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(54) ACTIVE ORTHOSIS FOR THE MOTION NEUROLOGICAL REHABILITATION OF LOWER LIMBS, SYSTEM COMPRISING SUCH ORTHOSIS AND PROCESS FOR OPERATING SUCH SYSTEM

AKTIVBANDAGE FÜR DIE MOTORISCHE NEUROREHABILITATION DER BEINE, SYSTEM MIT EINER DERARTIGEN AKTIVBANDAGE UND VERFAHREN ZUM BETRIEB EINES SOLCHEN SYSTEMS

ORTHÈSE ACTIVE POUR LA RÉADAPTATION NEUROLOGIQUE DES MOUVEMENTS DE MEMBRES INFÉRIEURS, SYSTÈME COMPRENANT UNE TELLE ORTHÈSE ET PROCÉDÉ DE MISE EN OELIGUVRE D'UN TEL SYSTÈME

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Description

[0001] The present invention refers to an active orthosis for the motion neurological rehabilitation of lower limbs, to a system comprising such orthosis and to a process for operating such system.

[0002] The prior art in the field of active exoskeletons used in motion rehabilitation of lower limbs in general has only machines with fixed station, with exoskeleton constrained thereto. They are in general rather rigid and heavy machines, that block some physiologic motions of the human walk and that allow treatments in general only on treadmill, with patient in general only with partial weight discharge. In almost no cases there is the ankle activation, and even less the chance of activating it in the same machine. The collected examples are sometimes also inadequate to control the actual man-machine interaction, with consequent generation of dynamic actions that cannot absolutely be controlled. Very often the patient has many difficulties in wearing the exoskeleton, thing that impair the correct and easy use of the system. The found example, moreover, have, with respect to the invention as described below, a strong lack of versatility in accommodating different pathologies and clinic protocols of various natures with a single system.

[0003] As known prior art, the following patents have been deemed pertinent, but not relevant, for the present invention:

- US-B-6,666,831 *"Method, apparatus and system for automation of body weight support training (BWST) of biped locomotion over a treadmill using a programmable stepper device (PSD) operating like an exoskeleton drive system from a fixed base",* December 2003
  Such patent refers to a rehabilitation system with fixed station using only the treadmill, and to an exoskeleton directly integrated with the fixed structure. It is based on external robotic arms, with telescopic and rotation movements, linked to the frame. There are also acceleration, force and torque sensors. A special shoe is used, equipped with sensors, to monitor the contact with the ground. The movement is imposed only on the sagittal plane, in a rigid way. The system according to the present invention, with respect to the one in this patent, allows treating a wider spectrum of pathologies with different therapeutic cases, not being compulsorily linked to a fixed station and having an exoskeleton that has been more recently and originally conceived.
- US-A-2004/0116839 *"Gait training apparatus",* June 2004
  This patent shows a fixed rehabilitation station with a very simple exoskeleton constrained to the fixed frame. This requires, among other things, a not very easy procedure to be worn on the patient. There are rotations of hip, knee and ankle, however obtained with a single linear motor, instead of two actuators connected in an acting/counteracting way, like the system according to the present invention.
  Differently from this latter one, the system of document US-A-2004/0116839 has a rather complex system for anthropometrical adjustments, with linear motors and adjusting mechanisms, which makes the physiotherapist work more complex and longer. Moreover, the system stiffness can produce forces on the patient's legs, while the use of linear actuators for adjusting femur and tibia segments does not guarantee the position, unless a mechanical brake is applied onto the cylinder. It is therefore a globally very complex and heavy structure, differently from the system according to the present invention.
- US-A-0143198 *"Powered gait orthosis and method of utilizing same",* July 2004
  This patent has a fixed rehabilitation station with exoskeleton constrained to the fixed structure. No modes are allowed for various types of walks, apart the one on treadmill with partial weight discharge. No motions are allowed outside the sagittal plane, thereby making a much more limited and rigid structure than the system according to the present invention. There is no ankle activation.
- US-B-7,041,069 *"Improved powered gait orthosis and method of utilizing same",* May 2006
  This patent, evolution of the previous one, has a fixed rehabilitation station with exoskeleton constrained to the fixed structure. No modes are allowed for various types of walks, apart the one on treadmill with partial weight discharge. No motions are allowed outside the sagittal plane, thereby making a much more limited, heavy and rigid structure than the system according to the present invention. There is no ankle activation. It is not easy to wear the patient.
- US-B-7,125,388 *"Robotic gait rehabilitation by optimal motion of the hip",* October 2006
  This patent has a fixed rehabilitation station with actuators, constrained to the base, that impose the motion to the patient pelvis. The system is used both to reactivate such motion and possibly for monitoring it. The patient arms are free and there is no actual driving exoskeleton. The system is based on the use of a treadmill, with patient always in suspension. Its conception and structure are very different from the system according to the present invention
- US-B-7,190,141 *"Exoskeleton device for rehabilitation",* March 2007
  At first sight, this patent seems to show a system similar to the one according to the present invention, but deep differences appear immediately evident. The exoskeleton has no ankle activation and seems more suitable for walking on place, instead of a trend of various rehabilitation protocols. It is focused on the concept of two-feet robot, forgetting the man-machine interaction, which can be foreseen with difficulty even by a sophisticated control system, especially for dynamic contributions. In this case, the patient is treated, therefore, as an inter object, without reaction capabilities. The system according to the present invention, instead, derives from the chance of exerting on the

patient various motion therapies, all comprising the effect of a personal contribution. Such effect is better pointed out, by lowering the working pressure of the exoskeleton, and thereby studying the autonomous walking capabilities of the examined patient.

- US-A-2007/0056592 *"Semi-powered lower extremity exoskeleton",* March 2007
  This patent has a walk-helping device, more than an actual rehabilitation exoskeleton. The system is semi-active, with the only activation of the knee joint. Conception and objects are different with respect to the system according to the present invention.
- US-B-7,33,906 *"Apparatus and method for repetitive motion therapy",* February 2008
  This patent has a fixed rehabilitation station with actuators, constrained to the base, and a treadmill. The actuators are fixed to the patient's legs, to which they impose a motion to be coordinated also with the treadmill speed, according to a scarcely physiological logic and with balance problem for the patient. There is no actuation on the ankle articulation, nor of various types of walk, unless with partial weight discharge through BWS. The exoskeleton has a different conception with respect to the system according to the present invention and is moreover stiffer and less versatile.
- US-A-0255488 *"Powered orthosis",* October 2008
  This patent has a fixed rehabilitation station with actuators, constrained to the base, and a treadmill. There is no actuation on the ankle articulation, The control system is complex and cumbersome, more typical of a robotic structure than of a rehabilitation exoskeleton, requiring suitable sensors and periodic calibrations. A strong maintenance action is thereby required, differently from the system according to the present invention. The motion is allowed only on the sagittal plane. Not using the principle of the acting/counteracting muscle, the structure requires more encumbrant and heavier actuators, taking to a rigid and scarcely versatile system, in addition to having strong friction actions. The exoskeleton has a different conception with respect to the system according to the present invention.
- US-A-0071442 *"Robot for walk training and operating method thereof",* March 2011
  The patent has a rehabilitation system with fixed station with exoskeleton constrained to the structure and to the patient on treadmill, with partial weight discharge through BWS, single possible treatment mode, differently from the versatility characteristic of the system according to the present invention. There is no actuation on the ankle articulation. The patent contains more a summarily description of a possible rehabilitation method than a presentation of an original machine. It is a system with a different conception with respect to the system according to the present invention.
- US-B-7,947,004 *"Lower extremity exoskeleton",* May 2011
  The patent is a revision of US-A1-2007/0056592. It is anyway referred to a walk-helping device, more than an actual rehabilitation exoskeleton. The system is semi-active with the single activation of the knee joint. It has different conception and objects from the system according to the present invention.

[0004] US2011/0066088 and US5282460 disclose orthoses according to the preamble of Claim 1.

[0005] Therefore, object of the present invention is solving the above prior art problems, by providing an active orthosis for motion neurological rehabilitation of the lower limbs, that allows treating clinical problems such as hemiplegia, tetraparesis, hemiparesis, comprising ictus, ischemia, brain haemorrhage, partial lesions of the spinal cord, with extension, in some cases, to muscle dystrophy and to motion degenerative pathologies. Such active orthosis is further useful in exercises and studies for motor learning that can also be applied on healthy individuals. The above described orthosis does not need the use of a treadmill, has a relatively simple, light-weight, compact, cheap and flexible construction, which can be easily controlled and used also by users with various types of motion difficulties.

[0006] The versatility of the active orthosis of the invention allows it anyway to possibly work both in a traditional way, namely in suspension, and on the ground, with patient motion in a room and partial weight discharge.

[0007] A further object of the present invention is providing a system comprising the above described orthosis, that, in addition to the advantages of the orthosis as described above, is equipped with a plurality of operating, maintenance, diagnostic and analysis functionalities, that make its application open to several solutions in the diagnostic, therapeutic, rehabilitation and research fields, both in medicine and in neurology.

[0008] Another object of the present invention is providing a process for operating the above described system.

[0009] The above and other objects and advantages of the invention, as will appear from the following description, are obtained with a orthosis like the one claimed in claim 1, a system equipped with such orthosis and a process for operating such system, as claimed in their respective claims. Preferred embodiments and non-trivial variations of the present invention are the subject matter of the dependent claims.

[0010] It is intended that all enclosed claims are an integral part of the present description.

[0011] The present invention will be better described by some preferred embodiments thereof, provided as a non-limiting example, with reference to the enclosed drawings, in which:

- Figure 1 is a perspective view of a preferred embodiment of the orthosis of the present invention;
- Figure 2 is a schematic view of the main components of the inventive system;
- Figure 3 is a view similar to Figure 1, that shows only a part of the inventive orthosis for a leg;
- Figure 4 is a side perspective view of Figure 3;
- Figure 5 is a side view of Figure 3;
- Figure 6 is a side perspective view of Figure 3, seen on the opposite side with respect to Figure 4;
- Figure 7 is a partial perspective view of the inventive orthosis in its part applied to the legs and in a movement position;
- Figure 8 is a perspective detailed view of a possible embodiment of the handle of the inventive system;
- Figure 9 is a detailed perspective view of a further embodiment of the handle of the inventive system;
- Figure 10 is an exploded perspective view of the handle of Figure 9;
- Figure 11 is a detailed perspective view of the handle of Figure 9;
- Figure 12 is a perspective view of a part of the handle of Figure 9;
- Figure 13 is a perspective view of the connection between handle, corset and hip joint;
- Figure 14 is an exploded perspective view of a possible embodiment of the joint for the hip articulation;
- Figure 15 is a perspective view of the external part of the joint for the hip articulation;
- Figure 16 is a perspective view of the placement of the pneumatic cylinders on the hip joint and of the ball knot at the end of the cylinder stem;
- Figures 17 to 19 are three side views of three possible operating positions of hip moving cylinders;
- Figure 20 is an exploded perspective view of the assembly of the hip moving cylinders;
- Figure 21 is a perspective view of the hip moving cylinders in their assembling position;
- Figure 22 is a perspective view to show the relative motion between femur slider and its guide;
- Figure 23 is a perspective view of a detail of Figure 22;
- Figure 24 is a perspective detailed view of Figure 22, from the opposite side with respect to Figure 23 and with assembled cylinders;
- Figure 25 is an exploded perspective view of the knee articulation joint;
- Figure 26 is an exploded perspective view of the orthosis part applied to calf and femur;
- Figure 27 is a perspective view of the lower part of the orthosis with the ankle-moving cylinder;
- Figure 28 is a view showing the rest configuration with the femur segment aligned with the tibia segment;
- Figure 29 is a view showing the flexing conditions of the tibia segment of Figure 28 with respect to the femur segment;
- Figure 30 is an exploded perspective view of the ankle articulating joint;
- Figure 31 is a side perspective view of the lower part of the inventive orthosis to be applied to the left leg of a patient;
- Figure 32 shows three side operating positions of the ankle movement obtained through the inventive orthosis;
- Figure 33 is an exploded perspective view of the lower part of the inventive orthosis for moving the ankle;
- Figure 34 is a schematic diagram of a preferred configuration of the ground box of the inventive system;
- Figure 35 is a preferred electro-pneumatic diagram of the inventive system;
- Figure 36 is a graph showing the angular behaviour of the hip articulation referred to the right leg (curve with solid line) and the left leg (dashed curve); and
- Figures 37 to 39 are side schematic views of possible operating positions of the inventive orthosis.

[0012] With reference to the Figures, some preferred embodiments of the orthosis, the system and the process according to the present invention are shown and described. It will be immediately obvious that numerous variations and modifications (for example related to shape, sizes, arrangements and parts with equivalent functionality) could be made to what is described, without departing from the scope of the present invention, as appears in the enclosed claims.

[0013] The invention deals, first of all, with an active orthosis 1, preferably with electro-pneumatic drive, for the motion neurological rehabilitation of the lower limbs, wherein such orthosis 1 is equipped with at least four, and preferably six degrees of freedom for the movement respectively of the two hips, of the two knees and optionally of the two ankles of a patient 1'.

[0014] The invention further deals with a system 3 for the motion neurological rehabilitation of lower limbs that therefore substantially comprises: at least one active orthosis 1 of the above mentioned type; at least one control box 5; and at least one computer (preferably a personal computer) 28 to acquire and process data, and manage the sitting by an operator.

[0015] Going on now to describe in detail the subject matter of the present invention, it has also been called "P.I.G.R.O." (Pneumatic Interactive Gait Rehabilitation Orthosis) and it is a bio-mechanical device with at least four, and preferably six, degrees of freedom, aimed to the robotized neurological rehabilitation of lower limbs in patients lacking mobility for cranial traumas, ictus or other.

[0016] From a first global perspective of the system according to the present invention, two important features can be distinguished. The first one is the movement of the ankle, a very important articulation very relevant in the walking process, even if normally not present in other devices, and the second one is the chance of performing different reha-

bilitation cycles in suspension or on the ground without treadmill. The gait cycle is performed with the patient 1' initially lifted from the ground through a winch (Body Weight Support or BWS) .

[0017] Figure 2 shows all necessary elements for operating the system 3 according to the present invention. It is composed of a orthosis 1, adapted to support the patient 1' and actuated by pneumatic actuators controlled by solenoid valves, that contains, in the rear part of the structure, a control and interface box 22, with at least one supply duct 23 for compressed air and at least one electric connection cable 25, and a ground managing system 5, equipped with adequate means and with at least one computing machine. The compressed air supply comes from a compressor 24 with cable 29 or from a distribution network. In case of a single duct 23, there is a single supply for the two legs; in case of many ducts, the supply can be separate for the two legs or according to the different pneumatic actuators. Inside the interface box 22, there are also possible control cards, connected to electronic interface drivers placed in a control box 26 also containing acquisition cards, through a serial cable or a fire wire or Ethernet or a wireless system. With them, feedback and commands are exchanged for the solenoid valves and the electric supplies between orthosis and ground managing system 5. The real time control can be made with commercial components assembled according to an innovative logic, that provides for one or more control cards on board the orthosis 1 in the box 22 and one or more cards in the control box 26. This allows using a single PC 28 of a traditional type connected to the control box 26 with a cable 27. It contains a control software, that can be used by a user through a suitable graphic interface. The PC is single, but is normally equipped with two monitors: the monitor 31 is dedicated to operator's needs, while the monitor 32 is the system bio-feedback, useful both for the operator, and for the patient, for a self-diagnosis action during the rehabilitation sitting.

[0018] As regards structure and actuators, the system is composed of a modular exoskeleton with six degrees of freedom with actuation of the hip, knee and ankle articulations, with movement chances mainly in the sagittal plane. The supply system allows moving two independent "legs" through actuators placed in acting-counteracting position, preferably of the pneumatic type, fastened to the structure, that guarantee a safe movement since they avoid forcing situations towards the patient 1' in case of muscle contraction, reduced costs, simple managing and controlling architecture.

[0019] For operating the inventive system 3, a distribution network for compressed air is necessary, generally present in all hospitals, in which the system 3 will preferably operate. With the use of pneumatic actuators, preferred in the embodiment, the use of electric wires is avoided, together with all those safety problems associated therewith, and this is a more adaptive system to possible reactions produced by the patient. The use of hydraulics actuators is less suitable, since contamination is not allowed in the medical environments due to possible fluid leakages from the system, and anyway they would not be particularly advantageous in terms of controllability.

[0020] The two legs are joined at the pelvis height through a read handle 92 that can be adjusted in its width, that prevents their relative rotation and allows placing a box 22 containing the valve assembly for supply and the pneumatic cylinders exhaust, a distribution plate for compressed air and the control card to which input and output signals are connected between orthosis 1 and ground managing system 5.

[0021] In case of separate supply of compressed air to the two legs, the distribution plate contains two supply channels that connect the inputs of the valves controlling the right or left leg, separately. There are therefore two pressure reducers in the control box 26, to have the chance of independently adjusting the pressure in the two legs. Therefore, there are two supply tubes between control box 26 and box 22. Outputs of all exhaust valves are instead conveyed inside the box 22, allowing to attenuate noise and local cooling. The supply valves are digital, normally closed 2/2 solenoid valves, controlled by a Pulse Width Modulation, PWM system, that allows obtaining a flow-rate with variable behaviour when the cycle changes. In order to take care of extreme situations, and therefore allow movement freedom to the patient that is dressed with the orthosis 1, when he enters in an emergency situation, the exhaust valves are of the normally open 2/2 type. In this way,, in an emergency, the actuators are getting exhausted and the patient, though still dressing the orthosis 1, is free of moving the lower limbs according to current needs. For every cylinder chamber, one or more normally closed solenoid valves for supply, and one or more normally open solenoid valves for exhaust can be used.

[0022] As regards the geometry of the inventive system, both the legs, and the rear handle are made through means, composed for example of elements that are able to slide one over the others, with possible locking in the desired position, in order to change the length of the femur and tibia segments depending on the anthropometrical sizes of the patient 1'. The possible adjustments determine:

A - pelvis width
B - femur length
C - tibia length

[0023] The anthropometrical sizes depend on several factors, among which sex, age and geographic provenience.

[0024] In order to guarantee a certain pelvis mobility, even outside the sagittal plane, the adjustable devices (blades and sliders) of the orthosis legs comprise elements (blades) made of harmonic steel. This allows a good suitability to different anatomic shapes of different patients, and possible pelvis motions even on the front plane.

[0025] The interface with the patient 1' occurs with a corset, that can be opened to insert the patient and can be closed

with fastening elements, that can be made of plastic or semi-rigid material with textile solutions, and fastened to the rear handle. In the version made of plastic material, the corset is equipped on the front part with many hinges, of the same number on each side, to allow its opening and enable the patient 1' to easily wear it. After that, the corset will be tightened to the waist of the patient 1', allowing him to keep an erect position. In order to be correctly adapted to the bust shape, many corsets are provided, for example for men and women, and/or with different sizes. It is also provided to use a semi-rigid corset with textile base.

[0026] In order to fasten the lower limbs to the structure, "showers" are provided, the showers being an orthopaedic term used to designate a channel obtained to contain and immobilize a limb. Characteristic of these showers is being open to allow inserting the limb and comprising means for locking the limb. The number of showers, their shape and their type of closure can change according to the embodiments. In an embodiment, here provided for, there are two showers at the thigh height, one shower for the tibia segment and finally another shower for the foot. The showers can be made of elastic steel or thermoplastic material. In order to close the showers, Velcro™-type strips can be used, that perform a partial adaptation to the physical features of the patient 1', or textile structures that can be closed.

[0027] As regards the articulation control system, the control architecture of the system according to the present invention is with closed loop.

[0028] As input, curves related to gait cycle are provided, obtained from literature and suitably modified, according to medical indications, being the rehabilitation in suspension and reactions with the ground being therefore null, or for other therapeutic purposes.

[0029] These curves are continuously compared with the feedbacks coming from potentiometers or other position transducers, placed in parallel with one of the cylinders for every articulation, in order to detect the behaviour of the real cycle performed by the exoskeleton. If the patient 1' contrasts the movement, the potentiometer of the articulation subjected to efforts will give a reduced movement signal with respect to the curve set as input; vice versa if the orthosis overlaps the patient 1'. The difference between the two, real and reference, signals produces an error that is processed by the software controlling the orthosis, sending suitable output signals to the actuating system of the solenoid valves (PWM).

[0030] As regard the control type, various types of controllers can be used, both of the PID (Proportional Integral Derivative) type, and of the Fuzzy type or others.

[0031] The PWM modifies the cycle amplitude following an error, and controls the related solenoid valves for actuating the pneumatic cylinders. In any cylinder chamber, there are also pressure transducers, necessary for evaluating the pressure behaviours therein and therefore the developed force, useful in some diagnostic steps.

[0032] The rehabilitation steps with the system according to the present invention provide, for the severest patients 1', a suspension path as described above, where the patient 1' is totally guided by the exoskeleton. In the following steps, always however in suspension, it is possible to increase the working load, reducing the pressure supplied to the pneumatic actuators, so that the user actively contributes to the movement. If required by the therapy, it is also possible to remove the ankle articulation, since the tibia segment is sliding and adapted to be detached from the remaining assembly. The patient 1' will then be able to walk on the ground, with partial weight discharge, and with hip and knee articulations always actuated by the system according to the present invention. The absence of a treadmill allows a more physiological walking with more perception of the movement in the surrounding environment, and it is possible, by changing the input curves, to move along different paths. In all cases, it will be possible to display the working sitting on a screen, in which reference curves are represented together with the feedback coming from the potentiometers.

[0033] At any time the patient 1' will be able to compare, with his therapist, his own movement with the ideal one (biofeedback monitor).

[0034] Herein below the main components of the inventive orthosis 1 will be described.

[0035] As regards the limbs, the reference limb for building the first leg is the right side, and reference will be made only to this side, since the left side is a mirror image thereof. Figure 3, seen from outside, shows the final result, and the following can be distinguished, starting from the top and going downwards: joint 31' for hip articulation, femur segment 32', knee articulation 33', tibia segment 34 and ankle join 35.

[0036] As regards the hip articulation, as can be seen in Figure 14, the joint 31' is composed of several elements, designed as to minimize frictions and encumbrances. It is composed of an external element 141 fastened through the two holes, placed in the upper part, to the rear handle 92, that prevents it from rotating. In the internal part, it is equipped with a hub, on which a bush 142 will be keyed-in, and a series of element alternating with wear-preventing rings 143, 144, 147, preferably made of nylon or turcite, to avoid metal-to-metal contacts. The component 201 is the femur slider hinge, parallel to the human limb, and is the one on which the pneumatic cylinders 160 will be placed, that rotate it with respect to the joint 31'. In order to reduce the components to a minimum, joints for hip 31' and knee 33 have been made very similar. In order to compensate the distances, a bush 145 is placed in the hip and serves exclusively as shim. Finally, a plate 148 and a small internal plate 149 are placed, that allow closing the joint 31' with two screws 150 with flared head.

[0037] Figure 15 shows the external side of the element 31', in which there are two threaded holes, symmetrical with

respect to the vertical, suitable to position two pins 152 necessary for placing the stems 159 of the cylinders 160. The end of the stems 159 is threaded, allowing their fastening to standard ball joints 154, to have a rotation and oscillation movement lacking friction and without play. The axial constraint is guaranteed on one side by a bush 153, and on the other side by a Seeger ring 155 placed in a suitable groove obtained on the pin 152. On the rotation axis of the hip articulation, a threaded pin 156 is placed, fastened to the element 31', and necessary as support for a protection carter, placed between spacer 157 and knob 158. The protection carter is wound around the whole exoskeleton, allowing the operator to adjust the distances between the joints, exclusively operating on the knobs without interacting with the actuation and control systems of the system 3 according to the present invention.

[0038] Figure 16 shows a global view pertaining to the placement of the pneumatic cylinders 160 on the joint 31' of the hip (on the left) and the ball joint at the end of the stem of the cylinder 160 (on the right).

[0039] The pneumatic cylinders 160 are constrained at their lower end by exploiting the presence of holes that are diametrically opposite to the surface of the cylinder 160 chamber (Figure 20). Assembling consists in inserting a suitably shaped pin 206 inside the seat of the femur slider 201 on one side, and inside the liner 202 of the cylinder 160 on the other side. The pin 206 axially constrains the cylinder 160, but must allow a rotation related to the pin 206 itself. Afterwards, a second pin 205, geometrically identical to the previous pin 206, is placed on the opposite side of the cylinder 160 and, after having repeated the same operations also for the other cylinder 160, a connecting bracket 203 is placed, fastened to the femur slider 201 with a system with screw 207 - self-locking nut 204. Function of the lower screw 207 is also placing a nylon spacer 208 necessary for fastening a thigh shower 210 through riveting (Figure 21). The central hole placed on the shower allows passing the screw suitable for fastening the assembly to the femur blade.

[0040] In order to actuate the hip, there are two pneumatic cylinders 160 with connection with crossed chamber, that operate in an acting-counteracting way. While the first actuator produces a frontward thrusting force, the second exerts a backwards force, allowing a rotation of the femur slider 201 with respect to the joint fastened to the rear handle 92. This configuration allows a smaller encumbrance with respect to a single cylinder 160 with greater bore and the thrusting surface is equal to the sum of the greater surface and the smaller surface.

[0041] The stroke of the cylinders 160 is sized depending on the limit angular excursion of the articulation, set by the physiological gait, and the compliance with these constraints is mechanically guaranteed when at least one plunger of the two cylinders 160 is at the end of its stroke.

[0042] Figures 17, 18 and 19 respectively show the configuration at rest, the extension step and the flexion step. Not knowing the actual internal sizes of the cylinders 160, modelling therein is only qualitative. Arrows A designate the supply to the cylinders 160, whole arrows B the exhaust.

[0043] As regards the femur segment, to allow the femur segment to be adjustable depending on the patient 1' features, the femur slider 201 (also called femur blade) is made slide inside a femur guide 228. The femur blade or slider 201 is made of harmonic steel, which allows the structure to flex also outside the sagittal plane, giving the patient 1' a less rigid movement, while for the guide, having bigger sizes, aluminium has been employed to assign a certain lightness thereto. To avoid seizure problems, a third element is interposed, fastened to the guide, and made of turcite, which guarantees low friction, reduced wear and long life. The relative motion between femur slider 201 and its guide is shown in Figure 22.

[0044] Locking of the femur segment in a certain position occurs by friction, namely by tightening the various components through a knob 227. The nylon spacer 222 of Figure 22, necessary for fastening a thigh shower 210, is equipped with two square breakings, as well as the guide, suitable to house two screws 221, with crowned head and square subhead, preventing their rotation. At the opposite end, a bracket 224 is placed in contact with the femur slider 201 and axially constrained by Seeger rings 225. Finally, a covering ring 226 is inserted outside the screw, obtaining the configuration shown in Figure 23. By tightening the knob 227, the elements included between screw 221 head and bracket 224 are packaged, preventing their sliding. The presence of Seeger rings is necessary since, should the knob 227 be wrongly removed, the screws 221 would remain assembled, preventing the system from being decomposed.

[0045] In the femur blade there is a slit which allows it to slide without interfering with the tightening screws, and which prevents its disassembling. The screws further provide a limit switch for the adjustment size ends included between 10%ile for women and 95%ile for men. Both on the femur guide 228 and on the bracket 224, two holes are obtained for placing the pneumatic cylinders 242 necessary for actuating the knee articulation. The arrangement is similar to the one described for the hip (Figure 24), as well as fastening a second thigh shower 241 onto the spacer with riveting.

[0046] The knee articulation is different with respect to the hip articulation only due to two components that are shown in Figure 25. More precisely, the femur guide 228 replaces the femur slider 201 and the part 145 of Figure 14, and the external element 254 replaces the previous one (part 141 of Figure 14) operating as guide also for the tibia segment. The element 254 is equipped with two holes for placing pins that support the stems of the cylinders 242, arranged rotated by 30° with respect to a plane perpendicular to the vertical, to allow only a 60° flexure allowed for the knee articulation. There is also an adjustment knob 251 with related support 252 connected to an adjustment rod 253.

[0047] The two pneumatic cylinders 242 have connections with crossed chambers and operate in an acting-counteracting way. Figure 28 and Figure 29 show the rest configuration (Figure 28) with the femur segment aligned with the tibia segment, and the flexure condition (Figure 29). Arrows C designate the supply of cylinders 242, while arrows D

designate the exhaust.

[0048] The tibia segment (Figure 26) is simpler with respect to the femur segment, and is composed of the aluminium guide 261 on which an element 262 made of turcite is overlapped with a similar geometry of its seat. The tibia blade 265 made of harmonic steel is placed thereon, and is able to slide if adjustments of the tibia length must be made. The relative sliding between the two elements is blocked by friction with the screw-nut screw type tightening. Two screws 269 are provided, with crowned head and square sub-head, that also allow fastening the tibia shower to the guide, by interposing a suitable spacer 266 and using two knobs 264. To guarantee a better fastening between tibia blade and its guide, also the screw 268 with know 263 is inserted.

[0049] Since in subsequent rehabilitation steps, it is provided that a patient 1' walks on the ground, it has been necessary to provide for the removal of the tibia segment and the related ankle articulation. For such purpose, an upward-opened groove is made on the tibia blade, which allows avoiding an interference with the screws and its easy removal.

[0050] In the lower part of the tibia blade, as shown in Figure 27, there are two holes adapted to fasten a support 273 of the pneumatic cylinder 275 for moving the ankle articulation. In this case, a single actuator is used, having reduced sizes with respect to the previous ones, both because the loads to be supported are lower, and due to encumbrance problems. The actuator is supported by a bracket 273, fastened to the tibia blade 265 with screws 274 with cylindrical head and hexagonal recess and related nut, and is placed in the front part of the structure, differently from previous cylinders 275 that are laterally placed. The actuator is fastened to the bracket by means of two diametrically opposite screws 272.

[0051] The ankle articulation (Figure 30) is composed of an aluminium plate 308 that is the foot flank, and on whose front end a pin 309 will be fastened for keying-in the cylinder 275 stem. The element 308 is equipped with a hub, on which a friction-preventing ring 305 is placed, which, in turn, supports the tibia blade 304, a shim element 306 and, at the two ends, a friction-preventing ring 303, 307, preferably made of nylon, to avoid the metal-to-metal contact. Closure of the joint occurs with a small external plate 302 and two screws 301 with flared head.

[0052] In the internal part of the foot flank bracket, the shower 310 is fastened for positioning the patient 1's foot. As shown in Figures 31 and 32, two spacers 312 with different thickness are arranged, to then place the shower 310 fastened to the structure with two screws 311 with crowned head and square sub-head, and nut. This type of screw avoids its rotation and is not uncomfortable for the patient 1'. In the opposite part, a threaded pin 313 is placed for housing the ball joint together with the stem of the cylinder 275. The axial displacement is prevented by a Seeger ring.

[0053] The angular excursion of the ankle has been increased with respect to the one of the physiological walk upon medical request, for reasons linked to waking in suspension.

[0054] Figure 32 shows, from left to right, the rest configuration, the plantar flexure and the dorsal flexure steps. Arrows E designate the cylinders supply while arrows F designate the exhaust.

[0055] From the first experimentation steps on healthy patients, it has been discovered that the body weight of the patient 1', abutting partly onto the foot shower, generated a downward flexure thereof on its internal leg side.

[0056] In order to solve the problem, it has been necessary to use supplementary support means, such as a connecting rod between foot shower and tibia shower (Figure 33).

[0057] It is composed of a system with screw 337 - nut screw 335 that allows the length adjustment, and at whose ends a ball joint 333, 338 is connected, to avoid making the structure hyper-static and to reduce overall sizes to a minimum. They are keyed-in on two pins 331, 341 inserted in the showers with a first nut 332, 340 that prevents a screw from being disassembled from the shower during adjustments, and a second, more external, nut 334, 339, which keeps the whole system in position. Next to the adjustment of the tibia segment, also the length of the connecting rod of the showers will have to be changed. It is enough to unscrew the nut 334, withdraw the joint 333 from the pin 331, move away the nut 336 operating as stopper, unscrew or screw, depending on needs, the system with screw 337 - nut screw 335, take back the nut 336 against the nut screw and insert again the joint 333 with the nut 336.

[0058] As regards the rear handle 92, it can be built according to various embodiments, a first one of which is shown in Figure 8. The handle is composed of two forks 81 placed at its ends, which allow fastening the exoskeleton at the height of the hip articulation. The pelvis width can be adjusted (manually or through an electric or pneumatic motor) by sliding two concentric tubular elements 82, 84. The presence of a slit on the element 84 and a pin fastened inside the structure on a plate, prevents the relative rotation between the two elements.

[0059] The rectilinear section above the knob 83 is used for fastening the box 22 containing the valve assembly and the distribution plate for compressed air. As regard fastening with a limb, inside the fork 81 the small external plate 31' is placed, for the hip articulation, and a plate (not shown) necessary for fastening the corset 210; everything is tightened with two through-screws with unscrewing-preventing nuts. The corset 210 is fastened to the structure by three screws, with their head oriented towards its internal part, and with self-locking nuts at the opposite end. A nylon spacer is also inserted, that allows coupling the curved shape of the corset 210 with the plane bracket surface.

[0060] According to a preferred embodiment, the rear handle 92, as shown in Figures 9 to 12, first of all comprises two handles 91. Figure 9 shows a global view of this element. In order to adapt it to a greater number of patients, a minimum adjusting distance is imposed, equal to 300 mm, with a maximum distance of 650 mm. It is composed of a

suitable shaped central block 112, inside which an electric motor 94 and a reducer 95 are placed. The rotation motion is transmitted to a worm screw with double slant through a toothed belt, or a pair of toothed wheels. Figure 11 schematically shows the kinematism with motor 94, reducer 95 and worm screw 96.

[0061] At the ends of the central block, two bearings are placed for keying-in therein the worm screw 96, together with other two bearings, placed at the ends of the worm screw 96 and constrained on plates 103 for closing the handle 92. In both cases, these are radial bearings, respectively designated with 101 and 102 in Figure 10. Between the two end plates 103, two guides 105, 106 with circular cross-section are placed and fastened to the structure, while two suitably shaped small plates 104 are externally placed as protection.

[0062] Depending on the rotation direction of the motor, and therefore of the worm screw, a translation is generated for two small nut screw blocks, on which the legs will be placed, when going near and away one from the other, by changing the pelvis length depending on the features of the patient 1' (Figure 11). The two small blocks 101, in addition to be coupled with the worm screw 113 (96), are kept in position by the two guides 112, 114 and externally to the framework.

[0063] Figure 12 shows more in detail the small block with the presence of four bushings 121, two on each part, for housing the guides, while in the front part, a tubular segment 123 is placed, fastened through two biting screws 122 with cylindrical head. A slit is obtained in the small block to make it easier to insert the cylindrical outline, while the screws allow approaching the two small block edges, generating a tightening.

[0064] In order to guarantee a correct motor stop with small nut screw block at the end of its stroke, two limit switches have been placed in the end heads, which stop the motor when their minimum or maximum opening is reached.

[0065] Figure 13 shows a series of elements that are connected at the opposite end of the tubular segment 123. The first one of them is the fork 132, inside which the small external plate 133 of the hip articulation 31' is placed, and from which the whole leg departs, and a bracket 134. Everything is tightened by two screws with flared head and self-locking nuts 139. A female dovetail 135 is fastened to the bracket 134 with other two screws with flared head and nuts 137, while inside it the respective male dovetail 136 is made slide with a suitably slanted surface, since it will have to follow the curved geometry of the corset 210 supporting it.

[0066] The element 136 is supported in the lower part by a plate 138 fastened to the female dovetail with three biting screws.

[0067] With this system, it is possible to adjust the position of the corset 210 depending on the anthropometrical sizes of the patient 1', making the male dovetail slide in its respective seat, and constraining it through a locking system placed on one side of the female dovetail.

[0068] Laterally to the structure, two handles will be placed, suitable for lifting and moving the exoskeleton 1, while in the rear part, through two brackets, the box 22 will be placed, that contains the valve assembly, the distribution plate for compressed air and the control cards.

[0069] Joining the rear handle 92 with the two legs, the result shown in Figure 1 is obtained.

[0070] In order to allow a gait cycle in suspension, it is necessary to lift the system according to the present invention through a hook placed on the tubular segment 123 of the rear handle 92.

[0071] The photograms of a gait cycle are shown in Figures 37 to 39.

[0072] Summarising, the active orthosis 1 of the present invention is used for the motion neurological rehabilitation of lower limbs, and it is equipped with at least four, and preferably six, degrees of freedom for a movement respectively of the two hips, of the two knees and optionally of the two ankles of a patient 1' without having to use supporting and handling treadmills; the orthosis 1 comprising:

- an elongated supporting structure 92;
- a first supporting and handling structure 201, 160 on the sagittal plane of the femur of the patient 1';
- a second supporting and handling structure 228, 242, 261 on the sagittal plane of at least one tibia, with respect to the femur, of the patient 1'; and
- a third supporting and handling structure 265, 275 on the sagittal plane of at least one foot, with respect to the tibia, of the patient 1', where the third supporting and handling structure 265, 275 is adapted to be operatively connected to and disconnected from the orthosis 1;

[0073] According to the invention, the elongated supporting structure 92 is so rigid as to allow the first, second and third supporting and handling structures 201, 160; 228, 242, 261; 265, 275 to perform mutually related movements, the elongated supporting structure 92 being also adjustable to be suited to sizes of the patient 1' when the patient 1' wears and uses the orthosis 1.

[0074] Moreover, the orthosis 1 is adapted to be used both in a suspended condition, and in a condition where the weight of the patient 1' is partially supported, and on the ground.

[0075] In particular, in order to obtain the above object, in the inventive orthosis 1, the first supporting and handling structure 201, 160 can comprise, for every lower limb of the patient 1', first supporting means 201 operatively coupled with first handling means 160 of the femur of the patient 1', where the first supporting means 201 are rotatingly connected

to the supporting structure 92 through at least one first junction element 31'; the first supporting means 201 are made of a flexible material along a plane passing through the axis of the first junction element 31', the first handling means (160) being of the acting/counteracting type and allowing a handling of the femur exclusively in the sagittal plane.

[0076] Still in particular, in order to obtain the above object, in the inventive orthosis 1, the second supporting and handling structure 228, 242, 261 can comprise, for every lower limb of the patient 1', second supporting means 228, second handling means 242 and third supporting means 261, where the second supporting means 228 are operatively coupled, in a sliding and adjustable way, with the first supporting means 201, and are operatively coupled with the second handling means 242 of at least one tibia of the patient 1'; the second supporting means 228 are rotatingly connected to the third supporting means 261 through at least one second junction element 33', the second handling means 242 being of the acting/counteracting type and allowing a handling of the tibia exclusively in the sagittal plane.

[0077] Also in particular, in order to obtain the above object, in the inventive orthosis 1, the third supporting and handling structure 265, 275 can comprise, for every lower limb of the patient 1', fourth supporting means 265 and third handling means 275, the fourth supporting means 265 being operatively coupled, in a sliding and adjustable way, with the third supporting means 261, and being operatively coupled with the third handling means 275 of at least one foot of the patient 1'; the fourth supporting means 265 are rotatingly connected to means 310 for abutting and supporting the foot through at least one third junction element 35; and the fourth supporting means 265 are made of a flexible material along a plane passing through the axis of the second junction element 33', the third handling means 275 being of the acting/counteracting type and allowing a handling of the foot exclusively in the sagittal plane, the fourth supporting means 265 being adapted to be operatively connected to and disconnected from the third supporting means 261.

[0078] In this arrangement, in order to obtain described effects, the first supporting means 201 and the fourth supporting means 265 can be sliders made of plates of harmonic steel, while the second supporting means 228 and the third supporting means 261 can be metallic guides.

[0079] Always in particular, in order to obtain the above object, in the inventive orthosis 1, the first supporting and handling structure 201, 160 can comprise, for every lower limb of the patient 1', first supporting means 201 operatively coupled with first handling means 160 of the femur of the patient 1', the first supporting means 201 being rotatingly connected to the supporting structure 92 through at least one first junction element 31'; the first supporting means 201 are of the acting/counteracting type and allow a handling of the femur exclusively in the sagittal plane.

[0080] Also in particular, in order to obtain the above object, in the inventive orthosis 1, the second supporting and handling structure 228, 242, 261 can comprise, for every lower limb of the patient 1', second supporting means 228, second handling means 242 and third supporting means 261, the second supporting means 228 being made of a flexible material on a plane passing through the axis of the first junction element 31', the second supporting means 228 being operatively coupled, in a sliding and adjustable way, with the first supporting means 201, and being operatively coupled with the second handling means 242 of at least one tibia of the patient 1', the second supporting means 228 being rotatingly connected to the third supporting means 261 through at least one second junction element 33', the third supporting means 261 being made of a flexible material along a plane passing through the axis of the second junction element 33', the second handling means 242 being of the acting / counteracting type and allowing a handling of the tibia exclusively in the sagittal plane.

[0081] Finally, also in particular, in order to obtain the above object, in the inventive orthosis 1, the third supporting and handling structure 265, 275 can comprise, for every lower limb of the patient 1', fourth supporting means 265 and third handling means 275, the fourth supporting means 265 being operatively coupled, in a sliding and adjustable way, with the third supporting means 261, and being operatively coupled with the third handling means 275 of at least one foot of the patient 1', the fourth supporting means 265 being rotatingly connected to means 310 for abutting and supporting the foot through at least one third junction element 35, the third handling means 275 being of the acting/counteracting type and allowing a handling of the foot exclusively in the sagittal plane, the fourth supporting means 265 being adapted to be operatively connected to and disconnected from the third supporting means 261.

[0082] In this arrangement, in order to obtain the described effects, the first supporting means 201 and the fourth supporting means 265 can be metallic guides, while the second supporting means 228 and the third supporting means 261 can be sliders made of plates of harmonic steel.

[0083] The first and the second handling means 160, 242 are preferably composed, on every lower limb, of pairs of pneumatic cylinders with crossed chambers and the third handling means 275 are composed, on any lower limb, preferably of a pneumatic cylinder, or the first, second and third handling means 160, 242, 275 can be composed of electric or hydraulic actuators.

[0084] In addition to the two example configuration described above, obviously, other combinations are possible, in which, for example, the first supporting means 201 and the third supporting means 261 are sliders made of harmonic steel plates, and the second supporting means 228 and the fourth supporting means 265 are metallic guides; or in which the second supporting means 228 and the fourth supporting means 265 are sliders made of harmonic steel plates, and the first supporting means 201 and the third supporting means 261 are metallic guides.

[0085] It can therefore be seen from above that the orthosis 1 of the invention, in its preferred embodiment, is composed

of five main groups: the first group is composed of the supporting structure 92 and the first supporting and handling structure 201, 160; the second and the third group are composed of the second supporting and handling structure 228, 242, 261, one for each of the lower limbs of the patient 1'; and the fourth and the fifth group are composed of the third supporting and handling structure 265, 275, one for each of the lower limbs of the patient 1'. This configuration with five groups could obviously be reduced to a configuration with less than five groups, by operatively and/or physically disconnecting those groups that currently are not useful for the patient and/or the therapy actually affected.

[0086] The active orthosis 1 consists in a modular supporting structure, with four or six degrees of freedom, adjustable, for example, from the 10%ile of women to the 95%ile of men, according to the anthropometrical sizes of the patient 1', preferably with a pneumatic actuation (the actuation could also be electric or hydraulic), closed into suitable safety carters and constrained to the basic structure.

[0087] It is in turn composed of modules aimed for pelvis, femur segment and tibia segment, mutually connected by low-friction joints and by harmonic steel plates.

[0088] In this way, an original system (alternatively also called machine herein below) has been obtained, not only able to be adapted to different physiological shapes, but above all a machine that allows, when walking on the ground, a certain pelvis mobility even outside the sagittal plane. In this way, the path imposed to the patient 1' during his therapeutic sitting is more natural and the treatment efficiency improves.

[0089] There is, in the system according to the present invention, an activation both on the hip articulation, and on the knee articulation, and on the ankle articulation, peculiarity of the system. In fact, the system according to the present invention can be made operate both in suspension, and on the ground, with partial or total discharge, or not, of the weight of the patient 1', according to therapeutic needs. During both treatments, it is very important to activate the tibia-tarsus articulation, since it allows major neuronal activations for a complete recovery of the patient 1'. In both cases, it is provided to use a Body Weight Support (BWS) able to always discharge the orthosis 1 weight, in addition to the patient 1' weight, if required.

[0090] It must be stated that the ankle activation in the examined orthosis 1 can also be removed, leaving the patient 1' free of autonomously moving his foot when walking on the ground, if this is required.

[0091] Walking on the ground, moreover, has been preferred to the one that can be obtained with a fixed station with the use of a treadmill, since the advancement inside a space provides the patient 1' with feelings and perceptions of a different nature, very important for the various rehabilitation steps; in any case, if required, it is anyway possible to use a treadmill.

[0092] The pelvis width, equipped with a corset 210 constrained to the back of the patient 1' due to fastening Velcro™ bands, can be modified due to the sliding and automated rear handle 92 to which the corset 210 is fastened. Purpose of the handle 92 is also keeping joined the two legs of the orthosis 1, making it easier for the patient 1' to wear it.

[0093] Along femur and tibia segments, whose length can be adjusted due to a prismatic coupling, the interface with the patient 1' is obtained through thigh members and showers closed with Velcro™ bands or textile elements.

[0094] The femur and tibia actuating assemblies consists in pairs of pneumatic cylinders with crossed chambers, that operate by simulating the principle of an acting and counteracting muscle, not pointed out in other patents. Such assembly allows using two actuators with smaller sizes with respect to solutions with a single motor. The cylinders of the system according to the present invention are fastened on the slider part that s integral with the articulation, and are covered by protecting carters in order to close every moving part: from these, only the knobs project that are necessary for the anthropometrical adjustment.

[0095] Every leg of the orthosis 1 is equipped with pressure sensors for detecting the pressure in the cylinder chambers and with position sensors, to detect the motion of the various articulations and use it as feedback in the control that manages the system.

[0096] The orthosis 1 is then equipped with a control box 22, placed behind the patient back, where the control solenoid valves and the electronic cards are placed, that are able to perform, on board the machine, a real time check, sending acquired data to a PC through a wire for transmitting coded signals, or with multi-pole cables or with wireless connections.

[0097] The Range Of Movement (ROM) has been increased on purpose, in case of the ankle, with respect to the physiological movements, to increase the activation of motion circuits of the patient 1'. The system ROMs according to the present invention are included in Table 1, not exclusively.

Table 1: ROMs for the various articulations of the system according to the present invention

Articulation	Max extension [°]	Max flexure [°]	R.O.M. [°]
Hip	20	20	40
Knee	0	60	60
Ankle	25	15	40

[0098] The anthropometrical adjustments allowed in the examined orthosis 1 are wide and are included in Table 2, not exclusively.

Table 2: Anthropometrical adjustments allowed in the system according to the present invention

	10%ile woman [mm]	95%ile man [mm]	Adjustment Range [mm]
Pelvis length	300	650	350
Femur length	370	500	130
Tibia length	360	500	140

[0099] The ground managing system 5 comprises: at least one card for managing the orthosis - PC connections; an electro-pneumatic control circuit; emergency systems: a preferred embodiment of such components is shown in Figure 34.

[0100] As regards emergencies, there are three types in the system: an emergency for the patient 1', that therefore, if able, can stop the sitting in case of need; a manual emergency and an emergency from software for the operator. All these actions force to go out of the software and to start again the sitting, saving it or not.

[0101] A peculiarity of the system is then the presence, in the control box 26, of two electronic pressure regulators, which allow independently adjusting from software, the pressure in the legs of the orthosis 1. This innovative aspect is extremely useful in case of treatments of hemiplegia, tetraparesis, hemiparesis, since it could be necessary to apply different activation forces to the two legs.

[0102] The pressure regulation in the actuators further allows changing the force that the orthosis 1 exerts on the legs of the patient 1' , thereby varying the man-machine interaction, since the more the pressure is reduced, the more the thrust to the legs lowers and the patient 1' must demonstrate to be able to autonomously work.

[0103] This allows various evaluations about the motion learning status and the rehabilitation improvements thereof, evaluated during the sitting through the biofeedback present in the system.

[0104] The computer 28 instead comprises the managing software and is connected to two monitors.

[0105] Of the two monitors, one is dedicated to the operator, the other one to the biofeedback. In this case, therefore, the input curves with the patient response are displayed and compared in real time on the monitor, for every articulation.

[0106] The managing software, instead, allows controlling in position the imposed motion, using as input the behaviours (physiological or not, even asymmetrical on the two legs, according to needs) of the angles of the various articulations, depending on the gait cycle, according to a follower logic.

[0107] The system is equipped with a suitable graphic interface, which allows the operator to quickly and flexibly use the device, in addition to analysis and data saving for every sitting.

[0108] The originality of the system herein described, with respect to what can be found in the prior art, can therefore be summarised in the following items:

1) The addition of the ankle articulation has been made depending on specific medical indications, which point out the chance of a quick and functional motion recovery in case of walk on the ground with a weight that is present or partially discharged. The articulation is also removable, should medical needs so require.

2) The structure yield allows having a certain pelvis mobility even outside the sagittal plane, in order to obtain a more physiological walk. This feature is obtained by using harmonic steel plates, instead of more rigid materials, as often happens in other exoskeletons.

3) The absence of a treadmill allows moving on variable and pre-established paths depending on the patient needs, with such a walk on the ground as to allow pelvis and trunk movements, fundamental to restore a correct autonomous walk. In case of need, however, the machine can also operate with treadmill.

4) The movement potentialities allowed by the system according to the present invention are therefore: treatments in suspension with the use of a Body Weight Support (BWS); ground walking on variable paths, with partial or total discharge, or not, of the patient weight through BWS; walking associated with a treadmill, if required by the treatment; ground walking with support of parallel or Canadian fixtures, using commands with single gait according to a known technique (voice command, key actuated by a hand, laser command from hat, etc.).

5) The system allows taking care of different pathologies. For such purpose, its software provides for a whole series of sitting variations, comprising:

- the gait cycle, obtained imposing physiologic, or not, curves to the legs, even in an asymmetrical mode if required, with cycle period that can be set by PC;
- knowledge learning evaluations of the patient 1', with chance of blocking the system in a random cycle position, to request the patient 1' to describe it and therefore understand his knowledge learning status;

- final or temporary interruption of the sitting, both to allow the patient 1' to rest, and to allow applying suitable clinical protocols adapted to evaluate the motion and knowledge rehabilitation improvement of the patient 1';
- recording partial and total times for every sitting.

6) The weight of the whole orthosis 1 is around 22 kg. With respect to many other devices in the art, therefore, it is more versatile and capable to be handled.

7) The mere construction cost of the prototype pieces is per se low and therefore, in perspective, the cost of the orthosis 1 is also economically competitive with respect to the known prior art.

8) The pneumatic actuation is per se very safe and reliable, and shows the following advantages: allowing to use the machine even with a graduation of the force imposed to the patient leg(s), acting on the cylinder pressure, allowing various types of evaluations during the sitting regarding the patient improvements and autonomy; it guarantees more comfort and safety in the motion imposed to the limbs, due to the capability of compressing air; it reduces the actuator costs.

9) The examined system, with its versatility and with its potentialities, also allows performing original and innovative therapeutic methods, often associated with functional Magnetic Resonance Imaging (fMRI) surveys on the brain. The fMRI survey, in fact, allows quickly evaluating the actual activation of motion circuits following one or more treatments with the system according to the present invention. This has already been proven by motor learning studies, performed on healthy individuals.

[0109] Given its wide potentialities in taking care of different pathologies, such as ictus, ischemia, brain haemorrhage, partial lesions of the spinal cord, with extension, in some cases, to muscle dystrophy and motion degenerating pathologies, in addition to motor learning studies both on healthy and on disabled people, the inventive system has many innovative technical features.

[0110] They can be summarises as follows:

- reduced weight;
- electro-pneumatic actuation, that can be replaced, if required, also with electric or hydraulic actuators;
- actuators assembled with crossed chambers, according to the principle of the acting and counteracting muscle, thereby allowing to reduce weight and overall sizes, and with the chance of replacing current cylinders with pneumatic muscles;
- possibility of performing both suspension exercises and ground walking, discharging the orthosis weight and with partial or total discharge of the patient weight through BWS;
- possibility of using a treadmill, if required;
- possibility of ground walking with parallel or Canadian fixtures, with single gait command;
- presence of an active ankle articulation, to increase and improve the activation of motion circuits of the patient 1'. The ankle activation, if necessary, can be removed;
- construction of the elements of the orthosis structure in harmonic steel, to allow the system to be worn on people with different sizes, to obtain a better comfort, to allow a person, when walking on the ground, to have pelvis movements even outside the sagittal plane, according to human physiological walk criteria;
- wide movement fields and anthropometrical regulations;
- motored pelvis anthropometrical regulation;
- possibility of setting different pressures in the two legs, in order to treat different pathologies and take care of various clinical protocols;
- possibility of setting different input curves, even asymmetrical, in order to be able to perform various motion therapeutic exercises;
- possibility of monitoring, analysing and saving every test parameter (articulation pressures and positions);
- presence of a real time control on board the machine;
- presence of three types of emergencies, with pneumatic-electric effects;
- managing, through software, a whole series of sitting variations, comprising:

  - setting sitting parameters (patient data; pathology; walking data; input curves; etc.);
  - saving acquired patient/sitting data and graphs;
  - gait cycle, obtained by imposing curves, physiological and not, to the legs, even asymmetrically if required, with a cycle period that can be set by PC;
  - knowledge learning evaluations for the patient 1', with possible system block in a random cycle position, to request the patient 1' to describe it and therefore understand his motion learning status;
  - final or temporary interruption of the sitting, both to make the patient 1' rest, and to allow applying suitable clinical protocols adapted to evaluate the motion and knowledge rehabilitation status of the patient 1';

- recording of partial and total times of every sitting;

- such versatility and potentiality as to allow also performing original and innovative therapeutic method, often associated with fMRI surveys for evaluating the activation of motion circuits following the treatment with the system according to the present invention.

Claims

1. Active orthosis (1) for the motion neurological rehabilitation of lower limbs, the orthosis (1) being equipped with at least four, and preferably six, degrees of freedom for a movement respectively of the two hips, of the two knees and optionally of the two ankles of a patient (1') without having to use supporting and handling treadmills, the orthosis (1) being comprising:

- an elongated supporting structure (92);
- a first supporting and handling structure (201, 160) on the sagittal plane of the femur of the patient (1');
- a second supporting and handling structure (228, 242, 261) on the sagittal plane of at least one tibia, with respect to the femur, of the patient (1'); and
- a third supporting and handling structure (265, 275) on the sagittal plane of at least one foot, with respect to the tibia, of the patient (1'), the third supporting and handling structure (265, 275) being adapted to be operatively connected to and disconnected from the orthosis (1);

characterised in that:

- the elongated supporting structure (92) is so rigid as to allow the first, second and third supporting and handling structures (201, 160; 228, 242, 261; 265, 275) to perform mutually related movements, the elongated supporting structure (92) being also adjustable to be suited to sizes of the patient (1') when the patient (1') wears and uses the orthosis (1), the elongated supporting structure (92) comprising:

  * a central block, inside which an electric motor (94), a reducer (95) and a worm screw (96) are placed, a rotation motion of the electric motor (94) being transmitted to a worm screw (96, 113);
  * two guides (112, 114) which contain two small nut screw blocks (111), each one in turn connected to a tubular segment (123) operatively connected to and supporting the first supporting and handling structure (201, 160), depending on the rotation direction of the motor (94), and therefore of the worm screw (96, 113), a translation being generated for the two small nut screw blocks (111), when going near and away one from the other, by changing the pelvis length depending on the features of the patient (1'), the two small blocks (111), in addition to be coupled with the worm screw (96, 113), being kept in position by the two guides (105, 106);

- the first supporting and handling structure (201, 160) comprises, for every lower limb of the patient (1'), first supporting means (201) operatively coupled with first handling means (160) of the femur of the patient (1'), the first supporting means (201) being rotatingly connected to the supporting structure (92) through at least one first junction element (31'), the first supporting means (201) being made of a flexible material along a plane passing through the axis of the first junction element (31'), the first handling means (160) being of the acting/counteracting type and allowing a handling of the femur exclusively in the sagittal plane, the first supporting means (201) being sliders made of plates of harmonic steel; and
- the orthosis (1) is adapted to be used both in a suspended condition, and in a condition where the weight of the patient (1') is partially supported, and on the ground.

2. Orthosis (1) according to claim 1, **characterised in that** the second supporting and handling structure (228, 242, 261) comprises, for every lower limb of the patient (1'), second supporting means (228), second handling means (242) and third supporting means (261), the second supporting means (228) being operatively coupled, in a sliding and adjustable way, with the first supporting means (201), and being operatively coupled with the second handling means (242) of at least one tibia of the patient (1'), the second supporting means (228) being rotatingly connected to the third supporting means (261) through at least one second junction element (33'), the second handling means (242) being of the acting/counteracting type and allowing a handling of the tibia exclusively in the sagittal plane.

3. Orthosis (1) according to claim 2, **characterised in that** the third supporting and handling structure (265, 275)

comprises, for every lower limb of the patient (1'), fourth supporting means (265) and third handling means (275), the fourth supporting means (265) being operatively coupled, in a sliding and adjustable way, with the third supporting means (261), and being operatively coupled with the third handling means (275) of at least one foot of the patient (1'), the fourth supporting means (265) being rotatingly connected to means (310) for abutting and supporting the foot through at least one third junction element (35), the fourth supporting means (265) being made of a flexible material along a plane passing through the axis of the second junction element (33'), the third handling means (275) being of the acting/counteracting type and allowing a handling of the foot exclusively in the sagittal plane, the fourth supporting means (265) being adapted to be operatively connected to and disconnected from the third supporting means (261) .

4. Orthosis (1) according to claim 1, 2 or 3, **characterised in that** the fourth supporting means (265) are sliders made of plates of harmonic steel, while the second supporting means (228) and the third supporting means (261) are metallic guides.

5. Orthosis (1) according to claim 1, **characterised in that** the first supporting and handling structure (201, 160) comprises, for every lower limb of the patient (1'), first supporting means (201) operatively coupled with first handling means (160) of the femur of the patient (1'), the first supporting means (201) being rotatingly connected to the supporting structure (92) through at least one first junction element (31'), the first handling means (160) being of the acting/counteracting type and allowing a handling of the femur exclusively in the sagittal plane.

6. Orthosis (1) according to claim 5, **characterised in that** the second supporting and handling structure (228, 242, 261) comprises, for every lower limb of the patient (1'), second supporting means (228), second handling means (242) and third supporting means (261), the second supporting means (228) being made of a flexible material on a plane passing through the axis of the first junction element (31'), the second supporting means (228) being operatively coupled, in a sliding and adjustable way, with the first supporting means (201), and being operatively coupled with the second handling means (242) of at least one tibia of the patient (1'), the second supporting means (228) being rotatingly connected to the third supporting means (261) through at least one second junction element (33'), the third supporting means (261) being made of a flexible material along a plane passing through the axis of the second junction element (33'), the second handling means (242) being of the acting/counteracting type and allowing a handling of the tibia exclusively in the sagittal plane.

7. Orthosis (1) according to claim 6, **characterised in that** the third supporting and handling structure (265, 275) comprises, for every lower limb of the patient (1'), fourth supporting means (265) and third handling means (275), the fourth supporting means (265) being operatively coupled, in a sliding and adjustable way, with the third supporting means (261), and being operatively coupled with the third handling means (275) of at least one foot of the patient (1'), the fourth supporting means (265) being rotatingly connected to means (310) for abutting and supporting the foot through at least one third junction element (35), the third handling means (275) being of the acting/counteracting type and allowing a handling of the foot exclusively in the sagittal plane, the fourth supporting means (265) being adapted to be operatively connected to and disconnected from the third supporting means (261) .

8. Orthosis (1) according to claim 5, 6 or 7, **characterised in that** the first supporting means (201) and the fourth supporting means (265) are metallic guides, while the second supporting means (228) and the third supporting means (261) are sliders made of plates of harmonic steel.

9. Orthosis (1) according to any one of claims 1 to 8, **characterised in that** the first and second handling means (160, 242) are composed, on every lower limb, of pairs of pneumatic cylinders with cross-chambers and the third handling means (275) are composed, on every lower limb, of a pneumatic cylinder with cross-chambers.

10. Orthosis (1) according to any one of claims 1 to 8, **characterised in that** the first, second and third handling means (160, 242, 275) are composed of electric or hydraulic actuators.

11. Orthosis (1) according to any one of the previous claims, **characterised in that** every leg of the orthosis (1) is equipped with pressure sensors for detecting the pressure in the cylinder chambers and with position sensors, for detecting a motion of the various joints and use it as feedback in the managing control of the orthosis (1).

12. Orthosis (1) according to any one of the previous claims, **characterised in that** it is further equipped with at least one control and interface box (22), in which control solenoid valves and electronic boards are placed, that are capable of performing a real-time check on board the orthosis (1), sending all acquired data to a managing computer.

13. System (3) for the motion neurological rehabilitation of lower limbs, comprising:

- at least one orthosis (1) according to any one of the previous claims; and
- at least one ground-type managing system (5) containing at least one computer (28) for acquiring and processing data, and for managing a motion neurological rehabilitation session by an operator.

14. System (3) according to claim 13, **characterised in that**:

- the control and interface box (22) is equipped with at least one supplying duct (23) of compressed air and at least one electric connection cable (25), the supply of compressed air coming from at least one compressor (24) or a distribution network;
- inside the control and interface box (22), there are also possible control boards, connected to electronic interface drivers placed in a control box (26) of the ground-type managing system (5) also containing the acquisition boards, thereby exchanging feedback signals and commands for solenoid valves and electric supply between orthosis (1) and ground-type managing system (5); and
- the computer (28) is connected to the control box (26) and contains a control software, that can be used by a user through a suitable graphic interface, the computer (28) being normally equipped with two monitors, a first monitor (31) dedicated to user's needs, and a second monitor (32) that shows the biofeedback of the system, useful both for the operator, and for the patient, for a self-diagnosis action during the rehabilitation session.

15. System (3) according to claim 13 or 14, **characterised in that** it is equipped with three types of emergencies: an emergency that allows the patient (1') to stop a session in case of need; a manual emergency and a software emergency for an operator, all these emergencies being adapted to stop an execution of the managing software and afterwards to re-start the execution, saving the session or not.

16. System (3) according to claim 13, 14 or 15, **characterised in that** it comprises, in the ground-type control system (5), at least two electronic pressure regulators, adapted to allow independently adjusting the pressure in the legs of the orthosis (1), this allowing to apply different activation forces to the two legs, the pressure adjustment in the actuators further allowing to change the force that the orthosis (1) exerts on the legs of the patient (1'), thereby changing the man-machine interaction, since the more the pressure is reduced, the lower the thrust to the legs, and the patient (1') having to demonstrate to be able to autonomously work.

Patentansprüche

1. Aktivbandage (1) für die motorische Neurorehabilitation der Beine, die Bandage (1) ist mit mindestens vier, vorzugsweise sechs, Freiheitsgraden für die Bewegung der Hüften, der Knie und wahlweise der Knöchel eines Patienten (1') ausgestattet, ohne unterstützende und sich bewegende Laufbänder zu verwenden, die Bandage (1) enthält:

- eine längliche Stützstruktur (92);
- eine erste Stütz- und Bewegungsstruktur (201, 160) auf der Sagittalebene des Oberschenkels des genannten Patienten (1');
- eine zweite Stütz- und Bewegungsstruktur (228, 242, 261) auf der Sagittalebene von mindestens einem Schienbein im Verhältnis zum Oberschenkel des Patienten (1'); und
- eine dritte Stütz- und Bewegungsstruktur (265, 275) auf der Sagittalebene von mindestens einem Fuß im Verhältnis zum Schienbein des Patienten (1'), die dritte Stütz- und Bewegungsstruktur (265, 275) dient dazu, für den Einsatz mit der Bandage (1) verbunden bzw. von ihr getrennt zu werden;

und ist **dadurch gekennzeichnet, dass**:

- die längliche Stützstruktur (92) so fest ist, dass sie der genannten ersten, zweiten und dritten Stütz- und Bewegungsstruktur (201, 160; 228, 242, 261; 265, 275) die Ausführung der jeweiligen Bewegungen untereinander ermöglicht, die längliche Stützstruktur (92) kann außerdem verstellt werden, um sich den Maßen des Patienten (1') anzupassen, wenn er die Bandage (1) trägt und verwendet, die längliche Stützstruktur (92) enthält:

  * einen zentralen Block, in dessen Inneren ein Elektromotor (94), ein Untersetzungsgetriebe (95) und eine Endlosschraube (96) angebracht sind, die Rotationsbewegung des Elektromotors (94) wird durch eine Endlosschraube (96, 113) übertragen;

* zwei Schienen (112, 114), die zwei Schraubenmutterblöcke (111) enthalten, die jeweils mit einem Rohrsegment (123) verbunden sind, das für den Einsatz mit der ersten Stütz- und Bewegungsstruktur (201, 160) verbunden ist und diese je nach der Rotationsrichtung des Motors (94) stützt und daher der Endlosschraube (96, 113), es wird eine Verschiebung für die beiden Schraubenmutterblöcke (111) erzeugt, wenn sie sich einander nähern und sich voneinander entfernen, wobei die Länge des Beckens je nach den Eigenschaften des Patienten (1') geändert wird, die beiden Schraubenmutterblöcke (111) werden zusätzlich zu der Verbindung mit der Schraubenmutter (96, 113) von den beiden Schienen (105, 106) in Position gehalten;

- Die erste Stütz- und Bewegungsstruktur (201, 160) enthält für jedes Bein des Patienten (1') erste Stützmittel (201), die für den Einsatz mit den ersten Bewegungsmitteln (160) der Hüfte des Patienten (1') verbunden sind, die ersten Stützmittel (201) sind rotierend mit der Stützstruktur (92) durch mindestens ein erstes Verbindungselement (31') verbunden, die ersten Stützmittel (201) sind aus biegsamem Material auf einer die Achse des ersten Verbindungselements (31') durchgehenden Ebene hergestellt, die ersten Bewegungsmittel (160) sind agonistisch/antagonistisch und ermöglichen die Bewegung der Hüfte ausschließlich auf der Sagittalebene, die ersten Stützmittel (201) sind mit Blechen aus harmonischem Stahl hergestellte Gleitschienen; und
- die Bandage (1) dient dazu, sowohl in einem hängenden Zustand als auch in einem Zustand, wo eine teilweise Entlastung des Gewichts des Patienten (1) erfolgt, sowie auch am Boden verwendet zu werden.

2. Bandage (1) gemäß Patentanspruch 1, die **dadurch gekennzeichnet ist, dass** die zweite Stütz- und Bewegungsstruktur (228, 242, 261) für jedes Bein des genannten Patienten (1') zweite Stützmittel (228), zweite Bewegungsmittel (242) und dritte Stützmittel (261) enthält, die zweiten Stützmittel (228) sind für den Einsatz gleitend und verstellbar mit den ersten Stützmitteln (201) verbunden, und sie sind für den Einsatz mit den zweiten Bewegungsmitteln (242) von mindestens einem Schienbein des Patienten (1') verbunden, die zweiten Stützmittel (228) sind rotierend mit den dritten Stützmitteln (261) durch mindestens ein zweites Verbindungselement (33') verbunden, die zweiten Bewegungsmittel (242) sind agonistisch/antagonistisch und ermöglichen die Bewegung des Schienbeins ausschließlich auf der Sagittalebene.

3. Bandage (1) gemäß Patentanspruch 2, die **dadurch gekennzeichnet ist, dass** die dritte Stütz- und Bewegungsstruktur (265, 275) für jedes Bein des Patienten (1') vierte Stützmittel (265) und dritte Bewegungsmittel (275) enthält, die vierten Stützmittel (265) sind für den Einsatz gleitend und verstellbar mit den dritten Stützmitteln (261) verbunden, und sie sind für den Einsatz mit den dritten Bewegungsmitteln (275) von mindestens einem Fuß des Patienten (1') verbunden, die vierten Stützmittel (265) sind rotierend mit Auflage- und Stützmitteln (310) des Fußes durch mindestens ein drittes Verbindungselement (35) verbunden, die vierten Stützmittel (265) sind aus biegsamem Material auf einer die Achse des zweiten Verbindungselements (33') durchgehenden Ebene hergestellt, die dritten Bewegungsmittel (275) sind agonistisch/antagonistisch und ermöglichen die Bewegung des Fußes ausschließlich auf der Sagittalebene, die vierten Stützmittel (265) dienen dazu, für den Einsatz mit den dritten Stützmitteln (261) verbunden bzw. von diesen getrennt zu werden.

4. Bandage (1) gemäß Patentanspruch 1, 2 oder 3, die **dadurch gekennzeichnet ist, dass** die genannten vierten Stützmittel (265) aus Blechen aus harmonischem Stahl hergestellte Gleitschienen sind, während die zweiten Stützmittel (228) und die dritten Stützmittel (261) Metallschienen sind

5. Bandage (1) gemäß Patentanspruch 1, die **dadurch gekennzeichnet ist, dass** die erste Stütz- und Bewegungsstruktur (201, 160) für jedes Bein des genannten Patienten (1') erste Stützmittel (201) enthält, die für den Einsatz mit den ersten Bewegungsmitteln (160) des Oberschenkels des Patienten (1') verbunden sind, die ersten Stützmittel (201) sind rotierend mit der Stützstruktur (92) durch mindestens ein erstes Verbindungselement (31') verbunden, die ersten Bewegungsmittel (160) sind agonistisch/antagonistisch und ermöglichen die Bewegung des Oberschenkels ausschließlich auf der Sagittalebene.

6. Bandage (1) gemäß Patentanspruch 5, die **dadurch gekennzeichnet ist, dass** die zweite Stütz- und Bewegungsstruktur (228, 242, 261) für jedes Bein des genannten Patienten (1') zweite Stützmittel (228), zweite Bewegungsmittel (242) und dritte Stützmittel (261) enthält, die zweiten Stützmittel (228) sind aus biegsamem Material auf einer die Achse des ersten Verbindungselements (31') durchgehenden Ebene hergestellt, die zweiten Stützmittel (228) sind für den Einsatz gleitend und verstellbar mit den ersten Stützmitteln (201) verbunden, und sie sind für den Einsatz mit den zweiten Bewegungsmitteln (242) von mindestens einem Schienbein des Patienten (1') verbunden, die

zweiten Stützmittel (228) sind rotierend mit den dritten Stützmitteln (261) durch mindestens ein zweites Verbindungselement (33') verbunden, die dritten Stützmittel (261) sind aus biegsamem Material auf einer die Achse des zweiten Verbindungselements (33') durchgehenden Ebene hergestellt, die zweiten Bewegungsmittel (242) sind agonistisch/antagonistisch und ermöglichen die Bewegung des Schienbeins ausschließlich auf der Sagittalebene.

7. Bandage (1) gemäß Patentanspruch 6, die **dadurch gekennzeichnet ist, dass** die dritte Stütz- und Bewegungsstruktur (265, 275) für jedes Bein des Patienten (1') vierte Stützmittel (265) und dritte Bewegungsmittel (275) enthält, die vierten Stützmittel (265) sind für den Einsatz gleitend und verstellbar mit den dritten Stützmitteln (261) verbunden, und sie sind für den Einsatz mit den dritten Bewegungsmitteln (275) von mindestens einem Fuß des Patienten (1') verbunden, die vierten Stützmittel (265) sind rotierend mit Auflage- und Stützmitteln (310) des Fußes durch mindestens ein drittes Verbindungselement (35) verbunden, die dritten Bewegungsmittel (275) sind agonistisch/antagonistisch und ermöglichen die Bewegung des Fußes ausschließlich auf der Sagittalebene, die vierten Stützmittel (265) dienen dazu, für den Einsatz mit den dritten Stützmitteln (261) verbunden bzw. von diesen getrennt zu werden.

8. Bandage (1) gemäß Patentanspruch 5, 6 oder 7, die **dadurch gekennzeichnet ist, dass** die ersten Stützmittel (201) und die vierten Stützmittel (265) Metallschienen sind, während die zweiten Stützmittel (228) und die dritten Stützmittel (261) mit Blechen aus harmonischem Stahl hergestellte Gleitschienen sind.

9. Bandage (1) gemäß einem beliebigen der Patentansprüche von 1 bis 8, die **dadurch gekennzeichnet ist, dass** die ersten und zweiten Bewegungsmittel (160, 242) an jedem Bein aus pneumatischen Zylinderpaaren mit überkreuzten Kammern bestehen und dass die dritten Bewegungsmittel (275) an jedem Bein aus einem pneumatischen Zylinder mit überkreuzten Kammern bestehen.

10. Bandage (1) gemäß einem beliebigen der Patentansprüche von 1 bis 8, die **dadurch gekennzeichnet ist, dass** die ersten, zweiten und dritten Bewegungsmittel (160, 242, 275) aus elektrischen oder hydraulischen Antrieben bestehen.

11. Bandage (1) gemäß einem beliebigen der vorhergehenden Patentansprüche, die **dadurch gekennzeichnet ist, dass** jedes Bein der Bandage (1) mit Drucksensoren für die Feststellung des Drucks in den Kammern der Zylinder und mit Positionssensoren für die Feststellung der Bewegung der verschiedenen Gliedmaße ausgestattet ist, um sie als Feedback für die Verwaltungskontrolle der Bandage (1) zu verwenden.

12. Bandage (1) gemäß einem beliebigen der vorhergehenden Patentansprüche, die **dadurch gekennzeichnet ist, dass** sie außerdem mit mindestens einem Steuer- und Schnittstellengehäuse (22) ausgestattet ist, in dem die Magnetsteuerventile und die elektronischen Steuerkarten untergebracht sind, die auf der Bandage (1) eine Echtzeitkontrolle mit Sendung der erfassten Daten an einen Verwaltungscomputer ausführen können.

13. System (3) für die motorische Neurorehabilitation der Beine, das Folgendes enthält:

- mindestens eine Bandage (1) gemäß einem beliebigen der vorhergehenden Patentansprüche; und
- mindestens ein Bodenverwaltungssystem (5), das mindestens einen Computer (28) für die Erfassung und Bearbeitung der Daten und für die Verwaltung einer motorischen Neurorehabilitationssitzung seitens eines Arztes enthält.

14. System (3) gemäß Patentanspruch 13, das **dadurch gekennzeichnet ist, dass**:

- das Steuer- und Schnittstellengehäuse (22) mit mindestens einer Druckluftversorgungsleitung (23) und mindestens einem Verbindungsstromkabel (25) ausgestattet ist, die Druckluftversorgung sieht mindestens einen Verdichter (24) oder ein Verteilungsnetz vor;
- im Steuer- und Schnittstellengehäuse (22) ggf. auch Steuerkarten vorhanden sind, die mit dem Driver der elektronischen Schnittstelle verbunden sind und in einer Kontrollbox (26) des Bodenverwaltungssystems (5) angebracht sind, welches auch die Erfassungssteuerkarten enthält, mit denen es Feedback-Signale und Steuerungen für die Magnetventile und die Stromversorgungen zwischen der Bandage (1) und dem Bodenverwaltungssystem (5) austauscht; und
- dadurch, dass der Computer (28) mit der Kontrollbox (26) verbunden ist und eine Kontrollsoftware enthält, die vom Benutzer durch eine entsprechende Grafikschnittstelle verwendet werden kann, der Computer (28) ist normalerweise mit zwei Monitoren ausgestattet, ein erster Monitor (31) ist für die Anforderungen des Bedieners bestimmt, und ein zweiter Monitor (32) stellt das Biofeedback des Systems dar, was sowohl für den Bediener

als auch für den Patienten während der Rehabilitationssitzung für eine Selbstdiagnosestellung nützlich ist.

15. System (3) gemäß Patentanspruch 13 oder 14, das **dadurch gekennzeichnet ist, dass** es mit drei Not-Aus-Schaltern ausgestattet ist: Ein Not-Aus-Schalter ermöglicht dem Patienten (1'), die Sitzung bei Bedarf zu unterbrechen; ein manueller Not-Aus-Schalter und ein Software-Not-Aus-Schalter für den Bediener, alle diese Not-Aus-Schalter dienen dazu, die Ausführung der Verwaltungssoftware zu unterbrechen und die Ausführung der Sitzung danach, mit oder ohne Speicherung, wiederaufzunehmen.

16. System (3) gemäß Patentanspruch 13, 14 oder 15, das **dadurch gekennzeichnet ist, dass** es im Bodenverwaltungssystem (5) mindestens zwei elektronische Druckregler enthält, die dazu dienen, eine unabhängige Druckregelung der Bandage (1) an den Beinen zu ermöglichen, dies ermöglicht die Anwendung verschiedener Wirkungskräfte auf beide Beine, die Druckregelung in den Antrieben ermöglicht außerdem die Änderung der Kraft, die die Bandage (1) auf die Beine des Patienten (1') ausübt, und somit die Änderung der Mensch-Maschinen-Interaktion, denn je mehr sich der Druck reduziert, desto mehr verringert sich der Druck auf die Beine, und der Patient (1') muss beweisen, dass er selbstständig zu arbeiten weiß.

Revendications

1. Orthèse active (1) per la neuro-rééducation motrice des membres inférieurs, l'orthèse (1) est dotée au moins de quatre (de préférence six) degrés de liberté pour le mouvement respectif des deux hanches, des deux genoux et, en option, des deux chevilles d'un patient (1') sans utiliser une structure (treadmill) de support et de mouvement, l'orthèse (1) comprend :

- une structure allongée de support (92) ;
- une première structure de soutien et de mouvement (201, 160) sur le plan sagittal du fémur du patient (1') ;
- une seconde structure de soutien et de mouvement (228, 242, 261) sur le plan sagittal au moins d'un tibia, par rapport au fémur, du patient (1') ; et
- une troisième structure de soutien et de mouvement (265, 275) sur le plan sagittal au moins d'un pied, par rapport au tibia, du patient (1') ; la troisième structure de soutien et de mouvement (265, 275) peut être attachée ou détachée opérationnellement de l'orthèse (1) ;

caractérisée en ce que :

- la structure allongée de support (92) est rigide afin de permettre à la première, à la seconde et à la troisième structure de soutien et de mouvement (201, 160; 228, 242, 261; 265, 275) d'exécuter les mouvements relatifs entre eux; la structure allongée de support (92) peut par ailleurs être réglée pour s'adapter à la taille du patient (1') quand il porte et utile l'orthèse (1) ; la structure allongée de support (92) comprend :

  * un bloc central qui accueille un moteur électrique (94), un réducteur (95) et une vis sans fin (96) ; le mouvement de rotation du moteur électrique (94) est transmis à une vis sans fin (96, 113) ;
  * deux guides (112, 114) qui accueillent deux blocs écrou (111) dont chacun est relié à un segment tubulaire (123) qui est relié opérationnellement à la première structure de support et de mouvement (201, 160) et la soutient ; selon la direction de rotation du moteur (94) et donc de la vis sans fin (96, 113), une translation est engendrée pour les deux blocs écrou (111), quand ils s'approchent et s'éloignent l'un de l'autre en modifiant la longueur du bassin selon les caractéristiques du patient (1') ; les deux blocs écrou (111), outre à être accouplés à l'écrou (96, 113) sont tenus en position par deux guides (105, 106) ;

    - la première structure de soutien et de mouvement (201, 160) comprend, pour chaque membre inférieur du patient (1'), des premiers moyens de soutien (201) accouplés opérationnellement aux premiers moyens de mouvement (160) du fémur du patient (1') ; les premiers moyens de soutien (201) sont reliés de manière pivotante à la structure de support (92) à travers au moins un premier élément de jonction (31') ; les premiers moyens de soutien (201) sont réalisés en matériau flexible sur un plan passant par l'axe du premier élément de jonction (31'); les premiers moyens de mouvement (160) sont du type agoniste/antagoniste et ils permettent le mouvement du fémur exclusivement dans le plan sagittal ; les premiers moyens de soutien (201) sont des glissières réalisées avec des lames en acier à ressort ; et
    - l'orthèse (1) est apte à être utilisée en condition suspendue, en condition avec allégement partiel du

poids du patient (1') et au sol.

2. Orthèse (1), selon la revendication 1, **caractérisée en ce que** la seconde structure de soutien et de mouvement (228, 242, 261) comprend, pour chaque membre inférieur du patient (1'), des seconds moyens de soutien (228), des seconds moyens de mouvement (242) et des troisièmes moyens de soutien (261) ; les seconds moyens de soutien (228) sont accouplés opérationnellement, de manière coulissante et réglable, aux premiers moyens de soutien (201), ils sont également accouplés opérationnellement aux seconds moyens de mouvement (242) au moins d'un tibia du patient (1') ; les seconds moyens de soutien (228) sont reliés de manière pivotante aux troisièmes moyens de soutien (261) à travers au moins un second élément de jonction (33') ; les seconds moyens de mouvement (242) sont du type agoniste/antagoniste et ils permettent le mouvement du tibia exclusivement dans le plan sagittal.

3. Orthèse (1), selon la revendication 2, **caractérisée en ce que** la troisième structure de soutien et de mouvement (265, 275) comprend, pour chaque membre inférieur du patient (1'), des quatrièmes moyens de soutien (265) et des troisièmes moyens de mouvement (275) ; les quatrièmes moyens de soutien (265) sont accouplés opérationnellement, de manière coulissante et réglable, aux troisièmes moyens de soutien (261), ils sont également accouplés opérationnellement aux troisièmes moyens de mouvement (275) au moins d'un pied du patient (1') ; les quatrièmes moyens de soutien (265) sont reliés de manière pivotante à des moyens (310) d'appui et de soutien du pied à travers au moins un troisième élément de jonction (35) ; les quatrièmes moyens de soutien (265) sont réalisés en matériau flexible sur un plan passant par l'axe du second élément de jonction (33') ; les troisièmes moyens de mouvement (275) sont du type agoniste/antagoniste et ils permettent le mouvement du pied exclusivement dans le plan sagittal ; les quatrièmes moyens de soutien (265) sont aptes à être attachés et détachés opérationnellement des troisièmes moyens de soutien (261).

4. Orthèse (1), selon la revendication 1, 2 ou 3, **caractérisée en ce que** les quatrièmes moyens de soutien (265) sont des glissières réalisées avec des lames en acier à ressort, tandis que les seconds moyens de soutien (228) et les troisièmes moyens de soutien (261) sont des guides métalliques.

5. Orthèse (1), selon la revendication 1, **caractérisée en ce que** la première structure de soutien et de mouvement (201, 160) comprend, pour chaque membre inférieur du patient (1'), les premiers moyens de soutien (201) accouplés opérationnellement aux premiers moyens de mouvement (160) du fémur du patient (1'); les premiers moyens de soutien (201) sont reliés de manière pivotante à la structure de support (92) à travers au moins un premier élément de jonction (31') ; les premiers moyens de mouvement (160) sont du type agoniste/antagoniste et ils permettent le mouvement du fémur exclusivement dans le plan sagittal.

6. Orthèse (1), selon la revendication 5, **caractérisée en ce que** la seconde structure de soutien et de mouvement (228, 242, 261) comprend, pour chaque membre inférieur du patient (1'), des seconds moyens de soutien (228), des seconds moyens de mouvement (242) et des troisièmes moyens de soutien (261) ; les seconds moyens de soutien (228) sont réalisés en matériau flexible sur un plan passant par l'axe du premier élément de jonction (31'); les seconds moyens de soutien (228) sont accouplés opérationnellement, de manière coulissante et réglable, aux premiers moyens de soutien (201), ils sont également accouplés opérationnellement aux seconds moyens de mouvement (242) au moins d'un tibia du patient (1') ; les seconds moyens de soutien (228) sont reliés de manière pivotante aux troisièmes moyens de soutien (261) à travers au moins un second élément de jonction (33') ; les troisièmes moyens de soutien (261) sont réalisés en matériau flexible sur un plan passant par l'axe du second élément de jonction (33') ; les seconds moyens de mouvement (242) sont du type agoniste/antagoniste et ils permettent le mouvement du tibia exclusivement dans le plan sagittal.

7. Orthèse (1), selon la revendication 6, **caractérisée en ce que** la troisième structure de soutien et de mouvement (265, 275) comprend, pour chaque membre inférieur du patient (1'), des quatrièmes moyens de soutien (265) et des troisièmes moyens de mouvement (275) ; les quatrièmes moyens de soutien (265) sont accouplés opérationnellement, de manière coulissante et réglable, aux troisièmes moyens de soutien (261), ils sont également accouplés opérationnellement aux troisièmes moyens de mouvement (275) au moins d'un pied du patient (1') ; les quatrièmes moyens de soutien (265) sont reliés de manière pivotante à des moyens (310) d'appui et de soutien du pied à travers au moins un troisième élément de jonction (35) ; les troisièmes moyens de mouvement (275) sont du type agoniste/antagoniste et ils permettent le mouvement du pied exclusivement dans le plan sagittal ; les quatrièmes moyens de soutien (265) sont aptes à être attachés et détachés opérationnellement des troisièmes moyens de soutien (261).

8. Orthèse (1), selon la revendication 5, 6, ou 7, **caractérisée en ce que** les premiers moyens de soutien (201) et les quatrièmes moyens de soutien (265) sont des guides métalliques, tandis que les seconds moyens de soutien (228)

et les troisièmes moyens de soutien (261) sont des glissières réalisées avec des lames en acier à ressort.

9. Orthèse (1) selon l'une des revendications de 1 à 8, **caractérisée en ce que** les premiers et les seconds moyens de mouvement (160, 242) sont composés, sur chaque membre inférieur, d'un couple de cylindres pneumatiques à chambres croisées et les troisièmes moyens de mouvement (275) sont composés, sur chaque membre inférieur, d'un cylindre pneumatique à chambres croisées.

10. Orthèse (1) selon l'une des revendications de 1 à 8, **caractérisée en ce que** les premiers, les seconds et les troisièmes moyens de mouvement (160, 242, 275) sont composés d'actionneurs électriques ou hydrauliques.

11. Orthèse (1) selon l'une des revendications précédentes, **caractérisée en ce que** chaque jambe de l'orthèse (1) est dotée de capteurs de pression pour relever la pression dans les chambres des cylindres ainsi que de capteurs de position pour relever le mouvement des différentes articulations et l'utiliser comme feedback pour le contrôle de gestion de l'orthèse (1).

12. Orthèse (1) selon l'une des revendications précédentes, **caractérisée en ce qu'**elle est dotée également d'une boîte de contrôle et d'interface (22) où se trouvent les électrovannes de commande et les cartes électroniques permettant d'effectuer (1) un contrôle en temps réel de l'orthèse et d'envoyer les données relevées à un ordinateur de gestion.

13. Système (3) pour la neuro-rééducation motrice des membres inférieurs, comprenant :

- au moins une orthèse (1) selon l'une des revendications précédentes ; et
- au moins un système de gestion à terre (5) contenant au moins un ordinateur (28) pour la saisie et le traitement des données, et pour la gestion d'une séance de neuro- rééducation motrice de la part d'un opérateur.

14. Système (3), selon la revendication 13, **caractérisée en ce que** :

- la boîte de contrôle et d'interface (22) est dotée au moins d'une tubulure d'alimentation (23) de l'air comprimé et au moins d'un câble de connexion électrique (25) ; l'air comprimé est alimenté par un compresseur (24) ou un réseau de distribution ;
- la boîte de contrôle et d'interface (22) contient également des cartes de contrôle éventuelles, reliés à des gestionnaires d'interface électronique situés dans un boîtier de contrôle (26) du système de gestion à terre (5) contenant aussi des cartes de saisie, avec lesquelles il échange des signaux de feedback, ainsi que des commandes pour les électrovannes et les alimentations électrique entre l'orthèse (1) et le système de gestion à terre (5) ; et
- l'ordinateur (28) est relié au boîtier de contrôle (26) et il contient un logiciel de contrôle dotée d'une interface graphique pour l'utilisateur ; l'ordinateur (28) est normalement équipé de deux écrans, un premier écran (31) dédié aux exigences de l'opérateur et un second écran (32) qui représente le biofeedback du système et est utilisé aussi bien par l'opérateur que par le patient pour l'autodiagnostic pendant la séance de rééducation.

15. Système (3), selon la revendication 13 ou 14, **caractérisé en ce qu'**il est doté de trois types d'urgences : une urgence qui permet au patient (1') d'interrompre la séance en cas de besoin ; une urgence manuelle et une urgence commandée à partir du logiciel par l'opérateur ; toutes ces urgences permettent d'interrompre l'exécution du logiciel de gestion et de la reprendre par la suite, en enregistrant ou pas la séance.

16. Système (3), selon la revendication 13, 14 ou 15, **caractérisé en ce qu'**il comprend, dans le système de contrôle à terre (5), au moins deux régulateurs de pression électroniques permettant de régler, de manière indépendante, la pression dans les jambes de l'orthèse (1) ; cela permet d'appliquer aux deux jambes des forces d'activation différentes ; le réglage de la pression des actionneurs permet par ailleurs de modifier la force que l'orthèse (1) exerce sur les jambes du patient (1'), en modifiant ainsi l'interaction homme-machine car plus on réduit la pression, plus la poussée au niveau des jambes diminue et le patient (1') doit démontrer de savoir travailler de manière autonome.

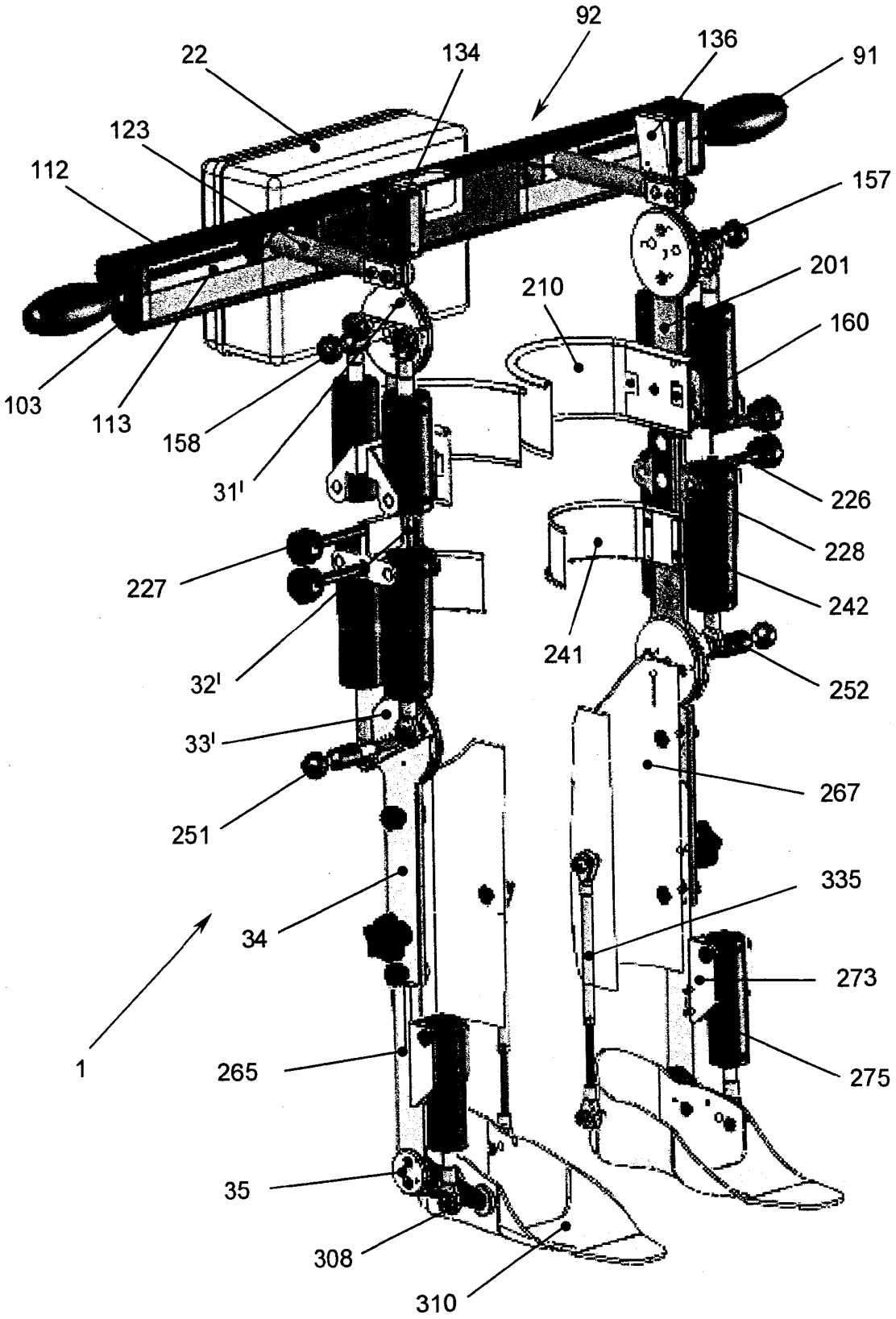
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FIG. 1

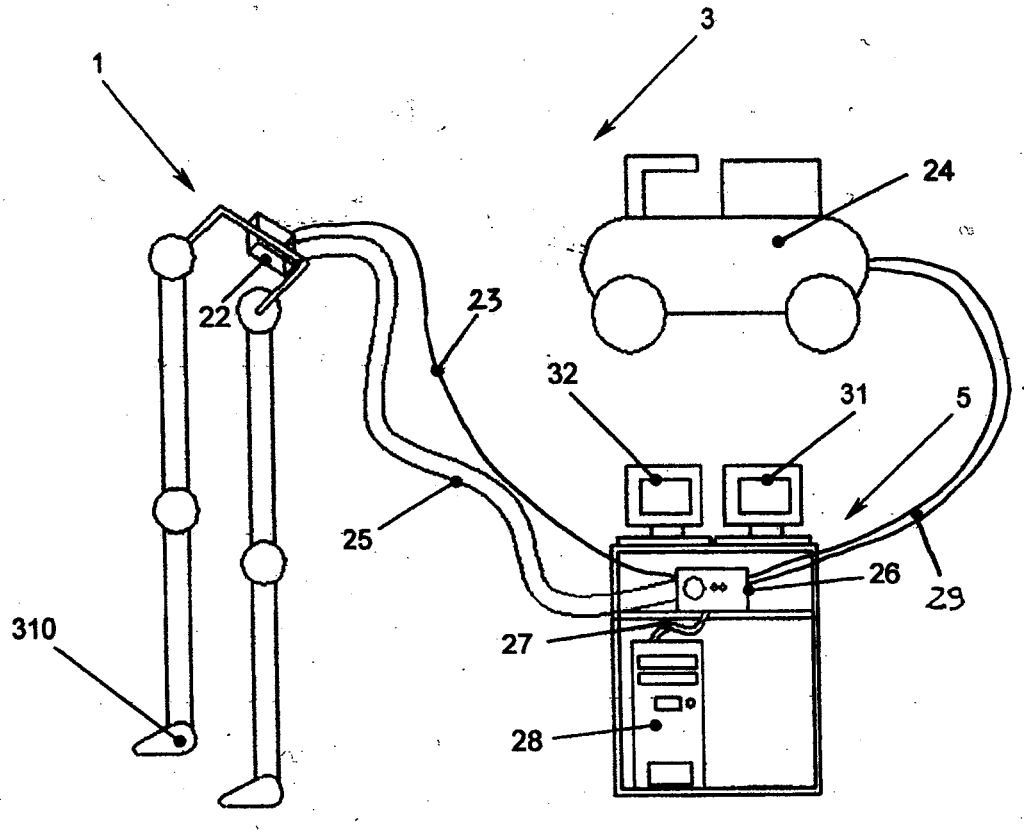

FIG. 2

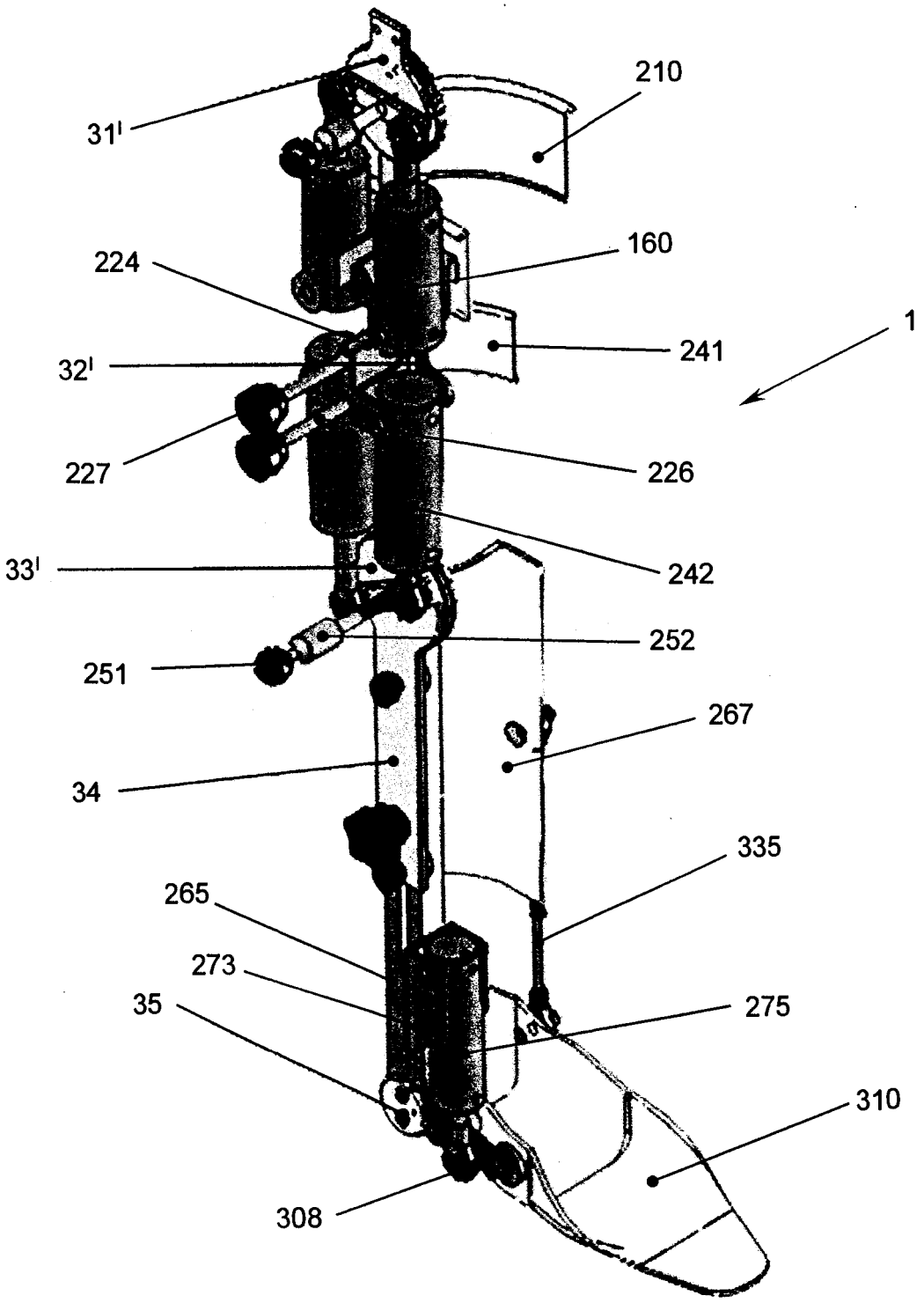
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FIG. 3

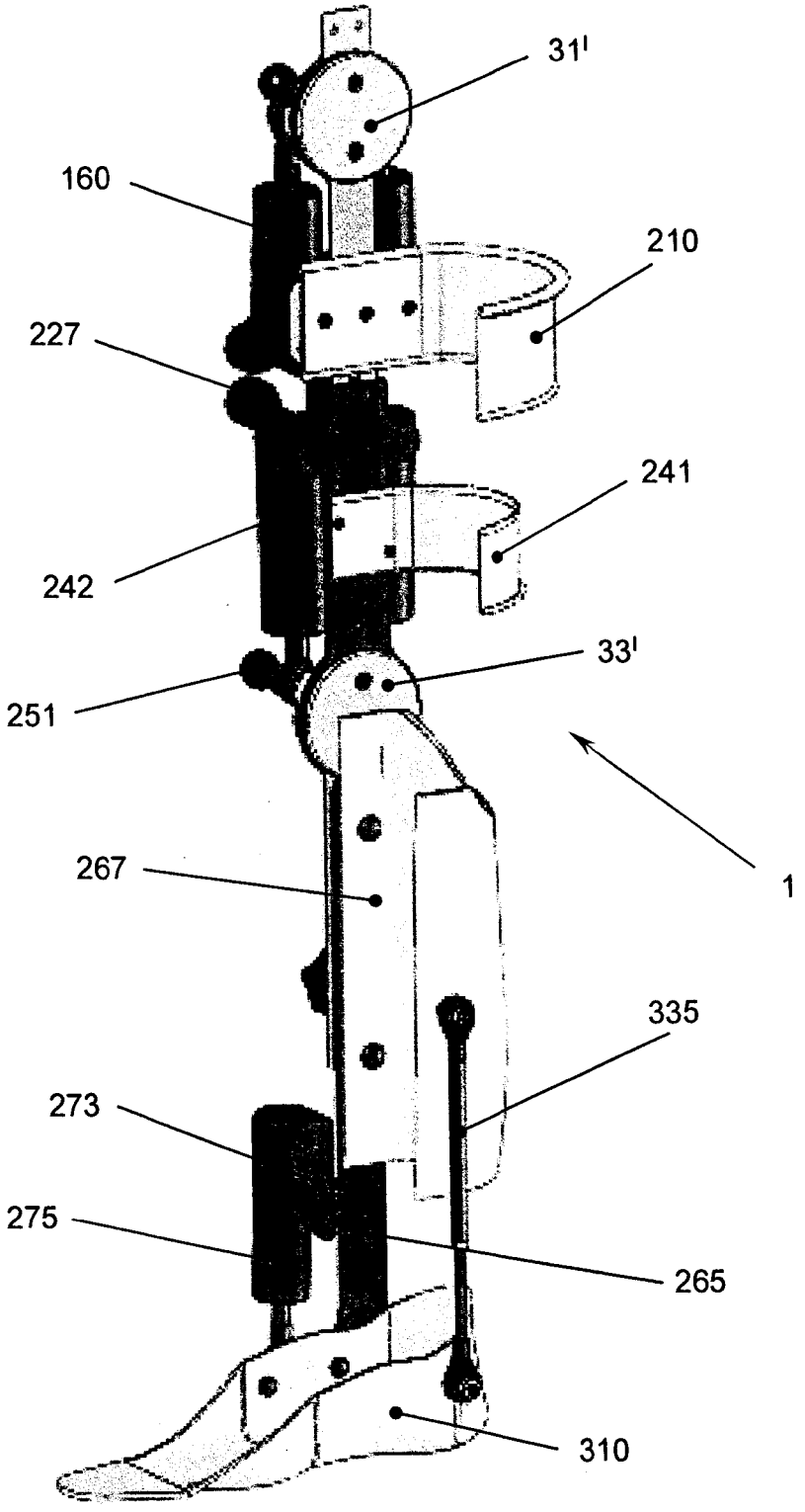

FIG. 4

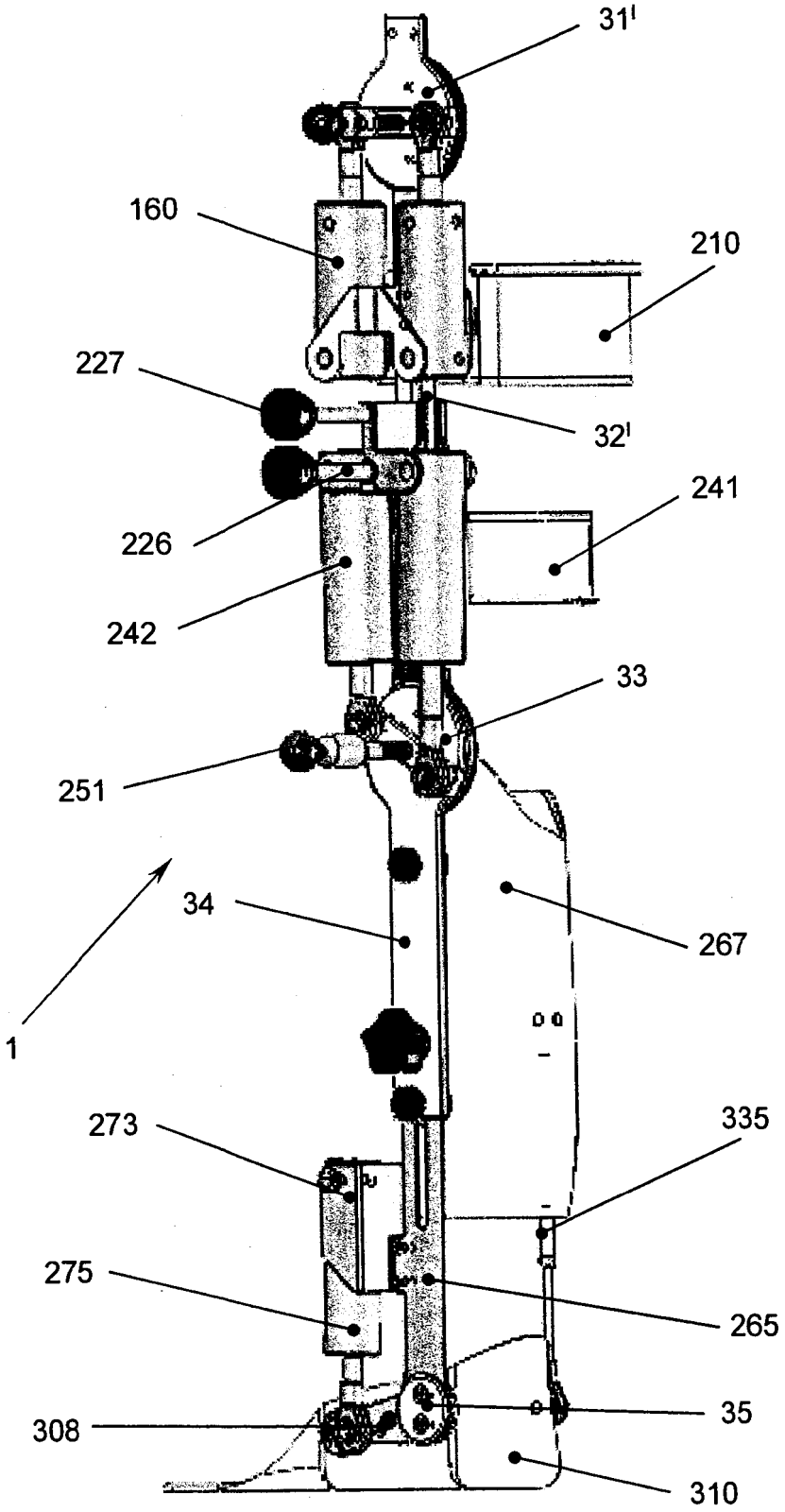
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FIG. 5

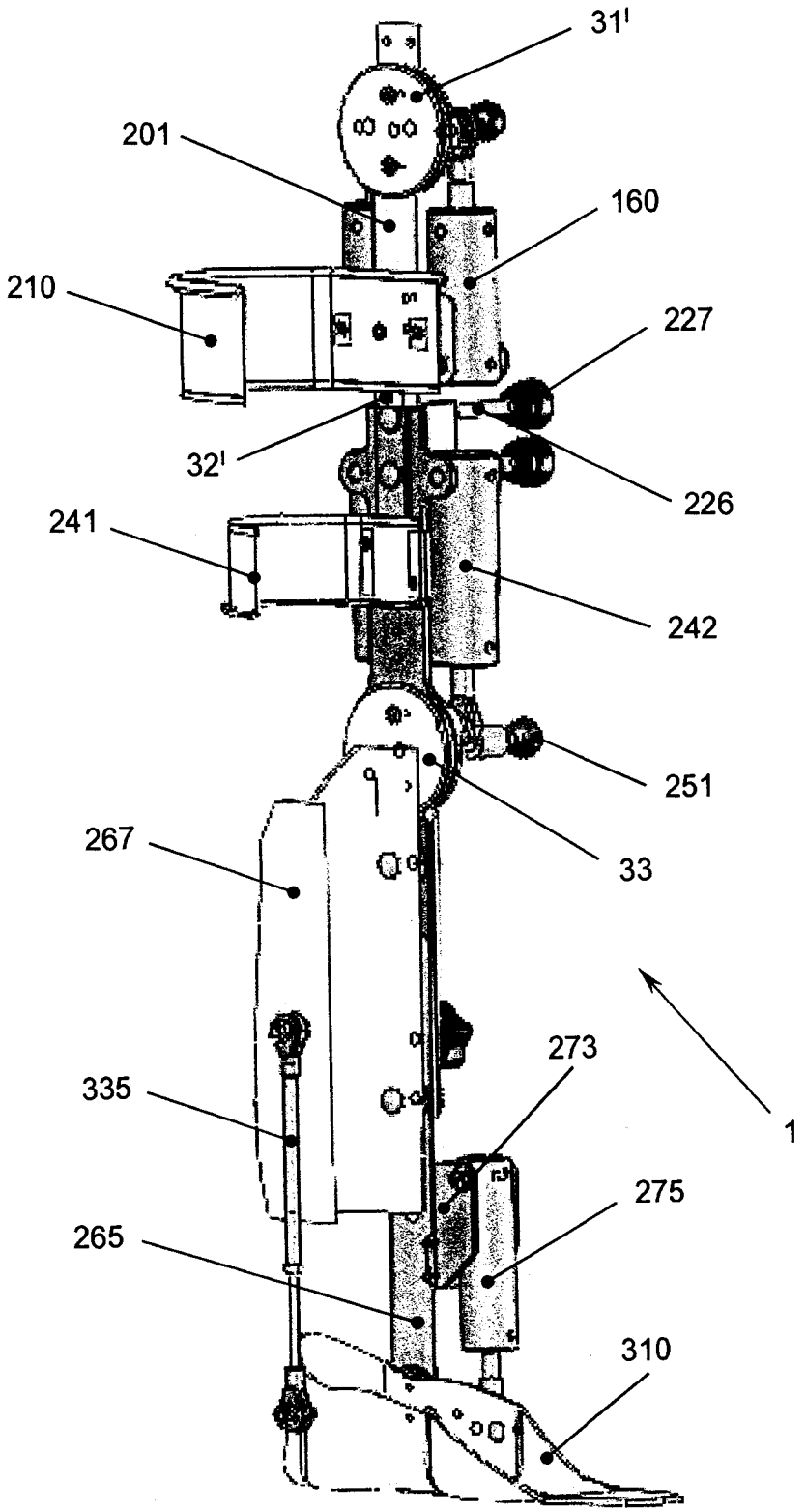

FIG. 6

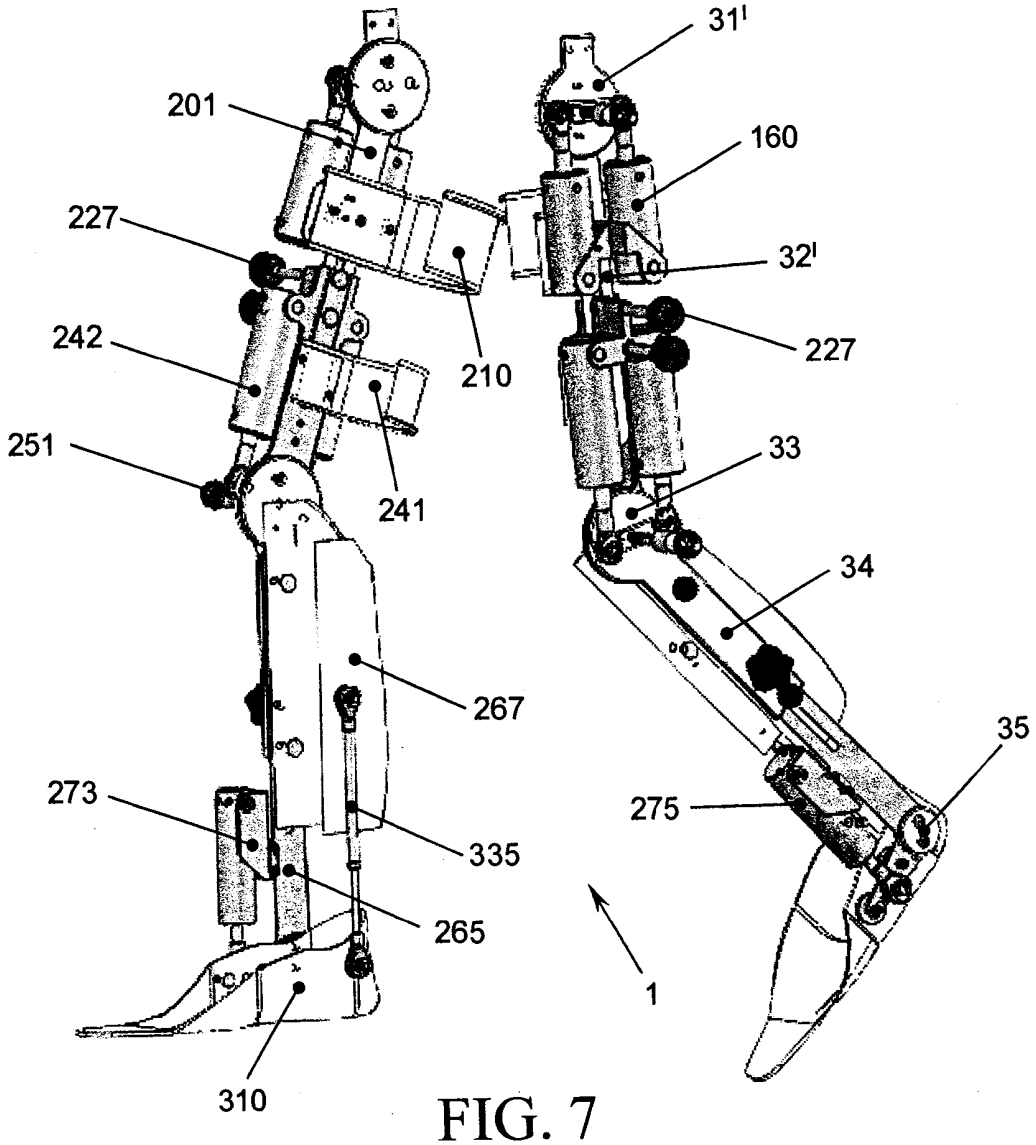
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FIG. 7

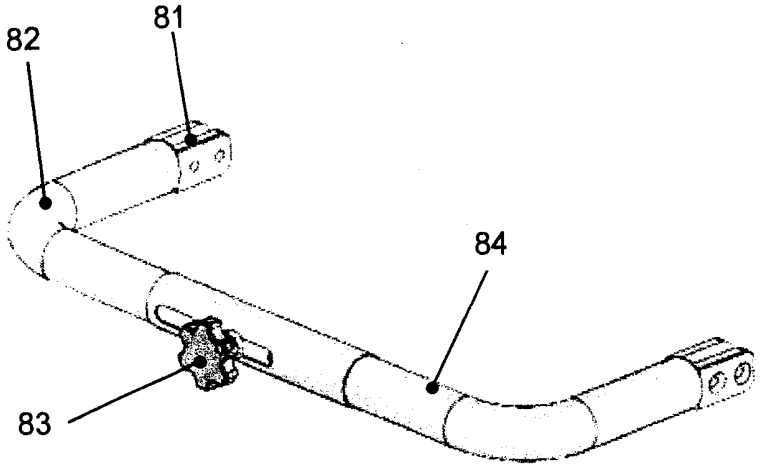
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FIG. 8

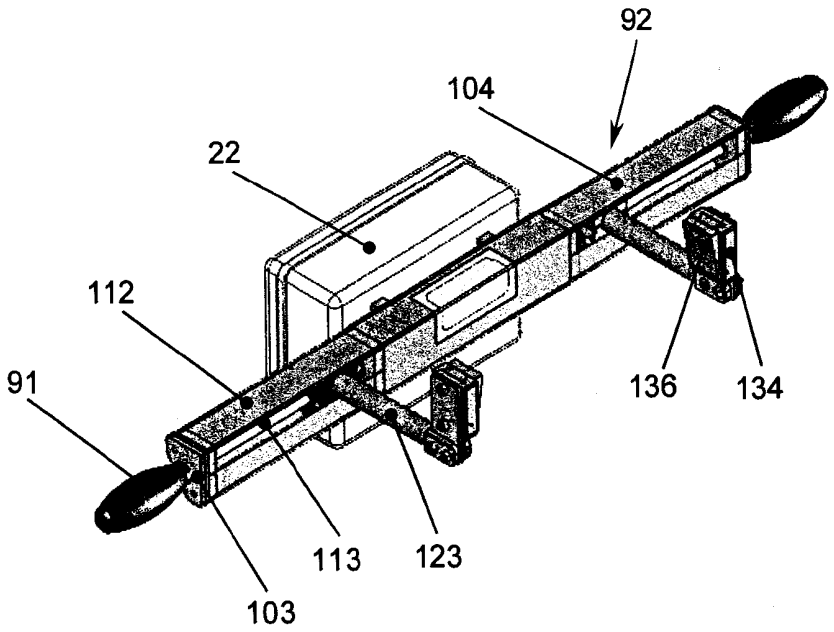

FIG. 9

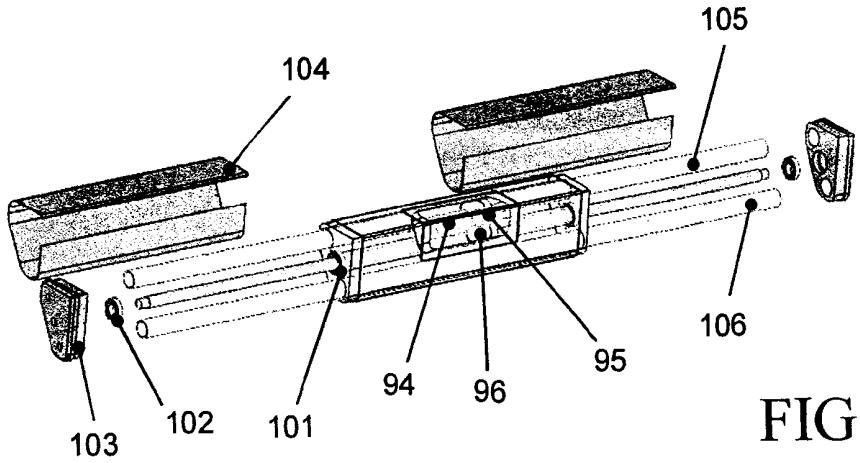

FIG. 10

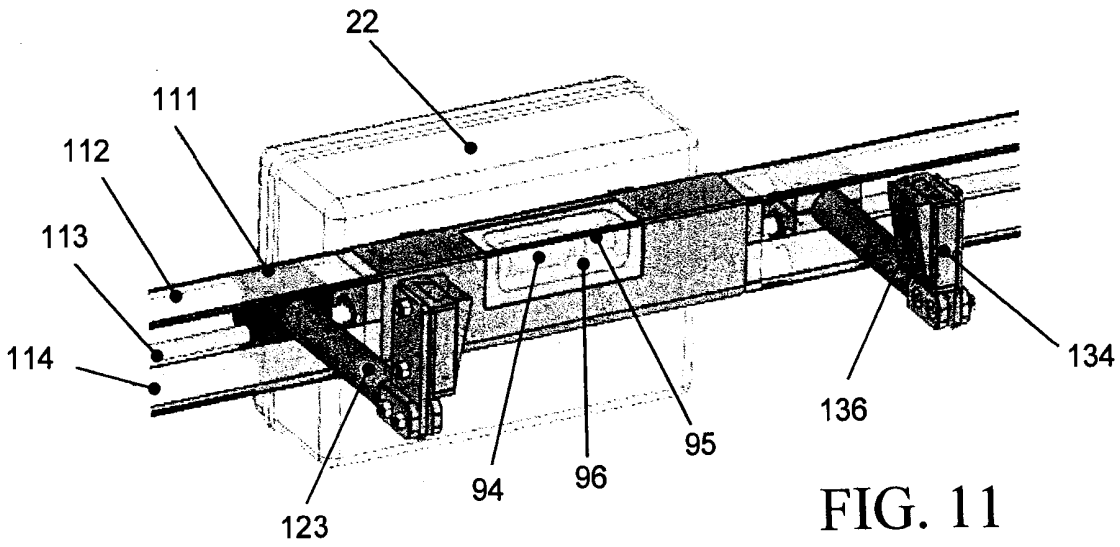

FIG. 11

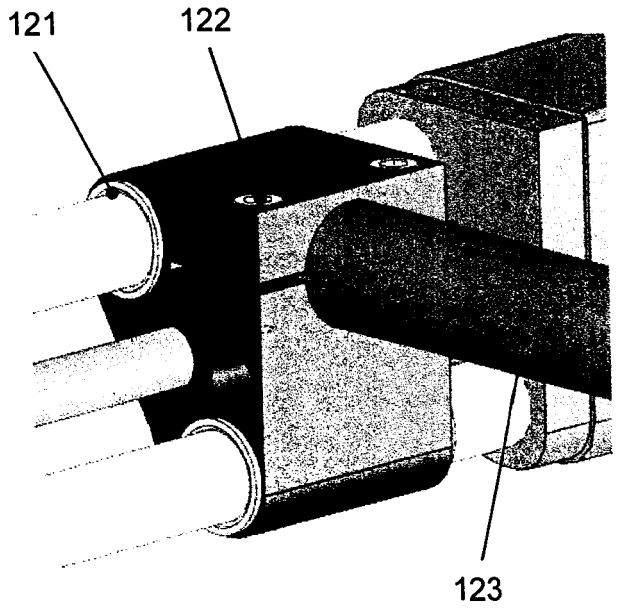

FIG. 12

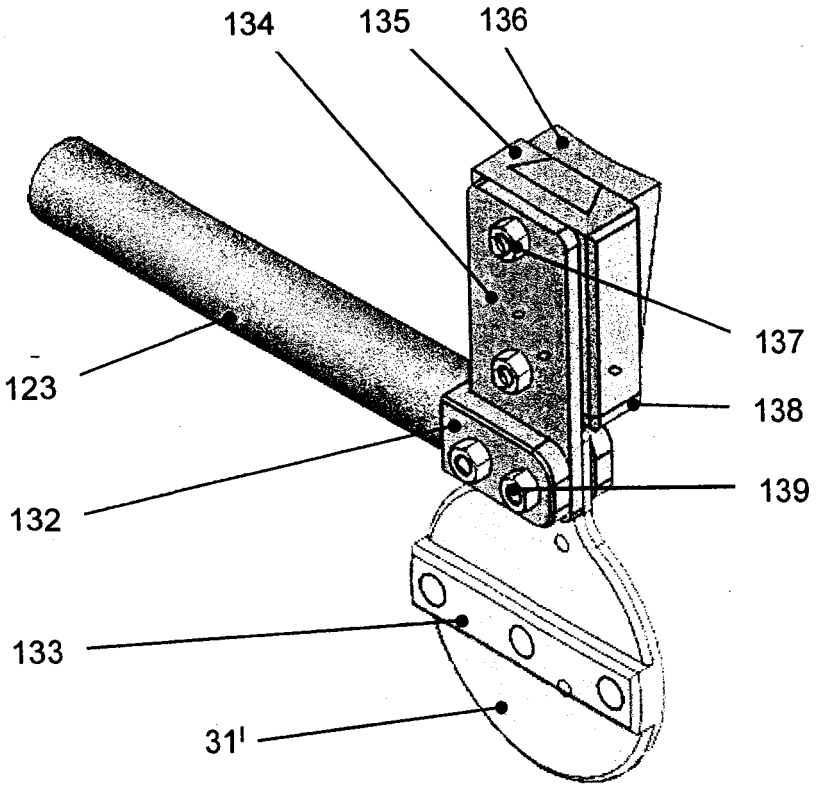

FIG. 13

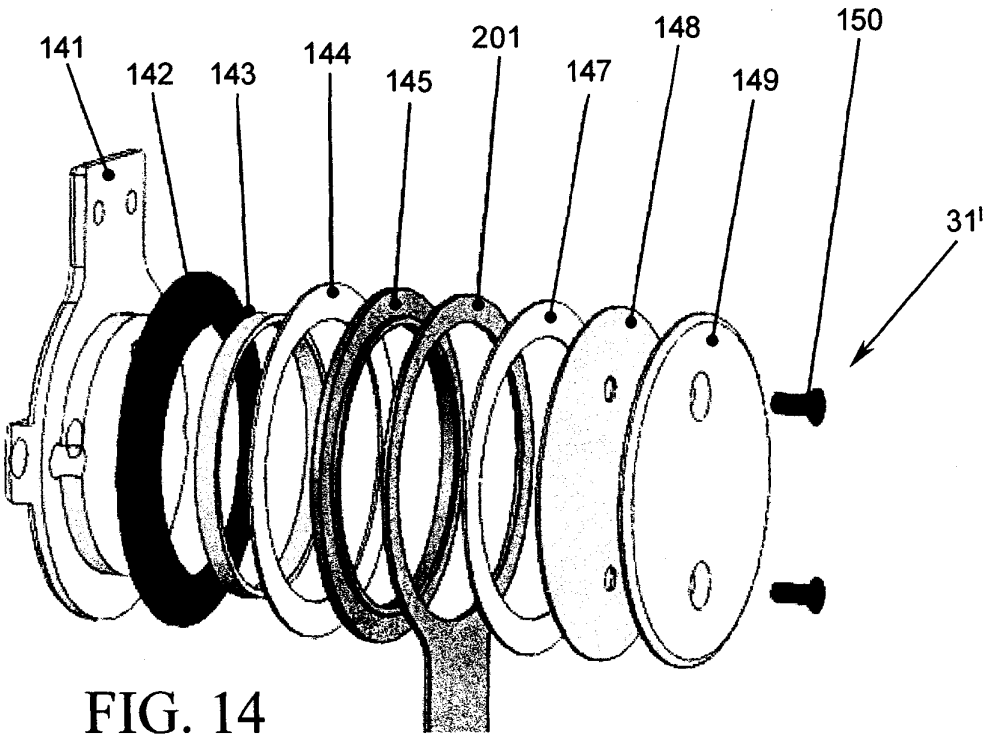
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FIG. 14

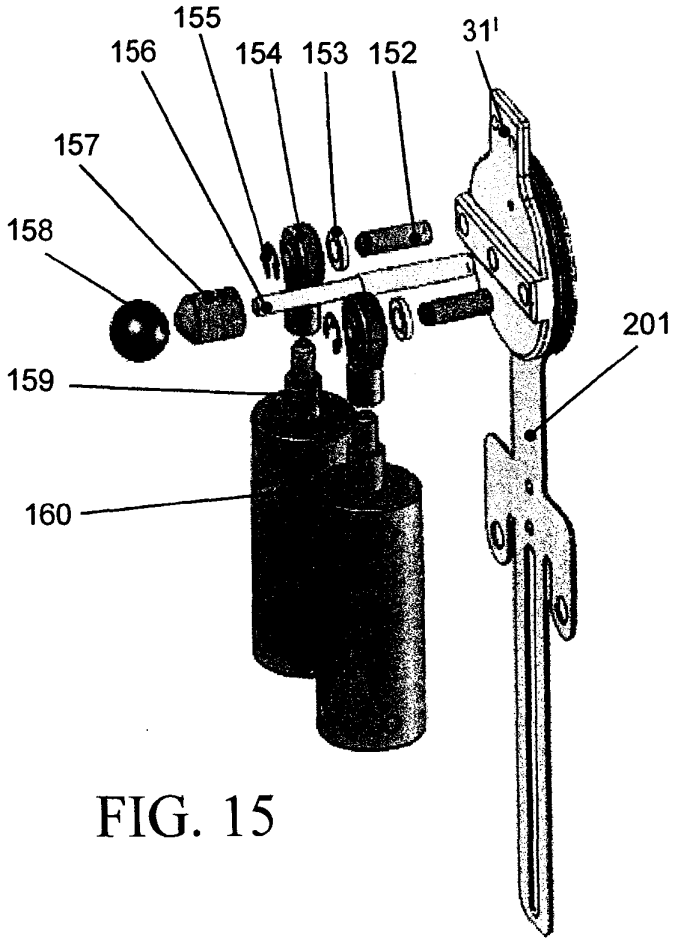
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FIG. 15

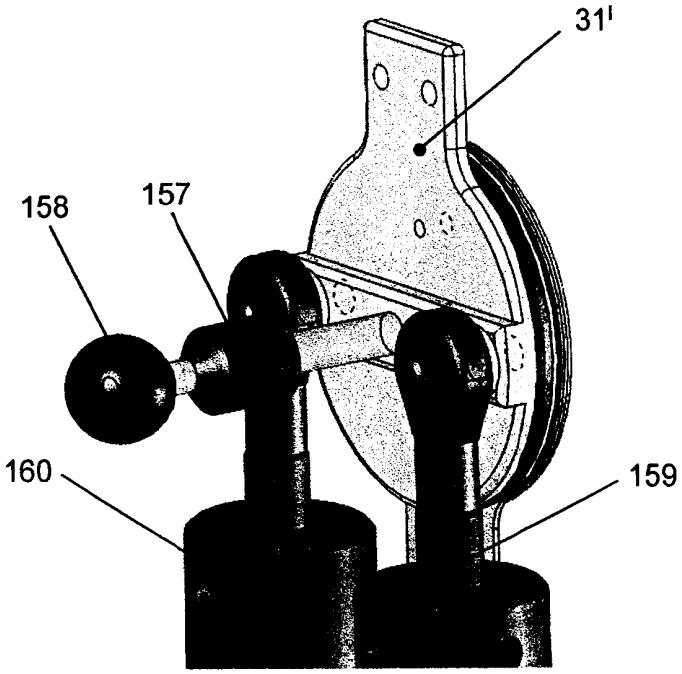

FIG. 16

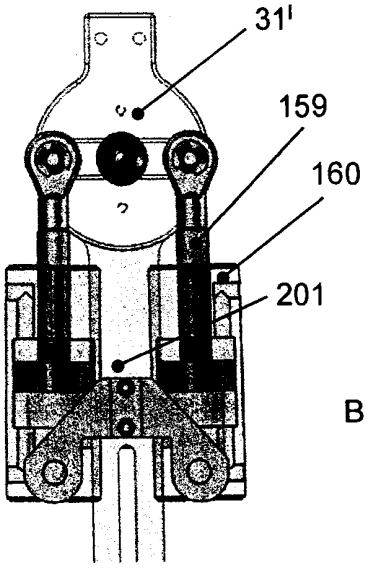

FIG. 17

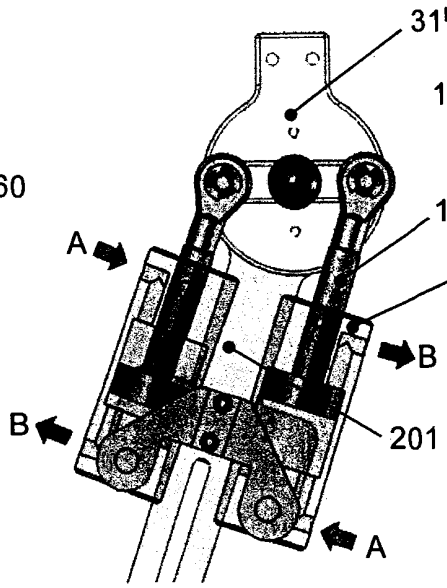

FIG. 18

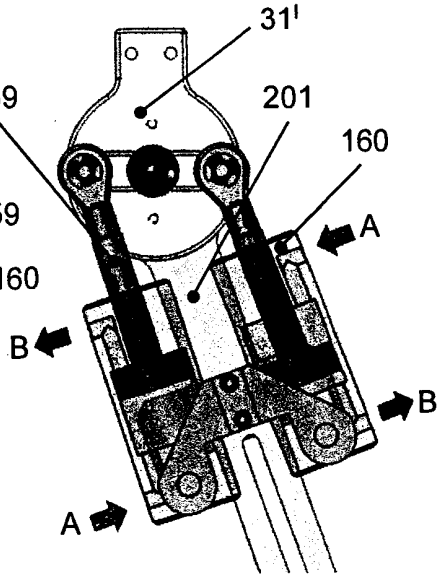

FIG. 19

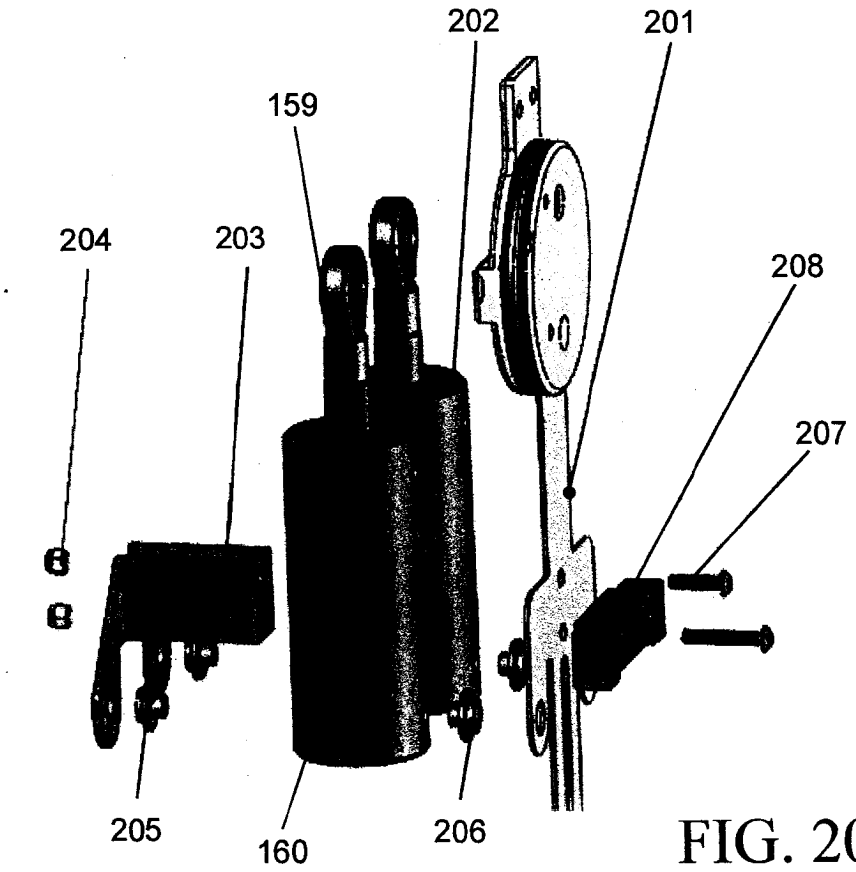

FIG. 20

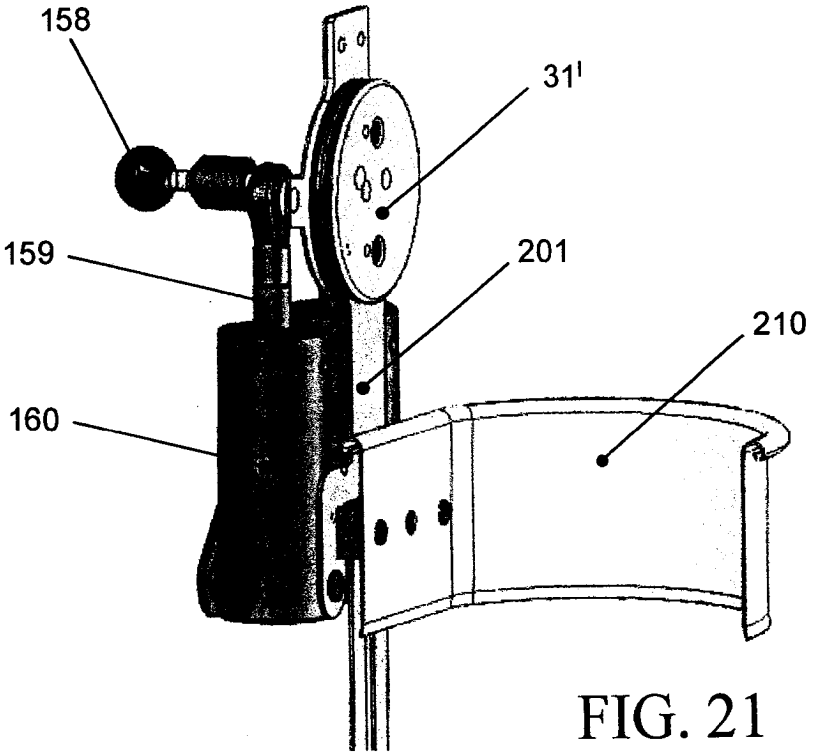

FIG. 21

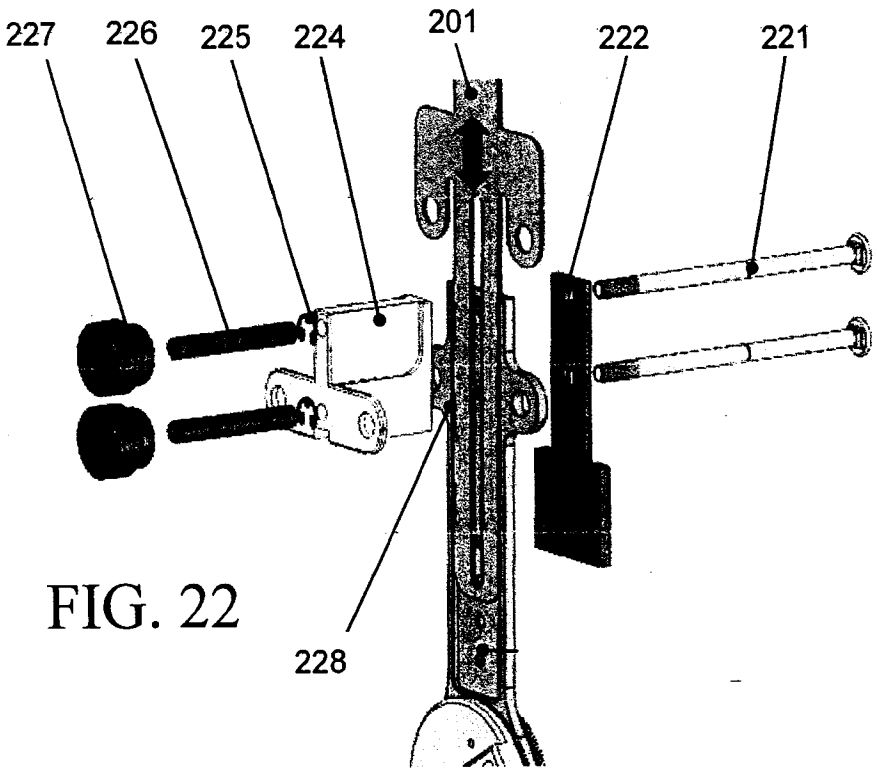

FIG. 22

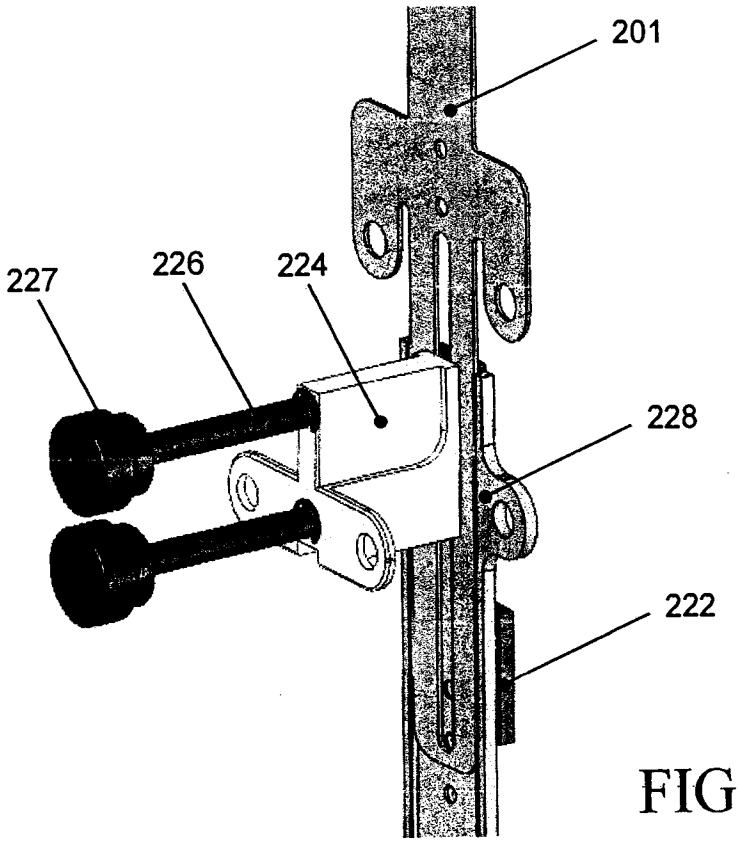

FIG. 23

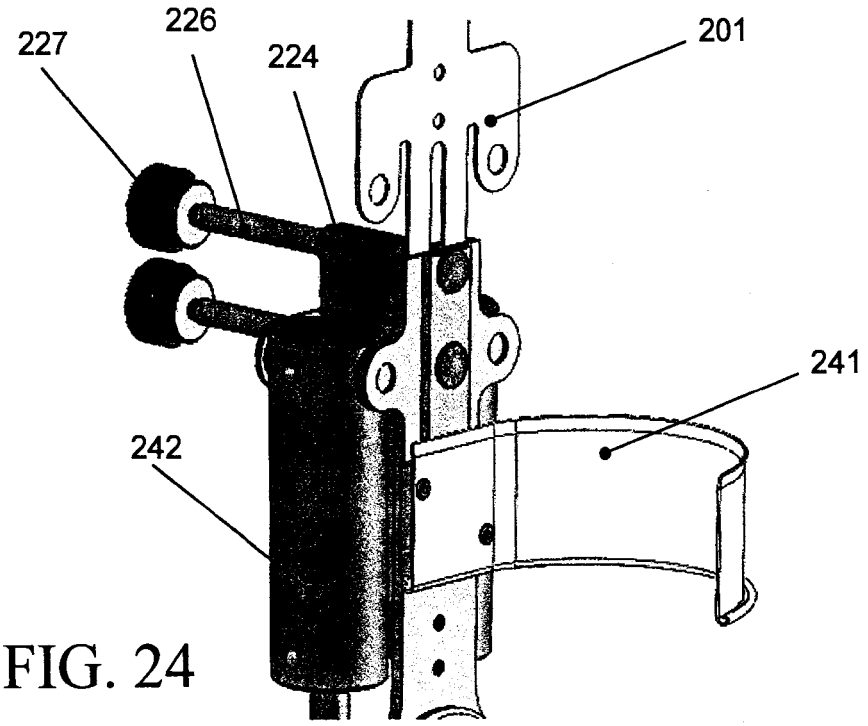
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FIG. 24

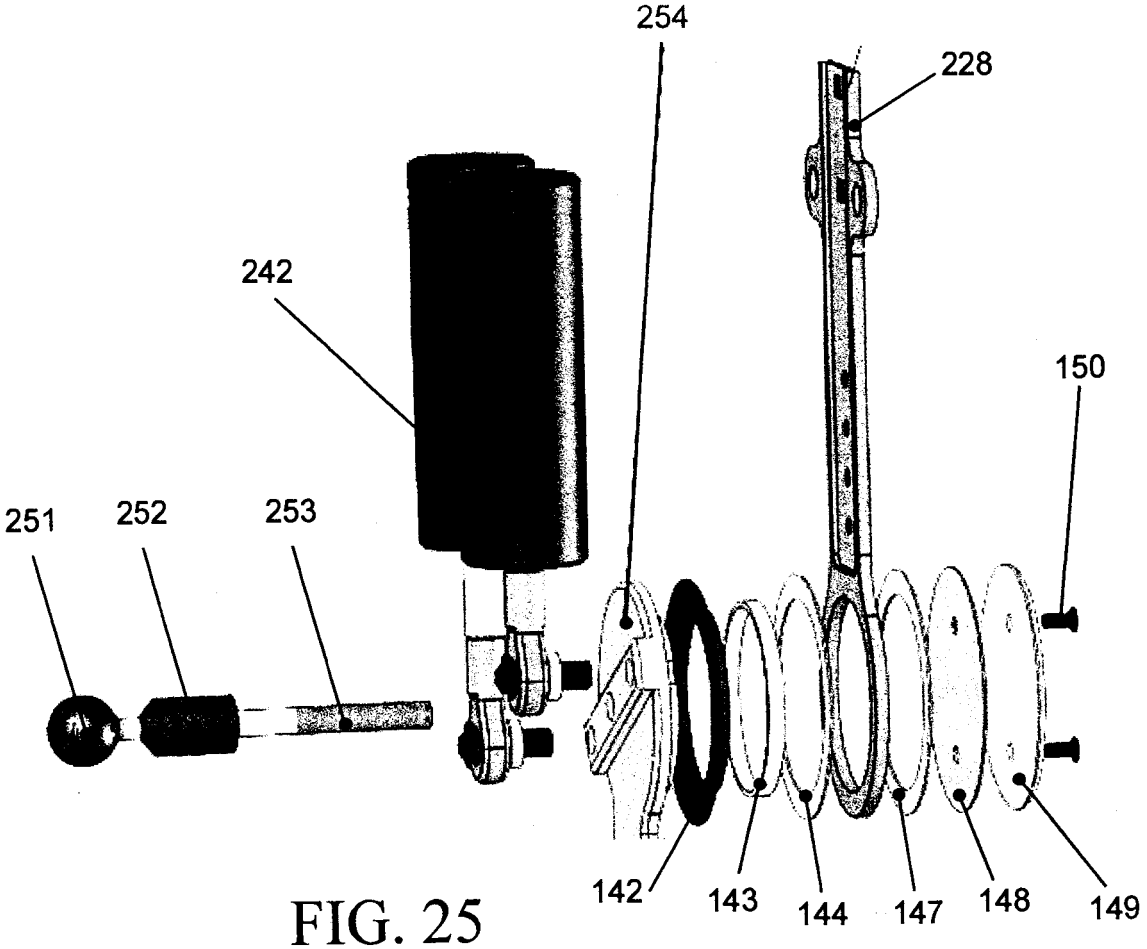
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FIG. 25

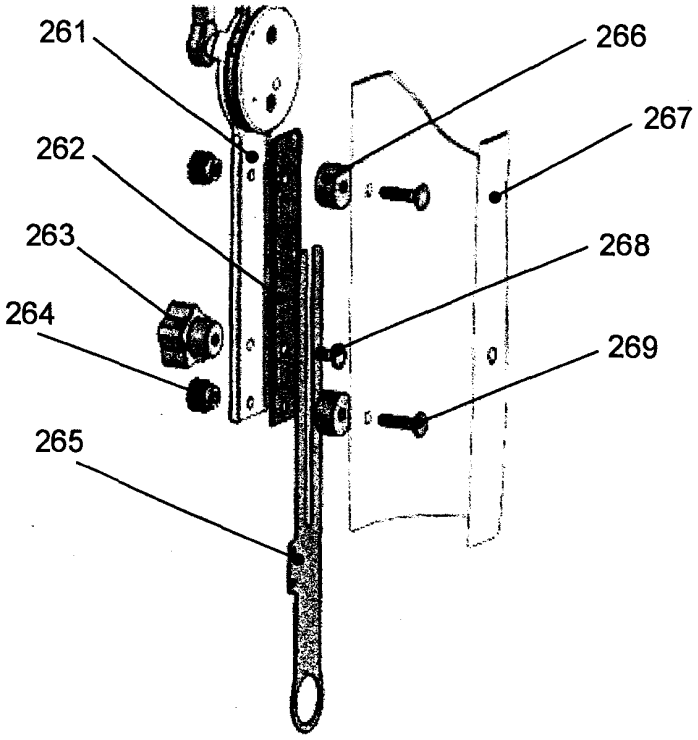


FIG. 26

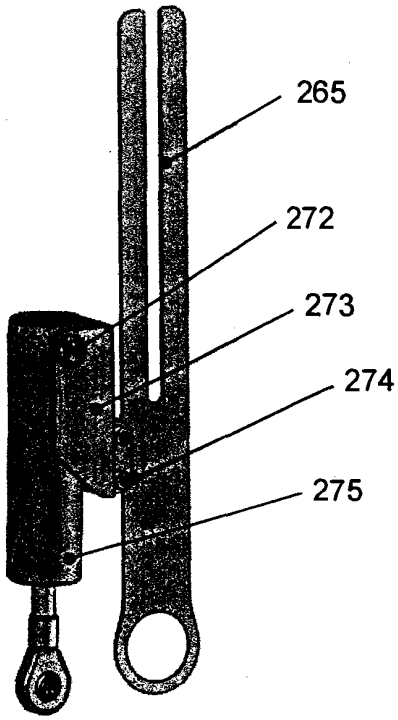


FIG. 27

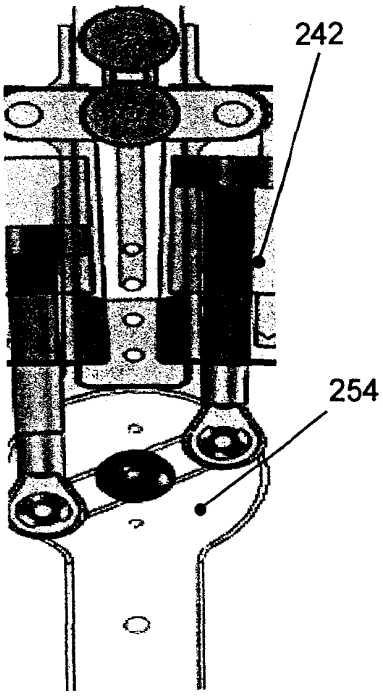


FIG. 28

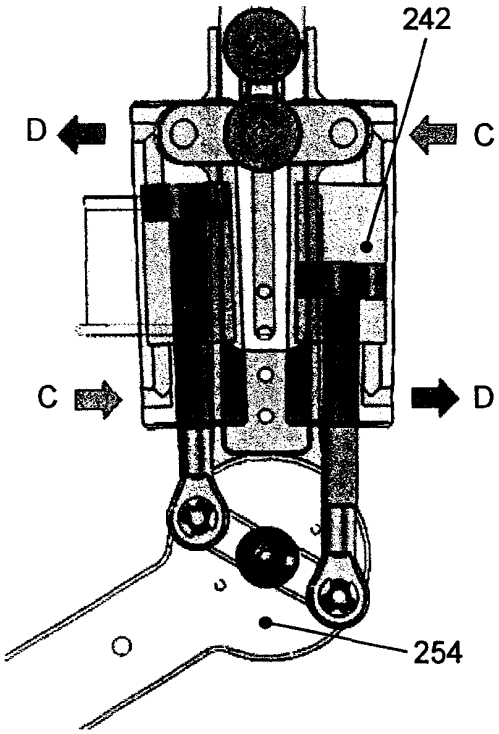


FIG. 29

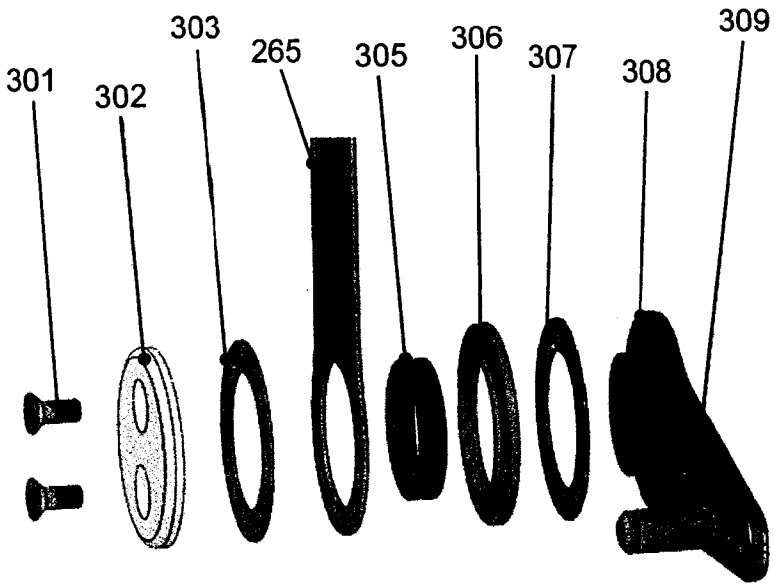
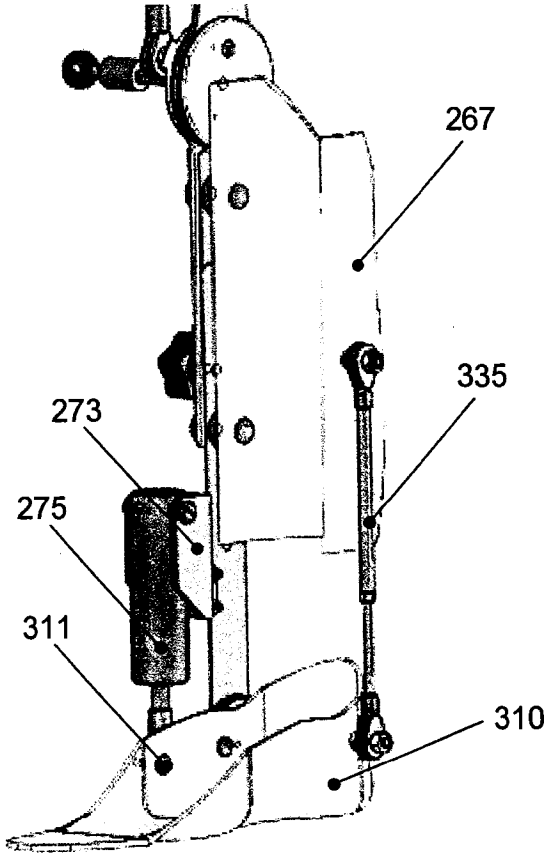


FIG. 30



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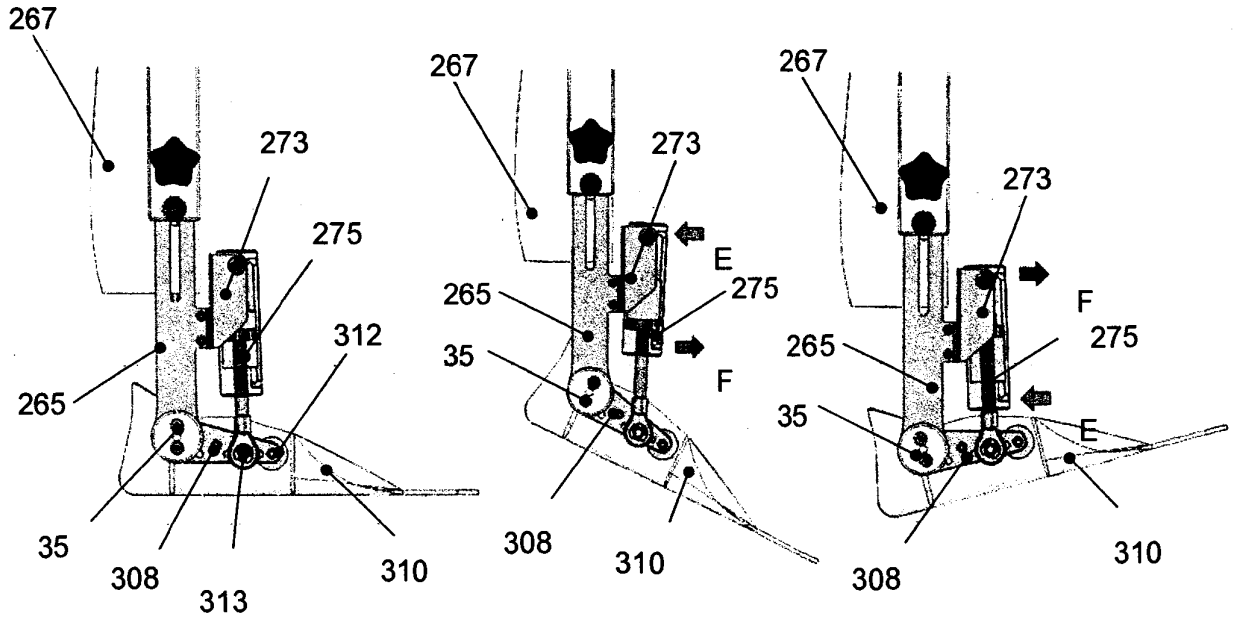
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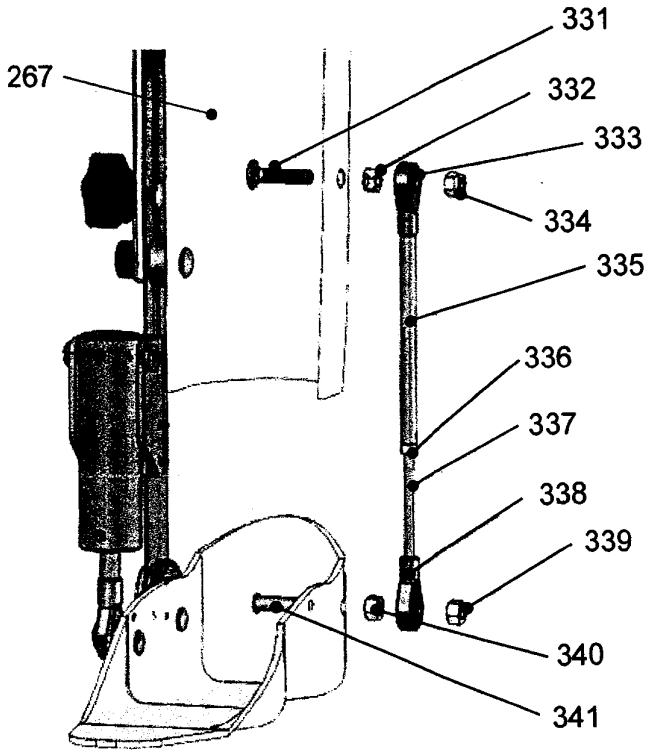
FIG. 32

FIG. 33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340
341

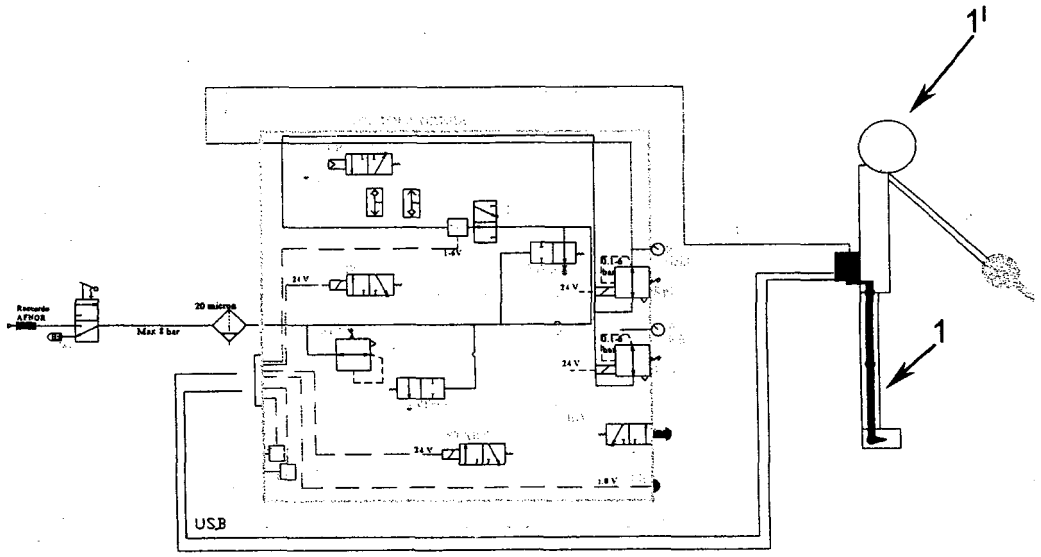
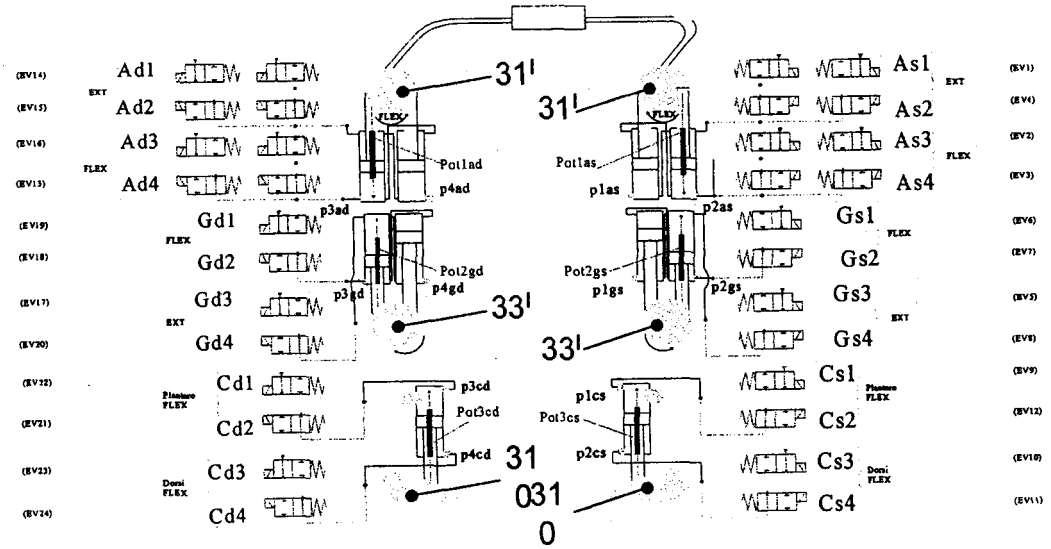

1'
1
USB

FIG. 34

FIG. 35


Ad1
Ad2
Ad3
Ad4
Gd1
Gd2
Gd3
Gd4
Cd1
Cd2
Cd3
Cd4
As1
As2
As3
As4
Gs1
Gs2
Gs3
Gs4
Cs1
Cs2
Cs3
Cs4
31'
33'
31
033
0

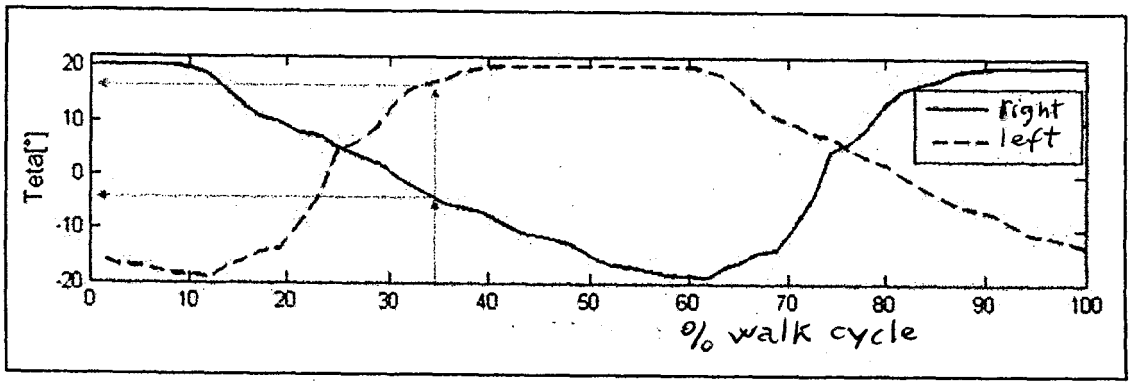

Teta[°]
20
10
0
-10
-20
0
10
20
30
40
50
60
70
80
90
100
% walk cycle
right
left

FIG. 36

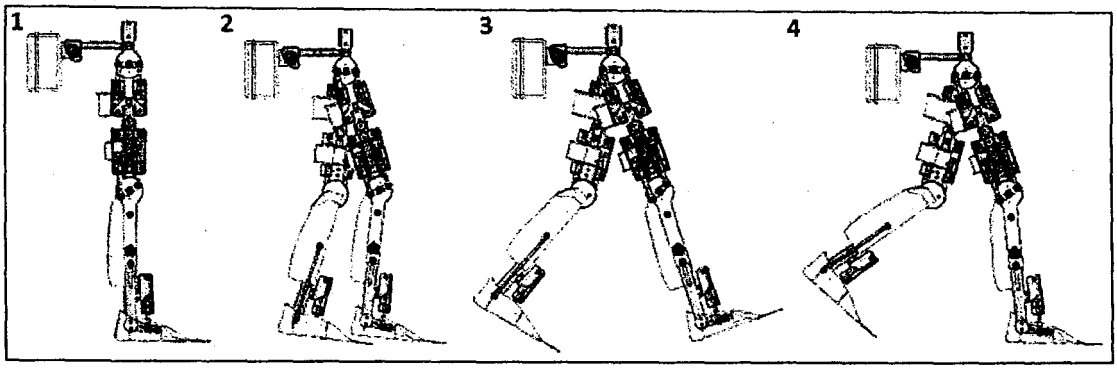

1
2
3
4

FIG. 37

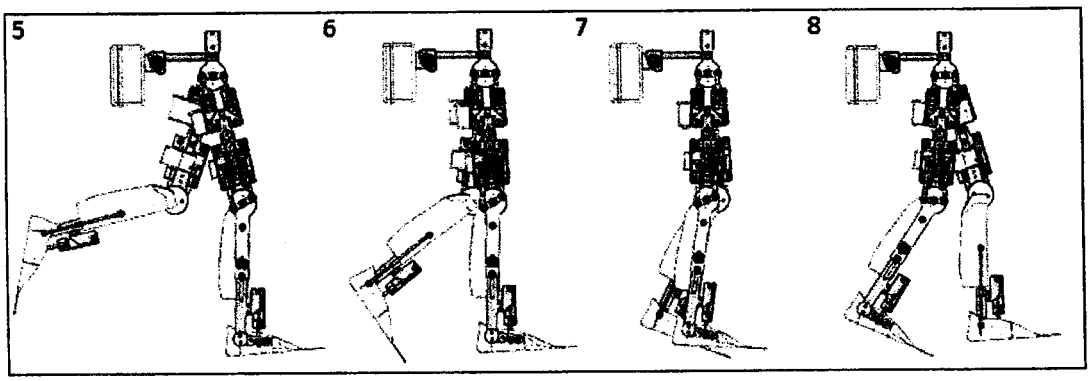


FIG. 38

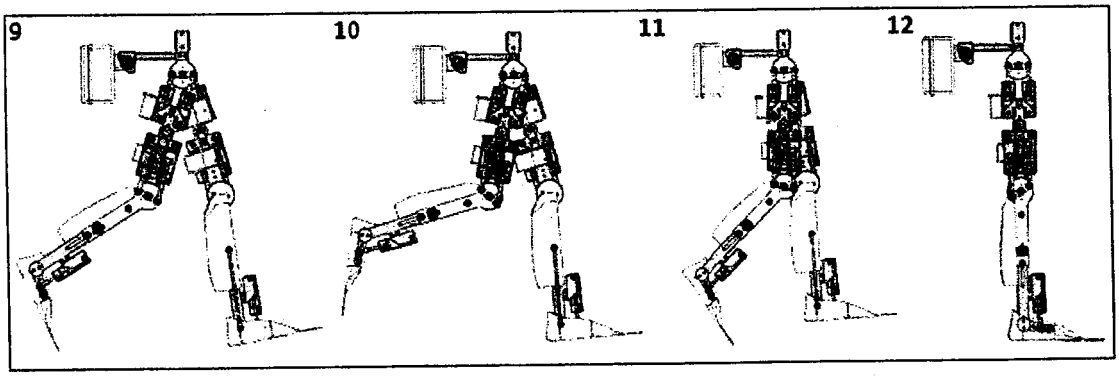


FIG. 39

REFERENCES CITED IN THE DESCRIPTION

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