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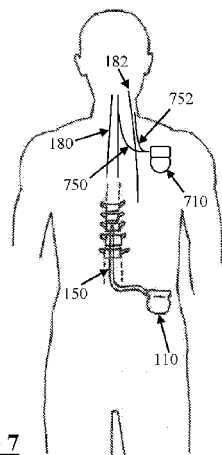
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(54) **Title:** METHOD AND DEVICE FOR NEURAL IMPLANT COMMUNICATION



**Figure 7**

(57) **Abstract:** Communications along a neural pathway are provided. The neural pathway is stimulated at a first location, in order to evoke neural responses which propagate along the neural pathway, the neural responses being modulated with data. At a second location spaced apart from the first location along the neural pathway the evoked neural responses are sensed. The sensed neural responses are then demodulated to retrieve the data. The stimulation could comprise peripheral sensory stimulation, and the second location could be at an implanted electrode array.

## METHOD AND DEVICE FOR NEURAL IMPLANT COMMUNICATION

Technical Field

[0001] The present invention relates to implanted neural devices, being devices which are able to evoke and/or sense neural activity upon a neural pathway, and in particular to a method and system for establishing communication with such devices.

Background of the Invention

[0002] A range of implanted neural devices exist, including: spinal cord implants which electrically stimulate the spinal column in order to suppress chronic pain; cochlear implants which electrically stimulate the auditory nerve to produce a hearing sensation; deep brain stimulators which electrically stimulate selected regions of the brain to treat conditions such as Parkinson's disease or epilepsy; and neural bypass devices which electrically stimulate either afferent sensory nerve fibres to reproduce impaired sensory function or efferent motor nerve fibres to reproduce impaired motor activity, or both.

[0003] With the advent of high capacity implantable batteries and power-efficient processing, implanted neural devices are becoming increasingly complex and in particular numerous aspects of operation of an implanted neural device may be reconfigurable. To control or reconfigure an implanted device thus requires the provision of a communications channel from a controller outside the body to the device within the body. Moreover, implanted neural devices are increasingly serving a data gathering role, and there exists a need to provide a communications channel from the device within the body to a data monitor outside the body.

[0004] Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

[0005] Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

[0006] In this specification, a statement that an element may be “at least one of” a list of options is to be understood that the element may be any one of the listed options, or may be any combination of two or more of the listed options.

### Summary of the Invention

[0007] According to a first aspect the present invention provides a method of communicating along a neural pathway, the method comprising:

stimulating the neural pathway at a first location by delivering a peripheral sensory input, in order to evoke neural responses which propagate along the neural pathway, the neural responses being modulated with data;

an implanted device sensing the evoked neural responses at a second location spaced apart from the first location along the neural pathway, and

the implanted device demodulating the sensed neural responses to retrieve the data, the data being configured to control or alter the operation of the implanted device.

[0007A] According to another aspect the present invention provides a system for communicating along a neural pathway, the system comprising:

an external control device configured to stimulate the neural pathway at a first location, in order to evoke neural responses which propagate along the neural pathway, the neural responses being modulated with data; and

an implanted device configured to sense the evoked neural responses at a second location spaced apart from the first location along the neural pathway, and to demodulate the sensed neural responses to retrieve the data, the data being configured to control or alter the operation of the implanted device.

[0008] According to a second aspect the present invention provides a method of receiving a communication from a neural pathway; the method comprising:

sensing on the neural pathway a plurality of evoked neural responses; and  
demodulating the sensed evoked responses to extract data.

[0009] According to a third aspect the present invention provides a method of transmitting information along a neural pathway, the method comprising:

evoking a plurality of neural responses on the neural pathway, the neural responses being modulated with data.

[0010] According to a fourth aspect the present invention provides an implantable device for communicating along a neural pathway, the device comprising:

sense electrodes and measurement circuitry for sensing neural responses passing along the neural pathway; and

a processor configured to demodulate sensed neural responses to extract data.

[0011] According to a fifth aspect the present invention provides a non-transitory computer readable medium for communicating along a neural pathway, comprising instructions which, when executed by one or more processors, causes performance of the following:

evoking a plurality of neural responses on the neural pathway, the neural responses being modulated with data.

[0012] The present invention thus utilises the neural pathway in a manner which is distinguishable from natural neural signals in order to enable an artificial function, being communication to and/or from an implanted neural device. That is, rather than detecting neural responses which are naturally arising, the present invention provides for the creation of artificially occurring neural responses which carry a data payload or are otherwise artificially modulated for the purpose of communication, but which need not have any intended meaningful sensory or motor purpose. The present invention thus utilises the neural pathway itself as a communications channel. In contrast to other communications techniques, such as wireless communications or bulk tissue conductance electrical propagation, which require considerable electrical power to establish the communications channel, the neural pathway does not need to be powered by the implanted device in order to function as a communications channel, as the action potential is a biological function requiring no electrical power input after the neural response is first evoked. That is, once evoked the action potential will continue to propagate for the full length of a healthy nerve without further external electrical power input.

[0013] The neural responses may be modulated with the data, such as being pulse width modulated, pulse amplitude modulated, pulse position modulated, amplitude or intensity modulated, delivered in bursts which are frequency modulated, modulated by analog or digital modulation, or they may be baseband on-off keying wherein presence of one or more neural responses within a given data bit window indicates a "1" and absence of a neural response within the window indicates a zero, or vice versa. The data is to be understood as being machine readable data, as distinct from neural signals having a biological function such as being intended for the brain. For example the data may be binary data.

[0014] In accordance with various embodiments of the invention, the implantable device may be configured to only receive data via the neural pathway, or to only transmit data via the neural pathway, or both. The implantable device may further be configured to communicate by other means, such as wireless transmission when desired.

[0015] In some embodiments of the invention, the neural responses evoked for the purposes of communication are configured to be comfortable for the implant recipient. Indeed in some embodiments the neural responses evoked for the purposes of communication may be configured to be minimally perceptible or wholly imperceptible by the implant recipient. Such embodiments recognise that certain low levels of neural activity are not perceived by the brain but can be selectively evoked by a suitable stimulator and detected by a suitable receiver. Such

embodiments may therefore be advantageous in avoiding the implant recipient perceiving any, or any significant, aberrant effects from communications stimuli. The perceptibility of the evoked communications responses may additionally or alternatively be minimised by using very short-time stimuli for communications purposes and/or delivering stimuli in an interleaved manner with therapeutic stimuli so that the communications stimuli are not perceived or at least are not unpleasant to the user. It is to be noted that where neural responses are evoked by motor activity such as the implant recipient activating a muscle, or by sensory input such as the user touching their leg, the neural responses thereby evoked are perceptible but not typically uncomfortable and may nevertheless be modulated in order to effect communications along the neural pathway.

[0016] The step of stimulating the neural pathway may comprise stimulating the nerve directly, whether a spinal nerve, dorsal root ganglion or peripheral nerve. For example the nerve may be directly stimulated by an electrical stimulus, an infrared or optical stimulus or a chemical stimulus, in order to create neural responses modulated with data which travel to another site along the neural pathway for detection by a neural monitoring device.

[0017] Alternatively, the neural pathway may be indirectly evoked by delivering a peripheral sensory input, such as a somatic touch or temperature input, or by proprioceptive activity such as may be caused by the user activating or clenching one or more muscles or making one or more motions in a particular predetermined manner which gives rise to neural activity which can be interpreted by a device monitoring the neural pathway. Additionally or alternatively, the neural pathway may be indirectly evoked by delivering a visceral or parasympathetic sensory input in a particular predetermined manner which gives rise to neural activity which can be interpreted by a device monitoring an associated neural pathway.

[0018] In some embodiments the communications may originate from an external control device, and may be configured to control or alter the operation of an implanted device. For example the external control device may drive an input device such as a TENS device or a vibrational or haptic input device, to deliver encoded peripheral sensory stimuli which give rise to neural responses modulated with data which propagate along the afferent sensory nerves to the implanted device. Such embodiments may permit improved control of the duration, time and intensity of each stimulus, and thus may be particularly suited to delivery of higher data rates to the implanted device as compared to manual sensory input.

[0019] In some embodiments, the vibrational device used to deliver sensory input to the neural pathway may be the mechanical vibrator of a smartphone. Such embodiments may be

particularly advantageous in utilising a device already owned by many implant recipients, and which has considerable computing power and thus may be programmed to provide advanced communications functionality with an implanted device by appropriately activating the mechanical vibrator for such communications purposes. The invention thus may be embodied in a smartphone app, which for example when executed controls a smartphone to communicate with an implant by vibrational sensory input.

[0020] Additionally or alternatively, in some embodiments the communications may originate from manual human sensory input, such as from the implant recipient. For example the communications originating from the implant recipient may be configured to control or alter the operation of an implanted device. In some such embodiments the implant recipient may manually deliver a sensory input to their peripheral nerves such as by tapping and/or stroking their leg(s) with their hand(s), in a predetermined pattern which gives rise to a pattern of neural responses which are detected and decoded by the implanted device. Additionally or alternatively, the communication may be initiated by motor input such as by the user clenching or activating one or more muscles or making one or more motions in a predetermined manner which gives rise to neural activity which can be detected and decoded by the implanted device monitoring the neural pathway. Initiating communications via motor activity rather than manual sensory input may be preferable if the implant recipient is self-conscious about delivering peripheral sensory inputs in public, as motor activity can be generated by activating muscles against resistance without requiring any movement and may thus be more discreet. While embodiments utilising manual sensory input are likely to achieve lower data rates than embodiments utilising an automated stimulus method, manual sensory input is nevertheless advantageous in permitting at least simple data input or device control to take place without the need for any external control device.

[0021] The encoding or modulation scheme used for manual sensory input communications is preferably configured to be distinguishable from normal motor activity, so that normal activity of the user is not undesirably detected as an instruction to change control settings of the implanted device. For example, motor or proprioceptive activity may be encoded by requiring consecutive motor actions or sensory inputs on one side of the body, so as to differentiate the encoded input from walking in which motor or proprioceptive activity occurs on alternating sides of the body. Formulating appropriate encoded sensory or motor input for a given implant recipient may be part of a fitting process after implantation of the implanted device. For example the user may have a preference of only tapping their feet to achieve such communications, or gently slapping



their thighs, or the like. The user's preferred input activity may thus be accommodated during device fitting, in some embodiments. Moreover, the or each input pattern may resemble the rhythm of a favourite song or the like, to improve intuitiveness of the system for the user. In such embodiments the implanted device may thus be configured at the time of fitting to attach a unique control meaning to whichever input modulations are preferred by the user.

[0022] In further embodiments in which the communications originate from manual human input or a relocatable peripheral input such as a handheld TENS device, the implanted device may be configured to interpret such input as having occurred at a location at which paraesthesia is required. This may occur during a temporary re-mapping mode which may be entered when the implant recipient or a clinician wishes to redefine device parameters in order to change a region of paraesthesia delivered by the implanted device. When the device is in such a mode, an array of electrodes of the implanted device may detect neural responses on each electrode in a manner which corresponds to the indicated location of the required paraesthesia. The device may then reconfigure a stimulus pattern in a manner that optimises the stimuli delivered from each stimulus electrode, in a manner which optimally delivers paraesthesia to the location defined by the sensory input. Electrodes to sense the location being indicated by the manual sensory input may be positioned adjacent to one or more dorsal root ganglion in order to ease the location mapping to within the corresponding dermatome. A similar effect may be achieved by external device input such as by using an external haptic device to deliver sensory input at the location of required paraesthesia. Such embodiments may be particularly useful in cases of inaccurate electrode array implantation during surgery, or post-surgical lead migration, to facilitate re-mapping of stimulus electrodes.

[0023] Additionally or alternatively, in some embodiments the communications may originate from one implanted device which electrically stimulates neural responses, and the evoked responses may propagate in either an efferent or afferent direction along the neural pathway to a second implanted device, in order to effect communications between two implanted devices. A communications network between a plurality of implanted devices may thus be achieved. The communication network may comprise more than one neural pathway if data communicated along a first neural pathway is transferred to a second neural pathway by a suitable device or devices.

[0024] Additionally or alternatively, in some embodiments the communications may originate from an implanted device and may be configured to propagate to another location on the neural

pathway to be detected and decoded by a device external to the body, such as cranial electrocardiography (ECG) electrodes configured to detect electrical neural activity or a surface electromyography (EMG) sensor configured to detect motor function such as a small muscle twitch or tic evoked by electrical stimulus of motor fibres by the implanted device, within the comfort range of the recipient, and modulated with data.

[0025] The communications delivered along the neural pathway may comprise instructions to activate or deactivate a radio or other communications component of the implanted device. Such embodiments thus permit the radio component to be deactivated when not required to permit a reduction in battery power consumption by the radio component, while also providing a means to reactivate the implanted radio, when required by a separate or external device or user.

[0026] The communications delivered along the neural pathway may comprise instructions to activate, deactivate or alter a therapeutic function of the implanted device. For example when the user of a spinal cord implant treating chronic pain intends to go to sleep they may instruct the device to turn off using communications in accordance with the present invention in order to save battery power overnight, and use equally simple inputs to reactivate the therapeutic function when they wake up.

[0027] The implanted device is preferably operable to differentiate between distally evoked neural activity and locally evoked neural activity, for example in the manner set forth in Australian Provisional Patent Application No. 2014904595, also by the present applicant. Such capability may be important in embodiments such as spinal cord implants where the implanted device's therapeutic function involves substantially continuous or ongoing locally evoked responses, from which distally evoked responses which carry a communications purpose for the device need to be differentiated.

#### Brief Description of the Drawings

[0028] An example of the invention will now be described with reference to the accompanying drawings, in which:

Figure 1 schematically illustrates an implanted spinal cord stimulator;

Figure 2 is a block diagram of the implanted neurostimulator;

Figure 3 is a schematic illustrating interaction of the implanted stimulator with a nerve;

Figure 4 illustrates neural activity observed upon a neural pathway;

Figure 5 illustrates modes of peripheral sensory data input to a neural device in accordance with one embodiment of the present invention;

Figure 6 illustrates a mode of peripheral sensory input to a neural device in accordance with another embodiment of the present invention; and

Figure 7 illustrates communication between two implanted neural devices along a neural pathway in accordance with another embodiment of the invention.

#### Description of the Preferred Embodiments

[0029] Figure 1 schematically illustrates an implanted spinal cord stimulator 100. Stimulator 100 comprises an electronics module 110 implanted at a suitable location in the patient's lower abdominal area or posterior superior gluteal region, and an electrode assembly 150 implanted within the epidural space and connected to the module 110 by a suitable lead. Numerous aspects of operation of implanted neural device 100 are reconfigurable by an external control device 192. Moreover, implanted neural device 100 serves a data gathering role, and gathered data needs to be communicated to external device 192. These functions of implanted device 100 thus require the provision of a communications channel 190 from a controller 192 outside the body to the device 100 within the body.

[0030] Figure 2 is a block diagram of the implanted neurostimulator 100. Module 110 contains a battery 112 and a telemetry module 114. In embodiments of the present invention, any suitable type of transcutaneous communication, such as infrared (IR), electromagnetic, capacitive and inductive transfer, may be used by telemetry module 114 to transfer power and/or data between an external device and the electronics module 110.

[0031] Module controller 116 has an associated memory 118 storing patient settings 120, control programs 122 and the like. Controller 116 controls a pulse generator 124 to generate stimuli in the form of current pulses in accordance with the patient settings 120 and control programs 122. Electrode selection module 126 switches the generated pulses to the appropriate electrode(s) of electrode array 150, for delivery of the current pulse to the tissue surrounding the selected electrode. Measurement circuitry 128 is configured to capture measurements of neural responses sensed at sense electrode(s) of the electrode array as selected by electrode selection module 126.

[0032] Figure 3 is a schematic illustrating interaction of the implanted stimulator 100 with a nerve 180, in this case the spinal cord however alternative embodiments may be positioned adjacent any desired neural tissue including a peripheral nerve, visceral nerve, parasympathetic nerve or a brain structure. Electrode selection module 126 selects a stimulation electrode 2 of

electrode array 150 to deliver an electrical current pulse to surrounding tissue including nerve 180, and also selects a return electrode 4 of the array 150 for stimulus current recovery to maintain a zero net charge transfer.

[0033] Delivery of an appropriate stimulus to the nerve 180 evokes a neural response comprising a compound action potential which will propagate along the nerve 180 as illustrated, for therapeutic purposes which in the case of spinal cord stimulator for chronic pain might be to create paraesthesia at a desired location.

[0034] The device 100 is further configured to sense the existence and intensity of compound action potentials (CAPs) propagating along nerve 180, whether such CAPs are evoked by the stimulus from electrodes 2 and 4, or otherwise evoked. Thus, communications originating elsewhere along the neural pathway and intended for the device 100, and comprising an encoded sequence of action potentials, may be sensed by the device 100. To this end, any electrodes of the array 150 may be selected by the electrode selection module 126 to serve as measurement electrode 6 and measurement reference electrode 8. Signals sensed by the measurement electrodes 6 and 8 are passed to measurement circuitry 128, which for example may operate in accordance with the teachings of International Patent Application Publication No. WO2012155183 by the present applicant, the content of which is incorporated herein by reference.

[0035] Figure 4 is a plot of neural activity observed upon the spinal cord 180 by the device 100. During the period shown, four minutes, the implant recipient was asked to perform certain movements, as follows: no movement at around 20-30 s, rubbing leg around 40-50s, lifting leg around 60-70s, and walking during the period 120-140 s. The present invention recognises that each active movement is distinguishable from a lack of movement, and that each such sensory or proprioceptive input can be deliberately modulated with data in order to communicate with the neural device 100.

[0036] Figure 5 illustrates modes of peripheral sensory data input involving the user tapping their feet and/or slapping their thighs. The user may know to perform such activities in a predefined pattern which can be distinguished in the neural signal as a communication, for example the user may tap their feet in Morse code or to replicate a favourite song. The user may also or alternatively clench or activate certain muscle(s) to communicate with the SCS 100.

[0037] Figure 6 illustrates machine-assisted sensory input to communicate with the implanted device 100, in the form of a smartphone 600 configured to deliver vibrational sensory inputs to the user's thigh, to induce afferent sensory activity on the lateral femoral cutaneous nerve 602, for detection by the device 100. In this embodiment, communication of external information or commands to the implanted system 100 is effected by placing the vibration device 600 on an area of skin which is neurologically addressed by the electrode array 150. External information or commands are encoded as a sequence of vibrations, and the device 600 is controlled to vibrate according to that sequence. The evoked sequence of neural stimuli then propagate afferently along nerve 602 and into the spinal cord 180 and are then observed through the electrodes 150. The observed neural response sequence is decoded by the implant 110 to recover the original information or commands. The encoding of the sequence of vibrations may be carried out in accordance with any suitable encoding scheme such as being pulse width modulated, pulse amplitude modulated, pulse position modulated, amplitude or intensity modulated, delivered in bursts which are frequency modulated, modulated by analog or digital modulation, or on-off keying. This arrangement has the advantage that there is no need for the telemetry module 114 to be constantly active to receive radio communications. Instead, sensory input communications from device 600 may be used to selectively activate telemetry module 114 only when needed, or may be used for any other communications purpose.

[0038] Device 600 operates in this manner under the control of an app, and such apps configured for communications with neural implants for therapeutic or other purposes are within the scope of the present invention.

[0039] The arrangement of Figure 6 may additionally or alternatively be used to re-program a site of paraesthesia effected by device 100. In such embodiments, the memory 118 is populated with a store of calibration data to assist in identifying the location where the skin is touched by device 600. The calibration data is produced as follows: (a) neural responses are measured by device 100 while touching specified locations on the skin, and (b) information is stored in the calibration store indicating the nature of measurements which arise for each location. Then when re-programming of the site of paraesthesia is required, as may be initiated by any suitable communications method including those described herein, a re-programming mode is entered in which the device 600 is held against the skin at a location of desired paraesthesia, and caused to deliver vibrational sensory inputs. The evoked neural activity is observed by device 100 and matched to the closest match(es) from the calibration store in memory 118, and used to re-set the patient settings 120 such as stimulus electrode selection.

[0040] Figure 7 illustrates communication between two implanted devices 110 and 710, along a neural pathway 180. Device 710 is a vagus nerve stimulator which comprises an implanted electrode array 752 configured to stimulate the vagus nerve 182 for therapeutic purposes such as treatment of epilepsy or depression. Device 710 further comprises an electrode array 750 implanted alongside the spinal cord 180 in order to enable communications with the device 110 along the communications channel provided by the spinal cord 180. Device 110 may thereby communicate with device 710 by causing the delivery of encoded stimuli from electrode array 150 to the spinal cord 180, in order to evoke neural responses which propagate along the spinal cord. Array 750 is then able to sense the passing sequence of neural activity evoked by the device 110, from which the device 710 decodes the communications. For example, device 110 may be operable to monitor a heart rate of the patient by reference to heartbeat modulations of observed neural responses on the spinal cord 180, and to communicate to device 710 at times when changed vagus nerve stimulation is required in order to influence a heart rate of the patient. The configuration of array 750 and the associated components of device 710 may be substantially the same as for device 100 as shown in Figure 3.

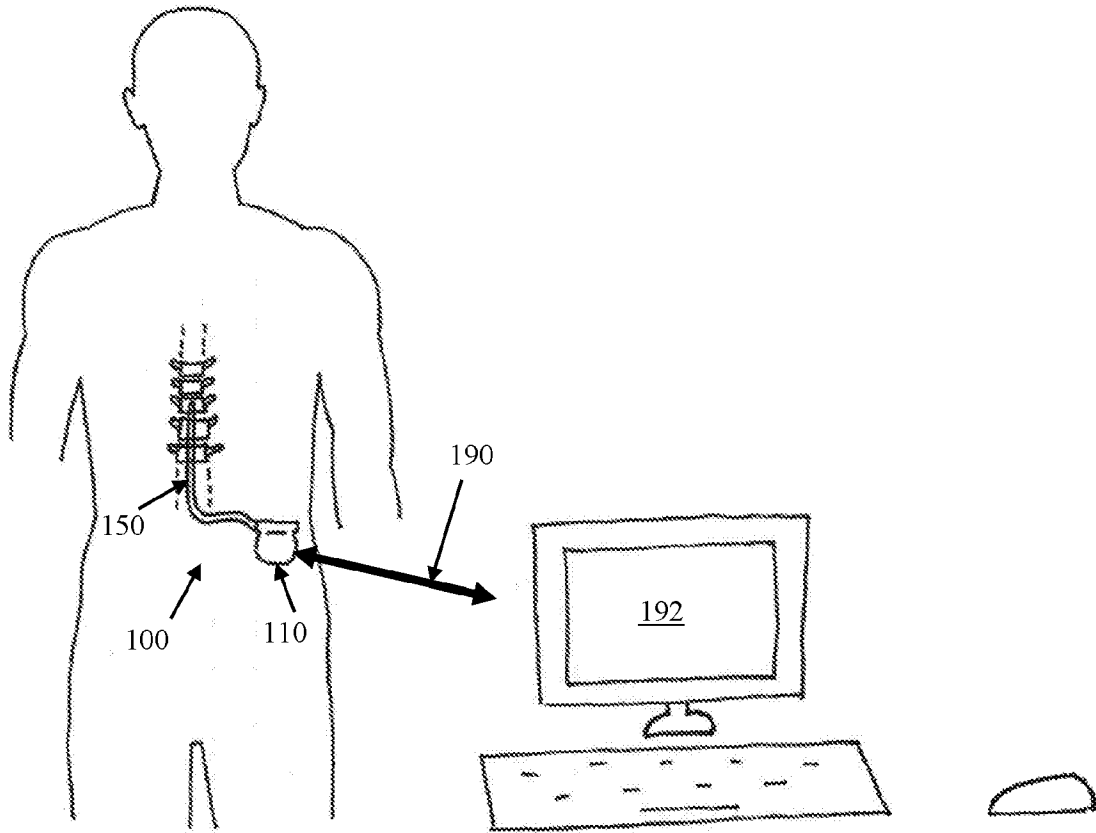
[0041] It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not limiting or restrictive.

## CLAIMS:

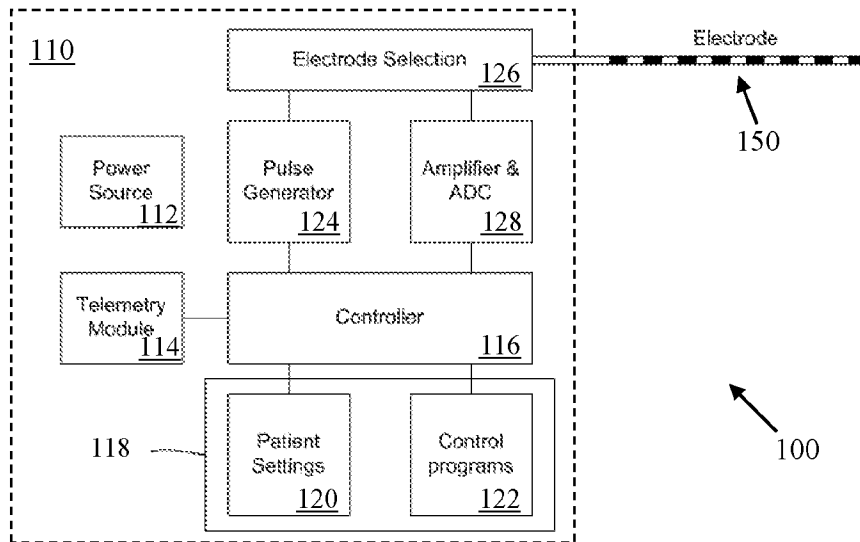
1. A method of communicating along a neural pathway, the method comprising:  
stimulating the neural pathway at a first location by delivering a peripheral sensory input, in order to evoke neural responses which propagate along the neural pathway, the neural responses being modulated with data;  
an implanted device sensing the evoked neural responses at a second location spaced apart from the first location along the neural pathway, and  
the implanted device demodulating the sensed neural responses to retrieve the data, the data being configured to control or alter the operation of the implanted device.
2. The method of claim 1 wherein the neural responses are modulated with the data by on-off keying.
3. The method of claim 1 or claim 2 wherein the communicated data instructs the implanted device to activate a wireless transceiver.
4. The method of any one of claims 1 to 3 wherein the neural responses evoked for the purposes of communication are configured to be minimally perceptible or imperceptible by the implant recipient.
5. The method of claim 4 wherein perception of the evoked communications responses is minimised by using short-time stimuli.
6. The method of claim 4 or claim 5 wherein perception of the evoked communications responses is minimised by delivering stimuli in an interleaved manner with therapeutic stimuli.
7. The method of any one of claims 1 to 6 wherein the modulated neural responses are evoked by motor activity.
8. The method of any one of claims 1 to 7 wherein the modulated neural responses are evoked by sensory input.
9. The method of any one of claims 1 to 8 wherein the modulated neural responses are evoked by stimulating the neural pathway directly.
10. The method of any one of claims 1 to 9 wherein the communications originate from an external control device.
11. The method of claim 10 wherein the external control device comprises a vibrational input device.
12. The method of claim 11 wherein the vibrational input device is a mechanical vibrator of a smartphone.
13. The method of any one of claims 1 to 12, further comprising formulating appropriate encoded sensory or motor input for a given implant recipient as part of a fitting process after implantation of the implanted device.

14. The method of claim 12 wherein the fitting process includes configuring the implanted device to attach a unique control meaning to input modulations selected by the user.
15. The method of any one of claims 1 to 14 further comprising entering a temporary re-mapping mode to redefine device parameters in order to change a region of paraesthesia delivered by the implanted device.
16. The method of any one of claims 1-15 wherein the communications delivered along the neural pathway comprise instructions to activate, deactivate or alter a therapeutic function of the implanted device.
17. The method of any one of claims 1 to 16 wherein the implanted device is operable to differentiate between distally evoked neural activity and locally evoked neural activity.
18. A system for communicating along a neural pathway, the system comprising:
  - an external control device configured to stimulate the neural pathway at a first location, in order to evoke neural responses which propagate along the neural pathway, the neural responses being modulated with data; and
  - an implanted device configured to sense the evoked neural responses at a second location spaced apart from the first location along the neural pathway, and to demodulate the sensed neural responses to retrieve the data, the data being configured to control or alter the operation of the implanted device.
19. The system of claim 18 wherein the implanted device is a spinal cord stimulator.
20. The system of claim 18 or claim 19 wherein the external device is a smartphone.
21. The system of any one of claims 18 to 20 wherein the communicated data comprises instructions for the implanted device to activate a wireless transceiver.

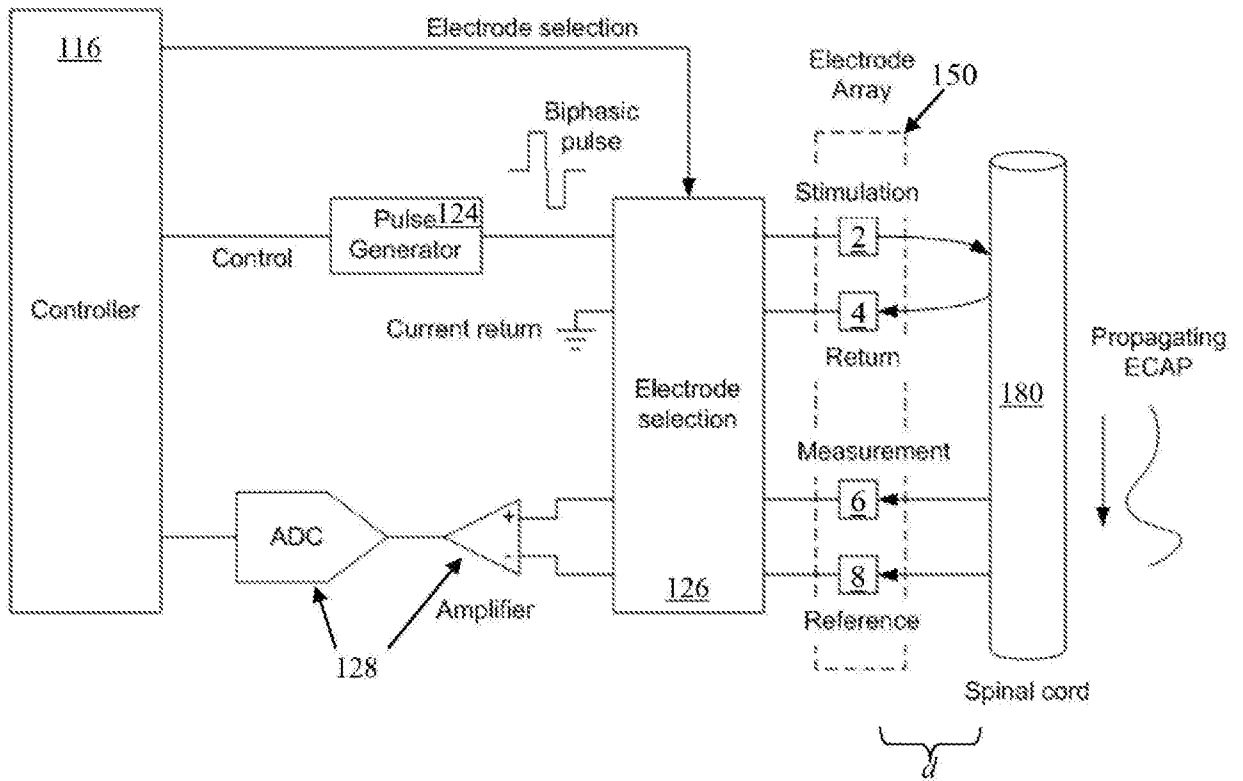




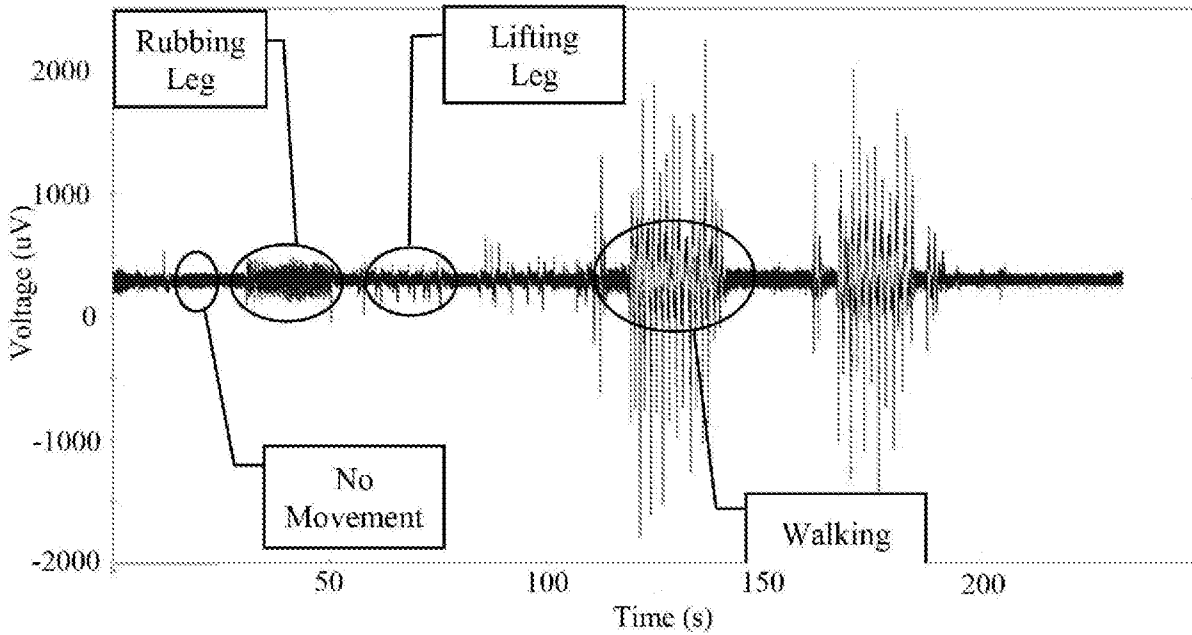
**Figure 1**



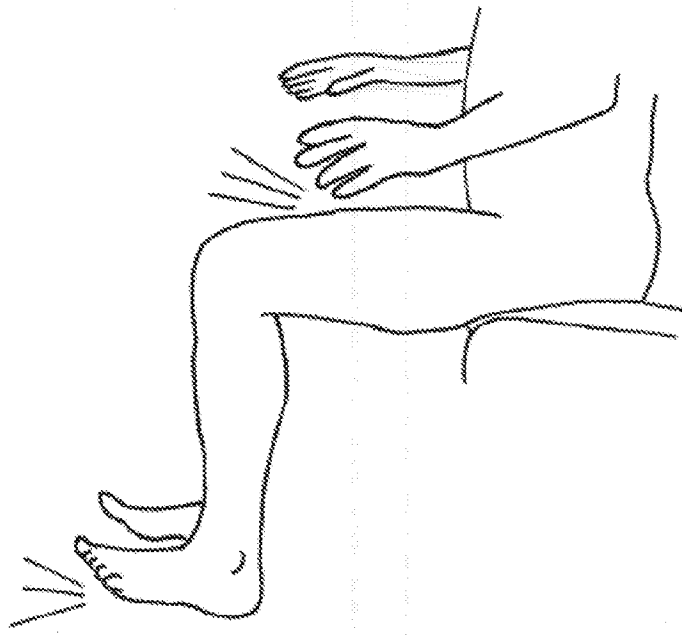
**Figure 2**



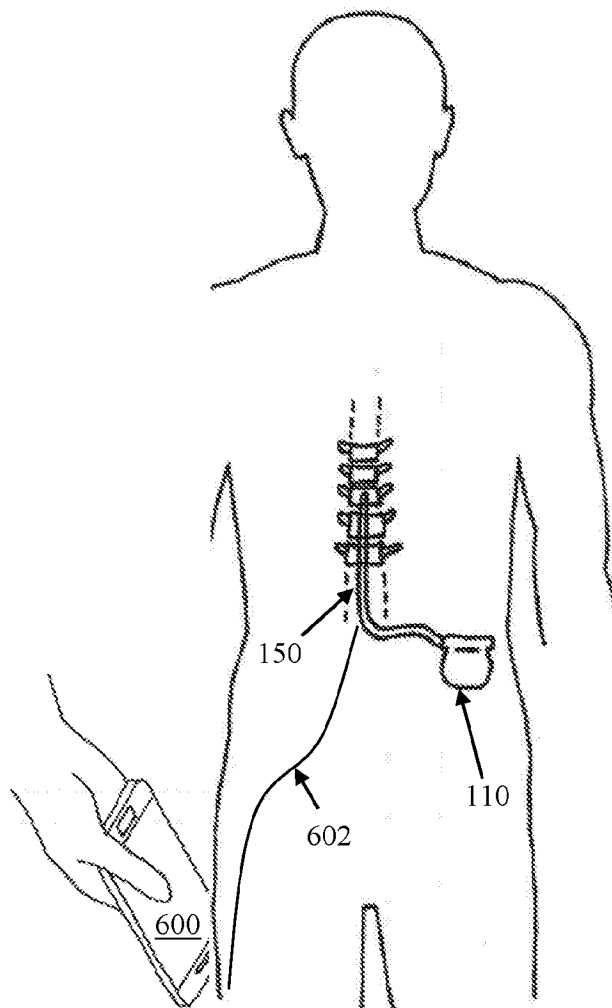
**Figure 3**



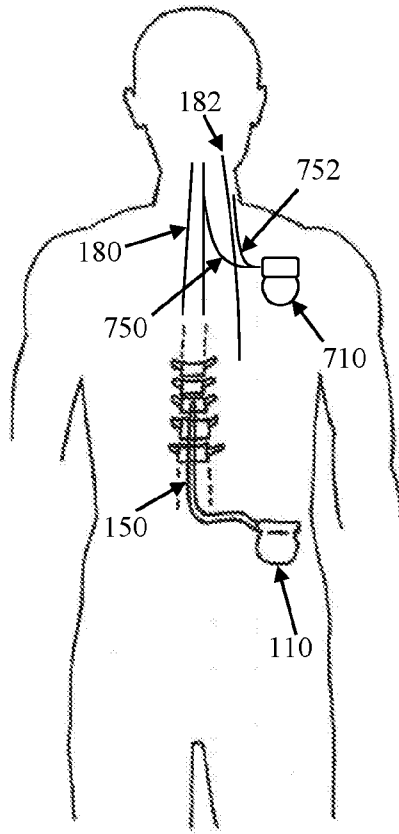
**Figure 4**



**Figure 5**



**Figure 6**



**Figure 7**