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(54) **Title:** BIOLOGICAL INTERFACE SYSTEM WITH CLINICIAN CONFIRMATION OF PARAMETER CHANGES

(57) **Abstract:** A system and method for a biological interface system (100) that processes multicellular signals of a patient (500) and controls an external device (300) is disclosed. The system includes a sensor that detects the multicellular signals and a processing unit for producing the control signal based on the multicellular signals. The system further includes a permission routine that requires an approval of a clinician or other specific operator of the system when specific system parameters are changed. Embedded automatic and semi-automatic calibration and configuration systems are also disclosed.

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BIOLOGICAL INTERFACE SYSTEM WITH CLINICIAN CONFIRMATION OF PARAMETER CHANGES

[001] This application claims the benefit of priority under 35 U.S.C. § 119(e) of U.S. provisional application no. 60/592,275, filed July 29, 2004.

FIELD OF THE INVENTION

[002] The present invention relates to biological interface systems that include a device controlled by processed multicellular signals of a patient. A processing unit produces a control signal based on multicellular signals received from a sensor consisting of multiple electrodes. More particularly, the system includes one or more integrated parameters used by the processing unit to perform a function. In order for the integrated parameters to be modified, the system includes a permission routine that requires clinician or other operator approval of the modification.

DESCRIPTION OF RELATED ART

[003] Biological interface devices, specifically neural interface devices, are currently under development for numerous patient applications including restoration of lost function due to traumatic injury or neurological disease. Sensors, such as electrode arrays, implanted in the higher brain regions that control voluntary movement, can be activated voluntarily to generate electrical signals that can be processed by a biological interface device to create a thought invoked control signal. Such control signals can be used to control numerous devices including computers and communication devices, external prostheses, such as an artificial arm or functional electrical stimulation of paralyzed muscles, as well as robots and other remote control devices. Patient's afflicted with amyotrophic lateral sclerosis (Lou Gehrig's Disease), particularly those in advanced stages of the disease, would also be applicable to receiving a neural interface device, even if just to improve communication to the external world, including Internet access, and thus improve their quality of life.

[004] Early attempts to utilize signals directly from neurons to control an external prosthesis encountered a number of technical difficulties. The ability to

identify and obtain stable electrical signals of adequate amplitude was a major issue. Another problem that has been encountered is caused by the changes that occur to the neural signals that occur over time, resulting in a degradation of system performance. Neural interface systems that utilize other neural information, such as electrocorticogram (ECoG) signals, local field potentials (LFPs) and electroencephalogram (EEG) signals have similar issues to those associated with individual neuron signals. Since all of these signals result from the activation of large groups of neurons, the specificity and resolution of the control signal that can be obtained is limited. However, if these lower resolution signals could be properly identified and the system adapt to their changes over time, simple control signals could be generated to control rudimentary devices or work in conjunction with the higher power control signals processed directly from individual neurons.

[005] Commercialization of these neural interfaces has been extremely limited, with the majority of advances made by universities in a preclinical research setting. As the technologies advance and mature, the natural progression will be to more sophisticated human applications, such as those types of devices regulated by various governmental regulatory agencies including the Food and Drug Administration in the United States.

[006] When sophisticated biological interface systems are commercially available it will become important for these systems to include numerous safety features required in the various settings of patient care and other patient settings. Also, systems which require minimal calibration, such as self-calibrating or self-adjusting systems will be required, especially when used outside a hospital or monitored patient care facility. Unfortunately, safety confirmation and other validation tests of a fully automated system requires a tremendous amount of actual, clinical experience and other system testing. The time required to gather such data can be extremely long and the costs can be prohibitive.

[007] There is therefore a need for an improved biological interface system which includes a safety routine that provides a safe and efficacious manner of modifying one or more parameters of the system, such as a parameter that has been changed by an automatic or semi-automatic calibration function of the system. Enforcement of these safety routines by the system, such as for

specific parameter changes, allows reduced manpower requirements to implement system parameter changes while ensuring safety and proper functionality for the patient.

SUMMARY OF THE INVENTION

[008] According to a first aspect of the invention, a biological interface system is disclosed. The biological interface system collects multicellular signals emanating from one or more living cells of a patient and transmits processed signals to a controlled device. The system comprises a sensor for detecting multicellular signals, the sensor consisting of a plurality of electrodes. The electrodes are designed to detect the multicellular signals. A processing unit is designed to receive the multicellular signals from the sensor and process the multicellular signals to produce the processed signals transmitted to the controlled device. The system includes one or more integrated parameters, utilized by the processing unit to perform a function. When one or more of the integrated parameters is modified, an integral permission routine requires approval of an operator of the system.

[009] In another preferred embodiment, the biological interface system includes an automated calibration function. This calibration function automatically determines a modification for one or more integrated parameters. The modification of certain parameters may invoke the permission routine while others may be automatically modified without operator intervention. The biological interface system may be a neural interface system, and may perform a diagnosis, provide a therapeutic benefit, restore lost function or otherwise enhance the patient's capabilities.

[010] In another preferred embodiment, the one or more cellular signals emanate from the central nervous system of the patient. Multicellular signals can comprise 2 cellular signals from a single cell, and the signals may comprise neuron spikes, electrocorticogram signals, local field potential signals, and electroencephalogram signals. The system may assign at least one cellular signal to a specific use.

[011] In another preferred embodiment, the patient is a human being. The patient may be a quadriplegic, a paraplegic, an amputee, a spinal cord injury

victim, a stroke victim or a physically impaired person. In an alternative embodiment, the patient is healthy, and the system of the present invention is used to enhance normal function.

[012] In yet another preferred embodiment, the sensor is an array of electrodes. The electrodes may be placed into neural tissue, such as brain tissue, and one or more electrodes may stimulate tissue as well as detect cellular signals. The sensor may comprise more than one discrete component, each component including at least one electrode. The sensor components may comprise one or more of an array of electrodes, wire or wire bundle electrodes, subdural grid electrodes, scalp electrodes and cuff electrodes.

[013] In yet another preferred embodiment, the integrated parameters include one or more of stored information, transmitted information and received information. The integrated parameters may represent one or more of: neuron spike sorting variables; cellular signal parameters; signal processing variables; signal selection variables; signal quality variables, external device parameters including approved device parameters; operator permission or other operator parameters; telemetry parameters; patient parameters; system performance criteria; alarm, alert or warning parameters; threshold parameters; calibration parameters; patient training parameters; and other system parameters.

[014] In yet another preferred embodiment, the function performed by the processing unit is to produce the processed signals transmitted to the controlled device. Alternative functions include: transferring information to a separate device; receiving information from a separate device; production of a processed signal for a second controlled device; activating an alarm, alert or warning; shutting down or resetting the system; ceasing or altering control of the controlled device; storing of information; and performing or completing a calibration procedure.

[015] In yet another preferred embodiment, the permission routine limits acceptable parameter modifications to specific operators. The system may include multiple levels for multiple operators. An interrogation function may be utilized to interrogate or otherwise diagnose the system and retrieve the resultant information. The permission routine includes one or more methods of confirming the identity of the operator including a confirmation of: username; password; and

IP address. In a preferred embodiment, the operator gives approval via the permission routine from a location remote from the patient location. Operator approval can be achieved by one or more of: activating an icon; performing one or more keystrokes on an input device; clicking a device such as a mouse; or performing one or more other tasks. The permission routine may require a double confirmation of the approval by the operator, and the operator can approve multiple parameters with a single approval event.

[016] In yet another preferred embodiment, one or more parameters are modified due to adaptive processing of the system. Parameters may also be modified due to: an alarm condition; a change in patient performance or condition; a cellular signal change; an initial setting of a parameter; and addition or deletion of a controlled device,

[017] In yet another preferred embodiment, the operator is at a remote location from the patient when the approval is given via the permission routine. Operators can be one or more of: a clinician; the patient; a technician; and other appropriate users of the system. The system may include two or more controlled devices in which multiple processed signals are output. The multiple processed signals can be based on different sets of cellular signals. The system may include a test routine, such as a routine that can be run by the approving operator each time a specific integrated parameter is modified. The system may include an adaptive processing routine such as where integrated parameters are suggested by this routine and modification performed when the operator approval is given.

[018] In yet another preferred embodiment, a monitoring routine is integral to the system, the monitoring routine can be based on current, real time and/or historic data. The system may include information transfer means, such as to transfer integrated parameter change information to a separate discrete component or a separate device. The system may include a parameter modification notification function, such as to automatically notify one or more operators of a pending or recommended change. The system may include an operator validation routine such as to confirm the identity of the operator prior to giving an approval via the permission routine. The system may include a second operator such as an operator with a different set of parameter modifying permissions than the first operator. The system may include a login function such

that the operator must log into the system prior to approving a parameter. The system may include a calibration system such as a patient activated calibration system or an automatic calibration system. The system may include a patient feedback module, such as a feedback system that provides the patient with audio, tactile and/or visual information to improve control of the controlled device. The system may include a drug delivery system, such as an implanted drug delivery system controlled by the processed signals. The system may include a patient confirmation routine such that the patient can control the controlled device, for a limited time only, with a parameter modified prior to the approval. The system may include an embedded ID, such as an ID used to confirm compatibility of one or more discrete components of the system. The system may include a visual display of cellular data, such as to display individual cellular signals to one or more operators. The system may include a permission routine activation log, such as a log storing failed attempts at approving a modification to an integrated parameter.

[019] According to another aspect of the invention, a method of modifying an integrated parameter of a biological interface system is disclosed. The method comprises the steps of first providing a biological interface system for collecting multicellular signals emanating from one or more living cells of a patient and for transmitting processed signals to a controlled device. The biological interface system includes a sensor for detecting the multicellular signals. The sensor may comprise a plurality of electrodes to allow for detection of the multicellular signals. The biological interface system also includes a processing unit. The processing unit receives the multicellular signals from the sensor, processes the multicellular signals to produce processed signals and transmits the processed signals to the controlled device. The biological interface system further includes the controlled device that receives the processed signals from the processing unit. The biological interface system further includes one or more integrated parameters utilized by the processing unit to perform a function. When one or more of the integrated parameters is modified, an integrated permission routine requires approval of an operator of the system.

[020] Both the foregoing general description and the following detailed description are exemplary and are intended to provide further explanation of the embodiments of the invention as claimed.

BRIEF DESCRIPTION OF THE DRAWINGS

[021] The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate various embodiments of the present invention, and, together with the description, serve to explain the principles of the invention. In the drawings:

[022] Fig. 1 illustrates a biological interface system consistent with the present invention;

[023] Fig. 2 illustrates an exemplary embodiment of a portion of the biological system including sensor electrodes implanted in the brain of a patient consistent with the present invention;

[024] Fig. 3 illustrates another exemplary embodiment of a biological interface system consistent with the present invention wherein an operator approves the modification of a parameter from a remote location.

[025] Fig. 4 illustrates another exemplary embodiment of a biological interface system consistent with the present invention wherein a patient controls multiple devices.

[026] Fig. 5 illustrates a cellular signal processing unit consistent with the present invention.

[027] Fig. 6 illustrates another exemplary embodiment of a biological interface system consistent with the present invention wherein a sensor includes two discrete components and the system controls multiple implants of the patient.

DESCRIPTION OF THE EMBODIMENTS

[028] To facilitate an understanding of the invention, a number of terms are defined immediately herebelow.

[029] Definitions

[030] As used herein, the term "biological interface system" refers to a neural interface system or any system that interfaces with living cells that produce electrical activity or cells that produce other types of detectable signals.

[031] As used herein, the term "cellular signals" refers to subcellular signals, intracellular signals, extracellular signals, single cell signals and signals emanating from one or more cells. "Subcellular signals" refers to a signal derived from a part of a cell; a signal derived from one particular physical location along or within a cell; a signal from a cell extension, such as a dendrite, dendrite branch, dendrite tree, axon, axon tree, axon branch, pseudopod or growth cone; or signals from organelles, such as golgi apparatus or endoplasmic reticulum. "Intracellular signals" refers to a signal that is generated within a cell or by the entire cell that is confined to the inside of the cell up to and including the membrane. "Extracellular signals" refers to signals generated by one or more cells that occur outside of the cell(s). "Cellular signals" include but are not limited to signals or combinations of signals that emanate from any living cell. Specific examples of "cellular signals" include but are not limited to: neural signals; cardiac signals including cardiac action potentials; electromyogram (EMG) signals; glial cell signals; stomach cell signals; kidney cell signals; liver cell signals; pancreas cell signals; osteocyte cell signals; sensory organ cell signals such as signals emanating from the eye or inner ear; and tooth cell signals. "Neural signals" refers to neuron action potentials or spikes; local field potential (LFP) signals; electroencephalogram (EEG) signals; electrocorticogram signals (ECoG); and signals that are between single neuron spikes and EEG signals.

[032] As used herein, "multicellular signals" refers to signals emanating from two or more cells, or multiple signals emanating from a single cell.

[033] As used herein, "patient" refers to any animal, such as a mammal and preferably a human. Specific examples of "patients" include but are not limited to: individuals requiring medical assistance; healthy individuals; individuals with limited function; and in particular, individuals with lost function due to traumatic injury or neurological disease.

General Description of the Embodiments

[034] Systems and methods consistent with the invention detect cellular signals generated within a patient's body and implement various signal processing techniques to generate processed signals for transmission to a device to be controlled. The system includes a sensor comprosomg a plurality of electrodes that detect multicellular signals from one or more living cells, such as from the

central or peripheral nervous system, of a patient. The system further includes a processing unit that receives and processes the multicellular signals and transmits a processed signal to the controlled device. The processing unit utilizes various electronic, mathematic, neural net and other signal processing techniques in producing the processed signal. Examples of controlled devices include but are not limited to prosthetic limbs, ambulation vehicles, communication devices, robots, computers or other controllable devices.

[035] In one exemplary embodiment, a biological interface system includes one or more integrated parameters that are used by the processing unit to perform a function. The system further includes a permission routine, which requires approval of a clinician or other operator when one or more parameters are modified.

[036] In another exemplary embodiment, a biological interface system includes multiple discrete components, such as those defined by a housing or other enclosing or partially enclosing structure, or those defined as being detached or detachable from another discrete component. Each discrete component can transmit electronic information to a separate component through the use of a physical cable, including one or more of electrically conductive wires or optical fibers. Alternatively or additionally, transmission of data or other information between discrete components can be accomplished wirelessly, by one or more discrete components including a transceiver that may transmit and receive data such as through the use of "Bluetooth" technology or according to any other type of wireless communication means, method, protocol or standard, including, for example, code division multiple access (CDMA), wireless application protocol (WAP), infrared or other optical telemetry, radiofrequency or other electromagnetic telemetry, ultrasonic telemetry or other telemetric technologies.

[037] Any one of the sensor, the processing unit and the controlled device may be wholly or partially included in a single discrete component, or a portion of one may be included with a portion or the entirety of another in a single discrete component. Any and all discrete components may be internal to the body of the patient, external to the body of the patient, as well as implanted in the patient but protruding through the skin such as to be accessible for connection to a physical cable. Discrete components can include, in whole or in part, numerous functions

and/or components of the biological interface system, or components to be used in combination with the biological interface system. These discrete components include but are not limited to: a multicellular sensor of the present invention, a processing unit of the present invention, a controlled device of the present invention, a display monitor, a calibration or system configuration module, a memory storage device, a telemetry device, a physical cable connecting device, a power supply module, a recharging module, an information recall and display unit, a system calibration unit, such as an automatic or semi-automatic calibration unit, and a system diagnostic unit. In the instance where a discrete component includes a configuration module, the configuration module may include configuration programs, settings and patient or system specific data for multiple patients and/or multiple systems. In those instances, all data for a specific single system is associated, or electronically linked, with a unique electronic identifier of that particular system. The configuration module uses the embedded unique electronic identifier during the configuration process to assure that the proper data is utilized.

[038] Electronic information or data is transmitted between one or more discrete components using one or more physical cables and/or wireless communication means. A unique electronic identifier, such as a unique alphanumeric code or serial number associated with the system, is included in one or more transmissions of information between discrete components or between any discrete component and a separate device outside the system. Any and all communications that include the unique electronic identifier can be used to confirm that each discrete component is from the same or at least a compatible system. In wireless communication, the unique electronic identifier can be included in various handshaking protocols used in one or more information transmissions, such handshaking protocols well known to those of skill in the art of wireless communication. This safety feature is extremely important especially as it relates to critical patient care devices such as a biological interface systems of the invention disclosed herein. If a discrete component that had been calibrated or otherwise configured for use with another system or patient, were accidentally attached to a discrete component of a different or otherwise incompatible system, undesired and potentially hazardous effects could occur. The described invention

of this application includes multiple embodiments that can detect such an incompatibility, prevent undesired device control and alert the patient or other involved party of the issue.

Detailed Description of the Embodiments

[039] Reference will now be made in detail to the present embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used throughout the drawings to refer to the same or like parts.

[040] Referring now to Fig. 1, a biological interface system 100 may comprise implanted components and components external to the body of patient 500. A sensor for detecting multicellular signals, not shown and preferably a two dimensional array of multiple protruding electrodes, has been implanted in the brain of patient 500, in an area such as the motor cortex. In a preferred embodiment, the sensor is placed in an area to record multicellular signals that are under voluntary control of the patient. Alternatively or additionally to the two dimensional array, the sensor may include one or more wires or wire bundles which include a plurality of electrodes. Patient 500 of Fig. 1 is shown as a human being, but other mammals and life forms that produce recordable multicellular signals would also be applicable. Patient 500 may be a patient with a spinal cord injury or afflicted with a neurological disease that has resulted in a loss of voluntary control of various muscles within the patient's body. Alternatively or additionally, Patient 500 may have lost a limb, and system 100 will include a prosthetic limb as its controlled device.

[041] The various electrodes of the sensor detect multicellular signals, such as neuron spikes that emanate from the individual neurons of the brain. The sensor can be placed at one or more various locations within the body of patient 500, such as at an extracranial site, and preferably in a location to collect multicellular signals directly from the central or peripheral nervous system. The electrodes can assume various shapes and forms, including the penetrating electrodes described hereabove, as well as atraumatic or blunt shapes such as those included in subdural grid electrodes and scalp electrodes.

[042] The sensor electrodes of system 100 can be used to detect various multicellular signals including neuron spikes, electrocorticogram signals (ECoG),

local field potential (LFP) signals, electroencelphalogram (EEG) signals and other cellular and multicellular signals. The electrodes can detect multicellular signals from clusters of neurons and provide signals midway between single neuron and electroencephalogram recordings. Each electrode is capable of recording a combination of signals, including a plurality of neuron spikes. The sensor can be placed on the surface of the brain without penetrating, such as to detect local field potential (LFP) signals, or on the scalp to detect electroencephalogram (EEG) signals.

[043] A processing unit, shown in Fig. 1 as comprising processing unit first portion 130a and processing unit second portion 130b, receives the multicellular signals from the sensor and performs various signal processing functions including but not limited to amplification, filtering, sorting, conditioning, translating, interpreting, encoding, decoding, combining, extracting, mathematically transforming and/or otherwise processing those signals to generate a processed signal, such as a control signal, for transmission to a controlled device. The processing unit may process signals that are mathematically combined, such as the combining of neuron spikes that are first separated using spike discrimination methods, these methods known to those of skill in the art. The processing unit may comprise multiple components as shown in Fig. 1, or a single component. Each of the processing unit components can be fully implanted in patient 500, be external to the body, or be implanted with a portion of the component exiting through the skin.

[044] In Fig. 1, controlled device 300 is a computer system including a computer display with cursor control, and patient 500 may be controlling one or more of a mouse, keyboard, cursor, joystick, other computer input device or combinations and/or multiples of these devices. Numerous other controlled devices can be included in system 100, individually or in combination, including but not limited to a computer, a computer display, a mouse, a cursor, a joystick, a personal data assistant, a robot or robotic component, a computer controlled device, a teleoperated device, a communication device or system, a vehicle such as a wheelchair, an adjustable bed, an adjustable chair, a remote controlled device, a Functional Electrical Stimulator device or system, a muscle stimulator, an artificial or prosthetic limb, a vision enhancing device, a vision restoring device,

a hearing enhancing device, a hearing restoring device, a movement assisting device, medical therapeutic equipment such as a drug delivery apparatus, medical diagnostic equipment such as epilepsy monitoring apparatus, other medical equipment such as a bladder control device, a bowel control device and a human enhancement device, closed loop medical equipment and other controllable devices applicable to patients with some form of paralysis or diminished function as well as any device that may be utilized under direct brain or thought control in either a healthy or unhealthy patient.

[045] The sensor is connected via a multi-conductor cable, not shown but implanted in patient 500, to processing unit first portion 130a which includes a transcutaneous pedestal, hidden, but behind intraprocessing unit first portion 130a which is shown attached to the transcutaneous pedestal in Fig. 1. The transcutaneous pedestal is mounted to the patient's skull and includes multiple conductive pads for connecting to mating pins of processing unit first portion 130a. The implanted multi-conductor cable includes a separate conductor for each electrode, as well as additional conductors to serve other purposes, such as providing reference signals and ground. Various descriptions of the sensor and multi-conductor cable are described in greater detail in relation to subsequent figures included herebelow.

[046] Processing unit first portion 130a may include various signal conditioning elements such as amplifiers, filters and signal multiplexing circuitry. Processing unit first portion 130a includes a unique electronic identifier, such as a unique serial number or any alphanumeric or other retrievable, identifiable code associated uniquely with the system 100 of patient 500. The unique electronic identifier may take many different forms in processing unit first portion 130a, such as a piece of electronic information stored in a memory module; a semiconductor element or chip that can be read electronically via serial, parallel or telemetric communication; pins or other conductive parts that can be shorted or otherwise connected to each other or to a controlled impedance, voltage or ground, to create a unique code; pins or other parts that can be masked to create a binary or serial code; combinations of different impedances used to create a serial code that can be read or measured from contacts, features that can be optically scanned and read by patterns and/or colors; mechanical patterns that can be read by

mechanical or electrical detection means or by mechanical fit, a radio frequency ID or other frequency spectral codes sensed by radiofrequency or electromagnetic fields, pads and/or other marking features that may be masked to be included or excluded to represent a serial code, or any other digital or analog code that can be retrieved from the discrete component.

[047] Alternatively or in addition to embedding the unique electronic identifier in processing unit first portion 130a, the unique electronic identifier can be embedded in the sensor and/or the multi-conductor cable connecting the sensor and processing unit first portion 130a. Under certain circumstances, the transcutaneous pedestal with multiple conductive pads, such as that which is attached to processing unit first portion 130a of Fig. 1, may need to be replaced. Under these circumstances, a system compatibility check between a new pedestal and the remaining implanted system, the implanted sensor and/or multi-conductor cable, can be confirmed at the time of the repair or replacement surgery through the use of the embedded unique electronic identifier.

[048] The unique electronic identifier can be embedded in one or more of the discrete components at the time of manufacture, or at a later date such as at the time of any clinical procedure involving the system, such as a surgery to implant the sensor electrodes into the brain of patient 500. Alternatively, the unique electronic identifier may be embedded in one or more of the discrete components at an even later date such as during a system configuration or calibration.

[049] Referring again to Fig. 1, processing unit first portion 130a is electrically attached to processing unit second portion 130b via intra-processing unit cable 140. Intra-processing unit cable 140, as well as other physical cables incorporated into system 100, may include electrical wires, optical fibers, other means of transmitting data and/or power and any combination of those means. The number of individual conductors of intra-processing unit cable 140 can be greatly reduced from the number of conductors included in the multi-conductor cable between the implanted sensor and processing unit first portion 130a through signal combination and/or signal multiplexing circuitry included in processing unit first portion 130a. Intra-processing unit cable 140, as well as all other physical cables incorporated into system 100, may include shielding elements to prevent or

otherwise reduce the amount of electro-magnetic noise added to the various cellular signals, processed cellular signals and other signals carried by those cables. In an alternative preferred embodiment, intra-processing unit cable 140 is replaced with a wireless connection for transmission between processing unit first portion 130a and processing unit second portion 130b. Wireless communication means, well known to those of skill in the art and described in more detail through this disclosure, can be utilized to transmit information between any of the components of system 100.

[050] A qualified individual, operator 110, may perform a calibration of system 100 at some time during the use of system 100, preferably soon after implantation of the sensor. In a preferred embodiment, at least one calibration routine is performed and successfully completed by operator 110 prior to use of system 100 by patient 500. As depicted in Fig. 1, operator 110 utilizes configuration apparatus 115 which includes two monitors, first configuration monitor 120a and second configuration monitor 120b, along with configuration keyboard 116 to perform the calibration routine and other configuration tasks such as patient training, algorithm and algorithm parameter selection and output device setup. The software programs and hardware required to perform the calibration can be included in the processing unit, such as processing unit second portion 130b, or be included in a central processing unit incorporated into configuration apparatus 115. Configuration apparatus 115 can include additional input devices, such as a mouse or joystick, not shown. Configuration apparatus 115 can include various elements, functions and data including but not limited to: memory storage for future recall of calibration activities, operator qualification routines, standard human data, standard synthesized or artificial data, neuron spike discrimination software, operator security and access control, controlled device data, wireless communication means, remote (such as via the Internet) calibration communication means and other elements, functions and data used to provide an effective and efficient calibration on a broad base of applicable patients and a broad base of applicable controlled devices. The unique electronic identifier can be embedded in one or more of the discrete components at the time of system configuration, including the act of identifying a code that was embedded into a

particular discrete component at its time of manufacture, and embedding that code in a different discrete component.

[051] In a preferred embodiment, an automatic or semi-automatic calibration function or routine is embedded in system 100. This embedded calibration routine can be used in place of a calibration routine performed manually by Operator 110 as is described hereabove, or can be used in conjunction with one or more manual calibrations. Automatic and/or semi-automatic calibration events can take many forms including but not limited to: monitoring of cellular activity, wherein the system automatically changes which particular signals are chosen to produce the processed signals; running parallel algorithms in the background of the one or more algorithms currently used to create the processed signals, and changing one or more algorithms when improved performance is identified in the background event; monitoring of one or more system functions, such as alarm or warning condition events or frequency of events, wherein the automated system shuts down one or more functions and/or improves performance by changing a relevant variable; and other methods that monitor one or more pieces of system data, identify an issue or potential improvement, and determine new parameters that would reduce the issue or achieve an improvement. In a preferred embodiment of the disclosed invention, when specific integrated parameters are identified, by an automated or semi-automated calibration or configuration routine, to be modified for the reasons described above, an integral permission routine of the system requires approval of a specific operator when one or more of the integrated parameters is modified.

[052] Operator 110 may be a clinician, technician, caregiver, patient family member or even the patient themselves in some circumstances. Multiple operators may be needed or required to perform a calibration or approve a modification of an integrated parameter, and each operator may be limited by system 100, via passwords and other control configurations, to only perform or access specific functions. For example, only the clinician may be able to change specific critical parameters, or set upper and lower limits on other parameters, while a caregiver, or the patient, may not be able to access those portions of the calibration procedure or the permission procedure. The calibration procedure includes the setting of numerous parameters needed by system 100 to properly

control controlled device 300. The parameters include but are not limited to various signal conditioning parameters as well as selection and de-selection of specific multicellular signals for processing to generate the device control creating a subset of signals received from the sensor to be processed. The various signal conditioning parameters include, but are not limited to, threshold levels for amplitude sorting, other sorting and pattern recognition parameters, amplification parameters, filter parameters, signal conditioning parameters, signal translating parameters, signal interpreting parameters, signal encoding and decoding parameters, signal combining parameters, signal extracting parameters, mathematical parameters including transformation coefficients and other signal processing parameters used to generate a control signal for transmission to a controlled device

[053] Operator 110 may be required by system 100 to perform certain tasks, not part of the actual calibration, to be qualified and thus allowed to perform the calibration routine or permission routine. The tasks may include analysis of pre-loaded multicellular signals, either of synthetic or human data, and may include previous data captured from patient 500. The mock analysis can be tested for accuracy, requiring a minimum performance for the calibration routine to continue or the permission routine to give the required approval.

[054] The calibration routine will result in the setting of various calibration output parameters. Calibration output parameters may comprise: electrode selection, cellular signal selection, neuron spike selection, electrocorticogram signal selection, local field potential signal selection, electroencephalogram signal selection, sampling rate by signal, sampling rate by group of signals, amplification by signal, amplification by group of signals, filter parameters by signal and filter parameters by group of signals. In a preferred embodiment, the calibration output parameters are stored in memory in one or more discrete components, and the parameters are linked to the system's unique electronic identifier.

[055] Calibration and configuration routines, including manual, automatic and semi-automatic routines, may be performed on a periodic basis, and may include the selection and deselection of specific cellular signals over time. The initial calibration routine may include initial values, or starting points, for one or more of the calibration output parameters. Setting initial values of specific

parameters may invoke the permission routine of the present invention. Subsequent calibration routines may involve utilizing previous calibration output parameters that have been stored in a memory storage element of system 100. Subsequent calibration routines may be shorter in duration than an initial calibration and may require less patient involvement. Subsequent calibration routine results may be compared to previous calibration results, and system 100 may require a repeat of calibration if certain comparative performance is not achieved.

[056] The calibration routine may include the steps of (a) setting a preliminary set of calibration output parameters; (b) generating processed signals to control the controlled device; (c) measuring the performance of the controlled device control; and (d) modifying the calibration output parameters. The calibration routine may further include the steps of repeating steps (b) through (d). The calibration routine may also require invoking the permission routine of the present invention.

[057] In the performance of the calibration routine, the operator 110 may involve the patient 500 or perform steps that do not involve the patient. The operator 100 may have patient 500 think of an imagined movement, imagined state, or other imagined event, such as a memory, an emotion, the thought of being hot or cold, or other imagined event not necessarily associated with movement. The patient participation may include the use of one or more cues such as audio cues, visual cues, olfactory cues and tactile cues. The patient 500 may be asked to imagine multiple movements, and the output parameters selected during each movement may be compared to determine an optimal set of output parameters. The imagined movements may include the movement of a part of the body, such as a limb, arm, wrist, finger, shoulder, neck, leg, angle, and toe, and imagining moving to a location, moving at a velocity or moving at an acceleration. The patient may imagine the movement while viewing a video or animation of a person performing the specific movement pattern. In a preferred embodiment, this visual feedback is shown from the patient's perspective, such as a video taken from the person performing the motion's own eye level and directional view. Multiple motion patterns and multiple corresponding videos may be available to improve or otherwise enhance the calibration process. The

calibration routine correlates the selected movement with modulations in the multicellular signals received from the sensor, such as by correlating the periodicity of the movement with a periodicity found in one or more cellular signals. Correlations can be based on numerous variables of the motion including but not limited to position, velocity and acceleration.

[058] The calibration routine will utilize one or more calibration input parameters to determine the calibration output parameters. In addition to the multicellular signals themselves, system or controlled device performance criteria can be utilized. Other calibration input parameters include various properties associated with the multicellular signals including one or more of: signal to noise ratio, frequency of signal, amplitude of signal, neuron firing rate, average neuron firing rate, standard deviation in neuron firing rate, modulation of neuron firing rate as well as a mathematical analysis of any signal property including but not limited to modulation of any signal property. Additional calibration input parameters include but are not limited to: system performance criteria, controlled device electrical time constants, controlled device mechanical time constants, other controlled device criteria, types of electrodes, number of electrodes, patient activity during calibration, target number of signals required, patient disease state, patient condition, patient age and other patient parameters and event based (such as a patient imagined movement event) variations in signal properties including neuron firing rate activity. In a preferred embodiment, one or more calibration input parameters are stored in memory and linked to the embedded, specific, unique electronic identifier.

[059] The calibration routine may classify one or more multicellular signals into three or more classifications for subsequent selection for further processing into the processed signal for transmission to the controlled device. The multiple classifications can be completed in the initial portion of the calibration routine, resulting in a count of each class of available signal. Based on various requirements including the requirements of the control device and applicable mathematical transfer functions, signals can be selected from the most appropriate classification, or a different number of classification states can be chosen and the signals reclassified in order to select the most appropriate signals for optimal device control.

[060] It may be desirous for the calibration routine to exclude one or more multicellular signals based on a desire to avoid signals that respond to certain patient active functions, such as non-paralyzed functions, or even certain imagined states. The calibration routine may include having the patient imagine a particular movement or state, and based on sufficient signal activity such as firing rate or modulation of firing rate, exclude that signal from the signal processing based on that particular undesired imagined movement or imagined state. Alternatively real movement accomplished by the patient may also be utilized to exclude certain multicellular signals emanating from specific electrodes of the sensor. In a preferred embodiment, an automated or semi-automated calibration or configuration routine may include through addition, or exclude through deletion, a signal based on insufficient activity during known patient movements.

[061] Patient 500 of Fig. 1 can be a quadriplegic, a paraplegic, an amputee, a spinal cord injury victim or a physically impaired person. Alternatively or in addition, Patient 500 may have been diagnosed with one or more of: obesity, an eating disorder, a neurological disorder, a psychiatric disorder, a cardiovascular disorder, an endocrine disorder, sexual dysfunction, incontinence, a hearing disorder, a visual disorder, sleeping disorder, a movement disorder, a speech disorder, physical injury, migraine headaches or chronic pain. System 100 can be used to treat one or more medical conditions of patient 500, or to restore, partially restore, replace or partially replace a lost function of patient 500.

[062] Alternatively, system 100 can be utilized by patient 500 to enhance performance, such as if patient 500 did not have a disease or condition from which a therapy or restorative device could provide benefit, but did have an occupation wherein thought control of a device provided an otherwise unachieved advancement in healthcare, crisis management and national defense. Thought control of a device can be advantageous in numerous healthy individuals including but not limited to: a surgeon, such as an individual surgeon using thought control to maneuver three or more robotic arms in a complex laparoscopic procedure; a crisis control expert, such as a person who in attempting to minimize death and injury uses thought control to communicate different pieces of information and/or control multiple pieces of equipment, such as urban search and rescue equipment, simultaneously during an event such as an earthquake or other

disaster, both natural disasters and those caused by man; a member of a bomb squad, such as an expert who uses thoughts to control multiple robots and/or robotic arms to remotely diffuse a bomb; and military personnel who use thought control to communicate with personnel and control multiple pieces of defense equipment, such as artillery, aircraft, watercraft, land vehicles and reconnaissance robots. It should be noted that the above advantages of system 100 to a healthy individual are also advantages achieved in a patient such as a quadriplegic or paraplegic. In other words, a quadriplegic could provide significant benefit to society, such as in controlling multiple bomb diffusing robots, in addition to his or her own ambulation and other quality of life devices. Patients undergoing implantation and use of the system 100 of the present invention may provide numerous occupational and other functions not available to individuals that do not have the biological interface system of the present invention.

[063] The systems of the present invention, such as system 100 of Fig. 1, include a processing unit that processes multicellular signals received from patient 500. Processing unit first portion 130a and processing unit second portion 130b, singly or in combination perform one or more functions. The functions performed by the processing unit include but are not limited to: producing the processed signals; transferring information to a separate device; receiving information from a separate device; producing processed signals for a second controlled device; activating an alarm, alert or warning; shutting down a part of or the entire system; ceasing control of a controlled device; storing information and performing a calibration.

[064] In order for the processing unit of system 100 to perform one or more functions, one or more integrated parameters are utilized. These parameters include pieces of information stored in, sent to, or received from, any component of system 100, including but not limited to: the sensor; processing unit first portion 130a; processing unit second portion 130b; or the controlled device 300. Parameters can be received from devices outside of system 100 as well, such as configuration apparatus 115, a separate medical therapeutic or diagnostic device, a separate Internet based device or a separate wireless device. These parameters can be numeric or alphanumeric information, and can change over

time, either automatically or through an operator involved calibration or other procedure.

[065] In order to change an integrated parameter, system 100 includes a permission routine, such as an embedded software routine or software driven interface that allows the operator to view information and enter data into one or more components of system 100. The data entered must signify an approval of the parameter modification in order for the modification to take place. Alternatively, the permission routine may be partially or fully located in a separate device such as configuration apparatus 115 of Fig. 1, or a remote computer such as a computer that accesses system 100 via the Internet or utilizing wireless technologies. In order to access the permission routine, and/or approve the modification of the integrated parameters, a password or security key, either mechanical, electrical, electromechanical or software based, may be required of the operator. Multiple operators may be needed or required to approve a parameter modification. Each specific operator or operator type may be limited by system 100, via passwords and other control configurations, to approve the modification of only a portion of the total set of modifiable parameters of the system. Additionally or alternatively, a specific operator or operator type may be limited to only approve a modification to a parameter within a specific range of values, such as a range of values set by a clinician when the operator is a family member. Operator or operator types, hereinafter operator, include but are not limited to: a clinician, primary care clinician, surgeon, hospital technician, system 100 supplier or manufacturer technician, computer technician, family member, immediate family member, caregiver and patient.

[066] Fig. 2 generally illustrates a brain implant apparatus consistent with an embodiment of the present invention. As shown in Fig. 2, the system includes an electrode array 210 inserted into a patient's brain 101 through an opening in the skull 222. Array 210 may include a plurality of electrodes 212 for detecting electrical brain signals or impulses. Array 210 may be placed in any location of a patient's brain allowing for array 210 to detect these brain signals or impulses. In a preferred embodiment, array 210 can be inserted into a part of brain 101 such as the cerebral cortex. Other locations for array 210, such as those outside of the cranium, can record multicellular signals as well. Non-penetrating electrode

configurations, such as subdural grids, cuff electrodes and scalp electrodes are applicable both inside the cranium such as to record LFPs, in, on or near peripheral nerves, and on the surface of the scalp such as to record EEGs. Though Fig. 2 depicts the sensor 200 as a single discrete component, in alternative embodiments the sensor comprise multiple discrete components. Multiple sensor components can be implanted entirely in the brain or at an extracranial location, or the multiple discrete sensor components can be placed in any combination of locations.

[067] In an alternative, preferred embodiment, a discrete component such as a sensor of the present invention is implanted within the cranium of the patient, such as sensor 200 of Fig. 2, a processing unit of the present invention is implanted in the torso of the patient, and one or more discrete components are external to the body of the patient. The processing unit may receive multicellular signals from the sensor via wired, including optic fibers, or wireless communication.

[068] Each sensor discrete component of the present invention can have as few as a single electrode, with the sensor including multiple sensor discrete components that collectively contain a plurality of electrodes. Each electrode is capable of recording a plurality of neurons or other electrical activity. In an alternative, preferred embodiment, one or more electrodes are included in the sensor to deliver electrical signals or other energy to the tissue neighboring the electrode, such as to stimulate. Specific electrodes may record only or deliver energy only, and specific electrodes may provide both functions.

[069] Electrode array 210 serves as the sensor for the biological interface system of the present invention. While Fig. 2 shows electrode array 210 as eight electrodes 212, array 210 may include one or more electrodes having a variety of sizes, lengths, shapes, forms, and arrangements. Moreover, array 210 may be a linear array (e.g., a row of electrodes) or a two-dimensional array (e.g., a matrix of rows and columns of electrodes), or wire or wire bundle electrodes. An individual wire lead may include a plurality of electrodes. Electrodes may have the same materials of construction and geometry, or there may be varied materials and/or geometries used in one or more electrodes. Each electrode 212 of Fig. 2 extends into brain 101 to detect one or more electrical cellular signals generated from the

neurons located in proximity to the electrode's placement within the brain. Neurons may generate such signals when, for example, the brain instructs a particular limb to move in a particular way. In a preferred embodiment, the electrodes reside within the arm portion of the motor cortex of the brain.

[070] In the embodiment shown in Fig. 2, sensor 200 includes sensor substrate 210 that includes multiple projections 211. At the end of each projection 211 is an electrode 212. Multiple electrodes, not shown, may be included along the length of one or more of the projections 211. Projections 211 may be rigid, semi-flexible or flexible, such flexibility such that each projection 211 can still penetrate into neural tissue, potentially with an assisting device or with the projections in a temporary more rigid condition. One or more projections 211 may be void of any electrode, such projections potential including anchoring means such as bulbous tips or barbs. Sensor 200 has been passed through a hole cut into skull 222, during a procedure known as a craniotomy, and inserted into brain 101 such that the projections pierce into brain 101 and sensor substrate 210 remains in close proximity to or preferably in light contact with the surface of brain 101. Processing unit 130 receives the multicellular signals from sensor 200, processes these signals and produces processed signals that are transmitted to the controlled device, not shown. The multicellular signals received from sensor 200 include a time code of brain activity.

[071] In the preferred embodiment depicted in Fig. 2, processing unit 130 has been used to close the hole made in the skull during the craniotomy, obviating the need for a prosthetic closure implant and/or reuse of the portion of removed bone. During the craniotomy, a bone shelf, shelf 227, was made such that processing unit 130's outer edge rests on shelf 227. Processing unit 130 includes a wide section and a narrow section such that the wide section rests on shelf 227 and the narrow section protrudes into the craniotomy hole in skull 222 beyond shelf 227. Processing unit 130 is attached to skull 222 with one or more bone screws, screw 232. In a preferred embodiment, processing unit 130 has an integrated camera, not shown, but oriented in such a way that an in-vivo, real time image is made available of sensor 200 at its implant location. In addition to brain motion and other visual physiologic information, the status of electrode location (e.g. undesirably out of the cortex) can be confirmed or ruled out. The information

produced by the integrated camera can be transmitted by processing unit 130 to an external device, or utilized, such as after image processing, by processing unit 130 to enhance the performance of the biological interface system of the present invention. In a preferred embodiment, the output of the camera is used by an automated or semi-automated calibration or configuration routine or function, such that improved performance and improved safety of the system is achieved. In chronic implantations, such as those lasting more than thirty days, it is important to minimize patient risks such as infections that might be caused by additional surgical procedures and other events that may compromise patient health.

[072] In an alternative embodiment, processing unit 130 may be placed entirely within skull 222 or be placed on top of skull 222 underneath the surface of the patient's scalp 223, such as that a portion of processing unit 130 lies in a recess made in skull 222, recess not shown. In either case, a prosthetic plate or the original portion of bone removed during the craniotomy will be placed in the hole in the skull and attached with surgical straps and/or screws. The processing unit can be in close proximity to the sensor, such as processing unit 130 and sensor 200 of Fig. 2 or otherwise within 1-2 cm, or a distance of 5-20 cm can separate the two components. In a preferred embodiment, the sensor is in the motor cortex, and a portion of the processing unit is above the skull, under the scalp near the ear, connected to the sensor with electrical wires or optical fibers. A wireless information receiving device is worn by the patient to receive signals for additional processing and transmission of the control signal.

[073] Electrodes 212 transfer the detected cellular signals to processing unit 130 via wiring 216. Each projection of electrode array 210 may include a single electrode, such as an electrode at the tip of the projection 211, or multiple electrodes along the length of each projection. Wiring 216 is a multi-conductor cable connecting each electrode to processing unit 130. Wiring 216 may include other electrical and non-electrical conduits, such as wires to establish signal reference and ground conditions. Each electrode 212 may be used to detect the firing of one or more neurons, as well as other cellular signals such as those from clusters of neurons. Additional electrodes, not shown, such as those integrated into subdural grids, scalp electrodes, cuff electrodes and other electrodes, can also detect cellular signals emanating from the central or peripheral nervous

system, or other part of the body generating cellular signals, such that processing unit 130 uses these signals to produce the processed signals to send to the controlled device, not shown. Examples of signals include but are not limited to: neuron spikes, electrocorticogram signals, local field potential signals, electroencephalogram signals and other signals between single neuron spikes and electroencephalogram signals. Processing unit 130 assigns at least one cellular signal to a specific use, such as a specific use correlated to a patient imagined event. In a preferred embodiment, the one or more cellular signals assigned to a specific use are under voluntary control of the patient. In an alternative embodiment, cellular signals are transmitted to processing unit 130 via wireless technologies, such as infrared communication, such transmissions penetrating the skull of the patient, and obviating the need for wiring 216 and any physical conduit passing through the skull after the surgical implantation procedure is completed.

[074] Referring back to Fig. 2, processing unit 130 may preprocess the received cellular signals (e.g., impedance matching, noise filtering, or amplifying), digitize them, and further process the cellular signals to extract neural information that it may then transmit to an external device (not shown), such as a further processing device and/or any device to be controlled by the processed multicellular signals. For example, the external device may decode the received neural information into control signals for controlling a prosthetic limb or limb assist device, for controlling a computer cursor or the external device may analyze the neural information for a variety of other purposes.

[075] Processing unit 130 may also conduct adaptive processing of the received cellular signals by changing one or more parameters of the system to achieve or improve performance. Examples of adaptive processing include, but are not limited to, changing a parameter during a system calibration, changing a method of encoding neural information, changing the type, subset, or amount of neural information that is processed, or changing a method of decoding neural information. Changing an encoding method may include changing neuron spike sorting methodology, calculations, thresholds, or pattern recognition. Changing a decoding methodology may include changing variables, coefficients, algorithms, and/or filter selections. Other examples of adaptive processing may include

changing over time the type or combination of types of signals processed, such as EEG, LFP, neural spikes, or other signal types.

[076] Processing unit 130 may also transmit signals to one or more electrodes 212 such as to stimulate the neighboring nerves or other cells. Stimulating electrodes in various locations can be used by processing unit 130 to transmit signals to the central nervous system, peripheral nervous system, other body systems, body organs, muscles and other tissue or cells. The transmission of these signals is used to perform one or more functions including but not limited to: pain therapy, muscle stimulation, seizure disruption and patient feedback.

[077] Processing unit 130 includes signal processing circuitry to perform one or more functions including but not limited to: amplification, filtering, sorting, conditioning, translating, interpreting, encoding, decoding, combining, extracting, mathematically transforming and/or otherwise processing multicellular signals to generate a control signal for transmission to a controlled device. Processing unit 130 transmits the control signal through integrated wireless communication means, such as radiofrequency communications, infrared communications, inductive communications, ultrasound communications and microwave communications. This wireless transfer allows the sensor 200 and processing unit 130 to be completely implanted under the skin of the patient, avoiding the need for implanted devices that require exit of a portion of the device through the skin surface. Processing unit 130 may further include a coil, not shown, which can receive power, such as through inductive coupling, on a continual or intermittent basis from an external power transmitting device. This integrated coil or a separate coil may be used to transmit information in addition to or in place of power transmission. The power and information can be delivered to processing unit 130 simultaneously such as through simple modulation schemes in the power transfer that are decoded into information for processing unit 130 to operate. The information transfer can be from the processing unit 130, through its coil, to the external device using similar techniques.

[078] In an alternative embodiment, not shown, processing unit 130, or a portion of processing unit 130, is integrated into sensor 200, such as through the use of a bonded electronic microchip. In another alternative embodiment, processing unit 130 may also receive biological signals in addition to the

multicellular signals described hereabove, including but not limited to: eye motion signals, eyelid motion signals, facial muscle signals and other electromyographic activity. Such biological signals may be used to turn the biological interface system of the present invention, or one of its discrete components, on or off, begin a calibration routine, or start or stop another system function. In another alternative embodiment, processing unit 130 produces one or more additional processed signals, to additionally control the controlled device of the present invention or to control one or more additional controlled devices.

[079] Referring now to Fig. 3, a biological interface system 100' is depicted. Patient 500 has been implanted with a sensor, not shown, such as a sensor implanted in the motor cortex of the patient's brain. Processing unit first portion 130a is attached to a connector on the patient's skull, not shown, which is electrically attached to each of the electrodes of the implanted sensor. Processing unit first portion 130a transmits signals to processing unit second portion 130b via intraprocessing unit cable 140. Processing unit second portion 130b is attached to a controlled device, patient computer 470 via cable 141. Cable 141 and cable 140 each include one or more of electrical conduits and fiber optic conduits. In alternative embodiments, either or both cable 141 or cable 140 are eliminated through the use of wireless communication means, such means well known to those of skill in the art.

[080] Patient computer 470 can have one or more functions, such as cursor or keyboard control, controlled by the processed signals of system 100'. Patient computer 470 may include a portion of the processing unit, such that final signal processing is performed by the electronics of patient computer 470. Processing unit second portion 130b may be eliminated by incorporating all of its functions into patient computer 470. In addition, patient computer 470 may be a surrogate or intermediate for another controlled device such that patient 500 utilizes patient computer 470 to control a separate external device such as a robot, a thermostat or numerous other devices controllable through a computer interface. In addition, patient computer 470 may include system configuration apparatus, such as configuration apparatus 115 of Fig. 1, thus reducing the need for multiple computers, computer monitors, etc.

[081] Patient computer 470 is attached to a network of computers, such as the Internet, a local group of computers, a LAN, a WAN, a WIFI connection, or other single or group of computers or other electronic devices in proximity to or remote from the patient's location, via computer communication means 471. Computer communication means 471 may include one or more of a phone cable and modem, a cable modem, a network routing device, a wireless transmission device, a wireless phone or other communication system and/or conduit.

[082] As depicted in Fig. 3, system 100' further includes clinician computer 460, a separate computer at a location remote from patient 500 such as a hospital or doctor's office. Utilizing clinician computer 460 is clinician 450, an operator of the biological interface system 100' of the present invention. Clinician 450 is one of the care providers that is knowledgeable of patient 500 and system 100'. Clinician 450 uses clinician computer 460 to access patient computer 470 such as via the Internet utilizing computer communication means 461. Through patient computer 470, one or more components of system 100' can be accessed such as processing unit second portion 130b, processing unit first portion 130a and potentially the sensor, not shown.

[083] The remote access provided in system 100' of Fig. 3 is beneficial in allowing calibrations, improvements, and other parameter modifying events to occur while one or more operators are at a remote location. While Fig. 3 depicts a clinician, such as a clinician at a hospital or office location, other operators and locations are applicable and beneficial as well. The manufacturer of system 100' or a contracted vendor or partner of the manufacturer, may access the equipment to perform upgrades, diagnose problems, configure the system, and perform other parameter modifying events. The manufacturer may be a global resource center for system configurations and improvements. The manufacturer, while accessing patient 500's system 100', may perform an analysis, with or without patient involvement, and make a modification or make a recommendation for a modification to an integrated parameter. In a preferred embodiment, after the manufacturer makes a recommendation for a modification to a parameter, clinician 450, at a separate location from both the patient 500 and the manufacturer, approves the modification utilizing system 100's permission routine. Prior to making the approval, clinician 450 may run one or more tests, with or

without patient involvement, and approve the modification only upon successful results from those tests.

[084] Nurse groups, clinical care organizations, clinical research organizations, rehabilitation groups, health care financial providers such as Blue Cross and other applicable groups may access the system for the benefit of the patient, the health care system or both. System 100' of the present invention can be configured to allow a single or multiple operators located at the patient site, remotely or both, to change one or more integrated parameters utilized by the processing unit to perform a function. Integrated into one or more components of system 100' is a permission routine that requires an operator, such as clinician 450 of Fig. 3, to provide an approval of the modification of one or more parameters. The permission routine can be implemented through the use of clinician computer 460 wherein clinician 450 uses an input device such as a mouse or keyboard to enter information confirming the acceptability of the change. Each parameter modification may be linked with one or more fees that the clinician charges. In a preferred embodiment, system 100' records these billable events and makes them available to clinician 450 on demand.

[085] There may be various reasons for one or more parameters of system 100' to be modified. Parameter modifications may improve performance, safety, longevity of use such as battery life, allow additional external devices to be controlled, and other progressive changes in a complex system. Parameters may be changed due to one or more of the following: adaptive processing of the system; alarm or warning condition; a change in patient performance; a change in patient condition; a cellular signal change such as a modulation change; the initial setting of an integrated parameter; adding a new device to be controlled, such as when adequate performance is achieved during a test; and removal of a controlled device such as when inadequate performance has been identified.

[086] In a preferred embodiment, the permission routine includes one or more embedded software routines which link specific operator approval with changes to specific parameters, such as via a lookup table stored in electronic memory. One or more computers or other data entry devices are used by system 100' to perform the permission routine. In a preferred embodiment, a dialog box appears on the monitor of clinician computer 460 including the parameter

description, current value, proposed new value, and an "OK" box that the clinician clicks with the mouse to approve the change. Approval can be signified by typing a code on one or more keyboards or other text entry devices in communication with the system, clicking or otherwise activating a specific icon on a display, clicking a mouse at one or more specific locations on a display, and entering approval data via spoken voice into a voice recognition system. In an alternative embodiment, a second confirmation, such as an "ARE YOU SURE" dialog box, is utilized after a first approval. In another alternative embodiment, the operator can approve multiple parameter modifications with a single action, such as a confirmatory mouse click. In another alternative embodiment, approval is required by two or more operators. In another alternative embodiment, the permission routine requires the operator to perform a task, such as entering a security code, performing a system test, performing a patient task such as control of a controlled device with modified parameters, or other task prior to or in conjunction with approving the parameter change with one of the various means described above.

[087] Integrated parameters can be stored within one or more components of system 100', transmitted from one or more components of system 100' or received by one or more components of system 100'. Integrated parameters can include the various patient specific values, coefficients and other variables that are set and/or changed in calibrating, configuring and utilizing system 100'. Integrated parameters include spike sorting variables such as amplitude threshold variables. Integrated parameters can include signal processing variables such as sampling rate by signal, sampling rate by group of signals, amplification by signal, amplification by group of signals, filter parameter by signal, filter parameter by group of signals, sorting variable, conditioning variable, translating variable, interpreting variable, encoding variable, decoding variable, extracting variable, mathematical transformation variable, signal to noise ratio variable, frequency of signal variable, amplitude of signal variable, neuron firing rate variable, standard deviation in neuron firing rate variable and modulation of neuron firing rate variable. Integrated parameters may include signal selection variables including but not limited to: electrode selection variable, cellular signal selection variable, neuron spike selection variable, electrocorticogram signal selection variable, local

field potential selection variable and electroencephalogram signal selection variable.

[088] Integrated parameters may also include one or more controlled device parameters including but not limited to: allowed devices that the patient can control; unique ID for device such as that used by a handshaking protocol in order to achieve secure and accurate signal transfer; parameter indicating partial control of a multi-function device; movement parameter of device; a position, velocity, acceleration, torque, direction and/or momentum variable of a device such as a maximum velocity parameter; a power parameter; a therapeutic device parameter such as dose amount, time for start of dose, rate of dose, duty cycle of dose and amount of energy such as stimulation energy; mechanical time constant variable and electrical time constant variable. Additional integrated parameters may also include: a list of permissions for specific operator or operator types; operator usernames; operator passwords; on or off variables; system reset parameters; maximum on time of system parameters and allowable times of day for system use by the patient.

[089] Additional integrated parameters may include calibration parameters including but not limited to: electrode selection; cellular signal selection; neuron spike selection; electrocorticogram signal selection; local field potential signal selection; electroencephalogram signal selection; sampling rate by signal; sampling rate by group of signals; amplification by signal; amplification by group of signals; filter parameters by signal and filter parameters by group of signals; patient activity during calibration; target number of signals required; patient disease state; patient condition; patient age and other patient parameters. Additional integrated parameters may include system performance criteria including but not limited to: target number of signals required; patient disease state; patient condition; patient age and other patient parameters. Additional integrated parameters include but are not limited to: algorithm selection parameter; group of mathematical algorithms parameter; information upload command; information download command; alarm, warning or alert parameter; criteria to determine adequate performance of system; failure threshold parameter.

[090] System 100' may include one or more automatic or semi-automatic calibration routine or other automatic configuration routines that run continuously, or on an intermittent basis, such routines described hereabove. Certain integrated parameters may be routinely modified by the system without any operator intervention required, such as the operator approval of the permission routine of the present invention. In a preferred embodiment, certain parameters can be identified automatically by the system, such that a modification to that parameter creates improved performance of the system. The system provides the parameter and the suggested new value to the operator, but requires approval of the operator for full implementation of the change. Referring back to Fig. 3, the approval is made by clinician 450, utilizing clinician computer 460 to communicate over the Internet to patient computer 470 and one or more other components of system 100' located at the remote patient location. Other types of integrated parameters, such as those not determined by an automatic routine of system 100' but rather by a technician, not shown but at the patient location, may also require clinician 450 to access the permission routine from a remote location. The technician may be performing a scheduled calibration or configuration, or may be diagnosing an issue that has been identified. In performing one or more of these events, an integrated parameter requiring approval of operator clinician 450 may be identified for modification. The technician would contact clinician 450, and via the Internet, review and approve, if appropriate, the parameter change by using the permission routine of the present invention.

[091] Numerous protection schemes can be included in system 100' to prevent unauthorized representation of a user including but not limited to password schemes, IP address confirmation, operator ID hardware such as fingerprint or retinal scan identification hardware as well as electromechanical and mechanical keys. In a preferred embodiment, system 100' further comprises an operator validation routine, using the measures listed above and other measures to confirm the identification of one or more operators. In another preferred embodiment, the system includes a login function, wherein each operator enters one or more of a user name, a user group, a user ID and a password. The login function may ensure that a mechanical or electronic key is in place at a specific port on the system, not shown. The login function may upload various pieces of

information, such as from a remote computer, including IP address, electronic key information, computer login information and other information.

[092] Permission routines may be required by a second operator, such as when a first operator determines an integrated parameter to be changed, a second operator must confirm the acceptability of the change. Numerous scenarios can be contemplated by those skilled in the art wherein one or more operators are required by the system to approve a modification to an integrated parameter. In some instances, the parameter may remain unchanged until the approval is received, while in other instances a temporary period, such as a tryout period, may use the system with the parameter modified, requiring the approval to maintain the modification for an extended period of time.

[093] Numerous operators can be defined as applicable to system 100' including but not limited to clinicians, caregivers, care providers, technicians, patient family members and the patients themselves. A matrix of parameters that can be controlled by the various operators can be included in system 100' such that only specific parameter modifications can be approved by certain operators. Defined levels for operators and operator groups can be established to control certain groups of parameters. Alternatively or additionally, the value ranges within which certain parameters can be modified, can also be operator specific. In a preferred embodiment, a limited, or relatively small number of parameters can be approved for modification by the patient.

[094] In a preferred embodiment, the system 100' of Fig. 3 includes an interrogation function which interrogates the system to retrieve certain information. Based on the analysis of the information, a recommendation for a parameter value change can be made available to an operator, such as the auto-calibration routines described hereabove that are initiated by the operator initiated interrogation function. After viewing the modification, the appropriate operator would approve the change via the permission routine, such as use a computer mouse to click "OK" on a confirmation box displayed on the monitor of clinician computer 460.

[095] In another preferred embodiment, system 100' of Fig. 3 includes a test routine. The test routine can be run any time by an operator, at the patient site or remotely, in determining whether or not a parameter should be changed, in

determining the final value for the change, or to confirm or otherwise test the change. For certain parameters, in addition to the approval required by the permission routine, system 100' may require the test routine be run. In yet another preferred embodiment, a successful performance during the test is also required for parameter modification.

[096] In another preferred embodiment, system 100' of Fig. 3 includes an adaptive processing routine, the adaptive processing having been described hereabove. The adaptive processing routine may suggest or otherwise display one or more parameters to be modified with approval of one or more specific operators. The adaptive processing routine suggested parameter change may include one or more of the following: a system calibration parameter such as the number of times a calibration procedure is to be performed; a method of encoding neural information parameter such as selection of algorithms, formulas, coefficients, calculations, threshold values, pattern recognition methodologies and other spike sorting variables; type, subset or amount of neural information processed parameter; and changing the type or combination of types of signals processed, for example EEG signals, EcoG signals, LFP signals and neural spikes. The adaptive processing routine suggested parameter change may also include changing the method of decoding neural information such as changing one or more algorithms, formulas, calculations, coefficients, filter parameters and pattern recognition methodologies.

[097] In system 100' of Fig. 3, one or more sources of neural activity, such as a single neuron or a cluster of neurons, are routed to at least one of a controlled device and a movement parameter. The adaptive processing includes changing this routing over time. Routing changes can be due to fluctuating signal amplitude, motor learning, cell death and other causes. Adaptive processing includes adjusting to changes in recorded signals such as that due to electrode drift, death of one or more cells, and a parameter of cells discharge. Adaptive processing includes setting of neural source gain and threshold parameters, other signal processing parameters, and other source parameters.

[098] In another preferred embodiment, the system 100' of Fig. 3 further comprises a monitoring routine. The monitoring routine is used by system 100' to automatically monitor system performance and other system parameters and

provide, to one or more operators, a recommendation for modifying one or more of the integrated parameters used by the processing unit, such as processing unit first portion 130a and/or processing unit second portion 130b, to perform a function. The recommendation may include the identification of an integrated parameter to be modified, but may also include a recommendation or target new value. The recommendation can be based on an analysis of real time or historic data, including neural and other information. In a preferred embodiment, the monitoring routine modifies the parameter for a limited time period without operator approval, such as to allow the patient to continue to communicate via system 100', potentially to a technician about an issue requiring the parameter modification. At a predetermined time, the parameter modification may revert back or the system performance may be otherwise modified such as ceasing control of one or more controlled devices. The monitoring routine includes software embedded in one or more components of system 100' that perform the analysis and monitoring. The monitoring routine may get information from the sensor of system 100' as well as other physiologic and non-physiologic sensors monitoring patient, environment, controlled device and other parameters. The monitoring routine may itself include one or more integrated parameters, such as those requiring operator approval via the permission routine of the present invention. The monitoring routine may involve an analysis of raw neural information, processed neural information, controlled device information, patient physiologic information, environment information and other information.

[099] In another preferred embodiment, system 100' includes an integrated parameter modification notification function, preferably activated automatically by the system, which notifies an operator, or multiple operators, of a suggested or pending change. The notification function may require that the parameter modification be made, and potentially tested, before performing the notification function. The integrated parameter modification notification function may be initiated by the monitoring function, calibration functions and configuration functions described in detail hereabove. The notification to the operator can take the form of one or more of an audible alert, a visual alert, olfactory cues, tactile feedback, email, phone call or message and other information sent via wired and wireless means. Modification of certain parameters, that have been notified to the

operator by the notification function, will require approval of the operator via the permission routine. This approval may be required before the parameter is modified, or a short time thereafter. The operator may perform a test, or may be required to perform a test, to confirm acceptability of the modification.

[0100] In another preferred embodiment, system 100' further comprises a patient confirmation routine, such as a software routine embedded in one or more components of system 100'. The patient confirmation routine requires that the patient, after temporarily controlling the device with new values for one or more integrated parameters, confirms acceptability of these modifications. After the acceptability has been confirmed, continuous or long term control of the controlled device with the now tested parameter modifications is provided.

[0101] In situations where patient 500 may be at a location remote from caregivers or family members, it may be desirous for system 100' to include a means for a disabled patient to turn on or off one or more components of system 100', or even reset the system. Switches that control these functions can be driven by eye motion, eyelid motion, facial muscle motion or other electromyographic activity. Alternatively, the switches could be driven by neural information or processed neural information, such as a timecode of brain activity.

[0102] Referring now to Fig. 4, a biological interface system 100" may comprise implanted components and components external to the body of patient 500. System 100" includes multiple controlled devices, controlled computer 3000, first controlled device 300a and second controlled device 300b. While three controlled devices are depicted, this particular preferred embodiment includes any configuration of two or more controlled devices for a single patient. First controlled device 300a and second controlled device 300b can include various types of devices such as prosthetic limbs or limb assist devices, robots or robotic devices, communication devices, computers and other controllable devices as have been described in more detail hereabove. The multiple controlled devices can include two or more joysticks or simulated joystick interfaces, two or more computers, a robot and another controlled device, and many other combinations and multiples of devices as have been described in detail hereabove. Each controlled device is one or more discrete components of the present invention, or a portion of a discrete component.

[0103] A sensor 200 for detecting multicellular signals, and preferably a two dimensional array of multiple protruding electrodes, has been implanted in the brain of patient 500, in an area such as the motor cortex. In a preferred embodiment, the sensor 200 is placed in an area to record multicellular signals that are under voluntary control of the patient. Alternatively or additionally to the two dimensional array, the sensor may include one or more wires or wire bundles which include a plurality of electrodes, subdural grids, cuff electrodes, scalp electrodes or other single or multiple electrode configurations. Sensor 200 is attached to transcutaneous connector 165 via wiring 216, a multi-conductor cable that preferably, though not necessarily, includes a separate conductor for each electrode of sensor 200. Transcutaneous connector 165 includes a pedestal which is attached to the scalp of the patient such as with glues and/or bone screws, preferably in the same surgical procedure in which sensor 200 is implanted in the brain of patient 500. Electronic module 170 attaches to transcutaneous connector 165 via threads, bayonet lock, magnetic coupling, velcro or other engagement means. Transcutaneous connector 165 and/or electronic module 170 may include integrated electronics including but not limited to signal amplifier circuitry, signal filtration circuitry, signal multiplexing circuitry and other signal processing circuitry, such that transcutaneous connector 165 and/or electronic module 170 provide at least a portion of the processing unit of the disclosed invention. Transcutaneous connector 165 preferably includes electrostatic discharge protection circuitry. Electronic module 170 includes wireless information transfer circuitry, utilizing one or more of radiofrequency, infrared, ultrasound, microwave or other wireless communication means. In an alternative embodiment, transcutaneous connector 165 includes all the appropriate electronic signal processing, electrostatic discharge protection circuitry, and other circuitry, and also includes wireless transmission means, such that the need for electronic module 170 is obviated.

[0104] In a preferred embodiment, electronic module 170 includes the wireless transmission means and a power supply, not shown, such that as the power supply is depleted, electronic module 170 can be easily replaced. Electronic module 170 transmits information to processing unit transceiver 131 which is integrated into a portion of system 100"s processing unit, processing unit

first portion 130a. In a preferred embodiment, processing unit transceiver 131 is a two-way wireless communication device and electronic module 170 is also a two-way wireless communication device such that information can be sent to or from electronic module 170.

[0105] All of the physical cables of Fig. 4, as well as all the other figures of this disclosure, can be in a permanently attached, or in detachable form. In addition, all of the physical cables included in system 100" of Fig. 4 as well as the systems of the other included figures can be eliminated with the inclusion of wireless transceiver means incorporated into the applicable, communicating discrete components. Processing unit first portion 130a, a discrete component as defined in this disclosure, includes various signal processing functions as has been described in detail in relation to separate figures hereabove. Processing unit first portion 130a preferably includes a system ID, a unique electronic identifier of the system, the makeup and applicability of the unique electronic identifier also described in detail hereabove. Processing unit first portion 130a electrically connects to processing unit second portion 130b via intra-processing unit cable 140. Cable 140 is detachable from processing unit second portion 130b via female plug 153 which is attached to processing unit second portion 130b at its input port, male receptacle 152. Cable 140 may be constructed of electrical wires and/or fiber optic cables. In a preferred embodiment, data is transmitted from processing unit first portion 130a to processing unit second portion 130b via a fiber optic cable. Information and other signals transmitted between processing unit first portion 130a and processing unit second portion 130b may be in analog format, digital format or a combination of both. In addition, wireless transmission of information can be provided, not shown, to replace intraprocessing unit cable 140 or work in conjunction with intraprocessing unit cable 140.

[0106] Processing unit second portion 130b includes further signal processing means which in combination with the signal processing of processing unit first portion 130a produces processed signals, such as to control multiple controlled devices. Processing unit first portion 130a and/or processing unit second portion 130b include various functions including but not limited to: a spike sorting function, such as a threshold based neuron spike sorting function; an amplifier function; a signal filtering function; a neural net software function; a

mathematical signal combination function; a neuron signal separation function such as a spike discrimination function or a minimum amplitude sorting function; and a database storage and retrieval function such as a database including a list of acceptable neural information or a database of unacceptable neural information each of which can be used to perform a system diagnostic. In another preferred embodiment, the processing unit assigns one or more cellular signals to a specific use, such as a specific use that is correlated to a patient imagined event.

[0107] The processed signals emanating from processed unit second portion 130b can be analog signals, digital signals or a combination of analog and digital. The processing unit of the present invention may include digital to analog conversion means as well as analog to digital conversion means. The processed signals can be transmitted to one or more controlled devices with a hardwired connection, a wireless connection or a combination of both technologies. As depicted in Fig. 4, controlled computer 3000, first controlled device 300a and second controlled device 300b are controlled by the processed signals produced by processing unit first portion 130a and processing unit second portion 130b. Similar to processing unit first portion 130a, processing unit second portion 130b preferably includes the system unique electronic identifier, which can be embedded in processing unit second portion 130b at the time of manufacture, during installation procedures, during calibration or other post-surgical configuration procedures, or at a later date.

[0108] The three controlled devices are shown permanently attached to physical cables, with each physical cable including a removable connection at the other end. Controlled computer 3000 is attached to controlled computer cable 3001 that has female plug 155 at its end. First controlled device 300a is attached to first controlled device cable 301a which has female plug 159 at its end. Second controlled device 300b is attached to second controlled device cable 301b which has female plug 157 at its end. Each physical cable can be attached and detached from processing unit second portion 130b. Female plug 159 attaches to male receptacle 158; female plug 157 attaches to male receptacle 156 and female plug 155 attaches to male receptacle 154.

[0109] Each of controlled computer 3000, first controlled device 300a and second controlled device 300b preferably has embedded within it, the unique

electronic identifier of the system. Additional codes, identifying the type of controlled device, may also be embedded. When any of the physical cables are first attached, such as controlled computer cable 3001 being attached via female plug 157 to male receptacle 156, a compatibility check is performed by system 100" to assure that the unique electronic identifier embedded in controlled computer 3000 is identical or otherwise compatible with a unique electronic identifier embedded in any and all other discrete components of system 100", such as the unique electronic identifier embedded in processing unit second portion 130b. Similar system compatibility checks can be performed with the attachment of first controlled device 300a or second controlled device 300b. If improper compatibility is determined by system 100", various actions that can be taken include but are not limited to: entering an alarm state, displaying incompatibility information, transmitting incompatibility information, deactivation of controlled device control, limiting controlled device control and other actions.

[0110] Also depicted in Fig. 4 is clinician control unit 400 which can be used by an operator, such as a clinician, as information transfer means of the system of the disclosed invention, to recall and/or display as well as send various pieces of information including but not limited to system data and system commands such as an approval of the permission routine. Other types of information transmitted from or received by clinician control unit 400 includes but is not limited to: integrated parameter values and acceptable ranges; calibration parameters and ranges; the unique electronic identifier of the system; unique discrete component identifiers; controlled device identifiers; and other information representative of the present system 100" configuration or a previous configuration of system 100", such historic information stored in one or more components of system 100". The clinician control unit 400 of Fig. 4 communicates with one or more discrete components of system 100" to transmit or recall information, such as integrated parameter information, via wireless communication. In an alternative, also preferred embodiment, a physical cable attaches clinician control unit 400 to one or more discrete components to transmit or recall one or more pieces of information, such as an integrated parameter's historic value, to or from one or more discrete components.

[0111] Clinician control unit 400 may include access passwords to prevent unauthorized use, and may also include a function, such as a permission routine function, to set or change one or more integrated parameters of system 100". Clinician control unit 400 may have other integrated functions such as system configuration or calibration functions as well as a calculator, cellular telephone, pager or personal data assistant (PDA) functions. Clinician control unit 400 may be a PDA that has been modified to access system 100" to modify one or more integrated parameters such as through the use of the permission routine of the present invention.

[0112] The clinician control unit 400 of Fig. 4 includes an integrated monitor for displaying the integrated parameter information, however in an alternative embodiment, the clinician control unit 400 can cause the integrated parameter information to be displayed on a separate visualization apparatus such as the monitor of controlled computer 3000. Alternatively or additionally, one or more of the functions of the clinician control unit 400 can be integrated into one or more discrete components of system 100".

[0113] Numerous configurations and types of controlled devices can be used with system 100" of Fig. 4. Numerous types of controlled devices have been described in detail in relation to system 100 of Fig. 1 and are applicable to system 100" of Fig. 4 as well. System 100" works with a single patient 500 who can control multiple controlled devices such as controlled computer 3000, first controlled device 300a and second controlled device 300b. In a preferred embodiment, patient 500 can control more than one controlled device simultaneously. While each controlled device is connected to the same discrete component, processing unit second portion 130b, in an alternative embodiment, the multiple controlled devices can be connected to multiple processing unit discrete components. Also, while patient 500 has been implanted with a sensor 200 comprising a single discrete component, sensor 200 may comprise multiple discrete components, not shown, such as multiple electrode arrays, implanted in different parts of the brain, or in other various patient locations to detect multicellular signals. Cellular signals from the individual sensor discrete components, such as a single electrode component, may be sent to individual processing units, or to a single processing unit. Separate processed signals can

be created from each individual discrete component of the sensor, and those particular signals tied to a specific controlled device. Thus, each controlled device can be controlled by processed signals from a different sensor discrete assembly, such as discrete components at different locations in the brain or other parts of the body. It should be appreciated that any combination of discrete component cellular signals can be used in any combination of multiple controlled devices. Alternatively, whether the sensor is embodied in a single discrete component or multiple discrete components, the processed signals for individual controlled devices may be based on specific cellular signals or signals from specific electrodes, such that individual device control is driven by specific cellular signals. Any combination of exclusively assigned cellular signals and shared cellular signals used to create processed signals for multiple controlled devices are to be considered within the scope of this application.

[0114] The system 100" of Fig. 4 may include two or more separate calibration routines, such as a separate calibration routine for each controlled device. Any and all discrete components of system 100" may have a unique electronic identifier embedded in it. The processing unit of system 100", comprising processing unit first portion 130a and processing unit second portion 130b, may conduct adaptive processing as has been described hereabove.

[0115] The unique electronic identifier is a unique code used to differentiate one system, such as the system of a single patient, from another system, as well as differentiate all discrete components of a system, especially detachable components, from discrete components of a separate, potentially incompatible system. The unique electronic identifier may be a random alphanumeric code, or may include information including but not limited to: patient name, other patient information, system information, implant information, number of electrodes implanted, implant location or locations, software revisions of one or more discrete components, clinician name, date of implant, date of calibration, calibration information, manufacturing codes and hospital name. In a preferred embodiment, the unique electronic identifier is stored in more than one discrete component such as a sensor discrete component and a processing unit discrete component. The unique electronic identifier may be programmable, such as one time programmable, or allow modifications for multiple time programming, such

programming performed in the manufacturing of the particular discrete component, or by a user at a later date. The unique electronic identifier can be configured to be changed over time, such as after a calibration procedure. The unique electronic identifier can be permanent or semi-permanent, or hard wired, such as a hard wired configuration in a transcutaneous connector of the system. The unique electronic identifier can be used in wireless communications between discrete components, or in wireless communications between one or more discrete components and a device outside of the system. The unique electronic identifier can represent or be linked to system status. System status can include but not be limited to: output signal characteristics, level of accuracy of output signal, output signal requirements, level of control needed, patient login settings, such as customized computer configuration information, one or more software revisions, one or more hardware revisions, controlled device compatibility list, patient permissions lists and calibration status.

[0116] The system 100" of Fig. 4 may include a library of various integrated parameters, such integrated parameters utilized by the processing units, processing unit first portion 130a and processing unit second portion 130b to perform a function including but not limited to the creation of the processed signals to control one or more controlled devices. Integrated parameters include various pieces of system data, such as data stored in electronic memory. In a preferred embodiment, the data being electronically linked with the unique electronic identifier of system 100". The integrated parameter data may be stored in memory of one or more discrete components, such as processing unit second portion 130b, or alternatively or additionally the integrated parameter data may be stored in a computer based network platform, separate from system 100' such as a local area network (LAN), a wide area network (WAN) or the Internet. The integrated parameter data can contain numerous categories of information related to the system including but not limited to: patient information such as patient name and disease state; discrete component information such as type of sensor and electrode configuration; system configuration information such as calibration dates, calibration output parameters, calibration input parameters, patient training data, signal processing methods, algorithms and associated variables, controlled device information such as controlled device use parameters and lists of

controlled devices configured for use with or otherwise compatible with the system; and other system parameters useful in using, configuring and assuring safe and efficacious performance of system 100".

[0117] In an alternative embodiment, system 100" of Fig. 4 further comprises a patient feedback module. The feedback module may include one or more of an audio transducer, a tactile transducer and a visual display. This patient feedback module may be used during patient training, or at all times that the patient is controlling an external device. Feedback can be used to enhance external device control as well as avoid unsafe or undesirable conditions. The feedback module may utilize one or more discrete components of system 100" such as sensor 200. In another preferred embodiment, one or more electrodes of sensor 200 can be stimulated, such as via a stimulation circuit provided by one or more of transcutaneous connector 165 or electronic module 170. The stimulation can evoke a variety of responses including but not limited to the twitching of a patient's finger. The feedback signal sent to the patient can take on a variety of forms, but is preferably a derivative of a modulating variable of the controlled device. For example, feedback can be a derivative of cursor position of controlled computer 3000. If audio feedback is implemented, a signal representing horizontal position and a signal representing vertical position can be combined and sent to a standard speaker. Other audio feedback, such as specific discrete sounds, can be incorporated to represent proximity to an icon, etc. Parameters of the feedback module should be considered integrated parameters of the systems of this invention, such that one or more feedback parameters require approval of an operator via the system's permission routine.

[0118] Referring now to Fig. 5, depicted is a cellular signal processing unit 600 which is used for viewing, sorting, selecting and otherwise processing cellular signals. Cellular signal processing can include one or more of: amplifying, filtering, translating, identifying, classifying, sorting, conditioning, interpreting, encoding, decoding, combining, extracting, providing analog representations, providing digital representations, mathematically transforming and/or otherwise processing cellular signals. Cellular signal processing unit 600 includes a central processing unit, NSPU CPU 601 which is attached to NSPU display 610, NSPU Mouse 650 and NSPU Keyboard 620. NSPU CPU 601 may include all computer

functions including hardware and software elements to perform the cellular signal processing. Also shown on NSPU display 610 is NSPU display cursor 611, which is controlled via NSPU mouse 650. Cellular signal processing unit 600 includes an input port, sensor input port 602 which can be attached directly to a multicellular signal sensor or to an intermediate device which carries processed multicellular singles, such as amplified multicellular signals. Additional input devices, such as a joystick and output devices, such as a speaker, can be attached to NSPU CPU 601 to aid an operator in the use of cellular signal processing unit 600.

[0119] One or more integrated parameters of the system of the present invention can be displayed, characterized and tested through the use of cellular signal processing unit 600. A permission routine, either embedded in NSPU CPU 601 or accessible from a discrete component, not shown, of the system, can be utilized by an operator to approve the modification of one or more integrated parameters. Cellular signal processing unit 600 can be used to access present as well as historic performance data of the system. Cellular signal processing unit 600 can be at the location of the patient, not shown, or at a remote location such as a support facility of the manufacturer of the system wherein communication is accomplished via the Internet.

[0120] Displayed on NSPU display 610 are various windows of information, such information containing one or more integrated parameters of the present invention, such as a matrix of neural information. Each cell of the matrix can represent individual sets of neural information, such as a single cell's activity, also called single unit activity, and multiple cell activity, also known as multiple unit activity. Also shown on NSPU display 610 is NSPU display cursor 611 which is controlled via NSPU mouse 650. NSPU Option One button 612 is a mouse clickable button which allows the operator, not shown, to view all channels. NSPU Option two 613 includes multiple clickable buttons that allow the user to select various sampling rates. NSPU Option three 614 includes multiple clickable buttons that allow the user to select various filtering parameters. NSPU Channel List 615 displays a list of applicable channels. In the embodiment of Fig. 5, the operator is provided a powerful graphical user interface to find channels that have specific parameters as well as easily change the parameters of individual or

groups of channels. Changing of one or more of the integrated parameters may require the activation of the permission routine, such as an "OK" clickable button on the NSPU display 610. The permission routine may include a requirement for a username, password or other identification authorization at the time that the "OK" button is activated, or at a time prior, such as at an initial login by the operator in which a username and password may be required.

[0121] The multiple integrated parameter viewing and selection made available by cellular signal processing unit 600 allows multiple integrated parameters to be modified simultaneously. The operator can pick a particular parameter, such as a 500 S/sec sampling rate, and all channels sampled at that rate will appear in NSPU Channel list 615. Alternatively, a particular channel can be selected, and the parameters associated with that channel will appear, not shown. In modifying one or more types of parameters, a single permission routine is implemented using the methods described above to change multiple parameters simultaneously. In the event that the permission routine is not completed successfully, for example the operator password is incorrect or the specific operator does not have permission to change one or more of the multiple variables, an error message can be displayed on NSPU display 610 alerting the user of the reason why permission is denied and the modification is not taking place. In a preferred embodiment, the system of the present invention includes a log of events involving the permission routine, including but not limited to failures in successfully approving a modification to an integrated parameter. The log of permission routine activation events can be stored in memory, such as memory included in one or more discrete components of the system.

[0122] The graphical user interface of cellular signal processing unit 600 allows easy viewing, setting and modifying of multiple parameters as mentioned above. The operator can use the mouse to select and drag, any channel or group of channels to the screen location of a particular parameter value, and the channel will then be set to that value. Select, click and drag terms and technologies, known to those of skill in the art of computer graphical interface design and use, may be used. Alternatively, the operator can select and drag any parameter value, or group of parameter values, to a screen location of a particular channel, and the channel will have its parameter values automatically changed to those

selected. Each time an integrated parameter requiring operator approval is changed, the permission routine is invoked by the system.

[0123] In a preferred embodiment, the list of integrated parameters requiring operator approval is stored in a memory element of one or more discrete components of the system. In another preferred embodiment, a limited number of operators can modify, either adding to or removing from, this list of integrated parameters requiring specific operator approval. This same list can also include a matrix of which operators can modify which parameters, as well as which specific ranges of values for each parameter specific operators can modify parameters within.

[0124] It should be appreciated that while Fig. 5 depicts sampling rate and filter methods, any appropriate parameter value would be applicable to this preferred embodiment. It should also be appreciated that numerous methods of selecting channels utilizing, singly or in combination, a mouse, computer keyboard, touch screen or other input device, can be employed.

[0125] Referring now to Fig. 6, another preferred embodiment of the system of the present invention is disclosed. System 100''' is shown wherein two separate sensors, first sensor 200a and second sensor 200b, are implanted in patient 500, both shown in the brain 101 of patient 500, but alternatively placed in any location that the electrodes of sensors 200a or 200b will detect cellular signals. Each of sensors 200a and 200b is attached via wiring 216 to processing unit first portion 136. Processing unit first portion 136 includes signal buffers, signal isolators, signal amplifiers and other signal processing elements known to those of skill in the art. Processing unit first portion 136 is connected to processing unit second portion 135 via connecting cable 161. Processing unit first portion 136 and processing unit second portion 135 make up the processing unit of the present invention, receiving the multicellular signals from first sensor 200a and second sensor 200b and producing processed signals to be transmitted to the controlled device.

[0126] One or more integrated parameters are utilized by processing unit first portion 136 and/or processing unit second portion 135 to perform a function, said function including but not limited to the production of the processed signals. A permission routine, such as a software routine embedded in one or more of

processed unit first portion 136 or processed unit second portion 135, is included in system 100''' such that when one or more specific integrated parameters are to be changed, such as by a recommendation from an embedded automatic or semi-automatic calibration routine, an operator is required by the permission routine to approve the modification. In one preferred embodiment, the parameter change is not implemented until the approval is received. In an alternative embodiment, the parameter change is implemented for a limited time, reverting back to the original setting or shutting off the system if an approval is not received, via the permission routine, within a predetermined time limit.

[0127] Processing unit second portion 135 includes a portion of the processing unit, as well as other elements such as a power supply, wireless communication means, memory storage, central processing unit, physiologic and other sensor input ports, control signal output ports and other functional elements. Processing unit second portion 135 is shown connected to various other implants including a series of implants, implanted control devices 311 which could be Functional Electrical Stimulation (FES) devices, other muscle stimulator devices wherein electrical signals are directed into muscle tissue, other control devices, sensory devices, or a combination control and sensory devices. Also shown connected to processing unit second portion 135 is an implanted drug infusion device, implanted pump 310. The processing unit portion of processing unit second portion 135 may produce multiple processed signals to control multiple devices with different functions such as implanted controlled devices 311, preferably a muscle stimulator device, as well as a drug delivery device, such as implanted pump 310. The controlled devices of system 100''' of Fig. 6 may receive processed signals from processing unit second portion 135 via wired connection or wireless communication means. The controlled devices of system 100''' may be external devices, implanted devices, or implanted devices that exit the skin such as FES stimulators that have transcutaneous wires exiting the skin near the insertion site.

[0128] Also depicted in Fig. 6 is configuration apparatus 115 which includes configuration monitor 120 and configuration CPU 125, preferably a central processing unit (CPU) that includes calibration routine software and other computer hardware and software. Alternatively, all calibration routine software

and hardware can be included in one or more components of system 100''', such as processing unit second portion 135, and configuration apparatus 115 simply include a monitor, one or more input devices, such as a keyboard and mouse, and communication means to transfer data to or from processing unit second portion 135. Shown in Fig. 6, configuration apparatus 115 communicates with processing unit second portion 135 via wireless communication, transcutaneous communication means 160 preferably radiofrequency or infrared communication means.

[0129] System 100''' may include integrated memory storage for storing any and all data collected during the calibration process, including but not limited to one or more integrated parameters that require operator approval of a modification via an embedded permission routine of system 100'''. This stored memory can be used for a number of functions including a second calibration procedure performed off line and/or away from patient 500. This remote calibration, under different conditions, may allow an enhanced calibration procedure to be performed on a different time scale or with different equipment. If applicable, the new calibration output parameters could be implemented at a later date, either remotely or at patient 500's site.

[0130] The calibration monitors described, such as configuration monitor 120, can display information separately for each electrode, as well as separately for each cellular signal, even if multiple signals are received from a single electrode. Also displayed is the timing of patient events, such as the start and stop of imagined motions, with time adjustable windows surrounding the cellular signal activity pre and post the time of the patient event. These window times could be adjusted by the operator, but may require specific operator approval via the embedded permission routine. Real time and cumulative calibration information can be displayed including spatial representations of data, such as that relative to the geometric construction of an electrode array. For ease of use, color schemes can accompany numeric output to indicate various cellular signal parameters such as firing rates of neuron spikes. Alternatively or additionally, configuration apparatus 115 may include output devices in addition to configuration monitor 120, such as audio devices, tactile devices, etc that can be used by the operator or the patient during calibration. While searching for

multicellular signals with high firing rate, audio feedback may be the most efficient way of sorting for signals with the highest rates.

[0131] The processing unit of system 100''' may be comprised of various functions including an integrated neuron spike sorting function. This sorting function may include a method of sorting that includes setting a minimum signal amplitude threshold. It is desirous for the calibration routine to be as automated as possible. Due to the critical nature of these type of devices, it may not be practical to eliminate all involvement of the clinician and appropriate health care professionals. In a preferred embodiment, the calibration routine of system 100''' invokes the permission routine of the present invention, at one or more automated calibration steps, and the operator performs a limited, but critical function of approving an integrated parameter change. This required approval is a confirmatory step to prevent an adverse event resulting from an improper automated calibration.

[0132] Numerous algorithms, mathematical and software techniques can be utilized by the processing unit to create the desired control signal. The processing unit may utilize neural net software routines to map cellular signals into desired device control signals. Individual cellular signals may be assigned to a specific use in the system. The specific use may be determined by having the patient attempting an imagined movement or other imagined state. For most applications, it is preferred that that the cellular signals be under the voluntary control of the patient.

[0133] Numerous methods are provided in the multiple embodiments of the disclosed invention. A preferred method embodiment includes a method of modifying an integrated parameter of a biological interface system. The method comprises the steps of: providing a biological interface system for collecting multicellular signals emanating from one or more living cells of a patient and for transmitting processed signals to a controlled device. The biological interface system comprises: a sensor for detecting the multicellular signals, the sensor consisting of a plurality of electrodes to allow for chronic detection of the multicellular signals; a processing unit for receiving the multicellular signals from the sensor, for processing the multicellular signals to produce processed signals, and for transmitting the processed signals to the controlled device; the controlled

device for receiving the processed signals; and one or more integrated parameters utilized by the processing unit to perform a function. A permission routine is performed when one or more of said parameters is modified by an operator of the system.

[0134] It should be understood that numerous other configurations of the systems, devices and methods described herein can be employed. It should be understood that the system includes multiple functional components, such as a sensor for detecting multicellular signals, a processing unit for processing the multicellular signals to produce processed signals, and the controlled device that is controlled by the processed signals. Different from the logical components are physical or discrete components, which may include a portion of a logical component, an entire logical component and combinations of portions of logical components and entire logical components. These discrete components may communicate or transfer information to or from each other, or communicate with devices outside the system. In each system, physical wires, such as electrical wires or optical fibers, can be used to transfer information between discrete components, or wireless communication means can be utilized. Each physical cable can be permanently attached to a discrete component, or can include attachment means to allow attachment and potentially allow, but not necessarily permit, detachment. Physical cables can be permanently attached at one end, and include attachment means at the other.

[0135] The sensors of the systems of this application can take various forms, including multiple discrete component forms, such as multiple penetrating arrays that can be placed at different locations within the body of a patient. The processing unit of the systems of this application can also be contained in a single discrete component or multiple discrete components, such as a system with one portion of the processing unit implanted in the patient, and a separate portion of the processing unit external to the body of the patient. Processing units may include various signal conditioning elements such as amplifiers, filters, signal multiplexing circuitry, signal transformation circuitry and numerous other signal processing elements. In a preferred embodiment, an integrated spike sorting function is included. The processing units performs various signal processing functions including but not limited to: amplification, filtering, sorting, conditioning,

translating, interpreting, encoding, decoding, combining, extracting, mathematically transforming and/or otherwise processing multicellular signals to generate a control signal for transmission to a controlled device. Numerous algorithms, mathematical and software techniques can be utilized by the processing unit to create the desired control signal. The processing unit may utilize neural net software routines to map cellular signals into desired device control signals. Individual cellular signals may be assigned to a specific use in the system. The specific use may be determined by having the patient attempt an imagined movement or other imagined state. For most applications, it is preferred that that the cellular signals be under the voluntary control of the patient. The processing unit may mathematically combine various cellular signals to create a processed signal for device control.

[0136] One or more discrete components of the systems of this application include a unique, readable identifier, termed a unique electronic identifier. The unique electronic identifier can be hardwired into the component, such as creating a pattern of conductors that are shorted or open circuits, a pattern of measurable impedances or voltages, or other permanent or semi-permanent, retrievable codes of information that can represent a serial number or other unique ID. Alternatively, the unique electronic identifier can be stored in a memory storage device such as electronic memory such as read only memory (ROM) or random access memory (RAM). The systems of this application can have various system checks for discrete component compatibility that can run routinely, such as on a predetermined cycle, or can be triggered by an event such as the attachment of a physical cable, or in the receiving of a wireless transmission. For wireless communication, the unique electronic identifier can be included in one or more handshaking protocols, well known to those of skill in the art, to confirm discrete component compatibility. In a preferred embodiment of each system, the system can automatically determine when a physical cable is attached, and a system compatibility check can be triggered.

[0137] In the event that a compatibility check is completed successfully, normal function of the system will commence or remain active. In the event that an incompatibility is determined, or the compatibility check otherwise fails, numerous actions can take place including but not limited to: system enters an

alarm or warning state, control of controlled device is blocked, control of controlled device is partially limited and any combination of the previous. In another preferred embodiment, the cause of the incompatibility is made available to a user.

[0138] Each of the systems of this application may include various display means to display unique electronic identifier information. Each system may include an integrated alarm or means for activating a separate alarm system. Alarms may include one or more of audio transducers, visual elements, olfactory elements and tactile transducers. Each of the systems of this application may include integrated memory storage elements, in one or more discrete components, to store the unique electronic identifier as well as other information. Each of the systems of this application may be configured to allow remote access, such as for configuration purposes, including access via wireless means, phone lines and the Internet. In remote access applications, confirmation of specific system ID, through the use of the unique electronic identifier, is critically important to prevent inadvertent configuration or other changes to a misidentified system.

[0139] Other embodiments of the invention will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope and spirit of the invention being indicated by the following claims.

WHAT IS CLAIMED IS:

1. A biological interface system for collecting multicellular signals emanating from one or more living cells of a patient and for transmitting processed signals to a controlled device, comprising:

a sensor for detecting the multicellular signals, the sensor comprising of a plurality of electrodes to allow for detection of the multicellular signals;

a processing unit for receiving the multicellular signals from the sensor, for processing the multicellular signals to produce processed signals, and for transmitting the processed signals to the controlled device;

the controlled device for receiving the processed signals;

and

one or more integrated parameters utilized by the processing unit to perform a function;

wherein a permission routine requires an approval of an operator when one or more of said integrated parameters is modified.

2. The system of claim 1 further comprising an automated calibration function.

3. The system of claim 2 wherein the automated calibration function automatically determines a modification for a first integrated parameter.

4. The system of claim 3 wherein the automated calibration function automatically determines a modification for a second integrated parameter.

5. The system of claim 4 wherein the permission routine is not required for modification of the second integrated parameter.

6. The system of claim 1 wherein said system is a neural interface system.

7. The system of claim 1 wherein said system is a brain machine interface.

8. The system of claim 1 wherein said system provides a therapeutic benefit.

9. The system of claim 8 wherein said therapeutic benefit is a treatment for one or more of: obesity, an eating disorder, a neurological disorder, a psychiatric disorder, a cardiovascular disorder, an endocrine disorder, sexual dysfunction, incontinence, a hearing disorder, a visual disorder, a sleeping disorder, a movement disorder, a speech disorder, physical injury, migraine headaches and chronic pain.

10. The system of claim 1 wherein said system provides a patient diagnosis.

11. The system of claim 10 wherein the patient diagnosis is a diagnosis of one or more of: obesity, an eating disorder, a neurological disorder, a psychiatric disorder, a cardiovascular disorder, an endocrine disorder, sexual dysfunction, incontinence, a hearing disorder, a visual disorder, sleeping disorder, a movement disorder, a speech disorder, physical injury, migraine headaches and chronic pain.

12. The system of claim 1 wherein said system restores a patient function.

13. The system of claim 12 wherein said patient function is one or more of vision, hearing, speech, communication, limb motion, limb motion, ambulation, reaching, grasping, standing, rolling over, bowel movement and bladder evacuation.

14. The system of claim 1, wherein said system is configured to be turned on or off by a patient with a monitored biological signal.

15. The system of claim 14, wherein the monitored biological signal is generated by one or more of eye motion, eyelid motion, facial muscle, or other electromyographic activity.

16. The system of claim 14, wherein the monitored biological signal is a time code of brain activity.

17. The system of claim 1 wherein the multicellular signals emanate from the central nervous system of the patient.

18. The system of claim 1 wherein the multicellular signals emanate from a single cell of the patient.

19. The system of claim 1 wherein the multicellular signals comprise of one or more of: neuron spikes, electrocorticogram signals, local field potential signals and electroencephalogram signals.

20. The system of claim 1 wherein the electrodes detect the multicellular signals from clusters of neurons and provide signals between single neuron and electroencephalogram recordings.

21. The system of claim 1, wherein the processing unit is for assigning at least one cellular signal to a specific use.

22. The system of claim 1, wherein the processing unit is for using at least one cellular signal generated under voluntary control of a patient.

23. The system of claim 1 wherein the patient is a human being.

24. The system of claim 1 wherein the patient is one or more of: a quadriplegic, a paraplegic, an amputee, a spinal chord injury victim and a physically impaired person.

25. The system of claim 1 wherein the patient is healthy and or otherwise is not utilizing said system to provide a therapeutic or restorative function.

26. The system of claim 25 wherein the controlled device is a piece of medical equipment.

27. The system of claim 26 wherein the medical equipment is used to perform a surgical event.

28. The system of claim 25 wherein the controlled device is a communication device.

29. The system of claim 28 wherein the communication device transmits different pieces of information simultaneously.

30. The system of claim 25 wherein the controlled device is a piece of equipment with controllable moving parts.

31. The system of claim 30 wherein the equipment is used to evacuate personnel.

32. The system of claim 30 wherein the equipment is used to diffuse a bomb.

33. The system of claim 30 wherein the equipment is used to provide a military defense function.

34. The system of claim 30 wherein the equipment is one or more of: watercraft, aircraft, land vehicle and reconnaissance robots.

35. The system of claim 1 wherein the processed signals transmitted to the controlled device include a system ID component.

36. The system of claim 1 wherein the processed signals transmitted to the controlled device include a communication handshaking algorithm.

37. The system of claim 1 wherein the processed signals transmitted to the controlled device include analog signals.

38. The system of claim 1 wherein the processed signals transmitted to the controlled device include digital signals.

39. The system of claim 1 wherein the processed signals are transmitted to the controlled device via a wired connection.

40. The system of claim 39 wherein the wired connection includes one or more of: electrical wires and optical fibers.

41. The system of claim 1 wherein the processed signals are transmitted to the controlled device via a wireless connection.

42. The system of claim 1 wherein the processed signals are transmitted into muscle tissue.

43. The system of claim 1 wherein the controlled device is one or more of the group comprising of: a computer, a computer display, a mouse, a cursor, a joystick, a personal data assistant, a robot or robotic component, a computer controlled device, a teleoperated device, a communication device or system, a vehicle such as a wheelchair, an adjustable bed, an adjustable chair, a remote controlled device, a Functional Electrical Stimulator device or system, a muscle stimulator, an artificial or prosthetic limb, a vision enhancing device, a vision restoring device, a hearing enhancing device, a hearing restoring device, a movement assist device, medical therapeutic equipment such as a

drug delivery apparatus, medical diagnostic equipment such as epilepsy monitoring apparatus, other medical equipment such as a bladder control device, a bowel control device and a human enhancement device, closed loop medical equipment and other controllable devices applicable to patients with some form of paralysis or diminished function as well as any device that may be utilized under direct brain or thought control in either a healthy or unhealthy patient.

44. The system of claim 1 wherein the sensor includes at least one multi-electrode array, said multi-electrode array including a plurality of electrodes.

45. The system of claim 44 wherein the plurality of electrodes are configured to penetrate into neural tissue of the brain to detect electric signals generated from neurons.

46. The system of claim 44 wherein the multi-electrode array includes at least one of a recording electrode, a stimulating electrode, and an electrode having recording and stimulating capabilities.

47. The system of claim 44 wherein the array includes multiple projections extending from a surface and one or more projections include at least one electrode along its length.

48. The system of claim 47 wherein said electrode is near the tip of said projection.

49. The system of claim 47 wherein at least one of the projections includes multiple electrodes along its length.

50. The system of claim 47 wherein the projections are rigid.

51. The system of claim 47 wherein the projections are flexible.

52. The system of claim 47 wherein all electrodes include the same materials of construction.

53. The system of claim 47 wherein a first electrode includes different materials of construction than a second electrode.

54. The system of claim 47 wherein all electrodes have the same geometry of construction.

55. The system of claim 47 wherein a first electrode has a different geometry of construction than a second electrode.

56. The system of claim 47 wherein one or more projections include no electrodes.

57. The system of claim 47 wherein one or more projections include anchoring means.

58. The system of claim 44 wherein the sensor further comprises a second multi-electrode array.

59. The system of claim 1 wherein the sensor includes multiple wires or wire bundle electrodes.

60. The system of claim 1 wherein the sensor includes electrodes incorporated into one or more of: a subdural grid, a scalp electrode, a wire electrode and a cuff electrode.

61. The system of claim 1, wherein the electrodes comprise wires and the sensor comprises a wire bundle.

62. The system of claim 1 wherein the sensor includes two or more discrete components.

63. The system of claim 62 wherein each of said discrete components includes one or more electrodes.

64. The system of claim 62 wherein each of the discrete components is comprised of one or more of the following: a multi-electrode array, a wire or wire bundle; a subdural grid and a scalp electrode.

65. The system of claim 1 wherein the electrodes are implanted near the central or peripheral nervous system.

66. The system of claim 1 wherein one or more electrodes are implanted within the brain.

67. The system of claim 66 wherein one or more electrodes are implanted within the motor cortex of the brain.

68. The system of claim 1 wherein one or more electrodes are placed at an extracranial site.

69. The system of claim 1 wherein one or more electrodes are placed above the patient's scalp.

70. The system of claim 1 wherein the sensor further comprises one or more electrodes that transmits electrical signals to the central nervous system.

71. The system of claim 70 wherein said one or more electrodes also detects cellular signals.

72. The system of claim 1 wherein the electrodes detect multicellular signals for less than twenty-four hours.

73. The system of claim 1 wherein the electrodes chronically detect multicellular signals.

74. The system of claim 1 wherein the sensor further comprises signal processing circuitry.

75. The system of claim 1 wherein the sensor transmits the multicellular signals through a wireless connection.

76. The system of claim 75 wherein the sensor transmits wirelessly to a receiver mounted on the skull of the patient.

77. The system of claim 1 wherein the sensor further comprises a coil for power transmission to said sensor.

78. The system of claim 1 wherein an implantation site of the sensor is an area that generates multicellular signals under a patient's voluntary control.

79. The system of claim 1 wherein the sensor is bonded to an electronic microchip including amplification circuitry.

80. The system of claim 1 wherein each of the plurality of electrodes is an individual lead.

81. The system of claim 1 wherein the plurality of electrodes are capable of recording from clusters of neurons and outputting detected signals comprising multiple neuron signals.

82. The system of claim 81 wherein detected signals are a measure of the local field potential response from neural activity.

83. The system of claim 81 wherein the multiple neuron signals comprise one or more of: electrocorticogram signals, local field potentials, electroencephalogram signals and peripheral nerve signals.

84. The system of claim 1 wherein one or more of the plurality of electrodes is capable of detecting a plurality of neuron signals.

85. The system of claim 1 wherein the processing unit comprises of two or more discrete components.

86. The system of claim 85 wherein the two or more discrete components include a first discrete component implanted within the skull of the patient and a second discrete component mounted extracranially on the skull of the patient.

87. The system of claim 85 wherein the two or more discrete components include a first discrete component implanted in the head of the patient, a second discrete components implanted in the torso of the patient, and a third discrete component external to the body of the patient.

88. The system of claim 87 further comprising a fourth discrete component implanted in the head of the patient.

89. The system of claim 85 wherein the sensor is for being implanted with the skull of the patient and at least a portion of the processing unit protrudes through said skull.

90. The system of claim 89 wherein the processing unit includes a camera whose lens is directed toward the sensor.

91. The system of claim 85 wherein a first discrete component is implanted within the skull of the patient.

92. The system of claim 91 wherein a second discrete component is external to the body of the patient.

93. The system of claim 85 wherein one or more discrete components are implanted in the patient and none of said implanted components includes a continual source of energy.

94. The system of claim 93 wherein one or more of said implanted components include power conversion means which receives power from a device external to the body of the patient.

95. The system of claim 85 wherein a first discrete component sends information to a second discrete component via wireless communication means.

96. The system of claim 95 wherein both of said first component and said second component are implanted in the patient.

97. The system of claim 96 wherein said first component is implanted within the skull of the patient.

98. The system of claim 1 wherein a portion of said processing unit is physically connected to the sensor.

99. The system of claim 1 wherein said processing unit includes an integrated neuron spike sorting function.

100. The system of claim 99 wherein said neuron spike sorting function classifies spikes with a minimum amplitude threshold.

101. The system of claim 1 wherein said processing unit includes an element to amplify the multicellular signals.

102. The system of claim 1 wherein said processing unit utilizes neural net software routines to map neural signals into said processed signals for control of said controlled device.

103. The system of claim 1 wherein said processing unit assigns one or more cellular signals to a specific use.

104. The system of claim 103 wherein said specific use is determined by the patient attempting an imagined movement or other imagined state.

105. The system of claim 1 wherein said processing unit utilizes one or more cellular signals that is under voluntary control of the patient.

106. The system of claim 1 wherein the processing unit utilizes two or more cellular signals that are mathematically combined to create the processed signals.

107. The system of claim 1 wherein the processing unit is for using a cellular signal from a neuron whose signal is separated from other nearby neurons.

108. The system of claim 107 wherein the processing unit is for separating signals by spike discrimination methods.

109. The system of claim 108 wherein the spike discrimination methods sort spikes by a minimum amplitude threshold.

110. The system of claim 1 wherein the processing unit includes a discrete component that is external to the skull.

111. The system of claim 110 wherein the processing unit is external to the body.

112. The system of claim 110 wherein the processing unit receives multicellular signals via a wired connection.

113. The system of claim 110 wherein the processing unit receives multicellular signals via wireless communication means.

114. The system of claim 113 wherein the wireless communication transmission pass through the skull of the patient.

115. The system of claim 1 wherein the processing unit is for converting an analog signal that represents a cellular signal to a digital signal.

116. The system of claim 1 wherein the processing unit includes a database of information categorizing received cellular information

117. The system of claim 116 wherein the database includes a list of acceptable cellular information

118. The system of claim 116 wherein the database includes a list of unacceptable cellular information.

119. The system of claim 1 wherein the processing unit receives one or more monitored biological signals of the patient.

120. The system of claim 119 wherein the monitored biological signal is generated by one or more of: eye motion, eyelid motion, facial muscle and other electromyographic activity.

121. The system of claim 119 wherein the monitored biological signal is a time code.

122. The system of claim 119 wherein the monitored biological signal is processed by the processing unit to produce a second processed signal.

123. The system of claim 122 wherein the second processed signal is used to control the controlled device.

124. The system of claim 122 wherein the second processed signal is used to modify one or more parameters of the system.

125. The system of claim 122 wherein the second processed signal is used to stop control of the controlled device.

126. The system of claim 122 wherein the second processed signal is used to reset the system.

127. The system of claim 1 wherein the integrated parameters include one or more of: stored information, transmitted information and received information.

128. The system of claim 1 wherein the integrated parameters include one or more neuron spike sorting variables.

129. The system of claim 128 wherein one or more spike sorting variables are one or more of an amplitude threshold variable and a signal pattern variable.

130. The system of claim 1 wherein the integrated parameters include one or more cellular signal parameters.

131. The system of claim 130 wherein one or more cellular signal parameters include one or more of a neuron spike parameter, a local field potential signal parameter, an electrocorticogram signal parameter, an electroencephalogram signal parameter and a peripheral nerve signal parameter.

132. The system of claim 130 wherein the one or more cellular signal parameters includes a parameter determining which types of cellular signals to be processed.

133. The system of claim 132 wherein the types of cellular signals to be processed include one or more of: neuron spikes, local field potential signals, electrocorticogram signals, electroencephalogram signals, peripheral nerve signals.

134. The system of claim 1 wherein the integrated parameters include one or more signal processing variables.

135. The system of claim 134 wherein one or more signal processing variables include one or more of: sampling rate by signal, sampling rate by group of signals, amplification by signal, amplification by group of signals, filter parameter by signal, filter parameter by group of signals, sorting variable, conditioning variable, translating variable, interpreting variable, encoding variable, decoding variable, extracting variable, mathematical transformation variable, frequency of signal variable, amplitude of signal variable, neuron firing rate variable, standard deviation in neuron firing rate variable and modulation of neuron firing rate variable

136. The system of claim 1 wherein the integrated parameters include one or more signal selection variables.

137. The system of claim 136 wherein one or more signal selection variables include one or more of: electrode selection variable, cellular signal selection variable, neuron spike selection variable, electrocorticogram signal selection variable, local field potential selection variable and electroencephalogram signal selection variable.

138. The system of claim 1 wherein the integrated parameters include one or more signal quality variables.

139. The system of claim 138 wherein one or more signal quality variables include one or more of a signal to noise ratio variable, noise level variable, a modulation parameter, a minimum number of neurons, a minimum number of electrodes from which signals are processed and a cross-talk variable.

140. The system of claim 1 wherein the integrated parameters include one or more external device parameters.

141. The system of claim 140 wherein the external device is said controlled device.

142. The system of claim 141 wherein the external device has multiple functions and the integrated parameter correlates to specific functions that the patient is permitted to control.

144. The system of claim 143 wherein the movement parameter is one or more of a position variable, a velocity variable, an acceleration variable , a torque variable, a direction variable and a momentum variable.

145. The system of claim 141 wherein the external device is a therapeutic device.

146. The system of claim 145 wherein the integrated parameters include one or more of: dose amount variable, start of dose variable, rate of dose variable, duty cycle of dose variable, and amount of energy variable.

147. The system of claim 141 wherein the integrated parameters include one or more of a mechanical time constant variable and an electrical time constant variable.

148. The system of claim 140 wherein the external device has a unique ID.

149. The system of claim 148 wherein a handshaking protocol confirms said controlled device is approved for patient control.

150. The system of claim 140 wherein one or more external device parameters is a power parameter of the external device.

151. The system of claim 1 wherein the integrated parameters include one or more permissions for a specific operator or operator type.

152. The system of claim 1 wherein the integrated parameters include an operator username.

153. The system of claim 1 wherein the integrated parameters include an operator password.

154. The system of claim 1 wherein the integrated parameters include one or more of a device on variable or a device off variable.

155. The system of claim 1 wherein the integrated parameters include a system reset variable.

156. The system of claim 1 wherein the integrated parameters included a maximum on time variable.

157. The system of claim 1 wherein the integrated parameters include an allowable time of day for use variable.

158. The system of claim 1 wherein the integrated parameters include a calibration parameter variable.

159. The system of claim 158 wherein the calibration parameter variable is one or more of: electrode selection, cellular signal selection, neuron spike selection, electrocorticogram signal selection, local field potential signal selection, electroencephalogram signal selection, sampling rate by signal, sampling rate by group of signals, amplification by signal, amplification by group of signals, filter parameters by signal and filter parameters by group of signals, patient activity during calibration, target number of signals required, patient disease state, patient condition, patient age and other patient parameters.

160. The system of claim 1 wherein the integrated parameters include a telemetry parameter.

161. The system of claim 160 wherein the telemetry parameter includes one or more of type of telemetry used, communication rate, handshaking protocol variable, error detection variable and encryption variable.

162. The system of claim 1 wherein the integrated parameters include a patient parameter.

163. The system of claim 162 wherein the patient parameter includes one or more of patient name variable, patient disease state variable, patient condition variable, patient medication variable, patient age variable, patient ID variable and patient history variable.

164. The system of claim 1 wherein the integrated parameters include a system performance criteria variable.

165. The system of claim 164 wherein the system performance criteria variable is one or more of: target number of signals required variable, patient disease state variable, patient condition variable, patient age variable and other patient parameter variables.

166. The system of claim 1 wherein the integrated parameters include a variable which selects a specific mathematical algorithm.

167. The system of claim 1 wherein the integrated parameters include an information download command variable.

168. The system of claim 1 wherein the integrated parameters include one or more of: an alarm variable, a warning variable and an alert variable.

169. The system of claim 1 wherein the integrated parameters include a criteria to determine adequate performance of the system.

170. The system of claim 1 wherein the integrated parameters include a failure threshold variable.

171. The system of claim 1 wherein the integrated parameters include one or more of: discrete component information such as type of sensor and electrode configuration; calibration data such as calibration dates, calibration output parameters, calibration input parameters; patient training data; and lists of controlled devices configured for use with or otherwise compatible with the system.

172. The system of claim 1 wherein the function is to produce the processed signals.

173. The system of claim 1 wherein the function is to transfer information to a separate device.

174. The system of claim 1 wherein the function is to receive information from a separate device.

175. The system of claim 1 wherein the function is to produce processed signals for a second controlled device.

176. The system of claim 1 wherein the function is to activate one or more of: an alarm, an alert and a warning.

177. The system of claim 1 wherein the function is to shut down the system.

178. The system of claim 1 wherein the function is to cease patient control of the controlled device.

179. The system of claim 1 wherein the function is to store information.

180. The system of claim 1 wherein the function is to perform a calibration procedure.

181. The system of claim 1 wherein the function is to complete a calibration procedure.

182. The system of claim 1 wherein the permission routine limits parameter modifications to specific operators.

183. The system of claim 182 further comprising an approved operator list.

184. The system of claim 182 wherein permission to modify individual integrated parameters are linked to specific operators.

185. The system of claim 182 wherein a specific operator is permitted to approve modification of a parameter within a range of values.

186. The system of claim 185 wherein the range of values is controlled by a second operator.

187. The system of claim 1 wherein the permission routine includes multiple levels including permissions for multiple operators.

188. The system of claim 187 wherein a first operator controls a first set of one or more integrated parameters and a second operator controls a second set of one or more integrated parameters.

189. The system of claim 188 wherein the first set of parameters includes one or more different parameters than the second set of parameters.

190. The system of claim 1 further comprising an interrogation function which interrogates said system and retrieves information stored therein.

191. The system of claim 190 wherein an analysis is performed on the retrieved information and an output is produced which recommends modifications to be made to at least one of said integrated parameters.

192. The system of claim 191 wherein the permission routine is used to allow specific operators to implement said recommended modifications.

193. The system of claim 192 wherein the first location is distant from the second location.

194. The system of claim 192 wherein the first location is a health care facility.

195. The system of claim 192 wherein the first location is an outside support agency.

196. The system of claim 1 wherein prior to implementing a modification, the permission routine checks one or more of: username, password, and IP address.

197. The system of claim 1 wherein the permission routine includes a confirmation of modifications prior to implementing a modification.

198. The system of claim 1 wherein the approval is accomplished by the operator activating an icon on a computer display.

199. The system of claim 1 wherein the approval is accomplished by the operator performing one or more keystrokes on an input device in communication with the system.

200. The system of claim 1 wherein the approval is accomplished by the operator activating a switch on an input device, said input device controlling a cursor on a computer screen.

201. The device of claim 200 wherein the input device is a computer mouse.

202. The device of claim 200 wherein the switch is activated when the cursor is above an icon representing acceptance of the modification of the parameter.

203. The system of claim 1 wherein the approval is accomplished by the operator performing a task which sets an internal parameter of the system.

204. The system of claim 1 wherein the approval represents acceptance of modification of multiple parameters simultaneously.

205. The system of claim 1 wherein the permission routine further requires a second approval of an operator of the system.

206. The system of claim 205 wherein said second approval must be entered by a second operator.

207. The system of claim 206 wherein a unique ID is required to identify each operator.

208. The system of claim 207 wherein said unique ID is a password.

209. The system of claim 1 wherein an integrated parameter is modified due to adaptive processing.

210. The system of claim 1 wherein an integrated parameter is modified due to an alarm, warning or alert condition.

211. The system of claim 1 wherein an integrated parameter is modified due to a change in patient performance.

212. The system of claim 1 wherein an integrated parameter is modified due to a change in patient condition.

213. The system of claim 1 wherein an integrated parameter is modified due to a cellular signal change.

214. The system of claim 1 wherein the modification includes the initial setting of a variable.

215. The system of claim 1 wherein the modification includes adding one or more devices to be controlled by the patient.

216. The system of claim 1 wherein the device is added based on an adequate performance of external device control by the patient.

217. The system of claim 1 wherein the modification includes removing one or more devices to be controlled by the patient based on inadequate performance by the patient in controlling said device.

218. The system of claim 1 wherein the operator is at a remote location from the patient when an integrated parameter is modified.

219. The system of claim 218 wherein the modification is performed over wireless communication means.

220. The system of claim 219 wherein the modification is performed over one or more of: computer network, LAN, WAN, WIFI and the Internet.

221. The system of claim 1 wherein the operator is a clinician.

222. The system of claim 221 wherein the clinician charges a fee for modifying an integrated parameter of the system.

223. The system of claim 222 wherein the clinician is remote from the patient when the modification occurs.

224. The system of claim 222 wherein the clinician and patient are at the same location when the modification occurs.

225. The system of claim 1 wherein the operator is the patient.

226. The system of claim 225 wherein said system has multiple parameters than can be modified, and the patient has a limited number of parameters that can be approved for modification by said patient.

227. The system of claim 1 wherein the operator is a technician.

228. The system of claim 1 wherein the operator modifies an integrated parameter by transmitting information over the Internet.

229. The system of claim 1 further comprising a second controlled device.

230. The system of claim 229 further comprising a third controlled device.

231. The system of claim 229 wherein the processing unit produces one or more additional processed signals, said additional signals transmitted to the second controlled device.

232. The system of claim 231 wherein said additional processed signals are based on a different set of cellular signals than the cellular signals used to generate the processed signals transmitted to the first controlled device.

233. The system of claim 231 wherein said additional processed signals are based on a different set of signal processing parameters than the processing parameters used to generate the processed signals transmitted to the first controlled device.

234. The system of claim 1 further comprising a memory storage module.

235. The system of claim 234 wherein one or more integrated parameters are stored in the memory storage module.

236. The system of claim 1 further comprising a test routine.

237. The system of claim 236 wherein the test routine is activated each time an integrated parameter is modified.

238. The system of claim 237 wherein the test routine is activated before an integrated parameter is modified.

239. The system of claim 236 wherein an integrated parameter is modified after successful completion of a permission routine and successful completion of a test routine.

240. The system of claim 1 further comprising an adaptive processing routine.

241. The system of claim 240 wherein one or more integrated parameters are suggested for modification by the adaptive processing routine and then approved by the operator prior to modification.

242. The system of claim 240 wherein changing an integrated parameter involves one or more of: changing an integrated parameter during a system calibration, changing a method of encoding cellular information, changing the type, subset, or amount of cellular information that is processed and changing a method of decoding cellular information.

243. The system of claim 242 wherein changing an encoding method includes changing a neuron spike sorting variable including one or more of: algorithm, formula, coefficients, calculation, threshold value and pattern recognition methodology.

244. The system of claim 242 wherein changing a decoding method includes changing one or more of: algorithm, formula, calculation, coefficient, filter parameter and pattern recognition methodology.

245. The system of claim 240 wherein the adaptive processing routine includes changing over time the type or combination of types of signals processed.

246. The system of claim 245 wherein the types of signals processed include one or more of EEG signals, ECoG signals, LFP signals and neural spikes.

247. The system of claim 240 wherein the adaptive processing routine modifies one or more integrated parameters due to changes in one or more cellular signals.

248. The system of claim 240 wherein the adaptive processing routine includes the performance of a calibration procedure.

249. The system of claim 248 wherein the calibration procedure is performed a plurality of times.

250. The system of claim 240 wherein one or more sources of cellular activity are routed to at least one of a control device and a movement parameter, and wherein the adaptive processing routine includes changing the routing over time.

251. The system of claim 250 wherein a source is a single neuron.

252. The system of claim 250 wherein a source is a cluster of neurons.

253. The system of claim 250 wherein the routing change is due to fluctuating signal amplitude.

254. The system of claim 250 wherein the routing change is due to motor learning.

255. The system of claim 240 wherein the adaptive processing routine includes adjusting to changes in recorded signals.

256. The system of claim 255 wherein the changes are due to one or more of electrode drift, a death of cells and an integrated parameter of cell discharge.

257. The system of claim 240 wherein adaptive processing includes setting at least one of cellular source gain, cellular source threshold, a signal processing parameter and a source parameter.

258. The system of claim 1 further comprising a monitoring routine, said monitoring routine providing a recommendation for modifying one or more integrated parameters.

259. The system of claim 258 wherein the recommendation is based on one or more of: real time data and historical data.

260. The system of claim 258 wherein the monitoring routine implements the modification without approval of the operator for a limited period of time.

261. The system of claim 260 wherein the system is shut down after said period of time unless an operator approves the modification via the permission routine.

262. The system of claim 260 wherein the function performed by the processing unit when utilizing the modified parameter is a communication function.

263. The system of claim 1 further comprising information transfer means, said information transfer means used to transfer information to modify an integrated parameter.

264. The system of claim 263 wherein the information transfer means sends the information over the Internet or other computer to computer connection.

265. The system of claim 263 wherein the information transfer means comprises a wireless device.

266. The system of claim 265 wherein the wireless device is a handheld device.

267. The system of claim 1 further comprising an integrated parameter modification notification function, said function producing a notification of one or more of a system initiated parameter modification recommendation, a long term parameter modification or a temporary parameter modification.

268. The system of claim 267 wherein the parameter modification notification function provides one or more of the following to an operator: audio information, visual information, olfactory information, tactile information and wireless information.

269. The system of claim 267 wherein the notification is of a parameter modification, and the system requires approval of an operator via the permission routine to maintain said modification.

270. The system of claim 1 further comprising an operator validation routine.

271. The system of claim 270 wherein the operator validation routine includes the check of a password entered by the operator.

272. The system of claim 270 wherein the operator validation routine includes a mechanical key.

273. The system of claim 270 wherein the operator validation routine includes an Internet IP address check.

274. The system of claim 270 wherein the operator validation routine includes a check of an operator username entered by the operator.

275. The system of claim 1 further comprising a second operator.

276. The system of claim 275 wherein the second operator has different permissions to modify integrated parameters than the first operator.

277. The system of claim 1 further comprising a login function.

278. The system of claim 277 wherein the login function requires the operator to enter one or more of: username and password.

279. The system of claim 277 wherein the login function confirms that a mechanical key is in place.

280. The system of claim 277 wherein the login function confirms that an electronic key is in place.

281. The system of claim 277 wherein the login function confirms the acceptability of an IP address from which information is being received.

282. The system of claim 1 further comprising a calibration system for calibrating the multicellular signals.

283. The system of claim 282 wherein the calibration system is capable of being activated by a biological signal.

284. The system of claim 282 wherein the calibration system includes a set of movements for calibration.

285. The system of claim 282 wherein the calibration system includes a video monitor.

286. The system of claim 282 wherein the calibration system includes a set of movements for calibration and the video monitor is capable of displaying a selected movement.

287. The system of claim 286 wherein the movements displayed are from a patient's perspective.

288. The system of claim 282 wherein the calibration system is capable of correlating the selected movement with a cellular signal obtained from tracking the selected movement.

289. The system of claim 282 wherein the calibration system is capable of correlating an integrated parameter relating to the selected movement with a cellular signal obtained from tracking the selected movement.

290. The system of claim 289 wherein the parameter is one or more of a position, a velocity or an acceleration.

291. The system of claim 282 wherein the calibration system includes a set of movements for calibration and the video monitor is capable of displaying a simulation of a selected movement.

292. The system of claim 291 wherein the simulation of selected movements is displayed from the patient's perspective.

293. The system of claim 1 further comprising a patient feedback module.

294. The system of claim 293 wherein the patient feedback module includes one or more of: an audio transducer, a tactile transducer, a video display, and an olfactory transducer.

295. The system of claim 293 wherein the patient feedback module includes a stimulator, and a one or more neurons are stimulated to cause movement or sensation in a part of the patient's body.

296. The system of claim 1 further comprising a drug delivery system, wherein the processing unit sends a signal to the drug delivery system to deliver a therapeutic agent or drug to at least a portion of the patient's body.

297. The system of claim 1 further comprising a patient confirmation routine.

298. The system of claim 297 wherein the patient confirmation routine involves the patient temporarily controlling the controlled device prior to providing continuous control to the controlled device.

299. The system of claim 1 further comprising an embedded ID.

300. The system of claim 299 wherein the embedded ID is used to confirm compatibility of one or more discrete components of the system.

301. The system of claim 1 further comprising a visual display of cellular information.

302. The system of claim 301 wherein the visual display displays cellular information in a matrix, wherein each cell of the matrix represents individual sets of cellular information.

303. The system of claim 302 wherein at least one cell of the matrix displays single unit neuron activity.

304. The system of claim 302 wherein at least one cell of the matrix displays combined multiple unit neuron activity.

305. The system of claim 1 further comprising a permission routine activation log.

306. The system of claim 305 wherein the log stores information regarding failed attempts at approving a modification.

307. The system of claim 306 wherein the log stores one or more of: operator identification information; parameter to be modified information; and time and date information.

308. The system of claim 305 wherein the log stores permission routine activation information in a memory element of a discrete device.

309. A method of modifying an integrated parameter of a biological interface system, said method comprising the steps of:

providing a biological interface system for collecting multicellular signals emanating from one or more living cells of a patient and for transmitting processed signals to a controlled device, comprising:

a sensor for detecting the multicellular signals, the sensor comprising of a plurality of electrodes to allow for detection of the multicellular signals;

a processing unit for receiving the multicellular signals from the sensor, for processing the multicellular signals to produce processed signals, and for transmitting the processed signals to the controlled device;

the controlled device for receiving the processed signals;

and

one or more integrated parameters utilized by the processing unit to perform a function;

wherein a permission routine is performed when one or more of said parameters is modified by an operator of the system.

310. The method of claim 309 wherein the operator is at a location distant from the patient.

311. The method of claim 309 wherein the operator is a clinician.

312. The method of claim 311 wherein the clinician charges a fee for modifying the one or more parameters.

313. The method of claim 309 wherein the operator is a patient.

314. The method of claim 309 wherein the operator enters a user name or user ID.

315. The method of claim 309 wherein the operator enters a password.

316. The method of claim 309 wherein the modification is performed due to adaptive processing.

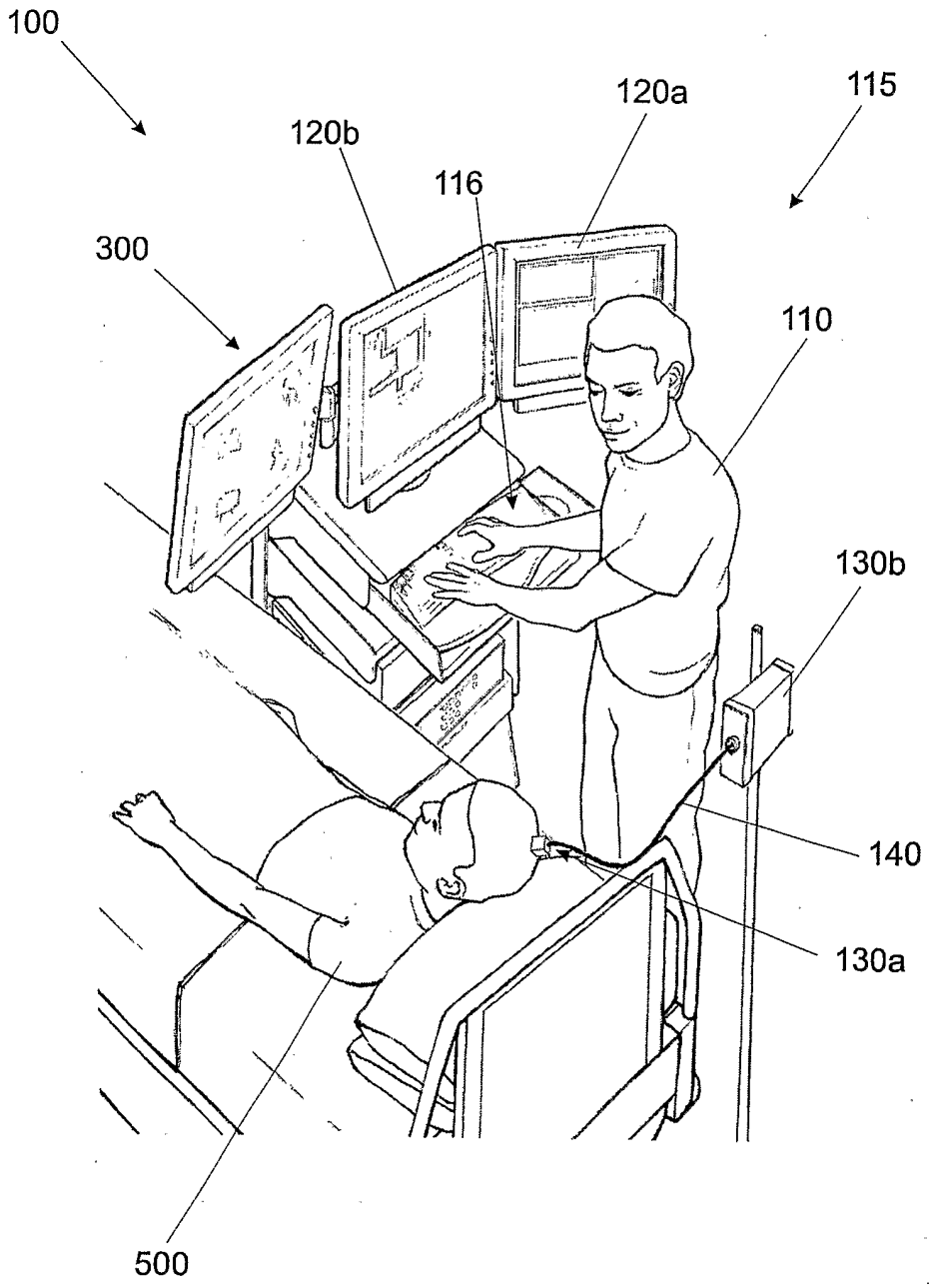
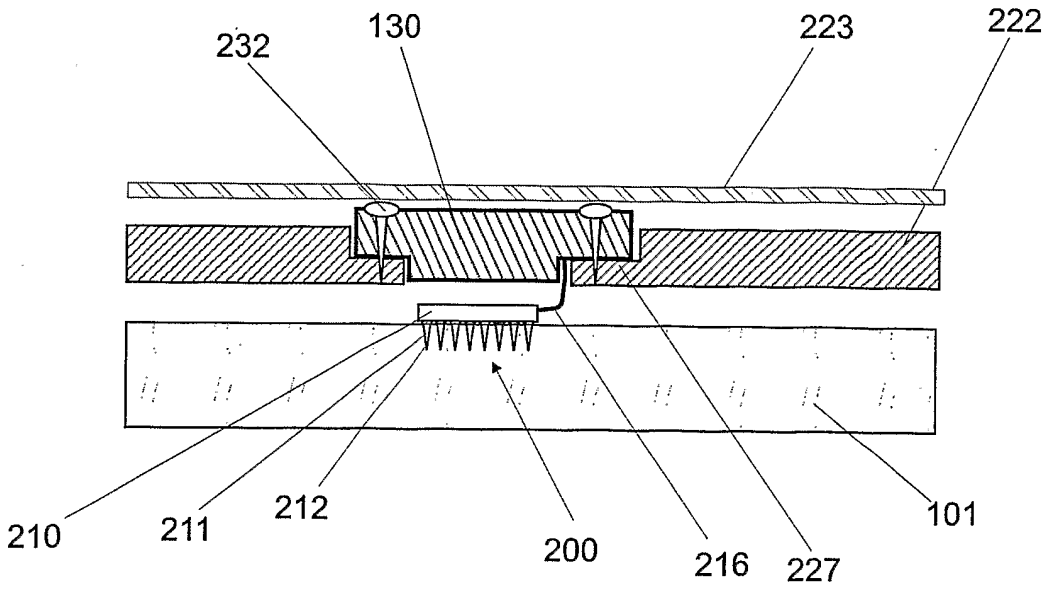


Figure 1



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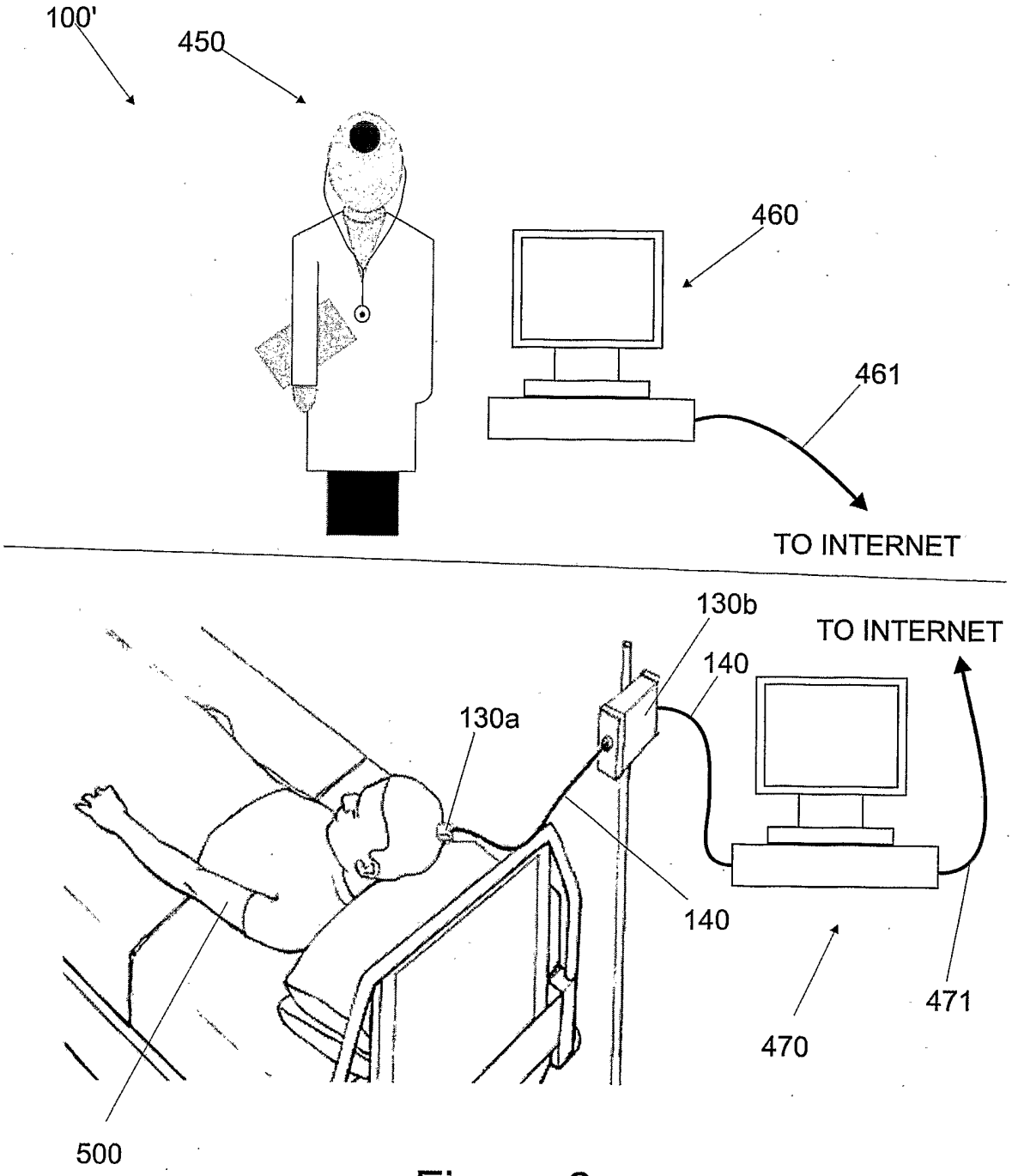
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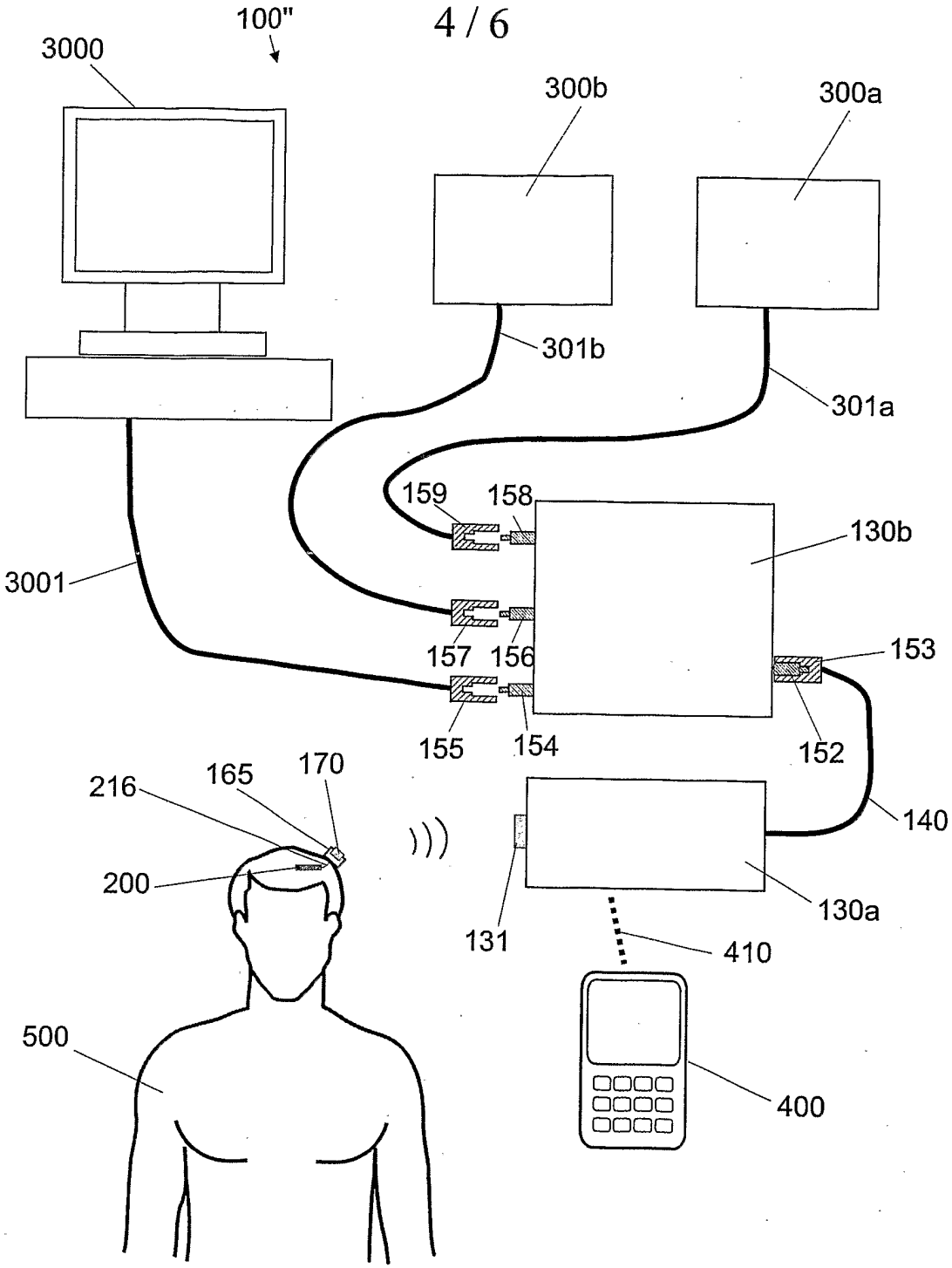
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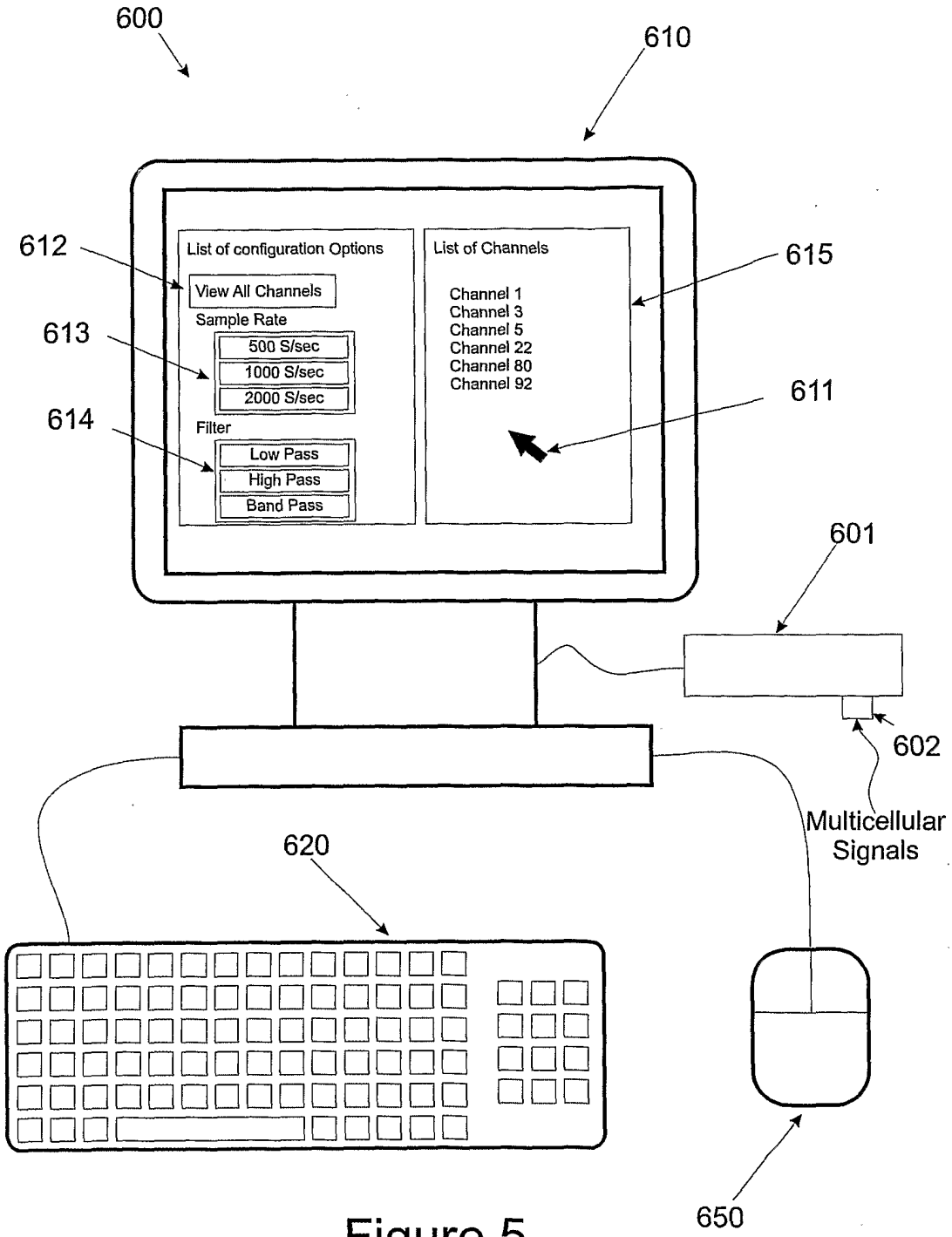
Figure 4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Filter
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Band Pass
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Channel 80
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Multicellular Signals
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Figure 5

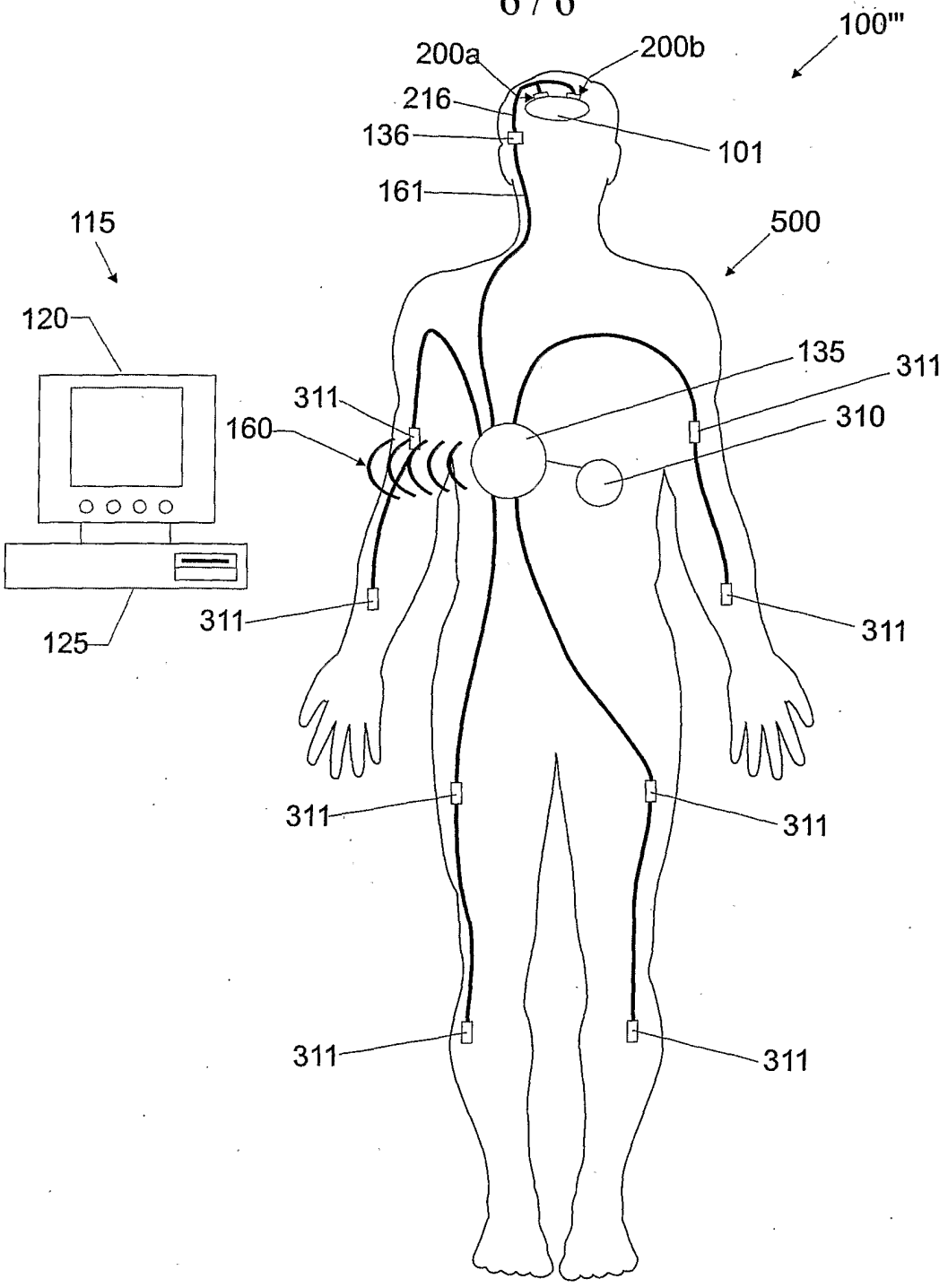
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Figure 6

INTERNATIONAL SEARCH REPORT

Application No
PCT/US2005/026564

A. CLASSIFICATION OF SUBJECT MATTER
A61B5/04

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B

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

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

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 03/037231 A (DUKE UNIVERSITY; NICOLELIS, MIGUEL, A.L; CHAPIN, JOHN, K; WESSBERG, JO) 8 May 2003 (2003-05-08) claim 1	1,309
A	WO 00/09008 A (EMORY UNIVERSITY) 24 February 2000 (2000-02-24) page 23, line 27 - page 25, line 23	1,309
A	US 2003/105409 A1 (DONOGHUE JOHN PHILIP ET AL) 5 June 2003 (2003-06-05) claims 1-3	1,309
P,X	WO 2005/046469 A (CYBERKINETICS, INC; DONOGHUE, JOHN, P; FLAHERTY, J., CHRISTOPHER; SERR) 26 May 2005 (2005-05-26) paragraph '0037!; claim 1	1,309

[ ] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
23 November 2005	05/12/2005

Name and mailing address of the ISA	Authorized officer
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1

Form PCT/ISA/210 (second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Application No
PCT/US2005/026564

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WO 2005046469 A	26-05-2005	US 2005143589 A1	30-06-2005