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(54) SYSTEM AND METHODS FOR DETERMINING NERVE PROXIMITY, DIRECTION, AND PATHOLOGY DURING SURGERY

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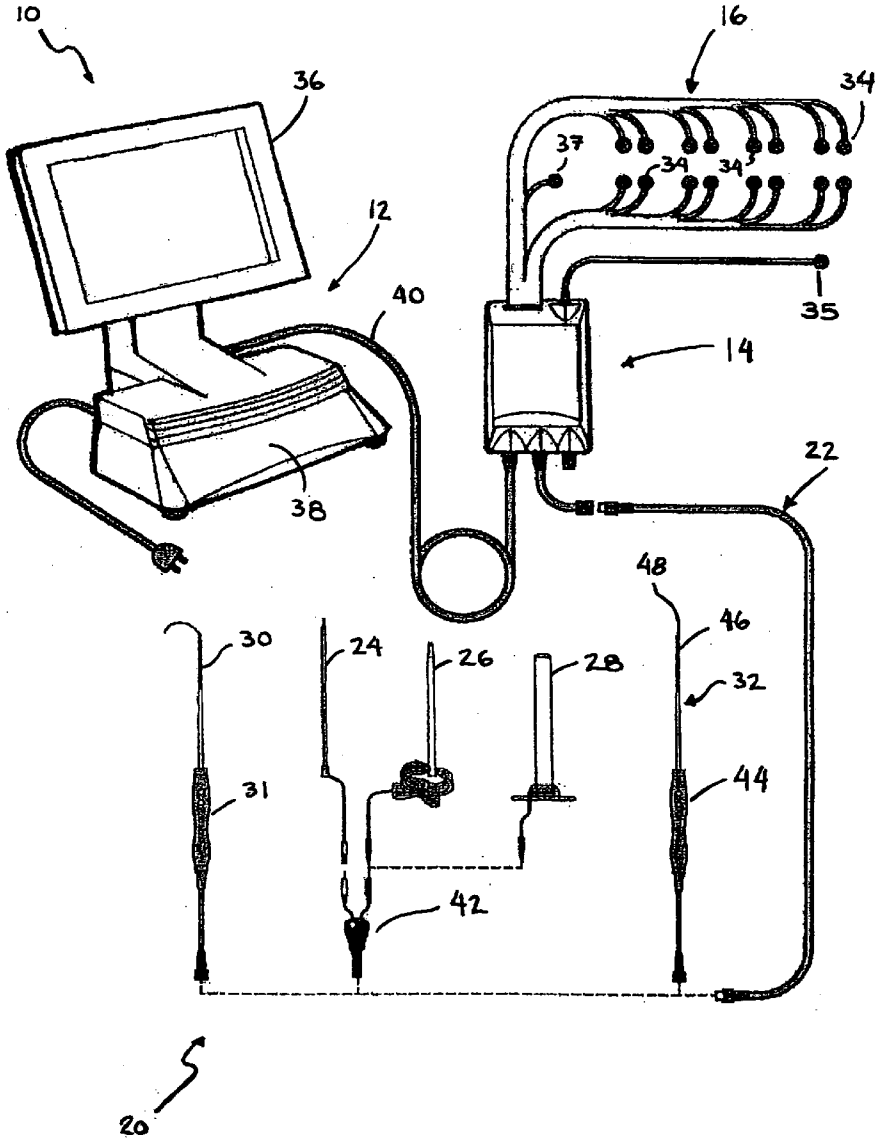
(52) **U.S. Cl.** **607/48**

(57) **ABSTRACT**

The present invention involves systems and methods for determining nerve proximity, nerve direction, and pathology relative to a surgical instrument based on an identified relationship between neuromuscular responses and the stimulation signal that caused the neuromuscular responses.



Cala Health Ex. 1007
Cala v. EMKinetics
USP 9,757,584

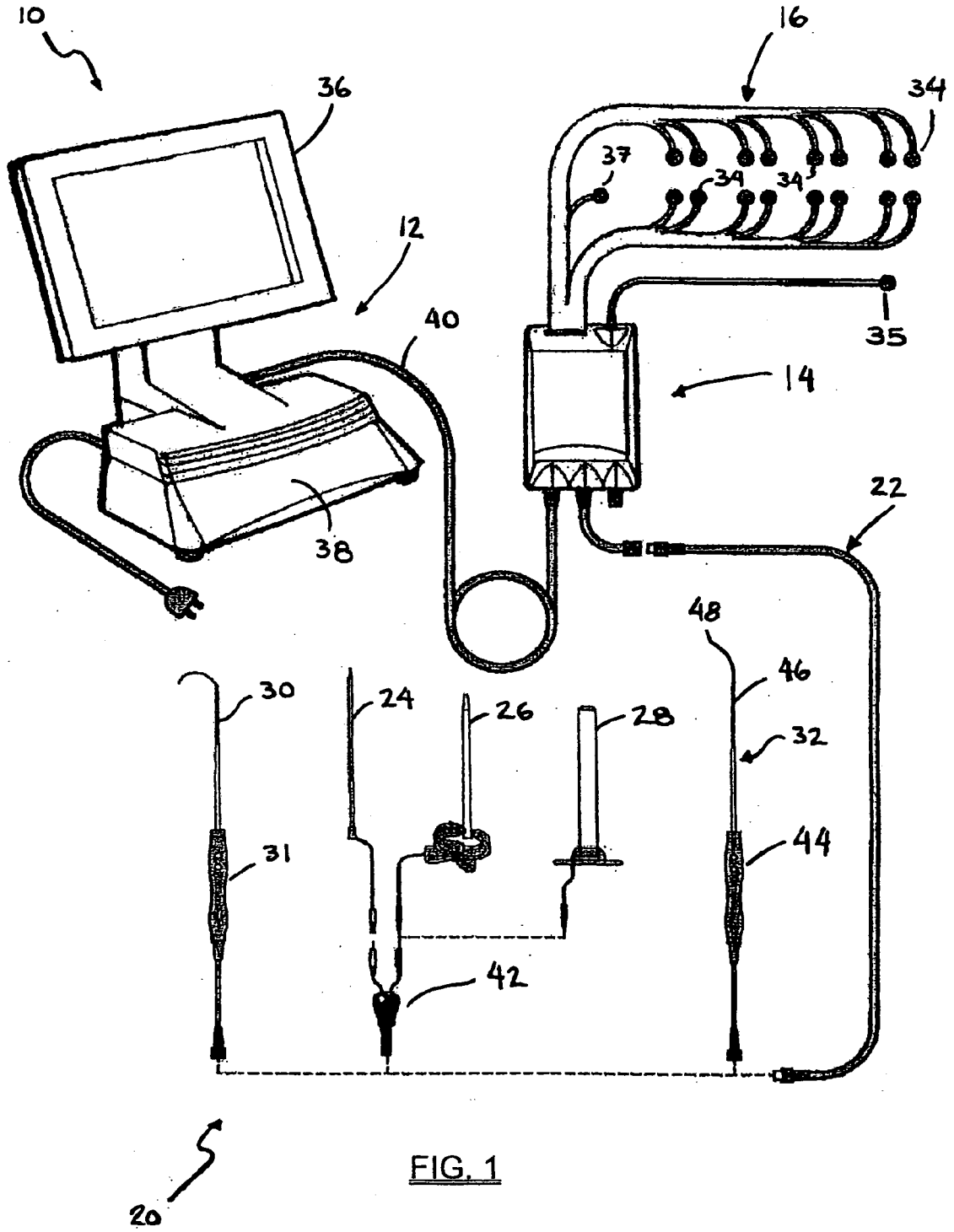


FIG. 1

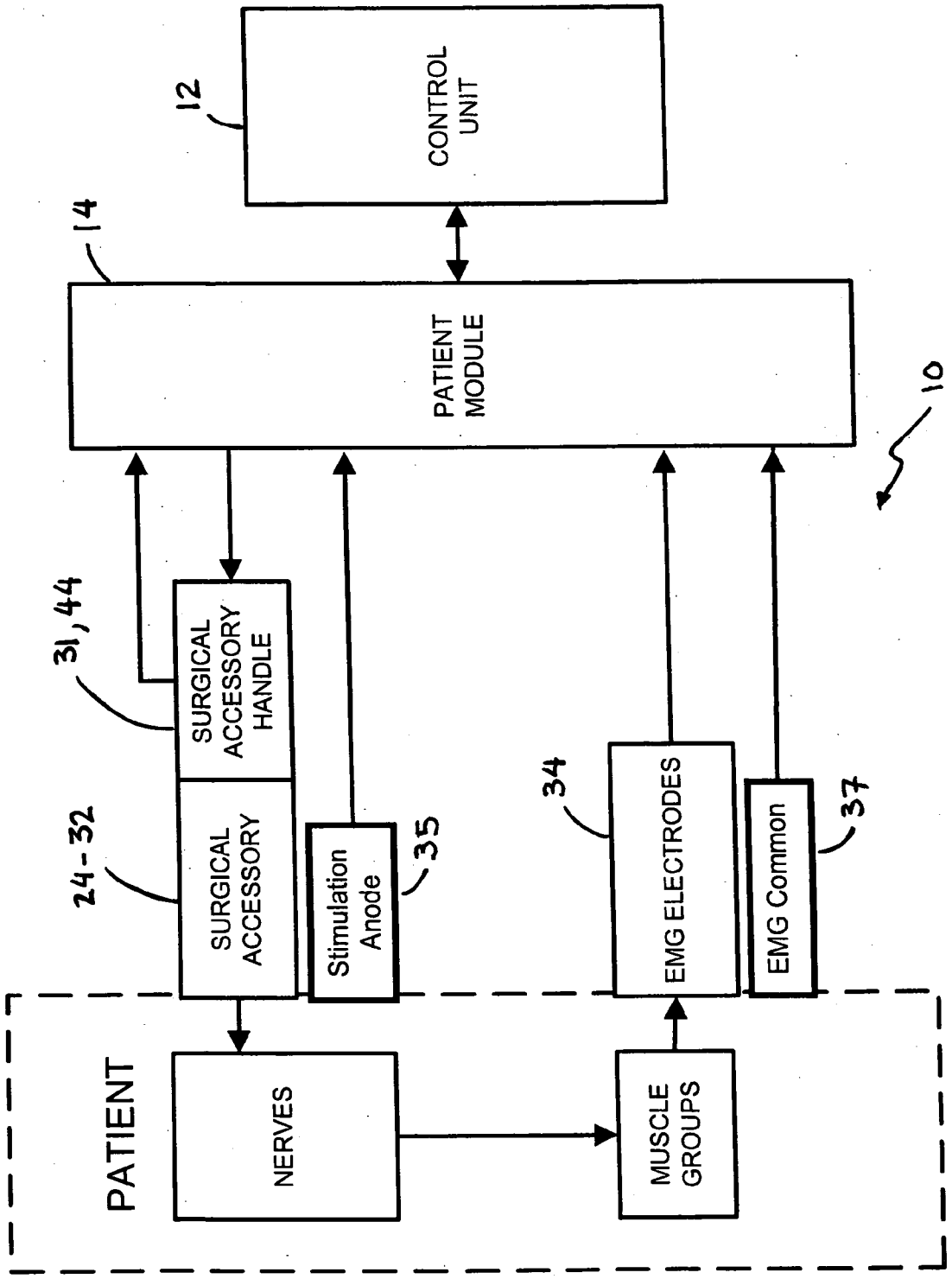

CONTROL UNIT
12
14
PATIENT MODULE
10
31, 44
SURGICAL ACCESSORY HANDLE
24-32
SURGICAL ACCESSORY
Stimulation Anode
35
34
EMG ELECTRODES
EMG Common
37
PATIENT
NERVES
MUSCLE GROUPS

FIG. 2

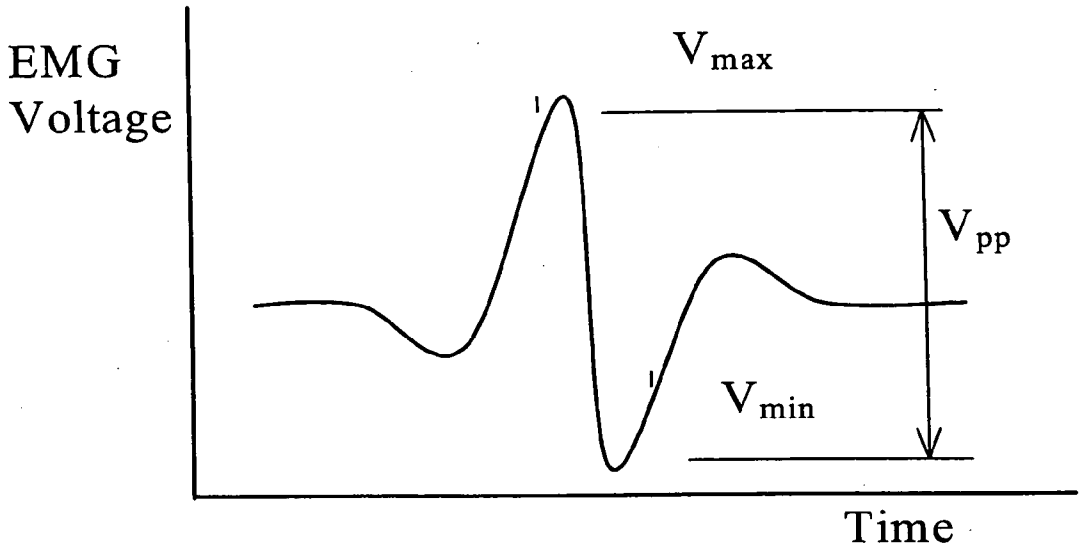


FIG. 3

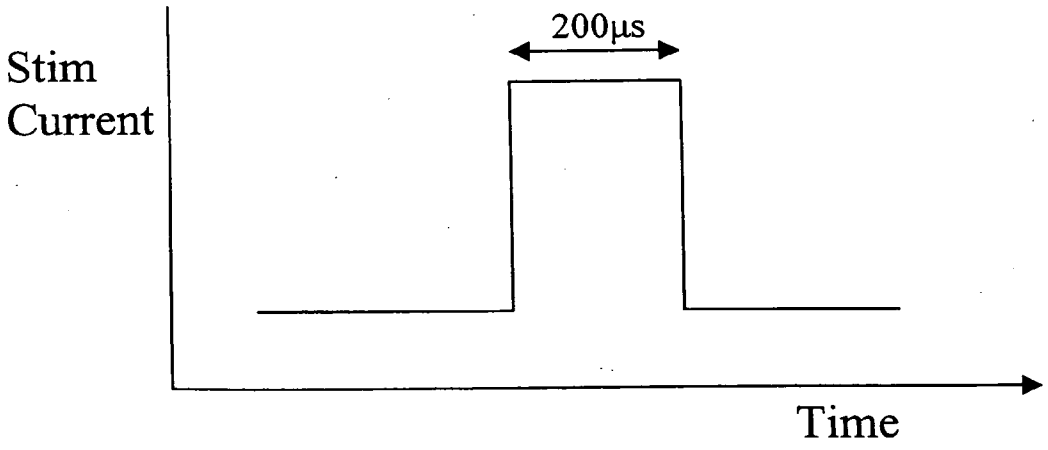


FIG. 4

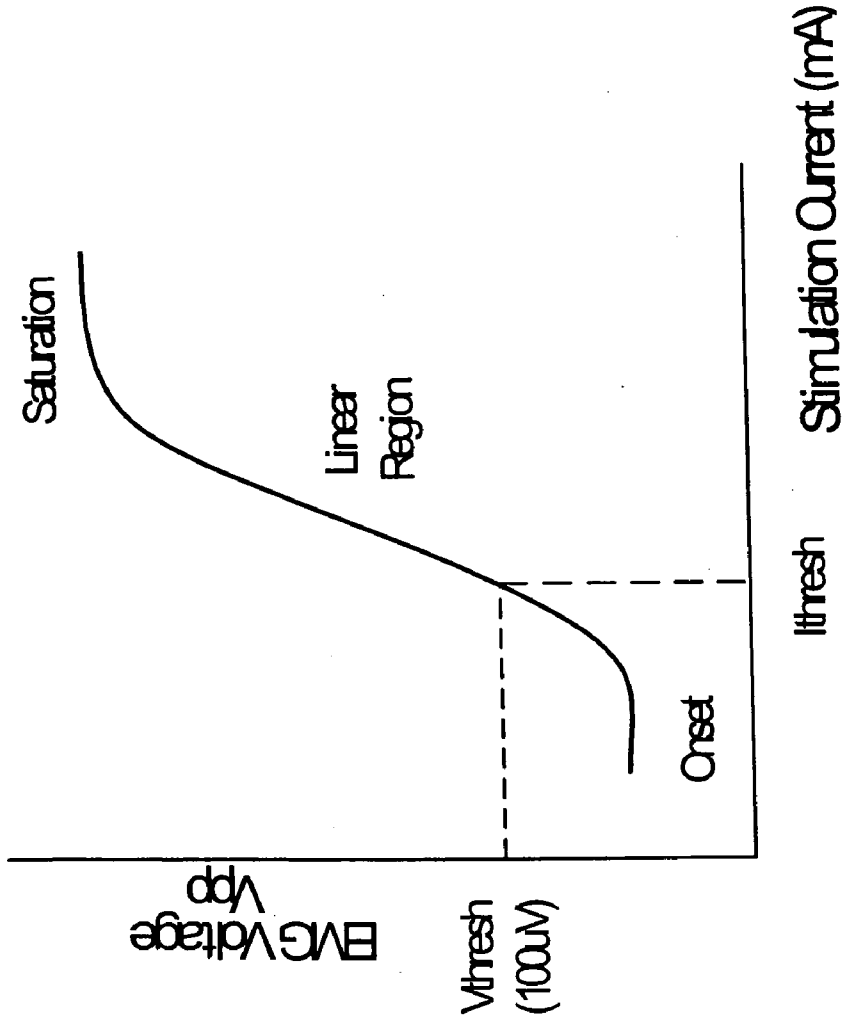

Saturation
Linear Region
Onset
EMG Voltage Vpp
Vthresh (100uV)
Ithresh
Stimulation Current (mA)

FIG. 5

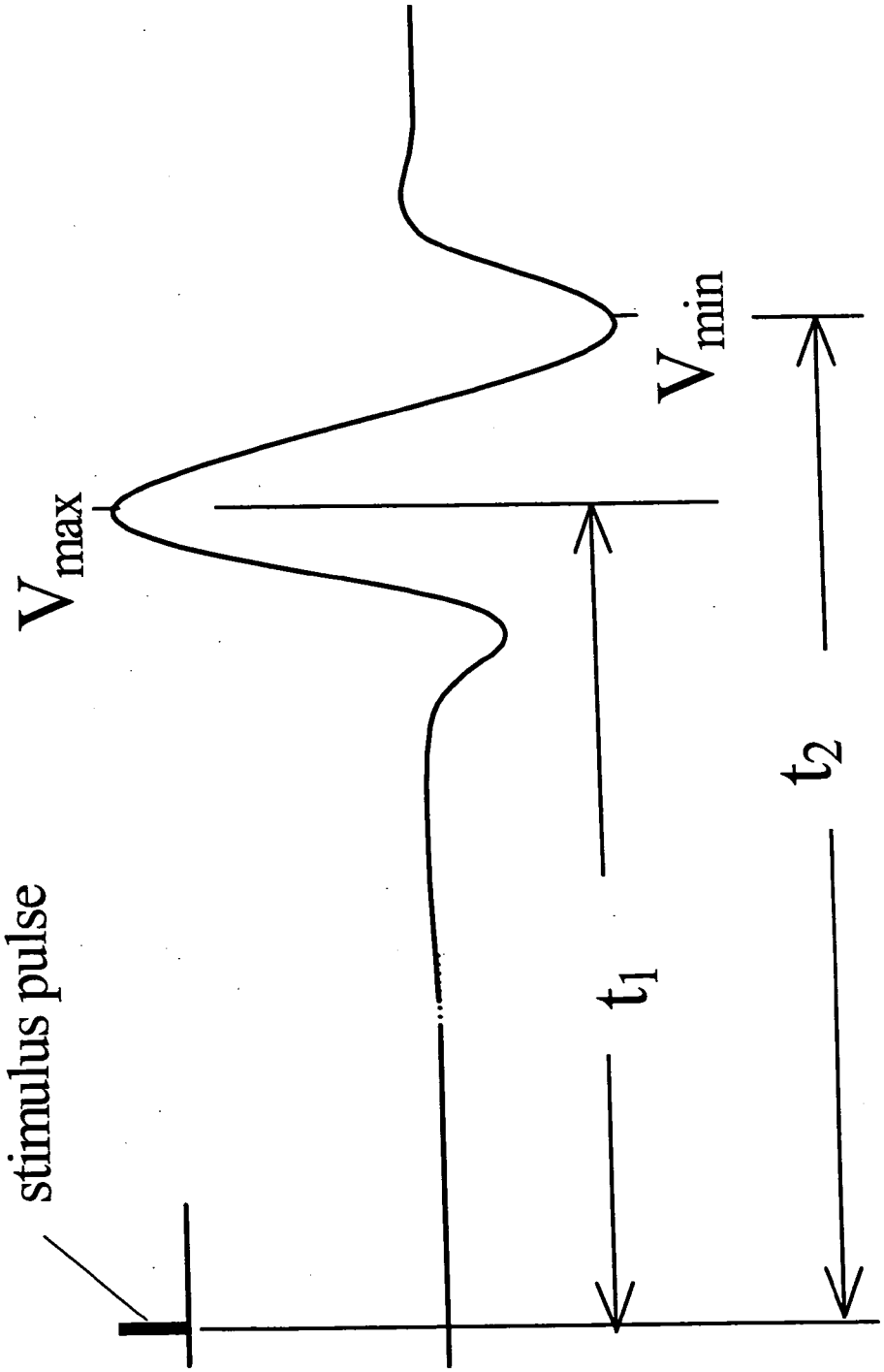


FIG. 6

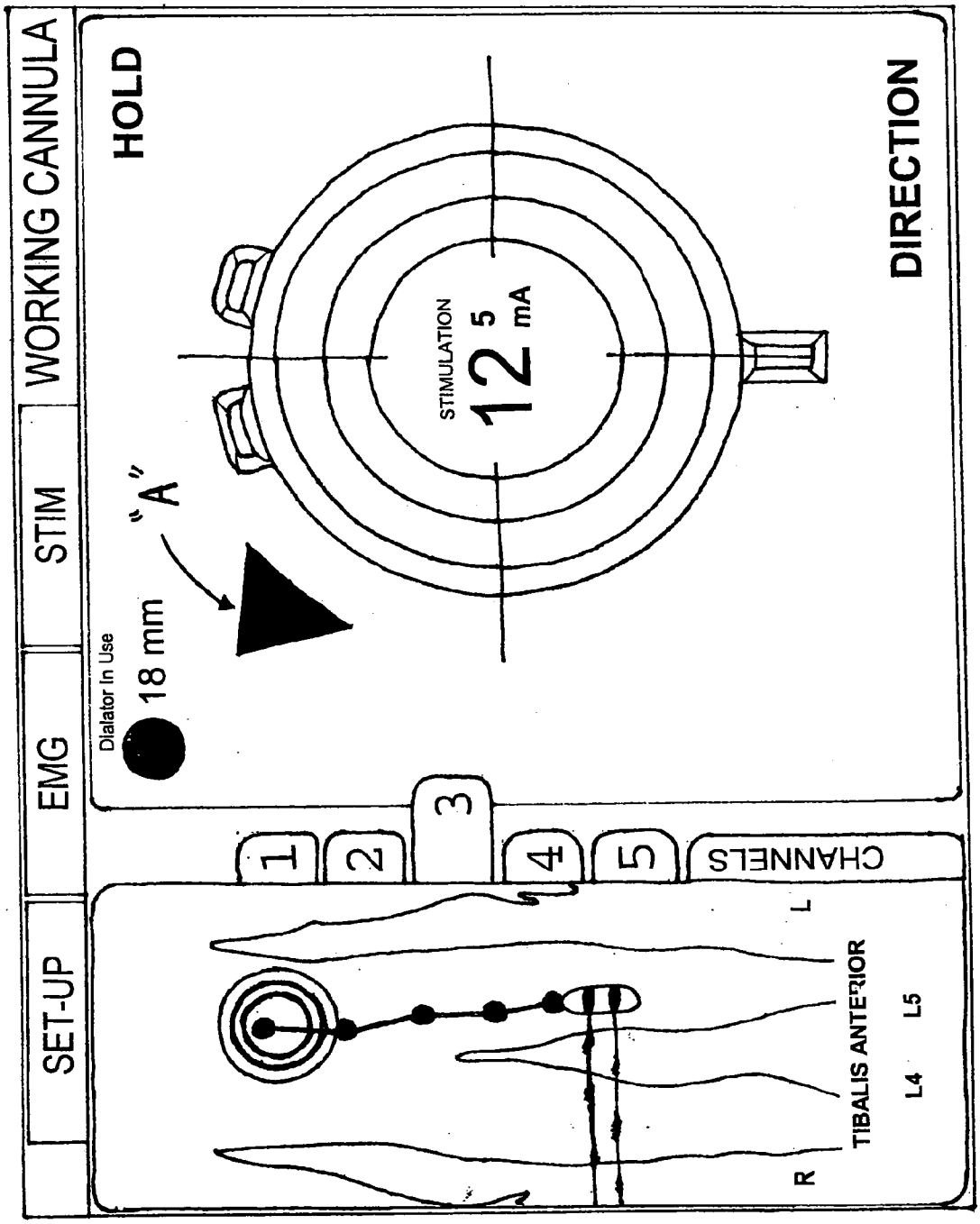

SET-UP
EMG
STIM
WORKING CANNULA
Dialator In Use
18 mm
"A"
HOLD
STIMULATION
12 5 mA
DIRECTION
1
2
3
4
5
CHANNELS
R
TIBALIS ANTERIOR
L
L4
L5

FIG. 7

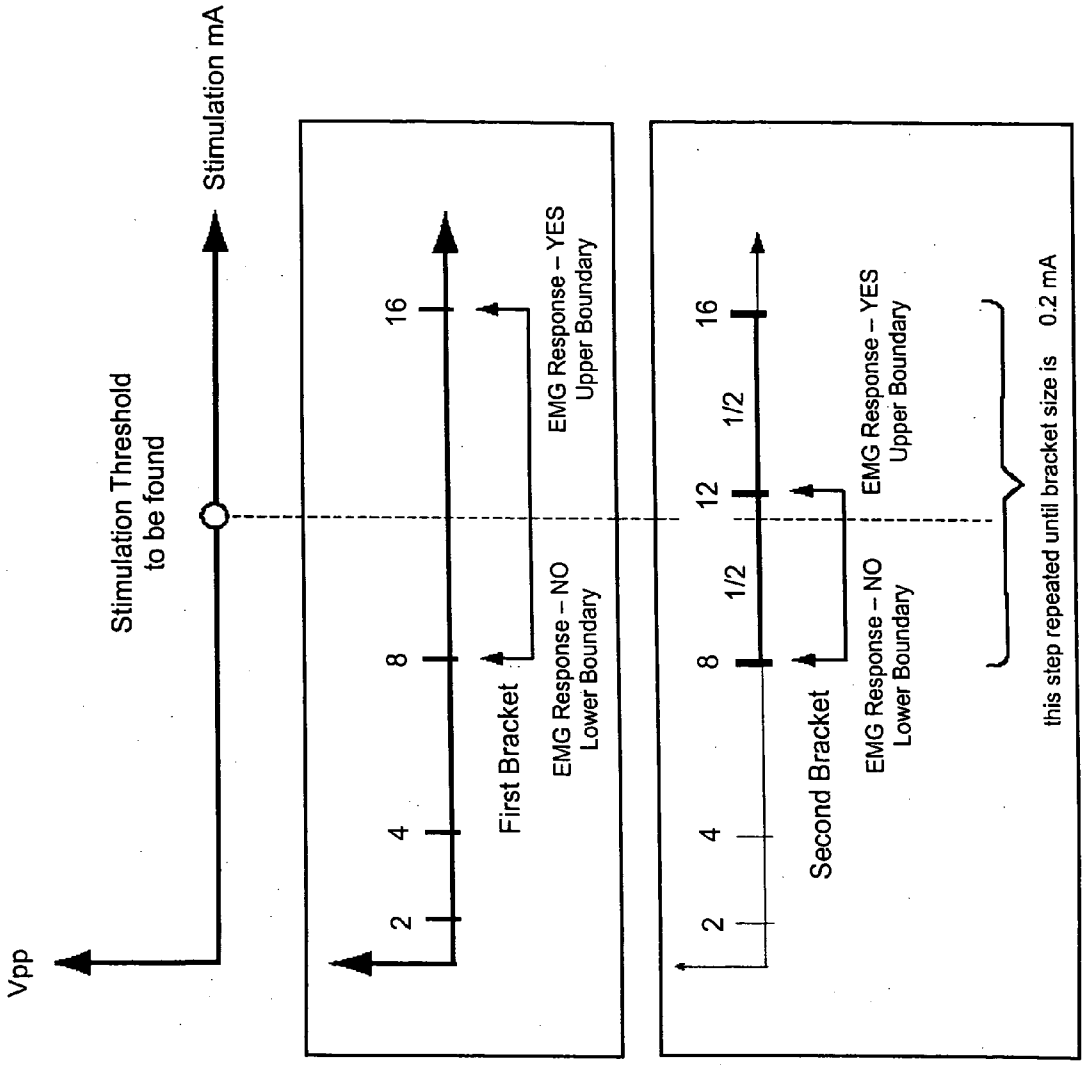


FIG. 8A

FIG. 8B

FIG. 8C

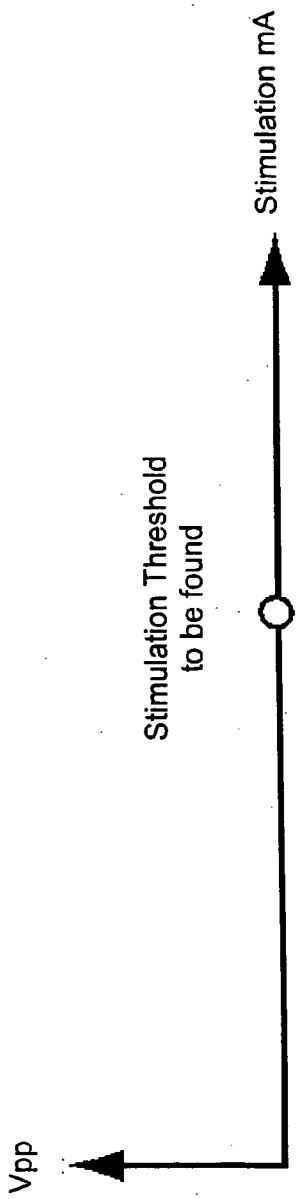


FIG. 8A

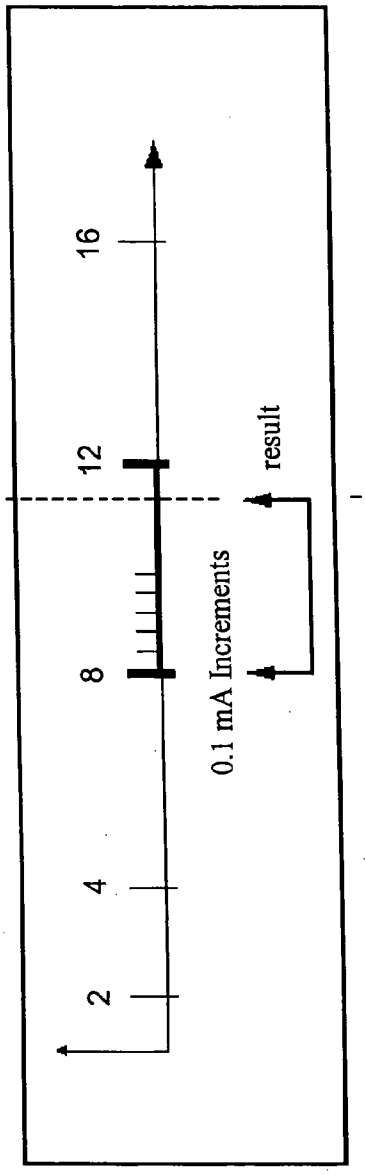


FIG. 8D

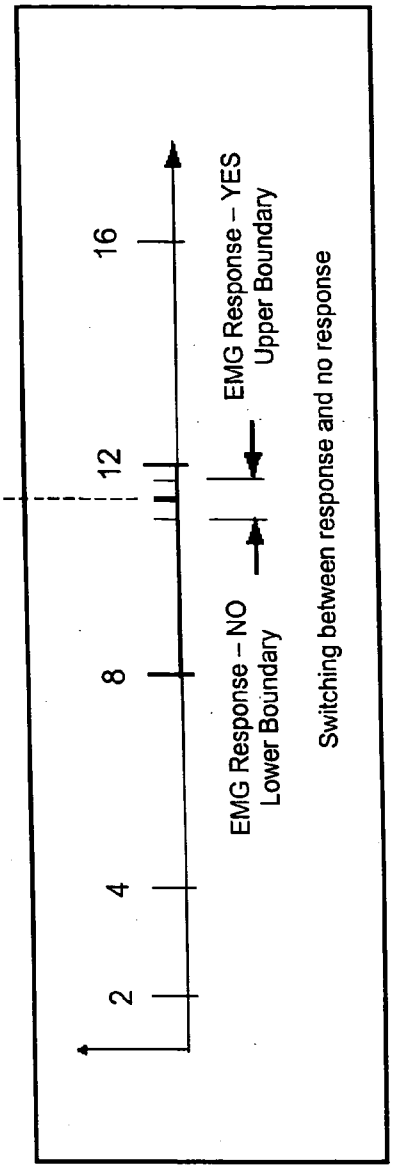


FIG. 8E

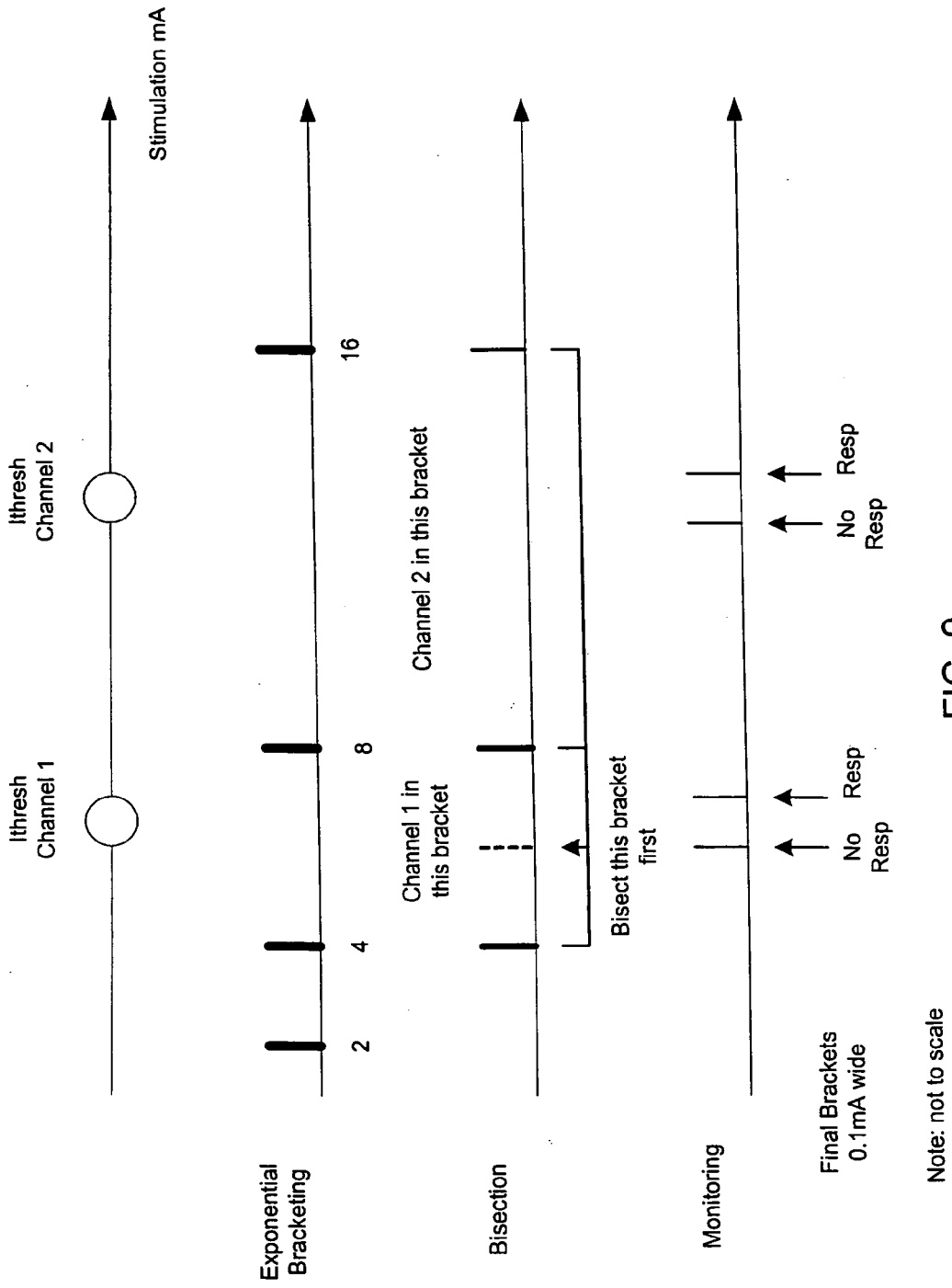

Stimulation mA
Ithresh Channel 1
Ithresh Channel 2
Exponential Bracketing
2
4
8
16
Bisection
Channel 1 in this bracket
Channel 2 in this bracket
Bisect this bracket first
Monitoring
No Resp
Resp
No Resp
Resp
Final Brackets 0.1mA wide
Note: not to scale

FIG. 9

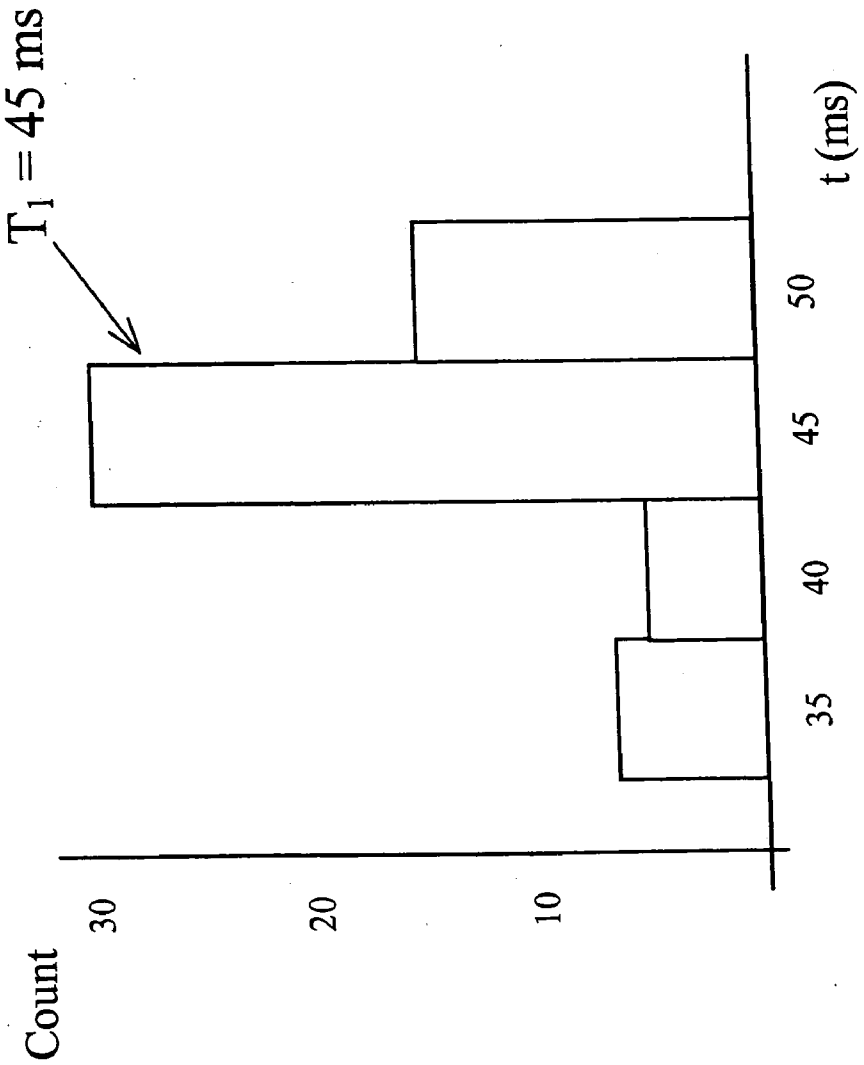


FIG. 10

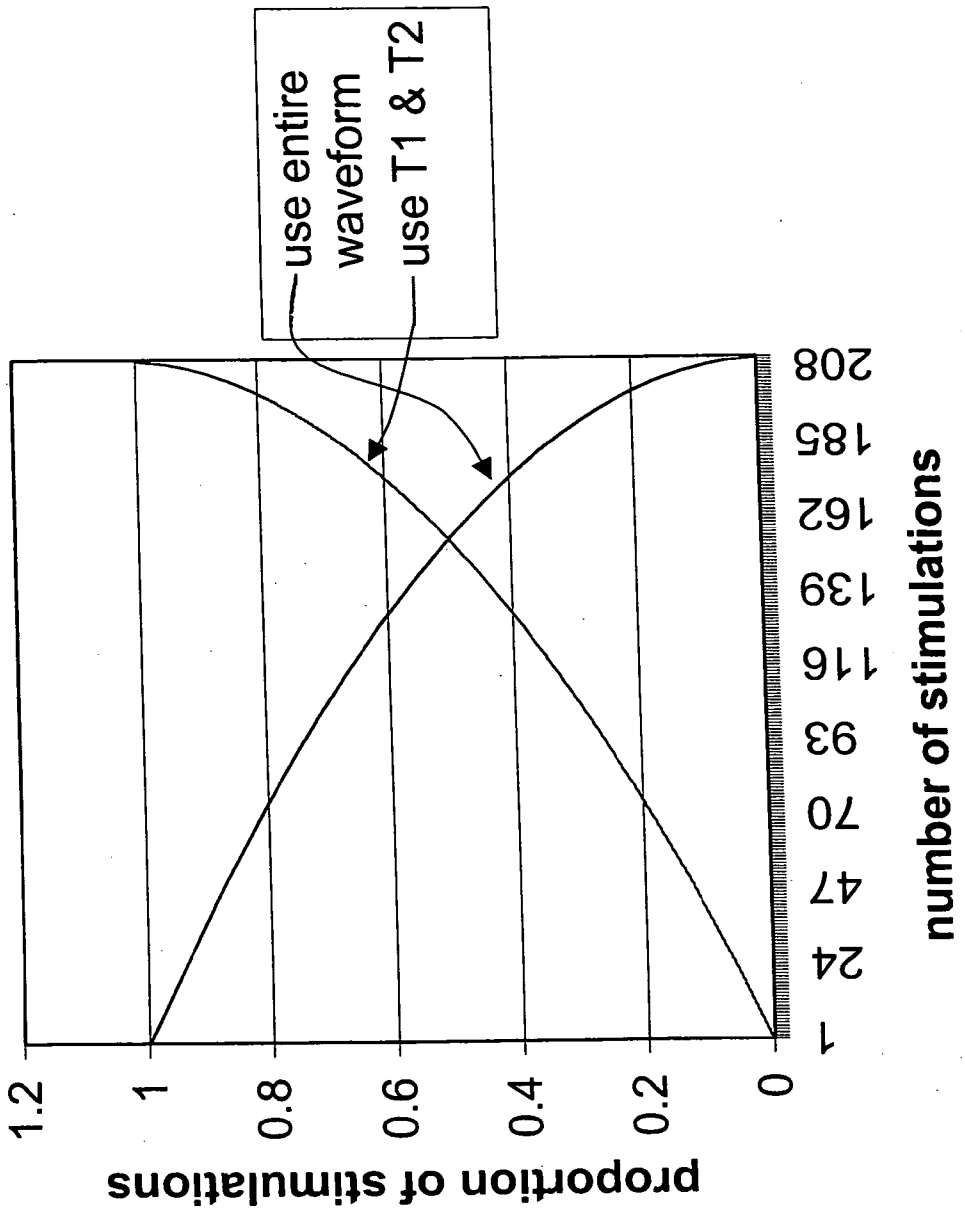

use entire waveform
use T1 & T2
proportion of stimulations
1.2
1
0.8
0.6
0.4
0.2
0
1
24
47
70
93
116
139
162
185
208
number of stimulations

FIG. 11

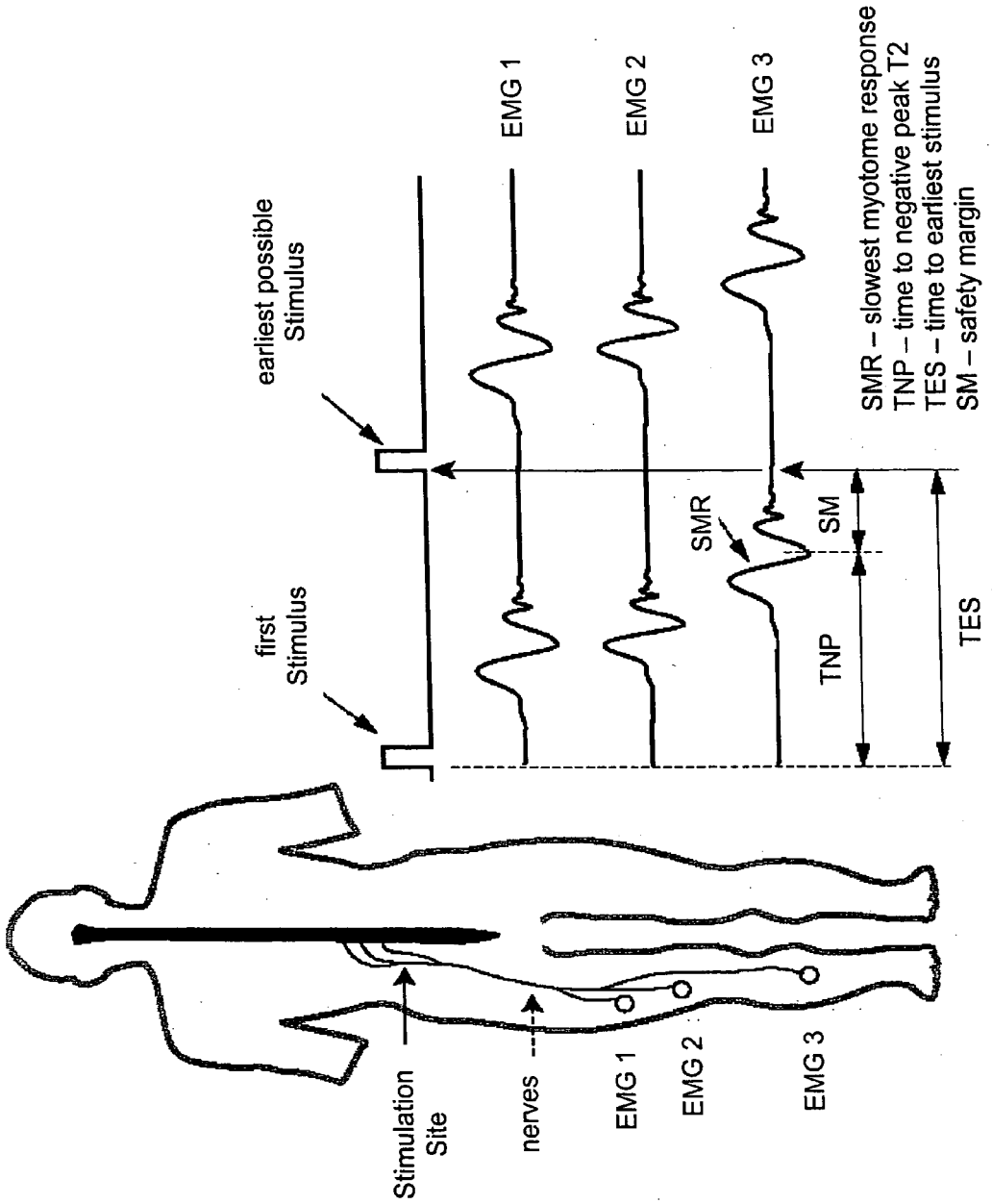

Stimulation Site
nerves
EMG 1
EMG 2
EMG 3
first Stimulus
earliest possible Stimulus
EMG 1
EMG 2
EMG 3
SMR
SM
TNP
TES
SMR – slowest myotome response
TNP – time to negative peak T2
TES – time to earliest stimulus
SM – safety margin

FIG. 12

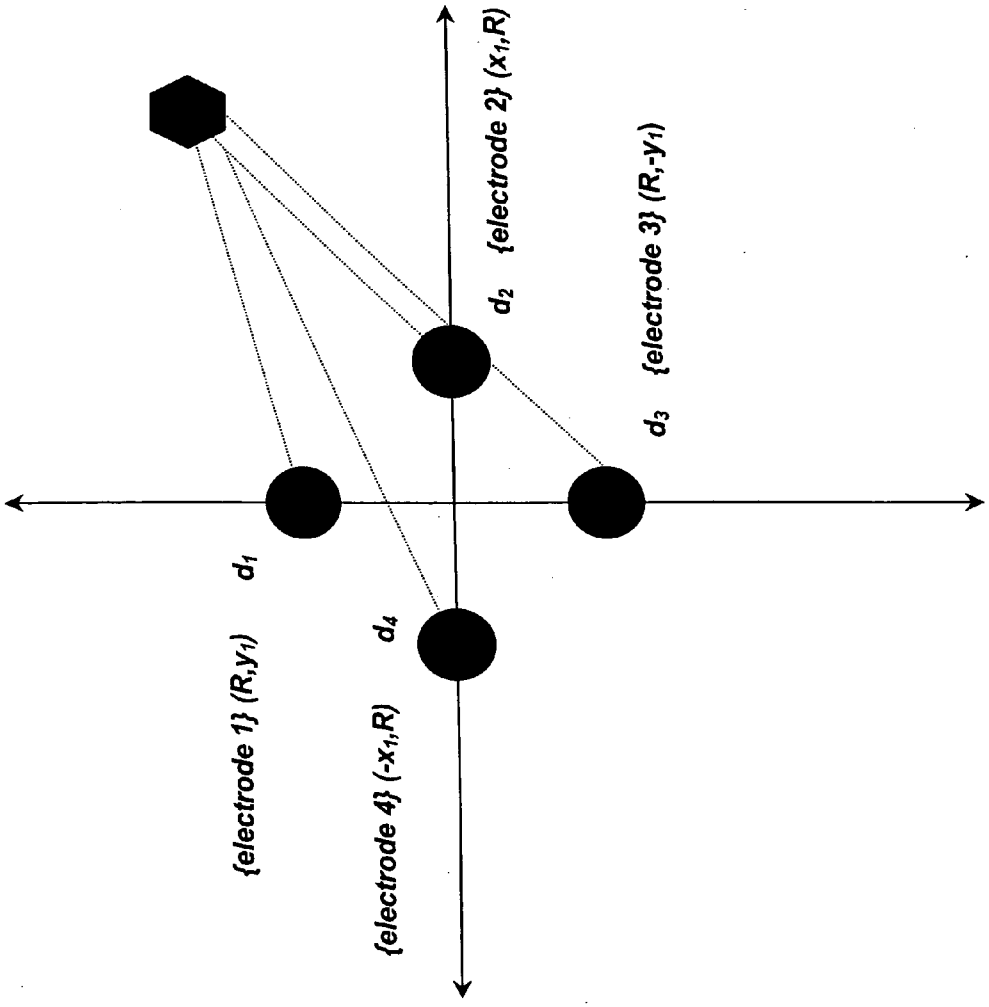

{electrode 1} (R,y1)
d1
{electrode 4} (-x1,R)
d4
d2
{electrode 2} (x1,R)
d3
{electrode 3} (R,-y1)

FIG. 13

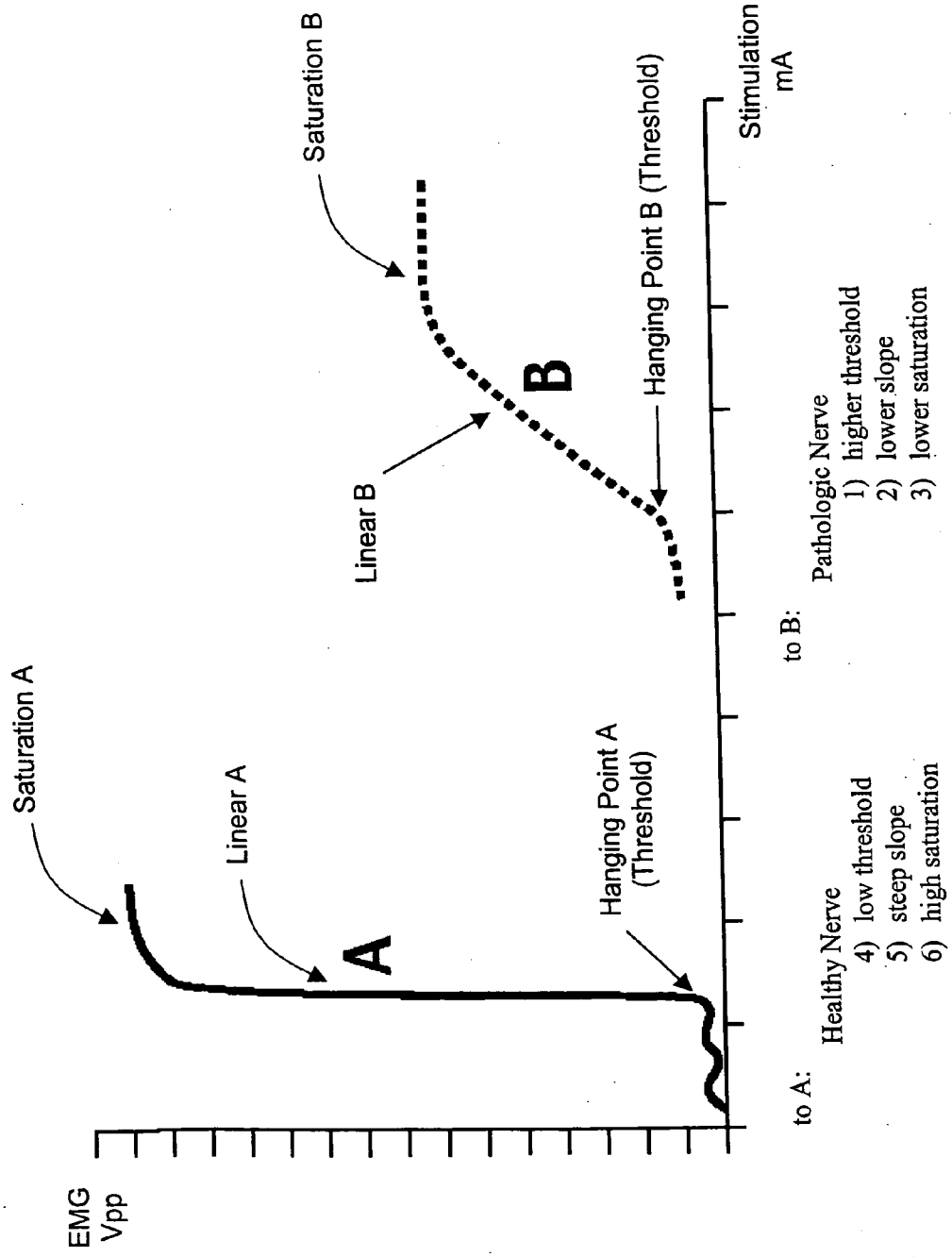

Saturation A
Linear A
A
Hanging Point A (Threshold)
Saturation B
Linear B
B
Hanging Point B (Threshold)
EMG Vpp
Stimulation mA
to A:
Healthy Nerve
4) low threshold
5) steep slope
6) high saturation
to B:
Pathologic Nerve
1) higher threshold
2) lower slope
3) lower saturation

FIG. 14

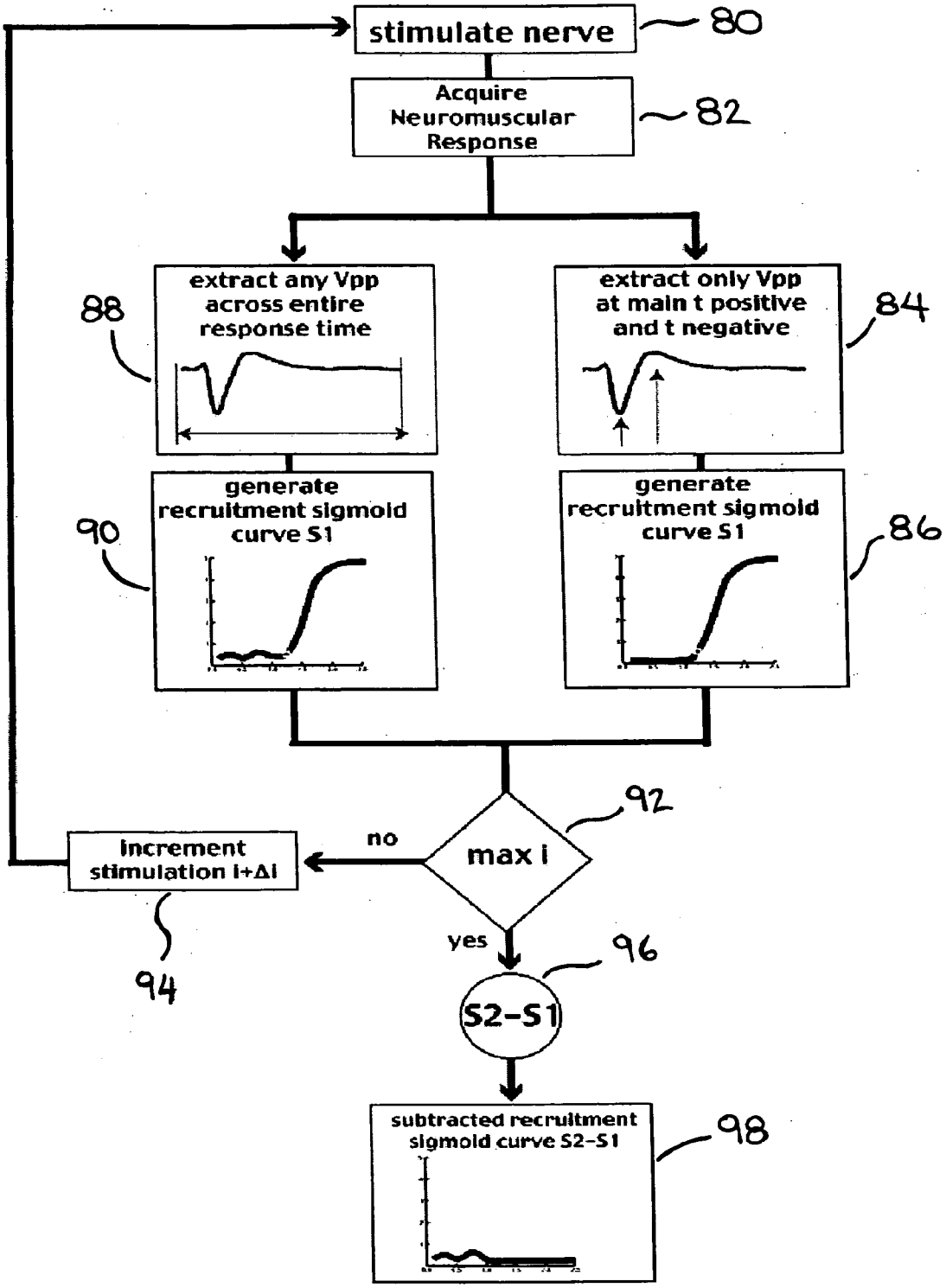

stimulate nerve
80
Acquire Neuromuscular Response
82
extract any Vpp across entire response time
88
extract only Vpp at main t positive and t negative
84
generate recruitment sigmoid curve S1
90
generate recruitment sigmoid curve S1
86
max i
92
no
increment stimulation i+Δi
94
yes
96
S2-S1
subtracted recruitment sigmoid curve S2-S1
98

FIG. 15

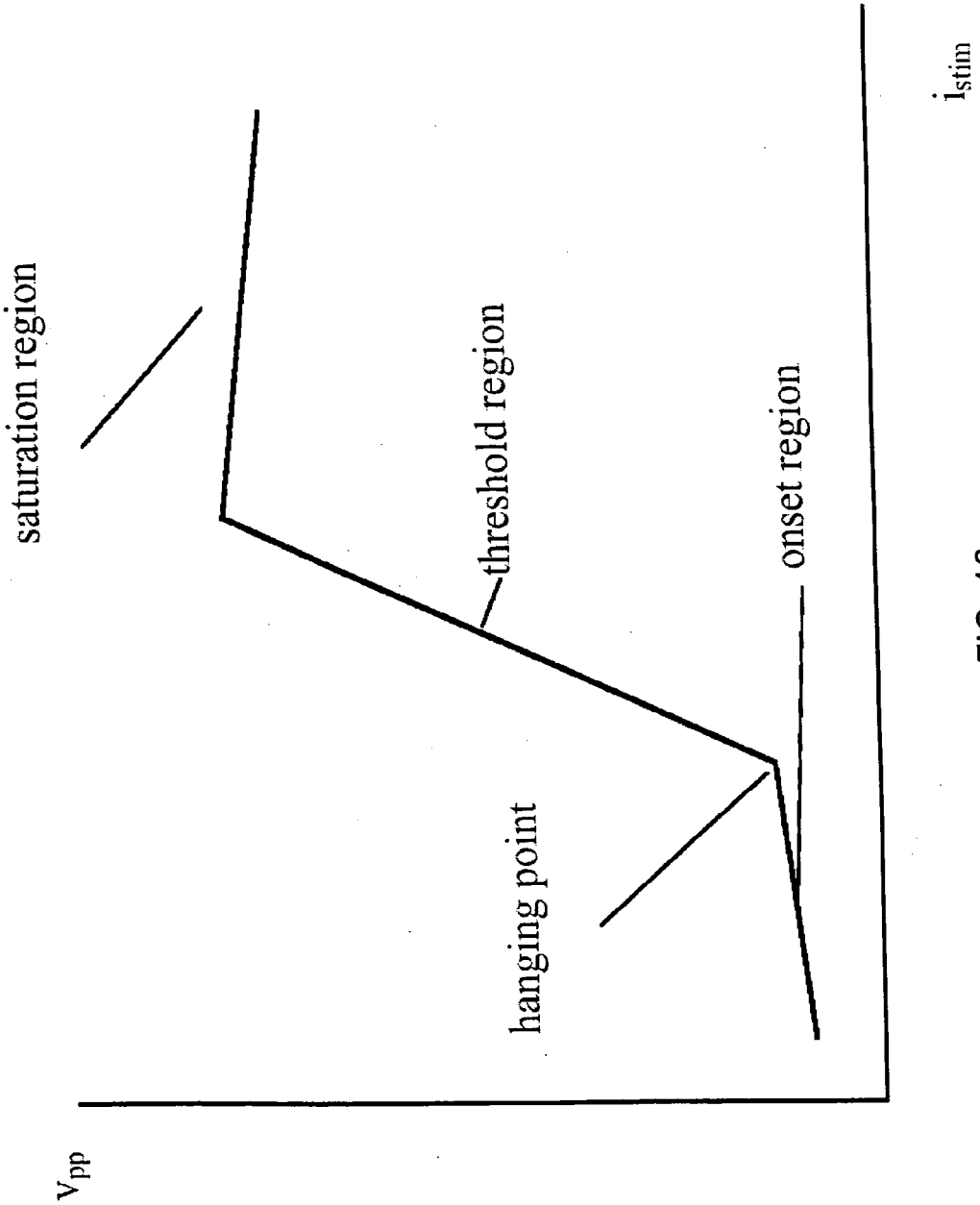

saturation region
threshold region
onset region
hanging point
V_{pp}
i_{stim}

FIG. 16

SYSTEM AND METHODS FOR DETERMINING NERVE PROXIMITY, DIRECTION, AND PATHOLOGY DURING SURGERY

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application is a regular patent application of and claims the benefit of priority from U.S. Provisional Patent Application Ser. No. 60/305,041, filed Jul. 11, 2001 and assigned to the Assignee hereof, the entire contents of which is hereby expressly incorporated by reference into this disclosure as if set forth fully herein.

BACKGROUND OF THE INVENTION

[0002] I. Field of the Invention

[0003] This invention relates to nerve monitoring systems and to nerve muscle monitoring systems, and more particularly to systems and methods for determining nerve proximity, nerve direction, and pathology during surgery.

[0004] II. Description of Related Art

[0005] Systems and methods exist for monitoring nerves and nerve muscles. One such system determines when a needle is approaching a nerve. The system applies a current to the needle to evoke a muscular response. The muscular response is visually monitored, typically as a shake or "twitch." When such a muscular response is observed by the user, the needle is considered to be near the nerve coupled to the responsive muscle. These systems require the user to observe the muscular response (to determine that the needle has approached the nerve). This may be difficult depending on the competing tasks of the user. In addition, when general anesthesia is used during a procedure, muscular response may be suppressed, limiting the ability of a user to detect the response.

[0006] While generally effective (although crude) in determining nerve proximity, such existing systems are incapable of determining the direction of the nerve to the needle or instrument passing through tissue or passing by the nerves. This can be disadvantageous in that, while the surgeon may appreciate that a nerve is in the general proximity of the instrument, the inability to determine the direction of the nerve relative to the instrument can lead to guess work by the surgeon in advancing the instrument and thereby raise the specter of inadvertent contact with, and possible damage to, the nerve.

[0007] Another nerve-related issue in existing surgical applications involves the use of nerve retractors. A typical nerve retractor serves to pull or otherwise maintain the nerve outside the area of surgery, thereby protecting the nerve from inadvertent damage or contact by the "active" instrumentation used to perform the actual surgery. While generally advantageous in protecting the nerve, it has been observed that such retraction can cause nerve function to become impaired or otherwise pathologic over time due to the retraction. In certain surgical applications, such as spinal surgery, it is not possible to determine if such retraction is hurting or damaging the retracted nerve until after the surgery (generally referred to as a change in "nerve health" or "nerve status"). There are also no known techniques or systems for assessing whether a given procedure is having a beneficial effect on a nerve or nerve root known to be pathologic (that is, impaired or otherwise unhealthy).

[0008] Based on the foregoing, a need exists for a better system and method that can determine the proximity of a surgical instrument (including but not limited to a needle, catheter, cannula, probe, or any other device capable of traversing through tissue or passing near nerves or nerve structures) to a nerve or group of nerves during surgery. A need also exists for a system and method for determining the direction of the nerve relative to the surgical instrument. A still further need exists for a manner of monitoring nerve health or status during surgical procedures.

[0009] The present invention is directed at eliminating, or at least reducing the effects of, the above-described problems with the prior art, as well as addressing the above-identified needs.

SUMMARY OF THE INVENTION

[0010] The present invention includes a system and related methods for determining nerve proximity and nerve direction to surgical instruments employed in accessing a surgical target site, as well as monitoring the status or health (pathology) of a nerve or nerve root during surgical procedures.

[0011] According to a broad aspect, the present invention includes a surgical system, comprising a control unit and a surgical instrument. The control unit has at least one of computer programming software, firmware and hardware capable of delivering a stimulation signal, receiving and processing neuromuscular responses due to the stimulation signal, and identifying a relationship between the neuromuscular response and the stimulation signal. The surgical instrument has at least one stimulation electrode electrically coupled to said control unit for transmitting the stimulation signal, wherein said control unit is capable of determining at least one of nerve proximity, nerve direction, and nerve pathology relative to the surgical instrument based on the identified relationship between the neuromuscular response and the stimulation signal.

[0012] In a further embodiment of the surgical system of the present invention, the control unit is further equipped to communicate at least one of alpha-numeric and graphical information to a user regarding at least one of nerve proximity, nerve direction, and nerve pathology.

[0013] In a further embodiment of the surgical system of the present invention, the surgical instrument may comprise at least one of a device for maintaining contact with a nerve during surgery, a device for accessing a surgical target site, and a device for testing screw placement integrity.

[0014] In a further embodiment of the surgical system of the present invention, the surgical instrument comprises a nerve root retractor and wherein the control unit determines nerve pathology based on the identified relationship between the neuromuscular response and the stimulation signal.

[0015] In a further embodiment of the surgical system of the present invention, the surgical instrument comprises a dilating instrument and wherein the control unit determines at least one of proximity and direction between a nerve and the instrument based on the identified relationship between the neuromuscular response and the stimulation signal.

[0016] In a further embodiment of the surgical system of the present invention, the dilating instrument comprises at least one of a K-wire, an obturator, a dilating cannula, and a working cannula.

[0017] In a further embodiment of the surgical system of the present invention, the surgical instrument comprises a screw test probe and wherein the control unit determines the proximity between the screw test probe and an exiting spinal nerve root to assess whether a medial wall of a pedicle has been breached by at least one of hole formation and screw placement.

BRIEF DESCRIPTION OF THE DRAWINGS

[0018] **FIG. 1** is a perspective view of a surgical system **10** capable of determining, among other things, nerve proximity, direction, and pathology according to one aspect of the present invention;

[0019] **FIG. 2** is a block diagram of the surgical system **10** shown in **FIG. 1**;

[0020] **FIG. 3** is a graph illustrating a plot of the neuromuscular response (EMG) of a given myotome over time based on a current stimulation pulse (similar to that shown in **FIG. 4**) applied to a nerve bundle coupled to the given myotome;

[0021] **FIG. 4** is a graph illustrating a plot of a stimulation current pulse capable of producing a neuromuscular response (EMG) of the type shown in **FIG. 3**;

[0022] **FIG. 5** is a graph illustrating a plot of peak-to-peak voltage (Vpp) for each given stimulation current level (I_{Stim}) forming a stimulation current pulse train according to the present invention (otherwise known as a "recruitment curve");

[0023] **FIG. 6** is a graph illustrating a plot of a neuromuscular response (EMG) over time (in response to a stimulus current pulse) showing the manner in which maximum voltage (V_{Max}) and minimum voltage (V_{Min}) occur at times T1 and T2, respectively;

[0024] **FIG. 7** is an exemplary touch-screen display according to the present invention, capable of communicating a host of alpha-numeric and/or graphical information to a user and receiving information and/or instructions from the user during the operation of the surgical system **10** of **FIG. 1**;

[0025] **FIGS. 8A-8E** are graphs illustrating a rapid current threshold-hunting algorithm according to one embodiment of the present invention;

[0026] **FIG. 9** is a series of graphs illustrating a multi-channel rapid current threshold-hunting algorithm according to one embodiment of the present invention;

[0027] **FIG. 10** is a graph illustrating a T1, T2 artifact rejection technique according to one embodiment of the present invention via the use of histograms;

[0028] **FIG. 11** is a graph illustrating the proportion of stimulations versus the number of stimulations employed in the T1, T2 artifact rejection technique according to the present invention;

[0029] **FIG. 12** is an illustration (graphical and schematic) of a method of automatically determining the maximum frequency (F_{Max}) of the stimulation current pulses according to one embodiment of the present invention;

[0030] **FIG. 13** is a graph illustrating a method of determining the direction of a nerve (denoted as an "octagon") relative to an instrument having four (4) orthogonally disposed stimulation electrodes (denoted by the "circles") according to one embodiment of the present invention;

[0031] **FIG. 14** is a graph illustrating recruitment curves for a generally healthy nerve (denoted "A") and a generally unhealthy nerve (denoted "B") according to the nerve pathology determination method of the present invention;

[0032] **FIG. 15** is flow chart illustrating an alternate method of determining the hanging point of a recruitment curve according to an embodiment of the present invention; and

[0033] **FIG. 16** is a graph illustrating a simulated recruitment curve generated by a "virtual patient" device and method according to the present invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

[0034] Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with system-related and business-related constraints, which will vary from one implementation to another. Moreover, it will be appreciated that such a development effort might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure. The systems disclosed herein boast a variety of inventive features and components that warrant patent protection, both individually and in combination.

[0035] **FIG. 1** illustrates, by way of example only, a surgical system **10** capable of employing the nerve proximity, nerve direction, and nerve pathology assessments according to the present invention. As will be explained in greater detail below, the surgical system **10** is capable of providing safe and reproducible access to any number of surgical target sites, as well as monitoring changes in nerve pathology (health or status) during surgical procedures. It is expressly noted that, although described herein largely in terms of use in spinal surgery, the surgical system **10** and related methods of the present invention are suitable for use in any number of additional surgical procedures wherein tissue having significant neural structures must be passed through (or near) in order to establish an operative corridor, or where neural structures are retracted.

[0036] The surgical system **10** includes a control unit **12**, a patient module **14**, an EMG harness **16** and return electrode **35** coupled to the patient module **14**, and a host of surgical accessories **20** capable of being coupled to the patient module **14** via one or more accessory cables **22**. The surgical accessories **20** may include, but are not necessarily limited to, surgical access components (such as a K-wire **24**, one or more dilating cannula **26**, and a working cannula **28**), neural pathology monitoring devices (such as nerve root retractor **30**), and devices for performing pedicle screw test

(such as screw test probe **32**). A block diagram of the surgical system **10** is shown in **FIG. 2**, the operation of which is readily apparent in view of the following description.

[**0037**] The control unit **12** includes a touch screen display **36** and a base **38**. The touch screen display **36** is preferably equipped with a graphical user interface (GUI) capable of communicating information to the user and receiving instructions from the user. The base **38** contains computer hardware and software that commands the stimulation sources, receives digitized signals and other information from the patient module **14**, and processes the EMG responses to extract characteristic information for each muscle group, and displays the processed data to the operator via the display **36**. The primary functions of the software within the control unit **12** include receiving user commands via the touch screen display **36**, activating stimulation in the requested mode (nerve proximity, nerve direction, nerve pathology, screw test), processing signal data according to defined algorithms (described below), displaying received parameters and processed data, and monitoring system status and report fault conditions.

[**0038**] The patient module **14** is connected via a serial cable **40** to the control unit **12**, and contains the electrical connections to all electrodes, signal conditioning circuitry, stimulator drive and steering circuitry, and a digital communications interface to the control unit **12**. In use, the control unit **12** is situated outside but close to the surgical field (such as on a cart adjacent the operating table) such that the display **36** is directed towards the surgeon for easy visualization. The patient module **14** should be located between the patient's legs, or may be affixed to the end of the operating table at mid-leg level using a bedrail clamp. The position selected should be such that the EMG leads can reach their farthest desired location without tension during the surgical procedure.

[**0039**] In a significant aspect of the present invention, the information displayed to the user on display **36** may include, but is not necessarily limited to, alpha-numeric and/or graphical information regarding nerve proximity, nerve direction, nerve pathology, stimulation level, myotome/EMG levels, screw testing, advance or hold instructions, and the instrument in use.

[**0040**] In one embodiment (set forth by way of example only) the display includes the following components as set forth in Table 1:

TABLE 1

Screen Component	Description
Menu/Status Bar	The mode label may include the surgical accessory attached, such as the surgical access components (K-Wire, Dilating Cannula, Working Cannula), nerve pathology monitoring device (Nerve Root Retractor), and/or screw test device (Screw Test Probe) depending on which is attached.
Spine Image	An image of a human body/skeleton showing the electrode placement on the body, with labeled channel number tabs on each side (1-4 on left and right). Left and Right labels will show the patient orientation. The Channel number tabs may be highlighted or colored depending on the specific function being performed.

TABLE 1-continued

Screen Component	Description
Display Area	Shows procedure-specific information.
Myotome & Level Names	A label to indicate the Myotome name and corresponding Spinal Level(s) associated with the channel of interest.
Advance/Hold	When in the Detection mode, an indication of "Advance" will show when it is safe to move the cannula forward (such as when the minimum stimulation current threshold I_{Thresh} (described below) is greater than a predetermined value, indicating a safe distance to the nerve) and "Hold" will show when it is unsafe to advance the cannula (such as when the minimum stimulation current threshold I_{Thresh} (described below) is less than a predetermined value, indicating that the nerve is relatively close to the cannula) and during proximity calculations.
Function	Indicates which function is currently active (Direction, Detection, Pathology Monitoring, Screw Test).
Dilator In Use	A colored circle to indicate the inner diameter of the cannula, with the numeric size. If cannula is detached, no indicator is displayed.

[**0041**] The surgical system **10** accomplishes safe and reproducible access to a surgical target site by detecting the existence of (and optionally the distance and/or direction to) neural structures before, during, and after the establishment of an operative corridor through (or near) any of a variety of tissues having such neural structures which, if contacted or impinged, may otherwise result in neural impairment for the patient. The surgical system **10** does so by electrically stimulating nerves via one or more stimulation electrodes at the distal end of the surgical access components **24-28** while monitoring the EMG responses of the muscle groups innervated by the nerves. In a preferred embodiment, this is accomplished via 8 pairs of EMG electrodes **34** placed on the skin over the major muscle groups on the legs (four per side), an anode electrode **35** providing a return path for the stimulation current, and a common electrode **37** providing a ground reference to pre-amplifiers in the patient module **14**. By way of example, the placement of EMG electrodes **34** may be undertaken according to the manner shown in Table 2 below for spinal surgery:

TABLE 2

Color	Channel ID	Myotome	Nerve	Spinal Level
Red	Right 1	Right Vastus Medialis	Femoral	L2, L3, L4
Orange	Right 2	Right TibialisAnterior	Peroneal	L4, L5
Yellow	Right 3	Right Biceps Femoris	Sciatic	L5, S1, S2
Green	Right 4	Right Gastroc. Medial	Post Tibialis	S1, S2
Blue	Left 1	Left Vastus Medialis	Femoral	L2, L3, L4
Violet	Left 2	Left Tibialis Anterior	Peroneal	L4, L5
Gray	Left 3	Left Biceps Femoris	Sciatic	L5, S1, S2
White	Left 4	Left Gastroc. Medial	Post Tibialis	S1, S2

[**0042**] Although not shown, it will be appreciated that any of a variety of electrodes can be employed, including but not limited to needle electrodes. The EMG responses provide a quantitative measure of the nerve depolarization caused by the electrical stimulus. Analysis of the EMG responses is

then used to determine the proximity and direction of the nerve to the stimulation electrode, as will be described with particularity below.

[**0043**] The surgical access components **24-28** are designed to bluntly dissect the tissue between the patient's skin and the surgical target site. An initial dilating cannula **26** is advanced towards the target site, preferably after having been aligned using any number of commercially available surgical guide frames. An obturator (not shown) may be included inside the initial dilator **26** and may similarly be equipped with one or more stimulating electrodes. Once the proper location is achieved, the obturator (not shown) may be removed and the K-wire **24** inserted down the center of the initial dilating cannula **26** and docked to the given surgical target site, such as the annulus of an intervertebral disc. Cannulae of increasing diameter are then guided over the previously installed cannula **26** until the desired lumen is installed. By way of example only, the dilating cannulae **26** may range in diameter from 6 mm to 30 mm. In one embodiment, each cannula **26** has four orthogonal stimulating electrodes at the tip to allow detection and direction evaluation, as will be described below. The working cannula **28** is installed over the last dilating cannula **26** and then all the dilating cannulae **26** are removed from inside the inner lumen of the working cannula **28** to establish the operative corridor therethrough. A stimulator driver **42** is provided to electrically couple the particular surgical access component **24-28** to the patient module **14** (via accessory cable **22**). In a preferred embodiment, the stimulator driver **42** includes one or more buttons for selectively activating the stimulation current and/or directing it to a particular surgical access component.

[**0044**] The surgical system **10** accomplishes neural pathology monitoring by electrically stimulating a retracted nerve root via one or more stimulation electrodes at the distal end of the nerve root retractor **30** while monitoring the EMG responses of the muscle group innervated by the particular nerve. The EMG responses provide a quantitative measure of the nerve depolarization caused by the electrical stimulus. Analysis of the EMG responses may then be used to assess the degree to which retraction of a nerve or neural structure affects the nerve function over time, as will be described with greater particularity below. One advantage of such monitoring, by way of example only, is that the conduction of the nerve may be monitored during the procedure to determine whether the neurophysiology and/or function of the nerve changes (for the better or worse) as the result of the particular surgical procedure. For example, it may be observed that the nerve conduction increases as the result of the operation, indicating that the previously inhibited nerve has been positively affected by the operation. The nerve root retractor **30** may comprise any number of suitable devices capable of maintaining contact with a nerve or nerve root. The nerve root retractor **30** may be dimensioned in any number of different fashions, including having a generally curved distal region (shown as a side view in **FIG. 1** to illustrate the concave region where the nerve will be positioned while retracted), and of sufficient dimension (width and/or length) and rigidity to maintain the retracted nerve in a desired position during surgery. The nerve root retractor **30** may also be equipped with a handle **31** having one or more buttons for selectively applying the electrical stimulation to the stimulation electrode(s) at the end of the nerve root retractor **30**. In one embodiment, the nerve root retractor **30** is disposable and the handle **31** is reusable and autoclavable.

[**0045**] The surgical system **10** can also be employed to perform screw test assessments via the use of screw test probe **32**. The screw test probe **32** is used to test the integrity of pedicle holes (after formation) and/or screws (after introduction). The screw test probe **32** includes a handle **44** and a probe member **46** having a generally ball-tipped end **48**. The handle **44** may be equipped with one or more buttons for selectively applying the electrical stimulation to the ball-tipped end **48** at the end of the probe member **46**. The ball tip **48** of the screw test probe **32** is placed in the screw hole prior to screw insertion or placed on the installed screw head. If the pedicle wall has been breached by the screw or tap, the stimulation current will pass through to the adjacent nerve roots and they will depolarize at a lower stimulation current.

[**0046**] Upon pressing the button on the screw test handle **44**, the software will execute an algorithm that results in all channel tabs being color-coded to indicate the detection status of the corresponding nerve. The channel with the "worst" (lowest) level will be highlighted (enlarged) and that myotome name will be displayed, as well as graphically depicted on the spine diagram. A vertical bar chart will also be shown, to depict the stimulation current required for nerve depolarization in mA for the selected channel. The screw test algorithm preferably determines the depolarization (threshold) current for all 8 EMG channels. The surgeon may also set a baseline threshold current by stimulating a nerve root directly with the screw test probe **32**. The surgeon may choose to display the screw test threshold current relative to this baseline. The handle **44** may be equipped with a mechanism (via hardware and/or software) to identify itself to the system when it is attached. In one embodiment, the probe member **46** is disposable and the handle **44** is reusable and autoclavable.

[**0047**] An audio pick-up (not shown) may also be provided as an optional feature according to the present invention. In some cases, when a nerve is stretched or compressed, it will emit a burst or train of spontaneous nerve activity. The audio pick-up is capable of transmitting sounds representative of such activity such that the surgeon can monitor this response on audio to help him determine if there has been stress to the nerve.

[**0048**] Analysis of the EMG responses according to the present invention will now be described. The nerve proximity, nerve direction, and nerve pathology features of the present invention are based on assessing the evoked response of the various muscle myotomes monitored by the surgical system **10**. This is best shown in **FIGS. 3-4**, wherein **FIG. 3** illustrates the evoked response (EMG) of a monitored myotome to the stimulation current pulse shown in **FIG. 4**. The EMG response can be characterized by a peak to peak voltage of $V_{pp}=V_{max}-V_{min}$. The stimulation current is preferably DC coupled and comprised of monophasic pulses of 200 microsecond duration with frequency and amplitude that is adjusted by the software. For each nerve and myotome there is a characteristic delay from the stimulation current pulse to the EMG response.

[**0049**] As shown in **FIG. 5**, there is a threshold stimulation current required to depolarize the main nerve trunk. Below this threshold, current stimulation does not evoke a

significant V_{pp} response. Once the stimulation threshold is reached, the evoked response is reproducible and increases with increasing stimulation, as shown in **FIG. 5**. This is known as a "recruitment curve." In one embodiment, a significant Vpp is defined to be a minimum of 100 uV. The lowest stimulation current that evoked this threshold voltage is called I_{thresh}. I_{thresh} decreases as the stimulation electrode approaches the nerve. This value is useful to surgeons because it provides a relative indication of distance (proximity) from the electrode to the nerve.

[0050] As shown in **FIG. 6**, for each nerve/myotome combination there is a characteristic delay from the stimulation current pulse to the EMG response. For each stimulation current pulse, the time from the current pulse to the first max/min is T_1 and to the second max/min is T_2. The first phase of the pulse may be positive or negative. As will be described below, the values of T_1, T_2 are each compiled into a histogram with bins as wide as the sampling rate. New values of T_1, T_2 are acquired with each stimulation and the histograms are continuously updated. The value of T_1 and T_2 used is the center value of the largest bin in the histogram. The values of T_1, T_2 are continuously updated as the histograms change. Initially Vpp is acquired using a window that contains the entire EMG response. After 20 samples, the use of T_1, T_2 windows is phased in over a period of 200 samples. Vmax and Vmin are then acquired only during windows centered around T_1, T_2 with widths of, by way of example only, 5 msec. This method of acquiring V_{pp} is advantageous in that it automatically performs artifact rejection (as will be described in greater detail below).

[0051] As will be explained in greater detail below, the use of the "recruitment curve" according to the present invention is advantageous in that it provides a great amount of useful data from which to make various assessments (including, but not limited to, nerve detection, nerve direction, and nerve pathology monitoring). Moreover, it provides the ability to present simplified yet meaningful data to the user, as opposed to the actual EMG waveforms that are displayed to the users in traditional EMG systems. Due to the complexity in interpreting EMG waveforms, such prior art systems typically require an additional person specifically trained in such matters. This, in turn, can be disadvantageous in that it translates into extra expense (having yet another highly trained person in attendance) and oftentimes presents scheduling challenges because most hospitals do not retain such personnel. To account for the possibility that certain individuals will want to see the actual EMG waveforms, the surgical system **10** includes an Evoked Potentials display that shows the voltage waveform for all 8 EMG channels in real time. It shows the response of each monitored myotome to a current stimulation pulse. The display is updated each time there is a stimulation pulse. The Evoked Potentials display may be accessed during Detection, Direction, or Nerve Pathology Monitoring.

[0052] Nerve Detection (Proximity)

[0053] The Nerve Detection function of the present invention is used to detect a nerve with a stimulation electrode (i.e. those found on the surgical access components **24-28**) and to give the user a relative indication of the proximity of the nerve to the electrode as it is advanced toward the surgical target site. A method of nerve proximity detection according one embodiment of the present invention is summarized as follows: (1) stimulation current pulses are emitted from the electrode with a fixed pulse width of 200 μs and a variable amplitude; (2) the EMG response of the associated muscle group is measured; (3) the Vpp of the EMG response is determined using T1, T2, and Fmax (NB: before T2 is determined, a constant Fsafe is used for Fmax); (4) a rapid hunting detection algorithm is used to determine I_{Thresh} for a known Vthresh minimum; (5) the value of I_t is displayed to the user as a relative indication of the proximity of the nerve, wherein the I_{Thresh} is expected to decrease as the probe gets closer to the nerve. A detailed description of the algorithms associated with the foregoing steps will follow after a general description of the manner in which this proximity information is communicated to the user.

[0054] The Detection Function displays the value of I_{thresh} to the surgeon along with a color code so that the surgeon may use this information to avoid contact with neural tissues. This is shown generally in **FIG. 7**, which illustrates an exemplary screen display according to the present invention. Detection display is based on the amplitude of the current (I_{thresh}) required to evoke an EMG Vpp response greater than V_{thresh} (nominally 100 uV). According to one embodiment, if I_{thresh} is <=4 mA red is displayed, the absolute value of I_{thresh} is displayed. If 4 mA<I_{thresh}<10 mA yellow is displayed. If I_{thresh}>=10 mA green is displayed. Normally, I_{thresh} is only displayed when it is in the red range. However, the surgeon has the option of displaying I_{thresh} for all three ranges (red, yellow, green). The maximum stimulation current is preferably set by the user and is preferably within the range of between 0-100 mA. Detection is performed on all 4 channels of the selected side. EMG channels on the opposite side are not used. The first dilator **26** may use an obturator having an electrode for stimulation. In one embodiment, all subsequent dilators **26** and the working cannula **28** use four electrodes for stimulation. The lowest value of I_{thresh} from the 4 electrodes is used for display. There is an "Advance/Hold" display that tells the surgeon when the calculations are finished and he may continue to advance the instrument.

[0055] The threshold-hunting algorithm employs a series of monopolar stimulations to determine the stimulation current threshold for each EMG channel that is in scope. The nerve is stimulated using current pulses with amplitude of Istim. The muscle groups respond with an evoked potential that has a peak to peak voltage of Vpp. The object of this algorithm is to quickly find I_{thresh}. This is the minimum Istim that results in a Vpp that is greater than a known threshold voltage Vthresh. The value of Istim is adjusted by a bracketing method as follows. The first bracket is 0.2 mA and 0.3 mA. If the Vpp corresponding to both of these stimulation currents is lower than Vthresh, then the bracket size is doubled to 0.2 mA and 0.4 mA. This exponential doubling of the bracket size continues until the upper end of the bracket results in a Vpp that is above Vthresh. The size of the brackets is then reduced by a bisection method. A current stimulation value at the midpoint of the bracket is used and if this results in a Vpp that is above Vthresh, then the lower half becomes the new bracket. Likewise, if the midpoint Vpp is below Vthresh then the upper half becomes the new bracket. This bisection method is used until the bracket size has been reduced to I_{Thresh} mA. I_{Thresh} is the value of Istim that is the higher end of the bracket.

[0056] More specifically, with reference to **FIGS. 8A-8E**, the threshold hunting will support three states: bracketing, bisection, and monitoring. A stimulation current bracket is a range of stimulation currents that bracket the stimulation current threshold I_{Thresh}. The upper and/or lower boundaries of a bracket may be indeterminate. The width of a bracket is the upper boundary value minus the lower boundary value. If the stimulation current threshold I_{Thresh} of a channel exceeds the maximum stimulation current, that threshold is considered out-of-range. During the bracketing state, threshold hunting will employ the method below to select stimulation currents and identify stimulation current brackets for each EMG channel in scope.

[0057] The method for finding the minimum stimulation current uses the methods of bracketing and bisection. The "root" is identified for a function that has the value −1 for stimulation currents that do not evoke adequate response; the function has the value +1 for stimulation currents that evoke a response. The root occurs when the function jumps from −1 to +1 as stimulation current is increased: the function never has the value of precisely zero. The root will not be known precisely, but only with some level of accuracy. The root is found by identifying a range that must contain the root. The upper bound of this range is the lowest stimulation current I_{Thresh} where the function returns the value +1, i.e. the minimum stimulation current that evokes V_{Thresh} response.

[0058] The proximity function begins by adjusting the stimulation current until the root is bracketed (**FIG. 8B**). The initial bracketing range may be provided in any number of suitable ranges. In one embodiment, the initial bracketing range is 0.2 to 0.3 mA. If the upper stimulation current does not evoke a response, the upper end of the range should be increased. The range scale factor is 2. The stimulation current should never be increased by more than 10 mA in one iteration. The stimulation current should never exceed the programmed maximum stimulation current. For each stimulation, the algorithm will examine the response of each active channel to determine whether it falls within that bracket. Once the stimulation current threshold of each channel has been bracketed, the algorithm transitions to the bisection state.

[0059] During the bisection state (**FIGS. 8C and 8D**), threshold hunting will employ the method described below to select stimulation currents and narrow the bracket to a width of 0.1 mA for each EMG channel with an in-range threshold. After the minimum stimulation current has been bracketed (**FIG. 8B**), the range containing the root is refined until the root is known with a specified accuracy. The bisection method is used to refine the range containing the root. In one embodiment, the root should be found to a precision of 0.1 mA. During the bisection method, the stimulation current at the midpoint of the bracket is used. If the stimulation evokes a response, the bracket shrinks to the lower half of the previous range. If the stimulation fails to evoke a response, the bracket shrinks to the upper half of the previous range. The proximity algorithm is locked on the electrode position when the response threshold is bracketed by stimulation currents separated by 0.1 mA. The process is repeated for each of the active channels until all thresholds are precisely known. At that time, the algorithm enters the monitoring state.

[0060] During the monitoring state (**FIG. 8E**), threshold hunting will employ the method described below to select stimulation currents and identify whether stimulation current thresholds are changing. In the monitoring state, the stimulation current level is decremented or incremented by 0.1 mA, depending on the response of a specific channel. If the threshold has not changed then the lower end of the bracket should not evoke a response, while the upper end of the bracket should. If either of these conditions fail, the bracket is adjusted accordingly. The process is repeated for each of the active channels to continue to assure that each threshold is bracketed. If stimulations fail to evoke the expected response three times in a row, then the algorithm transitions back to the bracketing state in order to reestablish the bracket.

[0061] When it is necessary to determine the stimulation current thresholds (It) for more than one channel, they will be obtained by time-multiplexing the threshold-hunting algorithm as shown in **FIG. 9**. During the bracketing state, the algorithm will start with a stimulation current bracket of 0.2 mA and increase the size of the bracket exponentially. With each bracket, the algorithm will measure the Vpp of all channels to determine which bracket they fall into. After this first pass, the algorithm will know which exponential bracket contains the I_t for each channel. Next, during the bisection state, the algorithm will start with the lowest exponential bracket that contains an I_t and bisect it until I_t is found within 0.1 mA. If there are more than one I_t within an exponential bracket, they will be separated out during the bisection process, and the one with the lowest value will be found first. During the monitoring state, the algorithm will monitor the upper and lower boundries of the brackets for each I_t, starting with the lowest. If the I_t for one or more channels is not found in it's bracket, then the algorithm goes back to the bracketing state to re-establish the bracket for those channels.

[0062] The method of performing automatic artifact rejection according to the present invention will now be described. As noted above, acquiring V_{pp} according to the present invention (based on T1,T2 shown in **FIG. 6**) is advantageous in that, among other reasons, it automatically performs artifact rejection. The nerve is stimulated using a series of current pulses above the stimulation threshold. The muscle groups respond with an evoked potential that has a peak to peak voltage of Vpp. For each EMG response pulse, T1 is the time is measured from the stimulus pulse to the first extremum (Vmax or Vmin). T2 is the time measured from the current pulse to the second extremum (Vmax or Vmin). The values of T1 and T2 are each compiled into a histogram with Thin msec bin widths. The value of T1 and T2 used for artifact rejection is the center value of the largest bin in the histogram. To reject artifacts when acquiring the EMG response, Vmax and Vmin are acquired only during windows that are T1±Twin and T2±Twin. Again, with reference to **FIG. 6**, Vpp is Vmax−Vmin.

[0063] The method of automatic artifact rejection is further explained with reference to **FIG. 10**. While the threshold hunting algorithm is active, after each stimulation, the following steps are undertaken for each EMG sensor channel that is in scope: (1) the time sample values for the waveform maximum and minimum (after stimulus artifact rejection) will be placed into a histogram; (2) the histogram bin size will be the same granularity as the sampling period;

(3) the histogram will be emptied each time the threshold hunting algorithm is activated; (4) the histogram will provide two peaks, or modes, defined as the two bins with the largest counts; (5) the first mode is defined as T1; the second mode is defined as T2; (6) a (possibly discontinuous) range of waveform samples will be identified; (7) for the first stimulation after the threshold hunting algorithm is activated, the range of samples will be the entire waveform; (8) after a specified number of stimulations, the range of samples will be limited to T1±0.5 ms and T2±0.5 ms; and (9) before the specified number of stimulations, either range may be used, subject to this restriction: the proportion of stimulations using the entire waveform will decrease from 100% to 0% (a sample of the curve governing this proportion is shown in **FIG. 11**). Peak-to-peak voltage (Vpp) will be measured either over the identified range of waveform samples. The specified number of stimulations will preferably be between 220 and 240.

[**0064**] According to another aspect of the present invention, the maximum frequency of the stimulation pulses is automatically obtained with reference to **FIG. 12**. After each stimulation, Fmax will be computed as: Fmax=1/(T2+Safety Margin) for the largest value of T2 from each of the active EMG channels. In one embodiment, the Safety Margin is 5 ms, although it is contemplated that this could be varied according to any number of suitable durations. Before the specified number of stimulations, the stimulations will be performed at intervals of 100-120 ms during the bracketing state, intervals of 200-240 ms during the bisection state, and intervals of 400-480 ms during the monitoring state. After the specified number of stimulations, the stimulations will be performed at the fastest interval practical (but no faster than Fmax) during the bracketing state, the fastest interval practical (but no faster than Fmax/2) during the bisection state, and the fastest interval practical (but no faster than Fmax/4) during the monitoring state. The maximum frequency used until F_{max} is calculated is preferably 10 Hz, although slower stimulation frequencies may be used during some acquisition algorithms. The value of F_{max} used is periodically updated to ensure that it is still appropriate. This feature is represented graphically, by way of example only, in FIG. **12**. For physiological reasons, the maximum frequency for stimulation will be set on a per-patient basis. Readings will be taken from all myotomes and the one with the slowest frequency (highest T2) will be recorded.

[**0065**] Nerve Direction

[**0066**] Once a nerve is detected using the working cannula **28** or dilating cannulae **26**, the surgeon may use the Direction Function to determine the angular direction to the nerve relative to a reference mark on the access components **24-28**. This is also shown in **FIG. 7** as the arrow A pointing to the direction of the nerve. This information helps the surgeon avoid the nerve as he or she advances the cannula. The direction from the cannula to a selected nerve is estimated using the 4 orthogonal electrodes on the tip of the dilating cannula **26** and working cannulae **28**. These electrodes are preferably scanned in a monopolar configuration (that is, using each of the 4 electrodes as the stimulation source). The nerve's threshold current (I_{thresh}) is found for each of the electrodes by measuring the muscle evoked potential response Vpp and comparing it to a known threshold Vthresh. This algorithm is used to determine the direction from a stimulation electrode to a nerve.

[**0067**] As shown in **FIG. 13**, the four (4) electrodes are placed on the x and y axes of a two dimensional coordinate system at radius R from the origin. A vector is drawn from the origin along the axis corresponding to each electrode that has a length equal to I_{Thresh} for that electrode. The vector from the origin to a direction pointing toward the nerve is then computed. This algorithm employs the T1/T2 algorithm discussed above with reference to **FIG. 6**. Using the geometry shown in **FIG. 13**, the (x,y) coordinates of the nerve, taken as a single point, can be determined as a function of the distance from the nerve to each of four electrodes. This can be expressly mathematically as follows:

[**0068**] Where the "circles" denote the position of the electrode respective to the origin or center of the cannula and the "octagon" denotes the position of a nerve, and d_1, d_2, d_3, and d_4 denote the distance between the nerve and electrodes **1-4** respectively, it can be shown that:

$$x = \frac{d_1^2 - d_3^2}{-4R} \text{ and } y = \frac{d_2^2 - d_4^2}{-4R}$$

[**0069**] Where R is the cannula radius, standardized to 1, since angles and not absolute values are measured.

[**0070**] After conversion from (x,y) to polar coordinates (r,θ), then θ is the angular direction to the nerve. This angular direction is then displayed to the user as shown in **FIG. 7**, by way of example only, as arrow A pointing towards the nerve. In this fashion, the surgeon can actively avoid the nerve, thereby increasing patient safety while accessing the surgical target site. The surgeon may select any one of the 4 channels available to perform the Direction Function. The surgeon should preferably not move or rotate the instrument while using the Direction Function, but rather should return to the Detection Function to continue advancing the instrument.

[**0071**] Insertion and advancement of the access instruments **24-28** should be performed at a rate sufficiently slow to allow the surgical system **10** to provide real-time indication of the presence of nerves that may lie in the path of the tip. To facilitate this, the threshold current I_{Thresh} may be displayed such that it will indicate when the computation is finished and the data is accurate. For example, when the detection information is up to date and the instrument is now ready to be advanced by the surgeon, it is contemplated to have the color display show up as saturated to communicate this fact to the surgeon. During advancement of the instrument, if a channel's color range changes from green to yellow, advancement should proceed more slowly, with careful observation of the detection level. If the channel color stays yellow or turns green after further advancement, it is a possible indication that the instrument tip has passed, and is moving farther away from the nerve. If after further advancement, however, the channel color turns red, then it is a possible indication that the instrument tip has moved closer to a nerve. At this point the display will show the value of the stimulation current threshold in mA. Further advancement should be attempted only with extreme caution, while observing the threshold values, and only if the clinician deems it safe. If the clinician decides to advance the instrument tip further, an increase in threshold value (e.g.

from 3 mA to 4 mA) may indicate the Instrument tip has safely passed the nerve. It may also be an indication that the instrument tip has encountered and is compressing the nerve. The latter may be detected by listening for sporadic outbursts, or "pops", of nerve activity on the free running EMG audio output (as mentioned above). If, upon further advancement of the instrument, the alarm level decreases (e.g., from 4 mA to 3 mA), then it is very likely that the instrument tip is extremely close to the spinal nerve, and to avoid neural damage, extreme caution should be exercised during further manipulation of the Instrument. Under such circumstances, the decision to withdraw, reposition, or otherwise maneuver the instrument is at the sole discretion of the clinician based upon available information and experience. Further radiographic imaging may be deemed appropriate to establish the best course of action.

[**0072**] Nerve Pathology

[**0073**] As noted above, the surgical system **10** accomplishes neural pathology monitoring by electrically stimulating a retracted nerve root via one or more stimulation electrodes at the distal end of the nerve root retractor **30** while monitoring the EMG responses of the muscle group innervated by the particular nerve. **FIG. 14** shows the differences between a healthy nerve (A) and a pathologic or unhealthy nerve (B). The inventors have found through experimentation that information regarding nerve pathology (or "health" or "status") can be extracted from the recruitment curves generated according to the present invention (see, e.g., discussion accompanying **FIGS. 3-5**). In particular, it has been found that a healthy nerve or nerve bundle will produce a recruitment curve having a generally low threshold or "hanging point" (in terms of both the y-axis or Vpp value and the x-axis or I_{Stim} value), a linear region having a relatively steep slope, and a relatively high saturation region (similar to those shown on recruitment curve "A" in **FIG. 14**). On the contrary, a nerve or nerve bundle that is unhealthy or whose function is otherwise compromised or impaired (such as being impinged by spinal structures or by prolonged retraction) will produce a recruitment curve having a generally higher threshold (again, in terms of both the y-axis or Vpp value and the x-axis or I_{stim} value), a linear region of reduced slope, and a relatively low saturation region (similar to those shown on recruitment curve "B" in **FIG. 14**). By recognizing these characteristics, one can monitor nerve root being retracted during a procedure to determine if its pathology or health is affected (i.e. negatively) by such retraction. Moreover, one can monitor a nerve root that has already been deemed pathologic or unhealthy before the procedure (such as may be caused by being impinged by bony structures or a bulging annulus) to determine if its pathology or health is affected (i.e. positively) by the procedure.

[**0074**] The surgical system **10** and related methods have been described above according to one embodiment of the present invention. It will be readily appreciated that various modifications may be undertaken, or certain steps or algorithms omitted or substituted, without departing from the scope of the present invention. By way of example only, certain of these alternate embodiments or methods will be described below.

[**0075**] a. Hanging Point Detection Via Linear Regression

[**0076**] As opposed to identifying the stimulation current threshold (I_{Thresh}) based on a predetermined V_{Thresh} (such as described above and shown in **FIG. 5**), it is also within the scope of the present invention to determine I_{Thresh} via linear regression. This may be accomplished via, by way of example only, the linear regression technique disclosed in commonly owned and co-pending U.S. patent application Ser. No. 09/877,713, filed Jun. 8, 2001 and entitled "Relative Nerve Movement and Status Detection System and Methods," the entire contents of which is hereby expressly incorporated by reference as if set forth in this disclosure in its entirety.

[**0077**] b. Hanging Point Detection Via Dynamic Sweep Subtraction

[**0078**] With reference to **FIG. 15**, the hanging point or threshold may also be determined by the following dynamic sweep subtraction method. The nerve is stimulated in step **80** using current pulses that increase from I_{Min} to I_{Max} (as described above). The resulting neuromuscular response (evoked EMG) for the associated muscles group is acquired in step **82**. The peak-to-peak voltage (Vpp) is then extracted in step **84** for each current pulse according to the T1, T2 algorithm described above with reference to **FIGS. 3-6**. A first recruitment curve (**S1**) is then generated by plotting Vpp vs. I_{Stim} in step **86**. The same nerve is then stimulated such that, in step **88**, the peak-to-peak voltage (Vpp) may be extracted by subtracting the V_{Max} from V_{Min} of each EMG response without the T1, T2 filters employed in step **84**. A second recruitment curve (**S2**) is then generated in step **90** by plotting Vpp vs. I_{Stim}. The generation of both recruitment curves **S1**, **S2** continues until the maximum stimulation current (I_{Max}) is reached (per the decision step **92**). If I_{Max} is not reached, the stimulation current I_{Stim} is incremented in step **94**. If I_{Max} is reached, then the first recruitment curve **S1** is subtracted from the second recruitment curve **S2** in step **96** to produce the curve "C" shown in step **98**. By subtracting **S1** from **S2**, the resulting curve "C" is actually the onset portion of the recruitment curve (that is, the portion before the threshold is reached) for that particular nerve. In this fashion, the last point in the curve "C" is the point with the greatest value of I_{Stim} and hence the hanging point.

[**0079**] c. Peripheral Nerve Pathology Monitoring

[**0080**] Similar to the nerve pathology monitoring scheme described above, the present invention also contemplates the use of one or more electrodes disposed along a portion or portions of an instrument (including, but not limited to, the access components **24-28** described above) for the purpose of monitoring the change, if any, in peripheral nerves during the course of the procedure. In particular, this may be accomplished by disposing one or more stimulation electrodes a certain distance from the distal end of the instrument such that, in use, they will likely come in contact with a peripheral nerve. For example, a mid-shaft stimulation electrode could be used to stimulate a peripheral nerve during the procedure. In any such configuration, a recruitment curve may be generated for the given peripheral nerve such that it can be assessed in the same fashion as described above with regard to the nerve root retractor, providing the same benefits of being able to tell if the contact between the instrument and the nerve is causing pathology degradation or if the procedure itself is helping to restore or improve the health or status of the peripheral nerve.

[**0081**] d. Virtual Patient for Evoked Potential Simulation

[**0082**] With reference to **FIG. 16**, the present invention also contemplates the use of a "virtual patient" device for

simulating a naturally occurring recruitment curve. This is advantageous in that it provides the ability to test the various systems disclosed herein, which one would not be able to test without an animal and/or human subject. Based on the typically high costs of obtaining laboratory and/or surgical time (both in terms of human capital and overhead), eliminating the requirement of performing actual testing to obtain recruitment curves is a significant offering. According to the present invention, this can be accomplished by providing a device (not shown) having suitable software and/or hardware capable of producing the signal shown in **FIG. 16**. The device will preferably accept a sweeping current signal according to the present invention (that is, 200 microseconds width pulses sweeping in amplitude from 0-100 mA) and produce a voltage pulse having a peak-to-peak voltage (Vpp) that varies with the amplitude of the current input pulse. The relationship of the output Vpp and the input stimulation current will produce a recruitment curve similar to that shown. In one embodiment, the device includes various adjustments such that the features of the recruitment curve may be selectively modified. For example, the features capable of being modified may include, but are not necessarily limited to, Vpp at onset, maximum stimulation current of onselt (hanging point), the slope of the linear region and/or the Vpp of the saturation region.

[**0083**] While this invention has been described in terms of a best mode for achieving this invention's objectives, it will be appreciated by those skilled in the art that variations may be accomplished in view of these teachings without deviating from the spirit or scope of the present invention. For example, the present invention may be implemented using any combination of computer programming software, firmware or hardware. As a preparatory step to practicing the invention or constructing an apparatus according to the invention, the computer programming code (whether software or firmware) according to the invention will typically be stored in one or more machine readable storage mediums such as fixed (hard) drives, diskettes, optical disks, magnetic tape, semiconductor memories such as ROMs, PROMs, etc., thereby making an article of manufacture in accordance with the invention. The article of manufacture containing the computer programming code is used by either executing the code directly from the storage device, by copying the code from the storage device into another storage device such as a hard disk, RAM, etc. or by transmitting the code on a network for remote execution. As can be envisioned by one of skill in the art, many different combinations of the above may be used and accordingly the present invention is not limited by the scope of the appended claims.

What is claimed is:

1. A surgical system, comprising:

a control unit having at least one of computer programming software, firmware and hardware capable of delivering a stimulation signal, receiving and processing neuromuscular responses due to the stimulation signal, and identifying a relationship between the neuromuscular response and the stimulation signal; and

a surgical instrument having at least one stimulation electrode electrically coupled to said control unit for transmitting the stimulation signal, wherein said control unit is capable of determining at least one of nerve proximity, nerve direction, and nerve pathology relative to the surgical instrument based on the identified relationship between the neuromuscular response and the stimulation signal.

2. The surgical system of claim 1 and further, wherein said control unit is further equipped to communicate at least one of alpha-numeric and graphical information to a user regarding at least one of nerve proximity, nerve direction, and nerve pathology.

3. The surgical system of claim 1 and further, wherein the surgical instrument may comprise at least one of a device for maintaining contact with a nerve during surgery, a device for accessing a surgical target site, and a device for testing screw placement integrity.

4. The surgical system of claim 1 and further, wherein the surgical instrument comprises a nerve root retractor and wherein the control unit determines nerve pathology based on the identified relationship between the neuromuscular response and the stimulation signal.

5. The surgical system of claim 1 and further, wherein the surgical instrument comprises a dilating instrument and wherein the control unit determines at least one of proximity and direction between a nerve and the instrument based on the identified relationship between the neuromuscular response and the stimulation signal.

6. The surgical system of claim 5 and further, wherein the dilating instrument comprises at least one of a K-wire, an obturator, a dilating cannula, and a working cannula.

7. The surgical system of claim 1 and further, wherein the surgical instrument comprises a screw test probe and wherein the control unit determines the proximity between the screw test probe and an exiting spinal nerve root to assess whether a medial wall of a pedicle has been breached by at least one of hole formation and screw placement.

8. A system comprising:

an instrument with an electrode configured to transmit electrical current signals with adjustable amplitudes to a tissue;

a sensor configured to detect a voltage response from a muscle; and

a control unit coupled to the instrument and the sensor, the control unit being configured to (a) command the electrode to transmit electrical current signals with adjustable amplitudes, (b) receive a voltage response from the sensor, and (c) determine a threshold stimulation current for a predetermined threshold voltage response value, the threshold stimulation current corresponding to a distance between the electrode and a nerve associated with the muscle.

9. The system of claim 8, wherein the control unit is configured to determine a peak-to-peak amplitude of the voltage response and derive a threshold response voltage vs. stimulation current recruitment curve to determine a proximity of a nerve to the electrode.

10. The system of claim 8, wherein the control unit comprises a display configured to display the determined threshold stimulation current.

11. The system of claim 8, wherein the control unit comprises a display configured to display a response voltage vs. stimulation current recruitment curve.

12. The system of claim 8, wherein the control unit comprises a display configured to display an advance icon to a user when the determined threshold stimulation current is above a predetermined level.

13. The system of claim 8, wherein the control unit comprises a display configured to display a hold icon to a user when the determined threshold stimulation current is below a predetermined level.

14. The system of claim 8, wherein the control unit is configured to send a signal to the electrode to generate monophase current pulses with a predetermined duration.

15. The system of claim 8, wherein the control unit is configured to cause the electrode to generate monophase current pulses with a configurable duration.

16. The system of claim 8, wherein the control unit comprises an audio output configured to emit an audible sound to a user, the sound indicating a distance between the electrode and a nerve associated with the muscle.

17. The system of claim 8, wherein the sensor comprises a plurality of electrodes configured to sense electromyographic (EMG) voltage responses from a plurality of muscle groups.

18. The system of claim 8, wherein the instrument comprises a plurality of cannulae with different diameters, each cannula having at least one electrode.

19. The system of claim 8, wherein the instrument comprises a reusable component configured to be inserted through a cannula to a surgical site within a body.

20. The system of claim 8, wherein the instrument comprises a disposable portion.

21. The system of claim 8, wherein the instrument comprises a pedicle screw hole probe.

22. A system comprising:

an instrument with a plurality of electrodes, each electrode being configured to transmit electrical current signals with adjustable amplitudes to a tissue;

a sensor configured to detect voltage responses from a muscle; and

a control unit coupled to the instrument and the sensor, the control unit being configured to (a) control the electrodes to transmit electrical current signals with adjustable amplitudes, (b) receive voltage responses from the sensor, and (c) for each electrode, determine a threshold stimulation current for a predetermined threshold voltage response value, the threshold stimulation currents of the electrodes corresponding to a direction with respect to the electrodes to a nerve associated with the muscle.

23. The system of claim 22, wherein the electrodes comprises four electrodes spaced orthogonally in a two-dimensional plane.

24. The system of claim 22, wherein the control unit is configured to determine a two-dimensional vector from a reference point of the instrument to a nerve by using:

$$x = \frac{1}{-4R}(d_1^2 - d_3^2) \text{ and } y = \frac{1}{-4R}(d_2^2 - d_4^2).$$

25. The system of claim 22, wherein the sensor comprises a plurality of electrodes configured to sense electromyographic (EMG) voltage responses from a plurality of muscle groups.

26. The system of claim 22, wherein the control unit is configured to display the direction of the nerve in the tissue associated with the muscle with respect to the electrodes.

27. An instrument configured to be partially inserted through tissue, the instrument having a plurality of electrodes near a distal end of the instrument, each electrode being configured to generate an electrical current to the tissue, wherein the electrical current stimulates a nerve in the tissue if the instrument is sufficiently close to the nerve.

28. The instrument of claim 27, wherein the instrument comprises a shaft and four electrodes in a two-dimensional plane.

29. The instrument of claim 28, wherein the four electrodes are orthogonal.

30. A system comprising:

an instrument with an electrode configured to transmit electrical current signals with adjustable amplitudes to a nerve;

a sensor configured to detect voltage responses from a muscle associated with the nerve; and

a control unit coupled to the instrument and the sensor, the control unit being configured to (a) control the electrode to transmit electrical current signals with adjustable amplitudes, (b) receive voltage responses from the sensor, and (c) determine a pathology of the nerve associated with the muscle by determining a relationship between a stimulation current and a voltage response.

31. The system of claim 30, wherein the relationship includes at least one of a threshold voltage response and threshold stimulation current.

32. The system of claim 30, wherein the relationship includes a ratio of the stimulation current and the corresponding voltage response.

33. The system of claim 30, wherein the relationship includes at least one of a saturation voltage response and a saturation stimulation current.

34. The system of claim 30, wherein the sensor comprises a plurality of electrodes configured to sense electromyographic (EMG) voltage responses from a plurality of muscle groups.

35. The system of claim 30, wherein the control unit comprises an audio output configured to emit an audible sound indicating a voltage response.

36. The system of claim 30, wherein the instrument comprises a nerve root retractor with a curved distal region.

37. A computer configured to (a) receive a plurality of voltage response signals, each voltage response value corresponding in time to a stimulation current signal with a configurable amplitude, and (b) determine a nerve stimulation current for a pre-determined voltage response value.

38. The computer of claim 37, being further configured to command an instrument to transmit the stimulation current signals.

39. The computer of claim 37, being configured to determine a peak-to-peak amplitude for each voltage response signal.

40. The computer of claim 37, being configured to store a first time duration from a stimulation current signal to a first peak of a voltage response.

41. The computer of claim 40, being configured to store a second time duration from the stimulation current signal to a second peak of the voltage response.

42. The computer of claim 41, being configured to store a plurality of first and second time durations as a plurality of stimulation current signals are generated and a plurality of

voltage response values are received, the processing unit using the plurality of first and second time durations to perform artifact rejection.

43. The computer of claim 37, being configured to execute a bracketing process with a plurality of pre-determined stimulation current levels to determine the stimulation current for the pre-determined voltage response value.

44. The computer of claim 37, being configured to execute a bisecting process with a plurality of pre-determined stimulation current levels to determine the stimulation current for the pre-determined voltage response value.

45. The computer of claim 37, being further configured to communicate the determined stimulation current for the predetermined threshold voltage response value to a user.

46. The computer of claim 37, being further configured to control a display unit configured to display the stimulation current for the pre-determined voltage response value.

47. The computer of claim 37, being further configured to receive user commands.

48. The computer of claim 37, further comprising a touch screen display configured to receive instructions from a user.

49. The computer of claim 37, being configured to receive a plurality of voltage response signals from a plurality of sensors located at various locations of a body.

50. The computer of claim 49, being configured to execute a time-multiplexing process to determine the stimulation current of each sensor for the pre-determined voltage response value.

51. A software application stored in a medium and executable by processor, the software application being configured to (a) receive a plurality of voltage response values and (b) bracket a threshold nerve stimulation current value corresponding to a predetermined threshold voltage response value.

52. The software application of claim 51, being configured to bisect a bracket that includes the threshold nerve stimulation current value corresponding to the predetermined threshold voltage response value.

53. The software application of claim 51, being configured to receive user commands.

54. The software application of claim 51, being configured to activate a nerve proximity determination mode.

55. The software application of claim 51, being configured to activate a nerve direction determination mode.

56. The software application of claim 51, being configured to activate a nerve pathology determination mode.

57. The software application of claim 51, comprising a graphical user interface configured to display a bracketed threshold nerve stimulation current value.

58. The software application of claim 51, comprising a graphical user interface configured to display a name of an instrument being used to deliver a plurality of electrical current signals.

59. The software application of claim 51, comprising a graphical user interface configured to display a symbol of an instrument being used to deliver a plurality of electrical current signals.

60. The software application of claim 51, comprising a graphical user interface configured to display locations of nerves and muscles.

61. The software application of claim 51, comprising a graphical user interface configured to display locations of a plurality of sensors.

62. The software application of claim 51, comprising a graphical user interface configured to display a color that indicates a determined threshold stimulation current value.

63. The software application of claim 51, configured to determine a maximum frequency of stimulation current pulses.

64. A software application stored in a medium and executable by processor, the software application being configured to adjust a frequency and an amplitude of a stimulation electrical current generated by an electrode on an instrument, the electrical current stimulating a nerve when the instrument is placed within a range of the nerve.

65. A module comprising:

an output connector configured to output a signal to an instrument to generate a stimulation electrical current to a tissue;

a plurality of input connectors configured to receive a plurality of voltage signals from a plurality of sensors in response to the stimulation current;

signal conditioning circuitry configured to convert the voltage signals to digital signals; and

a second output connector configured to output digital signals to a control unit.

66. The module of claim 65, further comprising a stimulator drive and steering circuitry.

67. The module of claim 65, further comprising a digital communications interface.

68. A surgical device with a plurality of electrodes along a longitudinal surface of the device, each electrode operable to generate an electrical stimulation current to a tissue proximate to the electrode, if the tissue comprises a nerve within range of an electrode, the current causes an electromyographic (EMG) response in a muscle associated with the nerve.

69. The surgical device of claim 68, comprising a cannula.

70. The surgical device of claim 68, comprising a nerve root retractor.

71. A system comprising:

a pedicle screw test probe having at least one electrode, the electrode being configured to deliver an electrical current signal to a hole sized to fit a pedicle screw;

a sensor configured to sense a voltage response from a muscle caused by the electrical current signal; and

a control unit configured to compare the electrical current signal and the voltage response to determine if the pedicle hole has been breached.

72. The system of claim 71, wherein the pedicle screw test probe has a ball-tipped distal end.

73. A device configured to simulate a nerve and muscle in a patient, the device comprising:

a input connector configured to receive electrical current stimulation signals with a plurality of amplitude levels from an instrument;

a processing unit configured to derive pre-determined voltage response signals in response to the electrical current stimulation signals; and

an output connector configured to output voltage response signals in response to the electrical current stimulation signals.

74. A method of providing a nerve stimulation system, the method comprises:

providing a control unit; and

loading software in the control unit, the software being configured to initiate a stimulation current signal upon receiving a user command, monitor a voltage response signal after initiating the stimulation current signal, and determine a stimulation current for a pre-determined voltage response value.

75. The method of claim 74, further comprising setting a threshold voltage response value.

76. The method of claim 74, further comprising configuring a maximum stimulation current.

77. A method comprising:

delivering a plurality of electrical current signals near a tissue region;

sensing a plurality of electromyographic (EMG) voltage responses of a muscle associated with a nerve in the tissue region; and

identifying a relationship between amplitudes of the current signals and the EMG voltage responses.

78. The method of claim 77, further comprising determining a stimulation current for a predetermined threshold voltage response.

79. The method of claim 77, wherein identifying a relationship comprises bracketing a threshold stimulation current.

80. The method of claim 77, wherein identifying a relationship comprises bisecting a bracket containing a threshold stimulation current.

81. The method of claim 77, further comprising inserting an instrument with an electrode through tissue near a spine.

82. The method of claim 77, further comprising establishing an operative corridor through tissues having neural structure.

83. The method of claim 77, further comprising advancing a cannula toward a target site.

84. The method of claim 77, wherein the target site is an annulus of an intervertebral disc.

85. The method of claim 77, further comprising determining a threshold current by linear regression.

86. The method of claim 77, further comprising a dynamic sweep subtraction process.

87. The method of claim 77, further comprising displaying a decreasing threshold stimulation current as a stimulation electrode moves closer to a nerve.

88. The method of claim 77, further comprising displaying a name of an instrument being used to deliver the plurality of electrical current signals.

89. The method of claim 77, further comprising displaying locations of sensors sensing a plurality of electromyographic (EMG) voltage responses of muscles.

90. The method of claim 77, further comprising notifying a user to advance a surgical instrument delivering the plurality of electrical current signals.

91. The method of claim 77, further comprising notifying a user to hold a surgical instrument delivering the plurality of electrical current signals.

92. The method of claim 77, further comprising notifying a user when a nerve is impinged.

93. The method of claim 77, further comprising determining peak-to-peak voltage values of the EMG voltage responses of a muscle myotome in response to the plurality of electrical current signals applied to a nerve.

94. The method of claim 77, further comprising delivering electrical current signals as monophase pulses with a predetermined duration and configurable amplitudes.

95. The method of claim 77, further comprising delivering electrical current signals as monophase pulses with configurable durations and amplitudes.

96. The method of claim 77, further comprising displaying a voltage response vs. stimulation current recruitment curve.

97. The method of claim 77, further comprising measuring a first time duration from a stimulation current pulse to a first peak of a voltage response waveform.

98. The method of claim 97, further comprising measuring a second time duration from a stimulation current pulse to a second peak of a voltage response waveform.

99. The method of claim 98, further comprising collecting multiple samples of the first and second time durations.

100. The method of claim 98, further comprising compiling the first and second time durations in a histogram.

101. The method of claim 77, further comprising displaying a direction of a nerve based on the relationship between amplitudes of the current signals and the EMG voltage responses.

102. The method of claim 77, further comprising displaying a pathology of a nerve based on the relationship between amplitudes of the current signals and the EMG voltage responses.

103. The method of claim 77, further comprising retracting the nerve.

104. The method of claim 77, further comprising displaying a function of the nerve in real-time as a surgical instrument is moved with respect to the nerve.

105. The method of claim 77, further comprising sensing and displaying a function of the nerve in real-time during a surgical procedure.

106. The method of claim 77, further comprising testing a pedicle hole.

107. The method of claim 77, further comprising testing a screw in a pedicle hole.

108. The method of claim 77, further comprising determining whether a pedicle wall has been breached by the screw.

109. The method of claim 77, further comprising displaying a channel with a lowest response among a plurality of channels.

110. The method of claim 77, further comprising concurrently displaying voltage waveforms of a plurality of electromyographic (EMG) responses from a plurality of sensors.

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