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(54) Title: A SYSTEM FOR PROVIDING STROKE REHABILITATION

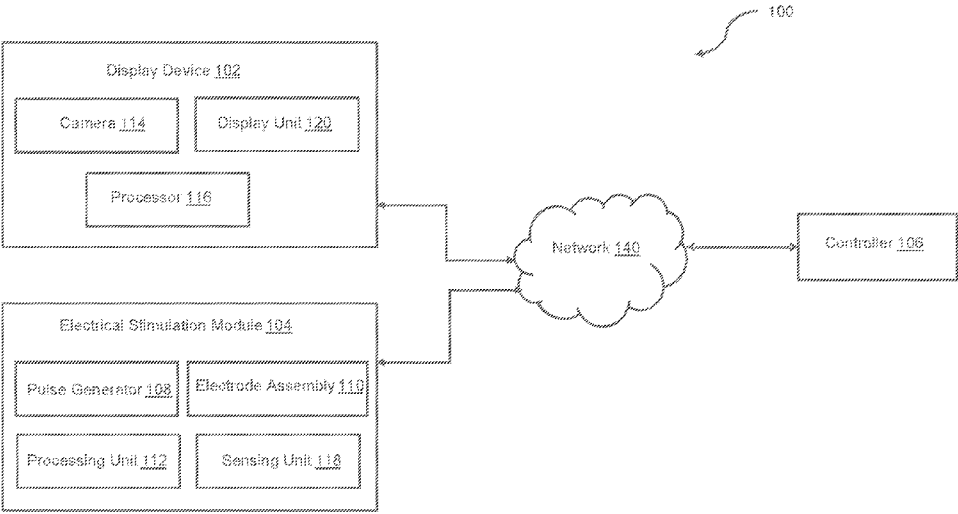


Figure 1A

(57) Abstract: A system for providing muscle stimulation, is provided. The system comprising a display device configured to display one or more actions to be performed by a user, the one or more actions involving the use of one or more target muscles which are to be stimulated. The system further comprises an electrical stimulation module having an electrical pulse generator coupled with at least one electrode assembly wearable by the user on a body part having the one or more target muscles, wherein the electrical stimulation module is configured to deliver electrical pulses to the one or more target muscles of the user in a stimulation pattern and measure a response of the one or more target muscles to the delivered electrical pulses. Furthermore, a controller is associated with the electrical stimulation module and the display device, wherein the controller is configured to control the display device and the stimulation pattern of the electrical stimulation module based on the response of the one or more target muscles.

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A SYSTEM FOR PROVIDING STROKE REHABILITATION

FIELD OF THE INVENTION

The present disclosure relates to stroke rehabilitation, and more specifically relates to a system and method for providing muscle stimulation for stroke
5 rehabilitation.

BACKGROUND

Stroke is a medical condition caused by a disruption in the blood supply to the brain, leading to a deprivation of oxygen, brain damage, and loss of bodily function.

10 Although there are a number of conventional therapies used to treat stroke patients, these are often insufficient, and many patients continue to require assistance with their daily activities due to poor healthcare management, lack of access to rehabilitation services, remote living, and poor health status.

Generally, the type and combination of interventions to be used to manage stroke
15 will vary depending on the individual's needs and the severity of their stroke. The primary goal of stroke rehabilitation is to help patients recover as much function as possible and improve their overall quality of life.

Stroke rehabilitation commonly involves several approaches, including physical therapy, occupational therapy, and the use of technology and robotics. Physical
20 therapy is often utilized to help stroke survivors recover strength, mobility, and coordination in affected limbs and muscles. It can also help improve balance, coordination, and overall physical function. Occupational therapy, on the other hand, focuses on helping people relearn daily activities such as bathing, dressing, and eating, while also improving hand-eye coordination, fine motor skills, and
25 cognitive function. In recent years, there has been an increased use of technology and robotics in stroke rehabilitation.

Throughout the stroke recovery process, patients often encounter several challenges that impede their progress, such as lack of adequate recovery resources and support, the need for frequent travel to medical facilities for treatment, low adherence to recovery protocols, and an increasing burden on a healthcare system. Many stroke patients face insufficient support during their recovery journey. Frequent travel to medical facilities for treatment can also be challenging, as it is often time-consuming, expensive, and places a strain on both the patient and their family. In addition, the repetitive nature of recovery protocols and the psychological changes associated with stroke can lead to low adherence to recommended treatments. Furthermore, an increasing demand for healthcare services and limited resources within the current healthcare system compound the challenges faced by stroke patients seeking necessary support.

It is an object of the present invention to make progress in addressing the above problems.

SUMMARY OF INVENTION

According to an aspect of the present invention, a system for providing stroke rehabilitation is disclosed. The system comprises a display device configured to display image data comprising an action to be performed by a user, the action involving the use of a target muscle to be stimulated. The system further comprising an electrical stimulation module having an electrical pulse generator coupled with an electrode assembly comprising a plurality of electrodes, the electrode assembly wearable by the user, wherein the electrical stimulation module is configured to deliver electrical pulses to the target muscle of the user with the electrodes of the electrode assembly, the electrical pulses delivered in a controlled stimulation pattern. Further, the system comprises a controller configured to control the display device and the electrical stimulation module to synchronise the display of the image data with the display device and the delivery of the stimulation pattern of the electrical stimulation module.

In this way, a system is achieved which can facilitate stroke rehabilitation for a user without requiring the user to physically visit the doctor or the healthcare

facility. A healthcare provider can remotely monitor the user (i.e., the patient) and can remotely deliver rehabilitation exercises to the user. Further, the invention utilises the synchronisation of both visual impulses and electrical stimuli to simultaneously rebuild the pathways in the brain and retrain the muscles associated with lost motor function. The provision of synchronised visual and electrical stimuli in this way provides improved results than the sum of either of these techniques individually and provides the prospect of significantly improved treatment outcomes. The system can simultaneously delivery rehabilitative therapy and measure the performance of the user to monitor their recovery. It further allows for the design and delivery of rehabilitation exercises specifically adapted to the medical condition of the user, thereby providing an improved personalisation of therapy to a particular user which helps the user to recover faster. The use of the display device along with the electrical stimulation helps to create an immersive engaging experience for the user, which can address issues with adherence in prior art systems and which further improves the recovery trajectory of the user. The present invention provides an easy to use and effective stroke rehabilitation solution which provides a personalized rehabilitation treatment to the user and can be implemented without the involvement of a trained clinician.

Preferably, the controller is configured to control the display device and the electrical simulation module such that the electrical pulses are delivered to electrodes of the electrode assembly to stimulate a target muscle to perform the action displayed on the display device. In particular, the stimulation pattern is specifically configured to stimulate a muscle or sequence of muscles used to perform the displayed action.

In this way, the system provides synchronised visual and electrical stimuli to provide a dual approach to retraining the lost motor functions. The system can be used by the user while performing day-to-day activities, thereby facilitating a rehabilitation solution that specifically targets activities of daily living for improved quality of life.

Preferably, the stimulation pattern comprises one or more of: a selection of electrodes to which the electrical pulses are applied; a time-duration for which one or more electrical pulses are delivered; an intensity of one or more electrical pulses; and wherein the controller is configured to provide a sequence of stimulations to stimulate one or more target muscles required to perform one or more actions by the user.

The electrical stimulation module may be configured to provide one or more of: Transcutaneous electrical nerve stimulation (TENS), Electrical muscle stimulation (EMS), Neuromuscular and Muscular Electrical Stimulation (NMES), Functional Electrical Stimulation (FES), Cranial electrotherapy stimulation (CES), spinal cord stimulation (SCS) or dorsal column stimulation (DCS), Transcranial direct current stimulation (tDCS). The electrical stimulation module may comprise multiple electrode assemblies each configured to provide a different electrical stimulation signal. Preferably the system comprises a first electrode assembly configured to provide FES and a second electrode assembly configured to provide tDCS.

Preferably, the controller is configured to receive data from a sensor while the user is performing the action; wherein the sensor comprises one or more of:

- a muscle response sensor for measuring electrical activity of the target muscle, where the muscle response sensor preferably comprises an electromyography, EMG, sensor;
- a motion sensor for measuring motion of the user's body while performing the action;
- a camera for capturing image data comprising the action performed by the user.

Preferably, the controller is configured to receive the sensor data and in response to the received sensor data adapt one or both of: the image data displayed with the display device; the stimulation pattern provided with the electrical stimulation module.

Accordingly, the system can track real time motion of the user using the stimulation. The real time motion tracking allows to precisely capture the movements of the body part resulting from the stimulation provided to the target muscles of the body part. Thus, a real time feedback is generated for the user
5 based on the real-time motion tracking of the body part on which the electrode assembly is worn.

Preferably, the controller is configured to use the sensor data to monitor the action performed by the user and synchronise the stimulation pattern with the action
10 performed by the user.

Preferably, the display device comprises a digital reality device. Preferably, the digital reality device comprises a Virtual Reality (VR) device or an Augmented Reality (AR) device, and is wearable by the user. The wearable AR or VR device
15 creates an immersive world for the user in which the user could interact with the designed rehabilitation workouts by performing actions shown to the user, thereby providing an effective alternative for physically visiting a medical facility for the rehabilitation programs.

20 Preferably, the control device is configured to control the display device and the stimulation module while the user performs or attempts to perform an action, such that:

the display device displays an augmented or virtual reality scene including a real time rendering of a part of the user's body performing the action, such that
25 the displayed action is synchronised with the user's efforts to perform the same action; and

the stimulation module delivers an electrical pulse to one or more electrodes of the electrode assembly, synchronised with the displayed action and the user's attempt to perform the action.

30

In this way, the provision of synchronised visual and electrical stimuli provides improved results than the sum of either of these techniques individually and provides the prospect of significantly improved treatment outcome. Further,

synchronization helps the controller to automatically make adjustments to the stimulation pattern which helps the user to perform one or more actions better, thereby making the recovery of the user faster and better. The automatic adjustments based on the synchronization eliminates the need of manual
5 monitoring by a healthcare professional.

Preferably, the control device is configured to control the display device to display an augmented version of the action, where range of motion of the displayed augmented action is greater than the range of motion in the user's performance
10 of the action.

Preferably, the digital reality device comprises a headset comprising a camera configured to capture the action to be performed by the user within its field of view, and the controller is configured to:

15 receive image data from the camera, where the image data includes the user's attempt to perform the action;

process the image data to provide augmented image data comprising augmented version of the action, where range of motion of the displayed augmented action is greater than the range of motion in the user's attempt to
20 perform the action;

output the augmented image data to the display device.

In this way, the rehabilitation program makes a positive impact on the user which further makes the stroke rehabilitation effective for the user. The displayed greater
25 range of the action impacts the user mentally in a positive way which further helps the user to recover faster.

Preferably, the control device is configured to control the display device to display a virtual object in the virtual or augmented reality scene, wherein the user may
30 interact with the virtual object by performing an action to move the real-time rendering of the part of their body to the position of the virtual object, wherein the display of the virtual object is varied to prompt a sequence of actions by the user.

Preferably, the control device is configured to control the display device to vary the position of a virtual object displayed in the virtual or augmented reality scene to prompt a sequence of different actions by the user.

5 Thus, the stroke rehabilitation program could be provided to the user in an interactive way. For example, the actions could involve daily living activities of the user which would improve the engagement level of the user with the rehabilitation program.

10 Preferably, the electrode assembly comprises one or more electrodes for measuring the electrical response of a target muscle.

Preferably, the electrode assembly comprises electrodes configured for delivery of the electrical pulses to a target muscle and electrodes configured for
15 measurement of an electromyography, EMG, signal from the target muscle. In this way, an improved electrical stimulation module is achieved which is capable of delivering the stimulation and further monitor responses of the muscles to the stimulation. Such an arrangement allows the stimulation module to be compact without requiring external sensors to measure the response of the muscles.

20

The controller is configured to vary the stimulation pattern of the electrical pulses based on the measured EMG signal.

Preferably, the controller is configured to change the stimulation pattern when the
25 measured response indicates that the one or more target muscles are not contracted in response to the delivery of the electrical pulses.

Thus, the controller optimises the use of electrical stimulation module to manage the stimulation pattern in line with the requirements of the one or more target
30 muscles. The automatic adjustments based on the response of the one or more target muscles eliminates the need of manual monitoring by a healthcare professional. Moreover, the overall time in delivering the stroke rehabilitation exercises is also optimized based on such adjustments.

The electrical stimulation module further comprises a motion sensor configured to measure the real-time motion of the body part on which the at least one electrode assembly is worn by the user.

5

Preferably, the control unit is configured to adapt the display of the image data and/or the stimulation pattern based on the real-time motion measured by the motion sensor. The real time motion tracking allows to precisely capture the movements of a body part resulting from the stimulation provided to the target muscles of the body part. Thus, a real time feedback is generated for the user based on the real-time motion tracking of the body part on which the electrode assembly is worn.

Preferably, the electrode assembly of the electrical stimulation module comprises: a wearable garment; an array of electrodes held against the skin of the user when the wearable garment is worn by the user.

Additionally, the wearable garment comprises: a sleeve, wearable on a limb of the user.

20

Preferably, a plurality of the electrodes of the array are individually selectable to deliver an electrical pulse and a plurality of electrodes of the array are configured to receive an EMG signal from the target muscle when the garment is worn by the user.

25

Preferably, the electrodes are arranged such that they are spaced apart on a body of the user when the wearable garment is worn by the user, and the electrical stimulation module is configured to control the delivery of the electrical pulses by the electrodes such that a stimulation of the muscles of the user is experienced at a virtual electrode position between the electrodes. The relative intensity of stimulation provided to each of the electrodes is controllable to vary the virtual electrode position on the body of the user.

30

The use of the virtual electrode position makes it easy to deliver the determined stimulation pattern irrespective of whether the electrodes physically placed on the body of the user are in precise positions or not.

- 5 Preferably, the electrical stimulation module further comprises a user input device configured to control the relative intensity of the stimulation at each of the plurality of electrodes. In this way, a user can conveniently control the stimulation manually if desired by the user.
- 10 Preferably, the electrical stimulation module is configured to receive a signal from a controller to control the relative intensity of the stimulation at each of the plurality of electrodes, and wherein the signal is received by the controller from the display device.
- 15 In this way, the intensity of the electrodes can be modulated to vary the virtual electrode position to any location across the electrical stimulation module, thereby allowing to deliver the determined stimulation pattern irrespective of whether the electrodes physically placed on the body of the user are in precise positions or not.
- 20 Preferably, the electrical stimulation module is configured to control the delivery of electrical pulses to the array of electrodes to vary the relative intensity between the electrodes, thereby varying a virtual electrode position across the array, at which the electrical stimulation is experienced by a user.
- 25 Preferably, when the sleeve is worn by the user on the arm, the electrodes are positioned on two sides of the arm. The electrodes are positioned symmetrically about an elongated axis of the arm.
- 30 Preferably, the electrode assembly comprises an array of electrodes positioned around all or part of the circumference of the arm.

Therefore, by using the virtual electrode position, the requirement of placing the electrodes of the electrode assembly precisely on a body part is eliminated as the virtual electrode position allows to provide stimulation even when the placement of the electrodes is not precise. This arrangement facilitates easy and convenient stroke rehabilitation for a user without requiring the user to physically visit the doctor or the healthcare facility, and without the involvement of a trained clinician to arrange the electrodes on the body of the user.

Preferably, the controller is configured to determine the stimulation pattern by performing a configuration routine, the configuration routine comprising:

- receiving sensor data from one or more sensors while the user performs a calibration action;

- processing the sensor data to determine a motion impairment metric representing the degree of impairment of the user's motion;

- determining the simulation pattern based on the motion impairment metric; wherein the sensors comprise one or more of:

- a muscle response sensor for measuring electrical activity of the target muscle, where the muscle response sensor preferably comprises an electromyography, EMG, sensor;

- a motion sensor for measuring real-time motion of the user's body while performing the action;

- a camera for capturing image data comprising the action performed by the user.

In this way, the system determines, in real-time, an impairment degree of the user and accordingly determines the stimulation pattern which is best suited to the user. Thus, personalised rehabilitation program is provided to the user which makes the rehabilitation effective for the user.

Preferably, the display device comprises a camera and the configuration routine comprises:

- receiving image data with the camera of the display device;

inputting the image data into a trained machine learning model, the machine learning model trained to output the motion impairment metric based on the input image data;

determining a simulation pattern based on the impairment metric.

5

Preferably, during the configuration routine, the controller is configured to control the display device to display image data prompting the user to perform a sequence of calibration actions, wherein the impairment metric is determined based on sensor data collected during the sequence of calibration actions.

10

Preferably, the controller is configured to determine the stimulation pattern by processing, using a trained machine learning model, medical data of the user.

The machine learning model is trained based on training data which comprises at least historical medical data of other users who have received the muscle stimulation, and wherein the machine learning model is configured to predict, using a machine learning algorithm, the simulation pattern based on the medical data of the user received as the input and the training data.

20 The use of the machine learning model in determining the stimulation pattern results in a stimulation pattern which is personalized to the user and is determined based on other users' experiences which dramatically increases the success rate of such a muscle stimulation for the user. The use of machine learning model eliminates the scope of a manual error in determining the stimulation pattern which results in a faster rehabilitation for the user whilst delivering the best possible rehabilitation program suitable as per the user's condition.

25

Preferably, the medical data includes physiological and electrophysiological parameters of the user, and/or medical history of the user.

30

Preferably, the historical medical data includes information of muscle stimulation provided to other users, medical history of other users, stimulation exercises

performed by the other users, results of the muscle stimulation for the other users, and/or physiological and electrophysiological parameters of the other users.

Optionally, the controller is remotely located to the electrical stimulation module
5 and the display device, or the controller is located within any one of the display device or the electrical stimulation module. Thus, the remote location of the controller could allow the healthcare professionals to remotely monitor, and control muscle stimulation provided to the user. Thus, the user will not be required to physically visit the healthcare facility and the user can receive the required
10 rehabilitation exercises remotely at the user's comfort.

Optionally, if the controller is located in any one of the display device or the electrical stimulation module, they could become an autonomous entity which will be in communication with a server through internet, and can perform or alter
15 stimulations and/or display of the display device based on the instructions received from the server. Thus, the above arrangement facilitates a portable system which the user could carry easily and can be controlled from anywhere through the internet.

20 In some example, the electrical stimulation module comprises a transcranial stimulation module, for applying transcranial direct current stimulation, tDCS, wherein the controller is configured to synchronise delivery of the tDCS with the display of the image data.

25 Additionally, the system comprising a weighted object for movement by the user when performing the action, wherein the weighted object comprises a motion sensor for recording motion of the weighted object.

In a further aspect of the invention, an electrical stimulation module is provided.
30 The electrical stimulation module comprises an electrode assembly comprising a wearable garment and an array of electrodes held against the skin of the user when the wearable garment is worn by the user; an electrical pulse generator coupled with the electrode assembly comprising a plurality of electrodes, wherein

the electrical stimulation module is configured to deliver electrical pulses to the electrodes of the electrode assembly, the electrical pulses delivered in a controlled stimulation pattern.

- 5 Preferably, the wearable garment comprises a sleeve, wearable on a limb of the user.

Preferably, a plurality of the electrodes of the array are individually selectable to deliver an electrical pulse and a plurality of electrodes of the array are configured
10 to receive an EMG signal from the target muscle when the garment is worn by the user. Preferably the electrical stimulation module further comprises a motion sensor configured to measure the motion of the wearable garment. .

According to another aspect of the present invention, a method of calibrating an electrical stimulation module is provided. The method includes providing, by an
15 electrical stimulation module, an electrical stimulation to one or more target muscles of a body part of a user; determining the motion of the body part of the user in response to receiving the electrical stimulation; and modifying the electrical stimulation until the desired motion is performed by the body part having the one or more target muscles, wherein the modifying comprises changing the intensity
20 and/or time-duration of the electrical stimulation to the one or more target muscles until the virtual electrode position is located at a position where the electrical stimulation results in the desired motion of the body part.

In this way, the calibration routine becomes convenient and faster by using the virtual electrode position as the use of the virtual electrode position provides
25 freedom of delivering the stimulation pattern without considering the exact physical arrangement of the electrodes. Moreover, the incorrect placement of the electrode assembly is compensated by using the virtual electrode position as explained above, facilitating an improved user experience for the user.

Preferably, the electrical stimulation is modified based on an input of a user
30 received by a user input device.

Alternatively, the electrical stimulation is modified automatically based on the motion of the body part having the one or more target muscles, and wherein the motion of the body part is determined based on imaging data captured by a camera of a display device. The display device is a digital reality device wearable
5 by the user. The imaging data corresponds to hand movements performed by the user and captured by the camera of the digital reality device.

In this way, the automatic calibration of the electrical stimulation module is accomplished using the virtual electrode position, providing an efficient, faster, and more convenient experience for the user. Precise electrode placement is
10 unnecessary, benefiting stroke patients with limited motor functions. This arrangement allows them to quickly calibrate the device according to their needs without external assistance.

It will be appreciated that the further aspect of the invention may also comprise any one or more of the features described in relation to the first aspect, either
15 alone or in combination.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1A illustrates a schematic diagram of a system 100 for providing stroke rehabilitation, in accordance with an embodiment of the present invention.

Figure 1B is a block diagram of a controller in the system 100 of figure 1A.

20 Figure 2 illustrates an electrical stimulation module, in accordance with an embodiment of the present invention.

Figure 3 illustrates a schematic diagram of a system 200 for providing stroke rehabilitation, in accordance with another embodiment of the present invention

Figure 4 illustrates an architecture 400 of a system for providing stroke
25 rehabilitation, in accordance with another embodiment of the present invention.

Figure 5 illustrates exemplary steps in providing stroke rehabilitation, in accordance with an embodiment of the present invention.

Figures 6A-6C illustrate a virtual electrode position, in accordance with an embodiment of the present invention.

5 DETAILED DESCRIPTION

The present invention relates a system for providing rehabilitative therapy to assist in the rebuilding of motor function, particularly following a stroke. At its core, the invention utilises the synchronisation of both visual impulses and electrical stimuli to simultaneously rebuild the pathways in the brain and retrain the muscles associated with lost motor function. The inventors have identified that the provision of synchronised visual and electrical stimuli in this way provides improved results than the sum of either of these techniques individually and provides the prospect of significantly improved treatment outcomes, while also (1) providing improved personalisation of therapy to a particular patient, (2) achieving greater compliance through engaging VR and AR content that may be delivered at home, without the presence of a clinician and (3) facilitating the combined assessment of symptoms, provision of therapy and monitoring of progress in a single system. There are number of specific implementation concepts within this overarching concept that are described in detail below.

20 System overview

Figure 1A illustrates a schematic diagram of a system 100 for providing stroke rehabilitation, in accordance with an embodiment of the present invention. The system 100 comprises a display device 102 configured to display image data comprising an action to be performed by a user, for examples as part of an exercise in a stroke rehabilitation programme, where the action involves the use of a target muscle to be rehabilitated. The system 100 further comprises an electrical stimulation module 104 having an electrical pulse generator coupled with at an electrode assembly comprising a plurality of electrodes. The electrode assembly is wearable by the user. In particular it may be attached to the user's

- body such that the electrodes are adjacent to one or more target muscles to be stimulated. The electrical stimulation module is configured to deliver electrical pulses to the target muscle of the user with the electrodes of the electrode assembly. The electrical stimulation module may be configured to deliver the electrical pulses delivered in a controlled stimulation pattern, where one or more parameters of the stimulation is actively controlled. The system 100 further comprises a controller 106 configured to control the display device 102 and the electrical stimulation module 104 to synchronise the display of the image data with the display device 102 and the delivery of the stimulation pattern of the electrical stimulation module 104. Neurorehabilitation therapy can thus be provided to the patient by providing controlled stimulation of the target muscles while those muscles are used during an action displayed to the user on the display. The combined visual and electrical stimuli synergistically act to promote brain plasticity and improved motor function.
- 15 The display device 102 displays image data comprising actions to be performed by a user. The display device may include an LCD (Liquid Crystal Display), a light emitting diode, LED, display, a two dimensional, 2D, display, a three dimensional, 3D, display, and/or a digital reality device. Please note that in the description below, the display device has been described with reference to a digital reality device, which has particular advantages for improved neuro-rehabilitation, promoting neuroplasticity. However, it is to be appreciated that visual stimuli in the form of image data can be provided through a conventional display, rather than a VR or AR display, and still achieve the above-described advantages of the invention. .
- 25 In figure 1A, the controller 106 is wirelessly connected with the display device 102 and the electrical stimulation module 104 through a network 140. However, the controller 106 may be connected through a wired connection with the display device 102 and the electrical stimulation module 104.
- 30 In one example, the controller 106 may be located at a remote server. In another example, the controller 106 may be integrated within the electrical stimulation module 104 or within the display device 102. If the controller is integrated within

the electrical stimulation module 104, then the controller 106 may replace a processing unit 112. If the controller 106 is integrated within the display device 102, then the controller 106 may replace a processor 116 in the display device 102.

- 5 The display device 102 may be a digital reality device which can be any one of a virtual reality, VR, device, extended reality, XR, device or an augmented reality, AR, device. The digital reality device creates an immersive experience for the user by displaying a virtual or augmented environment when the device is worn by the user. The display device 102 displays image data comprising one or more actions
- 10 to be performed by a user, where the one or more actions involve the use of one or more target muscles involved in an inhibited motor function that is to be rehabilitated. As will be described in more detail below, this image data may take a number of forms, within the common feature that it directs the required movement of the user to use, or attempt to use, specific target muscles.
- 15 In some examples the image data may comprise directions indicating the required action or motion to be performed, for example displaying arrows or virtual objects that the user may interact with to incite the required action. For example, the image data may comprise virtual objects or images that a user may interact with by performing certain motions (such as a virtual image of a ball that a user may reach
- 20 out to hit, grasp or touch). In these examples, the user may see their limbs moving as normal within the augmented or mixed reality scene. In other examples, the image data may comprise moving images comprising the user's own body parts, such as their limbs. In particular, the user may be directed, through the images or otherwise, to perform a certain motion and they may view their limbs performing
- 25 that motion, possibly to a greater extent than they are currently able to in reality, which has a beneficial impact on retraining the neural pathways for performing the actions. The image data thereby has the dual purpose of directing the actions to be performed and displaying motions that encourage neuroplasticity to aid with neurorehabilitation, and preferably doing both in an engaging manner to promote
- 30 prolonged compliance with a treatment programme. The image data, and the

electrical stimulation, may be adapted to the degree of motor function impairment and varied according to how the patient responds in their rehabilitation.

The one or more actions include rehabilitation exercises which are designed for the target muscles. In some implementations, the one or more muscles may be designated as target muscles by the user or by a healthcare professional. The healthcare professional may access the controller 106 to designate which muscles of the user are to be considered as the target muscles, as described in detailed later in the description. In another example, the controller 106 may automatically determine the target muscles based on medical data of the user, or through use of the device in a calibration routine, as also described later in the description.

The digital reality device 102 overlays digitally created content into the user's real-world environment. The digital reality device 102 comprises a camera 114 which captures the real-world environment as image data and provides it to a processor 116 which is connected with the camera 114. The image data is processed by the processor 116 to create the digital content by overlaying image data directing the one or more actions to be performed by the user into the captured real world environment. The processor 116 of the display device 102 is connected with the controller 106 to receive control signals therefrom. Based on the control signals, the processor 116 determines the one or more actions which are to be performed by the user. Accordingly, the processor 116 processes the image data to overlay the image data directing the determined one or more actions into the captured real world environment of the user.

In this way, image data is provided to the user to direct the actions to be performed as part of the rehabilitation programme. The actions may be specifically selected to encourage specific actions involving target muscles to be utilised. Taking the example of the "Ninja" game, the image data comprises virtual images of objects, such as falling fruit, overlaid on the captured real world environment (or a virtual environment) and the user is directed to perform swiping motions with their hands to cut the object. As the user moves their arms as directed to swipe at the objects, they can see their arms moving through the virtual display. That is, the camera 114 of the digital reality device 102 captures the motion of the arms and displays

it on the display 120 of the digital reality device 102. The virtual images of the objects are seen by the user as being chopped as they correctly perform the directed actions, providing an engaging “gamified” experience. By controlling the positioning of the virtual images of the objects in the virtual environment, the user
5 can be encouraged to perform specific actions to use specific muscles, for example swiping left to right horizontally with their right hand, or performing an upward swiping motion. In this way, specific activation of the target muscles may be achieved.

As will be described in more detail below, the user may preferably be displayed
10 an augmented version of the movement they are actually performing. For example, if a user can only manage a limited range of motion when swiping upwards, their motion may be captured by the camera and augmented when displayed in the virtual environment, so that the user views their arm exhibiting the full range or a greater proportion of the range of motion intended. This augmenting
15 of their motor function in the virtual environment aids brain plasticity and neurorehabilitation of the affected neural pathways, particularly when synchronised with the delivery of electrical stimulation as will be discussed.

The processor 116 further receives from the controller 106, control signals indicating real-time motion of a body part having the target muscles which are
20 stimulated or to be stimulated by the electrical stimulation module 104. The processor 116 updates in real-time the digital content corresponding to the indicated real-time motion in order to show a real-time progress of the rehabilitation exercises to the user.

In one example, the processor 116 receives the control signals from the controller
25 106 and generates the digital content for display based on the received control signals and the imaging data. In another example, the processor 116 may transmit the imaging data to the controller 106 and may receive, in response to transmitting the imaging data, prepared final digital data which merely needs to be displayed by the display device 102. In this example, the final digital data would have been
30 prepared by the controller 106 in the same way as prepared by the processor 116 of the display device 102.

In some implementations, the processor 116 is configured to locally perform image analysis on the imaging data captured by the camera 114 to detect real-time motion of the body part having the target muscles. The processor 116 further correlates the locally determined real-time motion with a real-time motion indicated by the control signals from the controller 106, to determine a final real-time motion which is to be updated in the digital reality content rendered on the display of the display device 102.

The digital content generated by the processor 116 may include virtual objects overlayed in the real-world environment captured by the camera 114. For example, one or more objects around the user in the imaging data could be replaced by virtual objects in order to have a mixture of real-world objects and virtual objects, thereby creating an immersive experience for the user. However, in one possible implementation, rather than augmenting one or more objects in the digital content, all objects in the imaging data may be augmented with virtual objects in order to create an augmented data which is completely different than the captured real-world data. In one example, the digital content may include games wherein the user would be prompted to perform one or more actions including rehabilitation exercises. Based on the determined real-time motion of the body part of the user receiving muscle stimulation, the game which is running on the display device 102 may be updated in the real-time to show movement of the body part and the real-time progress of the user in the game.

FIG. 1B illustrates a block diagram depicting the controller 106 of figure 1. The controller 106 comprises a processing unit 124, a data storage unit 126, a set of input/output (I/O) interfaces 128, a set of input devices 130, a set of output devices 132, and a network interface unit 134. Various elements of the controller 106 may be interconnected via a set of common buses 138, employing techniques known to those skilled in the art.

The controller 106 may also be connected to the network 140, which can include one or more types of communication infrastructures, such as a Local Area Network (LAN), a Wide Area Network (WAN), the Internet, a telephone network (e.g., the Public Switched Telephone Network (PSTN) and/or a cellular network), a satellite

network, and/or other suitable networks that facilitate real-time, interactive, isochronous, and/or delayed information transfer. In one example, the network 140 enables data transfer to and/or from one or more network attached storage (NAS) devices, servers or server farms, and/or databases (e.g., a medical database).

The processing unit 124 may comprise a microprocessor capable of executing program instructions, while the data storage unit 126 may consist of one or more fixed or removable data storage media, such as a hard disk drive, for storing program instructions and/or data. In one possible implementation, the data storage unit 126 stores medical data of the user. In another possible implementation, the data storage unit 126 may be associated with external databases which store medical data of the user and historical medical data of other users who have received muscle stimulation in the past. The data storage unit 126 may request and subsequently receive the medical data of the user and/or the historical medical data of other users from the external databases. The set of I/O interfaces 128 may include standard and/or proprietary interfaces, such as a Universal Serial Bus (USB) interface, and the like.

The set of I/O interfaces 128 may encompass both hardware and software (e.g., drivers) that facilitate communication with specific device types. The set of input devices 130 may include a keyboard, a mouse, a camera or image capture device, a microphone, or any other suitable device. The medical data of the user may be provided by the user or by a healthcare professional, using the set of input devices 130. The set of output devices 132 may comprise a display device, such as a computer monitor, a set of speakers, or any other appropriate device. The set of output devices 132 in combination with the set of input devices 130 facilitates a user interface which can be used by the user or a healthcare professional to interact with the controller 106 and to provide or manage the medical data and/or the historical medical data of other users. Further, the user interface can also be used by the user or a healthcare professional to provide a stimulation pattern which is to be used by the electrical stimulation module 104.

The data storage unit 126 may further consists of a computer-readable, operable, and/or programmable medium that includes volatile and/or non-volatile data storage elements, such as Random Access Memory (RAM) and Read-Only Memory (ROM). The data storage unit 126 may store an operating system which encompasses a set of programming instructions which are executed by the processing unit 124 enabling the controller 106 to generate the control signals for controlling the display device 102 and the electrical stimulation module 104.

The controller 106 may receive a request to determine a stimulation pattern for the user, from the display device 102 and/or the electrical stimulation module 104. In one example, when the user wants to receive muscle stimulation, the user may switch on the display device 102 and/or the electrical stimulation module 104 which will trigger a request to the controller 106 to generate a stimulation pattern for the electrical stimulation module 104. In response to the received request, the controller 106 may generate the stimulation pattern and provide it to the electrical stimulation module 104. Further, corresponding to the stimulation pattern, the controller 106 may determine one or more actions to be performed by the user and further indicate these actions to the display device 102 which displays the one or more actions to the user.

Display Device

In some implementations, the display device 102 is a head mounted digital reality device wearable by the user. The display device 102 may comprise a display unit 120 for conveying visual information to the user. The display unit 120 may be a 2D display or a 3D display. Although, the display device 102 is described herein as providing VR or AR images to the user, it is to be appreciated that in other embodiments, the images may be mixed reality images or video images.

In some implementations, the display device may be the 2D or 3D display screen disposed at a particular location relative to the user. The display screen may display the digital content (which may be a 2D or 3D digital content) which may be viewed by the user. Based on the digital content being displayed on the display screen, the user may perform the actions. The display screen may be associated

with an external camera unit for capturing images of the user while the user is performing the actions.

In one possible implementation, the display device 102 may comprise one or more sensors (not shown in the figures) for tracking head motion of the user as the user moves their head while using the display device 102. The one or more sensors determine data relating to the X, Y, Z coordinate positions and the roll, pitch, and yaw of the user's head. This data is provided to the processor 116 which processes the data so that the display unit 120 may display the updated VR or AR images (i.e., the digital content) in accordance with the head movements. For example, when the user moves his head to look to the left, the displayed images move to the left. In one example, the display device 102 is a head mounted digital reality device wearable by the user, and comprising the one or more sensors which may include an accelerometer for measuring the acceleration of the head. In another example, the one or more sensors may include gyroscopes and magnetometers for determining orientation of the head of the user.

The data from the one or more sensors associated with the display device 102 is received by the processor 116 which further provides the received data to the controller 106. The controller 106 further generates the control signals based on the data from the one or more sensors in the display device 102.

As discussed before, in some implementations, the controller 106 may be integrated within the display device 102. In such implementations, the processor 116 may be a part of the controller 106, and the display device 102 may communicate with the electrical stimulation module 104 through a wireless communication, such as a Bluetooth network, a Wi-Fi network, and the like, or through a wired connection. In another possible implementation, the display device 102 may be connected with the controller through a wireless network, wherein the processor 116 may communicate with the controller 106 through the network 140 (e.g. the internet) and may further communicate with the electrical stimulation module 104 through the network 140.

30 Electrical stimulation module

As shown in figure 1A, the electrical stimulation module 104 comprises an electrical pulse generator 108 coupled with at least one electrode assembly 110 wearable by the user on a body part suitable for stimulating the one or more target muscles. The target muscles are one or more muscles of a user having impaired function and requiring rehabilitation. The electrical pulse generator 108 delivers electrical pulses to the electrode assembly to stimulate the required target muscles.

The electrical stimulation module is preferably configured for delivering functional electrical stimulation (FES) to generate or augment body movements by generating muscle contraction by the delivery of electrical currents to the muscles. It can be used to re-train the central nervous system and allow a patient to relearn how to execute impaired motor functions, such as grasping, reaching, swallowing and other movements of the limbs that are often impaired by stroke.

The electrode assembly 110 preferably comprises an array of electrodes arranged to be provided against the body of the user, such electrodes are positioned adjacent the one or more target muscles. Preferably the electrode assembly (or the electrical stimulation module as a whole) is a wearable device. It preferably comprises an attachment for securing the electrode assembly against the body of the user. In one example, as shown in Figure 2, the electrode assembly 110 comprises a sleeve 111 arranged to be worn on the arm of the user. The array of electrodes 112 are arranged over the sleeve such that they are positioned adjacent to various muscles of the arm.

In Figure 2 the electrode assembly 110 comprises a sleeve 111 that just extends over a portion of the hand, the lower arm and a portion of the upper arm. In this way, electrodes may be positioned next to the main muscles responsible for grasping movements, lower arm movement and at least some upper arm movements. In other examples it may cover different parts of the body. In preferable examples for rehabilitation of the upper limbs, the sleeve 111 may extend over the shoulder, such that electrodes are positioned adjacent next to all muscles involved in upper arm movement. In other examples, an electrode assembly 110 may be configured to attach to a leg of the user, to provide

electrodes adjacent to one or more target muscles involved in lower limb movement. For example the electrode assembly may comprise a leg sleeve. In other example the electrode assembly may be configured to attach to the foot, for rehabilitation of foot movement, or to the throat, for rehabilitation of swallowing.

- 5 In the latter example the electrode assembly may be in the form of a collar with electrodes situated for stimulating muscles of the throat involved in swallowing.

More generally the electrode assembly may be provided as a wearable garment where an array of electrodes is positioned against the body and adjacent to one or more target muscles when the garment is worn. In some example the garment
10 may comprise trousers, leggings, a t shirt or a full body suit.

The electrical stimulation module 104 is configured to deliver electrical pulses to the one or more target muscles in a “stimulation pattern”. The stimulation pattern defines one or more parameters governing how the electrical pulses are provided by the electrodes of the electrode assembly 110. In particular the stimulation
15 pattern may define one or more of: the selection of electrodes providing a current pulse at any point in time, the intensity (or amplitude) of the current pulses and the duration of the current pulses. Put another way the stimulation pattern comprises a time dependent selection of electrodes and time dependent intensity of the current provided at each of the electrodes.

20 The electrical pulse generator 108 is configured to generate the electrical pulses based on the stimulation pattern provided by the controller 106. The electrical pulse generator 108 is connected to a processing unit 112, as shown in figure 1. The processing unit 112 receives the control signals generated by the controller 106 and, based on the received control signals, the processing unit 112 provides
25 instructions to the electrical pulse generator 108 to generate electrical pulses corresponding to the stimulation pattern generated by the controller 106.

The stimulation pattern may be configured to provide a sequence of stimulations corresponding to an action the user is required to perform. By using the controller to synchronise the stimulation pattern with the image data provided through the
30 display device, the electrical stimulation is provided as the user attempts to

perform an associated action. The control of the stimulation pattern (and the associated synchronised image data) may be performed in a number of different ways. In the most general case, a rehabilitation exercise is provided by the controller 106 by instructing the display device to display image data prompting an action to be performed by the user and instructing the electrical stimulation module to provide the stimulation pattern synchronised with the action to be performed. For example, in the case an exercise is selected to rehabilitate arm motion, involving lifting of the arm. The user may be shown image data comprising a virtual image of them lifting their arm and in synch with this the muscles involved in lifting the arm may be stimulated by selecting the correct electrodes to apply an electrical current in sequence. The difficulty of the exercise, for example the range of motion displayed, may be selected based on specific requirements of the patient, which may be determined in an initial calibration routine as described below. In preferable example of the invention, feedback from one or more sensors is used to synchronise the display of digital content and the electrical stimulation with the user's efforts to perform the required action.

In the above description, only one electrode assembly 110 is included in the electrical stimulation module 104. However, it will be appreciated that there can be plurality of electrode assemblies, each having suitable number of electrodes depending on the number and size of the one or more target muscles to be stimulated. In one example, the electrical stimulation module 104 performs functional electrical stimulation (FES). However, as will be described in further detail below, the electrical stimulation module 104 is not limited to only the FES and may further include transcutaneous electrical nerve stimulation, TENS, electrical muscle stimulation, EMS, neuromuscular and muscular electrical stimulation, NMES, cranial electrotherapy stimulation, CES, and/or transcranial direct current stimulation, tDCS.

Feedback mechanisms

At its most general, the method involves providing image data and a synchronised stimulation pattern according to a pre-determined protocol to encourage neurorehabilitation by allowing a patient to view the motion while stimulating it with

the stimulation module. However, to improve performance further, preferably the system is configured to receive feedback during use, i.e. during the display of the image data and provision of the electrical stimulation, in order to adapt one or both of the display of the image data and the stimulation pattern. This can be used to ensure that (1) the stimulation pattern and image data are properly synchronised and (2) that they are adapted appropriately according to the user's response to the task. As will be described in more detail below, these can also be used to measure a user's current level of impairment, for calibration of the device and monitoring rehabilitation over time.

- 10 The system according to the present invention may have a number of different feedback mechanisms, including:
- electromyography, EMG, feedback, wherein the one or more electrodes of the stimulation module are configured to measure muscle response or electrical activity;
 - 15 - measurement of the movement of the user's body during an activity using one or more movement sensors, such as one or more of an accelerometer, a magnetometer, a gyroscope, force sensors, extensometers, and/or goniometers;
 - imaging feedback using the camera 114 of the digital reality device (such as a VR/AR headset).
- 20

In some examples, one or more of these types of feedback data may be used simultaneously to adapt the delivery of the image data and electrical stimuli. In particular, by using multiple types of sensor data a more accurate measurement of the user's motor function and attempt to perform an action may be obtained.

- 25 For example, an algorithm may be used taking one or more of the above sensor data types to calculate the user's performance, and preferably use this to coordinate the stimuli.

Electromyography (EMG) is a technique for evaluating and recording the electrical activity produced by skeletal muscles. Electrodes may be used to detect the

electric potential generated by muscle cells when these cells are electrically or neurologically activated. EMG activity is linearly related to the amount of muscle contraction as well as the number of contracted muscles – or in other words, the stronger the muscle contraction and the higher the number of activated muscles, the higher the recorded voltage amplitude will be.

Electrodes may be provided on the electrical stimulation module 104, for example as part of the electrode assembly 110, that are configured to measure the EMG signal of the target muscles. This EMG signal may be used to monitor the response of the target muscles to the image content and electrical stimuli.

10 The electrodes in the electrode assembly 110, which are activated to provide an electrical charge to the target muscles, may also be configured to measure the EMG signal associated with a response of the target muscle. The processing unit 112 provides the response determined by the electrodes to the controller 106. In response the controller 106 may vary the stimulation pattern applied with the electrode assembly 110. For example, if the EMG signal indicates low muscle activity (for example, the muscle activity is not sufficient to deliver the prompted action or a predetermined proportion of the total prompted motion) then the controller can increase the intensity of the electrical stimulus applied within the stimulation pattern. In another example, where the user is instructed to carry out a repetitive motion and the EMG signal indicates the muscle contractions are out of synch with the delivered electrical stimuli, the timing of the stimulating current pulses within the stimulation pattern may be adapted to provide the stimulus at the right point in the performed action. In a further example, the EMG signal may indicate that certain muscles within the target muscle group are performing well but the activity of other muscles is below a threshold. In this case, the selection of electrodes may be varied, or the intensity increased on certain electrodes, and possible reduced on others.

In one example, the same electrodes providing the electrical charge can also measure the response of the target muscles. In another example, a different set of electrodes than the ones which are providing the charge, can be used to measure the response of the target muscles.

In some examples the processing unit 112 or controller 106 may calculate an amount of contraction based on the received EMG signals and this estimation of the contraction is used to adapt the stimulation pattern. In addition to feedback to the stimulation pattern, in some examples, feedback may be provided to the controller 106 which in turn adapts the image data provided to the display unit 120. For example, where the image data comprises a generated augmented image data of the user's limb moving, the timing or range of motion shown in the image data may be adapted to be more consistent with the timing and/or range of motion detected through EMG.

As described above, the electrical stimulation module 104 may further comprise a sensing unit 118 which includes one or more additional sensors. The sensing unit 118 may comprise sensors suitable for tracking real time motion of the body part on which the electrode assembly 110 is worn by the user. For example, the sensing unit 118 may comprise one or more of an accelerometer, a magnetometer, a gyroscope, force sensors, extensometers, and/or goniometers. The sensing data generated by the sensing unit 118 is provided to the processing unit 112 which may process the sensing data to perform an error correction before providing the sensing data to the controller 106. Based on the sensing data, the real-time motion of the body part on which the electrode assembly is worn by the user, may be tracked.

As above, motion data determined by the sensing unit 118 may be used to control the stimulation pattern delivered by the electrical stimulation module 104. In particular, the timing, intensity and/or selection of electrodes may be controlled, at least in part, based on the motion data determined by the sensing unit 118, as described above to enhance the synchronisation of the patient movement and the electrical stimulation. This motion data may be used to determine precise information on the user movement, such as limb velocity, angles of movement, range of movement, number of repetitions etc.

The motion data may also be used as feedback to control the display of the image data. In particular, the controller 106 generates control signals corresponding to the real-time motion being tracked based on the sensing data, and provides the

control signals to the display device 102. Based on the control signals indicating the tracked real-time motion, the display device may 102 update the digital content being displayed to the user. For example, the digital content may be updated to ensure it is consistent with the detected movement, for example to display a user
5 movement synchronised with the actual user movement, or to ensure the range of movement is properly defined relative to the actual user movement. It may be preferable to display a user motion as being greater than the actual user movement by a predetermined amount so tracking the actual movement allows this display to be adjusted. In addition to synchronisation considerations, the
10 digital content could also be updated according to a different progression of gameplay depending on the how the user is performing, for example making the upcoming parts of the activity more challenging.

The controller 106 receives the data generated by the sensing unit 118 of the electrical stimulation module 104 and further modifies the stimulation pattern
15 based on the received data. Additionally, or alternatively, the controller 106 receives response data from the processing unit 112, wherein the response data includes a muscle response, such as contraction of the muscles, measured by the one or more electrodes of the electrode assembly 110. The controller 106 changes the stimulation pattern of the electrical pulses when the measured response
20 indicates that the one or more target muscles are not contracted in response to the delivery of the electrical pulses. For example, the controller may increase the intensity and time duration of the electrical pulses or may change any one of the intensity or time duration, and/or the like, based on the measured response.

Along with the muscle response, the controller 106 further correlates the data of
25 the sensing unit 118 of the electrical stimulation module 104 to determine whether there is a change in a current state of the body part having the one or more target muscles which are receiving the stimulation. For example, there can be a contraction in the target muscles when the electrical pulses are delivered to the target muscles, as determined by the EMG signal sensed by the electrodes.
30 However, the motion data from the sensing unit 118 indicates that there is no movement or motion of the body part receiving the muscle stimulation. Thus, in

such a scenario, the controller 106 may still change the stimulation pattern. Accordingly, the controller 106 may change the stimulation pattern based on the data from the sensing unit 118 and/or the muscle response measured by the electrodes of the electrode assembly 110. More generally, the control of the
5 displayed image data and the stimulation pattern may be performed on both the EMG signal and the motion data.

The image data collected with a camera 114 of the display device 102 may also be used as a further feedback signal. In particular, as in conventional AR/VR/XR applications, the controller 106 may process the image data captured by the
10 camera 114 to generate the digital content by overlaying the real-world environment captured in the camera data with virtual or augmented data. The virtual or the augmented data may include one or more actions which are to be performed by the user who is wearing the display device 102 and receiving the muscle stimulation by the electrical stimulation module 104.

15 The camera data may be used as feedback to the controller 106 to generate the digital content. For example as the camera captures a user reaching to grasp a digital object, the image data will be adjusted to show the user holding and moving the digital object across the field of view of the camera 114. More generally, the image data received by the camera may be provided to the controller as an input
20 for processing and outputting the digital content. The user's movements may be tracked and used to determine how the digital content is presented and changed over time.

In some implementations, based on the camera data, the controller 106 may generate the digital content in which the captured imaging data is augmented in
25 such a way that the user can see the actions performed by the user with a gain parameter. For example, if the user is performing actions with their hand, then the movement of their hand in the digital content is augmented in such a way that it appears to the user that the hands are extending to a greater extent than in reality. The augmentation of the imaging data in such a way has a positive mental effect
30 on the user which improves the stroke rehabilitation for the users.

For example, if a user performs hand movements while having the electrical stimulation module 104 attached to the hand, then the digital reality device 102 may augment the captured real-world images of the hand in a mixed reality scene, such as a ninja game involving the use of the hand to chop digital objects.

- 5 In addition to providing feedback for control of the digital content displayed, the image data from the camera may also be used to control the electrical stimulation provided via the electrical stimulation module 104. The stimulation pattern may be timed relative to the actions which are to be performed by the user. Based on the image data, the controller 106 may know what action is currently being performed
10 by the user. In accordance with the action being performed, the controller may activate or deactivate electrodes of the electrode assembly 110 so that the electrodes may deliver the electrical pulses as per the required stimulation pattern at the right time to the correct designated target muscles.

- The electrical stimulation module may be controlled in response to feedback
15 received to provide stimulation to assist a required action. For example, where the displayed digital content involves the performing of a certain action, the stimulation may be provided to assist the required action. By receiving feedback, it can be determined when the user requires additional assistance, in the form of a particular stimulation pattern to perform the action. For example, the amount of
20 movement can be detected with the camera (e.g. by processing the image data received to recognise and track the action performed by the user), be an accelerometer, or EMG sensors. Where the movement is insufficient to perform the action, the intensity of the stimulation can be increased. Similarly where the movements are incorrect, the stimulation pattern can be adjusted to change the
25 induced movement to conform with that of the image data.

- Similarly, based on the image data presented in a mixed reality scene, the controller 106 may control the electrical stimulation module 104 to imitate the touch of a physical object. In particular, a simulation pattern can be applied that simulates a resistance to a movement, for example the closing of the hand around
30 an object. For example, if a user is trying to pick up an apple virtually in a mixed reality or virtual reality scene being displayed to a user on the display device 102,

the controller 106 may control the electrodes so that an antagonist muscle can be stimulated to create an artificial resistance when the user virtually grabs the apple. In one more example, the electrical stimulation can be applied to muscles so that when a virtual pen in the virtual reality or the mixed reality scene touches the user's hand, the user gets the imitation of touching a physical object. In this way, the present system provides tactile feedback or resistance to the user, which impacts the user mentally in a positive way which further helps the user to recover faster.

Above it is described how feedback from one or more of (1) an EMG signal received with the electrodes; (2) motion data received with the sensing unit; and (3) image data received with the camera of the digital display device may be used to control the display of digital content on the display unit 120 and to control the stimulation pattern delivered by the electrical stimulation module in real time, i.e. during the delivery of a particular rehabilitation activity. This ensures that both the visual content and the electrical stimulation and tailored and consistent to the actions of the user. However, the data collected with these sensors is also of clinical value and is important in the longer term in assessing the rehabilitation of the patient. The data collected from these sensors may therefore be used to automatically update a planned treatment plan, the type of exercises and the specific parameters of those exercises. It may also be used to calculate a metric indicating the current level of motor function impairment or recovery. In particular measurements from one or more of these sensors, preferably longitudinal measurements over time, may be input into a trained machine learning model, that may be trained to determine a score or class representing the patients symptoms, or one or more exercises to be performed to best rehabilitate the patient based on the determined symptoms.

The data from the electrical stimulation module 104 and the display device 102 is constantly relayed to the controller 106 in real-time, which allows the healthcare professional to deliver stroke rehabilitations remotely and also remotely monitor the progress of the user. Moreover, the controller 106 may change the stimulation patterns or the digital content remotely, and therefore the healthcare professionals

can design and manage the changes in the rehabilitation program of the user without requiring the user to visit a healthcare facility.

Virtual electrode

A significant problem with prior art FES stimulation modules is that electrodes
5 require precise positioning to target specific muscles and induce the required muscle fibre activations and associated movements. This generally means that FES must be applied in a clinical setting, in which the electrodes are positioned by a trained operator or clinician. The inventors of the present invention have identified a solution to this problem, by configuring an electrical stimulation module
10 to provide stimulation through a plurality of electrodes that is experienced by the user at a “virtual electrode” position- i.e. a location between the physical electrodes. Moreover, the location of this “virtual electrode” at which the stimulation is experienced can be varied by adjusting the stimulation applied to the physical electrodes. In this way, the physical electrodes do not need to be
15 precisely located over specific target muscles. Instead the stimulation applied to the physical electrodes can be adjusted until the experienced stimulation is at the required position. This is possible due to the superposition of the electrical fields of each electrode and the fact that muscles are composed of motor units: groups of muscle fibres innervated by a single motor neuron. By changing the intensity of
20 stimulation it is possible to selectively activate different motor units. Higher intensities are able to recruit larger motor units or those that are deeper within the muscle, leading to a stronger or different pattern of muscle contraction.

A feedback mechanism can be utilised to adjust the stimulation until the required activation of the muscles is achieved, as recognised through the induced
25 movement. In this way, the specific stimulation pattern required does not need to be predetermined but instead the stimulation parameters can be varied based on the determined movement. In one example, this may be done manually, with a user observing the movement of their hand, for example, and using a user input to adjust the stimulation intensity across the electrodes until the required
30 movement is observed (for example, their hand, with palm facing down, bending at the wrist to move directly upwards). In another example, the feedback loop can

be implemented automatically using a camera by determining the movement from the image data and adjusting the placement of the virtual electrode in response.

Typically, the muscle response is influenced by the superposition of electrical fields generated by each electrode. When the intensity of one positive electrode relative to the other is changed, the resultant electrical field is altered, leading to changes in the pattern of muscle fibre activation. For example, when two positive electrodes are close to each other and a negative electrode is more distant, the electrical field between the positive electrodes will be more localized. Adjusting the intensity of one of the positive electrodes changes the distribution of the current in that localized area, which can alter which muscle fibres are being stimulated.

Accordingly, at a very basic level, at least two electrodes of same polarity (either positive or negative) can be used with at least one opposing polarity electrode, to create a virtual electrode position in the middle of the two electrodes of the same polarity, as shown in figure 6A. Figure 6A illustrates an electrical stimulation module 600 in one embodiment of the present invention. The module 600 comprises a first positive electrode 602 and a second positive electrode 604, along with one negative electrode 606. The two positive electrodes 602 and 604 are close to each other and the negative electrode 606 is more distant relative to the first and second electrodes 602 and 604, which leads to the electrical field between the positive electrodes 602 and 604 to be more localized. Accordingly, when the intensity of one of the positive electrodes 602 and 604 is changed, the distribution of the current in the localized region is changed, thereby changing the muscles to be stimulated. The simultaneous delivery of electrical pulses by both the positive electrodes 602 and 604, and the negative electrode 606 is controlled such that a stimulation is experienced at a virtual electrode position 608 between the positive electrodes 602 and 604. The virtual electrode position 608 allows to target the muscle in between the two positive electrodes 606 precisely, allowing for creation of micromovement.

The virtual electrode position as discussed above is not limited to a combination of three electrodes and any number of electrodes in an electrode assembly can

form virtual electrode(s) of variable shape, size, and position, as shown in figures 6B and 6C. The virtual electrode position 608 can be moved to arbitrary locations within an electrode assembly 614 and 612 of the electrical stimulation module 600 as shown in figure 6C. Moreover, one or more positive electrodes, such as the positive electrode 610 may be switched off to assist in creating a virtual electrode position 608, as shown in figure 6B.

In one example, a plurality of virtual electrode positions 608 may be created in a way as explained above, and each virtual electrode position can be configured to stimulate with an individual intensity and for an individual time-duration.

Typically, muscles are composed of motor units, which are groups of muscle fibres innervated by a single motor neuron. By changing the intensity of stimulation it's possible to selectively activate different motor units. Higher intensities might recruit larger motor units or those that are deeper within the muscle, leading to a stronger or different pattern of muscle contraction. Similarly, nerves have different thresholds for activation. By adjusting the intensity, the selective stimulation of different types of nerve fibres (e.g., sensory versus motor neurons, or different motor neurons) is possible, resulting in different muscle movements. The use of the virtual electrode position 608, as discussed above, allows to provide stimulation to desired muscles or nerves without physically placing an electrode on a body part corresponding to those muscles or the nerves. Therefore, by using the virtual electrode position the requirement of placing the electrodes of the electrode assembly 110 precisely on a body part is eliminated as the virtual electrode position allows to provide stimulation even when the placement of the electrodes is not precise. This arrangement facilitates easy and convenient stroke rehabilitation for a user without requiring the user to physically visit the doctor or the healthcare facility, and without the involvement of a trained clinician to arrange the electrodes on the body of the user.

As discussed above, the electrodes in the electrode assembly 110, which are activated to provide an electrical charge to the target muscles, may also be configured to measure the EMG signal associated with a response of the target muscle.

Configuration of system

As described above, the stroke rehabilitation system according to the present invention functions by delivering synchronised electrical stimulation and visual content to a patient to promote neuro-rehabilitation. The electrical stimulation and
5 neuro-rehabilitation may be delivered as part of predetermined activities, exercises or games. These may be delivered as part of a wider treatment program in which the parameters of the exercises and the selection of the exercises themselves may be varied over time to promote rehabilitation.

The parameters of the exercises may be selected based on a patient's specific
10 needs and degree of impairment. The present invention also provides a method of automatically determining the patient's level of impairment and determining appropriate parameters for the exercises. In particular, the system may be configured to determine a degree of motor function impairment and determine parameters for the delivery of the displayed image data and electrical stimulation.
15 This may initially be performed in a calibration routine.

A user assessment may initially be performed as part of a calibration routine. In one example, the user is instructed to perform one or more calibration actions. These may be prompted by the display of visual data with the display device 102. For example, the controller may display a virtual object where the position of the
20 virtual object is varied to prompt the user to perform a sequence of different actions, suitable to test their motor function. The prompts may be provided in the form of a game, such as the "ninja game" described above. The camera of the display device 102 may capture image data of sequence of calibration actions. This image data may be processed to determine a measure of the user's motor
25 function. In particular, the system may be use a trained machine learning model, trained to take image data as an input (i.e. a sequence of images capturing the calibration actions) and process the image data to predict an impairment score (or motor function score) for the patient. In particular, it is possible to classify patients into one of a plurality of classes related to the type and severity of their motor
30 function impairment. A suitable rehabilitation programme, comprises a number of exercises may be determined based on the classification.

The imaging data may be processed by the controller 106 to determine movements of the body part having the target muscles which are to be stimulated. For example, the controller 106 may process the imaging data to perform gait analysis by performing walking or motion analysis of the user when the target
5 muscles are the leg muscles. Similarly, the controller 106 may process the imaging data to determine hand movements when the target muscles are the hand muscles.

A number of known image processing techniques may be implemented to identify the position and orientation of a body part in the image data, and track its
10 movement. For example, the imaging data may be processed to identify at least three tracking points within the image, at easily identifiable locations on on the hand of the user. For example the points could be the base of the thumb, index finger and little finger. The use of the tracking points allows the controller 106 to determine the hand movements with an improved accuracy. Additionally, the
15 imaging data may further be processed to identify a fourth tracking point which allows the controller to track the extension of a wrist when determining the hand movements. The determination of the wrist movement may further help the controller 106 in deciding to control the intensity of the electrical stimulation module 104.

20 Based on the determined movements of the body part having the target muscles, the controller 106 may determine a degree of impairment of the target muscles. The data corresponding to the determined degree of impairment may be processed using the trained machine learning model to determine a stimulation pattern which is required for the target muscles to treat the determined
25 impairment. Thus, based on initial exercises performed by the user, a degree of impairment may be analysed and accordingly stroke rehabilitation may be provided to the user.

In some implementations, one or more virtual electrode positions may be used for the calibration routine. In one example, based on the image data captured by the
30 camera 114, the controller 106 determines movements performed by a user, such as hand movements.

Based on the determined movements of the body, such as the hand movements, the controller 106 may determine a stimulation pattern which may require creation of one or more virtual electrode positions to deliver the stimulation pattern to the user. The electrical stimulation provided by the electrodes is modified until the
5 desired motion is performed by the body part having the one or more target muscles being stimulated. The electrical stimulation is modified by changing the intensity and/or time-duration of the electrical stimulation to the one or more target muscles until the virtual electrode position is located at a position where the electrical stimulation results in the desired motion of the body part.

10 For example, initially a stimulation is applied to the user's arm with the expectation of an upward movement, for example an upwards flexion of the wrist to raise the hand. However, if imaging data (captured by the digital reality device worn by the user) shows the arm moving left along with the upward motion, the intensity of the electrodes is modulated such that the virtual electrode position is created which
15 results in a counter-movement of the arm to the right, thereby achieving the desired upward motion of the hand.

The use of the virtual electrode position makes it easy to deliver the determined stimulation pattern irrespective of whether the electrodes physically placed on the body of the user are in precise positions or not. Therefore, the calibration routine
20 becomes convenient and faster by using the virtual electrode position as the use of the virtual electrode position provides freedom of delivering the stimulation pattern without considering the exact physical arrangement of the electrodes. Moreover, the incorrect placement of the electrode assembly, such as the assembly 612 and 614, is compensated by using the virtual electrode position as
25 explained above, facilitating an improved user experience for the user.

In some implementations, the calibration routine may be performed by a user manually. In one example, the electrical stimulation module 104 may comprise a user input device having one or more buttons to be used by the user to adjust the stimulation of the electrode assembly 110 and calibrate the system for use. The
30 one or more buttons may allow the user to control (increase or decrease) the intensity of the electrical pulses delivered by the electrodes. Every time the

electrical stimulation module 104 is to be used, the user may first calibrate the system by using the buttons to adjust the system as per the requirements of the user.

5 In another example, the user input device is detachable from the electrical stimulation module 104. In this way, the user input device can be plugged-in for recharging a battery once the battery runs out of power. Thus, the separation facilitates a straightforward charging process for the user input device which not only simplifies the overall charging procedure but also potentially increases the convenience and usability of the device. Preferably, the user input device is
10 provided with a recessed magnetic connector which necessitates intentional effort to separate the connectors, thereby significantly reducing the risk of unintentional disconnection and enhancing overall reliability. Furthermore, the use of the recessed magnetic connector in the user input device does not require fine motor controls in order to locate and plug the device, thereby making it suitable to be
15 used by stroke patients.

In other examples, the machine learning model may take other types of sensor data as input, for example motion sensor data and/or EMG data. The machine learning model may be trained to classify the patients motor function and determine one or more exercises (each defining the digital content to be displayed
20 and the electrical stimulation pattern to be applied) based on the classification.

More generally, the system may be configured to determine the stimulation pattern to be applied by processing one or more types of sensor data defined above as the user performs an action. In other examples, the machine learning model may use other types of data, for example, patient medical data.

25 The controller 106 may determine the stimulation pattern by processing, using a trained machine learning model, medical data of the user. Alternatively, the controller 106 may receive the stimulation pattern provided by the user or a healthcare professional using the set of input devices 130.

The medical data may include physiological and electrophysiological parameters of the user, and/or medical history of the user. The medical data may be extracted by the controller 106 based on electronic health records of the user. In one example, the controller 106 may receive the medical data of the user from an external device, wherein the external device would have extracted the medical data from the electronic health records in the same way as the controller 106.

In some implementations, the processing unit 124 of the controller 106 may process the request received from the display device 102 and/or the electrical stimulation module 104, using a machine learning model. The machine learning model is trained to process the medical data of the user to generate a stimulation pattern for the user, based on a received request to generate the stimulation pattern. For example, the machine learning model may have been trained on a training set of data that includes historical medical data of users who have received muscle stimulation in the past and stimulation patterns used for muscle stimulation for these users. In one example, the training set of data may include one or more of historical medical data of users who are in the same age group as of the user, historical medical data of users who have received stimulation for same target muscles as of the user, historical medical data of users who are having similar medical conditions, and/or the like. The training set of data may further include a degree of impairment of the users and stimulation patterns used by healthcare professionals for users who have received muscle stimulation in the past and whose historical medical data has been used in the training set. In one implementation, the historical medical data of users included in the training set may be extracted from electronic health records of the users.

In some implementations, the controller 106 may portion a set of data into a training set, a validation set, a test set, and/or the like. In some implementations, the controller 106 may train the machine learning model using, for example, a factorization machine technique, a random forest technique, gradient boosting technique, and/or the like, and based on the training set of the data. In some implementations, training of the machine learning model may include supervised training. For example, a healthcare professional accessing the controller 106 may

manually classify data to train the machine learning model. This may increase an accuracy of training of the machine learning model. In certain implementations, the controller 106 may employ various techniques to train a machine learning model. The controller 106 may utilize factorization machine technique, where the
5 model is trained on features present in a given dataset. Alternatively, or in addition, the controller 106 may utilize the random forest technique to train the machine learning model.

In some implementations, instead of conducting model training, the controller 106 may receive a pre-existing trained model from another device, such as a server
10 device. This server device may have generated the model by training it in a similar manner as described earlier. The model may be provided to the controller 106 in various ways, such as pre-loading a memory of the controller 106 with the model or responding to a request from the controller 106 for the model.

The trained machine learning model used by the controller 106 receives medical
15 data as an input and generates a stimulation pattern as an output. The use of the trained machine learning model enables the healthcare professionals to devise an improved rehabilitation program for the user based on stimulation patterns of other similar users, thereby making stroke rehabilitation process efficient for the user.

Sleeve module

20 As described above the electrical stimulation module (i.e. FES module) is preferably integrated into a wearable garment. In one example this is in the form of a sleeve comprising the electrode array, such that the electrodes are positioned over the arm, providing stimulation of the muscles required for movements of one or more of the arm, hand and fingers.

25 Generally, in prior art devices, careful attachment of electrodes is required, preventing the provision of a wearable FES module, that can be used in self-supervised rehabilitation by a patient themselves. However, the wearable garment (such as a sleeve) disclosed herein comprises a number of features that allow this wearable stimulation module to be used by the patient themselves. This

may be used in combination with the system for rehabilitation described herein, i.e. with a display devices such as a VR/AR headset. However, this wearable garment can also be used independently in other applications where the simultaneous display of image data is not required, for a user to self-administer
5 FES. The specific example of a sleeve is used below, but this can be extended to another wearable garments as described herein.

An important feature is the use of an electrical stimulation module configured to provide one or more virtual electrodes described above. In particular, the sleeve comprises a plurality of electrodes where the stimulation parameters delivered to
10 each are individually controllable to be able to vary an effective stimulation position in the muscles – the “virtual electrode” position. The relative intensity of stimulation between the electrode may be varied to adjust the effective position of the stimulation to provide a required movement.

In one example, the wearable sleeve may include an array or assembly of positive
15 electrodes 612 and the negative electrodes 614. The wearable sleeve may further include pads on which the positive electrode assembly 612 and the negative electrode assembly 614 are located. The pads are located such that when the wearable sleeve is worn by the user on the body part, the pads cover the area around the muscles of the body part with room for error in placement. By extending
20 the array of pads to be symmetric across the sleeve, the wearable sleeve would be able to be ambidextrous, so can be used on a left or right arm. This is an advantage over known devices in which careful positioning of the electrodes is required, such that a different arrangement is needed for the left and right arms. For example, if the sleeve is worn by the user on the arm, then there is no need
25 to determine a mid-point of flexor muscles of the arm, a single large pad on either side can be implemented to reduce the complexity of the design of the wearable sleeve.

In some examples, the wearable sleeve may incorporate two self-attaching elasticated Velcro straps. These straps are strategically positioned to secure the
30 front and back of the sleeve onto the body part. The Velcro mechanism allows for easy adjustment and ensures a secure fit, and providing targeted support. This

design offers flexibility and convenience, enabling users to quickly attach and remove the sleeve while maintaining the desired level of comfort. Since the sleeve does not require precise placement, such an attachment mechanism is suitable and may be used easily by the patient to secure the sleeve.

- 5 In other examples, the wearable sleeve may be a fully connected compression sleeve that delivers uniform pressure along the entire length of the body part. Unlike the first example, this arrangement does not rely on separate straps for attachment. Instead, it is a continuous sleeve that provides even compression throughout. This ensures consistent pressure distribution, which can enhance
10 comfort and therapeutic effectiveness.

The sleeve preferably includes a user interface providing user control of the stimulation parameters. In one example, the user interface may comprise a control for controlling the relative intensity of the stimulation across the electrodes. For example the device may comprise two electrodes positioned with one towards the
15 inner (medial/ulnar) side of the arm and one towards the outer (lateral/radial side of the arm). The electrodes (see for example electrode 602, 604 in Figure 6A) may be positioned at the same position along the length of the arm. The relative intensity control may comprise a dial or buttons allowing control of the relative intensity applied to the two electrodes. This will vary the position of the virtual
20 electrode across the arm between the electrodes. This can be extended to three electrodes, as shown in figure 6B or an array of electrodes, arranged to be positioned around all or part of the circumference of the arm, as shown in Figure 6C. By varying the relative intensity across the electrodes, the position of the effective stimulation (the virtual electrode) can be varied around the circumference
25 of the arm to stimulate the required muscles. This can be extended to have multiple circumferential arrays along the length of the arm to provide one or more virtual electrodes at any arbitrary points on the arm.

In this way, the user can control the intensity of stimulation applied to each electrode to vary the position of the stimulation themselves.

In another example, the sleeve may comprise an communication interface for receiving a wired or wireless signal to control the intensity. In this way, the sleeve may be used with the wider system described herein, for example to adjust the stimulation automatically in response to image data received from the VR headset or another feedback mechanism, such as EMG or accelerometer data.

Further optional components of the system

As described above, and illustrated in Figure 5A, in some preferable implementations the electrical stimulation module 104 may be in the form of a sleeve wearable by the user on the body part having one or more target muscles required to be stimulated. In some examples of the invention, the system may comprise alternative or additional stimulation modules.

In some examples, the system may comprises a tDCS module for applying transcranial direct current stimulation (tDCS). tDCS is a type of non-invasive brain stimulation which can improve motor performance in patients recovering from chronic stroke or mild to moderate stroke. The tDCS module may be worn on the user's head, with an array of electrodes positioned to stimulate target areas of the brain. The tDCS module may be controlled by the controller 106 and preferably the controller is configured to synchronise the tDCS stimulation with the display of the image data. In some examples tCDS may be combined with FES and both types of stimulation may be synchronised with the display of image data. Preferably, by receiving sensor data from one or more sensors, the tCDS stimulation is also synchronised with the patient's efforts in performing an action.

In other examples, the system may comprise one or more exercise objects usable by the patient when performing an action. For example the system may comprise a weighted object to be lifted or moved by the patient when performing an action. The exercise object may comprise one or more of: a ball; a weight; a dumbbell; a weighted garment; a wand; a controller. The objects may be configured for use with particular digital content or exercise activities. For example the exercise objects may be captured by the camera of the display device and the digital content may comprise a real time rendering of the object, possibly in augmented

form. The exercise object may comprise one or more sensors, for example a motion sensor of a type defined above, such as an accelerometer. Data may be received from the motion sensor and used as feedback for adapting one or both of the digital content displayed and the stimulation pattern.

- 5 An electrode assembly 110 may be disposed on the exercise object. For example, the user may hold the object and the electrodes may be attached to the body part having the one or more target muscles. Once, the electrodes are attached to the body part (preferably the fingers), digital content may be displayed to the user where the user may be asked to hold the or grasp the object. For example, the
- 10 user may be directed by the digital content to pick up a ball and, when the user tries to grip the ball, the electrodes may be activated which will deliver the electrical pulses to the target muscles. In response to the electrical pulses, the target muscles may contract which in turn will help the user to grip and hold the ball. In a similar manner, the electrode assembly may be disposed on a dumbbell..
- 15 In some implementations, the electrical stimulation module 104 may be in the form of a collar having electrodes. The collar may be worn by the user around the neck for providing stimulation to the muscles on the neck, thereby providing swallowing rehabilitation to the user. In such a scenario, the display device 102 may display a virtual or an augmented drink to the user which the user may try to drink. When
- 20 the user tries to drink, the electrodes on the collar will be activated to provide stimulation to the neck muscles which in turn will help the neck muscles to contract, thereby helping the user to practice swallowing the drink.

FIG. 3 illustrates a block diagram of a system 200 for providing stroke rehabilitation, in accordance with another embodiment of the present invention.

- 25 The system 200 comprises a display device 202, an electrical stimulation module 204, and a controller 206, which are same as the display device 102, the electrical stimulation module 104, and the controller 106 of FIG. 1A. Additionally, in the present embodiment, the system 200 comprises a robotic bicycle 208. The robotic bicycle 208 is a normal pedalling bicycle as known in the art. The robotic bicycle
- 30 may further include an electric motor (not shown in the figures) to generate power for operating pedals of the bicycle.

The robotic bicycle 208 is in communication with the controller 206 which generates control signals to control the operation of the robotic bicycle 208. Depending on the response of the target muscles to the electrical pulses, the controller 206 controls the operation of pedals of the robotic bicycle 208 to support the user in pedalling the bicycle. Based on the control signals received from the controller 106, the power provided to the pedals is regulated for controlling the speed of the pedalling. For example, if the target muscles (e.g., calf muscles on legs of the user) contracts in response to the electrical pulses while the user is riding the robotic bicycle 208, the controller 208 may regulate (e.g., increase or decrease) the amount of power provided to the pedals, thereby supporting the legs of the user to perform pedalling on the bicycle 208. The use of the robotic bicycle 208 in tandem with the electrical stimulation module 204 helps to improve motor function and accelerates the recovery of functional limb movements of the user, thereby improving upper and lower limb rehabilitation for the user.

Figure 4 illustrates an architecture 300 of a system for providing stroke rehabilitation, in accordance with another example of the present invention. The system 300, as with the above examples, comprises a display device 302, in this example in the form of a head mounted display for displaying VR or AR content to the patient. The system also comprises a stimulation module 303, comprising an FES module 304, in the form of a sleeve that is worn by the user. The system also comprises a controller 306, where in the example of Figure 3 a number of modules of the controller 306 are illustrated.

The system 300 includes devices, such as an external device 368 and a server device 366, which are connected with each other and further to the controller 306, through a wireless or a wired connection, facilitating remote stroke rehabilitation by a therapist. The therapist can control and monitor the stroke rehabilitation using an application on the external device 368 as shown in the figure 4. Alternatively, the therapist can use web application 370 to control and monitor the stroke rehabilitation. Based on patient data and using machine learning, the system is able to provide adaptive learning which can adapt the stroke rehabilitation

program to best suit the patient, thereby improving the stroke rehabilitation for the patient.

The controller 306 includes a session configuration module 361 which stores user profiles and rehabilitation programs configured to corresponding user profiles. The therapist can access the session configuration module 361 using the application on the external device to configure or select a user profile in the module. Based on the selected user profile, rehabilitation program may be selected.

The controller 306 further includes an adaptive learning module 362 which may receive data from VR training module 364, machine learning module 363, and/or external device data collection module 365. The adaptive learning module 362 may execute algorithms that enable the controller 306 to dynamically adjust their behaviour of stimulation module 303 and the display device 302, and improve their performance based on experience and feedback. By continuously analysing and processing data received from the above-mentioned modules, the adaptive learning module 362 may optimize their performance, make predictions on movement functioning, cognitive functioning, and emotional functioning of the patient, and even generate insights that may not be apparent to the therapist.

The external device data collection module 365 may collect data from electrical stimulation module 303 which may comprise transcranial stimulation or functional electrical stimulation, or other suitable stimulation technique. The VR training stimulation module 364 may receive data from a display device 302 which is a head mounted display device in this example. The data obtained from the display device 302 is analysed by the adaptive learning module 362 to generate digital content to be presented on the display device 302. For example, any one of virtual games 1, 2, 3, or 4 may be presented on the display device 302 by the controller 306.

Figure 5 illustrates exemplary steps in providing stroke rehabilitation, in accordance with an embodiment of the present invention. As shown in the figure 5, a user and a healthcare professional can interact through the system of the present invention, for stroke rehabilitation. The healthcare professional can

configure training sessions for the user, where the user can access the configured training sessions using a display device (e.g., the display device 102 of figure 1) and an electrical stimulation module (e.g., the electrical stimulation module 104 of figure 1). The healthcare professionals can configure the training sessions using
5 a controller (e.g., the controller 106 of figure 1) based on which the user can receive training tutorials.

As indicated by item 504 in the figure 4, the healthcare professional can also evaluate training sessions based on stimulation data of electrical stimulation provided to the user, and can change configured training sessions to provide a
10 best suited stroke rehabilitation training required by the user.

As indicated by item 502, the therapist can visualise electrical stimulation data and/or transcranial stimulation data using an application on an external device as shown in figure 3. The therapist can analyse the data to verify movement accuracy of target muscles of the user. In this way, the therapist can evaluate a stroke
15 rehabilitation session provided to the user. Further, as shown, the user can select different modes of VR games available to the user based on the type of target muscles user wants to stimulate or depending on the impairment degree of the target muscles/limb.

Thus, in this way, a stroke rehabilitation can be facilitated for a user without
20 requiring the user to physically visit the doctor or the healthcare facility. A healthcare provider can remotely monitor the user (i.e., the patient) and can remotely deliver rehabilitation exercises to the user.

CLAIMS

1. A system for providing stroke rehabilitation, the system comprising:
a display device configured to display image data comprising an action to be
5 performed by a user, the action involving the use of a target muscle to be
stimulated;
an electrical stimulation module having an electrical pulse generator coupled
with an electrode assembly comprising a plurality of electrodes, the electrode
assembly wearable by the user, wherein the electrical stimulation module is
10 configured to deliver electrical pulses to the target muscle of the user with the
electrodes of the electrode assembly, the electrical pulses delivered in a controlled
stimulation pattern, and
a controller configured to control the display device and the electrical
stimulation module to synchronise the display of the image data with the display
15 device and the delivery of the stimulation pattern of the electrical stimulation
module.
2. The system of claim 1 where the controller is configured to control the display
device and the electrical simulation module such that the electrical pulses are
20 delivered to electrodes of the electrode assembly to stimulate a target muscle to
perform the action displayed on the display device.
3. The system of claim 1 or claim 2 wherein the stimulation pattern comprises
one or more of:
25 a selection of electrodes to which the electrical pulses are applied;
a time-duration for which one or more electrical pulses are delivered;
an intensity of one or more electrical pulses; and wherein the controller is
configured to provide a sequence of stimulations to stimulate one or more target
muscles required perform one or more actions to performed by the user.

4. The system of any preceding claim where the controller is configured to receive data from a sensor while the user is performing the action; wherein the sensor comprises one or more of:

5 a muscle response sensor for measuring electrical activity of the target muscle, where the muscle response sensor preferably comprises an electromyography, EMG, sensor;

a motion sensor for measuring motion of the user's body while performing the action;

10 a camera for capturing image data comprising the action performed by the user.

5. The system of claim 4, wherein the controller is configured to receive the sensor data and in response to the received sensor data adapt one or both of:

15 the image data displayed with the display device;
the stimulation pattern provided with the electrical stimulation module.

6. The system of claim 4 or claim 5, wherein the controller is configured to use the sensor data to monitor the action performed by the user and synchronise the stimulation pattern with the action performed by the user.

20

7. The system of any preceding claim, wherein the display device comprises a digital reality device.

8. The system of claim 7, wherein the digital reality device comprises a Virtual Reality (VR) device or an Augmented Reality (AR) device, and is wearable by the user.

25

9. The system of claim 8 where the control device is configured to control the display device and the stimulation module while the user performs or attempts to perform an action, such that:

30

the display device displays an augmented or virtual reality scene including a real time rendering of a part of the user's body performing the action, such that

the displayed action is synchronised with the user's efforts to perform the same action; and

the stimulation module delivers an electrical pulse to one or more electrodes of the electrode assembly, synchronised with the displayed action and
5 the user's attempt to perform the action.

10. The system of claim 9 wherein the control device is configured to control the display device to display an augmented version of the action, where range of motion of the displayed augmented action is greater than the range of motion in
10 the user's performance of the action.

11. The system of claim 9 or claim 10 wherein the digital reality device comprises a headset comprising a camera configured to capture the action to be performed by the user within its field of view, and the controller is configured to:

15 receive image data from the camera, where the image data includes the user's attempt to perform the action;

process the image data to provide augmented image data comprising augmented version of the action, where range of motion of the displayed augmented action is greater than the range of motion in the user's attempt to
20 perform the action;

output the augmented image data to the display device.

12. The system of any of claims 9 to 11, wherein the control device is configured to control the display device to display a virtual object in the virtual or augmented
25 reality scene, wherein the user may interact with the virtual object by performing an action to move the real-time rendering of the part of their body to the position of the virtual object, wherein the display of the virtual object is varied to prompt a sequence of actions by the user.

30 13. The system of any of claim 12, wherein the control device is configured to control the display device to vary the position of a virtual object displayed in the virtual or augmented reality scene to prompt a sequence of different actions by the user.

- 5 14. The system of claim 13, wherein the electrode assembly comprises electrodes configured for delivery of the electrical pulses to a target muscle and electrodes configured for measurement of an electromyography, EMG, signal from the target muscle.
- 10 15. The system of claim 13 or 14, wherein the controller is configured to vary the stimulation pattern of the electrical pulses based on the measured EMG signal.
- 15 16. The system of claim 15, wherein the controller is configured to change the stimulation pattern when the measured response indicates that the one or more target muscles are not contracted in response to the delivery of the electrical pulses.
- 20 17. The system of any one of the preceding claims, wherein the electrical stimulation module further comprises a motion sensor configured to measure the real-time motion of the body part on which the at least one electrode assembly is worn by the user.
- 25 18. The system of claim 17, wherein the control unit is configured to adapt the display of the image data and/or the stimulation pattern based on the real-time motion measured by the motion sensor.
- 30 19. The system of any preceding claim wherein the electrode assembly of the electrical stimulation module comprises:
 a wearable garment;
 an array of electrodes held against the skin of the user when the wearable garment is worn by the user.
20. The system of claim 19 wherein the wearable garment comprises:

a sleeve, wearable on a limb of the user.

21. The system of claim 19 or 20 wherein a plurality of the electrodes of the array are individually selectable to deliver an electrical pulse and a plurality of electrodes
5 of the array are configured to receive an EMG signal from the target muscle when the garment is worn by the user.

22. The system of any one of the preceding claims wherein controller is configured to determine the stimulation pattern by performing a configuration
10 routine, the configuration routine comprising:

receiving sensor data from one or more sensors while the user performs a calibration action;

processing the sensor data to determine a motion impairment metric representing the degree of impairment of the user's motion;

15 determining the simulation pattern based on the motion impairment metric; wherein the sensors comprise one or more of:

a muscle response sensor for measuring electrical activity of the target muscle, where the muscle response sensor preferably comprises an electromyography, EMG, sensor;

20 a motion sensor for measuring real-time motion of the user's body while performing the action;

a camera for capturing image data comprising the action performed by the user.

25 23. The system of claim 22, wherein the display device comprises a camera and the configuration routine comprises:

receiving image data with the camera of the display device;

inputting the image data into a trained machine learning model, the machine learning model trained to output the motion impairment metric based on
30 the input image data;

determining a simulation pattern based on the impairment metric.

24. The system of any preceding claim wherein, during the configuration routine, the controller is configured to control the display device to display image data prompting the user to perform a sequence of calibration actions, wherein the impairment metric is determined based on sensor data collected during the sequence of calibration actions.

25. The system of any one of the preceding claims, wherein the controller is configured to determine the stimulation pattern by processing, using a trained machine learning model, medical data of the user.

10

26. The system of any one of the preceding claims, wherein the plurality of electrodes are positioned to be spaced apart on a body of the user, and the electrical stimulation module is configured to control the simultaneous delivery of the electrical pulses by the plurality of electrodes such that a stimulation is experienced at a virtual electrode position between the plurality of electrodes.

15

27. The system of claim 26, wherein the relative intensity of stimulation provided to each of the plurality of electrodes is controllable to vary the virtual electrode position on the body of the user.

20

28. An electrical stimulation module comprising:

an electrode assembly comprising a wearable garment and an array of electrodes arranged such that the electrodes are held against the skin of a user when the wearable garment is worn by the user; and

25

an electrical pulse generator coupled with the electrode assembly, wherein the electrical pulse generator is configured to deliver electrical pulses to the electrodes of the electrode assembly, the electrical pulses delivered in a controlled stimulation pattern.

30

29. The electrical stimulation module of claim 28, wherein the electrodes are arranged such that they are spaced apart on a body of the user when the wearable garment is worn by the user, and the electrical stimulation module is configured to control the delivery of the electrical pulses by the electrodes such that a

stimulation of the muscles of the user is experienced at a virtual electrode position between the electrodes.

5 30. The electrical stimulation module of claim 29, wherein a relative intensity of stimulation provided to each of the electrodes is controllable to vary the virtual electrode position on the body of the user.

10 31. The electrical stimulation module of claim 30, further comprises a user input device configured to control the relative intensity of the stimulation at each of the plurality of electrodes.

15 32. The electrical stimulation module of claim 30, wherein the electrical stimulation module is configured to receive a signal from a controller to control the relative intensity of the stimulation at each of the plurality of electrodes, and wherein the signal is received by the controller from the display device.

33. The electrical stimulation module of any one of claims 28-32, wherein the wearable garment is a sleeve, wearable on a limb of the user.

20 34. The electrical stimulation module of claim 33, wherein when the sleeve is worn by the user on the arm, the electrodes are positioned on two sides of the arm.

25 35. The electrical stimulation module of claim 34, wherein the electrodes are positioned symmetrically about an elongated axis of the arm.

30 36. The electrical stimulation module of any of claims 33 to 35 wherein the electrode assembly comprises an array of electrodes positioned around all or part of the circumference of the arm.

37. The electrical stimulation module of claim 36 wherein the electrical stimulation module is configured to control the delivery of electrical pulses to the array of electrodes to vary the relative intensity between the electrodes, thereby

varying a virtual electrode position across the array, at which the electrical stimulation is experienced by a user.

38. A method of calibrating an electrical stimulation module of any one of claims 5 29-35, the method comprising:

providing, by an electrical stimulation module, an electrical stimulation to one or more target muscles of a body part of a user;

determining the motion of the body part of the user in response to receiving the electrical stimulation;

10 modifying the electrical stimulation until the desired motion is performed by the body part having the one or more target muscles, wherein the modifying comprises:

changing the intensity and/or time-duration of the electrical stimulation to the one or more target muscles until the virtual electrode position is located at a
15 position where the electrical stimulation results in the desired motion of the body part.

39. The method of claim 38, wherein the electrical stimulation is modified based on an input of a user received by a user input device.

20

40. The method of claim 38, wherein the electrical stimulation is modified automatically based on the motion of the body part having the one or more target muscles, and wherein the motion of the body part is determined based on imaging data captured by a camera of a display device.

25

41. The method of claim 40, wherein the display device is a digital reality device wearable by the user, and wherein the imaging data corresponds to hand movements performed by the user and captured by the camera of the digital reality device.

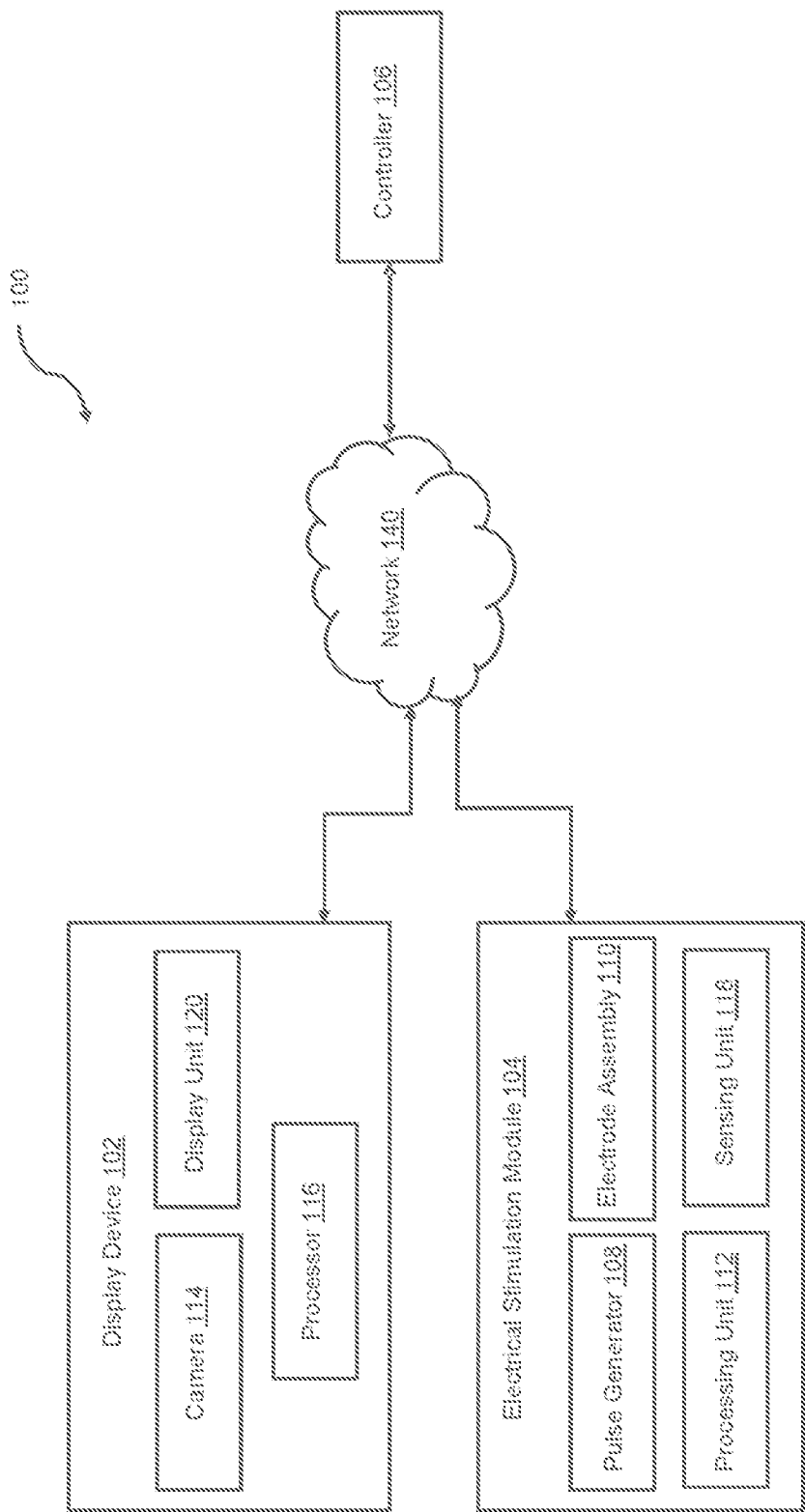


Figure 1A

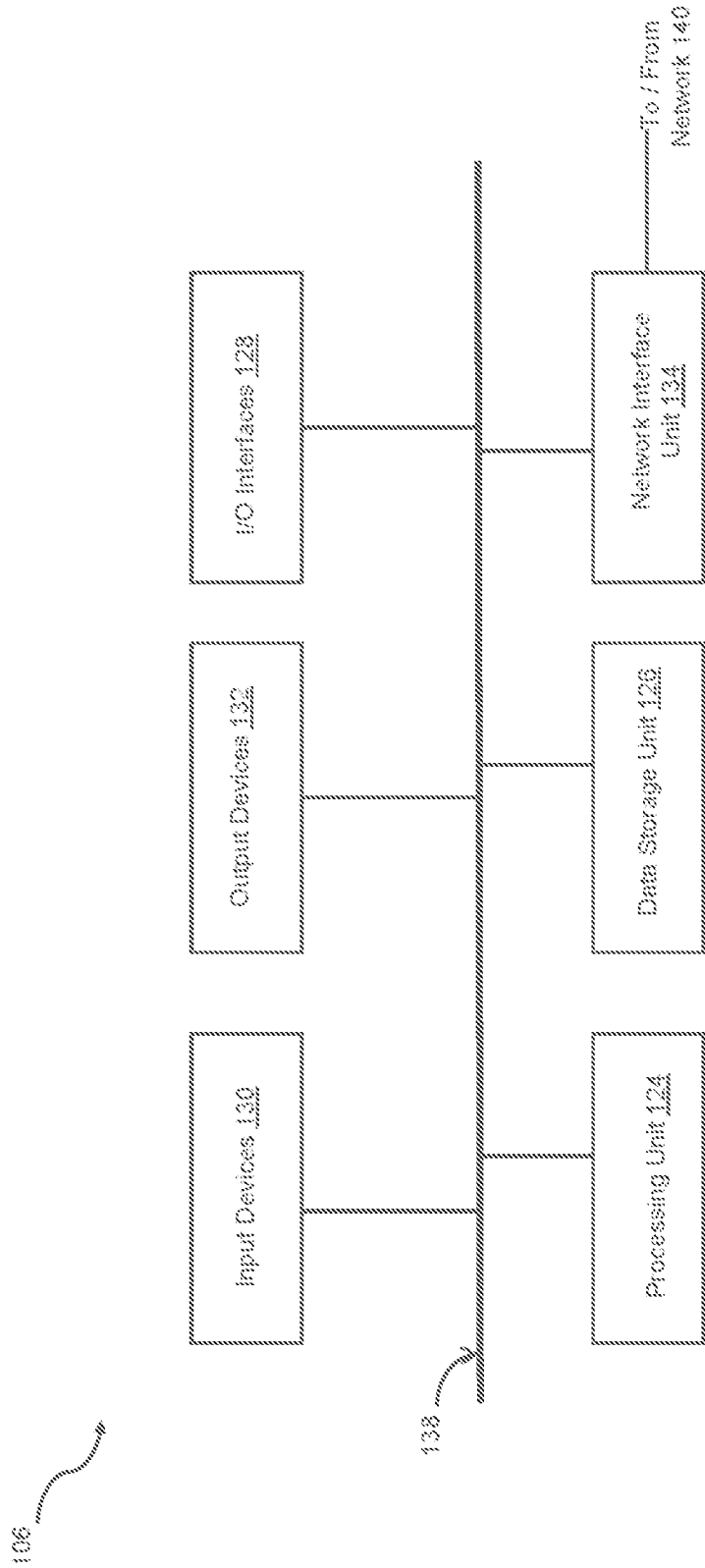


Figure 1B

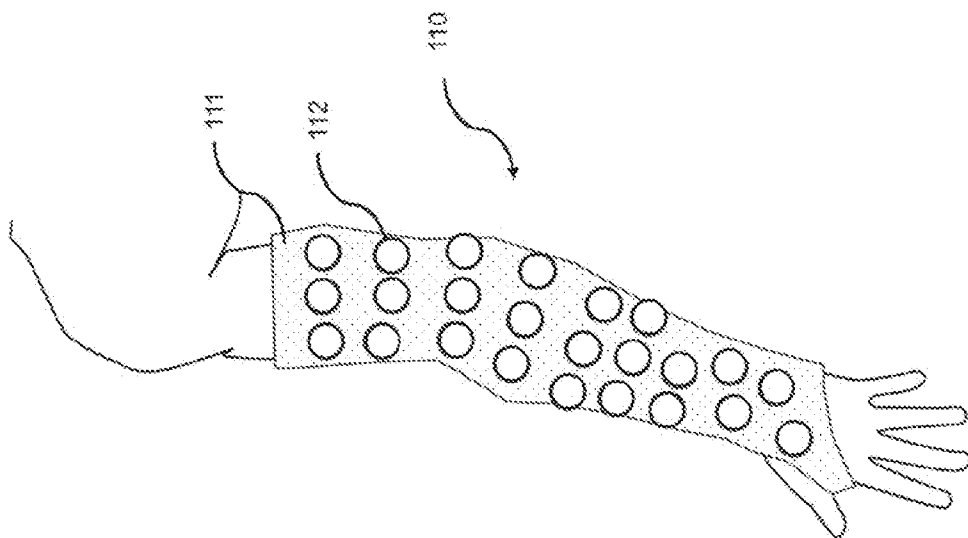


Figure 2

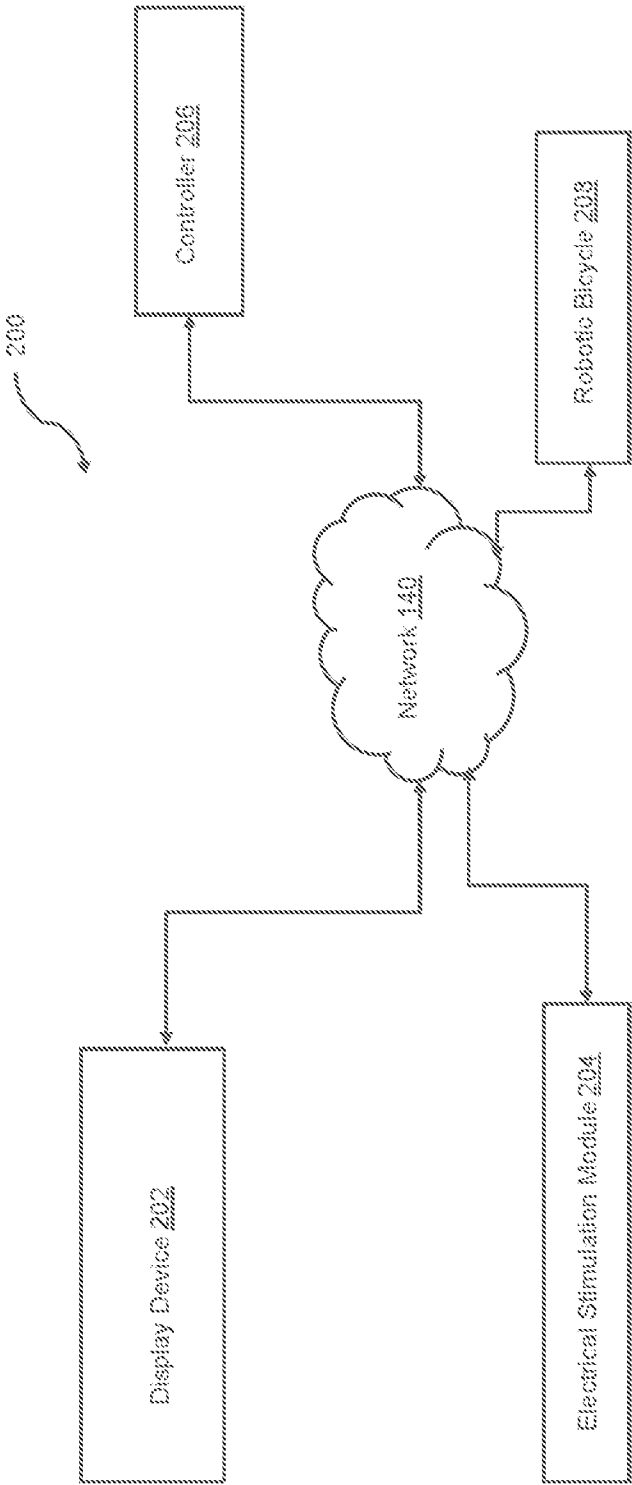


Figure 3

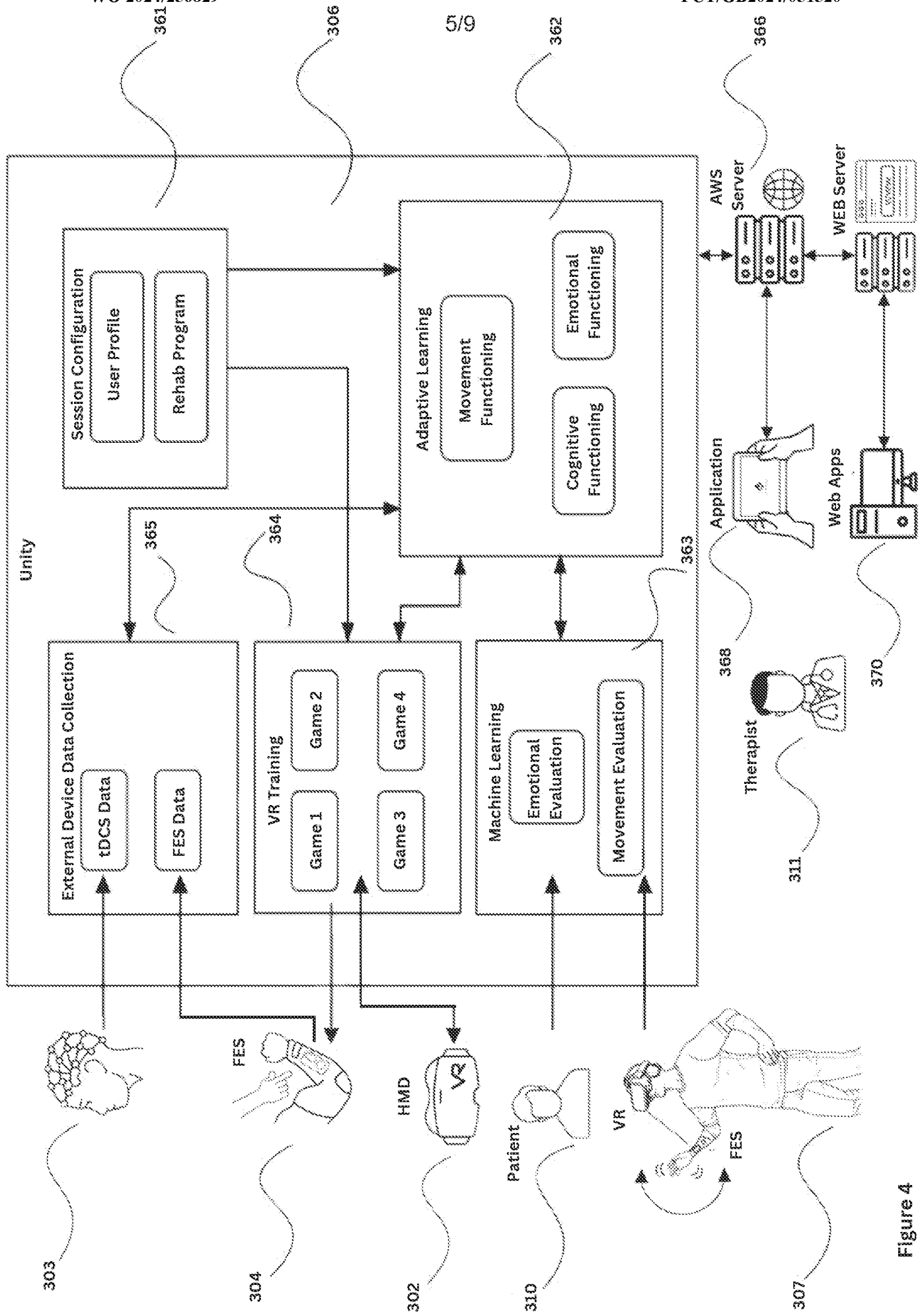


Figure 4

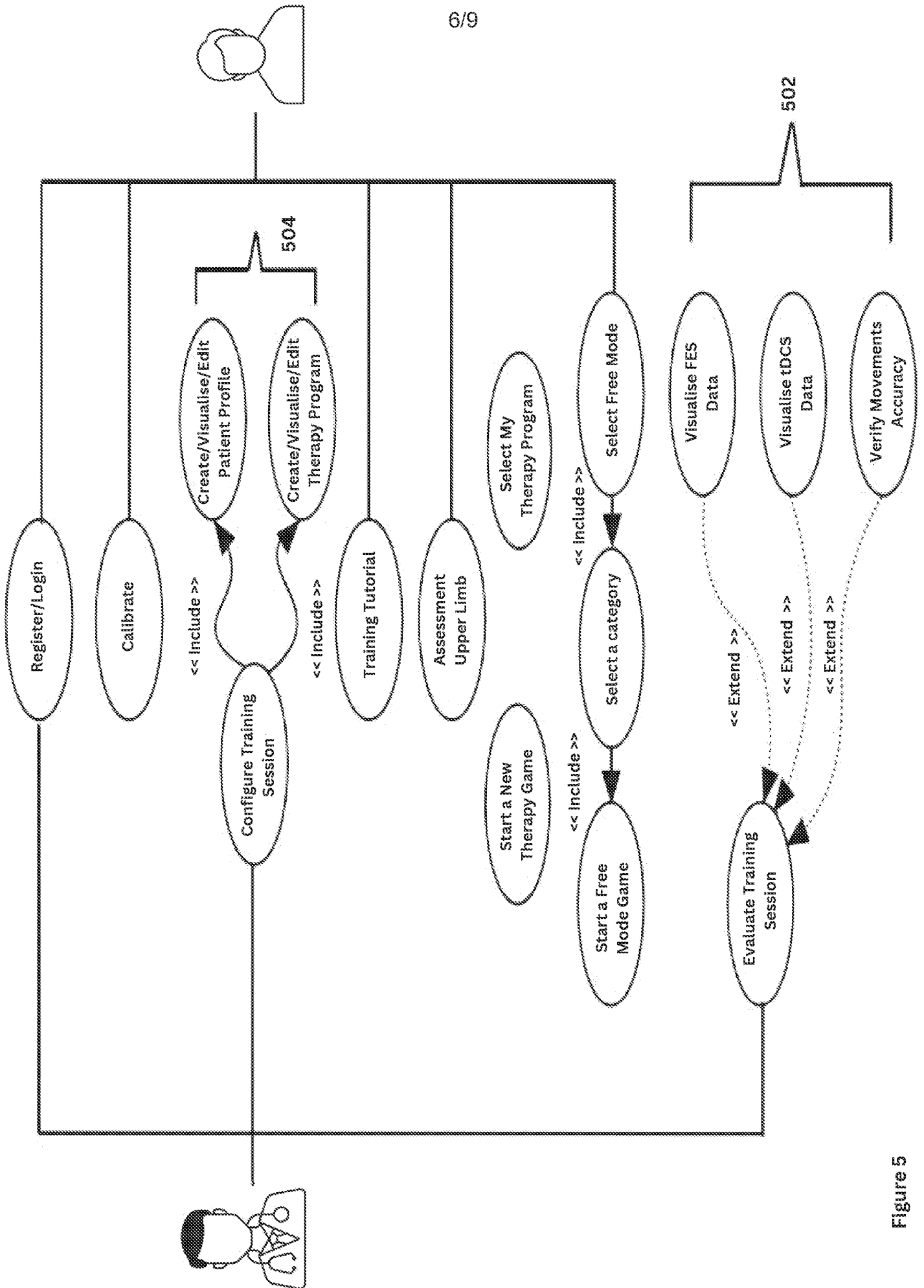


Figure 5

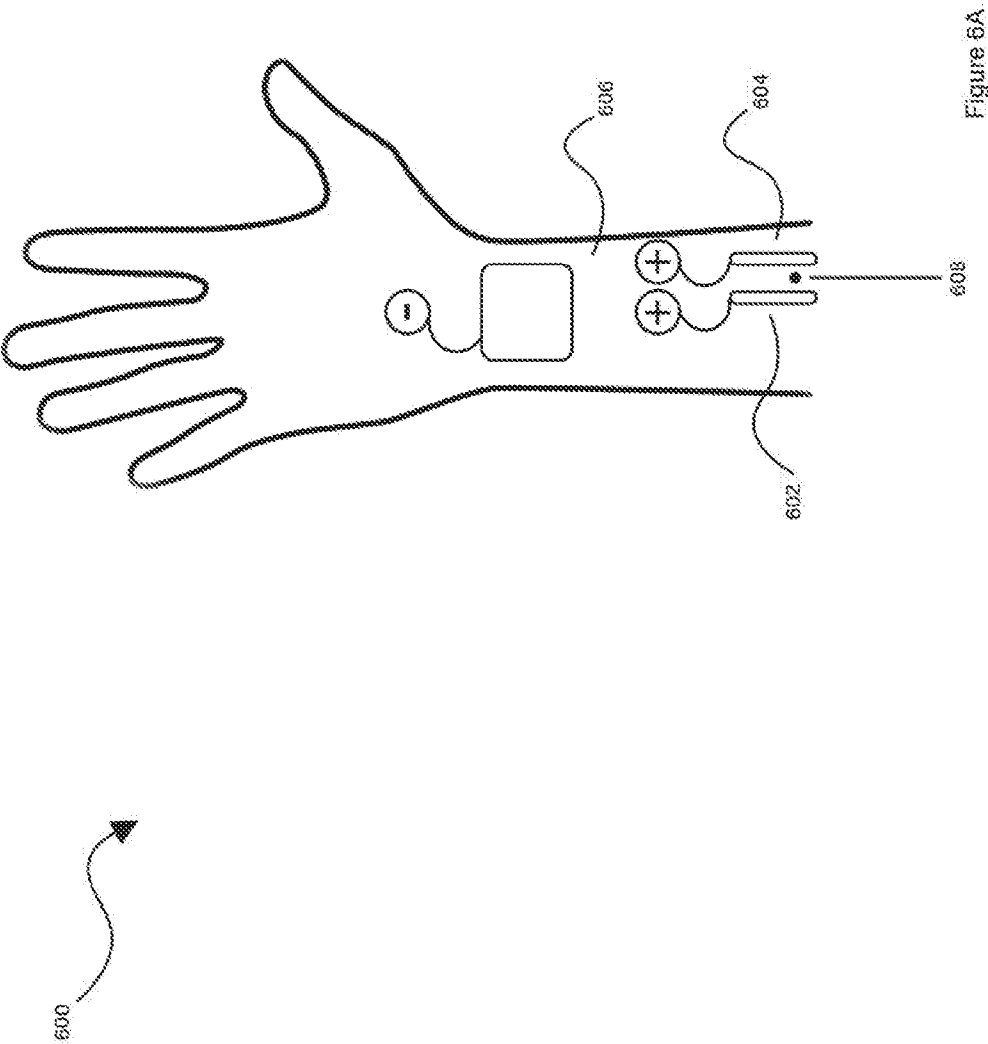
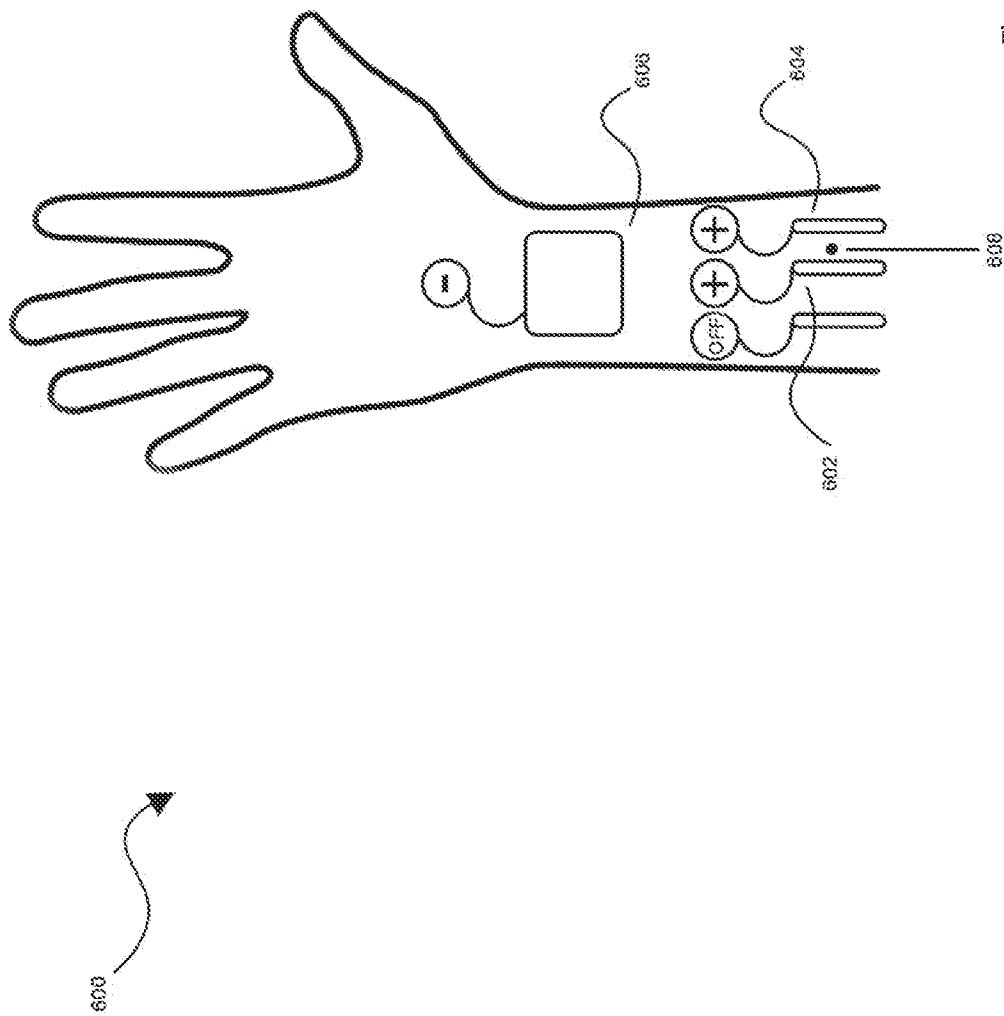
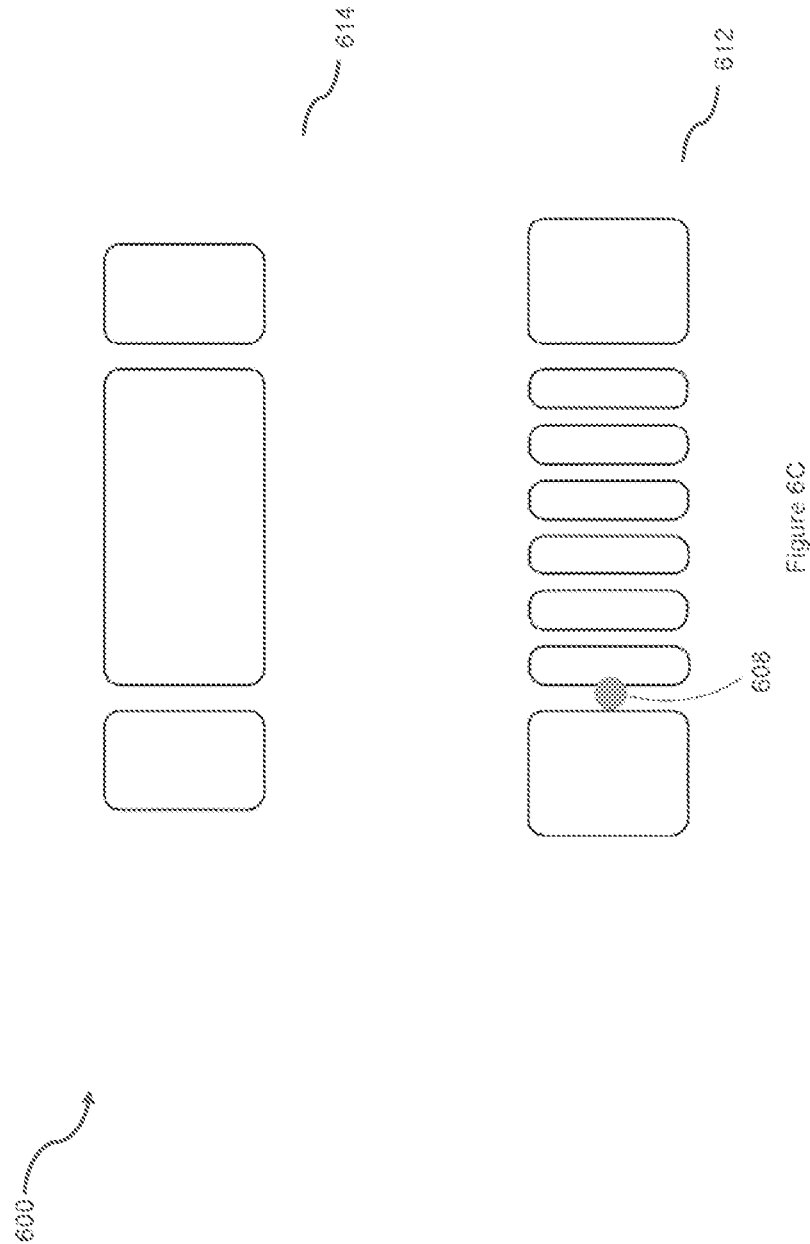


Figure 6A





INTERNATIONAL SEARCH REPORT

International application No

PCT/GB2024/051520

A. CLASSIFICATION OF SUBJECT MATTER

INV. A61N1/36

ADD. A61B5/11

A61B5/389

A61N1/04

G16H20/30

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2006/022307 A1 (UNIV KURUME [JP]; SHIBA NAOTO [JP] ET AL.) 2 March 2006 (2006-03-02)	1,2,4-6, 17-21, 26,27
Y	paragraphs [0024], [0028], [0031]; figure 1 -----	22-25
X	KR 101 641 581 B1 (UNIV DAEJEON IND UNIV COOP FOUND [KR]; BIO BRAIN CO LTD [KR]) 21 July 2016 (2016-07-21)	1-5,26, 27
	paragraphs [0015], [0027], [0037], [0049] - [0050], [0056], [0070] -----	
X	WO 2022/190738 A1 (UNIV OSAKA [JP]) 15 September 2022 (2022-09-15)	1-6,17, 18,26,27
	abstract; figure 1 ----- -/-	



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

20 August 2024

Date of mailing of the international search report

05/11/2024

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Rogala, Tomasz

INTERNATIONAL SEARCH REPORT

International application No
PCT/GB2024/051520

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	CN 215 017 698 U (BIOLOGICAL ISLAND LABORATORY) 7 December 2021 (2021-12-07) the whole document abstract figure 1 -----	1, 2, 7-18, 26, 27
Y	US 2023/039154 A1 (ROBISON JEREMIAH [US] ET AL) 9 February 2023 (2023-02-09) paragraphs [0073] - [0078] -----	22-25

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB2024/051520

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

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

1. ☒ Claims Nos.: 38 - 41
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims;; it is covered by claims Nos.:
1 - 27

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

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

1. claims: 1-27

A system for combined visual and electrical stimulation of the body

2. claims: 28-37

A wearable electrode array

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 38-41

The methods defined in claim 38 and claims 39-41 dependent thereon relates to therapeutical treatment of the human body, due to the step of "providing, ..., an electrical stimulation to one or more target muscles of a body part of a user". Thus, claims 38-41 are covered by the provisions of Article 17(2)(a)(i) PCT and Rule 39.1 (iv) PCT, i.e. the International Search Authority cannot be required to perform the search on their subject-matter. Moreover, according to Article 34(4)(a)(i) PCT and Rule 67.1 (iv) PCT, no examination is required to be carried out on these claims.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/GB2024/051520

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2006022307 A1	02-03-2006	JP 4840926 B2	21-12-2011
		JP WO2006022307 A1	31-07-2008
		WO 2006022307 A1	02-03-2006

KR 101641581 B1	21-07-2016	NONE	

WO 2022190738 A1	15-09-2022	JP WO2022190738 A1	15-09-2022
		US 2024149060 A1	09-05-2024
		WO 2022190738 A1	15-09-2022

CN 215017698 U	07-12-2021	NONE	

US 2023039154 A1	09-02-2023	CN 117794615 A	29-03-2024
		US 2023039154 A1	09-02-2023
