(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 February 2016 (25.02.2016)

WIPO | PCT

(10) International Publication Number
WO 2016/029138 Al

(51) International Patent Classification:
A61B 5/11 (2006.01)

(21) International Application Number:
PCT/US2015/046337

(22) International Filing Date:
21 August 2015 (21.08.2015)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
62/040,591 22 August 2014 (22.08.2014) US

(71) Applicant: THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA [US/US]; 3160 Chestnut Street, Suite 200, Philadelphia, PA 19104 (US).

(72) Inventors: QU, Feini; 4300 Spruce St, Apt. C-305, Philadelphia, PA 19104 (US). GEBHARD, Peter; 4300 Spruce St, Apt. C-305, Philadelphia, PA 19104 (US).

(74) Agents: RAGUSA, Paul, A. et al; Baker Botts LLP, 30 Rockefeller Plaza, New York, NY 10112-4498 (US).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report (Art. 21(3))*

(54) Title: SYSTEMS AND METHODS FOR JOINT ACTIVITY MONITORING

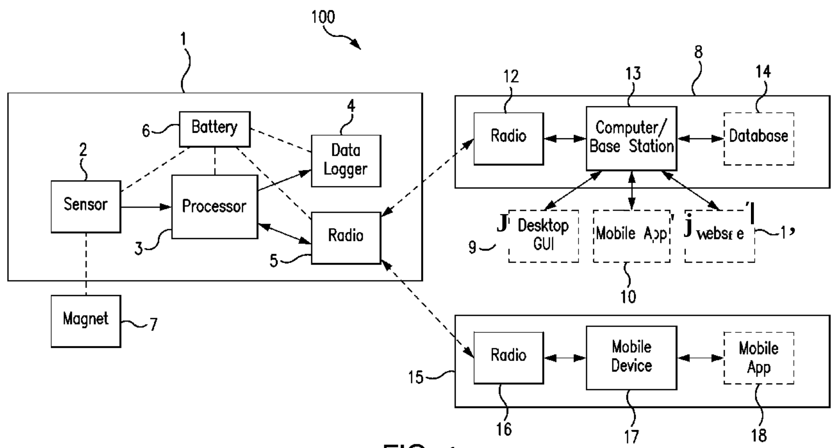


FIG. 1

(57) Abstract: Joint analysis system for analyzing kinematics of an anatomical including a sensor device, a storage device, a magnet, and an analysis engine. The sensor device can be configured to be disposed on a first side of the joint and can have one or more sensors, a processor coupled to the one or more sensors, a wireless data transmitter coupled to the processor, a data storage device coupled to the processor, and a battery coupled to the sensors, processor, wireless data transmitter, and data storage device. The magnet can be configured to be disposed on the second side of the joint. The analysis engine can be configured to receive data from the sensors.

SYSTEMS AND METHODS FOR JOINT ACTIVITY MONITORING

Cross-Reference to Related Applications

This application claims priority to United States Provisional Application Serial No. 62/040,591 filed on August 22, 2014, which is incorporated by reference herein in its entirety.

Background

Information regarding joint activity, for example, kinematics of joints, can be useful for a variety of uses. For example, physicians and physical therapists can monitor patient recovery time from orthopaedic injuries, track rehabilitation progress over time, and facilitate early detection of surgical complications. Additionally, objective quantification of joint function can be used for evaluating experimental treatments in translational models. Existing wearable animal monitors can use accelerometer-based sensors that can measure activity intensity. Existing devices that are capable of gait analysis can employ multiple sensors, can depend on species-dependent algorithms, and can be expensive.

Therefore, there is a need for a low-cost, all-in-one device that can provide information on joint kinematics in addition to basic activity level using a single sensor board.

Summary

The presently disclosed subject matter provides systems and methods for analyzing kinematics of an anatomical joint. The joint can have a first side and second side.

According to one aspect of the disclosed subject matter, systems for analyzing kinematics of a joint are provided. In an exemplary embodiment, the joint analysis can include a sensor device, a storage device, a magnet, and an analysis engine. The sensor device can be configured to be disposed on a first side of the joint and can include one or more sensors, a processor coupled to the one or more sensors, a wireless data transmitter coupled to the processor, a data storage device coupled to the processor, and a battery coupled to the sensors, processor, wireless data transmitter, and data storage device. The magnet can be configured to be disposed on the second side of the joint. The analysis engine can be configured to receive data from the sensors.

In some embodiments, the one or more sensors can include a magnetometer. The magnetometer sensor can be adapted to provide readings that are influenced by the magnetic field provided by the magnet to provide kinematic information of the joint. The one or more sensors can include an accelerometer. The one or more sensors can include a gyroscope.

In some embodiments, the one or more sensors can be configured to sense stride length. The one or more sensors can be configured to sense swing time. The one or more sensors can be configured to sense stance time. The one or more sensors can be configured to sense ambulation speed. The one or more sensors can be configured to sense distance traveled. The one or more sensors can be configured to sense gait symmetry. The one or more sensors can be configured to sense gait cadence. The one or more sensors can be configured to sense joint kinematics. The one or more sensors can be configured to sense a disrupted pattern of ambulation. The data analysis engine can be configured to recognize an abnormal gait or behavior.

In some embodiments, the system can include a base station. The base station can include a processor, a data storage device coupled to the processor, a user interface coupled to the processor, and a wireless data transmitter coupled to the processor and configured to communicate with the wireless data transmitter of the sensor device. The base station can include a display. The sensor device and magnet can be configured to be worn by an animal or human. The sensor device and the magnet can be configured to be implanted in an animal or human.

In another exemplary embodiment of the disclosed subject matter, methods to analyze kinematics of a joint of an animal are provided. An example method can include calibrating one or more sensors and a magnet relative the joint. The method can include sensing a magnetic field with the calibrated sensors while the joint exhibits motion and angular velocity to generate a signal. The method can include filtering signal noise, if any, from the signal and identifying joint motion based on the corresponding acceleration and angular velocity. The method can include calculating joint and gait kinematic parameters from the identified joint motion.

The description herein merely illustrates the principles of the disclosed subject matter. Various modifications and alteration to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. Accordingly, the disclosure herein is intended to be illustrative, but not limiting, of the scope of the disclosed subject matter.

Brief Description of the Drawings

Figure 1 illustrates a component diagram of an exemplary system in accordance with the disclosed subject matter.

Figure 2 illustrates a diagram of how an exemplary system of the disclosed subject matter can be used on a human knee.

Figure 3 shows exemplary sensor devices in accordance with the disclosed subject matter.

Figure 4 provides data that can be used to calibrate the sensors.

Figure 5 shows exemplary data related to joint angle and angular velocity of a human knee.

Figure 6 shows an exemplary method for detecting joint angle in an animal model.

Figure 7 shows exemplary data related to joint angle of a pig stifle joint (pig knee).

Figure 8 shows example data from detecting short-term activity results in an animal model.

Figure 9 shows example data from detecting long-term activity results in an animal model.

Figure 10 shows a flow chart of an exemplary method of analyzing kinematics of a joint of an animal according to the disclosed subject matter.

Description

The methods and systems presented herein can be used for remotely monitoring anatomical joint and gait kinematics, as well as general activity. As used herein, "anatomical joint" can refer to joints of animals or humans that are locations where bones connect and are configured to allow movement. For example and not limitation, anatomical joints can include the human knee, human elbow, and pig stifle joint (pig knee), and other joints. The disclosed subject matter can help physicians and physical therapists monitor patient recovery from orthopaedic injuries, track rehabilitation progress over time, and facilitate early detection of surgical complications. Through remote monitoring and continuous, long-term data collection, physicians and physical therapists can detect trends during the patient' s recovery process. The data can be used to highlight a need to adjust treatment based on recovery level and rate, identify additional rehabilitation exercises with faster recovery or revision surgery with slow recovery. Athletes, coaches and trainers can use the disclosed subject matter to characterize joint and gait kinematics during training. Such data can be used to enhance performance and prevent injury. When worn by the research subject, the device can wirelessly transmit data on acceleration, angular velocity, and magnetic field in 3D space, and can allow for remote, real time visualization and analysis of unprovoked and unsupervised activity. Additionally, the range of motion and frequency of joint flexion and extension can be derived by attaching a magnet distal to the articulating joint of interest and measuring changes in magnetic field strength. This can allow for a species-independent, individual assessment of joint kinematics using a single sensor. The device can facilitate the monitoring of pathological progression and therapeutic efficacy for animal and human subjects in orthopaedic research.

Figure 1 shows, for the purpose of illustration and not limitation, a component diagram of an exemplary system 100 of the disclosed subject matter. The sensor device 1 can include a sensor 2, a processor 3, a data logger, 4, and a radio 5. The sensor 2 can integrate a triple-axis magnetometer, triple-axis accelerometer, and/or a triple-axis gyroscope. The sensor device 1 can also include a battery 6. The device can be designed to sense the magnetic field produced by a nearby magnet 7 (or other magnetic field producing object).

The system 100 can also include a base station 8 which can process and store outputs from the sensor device 1, and can display it over a variety of possible interfaces, for example, a desktop graphical user interface (GUI) 9, a mobile application 10 of a mobile communication device, such as a phone, tablet, laptop computer, or personal digital assistance (PDA), or a website 11, which can be accessed by a device with access to the internet. The base station 8 can include a radio 12 which can be configured to communicate with the radio 5 of the sensor device 1. The base station 8 can also include a computer 13 (for example, a processor) and a database 14 for storing information. The system 100 can also include a mobile device 15, such as a phone, tablet, laptop computer, or personal digital assistance (PDA), which can be used to receive data from the sensor device 1 and display the data. The mobile device 15 can have a radio 16 which can be configured to communicate with the radio 5 of the sensor device 1. The mobile device 15 can include a processor 17 which can have a mobile application 18 installed thereon. The data can be minimally processed and temporarily stored on the mobile device 15, but can be reviewed by a non-expert user. For example, the data displayed on the mobile device 15 can be displayed in a clear, intuitive way via a mobile app interface.

Figure 2 shows, for the purpose of illustration and not limitation, an exemplary diagram of how an exemplary system can be used on a human knee. At 201, the device and magnet can be placed to span the joint, for example, a knee, at known distances. The device can be placed distal to the joint to detect motion and the magnet can be placed proximal to the joint. In some embodiments, the device can be placed proximal to the joint and the magnet can be placed distal to the joint. The magnetic sensor on the device can be calibrated based on the system orientation and relative positions of the device and magnet. At 202 data can be collected. The sensor can detect changes in the magnetic field, acceleration, and angular velocity with joint flexion and extension. Data can be locally stored on the device. At 203 data can be transmitted. The device can send data to a local or remote network. The base station can receive and store the information for multiple patients. At 204 the data can be analyzed. The software can detect joint movement. Joint flexion angle can be calculated based on change in magnetic field and known geometry of the joint. At 205 the data can be presented. The average range of motion or other parameters can be displayed on a user friendly mobile app. Comparisons can be made to baseline, for example, uninjured or opposite limbs.

The joint measurements can be visualized in real-time, and can reduce the time spent measuring range of motion with a conventional goniometer in a clinic or therapists office. By integrating the device into orthopaedic braces or clothing, the device can be incorporated into a user's daily activities. Real-time feedback displayed by a companion mobile application can help guide a patient' s recovery. The guidance provided through the application can be automated based on the application's analysis of device feedback or can be managed by the patient's surgeon and/or physical therapist. The platform can promote patient compliance and encourage goal-oriented behavior.

Fig. 3A shows an exemplary sensor device 301 having a battery 306, data logger 304, radio 305, sensor 302, and micro-controller (processor) 303. An exemplary magnet 307 is also provided. The black case of Fig. 3A can be made of plastic. The case can have dimensions of 7.5 cm x 6 cm x 2.5 cm and can weigh 27 g. The battery 306 can have a capacity of 2000 milliamp-hour (mAh), an energy rating of 7.4 watt-hour (Wh), dimensions that are 5.5 cm x 5 cm x 0.5 cm, and weigh 39 g. The sensor 302 can have dimensions of 3.5 cm x 1 cm x 0.3 cm and weigh 2 g. The micro-controller 303 can have dimensions of 6.5 cm x 2.7 cm x 1.5 cm and weigh 7 g. The radio 305 can dimensions of 2.7 cm x 2.5 cm x 0.7 cm and weigh 4 g. The data logger 304 can have dimensions of 1.9 cm x 1.5 cm x 0.3 cm and weigh 2g. The entire device of Fig. 3A can weigh 81 g. Fig. 3B shows a top and side view of an exemplary sensor device 401 having a battery 406, data logger 404, radio 405, sensor 402, and micro-controller (processor) 403. The micro-controller 403, data logger 404, and radio 405 can have the same dimensions and weight as the corresponding elements in Fig. 3A. The sensor 402 can dimensions of 3.3 cm x 1.5 cm x 0.3 cm and weigh 2g. The battery 406 can have a capacity of 850 mAh, a power rating of 3.1 Wh, dimensions of 4.8 cm x 3 cm x 0.4 cm, and weigh 16 g. The device 401 can have dimensions of 7 cm x 3.5 cm x 1.5 cm and can weigh 31 g. The circuit boards shown in Figs. 3 A and B can be standard multi-layer printed circuit boards built using FR-4 glass-reinforced epoxy. The wiring can be basic hook-up wire, 22 American wire gauge (AWG). The batteries 306 and 406 can be, for example, 3.7 V polymer lithium ion batteries. A quarters and a dime are provided in Figs. 3 A and B, respectively, to illustrate size.

The devices illustrated in Figs. 3 A and B can be light-weight, palm-sized devices capable of measuring acceleration, angular velocity, and magnetic field strength in three dimensions. The device can be developed with off-the-shelf components at low cost. The sensor board can integrate a triple-axis accelerometer, a triple-axis gyroscope, and a triple-axis magnetometer, and can be calibrated prior to use via a custom software tool. A computer with a radio peripheral can receive transmitted data to plot it in real time.

The magnet used with the system can be a rare-earth neodymium disc magnet with dimensions of 1" diameter x 0.25" thickness. The magnetic field at its surface can be 2952 Gauss. Its magnetization direction can be axial (poles on the flat ends of the disc). It can weigh 24 grams. Magnets of other strengths and/or geometries (such as a cylinder or bar) can be used.

Figure 4 shows, for the purpose of illustration and not limitation, data that can be used to calibrate the sensor. Fig. 4A shows a plot of magnetic field verse flexion angle. Fig. 4B shows a plot of magnetic field verse distance. Fig. 4C illustrates a plot of flexion angle verse magnetic field strength, which can provide a predicted angle based on the magnetic field strength measured. Inset in Fig. 4C illustrates how distance and flexion angle (Θ) can be defined for the system described in Figs. 4 A-C. "Flexion angle" as used in orthopaedics, and as used herein, is the supplementary angle of the angle between the sensor and the magnet. For example, the leg fully extended is given an angle of 0°, not 180°. The equations shown in Figs. 4 A-C are specific to the configuration shown inset in Fig. 4C (i.e., dependent on sensor-joint and magnet-joint distances). Fig. D illustrates how the relationship between magnetic field strength and flexion angle is affected by magnet strength. A stronger magnet results in greater sensitivity to changes in distance (and thus angle). To measure changes in joint angle, the device and neodymium magnet can be fixed opposite from a hinge joint. The device can be kept stationary and the magnet moved across a range of flexion angles at 5° intervals. Position can be held for 5 seconds at each angle and the magnetic field strength can be recorded at 40 Hz. An equation relating sensor-magnet angle as a function of magnetic field magnitude can be derived to predict flexion angle. Flexion angles can be predicted by positioning a magnet opposite the sensor across a hinge joint, where the magnetic field increases exponentially with decreasing distance between the sensor and magnet. The calibration curve can be dependent on the sensor-to-joint and magnet-to-joint distances, as well as the magnet strength and magnetic pole orientation.

The magnetic field strength can be inversely proportional to the cube of the distance from the surface of the magnet. Thus, it is possible to relate magnetic field and distance between the sensor and the magnet. The flexion angle can be derived via the law of cosines, which allows one to calculate the third side of a triangle if one knows two sides and the angle between them, and to calculate the angles of a triangle if one knows the three sides. When the distance (A) between the sensor and the joint, the distance (B) between the magnet and the joint, and the angle (ϕ) between the sensor and the magnet are known (i.e., $\phi = 180 - \Theta$), it is possible to calculate the distance between the sensor and the magnet. For example the distance (C) between the sensor and the magnet can be defined by equation 1:

$$C = \sqrt{A^2 + B^2 - 2AB\cos(\phi)} \quad (1)$$

When the distance (A) between the sensor and the joint, the distance (B) between the magnet and the joint, and the distance (C) between the sensor and the magnet are known, the angle (ϕ) between the magnet and the sensor can be defined by equation 2:

$$\phi = \arccos\left(\frac{A^2+B^2-C^2}{2AB}\right) \quad (2)$$

To derive an equation predicting the flexion angle, the magnetic field strength at various flexion angles (example: 0, 30, 60, 90, and 120°) can be measured for a fixed sensor-joint and magnet-joint distance (Fig. 4A). Using the law of cosines, the sensor-magnet distance for each known angle can be calculated using Equation 1. The linear regression that relates the magnetic field as a function of the inverse of the distance cubed ($1/\text{distance}^3$) (Fig. 4B) can be determined. Next, the distance can be calculated to determine what the sensor-magnet distance is for a given magnetic field, and the distance can be plugged it into Equation 2. This new equation allows one to calculate the flexion angle based on changes in the magnetic field strength (Fig. 4C). The relationship can allow one to solve for flexion angle for different distance and magnet combinations. Particular combinations would be sensitive enough to predict the angle at peak extension (far distance) without oversaturating the sensor at peak flexion (near distance), which can permit determination of the joint's full range of motion.

As an example and not by way of limitation, to measure changes in angle, the device and a neodymium magnet can be placed equidistant (6 inches) from a hinge joint. The device can be kept stationary and the magnet moved to flexion angles of 0, 45, 90, and 135° to simulate joint movement. Positions can be held for 5 s at each angle (n=3/group) and the magnetic field parallel to the magnetic dipole can be recorded. Significance can be assessed by two-way ANOVA with Bonferroni's post-hoc tests to compare magnetic field strength between groups ($p<0.0001$).

In a sample test, two magnets were tested: Weak (5/8" diameter, 1/5" thick) and Strong (1" diameter, 1/4" thick). The sensor detected changes in magnetic field strength when a magnet was positioned at various angles relative to a pivot point. Magnetic field values were significantly different between all angles for both Weak and Strong magnets, with a power law relationship ($p<0.0001$). The Strong magnet induced higher magnetic fields at each angle and was more sensitive to changes in position than the Weak magnet ($p<0.0001$) (Fig. 4D).

Figure 5 shows, for the purpose of illustration and not limitation, exemplary data related to joint angle and angular velocity of a human knee. To capture dynamic range of motion of the human knee during normal gait, the sensor and magnet can be fixed distal and proximal to the knee joint on the posterior surface, respectively. The subject can walk at a step frequency of approximately 1 Hz, and the magnetic field strange and angular velocity of the tibia in the sagittal plane can be recorded at 40 Hz. Ten individual steps can be used to obtain the range of motion, defined as the difference between the minimum and maximum angles of the gait cycle. Fig. 5A shows the flexion angle and angular velocity verse time for two continuous steps of a human subject. The flexion angle and angular velocity of the tibia appear as repetitive and predictable patterns during ambulation. The dynamic range of motion of the knee in Fig. 5A is 54+4°, with a peak flexion angle of 55+3°. Fig. 5B shows the average flexion angle verse time for ten isolated steps. Fig. 5C shows the average angular velocity verse time for ten isolated steps. As described herein, the system is sufficient for gathering joint kinematics for a single leg. By wearing the system simultaneously on both legs (i.e., two systems), gait parameters can further be elucidated. In addition, the system can be used for other joints (for example, the elbow joint) and is not limited to the knee.

Figure 6 shows, for the purpose of illustration and not limitation, an exemplary method for detecting joint angle in an animal model. The device can be attached to the femur and the magnet to the tibia of an animal. The device is described herein as attached to a pig; however, the method can be applied to any animal. The magnetic field can be measured as a function of flexion angle and an equation can be derived to relate changes in magnetic field to changes in flexion angle of the joint. High speed footage of a gait cycle is also shown, with device and magnet positions shown on the hind limb. The device can be attached proximal to the joint (above the joint). As in the human example discussed above, the configuration can be better suited for gathering gait data, since it is possible to obtain information about the acceleration and angular velocity of the tibia. Furthermore, the device and magnet can be incorporated into a brace, halter, clothing or other wearable article, to be worn by the user. The device and magnet can also be implanted into the animal. For example, the device can be inserted into the subcutaneous space, and a magnetic bone screw can be used in lieu of a traditional magnet.

Figure 7 shows, for the purpose of illustration and not limitation, exemplary data related to joint angle of a pig stifle joint (pig knee). Fig. 7A shows a plot of magnetic field verse flexion angle. Fig. 7B shows a plot of average flexion angle verse time for ten isolated steps. Fig. 7C shows flexion angle verse time for four continuous steps. In practice, the device and magnet can be attached to the hind limb proximal and distal to the stifle joint, respectively. The stifle can be manually flexed to angles of 20° (hyperextension), 30°, 60°, and 90°. The position can be held for 5 seconds at each angle and the magnetic field strength can be recorded at 8 Hz. An equation relating sensor-magnet angle as a function of magnetic field magnitude can be derived to predict flexion angle. The animal can be allowed to freely ambulate within a pen and the magnetic field strength can be recorded. Ten individual steps can be used to obtain the range of motion and can be visually confirmed with synchronized camera. The animal shown in Fig. 7 ambulated at a step frequency of approximately 1.25 Hz. The dynamic range of motion of the stifle during the gait cycle was 55+13°, with a peak flexion angle of 101+4°. Neutral stance flexion angle (the animal standing still) was measured as 53+13° and is indicated by the dashed line in Figs. 7 B and C. These values are consistent with previously reported porcine range of motion.

Fig. 8 shows, for the purpose of illustration and not limitation, example data from detecting short-term activity results in an animal model. In the example of Fig. 8, the device was attached to a harness worn by a castrated male Yucatan minipig (26 kg) pre- and post-surgery in an unrelated study involving bilateral arthrotomy of the stifle. Data was collected at 8 Hz for 30 minutes of unsupervised activity in a 4' x 6' pen on day -1 (pre-operative) and post-operative days 1, 2, and 7, with analgesics given for the first 5 days. Angular velocity (^{o}/s) parallel to the dorsal plane (animal turning left or right) was recorded and the absolute values binned into four activity intensity levels: 0-5 (rest), 5-50 (low), 50-100 (moderate), and >100 (high).

On day -1 (pre-operative), the animal had full range of motion and baseline assessment was characterized by rest (49.6%) and low (45.1%) intensity activity, punctuated by short periods of moderate (4.9%) and high (0.4%) intensity activity. On days 1 and 2 (post-operative), the animal was predominantly sedentary (96% rest) and ambulated slowly with a stiff and limping gait (4% low intensity activity). By day 7, the animal had partially regained its baseline range of motion and activity level, such that low (24%) and moderate (0.9%) intensity activity accounted for a quarter of the test period.

Figure 9 shows, for the purpose of illustration and not limitation, example data from detecting long-term activity results in an animal model. In the example in Fig. 9, the device was attached to a harness worn by a castrated male Yucatan minipig (26 kg) pre- and post-surgery in an unrelated study involving bilateral arthrotomy of the stifle. Data was collected at 8 Hz for 30 minutes of unsupervised activity in a 4' x 6' pen pre-operatively on day -1 (baseline) and post-operatively on day 1 and weekly thereafter until euthanasia at week 12. Angular velocity (^{o}/s) parallel to the dorsal plane (animal turning left or right) was recorded and the absolute values binned into four activity intensity levels: 0-5 (rest), 5-50 (low), 50-100 (moderate), and >100 (high).

On day -1 (baseline), the animal had full range of motion and activity was characterized by rest and low intensity activity, with short periods of moderate and high intensity activity. Immediately post-operative on day 1, the animal was primarily sedentary and ambulated with a stiff, limping gait. The animal had regained 50% of its pre-operative non-rest activity level by week 1, and was fully recovered by week 3. Non-rest activity levels were maintained until week 10, when it slightly decreased.

Figure 10 shows, for the purpose of illustration and not limitation, a flow chart of an exemplary method (1000) of analyzing kinematics of a joint of an animal according to the disclosed subject matter. The method can include calibrating the magnetic sensor based on the exact configuration of the magnet and sensor at the time the device has been attached (1001). The calibration process can involve some sampling of the magnetic field while the joint is at prescribed angles. This can provide a function to be used for calculating a specific distance based on the measured magnetic field. The method can include using sensors on the sensor device to gather any relevant motion (1002). For example, the sensors can measure magnetic field, acceleration, and angular velocity. The signals can be filtered and motion parameters can be detected to identify joint motion (1003). For example, acceleration and angular velocity can be used to identify joint motion. The method can include correlating the measured magnetic field to a distance using the function obtained during step 1001 (1004). The distance measured can be used to calculate a joint angle (1005). This can be done given that the fixed magnet and sensor distances from the joint are known. The off-axis distance between the magnet and sensor can be calculated and trigonometry can be used to calculate the joint angle by knowing each side length of the triangle formed. The method can include calculating various joint and gait parameters (1006), such as angle of flexion and extension, angles of inward and outward rotation, stride length, swing time, stance time, gait symmetry, cadence, range of motion, and others. Data can be stored locally (1007) and/or transmitted wirelessly (1008), for example, to be presented to the user via a user interface. In some instances, the level of processing necessary for steps 1000-1006 can be larger than possible on a small, wearable device. In those cases, the unprocessed, raw data can be stored locally (1007) and/or transmitted wirelessly to a receiver (1008) where additional processing and analysis can be performed.

After the joint and gait parameters are calculated, the output can be simultaneously stored locally (1007) (for example, for backup purposes) and/or transmitted wirelessly (1008) to another system where it can be displayed to the user in an intuitive manner (e.g., charts, scores, recommendations or other related formats), or it can be further processed and analyzed. If the receiver is a mobile device (1009), the output can be presented on a mobile application interface (1012). The user can be allowed to share the output with others or the doctor can be allowed to provide recommendations (for example, via the internet) (1013). If the receiver is not a mobile device (1009), the data can be stored in a database of a base station (1010) and the output can be presented via a desktop graphical user interface, a website, or transmitted to a mobile application interface (however without a direct link between the wearable device and the mobile device).

The foregoing merely illustrates the principles of the disclosed subject matter. Various modification and alterations to the described embodiments will be apparent to those skilled in the art in view of the teachings herein. It will thus be appreciated that those skilled in the art will be able to devise numerous techniques which, although not explicitly described herein, embody the principles of the disclosed subject matter and are thus within the spirit and scope.

Claims

1. A joint analysis system for analyzing kinematics of an anatomical joint, the joint having a first side and a second side, the joint analysis system comprising:

   a sensor device, configured to be disposed on the first side of the joint, the sensor device having:

   one or more sensors;

   a processor coupled to the one or more sensors;

   a wireless data transmitter coupled to the processor;

   a data storage device coupled to the processor; and

   a battery coupled to the sensors, processor, wireless data transmitter, and data storage device;

   a magnet, configured to be disposed on the second side of the joint; and

   an analysis engine, configured to receive data from the sensors.

2. The system of claim 1, wherein the one or more sensors includes a magnetometer.

3. The system of claim 2, wherein magnetometer sensor is adapted to provide readings that are influenced by the magnetic field provided by the magnet to provide kinematic information of the joint.

4. The system of claim 1, wherein the one or more sensors includes an accelerometer.

5. The system of claim 1, wherein the one or more sensors includes a gyroscope.

6. The system of claim 1, wherein the one or more sensors are further configured to sense stride length.

7. The system of claim 1, wherein the one or more sensors are further configured to sense swing time.

8. The system of claim 1, wherein the one or more sensors are further configured to sense stance time.

9. The system of claim 1, wherein the one or more sensors are further configured to sense ambulation speed.

10. The system of claim 1, wherein the one or more sensors are further configured to sense distance traveled.

11. The system of claim 1, wherein the one or more sensors are further configured to sense gait symmetry.

12. The system of claim 1, wherein the one or more sensors are further configured to sense gait cadence.

13. The system of claim 1, wherein the one or more sensors are further configured to sense joint kinematics.

14. The system of claim 1, wherein the one or more sensors are further configured to sense a disrupted pattern of ambulation.

15. The system of claim 1, wherein the data analysis engine is further configured to recognize an abnormal gait or behavior.

16. The system of claim 1, further comprising a base station, the base station comprising

a processor;

a data storage device coupled to the processor;

a user interface coupled to the processor; and

a wireless data transmitter coupled to the processor and configured to communicate with the wireless data transmitter of the sensor device.

17. The system of claim 16, wherein the base station further comprises a display.

18. The system of claim 1, wherein the sensor device and the magnet are configured to be worn by an animal or human.

19. The system of claim 1, wherein the sensor device and the magnetic are configured to be implanted in an animal or human.

20. A method of analyzing kinematics of an anatomical joint, comprising:

calibrating one or more sensors and a magnet relative the joint;

sensing a magnetic field with the calibrated sensors while the joint exhibits motion and angular velocity to generate a signal;

filtering signal noise, if any, from the signal and identifying joint motion based on the corresponding acceleration and angular velocity; and

calculating joint and gait kinematic parameters from the identified joint motion.

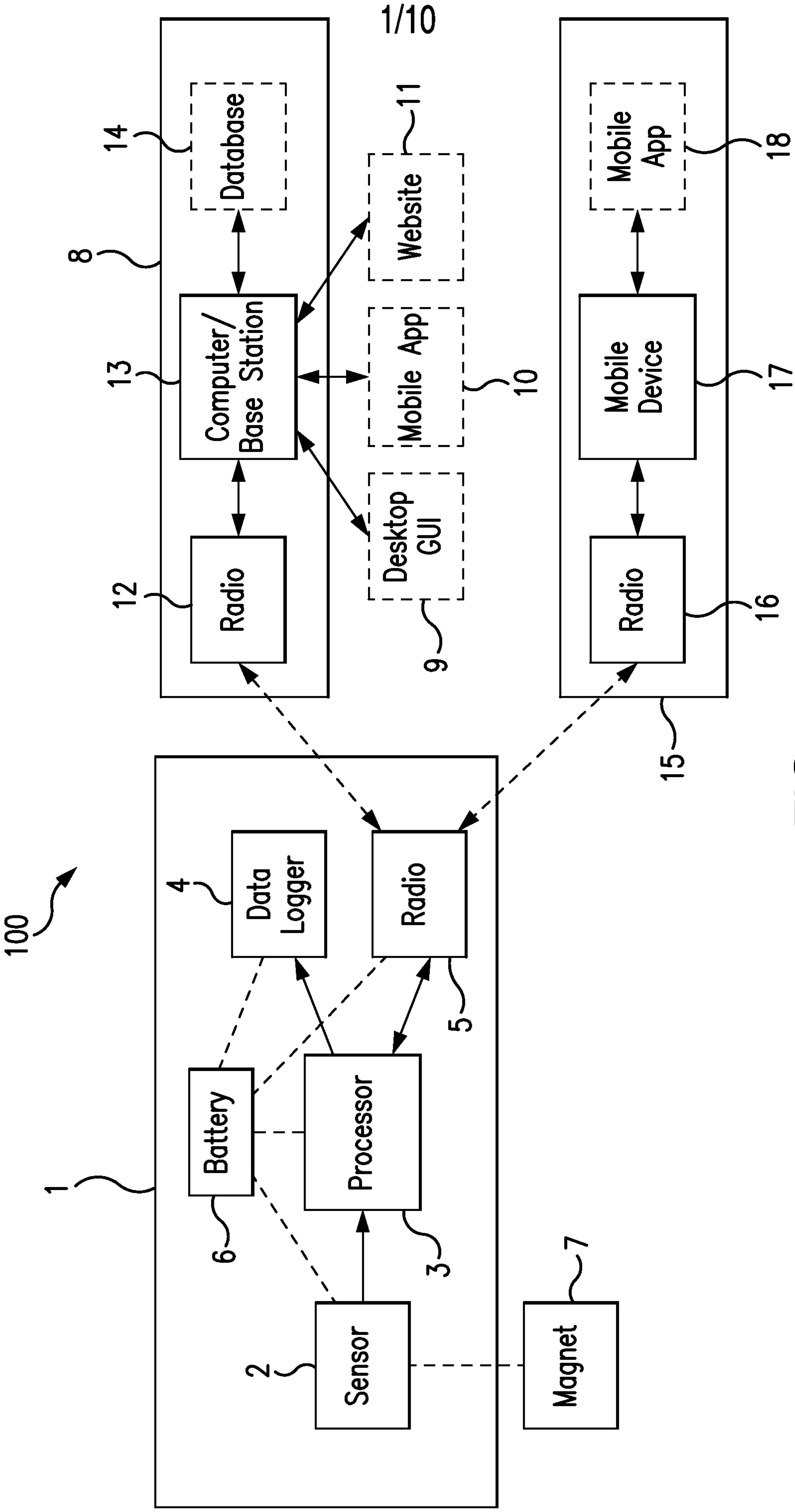
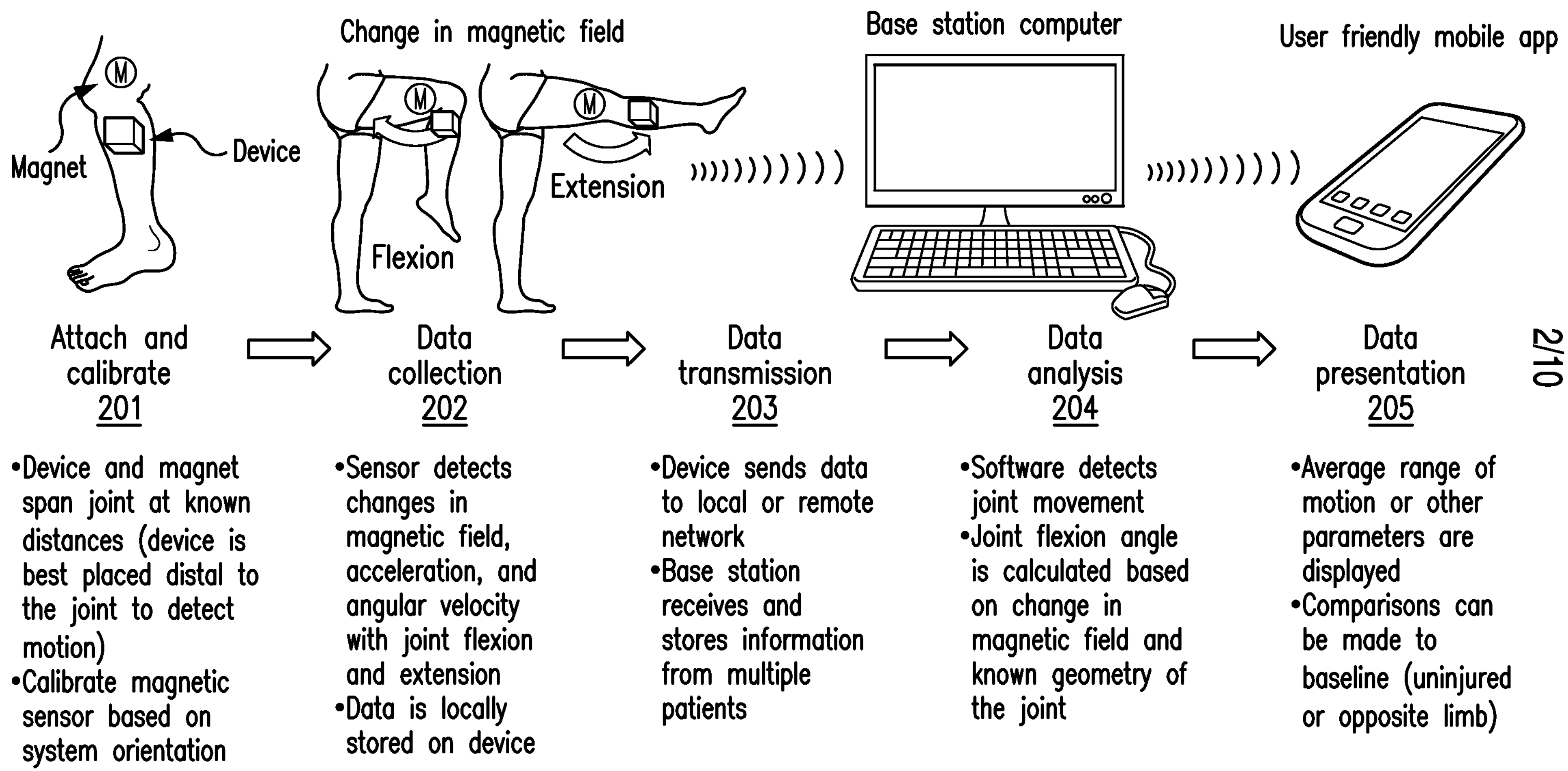

100
1
2
Sensor
Magnet
7
Battery
6
Processor
3
Data Logger
4
Radio
5
8
Radio
12
Computer/ Base Station
13
Database
14
Desktop GUI
9
Mobile App
10
Website
11
15
Radio
16
Mobile Device
17
Mobile App
18

FIG. 1



Change in magnetic field
Base station computer
User friendly mobile app
Magnet
Device
Flexion
Extension
Attach and calibrate 201
Data collection 202
Data transmission 203
Data analysis 204
Data presentation 205
•Device and magnet span joint at known distances (device is best placed distal to the joint to detect motion)
•Calibrate magnetic sensor based on system orientation
•Sensor detects changes in magnetic field, acceleration, and angular velocity with joint flexion and extension
•Data is locally stored on device
•Device sends data to local or remote network
•Base station receives and stores information from multiple patients
•Software detects joint movement
•Joint flexion angle is calculated based on change in magnetic field and known geometry of the joint
•Average range of motion or other parameters are displayed
•Comparisons can be made to baseline (uninjured or opposite limb)

FIG. 2

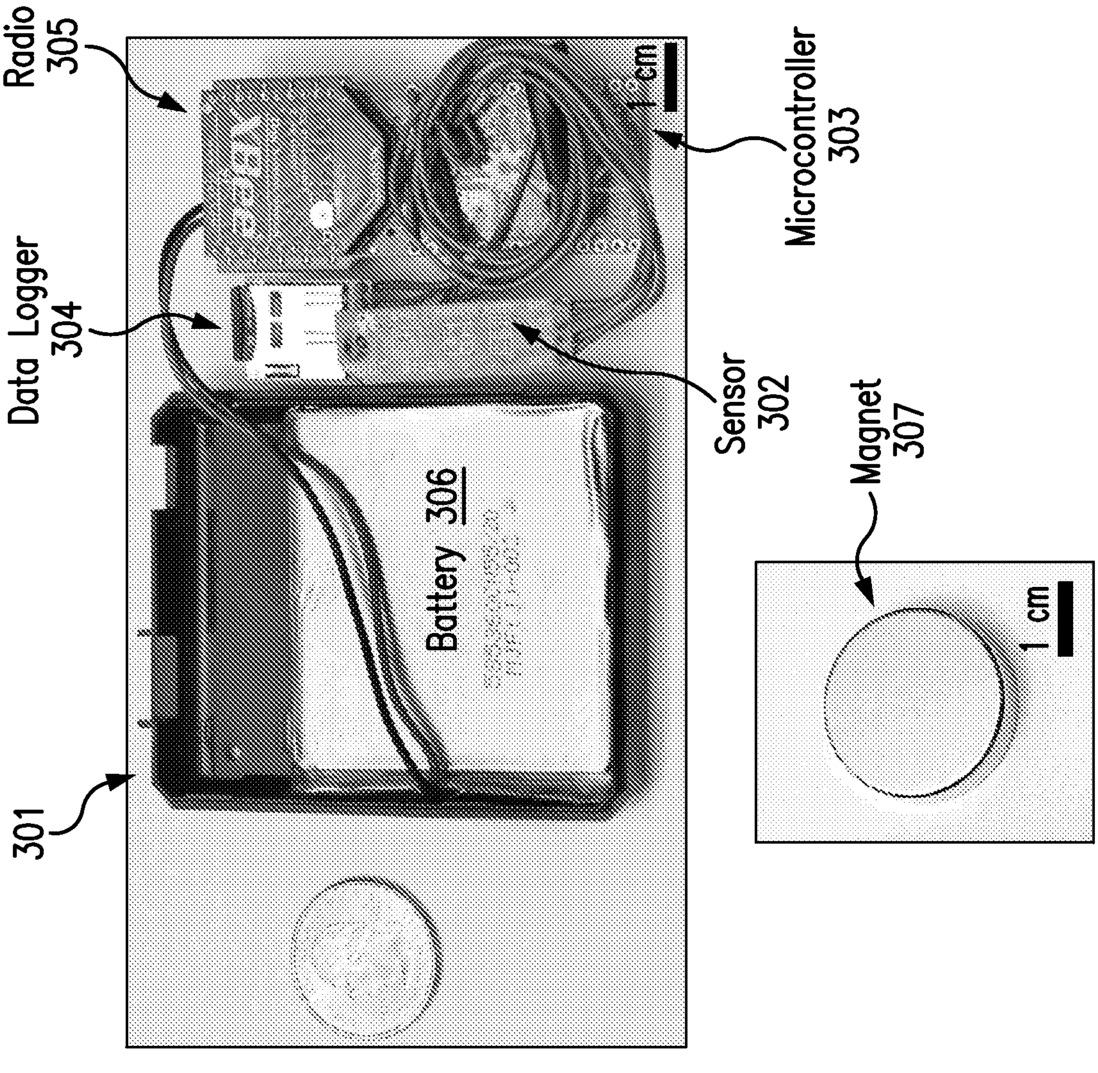

301
Data Logger
304
Radio
305
Battery 306
Sensor
302
Microcontroller
303
1 cm
Magnet
307
1 cm

FIG. 3A

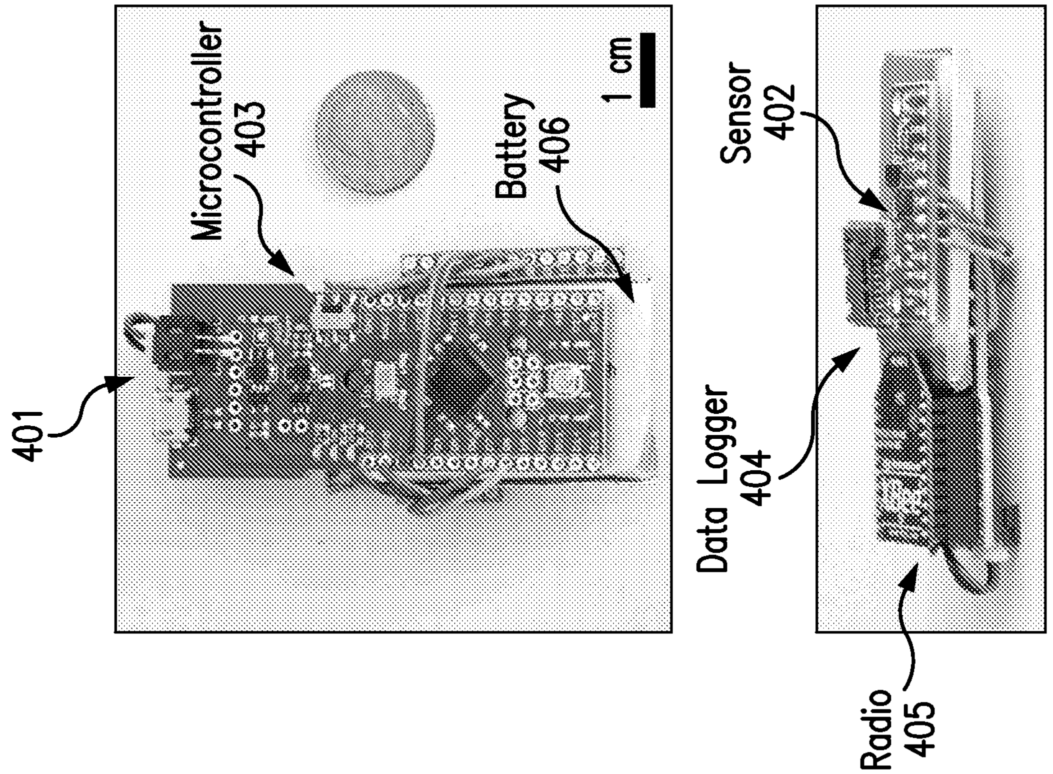

401
Microcontroller
403
Battery
406
1 cm
Data Logger
404
Sensor
402
Radio
405

FIG. 3B

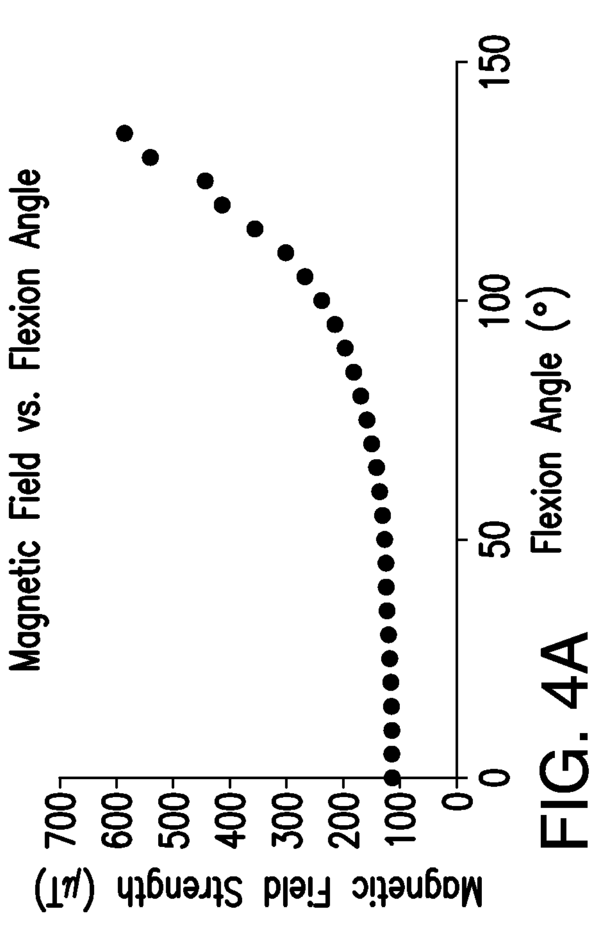


FIG. 4A

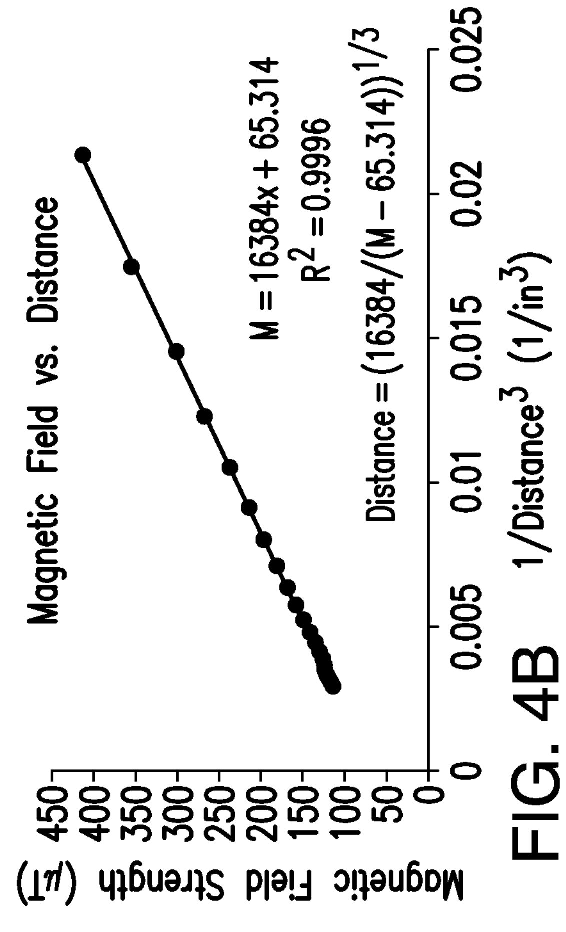


FIG. 4B

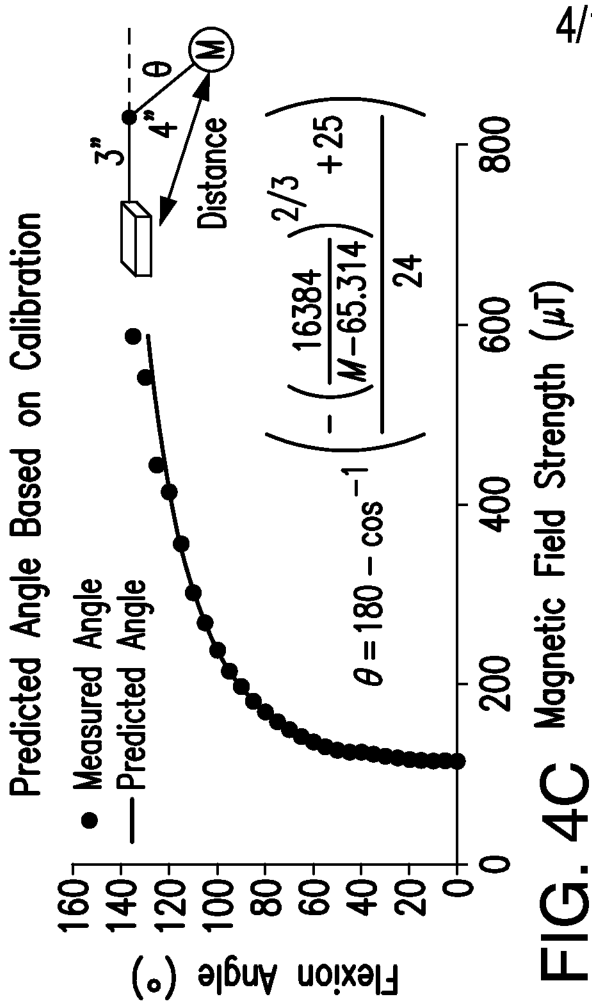


FIG. 4C

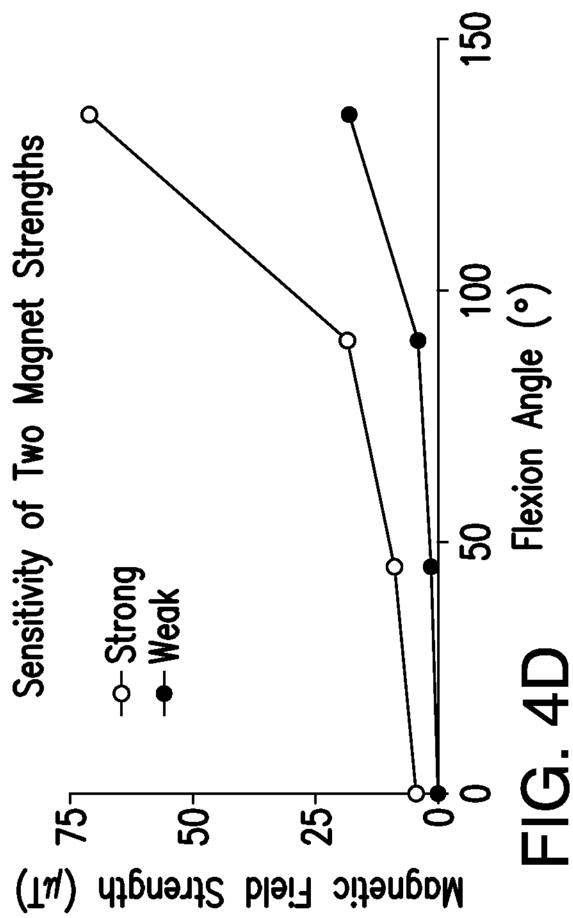


FIG. 4D

Detecting Joint Angle and Angular Velocity of a Human Knee

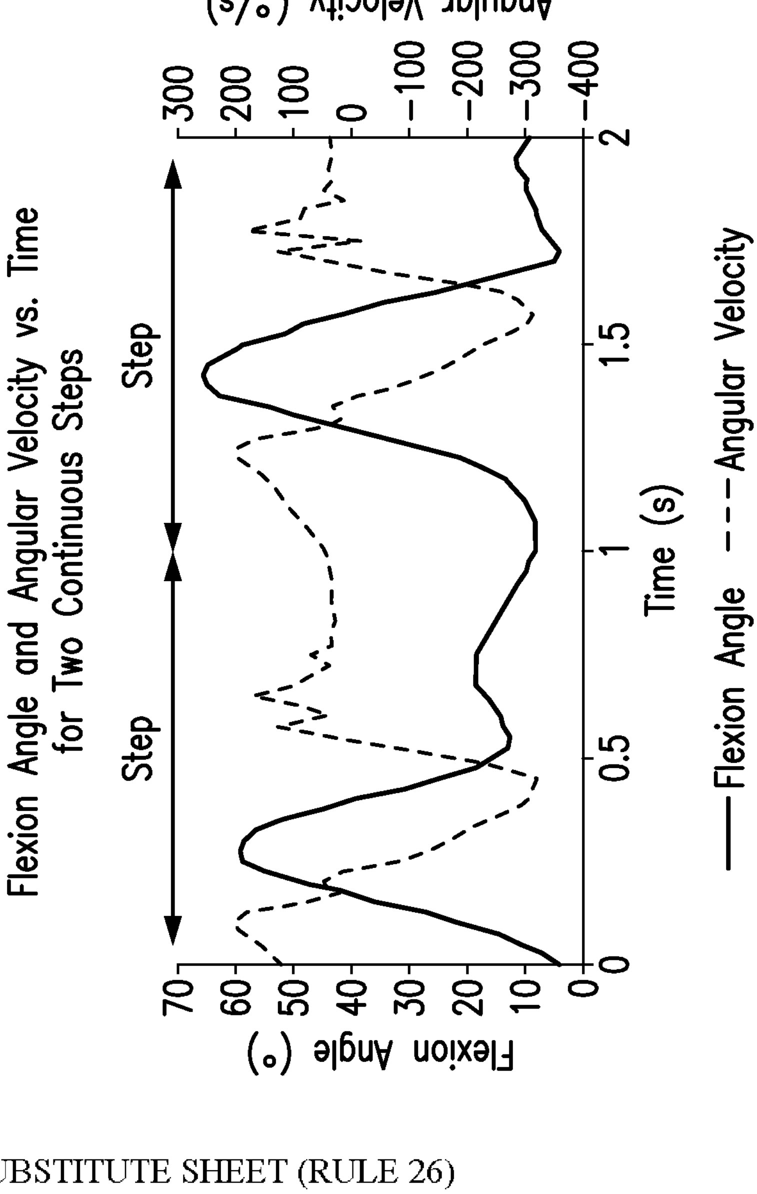


FIG. 5A

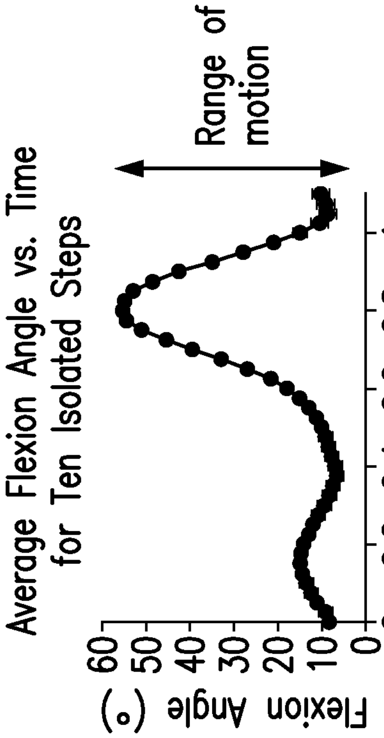


FIG. 5B

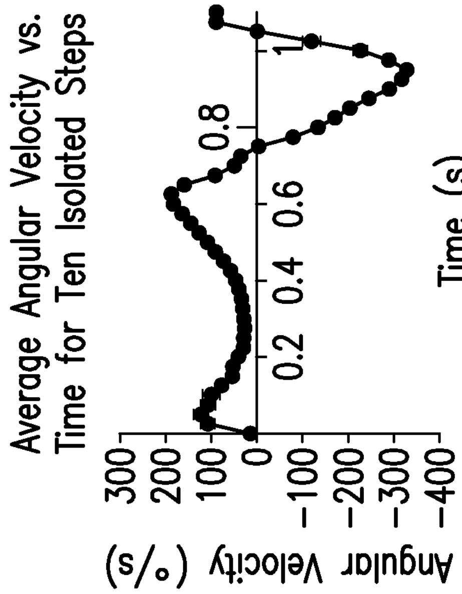


FIG. 5C

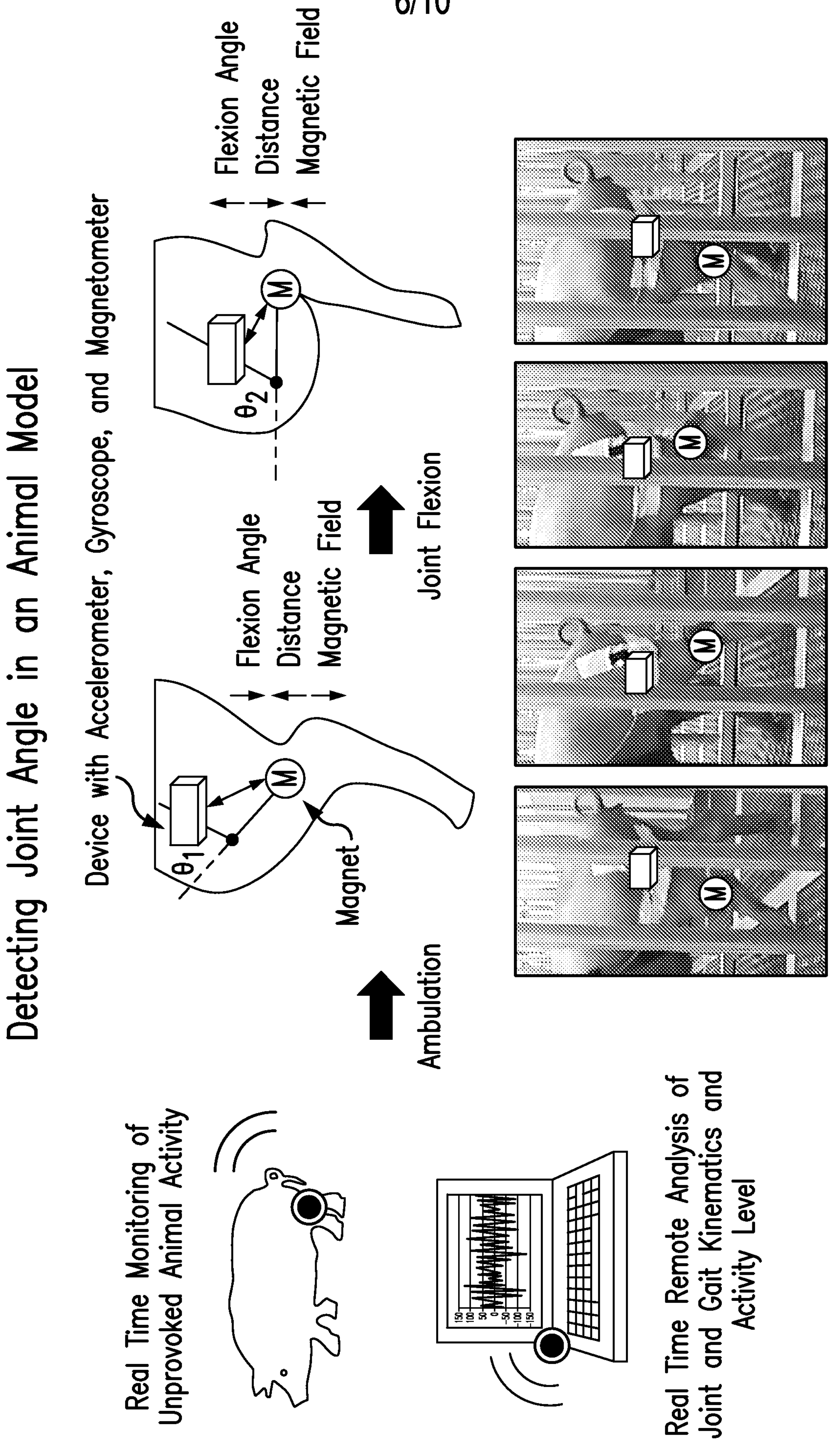

Detecting Joint Angle in an Animal Model
Device with Accelerometer, Gyroscope, and Magnetometer
θ_1
M
Magnet
Flexion Angle
Distance
Magnetic Field
θ_2
M
Flexion Angle
Distance
Magnetic Field
Ambulation
Joint Flexion
M
M
M
M
Real Time Monitoring of Unprovoked Animal Activity
150
100
50
0
-50
-100
-150
Real Time Remote Analysis of Joint and Gait Kinematics and Activity Level

FIG. 6

Detecting Joint Angle in an Animal Model

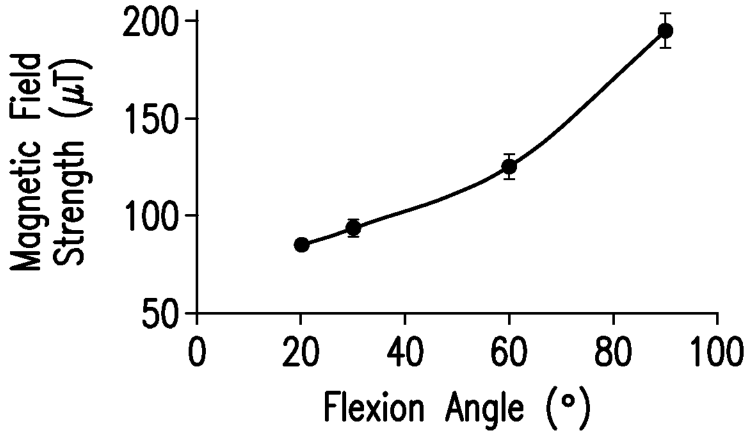


FIG. 7A

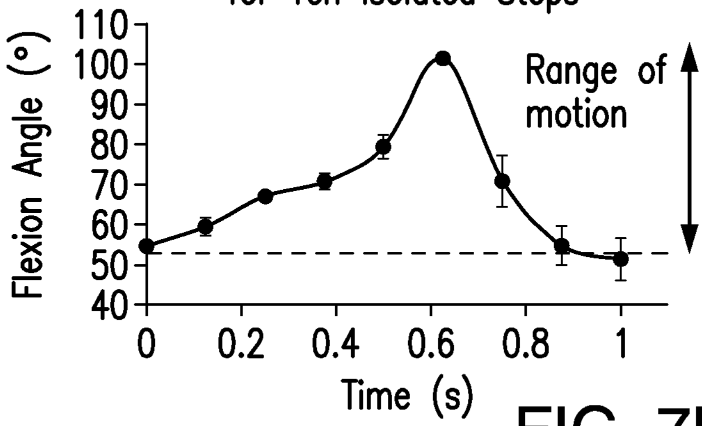


FIG. 7B

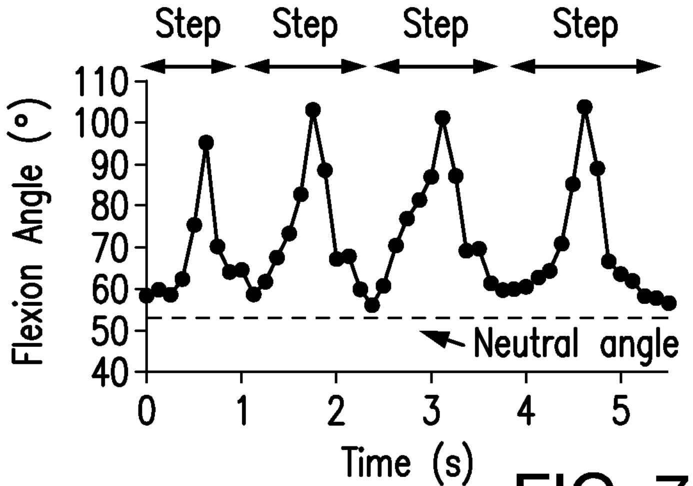


FIG. 7C

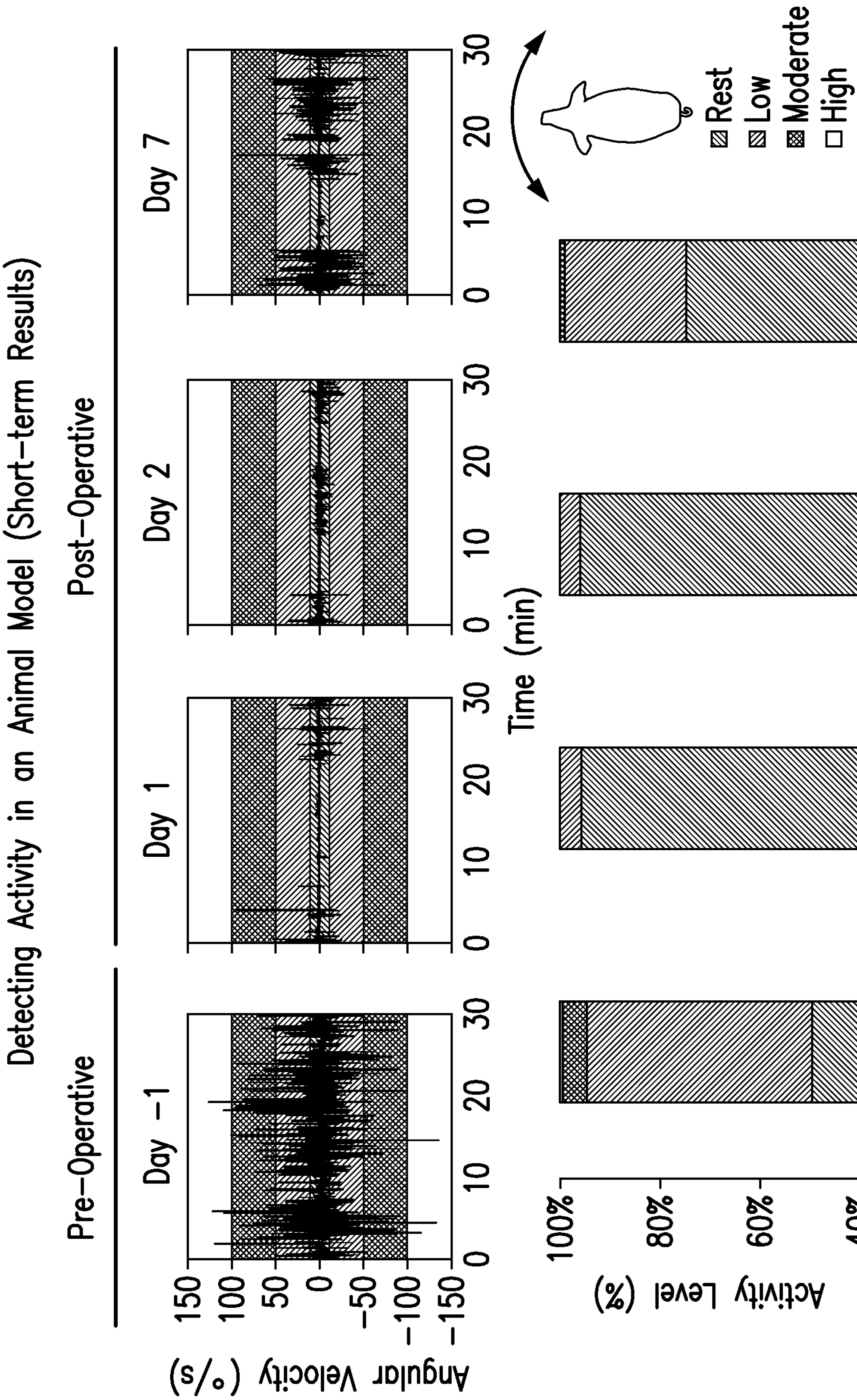

Detecting Activity in an Animal Model (Short-term Results)
Pre-Operative
Post-Operative
Day −1
Day 1
Day 2
Day 7
Angular Velocity (°/s)
150
100
50
0
−50
−100
−150
0
10
20
30
Time (min)
Activity Level (%)
100%
80%
60%
40%
Rest
Low
Moderate
High

FIG. 8

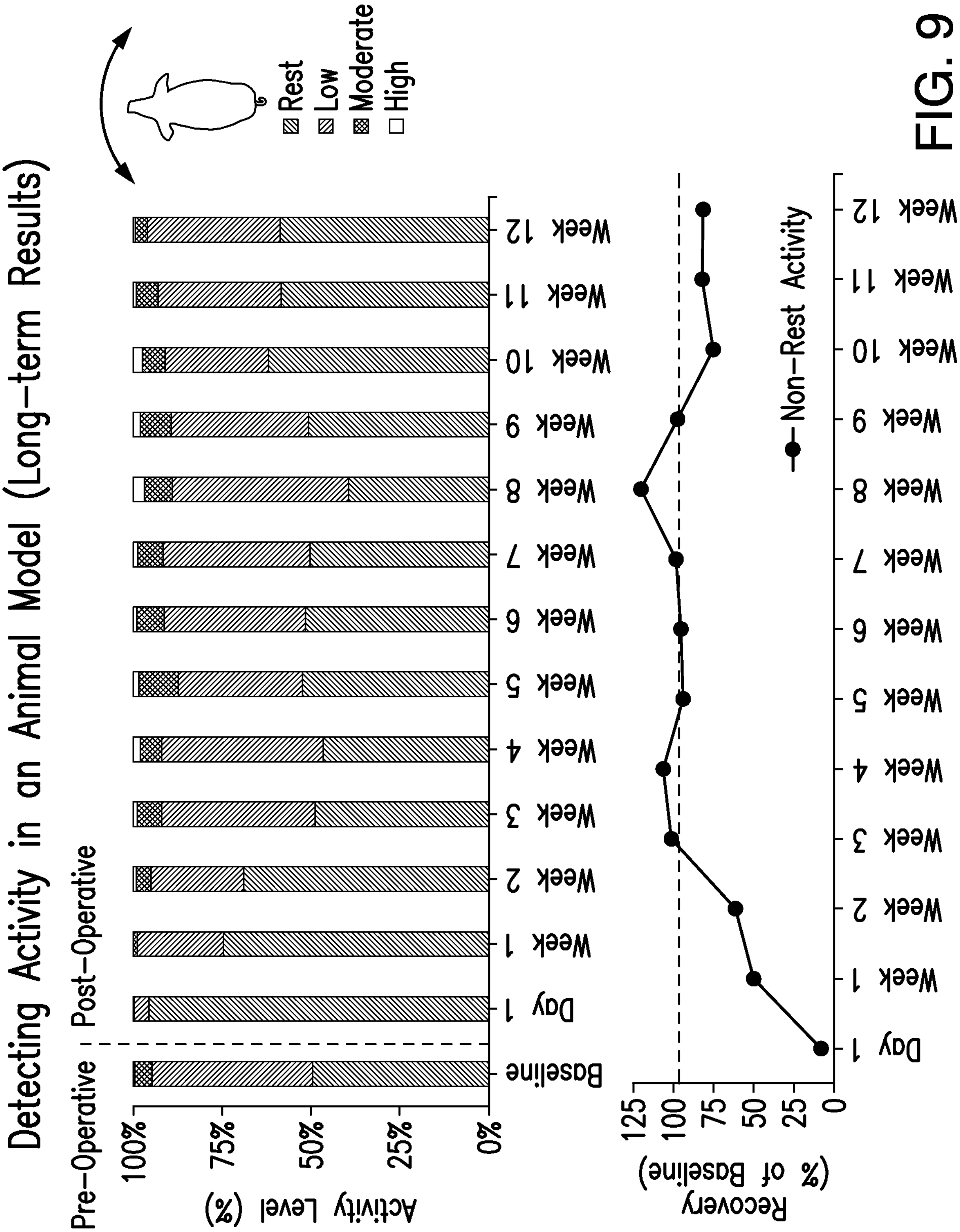

Detecting Activity in an Animal Model (Long-term Results)
Pre-Operative
Post-Operative
Activity Level (%)
100%
75%
50%
25%
0%
Baseline
Day 1
Week 1
Week 2
Week 3
Week 4
Week 5
Week 6
Week 7
Week 8
Week 9
Week 10
Week 11
Week 12
Rest
Low
Moderate
High
Recovery (% of Baseline)
125
100
75
50
25
0
Non-Rest Activity

FIG. 9

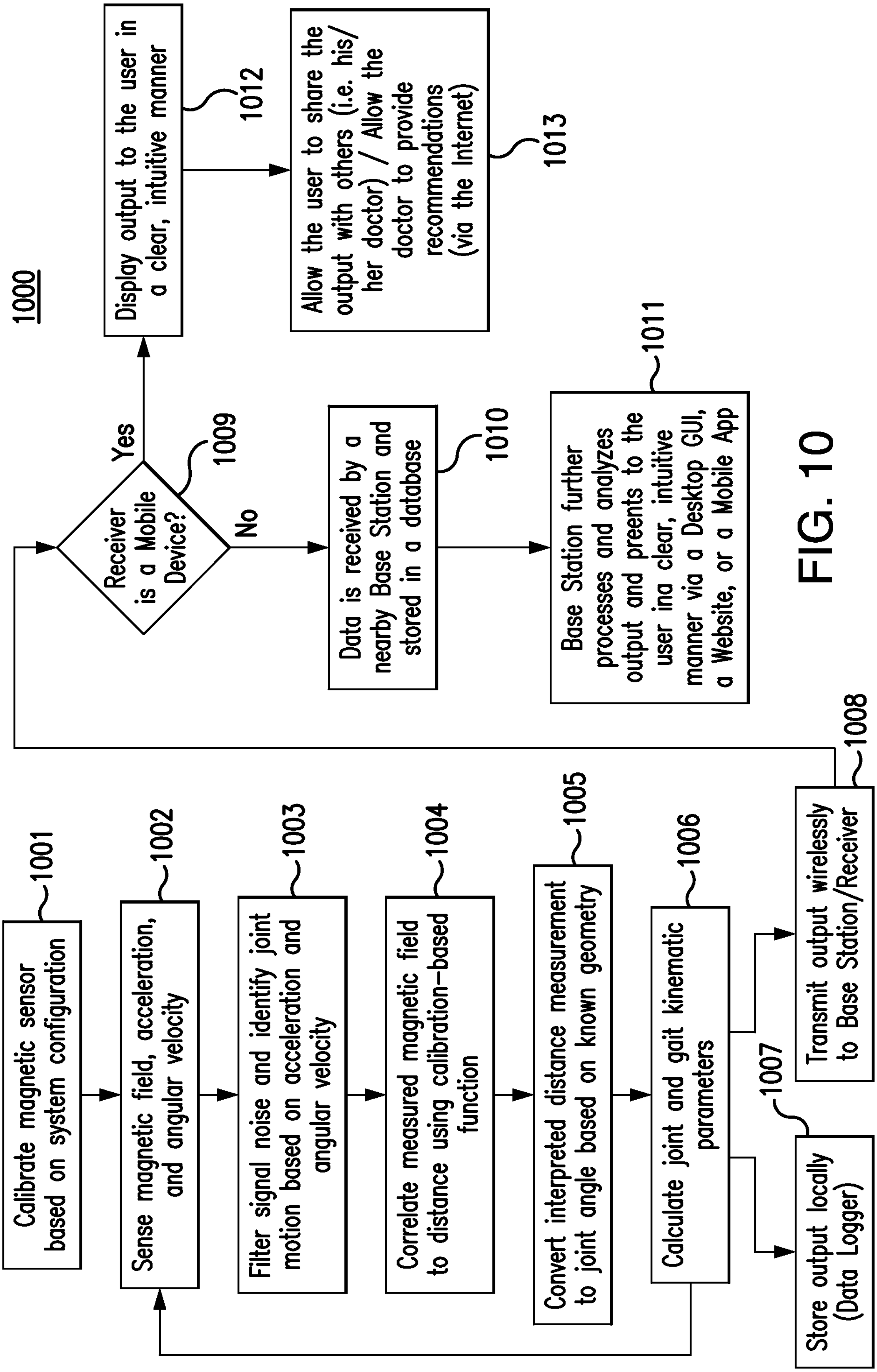

1000
Calibrate magnetic sensor based on system configuration
1001
Sense magnetic field, acceleration, and angular velocity
1002
Filter signal noise and identify joint motion based on acceleration and angular velocity
1003
Correlate measured magnetic field to distance using calibration–based function
1004
Convert interpreted distance measurement to joint angle based on known geometry
1005
Calculate joint and gait kinematic parameters
1006
Store output locally (Data Logger)
1007
Transmit output wirelessly to Base Station/Receiver
1008
Receiver is a Mobile Device?
1009
Yes
No
Data is received by a nearby Base Station and stored in a database
1010
Base Station further processes and analyzes output and preents to the user ina clear, intuitive manner via a Desktop GUI, a Website, or a Mobile App
1011
Display output to the user in a clear, intuitive manner
1012
Allow the user to share the output with others (i.e. his/her doctor) / Allow the doctor to provide recommendations (via the Internet)
1013

FIG. 10

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 15/46337

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 5/11 (2015.01)
CPC - A61B 5/4528; A61B 5/4585; A61B 5/112; A61B 5/1121; A61B 5/1122; A61B 5/1123; A61B 5/1126
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(8) - A61B 5/11 (2015.01)
CPC - A61B 5/4528; A61B 5/4585; A61B 5/112; A61B 5/1121; A61B 5/1122; A61B 5/1123; A61B 5/1126

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
UPC: 600/595; CPC: A61B 5/11, 5/110*, 5/111*, 5/112*, 5/113*
*(Search term limited; see below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWest (PGPB, USPT, EPAB, JPAB); Google; PatBase (All);
Search Terms: Kinematics, gait, Magnet*, ferromagnet*, magnometer, magnetometer, sensor, transducer, monitor, flux, field, permanent magnet, accelerometer, gyroscope, swing, stance, stride, length, distance, duration, time, period, gait, ambulation, wear, worn

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2010/0249576 A1 (ASKARINYA et al.) 30 September 2010 (30.09.2010) Entire document, especially Abstract, para[0002], para[0060]- para[0065], para[0111], para[0163] and FIGS. 3-4.	1-4, 13, 16-18 -------------------- 5-12, 14-15, 20
X	US 2005/0010301 A1 (DISILVESTRO et al.) 13 January 2005 (13.01.2005) Entire document, especially Abstract, para[0061]- para[0065], para[0070], para[0081]- para[0082], para[0091]- para[0092] and FIG. 1.	1, 19
Y	US 2006/0271199 A1 (JOHNSON) 30 November 2006 (30.11.2006) Entire document, especially Abstract, para[0017].	5
Y	US 2013/0131555 A1 (HOOK et al.) 23 May 2013 (23.05.2013) Entire document, especially Abstract, para[0033]- para[0038], para[0067], para[0077].	6-12, 14-15, 20
A	US 2012/0130280 A1 (LEE) 24 May 2012 (24.05.2012) Entire document.	1-20
A	US 2013/0324888 A1 (SOLINSKY) 05 December 2013 (05.12.2013) Entire document.	1-20
A	US 2010/0125229 A1 (RUDOLPH et al.) 20 May 2010 (20.05.2010) Entire document.	1-20
A	US 2003/0083596 A1 (KRAMER et al.) 01 May 2003 (01.05.2003) Entire document.	1-20
A	US 6,334,852 B1 (SEYL) 01 January 2002 (01.01.2002) Entire document.	1-20

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
02 October 2015 (02.10.2015)	23 NOV 2015
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-8300	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774