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(54) Title: CONTRACTION MONITORING BELT

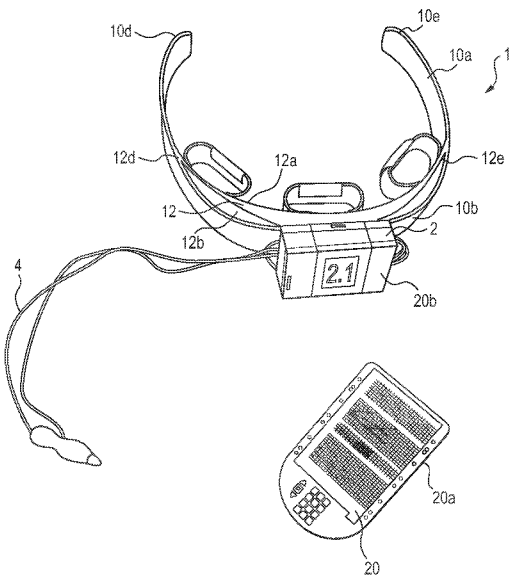

FIG. 1

(57) Abstract: A contraction monitoring belt (1) for monitoring the temporal variations in the uterine contractions a woman during her labor, includes: (1) a first elongated member (10) configured in a C-shape so as to encircle the abdominal region of the woman and to provide a spring-like tension between its ends (10d, 10e) so that it can snuggly fit around a woman's abdominal region, (2) a sensor (16) configured to detect electromygraphic (EMG) signals on the woman's abdominal surface and provide output data that quantifies the woman's uterine contractions, (3) a spring-like attachment (14) configured to attach between the belt and sensor and enhance the contact of the sensor with the woman's abdominal surface, and (4) the first elongated member (10) being fabricated from materials that can be quickly and easily sanitized so that the use of the belt (1) can be alternated between a plurality of women who are in labor.

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CONTRACTION MONITORING BELT

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of the following Provisional Patent Applications: No. 61/483,103 - filed May 6, 2011 which was filed by the present inventors. The teachings of this application are incorporated herein by reference to the extent that they do not conflict with the teaching herein.

BACKGROUND OF THE INVENTION

1. FIELD OF THE INVENTION

The present invention relates generally to medical diagnostic monitoring and testing. More particularly, the invention relates to a belt that is configured to be worn by a woman for measuring her maternal contractions during her labor period.

2. DESCRIPTION OF THE RELATED ART

Maternal health is a major health concern in developing countries. Deliveries outside of hospitals are very common in developing countries and their health care workers often receive minimal medical training and do not have at their disposal the sophisticated equipment that is commonly used by the health care workers in developed countries to assist them in managing the birthing process. This situation often results in delays in identifying complications when they arise and delays in providing in the proper, responsive health care that such complications warrant – often resulting in dire consequences. African women are 175 times more likely to die in childbirth than women in developed regions of the world.

A typical way to help identify the occurrence of complications that may arise during a woman's labor is to monitor and plot on especially-designed, record-keeping, graphical sheets or tables (e.g., a partograph or partogram) the temporary variations of various health parameters of the woman and her fetus (e.g., woman's pulse, temperature, number of contractions being experienced in a 10 minute interval, cervical size changes, level of protein in her urine, fetus' heart rate and distance of head descent). These parameters are then compared to those that are expected during a normal delivery and which are often pre-printed on the record keeping sheets to aid the comparison process. Around these temporal graphs of normal delivery parameters may also be shown boundary lines which, when crossed by the plot of the mother's or fetus' health parameters, help to alert a health care worker that complications may be beginning and that responsive action should be taken. The World Health Organization

(WHO) has been a leader in introducing the use of such partographs and these monitoring techniques in developing countries throughout the world.

One piece of equipment that it is helpful to use in the birth monitoring process is a "contraction monitoring belt," which, as the name suggests, aids in monitoring a woman's contractions during the birthing process. Today's typical contraction monitoring belt is usually part of a "cardiotocograph," a comparatively expensive piece of medical equipment that's more commonly known as an "electronic fetal monitor" and measures both uterine contractions and the fetal heartbeat. The belt portion of this piece of equipment is designed to wrap fully around a woman's belly and is fitted with a pressure-sensitive, contraction transducer, called a tocodynamometer (toco), that is connected to signal processing equipment which continuously monitors the temporal variation in her uterine contractions. The fetal heart monitor portion of this equipment uses an ultrasonic sensor that continuously emits ultrasound and detects motion of the fetal heart by the characteristics of the reflected sound.

Unfortunately, the limited resources of developing countries often results in the health care providers in these countries not being able to afford to use "electronic fetal monitor" and their contraction monitoring belts. Thus, there exists a need for an improved, low-cost, contraction monitoring belt that is suitable for use by heath care workers in developing countries. Such an improved, low-cost, contraction monitoring belt could help to reduce significantly maternal death rates in developing countries.

SUMMARY OF THE INVENTION

Recognizing the need for an improved, low-cost, contraction monitoring belt that is suitable for use by heath care workers in developing countries, the present invention is generally directed to overcoming the problems and disadvantages exhibited by existing contraction monitoring belt that have heretofore restricted their use in developing countries.

In accordance with the present invention, an improved contraction monitoring belt for monitoring the temporal variation in the uterine contractions a woman during her labor, includes: (1) a first elongated member configured in a C-shape so as to only encircle the abdominal region of the woman and to provide a spring-like tension between its ends so that it can snuggly fit around a woman's abdominal region, (2) a sensor configured to detect electromygraphic (EMG) signals on the woman's abdominal surface and provide output data that quantifies the temporal variations in her uterine contractions, and (3) a signal processor coupled to the sensor and configured to process the output data.

Further elements of this belt may also include: (4) a spring-like attachment means configured to attach between the belt and sensor and enhance the contact of the sensor with the woman's abdominal surface, (5) the first elongated member being fabricated from materials that can be quickly and easily sanitized so that the use of the belt can be alternated between a plurality of women who are in labor, (6) a second elongated member configured and attached to the first elongated member so as to further enhance the spring-like tension between the ends of the first elongated member, (7) a transfer device configured to connect to the signal processor and transfer the optimized output data to a data processing device, and (8) a data processing device configured to process said output data and display information pertaining to the temporal variations in the woman's uterine contractions during her labor.

Thus, there has been summarized above (rather broadly and understanding that there are other preferred embodiments which have not been summarized above) the

present invention in order that the detailed description that follows may be better understood and appreciated.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective, generally frontal view of a preferred embodiment of the present invention in the form of contraction monitoring belt.

FIG. 2 is a perspective, generally top view of a preferred embodiment of the present invention in the form of contraction monitoring belt.

FIG. 3 is a perspective, side view of a preferred embodiment of the present invention in which only the belt's main body and sensors are shown.

FIG. 4 is a perspective, side view of a preferred embodiment of a sensor that is suitable for use with the present invention.

FIG. 5 is a perspective, close-up view of a preferred embodiment of the sensors of the present invention and their attachment to the main body of the belt.

FIGS. 6A – 6B show an example of a "paper partograph."

FIG. 7 is a perspective view of a preferred embodiment of the electronic partogram that is suitable for use with the present invention.

DESCRIPTION OF THE PREFERRED EMBODIMENT

Before explaining at least one embodiment of the present invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and to the arrangements of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments and of being practiced and carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein are for the purpose of description and should not be regarded as limiting.

FIG. 1 shows a perspective view of a preferred embodiment of the present invention **1** in the form of a contraction monitoring belt **1**. It is shown here with a portable signal processing and data storage unit **2** which is especially sized so that it can be easily, detachably fitted to and worn on the belt **1**. This unit also has a data transfer device or means **4** for transferring data from it to an external electronic device or equipment **20** that can be used to further analyze and/or display the data or information transmitted from this unit.

The contraction monitoring belt **1** of the present invention includes a first, thin elongated member **10** that is C-shaped and has an inner **10a** and an outer **10b** surface, a middle section and two ends **10d**, **10e**. This belt is fabricated from suitable materials, preferably plastic, and configured so as to provide it with a spring-like tension between its free ends.

This configuration for this belt differs from that of today's current contraction belts which are configured to fit fully around the abdominal region and behind the back of a woman. This totally-enclosing-fit of current belts can be problematic when it is desired or necessary to quickly and easily put on or remove the otherwise standard or current contraction belt.

The improved belt of the current invention also has shorter, second, thin elongated member **12** that has an inner **12a** and an outer **12b** surface, a middle portion or section and two ends **12d**, **12e**. These ends **12d**, **12e** are attached to the inner surface of the first member and both of these members are joined together at a point on their middle sections. This configuration is seen to have the advantage of

providing for better and more reliable contact with the surface of a sensor that is being used to monitor the contractions of a woman whose abdominal surface is moving.

On the inner surface of this second, elongated member are affixed a number of loop members **14** or a spring-like attachment means; three of these are seen in the preferred embodiment of the present invention that is shown in FIGS. 1-4. These loop members are fabricated from construction materials that give them a spring-like tension between points on the opposite sides of their outer circumferential surfaces **14a** so as to enhance the contact of the sensor with the moving abdominal surface of a woman in labor.

Three, quasi J-shaped, EMG sensors **16** are located on the most inwardly projecting portion **14b** of the outer surface of each of these loops. These sensors monitor electromygraphic (EMG) signals on a woman's external abdominal surface. These sensors are seen to be quite different than the tocodynamometer sensors that have been used on prior contraction monitoring belts. The present invention's EMG sensors **16** are configured to aid in providing the best possible contact between the sensor's outer surface **16a** and the moving abdominal surface of a woman who is in labor. In the preferred sensor embodiment shown in FIG. 5, this is achieved by fabricating this sensor from a portion of a thin-walled, tubular, metallic (preferably steel) member which has one of its edges **16c** that lie parallel to its tubular axis bent inward at an angle in the range of 100 – 160 degrees so as to form the bottom a J-hook like portion of the sensor which can be used to help secure the sensor to the a loop's most inwardly projecting portion **14b**. See FIG. 6. In some instances, these sensors each have a quick-disconnect connector which allows them to be easily and quickly disconnected from the belt's loop member and the internal wiring that connects the sensors to the belt's power supply and/or its signal processing and data storage unit **2**.

The detachability of this belt's sensors and signal processing unit and the especially chosen materials of construction of the belts elongated members are unique attributes of the present invention. After the sensors and signal processing unit are removed, this allows the remaining portions of the belt to be easily cleaned and sanitized.

This proves to be a key advantage of the contraction monitoring belt of the present invention. In order to address the fact that it is desirable that the present

invention be designed such that it will be affordable for use in developing countries, the present invention has been designed so that it can be uniquely used in the health centers of developing countries that happen to be caring for multiple women, e.g., 2 – 5, who are relatively simultaneously in labor.

This improved belt's C-shaped configuration with spring-like tension between its ends means that it can be easily and quickly placed around and removed from the abdomen of a woman who is in labor. By removing a belt's sensors and signal processing unit, it can be easily and quickly sanitized – thereby making it possible to alternate its use among the multiple women being cared for in one of the health centers of a developing country. More particularly, the present invention is designed for use in busy labor rooms in developing countries, for multi-patient use and static measurements at 30 to 60 minute intervals.

The improved belt **1** of the present invention hugs a patient's abdominal region, securely pressing three, steel-plate sensors **16** or electrodes to the patient's skin, while not going around the patient's waist for easy donning and doffing of the belt. The belt's main body is one semi-rigid, waterproof plastic part that can be dipped in cleaning solution between its alternate use on multiple patients.

Its sensors are bent stainless steel plates, snapped onto the belt's inner plastic portions **14a**; thereby giving one the option of being easily replacing and/or maintaining these sensors. All three of them are detachably connected with wires to connectors located at the site where a signal processor **2** can be detachably affixed to the belt. Alternately, a means or housing can be fabricated into the belt and then used to contain an especially-designed circuit board for raw data filtering and initial processing.

An output connector from this circuit board can also be provided to allow the electronic signals and data from the belt to be transferred to external electronic equipment **20** for further processing or display. For example, this output signal can be fed into an appropriately configured, handheld, electronic version of the previously mentioned WHO-advocated partogram **6**. See FIG. 7.

The use of such a handheld "electronic partogram" **20a** is especially advantageous in developing countries where obstacles have arisen to the introduction of what we'll now call the previously discussed "paper partogram." See FIGS. 6A –

6B. The obstacles have included: (a) learning how to fill out the paper partogram can be difficult for minimally trained health care workers aunt, and (b) a health care worker or midwife may fail to see the benefit of the paper partogram, and when delivering multiple babies, she does not have or find the time to fill it out. The use of the present invention's electronic partogram overcomes these obstacles and increases the adoption of the maternal-death-rate-reducing techniques of monitoring, plotting and comparing the temporary variations of a woman and her fetus's health parameters with those expected during a normal delivery.

Such an electronic partogram can also be configured and programmed to receive the belt's output signal and thereby provide a graphical representation of the temporal variation in the uterine contractions of the woman during her labor. The electronic partogram may also include a telemetry or telemedicine module that communicates the belt's output signal to a distant location, e.g., a nearby hospital. Such devices are well known in the art and therefore will not be described further herein. This further inclusion allows physicians at the hospital to: (a) remotely monitor patients, (b) helps to improve the credibility of the local health care provider when she or he needs to request emergency support from the hospital, and (c) in response to the data received at the hospital, better advise local health care workers when complications arise and critical, responsive action needs to be taken.

Alternatively to the electronic partogram, the present invention may also include a custom-made, processing and display unit or module **20b** that is configured to process the output signal so that it can be directly expressed and displayed (e.g., on a LED display) as the temporal variations in a woman's number of contractions per unit time. This module can be configured so that it can be fitted directly to the belt or so that it exists as a stand-alone monitor that is external to the belt.

The contraction monitoring belt of the present invention extends the reach of quality obstetric care into undeveloped areas where maternal and fetal death rates are highest. By uploading data and making samples available as case studies, the collected data can also be used in training sessions and thereby serves an education tool for midwives in the field and other health care professionals.

The foregoing is considered as illustrative only of the principles of the present invention. Further, since numerous modifications and changes will readily occur to

those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described herein. Accordingly, all suitable modifications and equivalents may be resorted to, falling within the scope of the invention that are set forth in the claims to the invention.

CLAIMS

We claim:

1. A contraction monitoring belt (1), for monitoring the temporal variations in the uterine contractions a woman during her labor, comprising:

a first elongated member (10) configured in a C-shape so as to encircle the abdominal region of said woman, said first elongated member belt having an inner (10a) and an outer (10b) surface, and two ends (10d, 10e), said belt further configured to provide a spring-like tension between said ends so that said belt inner surface can snuggly fit around the abdominal region of any one of a number of women having a range of waist sizes,

a sensor (16) having an outer surface (16a) and configured to detect electromygraphic (EMG) signals on said woman's external abdominal surface and provide output data that quantifies said temporal variations in said uterine contractions, and

a signal processor (2) coupled to said sensor (16) and configured to process said output data.

2. The contraction monitoring belt as recited in Claim 1, further comprising:

a spring-like attachment means (14) configured to attach between said belt and sensor and enhance the contact of said outer surface (16a) of said sensor with said abdominal surface encircled by said first elongated member (10) during the movement of said abdominal surface as a result of said woman being in labor.

3. The contraction monitoring belt as recited in Claim 1, wherein:

said first elongated member (10) is fabricated from materials that can be quickly and easily sanitized so that the use of said belt (1) can be alternated between a plurality of women who are in labor.

4. The contraction monitoring belt as recited in Claim 2, wherein:

said first elongated member (10) is fabricated from materials that can be quickly and easily sanitized so that the use of said belt (1) can be alternated between a plurality of women who are in labor.

5. The contraction monitoring belt as recited in Claim 1, further comprising:

a second elongated member (12) having inner (12a) and outer (12b) surfaces and two ends (12d, 12e) and configured and attached to said first elongated member

(10) so as to further enhance said spring-like tension between said ends (10d, 10e) of said first elongated member.

6. The contraction monitoring belt as recited in Claim 2, further comprising:

a second elongated member (12) having inner (12a) and outer (12b) surfaces and two ends (12d, 12e) and configured and attached to said first elongated member (10) so as to further enhance said spring-like tension between said ends (10d, 10e) of said first elongated member.

7. The contraction monitoring belt as recited in Claim 3, further comprising:

a second elongated member (12) having inner (12a) and outer (12b) surfaces and two ends (12d, 12e) and configured and attached to said first elongated member (10) so as to further enhance said spring-like tension between said ends (10d, 10e) of said first elongated member.

8. The contraction monitoring belt as recited in Claim 4, further comprising:

a second elongated member (12) having inner (12a) and outer (12b) surfaces and two ends (12d, 12e) and configured and attached to said first elongated member (10) so as to further enhance said spring-like tension between said ends (10d, 10e) of said first elongated member.

9. The contraction monitoring belt as recited in Claim 1, further comprising:

a transfer device (4) configured to connect to said signal processor (2) and transfer said output data to an electronic device (20).

10. The contraction monitoring belt as recited in Claim 8, further comprising:

a transfer device (4) configured to connect to said signal processor (2) and transfer said output data to an electronic device (20).

11. The contraction monitoring belt as recited in Claim 1, further comprising:

an electronic device (20) configured to process said output data and display information pertaining to said temporal variation in the uterine contractions of said woman during her labor.

12. The contraction monitoring belt as recited in Claim 8, further comprising:

an electronic device (20) configured to process said output data and display information pertaining to said temporal variation in the uterine contractions of said woman during her labor.

13. The contraction monitoring belt as recited in Claim 11, wherein:

said electronic device (20) is chosen from the group consisting of an electronic partogram (20a) and a display unit (20b).

14. The contraction monitoring belt as recited in Claim 12, wherein:

said electronic device (20) is chosen from the group consisting of an electronic partogram (20a) and a display unit (20b).

15. The method of providing a contraction monitoring belt (1), for monitoring the temporal variation in the uterine contractions a woman during her labor, said method comprising the steps of:

providing a first elongated member (10) configured in a C-shape so as to encircle the abdominal region of said woman, said first elongated member belt having an inner (10a) and an outer (10b) surface, and two ends (10d, 10e), said belt further configured to provide a spring-like tension between said ends so that said belt inner surface can snuggly fit around the abdominal region of any one of a number of women having a range of waist sizes,

providing a sensor (16) having an outer surface (16a) and configured to detect electromygraphic (EMG) signals on said woman's external abdominal surface and provide output data that quantifies said temporal variations in said uterine contractions, and

providing a signal processor (2) coupled to said sensor and configured to process said output data.

16. The method of providing a contraction monitoring belt as recited in Claim 15, further comprising the step of:

providing a spring-like attachment means (14) configured to attach between said belt and sensor and enhance the contact of said outer surface (16a) of said sensor with said abdominal surface encircled by said first elongated member (10) during the movement of said abdominal surface as a result of said woman being in labor.

17. The method of providing a contraction monitoring belt as recited in Claim 15, wherein:

said first elongated member (10) is fabricated from materials that can be quickly and easily sanitized so that the use of said belt (1) can be alternated between a plurality of women who are in labor.

18. The method of providing a contraction monitoring belt as recited in Claim 16, wherein:

said first elongated member (10) fabricated from materials that can be quickly and easily sanitized so that the use of said belt (1) can be alternated between a plurality of women who are in labor.

19. The method of providing a contraction monitoring belt as recited in Claim 15, further comprising the step of:

providing a second elongated member (12) having inner (12a) and outer (12b) surfaces and two ends (12d, 12e) and configured and attached to said first elongated member (10) so as to further enhance said spring-like tension between said ends of said first elongated member.

20. The method of providing a method of providing a contraction monitoring belt as recited in Claim 16, further comprising the step of:

providing a second elongated member (12) having inner (12a) and outer (12b) surfaces and two ends (12d, 12e) and configured and attached to said first elongated member (10) so as to further enhance said spring-like tension between said ends of said first elongated member.

21. The method of providing a contraction monitoring belt as recited in Claim 17, further comprising the step of:

providing a second elongated member (12) having inner (12a) and outer (12b) surfaces and two ends (12d, 12e) and configured and attached to said first elongated member (10) so as to further enhance said spring-like tension between said ends of said first elongated member.

22. The method of providing a contraction monitoring belt as recited in Claim 18, further comprising the step of:

providing a second elongated member (12) having inner (12a) and outer (12b) surfaces and two ends (12d, 12e) and configured and attached to said first elongated member (10) so as to further enhance said spring-like tension between said ends of said first elongated member.

23. The method of providing a contraction monitoring belt as recited in Claim 15, further comprising the step of:

providing a transfer device (4) configured to connect to said signal processor and transfer said output data to an electronic device (20).

24. The method of providing a contraction monitoring belt as recited in Claim 22, further comprising the step of

providing a transfer device (4) configured to connect to said signal processor and transfer said output data to an electronic device (20).

25. The method of providing a method of providing a contraction monitoring belt as recited in Claim 15, further comprising the step of:

providing an electronic device (20) configured to process said output data and display information pertaining to said temporal variation in the uterine contractions of said woman during her labor.

26. The method of providing a contraction monitoring belt as recited in Claim 22, further comprising the step of:

providing an electronic device (20) configured to process said output data and display information pertaining to said temporal variation in the uterine contractions of said woman during her labor.

27. The method of providing a contraction monitoring belt as recited in Claim 25, wherein:

said electronic device (20) is chosen from the group consisting of an electronic partogram (20a) and a display unit (20b).

28. The method of providing a contraction monitoring belt as recited in Claim 26, wherein:

said electronic device (20) is chosen from the group consisting of an electronic partogram (20a) and a display unit (20b).

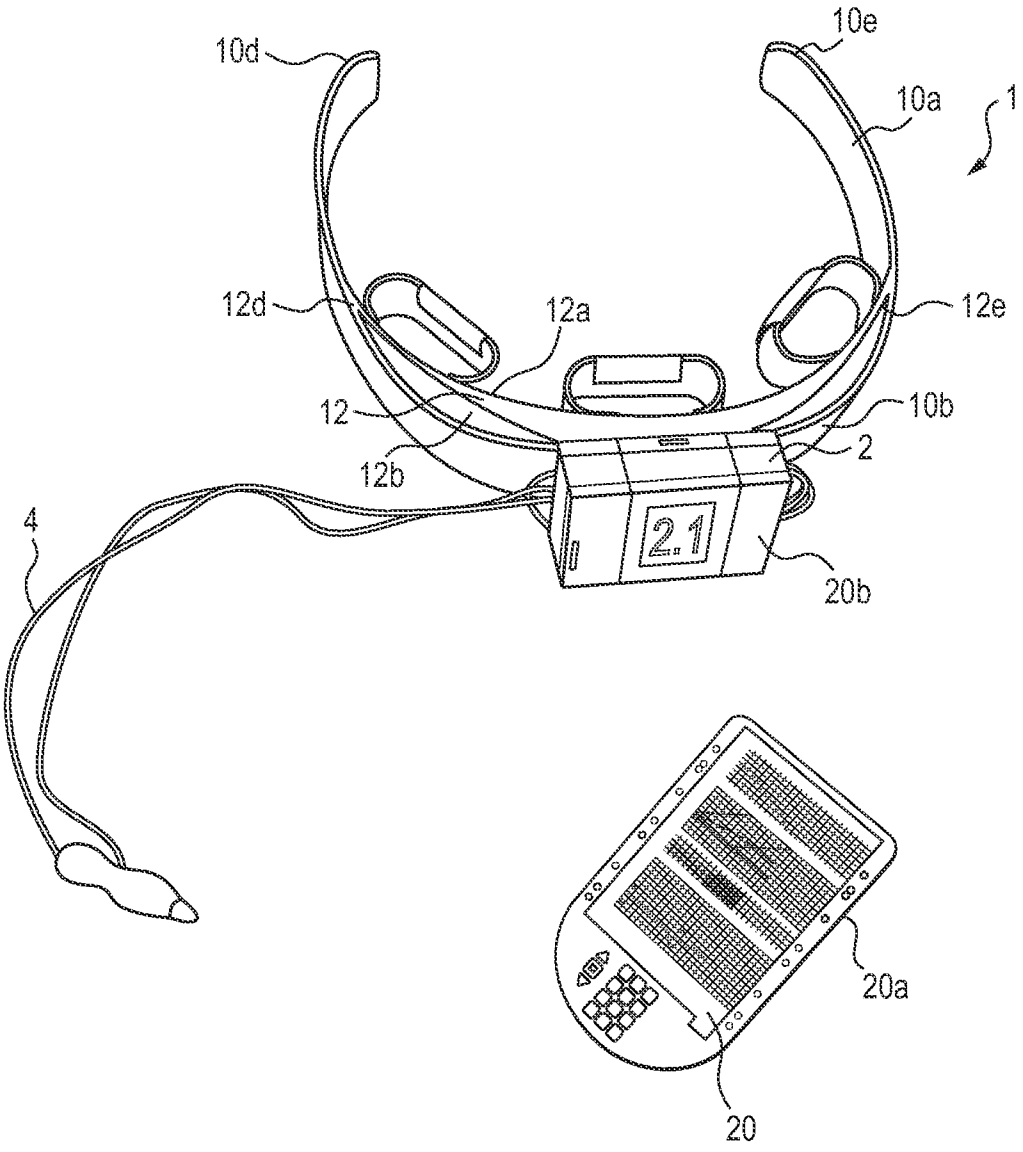


FIG. 1

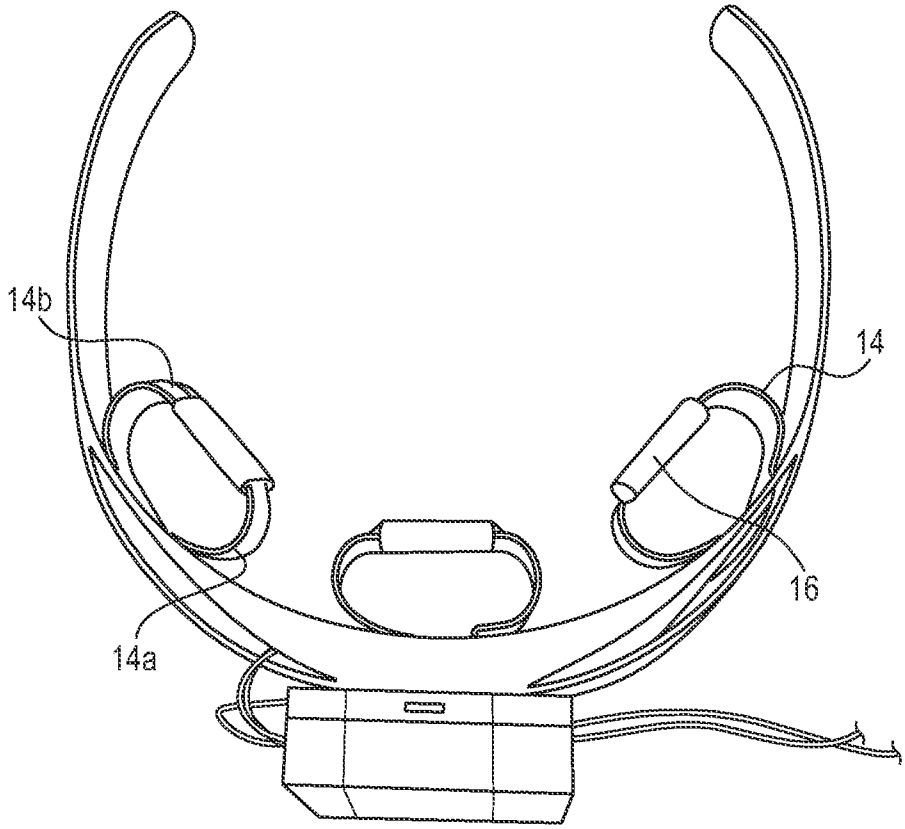


FIG. 2

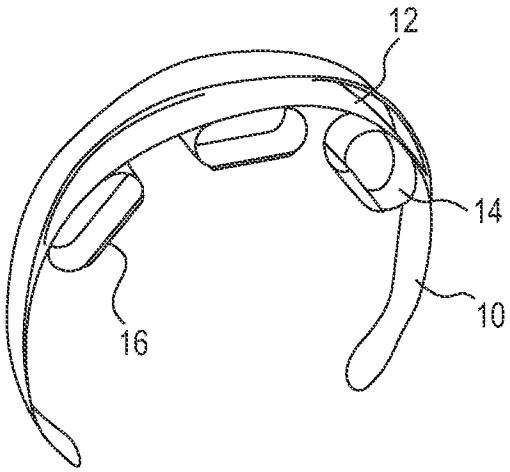


FIG. 3

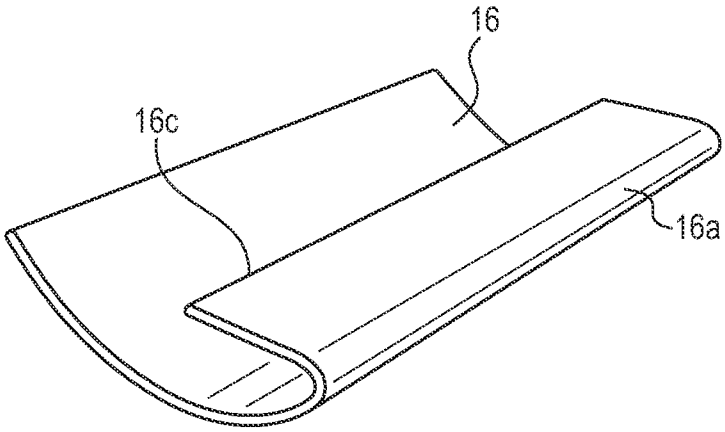


FIG. 4

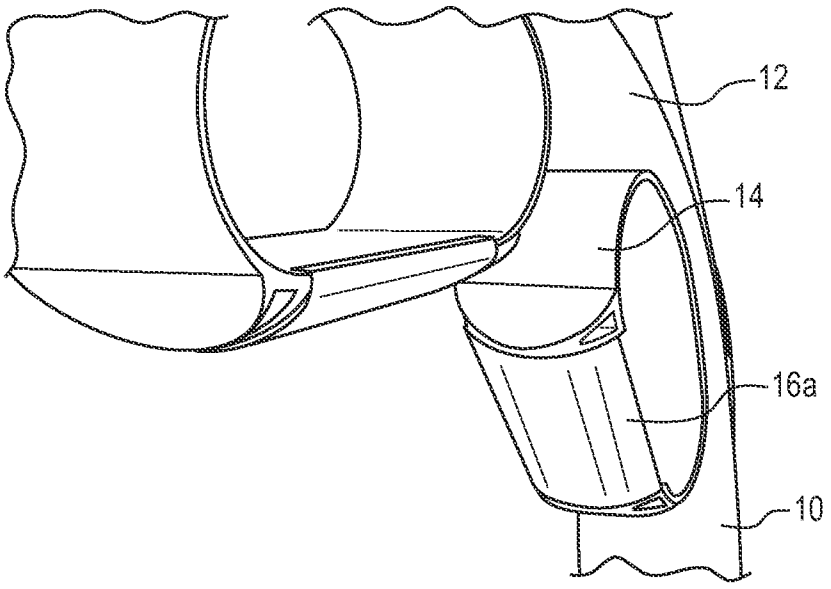


FIG. 5

FIG. 6A
FIG. 6B

FIG. 6

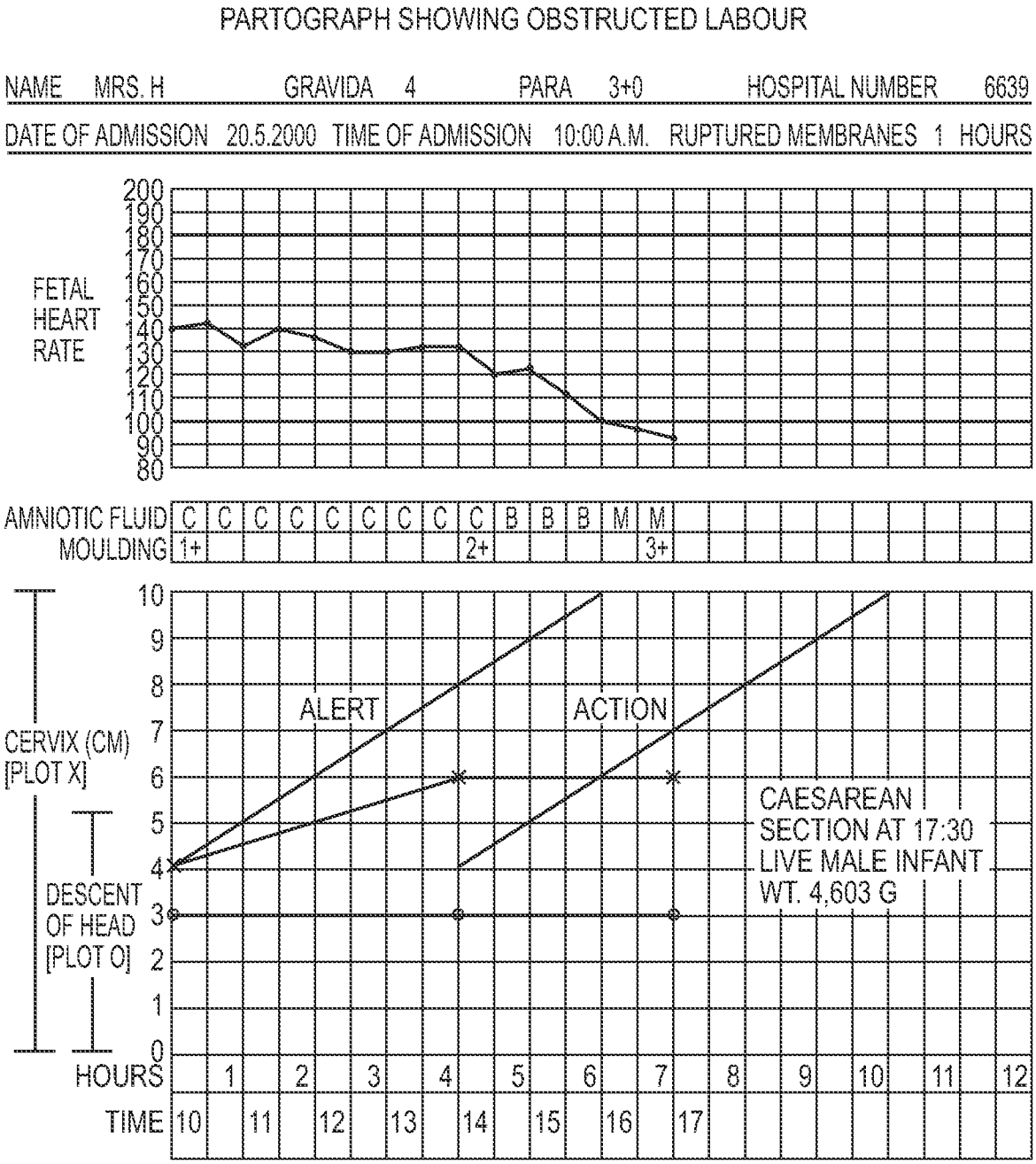
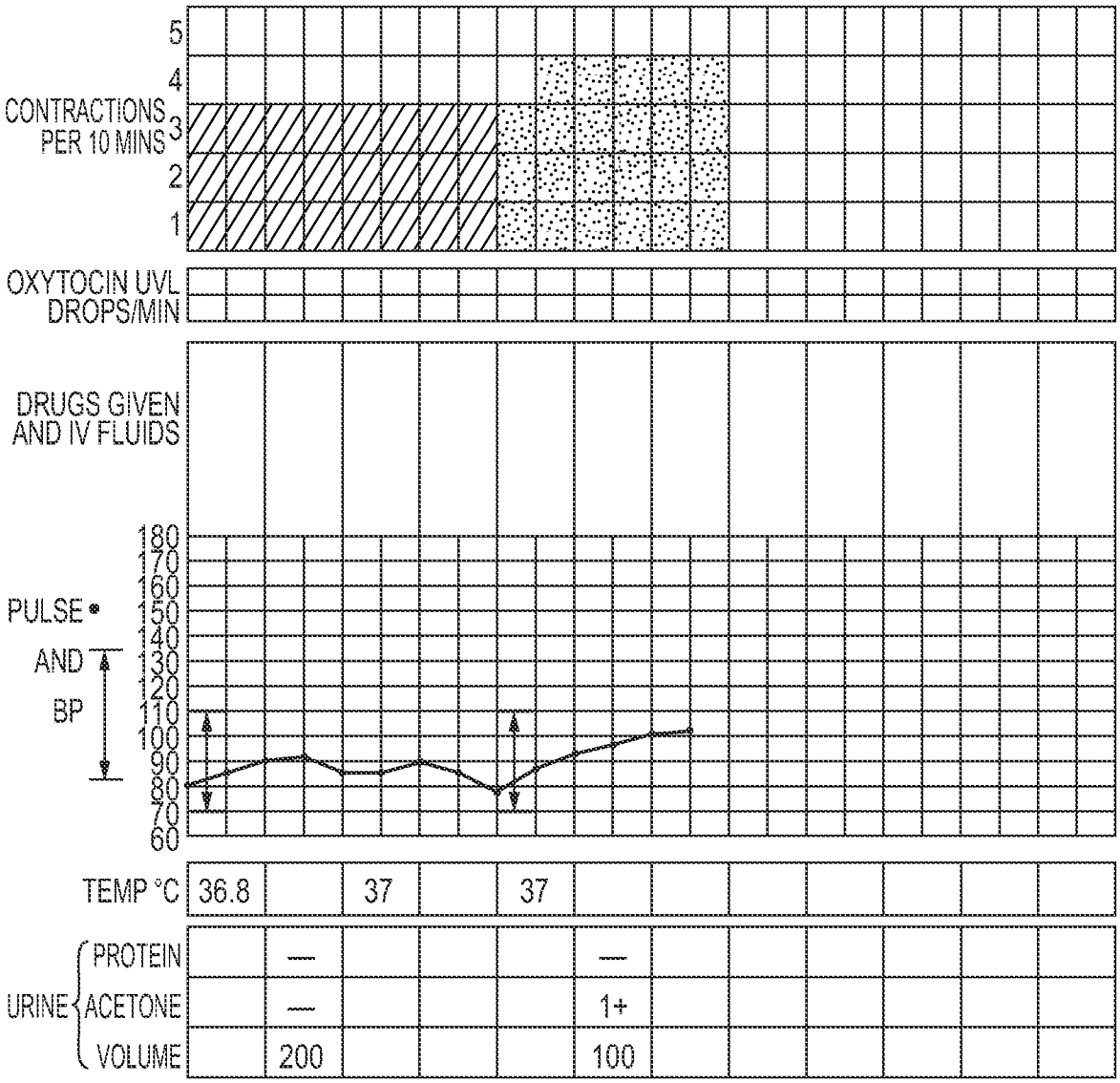


FIG. 6A


CONTRACTIONS PER 10 MINS
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4
3
2
1
OXYTOCIN UVL DROPS/MIN
DRUGS GIVEN AND IV FLUIDS
PULSE • AND BP
180
170
160
150
140
130
120
110
100
90
80
70
60
TEMP °C
36.8
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URINE
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200
—
1+
100

FIG. 6B

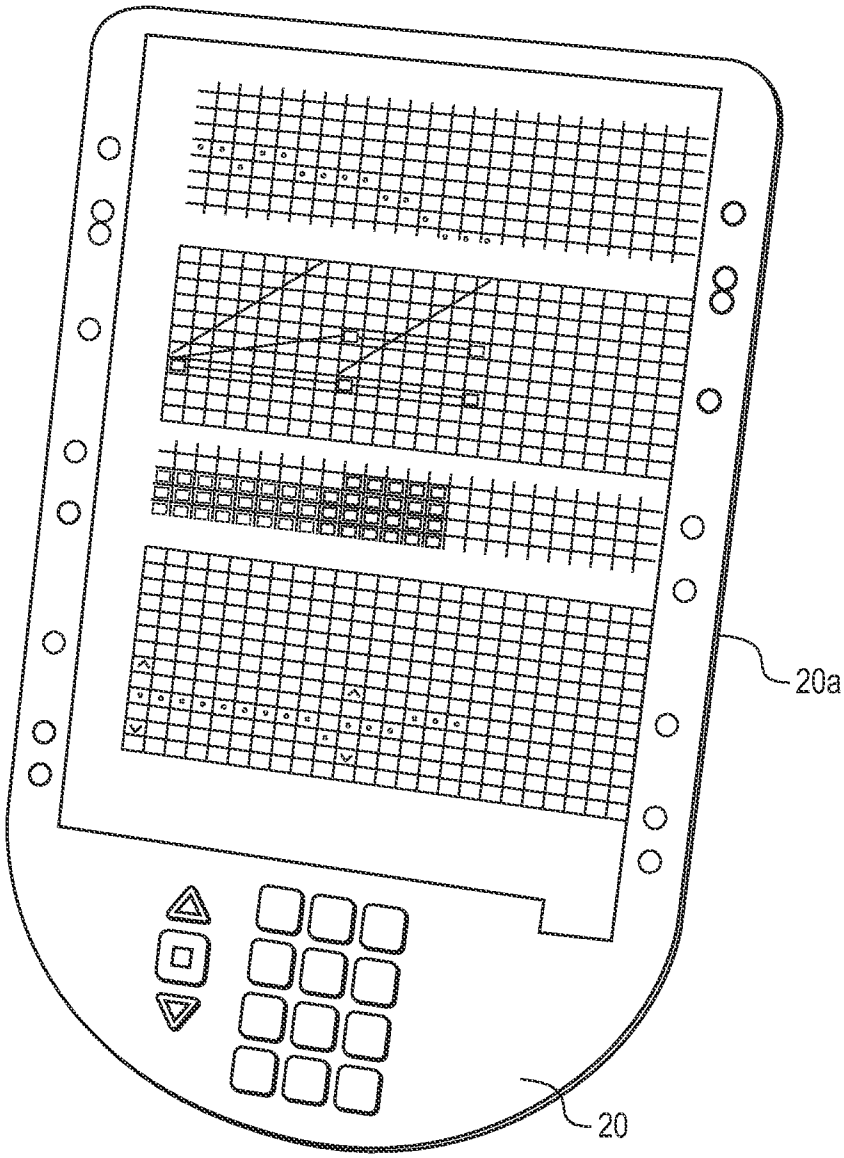

FIG. 7