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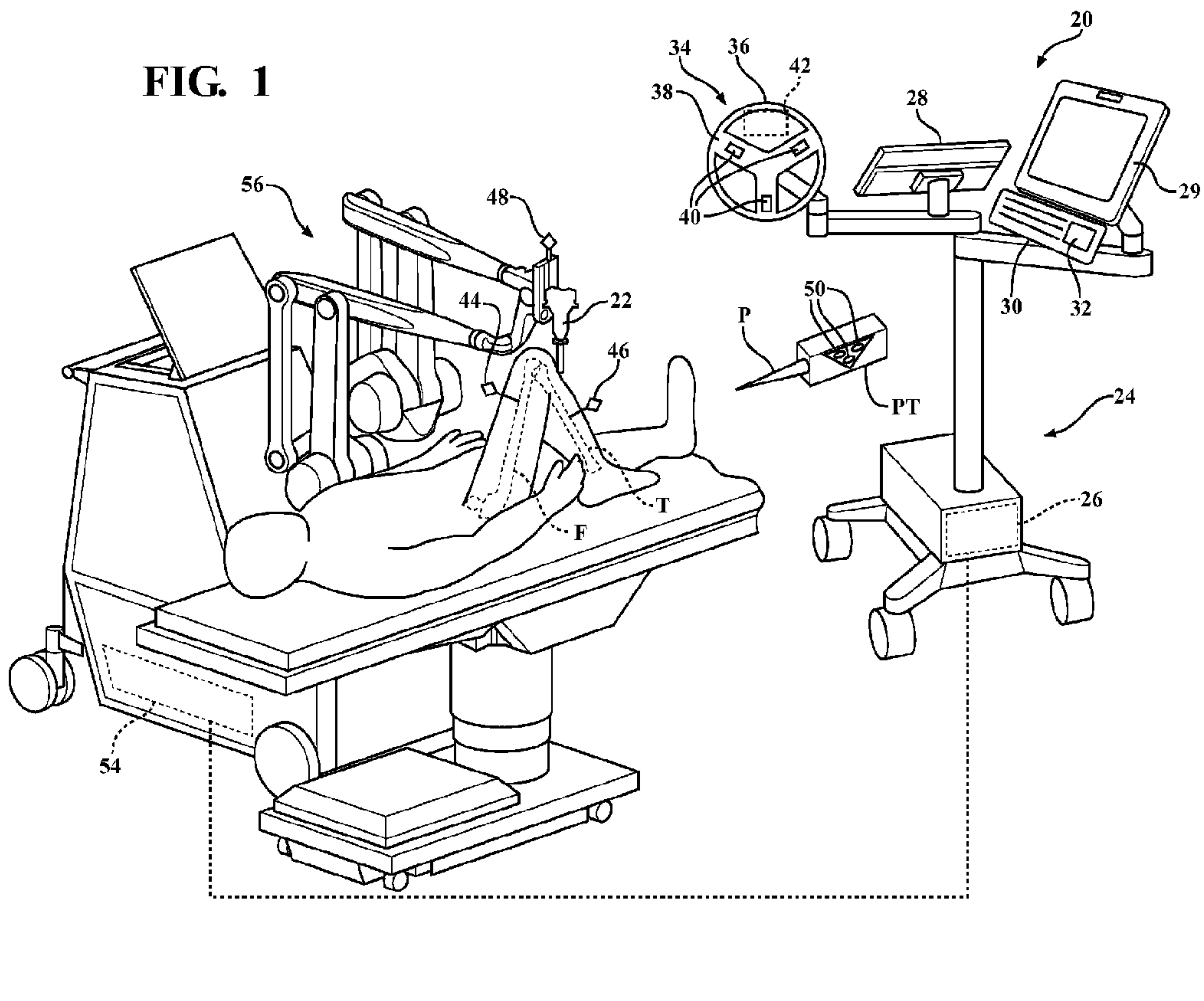
(54) Titre : SYSTEME D'AGENCEMENT D'OBJETS DANS UNE SALLE D'OPERATION EN VUE DE PROCEDURES CHIRURGICALES
(54) Title: SYSTEM FOR ARRANGING OBJECTS IN AN OPERATING ROOM IN PREPARATION FOR SURGICAL PROCEDURES

FIG. 1



(57) Abrégé/Abstract:
Systems and methods for arranging objects in an operating room in preparation for a surgical procedure. The objects are arranged based on surgical procedure information provided to a guidance station. The surgical procedure information dictates the desired placement of the objects. Placement of the objects is then guided according to their desired placement using one or more tracking elements.

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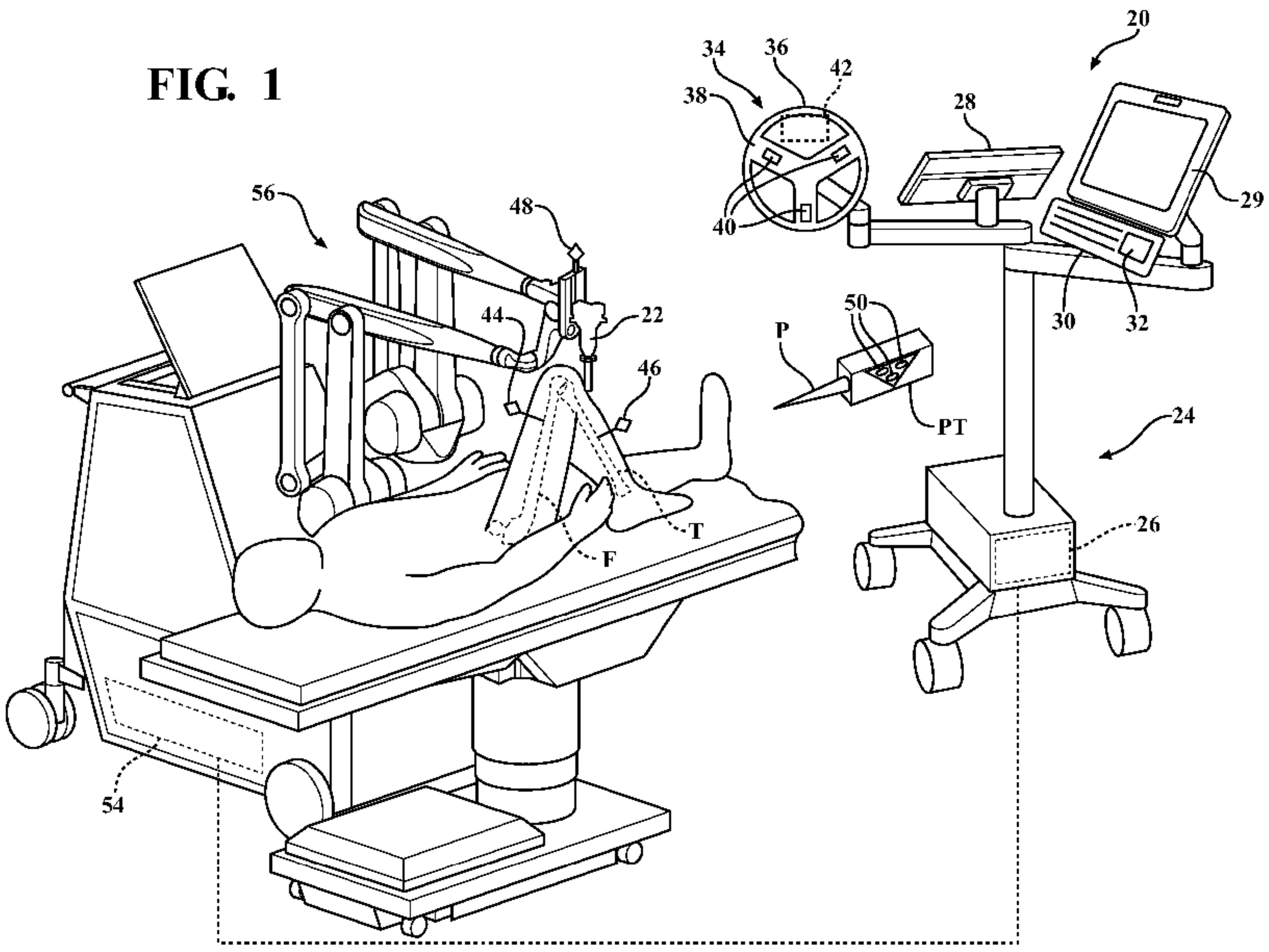
(54) **Title**: SYSTEM FOR ARRANGING OBJECTS IN AN OPERATING ROOM IN PREPARATION FOR SURGICAL PROCEDURES

FIG. 1



(57) **Abstract**: Systems and methods for arranging objects in an operating room in preparation for a surgical procedure. The objects are arranged based on surgical procedure information provided to a guidance station. The surgical procedure information dictates the desired placement of the objects. Placement of the objects is then guided according to their desired placement using one or more tracking elements.

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SYSTEM FOR ARRANGING OBJECTS IN AN OPERATING ROOM IN PREPARATION FOR SURGICAL PROCEDURES

RELATED APPLICATIONS

[0001] This application claims priority to and the benefit of U.S. Provisional Patent Application No. 61/779,725, filed on March 13, 2013, the entire contents of which are hereby incorporated by reference.

TECHNICAL FIELD

[0002] The present invention relates generally to a system and method for arranging objects in an operating room in preparation for a surgical procedure.

BACKGROUND

[0003] Before starting a surgical procedure, many objects need to be properly arranged in the operating room. Such objects include equipment, the patient, surgical personnel, instruments, and the like. Proper arrangement of these objects in the operating room, before the procedure begins, helps to ensure that the surgical procedure proceeds without unnecessary delays. Traditionally, objects are arranged according to written protocols that may include operating room layouts and written instructions associated with the particular procedure being performed.

[0004] In some surgical procedures, navigation equipment such as sensing devices (e.g., tracking cameras, magnetic field sensors, etc.) and tracking devices require arrangement before the procedure starts. Navigation systems employ such navigation equipment to assist users in locating objects. For instance, navigation systems assist surgeons in precisely placing surgical instruments relative to a patient's anatomy. Surgeries in which navigation systems are used include neurosurgery and orthopedic surgery. Typically, the instrument and the anatomy are tracked together with their relative movement shown on a display.

[0005] Navigation systems may employ light signals, sound waves, magnetic fields, RF signals, etc. in order to track the position and/or orientation of objects. Tracking devices are attached to the objects being tracked. A localizer, which includes the sensing devices, cooperates with the tracking devices to determine a position of the tracking devices, and ultimately to determine a position and/or orientation of the objects. The navigation system monitors movement of the objects via the tracking devices.

[0006] Many navigation systems rely on an unobstructed line-of-sight between the tracking devices and sensing devices. When the line-of-sight is obstructed, signals being transmitted from the tracking devices are not received by the sensing devices. As a result, errors can occur. Typically, in this situation, navigation is discontinued and error messages are conveyed to the user until the line-of-sight returns or the system is reset. This can cause delays to surgical procedures. In other types of navigation systems, such as those that rely on sensing magnetic fields, errors can also occur with respect to placement of the tracking and/or sensing devices. For example, metal in the magnetic field can cause inaccuracies in determining the position and/orientation of objects being tracked.

[0007] As a result, there is a need in the art for systems and methods to assist in arranging the tracking devices and/or sensing devices to help reduce possible errors. There is also a need in the art to use such systems and methods to arrange other objects in the operating room based on the particular procedure to be performed.

SUMMARY

[0008] In one embodiment a system is provided for arranging a plurality of objects in an operating room in preparation for a surgical procedure. The system includes a guidance station having a display and a control unit. A tracking element capable of communication with the guidance station is associated with a first of the plurality of objects so that the first object can be tracked. The control unit of the guidance station determines a desired placement of the plurality of objects based on the procedure information. The control unit then guides placement of the plurality of objects according to the desired placement.

[0009] In another embodiment a method for arranging a plurality of objects in an operating room using a guidance station having a display is provided. The method includes providing surgical procedure information to the guidance station. The method further includes determining a desired placement of the plurality of objects based on the procedure information wherein at least one of the plurality of objects includes a tracking element capable of communication with the guidance station. Placement of the plurality of objects is guided according to the desired placement.

[0010] One advantage of these embodiments is to facilitate arranging objects in the operating room in an efficient manner and based on the particular procedure to be performed so that the objects are placed in desired locations for that particular procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0011] Advantages of the present invention will be readily appreciated as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings wherein:

[0012] Figure 1 is a perspective view of a guidance station being used in conjunction with a robotic manipulator;

[0013] Figure 2 is a schematic view of the guidance station, tracking devices, pointer, and machining station;

[0014] Figure 3 is a flow diagram of steps carried out to create a pre-operative plan and load the pre-operative plan into the system;

[0015] Figure 4 is a flow diagram of steps carried out by the guidance station;

[0016] Figure 5 is a flow diagram of steps carried out by the guidance station to assist in arranging objects in an operating room;

[0017] Figure 5A is an illustration of a screen shot from an OR Setup software module providing instructions on placement of a camera unit;

[0018] Figure 5B is an illustration of an alternative screen shot from the OR Setup software module providing instructions on placement of the camera unit;

[0019] Figure 5C is an illustration of a screen shot from the OR Setup software module providing instructions on placement of a patient;

[0020] Figure 5D is an illustration of a screen shot from the OR Setup software module providing instructions on placement of trackers;

[0021] Figure 5E is an illustration of an alternative screen shot from the OR Setup software module providing instructions on placement of trackers;

[0022] Figure 6 is an overhead view of a sample right-handed operating room layout;

[0023] Figure 7 is an overhead view of a sample left-handed operating room layout;

[0024] Figure 8 is a flow diagram of steps carried out to place trackers relative to a patient;

[0025] Figure 9 is a flow diagram of steps carried out to place the machining station; and

[0026] Figure 9A is an illustration of a screen shot from the OR Setup software module providing instructions on placement of a machining station.

DETAILED DESCRIPTION

[0027] Systems and methods are disclosed for arranging objects in an operating room. Referring to Figures 1 and 2, in one embodiment, the system includes a guidance station 20 and tracking elements associated with various objects. The tracking elements are capable of communicating with the guidance station 20 to track the objects. Procedure information is provided to the guidance station 20. The procedure information may come from a pre-operative surgical plan and/or be provided intra-operatively. Based on the procedure information (e.g., identification of anatomy being treated, type of procedure – such as hip replacement surgery or total or partial knee replacement surgery, implant types/sizes, patient information, surgeon preferences, etc.), the guidance station 20 performs the steps of determining a desired placement of the objects and guiding surgical personnel to place the objects according to the desired placement. One advantage of this system and method is to reduce setup time in the operating room and improve the efficiency of surgeries.

[0028] In Figure 1, the guidance station 20 is shown in an operating room of a medical facility. The guidance station 20 is set up to track movement of the various objects in the operating room. Such objects include, for example, a surgical instrument 22, a femur F, and a tibia T. The guidance station 20 tracks these objects for purposes of displaying their relative positions and orientations to the surgeon and, in some cases, for purposes of controlling or constraining movement of the surgical instrument 22 relative to a predefined path or anatomical boundary. The guidance station 20 also assists in arranging these objects and other objects in the operating room prior to the start of a surgical procedure and/or intra-operatively, as will be discussed further below.

[0029] The guidance station 20 includes a computer cart assembly 24 that houses a navigation computer 26, or other type of control unit. A navigation interface is in operative communication with the navigation computer 26. The navigation interface includes a first display 28 adapted to be situated outside of the sterile field and a second display 29 adapted to be situated inside the sterile field. The displays 28, 29 are adjustably mounted to the computer cart assembly 24. First and second input devices 30, 32 such as a keyboard and mouse can be used to input information into the navigation computer 26 or otherwise select/control certain aspects of the navigation computer 26. Other input devices are contemplated including a touch screen (not shown) or voice-activation.

[0030] A localizer 34 communicates with the navigation computer 26. In the embodiment shown, the localizer 34 is an optical localizer and includes a camera unit 36 (also referred to as a sensing device). The camera unit 36 has an outer casing 38 that houses one or more optical position sensors 40. In some embodiments at least two optical sensors 40 are employed, preferably three or more. The optical sensors 40 may be three separate charge-coupled devices (CCD). In one embodiment three, one-dimensional CCDs are employed. It should be appreciated that in other embodiments, separate camera units, each with a separate CCD, or two or more CCDs, could also be arranged around the operating room. The CCDs detect infrared (IR) signals.

[0031] Camera unit 36 is mounted on an adjustable arm to position the optical sensors 40 with a field of view of the below discussed trackers that, ideally, is free from obstructions. The adjustable arm allows adjustment of the camera unit 36 in at least one degree of freedom and, in some embodiments, in two or more degrees of freedom.

[0032] The camera unit 36 includes a camera controller 42 in communication with the optical sensors 40 to receive signals from the optical sensors 40. The camera controller 42 communicates with the navigation computer 26 through either a wired or wireless connection (not shown). One such connection may be an IEEE 1394 interface, which is a serial bus interface standard for high-speed communications and isochronous real-time data transfer. The connection could also use a company specific protocol. In other embodiments, the optical sensors 40 communicate directly with the navigation computer 26.

[0033] Position and orientation signals and/or data are transmitted to the navigation computer 26 for purposes of tracking the objects. The displays 28, 29 and camera unit 36 may be like those described in U.S. Patent No. 7,725,162 to Malackowski, et al. issued on May 25, 2010, entitled “Surgery System”, hereby incorporated by reference.

[0034] The navigation computer 26 can be a personal computer or laptop computer. Navigation computer 26 has the displays 28, 29, central processing unit (CPU) and/or other processors, memory (not shown), and storage (not shown). The navigation computer 26 is loaded with software as described below. The software converts the signals/data received from the camera unit 36 into data representative of the position and orientation of the objects being tracked.

[0035] Guidance station 20 communicates with a plurality of tracking devices 44, 46, 48, also referred to herein as trackers. In the illustrated embodiment, one tracker 44 is firmly affixed to the femur F of the patient and another tracker 46 is firmly affixed to the tibia T of the patient. Trackers 44, 46 are firmly affixed to sections of bone. Trackers 44, 46 may be attached to the femur F and tibia T in the manner shown in U.S. Patent No. 7,725,162, hereby incorporated by reference. Trackers 44, 46 could also be mounted like those shown in U.S. Provisional Patent Application No. 61/753,219, filed on January 16, 2013, entitled, "Tracking Devices and Navigation Systems and Methods for Use Thereof", hereby incorporated by reference herein. In additional embodiments, a tracker is attached to the patella (not shown) to track a position and orientation of the patella. In yet further embodiments, the trackers 44, 46 could be mounted to other tissue types or parts of the anatomy.

[0036] An instrument tracker 48 is rigidly attached to the surgical instrument 22. The instrument tracker 48 may be integrated into the surgical instrument 22 during manufacture or may be separately mounted to the surgical instrument 22 in preparation for the surgical procedure. The working end of the surgical instrument 22, which is being tracked by virtue of the instrument tracker 48, may be a rotating bur, electrical ablation device, or the like.

[0037] The trackers 44, 46, 48 can be battery powered with an internal battery or may have leads to receive power through the navigation computer 26, which, like the camera unit 36, preferably receives external power.

[0038] In the embodiment shown, the surgical instrument 22 is an end effector of a machining station 56. Such an arrangement is shown in U.S. Provisional Patent Application No. 61/679,258, entitled, "Surgical Manipulator Capable of Controlling a Surgical Instrument in either a Semi-Autonomous Mode or a Manual, Boundary Constrained Mode", the disclosure of which is hereby incorporated by reference. A separate tracker (not shown) may be attached to a mobile cart 57 of the machining station 56 to track movement of the cart 57. Alternatively, through joint position sensors (not shown) such as position encoders, the guidance station 20 is able to determine a position of the cart 57 based on the position and orientation of the instrument tracker 48 and owing to the rigid connection of the instrument tracker 48 relative to the machining station 56.

[0039] The optical sensors 40 of the localizer 34 receive light signals from the trackers 44, 46, 48. In the illustrated embodiment, the trackers 44, 46, 48 are active trackers. In this embodiment, each tracker 44, 46, 48 has at least three active tracking elements or markers for transmitting light signals to the optical sensors 40. The active markers can be, for example, light emitting diodes or LEDs 50 transmitting light, such as infrared light. The optical sensors 40 preferably have sampling rates of 100 Hz or more, more preferably 300 Hz or more, and most preferably 500 Hz or more. In some embodiments, the optical sensors 40 have sampling rates of 8000 Hz. The sampling rate is the rate at which the optical sensors 40 receive light signals from sequentially fired LEDs 50. In some embodiments, the light signals from the LEDs 50 are fired at different rates for each tracker 44, 46, 48.

[0040] Referring to Figure 2, each of the LEDs 50 are connected to a tracker controller 62 located in a housing (not shown) of the associated tracker 44, 46, 48 that transmits/receives data to/from the navigation computer 26. In one embodiment, the tracker controllers 62 transmit data on the order of several Megabytes/second through wired connections with the navigation computer 26. In other embodiments, a wireless connection may be used. In these embodiments, the navigation computer 26 has a transceiver (not shown) to receive the data from the tracker controller 62.

[0041] In other embodiments, the trackers 44, 46, 48 may have passive markers (not shown), such as reflectors that reflect light emitted from the camera unit 36. The reflected light is then received by the optical sensors 40. Active and passive tracking elements are well known in the art.

[0042] The navigation computer 26 includes a navigation processor 52. The camera unit 36 receives optical signals from the LEDs 50 of the trackers 44, 46, 48 and outputs to the processor 52 signals relating to the position of the LEDs 50 of the trackers 44, 46, 48 relative to the localizer 34. Based on the received optical signals, navigation processor 52 generates data indicating the relative positions and orientations of the trackers 44, 46, 48 relative to the localizer 34. In some embodiments, the trackers 44, 46, 48 also include a gyroscope sensor 60 and accelerometer 70, such as the trackers shown in U.S. Provisional Patent Application No. 61/753,219, filed on January 16, 2013, entitled, "Tracking Devices and Navigation Systems and Methods for Use Thereof", hereby incorporated by reference.

[0043] It should be understood that the navigation processor 52 could include one or more processors to control operation of the navigation computer 26. The processors can be any type of microprocessor or multi-processor system. The term processor is not intended to limit the scope of the invention to a single processor.

[0044] Based on the positions of the LEDs 50 and previously loaded data relating to the patient's anatomy and the surgical instrument 22, navigation processor 52 determines the position and orientation of the surgical instrument 22 relative to the tissue (e.g., femur F and tibia T) against which the working end is to be applied. The previously loaded data includes data associated with pre-operative images, including MRI images, CT scans, etc. taken before the surgical procedure. The previously loaded data also includes geometric relationships between the working end of the surgical instrument 22 and the LEDs 50 on instrument tracker 48. Using well known navigation techniques for registration and coordinate system transformation, the patient's anatomy and the working end of the surgical instrument 22 can be registered into a coordinate reference frame of the localizer 34 so that the working end and the anatomy can be tracked together using the LEDs 50.

[0045] In some embodiments, navigation processor 52 forwards position and/or orientation data to a manipulator controller 54. The manipulator controller 54 can then use the data to control the machining station 56 as described in U.S. Provisional Patent Application No. 61/679,258, entitled, "Surgical Manipulator Capable of Controlling a Surgical Instrument in either a Semi-Autonomous Mode or a Manual, Boundary Constrained Mode," the disclosure of which is hereby incorporated by reference.

[0046] The navigation processor 52 also generates image signals that indicate the relative position of the surgical instrument working end to the surgical site. These image signals are applied to the displays 28, 29. Displays 28, 29, based on these signals, generate images that allow the surgeon and surgical personnel to view the relative position of the surgical instrument working end to the surgical site. The displays, 28, 29, as discussed above, may include a touch screen or other input/output device that allows entry of commands.

[0047] Referring to Figure 2, a localization engine 100 is a software module that can be considered part of the guidance station 20. Components of the localization engine 100 run on navigation processor 52. In some versions of the invention, the localization engine 100 may run on the manipulator controller 54.

[0048] Localization engine 100 receives as inputs the optically-based signals from the camera controller 42 and, in some embodiments, the non-optically based signals from the tracker controller 62. Based on these signals, localization engine 100 determines the pose of the trackers 44, 46, 48 in the localizer coordinate system. The localization engine 100 forwards the signals representative of the poses of trackers 44, 46, 48 to a coordinate transformer 102. Coordinate transformer 102 is a navigation system software module that runs on navigation processor 52. Coordinate transformer 102 references the data that defines the relationship between the pre-operative images of the patient and the patient trackers 44, 46. Coordinate transformer 102 also stores the data indicating the pose of the working end of the surgical instrument relative to the instrument tracker 48.

[0049] The coordinate transformer 102 then generates data indicating the position and orientation of the working end of the surgical instrument 22 relative to the tissue (e.g., bone) against which the instrument working end is applied. Image signals representative of these data are forwarded to displays 28, 29 enabling the surgeon and surgical personnel to view this information. To avoid interruption of this data, the line-of-sight between the trackers 44, 46, 48 and the sensors 40 is to be maintained. If there are obstructions to the line-of-sight, then errors may occur.

[0050] The guidance station 20 is configured to assist with the pre-surgery and/or intra-operative placement of objects, such as the trackers 44, 46, 48, used in the operating room during a surgical procedure. The guidance station 20 provides instructions on the arrangement of the objects to facilitate procedural efficiency and to reduce possible obstructions to navigation during the surgical procedure. Other objects that may be arranged according to instructions from the guidance station 20 may include, but are not limited to, the patient, the machining station 56, surgical personnel, the camera unit 36, other instruments, equipment, or stations, and the like. The instructions provided by the guidance station 20 may be based on procedure information such as the type of procedure being performed, preferences of the surgeon performing the procedure, implant types/sizes, patient information, and other factors.

[0051] Referring to Figure 3, in the embodiment shown, the instructions from the guidance station 20 are provided based on the pre-operative plan. The pre-operative plan is created in step 101. Pre-operative plans are prescribed by surgeons for each patient and describe in detail the type of procedure being performed, the target anatomy that is being treated, the types, sizes, and/or shapes of implants (if any) that are being implanted, surgeon preferences, and other information.

[0052] Creation of the pre-operative plan includes several steps. First, the patient is diagnosed to determine the appropriate treatment for the patient. Next, the surgeon prescribes the treatment. In the embodiment shown, the treatment is a total knee replacement. The surgeon's prescription includes the imaging of the patient's bones, i.e., the femur and tibia using MRI, CT scan, etc. Once imaging of the bones is complete, the images are used to prepare or select an appropriate design of a total knee implant. The design can also be based on a kinematic study of the patient performed in the operating room (OR) immediately prior to the surgery.

[0053] The design includes the type of implant, the size/shape of the implant, and the location on the bones to which the implant is to be fixed (which includes identifying the tissue to be removed to receive the implant). This information may be stored in electronic form in a computer readable format such as a text file, image file, or the like. The design may be prepared or selected by the surgeon or by a third party. Once the design of the knee implant is determined, the surgeon reviews the design, and if acceptable, approves the design and the surgical procedure is scheduled. Once the surgical procedure is scheduled, the operating room is prepared for the surgery, which includes arranging the objects based on the pre-operative plan.

[0054] In other embodiments, the objects are arranged based on procedure information determined at the time of the surgery, i.e., not pre-operatively.

[0055] The pre-operative plan is stored on the guidance station 20 in step 103. The pre-operative plan may be stored in the navigation computer 26 using a wired or wireless internet connection to the navigation computer 26, by flash memory device, or the like. In some cases, the surgeon or his or her designee transfers the encrypted pre-operative plan (including design information) to the guidance station 20, via hospital or surgical center secure local area network (Ethernet), secure USB flash drive, or secure wireless (WiFi) connection. In some embodiments, the pre-operative plan is created using the guidance station 20.

[0056] Referring to Figure 4, once the procedure information (e.g., information from pre-operative plan) is stored in the navigation computer 26, an OR Setup module 109 (see Figure 2) can be used to begin setting up the objects in the operating room. The OR Setup module 109 is a software module that runs on navigation computer 26. The surgical personnel can operate the OR Setup module 109 using the user interface and displays 28, 29 of the guidance station 20. When using the OR Setup module 109, the surgical personnel first load the procedure information (e.g., pre-operative plan) into the OR Setup module 109. When loaded, certain information is made available to the OR Setup module 109.

[0057] The OR Setup module 109 determines a prescribed arrangement of objects based on the procedure information in step 104. The prescribed arrangement of objects can be determined by looking for certain information loaded into the OR Setup module 109 and matching the information to one of a plurality of prescribed arrangements listed in a look-up table. The look-up table is stored on the navigation computer 26. For instance, the information loaded may identify the type of procedure as “TOTAL KNEE – LEFT”. The OR Setup module 109 is programmed to select a prescribed arrangement of objects based on this type of procedure by finding in the look-up table the specific arrangement associated with “TOTAL KNEE – LEFT”.

[0058] Prescribed arrangements include overhead layouts such as those shown in Figures 6 and 7. These overhead layouts may be stored in the navigation computer 26 as image files or other file types. Alternatively, the overhead layouts may be part of the pre-operative plan and/or loaded along with the procedure information into the OR Setup module 109. Different layouts may be associated with different procedure types. Different layouts may also be associated with different surgeon preferences. For example, the layout shown in Figure 6 is for a right-handed surgeon, while the layout shown in Figure 7 is for a left-handed surgeon.

[0059] Once the prescribed arrangement is determined, the guidance station 20 provides instructions to arrange the objects accordingly in step 105. Such instructions can be carried out in the order shown in Figure 5. Other orders of these instructions are also contemplated.

[0060] In step 108, the guidance station 20 displays the overhead layout determined by the OR Setup module. The overhead layout is shown on the displays 28, 29. The overhead layout provides the surgical personnel with instructions on the gross placement of the objects including the guidance station 20, the patient and operating table, the machining station 56, the surgeon, nurses, and other objects. As described further below, more precise positioning of trackers 44, 46 and the machining station 56 is also navigationally guided by the guidance station 20.

[0061] Now that the overhead layout is shown, the surgical personnel can move the guidance station 20 into its indicated position on the overhead layout. Once in position, the method moves to step 110 which directs placement of the camera unit 36. Transition to step 110 may require input from the surgical personnel, such as selecting “OK” or “DONE” on the displays 28, 29 with an input device to indicate to the OR Setup module 109 that the guidance station 20 is in position.

[0062] The camera unit 36 is adjustable about at least one degree of freedom and, in some cases, about two or more degrees of freedom. The guidance station 20, through the OR Setup module 109, instructs the surgical personnel on how to position the camera unit 36. This instruction may include written instructions present on displays 28, 29 to adjust the camera unit 36 to a predetermined height or a predetermine angle relative to ground. Referring to Figure 5A, the instruction for placement of the camera unit 36 may include visual guidance showing an exemplary setup for the camera unit 36. Once the camera unit 36 is properly placed, transition to step 112 may require input from the surgical personnel, such as selecting “OK” or “DONE” on the displays 28, 29 with an input device to indicate to the OR Setup module 109 that the camera unit 36 is in position.

[0063] In some embodiments, joints of the arms for moving the camera unit 36 may have position encoders that can be read by the navigation computer 26 and used to dynamically track movement of the camera unit 36 relative to the ground based on known geometric relationships between the cart assembly 24, ground, adjustment arms, and camera unit 36. In this case, referring to Figure 5B, visual guidance on the displays 28, 29 can include showing a representation of the current position of the camera unit 36 (shown in hidden lines) relative to a representation of the desired position of the camera unit 36. The representation of the current position dynamically moves on the displays 28, 29 toward or away from the representation of the desired position as the user adjusts a position of the camera unit 36. The OR Setup module 109 can transmit images to the displays 28, 29 showing the direction of required movement to reach the desired position, such as the arrow shown in Figure 5B. Once the current position of the camera unit 36 is within a predefined tolerance of the desired position, the OR Setup module 109 indicates that the desired position has been reached and moves to Step 112.

[0064] The patient is brought into the operating room on the operating table in step 112. The patient, in the case of a total knee replacement, is either brought in under anesthesia or anesthesia is administered in the operating room. The surgical staff may also secure the leg of interest in a leg holder, and drape the patient and equipment. One such leg holder is shown in U.S. Patent Application No. 13/554,010, entitled, “Multi-position Limb Holder”, published as U.S. Patent Application Publication No. 2013/0019883, hereby incorporated by reference.

[0065] Instructions on the placement of the patient may include written instructions on the displays 28, 29 regarding positioning of the operating table relative to the guidance station 20. Such instructions may include establishing a desired distance between the computer cart assembly 24 and the operating table or aligning a particular side of the operating table with respect to the camera unit 36. The instruction for placement of the patient may include visual guidance showing an exemplary setup for the patient relative to the camera unit 36.

[0066] In some embodiments, a video camera (not shown) is attached to the camera unit 36. The video camera is oriented such that a field of view of the camera unit 36 can be associated with the field of view of the video camera. In other words, the two fields of view may be matched or otherwise correlated such that if an object (e.g., LEDs 50) can be seen in video images streamed from the video camera, the objects are also within the field of view of the camera unit 36. Video images from the video camera can be streamed to the displays 28, 29 during any of the steps in Figure 5.

[0067] In step 112, while the displays 28, 29 show a window 113 with video images streaming from the video camera in the window 113, the instructions provided on the displays 28, 29 may also include written instructions stating to the surgical personnel to place the patient within the window 113. This is illustrated in Figure 5C. The window 113 may also show where certain edges or sides of the operating table are to be located by overlaying geometric visual aids (such as cross-hairs, edge lines, etc.) onto the video images and providing accompanying written instructions. Once the patient is located within the window and the operating table is properly aligned, the patient is positioned according to the pre-operative plan and/or other procedure information. Once the patient is in the proper position, transition to step 114 may require input from the surgical personnel, such as selecting “OK” or “DONE” on the displays 28, 29 with an input device to indicate to the OR Setup module 109 that the patient is in position.

[0068] Tracker placement is performed in step 114. One exemplary embodiment of instructions provided by the guidance station 20 for placing the trackers 44, 46 is shown in Figure 8. To begin, in step 120, representations of the femur F and tibia T are shown on the displays 28, 29 with desired tracker placement and associated instructions. An example of this is shown in Figure 5D. Generic bone representations are used to generally show proper placement based on distance from the knee joint, for example, or distances from certain anatomical landmarks associated with the knee joint (e.g, distances from patella, tibial tubercle, etc.). Written instructions on the displays 28, 29 can indicate distances from the anatomical landmarks to each of the trackers 44, 46 (distances may be indicated from landmark to the base of each tracker 44, 46 mounted to bone). A desired distance between trackers 44, 46 (or the bases thereof) may also be numerically and visually depicted on the displays 28, 29. In some embodiments, the instructions on the display 28, 29 include written instructions on the placement of the leg in a leg holder prior to placing the trackers 44, 46 and instructions on securing the leg holder in position. One such leg holder is shown in U.S. Patent Application No. 13/554,010, entitled, "Multi-position Limb Holder", published as U.S. Patent Application Publication No. 2013/0019883, hereby incorporated by reference.

[0069] The video camera described above may be integrated into a machine vision system of the guidance station 20 with ability to identify the leg of the patient using conventional machine vision technology. Referring to Figure 5E, once the leg is identified and shown in the window 113 on the displays 28, 29, the guidance station 20 overlays desired positions of the trackers 44, 46 on the displays 28, 29 (shown by arrows), while simultaneously and continuously showing the video images from the video camera, which shows the surgeon and/or surgical personnel placing the trackers 44, 46 (actual trackers not shown in Figure 5E).

[0070] The surgical personnel position the trackers 44, 46 in step 122. This may include placing bone pins and attaching the trackers 44, 46 to the bone pins, or this may include making an incision at the knee joint using manual instruments to gain access to the joint and mounting a bone plate and coupling tracking elements of the trackers 44, 46 to the bone plate such as shown in U.S. Provisional Patent Application No. 61/753,219, filed on January 16, 2013, entitled, "Tracking Devices and Navigation Systems and Methods for Use Thereof", hereby incorporated by reference. Once in position, the camera unit 36 is activated to begin receiving position-related signals from the LEDs 50, of the trackers 44, 46.

[0071] In step 124, the navigation computer 26 measures distances between the LEDs 50 on tracker 44 with the LEDs 50 on tracker 46. This provides a basic indication of how far apart the trackers 44, 46 are located on the bones, e.g., femur and tibia. In one embodiment, a shortest distance between the closest two LEDs 50 and a farthest distance between the farthest two LEDs 50 are measured. In step 126 these measure distances are compared to a predetermined range of distances. If both of the shortest and farthest measured distances fall within the range, the method proceeds to step 128. If not, the method goes back to step 120 and the trackers 44, 46 are repositioned according to the instructions in step 120. If the method goes back to step 120, the instructions can additionally include details on whether the trackers 44, 46 were too close together or too far apart – giving the surgical personnel additional guidance on where to position the trackers 44, 46. Repositioning of the trackers 44, 46 may simply require adjustment of the trackers 44, 46 about one or more adjustable degrees of freedom without requiring removal of the base (or bone pins) from the bone. In extreme cases, the trackers 44, 46 will need to be completely removed from the bone and re-mounted.

[0072] Once the trackers 44, 46 have been positioned within the predetermined range of distances, then the trackers 44, 46 are registered to the anatomy. Registration of bone surfaces and reference landmarks is well-known in the art using pointers P and will not be described in detail. Registration results in the pre-operative MRI or CT images being associated with positions of the LEDs 50 on the trackers 44, 46. As a result, movement of the femur F and tibia T can be tracked by tracking movement of the LEDs 50.

[0073] Once the positions and orientations of the femur F and tibia T are registered to the LEDs 50, the navigation computer 26 can simulate movement of the femur F and tibia T through a range of motion from flexion to extension and in all anticipated positions of the femur and tibia during the surgical procedure. For instance, the procedure may require the knee to be placed in maximum flexion and extension. The navigation processor 52 can simulate where the LEDs 50 will be located at maximum flexion and extension positions of the leg and determine whether the LEDs 50 will be within the field-of-view of each of the sensors 40 in all of these positions since the field-of-view of the sensors 40 is also known to the navigation computer 26. In other words, the navigation computer 26 can simulate movement of the femur F and tibia T during the procedure and detect whether any of the LEDs 50 will be blocked from the field-of-view of any of the sensors 40.

[0074] Alternatively, as opposed to running the simulation, the instructions on the displays 28, 29 may require the surgical personnel to actually move the leg through maximum extension and flexion in the leg holder, while the guidance station 20 tracks the LEDs 50 on the trackers 44, 46. Blockage is then identified by determining if at any position of the leg, any of the LEDs 50 is blocked from transmitting signals to the sensors 40.

[0075] If blockage is predicted in the simulation or actually detected when moving the leg, then the method proceeds to step 134. In step 134, representations of the actual bones of the patient are shown on the displays 28, 29 along with the current tracker placement and the desired tracker placement (similar to Figure 5E, but now using navigation position information). Instructions for moving or repositioning the trackers 44, 46 are also displayed on displays 28, 29. In some cases, repositioning may simply require sliding, tilting or rotating a head of one of the trackers 44, 46 using adjustment features of the trackers 44, 46, without requiring complete removal of the trackers 44, 46 from the bone. See, for example, adjustment features of the trackers shown in U.S. Provisional Patent Application No. 61/753,219, filed on January 16, 2013, entitled, "Tracking Devices and Navigation Systems and Methods for Use Thereof", hereby incorporated by reference. In other cases, one or both of the trackers 44, 46 need to be removed from the bones.

[0076] Once repositioned, the initial error check in step 124 is performed again. If the error is acceptable, then the trackers 44, 46 are re-registered to the anatomy and the remaining steps continue as before. At step 132, if no blockage is predicted or detected, the method proceeds to step 116. Transition to step 116 may be automatic after the simulations or movements are performed in step 132, or transition to step 116 may require input from the surgical personnel, such as selecting "OK" or "DONE" on the displays 28, 29 with an input device to indicate to the OR Setup module 109 that the patient is in position.

[0077] Prior to step 114, the trackers 44, 46 may be setup according to the procedure outlined in U.S. Provisional Patent Application No. 61/753,219, filed on January 16, 2013, entitled, "Tracking Devices and Navigation Systems and Methods for Use Thereof", hereby incorporated by reference, which may improve the likelihood that the trackers 44, 46 do not require repositioning during positioning in step 114.

[0078] The surgeon also has the ability to again review the design, confirm it matches the patient, and either give final approval or makes revisions in implant size, position, and/or orientation.

[0079] Instructions for placement of the machining station 56 are provided in step 116. One example of how these instructions are provided is shown in steps

136 through 142 in Figure 9. Once the camera unit 36, patient, and trackers 44, 46 are properly positioned, the guidance station 20 can assist in guiding the machining station 56 into position relative to the bones to be machined. In step 136, the desired placement of the machining station 56 is shown on displays 28, 29. The cart 57 of the machining station 56 also has an integrated display 59 which is in communication with the guidance station 20 (see Figure 1). The machining station display 59 additionally shows the desired placement of the machining station 56. The desired placement may be an overhead visual illustration of the cart 57 in a desired position, such as shown in Figures 6 and 7.

[0080] A position and orientation of the cart 57 is tracked by the guidance station 20 using the instrument tracker 48. More specifically, owing to rigid connections of the instrument tracker 48 to the end effector and the end effector to an arm/coupler structure of the machining station 56, the guidance station 20 is able to determine a position and orientation of the cart 57 based on the position and orientation of the instrument tracker 48 using: (1) joint angle data measured by position encoders located at joints in the machining station 56 and/or joint angle data calculated by a kinematics module, as described in U.S. Provisional Patent Application No. 61/679,258, entitled, "Surgical Manipulator Capable of Controlling a Surgical Instrument in either a Semi-Autonomous Mode or a Manual, Boundary Constrained Mode", the disclosure of which is hereby incorporated by reference; and (2) data relating to the arm/coupler structure (e.g., virtual model data) of the machining station 56, as described in U.S. Provisional Patent Application No. 61/679,258, entitled, "Surgical Manipulator Capable of Controlling a Surgical Instrument in either a Semi-Autonomous Mode or a Manual, Boundary Constrained Mode", the disclosure of which is hereby incorporated by reference. Alternatively, a separate tracker (not shown) is attached to and calibrated to a virtual model of the cart 57 to track a position and orientation of the cart 57.

[0081] In either case, the displays 28, 29, 59 in some embodiments not only show the desired overhead position of the cart 57, but also the current position of the cart 57. One example of representations of the cart 57 shown on displays 28, 29, 59 is shown Figure 9A. In Figure 9A, one visual representation is an image of the cart 57 (represented by a 2-D rectangle) shown in the desired position. Another visual representation is an image of the cart 57 (represented by a 2-D rectangle) shown in the current position. The representation of the cart 57 in the current position moves on the displays 28, 29, 59 as the cart 57 is moved. Further instructions provided by the guidance station 20 may include geometric images, such as an arrow, guiding the surgical personnel as to the direction in which to move the cart 57 to reach the desired position.

[0082] In step 138, the surgical personnel place the machining station 56 in the desired position by watching the displays 28, 29, 59, and moving the cart 57 such that the visual representations on the displays 28, 29, 59 of the actual cart position moves toward the visual representation of the desired position. In step 140, the OR Setup module 109 checks the error between actual position and desired position until the cart 57 reaches the desired position. Once the actual position of the machining station 56 is within a predetermined tolerance of the desired position, as depicted by the visual representation of the actual position of the cart 57 being aligned with the visual representation of the desired position of the cart 57, i.e., the rectangles are aligned, the OR Setup module 109 indicates that the machining station 56 is in the desired position and moves to step 118. The visual images on the displays 28, 29, 59 may blink or provide some other visual effect when the cart 57 has reached the desired position.

[0083] In step 118, the guidance station 20 instructs the surgical personnel on their proper positions relative to the patient, machining station 56, guidance station 20, etc. This may be done by re-displaying the overhead layout, such as those shown in Figures 6 and 7. Once the surgical personnel are in position and ready, the procedure can be started – see step 106 in Figure 4.

[0084] In some embodiments, the machining station 56 is a robotic surgical cutting system for cutting away material from a patient's anatomy, such as bone or soft tissue. Once the cutting system is determined to be in the proper position by the guidance station 20, the cutting system cuts away material to be replaced by surgical implants such as hip and knee implants, including unicompartmental, bicompartmental, or total knee implants. Some of these types of implants are shown in U.S. Patent Application No. 13/530,927, entitled, "Prosthetic Implant and Method of Implantation", the disclosure of which is hereby incorporated by reference. The guidance station 20 instructs the surgeon on proper procedures for locating these implants on bone and securing the implants in position, including the use of trial implants.

[0085] In other systems, the instrument 22 has a cutting tool that is movable in three degrees of freedom relative to a handheld housing and is manually positioned by the hand of the surgeon, without the aid of cutting jigs, guide arms or other constraining mechanism. Such systems are shown in U.S. Patent Application No. 13/600,888, entitled, "Surgical Instrument Including Housing, a Cutting Accessory that Extends from the Housing and Actuators that Establish the Position of the Cutting

Accessory Relative to the Housing", the disclosure of which is hereby incorporated by reference.

[0086] In these embodiments, the system includes a hand held surgical cutting instrument having a cutting tool. A control system controls movement of the cutting tool in at least 3 degrees of freedom using internal actuators/motors, as shown in U.S. Patent Application No. 13/600,888, entitled, "Surgical Instrument Including Housing, a Cutting Accessory that Extends from the Housing and Actuators that Establish the Position of the Cutting Accessory Relative to the Housing", the disclosure of which is hereby incorporated by reference. The guidance station 20 communicates with the control system. One tracker (such as tracker 48) is mounted to the instrument. Other trackers (such as trackers 44, 46) are mounted to a patient's anatomy.

[0087] In this embodiment, the guidance station 20 communicates with the control system of the hand held surgical cutting instrument. The guidance station 20 communicates position and/or orientation data to the control system. The position and/or orientation data is indicative of a position and/or orientation of the instrument 22 relative to the anatomy. This communication provides closed loop control to control cutting of the anatomy such that the cutting occurs within a predefined boundary (the term predefined boundary is understood to include predefined trajectory, volume, line, other shapes or geometric forms, and the like).

[0088] In alternative embodiments the trackers 44, 46, 48 could be other line-of-sight tracking devices or non line-of-sight tracking devices used for navigation. The trackers 44, 46, 48 could employ sound waves, magnetic fields, RF signals, and the like to determine position and/or orientation. In some of these embodiments, step 110 relates to placement of sensing devices, transmitters, generators, etc. associated with these other types of navigation systems. Likewise, steps 130 and 132 relate to checking for obstructions or other interference with signals from these other types of navigation systems. In essence, surgical personnel are instructed to place trackers of the navigation system with respect to the patient's anatomy, regardless of the type of navigation employed, so that obstructions or interference is minimized or within acceptable tolerances.

[0089] In some embodiments, the objects may be arranged with respect to an operating room table that is fixed in the operating room, i.e., unable to be readily moved, except for adjustments of portions of the operating room table. In some embodiments, some or all of the objects to be arranged according to their desired placement may be located outside the operating room and first need to be moved into the operating room. In other embodiments, some or all of the objects to be arranged according to their desired placement may already be located inside the operating room, but not yet in their desired placements.

[0090] In some embodiments, pre-surgery is considered the time leading up to any cutting or incision of the patient in the operating room for purposes of treatment. Such cutting may include the cutting of skin and tissue to access the knee joint for purposes of knee replacement or the hip joint for purposes of hip replacement.

[0091] In some embodiments, arranging the objects in the operating room may be performed manually such as by pushing a wheeled cart of the object into position, or manually attaching trackers to the patient. In other embodiments, arranging the objects may include guiding the objects into their desired placement remotely or by some automated control, such as by moving an automated cart using associated steering controls.

[0092] Several embodiments have been discussed in the foregoing description. However, the embodiments discussed herein are not intended to be exhaustive or limit the invention to any particular form. The terminology which has been used is intended to be in the nature of words of description rather than of limitation. Many modifications and variations are possible in light of the above teachings and the invention may be practiced otherwise than as specifically described.

CLAIMS

What is claimed is:

1. A method for arranging a plurality of objects in an operating room using a guidance station having a display, said method comprising:

providing surgical procedure information to the guidance station;

determining a desired placement of each of the plurality of objects in the operating room based on the procedure information wherein at least one of the plurality of objects includes a tracking element capable of communication with the guidance station; and

guiding placement of each of the plurality of objects in the operating room with respect to one another according to the desired placements.

2. A method as set forth in claim 1 wherein guiding placement of each of the plurality of objects includes guiding placement of the tracking element with respect to a bone.

3. A method as set forth in claim 2 wherein guiding placement of the tracking element includes guiding placement of a tracking device having the tracking element to avoid obstructions to line-of-sight between the tracking element and an optical sensor.

4. A method as set forth in claim 2 wherein guiding placement of each of the plurality of objects includes guiding placement of a machining station.

5. A method as set forth in claim 2 wherein providing the surgical procedure information to the guidance station includes providing an identification of a

bone to be cut and a desired implant to be attached to the bone.

6. A method as set forth in claim 2 wherein determining the desired placement of each of the plurality of objects includes determining a desired position of each of the plurality of objects.

7. A method as set forth in claim 2 wherein guiding placement of each of the plurality of objects includes displaying instructions to a user on the display.

8. A method as set forth in claim 1 wherein determining the desired placement of each of the plurality of objects includes determining the desired placement of first and second objects based on the procedure information wherein each of the first and second objects includes a tracking element capable of communication with the guidance station.

9. A method as set forth in claim 8 including guiding placement of the first and second objects in the operating room according to the desired placement.

10. A method as set forth in claim 9 wherein guiding placement of the first and second objects is further defined as guiding placement of a tracking device and guiding placement of a machining station having a cutting tool for cutting bone.

11. A method as set forth in claim 9 wherein guiding placement of the first and second objects is further defined as guiding placement of a first tracking device with respect to a first bone and guiding placement of a second tracking device with respect to a second bone.

12. A method as set forth in claim 11 including displaying representations of the first and second bones in combination with the desired placements of the first and second tracking devices on the first and second bones.

13. A method as set forth in claim 12 including checking for an error in the actual placement of the first and second tracking devices relative to the desired placements and determining whether the error is within a predefined tolerance.

14. A method as set forth in claim 13 including registering the first and second tracking devices to images of the first bone and the second bone.

15. A method as set forth in claim 13 including detecting for line-of-sight errors between the first and second tracking devices and a sensing device of the guidance station.

16. A method as set forth in claim 15 wherein detecting for errors includes modeling the first and second tracking devices and the sensing device for all positions of the tracking devices during the procedure.

17. A method as set forth in claim 2 including displaying a desired operating room layout on the display.

18. A method as set forth in claim 2 wherein the guidance station includes a camera and said method further comprises displaying instructions on placement of the camera.

19. A method as set forth in claim 2 including displaying instructions on placement of a patient.

20. A system for arranging a plurality of objects in an operating room according to surgical procedure information, said system comprising:

a guidance station having a display and a control unit;

a tracking element capable of communication with said guidance station and associated with a first of the plurality of objects so that the first object can be tracked;

wherein said control unit of said guidance station is configured to determine a desired placement of each of the plurality of objects based on the procedure information and said control unit is configured to guide placement of each of the plurality of objects in the operating room according to the desired placement.

21. A system as set forth in claim 20 wherein said control unit is configured to guide placement of said tracking element with respect to a bone.

22. A system as set forth in claim 21 wherein said control unit is configured to guide placement of a machining station having a cutting tool for cutting the bone.

23. A system as set forth in claim 21 wherein said guidance station includes an optical sensor and said control unit is configured to guide placement of said tracking element to avoid obstructions to line-of-sight between said tracking element and said optical sensor.

24. A system as set forth in claim 23 including a second tracking element capable of communication with said guidance station and associated with a second of the plurality of objects so that the second object can be tracked.

25. A system as set forth in claim 24 wherein said control unit is configured to guide placement of the first and second objects in the operating room according to the

desired placements based on signals from said tracking elements received by said optical sensor.

26. A system as set forth in claim 25 wherein said control unit is configured to guide placement of the first and second objects and a machining station having a cutting tool for cutting bone.

27. A system as set forth in claim 25 wherein said control unit is configured to guide placement of the first and second objects with respect to first and second bones wherein the first and second objects are further defined as first and second tracking devices, each having one of said tracking elements.

28. A system as set forth in claim 27 wherein said control unit is configured to display on said display representations of the first and second bones in combination with the desired placements of the first and second tracking devices on the first and second bones.

29. A system as set forth in claim 27 wherein said control unit is configured to check for an error in placement of the first and second tracking devices relative to the desired placements and determine whether the error is within a predefined tolerance.

30. A system as set forth in claim 23 wherein said control unit is configured to detect line-of-sight errors between said tracking element and said optical sensor.

31. A system as set forth in claim 30 wherein said control unit is configured to model the first and second tracking devices and said optical sensor for all positions of the tracking devices during the procedure to detect line-of-sight errors.

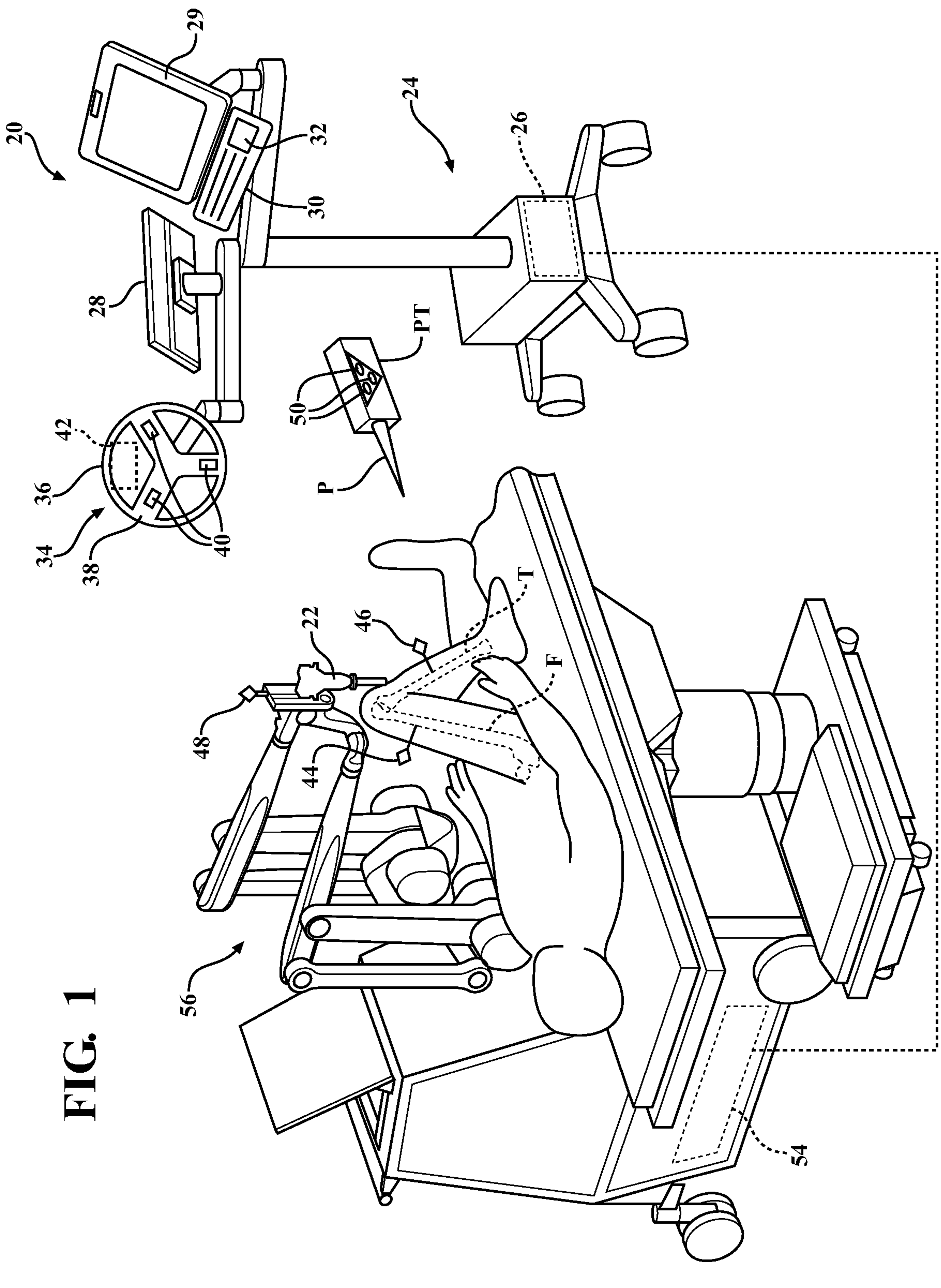


FIG. 1

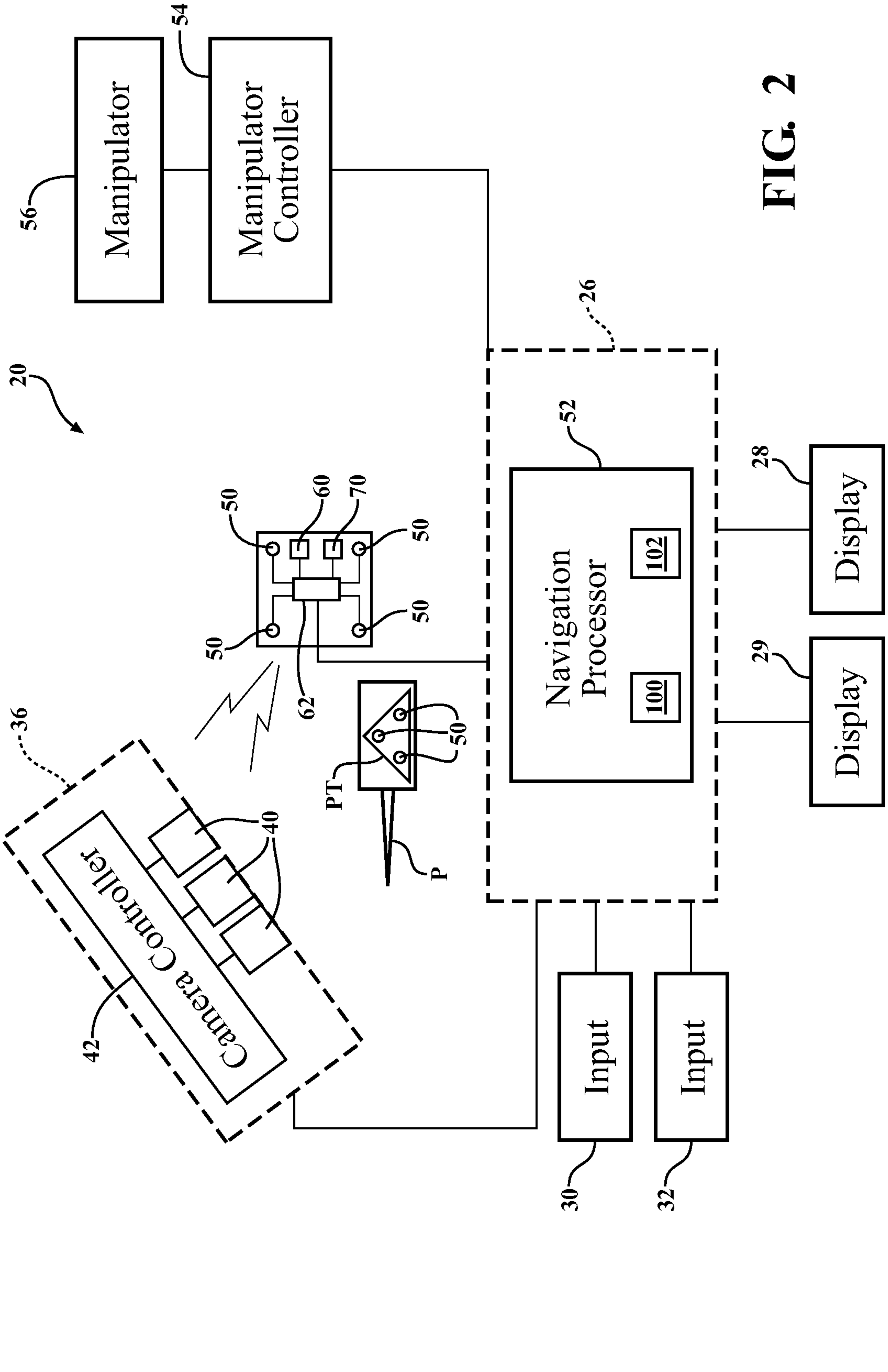

20
Manipulator
56
Manipulator Controller
54
26
Navigation Processor
52
100
102
Display
28
Display
29
Input
30
Input
32
Camera Controller
36
40
42
50
60
70
62
PT
P

FIG. 2

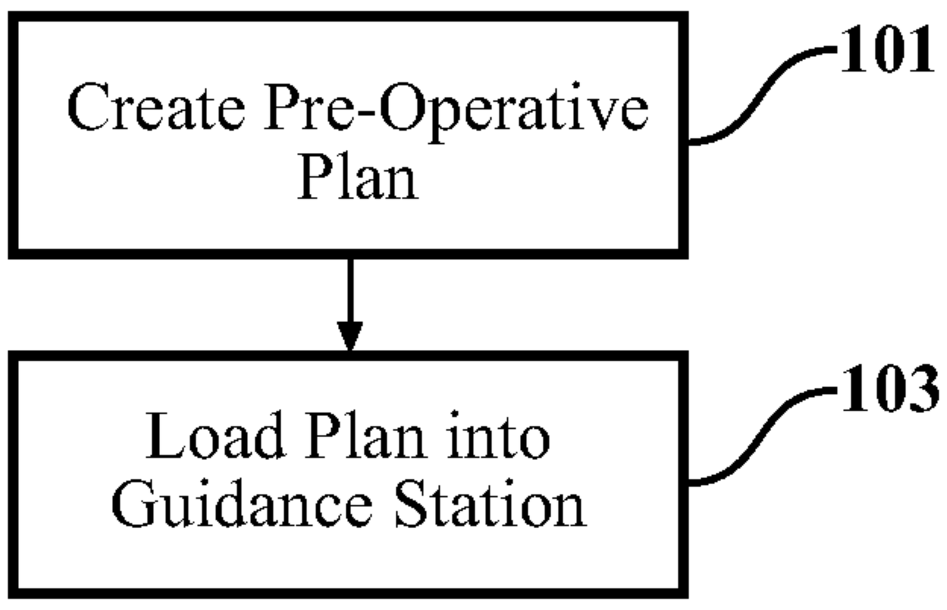


FIG. 3

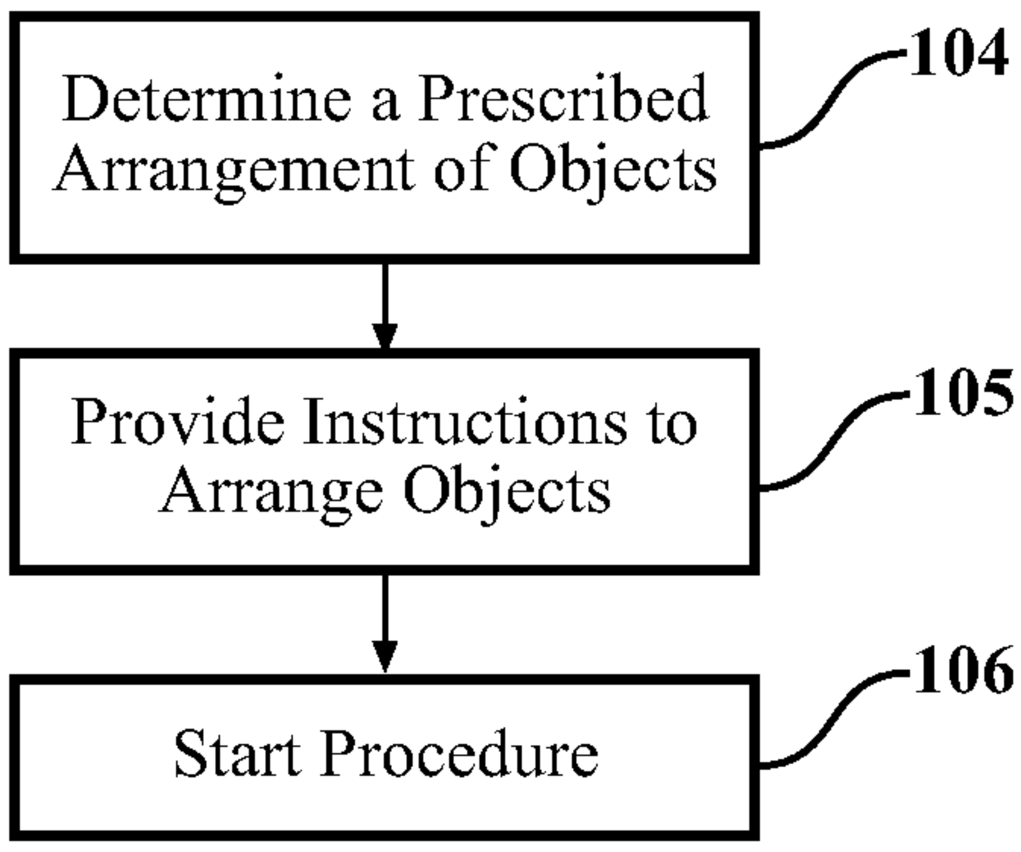


FIG. 4

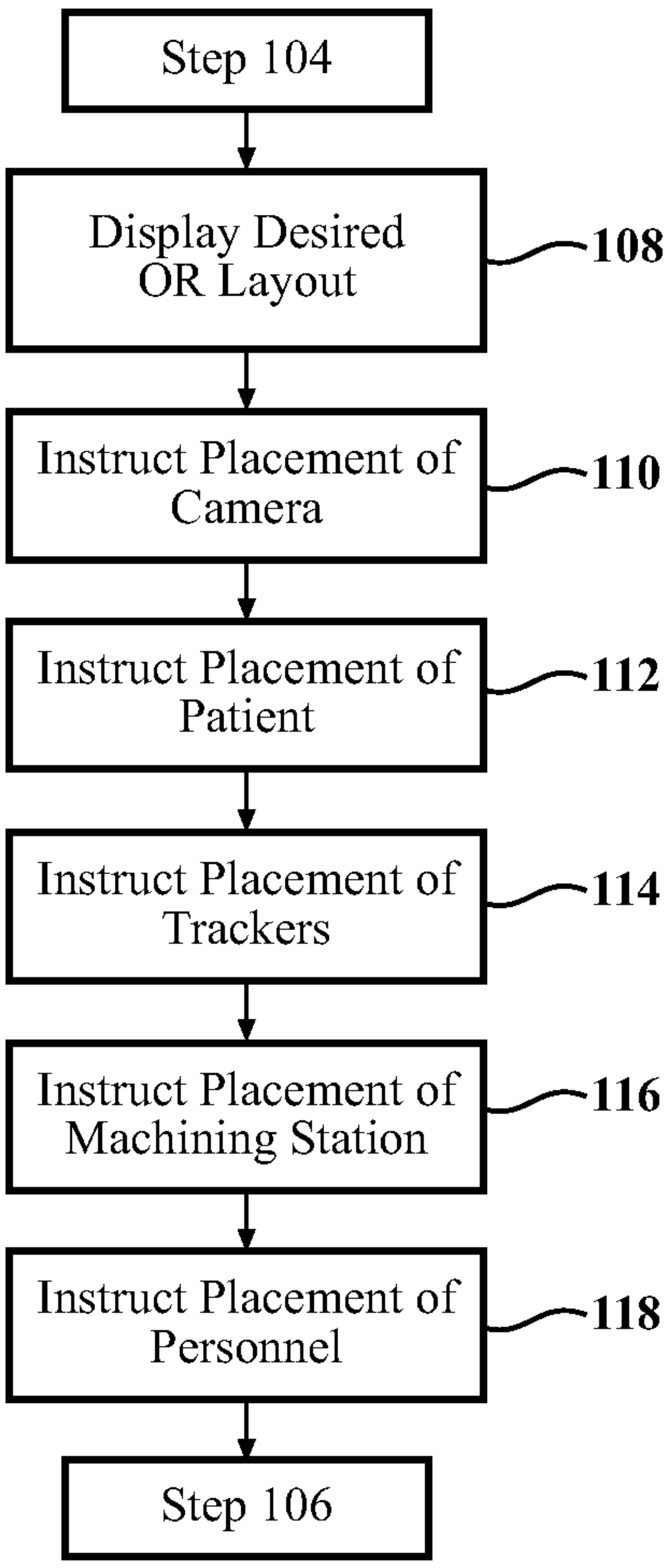


FIG. 5

FIG. 5A

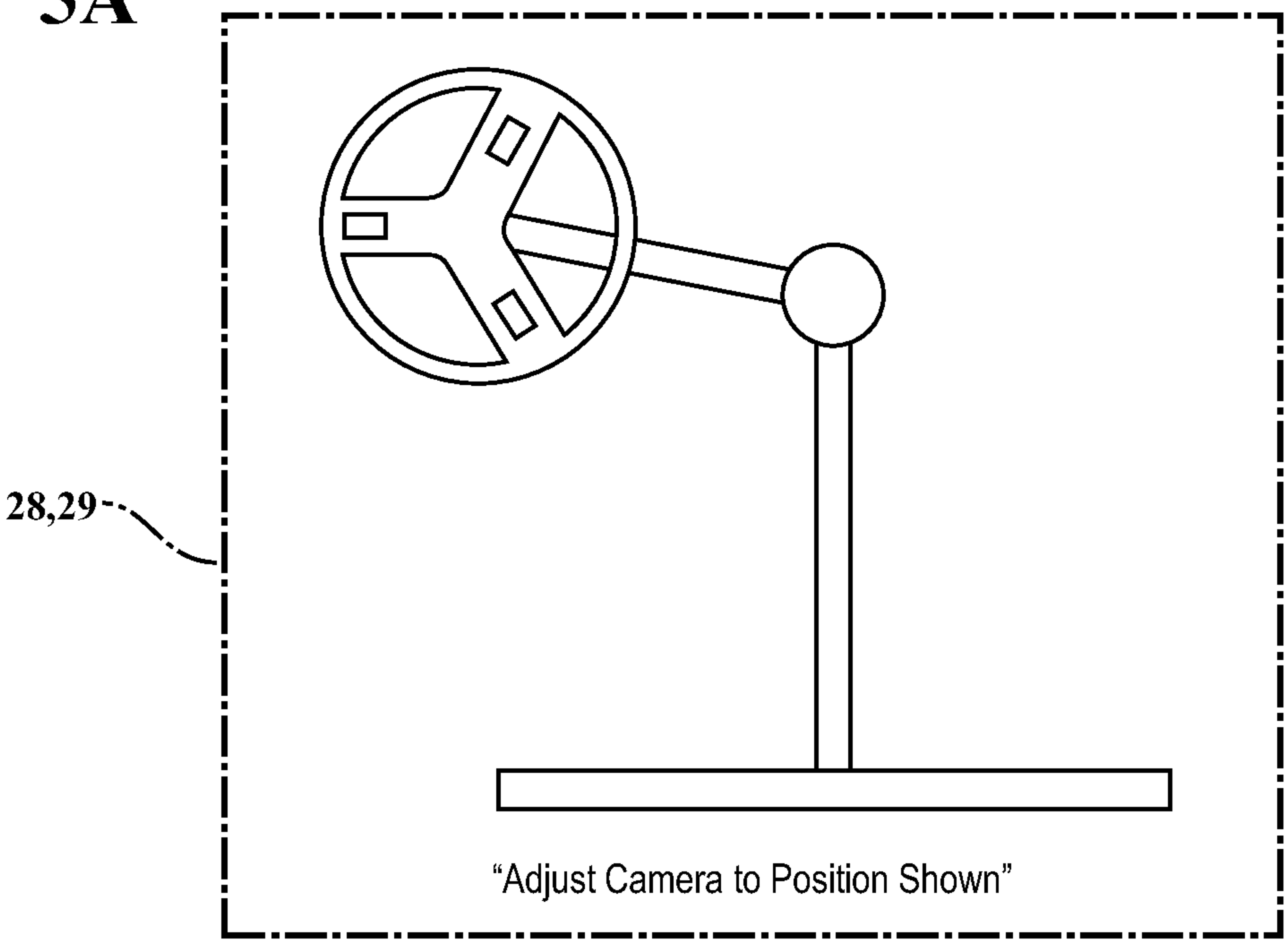

28,29
"Adjust Camera to Position Shown"

FIG. 5B

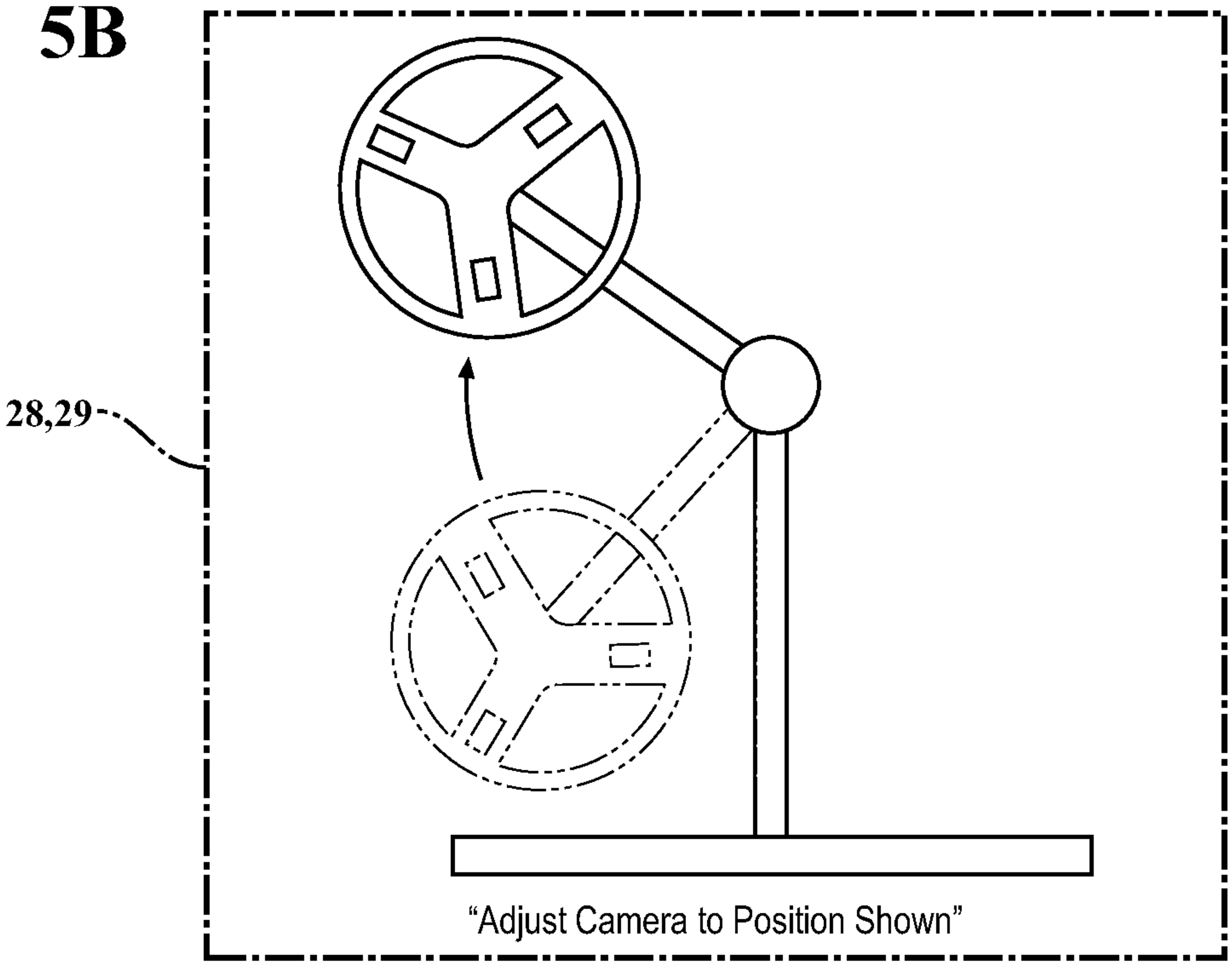

28,29
"Adjust Camera to Position Shown"

FIG. 5C

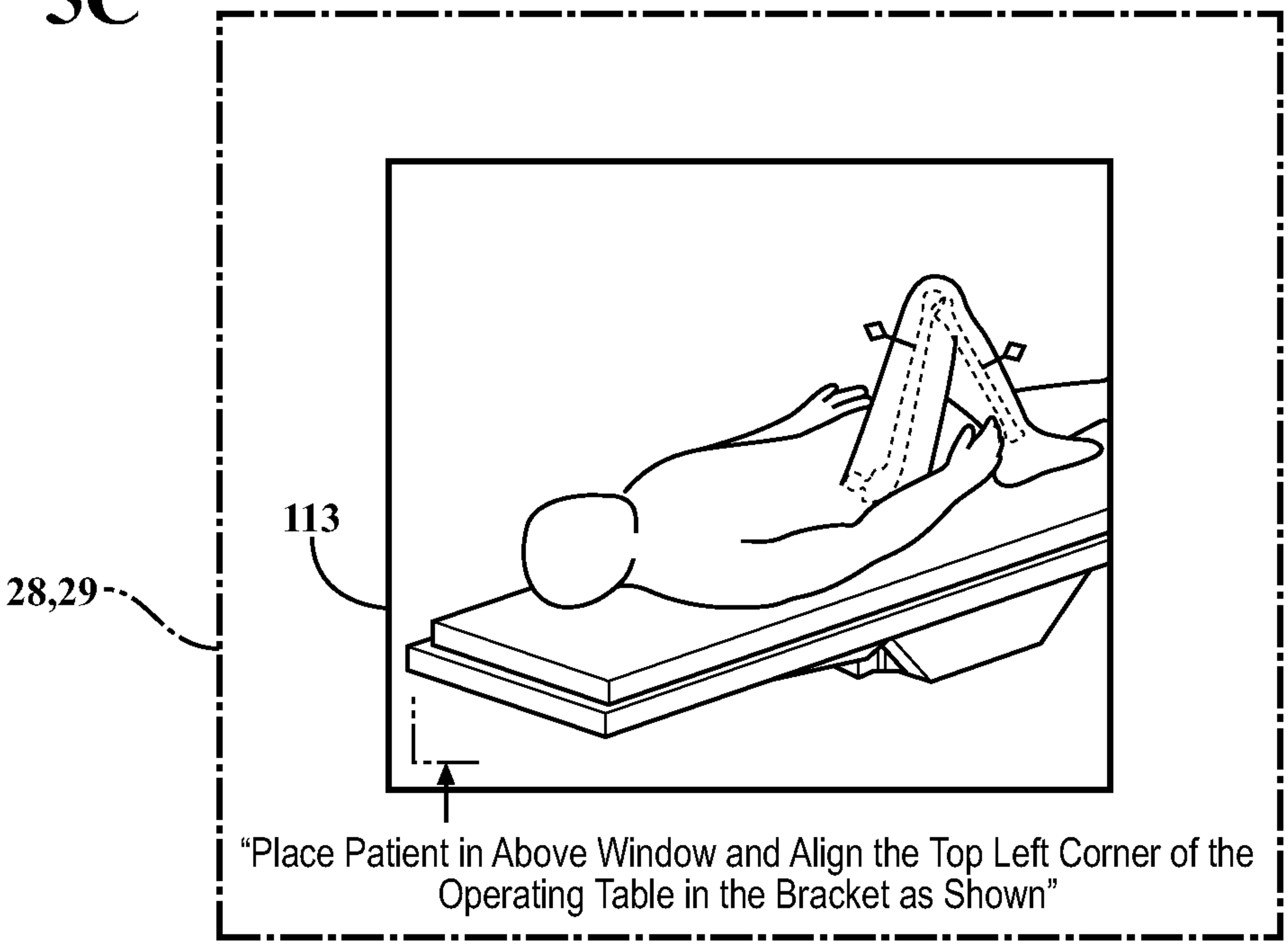
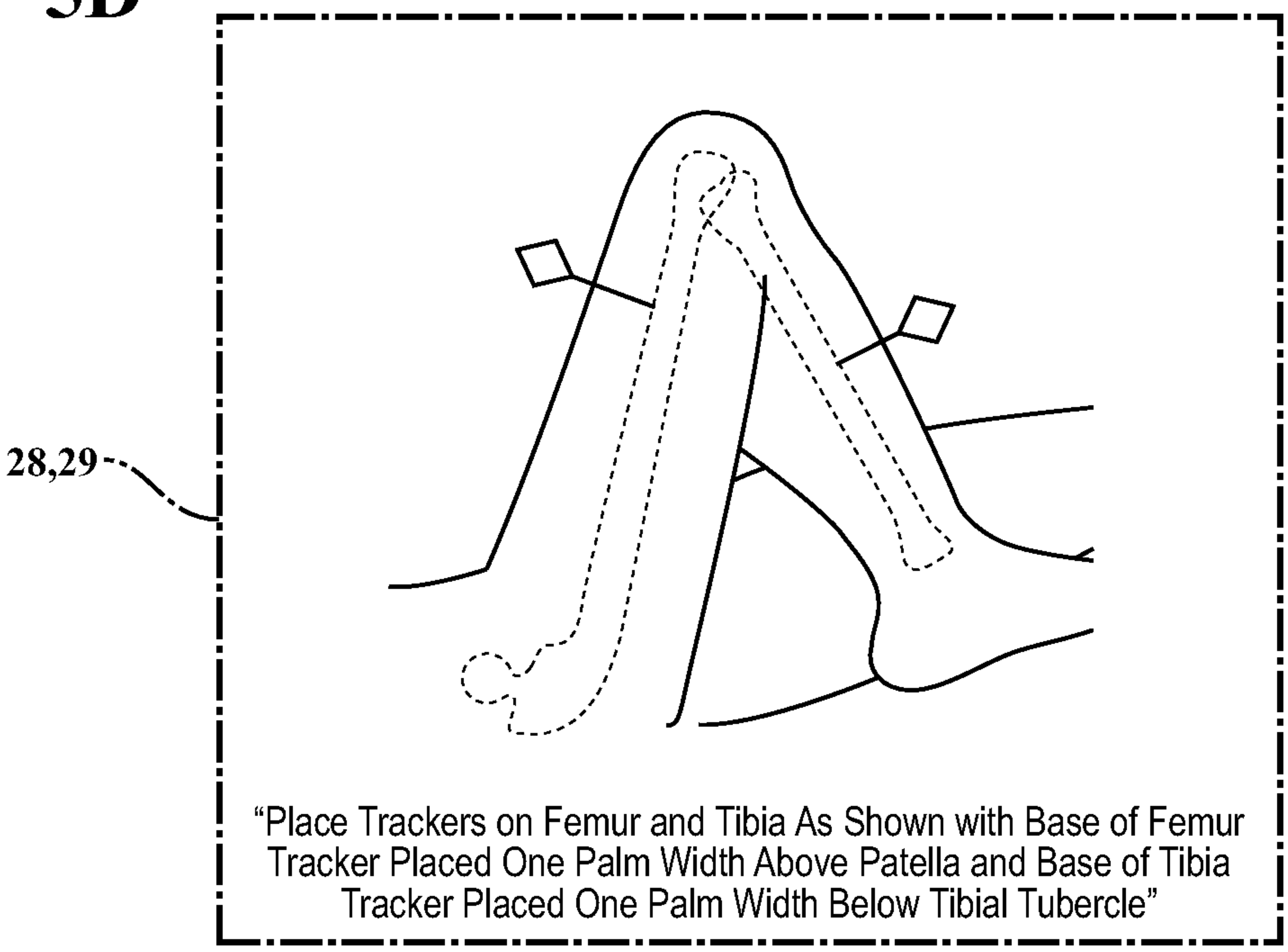

113
28,29
"Place Patient in Above Window and Align the Top Left Corner of the Operating Table in the Bracket as Shown"

FIG. 5D


28,29
"Place Trackers on Femur and Tibia As Shown with Base of Femur Tracker Placed One Palm Width Above Patella and Base of Tibia Tracker Placed One Palm Width Below Tibial Tubercle"

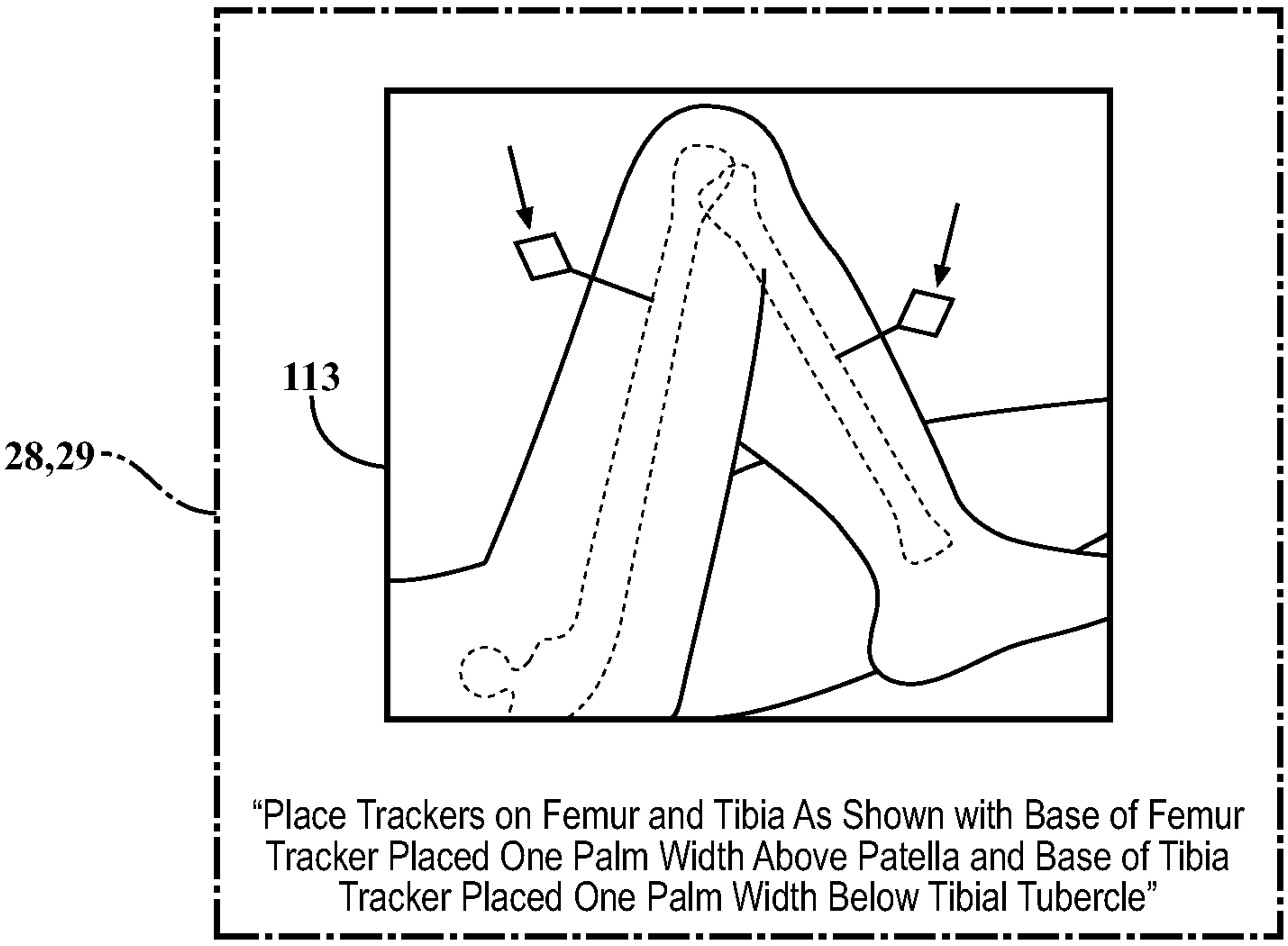

113
28,29
"Place Trackers on Femur and Tibia As Shown with Base of Femur Tracker Placed One Palm Width Above Patella and Base of Tibia Tracker Placed One Palm Width Below Tibial Tubercle"

FIG. 5E

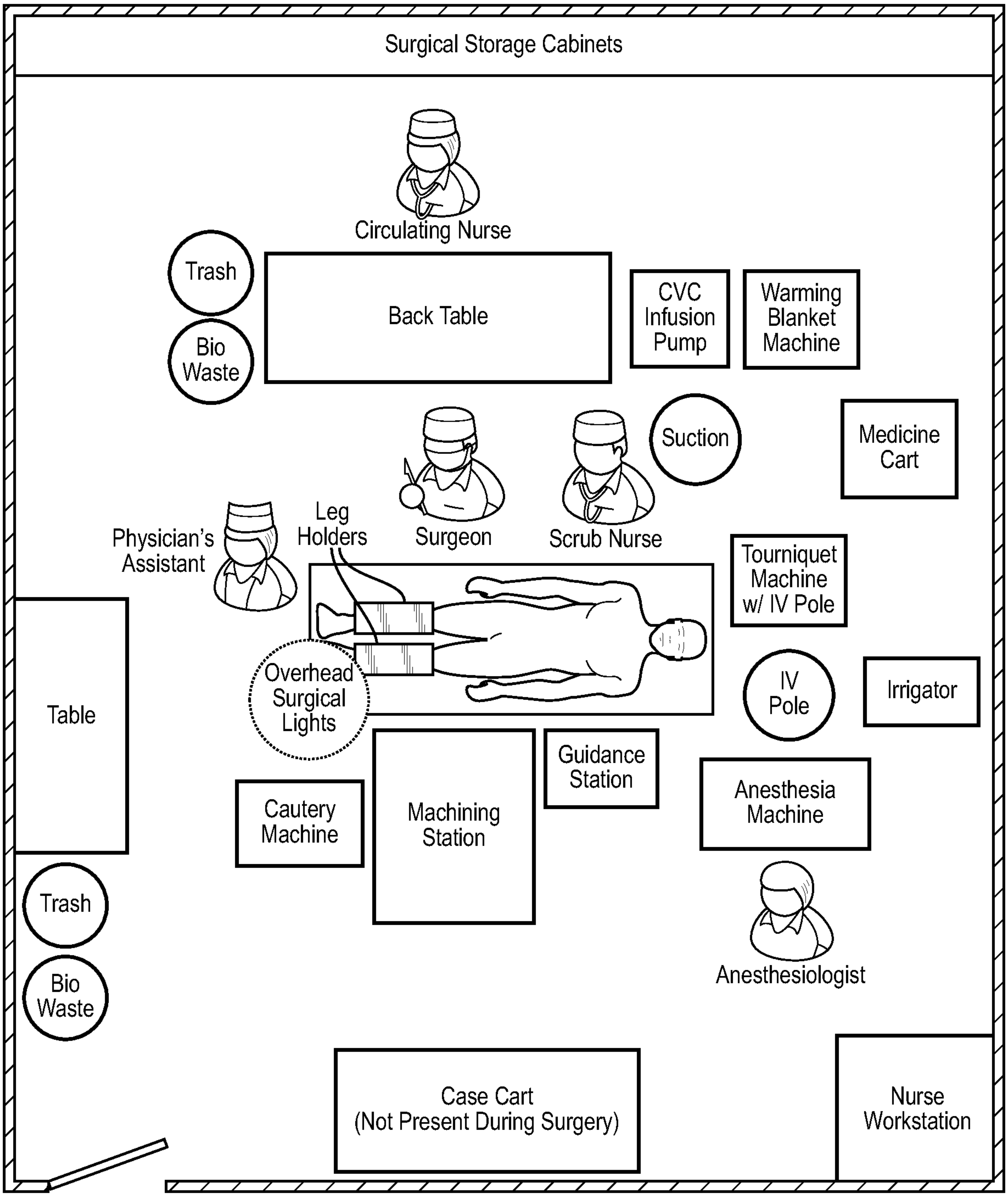

Surgical Storage Cabinets
Circulating Nurse
Trash
Bio Waste
Back Table
CVC Infusion Pump
Warming Blanket Machine
Suction
Medicine Cart
Surgeon
Scrub Nurse
Physician's Assistant
Leg Holders
Tourniquet Machine w/ IV Pole
IV Pole
Irrigator
Overhead Surgical Lights
Table
Guidance Station
Anesthesia Machine
Cautery Machine
Machining Station
Anesthesiologist
Trash
Bio Waste
Case Cart (Not Present During Surgery)
Nurse Workstation

FIG. 6

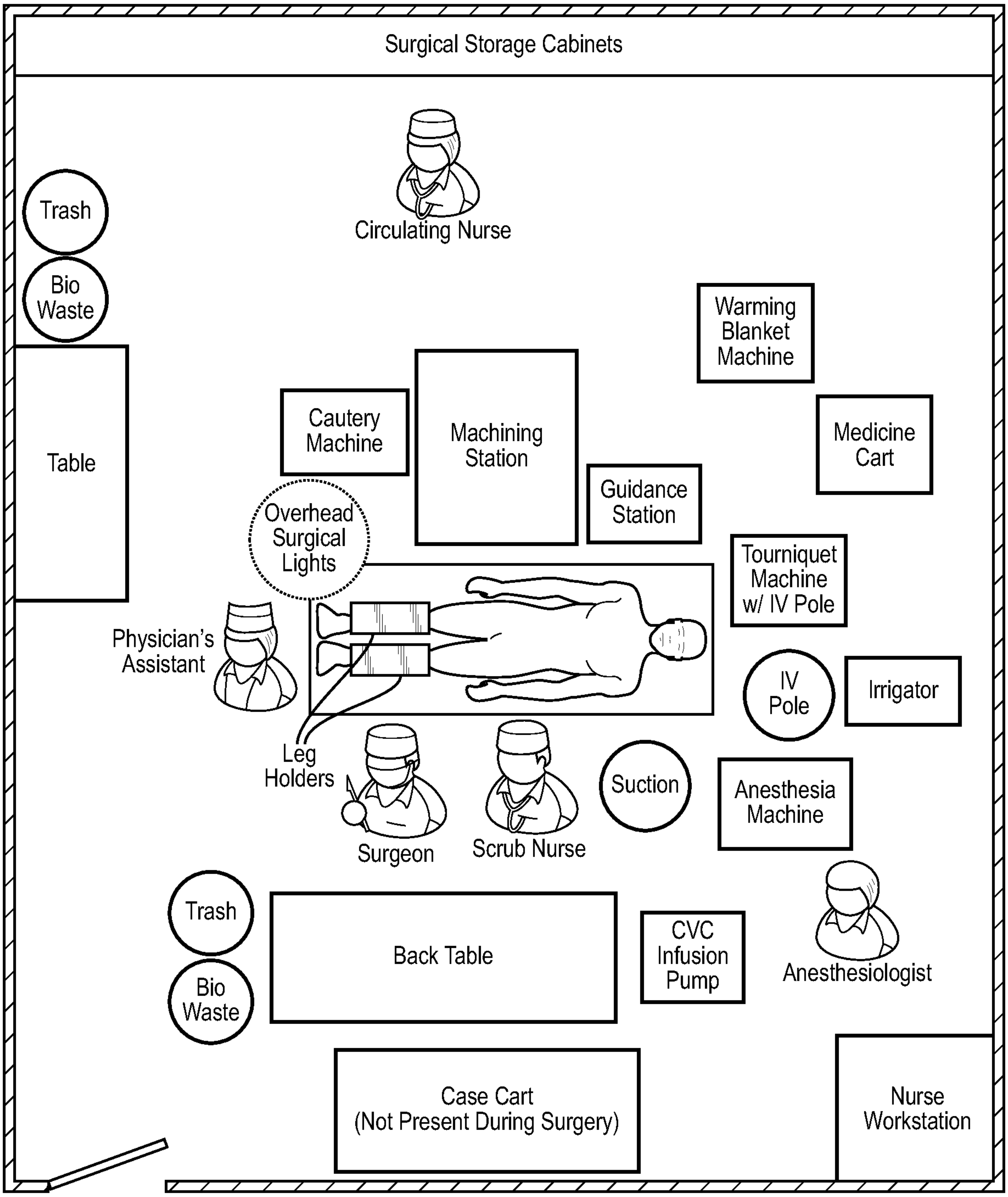

Surgical Storage Cabinets
Circulating Nurse
Trash
Bio Waste
Table
Warming Blanket Machine
Cautery Machine
Machining Station
Medicine Cart
Guidance Station
Overhead Surgical Lights
Tourniquet Machine w/ IV Pole
Physician's Assistant
IV Pole
Irrigator
Leg Holders
Suction
Anesthesia Machine
Surgeon
Scrub Nurse
Trash
Bio Waste
Back Table
CVC Infusion Pump
Anesthesiologist
Case Cart (Not Present During Surgery)
Nurse Workstation

FIG. 7

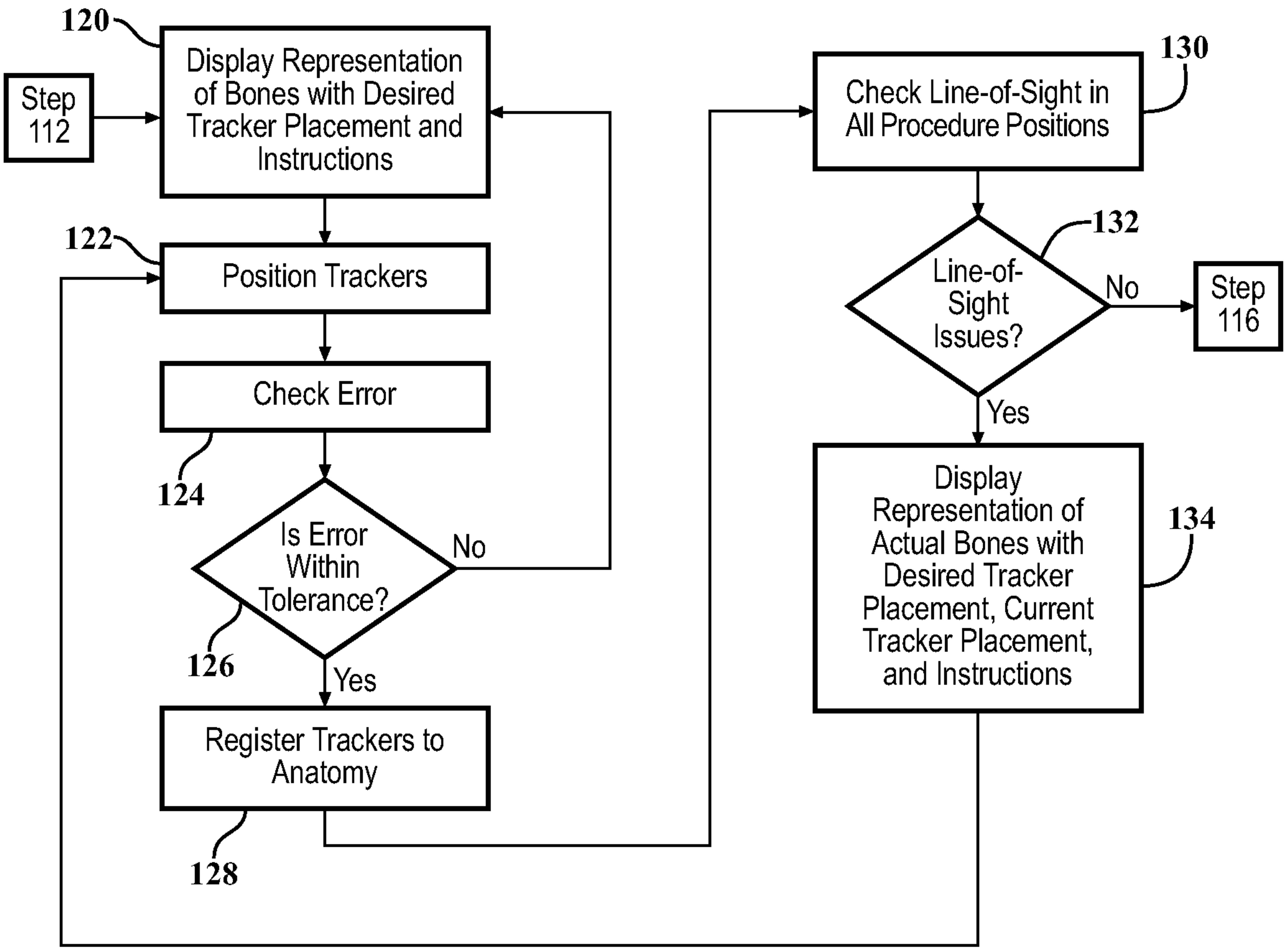

120
Step 112
Display Representation of Bones with Desired Tracker Placement and Instructions
122
Position Trackers
Check Error
124
Is Error Within Tolerance?
No
126
Yes
Register Trackers to Anatomy
128
Check Line-of-Sight in All Procedure Positions
130
132
Line-of-Sight Issues?
No
Step 116
Yes
Display Representation of Actual Bones with Desired Tracker Placement, Current Tracker Placement, and Instructions
134

FIG. 8

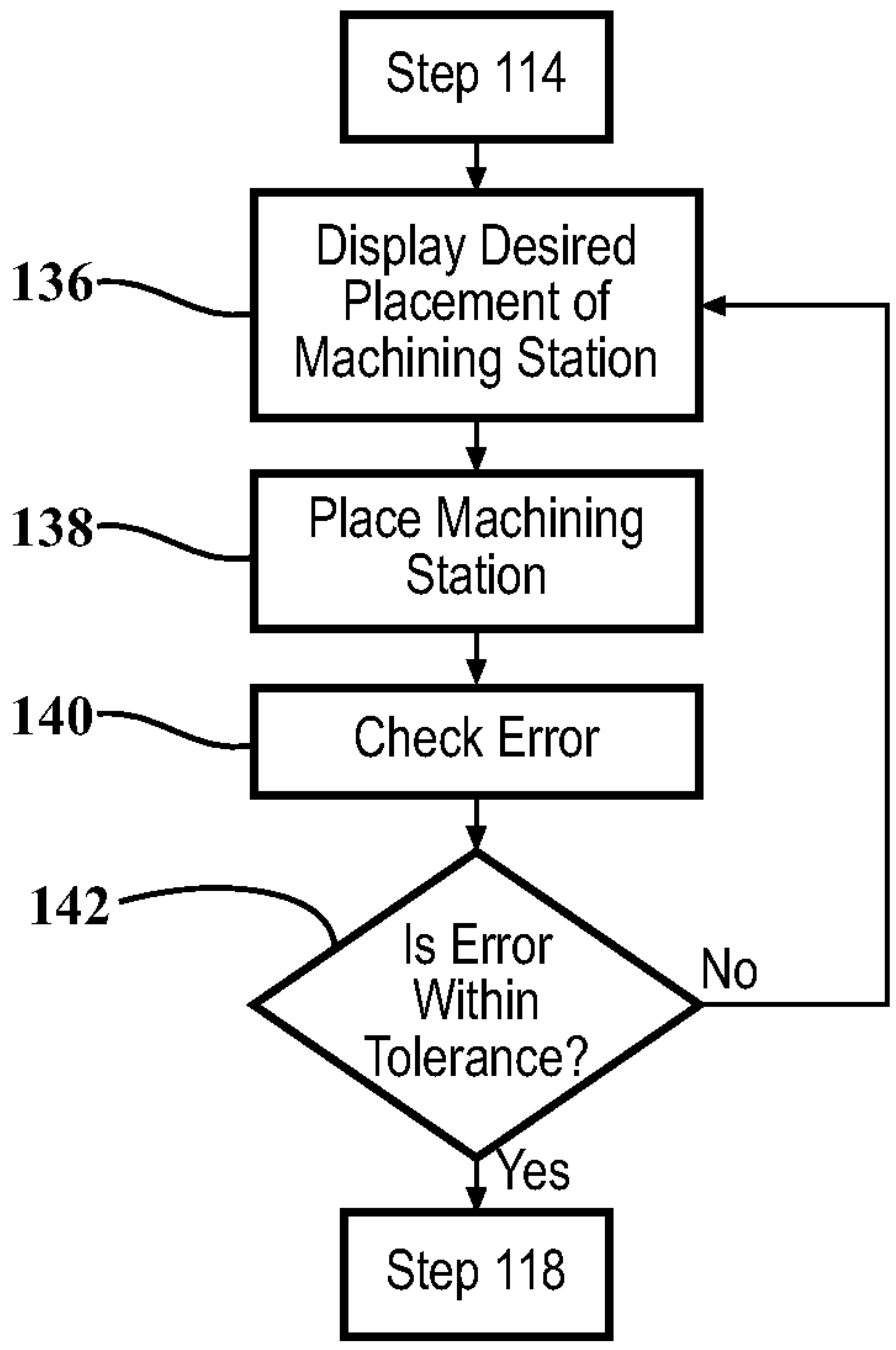

Step 114
136
Display Desired Placement of Machining Station
138
Place Machining Station
140
Check Error
142
Is Error Within Tolerance?
No
Yes
Step 118

FIG. 9

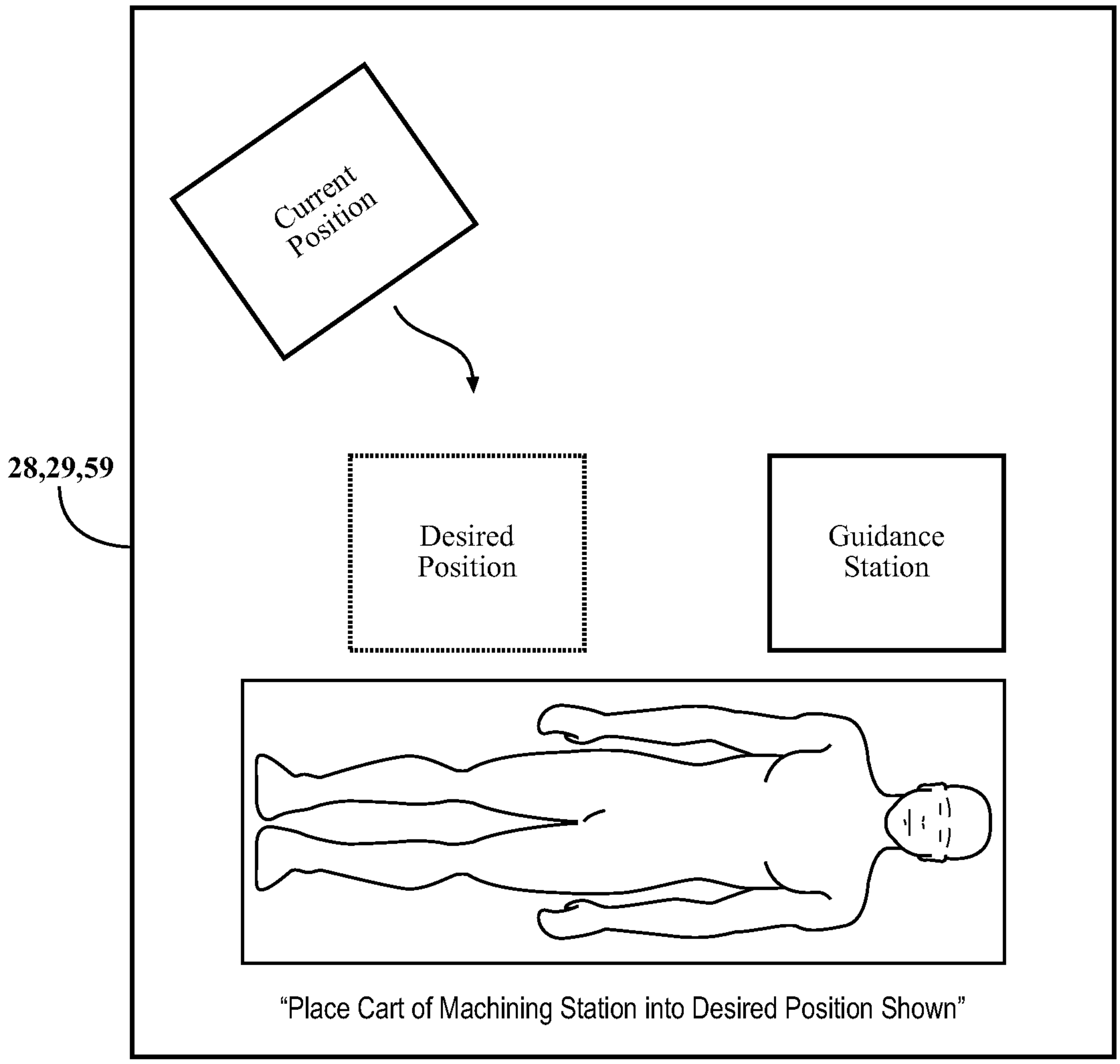

28,29,59
Current Position
Desired Position
Guidance Station
"Place Cart of Machining Station into Desired Position Shown"

FIG. 9A

FIG. 1