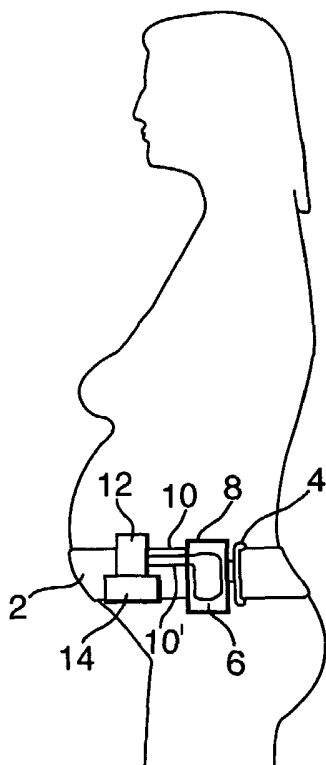
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(54) Title: SYSTEM AND METHOD FOR FETAL MONITORING



(57) Abstract: A system for monitoring fetal heart rate and fetal and maternal movements, including a flexible, but non-stretchable, belt portion, to be worn around the abdomen of a pregnant woman, a unit having a length of optical fiber leading from a light source to a light detector, the optical fiber is bent at least once on its way from the light source to the light detector, thereby producing a curvature, a mechanical linkage coupled between the belt portion and the bent fiber for converting a change in the circumference of the abdomen occasioned by the onset of fetal heart beat and/or fetal and/or maternal movement, to a corresponding change of the curvature, whereby light transmittance of the optical fiber is changed and detected by the detector. There is also provided a method for monitoring fetal heart rate and fetal and maternal movements.

WO 2004/016163 A1

SYSTEM AND METHOD FOR FETAL MONITORING

Field of the Invention

The present invention relates to a system and a method for monitoring fetal heart rate and fetal and maternal movements, for biophysical assessment of fetal well-being and tocodynamometry.

Background of the Invention

Fetal neuro-muscular activity is one of the basic physiological functions of the developing fetus and is necessary for its normal neural, muscular and skeletal development. Fetoplacental unit dysfunction or severe impairment of the supply of nutrients through maternal circulation are expected to, and do, lead to decreased fetal neuro-muscular activity. Accordingly, it has long been recognized that there is a direct correlation between fetal movement and the health of the pregnancy; in other words, reduced fetal movement has value as a predictor of intrauterine fetal death or as an ominous sign of the loss of fetal well-being. This knowledge has led to the clinical use of fetal movement assessment in preventing fetal death and untoward outcome of pregnancy, in both low and high risk pregnancies. Reassuring maternally perceived fetal activity has been defined as an average of four or more fetal movements per hour, when counting was performed for at least one hour per day. Three or less movements per hour, for two consecutive days, have been defined as abnormal.

Maternal compliance with any fetal movement-counting protocol is a major problem. Approximately only 80% of the patients adhere to the counting protocol; only 40-60% of those counting report decreased fetal movements when required to do so by the criteria set in their counting protocol. Thus, fetal movement-counting protocols are correctly exercised by only 50% of the participating patients. Given the unreliability of the measuring instrument, i.e., the mother, it is therefore truly remarkable that the great majority of the studies published to date clearly demonstrate the clinical usefulness of fetal movement-counting by the mother in preventing fetal death and exposure to danger.

Maternally perceived fetal movement-counting is undoubtedly beneficial. The difficulties encountered in implementing the different fetal movement-counting protocols render extremely important the development of a device that will facilitate the recording of maternally perceived fetal movement and standardize the interpretation of the movement record.

In view of the above, it is common practice today for the attending physician to stipulate to his patients the importance of fetal movements, and even to give them instructions for carrying out daily fetal movement counts. Unfortunately, these counts are subjective, are not completely reliable, are not reproducible and are bothersome to the patient. Furthermore, not uncommon false alarms are liable to lead to unnecessary anxiety and superfluous clinical testing, which in turn add costs to the health system.

A further parameter indicative of fetal well-being is the fetal heart rate, the determination of which assists the physician in deciding whether the condition of the fetus requires immediate medical attention. Several conventional fetal monitoring systems are routinely used in the care of patients, both prior to and during labor and delivery. Stethoscopes have been used to listen to the fetal heart rate; however, their use has been unsatisfactory, due to the high degree of extraneous or artifact noise or the maternal heart beat. In addition, such devices are impractical for in-home patient use.

Fetal heart beats are routinely detected indirectly from the interior abdominal wall, or directly by one of several methods. Such indirect methods of detection involve the use of electrodes, which pick up the weak fetal electrocardiogram on the maternal abdomen, or the employment of an ultrasonic Doppler transducer, which detects Doppler frequency shifts in ultrasonic energy reflected from moving components of the fetal cardiovascular system.

Ultrasonic Doppler systems for monitoring fetal heart rate have been generally inconvenient to use, because the fetal heart beat is difficult to locate and, once found, the device has to be frequently relocated. Most of the ultrasonic Doppler systems available today include an ultrasound probe together with processing circuitry attached by wires to

a loudspeaker. Other known systems which utilize Doppler probes are hard-wired to speakers which, for example, can be clipped to the physician's shirt pocket. Such systems, however, are not intended to be used by a patient for self-testing purposes, let alone to be used at home in conjunction with means enabling subsequent analysis by a physician.

Various other electronic monitoring apparatuses, in which an electrode is attached to the head of the fetus, which is possible only after the cervix has opened sufficiently and the amniotic sac ruptured, require the presences of a physician and are certainly not suitable for home use.

U.S. Patent No. 5,257,627 teaches a fetal monitoring apparatus comprising an ultrasonic transducer that generates ultrasonic vibrations which are directed at the fetal heart or other organs. The reflected ultrasonic waves are sensed by an appropriate sensor and are analyzed using the well-known Doppler principle. Such equipment, however, is relatively large and bulky, and cannot monitor fetal well-being while the mother goes about her daily life. Ultrasonic techniques also have the serious disadvantages of being of an invasive nature, applying a stream of high-frequency ultrasonic energy to the developing fetus and the fetal heart valves. Such invasive action may have significant detrimental effects on the fetus, as well as requiring a tedious alignment of the transducer with the fetal heart; even moderate movement of the patient will often result in erroneous readings.

U.S. Patent No. 5,140,992 teaches a passive fetal monitoring system, using a piezoelectric polymer material detector that is applied to the abdomen of the pregnant woman and produces an electrical signal as a result of fetal activity. The sensors used in this system are relatively large and of a limited sensitivity, making it difficult to detect very small potential differences, such as those generated by weak fetal activity. Furthermore, this method cannot be used with signals having an AC component, such as the signal produced by a heart beat.

Disclosure of the Invention

It is thus one of the objects of the present invention to provide a system for monitoring fetal movement, fetal heart rate that is free of the above-mentioned drawbacks and disadvantages of prior art monitors, inasmuch as it is lightweight, easily donned and doffed by the user herself without any assistance, totally non-intrusive, inexpensive and capable of functioning, i.e., producing objective data, around the clock.

According to the invention, the above objective is accomplished by providing a system for monitoring fetal heart rate and fetal and maternal movements, comprising a flexible, but non-stretchable, belt portion, to be worn around the abdomen of a pregnant woman; at least one unit comprising a length of optical fiber leading from a light source to a light detector, said optical fiber is bent at least once on its way from the light source to the light detector, thereby producing at least one curvature; a mechanical linkage coupled between said belt portion and said bent fiber for converting a change in the circumference of the abdomen occasioned by the onset of fetal heart beat and/or fetal and/or maternal movement, to a corresponding change of said curvature; whereby light transmittance of said optical fiber is changed and detected by said detector.

The invention further provides a method monitoring fetal heart rate and fetal and maternal movements, comprising providing at least one system including a flexible, but non-stretchable, belt portion, to be worn around the abdomen of a pregnant woman, at least one unit comprising a length of optical fiber leading from a light source to a light detector, said optical fiber is bent at least once on its way from the light source to the light detector, thereby producing at least one curvature; affixing said belt portion to the abdomen of a pregnant woman for detecting changes in the circumference of the abdomen occasioned by the onset of a fetal heart beat and/or a fetal or maternal movement; detecting changes in light transmittance resulting from changes of fiber curvature, and processing and interpreting the signals received from said light detector.

Brief Description of the Drawings

The invention will now be described in connection with certain preferred embodiments with reference to the following illustrative figures, so that it may be more fully understood.

With specific reference now to the figures in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

Fig. 1 represents a pregnant woman wearing the monitoring system of the present invention;

Fig. 2 illustrates a first embodiment of a monitoring system according to the present invention;

Fig. 3 illustrates a modification of the embodiment of Fig. 2;

Fig. 4 illustrates the monitoring system with the optical fiber loop in its initial state;

Fig. 5 illustrates the monitoring system with the optical fiber loop compressed, and

Fig. 6 represents a cascade arrangement of the monitoring system.

Detailed Description of Preferred Embodiments

Referring now to the drawings, there is shown in Fig. 1 a pregnant woman wearing around her abdomen the monitoring system according to a preferred embodiment of the present invention. The system is seen to comprise a belt portion or a belt 2 (hereinafter referred to as a "belt") made of a flexible but non-stretchable material, one end of which is threaded through a buckle 4 and pulled back and attached to the other end of the belt, advantageously by means of Velcro® fasteners. Further seen in

6

Fig. 1 is a loop 6 formed by a bent optical fiber 7 accommodated in housing 8. The ends 10, 10' of fiber 7 lead into another housing 12, containing a light source 11 (Figs. 2 and 4) which provides light for end 10 of loop 6, and a light detector 13 at end 10'. Further shown is a processing unit 14. Housings 8, 12 and processor 14 are fixedly attached to belt 2.

The working principle of this continuous monitoring system according to the present invention is based on the fact that light propagating in a light guide is attenuated when this light guide is bent, with attenuation increasing with increasing curvature. i.e., with a decreasing radius of the bend. The preferred embodiment utilizes one or several fiber loops for two reasons: the overlapping of several loops of a fiber provides a controlled, more accurate movement of the fiber and amplifies the effect of the attenuation of light at the bent portions of the fibers, resulting from the pulling of the belt, and the plurality of loops renders it to be springy, positively effecting its return to an initial position.

Propagation of light in the light guide is facilitated by the well-known phenomenon of total internal reflection. The attenuation coefficient α for a step index fiber is given by the expression

$$\alpha = 2n_1 k (\theta_c^2 - \theta^2) \exp \left[-\frac{2}{3} n_1 k R \left(\theta_c^2 - \theta^2 - \frac{2a}{R} \right) \right]^{\frac{3}{2}}$$

according to D. Gloge, "Bending Loss in Multimode Fibers with Graded and Ungraded Core Index", *Appl. Opt.* 11. 2506-2513 (1972).

wherein:

n_1 = refractive index of fiber core;

k = propagation constant ($k = \frac{2\pi}{\lambda}$, where λ = free-space wavelength of the light);

θ_c = critical angle, i.e., maximum value of incidence;

a = radius of fiber core, and

R = radius of the bend, as measured to the fiber axis.

The realization of the above principle is schematically illustrated in Figs. 2 to 5.

In Fig. 2 there is illustrated a further embodiment of the invention. Seen are the ends 2', 2'' of the belt 2, pull elements 16, 16', e.g., a pull rod, pull wire of the like, each attached to one end of a U-shaped bent fiber 7, forming a curvature 9, receiving light from the light source 11 and transmitting light at its other end 10' to the light detector 13.

A modification of the embodiment of Fig. 2 is shown in Fig. 3. Here, instead of a fiber 7 having a single curvature, the fiber is bent over to form at least one loop 6 having several curvatures 9, 9'. In addition, in order to increase reproducible, repetitive, accurate readings, there may advantageously be provided semi-rigid or rigid surfaces 17, 17', e.g., rods, bars, slats or the like, affixed to the linear portions of loop or loops 6, so as to avoid the bending of these portions, but only of the curved portions. This will result in a more accurate and sensitive monitoring system.

Shown in Fig. 4 is a light guide in the form of an optical fiber 7, one end 10 of which is exposed to a light source 11 mounted in housing 12, and the other end 10' of which leads to a light detector 13, also mounted in housing 12. On its way from light source 11 to light detector 13, optical fiber 7 forms an elongated loop 6, which may have one or more turns.

According to the invention, the slightest movement of the fetus, and even the miniscule pressure wave generated by the fetal heart beat, are transferred to belt 2 and are transmitted by the latter to a mechanical linkage comprised of buckle 4, to which are operatively attached non-stretchable pull element 16, a lever 18 and a rigid pressure surface 20, which is in constant contact with the non-curved portions of the loop 6. Lever 18, to which pull element 16 is articulated at point 22, has a fulcrum 24. Pressure surface 20 is articulated to the free end of lever 18.

When the fetus moves or emits a heart beat, this impulse, transferred by the mother's abdominal wall to non-stretchable belt 2, causes the pull element 16 attached to the buckle 4 to move from its position of rest by a distance q (Fig. 4). The pull element

16, articulated to lever 18 at point 22, exerts a tilting moment on lever 18, causing pressure surface 20 to compress loop 6 by the amount \underline{b} , thereby increasing the original curvature 9 of the loop to curvatures 9', 9'' (Fig. 5). The change in curvature produces an attenuation of the light flux originating in light source 11 and passing along optical fiber 7. This attenuation is sensed by light detector 13, which produces a signal that is led to processor 14. After the impulse has ebbed out, the elastic resilience of fiber loop 6 restores its original shape, as well as the original position of the mechanical linkage.

The sensitivity of the mechanical arrangement is determined by the relationship $\frac{a}{b} = \frac{S_1}{S_2}$. Thus, by reducing S_1 , sensitivity can be enhanced by increasing loop compression \underline{b} relative to required buckle movement \underline{a} .

Processor 14 includes an amplifier and a comparator. The voltage signals are amplified and compared with an array of previously determined signals characteristic of potential fetal and maternal activities. The processor may also include a digital recording system and computer memory, permitting the signals detected by detector 13 to be stored for later replay and analysis by a supervising clinician. Further envisioned are a real-time display screen, with signals supplied by processor 14, as well as an alarm block for real-time warning about dangerous changes in fetal (or maternal) conditions. Processor 14 may also provide the possibility to communicate with remote locations, using different linking means such as e-mail, mobile phone, telephone, and others. Processor 14 also includes a battery compartment.

In another preferred embodiment of the invention, belt 2 is not a one-piece belt, one end of which is threaded through buckle 4, pulled back and attached to the other end of the belt by Velcro® fasteners, but rather, consists of at least two separate, but mechanically interlinked sections, one section carrying housings 8 and 12 and processor 14, and the other section being fixedly attached to buckle 4, which serves as an interlinking member.

It is possible that in some cases, the fetal and/or maternal movements such as contractions are so large that compression of loop 6 would cause the critical angle θ_c to be exceeded, thus frustrating total internal reflection of the light. For such cases, the invention provides the cascade arrangement shown in Fig. 6, in which several units, such as those illustrated in Figs. 4 and 5, are series-connected. Unit I is provided with stops (not shown) that prevent the compression of loop 6 beyond the point where its critical angle θ_c would be exceeded. When this point has been reached, unit II is activated. Clearly, the loop 6 of unit II must be formed of a fiber 7 stiffer than that of unit I. Analogously, once the limit of unit II is about to be exceeded, unit III comes into action. Obviously, fiber 7 of unit III must be stiffer, than that of unit II. The signals from each unit have to be measured separately.

While the loops in the above-discussed embodiments had their curvatures increased to produce the desired light flux change by attenuation, the same effect can also be produced by augmentation caused by reducing the curvatures of the loops. This can be done by actively spreading the loops open through the pulling action of belt 2, as can be readily understood from the embodiment illustrated in Fig. 2.

Although the bent fibers and the loops shown in the drawings are half-turn, full-turn loops or, as mentioned above, multi-turn loops made of single fiber, twisting or braiding the curved portions of the fibers has an enhancing effect on the sensitivity of the arrangement.

While the specification relates to a belt to be worn around the abdomen of a pregnant woman, it should be clear that the belt need not necessarily surround the entire abdomen or waist and that the belt could be constituted by two sections, each connected at one end to the housing 8 and attachable to the body of a pregnant woman by means of stickers or sticking members, for example, at the body's sides or back.

It will be evident to those skilled in the art that the invention is not limited to the details of the foregoing illustrated embodiments and that the present invention may be embodied in other specific forms without departing from the spirit or essential attributes

thereof. The present embodiments are therefore to be considered in all respects as illustrative and not restrictive, the scope of the invention being indicated by the appended claims rather than by the foregoing description, and all changes which come within the meaning and range of equivalency of the claims are therefore intended to be embraced therein.

CLAIMS

1. A system for monitoring fetal heart rate and fetal and maternal movements, comprising:
 - a flexible, but non-stretchable, belt portion, to be worn around the abdomen of a pregnant woman;
 - at least one unit comprising a length of optical fiber leading from a light source to a light detector, said optical fiber is bent at least once on its way from the light source to the light detector, thereby producing at least one curvature;
 - a mechanical linkage coupled between said belt portion and said bent fiber for converting a change in the circumference of the abdomen occasioned by the onset of fetal heart beat and/or fetal and/or maternal movement, to a corresponding change of said curvature;
 - whereby light transmittance of said optical fiber is changed and detected by said detector.
2. The monitoring system as claimed in claim 1, further comprising processor for processing and interpreting the signals received from said light detector.
3. The monitoring system as claimed in claim 1, wherein said curvature is a single-turn curvature.
4. The monitoring system as claimed in claim 1, wherein said curvature is a multi-turn curvature forming at least one loop.
5. The monitoring system as claimed in claim 1, further comprising at least one rigid surface affixed to a non-curved portion of said fiber.
6. The monitoring system as claimed in claim 1, wherein said mechanical linkage comprises non-stretchable pull elements.
7. The monitoring system as claimed in claim 5, wherein said mechanical linkage further comprises lever means having a fulcrum stationary with respect to said belt, a pressure surface articulated to an end of the lever means and adapted to exert pressure on

a non-curved portion of said fiber, a pull element, one end of which is articulated to the lever means and the other end of which is attachable to an end portion of the belt.

8. The monitoring system as claimed in claim 1, comprising a plurality of said units arranged in series-connection.

9. The monitoring system as claimed in claim 7, wherein stiffness of the optical fibers of the loops of said plurality of light guide units progressively increases from unit to unit.

10. A method for monitoring fetal heart rate and fetal and maternal movements, comprising:

providing at least one system including a flexible, but non-stretchable, belt portion, to be worn around the abdomen of a pregnant woman, at least one unit comprising a length of optical fiber leading from a light source to a light detector, said optical fiber is bent at least once on its way from the light source to the light detector, thereby producing at least one curvature;

affixing said belt portion to the abdomen of a pregnant woman for detecting changes in the circumference of the abdomen occasioned by the onset of a fetal heart beat and/or a fetal or maternal movement;

detecting changes in light transmittance resulting from change of fiber curvature, and

processing and interpreting the signals received from said light detector.

11. The method as claimed in claim 10, further comprising the step of comparing the detected signals with previously detected signals and providing an alarm in cases where said comparison exceeds preset limits.

12. The method as claimed in claim 10, further comprising the step of continuously displaying the interpreted signals.

13. The method as claimed in claim 10, further comprising the step of transmitting the interpreted signals to remote locations, using any means of communication.

14. The method as claimed in claim 10, further comprising the step of determining the frequency, duration, amplitude and shape of pulses generated by fetal-maternal activity.

Fig.1.

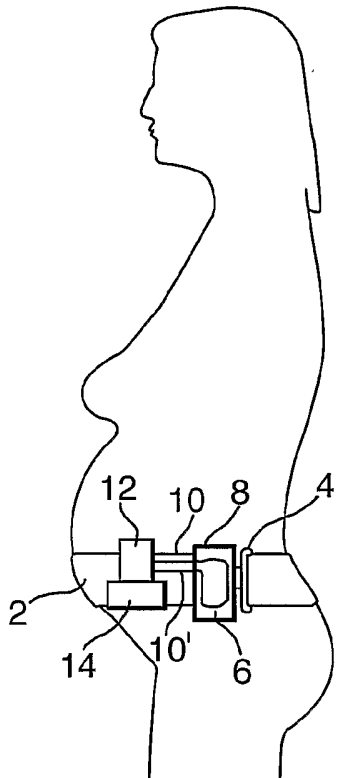


Fig.2.

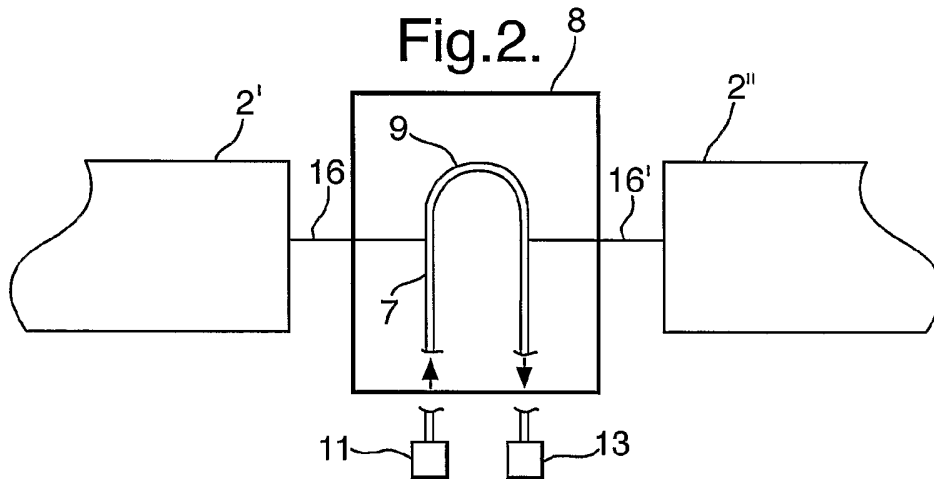


Fig.3.

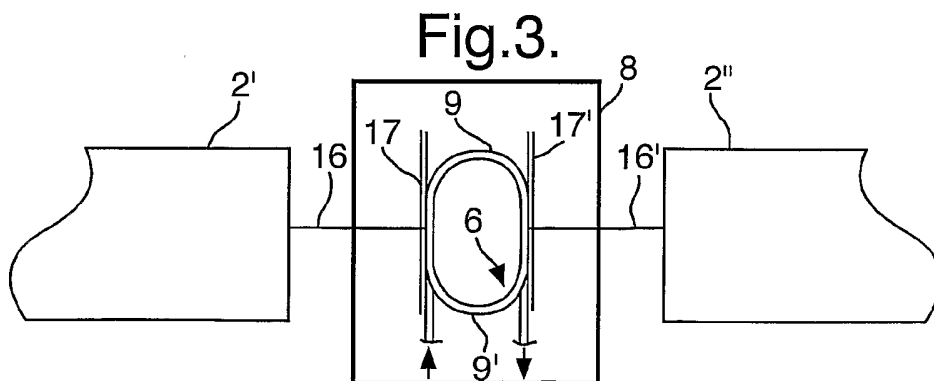


Fig.4.

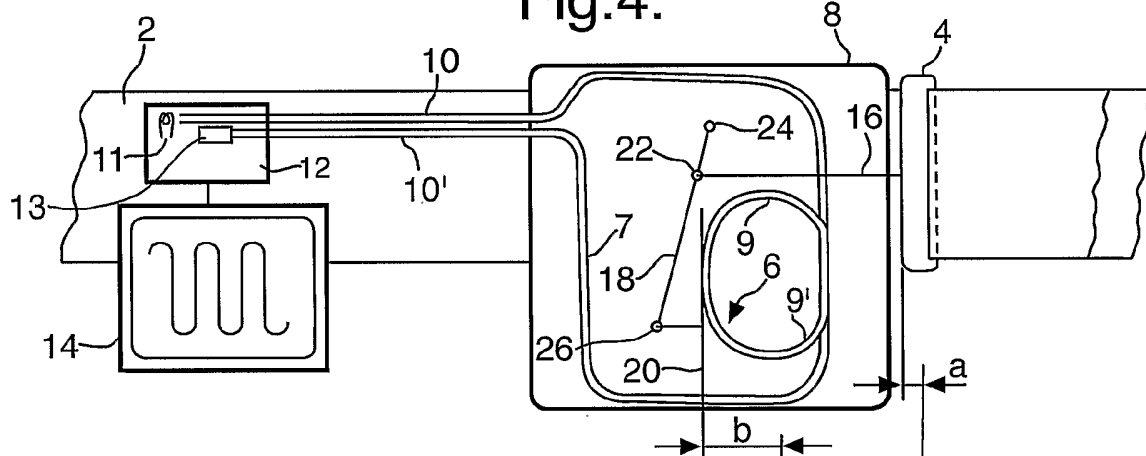
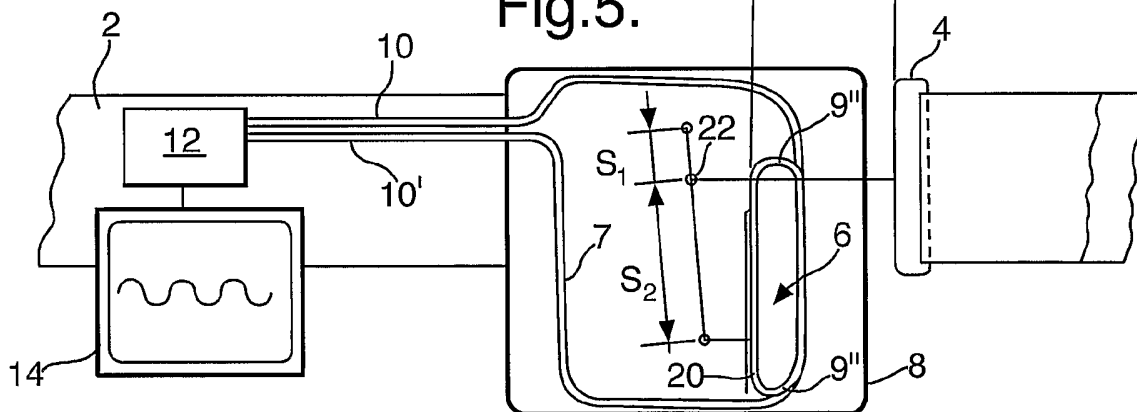
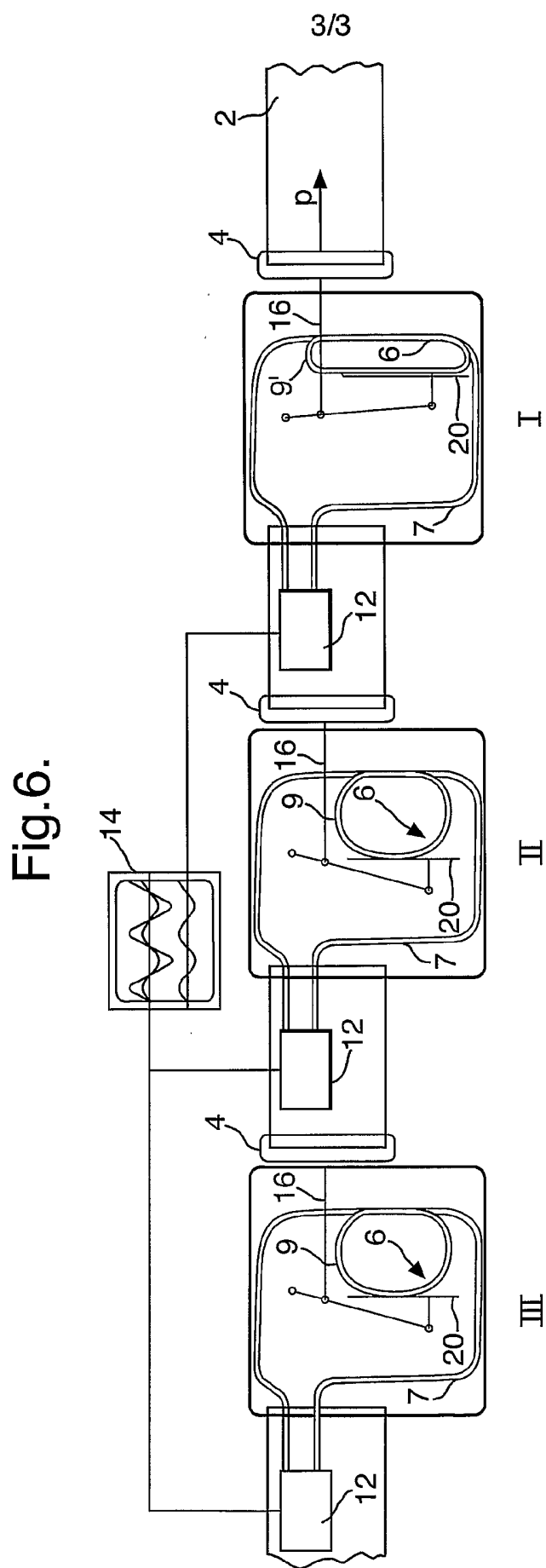


Fig.5.





INTERNATIONAL SEARCH REPORT

Internatio ... cation No
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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/024 A61B5/03

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 G01B

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)

WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 134 281 A (JOHNSON FRANK ET AL) 28 July 1992 (1992-07-28)	1-6, 8
Y	the whole document	10-14
Y	US 5 140 992 A (ZUCKERWAR ALLAN J ET AL) 25 August 1992 (1992-08-25) cited in the application	10-14
A	abstract	1
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Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

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- *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
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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
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- *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

28 November 2003

Date of mailing of the international search report

12/12/2003

Name and mailing address of the ISA

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Authorized officer

Clevorn, J

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IL 03/00667

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p> DATABASE WPI Week 9809 Derwent Publications Ltd., London, GB; AN 1998-089852 XP002263295 "Device for sensing movements of a body - comprises elastically interconnected members, and an optic fibre connected to a source of light" & IL 110 210 A ((JERU-N) JERUSALEM COLLEGE TECHNOLOGY), 20 November 1997 (1997-11-20) abstract ----- </p>	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/IL 03/00667

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			CA 2009033 A1	31-07-1991
			CA 2130429 A1	01-08-1991
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US 5140992	A	25-08-1992	NONE	
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IL 110210	A	20-11-1997	NONE	
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