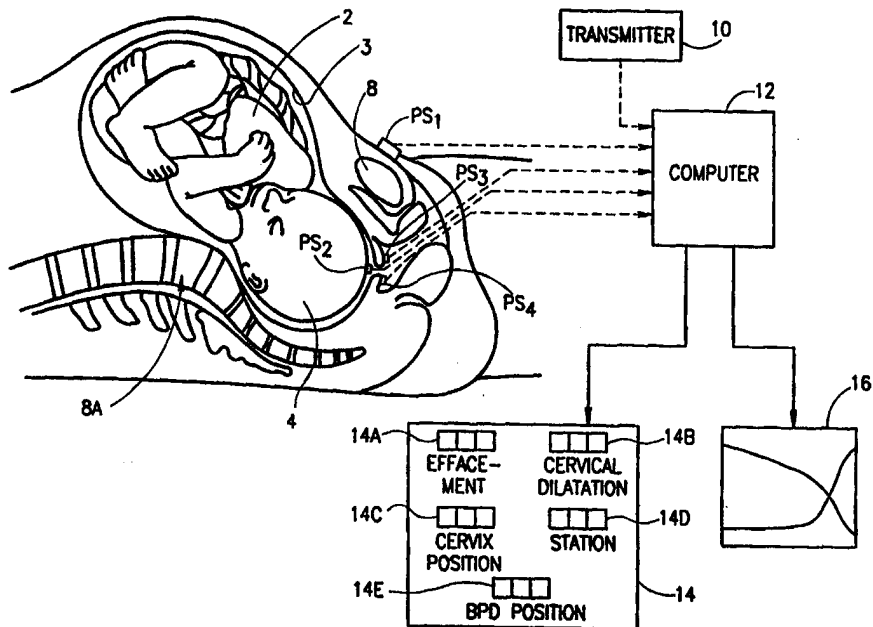


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<p>(21) International Application Number: PCT/IL98/00208 (22) International Filing Date: 4 May 1998 (04.05.98) (30) Priority Data: 60/045,556 5 May 1997 (05.05.97) US (71)(72) Applicant and Inventor: PALTIELI, Yoav [IL/IL]; 51 Einstein Street, 34602 Haifa (IL). (74) Agent: EITAN, PEARL, LATZER & COHEN-ZEDEK; Lumir House, Maskit Street 22, 46733 Herzelia (IL).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, GM, GW, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: METHOD AND APPARATUS FOR MONITORING THE PROGRESS OF LABOR



(57) Abstract

This invention is a method of monitoring the progress of labor in a mother during childbirth, by attaching a position sensor (PS1-PS4) to a predetermined point of the mother's pelvic bones; monitoring the location of the position sensor in three-dimensional space relative to a reference; and monitoring the location of the fetal presenting part (4) with respect to the predetermined point on the mother's pelvic bones. The location of the fetal presenting part may be indicated by a similar position sensor, or by imaging. Other conditions, such as effacement, cervical dilatation, and cervical position may also be monitored in a similar manner.

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METHOD AND APPARATUS FOR MONITORING THE PROGRESS OF LABOR

FIELD AND BACKGROUND OF THE INVENTION

The present invention relates to a method and apparatus for monitoring the progress of labor during childbirth.

5 Normal labor is generally divided into three stages: The first stage begins with the onset of labor and ends when dilatation of the cervix is complete; the second stage begins at that point and ends with the complete birth of the baby; and this is followed by the third stage which ends with the delivery of the placenta. During labor it is common to use either an external ultrasonic system
10 for recording the baby's heart rate, and an external system for detecting the mother's uterine contractions, or an electronic system to sense the baby's heart pulses by an electrode attached to the baby's head and the mother's contractions by a pressure catheter applied to the mother inside the uterus.

 However, a number of other physiological conditions of the mother and
15 baby during labor must also be monitored in order to determine the progress of labor. These additional conditions include: (1) effacement (the thinning out of the cervix that occurs before and during the first stage of labor); (2) cervical dilatation (the increase in size of the cervical opening); (3) position of the cervix (the relation of the cervix to the vaginal axis, normally the fetal head); and (4) station (the level
20 of a predetermined point of the fetal presenting part with reference to the mother's pelvis). The more common determination of station is the distance between the tip of the fetal head and the ischial spines which can be palpable by the physician;

but a more accurate determination of station is the distance between the bi-parietal diameter (BPD) of the fetal head and the mother's pelvic inlet.

The foregoing conditions are generally determined by a physical examination, i.e., by the insertion of a finger through the mother's vagina.

5 However, the accuracy of such a "finger" examination is very subjective and depends to a great extent on the experience, judgment, and even finger size, of the physician. Other drawbacks in such a physical examination are that it can be done only at spaced intervals, it generally produces discomfort to the mother, and it involves a number of risks including contamination, infection, dislodgment of a fetal monitor, injury to the baby, etc. Failure to interpret the precise stage of the labor progress from the physical examination can result in injury or even death of the baby or of the mother.

Many devices have been proposed in the past for automatically monitoring these conditions. As examples, US Patent 4,476,871 proposes an elongated tube having electrodes spaced along its length to monitor cervical dilatation during labor; US Patents 4,942,882 and 5,135,006 propose a fetal monitor probe attached to the fetal head to monitor heart beat, which probe is calibrated to monitor progress of descent; US Patent 5,222,485 proposes an elongated inflatable sac to monitor the position of the fetus and the configuration of the cervix; and US Patent 5,406,961 proposes a pessary to monitor the configuration of the cervix. However, for one reason or another, none of the previously proposed devices has come into any widespread use, and the historical "finger" examination continues to be the one in common use to this day.

OBJECTS AND BRIEF SUMMARY OF THE INVENTION

An object of the present invention is to provide a method and apparatus having advantages over the conventional "finger" examination technique for monitoring the progress of labor in a mother during childbirth.

5 According to one aspect of the present invention, there is provided a method of monitoring the progress of labor in a mother during childbirth, comprising: attaching a position sensor to a predetermined point on the mother's pelvic bones; monitoring the location of the position sensor in three-dimensional space relative to a reference; and monitoring the location of the fetal presenting
10 part with respect to the predetermined point on the mother's pelvic bones to provide an indication of the progress of labor.

 Three embodiments of the invention are described below for purposes of example. In one embodiment, the location of the fetal presenting part, and also of the opposite sides of the end of the mother's uterine cervix, are monitored by
15 position sensors attached to these respective elements. In a second described embodiment, the latter are monitored by operating an ultrasonic transducer to image the mother's cervix and pelvic bones, and the fetal head, on a screen, and by using a position sensor on the ultrasonic transducer, and a marker for marking the screen, to locate the positions of these elements. A third embodiment is
20 described utilizing both the four position sensors applied to the mother and the fetal presenting part, and a fifth position sensor applied to an ultrasonic transducer for imaging and locating the mother's cervix and pelvic bones and the fetal head

According to further features in the described first and third embodiments, the cervical dilatation of the mother's cervix is continuously indicated by continuously monitoring the positions of the position sensors applied to the opposite sides of the end of the cervix, and continuously displaying the spatial distance between them. The position of the fetal presenting part (e.g., fetal head) is also continuously indicated by continuously monitoring and displaying their respective locations

According to further features in the described preferred embodiments, the above conditions are computed and displayed in the form of units of distance (e.g., cm), and/or in the form of a graph, called a Partogram, showing the interrelation of the cervical dilatation and the descent of the fetal presenting part

According to a further aspect of the invention there is provided apparatus for monitoring the progress of labor in a mother during childbirth, comprising: a position sensor for attachment to a predetermined point on the mother's pelvic bones, and for producing an output signal identifying its location in space; means for sensing the location of the fetal presenting part with respect to the predetermined point on the mother's pelvic bones, and for producing an output signal identifying the location of the fetal presenting part; a computer connected to receive the output signals; and an output device controlled by the computer for outputting the position of the fetal presenting part with respect to the predetermined point of the mother's pelvic bones

The output device is preferably a display, but could be a plotter, recorder, or other device for displaying, recording, and/or processing the data outputted by the computer

As will be described more particularly below, such a method and apparatus permits the progress of labor to be monitored in a manner which is continuous rather than intermittent, which is less dependent for accuracy on the experience, judgment or finger size of the attendant in the conventional "finger examination", which subjects the mother to less discomfort, and which involves less risk of contamination, infection, dislodgment of a fetal monitor, or injury to or death of the baby or mother due to a wrong assessment of the fetal position or of labor progress. Moreover, this technique enables more precise monitoring of the critical condition, namely the changes in the spatial distance of the BPD of the baby's head with respect to the pelvic inlet

Further features and advantages of the invention will be apparent from the description below.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is herein described, by way of example only, with reference to the accompanying drawings, wherein:

Fig. 1 is a block diagram illustrating one form of system constructed in accordance with the present invention;

Fig. 2 illustrates one of the position sensors in the system of Fig. 1;

Fig. 3 is a block diagram of one type of position sensor system that may be used;

Fig. 4 more particularly illustrates the Partogram display in the system of Fig. 1;

Fig. 5 is a block diagram illustrating an imaging system for displaying the image of the mother's womb, particularly the cervix, pelvic bones, and the fetal head to better show the progress of the labor;

Figs. 6A - 6D illustrates typical displays produced by the system of Fig. 5 during the various stages of labor;

Fig. 7 illustrates a typical display produced by the system of Fig. 5 during the descent of the fetal head;

Fig. 8 illustrates how the monitored data may be processed to display the changes in the spatial distance of the BPD of the baby's head with respect to the mother's pelvic inlet; and

Fig. 9 illustrates a fetal heart monitoring display and uterine contractions that may be included in the above-described systems of Fig. 1 or Fig. 5.

DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 1 schematically illustrates the mother's womb particularly illustrated in Fig. 4, is of special value since it provides a visual display of the progress of labor and can be recorded if desired. By using the Partogram, a better determination can be made whether labor is progressing normally. "Alert" and "action" lines may be printed on the Partogram to provide a visible indication of whether labor is progressing normally or abnormally, and thereby to better alert the attending personnel to take prompt action if necessary. Such an "electronic Partogram" can also markedly reduce the number of prolonged labors, the rate of intrapartum, post partum and early neonatal infections, the number of unnecessary interventions, and neonatal trauma due to wrong assessment of the fetal head.

Fig. 5 illustrates a monitoring system similar to that of Fig. 1 but further equipped with an imaging system for imaging the womb area of the mother and for continuously displaying the mother's cervix, pelvic bones, and fetal head (or other presenting part).

Thus, Fig. 5 includes an ultrasonic transducer 40 for imaging the womb area, via the computer 12, on an image display 42. It also includes a position sensor PS5 attached to the ultrasonic transducer 40. Thus, any point in the image on display 42 may be selected by a marker device 43, such as a mouse or touch screen, and its location fed into the computer 12 to identify the location of the respective point with respect to the location of position sensor PS1 attached to the mother's pubic bones. With this information, the computer 12 can compute

the various relationships displayed in displays 14 and 16, thereby obviating the need for the positions sensors PS2, PS3 and PS4. The image displayed in display 42 may be used in the same manner for marking the BPD on the fetal head as illustrated in Fig. 8, thereby enabling particularly the spatial distance
5 between the fetal BPD and the pelvic inlet to be computed and monitored.

It will be appreciated that other reference points, other than the BPD or the tip of the fetus head, as well as any other point of the mother's pelvis, may be used as the reference points for monitoring the progress of the labor. This freedom is important because of the variety of preferences among various
10 physicians.

The imaging system illustrated in Fig. 5 could also be used to provide a visual image of the various stages of labor, e.g., as illustrated in Figs. 6A - 6D showing the progressive dilatation and effacement of the cervix, or as illustrated in Figs. 7 and 8 showing the progressive descent of the fetal head tip through the
15 various stations with respect to the ischial spines 7 (Fig. 7) or mother's pelvic inlet (Fig. 8).

If the imaging system is used together with all five position sensors PS1-PS5 illustrated in Fig. 5, the ultrasound imaging may be used only to measure the BPD at the beginning of labor or later. The computer then
20 determines the distance between the BPD and the tip of the fetal head, and thereafter it can use the position of the tip of the fetal head also to determine the BPD position. The ultrasound imaging may thereafter be used only for verification if desired. It can also be used to verify cervical dilatation and effacement.

If the system illustrated in Fig. 5 is used with only the ultrasound imaging and position sensors PS1 and PS5, the monitoring would preferably not be continuous but only intermittent, i.e., only when it is desired to monitor a specific stage in the progress of the labor.

5 The system illustrated in Fig. 5 may also be used for sensing contractions in the mother's uterus. Thus, during contractions, the fetal head moves slightly, and the dilatation also grows slightly; and after contractions, they both retract to their previous positions. By thus observing the dilatation and/or fetal head position as a function of time, the attending physician may discern the
10 occurrence of contractions as well as the duration and strength of such contractions. In addition, by including a heart pulse sensor in the fetal head position sensor PS2, the physician may observe the relation of the fetal heart rate (FHR) in relation to the uterine contractions (UC), to show the relationship
15 between the two as illustrated in Fig. 9. Computer 12 may be programmed to receive the above information from the various sensors and produce, in a monitor
45, a display corresponding to the fetal heart rate (FHR) in relation to the uterine contractions (UC), as illustrated in Fig. 9. Such information is particularly desirable if the presence of complications is established or anticipated.

 While separate displays are shown in the drawings, it will be appreciated
20 that these displays could be in the form of windows on the same large computer display.

 While the invention has been described with respect to several preferred embodiment, it will be appreciated that these are set forth merely for purposes of

example, and that many other variations, modifications and applications of the invention may be made.

CLAIMS

1. A method of monitoring the progress of labor in a mother during childbirth, comprising:
 - attaching a position sensor to a predetermined point on the
 - 5 mother's pelvic bones;
 - monitoring the location of said position sensor in
 - three-dimensional space relative to a reference; and
 - monitoring the location of the fetal presenting part with respect to
 - said predetermined point on the mother's pelvic bones to provide an
 - 10 indication of the progress of labor.
2. The method according to Claim 1, further comprising monitoring the location of the opposite sides of the end of the mother's uterine cervix with reference to each other to provide an indication of the dilatation of the mother's cervix.
- 15 3. The method according to Claim 2, further comprising monitoring the location of the opposite sides of the end of the mother's uterine cervix with reference to the fetal presenting part and the mother's pelvic bones to provide an indication of the cervical position of the mother.
4. The method according to either of Claims 2 or 3, wherein the location of
- 20 said fetal presenting part is monitored by attaching a second position sensor to the outer tip of the fetal presenting part and monitoring the location of said second position sensor.

5. The method according to the Claim 4, wherein the locations of said opposite sides of the mother's uterine cervix are monitored by attaching third and fourth position sensors to them, and monitoring their respective locations.
- 5 6. The method according to Claim 5, wherein the station of the fetal presenting part is continuously indicated by continuously monitoring the positions of said first and second position sensors, and continuously displaying the spatial distance between them.
7. The method according to Claim 6, wherein the cervical dilatation of the
10 mother's cervix is continuously indicated by continuously monitoring the positions of said third and fourth position sensors and continuously displaying the spatial distance between them.
8. The method according to Claim 7, wherein said cervical dilatation and said station are computed and displayed in centimeters.
- 15 9. The method according to Claim 7, wherein said cervical dilatation and said station are computed and displayed in the form of a Partogram showing the interrelation of the cervical dilation and the descent of the fetal presenting part.
10. The method according to any one of Claims 5-9, wherein effacement of
20 the mother's cervix is continuously indicated by continuously monitoring and displaying the spatial distance of said second position sensor from said third and fourth position sensors.

11. The method according to any one of Claims 5-10, wherein the position of the mother's cervix is continuously indicated by continuously monitoring and displaying the spatial distances between said first, second, third and fourth position sensors.
- 5 12. The method according to Claim 11, wherein said effacement and position of the mother's cervix are computed and displayed in centimeters.
13. The method according to any one of Claims 5-10, wherein the position of the mother's cervix is continuously indicated by continuously monitoring and displaying the angle of the cervical axis as indicated by said second,
10 third and fourth position sensors.
14. The method according to Claim 1, wherein the location of said fetal presenting part is monitored by attaching a position sensor to an ultrasonic transducer, operating said ultrasonic transducer to image said fetal presenting part on a screen, monitoring the location of said latter
15 position sensor and thereby the location of said ultrasonic transducer to which it is attached, and determining the location of the fetal presenting part as imaged on said screen.
15. The method according to Claim 14, wherein the monitored locations of the first-mentioned position sensor and of the fetal presenting part are
20 processed to provide an indication of the spatial distance of the bi-parietal diameter (BPD) of the fetal head with respect to the mother's pelvic inlet.

16. The method according to any one of Claims 1-15, wherein, before
attaching the position sensor to a predetermined point on the mother's
pelvic bones and monitoring its location, the entire spatial position of the
mother's pelvis is mapped.

5 17. The method according to Claim 16, wherein the mother's pelvis is
mapped by:

attaching a position sensor to one known point of the pelvis and
outputting an electrical signal identifying the location of said one
point;

10 attaching the position sensor to a second known point of the
pelvis and outputting an electrical signal identifying the location of
said second point;

attaching the position sensor to a third known point of the pelvis
and outputting an electrical signal identifying the location of said third
15 point; and

processing said first, second and third electrical signals to
compute the entire spatial position of the pelvis.

18. The method according to Claim 17, wherein said first point is the left
anterior superior spine; said second point is the central point of the
20 symphysis pubis; and said third point is the right anterior superior spine.

19. The method according to either of Claims 17 or 18, wherein, after the
entire spatial position of the pelvis is mapped, said position sensor at said

third point is left attached to said third point while its location is monitored during the mother's labor.

20. The method according to any one of Claims 5-19, wherein contractions in the mother's uterine cervix are sensed, and the fetal heart rate is sensed and is displayed in relation to the uterine contractions.

21. The method according to Claim 20, wherein said contractions in the mother's uterine cervix are sensed by monitoring said second, third and fourth position sensors to indicate the variations in the position of the fetal presenting part and of the cervix.

22. Apparatus for monitoring the progress of labor, comprising;

a position sensor for attachment to a predetermined point on the mother's pelvic bones, and for producing an output signal identifying its location in space;

means for sensing the location of the fetal presenting part with respect to said predetermined point on the mother's pelvic bones, and for producing an output signal identifying the location of said fetal presenting part;

a computer connected to receive said output signals; and

an output device controlled by said computer for outputting the position of said fetal presenting part with respect to said predetermined point of the mother's pelvic bones.

23. The apparatus according to Claim 22, further comprising means for
sensing the locations of the opposite sides of the mother's uterine cervix
with reference to each other to produce output signals which are received
by said computer and processed to control said output device for
5 outputting an indication of the dilatation of the mother's cervix.
24. The apparatus according to Claim 23, further comprising means for
sensing the locations of the opposite sides of the mother's uterine cervix
with reference to the fetal presenting part and the mother's pelvic bones
to produce output signals which are received by said computer and
10 processed to control said output device for outputting an indication of the
cervical position of the mother.
25. The apparatus according to either of Claims 23 or 24, wherein said
means for sensing the location of the fetal presenting part with reference
to said predetermined point of the mother's pelvic bones comprises a
15 second position sensor for attachment to the outer tip of the fetal head for
producing an output signal to the computer identifying the location of said
second position sensor.
26. The apparatus according to Claim 25, wherein said means for sensing
the locations of the opposite sides of the mother's uterine cervix include
20 third and fourth position sensors for attachment to the opposite sides of
the mother's uterine cervix and for producing output signals to the
computer identifying their respective locations.

27. The apparatus according to Claim 26, wherein said computer computes, and said output device displays, the station of the fetal presenting part as the spatial distance between said first and second position sensors
28. The apparatus according to Claim 27, wherein said computer computes, and said output device displays, the cervical dilatation of the woman's cervix as the spatial distance between said third and fourth position sensors.
29. The apparatus according to Claim 28, wherein said computer computes, and said output device displays, said cervical dilation and said station in centimeters.
30. The apparatus according to Claim 28, wherein said computer computes, and said output device displays, said cervical dilatation and said station in the form of a Partogram showing the interrelation of the cervical dilatation and the descent of the fetal presenting part.
31. The apparatus according to any one of Claims 26-30, wherein said computer computes, and said output device displays, the effacement of the mother's cavity as the spatial distance of said second position sensor from said third and fourth position sensors.
32. The apparatus according to any one of Claims 26-31, wherein said computer computes, and said output device displays, the position of the mother's cervix as the spatial distances between said first, second, third and fourth position sensors.

33. The apparatus according to Claim 32, wherein said effacement and
position of the mother's cervix are computed and displayed in centimeters

34. The apparatus according to any one of Claims 26-31, wherein said
computer computes, and said output device displays, the angle of the
5 cervical axis as indicated by said second, third and fourth position
sensors.

35. The apparatus according to either of Claims 23 or 24, wherein said
means for sensing the locations of the fetal presenting part and of the
opposite sides of the mother's uterine cervix comprises:

10 an ultrasonic transducer to image said fetal presenting part and
uterine cervix on a screen;

a position sensor attached to said ultrasonic transducer for
producing an output signal identifying its location to the computer;
and

15 a marker for marking a selected point of the fetal presenting part,
and the opposite sides of the mother's uterine cervix, as imaged on
the screen, and for outputting electrical signal identifying their
respective locations to the computer.

36. The apparatus according to Claim 35, wherein when said marker marks
20 the bi-parietal diameter (BPD) of the fetal head as imaged on the screen,
said computer computes the distance between said BPD and the
mother's pelvic inlet.

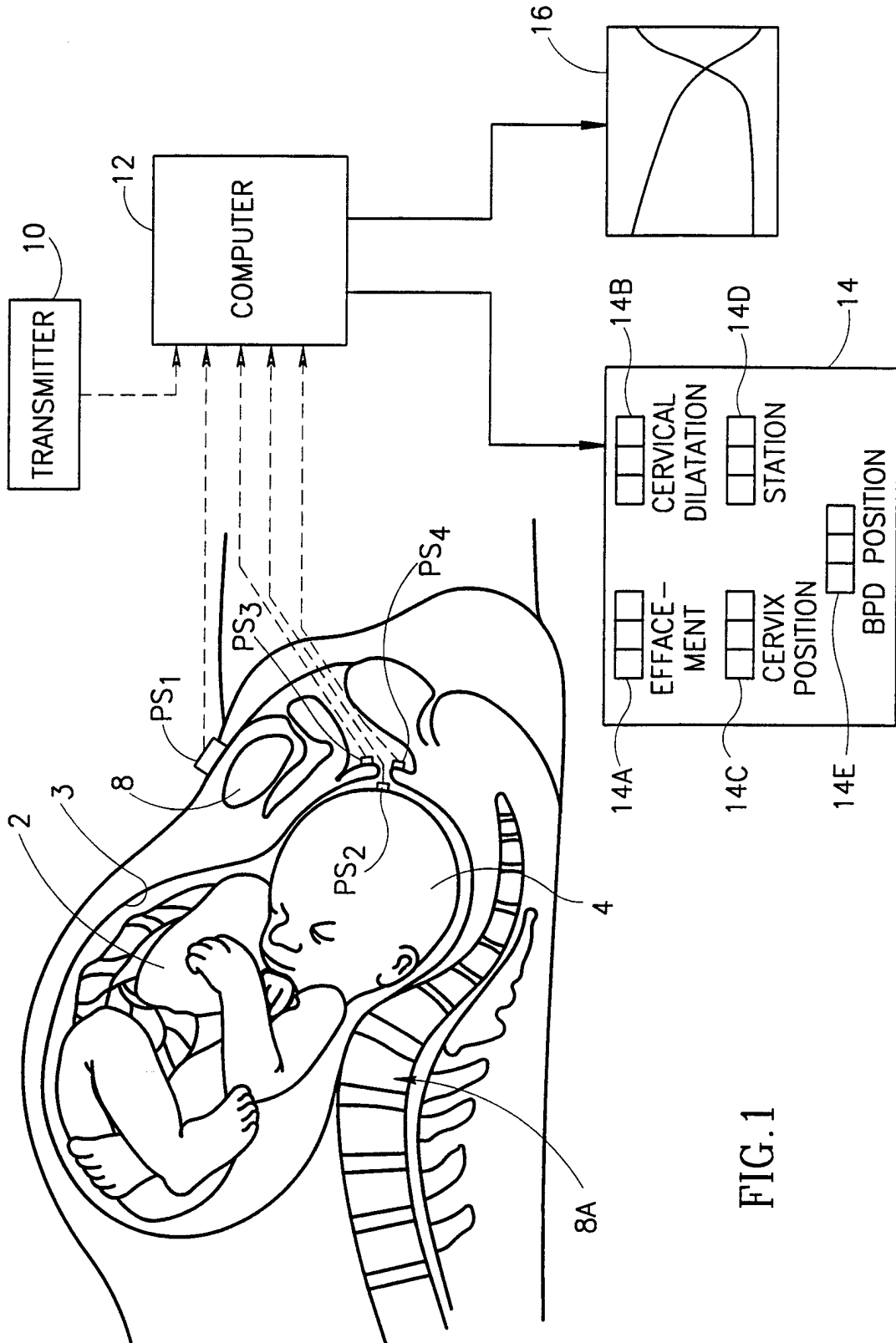


FIG. 1

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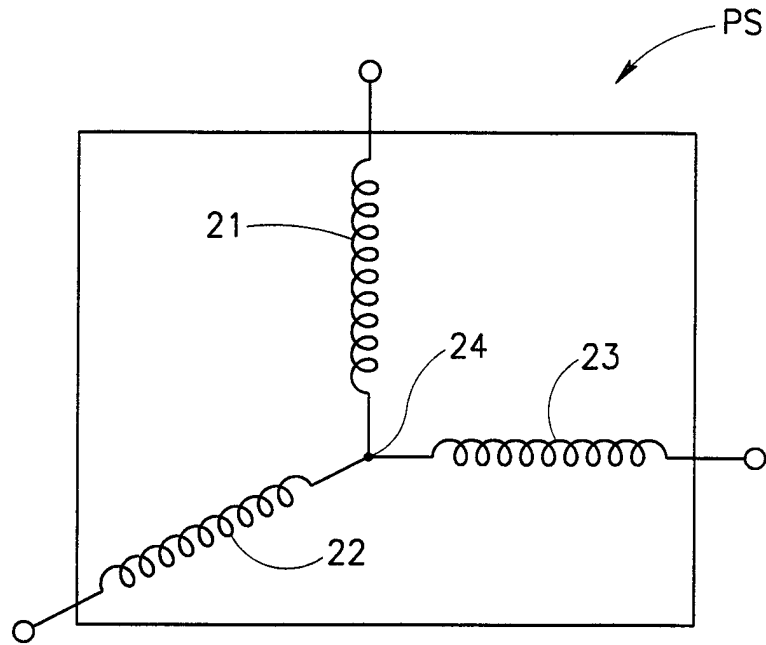


FIG.2

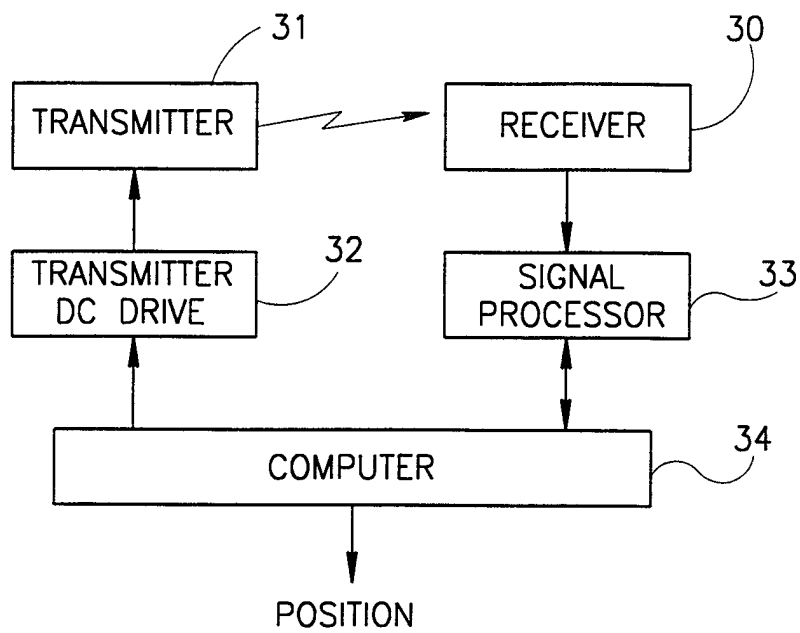


FIG.3

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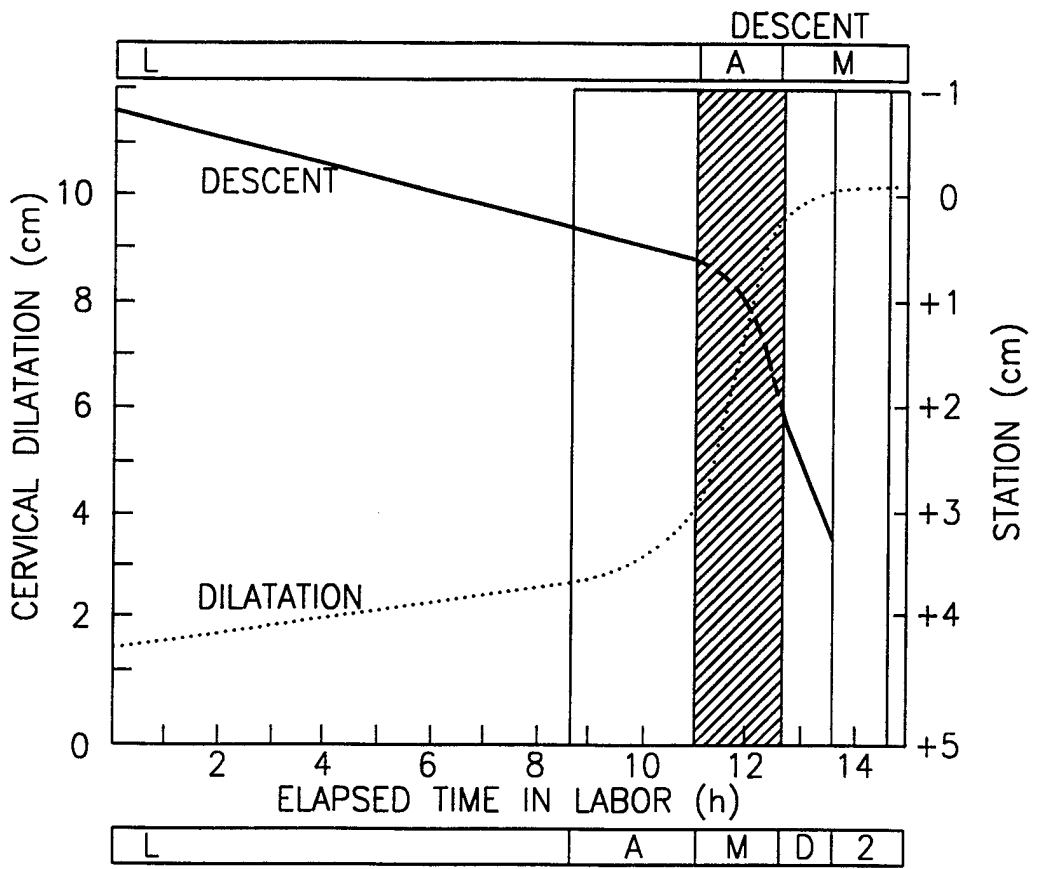


FIG.4

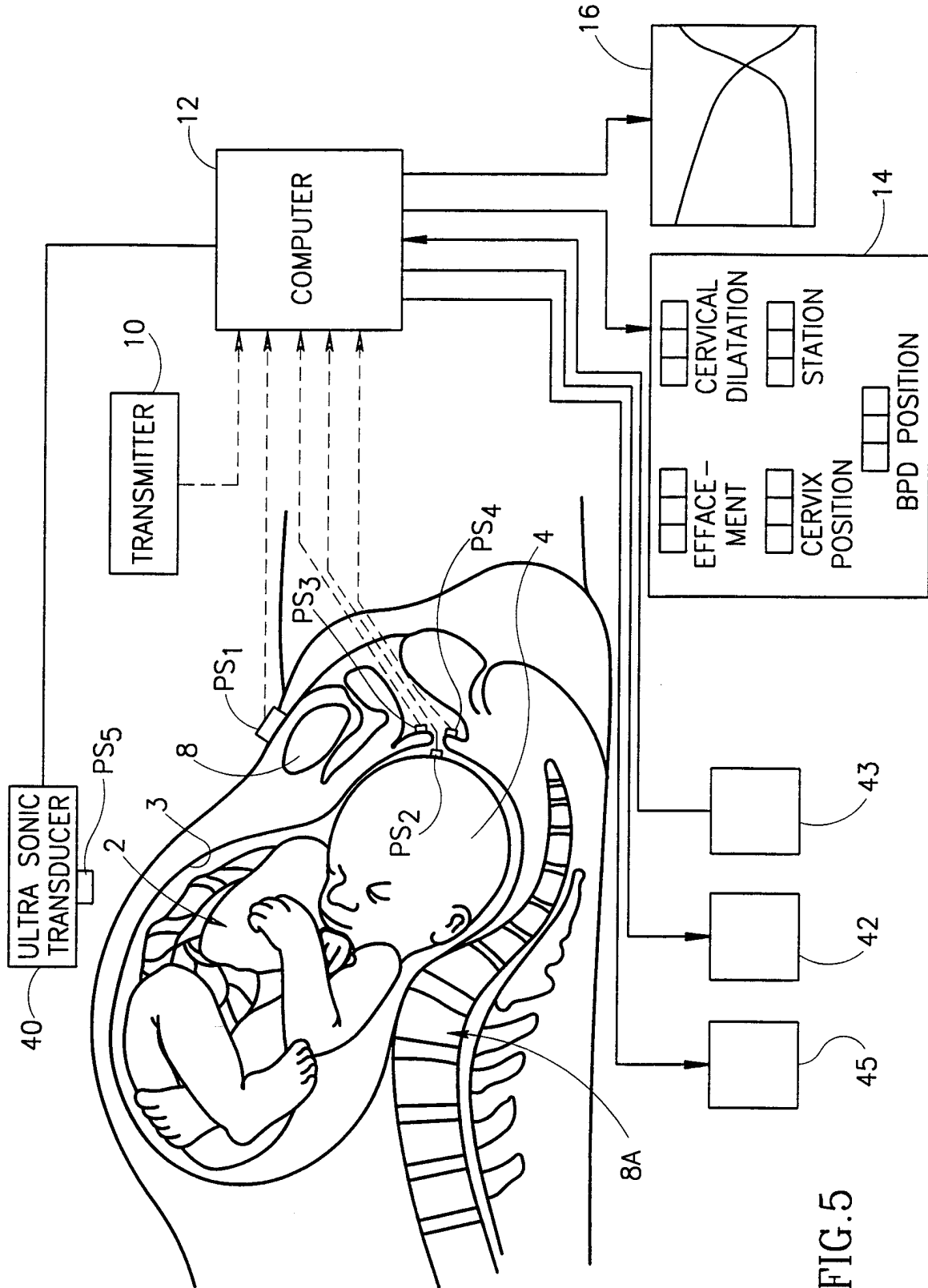


FIG. 5

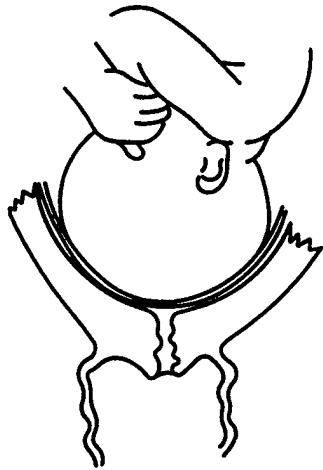


FIG. 6A

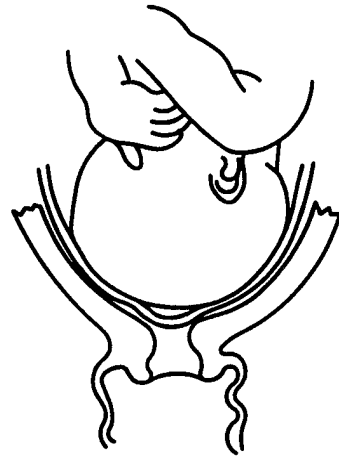


FIG. 6B

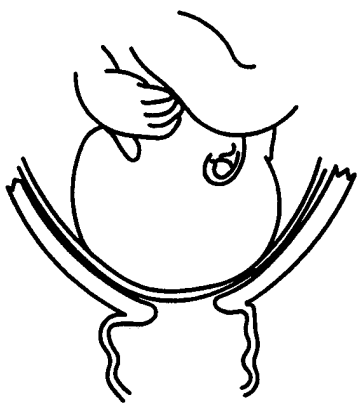


FIG. 6C



FIG. 6D

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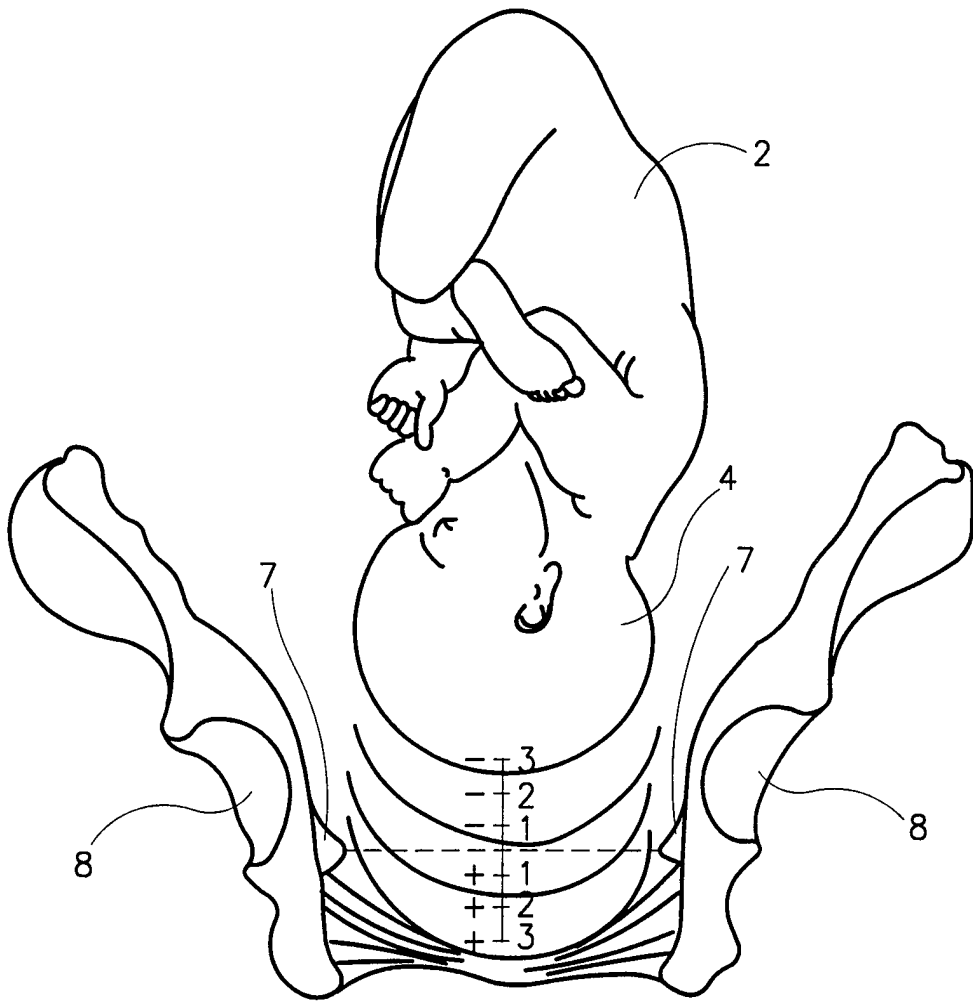


FIG.7

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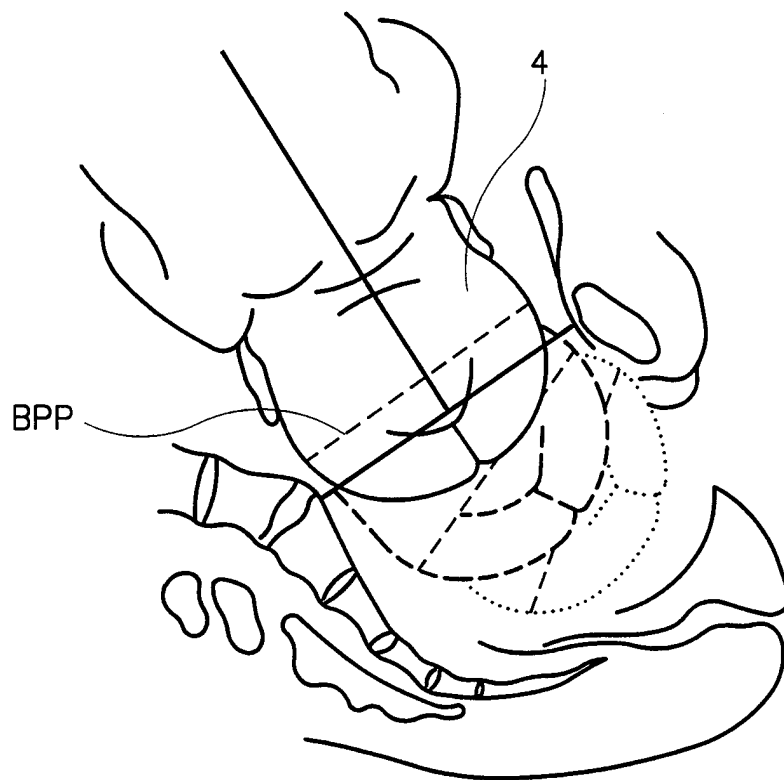


FIG.8

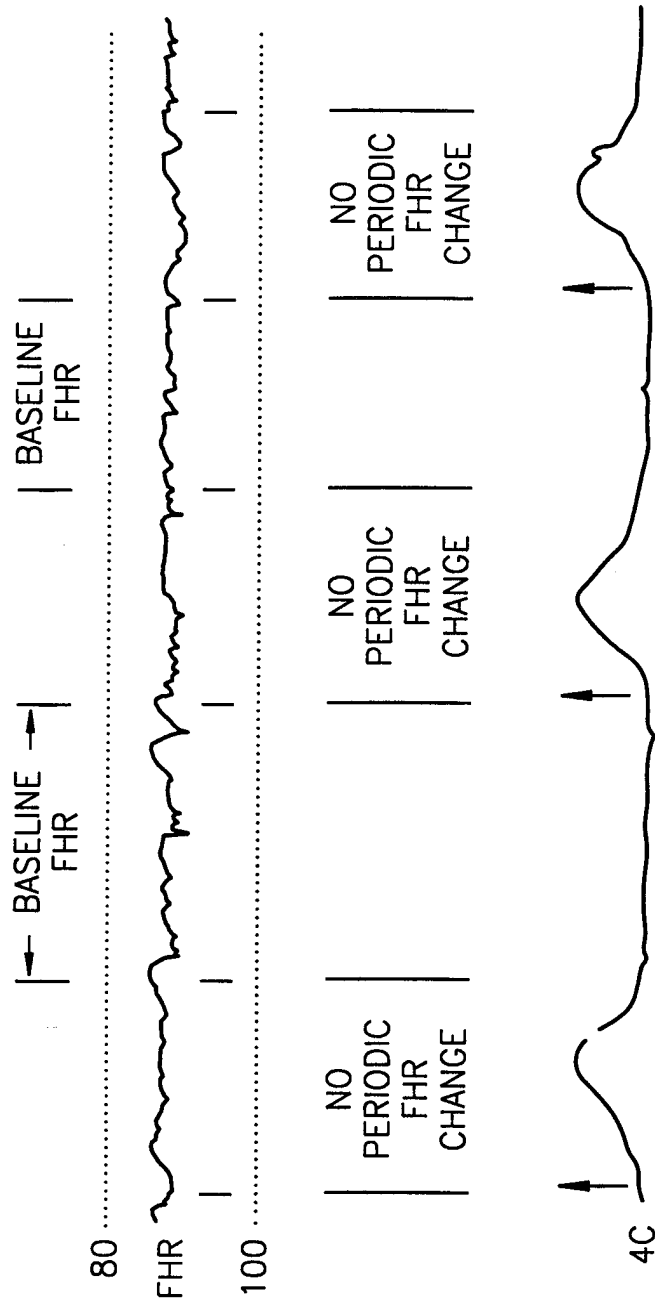


FIG.9

INTERNATIONAL SEARCH REPORT

International application No. _____
PCT/IL98/00208

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) : A61B 8/02
US CL : 600/437, 463
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. : 600/437, 453, 463

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)
APS

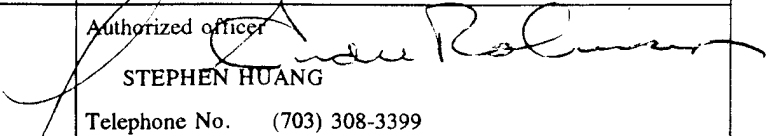
C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,222,485 A (JERATH) 29 June 1993, entire document.	1-36
A	US 5,088,497 A (IKEDA) 18 February 1992, entire document.	1-36

Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:	*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
A document defining the general state of the art which is not considered to be of particular relevance	*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
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P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 27 AUGUST 1998	Date of mailing of the international search report 16 SEP 1998
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