Abstract:

Title: BRAIN STIMULATION AND REHABILITATION HELD OF THE INVENTION

A method of rehabilitation management, comprising: providing a plurality of patients fitted with sensors; assigning tasks to said patients by a therapist; rehabilitating said patients not under the direct attention of said therapist; and monitoring the rehabilitating using data acquired by the sensors during performance of the tasks.
BRAIN STIMULATION AND REHABILITATION

FIELD OF THE INVENTION

The present invention relates to stimulating the brain, for example, as part of a rehabilitation process.

BACKGROUND

It has been found that stimulating the brain may have a beneficial effect on plasticity and hence on rehabilitation. Northstar Inc., a USA company, sells implantable stimulators for use in conjunction with rehabilitation. Following is a list of patent publications by this company, which generally relate to implantable brain stimulators, the disclosures of which are incorporated herein by reference:

WO06053143A2, WO06053114A2, WO06019766A2, WO06019764A2,
WO05068012A1, WO05011805A2, WO05002665A2, WO05002664A2,
WO05000153A2, WO04066820A2, WO04052183A2, WO04058347A1,
WO04052449A1, WO04052448A1, WO04050175A1, WO04036765A2 and
WO03082402A2.

A PCT application entitled MOTOR TRAINING WITH BRAIN PLASTICITY filed on 18 August, 2005 and published as WO 2006/021952 (fully incorporated herein by reference) describes use of measured brain parameters in conjunction with physical therapy.

Pope et al. (Identification of hazardous awareness states in monitoring environments (1992) 22nd International Conference on Environmental Systems; Seattle, WA; USA; pp. 1-9; fully incorporated herein by reference) describe a state identification procedure and model which provide a capability for evaluating the design of advanced flight deck automation concepts based on the pilot's ability to maintain effective states of awareness.

Hummel et al. (Effects of non-invasive cortical stimulation on skilled motor function in chronic stroke(2005)Brain 128:480-499; fully incorporated herein by reference) describes a double blind, Sham-controlled, crossover study conducted to test the hypothesis that non-invasive stimulation of the motor cortex could improve motor function in the paretic hand of patients with chronic stroke. Hand function was measured using the Jebsen-Taylor Hand Function Test (JTT). JTT measured in the paretic hand improved significantly with non-invasive transcranial direct current stimulation (tDCS), but not with Sham. The effect persisted after the stimulation
period in all patients tested and correlated with an increment in motor cortical excitability within the affected hemisphere, expressed as increased recruitment curves (RC) and reduced short-interval intracortical inhibition. These results document a beneficial effect of non-invasive cortical stimulation in patients with chronic stroke.

Hesse et al (Combined transcranial direct current stimulation and robot assisted arm training in subacute stroke patients: A pilot study (2007)) Restorative Neurology and Neurosciences 25: 9-15; fully incorporated herein by reference) describe a use of transcranial direct stimulation (tDCS) with robot-assisted arm training (AT) to inform planning a larger randomized controlled trial. Subjects received thirty 20 min-sessions of AT over six weeks. During the first 7 minutes, 1.5mA of tDCS was applied, with the anode over the lesioned hemisphere and the cathode above the contralateral orbit. Arm and language impairment were assessed with the Fugl-Meyer motor score (FM, full range 0-66) and the Aachener Aphasie Test. No major side effects occurred. Arm function of three patients out often (two with a subcortical lesion) improved significantly, with FM scores increasing from 6 to 28, 10 to 49 and 11 to 48. In the remaining seven patients with cortical lesions, arm function changed little and FM scores did not increase more than 5 points. Unexpectedly, aphasia improved in 4 patients. These results confirm the safety of tDCS and its potential clinical utility in treatment of aphasia.

Simple neurofeedback devices are commercially available. Examples of commercially available neurofeedback devices include those manufactured by S.M.A.R.T. BrainGames (owned by CyberLearning Technology, LLC) based on technology described in US Patents 5,377,100 and 6,450,820 (each fully incorporated herein by reference). These BCIs are intended for use with standard video games (e.g. playstation).

US 5,377,100 describes neurofeedback devices in which brain electrical activity is measured to determine levels of awareness and the difficulty level of the game is increased as the awareness level value decreases and is decreased as this awareness level value increases.

US 6,450,820 describes apparatus and methods for modulating control function of a computer simulation or game input device using physiological information so as to affect the user's ability to impact or control the simulation or game with the input device. Control modulation can be used along with a computer
simulation or game, to affect physiological state or physiological self-regulation according to some programmed criterion (e.g., increase, decrease, or maintain) in order to perform better at the game task.

Near-infrared spectroscopy (NIRS) is a technique for the non-invasive monitoring of cerebral hemodynamics and oxygenation. In NIRS light photons are injected into the skin over the motor cortex. Quantitation of reflectance as a function of wavelength is used to calculate concentrations of Hemoglobin and Deoxyhemoglobin. Once these concentrations are known, oxygen saturation levels (rSO2) can be calculated. Typically, NIRS employs an array of sensors each operating at multiple wavelengths to produce a map of oxygen saturation in an area in which the sensors are deployed. Typically NIRS sensors can be applied with less skin preparation than standard EEG electrodes.

Northstar Inc. has published plans for a feasibility study to evaluate an implanted cortical stimulation device (CSD):

(www.DOTnorthstarneuroDOTconi/clinicaltrials/patient_aphasia.asp; fully incorporated herein by reference)

with regard to its safety and effectiveness in improving the speech of chronic stroke patients with Broca’s aphasia (inability to speak or to organize muscular movements of speech). In the study, the experimental group will undergo surgery to implant the CSD and then undergo a speech-language therapy program. According to the protocol, the CSD is activated only during the speech-language therapy sessions at a level not felt by the patients. The CSD is to be removed approximately 2 weeks after the speech-language therapy is complete. A control group will participate in the same speech-language therapy sessions but will not have the CSD implanted. After speech-language rehabilitation is complete, participants from experimental and control groups will return for periodic follow-up visits.

SUMMARY OF THE INVENTION

An aspect of some embodiments of the invention relates to providing a response to a measured brain activity, wherein the response is designed to control the brain activity. According to various exemplary embodiments of the invention, the response can include one or more of guided imagination, cerebral stimulation (e.g. electrical or magnetic), visual image presentation, auditory stimulation, olfactory stimulation and motor stimulation.
In an exemplary embodiment of the invention, the response is provided as an adjunct to a therapy program, optionally during performance of therapy tasks or during a therapy session. Optionally, the therapy program includes one or more of visual presentation (e.g. as a series of images on a display), mechanical manipulation (e.g. by a passively or actively operated mechanical device) and guided imagination (e.g. an instruction to "imagine you are bending your left elbow to bring the palm of your hand to your right shoulder".

Optionally, visual presentation can be of therapy tasks and/or a portion of the response. In an exemplary embodiment of the embodiment the visual presentation comprises a video or animation sequence. In an exemplary embodiment of the invention, a controller receives an output signal indicative of the brain activity from a sensor and adjusts an administered therapy task as part of a response to the output signal.

In an exemplary embodiment of the invention, the apparatus is used for closed loop rehabilitation, where the input for the control loop comprises one or more of rehabilitation progress, physiological measures (e.g. O₂ saturation of relevant portions of the brain), quality of electrical sensing from brain (e.g. a signal to noise ratio), sensed brain signals and the output comprises changes in one or more of rehabilitation plan, rehabilitation exercise parameters, electrode location for sensing and/or stimulation parameters.

In an exemplary embodiment of the invention, an output signal from the sensor serves as an input signal for a brain computer interface (BCI) and the administered therapy comprises Transcranial Direct Current Stimulation (tDCS; Nitsche et al. (2003) Suppl. Clin. Neurophysiol. 56:255-276 and Paulus (2003) Suppl. Clin. Neurophysiol. 56:249-254; the contents of which are each fully incorporated herein by reference). Optionally, the BCI operates in conjunction with a robotic training element (e.g. motorized) to provide a stimulus for brain activity. Optionally, the BCI provides a biofeedback signal which indicates to the patient what effect on brain activity is sensed.

In an exemplary embodiment of the invention, the BCI trains a patient to distinguish (e.g., generate selectively) a desired pattern of brain activity associated with imagination of different simple motor actions, such as right or left hand movements. In an exemplary embodiment of the invention, the patient is trained to
regulate and to control their EEG. Optionally, control of EEG is achieved by implementing an algorithm which evaluates EEG patterns and presents a feedback to the patient in a simpler format (e.g. audible signal and/or presentation of a symbol on a computer screen).

In an exemplary embodiment of the invention, a person controls a computer based system using the BCI by changing specific parameters of their brain activity. Optionally, parameters can include one or more of mu rhythm, CNV and SCP. Optionally, different parameters can be used in a single BCI to control different applications.

In an exemplary BCI embodiment of the invention, a person's brain activity is recorded by EEG electrodes and the BCI software analyses the mu rhythm intensity of the recording. Optionally, if the intensity is below a set threshold, the software sends an electric stimulation signal to the brain to raise the brain activity to the threshold. When the intensity threshold is reached, the software cues the robot to move its arm (attached to the patients' hand) and/or shuts off the stimulation. In an exemplary embodiment of the invention, movement of the robot contributes to a positive feedback to the patient. Optionally, the positive feedback informs the person that brain activity was successfully changed.

A broad aspect of some embodiments of the invention relates to apparatus for stimulating brain tissue in conjunction with rehabilitation, the stimulation being external to the body.

In an exemplary embodiment of the invention, the apparatus comprises an ergonomic helmet which is adjustable per patient. In an exemplary embodiment of the invention, at least some parts of the helmet contacting a patient are disposable, for example, electrodes are disposable.

An aspect of some embodiments of the invention relates to using a same helmet design which includes electrodes for sensing and/or stimulating means at multiple types of locations. In an exemplary embodiment of the invention, the helmet is used in a plurality of locations selected from: hospital bed, hospital clinic, rehabilitation clinic, neurologist clinic, old age home, community center, home bed, home chair, home computer station and/or home ambulatory use. In an exemplary embodiment of the invention, the helmet is used in at least 3, at least 4, at least 5, or a
greater number of these locations. In an exemplary embodiment of the invention, the helmet is ported by a patient and/or while being worn by a patient.

In an exemplary embodiment of the invention, the helmet includes means for ensuring that stimulation and/or sensing are applied in a repeatable manner to desired locations on the skull and/or inside the brain.

By "helmet" is meant a device attached to and/or mounted on the head, which may be in the form, for example, of a skull cap, cap, hat a full helmet and/or a head band.

Optionally, the helmet can be provided as a detachable module, integrated into a larger therapy apparatus (e.g. attached to a chair, to a bed, fMRI system, to a rehabilitation robot). In an exemplary embodiment of the invention, helmets are designed in consideration of an intended use location(e.g. a therapy room or the patients home). In an exemplary embodiment of the invention, the helmet is cordless or equipped with a connecting cords sufficiently long to facilitate unfettered motion of a wearer throughout the intended use location.

In an exemplary embodiment of the invention, the helmet communicates with an external controller via a port (e.g. USB or bluetooth). Optionally, the external controller is incorporated into a stationary device (e.g. desktop computer) or a portable device (e.g. cellular telephone or personal digital assistant). In an exemplary embodiment of the invention, a portable therapy system is provided to a patient by providing a helmet with brain activity sensors and stimulation electrodes which communicate with a portable controller. Optionally, the portable controller is attached to or incorporated in the helmet.

In an exemplary embodiment of the invention, the helmet is associated with a safety circuit which prevents stimulation in certain cases. In an exemplary embodiment of the invention, stimulation is prevented if sensing is abnormal, if helmet is placed incorrectly and/or if patient is deemed incapable of handling more stimulation and/or rehabilitation.

In an exemplary embodiment of the invention, the helmet is associated with a data logger, which logs, for example, data generated by the helmet, patient information sensed by the helmet or by other means, external events and/or information sent from external devices. For example logging can include logging of one or more of activity events (e.g., related and/or unrelated to rehabilitation), sensed
signals, stimulation parameters (optionally including stimulation position), helmet operation, placement accuracy and/or physiological data, such as ECG and/or brain O2 saturation map data. Optionally, the logging includes logging activity at a home computer, for example, for tracking usage thereof in conjunction with a rehabilitation process.

In an exemplary embodiment of the invention, in ambulatory and/or home use, the helmet is associated with a data transmitting and/or instruction receiving unit, for example, a cellular telephone and/or a wireless or wired link to a personal computer. In some embodiments, during ambulatory use, only electrical stimulation is available. In others, no stimulation is available. In others, magnetic or other stimulation is available.

In an exemplary embodiment of the invention, for example for home and/or ambulatory use, the helmet is associated with and controls and/or receives data from one or more body sensors and/or stimulation units, for example, a sensor which measures limb position (or movement thereof) and/or visual stimulation by a computer display or DVD player. Optionally, the data is sent to a controller separate from the helmet which coordinates the activities/sensing of the helmet and sensors/stimulation units.

In an exemplary embodiment of the invention, clinical use by a neurologist is as follows. A patient is set up in a rehabilitation station (e.g., is stationed and a helmet attached to him and/or a rehabilitation system attached to him) and a neurologist sets up stimulation settings and/or applies stimulation.

Monitoring of the patient rehabilitation activity is optionally by computer and/or a nurse. When needed, the neurologist may be called to apply a new stimulation and/or assess the effects of a previously applied stimulation.

In an exemplary embodiment of the invention, the helmet can control internal (to the person) stimulation electrodes. In an exemplary embodiment of the invention, the helmet sends a control signal to a control box that is inside or outside the patient's body, which box powers and/or controls the stimulation electrodes. The signal may, for example, set stimulation parameters, trigger stimulation, prevent stimulation and/or select which of a plurality of implanted electrodes to stimulate. Optionally, the helmet includes or is associated with a power transmitter adapted to send power to the implanted electrodes and/or a controller thereof.
An aspect of some embodiments of the invention relates to a helmet device with position adjustable electrodes for sensing and a position adjustable stimulation system. In an exemplary embodiment of the invention, the stimulation system comprises magnetic stimulation. Alternatively or additionally, the stimulation system comprises electrical stimulation. Alternatively or additionally, other stimulation methods, for example as known in the art of brain stimulation, may be used.

In an exemplary embodiment of the invention, the helmet provides external stimulation which interacts with an implanted stimulation device. Optionally, the helmet receives control signals from the implanted stimulation device and/or synchronizes the external stimulation to stimulation from the implanted device. Optionally, the external stimulation interacts with a software module which can control it. According to various exemplary embodiments of the invention, control of the external and/or internal stimulation devices can be exercised by a helmet component or an external controller. For example, an external controller can control both implanted and external stimulation devices. Optionally, this configuration facilitates tuning of internal and external stimulation one to the other, and helmet so that you can then tune one or the other.

In an exemplary embodiment of the invention, parameters of stimulation protocol (e.g. DC pulsatile, bursts or oscillative), intensity, duration, phase, period and other characteristics of the signal, are determined by the type of the motor exercise (e.g. exercise mode, needed force, duration, range of motion) and/or are adjusted in response to a measure brain activity. Optionally, determination and/or adjustment of stimulation parameters is made in accord with a table or rule set or database or expert system or software module that matches parameters with type of motor exercise and/or measured brain activity. In an exemplary embodiment of the invention, a table or rule set or database or expert system or software module is customized to an individual patient.

In an exemplary embodiment of the invention, the adjustable electrodes are each adjustable in two axes. In an exemplary embodiment of the invention, the axes are perpendicular circumferential axes (e.g., treating the skull as a generalized sphere). Optionally, the electrodes lock in place once adjusted. Optionally, the electrodes are adjustable by hand. Alternatively or additionally, the electrodes are
adjustable using a motor, for example, a motor that is manually controlled and/or under computer control.

In an exemplary embodiment of the invention, an adjustable stimulator rides on a joint which supports motion of the stimulator in a surface parallel to the shape of the skull (or an idealization thereof, such as an ovoid).

In an exemplary embodiment of the invention, the helmet includes a head band section on which one or more elongate support elements are mounted, for example, 3, 4, 5 or 6 elongate elements, however other numbers, greater or smaller may be provided. An electrode may be selectively positioned on the elongate support element and the support element may be selectively positioned along the head band. Optionally, the elongate support elements are elastic and are biased to apply pressure on the skull. Optionally, the head band is adjustable in diameter and/or is flexible, so it can conform to a skull shape. Optionally, the head-band is plastically deformable by hand, to confirm to the skull shape.

Optionally, the helmet includes an ear electrode adapted to be located at or near an ear, for example, for providing a reference signal. Optionally, the ear electrode is mounted on an adjustable support element.

In an exemplary embodiment of the invention, the head band and/or electrodes and/or support elements are disposable, i.e., they are designed for single use. Optionally, the helmet includes or is associated with a control box, which is not disposable.

Optionally, the helmet includes a membrane adapted to fit on the skull, for example, in the form of a skull cap, and assist contact of electrodes with the skull. Optionally, a plurality of apertures are provided in the cap for the electrodes. Alternatively or additionally, the membrane is conductive through its thickness, and passes electrical signals from the skull to the electrodes. Optionally it has a lower conduction along the membrane. This lower conduction may be caused by a narrow thickness thereof.

In an exemplary embodiment of the invention, a stimulation element is provided which is selectively positionable relative to the helmet, for example, being mounted on a two axis joint.
Optionally, the helmet is marked with indications of standard stimulation and/or sensing locations. Alternatively or additionally, the helmet is marked with patient specific locations, for example, using a permanent marker.

An aspect of some embodiments of the invention relates to a helmet capable of sensing its correct configuration. In an exemplary embodiment of the invention, the helmet includes one or more sensors, for example, an encoder, which indicates a correct positioning of electrodes relative to the rest of the helmet. Optionally, the helmet does not operate if the electrode position does not match a preprogrammed electrode position.

In an exemplary embodiment of the invention, the helmet detects its position relative to the skull. Optionally, the position is detected based on measured electrical signals. Alternatively or additionally, the position is detected by matching of a detector on the helmet and a marker attached to the patient skull. If such matching fails, the helmet may be in an incorrect position. Two three or more markers can be provided. Alternatively or additionally, the marker includes a relative orientation indication (e.g., in the form of a graphic pattern).

An aspect of some embodiments of the invention relates to a helmet adapted for structural and/or functional attachment to a rehabilitation system. In an exemplary embodiment of the invention, the helmet is mounted on a rehabilitation system, thus reducing the weight applied to patient head.

In an exemplary embodiment of the invention, the helmet has a quick connect coupler for attachment and/or detachment from a rehabilitation system, for example a chair-based system.

In an exemplary embodiment of the invention, the helmet is balanced with a counter weight to reduce discomfort. Optionally, the coupler is adjustable, to match patient size and/or comfort.

In some embodiments of the invention, the helmet includes a circuit that controls the rehabilitation process. In other embodiments of the invention, the rehabilitation device controls the helmet (e.g., sets electrode sensing properties and/or stimulation properties) and/or uses signals from the helmet as triggers and/or input. Optionally, the helmet is designed to work also or only in a stand alone mode, in which the element measures and/or stimulates without an external command. In an
exemplary embodiment of the invention, the helmet stimulates in response to signals measured by the helmet or under helmet control.

In an exemplary embodiment of the invention, one or more articulated arms are used to hold the stimulation element and/or one or more electrodes for selective positioning on the skull. Optionally, helmet and/or head supports are provided at least for fixation of the patient head and/or marking of positions on the skull. Optionally, a vacuum connection, snap connection or other type of temporary connection is provided between the electrodes/stimulation element and the helmet. Such fixation may be useful, for example, when the helmet is provided as a rubber skull cap that does not limit patient head motion.

Optionally, the helmet includes at least one helmet electrode in the articulated arm embodiment. This is useful, for example, when the stimulation effect lasts several minutes and the patient is allowed to move his head during rehabilitation.

An aspect of some embodiments of the invention relates to a method of improving the accuracy of an external stimulation method, in which feedback and/or exact motion/stimulation of a body part (e.g. a limb or a portion of the mouth/face) are used to fine tune a position and/or focus an effect of stimulation. In an exemplary embodiment of the invention, stimulation at body portions other than the skull, for example, mechanical manipulation of a limb is used to increase sensitivity of the brain to external stimulation via the skull or via direct stimulation.

In an exemplary embodiment of the invention, measuring electrical signals from the skull in response to actuator-mediated motions or position sensor measured motions are used to indicate an exact location in the brain where stimulation may be useful and/or useful stimulation parameters.

In an exemplary embodiment of the invention, measuring electrical signals from the skull in response to initiated speech or other cognitive activity to indicate an exact location in the brain where stimulation may be useful and/or useful stimulation parameters.

In an exemplary embodiment of the invention, measuring an effect of brain stimulation on a motion of a body part, for example, using a position sensor and/or using an actuator attached to the body part (e.g. limb), are used to better select a desired stimulation point and/or stimulation parameters, and/or an optimal set of stimulating electrodes for each task (out of all the electrodes). Exemplary stimulation
parameters include, but are not limited to, intensity, duration, period, and protocol type. Exemplary protocol types include, but are not limited to, DC, pulsatile and oscillative. Optionally, motion of the body part can be measured in terms of direction of motion, applied force, tempo of movement, bilateral / unilateral motion, full body exercise vs. single joint.

In an exemplary embodiment of the invention, measuring an effect of brain stimulation on a specific cognitive response is used to better select a desired stimulation point and/or stimulation parameters. For example, auditory sensors can be employed to measure the amplitude of the speech response.

In an exemplary embodiment of the invention, an iterative process is carried out, whereby electrodes and/or a stimulation element are repositioned and/or their parameter settings changed in response to motion or cognitive activities as measured by position sensors and/or an actuator. Alternatively or additionally, the effect of exact/known motion (or other stimulation) of a limb, or the affect of exact cognitive activity on the brain is used to reposition electrodes and/or stimulator and/or set parameters.

Optionally, different locations and/or parameters are set for different uses. Optionally, rehabilitation exercises are selected based on the measurable effects of some types of stimulation on the body and/or ability to measure better the effect of an exercise.

An aspect of some embodiments of the invention relates to using an external stimulator and/or sensing array for assisting in using and/or configuring implanted brain electrodes, in conjunction with rehabilitation. In an exemplary embodiment of the invention, one or more external stimulators and one or more implanted brain electrodes are controlled by a common controller. In an exemplary embodiment of the invention, one or more implanted brain electrodes are operated based upon measurements of brain activity, optionally measurements from one or more helmet mounted sensors.

An aspect of some embodiments relates to a two tiered therapy process comprising a mapping or evaluation stage and a therapy stage. In an exemplary embodiment of the invention, the mapping or evaluation stage employs a greater number of sensors and/or stimulation electrodes than the therapy stage.

36160 claim summary
In an exemplary embodiment of the invention, there is provided a method of rehabilitation management, comprising:

- providing a plurality of patients fitted with sensors;
- assigning tasks to said patients by a therapist;
- rehabilitating said patients not under the direct attention of said therapist; and
- monitoring the rehabilitating using data acquired by the sensors during performance of the tasks.

Optionally, the rehabilitation is performed by a person other than said therapist.

Optionally, the rehabilitation is performed by a computerized system which adjusts the tasks in response to the monitoring in order to close a feedback loop.

Optionally, the method includes:

- producing a rehabilitation progress report.

Optionally, at least some of the sensors are external to the patients.

Optionally, at least some of the sensors are implanted in the patients.

Optionally, at least some of the sensors measure a brain activity.

Optionally, at least some of the sensors measure a muscle activity.

Optionally, the tasks are performed with a brain computer interface (BCI).

Optionally, the monitoring comprises computing a brain plasticity index (BPI).

Optionally, the method comprises applying a transcranial direct current stimulation (tDCS).

In an exemplary embodiment of the invention, there is provided a rehabilitation therapy kit, the kit comprising:

- a body adapted to be coupled to a head and adapted for communication with a therapy module;
- the therapy module mounted on the body and comprising at least one of:
  - (i) at least one sensor adapted to sense brain activity; and
  - (ii) at least one stimulator adapted to stimulate a brain;

- a machine readable media containing instructions for operation of the therapy module.

Optionally, the kit includes at least one peripheral device adapted for communication with a therapy module and adapted to perform at least one function selected from:

- (i) function as a sensor; and
respond to an instruction from a machine on which the instructions of the machine readable media have been installed.

Optionally, the the kit includes a logging module adapted to store data pertaining to at least one of:

- brain activity;
- signals provided by the at least one stimulator; and
- a motor response to the signals provided by the at least one stimulator.

In an exemplary embodiment of the invention, there is provided a treatment apparatus, the apparatus comprising:

(a) at least one sensor of brain activity capable of providing an output signal;
(b) a presentation module adapted to provide at least one task to a patient;
(c) analytic circuitry configured to analyze the output signal; and
(d) a controller adapted to adjust tasks presented by the therapy module in response to the analysis;

thereby adjusting the tasks closes a feedback loop.

Optionally, the the therapy module comprises a physical therapy component and the tasks comprise exercises of a body part.

Optionally, the apparatus includes a stimulation module adapted to apply electric stimulation to a specific target in a brain.

Optionally, the stimulation module is adapted to apply transcranial direct current stimulation (tDCS).

Optionally, the analysis computes a brain plasticity index (BPI) or an indication of change therein.

Optionally, the output signal operates a brain computer interface (BCI).

Optionally, the tasks comprise imagining a motor activity.

Optionally, the tasks comprise imagining a situation.

Optionally, the tasks comprise motor activities.

Optionally, the apparatus comprises:

(e) a logging module adapted to store data pertaining to at least one of:
   (i) brain activity;
   (ii) signals provided by at least one stimulator and
   (iii) a signal from a peripheral motor sensor.
In an exemplary embodiment of the invention, there is provided a treatment method, the method comprising:

(a) sensing brain activity and providing an output signal of the activity;
(b) presenting tasks to a patient;
(c) analyzing the output signal during performance of presented tasks; and
(d) closing a feedback loop by adjusting presented tasks in response to the analysis.

In an exemplary embodiment of the invention, there is provided a therapy apparatus, the apparatus comprising:

- a plurality of sensors adapted to sense brain activity;
- a brain computer interface (BCI) adapted to:
  - provide a positive user feedback if the brain activity exceeds a threshold; and
  - provide no positive user feedback if the brain activity does not exceed the threshold;
- a stimulation module adapted to apply a specified stimulation only if the brain activity does not exceed the threshold.

Optionally, the apparatus is configured so that a user feedback is provided in at least 50%, optionally 75%, optionally 90% of user attempts to produce brain activity which exceeds the threshold.

In an exemplary embodiment of the invention, there is provided a helmet-like device for rehabilitation, comprising:

- a body adapted to be coupled to a head;
- at least one external sensor adapted to sense brain activity and mounted on said body; and
- at least one external stimulator adapted to stimulate a brain and mounted on said body.

Optionally, the device is configured as a portable device or a stationary device.

Optionally, the device comprises circuitry configured to operate said device both when the device is physically attached to a rehabilitation system and when not attached, said operation being different in attached and unattached conditions.

Optionally, the circuitry closes a control loop between stimulation and sensing.
Optionally, the circuitry wirelessly interacts with at least one device not physically attached to said device.
Optionally, the wireless interaction is via a Bluetooth protocol.
Optionally, the device at least one of is controlled by and controls said rehabilitation system, when attached thereto.

Optionally, the at least one external sensor includes a Near-infrared spectroscopy (NIRS) sensor.
Optionally, the external stimulator is adapted to provide at least one stimulation type selected from the group consisting of electrical and magnetic.

In an exemplary embodiment of the invention, there is provided a helmet-like device for rehabilitation, comprising:
- a body adapted to be coupled to a head;
- at least one external stimulator adapted to stimulate a brain and mounted on said body; and
- circuitry configured to operate said helmet both when physically attached to a rehabilitation system and when not attached, said operation being different in both attached and unattached conditions.

Optionally, the device is configured as a portable or a stationary device.
Optionally, the device is adapted to connect both mechanically and functionally to said rehabilitation system.

Optionally, the device is adapted to attach to said rehabilitation system using a quick connect attachment.
Optionally, the device is counter balanced when attached to said rehabilitation system.
Optionally, the device is attached in a manner which reduces gravitational strain on a patient's head.

In an exemplary embodiment of the invention, there is provided a head-worn adjustable electrode device, comprising:
- a body; and
- a plurality of electrodes attached to said body and selectively positionable relative to a head, when said body is worn on a head, said body being adapted for selective positioning of electrodes.

Optionally, the body comprises a band and comprising a plurality of electrode supports circumferentially arrangable on said band.
Optionally, at least one of the electrode supports is an elongate electrode support defining multiple attachment positions for an electrode thereon.

Optionally, the body is adjustable.

Optionally, the body is plastically deformable.

Optionally, the device comprises at least one brain stimulation device coupled to said body and whose position is adjustable relative to said body.

Optionally, the head is approximated by a sphere, with a hemisphere corresponding to skull areas overlying the brain, said electrodes and said stimulator are selectively positionable substantially anywhere on at least half the surface of said hemisphere.

In an exemplary embodiment of the invention, there is provided a method of treating a patient, comprising:

- mounting a plurality of brain activity sensors on the patient using a head-worn device;
- rehabilitating the patient utilizing signals from said sensors, at least at a clinical setting and at a home setting.

Optionally, a same device design is used in the clinical setting and the home setting.

Optionally, a same device is used in multiple settings over a period of time of at least one week.

Optionally, the mounting comprises mounting at least one Near-infrared spectroscopy (NIRS) sensor.

Optionally, the method comprises:

- stimulating the patient during the rehabilitating; and
- monitoring an influence of the stimulating on the signals and adjusting the stimulating in response to the influence;

thereby forming a closed feedback loop.

Optionally, the stimulating comprises applying an electric stimulus.

Optionally, the stimulating comprises applying a motor stimulus.

In an exemplary embodiment of the invention, there is provided a method of rehabilitation management, comprising:

- providing a plurality of patients;
- while said patients are in a same care location, setting brain stimulation parameters for said patients by a therapist;
rehabilitating said patients at said care location by a person other than said therapist, not under the direct attention of said therapist; and monitoring said rehabilitation and an effect of stimulation by said therapist. Optionally, the stimulation is externally applied stimulation.

In an exemplary embodiment of the invention, there is provided an external head-mounted brain stimulator, comprising:

- at least one sensor input;
- a stimulator adapted to stimulate a brain; and
- circuitry which prevents stimulation responsive to signals from said sensor input.

Optionally, the sensor input comprises an EEG input.

Optionally, the sensor input comprises a Near-infrared spectroscopy (NIRS) input.

Optionally, the sensor input comprises a positioning indicating input.

Optionally, the sensor input comprises a contact-quality indicating input.

In an exemplary embodiment of the invention, there is provided a rehabilitation system, comprising:

- at least one articulated arm having a stimulator mounted thereon;
- a patient support positioned so that a head of a patient can be selectively stimulated at multiple locations using said stimulator; and
- a helmet adapted for mounting on the patient's head.

Optionally, the helmet includes a plurality of positionable sensing electrodes.

Optionally, the stimulator is selectively attachable to said helmet.

Optionally, the helmet is rigidly attached to said support.

In an exemplary embodiment of the invention, there is provided a method of enhancing the accuracy of sensing or modifying brain activity, comprising:

- placing in proximity to brain, at a first position, a sensing or stimulating element such that a certain effective brain volume is associated with the element;
- operating the element;
- causing measured motion of a body part;
- analyzing a relationship between said operating and said motion; and
- selectively moving said element to a new position in proximity to the brain, based on said analyzing.

Optionally, the element is external to the body.
Optionally, the element is internal to the body.

In an exemplary embodiment of the invention, there is provided a method of rehabilitation of a patient using an external sensing array, a rehabilitation system and an internal stimulator, comprising:

- stimulating a brain of the patient using said internal stimulator;
- locating an external sensing array in a position where it can sense brain activity;
- causing activity of said patient using said rehabilitation system;
- sensing brain activity using said array; and
- modifying at least one of said stimulating, said causing and a parameter of said sensing in response to at least one of a signal generated by said sensing and an effect of said causing other than on the brain.

Optionally, the method comprises applying external stimulation.

Optionally, the external array comprises a controller which controls said internal stimulator.

Optionally, the external array comprises Near-infrared spectroscopy (NIRS) optical fibers and detector fibers.

In an exemplary embodiment of the invention, there is provided a method of determining a correct electrode placement or activation profile, the method comprising:

- measuring brain activity at a plurality of locations while a subject sequentially:
  - engages in an activity to produce a signal measurement; and
  - refrains from the activity to produce a noise measurement;
- processing signal measurements and noise measurements from the plurality of locations to produce signal:noise ratio data; and
- selecting at least one preferred location characterized by a desired signal-to-noise ratio for electrode placement.

Optionally, the activity comprises imagining a motor activity.

Optionally, the activity comprises performing a motor activity.

Optionally, the activity is performed with an un-affected body part.

Optionally, the activity is performed with an affected body part corresponding to an unaffected body part.

Optionally, the method comprises placing a stimulation electrode at the at least one preferred location.
Optionally, the method comprises placing a sensor at the at least one preferred location.

In an exemplary embodiment of the invention, there is provided a method of determining a correct electrode placement or activation profile, the method comprising:

(a) measuring brain activity with two sets of sensors, each set characterized by a different resolution, at a plurality of locations while a subject sequentially:
   (i) engages in an activity to produce a first signal; and
   (ii) refrains from the activity to produce a second signal;
(b) analyzing said first and second signals from the plurality of locations to produce to produce a profile; and
(c) selecting at least one preferred location based upon the profile.

In an exemplary embodiment of the invention, there is provided a method of therapy, the method comprising:

(a) mapping neural activity in a brain of a patient to determine a disability focus;
(b) conducting rehabilitation training while monitoring neural activity at the disability focus.

There is thus provided in accordance with an exemplary embodiment of the invention, a portable helmet-like device for rehabilitation, comprising:

- a body adapted to be coupled to a head;
- at least one external sensor adapted to sense brain activity and mounted on said body; and
- at least one external stimulator adapted to stimulate a brain and mounted on said body.

Optionally, the device comprises circuitry configured to operate said device both when the device is physically attached to a rehabilitation system and when not attached, said operation being different in the two conditions. Optionally, said circuitry closes a control loop between stimulation and sensing. Alternatively or additionally, said circuitry wirelessly interacts with at least one device not physically attached to said device.

Optionally, the external stimulator and/or external sensor interact wirelessly with other components (e.g. wireless EEG electrodes). Optionally, a Bluetooth wireless communication protocol is implemented.
In an exemplary embodiment of the invention, said device at least one of is controlled by and/or controls said rehabilitation system, when attached thereto.

There is also provided in accordance with an exemplary embodiment of the invention, a portable helmet-like device for rehabilitation, comprising:

- a body adapted to be coupled to a head;
- at least one external stimulator adapted to stimulate a brain and mounted on said body; and
- circuitry configured to operate said helmet both when physically attached to a rehabilitation system and when not attached, said operation being different in the two conditions. Optionally, said device is adapted to connect both mechanically and functionally to said rehabilitation system. Alternatively or additionally, said device attaches using a quick connect attachment to said rehabilitation system. Alternatively or additionally, said device is counter balanced when attached to said rehabilitation system. Alternatively or additionally, said device is attached in a manner which reduces gravitational strain on a patient's head.

There is also provided in accordance with an exemplary embodiment of the invention, a head-worn adjustable electrode device, comprising:

- a body; and
- a plurality of electrodes attached to said body and selectively positionable relative to a head, when said body is worn on a head, said body being adapted for selective positioning of electrodes. Optionally, said body comprises a band and comprising a plurality of electrode supports circumferentially arrangable on said band. Optionally, at least one electrode support is an elongate electrode support defining multiple attachment positions for an electrode thereon.

In an exemplary embodiment of the invention, said body is adjustable. Optionally, said body is plastically deformable.

In an exemplary embodiment of the invention, the device comprises at least one brain stimulation device coupled to said body and whose position is adjustable relative to said body. Optionally, when said head is approximated by a sphere, with a hemisphere corresponding to skull areas overlying the brain, said electrodes and said stimulator are selectively positionable substantially anywhere on at least half the surface of said hemisphere.
There is also provided in accordance with an exemplary embodiment of the invention, a method of treating a patient, comprising:

mounting a plurality of brain activity sensors on the patient using a head-worn device;

rehabilitating the patient utilizing signals from said sensors, at least at a clinical setting and at a home setting, using a same device design. Optionally, a same device is used in multiple settings over a period of time of at least one week.

There is also provided in accordance with an exemplary embodiment of the invention, a method of rehabilitation management, comprising:

providing a plurality of patients;

while said patients are in a same care location, setting brain stimulation parameters for said patients by a therapist;

rehabilitating said patients at said care location by a person other than said therapist, not under the direct attention of said therapist; and

monitoring said rehabilitation and an effect of stimulation by said therapist. Optionally, said stimulation is externally applied stimulation.

There is also provided in accordance with an exemplary embodiment of the invention, an external head-mounted brain stimulator, comprising:

at least one sensor input;

a stimulator adapted to stimulate a brain; and

circuitry which prevents stimulation responsive to signals from said sensor input. Optionally, said sensor input comprises an EEG input and/or Near-infrared spectroscopy (NIRS) input. Alternatively or additionally, said sensor input comprises a positioning indicating input. Alternatively or additionally, said sensor input comprises a contact-quality indicating input.

There is also provided in accordance with an exemplary embodiment of the invention, a rehabilitation system, comprising:

at least one articulated arm having a stimulator mounted thereon;

a patient support positioned so that a head of a patient can be selectively stimulated at multiple locations using said stimulator; and

a helmet adapted for mounting on the patient's head. Optionally, said helmet includes a plurality of positionable sensing electrodes. Alternatively or additionally, said stimulator is selectively attachable to said helmet.
Alternatively or additionally, said helmet is rigidly attached to said support.
There is also provided in accordance with an exemplary embodiment of the invention, a method of enhancing the accuracy of sensing or modifying brain activity, comprising:

- placing in proximity to brain, at a first position, a sensing or stimulating element such that a certain effective brain volume is associated with the element;
- operating the element;
- causing measured motion of a body part;
- analyzing a relationship between said operating and said motion; and
- selectively moving said element to a new position in proximity to the brain, based on said analyzing.

Optionally, the method comprises causing measured cognitive activity.
Optionally, the analyzing comprises analyzing cognitive activity.
Optionally, said element is external to the body.
Alternatively or additionally, said element is internal to the body.

There is also provided in accordance with an exemplary embodiment of the invention, a method of rehabilitation of a patient using an external sensing array, an internal stimulator, a rehabilitation system and an internal stimulator, comprising:

- stimulating a brain of the patient using said internal stimulator;
- locating an external sensing array in a position where it can sense brain activity;
- causing activity of said patient using said rehabilitation system;
- sensing brain activity using said array; and
- modifying at least one of said stimulating, said causing and said parameters of said sensing in response to at least one of a signal generated by said sensing and an effect of said causing other than on the brain. In an exemplary embodiment of the invention, the method comprises applying external stimulation. Alternatively or additionally, said external array comprises a controller which controls said internal stimulator.

**BRIEF DESCRIPTION OF THE FIGURES**

Non-limiting embodiments of the invention will be described with reference to the following description of exemplary embodiments, in conjunction with the figures.
The figures are generally not shown to scale and any sizes are only meant to be exemplary and not necessarily limiting. In the figures, identical structures, elements or parts that appear in more than one figure are preferably labeled with a same or similar number in all the figures in which they appear, in which:

Fig. 1 is a side schematic perspective view of a rehabilitation system including a brain sensing and stimulation system in accordance with an exemplary embodiment of the invention;

Fig. 2 is a block diagram of a rehabilitation system in accordance with an exemplary embodiment of the invention;

Fig. 3 is a schematic illustration of a stimulation and sensing helmet and an attachment thereof to a patient and a support, in accordance with an exemplary embodiment of the invention;

Fig. 4 is a schematic illustration of an adjustable electrode portion of the helmet of Fig. 3, in accordance with an exemplary embodiment of the invention;

Fig. 5 illustrates an alternative external stimulation element, in accordance with an exemplary embodiment of the invention;

Fig. 6A and 6B illustrate helmet designs in accordance with alternative embodiments of the invention;

Fig. 7 illustrates an articulated arm based positionable stimulator for rehabilitation, in accordance with an exemplary embodiment of the invention;

Fig. 8 is a flowchart of a method of rehabilitation, in accordance with an exemplary embodiment of the invention;

Fig. 9 is a flowchart of a process of rehabilitation, in accordance with an exemplary embodiment of the invention;

Fig. 10 is a schematic representation of a therapy system according to an exemplary embodiment of the invention;

Fig. 11 is a simplified flow diagram of a treatment method according to an exemplary embodiment of the invention; and

Fig. 12 is a simplified flow diagram of a treatment method according to another exemplary embodiment of the invention.
DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

Overview

Fig. 1 is a side schematic perspective view of a rehabilitation system 100 including a brain sensing and stimulation system (helmet) 106 in accordance with an exemplary embodiment of the invention. In an exemplary embodiment of the invention, system 100 is used for rehabilitation of patients that suffer a stroke (e.g., paretic event), which reduces motor, cognitive and/or perceptive abilities. System 100 may also be used for other types of rehabilitation, for example, cognitive rehabilitation, or after body damage, after body disuse and/or for artificial limbs and/or brain/nerve interface prostheses. Non-rehabilitation uses are possible as well, for example, task or athletic training.

System 100 is shown in the form of a rehabilitation device, for example, a chair 104 that can be used to support movement of limbs of a patient 102. As will be described below, rehabilitation can be provided in accordance with some embodiments of the invention without a movement support.

 Optionally, chair 104 can operate in a "guided mode" and is adapted to actively move hands, legs, head or back of a patient seated therein as part of a therapy program as described below. In an exemplary embodiment of the invention, movement of hands, legs, head or back of a patient seated is in response to a measured brain activity.

 Optionally, the patient can adjust chair 194 by moving hands, legs, head or back to reposition corresponding portions of the chair. In an exemplary embodiment of the invention, active patient repositioning of a portion of the chair comprises a therapy task. In an exemplary embodiment of the invention, movement of hands, legs, head or back of a patient seated chair 104 is sensed (e.g. via an sEMG 218; Fig 2) and reported to a helmet controller (e.g. 216 in Fig. 2).

According to various exemplary embodiments of the invention, one or more of a back of chair 104, an armrest 119 a leg rest 121 and a footrest 123 can be fitted with sensors to measure patient initiated motion and/or robotic components to guide patient motion.

In an exemplary embodiment of the invention, system 100 provides the functions of measuring brain activity, stimulating the brain and interacting with body movement and/or sensing body motion and/or other (non-brain) physiological
parameters. For example, body parts may be moved, stimulated, measurement measured and/or intent of measurement measured, all in relation to brain measurement and stimulation. The system need not relate to movement, for example, the system may relate to pain or other senses. In an exemplary embodiment of the invention, system 100 includes at least one sensing electrode 108 and/or at least one stimulation element 110 (e.g., electrical or vibration). In the depicted embodiment sensing electrode 108 is depicted on a forearm, although exact placement can vary with the type of rehabilitation of a specific exemplary embodiment. For example, in speech or cognitive rehabilitation, sensing electrode 108 and/or stimulation element 110 can be placed in proximity to the mouth (e.g. on cheek, lips, throat, chest or tongue). Sensing parameters relevant to speech therapy include, but are not limited to, lingual and/or buccal movement, velocity of inhaled or exhaled air, jaw movement and contact between two orofacial body parts (e.g. tip of tongue to upper incisors).

Optionally, an estimation of orofacial movement is made based upon achieved vocalization (e.g. of diphthongs, words or sentences).

Alternatively, or additionally, a parametric model of of the human voice generating system is employed and/or parameters are matched to the patient and treatment goals include patient specific parametric changes.

In an exemplary embodiment of the invention, a display 114 is used to show instructions and/or to receive input from a patient, for example in conjunction with a voice input, mouse or a joystick 112. Optionally, joystick 112 is used to measure patient fine motor control. Optionally, the joystick includes force and/or vibration feedback. Optionally, a position sensor/accelerometer 118 is provided to indicate limb position and/or movement.

In an exemplary embodiment of the invention, content provided on display 114 and/or via speakers (not pictured) is governed by analytic circuitry (e.g. helmet controller 216 of Fig 2 which can optionally be provided as a PC with an appropriate software module installed) adapted for therapy management. Optionally, the software module guides the patient regarding tasks appropriate to a specific therapy plan and/or provides stimuli associated with the therapy. In an exemplary embodiment of the invention, the software is responsive to inputs from the patient (e.g. via microphone 117 or controller 203 of Fig. 2). Optionally, the software is interactive and responds to patient input. In some exemplary embodiments of the invention, interactive software
alters a degree of difficulty of presented exercises in response to a degree of patient success. In some exemplary embodiments of the invention, interactive software alters a degree of stimulation and/or specific stimulation parameters provided via helmet 106 in response to a degree or type of patient success. In an exemplary embodiment of the invention, patient success is measured primarily by, optionally exclusively by, sensed brain activity.

Sensor 118 is generally indicative of recording sensors located on the body outside helmet 106. In exemplary embodiments of the invention, sensors 118 are specifically adapted to the application of helmet 106 (e.g. microphone 117 and/or electrodes on or near the mouth for speech rehabilitation and/or muscles tone sensors applied to specific muscles for motor rehabilitation of that muscle).

Optionally, a camera 116 is provided to image limb position. Optionally, one or more stickers having detectable markings on them are used together with the camera, with the sticker attached to a body portion whose movement is to be detected. Non-optical sensors and indicators may be used as well.

In an exemplary embodiment of the invention, a microphone 117 is provided, optionally attached to helmet 106 as depicted. Microphone 117 can be used, for example, to record patient speech performance. Optionally, stereo microphones are provided. In an exemplary embodiment of the invention, a microphone is positioned near OOB ears of the patient so that the patient and/or therapist can listen to the patients voice as the patient hears it.

In the embodiment depicted in Fig. 1 and as described in some particular embodiments below, helmet 106 is adjustable to match patient needs, is optionally wholly or partly disposable, does not weigh to heavily on the patient’s head and/or includes safety features. Optionally, helmet 106 can be used in both stationary and ambulatory applications. Optionally, in an ambulatory application, helmet 106 is used without additional hardware and/or only with hardware available in a house or worn by a patient.

Optionally, the helmet 106 communicates with an external processor (e.g. PC 114 and other sensors wirelessly. According to various exemplary embodiments of the invention, wireless communication can be unidirectional or bidirectional. Optionally, wireless communication can be across a local network or a remote network.

**Generalized system description**
Fig. 2 is a block diagram of a rehabilitation system 200 in accordance with an exemplary embodiment of the invention. A dashed box 202 indicates an exemplary motoric rehabilitation system including a controller 203 and a limb motion support element 204, used to support motion of a limb 206. This is optionally a rehabilitation device as described in one of the below mentioned PCT applications. Alternative rehabilitation systems may be provided, for example as described herein, including systems where a limb is not moved by the rehabilitation system. Controller 203 may also be used for higher level functions, for example, planning and tracking of rehabilitation. Alternatively a remote system may provide these functions. Optionally, internet, telephone, cellular or other networks known in the art are used for communicating between a control center and system 200.

It should be noted that in this application the term "rehabilitation system" sometimes includes the helmet and sometimes does not, depending on the context.

A dashed box 213 indicates a plurality of different optional measurements of brain activity, including, for example, MU rhythm (214), MAC recording (212), SCP recording 210 and/or other measurements (211). It should be noted that these measurements may be provided using a same or different set of electrodes and processed to extract the desired data. Optionally, internal (to the body) electrodes are read out. This data extraction is optionally carried out by a helmet controller 216 which is optionally integrated with the helmet or is a separate unit. Optionally, this function is provided by system 202 (e.g., controller 203).

A stimulator 230, for example, magnetic, heat, electrical, ultrasonic, implanted and/or other known in the art of brain stimulation is provided for stimulation of a brain 208. Such stimulation is optionally general to a class of rehabilitation exercises, for example, independent of the particular exercise being carried out. Alternatively or additionally, the stimulation is specific to a certain brain region, for example, a brain region that is linked to a particular exercise or body part. In some embodiments of the invention, multiple stimulation sources are used, optionally they are used to stimulate the brain simultaneously. For example, multiple stimulation sources can be used for applying anodal tDCS to the ipsilesional hemisphere and cathodal tDCS on the contralesional hemisphere simultaneously. Optionally, even when not used simultaneously, a plurality of sources are used so that multiple points may be
stimulated in sequence without manual readjustment. Optionally, a motor is used to
move a stimulation source between positions a head of a patient.

A display 228 (paralleling display 114 of Fig. 1) is optionally used to display
information related to the rehabilitation or which serves as part of the rehabilitation,
for example, when rehabilitating cognitive functions that are not pure motoric.

In an exemplary embodiment of the invention, limb motion is measured or
caused by limb motion support element 204, for example a robotic actuator.
Optionally, measurement is provided by the user moving a joystick or a mouse or
other input element, and patient input analyzed to determine movement and/or effect.

Optionally, electromyographic measurement is performed, for example using a
multi-channel surface electromyography (sEMG) recording device 218, on a healthy
and/or paretic limb. A monitor/module 220 is optionally provided for monitoring the
recordings. In an exemplary embodiment of the invention, sEMG recordings are
correlated with brain measurement signals and/or mechanical output of the patient.

Optionally, a functional stimulator 222 is provided, to provide sub-threshold
and/or above threshold stimulation of muscles and/or nerves, in association with
sEMG measurement and/or other rehabilitation procedures. In an exemplary
embodiment of the invention, the stimulation is provided as a sequence of
stimulations of one or more muscle groups, for example in synchronization with a
time clock or in response (e.g., and/or delay) to a trigger. Optionally, the stimulation
is electrical or magnetic stimulation.

In an exemplary embodiment of the invention, one or more implanted
stimulators (wired or wireless) is used. Optionally, such implanted stimulators are
used for measuring EMG in addition or instead of being used for stimulation. In some
embodiments, the stimulators are replaced by reading devices.

Wireless implantable electronic stimulators have been described, for example
Pat. No. 5,324,316, U.S. Pat. No. 5,405,367, PCT Publication WO 98/37926, PCT
US application Ser. No. 09/077,662 and in an article "Micromodular Implants to
Provide Electrical Stimulation of Paralyzed Muscles and Limbs", by Cameron, et al.,
published in IEEE Transactions on Biomedical Engineering, Vol. 44, No. 9, pages
781-790. The disclosures of all of these references are incorporated herein by reference.

In an exemplary embodiment of the invention, a mechanical performance monitor module/software 224 is provided, for example, for assessing quality of motion and/or other motion parameters. Optionally, the actual motion is compared to planned motion. Data may be processed and or stored remotely, for example, at a mechanical activity processing and storage unit 226.

Optionally, a camera 215 (optionally paralling 116, Fig. 1, but no necessarily head mounted) is provided. A camera may be used, for example, to provide feedback to a patient, to acquire and capture images which can be analyzed to determine quality of motion, for assisting interaction with a remote or a local therapist (e.g., allowing a simultaneous view of more than one portion of the patient and a view of a portion without requiring the therapist move) and/or to generate cuing movies for indicating motions to a patient. In some embodiments of the invention a camera and/or a position sensor are used to detect patient motion instead of using a manipulator. Optionally, images of the camera are automatically analyzed to generate trigger events which control what data is logged. For example, motion of a certain type in a particular field of view of the camera may be considered a suitable trigger.

Optionally, system 100 includes a means, such as circuitry, for timing a provision of the drugs relative to the rehabilitation activity and/or stimulation.

Optionally, a therapist display 217 is provided, for example for showing instruction and/or feedback to a therapist. This display may be remote, for example.

Optionally, a virtual reality (VR) system 219 is provided, for example including one or more of visual goggles, a panoramic display, 3D sound, tactile sensors and/or tactile feedback. Optionally, the VR system is used to better emulate real-world situations a patient is to be rehabilitated for. Optionally, the VR system is used to enhance reality, for example by showing a desired motion overlaid on a view of the patient showing his limbs actually moving. Optionally, a standard display is used, in which a captured video stream is enhanced.

Optionally, feedback to the patient is provided using music. Optionally, audio feedback and/or voice control are provided in the helmet using a speaker (not shown) and/or microphone 117. Optionally, the speaker is provided as an earphone, optionally connected to or installed in helmet 106. In an exemplary embodiment of the invention,
earphones provide audio feedback and/or task instructions. Optionally, earphones are useful in cognitive rehabilitation and/or motor rehabilitation with auditory feedback because they contribute to a reduction in auditory distraction. In an exemplary embodiment of the invention, earphones contribute to therapy success in rehabilitation of hearing impaired, visually impaired or ADD subjects and/or when treatment occurs in an environment with significant distraction from non-therapy stimuli (e.g. outdoors or in a "gymnasium" where other patients are treated concurrently) by delivering audio information to the patient at a volume that overcomes audible distractions.

In an exemplary embodiment of the invention, rehabilitation therapy is provided to a patient using virtual reality as a tool for interacting with the patient. Optionally, a test is made to determine which virtual reality setting has a most calming effect on a patient or otherwise interacts favorably with the rehabilitation process. Optionally, EEG or other brain measurements are used to determine the effect on the patient. Optionally, EKG or other physiological measurements are carried out, for example, to detect a safety problem associated with rehabilitation and/or stimulation. Optionally, virtual reality comprises presentation of a video and/or animation sequence.

It should be noted that components of the above system may be connected using wired or wireless means, depending on the implementation of the system.

In an exemplary embodiment of the invention, the helmet and/or rehabilitation system include a logging function. In an exemplary embodiment of the invention, the logging includes one or more of: signal application parameters, actual applied signals (e.g., based on measured impedance and/or electrical sensors, not shown), variations in applied signals, measurements, positions of electrodes (e.g., using encoders), motor effects (e.g., limb positions), user input (e.g., voice commentary by user or data entered using an input device such as a keyboard), trigger events (e.g., in daily use) and/or home computer use, when the computer is linked to the helmet (e.g., using a wireless or wired link). Optionally, camera recordings are also stored. Optionally, triggering events and/or measurement values may be set which determine when logging will be carried out and of which variable or variables. Optionally, a periodic uploading (e.g., using a cellular connection or by asking patient to plug into a data transmission device, such as a computer or telephone socket) of data from the helmet
is performed. Optionally, a logging element separate from the helmet is provided, for example, worn by the patient.

In an exemplary embodiment of the invention, system 100 includes one or more safety features. In one example, helmet controller 216 prevents stimulation if the received EEG signals do not match a desired pattern. In another example, stimulation is blocked based on physiological measurements and/or on a lack of correct placement of the stimulator. In an exemplary embodiment of the invention, patient tremor or falling are detected using an accelerometer and used to prevent stimulation, stop rehabilitation exercises and/or initiate a call for help.

In an exemplary embodiment of the invention, helmet controller 216 blocks sensing and/or amplification and/or processing of signals by the sensing electrodes when electrical and/or magnetic stimulation are applied.

**Exemplary helmet embodiment**

Fig. 3 is a schematic illustration of stimulation and sensing helmet 106 and an attachment thereof to a patient and a support, in accordance with an exemplary embodiment of the invention.

The helmet includes, in general, a head band 302 on which are mounted a plurality of electrode elements 301. An optional resilient element 304 is used to ensure contact with the skull and/or provide an elastic coupling between the head band and the skull.

A magnetic stimulator 306 (an alternative embodiment is shown in greater detail in Fig. 5), is optionally mounted on a track element 308, and is movable along it. Optionally, the track element is mounted on a rotary joint 310 (which optionally includes a locking knob), so that the stimulation can be aimed at various locations in the skull. Optionally a depth control (not shown) is provided for the stimulation, for example, by providing relative displacement between two coils used in magnetic stimulator 306, for two-coil designs. Alternatively or additionally, a, radial motion relative to the skull is provided, for example with a distance adjusting screw (e.g., distance between stimulator and skull or distance between stimulator and the track on which it rides). Optionally, one or more motors or other actuators are provided for moving the stimulator. Alternatively or additionally, one or more position/motion encoders are used to report on the stimulator position.
In an exemplary embodiment of the invention, the stimulator is not mounted on the band, so as to not directly pass forces thereto.

One or more quick connect couplers 312 are optionally provided for attaching head band 302 to a rehabilitation chair. This attachment may prevent strain caused by the weight of the stimulator. In an exemplary embodiment of the invention, the quick connect coupler allows connection in one step or two or three steps. Alternatively or additionally, the quick connect takes less than 3 minutes, less than 1 minute, less than 30 seconds, less than 10 or less than 5 seconds.

In an exemplary embodiment of the invention, a counter-weight 318 is provided to balance the weight of stimulator 306.

In an exemplary embodiment of the invention, the attachment between the helmet and the chair is adjustable. This may increase patient comfort. For example, a first coupling joint 314 may provide horizontal motion and/or rotation and/or a second coupling joint 316 may provide vertical movement and/or rotation. An articulated arm design or other designs may be used instead. In an exemplary embodiment of the invention, an articulated arm design or other design which supports the helmet while providing low or zero resistance to patient head movement, are provided.

Fig. 4 is a schematic illustration of an adjustable electrode portion 320 of the helmet of Fig. 3, in accordance with an exemplary embodiment of the invention.

In an exemplary embodiment of the invention, portion 320 is provided with an adjustable sliding buckle 322. Alternatively or additionally, band 302 is deformable by hand to match a skull shape. Alternatively or additionally, one or more cushions (not shown), for example, sponge pads, are used to adjust the fit of the band to a skull.

In an exemplary embodiment of the invention, a plurality of electrode support elements 326 is provided. Each such element optionally has an electrode 328 mounted thereon. Optionally, some of the electrodes, for example, an electrode 336, are stimulation electrodes, for example, for DC stimulation. A common ground electrode may be provided, or a pair (or more) of stimulation electrodes may be provided. Optionally, one or more of electrodes 328 is an electrode array. Optionally, one or more of support elements 326 is elastically biased towards the skull, for example, to assist electrical contact. Optionally, one or more small electrically conducting plates are glued to the skull (e.g., using conductive glue) for ensuring good contact with the electrodes and maintaining good and/or repeatable conductive contact with the skull.
In an exemplary embodiment of the invention, a base section 330 of electrode support 326, rides on band 302 and optionally locks or clicks at set locations, for example, based on notches 324.

While electrode position adjustment is by hand, in the embodiment, as shown, optionally a motor is used, for example, an electrode motion motor 332 and/or a band position motor 334 for positioning the electrode support. Alternatively or additionally to motors, position and/or motion encoders are provided.

In an exemplary embodiment of the invention, the electrodes are moved under computer control, for example, as part of a process of sensing and/or stimulating at new locations and/or as part of a search for a best sensing/stimulation location.

In an exemplary embodiment of the invention, the positioning may be based on the effect of stimulating and/or on the type of signal detected. Optionally, the type of signal is evaluated in conjunction with limb stimulation and/or motion as caused by and/or measured by system 100.

In an exemplary embodiment of the invention, one or more system setup positions for the electrodes are provided. Optionally, a user (e.g., therapist) is guided via computer to position the electrodes at various places in sequence, until a system approved signal is measured.

In an exemplary embodiment of the invention, the electrodes and/or stimulator are arranged to cover a significant part of the skull overlying the brain. In an exemplary embodiment of the invention, the part covered is sufficient to selectively stimulate or measure from at least 30%, 40%, 50%, 60%, 70%, 80% or more of the cerebral cortex. In an exemplary embodiment of the invention, the resolution of selective placement (on skull) is better than 3 cm, better than 2 cm, better than 1 cm, or intermediate resolution. Optionally, the part covered includes the entire brain.

Optionally, the part covered includes a hemisphere of the skull overlying the brain, or at least 30%, 40%, 50%, 60%, 70% or intermediate coverage. Optionally, the area covered is a portion of the head above a plane defined by the ears and the eyes. Optionally, the plane is offset by at least 1 cm or at least 2 cm or at least 3 cm from a plane connecting the eyes and ears. Some relative orientations between the measurement start plane and the eye-ear brain may be tolerated, for example, 10 degrees, 20 degrees, 30 degrees or intermediate or greater values.
In an exemplary embodiment of the invention, the electrodes are wireless electrodes and include amplifiers. Optionally, power is provided via the helmet. Optionally, a common battery is shared by all the electrodes, for example, incorporated in buckle 322 or in a non-disposable part of the helmet, for example associated with helmet controller 216. Optionally, when the helmet is attached to a rehabilitation device, it receives power from that device and/or recharges its battery.

In an exemplary embodiment of the invention, separate data lines and/or a shared databus 338 are provided. Optionally, each electrode reads different lines of this bus and/or is encoded with a different ID code.

In an exemplary embodiment of the invention, one or more positioning sensors 340 are provided to ensure the helmet is correctly placed. In an exemplary embodiment of the invention, one or more markers are attached to the patient and/or marks made on the patient's skin. Positioning sensors generate a "correct positioning" signal if the sensors are aligned with these marks. Optionally, sensors 340 are movable. In an exemplary embodiment of the invention, the markers generate an electrical signal and the sensors read this signal.

In an exemplary embodiment of the invention, the electrodes are of a type that can read through a patient's hair, for example, including conical tips that touch the scalp. Alternatively or additionally, the electrodes comprise standard disposable electrodes that attach to elements 326. Alternatively or additionally, SQUIDS or other magnetic sensors and/or NIRS or other optical sensors or other brain activity sensors are used instead of electrodes. Optionally, optical sensing provides an indication of how much work, in general, is being done at a specific brain location. Optionally, EEG sensors provide a high degree of temporal sensitivity.

In an exemplary embodiment of the invention, band 302 and/or elements 326 are provided with markings indicating a standard coordinate system of the skull. Optionally, the marking is via LEDs or other electronic display. Optionally, after signals from a patient are measured, a patient specific map (or distortion of a standard map) are generated, and optionally printed out as a set of stickers which are applied to the helmet.

In an exemplary embodiment of the invention, the helmet is patient specific. In an exemplary embodiment of the invention, band 302 and/or elements 326 can be plastically deformed to conform to a patient's skull.
In an exemplary embodiment of the invention, parts of the helmet that contact
the patient are disposable. Alternatively or additionally, the entire helmet except for
the controller and/or stimulator are disposable. In an exemplary embodiment of the
invention, disposable means that they can only be used with one patient, for example,
by deformation to fitting the skull preventing further deformation or by locking of
electrodes in place preventing further motion of electrodes. In an exemplary
embodiment of the invention, a single helmet, once adapted for a user may be used
multiple times by that user, in multiple situations. Optionally, once adjusted, the
helmet need not be adjusted again.

In an exemplary embodiment of the invention, helmet portion 320 weighs less
than 500 grams, less than 200 grams, less than 100 grams or an intermediate weight.
Optionally, the helmet is made of plastic with some electrical wiring and/or
deformable metal wires. Optionally, the electrodes include local amplifiers.
Optionally, a separate unit with a power source and/or controller 216 is provided, for
example, optionally for wear on the neck, shoulder and/or waist.

Fig. 5 illustrates an alternative external stimulation element 500, in accordance
with an exemplary embodiment of the invention. In this design, a stimulator 504,
comprising two coil sections 506, 508, is mounted underneath a track element 512 by
a riding element 510. A selective locking button 514 is optionally provided. A base
502 of track element 512 optionally includes a hinged mounting (not shown) for
rotation of the track and stimulation element. As noted above, motors, position
encoders and/or displays may be provided, for example, to indicate when a correct
position is achieved and/or indicate a suggested movement direction. Element 500 can
replace elements 306, 308 and 310 in Fig. 3.

**Alternative helmet designs**

Fig. 6A and 6B illustrate helmet design features in accordance with alternative
embodiments of the invention.

Fig. 6A shows a helmet design 600, including an optional ear electrode 610,
used as a reference. Electrode 610 is optionally plastically deformable to adjust its
position. In the embodiment shown, a band 602 is not adjustable, but rather uses a
padding 612 for fitting purposes. This padding may be molded to fit a particular
patient. A plurality of electrode supports 604 are optionally plastically deformable.
Optionally, the electrodes supports or the electrodes (not shown) are elastic at their
tip. Also shown is a stimulator 608, which is optionally mounted on the helmet. Optionally, the helmet is rigidly mounted on a chair.

Fig. 6B shows an alternative helmet design 630, in which attachment to a chair is via a support 644 which attaches to a joint 646 at a side of helmet 630. This joint optionally allows motion of the helmet during use, for example, in response to and by patient head motions. Additional motion may be allowed by the connection of support 644 to a rehabilitation system (not shown). In an exemplary embodiment of the invention, a stimulator 642 is mounted on a track 640 which is coupled separately to support 644. In an exemplary embodiment of the invention, an elastic connection is provided between the stimulator and the electrodes, so as to reduce mechanical coupling between them.

Also shown in helmet 630 is an alternative adjustable electrode design, in which a cap 638 is provided mounted on a head band 632 and including a plurality of tracks 634 in/on which electrodes 636 can travel. In an exemplary embodiment of the invention, cap 638 is elastic, for example being made of a rubber membrane. Optionally, the tracks are provided at locations where measurement of electrical signals is typical. Alternatively or additionally, the cap is locally conductive, for example, including small sections of conductive material, which are non-contiguous, so that electrical signals can pass through the cap but not along the cap.

In an exemplary embodiment of the invention, helmet 630 is preset with a limited number (e.g. 1 or 2 or 5 or 10) tDCS of programs. Optionally, the programs consider a side of the brain which is damaged.

**Articulated arm system**

Fig. 7 illustrates a system 700 including an articulated arm based positionable stimulator for rehabilitation, in accordance with an exemplary embodiment of the invention.

As shown, system 700 generally comprises a rehabilitation station 702, for example a rehabilitation chair with a joystick/handgrip 706. A display 704 is optionally provided for displaying instructions and/or feedback to a patient. A motion mechanism 708 (shown schematically) is optionally used to move and/or measure movement of joystick 706. It should be noted that other rehabilitation designs are possible as well.
A positionable stimulator optionally comprises a stand 710 on which one or more articulated arms 712, 714 are provided. In use, these arms are used to position one or more stimulators 716 and/or electrodes 718 relative to a patient's skull. In an exemplary embodiment of the invention, a helmet is provided with sensing electrodes and only the stimulation is based on articulated arms. Alternatively, the sensing electrodes are not part of the helmet. Optionally, a helmet-like element, for example, a cap or hat, is provided with a grid and/or a plurality of holes or tracks at set locations to ensure correct placement of electrodes and/or stimulators. Optionally, the helmet is manufactured or modified to match a patient's needs and/or skull shape. Optionally, additional arms, for example, 3, 4, 5 or more articulated arms are provided.

In an exemplary embodiment of the invention, the moving elements (e.g., electrodes, stimulators) are adapted to lock or latch onto the helmet to prevent inadvertent motion thereof or allow patient head motion. Optionally, the articulated arms passively follow such motion, optionally with a small amount of resistance (e.g., enough to reduce the weight felt by a patient when there is no motion). Alternatively or additionally, the arms actively move when they sense force applied to them, for example using robotic technology as known in the art. In an exemplary embodiment of the invention, the locking/latching mechanism comprises vacuum and/or a click attachment.

**Exemplary rehabilitation**

Fig. 8 is a flowchart 800 of a method of rehabilitation, in accordance with an exemplary embodiment of the invention.

In general, as noted above, a loop is closed which includes stimulation and body response. Optionally, the loop also includes measurement of electrical activity in the brain. In an exemplary embodiment of the invention, the loop is closed on a short-term basis, for example, sensing immediately if a stimulation had an effect on electrical and/or motor behavior of a patient and modifying stimulation and/or exercise accordingly. Alternatively or additionally, the loop is closed on a longer-term basis, for example, changing stimulation parameters after significant information is collected regarding patient performance and/or after an effect of stimulation is measured or believed to be over. The time scales of closing the loop can be, for example, 1-60 seconds (for example 10), 1-60 minutes (for example 10), 1-10 hours (for example 2) and/or 1-10 days (for example 7 days) or longer or intermediate times.
An example of closing the loop on generally longer time scales is detecting that stimulation fails to give an improvement in rehabilitation improvement over a non-stimulation case. In an exemplary embodiment of the invention, every several stimulated exercises, one or more non-stimulated exercises are performed to see if patient improvement is indeed enhanced by stimulation. If the answer is negative or if improvement is hampered, stimulation parameters are optionally changed. Optionally, a reduction in amount of improvement is tracked to predict when stimulation parameters will need to be changed (which may require a particular professional).

At 802, a stimulation is applied. This stimulation is shown being applied before a rehabilitation plan is formulated and/or a patient performs a motion (804), for example, in order to assess negative and/or positive effects of stimulation before proceeding. The order may be changed.

At 808 various neurological measures are taken, for example, SCP. In some cases, the measures are taken before patient action happens.

At 806, alternatively or additionally, various physical measures are taken, for example, motion, sEMG and other measures for example as described above.

At 810, the measures are optionally analyzed to determine rehabilitation improvement. In response, for example, as noted above, stimulation parameters and/or position may be changed (814). 808 and 806 may be used to indicate side effects, for example, spasm, caused by stimulation.

It is noted that 808 through 810 and 814 may be carried out before and during a single motion by a patient. In particular, they may be carried out during a preparatory stage of the motion. At 812, the motion is actually carried out and stimulation parameters may be changed (814) in view of the actual motion.

At 816, the measures may be changed, for example, responsive to patient improvement, change in exercise and/or lack of usable data.

In an exemplary embodiment of the invention, stimulation parameter setting and/or the act of stimulation are carried out by a neurologist. The following are (additional) exemplary scenarios.

a. The helmet is made MRI compatible and fMRI imaging is applied in conjunction with electrical measurement and/or stimulation, optionally during the use of a limb robotic manipulator. Optionally, a head-fMRI device is provided mounted on a separate (e.g., robust) articulated arm.
b. A Neurologist reviews, for example, signals measured from one side of the brain and estimates what signals he would like to see on the other (damaged) side of the brain and sets stimulation and/or rehabilitation parameters accordingly. Optionally, the analysis can be more detailed. In an exemplary embodiment of the invention, the analysis comprises an evaluation session in which motor abilities and/or cortical impairment are scored. In an exemplary embodiment of the invention, the evaluation session includes collection of data useful in calculating a brain plasticity index (BPI). Exemplary considerations in calculation of a BPI are described hereinbelow beginning in "Exemplary customization of stimulation protocol". Optionally, the BPI contributes to a treatment recommendation by allowing the neurologist to evaluate the specific type of reduction in cortical function in the context of the specific patient.

c. Optimal electrode placement is determined for sensing by moving electrodes in conjunction with stimulation and/or movement or stimulation of limbs by the rehabilitation device until a the measured signal is optimized and/or improved.

d. Controlling implanted electrodes. In an exemplary embodiment of the invention, implanted electrodes, for stimulation and/or sensing are controlled by the helmet, for example, helmet controller 216 sends commands to and/or reads data from the helmet. In an exemplary embodiment of the invention, the commands and/or data readout are via a communication channel provided in an implanted stimulator or in an external stimulator with implanted electrodes. In an exemplary embodiment of the invention, the helmet and/or rehabilitation devices are used to determine which stimulation settings are useful in the implanted device. Optionally, once determined, these settings are programmed in and can be used also without the rehabilitation system and/or at home. In an exemplary embodiment of the invention, one of the settings determined is the timing and/or triggering of stimulation. In an exemplary embodiment of the invention, a setting comprises electrode section. In an exemplary embodiment of the invention, a setting comprises signal amplitude, for example, selecting, using the systems and methods as described herein, what signal amplitude has a useful effect and/or reduced side effects.

In an exemplary embodiment of the invention, rehabilitation in conjunction with stimulation combines a rehabilitation device as described herein or in the PCT applications listed below and an implanted stimulator. In some cases, some
stimulation (and/or sensing) is provided using an implanted stimulator and some using a helmet as described herein.

In an exemplary embodiment of the invention, sensing of EEG from multiple and/or non-stimulated parts of the brain is easier with a helmet than with an implanted stimulator and is used to help configure implant settings.

It should be noted that external stimulation, for example DC electrical stimulation may be applied for longer continuous periods of time than internal stimulation, as there is no direct electrical contact between the electrode and the brain. This may reduce polarization, ionization, charge transport problems and/or other problems typically associated with brain electrodes. In an exemplary embodiment of the invention, external stimulation is used together with internal stimulation with the external stimulation generally stimulating a larger brain area a certain amount and the internal electrode enhancing stimulation (with a same or different signal type) in a sub-portion or in a partially overlapping area.

e. In an exemplary embodiment of the invention, accuracy/selectively of external stimulation is enhanced by providing more exact feedback on the beneficial and/or side effects of stimulation parameters and/or location. In an exemplary embodiment of the invention, a stimulator is fixed in place or scans an area and multiple stimulation settings are tried until a desired stimulation effect is achieved. It should be noted that one cause of reduced accuracy of such determination in the prior art is simply relative motion between the simulator and the patient (e.g., when a stimulator is hand-held). This is optionally remedied using a coupling as described herein.

f. The stimulation may be synchronized to brain activity and/or motor activity in various manners, for example, in a positive manner and/or a negative manner, for example, using positive or negative rules. As an example of negative synchronization, rules may be provided (e.g., by a therapist, based on negative experience with this or other patients) as to when stimulation is not to be applied in addition to providing a general scheme describing when stimulation should be applied (e.g., time based periodic). For example, stimulation may be avoided during a motion planning stage (e.g., based on EEG measurement), while patient body is in motion (e.g., using an accelerometer) and/or when patient is awake (or asleep) (e.g., based on EEG signal).
Exemplary positive synchronization rules include stimulating at the times mentioned above and/or at set (or calculated) delays relative to them. It should be noted that in some patients and/or rehabilitation scenarios certain times are to be avoided, for example as stimulation at those times may upset a delicate balance.

Conversely, such times may be those at which a maximum effect may be achieved. Stimulating between motions, stimulating at certain times of a day and/or stimulating based on the presence of an external signal which indicates presence of the helmet (e.g., for internal electrodes) or a rehab system or a suitable computer (e.g., for a helmet embodiment stimulator).

Alternatively or additionally, stimulation rules may define maximum allowed amplitudes and/or sequence shape and/or length (or other parameter limitations) at certain times and/or what sensed signals to log and at what delay and/or duration relative to the stimulation, hi an exemplary embodiment of the invention, a set of rules is applied and remains in force for a set or calculated time, responsive to a trigger, for example, patient input, a patient activity and/or sensing physiological signals.

**Cortical "fingerprints" of specific movements / movement's intention**

In an exemplary embodiment of the invention, a patient is trained to generate selectively EEG patterns associated with imagination of different simple motor actions, such as right or left hand movements. Optionally, the patient can be presented with one or more biofeedback signals including, but not limited to audio feedback, visual feedback and motor feedback (e.g. a therapy robot manipulates a limb if a correct type of brain activity is produced. Optionally, a degree of correctness of brain activity is assessed in terms of one or more of magnitude, position and timing. Optionally, negative feedback is provided to the patient if the correct type of brain activity is not achieved.

In an exemplary embodiment of the invention, even if the signal is of insufficient magnitude and/or does not arrive at motor neurons of the relevant muscles, the positive feedback is provided.

During the imagination of motion, specific cortical activity patterns ("cortical fingerprints") for specific movements are identified, for example a fingerprint for the motion of pushing the hand forwards, in comparison to a fingerprint which is recorded by moving the hand leftwards (or backwards, or upwards etc.). In an exemplary
embodiment of the invention, in each of a series of trials, the patient will imagine one of several actions (e.g. right or left hand movement, forwards-backwards, left-right, diagonal, up-down movements) while EEG from electrodes over sensorimotor cortex (or other recording sites) will be submitted to frequency- and/or component analysis (or other analysis methods) to derive signal features. For each imagined action, an n-dimensional feature vector is optionally defined. These vectors are optionally used to establish a patient-specific classifier that determines, from the EEG, which action the patient is imagining. Optionally, for each patient, a "cortical fingerprints movement related dictionary" that matches a specific cortical activation to a specific movement is generated. Optionally, the movements are carried out only in the mind. Alternatively or additionally, a comparison between imagined and actual motions is stored. Optionally, a patient stores such patterns before a paretic event, for example, as part of a regular checkup or when danger is identified.

In subsequent sessions, the system can use the classifier (i.e. the "dictionary") to translate the patient's motor imagery into a continuous output (e.g. moving the robot arm in the desired direction), and/or into a discrete output (e.g. initiating robot movement). This output can be presented to the patient as, for example, i) a sensory feedback through his hand, and/or ii) through online visual/acoustic feedback on the computer screen. Other feedback means can also be used.

In another variation of this paradigm, the patient will actually move his unaffected hand and/or the affected hand which is connected to system 200, or manipulator 204 will move the patient's hand during the sessions. A set of one or more, optionally dense, electrodes arrays may be used to record brain activity during these movements. This activity will be compared to the activity recorded during the imagined movements in order to find correlations in brain activity during imagined and actual movements. These "cortical fingerprints" of a movement will then be optionally used to "guess" the patient's intention and to carry out the desired movement.

In an exemplary embodiment of the invention, cortical fingerprints serve as a "blueprint" for design of a brain stimulation program to induce a desired motor response.

Multiple location rehabilitation
Fig. 9 is a flowchart 900 of a process of rehabilitation, in accordance with an exemplary embodiment of the invention. A particular feature of some embodiments of the invention is that a same design or even physically same rehabilitation device can be used in multiple situations and can be associated with a particular patient, optionally due to low cost and/or lightness and/or configurability.

For example, the helmet of figs. 3-5 can be used in bed, at home, while walking and at a clinic. In some embodiments described herein, the helmet can be used without an associated rehabilitation system and used to track brain activity and/or effect of stimulation on such. The stimulation tracked may be externally applied or internally applied. In embodiments where the helmet is ambulatory, the stimulator may be mounted on the helmet or electrical stimulation may be provided.

In an exemplary embodiment of the invention, a same helmet can attach to multiple rehabilitation systems, including a chair, a whole body system, an arm system and wireless connection with computer based rehabilitation.

At 902, a patient is diagnosed, for example, by a neurologist in a neurology clinic.

At 904, rehabilitation is applied. In an exemplary embodiment of the invention, the rehabilitation is applied by a nurse at the clinic with the neurologist applying the stimulation, changing stimulation parameters (906), changing rehabilitation settings and/or monitoring progress and/or side effects. In an exemplary embodiment of the invention, this allows a single neurologist to monitor the rehabilitation of multiple patients which are located at a same rehabilitation clinic/building, for example, within walking distance or in neighboring rooms. In some cases, some of the monitored patients are monitored by remote, for example, using a network to transit data and/or an image (e.g., video) of the patient response to stimulation. In this context it is noted that in some cases a single stimulation can have an effect that lasts for several (e.g., 5-10) minutes, while side effects may be/ought to be visible within 1 minute. This provides a window of time for a neurologist to move to another patient and/or activity.

At 908 and 910, rehabilitation is continued elsewhere, for example at a patient's house or at a rehab clinic (e.g., without direct neurological supervision). Optionally, the same stimulation settings are used and the helmet will fail to stimulate if not positioned properly. Optionally, the helmet measures impedance of electrode
pairs and will not stimulate if impedance is improper, e.g., outside a range for the stimulation electrodes and/or sensing electrodes. In an exemplary embodiment of the invention, the helmet sends data indicative of the neurological state of the patient to a monitoring station, for example, one manned by a neurologist. In addition, a single stimulation setting and/or logic of settings (e.g., how to change parameters automatically in response to measurements) may continue to be useful (without modification by a neurologist) for several days or weeks, during which the patient can continue rehabilitation without direct attention of the neurologist.

In an exemplary embodiment of the invention, rehabilitation at home uses a personal computer, optionally with no special equipment attached. In an exemplary embodiment of the invention, the helmet communicates with the computer, for example, using an IR link, a Bluetooth link (an example of local wireless) or via a cellular (an example of large area wireless) or other wireless network, or using a wired network, for example, including a cable that plugs into a USB port.

In one type of rehabilitation, software executing on the computer, for example, downloaded from a web site or provided by (e.g., stored on and uploaded) or with the helmet, is used to instruct the user to carry out motions (e.g., with a mouse, joystick and/or keyboard) and these instruction are used to assess patient state and/or as a series of rehabilitating exercises. Stimulation and/or EEG measurement may supplement such diagnosis and/or rehabilitation.

It should be noted that mouse movements can represent a significant class of activity where rehabilitation may be useful, for general purposes and/or for re-acquisition of ability to carry out daily activities.

In another type of rehabilitation, software provided by the helmet or otherwise loaded on the user computer provides data regarding the activity of the user. This data is sent to the helmet and/or to a monitoring station, where it is correlated with measurements from the helmet and/or effect of stimulation by the helmet. Optionally, the helmet generates stimulation signals responsive to patient interaction with his computer. Optionally, the camera is used to capture the actual activity. Alternatively or additionally, data describing the activity is sent from the computer to the helmet and/or monitoring station.

Previous patent applications
The following is a table of patent applications sharing applicants and/or inventors with the present application and which provide various apparatus and methods possibly helpful for carrying out embodiments of the present invention.

<table>
<thead>
<tr>
<th>Title</th>
<th>Serial #</th>
<th>Filing Date</th>
<th>Exemplary contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methods and Apparatus for Rehabilitation and Training</td>
<td>PCT/IL2005/000142</td>
<td>02/04/2005</td>
<td>Describes various methods and apparatus for rehabilitation, including manipulators and methods of taking motivation into account.</td>
</tr>
<tr>
<td>Methods and Apparatuses for Rehabilitation Exercise and Training</td>
<td>PCT/IL2005/000136</td>
<td>02/04/2005</td>
<td>Describes method and apparatus for rehabilitating while sitting and/or rehabilitating balance and coordinated movements.</td>
</tr>
<tr>
<td>Gait Rehabilitation Methods and Apparatuses</td>
<td>PCT/IL2005/000138</td>
<td>02/04/2005</td>
<td>Describes method and apparatus for rehabilitating gait and other multi-joint and/or coordinated movements.</td>
</tr>
<tr>
<td>Rehabilitation with Music</td>
<td>PCT/IL2005/000137</td>
<td>02/04/2005</td>
<td>Describes using music as feedback and for guiding rehabilitation.</td>
</tr>
<tr>
<td>Neuromuscular Stimulation</td>
<td>PCT/IL2005/000135</td>
<td>02/04/2005</td>
<td>Describes using sEMG and FES as part of a rehabilitation process.</td>
</tr>
<tr>
<td>Fine Motor Control Rehabilitation</td>
<td>PCT/IL2005/000139</td>
<td>02/04/2005</td>
<td>Describes devices and methods for rehabilitating fine motor control, such as writing.</td>
</tr>
<tr>
<td>Motor Training with Brain Plasticity</td>
<td>PCT/IL2005/000906</td>
<td>08/18/2005</td>
<td>Describes methods and apparatus that relate to rehabilitation while monitoring a brain.</td>
</tr>
</tbody>
</table>
The disclosure of all of these applications are incorporated herein by reference. In general, the techniques and apparatus in these patent applications can be used for providing rehabilitation of various body parts and/or feedback and/or be used in conjunction with cerebral monitoring as described herein.

5 Exemplary **Electroencephalogram (EEG) sensors**

EEG sensors suitable for use in the context of exemplary embodiments of the invention are available from, for example, Mind Media BV (Roermond-Herten; Netherlands).

One of ordinary skill in the art will be able to incorporate a commercially available EEG sensor (e.g. a NeXus-10 SCP electrode from Mind Media BV) into one or more exemplary embodiments of the invention.

10 **Exemplary Near-infrared spectroscopy (NIRS) sensors**

NIRS sensors suitable for use in the context of exemplary embodiments of the invention are available from, for example, ISS (Champaign IL, USA;) and/or Hamamatsu Photonics K.K. (Hamamatsu City, Japan).

In an exemplary embodiment of the invention, use of NIRS sensors contributes to patient compliance with a therapy protocol. Optionally, improved patient compliance results from a reduction in an amount of skin (e.g. scalp) preparation prior to application of the sensors and/or a reduction in invasivity. In an exemplary embodiment of the invention, NIRS sensors are employed in a helmet configured for home use. Alternatively, or additionally, NIRS sensors are advantageously employed in conjunction with an electrical stimulation program because they are not affected by electromagnetic noise. In an exemplary embodiment of the invention, NIRS sensors are used concurrently with electrical stimulators in a same helmet. Optionally, the NIRS sensors neither interfere with, nor are subject interference from, stimulation electrodes.

Optionally, use of NIRS electrodes contributes to an ability to monitor a larger number of points and/or areas in the brain concurrently. In an exemplary embodiment of the invention, monitoring of a plurality of locations contributes to informativity of the monitoring.

In an exemplary embodiment of the invention, use of NIRS sensors contributes to increased accuracy and/or decreased response time in monitoring AP assessment of brain activation achieved while using a robot. Optionally, motor performance is correlated to displayed brain activation. Optionally, response time is sufficiently short that users perceive the sensor output as "real time" feedback.

In an exemplary embodiment of the invention, NIRS sensors provide


invention, optical fibers can be arranged in different patterns to map square or rectangular areas.

Exemplary **Resolution Characteristics**

Exemplary EEG sensors of the type described above measure electro-magnetic signals under the electrode and in a circular area of about 2cm diameter.

In an exemplary embodiment of the invention, EEG electrodes are deployed in a set to produce maps of electrical activity in larger areas. Optionally, the set comprises 64, optionally 48, optionally 32, optionally 24, optionally 12, optionally 10, optionally 8 electrodes or lesser or intermediate or greater numbers of electrodes.

Exemplary NIRS sensors of the type described above measure hemoglobin oxygen saturation with about the same resolution.

In an exemplary embodiment of the invention, NIRS optical sensors are deployed in a set to produce maps of hemoglobin oxygen saturation in larger areas. Optionally, the set comprises 64, optionally 48, optionally 32, optionally 24, optionally 12, optionally 10, optionally 8 optical sensors or lesser or intermediate or greater numbers of sensors. Optionally, the sensors are distributed over the entire cranium or are concentrated over a specific area of the brain known to be affected (e.g. by injury or stroke).

In an exemplary embodiment of the invention, EEG and NIRS sensors are employed together in a single apparatus. Optionally, the two sensor types map overlapping areas. Optionally, EEG and NIRS sensors provide complementary information. In an exemplary embodiment of the invention, the complementary information contributes to an increased ability to close a feedback loop. According to various exemplary embodiments of the invention, the loop is closed by providing or adjusting stimulation and/or by adjusting therapy tasks in response to sensed brain activity.

Exemplary **patient acceptance considerations**

In an exemplary embodiment of the invention, total helmet weight is less than 1000, optionally less than 500, optionally less than 400, optionally less than 300, optionally less than 200 grams. Optionally, a lower weight and/or a smaller size contribute to increased patient acceptance. Based upon currently available NIRS and EEG components, there is no significant difference in weight between exemplary
embodiments of the invention which employ NIRS and exemplary embodiments of
the invention which employ EEG.

Optionally, a low helmet weight is achieved by using Styrofoam, carbon fiber
or other known low density structural components.

Optionally, electric contact with skin contributes to quality of a signal from an
EEG electrode. In an exemplary embodiment of the invention, skin preparation
contributes to an increase in electric contact quality. Skin preparation can include, for
example, shaving and/or application of a conductant (e.g. gel or cream) and/or glue. Optionally, skin preparation is reduced by using dry electrodes. In an exemplary
embodiment of the invention, dry electrodes contribute to an increase in patient
acceptance.

Optionally, optical connection via a direct light link with the scalp with skin
colors to quality of a signal from an NIRS sensor. In some cases, shaving or
cutting of hair contributes to provision of a direct light link with the scalp.

In an exemplary embodiment of the invention, sensor type is selected in
consideration of patient willingness to accept skin preparation and/or hair
cutting/shaving and/or in consideration of an anticipated amount of interference (e.g.
from sweating and/or motion).

Exemplary  sensor positioning considerations

Optionally, areas in the brain responsible for different activities (motor
execution, motor planning, memory, etc.) are known. For example, motor activity is
believed to be controlled through a motor cortex.

Within the motor cortex, a map of where each body part is controlled is
available. In an exemplary embodiment of the invention, an available motor cortex
map is employed to position sensors to monitor activity of a relevant body part.

Exemplary  Stimulation modes

According to various exemplary embodiments of the invention, stimulation can be
implemented by electrical transcranial currents and/or magnetic fields. Electrical
stimulation can be, for example, DC, AC, and/or pulsatile and/or oscillative.

In an exemplary embodiment of the invention, DC stimulation is applied via
external electrodes located in the helmet (e.g. transcranial direct current stimulation;
tDCS). Optionally, anodal tDCS is applied to the ipsilesional hemisphere and cathodal
tDCS is applied to the contralesional hemisphere concurrently, optionally simultaneously.

One of ordinary skill in the art will be able to incorporate an available DC-stimulator into the context of exemplary embodiments of the invention. For example, the Eldith programmable DC-stimulator (neuroConn GmbH, Ilmenau, Germany) is suitable for use in some exemplary embodiments of the invention.

In an exemplary embodiment of the invention, Interferential Current (IFC) stimulation is applied via external electrodes located in the helmet. IFC is based on the summation of two alternating current signals of slightly different frequency that are delivered using two pairs of electrodes. Optionally, IFC produces a low-frequency current. In an exemplary embodiment of the invention, when the two AC signals are in phase, the low-frequency component sums to an amplitude that is sufficient to stimulate while no stimulation occurs when the two AC signals are out of phase. In an exemplary embodiment of the invention, the two AC signals that have slightly different frequencies and stimulate is produced by the beat.

In an exemplary embodiment of the invention, Oscillating current stimulation is applied via external electrodes located in the helmet. Optionally, transcranial application of oscillating current stimulation (e.g. 0.75 Hz) induces slowly oscillating potential fields in underlying neocortical tissue. In an exemplary embodiment of the invention, oscillating current stimulation is applied selectively during defined states of sleep and wakefulness (e.g. during REM). Optionally, oscillating current stimulation exploits resonance effects occurring in neuronal networks for defined oscillatory rhythms.

In an exemplary embodiment of the invention, Magnetic stimulation (rTMS) is applied via external electrodes located in the helmet. Exemplary rTMS protocols are described by George et al (Neuroreport (1995) 6(14):1853-6) and by Pomeroy et al. (Neurorehabil Neural Repair. 2007 Apr 4; e-publication preceding print publication). The contents of these articles are each fully incorporated herein by reference.

In an exemplary embodiment of the invention, a closed loop between measured brain activity and stimulation contributes to an ability to correctly adjust stimulation parameters independent of stimulation mode.

Exemplary Feedback Loops
According to exemplary embodiments of the invention, sensors provide feedback on patient response to stimulation delivery and/or task performance. Optionally, the feedback can provide data pertaining to a patient response to the delivered signal and/or the effect of an incremental change in delivered signal. In an exemplary embodiment of the invention, the sensors are installed in the helmet.

In some exemplary embodiments of the invention, data pertaining to patient response to the delivered signal, optionally short term response (e.g. during a therapy session), optionally substantially immediate (e.g. during performance of a single repetition of a therapy task) response, is provided by sensors installed in the helmet (e.g. EEG and/or NIRS) and/or by external sensors (e.g. fMRI) in communication with helmet controller 216 (Fig. 2) as illustrated in exemplary method 1600 (Fig. 11).

Optionally, EEG and/or NIRS sensors are placed in proximity to and/or at a distance from stimulation sources. Optionally, there is a tradeoff between sensor sensitivity for a relevant brain area and interference from stimulation electrodes directed towards the same brain area. Alternatively, or additionally, stimulating electrodes are wired to function as sensors.

In an exemplary embodiment of the invention, a large number of sensors is employed, each sensor with a known location relative to a subject's cranium and/or brain. In an exemplary embodiment of the invention, sensors are located in the helmet and/or deployed on the scalp. As the number of sensors increases, and/or distance between sensors decreases, spatial resolution improves. Optionally, 16, 24, 32, 40, 48, 56 or 64 or intermediate or greater numbers of sensors are employed.

Fig. 11 depicts an exemplary embodiment of the invention in which a large number (e.g. 32 or more) of electrodes are employed 1610 to determine or map a relevant brain area for subsequent stimulation.

In an exemplary embodiment of the invention, a method of the general type depicted in Fig. 11 serves as a mapping or evaluation stage in a two tiered therapy plan which also comprises a therapy stage. Optionally, the mapping or evaluation stage employs a greater number of sensors and/or stimulation electrodes than the therapy stage.

In an exemplary embodiment of the invention, the exemplary method of Figure 11 relies upon comparison between brain activity during task performance and not during
task performance at each location represented by a sensor. In the depicted example, four phases of evaluation with specific related tasks are presented.

In an exemplary first phase 1620 screening process designed for evaluation of therapy of a paralyzed hand after a stroke, the subject is asked to imagine 1640 a movement of the paretic hand (e.g. in response to a first stimulus) and not to imagine anything 1630 when in response to a second stimulus. Optionally, the first and second stimuli are visual stimuli (e.g. symbols on a computer screen) or audio stimuli (e.g. passages of music or spoken instructions). Optionally, symbols comprising visual stimuli are defined in terms of one or more of color, shape, size and position. In an exemplary embodiment of the invention, the second stimulus comprises an absence of the first stimulus (e.g. when the green light is on do "X" and when it goes off, do "Y"). Repetition of this first phase continues until a sufficient amount of data is collected. Optionally, a number of repetitions varies with a degree of variability of the collected data. In an exemplary embodiment of the invention, 30, 40, 50, 60, 70, 80, 90 or 100 or lesser or intermediate or greater numbers of repetitions are sufficient to provide a clinically useful and/or statistically significant data set.

In an exemplary second phase (beginning again from 1620) of the exemplary screening, the subject is asked to imagine 1640 a movement of the non paretic hand (e.g. in response to the first stimulus) and then not to imagine anything 1630 (e.g. in response to the second stimulus). Stimuli and repetition are as in the first phase.

In an exemplary third phase (returning again to 1620) of the exemplary screening, the subject is asked to actually move 1640 the paretic hand (e.g. in response to the first stimulus) and then not to do anything 1630 (e.g. in response to the second stimulus). Stimuli and repetition are as in the first and second phases.

In an exemplary fourth phase (returning again to 1620) of the exemplary screening, the subject is asked to actually move 1640 the non paretic hand (e.g. in response to the first stimulus), and then not to do anything 1630 (e.g. in response to the second stimulus). Stimuli and repetition are as above.

After completion of two, optionally three, optionally all 4 of the phases, data from all 32 electrodes is analyzed and/or processed 1650 by analytic circuitry (e.g. helmet controller 216, optionally using matlab software package; The MathWorks Inc.; Natick, MA, USA) to identify or find 1660 a brain area corresponding to an electrode in which the best response is received, Optionally, evaluation of mu-rhythm strength
is employed as an indicator. In an exemplary embodiment of the invention, mu-
rhythm is strongest over the motor cortex, either the damaged or the intact, depending on the cortex lesion. Once the brain area is identified, stimulation is applied through that area.

In an exemplary embodiment of the invention, application of stimulation to and/or monitoring of activity in the identified brain area is performed using a device with a relatively small number of electrodes (e.g. 1 or 2 or 4 stimulation electrodes and/or 4 or 8 or 12 sensors). Optionally, reducing the number of sensors and/or stimulation electrodes in the "second tier" therapy phase does not significantly reduce sensing resolution and/or accuracy of stimulation delivery. Optionally, a BCI interface is used for training 1670.

Fig. 12 depicts an additional exemplary method of treatment 1700 which implements a closed feedback loop based on measured brain activity. Optionally, method 1700 can employ any of the different helmet designs and/or sensor types described hereinabove or can rely on other sensor configurations (e.g. implanted sensors).

At 1710 the sensors sense brain activity. Optionally, sensing begins during a time when the patient has been instructed not to attempt to perform a task. The sensed brain activity is provided 1720 as an output signal. According to various exemplary embodiments of the invention, the output signal can be routed to a controller (e.g. controller 1100 of Fig. 10) and/or a computer (e.g. 1040 of Fig. 10).

As part of the therapy program, one or more tasks (e.g. tasks selected by a neurologist of other therapist) are presented 1730 to the patient. In an exemplary embodiment of the invention, sensing 1710 and providing 1720 of output signal continue as the patient performs the presented task(s).

In an exemplary embodiment of the invention, the output signal is analyzed 1740 and/or logged 1760 during performance of presented tasks 1730. Alternatively, or additionally, performance of presented tasks can be analyzed 1742 and/or logged 1760. Optionally, tasks are adjusted 1750 responsive to the analyses 1740 and/or 1742.

In some exemplary embodiments of the invention, adjusting 1750 occurs during a therapy session in which tasks are performed. For example, a patient that succeeds modifying brain activity to a desired degree after four repetitions of an "imagination
based" task, may be presented with a new task without completing a nominal ten
repetition cycle.

Optionally, stimulation parameters and/or tasks are changed in the middle of a
task. Optionally, stimulation parameters and/or tasks are evaluated and/or update
every 60, 30, 20, 10, 5 or 1 seconds or intermediate or greater or lesser numbers of
seconds.

In some exemplary embodiments of the invention, adjusting 1750 occurs after a
therapy session in which tasks are performed. For example, logging 1760 may involve
storage of data in a memory device (e.g. flash memory) and/or transmission to a
remote site (e.g. via a network connection available to work station 104). Optionally,
data stored in a log file can be analyzed 1740 periodically (e.g. after every therapy
session or every "n" therapy sessions. Optionally, an increase in n contributes to a
decrease in responsiveness of the feedback loop. Optionally, a decrease in
responsiveness of a feedback loop contributes to a reduction in influence of measured
noise.

Whatever the frequency of adjustment 1750, adjusted tasks are subsequently
presented 1730 to the patient. In an exemplary embodiment of the invention, this type
of feedback loop contributes to a reduction in direct supervision by therapists by
allowing implementation of decisions by software.

In some exemplary embodiments of the invention, brain stimulation 1770 is
applied based upon analyses 1740 and/or 1742 using one or more exemplary
parameters as described above. Optionally, applied brain stimulation influences brain
activity sensed at 1710. In an exemplary embodiment of the invention, the applied
stimulation is evaluated and/or adjusted based upon the activity sensed at 1710.

**Additional exemplary considerations in motor rehabilitation**

In an exemplary embodiment of the invention, stimulation of an identified
motor area of the brain is adapted to increase excitability of the identified motor area.
Alternatively, or additionally, an intact hemisphere of the brain can be stimulated to
inhibit its activation and/or to record normal brain activity for comparison to the
impaired activity of the injured hemisphere.

In an exemplary embodiment of the invention, brain activity in a healthy brain
portion is dampened and/or brain activity in a damaged brain portion is amplified by
one or more applied stimulation signals.
Additional rehabilitation

The above description has focused on motor rehabilitation, however a helmet and/or methods and apparatus as described herein may also be used for non-motor rehabilitation, for example for speech rehabilitation or (motor) planning rehabilitation.

In an exemplary embodiment of the invention, closing the loop, as in registering the effect of stimulation is manual, for example, by a neurologist. Alternatively or additionally, the closing is automatic. For example, rehabilitation directed to train a patient in generating a rhythm may be monitored by using an audio input that detects whistles generated by a patient on a whistle and/or generated at a user input using a healthy part of the body.

In addition, it should be noted that while most examples of motor and/or sense rehabilitation have focused on limbs, such rehabilitation also applies to other parts of the body, such as torso and face muscles. Measuring motion of such body parts is optionally using markers attached to the body part and imaged using a camera which detects motion of the markers and/or relative to a non-moving marker.

**Exemplary Speech rehabilitation**

In an exemplary embodiment of the invention, a speech rehabilitation therapy program includes stimulation of the relevant brain area. Optionally, the relevant area of the brain comprises Broca's area which is known to be involved in language processing, speech production and comprehension. Broca's are is located in the opercular and triangular sections of the inferior frontal gyrus of the frontal lobe of the cortex. Broca's and Wernicke's areas are found unilaterally in the brain.

Various brain areas may be damaged/stimulated with aphasia, including symbol sequencing areas, and motor areas.

In an exemplary embodiment of the invention, feedback, optionally vocal feedback, is received from the patient during therapy. Optionally, vocal feedback is via microphone 117 connected to helmet 106 (Fig. 1). Alternatively, or additionally, feedback can comprise measurements of movement and/or tone of relevant facial and/or lingual and/or labial muscles. Optionally, vocal feedback is analyzed with respect to one or more of amplitude, smoothness, pronunciation correctness and frequencies. In an exemplary embodiment of the invention, analysis is conducted by helmet controller 218 (Fig. 2). Relevant physical response parameters for speech therapy are described above.

Optionally, therapy parameters are adjusted in response to patient feedback immediately and/or based on analysis of progress over time. In an exemplary embodiment of the invention, adjustment includes tuning of one or more stimulation parameters including, but not limited to, stimulation delivery site, electric parameters of stimulation, magnetic parameters of stimulation and temporal parameters of stimulation.

In an exemplary embodiment of the invention, adjustable stimulation parameters include, but are not limited to, current, duration, pulsatility and frequency. Optionally, currents of for example 0.5, 1 or 2 mA (or intermediate or greater or lesser values) are initially applied and adjusted as needed. Optionally, a continuous current is applied for 5, 10, 20 or 40 minutes (or intermediate or greater or lesser times). Optionally, pulsatility of the current can be in seconds, tenths of seconds, hundredths of seconds or milliseconds. Optionally, low frequency (e.g. 2, 4, 8, 10, 20, 30 or 50 HZ or intermediate or greater or lesser values) AC currents are employed for stimulation.

In some exemplary embodiments of the invention, the patient may receive speech tasks concurrent with stimulation. Exemplary tasks include word repetition, phrase repletion, reading a passage of text and singing at least a portion of a song. Optionally, tasks are presented on display screen 114 (Fig. 1) and/or via speakers (optionally earphones; e.g. installed on ear electrode 610; Fig. 6B). Optionally, a human therapist administers the tasks. Optionally, tasks are administered via a module adapted for speech therapy. Exemplary adaptations for speech therapy include interfaces to a microphone and/or craniofacial sensors as described above. Optionally, sensing and/or stimulating electrodes are attached at relevant craniofacial locations. In
an exemplary embodiment of the invention, stimulation is provided before and/or during attempts to speak. Optionally, the patient is shown images of their mouth and/or hears recordings of their voice during task performance with and without stimulation.

5 **Exemplary Neurofeedback training**

In an exemplary embodiment of the invention, helmet 106 is configured as a brain computer interface (BCI). In an exemplary embodiment of the invention, the BCI employs brain signals to issue commands to a computer program. In an exemplary embodiment of the invention, when selected brain activity parameter at a relevant location reaches a threshold, the command is issued to the computer. Optionally, sensors (e.g. EEG or NIRs electrodes) monitor brain activity and send the signals to a BCI controller (e.g. computer running BCI software). In an exemplary embodiment of the invention, the software analyzes the signals and checks a degree of conformity to a specific goal (e.g. intensity and/or pattern). According to various exemplary embodiments of the invention, different responses to a high degree of conformity can occur. Optionally, the BCI activates a program and/or a rehabilitation system. Optionally, stimulation supplied through the helmet complements endogenous brain signals of the patient.

Optionally, helmet 106 comprises brain activity sensors (e.g. EEG and/or NIRS).

In an exemplary embodiment of the invention, sensor position is verified, for example using positioning sensors 340 as described hereinabove, to assure that brain activity of a correct area is sensed. An exemplary method for selection of a correct brain area is described in detail hereinabove.

Output from sensors in the helmet is optionally analyzed by analytic circuitry (optionally a software module). Based upon results of the analysis, the circuitry provides a feedback signal to the patient (e.g. using an installed software module and/or a display). The feedback signal comprises an indication of a degree of patient success in controlling a specific brain activity. According to various exemplary embodiments of the invention, the feedback signal comprises one or more of a visual signal, an auditory signal, and a motor signal (e.g. manipulation of a body part by a robotic device or contraction of a muscle by application of a controlled electric current or motion of a pinch and grip device) and an olfactory signal. Optionally, the feedback comprises at least a portion of a therapy task.
In an exemplary embodiment of the invention, the feedback signal contributes to development of conscious control over one or more specific components of neural brain activity which are not typically subject to conscious control. Optionally, conscious control over one or more specific components of neural brain activity which are not typically subject to conscious control is useful in physical rehabilitation (e.g. stroke patients, TBI patients) or non-physical rehabilitation purposes (e.g. anxiety control or substance abuse).

In an exemplary embodiment of the invention, applied stimulation modifies neural activity in the damaged area of the brain (e.g. by rerouting or recruiting). Optionally, positive feedback to conscious attempts to activate specific brain areas (e.g. augmentation of a motor movement) reinforces a connection between the attempted neural activity and the motor function for the patient.

Exemplary combination of BCI and Stimulation

Optionally, a BCI helmet and circuitry to analyze data from sensors and provide a feedback signal to the patient as described above additionally comprises a stimulator (e.g. tDCS). In an exemplary embodiment of the invention, if the analysis conducted by the circuitry indicates that the patient has not succeeded in modulating the appropriate brain activity to a desired degree (e.g. above or below a threshold) the circuitry signals the helmet controller which operates the stimulator. The stimulator provides a direct stimulation of the relevant brain areas to produce, or augment during a patient initiated attempt, the desired modulation of brain activity. Optionally, a designated amount of time is permitted to elapse before the patient is deemed not to have succeeded. In an exemplary embodiment of the invention, the designated amount of time is a few seconds to a few minutes.

A feedback signal as described above is optionally provided as soon as modulation of the appropriate brain activity to the desired degree is achieved whether "help" from the stimulator is needed or not.

Optionally, monitoring of patient success in modulation of the appropriate brain activity to the desired degree coupled with stimulation of the brain when needed contributes to increases an overall success rate. In an exemplary embodiment of the invention, patterned activation and deactivation of selected brain areas contributes to cortical reorganization. For example, manipulation of a limb by a robotic device as a
feedback for altered brain activity in a relevant brain area can contribute to a patient's ability to move the limb without aid of the robotic device.

Exemplary **use of stimulation with a robotic exercise device**

In an exemplary embodiment of the invention, one or more stimulators are operated in conjunction with a specific therapy exercise performed with a robotic therapy device. Optionally, electrodes which sense an intention to execute a specific motion are then operated as stimulation electrodes to initiate the action. Optionally, a subset of available stimulation electrodes is activated based upon one or more of a lookup table, a previous calibration session and a medical diagnosis.

Alternatively, or additionally, a subset of stimulators and/or sensors located in or adjacent to a specific brain area (e.g. represents certain motion) are employed when that motion is performed by the robot. Optionally, timing of stimulation is synchronized with the motion performed by the robot.

Optionally, stimulation provided by the stimulators is adjusted in response to a degree of active participation of the patient in the exercise. In an exemplary embodiment of the invention, adjustment of stimulation comprises adjusting one or more of an amount of stimulation and/or a stimulation parameter (e.g. voltage, current, duty cycle, temporal envelope and total duration.)

Optionally, intensity of current can be increased or reduced as described above and/or stimulation duration can be changed and/or a protocol of the stimulation can be changed (e.g. example, a therapist can try DC and pulsatile protocols and choose the one that has better affect on the motor performances) and/or a subset of stimulation electrodes employed and/or a number of regions to be stimulated (concurrently and/or sequentially).

In exemplary embodiments in which the stimulation protocol is other than DC (pulsatile, IFC, AC) frequencies for stimulation can be varied.

Optionally, pauses between stimulation sessions during a single session and/or a period between sessions can be varied (e.g. daily, weekly, monthly)

Active participation of the patient in the exercise can be evaluated via brain activity (e.g. using EEG or NIRS) or physical measures of exerted force (e.g. accelerometer or resistometer). Optionally, in a set of Y repetitions of an exercise, X repetitions are performed with no stimulation applied. In an exemplary embodiment of the invention, measurements of active participation are conducted during these X
repetitions. This methodology may be applied in a manner similar to computer "neural network" training. Optionally, stimulation electrodes placement is adjusted as a result of measured brain activity based on motor practice (e.g. with the robotic exercise device)^n

In an exemplary embodiment of the invention, stimulation of the brain during a specific robotic exercise is coupled with deactivation of neural signals to a healthy counterpart organ (e.g. hand) and/or a higher level area of the brain (e.g. motor planning center). Optionally, deactivation comprises applying a signal to a relevant brain location and/or one or more relevant muscles.

In an exemplary embodiment of the invention, brain stimulation is applied to two or more areas related to a same task. Optionally, application of the signal to the areas alternates in a rhythm synchronized to the rhythm of the robotic exercise. For example, stimulation at cognitive area during display of a visual stimulus followed (e.g with an expected and/or desired delay for a response from a BCI ) by stimulation of a motor area during manipulation of a body part by the robot.

Exemplary use of BCI with a robotic exercise device

In an exemplary embodiment of the invention, a BCI as described hereinabove is employed in conjunction with a robotic therapy device. Optionally, in response to brain activity measured by sensors in the helmet, a feedback signal comprising robotic motion is delivered to the patient. For example, if a patient achieves neuronal activity consistent [even partially] with flexing the left elbow, the robot responds by flexing the left elbow. Optionally, the feedback signal comprising robotic motion provides important reinforcement when the level of neuronal activity achieved is insufficient to produce motion and/or produce correct motion and/or correct timing of motion of the relevant body part. Optionally, the robotic motion contributes to motor skills and/or range of motion and/or muscle strength. This exemplary embodiment is expected to find utility in, for example, stroke, TBI and teaching conscious control of a prosthetic limb.

Exemplary construction of a cortical fingerprint dictionary

In an exemplary embodiment of the invention, sensors located in the helmet are used to identify specific cortical activity patterns ("cortical fingerprints") for specific movements. Optionally, while the patient executes a specific task, data from sensors (e.g. EEG) over sensorimotor cortex (or other relevant brain locations) is analyzed by
a software module to derive its features. In an exemplary embodiment of the invention, for each action, an n-dimensional feature vector will be defined. These vectors can serve as a patient-specific classifier that determines from sensor data (e.g. EEG) what neuronal activity correlates to a specific task. In an exemplary embodiment of the invention, a large number of classifiers serves as a "cortical fingerprints movement related dictionary" that matches a specific cortical activation to a specific movement for a specific individual.

According to various exemplary embodiments of the invention, any matching method known in the art, for example, RMS-closest match can be employed.

In an exemplary embodiment of the invention, controller 216 of system 200 (Fig. 2) uses the dictionary in subsequent sessions to translate the patient's motor action into a continuous output (e.g. moving the robot arm in the desired direction), or into a discrete output (e.g. initiating robot movement).

Optionally, the personalized dictionary of cortical fingerprints for specific movements can be useful for conscious control of a prosthetic limb. In an exemplary embodiment of the invention, the dictionary is built according to healthy limb movements, optionally mirrored to a contralateral limb. Once the dictionary is available, the patients' thoughts and intents of specific movement will be recorded by helmet electrodes, analyzed, and translated into real movements of the artificial arm.

In an exemplary embodiment of the invention, cortical fingerprints are used together with stimulating muscles directly, based on emg measured contralaterally.

In an exemplary embodiment of the invention, the personalized dictionary of cortical fingerprints for specific movements can be useful for transfer from one side of the body to the other. For example, a dictionary of right hand cortical fingerprints, can be used as a template for stimulation to achieve similar movements in a paralyzed left hand.

Rehabilitation Dosage

In an exemplary embodiment of the invention, the cortical effects are used to define a required dosage of rehabilitation and/or stimulation and/or to control billing.

In an exemplary embodiment of the invention, a match is made between an amount of activity by a user (for example, as measured by actual exercise time or cortical activity) and a therapeutic effect and/or a rehabilitation condition. In one example, 20 "active minutes" per day may be the dosage for medium severity pre-motor one
damage. Optionally, a range of possible doses may be defined, for example between a low dosage (not having sufficient effect) and a high dosage (possibly causing over compensation or undue tiredness). Optionally, the dosage prescribed for a patient is a relative dosage dependent on the patient's total ability and/or total number of rehabilitation issues. Optionally, system 100 is used to track the actual applied dosage and/or its effect. Optionally, system 100 can distinguish the actual dosage applied to each area (or issue) in need of treatment. In particular, system 100 may carry out these functions in an ambulatory mode.

Optionally, the dosage is defined as a function of one or more of physical exertion mental exertion and/or attention/engagement.

Optionally, dosage is measured in units of one or more of power, force or energy.

In an exemplary embodiment of the invention, system 100 is designed to apply a known amount of dosage and/or decide on changing an exercise schedule, once a certain dosage is reached and/or to prevent over-dosing.

In some cases, dosage is used to define a minimal level required to achieve benefit from rehabilitation, for example, a minimum exertion level or a minimal engagement level may be required.

In an exemplary embodiment of the invention, system 100 is used to ensure such minimal attention/exertion levels.

In an exemplary embodiment of the invention, attention is measured by measuring compliance and/or variation in response time to instruction. Absolute response time may be of interest, for example, if there is an expected response time based on previous activities.

While the present application focuses on physical activities, it should be noted that the methods described herein can also be used for cognitive and perceptive rehabilitation, including the usage of dosage. In an exemplary embodiment of the invention, cognitive and/or perceptive activity is detected directly. Optionally, a patient is requested to do a physical activity to indicate the cognitive or perceptive activity. Optionally, the effect of motor signals in the brain is ignored and/or used as a trigger to search for brain activity related to a decision to provide a response.

**Mental state**
In an exemplary embodiment of the invention, daily assessment of mental state is carried out as part of rehabilitation. In an exemplary embodiment of the invention, brain image, blood tests and/or EEG measurements are used to assess an instant mental state of a patient, for example, depression or anxiety. Optionally, depending on the motivational state of the patient additional motivation may be provided and/or lesser achievements may be expected. It should be noted that this type of depression relates to a mood, which can change hourly or daily and not to clinical depression which is a long term illness.

In an exemplary embodiment of the invention, cognitive rehabilitation progress is assessed using other means, such as problem solving or other cognitive tests. Optionally, cognitive progress is used to calibrate expected physical rehabilitation progression, for example, assuming that a same improvement rate is expected for areas with similar damage under similar exercise protocols. Optionally, an improvement template is adjusted to match a patient based on improvement in one or more functions and used to estimate expected improvements in other functions. Optionally, a template includes a correspondence between expected improvement rates for areas of different degrees of damage and/or degrees of accessibility to rehabilitation. Optionally, the template is adjusted according to actual rehabilitation effort.

In an exemplary embodiment of the invention, EEG measurements are used to determine settings, environmental cues and/or exercises that promote desired cortical brain activity and/or reduce noise that interferes with detection thereof.

In an exemplary embodiment of the invention, the environmental cues are selected from one or more of colors, images, language, or other means that have been documented to cause certain types of emotional reactions in people.

Optionally, a therapist and/or system 100 provide other motivational means, such as motivational talks, movies and positive feedback optionally timed to have a desired effect.

In an exemplary embodiment of the invention, system 100 controls simultaneously two or more of physical rehabilitation, brain stimulation, emotional control and instructions. Optionally, a rehabilitation plan is optimized to take into account the parameters being controlled.
In an exemplary embodiment of the invention, brain stimulation and/or an implantable stimulator are used for mood altering.

**Motion types**

In system 100 as illustrated, the motion which is controlled is generally that of a single point, e.g., a tip of the manipulator. By providing various attachments for the tip, the tip may be connected, for example to a bone, to a joint or to a different part of the body. The attachment may be rigid, for example using a strap or it may depend on cooperation of or action by the patient, for example, as a handle or a rest. Specific attachment devices, for example for a hand, arm, elbow, knee, ankle and/or shoulder may be provided. Multiple tips (optionally with individual manipulators) may be provided for attachment at different points of the body, on a same or different body part.

When providing rehabilitation various types of motion may be supported, for example, one or more of:

a) Passive Motion. The tip is moved (by system 100) and the patient moves with it.

b) Resisted Motion. The patient moves the tip and encounters resistance. The resistance may be of various magnitudes and may be uniform in all direction or be directional.

c) Assisted Motion. When a patient moves the tip, a positive feedback on the manipulator increases the force of motion in the direction moved by the patient.

d) Force Field Motion. The patient moves the tip. Along a certain trajectory one level of resistance (or none) is encountered. Deviation from the trajectory is not allowed or meets with resistance. Motion along a "correct" trajectory can be without resistance, or possibly assisted. An increased resistance is optionally exhibited in a volume surrounding the trajectory. An even greater resistance is optionally exhibited in a surrounding volume. A prevention of motion may be provided in an outside volume, hi an exemplary embodiment of the invention, a corrective force vector is applied when not on the trajectory, pointing towards the trajectory. Optionally, instead of a corrective force, resistance varies as a function of distance from the trajectory, thus, motion of the tip is naturally urged back to the trajectory. Optionally, the force is applied in the direction of the path. Alternatively, the force maybe a unidirectional force of resistance.
This type of motion may be used to help train the patient in a desired motion.

e) Mirrored Motion. Motion of the tip is required to mirror the trajectory of
motion of a different element, for example for dual limb rehabilitation as described
below.

f) Free Motion. Patient moves the tip in any way he desires, possibly receiving
feedback. As the patient (or therapist or helper) moves the tip, system 100, may record
it for future playback. In a playback mode the prerecorded motion (or path) is
optionally reconstructed using other modes. Optionally, the recorded path is modified
(e.g., smoothed or otherwise edited), for example automatically or manually.

g) General Force Field. A force field and/or an assistance field is defined
which is not related to any particular trajectory. For example, a range of trajectories
may be allowed to be practiced by a user, or a real or virtual situation simulated (e.g.,
water, areas with obstacles).

h) Local Force Field. A force field which is applied to only a small locality
and/or only in one or two dimensions.

i) Restricted Motion. One or more points of the body of a subject are
supported or prevented from moving. Optionally, the angles between such points and
the moving points on the patient are measured. In one example the elbow is locked
with a dedicated harness allowing only a shoulder motion. In some embodiments, the
restriction is partial and/or is provided by a movable element (e.g., the manipulator).

j) Initiated Motion. The patient initiates the motion (e.g., a 1 cm motion or 100
gram force) and system 100 completes or helps the patient complete the motion in
space. The completion may be of a whole trajectory or of part of a trajectory.

k) Implied Motion. System 100 begins the motion and the patient completes it.

System 100 may assist the rest of the motion in various manners (e.g., by changing to
one of the modes described herein after the motion starts). If the patient fails to pick
up the motion, system 100 may generate a cue, for example an audio reminder.
Different parts of a single motion trajectory may each have a machine initiation
definition. Optionally, if a patient is too slow in moving, system 100 begins the
motion.

l) Cued Motion. The patient receives a cue from the system before motion
according to a different mode starts. The cue can be, for example, vibration of the tip,
stimulation pads on the skin, audio or visual cue. In some embodiments of the
invention, the strength of the cue and/or its timing and/or other ongoing activities (e.g., a visual display and game) are used to help train the coordination between different modalities, for example, hand-eye coordination. A motion cue can be used to train a kinesthetic sense.

m) Teach Mode. System 100 is taught a motion. In one example, a therapist performs a motion and motion parameters at each point are recorded and can then be used for an exercise. Another way of teaching the system is to use a path that the therapist uses. The therapist may use a control to indicate a point to be taught or a continuous mode may be defined by which an entire trajectory is learned. Optionally the path and points are edited before replay. Optionally, the paths are abstracted, for example, by smoothing or identifying motion points, before playback.

n) Step Initiated. The patient initiates the motion (e.g., a 1 cm motion or 100 gram force) and system 100 completes or helps the patient complete the motion in space, however, patient initiated motion occurs in steps and/or increments. In some exemplary embodiments of the invention, a patient generated force in a predetermined "right" direction and/or range of directions must be applied at each step in order for system 100 to complete and/or help the patient complete the motion. A "right" direction is optionally defined as one in which the patient will receive a desired therapeutic benefit for moving in that direction. Optionally, the steps and/or increments are variable. Optionally, the steps and/or increments are pre-settable. Optionally, there is more than one "right" direction. The completion may be of a whole trajectory or of part of a trajectory.

o) Follow Assist. System 100 is pre-programmed with at least one point in a path of motion to be followed by the patient. In an exemplary mode of operation, patient initiates motion along the path of motion, optionally assisted by system 100. Motion along the path is optionally conducted at a pre-set speed in some exemplary embodiments of the invention. Optionally, the speed is not pre-set. Upon the arrival of patient at the pre-programmed point, motion by the patient in a "right" direction causes at least a brief acceleration in speed instigated by system 100. Optionally, a plurality of points are used to allow the patient to "connect the dots" in the motion path. Optionally, "arrival at a point" is determined considering vector of approach, speed of approach, elapsed time prior to arrival, and/or accuracy of arrival to the point. Optionally, the patient must hold at the point steadily (i.e. no wobble) before
being considered to have arrived at the point. In some exemplary embodiments of the
invention, the patient is assisted with movement along a predetermined proper path
for therapy. In some exemplary embodiments of the invention, system 100 moves
continuously at a predetermined speed and whenever the patient exerts a force above a
certain level and/or in the right direction), the speed of the exercise is increased.

In all of these modes, stimulation may be applied at various times, for
example, at one or more of before motion of a healthy limb, after healthy motion and
before paretic motion, after both motions are completed, after motion starts, at preset
times in a motion if/when motion falters and/or for only some motion events.

**Exemplary customization of stimulation protocol**

In an exemplary embodiment of the invention, training or therapy sequences are
adjusted and/or updated based upon current patient condition. Optionally,
adjustment/update comprises one or more of the following processes.

In some exemplary embodiments of the invention, a neurologist determines an
initial brain plasticity index (BPI). BPI represents quantitatively a change in neural
activity in a relevant brain area. Optionally, initial BPI is determined based upon data
received from the helmet and/or data acquired independently of the helmet. Data
acquired independently of the helmet includes, but is not limited to, data from an
independent Brain Imaging device (e.g. optical imaging, PET, fMRI). Optionally, the
independent Brain Imaging device is adapted to communicate with the helmet, for
example to provide data supplementary to that provided by sensors in the helmet.

Alternatively, or additionally, the neurologist can use a robotic assessment to
determine appropriateness of patient as a candidate for internal brain stimulation
and/or appropriate stimulation type. Optionally, a patient response to intense or other
robot therapy is measured before the brain stimulation intervention and/or after the
stimulation intervention to produce a BPI.

In an exemplary embodiment of the invention, stimulation parameters are
customized to an individual subject prior to initiation of therapy and/or during therapy
based on BPI. Customization during therapy optionally includes one or both of
immediate adjustment of stimulation parameters based upon patient response during a
single session and delayed adjustment of stimulation parameters based upon patient
response during a plurality of sessions.

**Exemplary evaluation of brain function by BPI**
In exemplary embodiments of the invention, BPI considers different facets of brain activity. Facets of brain activity include, but are not limited to, strength, duration, typical frequencies, phase, latency of response of the measured activity, and patterns of activation of areas and groups of areas.

In an exemplary embodiment of the invention, two or three or more of the facets are measured and compared to normative values to calculate BPI. In an exemplary embodiment of the invention, there is a tradeoff between increased accuracy from measuring a greater number of facets and difficulty in comparing an individual BPI to a multi-variable normative BPI.

Optionally, different types of BPI are computed for different task types (e.g. different movements for motor rehabilitation). In an exemplary embodiment of the invention, certain facets of brain activity are deemed more relevant to certain task types.

In an exemplary embodiment of the invention, a contralateral uninjured side of a brain in a same subject is used to provide a normative BPI for a specific task type. Optionally, use of the uninjured side of the brain in an individual reduces an effect of population variation on normative BPI values for any specific facet of brain activity and/or any specific task. Optionally, comparison between BPI in the two sides of the brain (injured and uninjured) is repeated during rehabilitation to evaluate progress.

Optionally, adjustment of BPI in the injured brain portion to match BPI in the uninjured side is evaluated as complete success. Optionally, complete success is judged in consideration of normal differences between sides in an individual (e.g. less dexterity in fingers of the left hand in a "right handed" individual with no brain injury).

Optionally, one goal can to dampen neural activity on the uninjured side, as often after injury it gets too strong and overpowers the injured side.

In an exemplary embodiment of the invention, the BPI includes a laterality index which indicates a relative difference between the two sides of the brain. Optionally, the laterality index indicates an extent of over activation of an intact hemisphere and/or an extent of a sub activation of the impaired hemisphere (e.g. spatial distribution, timing, synchronization and quality). It is believed that in addition to damaged neurons which cause sub activation of the injured region, the intact
hemisphere inhibits the impaired hemisphere. In some case, the laterality index increases as lesion severity increases.

In an exemplary embodiment of the invention, BPI data are used in conjunction with results of one or more additional tests that evaluate a subjects abilities in the impaired domain (e.g. Fugel-Mayer (FM) Test and/or Jebsen-Taylor Hand Function Test (JTT) for motor evaluation) to determine the general condition of the patient.

In an exemplary embodiment of the invention, a computer automatically evaluates data. Optionally, data from an independent Brain Imaging device and/or BPI data and/or scores from a relevant test (e.g. FM and/or JTT) are evaluated by a computer. In an exemplary embodiment of the invention, analytic circuitry (e.g. programmed with a diagnostic software module) receives the data as an input and provides a list of relevant tasks as an output.

In an exemplary embodiment of the invention, evaluation of brain function is repeated periodically throughout a recommended therapy regimen. Optionally, evaluation of brain function is used as an indicator of patient response to therapy. Optionally, data on patient response to therapy is useful in adjusting a recommended therapy regimen for an individual subject and/or for adjusting therapy recommendations for a population of subjects with similar brain injuries and/or medical histories (e.g. it may be discovered that patients under age 16 respond better to a larger number of shorter therapy sessions or that female patients respond better to a slightly higher delivered current than male patients (or the opposite)).

Exemplary Considerations in determining BPI

General observations on the learning process

The learning process is progressive and can be divided into stages, with each stage characterized by a pattern of brain activity related to activation and inactivation of certain brain areas. In an exemplary embodiment of the invention, stage specific patterns are identified by external sensors mounted in the helmet (e.g. EEG or NIRS) or independent of the helmet (fMRI).

Optionally, each stage of the learning process can be further characterized in terms of a set of exercise and/or application profile adapted to that stage, optionally in order to achieve desired effects. In an exemplary embodiment of the invention, adaptation is based upon one or more parameters including, but not limited to, which
exercise are selected, a number of repetitions of each selected exercise, a time period between exercises and/or sessions and an order of the selected exercises.

Patient to patient variation is to be anticipated so that learning progress rates can vary even when an experimentally determined "optimum stage specific exercise set" is used as a therapy regimen for an individual patient.

In an exemplary embodiment of the invention, BCI is implemented in each phase of the learning process to train the patient to modify their brain activity to conform to predicted brain activity for the next stage of learning. Optionally, phases of the learning process are defined by specific activity maps (e.g. the motor region will be divided to sub regions, and stage specific patterns determine which regions are activated to form a stage specific activity map). In an exemplary embodiment of the invention, understanding of the phases of the learning process contributes to an ability to implement a therapy program that aids a patient in progressing to a next phase.

In an exemplary embodiment of the invention, these general principles of learning are applied to activities of daily life (ADL). Optionally, ADL training employs a guiding program including exercises and/or tasks relevant to their personal environment (e.g. their chair, their bed, their door, their cup, their staircase) as opposed to generic ADL components typically encountered in a physical therapy gymnasium of a clinic. In an exemplary embodiment of the invention, portability of the helmet contributes to the success of an ADL based therapy program by allowing the patient to implement exercises in their own personal environment (e.g. home and/or workplace and/or school) with the aid of helmet mediated feedback.

In general, a determination of BPI comprises a comparison between brain activity at multiple time points (e.g. before and after the treatment). In an exemplary embodiment of the invention, brain activity is measured during a same exemplary exercise. Optionally, BPI represents a quantitative measure of change(s) caused by the treatment. A BPI measurement can be made using EEG, MRI, TMS, NIRS, PET or other known technologies for measuring brain function.

Optionally, BPI is based upon a pair of measurements (e.g. measurements performed before and after the first session or before and after a specified number of sessions). Optionally, time intervals between measurements are shortened and a measurement is made before and after each exercise. In an exemplary embodiment of the invention evaluation of BPI for each exercise contributes to an ability to gauge an
immediate effect of each task on neuronal activity and/or short term trends as a result of the treatment.

The temporal and or therapeutic difference which can be expected to produce a significant BPI measure can vary, for example, with one or more of sensitivity of the measurement technique, the therapy program and patient condition.

Optionally, BPI is based upon a series of measurements (e.g. at the end of each therapy session, weekly, monthly or quarterly). Optionally, the series is divided into pairs of measurements as above. In an exemplary embodiment of the invention, a progress graph for each of the above parameters or total BPI is prepared from the series of measurements.

BPI optionally considers one or more parameters selected from among: amplitudes of signals measured in one or more injured portions of the brain, areas involved in activation and a difference in activation between the ipsilesional and the contralesional portions of the brain. Alternatively, or additionally, measure of motor function can serve as indirect BPI parameters. Measures of motor function include, but are not limited to, range of motion, applied force, rate of motion and smoothness of motion.

In an exemplary embodiment of the invention, these parameters are measured while moving a paretic organ (e.g. arm or leg), a healthy organ, and both organs concurrently, optionally simultaneously (e.g. during task performance and/or stimulation and/or guided imagination)

In an exemplary embodiment of the invention, activation of a contralesional part of the brain is measured while moving a paretic organ (e.g. before and after the treatment).

Exemplary duration of response-adaptation for repetitive stimuli/motions: EEG

When EEG data is used as a basis for BPI calculations, negativity of CNV can serve as a parameter. CNV indicates readiness potential or the intention of executing the motion). In an exemplary embodiment of the invention, CNV is measured in damaged brain tissue, and healthy brain tissue while executing movements of the paretic and intact organs. The difference between the measurements serves as an EEG specific BPI parameter.

Alternatively, or additionally, spectral density analysis of EEG patterns can serve as a BPI parameter. Optionally, analysis of the typical frequencies for mu-
rhythm/SCP can be informative. In an exemplary embodiment of the invention, differences between before and after the treatment, between the injured and healthy brain portions, and a ratio between "interesting" frequencies and the background noise can serve as BPI parameters.

In an exemplary embodiment of the invention, analysis of spectral density focuses on specific frequencies of interest and/or their intensities relative to other frequencies. For example, a specific wave (e.g. beta wave) can be analyzed with respect to its energy before and after a treatment.

In an exemplary embodiment of the invention, BPI measurements based upon one or more parameters as described above are performed as a patient imagines or visualizes performing a task (e.g. elbow flex or forearm extension) as opposed to actually performing the task. Optionally, a same patient is evaluated with respect to an imagination BPI and a performance BPI.

Optionally, BPI data is evaluated and/or plotted separately for each learning stage. In an exemplary embodiment of the invention, learning-stage-specific evaluations and/or plots reveal one or more of slope of improvement, time to reach plateau, time duration of each stage.

In an exemplary embodiment of the invention, calculating a slope of improvement in each stage contributes to an ability to evaluate when a specific task has a reduced, optionally no, marginal utility for additional repetitions. Optionally, the task is modified or switched for a different task at this stage. In an exemplary embodiment of the invention, comparison of BPI plotted as a function of time for similar patient populations treated with different therapy regimens serves as a tool for evaluating the therapy regimens. In an exemplary embodiment of the invention, data of this type from a large group of patients serves as a population data set which contributes to an ability to design a therapy program for similar individuals.

Optionally, BPI plotted as a function of time indicates a learning rate for each stage of learning and/or for each patient and/or for a group of patients in a similar clinical situation.

Optionally, a single parameter in which there a significant improvement is selected as a clinically relevant indicator of BPI.

Alternatively, or additionally, one or more parameters are excluded when evaluating BPI because they are deemed non-informative. Optionally, a non-
informative parameter is one that is inconsistent with other parameters. For example, activation of different brain regions correlates with an increased total signal amplitude because more neurons are activated. However, a decrease in signal to noise ratio for important frequencies suggests the added neurons are activated with no synchrony.

In an exemplary embodiment of the invention, clinical relevance of direct measurements of BPI is evaluated by examining a degree of correlation to motor function improvement.

If there is good correlation between measured brain activity normalization and measured motor improvement, it suggests that an appropriate therapy regimen has been determined.

If there is a poor (or no) correlation between measured brain activity normalization and measured motor improvement it can suggest either that the current therapy regimen is incorrect or that there is severe disconnection in the neural system. In cases of disconnection, attempts to optimize brain stimulation parameters may be unwarranted.

In an exemplary embodiment of the invention, medication is administered systemically and/or locally to affect one or more of brain plasticity, excitation level and blood flow. In an exemplary embodiment of the invention, stimulation at least partially offsets side effect of medication and/or fatigue.

In an exemplary embodiment of the invention, stimulation of the brain which produces patterns of brain activity characteristic of an advanced stage of learning suggest that an improvement in motor function is imminent. Possibly, the patient does not perceive any change at this stage and may become frustrated. In an exemplary embodiment of the invention, a BCI which provides positive feedback can contribute to a decrease in patient frustration.

In an exemplary embodiment of the invention, evaluation of the effect of stimulation on cortical reorganization and motor improvement for the specific patient considers increases in appropriate neural activity and/or synchronization thereof, during stimulation and/or improvements in motor performance during stimulation and/or a time duration of improvements after the end of the stimulation.

In an exemplary embodiment of the invention, a comprehensive evaluation of patient progress logs the entire treatment course. The log may include, for example types of exercises, number of repetitions for each exercise, stimulation durations,
number of stimulation sets, number of BCI sessions prior to acquisition of control over the required activity and a time spent to progress from one exercise level to the next one.

In an exemplary embodiment of the invention, sEMG is measured during the treatment period and a graph of electrical activity of the muscles in the paretic limb is used as an indicator of treatment progress and/or BPI.

Exemplary visual stimuli

In some exemplary embodiments of the invention, a patient is presented with visual stimuli as an integral part of therapy, for example on display screen 114 (Fig. 1). Optionally, adjunct visual stimuli are presented before and/or during and/or after performance of a task. In an exemplary embodiment of the invention, visual stimuli are presented at intervals throughout a therapy session. Visual stimuli can be, for example, animation and/or video sequences which are referred to herein as "movies".

In an exemplary embodiment of the invention, the adjunct visual stimulus comprises a movie of someone performing a same task that the patient is being asked to perform (e.g. "touch the shoulder with your right hand"). Optionally, display screen 114 displays only the relevant organ (no face), so that the patient identifies with the presented image. In an exemplary embodiment of the invention, the sequences are custom tailored to an individual patient (e.g. by showing the patient's body part instead of a generic body part).

Optionally, the movie illustrates a correct way (optionally at actual speed or in slow motion) of performing the task and/or provides instructions for correct execution. Instructions can be provided as audio instructions, text instructions or graphic instructions (e.g. arrows superimposed over a portion of the image in the movie).

Optionally, direct stimulation of body parts is concurrently provided. Optionally, implanted electrodes are activated in a manner that causes brain activity corresponding to motion.

In an exemplary embodiment of the invention, patient performance is monitored during the task (e.g. by sEMG and/or by motion sensors 108). In an exemplary embodiment of the invention, monitoring data is evaluated by a software module after one or more repetitions of a specific task. Optionally, the patient is shown a movie with specific instructions for one or more corrections based upon the evaluation. In an
exemplary embodiment of the invention, the tasks are associated with ADL (e.g., take the cup with both hands and bring it to your mouth). Optionally, the movie is personalized so that the patient sees a coffee cup made by their own grandchild positioned on their own kitchen table in the movie.

In an exemplary embodiment of the invention, the movie is provided as an interactive game. Optionally, an input in the form of patient movement (e.g., a button press, mouse click or joystick movement) produces an output on display screen 114 (e.g., firing of a simulated weapon, movement of an animated figure or object or selection of an item). In an exemplary embodiment of the invention, this type of movie is employed for guided imagination.

In an exemplary embodiment of the invention, movies are adapted to guide the patient through a desired task. Optionally, a speech rehabilitation therapy which offers primary audio stimulus in the form a spoken word or phrase offers adjunct visual stimuli in the form of a movie depicting movements of the mouth associated with correct pronunciation. In an exemplary embodiment of the invention, the patient's actual pronunciation is recorded using camera 116 and/or microphone 117. Optionally, the recording of actual pronunciation is played back, optionally after filtering, for the patient and/or monitored by therapy personnel. In an exemplary embodiment of the invention, a software module offers playback of corrected pronunciation in the patient's voice and/or corrected images of the patient's mouth during pronunciation. Optionally, the patient can be aware of the correction or unaware of the correction.

In an exemplary embodiment of the invention, the movie is subject to input from a BCI. Optionally, brain activity corresponding to concentration or attention is measured and if concentration diminishes, the movie stops. Optionally, when attention is refocused on display screen 114 (as indicated by brain activity measurements), the movie resumes. Alternatively, or additionally, BCI provides positive reinforcements for desirable brain activity (e.g., positive visual images or music). Alternatively, or additionally, a level of detail in the movie can be adjusted in response to measured concentration or attention.

In an exemplary embodiment of the invention, the movie is designed to evoke a strong emotion (e.g., by depicting a life threatening situation such as fire, flood, danger of falling or a dangerous animal). Depiction of a life threatening situation in the movie
can trigger survival instincts and/or physiochemical responses which can influence brain activity. Optionally, the movie scenario makes it clear that the patient can escape the life threatening situation by performing a simple act. Optionally, instructions concerning the simple act are explicitly provided. According to different embodiments of the invention, the simple act can comprises a motor act (e.g. press a button or move a joystick) or a neural activity. Optionally, use of a neural motor activity as the simple act is mediated by a BCI which translates a target neural activity in the patient's brain to a life saving sequence in the movie (e.g. opening of a parachute to stop a fall or descent in fire stairs to escape a fire).

In an exemplary embodiment of the invention, tasks are adapted to encourage creativity and/or concentration. Exemplary creativity/concentration tasks employ a musical instrument (e.g. xylophone or keyboard) as an input device.

In an exemplary concentration task, a software module provides a sequence of musical notes via speakers and the task is to repeat the sequence of notes using the input device. As a number of notes in the sequence increases, a degree of concentration required for successful completion of the task increases. In an exemplary embodiment of the invention, stimulation provided through the helmet can supplement concentration when a level of difficulty of the presented task in conjunction with the instantaneous concentration and/or attention levels prevents success. In other exemplary embodiments of the invention, similar principles are applicable to non musical tasks.

In an exemplary creativity task, a software module provides a sequence of musical notes with a pattern via speakers and the task is to continue the pattern using the input device. As pattern complexity increases, a degree of creativity for successful completion of the task increases. In an exemplary embodiment of the invention, stimulation provided through the helmet can supplement creativity when a level of difficulty of the presented tasks prevents success. In other exemplary embodiments of the invention, similar principles are applicable to non musical tasks.

Exemplary psychological treatment

In an exemplary embodiment of the invention, the helmet is used as part of a psychological treatment program. Optionally, movies presented on display 114 are part of the program.
In an exemplary embodiment of the invention, the psychological treatment program treats a specific anxiety or phobia and the movies comprise an anxiety stimulus. For example, a patient with agoraphobia might be presented with a movie simulating a walk through an open field. Optionally, sensors located in the helmet monitor neural activity associated with anxiety or panic caused by the movie. Optionally, neural stimulation provided by the helmet adjusts neuronal activity to offset the feelings of anxiety.

In an exemplary embodiment of the invention, a BCI is used to train the patient to reduce the neural activity underlying anxiety. Optionally, stimulation is reduced over time as the patient learns to down regulate the neural activity underlying the anxiety.

In an exemplary embodiment of the invention, once a stimulation pattern which effectively reduces the anxiety is determined, the patient can use the (portable) helmet to deal with an actual anxiety stimulus (e.g. a real walk in the park), instead of a movie stimulation of the anxiety stimulus. Optionally, presentation of the anxiety stimulus in the movie can be gradual and/or systematic.

An additional exemplary embodiment of a psychological treatment programs which can be implemented using the helmet is substance abuse treatment.

Substance abuse treatment can be affected, for example, using a modified aversion therapy. For example, an alcoholic patient might be shown a movie of people drinking in a tavern. Optionally, sensors located in the helmet monitor neural activity associated with a desire for a drink. Optionally, neural stimulation provided by the helmet can be patterned to adjust neuronal activity to offset desire.

In an exemplary embodiment of the invention, once a stimulation pattern which effectively offsets desire is determined, the patient can use the (portable) helmet for a real visit to a tavern.

Alternatively, or additionally, substance abuse treatment can be affected using satisfaction therapy. For example, a cocaine addict might be given a measured amount of cocaine in a controlled setting while wearing the helmet. Optionally, sensors located in the helmet monitor neural activity associated with (1) a feeling of satiety induced by the cocaine initially and (2) a desire for additional cocaine after the feeling of satiety passes. Optionally, neural stimulation provided by the helmet can be patterned to adjust neuronal activity to emulate satiety and/or to offset desire. In an exemplary embodiment of the invention, once a stimulation pattern which effectively
emulate satiety and/or to offset desire the patient can use the helmet overcome their addiction.

In an exemplary embodiment of the invention, similar principles are applied to smoking and/or overeating.

Exemplary analytic circuitry

Implementation of devices, methods and systems according to exemplary embodiments of the invention involves performing or completing selected tasks or steps manually, automatically, or a combination thereof. Optionally, automated performance relies on analytic circuitry. Moreover, according to actual instrumentation and equipment of exemplary embodiments of the invention, several selected steps could be implemented by hardware or by software on any operating system of any firmware or a combination thereof. For example, as hardware, selected steps of the invention could be implemented as a chip or a circuit. As software, selected steps of the invention could be implemented as a plurality of software instructions being executed by a computer using any suitable operating system. In any case, selected steps of exemplary embodiments of the invention could be described as being performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, analytic circuitry can comprise a computer such as a PC, laptop computer or personal digital assistant and/or be incorporated into another device (e.g. a cellular telephone or MP 3 player). In an exemplary embodiment of the invention, the computer performs the functions of helmet controller 216 as described above.

Exemplary interfaces

In an exemplary embodiment of the invention, helmet controller 216 is provided as a computer with one or more relevant software modules installed and a plurality of ports. Optionally, helmet 106 and/or controller 203 and/or measuring devices 213 and/or 218 and/or camera 116 and/or 215 are connectable to the ports via a suitable connection interface. In an exemplary embodiment of the invention, the ports comprise USB ports and hardware components are connectable to the ports via a USB plug. Alternatively, or additionally, some hardware components communicate with controller 216 via a wireless interface (e.g. Bluetooth) which fulfils the port function.

Exemplary kits
In an exemplary embodiment of the invention, an exemplary helmet (e.g. including sensors and/or stimulation electrodes) equipped with a connector compatible with a computer port is provided with a machine readable media (e.g. CD ROM, DVD disc or Internet site) containing one or more software modules. Optionally, installation of an appropriated software module on a computer renders the computer an exemplary helmet controller 216. Optionally, additional peripheral devices are included. Peripheral devices include, but are not limited to, peripheral sensors (e.g. sEMG recorder 218, button 204, controller 203 and peripheral activity monitor module 220) and FES stimulation module 222.

Exemplary two tiered system

Fig. 10 depicts an exemplary two tiered system 1000 according to one exemplary embodiment of the invention. A first tier (depicted above the dashed line) represents an initial clinical evaluation (e.g. by a neurologist) conducted using a neurologist platform 1010 which receives data from a diagnostic chair 1020. Chair 1020 can be, for example, as depicted in Fig. 1 or Fig. 7 and/or can include a helmet of one of the types depicted in Figs. 1, 3, 4, 5, 6A, 6B or 7 and described hereinabove.

In an exemplary embodiment of the invention, the diagnostic chair 1020 includes a large number (e.g., at least 32) of sensors of brain activity and/or sensors placed in close proximity to one another over a particular brain region of interest. Brain activity data from the sensors is relayed to neurologist platform 1010, optionally via a wireless link 1014.

In an exemplary embodiment of the invention, the sensors collect data during performance of one or more tasks by the patient as described hereinabove. Optionally, neurologist platform 1010 uses one or more software modules to analyze the data from the sensors (e.g., to calculate a BPI as described hereinabove). According to various exemplary embodiments of the invention, data can be sorted by brain area and/or task type and/or injury state (e.g. contralateral comparison) and/or presence/absence of external stimulation. Based upon the analysis, the neurologist recommends a therapy program, optionally to be implemented without direct supervision by the neurologist (e.g. at home). The portion of Fig. 10 below the line depicts an exemplary therapy program and optional hardware for implementation. In some exemplary embodiments of the invention, the therapy program employs some,
or all, of the equipment depicted in/described in the context of the initial clinical evaluation.

In an exemplary embodiment of the invention, the therapy program centers around a helmet 1050 with stimulation electrodes and/or sensors 1052 (e.g. as depicted in Figs. 1, 3, 4, 5, 6A, 6B or 7 and described hereinabove) and a controller 1100. Optionally, controller 1100 and helmet 1050 are configured for wireless communication (e.g. via Bluetooth) as depicted. In an exemplary embodiment of the invention, controller 1100 communicates with and/or is incorporated into a user workstation 1040.

According to various embodiments of the invention the controller is adapted to receive user input from one or more of a mouse 1410, a joystick 1420, a pinch and grip device 1430, a robot 1300 and/or other motor devices 1440 (e.g. one or more of musical keyboard, alphanumeric keyboard, pen, touch-screen, bicycle, treadmill, flexion and extension device act). Optionally, the controller is adapted to provide motor input to the user (e.g. via robot 1300 and/or joystick 1420). Optionally, the motor input is a feedback provided in response to brain activity detected by sensors in helmet 1050 as described above.

In some exemplary embodiments of the invention, controller 1100 receives peripheral inputs (e.g. from sEMG 1500 and/or motion sensors 1510 and/or physiologic sensors 1520 (e.g. heart rate and/or respiration and/or temperature monitors) and/or other sensors 1530 (e.g. voice sensors and/or pain sensors).

Optionally, other devices 1200 are also attached to the controller. Other devices 1200 can include, but are not limited to activities of daily living (ADL) props (e.g., cup, plate, flatware), audio outputs (e.g., speakers or earphones), a camera to record task performance, a reflexology device, analgesic aid (e.g., a heating or cooling device or medication delivery pump) and a contraction device. Optionally, contraction devices are employed to activate muscles and/or increase blood flow.

**General**

While the above application has focused on motor training for rehabilitation, the methods and/or apparatus described herein may also be used for other applications. In an exemplary embodiment of the invention, motor training is used for enhancing the control of muscles by athletes. Alternatively or additionally, motor training is used for enhancing motor control of musicians. Optionally, musical
feedback is provided during training and corresponding to the exercises. However, it should be noted that some methods of the present invention find particular utility in rehabilitation, especially when motor control is weak, patchy and/or non-existent.

Various designs for robots and positioning devices (e.g., hexapods) are known in the art. It should be appreciated that various ones of the statements described herein may be adapted for such robots and/or positioning devices, in accordance with exemplary embodiments of the invention. Alternatively or additionally, software may be provided for such robots and devices for carrying out various of the methods described herein, all in accordance with exemplary embodiments of the invention.

In some embodiments of the invention, the systems described herein are used for uses other than motor rehabilitation, for example, cognitive rehabilitation, task training, testing and/or robotic manipulation.

It will be appreciated that the above described methods of rehabilitation may be varied in many ways, including, omitting or adding steps, changing the order of steps and the types of devices used. Additionally, components and/or actions ascribed to exemplary embodiments of the invention and depicted as a single unit may be divided into subunits. Conversely, components and/or actions ascribed to exemplary embodiments of the invention and depicted as sub-units may be combined into a single unit with the described/depicted function. For example, a single electrode can be employed as both a sensor and a stimulation electrode.

Alternatively, or additionally, features used to describe a method can be used to characterize an apparatus and features used to describe an apparatus can be used to characterize a method.

In addition, a multiplicity of various features, both of method and of devices have been described. In some embodiments mainly methods are described, however, also apparatus adapted for performing the methods are considered to be within the scope of the invention. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a particular embodiment are necessary in every similar embodiment of the invention.

Further, combinations of the above features are also considered to be within the scope of some embodiments of the invention. Also within the scope of the invention are kits which include sets of a device, one or more limb holding attachments and/or software. Also, within the scope is hardware, software and computer readable-media including
such software which is used for carrying out and/or guiding the steps described herein, such as control of arm position and providing feedback. Section headings are provided for assistance in navigation and should not be considered as necessarily limiting the contents of the section. When used in the following claims, the terms "comprises", "includes", "have" and their conjugates mean "including but not limited to". It should also be noted that the device is suitable for both male and female, with male pronouns sometimes being used for convenience.

It will be appreciated by a person skilled in the art that the present invention is not limited by what has thus far been described. Rather, the scope of the present invention is limited only by the following claims.
1. **A method of rehabilitation management**, comprising:
   providing a plurality of patients fitted with sensors;
   assigning tasks to said patients by a therapist;
   rehabilitating said patients not under the direct attention of said therapist; and
   monitoring the rehabilitating using data acquired by the sensors during performance of
   the tasks.

2. **A method according to claim 1**, wherein the rehabilitation is performed by a person
   other than said therapist.

3. **A method according to claim 1**, wherein the rehabilitation is performed by a
   computerized system which adjusts the tasks in response to the monitoring in order to close a
   feedback loop.

4. **A method according to any of claims 1 to 3**, comprising:
   producing a rehabilitation progress report.

5. **A method according to any of claims 1 to 4**, wherein at least some of the sensors are
   external to the patients.

6. **A method according to any of claims 1 to 5**, wherein at least some of the sensors are
   implanted in the patients.

7. **A method according to any of claims 1 to 6**, wherein at least some of the sensors
   measure a brain activity.

8. **A method according to any of claims 1 to 7**, wherein at least some of the sensors
   measure a muscle activity.

9. **A method according to any of claims 1 to 8**, wherein the tasks are performed with a
   brain computer interface (BCI).
10. A method according to any of claims 1 to 9, wherein the monitoring comprises computing a brain plasticity index (BPI).

11. A method according to any of claims 1 to 10, comprising applying a transcranial direct current stimulation (tDCS).

12. A rehabilitation therapy kit, the kit comprising:
   a body adapted to be coupled to a head and adapted for communication with a therapy module;
   the therapy module mounted on the body and comprising at least one of:
   (i) at least one sensor adapted to sense brain activity; and
   (ii) at least one stimulator adapted to stimulate a brain;
   a machine readable media containing instructions for operation of the therapy module.

13. A kit according to claim 12, comprising at least one peripheral device adapted for communication with a therapy module and adapted to perform at least one function selected from:
   (i) function as a sensor; and
   (ii) respond to an instruction from a machine on which the instructions of the machine readable media have been installed.

14. A kit according to claim 12 or claim 13, comprising a logging module adapted to store data pertaining to at least one of:
   brain activity;
   signals provided by the at least one stimulator; and
   a motor response to the signals provided by the at least one stimulator.

15. A treatment apparatus, the apparatus comprising:
   (a) at least one sensor of brain activity capable of providing an output signal;
   (b) a presentation module adapted to provide at least one task to a patient;
   (c) analytic circuitry configured to analyze the output signal; and
   (d) a controller adapted to adjust tasks presented by the therapy module in response to the analysis;
   thereby adjusting the tasks closes a feedback loop.
16. Apparatus according to claim 15, wherein the therapy module comprises a physical therapy component and the tasks comprise exercises of a body part.

17. Apparatus according to claim 15 or claim 16, comprising a stimulation module adapted to apply electric stimulation to a specific target in a brain.

18. Apparatus according to claim 17, wherein the stimulation module is adapted to apply transcranial direct current stimulation (tDCS).

19. Apparatus according to any of claims 15 to 18, wherein the analysis computes a brain plasticity index (BPI) or an indication of change therein.

20. Apparatus according to any of claims 15 to 19, wherein the output signal operates a brain computer interface (BCI).

21. Apparatus according to any of claims 15 to 20, wherein the tasks comprise imagining a motor activity.

22. Apparatus according to any of claims 15 to 21, wherein the tasks comprise imagining a situation.

23. Apparatus according to any of claims 15 to 22, wherein the tasks comprise motor activities.

24. Apparatus according to any of claims 15 to 23, comprising:
   (e) a logging module adapted to store data pertaining to at least one of:
       (i) brain activity;
       (ii) signals provided by at least one stimulator and
       (iii) a signal from a peripheral motor sensor.

25. A treatment method, the method comprising:
   (a) sensing brain activity and providing an output signal of the activity;
   (b) presenting tasks to a patient;
(c) analyzing the output signal during performance of presented tasks; and
(d) closing a feedback loop by adjusting presented tasks in response to the analysis.

26. A therapy apparatus, the apparatus comprising:
   a plurality of sensors adapted to sense brain activity;
   a brain computer interface (BCI) adapted to:
       provide a positive user feedback if the brain activity exceeds a threshold; and
       provide no positive user feedback if the brain activity does not exceed the threshold;
   a stimulation module adapted to apply a specified stimulation only if the brain activity does not exceed the threshold.

27. Apparatus according to claim 26, configured so that a user feedback is provided in at least 50% of user attempts to produce brain activity which exceeds the threshold.

28. Apparatus according to claim 26, configured so that a user feedback is provided in at least 75% of user attempts to produce brain activity which exceeds the threshold.

29. Apparatus according to claim 26, configured so that a user feedback is provided in at least 90% of user attempts to produce brain activity which exceeds the threshold.

30. A helmet-like device for rehabilitation, comprising:
   a body adapted to be coupled to a head;
   at least one external sensor adapted to sense brain activity and mounted on said body;
   and
   at least one external stimulator adapted to stimulate a brain and mounted on said body.

31. A device according to claim 30, configured as a portable device.

32. A device according to claim 30, configured as a stationary device.
33. A device according to any of any of claims 30 to 32, comprising circuitry configured to operate said device both when the device is physically attached to a rehabilitation system and when not attached, said operation being different in attached and unattached conditions.

34. A device according to claim 33, wherein said circuitry closes a control loop between stimulation and sensing.

35. A device according to claim 33 or claim 34, wherein said circuitry wirelessly interacts with at least one device not physically attached to said device.

36. A device according to claim 35, wherein the wireless interaction is via a Bluetooth protocol.

37. A device according to any of claims 30 to 36, wherein said device at least one of is controlled by and controls said rehabilitation system, when attached thereto.

38. A device according to any of claims 30 to 37, wherein the at least one external sensor includes a Near-infrared spectroscopy (NIRS) sensor.

39. A device according to any of claims 30 to 38, wherein the external stimulator is adapted to provide at least one stimulation type selected from the group consisting of electrical and magnetic.

40. A helmet-like device for rehabilitation, comprising:
   a body adapted to be coupled to a head;
   at least one external stimulator adapted to stimulate a brain and mounted on said body; and
   circuitry configured to operate said helmet both when physically attached to a rehabilitation system and when not attached, said operation being different in both attached and unattached conditions.

41. A device according to claim 40, configured as a portable device.

42. A device according to claim 40, configured as a stationary device.
43. A device according to any of claims 40 to 42, wherein said device is adapted to connect both mechanically and functionally to said rehabilitation system.

44. A device according to any of claims 40 to 43, adapted to attach to said rehabilitation system using a quick connect attachment.

45. A device according to any of claims 40 to 44, wherein said device is counter balanced when attached to said rehabilitation system.

46. A device according to any of claims 40 to 45, wherein said device is attached in a manner which reduces gravitational strain on a patient's head.

47. A head-worn adjustable electrode device, comprising:
   a body; and
   a plurality of electrodes attached to said body and selectively positionable relative to a head, when said body is worn on a head, said body being adapted for selective positioning of electrodes.

48. A device according to claim 47, wherein said body comprises a band and comprising a plurality of electrode supports circumferentially arrangable on said band.

49. A device according to claim 48, wherein at least one of the electrode supports is an elongate electrode support defining multiple attachment positions for an electrode thereon.

50. A device according to any of claims 47 to 49, wherein said body is adjustable.

51. A device according to claim 50, wherein said body is plastically deformable.

52. A device according to any of claims 47 to 51, comprising at least one brain stimulation device coupled to said body and whose position is adjustable relative to said body.

53. A device according to claim 52, wherein when said head is approximated by a sphere, with a hemisphere corresponding to skull areas overlying the brain, said electrodes and said
stimulator are selectively positionable substantially anywhere on at least half the surface of said hemisphere.

54. A method of treating a patient, comprising:
   mounting a plurality of brain activity sensors on the patient using a head-worn device;
   rehabilitating the patient utilizing signals from said sensors, at least at a clinical setting
   and at a home setting.

55. A method according to claim 54, wherein a same device design is is used in the clinical setting and the home setting.

56. A method according to claim 54, wherein a same device is used in multiple settings over a period of time of at least one week.

57. A method according to claim 54 or claim 56, wherein the mounting comprises mounting at least one Near-infrared spectroscopy (NIRS) sensor.

58. A method according to any of claims 54 to 57, comprising:
   stimulating the patient during the rehabilitating; and
   monitoring an influence of the stimulating on the signals and adjusting the stimulating
   in response to the influence;
   thereby forming a closed feedback loop.

59. A method according to claim 58, wherein the stimulating comprises applying an electric stimulus.

60. A method according to any of claims 58 or 59, wherein the stimulating comprises applying a motor stimulus.

61. A method of rehabilitation management, comprising:
   providing a plurality of patients;
   while said patients are in a same care location, setting brain stimulation parameters for said patients by a therapist;
rehabilitating said patients at said care location by a person other than said therapist, not under the direct attention of said therapist; and
monitoring said rehabilitation and an effect of stimulation by said therapist.

62. A method according to claim 61, wherein said stimulation is externally applied stimulation.

63. An external head-mounted brain stimulator, comprising:
at least one sensor input;
a stimulator adapted to stimulate a brain; and
circuitry which prevents stimulation responsive to signals from said sensor input.

64. A stimulator according to claim 63, wherein said sensor input comprises an EEG input.

65. A stimulator according to claim 63, wherein said sensor input comprises a Near-infrared spectroscopy (NIRS) input.

66. A stimulator according to any of claims 63 to 65, wherein said sensor input comprises a positioning indicating input.

67. A stimulator according to any of claims 63 to 66, wherein said sensor input comprises a contact-quality indicating input.

68. A rehabilitation system, comprising:
at least one articulated arm having a stimulator mounted thereon;
a patient support positioned so that a head of a patient can be selectively stimulated at multiple locations using said stimulator; and
a helmet adapted for mounting on the patient's head.

69. A system according to claim 68, wherein said helmet includes a plurality of positionable sensing electrodes.

70. A system according to claim 68 or claim 69, wherein said stimulator is selectively attachable to said helmet.
71. A system according to any of claims 68 to 70, wherein said helmet is rigidly attached to said support.

72. A method of enhancing the accuracy of sensing or modifying brain activity, comprising:
   placing in proximity to brain, at a first position, a sensing or stimulating element such that a certain effective brain volume is associated with the element;
   operating the element;
   causing measured motion of a body part;
   analyzing a relationship between said operating and said motion; and
   selectively moving said element to a new position in proximity to the brain, based on said analyzing.

73. A method according to claim 72, wherein said element is external to the body.

74. A method according to claim 72, wherein said element is internal to the body.

75. A method of rehabilitation of a patient using an external sensing array, a rehabilitation system and an internal stimulator, comprising:
   stimulating a brain of the patient using said internal stimulator;
   locating an external sensing array in a position where it can sense brain activity;
   causing activity of said patient using said rehabilitation system;
   sensing brain activity using said array; and
   modifying at least one of said stimulating, said causing and a parameter of said sensing in response to at least one of a signal generated by said sensing and an effect of said causing other than on the brain.

76. A method according to claim 75, comprising applying external stimulation.

77. A method according to claim 75 or claim 76, wherein said external array comprises a controller which controls said internal stimulator.
78. A method according to any of claims 75 to 77, wherein said external array comprises Near-infrared spectroscopy (NIRS) optical fibers and detector fibers.

79. A method of determining a correct electrode placement or activation profile, the method comprising:
   (a) measuring brain activity at a plurality of locations while a subject sequentially:
       (i) engages in an activity to produce a signal measurement; and
       (ii) refrains from the activity to produce a noise measurement;
   (b) processing signal measurements and noise measurements from the plurality of locations to produce signal/noise ratio data; and
   (c) selecting at least one preferred location characterized by a desired signal/noise ratio for electrode placement.

80. A method according to claim 79, wherein the activity comprises imagining a motor activity.

81. A method according to claim 79 or 80, wherein the activity comprises performing a motor activity.

82. A method according to claim 81, wherein the activity is performed with an un-affected body part.

83. A method according to claim 81, wherein the activity is performed with an affected body part corresponding to an unaffected body part.

84. A method according to any of claims 79 to 83, comprising placing a stimulation electrode at the at least one preferred location.

85. A method according to any of claims 79 to 84, comprising placing a sensor at the at least one preferred location.

86. A method of determining a correct electrode placement or activation profile, the method comprising:
(a) measuring brain activity with two sets of sensors, each set characterized by a different resolution, at a plurality of locations while a subject sequentially:
   (i) engages in an activity to produce a first signal; and
   (ii) refrains from the activity to produce a second signal;
(b) analyzing said first and second signals from the plurality of locations to produce to produce a profile; and
(c) selecting at least one preferred location based upon the profile.

87. A method of therapy, the method comprising:
   (a) mapping neural activity in a brain of a patient to determine a disability focus;
   (b) conducting rehabilitation training while monitoring neural activity at the disability focus.
FIG. 9
Screening with 32 or more electrodes

Session number 1-4

Cursor down

The patient doesn't imagine or move anything

Cursor up

The patient imagines or moves, the paretic or healthy hand

The patient

Processing

Finding the electrode with the optimal signal

Performing BCI training with this electrode

Fig. 11
Fig. 12

1700

1720 provide an output signal of the activity

sense brain activity 1710

1730 present tasks to patient

analyze output signal during performance of presented tasks

adjust tasks in response to analysis

Log output signal (optional) 1760

analyze performance of presented tasks 1750

brain simulation 1770

1740

1742