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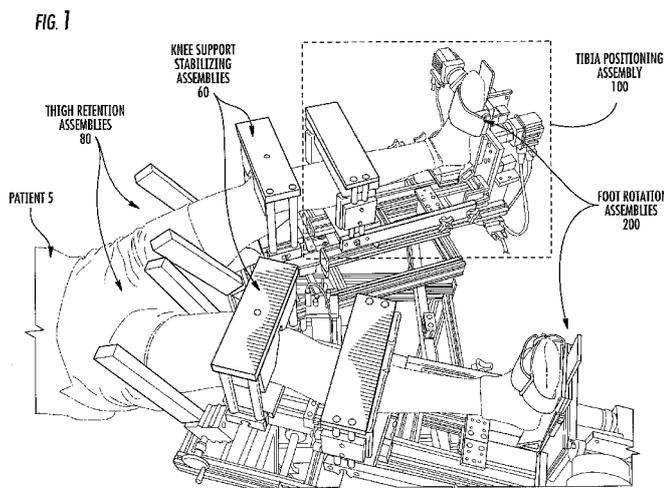
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(54) **Title:** ROBOTIC KNEE TESTING DEVICE, SUBJECTIVE PATIENT INPUT DEVICE AND METHODS FOR USING SAME



(57) **Abstract:** An apparatus for evaluating leg movement characteristics of a patient is provided. The apparatus comprises a base assembly configured to at least partially support the patient's torso; and first and second leg support assemblies independently pivotably mounted about a pivot axis relative to the base assembly. Each leg support assembly is configured to at least partially support a portion of a respective one of the first and second legs, independent of the support of the torso. Each of the leg support assemblies also comprises: a first leg support member including a foot rotation assembly configured to at least partially retain and support an associated foot of the patient and to rotate it about an axis of rotation relative to the base assembly; and a second leg support member configured for supporting a portion of the leg at a location proximal relative to the first leg support member.



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**ROBOTIC KNEE TESTING DEVICE, SUBJECTIVE PATIENT
INPUT DEVICE AND METHODS FOR USING SAME**

BACKGROUND

Field of Invention

The invention generally is directed towards a robotic knee device (an
5 “RKT” device) which controls the direction, rate, and magnitude of forces applied
in at least three directions, namely a flexion force in an x-axis of rotation, a valgus
force in a z-axis of rotation, and an internal rotation force in a y-axis rotation.

Description of Related Art

10 The knee is composed of the femur or thigh bone, the tibia or shin bone and
the patella or knee cap. They are connected by fibrous structures called ligaments
which allow a certain amount of ‘joint play’ to exist between the bone structures.
When this ‘joint play’ is increased or decreased an abnormal or pathological
condition exists in the knee. Attempts have been made in the past to quantify this
15 increase or decrease in ‘joint play’ of the knee with limited success.

An injury to the knee can cause damage to one or more of the structures of
the knee causing an increase in the ‘joint play’ of the knee. This increase in ‘joint
play’ can create the sensation to the patient that the knee is slipping or ‘coming out
of joint’. Commonly, this sensation described by the patient is referred to as the
20 feeling of ‘joint instability’. The ability of the two bones to actually ‘come out of
joint’ is related to the length of the fibrous structures or ligaments which connect
the two bones together as well as the shape and size of the two bones (or three).
The ability of the bones to ‘come out of joint’ or become unstable is related to the
amount of stretch or the amount of increased lengthening of each ligament, the
25 number of ligaments involved, and damage to other support structures of the knee
such as the bone itself and the menisci. Accurate measurement of this increased
ligament length can be critical to restore the knee to as close to its original
functional and anatomical state as possible.

Currently, there are only manual tests used by clinicians to aid in the
30 diagnosis of ligament damage or increased (decreased) joint play. As an example,
there are three manual tests to evaluate the increased joint play associated with an
ACL tear – the Lachman’s test, the Pivot Shift test and the Anterior Drawer Test.

All of these tests suffer from the clinician's subjective evaluation of both the extent of the ligament lengthening and the change in the compliance or stretchiness of the ligament.

5 The Lachman's test is performed by laying the patient in a supine position and bending the knee at approximately 20 to 30 degrees. The clinician places a hand on the patient's upper thigh and his other hand below the upper part of the patient's calf muscle. Pressure is applied under the patient's calf and down on the patient's thigh such that translation between the tibia and femur occurs.

10 Similar to the Lachman's test, the pivot shift test begins by positioning the patient on his back. The knee is flexed (x-axis rotation) and a valgus (z-axis rotation) force and an internal rotation (y-axis rotation) force is applied to the knee as the knee is brought into full extension (x-axis rotation). The clinician feels for an abnormal internal rotation (y-axis rotation) and anterior translation (z-axis translation) of the tibia with respect to the femur. This shift is felt to represent the
15 relative increased translation (z-axis translation) of the lateral side of the knee with respect to the increased translation (z-axis translation) of the medial side of the knee. Furthermore, the point of sudden shift represents the point at which the back part of the tibia bone slides in front of the radius of curvature of the curved end of the femur. The clinician subjectively rates the pivot shift as Grade I, Grade II or
20 Grade III depending upon the degree of rotational and translational shift felt during the test. This test is difficult to perform, difficult to teach and difficult to quantify.

Finally, the anterior drawer test is performed with the patient lying on his back and his knee bent to 90 degrees. With the patient's foot supported by a table or chair, the clinician applies pressure to the knee using her thumbs. This test is
25 graded based upon the amount or extent of anterior translation along the z-axis of the tibia with respect to the femur. Grade I has 0 to 5 mm of anterior translation (z-axis translation), Grade II has 6 to 10 mm of anterior translation, and Grade III has 11 to 15 mm of translation.

To diagnose an injured ACL using the described tests, the clinician must
30 determine whether the knee feels "abnormal." Thus, the accuracy of an ACL injury diagnosis using currently known tests depends on the skill and experience of the clinician. A misdiagnosis can lead to unnecessary delay in treatment, thereby placing the patient at increased risk for further damage to the knee.

There are manual tests for the LCL, MCL and the PCL. Each manual test relies on grading the extent of the ligament lengthening into three categories. There is no effort to grade the compliance of the ligament; however, the expert clinician will describe the ligament in terms of its 'feel'. The more ligaments and structures that are damaged; the more complex it becomes to perform a knee examination using the subjective manual exams.

There have been multiple attempts in the past to instrument the knee and quantify or measure the change in the structure of the knee after ligament damage. Only one device has attempted to accurately quantify the extent or relative displacement and compliance a ligament in the knee. The KT-1000 and the KT-2000 Medmetric® by measure the anterior-posterior translation of the tibia with respect to the femur along the z-axis. These devices attempt to quantify the findings found when the clinician uses the Lachman's test and the Anterior Drawer Test. Force is applied to a handle on the device which measures force and signals to the clinician the amount of force with a low pitched sound for the 15 pound force, a higher pitched sound for the 20 pound force. This force pulls anteriorly along the z-axis through a strap that wraps underneath the calf. The measurement of the translation uses a technique measuring the relative motion of a pad on the anterior tibia with respect to a pad placed on the patella. This device does not measure relative displacement or compliance in any of the other degrees of freedom previously described in the knee. Furthermore, the quantified results of the KT-1000 or KT-2000 have not been correlated with patient satisfaction whereas the subjective Pivot Shift test has been correlated with patient satisfaction.

Accordingly, there is a need for an accurate, objective, reliable and reproducible measure of the impact of damage to the ACL as well as other ligaments and structures in the knee that can be used in the clinical setting on patients. For example, since an injury to the ACL produces both an increase in anterior translation (z-axis translation) and rotation (y-axis rotation), an objective measure of these changes would both aid in the diagnosis of the injury as well as verify its restoration after ligament reconstruction surgery. Additionally, measurement of displacement and compliance around different degrees of freedom in the knee would help objectively describe the individual and complex changes to 'joint play' that occur with an injury to the knee. A need exists for systems and methods that can provide accurate, reproducible and objective data on the changes

in 'joint play' that occur with an injured knee compared to their normal knee and to the population as a whole such that the clinician can achieve patient satisfaction with focused, biomechanical and proven surgical interventions individualized for that injury and for that knee across the entire population of damaged knees.

5 Needs also exist for systems and methods, and devices which accommodate variances of patient body structure; it may well be understood that each human body is different and may require particular attention when being treated and/or analyzed; this may be particularly evident in the case of abnormalities of bone, tendon, joint, etc., due to injury or the like.

10

SUMMARY

Generally described, the present invention to provide apparatuses and methods for evaluating the performance of joints and their associated elements.

In accordance with the purposes of the various embodiments of the present invention as described herein, an apparatus for evaluating leg movement characteristics of a patient, the patient having a torso, and also having a first and a second leg extending from the torso, each leg including a femur, patella, and a foot, is provided. The apparatus comprises: A) a base assembly configured to at least partially support the torso; and B) first and second leg support assemblies independently pivotably mounted about a pivot axis relative to the base assembly, each leg support assembly configured to at least partially support a portion of a respective one of the first and second legs, the support being independent of the support of the torso. Each of the leg support assemblies comprises: 1) a first leg support member itself comprising a foot rotation assembly configured to at least partially retain and support an associated foot of the patient and to rotate it about an axis of rotation relative to the base assembly; and 2) a second leg support member configured for supporting a portion of the leg at a location proximal relative to the first leg support member during the rotation of the foot, each the foot rotation assembly configured to rotate the associated foot such that an associated leg movement is provided and can be measured.

25
30

In accordance with an additional aspect of the present invention as described herein, an apparatus for evaluating leg movement characteristics of a patient, the patient having a torso, and also having a first and a second leg extending from the torso, each leg including a femur, patella, and a foot, is

provided. The apparatus comprises: A) a base assembly configured to at least partially support the torso; and B) first and second leg support assemblies independently pivotably mounted about a pivot axis relative to the base assembly, each leg support assembly configured to at least partially support a portion of a
5 respective one of the first and second legs, the support being independent of the support of the torso. Each of the leg support members further comprises: 1) a first leg support member itself including a foot rotation assembly configured to at least partially retain and support an associated foot of the patient and to rotate it about
10 an axis of rotation relative to the base assembly; 2) a second leg support member configured for supporting a portion of the associated leg at a location proximal relative to the first leg support member during the rotation of the foot; and 3) a tibia positioning assembly configured to contact the lower leg portion of the associated leg at a location generally intermediate that of the first and second leg support members. Each of the foot rotation assemblies are further configured to
15 rotate the associated foot such that associated leg movement is provided and can be measured while the tibia retention assembly at least partially laterally retains tibia movement.

In accordance with an additional aspect of the present invention as described herein, an apparatus for evaluating leg movement characteristics of a
20 patient, the patient having a torso, and also having a first and a second leg extending from the torso, each leg including a femur, patella, and a foot, is provided. The apparatus comprises: A) a base assembly configured to at least partially support the torso; and B) first and second leg support assemblies independently pivotably mounted about a pivot axis relative to the base assembly,
25 each leg support assembly configured to at least partially support a portion of a respective one of the first and second legs, the support being independent of the support of the torso. Each of the leg support members itself comprises: 1) a first leg support member itself including a foot rotation assembly configured to at least partially retain and support an associated foot of the patient and to rotate it about
30 an axis of rotation relative to the base assembly; 2) a second leg support member configured for supporting a portion of the associated leg at a location proximal relative to the first leg support member during the rotation of the foot; and 3) a tibia positioning assembly configured to contact the lower leg portion of the associated leg at a location generally intermediate that of the first and second leg

support members, the tibia positioning assembly mounted for linear adjustment relative to the pivoting leg support frame assembly, the tibia positioning assembly providing pivoting support of the foot rotation assembly to provide the axis of rotation relative to the base assembly. Each the foot rotation assembly is further
5 configured to rotate the associated foot such that the associated leg movement is provided and can be measured while the tibia retention assembly at least partially laterally retains tibia movement.

In accordance with an additional aspect of the present invention, a method for evaluating leg movement characteristics of a patient, the patient having a torso,
10 and also having a first and a second leg extending from the torso, each leg including a femur, patella, and a foot, is provided. The method comprising the steps of: A) providing an apparatus comprising: 1) a base assembly configured to at least partially support the torso; and 2) first and second leg support assemblies independently pivotably mounted about a pivot axis relative to the base assembly,
15 each leg support assembly configured to at least partially support a portion of a respective one of the first and second legs, the support being independent of the support of the torso, each of the leg support assemblies including: a) a first leg support member itself including a foot rotation assembly configured to at least partially retain and support an associated foot of the patient and to rotate it about
20 an axis of rotation relative to the base assembly; and b) a second leg support member configured for supporting a portion of the leg at a location proximal relative to the first leg support member during the rotation of the foot; and B) placing a patient in the device, rotating the associated foot such that the associated leg movement is provided, and measuring the movement.

25 In accordance with an additional aspect of the present invention, a method for evaluating leg movement characteristics of a patient, the patient having a torso, and also having a first and a second leg extending from the torso, each leg including a femur, patella, and a foot, the method comprising the steps of: A) providing an apparatus comprising: 1) a base assembly configured to at least
30 partially support the torso; and 2) first and second leg support assemblies independently pivotably mounted about a pivot axis relative to the base assembly, each leg support assembly configured to at least partially support a portion of a respective one of the first and second legs, the support being independent of the support of the torso, each of the leg support members including: a) a first leg

support member itself including a foot rotation assembly configured to at least partially retain and support an associated foot of the patient and to rotate it about an axis of rotation relative to the base assembly; b) a second leg support member configured for supporting a portion of the associated leg at a location proximal
5 relative to the first leg support member during the rotation of the foot; and c) a tibia positioning assembly configured to contact the lower leg portion of the associated leg at a location generally intermediate that of the first and second leg support members; and B) placing a patient in the device, rotating the associated foot such that the associated leg movement is provided, and measuring the
10 movement.

In accordance with an additional aspect of the present invention, a method for evaluating leg movement characteristics of a patient, the patient having a torso, and also having a first and a second leg extending from the torso, each leg including a femur, patella, and a foot, the method comprising the steps of: A)
15 providing an apparatus that has a knee support configuration that allows for alternate uses, including a support mode for varus-valgus testing, and also a stabilizing mode for both anterior-posterior and rotational testing; B) using the knee support apparatus in the support mode for varus-valgus testing; and C) using the knee support apparatus in the stabilizing mode for both anterior-posterior and
20 rotational testing.

Other aspects, features, and advantages of the present invention will become apparent upon reading the following detailed description of the preferred embodiment of the invention when taken in conjunction with the drawing and the appended claims.

25

BRIEF DESCRIPTION OF THE DRAWINGS

Having thus described the invention in general terms, reference will now be made to the accompanying drawings, which are not necessarily drawn to scale, and wherein:

30 Figure 1 is a perspective view of the overall RKT apparatus **10**.

Figure 2 is an illustrative side elevational view of the general components and operation of the overall RKT apparatus **10**.

Figure 3 is a closer view of a portion of that shown in Figure 2.

Figure 4 is a closer view of a portion of that shown in Figure 3.

Figure 5 is a closer view of a portion of that shown in Figure 4.

Figure 6 is an illustrative top elevational view of the general components and operation of the overall RKT apparatus **10**. The two pivoting leg support frame assemblies are shown in generally parallel fashion.

5 Figure 7 is a view similar to that shown in Figure 6, except that the two sliding support frameworks are shown in different extension configurations.

Figure 8 is a view similar to that shown in Figure 6, except that the two pivoting leg support frame assemblies **50** are shown in different angular relationships.

10 Figure 9 is a view similar to that shown in Figure 6, except that the two pivoting leg support frame assemblies **50** are shown in different extension relationships.

Figure 10 is a view similar to that shown in Figure 6, except that the two pivoting leg support frame assemblies **50** are shown in different extension
15 relationships in order to accept the legs of a user **5**.

Figure 11 is a closer view of a portion of that shown in Figure 3, showing Action D.

Figure 12 is an illustrative view showing the transverse cross section of a thigh of a user in association with a corresponding thigh retention assembly **80**.

20 Figure 13 is an illustrative view, showing the transverse cross section of a knee of a user in association with a corresponding knee support/stabilizing assembly **60** (in support mode).

Figure 14 is an illustrative view, showing the transverse cross section of a knee of a user in association with a corresponding knee support/stabilizing
25 assembly **60** (in stabilizing mode).

Figure 15 is an illustrative view showing the transverse cross section of a tibia of a user in association with a corresponding tibia retention assembly **60**.

Figure 16 is a pictorial illustrative view of the pivoting interaction between the sliding frame **122** of a tibia positioning assembly **100**, a corresponding pivoting
30 frame **142** of a first pivoting assembly **140** (pivots relative to sliding frame **120** via Action F, about a vertical, “Y” axis) a corresponding pivoting frame **162** of a corresponding second pivoting assembly **160**, (pivots relative to first pivoting assembly **140** along Action G, along a horizontal axis) and a foot plate **202**, which (pivots relative to pivoting frame 162 along Action H).

Figure 17 shows a subjective measurement module **2000** including a subjective measurement module dial **2001** (operated by the user) and an output display **2002**.

5 Figure 18 shows a subjective measurement module **2200** including a subjective measurement module slide **2201** (operated by the user) and an output display **2202**.

Figure 19 is another pseudo-overhead view of the overall RKT apparatus **10**.

10 Figure 20 is a view similar to Figure 19, with the Tibia Positioning Assemblies **100** and their respective Tibia Containing Assemblies **180** “splayed” relative to the parallel configuration of Figure 19.

Figure 21 is similar to Figure 20 but from different viewpoint and with patient **5** in place.

Figure 22 is similar to Figure 21 but a closer view.

15 Figure 23 is similar to Figure 20 but without knee support stabilizing assemblies **60**.

Figure 24 is similar to Figure 23 but more approximating a side elevational view.

20 Figure 25 is even more approximating a side elevational view relative to Figure 24.

Figure 26 is a view of the main frame assembly **20** and other lower situation elements.

Figure 27 is a slight overhead view from the foot of the device **10**, shown without knee support stabilizing assemblies **60**.

25 Figure 28 is a slight overhead view from the foot of the device **10**, showing two motors **168** and **206**, and the foot rotation assembly **200** (which includes straps for holding the foot).

30 Figure 29 is a slight overhead view from the foot of the device **10**, showing two motors **168** and **206**, the foot rotation assembly **200** (which includes straps for holding the foot), and the pivoting frame **142**.

Figure 30 is a slightly lower view than Figure 29.

Figure 31 is a slightly pulled back view than Figure 30.

Figure 32 is a view from the head of the device, without the bars **84** shown for viewing ease.

Figure 33 is a view similar to Figure 32.

Figure 34 shows the movement axis of one of the laterally slidable knee support pads **64**.

Figure 35 is a view of an exemplary sensor cluster **1000**.

5 Figure 36 shows a subjective measurement module **2100** including a subjective measurement module dial **2101** and an overall machine stop button **2102**.

Figure 37 is a slight overhead view of an additional embodiment of the overall RKT apparatus **10** containing tibia containing assemblies **1180** and a
10 plurality of bladders **1190**.

Figure 38 is a front view of the tibia containing assemblies **1180** and bladders **1190** of Figure 37.

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

15 **I. GENERAL OVERVIEW**

The present inventions now will be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the inventions are shown. Indeed, these inventions may be embodied in many different forms and should not be construed as limited to the embodiments set forth
20 herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Like numbers refer to like elements throughout.

Generally described, various embodiments of the present invention provide robotically controlled devices and methods for evaluating the knee, although other joints and limbs can likewise be evaluated such as the elbow and arm. In one
25 aspect of the invention, devices and methods are provided, which apply a known torque to the lower leg of a user and monitor the reaction to this torque at the knee. Such devices and methods may be generally configured to control the direction, rate, and magnitude of force and/or torque application in all three directions (e.g., the x, y, and z axes, as described in further detail below), independently to two legs
30 of a patient. In various embodiments, the user's femur and ankle are stabilized such that the movement of the tibia at the knee in response to a given torque can be accurately measured.

In various embodiments of the present invention, the torque is applied by one or more computer controlled motors. In at least one embodiment, such is accomplished by the use of six (6) brushless servo motors. The computer may be programmed to instruct the motor(s) to perform any desired diagnostic routine.

5 Custom software may be utilized on the computer to calculate the appropriate amount of torque to be used by each motor during testing based on the person's height and weight. The desired torque thresholds are then communicated with the motors.

After the person has been properly positioned, the software may then signal

10 the motor(s) to perform the knee laxity testing. For example, the diagnostic routine may comprise rotating the user's lower leg in a clockwise direction from a neutral position until a predetermined threshold is reached and then back to neutral. This procedure may be repeated for three (3) or more cycles. Then, the user's leg may be rotated from a neutral position in a counterclockwise direction until a

15 predetermined threshold is reached and back to neutral for three cycles. In another example, the diagnostic routine may comprise the rotating of a user's lower leg in a clockwise direction until a predetermined threshold is met and then rotate in a clockwise direction until a predetermined threshold is met in a substantially fluid motion. This procedure may be repeated for several cycles. Clockwise and

20 counterclockwise rotations can be made in either the x, y, or z axes, by placing the motor in different orientations.

In various embodiments, both of the user's lower legs may be rotated simultaneously. For example, the user's left leg may be rotated counter clockwise (external rotation) and then clockwise (internal rotation) while the user's right leg

25 is rotated clockwise (external rotation) and then counter clockwise (internal rotation). By rotating the legs simultaneously in opposite directions, the movement in the hip area can be minimized since the motions counter act each other. This allows evaluation of not only two limbs simultaneously, but also both joints of both limbs (e.g. two knees and two ankles).

30 While the diagnostic routine is performed, various parameters may be monitored to evaluate the performance of the knee. In one embodiment, angle of rotation and torque measurements are taken at regular intervals during the diagnostic routine. In certain embodiments, the regular intervals may be 120 times per second, collecting the torque currently being applied by each motor and each

motor's encoder position. From this data, a hysteresis curve can be generated, which may be used to evaluate the performance of the knee. Further, knee joint laxity may be determined by measuring the amount of motion of the tibia relative to the femur as the tibia is perturbed in single and/or multiplanar motions. More
 5 detailed measurement techniques are described elsewhere in this application.

II. ELEMENTS LIST

The invention is configured to be used by a patient/user 5. The elements of the invention include the following:

- 10 10. Overall RKT Apparatus
- 20. Stationary Base Frame Assembly
- 30 support cushion

- 40. sliding support framework
- 15 42 Clamping members

- 50 Pivoting Leg Support Frame Assemblies (2)

- 60 Knee Support/Stabilizing Assembly
- 20 62 telescoping pedestal
- 64 Laterally Slidable Support pad
- 66 clamp assembly
- 68 Top plate
- 70 rods (4) extending from one side of plate
- 25 72 main stabilizing pad
- 78 rod clamp assembly

- 80 Thigh Retention Assembly
- 82 Base
- 30 84 Retention bars
- 86 Adjustment Assembly
- 87 Adjustment Assembly Handwheel

- 100 Tibia Positioning Assembly

	120	sliding frame
	140	first pivoting assembly
	142	Pivoting frame
	148	motor
5	160	second pivoting assembly
	162	Pivoting frame
	168	motor
	180	tibia retention assembly
	182	base
10	184	adjustment rods
	185	cap
	186	clamp assembly
	188	Pad support plates
	189	pads
15	200	<u>Third Pivoting Assembly</u> (a.k.a foot rotation assembly 200)
	202	foot plate
	204	rotating shaft
	206	motor

20

III. DETAILS

Overall RKT Apparatus 10

As illustrated in at least Figures 1-2, 19, and 22, various embodiments of the overall RKT (Robotic Knee Testing) Device **10** may include the following features:

25

- Stationary Base Frame Assembly **20**;
- Support Cushion **30**;
- Sliding Support Framework **40**;
- Two (2) Pivoting Leg Support Frame Assemblies **50**;
- Two (2) Knee Support/Stabilizing Assemblies **60**;
- Two (2) Thigh Retention Assemblies **80**;
- Two (2) Tibia Positioning Assemblies **100**;
- Two (2) Third Pivoting Assemblies **200** (a.k.a. Foot Rotation Assemblies **200**).

30

In use, as will be described in further detail below, a patient **5** may be positioned within the various embodiments of the overall RKT device **10**, such that their knees are adjacent the knee support/stabilizing assemblies **60**, and their feet are retained within the third pivoting assemblies **200**.

5 Each of these features and their use will now be described in further detail herein-below.

Stationary Base Frame Assembly 20

As illustrated in at least Figures 2-4, the stationary base frame assembly **20** according to various embodiments of the overall RKT device **10** is configured to be situated atop and supported by a supporting surface such as a floor (not shown). In certain embodiments, this assembly supports all of the other elements of the overall RKT device **10**. In at least one embodiment, the stationary base frame assembly **20** is substantially rigid and is comprised of a plurality of substantially
15 rigid frame members, such as those shown in Figure 26.

Support Cushion 30

As illustrated in at least Figures 2-4, the support cushion **30** according to various embodiments may be configured to be attached to and supported by the
20 stationary base frame assembly **20**. In other envisioned embodiments, the cushion **30** may be integrally formed as part of the assembly **20**, as illustrated, for example, in Figure 19 (although not numbered). In any of these and still other envisioned embodiments, the support cushion **30** is generally configured to support the posterior of a patient **5** such that the patient can lie on the patient's back, and the
25 patient's legs can be situated in the overall RKT device **10**, as shown for example in at least Figures 1, 3, 21, and 23.

Sliding Support Framework 40

As illustrated in at least Figures 2-4 and 26, the sliding support framework
30 **40** according to various embodiments, may comprise a substantially rigid substructure slidably supported atop the stationary base frame assembly **20**. In this manner, the support framework **40** may, in these and still other envisioned embodiments, be configured to slide relative to the stationary base frame assembly **20** along a linear X axis. This movement is designated as "Action A" by the arrows

in, for example, Figure 2.

In various embodiments, the “Action A” movement is configured to facilitate adjustment of the sliding support framework **40** prior to its testing function. In certain embodiments, this adjustment allows for the sliding support framework **40** to be properly positioned relative to the patient. This adjustment is
5 not made to accommodate varying leg lengths, but allows for proper positioning of the testing apparatus even if the patient is positioned too far toward either the head or foot of the bed. While in the embodiment shown in Figure 2 this adjustment is along the X axis and is linear, alternative possible, single or multiple, axes of
10 adjustment may be envisioned as within the scope of the present invention.

As will be described below in further detail, the two pivoting leg support frame assemblies **50** according to various embodiments may be attached above and supported by the sliding support framework **40**. In this manner, in at least certain embodiments, the frame assemblies **50** may be likewise adjusted as the sliding
15 support framework **40** is adjusted, as may be desirable for particular applications.

In use, according to various embodiments, in order to adjust the sliding support framework **40** relative to the stationary base frame assembly **20**, the patient **5** (a.k.a. user **5**) may be first positioned in place as generally shown in at least Figures 1 and 3. During such positioning, a releasable connection **42** according to
20 various embodiments between the sliding support framework **40** and the stationary base frame assembly **20** is disengaged, thereby permitting adjustment of the framework **40** relative to the assembly **20**, as necessary to fine-tune the positioning of the patient **5**. In at least one embodiment the releasable connection comprises at least two clamping members **42**, as illustrated in in Figure 3, although in other
25 envisioned embodiments, any of a variety of alternative type or number of connections may be employed between the sliding support framework **40** and the stationary base frame assembly **20**.

In any of the above-discussed embodiments, once the patient is positioned precisely as desired or needed, then the releasable connection **42** between the
30 sliding support framework **40** and the stationary base frame assembly **20** may be engaged (*see e.g.*, clamps **42** in Figure 3). In this manner, once the connection or clamps **42** are engaged, relative movement between the framework **40** and the assembly **20** may be prevented, so as to maintain the patient **5** in the proper or desired position.

Two (2) Pivoting Leg Support Frame Assemblies 50

As illustrated in at least Figures 2-4 and 26, the general function of each of the two pivoting leg support frame assemblies **50** according to various embodiments of the overall RKT device **10** is to provide a framework to support a
5 corresponding leg of the patient/user such as **5**.

In various embodiments, the two pivoting leg support frame assemblies **50** are pivotably attached above and supported by the sliding support framework **40**. In this manner, the assemblies **50** may be likewise adjusted as the sliding support framework **40** is adjusted, as previously described herein and as illustrated in, for
10 example Figures 6, 7, and 9.

In various embodiments, each of the two pivoting leg support frame assemblies **50** is pivotably mounted relative to the framework about an axis lying parallel to the Y axis (see Figure 2); thus they lie substantially along mutually parallel axes. In these and other embodiments, as best understood from Figure 6,
15 the pivoting actions of the assemblies **50** may be independent, in that one can pivot without the other. In still other envisioned embodiments, depending upon a particular application, the pivoting actions of the assemblies **50** may be interdependent, illustrated, at least in part by Figure 10. In any of these described and still further envisioned embodiments, the pivoting action is an adjustment such
20 as that identified as "Action B" in, for example, Figure 2 and more fully illustrated in Figure 8. Action B adjustment allows the individual leg testing apparatuses to be aligned according to the patient's natural alignment. Improper alignment would pre-tension ligaments thus creating error in the test results. This adjustment is made to avoid such errors.

25 According to various embodiments, each pivoting leg support frame assembly **50** is substantially similar to the other, and thus one can be described as an example of the other. In other envisioned embodiments (not shown), however, each of the assemblies **50** may differ in one or more respects, as may be desirable for a particular application.

30 Further, as noted above, each pivoting leg support frame assembly **50** may, according to various embodiments, comprise a substantially rigid substructure. In certain embodiments, each pivoting leg support frame assembly **50** itself slidably supports a corresponding one of two tibia positioning assemblies **100**, as illustrated in, for example, Figure 3, and described in further detail below. In various

embodiments, as one pivoting leg support frame assembly **50** pivots, so does its corresponding tibia positioning assembly **100**. However, it should be appreciated that in still other envisioned embodiments, the respective assemblies **50** and their corresponding assemblies **100** may one or both pivot independently relative to one another, in any of a variety of combinations, as may be desired for a particular application.

According to various embodiments, the pivoting movement of the respective assemblies **50** and their corresponding assemblies **100** is substantially about an axis parallel to the “X” direction, as illustrated in, for example, Figure 2. In at least one embodiment there are no clamps between **50** and **100**, although the pivoting movement could be prevented via clamping after suitable adjustment. In the embodiment without clamps, each of the two pivoting leg support frame assemblies **50** is free to pivotably relative to the sliding support framework **40**.

Two (2) Knee Support/Stabilizing Assemblies 60

As illustrated in at least Figures 13 and 14, the general function according to various embodiments of the knee support/stabilizing assemblies **60** is to support the knee, when in their “support mode” (see Figure 13), and to support and stabilize the knees when in their “stabilizing mode” (see Figure 14). In certain embodiments, the knee support/stabilizing assemblies **60** are used in support mode for varus-valgus testing. In those and other embodiments, the knee support/stabilizing assemblies **60** are used in “stabilizing mode” for both antero-posterior and rotational testing. In still other embodiments, the knee assemblies **60** may be used in either support or stabilizing mode for any of a variety of tests, as may be desired for a particular application. Each of these modes will be discussed in further detail below, although it should be further appreciated that at least certain envisioned embodiments will include no knee support/stabilizing assemblies **60** of any kind, as illustrated, for example, in Figures 23 and 27.

Support Mode (generally used in Varus-Valgus Testing)

As best illustrated in Figures 13 and 21, according to various embodiments, the knee support/stabilizing assemblies **60** may be used in support mode for varus-valgus testing. When in “support mode”, the knee support/stabilizing assemblies **60** only support the knee region of the leg from underneath, and is free to move side to

side. When in this mode, each of the knee support/stabilizing assemblies **60** includes the following elements, as illustrated in at least Figures 11 and 13:

- Telescoping Pedestal **62**
- Laterally Slidable Knee Support Pad **64** (slidable in this mode)
- 5 Clamp Assembly **66**
- Plate **68**
- Rods **70** (4) extending from one side of plate
- Stabilizing Pad **72**

According to various embodiments, the telescoping pedestal **62** has a lower
 10 end which is configured to be attached atop a corresponding pivoting leg support
 frame assembly **50**. In certain embodiments, the telescoping pedestal **62** supports at
 its top end a laterally slidable knee support pad **64**, which is configured to contact
 and support a portion of the leg of a patient **5** proximate the knee as shown in for
 example Figure 3. When in this mode, according to these and other envisioned
 15 embodiments, the pad **64** may be free to move laterally along with the underneath
 portion of the leg being supported. This is also known as Action J, as illustrated in
 at least Figure 13.

With reference to Figure 13 in view of Figure 3, according to various
 embodiments, during varus-valgus testing, as the device rotates about pivot point
 20 shown in Action F, it will be necessary to allow the knee move laterally side to
 side in order to actually perform the test. This is facilitated by the provision of the
 laterally slidable knee support pad **64**. Further according to various embodiments,
 during the varus-valgus testing, the knee itself need not be stabilized as in the
 anteroposterior and rotational tests described immediately below. However, the
 25 proximal thigh may, in certain embodiments, be stabilized by the thigh retention
 assembly **80** while the foot may be stabilized by the foot rotation assembly **200**, as
 illustrated in at least Figure 3, for example.

Therefore it may be seen that the knee support/stabilizing assemblies **60**
 may be used according to various embodiments in support mode to allow for a
 30 consistent degree of knee flexion during varus-valgus testing. Such benefit arises
 in at least certain embodiments due to the sliding pads **64** allowing the knees to
 slide laterally or otherwise, as previously described herein.

Stabilizing Mode (generally used in antero-posterior and rotational testing)

According to various embodiments, as illustrated in at least Figures 14 and 25, the knee support/stabilizing assemblies **60** may likewise be used in “stabilizing mode” for both anteroposterior and rotational testing. In these and other
 5 other embodiments, during anteroposterior and rotational testing, a clamp assembly **66** may be added to minimize motion of the femur, as described in further detail below.

When in “stabilizing mode” according to various embodiments, each of the
 10 knee support/stabilizing assemblies **60** may include one or more of the following elements, generally depicted in Figures 11 and 14, as will be described in further detail below:

- 15 Telescoping Pedestal **62**
- Support Pad **64**
- Clamp Assembly **66**
- Top Plate **68**
- Rods **70** (4) extending from one side of plate
- Main Stabilizing Pad **72**
- 20 Rod clamp assembly **78**

In certain embodiments, the knee support/stabilizing assemblies **60** may be used in stabilizing mode to allow for a consistent degree of knee flexion, as was done during varus-valgus testing described above. However, when in stabilizing mode, each of the knee support/stabilizing assemblies **60** also includes a clamp
 25 assembly **66**, as described in further detail below.

This clamp assembly **66** according to various embodiments may be configured to cooperate with the support pad **64** so as to substantially encircle the leg and to substantially engage or grip it from the top, as illustrated in at least Figures 14 and 21 (in the latter as assembly **60** generally). When in this mode
 30 according to certain embodiments, the pad **64** may not be adjusted laterally relative to the general longitudinal axis of the leg, as it is captured on its ends by at least the rods **70**. According to these and other envisioned embodiments, the clamp assembly **66** may include the following:

Top Plate **68**

Adjustment Rods **70** (4) extending from one side of plate

Main Stabilizing Pad **72**

Rod clamp assembly **78**

5 According to various embodiments, the top plate **68** may be configured such that the upper ends of four rods **70** may be attached to its underside. So configured, the rods **70** in at least certain embodiments may extend substantially downwardly and slidably into through-holes defined by the pedestal **62** until they are clamped in place. In at least one embodiment, the rod clamp assembly **78** is
10 configured to clamp the rods relative to the pedestal **62** such that the top plate **68** is retained in place. When so retained according to these and still other embodiments, the pads **64** and **72** substantially surround and contact the patient's leg, as illustrated in at least Figure 14. In still other envisioned embodiments, the rods **70** themselves may also provide some degree of containment of the patient's leg.

15 Remaining with Figure 14, according to various embodiments, the shape of pad **72** may be at least in part dictated by the need to stabilize the patella within the femoral trochlea. Such stabilization, in certain embodiments, prevents undesirable rotation and anteroposterior translation of the femur, while also satisfying a need to place an electromagnetic sensor, retro-reflective ball or array, ultrasonic sensor, or
20 other motion tracking device on the patella. In certain embodiments, the pad may be "V-shaped," which then allows the device to adequately capture the patella no matter the patellar dimensions of a given patient. In these and still other embodiments, the apex of the "V" shape may be deepened and/or widened in order to create a channel or pocket for the motion tracking device to be placed on the
25 patella, as may be desired for a particular application.

 In various embodiments, adjustments may be made such that the rod clamp assembly **78** is applied around the patient's leg, and in particular the patient's patella, by using a consistent known amount of force. For example, a downward (e.g., posteriorly-directed) force of 25 pounds may be used when positioning all
30 patients. In these and still other envisioned embodiments, a substantially consistent force should be used to allow for accurate and repeatable side-to-side comparisons. Indeed, inconsistent force application would allow one femur to be more easily moveable than the other, thus potentially creating error in the bilateral comparisons of translation and rotation of the tibia relative to the femur between the person's

right and left knees.

Height Adjustment of Knee Support/Stabilizing Assemblies 60

Whether or not the knee support/stabilizing assemblies **60** according to various embodiment are configured in support or stabilizing mode, the height the assemblies support the leg may be variable via adjustment of the telescopic portion
5 of the telescoping pedestal **62**. This adjustment is illustrated as Action D in at least Figure 2.

According to various embodiments, Action D adjustment may be provided either prior to testing in one embodiment or to change the degree of knee flexion in
10 an effort to be consistent with previously accepted clinical evaluation procedures, as may be desirable or necessary for a given application.

Two (2) Thigh Retention Assemblies 80

As illustrated in at least Figure 12, the general function of each of the thigh
15 retention assemblies **80** is to retain the thigh of the patient/user **5** such that internal/external and varus/valgus rotations of the femur are limited.

According to various embodiments, each thigh retention assembly may include two retention bars **84**, which are positioned on either side of the thigh of the patient/user's **5** thigh **82** so as to discourage it from movement lateral to the
20 longitudinal axis of the tibia. In certain embodiments, the two retention bars **84** are configured for centered adjustment, in that they are commonly mounted within an adjustment sub-apparatus that facilitates their common adjustment relative to a common central point. In this manner, in at least one embodiment, as one bar is moved a given distance in one lateral direction, the other bar moves a given
25 distance in the opposite lateral direction. This allows tightening or loosening of the bars about the intermediate thigh without moving the thigh to one side or the other. This could be considered a "self-centering" feature in at least certain of the envisioned embodiments.

Turning now to Figure 11, each thigh retention assembly **80** according to
30 various embodiments may include the following:

Base **82**

Two (2) Retention bars **84**

Adjustment Assembly **86** (see also Figures 32 and 33)

Adjustment Assembly Handwheel **87**

According to various embodiments, the base **82** of the thigh retention assembly **80** may be rigidly attached atop a corresponding one said pivoting leg support assemblies **50**. In certain embodiments, the base **82** may support a corresponding adjustment assembly **86**, which in turn may adjustably support two retention bars **84**, as further illustrated in at least Figure 12. In operation according to at least one embodiment, an adjustment assembly hand wheel **87** allows an operator (such as a clinician, not shown) to rotate the handwheel **87**. Rotation of the hand wheel **87** in this manner, according to various embodiments, rotates a threaded rod (or analogous mechanism, as commonly known or understood in the art) having two threaded portions of opposite direction, each one engaging relative to one of said retention bars **84**, such that adjustment of the spacing of the two retention bars **84** is facilitated such that a thigh can be suitably clamped therebetween.

Each of the two thigh retention assemblies **80** may according to various embodiments be attached atop a corresponding pivoting leg support frame assembly **50**, such that pivoting of the pivoting leg support frame assembly **50** about its vertical axis (e.g., during adjustment, as previously described herein) likewise facilitates pivoting of the corresponding thigh retention assembly **80**.

During patient set-up, it should be understood that the two retention bars **84** may generally squeeze the thigh in order to stabilize the femur while ensuring that the femur is centrally located in relation to both of the retention bars.

Two (2) Tibia Positioning Assemblies 100

Returning now to Figures 2 and 3, the general function of each of the two tibia retention assemblies **100** according to various embodiments is to position the tibia of the patient/user **5**. In certain embodiments, each of the tibia retention assemblies **100** includes the following features:

- sliding frame **120**
- first pivoting assembly **140**
- second pivoting assembly **160**

According to various embodiments, the sliding frame **120** of the tibia positioning assembly **100** provides the sliding connection between the tibia positioning assembly **100** and the pivoting leg support frame assembly **50**, as there is a sliding connection between elements **50** and **120**, which is Action E. Action E,

as illustrated in at least Figure 2 provides a degree of adjustment, which allows the tibia positioning assembly **100** to be adjusted according to the patient's leg length.

First Pivoting Assembly 140

5 Turning now to Figure 5, the first pivoting assembly **140** according to various embodiments may be pivotably mounted relative to the sliding frame **120** of the tibia positioning assembly **100**. In this manner, in certain embodiments, the first pivoting assembly **140** may be configured to pivot relative to sliding frame **120** via Action "F" (*see e.g.*, Figure 2), about a vertical axis along the "Y" axis.

10 Remaining with Figure 2, it should be understood that Action "F" action according to various embodiments is driven and controlled by motors **148** (see at least Figures 30 and 31), and provides a varus-valgus torque to the knee. Such action around the axis of rotation is used for valgus-varus or medial-lateral testing. One current embodiment uses a servomotor to provide the rotational force,
15 although other manual or mechanical methods of force application could be used.

According to various embodiments, the first pivoting assembly **140** includes the following:

Pivoting frame **142** (See, e.g., Figure 16)

Motor **148** (see at least Figures 30 and 31)

20 Focusing upon at least Figure 16, it should be understood that the pivoting frame **142** according to various embodiments provides the pivoting connection between the first pivoting assembly **140** and the sliding frame **120** and in at least certain embodiments the motor **148** (see Figures 30 and 31) drives this pivoting action. Further, in at least certain embodiments, the pivoting frame **142** may be
25 configured in substantially the same manner as pivoting frame **162**, as will be described in further detail here-below. In other embodiments, the pivoting frame **142** and frame **162** may be substantially different in shape, size and/or configuration, as may be desired for a particular application.

Second Pivoting Assembly 160

30 Returning to Figure 5, the second pivoting assembly **160** according to various embodiments may be configured to be pivotably mounted relative to the first pivoting assembly **140**, such that the second pivoting assembly **160** pivots relative to the first pivoting assembly **140** via Action "G" (see Figure 2), about a

horizontal axis shown by pivot point GPP (see Figure 4). In certain embodiments, this axis is the axis of rotation (normal to the drawing plane, in axis "Z") for anteroposterior laxity testing, causing the rotation indicated as Action G. At least one current embodiment uses a servomotor **168**, as illustrated in at least Figure 5, so as to provide the rotational force, although other manual or mechanical methods of force application may be envisioned and/or used, as desirable for any of a variety of applications.

According to various embodiments, Action G, whether manually driven or driven and controlled by motors **168**, is configured to provide internal-external rotation torque to the tibias, as will be described in further detail below. In these and still other envisioned embodiments, the second pivoting assembly **160** may include any or all of the following features:

Pivoting frame **162**

Clamp **163** (see Figure 5)

Motor **168** (see Figures 5 and 27-29 and 31)

Tibia Retention Assembly **180**

The pivoting frame **162** according to various embodiments provides the pivoting connection between the second pivoting assembly **160** and the first pivoting assembly **140**, and in at least the illustrated embodiment the motor **168** drives this pivoting action. In other embodiments, as previously described, alternative manual or mechanical methods and/or devices may be employed. In any of these and other envisioned embodiments, the tibia retention assembly **180**, as illustrated in at least Figures 20, 21 and 25, may be configured to be attached at the free end of the pivoting frame **162**. According to various embodiments, the location along the patient/user's leg that the tibia retention assembly **180** contacts the leg may be adjustable via Action "I" as illustrated in at least Figures 2, 4, and 5, which is an adjustment of the length of the pivoting frame **162**.

Turning specifically to Figure 4, Action I adjustment according to various embodiments, may be provided so that the location of force application during the anteroposterior, mediolateral, or valgus/varus testing can be held consistent for each patient. For example, the location of force application may need to be 1" distal to the tibial tuberosity; therefore, this portion of the frame must be adjusted so that the location of force application can be consistently located for patients. Once Action I adjustment is provided clamps such as **163**, as provided according to

various embodiments, may be clamped down so Action I movement is restricted. In other embodiments, any of a variety of commonly known and understood mechanisms may be used and operated so as to selectively permit and/or restrict Action I movement.

5

Tibia Retention Assembly 180

Referring now to at least Figures 5 and 15, the tibia retention assembly **180** according to various embodiments may be configured to laterally retain the tibia during at least the anteroposterior and varus-valgus testing processes. In at least
10 certain embodiments, the tibia retention assembly **180** includes the following, each of which as illustrated in at least Figure 15:

Base **182**

Adjustment rods **184**

Cap **185**

15

Clamp assembly **186**

Pad support plates **188**

Pads **189**

According to various embodiments, the base **182** of the tibia retention assembly **180** may be attached to the free end of the free end of pivoting frame **162**
20 (which as seen in Figures 5 and 24 may comprise one or more pair of telescoping rails). In certain embodiments, the two rail-like free ends of the pivoting frame **162** each define holes through which the adjustment rods **189** can slidably fit until they are clamped in place. The adjustment rods **189** all have one end rigidly mounted to the cap **185**. In at least one embodiment, the clamp assembly **186** may be
25 configured to clamp the rods relative to the base such that the cap **185** is retained in place. In these and still other envisioned embodiments, the pads **189** may be configured to substantially surround and contact the patient/user's leg. In at least the illustrated embodiment of Figures 15, the pads are attached to the rods via the pad support plates **188**, although in still other envisioned embodiments, the pads
30 may be attached relative to the rods via any of a variety of methods and devices, as commonly known and understood in the art and desirable for a given application.

Remaining with Figure 15, adjustment of the clamp assembly **186** according to various embodiments may be made such that the location of the anterior pad (**185** attached to **189**) is 1-2 cm above the anterior aspect of the low leg, with the entire system rotated about pivot point GPP so that the posterior pad (**182** attached to **189**) is located 1-2 cm below the posterior aspect of the low leg. Tightening the clamp assembly **186** fixes this position allowing for the system to function rigidly during anteroposterior and varus-valgus testing, and further allows for subtle changes in tibial anteroposterior position during rotational testing.

10 **Tibia Retention Assembly 1180**

Referring now to at least Figures 37 and 38, an alternative tibia retention assembly **1180** according to various embodiments may be configured substantially the same as tibia retention assembly **180** so to laterally retain the tibia during at least the anteroposterior and varus-valgus testing processes. In at least certain 15 embodiments, the tibia retention assembly **1180** further includes a plurality of bladders **1190** configured for applying a force so as to retain at least a portion of the patient's tibia within the assembly. In at least one embodiment, the plurality of bladders **1190** are contained within corresponding cuffs that are positioned relative to the assembly **1180** such that two cuffs are adjacent opposing side portions of the 20 assembly, one cuff is adjacent a top portion of the assembly, and one cuff is adjacent a bottom portion of the assembly, as best illustrated in at least Figure 38. In other embodiments, any combination of bladders **1190** and cuffs may be incorporated (e.g., merely one atop and one below the leg or merely two side opposing ones) as may be desired for a particular application.

25 In use according to various embodiments, each of the bladders **1190** may be selectively inflated so as to apply or increase a corresponding force to the portion of the patient's tibia positioned substantially adjacent each bladder. In certain embodiments, the bladders **1190** may be likewise selectively deflated so as to remove or decrease the corresponding force, as desirable. In at least these and 30 other envisioned embodiments, the bladders **1190** may all be inflated and/or deflated simultaneously, while in still other envisioned embodiments, each of the bladders **1190** may be manipulated individually.

According to various embodiments, a single pressure sensor may be connected to the bladders **1190** (e.g., via the lines or tubes, as seen (but not

numbered) in at least Figure 38)) and used to measure the change in pressure for the same. In certain embodiments, multiple pressure sensors may be employed, as may be desirable for a particular application. Still other embodiments may employ additional and/or alternative sensors or measurement tools, as may be desired.

5

Two (2) Third Pivoting Assemblies 200 (a.k.a. Foot Rotation Assemblies 200)

Returning again to Figure 5, each third pivoting assembly **200** according to various embodiments includes at least the following features:

- 10 foot plate **202**
 rotating shaft **204**
 motor **206**

According to various embodiments, the foot plate **202** of each of the third pivoting assemblies **200** may be pivotably mounted relative to the pivoting frame **162** of the second pivoting assembly **160** via a rotating shaft **204**, such that the foot plate **202** pivots relative to the pivoting frame **162** via Action “H,” as illustrated in at least Figure 4.

Action “H” of Figure 4 is powered movement about an axis of rotation for tibial internal and external rotation testing. At least one current embodiment uses a servomotor **206** to provide the rotational force, although other manual or mechanical methods of force application could be used, as desirable for any of a variety of given applications, as commonly known and understood in the art. In these and still other embodiments using the motor **206**, such may be configured with a housing mounted relative to the pivoting frame **162**, such that the motor drives the rotating shaft **204**, which itself drives the foot plate **202**. Of course, it should be understood that any of a variety of alternative configurations may be envisioned as within the scope of the present invention, as may be desirable for a given application.

30 **Actions of the Apparatus**

Reference is made to Figures 2 and 3, which show all the actions performed by various embodiments of the overall RKT device **10**. These actions are designated primarily upon Figure 2, with capital letters in circles; for example Action is designated with a circle with an “A” inside.

Action A – This adjustment according to various embodiments allows for the entire testing system to be properly positioned relative to the patient. This adjustment is not made to accommodate varying leg lengths, but allows for proper
5 positioning of the testing apparatus even if the patient is positioned too far toward either the head or foot of the bed. In at least the shown embodiment this adjustment is along the X axis and is linear.

Action B – This adjustment according to various embodiments allows the individual tibia positioning assemblies to be aligned according to the patient's
10 natural alignment, as may be seen in at least Figures 8 and 10, respectively. Improper alignment can potentially pre-tension ligaments, thus creating error in the test results. The adjustment of Action B according to various embodiments is made to avoid such errors. In one embodiment, the tibia positioning assemblies are able to be moved by hand on sliding contact C; however, the coefficient of friction is
15 such that the valgus-varus position of the tibia positioning assemblies may be maintained during laxity testing. In another embodiment the tibia positioning assemblies pivot freely and independently, including during testing, to allow for proper varus-valgus alignment of the limb to match the person's natural alignment. In another embodiment, the tibia positioning assemblies are clamped relative to
20 their supporting frame just prior to testing.

Action C – This is a frictional sliding contact point (1 of 2) which supports the tibia positioning assemblies as they pivot according to various embodiments.

Action D – As noted above, Action D adjustment is provided prior to testing in one embodiment to change the degree of knee flexion in an effort to be
25 consistent with previously accepted clinical evaluation procedures. However, alternate embodiments and methods include the use of automated actions to perform more complicated, multi-planar motions. For example, the apparatus could be so used to simulate the pivot shift test which involves applying internal rotation and valgus torques while at the same time increasing the degree of knee flexion. As
30 noted, Action D according to these and still other envisioned embodiments changes the degree of knee flexion.

Action E – This adjustment according to various embodiments allows the tibia positioning assembly **100** to be adjusted according to the patient's leg length. In a second embodiment, this action can be automated with the use of a ball screw, worm gear, or other motorized linear actuator. The entire tibial positioning
5 assembly **100** may then be moved closer to or further away from the support cushion **30**. Moving the tibial positioning assembly closer to the support cushion would increase the degree of knee flexion and moving further away from the support cushion **30** would then move the knee into extension. This allows, in at least certain embodiments, for individualized static positioning of the knee for each
10 person or would allow for the degree of knee flexion or extension to be changed during laxity testing, and could be coordinated to perform multiplanar testing with any or all of the three testing axes (Actions F, G, and H).

Action F – This action according to various embodiments is driven and controlled by motors **148**, and provides a varus-valgus torque to the knee. Such
15 action around the axis of rotation is used for valgus-varus or medial-lateral testing. At least one envisioned embodiment uses a servomotor to provide the rotational force, although other manual or mechanical methods of force application could be used.

Action G, about Pivot Point GPP – According to various embodiments,
20 GPP is the axis of rotation (normal to the drawing plane, in axis “Z”) for anteroposterior laxity testing, causing the rotation indicated as Action G. At least one envisioned embodiment uses a servomotor **168** to provide the rotational force, although other manual or mechanical methods of force application could be used.

Action H – This is the axis of rotation for tibial internal and external
25 rotation testing according to various embodiments. At least one envisioned embodiment uses a servomotor **206** to provide the rotational force, although other manual or mechanical methods of force application could be used.

Action I – This action may be adjusted according to various embodiments so that the location of force application during the anteroposterior, mediolateral, or
30 valgus/varus testing can be held consistent for each patient. For example, the location of force application may need to be 1" distal to the tibial tuberosity; therefore, this portion of the frame must be adjusted so that the location of force application can be consistently located for patients.

Action J – This action according to various embodiments is lateral sliding movement of laterally slidable knee support pad **64** knee support/stabilizing assembly **60**. The laterally slidable knee support pad is slidably mounted relative to the pedestal **62** of the knee support/stabilizing assembly **60**, such that it can move
5 about an axis such as shown by the arrows in Figures 15 and 34.

Input/Output Signals of the Device

As may be seen from Figures 27-31, various embodiments of the testing procedures made possible by the overall RKT device **10** may be accomplished by
10 the use of six (6) brushless servo motors, namely two motors **148**, two motors **168**, and two motors **208**. It should be understood that fewer or additional motors may be employed, as may be desirable for any of a variety of envisioned applications, in particular those involving one or more manual inputs, as previously described herein.

15 In certain embodiments, perhaps best illustrated in Figure 31, all input and output signals are accomplished through the use of these motors. However, it should be noted that other motion tracking systems may be used in conjunction with the motors in order to accurately and reliably measure motion of the tibia relative to the femur. Examples of motion tracking systems would include, but not
20 limited to, optoelectronic, electromagnetic, ultrasonic, fluoroscopic, stereo bi-plane radiographic, and other imaging methods commonly used to measure motion of the tibia relative to the femur in vivo.

According to various embodiments, input signals are sent to the motors regarding the target torque thresholds for each of the three tests for each patient, as
25 well as the signals to start and complete each test. In a similar fashion according to various embodiments, output signals are sent from or regarding the motors regarding the amount and direction of torque from each motor as well as the encoder count for each motor.

The Testing Processes

30 As may be understood at least initially from Figure 1, the patient **5** may be positioned supine, and motion tracking sensors are applied to each tibia, femur, and the patella as needed. The patient's feet are then strapped into the corresponding Foot Rotation Assemblies **200**.

The underlying rationale of the laxity testing methods described in the following paragraphs is that the tibia, which is an intercalary bone, is perturbed in a given direction by the device, and the motion of the tibia relative to the femur is measured. This is inherently different from all other techniques and devices and methods previously utilized to evaluate knee joint laxity. Simply put, the tibia retention assembly does not squeeze tightly on the lower leg, but leaves gaps between the assembly and the anterior, posterior, medial, and lateral aspects of the proximal low leg. Squeezing tightly on the proximal low leg makes it more difficult to accurately measure motion of the tibia itself, as the act of squeezing the proximal low leg causes compression of soft tissues thus resulting in greater soft tissue artifact or error in the measurements of tibial motion. Squeezing makes it more difficult to differentiate motion of the tibia from motion of the skin, muscle, adipose, etc. On the contrary, by perturbing the tibia in a given direction, only one aspect of the low leg is compressed, thus allowing accurate measurements of tibial motion relative to the femur. It is for this reason that this system has demonstrated excellent reliability ($ICC > 0.87$) with accuracies of ± 0.3 mm and $\pm 0.5^\circ$.

Once the patient is properly positioned in the RKT apparatus **10**, the RKT apparatus **10** simultaneously cycles both knees into 1) internal and external rotation, 2) anterior and posterior translation, and 3) varus and valgus rotations. Each test can be performed individually or performed in any combination or order of the three motions.

Each of these three motions may be tested separately. For each motion, three cycles of each motion are performed to precondition the structures of the knee, and both the amount of torque applied and the rate at which the torque was applied are controlled by the system. Following the three preconditioning cycles, three test cycles are performed with the magnitude, direction, and rate of force/torque application as well as motion of the tibia relative to the femur being collected. Each of the three motions will now be discussed individually.

Internal and External Rotation

First, according to various embodiments, the patient is suitably positioned within the RKT apparatus **10**, and patient's feet are ensured to be suitably strapped into the corresponding Foot Rotation Assemblies **200**. Each of the knee support/stabilizing assemblies are configured in stabilizing mode (clamp assembly

66 in place, see, for example Figure 21) and adjusted such that the knee is suitably stabilized. As each of the two pivoting leg support frame assemblies **50** is free to pivot relative to the sliding support framework **40**, the legs of the patient, the two pivoting leg support frame assemblies **50** thus tend to be aligned according to the patient's natural alignment. Improper alignment would pre-tension ligaments thus creating error in the test results. All adjustments are then complete and the patient is then ready to be tested.

According to various embodiments, the knee is preconditioned by performing at least three complete rotational cycles. Following the 3 preconditioning cycles, 3 additional test cycles will be performed and the data from these test cycles will be used for analysis. Of course, it should be understood that in other envisioned embodiments, any of a variety of cycles or testing programs may be employed, as desirable for a particular application.

After such preconditioning, the RKT apparatus **10** then provides torque first in tibial external rotation at a velocity of $5^\circ/\text{sec}$ until the desired torque threshold of 6 N-m is reached. The RKT apparatus **10** then reverses direction until the threshold is reached in internal rotation, thus completing one cycle. The RKT again reverses direction and repeats this process for two additional cycles. The number of cycles performed can be increased or decreased as necessary and the torque threshold and test velocity can also be individually adjusted if deemed appropriate. Testing for internal and external rotation is thus complete.

Anterior and Posterior Translation

First, the patient is suitably positioned within the RKT apparatus **10**, and patient's feet are ensured to be suitably strapped into the corresponding Foot Rotation Assemblies **200**. Each of the knee support/stabilizing assemblies are configured in stabilizing mode (clamp assembly **66** in place) and adjusted such that the knee is suitably stabilized. As each of the two pivoting leg support frame assemblies **50** is free to pivotably relative to the sliding support framework **40**, the legs of the patient, the two pivoting leg support frame assemblies **50** thus tend to be aligned according to the patient's natural alignment. Improper alignment would pre-tension ligaments thus creating error in the test results. The pivoting frame **162** is adjusted to control the location of force application so that force is applied with the tibia containing assembly **180** in a location that proximal to the gastrocnemius

muscle belly and distal to the tibial tuberosity. The position is then maintained by tightening clamp **163**. The tibia containing assembly **180** is then adjusted so that the pads **189** are located 1 cm away from both the anterior aspect of the tibia and the posterior aspect of the gastrocnemius. This adjustment is made using
5 adjustment rods **184** and the position is maintained by tightening clamp **186**. According to certain embodiments, all adjustments are then complete and the patient is then ready to be tested. In other embodiments having an alternative tibia containing assembly **1180** having a plurality of bladders **1190** contained within cuffs (e.g., pads substantially similar to pads **189**) further adjustment of the
10 bladders (e.g., by inflation and/or deflation thereof) may be completed prior to performing patient testing.

The knee is preconditioned by performing 3 complete rotational cycles. Following the 3 preconditioning cycles, 3 additional test cycles will be performed and the data from these test cycles will be used for analysis.

15 During both preconditioning and test cycles, the RKT apparatus **10** provides torque first in anterior translation at a velocity of 1 mm/s (The 1 mm/s was based on the velocity at the knee joint of an average male using accepted anthropometric normative values.) until the desired force threshold is reached. The RKT apparatus **10** then reverses direction until the threshold of 223 N is reached in
20 posterior translation, thus completing one cycle. In anterior translation, the applied force takes into account the patient's height and weight, equaling 134 N in addition the force necessary to raise the mass of the low leg. The weight of the low leg can be estimated based on the patient's height and weight based on accepted anthropometric measures. For example, the force necessary to raise a low leg that
25 weighs 20 lb is 89 N. The force threshold is then 134 N plus 89 N, for a total of 223 N.

The RKT again reverses direction and repeats this process for two additional cycles. The number of cycles performed can be increased or decreased as necessary and the force threshold and test velocity can also be individually
30 adjusted if deemed appropriate. Testing for anterior and posterior translation is thus complete.

Varus and Valgus Rotation

The knee is preconditioned by performing 3 complete varus-valgus cycles. Following the 3 preconditioning cycles, 3 additional test cycles will be performed and the data from these test cycles will be used for analysis.

5 After such preconditioning, the RKT apparatus **10** then provides torque **first** in varus rotation at a velocity of 1°/sec until the desired torque threshold is reached. The torque threshold is calculated based on the patient's height and weight, and is equal to 1 N-m per unit of Body Mass Index (kg/m²). Since there is a frictional component of the slide attached to the knee pedestal and since the force
10 is being applied at varying lever lengths based on patient height, we are increasing/decreasing the force based on patient height and weight in order to apply enough force to move the joint in this plane. The RKT apparatus **10** then reverses direction until the threshold is reached in valgus rotation, thus completing one cycle. The RKT again reverses direction and repeats this process for two
15 additional cycles. The number of cycles performed can be increased or decreased as necessary and the torque threshold and test velocity can also be individually adjusted if deemed appropriate. Testing for varus-valgus rotation is thus complete.

Testing for varus and valgus rotation according to various embodiments is thus complete.

20

Sensing Devices and Methods of Use

As shown in at least Figure 35, a Sensor Cluster **1000** is shown. This sensor cluster in various embodiments anticipates the use of electromagnetic motion tracking system consisting of an electromagnetic transmitter and 4 to 6 (or any of a
25 variety number of) electromagnetic sensors. The electromagnetic system outputs the location and orientation of each sensor, and a custom software is used to calculate the six degree of freedom kinematics of the knee during laxity testing. The tracking system and custom software allow for accurate and clinically meaningful measurements of motion of the tibia relative to the femur. In further
30 embodiments, the motion tracking system is a Polaris Spectra® system manufactured by Northern Digital Inc., of Waterloo, Canada. The Polaris® System uses a camera to measure three-dimensional positions and orientations of retro-reflective markers placed on a patient. The reflective markers are affixed to rigid arrays that are then applied to the patient's thigh, low leg, and foot. The

Polaris® system is able to determine the position and orientation of each of the rigid arrays in space, and therefore the relative position and orientation of the patient's knee. It is able to measure joint motion in six degrees of freedom, meaning that it can determine both rotation and translation of the joint about all three planes of motion. In additional embodiments, opto-electronic tracking devices may be used, which emit optical signals that are received by a camera and the camera is configured to follow the three-dimensional position of each sensor. In further embodiments, ultrasonic devices may be used. These devices determine their three-dimensional position and orientation with respect to one another.

10

Uses of the above Devices with Subjective Measurement Modules, such as 2000, 2100, or 2200

Reference is now made to subjective measurement modules **2000**, **2100**, and **2200** shown in Figure 17, Figure 36, and Figure 18, respectively.

15 Figure 17 shows a subjective measurement module **2000** including a subjective measurement module dial **2001** (operated by the user) and an output display **2002**.

Figure 36 shows a subjective measurement module **2100** including a subjective measurement module dial **2101** and an overall machine stop button **2102**.

20 Figure 18 shows a subjective measurement module **2200** including a subjective measurement module slide **2201** (operated by the user) and an output display **2202**.

The device described consists of a digital potentiometer or similar device that a patient can continuously adjust to rate their current level of pain (either a 0-10 scale or "no pain" to "maximum pain" scale) during joint laxity testing. To our knowledge, no other joint laxity measurement system has the ability to capture subjective pain ratings from the patient that can then correlated with the instantaneous torque, position, and angle data being captured as part of the joint laxity examination. The ability to incorporate subjective pain ratings with the objective measures being collected with the laxity test system allows surgeons and other medical professionals to better understand the anatomic structure(s) that may be involved.

30

The proposed device may according to various embodiments comprise a separate hand-held pendant to be used by a patient during instrumented joint laxity testing. In certain embodiments, the device may have either a dial (see modules **2000** and **2100**) or slide potentiometer (see module **2200**) that a patient would
5 adjust according to his/her pain level at any given moment. In other embodiments, the patient would be able to rate his/her pain with a single hand through the use of a hand-held device featuring either a plunger that could be depressed with the thumb and/or a lever or other “trigger” that could be depressed with the fingers. The patient could then use either depress the thumb plunger or squeeze the trigger
10 to report increasing levels of pain and/or discomfort. Examples of hand held systems that could be used include, but are not limited to, the Aurora AFX Adjustable Control or the Omron A4EG. The Aurora device features a trigger mechanism that could be squeezed to indicate the patient’s current level of pain and the Omron device features a compressible area that can be squeezed by the
15 fingers as well as an emergency stop button that can be activated with the thumb.

According to various embodiments, the subjective ratings of pain would be output not only to the output displays shown, but also to a dedicated computer that would also be collecting torque and position data from the motors as well as the position and angle data from the three-dimensional motion tracking system. The
20 pain ratings would be captured at regular sub-second intervals and synchronized with the torque, position, and angle data. Data could be sent from the Subjective Measurement Module to the computer by a number of means including, but not limited to direct USB cable or other cables, or wirelessly with a Bluetooth connection or other wireless means.

25 The patient’s pain rating may be output to a visual display on the pendant in real time. Pain ratings could either be displayed using a numeric display or graphical display. The numeric display (*see e.g.*, Figure 17) could range from 0.0 to 10.0, with 0 representing “No Pain” and 10 representing “Max Pain”. The graphical display (*see e.g.*, Figure 18) may use a scrolling horizontally-directed
30 line to indicate pain (y-axis) as a function of time (x-axis).

The pain measurement device may according to various embodiments also be used as an additional safety measure for the laxity system, such that when the patient indicates maximum pain or pain above a pre-determined threshold (8 out of 10 for example), then the motors applying the torque would either reverse direction

or be disengaged. This threshold could vary in intensity for different tests or patient profiles, as some patients will perceive pain differently from others. In embodiments that feature multiple methods for patient input, one input could be used to rate pain and the other input be used as an emergency stop for the knee testing system. For example, the subjective measurement module **2100** (see e.g.,
5 Figure 36) features two such patient inputs. One input in certain embodiments, the subjective measurement module dial **2101**, would be used by the patient to indicate his or her level of pain. The second input, stop button **2102**, would then be used as an emergency stop switch that would disengage the motors and terminate a given
10 laxity test. In the embodiment with thumb plunger and finger “trigger” patient inputs, the “trigger” could be squeezed by the patient to indicate his or her current level of pain, and the thumb plunger could be used as an emergency stop button that would disengage the motors and terminate a given laxity test.

In addition to pain ratings, the Subjective Measurement Module may
15 according to various embodiments also be used by patients to rate other subjective measures. For example, the same 0 to 10 rating system could be used for patients to rate their sensations of instability or the feeling of “giving way”, which is clinically associated with joint laxity or instability.

It should also be understood that the subjective measurement module
20 described above could be used with other devices such as those described in USPATNOS 6,669,660, 6,872,186, and 7,547,289, each of which are incorporated herein by reference, as well as any other devices which provide range of motion or other similar flexion analysis and/or therapy.

25 IV. CONCLUSION

The foregoing description of the various embodiments of the present invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings.
30 The embodiments were chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by

the appended claims when interpreted in accordance with the breadth to which they are fairly, legally and equitably entitled.

The drawings and preferred embodiments do not and are not intended to limit the ordinary meaning of the claims in their fair and broad interpretation in
5 any way.

CLAIMS

What is claimed is:

- 5 1. An apparatus for evaluating leg movement characteristics of a patient, said patient having a torso, and also having a first and a second leg extending from said torso, each leg including a femur, patella, and a foot, said apparatus comprising:
- 10 A) a base assembly configured to at least partially support said torso; and
 B) first and second leg support assemblies independently pivotably mounted about a pivot axis relative to said base assembly, each leg support assembly configured to at least partially support a portion of a respective one of said first and second legs, said support being independent of said support of said torso, each of said leg support assemblies including:
- 15 1) a first leg support member itself comprising a foot rotation assembly configured to at least partially retain and support an associated foot of said patient and to rotate it about an axis of rotation relative to said base assembly; and
 2) a second leg support member configured for supporting a portion of
20 said leg at a location proximal relative to said first leg support member during said rotation of said foot,
 each said foot rotation assembly configured to rotate said associated foot such that an associated leg movement is provided and can be measured.
- 25 2. The apparatus as claimed in Claim 1, wherein said leg support assemblies pivot about substantially parallel axes.
- 30 3. The apparatus as claimed in Claim 2, wherein said pivot axes are substantially vertical.
4. The apparatus as claimed in Claim 1, wherein said second leg support member is a knee support member.

5. The apparatus as claimed in Claim 4, further comprising a third leg support member, being a thigh retention assembly configured to retain the upper leg so as to at least partially restrict movement of said tibia during rotation of said associated foot.
- 5
6. The apparatus as claimed in Claim 1, wherein said second leg support member is a thigh retention assembly configured to retain the upper leg so as to at least partially restrict movement of said tibia during rotation of said associated foot.
- 10
7. The apparatus as claimed in Claim 6, wherein said thigh retention assembly is configured to be laterally adjustable relative to the longitudinal axis of the associated thigh, so as to accommodate a patient's particular valgus/varus knee condition.
- 15
8. The apparatus as claimed in Claim 1, wherein said base assembly includes:
- a main frame assembly including a torso support portion; and
 - a sliding support framework providing said independent pivoting support of
- 20 said first and second leg support assemblies relative to said base assembly,
- said sliding support framework slidably mounted along a linear axis relative to said base assembly, such that said sliding support framework, and both of said leg support assemblies pivotably supporting thereon, may be slidably adjusted relative to said torso support portion.
- 25
9. The apparatus as claimed in Claim 1, wherein said foot rotation assembly is mounted in a "three axis gimbal" configuration relative to said base assembly to at least partially capture and support an associated foot of said patient and to rotate it about three separate axes, being substantially mutually
- 30 perpendicular to each other.

10. An apparatus for evaluating leg movement characteristics of a patient, said patient having a torso, and also having a first and a second leg extending from said torso, each leg including a femur, patella, and a foot, said apparatus comprising:

5 A) a base assembly configured to at least partially support said torso; and
B) first and second leg support assemblies independently pivotably mounted about a pivot axis relative to said base assembly, each leg support assembly configured to at least partially support a portion of a respective one of said first and second legs, said support being independent of said
10 support of said torso, each of said leg support members including:

1) a first leg support member itself including a foot rotation assembly configured to at least partially retain and support an associated foot of said patient and to rotate it about an axis of rotation relative to said base assembly;

15 2) a second leg support member configured for supporting a portion of said associated leg at a location proximal relative to said first leg support member during said rotation of said foot; and

3) a tibia positioning assembly configured to contact the lower leg portion of said associated leg at a location generally intermediate that of
20 said first and second leg support members,

each said foot rotation assembly configured to rotate said associated foot such that associated leg movement is provided and can be measured while said tibia retention assembly at least partially laterally retains tibia movement.

25 11. The apparatus as claimed in Claim 10, wherein said leg support assemblies pivot about substantially parallel axes.

12. The apparatus as claimed in Claim 11, wherein said pivot axes are substantially vertical.

30

13. The apparatus as claimed in Claim 10, wherein said second leg support member is a knee support member.

14. The apparatus as claimed in Claim 13, further comprising a third leg support member, being a thigh retention assembly configured to retain the upper leg so as to at least partially restrict movement of said tibia during rotation of said associated foot.

5

15. The apparatus as claimed in Claim 10, wherein said second leg support member is a thigh retention assembly configured to retain the upper leg so as to at least partially restrict movement of said tibia during rotation of said associated foot.

10

16. The apparatus as claimed in Claim 15, wherein said thigh retention assembly is configured to be laterally adjustable relative to the longitudinal axis of the associated thigh, so as to accommodate a patient's particular valgus/varus knee condition.

15

17. The apparatus as claimed in Claim 10, wherein said base assembly includes:

a main frame assembly including a torso support portion; and

a sliding support framework providing said independent pivoting support of said first and second leg support assemblies relative to said base assembly,

20

said sliding support framework slidably mounted along a linear axis relative to said base assembly, such that said sliding support framework, and both of said leg support assemblies pivotably supporting thereon, may be slidably adjusted relative to said torso support portion.

25

18. The apparatus as claimed in Claim 10, wherein said foot rotation assembly is mounted in a "three axis gimbal" configuration relative to said base assembly to at least partially capture and support an associated foot of said patient and to rotate it about three separate axes, being substantially mutually perpendicular to each other.

30

19. An apparatus for evaluating leg movement characteristics of a patient, said patient having a torso, and also having a first and a second leg extending from said torso, each leg including a femur, patella, and a foot, said apparatus comprising:

- 5 A) a base assembly configured to at least partially support said torso; and
 B) first and second leg support assemblies independently pivotably mounted about a pivot axis relative to said base assembly, each leg support assembly configured to at least partially support a portion of a respective one of said first and second legs, said support being independent of said
10 support of said torso, each of said leg support members including:
 1) a first leg support member itself including a foot rotation assembly configured to at least partially retain and support an associated foot of said patient and to rotate it about an axis of rotation relative to said base assembly;
 15 2) a second leg support member configured for supporting a portion of said associated leg at a location proximal relative to said first leg support member during said rotation of said foot; and
 3) a tibia positioning assembly configured to contact the lower leg portion of said associated leg at a location generally intermediate that of
20 said first and second leg support members, said tibia positioning assembly mounted for linear adjustment relative to said pivoting leg support frame assembly, said tibia positioning assembly providing pivoting support of said foot rotation assembly to provide said axis of rotation relative to said base assembly,
25 each said foot rotation assembly configured to rotate said associated foot such that said associated leg movement is provided and can be measured while said tibia retention assembly at least partially laterally retains tibia movement.

30

20. A method for evaluating leg movement characteristics of a patient, said patient having a torso, and also having a first and a second leg extending from said torso, each leg including a femur, patella, and a foot, said method comprising the steps of:

5 A) providing an apparatus comprising:

1) a base assembly configured to at least partially support said torso;
and

2) first and second leg support assemblies independently pivotably
10 mounted about a pivot axis relative to said base assembly, each leg
support assembly configured to at least partially support a portion of
a respective one of said first and second legs, said support being
independent of said support of said torso, each of said leg support
assemblies including:

a) a first leg support member itself including a foot rotation
15 assembly configured to at least partially retain and support
an associated foot of said patient and to rotate it about an
axis of rotation relative to said base assembly; and

b) a second leg support member configured for supporting a
portion of said leg at a location proximal relative to said first
20 leg support member during said rotation of said foot; and

B) placing a patient in said device, rotating said associated foot such that
said associated leg movement is provided, and measuring said movement.

21. The method as claimed in Claim 20, further comprising the step of
25 using a subjective pain device to affect operation of said apparatus, wherein said
user is able to provide the user's subjective feedback to pain being encountered
during said method.

22. The method as claimed in Claim 20, wherein step "B" also includes
30 measuring a force required to rotate said foot.

23. The method as claimed in Claim 20, wherein step "B" includes
rotating said foot first in a first direction, and then in a second, substantially
opposite, direction.

24. The method as claimed in Claim 20, wherein step "B" includes rotating said foot about an axis that is substantially along the longitudinal axis of the tibia of the patient.

5 25. The method as claimed in Claim 20, wherein step "B" includes rotating said foot about an axis that is substantially perpendicular to the longitudinal axis of the tibia of the patient.

10 26. A method for evaluating leg movement characteristics of a patient, said patient having a torso, and also having a first and a second leg extending from said torso, each leg including a femur, patella, and a foot, said method comprising the steps of:

A) providing an apparatus comprising:

15 1) a base assembly configured to at least partially support said torso;
and

20 2) first and second leg support assemblies independently pivotably mounted about a pivot axis relative to said base assembly, each leg support assembly configured to at least partially support a portion of a respective one of said first and second legs, said support being independent of said support of said torso, each of said leg support members including:

25 a) a first leg support member itself including a foot rotation assembly configured to at least partially retain and support an associated foot of said patient and to rotate it about an axis of rotation relative to said base assembly;

b) a second leg support member configured for supporting a portion of said associated leg at a location proximal relative to said first leg support member during said rotation of said foot; and

30 c) a tibia positioning assembly configured to contact the lower leg portion of said associated leg at a location generally intermediate that of said first and second leg support members; and

B) placing a patient in said device, rotating said associated foot such that

said associated leg movement is provided, and measuring said movement.

27. The method as claimed in Claim 26, wherein step “B” further comprises the step of measuring the force of contact between said tibia positioning
5 assembly and said lower leg of said patient.

28. The method as claimed in Claim 26, wherein step “B” also includes measuring a force required to rotate said foot.

10 29. The method as claimed in Claim 26, wherein step “B” includes rotating said foot about an axis that is substantially along the longitudinal axis of the tibia of the patient.

15 30. The method as claimed in Claim 26, wherein step “B” includes rotating said foot about an axis that is substantially perpendicular to the longitudinal axis of the tibia of the patient.

20 31. A method for evaluating leg movement characteristics of a patient, said patient having a torso, and also having a first and a second leg extending from said torso, each leg including a femur, patella, and a foot, said method comprising the steps of:

A) providing an apparatus that has a knee support configuration that allows for alternate uses, including a support mode for varus-valgus testing, and also a stabilizing mode for both anterior-posterior and rotational testing;

25 B) using said knee support apparatus in said support mode for varus-valgus testing; and

C) using said knee support apparatus in said stabilizing mode for both anterior-posterior and rotational testing.

30

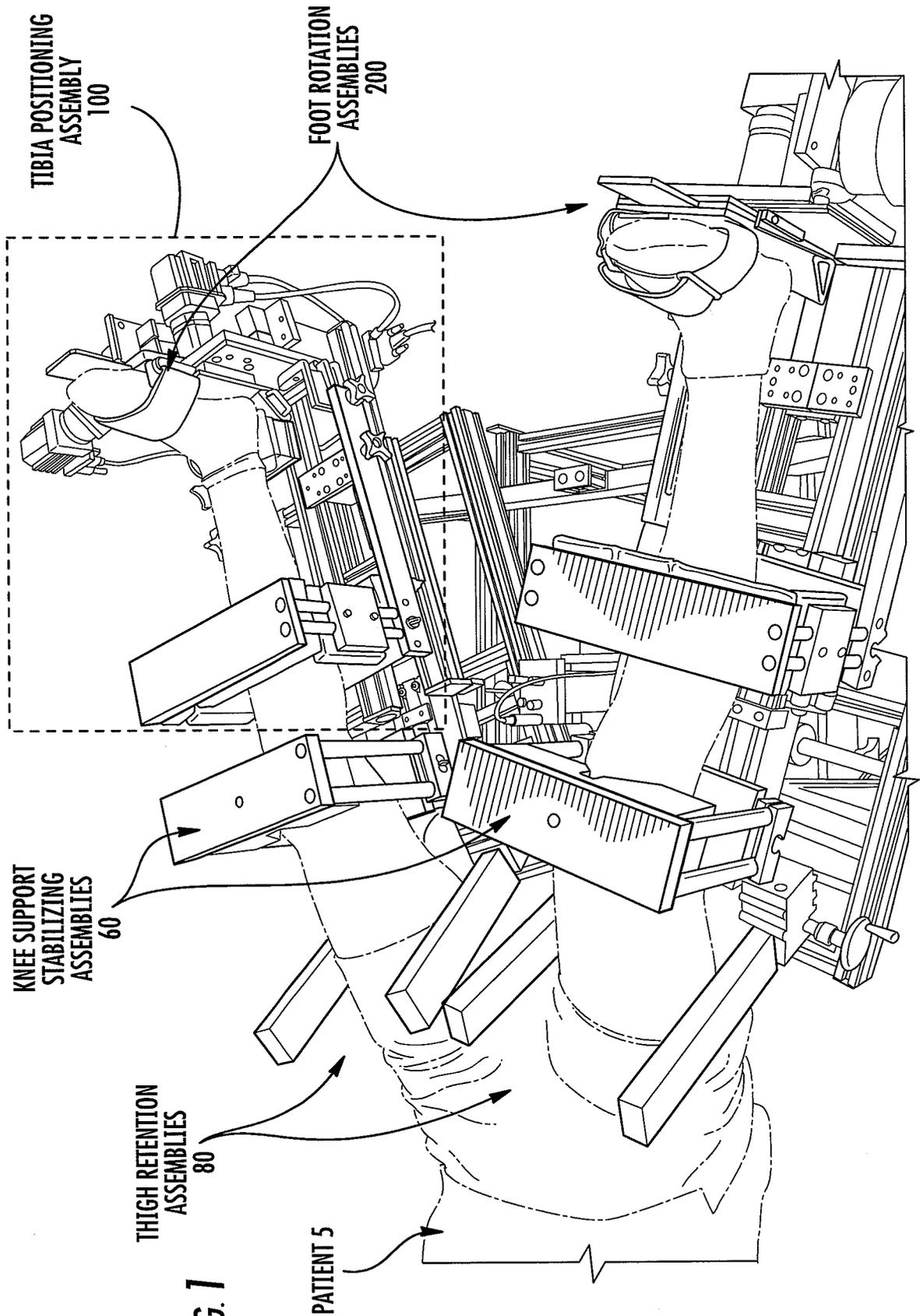
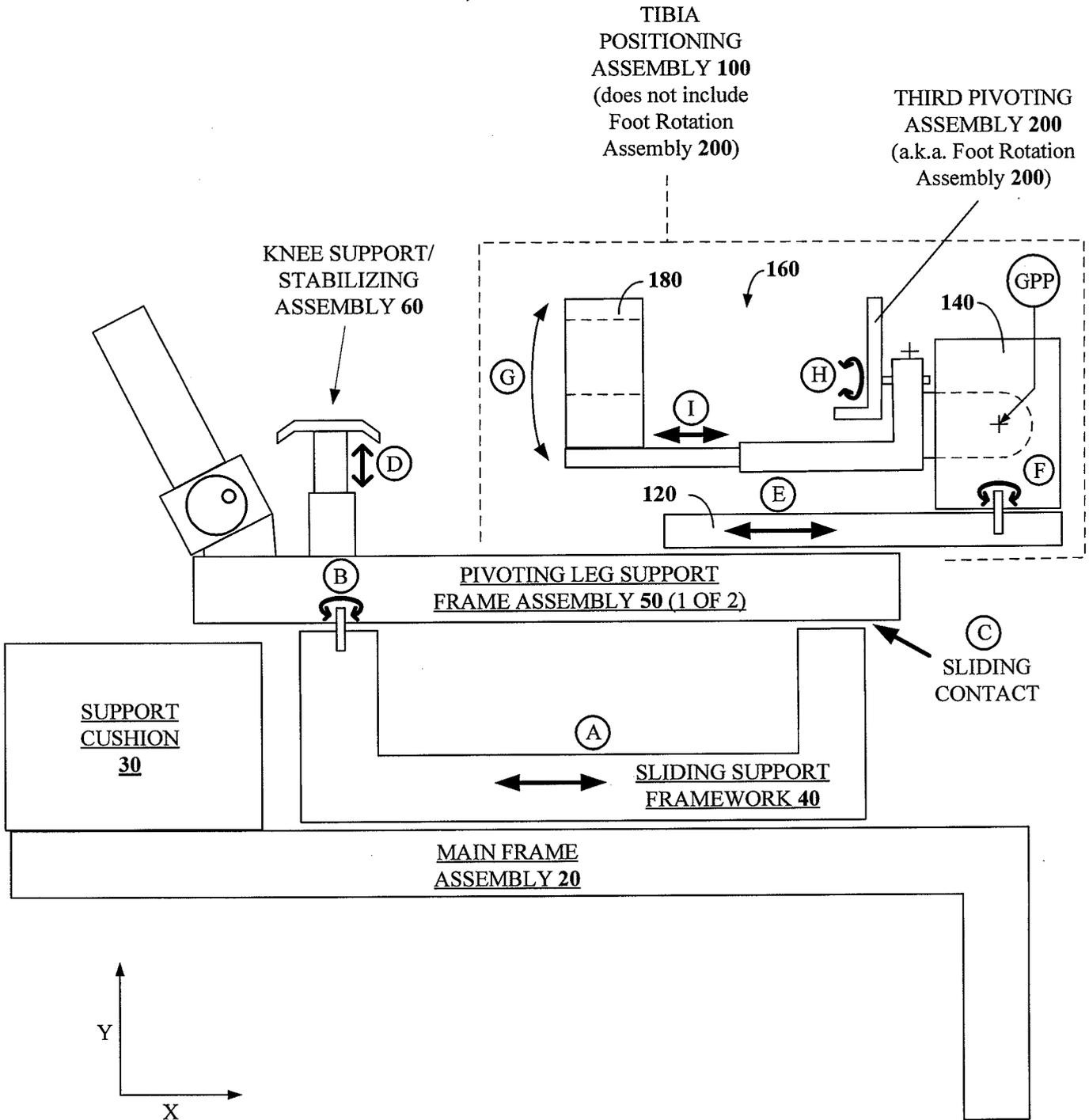


FIG. 1

Fig. 2



(Z axis is normal to plane of drawing)

Fig. 3

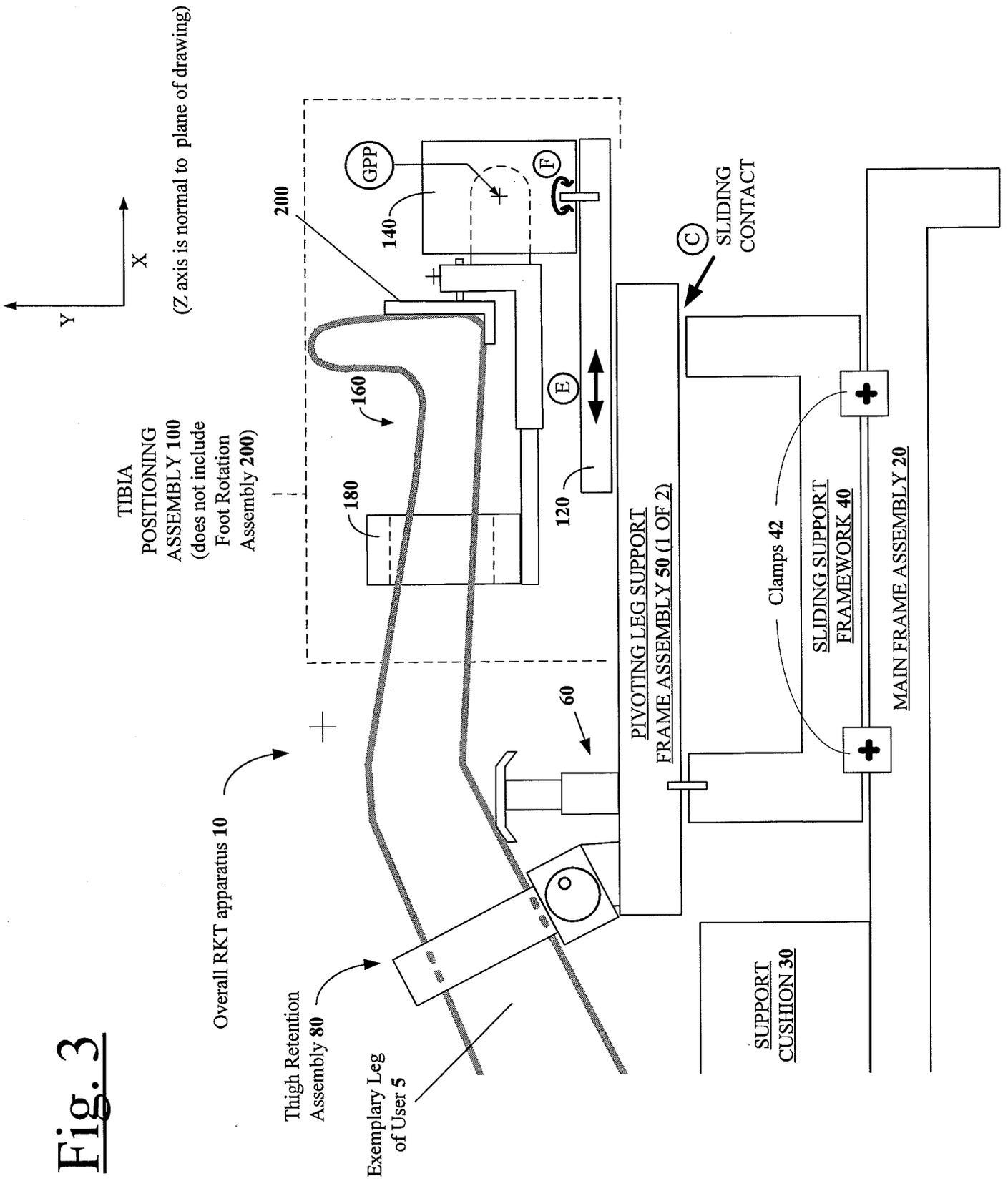


Fig. 4

Overall RKT apparatus 10
(exploded)

TIBIA POSITIONING ASSEMBLY 100
(does not include Foot Rotation Assembly 200)

THIRD PIVOTING ASSEMBLY 200
(a.k.a. Foot Rotation Assembly 200)

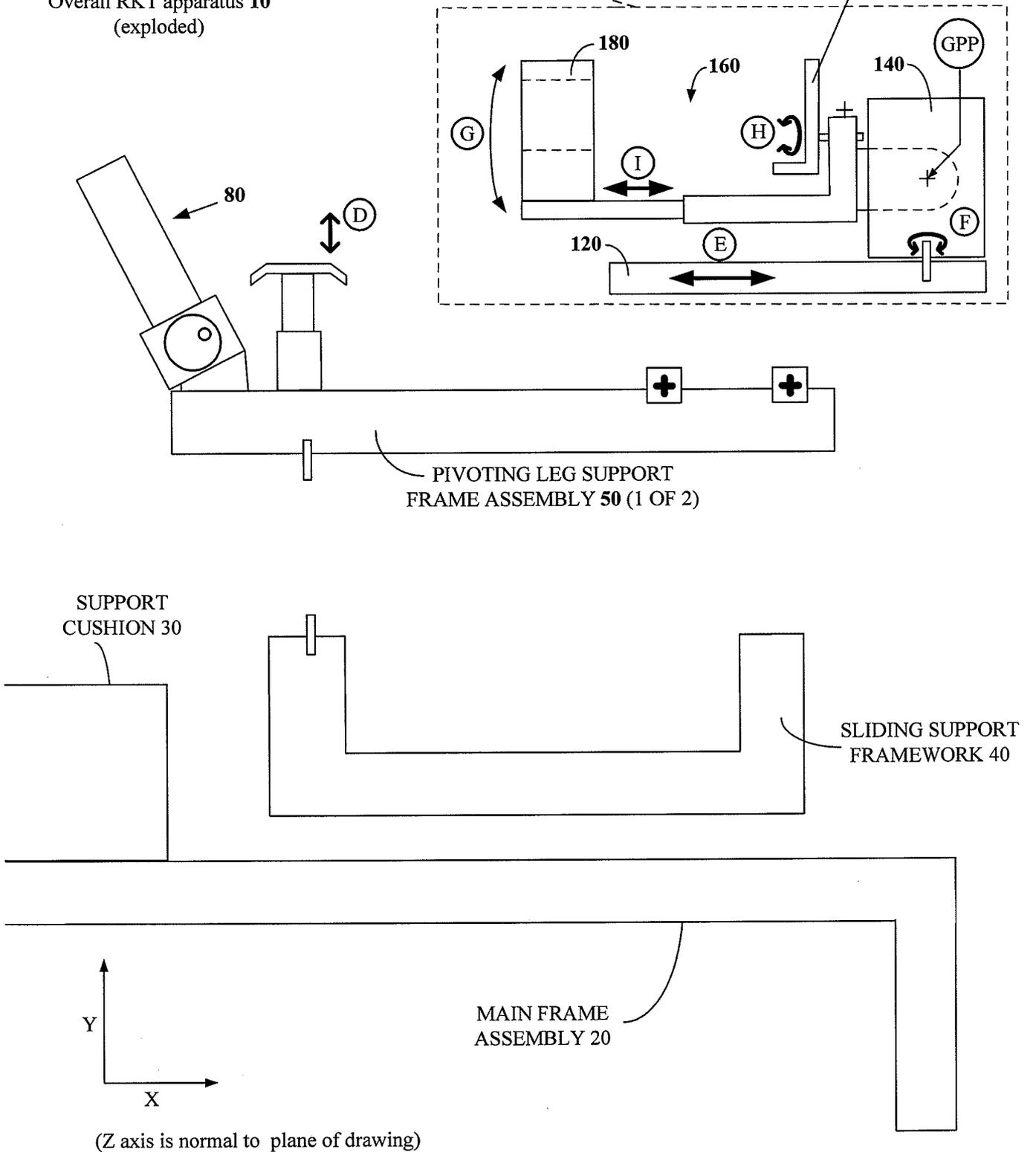
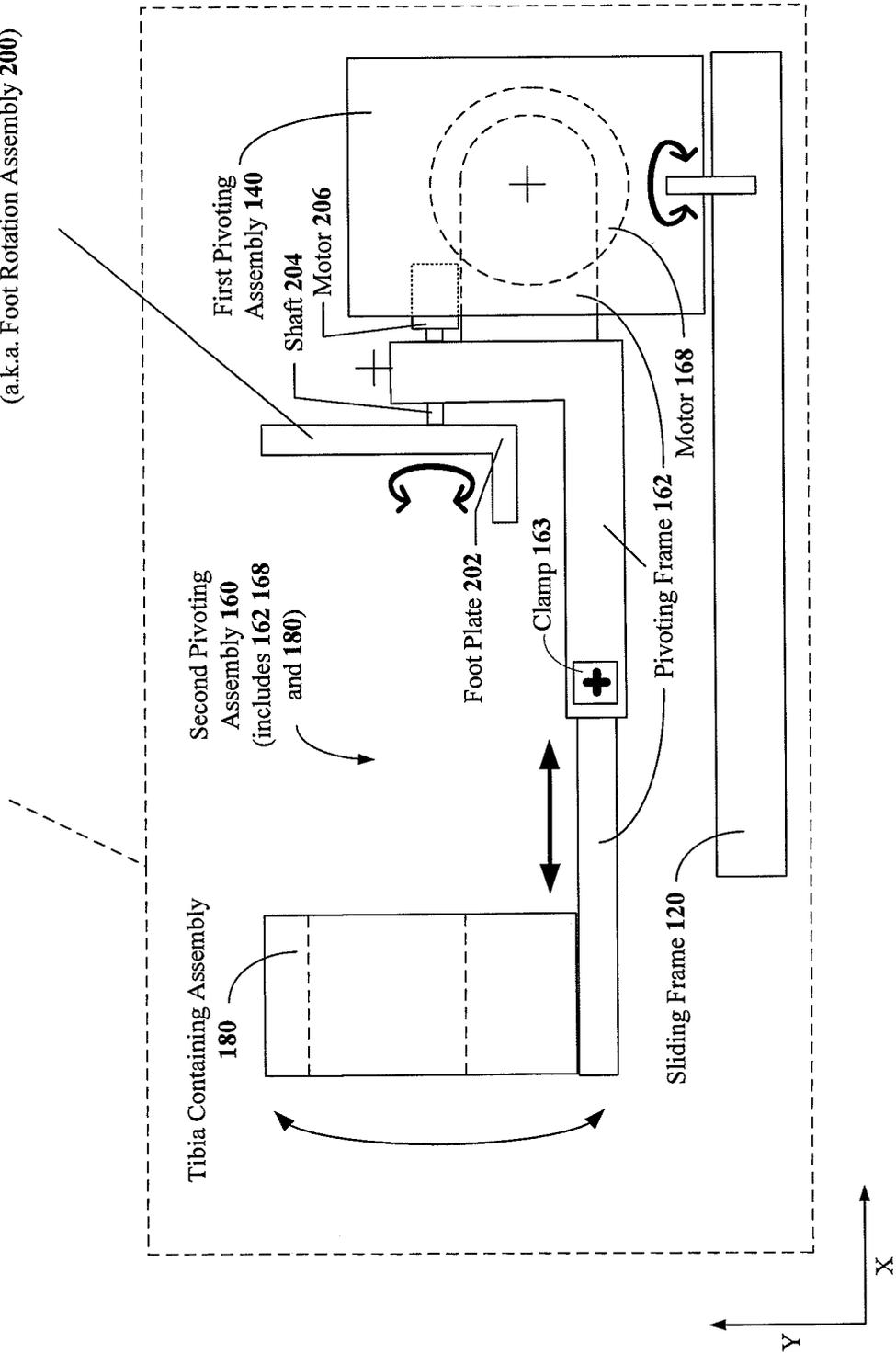


Fig. 5

TIBIA POSITIONING ASSEMBLY 100
(does not include Foot Rotation Assembly 200)

THIRD PIVOTING ASSEMBLY 200
(a.k.a. Foot Rotation Assembly 200)



(Z axis is normal to plane of drawing)

Fig. 6

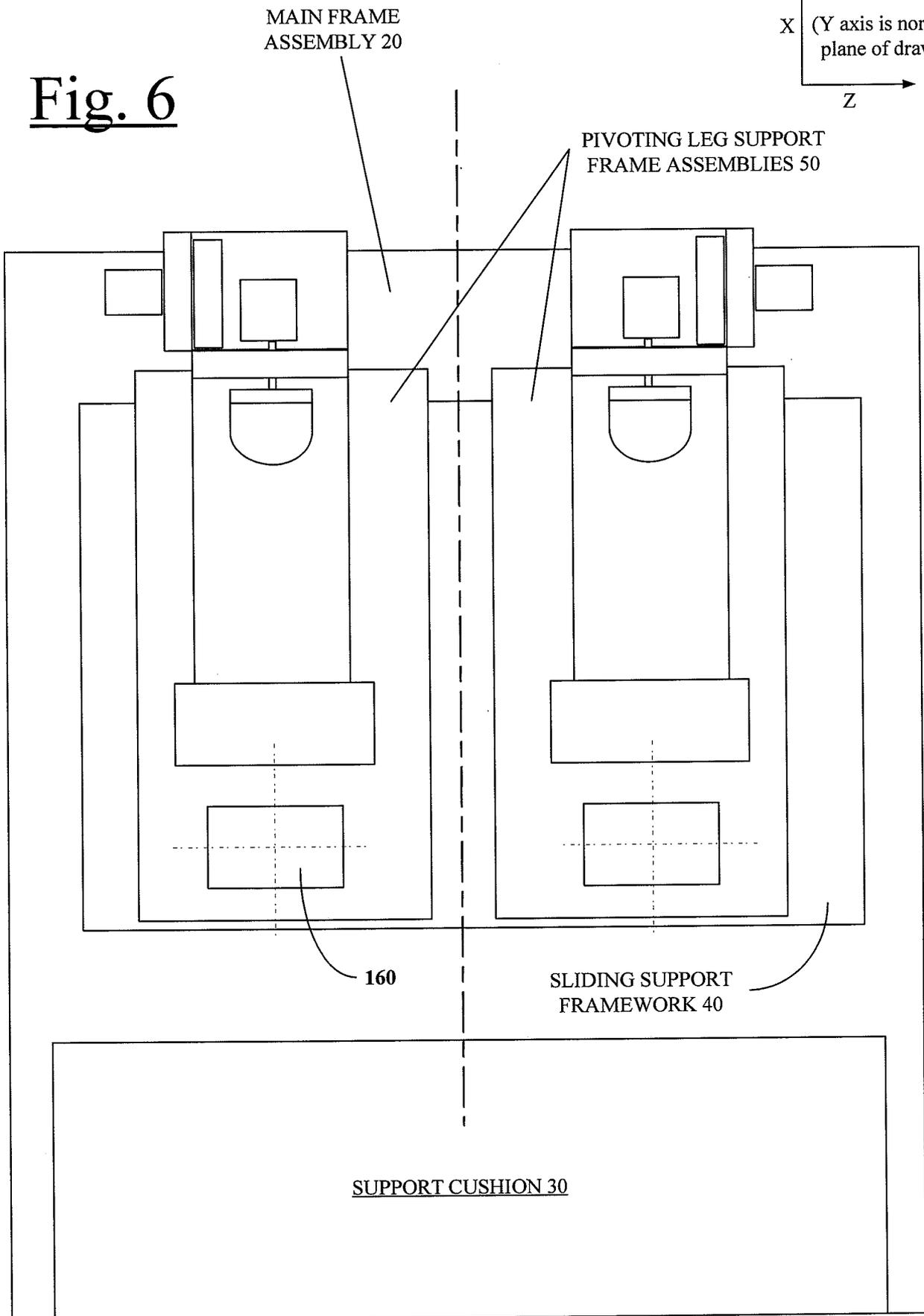
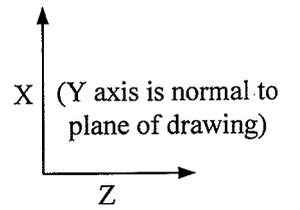


Fig. 7

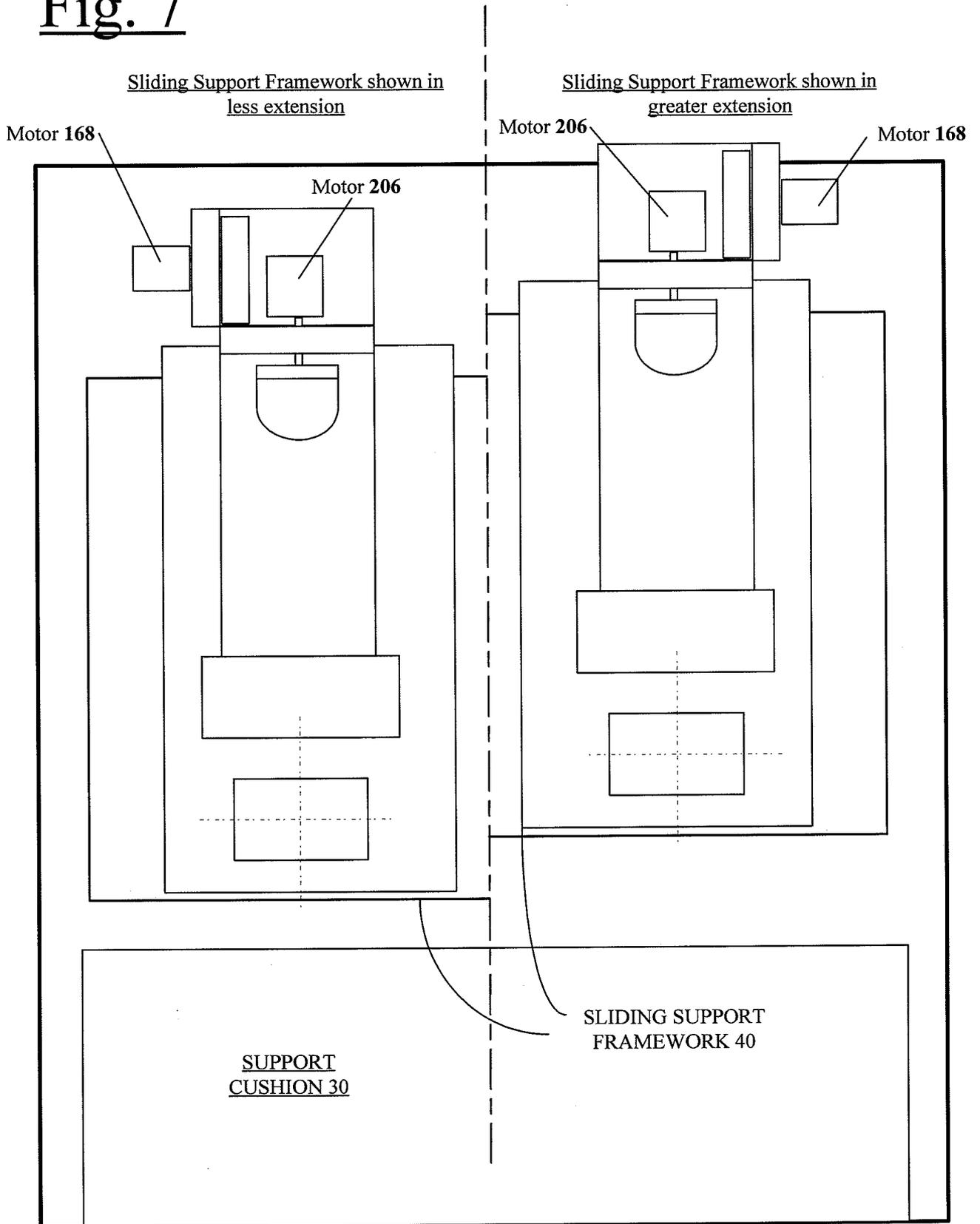


Fig. 8

Left Tibia Positioning Assembly shown at an angle (pivoted according to Action "B")

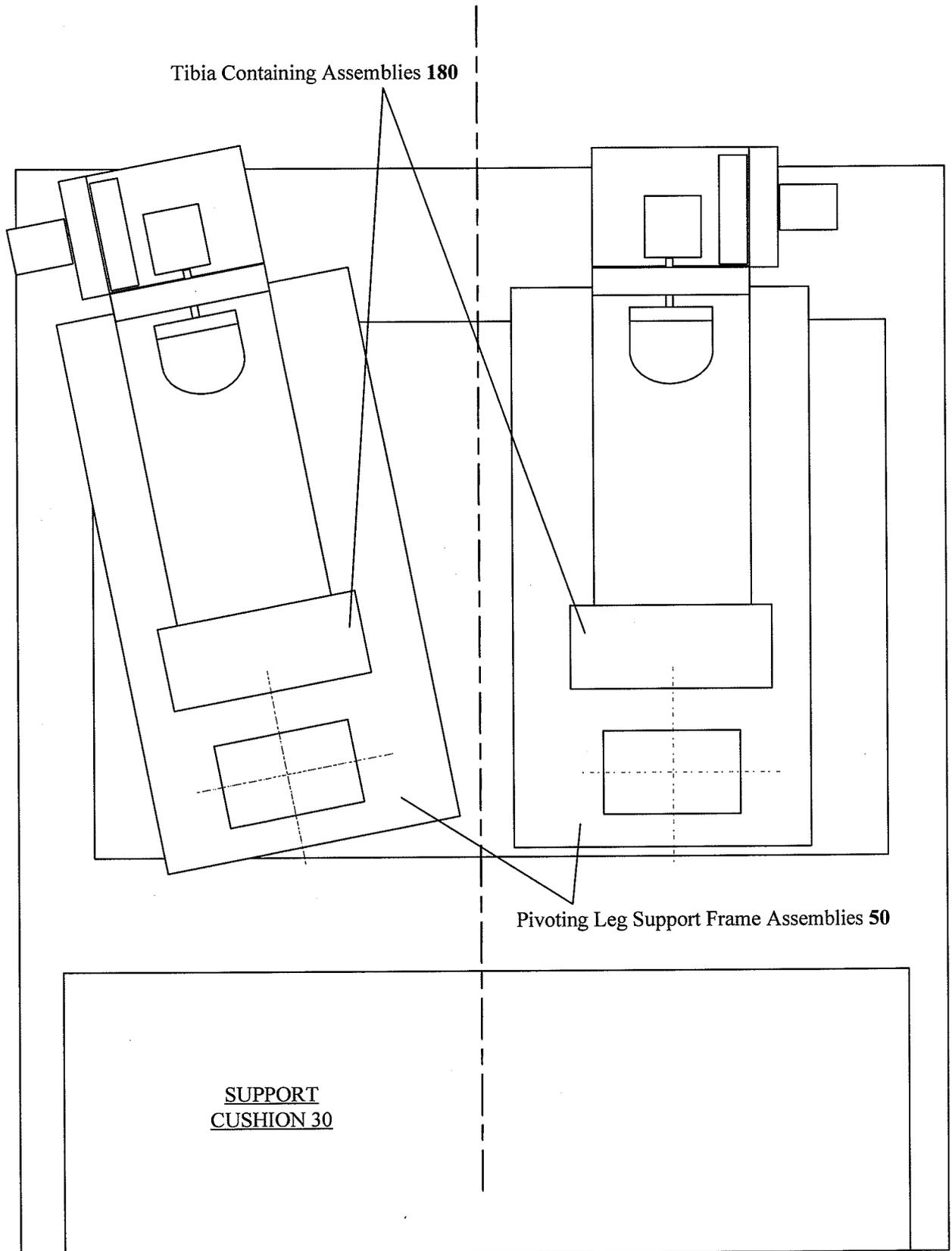


Fig. 9

LEFT PIVOTING LEG SUPPORT FRAME ASSEMBLY 50 MORE EXTENDED THAN THE RIGHT ONE

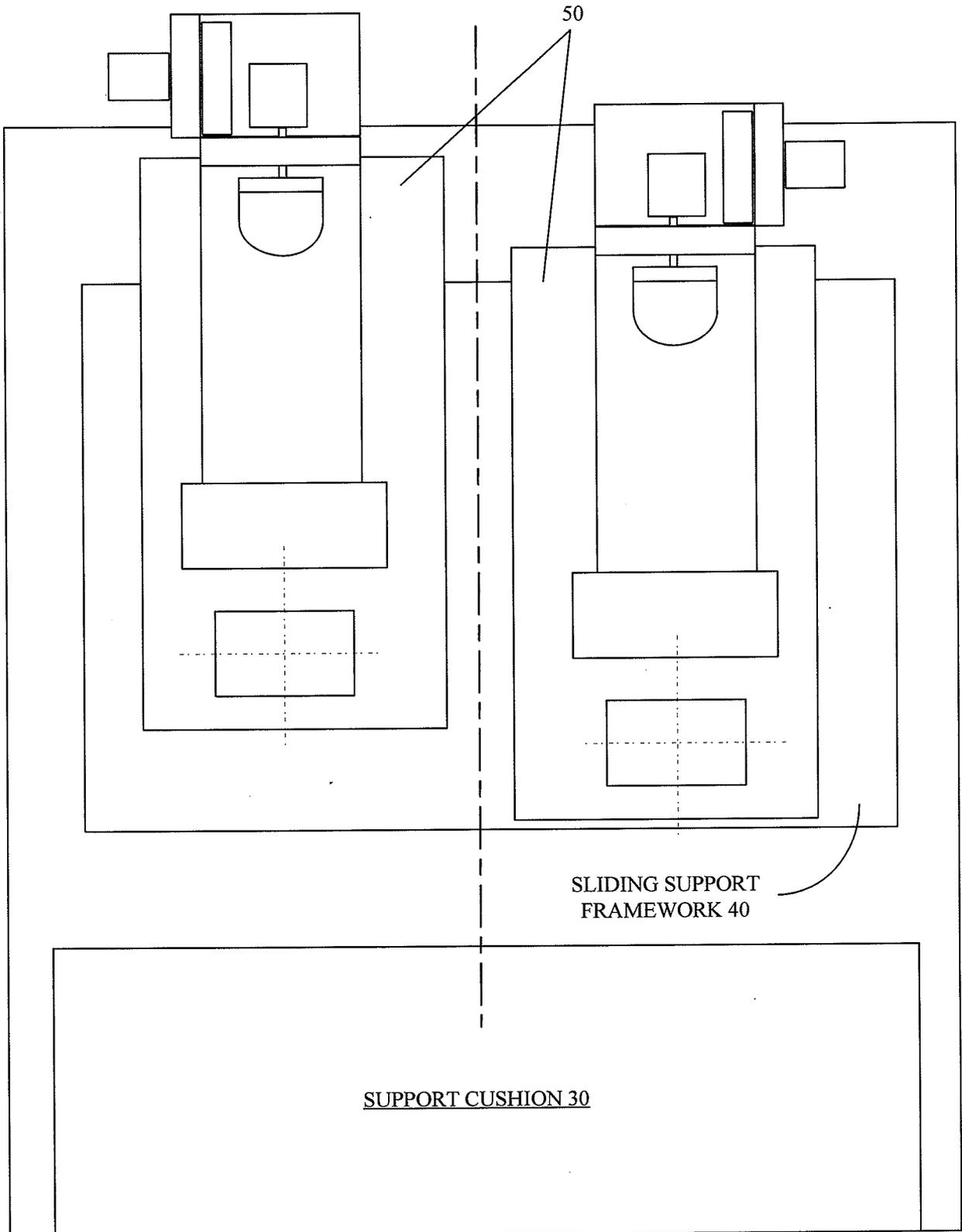


Fig. 10

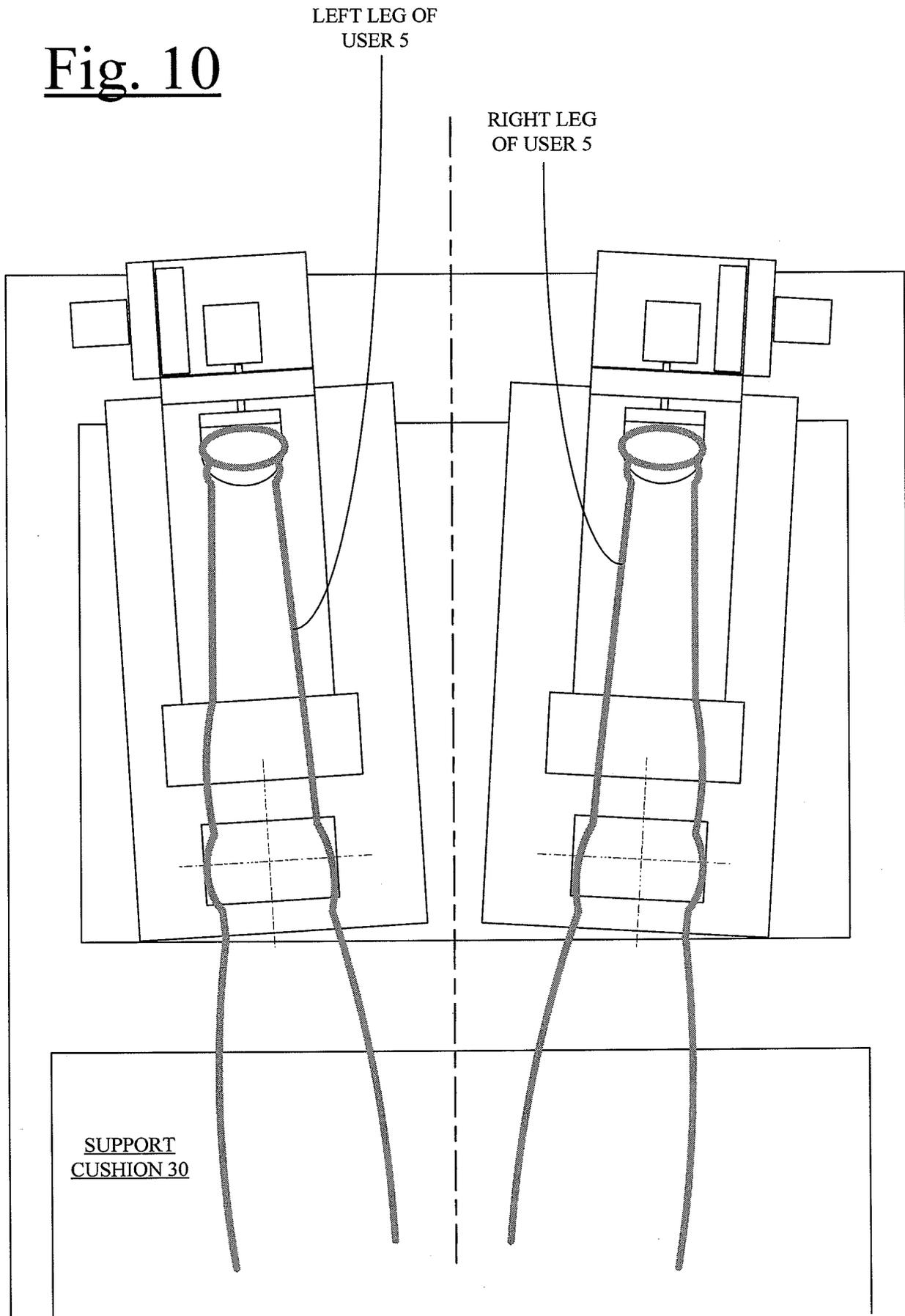


Fig. 11

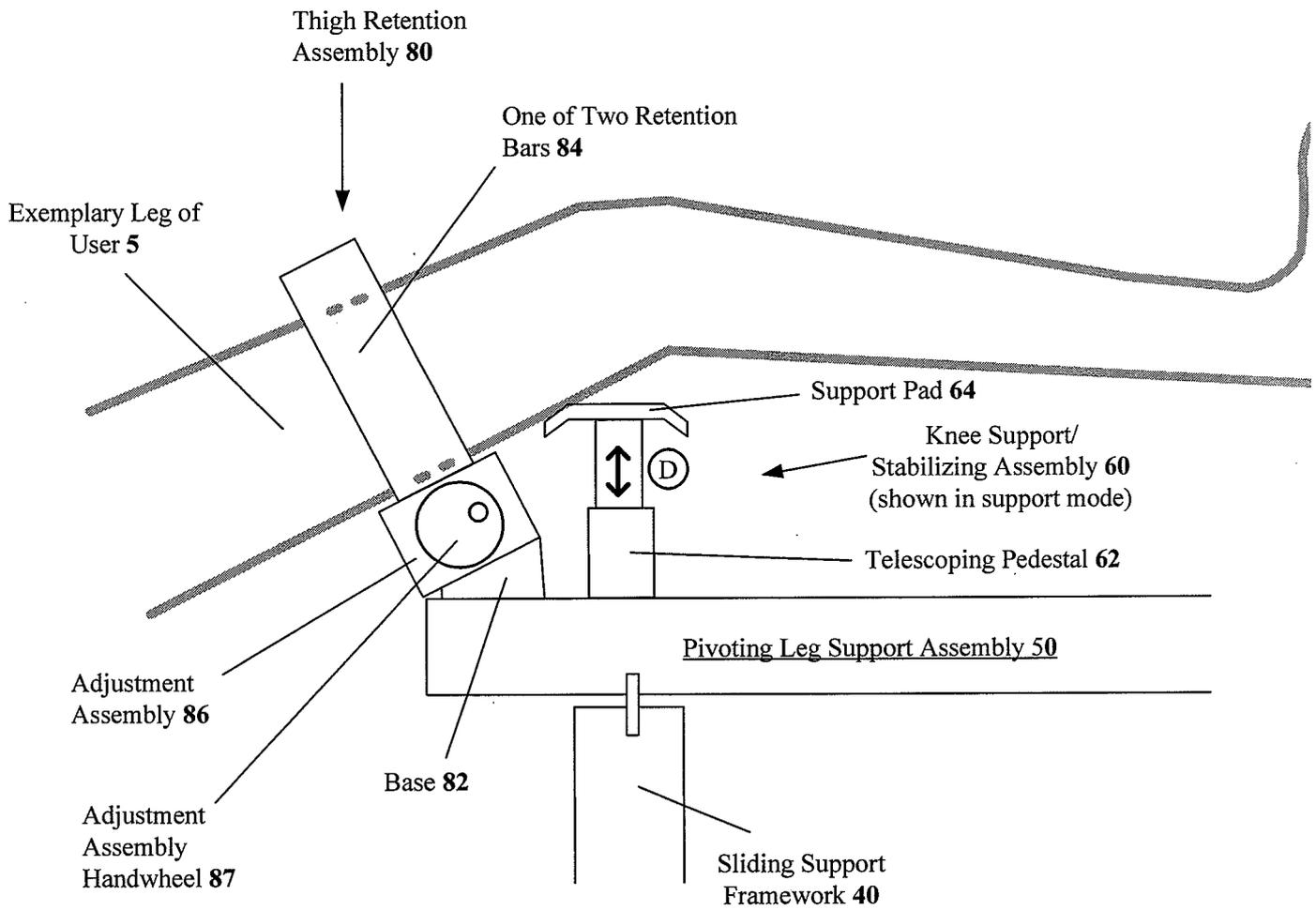


Fig. 12
Thigh Retention Assembly 80

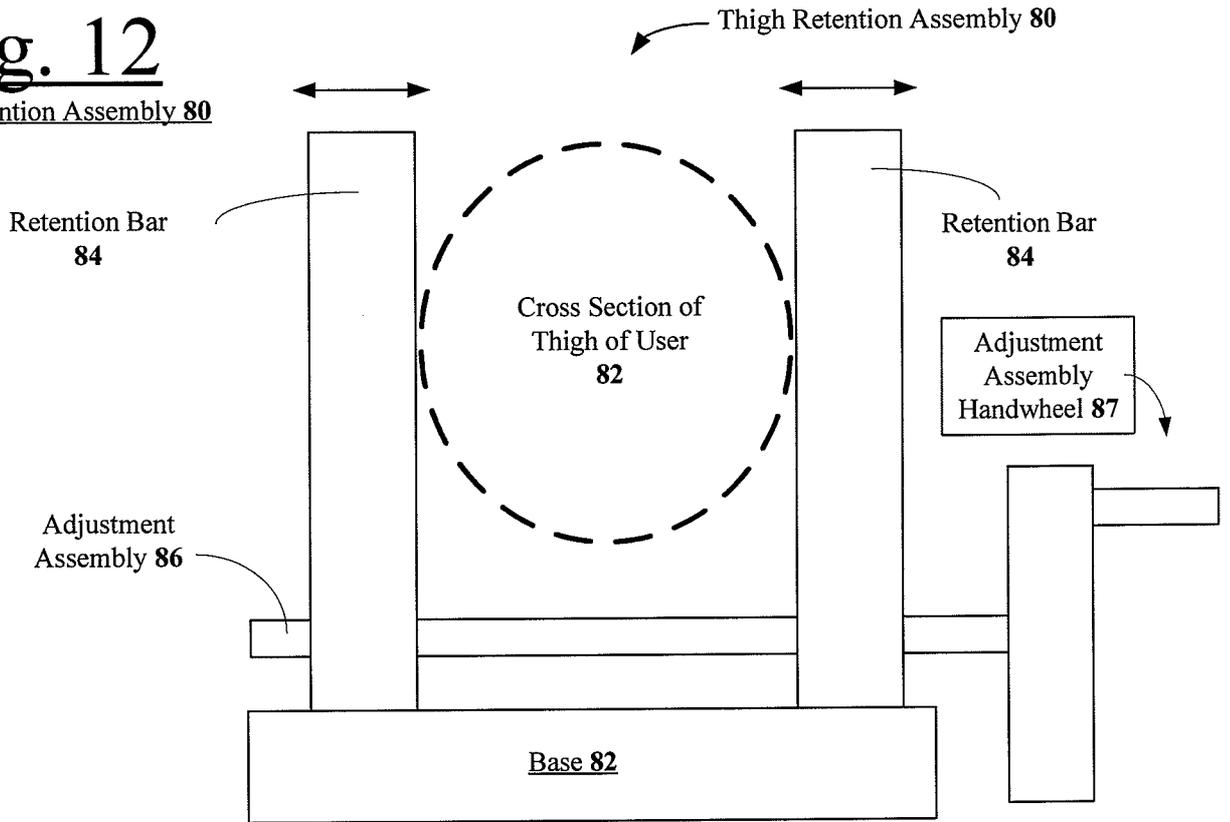


Fig. 13

Knee Support/
Stabilizing
Assembly 60
(in support
mode)

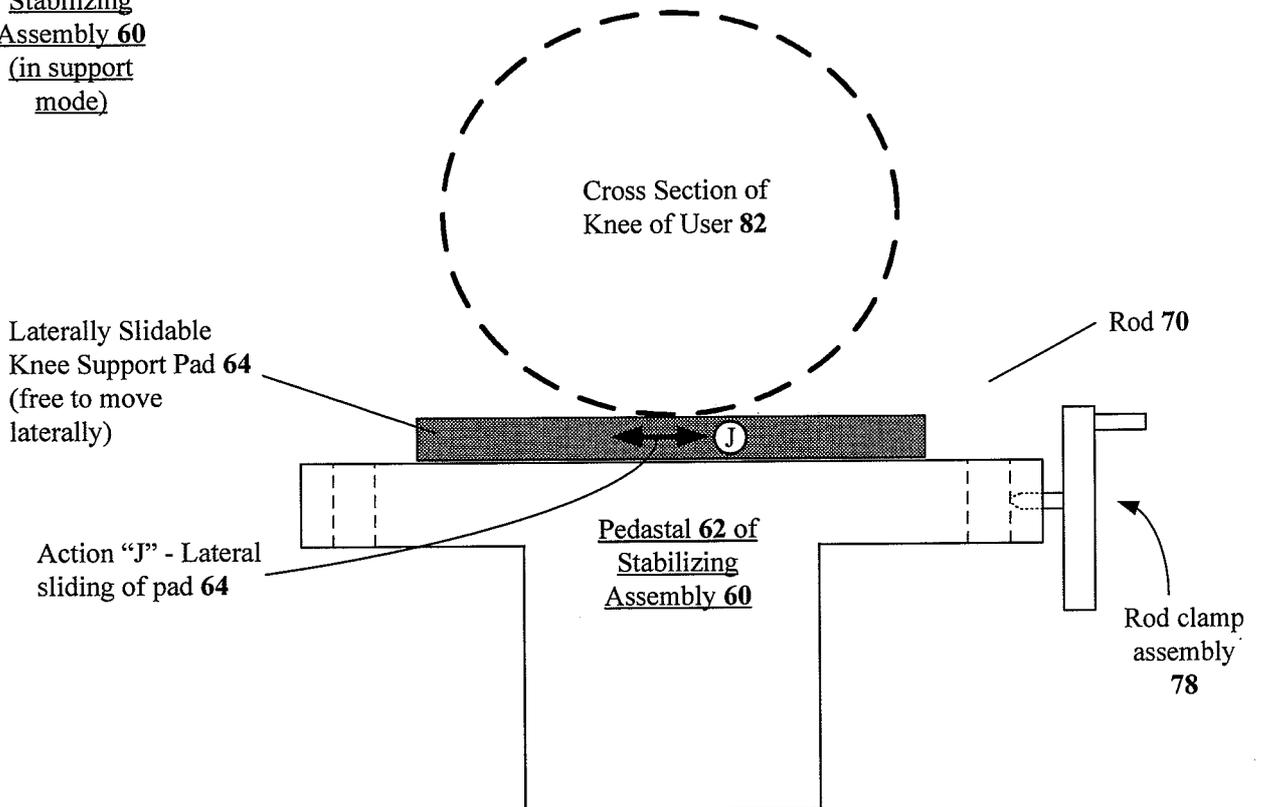


Fig. 14

Knee Support/
Stabilizing
Assembly 60
(in stabilizing
mode)

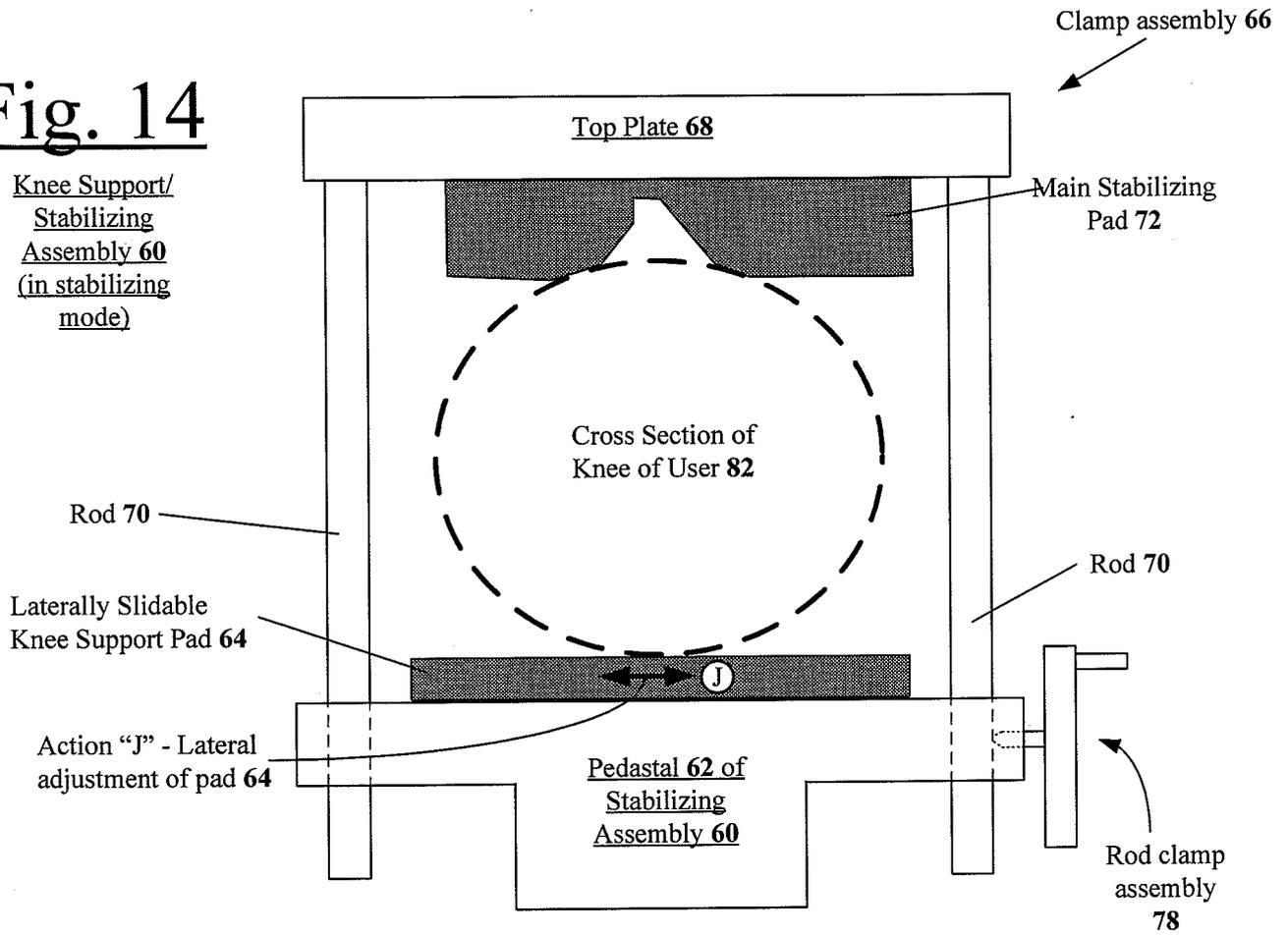


Fig. 15

Tibia Retention
Assembly 180

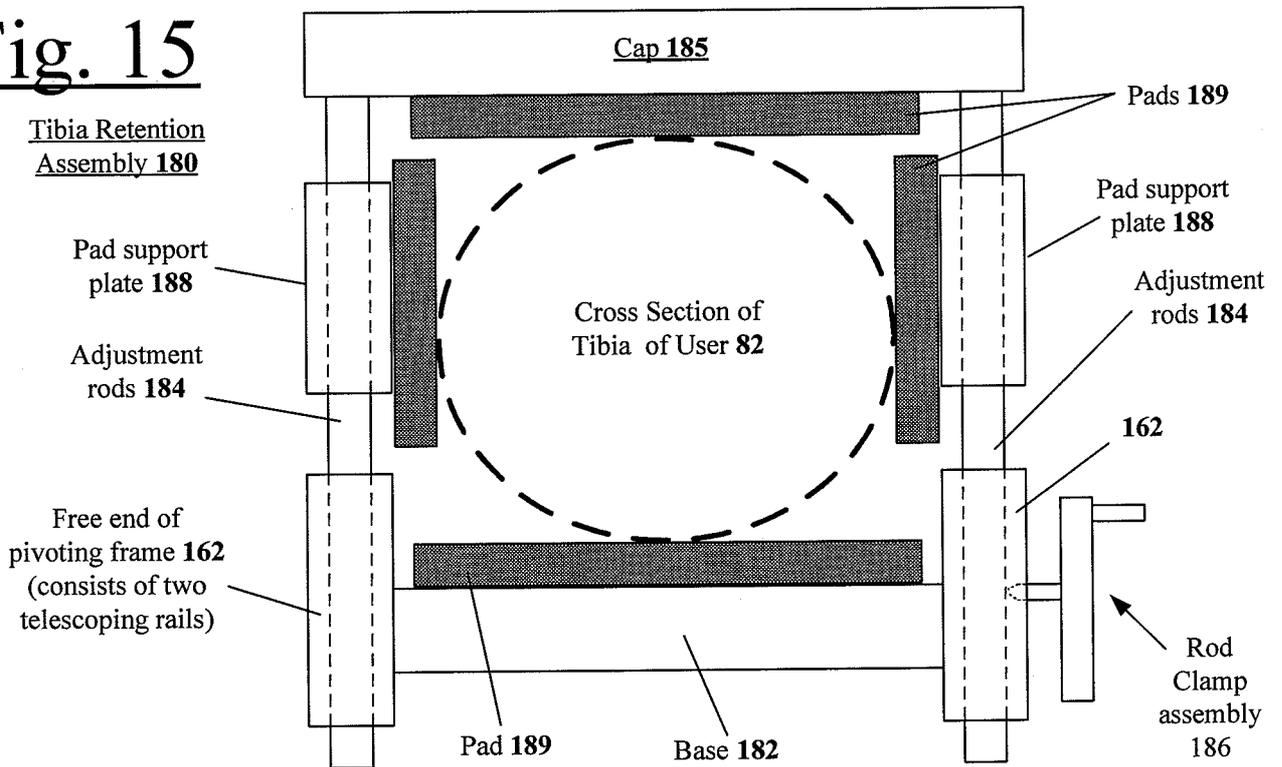


Fig. 16

Foot plate 202
Pivots relative to
Pivoting Frame 162
along Action "H". Part of
THIRD PIVOTING
ASSEMBLY 200
(a.k.a. Foot Rotation
Assembly 200)

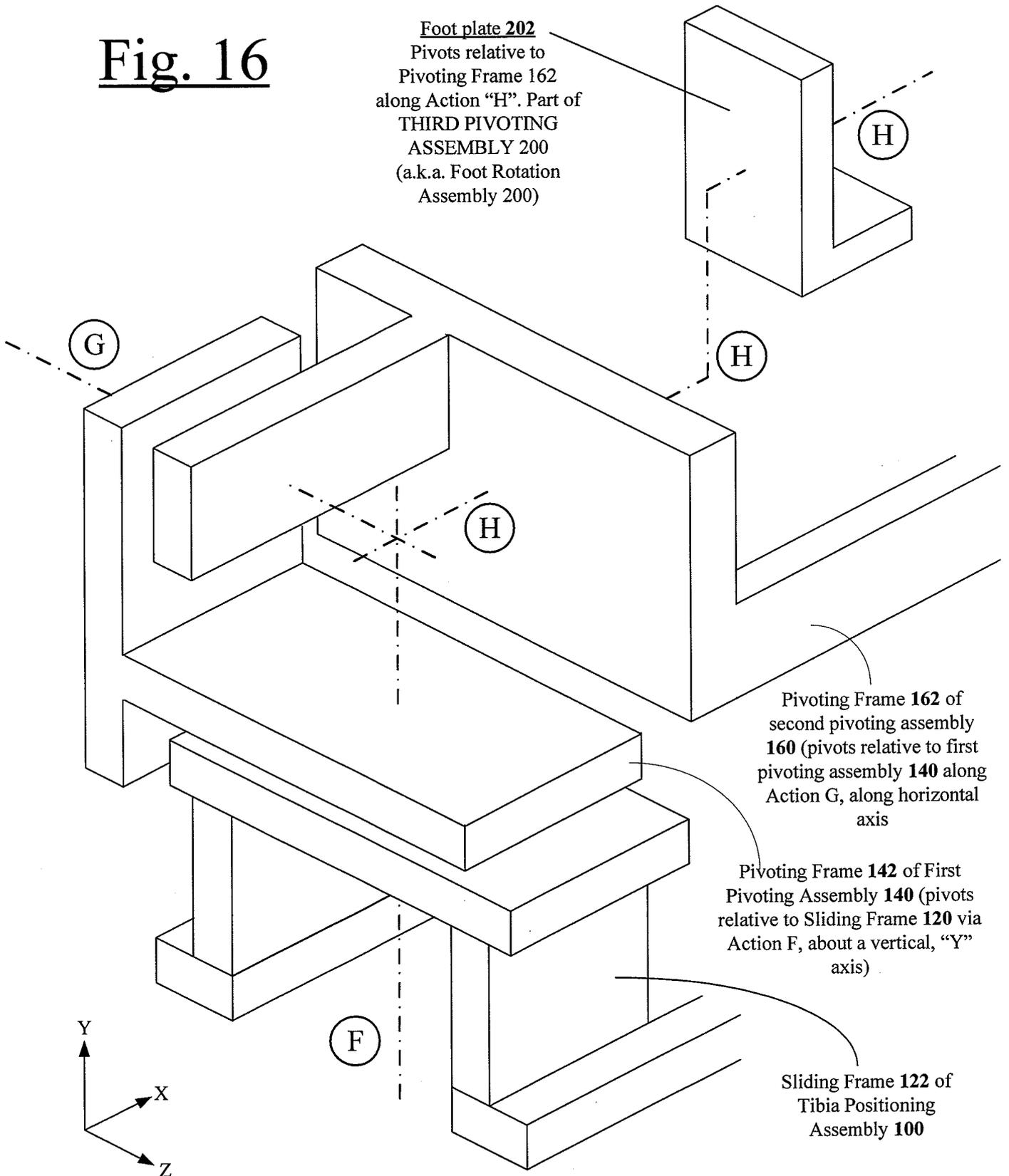


Fig. 17

Subjective Measurement Module 2000

Output Display 2002
(showing previous reading
- not corresponding to
current dial position)

Dial 2001
(operated by
user)

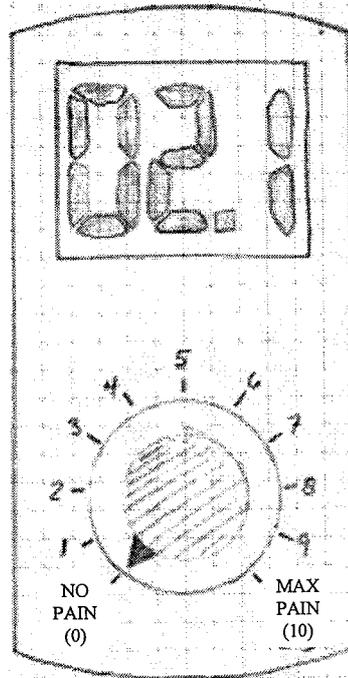
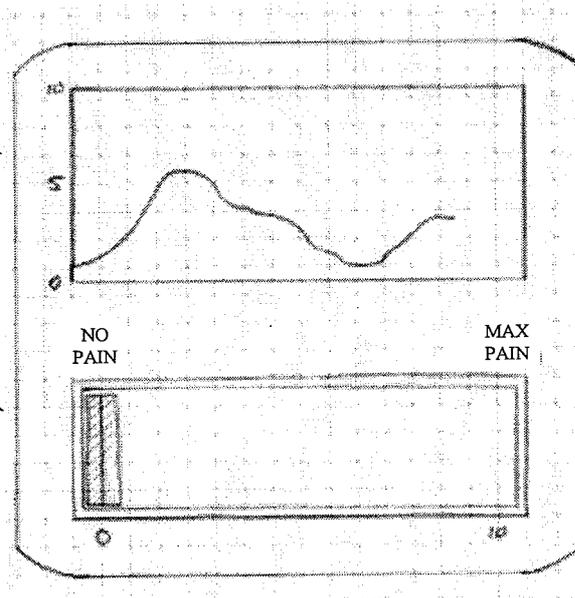


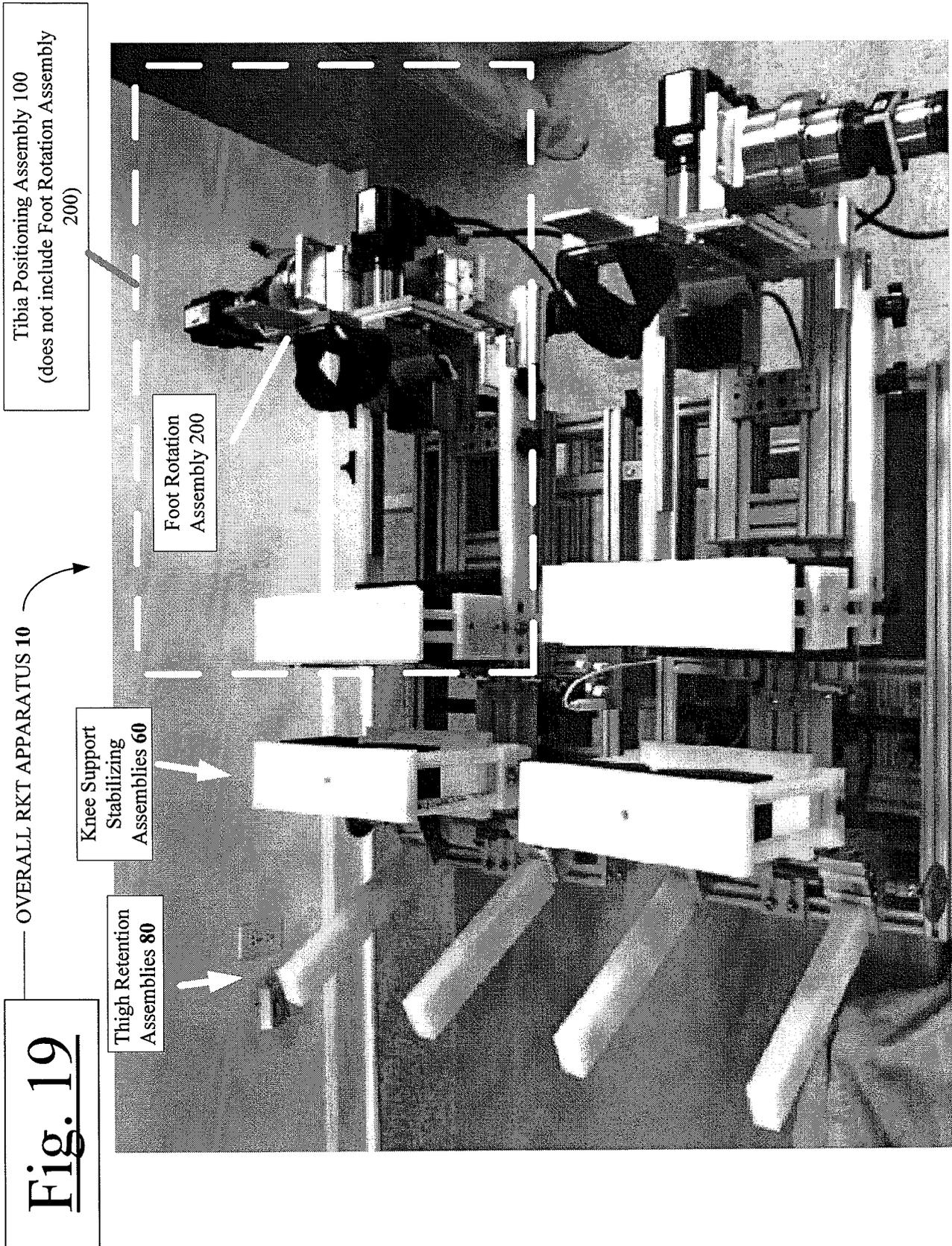
Fig. 18

Subjective Measurement Module 2200

Output Display 2202
(showing previous reading
- not corresponding to
current dial position)

Slide 2201
(operated by
user)





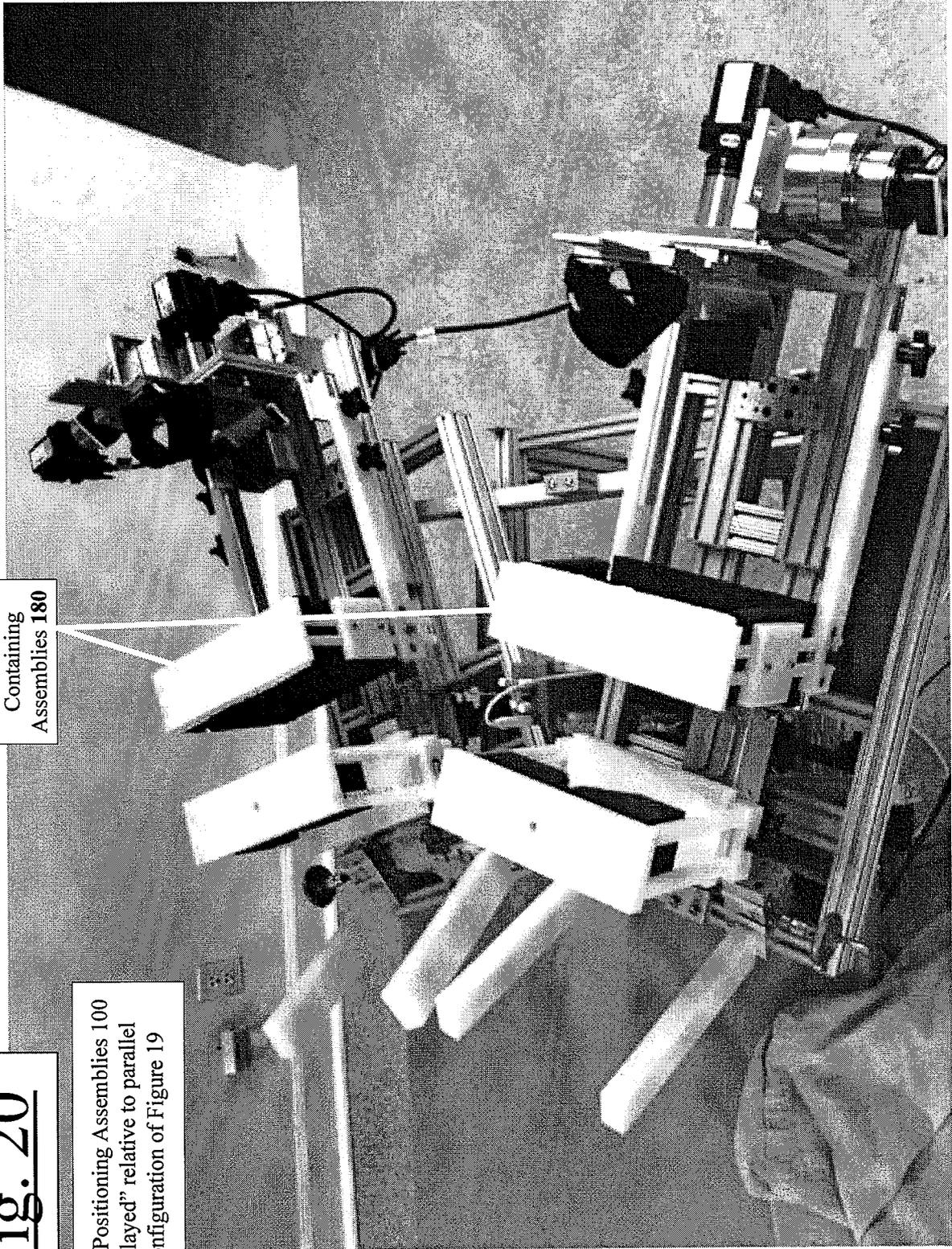


Fig. 20

Tibia Positioning Assemblies 100
“splayed” relative to parallel
configuration of Figure 19

Tibia
Containing
Assemblies 180

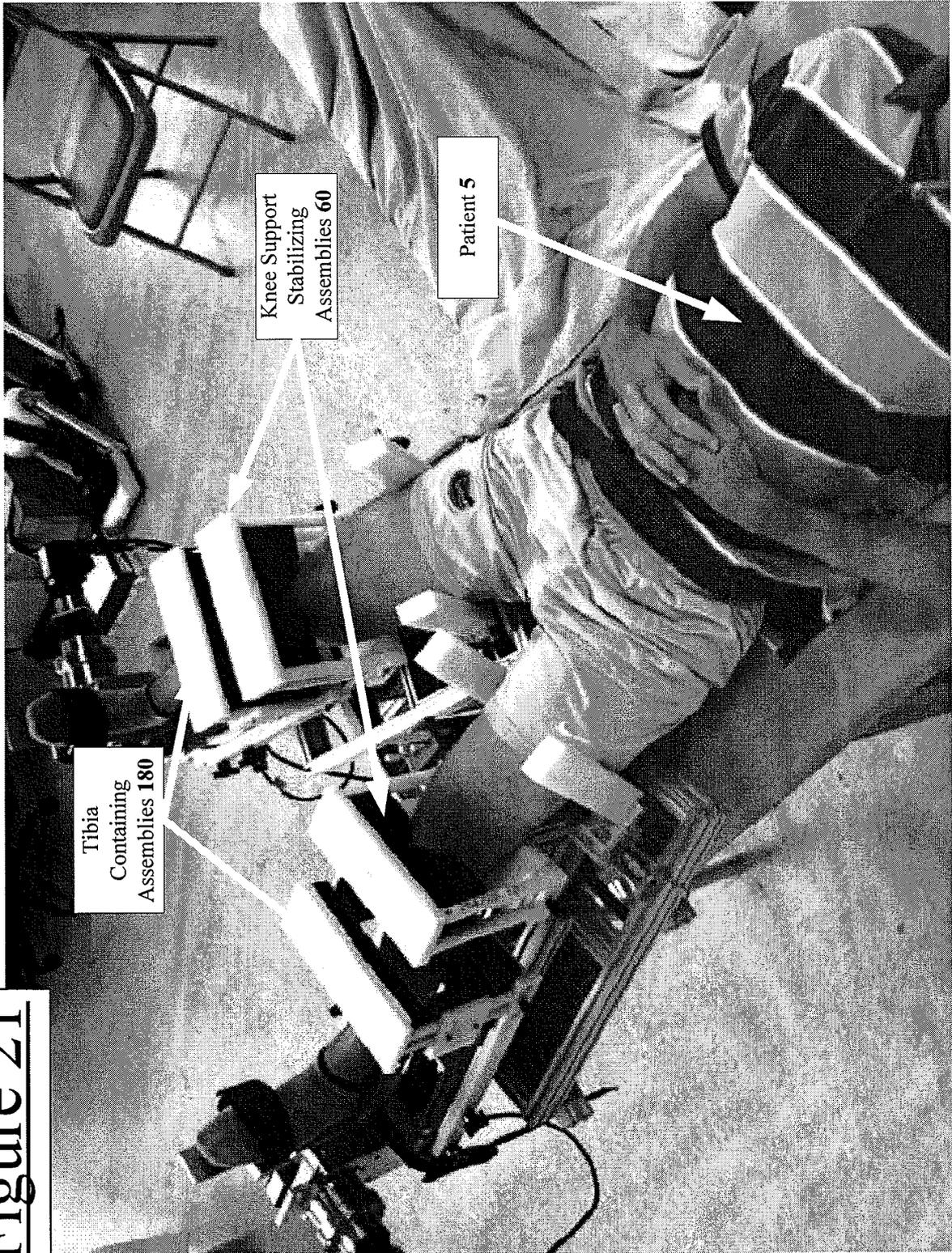


Figure 21

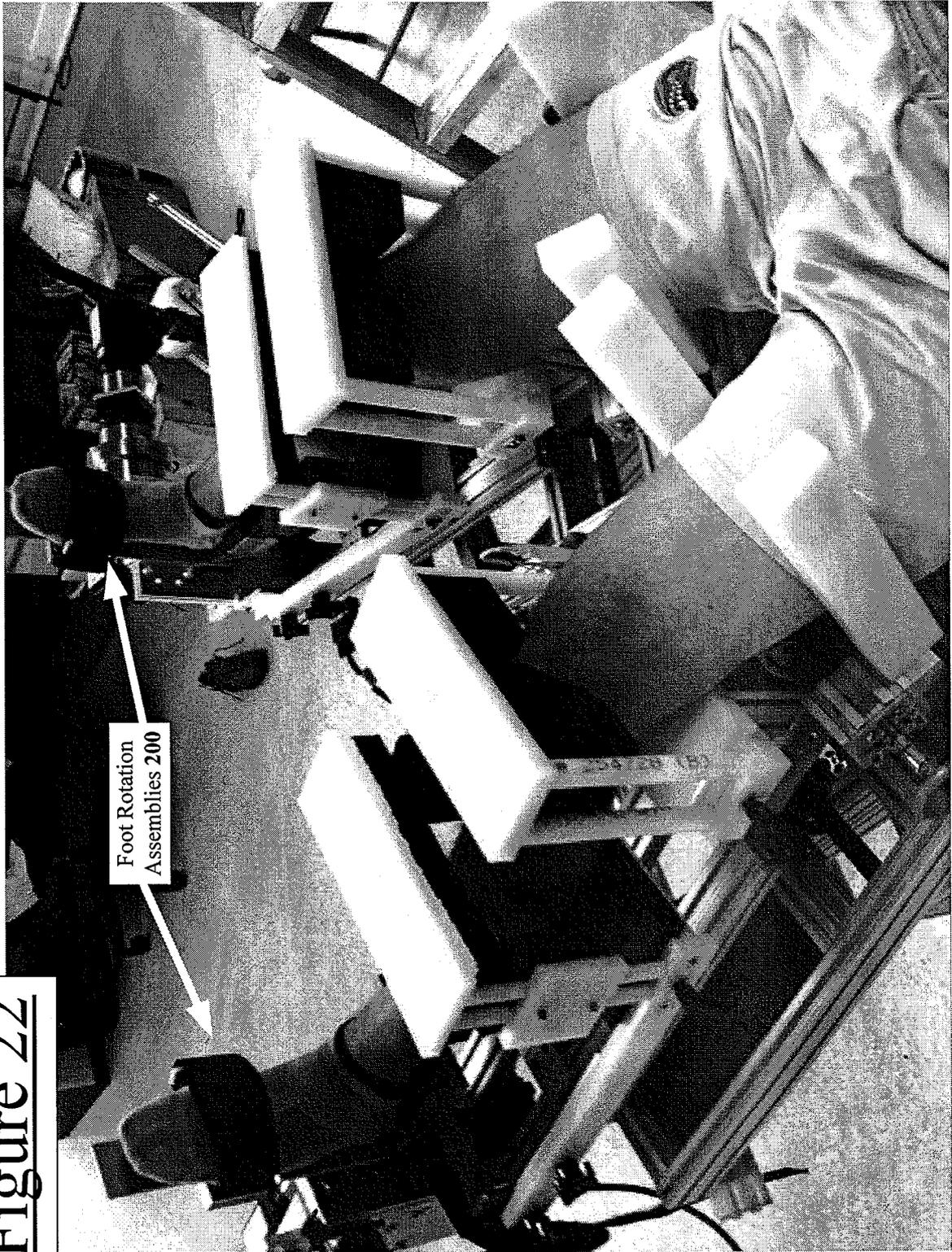


Figure 22

Figure 23

Similar to Figure 20 but without Knee Support Stabilizing Assemblies 60

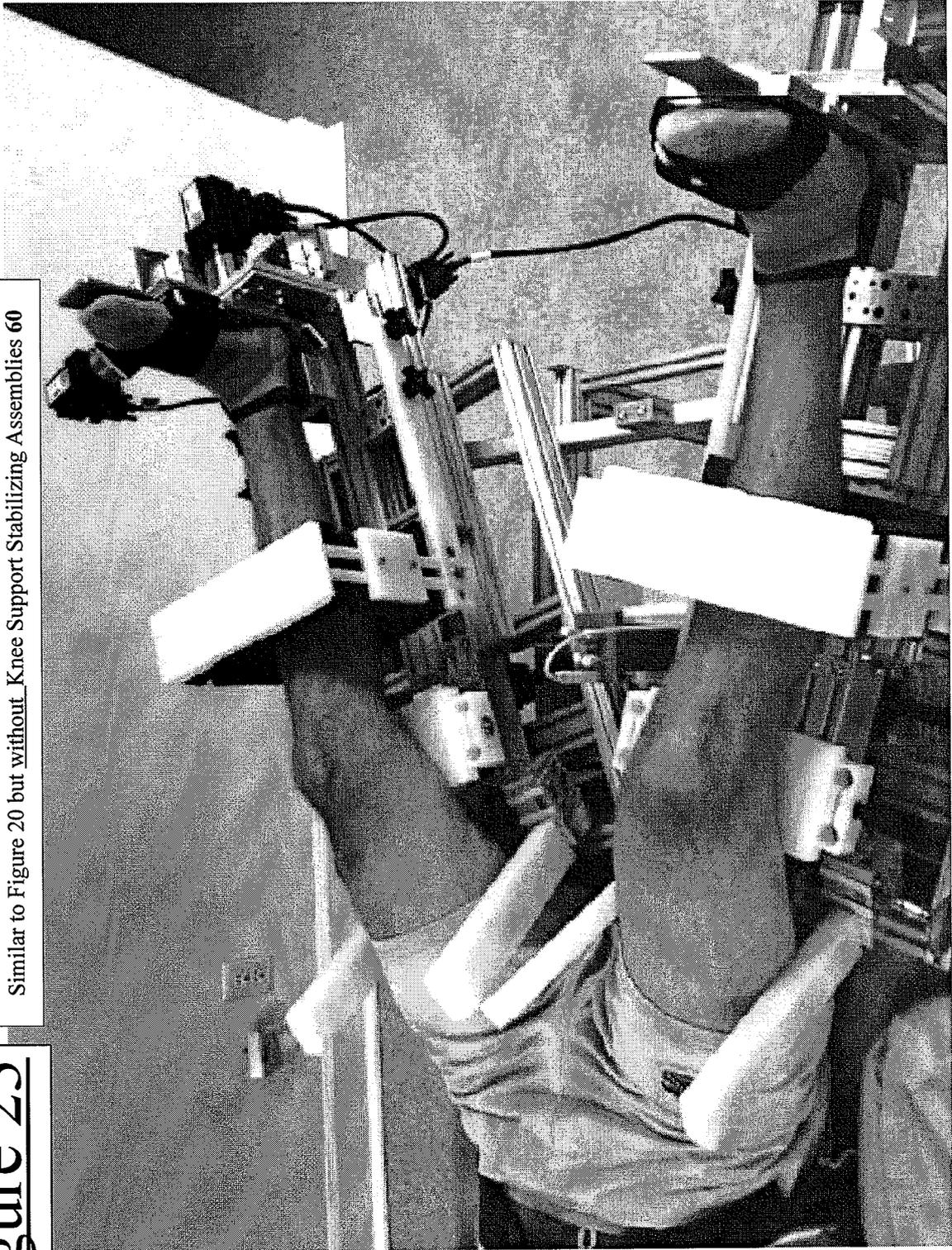


Figure 24

Same as Figure 23 but More Approximating a Side
Elevational View

Foot Rotation
Assemblies 200

Pairs of telescoping rails of
pivoting frame 162, adjustable in
length by the two shown
adjustment knobs
PAIR ONE PAIR TWO

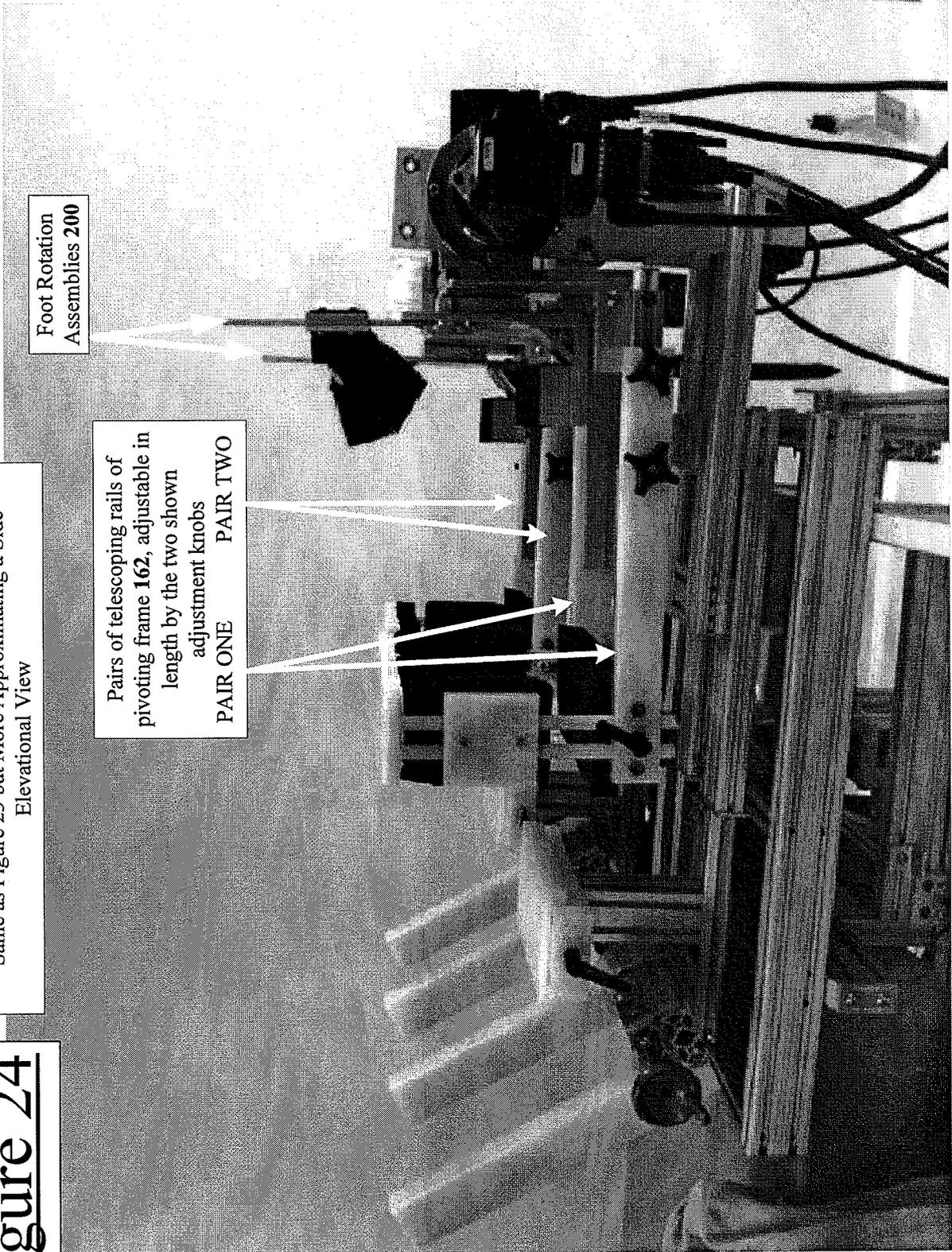
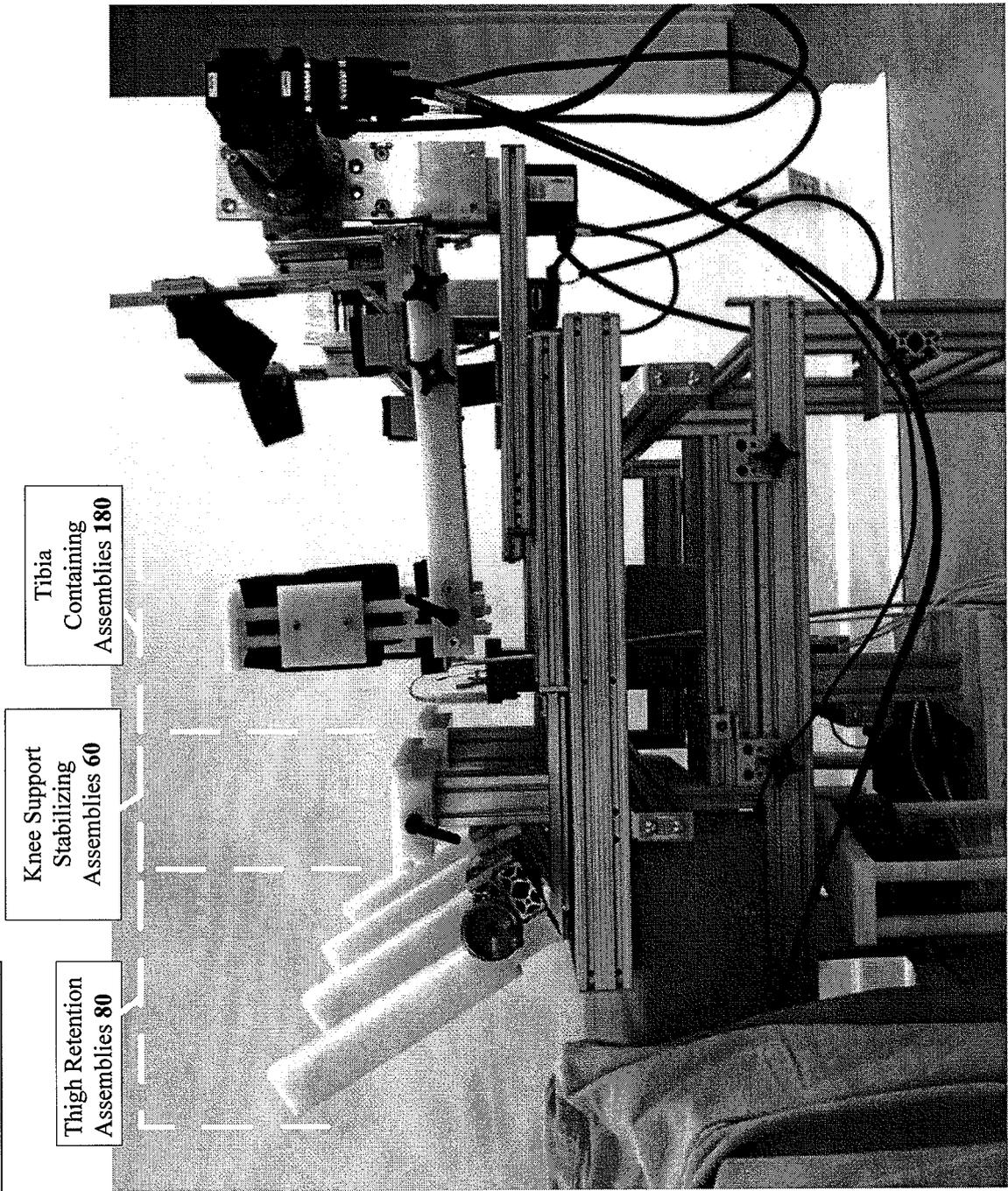


Figure 25

Even More Approximating a Side Elevational View relative to Figure 24



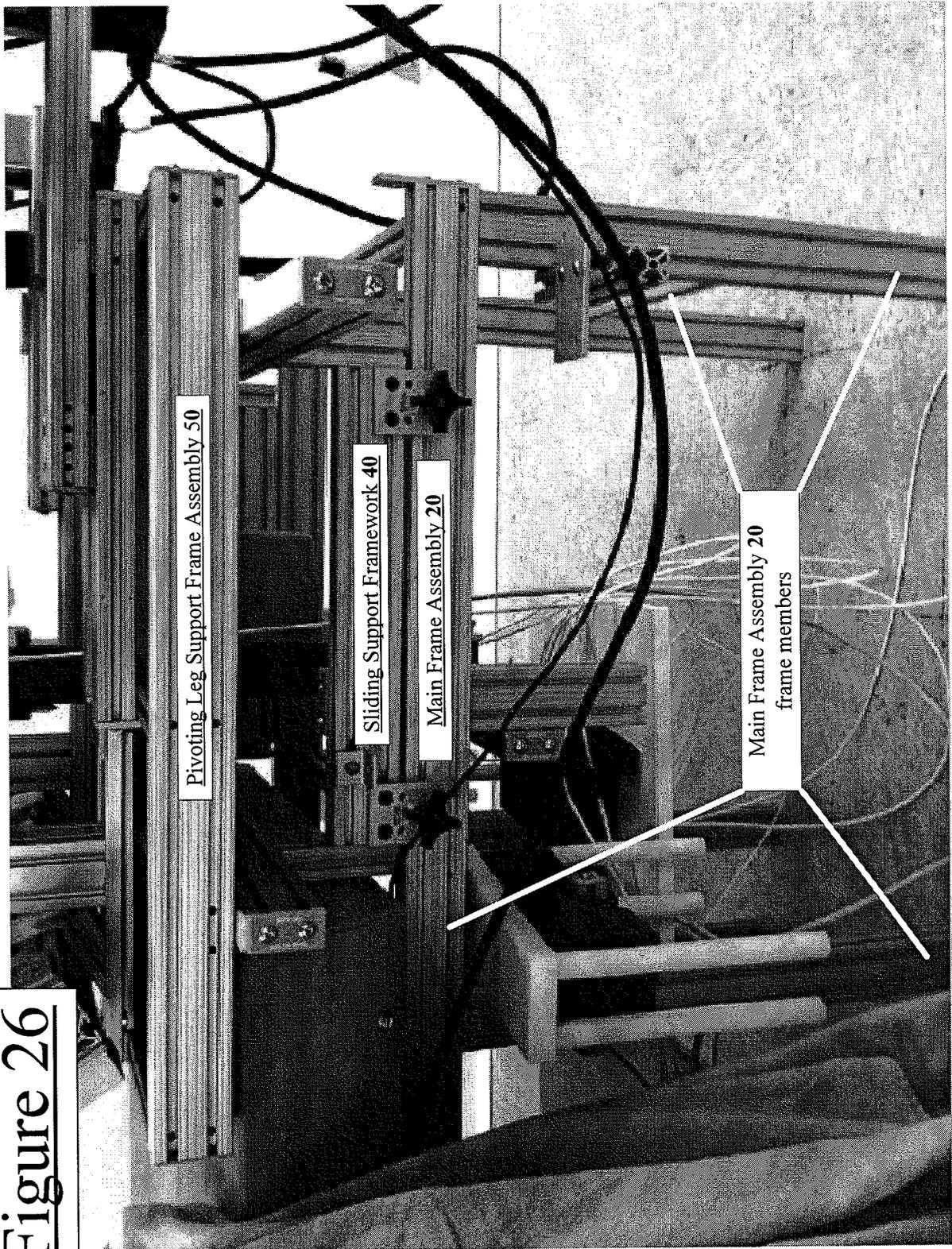


Figure 26

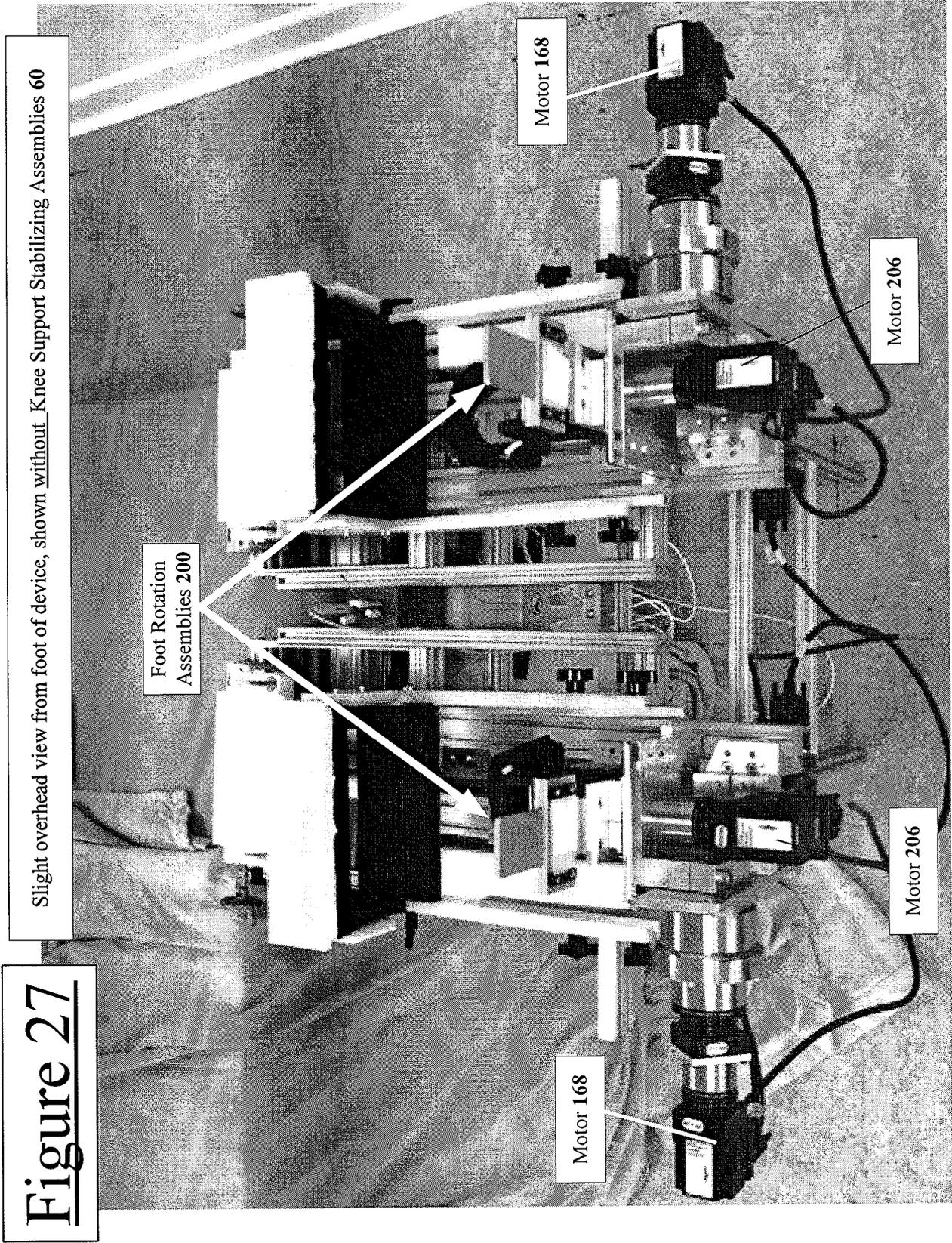


Figure 27



Figure 28



Figure 29

Foot Rotation
Assemblies 200

Motor 168

Motor 206
MADE IN THE
UNITED STATES OF AMERICA
Model No. 168
1/2 HP 115V 60Hz
W. M. 200310000
JAN 10 2011 1007 7700
TVA PRODUCTS, USA

Pivoting
Frame 142

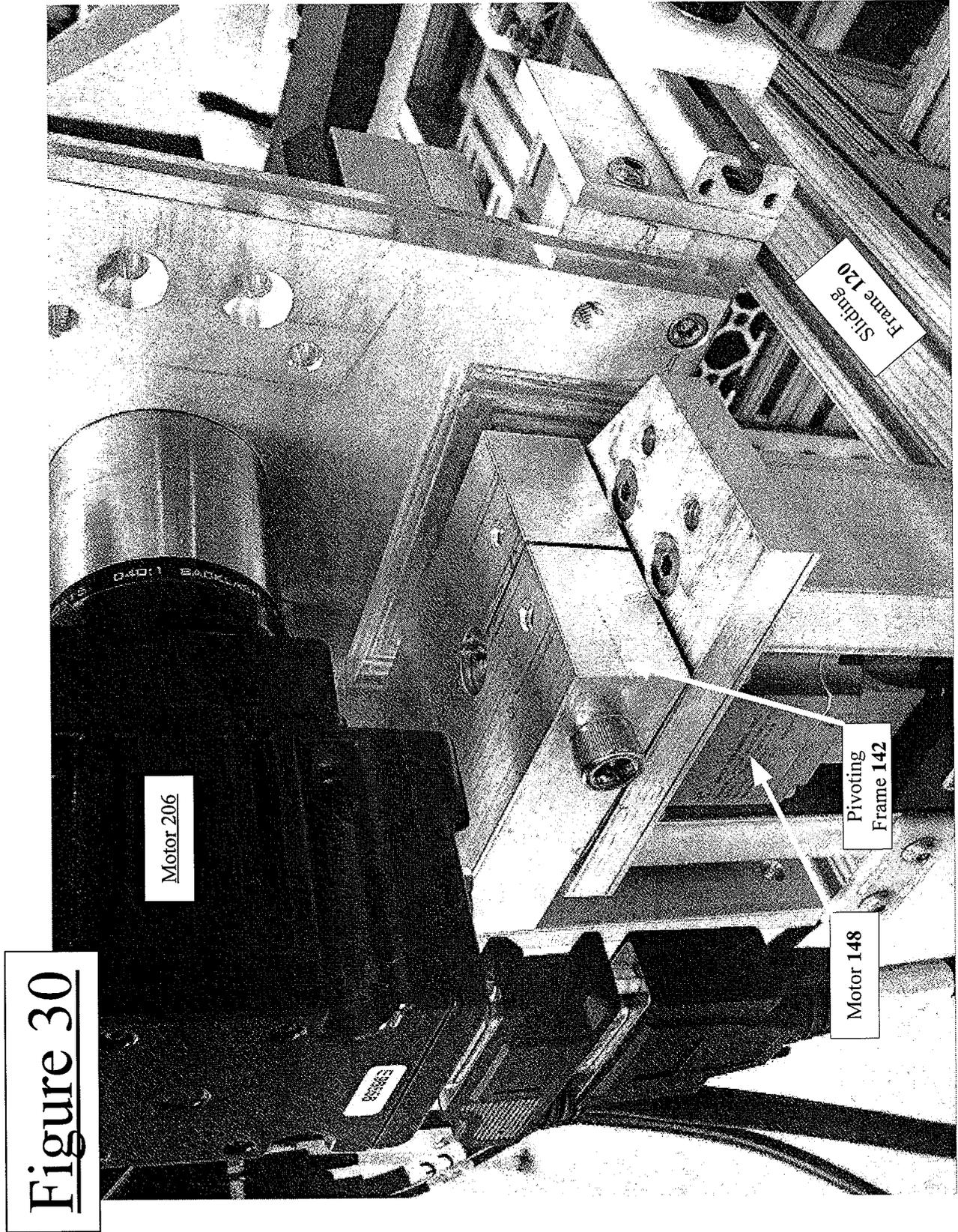


Figure 30

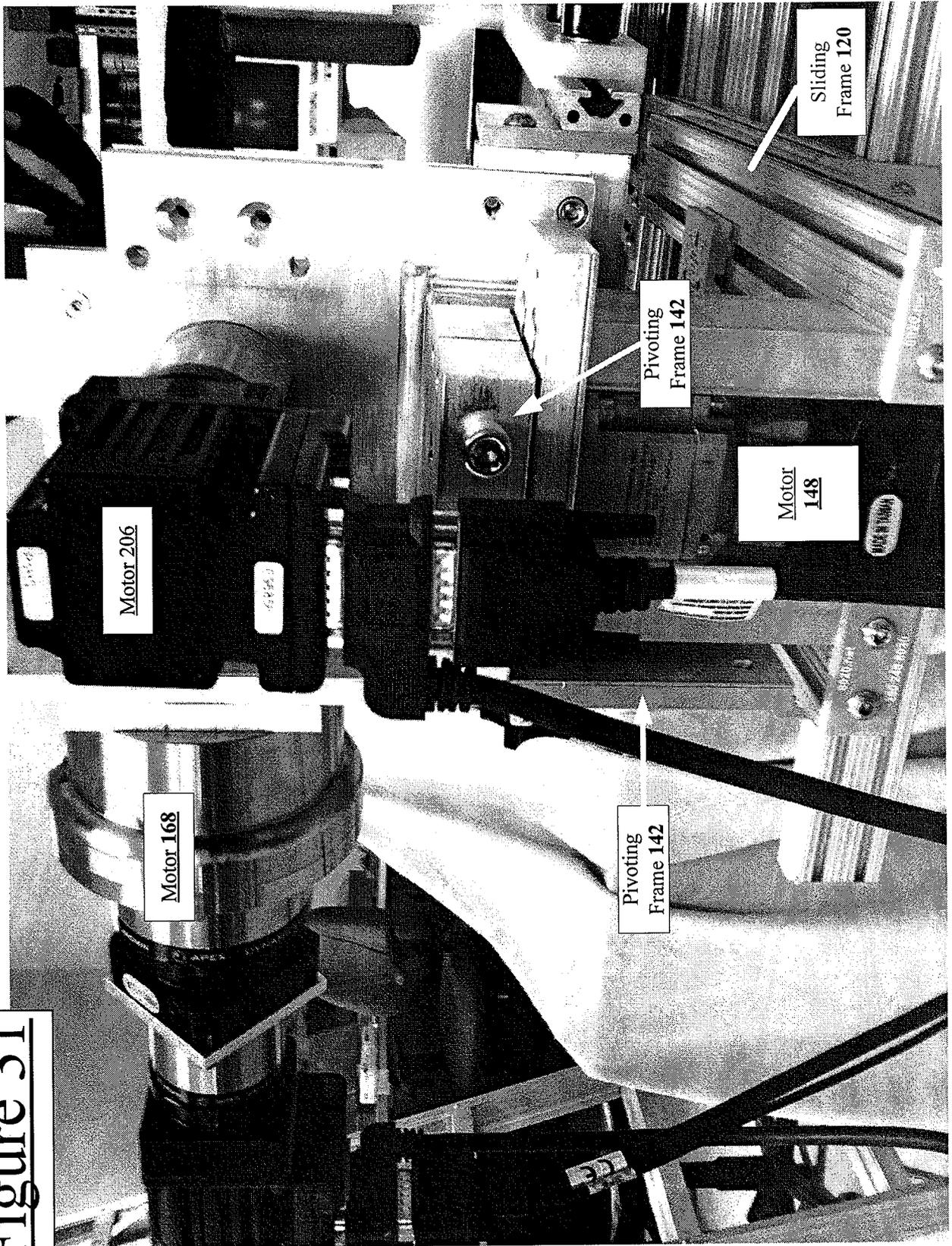
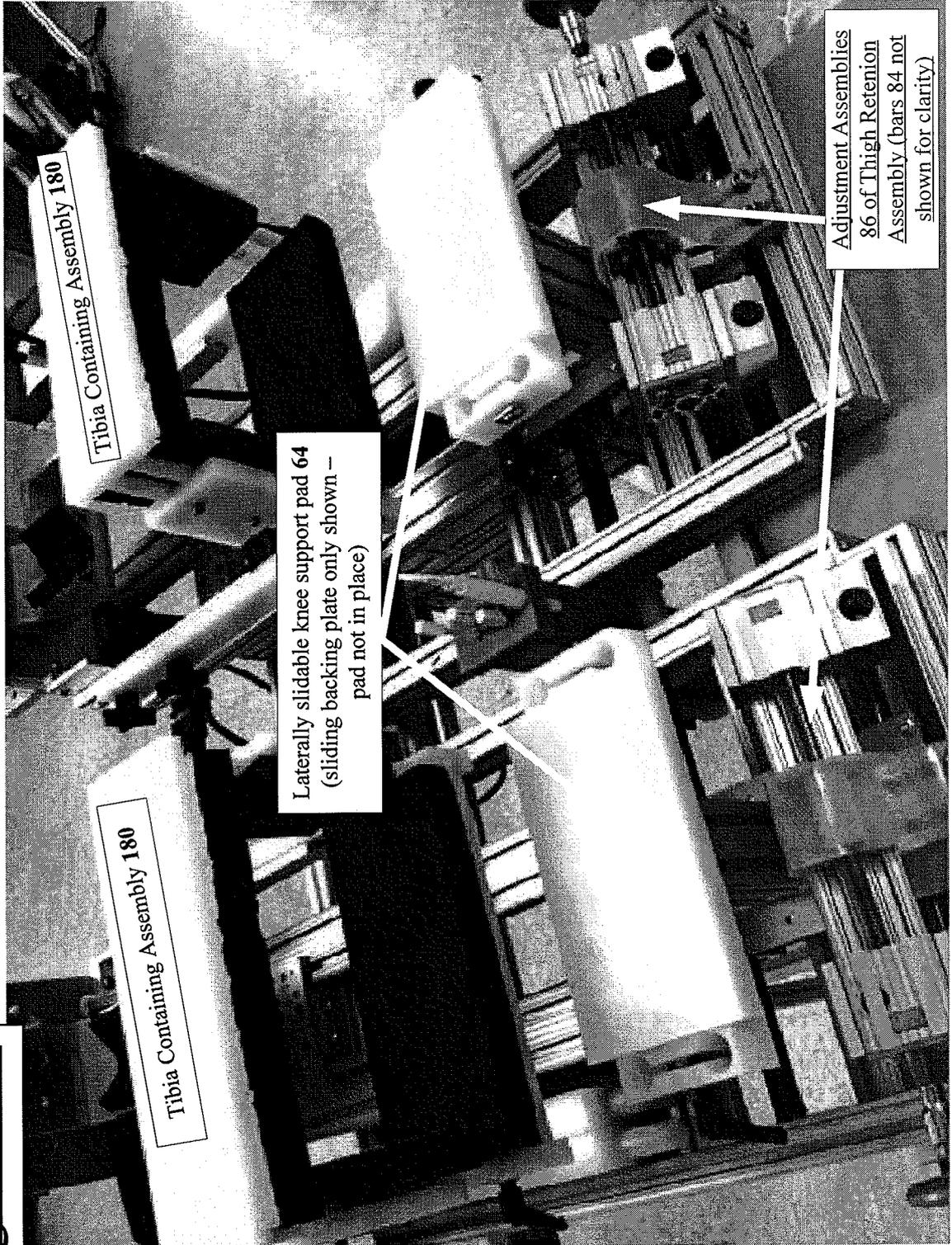


Figure 31

Figure 32



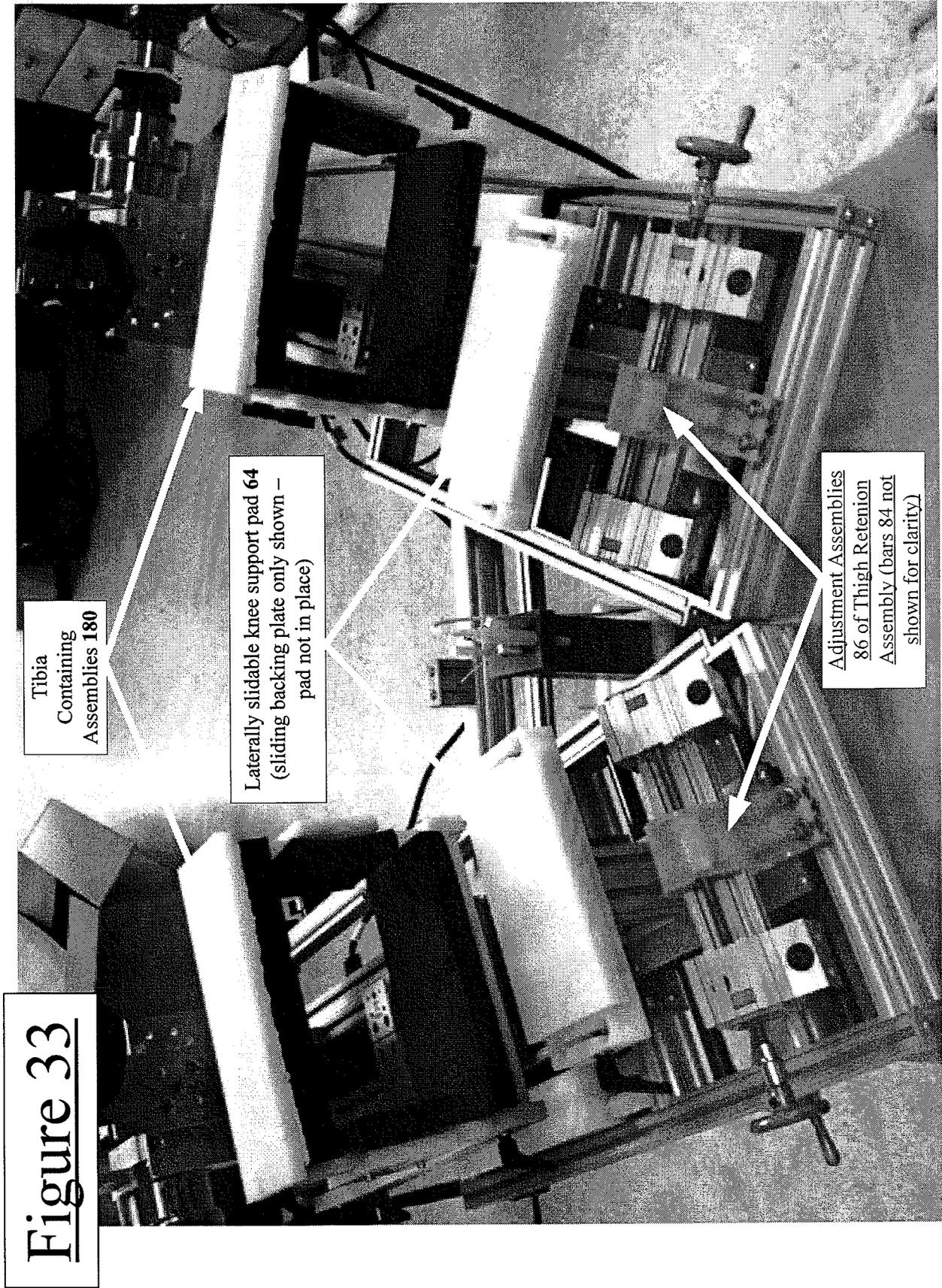


Figure 33

Tibia
Containing
Assemblies 180

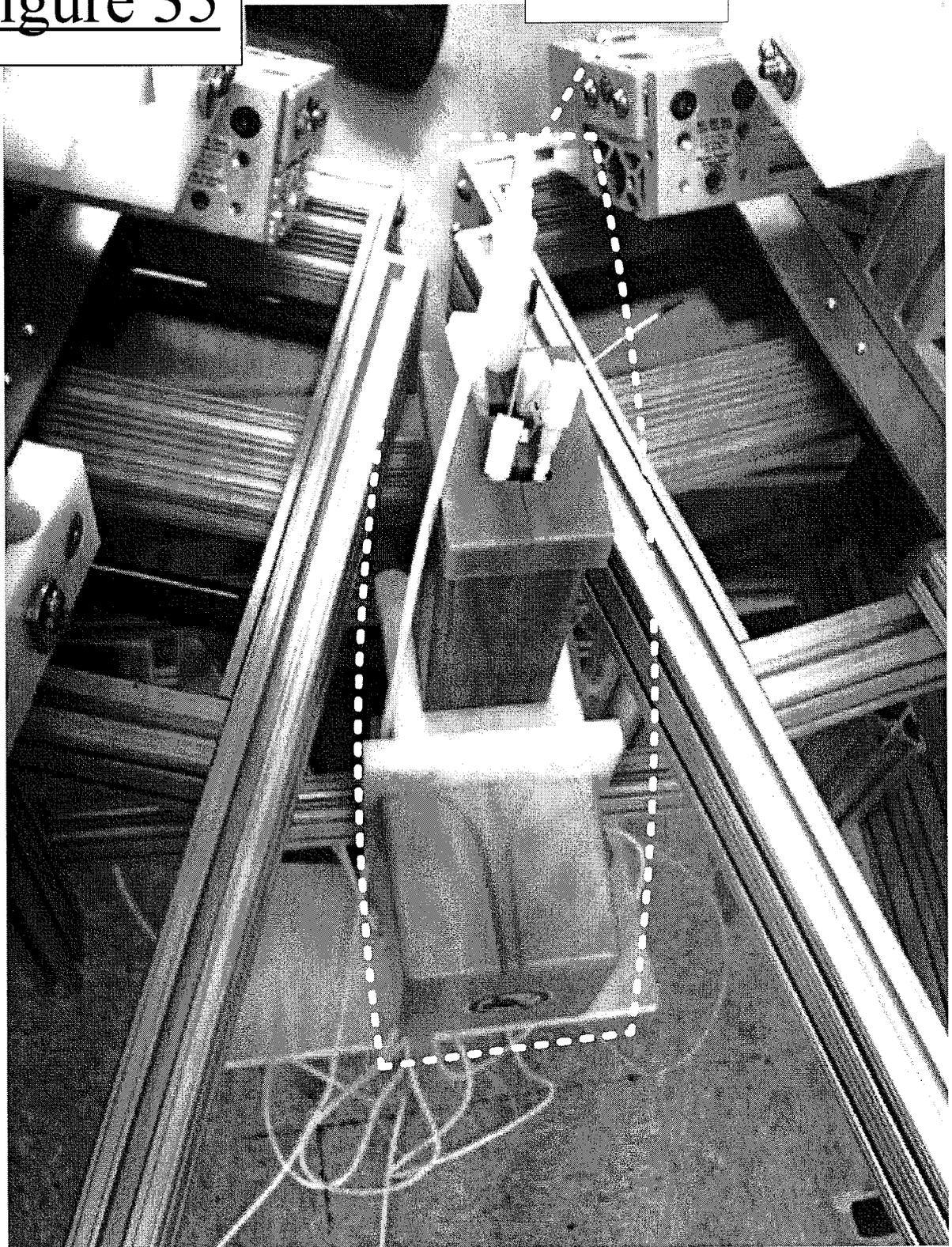
Laterally slidable knee support pad 64
(sliding backing plate only shown -
pad not in place)

Adjustment Assemblies
86 of Thigh Retention
Assembly (bars 84 not
shown for clarity)



Figure 35

Sensor Cluster 1000



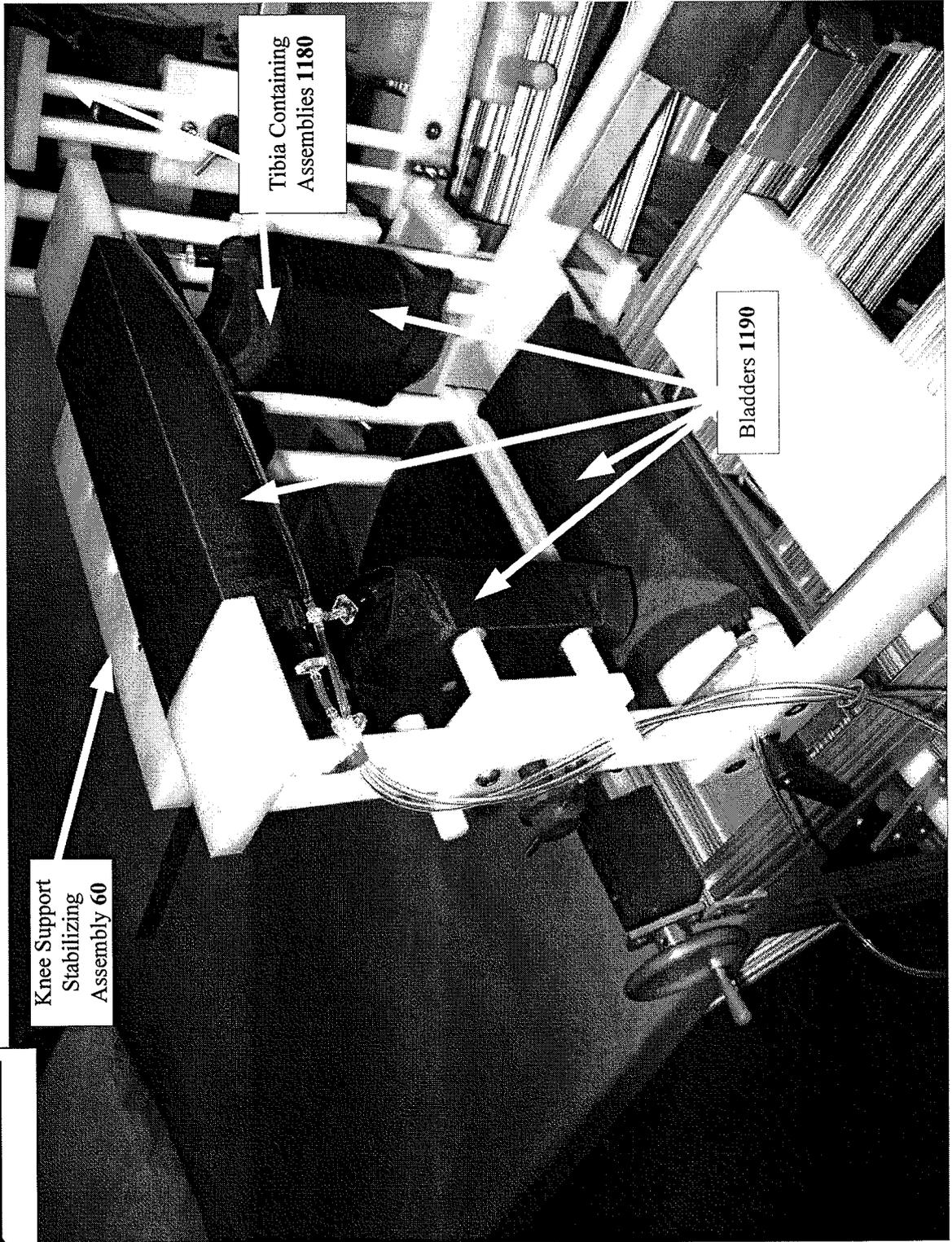
Subjective Measurement Module 2100

Figure 36



Figure 37

Tibia Container Assemblies 1180



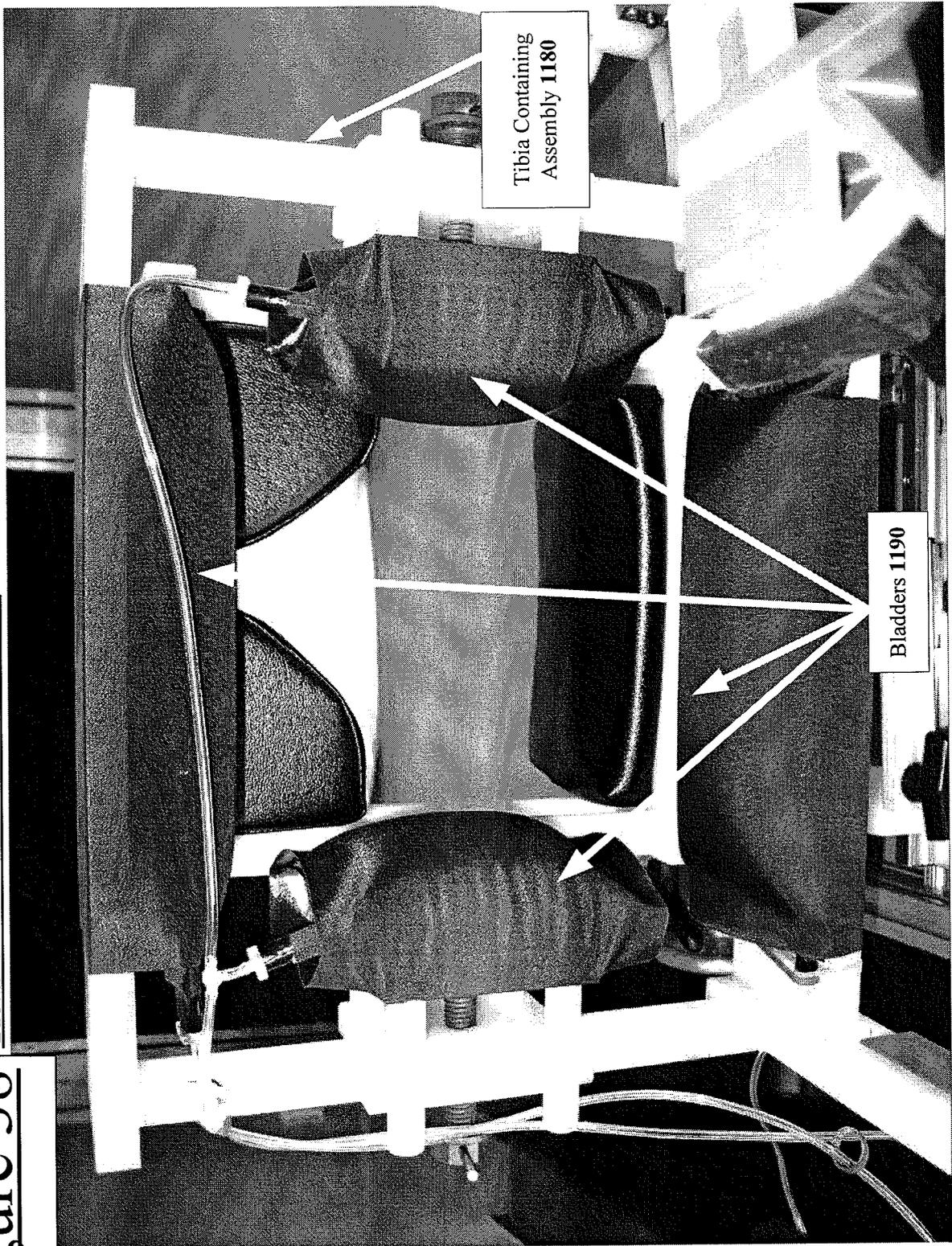
Knee Support
Stabilizing
Assembly 60

Tibia Containing
Assemblies 1180

Bladders 1190

Tibia Container Assemblies 1180

Figure 38



INTERNATIONAL SEARCH REPORT

International application No PCT/US2011/047453

A. CLASSIFICATION OF SUBJECT MATTER INV. A61B5/103 A61B5/11 ADD.				
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) A61B A63B				
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, BIOSIS				
C. DOCUMENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.		
X	US 2007/055176 A1 (BRANCH THOMAS P [US] ET AL) 8 March 2007 (2007-03-08) paragraph [0058] - paragraph [0150]; claims; figures -----	1-31		
X	US 2009/124936 A1 (BRANCH THOMAS P [US] ET AL) 14 May 2009 (2009-05-14) paragraphs [0035] - [0037], [0106] - [0176]; claims; figures ----- -/--	1-9,20, 22-25,31		
<table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C.</td> <td style="width: 50%; border: none;"><input checked="" type="checkbox"/> See patent family annex.</td> </tr> </table>			<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C.	<input checked="" type="checkbox"/> See patent family annex.
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C.	<input checked="" type="checkbox"/> See patent family annex.			
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"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			
27 October 2011	17/11/2011			
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 Crisan, Carmen-Clara			

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2011/047453

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	SHULTZ SANDRA J ET AL: "Measurement of varus-valgus and internal-external rotational knee laxities in vivo--Part I: assessment of measurement reliability and bilateral asymmetry", JOURNAL OF ORTHOPAEDIC RESEARCH, vol. 25, no. 8, 1 August 2007 (2007-08-01) , pages 981-988, XP002515908, JOHN WILEY & SONS, INC, NEEDHAM, MA ISSN: 0736-0266, DOI: 10.1002/JOR.20397 the whole document	1-26, 28-31
A	----- US 2009/264797 A1 (MAYR HERMANN [DE]) 22 October 2009 (2009-10-22) the whole document	1-31
A	----- EP 0 293 372 B1 (LUSUARDI WERTHER [CH]; AL TURAICI MOHAMMED H S [SA]) 19 June 1991 (1991-06-19) the whole document	1-31
A	----- SHINO K ET AL: "Measurement of anterior instability of the knee. A new apparatus for clinical testing", JOURNAL OF BONE AND JOINT SURGERY. BRITISH VOLUME, vol. 69, no. 4, 1 August 1987 (1987-08-01) , XP002515909, LIVINGSTONE, LONDON, GB ISSN: 0301-620X the whole document	1-31
A	----- BRANCH THOMAS P ET AL: "Instrumented Examination of Anterior Cruciate Ligament Injuries: Minimizing Flaws of the Manual Clinical Examination", ARTHROSCOPY, vol. 26, no. 7, July 2010 (2010-07), pages 997-1004, XP002662082, ISSN: 0749-8063, DOI: 10.1016/J.ARTHRO.2010.01.019 the whole document	1-31

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No PCT/US2011/047453

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US 2009264797 A1	22-10-2009	EP 2110077 A1 WO 2009127654 A1	21-10-2009 22-10-2009

EP 0293372 B1	19-06-1991	DE 3679912 D1 WO 8804536 A1 EP 0293372 A1	25-07-1991 30-06-1988 07-12-1988
