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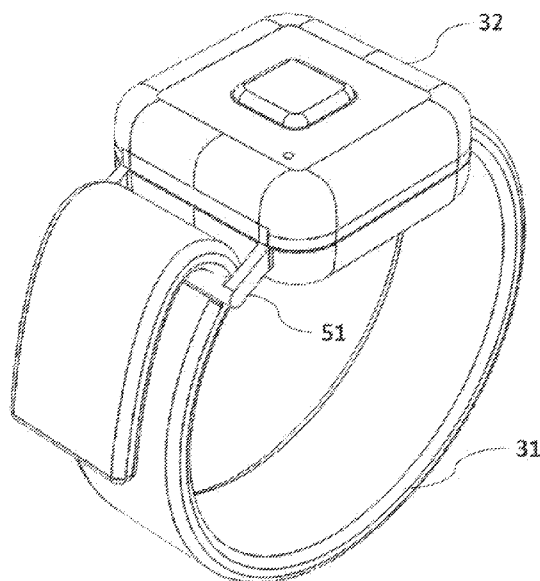


Fig. 5

(57) Abstract: A multimodal wearable band which uses mechan-
ical vibrations to stimulate sensory neurons in the wrist or ankle in
order to reduce the severity of tremors, rigidity, involuntary mus-
cle contractions, and bradykinesia caused by neurological move-
ment disorders and to free users from freezing induced by move-
ment disorders. The device uses sensors to provide output used
by a processing unit to determine the optimal stimulation pattern
for each user and to determine when stimulation is necessary, and
then uses one or more vibration motors to accordingly stimulate
the user's neurological pathways to lessen the severity of a user's
symptoms. The device can also be adapted to integrate with 3rd
party devices.

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APPARATUS AND METHOD FOR REDUCTION OF NEUROLOGICAL MOVEMENT DISORDER SYMPTOMS USING WEARABLE DEVICE

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This patent application claims priority to U.S. Patent Application No. 18/448,385, filed on August 11, 2023, the entirety of which is incorporated herein by reference.

TECHNICAL FIELD

[0002] The present invention relates to wearable medical devices and in particular to wearable medical devices that mitigate symptoms of neurological movement disorders.

BACKGROUND ART

[0003] There are a number of neurological movement disorders which exhibit a range of somewhat similar symptoms, examples of which follow. Essential tremor is characterized by tremor of the extremities. Parkinson's Disease (PD) can cause tremor, rigidity, bradykinesia, and temporary freezing or inability to begin a motion. Restless Leg Syndrome does not cause a tremor; however, it causes a strong compulsion to move and shake the patient's legs. Tremor can also be present as a side effect of certain medications.

[0004] There are approximately 10 million people living with Parkinson's Disease (PD) in the world today, and over 70% of these patients experience tremors - the involuntary trembling or shaking of the extremities. Other symptoms of PD include stiffness or rigidity of the muscles, bradykinesia (defined as slowness of movement), and freezing (defined as the temporary, involuntary inability to move).

[0005] Parkinson's Disease has no cure. Treatments at the moment consist of medications to address patients' symptoms, though these do not reverse the effects of the disease. Patients often take a variety of medications at different doses and different times of day to manage symptoms. PD medications are most often dopaminergic, either supplying or mimicking the effects of dopamine to replenish the depleted dopamine state caused by the disease.

[0006] Surgical procedures can be prescribed for patients who have exhausted their medical treatment options. The first method of surgical treatment is Deep Brain Stimulation (DBS). In this procedure, electrodes are inserted into the brain, and then an impulse generator battery is implanted under the collar bone or in the abdomen. The patient uses a controller to power the device on or off, as needed, to help control tremors. DBS can be effective for both Parkinson's disease and essential tremor, but this procedure is incredibly invasive and expensive.

[0007] The second surgical procedure available for Parkinson's patients is Duopa therapy. Duopa therapy requires a small hole (a stoma) to be surgically made in the stomach to place a tube in the intestine. Duopa, which is similar to normal PD medications taken through pills, is then pumped directly into the intestine, which improves absorption and reduces off-times of medications taken by pill.

[0008] A similar disorder, called essential tremor, has an even higher incidence rate with an estimated 100 million cases worldwide. These tremors can get bad enough that patients no longer have the ability to cut their food, tie their shoes, or sign their name. Essential tremor medications can include beta blockers and anti-seizure medications. These medications are known to cause fatigue, heart problems, and nausea.

[0009] Restless Leg Syndrome (RLS) affects roughly 10% of the population in the United States. RLS can also be a side effect of primary Parkinson's Disease. RLS is characterized by unpleasant tingling sensations in the patient's legs. These sensations occur when the legs are still and are alleviated when the legs are in motion. As a result, RLS patients are compelled to move or shake their legs. This is particularly detrimental to the quality of patients' sleep as they are unable to remain still.

[0010] RLS is commonly treated by dietary changes, medications, and/or physical therapy. Dietary changes can include eliminating caffeine, alcohol, and tobacco. Medications prescribed for RLS can include the same type of medications prescribed for Parkinson's Disease (such as dopamine agonists and carbidopa-levodopa) and benzodiazepines (such as lorazepam, Xanax, Valium, and Ativan). Physical therapy for RLS can include massaging the legs or electrical or vibrational stimulation.

[0011] One example of a device that uses vibration to treat RLS is described in "Systems, devices, and methods for treating restless leg syndrome and periodic limb movement disorder,"

Walter, T. J., & Marar, U. (2010), *U.S. Patent Application Publication No. US20100249637A1*. This device is a lower leg sleeve with sensors and actuators, but it does not store or transmit data, nor does it address any of the other symptoms common to neurological movement disorders.

[0012] There are also a number of pharmaceutical avenues for the management of neurological movement disorder that function by promoting dopamine, a chemical produced by the brain which helps control body movement. This chemical is lacking in the brains of patients with diseases such as Parkinson's disease. Pharmaceutical treatment for Parkinson's disease is expensive, costing users thousands of dollars annually; ineffective, wearing off quickly; and thought to actually accelerate neurodegeneration.

[0013] There also exists an injection-based Botox treatment for more severe tremors which costs tens of thousands of dollars annually and works by killing the nerves responsible for the tremors. This is effective in reducing the tremors, but the death of the nerves also causes a significant decrease in mobility. Additionally, this treatment is only available at very specialized treatment centers and therefore is not an option for the vast majority of patients.

[0014] There are a number of devices that attempt to control unwanted movement using surface-based treatment, but none have proven to be completely non-invasive and effective. Many have settled on electrical stimulation as their chosen mode of neurostimulation for the relief of unwanted movement. This can involve various equipment and inconvenient procedures such as gel pads or electrodes that require shaving for proper attachment. See "Closed-loop feedback-driven neuromodulation," DiLorenzo, D. J. (2014), *U.S. Patent No. US8762065B2*. These devices only work after the electrical treatment is concluded, and the effects have not been shown to last for extended periods of time, leading to the assumption that many of these inconvenient treatments must be administered throughout the day to maintain tremor reduction. See "Devices and methods for controlling tremor," Rosenbluth, K. H., Delp, S. L., Paderi, J., Rajasekhar, V., & Altman, T. (2016), *U.S. Patent No. US9452287B2*; "Systems for peripheral nerve stimulation to treat tremor," Wong, S. H., Rosenbluth, K. H., Hamner, S., Chidester, P., Delp, S. L., Sanger, T. D., & Klein, D. (2017), *U.S. Patent No. US9802041B2*. The aforementioned treatment poses significant risk for patients with pacemakers, and has also been found to cause skin irritation. They provide benefit only for tremor and do not provide relief from other symptoms of neurological movement disorders, such as bradykinesia, freezing of gait, dystonia, or involuntary or compulsive rhythmic movement.

[0015] Perhaps the most relevant studies have emerged in the last few years and demonstrate that using vibration may improve motor performance. It seems that there is much variation in efficacy, which depends on the frequency of vibration, as well as the patient's condition. Macerollo et al. demonstrated that 80 Hz peripheral tactile vibration may result in less slowing and a decrease in repetitive hand movement in "Effect of Vibration on Motor Performance: A new Intervention to Improve Bradykinesia in Parkinson's Disease?", Macerollo A, et al., (2016), *Neurology* Apr 2016, 86 (16 Supplement) P5.366. For post-stroke patients, 70 Hz has proven effective. This is demonstrated by Conrad MO, et al., in two separate papers: "Effects of wrist tendon vibration on arm tracking in people poststroke," Conrad MO, Scheidt RA, Schmit BD (2011), *J Neurophysiol*, 2011;106(3):1480-8; and "Effect of Tendon Vibration on Hemiparetic Arm Stability in Unstable Workspaces," Conrad MO, Gadhoke B, Scheidt RA, Schmit BD (2015), *PLoS ONE* 10(12): e0144377. Even paretic muscles are proven to respond to frequencies between 150 and 160 Hz, and the effects of such vibration are seen in a lasting reduction in weakness and spasticity in the treated muscles. See "The effects of muscle vibration in spasticity, rigidity, and cerebellar disorders," Hagbarth, K. E., & Eklund, G. (1968), *Journal of neurology, neurosurgery, and psychiatry*, 31(3), 207-13. There exists one device which provides haptic signals around a user's wrist using actuators positioned along a band. These actuators slide along the band to change location relative to one another in order to provide signals in the correct location. See "Wearble device," Zhang, Haiyan, Helmes, John Franciscus Marie, Villar, Nicolas (2018), *U.S. Patent No. US20180356890A1*.

[0016] Therefore, there is a need for a device that non-invasively, reliably, and affordably relieves symptoms of neurological movement disorders.

SUMMARY OF THE EMBODIMENTS

[0017] In accordance with one embodiment of the invention, a wearable device for mitigating a movement disorder of a subject. The device includes an attachment system configured to be attached to a body part of a subject. The device further includes a set of body part sensors to provide a set of sensor outputs related to a body part parameter. The device also includes a processing unit operationally coupled to the set of body part sensors. The processing unit is configured to quantify an extent or characteristic of the movement disorder based on the set of sensor outputs. The device further includes a set of mechanical transducers operationally

coupled to the processing unit to provide a set of mechanical outputs. The processing unit is further configured to control the set of mechanical outputs of the set of mechanical transducers so as to mitigate an extent of the movement disorder through a feedback loop.

[0018] Optionally, the attachment system includes a wristband, and the mechanical transducers are distributed throughout the circumference of the wristband. Optionally, the device is operated by a button on a face of the device, the button is configured on the face to allow for ease of use by a patient whose fine motor control is affected by a neurological movement disorder. Optionally, the wristband is configured with a hook-and-loop fastener, such that the wristband can be fastened with a single hand for ease of use by those whose fine motor control is affected by a neurological movement disorder. Optionally, the device further includes a battery that can be coupled to a magnetically aligned charging cable for charging the device, which provides ease of use by a patient whose fine motor control is affected by a neurological movement disorder.

[0019] Optionally, the device is configured to be fully autonomous, using passive movement disorder sensing to initiate active operation. Optionally, the processing unit is further configured to use closed loop control, along with a state machine, to address symptoms. Optionally, the processing unit is further configured to control the mechanical transducers, without requiring control inputs from external control units. Optionally, the processing unit is further configured to collect and store data.

[0020] Optionally, the symptoms are selected from the group consisting of tremor, rigidity, bradykinesia, compulsion to move, and combinations thereof. Optionally, the processing unit is further configured to detect a freezing gait of a patient with Parkinson's Disease. Alternatively or additionally, the processing unit is further configured to control the set of mechanical transducers so as to relieve freezing gait of a patient with Parkinson's Disease.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] The foregoing features of embodiments will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

[0022] Fig. 1 illustrates a system for mitigating movement disorder in accordance with an embodiment of the present invention.

[0023] Fig. 2 is an electrical schematic highlighting the main sub-circuits of the system in Fig. 1.

[0024] Fig. 3 is an isometric view of a wearable device in accordance with an embodiment of the present invention.

[0025] Fig. 4 is an exploded isometric view of a wearable device, in which the vibration motors are housed in the band rather than in the main electronics housing, in accordance with an embodiment of the present invention.

[0026] Fig. 5 is an isometric view of a wearable device, in which the device includes a loop mechanism to allow single handed adjustment of the band on the user's wrist, in accordance with an embodiment of the present invention.

[0027] Fig. 6 shows an embodiment of the present invention worn on a hand viewed from above.

[0028] Fig. 7 shows an embodiment of the present invention worn on a hand viewed from the side.

[0029] Fig. 8 shows a testing configuration for the wearable medical device, which may be used for more rigorous data collection, in accordance with an embodiment of the present invention.

[0030] Fig. 9 illustrates a wearable device for mitigating movement disorder, in which the device is an accessory to a third-party smartwatch or other wearable computing device, in accordance with an embodiment of the present invention.

[0031] Fig. 10 shows a side view of a wearable device, which is as an accessory band for a third-party smartwatch or other wearable computing device, in accordance with an embodiment of the present invention.

[0032] Fig. 11 shows a process by which a raw sensor input may be used to compute a set of stimulation parameters in accordance with an embodiment of the present invention.

[0033] Fig. 12 shows a feature extraction process in accordance with an embodiment of the present invention.

[0034] Fig. 13 shows a stimulation optimization algorithm in accordance with an embodiment the present invention.

[0035] Fig. 14 shows a neurological signal cancelling system, illustrating how the wearable device and body interact, in accordance with an embodiment of the present invention.

[0036] Fig. 15 is a pair of renderings by a Parkinson's patient of a spiral under conditions without and with treatment by a device in accordance with an embodiment of the present invention.

[0037] Fig. 16 illustrates an embodiment of a simple non-convex gradient descent optimization used in embodiment of the present invention for symptom reduction by searching over the parameter configuration space.

[0038] Fig. 17 shows a power spectral density (PSD) plot of the postural tremor of a Parkinson's Disease patient with and without the use of a device in accordance with an embodiment of the present invention.

[0039] Fig. 18 shows a power spectral density (PSD) plot of the postural tremor of an Essential Tremor patient with and without the use of a device in accordance with an embodiment of the present invention.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

[0040] Definitions. As used in this description and the accompanying claims, the following terms shall have the meanings indicated, unless the context otherwise requires:

[0041] A "set" includes at least one member.

[0042] A "body part" is a part of a human body, such as a limb (examples of which include an arm, a leg, an ankle, and a wrist) or the neck.

[0043] A "body part sensor" is a sensor responsive to a parameter, associated with a body part, the parameter selected from the group consisting of force, motion, position, EMG signal directed to a set of muscles of the body part and combinations thereof.

[0044] A "mechanical transducer" is a device having an electrical input and a mechanical output configured to provide physical stimulation to a subject.

[0045] A "movement disorder sensor" is a sensor that is configured to provide a measurement associated with a neurological movement disorder.

[0046] An "attachment system" is a system or a device having a means to mechanically affix component subsystems to the user's person.

[0047] A "housing" is a primary enclosed casing which contains one or more component subsystems.

[0048] A “band” is a flexible segment of material which encircles a body part or portion of a body part for the purpose of affixment which may also house one or more component subsystems.

[0049] The term “vibrational stimulus” refers to a vibration or series of vibrations produced by a vibration motor or group of vibration motors embedded in the device. These vibrations are used to stimulate a response from the targeted proprioceptors in the user’s body.

[0050] The term “stimulation pattern” refers to a vibrational stimulus which is characterized by a number of parameters including frequency, amplitude, and waveform. A “stimulation pattern” can also refer to a longer time scale behavior over which the above-mentioned parameters evolve over time.

[0051] The term “proprioception” refers to the sense of the position of one’s own limbs or body parts and the intensity of force being applied through that body part. A proprioceptor is a sensory neuron which is used for proprioception. There are two types of proprioceptors: “muscle spindles” which are located in the muscle and the “Golgi tendon organs” which are located in the tendons.

[0052] The term “neurological movement disorder” refers to any of the neurological conditions that cause abnormally increased or decreased movements which may be voluntary or involuntary. These include but are not limited to: Ataxia, cervical dystonia, chorea, dystonia, functional movement disorder, Huntington's disease, multiple system atrophy (MSA), paresis, hemiparesis, quadriparesis, post-stroke movement disorders, myoclonus, Parkinson's disease (PD), Parkinsonism, drug induced Parkinsonism (DIP), progressive supranuclear palsy (PSP), restless legs syndrome (RLS), tardive dyskinesia, Tourette syndrome, spasticity, rigidity, bradykinesia, tremor, essential tremor (ET), alcohol or drug withdrawal induced tremor, drug induced tremor, psychogenic tremor, rest tremor, action tremor, cerebellar lesion, rubral tremor, isometric tremor, task-specific tremor, orthostatic tremor, intention tremor, postural tremor, periodic limb movement disorder, and Wilson's disease.

[0053] The term “training period” refers to a period or phase of the device’s operation during which the device is conducting experimentation or collecting and analyzing data for the purpose of deducing the optimal stimulation pattern.

[0054] The present disclosure is directed generally towards wearable medical devices and in particular towards the mitigation of tremors, rigidity, bradykinesia, involuntary rhythmic movements, and freezing associated with neurological movement disorders through mechanical vibrational stimulation of the tendon bundles in the wrist and autonomous sensing, feedback, and adjustment. There are also a number of considerations taken into the embodiment of the device which facilitate ease of use by the disabled populations for whom the invention is intended, including integration with 3rd party devices.

[0055] Embodiments of the present disclosure include systems and methods of treating symptoms of neurological movement disorders by stimulating proprioceptors. In some embodiments, the systems are wearable devices. In some embodiments, the systems and methods can be used for any neurological movement disorder, including but not limited to Parkinson's Disease, Essential Tremor, post-stroke movement disorders, or Restless Leg Syndrome. In some embodiment, the symptoms treated include tremor, rigidity, bradykinesia, stiffness, hemiparesis, and freezing. In some embodiments, the symptoms treated include muscle contraction caused by dystonia. In some embodiments, the symptoms treated include the inability to locate one's limbs in space. In some embodiments, the proprioceptors targeted for stimulation are located in the wrist. In some embodiments, the proprioceptors targeted for stimulation are located in the ankle. In some embodiments, the proprioceptors targeted for stimulation are located in the neck.

[0056] In some embodiments, the systems provide stimulus to the proprioceptive nerves (proprioceptors) for reducing symptoms by the use of vibration motors positioned around the surface of the wrist. In some embodiments, the systems cycle through frequency patterns and waveforms of stimulation to find the pattern that results in the greatest reduction of movement disorder symptoms. In some embodiments, the systems use random white-noise subthreshold stimulation in order to leverage the effect of sensory stochastic resonance. In some embodiments, the systems are coupled to one or more sensors that measure the user's tremor for each of a set of possible stimulation patterns, and the systems assign the pattern of stimulation that relates to the biggest measured decrease in tremor amplitude of that user relative to the tremor exhibited in the absence of stimulation.

[0057] In some embodiments, the device finds (learns) the optimal stimulation parameters for use in reducing the symptoms by using sensor-based optimization, including but

not limited to model free reinforcement learning, genetic algorithms, Q-learning. These parameters can include any quantities used to define a stimulation waveform such as frequency, amplitude, phase, duty cycle, etc. In some embodiments, these learned parameters also describe the longer time scale behavior of the stimulation pattern evolving over time. In some embodiments, the device determines the optimal stimulation as the weighted average of the optimal stimulations for each of the independent symptoms observed where the weights are proportional to the symptom severity relative to the other observed symptoms. For example, if the patient experienced tremors and rigidity, and the severity of the tremors was double that of the rigidity, the output stimulation would be two times the optimal tremor reducing pattern superposed with one times the optimal rigidity reducing pattern. In some embodiments, the device senses all of the active symptoms and elects to reduce only the symptom with the worst severity. In some embodiments, the device, via sensors, measures the shaking due to RLS of the user and assigns the pattern that relates to the biggest decrease in shaking amplitude of that user where the amplitude is that of the sensor signal and the difference is defined relative to the amplitude observed in the absence of stimulation from the device.

[0058] In some embodiments, the sensors coupled to the device are a combination of accelerometers, gyroscopes, IMUs, or other motion-based sensors. In some embodiments, the sensors coupled to the device also include electromyography (EMG) sensors to monitor muscle activation in order to sense tremor severity, rigidity, or movement due to RLS. In some embodiments, the device collects data on the characteristics of the user's symptoms, such as motion amplitude and frequency or muscle activity with sensors contained in the device such as an accelerometer, pressure sensors, force sensors, gyroscope, Inertial Measurement Unit (IMU), or electromyography (EMG) sensors. In some embodiments, the above-mentioned data would be stored through storage components contained within the device. In some embodiments, the above-mentioned data is regularly consolidated for the purpose of larger scale data analysis through a wired or wireless transfer of data to a larger storage location not on the device.

[0059] In some embodiments, the actuators are resistive heating elements rather than vibration motors. In some embodiments, the actuators are vibration motors. In some embodiments, the actuators are electromagnets. In some embodiments, the actuators are electropermanent magnets. In some embodiments, the actuators are piezoelectric actuators. In some embodiments, the actuators are voice coil vibration motors. In some embodiments, the

actuators are rotating eccentric mass vibration motors. The actuators may include one or more sonic transducers. Sonic transducers may include, without limitation, ultrasonic transducers or other sonic transducers. Ultrasonic transducers may also be interchangeably referred to as “ultrasonic emitters” throughout this disclosure. Ultrasonic transducers in some embodiments may output a frequency of about 1 Hz to about 1 GHz. One or more ultrasonic transducers may be configured to target specific parts of a user’s body and/or at specific frequency ranges. For instance, one or more ultrasonic transducers may be configured to output a low-frequency ultrasound. A low-frequency ultrasound may include a frequency of about 20 kHz to about 100 kHz which may target larger nerve bundles, deep soft tissues, and/or joints of a user. A frequency of about 20 kHz to about 100 kHz may provide deep tissue penetration with less superficial heating. One or more ultrasonic transducers may be configured to output a medium-frequency ultrasound. A medium-frequency ultrasound may include a frequency of about 100 kHz to about 500 kHz. A frequency of about 100 kHz to about 500 kHz may be used to target deeper nerves, muscles, tendons, and/or ligaments of a user. A frequency of about 100 kHz to about 500 kHz may penetrate one or more tissues at intermediate depths and may affect structures like tendons and/or ligaments, may improve tissue perfusion, increase collagen extensibility, and potentially modulate nerve activity. In some embodiments, one or more ultrasonic transducers may be configured to output a high-frequency ultrasound. A high-frequency ultrasound may include a frequency of about 500 kHz to about 1 MHz. A frequency of about 500 kHz to about 1 MHz may target superficial nerves, tendons, and/or ligaments of a user and may offer high resolution imaging of one or more parts of a user. A frequency of about 500 kHz to about 1 MHz may be used to target tissues closer to a skin surface of a user and may be used for localized treatments. In some embodiments, one or more ultrasonic transducers may be configured to output a diagnostic ultrasound. A diagnostic ultrasound may include a frequency of about 1 MHz to about 10 MHz. A frequency of about 1 MHz to about 10 MHz may provide imaging and visualization of soft tissues, organs, and/or superficial nerves. A frequency of about 1 MHz to about 10 MHz may provide for diagnostic imaging without therapeutic effects. In some embodiments, one or more ultrasonic transducers may be configured to output a very high-frequency ultrasound. A very high-frequency ultrasound may include a frequency of about or greater than 10 MHz. A frequency at about or greater than 10 MHz may target superficial structures such as skin layers and nerves close to a skin surface. A frequency at about or greater

than 10 MHz may provide for ultra-high resolution imaging for dermatology, superficial nerve assessments, and/or visualization of superficial skin conditions. In an embodiment, two or more ultrasonic transducers may be used. Ultrasonic transducers may include piezoelectric, capacitive, or other transducers. In some embodiments, one or more ultrasonic transducers may be configured to apply a waveform output to a part of a user. A waveform output of one or more ultrasonic transducers may be about 1MHz in frequency.

[0060] In some embodiments, the actuators may include electric transducers. Electric transducers may include, without limitation, piezoelectric, capacitive, or other transducers. Electric transducers may be configured to output an electrical signal to a part of a user. For instance, and without limitation, electric transducers may be configured to output an AC (alternating current), DC (direct current), or other signal to a user. One or more electric transducers may be configured to output a waveform with a voltage of about 1v to about 5v, a current of about 10mA to about 50mA, and a frequency of about 50Mhz, without limitation. One or more electric transducers may be configured to perform transcutaneous electrical nerve stimulations (TENS), functional electric stimulations (FES), and/or other stimulations. One or more electric transducers may be configured to output amps in a range of about, but not limited to 1 mA to about 80 mA. In some embodiments, one or more electric transducers may be configured to output a voltage of about 0V to about 50V. One or more electric transducers may be configured to output a frequency of about 1Hz to about 100 Hz. In some embodiments, one or more electric transducers may be configured to output a frequency of about 100 Hz to about 10,000 Hz. One or more electric transducers may be configured to provide conventional TENS, high-frequency or burst TENS, and/or modulation TENS. One or more electric transducers may be configured to output time-varying frequencies, square waveforms, pulse waveforms, and the like of one or more voltages, currents, and the like.

[0061] One or more electric transducers may be configured to provide an intensity calibration of a stimulation for a user. As a non-limiting example, in TENS and/or FES intensity calibration, an intensity range of about 1 mA to about 5 mA may be used initially and may gradually increase until one or more parameters are met, such as if a user feels a tingling or mild muscle twitching. Continuing this example, a current may be adjusted to about 10 mA to about 80 mA, depending on a treatment area and a patient's comfort.

[0062] One or more electric transducers may have one or more electrodes. Electrodes of one or more electric transducers may include shapes, sizes, dimensions, and the like. For instance, electrodes may include shapes such as, but not limited to, square, rectangular, round, butterfly, and the like. Electrodes of one or more electric transducers may have a small size of about 2 cm by cm to about 5 cm by 5 cm. Electrodes may have a medium size of about 5 cm by 5 cm to about 10 cm by 5 cm. Electrodes may have a large size of about 10 cm by 5 cm or greater. Electrodes of one or more electric transducers may include material such as, but not limited to, carbon rubber electrodes, silver-based electrodes, and the like. Electrodes of one or more electric transducers may have a resistance of about 1,000 ohms to about 5,000 ohms, without limitation. In some embodiments, electrodes of one or more electric transducers may have a resistance less than 1,000 ohms or greater than 5,000 ohms, without limitation.

[0063] In some embodiments, the device is an accessory band to a third-party smartwatch or other wearable computing device. In some embodiments, the device can connect wirelessly (for example via Bluetooth) to the user's smartphone. In some embodiments, the device can be configured to provide contextualized data about the user's condition. For example, the system can correlate symptom onset or degree with time of day, activity level, medication, diet, other symptoms, etc. In some embodiments, this can be accomplished by transmitting extracted sensor signal features to the user's smartphone. An accompanying smartphone application can periodically prompt the user to input other information like activity level, diet, and medication. The application then logs this data with time matched symptom sensor signal features to be reviewed by the user and/or their physician. In some embodiments, the device can be started by passive sensing of the onset of symptoms such as the on/off phenomenon of Parkinson's patients taking L-dopa. In some embodiments, this can be accomplished by continuously reading sensor data, even while in the "off" state, and then switching to the "on" state when one of the sensor data features, such as amplitude, surpasses a preset threshold value. In some embodiments, the device can be used to amplify an existing but subtle tremor for the purpose of early diagnosis. In some embodiments, this can be accomplished by manually testing a set of stimulation patterns until the tremor is apparent, either visually or as detected by an extracted feature of the sensor data surpassing some preset threshold. In some embodiments, this can be accomplished autonomously by inverting the stimulation selection algorithm heuristic such that it converges to

the stimulation pattern which maximizes tremor amplitude as measured by the symptom sensor relative to the tremor amplitude measured in the absence of stimulation from the device.

[0064] Fig. 1 illustrates a system for mitigating movement disorder in accordance with an embodiment of the present invention. Fig. 1 shows a wearable device 11 interfacing with a user's body 12. The user's body 12 includes proprioceptive nerves 1201, perceived limb position and motion 1202, a nervous system 1203, desired activation control signal 1204, and muscles 1205. The muscles 1205 output electrical activity 14, which is detected by the EMG sensor 1107 in the wearable's sensor suite 1106, and collected as local data 1103. The muscles 1205 also output motion 15, which is detected by the inertial measurement unit (IMU) 1108. The IMU 1108 measures the body's specific force, angular rate, and orientation, and reports to the processing unit 1101. The processing unit 1101 receives the local data 1103 and executes a local algorithm 1102. Using the local data 1103, the processing unit 110, based on results of the local algorithm 1102, instructs the mechanical transducers 1105 to deliver a specific vibrational stimulus 13. In some embodiments, the processing unit 110 may instruct one or more ultrasonic, electric, or other transducers to deliver an output to one or more proprioceptive nerves 1201. For instance, the processing unit 110 may deliver a sound wave to one or more proprioceptive nerves 1201 through one or more ultrasonic transducers. In an embodiment, the processing unit 110 may instruct one or more electric transducers to deliver an output of electric energy to one or more proprioceptive nerves 1201. The processing unit 110 may instruct a combination of ultrasonic, electric, and/or mechanical transducers to apply outputs of mechanical, audible, and/or electrical energy to one or more proprioceptive nerves 1201. In some embodiments, the processing unit 110 may alternatively, without limitation, cycle through one or more types of transducers that may be employed. For instance and without limitation, the processing unit 110 may cycle through a set of mechanical transducers to apply vibrational stimulus 13 to the proprioceptive nerves 1201 for a period of time, then through a set of electrical transducers for a period of time, and then through a set of ultrasonic transducers for a period of time. The processing unit 110 may adjust one or more outputs of one or more mechanical, ultrasonic, and/or electrical transducers based on feedback received from one or more sensors, such as the IMU 1108 and/or the EMG sensor 1107. The proprioceptive nerves 1201 detect the vibrational stimulus 13 and send the perceived limb position and motion 1202 to the nervous system 1203. Based on that signal, the nervous system 1203 sends a desired activation control signal 1204 to activate the

muscles 1205 in a way that either alters or perpetuates their electrical activity 14 and motion 15. The local data 1103 collected by the sensor suite 1106 continues to be processed by the local algorithm 1102 again, and continues to affect the output of the mechanical transducers 1105. The local data 1103 is also transmitted via the communication module 1104 to a remote processing algorithm 16, and to a remote database 18 for long-term data storage and access by researcher 19. The remote database 18 also receives data from the greater population, or the crowd 17, and sends this data to the remote processing algorithm 16. The remote processing algorithm 16 analyzes the data and returns the results of the analysis both to the processing unit 1101, via the communication module 1104, and also to the crowd 17. In this way, data from the crowd 17 may influence the way that the local algorithm 1102 operates.

[0065] Fig. 2 is an electrical schematic highlighting the main sub-circuits of the system in Fig. 1. Fig. 2 shows the processing unit 1101, which receives tremor vibration data from the inertial measurement unit 1108 in the inertial measurement unit circuit 24. This data is used by the processing unit 1101 to drive the mechanical transducers 1105 in the mechanical transducer circuit 23 at various frequencies and amplitudes. In some embodiments, the processing unit 1101 may drive one or more ultrasonic, electric, or other transducers in addition to or in replace of the mechanical transducers 1105. The entire system receives power from a rechargeable battery 26 in the power/charging circuit 21. The reprogramming/charging port 25 can be used to both recharge the battery 26 and reprogram the processing unit 1101. The power is switched on and off via the on/off button 22.

[0066] Fig. 3 is an isometric view of a wearable device in accordance with an embodiment of the present invention. Fig. 3 shows the main electronics housing 32 of the device and the band 31 of the device that interfaces with the user's wrist.

[0067] Fig. 4 is an exploded isometric view of a wearable device, in which the vibration motors are housed in the band rather than in the main electronics housing, in accordance with an embodiment of the present invention. The mechanical transducers 1105 are housed in the band 31 which interfaces with the user's wrist. In some embodiments, the mechanical transducers 1105 may be replaced with ultrasonic, electric, or other transducers. Between the top and bottom halves of the housing 321 322, there is a printed circuit board (PCB) 42, a silicone square to insulate the bottom of the PCB 43, and a rechargeable battery 26. The battery 26 includes protection circuitry to protect from overcharging and unwanted discharging. To recharge the

battery 26, a magnetic plug-in head 421 is inserted into the PCB 42. The magnetic plug-in head 421 allows patients who have difficulty performing tasks that require fine motor skills to easily charge the device with a magnetic charging cable. The device is intended to work after the patient turns the device on by pressing the single, large button 323 on top of the electronic housing top 321. The button is provided for ease of use by a patient whose fine motor control is affected by a neurological movement disorder.

[0068] Fig. 5 is an isometric view of a wearable device, in which the device includes a loop mechanism 51 to allow single handed adjustment of the band 31 on the user's wrist, in accordance with an embodiment of the present invention. Fig. 5 shows the main electronics housing 32, the band 31 as it looks when worn on the user's wrist, and an adjustment mechanism 51 that is integrated into the main electronics housing 32.

[0069] Fig. 6 shows an embodiment of the present invention worn on a hand viewed from above. Fig. 6 shows the main electronics housing 32 and the band 31 that interfaces with the user's wrist.

[0070] Fig. 7 shows an embodiment of the present invention worn on a hand viewed from the side. Fig. 7 shows the main electronics housing 32, the band 31 that interfaces with the user's wrist, and the on/off button 323 that a patient may use to begin/stop the vibrational stimulation. The on/off button 323 is integrated into the main electronics housing 32.

[0071] Fig. 8 shows a testing configuration for the wearable medical device, which may be used for more rigorous data collection, in accordance with an embodiment of the present invention. Fig. 8 shows the main electronics housing 32 and the band 31 that interfaces with the user's wrist. These are connected to a data logging apparatus 81 which collects and stores data. Data can continue to be collected and stored over a larger time scale than on the device alone, as this testing configuration is equipped with a larger processor and storage capacity. At the time of analysis, more complex and computationally heavy data analysis is possible on the collected data stored in the data logging apparatus 81 utilizing the larger processor.

[0072] Fig. 9 illustrates a wearable device for mitigating movement disorder, in which the device is an accessory to a third-party smartwatch or other wearable computing device 91, in accordance with an embodiment of the present invention. In such an embodiment, some or all of the computation 912 and sensing 911 are offloaded to the third-party wearable device 91. The third-party device then sends a set of motor commands wirelessly 94 (over Bluetooth for

example 913 925) to a processing unit 1101 on the accessory band 92. This processing unit 1101 interfaces with the transducers 1105 on the band to execute the desired motor commands. In this embodiment, the accessory band 92 has its own battery 925. In some embodiments, the band also has its own specialized sensors 923 (such as electromyography sensors), the signals of which are communicated to the third-party processing unit 912 via the accessory processing unit 1101, and wireless communication 913 925 94. Data may also be logged to the user's smartphone over the same wireless connection 94.

[0073] Fig. 10 shows a side view of a wearable device, which is as an accessory band for a third-party smartwatch or other wearable computing device, in accordance with an embodiment of the present invention. It shows the main electronics housing 32 and the band 31 which contains the mechanical transducers 1105. The band 31 interfaces with the user's wrist. This view illustrates an example placement of the accessory battery 925 and processing unit 1101.

[0074] Fig. 11 shows a process by which a raw sensor input may be used to compute a set of stimulation parameters in accordance with an embodiment of the present invention. The stimulation parameters are continuously updated in closed loop. These parameters can include any quantities used to define a stimulation waveform such as frequency, amplitude, phase, duty cycle, etc. At each iteration of the update loop, the current stimulation parameters 111 and raw sensor input 112 are used to filter out transducer/sensor crosstalk 113 either by using knowledge of the output waveform to subtract from the sensed waveform or by using knowledge of the timing of the output waveform to limit sensing to the "off" phases of a pulsing stimulation. This filtering subsequently allows for feature extraction 114 of the raw sensor input 112. The stimulation selection algorithm 115 then uses the current stimulation parameters 111 and the extracted features 114 to select new stimulation parameters 116. This process is illustrated in greater depth in Figure 13. When the process repeats, the previously new stimulation parameters 116 become to the current stimulation parameters 111.

[0075] Fig. 12 shows a feature extraction process in accordance with an embodiment of the present invention. This process takes in a filtered sensor signal, as described with respect to Fig. 11, and extracts temporal 1141 1142 1143 and/or spectral features 1144. Examples of common temporal features include the minimum value, the maximum value, first three standard deviation values, signal energy, root mean squared (RMS), zero crossing rate, principal component analysis (PCA), kernel or wavelet convolution, or autoconvolution. Examples of

common spectral features include the Fourier Transform, fundamental frequency, (Mel-frequency) Cepstral coefficients, the spectral centroid, and bandwidth. Features are extracted with standard digital signal processing techniques onboard the main processing unit of the device. The set of collected features is then fed into the stimulation selection algorithm.

[0076] Fig. 13 shows a stimulation optimization algorithm in accordance with an embodiment of the present invention. The stimulation selection algorithm takes in the extracted features 114 and the current stimulation parameters 111 and uses them to determine the set of new stimulation parameters 116. The process by which the new parameters are determined is an optimization to minimize the symptom severity. Given that there is no analytical model for the symptom's response to stimulation patterns, this optimization is inherently model free. Examples of model free policy optimization techniques are argmin (or minimization over the set of input arguments), Q-learning, neural networks, genetic algorithms, differential dynamic programming, iterative quadratic regulator, and guided policy search. Descriptions of some such algorithms can be found in Deisenroth, M. P. (2011), "A Survey on Policy Search for Robotics," *Foundations and Trends in Robotics*, 2(1-2), 1-142. doi:10.1561/23000000021; and Beasley, D., Bull, D. R., & Martin, R. (1993), "An Overview of Genetic Algorithms: Part 1, Fundamentals," 1-8, (herein incorporated, in their entirety, by reference).

[0077] In an example, an extracted feature may be the amplitude of the tremor and the set of current stimulation parameters could be a stimulation frequency and amplitude. A stimulation selection algorithm can then compare the tremor amplitude observed with the current set of stimulation parameters to the tremor amplitude observed with a previous set of stimulation parameters to determine which of the two sets of stimulation parameters resulted in the lowest tremor amplitude. The set with the lowest resulting tremor amplitude could then be used as the baseline for the next iteration of the stimulation selection algorithm which would compare it to a new set.

[0078] Two example stimulation selection algorithms that may be used in embodiments follow:

Algorithm 1 Determine Optimal Vibration Motor State**Input:** Feed of x,y,z accelerometer data**Output:** Output state which minimizes tremor magnitude

- 1: $AmplitudeStates = \{A_1, A_2, \dots, A_n\} = \{\mathbf{A}\}_n$
- 2: $FrequencyStates = \{F_1, F_2, \dots, F_m\} = \{\mathbf{F}\}_m$
- 3: $OutputStates = \{\mathbf{A} \times \mathbf{F}\}_{n \times m}$
- 4: $TremorResponses = \{0\}_{n \times m}$
- 5:
- 6: **for** State **in** OutputStates **do**
- 7: Output $\leftarrow$ State
- 8: TremorResponses[State] $\leftarrow$ ReadAccelerometer
- 9: OptimalState $\leftarrow$ argmin TremorResponses
- $\{\mathbf{A}\}, \{\mathbf{F}\}$

Algorithm 2 Q-learning Algorithm**Input:** Feed of x,y,z accelerometer data**Output:** Output state which minimizes tremor magnitude

- 1: $AmplitudeStates = \{A_1, A_2, \dots, A_n\} = \{\mathbf{A}\}_n$
- 2: $FrequencyStates = \{F_1, F_2, \dots, F_m\} = \{\mathbf{F}\}_m$
- 3: $OutputStates = \{\mathbf{A} \times \mathbf{F}\}_{n \times m} = \mathbf{S}$
- 4: $Choices = \{IncreaseAmplitude, IncreaseFrequency\} = \mathbf{C}$
- 5: $QTable = \mathbf{Q} : \mathbf{S} \times \mathbf{C} \rightarrow \mathbb{R}$
- 6: **for** Epoch **in** MaxEpochs **do**
- 7: **for** s **in** OutputStates **do**
- 8: **for** c **in** Choices **do**
- 9: $r \leftarrow$ ReadAccelerometer
- 10: $Q(s,c) \leftarrow (1 - \alpha) \cdot Q(s,c) + \alpha \cdot (r + \gamma \cdot \min_{k \in \mathbf{C}} Q(s+1, k))$
- 11: OptimalState $\leftarrow$ argmin $\mathbf{Q}$
- s

[0079] In some embodiments, the structure of the output stimulation pattern may be a weighted average of optimized patterns corresponding to each symptom where the weights are proportional to the symptom severity relative to the other observed symptoms. In some embodiments, the structure of the output stimulation pattern may just be the pattern optimized to reduce the most severe symptom.

[0080] Fig. 14 shows a neurological signal cancelling system, illustrating how the wearable 11 device and body 12 interact, in accordance with an embodiment of the present invention. The system comprises of the user's nervous system 1203, which sends control signals 141 to the body 12. The wearable 11 senses the body's movement and sends an opposing control

signal which is defined by the output of the stimulation parameter selection algorithm. 142. The control signals undergo a signal cancelling process within the nervous system of the user 143, which results in a smoother perceived motion signal 143.

[0081] Fig. 15 is a pair of renderings 151 152 by a tremor patient of an Archimedes spiral under conditions without and with treatment by a device in accordance with an embodiment of the present invention. The spiral tracing test allows doctors to gain insight on the frequency, amplitude, and direction of their patients' tremors. It can also inform the doctor of abnormal movement of hypokinesia, dystonia, and tremor. The task requires the patient to continuously trace the Archimedes spiral. Patients who have tremors will have difficulty following the spiral and will trace off the spiral line resulting in a disordered spiral 151. Wearing a device in accordance with an embodiment of the present invention, the patient is able to trace the spiral more accurately resulting in a smoother spiral 152.

[0082] Fig. 16 illustrates an embodiment of a simple non-convex gradient descent optimization used in embodiment of the present invention for symptom reduction by searching over the parameter configuration space. It is a graphical representation of the stimulation selection algorithm 163 associated with the present invention. The algorithm 163 moves through the stimulation parameter space 162 and attempts to minimize symptom severity 161. The movement through the stimulation parameter space can be thought of as trying different sets of stimulation parameters and comparing their resulting symptom severities as quantified by their respective sensors. The algorithm attempts to minimize symptom severity by testing different sets of parameters until an optimal set for minimizing symptom severity is found.

[0083] Alternative benchtop versions of the device can be used to elicit tremors in Parkinson's patients for the purposes of early detection. This is done using the same mechanisms as in reducing tremor but using an inverted stimulation parameter search heuristic. User testing has shown that for each patient, there exists a stimulation pattern which when applied to the Parkinson's patient with very slight tremor will produce a very large tremor. This effect does not occur in users who do not have Parkinson's Disease. This could be used for earlier detection and diagnosis of Parkinson's Disease which can be difficult to diagnose.

[0084] Figs. 17 and 18 each shows a power spectral density (PSD) plot of the postural tremor of a Parkinson's Disease and Essential Tremor patient, respectively, with and without the use of a device in accordance with an embodiment of the present invention. The data was taken

by asking each patient to hold his or her hand out for 10 seconds, with and without the device. In Figs. 17 and 18, tremor amplitude is compared with and without the device.

[0085] The following describes a test case of an embodiment of the present invention. Participants were asked to trace a printed Archimedes Spiral, a common test used to diagnose Parkinson's, with and without the device, as shown in Fig. 15. The results were measured by using image processing software to evaluate the accuracy of the traced spirals. In the first round of testing, the device was tested on around 20 participants with Parkinson's and 1 participant with a resting tremor. The majority of the participants, however, either did not experience tremors or were already being treated for Parkinson's and only experienced slight tremors. It was observed that the reduction in tremor severity was strongly correlated to the initial tremor severity. That is, patients with minimal tremors experienced minimal benefit while patients with more extreme tremors experienced more dramatic benefit. The participant with the most severe resting tremor, caused by Parkinson's Disease, saw the most improvement in performance as shown in Fig. 17. Another participant with a resting tremor, caused by Essential Tremor, also showed significant improvement as shown in Fig. 18. The results were repeatable with both of these participants. Participants who suffered from rigidity observed that they had a larger range of movement in their hands and completed their spiral tests faster with the device than without.

[0086] While the above embodiments reference accelerometers, vibration motors, microUSB, and wristbands the invention is not limited to such implementations. Additionally, the above embodiments are not intended to limit the scope of the invention. For example, various modifications and variations of interfaces, types of electromyography sensors, gyroscopes, inertial measurement units, piezoelectrics, electromagnets, electropermanent magnets, pneumatics, voice coils, hydraulics, resistive heating elements should be included. The scope of form factors should also include headbands, collars, anklets, armbands, and rings. The scope of electrical interfaces should include Thunderbolt cables, USB, USB C, microUSB, wireless communication, wireless charging, and Bluetooth communication.

[0087] The embodiments of the invention described above are intended to be merely exemplary; numerous variations and modifications will be apparent to those skilled in the art. All such variations and modifications are intended to be within the scope of the present invention as defined in any appended claims.

What is claimed is:

1. A wearable device for mitigating a movement disorder of a subject, the device comprising:
a sensor configured to be attached to the subject and to provide a sensor output;
a processing unit operationally coupled to the sensor and configured to quantify the sensor output; and
an actuator configured to be attached to the subject and operationally coupled to the processing unit, wherein the actuator is configured to stimulate proprioceptive nerves of the subject;
wherein the processing unit is further configured, as part of a feedback loop including the sensor, the actuator, and the subject, to adjust parameters of an output of the actuator in a manner to reduce symptoms of the movement disorder as measured by the sensor.
2. The wearable device of claim 1, wherein the sensor output is related to involuntary movement of a body part attributable to a movement disorder of the subject.
3. The wearable device of claim 1, wherein the processing unit is further configured to quantify a frequency and amplitude of the sensor output.
4. The wearable device of claim 1, wherein the actuator is a vibration motor and is further configured to output a stimulation waveform to the proprioceptive nerves of the subject.
5. The wearable device of claim 1, wherein the processing unit is further configured to filter sensor crosstalk of sensor input of the sensor by subtracting an output waveform of the output of the actuator from a sensed waveform of the sensor input.
6. The wearable device of claim 1, wherein the processing unit is further configured to, as part of the feedback loop, generate new stimulation parameters through a stimulation selection algorithm.

7. The wearable device of claim 6, wherein the processor is further configured to:
perform feature extraction of the sensor output to generate extracted features of a
sensed waveform of the sensor output; and
select a new stimulation parameter based on the extracted features from the sensor
output.
8. The wearable device of claim 1, wherein the actuator is an ultrasonic emitter.
9. The wearable device of claim 8, wherein the ultrasonic emitter is configured to
produce sound waves that stimulate the proprioceptive nerves of the subject.
10. The wearable device of claim 8, wherein the ultrasonic emitter is configured to
generate an ultrasonic wave having a frequency of about 1 MHz.
11. A method of mitigating a movement disorder, comprising:
receiving data at a sensor configured to be attached to a subject;
generating, at the sensor, sensor output based on the data;
communicating the sensor output from the sensor to a processing unit; and
stimulating, through an actuator in communication with the processing unit,
proprioceptive nerves of the subject based on the sensor output, wherein the
processing unit is configured, as part of a feedback loop including the sensor,
the actuator, and the subject, to adjust parameters of an output of the actuator
in a manner to reduce symptoms of a movement disorder of the subject.
12. The method of claim 11, wherein the sensor output is related to involuntary
movement of a body part attributable to a movement disorder of the subject.
13. The method of claim 11, further comprising quantify, through the processing unit, a
frequency and amplitude of the sensor output.

14. The method of claim 11, wherein the actuator is a vibration motor and is configured to output a stimulation waveform to the proprioceptive nerves of the subject.
15. The method of claim 14, wherein the sensor output includes vibration data.
16. The method of claim 11, further comprising, as part of the feedback loop, generating new stimulation parameters through a stimulation selection algorithm by the processing unit.
17. The method of claim 11, further comprising activating the actuator based on a passive sensing of the sensor, wherein the passive sensing includes sensing of a movement disorder of the subject.
18. The method of claim 11, wherein the actuator is an ultrasonic emitter.
19. The method of claim 18, further comprising producing, through the ultrasonic emitter, sound waves that stimulate the proprioceptive nerves of the subject.
20. The method of claim 11, wherein the actuator is an electric stimulation device.

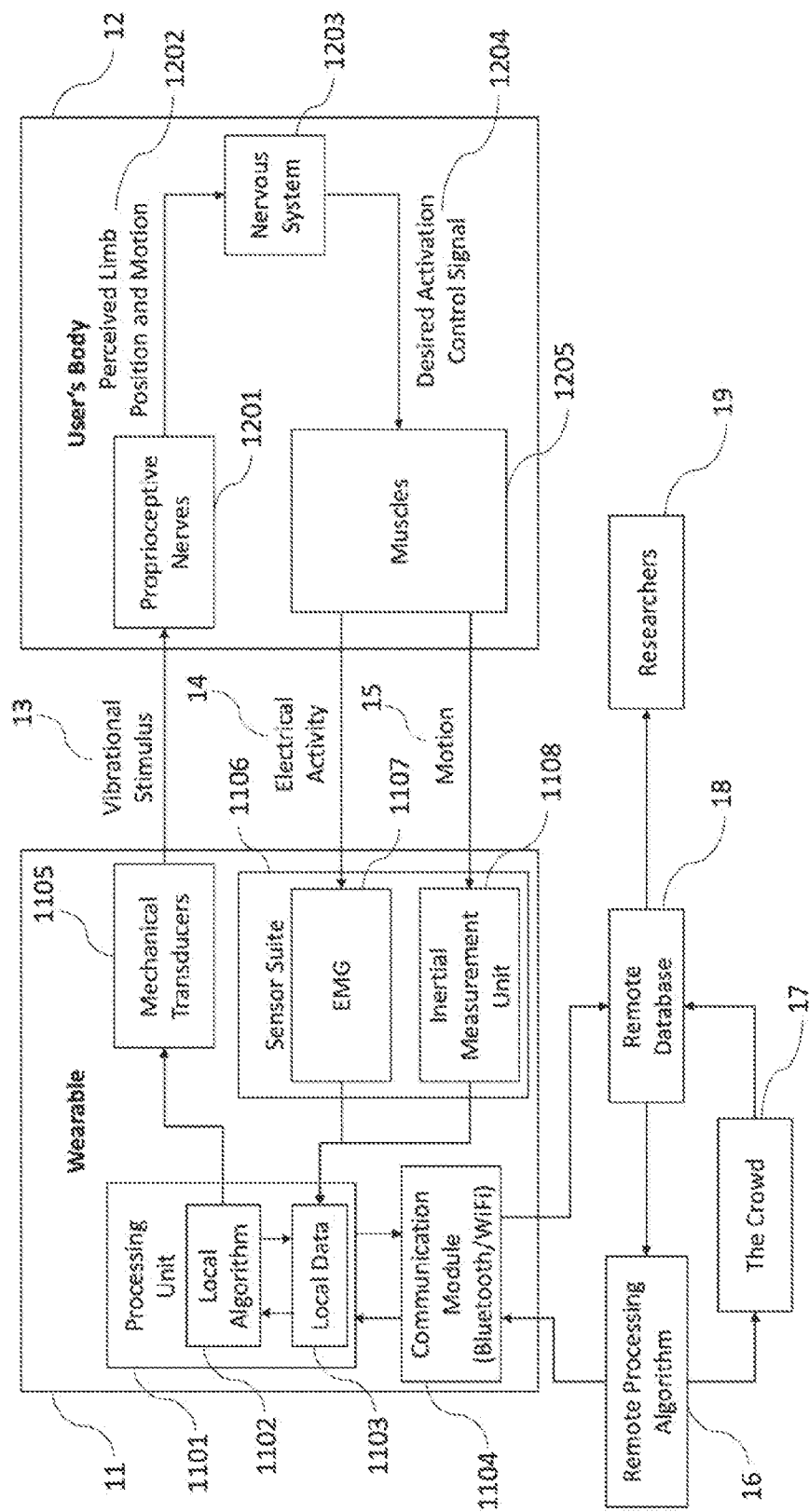


Fig. 1

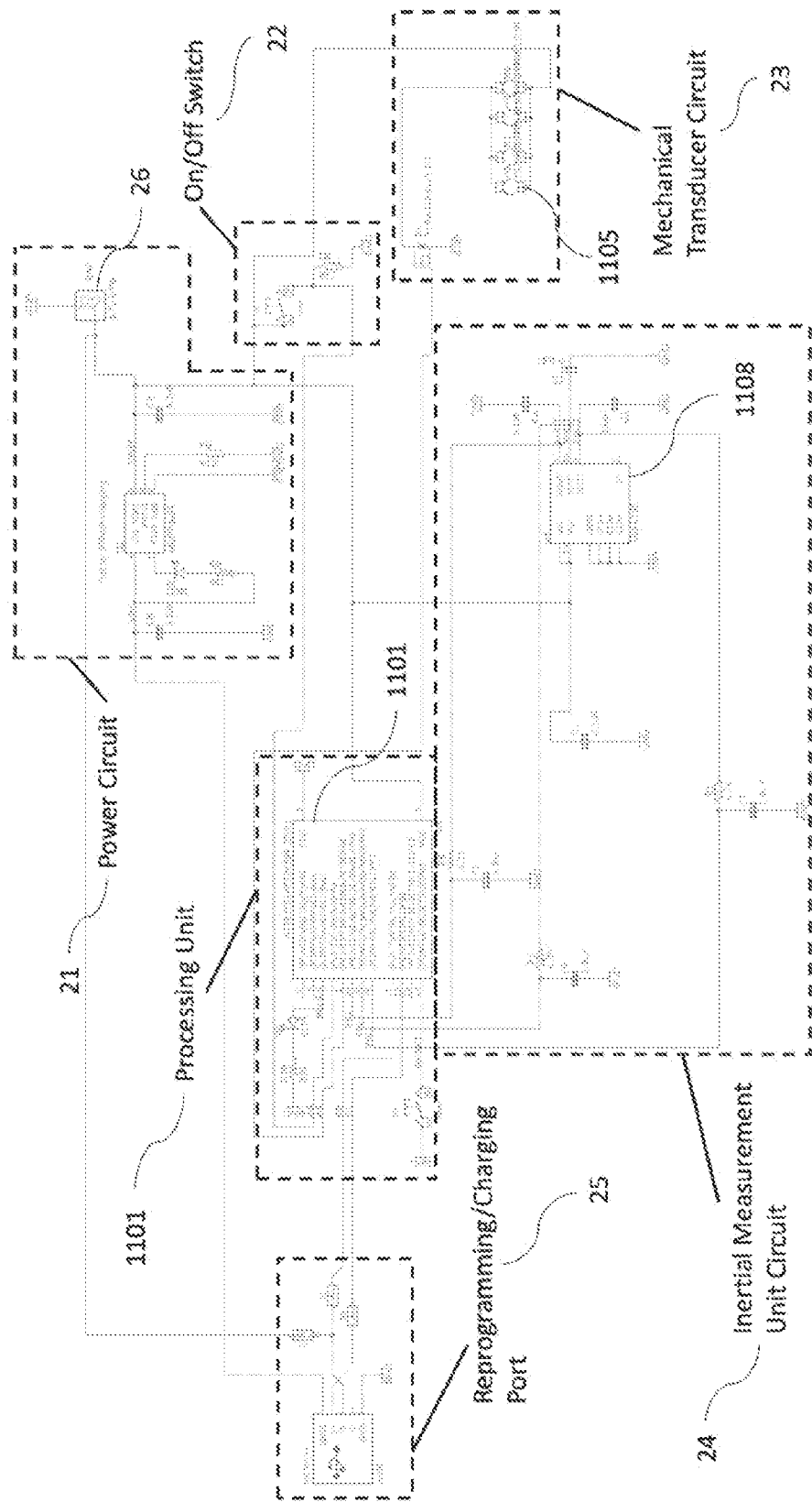


Fig. 2

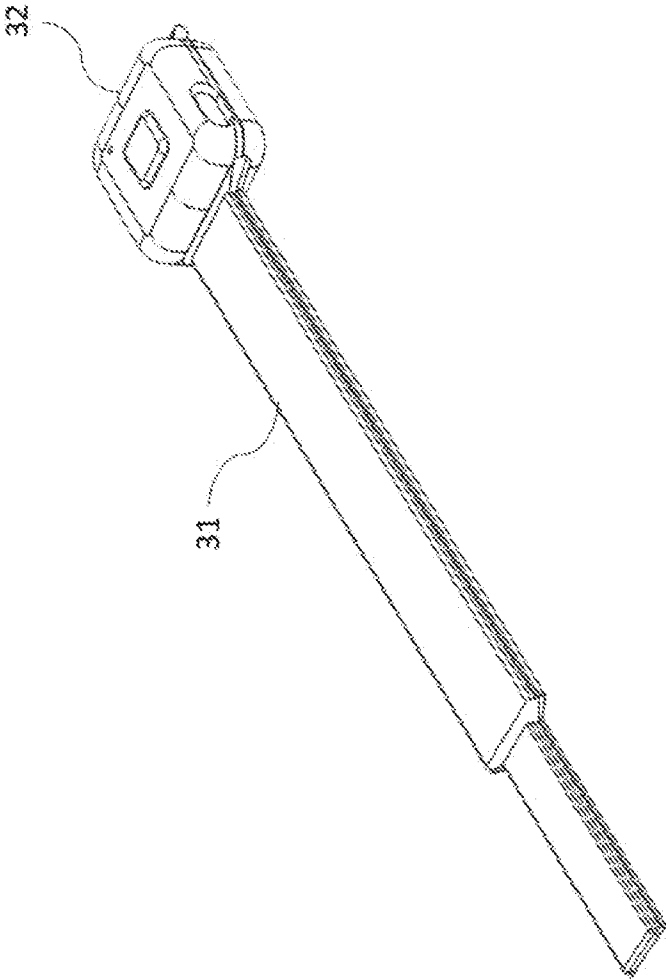


Fig. 3

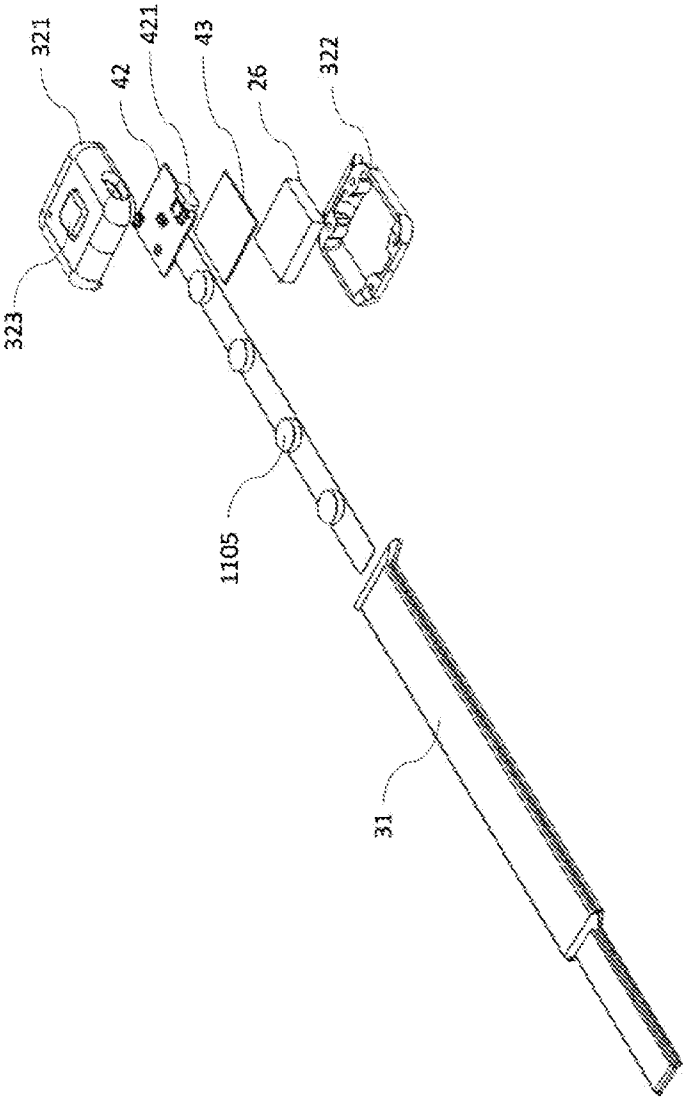


Fig. 4

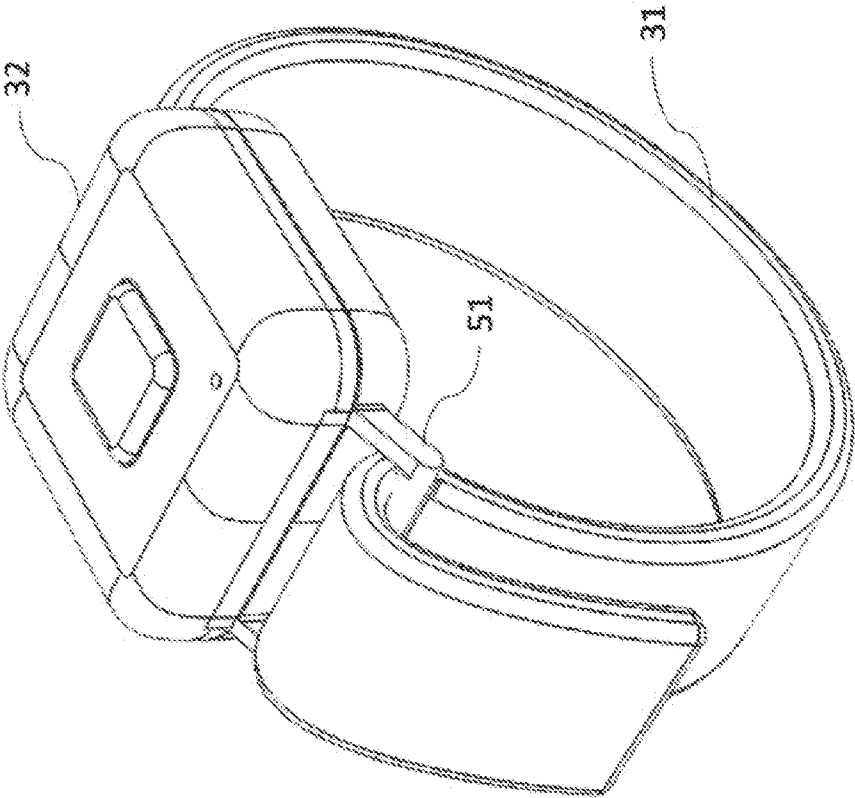


Fig. 5

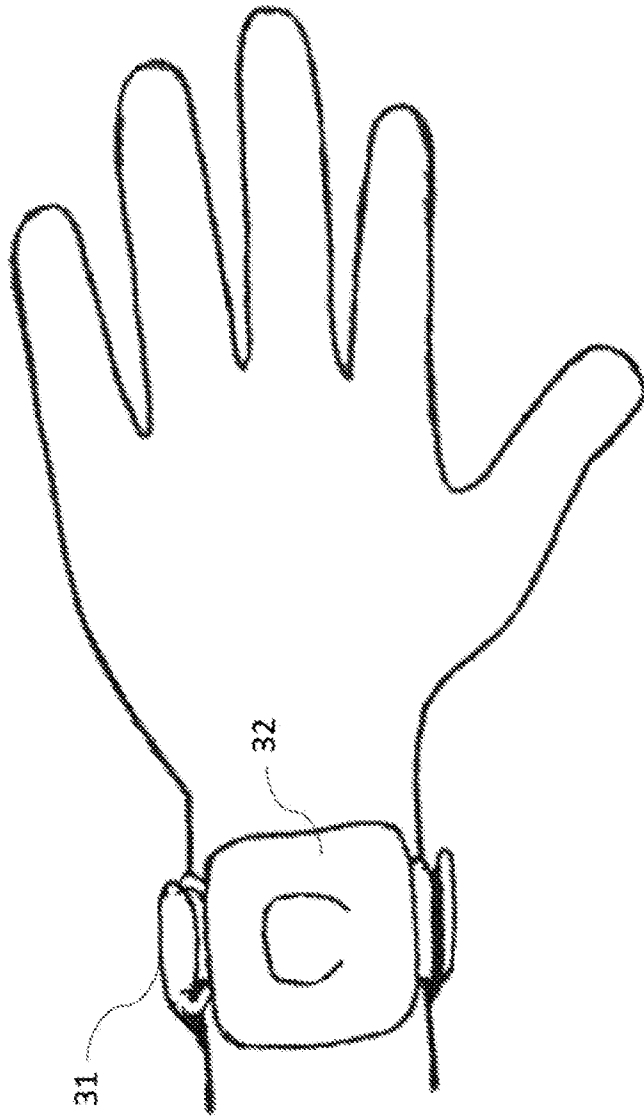


Fig. 6

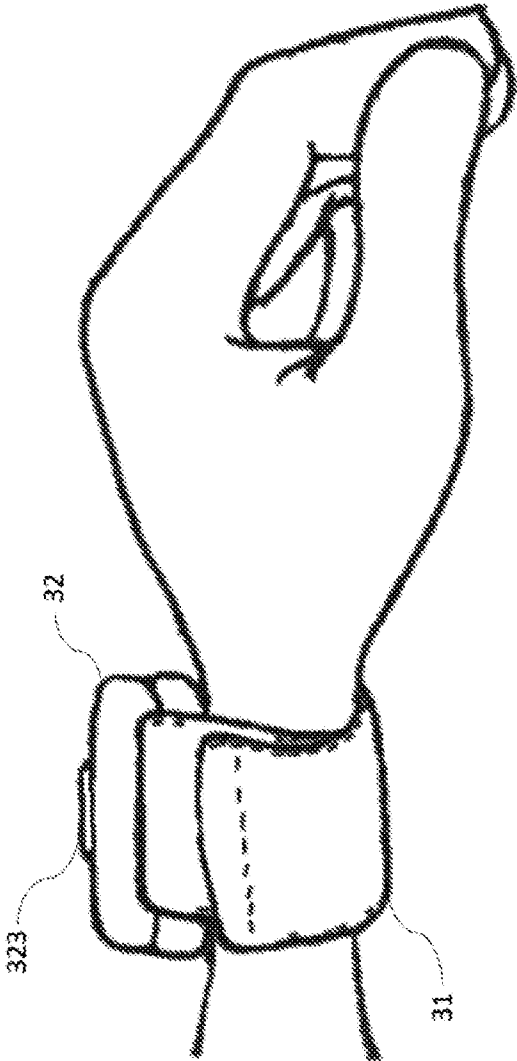


Fig. 7

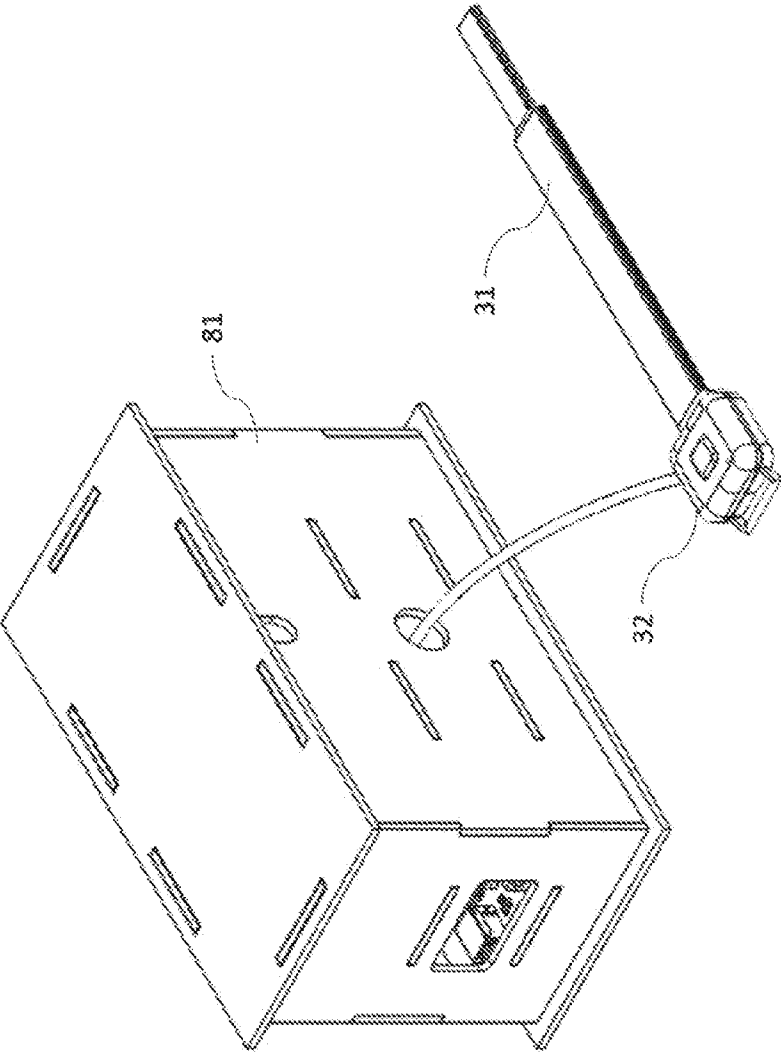


Fig. 8

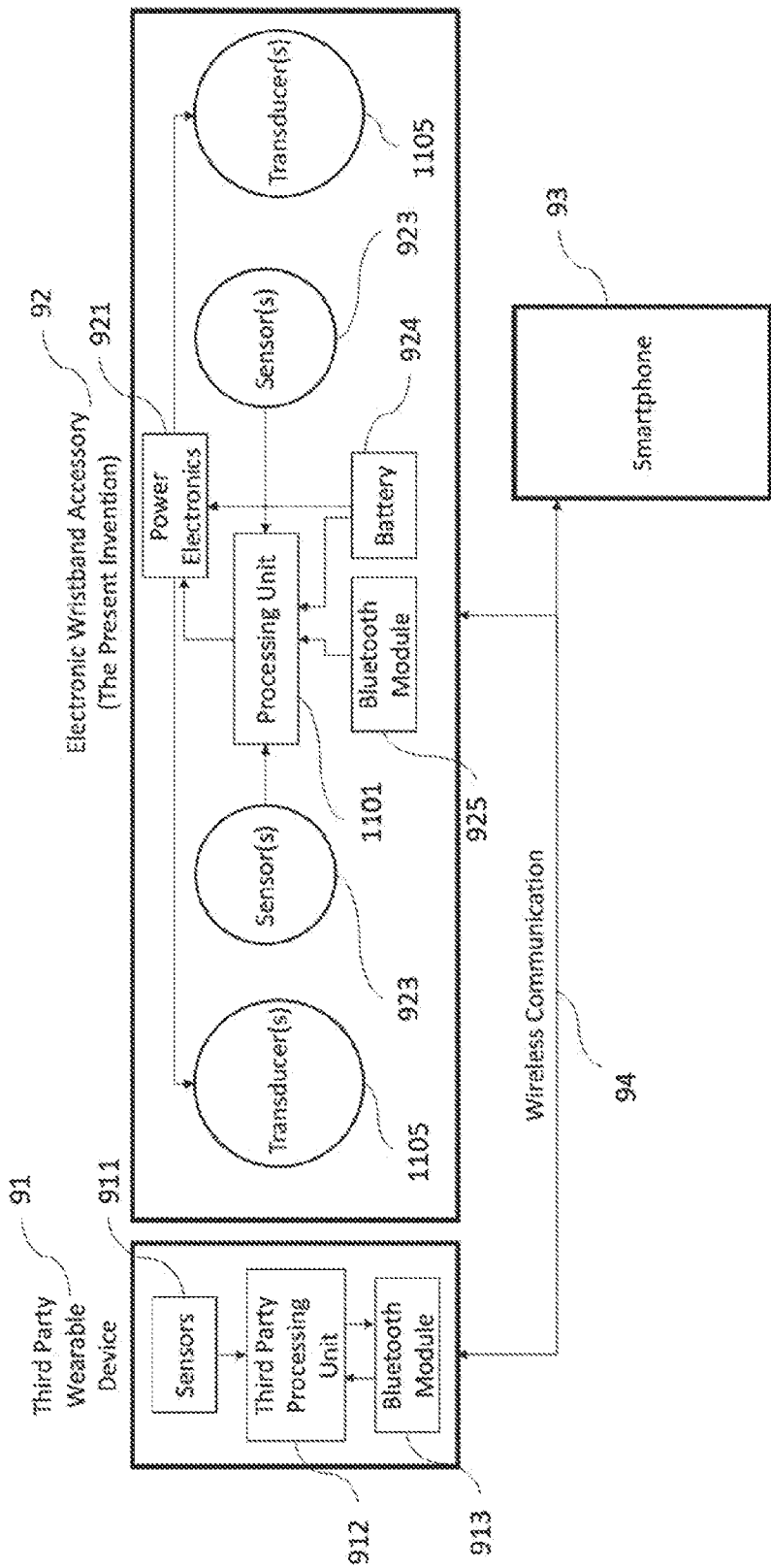


Fig. 9

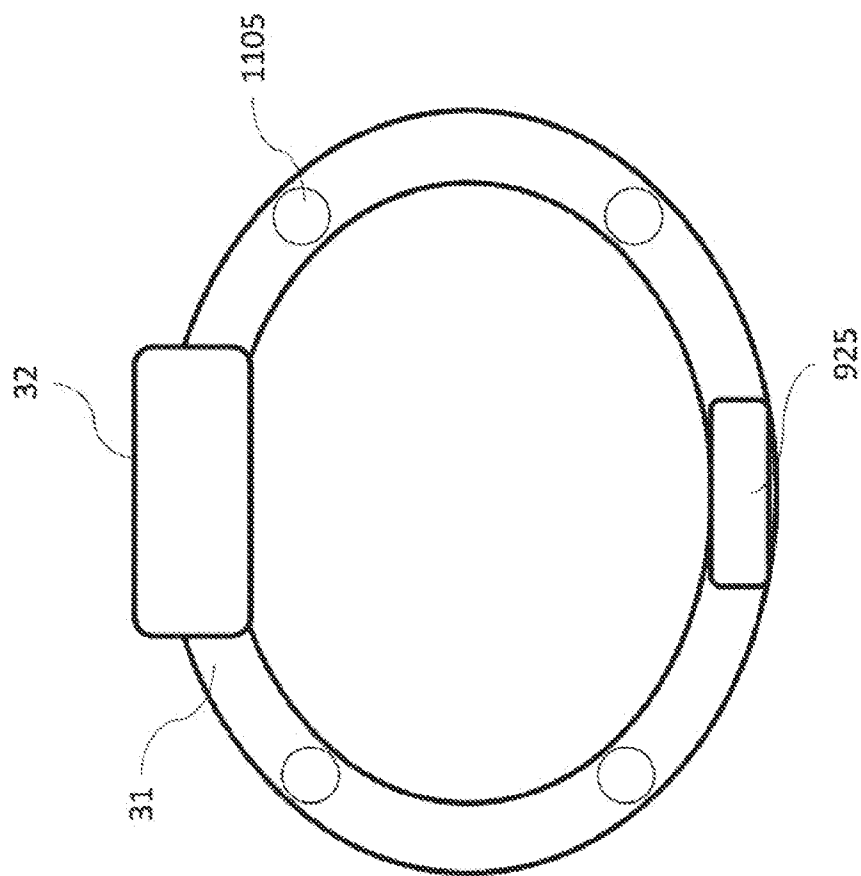


Fig. 10

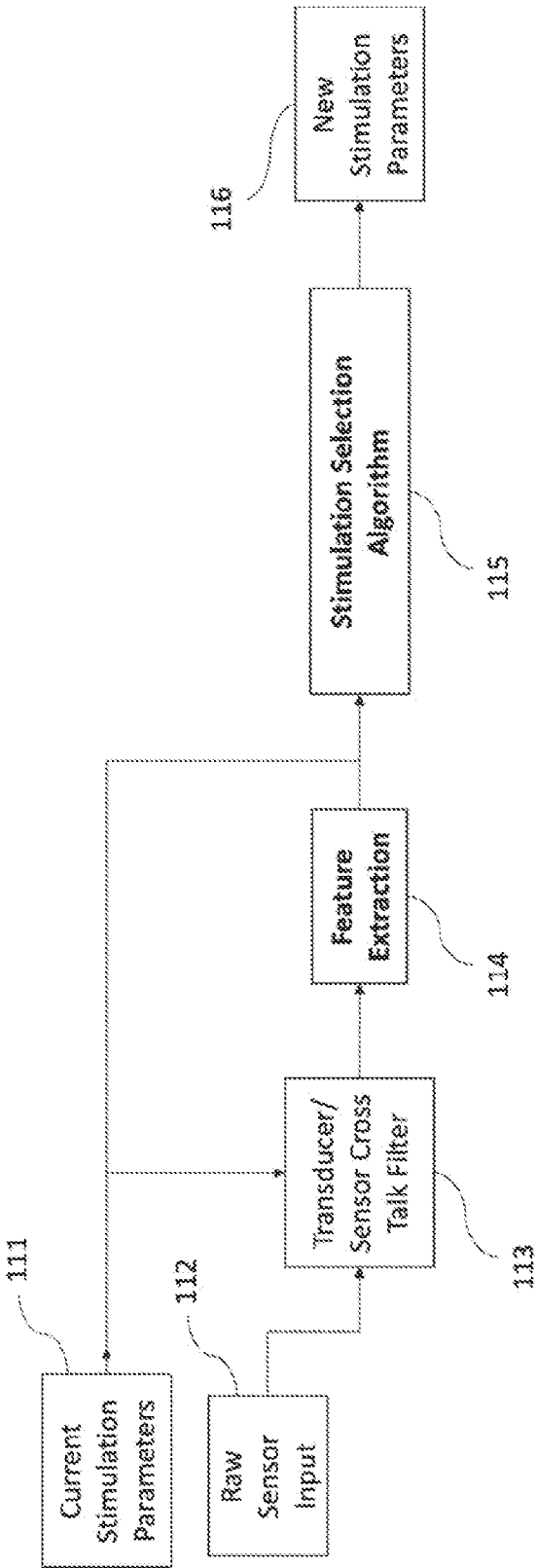


Fig. 11

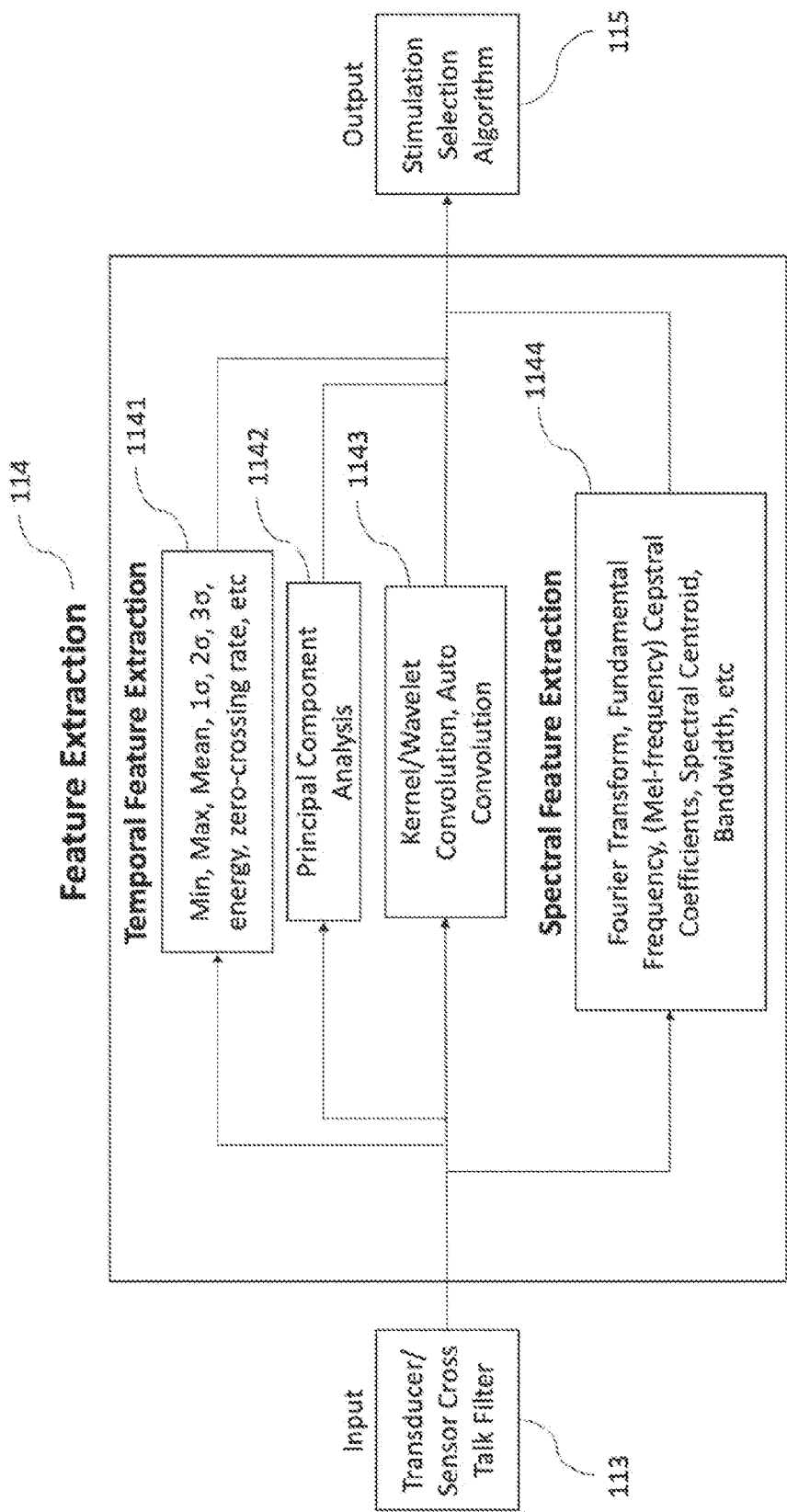


Fig. 12

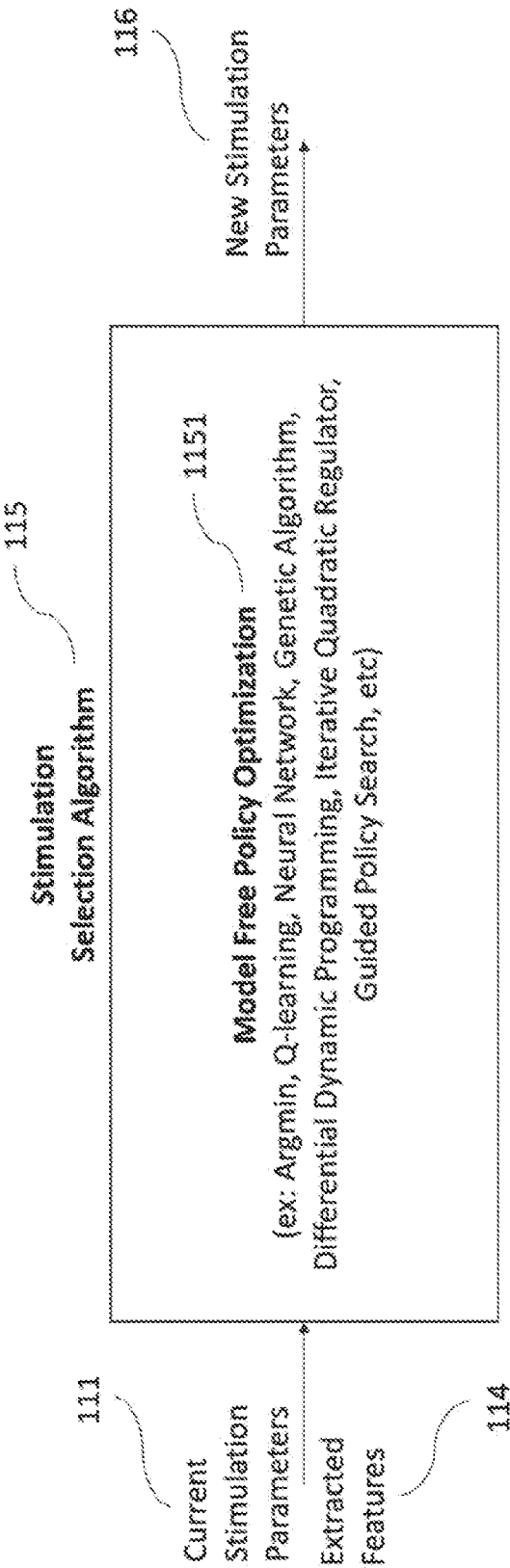


Fig. 13

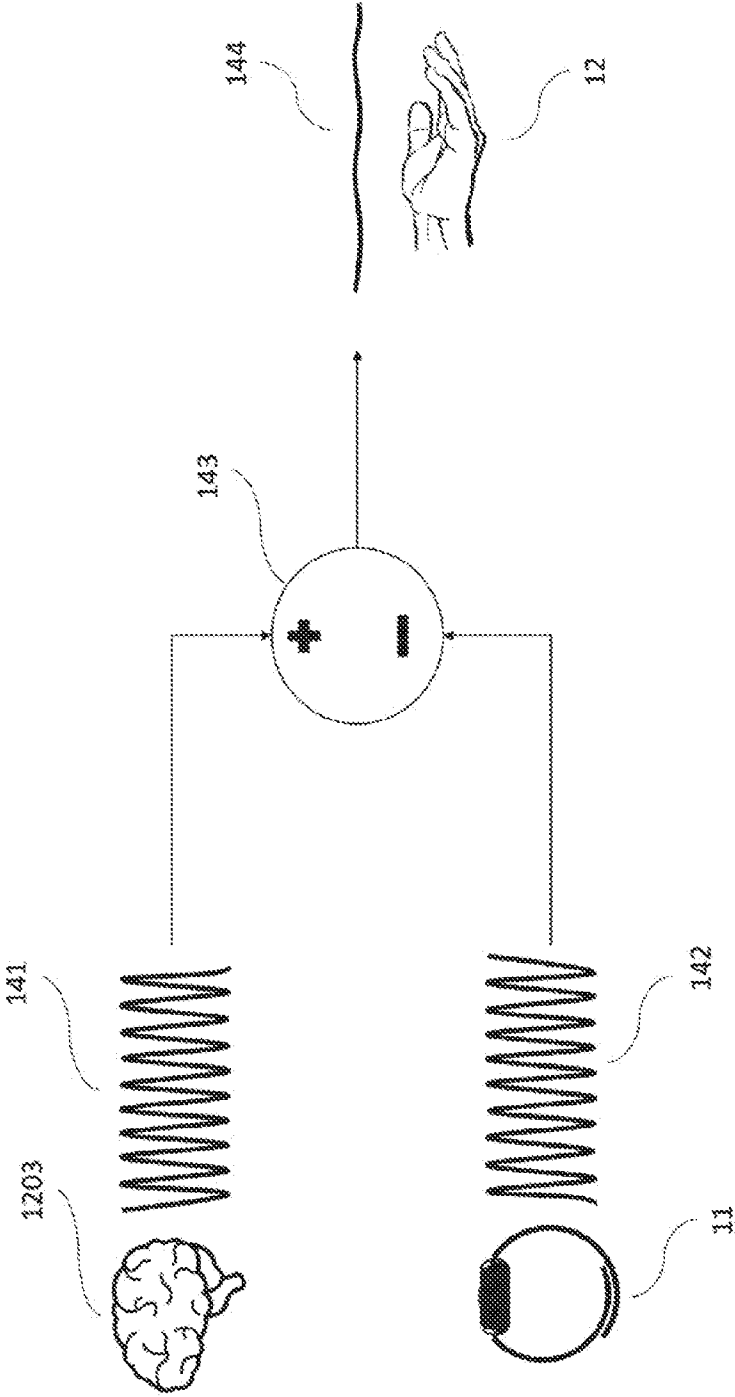


Fig. 14

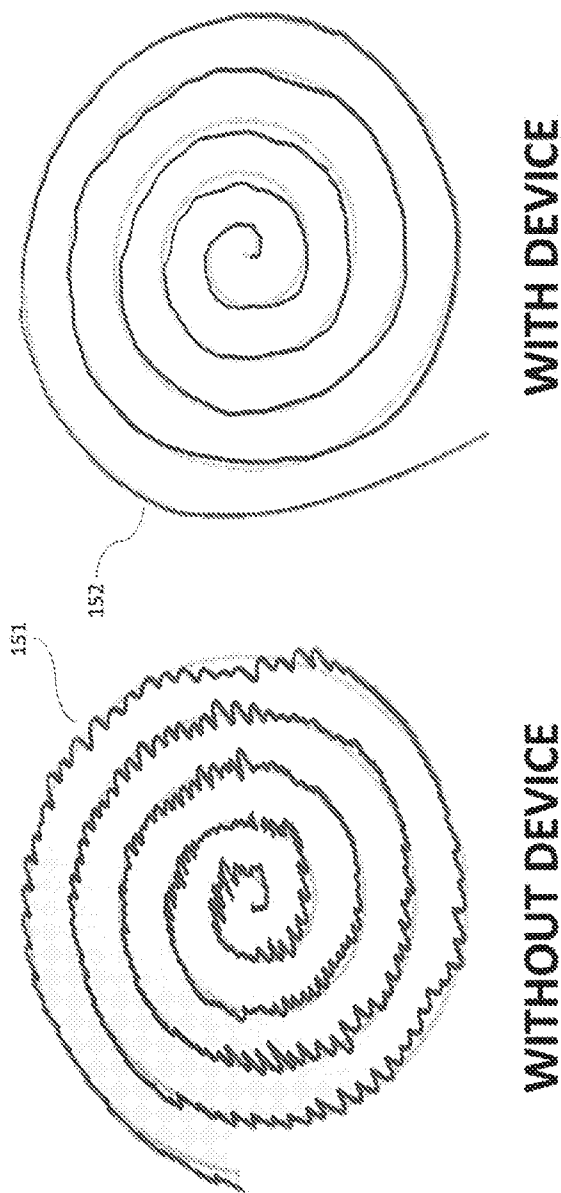


Fig. 15

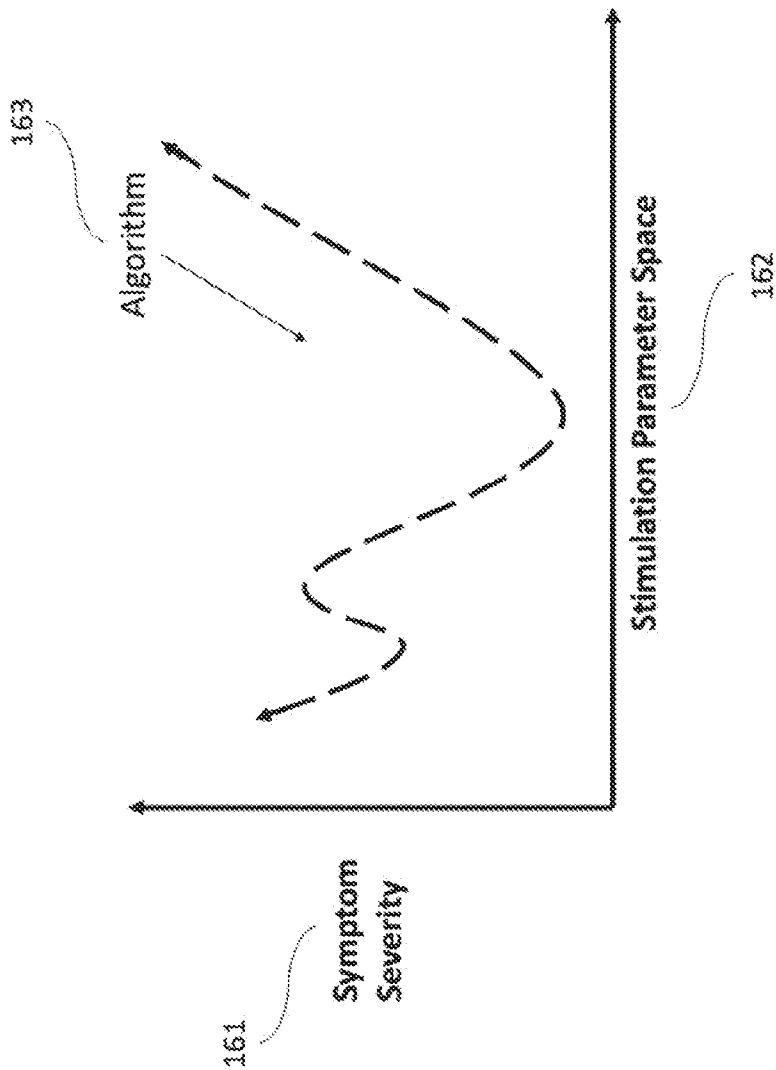


Fig. 16

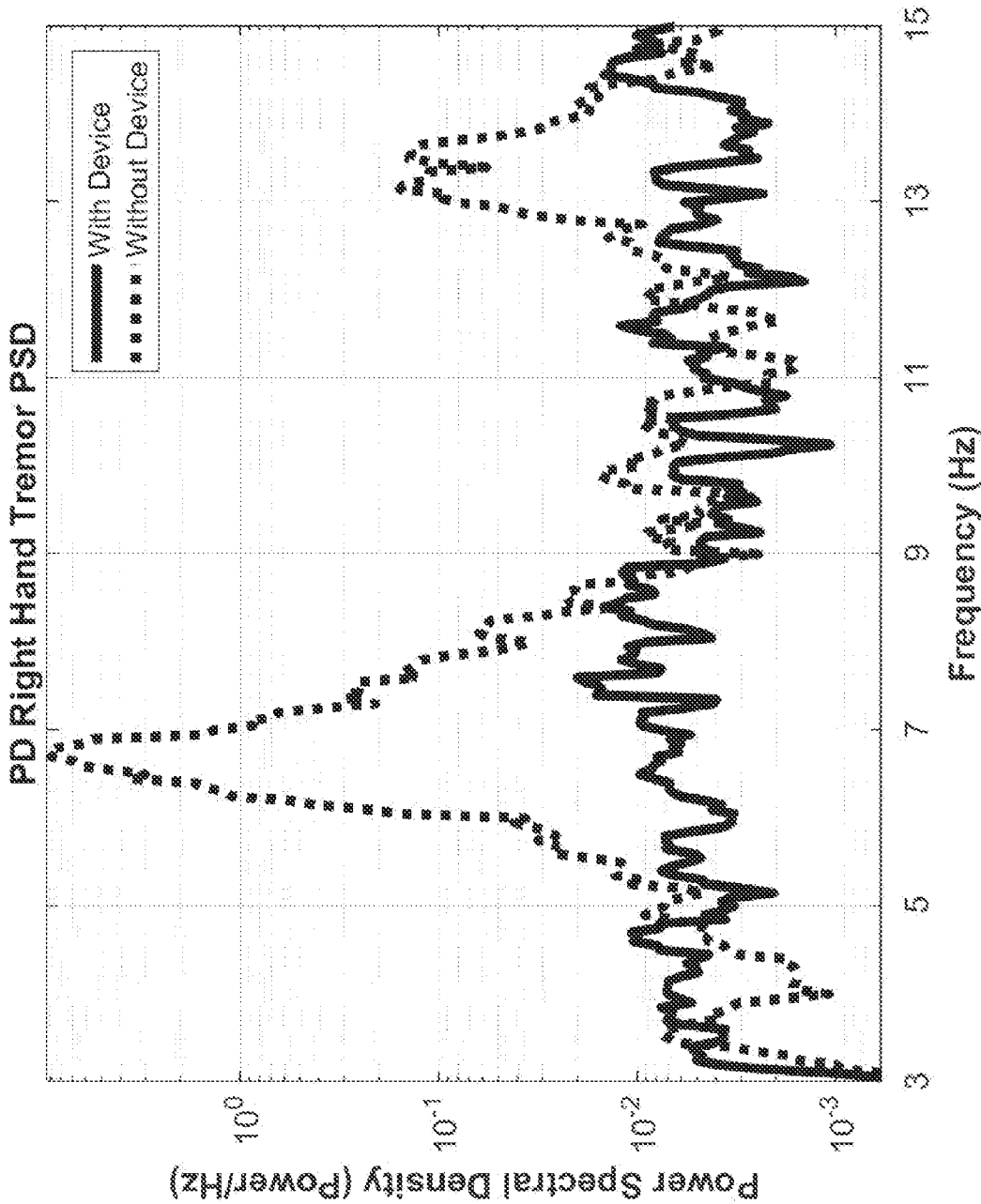


Fig. 17

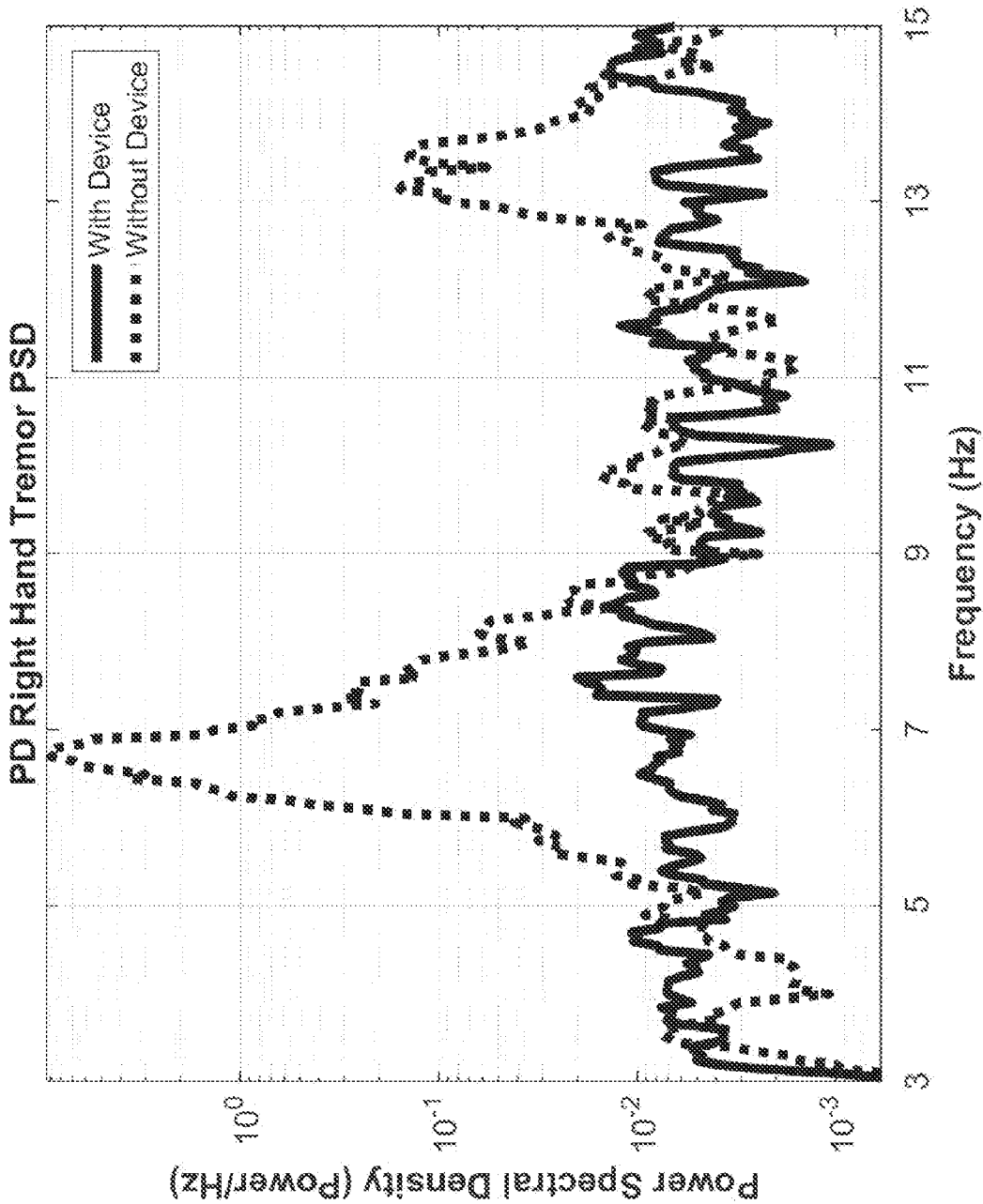


Fig. 18

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2024/041732

A. CLASSIFICATION OF SUBJECT MATTER INV. A61H23/02 ADD.		
According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A61H 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, WPI Data		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2022/008283 A1 (CARBALLO DANIEL [US] ET AL) 13 January 2022 (2022-01-13) paragraphs [0088] - [0089]; claims 1-26; figures 1-21 -----	1 - 7
X	WO 2020/006048 A1 (CALA HEALTH INC [US]) 2 January 2020 (2020-01-02) paragraph [0164] - paragraphs [0345] - [0349]; claims 1-27; figures 1-27 -----	1 - 10
X	US 2018/140842 A1 (Ó LAIGHIN GEARÓID [IE] ET AL) 24 May 2018 (2018-05-24) claims; figures -----	1 - 7
X	US 9 452 287 B2 (ROSENBLUTH KATHRYN H [US]; DELP SCOTT LEE [US] ET AL.) 27 September 2016 (2016-09-27) claims; figures ----- - / - -	1 - 9
☒ 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 23 October 2024		Date of mailing of the international search report 05/11/2024
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016		Authorized officer Shmonin, Vladimir

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2024/041732

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2022/062096 A1 (CARBALLO DANIEL [US] ET AL) 3 March 2022 (2022-03-03) claims; figures -----	1 - 7
X	US 2022/233860 A1 (HAMNER SAMUEL RICHARD [US] ET AL) 28 July 2022 (2022-07-28) claims; figures -----	1 - 10
X	AU 2022 203 028 A1 (BURTON DAVID [AU]) 26 May 2022 (2022-05-26) claims; figures -----	1 - 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2024/041732

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.: 11 - 20
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:

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.:

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

Continuation of Box II.1

Claims Nos.: 11-20

A search is not carried out on the basis of claims 11-20 because these claims are directed to Rule 39.1(iv) PCT (Method for treatment of the human or animal body by therapy). In particular, independent method claim 11 is directed to a method of mitigating a movement disorder of the patient the purpose and inevitable effect being therapeutic, namely motor function recovery. The method's proprioceptive nerve stimulation provides therapeutic effects by improving motor control, reducing dependence on medication, and fostering neuroplasticity, all of which directly enhance the patient's quality of life and physical functioning. These benefits, integral to managing neurological disorders, classify the method as therapeutic, even if the underlying condition is incurable. In conclusion, the claims 11-20 define a method for treatment of the human body by therapy. This Authority is not required to search the present application with respect to the aforementioned claims (Article 17(2)(b) PCT and Rule 39.1(iv) PCT). Consequently, no International Search Report and no Written Opinion (Rule 67.1 PCT in combination with Rule 43bis.1(b) PCT) have been established with respect to them.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2024/041732

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