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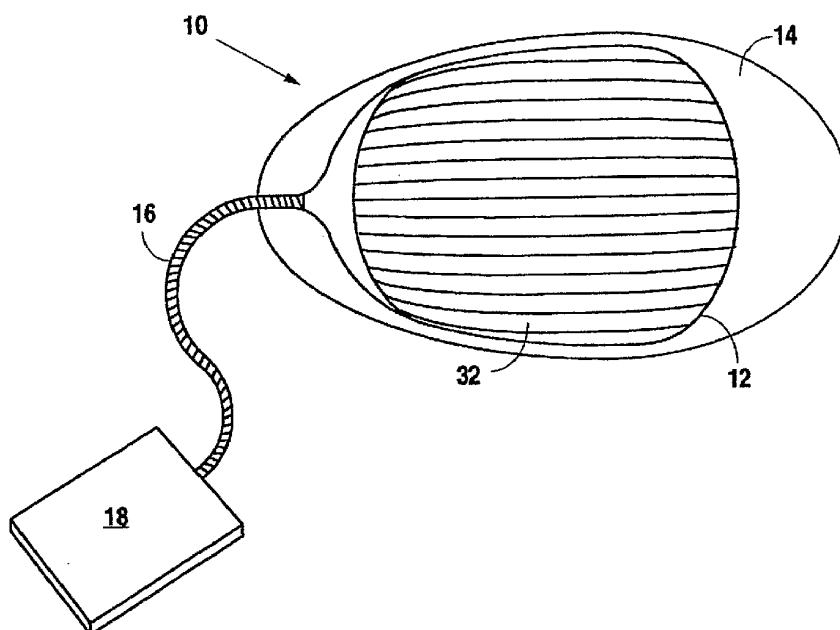
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[Continued on next page]

(54) Title: **BELTLESS LABOR CONTRACTION AND HEART RATE MONITORING APPARATUS**



(57) Abstract: A beltless device for monitoring labor contractions via a fiber optic cable and fetal heartbeats via an ultrasound sensor. The same or separate fiber optic cables may be used to provide a visual indication of labor contractions and fetal heartbeats. The device comfortably attaches to the abdomen of a pregnant mother and is preferably wireless to allow full mobility to the mother. The device may also be used to monitor heartbeats of children and adults.

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Title: Beltless Labor Contraction and Heart Rate Monitoring Apparatus

Inventor: Richard L. Watson, Jr.

Background of Invention

[0001] The present invention relates to a device for monitoring labor contractions during childbirth. Particularly, the present invention relates to a fiber optic labor contraction sensor adapted to adhere to a female's abdomen without the use of a belt or strap. More particularly, the beltless fiber optic labor contraction sensor includes a fiber optic strain sensor that generates an output signal in response to labor contractions and communicates the output signal to a signal transceiver. The signal transceiver is operable to communicate the incidence of labor contractions through radiotelemetry or other wireless communication.

[0002] During childbirth, both the strength and frequency of the mother's labor contractions are monitored. To monitor labor contractions, medical personnel typically utilize force-type strain gauges held against the mother's abdomen by an elastic belt placed around the mother's waist. In use, such monitors are, however, bulky and extremely uncomfortable. Further, conventional monitors are generally highly cumbersome and fail to provide the mother with mobility outside the bed during the birthing process. More specifically, a mother is normally restricted to the bed during childbirth and if the mother needs to exit the bed and move about, she must first remove the attached monitor. Another limitation of presently employed monitoring devices is the limited range of mobility afforded the mother due to the signal cables connecting the monitoring device to a contraction recording system.

[0003] The problems described above are not intended to be exhaustive but are merely a few of those tending to reduce the effectiveness of the monitors presently used to detect labor contractions. These problems demonstrate that presently used monitors are not satisfactory and illustrate further the need for an improved device for detecting labor contractions.

[0004] As is known in the art, the heart rate of a fetus may be determined by using an

ultrasound transducer to measure the Doppler shift of an ultrasound signal reflected from the moving fetal heart. Such ultrasound fetal heart rate measurements are described, for example, in U.S. Patent No. 6,379,305 (Eugley), U.S. Patent No. 5,827,969 (Lee et al. I), U.S. Patent No. 5,640,960 (Jones et al.), U.S. Patent No. 5,630,418 (Lee et al. II), U.S. Patent No. 5,289,820 (Beach et al. I), U.S. Patent No. 5,183,046 (Beach et al. II), U.S. Patent No. 5,170,791 (Boos et al.), U.S. Patent No. 5,088,498 (Beach et al. III), U.S. Patent No. 4,890,624 (Ganguly et al.), U.S. Patent No. 4,569,356 (Kyojuka), U.S. Patent No. 4,503,861 (Entrekin), U.S. Patent No. 4,413,629 (Durley), U.S. Patent No. 4,143,650 (Hatke), and U.S. Patent No. 3,991,365 (Takeuchi), for each of which the entire disclosure thereof is incorporated herein by reference. However, known ultrasound devices used for measuring fetal heart rate have several drawbacks. For example, ultrasound devices typically used by obstetricians in their offices generally involve bulky, cabinet-type or cart-mounted devices having a wand or probe that the obstetrician places on the abdomen of the pregnant mother, usually with some gel to enhance the performance of the ultrasound transducer. In addition to being bulky and limited in mobility, such devices require the presence and attention of the obstetrician during operation. Although some portable, hand-held ultrasound devices are commercially available for use at home, such as the Belly Beats™ fetal Doppler heart monitor described at www.bellybeats.com or the Sweetbeats™ fetal Doppler heart monitor described at www.sweetbeats.net, such hand-held devices require the mother or another person to apply a gel and hold the wand in place on the mother's abdomen much like the more sophisticated devices used by obstetricians. Additionally, although such devices are portable, they are cumbersome to carry around and are not suitable for continuous use.

[0005] Accordingly, it would be a significant improvement in the art to provide an ultrasound fetal heart rate monitoring device that could be comfortably applied to a pregnant mother's abdomen for continuous use without the need for the application of a special gel or the attention of a health care professional during use.

Summary of Invention

[0006] In accordance with the present invention, a labor contraction sensing device includes a fiber optic strain sensor that is adhered to the mother's abdomen for detecting the strength and frequency of labor contractions during childbirth. The fiber optic strain sensor is in signal communication with a signal transceiver having a signal transmitter that is preferably in wireless communication with a standard contraction recording device or other monitoring equipment.

[0007] Therefore, in accordance with a general embodiment of the present invention, there is provided a fiber optic strain sensor including at least one fiber optic cable having first and second ends. A light source is located at one end of the fiber optic cable for transmitting a light beam through the fiber optic cable to the opposite end of the fiber optic cable. A light detector is located at the opposite end of the cable for detecting fluctuations in the transmitted fiber optic light beam. In operation, any external forces acting against the fiber optic cable, such as the tightening of the mother's abdomen due to the onset of a contraction, results in changes in the optical signal of the transmitted light beam. These fluctuations are detected by the light detector and an appropriate output signal is generated by optical signal processing electronics. The sensor output signal is communicated to a signal transceiver, which includes a signal receiver and transmitter. The same fiber optic cable or a separate fiber optic cable may also be used to provide a visual indication of the labor contraction.

[0008] In a further embodiment, the signal transmitter is a radio transmitter. Utilizing a radio transmitter as the signal transmitter provides the user with wireless communication between the labor contraction sensing device and a standard contraction recording system. Additionally, the fiber optic strain sensor is specially designed to be adhered to the mother's abdomen without the use of a belt. Specifically, the fiber optic strain sensor preferably includes an adhesive surface or is placed within an adhesive cover or jacket that allows the fiber optic strain sensor to be conveniently and comfortably adhered to the abdomen of the mother. The beltless design together with wireless communication provides a labor contraction sensing device that offers increased mobility to the expecting mother relative to existing contraction sensing devices. The labor contraction output signals may be indicated via an output device either locally at the labor contraction sensing device or remotely at a separate monitoring station.

[0009] In another embodiment, an ultrasound fetal heart rate monitoring apparatus is provided with an adhesive pad for adhering the apparatus to the abdomen of a pregnant female without the use of a belt. An ultrasound transducer and associated electronics within the apparatus are operable to measure the fetal heart rate according to methods known in the art. Output signals representative of the fetal heart rate may be indicated at the apparatus itself via a visual display or a speaker, for example, or the output signals may be transmitted via a wireless signal transmitter to a remote monitoring station, such as a nurse's station. The apparatus may also include a fiber optic cable or other light-generating member for providing a visual indication of the fetal heartbeat. The apparatus may also be used to monitor the heart rate of other living individuals, such as children and adults, by placing the apparatus on the

body of such individuals, preferably on the chest, side, or back.

[0010] In yet another embodiment, both a fiber optic labor contraction sensor and an ultrasound transducer are provided in an apparatus having an adhesive pad for attaching the apparatus to the abdomen of a pregnant female without the use of a belt. Separate fiber optic cables may be used for monitoring labor contractions and providing a visual indication of the fetal heart rate, or the same fiber optic cable may be used both for sensing labor contractions and providing a visual indication of the fetal heartbeat. The fetal heartbeat output signals may be indicated via an output device either locally at the ultrasound fetal heart rate sensing device or remotely at a separate monitoring station.

Brief Description of Drawings

[0011] FIG. 1 is a top perspective view of a labor contraction sensing device in accordance with the present invention.

[0012] FIG. 2 is a side perspective view of the labor contraction sensing device of FIG. 1.

[0013] FIG. 3 is a partially cross-sectional, partially schematic top view of the labor contraction sensing device illustrated in FIG. 1.

[0014] FIG. 4 is a cross-sectional side view of a preferred embodiment of a labor contraction sensing device in accordance with the present invention installed on the abdomen of a pregnant female.

[0015] FIG. 5 is a cross-sectional side view of an alternative embodiment of a labor contraction sensing device in accordance with the present invention installed on the abdomen of a pregnant female.

[0016] FIG. 6 is a top perspective view of a fetal heart rate monitoring device in accordance with the present invention.

[0017] FIG. 7 is a cross-sectional side view of the fetal heart rate monitoring device of FIG. 6 taken in the direction of arrows 7-7.

[0018] FIG. 8 is a cross-sectional side view of an alternative fetal heart rate monitoring device in accordance with the present invention.

[0019] FIG. 9 is a perspective view of the electronics box and fiber optic cable connection of the device of FIG. 8.

[0020] FIG. 10 is a top view of a portion of a combined labor contraction and fetal heart rate monitoring device in accordance with the present invention showing one preferred layout of fiber optic cables therein.

[0021] FIG. 11 is a top view of a portion of a combined labor contraction and fetal heart rate monitoring device in accordance with the present invention showing an alternative layout of fiber optic cables therein.

[0022] FIG. 12 is a cross-sectional side view of another embodiment of a combined labor contraction and fetal heart rate monitoring device in accordance with the present invention.

[0023] FIG. 13 is a top perspective view of yet another embodiment of a combined labor contraction and fetal heart rate monitoring device in accordance with the present invention.

[0024] FIG. 14 is a schematic block diagram of a fetal heart rate monitoring device in accordance with the present invention.

[0025] FIG. 15 is a schematic block diagram of a combined labor contraction and fetal heart rate monitoring device in accordance with the present invention.

[0026] FIG. 16 is a top view of another embodiment of a fetal heart rate monitoring device in accordance with the present invention.

[0027] FIG. 17 is a side view of the fetal heart rate monitoring device of FIG 16.

[0028] FIG. 18 is cross-sectional view of the fetal heart rate monitoring device of FIG. 16 taken in the direction of arrows 18-18.

[0029] FIG. 19 is a schematic view showing the fetal heart rate monitoring device of FIG. 16 placed on the abdomen of a pregnant female.

Detailed Description

[0030] Before describing the invention, it should be first understood that the term "fiber optic strain sensor" can refer to any optical detection system utilizing fiber optics, wires, lines, or cables through which a light beam is passed and fluctuations or changes in that light beam caused by the external application of force upon the system are identified as changes in the transmitted optical signal. Similarly, as used herein, the term "fiber optic cable" should be understood to mean any optical transmission line through which a light beam may be passed. As used herein, the term "communication" should be understood to encompass direct or indirect communication. That is, two components that are said to be in communication with one another may be in direct communication with each other without any intermediate components, or the two components may be in indirect communication with each other through one or more intermediate components. Also, as used herein, the term "light-generating member" should be understood to mean any device that is capable of producing light. Similarly, the term "sound-generating member" should be understood to mean any device that is capable of producing sound. The term "computer processor" as used herein should be understood to mean any electronic information processor, including but not limited to a microprocessor, a digital signal processor, or the like. As used herein, the term "output device" should be understood to mean any device that is capable of producing an indication of an event or condition, whether by sound, light, vibration, smells, or any other indication susceptible of sensory perception.

[0031] Referring to FIGS. 1 through 5, there is shown embodiments of a labor contraction sensing device (10) of the present invention. As illustrated in FIG. 1, a contraction sensing device (10) embodying the present invention comprises a fiber optic strain sensor (12) having a generally elliptical shape to better conform to the contour of the mother's abdomen. The strain sensor (12) is secured to an adhesive pad (14) that provides removable attachment of the strain sensor (12) to the mother's skin surface (44). As discussed below, a signal line (16) provides communication between the sensor electronics housed in an electrical box (18) and the fiber optic portion of the strain sensor (12). In a preferred embodiment, the electronics box (18) houses a wireless signal transmitter (28) for transmitting an output signal that corresponds to the labor contractions detected by the strain sensor (12). In use, the mother's movement is therefore not restricted by one or more communication lines extending between the device (10) and a standard contraction recording device as are present with standard contraction monitoring systems.

[0032] Referring to FIG. 2, there is illustrated a side view of the contraction sensing device (10). As shown, the strain sensor (12) and underlying adhesive pad (14) are preferably thin. Such a narrow design is not bulky or cumbersome, and thus it reduces user discomfort associated with traditional contraction monitoring systems. Though the preferred embodiment is designed to be narrow in thickness, multiple surface shapes and configurations can be used without deviating from the scope of the present invention. For instance, the sensing device (10) can have rectangular or circular surfaces. Alternatively, the sensing device (10) can be fabricated with different surface portions having alternate shapes for conforming to varying contours of the abdominal surface. It is preferable, however, that the strain sensor be fabricated as narrow as possible to maximize user comfort.

[0033] Referring to FIGS. 1 and 2, a signal line (16) provides communication between the strain sensor (12) and the electronics box (18). Within the electronics box (18) is framed the components necessary to inject a light beam through the fiber optic cable (20) of the strain sensor (12), which is preferably located within signal line (16), and to detect any fluctuations in the optical signal. Such components include a light source, light detector and optical signal processing electronics. A preferred embodiment includes a wireless signal transmitter (28) operable to communicate with a contraction recording device. Such contraction recording devices are well known in the art and one skilled in the art would readily know how to place the recording device in wireless communication with the signal transmitter.

[0034] As shown in FIG. 3, the preferred strain sensor (12) includes a fiber optic cable (20) embedded within a sensor cover (32). In another embodiment (not shown), some or all of the electronic components, including a light source, light detector, optical signal processing electronics and power supply may be embedded within the sensor cover (32). The sensor cover (32) is preferably fabricated from soft flexible plastic; however, any other material that is flexibly responsive to labor induced changes in the surface contour of the mother's abdomen can be used. For instance, materials suitable for use in the present invention include rubber, fabric, nylon mesh, or other like materials. As will be appreciated from further descriptions of the alternative embodiments described herein, the fiber optic sensor (12) may be held against the skin surface (44) by a conventional drape (not shown). More particularly, the drape is shaped to overly the sensor (12) and the perimeter of the drape is adapted to engage the skin surface (44) so that the sensor (12) is held firmly against the skin surface (44).

[0035] As illustrated in FIG. 4, a preferred embodiment of the present invention provides unitary fabrication of the strain sensor (12) and adhesive pad (14). Particularly, the adhesive pad (14) and sensor (12) are made as a single component for more cost effective fabrication

and convenient disposal following use. As shown, a preferred adhesive pad (14) includes a lower adhesive surface (36a) and upper cover surface (36b). The upper and lower surfaces (36a-b) of the adhesive pad (14) are joined together to form a sensor jacket (22) defining an interior compartment or pouch (54) for holding the electronics box (18) and any other necessary components. Referring to FIGS. 3 and 4, the inner edge of the lower surface (36a) of the adhesive pad (14) is preferably attached about the outer edge (48) of the sensor cover (32) using commonly known welding or stitching techniques. In embodiments of the present invention, many of the components, including the sensor jacket (22), sensor cover (32) and adhesive pad (14) can be formed from single or multiple layers of a flexible polymer sheet (or drape), or mesh fabric. A suitable material for forming these components is a clear polymer sheet sold under the tradename "TEGADERM" from Minnesota, Mining and Manufacturing Company, which is commonly known as 3M. As the preferred embodiment in FIG. 4 illustrates, adhering the pad lower surface (36a) directly to the mother's skin surface (44) allows the lower surface (50) of the sensor (12) to be positioned substantially adjacent to the mother's skin surface (44). In this embodiment, the sensor lower surface (50) can also have an adhesive surface for providing further attachment to the skin surface (44).

[0036] In a further embodiment (not shown), the components housed in the electronics box (18) are embedded together with the fiber optic cable (20) within the sensor cover (32) to form the sensor (12). In use, the sensor (12) is positioned against the mother's skin surface (44) and a drape material such as the polymer sheet described above is placed in overlying relation to the sensor (12). The perimeter of the drape material is then adapted to engage the mother's skin surface (44) such that the sensor (12) is held against the mother's abdomen.

[0037] In an alternative embodiment, shown in FIG. 5, the sensor (12) is held within a sensor jacket (52) in overlapping relation to the adhesive pad (14). In this embodiment, the adhesive pad (14) is provided with an upper adhesive surface (34a) for holding the sensor (12) and a lower adhesive surface (34b) for adhering to the mother's skin (44). Providing pad (14) with an upper adhesive surface (34) allows for the removable detachment of the strain sensor (12) from the adhesive pad (14), thereby enabling the user to recycle the strain sensor (12) together with a new adhesive pad (14). It should be understood by those skilled in the art, however, that a variety of sensor (12) and adhesive pad (14) configurations and combinations can be used without deviating from the scope of the present invention. Thus, the sensor (12) and pad (14) can be detachably connected or fabricated as an integral component.

[0038] The electronics box (18) is preferably not fabricated as a disposable component. As such, the electronics box (18) can be provided with an adhesive surface (46) for adhering to the

box (18) to the surface of the sensor cover (32), or alternatively, for adhering the electronics box (18) directly to the mother's skin surface (44). Referring to FIG. 4, the electronics box (18) can be releasably positioned within the pouch (54) of the sensor jacket (22). In this way, the user of the device (10) simply inserts the electronic box (18) into the jacket pouch (54) and plugs the signal line (16) into a socket (56) to connect the fiber optic cable (20) with the electronics box (18), which houses the light source (30), light detector (24) and signal transceiver (42). As shown in FIG. 3, the box (18) is preferably provided as a component apart from the sensor (12). In either embodiment shown in FIGS. 3 and 4, however, the electronics box (18) can be readily unplugged from the fiber optic cable (20) or signal line (16) and the used sensor (12), pad (14) and/or jacket (22) properly disposed of. Though it is envisioned that the electronics box (18) is fabricated as a separate component, the electronics could be provided as an integral component of the device (10) without deviating from the scope of the present invention.

[0039] Referring to FIG. 3, the strain sensor (12) preferably comprises a fiber optic cable or other optical transmission line (20) embedded within a sensor cover (32). The fiber optic cable (20) has a first end (38) and a second end (40). The fiber optic cable (20) can be any typical fiber optic cable or other optical transmission line known to those skilled in the art. A light source (30) is positioned adjacent to the first end (38) for transmitting a light beam or optical signal through the fiber optic cable (20). Positioned adjacent to the second end (40) of the fiber optic cable (20) is a light detector (24a) and signal decoder (24b) for monitoring variations in the optical signal as it passes through the fiber optic cable (20). In this way, the light source (30) transmits a light beam through the fiber optic cable (20) and any external applications of force against the cable (20), such as the force of a labor contraction, results in fluctuations in the optical signal that are identified by the light detector (24a) as changes in the optical signal. A signal decoder (24b) is operable to decode the identified optical signal and generate an appropriate response, such as an electrical output signal, that is transmitted to a signal transceiver (42).

[0040] In the preferred embodiment, the signal transceiver (42) comprises a signal receiver (26) in communication with a signal transmitter (28). The signal receiver (26) is operable to transmit the output signal received from the signal decoder (24b) to the signal transmitter (28). In its preferred embodiment, the signal transmitter (28) is a radio transmitter in wireless communication with a standard contraction recording device. However, other wireless communication devices can be used without deviating from the scope of the present invention.

[0041] It is well known to those skilled in the art that any number of light sources (30) can be used with the present invention. Such light sources (30) include light emitting diodes. For instance, an infrared laser diode is a suitable light source for use with the present invention. The present invention further includes a light detector (24a) responsive to changes in light beam emitted by the light source (30). Again, it is well known in the art that a wide variety of light detectors can be incorporated for use with the present invention. For example, the light detector (24a) can be a phototransistor, a photocell, a photosensitive diode or any other suitable light detector known in the art. Additionally, the signal decoder (24b) can include any of the various optical signal processing electronics known in the art. It should be understood, however, that in a broad sense the signal decoder (24b) is operable to convert into an appropriate output signal any change in the optical signal detected by the light detector (24a).

[0042] In a preferred embodiment, the signal transmitter (28) is a radio transmitter or other like wireless signal transmitter. Again, it is well known to those skilled in the art the extensive variety of radio transmitters that can be used in the present invention. In a preferred embodiment, the radio transmitter bandwidth is unique to the particular contraction recording device so as to prevent interference of the radio signal with other radio transmitting labor contraction devices (10) that may be in use. In this embodiment, the signal transmitter (28) can also provide communication with other monitoring equipment besides the contraction recording device. For instance, the transmitter (28) can be in communication with computer analysis equipment located at the nurses station or other remote location. It should also be understood that the transmitter (28) should provide a sufficient range of communication between the device (10) and the monitoring equipment to allow the mother to move freely about during the childbirth process. For example, a preferred transmitter (28) allows the mother to move outside the hospital room or about her own house during childbirth. Signal transmitters (28) providing the required range of communication distance are well known in the art.

[0043] As illustrated by FIG. 3, the fiber optic strain sensor (12) preferably comprises a single loop of fiber optic cable (20). When the cable (20) is not subject to external forces, the optical signal transmitted through the cable (20) is assigned a normal value. Upon the application of force, such as with a labor contraction, the cable (20) is distorted from its normal shape and a change in the optical signal of the light transmitted through the cable occurs. This change is detected by the light detector (24) and the signal is assigned a new value. It should therefore be understood that the present invention covers within its scope the use of more than one fiber optic cable (20) to amplify any changes in the optical signal. More specifically, for example, a fiber optic sensor (12) can be provided having multiple fiber optic

cables placed in parallel, wherein each individual cable (20) can be positioned at varying locations along the surface of the mother's abdomen. Additionally, more than one detector and/or light source can be utilized without deviating from the scope of the present invention.

[0044] It should be understood by those skilled in the art that power for the present invention can be provided by way of a standard power source (not shown). Importantly, the power source should be sufficient to provide continuous power to the device (10) for the entire period of labor. Suitable power sources generally include a battery pack comprising cadmium oxide or silver oxide batteries. It is clear, however, that the utilized batteries should be sized to allow packaging within the electronics box (18) or other placement so as to not limit patient mobility.

[0045] Referring to FIGS. 6, 7 and 14, a beltless ultrasound fetal heart rate sensing device (60) is shown having an electronics box (66) that contains, among other things, an ultrasound transducer (148). Ultrasound transducer (148), which preferably comprises one or more piezo-electric crystals as known in the art, may be any type of device that is capable of transmitting ultrasound waves toward the fetal heart. For example, the ultrasound transducer of the Corometrics™ 170 series fetal monitors available from General Electric could be adapted for use in the present invention. Electronics box (66) is preferably connected to a fiber optic cable (64), which is preferably embedded in a flexible pad (62) having a translucent top layer (82) and a lower layer (84) that may be translucent or opaque. Flexible pad (62) is preferably made of a soft, flexible plastic, much like sensor cover (32) described above. Pad (62) may also be made of any other suitable material that is adaptable for conforming to the contour of the mother's abdomen, such as rubber, fabric, or other similar materials. An adhesive layer (80) is preferably provided underneath the lower layer (84) of pad (62) for affixing device (60) to the abdomen of a pregnant female without the use of a belt. Adhesive layer (80) preferably has a peel-off backing (not shown) as is known in the art. Alternatively, lower layer (84) may be made of a type of plastic that readily adheres to skin. As shown in FIG. 6, pad (62) preferably has a generally elliptical shape for better conforming to the contour of the mother's abdomen, but any other suitable shape may also be used. A gel pad (78) is preferably provided underneath electronics box (66) to enhance the performance of the ultrasound transducer (148), much like traditional gels or lotions that are used with conventional ultrasound devices, except that gel pad (78) is more convenient because it is self-contained and not as messy as a traditional gel or lotion. For example, gel pad (78) may be made from defibrillator pads such as stock number 2346N available from 3M™ (Minnesota Mining & Manufacturing).

[0046] Referring more particularly to FIG. 14, electronics box (66) preferably has a power

supply (140), such as a battery, preferably a rechargeable battery, which supplies power to a microprocessor (142) and other electronic components within electronics box (66). A memory unit (146) may be provided in electronic communication with microprocessor (142) for storing information generated by device (60) as discussed further below. An input/output (I/O) unit (144) is also preferably provided in electronic communication with microprocessor (142) to facilitate control of device (60) by the user and output of information to the user according to methods well known in the art. Ultrasound transducer (148), which is controlled by microprocessor (142), transmits ultrasound waves which are reflected off the moving fetal heart, and the reflected waves are received by a signal receiver (150), which may be part of ultrasound transducer (148). Indeed, in a preferred embodiment, the same piezo-electric crystal or crystals which transmit ultrasound waves also receive the reflected, Doppler shifted waves as known in the art. Signal receiver (150) preferably sends the resulting signals to a signal conditioner (152), which processes the received signals according to methods known in the art. Signal conditioner (152) then sends the conditioned signals to a signal transmitter (154), which in turn sends control signals to a light source (156), which may be any suitable type of light-generating member. In response to the control signals, light source (156) emits a periodic light beam into fiber optic cable (64) representative of each beat of the fetal heart. Because upper layer (82) of pad (62) is preferably translucent, the light within fiber optic cable 64 is visible from outside the device (60). Fiber optic cable (64) thus serves as a visual indication of the fetal heartbeat. As shown in FIG. 6, fiber optic cable (64) may be configured in a heart shape as an additional symbolic confirmation that the fetal heartbeat is being represented by the flashing light passing through cable (64). However, cable (64) may be configured in any desired shape other than a heart shape.

[0047] In the embodiment illustrated in FIGS. 6 and 7, the outer surface of electronics box (66) is preferably provided with a number of control and output elements as part of I/O unit (144) that are accessible by the user. For example, I/O unit (144) may have a master on-off switch (68) for turning device (60) on and off and a light on-off switch (70) for controlling the operation of light source (156). A speaker (76) or other sound-generating member may also be provided as part of I/O unit (144) for producing an audible indication of the fetal heartbeat in response to the control signals from signal transmitter (154), in which case a volume control (72) and a speaker on-off switch (74) are preferably provided to control the operation of speaker (76). Also, a display unit (not shown) may be provided as part of I/O unit (144) for producing a textual or graphical representation of one or more characteristics of the fetal heartbeat. A variety of suitable display units are known in the art, such as LED displays, LCD displays, and the like. For example, the display unit may indicate the average fetal heart rate per unit time, such as the number of beats per minute. Additionally, a vibrator (not shown) or

other type of output device may be provided to give another type of indication of the fetal heart rate in response to the control signals from signal transmitter (154). Preferably, light source (156), speaker (76), and any other included output device may be controlled independently of one another. Thus, for example, the user may choose to see a visual indication of the fetal heartbeat as represented by cable (64) without any sound being produced by speaker (76), or the user may choose to hear an audible indication of the fetal heartbeat as produced by speaker (76) without any light being emitted by cable (64), or the user may choose to obtain both a visual indication and an audible indication of the fetal heartbeat by operating both cable (64) and speaker (76) simultaneously. Optionally, device (60) may be provided with a wireless transmitter (not shown) for transmitting a wireless signal representative of the fetal heartbeat to a remote monitoring station, such as a nurse's station. In this way, medical personnel could monitor the fetal heartbeat even if the mother chooses not to see or hear any indications of the fetal heartbeat at device (60), such as when the mother desires to sleep.

[0048] Although it is preferable to have a fiber optic cable (64) to provide a visual indication of the fetal heartbeat, the present invention may comprise an ultrasound apparatus as described for device (60) above but without a fiber optic cable (64). In this instance, the output signals representative of the fetal heartbeat are preferably displayed visually on a display (not shown) or represented audibly via speaker (76) or otherwise indicated via some other output device as discussed above.

[0049] Alternatively, as shown in FIGS. 16-19, an ultrasound fetal heart rate monitoring device (170) may comprise a flexible patch (172) having a recess or pouch for containing an ultrasound sensor (180). Patch (172) is preferably made of soft, flexible plastic or another suitable material, such as rubber or fabric, with adhesive on its underside surface (178) for securing device (170) to the abdominal skin (44) of a pregnant female. Ultrasound sensor (180) may be permanently embedded or integrally formed in patch (172), but ultrasound sensor (180) is preferably removable from patch (172) so that sensor (180) may be re-used. Once again, patch (172) preferably has a generally elliptical shape to help conform patch (172) to the contour of the mother's abdomen, but other shapes are also possible as discussed above. Ultrasound sensor (180) preferably has a power source (174), a signal processor (176), an ultrasound transducer (148), a signal transmitter (154), and a gel pad (78) for contacting the mother's abdominal skin (44) to enhance the performance of ultrasound transducer (148) as discussed above. Much like the embodiments discussed above, ultrasound transducer (148) produces a signal representative of the fetal heartbeat in cooperation with signal processor (176) according to methods known in the art. In this embodiment, signal transmitter (154) preferably transmits the resulting signal representative

of the fetal heartbeat to a remote receiver for monitoring, preferably via wireless transmission.

[0050] Referring to FIGS. 8 and 9, an alternative ultrasound fetal heart rate monitoring device (160) is shown in which electronics box (66) is placed within a pouch or compartment (164) formed by a cover (162). Much like device (60) discussed above, device (160) preferably has a gel pad (78) underneath electronics box (66) for contacting the skin (44) of the pregnant mother and an adhesive layer (80) for attaching device (160) to the skin (44) without the need for a belt. Fiber optic cable (64) is disposed within a pad (62) that comprises a lower layer (84) and an upper layer (82), which is preferably translucent. In this embodiment, cover (162) is placed on top of pad (62) and forms a pouch or compartment (164) for housing the electronics box (66). Preferably, cover (162) does not overlap the portion of pad (62) in the vicinity of cable (64) so that the light emitted by cable (64) in response to the fetal heartbeat is visible from outside device (160). In this embodiment, rather than having a series of controls on electronics box (66) that are accessible by the user from the outside of device (160), the operation of electronics box (66) is preferably controlled by software or firmware, either within electronics box (66) or in a remote processor, according to methods known in the art. Alternatively, electronics box (66) may have the same types of controls as described above in connection with device (60), but the user would first need to open cover (162) to gain access to the controls on box (66) in compartment (164). As another alternative, cover (162) may permit operation of such controls on box (66) without opening cover (162). For example, a cover (162) comprising a thin, flexible plastic would permit operation of controls on box (66) without the need for access to compartment (164). In any event, in this embodiment, electronics box (66) is preferably removable from compartment (164) and the remainder of device (160) is disposable. To facilitate this disposable arrangement, fiber optic cable (64) preferably terminates with a connector (168) which is removably inserted into a mating jack (166) on box (66). In this manner, cable (64) may be unplugged from electronics box (66), which may be re-used in another device (160). Likewise, pad (62) is preferably removable from adhesive layer (80) and gel pad (78) so that pad (62) may be re-used.

[0051] Referring again to FIG. 14, as mentioned above, a memory unit (146) is preferably provided in electronics box (66) to store information generated by device (60) or (160). For example, microprocessor (142) may track the fetal heartbeat over time, calculate an average heart rate per a given unit of time, and periodically store such average heart rate in memory unit (146). As another example, microprocessor (142) may track the fetal heartbeat over time and store a record of each occurrence of a missed heartbeat in memory unit (146). Persons reasonably skilled in the art will appreciate that memory unit (146) may be used to store many

other types of information related to the fetal heartbeat.

[0052] Referring to FIGS. 10-12, it will be appreciated that a combined labor contraction and fetal heart rate monitoring device may be achieved by combining the functionalities described above. As shown in FIGS. 10 and 11, such a combination device may comprise two separate fiber optic cables: one for the labor contraction monitoring function, and another for the fetal heart rate monitoring function. In FIG. 10, fiber optic cables (86) and (88) are embedded in the same pad (62), with cable (88) being connected to the labor contraction electronics box (18) and cable (86) being connected to the ultrasound fetal heart rate electronics box (66). Similarly, FIG. 11 shows two separate fiber optic cables (90) and (92) embedded in the same pad (62) in a slightly different configuration, with cable (92) being connected to labor contraction electronics box (18) and cable (90) being connected to ultrasound fetal heart rate electronics box (66). Persons of ordinary skill in the art will appreciate that the fiber optic cables, whether for labor contraction monitoring or fetal heart rate indications, may be arranged in any desirable configuration. Although electronics boxes (18) and (66) are illustrated as being separate units, persons reasonably skilled in the art will appreciate that boxes (18) and (66) may be combined into a single electronics box having the full functionality of both labor contraction monitoring and fetal heart rate monitoring, such as electronics box (110) described below.

[0053] Referring to FIG. 12, an alternative combined device (100) for monitoring labor contractions and fetal heart rate is shown. In device (100), a first fiber optic cable (104) for indicating the fetal heart rate is embedded within an upper layer (108), and a second fiber optic cable (106) for sensing labor contractions is embedded within a lower layer (112). Like devices (10), (60), and (160) described above, device (100) preferably has an adhesive layer (not shown) on its underside for attaching device (100) to the abdominal skin (44) of a pregnant mother. Additionally, like devices (60) and (160) described above, device (100) preferably has a gel pad (78) for placement adjacent the mother's skin for enhancing the performance of the ultrasound transducer, which is housed in electronics box (110). In this embodiment, electronics box (110) is removably held in a receptacle (102) and contains the components of both electronics box (18) described above for labor contraction monitoring and electronics box (66) described above for ultrasound fetal heart rate monitoring. Upper layer (108) is preferably translucent so that the light emitted by cable (104) in response to the fetal heartbeat is visible from the exterior of device (100). Lower layer (112) is preferably opaque so that the light emitted by cable (104) does not interfere with cable (106). Cables (104) and (106) are connected to the ultrasound and labor contraction portions, respectively, of electronics box (110). In addition to serving as a visual indication of the fetal heartbeat, fiber

optic cable (104) may also be used to provide a visual indication of the occurrence and strength of a labor contraction. For example, upon the occurrence of a labor contraction, a continuous light signal may be superimposed over the periodic fetal heartbeat light signal in cable (104). Alternatively, the occurrence of a labor contraction may be indicated by a change in color of the light pulsing through cable (104). Further, the intensity of the continuous light signal representative of the labor contraction may be increased or decreased according to the strength of the labor contraction.

[0054] Referring to FIGS. 13 and 15, an alternative combined labor contraction and fetal heart rate monitoring device (120) with an electronics box (130) is shown. In this embodiment, the same fiber optic cable (124) is used both for sensing labor contractions and for visually indicating the fetal heartbeat. Cable (124) is preferably embedded in a soft, flexible pad (122) having a translucent outer layer above cable (124), much like pad (62) described above. Like the embodiments described above, device (120) preferably has an adhesive layer (not shown) on its underside for attaching device (120) to the skin of the mother and a gel pad (not shown) for enhancing the performance of the ultrasound transducer (148). A receptacle (126) is provided on pad (122) for removably holding electronics box (130). Cable (124) is connected to electronics box (130), preferably by one or more optical signal contact junctions (not shown) that mate with electronics box (130) when box (130) is snapped into place in receptacle (126). Suitable optical signal contact junctions are well known in the art. Much like electronics box (110) described above, electronics box (130) contains the components of box (18) described above for processing the labor contraction signals and the components of box (66) described above for processing the ultrasound fetal heart rate signals. As shown in FIG. 15, fiber optic cable (124) is in optical communication at one end with light source (156) and at another end with light detector (24a). Light source (156) emits substantially continuous light beams into cable (124) for monitoring labor contractions as discussed above in connection with FIGS. 1-5, and light source (156) emits periodic light beams in response to the ultrasound fetal heart rate signals generated by the ultrasound transducer (148) as discussed above in connection with FIGS. 6-12 and 14. Thus, device (120) is useful in monitoring both labor contractions and fetal heart rates. Like cable (104) of device (100) described above, in addition to serving as a visual indication of the fetal heartbeat, fiber optic cable (124) may also be used to provide a visual indication of the occurrence and strength of a labor contraction. For example, upon the occurrence of a labor contraction, a continuous light signal may be superimposed over the periodic fetal heartbeat signal in cable (124). Alternatively, the occurrence of a labor contraction may be indicated by a change in color of the light pulsing through cable (124). Further, the intensity of the continuous light signal representative of the labor contraction may be increased or decreased according to the strength of the labor

contraction. In this embodiment, ambient light entering cable (124) should be offset according to methods known in the art. Various labor contraction data, such as frequency and strength, and fetal heartbeat data, such as average heart rate, may be stored in memory unit (146) according to methods known in the art.

[0055] To maximize the effectiveness of the ultrasound transducer, it is preferable for the ultrasound transducer (and thus the electronics box) to be substantially adjacent the skin of the mother, with only a gel pad separating the electronics box from the skin. If any other material is located between the skin and the ultrasound transducer, such other material is preferably sonically transparent so as not to interfere with the ultrasound signals.

[0056] Various embodiments of the present invention have been described herein. It should be understood by those of ordinary skill in the art, however, that the above described embodiments of the present invention are set forth merely by way of example and should not be interpreted as limiting the scope of the present invention, which is defined by the appended claims. Many other alternative embodiments, variations and modifications of the foregoing embodiments that embrace various aspects of the present invention will also be understood upon a reading of the detailed description in light of the prior art. For instance, it will be understood that features of one embodiment may be combined with features of other embodiments while many other features may be omitted (or replaced) as being nonessential to the practice of the present invention. For example, although the electronics are described herein as preferably being contained in a box, the electronic components may be simply embedded in another part of the apparatus, such as a flexible pad. Additionally, persons of ordinary skill in the art will appreciate that the ultrasound heart rate sensing devices described herein may also be used to monitor the heartbeat of an individual other than a fetus, such as a child or adult, by placing the sensing device on the body of the individual, preferably on the chest, side, or back of the individual. The operation of the ultrasound heart rate sensing device as applied to a child or adult would be the same as described herein for a pregnant mother. Therefore, the invention should not be limited to the details shown and described herein.

Claims

I claim:

1. A device for monitoring the heartbeat of a fetal heart comprising:
a flexible pad having an attachment surface adaptable for adhering to abdominal skin of a pregnant female;
an ultrasound transducer mounted to said flexible pad;
said ultrasound transducer being operable for transmitting outbound ultrasound waves toward the fetal heart and receiving inbound ultrasound waves reflected from the fetal heart;
a computer processor in communication with said ultrasound transducer;
said computer processor being operable for processing said inbound ultrasound waves and generating a control signal representative of the heartbeat of the fetal heart; and
an output device in communication with said computer processor;
said output device being operable for receiving said control signal and producing an indication of the heartbeat of the fetal heart in response to said control signal.
2. The device of claim 1 wherein said output device comprises a light-generating member and said indication comprises a visual indication.
3. The device of claim 2 wherein said light-generating member comprises a fiber optic cable.
4. The device of claim 1 wherein said output device comprises a sound-generating member and said indication comprises an audible indication.
5. The device of claim 1 further comprising a gel pad positionable between said ultrasound transducer and the abdominal skin.
6. The device of claim 1 further comprising a signal transmitter in communication with said computer processor;
said signal transmitter being operable for receiving said control signal and transmitting a wireless signal representative of the heartbeat of the fetal heart to a remote receiver in response to said control signal.
7. The device of claim 1 further comprising a signal transmitter in communication with said ultrasound transducer;

said signal transmitter being operable for receiving said inbound ultrasound waves and wirelessly transmitting said inbound ultrasound waves to said computer processor; wherein said computer processor is remote from said flexible pad.

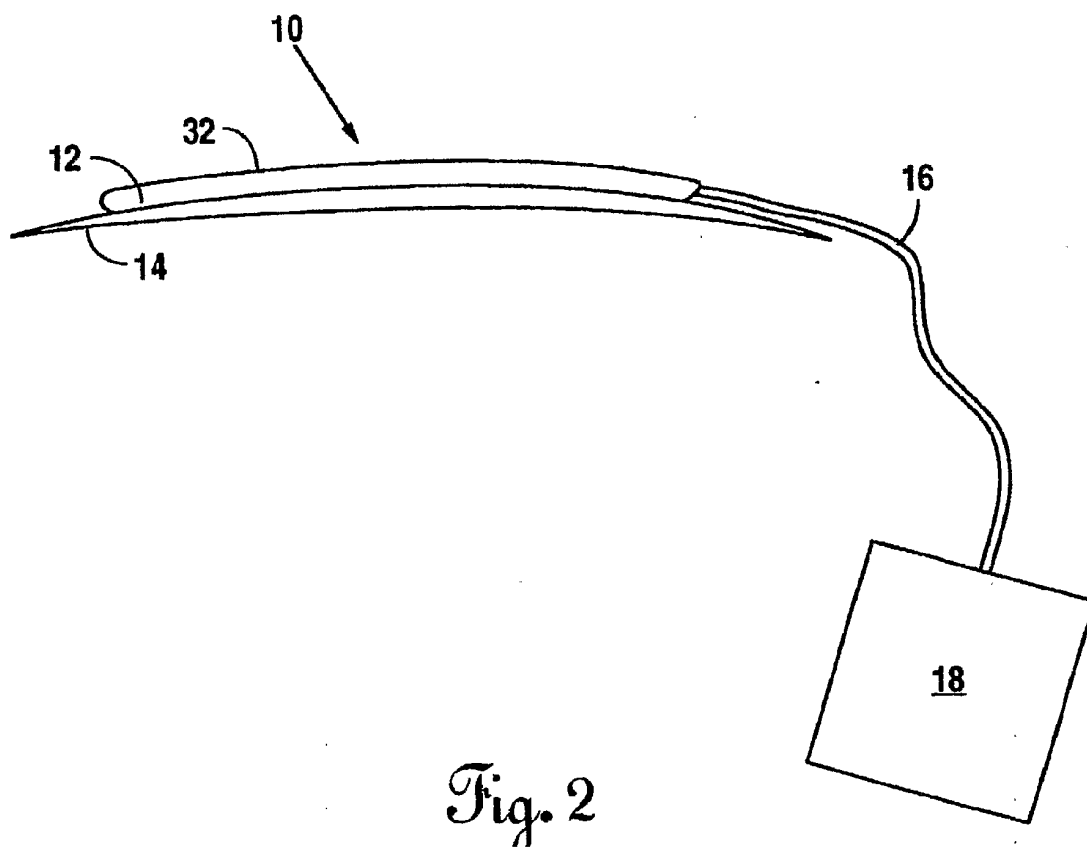
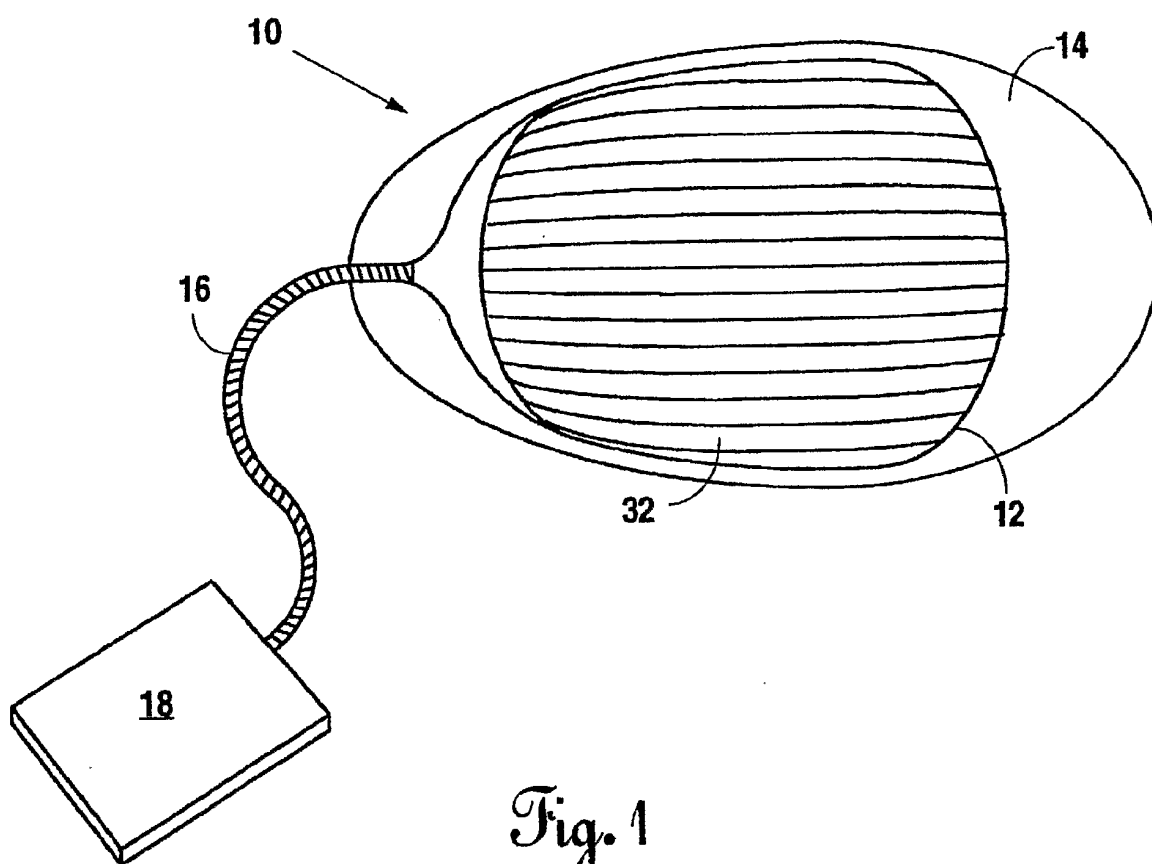
8. The device of claim 1 wherein said attachment surface comprises an adhesive material.
9. The device of claim 1 wherein said attachment surface comprises a self-adhering plastic material.
10. The device of claim 1 wherein said ultrasound transducer and said computer processor are housed in an electronics box; and wherein said electronics box is removable from said device.
11. A labor contraction sensing device comprising:
a fiber optic strain sensor having at least one fiber optic cable and an attachment surface adaptable for adhering to abdominal skin of a pregnant female;
said fiber optic strain sensor being operable for generating an output signal in response to a labor contraction of the pregnant female;
wherein said at least one fiber optic cable is operable for producing a visual indication of the labor contraction in response to said output signal.
12. The device of claim 11 wherein said visual indication comprises light having an intensity proportional to the strength of the labor contraction.
13. The device of claim 11 wherein said visual indication comprises light that changes color in response to a variation in the strength of the labor contraction.
14. A device for monitoring labor contractions and the heartbeat of a fetal heart, said device comprising:
a flexible pad having an attachment surface adaptable for adhering to abdominal skin of a pregnant female;
at least one fiber optic cable disposed within said flexible pad;
said at least one fiber optic cable being operable for generating a first output signal in response to a labor contraction of the pregnant female;
an ultrasound transducer mounted to said flexible pad;
said ultrasound transducer being operable for transmitting outbound ultrasound waves toward the fetal heart and receiving inbound ultrasound waves reflected from the fetal heart;

a computer processor in communication with said ultrasound transducer;
said computer processor being operable for processing said inbound ultrasound waves and generating a second output signal representative of the heartbeat of the fetal heart; and
at least one output device in communication with said computer processor and said at least one fiber optic cable;
said at least one output device being operable for receiving said first and second output signals and producing a first indication representative of the labor contraction in response to said first output signal and a second indication representative of the heartbeat of the fetal heart in response to said second output signal.

15. The device of claim 14 wherein said at least one fiber optic cable comprises said at least one output device.
16. The device of claim 14 wherein said at least one fiber optic cable comprises a first fiber optic cable and a second fiber optic cable;
wherein said first fiber optic cable is operable for generating said first output signal in response to a labor contraction of the pregnant female; and
wherein said second fiber optic cable is operable for producing said second indication representative of the heartbeat of the fetal heart in response to said second output signal.
17. The device of claim 14 wherein said at least one fiber optic cable comprises a single fiber optic cable which is operable for:
(a) generating said first output signal in response to a labor contraction of the pregnant female, and
(b) producing said second indication representative of the heartbeat of the fetal heart in response to said second output signal.
18. The device of claim 17 wherein said single fiber optic cable is further operable for producing said first indication representative of the labor contraction in response to said first output signal.
19. The device of claim 14 further comprising a gel pad positionable between said ultrasound transducer and the abdominal skin.
20. The device of claim 14 wherein said at least one output device comprises a light-generating member and wherein at least one of said first and second indications comprises a visual indication.

21. The device of claim 14 wherein said at least one output device comprises a sound-generating member and wherein at least one of said first and second indications comprises an audible indication.
22. The device of claim 14 further comprising a signal transmitter in communication with said at least one fiber optic cable;
wherein said signal transmitter is operable for receiving said first output signal and transmitting a wireless signal representative of the labor contraction to a remote receiver in response to said first output signal.
23. The device of claim 14 further comprising a signal transmitter in communication with said computer processor;
wherein said signal transmitter is operable for receiving said second output signal and transmitting a wireless signal representative of the fetal heartbeat to a remote receiver in response to said second output signal.
24. The device of claim 14 wherein said ultrasound transducer and said computer processor are housed in an electronics box; and
wherein said electronics box is removable from said device.
25. The device of claim 24 wherein said electronics box further houses:
a light source in communication with said at least one fiber optic cable;
a light detector in communication with said at least one fiber optic cable; and
an optical signal processor in communication with said light detector.
26. A device for monitoring the heartbeat of an individual having a heart, said device comprising:
a flexible pad having an attachment surface adaptable for adhering to skin of the individual;
an ultrasound transducer mounted to said flexible pad;
said ultrasound transducer being operable for transmitting outbound ultrasound waves toward the heart and receiving inbound ultrasound waves reflected from the heart;
a computer processor in communication with said ultrasound transducer;
said computer processor being operable for processing said inbound ultrasound waves and generating a control signal representative of the heartbeat of the heart; and
an output device in communication with said computer processor;
said output device being operable for receiving said control signal and producing an indication of the heartbeat of the heart in response to said control signal.

1/8



2/8

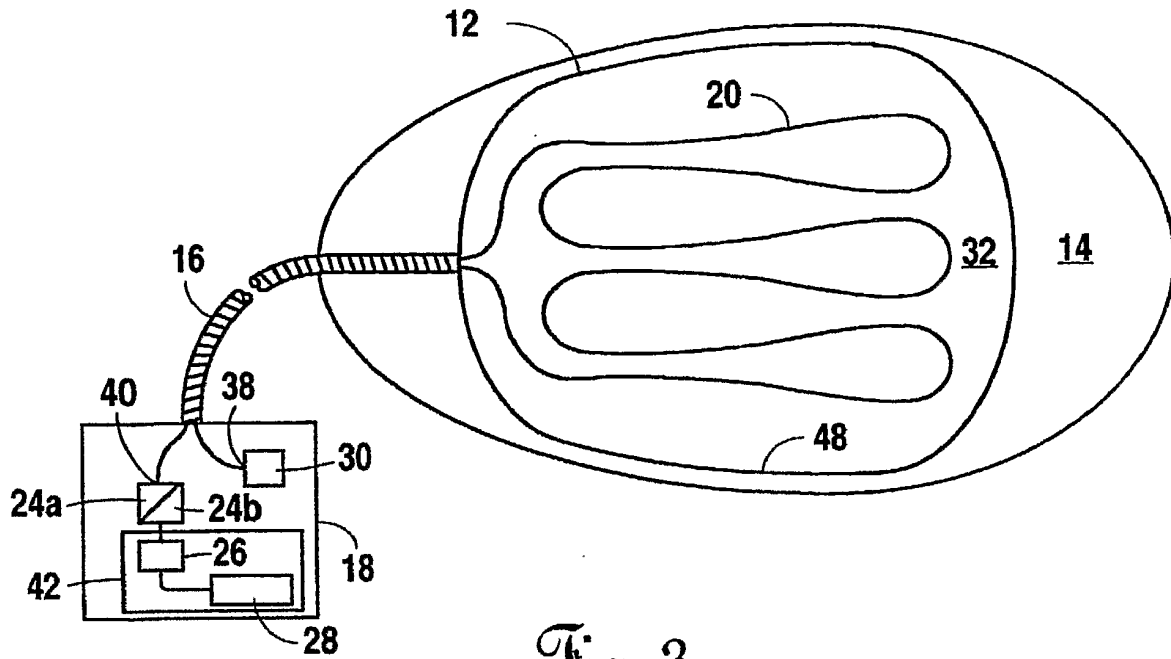


Fig. 3

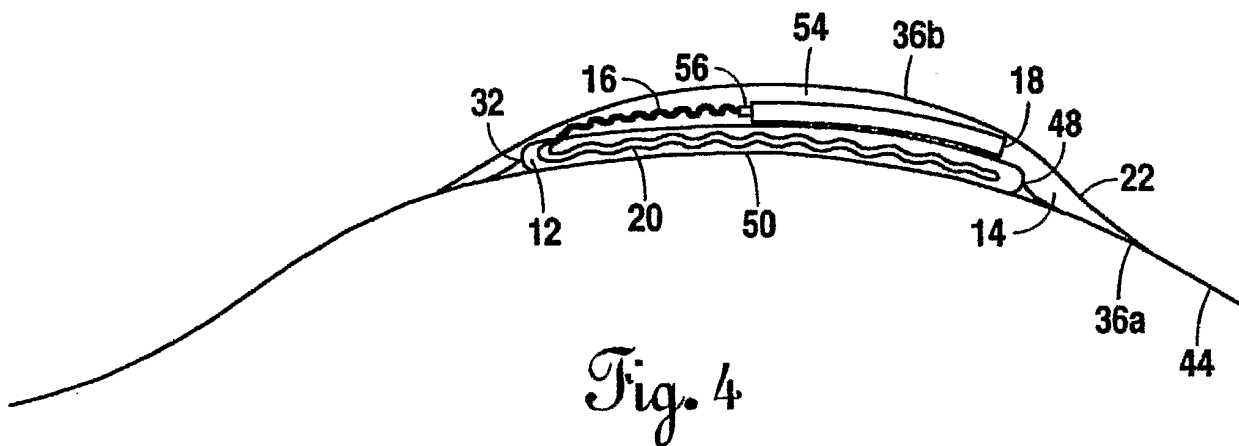


Fig. 4

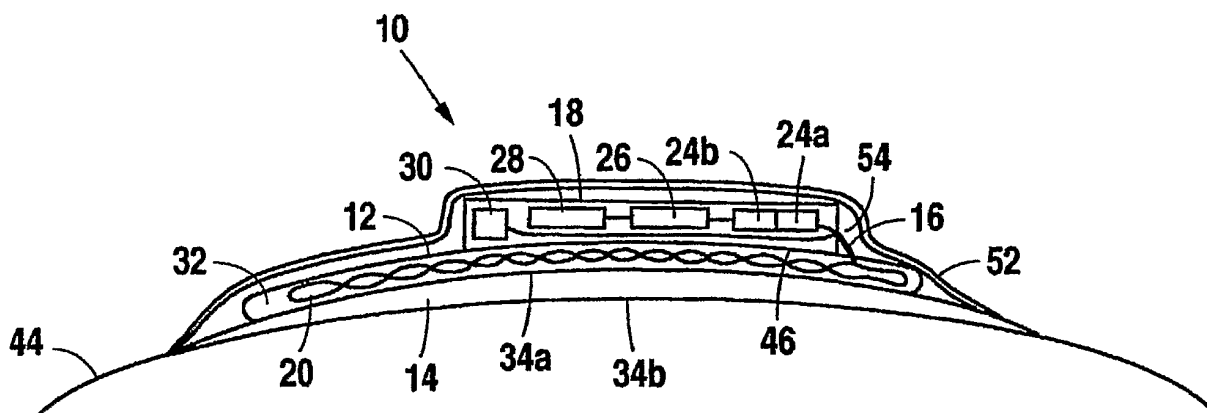


Fig. 5

3/8

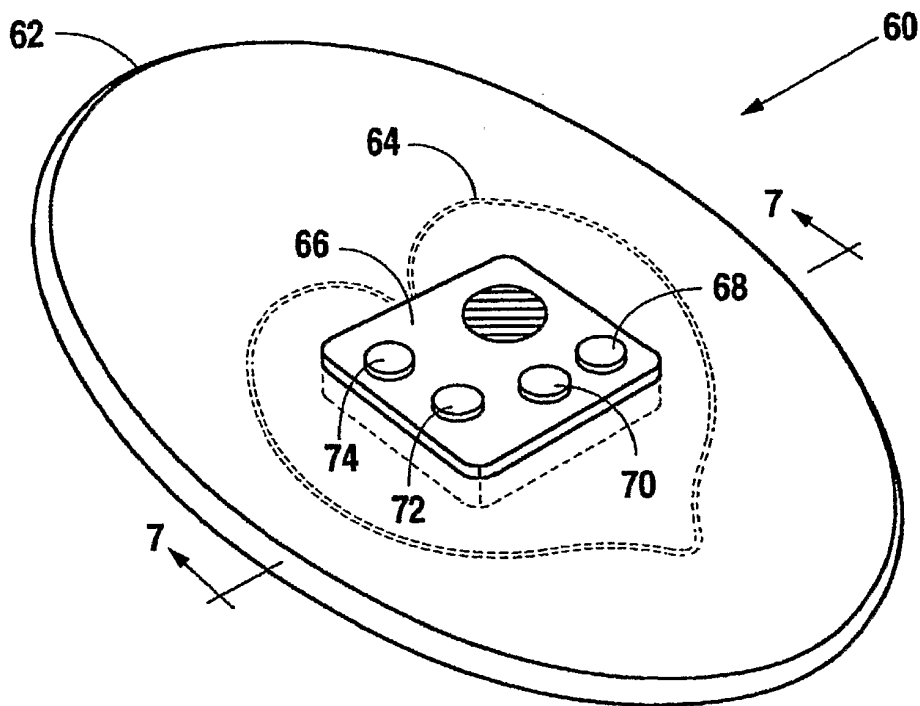


Fig. 6

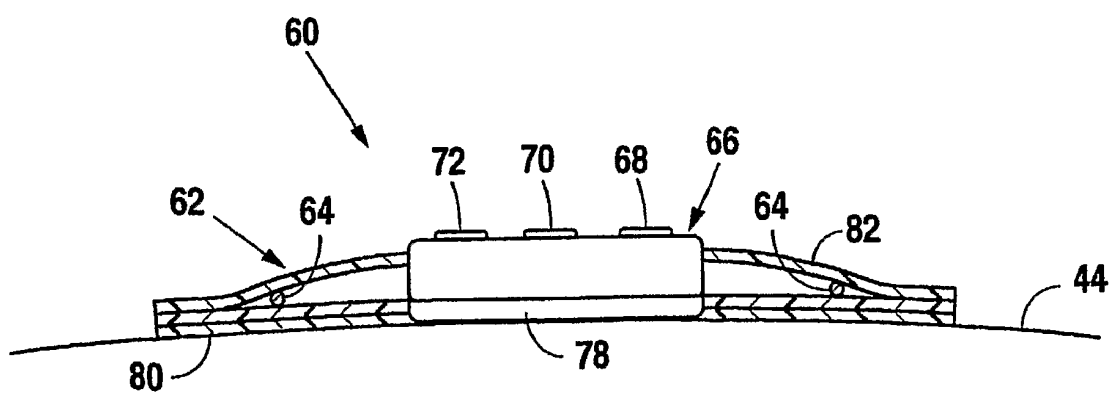
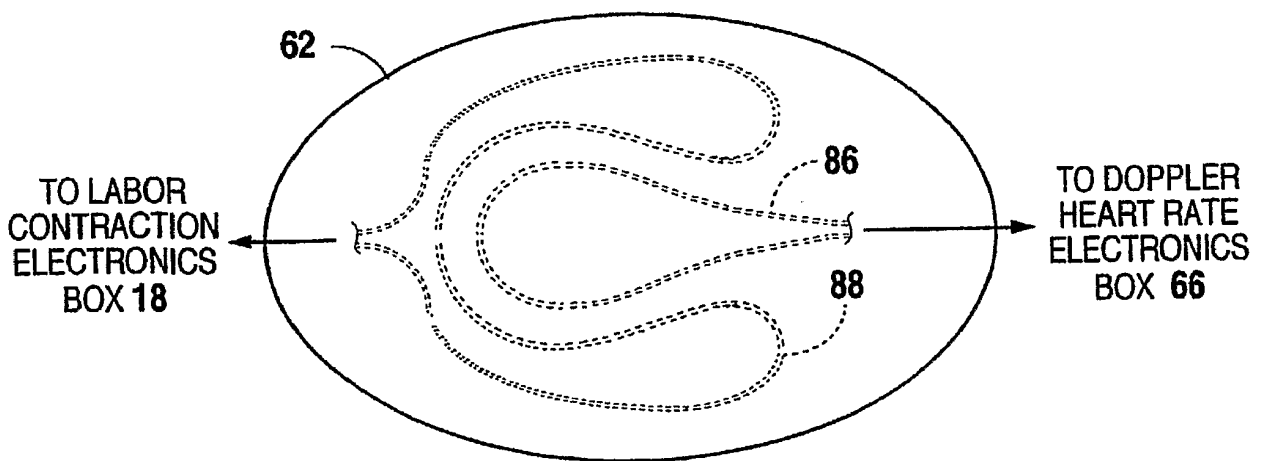
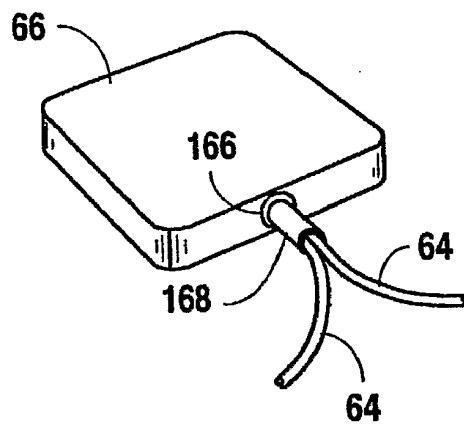
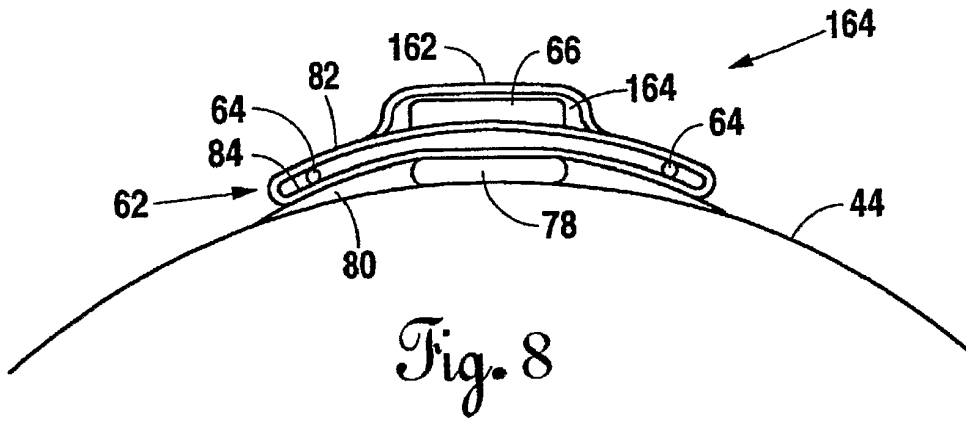


Fig. 7

4/8



5/8

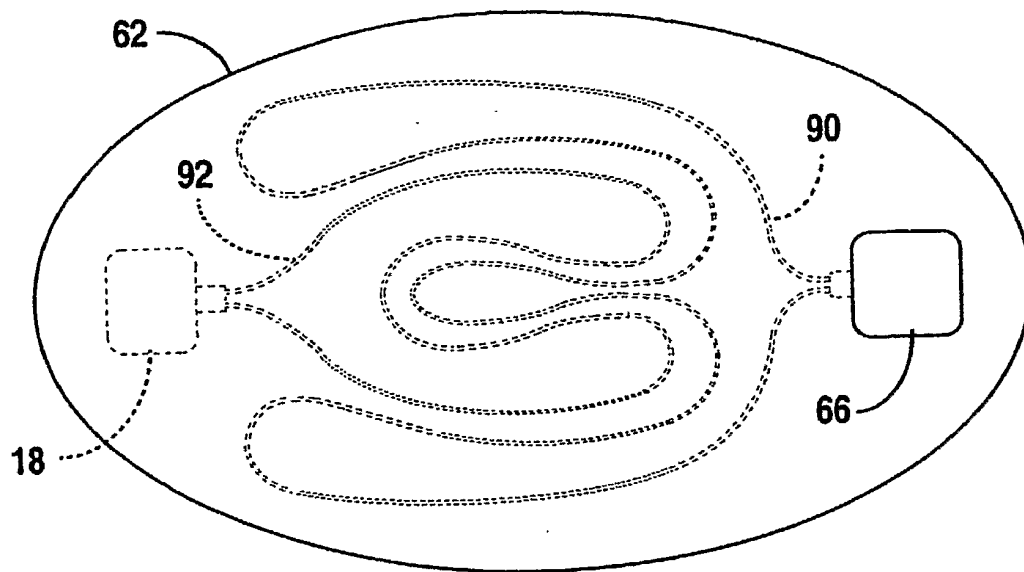


Fig. 11

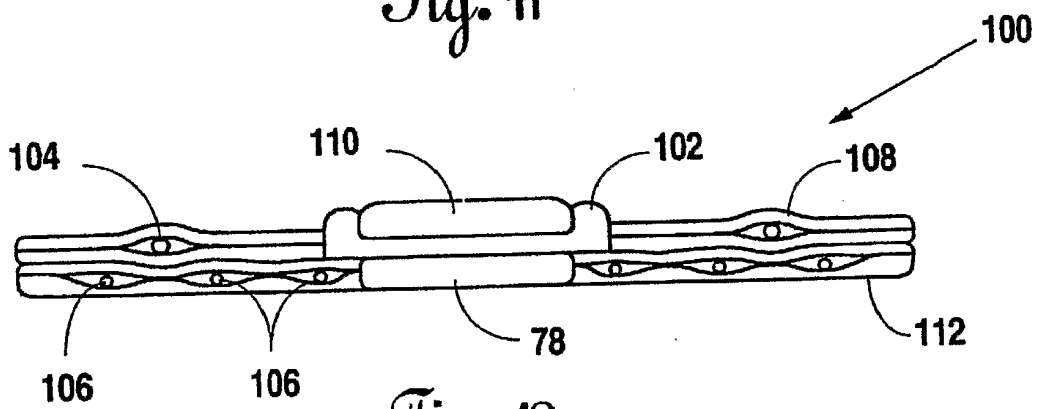


Fig. 12

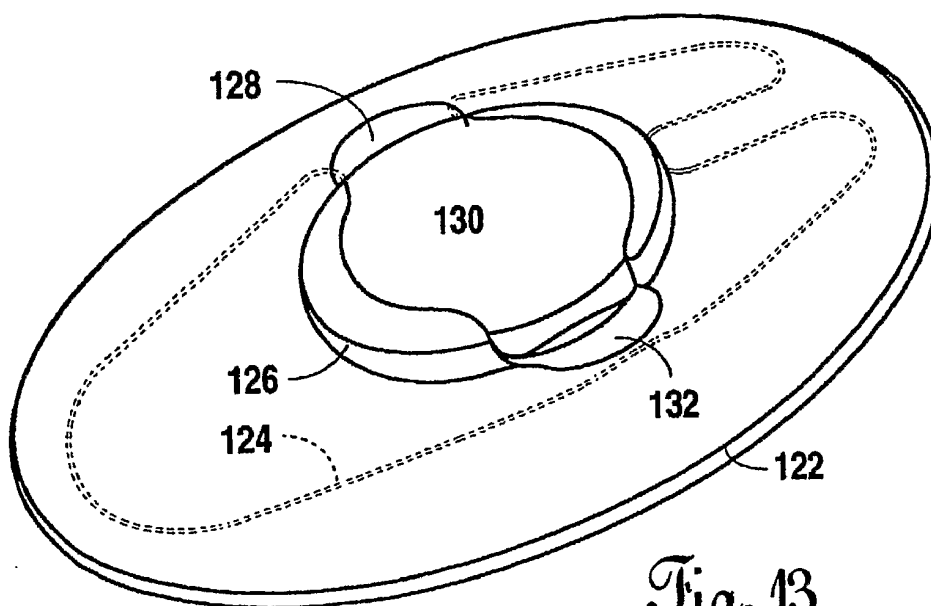


Fig. 13

6/8

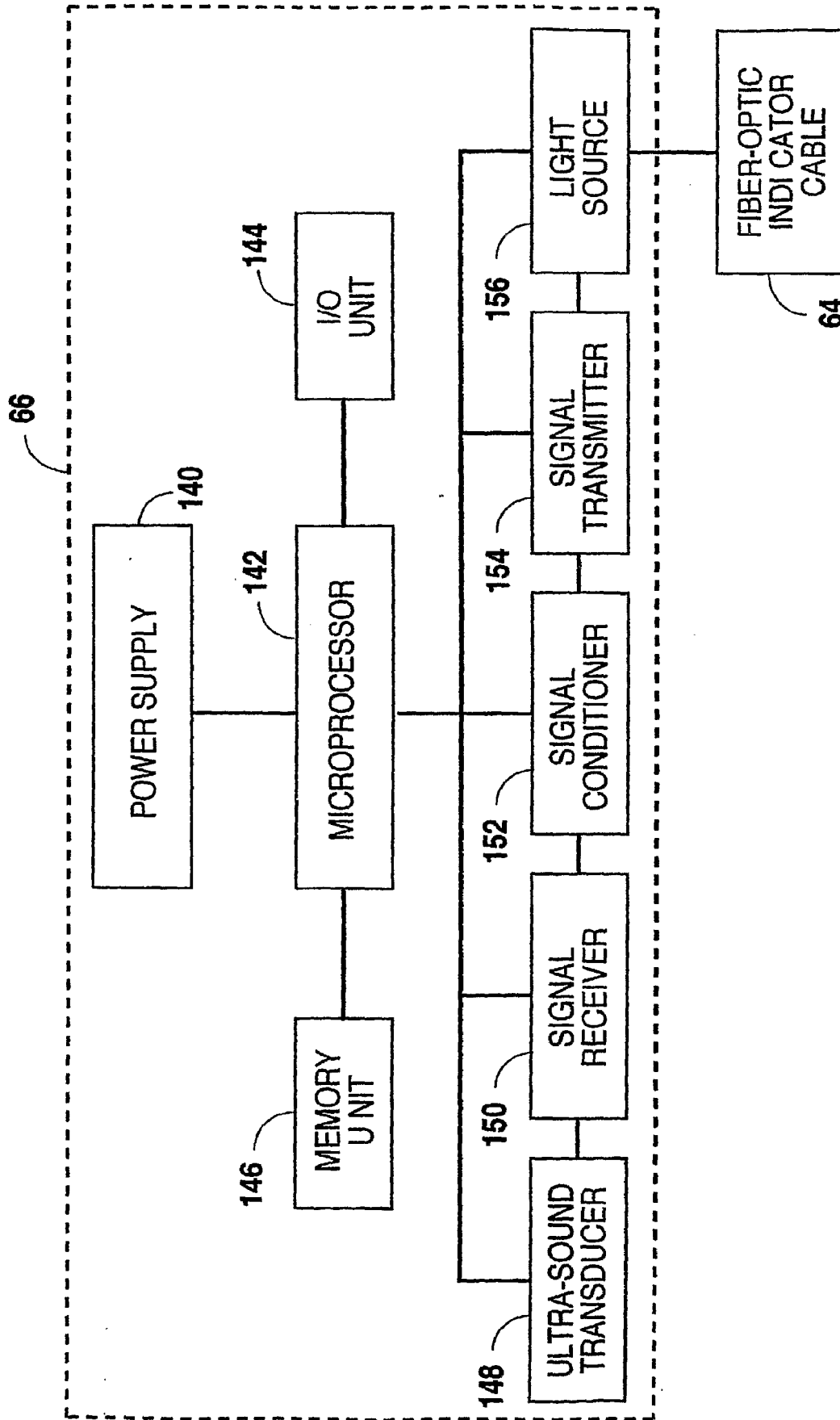


Fig. 14

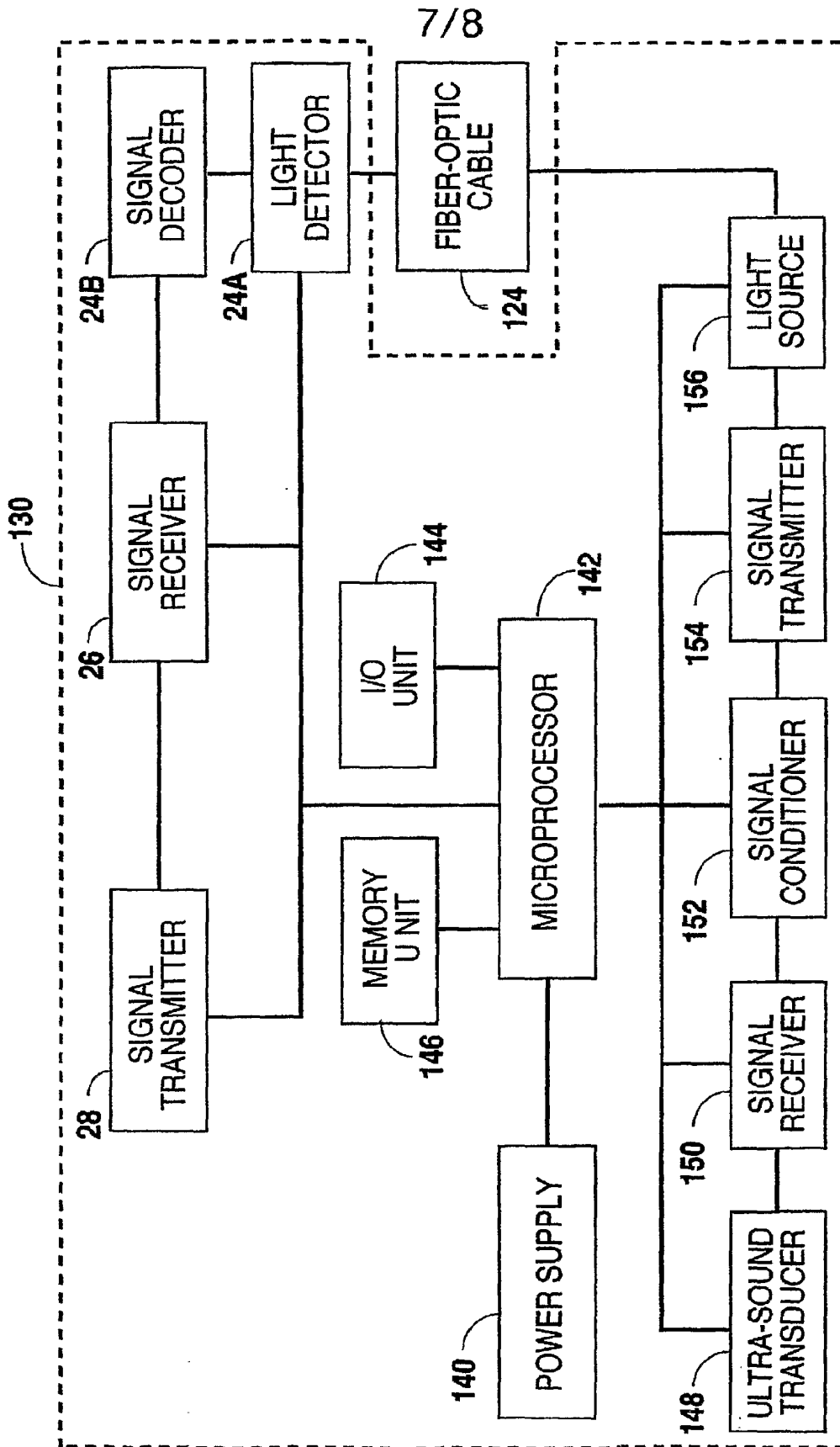


Fig. 15

8/8

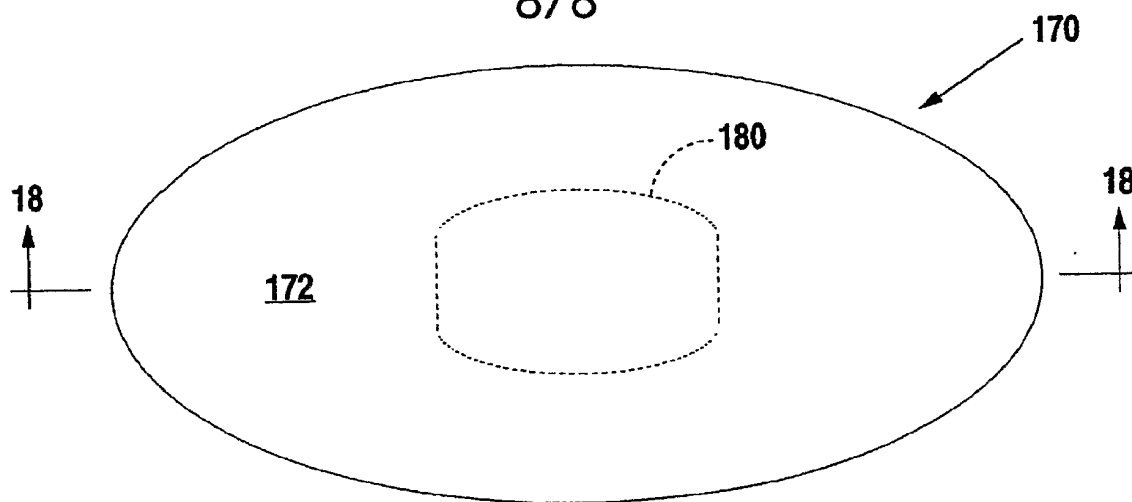


Fig. 16

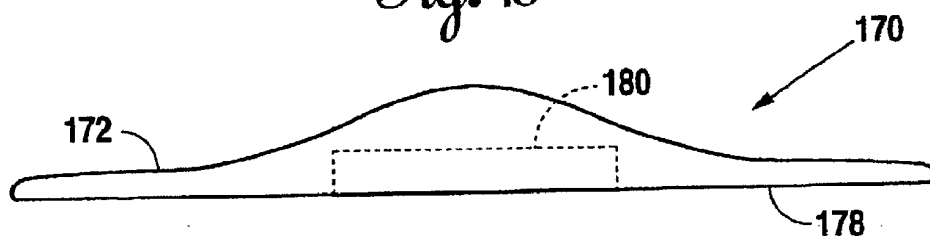


Fig. 17

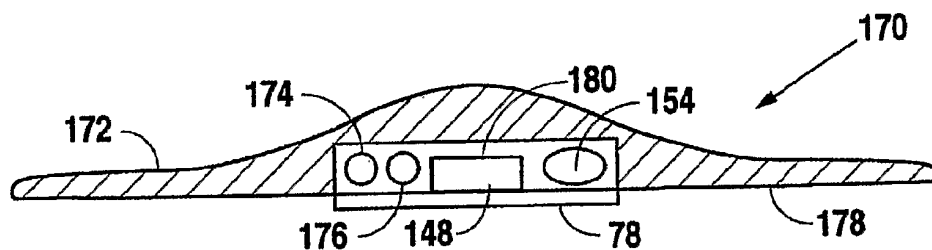


Fig. 18

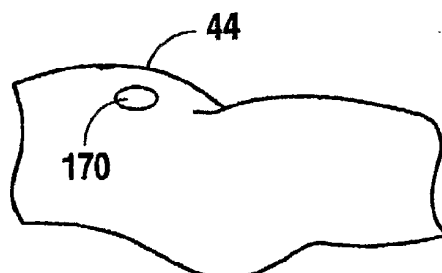


Fig. 19

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US05/16406

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 8/00

US CL : 600/437

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. : 600/437-472, 588, 591; 128/916; 73/625, 626; 367/7, 11, 130, 138

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)

Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6,607,486 B1 (WATSON) 19 August, 2003 (19.08.2003), entire document.	11-13
A	US 2003/0073910 A1 (CH ANCE) 17 April 2003 (17.04.2003), entire document.	1-10, 14-25

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Further documents are listed in the continuation of Box C.

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See patent family annex.

* Special categories of cited documents:

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

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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

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

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

16 August 2005 (16.08.2005)

Date of mailing of the international search report

29 AUG 2005

Name and mailing address of the ISA/US

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US05/16406

Continuation of B. FIELDS SEARCHED Item 3:

EAST

search terms: ultrasound, doppler, fetus, fetal, pregnant, wearable, labor, contraction, fiber optic

专利名称(译)	无腰带劳动收缩和心率监测装置		
公开(公告)号	EP1750587A4	公开(公告)日	2009-08-19
申请号	EP2005748409	申请日	2005-05-11
[标]申请(专利权)人(译)	MATERNUS合作伙伴		
申请(专利权)人(译)	MATERNUS PARTNERS , LTD.		
当前申请(专利权)人(译)	MATERNUS PARTNERS , LTD.		
[标]发明人	WATSON RICHARD L JR		
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摘要(译)

一种无带装置，用于通过光纤电缆和胎儿心跳通过超声传感器监测分娩收缩。可以使用相同或单独的光缆来提供分娩收缩和胎儿心跳的视觉指示。该装置舒适地连接到怀孕母亲的腹部，并且优选地是无线的以允许母亲完全移动。该装置还可用于监测儿童和成人的心跳。

