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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 March 2005 (03.03.2005)

PCT

(10) International Publication Number
WO 2005/018453 A1

(51) International Patent Classification[7]: A61B 5/103

(21) International Application Number: PCT/IT2003/000517

(22) International Filing Date: 26 August 2003 (26.08.2003)

(25) Filing Language: Italian

(26) Publication Language: English

(71) Applicant *(for all designated States except US)*: **SCUOLA SUPERIORE DI STUDI UNIVERSITARI E DI PERFEZIONAMENTO SANT'ANNA** [IT/IT]; 33 Piazza Martiri della Libertà, I-56127 Pisa (IT).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **SCOGLIO, Andrea** [IT/IT]; 1, Via Garofani, I-56125 Pisa (IT). **ZACCONE, Franco** [IT/IT]; 4 Via Dolomiti, I-75025 Policoro (IT). **MICERA, Silvestro** [IT/IT]; 22 Via del Tidi, I-56126 Pisa (IT). **DARIO, Paolo** [IT/IT]; Via Cimabue 3, I-57128 Livorno (IT).

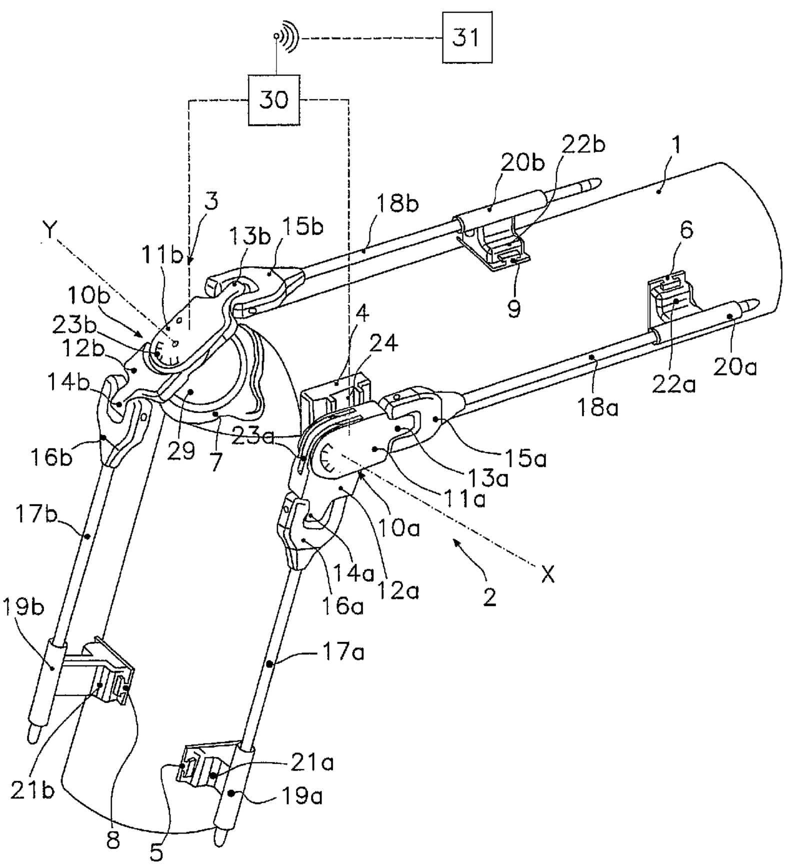
(74) Agents: **BARDINI, Marco, Luigi** et al.; Società Italiana Brevetti S.p.A., Corso dei Tintori, 25, I-50122 Firenze (IT).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,

[Continued on next page]

(54) Title: A WEARABLE MECHATRONIC DEVICE FOR THE ANALYSIS OF JOINT BIOMECHANICS



(57) Abstract: A wearable mechatronic device for monitoring the movements of a body joint comprising a support (1) that can be applied to the limb comprising the joint, magnetic sensor means (10a, 10b) arranged in correspondence with at least one axis of rotation (X, Y) of the joint and capable of generating an electric signal of an intensity correlated with the magnitude of the angular movement around said axis, means (17a,b-22a,b; 24; 29) for positioning said magnetic sensor means in correspondence with said at least one axis or rotation, fixable to said support (1) on the joint and both above and below it.

WO 2005/018453 A1

SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:

— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

TITLE

A WEARABLE MECHATRONIC DEVICE FOR THE ANALYSIS OF JOINT BIOMECHANICS

DESCRIPTION

Field of the invention

The present invention relates to a wearable mechatronic device for the analysis of joint biomechanics and, more particularly, for monitoring the movements of body joints. More precisely, the invention relates to a device that makes it possible to measure and analyze in real time the movements of articulated body joints with one or two degrees of freedom (capable of being applied, for example, to the knee).

Background of the invention

The growing interest shown in recent years by the medical and bio-engineering environment in studies of posture and locomotion has provided a strong stimulus for the development of devices and methods of acquiring and processing data and signals obtained from body parts and surfaces both in static positions and in movement. These researches also led to the construction of some items of equipment that are today extensively used even in sectors other than those of traditional bioengineering. These studies are motivated by the ever growing clinical and applicative need for advanced methods of quantitative and multi-factorial evaluation of the functional alterations associated with control of the posture and the movements.

The great functional complexity of the physiological systems involved in the various pathological forms and the close operational synergy by means of which these systems contribute to the picture of the pathology have suggested the development of highly specialized measurement instruments and protocols that, together with adequate characteristics of accuracy and precision, assure compliance with some further sectoral peculiarities: non-invasiveness, three-dimensionality, computation of specific diagnostic and prognostic parameters, maximum automation of the calculation and restitution processes, etc.

Furthermore, the methods and equipment developed within the traditional medical field have assumed enormous importance also in sports medicine. Recent years, in fact, have seen sport play an ever more important part in national and international socio-economic life. The number of practitioners of sporting activities at the professional or amateur level or for the purposes of social reinsertion (sport for the handicapped, for example) has generated a process of refinement of training procedures that attach ever greater importance to the aspects of optimizing the interactions between athlete and instrument in order to maximize the final performance.

A complete and accurate description of even the simplest movement calls for a large number of data: for example, describing the movement of a lower limb in the sagittal plane during walking calls for up to fifty variables (relative and/or absolute linear-angular measurements). The relative measurements call for all the anatomical coordinates to be calculated with respect to a fixed anatomical point, while the absolute measurements require the anatomical coordinates to be related to a fixed external reference point.

There exist many different systems for carrying out kinematical measurements of a biological joint. Among these one may here recall the electro-mechanical systems comprising articulated quadrilateral devices and electrogoniometers. The latter are devices capable of detecting a single movement of rotation for each joint, so that - in the case, for example, of an essentially two-dimensional joint like the knee - there have to be installed two separate electrogoniometers, each operating on a single axis of rotation (flexion-extension axis, transverse rotation axis). The use of these devices calls for distinct fastening systems which can result in a rather complex positioning of these devices on the patient's body without guaranteeing the necessary accuracy of the effected measurements. This problem becomes more and more complex as the number of degrees of freedom of the articulated joint increases.

United States patent No. 4883069 describes an instrument for the measurement of the movement of the knee in the three reference planes. The measurement is made by means of three rotoidal potentiometers mounted on three axes positioned at 90° with respect to each other. The potentiometers are positioned on a single support (triaxial joint) placed in a lateral position with respect to the knee. The support of the potentiometers is defined by a tubular mechanical structure attached to the lower limb by means of a band-type fastening system placed upstream (femur) and downstream (tibia/thigh) of the knee. In the medical field the device is used for both therapeutic and technical-sporting uses. Although the device is triaxial, light and of limited encumbrance, the device has a single axis of rotation in line with the physiological one of the patient. As far as the remaining two axes are concerned, it carries out an indirect measurement, because these axes are not in line with the corresponding physiological axes. Consequently, the kinematic solution adopted in this patent produces an error that becomes larger as the distance between the kinematic axis of the system and the corresponding physiological axis of the knee becomes greater. Furthermore, the device in accordance with US 4883069 is not provided with points for direct fixing to the knee. The fastening points are referred to the muscular parts of the lower limb. In this way the system, being devoid of objectively determinate references, is not capable of assuring that even the same patient will wear it in the same position on two successive occasions: in the absence of any direct fastening points on the knee, in fact, the positioning of the sensitive part of the device (reading system) cannot assure proper alignment with the appropriate kinematic axis of rotation. The considered system of attachment to the lower limb is constituted by a system of bands that inevitably introduces relative sliding between the mechanical system and the lower limb. Lastly, the device is not equipped with a system of alignment to anatomical parts, so that it is possible to measure only the magnitude of the rotation relative to the joint that is being examined, though without knowing the starting point, and it is not therefore possible to make comparisons between measurements made at different times.

Other widely used systems are the optical ones, which are normally based on two operating principles. The first (system of passive markers with threshold recognition) is based on the positioning on the body of the interested patient of small markers that can be recognized by an infrared rays system. A series of two or more telecameras are placed around the element in movement and capture the markers within their field of vision. A suitable software system, using complex mathematical algorithms, performs a correlation of the various positions of the markers, resorting to different perspectives to calculate the space coordinates of each marker and exploiting the principle of redundance of the information available for each point.

The optical systems of the passive-marker type with form recognition, on the other hand, make use of a single infrared telecamera capable of capturing the contours of the image of the object to be examined, which are then analyzed to determine the position of the various parts of the body and its gestures.

Both methods require that there must be no disturbing elements between the transmitter and the receiver. This means that the work environment must be such as to permit these systems to be operated without any occurrence of interferences or shadow zones caused by possible discontinuities between emitter and receiver. These systems do not give rise to the typical drawback of numerous movement analysis systems that consists of the presence of connecting cables between the measuring system and the support for storing and analyzing the data. All the same, the principal difficulty associated with their use is the impossibility of maintaining the position of the markers constant at the points defined by the joint on account of the small relative movements that occur between the skin and the bone structure. Furthermore, their use calls for highly specialized personnel to process the data and implies considerable costs.

The magnetic systems, of which the 3 SPACE FASTRACK device manufactured by the US firm Polhemus is an example, generally make use of a source that emits a magnetic field and a small sensor that refers its own position and orientation with respect to the emission source. Unlike the acoustic and optical systems, these systems are not based on observations by means of the so-called "lines of sight", but metallic objects present in the work environment can distort the magnetic field and give rise to reading errors of the position of the point of which the exact spatial position is to be determined. Though the presence of one or more transmitters of small weight and size and a receiver physically connected to the central unit assures an absolute measurement of the parameter to be recorded, it is also associated with the problem of greatly limiting the movements of the subject on whom the measurements are made.

Objects and summary of the invention

The object of the present invention is to provide a mechatronic device that can readily be worn by the user (patient), is simple to use for the operator (phisician) and capable of monitoring with sufficient accuracy the dynamic behaviour of a body joint such as, for example, the knee.

Another aim of the present invention is to provide a wearable mechatronic device of the aforementioned type that will make it possible to read the angles of a body joint in a simple and rapid manner and with a small positioning error.

Another aim of the present invention is to provide a wearable mechatronic device of the aforementioned type that will assure wide freedom of movement for the user/ patient by not making use of any cables to connect it to a central data acquisition unit.

Yet another aim of the present invention is to provide a wearable mechatronic device of the aforementioned type that will be symmetrical, i.e. can be adapted in a very brief space of time for use on both the limbs.

These aims are attained by means of the wearable mechatronic device for monitoring the movements of body joints in accordance with the invention, comprising a support that can be applied to the limb comprising said joint and magnetic sensor means associated with the support and arranged on at least one axis of rotation of the joint, said means being capable of generating an electric signal of an intensity correlated with the magnitude of the angular movement around the axis of rotation. Means for positioning the magnetic sensor means on the axis of rotation are provided, said positioning means being attachable to said support in correspondence to the joint and both above and below it.

In a preferred embodiment the magnetic sensor means comprise a first element carrying at least one Hall sensor and a second element, hinged to the first element around an axis and carrying at least one magnet, while the positioning means comprise a first connection for the magnetic sensor means arranged on the support in a position intermediate with respect to its two ends, so that the hinge axis can be brought into substantial alignment with the axis of rotation of the joint. Second connections are arranged upstream of and, respectively, downstream of the first connection and are connected to the first and the second element of the magnetic sensor means.

Brief description of the drawings

The characteristics and advantages of the wearable mechatronic device for monitoring body joints in accordance with the invention will appear more clearly by the following description of a particular embodiment thereof, which is given by way of example and is not to be considered limitative in any way, the description making reference to the attached drawings, of which:

- Figure 1 shows a perspective view of the wearable mechatronic device in accordance with the invention in an embodiment suitable for monitoring the joint of the knee;

- Figure 2 shows a partly sectional plan view of the connection of the sensor unit of the system for detecting flexion-extension movements;

- Figure 3 shows a side elevation views of the connection of Figure 2 as seen in the direction of the arrow F.

Detailed description of the invention

Referring to Figure 1, the reference number 1 indicates an elastic tubular support of the type used in common commercial knee braces intended to be applied to a lower limb at the knee joint. Fixed to the support 1 is a mechatronic structure comprising a unit for the detection of flexion-extension movements (movements of the femur-tibia joint in the sagittal plane), generically indicated by 2, and a unit for the detection of abduction-adduction movements (movements of the femur-tibia joint in the frontal plane), generically indicated by 3. As is known, the flexion-extension movement is the rotation movement of the knee in the sagittal plane around an axis passing through the femoral epicondyles. The abduction-adduction (or varus/valgus) movement of the knee, on the other hand, is the angular movement of the tibia with respect to the femur in the frontal plane. The two rotation axes as aforesaid are indicated in Figure 1 by, respectively, X and Y.

Support 1 is provided with connection means for the two detection units 2 and 3. For unit 2 that detects the flexion-extension movement, in particular, there are provided a central connection 4 arranged in an intermediate position on support 1 and two terminal connections 5 and 6 arranged in proximity of the ends of support 1 and therefore above and below the central connection 4 in the direction of the length of support 1. Similarly, for unit 3 that detects the abduction-adduction movements there are provided a central connection 7 arranged on support 1 in an intermediate position, substantially at 90° with respect to central connection 4 provided for unit 3, and two terminal connections 8 and 9 arranged in proximity of the ends of support 1 and therefore above and below central connection 7 and substantially arranged at right angles with respect to the corresponding terminal connections 5 and 6 provided for unit 2.

The central connections 4 and 7 and the terminal connections 5, 6 and 8, 9 are fixed to the support 1 in any known manner, for example by means of gluing or with screws.

Central connection 7 of detection unit 3 is arranged in such a position on support 1 as to permit it to be readily positioned in coincidence with the rotula of the knee and to this end it is provided with a central opening, not visible in the figures, for visual centring of the rotula.

The relative position of central connection 4 of detection unit 2 with respect to the position of central connection 7 of detection unit 3 is such that they will be situated substantially on the tibial condyles when support 1 is worn in such a way that central connection 7 is positioned on the rotula and aligned with the axis of the varus/valgus movement. With a view to taking due account of the different morphological sizes of the various users, there is also provided a fine adjustment system to regulate the position of the sensor unit applied to him, and this will be described in greater detail further on.

Fixed to the central connection 4 of unit 2 for detecting the flexion-extension movements there is a sensor unit 10a within which there are housed the movement sensors that will be described further on. Similarly, fixed to the central connection 7 of unit 3 for detecting the abduction-adduction movements there is a sensor unit 10b carrying movement sensors that will be described further on.

The two units 2 and 3 for detecting the flexion-extension and abduction-adduction movements are structurally similar and in the present description only one of them will therefore be described, indicating between parentheses the reference numbers of the corresponding components of the other.

Sensor unit 10a (10b) is a body made up of two parts or elements 11a, 12a (11b, 12b) rotatably connected to each other around an axis perpendicular to the plane in which they lie, this axis substantially coinciding with the axis X (Y) of the knee. In particular, element 11a (11b) has a substantially C-shaped part within which element 12a (12b) is engaged. From the two elements 11a, 12a (11b, 12b) of sensor unit 10a (10b) there extend respective longitudinal appendices 13a, 14a (13b, 14b) engaging with the corresponding fork-shaped ends 15a, 16a (15b, 16b) of two rods 17a, 18a (17b, 18b). Appendices 13a, 14a (13b, 14b) are rotatably connected to fork-shaped ends 15a, 16a (15b, 16b) around axes coplanar with the plane in which there lies sensor 10a (10b) and perpendicular to rods 17a, 18a (17b, 18b), which are slidingly mounted in respective tubular guides 19a, 20a (19b, 20b) connected to slides 21a, 22a (21b, 22b) frictionally engaging with the terminal connections 5 and 6 (8 and 9).

It may be noted from the above description that each of the two detection units 2 and 3 is provided with an active articulation, namely the one between the two elements 11a, 12a (11b, 12b) of the respective sensor unit 10a (10b), by means of which it detects the corresponding movement of the body joint, and a passive articulation, namely the one between rods 17a, 18a (17b, 18b) and sensor unit 10a (10b), by means of which a detection unit follows the movement that the other unit is called upon to detect.

Advantageously, on element 11a (11b) there may be mounted a reference goniometer 23a (23b) - shown only in a schematic manner - for the initial regulation (search for the initial zero) and for fixing some parameters of the processing software.

The sliding connections between the rods and the relative terminal connections assure a correct operation even in the presence of possible small positioning errors - and the relative kinematic errors that derive therefrom - and make it possible for the two units to be quickly and easily attached to the elastic support 1. Furthermore, in the case of unit 3 for the detection of the abduction-adduction movement, since this unit is positioned frontally on the rotula and therefore very far from the neutral axis of the lower limb, identified as a projection of the axis of the rods of unit 2, the unit is subject to cyclical lengthenings and shortenings due to the flexion and extension of the knee, both of which are compensated without any mechanical interference by the sliding connection between rods 17b, 18b and respective tubular guides 19b and 20b.

The connection between slides 21a, 22a (21b, 22b) carrying tubular guides 19a, 20a (19b, 20b) and respective terminal connections 5, 6 (8, 9) is accomplished by means of a transversely slidable jointing system, i.e. in the direction at right angles to the longitudinal axis of the limb. The connection is moderately forced, so that the position of slides 21a, 22a (21b, 22b) with respect to corresponding terminal 5, 6 (8, 9) can be adjusted by making the former slide on the latter. The connection between the sensor unit 10a for the flexion-extension movement and the respective central attachment pad 4, on the other hand, makes it possible to obtain a fine adjustment of the position of slide 24 on said terminal connection.

This regulation is necessary in order to identify unambiguously the position of the flexion-extension detection unit 2 with respect to the femur-tibia reference joint, which is identified by the position of femoral epicondyles, given the different morphological dimensions of the users. In fact, the position of the rotula is the sole absolute positioning of the system that is indifferent to the different size of each particular user. To this end, with a view to referring the wearable mechatronic system in accordance with the invention to the femoral epicondyles, as shown in Figures 2 and 3, central connection 4, which is in any case fixed to support 1 in such a way as to be situated in proximity of the femur-tibia joint once support 1 has been applied, is provided with a seating 25 with a perimetric groove 25a with which the edge 24a of slide 24 is slidingly engaged. Into groove 25a there projects the end of an elastic presser 26 capable of engaging selectively with one of the corresponding blind holes 27 provided along the edge 24a of the slide 24, thus constituting a snap connection between the two elements. This regulation must be such as to permit an excursion of at least 25 mm with a distance between the holes 26 of the order of 5 mm. The mutual locking of the components can be obtained, for example, by means of a stop pin 28 situated on central connection 4 and readily handled by the operator. A slight tightening of the pin is sufficient to univocally fix the position determined by the elastic presser 28 situated on the opposite side of the central connection 4.

Sensor unit 10a, on the other hand, is connected to the respective central connection 7 by means of a bayonet joint 29. The aforesaid type of connection makes it possible for the detection unit to be rapidly attached to and detached from elastic support 1 and this, in turn, makes it possible for the device for measuring movements of body joints with two degrees of freedom to be quickly converted into a device for measuring movements of body joints with one degree of freedom and vice versa.

It should also be noted that the device in accordance with the invention can be employed both for the right leg and the left leg by simply detaching detection unit 2 from connections 4, 5 and 6 and then re-attaching it to the corresponding connections (not visible in the figures) provided on the diagonally opposite part of elastic support 1.

The transduction system utilized for transforming the angular displacement between the two elements 11a, 12a (11b, 12b) of sensor unit 10a (10b) around the respective rotation axis into electric signals is based on the principle of the Hall effect. According to this effect, an appropriate voltage (source) applied to a semiconductor element will cause an induced current to flow within it. If no magnetic field is present at the ends of the semiconductor, the voltage output will be almost zero. When the semiconductor (basic Hall element) is placed in a magnetic field oriented at right angles to the Hall current, the (voltage) output will be directly proportional to the intensity of the magnetic field. The Hall sensor is essentially a transducer that responds with a voltage output whenever the applied magnetic field changes. As is known, the characteristic voltage-displacement curve of a Hall-effect sensor is similar to a Gaussian curve, so that, working on a part of this curve, it is possible to obtain, in a repeatable manner and with negligible hysteresis, a practically linear pattern of the voltage variation due to the displacement that has been produced between the sensor and the magnetic source. In the case of the present invention the Hall sensor is fixed to element 11a (11b), while the magnet is fixed to element 12a (12b). Obviously, the inverse arrangement is altogether equivalent.

The output signals of the transducer are acquired (conditioned and digitalized) by a local electronic system 30 integral with the knee brace or worn by the user, on his belt for example, and connected by means of two wires to the sensorized support and transmitted, by means of radio-frequency communication for example, to a receiving unit connected to a remote processing system 31. Once the obtained final data have been stored, they are displayed in numerical and/or graphical format.

The advantages of the wearable mechatronic device for monitoring body joints in accordance with the invention are clearly brought out by the above description. In fact, it associates a particularly simple, light and modular structure with an arrangement of the sensor units such as to assure substantial alignment of the kinematic axes of rotation with the physiological axes of the limb and extremely small positioning errors due to the fact that the positioning of a sensor unit on the rotula, carried out visually by the operator, also determines the automatic positioning of the other sensor unit at the flexion-extension joint.

The device in accordance with the present invention can also be mounted indifferently on either of the lower limbs without any substantial modification and doing nothing other than shifting the detection unit 2 from one side of elastic support 1 to the other.

If accurate responses are to be obtained from the device in accordance with the present invention, it is necessary to carry out a phase of aligning the two sensor units with the anatomical markers after the device has been put on, thus obtaining alignment with the effective position of the femur-tibia structure in both the sagittal and the frontal plane. To this end the operator has to identify some reference points on the patient's body and, more precisely, two significant points of the bone structure of the femur that can be easily identified by touch, for example, the minor trochanter (or femur head) and the major trochanter, situated respectively in the frontal plane and the sagittal plane, the femoral epicondyles and two significant points of the tibio-tarsal joint of the ankle (forming part of the astragalus for example), these once again referred to the sagittal and frontal planes, and then align rods 17b and 18b of the varus/valgus detection unit 3 with them.

Although in the present description reference has always been made to a joint of the human body, it is obvious that, with appropriate dimensional modifications, the device in accordance with the present invention can also be applied to the joints of animals (such as, for example, horses).

Variants and/or modifications may be introduced in the wearable mechatronic device for monitoring the movements of body joints in accordance with the present invention without departing from the scope of the invention as defined in the claims attached hereto.

CLAIMS

1. A wearable mechatronic device for monitoring the movements of a body joint characterized in that it comprises a support (1) that can be applied to the limb comprising said joint, magnetic sensor means (10a, 10b) arranged on at least one axis of rotation (X, Y) of said joint and capable of generating an electric signal of an intensity correlated with the magnitude of the angular movement around said axis, means (17a,b - 22a,b; 24; 29) for positioning said magnetic sensor means on said at least one axis of rotation, fixable to said support (1) at said joint and both above and below it.

2. A wearable mechatronic device in accordance with claim 1, wherein said magnetic sensor means comprise a first element (11a,b) carrying at least one Hall sensor and a second element (12a,b), hinged to said first element around one axis and carrying at least one magnet, said positioning means comprising a first connection (4, 7) for said magnetic sensor means (10a, 10b) arranged on said support in a position intermediate with respect to its ends, so that the hinge axis can be brought into substantial alignment with the axis of rotation of the joint, and second connections (5, 6, 8, 9) arranged above and, respectively, below said first (11a,b) and said second (12a,b) element.

3. A wearable mechatronic device in accordance with claim 1 or claim 2, wherein said magnetic sensor means are arranged on two axes of rotation (X, Y) of said joint substantially orthogonal with respect to each other.

4. A wearable mechatronic device in accordance with claim 3, wherein said joint is the knee joint and said magnetic sensor means comprise a first and a second sensor unit

(10a,b), each sensor unit comprising a first element (11a,b) carrying at least one Hall sensor and a second element (12a,b) hinged to said first element around one axis and carrying at least one magnet, for each of said sensor units there being provided a first connection (4, 7) arranged on said support (1) in a position intermediate with respect to its ends, so that the hinge axis of at least one of said sensor units can be aligned with the respective axis of rotation of the joint, and second connections (5, 6, 8, 9) arranged above and below said first connection and connected, respectively, to said first and second element, the relative position of the first connection of said first and second sensor unit being such that, once one of said sensor units (10b) has been fixed on the rotula, the other unit (10a) is substantially aligned with the flexion-extension axis of the knee.

5. A wearable mechatronic device in accordance with claim 4, wherein said first (11a,b) and second (12a,b) element of each sensor unit (10a,b) are hinged to an end of respective rods (18a,b; 17a,b) connected to the second connections (5, 6, 8, 9).

6. A wearable mechatronic device in accordance with claim 5, wherein said rods (18q,b; 17a,b) are slidingly connected to the second connections (5, 6, 8, 9).

7. A wearable mechatronic device in accordance with any one of the preceding claims, wherein said magnetic sensor means are connected to local means (30) for processing the generated electric signal and transmitter means for sending the processed signal to a remote processing system (31).

8. A wearable mechatronic device in accordance with any one of the preceding claims, wherein the first connection (7) of the sensor unit (10a) intended to be positioned on the rotula is fixed to said support (1) in a position that coincides with an opening provided on the support to permit visual centring of the rotula therein.

9. A wearable mechatronic device in accordance with any one of the preceding claims, wherein the first connection (4) of the sensor unit (10a) intended to be positioned at the femur-tibia joint is slidingly connected to a slide (24) carrying said sensor unit (10a), on said connection (4) and said slide (24) there being provided means for regulating their position with respect to each other and then locking them in the selected position.

10. A wearable mechatronic device in accordance with any one of the preceding claims, wherein a goniometer is provided on the first element (11a,b) of said sensor units (10a,b).

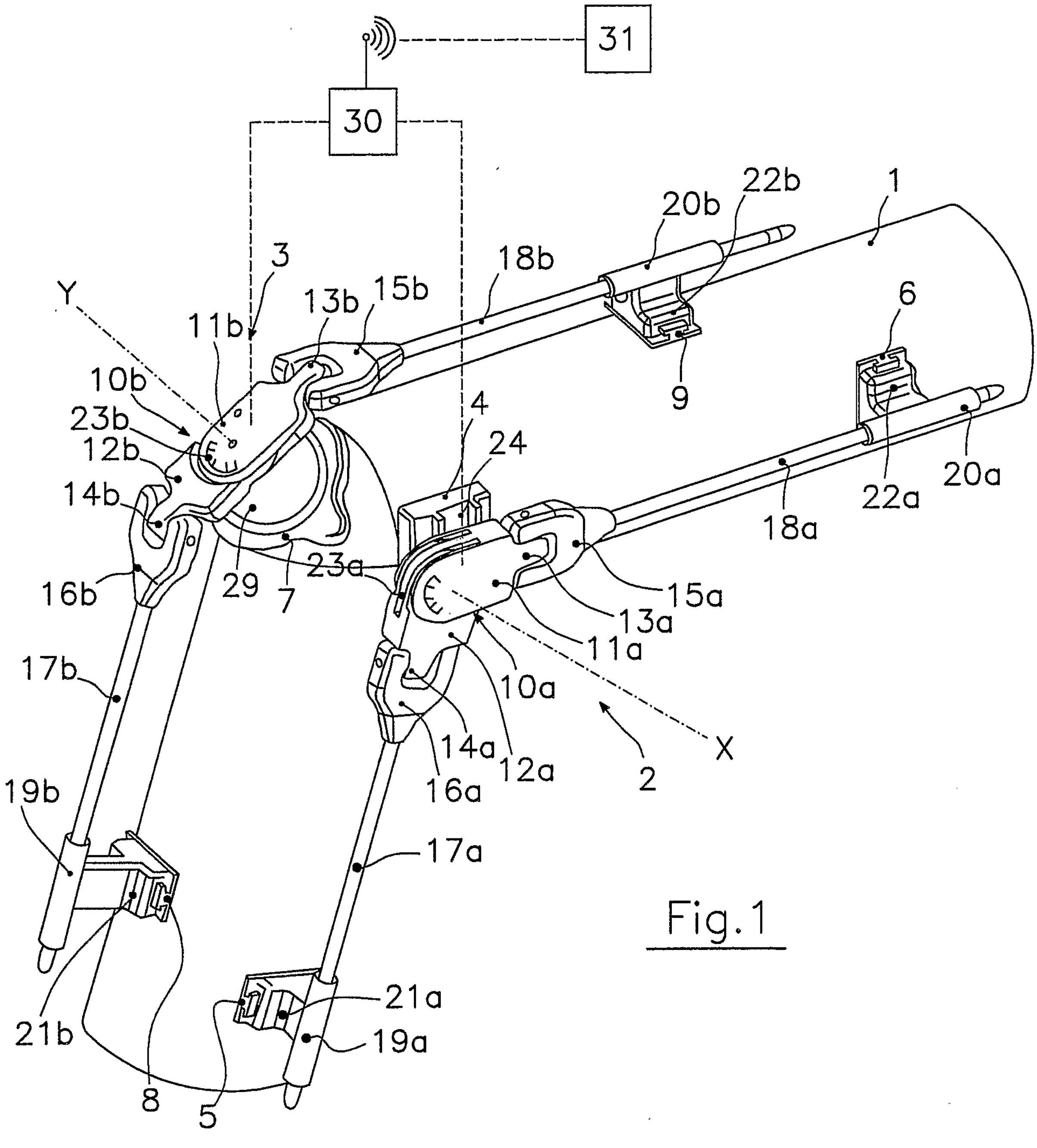

31
30
1
2
3
4
5
6
7
8
9
10a
10b
11a
11b
12a
12b
13a
13b
14a
14b
15a
15b
16a
16b
17a
17b
18a
18b
19a
19b
20a
20b
21a
21b
22a
22b
23a
23b
24
29
X
Y

Fig.1

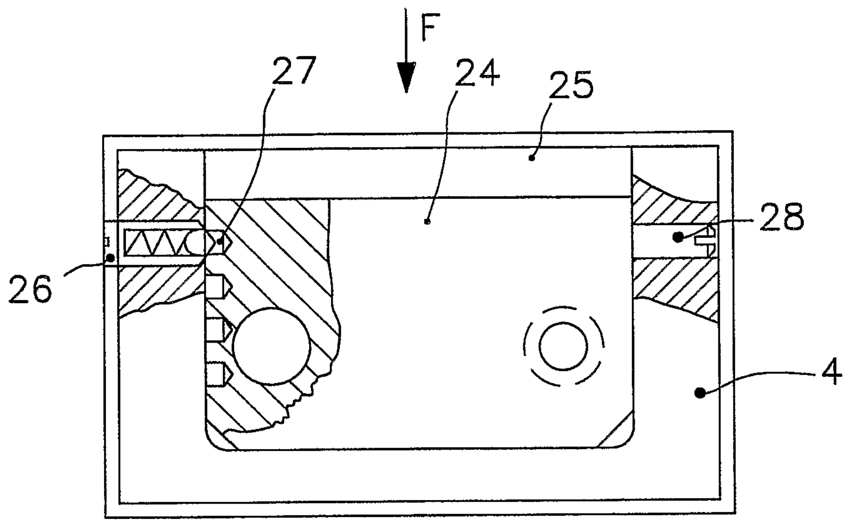


Fig.2

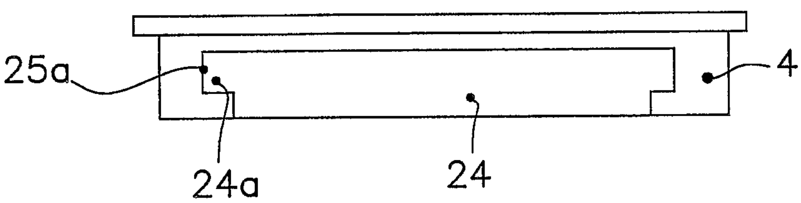


Fig.3

INTERNATIONAL SEARCH REPORT

ational Application No
ı ᴗ ı/IT 03/00517

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B5/103

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

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

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

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00/40171 A (IZEX TECHNOLOGIES INC) 13 July 2000 (2000-07-13) column 10, line 23 -column 11, line 6; figure 1	1,2,7-10
X	US 4 940 063 A (CHALLIS BRIAN) 10 July 1990 (1990-07-10) column 3, line 21 - line 25; figure 1	1,3
X	WO 01/49235 A (DJ ORTHOPEDICS LLC) 12 July 2001 (2001-07-12) page 3, line 16 - line 24; figure 2	1,3
X	US 2003/083596 A1 (ANANNY JOHN M ET AL) 1 May 2003 (2003-05-01) paragraphs ‘0126!,‘0161! paragraph ‘0186! - paragraph ‘0188!	1,3

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 May 2004	19/05/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Clevorn, J

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 263 492 A (VOYCE GUY) 23 November 1993 (1993-11-23) figure 1 ---	1,2,8-10
A	US 5 457 891 A (TAYLOR DEAN A) 17 October 1995 (1995-10-17) figures 1,4 ---	1,2,8-10
A	US 5 772 610 A (MCGORRY RAYMOND W ET AL) 30 June 1998 (1998-06-30) abstract ---	1
A	US 4 883 069 A (MCLEOD PAUL C) 28 November 1989 (1989-11-28) figure 1 ---	1-10
A	US 5 754 121 A (BULLINGER MICHAEL S ET AL) 19 May 1998 (1998-05-19) figure 2 ---	1-3
A	US 6 447 425 B1 (FRITSCHI HANS ET AL) 10 September 2002 (2002-09-10) figure 1 ---	1
A	US 6 390 994 B1 (HALE JOSEPH E ET AL) 21 May 2002 (2002-05-21) figure 1 ---	1
X	PRATT D J: "THREE-DIMENSIONAL ELECTROGONIOMETRIC STUDY OF SELECTED KNEE ORTHOSES" CLINICAL BIOMECHANICS, BUTTERWORTH SCIENTIFIC LTD, GUILDFORD, GB, vol. 6, no. 2, 1 May 1991 (1991-05-01), pages 67-72, XP000215846 ISSN: 0268-0033 figures 1,2 -----	1-10

INTERNATIONAL SEARCH REPORT

Information on patent family members

ıational Application No
PCT/IT 03/00517

Patent document cited in search report		Publication date	Patent family member(s)			Publication date
WO 0040171	A	13-07-2000	AU	2218100	A	24-07-2000
			CA	2358468	A1	13-07-2000
			CN	1344140	T	10-04-2002
			EP	1148853	A2	31-10-2001
			JP	2002534153	T	15-10-2002
			WO	0040171	A2	13-07-2000
US 4940063	A	10-07-1990	NONE			
WO 0149235	A	12-07-2001	AU	2928201	A	16-07-2001
			CA	2395722	A1	12-07-2001
			EP	1274376	A2	15-01-2003
			JP	2003518988	T	17-06-2003
			WO	0149235	A2	12-07-2001
			US	2002143279	A1	03-10-2002
US 2003083596	A1	01-05-2003	US	6428490	B1	06-08-2002
			US	6050962	A	18-04-2000
			AU	7161598	A	13-11-1998
			WO	9847426	A1	29-10-1998
			US	6110130	A	29-08-2000
US 5263492	A	23-11-1993	NONE			
US 5457891	A	17-10-1995	CA	2140043	A1	19-09-1995
US 5772610	A	30-06-1998	NONE			
US 4883069	A	28-11-1989	US	4306571	A	22-12-1981
			US	4804001	A	14-02-1989
			US	4834057	A	30-05-1989
US 5754121	A	19-05-1998	NONE			
US 6447425	B1	10-09-2002	NONE			
US 6390994	B1	21-05-2002	WO	03096901	A1	27-11-2003