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[Continued on next page]

#### (54) Title: DORSIFLEXION RECREATION DEVICE

310 230\_ 150

Fig. 1

(57) Abstract: A dorsiflexion recreation device is disclosed. The dorsiflexion recreation device includes a harness having at least one terminal portion, a retraction mechanism having at least one retraction point, a manchette used to affix the retraction mechanism to a cms and at least one pressure sensor to collect information about the dynamics of the steppage gait.





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#### DORSIFLEXION RECREATION DEVICE

#### **TECHNICAL FIELD**

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[001] The present invention generally relates to orthopedic systems and methods. In particular, the invention relates to a method and mechanical or electromechanical device for physically facilitating foot dorsiflexion; thereby preventing a foot drop effect thus providing for rehabilitation from steppage gait abnormalities.

#### **BACKGROUND ART**

10 [002] The US patents Ser. Nos. 3916886, 4329982, 4817589, 5112296, 5259834, 6361517, 6602217, 7125392, 7458950 and US applications Ser. Nos. 2003/0073938, 2005/0010265 and 2006/046909 are believed to represent the current state of the art.

#### 15 **SUMMARY OF THE INVENTION**

[003] There is provided in accordance with embodiments of the present invention a method and mechanical or electromechanical device for physically facilitating foot dorsiflexion.

[004] The dorsiflexion recreation device of the present invention is useful for preventing a foot drop effect thus providing for rehabilitation from steppage gait abnormalities.

#### **DEFINITIONS**

[005] The following terms used throughout the specification are defined as:

Stance – The period in the gate cycle when the foot is in contact with the floor; Swing – The period in the gate cycle when the foot is not in contact with the floor; Dorsiflexion – Movement of the foot towards the anterior surface of the tibia while bending the ankle; Plantarflexion - Movement of the foot away from the anterior surface of the tibia, straightening the ankle joint; Zero angle - position of the foot in perpendicular to the crus.

[006] It should be understood, however, that the definitions hereinabove are not intended to limit the invention to the particular terms, but on the contrary, the intention is to cover all modifications, equivalents, and alternatives falling within the scope of the invention.

#### 35 BRIEF DESCRIPTION OF THE DRAWINGS

[007] The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the appended drawings in which:

- **Fig. 1** is a schematic geometrical diagram showing the vectors of force exerted by the dorsiflexion recreation device of the invention and the dynamics of their action on the human feet;
- **Fig. 2** is a schematic diagram of the abscissa plane, showing the preferred sites for the disposing the sensor and the strap of the harness adjoining the abscissa plane; 5
- **Figs 3A** to **3E** are perspective views of various embodiments of the harness of the dorsiflexion recreation device of the invention;
- **Fig. 4** is an isometric view of an embodiment of the retraction mechanism the dorsiflexion recreation device of the invention;
- Figs 5A and 5B are isometric views of another embodiment of a double-action retraction mechanism the dorsiflexion recreation device of the invention;
  - **Fig. 6** is an isometric view of a preferred embodiment of the retraction mechanism employing electro-active polymer.
  - [008] While the invention is susceptible to various modifications and alternative forms, specific embodiments thereof have been shown by way of example in the drawings. The components in the drawings are not necessarily to scale, emphasis instead being placed upon clearly illustrating the principles of the present invention.

#### **DISCLOSURE OF THE INVENTION**

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- [009] Illustrative embodiments of the invention are described below. In the interest of clarity, not all features of an actual implementation are described in this specification. It will of course be appreciated that in the development of any such actual embodiment, numerous implementation-specific decisions must be made to achieve the developers' specific goals, such as compliance with technology- or business-related constraints, which may vary from one implementation to another. Moreover, it will be appreciated that the effort of such a development might be complex and time-consuming, but would nevertheless be a routine undertaking for those of ordinary skill in the art having the benefit of this disclosure.
- [010] The dorsiflexion recreation device (hereinafter DRD) of the invention comprises a mechanical retraction mechanism, harness and manchette. The retraction mechanism typically includes a portable energy source, e.g. electrical battery, and a control module. The control module can be any computing means known in the art. The harness is used to convey the action of the retraction mechanism to the feet or a sole or insole implemented therewith. The manchette is used to affix the DRD and particularly the retraction mechanism thereof, preferably to the posterior portion of the crus.
- [011] To illustrate the general geometry of the vectors of force exerted by the retraction mechanism of the dorsiflexion recreation device (hereinafter DRD) of the invention and the dynamics of their action on the human feet, reference is now made to **Fig. 1**. A plane is herby defined by the abscissa (X-axis) and the ordinate (Y-axis) essentially in parallel to the sagittal plane of crus **10**. Abscissa represents a side-view of a plane (hereinafter abscissa plane) tangent to the bottom face of feet **12**, essentially paralleling the transverse plane. It should be acknowledged that in implementation of the

DRD an insole or sole may be employed, wherein abscissa plane is more correctly to represent the plane tangent to the bottom face of such sole or insole (not shown); however for the sake of simplicity merely the ideal implementation of the DRD on feet 12 is shown in Fig. 1, while those of ordinary skill in the art shall be able to make the proper implementation-specific adjustments. Ordinate represents the position of the retraction point of the retraction mechanism of the DRD, in perpendicular to abscissa, as will be elaborated infra. The retraction point is typically positioned on the ordinate within the range of 150mm to 310mm from the origin and preferably approximately at 230mm above the abscissa plane. The marks 150 and 310 represent the preferable range and the mark 230 represents the preferred position of the retraction point on the ordinate.

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- [012] Axis **A** represents the extremum counterclockwise angular translation of the abscissa relatively to the ordinate, at the maximal dorsiflexion angle  $\alpha$ , whereas axis **B** represents the extremum clockwise angular translation of the abscissa relatively to the ordinate, at the maximal plantarflexion angle  $\beta$ . Angle  $\alpha$  equals approximately 10 to 15 degrees, while angle  $\beta$  equals approximately 20 degrees. Arc **14** represents the trajectory of the attachment point of the harness (not shown) of DRD to feet **12** or mutatis mutandis to sole or insole (not shown). Lines **16** and **18** represent the direction of the extrema vectors of force exerted by the DRD on to the harness (not shown) and vice versa. Distances **16** and **18**, respectively, represent the closest and the most distanced positions of the attachment point of the harness during the operation of DRD.
- [013] The operation of the DRD is synchronized with dynamics of the steppage gait by means of at least one primary sensor. The primary sensor, inter alia, can be attached to the feet, embedded in the insole or sole or disposed within a strap of the harness adjoining the abscissa plane. Referring now to **Fig. 2**, which is a schematic view of the abscissa plane, showing the preferred sites for the disposing the sensor and the strap of the harness adjoining the abscissa plane. The X-axis represents the lateral dimensions of the aforementioned sites across the width of feet **20**, whereas the Y-axis represents the longitudinal dimensions along the length of feet **20**.
- Primary sensor 21 is a pressure sensor, deployed at predetermined locations under feet 20 to collect data reflecting the change in the pressure exerted over the abscissa plane; thereby providing information regarding the dynamics of the steppage gait. Primary sensor 21 is preferably positioned between longitudinal marks 22 and 24 along the Y-axis. Sensor 21 is typically disposed at the most apical portion of the metatarsal area. Mark 22 is located at about 98 percent of the total length of feet 20. Mark 24 is located at about 58 percent of the total length of feet 20. Sensor 21 is preferably positioned between lateral marks 30 and 32 along the X-axis. Mark 30 is located at about 6 percent of the total width of feet 20, whereas mark 32 is located at about 94 percent of the total width of feet 20.
- [015] In some embodiments sensor **21** is a multi-site pressure sensor, comprising an array of individual pressure sensors deployed across an area. In other embodiments, the primary sensor is a two-dimensional surficial resolution pressure sensor able to provide data reflecting gradual change in the pressure exerted across the surface area of the sensor.

[016] The primary sensor collects the data reflecting the changes in the pressure exerted across the area of abscissa plane and transmits these data to the control module of the DRD. In some embodiments one or more wires can be embedded in or interwoven with the harness, whereas in other embodiments a wireless communication link, well-known in the art, can be employed to transmit the aforementioned data; instances of the latter can be found in the electronic orthosis device with an integrated stimulation unit and electrode, available from Orthomedics, at 8610 West Dodge Rd. Omaha, NE 68114, USA, and commercialized under the tradename of Ness L300 - Functional Electrical Stim For Foot Drop.

- 10 [017] Optionally an additional secondary sensor (not shown) is employed to provide more comprehensive information regarding the dynamics of the steppage gait. The secondary sensor (not shown) is typically disposed at the most apical portion of the tarsal area. The additional sensor is located between about 24 percent and about 6 percent of the total length of feet **20**. The additional sensor is located between about 20 percent and about 80 percent of the total width of feet **20**.
  - [018] The strap (not shown) of the harness adjoining the abscissa plane is preferably positioned between longitudinal marks **26** and **28** along the Y-axis. Mark **26** is located at about 70 percent of the total length of feet **20**, whereas mark **28** is located at about 40 percent of the total length of feet **20**.
- [019] Referring now to **Figs 3A** to **3E**, which are schematic representations of some embodiments of the harness of the DRD of the present invention. The harness shown in **Fig. 3A** applied to crus **40** and feet **42** comprises cuff **45** circumfering the medial arch of the feet typically at the metatarsal and/or transverse arch area. Cuff **45** comprises two flanking straps **47**, which are drawn to the retraction point (not shown) of the DRD, at the posterior portion of crus **40**.
  - [020] The harness shown in **Fig. 3B** applied to crus **40** and feet **42** comprises cuff **50** circumfering the medial arch of the feet typically at the metatarsal and/or transverse arch area. Cuff **50** comprises two intercrossing straps **52**, which are drawn to the retraction point (not shown) of the DRD, at the posterior portion of crus **40**.
- The harness shown in **Fig. 3C** applied to crus **40** and feet **42** comprises cuff **55** circumfering the medial arch of the feet typically at the metatarsal and/or transverse arch area. Cuff **55** comprises primary strap **57**. Primary strap **57** further comprises two bifurcating straps **59**, which are drawn to the retraction point (not shown) of the DRD, at the posterior portion of the crus **40**.
- The harness shown in **Fig. 3D** applied to crus **40** and feet **42** comprises two intercrossing straps **60**, which threaded below the feet, into or onto the sole or insole (not shown). Intercrossing straps **60** may be connected or affixed to the sole or insole (not shown) at the flanks thereof. Straps **60** are drawn to the retraction point (not shown) of the DRD, at the posterior portion of crus **40**.
- [023] The harness shown in **Fig. 3E** applied to crus **40** and feet **42** comprises two flanking straps **62**, which threaded below the feet, into or onto the sole or insole (not shown). Straps **62** may be connected or affixed to the sole or insole (not shown) at the

flanks thereof. Straps **62** are drawn to the retraction point (not shown) of the DRD, at the posterior portion of crus **40**.

[024] The embodiments of the harness of the DRD shown **Figs 3A** to **3E** are particularly adapted to the embodiments of DRD affixed at the posterior portion of the crus. It should be acknowledged, however, that various other embodiments adapted to the embodiments of DRD affixed at the anterior portion of the crus and elsewhere are provided within the scope of the present invention, as will be elaborated infra.

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Referring now to **Fig. 4**, which is an isometric view of exemplary retraction mechanism **80** of the DRD of the present invention. Retraction mechanism **80** comprises structural framework **81**. Electrical motor **82** is mounted onto structural framework **81**. Motor **82** is preferably capable of performing from about 2000 to about 7000 revolutions per minute (RPM) and producing a substantial rotational torque. The rotor of motor **82** is operationally coupled to the driving shaft ending with sprocket **84**. Conveying belt **86** couples the rotation of the driving shaft ending with sprocket **84** to driven shaft **89** ending with sprocket **90**. Tensioner assembly **92** may be employed to continuously facilitate tension of belt **86**; thereby effectively coupling the rotation of the driving shaft ending with sprocket **84** to driven shaft **89** ending with sprocket **90**. Driven shaft **89** is furnished with a screw threading (not shown); whereas harness retracting/releasing element **94** is furnished with a matching screw threading (not shown).

The helical pitch of the screw threading furnishing driven shaft **89** and harness retracting/releasing element **94** is preferably from about 0.4 to about 1.2 millimeter (mm) per rotation. Retracting/releasing element **94** is threaded onto pivot **96**, disposed coaxially to shaft **89**; thereby upon rotation of shaft **89** element **94** performers axial translation about pivot **96**, in accordance with the parameters of such rotation, i.e. direction and RPM, and the parameters of the helical pitch of the screw threading furnishing driven shaft **89** and harness retracting/releasing element **94**.

[027] Upon axial translation of element **94** about pivot **96**, the retraction/release of terminal portion **98** of the strap is accomplished. Aperture **100** in structural framework **81**, is to be considered as an exemplary retraction point denoted hereinabove.

[028] In some embodiments the retraction point is not affixed but rather translated along the crus. The retraction mechanism of the embodiments in which the retraction point translated along the crus, are typically comprise a rod protruding from the mechanism and protracted/retracted respectively from/into the mechanism. The terminal portions of the harness are connected to the rod and each time the rod is protracted/retracted, the retraction point is translated along the crus; thereby retracting/releasing the harness.

[029] In some preferred embodiments the DRD comprises two or more retraction mechanisms respectively forming two or more retraction points, each of which retracts/releases a different terminal portion of the harness; wherein each terminal portion of the harness is affected by the respective retraction mechanism independently. In some other embodiments the DRD comprises a double or twofold retraction mechanism respectively forming two retraction points; wherein two different terminal portions of the harness are affected by the same retraction mechanism simultaneously. The double or twofold retraction mechanism may employ pulleys or alike to facilitate a premeditated displasment of the harness relatively to the mechanism. These types of retraction

mechanisms are particularly adapted for the types of harnesses comprising more than one terminal portion, as will be elaborated infra.

[030] In some preferred embodiments the retraction mechanism comprises a reel or a couple of reels coaxially affixed to a driven shaft. To exemplify a reels-employing mechanism, reference is now made to **Figs 5 A-B**, showing retraction mechanism **101** in accordance with some embodiments of the DRD of the present invention. Retraction mechanism **101** comprises structural platform **102** characterized by concave surface **102A** and slot **103**. Structural platform **102** is designed to be appended to the posterior portion of the crus (not shown), so that concave surface **102A** conforms to the convex surface of the crus and slot **103** accommodates the Achilles tendon. Platform **102** is covered by housing **104** enclosing the components of mechanism **101**.

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[031] Retraction mechanism **101** further comprises motor **105** mounted onto platform **102**. The rotor of motor **105** terminates with sprocket **107**. Sprocket **106** rotationally coupled via conveying belt **107** to sprocket **108**. Sprocket **108** is coupled to driven shaft **109**, which is flanked by reels **112** and **114**.

[032] Upon rotation of driven shaft **107** terminal portions **116** and **117** of the harness got wound/unwound onto/from the reel/s **112** and **114**, respectively, via retraction points **118** and **119**; thereby retracting/releasing the harness.

[033] The retraction mechanism shall be able to apply a force of at least 22 Newton and induce a torque of at least 1 Newton per meter. The retraction mechanism should be able to perform a displacement of about at least 25 millimeters. The minimal capacity of the battery is preferably of about 23 kJoul, which shall suffice for 10,000 assuming that not more than 50 percent of the battery's energy will be utilized.

[034] DRD retraction mechanism is affixed by the means of a manchette (not shown) preferably to the posterior portion of the crus. The manchette encircles the crus above ankle, preferably ergonomically conforming therewith. Examples of a similar manchette can be found in the electronic orthosis housing with an integrated stimulation unit and electrode, available from Orthomedics, at 8610 West Dodge Rd. Omaha, NE 68114, USA, and commercialized under the tradename of Ness L300 - Functional Electrical Stim For Foot Drop. The manchette is preferably encircles the crus above the lateral prominences of the ankle rather tightly; thereby effectively precluding the movement of the retraction mechanism inferiorly during the operation of DRD.

[035] In some preferred embodiments the retraction mechanism is affixed by the manchette to the posterior portion of the crus while positioned below the retraction point; whereas in other embodiments the retraction mechanism is affixed by the manchette to the posterior portion of the crus while positioned above the retraction point. Thus retraction mechanism **80** shown in **Fig. 4** is preferably affixed by the manchette to the posterior portion of the crus **10** shown in **Fig. 1**, at the inclination of the calf beneath the prominence formed by the gastrocnemius, while the retraction point formed at aperture **100** is located on the top face of mechanism **80**.

[036] In some embodiments the retraction mechanism is affixed by the manchette to the anterior portion of the crus, positioned typically above the retraction point.

[037] It should be acknowledged that the embodiments of the harness shown in **Figs 3A** to **3E** may be subject to modifications so as to accommodate a particular positioning, orientation and/or type of the retraction mechanisms and/or retraction point/s thereof. Thus in some embodiments, the harness comprises two different straps drawn to the retraction mechanism, whereby the terminal portions thereof are each independently retracted/released by the retraction mechanism of the DRD. Examples of such straps include flanking straps **47**, intercrossing straps **52**, bifurcating straps **59**, intercrossing straps **60** and flanking straps **62** shown in **Figs 3A** to **3E**.

[038] In other embodiments, the harness comprises a single strap drawn to the retraction mechanism, merely the terminal portion of which, such as terminal portion 98 shown in Fig. 4, is retracted/released by the retraction mechanism of the DRD. Such straps can be formed by joining of two different straps, such as flanking straps 47, intercrossing straps 52, bifurcating straps 59, intercrossing straps 60 and flanking straps 62 shown in Figs 3A to 3E, the joined/unified terminal portion of which is retracted/released by the retraction mechanism of the DRD.

[039] In yet some other embodiments, the harness comprises merely a single strap drawn to the retraction mechanism, the terminal portion of which is retracted/released by the retraction mechanism of the DRD. Example of such single strap harness include a modified harness shown in **Fig. 3C**, comprising merely cuff **55** and primary strap **57**, which is drawn to the retraction point (not shown) of the DRD, at the anterior portion of crus **40**.

[040] In some embodiments, the harness comprises a tension sensor (not shown) providing data regarding the tensile force applied to the harness in a given time. The tension sensor may be embedded in a strap of the harness or otherwise form a part thereof.

[041] The strength of the force applied by the retraction mechanism during operation of the DRD and the energy consumed are summarized in Table No. 1:

Energy [Joul]	]N [ Force	Angle Range	Stage	No.
N/A	N/A	O°	Initial Contact	1
0.073	0.6	÷ 0° -7°°0°	Loading	2
			Response	
0.0	0.0	0° ÷ 10°	Mid Stance	3
0.0	0.0	10° ÷ - 20°	Terminal Stance	4
N/A	N/A	N/A	Pre-Swing	5
0.1040	0.6	N/A	Initial Swing	6
0.104	0.6	-20° ÷ 0°	Mid Swing	7
0.020	0.6	N/A	Terminal Swing	8

Table No. 1

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#### Operation of the DRD

[042] An average pedometric pace of a human is 110 steps per minute. This results with 55 walking cycles per leg. The dorsiflexion is typically to be facilitated during 14 percent of each walking cycle of each leg. At average pedometric pace the dorsiflexion is

typically to be facilitated during about ~0.15 seconds. The onset timing of dorsiflexion and the duration thereof is to be adjusted in accord with a given pedometric pace and its changes. Primary sensor of the DRD, such as sensor **21** the location of which is depicted in **Fig. 2**, is able to provide the information about the pedometric pace as well as to indicate the preferred onset timing for dorsiflexion facilitation.

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[043] It is noted that the harness is typically subject to some elastic hysteresis and hence the onset the retraction action typically precedes the onset timing of effectively facilitating dorsiflexion. Similarly the offset of the retraction action or the onset of the release action typically precedes the offset timing of effectively facilitating dorsiflexion.

[044] Since the harness is typically characterized by some intrinsic elasticity, the total displacement applied by the retraction mechanism (hereinafter  $\Delta D$ ) on the terminal portion of the harness, e.g. at the retraction point, is somewhat larger than the effective displacement (hereinafter  $f\Delta D$ ) resultantly induced at the attachment point of the harness. Referring not to **Fig. 1**, the  $f\Delta D$  can be calculated as the difference between the lengths of distances **16** and **18**; whereas the  $\Delta D$  can be calculated from the aforementioned difference, provided the parameters of the intrinsic elasticity of the harness. The  $f\Delta D$  is typically equals to about 25 millimeters; whereas  $\Delta D$  typically ranges between about 30 and 50 millimeters, depending on the intrinsic elasticity parameters of the harness.

[045] At the maximal retraction applied by the retraction mechanism, the attachment point is located at the intersection of arc **14** and axis **A**; whereby feet **12** assumes the maximal dorsiflexion angle  $\alpha$ . At the maximal release of the harness from the retraction mechanism, i.e. no retraction applied, the attachment point may be located at the intersection of arc **14** and axis **B**; whereby the feet may assum the maximal plantarflexion angle  $\beta$ .

[046] In some embodiments, the aforementioned tension sensor of the harness provides a real-time data regarding the tensile force applied to the harness and the release of the terminal portion/s of the harness is controlled in accord with the data provided by the tension sensor. Thus the sensor may facilitate release of the harness by the retraction mechanism if the tensile force applied to the harness exceeds a predetermined threshold, for instance during a given stage of the pedometric cycle.

[047] The activity of the DRD during the pedometric cycle may be characterized in accordance with the Table No. 2:

DRD	Description	% of cycle	Stage	No.
Active	Foot just touches the floor	0÷2%	Initial Contact	1
Not Active	Starts with initial floor contact and	0÷10%	Loading	2
	continues until the other foot is lifted		Response	
	for swing			
Not Active	Starts as the other foot is lifted and	10÷30%	Mid Stance	3
	continues until weight is aligned over			
	the forefoot			
Not Active	Begins with the rise of the heel and	30÷50%	Terminal	4
	continues until the other foot strikes		Stance	
	the ground			

Not Active	Begins with the initial contact of the opposite limb and ends with ipsilateral toe-off	50÷60%	Pre-Swing	5
Active	Begins with the lift of the foot from the floor and ends when the swinging foot is opposite the stance foot	60÷73%	Initial Swing	6
Active	Begins as the swinging limb is opposite the stance limb and ends when the swinging limb is forward and the tibia is vertical	73÷87%	Mid Swing	7
Active	Begins with vertical tibia and ends when the foot strikes the floor	87÷100%	Terminal Swing	8

Table No. 2

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#### BEST MODE FOR PRACTICING AND CARRYING OUT THE INVENTION

In accordance with some preferred embodiments of the present invention the retraction mechanism comprises an electro-active polymer (hereinafter EAP). The EAP is preferably of a rectangular-parallelepiped or cuboid shape. To exemplify the structure of a retraction mechanism employing EAP, reference is now made to Fig. 6. Retraction mechanism 120 comprises EAP block 122, accommodated in a structural framework housing (not shown), which is affixed by the means of a manchette (not shown) preferably to the posterior portion of the crus. Examples of EAP include materials disclosed by Yoseph Bar-Cohen in Electroactive Polymer (EAP) Actuators as Artificial Muscles: Reality, Potential, and Challenges, at SPIE Press Monograph, Vol. PM98, 2001. EAP block 122 comprises first electrical terminal 124, coupled to electrical conduit 126. Terminal 124 can be formed by a strip of foil-like electrically conductive material, capable of deformation/folding upon contraction/expansion of block 122. EAP block 122 further comprises a second electrical terminal (not shown) disposed on the opposite side thereof and coupled to the respective electrical conduit (not shown).

[049] The bottom face (not shown) of EAP block **122** is affixed to the structural framework housing (not shown), whereas the top face is operationally connected to terminal portion **128** of the harness. It should be acknowledged that additional terminal portions of the harness can be operationally connected to the top face of EAP block **122**, for the types of harnesses comprising more than one terminal portion, as will be elaborated infra.

[050] Upon application of an electrical potential difference of a predetermined voltage to the electrical conduits coupled to the respective electrical terminals, EAP block 122 contracts in direction of arrow 130; thereby terminal portion 128 of the harness is retracted downwards. Upon outage of the aforementioned electrical potential difference or a decrement thereof EAP block 122 expands in the direction opposite to arrow 130, inter alia due to the intrinsic bias of the contracted polymeric material of block 122; thereby terminal portion 128 of the harness is released upwards.

#### **CLAIMS**

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- 1. A dorsiflexion recreation device comprises:
  - [a] a harness having at least one terminal portion, wherein a strap of said harness is operationally connected to or forming a part of at least one selected from:
    - [1] a foot,
    - [2] an insole, and
    - [3] a sole;
  - [b] a retraction mechanism, said retraction mechanism is characterized by at least one retraction point, wherein said at least one terminal portion of said harness is drawn to said at least one retraction point;
  - [c] a manchette, used to affix said retraction mechanism to a crus for the foot of which the recreation of dorsiflexion is to be achieved;
  - [d] at least one pressure sensor disposed at the abscissa plane, said pressure sensor is adapted to continuously collect an information about the dynamics of the steppage gait, and
  - [e] a control module receiving said information collected by said pressure sensor and controlling the operation of said retraction mechanism;

wherein at predetermined stage/s of the pedometric cycle, determined by said control module from said information collected by said pressure sensor, said retraction mechanism performs a retracting action, thereby applying a tensile force to said at least one terminal portion of said harness and actively facilitating a dorsiflexion of said foot, and

wherein at other stage/s than said predetermined stage/s of the pedometric cycle, said retraction mechanism performs a releasing action, thereby allowing a plantarflexion of said foot.

- 2. The dorsiflexion recreation device as in claim 1, wherein said predetermined stage/s of the pedometric cycle is/are selected from the group consisting of: an initial contact, initial swing, mid-swing and terminal swing.
- 3. The dorsiflexion recreation device as in claim 1, further comprising a portable energy source.
- 4. The dorsiflexion recreation device as in claim 1, wherein said pressure sensor is a multi-site pressure sensor, comprising an array of individual pressure sensors deployed across an area,
- 5. The dorsiflexion recreation device as in claim 1, wherein said pressure sensor is a two-dimensional surficial resolution pressure sensor, able to provide data reflecting gradual change in the pressure exerted across the surface area thereof.
- 6. The dorsiflexion recreation device as in claim 1, wherein said pressure sensor is attached to said foot, embedded in said insole or said sole, or disposed within said

strap of said harness adjoining the abscissa plane.

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- 7. The dorsiflexion recreation device as in claim 1, wherein said pressure sensor is positioned between about 98 percent and about 58 percent from the total length said foot.
- 8. The dorsiflexion recreation device as in claim 1, wherein said pressure sensor is positioned between about 6 percent and about 94 percent of the total width of said foot.
- 9. The dorsiflexion recreation device as in claim 1, wherein said data collected by said pressure sensor is transmitted to said control module via at least one wire embedded in or interwoven with said harness, or via a wireless communication link.
- 10. The dorsiflexion recreation device as in claim 1, further comprising an additional pressure sensor used to provide more comprehensive information regarding said dynamics of said steppage gait.
- 11. The dorsiflexion recreation device as in claim 1, wherein said strap of said harness is preferably positioned between about 70 percent and about 40 percent of the total length said foot.
  - 12. The dorsiflexion recreation device as in claim 1, wherein said harness comprises a cuff circumfering the medial arch of said foot and two flanking straps drawn to said at least one retraction point of said mechanism.
  - 13. The dorsiflexion recreation device as in claim 1, wherein said retraction mechanism is affixed by said manchette to the posterior portion of said crus.
- 14. The dorsiflexion recreation device as in claim 1, wherein said harness comprises a cuff circumfering the medial arch of said foot and intercrossing straps drawn to said at least one retraction point of said mechanism.
  - 15. The dorsiflexion recreation device as in claim 1, wherein said harness comprises a cuff circumfering the medial arch of said foot, a primary strap further comprising two bifurcating straps drawn to said at least one retraction point of said mechanism.
    - 16. The dorsiflexion recreation device as in claim 1, wherein said harness comprises two intercrossing straps operationally connected at attachment points to said foot, said sole or said insole at the flanks thereof and drawn to said at least one retraction point of said mechanism.

17. The dorsiflexion recreation device as in claim 1, wherein said harness two flanking straps operationally connected at attachment points to said foot, said sole or said insole at the flanks thereof and drawn to said at least one retraction point of said mechanism.

18. The dorsiflexion recreation device as in claim 1, wherein said retraction mechanism

- [a] a structural framework on which the components of said mechanism are mounted;
- [b] an electrical motor the rotor of which is rotationally coupled to a driving shaft sprocket;
- [c] a driven shaft furnished with a screw threading and rotationally coupled to a sprocket;
- [d] a conveying belt coupling the rotation of said sprockets;
- [e] a pivot disposed coaxially to said driven shaft;
- [f] a harness retracting/releasing element furnished with a screw threading respectively matching said screw threading of said driven shaft, said retracting/releasing element is threaded onto said driven shaft and onto said pivot;

wherein upon rotation of said driven shaft said retracting/releasing element performers axial translation along said pivot thereby retracting/releasing said harness.

- 19. The dorsiflexion recreation device as in claim 1, wherein said retraction mechanism comprises:
  - [a] a structural platform;

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- [b] a motor mounted onto said platform; the rotor of said motor terminates with sprocket
- [c] a driven shaft comprising a sprocket and at least one reel/s, and
- [d] a conveying belt rotationally coupling said sprockets; wherein upon rotation of said driven shaft said at least one terminal portion/s of said harness is wound/unwound onto/from said at least one reel/s; thereby retracting/releasing said harness.
- 20. The dorsiflexion recreation device as in claim 18, wherein said platform is characterized by a concave surface and a slot, wherein said platform is to be appended to the posterior portion of the crus, so that concave said surface thereof conforms with the convex surface of said crus and said slot accommodates the Achilles tendon.
  - 21. The dorsiflexion recreation device as in claim 1, wherein said retraction mechanism is able to apply a force of at least 22 Newton and induce a torque of at least 1 Newton per meter.

- 22. The dorsiflexion recreation device as in claim 1, wherein said retraction mechanism is be able to perform a displacement of about at least 25 millimeters.
- 23. The dorsiflexion recreation device as in claim 1, wherein said portable energy source is characterized by the minimal capacity of about 23,000 Joule.
- 24. The dorsiflexion recreation device as in claim 1, wherein said retraction mechanism comprises an electro-active polymer.
- 25. The dorsiflexion recreation device as in claim 1, further comprising a tension sensor providing a real-time data regarding the tensile force applied to said harness.
  - 26. The dorsiflexion recreation device as in claim 24, wherein the release of said at least on terminal portion/s of said harness is allowed whenever the tensile force applied to said harness exceeds a predetermined threshold, for a given stage of the pedometric cycle.
  - 27. A dorsiflexion recreation device comprises:
    - [a] a harness having at least one terminal portion, wherein a strap of said harness is operationally connected to or forming a part of at least one selected from:
      - [1] a foot,

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- [2] an insole, and
- [3] a sole;
- [b] a retraction mechanism, said retraction mechanism is characterized by at least one retraction point, wherein said at least one terminal portion of said harness is drawn to said at least one retraction point;
- [c] a manchette, used to affix said retraction mechanism to a crus for the foot of which the recreation of dorsiflexion is to be achieved;
- [d] at least one pressure sensor disposed at the abscissa plane, said pressure sensor is adapted to continuously collect an information about the dynamics of the steppage gait, and
- [e] a control module receiving said information collected by said pressure sensor and controlling the operation of said retraction mechanism;
- wherein at predetermined stage/s of the pedometric cycle, determined by said control module from said information collected by said pressure sensor, said retraction mechanism performs a retracting action, thereby applying a tensile force to said at least one terminal portion of said harness and actively facilitating a dorsiflexion of said foot, and
- wherein at other stage/s than said predetermined stage/s of the pedometric cycle, said retraction mechanism performs a releasing action, thereby allowing a plantarflexion of said foot.
- 28. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said predetermined stage/s of the pedometric cycle is/are selected from the group consisting of: an initial contact, initial swing, mid-swing and terminal swing.

- 29. The dorsiflexion recreation device as in any of the claims 27 to 52, further comprising a portable energy source.
- 30. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said pressure sensor is a multi-site pressure sensor, comprising an array of individual pressure sensors deployed across an area,

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- 31. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said pressure sensor is a two-dimensional surficial resolution pressure sensor, able to provide data reflecting gradual change in the pressure exerted across the surface area thereof.
- 32. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said pressure sensor is attached to said foot, embedded in said insole or said sole, or disposed within said strap of said harness adjoining the abscissa plane.
- 33. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said pressure sensor is positioned between about 98 percent and about 58 percent from the total length said foot.
- 34. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said pressure sensor is positioned between about 6 percent and about 94 percent of the total width of said foot.
- 35. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said data collected by said pressure sensor is transmitted to said control module via at least one wire embedded in or interwoven with said harness, or via a wireless communication link.
- 36. The dorsiflexion recreation device as in any of the claims 27 to 52, further comprising an additional pressure sensor used to provide more comprehensive information regarding said dynamics of said steppage gait.
- 37. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said strap of said harness is preferably positioned between about 70 percent and about 40 percent of the total length said foot.
  - 38. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said harness comprises a cuff circumfering the medial arch of said foot and two flanking straps drawn to said at least one retraction point of said mechanism.
  - 39. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said retraction mechanism is affixed by said manchette to the posterior portion of said crus.

- 40. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said harness comprises a cuff circumfering the medial arch of said foot and intercrossing straps drawn to said at least one retraction point of said mechanism.
- 41. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said harness comprises a cuff circumfering the medial arch of said foot, a primary strap further comprising two bifurcating straps drawn to said at least one retraction point of said mechanism.
- 42. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said harness comprises two intercrossing straps operationally connected at attachment points to said foot, said sole or said insole at the flanks thereof and drawn to said at least one retraction point of said mechanism.
- 43. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said harness two flanking straps operationally connected at attachment points to said foot, said sole or said insole at the flanks thereof and drawn to said at least one retraction point of said mechanism.
- 44. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said retraction mechanism comprises:
  - [a] a structural framework on which the components of said mechanism are mounted;
  - [b] an electrical motor the rotor of which is rotationally coupled to a driving shaft sprocket:
  - [c] a driven shaft furnished with a screw threading and rotationally coupled to a sprocket;
  - [d] a conveying belt coupling the rotation of said sprockets;
  - [e] a pivot disposed coaxially to said driven shaft;
  - [f] a harness retracting/releasing element furnished with a screw threading respectively matching said screw threading of said driven shaft, said retracting/releasing element is threaded onto said driven shaft and onto said pivot;
  - wherein upon rotation of said driven shaft said retracting/releasing element performers axial translation along said pivot thereby retracting/releasing said harness.
- 45. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said retraction mechanism comprises:
  - [a] a structural platform;

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- [b] a motor mounted onto said platform; the rotor of said motor terminates with sprocket
- [c] a driven shaft comprising a sprocket and at least one reel/s, and
- [d] a conveying belt rotationally coupling said sprockets; wherein upon rotation of said driven shaft said at least one terminal portion/s of said

- harness is wound/unwound onto/from said at least one reel/s; thereby retracting/releasing said harness.
- 46. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said platform is characterized by a concave surface and a slot, wherein said platform is to be appended to the posterior portion of the crus, so that concave said surface thereof conforms with the convex surface of said crus and said slot accommodates the Achilles tendon.
- 47. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said retraction mechanism is able to apply a force of at least 22 Newton and induce a torque of at least 1 Newton per meter.

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- 48. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said retraction mechanism is be able to perform a displacement of about at least 25 millimeters.
- 49. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said portable energy source is characterized by the minimal capacity of about 23,000 Joule.
- 50. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein said retraction mechanism comprises an electro-active polymer.
- 51. The dorsiflexion recreation device as in any of the claims 27 to 52, further comprising a tension sensor providing a real-time data regarding the tensile force applied to said harness.
- 52. The dorsiflexion recreation device as in any of the claims 27 to 52, wherein the release of said at least on terminal portion/s of said harness is allowed whenever the tensile force applied to said harness exceeds a predetermined threshold, for a given stage of the pedometric cycle.

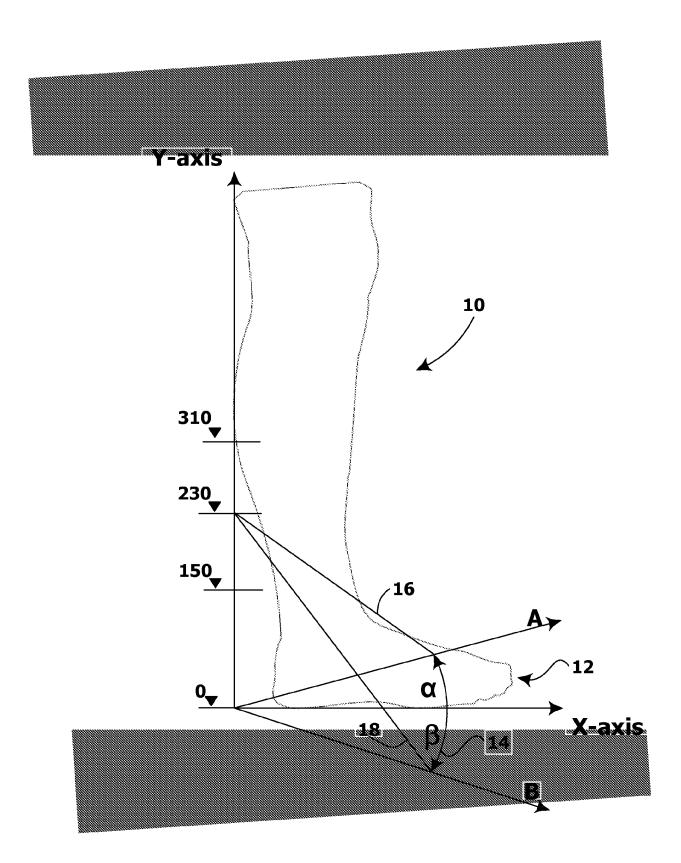


Fig. 1

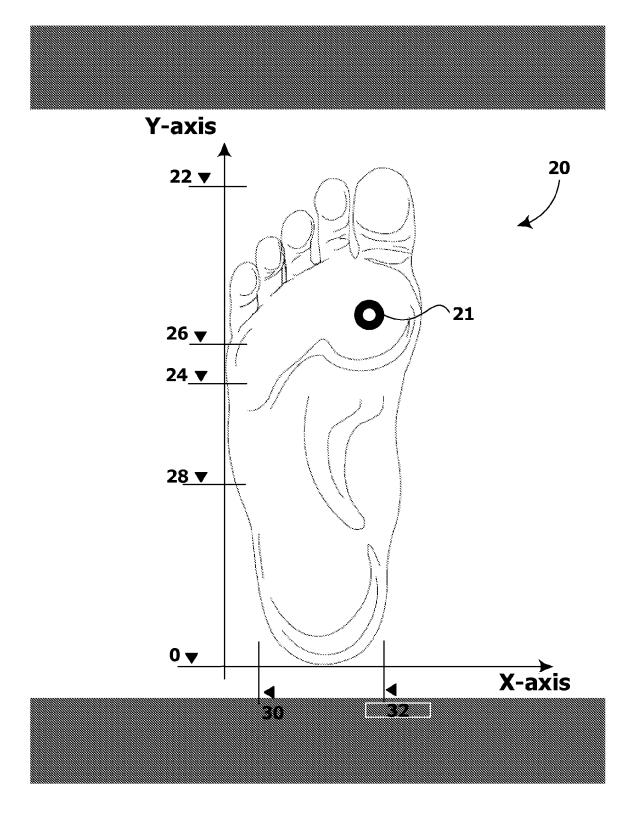


Fig. 2

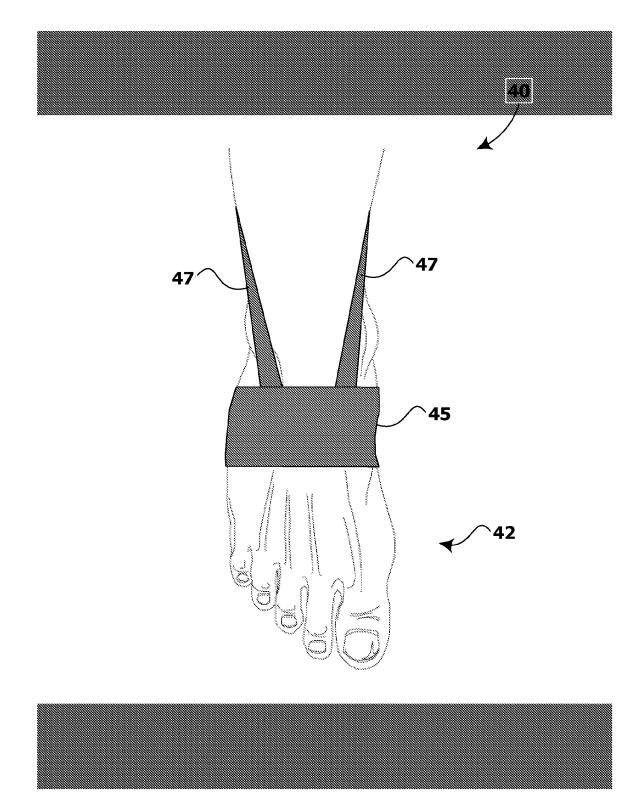


Fig. 3A

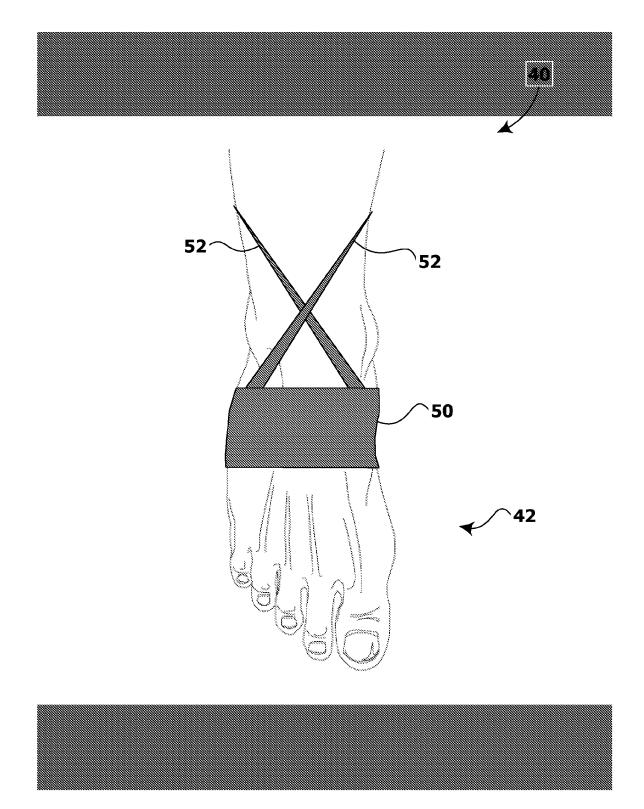


Fig. 3B

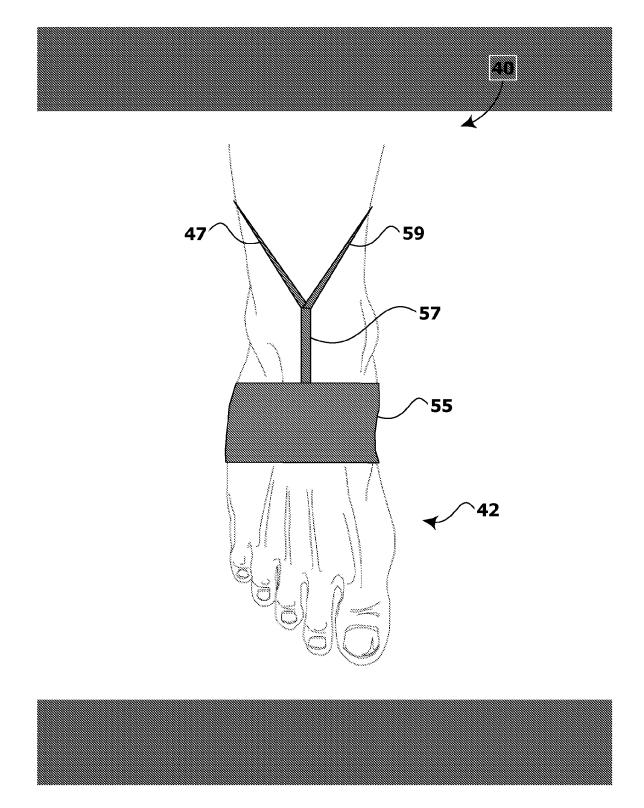


Fig. 3C

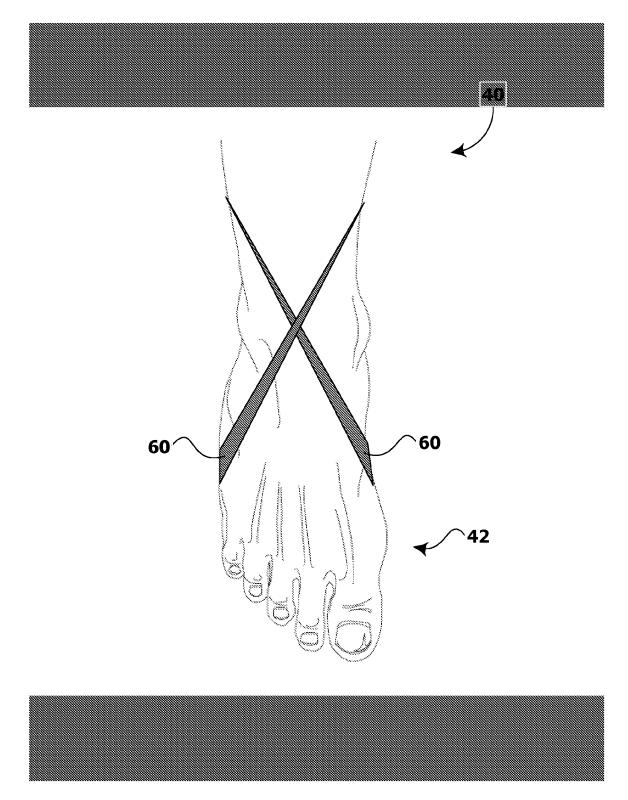


Fig. 3D



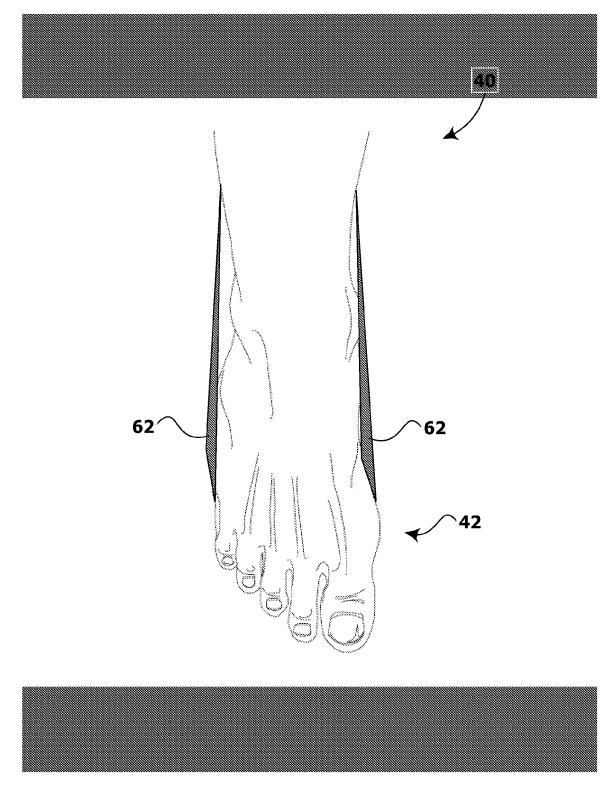


Fig. 3E

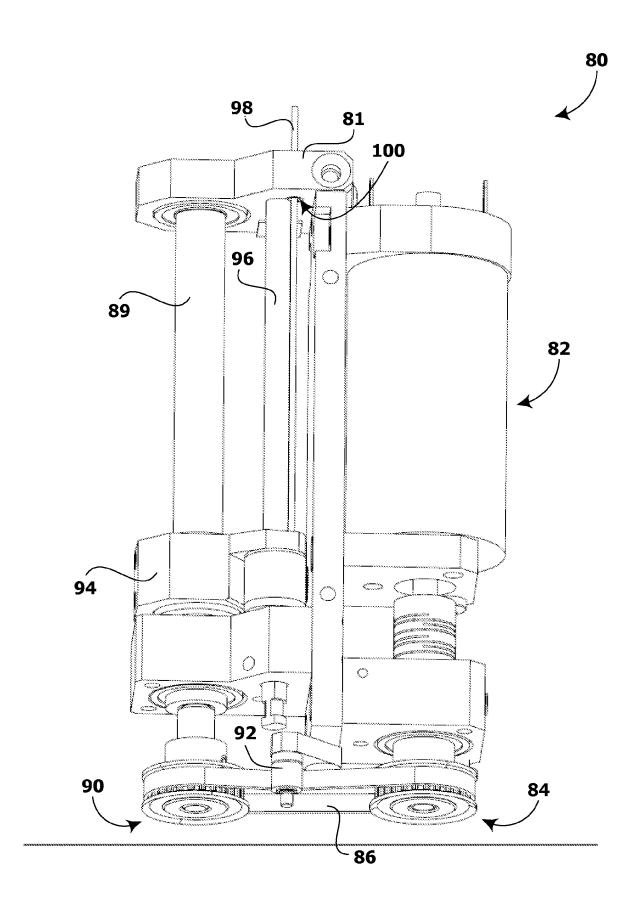
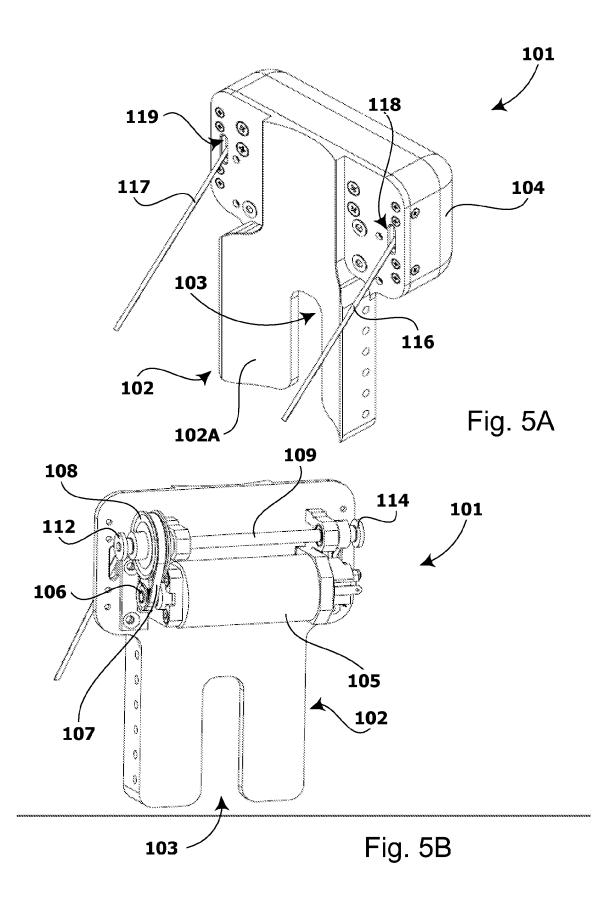


Fig 4



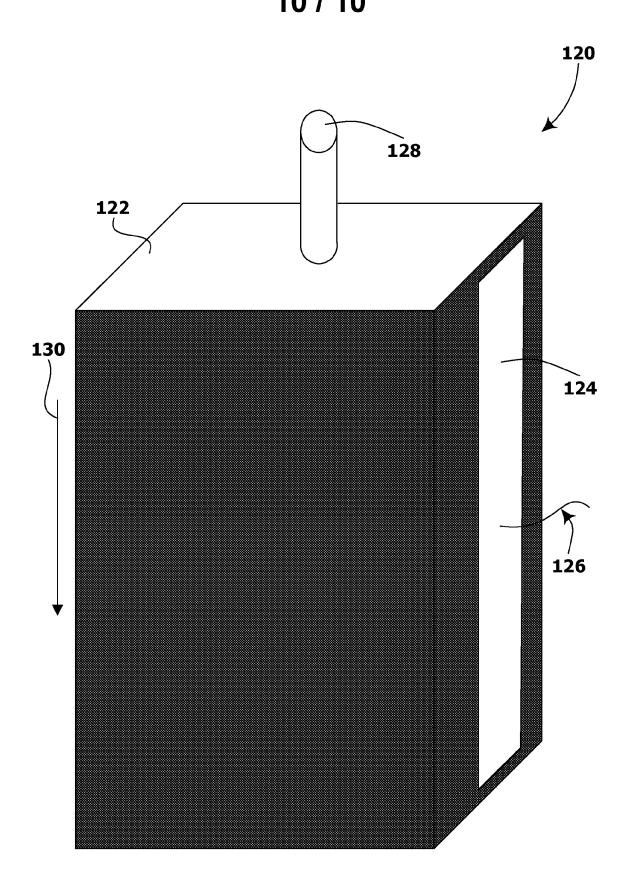


Fig. 6

#### INTERNATIONAL SEARCH REPORT

International application No PCT/IB2010/056102

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F5/01 A61F2/70
ADD. A61F2/76 A61F2/50

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)

A61F

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.
Α	WO 2004/078076 A1 (HJORTH KNUD [DK]) 16 September 2004 (2004-09-16) abstract; figures page 2, lines 13-29	1-52
А	US 2003/073938 A1 (CRAWFORD MICHAEL K [US] ET AL) 17 April 2003 (2003-04-17) cited in the application abstract; figures paragraphs [0022] - [0026]	1-52
А	US 7 458 950 B1 (IVANY MICHAEL [US]) 2 December 2008 (2008-12-02) cited in the application abstract; figures column 3, lines 49-65 column 4, lines 50-64	1-52
		I

X Further documents are listed in the continuation of Box C.	X See patent family annex.
"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  13 April 2011	Date of mailing of the international search report $26/04/2011$
Name and mailing address of the ISA/ European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Authorized officer  Lager, Johan

## **INTERNATIONAL SEARCH REPORT**

International application No
PCT/IB2010/056102

-(	tion). DOCUMENTS CONSIDERED TO BE RELEVANT	
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
А	US 4 329 982 A (HEANEY AUDREY C) 18 May 1982 (1982-05-18) cited in the application abstract; figures	1-52
Α	US 4 817 589 A (WERTZ LARRY W [US]) 4 April 1989 (1989-04-04) cited in the application abstract; figures	1-52
A	US 5 112 296 A (BEARD JOHN [US] ET AL) 12 May 1992 (1992-05-12) cited in the application abstract; figures 1,6	1-52

## **INTERNATIONAL SEARCH REPORT**

Information on patent family members

International application No
PCT/IB2010/056102

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