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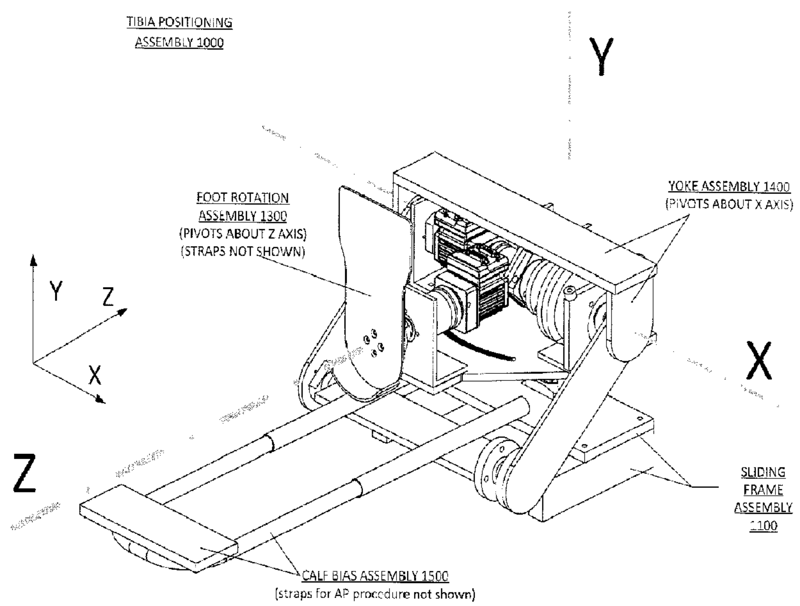
(54) **Titre** : DISPOSITIF DE TEST DE GENOU ROBOTIQUE (RKT) AYANT UNE CAPACITE DE COMMANDE DECOUPLEE, ET SYSTEMES ET PROCEDES LE COMPRENANT
(54) **Title:** ROBOTIC KNEE TESTING (RKT) DEVICE HAVING DECOUPLED DRIVE CAPABILITY AND SYSTEMS AND METHODS PROVIDING THE SAME



(57) **Abrégé/Abstract:**
Various limb manipulation and evaluation devices are provided. The devices generally include three drives, namely a first drive configured to manipulate a first bone relative to a second bone in a first direction, a second drive configured to manipulate the first bone relative to the second bone in a second direction, a third drive configured to manipulate the first bone relative to the second bone in a second direction. The three directions are different relative to each other and in some embodiments represent three distinct axes. The devices are further configured such that at least one of the drives is mutually decoupled relative to at least one other drive, such that operation of the one drive does not affect the position or movement of the another drive. One or multiple of the drives may be decoupled. A corresponding method of operating such decoupled drives is also provided.

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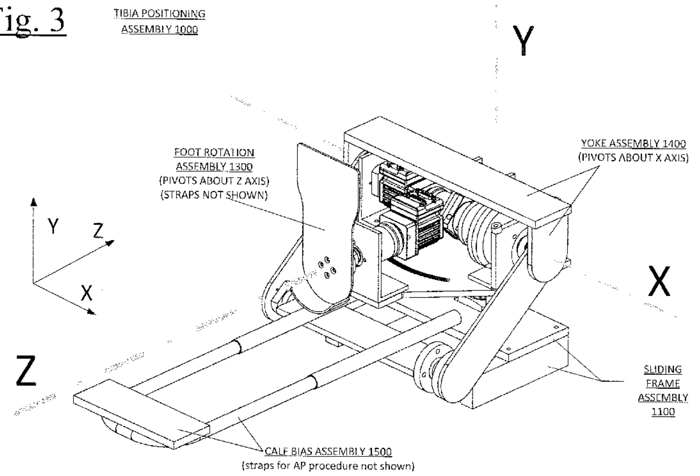
(54) **Title**: ROBOTIC KNEE TESTING (RKT) DEVICE HAVING DECOUPLED DRIVE CAPABILITY AND SYSTEMS AND METHODS PROVIDING THE SAME

Fig. 3



(57) **Abstract**: Various limb manipulation and evaluation devices are provided. The devices generally include three drives, namely a first drive configured to manipulate a first bone relative to a second bone in a first direction, a second drive configured to manipulate the first bone relative to the second bone in a second direction, a third drive configured to manipulate the first bone relative to the second bone in a second direction. The three directions are different relative to each other and in some embodiments represent three distinct axes. The devices are further configured such that at least one of the drives is mutually decoupled relative to at least one other drive, such that operation of the one drive does not affect the position or movement of the another drive. One or multiple of the drives may be decoupled. A corresponding method of operating such decoupled drives is also provided.

ROBOTIC KNEE TESTING (RKT) DEVICE HAVING DECOUPLED DRIVE CAPABILITY AND SYSTEMS AND METHODS PROVIDING THE SAME

BACKGROUND

Field of Invention

This generally relates to three-dimensional joint motion evaluation using computer-controlled torque application via, for example, a robotic knee testing device (an "RKT" device) which controls the direction, rate, and magnitude of forces applied in at least three directions. The respective forces are configured to evaluate "IE" (internal-external) movement about a Z-axis of rotation distal to the foot, varus-valgus conditions about a Y-axis of rotation distal to the foot, and "AP" (anterior-posterior) movement of the tibia through a proximal tibia contact arm which rotates about a X-axis of rotation distal to the foot.

Description of Related Art

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' or motion 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 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' or motion 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 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 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 diagnosis of ligament damage resulting in a change in 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.

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. Pressure is applied under the patient's calf and down on the patient's thigh such that there is a translation between the femur and the tibia..

Similar to the Lachman's test, the pivot shift test begins by positioning the patient on his back. The knee is placed in full extension (x-axis rotation) and a valgus (y-axis rotation) force and an internal rotation (z-axis rotation) force is applied to the knee to allow the lateral tibia to slip anteriorly from underneath the lateral femoral condyle as the knee is flexed (x-rotation) the tibia is allowed to slip suddenly back underneath the femoral condyle. The clinician feels for an abnormal external rotation (z-axis rotation) and posterior translation (y-axis translation) of the tibia with respect to the femur. This shift is felt to represent the relative increased translation (y-axis translation) of the lateral side of the knee with respect to the increased translation (y-axis translation) of the medial side of the knee. Furthermore, the point of sudden shift represents the point at which the tibia bone slides from in front of the radius of curvature of the curved end of the femur back to its normal position under the femoral condyle. The clinician subjectively rates the pivot shift as Grade I, Grade II or 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 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 graded based on the amount or extent of anterior translation of the tibia with respect to the femur. Grade I has 0 to 5 mm of anterior translation Grade II has 6 to 10 mm of anterior translation, and Grade III has 11 to 15 mm of anterior translation.

To diagnose an injured ACL using the described tests, the clinician must 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 ligament lengthening based upon relative increase in joint play 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 manual knee examination with accuracy.

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. Several devices have attempted to accurately quantify the extent or relative displacement and compliance of a ligament in the knee. One of these devices is The KT-1000 and the KT-2000 Medmetric®, which measures the anterior-posterior translation of the tibia with respect to the femur along the y-axis, but disadvantageously attach to the tibia. 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 a 15 pound force and a higher pitched sound for a 20 pound force. This force pulls anteriorly along the y-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. Other devices such as the Stryker KLT, the Rolimeter, and the KSS system use similar mechanisms to attempt to quantify the normal amount of 'joint play' or motion between the femur and tibia, along with any increased 'joint play' or motion which is associated with ligament lengthening and damage.

Many non-invasive systems utilize sensors or markers that are attached to the skin, including but not limited to optoelectronic, ultrasonic, and electromagnetic motion analysis systems. These skin sensors or markers are merely representations of location of the underlying bones; however, many published reports have documented the measurement error related to skin artifact with this system. In order to avoid the inaccuracies associated with skin artifact, medical imaging systems may be utilized in order to precisely determine the position/location of the bones accurately

Surgeons manually examine the joint for altered play; however, due to the variability in size of the patient, size and experience of the surgeon, and the subtlety of injury, consistent and reproducible reports of joint play between surgeons is not possible. The need that must be met is to provide a controlled application of torque during joint examination, with the magnitude, direction, and rate of torque application being controlled. Many reports have documented that, whether performed by hand or with manual arthrometers, the manual application of torque varies between clinicians, thus creating inconsistencies in the examination of joint play.

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 or combination of ligaments and other 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 (y-axis translation) and rotation (z-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 occurs in an injured knee with structural damage. A need exists for systems and methods that can provide accurate, reproducible and objective data on the changes in 'joint play' or motion that occurs with an injured knee compared to their healthy knee and to the population as a whole such that the clinician can achieve patient satisfaction with focused, biomechanical and proven surgical interventions specific to that injury and for that knee across the entire population of damaged knees.

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 bones, tendons, joints, etc., due to injury or the like. Needs also exists for systems and methods, and devices that can provide the type of accurate, reproducible and objective data described above without inherently and/or indirectly adversely impacting the accuracy, reproducibility, and/or objectiveness of the tests and measured data therein.

SUMMARY

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

According to various embodiments a limb manipulation and evaluation device including three drives is provided. The device comprises: a first drive configured to manipulate a first bone relative to a second bone in a first direction; a second drive configured to manipulate the first bone relative to the second bone in a second direction; and a third drive configured to manipulate the first bone relative to the second bone in a second direction. The first, second, and third directions are different relative to each other, and at least one of the drives is mutually decoupled relative to another drive, such that operation of the one drive does not affect the position or movement of the another drive.

According to various embodiments a limb manipulation and evaluation device including three drives is provided. The device comprises: a first drive configured to manipulate a first bone relative to a second bone about a first axis; a second drive configured to manipulate the first bone relative to the second bone about a second axis; and a third drive configured to manipulate the first bone relative to the second bone about a third axis, wherein: the first, second, and third axes are each oriented at an angle relative to each other, and at least one of the drives is mutually decoupled relative to another of the drives, such that operation of the one drive does not affect the rotational axis of the another of the drives.

According to various embodiments a limb manipulation and evaluation device including three drives is provided. The device comprises: a first drive configured to manipulate a first bone relative to a second bone about a first axis, a second drive configured to manipulate the first bone relative to the second bone about a second axis, and a third drive configured to manipulate the first bone relative to the second bone about a third axis, wherein: the first, second, and third axes are each oriented at an angle relative to each other, and at least two of the drives are decoupled relative to a third drive, such that operation of either of the two drives does not affect the rotational axis of the third drive.

According to various embodiments a limb manipulation and evaluation device including three drives is provided. The device comprises: a first drive configured to manipulate a first bone relative to a second bone about a first axis, a second drive configured to manipulate the first bone relative to the second bone about a second axis, and a third drive configured to manipulate the first bone relative to the second bone about a third axis, wherein: the first, second, and third axes are each oriented at an angle relative to each other, and at least one of the drives is mutually decoupled relative to the other two drives, such that operation of the at least one drive does not affect the rotational axis of the other two drives.

According to various embodiments a limb manipulation and evaluation device including three drives is provided. The device comprises: a first drive configured to manipulate a tibia relative to a femur about a first axis, the first drive providing internal and external rotation of the tibia relative to the femur; a second drive configured to manipulate the tibia relative to the femur about a second axis, the second drive providing anterior-posterior movement of the tibia relative to the femur, and a third drive configured to manipulate the tibia relative to a femur about a third axis, the third drive providing valgus-varus movement of the tibia relative to the femur, wherein: the first, second, and third axes are each oriented at an angle relative to each other; the first drive is decoupled from the second drive; and the first and second drives are coupled with the third drive.

According to various embodiments a limb manipulation and evaluation device including three drives is provided. The device comprises: a first drive configured to manipulate a tibia relative to a femur about a first axis, the first drive providing internal and external rotation of the tibia relative to the femur; a second drive configured to manipulate the tibia relative to the femur about a second axis, the second drive providing anterior-posterior movement of the tibia relative to the femur, and a third drive configured to manipulate the tibia relative to a femur about a third axis, the third drive providing valgus-varus movement of the tibia relative to the femur, wherein: the first, second, and third axes are each oriented at an angle relative to each other; the first drive is coupled to the third drive; the second drive is decoupled from the first and third drives; and the third drive is decoupled from the first and second drives.

According to various embodiments a method of using three drives to manipulate a first bone relative to a second bone is provided. The method comprises the steps of: operating a first drive configured to manipulate the first bone relative to the second bone about a first axis; operating a second drive configured to manipulate the first bone relative to the second bone about a second axis; and operating a third drive configured to manipulate the first bone relative to the second bone about a third axis, wherein: the first, second, and third axes are each oriented at an angle relative to each other, and the operation of at least one of the drives is mutually decoupled relative to each other, and the operation of at least one of the drives is mutually decoupled relative to another of the drives, such that the operation of the one drive does not affect the rotational axis of the another of the drives.

In a broad aspect, the present invention pertains to a limb manipulation and evaluation device comprising a frame, a first drive supported by the frame and configured to manipulate a first bone relative to a second bone in a first direction, a second drive supported by the frame and configured to manipulate the first bone relative to the second bone in a second direction, and a third drive supported by the frame and configured to manipulate the first bone relative to the second bone in a third direction. The first, second and third directions are different relative to each other. At least one drive of the first, second and third drives is mutually decoupled relative to another drive of the first, second and third drives, such that operation of the one drive does not affect position of the another drive relative to the frame and such that operation of the another drive does not affect position of the one drive.

In a further aspect, the present invention provides a method of manipulating a first bone relative to a second bone, the method comprising operating a first drive configure to manipulate the first bone relative to the second bone about a first rotational axis, operating a second derive configured to manipulate the first bone relative to the second bone about a second rotational axis, and operating a third drive configured to manipulate the first bone relative to the second bone about a third rotational axis. The first, second and third rotational axes are each oriented at an angle relative to each other. the operation of at least one drive of the first, second, and third is mutually decoupled relative to another drive of the first, second, and third drives, such that the operation of the one drive does not affect a rotation axis of the another drive, and such that the operation of the another drive does not affect a rotational axis of the one drive.

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 to scale. In the drawings:

Figure 1 is a perspective view of the overall device **10**, including two tibia positioning assemblies **1000** according to various embodiments;

Figure 2 is a view of a portion of Figure 1, and in particular illustrates a perspective view of the two tibia positioning assemblies **1000** according to various embodiments;

Figure 3 is an isolated view of the various elements of the tibia positioning assembly **1000** according to various embodiments;

Figure 4 is an exploded view of the various elements of the tibia positioning assembly **1000** of Figure 3 according to various embodiments;

Figure 5 is a view of the tibia positioning assembly **1000** of Figure 3, but from an alternative facing perspective relative to that of Figure 3, illustrating exemplary axes X, Y, and Z of rotation, along with calf bias assembly **1500** according to various embodiments;

Figure 6 is yet another view of the tibia positioning assembly **1000** of Figures 3 and 6, also illustrating an exemplary foot plate assembly **1300** according to various embodiments;

Figure 7 is an exploded view of the various elements of a sliding frame assembly **1100** and a "Y" axis drive assembly **2100** of the tibia positioning assembly **1000** of Figure 3 according to various embodiments;

Figure 8 is a top plan view of the tibia positioning assembly **1000** of Figure 3, in an exemplary "right leg" configuration according to various embodiments;

Figure 9 is a side view of the tibia positioning assembly **1000** of Figure 8 according to various embodiments;

Figures 10 and 11 illustrate two sequential steps of movement of the device during operation of a "X" axis drive assembly **2000** according to various embodiments;

Figure 12 illustrates a view along the "Z" axis of the tibia positioning assembly **1000** of Figure 3 according to various embodiments, further illustrating exemplary X, Y, and Z axis drive assemblies **2000**, **2100**, and **2200** (note that the illustrated "Z" axis extends positive perpendicular to the foot plate extending distal to the foot plate, the illustrated "Y" axis extends positive straight up from "Z" axis and away from floor/ground, and the illustrated "X" axis is parallel to the bottom of the foot plate and is also parallel to the floor/ground according to various embodiments so as to provide three mutually orthogonal axes);

Figure 13 is an alternate configuration according to various embodiments, illustrating the use of exemplary spherical elements **3001, 3002** for manipulating the lower leg of a patient (shown in dotted line)about centers of the spheres, wherein sphere **3001** is driven by an exemplary roller and drive assembly **3001A**;

Figure 14 is another alternate configuration illustrating the use of an exemplary spherical element **3003** according to various embodiments, with a center of rotation **C3**locatedeven further distal to the foot and an exemplary calf bias member (aka extender bar); and

Figure 15 is yet another alternate configuration including a spherical cage **4000** comprised of a plurality of cage bars **4005** according to various embodiments.

Figure 16 shows an alternate configuration for the L Bracket 1220, in that L Bracket **1220**, which supports the Z Drive motor, can if desired slide along the Z axis relative to pivoting plate assembly **1200** in order to accommodate "pistoning" of foot in varus valgus procedure, allowing for the foot to move in a more natural arc during varus-valgus testing. The foot plate and motor all move together.

Figure 17 is a side illustrative view of a leg testing apparatus **5000**, in combination with an exemplary CT scanner **4900**, and a patient's body support apparatus **4950**. The three devices are configured to be typically situated atop an unnumbered supporting surface. Also shown is an exemplary patient, including a patient upper body **4951**, patient lower leg **4950**, and patient upper leg **4950**.

The patient body support apparatus **4950** includes a patient back support **4956**, a shoulder restraint **4959**, and a thigh restraint **4952**.

Figure 18 is a perspective view of a leg testing apparatus **5000** according to one aspect of the present inventions, which includes left lower leg supporting apparatus **5200**, right lower leg supporting apparatus **5300**, and lower frame number **5100**.As maybe seen, the "Z" axes of the two apparatuses **5200**, and **5300**, are not aligned. This will be discussed elsewhere in this application.

Figure 19 is a top elevation view of the leg testing apparatus **5000** of Figure 18, illustrating the relationship of the left lower leg supporting apparatus **5200** and the right lower leg supporting apparatus **5300**, relative to the inner surface of the scanning device **4900**. As may be seen, the "X" axes of the two apparatuses **5200**, and **5300**, are also not aligned, and in the embodiment shown, the angle between the two is fixed.

Figure 20 is a rear elevation view of the leg testing apparatus **5000** of Figure 18, which includes left lower leg supporting apparatus **5200**, right lower leg supporting apparatus **5300**, and lower frame number **5100**.

Figure 21 is a front elevation view of the leg testing apparatus **5000** of Figure 20.

Figure 22 is a pictorial view of the right lower leg supporting apparatus **5300**, with certain elements not included for purposes of explanation.

Figure 23 is a right side elevation view of the right lower leg supporting apparatus **5300**, with certain elements not shown for purposes of explanation.

Figure 24 is a pictorial view of a portion of the right lower leg supporting apparatus **5300** of Figure 23, showing certain details.

Figure 25 is a pictorial view of a portion of the right lower leg supporting apparatus **5300**, taken from the opposite side as that shown in Figure 24.

Figures 26A and 26B show two sequential illustrative views similar to Figure 17, except that the leg testing apparatus **5000** is configured to be moved between the two positions shown, resulting in different flexions of the knee (Note that 26A knee is in a more extended position than the 26B knee.)

DETAILED DESCRIPTION OF VARIOUS EMBODIMENTS

Various embodiments of the present invention will now be described more fully hereinafter with reference to the accompanying drawings, in which some, but not all embodiments of the invention are shown. Indeed, embodiments of the invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Unless otherwise defined, all technical and scientific terms used herein have the same meaning as commonly known and understood by one of ordinary skill in the art to which the invention relates. The term "or" is used herein in both the alternative and conjunctive sense, unless otherwise indicated. Like numbers refer to like elements throughout.

I. ELEMENT LIST

10 Overall RKT apparatus

- 20 main frame assembly
- 30 support cushion
- 40 sliding support framework
- 50 pivoting leg support frame assemblies (2)
- 60 knee support/stabilizing assemblies (2)
- 80 thigh retention assemblies (2)

1000 tibia positioning assembly

1100 sliding frame assembly (supports Y drive assembly)

- 1101 sliding frame members (figure 7)
- 1102 bearings (figure 7)
- 1103 flange adaptor (figure 7)
- 1104 torque transducer (Y axis)
- 1110 frame cap assembly (attached to pivot plate)

1200 pivoting plate assembly (supports X/Z/yoke/calf)

- 1201 pivoting plate
- 1210 L-shaped flange brackets (2) (support X)
- 1211 bearing (support X)
- 1212 stub flange (supports yoke/calf)
- 1213 flange bracket (supports yoke/calf)
- 1220 L bracket (support Z)
- 1221 flange adaptor (support Z)

1222 torque transducer (Z axis)

1300 foot rotation assembly

1400 yoke assembly (figure 4)

1410 yoke top plate

1420 yoke end plates (2)

1430 limit plate

1500 calf bias assembly

1510 side leg members (2)

1520 plate

1530 torque transducer (X axis)

1540 stub flange

1550 bearing

1560 telescoping rod assembly

1570 calf bias plate

2000 x-axis drive assembly

2010 drive motor

2020 gear box

2030 output shaft

2100 y-axis drive assembly

2110 drive motor (Figure 7)

2120 gear box

2130 output shaft

2200 z-axis drive assembly

2210 drive motor

2220 gear box

2230 output shaft

3001 Spherical member (with center C1)

3002 Spherical member (with center C2)

3003 Spherical member (with center C3)

4000 Spherical cage

4900 Exemplary CT scanning device
- 4950 Patient body support apparatus
- 4951 Link
- 4952 Patient thigh restraints
- 4956 Patient back support
- 4959 Patient shoulder restraint

- 4960 Patient body
- 4961 Patient upper body
- 4962 Patient upper leg
- 4964 Patient Lower leg

5000 Overall Leg Testing Apparatus
- 5100 Lower Frame Member
  - 5101 Slide assemblies (4 shown)
- 5200 Left Lower Leg Supporting Apparatus
- 5260 Calf bias assembly
- 5300 Right Lower Leg Supporting Apparatus

5400 X Drive Assembly (for AP)
5500 Y Drive Assembly (for Varus Valgus)
- 5501 Coupling
- 5502 Vertical Shaft
- 5504 Lower Bearing
- 5505 Upper Bearing
- 5507 Plate-to-shaft mounting flange

5600 Z Drive Assembly (for internal and external rotation)

5300 Right Lower Leg Supporting Apparatus
5310 Lower Vertical Frame Members (2)
5312 Lower Frame Table
5314 Intermediate Vertical Frame Members (2)

5320 Intermediate Frame Table
5322 Short Upper Vertical Frame Members (2)
5330 Upper Frame Table
5332 Long Upper Vertical Frame Members (2)
5340 Pivoting Horizontal Foot Support Plate
5341 Pivoting Vertical Foot Support Flange
5344 Foot Plate
5340 Yoke Assembly
- 5342 yoke top plate
- 5344 yoke end plates (2)
- 5346 limit plate

5360 Calf bias assembly (Similar to calf bias assembly 1500)
- 5362 Calf bias plate
- 5363 Extendible rod assembly
- 5364 Side leg members (2)

II. DETAILED DESCRIPTION

Reference will now be made in detail to one or more embodiments of the present assembly, an example of which is illustrated in the accompanying drawings. The embodiments are described by way of explanation, and not by way of limitation. Indeed, embodiments of the invention may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein. Rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements.

A) THE OVERALL APPARATUS 10

1. Generally

As illustrated in at least Figures 1-4, various embodiments of the overall RKT (Robotic Knee Testing) device **10** may include the following features:

Main Frame Assembly **20**(Figure 2);
Support Cushion **30**(Figure 2);
Sliding Support Framework **40**(Figure 2);
Two (2) Pivoting Leg Support Frame Assemblies **50**(Figure 2);
Two (2) Knee Support/Stabilizing Assemblies **60** (Figure 2);

Two (2) Thigh Retention Assemblies **80** (Figure 2);

Two (2) Tibia Positioning Assemblies **1000** (Figure 2);

Sliding Frame Assembly **1100** (Figure 3);

Pivoting Plate Assembly **1200** (Figure 4);

Two (2) Foot Rotation Assemblies **1300** (Figure 3);

Yoke Assembly **1400** (Figure 3);

Calf Bias Assembly **1500** Figure 3);

"X" axis Drive Assembly **2000** (Figure 4);

"Y" axis Drive Assembly **2100** (Figure 4); and

"Z" axis Drive Assembly **2200** (Figure 4).

With particular reference to Figure 2, it should be understood that according to various embodiments, at least certain elements of the overall RKT device **10** may be sized, shaped, and/or configured in substantially the same manner as the device described in co-owned U.S. Patent Application Publication No. 2012/0046540-A1, as published on February 23, 2012, which may be referred to for further details. As non-limiting examples, the main frame assembly **20**, the support cushion **30**, the sliding support framework **40**, the pivoting leg support frame assembly **50**, the knee support/stabilizing assembly **60**, and the thigh retention assembly **80** illustrated in at least Figure 2 may be configured, sized, and/or shaped substantially the same as the comparable elements, as described in U.S. publication 2012/0046540 A1, which may be referred to for further details. Of course, certain embodiments, including those indicated hereinabove or otherwise, of the overall RKT device **10** may have one or more of these elements sized, shaped, and/or configured in a substantially different manner than that described in Serial No. 13/209,380, as may be desirable for one or more applications.

In use, as will be descried in further detail below, a patient (see Figures 10-11) 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**, their thighs are adjacent the thigh retention assemblies **80**, and their feet are retained within the tibia pivoting assemblies **1000**, particularly adjacent a foot plate **1300** thereof (see Figure 4).

Movement of the lower leg of the patient may be detected by non-invasive systems utilizing sensors or markers that are attached to the skin, including but not limited to optoelectronic, ultrasonic, and electromagnetic motion analysis systems.

<u>2. *Tibia Positioning Assemblies* ***1000***</u>

According to various embodiments, with reference to Figure 2, the overall RKT device **10** comprises may comprise two tibia positioning assemblies **1000,** each generally configured to support and/or constrain at least one of a patient's tibia and foot so as to facilitate evaluation of movement thereof in response to the imposition of one or more forces about one or more axes (e.g., the X, Y, and/or Z axes, as described later herein). In certain embodiments, the two the tibia positioning assemblies **1000** may be substantially identical in size, shape, and configuration. In other embodiments, only a single tibia positioning assembly **1000** may be provided, for example, where only a single leg of a patient is of concern for treatment.

It should be noted, however, that according to various embodiments, at least the X-axis drive assemblies **2000** of Figure 4 that form a portion of each tibia positioning assembly **1000** may be configured so as to be substantially mirror images of one another, even though such a configuration is not expressly illustrated in Figure 2. Instead, in the illustrated embodiment of Figure 2, the "X" axis drive assemblies **2000** (see again Figure 4) are not substantially mirror images of one another, as may be desirable for certain applications. In those embodiments involving mirror image positioned X axis drive assemblies **2000**, however, it should be understood that when certain movements (e.g., anterior-posterior, varus-valgus, internal-external rotation, etc.) are imposed upon the patient's limb during operation, the same movement and in particular the same orientation of movement will be imposed upon both limbs. As a non-limiting example, when anterior movement is imposed upon a patient's first tibia via rotation of one of the drive assemblies, the same activation signal will likewise impose anterior movement upon the patient's second tibia in those embodiments having the X axis drive assemblies positioned as substantial mirror images relative to one another. In contrast, in those other embodiments, as may be desirable for particular applications, where the tibia positioning assemblies **1000** may not be "mirror-imaged" relative to one another, a single activation signal would impose anterior movement upon one tibia and posterior movement upon the other (or varus upon one and valgus upon the other, or internal rotation upon one and external rotation upon the other, etc.). This should be understood with reference to at least Figures 2 and 4 in concert with one another.

With that in mind and turning now to Figures 3 and 4 in combination, various embodiments of each tibia positioning assembly **1000** (isolated for purposes of a concise and clear disclosure) generally comprise a sliding frame assembly **1100**, a pivoting plate assembly **1200**, a foot rotation assembly **1300**, a yoke assembly **1400**, a calf bias assembly **1500**, a X-axis drive assembly **2000**, a Y-axis drive assembly **2100**, and a Z-axis drive assembly **2200**. These assemblies will now be described, in turn, below.

3. Sliding Frame Assembly 1100

According to various embodiments, each tibia positioning assembly **1000** comprises a sliding frame assembly **1100** that provides an interface between at least the Y-axis drive assembly **2100** and the main frame assembly **20** of the RKT device**10**. As may be seen from Figure 2, the sliding frame assembly **1100** is, in certain embodiments, linearly slidable along the pivoting leg support frame assembly **50**, so as to accommodate varying lengths of patient legs. In at least one embodiment, the sliding frame assembly **1100** may be configured for translational movement relative to the pivoting leg support frame assembly **50** and/or the main frame assembly **20** of the RKT device **10** in a manner substantially the same as the sliding frame **120** described in U.S. Publication No. 2012/ 0046540-A1, as noted previously, and as may be desirable for one or more applications.

Turning for a moment to Figure 7, it may be seen that the sliding frame assembly **1100** generally comprises a plurality of sliding frame members **1101**, each configured to form a platform for substantially supporting a first (e.g., lower positioned) portion of the Y-axis drive assembly **2100**. In certain embodiments, the sliding frame assembly **1100** comprises a pair of bearings **1102** and a flange adaptor **1103** configured to attach a second (e.g., higher positioned) portion of the Y-axis drive assembly **2100** relative to the pivoting plate assembly **1200**, as will be described in further detail below.A torque transducer **1104** may also be provided to evaluate the torque along the drive line between an output shaft **2130**of the Y-axis drive assembly **2100** and a pivoting plate **1201**, all as will be described in further detail below. In these and still other embodiments, the sliding frame assembly **1100** may further comprise a frame cap assembly **1110**, which incorporates a plurality of members (shown, but not numbered) that cover (and thus protect) the second portion of the Y-axis drive assembly **2100**.

Remaining with Figure 7 and also with reference to Figures 5-6, it should be understood that the sliding frame assembly **1100**, beyond being configured to permit selectable translational movement thereof relative to the main frame assembly **20** of the RKT device **10**, is configured to support the Y-axis drive assembly **2100**such that a longitudinal axis thereof lies substantially along the Y-axis (*see* in particular Figures 5 and 6). In this manner, during operation of the RKT device **10**, activation of the Y-axis drive assembly **2100** provides rotation about the Y-axis. As should be understood from Figures 1-4 generally, such rotation about the Y-axis, as has been previously mentioned, may in turn be configured to impose varus-valgus movement upon an associated positioned patient's leg.

It should also be noted, with reference to Figures 4-5 and 7, and as will be described in further detail below in the context of operation of the RKT device **10**, the pair of bearings **1102** and the flange adaptor **1103**, which operatively connect the Y-axis drive assembly **2100** and the sliding frame assembly **1100** relative to the pivoting plate assembly **1200** are configured such that rotation about the Y-axis results in corresponding movement of the foot plate **1300** and thus the patient's foot and/or tibia about the same. Such movements, imposed as the result of operation will, however, be described in further detail elsewhere herein.

*4. Pivoting Plate Assembly **1200***

Returning now with particular emphasis upon Figure 4, the pivoting plate assembly **1200** of the tibia positioning assembly **1000** is illustrated. The pivoting plate assembly **1200** according to various embodiments comprises a pivoting plate **1201**, which is mounted relative to the sliding frame members **1101** of the sliding frame assembly **1100** (see, e.g., Figure 7). In certain embodiments, as illustrated in Figure 4, the pivoting plate **1201**is mounted to the frame cap assembly **1110**(see again Figure 7), so as to also provide a platform for supporting the X-axis and Z-axis drive assemblies **2000**, **2200**, the configuration of which as will be described elsewhere herein.

In various embodiments, as mentioned, the pivoting plate assembly **1200** comprises a pivoting plate **1201** that is mounted to the frame cap assembly **1110**. In this manner, the mounting of the pivoting plate **1201** relative to the frame cap assembly **1110** serves to fixedly couple movement of the pivot plate **1201** to movement imposed by the Y-axis drive assembly **2100** about the Y-axis.

The pivoting plate assembly **1200** according to various embodiments further comprises a pair of L-shaped flange brackets **1210**(see Figure 4), each configured to be mounted on opposing ends of the pivoting plate **1201**, such that the X-axis drive assembly **2000** may be mounted there-between. In certain embodiments, as may be seen in Figure 4, each of the L-shaped flange brackets **1210** may comprise an opening configured to receive at least a portion of the X-axis drive assembly **2000**. In at least the illustrated embodiment, the pivoting plate assembly **1200** further comprises a bearing

1211 and a stub flange **1212**, each of which are mounted adjacent the second of the two L-shaped flange brackets **1210**, namely further adjacent the drive motor **2010** of the X-axis drive assembly **2000**. A flange bracket **1213** is similarly attached adjacent the first of the two L-shaped brackets **1210**, namely substantially adjacent the gear box **2020** of the X-axis drive assembly **2000**. In this manner, the L-shaped flange brackets **1210** provide stable support for the X-axis drive assembly **2000**.

With continued reference to Figure 4, it should be understood that the configuration of the previously described components of the pivoting plate assembly **1200** relative to the X-axis drive assembly **2000** are configured such that rotation of the X-axis drive assembly substantially about the X axis (see Figure 5) translates into rotational movement of the yoke assembly **1400** and the calf bias assembly **1500**, both as will be described in further detail below. Such movement is imparted due, at least in part, to the further mounting of the flange bracket **1213** and the stub flange **1212** of the pivoting plate assembly **1200** to opposing ones of a pair of side leg members **1510** of the yoke assembly **1500**, again, as will be detailed further below.

Beyond the above-described components of the pivoting plate assembly **1200** configured to support and/or translate movement imposed by the X-axis drive assembly **2000**, the plate assembly **1200** further comprises according to various embodiments certain components configured to support the Z-axis drive assembly **2200**.In particular, with continued reference to Figure 4, it may be seen that the pivoting plate assembly **1200** in certain embodiments further comprises an L bracket **1220**, a flange adaptor **1221**, and a torque transducer **1222**, all oriented relative to and along the Z-axis.

The L bracket **1220** according to various embodiments is mounted to the pivoting plate **1201** such that it is oriented substantially perpendicular relative to the pair of L-shaped flange brackets **1210**described previously herein as being configured for supporting the X-axis drive assembly **2000**. In this manner, as illustrated further in Figures 5-6, it should be understood that the X-axis drive assembly **2000** and the Z-axis drive assembly **2200** are likewise positioned substantially perpendicular relative to one another, so as to provide respective rotation about the likewise mutually perpendicular X and Z axes.

The flange adaptor **1221** and the torque transducer **1222** are likewise mounted to the L bracket **1220** and the foot plate **1300**(described elsewhere herein), such that rotational movement of the Z-axis drive assembly **2200** is converted into a rotational force about the Z-axis that is not only measured by the torque transducer **1222** (e.g., to ensure an appropriate or desired force is supplied/imposed) but also transferred onto the foot plate **1300**, resulting in corresponding rotational movement thereof about the Z-axis. Notably, as will be described further below, the rotational movement of the foot plate **1300** about the Z-axis is configured to provide internal and/or external rotation a patient's tibia during operational testing performed according to various embodiments.

*5. Foot Rotation Assembly **1300***

According to various embodiments, as may be understood from at least Figures 3-4 and 7, the foot plate assembly **1300** of each of the tibia positioning assemblies **1000** may be pivotably mounted relative to the pivoting plate assembly **1200** of the (linearly) sliding frame assembly **1100** via the Z-axis drive assembly **2200**, as will be described in further detail below. In certain embodiments, the foot plate assembly **1300** is configured to rotate about the Z axis in response to rotation of (e.g., to) an output shaft **2230** of the Z-axis drive assembly **2200** (see also Figure 7), as will also be described in further detail below. In these and still other embodiments, with reference also to Figure 4, the foot plate assembly **1300** is mounted in series to the torque transducer **1222**, the flange adapter **1221**, and the L bracket **1220** of the pivoting plate assembly **1200**.

With reference again to Figure 3 and also to Figure 10, it should be understood that rotation of the foot plate assembly **1300** about the Z axis, as imposed by the Z-axis drive assembly **2200** is configured to provide movement for tibia internal and external rotation testing. Details of the drive assembly **2200** will be described in further detail below in the context of operational parameters of the RKT device **10**.

It should also be understood, however, that rotation of the pivoting plate assembly **1200** about the Y axis, via the "Y" Axis drive assembly will also impose movement upon the foot plate **1300**, namely via its fixed mounting relative to at least the pivoting plate assembly about the "Y" axis. In other words, in certain embodiments, although the foot plate **1300** may be configured to rotate about the Z axis, it may also be configured to move (e.g., to swivel) in response to rotation of the pivoting plate assembly **1200** about the Y axis, all as will be described in further detail below.

*6. Yoke Assembly **1400***

Returning to Figures 3-4 and 7, various embodiments of the tibia positioning assembly **1000** further comprise a yoke assembly **1400**. In certain embodiments, the yoke assembly **1400** comprises a yoke top plate **1410**, a pair of yoke end plates **1420**, and at least one limit plate **1430**. Each of these components may be seen, in particular, in the exploded view of Figure 4.

Indeed, with particular reference to Figure 4, the yoke end plates **1420** are generally configured according to various embodiments to operatively mount, respectively, to the flange bracket **1213** and the stub flange **1212** of the pivoting plate assembly **1200**, as such components have been previously described herein. In certain embodiments, respective side leg members **1510** of a calf bias assembly **1500**, as will be described below, may be positioned intermediate the yoke end plates **1420** and the respective flange bracket **1213** and stub flange **1212**. In this manner, as will be described in further detail below, rotational forces imposed by rotational movement of the X-axis drive assembly **2000** about the X-axis may be transferred from the drive assembly**2000** and onto both the side leg members **1510** of the calf bias assembly **1500** and the yoke end plates **1420** of the yoke assembly **1400**.

Remaining with Figure 4 and also with reference to Figure 5, it may be seen that the yoke top plate **1410** is, according to various embodiments, positioned so as to extend substantially between the respective yoke end plates **1410**. In this manner, as rotational movement of the X-axis drive assembly **2000** transfers rotational movement onto the yoke end plates **1420**, the latter further transfers the same rotational movement onto the yoke top plate **1410**. In certain embodiments, the limit plate **1430** of the yoke assembly **1400**may be further configured with at least two rubber stops that are positioned so as to contact opposing sides of the yoke top plate **1410** and thus define a "limited" range of motion thereof, in response to rotational movement imposed by the X-axis drive assembly **2000**. In this manner, a degree of movement and/or force and/or torque that may be imposed upon a patient's limb may be restricted for joint protection and/or patient comfort.

Still further, it should be appreciated that the yoke assembly **1400**, and in particular, the yoke end plates **1420** are further configured to transfer rotational movement imposed by the X-axis drive assembly **2000** onto at least the side leg members **1510** of the calf bias assembly **1500**, as described immediately below. Of course, in certain embodiments, it should be appreciated that it is the flange bracket **1213** and the stub flange **1212** of the pivot plate assembly **1200** and their respectively fixed mounts to each of the yoke end plates **1420** and the side leg members **1510** that transfers the rotational movement thereupon. In other embodiments, the yoke assembly **1400**may be otherwise configured, as may be desirable for particular applications.

Returning for a moment to Figure 4, with reference also to Figures 10-11, it should be appreciated that the above-described transference of rotational force (and thus movement) from the X-axis drive assembly **2000** is configured such that the RKT device **10** may pivot, as illustrated, along the X-axis, so as to move a patient's tibia from the illustrated position of Figure 10 to that of Figure 11 (and vice versa). Of course, such rotation involves not only rotational movement of the yoke assembly **1400** about the X-axis, but also the same by the calf bias assembly **1500**, which will now be described immediately below. As also described in further detail below, in certain embodiments, such movement may impose rotational movement of the patient's limb, whether about the same X-axis or about a secondary and parallel X-axis, as may be seen in at least Figure 10. These and other features, as may be appreciated better with consideration to relative movements imposed during operation of the RKT device will be described in further detail below.

*7. Calf Bias Assembly **1500***

According to various embodiments, returning again to Figure 4, the tibia positioning assembly **1000** further comprises a calf bias assembly **1500**, which may itself comprise a pair of side leg members **1510**, a cross plate **1520**, a torque transducer **1530**, a stub flange **1540**, a bearing **1550**, a telescoping rod assembly **1560**, and a calf bias plate **1570**.

With continued reference to Figure 4, the pair of side leg members **1510** are, according to various embodiments, fixedly attached at a first end thereof to the flange bracket **1213** and the stub flange **1212** of the pivoting plate assembly **1200**, which also supports at least the X-axis drive assembly **2000** and the yoke assembly **1400**. In this manner (i.e., via this connection/attachment), the calf bias assembly **1500** is likewise supported by the pivoting plate assembly **1200** according to various embodiments.

Opposing ends of the side leg members **1510** are configured according to various embodiments to mate with either a stub flange **1540** / bearing **1550** pairing or a torque transducer **1530**. Such is configured substantially the same as the torque transducer **1222** and the bearing **1211** / stub flange **1212** pairing previously described herein. In other words, the torque transducer **1530** is configured to measure and transfer a force imposed upon the side leg members **1510** by the X axis drive assembly **2000** onto at least the plate **1520** and/or the calf bias plate **1570** of the calf bias assembly **1500**.

Returning to Figure 4, a plate **1520** and a telescoping rod assembly **1560** are also provided and configured to fixedly link the torque transducer **1530** to the calf bias plate **1570**. With reference to Figures 10-11, and as will be described in further detail below, this configuration facilitates transfer of the rotational force (and thus torque) imposed upon the yoke assembly **1400** by the X-axis drive assembly **2000** onto not only the calf bias assembly **1500**, but also the patient's tibia positioned substantially adjacent to the the calf bias plate **1570**. Indeed, as should be understood from these figures, imposing a force in the clockwise direction (relative to Figures 10-11, in particular) results in a substantially "upward" movement of the tibia, further accompanied by rotation about the illustrated tibia pivot point. In this manner, as will be described in further detail, activation of the X axis drive assembly results in forces being applied to the tibia substantially along the Y axis in the anterior and/or posterior direction relative to the tibia.

Although reference has been made herein to a telescoping rod assembly **1560**, which should be understood to be extendable in length (e.g., between the calf bias plate **1570** and the plate **1520** adjacent the pivoting plate assembly **1200**, certain embodiments may have otherwise configured assemblies **1560**, provided such are capable of accommodating differing lengths of patient's legs positioned adjacent thereto. In still other embodiments, the rod assembly **1560** may even not be adjustable, in a telescoping fashion or otherwise, as may be desirable for particular applications.

<u>*8. "X"-axis Drive Assembly **2000***</u>

Remaining with Figure 4, the X-axis drive assembly **2000** is illustrated, as configured such that a longitudinal axis thereof lies substantially along the further illustrated X-axis, as also defined in at least Figure 5. With reference to Figures7 and 12, it should be understood that various embodiments of the X-axis drive assembly **2000** comprise a drive motor **2010**, a gear box **2020**, and an output shaft **2030** operatively coupled to the gear box.

In certain embodiments, the drive motor **2010** may comprise a servomotor configured to provide a rotational force, although still other embodiments may include alternative mechanical or even manual methods of force generation and application, as may be desirable for particular applications and as commonly known and understood in the art. 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.

In certain embodiments, the drive motor **2010**, however particularly configured, may be at least configured with a housing mounted relative to the pivoting plate assembly **1200**, such that the drive motor drives the corresponding output shaft **2030**, which itself drives at least the yoke assembly **1400** and the calf bias assembly **1500** based upon the structural relationships previously described herein. In this manner, according to various embodiments, the X-axis drive assembly **2000** is configured to facilitate rotation of at least a portion of the RKT device **10** about the X-axis (see Figure 5), such that a user of the device may evaluate "AP" (anterior-posterior) movement of the tibia with respect to the femur at the knee about an X-axis of rotation distal to the foot.

*9. "Y"-axis Drive Assembly **2100***

Turning now with particular reference to Figure 7, the Y-axis drive assembly **2100** is illustrated, as may be configured according to various embodiments such that a longitudinal axis thereof lies substantially along the Y-axis, the latter of which as is defined in at least Figure 5. With reference to Figure 12, it should be understood that various embodiments of the Y-axis drive assembly **2100** comprise a drive motor **2110**, a gear box **2120**, and an output shaft **2130** operatively coupled to the gear box.

In certain embodiments, the drive motor **2110** may comprise a servomotor configured to provide a rotational force, although still other embodiments may include alternative mechanical or even manual methods of force generation and application, as may be desirable for particular applications and as commonly known and understood in the art. 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.

In certain embodiments, the drive motor **2110**, however particularly configured, may be at least configured with a housing mounted relative to the pivoting plate assembly **1200**, such that the drive motor drives the corresponding output shaft **2130**, which itself imposes rotation upon at least the pivoting plate assembly **1200** and thefoot plate assembly **1300**based upon the structural relationships previously described herein. In this manner, according to various embodiments, the Y-axis drive assembly **2100** is configured to facilitate rotation of the foot plate assembly **1300** about the Y-axis (see Figure 6), such that a user of the device may evaluate varus-valgus conditions about a Y-axis of rotation distal to the foot.

10. "Z"-axis Drive Assembly ***2200***

Returning again to Figures4 and 12, the Z-axis drive assembly **2200** is illustrated according to various embodiments, as may be configured such that a longitudinal axis thereof lies substantially along the Z-axis, the latter of which as is defined in at least Figure 5. With reference to Figure 12, it should be understood that various embodiments of the Z-axis drive assembly **2200** comprise a drive motor **2210**, a gear box **2220**, and an output shaft **2230** operatively coupled to the gear box.

In certain embodiments, the drive motor **2210** may comprise a servomotor configured to provide a rotational force, although still other embodiments may include alternative mechanical or even manual methods of force generation and application, as may be desirable for particular applications and as commonly known and understood in the art. 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.

In certain embodiments, the drive motor **2210**, however particularly configured, may be at least configured with a housing mounted relative to the foot plate assembly **1300** based upon the structural relationships previously described herein. In this manner, according to various embodiments, the Z-axis drive assembly **2200** is configured to facilitate rotation of the foot plate assembly **1300** about the Z-axis (see Figure 6), such that a user of the device may evaluate (internal-external) movement about a Z-axis of rotation.

It should further be understood that any of the X-, Y-, or Z-axis drive assemblies **2000-2200** may be structurally configured substantially the same relative to one another, with the only substantive difference being the relative axis of rotation about which each is oriented. Of course, it should also 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.

It should also be understood that although in certain embodiments, the X-, Y-, and/or Z-axis drive assemblies **2000-2200** may be oriented such that at least two thereof are mutually orthogonal and intersecting relative to one another, in other embodiments, one or more of the drive assemblies **2000-2200** may be offset relative to the remainder of the drive assemblies, such that non-intersecting, although orthogonal axes are defined.

This feature and further variations thereof are described in further detail elsewhere herein, and may be understood generally with reference to at least Figure 7 (showing how the Y and X axis may be offset relative to one another, as along a longitudinal axis of the RKT device in its entirety); Figures 8 and 9 (showing the same relative offset between the X and Y axes, when viewed in combination); and Figures 13-15 (as will be described elsewhere herein).

B) OVERALL OPERATION

Each of the various above-described features and their use will now be described in further detail herein-below.

1. Generally

Three drive assemblies are used, namely a "X" axis drive assembly **2000**, a "Y" axis drive assembly **2100**, and a "Z" axis drive assembly **2200**. Each drive assembly can be understood to include, in various embodiments, a mounting frame, a drive motor and a gearbox having an output shaft, as all previously described herein. By operation of any of the drive motors, rotational movement is provided to a corresponding output shaft with intermediate reduction (or expansion) gearing as needed to provide adequate torque and rotational speed.

According to various embodiments, torque sensors are provided in the power line in order to provide torque readings as known in the art relating to each of these three drive assemblies. These torque readings may be calibrated and calculated as needed to correspond to known torque or force values imparted to a patient's limb(s).

As noted elsewhere, movement of the patient's body parts may be detected by non-invasive systems utilizes sensors or markers that are attached to the skin, including but not limited to vision, optoelectronic, ultrasonic, and electromagnetic motion analysis systems.

The three drive assemblies are configured about mutually perpendicular X-, Y-, and Z-axes of rotation, as illustrated in at least Figure 5. As such, the respective forces (and corresponding torque) imposed by the drive assemblies are configured to selectively evaluate "AP" (anterior-posterior) movement of the tibia with respect to the femur at the knee about the X-axis of rotation distal to the foot, varus-valgus conditions about the Y-axis of rotation distal to the foot, and "IE" (internal-external) movement about the Z-axis of rotation. Similarly, motions can be defined in such a way as to be relative to a co-ordinate system defined by the tibia as opposed to the femur.

According to various embodiments, the patella is clamped in place for all three types of testing procedures. In these and still other embodiments, a strap (not illustrated) may be coupled with the calf bias plate of assembly **1500** for use only during AP testing. Such a strap/plate or cage or box assembly may be configured as commonly known and understood in the art so as to provide selective restraint of the user's limb (e.g., as a non-limiting example, the strap may be operatively connected to one or the other sides of the calf bias plate **1570** and selectively attachable (e.g., via Velcro or the like) on the opposing side, with the strap also being in certain embodiments, selectively adjustable, as may be desirable). The strap/plate, cage or box assembly could be situated such that all sides are in constant contact with the calf or it could be configured such that there is space between the strap/plate, cage or box assembly and the calf. When there is space the assembly will move for a small distance before it contacts the calf and applies appropriate forces.

2. X-Axis Drive Operation due to Component Relationships

Movement about the X axis is configured to provide "AP" (anterior-posterior) movement of the tibia, due to forces up or down on the tibia as the foot is maintained in a stationary position by the foot plate assembly **1300**. In particular, the tibia pivots about an X oriented axis passing through the ankle – note this is a different X axis (albeit parallel) to the X axis "of the machine", aka the "machine X axis," all of which may be understood with reference to Figure 11.

With reference to Figure 4, according to various embodiments, the X drive assembly **2000** has its frame attached to the first of the two L-shaped flange brackets **1210**, which is itself attached to the pivoting plate **1201**. The output shaft of the X drive assembly goes through the hole in the L-shaped flange bracket (1st of 2), which in certain embodiments has a larger hole than its sister L-shaped bracket (2^{nd} of 2). The output shaft of the X drive assembly drives a flange bracket **1213**, which drives one end of a side leg member **1510** of the calf bias assembly **1500**, as previously described herein. A yoke end plate **1420** and the flange bracket **1213** sandwich the end of the side leg member, such that relative movement is transferred there-between during operation.

The yoke end plate **1420** is part of a rigid yoke assembly **1400** that includes a yoke top plate **1410** and two yoke end plates **1420**. Notably, during operation according to various embodiments, as the 1^{st} of the two yoke end plates rotate about the X axis so does the entire yoke assembly **1400**. The 2^{nd} yoke end plate **1420** is attached to the upper one end of a 2nd of two side leg members **1510** of the calf bias assembly **1500**, with that end also being attached to a stub flange **1212** that is pivotably mounted relative to the 2nd of two flange brackets. The bearing **1211** supporting the stub flange **1212** does not interact with the X axis drive assembly **2000**, such that the X axis drive assembly is thus solely supported by the 1st of two flange brackets **1210**, as attached to the pivoting plate **1201**.

As previously described herein, the lower end of the 1st of two side leg members **1510** is attached to a spool-shaped torque transducer **1530**, which is itself attached to a plate **1520** which supports a telescoping rod assembly **1560** that supports a calf bias plate **1570**.

The lower end of the 2nd of 2 side leg members**1510** has a bearing **1550** attached thereto, which supports stub flange **1540**. This stub flange **1540** is attached to the end of the plate **1520** opposite the spool-shaped torque transducer.

In this manner, upon activation of the X-axis drive assembly, any rotational force generated by the drive thereof is transferred to the associated gear box **2020** and output shaft **2030**, the latter of which rotates the flange bracket **1213**. Rotation of the flange bracket **1213** causes rotation of the side leg member **1510** of the calf bias assembly **1500**, which is operatively coupled to the calf bias plate **1570** via at least a telescoping rod assembly **1560**, which may include one or more telescoping rods configured to accommodate varying patient limb lengths.

The resulting movement imposed upon the calf bias plate **1570** is further illustrated in Figures 10-11, wherein pre- and post-movement positions are respectively shown. As may be further understood from these figures, rotation occurs not only about the X-axis about which the X drive assembly **2000**, but also about a tibia pivot point about a stationary constrained ankle, as restrained in the foot rotation assembly **1300**. In this manner, a user of the device may selectively evaluate "AP" (anterior-posterior) movement of the tibia with respect to the femur at the knee about an X-axis of rotation distal to the foot. In certain embodiments, such selective evaluation involves selective locking of the one or more of the remaining Y- and Z-axis drive assemblies, upon activation of the X-axis drive assembly **2000**. This selective locking can result in the foot remaining still while the x-axis motor rotates about the X-axis distal to the foot resulting in the calf being manipulated in the anterior-posterior direction representing Y-axis translation.

3. Y-Axis Drive Operation due to Component Relationships

The Y-Axis drive assembly **2100** is configured according to various embodiments to rotate the foot plate about the Y axis relative to the sliding frame assembly **1100**, so as to evaluate varus-valgus conditions. The strap associated with the calf support member is not used. However the patella is clamped in place, as previously described herein.

As described previously herein with reference to Figure 7, the frame of the Y axis drive assembly **2100** is attached to the underside of the pivoting plate **1201** (see also Figure 4), and includes an output shaft **2130** that extends upwardly through a hole in the pivot plate. This output shaft **2130** attaches to a flange adaptor **1103** that attaches to a Y torque transducer **1104**, which in turn attaches to a frame cap assembly **1110**, which attaches to the pivoting plate **1201**, all as also previously described herein. The torque transducer **1104** thus evaluates the torque along the drive line between the output shaft **2130** and the pivoting plate **1201**.

With continued reference to Figures 4 and 7, it may be understood that because the output shaft **2130** of the Y-axis drive assembly **2100** and the foot plate **1300** are both fixedly attached to the pivoting plate (e.g., the latter via the L bracket **1220**, as previously described herein), rotation transferred from the Y-axis drive assembly **2100** onto the pivoting plate **1201**, resulting in it pivoting about the Y axis, is thus transferred further onto the foot plate **1300**, also causing it to move about the Y axis. Notably, when such occurs without concurrent rotational transfer from the Z-axis drive assembly **2100**, movement of the foot plate **1300** will thus be isolated to about the Y axis, with no rotation occurring about the Z-axis.

During operation, such isolated rotation about the Y axis facilitates evaluation of varus-valgus conditions about the Y-axis of rotation, as previously described herein. Note that rotation of about the Y-axis distal to the foot causes the foot to move in an X-axis translation which results in a Y-axis rotation about the knee. It is this Y-axis rotation at the knee that is the varus-valgus rotation. Note that the distance from the footplate to the motor determines how far the footplate will translate along the X-axis. The more the footplate translates along the X-axis the more varus-valgus movement is effected at the knee. Furthermore, the Y-axis motor may be position such that it moves the footplate but that the X-axis motor and/or the Z- axis motor are not moved during the process.

4. Z-Axis Drive Components and Operation

The Z-Axis drive assembly is configured to rotate the foot plate about the Z axis relative to the sliding frame member, so as to evaluate "IE" (internal-external) rotational movement of the patient's tibia and/or limb. The strap associated with the calf support member is not used.

With reference to Figure 4, the foot plate **1300** is attached to a torque transducer "IE" (internal-external) movement **1222** which is attached to a flange adaptor **1221** which is attached to the output shaft **2330** (see Figure 12) of the Z-Axis drive assembly **2300**. The frame of the Z-Axis drive assembly is attached to an L Bracket**1220** which is fixedly attached to the pivot plate **1201**, as described elsewhere. Also as described elsewhere, the pivot plate **1201** is attached relative to the linearly sliding frame assembly **1100** about a pivoting axis Y. However, if the Y-Axis drive assembly is not in use and is selectively locked (which it is capable of, as are the other two), then the pivot plate **1201** is likewise substantially rigidly attached relative to the sliding frame assembly **1200**.

In this manner, upon activation of the Z-axis drive assembly **2200**, a rotational movement and accompanying torque are transferred via the output shaft **2330** directly to the foot plate **1300**, thereby providing resulting rotation of the foot plate about the Z-axis. Such permits users to, amongst other things, evaluate "IE" (internal-external) rotational movement of the patient's tibia and/or limb.

*5.Right versus Left Oriented Tibia Positioning Assemblies **1000***

Although it has been previously described herein with reference to Figure 2, it should be again noted that although only one tibia positioning assembly **1000** has been described herein, various embodiments of the overall RKT device **10** comprise two such assemblies **1000**. In certain embodiments, the two assemblies are symmetrical mirror images of one another, about a center-line axis of the device **10** as a whole. In this manner, it should be understood that, as a non-limiting example, if the same activation signal is sent to each of the X-axis drive assemblies **2000**, the resulting movement of each will result in anterior movement of both of the user's tibias. Consider the alternative, in the absence of a symmetrical mirror image configuration, in which instance such a signal would result in anterior movement of one tibia and posterior movement of the other. Although such a nonsymmetrical configuration may be desirable in at least one embodiment, it should be understood that according to certain embodiments described herein, the assemblies **1000** should be understood to be substantially symmetrically configured.

Still further, it should be understood that although the previous description has focused upon a single tibia positioning assembly **1000**, both of the assemblies of the overall RKT device **10** are according to certain embodiments configured, sized, and shaped in substantially the same manner. Of course, it should also be appreciated that in still other embodiments, it may be desirable to have substantially differently sized, shaped, and/or configured tibia positioning assemblies **1000**, such as the non-limiting example whereby at least one of the two assemblies substantially corresponds to the tibia positioning assembly described in U.S. publication No. 13/209,380.

6. Drive Assembly Decoupling

It should be understood that any drive assembly configuration **2000-2200** may be according to various embodiments decoupled from any of the other two. In fact, each of the three drive configurations could be decoupled from each of the other two so that substantially independent rotation about the respective axes thereof may be provided and thus imposed upon the patient's limb, as may be desirable for particular applications. In still other embodiments, it should be understood that two or more, and even all three drive assemblies **2000-2200** may be mutually coupled relative to one another such that movements are substantially simultaneously imposed upon the patient's limb during operation of the overall RKT device. That being said, it is often advantageous to isolate each respective movement; thus isolation (i.e., decoupling) of the movements of each of the respective drive assemblies **2000-2200** may be likewise desirable for particular applications as have been described elsewhere herein.

C) ADDITIONAL CONFIGURATIONS

1. Spherical Configurations

Spherical configurations can be also be used to provide manipulation of the lower leg of a patient about the centers of the spheres.

Figure 13 is an alternate configuration showing the use of spherical elements **3001, 3002** for manipulating the lower leg of a patient (shown in dotted line) about the centers of the spheres.

Sphere **3001** is driven by the exemplary roller and drive assembly (which can include two rollers and one cylindrical drive member as known in the “mouse-ball” art). Depending on the number of and orientation of roller and drive assemblies used in conjunction with the sphere **3001**, it may be understood that the sphere **3001** may be rotated about its center **C1** about a number of rotational axes passing through the center **C1**, including at least three mutually orthogonal axes. In this configuration the Center **C1** is approximately in the center of the ankle of the user.

Sphere **3002** is driven by the exemplary roller and drive assembly (which can also include two rollers and one cylindrical drive member as known in the “mouse-ball” art, although these are not shown). Depending on the number of and orientation of roller and drive assemblies used in conjunction with the sphere **3002**, it may be understood that the sphere **3002** may be rotated about its center **C2** about a number of rotational axes passing through the center **C2**, including at least three mutually orthogonal axes. In this configuration the Center **C2** is distal to the ankle and foot of the user.

It may be understood, therefore, that such a spherical-based configuration could be used to provide at least some of the rotational movements described in association with Figs 1-12.

Figure 14 is an alternate configuration showing the use of a spherical element **3003**, except that the center of rotation **C3** is even further distal to the foot, and an exemplary calf bias member (aka extender bar) is also used for the AP movement only, with the two other movements being provided without the bias member.

Figure 15 shows an alternate configuration including a spherical cage **4000** comprised of a plurality of cage bars **4005**. Rotation of the cage is done by use of one or more stationary motors such as **4010**.

Stationary motor **4010** and rollers **4020** are mounted relative to frame member 4011. Motor **4010** drives rollers **4020**, with the two rollers capturing an associated cage bar. This rotation of the spherical cage **4000** can be provided about an axis extending through the center of the cage and normal to a plane including the particular arcuate cage bar. Either of or both rollers can drive the bar. The point of this is to illustrate that many types of drive configurations can be used to provide the motions in certain of the embodiments herein, either from the inside of the sphere, or the outside.

2. Additional RKT Features

Note that the semicircular notch (not numbered) in the pivoting plate **1201** (see for example just under the "Z" axis DRIVE ASSEMBLY 2200 in Fig. 4) is configured to accept a vertical support shaft (not shown) which is anchored at its base and extends upwardly through the plate. The shaft has two slide bearings (not shown) on either side which bear on the two primary planar surfaces of the pivoting plate. This limits up and down deflection of the plate from its pivot point during the AP testing process. During the Y-axis movement, the shaft moves within the slot.

As previously mentioned, it should be understood that any drive configuration could be decoupled from any of the other two – in fact, each of the three drive configurations could be decoupled from each of the other two so that substantially independent rotation about the respective axes thereof may be provided and thus imposed upon the patient's limb, however, as may be desirable for particular applications.

In still other embodiments, it should be understood that two or more, and even all three drive assemblies **2000-2200** may be mutually coupled relative to one another such that movements are substantially simultaneously imposed upon the patient's limb during operation of the overall RKT device. That being said, it is often advantageous to isolate each respective movement; thus isolation (i.e., decoupling) of the movements of each of the respective drive assemblies **2000-2200** may be likewise desirable for particular applications as have been described elsewhere herein.

3. RKT Device for CT Scanning

Additional details regarding imaging protocols, including the use of CT scanning components in conjunction with limb and ligament evaluation apparatuses may be found in Applicant's commonly owned U.S. Patent Application Publication No. 2012/0046540-A1, as published on February 23, 2012, which may be referred to for further details.

Further very general disclosure of incorporation of CT scanning components within limb and ligament evaluation apparatuses may be found in Applicant's commonly owned U.S. Patent Application Publication No. 2009/0124936-A1, as published on May 14, 2009 and which may be referred to for further details.

Here begins a discussion of a second embodiment RKT device **5000**, which includes similarities to the above-described RKT device B, but also includes differences. Some of these differences facilitate its use in conjunction with a CT scanner to evaluate the knee of a human. However, it should be understood that this is not to be limited to such scanners or joints, and is only an example. The device **5000**could also be used in conjunction with MRI or other scanners, and indeed some of its features may be used with sensors such as those used with the non-radiographic device **10** above, which include non-invasive systems utilizing sensors or markers that are attached to the skin, including but not limited to optoelectronic, ultrasonic, and electromagnetic motion analysis systems.

Reference is first made to Figure 17, which is a side illustrative view of a leg testing apparatus **5000** according to one of the inventions herein, in combination with an exemplary CT scanner **4900**, and a patient's body support apparatus **4950**.The three devices are configured to be typically situated atop an unnumbered supporting surface. Also shown is an exemplary patient, including a patient proper body **4951**, patient lower leg **4950**, and patient upper leg **4950**.

It may be understood that inventions and novelties relate to and include the leg testing apparatus **5000** and its use on its own, as well as the leg testing apparatus **5000** and its use in combination with the CT scanner **4900**, as well as the leg testing apparatus **5000** and its use in combination with the patient body support apparatus **4950**, as well as the three components **5000**, **4950**, and **4900** together.

As may be understood, the leg testing apparatus **5000** manipulates the leg of the patient, while the patient is supported on the patient body support apparatus **4950.** A portion of the patient's body, in this example the lower leg, is shown in Figure 17 as within the opening of the CT scanner **4900**, such that the lower leg can be scanned by the CT scanner. This scanning may be done while the leg testing apparatus is in any one of a multiplicity of modes of operation, including but not limited to its testing of the patients knee in "AP" (anterior-posterior) movement, varus-valgus movement, and/or internal and external rotation.

The upper torso of the patient is supported by the patient body support apparatus **4950**, which includes a back support **4956** (upon which the patient lies), which supports a thigh restraint assembly **4952** (which contains the upper thighs of the patient), and which also supports a shoulder restraint **4959** (which serve to discourage the patient from moving to the right as Figure 17 is viewed.

It may be understood that under one embodiment of the invention, the patient body support apparatus **4950** includes a structural link member **4951** which connects to the leg testing apparatus **5000**, to allow the two to slide together as a unit (with both 5000 being on rollers or suitably aligned tracks). Alternately, the two members could be separately driven via coordinated synchronized drive means.

Reference is now made to Figure 18, which is a perspective view of a leg testing apparatus **5000** according to one aspect of the present inventions, which includes left lower leg supporting apparatus **5200**, right lower leg supporting apparatus **5300**, and lower frame number **5100**.

As may be seen, in Figure 18, the "Z" axes of the two apparatuses **5200**, and **5300**, are not aligned with each other. These two axes are referenced as "***Z axis – left***", the Z axis of the left apparatus 5200, and "***Z axis – right***", the Z axis of the right apparatus **5300.** The Z axis for purpose of this discussion should be understood as the axis of rotation of the foot plate as discussed in later detail

In Figure 18, these two Z axes are positioned in "alignment" with their related calf bias assemblies **5260**, **5360**. However it will be understood from later discussion that while the positions of the "Z" axes of the two apparatuses **5200** and **5300** can be varied, the calf bias assemblies are not configured to rotate about a vertical axis (although they can each rotate about their own horizontal "X" axis to provide an AP action).This is to accommodate the use of the apparatus **5000** within the relatively narrow space within the CT scanner.

Figure 19 is a top elevation view of the leg testing apparatus **5000** of Figure 18, illustrating the relationship of the left lower leg supporting apparatus **5200** and the right lower leg supporting apparatus **5300**, relative to the inner surface of the scanning device **4900**. As may be seen, the "X" axes of the two apparatuses **5200**, and **5300**, are also not aligned, and in the embodiment shown, the angle between the two is fixed.

Figure 20 is a rear elevation view of the leg testing apparatus **5000** of Figure 18, which includes left lower leg supporting apparatus **5200**, right lower leg supporting apparatus **5300**, and lower frame number **5100**. Figure 21 is a front elevation view of the same leg testing apparatus **5000**.

Figure 22 is a pictorial view of the right lower leg supporting apparatus **5300**, with certain elements not included for purposes of explanation. In reference to this as well as Figures G and H – for example, here follows a description of right leg supporting apparatus **5300**; a similar description could be made of left lower leg supporting apparatus **5200**, as the two are essentially mirror images of each other.

The right lower leg supporting apparatus **5300** is slidably mounted relative to the lower frame member via slide assemblies **5101**, such that the two apparatuses **5200**, **5300**, slide in tandem along parallel slide paths. There are smaller slide mounts that allow 5200 and 5300 to slide independently along the same path.

The two slide assemblies **5101** are attached to the bottom of corresponding two lower vertical frame members **5310**. A lower frame table **5312** is rigidly attached to the top of the two lower vertical frame members **5310**.

Two intermediate vertical frame members **5314** are rigidly attached to the top of the lower frame table **5312**. An intermediate frame table **5320** is rigidly attached to the top of the two intermediate vertical frame members **5314**.

Two short upper vertical frame members **5322** are rigidly attached to the top of the upper frame table **5312**. An upper frame table **5333** is rigidly attached to the top of the two short upper vertical frame members **5322**.

Two long upper vertical frame members **5332** are also rigidly attached to the top of the upper frame table **5312**. These frame members support the **X** drive assembly **5600** in a manner similar to that described in the apparatus earlier in this application.

*4. "X"-axis Drive Assembly **5600** Construction and Operation*

The "X"-axis Drive Assembly **5600** is configured to drive the calf bias assembly **5360** substantially about the X axis, similar to the manner in which the calf bias assembly **1500** of the device **10**described above was driven by its "X"-axis Drive Assembly **2000.**Torque about the X axis is also similarly determined by a similar torque transducer. As in device **10**, this provides for an evaluation of "AP" (anterior-posterior) movement of the tibia with respect to the femur at the knee about an X-axis of rotation distal to the foot. It should be understood that such an evaluation, as with any of the movements herein, includes an evaluation of the degree of rotation or pivot as well as the torque involved during such rotation or pivoting.

5. "Y" Drive Assembly Construction and Operation

The "Y" Drive Assembly **5500** is configured to pivot the foot plate **5344** about the horizontal Y axis, such that a foot captured by the foot plate causes varus-valgus conditions prompted by forces about a Y-axis of rotation distal to the foot.

The associated Y drive configuration is different than its counterpart in the above device **10**. The Y drive assembly **5500** is attached to the underside of lower frame table**5312**. It includes an inline reducer and a torque sensor and drives a vertical shaft **5502** which is captured in two bearings, upper and lower bearings **5505** and **5504**, respectively. The upper end of the shaft **5502** is rigidly attached to the pivoting horizontal foot support plate **5340** via a flange **5507**, such that rotation of the shaft causes rotation of the foot support plate **5340**.

A shown in Figure 25, at the front of the pivoting horizontal foot support plate **5340** is rigidly mounted to a pivoting vertical foot support flange **5341.** Flange **5341** supports the Z axis drive assembly **5600**, such that operation of the Z axis drive assembly **5600** causes rotation of the foot plate **5344** relative to the flange **5341**, about the Z axis. As may be understood, this Z axis can be moved within a horizontal plane, via movement of the "Y" drive assembly.

6. Z Drive Assembly Construction and Operation

As noted above, the Z axis drive assembly **5600** causes rotation of the foot plate **5344** relative to the support flange **5341**, about the Z axis. When a foot is contained in the foot plate, this can provide internal and external rotation of the foot and thus the tibia.

7. More Discussion of Decoupling; Different Movements Possible

One drive is "decoupled" from the other if motion by the first drive does not change the position of the second drive in any direction. However, coupling of drive A to drive B does not imply coupling of drive B to drive A. Similarly, decoupling of drive A relative to drive B does not imply decoupling of drive B relative to drive A.

This concept extends to multiple drives such that a system can be configured to have a complex chain of drives working both dependently and/or independently to influence motion of one limb segment with respect to another limb segment. In a global sense, system A of drives could influence the system B of drives but not vice versa.

A first drive is coupled to a second drive if motion of the first drive changes the position of the second drive in any direction. All drives are 'decoupled' when each drive has its own unique independent influence on the position of the tibia with respect to the femur. In the first version described above (leg testing device **10**):

- The IE Rotation Drive is decoupled from the AP Drive
- Both IE Rotation and AP Drives are coupled relative to the Valgus Drive (movement of Valgus Drive affects axis of the other two)

In the second version described above (leg testing device **5000**)

- AP Drive is totally decoupled
- Valgus Drive totally decoupled
- IE Rotation Drive is coupled relative to Valgus Drive (movement of Valgus affects axis of IE)

In device **5000**, this allows for the following actions:

- First place patient limb in extreme internal rotation, then conduct AP test.
- First place patient limb in full Valgus as well as full AP, then do anIErotation test
- First push patient limb posteriorly, then do varus-valgus test
- First put patient limb in extreme varus, then do IErotation test
- First place patient limb in extreme varus and extreme rotation, then do AP test

8. Output Data

As may be understood, the degrees of the various movements (Varus-Valgus, AP, IE) can be measured by measuring the movements of the machines **10**, **5000**, themselves, by measuring the degrees of rotation of the drives (by encoding for example) and calibrating as necessary. The torque encountered during each such movement may also be measured, suitably calibrated to the limb movement, and recorded. In the case of the device **10**, separate "external" measurement of the limb of the patient may be detected by non-invasive systems utilizes sensors or markers that are attached to the skin, including but not limited to optoelectronic, ultrasonic, and electromagnetic motion analysis systems. In the case of the device **5000**, separate measurement of the movement of the limb of the patient may be by using landmarks seen on the actual bones. There are no markers; one can see the bones in the CT images.

9. Testing for Different Degrees of Leg Flexion

It may be understood that during the above tests (AP, varus-valgus, or rotation), there is no flexing of the knee into flexion or extension. However, as shown in Figures 26A and 26B, one of the present inventions also includes the additional capability to flex the knee into flexion or extension. This would allow for similar tests (such as the examples above) done for different degrees of knee flex.

10. Variations

Note that instead of the two apparatuses **5200** and **5300** being commonly attached to the lower frame member **5100**, they could be each be attached to a separate frame member such that their relative positions on the floor could be independently varied.

The lower frame member **5100** also slides relative to the floor so the whole machine can go in and out

III. CONCLUSION

Many modifications and other embodiments of the invention set forth herein will come to mind to one skilled in the art to which this invention pertains having the benefit of the teachings presented in the foregoing descriptions and the associated drawings.

Therefore, it is to be understood that the invention is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims. Although specific terms are employed herein, they are used in a generic and descriptive sense only and not for purposes of limitation.

Although distinct embodiments have been described, the skilled person will understand how features of different embodiments may be combined.

WHAT IS CLAIMED IS:

1. A limb manipulation and evaluation device (10, 5000) comprising:

a frame (20);

a first drive (2200, 5600) supported by the frame (20) and configured to manipulate a first bone relative to a second bone in a first direction;

a second drive (2000, 5400) supported by the frame (20) and configured to manipulate said first bone relative to said second bone in a second direction; and

a third drive (2100, 5500) supported by the frame (20) and configured to manipulate said first bone relative to said second bone in a third direction,

wherein

said first, second, and third directions are different relative to each other, and

at least one drive of the first, second, and third drives is mutually decoupled relative to another drive of the first, second, and third drives, such that operation of said one drive does not affect position of said another drive relative to the frame (20), and such that operation of said another drive does not affect position of said one drive.

2. The limb manipulation and evaluation device (10, 5000) of Claim 1, further comprising a device (1104, 1222, 1530, 4900) for recording rotation by or torque encountered upon a respective drive of the first, second, and third drives.

3. The limb manipulation and evaluation device (10, 5000) of Claim 1, wherein:

the first, second, and third directions are about first, second and third rotational axes, respectively;

said first, second and third rotational axes are substantially mutually orthogonal.

4. The limb manipulation and evaluation device (10, 5000) of Claim 1, wherein:

the first, second, and third directions are about first, second, and third rotational axes, respectively;

at least two of the first, second, and third rotational axes lie in a same plane.

5. The limb manipulation and evaluation device (10, 5000) of Claim 1, wherein:

the first, second, and third directions are about first, second and third rotational axes, respectively;

the first second, and third rotational axes lie in respective, different planes.

6. The limb manipulation and evaluation device (10, 5000) of Claim 1, wherein:

the first, second, and third directions are about first, second and third rotational axes, respectively;

said first, second, and third rotational axes are each oriented at an angle relative to each other,

operation of said one drive does not affect a rotational axis of said another drive, and

operation of said another drive does not affect a rotational axis of said one drive.

7. The limb manipulation and evaluation device (10, 5000) of Claim 6, wherein said first, second, and third rotational axes are substantially orthogonal to one another.

8. The limb manipulation and evaluation device (10, 5000) of Claim 6, wherein at least two of the first, second, and third rotational axes lie in a same plane.

9. The limb manipulation and evaluation device (10, 5000) of Claim 6, wherein the first, second, and third rotational axes lies in respective, different planes.

10. The limb manipulation and evaluation device (10, 5000) of Claim 1, wherein:

the first, second, and third directions are about first, second, and third rotational axes, respectively;

said first, second, and third rotational axes are each oriented at an angle relative to each other, and

two drives of the first, second, and third drives are mutually decoupled relative to another drive of the first second, and third drives, such that operation of either of said two drives does not affect a rotational axis of said another drive, and such that operation of said another drive does not affect a respective rotational axis of either of said two drives.

11. The limb manipulation and evaluation device (10, 5000) of Claim 1, wherein:

the first, second, and third directions are about first, second and third rotational axes, respectively;

the first, second and third rotational axes are each oriented at an angle relative to each other, and

said at least one drive is mutually decoupled relative to the other two drives of the first, second, and third drives, such that operation of said at least one drive does not affect the rotational axes of said other two drives, and such that operation of said other two drives does not affect a rotational axis of said at least one drive.

12. The limb manipulation and evaluation device (10, 5000) of Claim 1, wherein:

the first drive (2200, 5600) is configured to manipulate a tibia relative to a femur about a first axis, said first drive (2200, 5600) providing internal and external rotation of said tibia relative to said femur;

the second drive (2000, 5400) is configured to manipulate said tibia relative to said femur about a second axis, said second drive 2000, 5400) providing anterior-posterior movement of said tibia relative to said femur,

the third drive (2100, 5500) is configured to manipulate said tibia relative to a femur about a third axis, said third drive (2100, 5500) providing valgus-varus movement of said tibia relative to said femur, said first drive (2200, 5600) is mutually decoupled from said second drive (2000, 5400) such that operation of said first drive (2200, 5600) does not affect a rotational axis of said second drive (2000, 5400), and such that operation of said second drive (2000, 5400) does not affect a rotational axis of said first drive (2200, 5600); and

said first drive (2200, 5600) is coupled with said third drive (2100, 5500).

13. The limb manipulation and evaluation device (10, 5000) of Claim 1, wherein:

the first drive (2200, 5600) is configured to manipulate a tibia relative to a femur about a first axis, said first drive (2200, 5600) providing internal and external rotation of said tibia relative to said femur;

the second drive (2000, 5400) is configured to manipulate said tibia relative to said femur about a second axis, said second drive (2000, 5400) providing anterior-posterior movement of said tibia relative to said femur,

the third drive (2100, 5500) is configured to manipulate said tibia relative to a femur about a third axis, said third drive (2100, 5500) providing valgus-varus movement of said tibia relative to said femur,

said first drive (2200, 5600) is coupled to said third drive (2100, 5500); and

said second drive (2000, 5400) is mutually decoupled from said first and third drives such that operation of said second drive (2000, 5400) does not affect a respective rotational axis of either said first drive (2200, 5600) or said third drive (2100, 5500), and such that operation of said first drive (2200, 5600) and said third drive (2100, 5500) does not affect a rotational axis of said second drive (2000, 5400).

14. A method of manipulating a first bone relative to a second bone, said method comprising:

operating a first drive (2200, 5600) configured to manipulate said first bone relative to said second bone about a first rotational axis;

operating a second drive (2000, 5400) configured to manipulate said first bone relative to said second bone about a second rotational axis; and operating a third drive (2100, 5500) configured to manipulate said first bone relative to said second bone about a third rotational axis,

wherein:

said first, second, and third rotational axes are each oriented at an angle relative to each other, and

said operation of at least one drive of the first, second, and third drives is mutually decoupled relative to another drive of the first, second, and third drives, such that said operation of said one drive does not affect a rotational axis of said another drive, and such that said operation of said another drive does not affect a rotational axis of said one drive.

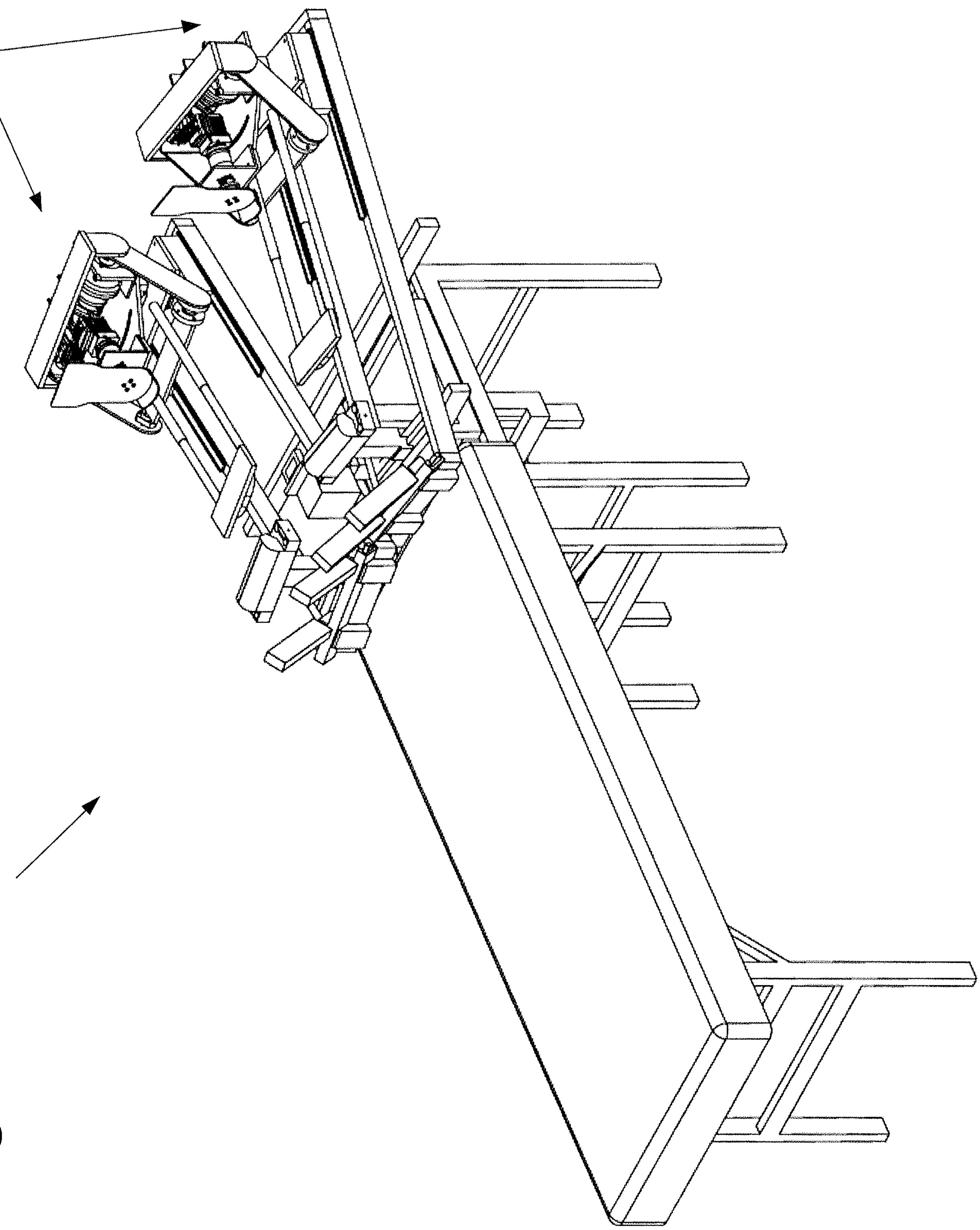


Fig. 1

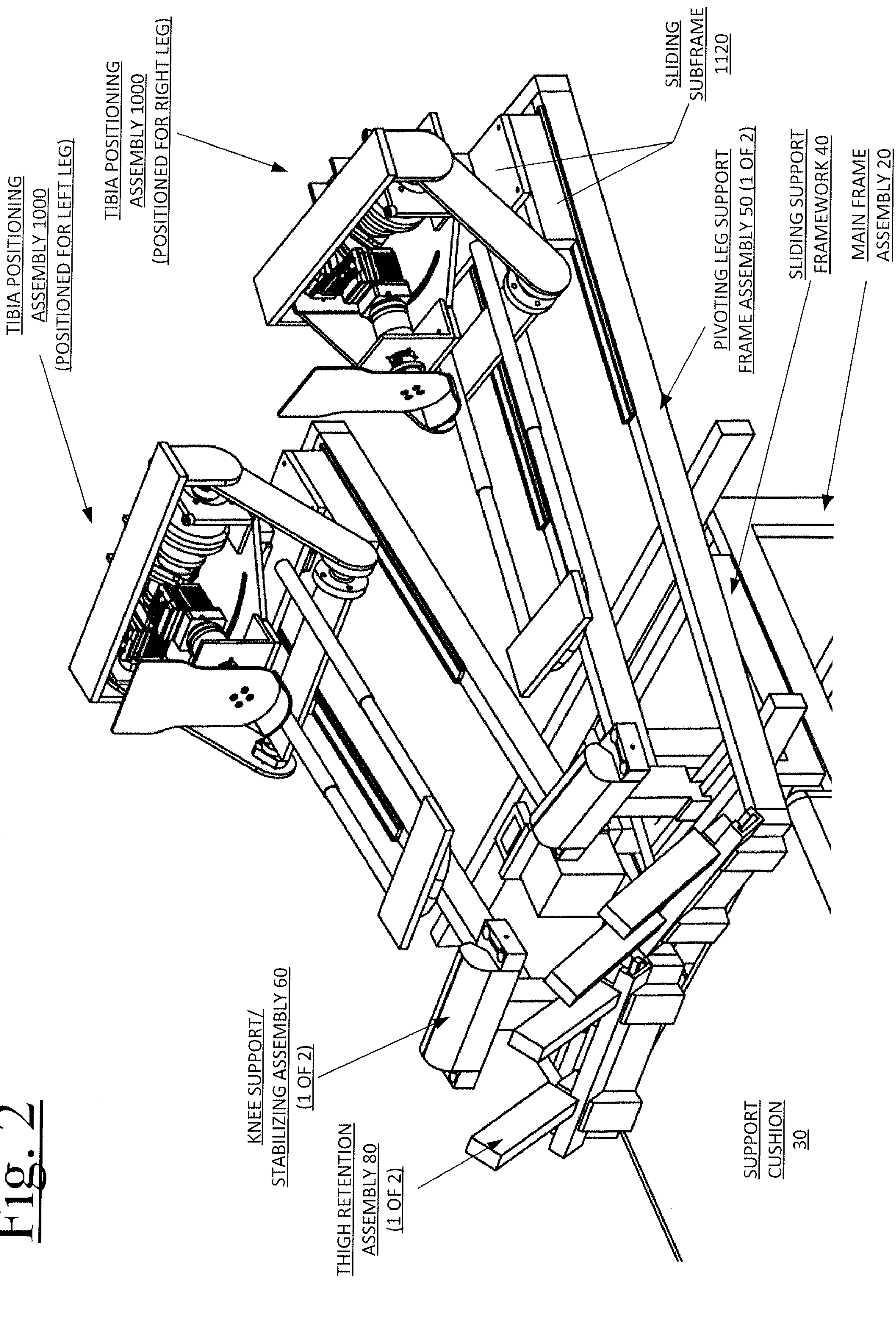

TIBIA POSITIONING
ASSEMBLY 1000
(POSITIONED FOR LEFT LEG)
TIBIA POSITIONING
ASSEMBLY 1000
(POSITIONED FOR RIGHT LEG)
SLIDING
SUBFRAME
1120
PIVOTING LEG SUPPORT
FRAME ASSEMBLY 50 (1 OF 2)
SLIDING SUPPORT
FRAMEWORK 40
MAIN FRAME
ASSEMBLY 20
KNEE SUPPORT/
STABILIZING ASSEMBLY 60
(1 OF 2)
THIGH RETENTION
ASSEMBLY 80
(1 OF 2)
SUPPORT
CUSHION
30

Fig. 2

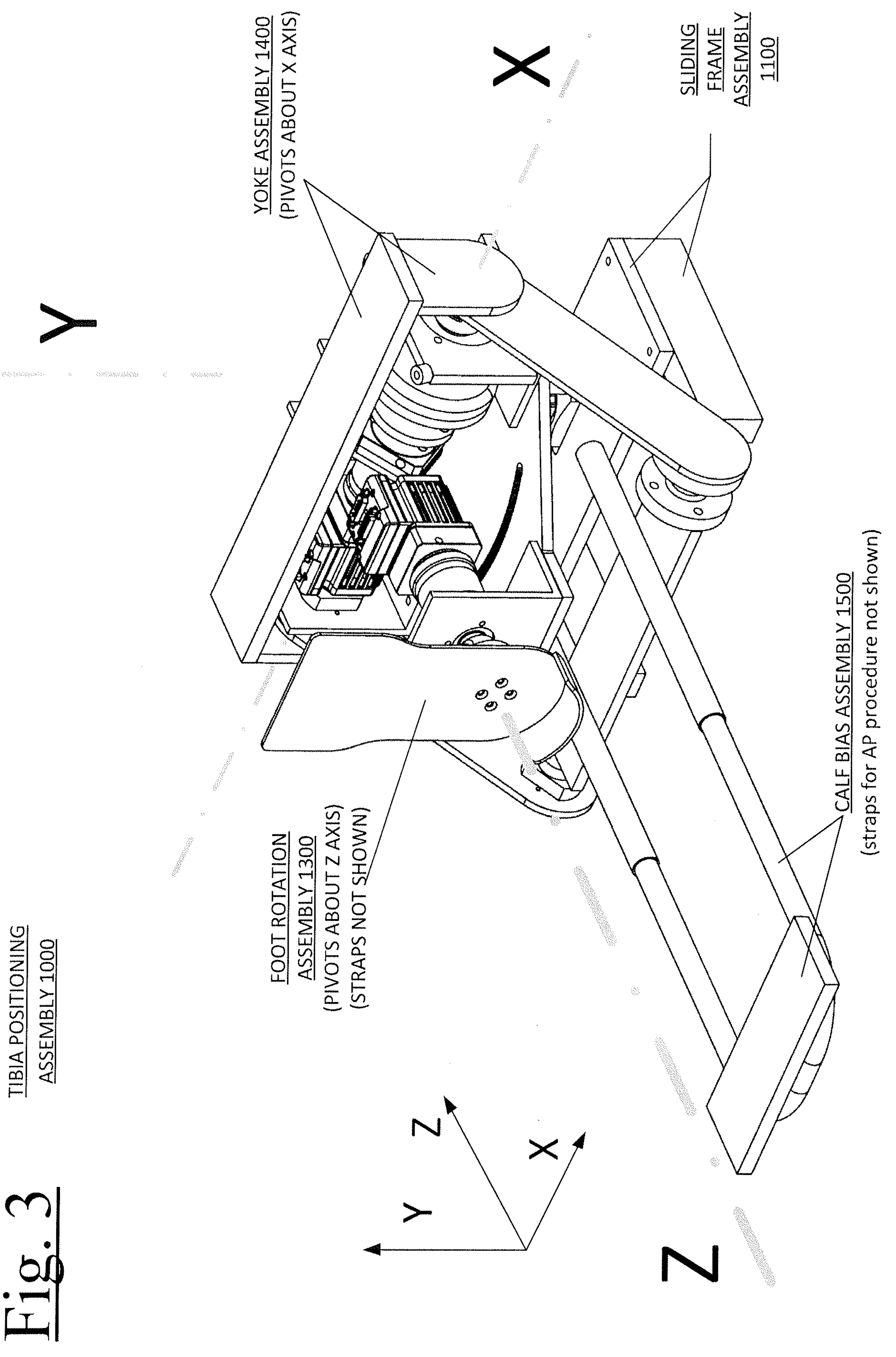

YOKE ASSEMBLY 1400
(PIVOTS ABOUT X AXIS)
X
SLIDING
FRAME
ASSEMBLY
1100
Y
CALF BIAS ASSEMBLY 1500
(straps for AP procedure not shown)
FOOT ROTATION
ASSEMBLY 1300
(PIVOTS ABOUT Z AXIS)
(STRAPS NOT SHOWN)
TIBIA POSITIONING
ASSEMBLY 1000
Z
X
Y
Z

Fig. 3

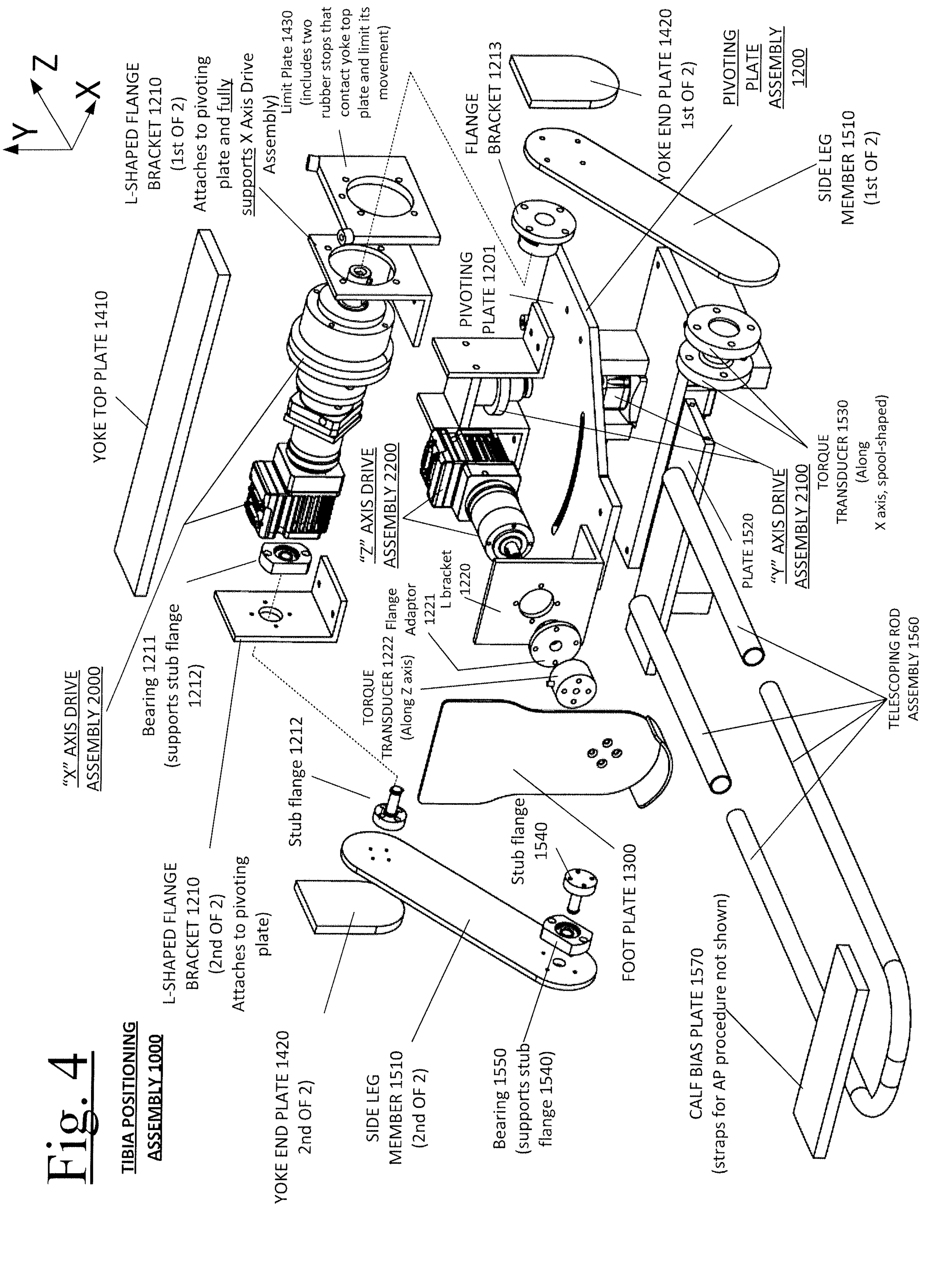

Y
Z
X
YOKE TOP PLATE 1410
L-SHAPED FLANGE BRACKET 1210 (1st OF 2) Attaches to pivoting plate and fully supports X Axis Drive Assembly)
Limit Plate 1430 (includes two rubber stops that contact yoke top plate and limit its movement)
FLANGE BRACKET 1213
YOKE END PLATE 1420 1st OF 2)
PIVOTING PLATE ASSEMBLY 1200
SIDE LEG MEMBER 1510 (1st OF 2)
PIVOTING PLATE 1201
"Z" AXIS DRIVE ASSEMBLY 2200
"Y" AXIS DRIVE ASSEMBLY 2100
TORQUE TRANSDUCER 1530 (Along X axis, spool-shaped)
PLATE 1520
"X" AXIS DRIVE ASSEMBLY 2000
Bearing 1211 (supports stub flange 1212)
L bracket 1220
Flange Adaptor 1221
TORQUE TRANSDUCER 1222 (Along Z axis)
TELESCOPING ROD ASSEMBLY 1560
Stub flange 1212
L-SHAPED FLANGE BRACKET 1210 (2nd OF 2) Attaches to pivoting plate)
Stub flange 1540
FOOT PLATE 1300
YOKE END PLATE 1420 2nd OF 2)
SIDE LEG MEMBER 1510 (2nd OF 2)
Bearing 1550 (supports stub flange 1540)
CALF BIAS PLATE 1570 (straps for AP procedure not shown)
TIBIA POSITIONING ASSEMBLY 1000

Fig. 4

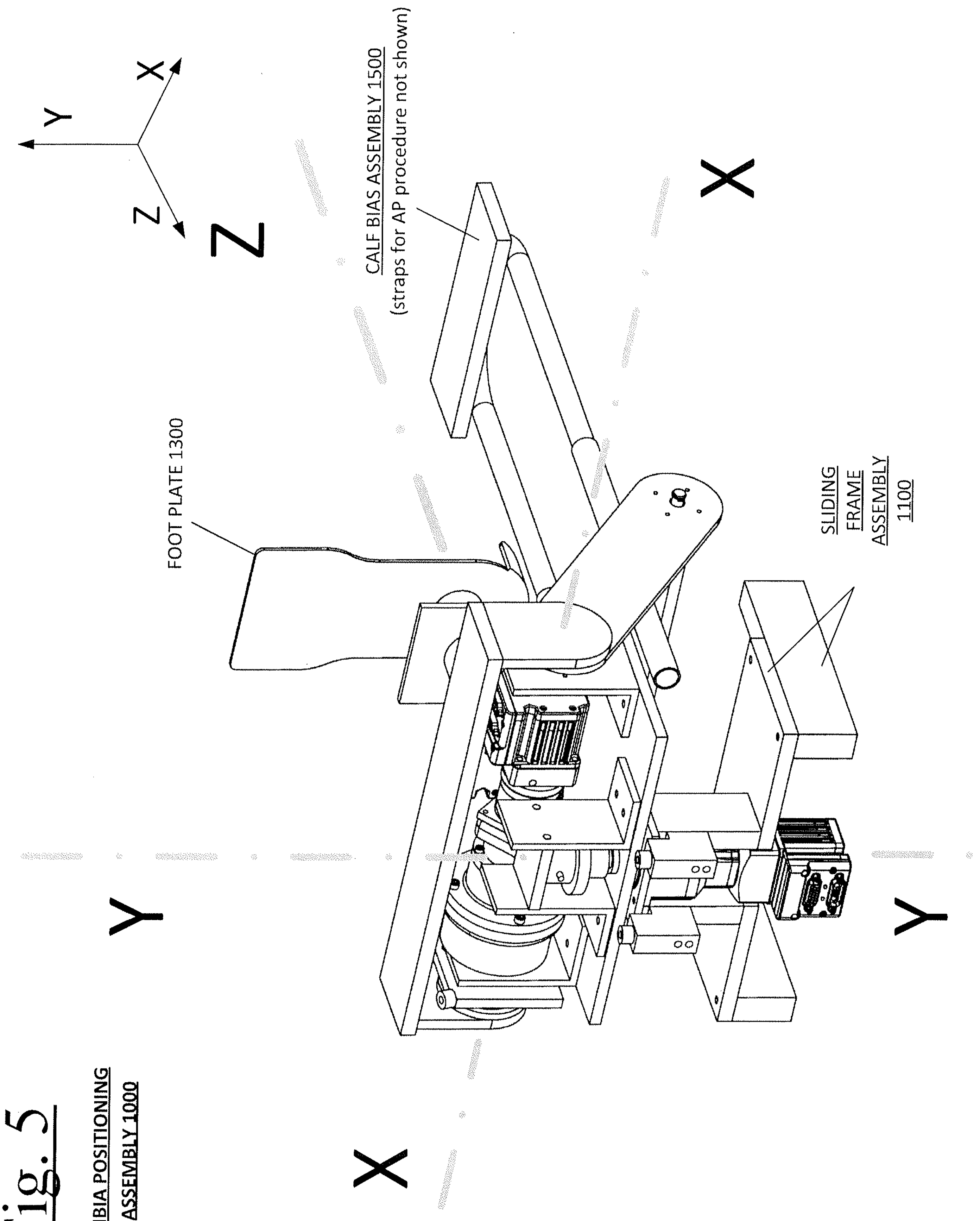


Fig. 5

TIBIA POSITIONING ASSEMBLY 1000

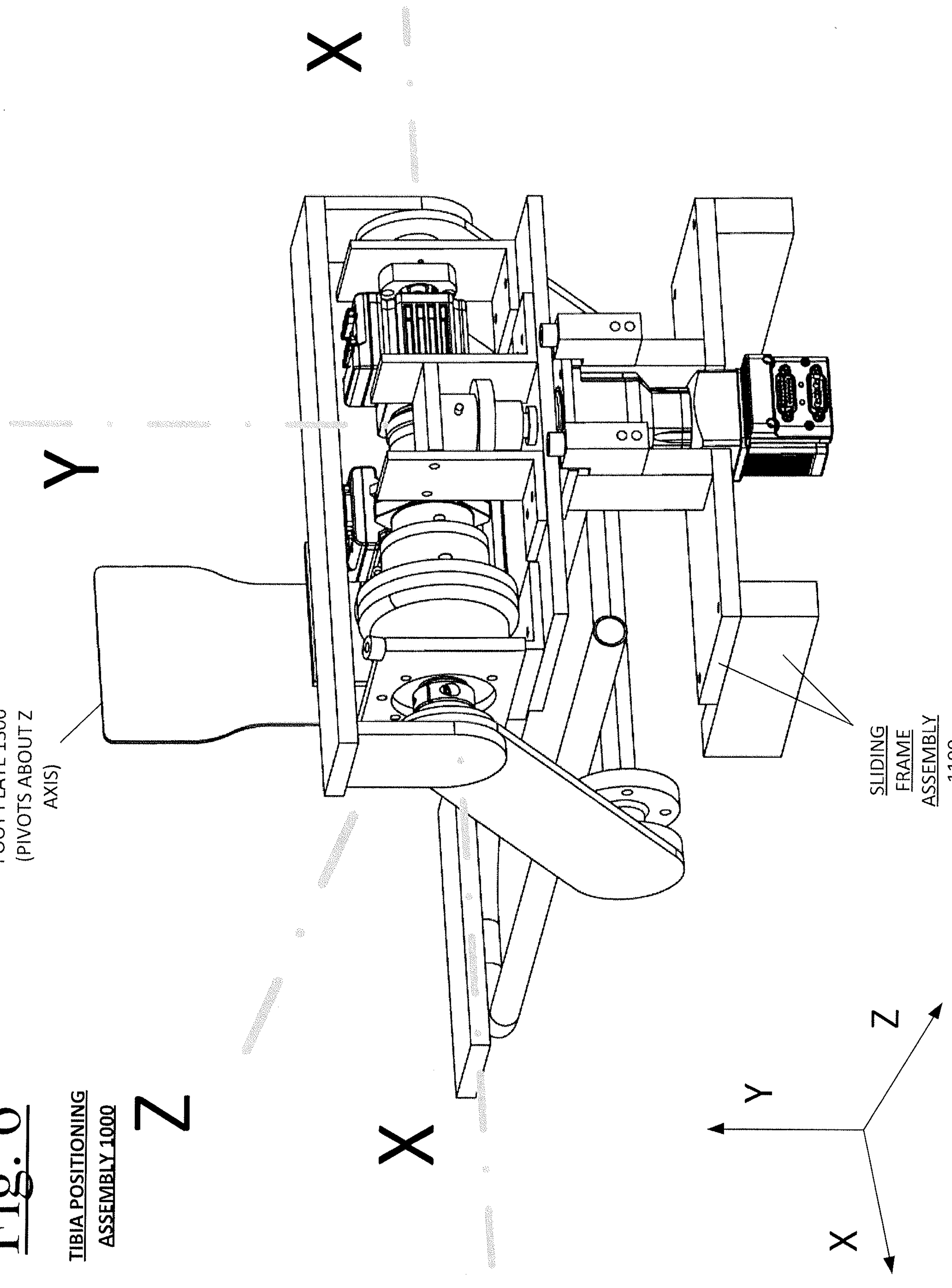

TIBIA POSITIONING ASSEMBLY 1000
FOOT PLATE 1300 (PIVOTS ABOUT Z AXIS)
SLIDING FRAME ASSEMBLY 1100
X
Y
Z
X
Y
Z
X

Fig. 6

Fig. 7

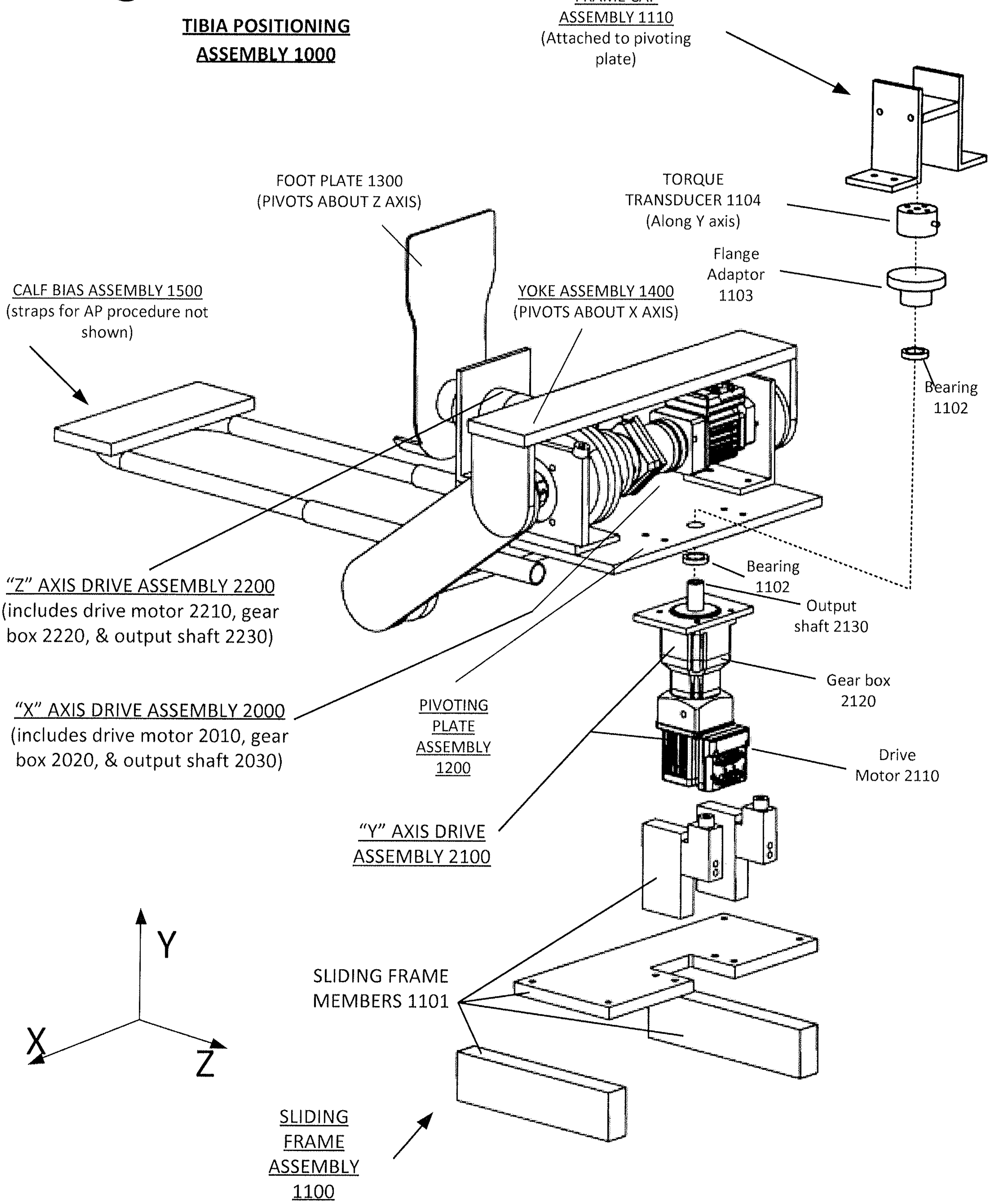
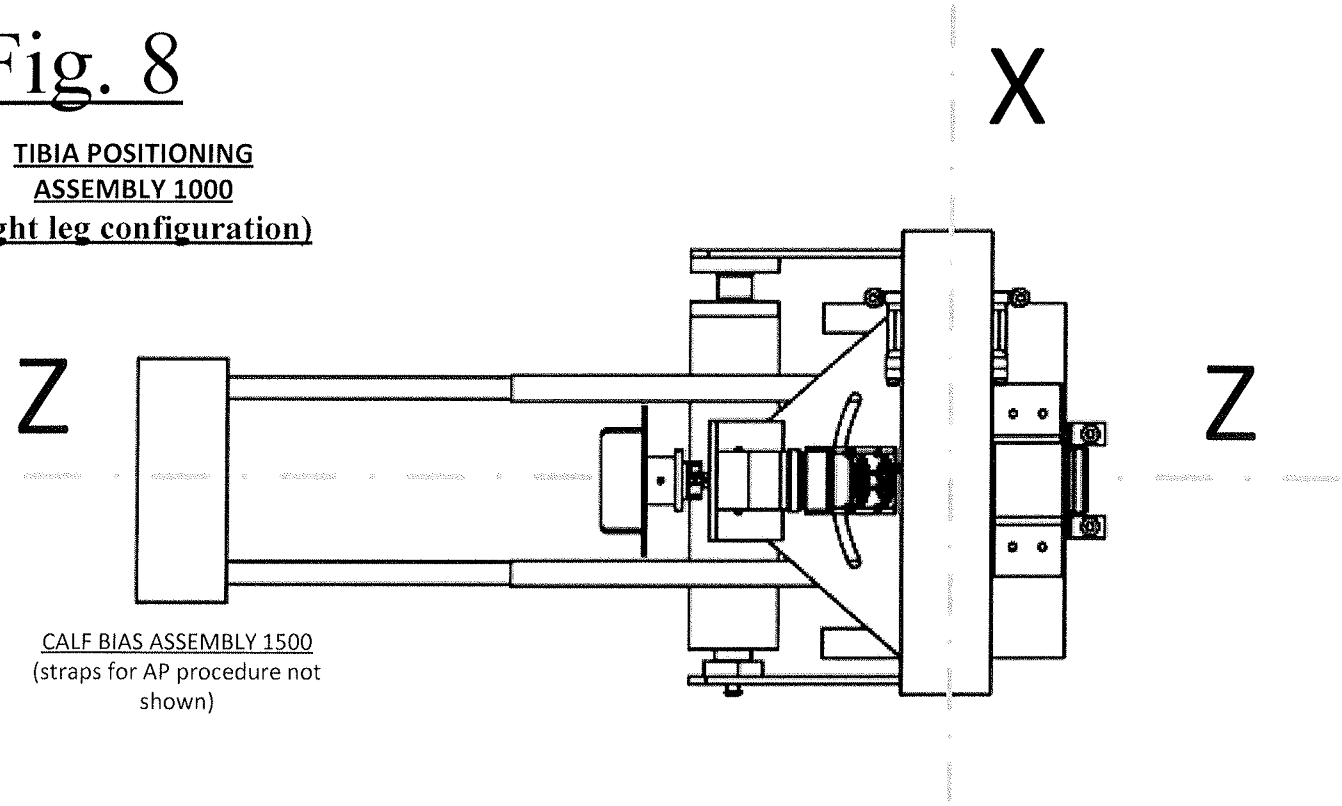

TIBIA POSITIONING ASSEMBLY 1000
FRAME CAP ASSEMBLY 1110 (Attached to pivoting plate)
FOOT PLATE 1300 (PIVOTS ABOUT Z AXIS)
TORQUE TRANSDUCER 1104 (Along Y axis)
Flange Adaptor 1103
CALF BIAS ASSEMBLY 1500 (straps for AP procedure not shown)
YOKE ASSEMBLY 1400 (PIVOTS ABOUT X AXIS)
Bearing 1102
Bearing 1102
Output shaft 2130
"Z" AXIS DRIVE ASSEMBLY 2200 (includes drive motor 2210, gear box 2220, & output shaft 2230)
Gear box 2120
"X" AXIS DRIVE ASSEMBLY 2000 (includes drive motor 2010, gear box 2020, & output shaft 2030)
PIVOTING PLATE ASSEMBLY 1200
Drive Motor 2110
"Y" AXIS DRIVE ASSEMBLY 2100
Y
X
Z
SLIDING FRAME MEMBERS 1101
SLIDING FRAME ASSEMBLY 1100

Fig. 8

TIBIA POSITIONING ASSEMBLY 1000
(right leg configuration)



CALF BIAS ASSEMBLY 1500
(straps for AP procedure not shown)

Fig. 9

TIBIA POSITIONING ASSEMBLY 1000
(right leg configuration)

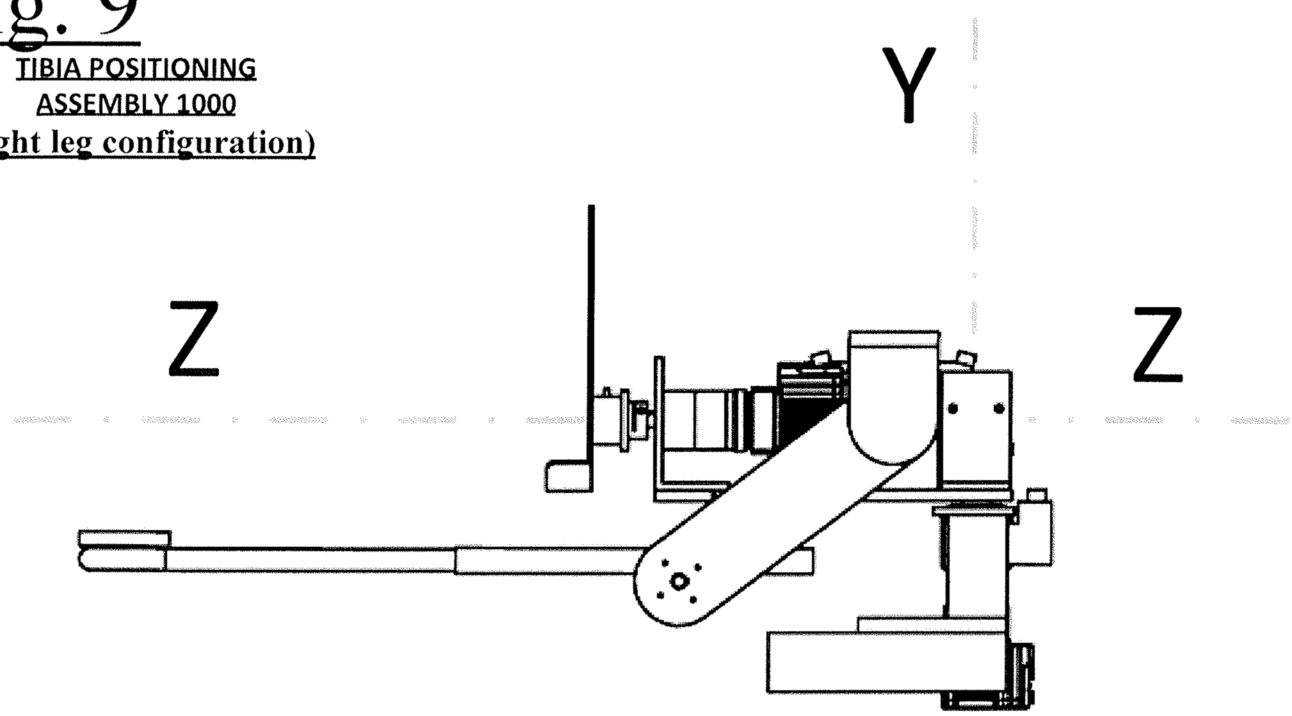


Fig. 10

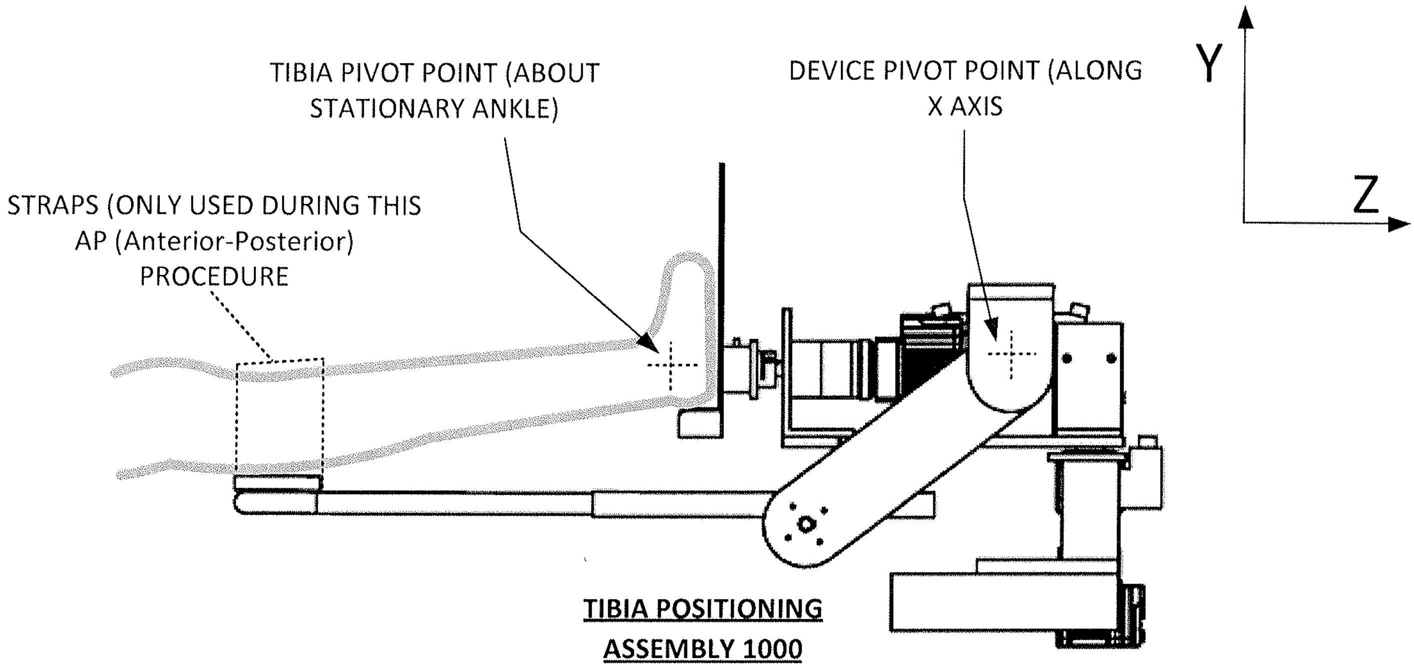

TIBIA PIVOT POINT (ABOUT STATIONARY ANKLE)
DEVICE PIVOT POINT (ALONG X AXIS
Y
Z
STRAPS (ONLY USED DURING THIS AP (Anterior-Posterior) PROCEDURE
TIBIA POSITIONING ASSEMBLY 1000

Fig. 11

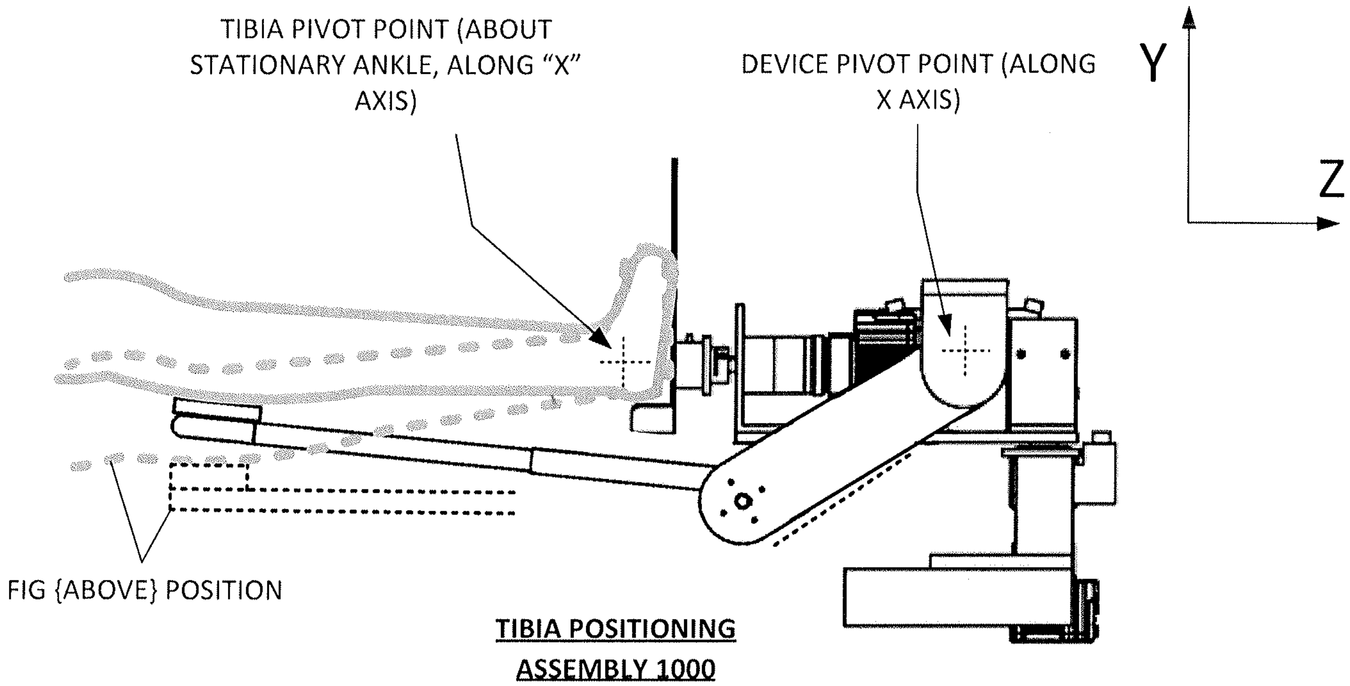

TIBIA PIVOT POINT (ABOUT STATIONARY ANKLE, ALONG "X" AXIS)
DEVICE PIVOT POINT (ALONG X AXIS)
Y
Z
FIG {ABOVE} POSITION
TIBIA POSITIONING ASSEMBLY 1000

Fig. 12

TIBIA POSITIONING ASSEMBLY 1000
(left leg configuration)

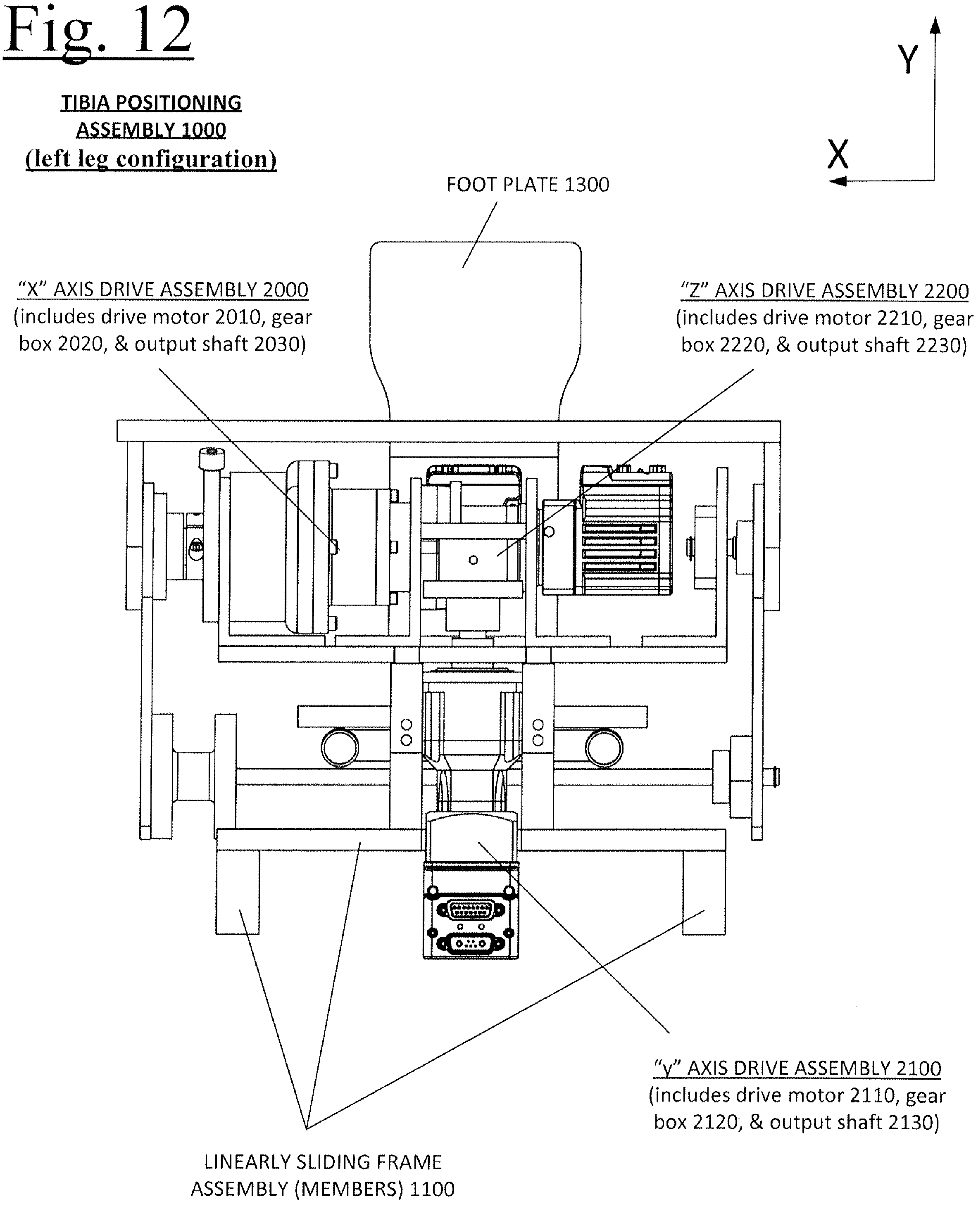


Fig. 13

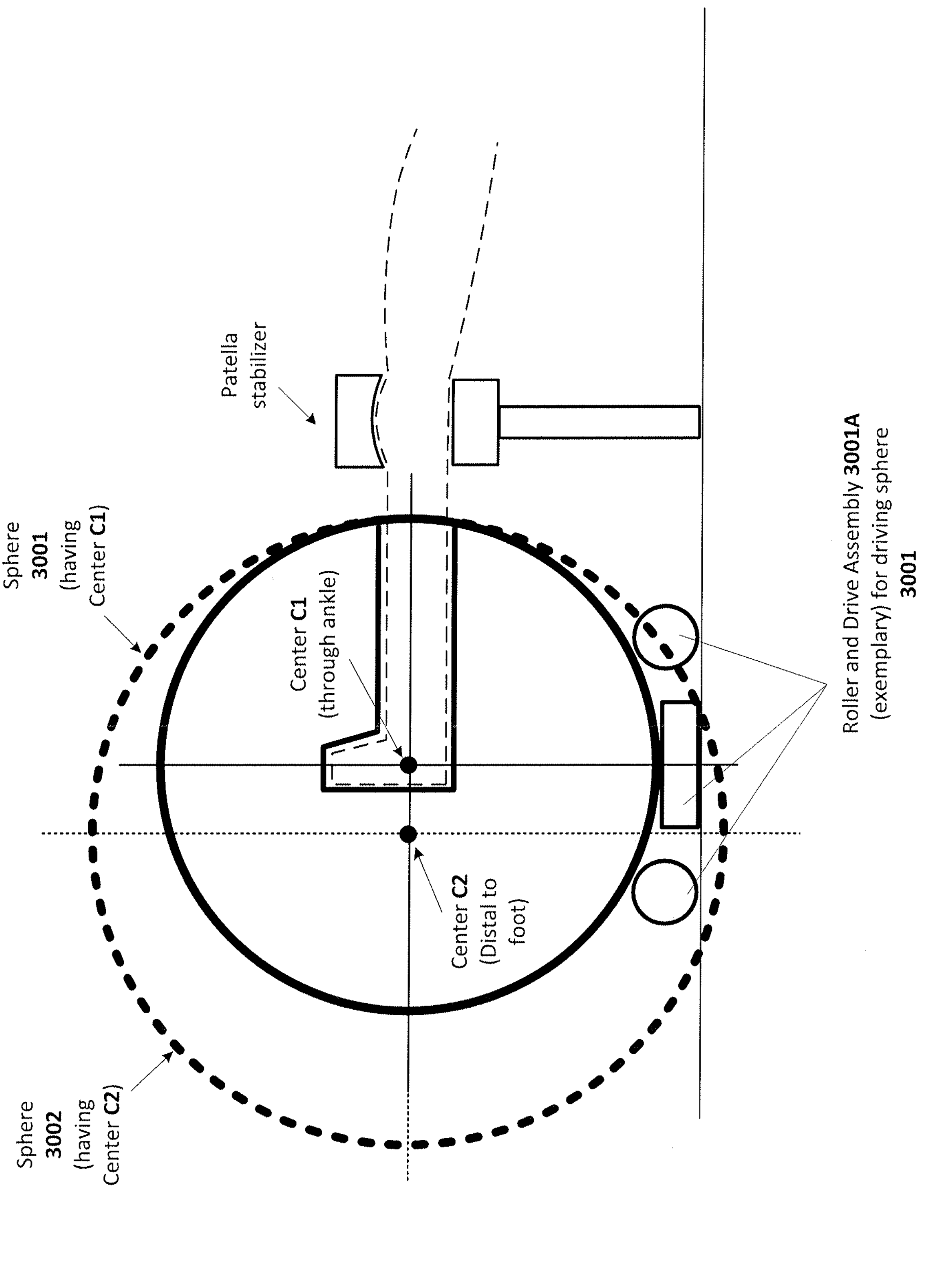
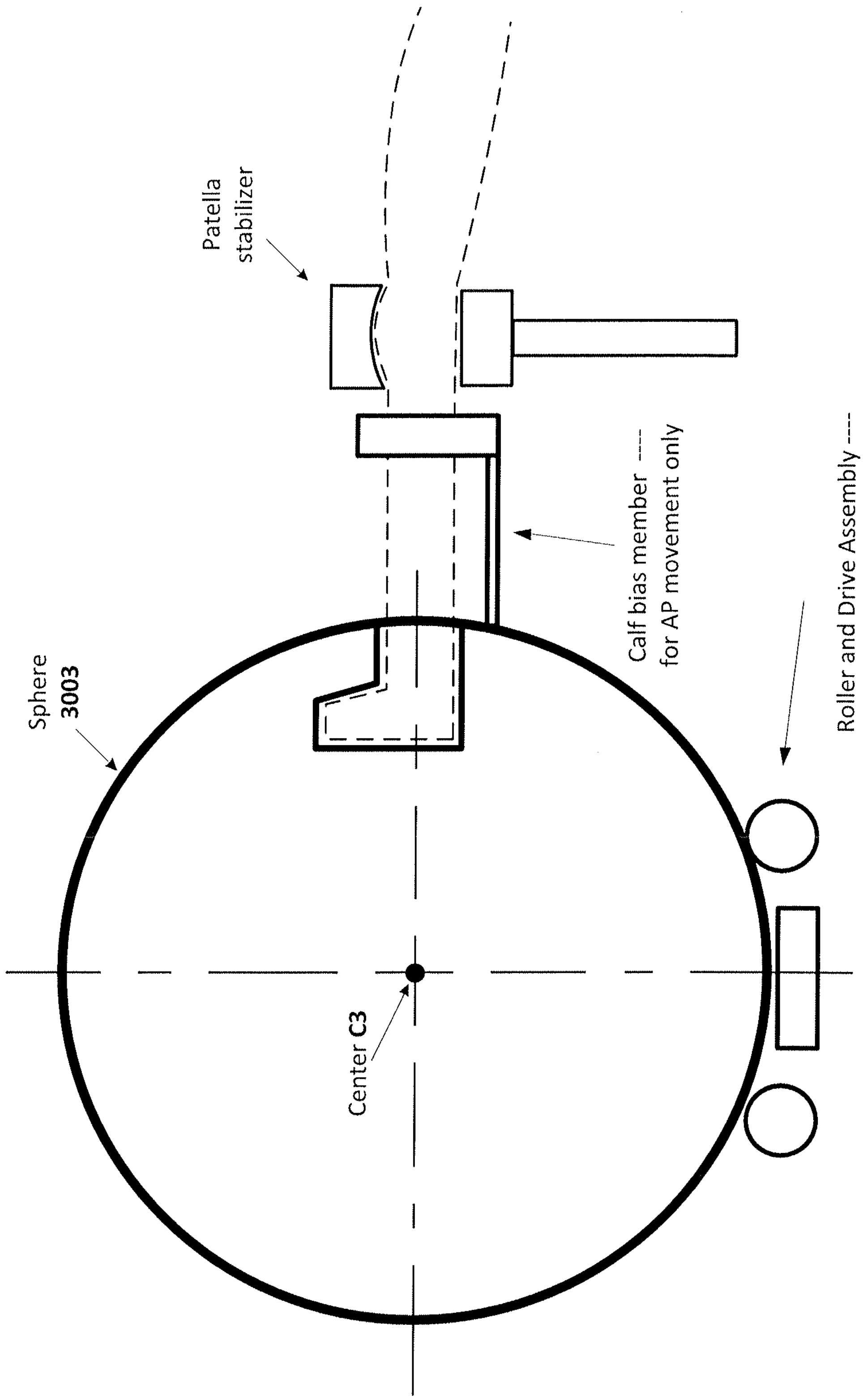

Sphere 3001 (having Center C1)
Sphere 3002 (having Center C2)
Center C1 (through ankle)
Center C2 (Distal to foot)
Patella stabilizer
Roller and Drive Assembly 3001A (exemplary) for driving sphere 3001

Fig. 14


Patella stabilizer
Calf bias member ---
for AP movement only
Roller and Drive Assembly ---
(exemplary)
Sphere
3003
Center C3

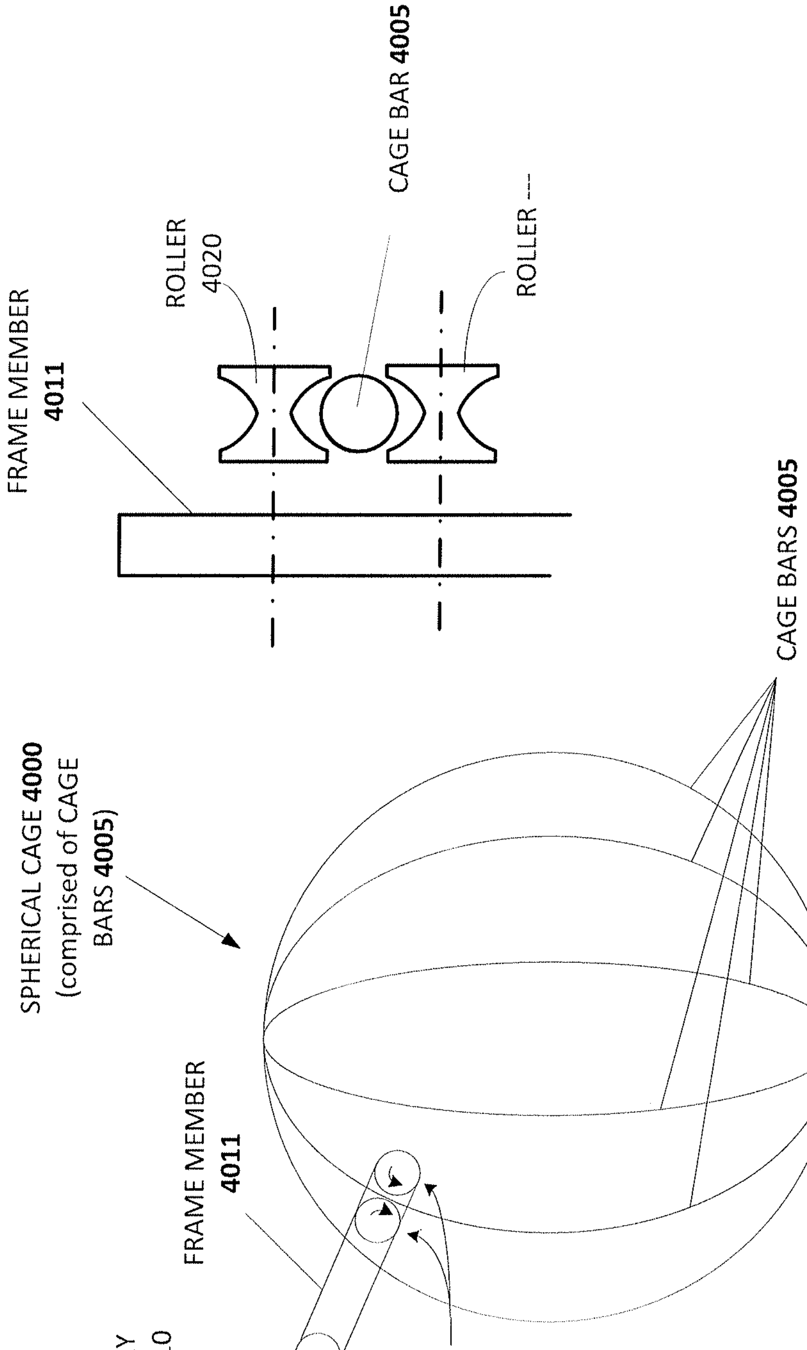
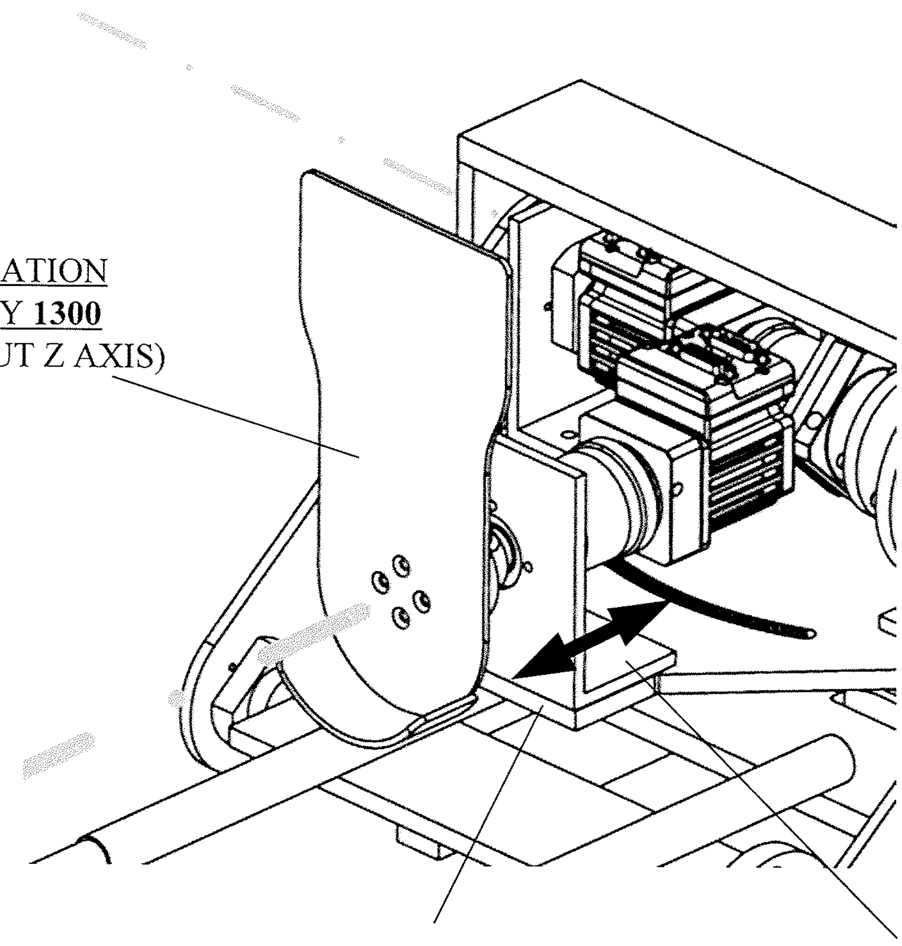

FRAME MEMBER
4011
ROLLER
4020
CAGE BAR 4005
ROLLER ---
SPHERICAL CAGE 4000
(comprised of CAGE
BARS 4005)
CAGE BARS 4005
FRAME MEMBER
4011
STATIONARY
MOTOR 4010
ROLLERS
4020

Fig. 15

Fig. 16



The L Bracket **1220**, which supports the Z Drive motor, can if desired slide along the Z axis relative to pivoting plate assembly 1200 in order to accommodate "pistoning" of foot in varus valgus procedure, allowing for the foot to move in a more natural arc during varus-valgus testing. The foot plate and motor all move together.

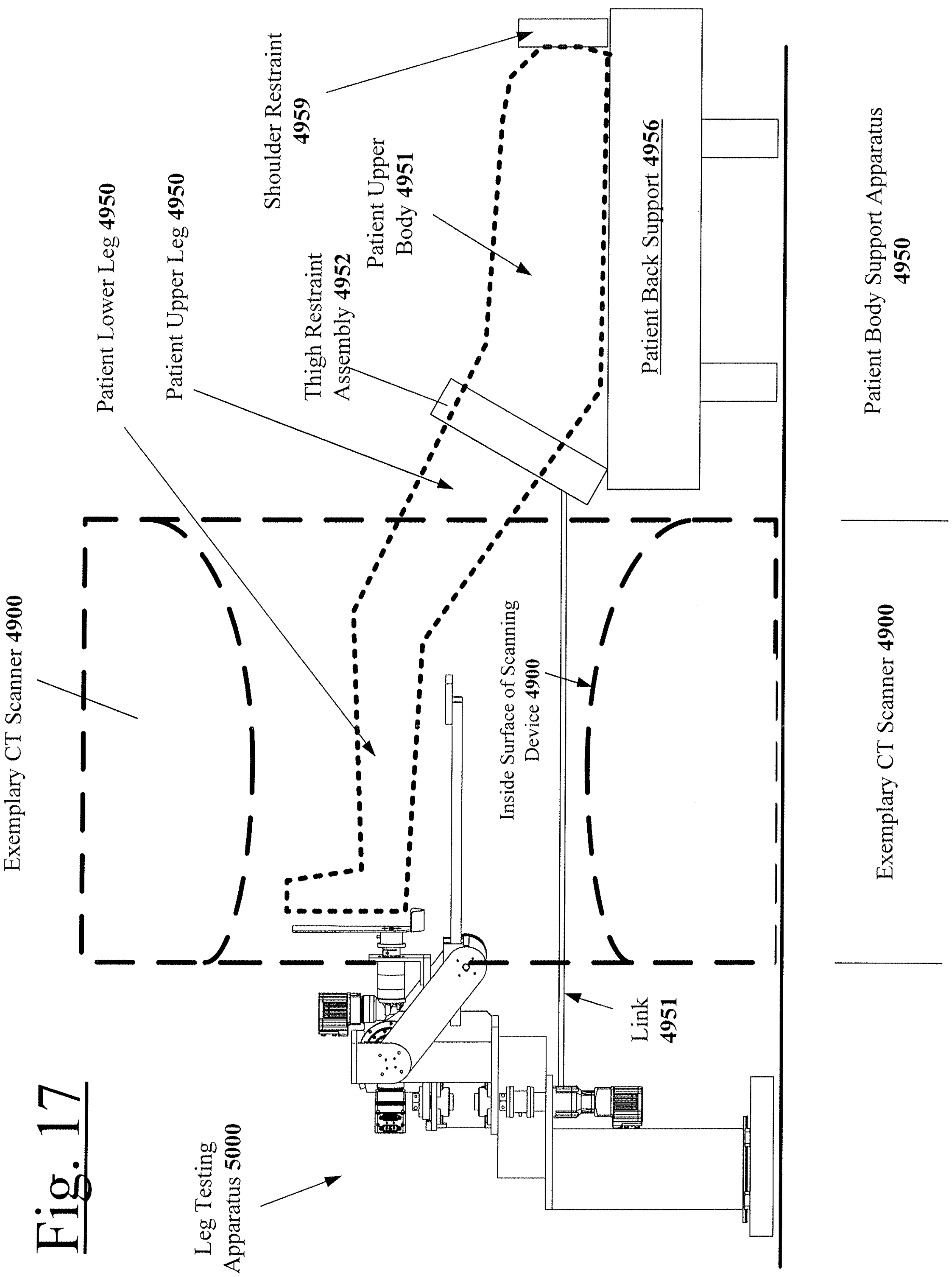

Shoulder Restraint 4959
Patient Upper Body 4951
Patient Back Support 4956
Patient Body Support Apparatus 4950
Thigh Restraint Assembly 4952
Patient Lower Leg 4950
Patient Upper Leg 4950
Exemplary CT Scanner 4900
Inside Surface of Scanning Device 4900
Exemplary CT Scanner 4900
Link 4951
Leg Testing Apparatus 5000

Fig. 17

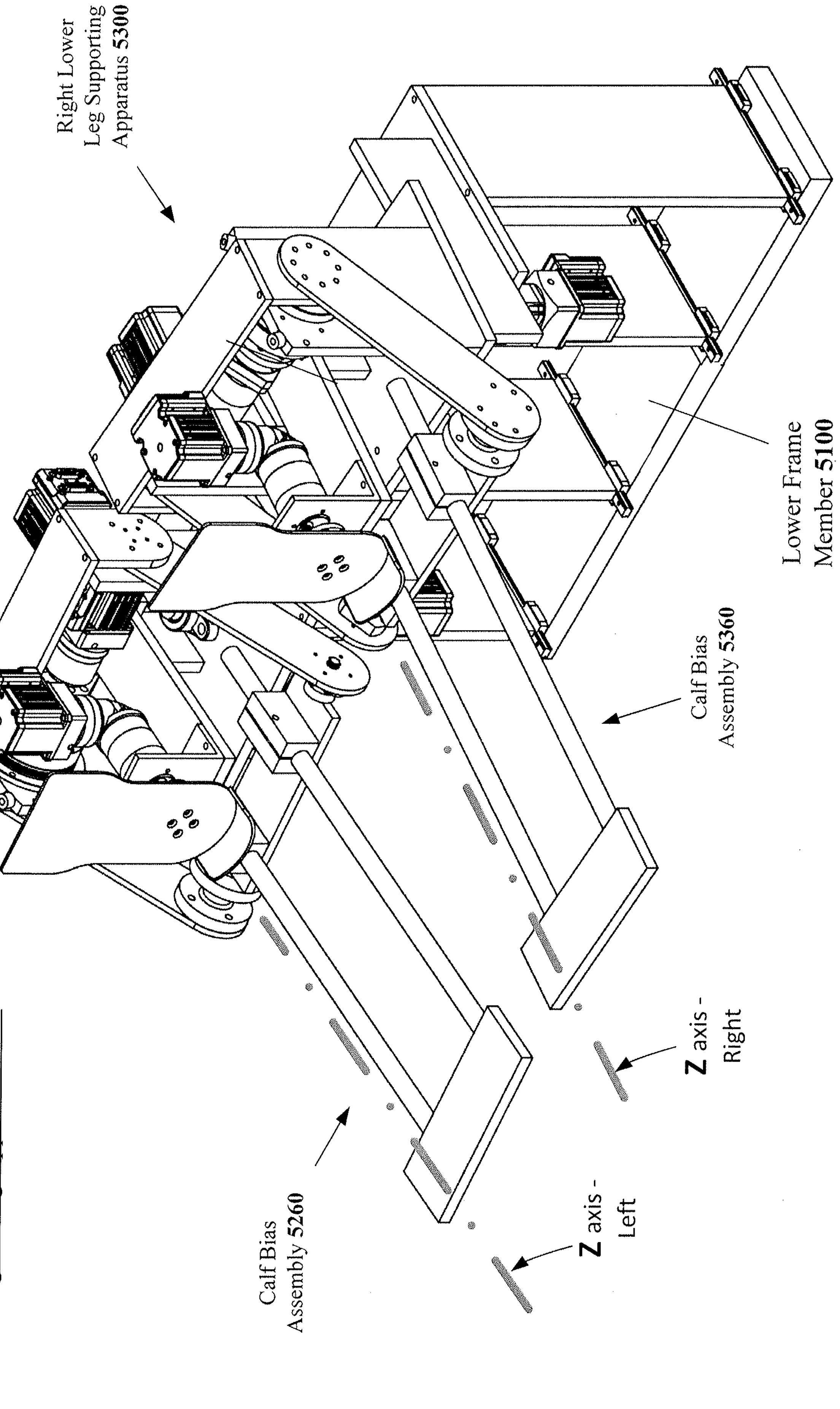


Fig. 18

Leg Testing Apparatus 5000

Fig. 19

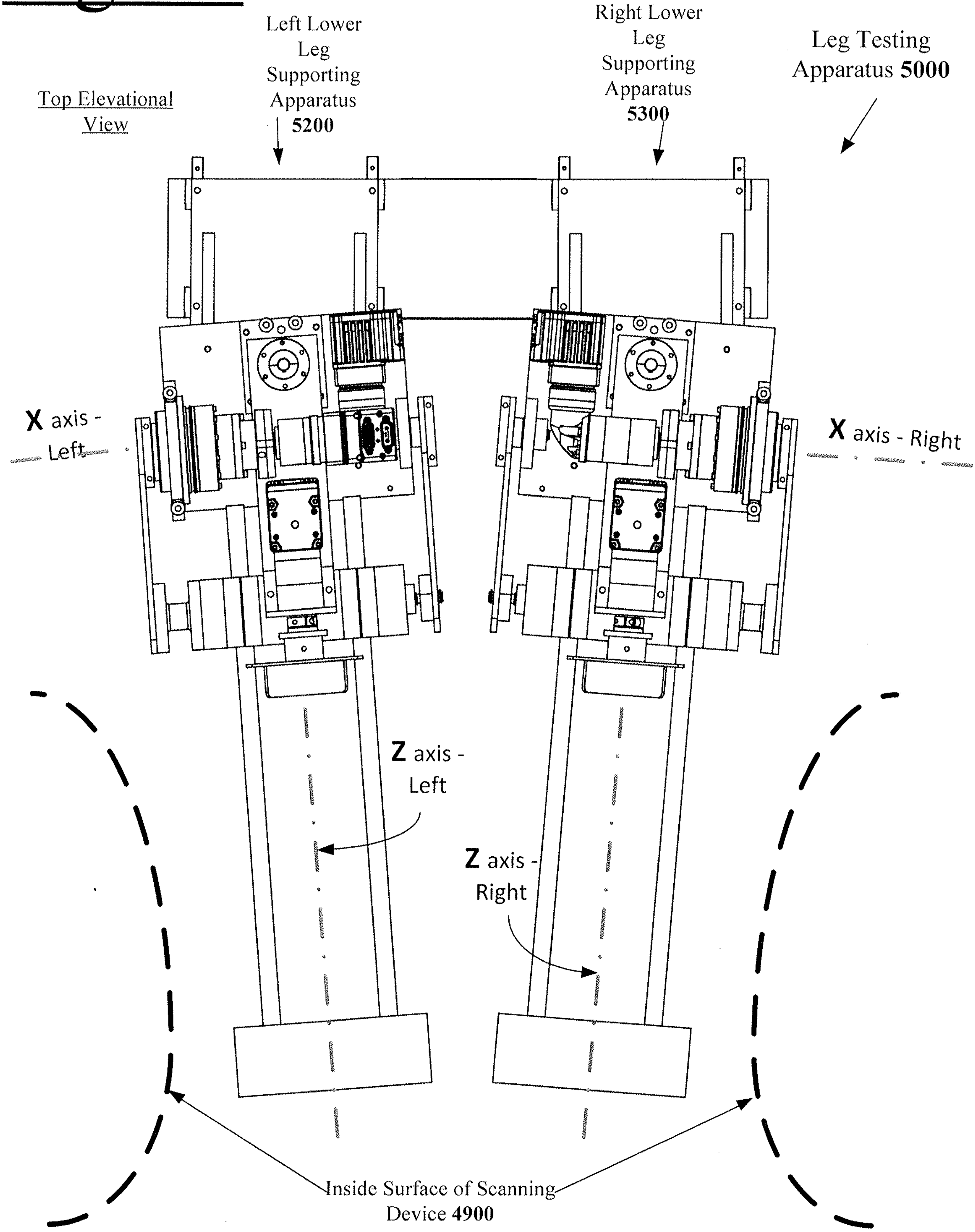

Top Elevational View
Left Lower Leg Supporting Apparatus 5200
Right Lower Leg Supporting Apparatus 5300
Leg Testing Apparatus 5000
X axis - Left
X axis - Right
Z axis - Left
Z axis - Right
Inside Surface of Scanning Device 4900

Fig. 20

Rear Elevational View

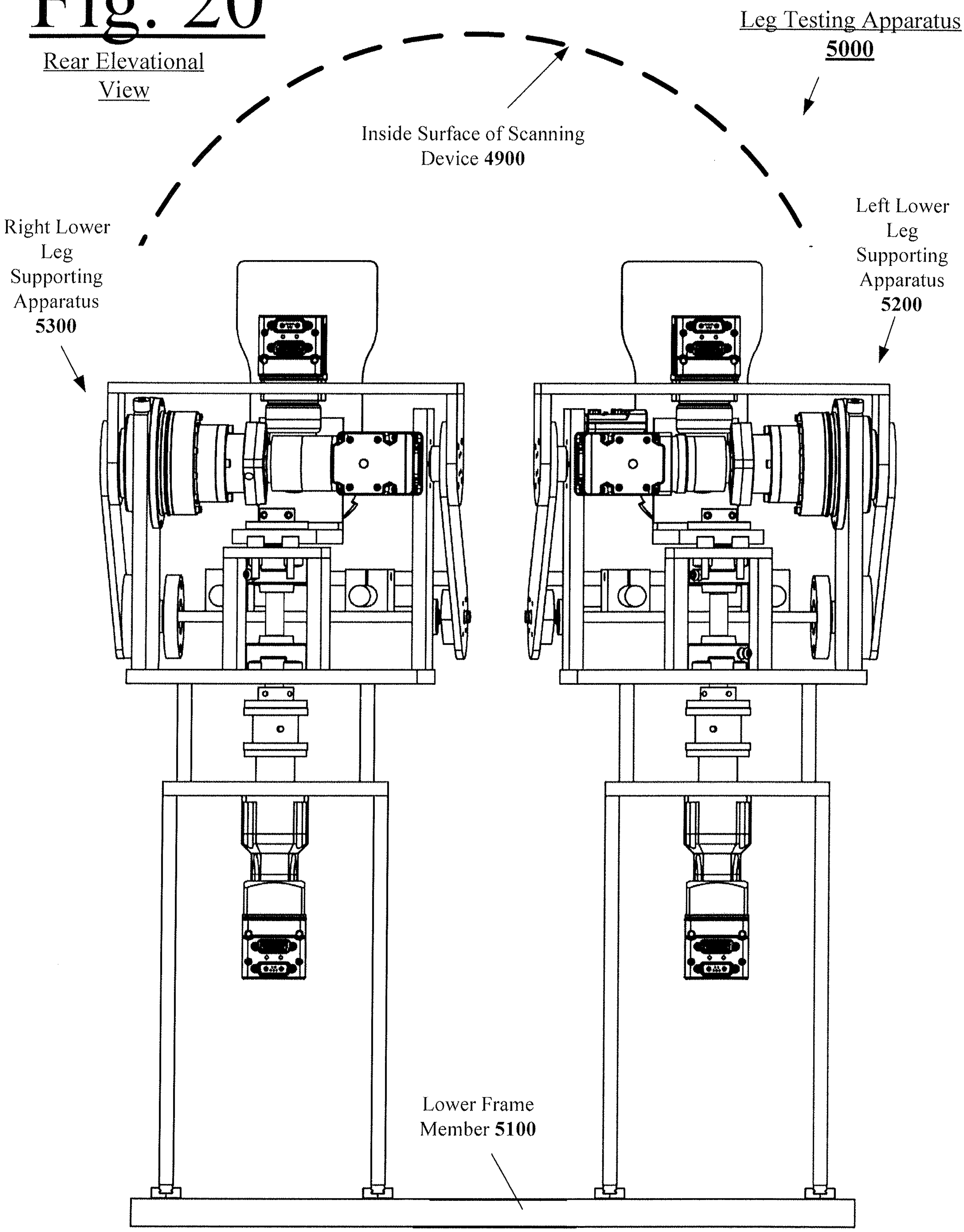
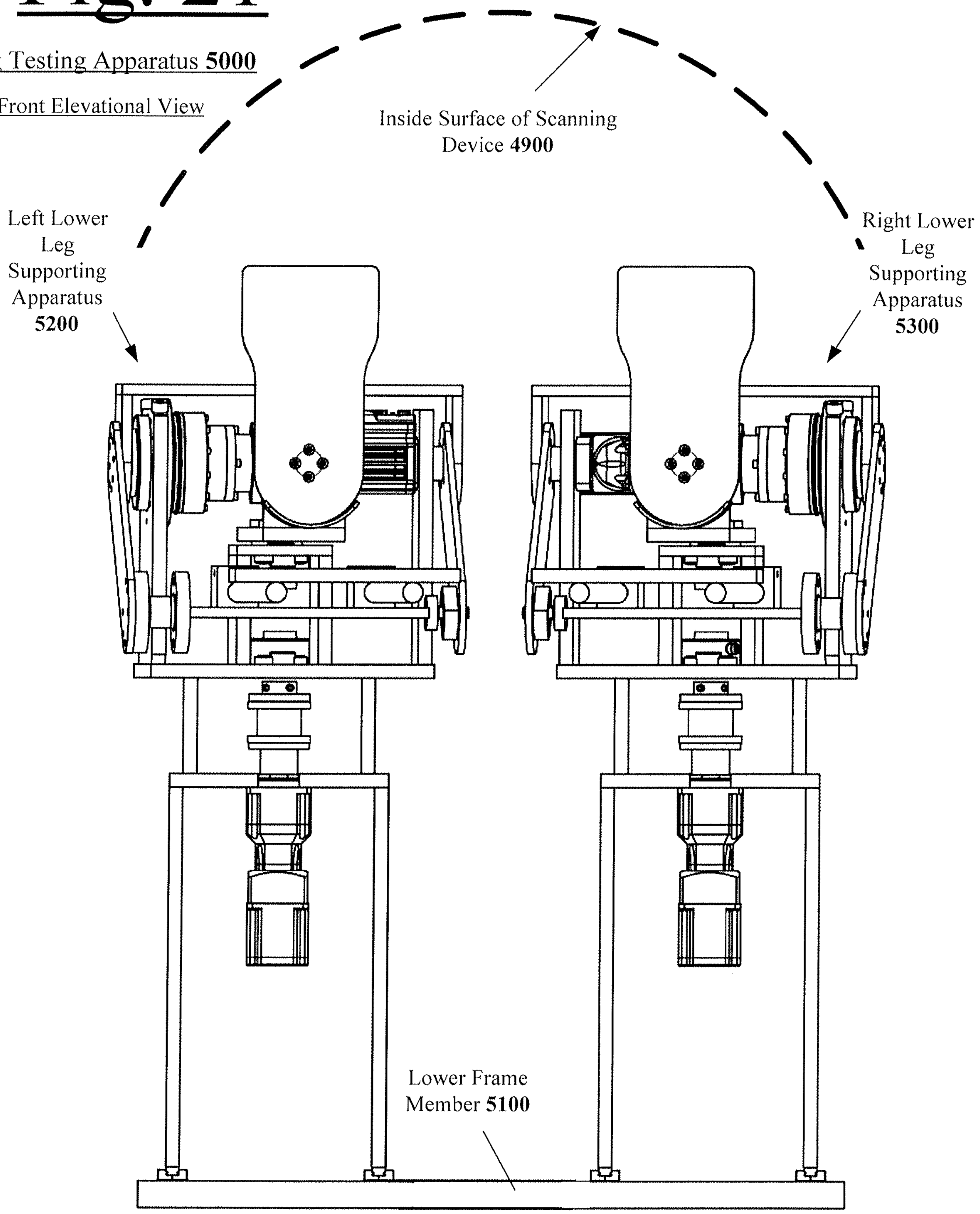


Fig. 21

Leg Testing Apparatus **5000**

Front Elevational View



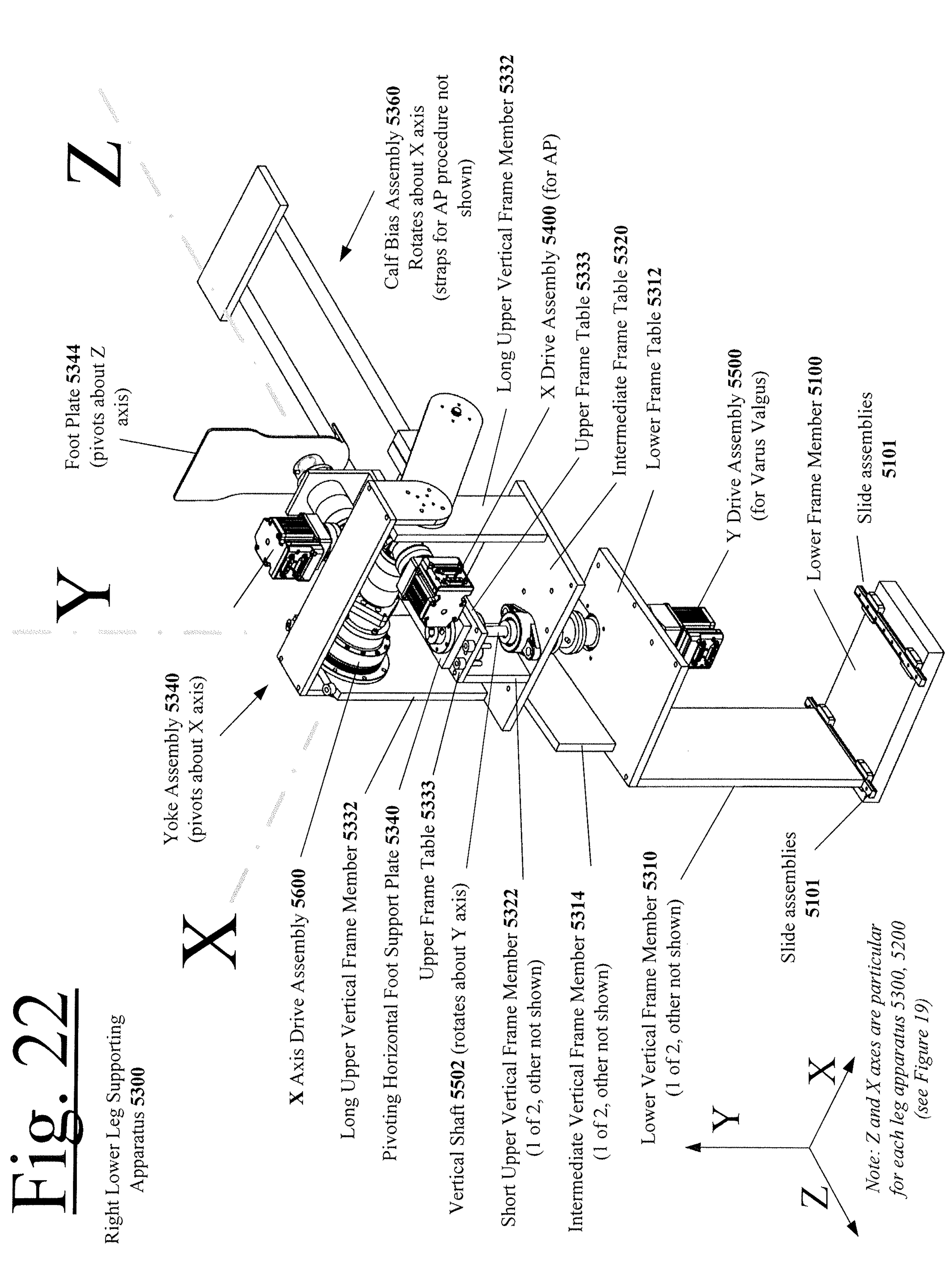
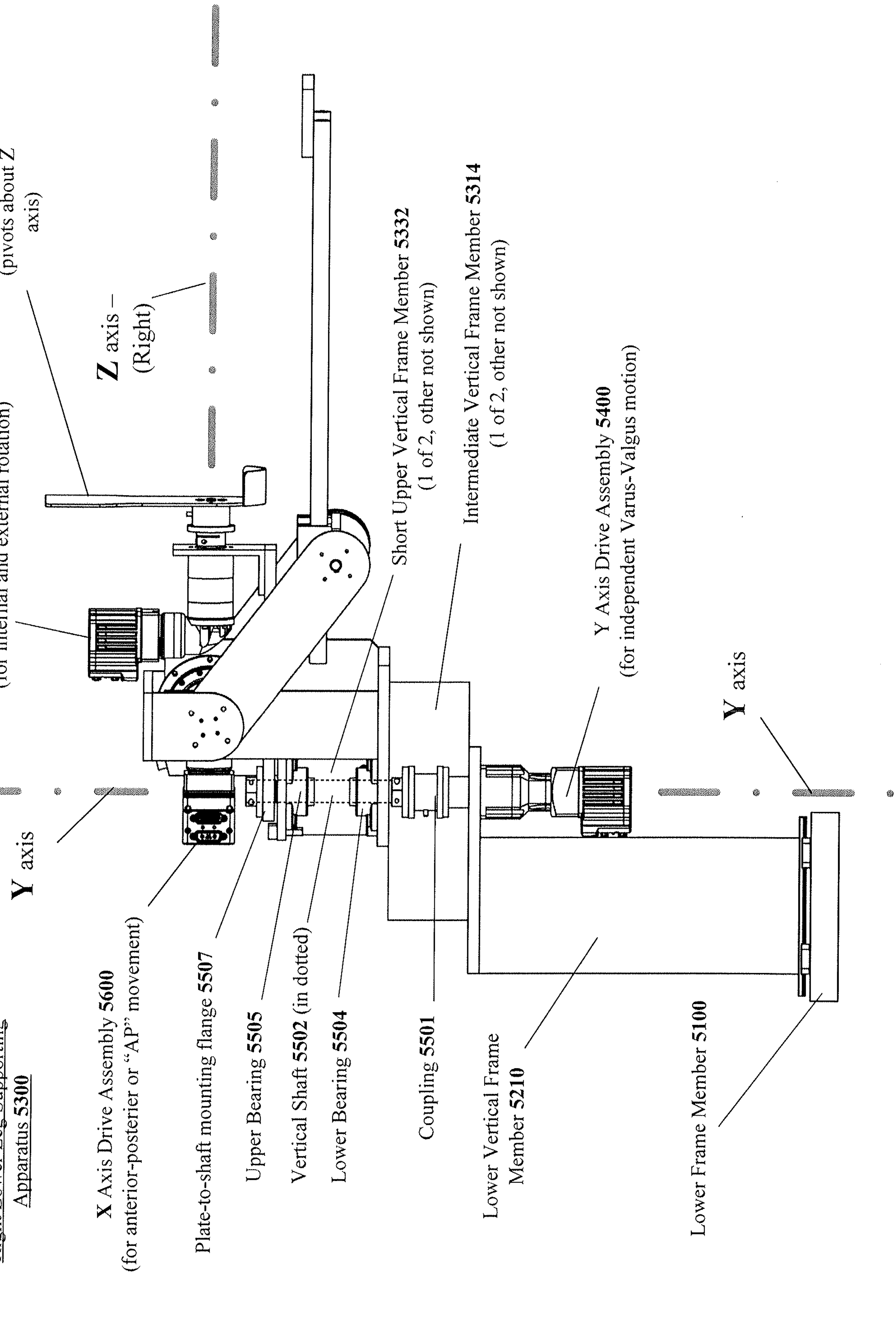

Right Lower Leg Supporting Apparatus 5300
X
Y
Z
Yoke Assembly 5340 (pivots about X axis)
Foot Plate 5344 (pivots about Z axis)
Calf Bias Assembly 5360 Rotates about X axis (straps for AP procedure not shown)
Long Upper Vertical Frame Member 5332
X Drive Assembly 5400 (for AP)
Upper Frame Table 5333
Intermediate Frame Table 5320
Lower Frame Table 5312
Y Drive Assembly 5500 (for Varus Valgus)
Lower Frame Member 5100
Slide assemblies 5101
X Axis Drive Assembly 5600
Long Upper Vertical Frame Member 5332
Pivoting Horizontal Foot Support Plate 5340
Upper Frame Table 5333
Vertical Shaft 5502 (rotates about Y axis)
Short Upper Vertical Frame Member 5322 (1 of 2, other not shown)
Intermediate Vertical Frame Member 5314 (1 of 2, other not shown)
Lower Vertical Frame Member 5310 (1 of 2, other not shown)
Slide assemblies 5101
Note: Z and X axes are particular for each leg apparatus 5300, 5200 (see Figure 19)

Fig. 22

Fig. 23

Right Lower Leg Supporting Apparatus 5300



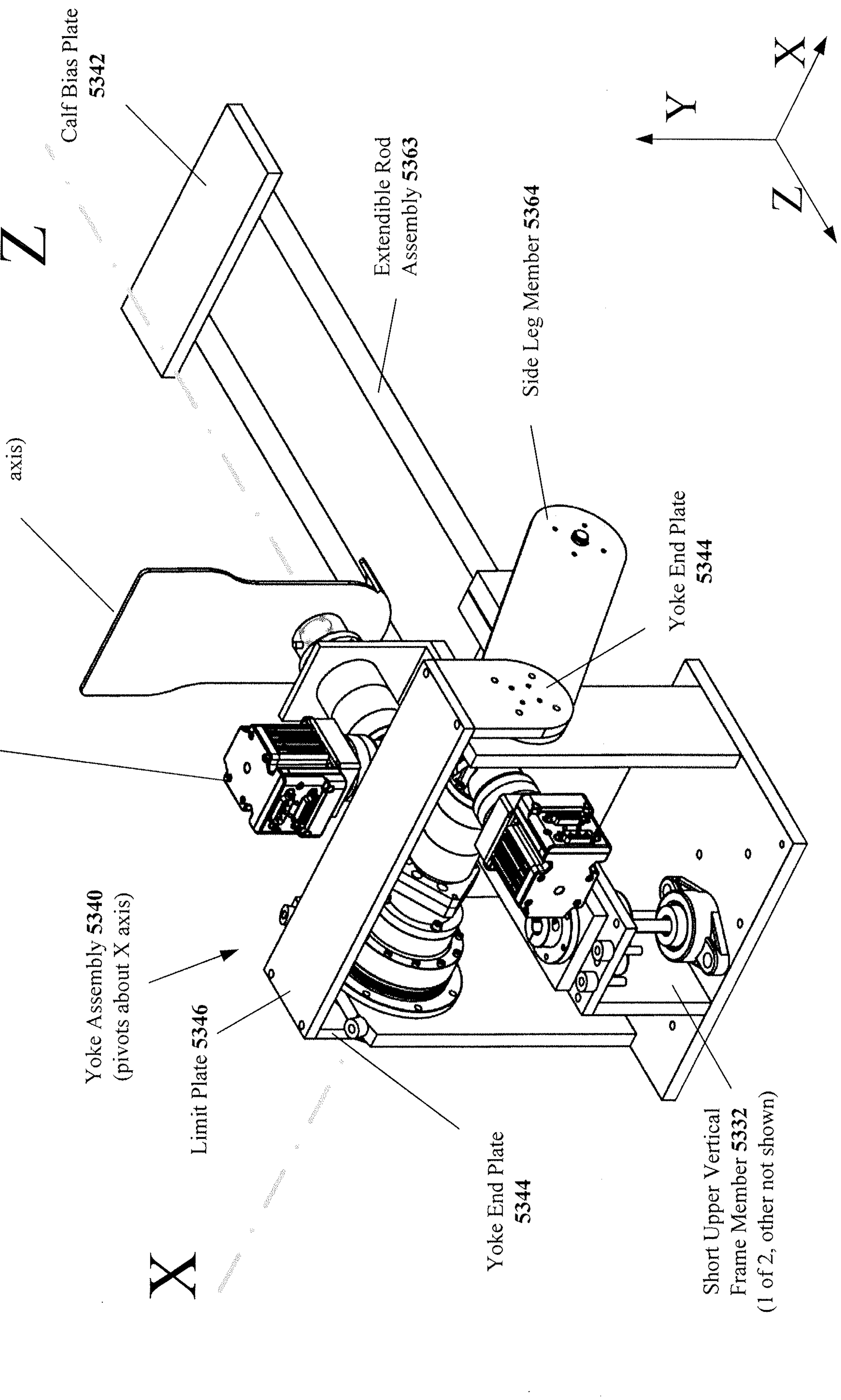


Fig. 24
Right Lower Leg Supporting Apparatus 5300

Fig. 25

Right Lower Leg Supporting Apparatus **5300**

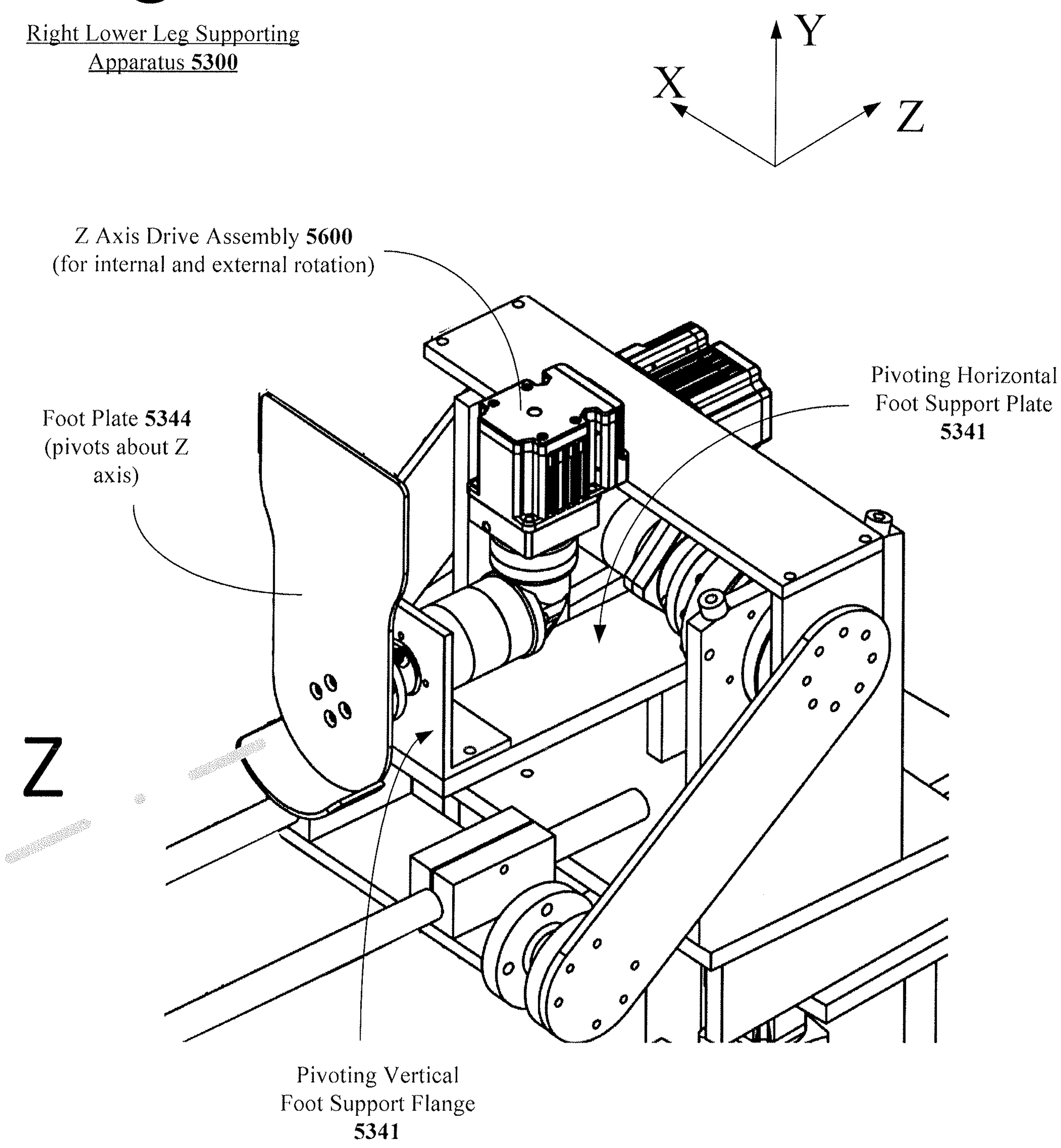


Fig. 26A

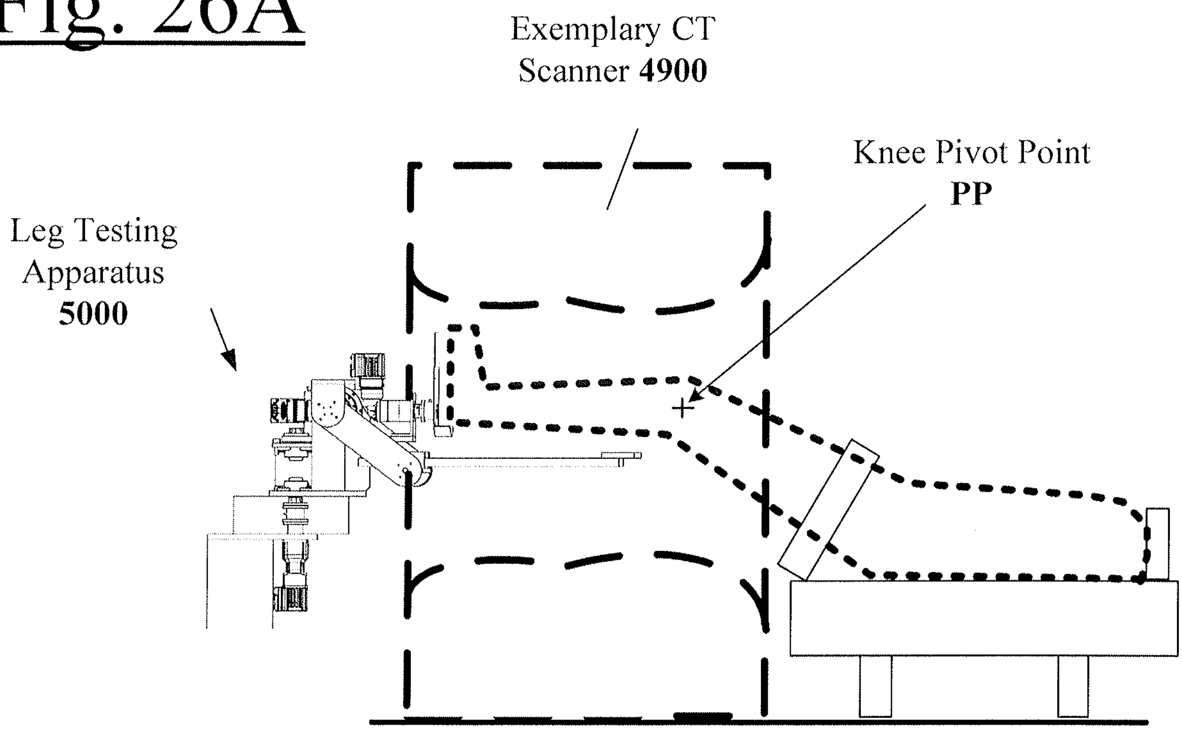
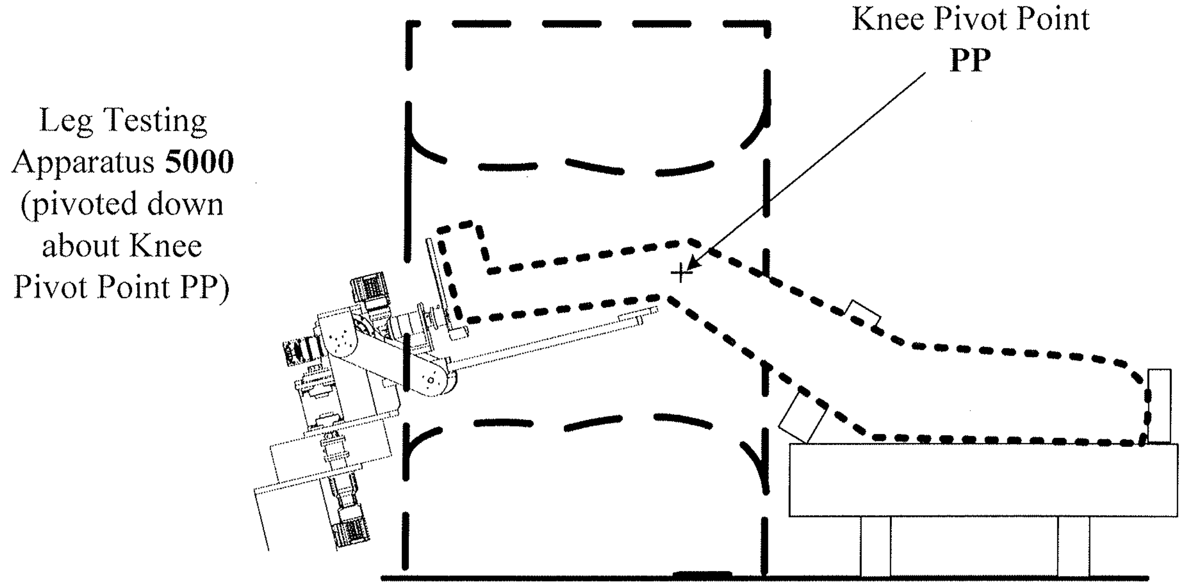
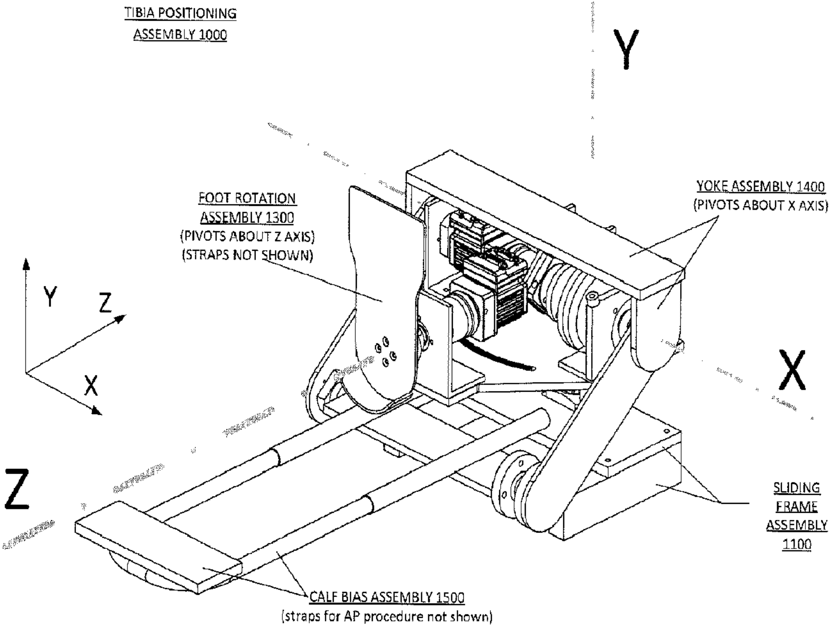


Fig. 26B




TIBIA POSITIONING
ASSEMBLY 1000
Y
FOOT ROTATION
ASSEMBLY 1300
(PIVOTS ABOUT Z AXIS)
(STRAPS NOT SHOWN)
YOKE ASSEMBLY 1400
(PIVOTS ABOUT X AXIS)
Y
Z
X
X
Z
SLIDING
FRAME
ASSEMBLY
1100
CALF BIAS ASSEMBLY 1500
(straps for AP procedure not shown)