

(12) STANDARD PATENT
(19) AUSTRALIAN PATENT OFFICE

(11) Application No. **AU 2006200860 B2**

(54) Title
Systems and methods for intra-operative stimulation

(51) International Patent Classification(s)
A61B 5/0488 (2006.01) **A61N 1/08** (2006.01)

(21) Application No: **2006200860** (22) Date of Filing: **2006.02.28**

(30) Priority Data

(31) Number	(32) Date	(33) Country
11/099848	2005.04.06	US
60/657277	2005.03.01	US

(43) Publication Date: **2006.09.21**

(43) Publication Journal Date: **2006.09.21**

(44) Accepted Journal Date: **2011.09.08**

(71) Applicant(s)
NDI Medical, LLC

(72) Inventor(s)
Strother, Robert B;Thrope, Geoffrey B;Mrva, Joseph J

(74) Agent / Attorney
Griffith Hack, Level 3 509 St Kilda Road, Melbourne, VIC, 3004

(56) Related Art
US 5775331
US 6325764
US 4962766
US 5284154

Abstract

Improved assemblies, systems, and methods provide safeguarding against nerve injury during surgical procedures and/or identify nerve damage occurring prior to surgery and/or verify range of motion or attributes of muscle contraction during reconstructive surgery. A stimulation control device may incorporate a range of low and high intensity stimulation to provide a stimulation and evaluation of both nerves and muscles. A stimulation control device is removably coupled to a surgical device or is imbedded within the medical device to provide a stimulation and treatment medical device.

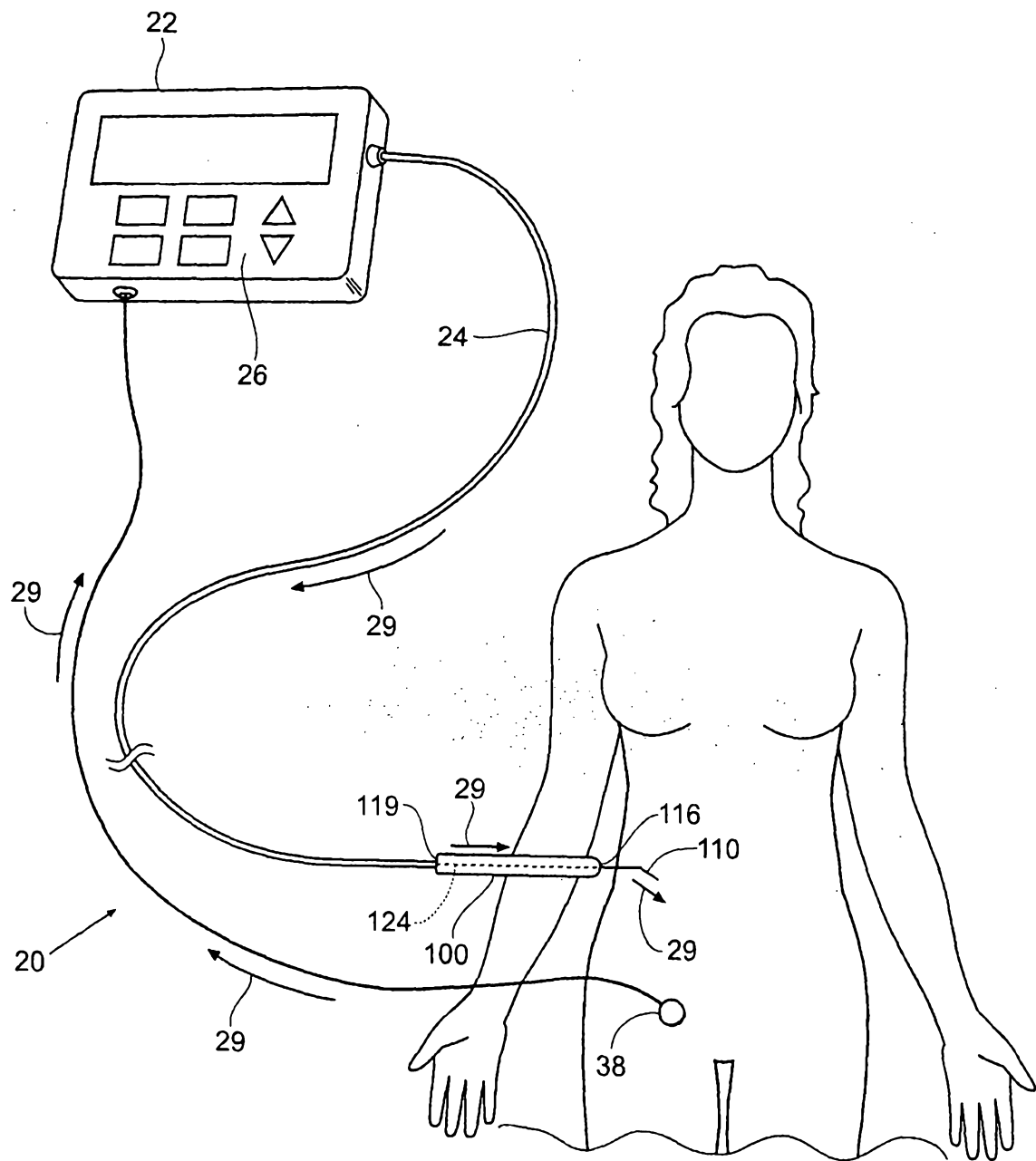


Fig. 2

2006200860 28 Feb 2006

AUSTRALIA
Patents Act 1990

COMPLETE SPECIFICATION
STANDARD PATENT

Applicant(s) :

NDI Medical, LLC

Invention Title:

SYSTEMS AND METHODS FOR INTRA-OPERATIVE STIMULATION

The following statement is a full description of this invention, including the best method of performing it known to me/us:

- 1A-

SYSTEMS AND METHODS FOR INTRA-OPERATIVE STIMULATION**Related Application**

This application claims the benefit of United States Provisional Patent Application Serial No. 5 60/657,277, filed March 1, 2005, and entitled "Systems and Methods for Intra-Operative Stimulation" which is incorporated herein by reference.

Field of the Invention

10 The invention relates generally to nerve and muscle identification and integrity testing, and more particularly to systems and methods for safeguarding against nerve and muscle injury during surgical procedures, identification and assessment of nerve and muscle integrity following traumatic injuries, and 15 verification of range of motion and attributes of muscle contraction during reconstructive surgery.

Background of the Invention

Even with today's sophisticated medical devices, surgical procedures are not risk-free. Each 20 patient's anatomy differs, requiring the surgeon to be ever vigilant to these differences so that the intended result is accomplished. The positioning of nerves and other tissues within a human or animal's body is one example of how internal anatomy differs from patient to 25 patient. While these differences may be slight, if the

surgeon fails to properly identify one or several nerves, the nerves may be bruised, stretched, or even severed during an operation. The negative effects of nerve damage can range from lack of feeling on that part of the body to loss of muscle control.

Traumatic injuries often require surgical repair. Determining the extent of muscle and nerve injury is not always possible using visual inspection. Use of an intra-operative stimulator enables accurate evaluation of the neuromuscular system in that area. This evaluation provides valuable knowledge to guide repair/reconstructive surgery following traumatic injury, and when performing a wide range of surgeries.

Summary of the Invention

The invention provides devices, systems, and methods for intra-operative stimulation. The intra-operative stimulation may enable accurate evaluation of the neuromuscular system to guide repair or reconstructive surgery.

One aspect of the invention provides devices, systems, and methods comprising a tissue stimulation system comprising a housing, such as a tubular shaped housing, having a proximal end and a distal end, an operative element having an electrically conductive surface sized and configured for electrical stimulation of a targeted tissue region, the operative element extending from the distal end of the housing, and wherein the electrical stimulation is in the form of a signal having an amplitude and a duration for providing a first indication to the user of close proximity of the operative element to the targeted tissue region, and a stimulation control device electrically coupled to the operative element, the stimulation control device comprising stimulation signal generating circuitry. The housing may include a first control device for turning

the stimulation signal to the operative element on and off and for providing adjustment of the stimulation signal amplitude, the first control device being electrically coupled to the stimulation control device.

- 5 The housing may also include a second control device for providing adjustment of the stimulation signal duration, the second control device being electrically coupled to the stimulation control device.

Additional aspects of the invention provide a
10 tissue stimulation system that may be sterilized and prepackaged for single use. The stimulation signal of the tissue stimulation system includes an amplitude that may range between about zero milliamps and about 20 milliamps, allowing for accurate selective stimulation of
15 both muscles and nerves, and also identification of nerves and muscles, muscle attachments, or to contract muscles to assess the quality of surgical interventions. The tissue stimulation signal duration may include a range between about zero microseconds and about 200
20 microseconds, for example. The first indication provided by the tissue stimulation system may include, for example, audio and visual indications. The tissue stimulation system may further include a second indication means to provide confirmation of power on to
25 the device and delivery of a stimulation signal to the electrically conductive surface. The operative element of the tissue stimulation system may comprise a probe, for example, where the electrically conductive surface of the probe comprises between about 1 millimeter and about 10
30 millimeters of the distal end of the probe, and the probe comprises a diameter between about 0.5 millimeters and about 1 millimeter. The tissue stimulation system may also further include a return electrode electrically coupled to the stimulation control device.

- 35 Additional aspects of the invention provide a

- 4 -

tissue stimulation system, such as a medical device comprising a housing having a proximal end and a distal end, the housing sized and configured to be held by a user, a probe having an electrically conductive surface
5 sized and configured for electrical stimulation of a targeted tissue region, the probe extending from the distal end of the housing, and wherein the electrical stimulation is in the form of a signal having an amplitude and a duration for providing a physical motor
10 response, a stimulation control device electrically coupled to the probe and sized and configured to be positioned within the housing, the stimulation control device comprising stimulation signal generating circuitry. The housing may include a first control device
15 for turning the stimulation signal to the probe on and off and for providing adjustment of the stimulation signal amplitude, the first control device being electrically coupled to the stimulation control device. The housing may also include a second control device for
20 providing adjustment of the stimulation signal duration, the second control device being electrically coupled to the stimulation control device.

According to another aspect of the invention, a stimulation control device electrically coupled to at
25 least one surgical tool, which can comprise, e.g., a cutting, grasping, drilling, screwing, and/or viewing tool. The application of stimulation voltage or current to the device allows the clinician to observe muscle contraction or changes in the nervous system response
30 when the surgical tool is in close proximity to viable nerve or muscle tissue. The surgical tool thus becomes a neural/muscular stimulating electrode. In use, different surgical tools, individually deployed in association with different medical procedures, can make use of a single,
35 stimulation control device, to which a selected surgical

tool can be temporarily coupled for use.

According to yet another aspect of the invention, the stimulation control device may be embedded within the surgical tool to provide a medical device
5 capable of providing stimulation, as described above.

Another aspect of the invention provides devices, systems, and methods comprising a stimulation monitor or probe and at least one electrode. In one embodiment, a hand held stimulation probe or monitor
10 includes the stimulation control device and at least one stimulation electrode within a unified housing to provide an ergonomic stimulation device. The hand held stimulation probe can be a sterile, single use instrument intended for use during surgical procedures to identify
15 nerves and muscles, muscle attachments, or to contract muscles to assess the quality of surgical interventions or the need for surgical interventions, or to evaluate the function of nerves already identified through visual or audible means, or by other nervous system monitoring
20 instruments.

Additional aspects of the invention provide a stimulation control device electrically coupled to a tissue cutting instrument, or a stimulation control device electrically coupled to a drilling instrument, or
25 a stimulation control device electrically coupled to a pilot auger for hard surface rotary probing prior to pilot hole drilling, or a stimulation control device electrically coupled to a fixation device, which is commonly used in spinal stabilization procedures and
30 internal bone fixation procedures.

In accordance with a further aspect of the present invention, there is provided a hand-held tissue stimulation system comprising:

a tubular housing having a proximal end and
35 a distal end, the housing being sized and

- 5a -

configured to be held and controlled entirely within a surgical field and in a single hand by a user;

5 a stimulation control device positioned entirely within the housing, the stimulation control device comprising stimulation signal generating circuitry for generation of an electrical stimulation signal having an amplitude and a duration, a microcontroller electrically
10 coupled to the stimulation signal generating circuitry, and a source of power for the stimulation control device;

a probe extending from the distal end of the housing and having an electrically conductive
15 surface electrically coupled to the signal generating circuitry, the electrically conductive surface being sized and configured for contact with a targeted tissue region and, when in contact, applying the electrical stimulation
20 signal to the targeted tissue region;

a return electrode electrically coupled to the signal generating circuitry and being sized and configured for contact with tissue to provide an electrical flow path for the stimulation
25 signal from the probe back to the stimulation control device;

a first control device carried on the housing and electrically coupled to the microcontroller, the first control device being
30 movable by a user from a first position to a second position for providing a power control input to the microcontroller to turn the stimulation signal generating circuitry on and from the second position through a plurality of
35 control positions for providing amplitude control

- 5b -

inputs to the microcontroller to control selection of the amplitude within a predefined amplitude range;

5 a second control device carried on the housing separate from the first control device and being electrically coupled to the microcontroller, the second control device being adjustable by a user independent of the first control device within a range of control
10 positions for providing duration control inputs to the microcontroller to control adjustment of the duration from a predefined duration range; and
a single visual indicator carried on the housing and
15 being electrically coupled to the microcontroller for confirming status conditions during operation of the stimulation control device, the microcontroller configured to cause the single visual indicator to display: a prescribed colour and/or flash rate of light
20 confirming, independent of contact between the probe and the targeted tissue region, that power to the stimulation signal generating circuitry is on due to operation of the first control device, and a different prescribed colour and/or flash rate of light confirming, when there is
25 contact between the probe and the targeted tissue region, the delivery of the stimulation signal to the targeted tissue region through the probe and back to the stimulation control device through the return electrode, due to operation of the first and/or second control
30 device.

Features and advantages of the inventions are set forth in the following Description and Drawings, as well as the appended description of technical features.

Brief Description of the Drawings

35 Fig. 1 is a diagrammatic view of a system

- 6 -

usable in association with a family of different monitoring and treatment devices for use in different medical procedures.

5 Fig. 2 is a perspective view showing an exemplary embodiment of the system shown in Fig. 1, the stimulation control device being removably coupled to a stimulation probe, and showing the stimulation signal path through the system.

10 Fig. 3A is a perspective view showing the stimulation control device in use with a stimulation probe.

15 Fig. 3B is a perspective view with a portion broken away and in section showing the stimulation probe having the stimulation control device embedded within the stimulation probe, and showing an optional needle-like return electrode.

Fig. 4 is a block diagram of a circuit that the stimulation control device shown throughout the Figs. can incorporate.

20 Figs. 5A and 5B are perspective views showing the stimulation control device in use with a cutting device.

25 Figs. 6A & 6B are perspective views showing the stimulation control device in use with a drilling or screwing device.

Figs. 7A & 7B are perspective views showing the stimulation control device in use with a pilot auger device.

30 Figs. 8A and 8B are perspective views showing the stimulation control device in use with a fixation device.

Fig. 9 is a view showing how the geometry of the stimulation control device shown in Fig. 2 aids in its positioning during a surgical procedure.

35 The invention may be embodied in several forms

without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall
5 within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

Description of Preferred Embodiments

This Specification discloses various systems and methods for safeguarding against nerve, muscle, and
10 tendon injury during surgical procedures or confirming the identity of nerves, muscles, and tendons and evaluating their function or the function of muscles enervated by those nerves. The systems and methods are particularly well suited for assisting surgeons in
15 identification of nerves and muscles in order to assure nerve and muscle integrity during medical procedures using medical devices such as stimulation monitors, cutting, drilling, and screwing devices, pilot augers, and fixation devices. For this reason, the systems and
20 methods will be described in the context of these medical devices.

The systems and methods desirably allow the application of a stimulation signal at sufficiently high levels for the purpose of stimulating and evaluating
25 nerve or muscle, or both nerve and muscle integrity in numerous medical procedures, including, but not limited to, evaluating proximity to a targeted tissue region, evaluating proximity to a nerve or to identify nerve tissue, evaluating if a nerve is intact (i.e., following
30 a traumatic injury) to determine if a repair may be needed, evaluating muscle contraction to determine whether or not the muscle is innervated and/or whether the muscle is intact and/or whether the muscle is severed, and evaluating muscle and tendon length and
35 function following a repair or tendon transfer prior to

- 8 -

completing a surgical procedure.

Still, it should be appreciated that the disclosed systems and methods are applicable for use in a wide variety of medical procedures with a wide variety of medical devices. By way of non-limiting example, the various aspects of the invention have application in procedures requiring grasping medical devices and internal viewing devices as well.

I. Overview of the System

Fig. 1 shows an illustrative system 20 for safeguarding against nerve injury during surgical procedures. In the illustrated embodiment, the system 20 is configured for monitoring and stimulating nerves and other structures throughout the body. The system 20 includes a stimulation control device 22 operating individually or in conjunction with one or more of a family of stimulating medical devices including, for example, a stimulation monitor or probe 100, a cutting device 200, a drilling or screwing device 300, a pilot auger 400, and a fixation device 500.

In an exemplary embodiment, and as can be seen in Fig. 2, the stimulation control device 22 functions in the system 20 to generate an electrical stimulation signal 29. The stimulation signal 29 flows from the stimulation control device 22 through a lead 24 to a medical device (e.g., stimulation probe 100). The stimulation signal 29 then flows through a predefined insulated path 124 within the stimulation probe 100 and to an operative element, such as an electrically conductive surface, i.e., a coupled electrode 110. The electrode is to be positioned on or near a region of a patient to be stimulated. In monopolar operation, a return electrode (or indifferent electrode) 38 provides an electrical path from the body back to the control device 22. The stimulation control device 22 may operate

- 9 -

in a monopolar or bipolar configuration, as will be described in greater detail later.

The stimulation signal 29 is adapted to provide an indication. The indication may include a physical motor response (e.g., twitching), and/or a visual or audio signal from the stimulation control device 22, which indicate to the surgeon close proximity of the electrode 110 to a nerve, or a muscle, or a nerve and a muscle. The stimulation control device may also indicate to the surgeon that the stimulation control device is operating properly and delivering a stimulus current.

II. Medical Devices

The configuration of the stimulating medical devices that form a part of the system can vary in form and function. Various representative embodiments of illustrative medical devices will be described.

A. Stimulation Probe

Figs. 3A and 3B show various embodiments of a hand held stimulation monitor or probe 100 for identification and testing of nerves and/or muscles during surgical procedures. The stimulation probe 100 is preferably a sterile, single use instrument intended for use during surgical procedures to identify nerves and muscles, muscle attachments, or to contract muscles to assess the quality of surgical interventions or the need for surgical interventions, or to evaluate the function of nerves already identified through visual means.

The stimulation probe is preferably sized small enough to be held and used by one hand during surgical procedures. The angle of the stimulating tip facilitates access to deep as well as superficial structures without the need for a large incision. A visual or audio indicator 126 incorporated in the housing

- 10 -

provides reliable feedback to the surgeon as to the request and delivery of stimulus current.

In one embodiment, the stimulation probe 100 includes a housing 112 that carries an insulated lead 124. The insulated lead 124 connects to an electrode 110 positioned at the housing's distal end 114. The lead 124 within the housing 112 is insulated from the housing 112 using common insulating means (e.g., wire insulation, washers, gaskets, spacers, bushings, and the like). The electrode 110 is positioned in electrical conductive contact with at least one muscle, or at least one nerve, or at least one muscle and nerve.

In an additional embodiment, the stimulation probe 100 is mono-polar and is equipped with a single electrode 110 at the housing's distal end 114. Electrode 38 may be any of a variety of electrode types (e.g., paddle, wire, or surface), depending on the surgical procedure being performed. In an alternative embodiment, the stimulation device 100 itself may be bipolar, which precludes the use of the return electrode 38.

As shown in Figs. 3A and 3B, the stimulation probe 100 may accommodate within the housing 112 the electrical circuitry of a stimulation control device 22. In this arrangement, the stimulation probe 100 may have two operational slide controls, 155 and 160. Power switch 155 serves a dual purpose of turning the stimulation signal to the probe 100 on and off, and also can be stepped to control the stimulation signal amplitude selection within a predefined range (e.g., 0.5, 2.0, and 20 mA). The pulse control switch 160 allows for adjustment of the stimulation signal pulse width from a predefined range (e.g., 0 through 200 microseconds).

An operative element, such as a stimulus probe 110, exits the housing at the distal end 114 to deliver stimulus current to the excitable tissue. The probe or

electrode 110 comprises a length and a diameter, and is desirably fully insulated with the exception of the most distal end, e.g. about 1.0 millimeters to about 10 millimeters, and desirably about 4 millimeters to about 6 millimeters, which is non-insulated and serves as the stimulating surface to allow the surgeon to deliver the stimulus current only to the intended tissue. The small area of the probe (the active electrode) ensures a high current density that will stimulate nearby excitable tissue. The probe diameter may range between about 0.5 millimeters to about 1.0 millimeters, and may be desirably about 0.75 millimeters.

In monopolar operation, a return electrode (or indifferent electrode) 130 provides an electrical path from the body back to the control device 22. The return electrode 130 may be placed on the surface of intact skin (e.g., surface electrodes as used for ECG monitoring during surgical procedures) or it might be needle-like 131 (see Fig. 3B), and be placed in the surgical field or penetrate through intact skin. The housing's proximal end 118 can incorporate a connector or jack 120 which provides options for return current pathways, such as through a surface electrode 130 or a needle electrode 131, having an associated plug 122.

Additionally, the device 100 may desirably incorporate a visual or audio indicator 126 for the surgeon. This visual or audio indicator 126 allows the surgeon to confirm that the stimulator 100 is delivering stimulus current to the tissue it is contacting. Through the use of different tones, colors, different flash rates, etc., the indicator 126 (which can take the form, e.g., of a light emitting diode -- LED) allows the surgeon to confirm that the stimulating tip 110 is in place, the instrument is turned ON, and that stimulus current is flowing. Thus the surgeon has a much greater

- 12 -

confidence that the failure to elicit a muscle contraction is because of lack of viable nervous tissue near the tip of the stimulator 100 rather than the failure of the return electrode connection or some other
5 instrumentation problem.

Audio feedback also makes possible the feature of assisting the surgeon with monitoring nerve integrity during surgery. The insulated lead 124 connects to an electrode 110 that, in use, is positioned within the
10 surgical field on a nerve distal to the surgical site. Stimulation of the nerve causes muscle contraction distally. The stimulation control device 22 may be programmed to provide an audio tone followed by a stimulation pulse at prescribed intervals. The audio tone
15 reminds the surgeon to observe the distal muscle contraction to confirm upon stimulation that the nerve is functioning and intact.

Alternatively, as Fig. 2 shows, the stimulation control device 22 may be housed in a separate
20 case, with its own input/output (I/O) controls 26. In this alternative arrangement, the stimulation control device 22 is sized small enough to be easily removably fastened to a surgeon's arm or wrist during the surgical procedure, or otherwise positioned in close proximity to
25 the surgical location (as shown in Fig. 9), to provide sufficient audio and visual feedback to the surgeon. In this arrangement, the separate stimulation control device 22 can be temporarily coupled by a lead to a family of various medical devices for use.

30 The present invention includes a method of locating a nerve in a patient that comprises the steps of providing a hand-held stimulation probe 100 as set forth above, engaging a patient with the first electrode 110 and the second electrode 130, moving the power switch 155
35 to an activation position causing a stimulation signal 29

to be generated by the stimulation control device 22 and transmitted to the first electrode 110, through the patient's body to the second electrode 130, and back to the stimulation control device 22.

5 **B. The Stimulation Control Device**

As Fig. 4 shows, the stimulation control device 22 includes a circuit 32 that generates electrical stimulation waveforms. A battery 34 internal to the stimulator 100 desirably provides the power. The pulse generator 28 also desirably includes an on-board, programmable microprocessor 36, which carries embedded code. The code expresses pre-programmed rules or algorithms for generating the desired electrical stimulation waveforms using the stimulus output circuit 46 and for operating the visible or audible indicator 126 based on the controls actuated by the surgeon.

In one form, the size and configuration of the stimulation control device 22 makes for an inexpensive device, which is without manual internal circuit adjustments. It is likely that the stimulation control device 22 of this type will be fabricated using automated circuit board assembly equipment and methods.

20 **C. Incorporation with Surgical Devices**

A stimulation control device 22 as just described may be electrically coupled through a lead, or embedded within various devices commonly used in surgical procedures.

25 **1. Cutting Device**

In Figs. 5A and 5B, a device 200 is shown that incorporates all the features disclosed in the description of the stimulation probe 100, except the device 200 comprises the additional feature of providing an "energized" surgical device or tool. Fig. 5A shows the tool to be a cutting device 200 (e.g., scalpel) removably

coupled to a stimulation control device 22.

In the embodiment shown, the cutting device 200 includes a body 212 that carries an insulated lead 224. The insulated lead 224 connects to an operative
5 element, such as electrode 210, positioned at the body proximal end 214 and a plug-in receptacle 219 at the body distal end 118. The lead 224 within the body 212 is insulated from the body 212 using common insulating means (e.g., wire insulation, washers, gaskets, spacers,
10 bushings, and the like).

In this embodiment, the electrode 210 performs the cutting feature (e.g., knife or razor). The electrode 210 performs the cutting feature in electrical conductive contact with at least one muscle, or at least one nerve,
15 or at least one muscle and nerve. The cutting device 200 preferably includes a plug-in receptacle 216 for the electrode 210, allowing for use of a variety of cutting electrode shapes and types (e.g., knife, razor, pointed, blunt, curved), depending on the specific surgical
20 procedure being performed. In this configuration, the lead 224 electrically connects the electrode 210 to the stimulation control device 22 through plug-in receptacle 219 and lead 24.

In one embodiment, the cutting device 200 is
25 mono-polar and is equipped with a single electrode 210 at the body proximal end 214. In the mono-polar mode, the stimulation control device 22 includes a return electrode 38 which functions as a return path for the stimulation signal. Electrode 38 may be any of a variety of electrode
30 types (e.g., paddle, wire, or surface), depending on the surgical procedure being performed. The return electrode 38 may be attached to the stimulation device 22 by way of a connector or plug-in receptacle 39. In an alternative embodiment, the cutting device 200 may be bipolar, which
35 precludes the use of the return electrode 38.

In the embodiment shown in Fig. 5B, the cutting device 200 accommodates within the body 212 the electrical circuitry of the stimulation control device 22. In this arrangement, the cutting device 200 may have
5 at least two operational slide controls, 255 and 260. Power switch 255 serves a dual purpose of turning the stimulation signal to the cutting device 200 on and off, and also is stepped to control the stimulation signal amplitude selection from a predefined range (e.g., 0.5,
10 2.0, and 20 mA). The pulse control switch 260 allows for adjustment of the stimulation signal pulse width from a predefined range (e.g., 0 through 200 microseconds).

At the body distal end 218, a second plug-in receptacle 220 may be positioned for receipt of a second
15 lead 222. Lead 222 connects to electrode 230 which functions as a return path for the stimulation signal when the cutting device 200 is operated in a mono-polar mode.

Additionally, the device 200 may incorporate a
20 visual or audio indicator for the surgeon, as previously described.

In one embodiment, the present invention includes a method of locating a nerve in a patient that comprises the steps of providing cutting device 200 as
25 set forth above, engaging a patient with the first electrode 210 and the second electrode 230, moving the power switch 255 to an activation position causing a stimulation signal 29 to be generated by the stimulation control device 22 and transmitted to the first electrode
30 210, through the patient's body to the second electrode 230, and back to the stimulation control device 22.

2. Drilling Device

In Figs. 6A and 6B, a device 300 is shown that incorporates all the features disclosed in the
35 description of the stimulation probe 100, except the

- 16 -

device 300 comprises the additional feature of providing an "energized" surgical device or tool, which comprises a drilling device 300. In Fig. 6A is drilling device 300 is removably coupled to a stimulation control device 22.

5 In the embodiment shown, the drilling device 300 includes a body 312 that carries an insulated lead 324. The insulated lead 324 connects to an operative element, such as electrode 310, positioned at the body proximal end 314 and a plug-in receptacle 319 at the body
10 distal end 318. The lead 324 within the body 312 is insulated from the body 312 using common insulating means (e.g., wire insulation, washers, gaskets, spacers, bushings, and the like).

 In this embodiment, the electrode 310 performs
15 the drilling feature. The electrode 310 may also perform a screwing feature as well. The electrode 310 performs the drilling feature in electrical conductive contact with a hard structure (e.g., bone).

 The drilling device 300 preferably includes a
20 plug-in receptacle or chuck 316 for the electrode 310, allowing for use of a variety of drilling and screwing electrode shapes and sizes (e.g., 1/4 and 3/8 inch drill bits, Phillips and flat slot screw drivers), depending on the specific surgical procedure being performed. In this
25 configuration, the lead 324 electrically connects the electrode 310 to the stimulation control device 22 through plug-in receptacle 319 and lead 324.

 In one embodiment, the drilling device 300 is mono-polar and is equipped with a single electrode 310 at
30 the body proximal end 314. In the mono-polar mode, the stimulation control device 22 includes a return electrode 38 which functions as a return path for the stimulation signal. Electrode 38 may be any of a variety of electrode types (e.g., paddle, wire, or surface), depending on the
35 surgical procedure being performed. The return electrode

38 may be attached to the stimulation device 22 by way of a connector or plug-in receptacle 39. In an alternative embodiment, the drilling device 300 may be bipolar, which precludes the use of the return electrode 38.

5 In Fig. 6B, the drilling device 300 is shown to accommodate within the body 312 the electrical circuitry of the stimulation control device 22. The drilling device 300 may have at least two operational slide controls, 355 and 360. Power switch 355 serves a
10 dual purpose of turning the stimulation signal to the drilling device 300 on and off, and also is also stepped to control the stimulation signal amplitude selection from a predefined range (e.g., 0.5, 2.0, and 20 mA). The pulse control switch 360 allows for adjustment of the
15 stimulation signal pulse width from a predefined range (e.g., 0 through 200 microseconds). At the body distal end 318, a second plug-in receptacle 320 may be positioned for receipt of a second lead 322. Lead 322 connects to electrode 330 which functions as a return
20 path for the stimulation signal when the drilling device 300 is operated in a mono-polar mode.

 Additionally, the device 300 may incorporate a visual or audio indicator for the surgeon, as previously described.

25 In one embodiment, the present invention includes a method of locating a nerve in a patient that comprises the steps of providing a drilling device 300 as set forth above, engaging a patient with the first electrode 310 and the second electrode 330, moving the
30 power switch 355 to an activation position causing a stimulation signal 29 to be generated by the stimulation control device 22 and transmitted to the first electrode 310, through the patient's body to the second electrode 330, and back to the stimulation control device 22.

35 **3. Pilot Auger**

An additional aspect of the invention provides systems and methods for controlling operation of a family of stimulating devices comprising a stimulation control device electrically coupled to a pilot auger for hard
5 surface rotary probing.

This embodiment incorporates all the features disclosed in the description of the stimulation probe 100, except this embodiment comprises the additional feature of providing an "energized" surgical device or
10 tool. Fig. 7A shows a pilot auger device 400 removably coupled to a stimulation control device 22. In the embodiment shown, the pilot auger device 400 includes a body 412 that carries an insulated lead 424. The insulated lead 424 connects to an operative element, such
15 as an electrode 410, positioned at the body proximal end 414 and a plug-in receptacle 419 at the body distal end 418. The lead 424 within the body 412 is insulated from the body 412 using common insulating means (e.g., wire insulation, washers, gaskets, spacers, bushings, and the
20 like). In this embodiment, the electrode 410 performs the pilot augering feature. The electrode 410 performs the pilot augering feature in electrical conductive contact with a hard structure (e.g., bone). The pilot auger device 400 preferably includes a plug-in receptacle or
25 chuck 416 for the electrode 410, allowing for use of a variety of pilot augering electrode shapes and sizes (e.g., 1/32, 1/16, and 1/8 inch), depending on the specific surgical procedure being performed. In this configuration, the lead 24 electrically connects the
30 electrode 410 to the stimulation control device 22 through plug-in receptacle 419 and lead 24.

In one embodiment, the pilot auger device 400 is mono-polar and is equipped with a single electrode 410 at the body proximal end 414. In the mono-polar mode, the
35 stimulation control device 22 includes a return electrode

38 which functions as a return path for the stimulation signal. Electrode 38 may be any of a variety of electrode types (e.g., paddle, wire, or surface), depending on the surgical procedure being performed. The return electrode
5 38 may be attached to the stimulation device 22 by way of a connector or plug-in receptacle 39. In an alternative embodiment, the pilot auger device 400 may be bipolar, which precludes the use of the return electrode 38.

As Fig. 7B shows, the pilot auger device 400
10 may accommodate within the body 412 the electrical circuitry of the stimulation control device 22. At the body distal end 418, a second plug-in receptacle 420 may be positioned for receipt of a second lead 422. Lead 422 connects to electrode 430 which functions as a return
15 path for the stimulation signal when the pilot auger device 400 is operated in a mono-polar mode.

The pilot auger device 400 includes a power switch 455. When moved to an activation position, a stimulation signal is generated by the stimulation
20 control device 22. Additionally, the device 400 may incorporate a visual or audio indicator for the surgeon, as previously described.

In one embodiment, the present invention includes a method of locating a nerve in a patient that
25 comprises the steps of providing a pilot auger device 400 as set forth above, engaging a patient with the first electrode 410 and the second electrode 430, moving the power switch 455 to an activation position causing a stimulation signal to be generated by the stimulation
30 control device 22 and transmitted to the first electrode 410, through the patient's body to the second electrode 430, and back to the stimulation control device 22.

D. Incorporation with Fixation Devices

An additional aspect of the invention provides
35 systems and methods for controlling operation of a family

- 20 -

of stimulating devices comprising a stimulation control device electrically coupled to a fixation device or a wrench or screwdriver for placing the fixation device. A fixation device (e.g., orthopedic hardware, pedicle screws) is commonly used during spinal stabilization procedures (fusion), and internal bone fixation procedures.

This embodiment incorporates all the features disclosed in the description of the stimulation probe 100, except this embodiment comprises the additional feature of providing an "energized" fixation device or tool. Fig. 8A shows a fixation device 500 removably coupled to a stimulation control device 22. In the embodiment shown, the fixation device 500 includes a 15 rectangularly shaped body 512 that also serves as an operative element, such as electrode 510. The fixation device 500 may take on an unlimited number of shapes as necessary for the particular procedure taking place. Pedicle screws 535 may be used to secure the fixation 20 device to the bony structure. The electrode 510 performs the fixation feature in electrical conductive contact with a hard structure (e.g., bone). The fixation device 500 or wrench or screwdriver for placing the fixation device preferably includes a plug-in receptacle 519. The 25 fixation device 500 may take on an unlimited variety of shapes and sizes depending on the specific surgical procedure being performed. In this configuration, the lead 24 electrically connects the electrode 510 to the stimulation control device 22 through plug-in receptacle 30 519.

In one embodiment, the fixation device 500 is mono-polar and is equipped with the single electrode 510. In the mono-polar mode, the stimulation control device 22 includes a return electrode 38 which functions as a 35 return path for the stimulation signal. Electrode 38 may

be any of a variety of electrode types (e.g., paddle, wire, or surface), depending on the surgical procedure being performed. The return electrode 38 may be attached to the stimulation device 22 by way of a connector or
5 plug-in receptacle 39. In an alternative embodiment, the fixation device 500 may be bipolar, which precludes the use of the return electrode 38.

In yet an additional alternative embodiment (see Fig. 8B), the fixation device may be a pedicle screw
10 535. The pedicle screw 535 is removably coupled to a stimulation control device 22. In the embodiment shown, the pedicle screw 535 includes a head 570 and a shaft 572, which both serve as an operative element, such as electrode 574. The electrode 574 performs the fixation
15 feature in electrical conductive contact with a hard structure (e.g., bone), as the pedicle screw 535 is being positioned within a bony structure. The lead 24 electrically connects the electrode 574 to the stimulation control device 22, through a break-away connection or
20 other similar electrical connective means. The fixation device 535 may take on an unlimited variety of shapes and sizes depending on the specific surgical procedure being performed.

In the mono-polar mode, the stimulation control
25 device 22 includes a return electrode 38 which functions as a return path for the stimulation signal. Electrode 38 may be any of a variety of electrode types (e.g., paddle, wire, or surface), depending on the surgical procedure being performed. In an alternative embodiment, the
30 fixation device 500 may be bipolar, which precludes the use of the return electrode 38.

In one embodiment, the present invention includes a method of locating a nerve in a patient that comprises the steps of providing a fixation device 500 as
35 set forth above, engaging a patient with the first electrode 510 and the

- 22 -

second electrode 38, turning power on to the stimulation control device 22 through the I/O controls 26, causing a stimulation signal 29 to be generated by the stimulation control device 22 and transmitted to the first electrode 510, through the patient's body to the second electrode 38, and back to the stimulation control device 22.

IV. Technical Features

The stimulation control device 22 can incorporate various technical features to enhance its universality.

A. Small Size

According to one desirable technical feature, the stimulation control device can be sized small enough to be held and used by one hand during surgical procedures, or to be installed within a stimulation probe or surgical device. The angle of the stimulating tip facilitates access to deep as well as superficial structures without the need for a large incision. Visual and/or audible indication incorporated in the housing provides reliable feedback to the surgeon as to the request and delivery of stimulus current.

According to an alternative desirable technical feature, the stimulation control device 22 may also be sized small enough to be easily removably fastened to a surgeon's arm or wrist during the surgical procedure, or positioned in close proximity to the surgical location (as shown in Fig. 9), to provide sufficient audio and visual feedback to the surgeon.

B. Power Source

According to one desirable technical feature, power is provided by a primary battery for single use mounted inside the housing on or near the circuit board 22.

C. The Microprocessor/Microcontroller

According to one desirable technical feature, the stimulation control device 22 desirably uses a standard, commercially available micro-power, flash programmable microcontroller 36. The microcontroller 36
5 reads the controls operated by the surgeon, controls the timing of the stimulus pulses, and controls the feedback to the user about the status of the instrument (e.g., an LED or 1, 2, or more colors that can be on, off, or flashing).

10 The microcontroller operates at a low voltage and low power. The microcontroller sends low voltage pulses to the stimulus output stage that converts these low voltage signals into the higher voltage, controlled voltage, or controlled current, stimulus pulses that are
15 applied to the electrode circuit. This stimulus output stage usually involves the use of a series capacitor to prevent the presence of DC current flow in the electrode circuit in normal operation or in the event of an electronic component failure.

20 The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and
25 operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

30

In the claims which follow and in the preceding description of the invention, except where the context requires otherwise due to express language or necessary implication, the word "comprise" or variations such as "comprises" or "comprising" is used in an inclusive sense, i.e. to specify the presence of the stated features but not to preclude the presence or addition of further features in various embodiments of the invention.

It is to be understood that, if any prior art publication is referred to herein, such reference does not constitute an admission that the publication forms a part of the common general knowledge in the art, in Australia or any other country.

The Claims Defining the Invention are as Follows:

1. A hand-held tissue stimulation system comprising:

a tubular housing having a proximal end and a distal end, the housing being sized and configured to be held and controlled entirely within a surgical field and in a single hand by a user;

a stimulation control device positioned entirely within the housing, the stimulation control device comprising stimulation signal generating circuitry for generation of an electrical stimulation signal having an amplitude and a duration, a microcontroller electrically coupled to the stimulation signal generating circuitry, and a source of power for the stimulation control device;

a probe extending from the distal end of the housing and having an electrically conductive surface electrically coupled to the signal generating circuitry, the electrically conductive surface being sized and configured for contact with a targeted tissue region and, when in contact, applying the electrical stimulation signal to the targeted tissue region;

a return electrode electrically coupled to the signal generating circuitry and being sized and configured for contact with tissue to provide an electrical flow path for the stimulation signal from the probe back to the stimulation control device;

a first control device carried on the housing and electrically coupled to the microcontroller, the first control device being movable by a user from a first position to a second position for providing a power control input to the microcontroller to turn the stimulation signal generating circuitry on and from the second position through a plurality of control positions for providing amplitude control inputs to the microcontroller to control selection of the amplitude within a predefined amplitude range;

a second control device carried on the housing separate from the first control device and being electrically coupled to the microcontroller, the second control device being adjustable by a user independent of the first control device within a range of control positions for providing duration control inputs to the microcontroller to control adjustment of the duration from a predefined duration range; and

a single visual indicator carried on the housing and being electrically coupled to the microcontroller for confirming status conditions during operation of the stimulation control device, the microcontroller configured to cause the single visual indicator to display: a prescribed colour and/or flash rate of light confirming, independent of contact between the probe and the targeted tissue region, that power to the stimulation signal generating circuitry is on due to operation of the first control device, and a different prescribed colour and/or flash rate of light confirming, when there is contact between the probe and the targeted tissue region, the delivery of the stimulation signal to the targeted tissue region through the probe and back to the stimulation control device through the return electrode, due to operation of the first and/or second control device.

2. A hand-held tissue stimulation system according to claim 1, wherein the predefined amplitude range includes about zero milliamps and increases to milliamps values greater than about zero.

3. A hand-held tissue stimulation system according to claim 1 or claim 2, wherein the predefined duration range includes about zero microseconds and increases through microseconds values greater than about zero.

4. A hand-held tissue stimulation system according to any one of the preceding claims, wherein the stimulation signal is adapted to provide a physical motor response.

5. A hand-held tissue stimulation system according to any one of the preceding claims, wherein the stimulation signal is adapted to provide an indication of an intact nerve to determine if a repair is needed.

6. A hand-held tissue stimulation system according to any one of claims 1 to 4, wherein the stimulation signal is adapted to provide an indication of a muscle condition to identify whether the muscle is innervated or whether the muscle is intact or whether the muscle is severed.

7. A hand-held tissue stimulation system according to any one of claims 1 to 4, wherein the stimulation signal is adapted to provide an indication of muscle and tendon length and function following a repair or tendon transfer prior to completing a surgical procedure.

8. A hand-held tissue stimulation system according to any one of the preceding claims, wherein the electrically conductive surface of the probe comprises between about 1 millimeter and about 10 millimeters of a distal end of the probe.

9. A hand-held tissue stimulation system according to any one of the preceding claims, wherein the probe comprises a diameter between about 0.5 millimeters and about 1.0 millimeters.

10. A hand-held tissue stimulation system according to claim 2, wherein the predefined amplitude range includes about zero milliamps and increases in steps to about 20 milliamps.

11. A hand-held tissue stimulation system according to claim 3, wherein the predefined duration range includes about zero microseconds and increases through about 200 microseconds.

12. A hand-held tissue stimulation system substantially as hereinbefore described with reference to at least one of the accompanying drawings.

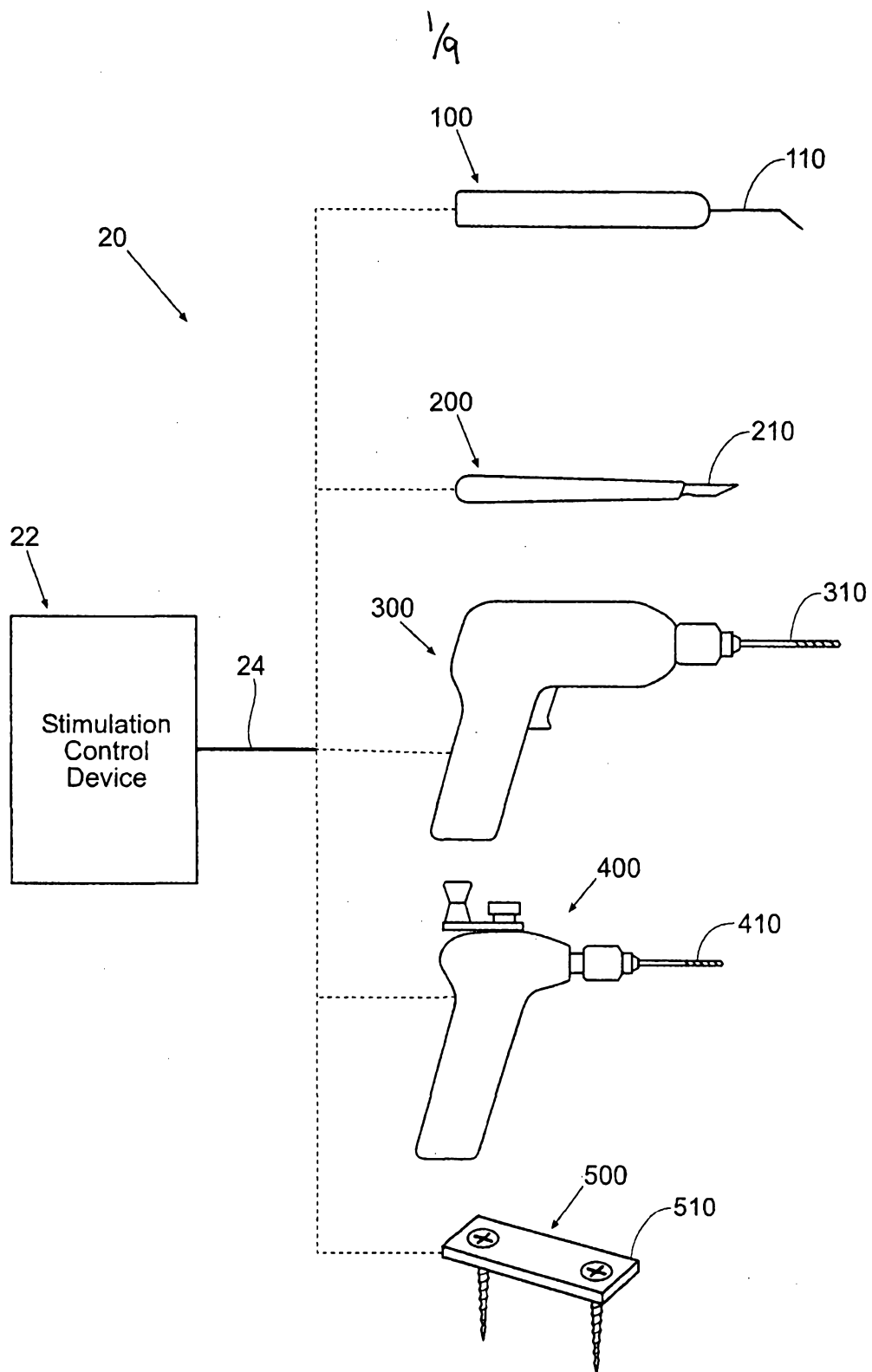


Fig. 1

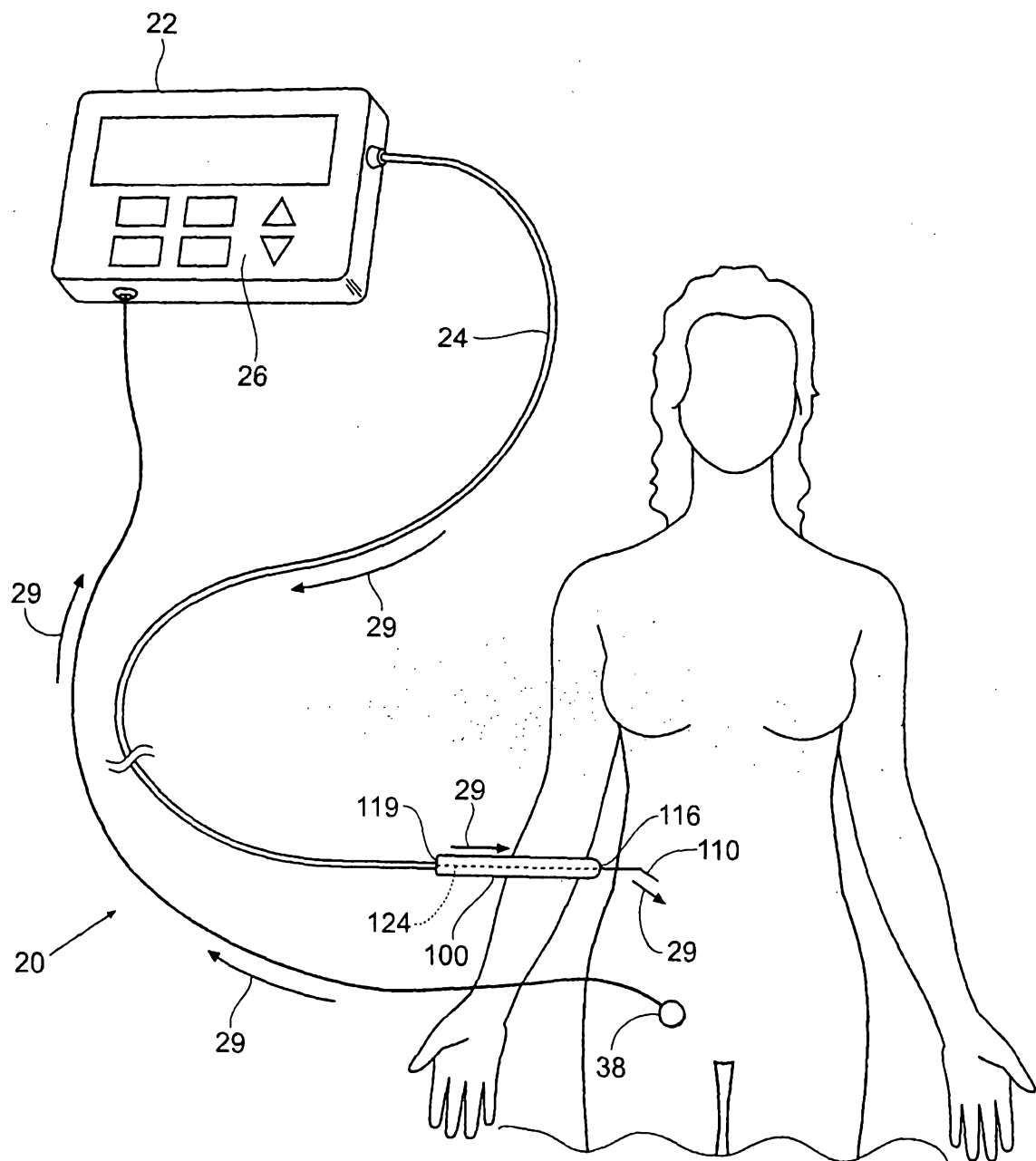
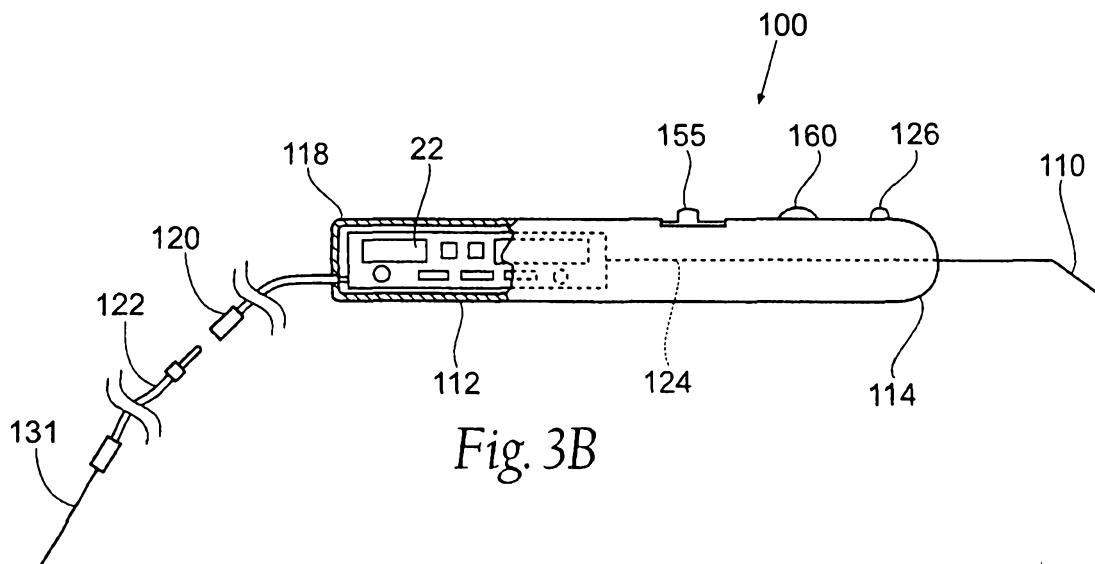
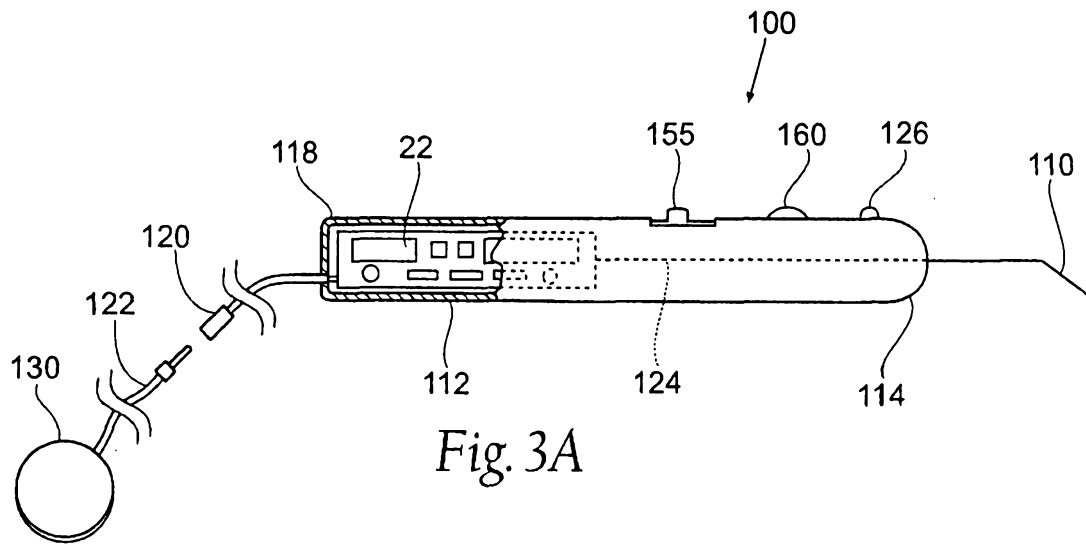


Fig. 2

3/q



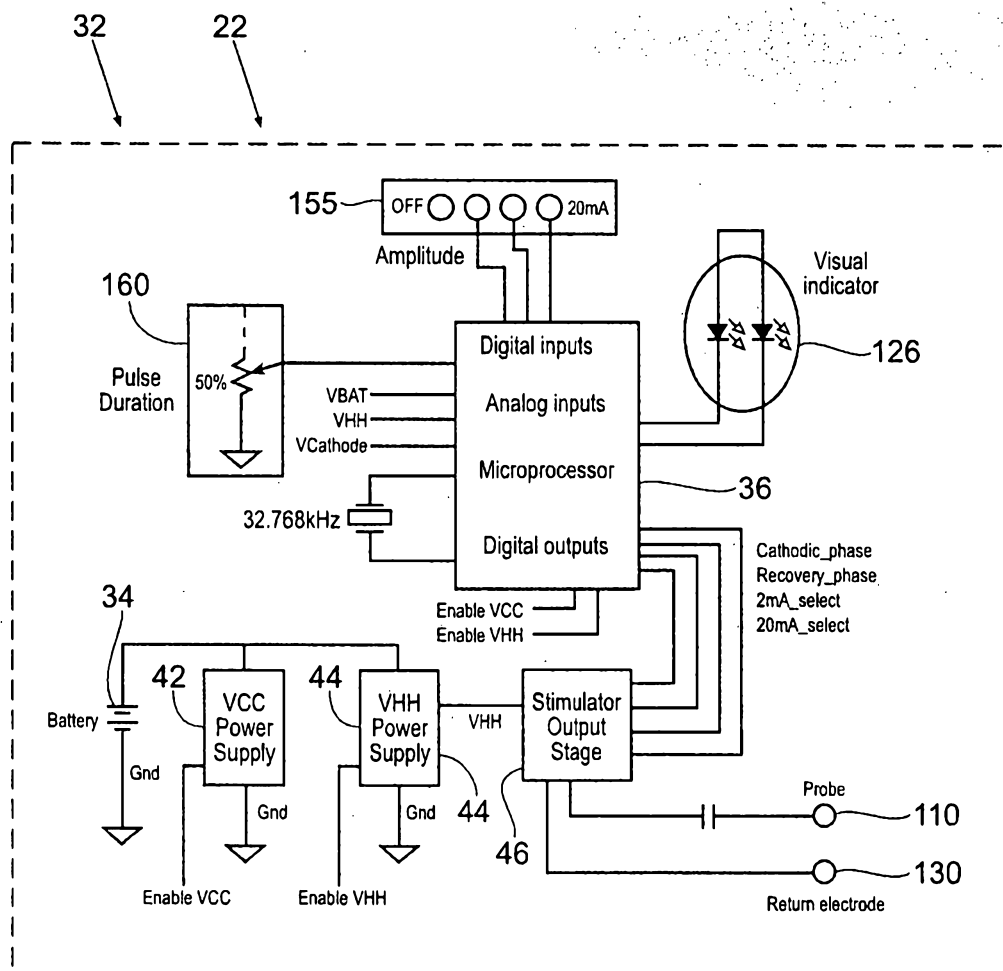


Fig. 4

5/9

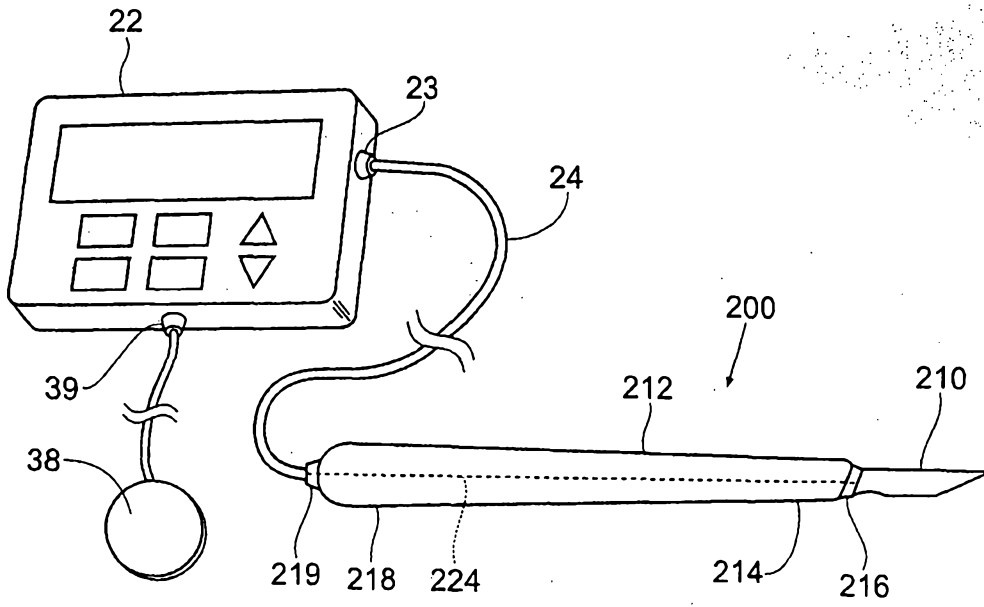


Fig. 5A

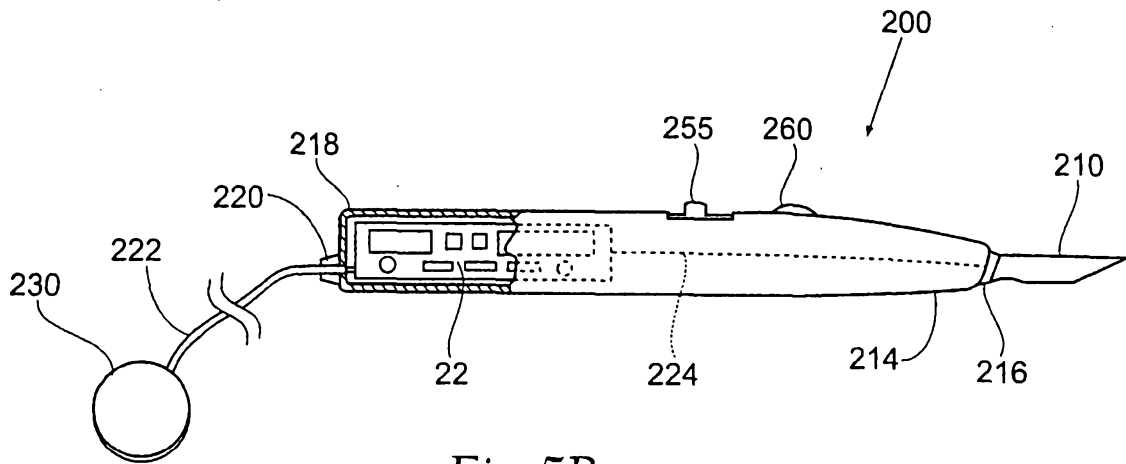


Fig. 5B

6/9

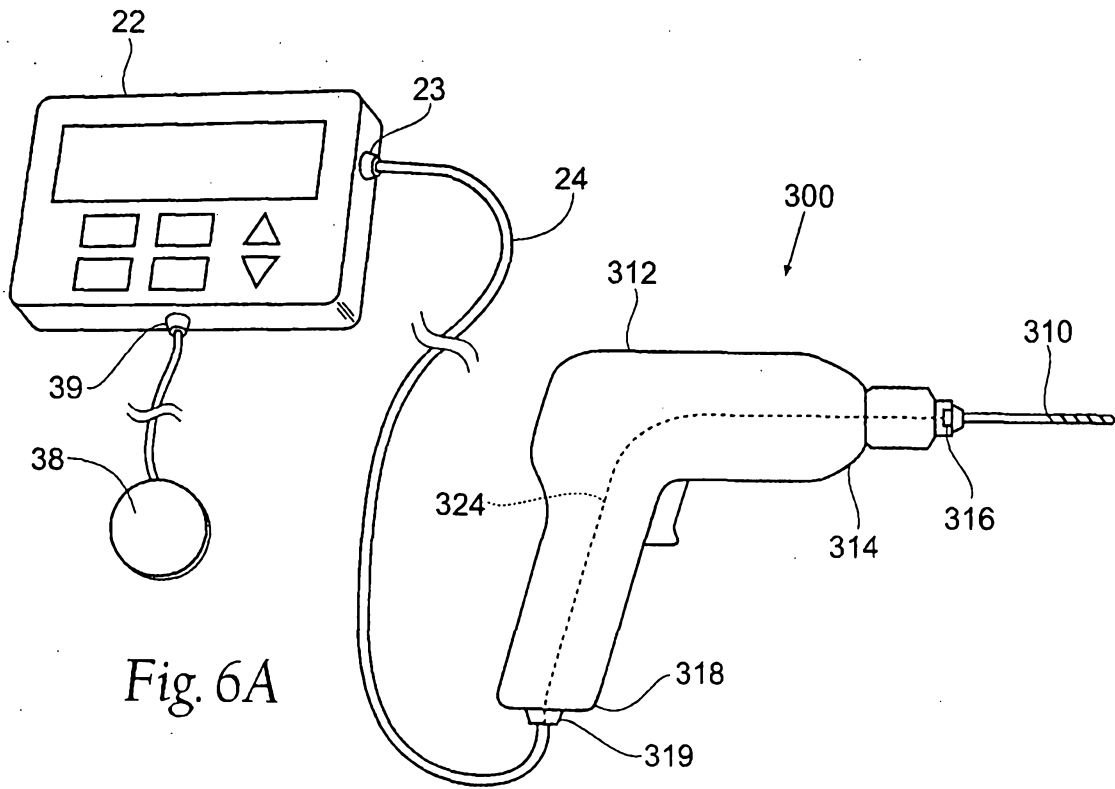


Fig. 6A

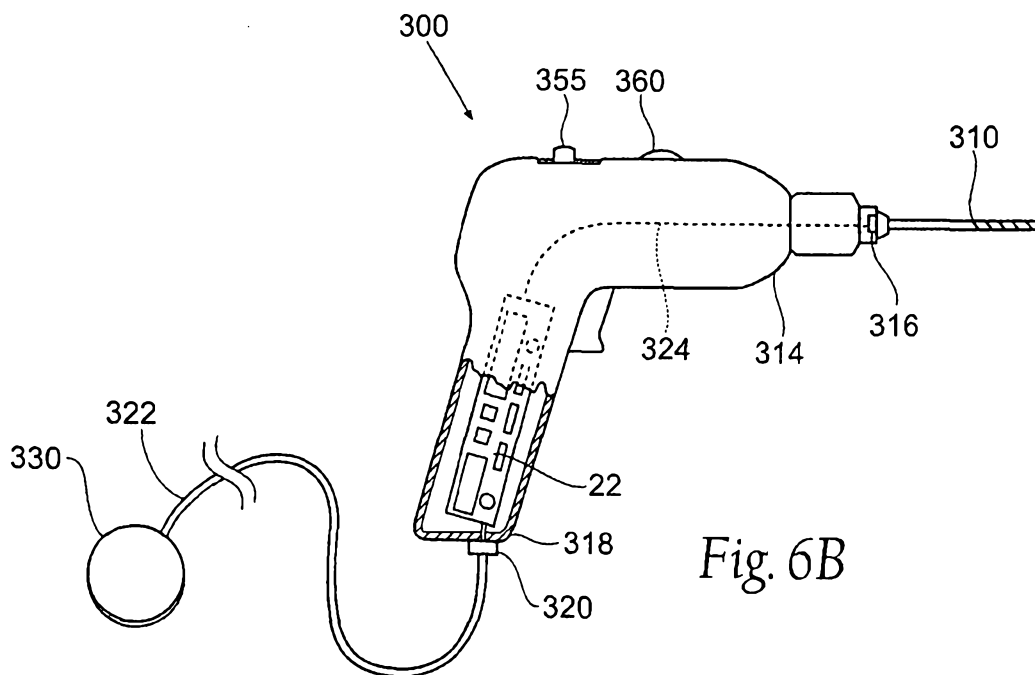


Fig. 6B

7/9

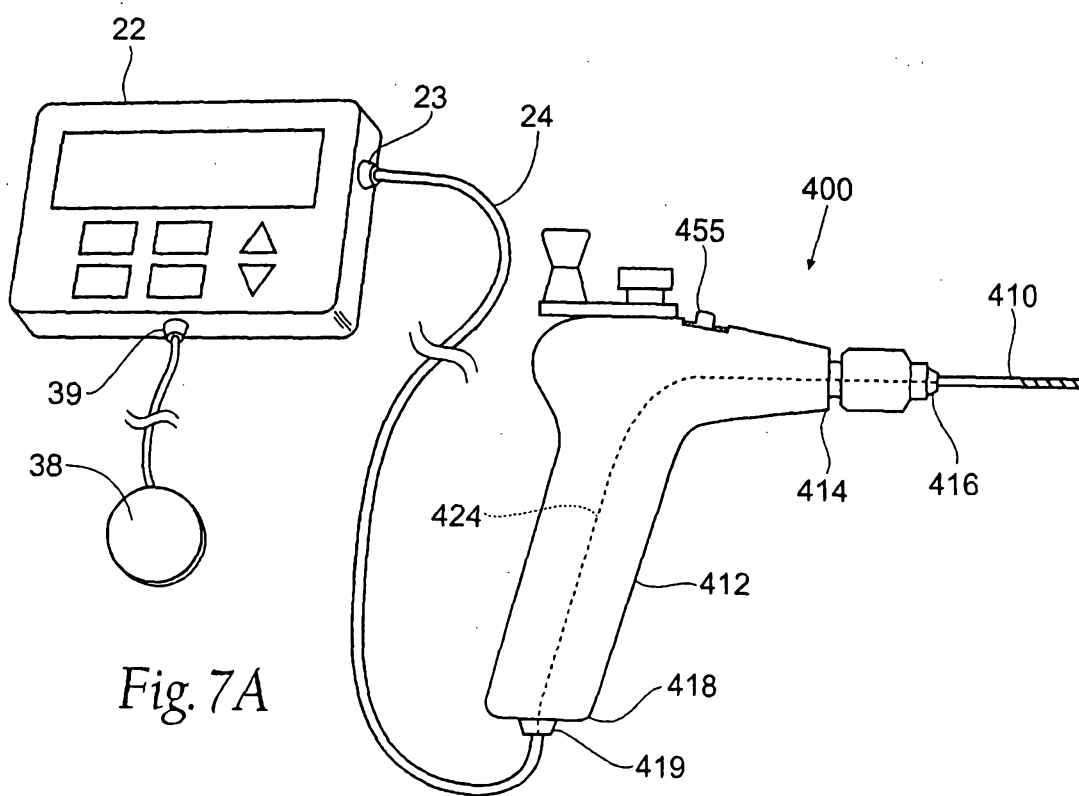


Fig. 7A

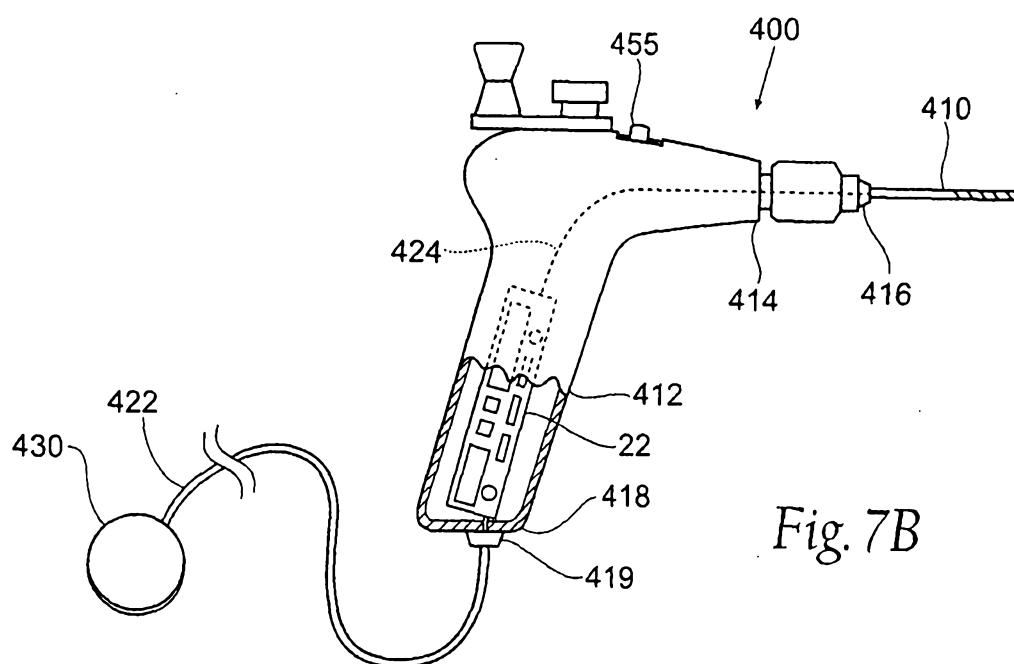
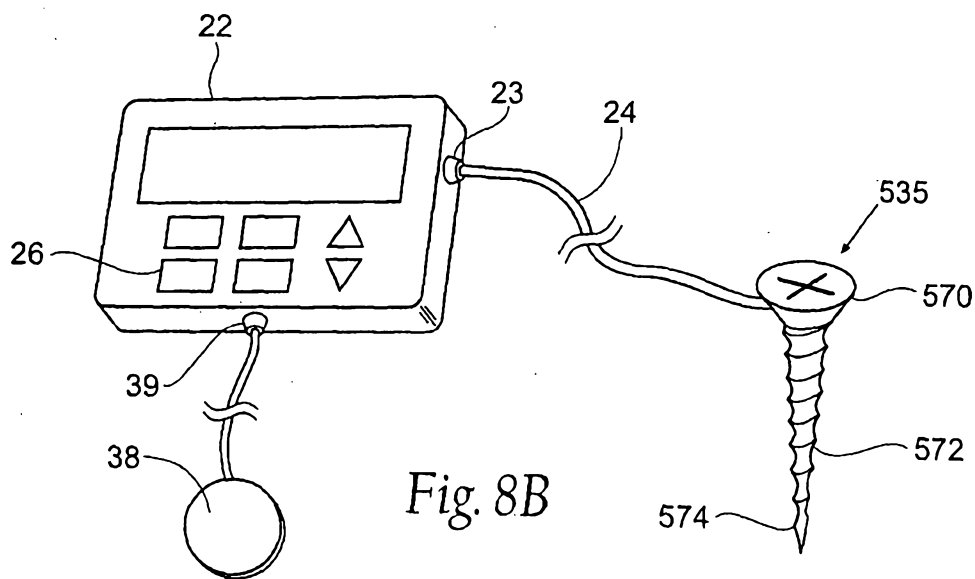
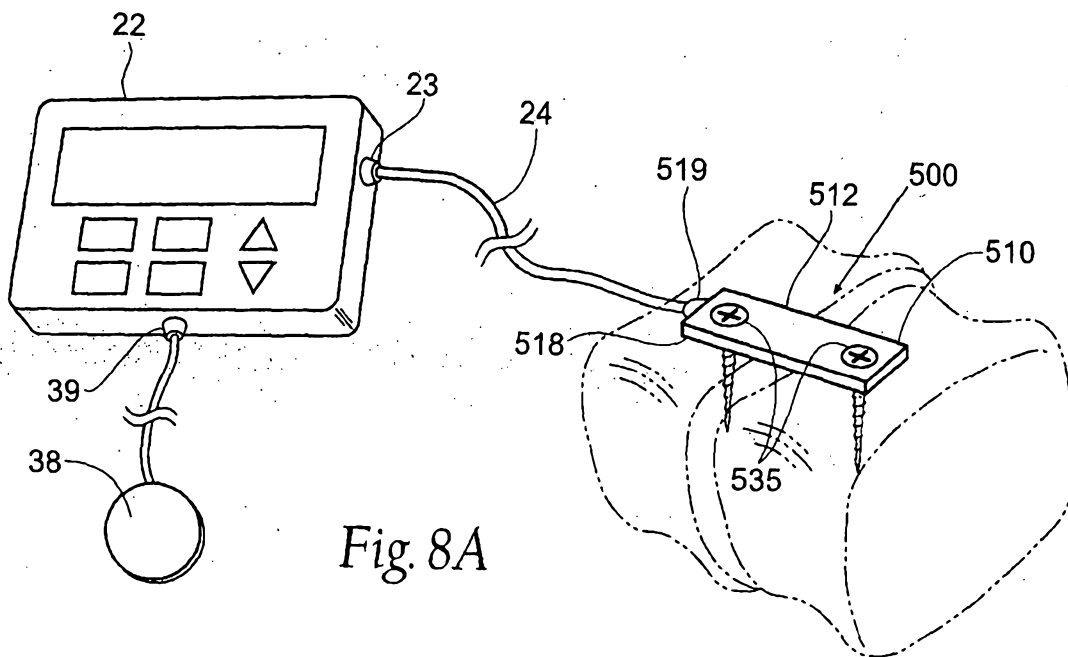


Fig. 7B



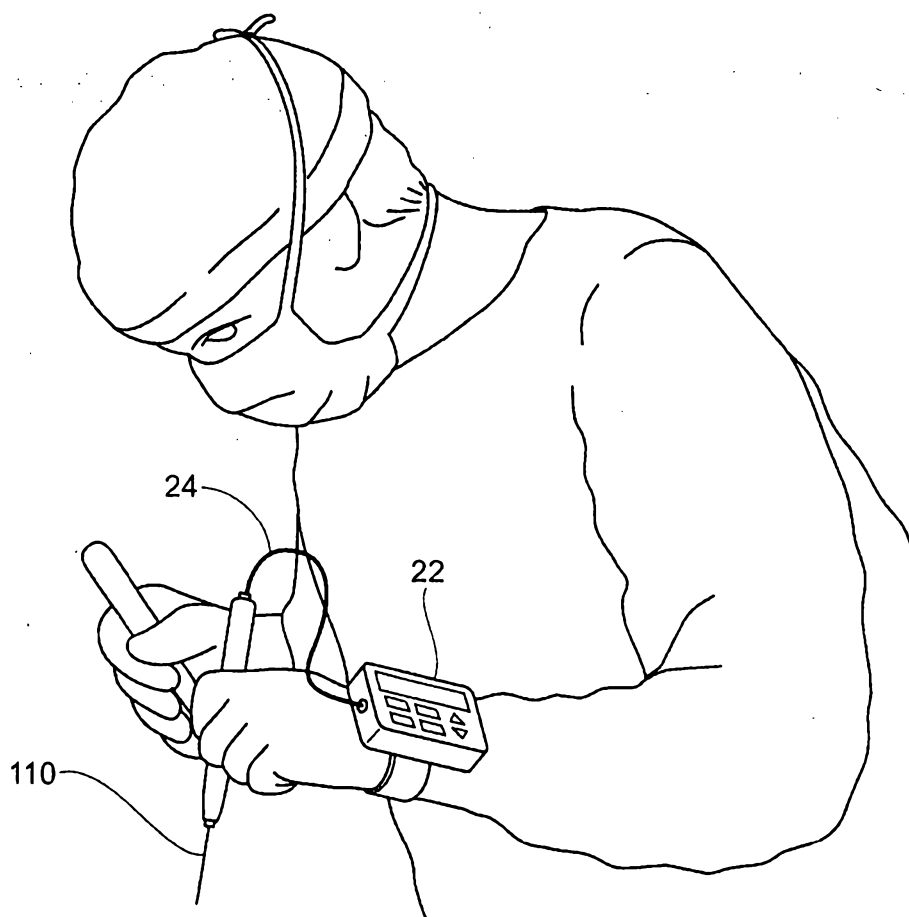


Fig. 9