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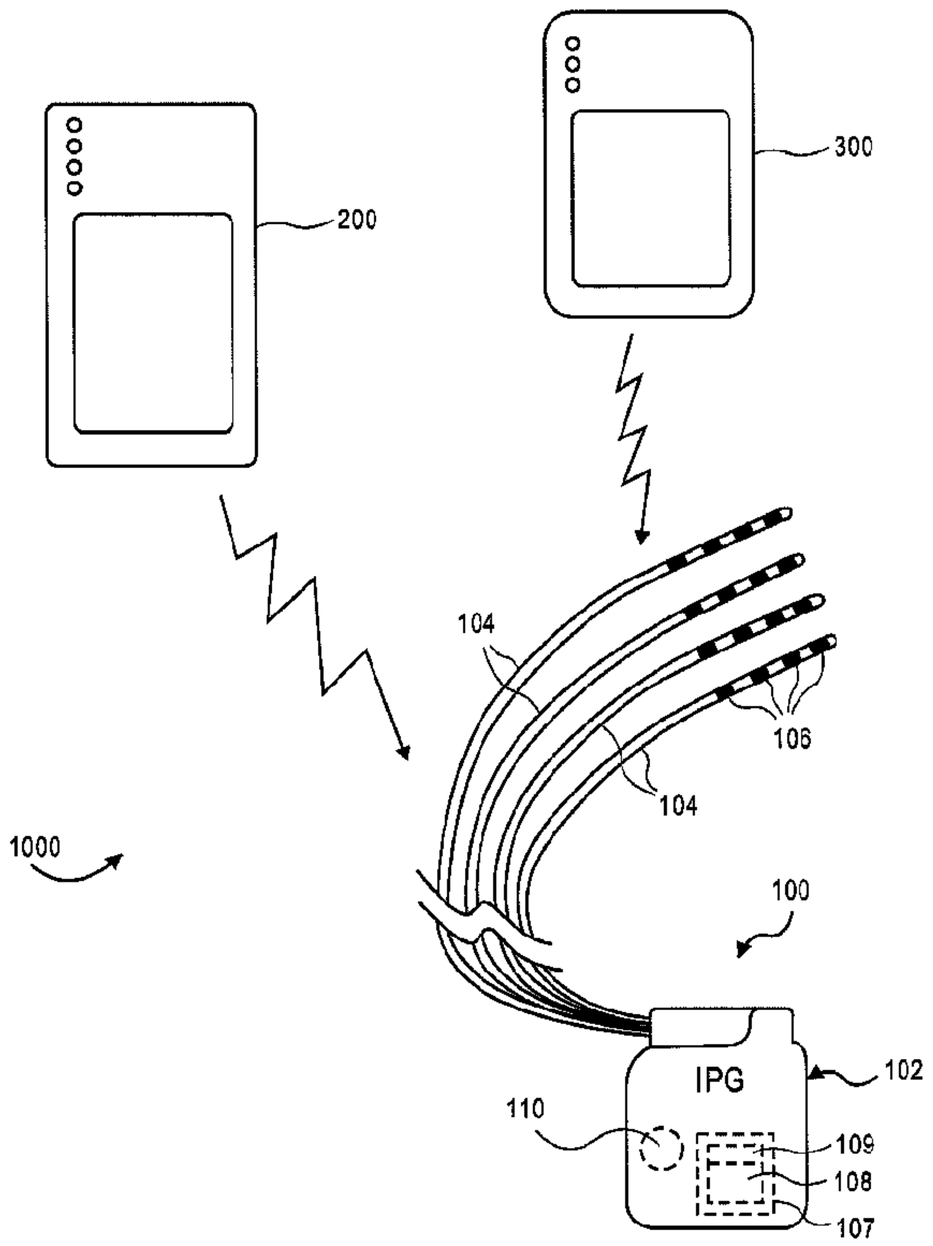

(57) Abrégé/Abstract:
Devices, systems and methods are provided for targeted treatment of a variety of conditions, particularly conditions that are associated with or influenced by the nervous system, such as pain. Targeted treatment of such conditions is provided with minimal deleterious side effects, such as undesired motor responses or undesired stimulation of unaffected body regions. This is achieved by directly neuromodulating a target anatomy associated with the condition while minimizing or excluding undesired neuromodulation of other anatomies.

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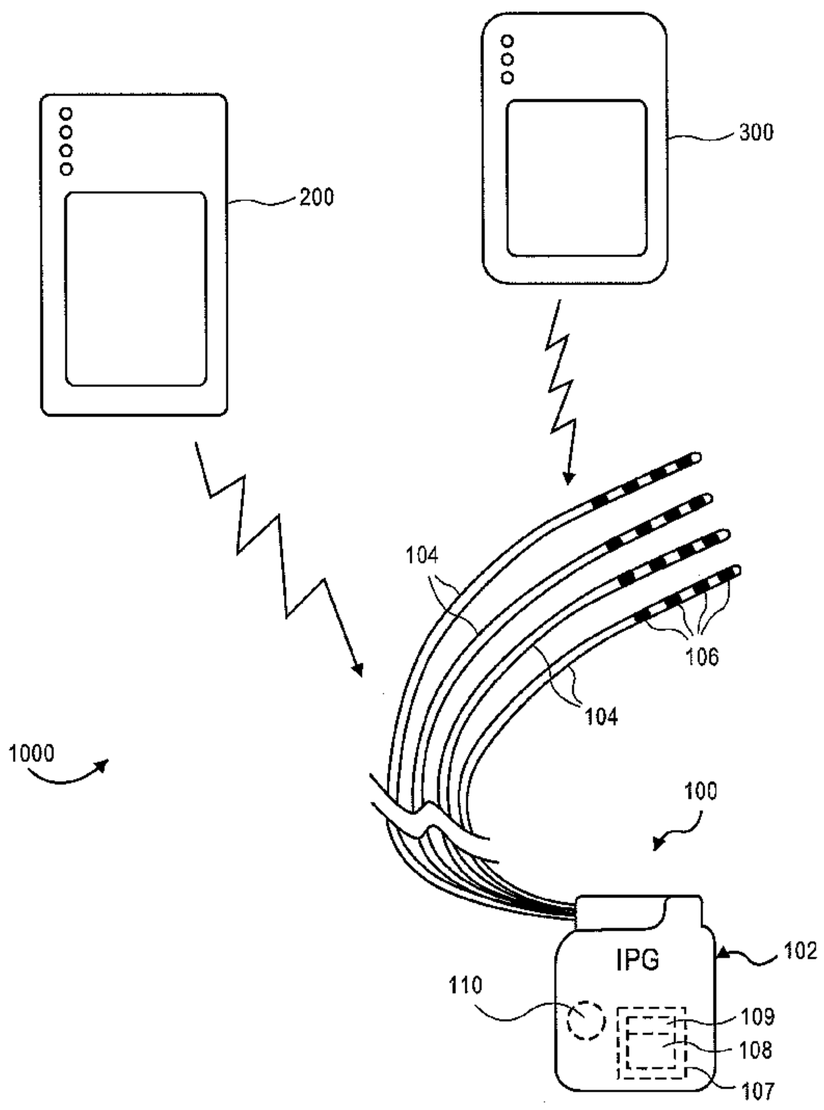

FIG. 11

(57) Abstract: Devices, systems and methods are provided for targeted treatment of a variety of conditions, particularly conditions that are associated with or influenced by the nervous system, such as pain. Targeted treatment of such conditions is provided with minimal deleterious side effects, such as undesired motor responses or undesired stimulation of unaffected body regions. This is achieved by directly neuromodulating a target anatomy associated with the condition while minimizing or excluding undesired neuromodulation of other anatomies.

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SELECTIVE STIMULATION SYSTEMS AND SIGNAL PARAMETERS FOR MEDICAL CONDITIONS

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] This application claims priority to U.S. Provisional Patent Application No. 61/108,836, entitled "Selective Stimulation Systems and Signal Parameters for Pain Management", filed October 27, 2008.

STATEMENT AS TO RIGHTS TO INVENTIONS MADE UNDER FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

[0002] NOT APPLICABLE

REFERENCE TO A "SEQUENCE LISTING," A TABLE, OR A COMPUTER PROGRAM LISTING APPENDIX SUBMITTED ON A COMPACT DISK.

[0003] NOT APPLICABLE

BACKGROUND OF THE INVENTION

[0004] Pain of any type is the most common reason for physician consultation in the United States, prompting half of all Americans to seek medical care annually. It is a major symptom in many medical conditions, significantly interfering with a person's quality of life and general functioning. Diagnosis is based on characterizing pain in various ways, according to duration, intensity, type (dull, burning, throbbing or stabbing), source, or location in body. Usually if pain stops without treatment or responds to simple measures such as resting or taking an analgesic, it is then called 'acute' pain. But it may also become intractable and develop into a condition called chronic pain in which pain is no longer considered a symptom but an illness by itself.

[0005] The application of specific electrical energy to the spinal cord for the purpose of managing pain has been actively practiced since the 1960s. It is known that application of an electrical field to spinal nervous tissue can effectively mask certain types of pain transmitted from regions of the body associated with the stimulated nervous tissue. Such masking is known as paresthesia, a subjective sensation of numbness or tingling in the afflicted bodily regions. Such electrical stimulation of the spinal cord, once known as dorsal column stimulation, is now referred to as spinal cord stimulation or SCS.

[0006] Figs. 1A-1B illustrate conventional placement of an SCS system 10. Conventional SCS systems include an implantable power source or implantable pulse generator (IPG) 12 and an implantable lead 14. Such IPGs 12 are similar in size and weight to cardiac pacemakers and are typically implanted in the buttocks or abdomen of a patient P. Using fluoroscopy, the lead 14 is implanted into the epidural space E of the spinal column and positioned against the dura layer D of the spinal cord S, as illustrated in Fig. 1B. The lead 14 is implanted either through the skin via an epidural needle (for percutaneous leads) or directly and surgically through a mini laminotomy operation (for paddle leads or percutaneous leads). A laminotomy is a neurosurgical procedure that removes part of a lamina of the vertebral arch. The laminotomy creates an opening in the bone large enough to pass one or more leads through.

[0007] Fig. 2 illustrates example conventional paddle leads 16 and percutaneous leads 18. Paddle leads 16 typically have the form of a slab of silicon rubber having one or more electrodes 20 on its surface. Example dimensions of a paddle lead 16 are illustrated in Fig. 3. Percutaneous leads 18 typically have the form of a tube or rod having one or more electrodes 20 extending therearound. Example dimensions of a percutaneous lead 18 are illustrated in Fig. 4.

[0008] Implantation of a percutaneous lead 18 typically involves an incision over the low back area (for control of back and leg pain) or over the upper back and neck area (for pain in the arms). An epidural needle is placed through the incision into the epidural space and the lead is advanced and steered over the spinal cord until it reaches the area of the spinal cord that, when electrically stimulated, produces a tingling sensation (paresthesia) that covers the patient's painful area. To locate this area, the lead is moved and turned on and off while the patient provides feedback about stimulation coverage. Because the patient participates in this operation and directs the operator to the correct area of the spinal cord, the procedure is performed with conscious sedation.

[0009] Implantation of paddle leads 16 typically involves performing a mini laminotomy to implant the lead. An incision is made either slightly below or above the spinal cord segment to be stimulated. The epidural space is entered directly through the opening in the bone and a paddle lead 16 is placed over the region to stimulate the spinal cord. The target region for stimulation usually has been located before this procedure during a spinal cord stimulation trial with percutaneous leads 18.

[0010] Although such SCS systems have effectively relieved pain in some patients, these systems have a number of drawbacks. To begin, as illustrated in Fig. 5, the lead 14 is positioned upon the spinal cord dura layer D so that the electrodes 20 stimulate a wide portion of the spinal

cord and associated spinal nervous tissue (as indicated by perimeter 21). The spinal cord is a continuous body and three spinal levels of the spinal cord are illustrated. For purposes of illustration, spinal levels are sub-sections of the spinal cord S depicting that portion where the dorsal root DR and ventral root VR join the spinal cord S. The spinal nerve N divides into the dorsal root DR and the dorsal root ganglion DRG and the ventral nerve root VR each of which feed into the spinal cord S. Generally, the dorsal roots DR feed into the posterior side of the spinal cord S and the ventral roots VR feed into the anterior side of the spinal cord S. For simplicity, each level shown illustrates the nerves of only one side and a normal anatomical configuration would have similar nerves on the opposite side of the spinal cord.

[0011] Fig. 6 illustrates a cross-sectional view of the lead 14 of Fig 5 at a spinal level. Thus, as shown, the lead 14 is positioned against the dura layer D near the midline of the spinal cord S. The electrode 20 stimulates a wide portion of the spinal cord. In this example, the lead 14 is a unidirectional paddle lead so the stimulation energy 15 (indicated by perimeter 21) extends to one side of the lead 14. Significant energy 15 is utilized to penetrate the dura layer D and cerebral spinal fluid CSF to activate fibers in the spinal column extending within the posterior side of the spinal cord S, post-synaptically to the dorsal roots. And, in cases of omnidirectional leads, even more energy may be required due to loss of energy that is directed away from the target. Sensory spinal nervous tissue, or nervous tissue from the dorsal nerve roots, transmit pain signals. Therefore, such stimulation is intended to block the transmission of pain signals to the brain with the production of a tingling sensation (paresthesia) that masks the patient's sensation of pain. However, excessive tingling may be considered undesirable. Further, the energy 15 also typically penetrates the anterior side of the spinal cord S, stimulating the ventral horns, and consequently the ventral roots extending within the anterior side of the spinal cord S. Motor spinal nervous tissue, or nervous tissue from ventral nerve roots, transmits muscle/motor control signals. Therefore, electrical stimulation by the lead 14 often causes undesirable stimulation of the motor nerves in addition to the sensory spinal nervous tissue. The result is undesirable muscle contraction.

[0012] Because the electrodes span several levels and because they stimulate medial to spinal root entry points, the generated stimulation energy 15 stimulates or is applied to more than one type of nerve tissue on more than one level. Moreover, these and other conventional, non-specific stimulation systems also apply stimulation energy to the spinal cord and to other neural tissue beyond the intended stimulation targets. As used herein, non-specific stimulation refers to the fact that the stimulation energy is provided to multiple spinal levels including the nerves and the spinal cord generally and indiscriminately. This is the case even with the use of

programmable electrode configurations wherein only a subset of the electrodes are used for stimulation. In fact, even if the epidural electrode is reduced in size to simply stimulate only one level, that electrode will apply stimulation energy non-specifically and indiscriminately (i.e. to many or all nerve fibers and other tissues) within the range of the applied energy.

[0013] Therefore, improved stimulation systems, devices and methods are desired that enable more precise and effective delivery of stimulation energy. At least some of these objectives will be met by the present invention.

BRIEF SUMMARY OF THE INVENTION

[0014] The present invention provides devices, systems and methods for targeted treatment of a variety of conditions, particularly conditions that are associated with or influenced by the nervous system. Examples of such conditions include pain, itching, Parkinson's Disease, Multiple Sclerosis, demylenating movement disorders, spinal cord injury, asthma, chronic heart failure, obesity and stroke (particularly acute ischemia), to name a few. The present invention provides for targeted treatment of such conditions with minimal deleterious side effects, such as undesired motor responses or undesired stimulation of unaffected body regions. This is achieved by directly neuromodulating a target anatomy associated with the condition while minimizing or excluding undesired neuromodulation of other anatomies. In most embodiments, neuromodulation comprises stimulation, however it may be appreciated that neuromodulation may include a variety of forms of altering or modulating nerve activity by delivering electrical or pharmaceutical agents directly to a target area. For illustrative purposes, descriptions herein will be provided in terms of stimulation and stimulation parameters, however, it may be appreciated that such descriptions are not so limited and may include any form of neuromodulation and neuromodulation parameters.

[0015] Typically, the systems and devices are used to stimulate portions of neural tissue of the central nervous system, wherein the central nervous system includes the spinal cord and the pairs of nerves along the spinal cord which are known as spinal nerves. The spinal nerves include both dorsal and ventral roots which fuse in the intravertebral foramen to create a mixed nerve which is part of the peripheral nervous system. At least one dorsal root ganglion (DRG) is disposed along each dorsal root prior to the point of mixing. Thus, the neural tissue of the central nervous system is considered to include the dorsal root ganglions and exclude the portion of the nervous system beyond the dorsal root ganglions, such as the mixed nerves of the peripheral nervous system. Typically, the systems and devices of the present invention are used to stimulate one or more dorsal root ganglia, dorsal roots, dorsal root entry zones, or portions thereof, while minimizing or excluding undesired stimulation of other tissues, such as

surrounding or nearby tissues, ventral root and portions of the anatomy associated with body regions which are not targeted for treatment. However, it may be appreciated that stimulation of other tissues are contemplated.

[0016] In a first aspect of the present invention, a system is provided stimulating at least a portion of a target dorsal root. In some embodiments, the system comprises a lead having at least one electrode, wherein the lead is configured to be positioned so that at least one of the at least one electrodes is able to stimulate the at least a portion of the target dorsal root, and an implantable pulse generator connectable with the lead, wherein the generator provides a stimulation signal to the lead which has an energy below an energy threshold for stimulating a ventral root associated with the target dorsal root while the lead is so positioned. In some embodiments, the at least a portion of the target dorsal root comprises a dorsal root ganglion.

[0017] In some embodiments, the stimulation signal has a current amplitude of less than or equal to approximately 4mA. Optionally, the current amplitude may be less than or equal to approximately 800μA. In some instances the at least one of the at least one electrodes has an average electrode surface area of less than or equal to approximately $6mm^2$. Optionally, the the average electrode surface area is less than or equal to approximately $4mm^2$.

[0018] In some embodiments, the system further comprises a second lead having at least one electrode, wherein the second lead is configured to be positioned so that at least one of its electrodes is able to stimulate at least a portion of a second target dorsal root, and wherein the second lead is connectable to the implantable pulse generator which provides a stimulation signal to the second lead, wherein the stimulation signal to the second lead has an energy below an energy threshold for stimulating a ventral root associated with the second target dorsal root while the second lead is so positioned. In some instances, the target dorsal root and the second target dorsal root are on different spinal levels. Optionally, the stimulation signal to the lead and the stimulation signal to the second lead are different.

[0019] In a second aspect of the present invention, a system is provided for stimulating a target neural tissue of the central nervous system. In some embodiments, the system comprises a lead having at least one electrode, wherein the lead is configured to be positioned so that at least one of the at least one electrodes is able to stimulate the target neural tissue, and an implantable pulse generator connectable with the lead, wherein the generator provides a stimulation signal having a current amplitude which is less than 100μA. Typically, the target spinal neural tissue comprises a dorsal root ganglion.

[0020] In a third aspect of the present invention, a system is provided for stimulating at least a portion of a target dorsal root, wherein the system includes a lead having at least one electrode, and wherein the lead is configured to be positioned so that at least one of the at least one electrodes is able to stimulate the at least a portion of the target dorsal root when provided a stimulation signal The system also includes an implantable pulse generator connectable with the lead, wherein the generator provides the stimulation signal which has an energy of less than approximately 100nJ per pulse. In some embodiments, the stimulation signal has an energy of less than approximately 50nJ per pulse. Optionally, the stimulation signal may have an energy of less than approximately 10nJ per pulse. Typically, the at least a portion of the target dorsal root comprises a dorsal root ganglion.

[0021] In a fourth aspect of the present invention, a system is provided for stimulating at least a portion of a target dorsal root, wherein the system includes a lead having at least one electrode, wherein the lead is configured to be positioned so that at least one of the at least one electrodes is able to stimulate the at least a portion of the target dorsal root when provided a stimulation signal. The system also includes an implantable pulse generator connectable with the lead, wherein the generator provides a stimulation signal which has a current amplitude of less than 4mA.

[0022] In a fifth aspect of the present invention, a system is provided for stimulating at least a portion of a target dorsal root, wherein the system includes a lead having at least one electrode, and wherein the lead is configured so that at least one of the at least one electrodes is positionable on or near the at least a portion of the target dorsal root. The system also includes an implantable pulse generator connectable with the lead, wherein the generator provides a stimulation signal to the at least one of the at least one electrode which selectively stimulates the at least a portion of the target dorsal root due to at least one signal parameter. In some embodiments, the at least one signal parameter includes current amplitude. In these embodiments, the current amplitude may be less than or equal to approximately 4 mA. Likewise, in some embodiments, the at least one signal parameter includes pulse width and the pulse width is less than 500μs. Typically, the at least a portion of the target dorsal root comprises a dorsal root ganglion.

[0023] In a sixth aspect of the present invention, a system for stimulating a target dorsal root ganglion is provided comprising a lead having at least one electrode, wherein the lead is configured so that at least one of the at least one electrodes is positionable on or near the target dorsal root ganglion. The system also includes an implantable pulse generator connectable with the lead, wherein the generator energizes the at least one of the at least one electrodes which

selectively stimulates the target dorsal root ganglion due to its proximity to the target dorsal root ganglion.

[0024] In a seventh aspect of the present invention, a system is provided for stimulating a target neural tissue of the central nervous system comprising a lead having at least one electrode, wherein the lead is configured to be positioned so that at least one of the at least one electrodes is able to stimulate the target neural tissue, and an implantable pulse generator connectable with the lead, wherein the generator provides a stimulation signal having a current amplitude which is adjustable in increments of 50μA or less. In some embodiments, the current amplitude is adjustable in increments of 25μA or less.

[0025] In another aspect of the present invention, a method is provided for stimulating at least a portion of a target dorsal root comprising positioning a lead having at least one electrode so that at least one of the at least one electrodes is on or near the at least a portion of the target dorsal root, and energizing at least one of the at least one electrodes with an energy level below an energy threshold for stimulating a ventral root associated with the target dorsal root while the lead is so positioned. In some embodiments, energizing comprises providing a stimulation signal having a current amplitude of less than or equal to approximately 4mA. Optionally, the current amplitude is less than or equal to approximately 1.0mA. In some embodiments, positioning the lead comprises advancing the lead using an epidural approach. In these embodiments, positioning the lead may comprise advancing the lead using an antegrade approach or a retrograde approach. It may also be appreciated that the lead may be positioned by advancing the lead using transforamenal approach from outside of the spinal column. Typically, the at least a portion of the target dorsal root comprises a dorsal root ganglion. In some embodiments, the average electrode surface area is less than or equal to approximately $4mm^2$.

[0026] In some embodiments, the method further comprises positioning a second lead having at least one electrode so that at least one of its at least one electrodes is on or near at least a portion of a second target dorsal root, and energizing at least one of the at least one electrodes of the second lead with an energy level below an energy threshold for stimulating a ventral root associated with the second target dorsal root while the second lead is so positioned. In some embodiments, the target dorsal root and the second target dorsal root are on different spinal levels. Likewise, in some embodiments, the energy level of the lead and the second lead are different.

[0027] In another aspect of the present invention, a method of stimulating a target spinal neural tissue within an epidural space is provided comprising positioning a lead having at least one

electrode, so that at least one of the at least one electrodes is able to stimulate the target spinal neural tissue, and energizing the at least one of the at least one electrodes with a stimulation signal which has a current amplitude which is less than 100μA.

[0028] In another aspect of the present invention, a method of stimulating at least a portion of a target dorsal root is provided comprising positioning a lead having at least one electrode, so that at least one of the at least one electrodes is able to stimulate the at least a portion of the target dorsal root and energizing the at least one of the at least one electrodes with a stimulation signal which has an energy of less than approximately 100nJ per pulse.

[0029] In another aspect of the present invention, a method for stimulating at least a portion of a target dorsal root is provided comprising positioning a lead having at least one electrode, so that at least one of the at least one electrodes is able to stimulate the at least a portion of the target dorsal root and energizing the at least one of the at least one electrodes with a stimulation signal which has a current amplitude of less than 4mA.

[0030] In another aspect of the present invention, a method for stimulating at least a portion of the target dorsal root is provided comprising positioning a lead having at least one electrode so that at least one of the at least one electrode is on or near the at least a portion of the target dorsal root and energizing at least one of the at least one electrodes with a stimulation signal which selectively stimulates the at least a portion of the target dorsal root due to at least one signal parameter.

[0031] In yet another aspect of the present invention, a method is provided for stimulating a target neural tissue of the central nervous system comprising positioning a lead having at least one electrode so that at least one of the at least one electrode is able to stimulate the target neural tissue, and energizing at least one of the at least one electrodes with a stimulation signal having a current amplitude which is adjustable in increments of 50μA or less.

[0032] Due to variability in patient anatomy, pain profiles, pain perception and lead placement, to name a few, signal parameter settings will likely vary from patient to patient and from lead to lead within the same patient. Signal parameters include voltage, current amplitude, pulse width and repetition rate, to name a few. In some embodiments of the stimulation system of the present invention, the voltage provided is in the range of approximately 0-7 volts. In some embodiments, the current amplitude provided is less than approximately 4 mA, particularly in the range of approximately 0.5-2mA, more particularly in the range of approximately 0.5-1.0mA, 0.1- 1.0mA, or 0.01-1.0mA. Further, in some embodiments, the pulse width provided is less than approximately 2000 μs, particularly less than approximately 1000μs, more particularly less

than approximately 500μs, or more particularly 10-120μs. And, in some embodiments, the repetition rate is in the range of approximately 2-120Hz, up to 200 Hz or up to 1000Hz.

[0033] Typically, stimulation parameters are adjusted until satisfactory clinical results are reached. Thus, there is an envelope of stimulation parameter value combinations between the threshold for DRG stimulation and ventral root stimulation for any given lead positioned in proximity to any given DRG per patient. The specific combinations or possible combinations that could be used to successfully treat the patient are typically determined perioperatively in vivo and postoperatively ex vivo and depend on a variety of factors. One factor is lead placement. The closer the desired electrodes are to the DRG the lower the energy required to stimulate the DRG. Other factors include electrode selection, the anatomy of the patient, the pain profiles that are being treated and the psychological perception of pain by the patient, to name a few. Over time, the parameter values for any given lead to treat the patient may change due to changes in lead placement, changes in impedance or other physical or psychological changes. In any case, the envelope of parameter values is exceedingly lower than those of conventional stimulation systems which require energy delivery of at least an order of magnitude higher to treat the patient's pain condition.

[0034] Given the lower ranges of parameter values, the granularity of control is also smaller in comparison to conventional stimulation systems. For example, current in a conventional stimulation system is typically adjustable in increments of 0.1 mA. In some embodiments of the present invention, this increment is larger than the entire range of current amplitude values that may be used to treat the patient. Thus, smaller increments are needed to cycle through the signal parameter values to determine the appropriate combination of values to treat the condition. In some embodiments, the system of the present invention provides control of current amplitude at a resolution of approximately 25 μA, particularly when using a current amplitude under, for example, 2mA, however it may be appreciated that smaller increments may be used such as approximately 10 μA, 5 μA or 1μA . In other embodiments, control of current amplitude is provided at a resolution of approximately 50μA, particularly when using a current amplitude of, for example, 2mA or greater. It may be appreciated that such a change in resolution may occur at other levels, such as 1mA. Similarly, voltage in a conventional stimulation system is typically adjustable in increments of 100mV. In contrast, some embodiments of the present invention provide control of voltage at a resolution of 50 mV. Likewise, some embodiments of the present invention provide control of pulse width at a resolution of 10μs. Thus, it may be appreciated that the present invention provides a high granularity of control of stimulation parameters due to the low ranges of parameter values.

[0035] It may be appreciated that in some instances even lower levels of energy may be used to successfully treat a patient using the stimulation system of the present invention. The closer a lead is positioned to a target DRG, the lower the level of energy that may be needed to selectively stimulate the target DRG. Thus, signal parameter values may be lower than those stated herein with correspondingly higher granularity of control.

[0036] Such reductions in energy allows a reduction in electrode size, among other benefits. In some embodiments, the average electrode surface area is approximately 1-6mm^2, particularly approximately 2-4mm^2, more particularly 3.93mm^2 whereas conventional spinal cord stimulators typically have a much larger average electrode surface area, such as 7.5mm^2 for some leads or 12.7mm^2 for traditional paddle leads. Likewise, in some embodiments an average electrode length is 1.25mm whereas conventional spinal cord stimulators typically have an average electrode length of 3mm. Such reduced electrode sizing allows more intimate positioning of the electrodes in the vicinity of the DRG and allows for IPGs having different control and performance parameters for providing direct and selective stimulation of a targeted neural tissue, particularly the DRG. In addition, in some embodiments the overall dimensions of one or more electrodes and the spacing of the electrodes is selected to match or nearly match the overall dimensions or size of the stimulation target.

[0037] Effective treatment of a condition may be achieved by directly stimulating a target anatomy associated with the condition while minimizing or excluding undesired stimulation of other anatomies. When such a condition is limited to or primarily affects a single dermatome, the present invention allows for stimulation of a single dermatome or regions within a dermatome (also referred to as subdermatomal stimulation).

[0038] In one aspect of the present invention, a method of treating a condition associated with a spinal neural tissue is provided, wherein the treatment is applied substantially within a single dermatome. In some embodiments, the method comprises positioning a lead having at least one electrode so that at least one of the at least one electrodes is in proximity to the spinal neural tissue within an epidural space, and energizing the at least one of the at least one electrodes so as to stimulate the spinal neural tissue causing a treatment effect within the single dermatome while maintaining body regions outside of the single dermatome substantially unaffected. In some embodiments, energizing the at least one electrode comprises energizing the at least one of the at least one electrode so as to stimulate the spinal neural tissue causing a treatment affect within a particular body region within the single dermatome while maintaining body regions outside of the particular body region substantially unaffected. Typically, the spinal neural tissue comprises

a dorsal root ganglion and the treatment effect comprises paresthesia. In some embodiments, the particular body region comprises a foot.

[0039] In another aspect of the present invention, a method of treating a condition of a patient is provided, wherein the condition is associated with a portion of a dorsal root ganglion and is not substantially associated with other portions of the dorsal root ganglion. In some embodiments, the method comprises positioning a lead having at least one electrode so that at least one of the at least one electrode resides in proximity to the portion of a dorsal root ganglion, and providing a stimulating signal to the at least one of the at least one electrode so as to stimulate the portion of the dorsal root ganglion in a manner that affects the condition while not substantially stimulating the other portions. In some embodiments, the condition comprises pain. In such embodiments, affecting the condition may comprise alleviating the pain without causing a perceptible motor response.

[0040] In some embodiments, the condition is sensed by a patient at a location within a dermatome, and the other portions of the dorsal root ganglion are associated with other locations within the dermatome. It may be appreciated, that the stimulating signal may have a current amplitude of less than or equal to approximately 4mA. Optionally, the stimulating signal may have current amplitude of less than or equal 1 mA. Typically, positioning the lead comprises advancing the lead using an epidural approach but is not so limited.

[0041] In another aspect of the present invention, a method of providing subdermatomal stimulation is provided comprising positioning a lead having at least one electrode so that at least one of the at least one electrode resides near a dorsal root ganglion within a dermatome, and providing a stimulating signal to the at least one of the at least one electrode so as to stimulate the dorsal root ganglion in a manner which affects a condition in a subdermatomal region of the dermatome.

[0042] In another aspect of the present invention, a system is provided for stimulating a portion of a dorsal root ganglion, wherein the portion of the dorsal root ganglion is associated with a particular region within a dermatome. In some embodiments, the system comprises a lead having at least one electrode, wherein the lead is configured to be positioned so that at least one of the at least one electrode is able to stimulate the portion of the dorsal root ganglion, and a pulse generator connectable with the lead, wherein the generator provides a stimulation signal to the at least one of the at least one electrode which stimulates the portion of the dorsal root ganglion to cause an effect within the particular region of the dermatome.

[0043] In some embodiments, the combination of the at least one of the at least one electrode and the stimulation signal creates an electric field having a shape which allows for stimulation of the portion of the dorsal root ganglion while substantially excluding other portions of the dorsal root ganglion. In some embodiments, the at least one of the at least one electrode comprises two electrodes spaced 0.250 inches apart from approximate center to center of each electrode. In some embodiments, stimulation signal has a current amplitude of less than or equal to approximately 4mA. Optionally, the stimulating signal may have a current amplitude of less than or equal 1 mA. In some embodiments, the stimulation signal has an energy of less than approximately 100nJ per pulse.

[0044] In another aspect of the present invention, a system for providing subdermatomal stimulation within a patient is provided comprising a lead having at least one electrode, wherein the lead is configured so that the at least one electrode is positionable in proximity to a dorsal root ganglion associated with a dermatome, and a pulse generator connectable with the lead. In some embodiments, the generator provides a first stimulation signal to at least one of the at least one electrode to create a first electric field which stimulates the dorsal root ganglion causing a first effect within a first body region of the dermatome and the generator provides a second stimulation signal to at least one of the at least one electrode to create a second electric field which stimulates the dorsal root ganglion causing a second effect within a second body region of the dermatome. In some instance, the first and second stimulation signals have different stimulation parameters. In some embodiments, the at least one of the at least one electrodes receiving the first stimulation signal differs from the at least one of the at least one electrodes receiving the second stimulation signal.

[0045] In some embodiments, the first and second electric fields have different shapes. Likewise, the first and second electric fields may have different sizes. In some embodiments, the first effect comprises relief from pain. In some embodiments, the first body region resides along a foot of the patient and the second body region resides along a back of the patient.

[0046] In yet another aspect of the present invention, a method for providing subdermatomal stimulation within a patient is provided comprising positioning a lead having at least one electrode in proximity to a dorsal root ganglion associated with a dermatome, applying a stimulation signal to the at least one electrode which stimulates the dorsal root ganglion causing an effect within a first body region of the dermatome, and repositioning the lead along the dorsal root ganglion so that the application of the stimulation signal to the least one electrode stimulates the dorsal root ganglion to cause a second effect within a second body region of the dermatome. In some embodiments, the first effect comprises relief from pain. In some embodiments, the first

body region resides along a foot of the patient and the second body region resides along a back of the patient.

[0046a] In yet another aspect of the present invention, there is provided a system for stimulating a target dorsal root ganglion to perform a targeted treatment, the system comprising: a lead having at least one electrode, wherein the lead is configured to be positioned so that at least one of the at least one electrode is able to stimulate the target dorsal root ganglion; and an implantable pulse generator connectable with the lead and configured to output a stimulation signal; wherein a current amplitude of the stimulation signal output by the pulse generator is incrementally adjustable in response to user inputs accepted by an external programmer that wirelessly communicates with the implantable pulse generator; wherein the system is configured such that when said current amplitude of the stimulation signal output by the pulse generator is at least a specified level said current amplitude is adjustable in first increments of 50 μA or less in response to user inputs accepted by the external programmer, and when said current amplitude is less than the specified level said current amplitude is adjustable in second increments of 25 μA or less in response to user inputs accepted by the external programmer; wherein the specified level is a current amplitude level at which an increment resolution transitions from the first increments to the second increments, or vice versa; wherein the second increments are less than the first increments; and wherein the first and second increments enable adjustments to the current amplitude in small enough increments to identify a magnitude for the current amplitude that stimulates the target dorsal root ganglion, to achieve the targeted treatment, without stimulating a ventral root associated with the target dorsal root ganglion.

[0047] Other objects and advantages of the present invention will become apparent from the detailed description to follow, together with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0048] Fig. 1A-1B, 2, 3, 4, 5, 6 illustrate prior art.

[0049] Fig. 7 illustrates an embodiment of a stimulation system of the present invention.

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[0050] Fig. 8 provides a perspective view of an embodiment of an implantable pulse generator of the present invention.

[0051] Fig. 9 illustrates the IPG of Fig. 8 with a portion of the housing removed to reveal the internal components.

[0052] Fig. 10 provides a schematic block diagram of printed circuit boards which are part of the electronic circuitry of one embodiment of the IPG.

[0053] Fig. 11 illustrates at least one external programming device communicating the IPG using telemetry.

[0054] Fig. 12 illustrates an example of possible parameters of a stimulation signal which can be varied.

[0055] Fig. 13 is a simplified block diagram that illustrates possible components of the electronic circuitry of the IPG.

[0056] Fig. 14 is a simplified block diagram that illustrates possible components of an external programmer, such as a clinical programmer.

[0057] Fig. 15A provides a perspective expanded view of an embodiment of a clinical programmer.

[0058] Fig. 15B and Fig. 15C illustrate embodiments of screenshots of a clinical programmer.

[0059] Fig. 16 is a simplified block diagram that illustrates possible components of another external programmer, such as a patient programmer.

[0060] Fig. 17 illustrates example placement of the leads of the embodiment of Fig. 7 within the patient anatomy.

[0061] Fig. 18 illustrates a cross-sectional view of an individual spinal level showing a lead of the stimulation system positioned near a target DRG.

[0062] Fig. 19A illustrates an embodiment of a trace representing a stimulation signal of the present invention and Fig. 19B illustrates an embodiment of a corresponding trace showing the voltage response to a complex impedance stimulating biological tissue.

[0063] Fig. 20A illustrates an embodiment of a trace representing an example stimulation signal of a conventional spinal cord stimulator and Fig. 20B illustrates an embodiment of a corresponding trace showing the voltage response to a complex impedance stimulating biological tissue.

[0064] Fig. 21 illustrates data indicating the stimulation signal parameters which selectively targeted the DRG wherein there is an energy threshold in which the DRG is stimulated which is below the energy threshold in which the ventral root is stimulated.

[0065] Fig. 22 illustrates the dermatomal arrangement or "map" of dermatomes along a patient.

[0066] Fig. 23 schematically illustrates DRGs on various spinal levels with associated body regions that may be affected by selective stimulation of the individual DRGs.

[0067] Fig. 24A illustrates the patient from the back, including the dermatomes of the lower body and a schematic representation of the general area of the DRGs, and Fig. 24B illustrates the patient from the front, including the dermatomes of the lower body.

[0068] Fig. 25 schematically illustrates selective stimulation of a DRG according to aspects of the present invention.

[0069] Figs. 26A, 26B, 26C, 26D illustrate perspective views of a lead stimulating a portion of a DRG to affect a specific region within a dermatome.

[0070] Fig. 27 and Fig 28 provide tables of clinical data from Patient No. 1 and Patient No. 2 respectively.

DETAILED DESCRIPTION OF THE INVENTION

[0071] In some embodiments, a target DRG is stimulated with a lead having at least one electrode thereon. The lead is advanced through the patient anatomy so that the at least one electrode is positioned on, near or about the target DRG. The lead is sized and configured so that the electrode(s) are able to minimize or exclude undesired stimulation of other anatomies. Such

configuration may include a variety of design features, including signal parameters, which will be described herein.

[0072] Fig. 7 illustrates an embodiment of an implantable stimulation system 100 of the present invention. The system 100 includes an implantable pulse generator (IPG) 102 and at least one lead 104 connectable thereto. In preferred embodiments, the system 100 includes four leads 104, as shown, however any number of leads 104 may be used including one, two, three, four, five, six, seven, eight, up to 58 or more. Each lead 104 includes at least one electrode 106. In preferred embodiments, each lead 104 includes four electrodes 106, as shown, however any number of electrodes 106 may be used including one, two, three, four five, six, seven, eight, nine, ten, eleven, twelve, thirteen, fourteen, fifteen, sixteen or more. Each electrode can be configured as off, anode or cathode. In some embodiments, even though each lead and electrode are independently configurable, at any given time the software ensures only one lead is stimulating at any time. In other embodiments, more than one lead is stimulating at any time, or stimulation by the leads is staggered or overlapping.

[0073] Referring again to Fig. 7, the IPG 102 includes electronic circuitry 107 as well as a power supply 110, e.g., a battery, such as a rechargeable or non-rechargeable battery, so that once programmed and turned on, the IPG 102 can operate independently of external hardware. In some embodiments, the electronic circuitry 107 includes a processor 109 and programmable stimulation information in memory 108.

[0074] Fig. 8 provides a perspective view of an embodiment of an IPG 102 of the present invention. Here the electronic circuitry 107 and power supply 110 are enclosed in a housing 105 (also referred to as a "case" or "can"). It may be appreciated, that alternatively, the power supply may be located outside of the housing 105, such as within an external device which supplies power to the IPG 102, such as via inductive coupling, RF or photoactivation. In some embodiments, the IPG 102 as a volume not exceeding approximately 32cc, , a thickness not exceeding approximately 1.2 cm or a weight not exceeding approximately 30g. It may be appreciated that in other embodiments, the IPG 102 has a volume not exceeding approximately, 0.2, 5, 10, 15, 20, 30, 40, 50, 60 or 70 cc. The IPG 102 may have a variety of shapes, including an oval, circular, rounded square or rounded rectangular shape. In some embodiments, the IPG 102 has a height of approximately 61 mm, a width of approximately 48 mm and a thickness of approximately 11mm.

[0075] In some embodiments, the housing 105 of the IPG 102 is electrically conductive. In such embodiments, the housing 105 can act as an electrode, as explained in more detail below.

The at least one electrode 106 is electrically coupled to the electronic circuitry 107 by coupling the lead 104 to a connector 111 of the IPG 102. In this embodiment, each lead 104 is insertable into a separate port 115 in the IPG 102 to provide electrical connection to each lead 104.

[0076] Fig. 9 illustrates the components within the IPG 102 of Fig. 8 . In this embodiment, the internal components include a power supply 110, electronic circuitry 107, an antenna 132, and a lead connector 111. In this embodiment, the electronic circuitry 107 includes three printed circuit boards to allow the circuitry to reside in a small space. Fig. 10 provides a schematic block diagram of these boards, which include an RF board 136, an MCU board 138 and an electrode board 140. The MCU board includes a microcontroller unit (MCU) which is a small computer on a single integrated circuit comprising a CPU combined with support functions such as a crystal oscillator, timers, serial and analog I/O etc. Program memory, such as in the form of NOR flash or OTP ROM, may also be included on the chip, as well as RAM. It may be appreciated that the electronic circuitry 107 may include other arrangements and components.

[0077] Referring to Fig. 11, the IPG 102 is turned on and off and programmed to generate the desired stimulation pulses from at least one external programming device using telemetry, such as transcutaneous electromagnetic or RF links or a transmitting coil. In some embodiments, an RF link is used which complies with the MICS standard. This standard allocates a 402-405 MHz frequency spectrum intended for implantable medical devices. In other embodiments, the RF link utilizes a frequency of 400MHz or greater. In still other embodiments, the RF link utilizes a frequency of 2.45GHz. In some embodiments, telemetry is initiated by a magnet within or associated with the external programmer. The magnet actuates a magnetic sensor in the implanted IPG 102 when placed on the skin directly over the implant or within a suitable range of the implant. In addition, in some embodiments, the IPG 102 sniffs on all channels for communication attempts by external programmers. In some embodiments, such sniffing occurs over at predetermined intervals, such as every 10 min, and such intervals can be programmable. This is a backup communication link should the IPG fail to detect the magnet. Should the IPG detect the presence of an external programmer, the IPG typically responds to the programmer within thirty seconds, 15 seconds or less.

[0078] In some embodiments, the at least one external programming device comprises a clinical programmer 200 and a patient programmer 300. The clinical programmer 200 is used to program the stimulation information of the IPG 102, as determined by the clinician or investigator. The stimulation information includes signal parameters such as voltage, current, pulse width, repetition rate, and burst rates. Fig. 12 illustrates an example of possible parameters of a stimulation signal which may be varied. Using embodiments of the present invention, the

amplitude, current, pulse width and repetition rate (also referred to as frequency) which provide the optimal therapeutic result can be determined. It may be appreciated that a constant current with a variable amplitude may be used, or a constant amplitude with a variable current may be used.

[0079] Referring back to Fig. 11, the patient programmer 300 allows the patient to adjust the stimulation settings of the IPG 102 within limits preset by the clinician. The patient programmer 300 also allows the patient to turn stimulation off, if necessary. The clinical and patient programmers 200, 300 are portable, hand-held devices that can be plugged into a power outlet or powered by an internal battery. The battery is typically rechargeable using a power supply and a power outlet. In some embodiments, the programmers 200, 300 contain an internal magnet to initiate communication with the IPG 102. The patient programmer 300 is designed to be easy to use and establishes two-way communication with the IPG 102 to control the stimulation. Together the implantable stimulation system 100, clinical programmer 200 and patient programmer 300 form a system 1000 which operates to provide personalized treatment for each patient, as will be described in more detail below.

[0080] It may be appreciated that the embodiments of Figs. 8, 9, 10, 11 are for illustrative purposes, wherein the components may vary. For example, Fig. 13 is a simplified block diagram that illustrates possible components of the electronic circuitry of the IPG. In this embodiment, the electronic circuitry 418 is shown as including a battery 430, pulse generator 432, a controller 434, a switch device 436, telemetry circuitry 438 and memory 439.

[0081] The battery 430 can be used to power the various other components of the electronic circuitry 418. Further, the battery 430 can be used to generate stimulation pulses. As such, the battery can be coupled to the pulse generator 432, the controller 434, the switch device 436, the telemetry circuitry 438 and the memory 439. A voltage regulator (not shown) can step up or step down a voltage provided by the battery 430 to produce one or more predetermined voltages useful for powering such components of the electronic circuitry 418. Additional electronic circuitry, such as capacitors, resistors, transistors, and the like, can be used to generate stimulation pulses, as is well known in the art.

[0082] The pulse generator 432 can be coupled to electrodes 106 of the lead(s) 104 via the switch device 436. The pulse generator 432 can be a single- or multi-channel pulse generator, and can be capable of delivering a single stimulation pulse or multiple stimulation pulses at a given time via a single electrode combination or multiple stimulation pulses at a given time via multiple electrode combinations. In one embodiment, the pulse generator 432 and the switch

device 136 are configured to deliver stimulation pulses to multiple channels on a time-interleaved basis, in which case the switch device 436 time division multiplexes the output of pulse generator 432 across different electrode combinations at different times to deliver multiple programs or channels of stimulation energy to the patient.

[0083] The controller 434 can control the pulse generator 432 to generate stimulation pulses, and control the switch device 436 to couple the stimulation energy to selected electrodes. More specifically, the controller 434 can control the pulse generator 432 and the switch device 436 to deliver stimulation energy in accordance with parameters specified by one or more stimulation parameter sets stored within the memory 439. Exemplary programmable parameters that can be specified include the pulse amplitude, pulse width, and pulse rate (also known as repetition rate or frequency) for a stimulation waveform (also known as a stimulation signal). Additionally, the controller 434 can control the switch device 436 to select different electrode configurations for delivery of stimulation energy from the pulse generator 432. In other words, additional programmable parameters that can be specified include which electrodes 106 of which lead(s) 104 are to be used for delivering stimulation energy and the polarities of the selected electrodes 106. Each electrode 106 can be connected as an anode (having a positive polarity), a cathode (having a negative polarity), or a neutral electrode (in which case the electrode is not used for delivering stimulation energy, i.e., is inactive). A set of parameters can be referred to as a stimulation parameter set since they define the stimulation therapy to be delivered to a patient. One stimulation parameter set may be useful for treating a condition in one location of the body of the patient, while a second stimulation parameter set may be useful for treating a condition in a second location. It may be appreciated that each of the electrodes on an individual lead may provide a signal having the same signal parameters or one or more electrodes on the lead may provide a signal having differing signal parameters. Likewise, an individual electrode may provide a signal having differing signal parameters over time.

[0084] The controller 434 can include a microprocessor, a microcontroller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), a state machine, or similar discrete and/or integrated logic circuitry. The switch device 436 can include a switch array, switch matrix, multiplexer, and/or any other type of switching device suitable to selectively couple stimulation energy to selected electrodes. The memory 439 can include RAM, ROM, NVRAM, EEPROM or flash memory, but is not limited thereto. Various programs and/or stimulation parameter sets can be stored in the memory 439, examples of which are discussed herein.

[0085] Once a desired stimulation parameter set is determined, the IPG 102 can be programmed with the optimal parameters of the set. The appropriate electrode(s) 106 on the lead 104 then stimulate the nerve tissue with the determined stimulation signal.

[0086] Fig. 14 is a simplified block diagram that illustrates possible components of an external programmer, such as a clinical programmer 200. Referring to Fig. 14, the clinical programmer 200 is shown as including a power supply 440, a user interface 442, a controller 444, input and output (I/O) circuitry 446, telemetry circuitry 448 and memory 449.

[0087] The power supply 440, which can include a battery, can be used to power the various other components of the external programmer. As such, the power supply 440 can be coupled to the user interface 442, the controller 444, the input and output (I/O) circuitry 446, the telemetry circuitry 448 and the memory 449. A voltage regulator (not shown) can step up or step down a voltage provided by a battery or an external power source to produce one or more predetermined voltages useful for powering such components of the external programmer.

[0088] The clinician or other operator may utilize the clinical programmer 200 to perform a variety of functions. For example, in some embodiments the clinical programmer 200 can be used to:

- Turn OFF all stimulation.
- Turn stimulation ON for up to four leads and measure lead impedance.
- Assign body regions, electrode configurations and stimulation settings for each lead.
- Enter patient and lead identification information, clinician and clinic name and contact information, and clinician's notes.
- Perform a real time test to assess the patient stimulation response for each lead.
- Enable Patient Controlled Therapy and configure Patient Controlled Therapy settings for each lead.
- Acquire identification, diagnostic, and historic information about the IPG 102.
- Program configured therapy settings, and patient and clinician information into the IPG 102 device.

[0089] The clinician may interact with the controller 444 via the user interface 442 in order to test various stimulation parameter sets, input user feedback, select preferred or optimal programs, and the like. The user interface 442 can include a display, a keypad, a touch screen,

one or more peripheral pointing devices (e.g., a mouse, touchpad, joystick, trackball, etc.), and the like. The controller 444 can provide a graphical user interface (GUI) via the user interface 442 to facilitate interaction with the clinician. The controller 444 can include a microprocessor, a microcontroller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), a state machine, or similar discrete and/or integrated logic circuitry. The I/O circuitry 446 can include transceivers for wireless communication, ports for wired communication and/or communication via removable electrical media, and/or appropriate drives for communication via removable magnetic or optical media. The telemetry circuitry 448 can be the telemetry circuitry described above, or separate but similar telemetry circuitry.

[0090] Fig. 15A provides a perspective expanded view of an embodiment of a clinical programmer 200. In this embodiment, the clinical programmer 200 comprises a handheld computer 202, such as a personal digital assistant, an antenna 204, a ground plane 206, and a telemetry controller 208 or "Base Station" (micro) plus RF board. As shown, the handheld computer 202 includes a touch screen user interface 210 and an input and output (I/O) port 212. In this embodiment, these components are disposed within a housing comprising a cradle 214 and a faceplate 216, as shown.

[0091] Referring back to Fig. 14, the controller 444 can collect information relating to tested electrode parameters (e.g., combinations) and stimulation signal parameters, and store the information in the memory 449 for later retrieval and review by a clinician or by the controller 444 to facilitate identification of one or more preferred stimulation parameter sets. The controller 444 can send instructions to the IPG 102 via the telemetry circuit 448 to cause the testing of various stimulation parameter sets. For example, the controller 444 can effectuate the testing of stimulation parameter sets created by the controller 444 or clinician to the IPG 102.

[0092] The memory 449 can include program instructions that, when executed by the controller 444, cause the programmer 422 to perform at least some of the functions described herein. For example, the controller 444 can execute program instructions that specify protocols for testing various stimulation parameter sets and selecting one or more preferred stimulation parameter sets. The memory 449 can also store one or more stimulation parameter sets determined to treat a particular condition of a patient, along with information about the patient. The memory 449 can include any volatile, non-volatile, fixed, removable, magnetic, optical, or electrical media, such as a RAM, ROM, CD-ROM, hard disk, removable magnetic disk, memory cards or sticks, NVRAM, EEPROM, flash memory, and the like.

[0093] In some embodiments, the clinical programmer 200 includes "workspaces" which are used to view and program the therapy settings and to obtain diagnostic information. A record of the programmed settings and diagnostic information is generated after every session. In some embodiments, four workspaces are provided: "Patient", "Leads", "Therapy" and "Stimulator". Fig. 15B provides an example screenshot 250 of the clinical programmer 200. The four workspaces are shown as workspace tabs 252 near the top of the screenshot 250.

[0094] In some embodiments, the Patient Workspace is used to: Enter patient identification information; Enter IPG device information; Enter clinician, clinic name and contact information; and Enter clinician's notes. In some embodiments, the Patient Workspace is divided into three tabs: "Patient Information", "Clinician", and "Notes". Under the Patient Information tab, information may be entered such as one or more of the following: Patient Name, Date of Birth, Patient Address, Patient ID Number, Stimulator Serial Number, Date of Implant, Lead Serial Numbers. Under the Clinician tab, information may be entered such as one or more of the following: Physician Name, Clinic Name, Clinic Address, Clinic Phone Number, Clinic Email Address. Under the Notes tab, a text field is provided to enter free text notes. Optionally, any previous information that has been entered in the text field will be erased when the text field is updated.

[0095] In some embodiments, the Leads Workspace is used to: Activate (turn on) up to four leads; Adjust electrode configuration; Measure impedance; Set nominal values to begin stimulation; Perform trial mapping; Confirm and assign specific body regions to be stimulated. There is one Lead tab for each lead, each Lead tab may be labeled with the corresponding body region receiving stimulation. Each body region can have stimulation adjusted as described herein. Fig. 15B illustrates four body region tabs 254, one each for right foot, left ankle, left foot, and lower back. As mentioned, in some embodiments each lead has four electrodes. Each of the electrodes can be programmed with a positive or negative pulse, or be programmed as neutral (off). For each lead, the pulse parameters are also programmable. Typically, the pulse parameters include: Pulse Amplitude (μA), Pulse Width (μs), Pulse Repetition Rate (Hz), and Allowed Impedance Range (Ω). The Allowed Impedance Range is dependent on voltage and amplitude combinations. In some embodiments, each pulse parameter is selected from a drop-down table. The parameter choices are specific to a variety of factors, including the anatomical target, and will be described in later sections below.

[0096] Typically, each lead has a Maximum Allowable Charge. The calculated value of the maximum allowable charge delivered by each lead may be displayed under its associated Lead tab. This value is calculated based on the assigned pulse parameter settings and the lead's

electrode configuration. Thus, combinations of amplitude and pulse width selections are typically limited by the maximum allowable charge. Therefore, for certain amplitude settings, only certain pulse width settings may be selectable. Similarly, for certain pulse width settings, only certain amplitude settings may be selectable.

[0097] In some embodiments, a Measure Impedance Button is included. The Measure Impedance Button is activated to measure the lead's impedance. Once activated, the impedance value may be displayed.

[0098] In some embodiments, the clinical programmer 200 is used for Trial Mapping. Trial Mapping allows the clinician to test and confirm patient stimulation response for each lead target or body region in real time. Typically, Trial Mapping starts with the use of signal parameters set to relatively low settings. Parameter settings are increased or decreased by pressing the "Up" or "Down" arrow button respectively. Fig. 15C illustrates an embodiment of a screenshot 260 showing a selectable step size buttons 262 when changing parameter settings. As will be described in later sections, since the parameter values for the system 100 are lower than conventional stimulation systems, the granularity of control or step size is also smaller. Thus, smaller increments are needed to cycle through the signal parameter values to determine the appropriate combination of values to treat the condition. However, the clinician may desire a variety of step sizes to narrow the range of parameter values. For example, the clinician may start with a larger step size (>>>) for gross changes in parameters values and then move to a smaller step size (>>) and even smaller step size (>) when approaching the desired parameter value. Each enabled lead pulse parameter setting is adjusted until a desired response is achieved. The actual step sizes corresponding to the selectable step size buttons 262 are preprogrammed into the programmer 200. It may be appreciated that as the clinician scrolls through different ranges of the parameter values, the step size will automatically change to a granularity appropriate for the range. The settings are then saved to memory in preparation for programming of the IPG. The Trial Mapping process is then repeated for each activated body region.

[0099] In some embodiments, the Therapy workspace is used to: Enable or disable patient controlled therapy for each lead; and Set maximum current amplitude accessible for adjustment by the patient. Selecting "ON" enables Patient Controlled therapy. This allows the patient to adjust therapy settings using their Patient Programmer. Selecting "OFF" disables and blocks patient access to Patient Controlled therapy. When setting Maximum Stimulation Amplitude Settings, the clinician typically enters the maximum stimulation amplitude from a clinically set amplitude, such as up to 4.0 mA, that the patient is allowed to set for each lead.

[0100] In some embodiments, the Stimulator Workspace is used to: Acquire identification, diagnostic, and historic information about the IPG; Program the IPG with therapy settings; and Program patient and clinician information. In some embodiments, the Stimulator Workspace has two tabs, "Information" and "Program". When the "Information" tab is selected, the screen displayed is read only and may display one or more of the following: Neurostimulator Serial Number (displays the serial number for the IPG); NS Firmware Version (displays the Stimulator firmware version); Lead Serial Numbers (Displays each lead's serial number; Neurostimulator Clock Information (displays the time when the IPG was first queried for that specific therapy session); and Implant Battery Information.

[0101] The "Program" tab is used to program the IPG with the configured settings including Leads settings and Patient Controlled therapy settings. In some embodiments, Patient and Stimulator Identification Information is displayed under the "Program" tab. Such information may include Patient Name; Patient Date of Birth; Stimulator Serial Number; and Stimulation Therapy Summary Table. The Stimulation Therapy Summary Table, also referred to as "Stimulator Settings", displays configured stimulation therapy settings. In some embodiments, there are three columns: the first lists the parameter names; the second lists the retained values in the Clinical Programmer; the third lists the programmed values in the IPG. Optionally, stimulation therapy parameters may be highlighted, such as using red text, to indicate parameters that have been modified since the last stimulation therapy was programmed to the IPG. Data may be presented in this order: Patient, Leads, and Therapy. Use of the vertical scroll bar may be used to display the different parameters.

[0102] Additionally, in some embodiments, a "Program Stimulator" button is provided under the "Program" tab. The "Program Stimulator" button is used to transfer the programmed values to the IPG. A table below the "Program Stimulator" button displays a summary of the configured stimulation therapy settings. A confirmation window may be displayed to confirm whether it is desired to program the IPG. Selecting a "Yes" button programs the settings displayed. Selecting a "No" button cancels programming the IPG.

[0103] Typically, the patient programmer 300 that is to be used by the patient is specifically bound to the patient's IPG in order for the patient to be able to minimally adjust the stimulation settings. Likewise, the patient programmer 300 may be bound to multiple IPGs within a patient if the patient has been implanted with more than one IPG.

[0104] Fig. 16 is a simplified block diagram that illustrates possible components of an external programmer, such as a patient programmer 300. Referring to Fig. 16, the patient programmer

300 is shown as including a power supply 450, a user interface 452, a controller 454, input and output (I/O) circuitry 456, telemetry circuitry 458 and memory 459. The power supply 450, which can include a battery, can be used to power the various other components of the patient programmer 300. As such, the power supply 450 can be coupled to the user interface 452, the controller 454, the input and output (I/O) circuitry 456, the telemetry circuitry 458 and the memory 459. A voltage regulator (not shown) can step up or step down a voltage provided by a battery or an external power source to produce one or more predetermined voltages useful for powering such components of the patient programmer 300.

[0105] A patient can interact with the controller 454 via the user interface 452 in order to select, modify or otherwise control delivery of stimulation therapy. For example, the patient may be able to select among various stimulation parameter sets that are stored in the memory 459. Additionally, or alternatively, the patient may be able to increase or decrease specific stimulation signal parameters, such as amplitude, to tailor the therapy to the symptoms being experienced at the time. The user interface 442 can include a display, a keypad, a touch screen, one or more peripheral pointing devices (e.g., a mouse, touchpad, joystick, trackball, etc.), and the like. The controller 454 can provide a graphical user interface (GUI) via the user interface 452 to facilitate interaction with a patient. The controller 454 can include a microprocessor, a microcontroller, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field-programmable gate array (FPGA), a state machine, or similar discrete and/or integrated logic circuitry. The I/O circuitry 446 can include transceivers for wireless communication, ports for wired communication and/or communication via removable electrical media, and/or appropriate drives for communication via removable magnetic or optical media.

[0106] In some embodiments, the memory 459 can store data related to stimulation parameter sets that are available to be selected by the patient for delivery of stimulation therapy to the patient using the IPG 102 implanted within the patient. In some embodiments, the controller 454 can record usage information and store usage information in the memory 459. The memory 459 can include program instructions that, when executed by the controller 454, cause the patient programmer 426 to perform functions ascribed to the patient programmer 300. The memory 459 can include any volatile, non-volatile, fixed, removable, magnetic, optical, or electrical media, such as a RAM, ROM, CD-ROM, hard disk, removable magnetic disk, memory cards or sticks, NVRAM, EEPROM, flash memory, and the like. Memory in IPG can record impedance data, current, voltage, time of day, time of therapy changes, built in circuit testing, battery data, to name a few. Upon connection with an external programmer, the programmer can record the IPG recorded data. This data can then be used to reprogram the IPG.

[0107] The telemetry circuitry 458 allows the controller to communicate with IPG 102, and the input/output circuitry 456 may allow the controller 454 to communicate with the clinician external programmer 200. The controller 454 can receive selections of, or adjustments to, stimulation parameter sets made by the patient via the user interface 452, and can transmit the selection or adjustment to the IPG 102 via telemetry circuitry 458. Where the patient programmer 300 stores data relating to stimulation parameter sets in the memory 459, the controller 454 can receive such data from the clinician programmer 200 via the input/output circuitry 456 during programming by a clinician or physician. Further, the patient programmer 300 can transmit data relating to stimulation parameter sets to the IPG 102 via the telemetry circuitry 458.

[0108] The patient may utilize the patient programmer 300 to perform a variety of functions. For example, in some embodiments the patient programmer 300 can be used to:

- Turn OFF all stimulation, if desired.
- Turn stimulation ON or OFF for each body region to be stimulated.
- Adjust the amount of stimulation for each body region.
- View the IPG identification information including the stimulator serial number, each lead's serial number, and the date when the IPG was last programmed.
- View the patient's name (optionally, the study ID number).
- View the lead placement date.
- View the clinician name, clinic name and contact information.

[0109] Typically, the patient programmer 300 includes a Main Menu which displays two main functions: Adjust Stimulation Settings and Programmer Setup. The Adjust Stimulation Settings allows the user to set up communication with the IPG and adjust stimulation settings. The Programmer Setup allows the patient to set the Patient Programmer date and time, and to view information about the IPG and Patient Programmer controls. Often the Main Menu has some basic information identifying the device. In addition, the physician, clinic and the clinic phone number are typically displayed, along with the Programmer Serial Number, Software Version and Base Station Firmware Version. Further, the Main Menu may include the IPG connection status, the battery charge level and the time.

[0110] In some embodiments, the patient can cause the IPG to check for communication from the patient programmer 300 with the use of a magnet within or associated with the patient

programmer 300. The patient may place the magnet near the IPG, such as within 6 feet, for a period of time, such as 5 seconds or more.

[0111] When four leads are implanted and programmed by the clinician for use, the patient can turn stimulation therapy ON or OFF for up to four areas of the body and adjust the amount of stimulation any of those areas are receiving as allowed by the clinical programmer. It may be appreciated that such functionality applies to any number of leads which are implanted and programmed for use. To turn stimulation therapy ON or OFF, the Patient Programmer 300 may display the names of one to four designated body regions that the leads have been placed to stimulate and the patient individually turns stimulation of each region on or off.

[0112] In some embodiments, when stimulation is ON, the patient may adjust the amount of stimulation to the body region. For example, once the correct tab has been selected for the specific body region to be adjusted, the patient may press the "Down" button to decrease the stimulation level or press the "Up" button to increase the stimulation level. In some embodiments, a stimulation level indicator between the "Up" and "Down" buttons moves up or down as the patient changes the stimulation level for the selected body region. Further, the stimulation level indicator may also show the current stimulation level and where it is compared to the maximum set by the clinician. The adjustments may then be saved and the patient can continue to adjust stimulation to other specific body regions.

[0113] The above described implantable stimulation system 100 can be used to stimulate a variety of anatomical locations within a patient's body. In preferred embodiments, the system 100 is used to stimulate one or more dorsal roots, particularly one or more dorsal root ganglions. Fig. 17 illustrates example placement of the leads 104 of the embodiment of Fig. 7 within the patient anatomy. In this example, each lead 104 is individually advanced within the spinal column S in an antegrade direction. Each lead 104 has a distal end which is guidable toward a target DRG and positionable so that its electrodes 106 are in proximity to the target DRG. Specifically, each lead 104 is positionable so that its electrodes 106 are able to selectively stimulate the DRG, either due to position, electrode configuration, electrode shape, electric field shape, stimulation signal parameters or a combination of these as will be discussed in more detail in a later section. Fig. 17 illustrates the stimulation of four DRGs, each DRG stimulated by one lead 104. These four DRGs are located on three levels, wherein two DRGs are stimulated on the same level. It may be appreciated that number of DRGs and any combination of DRGs may be stimulated with the stimulation system 100 of the present invention. It may also be appreciated that more than one lead 104 may be positioned so as to stimulate an individual DRG and one lead 104 may be positioned so as to stimulate more than one DRG.

[0114] Fig. 18 illustrates an example cross-sectional view of an individual spinal level showing a lead 104 of the stimulation system 100 positioned on, near or about a target DRG. The lead 104 is advanced along the spinal cord S to the appropriate spinal level wherein the lead 104 is advanced laterally toward the target DRG. In some instances, the lead 104 is advanced through or partially through a foramen. At least one, some or all of the electrodes 106 are positioned on, about or in proximity to the DRG. In preferred embodiments, the lead 104 is positioned so that the electrodes 106 are disposed along a surface of the DRG opposite to the ventral root VR, as illustrated in Fig. 18. It may be appreciated that the surface of the DRG opposite the ventral root VR may be diametrically opposed to portions of the ventral root VR but is not so limited. Such a surface may reside along a variety of areas of the DRG which are separated from the ventral root VR by a distance.

[0115] In some instances, such electrodes 106 may provide a stimulation region indicated by dashed line 110, wherein the DRG receives stimulation energy within the stimulation region and the ventral root VR does not as it is outside of the stimulation region. Thus, such placement of the lead 104 may assist in reducing any possible stimulation of the ventral root VR due to distance. However, it may be appreciated that the electrodes 106 may be positioned in a variety of locations in relation to the DRG and may selectively stimulate the DRG due to factors other than or in addition to distance, such as due to stimulation profile shape and stimulation signal parameters, to name a few. It may also be appreciated that the target DRG may be approached by other methods, such as a retrograde epidural approach. Likewise, the DRG may be approached from outside of the spinal column wherein the lead 104 is advanced from a peripheral direction toward the spinal column, optionally passes through or partially through a foramen and is implanted so that at least some of the electrodes 106 are positioned on, about or in proximity to the DRG.

[0116] In order to position the lead 104 in such close proximity to the DRG, the lead 104 is appropriately sized and configured to maneuver through the anatomy. Such maneuvering includes atraumatic epidural advancement along the spinal cord S, through a sharp curve toward a DRG, and optionally through a foramen wherein the distal end of the lead 104 is configured to then reside in close proximity to a small target such as the DRG. Consequently, the lead 104 is significantly smaller and more easily maneuverable than conventional spinal cord stimulator leads. Example leads and delivery systems for delivering the leads to a target such as the DRG are provided in US Provisional Patent Application No. 61/144,690, filed January 14, 2009 entitled "STIMULATION LEAD, DELIVERY SYSTEM AND METHODS OF USE" by Fred I. Linker et al.

[0117] In addition, by positioning the electrodes 106 in close proximity to the target tissue, less energy is required for stimulation. This reduction in energy allows a reduction in electrode size, among other benefits. In some embodiments, the average electrode surface area is approximately 1-6 mm^2, particularly approximately 2-4 mm^2, more particularly 3.93 mm^2 whereas conventional spinal cord stimulators typically have a much larger average electrode surface area, such as 7.5 mm^2 for some leads or 12.7mm^2 for traditional paddle leads. Likewise, in some embodiments an average electrode length is 1.25mm whereas conventional spinal cord stimulators typically have an average electrode length of 3mm. Such reduced electrode sizing allows more intimate positioning of the electrodes in the vicinity of the DRG and allows for IPGs having different control and performance parameters for providing direct and selective stimulation of a targeted neural tissue, particularly the DRG. In addition, in some embodiments, the overall dimensions of one or more electrodes and the spacing of the electrodes is selected to match or nearly match the overall dimensions or size of the stimulation target. In an embodiment where the targeted neural tissue is a substantial portion of a dorsal root ganglion, the electrode or electrodes arrayed along the lead are sized and spaced so that a majority of the electrodes lie along the overall dimensions of the dorsal root ganglion. For example, if there are 4 electrodes on a lead to stimulate a dorsal root ganglion having a length of about 8 mm, then the overall length of the electrode portion of the lead should be between about 6-10 mm. Fig. 18 illustrates one example where all 4 of the electrodes on the lead are within the lateral dimension of the DRG as shown. The size and spacing of the electrodes may align with other DRG dimensions as well. In one specific aspect, the spacing of the electrodes is such that when placed near the targeted dorsal root ganglion two or more electrodes are in position to provide therapeutic energy to the targeted dorsal root ganglion. Since the size of the ganglion depends on the spinal level and other factors, a variety of different electrode sizes and spacing may be used to tailor the electrode portion to selected dorsal root ganglia. It may also be appreciated that in some embodiments, the electrodes 106 are directional so as to provide direct and selective stimulation and further decrease energy required for stimulation.

[0118] In some embodiments, the electrodes 106 are spaced 5 mm apart along the distal end of the lead 104. In other embodiments, the electrodes 106 are spaced 0.250 inches apart, from center to center, and 0.200 inches apart, from inside edge to inside edge. In most patients, the DRG has a size of 5-10mm. Therefore, typical spacing would allow two electrodes 106 to be in contact with the target DRG while the remaining two electrodes are in the vicinity of the target DRG. In some instances, the two electrodes 106 in contact with the DRG are used to stimulate the DRG while the remaining two electrodes 106 do not provide stimulation energy. In other instances, all four electrodes 106 provide stimulation energy to the DRG, two electrodes

providing energy to the DRG at a distance somewhat closer to the DRG than the other two electrodes. It may be appreciated that any combination of electrodes 106 may provide stimulation energy and each electrode 106 may provide a different level or type of stimulation signal. Consequently, a variety of electric field shapes may be generated, each shape potentially causing a different treatment effect. In many embodiments, the electric field shape will be elliptical. Likewise, the position of the electric field in relation to the anatomy may also be adjusted to potentially cause different treatment effects. Such effects will be described in greater detail below. It may also be appreciated that the electrodes 106 providing stimulation energy may change over time. For example, if a lead 104 has migrated, a different combination of electrodes 106 may be used to stimulate the target DRG in the new lead position.

[0119] As mentioned above, the intimate positioning of the leads 104 of the present invention allows the stimulation system 100 to have a variety of additional beneficial features. For example, positioning the leads 104 in such close proximity to the target tissue allows for smaller stimulation regions. This in turn allows for smaller electrode surface areas and reduced energy requirements. A reduction in energy requirements allows for smaller battery size, increased battery longevity and the possibility of the elimination of battery replacement or recharging altogether. Typically, patients with conventional systems either have an IPG with a standard battery wherein the IPG is surgically replaced when the battery wears out or they have an IPG with a rechargeable battery wherein the battery is recharged by an external device worn for a few hours every two or three weeks. In contrast, the system 100 of the present invention draws such low energy that the battery longevity is sufficient for the life of the device. Thus, the patient will not need to undergo additional surgeries to replace the battery, therefore reducing any risks of surgical complications. The patient will also not need to recharge the battery which increases quality of life and provides for more continuous therapy. In both cases, less clinical follow-up may be necessary which reduces costs and increases patient satisfaction. However, it may be appreciated that rechargeable batteries may be used.

[0120] The energy requirement for the stimulation system 100 of the present invention is exceptionally low, particularly in comparison to conventional spinal cord stimulation systems. Energy is the work done in moving an electric charge (q) between two points with a potential difference (v) between them. Recall that if (q) is the electric charge, which varies with time (t), then the resulting current is given by i=dq/dt. The unit of current is the ampere. Power is the rate in which work is done. Consider a charge (dq) moving from point A to point B in a time interval (dt) and let the potential difference between A and B be (v). Then the work done on the charge (dq) is

$$dw = v\,dq = v(i\,dt)$$

Then the power is given by

$$p = dw/dt = vi$$

The unit of power is the watt. One watt equals 1 joule/second. As mentioned, energy is the work done in moving an electric charge (q) between two points with a potential difference between them. Since power equals the derivative of energy, energy equals the integral of power. The energy delivered or received by a component at time (t) is therefore given by

$$w(t) = \int p(t)dt$$

The unit of energy is joules. The movement of electric charge (q) between these two points depends on the resistance R.

$$R = v(t)/i(t)$$

A unit of resistance is the ohm (Ω). Therefore, one ohm equals 1 volt/amp. And, therefore:

$$p(t) = R[i(t)]^2$$

Thus, energy delivered or received by a component at a time (t) is also related to resistance.

[0121] To determine the differences in energy requirement between the stimulation system 100 of the present invention and conventional spinal cord stimulation systems, the respective stimulation signals can be compared. In one embodiment, the stimulation signal of the present invention has a rectangular waveform, such as illustrated by a trace 120 shown in Fig. 19A, wherein the pulse width is approximately 80μs and the current amplitude is approximately 200μA. The integral of this curve (i.e. the area under this curve) is the total charge, corresponding to the energy and related to tissue impedance. In this example, the charge delivered is (200μA)x(80μs)=16nC per pulse. Fig. 19B illustrates an embodiment of a trace 122 showing the voltage response to a complex impedance stimulating biological tissue. Thus, the total energy used is 7nJ, wherein the Warburg resistance is 650 Ω, the Warburg capacitance is 0.2μF and the tissue resistance is 1000 Ω.

[0122] Fig. 20A illustrates a trace 124 representing an example stimulation signal of a conventional spinal cord stimulator. Here the pulse width is approximately 200μs and the current amplitude is approximately 1.7mA (or 1700μA) which is around an order of magnitude greater than the current amplitude of the stimulation system 100 of the present invention. Thus, the charge delivered is (200μs)x(1.7mA)=340nC. Fig. 20B illustrates an embodiment of a trace 126 representing the voltage response to a complex impedance stimulating biological tissue.

Thus, the total energy used is 1294nJ, wherein the Warburg resistance is 200 Ω, the Warburg capacitance is 0.5μF and the tissue resistance is 1000 Ω. In this example, the energy supplied by the stimulation system 100 of the present invention is 0.54% (7nJ/1294nJ) of the energy supplied by conventional stimulation systems. This significant reduction in energy is due to the lower energy requirements of selectively stimulating the target anatomy, particularly the DRG. Typically, the energy supplied by the stimulation system 100 of the present invention is less than 10% of conventional systems, particularly less than 5%, more particularly less than 1%.

[0123] It may be appreciated that the above example is for illustrative purposes. Fig. 21 illustrates additional data indicating the stimulation signal parameters which selectively targeted the DRG. As shown, there is an energy threshold in which the DRG is stimulated which is below the energy threshold in which the ventral root is stimulated. By providing stimulation signals below the ventral root threshold, the patient's pain sensations may be blocked without the negative side effects of ventral root stimulation.

[0124] Due to variability in patient anatomy, pain profiles, pain perception and lead placement, to name a few, signal parameter settings will likely vary from patient to patient and from lead to lead within the same patient. Signal parameters include voltage, current amplitude, pulse width and repetition rate, to name a few. In some embodiments of the stimulation system 100 of the present invention, the voltage provided is in the range of approximately 0-7 volts. In some embodiments, the current amplitude provided is less than approximately 4 mA, particularly in the range of approximately 0.5-2mA, more particularly in the range of approximately 0.5-1.0mA, 0.1- 1.0mA, or 0.01-1.0mA. Further, in some embodiments, the pulse width provided is less than approximately 2000 μs, particularly less than approximately 1000μs, more particularly less than approximately 500μs, or more particularly 10-120μs. And, in some embodiments, the repetition rate is in the range of approximately 2-120Hz, up to 200 Hz or up to 1000Hz.

[0125] Typically, stimulation parameters are adjusted until satisfactory clinical results are reached. Thus, there is an envelope of stimulation parameter value combinations between the threshold for DRG stimulation and ventral root stimulation for any given lead positioned in proximity to any given DRG per patient. The specific combinations or possible combinations that could be used to successfully treat the patient are typically determined perioperatively in vivo and postoperatively ex vivo and depend on a variety of factors. One factor is lead placement. The closer the desired electrodes are to the DRG the lower the energy required to stimulate the DRG. Other factors include electrode selection, the anatomy of the patient, the pain profiles that are being treated and the psychological perception of pain by the patient, to name a few. Over time, the parameter values for any given lead to treat the patient may change

due to changes in lead placement, changes in impedance or other physical or psychological changes. In any case, the envelope of parameter values is exceedingly lower than those of conventional stimulation systems which require energy delivery of at least an order of magnitude higher to treat the patient's pain condition.

[0126] Given the lower ranges of parameter values for the system 100 of the present invention, the granularity of control is also smaller in comparison to conventional stimulation systems. For example, current in a conventional stimulation system is typically adjustable in increments of 0.1 mA. In some embodiments of the present invention, this increment is larger than the entire range of current amplitude values that may be used to treat the patient. Thus, smaller increments are needed to cycle through the signal parameter values to determine the appropriate combination of values to treat the condition. In some embodiments, the system 100 of the present invention provides control of current amplitude at a resolution of approximately 25 μA, particularly when using a current amplitude under, for example, 2mA, however it may be appreciated that smaller increments may be used such as approximately 10 μA, 5 μA or 1μA . In other embodiments, control of current amplitude is provided at a resolution of approximately 50μA, particularly when using a current amplitude of, for example, 2mA or greater. It may be appreciated that such a change in resolution may occur at other levels, such as 1mA. Similarly, voltage in a conventional stimulation system is typically adjustable in increments of 100mV. In contrast, some embodiments of the present invention provide control of voltage at a resolution of 50 mV. Likewise, some embodiments of the present invention provide control of pulse width at a resolution of 10μs. Thus, it may be appreciated that the present invention provides a high granularity of control of stimulation parameters due to the low ranges of parameter values.

[0127] It may be appreciated that in some instances even lower levels of energy may be used to successfully treat a patient using the stimulation system 100 of the present invention. The closer a lead is positioned to a target DRG, the lower the level of energy that may be needed to selectively stimulate the target DRG. Thus, signal parameter values may be lower than those stated herein with correspondingly higher granularity of control.

[0128] Utilizing these signal parameter values, the stimulation profile is customized for the patient and programmed into the memory 108 of the IPG 102. As mentioned above, the IPG 102 is typically programmed through a computerized programming station or programming system. This programming system is typically a self-contained hardware/software system, or can be defined predominately by software running on a standard personal computer (PC). The PC or custom hardware can have a transmitting coil attachment or antenna to allow for the programming of implants, or other attachments to program external units. Patients are generally

provided hand-held programmers (patient programmer 300) that are more limited in scope than are the physician-programming systems (clinical programmer 200), with such hand-held programmers still providing the patient with some control over selected parameters. Thus, this allows for easy changes to the stimulation profile over time, as needed.

[0129] As mentioned previously, effective treatment of a condition may be achieved by directly stimulating a target anatomy associated with the condition while minimizing or excluding undesired stimulation of other anatomies. When such a condition is limited to or primarily affects a single dermatome, the present invention allows for stimulation of a single dermatome or regions within a dermatome (also referred to as subdermatomal stimulation). A dermatome is considered the body region that is innervated by a single spinal level. Fig. 22 illustrates the dermatomal arrangement or "map" of dermatomes along a patient P. The dermatomes form into bands around the trunk but in the limbs their organization is more complex as a result of the dermatomes being "pulled out" as the limb buds form and develop into the limbs during embryological development. Each dermatome is labeled according to its associated spinal level. Upper bodily regions are innervated by nerves traveling in the cervical spinal segments and as the innervation pattern progresses caudally so do the spinal segments innervating the dermatome. Thus, regions in the middle of the body (thorax, etc) are innervated by thoracic spinal segments and lower bodily regions are innervated by lumbar and sacral spinal segments.

[0130] The nerves innervating a dermatome originate from DRGs on the associated spinal level Since each dermatome is supplied by a single pair of DRGs, stimulation of one or both of these DRGs will substantially effect a single dermatome. Referring back to Fig. 17, the present invention provides for stimulation of a single DRG or a pair of DRGs on a single spinal level independently of other DRGs or nerve tissues in the surrounding area. This allows for a single dermatome to be stimulated. It may be appreciated that there is overlap of innervation between adjacent dermatomes. However, stimulation of one or more DRGs on a spinal level will largely affect the directly associated dermatome with significantly lesser affects in adjacent dermatomes. Likewise, stimulation of a single DRG on, for example, the right side of the spinal column will largely affect the right side of the body within the directly associated dermatome. Thus, stimulation of a single DRG may stimulate a portion of a single dermatome. This is not the case with conventional spinal stimulation systems which simultaneously stimulate multiple dermatomes. By design, such conventional systems cannot isolate a single dermatome or a portion of a dermatome for treatment and such stimulation will substantially affect more than one dermatome.

[0131] Fig. 23 schematically illustrates DRGs on various spinal levels with associated body regions that may be affected by selective stimulation of the individual DRGs. For example, stimulation of DRG1 on the right side of L5 may affect the foot, lower leg and/or low back on the right side of the patient. Likewise, stimulation of DRG2 on the right side of L4 may affect the leg and/or low back on the right side of the patient. Figs. 24A-25B illustrate these body regions along the dermatomes of the patient P. Fig. 24A illustrates the patient P from the back, including the dermatomes of the lower body and a schematic representation of the general area of the DRGs. The region of the L5 dermatome that is likely affected by stimulation of DRG1 is indicated by double-hatched lines. Likewise, Fig. 24B illustrates the patient P from the front, including the dermatomes of the lower body. Again, the region of the L5 dermatome that is likely affected by stimulation of DRG1 is indicated by double-hatched lines. This portion of the dermatome extends along the bottom of the right foot, the top of the right foot, along the lower leg and up to the low back. Similarly, the region of the L4 dermatome that is likely affected by stimulation of DRG2 is indicated by hatched lines in both Fig. 24A and Fig. 24B. This portion of the dermatome mainly extends along the front of the lower leg and up to the low back. Thus, for patients having pain or another condition in these body regions, DRG1 and DRG2 may be stimulated so as to treat such conditions while minimally or not affecting other body regions.

[0132] Referring back to Fig. 23, traditional placement of a conventional spinal stimulation system (such as illustrated in Fig. 5) is also illustrated wherein the lead 14 is positioned along the midline of the spinal column S so that the electrodes 20 are aligned with the saggittal and parasaggittal midline. Such placement causes the electrodes 20 to stimulate many neural fibers innervating body regions unassociated and unaffected by the condition for which treatment is desired. In this example, stimulation by the electrodes 20 would affect the T12, L1, L2, L3, L4, L5 dermatomes on both sides of the patient's body.

[0133] Fig. 25 schematically illustrates selective stimulation of DRG1 according to aspects of the present invention. As shown, a lead 104 is positioned so that at least one of the at least one electrode 106 is positioned on, near or about the target DRG (DRG1). Different body regions associated with DRG1 (foot, lower leg, low back) may be traced to specific sensory neurons within the DRG1. In particular, each sensory neuron includes a cell body or soma which may be targeted to stimulate the sensory neuron independently of other surrounding neurons. In this example, the lower leg is associated with soma N1, the low back is associated with soma N2, and the foot is associated with soma N3. It has been suggested by a variety of scientific studies that there is a specific somatotopic orientation of neurons (and associated somas) within the DRG subserving sensory function to distinct anatomy.

[0134] A somatotopic map is an anatomically specific orientation of sensory integration. It is well-known that once sensory information has traveled into the central nervous system, a "somatotopic" map is organized in the cortex of the brain. Thus, specific regions of the somatosensory cortex are involved in sensory processing from specific anatomical regions. Thus, stimulation of various regions of specific sub-regions of the somatosensory cortex will result in the perception of sensory input from specific anatomical regions. In addition, research has suggested that not only are there somatotopic maps within the central nervous system, but also in spinal neural structures such as the dorsal root ganglion. Typically, such mapping has been completed in animal studies by injecting tracer chemicals in peripheral anatomical structures and then looking at labeled cells in the DRG to see the relative distribution of those labeled cells. The dorsal root ganglion is a special neural structure that contains the cell bodies (soma) of the neurons that are innervating specific dermatomes. The understanding of a somatotopic map for the dorsal root ganglion may allow for the targeting of portions of the DRG to provide therapy to one or more specific regions within the dermatome associated with that DRG. Thus, subdermatomal targeting may allow very specific therapeutic application in the treatment of pain and other conditions.

[0135] Referring again to Fig. 25, portions of the DRG may be selectively stimulated to affect specific regions within a dermatome. In this embodiment, soma N1, soma N2, or soma N3 may be stimulated to cause different treatment effects. Likewise, two or more of the somas N1, N2, N3 may be stimulated in combination to cause further treatment effects. Each soma may be selectively stimulated by manipulation of one or more of the following features: position of the electrode(s) 106 in relation to the DRG, selection of the electrode combinations for stimulation, and programming of the stimulation signal parameters, such as pulse width, amplitude, and frequency. By such manipulation, a desired electrical field is generated and positioned relative to the DRG to stimulate a particular portion of the DRG in three-dimensional space. This particular portion typically includes the one or more somas which are targeted to influence the desired treatment effect.

[0136] Figs. 26A-26D illustrate perspective views of a lead 104 stimulating a portion of DRG1 to affect a specific region within a dermatome. Referring to Fig. 26A, DRG1 is shown to include soma N1, soma N2, and soma N3. The lead 104 is positioned on, near or about the DRG1 according to the methods of the present invention. In this example, two electrodes 106a, 106b are selected for stimulation while the remaining two electrodes 106c, 106d are neutral. An electric field 500 is generated by the two electrodes 106a, 106b according to chosen stimulation signal parameters so as to stimulate soma N3 while providing minimal or no stimulation to soma

N1 and soma N2. In this embodiment, soma N3 is associated with the body region of the foot whereas soma N1 is associated with the low back and soma N2 is associated with the lower leg. Thus, the patient will have a targeted treatment effect in the foot without a treatment effect in the low back and lower leg within the same dermatome. Fig. 26B rotates the view of Fig. 26A to illustrate the three-dimensional electric field 500 and its inclusion of soma N3 along with exclusion of soma N1 and soma N2. Likewise, Fig. 26C rotates the view of Fig. 26A to provide a perspective end view, wherein again the three-dimensional electric field 500 is shown to include soma N3 while excluding soma N1 and soma N2. And further, Fig. 25D rotates the view of Fig. 25A to provide a perspective bottom view of the lead 104 in proximity to the DRG1 so that the electric field 500 stimulates soma N3 while excluding soma N1 and soma N2.

[0137] Different somas may be selectively stimulated by physically moving the lead 104 in relation to the DRG1. For example, by moving the lead 104 along the surface of the DRG1, the electric field 500 can be moved to select different somas, such as soma N1 while excluding somas N2, N3. Or, the lead 104 can remain stationary in relation to the DRG1, and different electrodes 106 may be utilized for stimulation to move the electric field 500. Likewise, the shape of the electric field 500 can be changed by changing the electrode combination and/or changing the stimulation signal parameters. For example, the electric field 500 may be increased in size by changing stimulation signal parameters, such as increasing the amplitude. Or, the size of the electric field 500 may be increased by changing the electrode combination, such as by utilizing an additional electrode for stimulation. In this example, the size of the electric field 500 may be increased to include both soma N3 and soma N1, while substantially excluding soma N2. This would cause the patient to have a targeted treatment effect in the foot and low back without a treatment effect in the lower leg within the same dermatome. Similarly, the size of the electric field 500 may be increased to include somas N1, N2, N3. This would cause the patient to have a targeted treatment effect in the foot, low back and lower leg within the same dermatome.

[0138] Figs. 27-28 provide clinical data which illustrate the correlation between changes in electrode combination and/or signal parameters and the resultant changes in affected body region. The clinical data was gathered during a clinical trial in which the patient subjects were implanted with one or more leads 104 in accordance with the present invention. Each lead 104 was positioned so that at least one of its one or more electrodes 106 was on, near or about a DRG, such as illustrated in Figs. 17-18.

[0139] Fig. 27 provides a table of clinical data from Patient No. 1, wherein one lead (Lead No. 2) was implanted so as to stimulate a DRG on level L5. As shown in Row 1 of the table, each electrode or contact along the lead is labeled by number (1, 2, 3, 4) wherein there were four

electrodes present. Contact 1 and Contact 2 were configured as Off or Neutral (N). And, Contact 3 was configured as an anode (+) while Contact 4 was configured as a cathode (-). The signal parameters were set as follows: amplitude = 800μA, pulse width = 60μs, frequency = 70Hz. It may be appreciated that this clinical data was gathered in an effort to map body regions affected by stimulation of portions of the associated DRG. Therefore, the parameter settings were not necessarily within the desired ranges for treatment. At these signal parameter settings, the bottom of the patient's foot was affected by the stimulation. As shown in Row 2 of the table, the amplitude was raised to 1.8mA while all other variables remained the same. Consequently, both the patient's foot and calf were affected by the stimulation. Thus, the electric field provided by Contact 3 and Contact 4 was enlarged causing additional sensory neurons to be stimulated. Further, Row 3 of the table shows that when the amplitude was raised to 2.25mA, the affected body region was expanded to include the back of the knee. Likewise, Row 4 of the table shows that when the amplitude was raised to 2.75mA, the affected body region was expanded to include the hip and Row 5 of the table shows that when the amplitude was raised to 3.0mA, the affected body region was expanded to include the buttock. Thus, as the electric field provided by Contact 3 and Contact 4 changed shape, additional sensory neurons were stimulated causing additional body regions of the dermatome to be affected. This illustrates that subdermatomal stimulation may be achieved by manipulating the electric field and signal parameters.

[0140] Fig. 28 provides a table of clinical data from a different patient, Patient No. 2, wherein one lead (Lead No. 1) was implanted so as to stimulate a DRG on level L4. As shown in Row 1 of the table, each electrode or contact along the lead is labeled by number (1, 2, 3, 4) wherein there were four electrodes present. Contact 1 and Contact 2 were configured as Off or Neutral (N). And, Contact 3 was configured as an anode (+) while Contact 4 was configured as a cathode (-). The signal parameters were set as follows: amplitude = 325μA, pulse width = 120μs, frequency = 60Hz. Again, it may be appreciated that this clinical data was gathered in an effort to map body regions affected by stimulation of portions of the associated DRG. Therefore, the parameter settings were not necessarily within the desired ranges for treatment. At these signal parameter settings, the patient's calf was affected by the stimulation. As shown in Row 2 of the table, the amplitude was raised to 350 μA while all other variables remained the same. Consequently, both the patient's calf and knee were affected by the stimulation. Thus, the electric field provided by Contact 3 and Contact 4 was enlarged causing additional sensory neurons to be stimulated. Further, Row 3 of the table shows that when the amplitude was raised to 425 μA, the affected body region was expanded to include the hip. Thus, as the electric field provided by Contact 3 and Contact 4 was enlarged, additional sensory neurons were stimulated causing additional body regions of the dermatome to be affected.

[0141] Row 4 of the table of Fig 28 shows a change in the electrode configuration. Here, Contact 1 remained Off or Neutral (N) while Contact 2 was configured as a cathode (-), Contact 3 was configured as an anode (+) and Contact 4 was configured as a cathode (-). The signal parameters were set as follows: amplitude = 275μA, pulse width = 120μs, frequency = 60Hz. Consequently, at these signal parameter settings, the patient's calf to ankle was affected by the stimulation. Thus, in comparison to Row 1, although the amplitude was lowered, the altered shape of the electric field provided by the new electrode configuration allowed for additional sensory neurons to be stimulated.

[0142] A comparison of Row 5 and Row 6 illustrate the effect of changing electrode configuration while other variables remain the same. As shown in Row 5 of the table, Contact 1 was Off or Neutral (N) while Contact 2 was configured as a cathode (-), Contact 3 was configured as an anode (+) and Contact 4 was configured as a cathode (-). The signal parameters were set as follows: amplitude = 625μA, pulse width = 120μs, frequency = 60Hz. At these signal parameter settings, affected body regions were above the knee and to the side of the thigh. While keeping the same signal parameter settings, the electrode configuration was changed so that Contact 1 was Off or Neutral (N) while Contact 2 was configured as an anode (+), Contact 3 was configured as an cathode (-) and Contact 4 was configured as an anode (+), as shown in Row 6 of the table. This change in the electric field caused the affected body region to change to the front of the calf. Raising the amplitude, as shown in Row 7, increased the affected body region to include the knee. Row 8 shows a change in both amplitude and pulse width, which creates a different affect within the dermatome. And, again, raising the amplitude, as shown in Row 9, increases the affected body region. This further illustrates that subdermatomal stimulation may be achieved by manipulating the electric field and signal parameters to affect particular body regions while leaving other body regions substantially unaffected.

[0143] It may be appreciated that in some embodiments subdermatomal stimulation is achieved by factors other than or in addition to somatotopic mapping of the DRG. In these embodiments, body regions that are considered as focal areas of the condition for which the patient is being treated were preferentially affected by the stimulation. For example, when the condition being treated is pain, body regions that the patient considered to be painful are preferentially affected by the stimulation. This suggests that DRG stimulation therapy preferentially neuromodulates neural elements that are involved in the pain condition specific to the area of pain. This corroborates with basic neurophysiologic data that suggest both small diameter soma and large diameter neurons residing in the DRG involved in the neural transduction of pain and other somatosensory signals undergo physiologic changes that affect the

biophysics of the cell membrane. This suggests that neurons become hyperexcitable possibly through the altered function of transmembrane integral membrane proteins – in particular ion channels. This altered biophysical function of the cells involved in the processing of pain information would provide a basis for enhanced ability to neuromodulate the cell function with electrical fields. This, in turn, would underlie the ability to preferentially generate pain relief and paresthesias in the selected anatomically painful regions.

[0144] A variety of pain-related conditions are treatable with the systems, methods and devices of the present invention. In particular, the following conditions may be treated:

1) Failed Back Surgery syndrome

2) Chronic Intractable Low Back Pain due to:

A) Unknown Etiology

B) Lumbar facet disease as evidenced by diagnostic block(s)

C) Sacroiliac Joint disease as evidenced by diagnostic block(s)

D) Spinal Stenosis

E) Nerve root impingement – non-surgical candidates

F) Discogenic Pain – discography based or not

4) Complex Regional Pain Syndrome

5) Post-Herpetic Neuralgia

6) Diabetic Neuropathic Pain

7) Intractable Painful Peripheral Vascular Disease

8) Raynaud's Phenomenon

9) Phantom Limb Pain

10) Generalized Deaffrentation Pain Conditions

11) Chronic, Intractable Angina

12) Cervicogenic Headache

13) Various Visceral Pains (pancreatitis, etc.)

14) Post-Mastectomy Pain

15) Vuvlodynia

16) Orchodynia

17) Painful Autoimmune Disorders

18) Post-Stroke Pain with limited painful distribution

19) Repeated, localized sickle cell crisis

20) Lumbar Radiculopathy

21) Thoracic Radiculopathy

22) Cervical Radiculopathy

23) Cervical axial neck pain, "whiplash"

24) Multiple Sclerosis with limited pain distribution

Each of the above listed conditions is typically associated with one or more DRGs wherein stimulation of the associated DRGs provides treatment or management of the condition.

[0145] Likewise, the following non-painful indications or conditions are also treatable with the systems, methods and devices of the present invention:

1) Parkinson's Disease

2) Multiple Sclerosis

3) Demylenating Movement Disorders

4) Physical and Occupational Therapy Assisted Neurostimulation

5) Spinal Cord Injury - Neuroregeneration Assisted Therapy

6) Asthma

7) Chronic Heart Failure

8) Obesity

9) Stroke – such as Acute Ischemia

Again, each of the above listed conditions is typically associated with one or more DRGs wherein stimulation of the associated DRGs provides treatment or therapy. In some instances, Neuroregeneration Assisted Therapy for spinal cord injury also involves stimulation of the spinal column.

[0146] It may be appreciated that the systems, devices and methods of the present invention may alternatively or additionally be used to stimulate ganglia or nerve tissue. In such instances, the condition to be treated is associated with the ganglia or nerve tissue so that such stimulation provides effective therapy. The following is a list of conditions or indications with its associated ganglia or nerve tissue:

1) Trigeminal Neuralgia (Trigeminal Ganglion)

2) Hypertension (Carotid Sinus Nerve / Glossopharangyl Nerve)

3) Facial Pain (Gasserian Ganglion)

4) Arm Pain (Stellate Ganglion)

5) Sympathetic Associated Functions (Sympathetic Chain Ganglion)

6) Headache (Pterygoplatine Ganglion/Sphenopalatine Ganglion)

[0147] It may also be appreciated that the systems and devices of the present invention may also be used to stimulate various other nerve tissue including nerve tissue of the peripheral nervous system, somatic nervous system, autonomic nervous system, sympathetic nervous system, and parasympathetic nervous system, to name a few. Various features of the present invention may be particularly suited for stimulation of portions of these nervous systems. It may further be appreciated that the systems and devices of the present invention may be used to stimulate other tissues, such as organs, skin, muscle, etc.

[0148] It may be appreciated that although the lead is described herein as positionable so that the at least one electrode is on, near or about a target anatomy, at least one of the at least one electrode may optionally be positioned in the target anatomy.

[0149] Although the foregoing invention has been described in some detail by way of illustration and example, for purposes of clarity of understanding, it will be obvious that various alternatives, modifications, and equivalents may be used and the above description should not be taken as limiting in scope of the invention which is defined by the appended claims.

56179-2

CLAIMS:

1. A system for stimulating a target dorsal root ganglion to perform a targeted treatment, the system comprising:

a lead having at least one electrode, wherein the lead is configured to be positioned so that at least one of the at least one electrode is able to stimulate the target dorsal root ganglion; and

an implantable pulse generator connectable with the lead and configured to output a stimulation signal;

wherein a current amplitude of the stimulation signal output by the pulse generator is incrementally adjustable in response to user inputs accepted by an external programmer that wirelessly communicates with the implantable pulse generator;

wherein the system is configured such that when said current amplitude of the stimulation signal output by the pulse generator is at least a specified level said current amplitude is adjustable in first increments of 50 μA or less in response to user inputs accepted by the external programmer, and when said current amplitude is less than the specified level said current amplitude is adjustable in second increments of 25 μA or less in response to user inputs accepted by the external programmer;

wherein the specified level is a current amplitude level at which an increment resolution transitions from the first increments to the second increments, or vice versa;

wherein the second increments are less than the first increments; and

wherein the first and second increments enable adjustments to the current amplitude in small enough increments to identify a magnitude for the current amplitude that stimulates the target dorsal root ganglion, to achieve the targeted treatment, without stimulating a ventral root associated with the target dorsal root ganglion.

2. A system as in claim 1, wherein the current amplitude of the stimulation signal output by the pulse generator is less than or equal to approximately 4 mA.

3. A system as in claim 2, wherein the current amplitude of the stimulation signal output by the pulse generator is less than or equal to approximately 800 μA.

4. A system as in claim 1, wherein the at least one of the at least one electrodes has an average electrode surface area of less than or equal to approximately 6 mm2.

5. A system as in claim 4, wherein the average electrode surface area is less than or equal to approximately 4 mm2.

6. A system as in claim 1, further comprising a second lead having at least one electrode, wherein the second lead is configured to be positioned so that at least one of its electrodes is able to stimulate at least a portion of a second target dorsal root ganglion, and wherein the second lead is connectable to the implantable pulse generator which provides a second stimulation signal to the second lead, wherein the second stimulation signal to the second lead has an energy below an energy threshold for stimulating a ventral root associated with the second target dorsal root ganglion while the second lead is so positioned.

7. A system as in claim 6, wherein the target dorsal root ganglion and the second target dorsal root ganglion are on different spinal levels.

8. A system as in claim 6, wherein the stimulation signal to the lead and the second stimulation signal to the second lead are different.

9. A system as in claim 3 wherein the current amplitude of the stimulation signal output by the pulse generator is less than 100 μA.

10. A system as in claim 1 wherein the generator provides the stimulation signal which has an energy of less than approximately 100 nJ per pulse.

11. A system as in claim 10, wherein the stimulation signal has an energy of less than approximately 50 nJ per pulse.

12. A system as in claim 11, wherein the stimulation signal has an energy of less than approximately 10 nJ per pulse.

13. The system as in claim 1, wherein the specified level is 2 mA.

14. The system as in claim 1, wherein the specified level is 1 mA.

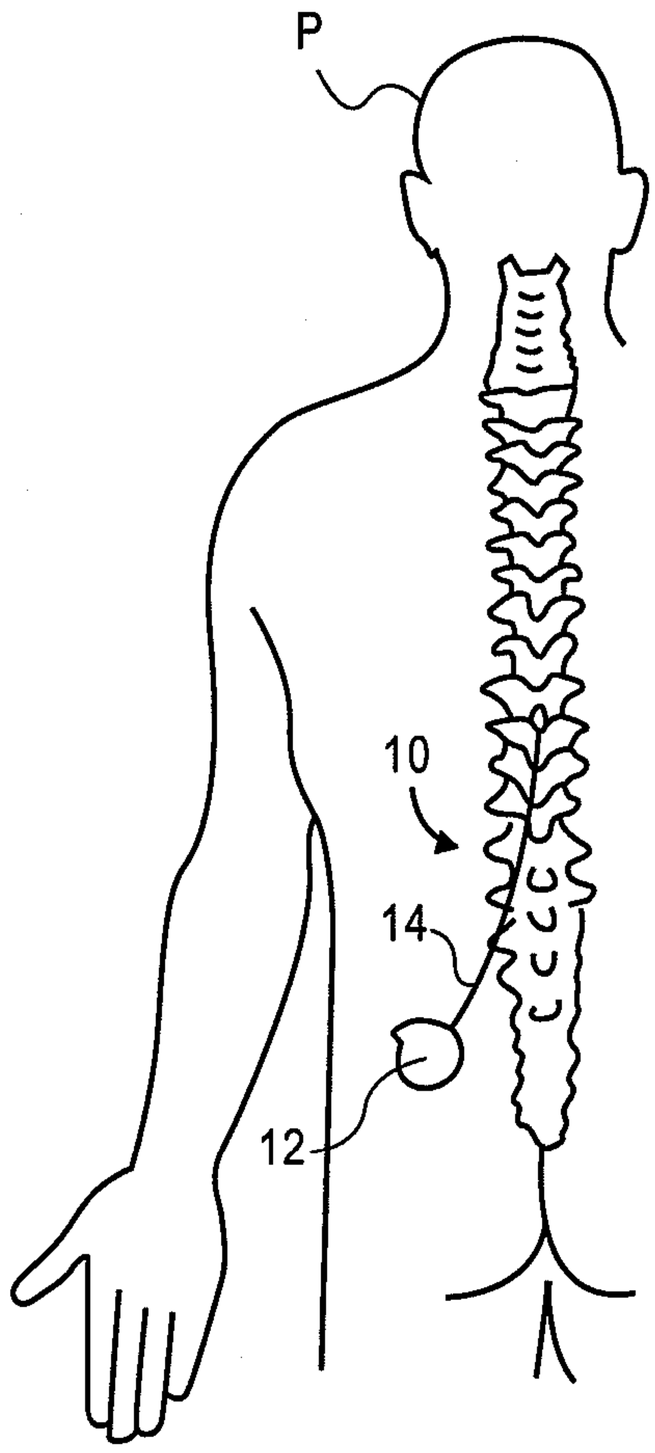

FIG. 1A
(PRIOR ART)

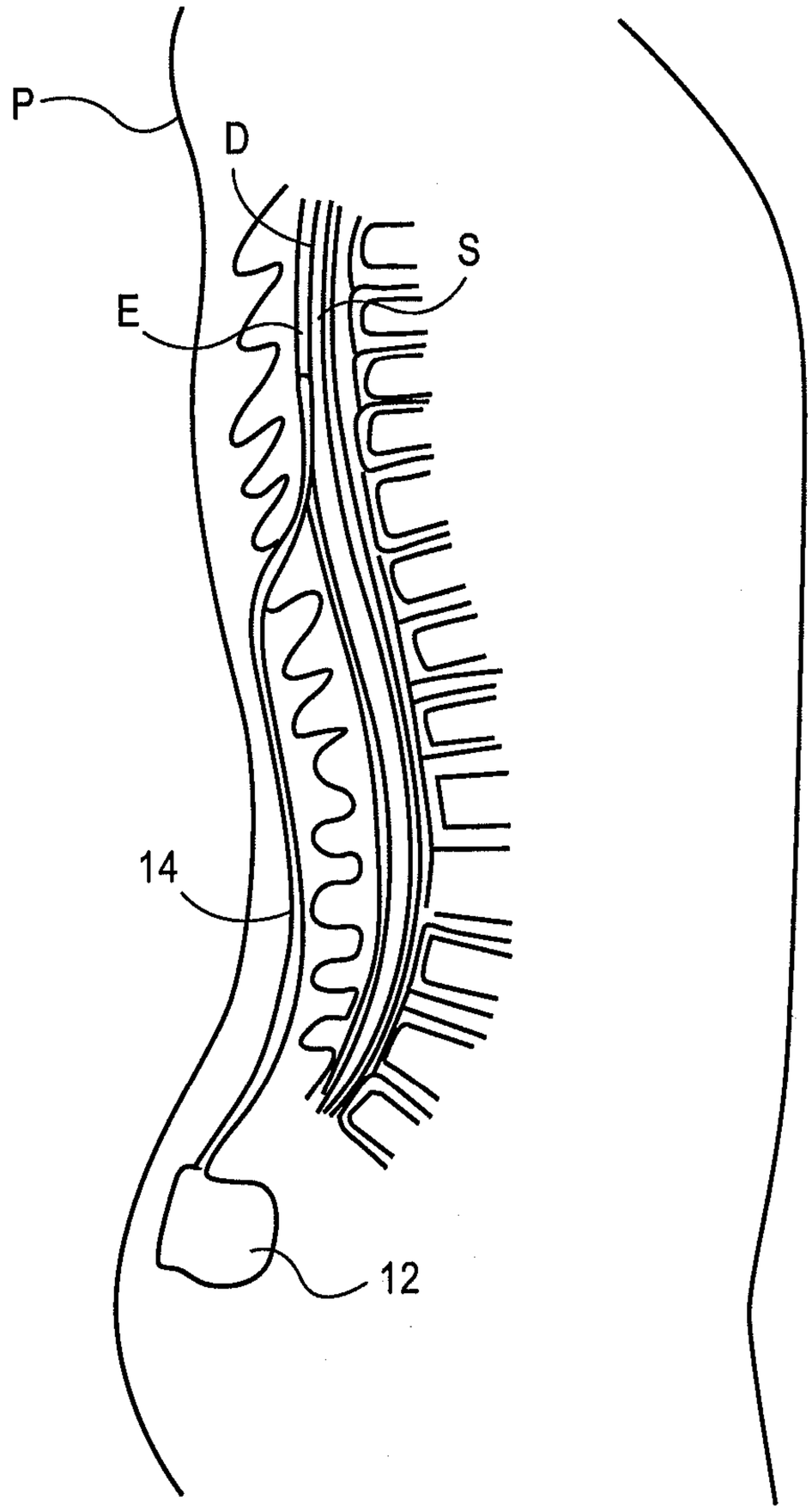

FIG. 1B
(PRIOR ART)

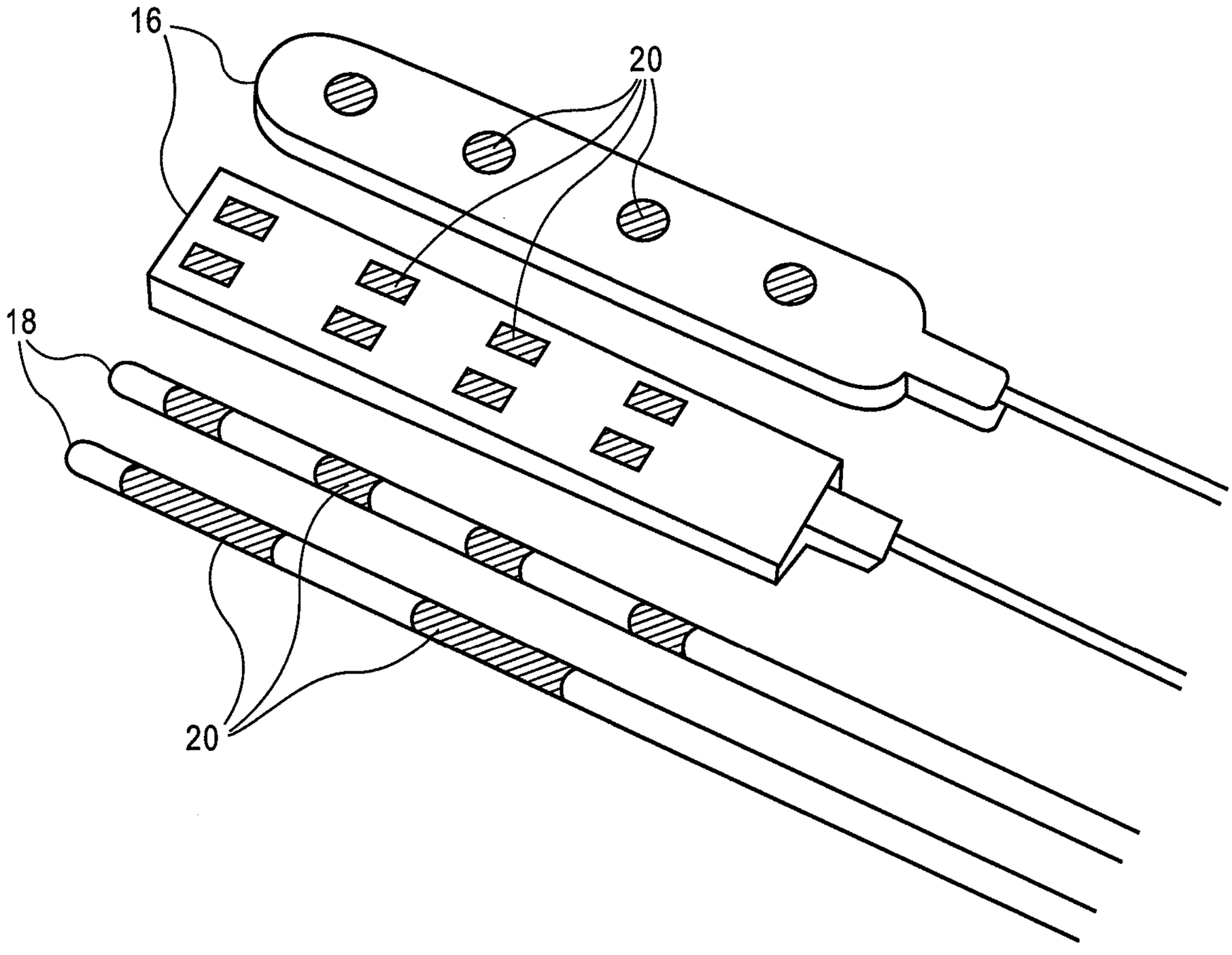

FIG. 2
(PRIOR ART)

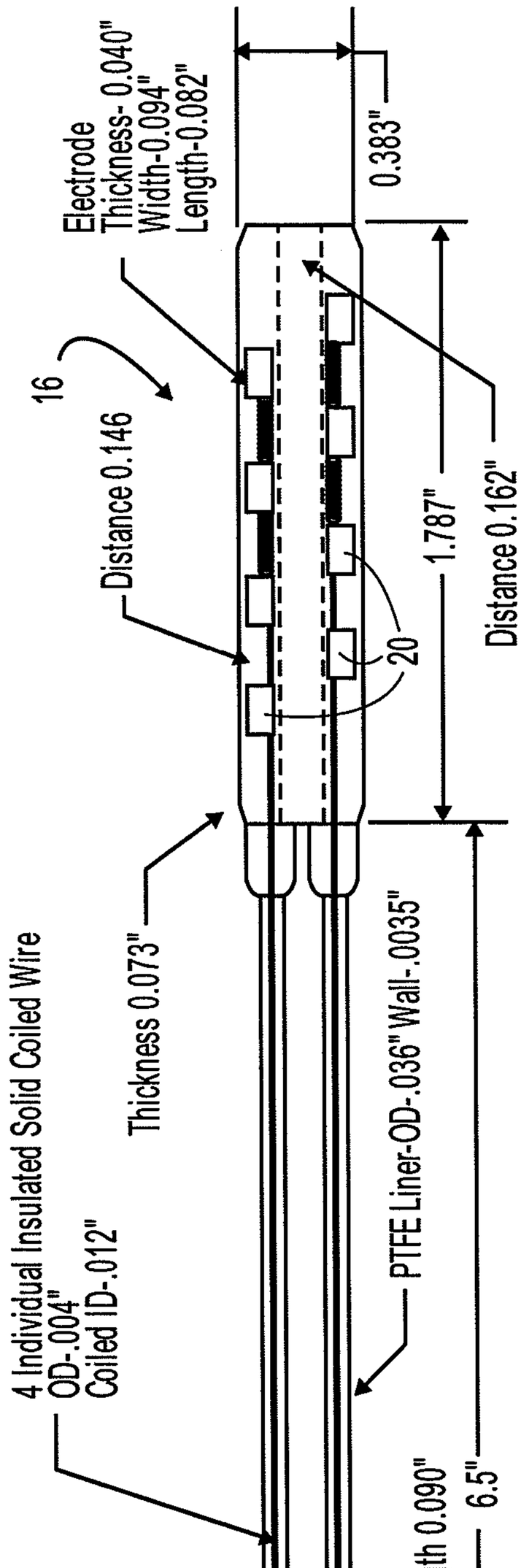

FIG. 3
(PRIOR ART)

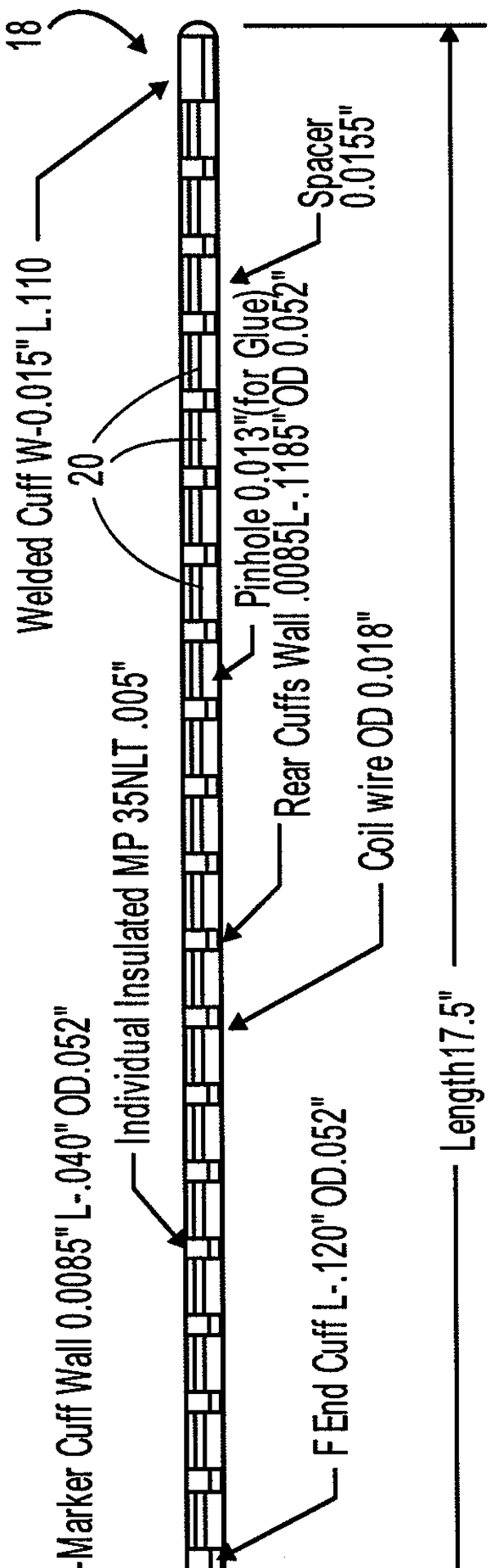

FIG. 4
(PRIOR ART)

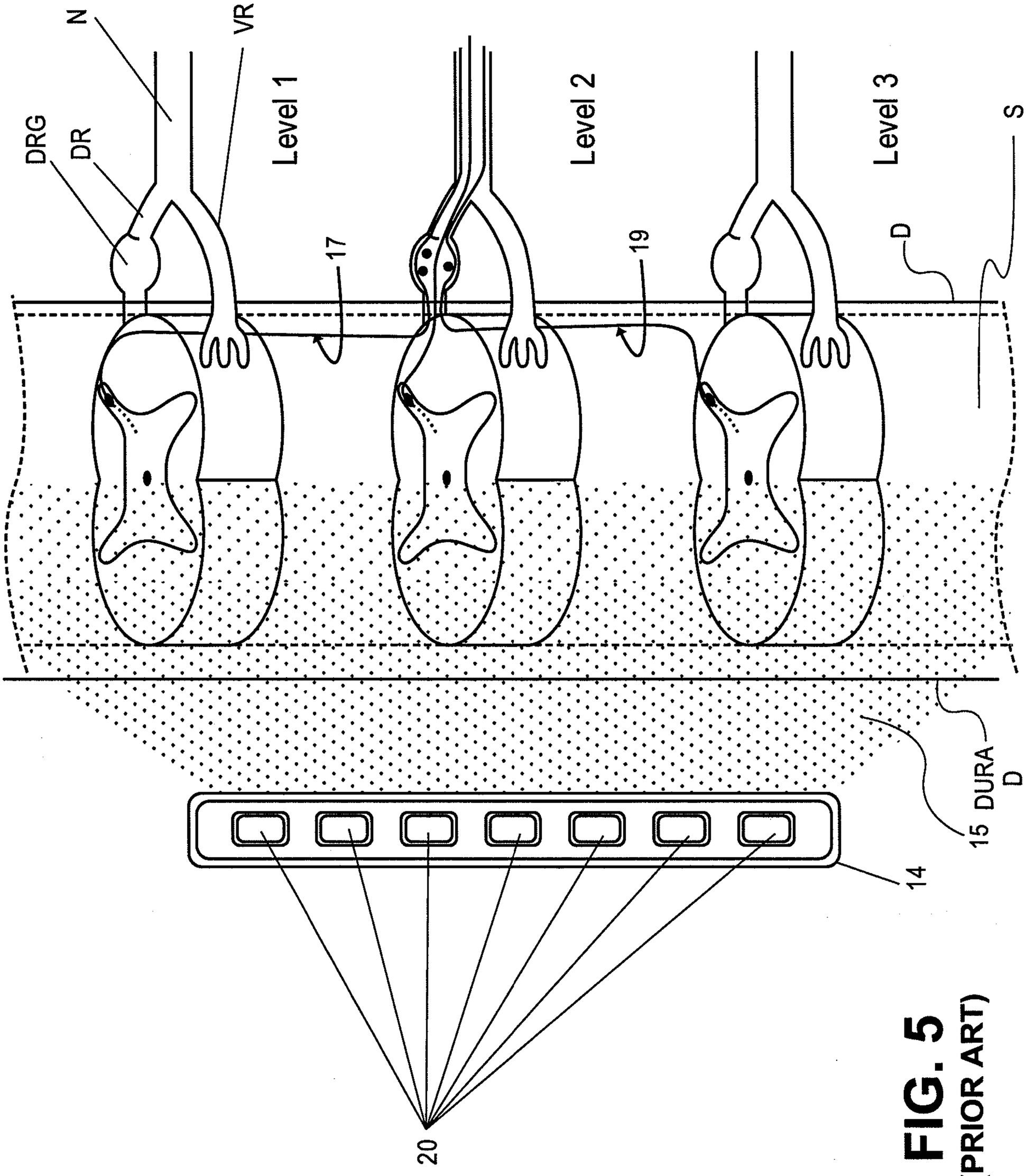

FIG. 5
(PRIOR ART)

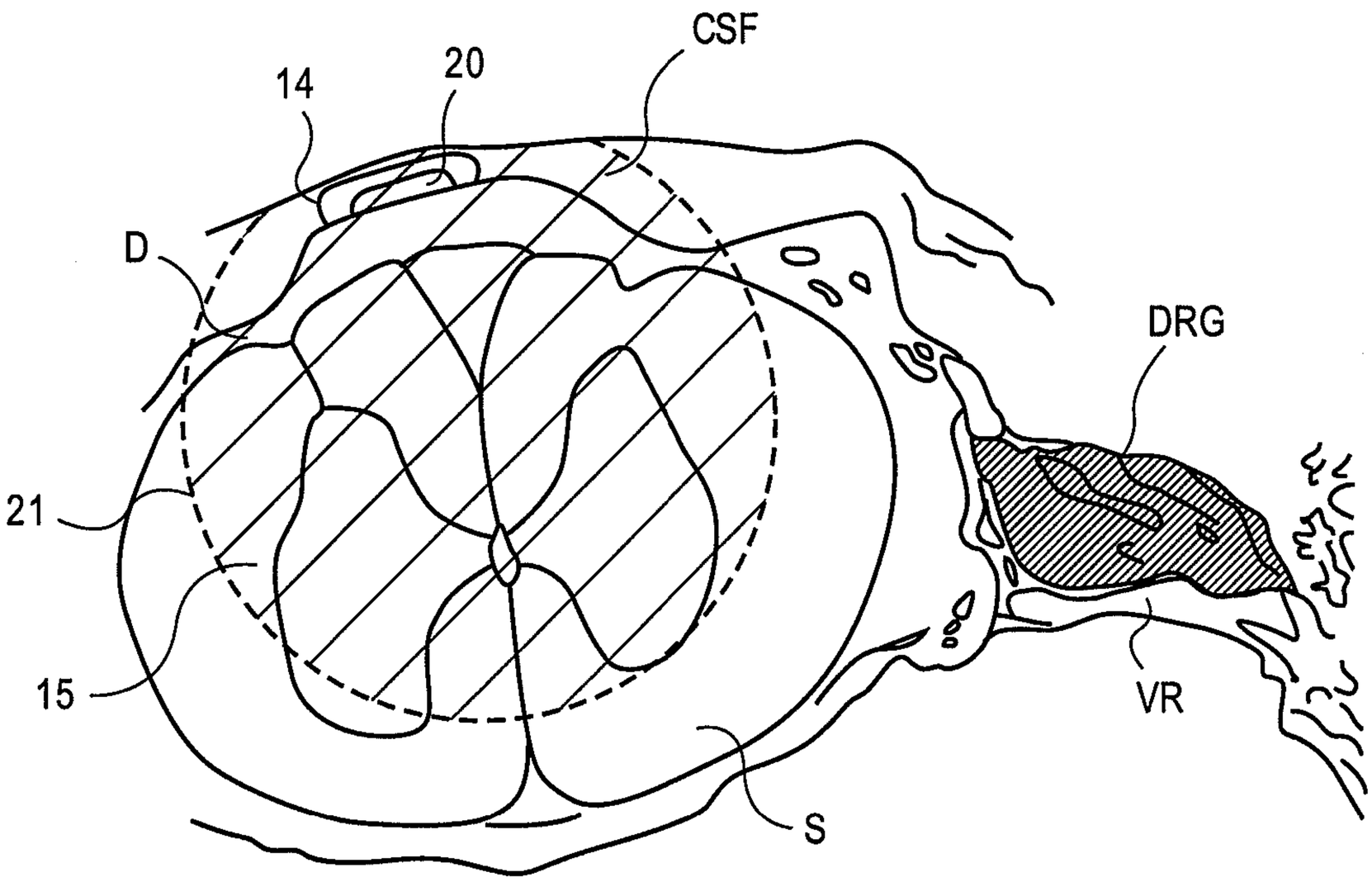

FIG. 6
(PRIOR ART)

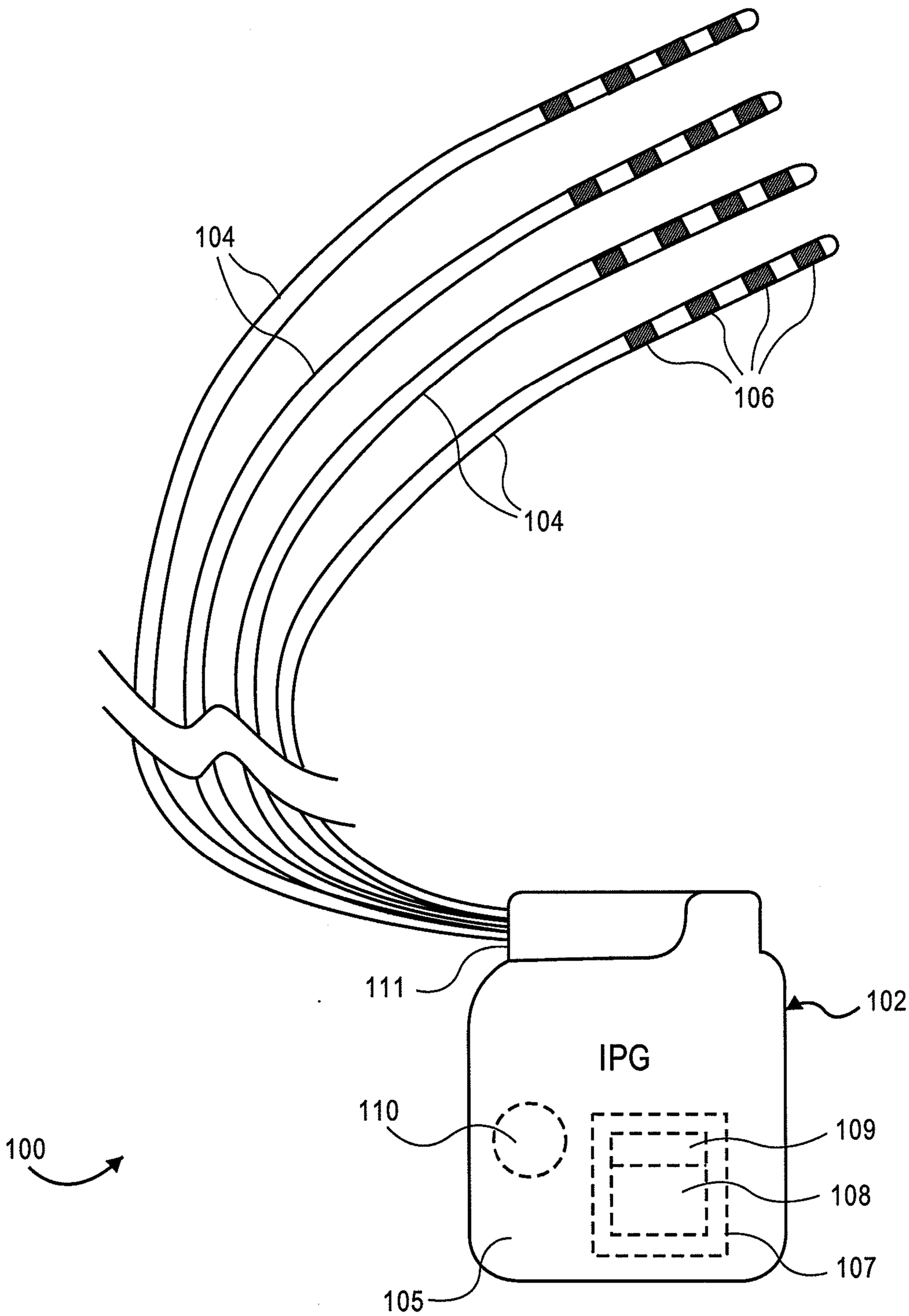

FIG. 7

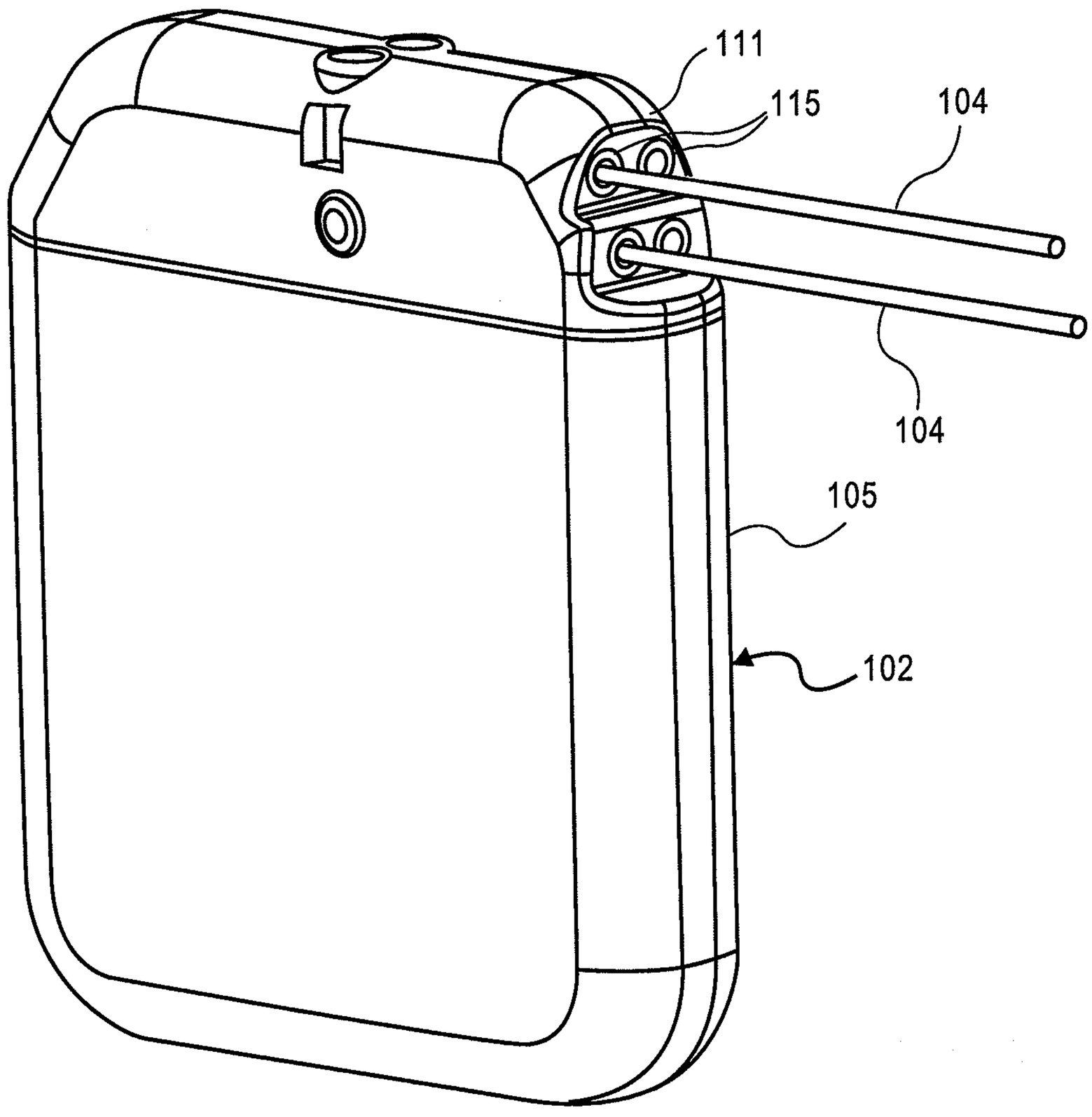

FIG. 8

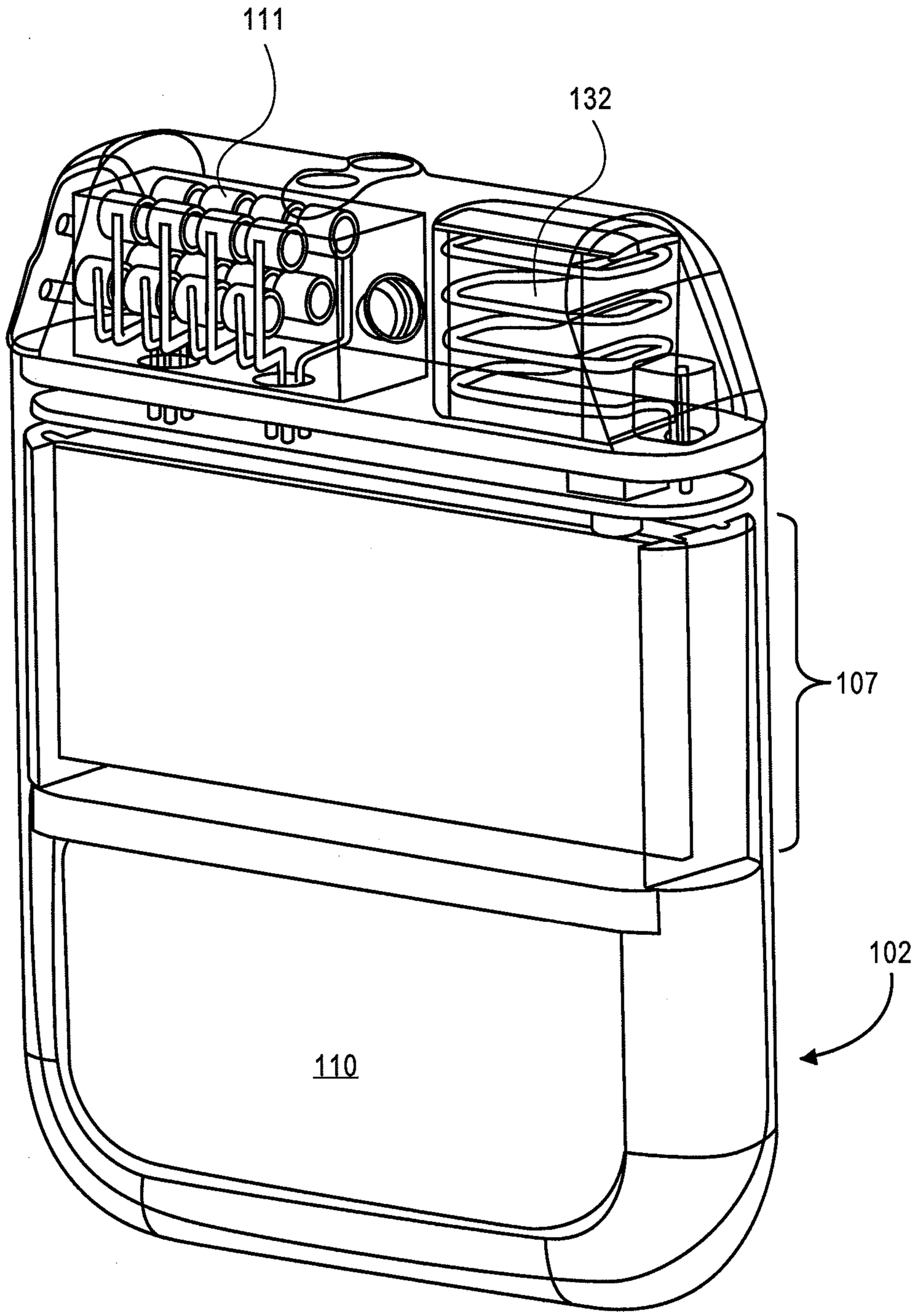

FIG. 9

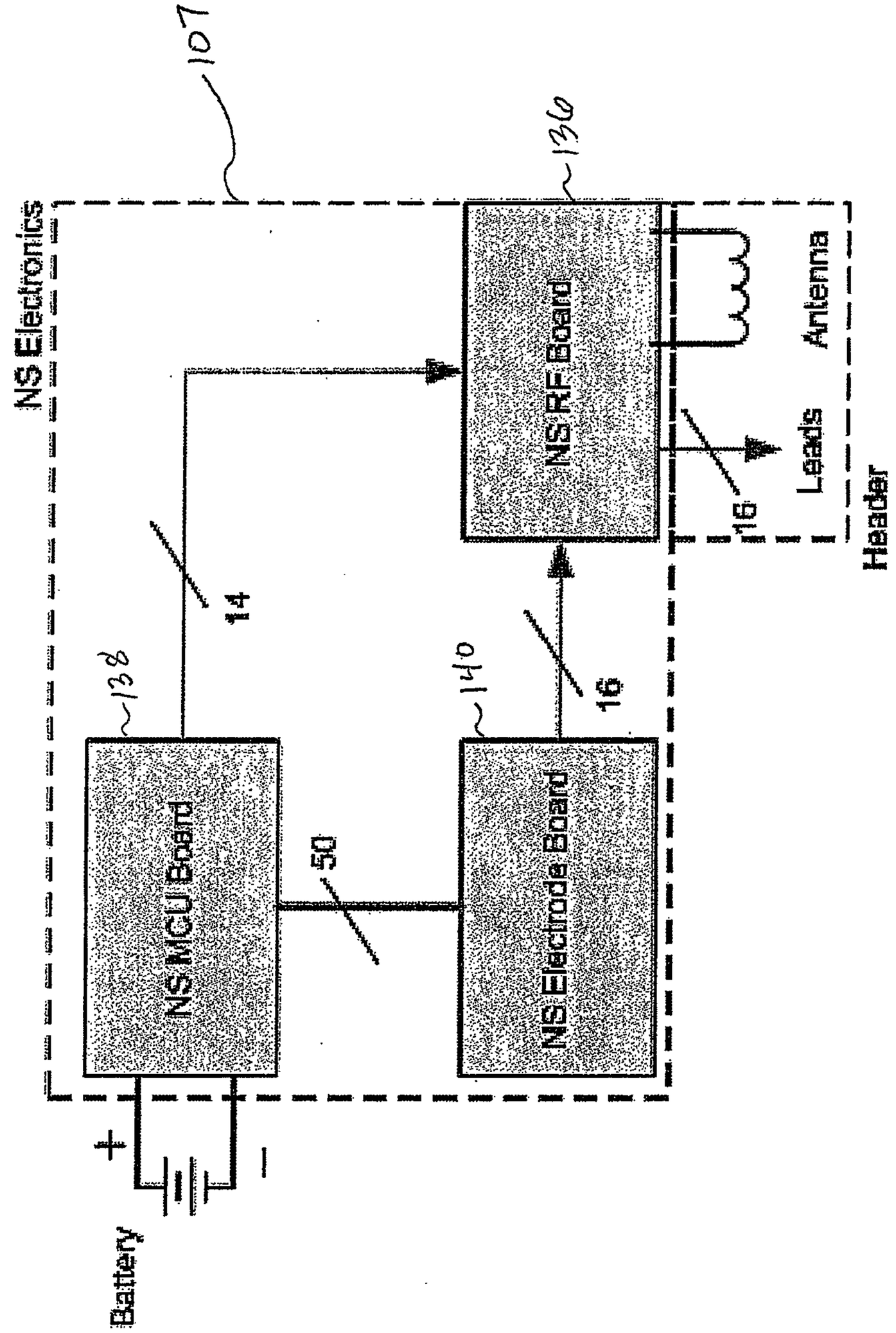
NS Electronics
107
130
NS RF Board
Antenna
Leads
Header
16
14
138
140
16
50
NS MCU Board
NS Electrode Board
+
-
Battery

FIG-1b

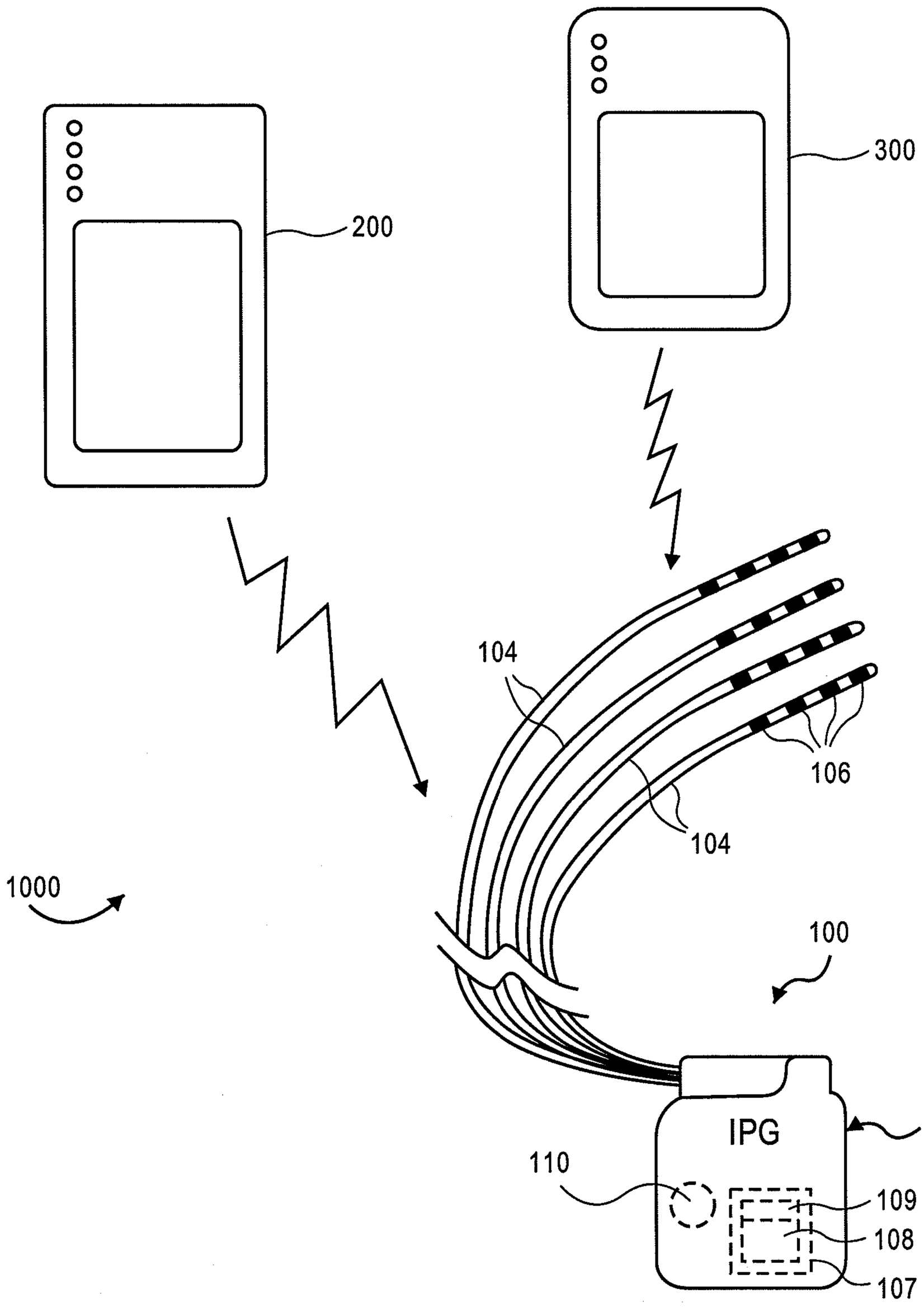

FIG. 11

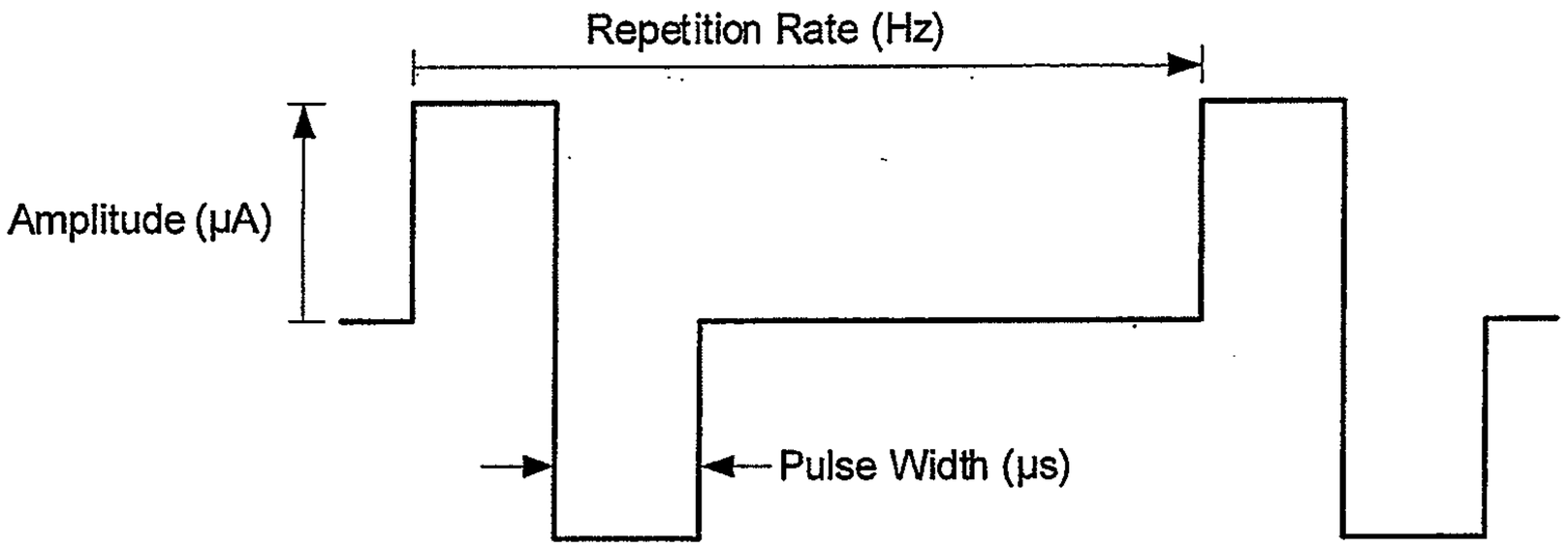
Repetition Rate (Hz)
Amplitude (μA)
Pulse Width (μs)

FIG_12

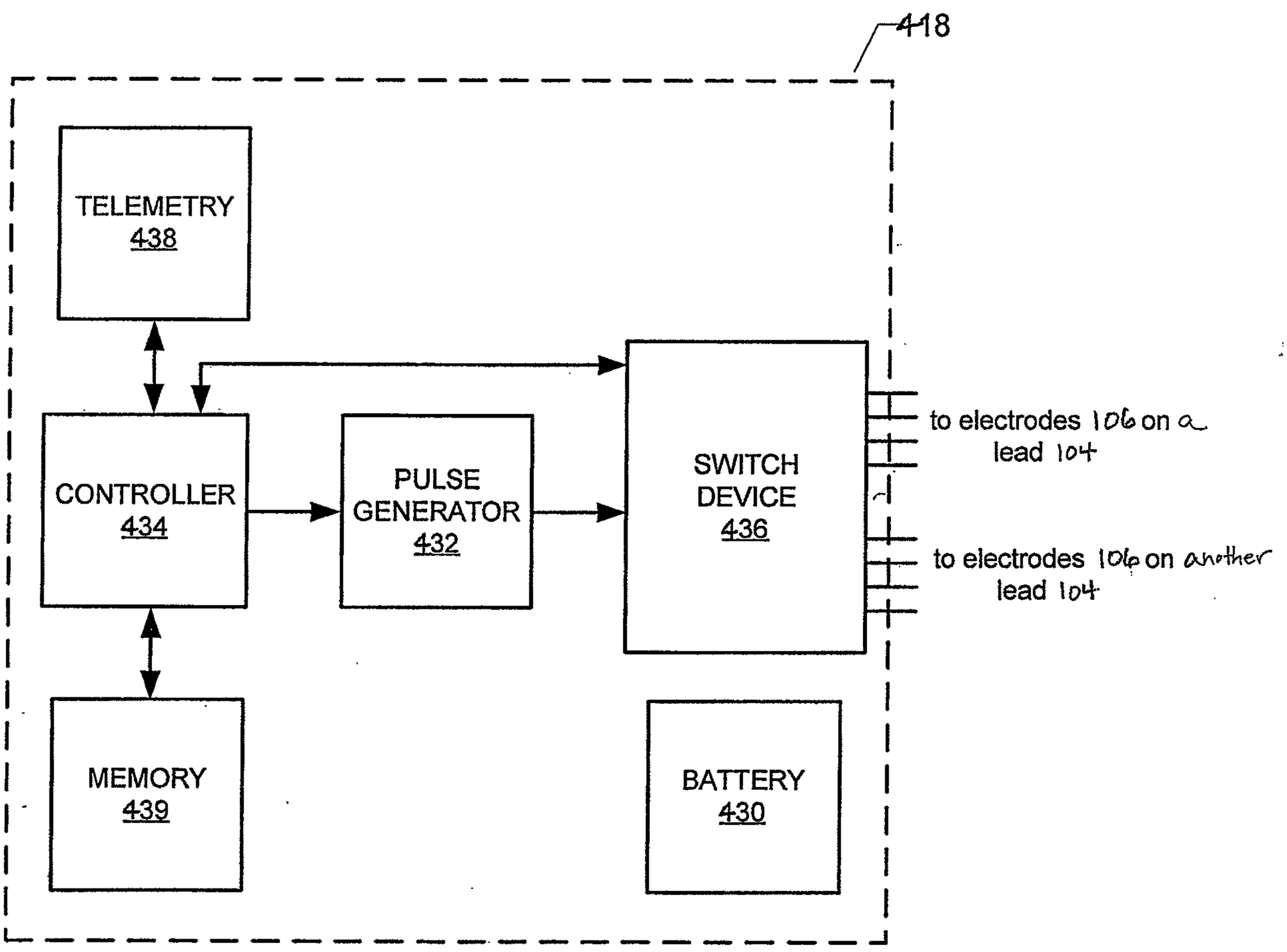
418
TELEMETRY
438
CONTROLLER
434
PULSE
GENERATOR
432
SWITCH
DEVICE
436
to electrodes 106 on a lead 104
to electrodes 106 on another lead 104
MEMORY
439
BATTERY
430

FIG_13

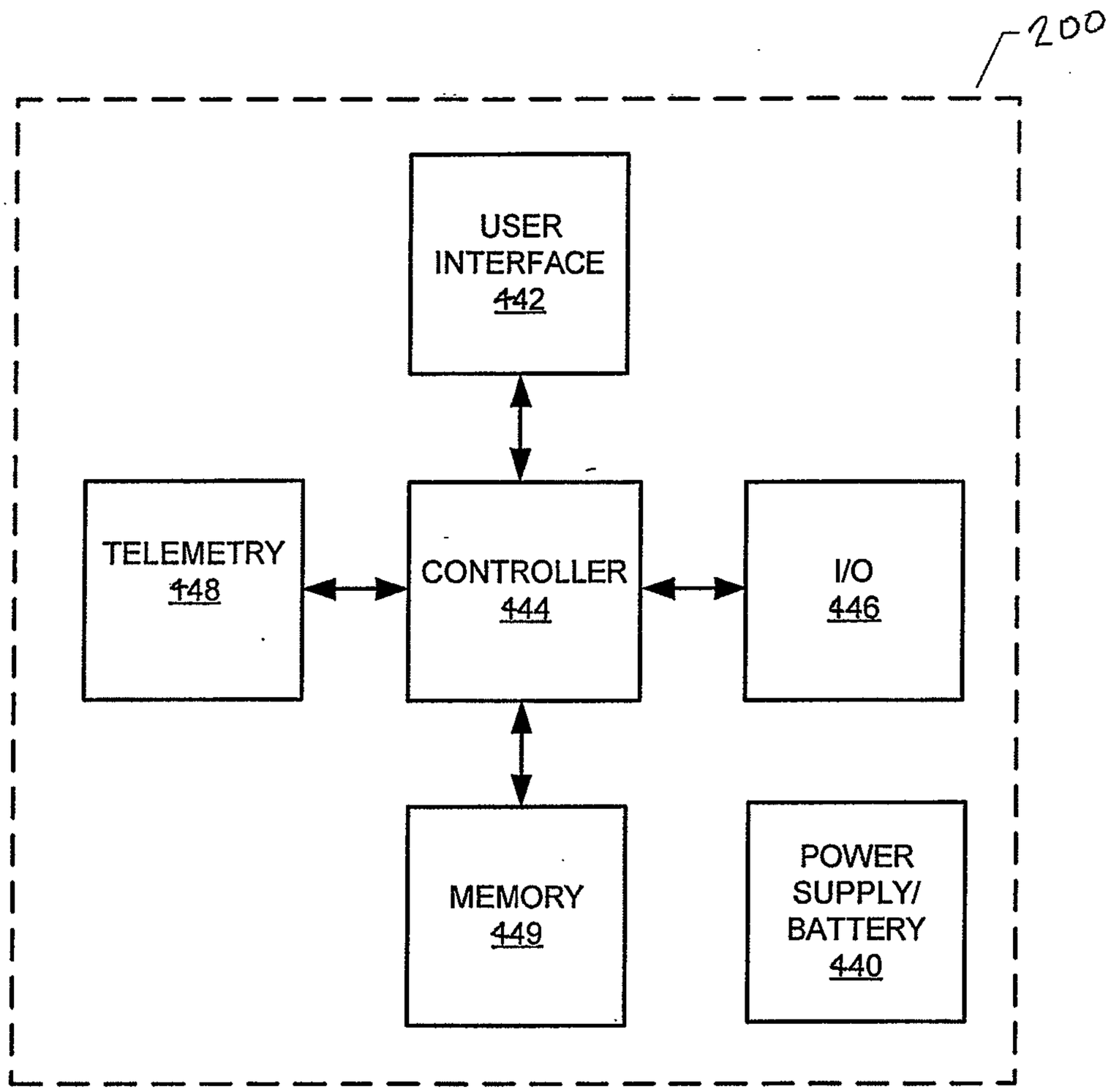
200
USER INTERFACE 442
TELEMETRY 448
CONTROLLER 444
I/O 446
MEMORY 449
POWER SUPPLY/ BATTERY 440

FIG. 14

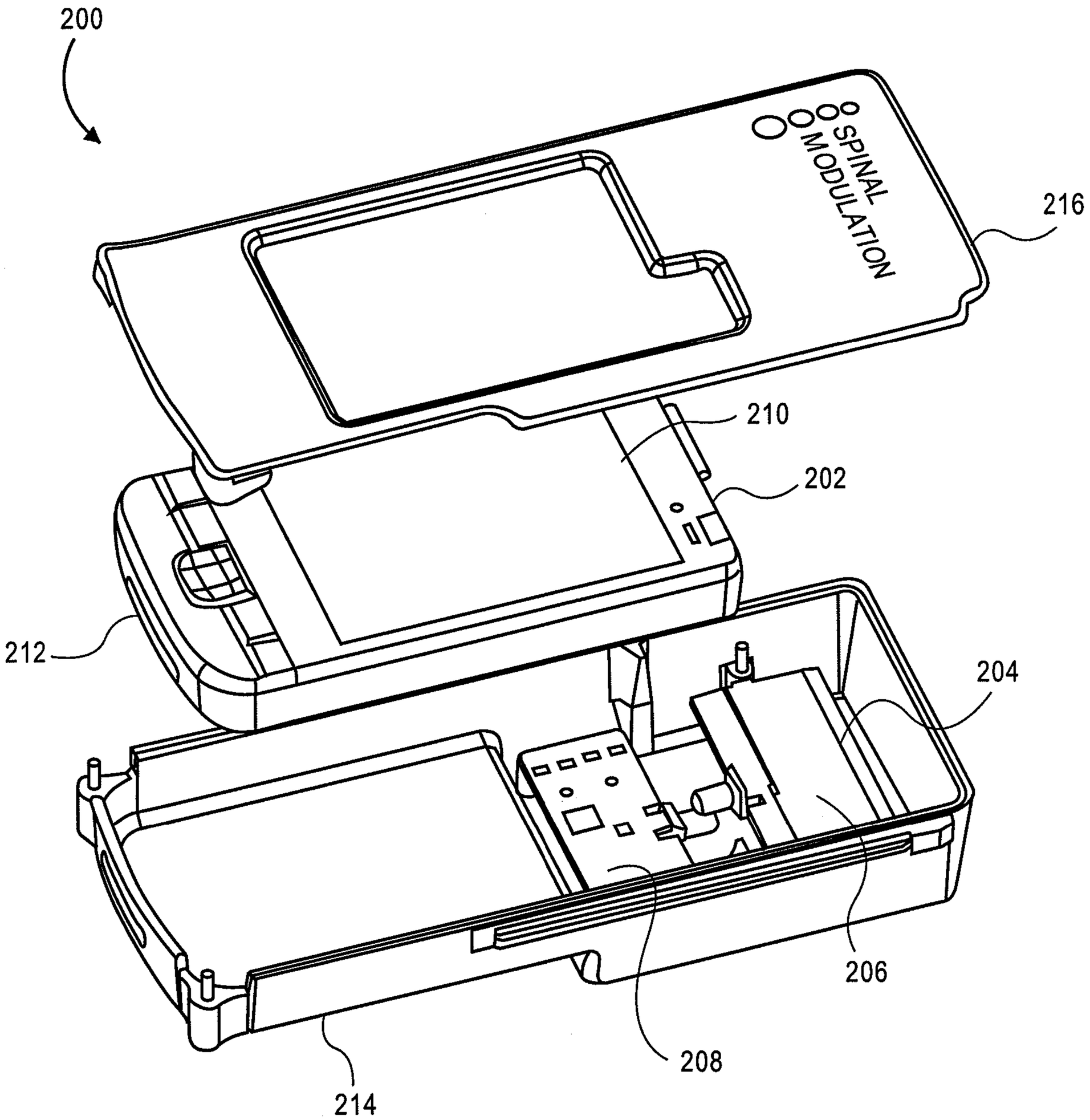

FIG. 15A

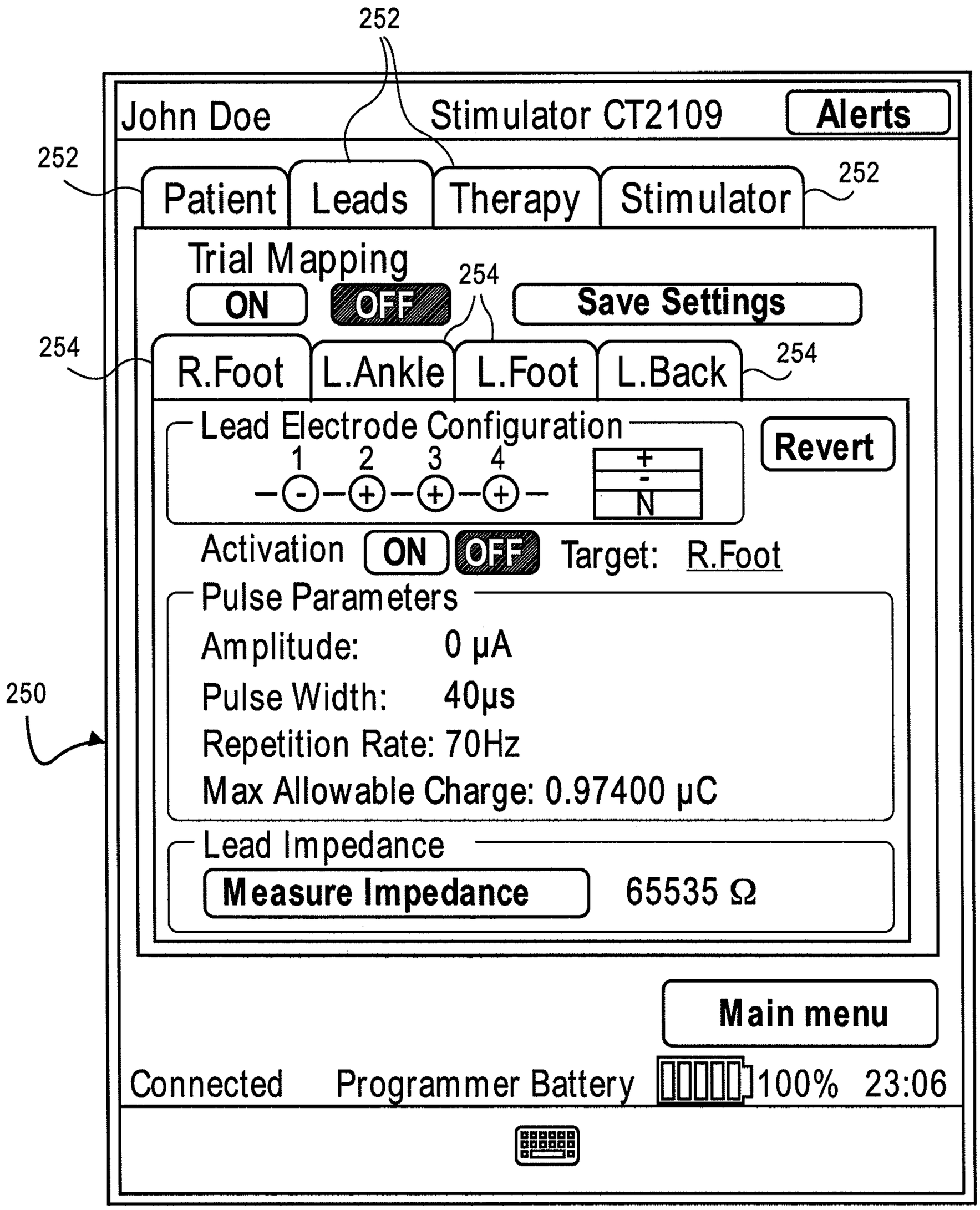
252
John Doe
Stimulator CT2109
Alerts
252
Patient
Leads
Therapy
Stimulator
252
Trial Mapping
ON
OFF
254
Save Settings
254
R.Foot
L.Ankle
L.Foot
L.Back
254
Lead Electrode Configuration
1 2 3 4
+
-
N
Revert
Activation ON OFF Target: R.Foot
Pulse Parameters
Amplitude: 0 µA
Pulse Width: 40µs
Repetition Rate: 70Hz
Max Allowable Charge: 0.97400 µC
Lead Impedance
Measure Impedance
65535 Ω
250
Main menu
Connected
Programmer Battery
100%
23:06

FIG. 15B

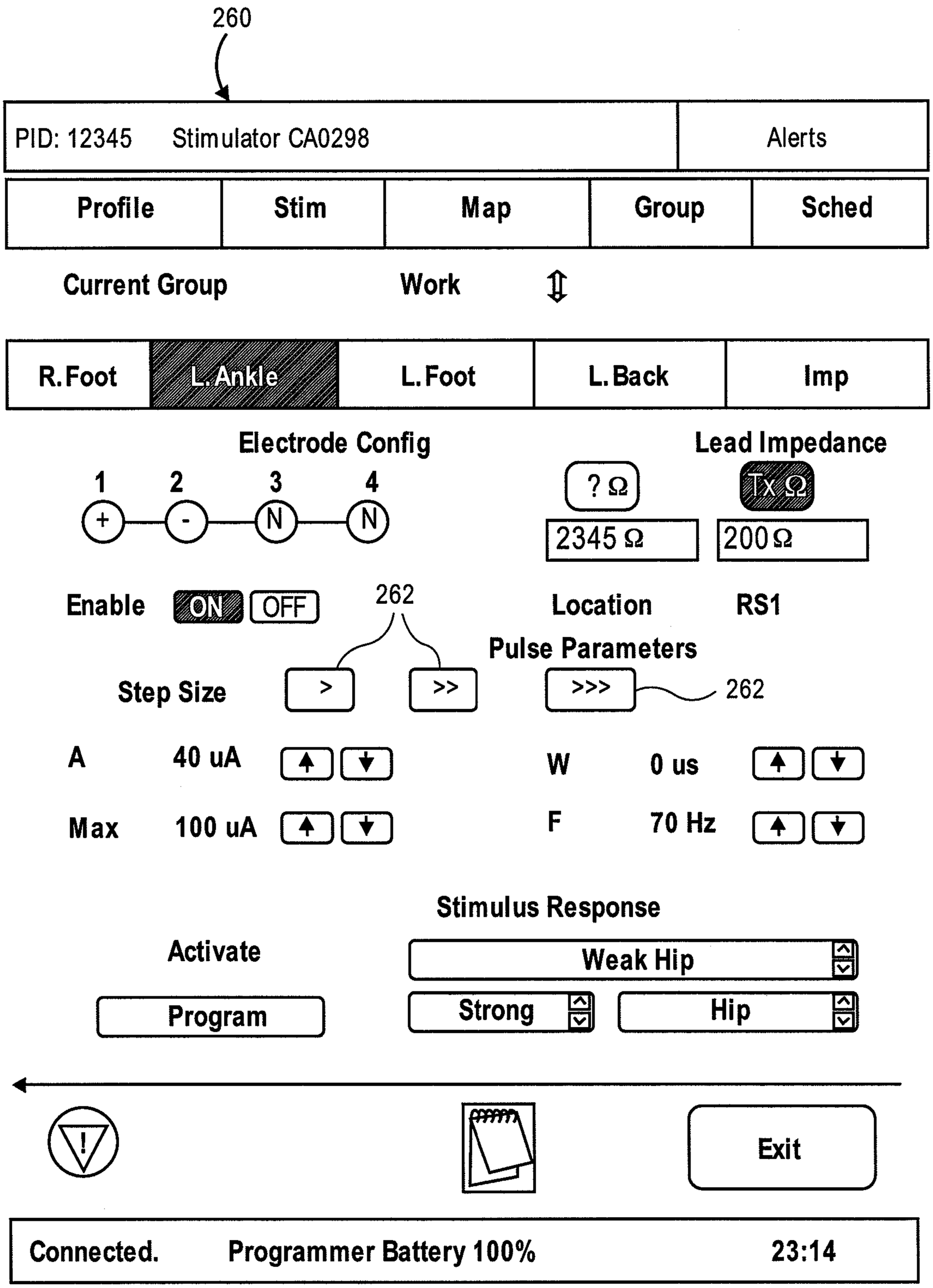
260
PID: 12345 Stimulator CA0298
Alerts
Profile
Stim
Map
Group
Sched
Current Group
Work
R.Foot
L.Ankle
L.Foot
L.Back
Imp
Electrode Config
1
2
3
4
+
-
N
N
Lead Impedance
? Ω
Tx Ω
2345 Ω
200 Ω
Enable
ON
OFF
262
Location
RS1
Pulse Parameters
Step Size
>
>>
>>>
262
A
40 uA
W
0 us
Max
100 uA
F
70 Hz
Stimulus Response
Activate
Weak Hip
Program
Strong
Hip
Exit
Connected.
Programmer Battery 100%
23:14

FIG. 15C

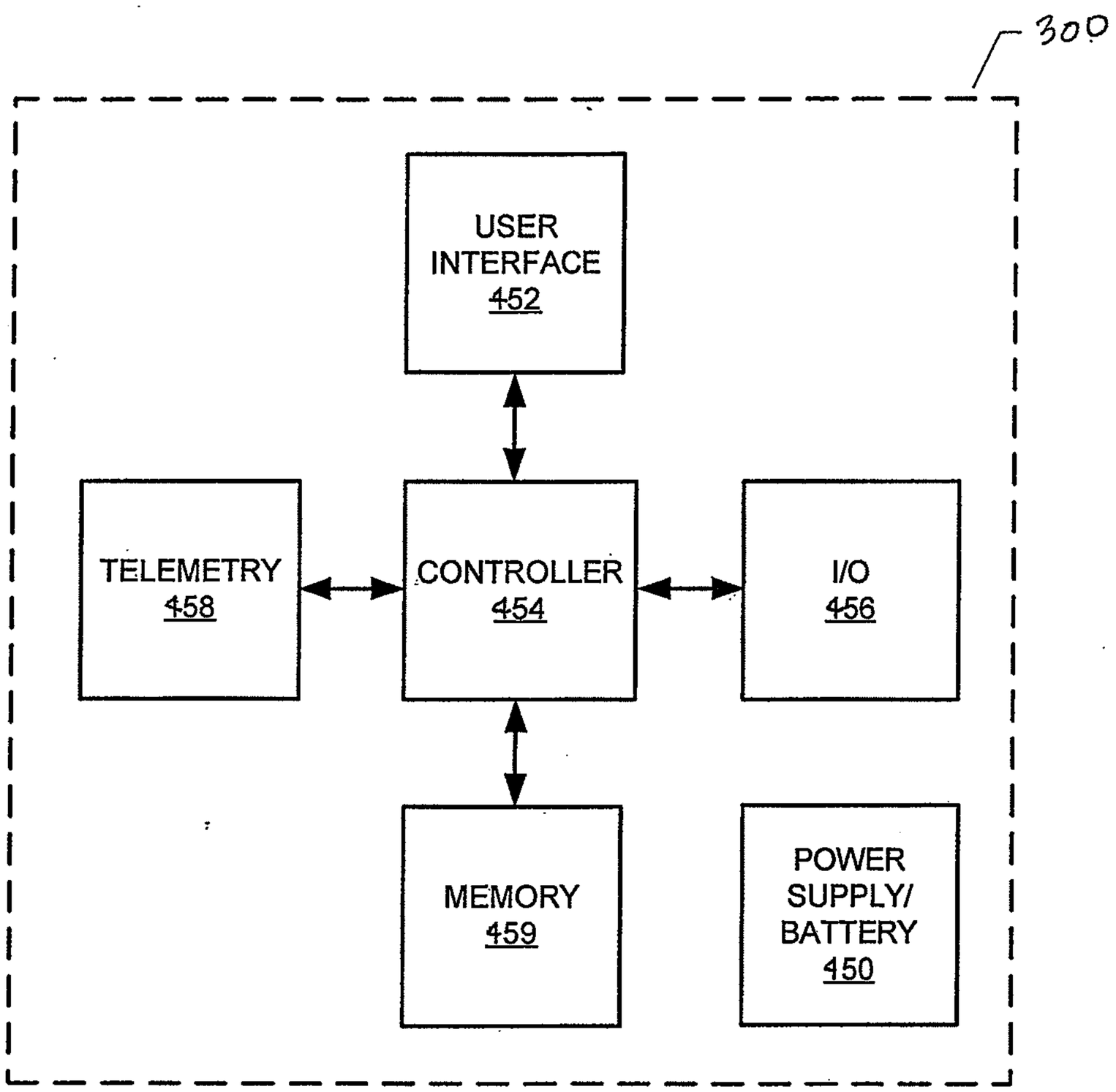
300
USER INTERFACE 452
TELEMETRY 458
CONTROLLER 454
I/O 456
MEMORY 459
POWER SUPPLY/ BATTERY 450

FIG. 16

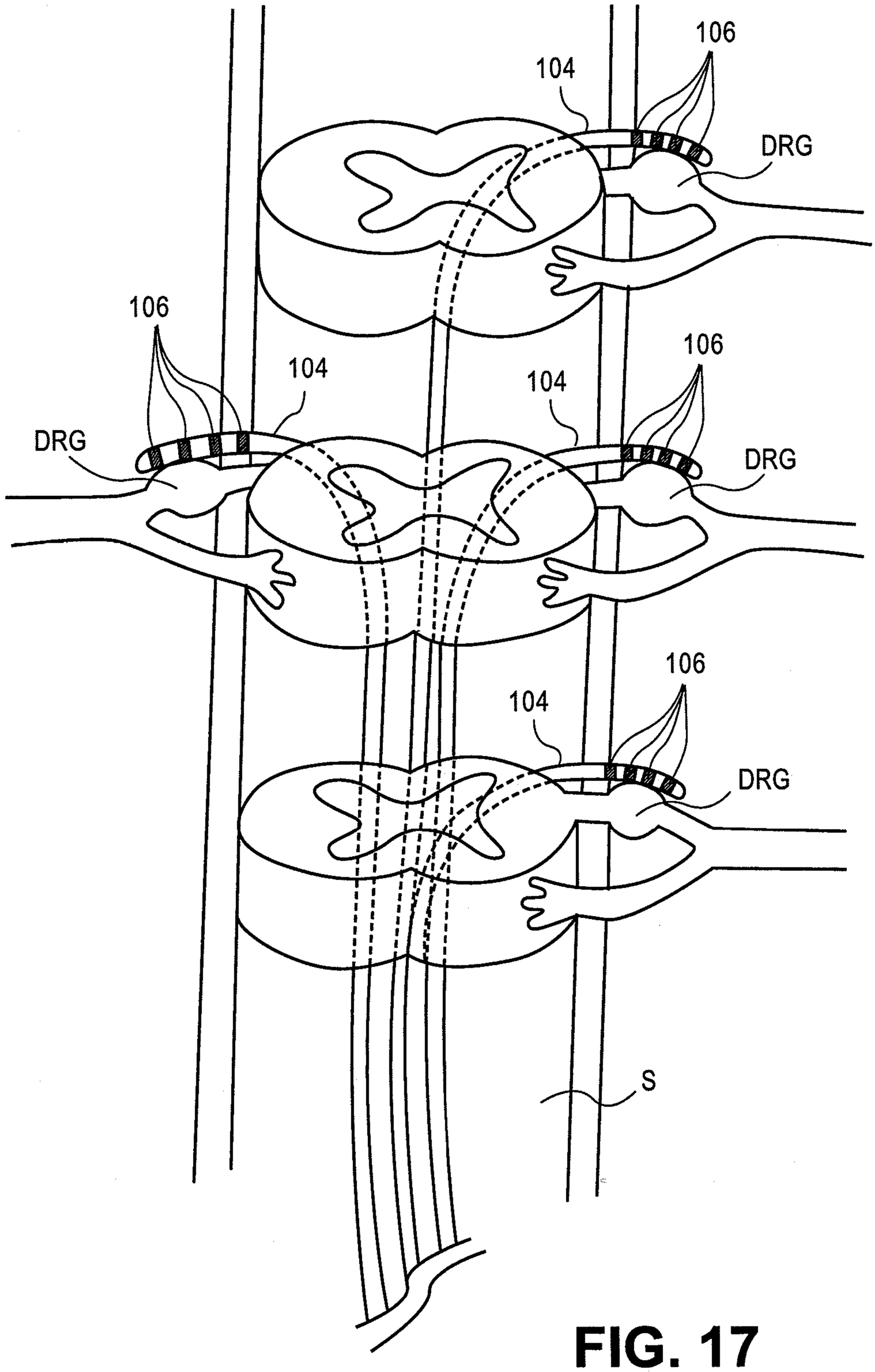

FIG. 17

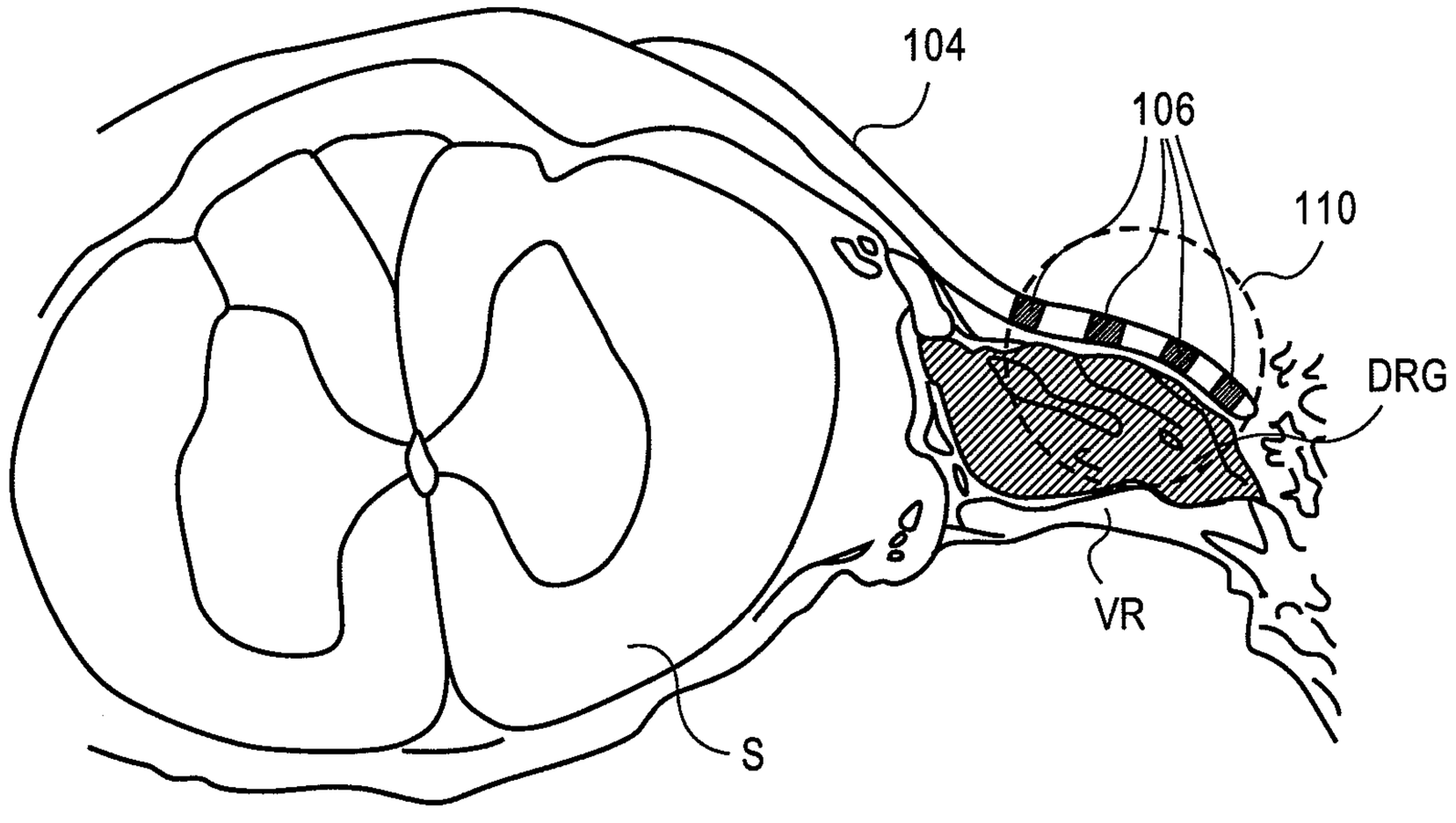

FIG. 18

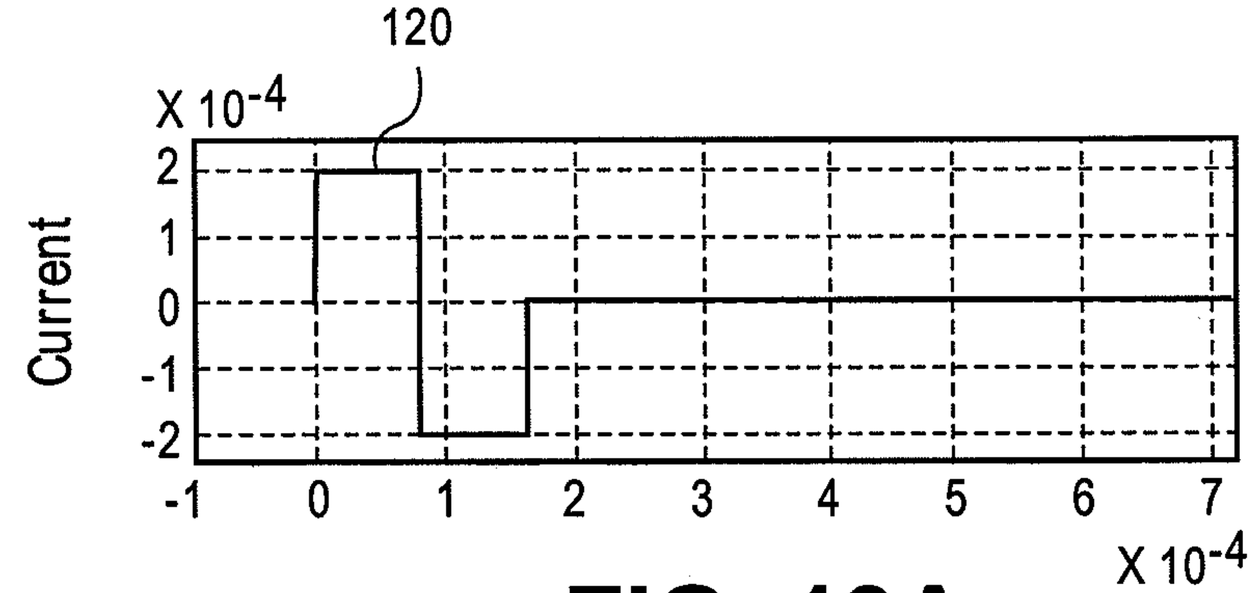

FIG. 19A

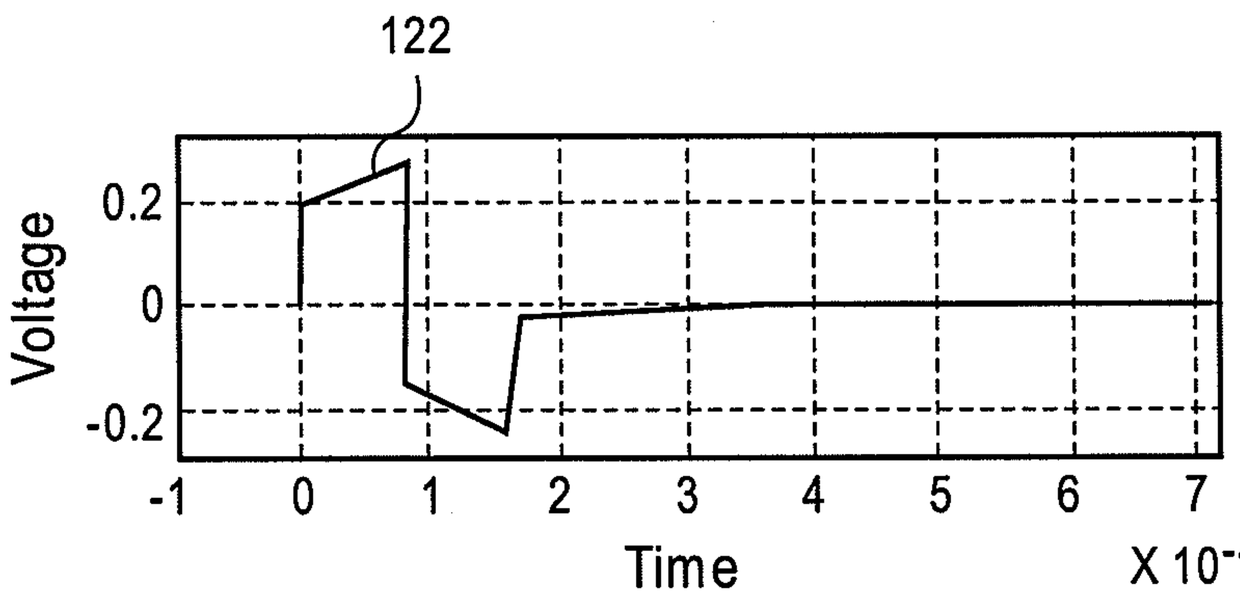

FIG. 19B

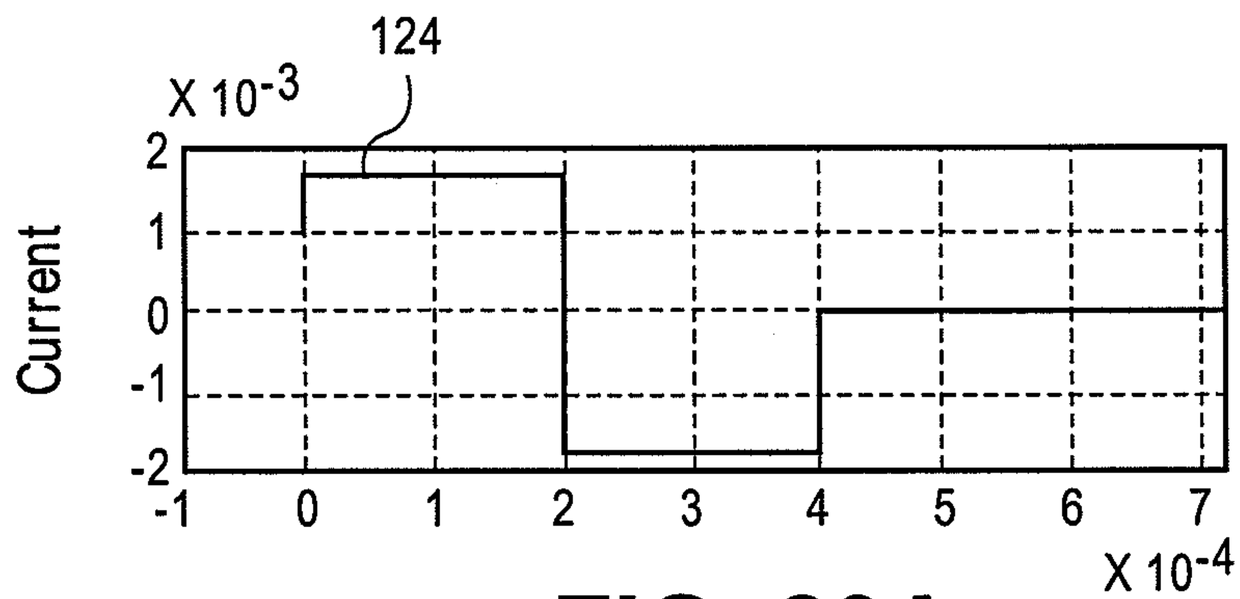

FIG. 20A

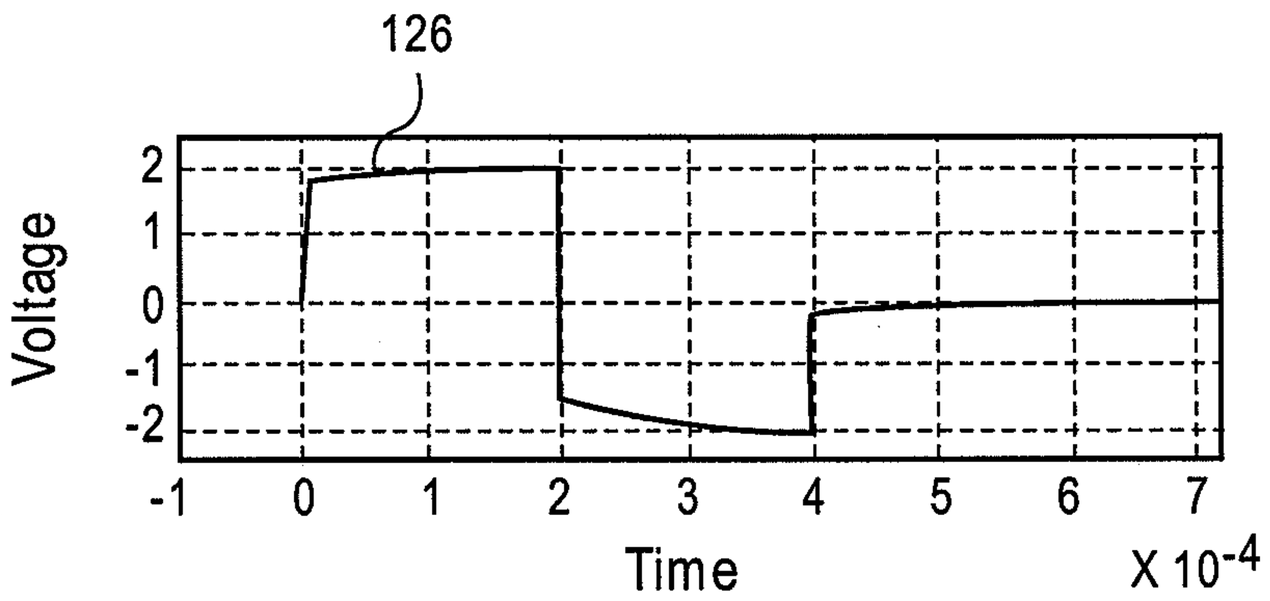

FIG. 20B

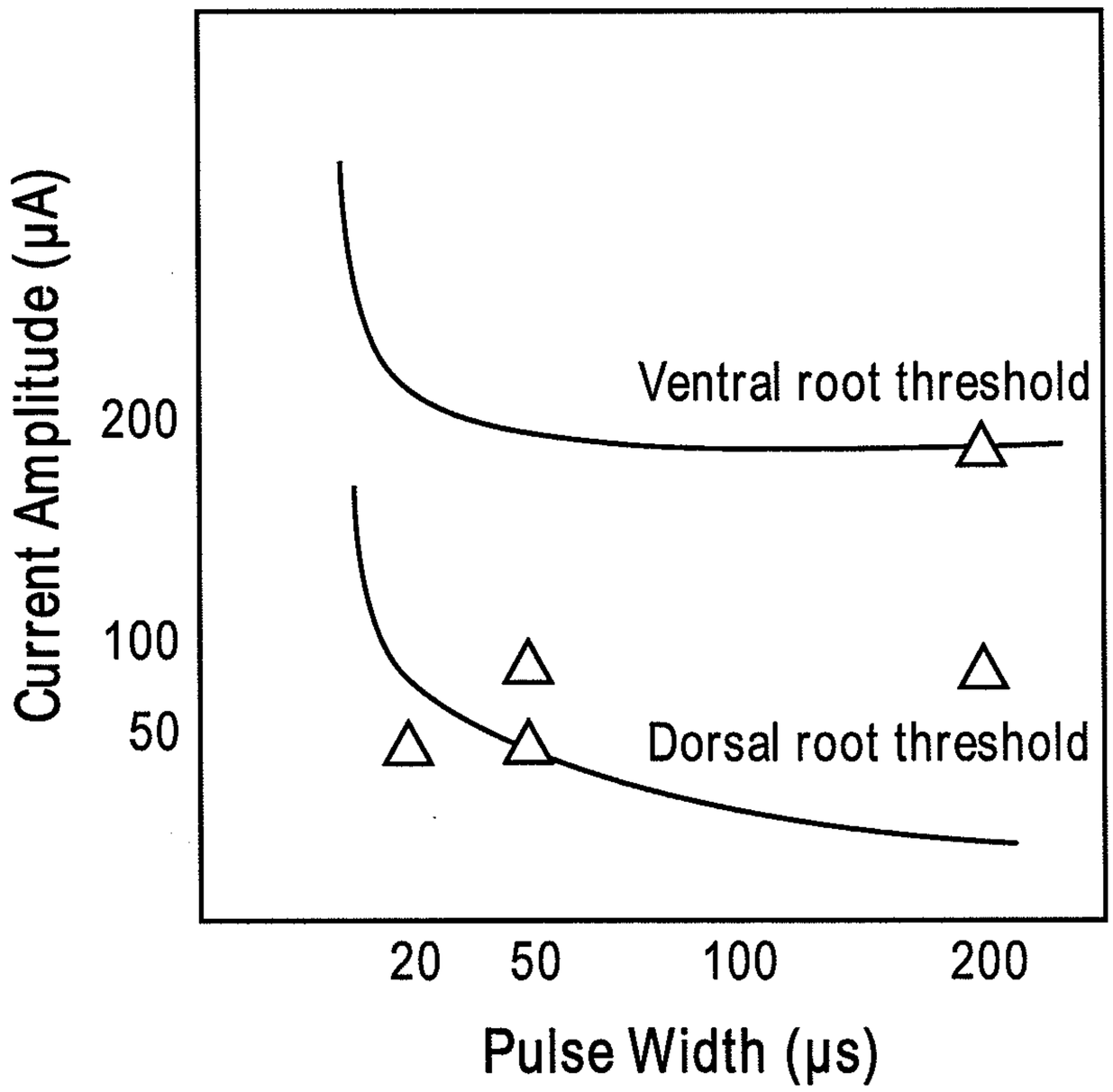

FIG. 21

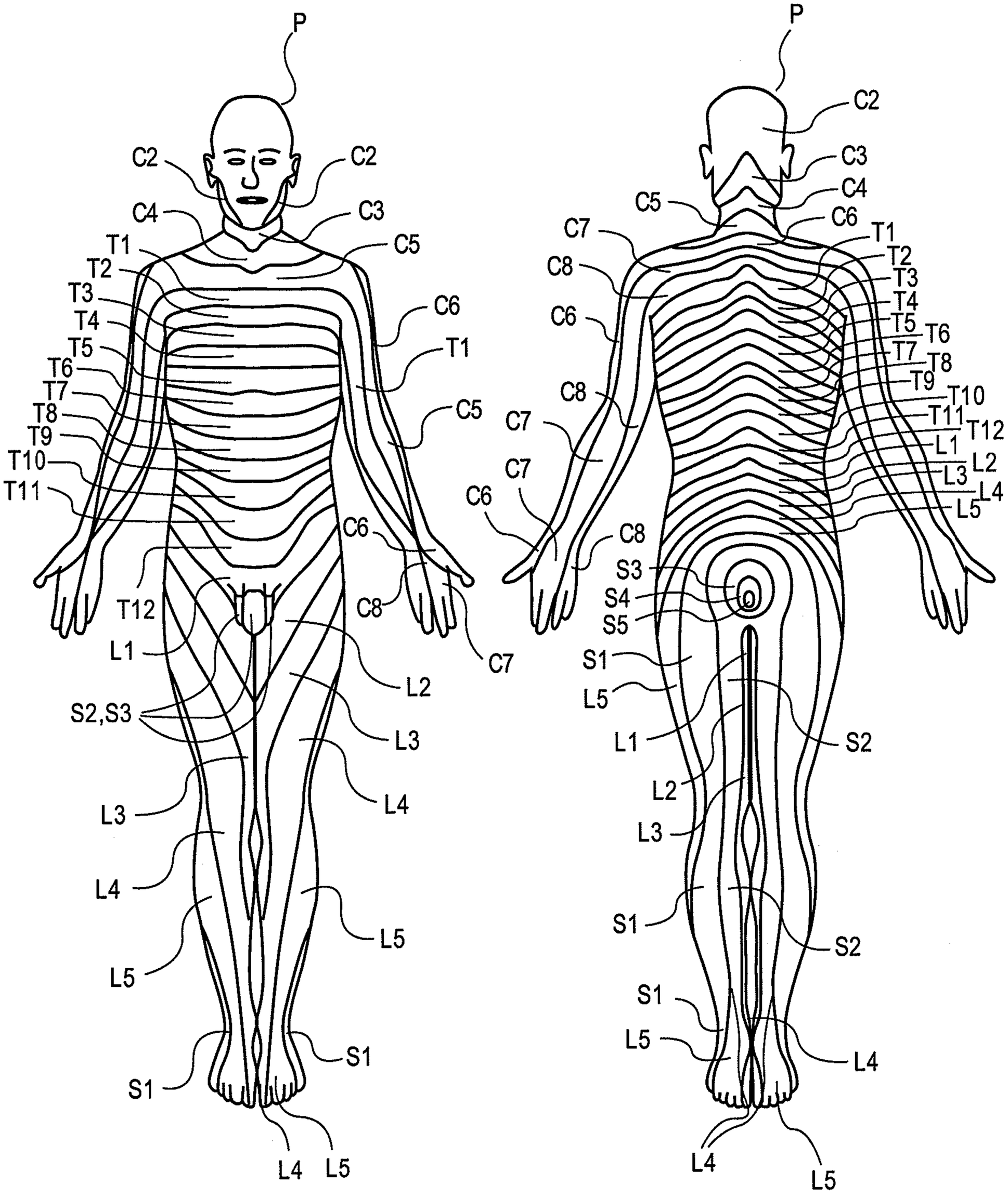
P
C2
C2
C4
C3
C5
T1
T2
T3
T4
T5
T6
T7
T8
T9
T10
T11
C6
T1
C5
C6
T12
C8
L1
L2
S2,S3
L3
L3
L4
L4
L5
L5
S1
S1
L4
L5
P
C2
C3
C4
C5
C6
C7
T1
T2
T3
T4
T5
T6
T7
T8
T9
T10
T11
T12
L1
L2
L3
L4
L5
C8
C6
C8
C7
C7
C6
C8
S3
S4
S5
S1
L5
L1
S2
L2
L3
S1
S2
S1
L5
L4
L4
L5

FIG. 22

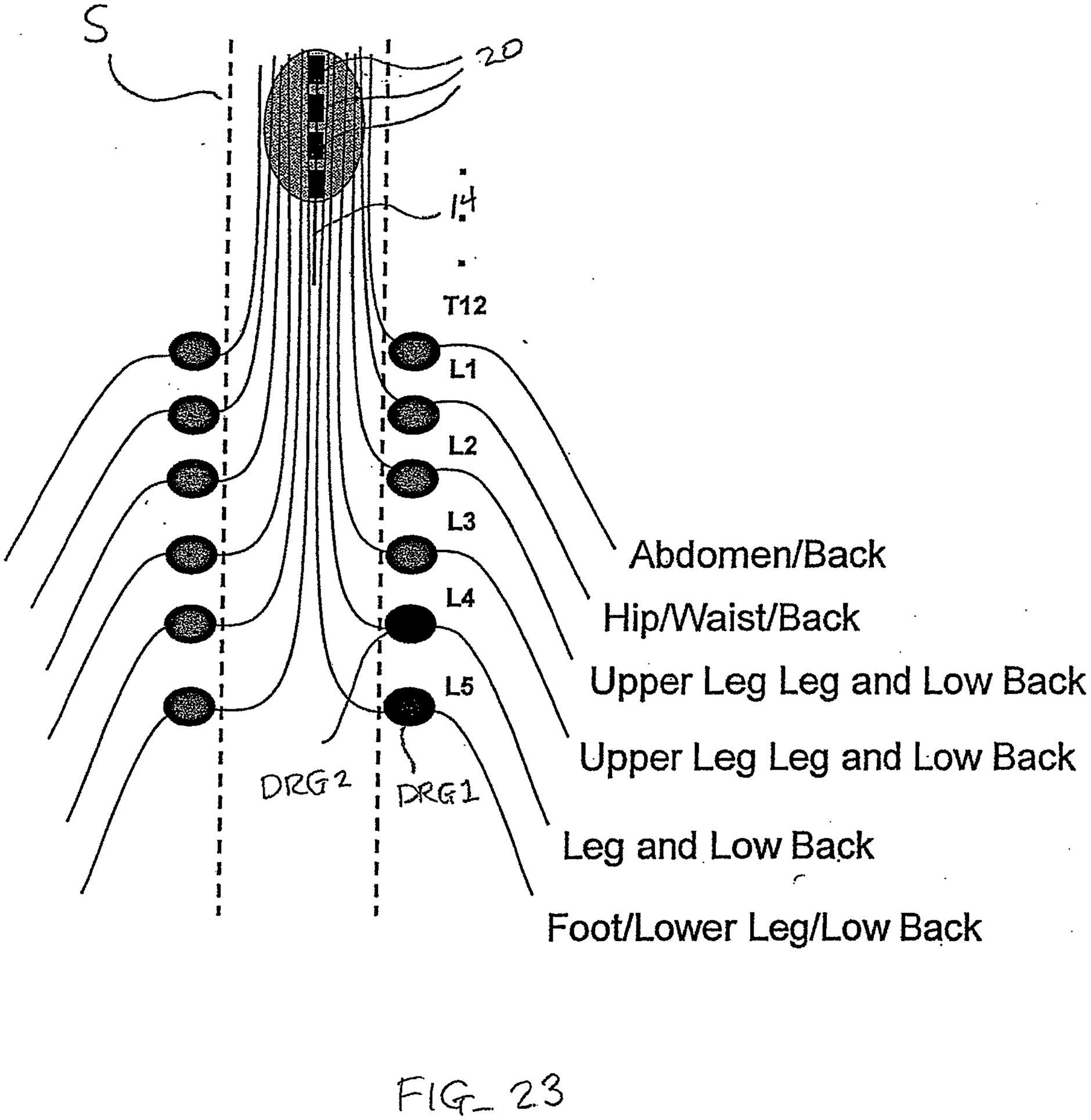
S
20
14
T12
L1
L2
L3
L4
L5
Abdomen/Back
Hip/Waist/Back
Upper Leg Leg and Low Back
Upper Leg Leg and Low Back
Leg and Low Back
Foot/Lower Leg/Low Back
DRG2
DRG1

FIG_23

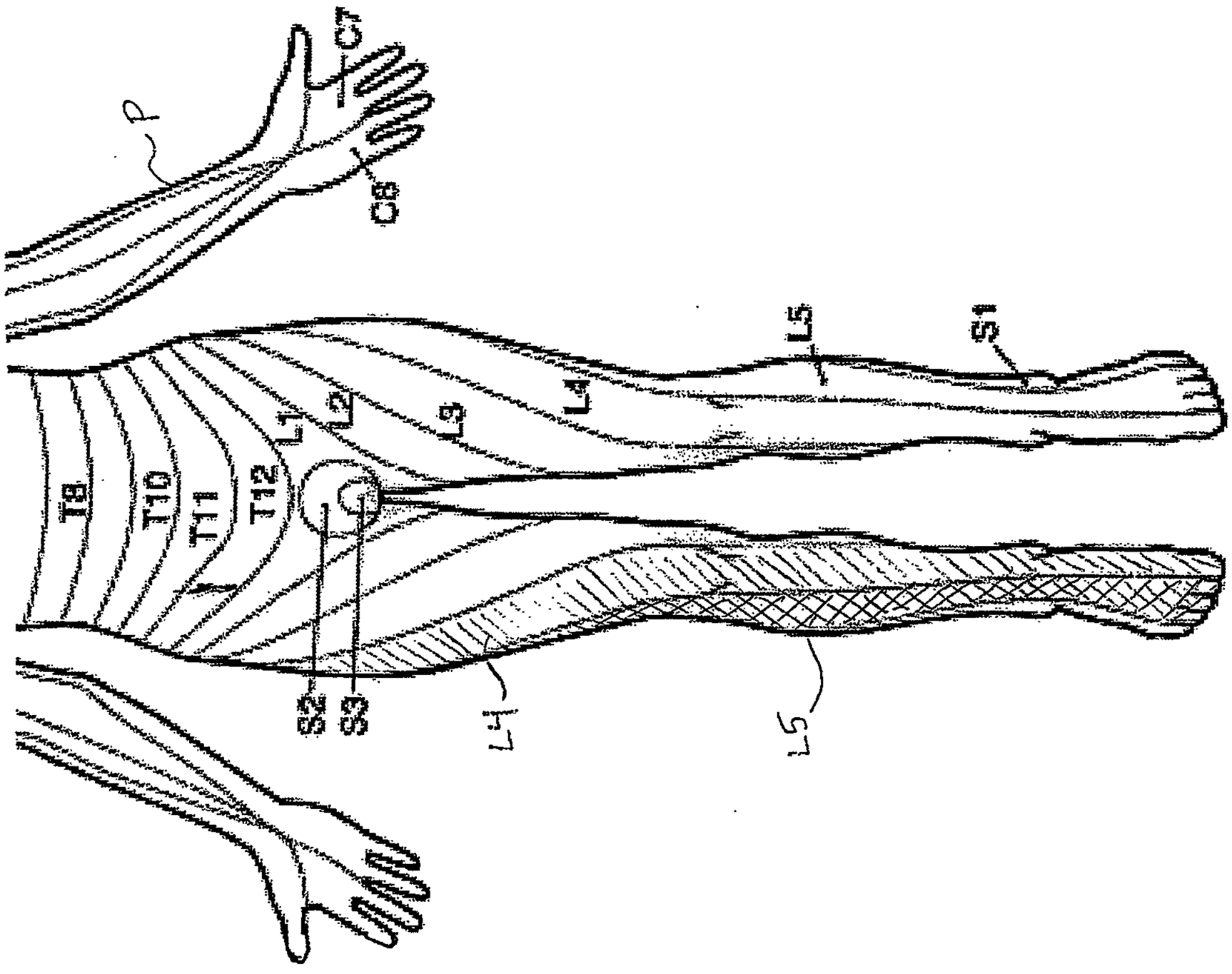

FIG_24B

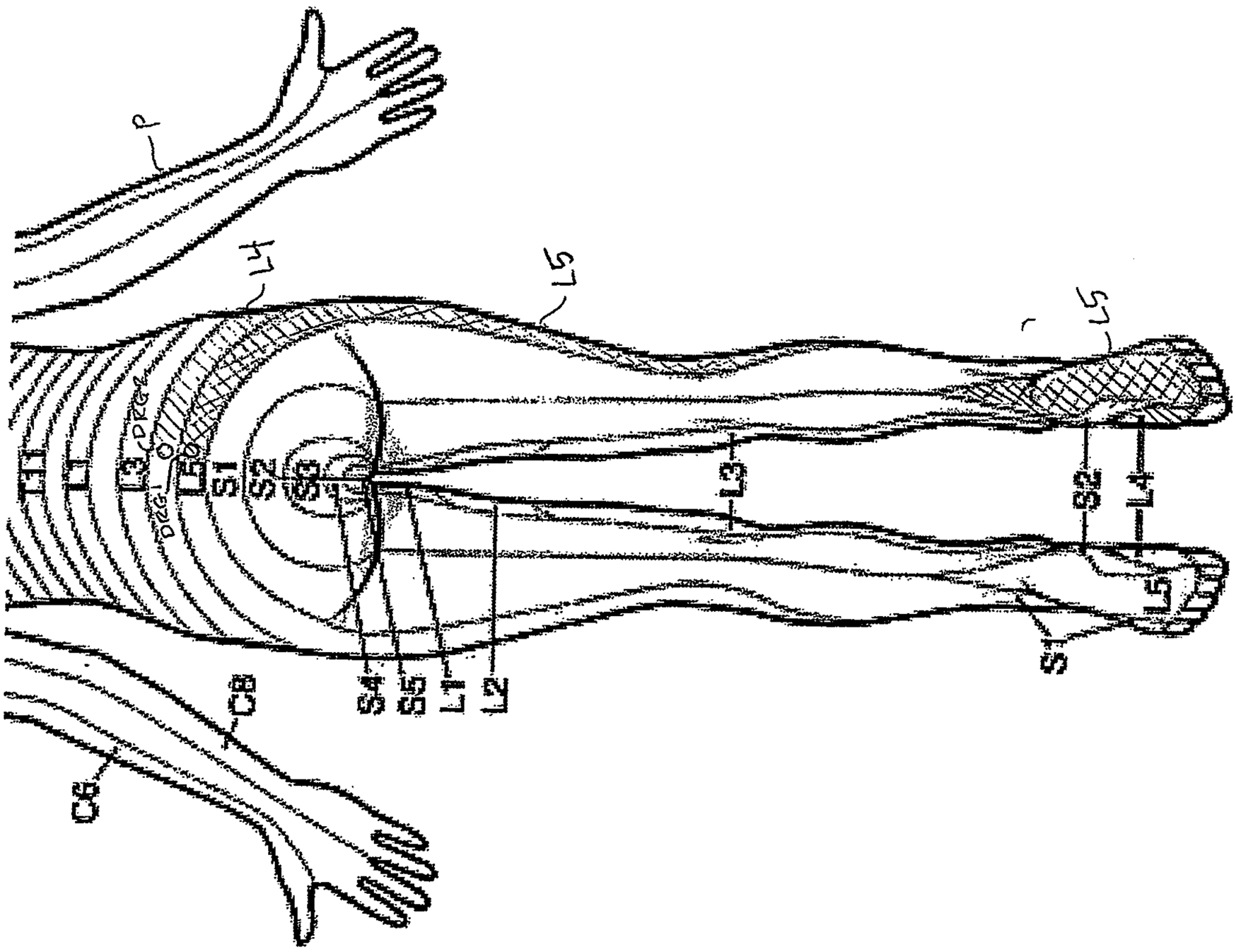

FIG_24A

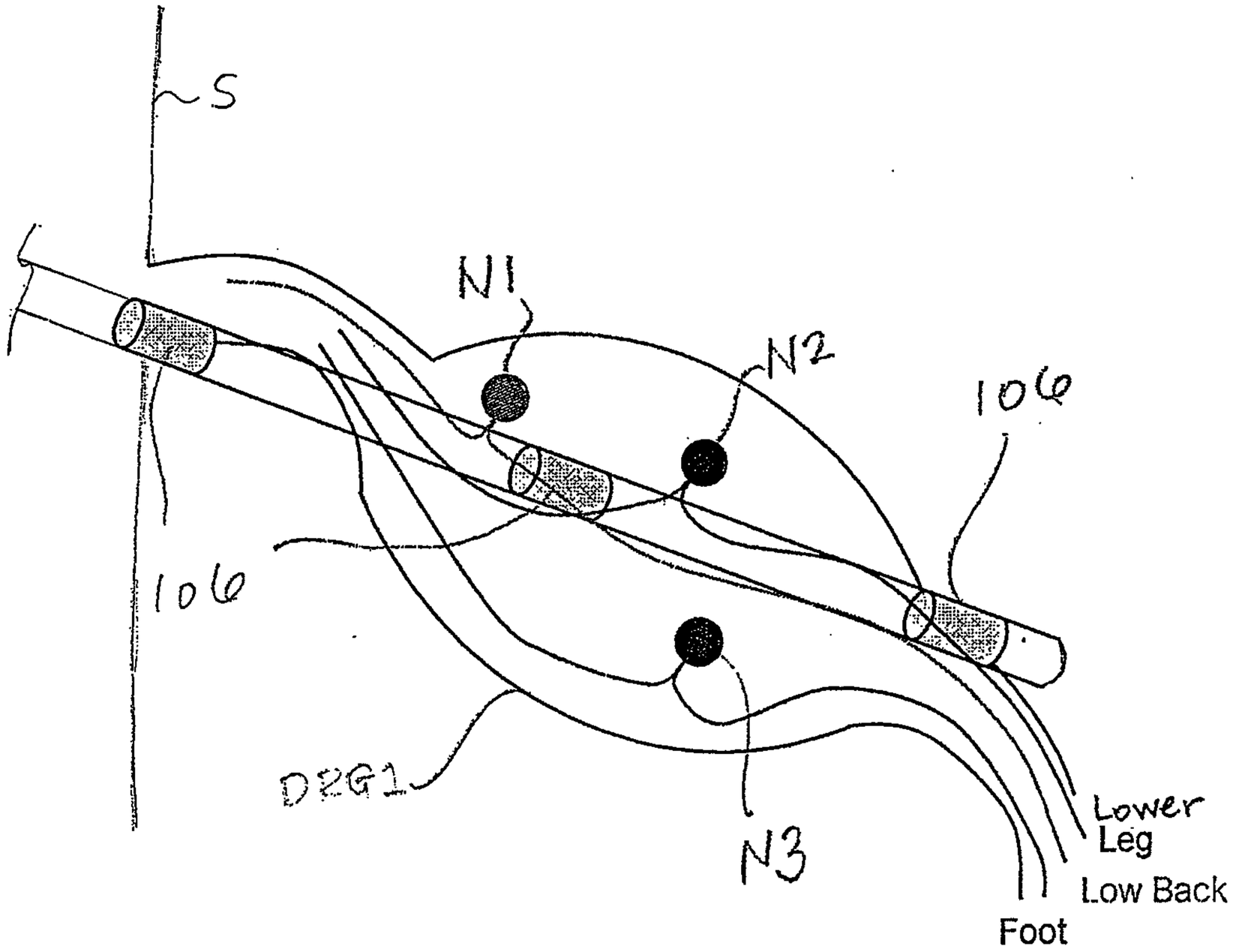

FIG_25

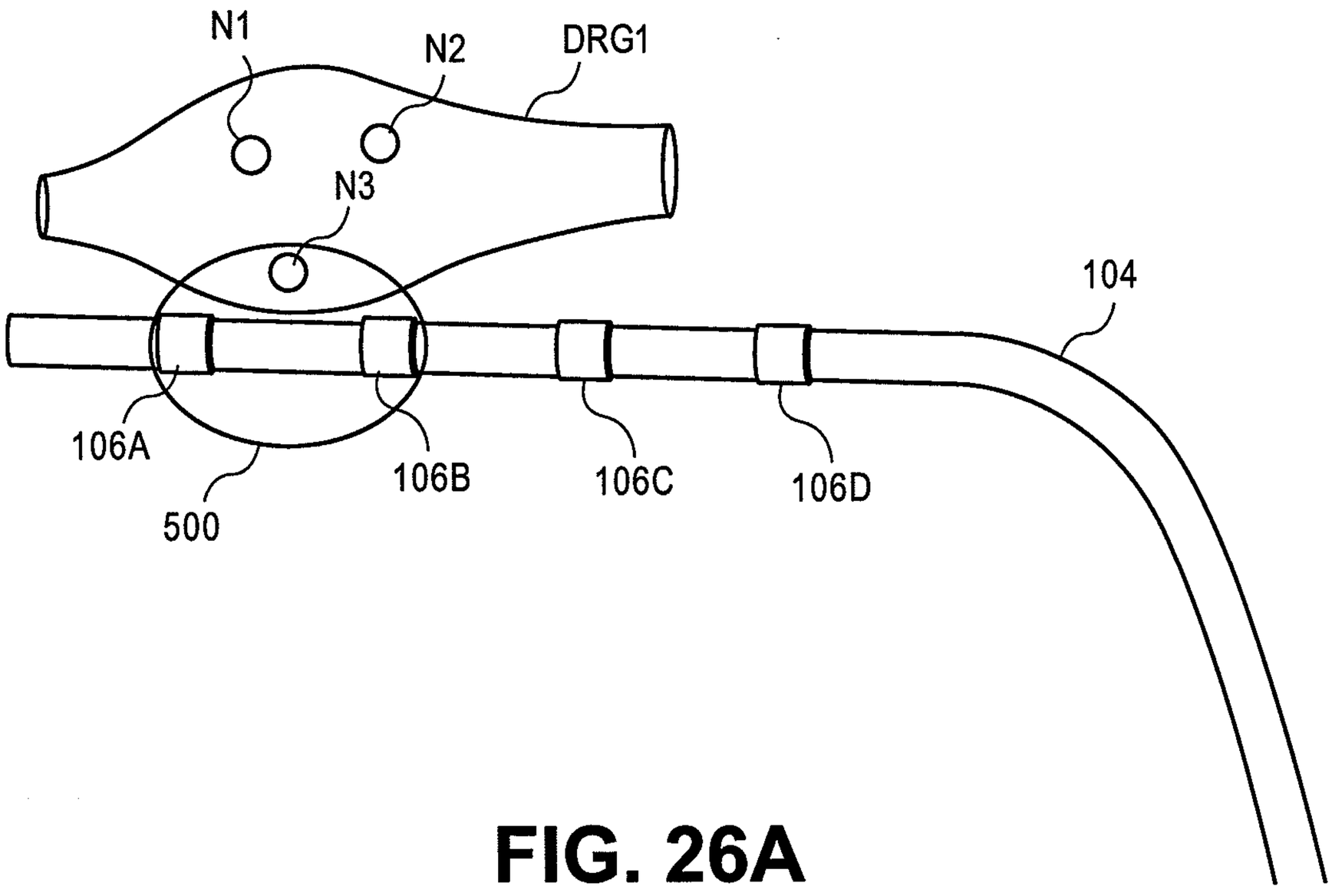

FIG. 26A

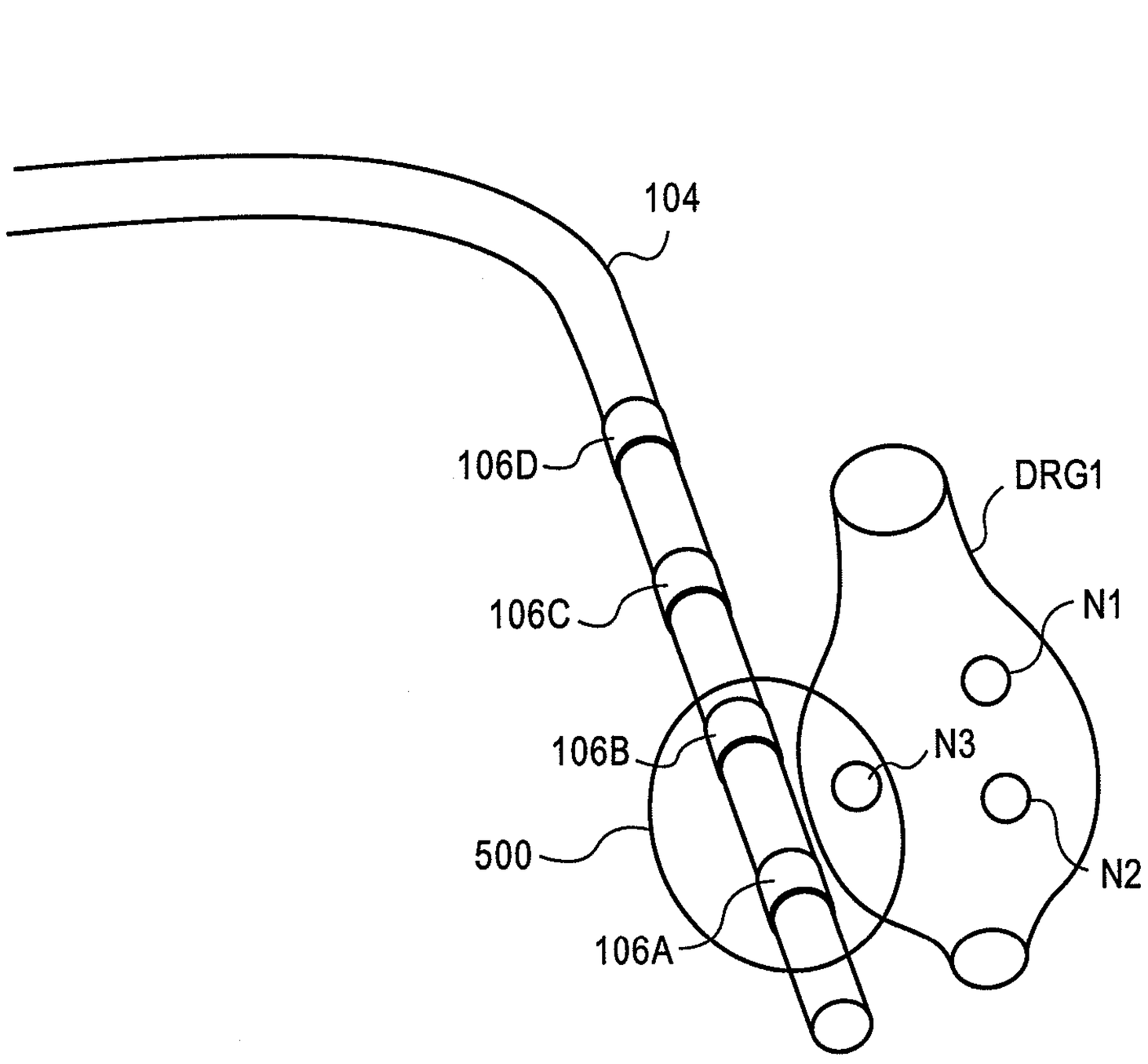

FIG. 26B

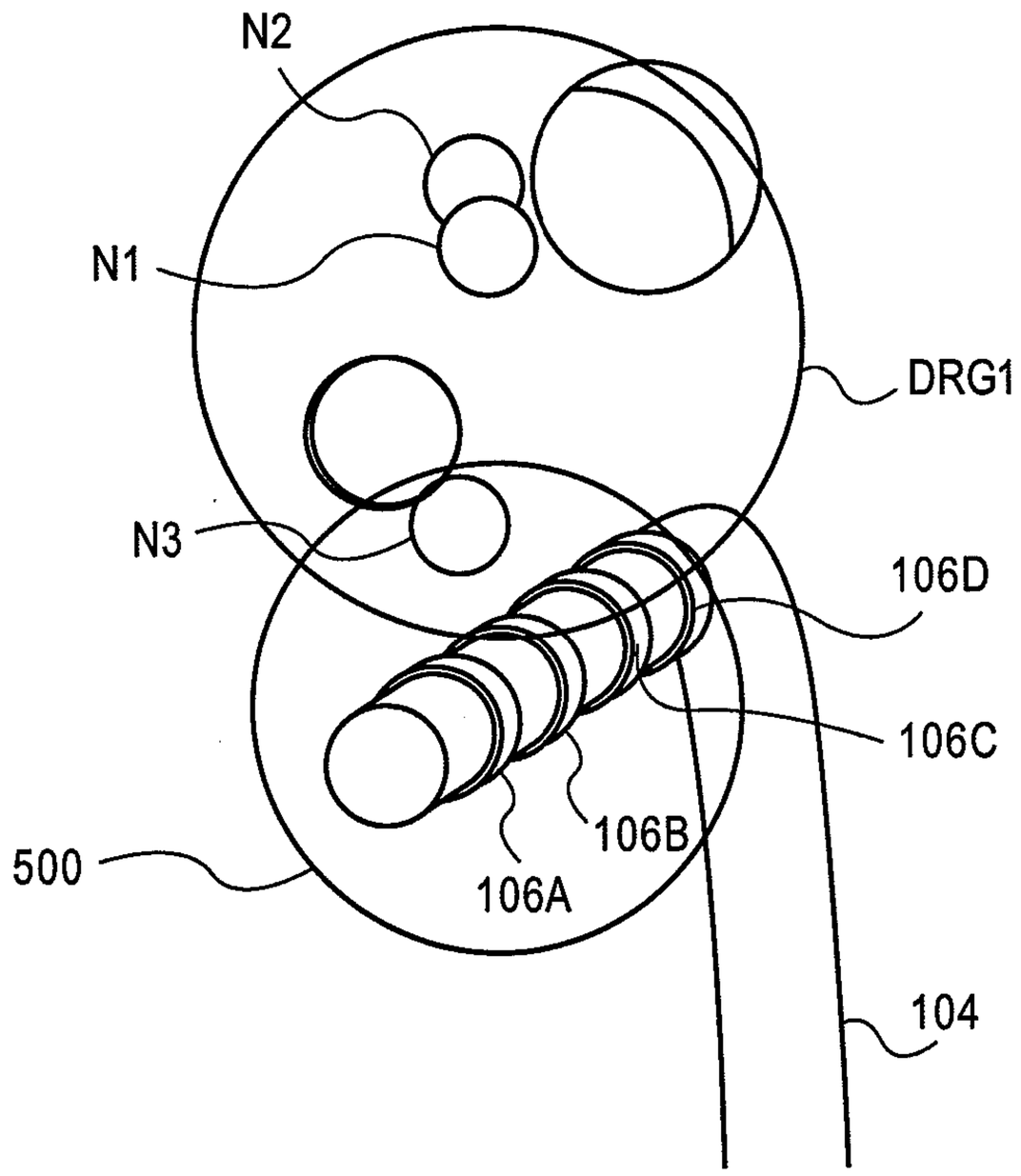

FIG. 26C

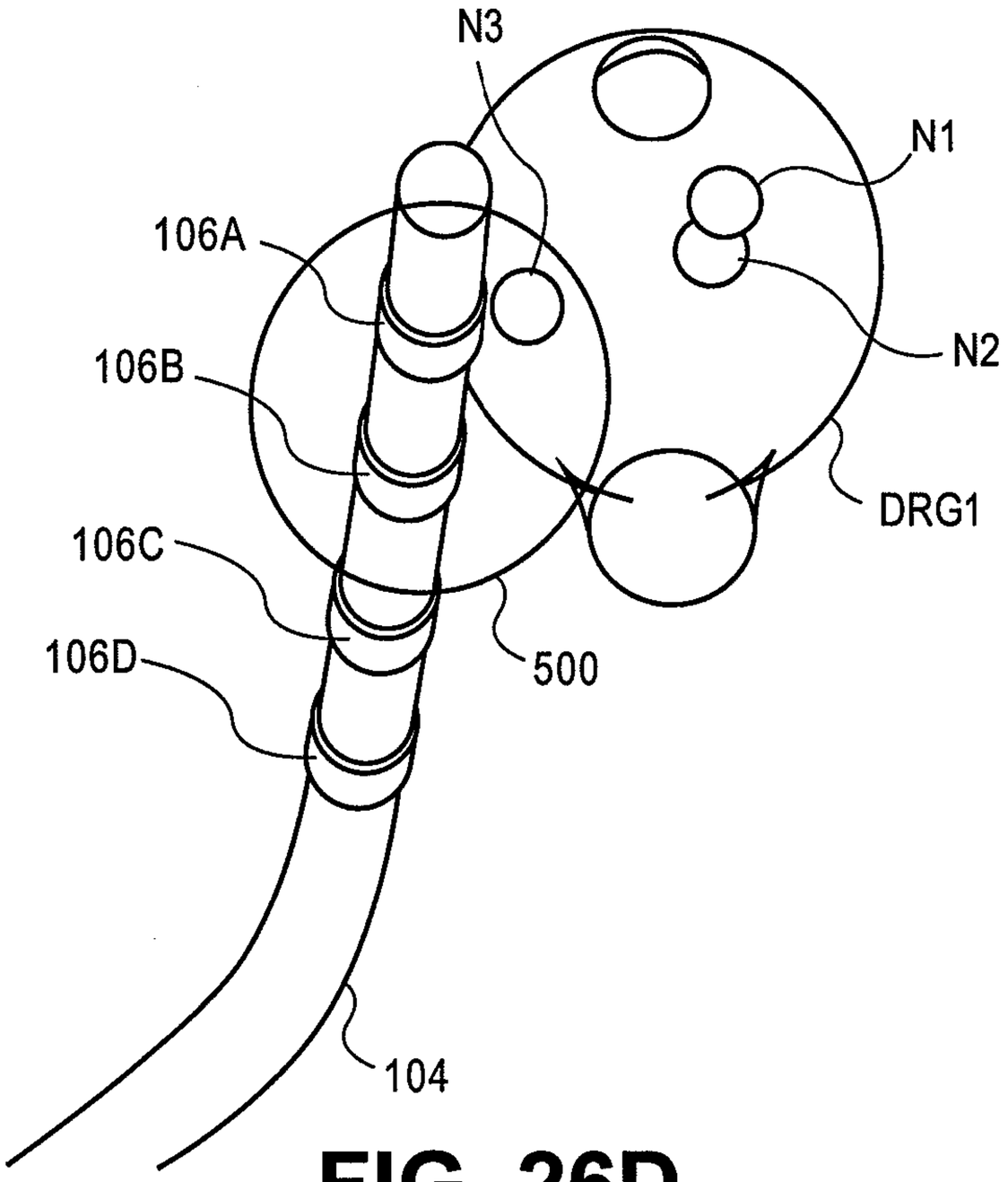

FIG. 26D

PATIENT NO.1

Row No.	Lead No.	Contact 1	Contact 2	Contact 3	Contact 4	Amplitude (µA)	Pulse Width (µS)	Frequency (Hz)	Affected Body Region
1	2	N	N	+	-	800	60	70	foot bottom
2	2	N	N	+	-	1.8 mA	60	70	calf and foot
3	2	N	N	+	-	2.25 mA	60	70	calf, foot and back of knee
4	2	N	N	+	-	2.75 mA	60	70	calf, foot, back of knee and hip
5	2	N	N	+	-	3.0 mA	60	70	calf, foot, back of knee, hip and buttock

FIG-27

PATIENT NO. 2

Row No.	Lead No.	Contact 1	Contact 2	Contact 3	Contact 4	Amplitude (µA)	Pulse Width (µS)	Frequency (Hz)	Affected Body Region
1	1	N	N	+	-	325	120	60	calf light
2	1	N	N	+	-	350	120	60	calf and knee
3	1	N	N	+	-	425	120	60	calf and knee, radiating up to hip
4	1	N	-	+	-	275	120	60	calf to ankle
5	1	N	-	+	-	625	120	60	above knee and to side of thigh
6	1	N	+	-	+	625	120	60	front of calf
7	1	N	+	-	+	650	120	60	front of calf, and knee
8	1	N	+	-	+	425	240	60	calf dull
9	1	N	+	-	+	525	240	60	all calf up to knee radiating up leg

FIG_28

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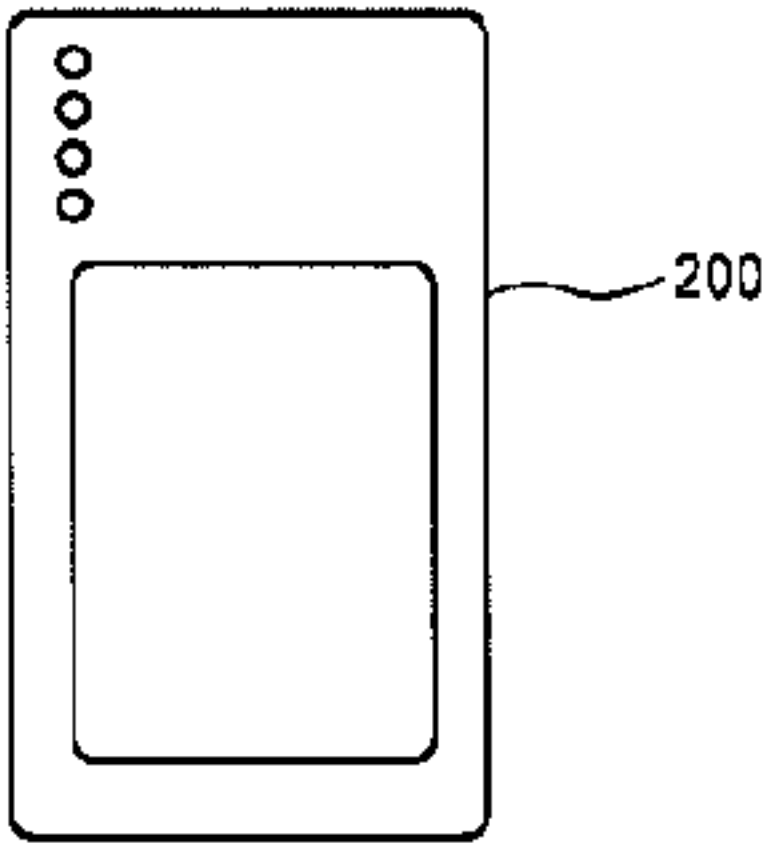

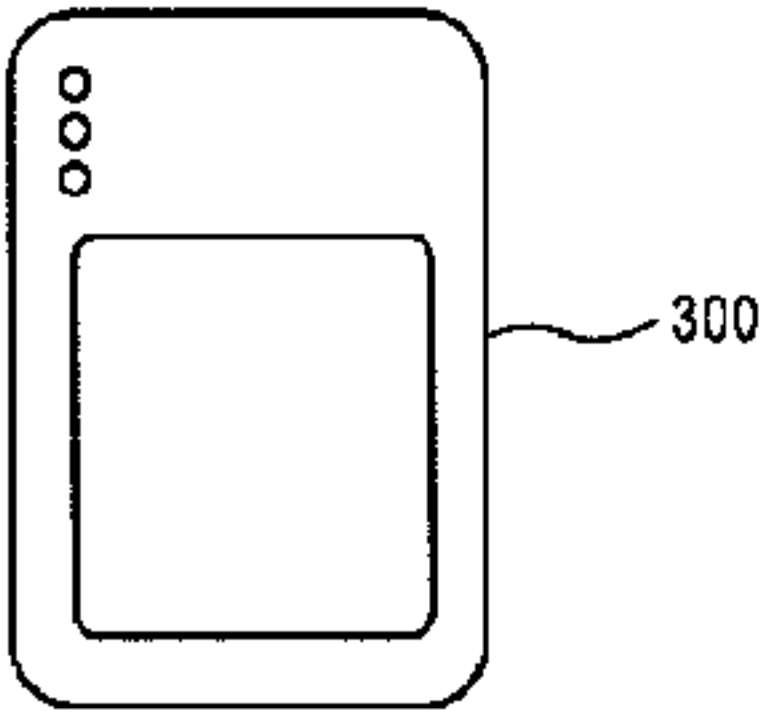

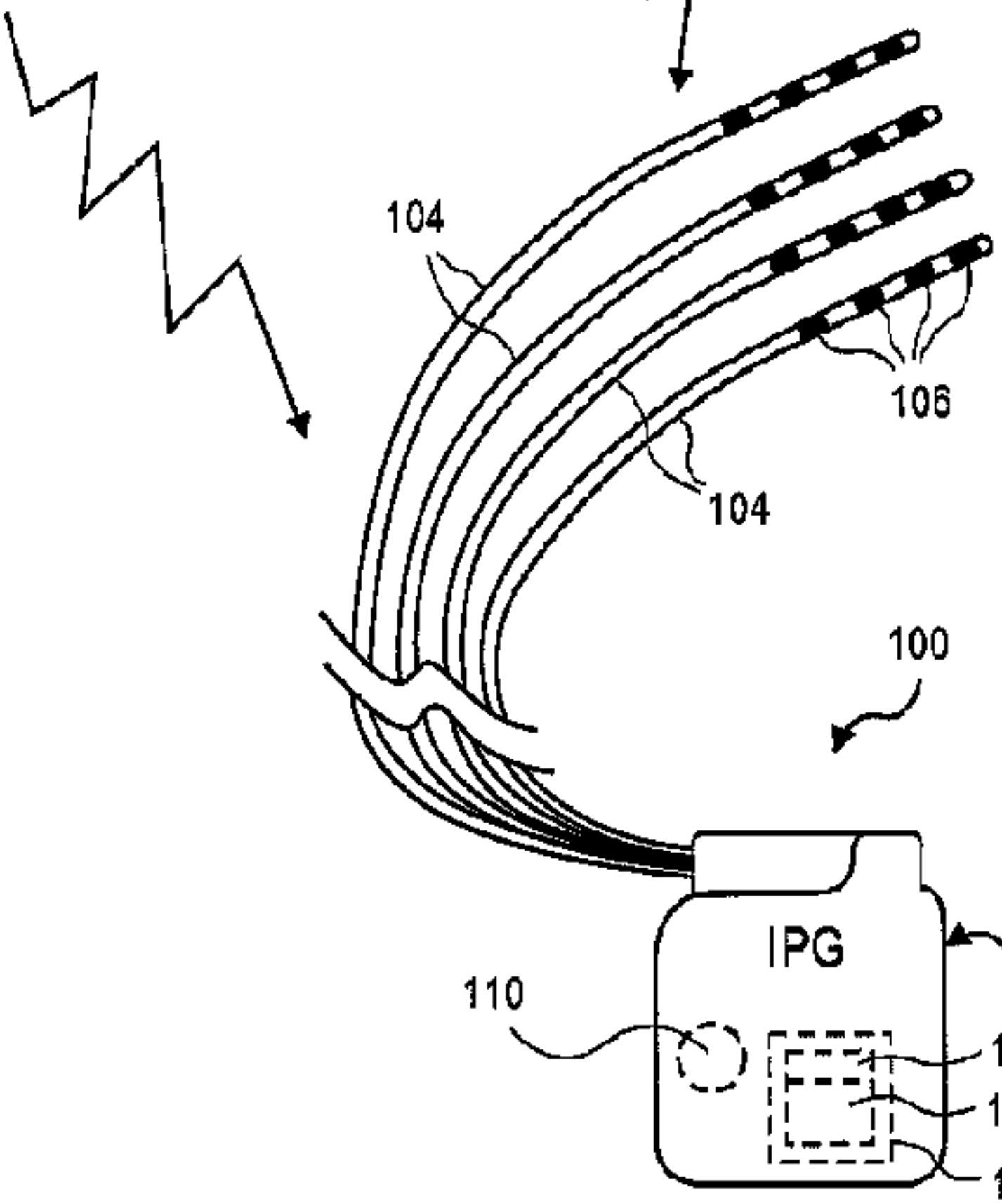

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