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(54) Title: METHODS FOR ASSISTING USER HAVING PARALYZED MUSCLES IN WALKING

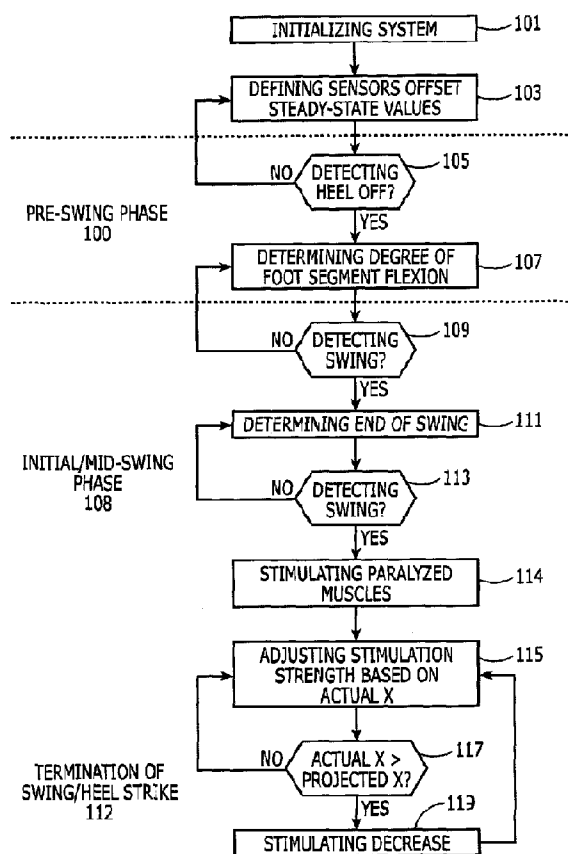


FIG. 1

(57) Abstract: The methods for assisting a user having paralyzed muscles in walking. The methods focus on addressing foot drop and stimulating arm swing to aid in balance and mimic a "normal" person's walk. The methods utilize a system capable of monitoring the gait cycle of the user and wireless transmitting signals to stimulation devices attached to the user's body.

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European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI,
FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MT, NL,
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CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

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Title

A method for assisting a user with paralyzed muscles to walk

Technical Field

5 The invention concerns a method of assisting a user with paralyzed muscles in walking and a method for addressing foot drop of a user and stimulating arm swing of a muscle paralyzed user.

Background of the Invention

10 Functional Electrical Stimulation (FES) is a technique for applying electrical currents to neural tissue in order to restore a degree of control over abnormal or absent body-functions via the generation of muscle contraction. However, accurate and stable control of limbs by FES is difficult because electrically stimulated musculoskeletal systems have strong nonlinearity, time variability, large latency, and fatigue in their response. Moreover, over-stimulated muscles will
15 easily cause fatigue. Optimal control of FES is necessary for extended time use.

 For the reasons stated above, as well as other deficiencies in the prior art, a new control system and methods of stimulation have been developed to achieve optimal control of stimulation with a goal of reducing the degree of muscle fatigue.

20 It is an advantage of at least one embodiment of the present invention to address the disadvantages and problems of the prior art.

Summary of the Invention

In a first preferred aspect, there is provided a method for assisting a user with paralyzed muscles to walk, the method comprising:

25 initializing a system to electrically stimulate the paralysed muscles for restoring a normal walking motion;

 defining kinematic sensor offset and steady-state values for gait phase detection;

30 detecting a heel off phase in walking from a kinematic sensor, where if the heel is detected as off, the degree of foot segment inclination is determined, otherwise the kinematic sensor offset and steady state values are redefined until the heel is detected as off;

 detecting a swing, where if the swing is detected, the paralyzed muscles are stimulated, otherwise the degree of foot segment inclination is redetermined until the swing is detected;

35 determining whether the actual measurement of a joint during stimulation is greater than the projected measurement in the termination of a swing phase, where if the actual measurement is greater than the projected measurement, the stimulation strength is decreased for the next walking cycle.

The degree of foot segment inclination may be determined from about 20° to about 35° from a ground surface.

5 Detection of a swing may be determined by noting the increase in angle change of the foot segment to a contact surface from the kinematic sensor.

Determining the termination of the swing may be based on a decrease in angle between the foot segment and a contact surface from the kinematic sensor.

10 Stimulating the paralyzed muscles may occur by electrically stimulating an upper limb for generating arm swing and electrically stimulating a lower limb for generating dorsiflexion to address foot drop of a user.

15 In a second aspect, there is provided a method for addressing foot drop of a user, the method comprising:

attaching a first module to transmit a signal from a foot segment of said user;

attaching a second module for providing electrical stimulation to a shank to prevent foot drop of said user; and

20 sending a signal wirelessly from said first module to said second module in response to movement during electrical stimulation of said first module for feedback control on the stimulation parameters.

25 Said first module may include at least one kinematic gait phase detector, a memory storage device, a controller, a feedback controller, a device for estimating the position of the user, and a wireless data transmitter.

Said second module may include a plant device for attachment to said shank and a sensor for detecting a wireless signal.

30 Said kinematic gait phase detector may include an accelerometer and a gyroscope.

Sending said signal wirelessly may occur by radio-frequency.

Movement of the first module may occur during a gait phase cycle.

35

In a third aspect, there is provided a method for addressing foot drop and stimulating arm swing of a user with paralyzed muscles, the method comprising:

attaching a first module with a kinematic gait phase detector for transmitting a signal from a foot segment of said user;

attaching second modules for providing electrical stimulation to a shank and the arm of said user; and

5 sending a signal wirelessly from said first module to said second modules in response to movement during electrical stimulation of said first module for feedback control on stimulation parameters.

10 The present invention provides a method of providing electrostimulation to alleviate foot drop and/or initiate arm swing, such method being suitable for optimally controlling stimulation to avoid fatigue over extended time use to generate a normal walking motion.

15 The present invention also provides systems for providing electrical stimulation. The system includes two separated modules, wherein the modules communicate with one another via wireless means.

20 The present invention provides an optimization of electrical stimulation by incorporating the method unto the system of the present invention, as well as by positioning components of the system in strategic places on the user's body.

25 The present invention provides a method and system to produce an artificial arm swing through the stimulation of triceps to generate the elbow extension for body balancing to improve gait quality. Further, the method addresses foot drop by stimulating muscle to generate ankle dorsiflexion to make walking easier and more "normal"-like.

Brief Description of the Drawings

An example of the invention will now be described with reference to the accompanying drawings, in which:

- 30 FIG 1 shows a method of stimulating paralyzed muscles of a user for assisting in walking;
FIG 2 shows the system of the present invention, containing a module A and module B;
FIG 3 shows an embodiment for module B of the system;
FIG 4 shows an embodiment for module A of the system;
FIG 5 shows a user using the system of the present invention;
FIG 6 shows signals generated by the system;
35 FIG 7 shows examples of the gait phase; and
FIG 8 shows a prior art gait cycle.

Detailed Description of the Drawings

The following description of certain exemplary embodiment(s) is merely exemplary in nature and is in no way intended to limit the invention, its application, or uses. Throughout this description, the term "gait" refers to a particular way or manner of moving on foot.

5 Referring to FIGs 1-8, the present invention has a goal of addressing paralyzed muscles for walking functions, such paralysis being brought about by stroke or lesions. Addressing the paralyzed muscles can occur by stimulating the muscles during the swing phase of a gait cycle, notably to reduce or positively influence foot drop and enhance arm swing. The present invention includes methods of stimulating arm swing and decreasing foot drop, and apparatuses
10 incorporating wireless means for stimulating paralyzed muscles. It is believed the present invention will assist people suffering from debilitating illnesses by electronically stimulating nerve and muscles to improve walking gesture.

In the present invention, kinematic sensors are used to measure the motion of the foot
15 segment in walking, and include a gyroscope and an accelerometer. Other heel switch systems are not able to provide the motion information for feedback control during electrical stimulation as they only provide simple information of foot contact on the ground. The present invention uses kinematic sensors to monitor foot segment motion in walking and provides information on when to trigger the stimulation by identifying the gait phases (include stance and swing) through the foot
20 segment inclination (i.e. angle of the foot segment to the surface). The stimulation strength is adjusted based on the motion information during stimulation. If the motion of a joint is too large during stimulation, which means the stimulation strength is too strong, in the next walking cycle the stimulation intensity is reduced. If the joint motion is not large enough, then the stimulation strength is increased for the next cycle.

25 FIG 1 is a method of assisting people in walking, such people generally having paralyzed muscles, utilizing a stimulation apparatus of the present invention. The method can be broken down into three sections in the swing phase of a gait cycle: pre-swing phase 100, initial to mid-swing phase 108, and termination of the swing to the heel strike phase 112.

30 Firstly, in the pre-swing phase 100 the system delivering the method is initialized 101. Initialization can include turning on the instrument, allowing the system to perform a systems check, having the system establish remote contacts, and so forth.

The system can then define required values necessary to successfully perform the method 103. Values can refer to angular values, timing values, etc. As the system will rely on on-
35 board instrumentation for determining when the user is in a particular phase of the gait, the kinematic sensors for gait detection are "zeroed" to avoid false positives or missed periods of required stimulation for the user. The instrumentation may also be modified to provide training

and conditioning, for example decreasing or increasing the sensitivity of the instrumentation to provide a less stringent or more stringent exercise.

5 The algorithmic function of detecting whether the user's heel is "off" the ground is determined 105. The stance phase in a gait cycle ends and the swing phase initiates when the heel of a foot is lifted off the surface while the toes remain in contact with the surface (see FIG 8 for a pictorial illustration). If the heel is not detected "off", the algorithm is looped back to defining the offset values of the kinematic sensors 103. In the event the heel is detected "off", further analysis is made.

10 If the heel is detected "off", the degree of the foot segment inclination is determined 107. In the period between heel off and toe off, the ankle moves from dorsiflexion to plantarflexion. Generally, from the time of heel-off, the foot measures at an angle of from about 20 to about 35 degrees from the surface. The increase in ankle degree occurs as the swing progresses, and measurement is continually made.

15 As the swing progresses to the toe-off, an algorithm is enacted to determine whether swing is detected 109. A swing can be detected by noting the increase in angle change of the foot segment to the surface. In another embodiment, a detection of swing can be determined by noting the changes in the hips, knees, ankle, or upper body. Changes that can be noted include angle change, pressure, weight, and/or extension. If swing is not detected, the algorithm is looped
20 for determination of the foot segment inclination degree.

If the swing is detected, a determination is made when the swing has ended 111. A swing is generally terminated at the heel strike of the swinging foot. Determining the end of the swing can be based on decrease angle between the foot segment and the contact surface. In another embodiment, determination of the end of the swing can be based on change of pressure, angle,
25 weight, extension as exhibited by the hips, knees, ankle, or upper body.

An end of a swing on one foot will initiate the beginning of the swing phase on the alternate foot.

An algorithm is then made as to whether the alternate foot is being swung 113. If "yes", stimulating paralyzed muscles can occur 114. Stimulation of paralyzed muscles is electrical
30 stimulation. Electrical stimulation can occur by positioning electrical conducting devices on or around the paralyzed muscles of the user. The electrical conducting devices can be pads, wrap around implements, wires, or embedded devices into the body of the user. Stimulation preferably occurs at the proper moment in order to make the users walk appear "normal", i.e. similar to a non-paralyzed person's walk.

35 Stimulation may occur to the lower limb of the user, such as leg, or an upper limb such as the arm. For example, stimulation is focused on the arm of the user to mimic the arm swing of a "normal" person. In one embodiment, more than one body part of a person is stimulated, for

example both the arm and leg are stimulated. In such an embodiment, stimulation of a lower limb and upper limb may alternate to simulate a "normal person" and achieve an effective walking motion. As discussed later, stimulation occurs via wireless means.

Stimulation may be adjusted as need be to better effectuate a particular gait 115. For example, if a gait is at a higher rate of speed than normal speed of walking, strong stimulation may be required to be delivered to the user to provide wider range of movement on the affected ankle joint to prevent drop foot. In another example, the stimulation may be decreased if a slower gait is being exhibited. Adjustment of the stimulation will be based on the actual variable compared against a projected variable 117. For example the actual speed of the user can be compared against a projected, or programmed, speed. If necessary, stimulation can be decreased 119. In other embodiments, stimulation may be increased. The kinematics sensors include an accelerometer and a gyroscope which can be used to detect acceleration and angular velocity for calculating the walking speed.

FIG 2 is an embodiment of a system 200 of the present invention used for assisting a user with paralyzed muscles in walking. The system 200 includes two modules, a module A 202 and a module B 212. Module A 202 serves as a monitoring and data transmitting device, and Module B 212 serves as a data processing and stimulation adjuster for paralyzed muscles.

Module A 202 can include a memory device for storing gait history 201, a device for storing predefined data 203, a gait phase detector 205, a controller 207, a feedback controller 209, and a device for estimating the position of the user 211. Module A 202 also includes sensors for passing data via wireless means 210.

Module B 212 can include a plant device 213 for attachment to a muscle location on the user, and a sensor module 215 for detecting a wireless signal sent from Module A 202.

Module A 202 and Module B 212 can be configured to operate in 3 modes. Mode 1 is a foot drop stimulator with real-time feedback control. In this mode, Module A is attached to a foot segment to act as an electrical stimulation trigger and foot flexion monitoring device. Data captured by the sensors are transmitted via wireless means, such as radio-frequency, to Module B. Module B processes the received data with the gait phase detection algorithm of the present invention and applies a different control strategy to adjust stimulation parameters at different gait phases.

Mode 2 is a combination mode, combining Modules A and B into a single device to act as a foot drop stimulator. The single device is attached to the shank and electrical stimulation is triggered by the movement of the device.

Mode 3 is a combination of modes 1 and 2, i.e., a foot drop stimulator combined with an arm swing stimulator. In this mode, Module A monitors the gait phase of the user and transmits gait data to module B of the foot drop stimulator and arm swing stimulator. The arm swing

stimulator produces stimulation at appropriate gait phase, and the shank stimulator addresses the foot drop problem.

The transmission of data between Module A and Module B occurs by wireless means, for example RF, WIFI, satellites, BLUETOOTH®, and other wireless technologies. Preferably, a
5 wireless transmitter is installed in Module A and a receiver is installed in Module B.

FIG 3 is an embodiment of Module B 300 of the system of the present invention. The embodiment 300 is primarily composed of a main control unit (MCU) 310 such as a microprocessor, and radio frequency receiver 309. The embodiment 300 further includes resistors
10 302, switches 311, converters 301, memory such as RAM 306, pulse with modulators 315, input/output parts 313/305, interfaces (SPI and SCI) 317/307, transistors 325/329, transformer 327, power supply 323, and connection means 321/331. It will be well known to one with ordinary skill in the art that the components may be substituted or supplemented with other electronic components.

15 FIG 4 is an embodiment of Module A of the system of the present invention. The embodiment 400 includes filters and amplifiers 423/427, main control units 413 such as microprocessors, and a radio frequency transmitter. Notably, the embodiment 400 includes an accelerometer 429 and gyroscope 431 as gait phase detectors, allowing the system to determine
20 at what phase of the gait cycle the user is in. This allows the apparatus to time when a stimulation signal should be sent from Module A to Module B. The embodiment 400 can also include memory such as RAM 405, input/output parts 407/419, pulse width modulators 403, interfaces 409/415, converters 417, and switches 421. In the event the system is used for a foot drop stimulator, the embodiment 400 can include a heel switch 425. It will be known to one with ordinary skill in the
25 art that the components may be substituted or supplemented with other electronic components.

FIG 5 exhibits the attachment of the system on a user, the system comprising a Module A 501 and Modules B 511/509, wherein the Modules B are an arm mounted module B 511 and a shank mounted module B 511.

30 Module A 501 is preferably attached adjacent to the foot of the user. In one embodiment, the Module A 501 can be attached to the shoe of the user, in one embodiment on the top side of the shoe. The gait phase detector 505 may be incorporated into the inside sole 503 of the shoe. As previously mentioned, the gait phase detector 505 is used to determine whether the foot is in the swing phase of the gait cycle and, if so, what section of the swing phase.

35 In use, the Module A 501 transmits signals 507 to the modules B 511/509, pertaining to whether electro-stimulation by the Module B should be provided. The Module A 501 may also send a signal to a remote location 513, such as a computer system, for recording information

about the user's gait, swing phase, and the like. In a preferred embodiment, if mode 3 is enacted, i.e. a Module B is utilized for arm swing and foot drop stimulation the modules should either be positioned in an alternating manner (left leg/right arm, or right leg/left arm) or stimulation should be provided in an alternating manner, i.e., left leg stimulation, no right arm stimulation/no left leg stimulation, right arm stimulation. In this way, the gait cycle of a "normal" person can better be mimicked by the muscle-paralyzed user.

The system will operate according to the previously mentioned method (FIG 1) including detecting heel off, determining degree, detecting swing, stimulating muscles, and adjusting stimulation as needed.

EXAMPLES

FIG 6 shows the signals as captured by the gait phase detectors gyroscope and accelerometer during the gait cycle for normal and stroke subject with foot drop problem.

FIG 7 shows examples of the gait phase detected by the system of the present invention utilizing the gait phase detection method.

FIG 8 shows the gait cycle for a human. The system and method of the instant invention have their usefulness during the swing phase 801 of the cycle

Having described embodiments of the present system with reference to the accompanying drawings, it is to be understood that the present system is not limited to the precise embodiments, and that various changes and modifications may be effected therein by one having ordinary skill in the art without departing from the scope or spirit as defined in the appended claims.

In interpreting the appended claims, it should be understood that:

a) the word "comprising" does not exclude the presence of other elements or acts than those listed in the given claim;

b) the word "a" or "an" preceding an element does not exclude the presence of a plurality of such elements;

c) any reference signs in the claims do not limit their scope;

d) any of the disclosed devices or portions thereof may be combined together or separated into further portions unless specifically stated otherwise; and

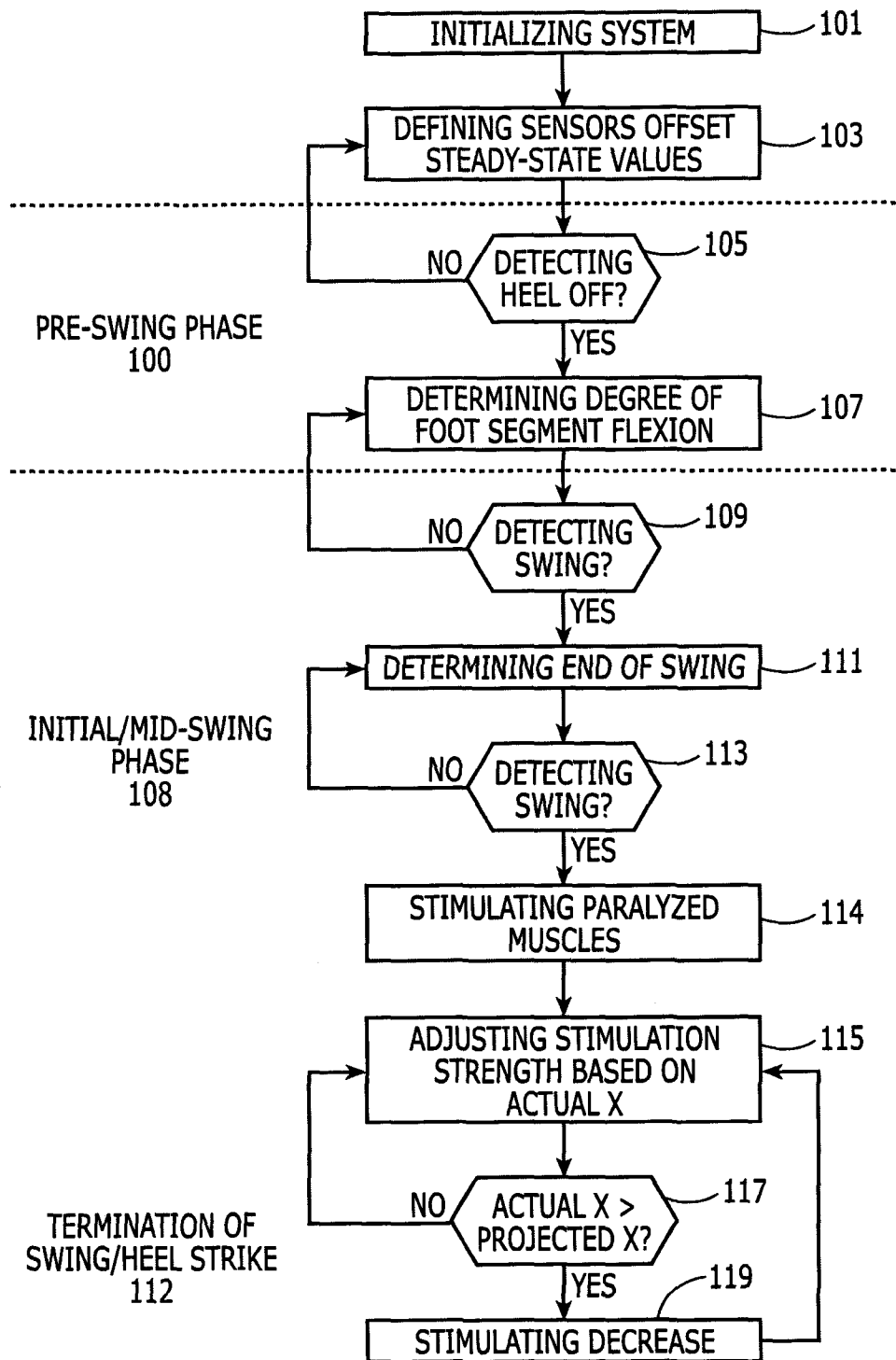
e) no specific sequence of acts or steps is intended to be required unless specifically indicated.

WE CLAIM:

1. A method for assisting a user with paralyzed muscles to walk, the method comprising:
initializing a system to electrically stimulate the paralysed muscles for restoring a normal
5 walking motion;
defining kinematic sensor offset and steady-state values for gait phase detection;
detecting a heel off phase in walking from a kinematic sensor, where if the heel is
detected as off, the degree of foot segment inclination is determined, otherwise the kinematic
sensor offset and steady state values are redefined until the heel is detected as off;
10 detecting a swing, where if the swing is detected, the paralyzed muscles are stimulated,
otherwise the degree of foot segment inclination is redetermined until the swing is detected; and
determining whether the actual measurement of a joint during stimulation is greater than
the projected measurement in the termination of a swing phase, where if the actual measurement
is greater than the projected measurement, the stimulation strength is decreased for the next
15 walking cycle.
2. The method according to claim 1, wherein the degree of foot segment inclination is
determined from about 20° to about 35° from a ground surface.
3. The method according to claim 1, wherein detection of a swing is determined by noting
the increase in angle change of the foot segment to a contact surface from the kinematic sensor.
- 20 4. The method according to claim 1, wherein determining the termination of the swing is
based on a decrease in angle between the foot segment and a contact surface from the kinematic
sensor.
5. The method according to claim 1, wherein stimulating the paralyzed muscles occurs by
electrically stimulating an upper limb for generating arm swing and electrically stimulating a lower
25 limb for generating dorsiflexion to address foot drop of a user.
6. A method for addressing foot drop of a user, the method comprising:
attaching a first module to transmit a signal from a foot segment of said user;
attaching a second module for providing electrical stimulation to a shank to prevent foot
drop of said user; and
30 sending a signal wirelessly from said first module to said second module in response to
movement during electrical stimulation of said first module for feedback control on the stimulation
parameters.
7. The method according to claim 6, wherein said first module includes at least one
kinematic gait phase detector, a memory storage device, a controller, a feedback controller, a
35 device for estimating the position of the user, and a wireless data transmitter.
8. The method according to claim 6, wherein said second module includes a plant device for
attachment to said shank and a sensor for detecting a wireless signal.

9. The method according to claim 7, wherein said kinematic gait phase detector includes an accelerometer and a gyroscope.
10. The method according to claim 6, wherein sending said signal wirelessly occurs by radio-frequency.
- 5 11. The method according to claim 6, wherein movement of the first module occurs during a gait phase cycle.
12. A method for addressing foot drop and stimulating arm swing of a user with paralyzed muscles, the method comprising:
- 10 attaching a first module with a kinematic gait phase detector for transmitting a signal from a foot segment of said user;
- attaching second modules for providing electrical stimulation to a shank and the arm of said user; and
- 15 sending a signal wirelessly from said first module to said second modules in response to movement during electrical stimulation of said first module for feedback control on stimulation parameters.

1/8

**FIG. 1**

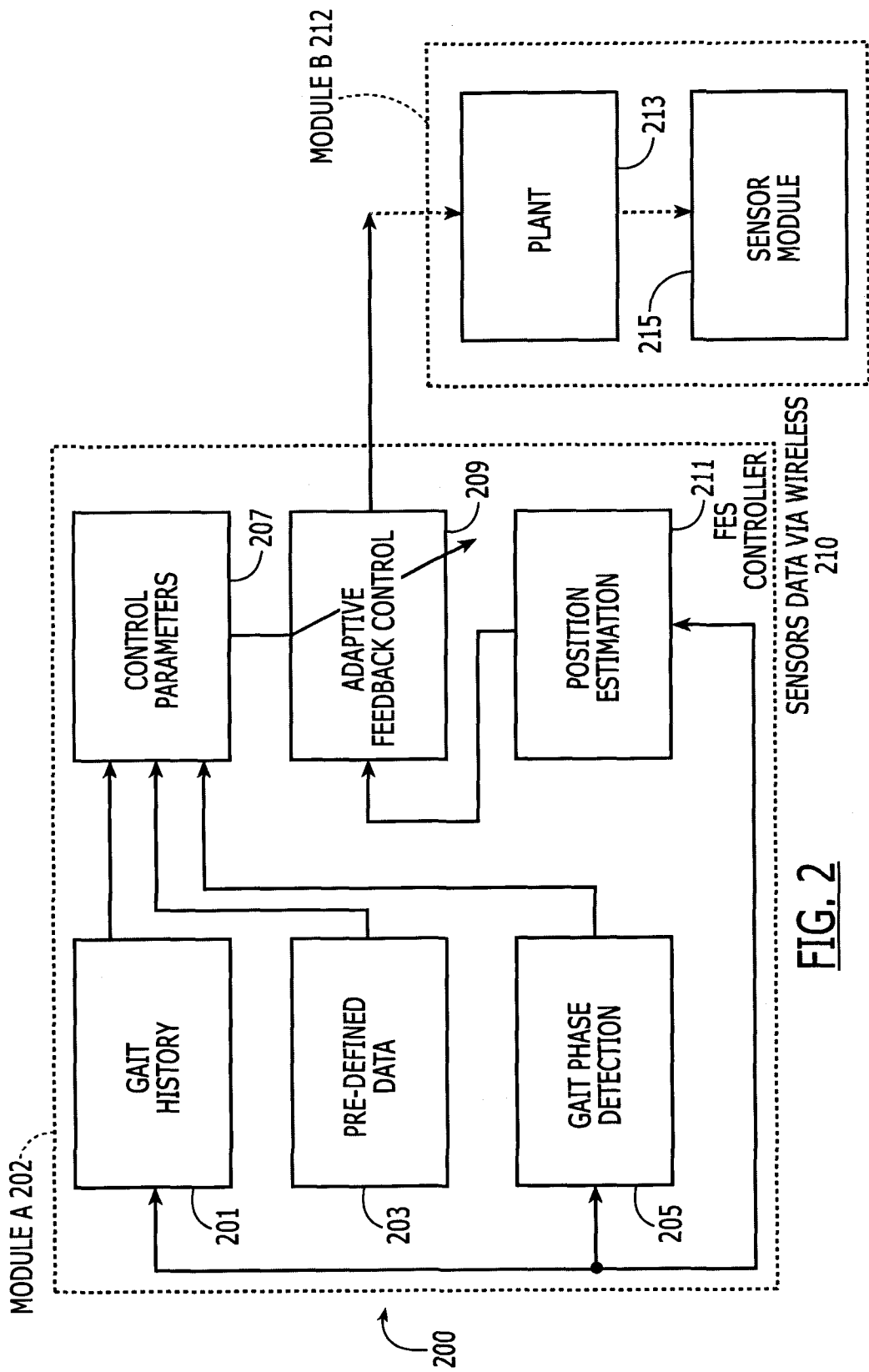


FIG. 2

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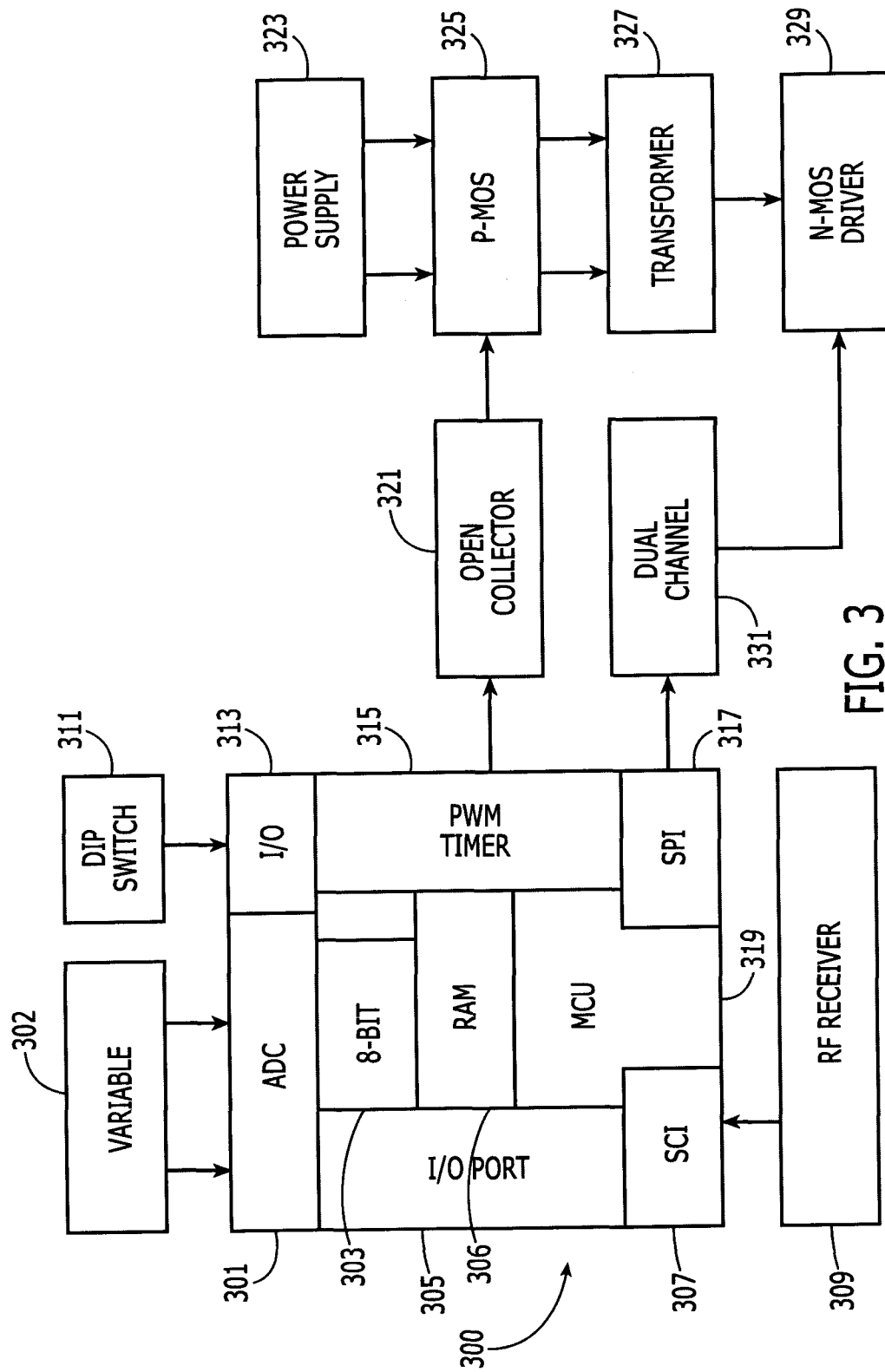


FIG. 3

4/8

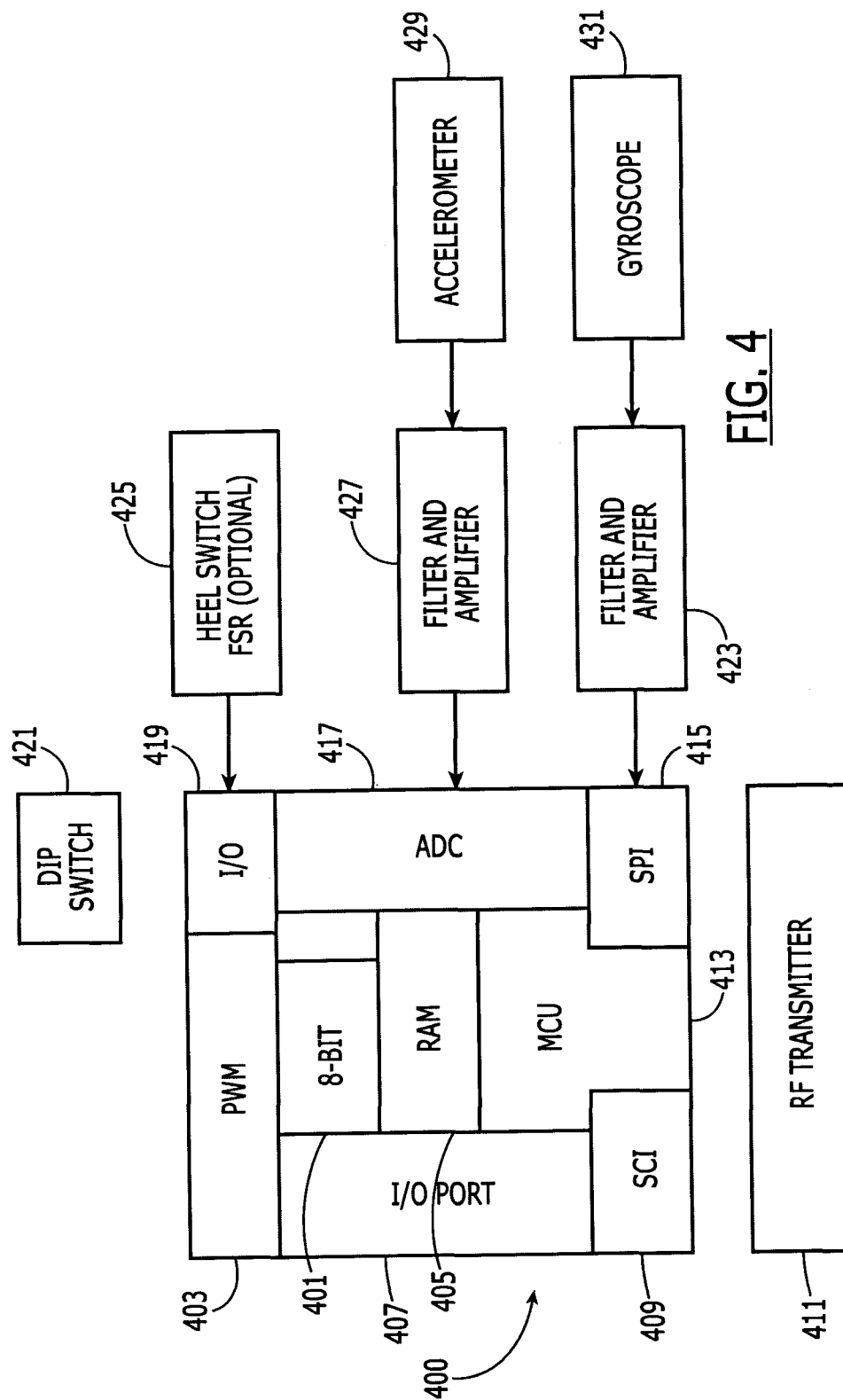
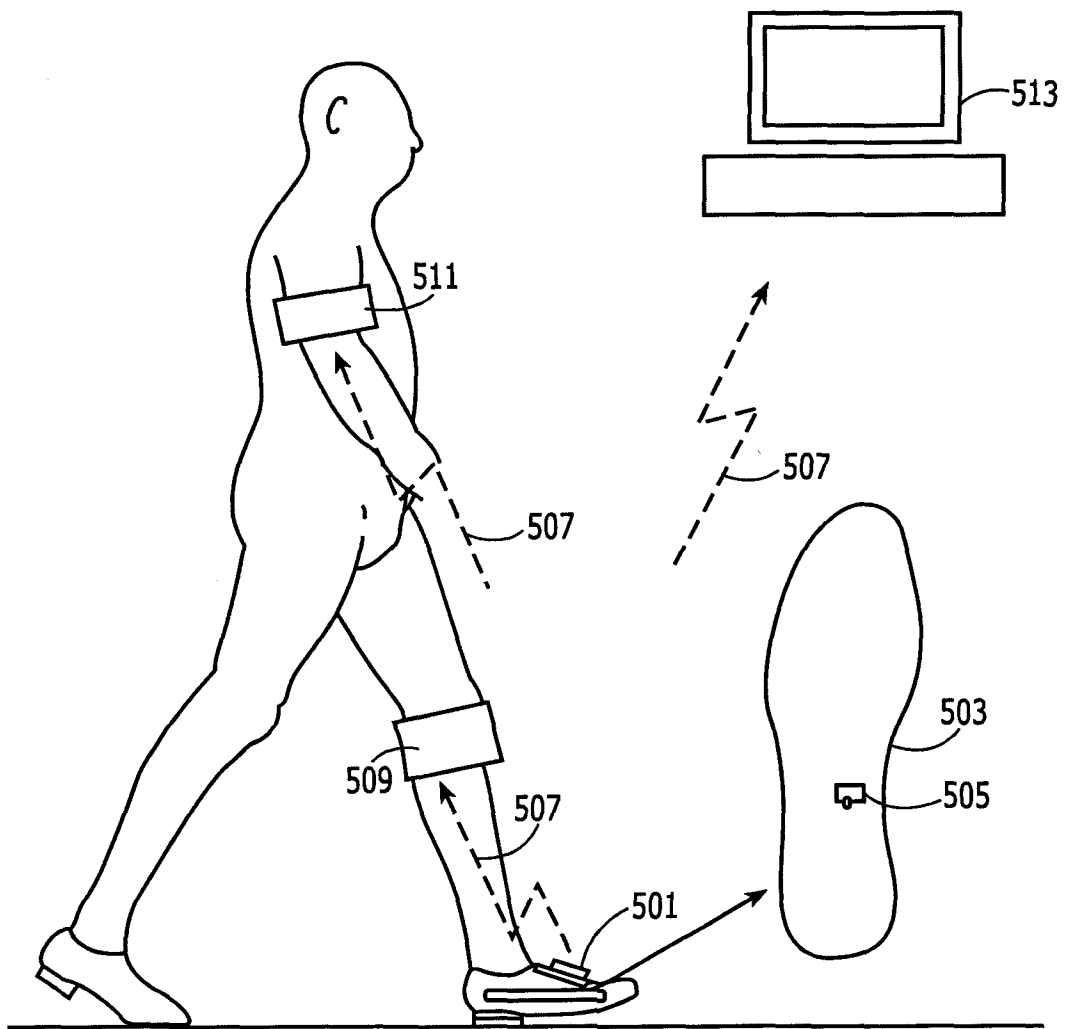


FIG. 4

5/8

**FIG. 5**

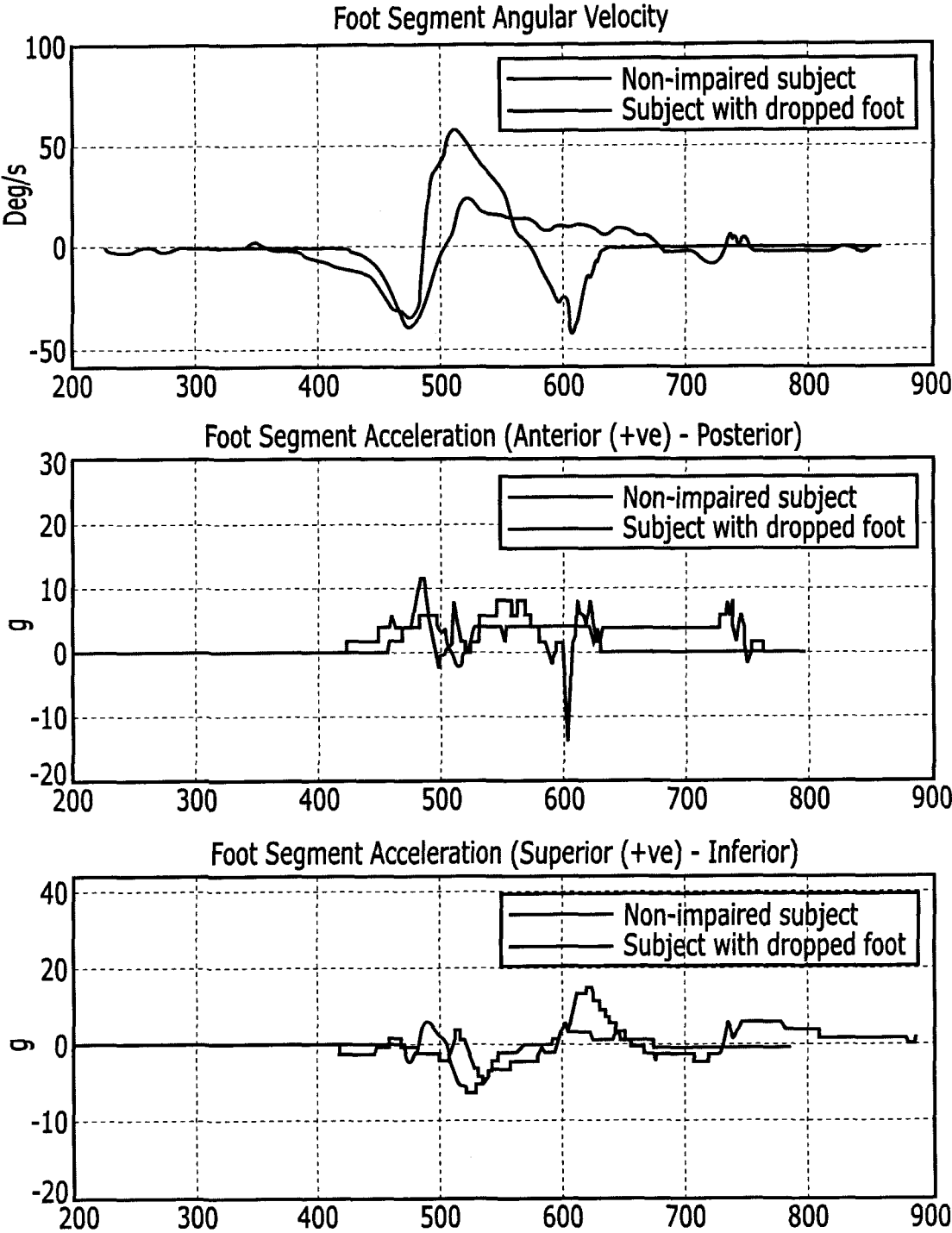


FIG. 6

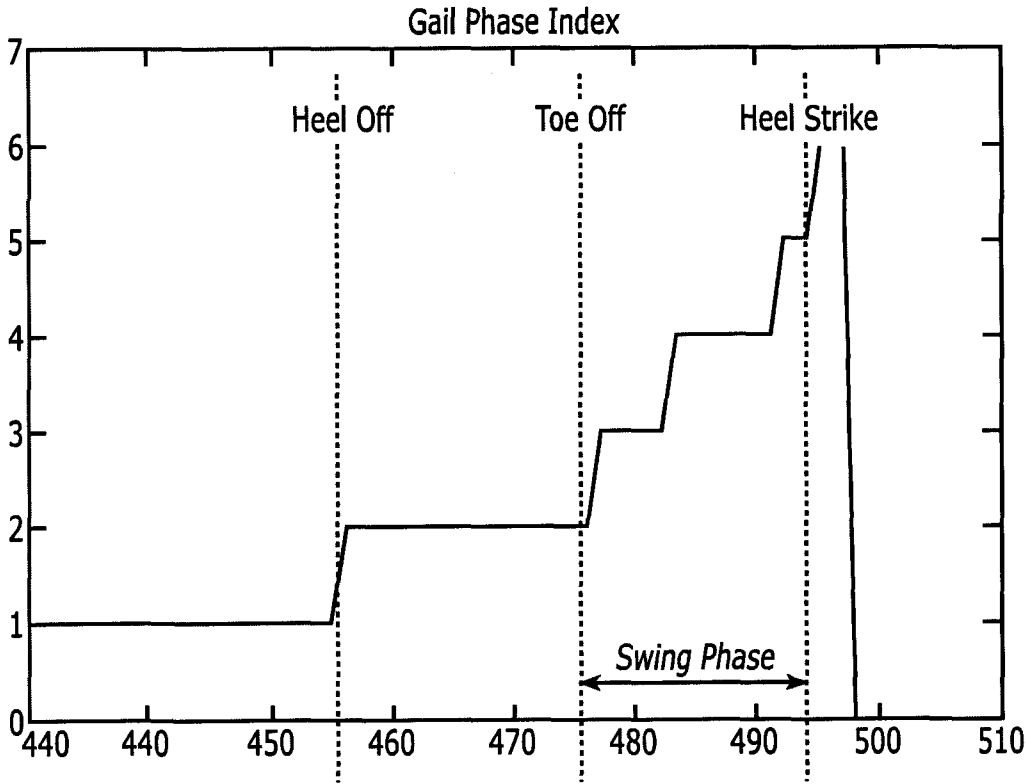


FIG. 7

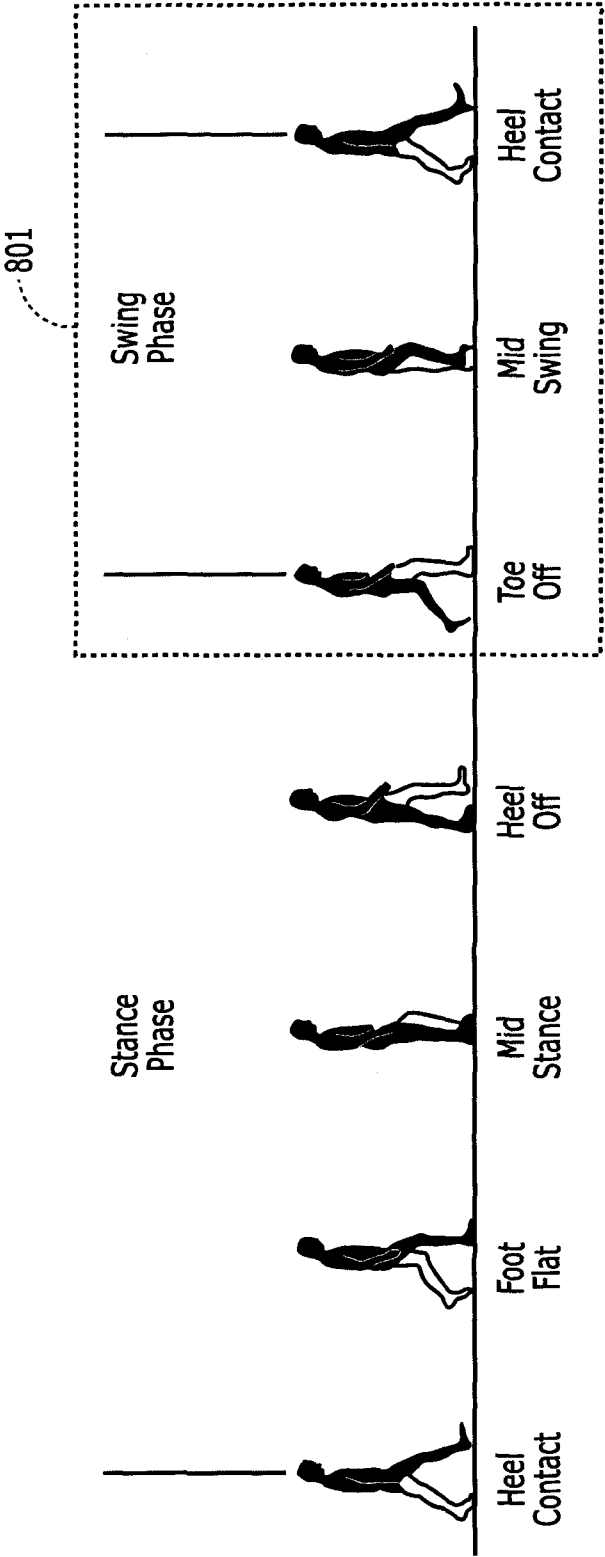


FIG. 8
(PRIOR ART)

INTERNATIONAL SEARCH REPORT

International application No.

PCT/CN2008/071904

A. CLASSIFICATION OF SUBJECT MATTER

See extra sheet

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)

IPC A61B A61N A61H A63B21

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)

WPI, EPODOC, PAJ, CNPAT, CNKI

FUNCTIONAL W ELECTRICAL W STIMULATION, GAIT AND SENSOR?, PARALY???, SWING W PHASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US2007/0173903A1 (BIOQ INC), 26 Jul.2007 (26.07.2007), paragraphs [0018]-[0024] in the specification, figs. 1-4.	1-12
A	US2007/0179561A1 (GOOD SAMARITAN CHILDREN S THER), 02 Aug.2007 (02.08.2007), paragraphs [0019]-[0028] in the specification, figs. 1-4.	1-12
A	US2005/0049652A1 (TONG K), 03 Mar.2005 (03.03.2005), the whole document.	1-12
A	WO2004037344A1 (LOCKHEED CORP), 06 May 2004 (06.05.2004), the whole document.	1-12
A	CN1846805A (HONG KONG SCIENCE & ENGINEERIN), 18 Oct.2006 (18.10.2006), the whole document.	1-12
A	CN1215614 A (UNIV QINGHUA), 05 May 1999 (05.05.1999), the whole document.	1-12

☐ 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)

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“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
22 Oct.2008(22.10.2008)

Date of mailing of the international search report
20 Nov. 2008 (20.11.2008)

Name and mailing address of the ISA/CN
The State Intellectual Property Office, the P.R.China
6 Xitucheng Rd., Jimen Bridge, Haidian District, Beijing, China
100088
Facsimile No. 86-10-62019451

Authorized officer
TIAN, Yunqing
Telephone No. (86-10)62085631

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.

PCT/CN2008/071904

Patent Documents referred in the Report	Publication Date	Patent Family	Publication Date
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INTERNATIONAL SEARCH REPORT

International application No.

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CLASSIFICATION OF SUBJECT MATTER

A61B 5/11 (2006.01) i
A61N 1/36 (2006.01) i
A61H 3/00 (2006.01) i
A63B 21/00 (2006.01) i