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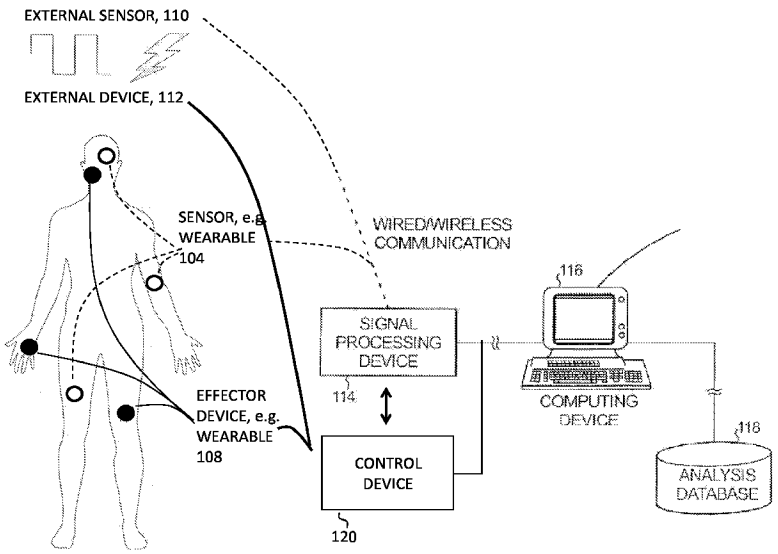

Fig. 1 Schematic of Enciphered Functional Network

(57) Abstract: The present invention relates generally and specifically to combining biological sensors with external machines using machine learning to form computerized representations that can control effectors to deliver therapy or enhance performance.

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METHOD AND SYSTEM FOR COMBINING PHYSIOLOGICAL AND MACHINE INFORMATION TO ENHANCE FUNCTION

Field

[0001] The present invention relates generally and specifically to combining biological sensors with external machines using machine learning to form computerized representations capable of controlling effectors to deliver therapy or enhance performance. The invention integrates sensed signals from body systems and artificial devices with outputs from measureable body systems and artificial devices to create learned networks. Measurable body systems include the central and peripheral nervous systems, cardiovascular system, respiratory system, skeletal muscles and skin well as any other body systems that are capable of producing measurable signals. Artificial devices include diagnostic sensors, medical stimulating or prosthetic devices and/or non-medical systems. The invention has applications in sleep and wakefulness, sleep-disordered breathing, memory and cognition, monitoring and responding to obesity or heart failure and other conditions, or more generally in enhancing performance via external devices. This disclosure outlines several applications of this invention, using as an example methods and systems to enhance sleep-related bodily functions for use in normal individuals or patients with sleep-breathing disorders.

[0002] This application incorporates by reference the entire subject matter and application of attorney docket #2480-2 PCT (application PCT/US15/46819, filed August 25, 2015).

Brief Discussion of Related Art

[0003] The human body has long been interfaced with artificial devices or machines. Prosthetic limbs have for centuries been made of wood combined with metal and other materials. Through recent technological advances, devices often now have sophisticated materials, design and control for a specific purpose – such as a robotic limb (see for instance http://singularityhub.com/2013/07/24/darpas-brain-controlled-prosthetic-arm-and-a-bionic-hand-that-can-touch) or a glucose-sensing insulin infusion pump.

[0004] Many of these functions are mediated by the brain (central nervous system) and/or peripheral nervous system. These functions include classical

"neurological" functions such as vision or hearing, but also nearly all activities of daily life, including learning, moving, or operating machinery.

[0005] In many situations, the body's ability to perform such functions is constrained. Constraint can take many forms and may be physical or functional. Physical constraints include an external obstacle preventing movement of a limb in an enclosed space such as may affect a warrior or scuba diver. A physical constraint may also be internal, such as loss of a limb from amputation. Functional constraints may include a classical disease, such as stroke that prevents an individual's ability to move the foot. However, functional constraints may also include underperformance on a task due to insufficient training, knowledge or acquisition of skills, or through disuse.

[0006] What is lacking is how devices can be used to automatically ("intelligently") tailor therapy to restore lost physiological function or enhance an existing function in a specific individual. This inability for prior and current devices to automatically tailor therapy and restore or enhance a function is striking when examining how the human brain senses, integrates and controls bodily functions.

[0007] The prior art has extensively studied, yet imprecisely defined, which regions of the brain control bodily functions and how they interact with other physiological components in a network. Simple bodily functions, such as moving the biceps of the left arm or sensing from the right index finger, are well defined and often conserved between individuals. Functional mapping or "atlases" are debated even for some "simple sensations" such as visual recognition of a face. Moreover, other bodily functions including "higher cortical" functions are neither well defined nor conserved. This includes sleep, cognition, memory, mood, alertness, sensory-motor and many other activities.

[0008] Currently, machines that modulate bodily function are largely based on a precise detailed knowledge of physiology, which for the brain would include neuroimaging, brain mapping and peripheral nerve mapping of normal and abnormal functions. Unfortunately, such detailed knowledge is often incomplete. Mapping of functional locations often vary between individuals – and even in the same person at different times. Many functions are poorly mapped, such as memory, cognition and

mental performance. Even for well mapped functions, studies that define physiological function often raise additional uncertainties in this functionality.

[0009] Mapping functional domains of a bodily function – the network of physiological systems associated with that function including sensed signals and biological effectors that control it – is difficult. Mapping of functional domains is particularly difficult for functions involving the brain. However, there is an urgent need to sense and modulate functional domains whose altered function may cause disease or suboptimal performance.

[0010] In traditional theory, sleep and wakefulness are modulated by brain regions including the posterior hypothalamus, while memory is encoded by the hippocampus and other regions of the limbic system. However, it is not clear what brain regions are responsible for controlling sleep, or for mediating abnormal breathing in central sleep apnea. Regions of the brainstem that control airway muscles are better characterized, such as nuclei in the medulla oblongata for the hypoglossal nerve (twelfth cranial nerve) that controls tongue movement. Yet, how nuclei are integrated into abnormal breathing to produce obstructive sleep apnea is not understood. As a result, it has been difficult to treat this condition even using novel systems that activate tongue motion to reduce obstruction.

[0011] Sleep is a bodily function that integrates the nervous system, skeletal muscle, cardiopulmonary, and other body systems. Sleep alternates with and enables subsequent wakefulness, and is required for normal functioning of most organ systems. Sleep is traditionally considered to be controlled by specific regions of the brainstem (primitive brain) that both regulate and are modulated by function of the higher brain (cerebral cortex), muscles controlling breathing, other involuntary muscles such as sphincters of the gastrointestinal and genitourinary tracts, voluntary muscles such as muscles of the legs or arms, sensory function, and other bodily functions.

[0012] Much work over several decades has strived to define which regions of the brain subtend bodily functions such as sleep. As outlined above, while functional mapping is well defined for "simple" functions such as controlling a defined muscle (e.g., the biceps of the upper arm) or sensation (e.g., the right index finger), it is far less clear

for sleep. Interactions between the multiple organ systems impacted by sleep further complicate precise mapping.

[0013] An individual's ability to sleep may be compromised in many ways. Among the most important and common are sleep hypopnea (reduced breathing) and apnea (absence of breathing), in which impaired breathing in sleep interrupts sleep functioning, and primary sleep disorders such as insomnia, where the individual cannot sleep efficiently or sufficiently. All sleep disorders negatively impact wakefulness, producing daytime drowsiness that impairs daily activities. Sleep disorders can also lead to disorders from breathing such as low oxygen levels with metabolic effects including acidosis, disorders of the heart such as failure and abnormal rhythms, disorders of the immune system causing susceptibility to infection, psychological disorders such as stress, depression, anxiousness and psychosis, and several other states of poor functioning and disease.

[0014] Sleep apnea may be obstructive or central. Obstructive sleep apnea is increasingly recognized in individuals who snore, who are overweight and who may develop sequelae such as heart failure. Central sleep apnea is also common, yet is under-recognized and associated with comorbidities such as heart failure. It is likely that central sleep apnea also occurs alongside obstructive sleep apnea, since treatments that physically open the throat muscles and prevent obstruction may sometimes leave residual apnea.

[0015] Obstructive sleep apnea (OSA) results from complete or partial airway collapse in sleep. Conversely, central sleep apnea (CSA) results from reduced brain stimulation of the respiratory muscles in sleep. Both forms are typically diagnosed using overnight polysomnography (PSG), a test that measures at least eight (8) channels including the electroencephalogram (EEG), electrooculogram (EOG), electrocardiogram (ECG), chin electromyogram (EMG), airflow, respiratory "effort," oxygen saturation (SaO_2 or sat), and body position. However, this is a cumbersome test typically performed with an overnight hospital stay attended by physicians, is not well liked by patients, cannot easily be repeated to assess the impact of therapy and is difficult to perform at home. Recent studies have shown that commercial tests offered to circumvent traditional polysomnography are suboptimal at best.

[0016] From a polysomnogram, apnea is defined as absence of breathing (no tidal volume) for at least 10 seconds, while hypopnea is defined as decrease in tidal volume of 30% for at least 10 seconds accompanied by at least a 3% decrease in oxygen saturation or terminated by arousal from sleep. Apnea is defined as obstructive if accompanied by inspiratory effort against the occluded pharynx. Without such accompanying effort, apnea is defined as central. Similarly, hypopnea is obstructive if there are signs of upper airway flow limitation, and is otherwise considered central. The apnea-hypopnea index (AHI) is the ratio of apnea-to-hypopnea per hour of sleep, and is classified as no sleep apnea (AHI < 5), mild sleep apnea (AHI of 5-15), moderate sleep apnea (AHI of 15-30) or severe sleep apnea (AHI > 30).

[0017] Several treatments are available for obstructive sleep apnea, but these are often not well tolerated. The most commonly used treatment currently is continuous positive airway pressure to keep the airway open and reduce/eliminate obstruction. Other options include mechanical splints and even surgical procedures to reduce/eliminate obstruction. Some recent devices have applied stimulation to the muscles of the tongue or face to eliminate obstruction, but it is unclear how well they will work in the broad population.

[0018] Few strategies have been proposed to improve central sleep apnea – or more generally the central control of sleep. Since central sleep apnea may relate directly to sleep disorders, treatments for central sleep apnea may potentially also help other conditions. It is increasingly appreciated that central sleep apnea makes heart failure worse, and so treatment for central sleep apnea may improve symptoms of heart failure, and other cardiac and non-cardiac conditions such as insomnia and psychological sequelae.

[0019] Pharmacological drug therapy is often used to induce sleep, but these agents are not useful in sleep apnea. These drugs rarely mimic the natural stages of sleep, rarely induce rapid eye movement (REM) sleep that is essential for restfulness, and may paradoxically worsen sleep disorders and produce daytime drowsiness despite nighttime unconsciousness.

[0020] New therapeutic modalities are clearly needed to modulate the complex functions outlined above – often including a component of central or peripheral nervous system involvement. Emerging modalities involve electrical stimulation/modulation of brain or nervous system activity, typically at a specific target region. All these current modalities suffer from a significant common problem, as they attempt to perform therapy with no or minimal sensory input, feedback, or modulation of such therapy based upon the individual patient's neurological activity.

[0021] One example of electrical stimulation therapy is noninvasive or minimally invasive trigeminal nerve stimulation (e.g., NEUROSIGMA®) that is being evaluated to treat depression and seizures. Unfortunately, the true mechanism of action of such therapy is unclear. Whether this is due to the actual trigeminal nerve being stimulated, direct stimulation of the frontal lobe of the brain, indirect inhibition of cerebral blood flow or some other as yet unknown mechanism, still remains to be determined and will affect the ability of such therapy to be applied successfully. Additionally, this therapy is applied as a "one-size-fits-all" approach without any adaptation for individual patient responses.

[0022] Other non-invasive neuromodulation/stimulation approaches are also being considered include stimulation of the vagus nerve for seizures (Carbomed, Inc.). Similar to trigeminal nerve stimulation, the mechanism is poorly understood, the actual stimulation of the vagus nerve is unclear via this noninvasive approach, and there is no individual patient adaptation. A number of technologies are attempting to treat depression via noninvasive transcranial application of an electrical and/or magnetic field (Neuronetics Inc., Neosync Inc., Brainsway Inc., Cervel Neurotech Inc., and Tal Medical Inc.). All of these approaches, even though they show interesting preliminary data suffer, from the same problems as above, namely, poor understanding of mechanism and lack of patient-tailored therapy due to a lack of feedback and adaptation for individual patients.

[0023] For apnea specifically, approaches that try to modulate obstructive sleep apnea, including stimulation of the hypoglossal nerve (Inspire Med Inc.) or other throat muscle (Apnex Medical Inc.) – are being evaluated but typically do not have individual patient-tailored therapies. In fact, whether direct management of the obstruction

resolves the problem of apnea is also unclear due to commonality of a central sleep apnea component in most patients.

[0024] Invasive approaches to neuromodulation include vagal nerve stimulation to treat seizures and depression (Cyberonics), spinal cord stimulation to treat pain (such as Medtronic Inc., Boston Scientific Inc., Advanced Neuromed Inc.), direct deep brain stimulation to treat seizures (Medtronic Inc., Boston Scientific Inc.) or even cognitive disorders (Thync Inc.). However, these therapies target single components of the physiologic network for a bodily function, and are limited because they do not consider the remaining network. This may lead to suboptimal therapy, compensatory mechanisms that further diminish the efficacy of therapy, or unwanted effects. Moreover, these therapies are only as good as the accuracy of their specific targets, and brain/nerve regions are imprecisely defined for many bodily functions including sleep control, sleep-breathing conditions, cognition, alertness, memory, overall mental performance, or response to obesity.

[0025] Traditional therapies have also not typically been effective for managing central sleep apnea, other cognitive or performance functions, alertness, heart failure or obesity.

[0026] When devices are used for other functions, such as the increasing use of virtual environments, the goal is usually to create an illusionary or representative environment by feeding specific sensory inputs (primarily visual, tactile and/or auditory) to replicate existing real-world experiences. Unfortunately, such approaches may be limited in that normal pathways vary from individual to individual. Thus, simulating *normal* often may not accurately replicate that function for an individual nor represent normal for that individual.

[0027] In other situations, the use of devices to enhance or compensate for other functions such as motor tasks are limited or constrained. Constraint can take many forms and may be physical or functional. Physical constraints include an external obstacle preventing movement of a limb in an enclosed space such as may affect a warrior or scuba diver. A physical constraint may also be internal, such as loss of a limb from amputation. Functional constraints may include a classical disease, such as stroke

that prevents an individual's ability to move the foot. However, functional constraints may also include underperformance on a task due to insufficient training, knowledge or acquisition of skills, or through disuse.

[0028] Many attempts have been made to address these constraints, using a familiar paradigm that body sensors (e.g., the eye), nervous function (e.g., the central and peripheral nervous system) and effector organs (e.g., a muscle group) can often be functionally mapped to specific anatomic locations. However, the precise locations of the brain or other physiological systems that control each task are not well defined. Such functional maps or "atlases" are often debated for complex functions. Much data has come from animal models that are not well suited to model or analyze complex human functions or mental functions.

[0029] It would be of great benefit to society to develop a device to enhance bodily functions by modulating its interfaced functional components. For instance, a device to restore sleep functionality, i.e., to prevent or treat central sleep disorders, would be of great value. Such devices may improve daytime performance in individuals without disease, or reduce symptoms in patients with disorders associated with central sleep apnea such as heart failure. It would also be of immense benefit to construct a device able to restore/enhance other functions such as motor activity or even some aspects of neural functioning without the need to define precise physiological, neural or other pathways to guide therapy. Currently, there are few methods in the prior art to achieve these goals.

SUMMARY OF THE PRESENT INVENTION

[0030] The invention is designed to monitor and modulate a complex bodily function using a combined biological and machine approach. Unlike the prior art, the current invention uses machine learning to derive a robust relationship between sensed signatures of measurable body systems and bodily functions in animals and in particular human beings, but does not require presumed physiological relationships or mechanisms. The invention is then able to enhance performance of function or re-instate lost functions using this robust relationship or enciphered functional network.

[0031] For the purposes of this disclosure, the following definitions apply.

[0032] Associative learning is defined as the process of linking sensed signatures and other inputs with a body task. For this disclosure, body tasks are typically complex tasks rather than reflexive or other simple tasks. Associative learning may be iterative, such that associations are modified ("learned") based upon patterns of change between these processes. For the purposes of this disclosure, this may be associating low impedance with abnormal breathing.

[0033] Bodily function is defined as the processes needed to perform a task, that may include physiologic or pathological processes. Examples include sleep, sleep apnea, mental performance, or the response to obesity. Bodily functions involve a network of several functional domains that often interact including the brain and central nervous system, peripheral nervous system, cardiovascular, pulmonary, gastrointestinal, genitourinary, immune, skin and other systems. A bodily function may result from biological activity/function, and may involve a non-biological or artificial component, e.g., reading with glasses, driving, using remote control unit, a patient moving a combined natural/cybernetic limb, etc.

[0034] Bodily signal means signals generated by and/or sensed from a human, animal, plant, bacterial or other single-cell-based body or multi-cell-based body. For purposes of this definition, viruses and prions are included. Bodily signals particularly include signals generated by and/or sensed from the human body. Bodily signals are generally associated with bodily functions. The term "non-bodily signal" indicates that it is generated from a source other than a single- or multi-cell-based body. Examples include an external "signal" from an external electrical source, machine, sensor, etc. When the term "signal" is used without the term "bodily" or "non-bodily", the term "signal" indicates that it includes both "bodily signals" and "non-bodily" signals, i.e., it includes all signals.

[0035] Body means the physical structure of a single-celled organism, a multi-celled organism, viruses and prions. Organisms include animals (such as, but not limited to, humans), plants, bacteria, etc.

[0036] Effector is a means of performing a bodily task, and may include a physical effector such as for moving a limb or moving the diaphragm to enhance breathing during sleep, or an artificial effector such as a cybernetic limb or electrical stimulation to complete a task.

[0037] Effector response is the result of the effector, which may or may not complete a bodily task. For instance, if the effector is the triceps muscle in the arm, an effector response is to extend the arm by 30 degrees, while the entire task may be to fully straighten the arm.

[0038] Effector signal is the signal delivered by the invention to the effector to produce the effector response.

[0039] Functional domain is the aggregation of all the elements relating to a distinct bodily function, sometimes associated with a specific organ system or a combination of systems that results in the overall function, e.g., breathing. For a simple function, this may reduce to a sensed "dermatomal distribution", for instance sensation at the shoulder is mediated by sensory nerves from the C435 distribution of the spinal cord. However, even such simple domains are more complex (and networked), in that shoulder sensation is mediated by nerves that also supply the heart. Functional domains include nerves, blood vessels, the lymphatic system, interstitial tissue planes and hormonal centers. Sensed signatures are measurable physiological parameters or indices, used individually or in combination from body systems above, that are linked with a body function and in aggregate describe that function.

[0040] Other definitions include a biological function, which means any function that is the direct result of natural biological activity such as breathing, heart beating, walking, running, sleeping, dreaming and so on.

[0041] A symbolic model herein is a mathematical representation of a function, linking measured sensed activity with a task even if complete physiological description for that task are lacking. It can also be termed a symbolic representation. This may include analog recorded physiological signals, digital coded ciphers, computer code, visual representations such as photographs or graphics, and so on, and can be used to

aid in rapid, clear transformation to perform a specified method. Associative learning is an iterative process of linking processes, typically including sensed signatures and complex biological tasks, and modifying these associations ("learning") based upon patterns of change between these processes (for instance, associating low impedance with abnormal breathing).

[0042] Enciphered network or enciphered functional network (EFN) is defined as a model associating measured parameters (sensed signatures) with aspects of the bodily task including effectors and other sensors. This enables monitoring and improved functionality of that body function. The enciphered network is designed to parameterize a functional domain, for example it links sensed activity with a task even if complete physiological or mechanistic description for that task is lacking. This departs from the traditional approach of meticulously mapping or recapitulating functions in each biological organ system. The network can be symbolic in the form of a symbolic representation such as symbolic code, in which case it may be a mathematical or other abstract representation. If applied to the nervous system, this can be termed an enciphered nervous system.

[0043] Encipher is defined as the process of coding information.

[0044] Enhanced performance or enhancement is defined as improvement to the normal healthy and non-diseased baseline function in an individual. Enhanced performance thus would not include therapies for disease such as pacing in an individual with abnormally slow heart rates or in a patient or an insulin pump in known diabetic patients.

[0045] External machine is defined as a mechanical, electrical, computational or other non-natural (native biological) device. This may be external to the body but can be in contact with or implanted within the body.

[0046] Extremity of the body is defined as limbs and associated structures of the body including arms, legs, hands, feet, fingers, toes, and subsegments thereof.

[0047] Functional domain is defined as the elements relating to a bodily task. This may include sensed elements, analysis elements and effector elements. Analysis

elements may be "learned", preprogrammed, reflexive, or passive. Each element may be biological, non-biological or artificial.

[0048] For example, a functional domain may sometimes be associated with a specific organ system or a combination of systems that results in the overall function, e.g., breathing. For a simple function, this may reduce to a sensed "dermatomal distribution", for instance sensation at the shoulder is mediated by sensory nerves from the C435 distribution of the spinal cord. However, even simple domains may be more complex, in that shoulder sensation is mediated by nerves that also supply the heart. Functional domains thus include nerves, blood vessels, the lymphatic system, interstitial tissue planes and hormonal organs. Sensed signatures are measurable physiological parameters or indices from these organ systems, used individually or in combination that are associated with a body function and in aggregate describe that function.

[0049] Functionally associated is defined as sensed signals or functional domains that occur together when that function occurs. An example would be activity in portions of the brain controlling breathing with activity in muscles of breathing such as the intercostal muscles or diaphragm. Functional association does not need to follow biological pathways. For example, a functional association includes sensed activity in shoulder nerves with heart related problems such as angina, in which shoulder nerve activity is not part of the biological processes causing heart problems.

[0050] Machine learning is defined as a series of analytic methods and algorithms that can learn from and make predictions on data by building a model rather than following strictly static programming instructions. These machine learning approaches "learn" patterns and functions with at least some components that are not preprogrammed (i.e., instructed). In this sense, machine learning creates individualized solutions rather than generic ones. Machine learning can take many forms, including artificial neural networks, heuristics, deterministic rules and combined approaches.

[0051] Sensed signatures are defined as one or more signals from sensors related to a bodily task. Sensors may be biological, non-biological or artificial. Sensed signatures are inputs of the functional domain. Sensed signatures can be physiological

parameters such as nerve firing rates and oxygenation level, that are associated with the function in question such as sleep disordered breathing.

[0052] Mental alertness is defined as an awake state that focuses on a specific desired task, that can be measured by performance at that task. Improved mental alertness is characterized by being awake and performing mental and other tasks well. Reduced mental alertness can include many states that include but are not limited to impaired performance of a task, "mental fatigue", loss of focus, attention deficit, somnolescence, sleepiness, narcolepsy, sleep and disease processes that include the above as well as coma, "fugue" state and others.

[0053] "Task" means a piece of work, action or movement to be done, completed or undertaken. The term "bodily task" means a piece of work, action or movement to be done, completed or undertaken by a "body", defined herein.

[0054] Therapeutically effective is defined as an effector function or dose of an intervention or therapy that produces measurable improvement in one or more patient outcomes. An example would be patterns of energy directed to the scalp to stimulate target regions controlling breathing, in order to treat central sleep apnea. Ideally, an intervention will minimize impact to other regions of the body, in this case the scalp which may be achieved by a small contact device rather than a cap that encompasses the entire scalp, or focusing energy from a non-contact device on the target region and not the entire head.

[0055] Other biological terms take their standard definitions, such as heart failure, tidal volume, sleep apnea, obesity and so on.

[0056] This invention creates an enciphered functional network. The potential number of uses of this invention are broad.

[0057] In one aspect, there is provided a method for interacting with the human body, the method including detecting bodily signals associated with one or more bodily functions at one or more sensors associated with the human body, processing the bodily signals to create one or more sensed signatures of the one of more bodily functions, processing the signatures using an enciphered functional network utilizing machine

learning to determine one or more effector responses needed to control a bodily task, delivering via the enciphered functional network one or more effector signals (the effector signals based on the one or more effector responses), and controlling a bodily task.

[0058] In another aspect, there is provided a method to enhance performance of a bodily task, the method including detecting signals associated with the task at one or more sensors, processing the signals to create one or more sensed signatures, processing the signatures using an enciphered functional network to determine one or more effector responses needed to enhance performance of the bodily task, delivering via the enciphered functional network one or more effector signals (the effector signals based on the one or more effector responses), and enhancing performance of the task.

[0059] In another aspect, there is provided a method for treating a disease, the method including detecting signals associated with one or more bodily functions at one or more sensors associated with the human body, processing the signals to create one or more sensed signatures of the one of more bodily functions, processing the signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to treat a disease, delivering via the enciphered functional network one or more effector signals (the effector signals based on the one or more effector responses), and treating the disease.

[0060] In another aspect, there is provided a method for transforming nerve activity associated with one or more bodily functions, the method including detecting bodily signals of nerve activity associated with the one or more bodily functions at one or more sensors, processing the bodily signals to create one or more sensed signatures of the one or more bodily functions, processing the signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to transform nerve activity, delivering via the enciphered functional network one or more effector signals (the effector signals based on the one or more effector responses), and transforming nerve activity.

[0061] In another aspect, there is provided a method for controlling a device using an enciphered functional network, the method including detecting bodily signals

from a body using one or more sensors, processing the bodily signals to create a sensed signature, processing the sensed signature using an enciphered functional network utilizing machine learning to determine one or more effector responses to control the device, delivering via the enciphered functional network one or more effector signals (the effector signals based on the one or more effector responses), and controlling the device.

[0062] In another aspect, there is provided a method to measure bodily function in an animal, the method including detecting bodily signals associated with sensory activation, processing the bodily signals to create one or more sensed signatures, and processing the sensed signatures using an enciphered functional network to determine one or more effector responses needed to enhance the bodily function of the animal.

[0063] In another aspect, there is provided a method of improving a specific human performance, the method including identifying one or more regions of a human body associated with parts of the brain that serve a specific function, placing low energy stimulating electrodes proximate to the one or more regions of the human body, applying stimulation through the electrodes to activate the parts of the brain, and measuring changes related to the parts of the brain to verify improvement of the specific human performance.

[0064] In another aspect, there is provided a method for treating a sleep disorder, the method including selecting one or more regions of a patient's central nervous system and/or peripheral nervous system associated with sleep functioning, and applying low energy stimulation through electrodes to activate the patient's one or more regions of central nervous system and/or peripheral nervous system to treat the sleep disorder.

[0065] In another aspect, there is provided a method of enhancing attention, the method including selecting one or more regions of a patient's central nervous system and/or peripheral nervous system associated with an attention disorder, and applying low energy stimulation through electrodes to activate parts of a patient's central nervous system and/or peripheral nervous system to treat the attention disorder.

[0066] In another aspect, there is provided a method of treating central sleep apnea, the method including identifying a target region from one or more local areas of the head and neck (the target region being functionally associated with one or parts of the brain that control sleep), and delivering a therapeutically effective amount of energy to stimulate the target region to treat the central sleep apnea, while minimizing stimulation of other regions of the body.

[0067] In another aspect, there is provided a method of modulating mental function, the method including identifying a target region selected from localized areas of the body (the target region being functionally associated with parts of the brain that govern the mental function), the mental function including one or more of alertness, cognition, memory, mood, attention and awareness, and delivering a therapeutically effective amount of energy to stimulate the target region to modulate the mental function, while minimizing stimulation of other regions of the body.

[0068] In another aspect, there is provided a system for interacting with the human body, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including detecting bodily signals associated with one or more bodily functions at one or more sensors associated with the human body, processing the bodily signals to create one or more sensed signatures of the one of more bodily functions, processing the signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to control a bodily task, delivering via the enciphered functional network one or more effector signals (the effector signals based on the one or more effector responses), and controlling a bodily task.

[0069] In another aspect, there is provided a system to enhance performance of one or more tasks, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including detecting signals associated with the task at one or more sensors, processing the signals to create one or more sensed signatures, processing the signatures using an enciphered functional network to determine one or more effector responses needed to enhance performance of the bodily task, delivering via the enciphered functional network one or more effector

signals (the effector signals based on the one or more effector responses), and enhancing performance of the task.

[0070] In another aspect, there is provided a system to treat a disease, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including detecting bodily signals associated with one or more bodily functions at one or more sensors associated with the human body, processing the bodily signals to create one or more sensed signatures of the one of more bodily functions, processing the signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to treat a disease, delivering via the enciphered functional network one or more effector signals (the effector signals based on the one or more effector responses), and treating the disease.

[0071] In another aspect, there is provided a system to transform nerve activity associated with one or more biological functions, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including detecting bodily signals of nerve activity associated with the one or more bodily functions at one or more sensors, processing the bodily signals to create one or more sensed signatures of the one or more bodily functions, processing the signatures using an enciphered functional network utilizing machine learning to transform nerve activity, delivering via the enciphered functional network one or more effector signals (the effector signals based on the one or more effector responses), and transforming nerve activity.

[0072] In another aspect, there is provided a system to control a device using biological signals, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including detecting bodily signals from a body using one or more sensors, processing the bodily signals to create a sensed signature, processing the sensed signature using an enciphered functional network utilizing machine learning to determine one or more effector responses to control the device, delivering via the enciphered functional network one or more effector signals (the effector signals based on the one or more effector responses), and controlling the device.

[0073] In another aspect, there is provided a system to measure visual function in an animal, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including detecting bodily signals associated with sensory activation, processing the bodily signals to create one or more sensed signatures representing quantitative measures of sensation, and processing the sensed signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to enhance the bodily function of the animal.

[0074] In another aspect, there is provided a system for improving a specific human performance, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including identifying one or more regions of a human body associated with parts of the brain that serve a specific function, placing low energy stimulating electrodes proximate to the one or more regions of the human body, applying stimulation through the electrodes to activate the parts of the brain, and measuring changes related to the parts of the brain to verify improvement of the specific human performance.

[0075] In another aspect, there is provided a system for treating a sleep disorder, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including selecting one or more regions of a patient's central nervous system and/or peripheral nervous system associated with sleep functioning, and applying low energy stimulation through electrodes to activate the patient's one or more regions of central nervous system and/or peripheral nervous system to treat the sleep disorder.

[0076] In another aspect, there is provided a system to enhance attention, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including selecting one or more regions of a patient's central nervous system and/or peripheral nervous system associated with an attention disorder, and applying low energy stimulation through electrodes to activate parts of a patient's central nervous system and/or peripheral nervous system to treat the attention disorder.

[0077] In another aspect, there is provided a system to treat central sleep apnea, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including identifying a target region from one or more local areas of the head and neck (the target region being functionally associated with one or more parts of the brain that control sleep), and delivering a therapeutically effective amount of energy to stimulate the target region to treat the central sleep apnea, while minimizing stimulation of other regions of the body.

[0078] In another aspect, there is provided a system to modulate mental function, the system including a processor and a memory storing instructions that, when executed by the processor, performs operations including identifying a target region selected from localized areas of the body (the target region being functionally associated with parts of the brain that govern the mental function, including one or more of alertness, cognition, memory, mood, attention and awareness), and delivering a therapeutically effective amount of energy to stimulate the target region to modulate the mental function, while minimizing stimulation of other regions of the body.

[0079] One motivation for this invention is that detailed deterministic solutions for many complex bodily functions are inherently limited for therapy. This reflects several factors. First, there is inter-individual variation in regions of control – for instance, the biological neural network to talk in one person differs from the biological neural network to talk in another. For functions with a nervous component, this may represent the unique fashion in which higher cognitive functions and memories are shaped during growth and development in each person or potentially genetically established. Secondly, many brain functions are plastic – changes in the environment or disease can alter control regions. Changes can be gradual or abrupt, causing variations over years, months or even weeks that may reflect normal development, aging or dysfunction. This may explain why traditional therapies that are initially effective become ineffective over time. Thirdly, our conceptual knowledge of functional domains in the central and peripheral nervous system is in its infancy. It is thus a major challenge to understand a bodily function using a classical paradigm of observing then stimulating a specific target to map its region(s) of control.

[0080] Several innovations separate this invention from the prior art. First, the invention creates an enciphered network for the bodily function. This reconstructs the function as network of functional domains. This departs from the traditional approach of meticulously mapping or recapitulating each biological organ system. Instead, second, it identifies sensed signatures and effectors for each function. Signatures can be nervous or non-nervous system related. Third, the invention applies a feedback loop to apply measured and quantitatively determined therapy that may change over time even in the same individual . This is inherent because the enciphered network can be trained over time using an ongoing machine learning processes. Fourth, the core logic of the invention is patient-tailored, distinct from the majority of current devices that use "one-size-fits-all", generic or stereotypic therapy. Fifth, therapy is adaptive through continued machine learning, such that a similar abnormality in the same individual may produce different signatures and/or require different effector responses at two or more distinct periods in time. Sixth, certain embodiments of the device combine biological and non-biologic devices, together or individually. The enciphered representation can accommodate novel signatures over time, that can be extrinsic artificial signals as well as intrinsic biological ones. Therapy can ultimately be delivered by an external device and/or by direct stimulation or inhibition of an effector. Embodiments include improvements of sleep apnea, the body's response to heart failure, obesity, alertness, memory and mental performance or cognition.

[0081] The concept of accessing functional domains for a task by measuring from or stimulating an interconnected region of the network, that may be neural, vascular or other, is novel at several levels and has not been addressed by devices in the prior art. One example way to better understand this concept is by considering the disease of central sleep apnea.

[0082] The functional domain for central sleep apnea in this invention includes sensed signatures of brain function (measurable on the EEG), reduced oxygenation levels and increased carbon monoxide levels in the blood (measurable from skin sensors), and in some individuals increased heart rate and altered patterns of heart rate and other less defined functions. Observed but unexplained signatures may include nocturnal rostral fluid shift from the legs (that may link sleep apnea with heart failure).

Effector responses for central sleep apnea is to nerve function to the neck muscles, diaphragm, intercostal muscles and accessory muscles (measurable by nerve firing rates). The present invention will use these sensed signatures of brain or nerve activity, chest wall movement, bioimpedance at the skin (to assess for a rostral fall), or oxygenation for diagnosis and monitoring. In an embodiment for treatment, the invention may result in varying effector responses.

[0083] Chest wall impedance can be expressed in many forms. In this invention, the sensed signature of abnormal chest wall impedance includes a ratio of lower body impedance (e.g., leg, lower back) to higher body impedance (neck and chest) – i.e., higher impedance in lower body (less extracellular water), lower impedance in upper body (more extracellular water). This could also be expressed as upper-to-lower body conductance. This could also include measuring impedance to different forms, patterns, or waveforms of electrical energy.

[0084] In one preferred embodiment, machine learning is used to associate repeatedly measured signatures with normal breathing . If apnea arises during sleep, the invention will apply tailored therapy adaptively to alter domain activity and alleviate sleep apnea. The response to therapy (e.g., effector response) can also be assessed repeatedly via sensed signatures, and the therapy can be withdrawn or continued based upon these signatures. This differs from the prior art in which therapies such as continous positive airway pressure or nerve stimulation are often delivered empirically, continuously or in predetermined fashions without adaptive algorithms to tailor therapy.

[0085] Other sensed signatures include altered nerve firing rates for mental performance or sleep, vasodilation during sleep, reduced skin galvanic resistance (from altered electrolytes or edema) in the body's response to heart failure or sleep-breathing disorders, altered skin absorption or emission of near-infrared or other components of the electromagnetic spectrum during sleep disorders, measured alterations to other forms of applied non-electrical energy including optical signals (altered reflectance), sound or ultrasound (different sonic reflectance and scattering), and potentially altered spectroscopic signals of body chemistry that can be sensed.

[0086] The network of functional domains is a unique approach for interfacing with bodily functions. For instance, a patient with heart pain (angina pectoris) or a heart attack (myocardial infarction) often experiences "radiated pain" to the left arm, shoulder or other regions. Some patients experience only arm pain from cardiac ischemia – i.e., arm pain is a sensed signature. This signature may not be relevant to other individuals *a priori* – but can be learned by the enciphered network for that individual. In this way, the invention can now detect nerve activity in the arm below the typical nerve firing rates for sensed "pain", providing the device with an early warning sensor for heart pain ("angina") to provide therapy or alert medical personnel.

[0087] In another example, patients with problems of the abdominal viscera (stomach, small intestine, large intestine) that may include normal "indigestion" as well as diseases often experience vague discomfort on the abdominal wall through imprecisely defined and variable visceral and somatic nerves. Massaging this region is an example of counter-stimulation that can alleviate the visceral organ pain. In one embodiment, the invention will thus provide algorithmically determined vibratory stimulation to appropriate skin regions within the "functional domain" of the bodily function to alleviate pain.

[0088] As yet another example, nerve firing in cutaneous or other accessible nerves (e.g., mucous membranes of mouth, anus, or skin of the external auditory meatus) may share neural control regions with other organs, such as heart pain or even abnormal heart rhythms. Effector signals can be delivered to specific regions of the functional domain to alleviate heart pain or other abnormalities. Other components of a functional domain may include blood vessel flow, vasomotor reactivity, skin electrical conductivity, heart rate or heart rate variations, breathing rate, cellular edema and other indices illustrated throughout the specification.

[0089] Therapy is individually tailored and not empirically delivered. Baseline signatures such as rates and patterns of nerve firing during a desired level of functioning are analyzed and learned in each individual and may be combined with other signatures within the enciphered functional network. In states such as sleep-disordered breathing, heart failure, fatigue and others, fluctuations outside this normal range are detected and can be used to monitor disease or performance. Therapy such

as stimulating neck muscles for obstructive sleep apnea, stimulating accessory muscles or alertness centers for central apnea, or therapy for heart failure and other conditions can be monitored (e.g., by effector response) and tailored to machine learned signatures. Functionality can thus be modulated without direct knowledge or access to the primary physiological target and without detailed pathophysiological knowledge of that function.

[0090] Nerve signatures may be shared between many functions, e.g., based on dermatomal distributions of peripheral nerves. One example is sensation of the tip of shoulder blade at the "C234" region, control of deltoid muscle function by the "C56" region, and control of the diaphragm muscles and hence breathing at the "C345" region. Thus, sensation at the shoulder can indicate shoulder stimulation, or pain in portions of the heart adjacent to the diaphragm. Stimulation at these regions by direct electrical stimulation, vibratory stimuli, heat or other can produce a counter-irritant to the measured function.

[0091] Brain signatures can be assessed directly via the EEG or simplified EEG measured from the scalp by many types of electrical sensor. For instance, scalp activity in the alpha (7.5-12.5 Hz), beta (12.5-30 Hz) or gamma (25-40 Hz) bands indicate states of awakeness (wakefulness) or heightened or alertness; activity in the delta (0.1-3 Hz) or theta (4-7 Hz) bands indicate drowsy (or comatose) states. Depending on sensed activity, interventions can be applied to the scalp or other domains of the network while monitoring alpha, beta or gamma signatures to facilitate alertness. In each case, the invention is novel in that it derives patient-tailored signatures for a given function using machine learning, and will apply interventions algorithmically in a tailored feedback loop. In one preferred embodiment this will enhance sleep function.

[0092] Peripheral nerve signatures are numerous. For instance, increased nerve firing of the cervical sympathetic plexus in the head and neck may be associated with alertness or rapid eye movement (REM) sleep, and reduced activity may be associated with drowsiness or stages I-IV of sleep. Stimulation of those regions of the head and neck can be used to increase alertness. Increased firing of the accessory (XI), facial (VII) or other cranial nerves may indicate impending obstructive sleep apnea, and may provide targets for therapy.

[0093] There are several non-nerve domain signatures. For instance, deoxygenation of an oxygen sensor on the skin of a finger (via optical reflectance or plethysmography) can indicate hypopnea or apnea. Increased skin temperature or blood flow (absorption in red wavelengths on an optical sensor) may occur in stages I-IV sleep from parasympathetic activation. Novel skin sensors can detect changes in biomarkers such as glucose (to detect diabetic states, need to eat), INR (a test of blood thickness for some patients on blood thinners) and a new generation of sensors for drugs in the blood stream, chemical changes on the skin and so on, Interpretation of these signatures can be troublesome but is linked in this invention by machine learning to a specific function, e.g., fever increases skin temperature, but is accompanied by increased breathing rate and altered skin biochemistry/impedance (due to perspiration). By learning based on multiple signatures, temperature information can be used in this case to distinguish changes in breathing rates due to fever from that due to central sleep apnea.

[0094] This invention adapts to concepts of neural plasticity. Plasticity refers to alterations in the pathways of nerves and connections (synapses) from changes in behavior, environment, neural processes, thinking, and emotions, and also to changes resulting from injury. This concept has replaced prior teachings that the brain and nervous systema are static organs. New studies show that the brain changes in anatomy (structure) and physiology (functioning) over time. There are several examples, e.g., DARPA limb projects, stroke victims recovering function after months or years of physical or occupational therapy despite having infarcted the traditional brain areas for the target function. Plasticity is also observed in peripheral nerves, for instance the distribution of a functioning nerve (dermatome) can expand into an adjacent distribution of diseased nerve supply. In other words, a singular function can be assumed or subsumed by different regions of the central or peripheral nervous system, that will also have non-neural implications, e.g., on measured blood flow, galvanic skin resistance or other physiological parameters.

[0095] This invention uses the principle that continuous machine learning will enable its functionality to be retained even when plasticity occurs, and again without precise precise physiological mapping knowledge for that function. For instance, in

classical Pavlovian training, dogs were trained to salivate when exposed to non-food-related stimuli that had previously been associated with food in training. In other words, a new trained stimulus – function interaction – was used without knowledge of detailed physiological linking for that function.

[0096] This invention also encompasses personalized learned feedback loops, to modulate a desired bodily function by algorithmic machine learning analogous to classical Pavlovian conditioning. In a training mode, stimulation is applied during normal periods – for instance, vibratory stimulation of the skin of the lower back on days of anticipated restful sleep. Subsequently, if sleep is interrupted, trained modes of stimulation are applied. This mode can be applied to various bodily functions including but not limited to alertness, memory, sleep and sleep-disordered breathing.

[0097] The present invention identifies functional domains empirically, and provides computational customized, individualized solutions. This differs from the prior art in which, for example, preferred embodiment for sleep disordered breathing stimulate cranial nerves (e.g., trigeminal or hypoglossal), but through unclear mechanisms that may in fact inadvertently work by training certain responses or stimulating other regions than those intended.

[0098] In another set of preferred embodiments, the enciphered network can be used to enhance body performance in non-disease states. One direction is to utilize unused body capacity. In daily western life, humans often underuse torso, leg and arm sensors and effectors yet frequently use eye and hand sensors and effectors. Stimulation of underused regions by a device can extend the sensory capacity (bandwidth) of an individual. When combined with artificial sensors, these underused regions can also be used to provide a "sixth sense" (see drawings) to extend sensation to biologically unsensed stimuli (e.g., a carbon monoxide sensor can provide vibratory stimuli to unused portions of the body), to train the body (e.g., improve alertness) or other function.

[0099] Enhancement of performance may require specific stimulation patterns that vary based on frequencies, amplitudes and sites of stimulation. This information can be derived by machine learning of sensed signatures or patterns in each individual.

Another approach is to use patterns from individuals who are highly functioning in that desired modality – from a de-identified database, by crowd sourced data collection from wearable devices or by other means. These patterns can then serve as inputs for machine learning algorithms in the enciphered network, that will interface them to the symbolic representation for an individual to tailor them appropriately.

[00100] Effector stimulation should avoid inadvertent recruitment of existing bodily functions by applying non-physiological or atypical physiological stimuli. This can be achieved by using neural frequencies or patterns that are not part of normal processing or pathways, such as outside the normal sensed frequency, or with a different pattern, or at a different (lower) amplitude. Using other examples in this disclosure, the invention may detect subclinical nerve firing in the functional domain for cardiac ischemia as an early warning for angina, or application of subclinical amplitudes of nerve stimulation to the accessory muscles to stimulate breathing (for central sleep apnea) or neck (to improve alertness). These safeguards will avoid invoking behavioral change, sensation by the brain and/or changing memory of an event (Redondo et al., Nature 2014).

[00101] The invention can work with several types of sensors individually or in combination. Examples include solid physical sensors such as FINE (http://singularityhub.com/2013/07/24/darpas-brain-controlled-prosthetic-arm-and-a-bionic-hand-that-can-touch/), traditional ECG- or EEG- electrical sensors, non-solid sensors such as electrostatic creams, sensors for bioimpedance, piezoelectric film sensors, printed circuit sensors, photosensitive film, thermosensitive film, and external-oriented sensors not in contact with the body such as video, IR, temperature, gas sensors, as well as other sensors. These sensors detect stimuli and transduce the information through a constructed/created (non standard or non-somatotopic) path to active nerves.

[00102] Processing elements include a digital signal processor to interface with output elements that can stimulate different parts/nerves of the body, or cause mechanical action in an external machine. Such elements could include traditional computing machines with integrated circuits in isolation or networked (e.g., cloud computing), biological computing, integrated biological/artificial devices (cybernetic)

or utilizing unused biological capacity to perform specific, directed tasks. One potential embodiment is to use unused computational capacity of the central nervous system to perform pattern recognition in lieu of programming an artificial computer for this purpose. This can be accomplished by training an individual to recognize a visual/auditory/olfactory or other sensation and then sensing the sensed signature of that evoked response when that stimulus is subsequently encountered.

[00103] Effector elements can include direct electrical outputs, piezoelectrical devices, visual/infrared or other stimulatory systems, nerve stimulating electrodes or servo motors to control a limb, digitized electronic signals such as radiofrequency or infrared transmissions, or even virtualized data such as avatars in a virtual world interface or elements in a large database that can be queried, as well as other effector elements now existing or yet to be developed.

[00104] Applications of effector elements can be for diagnostic purposes such as detecting stimuli or body functions (e.g., visual function, visual disease progression, mood, alertness, detecting injury such as traumatic brain injury, cardiac electrical and/or mechanical function, subclinical seizure detection), detecting external world situations or environments without subjecting the human body to discomfort (e.g., sensing heat in a fire, detecting oxygen or toxic gas content in the external environment such as a mine).

[00105] Effectors can be applied for medically related therapy such as brain related function (e.g., brain stimulation for patients with sleep disorders or central apnea, biofeedback for stroke rehabilitation, deep brain stimulation for motion or seizure disorders), other neurological diseases (e.g., substituting artificial sensor data in patients with peripheral neuropathy, biofeedback stimulation of muscles), cardiac disease (e.g., arrhythmias treated with implanted devices, cardiac function improved with mechanical or electrical devices), response to obesity, or other organ disease modified with directed electrical or mechanical elements.

[00106] Applications of machine learned therapy using this invention can be for training, learning and performing of physiological activities or mechanical, non-physiologic functions. Unlike the prior art that applies non-specific stimulation, e.g.,

transcranial direct current stimulation (ref: http://www.scientificamerican.com/article/amping-up-brain-function), the present invention can sense, machine learn, optimize, and then deliver specific therapy modulated via a feedback loop. This will provide tailored therapy to modify many complex functions.

[00107] Other applications for this invention include improving athletic performance after injury (e.g., direct stimulation to muscles to regain lost function, biofeedback to maintain heart rate within desired range during controlled exercise, brain stimulation), enhancing sensory perceptions (e.g., artificial visual sensors for facial recognition, artificial auditory sensors to detect previously inaudible information), performing tasks in non-typical ways by overcoming constraints or developing more efficient solutions (e.g., driving a car with small finger movements or eye motion amplified by artificial device, controlling an external device biologically, e.g., small eye or limb movements to control a computer interface). Examples of mechanical functions include biological operation of a mechanical exoskeleton for soldiers, performing tasks too difficult or dangerous for humans such as deep sea exploration, armed combat, or basic tasks such as controlling a computer, video games or remote controls.

[00108] In summary, the invention incorporates a combined biological-artificial network, referred to as enciphered network (or representation), to modulate specific tasks (such as complex bodily functions often requiring brain or nerve involvement, or higher cortical functions). Sensors (biological or artificial) sense the activity of the measured task. This sensed activity is enciphered, and then machine learning algorithms and specific hardware modulate the network using biological, artificial or hybrid effectors (e.g., stimulating electrodes). The network can directly augment a function (e.g., sleep), or form a new function via existing elements ("retasking" a function, e.g., associating lower back stimulation with sleep).

[00109] The enciphered network can operate internally using symbolic internal representation specific to each task. Specific representations of each task may be important because the pattern, frequency, and amplitude of stimulation differ

considerably between tasks – e.g., modulating electrical activity on the scalp versus the neck or other parts of the body, or stimulating neural elements versus blood vessels.

BRIEF DESCRIPTION OF THE DRAWINGS

[00110] Some embodiments are illustrated by way of example and not limitation in the figures of the accompanying drawings, in which:

[00111] FIG. 1 shows a schematic representation of the invention, including biological sensors or external sensors, a signal processing unit and a computing device that uses machine learning and can interface a database to create a symbolic representation of bodily functions, e.g., an "enciphered functional network". A control unit can be used to treat abnormal physiological functions via a device or biological organ ("effector") tailored by measuring response to therapy in a feedback loop.

[00112] FIG. 2 illustrates the relative relationship of sensors, sensed signatures for functional domain(s), the enciphered functional network (with analysis engine), the effector group(s) for a functional domain for a bodily function.

[00113] FIG. 3 shows a flowchart illustrating how the enciphered functional network represents a bodily function in an individual person, as functional domains represented by sensed signatures. Sensed signatures are analyzed by machine learning algorithms relative to desired and undesired behavior, and to databases in the enciphered network of "population behavior" or historical behavior of that individual, to monitor function, guide and assess response to therapy.

[00114] FIG. 4 shows an example of sensed signatures for a given bodily function, for functional domains representing physiology in the nervous system and not in the nervous system. The portfolio of sensed signatures becomes the measured representation of that bodily function for an individual person.

[00115] FIG. 5 shows examples of modifying bodily function using the enciphered network. Modification is tailored to the individual via personalized sensory signatures and machine learning in the enciphered network. Modification includes therapy, such as for sleep-disordered breathing, but can also enhance normal function for that

individual. Modification operates in a continuous feedback, assessing response via the enciphered network to prevent excessive or deleterious modification.

[00116] FIG. 6 shows illustrative body locations for sensed signatures and modifying various functional domains. Sensor locations are indicated by open (white) regions and effector (modifying) regions by filled (black) regions. Their relative size varies in each individual, is determined by machine learning for each individual and is not portrayed to scale.

[00117] FIG. 7 shows examples of a body sensor, with a sensor element, power source, microprocessor element, nonvolatile storage and communication element. Several types of sensor element are illustrated, such as photodetector (for skin temperature, metabolic light sensing, drug sensing), galvanometer (for skin impedance), pressure (for weight, skin breakdown), temperature or chemical. The invention can also use external sensors (FIGs. 1, 12-18) that provide a variety of extrinsic or artificial signatures (FIGs. 12-18).

[00118] FIG. 8 shows an example of an embodiment of sensed signatures in sleep disordered breathing.

[00119] FIG. 9 shows an example of an embodiment of effector locations for sleep disordered breathing.

[00120] FIG. 10 shows an example of an embodiment of sensed signature for heart failure.

[00121] FIG. 11 shows an example of an embodiment of sensed signature of body response to obesity.

[00122] FIG. 12 shows an example of an embodiment of sensed signatures for other conditions.

[00123] FIG. 13 shows an enciphered (symbolic) network model for physiology of sleep-disordered breathing.

[00124] FIG. 14 shows enhancement of body function using enciphered network.

[00125] FIG. 15 shows cybernetic enhancement of body function using enciphered functional network.

[00126] FIG. 16 shows an example of a transformation of motor function. The flowchart shows one embodiment for enhancing motor (muscle control) function of the nervous system. This is illustrated for leg muscle function, for enhancement (e.g., in military or sports use) or for medical purposes (e.g., after a stroke).

[00127] FIG. 17 shows an example of enhancing sensory function. The flowchart indicates embodiment for enhancing sensory perception/sensation of the nervous system. This is illustrated for alertness, for enhancement (e.g., military or sports use), for medical purposes (e.g., monitoring drowsiness or coma) or for consumer safety (e.g., identifying drowsiness while driving to control a feedback device).

[00128] FIG. 18 shows an example of transformation of sensory function. The flowchart indicates an embodiment for transposing, or enhancing sensory perception. This is illustrated for hearing, with the invention enhancing hearing and transposing hearing function to another nervous function.

[00129] FIG. 19 shows an example of creating a novel "cybernetic" sensory function. The flowchart indicates an embodiment for providing a sensory function that does not currently exist. This is illustrated for integrating sensation from a biosensor for a biotoxin.

[00130] FIG. 20 shows another example of creating a novel "cybernetic" sensory function. The flowchart indicates an embodiment for using the biological nervous system for recognition of a desired pattern.

[00131] FIG. 21 shows computer hardware for machine learning.

DETAILED DESCRIPTION

[00132] A system and method for enhancing and modifying complex functions of the body are disclosed herein. In the following description, for the purposes of explanation, numerous specific details are set forth in order to provide a thorough

understanding of example embodiments. It will be evident, however, to one skilled in the art, that an example embodiment may be practiced without all of the disclosed specific details.

[00133] The invention modulates and enhances complex and higher bodily functions by modulating a series of functional domains. Typically, the complex function will include a component of brain or nervous activity. One innovation is the creation of an enciphered (symbolic) representation to model the complex function. Such a representation model may also be called a network, and is learned in this invention. This is created by, then used to interpret sensed signals from functional domains that comprise the function. The enciphered network is then used to effect change. In one preferred embodiment, this is applied to improve sleep apnea, but other embodiments modulate heart failure, obesity, alertness, mood, memory and mental performance or cognition.

[00134] **FIG. 1** illustrates an example system to modify and enhance complex body functions in a human being. Specifically, the example system 100 is configured to access external signals from biological sensors 104 and from external sensors 110.

[00135] The biological sensors 104 can sense biological signals, from an individual, from another individual, or from a database of signals 118. The biological sensors 104 can be wearable.

[00136] External sensors 110 can sense biological signals, from an individual, from another individual or from a database of signals 118. In turn, signals may arise from the central nervous system, peripheral nervous system, cardiovascular system, pulmonary system, gastrointestinal system, genitourinary system, skin or other systems.

[00137] External sensors 110 can provide many types of information including, but not limited to, those normally sensed including pressure/physical movement (tactile, touch sensation), temperature (thermal information, infrared sensing), chemical (galvanic skin resistance, impedance, detection of specific ions from the skin),

sound (auditory sensation), electromagnetic radiation in the visible spectrum (visual sensation), movement (a measure of muscle function and balance).

[00138] External sensors 110 can also provide information related to normal sensation but that is not normally sensed including, but not limited to, the invisible electromagnetic spectrum (such as gamma radiation, X-rays, radiowaves), sound waves outside the normal physiological range for humans (roughly 20 Hz to 20 kHz) but including the range sensed by animals (for instance, dogs can sense higher frequencies).

[00139] External sensors 110 can provide information outside normal sensory modalities including, but not limited to, toxins such as carbon monoxide or excessive carbon dioxide, forms of radiation (such as alpha and beta radiation), biotoxins such as toxins of Escherichia coli bacteria associated with food poisoning (type 0157), anthrax or other agents. Clearly, such information would be of value for military and security applications.

[00140] In FIG. 1, signals are delivered either wirelessly or via connected communication to a signal processing device 114 functioning with a computing device 116 that has access to an analysis database 118. The computing device 116 and signal processing device 114 communicate with a control device 120, which in turn controls a biological device 108 or an external device 112. The biological device 108 is an effector device, which can be wearable by the individual. The computing, signal processing and control devices with sensors and effectors together form an "enciphered functional network" (EFN).

[00141] FIG. 2 illustrates the relationship between sensors, sensed signatures for functional domain(s), the enciphered functional network (with analysis engine) and the effector group(s) within the functional domain for a bodily function. At item 150 one can see the entire functional network domain for a particular bodily function, such as sleep or breathing. At 155 are illustrated sensors 1, 2, ... n that are used to provide sensed signatures 160 for this functional domain. The enciphered functional network 165 for this functional domain controls and analyzes the information from the sensors and sensed signatures Of note, the enciphered network can recruit additional sensors or stored patterns (such as from a database, shown in FIG. 3) depending on its learned

or programmed behaviors. Many forms of analysis can be performed as discussed below. Item 170 shows that the enciphered functional network includes communication with an effector group for that bodily function, which in turn signals effectors 1, 2, ... n at step 175. A key element of the invention is interconnectivity and links between each element within/with the enciphered functional network, indicated by double arrows.

[00142] FIG. 3 gives more detail on the enciphered functional network for a normal bodily function or abnormal bodily functions. The list of bodily functions addressed by this invention are broad, and typically span multiple physiological systems (represented as functional domains). They may include but are not limited to sleep, sleep disordered breathing, cognition, mental performance, response to obesity, response to heart failure.

[00143] In FIG. 3, a body function is represented by nervous system 220 and non-nervous system (non-neural) 260 networks. The networks 220, 260 comprise respective functional domains 230, 270, defined by signatures 240, 280 based on a variety of sensors. This produces nerve and non-nerve signatures for the body function, which can be normal 250 and abnormal 290 – or desired 250 and undesired 290. It should be noted that the networks can interact via interactions 225 and signatures may be inter-related by relationships 245.

[00144] Machine learning algorithms of the enciphered functional network are enabled using artificial intelligence (autobot, fuzzy logic circuits). This can be done via neural networks (e.g., 3 layer back-propagation networks or other designs), techniques of deep learning, heuristics, linear classifiers or other forms of fuzzy logic. An important feature of such systems is that they do not need to know much about the specifics of human pathophysiology, but need to learn information about factors influencing behavior that is provided by the sensed signatures. They are thus well suited to the problem of complex bodily functions that are often incompletely defined or mapped pathophysiologically. This is not structured by theoretical "textbook" classification schemes. Certain elements of the system can be layered as rule-based, using for instance deterministic solutions from a database such as the dermatomal distribution of

a nerve in the shoulder or the fact that some fluctuations in skin oxygenation reflect heart rate.

[00145] Thus, the symbolic model of simple and complex functions is akin to representing something that is visualized by an "impressionist" painter rather than a detailed physiological representation – by one trained in the "realist" school. Again, this approach is based largely on the premise that in addition to the primary physiological systems required for a task, that is difficult to precisely define, secondary networked regions become involved.

[00146] Machine learning nominally links signatures with normal function 250 in order to create a patient specific range to detect abnormal function 290 as outliers. In practice, the best results are obtained when the machine learning algorithms perform repeated pattern classification interactions 255 between sensed signatures for normal 250 and abnormal 290 functions. This interconnectivity is necessary, but its complexity makes the system ideally suited for a computational machine learning paradigm to modify and treat the networks 235.

[00147] In FIG. 3, digital learned representations enable personalized diagnosis and therapy. A database of learned networks (representations) between individuals forms the core of a multimodal digital network of population health and disease, that is actionable – i.e., can be used to monitor and treat disease or improve performance. For health care or screening purposes, this database (component 215) is de-identified, but if individual consent is obtained, e.g., in military or Institutional settings, abnormalities can be traced from or applied to specific individuals to improve their performance in the population. This forms the basis for a novel approach to crowd-sourced health or wellness screening, crowd-sourced disease monitoring, and crowd-sourced delivery of therapy.

[00148] FIG. 4 provides detail of signatures sensed 310 by the invention to represent a given bodily function in an individual person. Body functions comprise multiple functional domains, broadly classed as primarily nervous system related and not nervous system related physiology. Sensed nerve signatures 315 would typically represent the sensing location 320, patterns of activity 325 (e.g., periodic with a certain

frequency spectrum, or more complex and potentially represented non-linearly by fractal dimension or measures of entropy), or rate of firing 330 (e.g., the fundamental or "dominant" frequency of a spectrum or first peak on an autocorrelation function).

[00149] Numerous other nerve-related parameters are possible, e.g., nuclear scans of neuro-tissue function, e.g., MIBG scanning for autonomic ganglia, metabolic quantification using positron emission tomography based sensor information, serum levels of norepinephrine and other nerve-related signatures familiar to one skilled in the art.

[00150] Non-nerve signatures 335 represent other modalities 340 that are not primarily in the nervous system. Represented modalities have one or more defined signatures, e.g., hypervolemia is detectable by reduced electrical impedance of tissue, sympathetic activation via "clammy skin" – reduced galvanic skin resistance and altered ionic composition, apnea via reduced oxygenation measurable as reduced skin absorption in the near-infrared end of the electromagnetic spectrum. These signatures also possess information on location 345, rate 350 and temporal patterns over time 355. Numerous other parameters are currently possible and may develop over time and be incorporated into this invention, e.g., tissue concentrations of neurohormones such as B-type natriuretic peptide or prolactin from a pharmacological sensor, signal intensity from a photodetector to detect drug concentrations in skin or cutaneous blood vessels, drug or alcohol levels in exhaled breath from an oropharyngeal sensor, drug or alcohol levels in urine from a penile sensor, and other sensors relevant to the functional domain under consideration.

[00151] The network of sensed signatures exemplified in FIG. 4 becomes the measured representation of that bodily function for an individual person. This is a form of "digital phenotype" of components of the bodily function. It is recognized that nervous and non-nervous physiological elements are deeply integrated biologically, but this formulation is a convenient approach to parameterize complex physiology into tracks that can be measured, mathematically modeled and learned. Other more integrated formulations are possible.

[00152] Note that not all possible measured signatures are needed for the invention to work – in simple clinical practice, heart failure can be monitored quite well from the simple measure of weight gain alone; this invention uses machine learning to mathematically weight the most important signature but also to use information from whatever is currently available.

[00153] FIG. 5 illustrates modification of the bodily function using the enciphered network, tailored to sensed signatures. Modifications include therapy, such as for sleep-disordered breathing, but can also include enhancement of normal function for that individual. Modification through the enciphered network operates via a feedback loop, in which response is measured to prevent excessive or deleterious modification. Nerve-related domains can be modified by direct energy delivery 400 to stimulate or suppress a domain. For instance, counterstimulation of skin on the abdominal wall (e.g., by vibration via a piezoelectric device, heat via an infrared generator) may suppress the sensation of pain from organs supplied by visceral nerves of lumbosacral origin (lower back). Domains 410 may thus lie in the peripheral nervous or in the central nervous system 420, such as scalp stimulation to modify cranial nerves or light delivery to modulate the ophthalmic nerve or (indirectly) pineal gland activity. In this way, the bodily function can be treated, enhanced or otherwise altered 430. Non-nerve domains can be modified 440 in many ways including vibratory stimulation via a piezoelectric device to stimulate a muscle, infrared heat to reduce muscle spasm to modulate the domain 450 and network 460 to modify the bodily function 430. Notably, modification is individually tailored via personalized sensory signatures and the enciphered network.

[00154] Modulation of nerve-related domains 410 can be linked to modulation of non-nervous domains by modulation connection 415. Moreover, the central and peripheral nervous network 420 can be linked to the non-nervous system physiologic network by network connection 425.

[00155] FIG. 6 indicates several potential body 500 locations for sensing signatures and modifying different functional domains. Bodily functions can be measured by sensor 505 and/or modified by effector 510 sites. Sensor locations are shown by open (white) regions, and effector (modifying) locations by filled (black) regions. Their relative size varies in each individual and is not shown to scale. FIG. 6

indicates sensor locations on the body 500 to detect signatures of the nervous 535, cardiovascular 540, pulmonary 540, gastrointestinal 545, genitourinary 550, skin 550 and other domains. Body functions measured and/or modified by the enciphered functional network include sleep and central sleep apnea 515, cognitive performance 520 such as alertness, obstructive sleep apnea 525, and the bodily response to obesity 530. A variety of signatures are indicated by way of example and not to limit the scope of the invention. These are discussed in more detail with regards to other figures in this disclosure.

[00156] FIG. 7 illustrates an example of a body sensor 600, comprising sensor element 605, power source 610, processing components 615, nonvolatile storage 620 (e.g., E2PROM, powered RAM), communication element 625 on a structural platform 630. Several types of sensor elements are illustrated Biological sensors include, but are not limited to, photosensitive sensors 640 to detect skin reflectance (indicating oxygenated hemoglobin, and perfusion), galvanometers 650 to detect skin impedance or conductance (a measure of body chemistry), transcutaneous or invasive nerve activity (neural electrical activity) or muscle electrical activity (myopotentials), pressure detectors 660 (to detect pressure, e.g., weight, mechanical joint movement or position), thermal detectors 670 to detect temperature (a measure of metabolic activity and other disease states), and chemical detectors 680 to perform assays for norepinephrine or drugs, body pH from the skin, mouth, or elsewhere in the gastro-intestinal or genitourinary tracts, enzymatic profile in the gastrointestinal tract, DNA profile (for instance, a gene chip on the lining of the mouth), and other sensors such as for heart rate, ventilation (breathing).

[00157] The invention can also use external sensors (Figs. 1, 12-18) that provide a variety of extrinsic or artificial signatures (Figs. 12-18) to provide cybernetic sensor inputs or effectors to the enciphered functional network.

[00158] FIG. 8 indicates an example embodiment of sensed signatures in sleep-breathing disorders. As typical for many bodily functions, sleep-disordered breathing impacts multiple nervous and non-nervous system domains. While all domains can be sensed, not all domains need to be sensed in every patient, and the actual sensed domains (and hence sensors) can be tailored to signatures in a given individual and

practical considerations. As seen in FIG. 8, sensor types can include but are not limited to skin impedance, other electrical sensors (nerve firing in the periphery and on the scalp, and heart rate), temperature, chemical sensors, optical sensors of skin color (that can detect oxygen saturation of peripheral blood), motion sensors and pressure sensors.

[00159] FIG. 9 indicates example embodiments for various effector or treatment options for sleep-disordered breathing using the enciphered functional network. These are provided by way of example and in no way limit the scope of effectors and treatment options that can be provided for this condition or other bodily functions. The body 800 is interfaced with effector devices 810, tailored to each modality. For sleep apnea 820 of the central type, examples include direct stimulation of breathing centers including the brain (via low energy scalp stimulation), accessory muscles in the neck and the diaphragm. For obstructive sleep apnea, examples include direct stimulation of pharyngeal and neck muscles to maintain tone and prevent obstruction. For central sleep apnea, the invention can activate pro-breathing centers, tricking the brain to breathe more by stimulating sensors of low oxygenation/high carboxyhemoglobin in the finger, by providing CO2 or equivalent index of low breathing to regions of the periphery that are not harmful. For central and obstructive forms of sleep apnea, there is evidence that chest edema accumulates and can be measured as increased rostral-to-peripheral ratio of skin impedance (FIG. 7). Accordingly, controlled negative pressure in the lower extremities 840 can reverse this rostral fluid accumulation. Direct stimulation of pro-sleep centers by other methods 850 include stimulating the pineal gland through light exposure of the appropriate wavelength in the visible and infrared spectra. Light can be provided in patterns that are specific to each individual. Other pro-sleep sensors include activation of vibratory sensors 860 to mimic the somnorific impact of massage, or stimulation of post-prandial satiety sensors 870 including stimulating peripheral skin sensors of hyperglycemia. Other specific stimuli can also be provided as familiar to one skilled in the art of sleep disorders, and can be added to the infrastructure of the invention as new modalities and sensed signatures are developed.

[00160] FIG. 10 indicates an example embodiment of sensed signatures in response to heart failure. As typical for many bodily functions, heart failure impacts multiple nervous and non-nervous system domains. While all domains can be sensed,

not all domains need to be sensed in every patient, and the actual sensed domains (and hence sensors) can be tailored to signatures in a given individual and practical considerations. As seen in FIG. 10, sensor types can include but are not limited to skin impedance, other electrical sensors (nerve firing in the periphery and on the scalp, and heart rate), temperature, chemical sensors, optical sensors of skin color (that can detect oxygen saturation of peripheral blood), motion sensors and pressure sensors.

[00161] FIG. 11 indicates an example embodiment of sensed signatures in response to obesity. As typical for many bodily functions, obesity impacts multiple nervous and non-nervous system domains. While all domains can be sensed, not all domains need to be sensed in every patient, and the actual sensed domains (and hence sensors) can be tailored to signatures in a given individual and practical considerations. As seen in FIG. 11, sensor types can include but are not limited to skin impedance, other electrical sensors (nerve firing in the periphery and on the scalp, and heart rate), temperature, chemical sensors, optical sensors of skin color (that can detect oxygen saturation of peripheral blood), motion sensors and pressure sensors.

[00162] FIG. 12 shows an example of sensed signatures for other conditions. One example is for chronic obstructive pulmonary disease which, as typical for many bodily functions, impacts multiple nervous and non-nervous system domains. While all domains can be sensed, not all domains need to be sensed in every individual. The actual sensed domains (and hence sensors) can be tailored to signatures in a given individual and practical considerations. As seen in FIG. 12, sensor types can include but are not limited to skin impedance, other electrical sensors (nerve firing in the periphery and on the scalp, and heart rate), temperature, chemical sensors, optical sensors of skin color (that can detect oxygen saturation of peripheral blood), motion sensors and pressure sensors.

[00163] FIG. 13 summarizes the invention, a computerized representation of a complex body function, paired to biological and artificial (cybernetic) sensors, and biological and artificial (cybernetic) effectors. The enciphered functional network is trained by machine learning algorithms for specific bodily functions. In the simplest case, sensed and effector functions are natural physiological functions, such as sensing a painful stimulus from the leg and moving the leg away. In more complex embodiments,

the invention has the ability to enhance normal function (performance enhancement), enhance impaired function (e.g., sleep-disordered breathing) or treat a disease or in cases where normal function cannot be manifest (e.g., in warfare or other situations of constraint).

[00164] More specifically, FIG. 13 outlines an enciphered network for sleep-disordered breathing. The left panel shows the actual physiology measured for sleep disordered breathing, while the right panel shows the computerized representation of the enciphered functional network.

[00165] In measuring the actual physiology of sleep-disordered breathing in an individual 1200, biological signals are sensed 1205. These include biological signals of control regions 1210 including activation of the amydala and other parts of the limbic system that control alertness, wakefulness and relate to sleep. These signals have scalp representations that can be detected by skin nerve sensors, but can also be detected by medical devices such as the BOLD signal from functional magnetic resonance imaging, or metabolic images from positron emission tomography in medical applications. Physiologically, sleep is also triggered from intrinsic but natural signals such as darkness, sound (e.g., soothing music or the sound of waves), tactile sense (e.g., massage of parts of the body). The intrinsic sleep control regions of the brain 1210 then integrate these inputs with sensors related to breathing including low oxygenation, measureable in the fingertips 1225, that stimulates breathing, and stimulation of the diaphragm 1220 to enable ventilation of the lungs.

[00166] The schematic shown in the left panel of FIG. 13 is of course a simplified view of sleep-related-breathing, but it illustrates how a series of sensors and effectors are integrated by the biological control regions. Other sensors and effectors can be involved at other times, and can be measured in connection with the sleep-related breathing. This is a strength of the invention, that additional sensed signals can be added and will be adaptively integrated by the enciphered network.

[00167] In the right panel of FIG. 13, the parallel enciphered network for sleep-disordered breathing also has sensors, control logic and effectors, but these are a combination of biological and engineered (artificial) components. Sensors can detect

intrinsic signals 1240 (such as oxygen saturation) or extrinsic signals 1245 (such as the presence, intensity and patterns of visible light). A sensor matrix 1250 then combines these biological and non-biological signals either separately or by multiplexing them, e.g., using a weighted function. The computational logic 1255 is the central processor of the enciphered functional network.

[00168] The computational element 1255 forms a symbolic relationship between sensed signals and biological function (e.g., elements 250-290 in FIG. 1). It is linked to a database 1260 to store multiple states for this individual person as training datasets for machine learning (i.e., fuzzy logic, artificial intelligence) in order to learn normal sleep patterns and breathing from disordered ones (elements 250 versus 290 in FIG. 2). This is then mapped to effectors 1265 that can be biological, such as brain regions (related to control regions 1210 and unrelated to control regions 1210) as well as muscles (the diaphragm 1220 as well as other muscles that are less notable but also involved in sleep such as the *levator labii superioris alaeque nasi* muscles). Effectors can also be cybernetic 1275, in that they interface artificially engineered devices with the body. For instance, a peripheral low oxygen state can be mimicked by small wearable chambers ("treatment gloves") surrounding one or more fingers that will stimulate breathing from intrinsic sleep-brain control centers (control regions 1210). Similarly, appropriate learned patterns of light or of vibratory stimuli can be applied using appropriate devices, to stimulate sleep-breathing patterns learned from normal states and stored on the database 1260.

[00169] The symbolic relationship of the enciphered network in FIG. 13 is a mathematical relationship. This relationship is empirical and functional that uses machine learned relationships between sensed signatures and body function in each individual – and not on detailed neurophysiological mapping. It is thus distinct and may not be concordant with "classical" neurophysiology. For instance, sufficient pain in the leg causes elevated nerve activity in other parts of the body. This will produce "associated with leg pain" signals in sensors located more conveniently in the body. The empirical functional relationship is mathematical, and can be deterministic (e.g., equation based), or can be trained/learned such as via neural network.

[00170] In the simplest case, the enciphered symbolic relationship is a matrix in which a signal X causes a function Y; for instance, a noxious stimulus such as pain sensed by a sensor/sensory nerve in the leg (X) causes activity in a motor nerve causing withdrawal of that leg (Y). This function is not represented in the device based upon a detailed neurophysiological representation of leg sensation (in the primary somatosensory cortex, in the post-central gyrus), or the precise nerves that control the leg. Instead, this function is mapped empirically – sensation on any nerve associated with the painful stimulus can result in actions leading to leg withdrawal.

[00171] The advantage of this approach is that it can analyze the multiple effects of a particular stimulus. For instance, an acute painful stimulus often produces activation on nerves remote from the original site of stimulation. Hence, pain in the leg, that may be inaccessible, may be detected from nerve activity quite distant from the sensation such as the chest wall, that may be more accessible.

[00172] In FIG. 13, generalizing from the example for sleep-breathing, sensing is processed and results in output to an effector. For instance, the sensed noxious stimulus can produce an effector function to move the leg, or control a device to administer a pain killing medication or therapy. In other examples that will be discussed below, the stimulus can move a prosthetic limb or alter biological function.

[00173] Moreover, FIG. 13 shows that the enciphered network determines precise action by defining interactions with the device or bodily function. This is a programmed function, depending upon the desired functionality of the invention. This then produces a real output requiring application of energy that results in interaction with the device or a bodily function.

[00174] FIG. 14 illustrates a preferred mode of action of the invention to provide computational enhancement of the bodily function via the enciphered functional network. The flowchart for the invention senses signatures for a given bodily function 1305, comprising biological signals (e.g., breathing rate, finger oxygenation) or extrinsic signals (e.g., tissue impedance indicating volume load, emitted infrared indicating temperature, or carbon dioxide concentrations in exhaled air indicating the efficiency of breathing).

[00175] Item 1310 applies the symbolic model of the enciphered network, as identified in FIG. 8 to map sensed signals to a bodily function based on practical measurable signatures rather than classical, detailed physiology mapping that may be ill-defined, rapidly changing and inaccessible to measurement.

[00176] As described above, the symbolic model uses machine learning to map sensor input to normal and abnormal function of that bodily functionality. This comprises training sets of different patterns for that individual, that are both personalized and continuously adaptive.

[00177] In FIG. 14, step 1315 transforms an effector (motor) function, i.e., controlled by an existing motor nerve. In step 1320, the motor nerve signal is "re-routed" to control a prosthetic device or another muscle group. For instance, in the case of an amputee, the signature of motor nerve output to the leg may be detected from the skin above the amputation site. The range of sensed nerve activity on the skin may typically be 7-15 Hz (depending on the precise nerve). Sensing these signals, and mapping them to specific movement of a prosthetic limb may enable control of the limb. This control may require subsequent training – for instance, behavioral training in which the individual attempts to flex the amputated limb, and detecting the skin signals as those that will flex the prosthetic limb *in that person*. Similar personalized mapping is used to train other motions of the prosthesis. In this instance, the invention is one embodiment of a personalized "enciphered nervous system".

[00178] In FIG. 14, step 1325 is another embodiment – to enhance performance of this body function. Instead of expending the energy required to move a finger, the enciphered network can sense sub-threshold activity of the motor nerve and "boost" the signal to move the finger 1325. This is useful for individuals with nerve degeneration, those with musculoskeletal disorders or those under some form of sedation who would normally not be able to communicate via this finger.

[00179] Furthermore, the invention can 1325 artificially generate signals needed to stimulate the muscle. Since the frequency and amplitude of nerve activity that controls a muscle lies within a range for each individual, the enciphered network can simulate the nerve activity controlling the quadriceps femoris muscle and deliver it

programmatically to regions of the skin associated with contraction and relaxation of that muscle for that individual (part of the functional domain). This can be used when the nerve is degenerated or anesthetized (for instance, to prevent pressure ulcers in patients on prolonged ventilation). It can also be used for performance enhancement – for instance, to perform isometric exercises during rest or sleep to prevent or reverse muscle atrophy, or to improve muscle function or increase metabolic rate to lose weight.

[00180] In FIG. 14, step 1330 is another embodiment of the invention – to retask biological motor activity. In this case, it is directed to control an artificial device. This cybernetic application is further developed in FIG. 14. In FIG. 13, instead of actually moving a finger to control a remote control unit for an electronic device, nerve activity below the threshold of actually moving that finger will control the device. This enables functionality without expending as much biological energy, and also in individuals who have lost biological function or are constrained and unable to perform that motor function (e.g., in a military situation). Sensors on the finger detect this subthreshold motor nerve activity (e.g., of lower amplitude than biologically required to move the finger), and the enciphered network converts this to signals that represent play, pause, rewind or other functions and transmits them to control the remote control unit. This may be for a consumer device. Clearly, this function can be extended to training an individual to move a portion of the face to represent the "play" function, and having a sensor transduce this function, and similarly for other surrogate regions of the body and retasked functions.

[00181] In FIG. 14, step 1335 is a distinct embodiment that transforms sensed signals. Step 1340 retasks the sensed signal. For instance, sensation of a specific smell that is trained over time, can elicit a different response or control a device. Step 1345 improves performance, augmenting biological outside of normally sensed ranges. For instance, sensing signals in the "inaudible to humans" frequency range, transducing the signal to the audible range, and transmitting it via vibration (bony conduction) to auditory regions of the brain (auditory cortex) could be used for private communication, encryption, recreation or other purposes. Medically, this invention could be used to treat hearing loss. This same invention with sensors of vibration could

be used to compensate for loss of this sensation in diseases such as peripheral neuropathy, by transmitting this sensation to an intact sensation in a nearby or remote part of the body.

[00182] Another embodiment of performance improvement (step 1345) is to increase alertness. Stimulation of the scalp in the temporal region and other function-specific zones can increase brain activity in these regions. The invention tailors stimulation to the enciphered representation of awakeness (i.e., alertness). As a corollary, drowsiness can be detected by the enciphered network and used in a feedback loop to trigger low intensity stimulation by a cutaneous device elsewhere on the body. This has several applications, including detecting and trying to prevent drowsiness while driving, in the intensive care unit during pre-comatose states or during drug-overdoses, as a monitor for excessive alcohol or medication ingestion, or during excessive fatigue states, e.g., in the military.

[00183] Sensors can detect alertness versus drowsiness from large groups of neurons using electroencephalography (EEG) over a wide range of frequencies. EEG signals have a broad spectral content but exhibit specific oscillatory frequencies. The alpha activity band (8–13 Hz) can be detected from the occipital lobe (or from electrodes placed over the occipital region of the scalp) during relaxed wakefulness and increase when the eyes close. The delta band is 1–4 Hz, theta from 4–8 Hz, beta from 13–30 Hz and gamma from 30–70 Hz. Faster EEG frequencies are linked to thought (cognitive processing) and alertness, and EEG signals slow during sleep and during drowsiness states such as coma and intoxication.

[00184] In FIG. 14, step 1350 is a function detecting and/or forming a *de novo* function. One example is creating a cybernetic "sixth sense" – that is, adding to the 5 biological senses using artificial sensors to detect an extended set of stimuli. The set of sensors is nearly infinite, but includes several of particular relevance to the field of industrial or military use, including sensors for alpha or beta-radiation. Once sensed, the enciphered network can transduce this signal to an existing sense, such as vibration delivered through a skin patch to a relatively unused skin region, e.g., lower back. A combat soldier exposed to alpha or beta particles will now "feel" radiation as a programmable/trainable set of vibrations in his lower back. Similarly, sensors for

carbon monoxide or other respiratory hazards could be transduced as "sixth senses" into – for instance – low frequency vibration on the nostril. This approach is far more efficient than a visual readout or other existing devices – because they use the enciphered network to essentially reprogram the natural nervous system for these functions.

[00185] FIG. 15 generalizes cybernetic enhancement of body function using the enciphered network. This is a further application beyond the use of intrinsic biological signals. One application is to apply purposeful interventions when natural body functions are constrained, e.g., a soldier can use a finger to activate a device if his/her foot cannot activate a pedal due to an obstacle, or, in an amputee, interfacing a robotic arm to specific nerve fibers that formerly controlled the biological arm.

[00186] FIG. 15 is an embodiment in which intrinsic biological signals and extrinsic non-biological signals are sensed (step 1400). The enciphered network does not simply map learned function to sensed signals, but instead extrapolates from learned functions to create novel function 1410. The enciphered representation of the body function to sensed signals is extended to a personalized network in step 1420 via machine learning. This involves a series of steps, including 1430 multiplexing or otherwise combining intrinsic with extrinsic signals, to programmatically modify external signals in a personalized fashion. Signal multiplexing is performed to achieve the desired function 1440 that may be storage of non biological information (e.g., word processing documents, images) in the patient's brain, i.e., using biological storage as digital memory, and so on. Signals can be combined based on data from this person alone, from a database of multiple individuals (e.g., item 1260 in FIG. 12), or by a technique such as crowd-sourcing in which information from multiple persons is integrated to train the enciphered network. Data from multiple persons could be combined in a formal database, or by applying machine learnng to the wider set of sensed signals and biological outputs between individuals (not just for one individual).

[00187] Step 1450 in FIG. 15 shows the effector layer, the interface between the output of the enciphered network for a designed cybernetic function and a series of biological (e.g., motor nerve, muscle) or external (e.g., prosthetic limb, computer) effector devices.

[00188] Several embodiments exist. In step 1460, the invention uses a biological signal to control an external device (e.g., motor nerve control of a prosthetic limb), or an external signal to control a biological function (e.g., external signal stimulation of a skeletal muscle). As described, skeletal muscle is typically stimulated by nerve activity at a frequency of 7-15 Hz (varying with precise nerve distribution, see Dorfman et al. Electroencephalography and Clinical Neurophysiology, 1989; 73: 215-224). Such external stimulation can improve muscle strength by stimulating it, and would enable performance improvement of, e.g., programmable improvement in leg muscle function. Another example is to treat central sleep apnea, using an external sensor of oxygen desaturation ("desat") to activate a device that stimulates the phrenic nerve and hence the diaphragm. This may have substantial clinical implications.

[00189] FIG. 15 step 1470 shows an embodiment in which the invention replaces a biologically lost or unavailable function in that individual with function from the enciphered network. This is an extension of boosting performance in FIG. 14 (step 1325). For instance, the unavailable function of hearing outside the normal 20 Hz to 20 KHz range can be provided using external sensors and the signal transduced to the audible frequency range (e.g., vibrations delivered via bone conduction to the inner ear using a device placed near the mastoid processes, e.g., attached to the side-arms of eyeglasses) or to another sensible modality (e.g., vibration on the arm). In an individual with hearing loss, the sensed signal will lie within the normal but compromised auditory range for this individual.

[00190] In FIG. 15 step 1480, the invention enables biological control of a computer. An example of this function is to provide an intelligent control framework for an infusion pump. For instance, glucose control is not determined simply by the reaction of the pancreas and other sensing regions to plasma glucose. Instead, higher brain centers that control activities of daily living anticipate actions such as imminent exercise or stress, and produce increased heart rate and a hormonal surge (e.g., adrenaline, epinephrine) that in turn increases blood glucose. Current glucose infusion pumps actually cannot mimic such higher cognitive input, and instead wait for drops in glucose from metabolic demands before infusing glucose. Such devices will always lag behind ideal physiological control and will produce suboptimal performance.

[00191] In FIG. 15 step 1490, the invention can provide *de novo* functionality. This exploits the full potential of the enciphered functional network, in this case for the nervous system, and extends beyond sensory or motor performance improvement in steps 1325 (motor) or 1345 (sensory).

[00192] In FIG.15 step 1490, novel functionality can be provided for motor function (i.e., previously unavailable movements) or sensory function (i.e., a cybernetic 6th sense). A large proportion of cerebral processing power is dormant at any given time, but may be activated subconsciously during daily activity (e.g., daydreaming). The enciphered network can access some of this brain capacity to use the biological nervous system as a computer. One task for which the human brain/nervous system is particularly adept is pattern recognition. Recognition of faces, spatial patterns and other complex datasets is performed by people far better than by artificial computers. The selected example trains the individual to detect the pattern via repeated overt or subclinical exposure to an image. The biological response to this image (symbolic representation) is detected by sensors on the temporal or frontal scalp. Again, this is empirical – the primary memory encoding regions do not have to be identified or mapped, and it is sufficient to sense a secondarily activated region of the brain/scalp. Once this is accomplished, detection of the pattern or a similar pattern will subconsciously trigger the response that can be sensed and coded as a "1" or "0" to control a device (e.g., a pattern classifier computer) or cause a certain function – such as to trigger an alarm if this is a dangerous pattern/image.

[00193] FIG. 16 illustrates an embodiment of motor function controlled by the enciphered network. The Flowchart in FIG. 16 provides a preferred embodiment to transform leg movement. A symbolic model is to link motor nerve function, sensed at a signature of the primary motor region (scalp, near the superior portion of the contralateral precentral gyrus) or a secondary region, with a plurality of leg motions in step 1510. Once done, functional mapping can be reprogrammed using external sensed signals (step 1515) including those not normally associated with leg function. An example would be for motion in an index finger to control the leg movement, in patients with leg disease or soldiers who cannot move their leg in a certain task. Functional mapping can also use the existing signal (step 1520).

[00194] In step 1525, a signal multiplexor links the intrinsic or extrinsic signals in order to control the desired programmed function. In step 1530, this is achieved to enhance biological leg function (e.g., via cutaneous/direct electrical stimulation as described). In step 1535, this is performed to control a prosthetic limb.

[00195] FIG. 17 shows an embodiment of enhancing sensory function via the enciphered network. FIG. 17 is an embodiment for enhancing alertness. A symbolic model is created in step 1610 using a signature of sensed scalp nerve activity, e.g., from the temporal region that is empirically associated with alertness. Functional mapping is reprogrammed using intrinsic sensed signatures (step 1615) or signals not normally associated with alertness (e.g., a specific auditory sensed frequency), or the existing scalp signal (step 1620). In step 1625, a multiplexor links the intrinsic and extrinsic signals with an effector to achieve the desired function – electrical stimulation of the scalp to increase alertness (step 1630). Step 1635 provides an alertness monitor to alarm or produce the desired function, and that can detect and try to avoid drowsiness or coma, such as during driving, on the battlefield or from toxin ingestion.

[00196] FIG. 18 depicts an embodiment of the invention to transform sensory function. FIG. 18 is a flowchart of an embodiment to enhance sensory performance – in this case hearing. Step 1710 is the symbolic representation of sensed signals from a readily accessible sensor of the signature near the ear, as well as secondarily associated skin regions. Step 1715 uses sensors to detect signatures of frequencies outside the normally sensed frequency spectrum. Step 1720 uses a signal normally associated with hearing. Step 1725 uses a multiplexor and control logic to transduce the signal to the audible range (step 1730), transmitted via vibration (bony conduction) to the hearing regions of the brain (cochlear nerve/auditory cortex) using a device that could be used for private communication, encryption, recreational or other purposes. Medically, this invention has application as a sophisticated hearing aid. This same invention with vibration sensors compensates for loss of this sensation in diseases such as peripheral neuropathy, by transmitting this sensation to an intact sensation in a different part of the body. At 1735, the multiplexor transduces this signal to a different "surrogate" sensation, e.g., skin stimulation.

[00197] FIG. 19 shows an embodiment to create novel "cybernetic" sensory functions. FIG. 19 is a flowchart of an embodiment to create a cybernetic "sixth sense" (e.g., sensing a biotoxin). The invention summarized in FIG. 19 incorporates information associated with the example of sensing carbon monoxide. Specific sensed signals cause damage, to calibrate sensing and delivery of therapy functions. For instance, exposure to carbon monoxide is dangerous, yet this toxin is often undetected. Federal agencies in the U.S. such as OSHA put a highest limit on long-term workplace exposure levels of 50 ppm, with a "ceiling" of 100 ppm. Exposures of 800 ppm (0.08%) lead to dizziness, nausea, and convulsions within 45 min, with the individual becoming insensible within 2 hours. Clearly, an invention to detect this toxin early and cause biofeedback through the enciphered nervous system may have extremely practical implications in industrial environments. Other nomograms can be developed to identify thresholds for "safe" versus "actionable" exposure to various stimuli including but not limited to chemicals, biological toxins, radiation, electrical stimuli, visual stimuli and auditory stimuli.

[00198] The invention summarized in FIG. 19 can also be used to create novel human functionality, by using the enciphered network to pair sensed biological or external signals to any programmed biological or external device. It thus forms an embodiment of a cybernetic nervous system operating in parallel with the body's natural nervous system. The extent to which these nervous systems are parallel or integrated will depend upon the extent to which sensed signals are multiplexed and effector "control" signals are combined. Examples are discussed below.

[00199] The invention outlined in FIG. 19 thus provides hitherto unavailable programmatic control of plasticity – that is, actually observed at some level on a regular basis in normal life. In the realm of sensory physiology, training can enable an individual to perceive a sensation that was previously present but not registered/recognized. Examples include musical training to detect tonality, or combat training to detect subtle sounds or visual cues. In the realm of motor control, physical training can enable an individual to use muscle groups that were previously unused. In the realm of disease, normal "healing functions" cause undiseased regions of the central nervous system to take over functions now lost due to a stroke (cortical plasticity), or

unaffected peripheral nerves to take over functions of a nerve lost due to trauma or neuropathy (expansion/plasticity of peripheral dermatomes).

[00200] The current invention extends known interventions based upon cortical plasticity. For instance, it is known that the dermatomal distribution of a functioning peripheral nerve expands when an adjacent distribution is served by a diseased nerve. In other words, the same function can now be served by different regions of the central or peripheral nervous system.

[00201] The invention also substantially extends normal plasticity – by programming desired and directed regions of the body to sense and effect functions normally reserved for other regions of the body that are currently inaccessible (e.g., in military combat) or unavailable (e.g., due to disease).

[00202] The invention also substantially advances normal plasticity by integrating external sensors (e.g., for normally inaudible sound frequencies or sensations) or devices (e.g., prosthetic limbs, other electronic devices) into the ENS.

[00203] FIG. 19 may also include embodiments for enhancing sensory alertness. The steps are analogous to the prior examples. The symbolic model of scalp sensed nerve activity, e.g., in the temporal region is empirically associated with varying alertness levels (self-reported or monitored) in step 1710. This functional mapping is reprogrammed using external sensed signals (step 1715) or signals not normally associated with alertness (e.g., a specific auditory sensed frequency), or the existing scalp signal (step 1720). In step 1725 a signal multiplexor mathematically associates the non-associated or associated signals to program the desired function – electrical stimulation of the scalp to increase alertness (step 1730). Step 1735 provides an alertness monitor that can provide an alarm or actually result in stimulated function (to close the artificial/cybernetic feedback loop in the enciphered nervous system) to detect and try to avoid drowsiness, coma or toxin ingestion.

[00204] FIG. 19 depicts an embodiment to use the ENS to integrate functionality that does not exist in nature into a personalized biofeedback loop – in this case, detecting a toxin. Examples include inhalation of carbon monoxide, a toxic gas that is

colorless, odorless, tasteless, and initially non-irritating, that is very difficult for people to detect. Another example is exposure to a biotoxin, that may not be sensed until symptoms and signs of a disease occur hours, days weeks later. The inventive approach to provide a "sixth sense" (step 1800) is cybernetic, since the toxin may produce both a direct signal from a specific sensor (detected at step 1820) and an associated biological signal (step 1830), that are blended (or multiplexed) in the invention. Examples of a direct signal from a dedicated sensor (element 1810) are the chemical detection of carbon monoxide, or a biological assay for an infective agent (viruses, bacteria, fungi). Ideally, this sensor operates in near-real time, although this is not a requirement and if not the case will simply provide a slower, non-real time signal. Examples of an associated biological signal to carbon monoxide – a toxin that is traditionally considered "unsensed" –is the specific cherry red colorimetric change of hemoglobin from carbon monoxide and the non-specific reduction in oxygenated hemoglobin that results when carbon monoxide binds to oxygen binding sites.

[00205] FIG. 19 further depicts that the enciphered nervous system of the invention forms an associative symbolic representation (step 1820) between the direct and associated biological sensed signals. The symbolic relationship may include a direct mathematical transform, such as a quantitive relationship of the sensed signal to carbon monoxide or the associated biological signal of cherry red discoloration of hemoglobin to biologically relevant concentrations. The symbolic relationship may also use an artificial neural network or other pattern-learning or relational approaches to link, e.g., elevated heart rate or oxygen desaturation to the toxin.

[00206] In FIG. 19 step 1840, signals are multiplexed in a non-linear analytical fashion, as defined in the symbolic representation for any specific toxin. Computer logic is then used to control a biological or artificial effector device. Several therapy or monitor functions can be programmed to close a biofeedback loop. For instance, the signal from the normally unsensed toxin can be transduced into a specific signal on a naturally sensed "channel" (step 1860), e.g., low intensity vibration on skin on the nostril (intuitively linked with inhalation), or stimulation of skin over a scalp region normally associated with deoxygenation. This latter biofeedback uses information from training related to the individual person (contributing to the personalized enciphered

nervous system), or a database of symbolic representations from many individuals associating related stimuli (here, de-oxygenation) to biological signals. This is an example of a population-based, or potentially crowd-sourced enciphered nervous system. Another biofeedback option is therapeutic (1860) – delivery of an antidote, by sending control signals to a device. For carbon monoxide exposure, therapy includes increasing oxygen concentrations (using hyperbaric oxygen in extreme cases) and administering methylene blue.

[00207] Nomograms of the detrimental impact of sensed signals are used to calibrate sensing and delivery of therapy functions from the enciphered nervous system. For carbon monoxide, exposures at 100 ppm (0.01%) or greater can be dangerous to human health. Accordingly, in the United States, Federal agencies such as OSHA put a highest limit on long-term workplace exposure levels of 50 ppm, but individuals should not be exposed to an upper limit ("ceiling") of 100 ppm. Exposures of 800 ppm (0.08%) lead to dizziness, nausea, and convulsions within 45 min, with the individual becoming insensible within 2 hours. Clearly, detecting this toxin early would have extremely practical implications in industrial environments, for instance. Other nomograms can be developed to identify thresholds for "safe" versus "actionable" exposure to various stimuli including but not limited to chemicals, biological toxins, radiation, electrical stimuli, visual stimuli and auditory stimuli.

[00208] FIG. 20 provides another embodiment using the enciphered network to access to the processing power of the natural nervous system to perform an arbitrary task, such as pattern recognition (step 1905). This embodiment of the invention is based upon 3 concepts. First, that the brain is more efficient at some tasks than even the most powerful and well-programmed artificial electronic computers. Pattern recognition, e.g., facial recognition, is an excellent example that is easily accomplished by most people yet that is suboptimal by computers even with very sophisticated programming. Second, that the brain output from a presented stimulation can be sensed. Third, that the brain has unused capacity that can be accessed for this purpose. For instance, for neural processing, only a minority is used even in highly stressful human activities such as warrior combat (e.g., 40% capacity used). In highly focused, non-life-or-death situations, a minority is still used, likely 20-40%, e.g., NBA finals, SAT

testing. Therefore, there is substantial residual capacity at any one time. This third item also presents safety limits, however, and in the case of pattern recognition, the invention must not be used for bioencoding images or data that would be emotionally harmful or sensitive.

[00209] Steps 1910 and 1915 link the pattern (e.g., a face) to the biological sensed response – for instance, activity of nerves in the scalp over the parietal lobes of the brain, or over the forehead indicating "recognition". This is used to create the elements of enciphered nervous system for this task (step 1920). This will be personalized, but can also take inputs from a multi-person (population, crowd-sourced) encyphered nervous system. Once this link has been made, then presentation of the pattern will result in a "sensed" biological pattern, which is used by the multiplexer or control logic in step 1925 to deliver a "1" (recognized) or "0" (not recognized) to control a device (step 1930) (e.g., external computer classifier) or stimulate the individual via a surrogate sensation (step 1935) (e.g., vibration at the left upper arm if a recognized pattern is detected). Uses for this invention include pure biocomputing (pattern recognition of familiar or abstract shapes/codes), formally encoding and enhancing memory of faces for a particular person, and security such that only a hostile pattern/face elicits a specific surrogate sensation or activates a device. One other advantage of this approach over waiting for a cognitive recognition of the pattern is that this can function as a "background process" and/or provide faster pattern recognition.

[00210] Thus, this invention can improve and enhance function of traditional senses, if a device is used that integrates sensors that sense outside the normal physiological range can be used to enhance the range of normal physiological sensation. For instance, sensing signals in the "inaudible to humans" part of the frequency spectrum, transducing the signal to the audible range, and transmitting it via bony conduction using a device could be used for private communication, encryption, recreational or other purposes. Medically, this invention could be used to compensate for hearing loss. This same invention with sensors of vibration could be used to compensate for loss of this sensation in certain neurological diseases such as peripheral neuropathy, by transmitting this sensation to an intact sensation in a different part of the body.

[00211] Important safety issues must be raised at this stage. While no untoward, dangerous or otherwise undesired functionality has been observed with this invention, certain limits must be imposed. First, no stimulation intensity provided by the device can reach painful or dangerous levels. Second, no sensory input can be allowed to reach disturbing or undesired levels. Third, any sensor or device (effector) should have acceptable and tested safety profiles.

[00212] **FIG. 21** is a block diagram of an illustrative embodiment of a general computer system 2000. The computer system 2000 can be the signal processing device 114 and the computing device 116 of FIG. 1. The computer system 2000 can include a set of instructions that can be executed to cause the computer system 2000 to perform any one or more of the methods or computer based functions disclosed herein. The computer system 2000, or any portion thereof, may operate as a standalone device or may be connected, e.g., using a network or other connection, to other computer systems or peripheral devices. For example, the computer system 2000 may be operatively connected to signal processing device 114, analysis database 118, and control device 120.

[00213] In operation as described in FIGS. 1-20, the modification or enhancement of the nervous system of the body by creating and using an enciphered functional network as described herein can be used to enhance performance in normal individuals or restore or treat lost function in patients.

[00214] The computer system 2000 may be implemented as or incorporated into various devices, such as a personal computer (PC), a tablet PC, a personal digital assistant (PDA), a mobile device, a palmtop computer, a laptop computer, a desktop computer, a communications device, a control system, a web appliance, or any other machine capable of executing a set of instructions (sequentially or otherwise) that specify actions to be taken by that machine. Further, while a single computer system 2000 is illustrated, the term "system" shall also be taken to include any collection of systems or sub-systems that individually or jointly execute a set, or multiple sets, of instructions to perform one or more computer functions.

[00215] As illustrated in FIG. 21, the computer system 2000 may include a processor 2002, e.g., a central processing unit (CPU), a graphics-processing unit (GPU), or both. Moreover, the computer system 2000 may include a main memory 2004 and a static memory 2006 that can communicate with each other via a bus 2026. As shown, the computer system 2000 may further include a video display unit 2010, such as a liquid crystal display (LCD), a light emitting diode such as an organic light emitting diode (OLED), a flat panel display, a solid state display, or a cathode ray tube (CRT). Additionally, the computer system 2000 may include an input device 2012, such as a keyboard, and a cursor control device 2014, such as a mouse. The computer system 2000 can also include a disk drive unit 2016, a signal generation device 2022, such as a speaker or remote control, and a network interface device 2008.

[00216] In a particular embodiment, as depicted in FIG. 21, the disk drive unit 2016 may include a computer-readable medium 2018 in which one or more sets of instructions 2020, e.g., software, can be embedded. Further, the instructions 2020 may embody one or more of the methods or logic as described herein. In a particular embodiment, the instructions 2020 may reside completely, or at least partially, within the main memory 2004, the static memory 2006, and/or within the processor 2002 during execution by the computer system 2000. The main memory 2004 and the processor 2002 also may include computer-readable media.

[00217] In an alternative embodiment, dedicated hardware implementations, such as application specific integrated circuits, programmable logic arrays and other hardware devices, can be constructed to implement one or more of the methods described herein. Applications that may include the apparatus and systems of various embodiments can broadly include a variety of electronic and computer systems. One or more embodiments described herein may implement functions using two or more specific interconnected hardware modules or devices with related control and data signals that can be communicated between and through the modules, or as portions of an application-specific integrated circuit. Accordingly, the present system encompasses software, firmware, and hardware implementations.

[00218] In accordance with various embodiments, the methods described herein may be implemented by software programs tangibly embodied in a processor-readable

medium and may be executed by a processor. Further, in an exemplary, non-limited embodiment, implementations can include distributed processing, component/object distributed processing, and parallel processing. Alternatively, virtual computer system processing can be constructed to implement one or more of the methods or functionality as described herein.

[00219] It is also contemplated that a computer-readable medium includes instructions or receives and executes instructions 2020 responsive to a propagated signal, so that a device connected to a network 2024 can communicate voice, video or data over the network 2024. Further, the instructions 2020 may be transmitted or received over the network 2024 via the network interface device 2008.

[00220] While the computer-readable medium is shown to be a single medium, the term "computer-readable medium" includes a single medium or multiple media, such as a centralized or distributed database, and/or associated caches and servers that store one or more sets of instructions. The term "computer-readable medium" shall also include any medium that is capable of storing, encoding or carrying a set of instructions for execution by a processor or that cause a computer system to perform any one or more of the methods or operations disclosed herein.

[00221] In a particular non-limiting, example embodiment, the computer-readable medium can include a solid-state memory, such as a memory card or other package, which houses one or more non-volatile read-only memories. Further, the computer-readable medium can be a random access memory or other volatile re-writable memory. Additionally, the computer-readable medium can include a magneto-optical or optical medium, such as a disk or tapes or other storage device to capture carrier wave signals, such as a signal communicated over a transmission medium. A digital file attachment to an e-mail or other self-contained information archive or set of archives may be considered a distribution medium that is equivalent to a tangible storage medium. Accordingly, any one or more of a computer-readable medium or a distribution medium and other equivalents and successor media, in which data or instructions may be stored, are included herein.

[00222] In accordance with various embodiments, the methods described herein may be implemented as one or more software programs running on a computer processor. Dedicated hardware implementations including, but not limited to, application specific integrated circuits, programmable logic arrays, and other hardware devices can likewise be constructed to implement the methods described herein. Furthermore, alternative software implementations including, but not limited to, distributed processing or component/object distributed processing, parallel processing, or virtual machine processing can also be constructed to implement the methods described herein.

[00223] It should also be noted that software that implements the disclosed methods may optionally be stored on a tangible storage medium, such as: a magnetic medium, such as a disk or tape; a magneto-optical or optical medium, such as a disk; or a solid state medium, such as a memory card or other package that houses one or more read-only (non-volatile) memories, random access memories, or other re-writable (volatile) memories. The software may also utilize a signal containing computer instructions. A digital file attachment to e-mail or other self-contained information archive or set of archives is considered a distribution medium equivalent to a tangible storage medium. Accordingly, a tangible storage medium or distribution medium as listed herein, and other equivalents and successor media, in which the software implementations herein may be stored, are included herein.

[00224] Thus, a system and method of identifying a source of a heart rhythm disorder, by identification of rotational of focal activation in relation to one or more spatial elements associated with the source of the heart rhythm disorder, have been described. Although specific example embodiments have been described, it will be evident that various modifications and changes may be made to these embodiments without departing from the broader scope of the invention. Accordingly, the specification and drawings are to be regarded in an illustrative rather than a restrictive sense. The accompanying drawings that form a part hereof, show by way of illustration, and not of limitation, specific embodiments in which the subject matter may be practiced. The embodiments illustrated are described in sufficient detail to enable those skilled in the art to practice the teachings disclosed herein. Other embodiments

may be utilized and derived, such that structural and logical substitutions and changes may be made without departing from the scope of this disclosure. This Detailed Description, therefore, is not to be taken in a limiting sense, and the scope of various embodiments is defined only by the appended claims, along with the full range of equivalents to which such claims are entitled.

[00225] Such embodiments of the inventive subject matter may be referred to herein, individually and/or collectively, by the term "invention" merely for convenience and without intending to voluntarily limit the scope of this application to any single invention or inventive concept if more than one is in fact disclosed. Thus, although specific embodiments have been illustrated and described herein, it should be appreciated that any arrangement calculated to achieve the same purpose may be substituted for the specific embodiments shown. This disclosure is intended to cover any and all adaptations or variations of various embodiments. Combinations of any of the above-described embodiments, and other embodiments not specifically described herein, may be used and are fully contemplated herein.

[00226] The Abstract is provided to comply with 37 C.F.R. §1.72(b) and will allow the reader to quickly ascertain the nature and gist of the technical disclosure. It is submitted with the understanding that it will not be used to interpret or limit the scope or meaning of the claims.

[00227] In the foregoing description of the embodiments, various features are grouped together in a single embodiment for the purpose of streamlining the disclosure. This method of disclosure is not to be interpreted as reflecting that the claimed embodiments have more features than are expressly recited in each claim. Rather, as the following claims reflect, inventive subject matter lies in less than all features of a single disclosed embodiment. Thus the following claims are hereby incorporated into the Description of the Embodiments, with each claim standing on its own as a separate example embodiment.

WHAT IS CLAIMED IS

1. A method for interacting with the human body, the method comprising:

detecting bodily signals associated with one or more bodily functions at one or more sensors associated with the human body;

processing the bodily signals to create one or more sensed signatures of the one of more bodily functions;

processing the signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to control a bodily task;

delivering via the enciphered functional network one or more effector signals, the effector signals based on the one or more effector responses; and

controlling a bodily task.

2. The method of claim 1, wherein the machine learning includes combining sensed signatures with prior data relating to one or more functional domains.

3. The method of claim 2, wherein the prior data are from one or more of a common database, individual patient-specific information, and scientific knowledge of biological processes and mechanisms.

4. The method of claim 1 wherein the bodily signals associated with a biological function are one of central or peripheral nervous system signals, autonomic nervous system signals, muscular activity signals, non-neurologic physiological signals, galvanic skin signals and combinations thereof.

5. The method of claim 1, wherein the bodily task is a biological function.

6. The method of claim 1, wherein the bodily task is control of activity of a machine external to the body.

7. The method of claim 1, wherein the bodily task is control of activity of a machine on or inside the body.

8. The method of claim 1, wherein the bodily task is a combination of an external machine and biological function.

9. The method of claim 1, wherein the enciphered functional network is represented by symbolic code.

10. The method of claim 9, wherein the symbolic code is a cypher.

11. The method of claim 1, wherein the effector signal directs one or more of a mechanical, an electrical and a computational device.

12. The method of claim 1, wherein the detecting and the delivering comprise different regions of the human body.

13. The method of claim 1, wherein the detecting and the delivering comprise identical regions of the human body.

14. The method of claim 1, wherein the controlling comprises treating a biological disease or a biological condition.

15. The method of claim 1, wherein the controlling comprises enhancing the performance of a bodily task directly.

16. The method of claim 1, wherein the controlling comprises enhancing the performance bodily task using an external machine.

17. A method to enhance performance of a bodily task, the method comprising:
detecting signals associated with the task at one or more sensors;
processing the signals to create one or more sensed signatures;
processing the signatures using an enciphered functional network to determine one or more effector responses needed to enhance performance of the bodily task;
delivering via the enciphered functional network one or more effector signals, the effector signals based on the one or more effector responses; and
enhancing performance of the task.

18. The method of claim 17, wherein the task is one or more of operating a mode of transportation, firing a weapon, controlling an artificial limb, controlling an exoskeleton and combinations thereof.

19. The method of claim 17, wherein the mode of transportation is one or more of automobile, train, bus, airplane, boat, spacecraft, motorcycle, motorized human transport, and bicycle.

20. The method of claim 17, wherein the signals are detected on the scalp overlying brain regions controlling one or more of the body's extremities.

21. The method of claim 17, wherein said representation is a direct mathematical transformation from patterns of nerve firing during said task.

22. The method of claim 17, wherein the processing of the signals involves associative learning between the sensed signals and performance of the task.

23. The method of claim 17, wherein the processing of the signatures involves associative learning between sensed signatures and performance of the task.

24. The method of claim 17, wherein the delivering of effector signals involves electrical impulses.

25. The method of claim 24, wherein the electrical impulses are delivered to control one of a digital device, a mechanical device, an external machine, and a bodily function.

26. The method of claim 17, wherein the enhancing performance includes performing the task when movement of the body is physically constrained.

27. The method of claim 17, wherein the enhancing performance includes performing the task when movement of the body is mentally constrained including one or more of voluntary conscious constraint, unconscious constraint and constraint due to debilitation.

28. The method of claim 27, wherein the unconscious constraint is due to one or more of sleep, fatigue and psychiatric illness.

29. The method of claim 27, wherein the constraint due to debilitation is one or more of injury, stroke, transient cerebral ischemia and myocardial ischemia.

30. A method for treating a disease, the method comprising:
detecting signals associated with one or more bodily functions at one or more sensors associated with the human body;
processing the signals to create one or more sensed signatures of the one of more bodily functions;
processing the signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to treat a disease;
delivering via the enciphered functional network one or more effector signals, the effector signals based on the one or more effector responses; and
treating the disease.

31. The method of claim 30, wherein the disease is a stroke affecting an extremity of the human body.

32. The method of claim 30, wherein the signals are detected on the affected extremity.

33. The method of claim 30, wherein the machine learning utilizes data that are directly transformed from patterns of nerve firing.

34. The method of claim 30, wherein the machine learning does not utilize data directly transformed from patterns of nerve firing.

35. The method of claim 30, wherein delivering involves energy delivered to the scalp overlying brain regions.

36. The method of claim 30, wherein delivering involves delivery of energy to regions of the body not including the scalp overlying brain regions.

37. A method for transforming nerve activity associated with one or more bodily functions, the method comprising:

detecting bodily signals of nerve activity associated with the one or more bodily functions at one or more sensors;

processing the bodily signals to create one or more sensed signatures of the one or more bodily functions;

processing the signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to transform nerve activity;

delivering via the enciphered functional network one or more effector signals, the

effector signals based on the one or more effector responses; and

transforming nerve activity.

38. The method of claim 37, wherein the bodily function is the sense of vision.

39. The method of claim 37, wherein the bodily function is one of skeletal muscular movement and cardiac muscular movement.

40. The method of claim 37, wherein the bodily signals are electrical.

41. The method of claim 37, wherein correlation is used in one or more of processing the bodily signals and processing the signatures.

42. The method of claim 37, wherein the bodily signals result from one or more of evoked response to visible light, eye movement, eyelid movement, ocular blood flow, pupil diameter changes, and lacrimal duct activity.

43. The method of claim 37, wherein the effector responses comprise one or more of movement of facial muscles, blinking, tearing, and pupil diameter changes.

44. The method of claim 37, wherein the one or more sensed signatures comprise one or more of a specific numerical pattern, a non-numerical visual pattern, and a non-numerical nonvisual pattern.

45. The method of claim 37, wherein the bodily function is sense of hearing.

46. The method of claim 37, wherein the bodily function is sense of touch.

47. The method of claim 37, wherein the bodily function is sense of smell.

48. The method of claim 37, wherein the bodily function is physically moving an object.

49. The method of claim 37, wherein the bodily function is purposeful communication using movement.

50. The method of claim 49, wherein the communication controls a device.

51. The method of claim 37, wherein the bodily function is mental alertness.

52. The method of claim 37, wherein the bodily function is a biological disease.

53. The method of claim 52, wherein the biological disease affects the brain.

54. The method of claim 52, wherein the biological disease affects the eye.

55. The method of claim 52, wherein the biological disease affects the peripheral nervous system.

56. The method of claim 52, wherein the biological disease affects an extremity of the body.

57. The method of claim 52, wherein the biological disease affects the heart.

58. The method of claim 52, wherein the biological disease affects the lungs.

59. The method of claim 52, wherein the biological disease affects the gastrointestinal tract.

60. The method of claim 52, wherein the biological disease affects the kidneys.

61. The method of claim 52, wherein the biological disease affects the skin.

62. A method for controlling a device using an enciphered functional network, the method comprising:

detecting bodily signals from a body using one or more sensors;

processing the bodily signals to create a sensed signature;

processing the sensed signature using an enciphered functional network utilizing machine learning to determine one or more effector responses to control the device;

delivering via the enciphered functional network one or more effector signals, the effector signals based on the one or more effector responses; and

controlling the device.

63. The method of claim 62, wherein the device is an electromechanical device.

64. The method of claim 62, wherein the enciphered functional network is in the form of a standard digital code.

65. The method of claim 62, wherein the bodily signal has a specific pattern that results from manual or behavioral training.

66. The method of claim 62, wherein the bodily signals results from one or more of blinking of the eye, moving one's mouth or face, adjusting anal or pelvic tone and moving one or more skeletal muscles.

67. The method of claim 64 wherein the standard digital code is compatible with the device.

68. A method to measure bodily function in an animal, the method comprising:

detecting bodily signals associated with sensory activation;

processing the bodily signals to create one or more sensed signatures; and

processing the sensed signatures using an enciphered functional network to determine one or more effector responses needed to enhance the bodily function of the animal.

69. The method of claim 68, further comprising delivering via the enciphered functional network one or more of the effector signals; and

enhancing the bodily function of the animal.

70. The method of claim 68, wherein the processing includes the use of a database of normal values of sensory activation.

71. The method of claim 68, further comprising reviewing the sensed signature over time to determine changes of the sensory activation.

72. The method of claim 71, further comprising determining and delivering optimal therapy based on the changes of the sensory activation.

73. The method of claim 71, wherein the sensory activation is one or more of visual, auditory, tactile, olfactory, and taste.

74. The method of claim 71, further comprising determining one or more of alertness, mood, emotion, physical function, and brain injury using the sensed signature.

75. A method of improving a specific human performance, the method comprising:
identifying one or more regions of a human body associated with parts of the brain that serve a specific function;
placing low energy stimulating electrodes proximate to said one or more regions of the human body;
applying stimulation through said electrodes to activate said parts of the brain; and
measuring changes related to said parts of the brain to verify improvement of the specific human performance.

76. The method of claim 75, wherein said parts of the brain are responsible for alertness.

77. The method of claim 76, wherein alertness includes one or more of narcolepsy, central sleep disorders, central sleep apnea, wakefulness, insomnia, and mixed central and obstructive sleep apnea.

78. The method of claim 75, wherein said parts of the brain are responsible for mood.

79. A method for treating a sleep disorder, the method comprising:
selecting one or more regions of a patient's central nervous system and/or peripheral nervous system associated with sleep functioning; and
applying low energy stimulation through electrodes to activate the patient's one or more regions of central nervous system and/or peripheral nervous system to treat the sleep disorder.

80. The method of claim 79, wherein said parts of the central nervous system or peripheral nerves are responsible for alertness.

81. The method of claim 79, wherein alertness includes one or more of narcolepsy, central sleep disorders, central sleep apnea, wakefulness, insomnia, and mixed central and obstructive sleep apnea.

82. The method of claim 79, wherein said parts of the brain are responsible for mood.

83. The method of claim 79, wherein said stimulation may be one or more of electrical, infrared, ultrasound, mechanical, auditory, or visual.

84. The method of claim 83, wherein electrical stimulation consists of high frequency stimulation without any side effects of pain or serious discomfort.

85. A method of enhancing attention, the method comprising:
selecting one or more regions of a patient's central nervous system and/or peripheral nervous system associated with an attention disorder; and
applying low energy stimulation through electrodes to activate parts of a patient's central nervous system and/or peripheral nervous system to treat the attention disorder.

86. The method of claim 85, wherein the attention disorders consist of one of attention deficit or hyperactivity disorder, narcolepsy, shift work syndrome, jet lag, and sleep apnea.

87. A method of treating central sleep apnea, the method comprising:
identifying a target region from one or more local areas of the head and neck, the target region being functionally associated with one or parts of the brain that control sleep; and

delivering a therapeutically effective amount of energy to stimulate said target region to treat the central sleep apnea, while minimizing stimulation of other regions of the body.

88. The method of claim 87, wherein said energy is adjusted in response to sensed patterns of nerve activity or muscle activity associated with sleep.

89. The method of claim 88, wherein said adjustment alters the rate, frequency, pattern, intensity or site of delivery of energy.

90. The method of claim 88, wherein said sensed patterns of nerve activity include rate, irregularity, periodic activity, phasic activity in target regions.

91. The method of claim 88, wherein said sensed patterns of nerve activity include rate, irregularity, periodic activity, phasic activity in regions other than target regions.

92. The method of claim 88, wherein said muscle activity includes tonic contraction, periodic contraction or relaxation in target regions.

93. The method of claim 88, wherein said muscle activity includes tonic contraction, periodic contraction or relaxation in regions other than target regions.

94. The method of claim 87, wherein the energy comprises one or more of electrical, magnetic, mechanical, electromagnetic, sound and ultrasound.

95. The method of claim 87, wherein the energy is applied continuously or intermittently.

96. The method of claim 94, wherein the mechanical energy applied to the target region comprises one or more of vibratory energy, energy that produces intermittent mechanical deformations or energy that produces continuous mechanical deformations.

97. The method of claim 96, wherein the mechanical energy at the target region is applied continuously or intermittently.

98. The method of claim 94, wherein the electromagnetic energy comprises one or more of ultraviolet, microwave, visible light, and infrared.

99. The method of claim 87, wherein said delivering is via an energy source in direct contact with the said target region.

100. The method of claim 87, wherein said delivering is via an energy source not in direct contact with the said target region.

101. The method of claim 87, wherein said delivering is accomplished by a device in contact with the body.

102. The method of claim 87, wherein said delivering is accomplished by a device not in contact with the body.

103. The method of claim 102, wherein said device is placed outside the body surface.

104. The method of claim 101, wherein said device is placed inside the body.

105. The method of claim 87, wherein the therapeutically effective amount is at least a minimum amount of energy that reduces periods of long pauses between breaths during sleep.

106. The method of claim 105, wherein the therapeutically effective amount of energy provides at least 1 microCoulomb/cm^2 in the functionally associated parts of the brain.

107. The method of claim 105, wherein the therapeutically effective amount of energy provides 4 mg glucose utilization per 100g tissue/min in the functionally associated parts of the brain.

108. The method of claim 87, wherein minimizing stimulation to other regions of the body prevents pain, discomfort, rashes, burns, chemical injury, phototoxic injury, and other temporary or permanent effects of stimulation on said other regions of the body.

109. The method of claim 108 wherein minimizing stimulation to other regions of the body is accomplished by one or more of focusing energy delivery on targeted regions of the body, utilizing the minimum amount of energy needed to achieve therapeutic efficacy, the use of a barrier to insulate zones outside the target region from energy

exposure, the use of a barrier to direct energy delivery to target regions and away from other regions of tissue, increasing the rapid dissipation of energy.

110. The method of claim 87, wherein said target region is functionally associated with parts of the brain by one or more of nerves, blood vessels, hormones, or structural elements of the body.

111. The method of claim 87, wherein said target region is functionally associated with parts of the brain by innate connections, trained connections, or a combination thereof.

112. The method of claim 87, wherein identification of said target region is based on being linked by nerves or blood vessels to said parts of the brain.

113. The method of claim 87, wherein identification of said target region is based on learned association with said parts of the brain.

114. The method of claim 113, wherein said learned association is not a direct link of nerves or blood vessels between the target region and said parts of the brain.

115. The method of claim 113, wherein the learned association is a symbolic representation between the target region and said parts of the brain.

116. The method of claim 87, wherein said control comprises modification of one or more stages of the sleep cycle, wherein said stages comprise one or more of periods of

rapid eye movement sleep, non-rapid eye movement sleep, somnolence and combinations thereof.

117. The method of claim 87, wherein simulation is provided according to predefined algorithms.

118. The method of claim 117, wherein said algorithms vary the rate of delivery of stimuli.

119. The method of claim 117, wherein said algorithms vary the numerical patterns of stimuli.

120. The method of claim 117, wherein said algorithms vary the intensity of stimuli.

121. The method of claim 117, wherein said algorithms are varied based on a signal detected from the body.

122. The method of claim 117, wherein said signal is detected from a sensor.

123. The method of claim 122, wherein said sensor is in contact with the body.

124. The method of claim 122, wherein said sensor is in not in contact with the body.

125. The method of claim 122, wherein said sensor is linked with a means for delivering energy.

126. The method of claim 87, wherein treatment comprises at least one of reducing periods of long pauses between breaths during sleep or reducing periods of somnolence between periods of sleep.

127. The method of claim 87, wherein treatment further comprises reducing symptoms including shortness of breath, swelling of the ankles, heart failure, abnormal heart rhythms, embolism or stroke.

128. A method of modulating mental function, the method comprising:
Identifying a target region selected from localized areas of the body, the target region being functionally associated with parts of the brain that govern the mental function, the mental function including one or more of alertness, cognition, memory, mood, attention and awareness; and
delivering a therapeutically effective amount of energy to stimulate said target region to modulate the mental function, while minimizing stimulation of other regions of the body.

129. The method of claim 128, wherein said target region is functionally associated with parts of the brain by one or more of nerves, blood vessels, hormones, or structural elements.

130. The method of claim 128, wherein the energy comprises one or more of electrical, magnetic, mechanical, electromagnetic, sound and ultrasound.

131. The method of claim 128, wherein the mechanical energy applied to the target region comprises one or more of vibratory, intermittent or continuous mechanical deformations.

132. The method of claim 128, wherein the mechanical energy at the target region is applied continuously.

133. The method of claim 128, wherein the mechanical energy is applied intermittently.

134. The method of claim 128, wherein said target region is functionally associated with parts of the brain by innate connections, trained connections, or a combination thereof.

135. The method of claim 128, where said modulation comprises modulation of one or more stages of the alert cycle, wherein said stages comprise impaired performance of a task, "mental fatigue", loss of focus, attention deficit, somnolence, sleepiness, narcolepsy, sleep and disease processes thereof, coma and fugue state.

136. The method of claim 128, wherein the stimulation is provided according to predefined algorithms.

137. The method of claim 128 wherein the therapeutically effective amount of energy provides at least 1 microCoulomb/cm^2 in the functionally associated parts of the brain.

138. The method of claim 128, wherein the therapeutically effective amount of energy provides 4 mg glucose utilization per 100g tissue/minute in the functionally associated parts of the brain.

139. The method of claim 129, wherein minimizing stimulation to other regions of the body prevents pain, discomfort, rashes, burns, chemical injury, phototoxic injury, and other temporary or permanent effects of stimulation on said other regions of the body.

140. A system for interacting with the human body, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

detecting bodily signals associated with one or more bodily functions at one or more sensors associated with the human body;

processing the bodily signals to create one or more sensed signatures of the one of more bodily functions;

processing the signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to control a bodily task;

delivering via the enciphered functional network one or more effector signals, the effector signals based on the one or more effector responses; and

controlling a bodily task.

141. A system to enhance performance of one or more tasks, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

detecting signals associated with the task at one or more sensors;

processing the signals to create one or more sensed signatures;

processing the signatures using an enciphered functional network to determine one or more effector responses needed to enhance performance of the bodily task;

delivering via the enciphered functional network one or more effector signals, the effector signals based on the one or more effector responses; and

enhancing performance of the task.

142. A system to treat a disease comprising, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

detecting bodily signals associated with one or more bodily functions at one or more sensors associated with the human body;

processing the bodily signals to create one or more sensed signatures of the one of more bodily functions;

processing the signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to treat a disease;

delivering via the enciphered functional network one or more effector signals, the effector signals based on the one or more effector responses; and

treating the disease.

143. A system to transform nerve activity associated with one or more biological functions, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

detecting bodily signals of nerve activity associated with the one or more bodily functions at one or more sensors;

processing the bodily signals to create one or more sensed signatures of the one or more bodily functions;

processing the signatures using an enciphered functional network utilizing machine learning to transform nerve activity;

delivering via the enciphered functional network one or more effector signals, the effector signals based on the one or more effector responses; and

transforming nerve activity.

144. A system to control a device using biological signals, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

detecting bodily signals from a body using one or more sensors;

processing the bodily signals to create a sensed signature;

processing the sensed signature using an enciphered functional network utilizing

machine learning to determine one or more effector responses to control the device;

delivering via the enciphered functional network one or more effector signals, the effector signals based on the one or more effector responses; and

controlling the device.

145. A system to measure visual function in an animal, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

detecting bodily signals associated with sensory activation;

processing the bodily signals to create one or more sensed signatures representing quantitative measures of sensation; and

processing the sensed signatures using an enciphered functional network utilizing machine learning to determine one or more effector responses needed to enhance the bodily function of the animal.

146. A system for improving a specific human performance, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

identifying one or more regions of a human body associated with parts of the brain that serve a specific function;

placing low energy stimulating electrodes proximate to said one or more regions of the human body;

applying stimulation through said electrodes to activate said parts of the brain; and measuring changes related to said parts of the brain to verify improvement of the specific human performance.

147. A system for treating a sleep disorder, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

selecting one or more regions of a patient's central nervous system and/or peripheral nervous system associated with sleep functioning; and

applying low energy stimulation through electrodes to activate the patient's one or more regions of central nervous system and/or peripheral nervous system to treat the sleep disorder.

148. A system to enhance attention, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

selecting one or more regions of a patient's central nervous system and/or peripheral nervous system associated with an attention disorder; and

applying low energy stimulation through electrodes to activate parts of a patient's central nervous system and/or peripheral nervous system to treat the attention disorder.

149. A system to treat central sleep apnea, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

identifying a target region from one or more local areas of the head and neck, the target region being functionally associated with one or more parts of the brain that control sleep; and

delivering a therapeutically effective amount of energy to stimulate said target region to treat the central sleep apnea, while minimizing stimulation of other regions of the body.

150. A system to modulate mental function, the system comprising:

a processor;

a memory storing instructions that, when executed by the processor, performs operations comprising:

identifying a target region selected from localized areas of the body, the target region being functionally associated with parts of the brain that govern the mental function, the mental function including one or more of alertness, cognition, memory, mood, attention and awareness; and

delivering a therapeutically effective amount of energy to stimulate said target region to modulate the mental function, while minimizing stimulation of other regions of the body.

151. The method of claim 1, including the elements of any of claims 2-16.

152. The method of claim 17, including the elements of any of claims 18-29.

153. The method of claim 30, including the elements of any of claims 31-36.

154. The method of claim 37, including the elements of any of claims 38-61.

155. The method of claim 62, including the elements of any of claims 63-67.

156. The method of claim 68, including the elements of any of claims 69-74.

157. The method of claim 75, including the elements of any of claims 76-78.

158. The method of claim 79, including the elements of any of claims 80-84.

159. The method of claim 85, including the element of claim 86.

160. The method of claim 87, including the elements of any of claims 88-127.

161. The method of claim 128, including the elements of any of claims 129-139.

162. The system of claim 140, including the elements of any of claims 2-16.

163. The system of claim 141, including the elements of any of claims 18-29.

164. The system of claim 142, including the elements of any of claims 31-36.

165. The system of claim 143, including the elements of any of claims 38-61.

166. The system of claim 144, including the elements of any of claims 63-67.

167. The system of claim 145, including the elements of any of claims 69-74.

168. The system of claim 146, including the elements of any of claims 76-78.

169. The system of claim 147, including the elements of any of claims 80-84.

170. The system of claim 148, including the elements of claim 86.

171. The system of claim 149, including the elements of any of claims 88-127.

172. The system of claim 150, including the elements of any of claims 129-139.

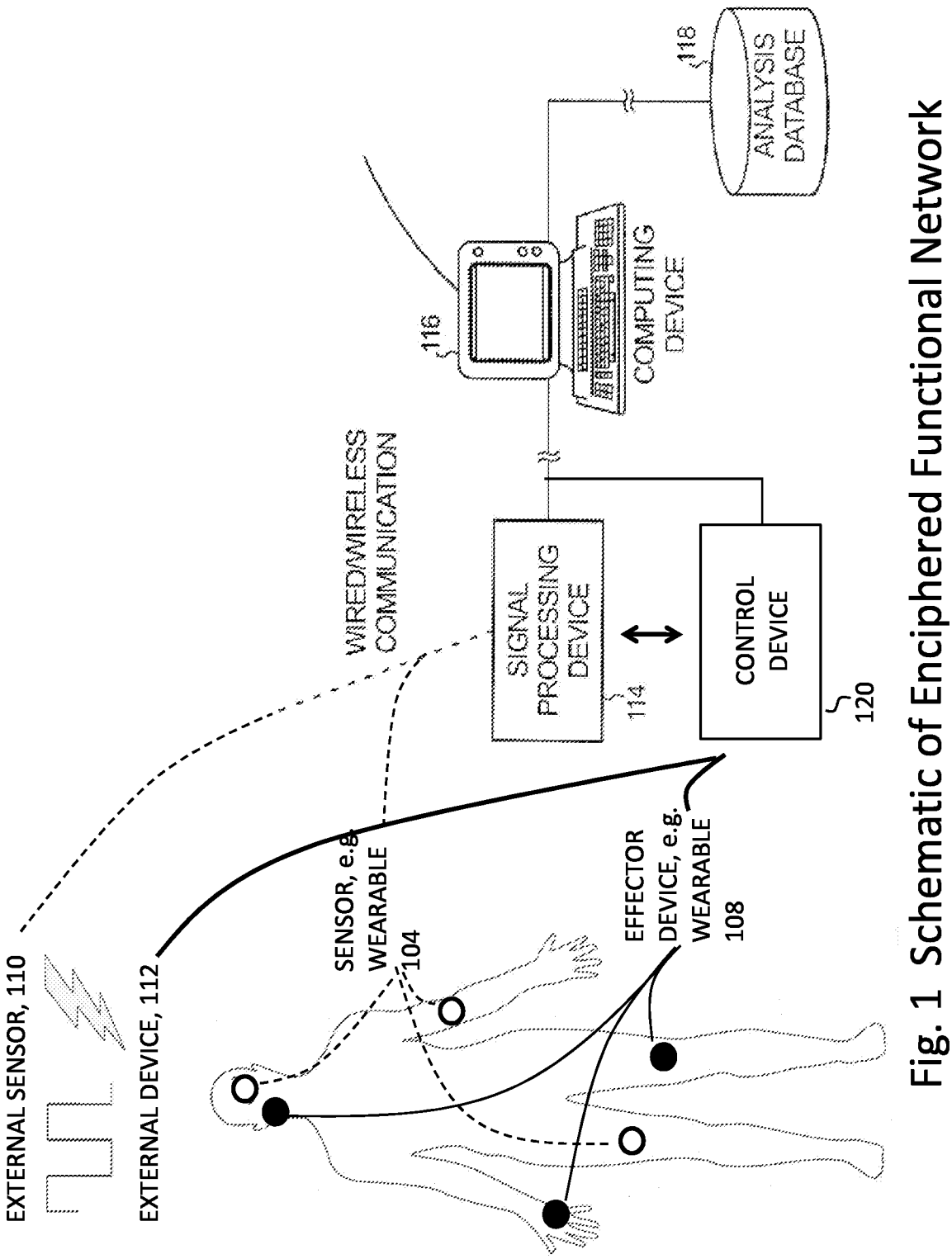


Fig. 1 Schematic of Enciphered Functional Network

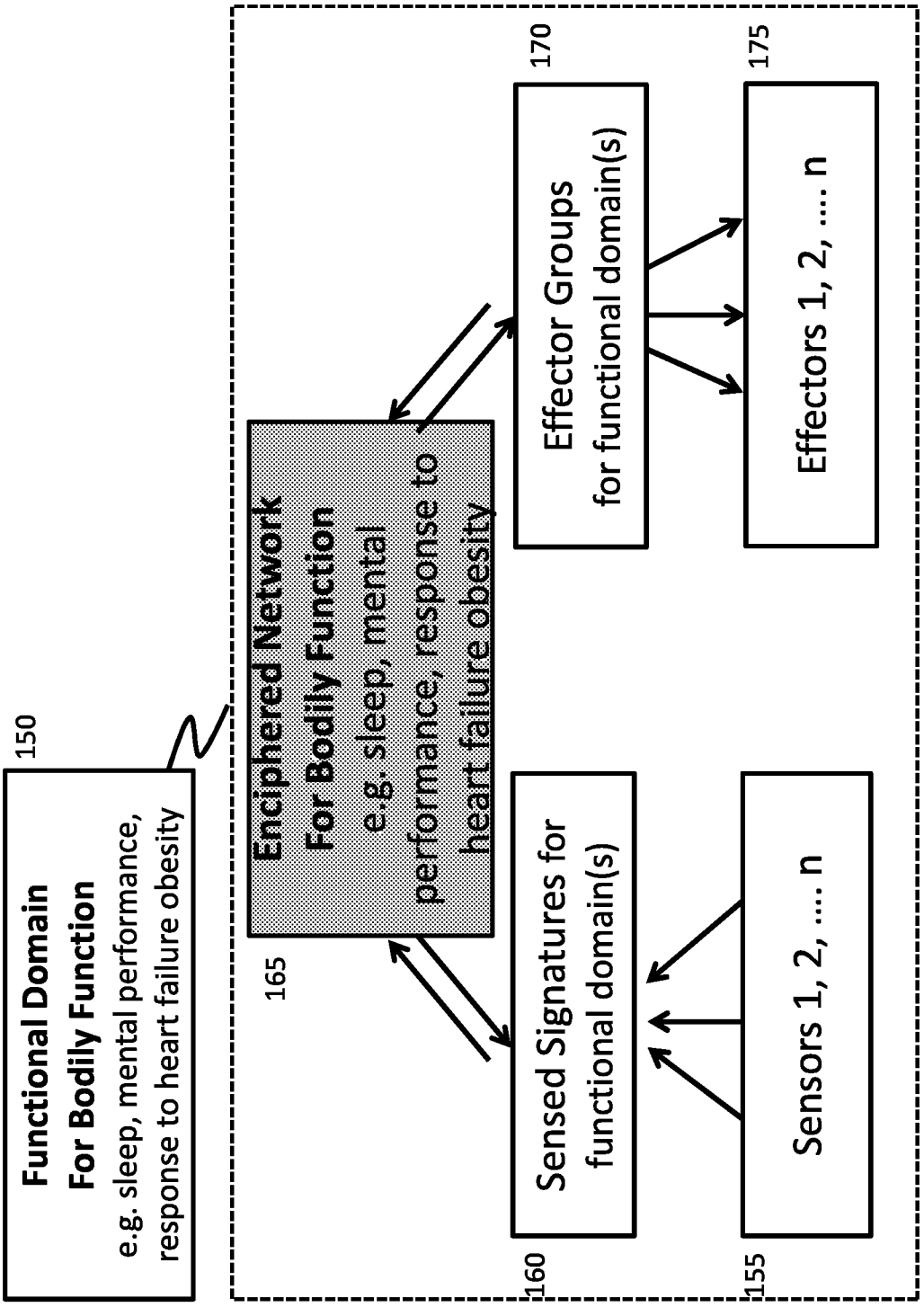


Figure 2. Relationship of Sensed Signatures, Enciphered Functional Network Analysis Engine, and Effectors in the Functional Domain for a bodily function

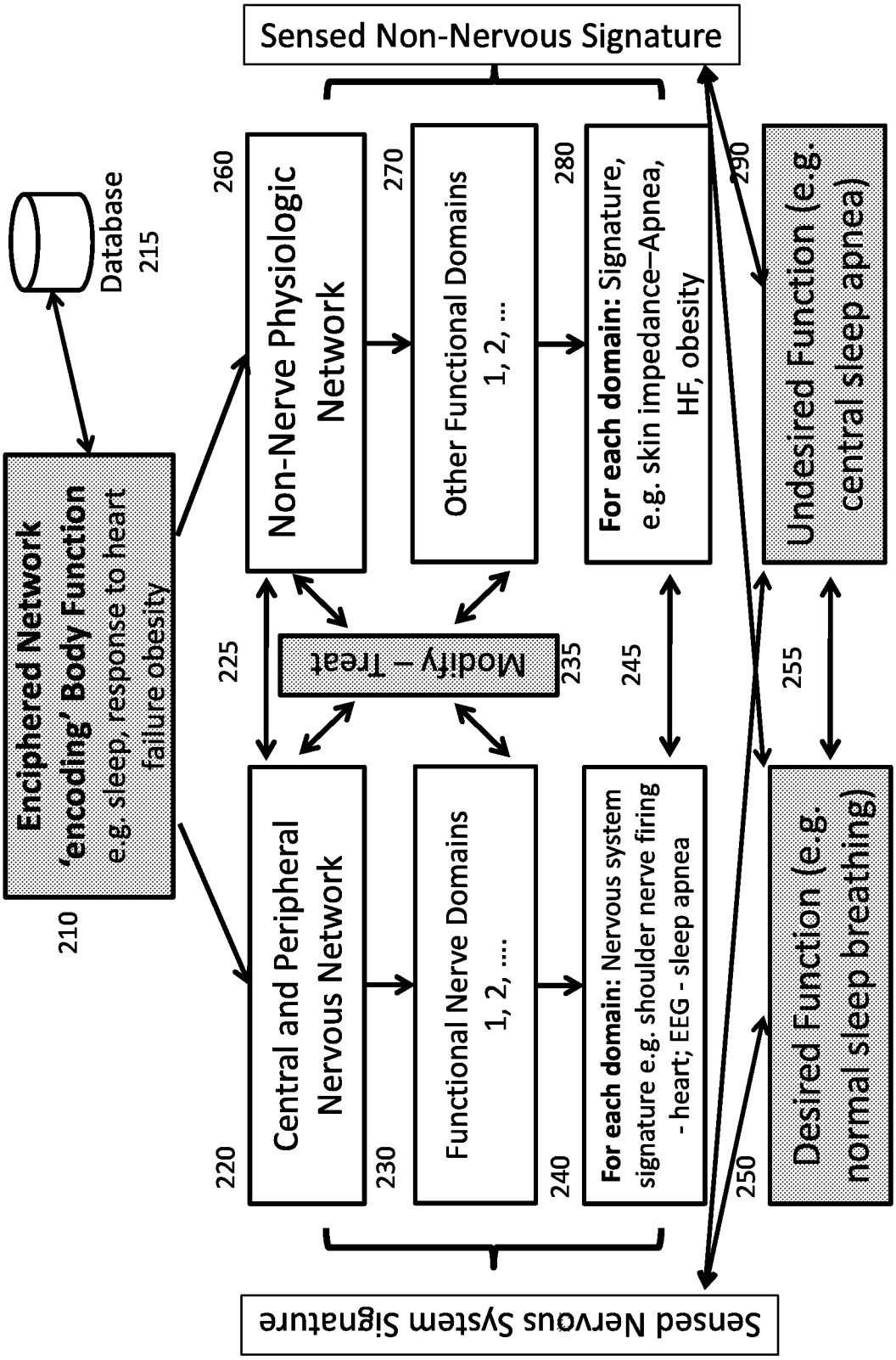


Figure 3. Enciphered Functional Network for Bodily Function as a Network of Sensed Signatures for each Functional Domains

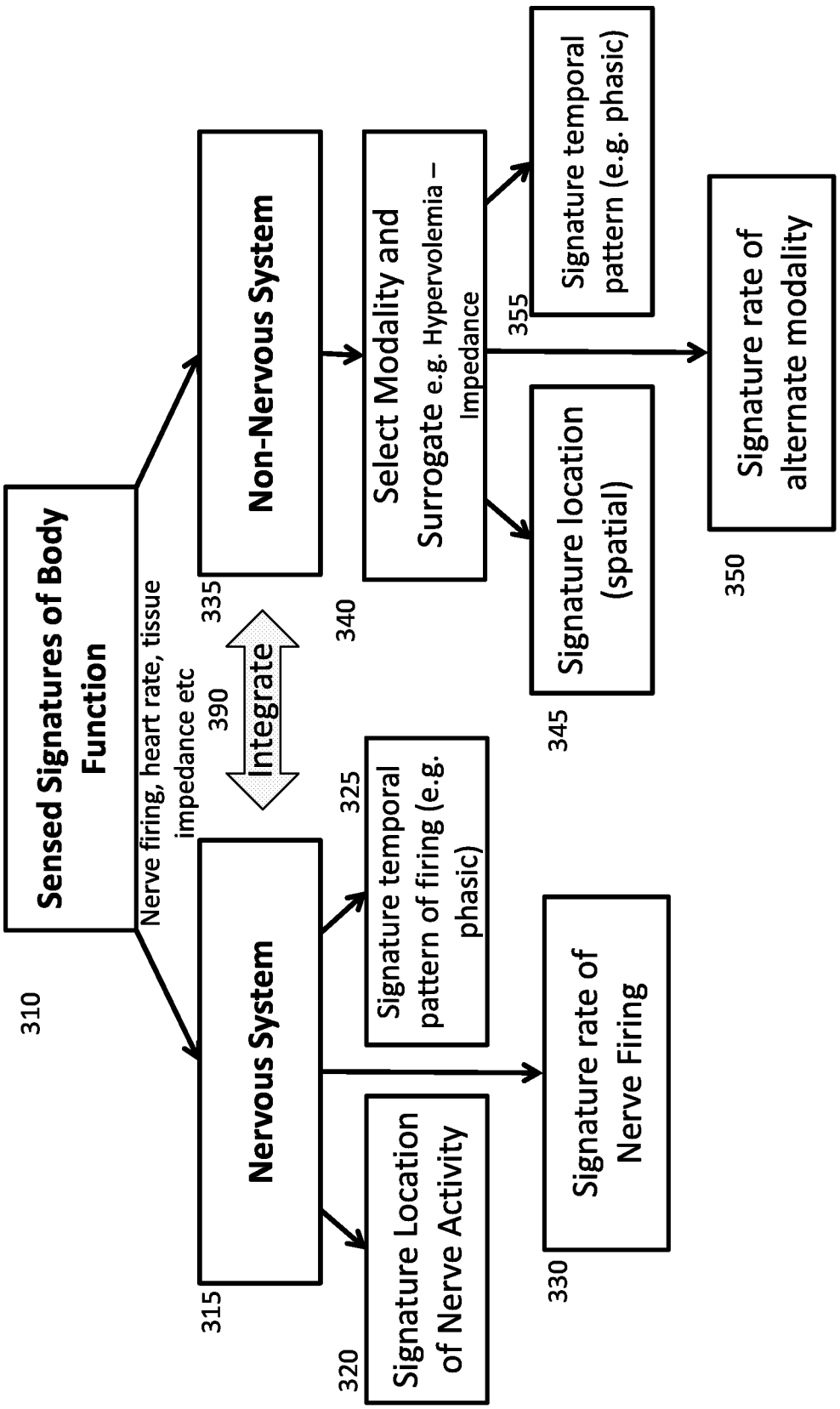


Figure 4. Example Sensed Signatures within Enciphered Functional Network

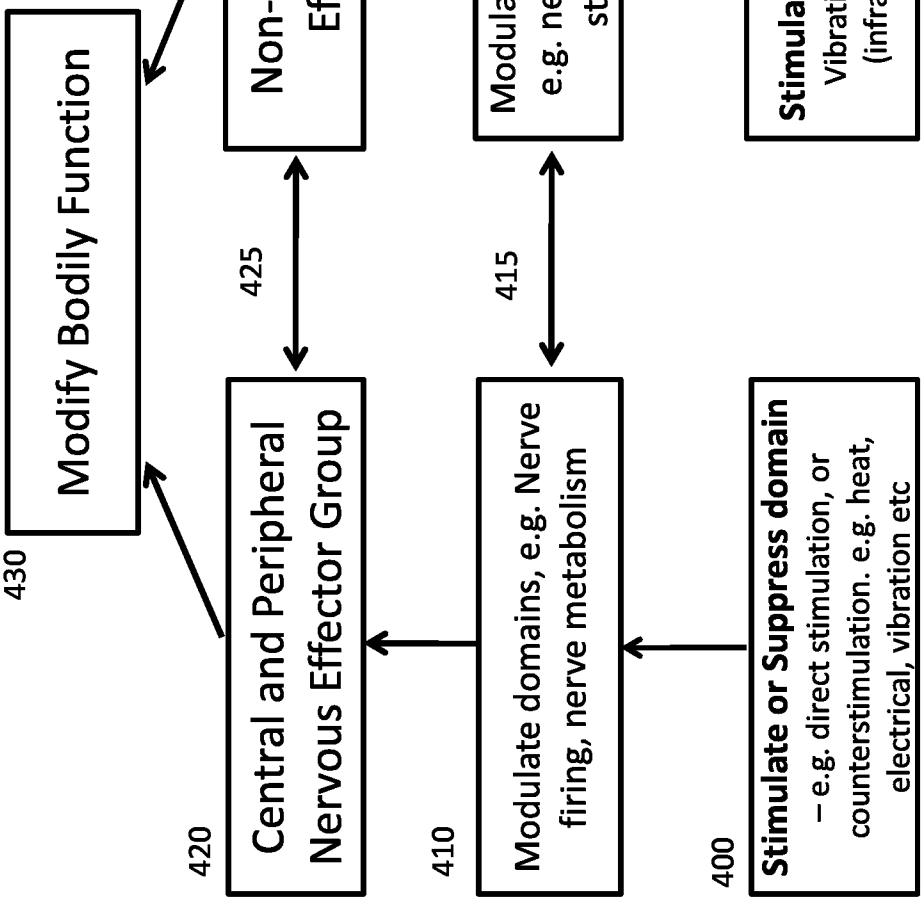


Figure 5. Examples of Modifying Bodily Function via the Enciphered Network

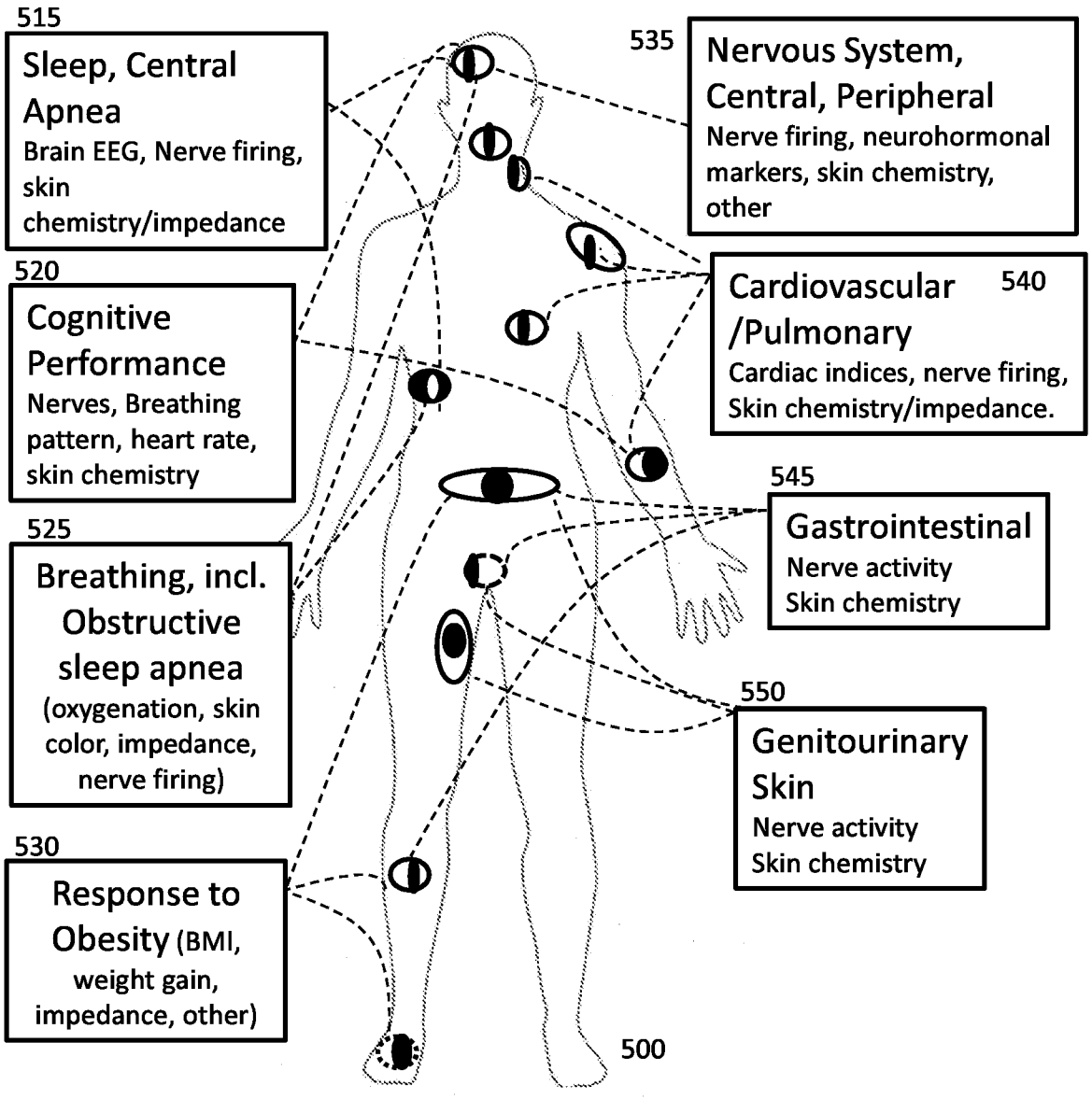


Fig. 6 Example Body Locations of Sensed Signatures for various domains and bodily functions

Domains

505 Sensor

510 Effector

Sensor Domain may be larger or smaller than effector domain; may or may not overlap.

Dashed lines are illustrative only.

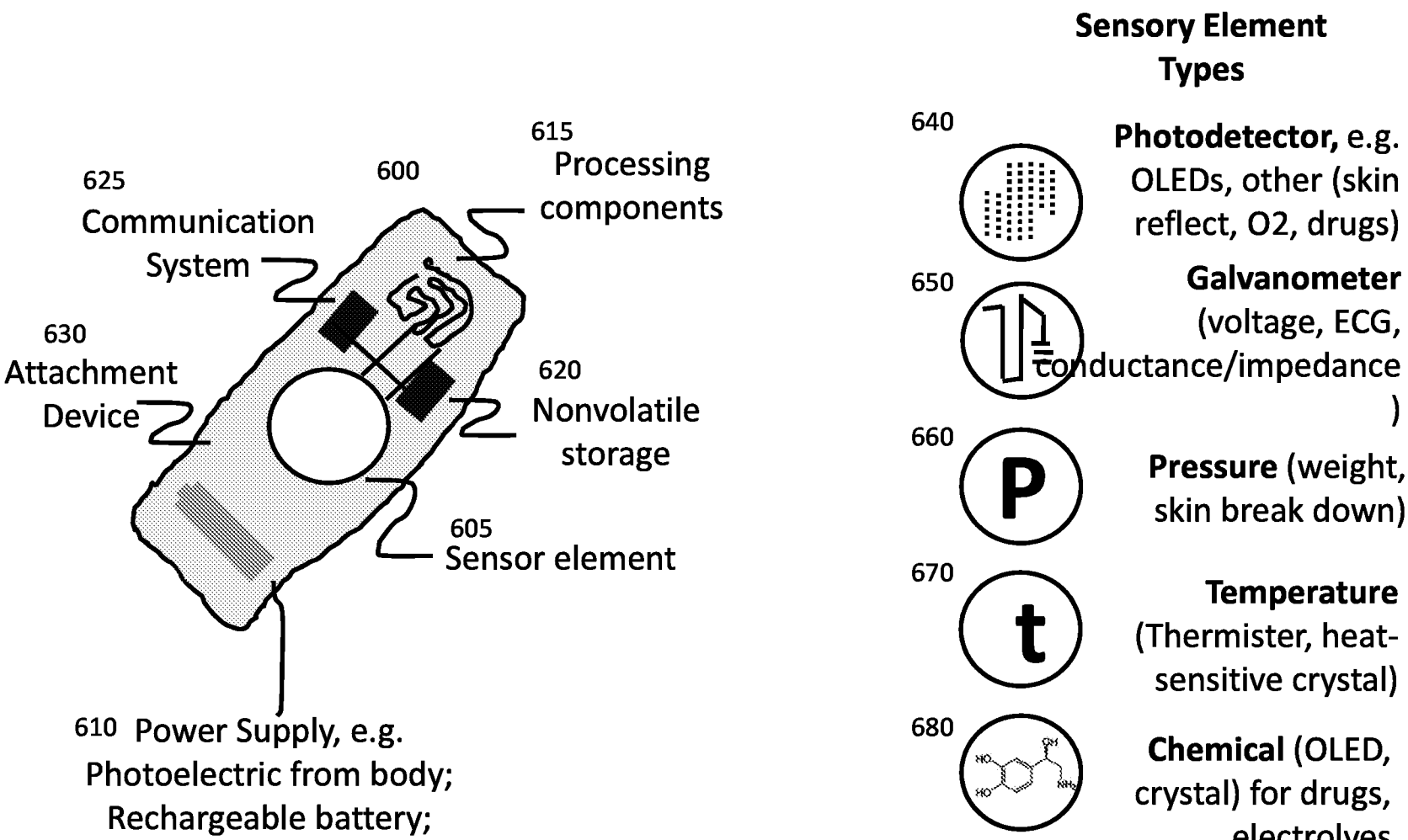


Figure 7. Example of a Body Sensor

	Sensor and Sensed Signature – Sleep Disorders								
	Impedance	**Electrical (Other)**			**Heat**	**Chemical**	**Optical**	**Motion**	**Pressure/ Acoustic**
Condition	**Skin sensor, e.g.** **Head/chest (Rostral) vs periphery**	**Skin Nerve Firing, e.g.** **Peripheral**	**Skin Nerve Firing, e.g.** **Mini EEG**	**Skin ECG, e.g.** **Heart Rate**	**Temp, e.g.**	**Skin Chemical, e.g. Glucose/Na /K/Cl/Urea/ HCO3 Lipid, drugs**	**Skin Color, e.g. O2 Sat, bile, CO,CO2 anemia**	**Accelerometer, e.g.** **Activity**	**Skin Pressure, e.g.** **Weight Piezo**
Normal Sleep	Nml Phasic NREM/REM	Acc muscles Periodic	EEG: δ and α Periph Nml	Slow, even in REM	cool	Nml profile	Nml tidal No Desat	Nml tidal movemt, Nml body movemt	Metabolic wt loss, Nml pressure points
Central Sleep Apnea	Rostral fall (neck edema)	Accessory muscles reduced Periodicity	EEG: Drowsy δ	Tachycardia ↓HRV	warm	Acidemic pattern	Desat in Apnea	↓ Tidal movemt+ ↓ body movemt	↑ wt loss + shifting pressure + rostral edema
Obstruct sleep apnea	Rostral fall (chest edema)	Accessory muscles exagger Periodicity	EEG: β Agitated no REM ↑ symp	Tachycardia ↓HRV	warm	Adrenergic Acidemic	Desat in apnea; ↑ Sat	↑ Tidal movemt+ shifting body movemt	↑ wt loss + shifting pressure + rostral edema

Figure 8. Example Embodiment – Sensed Signature in Sleep Disorders

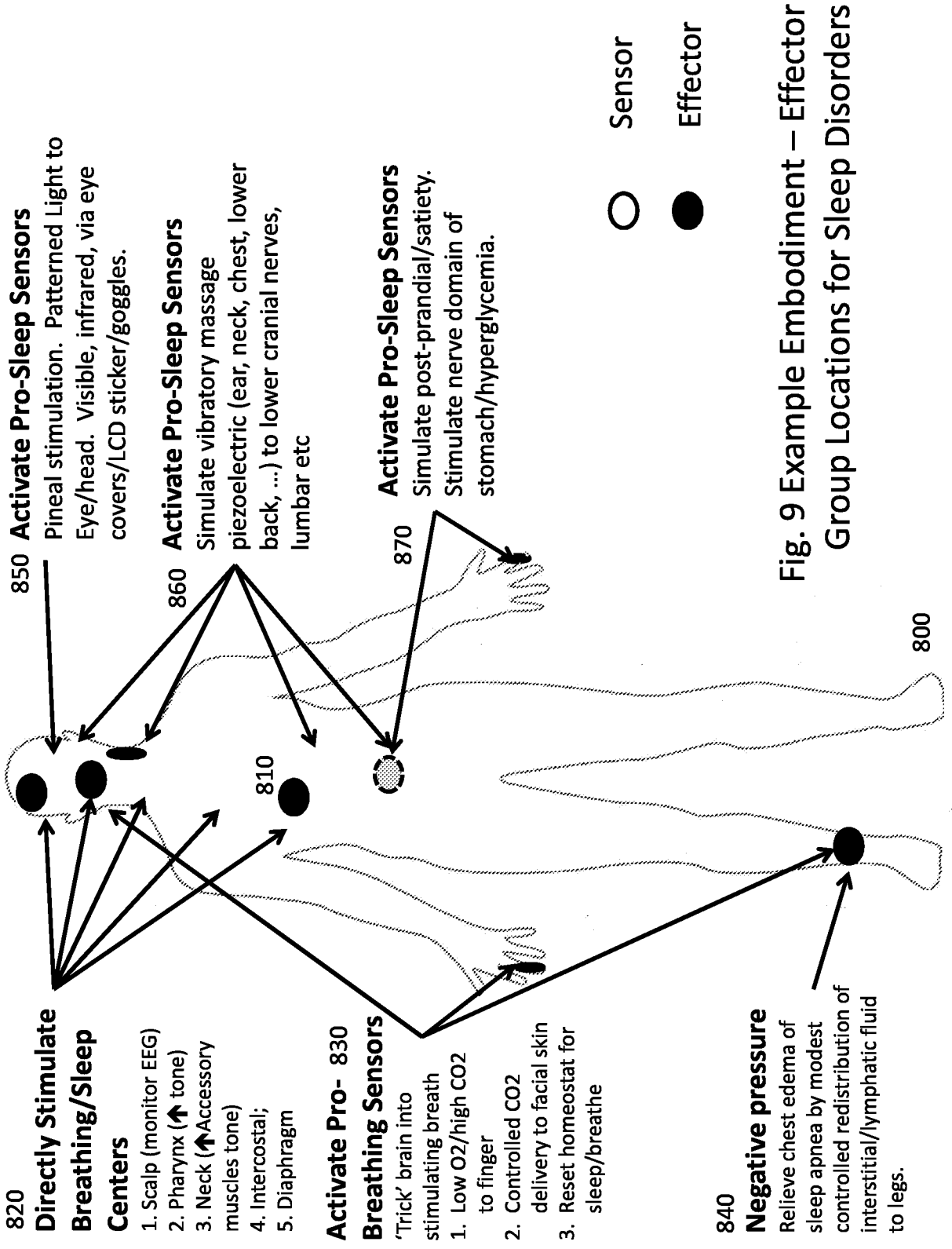


Fig. 9 Example Embodiment – Effector Group Locations for Sleep Disorders

	Sensor and Sensed Signature – Heart Failure								
Type/ Category	**Impedance**	**Electrical (Other)**			**Heat**	**Chemical**	**Optical**	**Motion**	**Pressure/ Acoustic**
Condition	**Skin sensor, e.g. Head/chest (Rostral) vs periphery**	**Skin Nerve Firing, e.g. Peripheral**	**Skin Nerve Firing, e.g. Mini EEG**	**Skin ECG, e.g. Heart Rate**	**Temp, e.g.**	**Skin Chemical, e.g. Glucose/Na/ K/Cl/Urea/ HCO3 Lipid, drugs**	**Skin Color, e.g. O2 Sat, bile, CO,CO2 anemia**	**Accelerometer (both body and external), e.g. Activity**	**Skin Pressure, Barometric pressure e.g. Weight Piezoelectric**
Normal	Nml	Chest, Periph Nml Phasic	Nml	Nml	Nml	Nml	Nml	Nml	Nml
HFREF, volume overload	Neck/chest fall (edema)	↑Accessory movemt ↑Symp	Central sleep apnea pattern	Faster; HRV reduced	Cool	Clammy Adrenergic Acidemic	Pale for pt; ↑Deoxy Hb	↑ Tidal movemt+ ↓ leg movemt	↑ wt loss sedentary pressure + rostral edema
HFPEF, volume overload	Neck/chest fall (edema)	↑Accessory movemt ↑Symp	Central sleep apnea pattern	Faster HRV reduced	Cool	Clammy Adrenergic Acidemic	Pale for pt; ↑Deoxy Hb	↑ Tidal movemt+ ↓ leg movemt	↑ wt loss sedentary pressure + rostral edema

Figure 10. Example Embodiment – Sensed Signature of CHF

	Sensor and Sensed Signature – Response to Obesity								
Type/ Category	**Impedance**	**Electrical (Other)**			**Heat**	**Chemical**	**Optical**	**Motion**	**Pressure/ Acoustic**
Condition	**Skin sensor, e.g.** **Head/chest (Rostral) vs periphery**	**Skin Nerve Firing, e.g.** **Peripheral**	**Skin Nerve Firing, e.g.** **Mini EEG**	**Skin ECG, e.g.** **Heart Rate**	**Temp, (may also use ambient temp sensors for relative changes) e.g. skin, ambient temp**	**Skin Chemical, e.g. Glucose/Na/K /Cl/Urea/ HCO3 Lipid, drugs**	**Skin Color, e.g. O2 Sat, bile, CO,CO2 anemia**	**Accelerometer (both body and external), e.g.** **Activity**	**Skin Pressure, barometric pressure e.g.** **Weight Piezoelectric**
Under weight	↑Overall Regional variations	Nml	Nml	Nml	Nml	↑Ketones, urea	Nml	Nml	↓ regional
Normal	Nml	Nml	Nml	Nml	Nml	Nml	Nml	Nml	Nml
Obesity	↓Overall Regional variations	Chest, ↑ sympathetic tone	Obstruc sleep apnea pattern	Nml	Nml	Possible pre-diabetic (↑glycemia)	Nml	↓Legs	↑ regional

Figure 11. Example Embodiment – Sensed Signature of Response to Obesity

	Sensor and Sensed Signature – Other								
Type/ Category	Impedance	Electrical (Other)			Heat	Chemical	Optical	Motion	Pressure/ Acoustic
Sensor	Skin Impedance	Skin Nerve Firing	Skin Nerve Firing	Skin ECG	Skin, ambient Temp	Skin Chemical	Skin Optical	Body Accelerometer, External activity sensor	Skin Pressure, barometric pressure
Parameter	Head/chest (Rostral) vs periphery	Peripheral	Mlni EEG	Heart Rate		Glucose/Na/ K/Cl/Urea/ HCO3 Lipid, drugs	O2 Sat, bile, CO,CO2 anemia	Activity	Weight Piezoelectric
COPD	↓Chest	↑Chest sympath	EEG agitated α β	Nml	Nml	↑CO2 ↓O2	Cyanotic	↑accessory muscles	Nml

Figure 12. Example of Sensed Signatures for other conditions

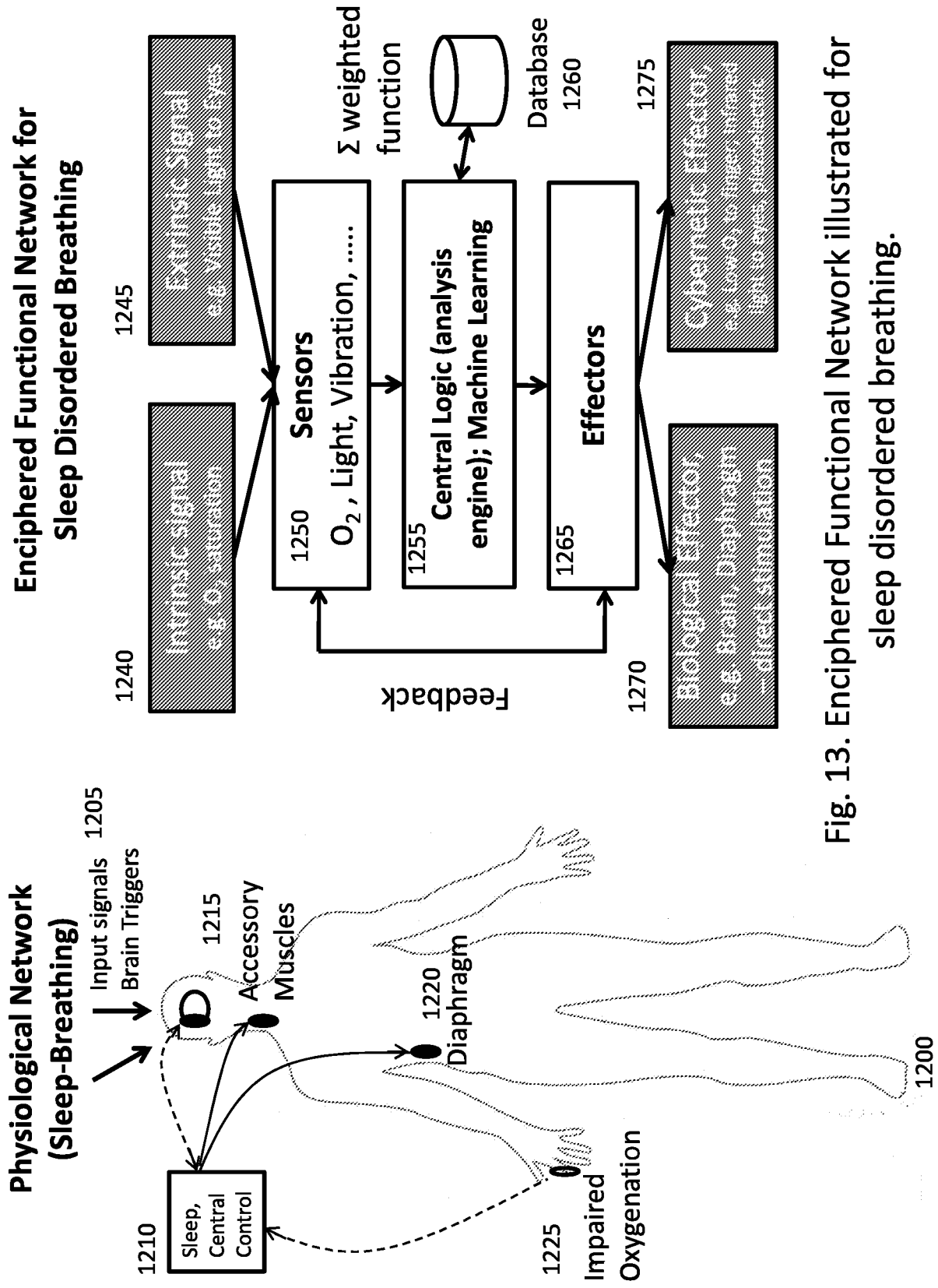


Fig. 13. Enciphered Functional Network illustrated for sleep disordered breathing.

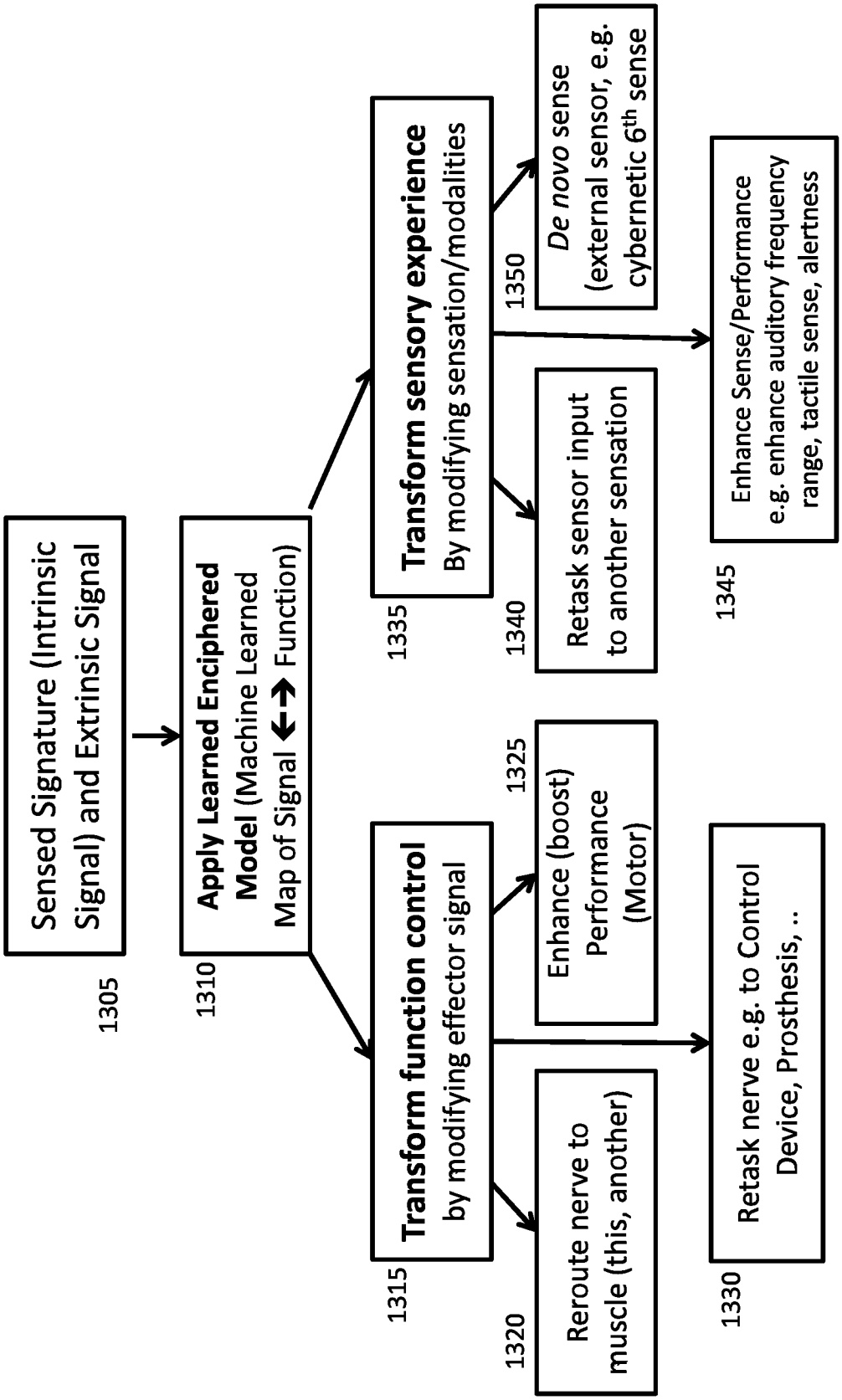
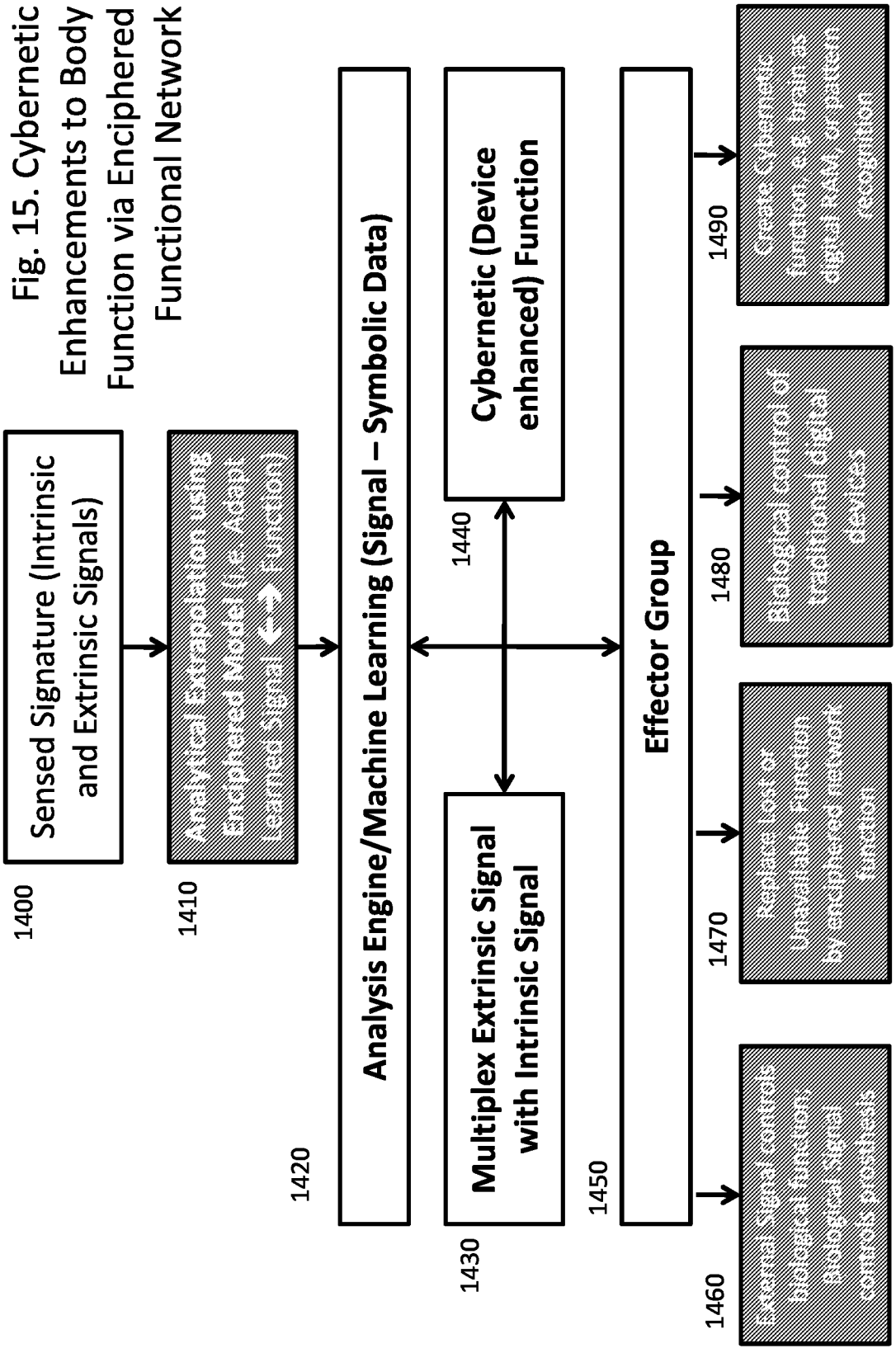


Fig. 14. Enhance Body Function via Enciphered Functional Network

Fig. 15. Cybernetic Enhancements to Body Function via Enciphered Functional Network



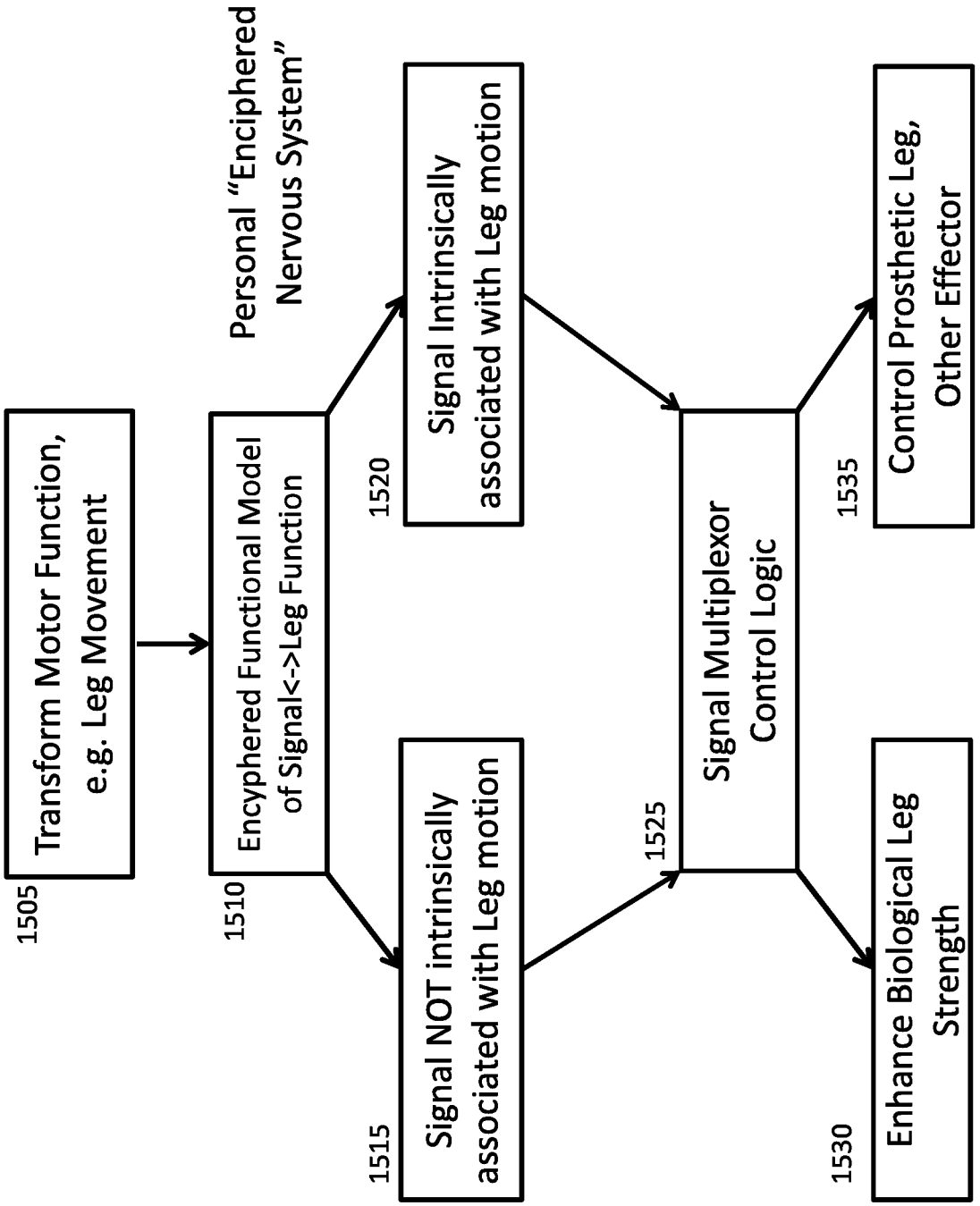


Fig. 16 Example Transformation of Motor Function

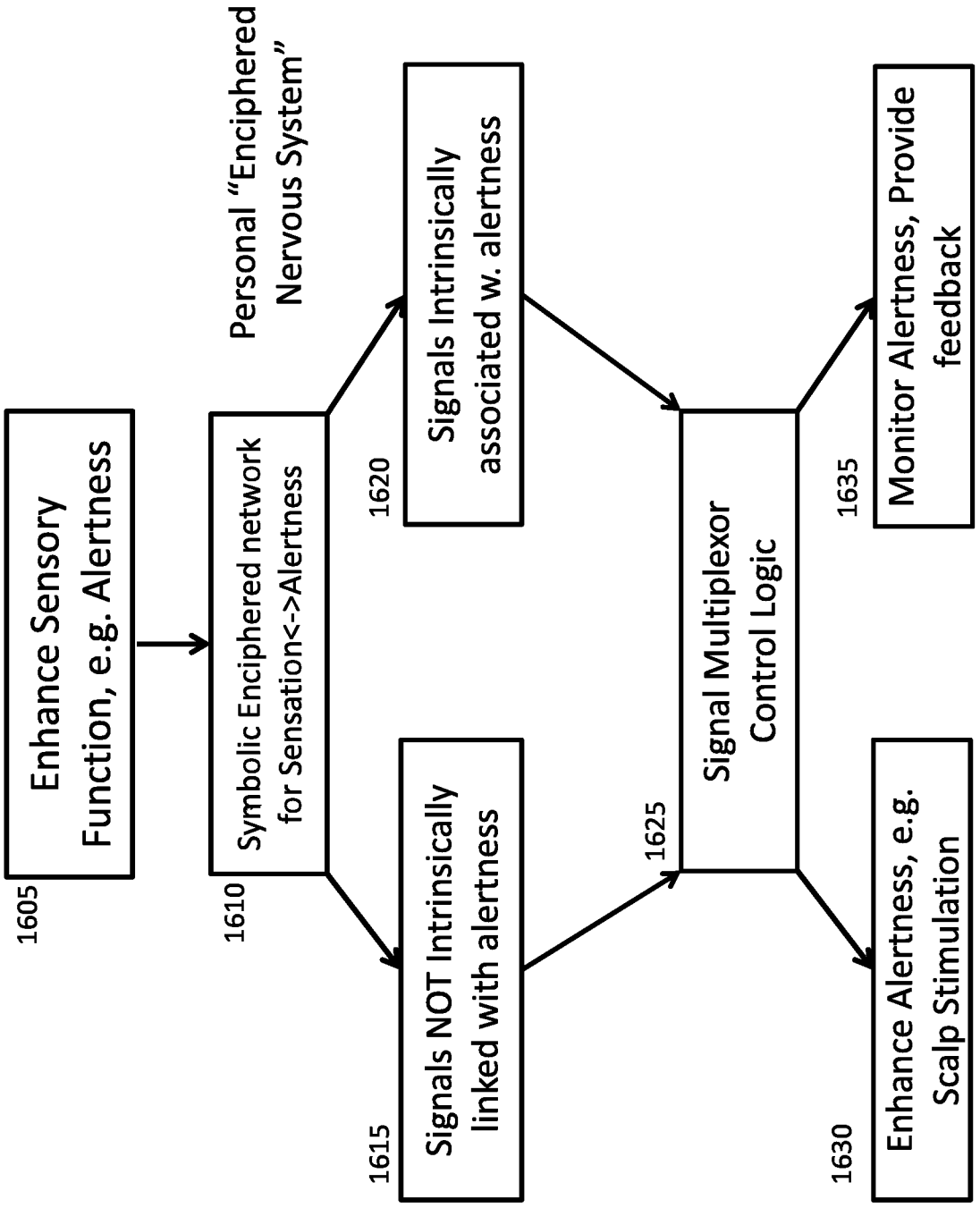


Fig. 17. Example of enhancing sensory function

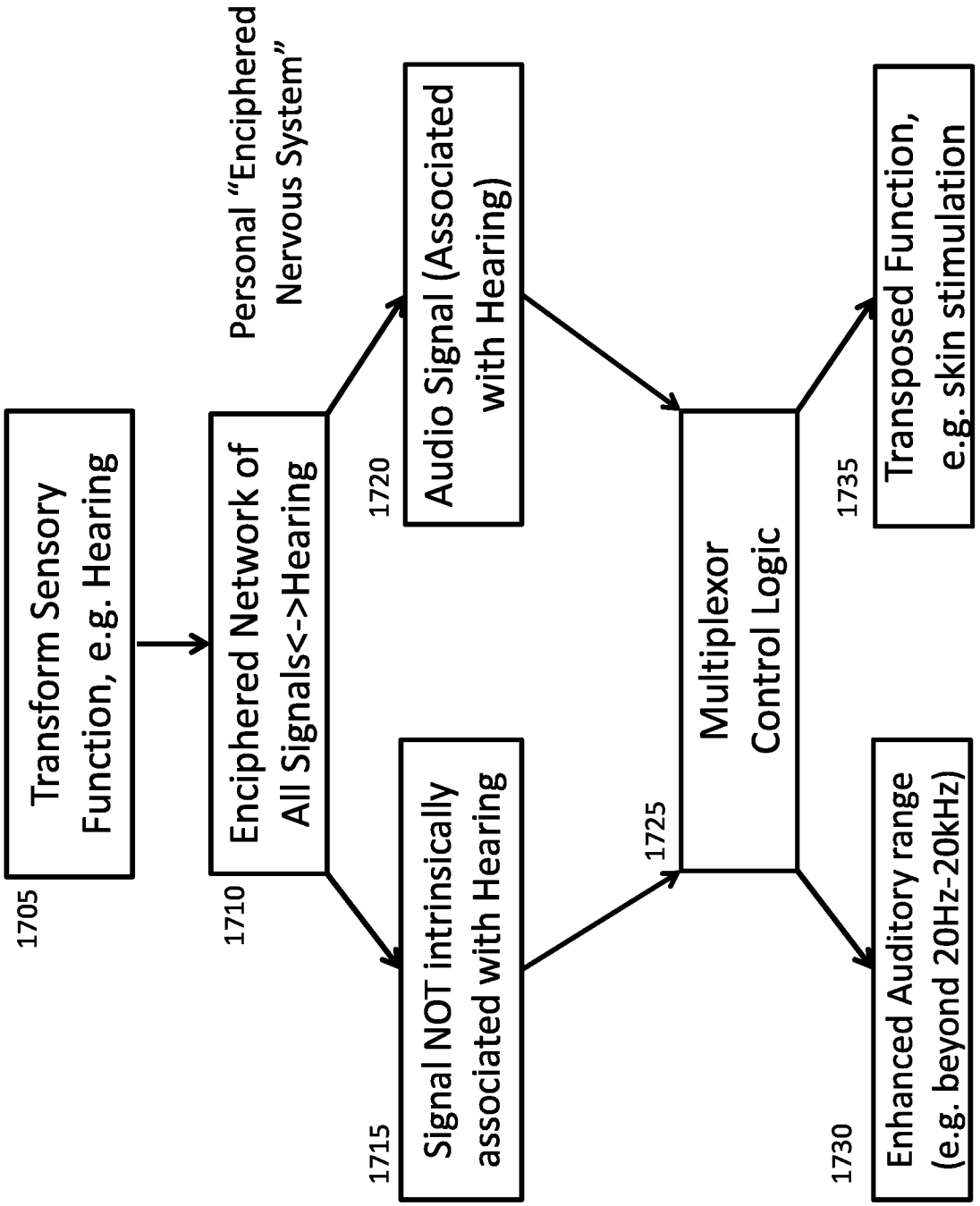


Fig. 18. Example Transformation of Sensory Function

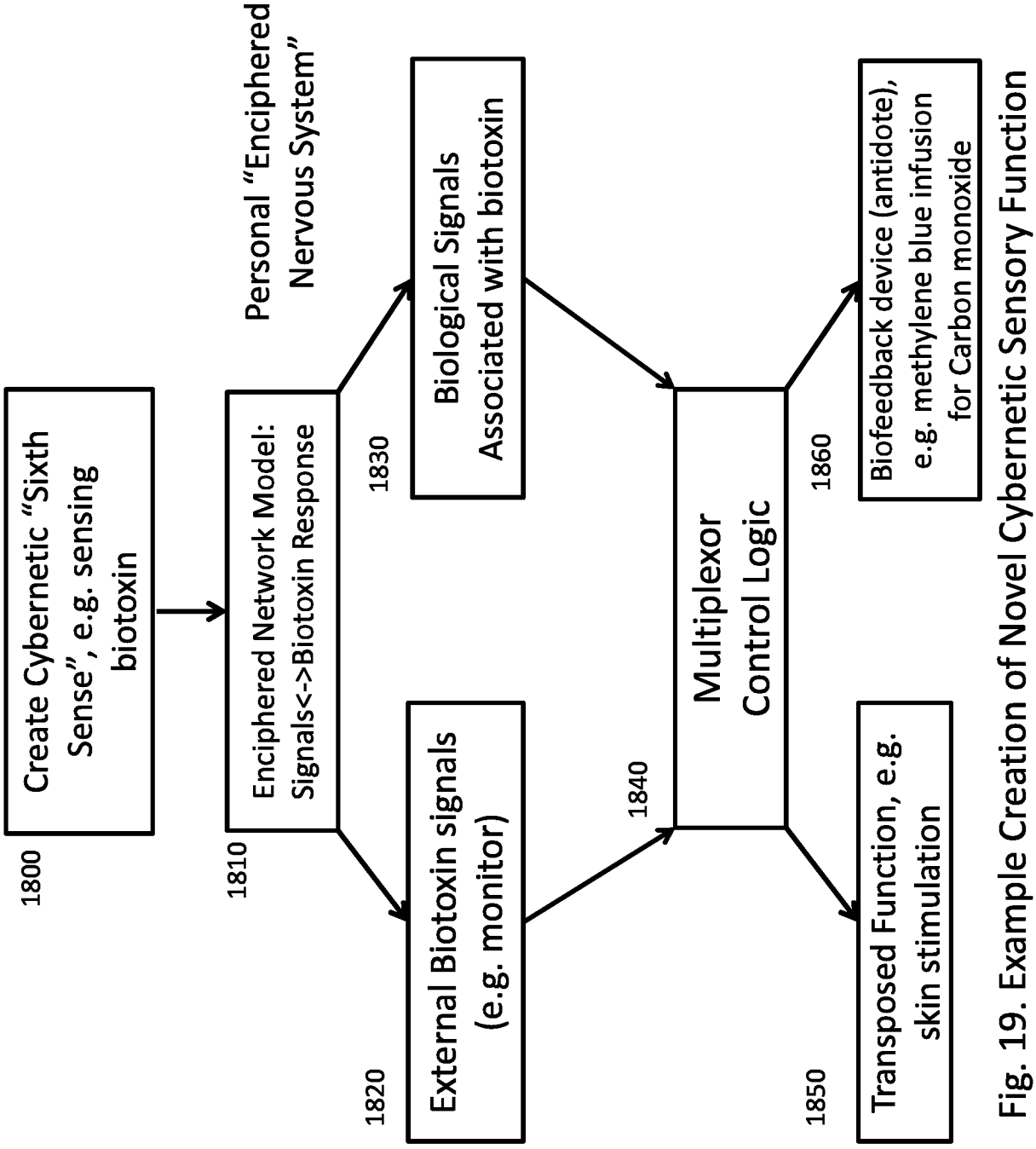


Fig. 19. Example Creation of Novel Cybernetic Sensory Function

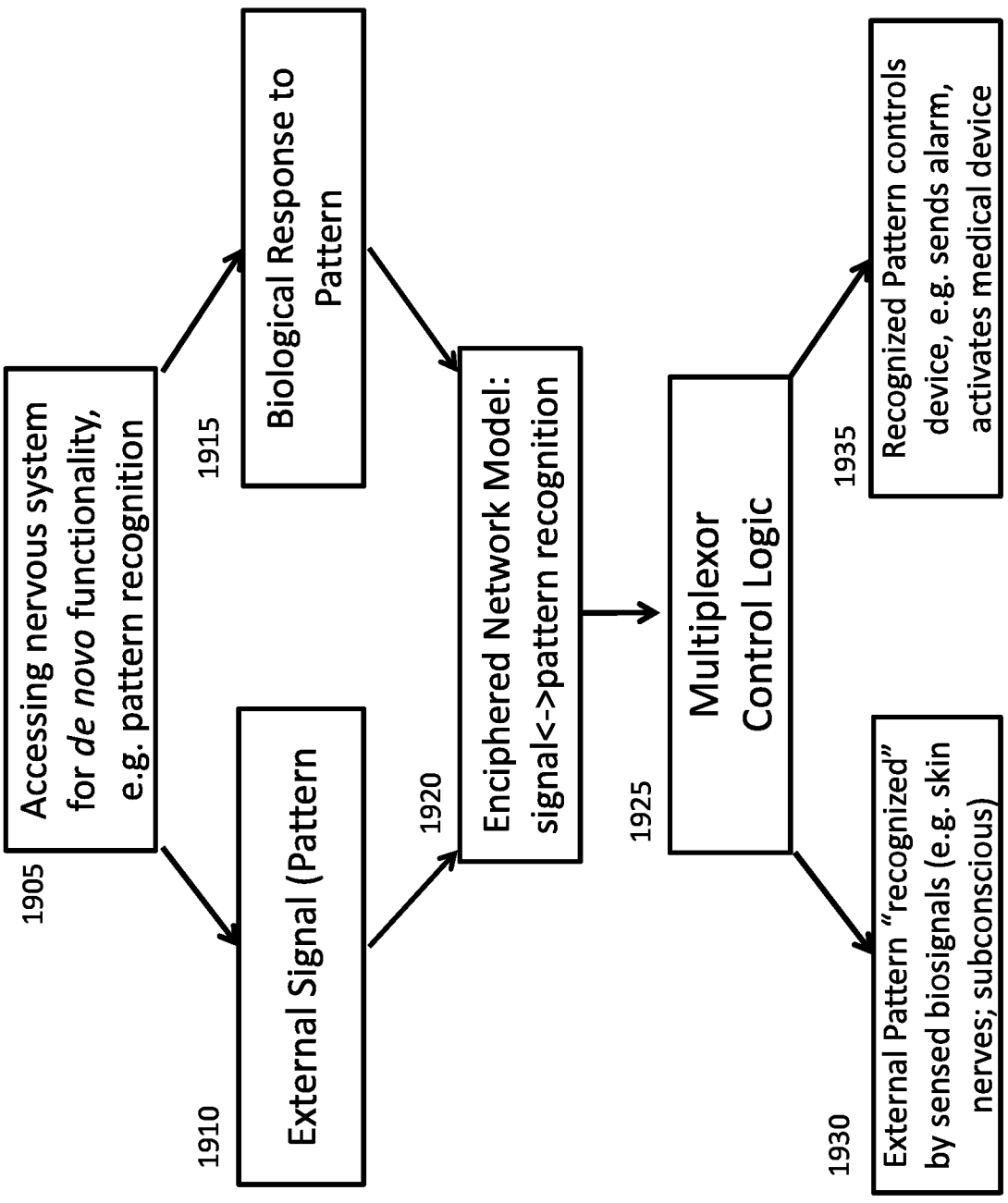


Fig. 20. Another Example of Creating Novel Cybernetic Sensory Function

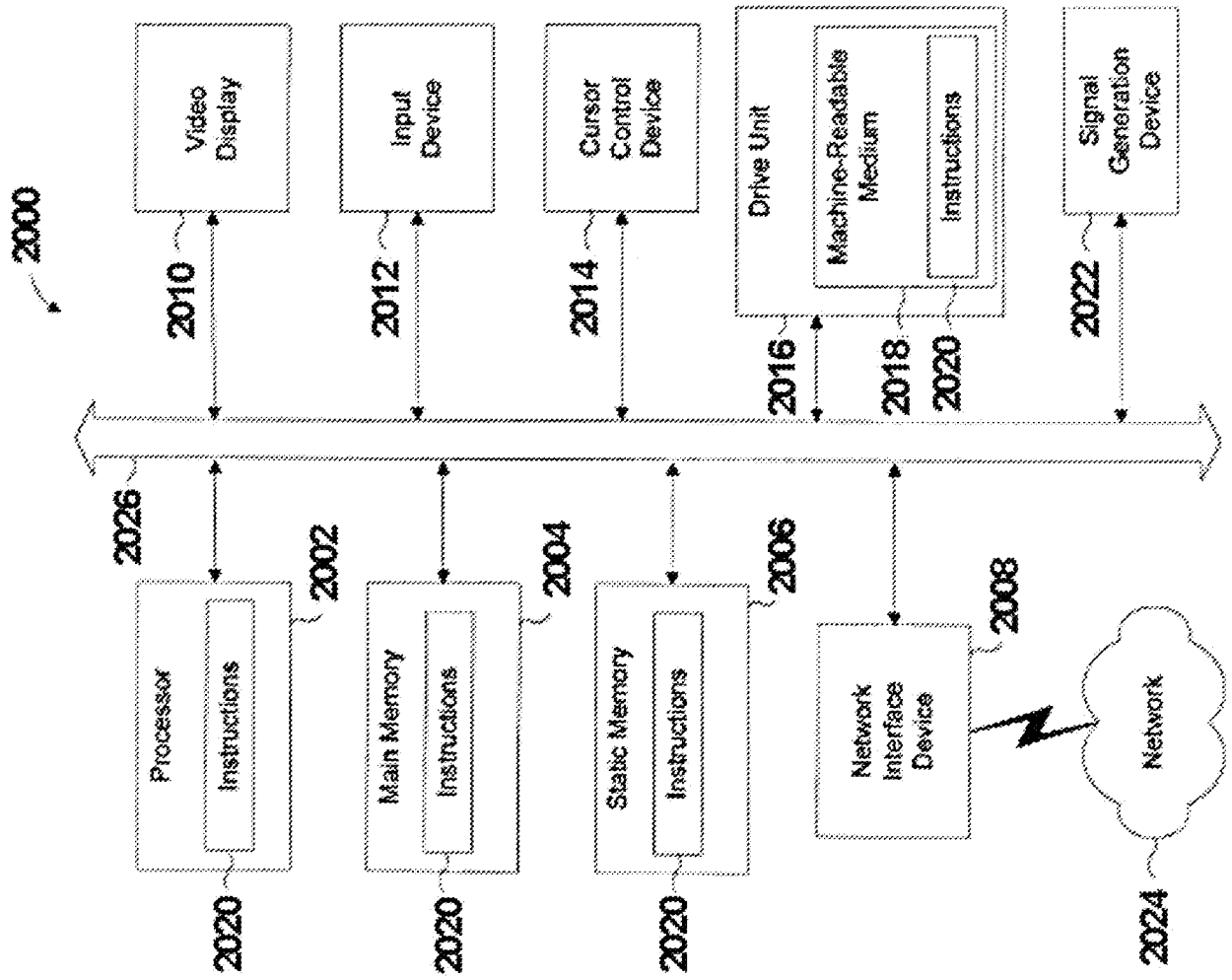

2000
Video Display
2010
Input Device
2012
Cursor Control Device
2014
Drive Unit
Machine-Readable Medium
Instructions
2016
2018
2020
Signal Generation Device
2022
2026
Processor
Instructions
2002
2020
Main Memory
Instructions
2004
2020
Static Memory
Instructions
2006
2020
Network Interface Device
2008
Network
2024

Fig. 21

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2015/047820

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-16, 140, 151, 162

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/047820

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B5/00 A61B5/04
ADD.

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 practicable, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	MALASRI K ET AL: "Securing wireless implantable devices for healthcare: Ideas and challenges", IEEE COMMUNICATIONS MAGAZINE, IEEE SERVICE CENTER, PISCATAWAY, US, vol. 47, no. 7, 1 July 2009 (2009-07-01), pages 74-80, XP011282138, ISSN: 0163-6804, DOI: 10.1109/MCOM.2009.5183475 IMDs; page 77 Data Encryption; page 78; figures 2, 5 Addressing Data Spoofing; page 79 ICDs; page 79 figure 1 ----- -/--	1-16, 140,151, 162

[X] Further documents are listed in the continuation of Box C. [ ] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"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
27 October 2015	12/01/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Weiss-Schaber, C

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Form PCT/ISA/210 (second sheet) (April 2005)

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2015/047820

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	ALEMDAR H ET AL: "Wireless sensor networks for healthcare: A survey", COMPUTER NETWORKS, ELSEVIER SCIENCE PUBLISHERS B.V., AMSTERDAM, NL, vol. 54, no. 15, 28 October 2010 (2010-10-28), pages 2688-2710, XP027289934, ISSN: 1389-1286 [retrieved on 2010-05-11] 2.2 Personal Area Network Subsystem; page 2691 - page 2692 2.5 End-user healthcare monitoring application; page 2692 - page 2693 4.7.1 Security; page 2706 4.7.2 Privacy; page 2706	1-16, 140,151, 162
X	JEONGGIL KO ET AL: "Wireless Sensor Networks for Healthcare", PROCEEDINGS OF THE IEEE., vol. 98, no. 11, 1 November 2010 (2010-11-01), pages 1947-1960, XP055221750, US ISSN: 0018-9219, DOI: 10.1109/JPROC.2010.2065210 A. Medical Sensing; page 1948 - page 1949 B. Wireless Sensor Platforms; page 1949 III . HEALTHCARE APPLICATIONS; page 1949 - page 1950 B. Privacy and Security; page 1951 - page 1953 C. Large-Scale Physiological and Behavioral Studies; page 1953 - page 1955	1-16, 140,151, 162
A	NATHANAEL PAUL ET AL: "A Review of the Security of Insulin Pump Infusion Systems Author Affiliations", JOURNAL OF DIABETES SCIENCE AND TECHNOLOGY VOLUME DIABETES TECHNOLOGY SOCIETY J DIABETES SCI TECHNOL, vol. 55, no. 6, 1 November 2011 (2011-11-01), pages 1557-1562, XP055139696, Category 3: Continuous Glucose Monitor; page 1560 Confidentiality; page 1561 Conclusion; page 1561 - page 1562	1-16, 140,151, 162

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FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-16, 140, 151, 162

   Controlling a bodily task
   ---

2. claims: 17-29, 141, 152, 163

   Performance Enhancement of a bodily task
   ---

3. claims: 30-36, 142, 153, 164

   Treatment of disease
   ---

4. claims: 37-61, 143, 154, 165

   Transforming nerve activity
   ---

5. claims: 62-67, 144, 155, 166

   Controlling a device
   ---

6. claims: 68-74, 145, 156, 167

   Measurement method
   ---

7. claims: 75-78, 146, 157, 168

   Improving human performance
   ---

8. claims: 79-84, 147, 158, 169

   Treatment of sleep disorder
   ---

9. claims: 85, 86, 148, 159, 170

   Treatment of attention disorder
   ---

10. claims: 87-127, 149, 160, 171

    Treating central sleep apnea
    ---

11. claims: 128-139, 150, 161, 172

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Modulating mental function

专利名称(译)	用于组合生理和机器信息以增强功能的方法和系统		
公开(公告)号	EP3185755A1	公开(公告)日	2017-07-05
申请号	EP2015766279	申请日	2015-08-31
[标]发明人	NARAYAN SANJIV M SEHRA RUCHIR		
发明人	NARAYAN, SANJIV, M. SEHRA, RUCHIR		
IPC分类号	A61B5/00 A61B5/04		
CPC分类号	A61B5/04001 A61B5/40 A61B5/6877 A61B5/4836 A61B5/7267 G16H50/70 A61B5/01 A61B5/0205 A61B5/024 A61B5/0402 A61B5/0408 A61B5/0476 A61B5/0488 A61B5/04888 A61B5/0492 A61B5/0531 A61B5/0816 A61B5/14539 A61B2560/0242 A61F2/72		
优先权	62/043760 2014-08-29 US PCT/US2015/046819 2015-08-25 WO		
外部链接	Espacenet		

摘要(译)

本发明一般地且具体地涉及使用机器学习将生物传感器与外部机器组合以形成可以控制效应器来递送治疗或增强性能的计算机化表示。