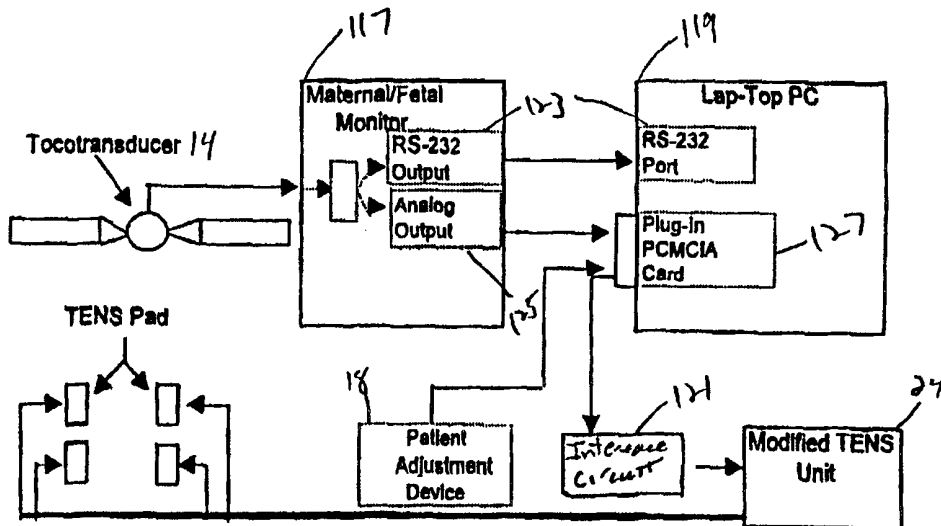




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(54) Title: APPARATUS AND METHODS FOR REDUCING PAIN AND/OR RETRAINING MUSCLES



(57) Abstract

Apparatus (10, 100) and methods for reducing pain associated with contractions such as uterine or other muscle contractions and/or for retraining muscles are disclosed. The apparatus includes a sensor (14, 252) for developing a signal indicative of a contraction experienced by a muscle. They also include a stimulator (24) for applying stimulation to the patient. The apparatus also includes a control unit (16, 116) for automatically adjusting the stimulation provided by the stimulator at least partially in response to the signal developed by the sensor.

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APPARATUS AND METHODS FOR REDUCING PAIN AND/OR RETRAINING MUSCLES

RELATED APPLICATION

This patent claims priority from U.S. Provisional Application Serial
5 No. 60/125,970 which was filed on March 24, 1999.

FIELD OF THE INVENTION

The invention relates generally to pain control and muscle stimulation,
and, more particularly, to apparatus and methods for reducing pain and/or
retraining muscles.

10

BACKGROUND OF THE INVENTION

Pain management is a complex challenge for physicians, other
healthcare providers and patients. Many are reluctant to use drugs for pain
control, especially with pregnant women because of possible side effects for
both the mother and baby.

15

Labor pain can last for up to 36 hours. Conventional pain medications
such as epidural drug injections are usually withheld until the cervix is dilated
over 4 cm. Currently, as the cervix dilates from 0-4 cm, women receive either
no medication or intravenous medication such as Nisental or Demerol. Even
when such medication is used, the patient can still experience significant pain.

20

Moreover, these drugs sedate the patient at a time when the typical mother
wants to be with her family and experience the miracle of birth. For these and
other reasons, many women prefer to deliver their babies without drugs even
in the final stages of labor.

25

Many non-pharmacologic methods for managing labor pain have been
tried including rapid breathing, TENS (transcutaneous electrical nerve
stimulation) and others. While these methods can be somewhat helpful, labor
remains a painful experience for tens of millions of women around the world.

- 2 -

Pain specialists recognize that it is better to initiate early pain management strategies because later intervention is often more difficult. Therefore, initiating TENS therapy before the pain of a uterine contraction is felt by the patient increases TENS efficacy.

5 The TENS technique has been widely used for labor analgesia for over twenty years. It has also been successfully and safely used for over twenty years to treat constant, chronic pain of the sort caused by injury and disease. For example, it is widely used for back pain and sports injuries.

10 In the context of treating labor pain, the TENS technique employs a small battery-powered source of high frequency electrical energy applied to the skin of the mother in labor using disposable electrode pads attached to the abdomen. The TENS unit is powered and shut off on demand by an operator (i.e., either the mother, a labor coach such as the father, or an attending health care provider). A perceptive coach or health care provider could watch the
15 output of a standard tocometer (uterine contraction monitor) to predict and make adjustments to the TENS output in response to growing or declining uterine contractions. The mother, thus, receives the benefits of electrical stimulation which rises and falls with the contraction intensity without requiring her involvement in manipulating the TENS unit.

20

SUMMARY OF THE INVENTION

 In accordance with an aspect of the invention, an apparatus is disclosed for use in reducing pain experienced by a patient. The apparatus includes a sensor structured to develop a signal indicative of a contraction experienced by the patient, and a stimulator structured to apply stimulation to the patient. In
25 addition, the apparatus includes a control unit in communication with the sensor and the stimulator for automatically adjusting the stimulation applied by the stimulator at least partially in response to the signal developed by the sensor to reduce the pain associated with the contraction.

- 3 -

In accordance with another aspect of the invention, an apparatus is disclosed for use in retraining a muscle of a patient. The apparatus includes a stimulator structured to apply stimulation to the muscle of the patient in order to adjust a contraction condition of the muscle. It also includes a sensor
5 structured to develop a signal indicative of the contraction condition of the muscle of the patient. Additionally, the apparatus is provided with a memory storing data representative of a predetermined contraction and relaxation activity for the muscle. Moreover, the apparatus is provided with a control unit in communication with the memory, the sensor and the stimulator for
10 automatically adjusting the stimulation applied by the stimulator in response to the data stored in the memory and the signal developed by the sensor.

In accordance with another aspect of the invention, a method is provided for reducing labor pain experienced by a patient. The method includes the steps of positioning a sensor on the patient in a location for
15 developing a signal indicative of a uterine contraction; and coupling a stimulator to the patient in a location to apply electrical stimulation reducing the labor pain. The method also includes the steps of employing the sensor to develop the signal indicative of the uterine contraction; and responding to the signal indicative of the uterine contraction by adjusting the electrical
20 stimulation applied by the stimulator to reduce the labor pain.

In accordance with still another aspect of the invention, a method is disclosed for retraining a muscle of a patient. The method includes the steps of: (a) reading data representative of at least a portion of a predetermined contraction and relaxation activity for the muscle from a memory; and (b)
25 measuring a contraction condition of the muscle of the patient. The method also includes the steps of: (c) comparing at least a portion of the data read from the memory to a signal representative of the contraction condition of the muscle of the patient; and (d) automatically adjusting a stimulation signal applied to the muscle by a stimulator based upon the comparison to adjust the
30 contraction condition of the muscle.

- 4 -

Other features and advantages are inherent in the disclosed apparatus or will become apparent to those skilled in the art from the following detailed description and its accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

5 FIG. 1 is a schematic illustration of an apparatus constructed in accordance with the teachings of the instant invention and being used with a patient.

 FIG. 2 is a block diagram illustrating one possible implementation of the apparatus of FIG. 1.

10 FIG. 3 is a block diagram showing another possible implementation of the apparatus of FIG. 1.

 FIG. 4 is a flow chart illustrating a possible program executed by the apparatus of FIG. 3.

 FIG. 5 is a block diagram of another apparatus constructed in accordance with the teachings of the invention.

15 FIG. 6 is a flow-chart illustrating a possible program executed by the apparatus of FIG. 5.

 FIG. 7 is a block diagram illustrating a preferred apparatus constructed in accordance with the teachings of the invention.

20

DESCRIPTION OF THE PREFERRED EMBODIMENTS

 An apparatus 10 constructed in accordance with the teachings of the invention for reducing pain caused by, for example, uterine contractions during childbirth, muscle spasms such as back spasms, and/or menstrual cramps is shown in FIG. 1. Although the apparatus 10 will be described primarily in the context of controlling labor pain and retraining muscles in paralytics, persons of ordinary skill in the art will readily appreciate that the teachings of the invention are not limited to any particular environment of use. On the contrary, the teachings of the invention may be employed in any

- 5 -

application where the pain control and/or muscle retraining capabilities it provides would be useful without departing from the scope or spirit of the invention.

By way of an overview, the disclosed apparatus 10 delivers pain
5 controlling electrical stimulation through skin electrodes 12 or carefully placed
needles in appropriate body sites. (Persons of ordinary skill in the art will
readily appreciate that optimal electrode placement is not the same for all
patients. Electrode placement should be determined and/or adjusted as
appropriate by an attending physician or nurse). The electrical stimulation
10 (intensity, time, etc.) delivered by the apparatus 10 is controlled by reacting to
uterine contractions typically measured during labor. The timing and type of
the electrical stimulation (frequency, amplitude, wavelength, duration, etc.) is
preferably linked to the uterine contractions measured by the
tocodynamometer or similar devices 14. Preferably, the body's uterine
15 contraction is picked up by the tocodynamometer or similar device 14 which
sends a signal through a feedback loop to the electrical stimulation device or
control unit 16 which then generates and delivers the electrical stimulation at
the right time and intensity. The intensity and timing of the stimulation are
controlled by a closed loop feedback loop which reacts to the ever changing
20 uterine contractile state (i.e., more intense when there is a stronger contraction,
and less intense when the contractile state is lower). Advantageously, the
tocodynamometer 14 detects the contraction before it is perceived by the
mother. Thus, the apparatus 10 can begin treating labor pain before it actually
occurs.

25 To use the apparatus 10, one should first explain the system to the
mother and gain her agreement to utilize this pain control method. The
patient's healthcare provider should, of course, be in agreement. Once
agreement is reached, the sensor(s) 14 that read the muscular contraction from
the uterus or other muscles, as well as the electrodes 12 that deliver the
30 comforting electrical stimulation should be positioned on the patient at

- 6 -

appropriate locations. The proximal ends of the electrodes 12 and sensors 14 should then be connected to the control unit 16.

The control unit 16 is then energized. The control unit 16 automatically synchronizes release of electrical stimulation with the start of
5 uterine contractions and automatically adjusts its output according to the measured contractile intensity thereby providing pain control without constant patient or healthcare provider intervention. Because it is easier to control pain before it begins or before it becomes significant, the therapeutic electrical stimulation is delivered at the very beginning of a uterine contraction, either
10 before it is perceived by the patient or before it becomes significant. The therapeutic electrical stimulation delivery continues until the contraction is over. More specifically, when a woman has a contraction, the stimulator will increase its output (preferably in a step-ladder fashion) as the uterus contracts and taper down the output (again, preferably in a step-ladder fashion) as the
15 uterus relaxes.

The patient (mother) may optionally be provided with a hand-controlled switch 18 to turn the device off, turn it down, signal for help if the system is not providing benefit, or increase the electrical stimulation, thereby providing a Patient Controlled Analgesia or "P.C.A." This can be useful
20 because each person has a different perception of pain and a different reaction to pain treatment. Therefore, a treatment that is helpful to some people may be too much or not enough for others. By allowing the patient to control some or all of the variables of intensity, frequency, duration, amplitude, etc., maximum, individualized efficacy can be achieved. In addition, providing the
25 mother with input to the pain control apparatus may psychologically empower the patient. This sense of control may allay anxiety and fear which are large contributors to pain during labor.

Optionally, the device 10 can be structured or programmed to "learn" the patient level preferences and adjust automatically for the next cycle.
30 Further, because labor contractions are generally rhythmic and, therefore,

- 7 -

somewhat predictable, it is also possible to structure or program the device to "learn" the patient's individual pattern and predict a contraction before it occurs. The ability to anticipate a contraction is another way to "preemptively" deliver treatment.

5 The above steps may be performed in a hospital, at home, or even in a remote area, as long as electrical energy of any type is available (AC or DC current, commercial or battery power). Furthermore, the system 10 may be utilized by any care giver trained in its proper use; even people without specific medical training, provided local laws and customs allow it.

10 The control unit 16 should be as small as possible with as few controls as possible. It is preferably battery operated but could also operate on readily available AC current (transformed to DC) without departing from the scope or spirit of the invention. Further, a wireless system which uses available wireless technologies could be used to allow the patient maximum mobility.

15 The freedom to move, shower, bathe, etc. can also reduce pain and allow the patient to be more comfortable.

 Preferably, the control unit 16 graphically displays both the level of contraction strength and the level of therapeutic electrical impulse strength.

20 The impulse 12 and sensor 14 leads are preferably disposable and as few in number as possible to provide optimal benefit. Further, the impulse 12 and sensor 14 leads preferably interface with only the correct connection points on the control unit 16 to avoid any possible misuse. Both shape and color coding may be used to accomplish this end. The impulse 12 and sensor 14 leads may alternatively be reusable.

25 To make the product easier to use and to minimize lead tangling, the electrodes 12, 14 may be wireless. Furthermore, wireless electrodes allow the patient to be mobile and allow women to stand and ambulate, thereby benefitting from the therapeutic effect of gravity, facilitating the movement of the fetus.

- 8 -

The electrodes 12 and sensors 14 are preferably placed and designed to minimize or eliminate feedback or interference between "I" and "S" leads.

The control unit 16 may optionally offer the operator significant manual control over the duration, intensity, frequency and amplitude of the impulse. Further, it may provide the operator with the large amounts of patient (mother and baby) monitoring information typical of a conventional fetal monitor and/or tocodynamometer. This may help the operator to customize the unit's performance for the needs of individual patients (mothers). Additionally, a more sophisticated device 16 may be useful in researching the optimal standard settings to be built into a simpler unit 16. Because each patient has a different perception of pain and a different response to treatment, customized treatment is preferred. This is true in drug therapy, where one patient may receive a different drug dosage level than another patient. This is also true with electrical stimulation. However, the ability to precisely control the electrical energy is almost infinite. A sophisticated research device 16 would facilitate general research as well as determining initial settings for a simpler unit.

The control unit 16 may be designed to interface with existing fetal or labor monitoring devices such as tocodynamometers.

Additionally, although the control unit 16 shown in FIG. 1 is a large, table top unit, persons of ordinary skill in the art will appreciate that it can be miniaturized so it can be carried by a walking mother without departing from the scope or spirit of the invention. Such a miniaturized unit preferably combines a portable tocodynamometer and TENS device in a single housing. Transmitters and receivers may optionally be used to wirelessly transfer data from the portable control unit to a display device for recording and displaying data. The miniaturized unit 16 may be provided with a port which allows the unit 16 to be physically connected to the display device when ambulation is no longer possible or desired.

- 9 -

A more detailed illustration of an apparatus 10 constructed in accordance with the teachings of the invention is shown in FIG. 2. As shown in that figure, the apparatus 10 includes one or more sensors 14 for developing signal(s) representative of a contraction experienced by a patient. As
5 mentioned above, although persons of ordinary skill in the art will readily appreciate that many different types of devices may be utilized to implement the sensor(s) 14, in the preferred embodiment, the sensor 14 is implemented by a conventional tocodynamometer.

For the purpose of applying stimulation to the patient, the apparatus 10
10 is further provided with a stimulator 24. Although persons of ordinary skill in the art will readily appreciate that many different devices (e.g., magnetic devices) may be utilized to implement the stimulator 24, in the preferred embodiment, the stimulator 24 is implemented by a conventional
15 transcutaneous electrical nerve stimulator (TENS). Alternatively, the stimulator 24 can be implemented by an electrical contact adapted to deliver direct electrical stimulation to the spinal cord prior to, or concurrent with, drug therapy. Spinal nerve stimulation is a common pain management method, but it is not commonly used in labor. By placing the epidural catheter, the patient is prepared for delivery of drugs. However, prior to the delivery of drugs, the
20 electrical contact 24 could be placed in the epidural space (with or without an electrolyte solution to enhance conductivity) to deliver therapeutic electrical stimulation. If effective, the electrical stimulator would reduce or eliminate the need for drugs. This direct spinal cord stimulation would most likely be used during the 4-10 cm phase of labor.

25 Returning to FIG. 2, for the purpose of automatically adjusting the stimulation applied by the stimulator 24 at least partially in response to the signal developed by the sensor 14 to reduce pain associated with the sensed contraction, the apparatus 10 is further provided with the control unit 16. The control unit 16 is in communication with the sensor 14 and the stimulator 16
30 to form a closed loop feedback loop through the patient. The control unit 16,

- 10 -

the sensor 14 and the stimulator 16 may optionally be contained in one housing as shown in FIG. 1 and may optionally be powered from a single power supply 26. (For simplicity of illustration, not all of the power supply connections are shown in FIG. 2.) The power supply 26 may comprise a
5 battery or an AC/DC transformer with appropriate conventional smoothing and surge protection circuitry coupled to an AC commercial power supply without departing from the scope or spirit of the invention.

In the apparatus shown in FIG. 2, the control unit 16 includes a comparing circuit 30 for comparing the signal(s) developed by the sensor 14 to
10 signal(s) representative of the stimulation being applied by the stimulator 24. In the analog circuit shown in FIG. 2, the comparing circuit 30 is implemented by a conventional comparator.

To ensure the signals delivered to the comparing circuit 30 are at appropriate voltage levels and strength, the control unit 16 is further provided
15 with conventional signal conditioning circuitry 32. The signal conditioning circuitry 32 includes filters for noise reduction, amplifiers for strength adjusting and/or voltage level adjusters for ensuring all signals to be compared are appropriately scaled. Such signal conditioning circuitry is highly conventional and will not be further discussed herein.

In operation, the comparing circuit 30 receives and compares the filtered, amplified, and/or scaled signal representative of the measured contraction from the sensor 14 and the similarly conditioned signal representative of the output signal generated by the stimulator 24 to develop a difference signal. The difference signal is then passed to the stimulator 24
20 (after being level shifted, filtered, and/or amplified as appropriate by the signal conditioning circuitry 32). The stimulator 24 responds to a non-zero difference signal by increasing or decreasing the stimulation it is outputting (depending upon the sign of the difference signal). A signal representative of the new stimulation is returned to the comparing circuit 30 for comparison
25 against the signal representative of the most current measured contraction
30

- 11 -

state. In this way, the output of the stimulator 24 automatically tracks the measured intensity of the contraction to thereby reduce the pain experienced by the mother.

As mentioned above, the pain experience is highly individualized.

5 Therefore, in order to enable a patient to manually increase or decrease the output level of the stimulator 24, the apparatus 10 is further provided with a manual input 18. By manipulating the input 18, the patient can input a positive, zero, or negative signal to the control unit 16. This input signal is passed through the signal conditioning circuitry 32 and input to a summer 40
10 of conventional design.

The summer 40 adds the input signal from the manual input 18 with the signal generated by the sensor 14. As mentioned above, the input signal from the manual input 18 can be positive, zero or negative. A positive input signal from the manual input 18 will increase the level of the signal from the sensor 14 to thereby develop a combined signal that appears to the comparing
15 circuit 30 as if the sensor 14 has sensed a proportionally stronger contraction than was actually sensed. If the input signal from the manual input 18 is negative, it will decrease the level of the signal 14 from the sensor 14 to thereby develop a combined signal that appears to the comparing circuit 30 as
20 if the sensor 14 has sensed a proportionally weaker contraction than was actually sensed. Of course, adjusting the level of the signal input to the comparing circuit 30 will directly adjust the level of the difference signal the comparing circuit develops and, thus, will directly effect the level of stimulation generated by the stimulator 24. Automatic control of the
25 stimulation level will then continue as explained above based on the output of the stimulator 24 and the input signals received from the sensor 14 and the manual input 18.

Preferably, the manual input 18 is constructed so that the mother can increase or decrease the output of the stimulator 24 in five to ten percent
30 increments.

- 12 -

As mentioned above, it is desirable to permit the patient to turn off the stimulator 24. To this end, the control unit 16 is provided with a switch 42 which may optionally be implemented by a MOSFET. The switch 42 has a first state wherein the switch 42 couples the stimulator 24 to the power supply 26. It also has a second state wherein the switch 42 isolates or disconnects the stimulator 24 from the power supply 26. The state of the switch 42 can be controlled by an input signal generated by the manual input 18.

As also mentioned above, it is also desirable to provide a visual indication of the contractions measured by the sensor 14. To this end, the control unit 16 is provided with a conventional graphics drive which is adapted to output a signal corresponding to the signal received from the sensor 14 for display on a display device 48. Optionally, the signal representative of the stimulator 24 output could also be delivered to the graphics drive 44 (see the dashed line in FIG. 2) for display on the display device 48.

Another apparatus 100 constructed in accordance with the teachings of the invention is shown in FIG. 3. The apparatus 100 is substantially similar to the apparatus 10. However, whereas the control unit 16 of the apparatus 10 was an analog circuit, the control circuit 116 of the apparatus 100 is a microprocessor based, digital circuit. Structures bearing the same reference numbers in FIGS. 2 and 3 are identical. Similar, but not identical structures, appearing in FIGS. 2 and 3 employ reference numerals separated by one hundred (e.g., 30 in FIG. 2 is 130 in FIG. 3).

In the apparatus 100 of FIG. 3, the comparing circuit is implemented by a microprocessor 130. As a result, the signal conditioning circuitry 132 includes conventional analog to digital converters and/or digital to analog converters in addition to filtering, amplifying and/or level shifting circuitry.

The microprocessor 130 is programmed to executed a program such as the exemplary program illustrated by the flowchart shown in FIG. 4. In that program, the stimulator 24 is first set to zero output through an initialization procedure. The microprocessor 130 then sums the input received from the

- 13 -

manual input 18 (input "Y" in FIG. 4) with the input received from the sensor 14 (input "X" in FIG. 3) to determine if the sum of those inputs (X and Y) is non-zero (block 160). If a non-zero sum is present, then the stimulator 24 must develop a non-zero output to counteract the pain associated with the
5 sensed contraction. If a zero sum is present, no output is required from the stimulator 24 because either no contraction has been sensed by the sensor 14 (i.e., $X = 0$) and the manual input is set to zero (i.e., $Y = 0$), or because the manual input has been manipulated to exactly offset the signal developed by the sensor (i.e., $X = -Y$) as might be the case with a patient who does not need
10 as much pain intervention as the average patient.

Assuming that the inputs of the sensor 14 and manual input 18 create a non-zero sum, the microprocessor 130 then updates the display device with the current sensed inputs from the sensor 14 and manual input (X and Y) and the current second output of the stimulator 24 ("T" in FIG. 3) via the digital
15 graphics driver 144 (block 162). The microprocessor 130 next determines whether the second output (T) of the stimulator 24 is equal to the sum of the inputs (X and Y) from the sensor 14 and the manual input 18 (block 164). If the output of the stimulator 24 matches the sum of the inputs (X and Y) from the sensor 14 and the manual input 18, control returns to block 160.

20 Otherwise, control proceeds to block 166.

At block 166, the microprocessor 130 adjusts the output (T) of the stimulator 24 either up or down to equal the sum of the inputs (X and Y) from the sensor 14 and manual input 18. The microprocessor 130 then updates the display device via the graphics driver 144 (block 168) and checks the
25 measured output (T) of the stimulator 24 to determine whether its output (T) has reached the desired level (i.e., $X + Y$) (block 170). The microprocessor continues to execute blocks 166-170 until the output (T) of the stimulator 24 equals the sum of the inputs (X + Y) of the sensor 14 and the manual input 18 (block 170). Control then returns to block 160.

- 14 -

Persons of ordinary skill in the art will appreciate that the sensed inputs (X + Y) will often change during the adjustment of the stimulator 24.

Therefore, control will often remain in the loop comprising blocks 166-170 for the duration of a contraction, and control will typically only return to block
5 160 nearer the end of a contraction when the sensed intensity is changing less rapidly.

A further view of the device 100 of FIG. 3 is shown in FIG. 7. As shown in FIG. 7, the control unit 116 of the apparatus 100 may be implemented by a conventional fetal monitor 117, a personal computer 119
10 and an interface circuit 121 for permitting the computer 119 and the TENS unit 24 to communicate. The interface circuit 121 may optionally be internal to the computer 119 or the stimulator 24. The TENS unit 24 is modified from a conventional unit to facilitate communication with, and control by, the computer 119.

15 As also shown in FIG. 7, the fetal monitor 117 can communicate with the personal computer 119 via RS-232 ports 123 or via an analog output 125 and a PCMCIA card 127 in a conventional fashion. Preferably, the PCMCIA card 127 is used to communicate with the interface circuit 121.

From the foregoing, persons of ordinary skill in the art will readily
20 appreciate that pain control apparatus have been disclosed for controlling pain without the use of drugs.

Specifically, the disclosed apparatus optimally deliver a well understood and commonly practiced method of pain management in a simple controlled way, which is timed to the needs of the patient with the option of
25 being modulated by direct patient feedback. The ability to "preemptively" deliver therapy is advantageous because it is easier to control pain before it begins or before it becomes significant. This makes treatment easier and more effective. The disclosed pain control apparatus are safer than drugs.

The disclosed pain control apparatus can be used during the often long
30 labor period prior to 4 cm of cervical dilation when drugs are not typically

- 15 -

used, thereby providing the mother with pain relief over a longer period of time and making the entire birthing process a more pleasant experience. In other words, the disclosed pain control apparatus provide analgesia during 0-4 cm where there are few other pain relief options. Further, by minimizing
5 drugs before, during and after delivery, there is less drug in breast milk and therefore increased safety for the baby as well as the mother.

Moreover, the disclosed pain control apparatus can also be used in conjunction with, or in place of, epidural pain control once the cervix is dilated more than 4 cm.

10 Electrical stimulation may also be in response to or coordinated with other body contractions such as back and neck muscle spasms. Similarly, measurement and output response can be performed on other muscles or nerves. The device also may be of significant benefit for patients who suffer from urinary sphincter dysfunction and stress incontinence.

15 The disclosed pain control apparatus help women, physicians, midwives and others to make the long labor period more comfortable during the time when drugs are typically withheld. This enables the mother to be more rested and have a higher physical and mental capability to deal with the final labor period without drugs or a lower level of drugs, thereby protecting
20 the mother and baby from drug side effects.

The disclosed pain control apparatus can eliminate the need for the traumatic, invasive epidural injection as well as the potential toxic and deleterious side effects of epidural injections. Further, the cost of epidural injection is very high.

25 The disclosed pain control apparatus also provide a non-drug, low cost, simple pain management system that is available for hospital and/or home delivery in both industrialized countries as well as underdeveloped countries where financial resources and the availability of highly skilled anesthesiologists are generally quite limited.

- 16 -

The disclosed pain control apparatus further provide "preemptive" pain relief prior to the actual onset of pain or prior to experiencing a significant level of pain. While in labor, women's uterine contractions are typically monitored with a tocodynamometer. This and other similar devices can sense the beginning of a uterine contraction before it is perceived by the patient. By linking a tocodynamometer (or similar device) with the TENS unit so that the TENS is applied or increased in a coordinated way with a uterine contraction, efficacy is enhanced. Furthermore, the patient, nurse, midwife or family member is totally or at least partially relieved from constantly operating the TENS device.

Although the apparatus 10, 100 of FIGS. 1-4 have been described for use in controlling pain associated with contractions such as uterine contractions experienced during labor and spasms (i.e., muscle spasms in the back or neck), the teachings of the present invention may also be used in muscle retraining of, for example, paraplegics, quadriplegics, stroke sufferers, or other patients (e.g., patients with paralytic intestines and dysfunctional urinary sphincters).

An apparatus 200 constructed in accordance with the teachings of the invention for performing muscle retraining is shown in FIG. 5. Like the apparatus 10, 100 described above, the apparatus 200 includes a stimulator which is preferably implemented by a TENS device. The stimulator of the apparatus 200 is controlled to apply stimulation to the muscle to be retrained in order to adjust a contraction condition of the muscle. The contraction condition of the muscle refers to any state of contraction between totally relaxed and completely contracted, and is preferably inclusive of those two extremes.

For the purpose of developing a signal indicative of the contraction condition of the muscle to be retrained, the apparatus 200 is further provided with a sensor 14. The sensor 14 of the apparatus 200, like the sensors 14 of the apparatus 10, 100, is preferably implemented by a tocodynamometer.

- 17 -

For the purpose of storing data representative of a predetermined contraction and relaxation activity to be performed by the muscle to be retrained, the apparatus 200 is preferably provided with a memory 250. The memory 250 can be implemented by a conventional read only memory (e.g., EEPROM, CD ROM, etc.), but preferably is implemented by a read/write
5 memory such as a SRAM, hard drive, or other conventional memory device. The predefined contraction and relaxation activity can be any desired activity, but typically will comprise data representative of a curve increasing the contraction state of the muscle from a relaxed condition to a fully flexed or
10 contracted condition and then decreasing the contraction state of the muscle from the fully flexed or contracted condition to the relaxed condition. Preferably, the predetermined contraction and relaxation activity will allow for relaxation of the muscle in a gradual manner, thus, facilitating the natural activity of activating reciprocal muscle groups to obtain flexion then
15 extension, which is typical for activity for walking.

In order to automatically adjust the stimulation applied by the stimulator 24 to the muscle being retrained in response to the data stored in the memory 250 and the output of the sensor 14, the apparatus 200 is further provided with a control unit 230. As shown in FIG. 5, the control unit 230 is
20 in communication with the memory 250, the stimulator 24 and the sensor 14. As with the apparatus 10, 100, signal conditioning circuitry 232 is provided for filtering, level shifting, amplifying and/or converting signals passing between two or more of the control unit 230, the stimulator 24 and/or the sensor 14.

25 The control unit 230 includes a comparing circuit for comparing the signal developed by the sensor 14 to data from the memory 250. Persons of ordinary skill in the art will readily appreciate that the comparing circuit can be implemented in many ways without departing from the scope or spirit of the invention. For example, the comparing circuit can be implemented by a
30 comparator such as that shown in FIG. 2. However, in the preferred

- 18 -

embodiment shown in FIG. 5, the comparing circuit is implemented by a microprocessor 230.

In order to enable a partially paralyzed individual to initiate the retraining process after the sensor 14 and stimulator 24 are affixed to the muscle or muscle group to be stimulated, the apparatus 200 is preferably
5 provided with a sensor 252. Persons of ordinary skill in the art will readily appreciate that the sensor 252 can be implemented in many ways without departing from the scope or spirit of the invention. For example, the sensor 252 can be implemented by a blowtube or other conventional sensor capable
10 of sensing, for example, tongue movement, eyeball movement, or movement of another appendage.

An exemplary program which can be executed by the microprocessor 230 is shown in FIG. 6. After performing various conventional initialization processes such as setting the output of the stimulator 24 to zero, the
15 microprocessor 230 enters a loop wherein it awaits a start command from the sensor 252 (block 274). Once that start command is received (block 274), the microprocessor 230 retrieves one or more data values from the memory 250 corresponding to the predetermined contraction and relaxation activity (block 276). The microprocessor 250 then compares the input received from the
20 sensor 14 (i.e., a signal representative of a measured contraction condition of the muscle) to the first data point in the predetermined contraction and relaxation activity (block 278). If the input signal received from the sensor 14 and the first data point are substantially equal (block 278), control proceeds to block 288. Otherwise control proceeds to block 280.

25 At block 280, the microprocessor 280 determines if the measured contraction condition of the muscle is less than the contraction condition specified by the data point from the memory 250. If so, the microprocessor 250 increases the output of the stimulator 24 by a predetermined amount (block 284). Otherwise, the microprocessor decreases the output of the
30 stimulator 24 by a predetermined amount (block 282). Regardless of whether

- 19 -

the stimulator 24 has been instructed to increase or decrease its output, the microprocessor 230 determines whether a timeout condition has been reached (block 286). A timeout can occur, for example, if the desired muscle contraction state is not reached within a predetermined time (e.g., stimulator
5 24 is not connected properly, etc.). Control continues to loop between blocks 278-286 until the sensed contraction state substantially equals the contraction state specified by the data point from memory (block 278), or until a timeout condition (block 286) is reached. If a timeout condition occurs (block 286), the exercise terminates until a new start command is received (block 274).

10 If, on the other hand, the loop defined by blocks 278-286 is exited at block 278, the microprocessor 230 determines whether the exercise is complete (i.e., the muscle being retrained has entered the contraction/relaxation state specified by every data point in the predetermined contraction and relaxation activity) (block 288). If so, control returns to block
15 274 where the microprocessor 230 awaits a command to start another exercise. Otherwise, control proceeds to block 290.

At block 290, the microprocessor 230 determines whether it is time to advance to the next point in the contraction and relaxation activity. When the time to move to the next stage of the activity is reached (block 290), control
20 proceeds to block 276 where the next data point in the activity is retrieved. The process then continues as explained above by comparing the measured contraction condition of the muscle to the desired contraction condition specified by the new data point (block 278) and adjusting the output of the stimulator 24, if necessary. Control continues to loop through blocks 276-290
25 until the exercise specified by the predetermined contraction and relaxation activity has been performed by the muscle being retrained (block 288), or until a timeout error occurs (block 286).

Although certain apparatus constructed in accordance with the teachings of the invention have been described herein, the scope of coverage
30 of this patent is not limited thereto. On the contrary, this patent covers all

- 20 -

embodiments of the teachings of the invention fairly falling within the scope of the appended claims either literally or under the doctrine of equivalents.

- 21 -

What is claimed is:

1. For use in reducing pain experienced by a patient, an apparatus comprising:
 - a sensor structured to develop a signal indicative of a contraction experienced by the patient;
 - a stimulator structured to apply stimulation to the patient; and
 - a control unit in communication with the sensor and the stimulator for automatically adjusting the stimulation applied by the stimulator at least partially in response to the signal developed by the sensor to reduce the pain associated with the contraction.
2. An apparatus as defined in claim 1 wherein the sensor comprises a tocodynamometer.
3. An apparatus as defined in claim 1 wherein the signal developed by the sensor is indicative of a uterine contraction.
4. An apparatus as defined in claim 1 wherein the stimulator comprises a transcutaneous electrical nerve stimulator.
5. An apparatus as defined in claim 1 wherein the control unit further comprises a comparing circuit for comparing the signal developed by the sensor to a signal representative of the stimulation applied by the stimulator.
6. An apparatus as defined in claim 5 wherein the comparing circuit comprises a microprocessor.
7. An apparatus as defined in claim 5 wherein the comparing circuit comprises a comparator.

- 22 -

8. An apparatus as defined in claim 1 further comprising a manually operable input device in communication with the control unit for enabling input of an input signal.

9. An apparatus as defined in claim 8 wherein the control unit further comprises a summer for summing the input signal from the input device and the signal developed by the sensor to develop a sum signal, and wherein the control unit automatically adjusts the stimulation applied by the stimulator in response to the sum signal.

10. An apparatus as defined in claim 8 wherein the control unit automatically adjusts the stimulation applied by the stimulator in response to the input signal from the input device and the signal developed by the sensor.

11. An apparatus as defined in claim 8 wherein the control unit is responsive to the input signal to terminate the stimulation applied by the stimulator.

12. An apparatus as defined in claim 11 wherein the control unit further comprises a switch having a first state wherein the switch couples the stimulator to a power supply and a second state wherein the switch isolates the stimulator from the power supply, and wherein the state of the switch is controlled by the input signal.

13. An apparatus as defined in claim 1 further comprising a graphics driver for outputting a signal indicative of the signal developed by the sensor to a display device.

14. An apparatus as defined in claim 1 wherein the stimulator is adapted to be inserted into an epidural space of the patient.

- 23 -

15. For use in retraining a muscle of a patient, an apparatus comprising:
- a stimulator structured to apply stimulation to the muscle of the patient in order to adjust a contraction condition of the muscle;
 - a sensor structured to develop a signal indicative of the contraction condition of the muscle of the patient;
 - a memory storing data representative of a predetermined contraction and relaxation activity for the muscle; and
 - a control unit in communication with the, memory, the sensor and the stimulator for automatically adjusting the stimulation applied by the stimulator in response to the data stored in the memory and the signal developed by the sensor.
16. An apparatus as defined in claim 15 wherein the sensor comprises a tocodynamometer.
17. An apparatus as defined in claim 15 wherein the stimulator comprises a transcutaneous electrical nerve stimulator.
18. An apparatus as defined in claim 15 wherein the control unit further comprises a comparing circuit for comparing the signal developed by the sensor to the data from the memory.
19. An apparatus as defined in claim 18 wherein the comparing circuit comprises a microprocessor.
20. An apparatus as defined in claim 18 wherein the comparing circuit comprises a comparator.

- 24 -

21. A method for reducing labor pain experienced by a patient comprising the steps of:

positioning a sensor on the patient in a location for developing a signal indicative of a uterine contraction;

coupling a stimulator to the patient in a location to apply electrical stimulation reducing the labor pain;

employing the sensor to develop the signal indicative of the uterine contraction; and

responding to the signal indicative of the uterine contraction by adjusting the electrical stimulation applied by the stimulator to reduce the labor pain.

22. A method as defined in claim 21 wherein the step of responding to the signal indicative of the uterine contraction further comprises the steps of:

comparing the signal indicative of the uterine contraction to a signal representative of the electrical stimulation applied by the stimulator; and

adjusting the electrical stimulation developed by the stimulator based upon the comparison.

23. A method for retraining a muscle of a patient comprising the steps of:

(a) reading data representative of at least a portion of a predetermined contraction and relaxation activity for the muscle from a memory;

(b) measuring a contraction condition of the muscle of the patient;

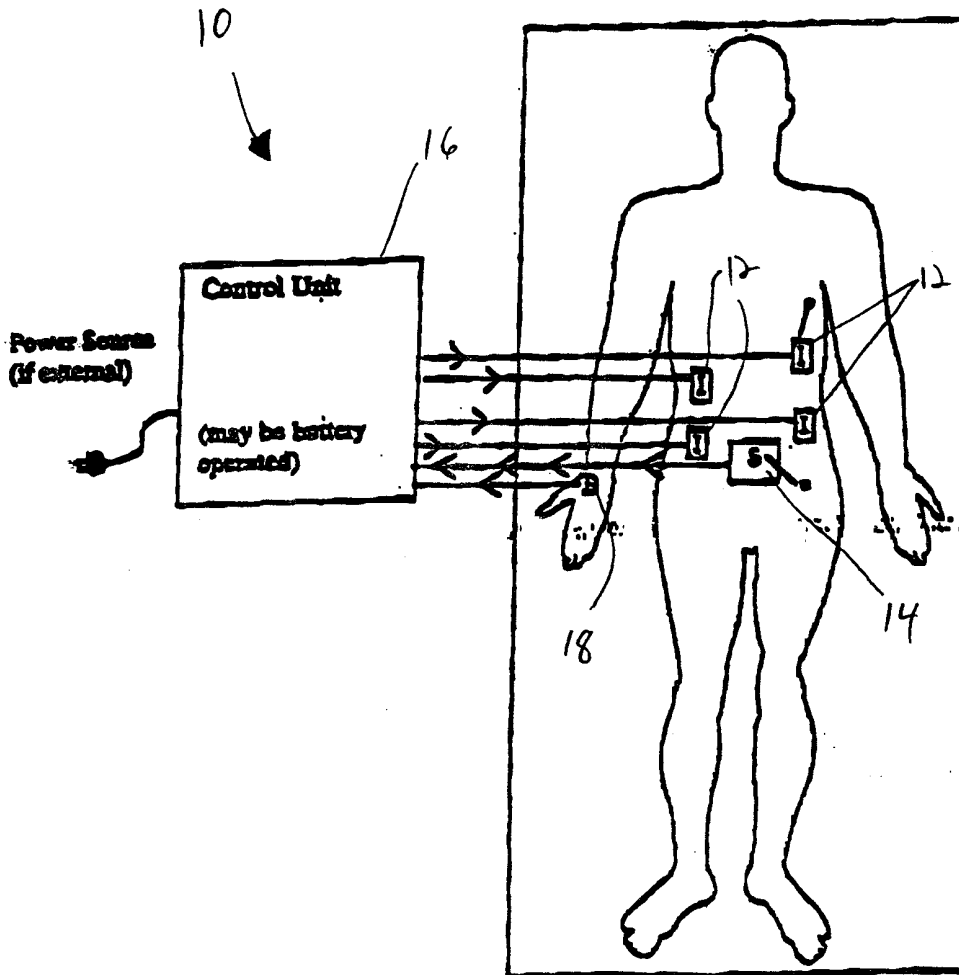
(c) comparing at least a portion of the data read from the memory to a signal representative of the contraction condition of the muscle of the patient; and

- 25 -

(d) automatically adjusting a stimulation signal applied to the muscle by a stimulator based upon the comparison to adjust the contraction condition of the muscle.

24. A method as defined in claim 23 wherein at least steps (b)-(d) are repeated until the muscle has performed the predetermined contraction and relaxation activity at least one time.

FIG. 1



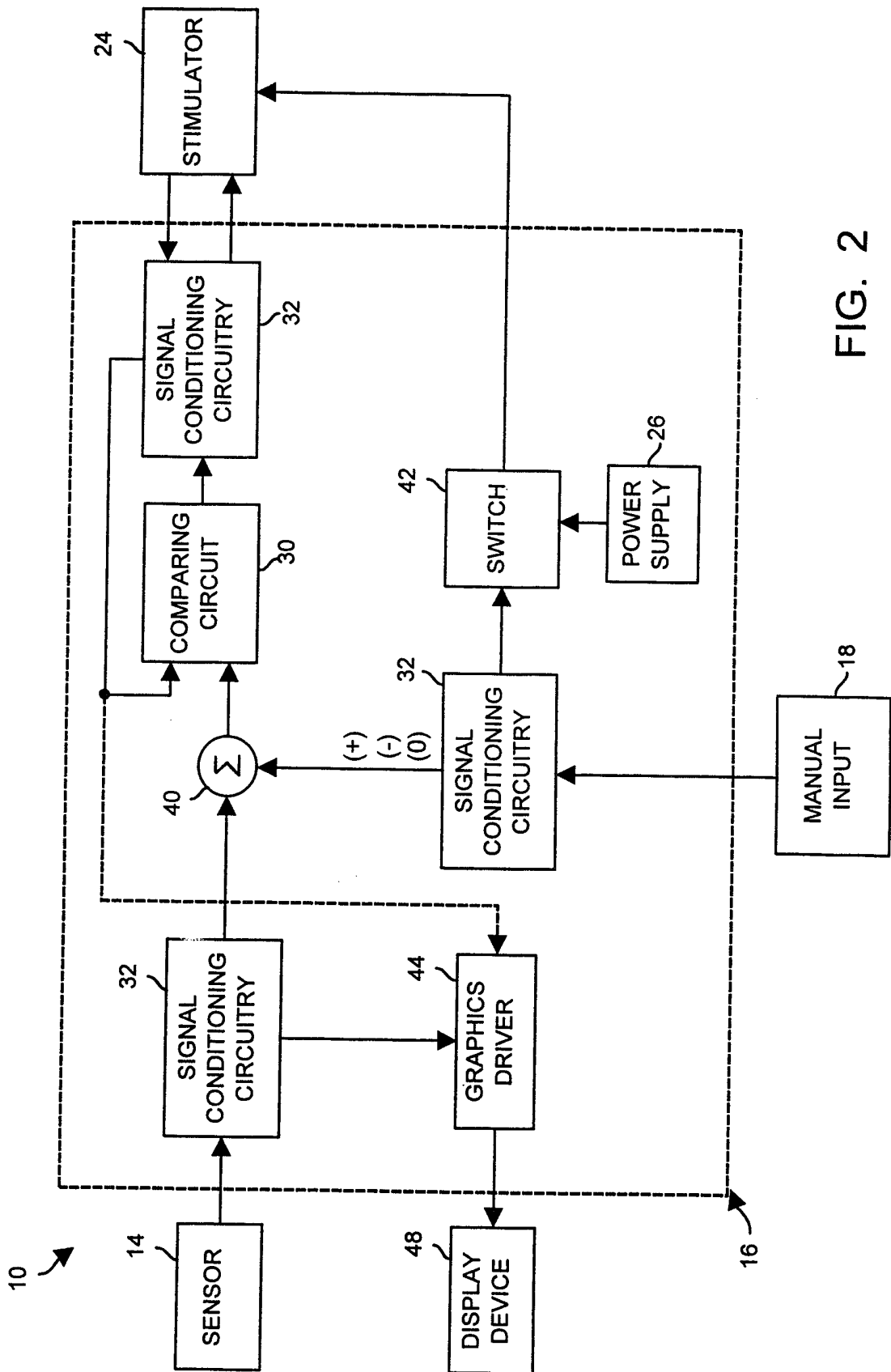


FIG. 2

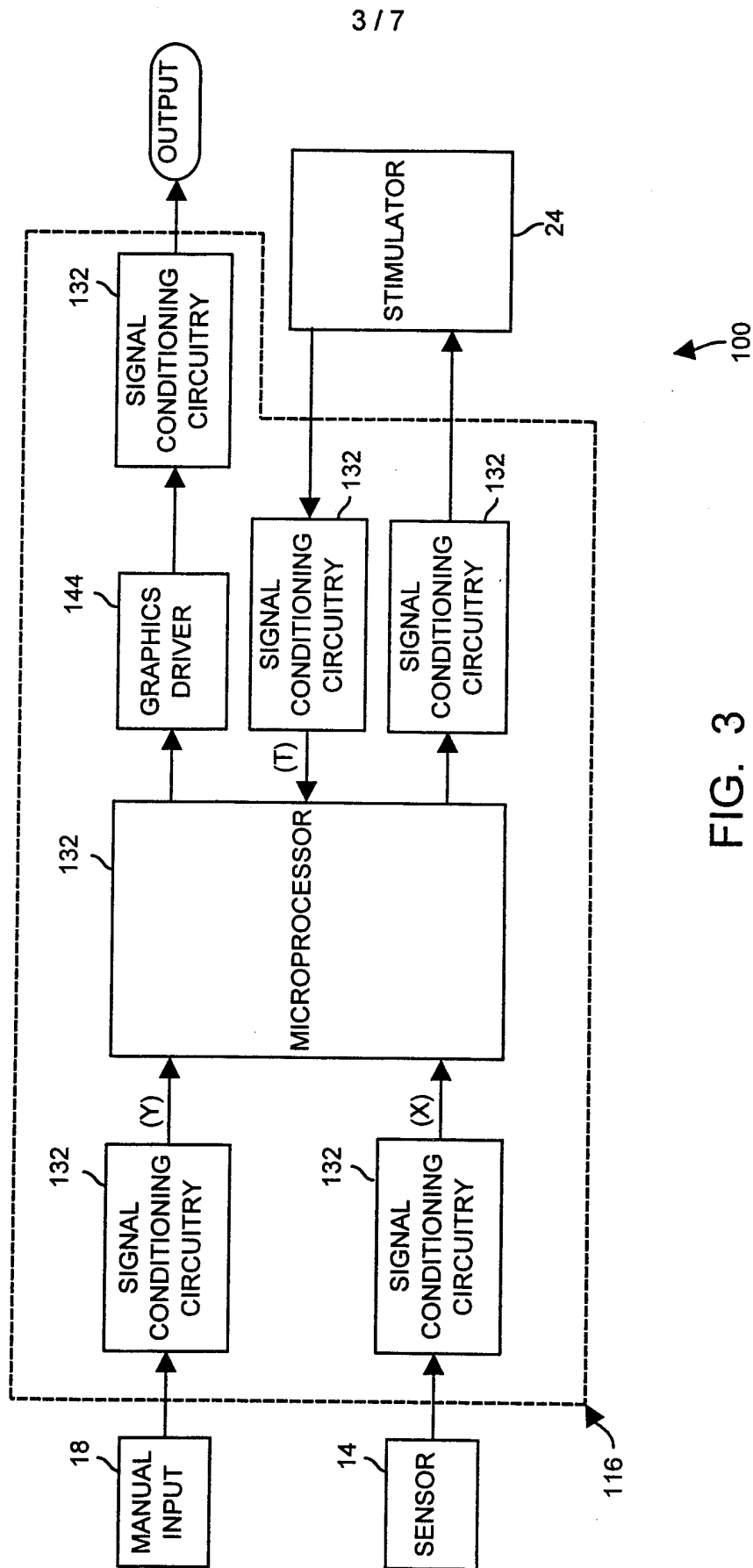


FIG. 3

4 / 7

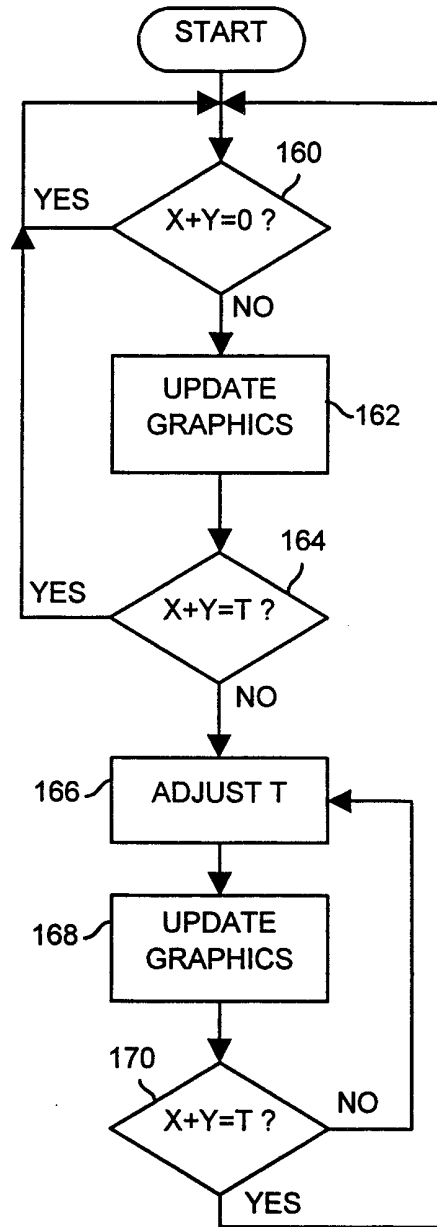


FIG. 4

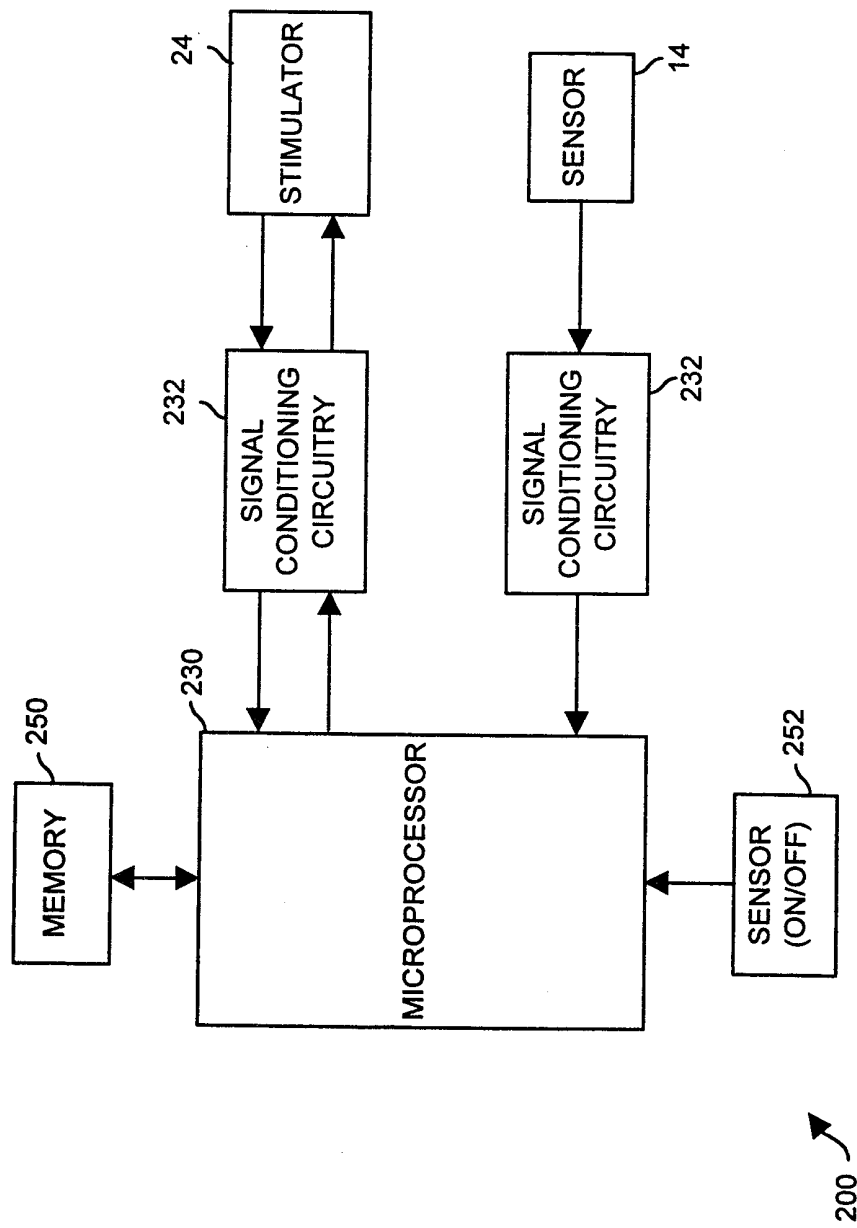
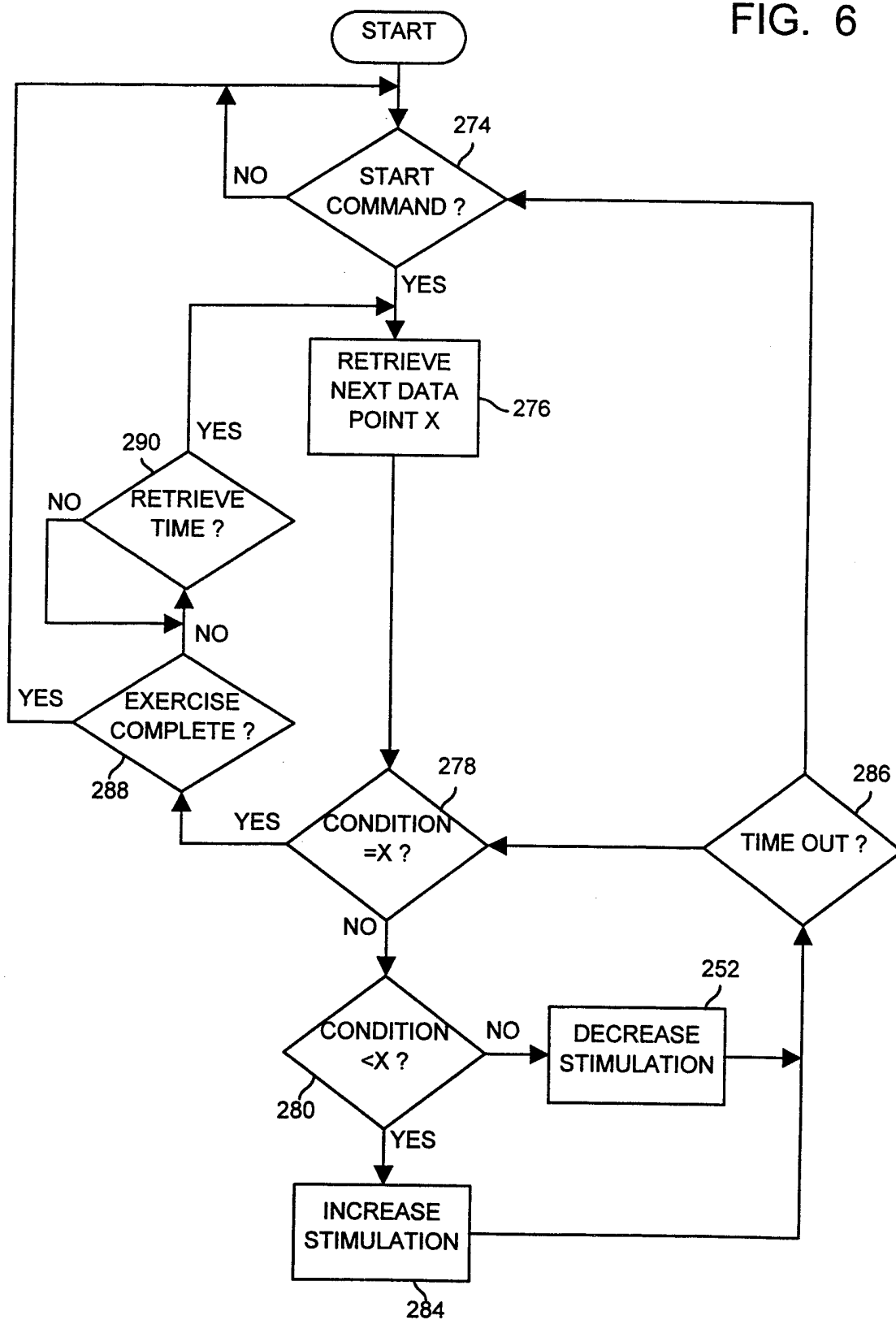


FIG. 5

FIG. 6



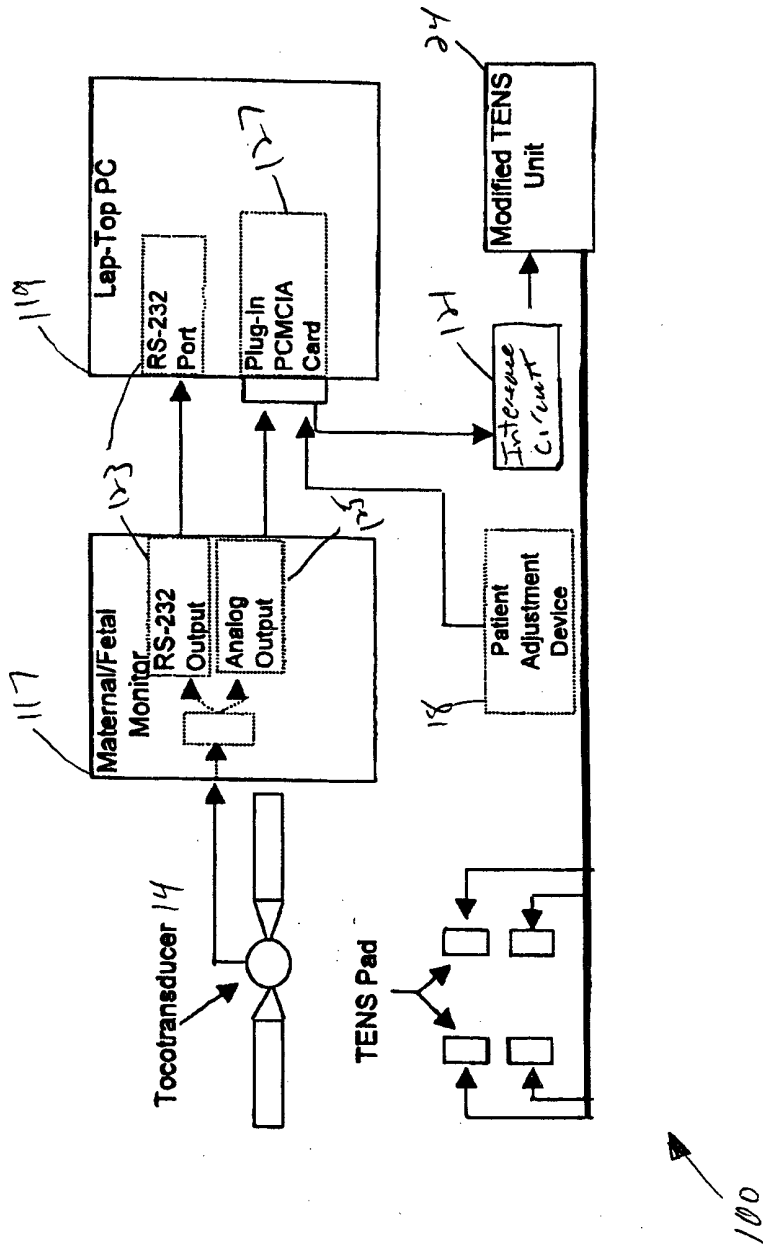


FIG. 7

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 00/07863

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N1/34

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A A A	<p>US 5 540 730 A (BAKER JR ROSS G ET AL) 30 July 1996 (1996-07-30) column 5, line 18 -column 10, line 50; figures</p> <p style="text-align: center;">---</p> <p>US 4 556 214 A (PETROFSKY JERROLD S ET AL) 3 December 1985 (1985-12-03) column 3, line 57 -column 5, line 28; figures 1-6</p> <p style="text-align: center;">---</p> <p>US 5 224 490 A (ALLEN GEORGE R ET AL) 6 July 1993 (1993-07-06) column 3, line 8 -column 4, line 47; figures</p> <p style="text-align: center;">---</p> <p style="text-align: center;">-/--</p>	<p>15</p> <p>1,5,6, 18,19</p> <p>1,4-6, 15,17-19</p> <p>1-3,15, 16</p>

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
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Date of the actual completion of the international search <p style="text-align: center; font-weight: bold;">14 July 2000</p>	Date of mailing of the international search report <p style="text-align: center; font-weight: bold;">21/07/2000</p>
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Authorized officer <p style="text-align: center; font-weight: bold;">Rakotondrajaona, C</p>

INTERNATIONAL SEARCH REPORT

Int'l Application No

PCT/US 00/07863

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 861 017 A (IGNATOSKI MICHAEL ET AL) 19 January 1999 (1999-01-19) column 1, line 55 -column 2, line 34; figures -----	1,6,15, 17,19
A	WO 93 08874 A (MEDTRONIC INC) 13 May 1993 (1993-05-13) page 3, line 6 -page 5, line 35; figures -----	1,15
A	US 5 824 021 A (RISE MARK T) 20 October 1998 (1998-10-20) column 2, line 19 -column 3, line 65; figures -----	1
A	US 4 499 900 A (PETROFSKY JERROLD S ET AL) 19 February 1985 (1985-02-19) column 2, line 58 -column 9, line 65; figures -----	1,5,6, 15,18,19

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. Patent Application No

PCT/US 00/07863

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5540730	A	30-07-1996	NONE
US 4556214	A	03-12-1985	US 4480830 A 06-11-1984 CA 1209001 A 05-08-1986 EP 0103490 A 21-03-1984 JP 1712654 C 27-11-1992 JP 3076951 B 09-12-1991 JP 59146669 A 22-08-1984
US 5224490	A	06-07-1993	NONE
US 5861017	A	19-01-1999	EP 1017448 A 12-07-2000 WO 9855177 A 10-12-1998 US 5983140 A 09-11-1999
WO 9308874	A	13-05-1993	AU 3058092 A 07-06-1993 CA 2120617 A 13-05-1993 EP 0610428 A 17-08-1994 JP 6510461 T 24-11-1994 US 5358519 A 25-10-1994
US 5824021	A	20-10-1998	NONE
US 4499900	A	19-02-1985	CA 1219641 A 24-03-1987