



(51) International Patent Classification:
A61B 19/00 (2006.01)

(21) International Application Number: PCT/US2013/061642

(22) **International Filing Date:** 25 September 2013 (25.09.2013)

(25) **Filing Language:** English

(26) **Publication Language:** English

(30) Priority Data:

| | | |
|------------|--------------------------------|----|
| 61/705,804 | 26 September 2012 (26.09.2012) | US |
| 14/035,207 | 24 September 2013 (24.09.2013) | US |

(71) **Applicant:** STRYKER CORPORATION [US/US]; 2825 Airview Blvd., Kalamazoo, MI 49002 (US).

(72) **Inventor:** WU, Chunwu; 5705 Bobwhite Avenue, Kalamazoo, MI 49009 (US).

(74) **Agents:** ENGLISH, Trent, K. et al.; HOWARD & HOWARD ATTORNEYS PLLC, 450 West Fourth Street, Royal Oak, MI 48067 (US).

(81) Designated States (*unless otherwise indicated, for every kind of national protection available*): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT,

HN, HR, HU, ID, IL, IN, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (*unless otherwise indicated, for every kind of regional protection available*): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CI, CG, CL, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

— *of inventorship (Rule 4.17(iv))*

Published:

— *with international search report (Art. 21(3))*

- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments (Rule 48.2(h))

(54) Title: NAVIGATION SYSTEM INCLUDING OPTICAL AND NON-OPTICAL SENSORS

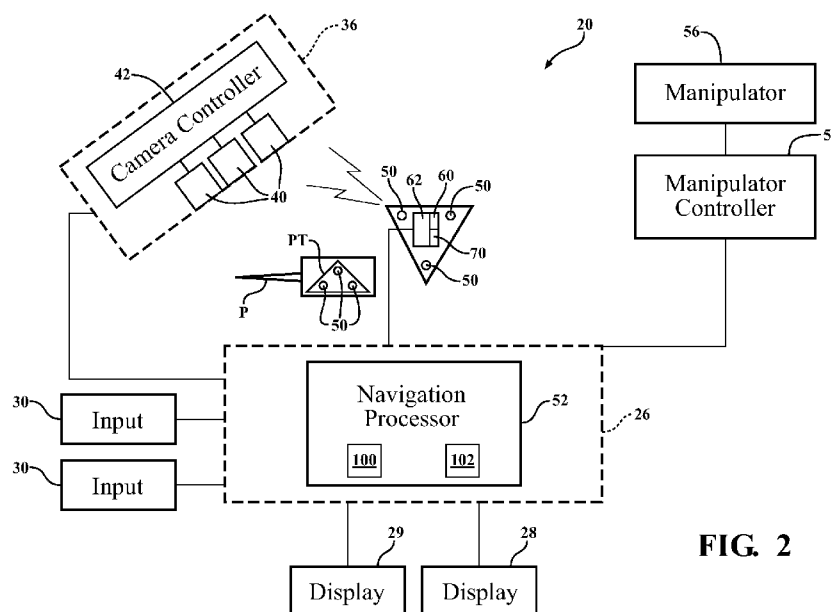


FIG. 2

(57) Abstract: Systems and methods that utilize optical sensors and non-optical sensors to determine the position and/or orientation of objects. A navigation system (20) includes an optical sensor (40) for receiving optical signals from markers (50) and a non-optical sensor (60), such as a gyroscope, for generating non-optical data. A navigation computer (26) determines positions and/or orientations of objects based on optical and non-optical data.

NAVIGATION SYSTEM INCLUDING OPTICAL AND NON-OPTICAL SENSORS

RELATED APPLICATIONS

[0001] This application claims priority to and the benefit of U.S. Provisional Patent Application No. 61/705,804, filed on September 26, 2012 and U.S. Non-Provisional Application No. 14/035207, filed on September 24, 2013 the entire contents of which are hereby incorporated by reference.

FIELD OF THE INVENTION

[0002] The present invention relates generally to a navigation system that tracks objects in space by determining changes in the position and/or orientation of such objects over time. More specifically, the present invention relates to navigation systems that utilize optical sensors and non-optical sensors to determine the position and/or orientation of objects.

BACKGROUND OF THE INVENTION

[0003] Navigation systems assist users in precisely locating objects. For instance, navigation systems are used in industrial, aerospace, defense, and medical applications. In the medical field, navigation systems assist surgeons in precisely placing surgical instruments relative to a patient's anatomy.

[0004] Surgeries in which navigation systems are used include neurosurgery and orthopedic surgery. Often the instrument and the anatomy are tracked together with their relative movement shown on a display. The navigation system may display the instrument moving in conjunction with a preoperative image or an intraoperative image of the anatomy. Preoperative images are typically prepared by MRI or CT scans, while intraoperative images may be prepared using a fluoroscope, low level x-ray or any similar device. Alternatively, some systems are image-less in which the patient's anatomy is "painted" by a navigation probe and mathematically fitted to an anatomical model for 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 the instrument and anatomy. Optical navigation systems are widely used due to the accuracy of such

systems.

[0006] Prior art optical navigation systems typically include one or more camera units that house one or more optical sensors (such as charge coupled devices or CCDs). The optical sensors detect light emitted from trackers attached to the instrument and the anatomy. Each tracker has a plurality of optical emitters such as light emitting diodes (LEDs) that periodically transmit light to the sensors to determine the position of the LEDs.

[0007] The positions of the LEDs on the instrument tracker correlate to the coordinates of a working end of the instrument relative to a camera coordinate system. The positions of the LEDs on the anatomy tracker(s) correlate to the coordinates of a target area of the anatomy in three-dimensional space relative to the camera coordinate system. Thus, the position and/or orientation of the working end of the instrument relative to the target area of the anatomy can be tracked and displayed.

[0008] Navigation systems can be used in a closed loop manner to control movement of surgical instruments. In these navigation systems both the instrument and the anatomy being treated are outfitted with trackers such that the navigation system can track their position and orientation. Information from the navigation system is then fed to a control system to control or guide movement of the instrument. In some cases, the instrument is held by a robot and the information is sent from the navigation system to a control system of the robot.

[0009] In order for the control system to quickly account for relative motion between the instrument and the anatomy being treated, the accuracy and speed of the navigation system must meet the desired tolerances of the procedure. For instance, tolerances associated with cementless knee implants may be very small to ensure adequate fit and function of the implant. Accordingly, the accuracy and speed of the navigation system may need to be greater than in more rough cutting procedures.

[0010] One of the limitations on accuracy and speed of optical navigation systems is that the system relies on the line-of-sight between the LEDs and the optical sensors of the camera unit. When the line-of-sight is broken, the system may not accurately determine the position and/or orientation of the instrument and anatomy being tracked. As a result, surgeries can encounter many starts and stops. For instance, during control of robotically assisted cutting, when the line-of-sight is broken, the cutting tool must be disabled until the line-of-sight is regained. This can cause significant delays and

added cost to the procedure.

[0011] Another limitation on accuracy occurs when using active LEDs on the trackers. In such systems, the LEDs are often fired in sequence. In this case only the position of the actively fired LED is measured and known by the system, while the positions of the remaining, unmeasured LEDs are unknown. In these systems, the positions of the remaining, unmeasured LEDs are approximated. Approximations are usually based on linear velocity data extrapolated from the last known measured positions of the currently unmeasured LEDs. However, because the LEDs are fired in sequence, there can be a considerable lag between measurements of any one LED. This lag is increased with each additional tracker used in the system. Furthermore, this approximation does not take into account rotations of the trackers, resulting in further possible errors in position data for the trackers.

[0012] As a result, there is a need in the art for an optical navigation system that utilizes additional non-optically based data to improve tracking and provide a level of accuracy and speed with which to determine position and/or orientations of objects for precise surgical procedures such as robotically assisted surgical cutting.

SUMMARY OF THE INVENTION

[0013] The present invention relates to systems and methods that utilize optical sensors and non-optical sensors to determine the position and/or orientation of objects.

[0014] In one version of the invention a navigation system is provided for tracking an object. The navigation system includes an optical sensor that receives optical signals from one or more markers on a tracker. The tracker also includes a non-optical sensor that generates non-optical signals. A computing system determines a position of one of the markers at a first time based on a first optical signal. The computing system also determines a position of one or more of the other markers at the first time based on the first optical signal and non-optical signals from the non-optical sensor. The determined positions are then correlated to the object to track a position of the object.

[0015] In another version of the invention a navigation system is provided for tracking an object. The navigation system includes an optical sensor that receives optical signals sequentially from three markers on a tracker. The tracker also includes a non-optical sensor that generates non-optical signals. A computing system determines a

position of a first of the markers at a first time based on a first optical signal from the first marker. The computing system also determines a position of a second and third of the markers at the first time based on the first optical signal and non-optical signals from the non-optical sensor. The determined positions are then correlated to the object to track a position of the object.

[0016] In yet another version of the invention, a robotic surgical cutting system is provided. The system includes a robotic manipulator and a cutting tool. A robotic control system controls or constrains movement of the cutting tool in at least 5 degrees of freedom. A navigation system communicates with the robotic control system. The navigation system includes at least one optical sensor and a tracker mounted to the robotic manipulator. A tracker is also provided for mounting to a patient's anatomy. This anatomy tracker includes three markers and a non-optical sensor. The optical sensor receives optical signals from the markers and the non-optical sensor generates non-optical signals. The navigation system communicates position data indicative of a position of the anatomy to the robotic control system to control cutting of the anatomy such that the cutting occurs within a predefined boundary.

[0017] In another version of the invention a navigation system is provided that includes a localizer having at least one optical sensor. A tracker communicates with the optical sensor. The tracker includes three markers and a non-optical sensor. A computing system determines a position of each of the three markers in a localizer coordinate system based on optical signals and non-optical signals. The computing system performs a matching algorithm to match the determined positions of one or more of the markers in the localizer coordinate system with positions of the one or more of said markers in a model of the tracker established relative to a tracker coordinate system to obtain a transformation matrix to transform the tracker coordinate system to the localizer coordinate system.

[0018] In another version of the invention, a system is provided for tracking an object. The system comprises at least two optical sensors and a tracker for mounting to the object. The tracker has three markers and a non-optical sensor. The at least two optical sensors receives optical signals from the markers at an optical-sensing frequency of at least 100 Hz. The non-optical sensor generates non-optical signals at a non-optical sensing frequency of at least 100 Hz.

[0019] A method for tracking an object is also provided. The method includes

operating an optical sensor to receive optical signals sequentially from markers and operating a non-optical sensor to generate non-optical signals. A position of a first of the markers at a first time is determined based on a first optical signal from the first marker. A position of a second and third of the markers at the first time is determined based on the first optical signal and non-optical signals from the non-optical sensor. The determined positions of the first, second, and third markers are correlated to the object to track a position of the object during the surgical procedure.

[0020] Another method for tracking an object during a surgical procedure is provided. In this method three markers are positioned in the field of view of the optical sensor so that the optical sensor receives optical signals sequentially from the markers. A computing system is then operated to determine a position of a first of the markers at a first time based on a first optical signal from the first marker and determine a position of a second and third of the markers at the first time based on the first optical signal and non-optical signals from a non-optical sensor. The positions are then correlated to the object to track a position of the object during the surgical procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] 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:

[0022] Figure 1 is a perspective view of a navigation system of the present invention being used in conjunction with a robotic manipulator;

[0023] Figure 2 is a schematic view of the navigation system;

[0024] Figure 3 is schematic view of coordinate systems used with the navigation system;

[0025] Figure 4 is a flow diagram of steps carried out by a localization engine of the navigation system;

[0026] Figure 4A is a schematic illustration of matching measured LEDs with a tracker model to obtain a transformation matrix;

[0027] Figure 5 is a flow diagram of steps carried out by the localization engine in a first alternative embodiment;

[0028] Figure 5A is an illustration of a tracker model including real and virtual LEDs;

[0029] Figure 6 is a flow diagram of steps carried out by the localization engine in a second alternative embodiment; and

[0030] Figure 7 is a flow diagram of steps carried out by the localization engine when one or more LEDs are blocked from measurement.

DETAILED DESCRIPTION

I. OVERVIEW

[0031] Referring to Figure 1 a surgical navigation system 20 is illustrated. System 20 is shown in a surgical setting such as an operating room of a medical facility. The navigation system 20 is set up to track movement of various objects in the operating room. Such objects include, for example, a surgical instrument 22, a femur F of a patient, and a tibia T of the patient. The navigation system 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.

[0032] The surgical navigation system 20 includes a computer cart assembly 24 that houses a navigation computer 26. A navigation interface is in operative communication with the navigation computer 26. The navigation interface includes a display 28 adapted to be situated outside of the sterile field and a display 29 adapted to be situated inside the sterile field. The displays 28, 29 are adjustably mounted to the computer cart assembly 24. Input devices 30, 32 such as a mouse and keyboard 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) on displays 28, 29 or voice-activation.

[0033] 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. The camera unit 36 has an outer casing 38 that houses one or more optical sensors 40. In some embodiments at least two optical sensors 40 are employed, preferably three. The optical sensors 40 may be three separate high resolution 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.

[0034] Camera unit 36 is mounted on an adjustable arm to position the optical sensors 40 above the zone in which the procedure is to take place to provide the camera unit 36 with a field of view of the below discussed trackers that, ideally, is free from obstructions.

[0035] 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. Connection could also use a company specific protocol. In other embodiments, the optical sensors 40 communicate directly with the navigation computer 26.

[0036] Position and orientation signals and/or data are transmitted to the navigation computer 26 for purposes of tracking the objects. The computer cart assembly 24, display 28, 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.

[0037] The navigation computer 26 can be a personal computer or laptop computer. Navigation computer 26 has the display 28, 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 received from the camera unit 36 into data representative of the position and orientation of the objects being tracked.

[0038] Navigation system 20 includes 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 in the manner shown in U.S. Patent No. 7,725,162, hereby incorporated by reference. In further embodiments, an additional tracker (not shown) is attached to the patella to track a position and orientation of the patella. In further embodiments, the trackers 44, 46 could be mounted to other tissue types or parts of the anatomy.

[0039] An instrument tracker 48 is firmly 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 procedures. The working end of the surgical instrument 22, which is being tracked, may be a rotating bur, electrical ablation device, or the like. In the embodiment shown, the surgical instrument 22 is an end effector of a surgical manipulator. 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, and also in U.S. Patent Application No. 13/958,834, entitled, “Navigation System for use with a Surgical Manipulator Operable in Manual or Semi-Autonomous Mode”, the disclosure of which is hereby incorporated by reference.

[0040] 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.

[0041] In other embodiments, the surgical instrument 22 may be manually positioned by only the hand of the user, without the aid of any cutting guide, jib, or other constraining mechanism such as a manipulator or robot. Such a surgical instrument is described in U.S. Provisional Patent Application No. 61/662,070, 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”, hereby incorporated by reference, and also 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”, hereby incorporated by reference.

[0042] 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 markers 50 for transmitting light signals to the optical sensors 40. The active markers 50 can be light emitting diodes or LEDs 50. 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

1000 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.

[0043] 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.

[0044] 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 arrangements are well known in the art.

[0045] Each of the trackers 44, 46, 48 also includes a 3-dimensional gyroscope sensor 60 that measures angular velocities of the trackers 44, 46, 48. As is well known to those skilled in the art, the gyroscope sensors 60 output readings indicative of the angular velocities relative to x-, y-, and z- axes of a gyroscope coordinate system. These readings are multiplied by a conversion constant defined by the manufacturer to obtain measurements in degrees/second with respect to each of the x-, y-, and z- axes of the gyroscope coordinate system. These measurements can then be converted to an angular velocity vector $\vec{\omega}$ defined in radians/second.

[0046] The angular velocities measured by the gyroscope sensors 60 provide additional non-optically based kinematic data for the navigation system 20 with which to track the trackers 44, 46, 48. The gyroscope sensors 60 may be oriented along the axis of each coordinate system of the trackers 44, 46, 48. In other embodiments, each gyroscope coordinate system is transformed to its tracker coordinate system such that the gyroscope data reflects the angular velocities with respect to the x-, y-, and z- axes of the coordinate systems of the trackers 44, 46, 48.

[0047] Each of the gyroscope sensors 60 communicate with the tracker controller 62 located within the housing of the associated tracker that transmits/receives data to/from the navigation computer 26. The navigation computer

26 has one or more transceivers (not shown) to receive the data from the gyroscope sensors 60. The data can be received either through a wired or wireless connection.

[0048] The gyroscope sensors 60 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 gyroscope sensors 60 have sampling rates of 1000 Hz. The sampling rate of the gyroscope sensors 60 is the rate at which signals are sent out from the gyroscope sensors 60 to be converted into angular velocity data.

[0049] The sampling rates of the gyroscope sensors 60 and the optical sensors 40 are established or timed so that for each optical measurement of position there is a corresponding non-optical measurement of angular velocity.

[0050] Each of the trackers 44, 46, 48 also includes a 3-axis accelerometer 70 that measures acceleration along each of x-, y-, and z- axes of an accelerometer coordinate system. The accelerometers 70 provide additional non-optically based data for the navigation system 20 with which to track the trackers 44, 46, 48.

[0051] Each of the accelerometers 70 communicate with the tracker controller 62 located in the housing of the associated tracker that transmits/receives data to/from the navigation computer 26. One or more of the transceivers (not shown) of the navigation computer receives the data from the accelerometers 70.

[0052] The accelerometers 70 may be oriented along the axis of each coordinate system of the trackers 44, 46, 48. In other embodiments, each accelerometer coordinate system is transformed to its tracker coordinate system such that the accelerometer data reflects the accelerations with respect to the x-, y-, and z- axes of the coordinate systems of the trackers 44, 46, 48.

[0053] 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. The gyroscope sensors 60 transmit non-optical signals to the processor 52 relating to the 3-dimensional angular velocities measured by the gyroscope sensors 60. Based on the received optical and non-optical signals, navigation processor 52 generates data indicating the relative positions and orientations of the trackers 44, 46, 48 relative to the localizer 34.

[0054] 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.

[0055] Prior to the start of the surgical procedure, additional data are loaded into the navigation processor 52. Based on the position and orientation of the trackers 44, 46, 48 and the previously loaded data, navigation processor 52 determines the position of the working end of the surgical instrument 22 and the orientation of the surgical instrument 22 relative to the tissue against which the working end is to be applied. In some embodiments, navigation processor 52 forwards these data to a manipulator controller 54. The manipulator controller 54 can then use the data to control a robotic manipulator 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, and also in U.S. Patent Application No. 13/958,834, entitled, "Navigation System for use with a Surgical Manipulator Operable in Manual or Semi-Autonomous Mode", the disclosure of which is hereby incorporated by reference.

[0056] 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 staff 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.

II. COORDINATE SYSTEMS AND TRANSFORMATION

[0057] Referring to Figure 3, tracking of objects is generally conducted with reference to a localizer coordinate system LCLZ. The localizer coordinate system has an origin and an orientation (a set of x-, y-, and z-axes). During the procedure one goal is to keep the localizer coordinate system LCLZ stationary. As will be described further below, an accelerometer mounted to the camera unit 36 may be used to track sudden or unexpected movement of the localizer coordinate system LCLZ, as may occur when the camera unit 36 is inadvertently bumped by surgical personnel.

[0058] Each tracker 44, 46, 48 and object being tracked also has its own coordinate system separate from localizer coordinate system LCLZ. Components of the navigation system 20 that have their own coordinate systems are the bone trackers 44, 46 and the instrument tracker 48. These coordinate systems are represented as, respectively, bone tracker coordinate systems BTRK1, BTRK2, and instrument tracker coordinate system TLTR.

[0059] Navigation system 20 monitors the positions of the femur F and tibia T of the patient by monitoring the position of bone trackers 44, 46 firmly attached to bone. Femur coordinate system is FBONE and tibia coordinate system is TBONE, which are the coordinate systems of the bones to which the bone trackers 44, 46 are firmly attached.

[0060] Prior to the start of the procedure, pre-operative images of the femur F and tibia T are generated (or of other tissues in other embodiments). These images may be based on MRI scans, radiological scans or computed tomography (CT) scans of the patient's anatomy. These images are mapped to the femur coordinate system FBONE and tibia coordinate system TBONE using well known methods in the art. In one embodiment, a pointer instrument P, such as disclosed in U.S Patent No. 7,725,162 to Malackowski, et al., hereby incorporated by reference, having its own tracker PT (see Figure 2), may be used to map the femur coordinate system FBONE and tibia coordinate system TBONE to the pre-operative images. These images are fixed in the femur coordinate system FBONE and tibia coordinate system TBONE.

[0061] During the initial phase of the procedure, the bone trackers 44, 46 are firmly affixed to the bones of the patient. The pose (position and orientation) of coordinate systems FBONE and TBONE are mapped to coordinate systems BTRK1 and BTRK2, respectively. Given the fixed relationship between the bones and their bone trackers 44, 46, the pose of coordinate systems FBONE and TBONE remain fixed relative to coordinate systems BTRK1 and BTRK2, respectively, throughout the procedure. The pose-describing data are stored in memory integral with both manipulator controller 54 and navigation processor 52.

[0062] The working end of the surgical instrument 22 (also referred to as energy applicator distal end) has its own coordinate system EAPP. The origin of the coordinate system EAPP may represent a centroid of a surgical cutting bur, for example. The pose of coordinate system EAPP is fixed to the pose of instrument

tracker coordinate system TLTR before the procedure begins. Accordingly, the poses of these coordinate systems EAPP, TLTR relative to each other are determined. The pose-describing data are stored in memory integral with both manipulator controller 54 and navigation processor 52.

III. SOFTWARE

[0063] Referring to Figure 2, a localization engine 100 is a software module that can be considered part of the navigation system 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.

[0064] Localization engine 100 receives as inputs the optically-based signals from the camera controller 42 and the non-optically based signals from the tracker controller 62. Based on these signals, localization engine 100 determines the pose (position and orientation) of the bone tracker coordinate systems BTRK1 and BTRK2 in the localizer coordinate system LCLZ. Based on the same signals received for the instrument tracker 48, the localization engine 100 determines the pose of the instrument tracker coordinate system TLTR in the localizer coordinate system LCLZ.

[0065] 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.

[0066] During the procedure, the coordinate transformer 102 receives the data indicating the relative poses of the trackers 44, 46, 48 to the localizer 34. Based on these data and the previously loaded data, the coordinate transformer 102 generates data indicating the relative position and orientation of both the coordinate system EAPP, and the bone coordinate systems, FBONE and TBONE to the localizer coordinate system LCLZ.

[0067] As a result, coordinate transformer 102 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 staff to view this information. In certain embodiments, other signals representative of these data can be forwarded to the manipulator controller 54 to control the manipulator 56 and corresponding movement of the surgical instrument 22.

[0068] Steps for determining the pose of each of the tracker coordinate systems BTRK1, BTRK2, TLTR in the localizer coordinate system LCLZ are the same, so only one will be described in detail. The steps shown in Figure 4 are based on only one tracker being active, tracker 44. In the following description, the LEDs of tracker 44 shall be represented by numerals 50a, 50b, 50c which identify first 50a, second 50b, and third 50c LEDs.

[0069] The steps set forth in Figure 4 illustrate the use of optically-based sensor data and non-optically based sensor data to determine the positions of the LEDs 50a, 50b, 50c of tracker 44. From these positions, the navigation processor 52 can determine the position and orientation of the tracker 44, and thus, the position and orientation of the femur F to which it is attached. Optically-based sensor data derived from the signals received by the optical sensors 40 provide line-of-sight based data that relies on the line-of-sight between the LEDs 50a, 50b, 50c and the optical sensors 40. However, the gyroscope sensor 60, which provides non-optically based signals for generating non-optically based sensor data do not rely on line-of-sight and thus can be integrated into the navigation system 20 to better approximate positions of the LEDs 50a, 50b, 50c when two of the LEDs 50a, 50b, 50c are not being measured (since only one LED measured at a time), or when one or more of the LEDs 50a, 50b, 50c are not visible to the optical sensors 40 during a procedure.

[0070] In a first initialization step 200, the system 20 measures the position of the LEDs 50a, 50b, 50c for the tracker 44 in the localizer coordinate system LCLZ to establish initial position data. These measurements are taken by sequentially firing the LEDs 50a, 50b, 50c, which transmits light signals to the optical sensors 40. Once the light signals are received by the optical sensors 40, corresponding signals are generated by the optical sensors 40 and transmitted to the camera controller 42. The frequency between firings of the LEDs 50a, 50b, 50c is 100 Hz or greater, preferably 300 Hz or greater, and more preferably 500 Hz or greater. In some cases, the frequency between firings is 1000 Hz or 1 millisecond between firings.

[0071] In some embodiments, only one LED can be read by the optical sensors 40 at a time. The camera controller 42, through one or more infrared or RF transceivers (on camera unit 36 and tracker 44) may control the firing of the LEDs 50a, 50b, 50c, as described in U.S. Patent No. 7,725,162 to Malackowski, et al., hereby incorporated by reference. Alternatively, the tracker 44 may be activated locally (such as by a switch on tracker 44) which then fires its LEDs 50a, 50b, 50c sequentially once activated, without instruction from the camera controller 42.

[0072] Based on the inputs from the optical sensors 40, the camera controller 42 generates raw position signals that are then sent to the localization engine 100 to determine the position of each of the corresponding three LEDs 50a, 50b, 50c in the localizer coordinate system LCLZ.

[0073] During the initialization step 200, in order to establish the initial position data, movement of the tracker 44 must be less than a predetermined threshold. A value of the predetermined threshold is stored in the navigation computer 26. The initial position data established in step 200 essentially provides a static snapshot of position of the three LEDs 50a, 50b, 50c at an initial time t_0 , from which to base the remaining steps of the process. During initialization, velocities of the LEDs 50a, 50b, 50c are calculated by the localization engine 100 between cycles (i.e., each set of three LED measurements) and once the velocities are low enough, i.e., less than the predetermined threshold showing little movement occurred, then the initial position data or static snapshot is established. In some embodiments, the predetermined threshold (also referred to as the static velocity limit) is 200 mm/s or less, preferably 100 mm/s or less, and more preferably 10 mm/s or less along any axis. When the predetermined threshold is 100 mm/s, then the calculated velocities must be less than 100 mm/s to establish the static snapshot.

[0074] Referring to FIGS. 4 and 4A, once the static snapshot is taken, the positions of the measured LEDs 50a, 50b, 50c are compared to a model of the tracker 44 in step 202. The model is data stored in the navigation computer 26. The model data indicates the positions of the LEDs on the tracker 44 in the tracker coordinate system BTRK1. The system 20 has stored the number and position of the LEDs 50 of each tracker 44, 46, 48 in each tracker's coordinate system. For trackers 44, 46, 48 the origin of their coordinate systems is set at the centroid of all LED positions of the tracker 44.

[0075] The localization engine 100 utilizes a rigid body matching algorithm or point matching algorithm to match the measured LEDs 50a, 50b, 50c in the localizer coordinate system LCLZ to the LEDs in the stored model. Once the best-fit is determined, the localization engine 100 evaluates the deviation of the fit to determine if the measured LEDs 50a, 50b, 50c fit within a stored predefined tolerance of the model. The tolerance may be based on a distance between the corresponding LEDs such that if the fit results in too great of a distance, the initialization step has to be repeated. In some embodiments, the positions of the LEDs must not deviate from the model by more than 2.0 mm, preferably not more than 0.5 mm, and more preferably not more than 0.1 mm.

[0076] If the fit is within the predefined tolerance, a transformation matrix is generated to transform any other unmeasured LEDs in the model from the bone tracker coordinate system BTRK1 into the localizer coordinate system LCLZ in step 204. This step is utilized if more than three LEDs are used or if virtual LEDs are used as explained further below. In some embodiments, trackers 44, 46, 48 may have four or more LEDs. Once all positions in the localizer coordinate system LCLZ are established, an LED cloud is created. The LED cloud is an arrangement of all LEDs 50a, 50b, 50c on the tracker 44 in the localizer coordinate system LCLZ based on the x-, y-, and z- axis positions of all the LEDs 50a, 50b, 50c in the localizer coordinate system LCLZ.

[0077] Once the LED cloud is initially established, the navigation system 20 can proceed with tracking the tracker 44 during a surgical procedure. As previously discussed, this includes firing the next LED in the sequence. For illustration, LED 50a is now fired. Thus, LED 50a transmits light signals to the optical sensors 40. Once the light signals are received by the optical sensors 40, corresponding signals are generated by the optical sensors 40 and transmitted to the camera controller 42.

[0078] Based on the inputs from the optical sensors 40, the camera controller 42 generates a raw position signal that is then sent to the localization engine 100 to determine at time t_1 the new position of LED 50a relative to the x-, y-, and z- axes of the localizer coordinate system LCLZ. This is shown in step 206 as a new LED measurement.

[0079] It should be appreciated that the designation of time such as t_0 ,

t1...tn is used for illustrative purposes to indicate different times or different ranges of time or time periods and does not limit this invention to specific or definitive times.

[0080] With the new position of LED 50a determined, a linear velocity vector of LED 50a can be calculated by the localization engine 100 in step 208.

[0081] The tracker 44 is treated as a rigid body. Accordingly, the linear velocity vector of LED 50a is a vector quantity, equal to the time rate of change of its linear position. The velocity, even the acceleration of each LED, in localizer coordinate system LCLZ, can be calculated from the previously and currently measured positions and time of that LED in localizer coordinate system LCLZ. The previously and currently measured positions and time of a LED define the position history of that LED. The velocity calculation of LED 50a can take the simplest form of:

$$\vec{v}(LED50a) = \frac{\vec{x}_n - \vec{x}_p}{t_n - t_p}$$

Where $\vec{x}_p = (x, y, z)_p$ and is the previously measured position of LED 50a at time t_p ; and $\vec{x}_n = (x, y, z)_n$ and is the currently measured position of LED 50a at time t_n . One can also obtain the velocity and/or acceleration of each LED by data fitting the LED position history of that LED as is well known to those skilled in the art.

[0082] At time t1, in step 210, the gyroscope sensor 60 is also measuring an angular velocity of the tracker 44. Gyroscope sensor 60 transmits signals to the tracker controller 62 related to this angular velocity.

[0083] The tracker controller 62 then transmits a corresponding signal to the localization engine 100 so that the localization engine 100 can calculate an angular velocity vector $\vec{\omega}$ from these signals. In step 210, the gyroscope coordinate system is also transformed to the bone tracker coordinate system BTRK1 so that the angular velocity vector $\vec{\omega}$ calculated by the localization engine 100 is expressed in the bone tracker coordinate system BTRK1.

[0084] In step 212, a relative velocity vector \vec{v}^R is calculated for the origin of the bone tracker coordinate system BTRK1 with respect to position vector $\vec{x}(LED50a \text{ to } ORIGIN)$. This position vector $\vec{x}(LED50a \text{ to } ORIGIN)$ is also stored in memory in the navigation computer 26 for access by the localization engine

100 for the following calculation. This calculation determines the relative velocity of the origin \vec{v}_R (*ORIGIN*) of the bone tracker coordinate system BTRK1 by calculating the cross product of the angular velocity vector $\vec{\omega}$ derived from the gyroscope signal and the position vector from LED 50a to the origin.

$$\vec{v}_R (\text{ORIGIN}) = \vec{\omega} \times \vec{x} (\text{LED50a to ORIGIN})$$

[0085] The localization engine 100 then calculates relative velocity vectors \vec{v}_R for the remaining, unmeasured LEDs 50b, 50c (unmeasured because these LEDs have not been fired and thus their positions are not being measured). These velocity vectors can be calculated with respect to the origin of bone tracker coordinate system BTRK1.

[0086] The calculation performed by the localization engine 100 to determine the relative velocity vector \vec{v}_R for each unmeasured LED 50b, 50c at time t1 is based on the cross product of the angular velocity vector $\vec{\omega}$ at time t1 and the position vectors \vec{x} (*ORIGIN to LED50b*) and \vec{x} (*ORIGIN to LED50c*), which are taken from the origin of bone tracker coordinate system BTRK1 to each of the unmeasured LEDs 50b, 50c. These position vectors \vec{x} (*ORIGIN to LED50b*) and \vec{x} (*ORIGIN to LED50c*) are stored in memory in the navigation computer 26 for access by the localization engine 100 for the following calculations:

$$\begin{aligned}\vec{v}_R (\text{LED50b}) &= \vec{\omega} \times \vec{x} (\text{ORIGIN to LED50b}) \\ \vec{v}_R (\text{LED50c}) &= \vec{\omega} \times \vec{x} (\text{ORIGIN to LED50c})\end{aligned}$$

[0087] Also in step 212, these relative velocities, which are calculated in the bone tracker coordinate system BTRK1, are transferred into the localizer coordinate system LCLZ using the transformation matrix determined in step 202. The relative velocities in the localizer coordinate system LCLZ are used in calculations in step 214.

[0088] In step 214 the velocity vector \vec{v} of the origin of the bone tracker coordinate system BTRK1 in the localizer coordinate system LCLZ at time t1 is first calculated by the localization engine 100 based on the measured velocity vector \vec{v} (*LED50a*) of LED 50a at time t1. The velocity vector \vec{v} (*ORIGIN*) is calculated

by adding the velocity vector $\vec{v}(LED50a)$ of LED 50a at time t1 and the relative velocity vector $\vec{v}R(ORIGIN)$ of the origin at time t1 expressed relative to the position vector of LED 50a to the origin. Thus, the velocity vector of the origin at time t1 is calculated as follows:

$$\vec{v}(ORIGIN) = \vec{v}(LED50a) + \vec{v}R(ORIGIN)$$

[0089] Velocity vectors of the remaining, unmeasured LEDs in the localizer coordinate system LCLZ at time t1 can now be calculated by the localization engine 100 based on the velocity vector $\vec{v}(ORIGIN)$ of the origin of the bone tracker coordinate system BTRK1 in the localizer coordinate system LCLZ at time t1 and their respective relative velocity vectors at time t1 expressed relative to their position vectors with the origin of the bone tracker coordinate system BTRK1. These velocity vectors at time t1 are calculated as follows:

$$\begin{aligned}\vec{v}(LED50b) &= \vec{v}(ORIGIN) + \vec{v}R(LED50b) \\ \vec{v}(LED50c) &= \vec{v}(ORIGIN) + \vec{v}R(LED50c)\end{aligned}$$

[0090] In step 216, the localization engine 100 calculates the movements, i.e., the change in position Δx (in Cartesian coordinates), of each of the unmeasured LEDs 50b, 50c from time t0 to time t1 based on the calculated velocity vectors of LEDs 50b, 50c and the change in time. In some embodiments the change in time Δt for each LED measurement is two milliseconds or less, and in some embodiments one millisecond or less.

$$\begin{aligned}\Delta x(LED50b) &= \vec{v}(LED50b) \times \Delta t \\ \Delta x(LED50c) &= \vec{v}(LED50c) \times \Delta t\end{aligned}$$

[0091] These calculated changes in position (x, y, z) can then be added to the previously determined positions of each of LEDs 50b, 50c in the localizer coordinate system LCLZ. Thus, in step 218, changes in position can be added to the previous positions of the LEDs 50b, 50c at time t0, which were determined during the static snapshot. This is expressed as follows:

$$x(LED50b)_{t1} = x(LED50b)_{t0} + \Delta x(LED50b)$$

[0092] In step 220, these calculated positions for each of LEDs 50b, 50c at time t1 are combined with the determined position of LED 50a at time t1. The newly determined positions of LEDs 50a, 50b, 50c are then matched to the model of tracker 44 to obtain a best fit using the point matching algorithm or rigid body matching algorithm. The result of this best fit calculation, if within the defined tolerance of the system 20, is that a new transformation matrix is created by the navigation processor 52 to link the bone tracker coordinate system BTRK1 to the localizer coordinate system LCLZ.

[0093] With the new transformation matrix the newly calculated positions of the unmeasured LEDs 50b, 50c are adjusted to the model in step 222 to provide adjusted positions. The measured position of LED 50a can also be adjusted due to the matching algorithm such that it is also recalculated. These adjustments are considered an update to the LED cloud. In some embodiments, the measured position of LED 50a is fixed to the model's position of LED 50a during the matching step.

[0094] With the best fit transformation complete, the measured (and possibly adjusted) position of LED 50a and the calculated (and adjusted) positions of LEDs 50b, 50c in the localizer coordinate system LCLZ enable the coordinate transformer 102 to determine a new position and orientation of the femur F based on the previously described relationships between the femur coordinate system FBONE, the bone tracker coordinate system BTRK1, and the localizer coordinate system LCLZ.

[0095] Steps 206 through 222 are then repeated at a next time t2 and start with the measurement in the localizer coordinate system LCLZ of LED 50b, with LEDs 50a, 50c being the unmeasured LEDs. As a result of this loop at each time t1, t2...tn positions of each LED 50a, 50b, 50c are either measured (one LED being fired at each time) or calculated with the calculated positions being very accurately approximated based on measurements by the optical sensor 40 and the gyroscope sensor 60. This loop of steps 206 through 222 to determine the new positions of the LEDs 50 can be carried out by the localization engine 100 at a frequency of at least 100 Hz, more preferably at least 300 Hz, and most preferably at least 500 Hz.

[0096] Referring to Figure 5, the LED cloud may also include virtual LEDs, which are predetermined points identified on the model, but that do not actually correspond to physical LEDs on the tracker 44. The positions of these points may also be calculated at times t_1, t_2, \dots, t_n . These virtual LEDs can be calculated in the same fashion as the unmeasured LEDs with reference to FIG. 4. The only difference is that the virtual LEDs are never fired or included in the sequence of optical measurements, since they do not correspond to any light source, but are merely virtual in nature. Steps 300-322 show the steps used for tracking the trackers 44, 46, 48 using real and virtual LEDs. Steps 300-322 generally correspond to steps 200-222 except for the addition of the virtual LEDs, which are treated like unmeasured LEDs using the same equations described above.

[0097] One purpose of using virtual LEDs in addition to the LEDs 50a, 50b, 50c, for example, is to reduce the effect of errors in the velocity calculations described above. These errors may have little consequence on the calculated positions of the LEDs 50a, 50b, 50c, but can be amplified the further away from the LEDs 50a, 50b, 50c a point of interest is located. For instance, when tracking the femur F with tracker 44, the LEDs 50a, 50b, 50c incorporated in the tracker 44 may experience slight errors in their calculated positions of about 0.2 millimeters. However, consider the surface of the femur F that may be located over 10 centimeters away from the LEDs 50a, 50b, 50c. The slight error of 0.2 millimeters at the LEDs 50a, 50b, 50c can result in 0.4 to 2 millimeters of error on the surface of the femur F. The further away the femur F is located from the LEDs 50a, 50b, 50c the more the error increases. The use of virtual LEDs in the steps of Figure 5 can reduce the potential amplification of such errors as described below.

[0098] Referring to Figure 5A, one virtual LED 50d can be positioned on the surface of the femur F. Other virtual LEDs 50e, 50f, 50g, 50h, 50i, 50j, 50k can be positioned at random locations in the bone tracker coordinate system BTRK1 such as along each of the x-, y-, and z- axes, and on both sides of the origin along these axes to yield 6 virtual LEDs. These virtual LEDs are included as part of the model of the tracker 44 shown in Figure 5A and used in steps 302 and 320. In some embodiments, only the virtual LEDs 50e-50k are used. In other embodiments, virtual LEDs may be positioned at locations along each of the x-, y-, and z- axes, but at different distances from the origin of the bone tracker coordinate system BTRK1. In

still further embodiments, some or all of the virtual LEDs may be located off of the axes x-, y-, and z-.

[0099] Now in the model are real LEDs 50a, 50b, 50c and virtual LEDs 50d-50k. At each time $t_1, t_2 \dots t_n$ this extended model is matched in step 320 with the measured/calculated positions of real LEDs 50a, 50b, 50c and with the calculated positions of virtual LEDs 50d-50k to obtain the transformation matrix that links the bone tracker coordinate system BTRK1 with the localizer coordinate system LCLZ. Now, with the virtual LEDs 50d-50k included in the model, which are located at positions outlying the real LEDs 50a, 50b, 50c, the error in the rotation matrix can be reduced. In essence, the rigid body matching algorithm or point matching algorithm has additional points used for matching and some of these additional points are located radially outwardly from the points defining the real LEDs 50a, 50b, 50c, thus rotationally stabilizing the match.

[00100] In another variation of the process of Figure 5, the locations of the virtual LEDs 50e-50k can be changed dynamically during use depending on movement of the tracker 44. The calculated positions of the unmeasured real LEDs 50b, 50c and the virtual LEDs 50e-50k at time t_1 are more accurate the slower the tracker 44 moves. Thus, the locations of virtual LEDs 50e-50k along the x-, y-, and z-axes relative to the origin of the bone tracker coordinate system BTRK1 can be adjusted based on speed of the tracker 44. Thus, if the locations of the virtual LEDs 50e-50k are denoted $(s,0,0)$, $(-s,0,0)$, $(0,s,0)$, $(0,-s,0)$, $(0,0,s)$, $(0,0,-s)$, respectively, then s would increase when the tracker 44 moves slowly and s would decrease to a smaller value when the tracker 44 moves faster. This could be handled by an empirical formula for s or s can be adjusted based on an estimate in the error in velocity and calculated positions.

[00101] Determining new positions of the LEDs 50 (real and virtual) can be carried out at a frequency of at least 100 Hz, more preferably at least 300 Hz, and most preferably at least 500 Hz.

[00102] Data from the accelerometers 70 can be used in situations where optical measurement of an LED 50 is impeded due to interference with the line-of-sight. When an LED to be measured is blocked, the localization engine 100 assumes a constant velocity of the origin to estimate positions. However, the constant velocity assumption in this situation may be inaccurate and result in errors. The

accelerometers 70 essentially monitor if the constant velocity assumption in the time period is accurate. The steps shown in Figures 6 and 7 illustrate how this assumption is checked.

[00103] Continuing to use tracker 44 as an example, steps 400-422 of Figure 6 generally correspond to steps 300-322 from Figure 5. However, in step 424, the system 20 determines whether, in the last cycle of measurements, less than 3 LEDs were measured - meaning that one or more of the LEDs in the cycle could not be measured. This could be caused by line-of-sight issues, etc. A cycle for tracker 44 is the last three attempted measurements. If during the last three measurements, each of the LEDs 50a, 50b, 50c were visible and could be measured, then the system 20 proceeds to step 408 and continues as previously described with respect to Figure 5.

[00104] If the system 20 determines that one or more of the LEDs 50a, 50b, 50c could not be measured during the cycle, i.e., were blocked from measurement, then the algorithm still moves to step 408, but if the new LED to be measured in step 406 was the one that could not be measured, the system makes some velocity assumptions as described below.

[00105] When a LED, such as LED 50a, is not seen by the optical sensor 40 at its measurement time t_n in step 406, the previously calculated velocity vector \vec{v} (*ORIGIN*) of the origin of the tracker 44 in the localizer coordinate system LCLZ at the previous time $t(n-1)$ is assumed to remain constant. Accordingly, velocity vectors of LEDs 50a, 50b, 50c in the localizer coordinate system LCLZ can be calculated based on the previously calculated velocity vector \vec{v} (*ORIGIN*) in the localizer coordinate system LCLZ and the relative velocity vectors of LEDs 50a, 50b, 50c, which are derived from a newly measured angular velocity vector from the gyroscope 60. The equations described in steps 316-322 can then be used to determine new positions of the LEDs 50a, 50b, 50c.

[00106] To start, when LED 50a is to be measured at step 406, but is obstructed, the velocity vector of the origin is assumed to be the same as the previous calculation. Accordingly, the velocity of the new LED is not calculated at step 408:

$$\vec{v} \text{ (ORIGIN)} = \text{previous calculation}$$

[00107] Step 410 proceeds the same as step 310.

[00108] The relative velocity vectors $\vec{v}R$ of LEDs 50a, 50b, 50c calculated in step 412 are then based on the previous velocity vector \vec{v} (*ORIGIN*) and the newly measured angular velocity vector from the gyroscope 60 in the bone tracker coordinate system BTRK1:

$$\vec{v}R (LED50a) = \vec{\omega} (current) \times \vec{x} (ORIGIN \text{ to } LED50a)$$

$$\vec{v}R (LED50b) = \vec{\omega} (current) \times \vec{x} (ORIGIN \text{ to } LED50b)$$

$$\vec{v}R (LED50c) = \vec{\omega} (current) \times \vec{x} (ORIGIN \text{ to } LED50c)$$

[00109] In step 414, velocity vectors in the localizer coordinate system LCLZ can be calculated using the origin velocity vector \vec{v} (*ORIGIN*) and the relative velocity vectors $\vec{v}R$ of LEDs 50a, 50b, 50c:

$$\vec{v} (LED50a) = \vec{v} (ORIGIN) + \vec{v}R (LED50a)$$

$$\vec{v} (LED50b) = \vec{v} (ORIGIN) + \vec{v}R (LED50b)$$

$$\vec{v} (LED50c) = \vec{v} (ORIGIN) + \vec{v}R (LED50c)$$

[00110] Steps 416 through 422 proceed the same as steps 316-322.

[00111] If the system 20 determines at step 424 that one or more of the LEDs 50a, 50b, 50c could not be measured during the cycle, i.e., were blocked from measurement, another algorithm is carried out simultaneously at steps 500-506 shown in Figure 7 until a complete cycle of measurements is made where all of the LEDs 50a, 50b, 50c in the cycle were visible to the optical sensor 40. Thus, the system 20 is considered to be in a “blocked” condition until the complete cycle with all visible measurements is made.

[00112] Steps 500-506 are carried out continuously while the system 20 is in the blocked condition.

[00113] In step 500 the navigation processor 52 starts a clock that tracks how long the system 20 is in the blocked condition. The time in the blocked condition is referred to below as t (*blocked*).

[00114] In step 502, the accelerometer 70 measures accelerations along the x-, y-, and z- axes of the bone tracker coordinate system BTRK1 to track errors in the constant velocity assumption. Accelerometer readings, like gyroscope readings are

transformed from the accelerometer coordinate system to the bone tracker coordinate system BTRK1.

[00115] If the accelerometer 70 detects acceleration(s) that exceed predefined acceleration tolerance(s), the navigation computer 26 will put the system 20 into an error condition. The acceleration tolerances could be defined differently along each x-, y-, and z- axis, or could be the same along each axis. If a measured acceleration exceeds a tolerance then the constant velocity assumption is unreliable and cannot be used for that particular application of surgical navigation. Different tolerances may be employed for different applications. For instance, during robotic cutting, the tolerance may be very low, but for visual navigation only, i.e., not feedback for cutting control loop, the tolerance may be set higher.

[00116] In step 504, velocity errors associated with the positions of the LEDs 50 relative to the optical sensor 40 are taken into account and monitored during the blocked condition. For each of the LEDs 50, the velocity error v_{error} multiplied by the time in the blocked condition $t_{blocked\ condition}$ must be less than a position error tolerance γ and thus must satisfy the following equation to prevent the system 20 from being put into an error condition:

$$v_{error} \times t_{blocked\ condition} < \gamma$$

[00117] In this equation, the velocity error v_{error} is calculated for each of the LEDs 50a, 50b, 50c as follows:

$$v_{error} = \frac{x_{error(t)} + x_{error(t-1)}}{\Delta t}$$

[00118] Position errors $x_{error(t)}$ and $x_{error(t-1)}$ are predefined position errors in the system 20 that are based on location relative to the optical sensors 40 at times t and t-1. In essence, the further away the LEDs 50a, 50b, 50c are located from the optical sensors 40, the higher the potential position errors. These positions errors are derived either experimentally or theoretically and placed in a look-up table or formula so that at each position of the LEDs 50a, 50b, 50c in Cartesian coordinates (x, y, z) an associated position error is provided.

[00119] In step 504, the localization engine 100 accesses this look-up table or calculates this formula to determine the position errors for each of LEDs 50a, 50b, 50c at the current time t and at the previous time $t-1$. The position errors are thus based on the positions in Cartesian coordinates in the localizer coordinate system LCLZ calculated by the system 20 in step 422 for the current time t and at the previous time $t-1$. The time variable Δt represents the time it takes for subsequent position calculations, so the difference between t and $t-1$, which for illustrative purposes may be 1 millisecond.

[00120] The position error tolerance γ is predefined in the navigation computer 26 for access by the localization engine 100. The position error tolerance γ could be expressed in millimeters. The position error tolerance γ can range from 0.001 to 1 millimeters and in some embodiments is specifically set at 0.5 millimeters. Thus, if the position error tolerance γ is set to 0.5 millimeters, the following equation must be satisfied:

$$v_{error} \times t_{blocked\ condition} < 0.5\ millimeters$$

[00121] As can be seen, the longer the system 20 is in the blocked condition, the larger the effect that the time variable has in this equation and thus the smaller the velocity errors that will be tolerated. In some embodiments, this equation is calculated by the localization engine 100 in step 504 separately for each of the LEDs 50a, 50b, 50c. In other embodiments, because of how closely arranged the LEDs 50a, 50b, 50c are on the tracker 44, the velocity error of only one of the LEDs 50a, 50b, 50c is used in this calculation to determine compliance.

[00122] In step 506, when the error(s) exceeds the position error tolerance γ , the system 20 is placed in an error condition. In such a condition, for example, any control or movement of cutting or ablation tools is ceased and the tools are shut down.

IV. OTHER EMBODIMENTS

[00123] In one embodiment, when each of the trackers 44, 46, 48 are being actively tracked, the firing of the LEDs occurs such that one LED from tracker 44 is fired, then one LED from tracker 46, then one LED from tracker 48, then a second LED from tracker 44, then a second LED from tracker 46, and so on until all LEDs

have been fired and then the sequence repeats. This order of firing may occur through instruction signals sent from the transceivers (not shown) on the camera unit 36 to transceivers (not shown) on the trackers 44, 46, 48.

[00124] The navigation system 20 can be used in a closed loop manner to control surgical procedures carried out by surgical cutting instruments. Both the instrument 22 and the anatomy being cut are outfitted with trackers 50 such that the navigation system 20 can track the position and orientation of the instrument 22 and the anatomy being cut, such as bone.

[00125] In one embodiment, the navigation system is part of a robotic surgical system for treating tissue. In some versions, the robotic surgical system is a robotic surgical cutting system for cutting away material from a patient's anatomy, such as bone or soft tissue. The cutting system could be used to prepare bone for surgical implants such as hip and knee implants, including unicompartamental, bicompartamental, 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.

[00126] The robotic surgical cutting system includes a manipulator (see, for instance, Figure 1). The manipulator has a plurality of arms and a cutting tool carried by at least one of said plurality of arms. A robotic control system controls or constrains movement of the cutting tool in at least 5 degrees of freedom. An example of such a manipulator and control system are 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", hereby incorporated by reference, and also in U.S. Patent Application No. 13/958,834, entitled, "Navigation System for use with a Surgical Manipulator Operable in Manual or Semi-Autonomous Mode", the disclosure of which is hereby incorporated by reference.

[00127] In this embodiment, the navigation system 20 communicates with the robotic control system (which can include the manipulator controller 54). The navigation system 20 communicates position and/or orientation data to said robotic control system. The position and/or orientation data is indicative of a position and/or orientation of 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.

[00128] In this embodiment, manipulator movement may coincide with LED measurements such that for each LED measurement taken, there is a corresponding movement of the instrument 22 by the manipulator 56. However, this may not always be the case. For instance, there may be such a lag between the last LED measurement and movement by the manipulator 56 that the position and/or orientation data sent from the navigation computer 26 to the manipulator 56 for purposes of control loop movement becomes unreliable. In such a case, the navigation computer 26 can be configured to also transmit to the manipulator controller 54 kinematic data. Such kinematic data includes the previously determined linear and angular velocities for the trackers 44, 46, 48. Since the velocities are already known, positions can be calculated based on the lag of time. The manipulator controller 54 could then calculate, for purposes of controlling movement of the manipulator 56, the positions and orientations of the trackers 44, 46, 48 and thus, the relative positions and orientations of the instrument 22 (or instrument tip) to the femur F and/or tibia T.

[00129] In this embodiment, the instrument 22 is held by the manipulator shown in Figure 1 or other robot that provides some form of mechanical constraint to movement. This constraint limits the movement of the instrument 22 to within a predefined boundary. If the instrument 22 strays beyond the predefined boundary, a control is sent to the instrument 22 to stop cutting.

[00130] When tracking both the instrument 22 and the anatomy being cut in real time in these systems, the need to rigidly fix anatomy in position can be eliminated. Since both the instrument 22 and anatomy are tracked, control of the instrument 22 can be adjusted based on relative position and/or orientation of the instrument 22 to the anatomy. Also, representations of the instrument 22 and anatomy on the display can move relative to one another – to emulate their real world motion.

[00131] In one embodiment, each of the femur F and tibia T has a target volume of material that is to be removed by the working end of the surgical instrument 22. The target volumes are defined by one or more boundaries. The boundaries define the surfaces of the bone that should remain after the procedure. In some embodiments, system 20 tracks and controls the surgical instrument 22 to ensure that working end, e.g., bur, only removes the target volume of material and does not extend beyond the boundary, as disclosed in 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”, hereby incorporated by reference.

[00132] In the described embodiment, control of the instrument 22 is accomplished by utilizing the data generated by the coordinate transformer 102 that indicates the position and orientation of the bur or other cutting tool relative to the target volume. By knowing these relative positions, the surgical instrument 22 or the manipulator to which it is mounted, can be controlled so that only desired material is removed.

[00133] 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 jig, guide arm or other constraining mechanism. Such systems are shown in U.S. Provisional Patent Application No. 61/662,070, 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.

[00134] 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. Provisional Patent Application No. 61/662,070, 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 navigation system 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.

[00135] In this embodiment, the navigation system 20 communicates with the control system of the hand held surgical cutting instrument. The navigation system 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).

[00136] Features of the invention may be used to track sudden or unexpected movements of the localizer coordinate system LCLZ, as may occur when the camera unit 36 is bumped by surgical personnel. An accelerometer (not shown) mounted to camera unit 36 monitors bumps and stops system 20 if a bump is detected. In this embodiment, the accelerometer communicates with the camera controller 42 and if the measured acceleration along any of the x, y, or z axes exceeds a predetermined value, then the camera controller 42 sends a corresponding signal to the navigation computer 26 to disable the system 20 and await the camera unit 36 to stabilize and resume measurements. In some cases, the initialization step 200, 300, 400 would have to be repeated before resuming navigation.

[00137] In some embodiments, a virtual LED is positioned at the working tip of the instrument 22. In this embodiment, the virtual LED is located at the location of the working tip in the model of the instrument tracker 48 so that the working tip location is continuously calculated.

[00138] It is an object of the intended claims to cover all such modifications and variations that come within the true spirit and scope of this invention. Furthermore, the embodiments described above are related to medical applications, but the inventions described herein are also applicable to other applications such as industrial, aerospace, defense, and the like.

CLAIMS

What is claimed is:

1. A navigation system for tracking an object, said navigation system comprising:

an optical sensor;

a tracker for mounting to the object and including;

three markers, and

a non-optical sensor,

wherein said optical sensor is configured to receive optical signals sequentially from said markers and said non-optical sensor is configured to generate non-optical signals;

a computing system configured to:

determine a position of a first of said markers at a first time based on a first optical signal from said first marker;

determine a position of a second and third of said markers at said first time based on said first optical signal and a non-optical signal from said non-optical sensor; and

correlate said determined positions of said first, second, and third markers to the object to track a position of the object.

2. A navigation system as set forth in claim 1 wherein said non-optical sensor is disposed in a known position relative to each of said markers.

3. A navigation system as set forth in claim 1 wherein said markers are passive reflectors.

4. A navigation system as set forth in claim 1 wherein said markers are active emitters.

5. A navigation system as set forth in claim 3 wherein said active emitters are light emitting diodes.

6. A navigation system as set forth in claim 1 wherein said optical sensor is housed in a camera unit and said camera unit includes a second optical sensor.

7. A navigation system as set forth in claim 6 wherein said camera unit includes a third optical sensor.

8. A navigation system as set forth in claim 7 wherein said optical sensors are one-dimensional charge coupled devices.

9. A navigation system as set forth in claim 1 including a second tracker having three markers and a second non-optical sensor.

10. A navigation system as set forth in claim 9 wherein said second tracker is configured for mounting to bone.

11. A navigation system as set forth in claim 1 wherein said computing system includes a processor that calculates said position of said second and third markers by calculating a first velocity of said first marker based on said first optical signal and by calculating velocities of said second and third markers based on said first velocity and said non-optical signal in said first time.

12. A navigation system as set forth in claim 1 wherein said computing system correlates said determined positions of said first, second, and third markers to the object to track a position and orientation of the object.

13. A navigation system as set forth in claim 12 including a probe adapted to select landmarks on a patient's anatomy, said probe having a plurality of markers that transmit signals to said optical sensor during selection of the landmarks.

14. A navigation system as set forth in claim 1 wherein said computing system is configured to measure positions of said first, second, and third markers at an initial time to establish initial position data.

15. A navigation system as set forth in claim 14 wherein said computing system is configured to measure the positions of said first, second, and third markers to establish the initial position data by sequentially firing said first, second, and third markers to transmit light signals to said optical sensor.

16. A navigation system as set forth in claim 14 wherein said computing system is configured to calculate velocities of said first, second, and third markers while establishing the initial position data and is configured to compare the calculated velocities to a predetermined threshold.

17. A navigation system as set forth in claim 14 wherein said computing system is configured to compare the measured positions of said first, second, and third markers at said initial time to a model of said first, second, and third markers stored in said computing system.

18. A navigation system as set forth in claim 17 wherein said computing system is configured to match said first, second, and third markers to said model and provide a best-fit to said model.

19. A navigation system as set forth in claim 18 wherein said computing system is configured to match one or more virtual markers to said model to provide the best-fit to said model.

20. A navigation system as set forth in claim 17 wherein said computing system is configured to generate a transformation matrix from a coordinate system of said tracker to a localizer coordinate system.

21. A navigation system as set forth in claim 1 wherein said computing system is configured to calculate a linear velocity vector of said first marker.

22. A navigation system as set forth in claim 21 wherein said computing system is configured to measure an angular velocity of said tracker at said first time.

23. A navigation system as set forth in claim 22 wherein said computing system is configured to calculate a relative velocity vector of an origin of a tracker coordinate system based on said measured angular velocity.

24. A navigation system as set forth in claim 23 wherein said computing system is configured to calculate relative velocity vectors for said second and third markers based on said measured angular velocity.

25. A navigation system as set forth in claim 24 wherein said computing system is configured to calculate a velocity vector of an origin of said tracker coordinate system based on said calculated linear velocity vector of said first marker and said calculated relative velocity vector of said origin.

26. A navigation system as set forth in claim 25 wherein said computing system is configured to calculate velocity vectors of said second and third markers at said first time based on said calculated velocity vector of said origin and said calculated relative velocity vectors of said second and third markers.

27. A navigation system as set forth in claim 26 wherein said computing system is configured to calculate the position of said second and third markers at said first time based on said calculated velocity vectors of said second and third markers at said first time.

28. A navigation system as set forth in claim 27 wherein said computing system is configured to calculate relative velocity vectors for one or more virtual markers.

29. A navigation system as set forth in claim 28 wherein said computing system is configured to calculate velocity vectors of said one or more virtual markers at said first time based on said calculated velocity vector of said origin and said calculated relative velocity vectors of said one or more virtual markers.

30. A navigation system as set forth in claim 29 wherein said computing system is configured to calculate the position of said one or more virtual markers at said first time based on said calculated velocity vectors of said one or more virtual markers at said first time.

31. A robotic surgical cutting system comprising:
a robotic manipulator and a cutting tool;
a robotic control system for controlling or constraining movement of said cutting tool in at least 5 degrees of freedom;
a navigation system in communication with said robotic control system and including at least one optical sensor;
a tracker mounted to said robotic manipulator;
a tracker for mounting to a patient's anatomy and including three markers and a non-optical sensor,
wherein said optical sensor receives optical signals from said markers and said non-optical sensor generates non-optical signals and wherein said navigation system communicates position data indicative of a position of the anatomy to said robotic control system to control cutting of the anatomy such that the cutting occurs within a predefined boundary.

32. A navigation system comprising:
a localizer including at least one optical sensor;
a tracker for communicating with said optical sensor and including three markers and a non-optical sensor; and
a computing system configured to determine a position of each of said three markers in a localizer coordinate system based on optical signals and non-optical signals wherein said computing system performs a matching algorithm to match the determined positions of one or more of said markers in said localizer coordinate system with positions of said one or more of said markers in a model of said tracker established relative to a tracker coordinate system to obtain a transformation matrix to transform said tracker coordinate system to said localizer coordinate system.

33. A navigation system as set forth in claim 32 wherein said computing

system includes a processor configured to match calculated positions of virtual points in said localizer coordinate system with positions of said virtual points in said model to obtain said transformation matrix.

34. A navigation system as set forth in claim 32 wherein said computing system includes a processor configured to re-calculate one or more of said determined positions of said markers in said localizer coordinate system based on said transformation matrix.

35. A system for tracking an object, said system comprising:
at least two optical sensors;
a tracker for mounting to the object and including three markers and a non-optical sensor,
wherein said at least two optical sensors receives optical signals from said markers at an optical-sensing frequency of at least 100 Hz and said non-optical sensor generates non-optical signals at a non-optical sensing frequency of at least 100 Hz.

36. A system as set forth in claim 35 wherein said optical-sensing frequency is at least 300 Hz and said non-optical sensing frequency is at least 300 Hz.

37. A method for tracking an object during a surgical procedure using an optical sensor, a tracker mounted to the object including three markers and a non-optical sensor, and a computing system, said method comprising the steps of:

- receiving optical signals sequentially from the markers;
- generating non-optical signals;
- determining a position of a first of the markers at a first time based on a first optical signal from the first marker;
- determine a position of a second and third of the markers at the first time based on the first optical signal and a non-optical signal from the non-optical sensor wherein the optical sensor receives no optical signals from the second and third markers at the first time; and
- correlating the determined positions of the first, second, and third markers to the object to track a position of the object during the surgical procedure.

38. A method as set forth in claim 37 including measuring positions of the first, second, and third markers at an initial time to establish initial position data.

39. A method as set forth in claim 38 wherein measuring the positions of the first, second, and third markers to establish the initial position data includes sequentially firing the first, second, and third markers to transmit light signals to the optical sensor.

40. A method as set forth in claim 38 including calculating velocities of the first, second, and third markers while establishing the initial position data and comparing the calculated velocities to a predetermined threshold.

41. A method as set forth in claim 38 including comparing the measured positions of the first, second, and third markers at the initial time to a model of the first, second, and third markers stored in the computing system.

42. A method as set forth in claim 41 including matching the first, second, and third markers to the stored model and providing a best-fit to the model.

43. A method as set forth in claim 42 including matching one or more virtual markers to the stored model to provide the best-fit to the model.

44. A method as set forth in claim 38 including generating a transformation matrix from a coordinate system of the tracker to a localizer coordinate system.

45. A method as set forth in claim 37 including calculating a linear velocity vector of the first marker.

46. A method as set forth in claim 45 including measuring an angular velocity of the tracker at the first time.

47. A method as set forth in claim 46 including calculating a relative velocity vector of an origin of a tracker coordinate system based on the measured angular velocity.

48. A method as set forth in claim 47 including calculating relative velocity vectors for the second and third markers based on the measured angular velocity.

49. A method as set forth in claim 48 including calculating a velocity vector of an origin of the tracker coordinate system based on the calculated linear velocity vector of the first marker and the calculated relative velocity vector of the origin.

50. A method as set forth in claim 49 including calculating velocity vectors of the second and third markers at the first time based on the calculated velocity vector of the origin and the calculated relative velocity vectors of the second and third markers.

51. A method as set forth in claim 50 including calculating the position of the second and third markers at the first time based on the calculated velocity vectors of the second and third markers at the first time.

52. A method as set forth in claim 51 including calculating relative velocity vectors for one or more virtual markers.

53. A method as set forth in claim 52 including calculating velocity vectors of the one or more virtual markers at the first time based on the calculated velocity vector of the origin and the calculated relative velocity vectors of the one or more virtual markers.

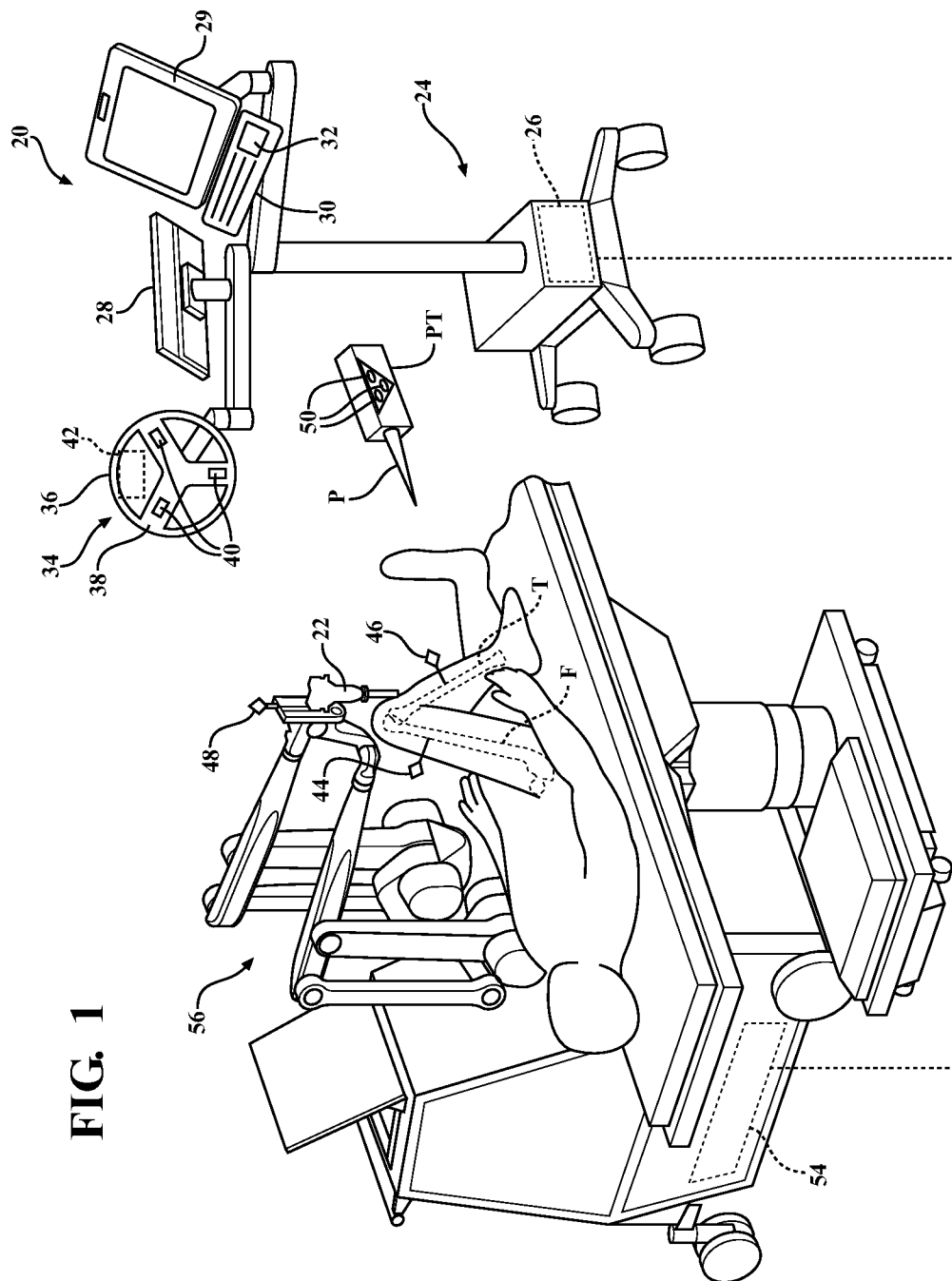
54. A method as set forth in claim 53 including calculating the position of

the one or more virtual markers at the first time based on the calculated velocity vectors of the one or more virtual markers at the first time.

55. A method for tracking an object during a surgical procedure using an optical sensor, a tracker mounted to the object including three markers and a non-optical sensor, and a computing system, said method comprising the steps of:

positioning the three markers in the field of view of the optical sensor so that the optical sensor receives optical signals sequentially from the markers;

operating the computing system to: determine a position of a first of the markers at a first time based on a first optical signal from the first marker; determine a position of a second and third of the markers at the first time based on the first optical signal and a non-optical signal from the non-optical sensor wherein the optical sensor receives no optical signals from the second and third markers at the first time; and correlate the determined positions of the first, second, and third markers to the object to track a position of the object during the surgical procedure.



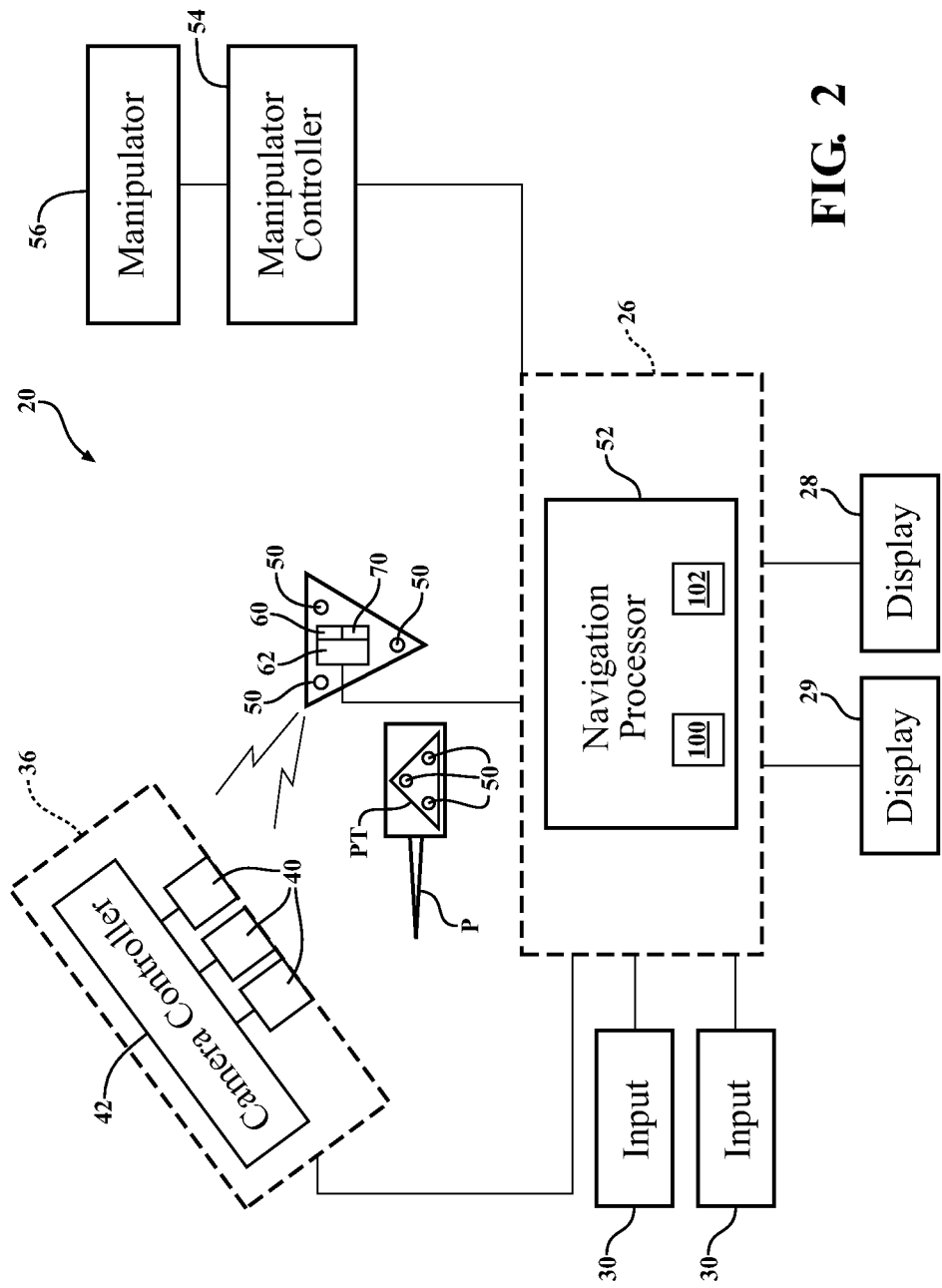


FIG. 2

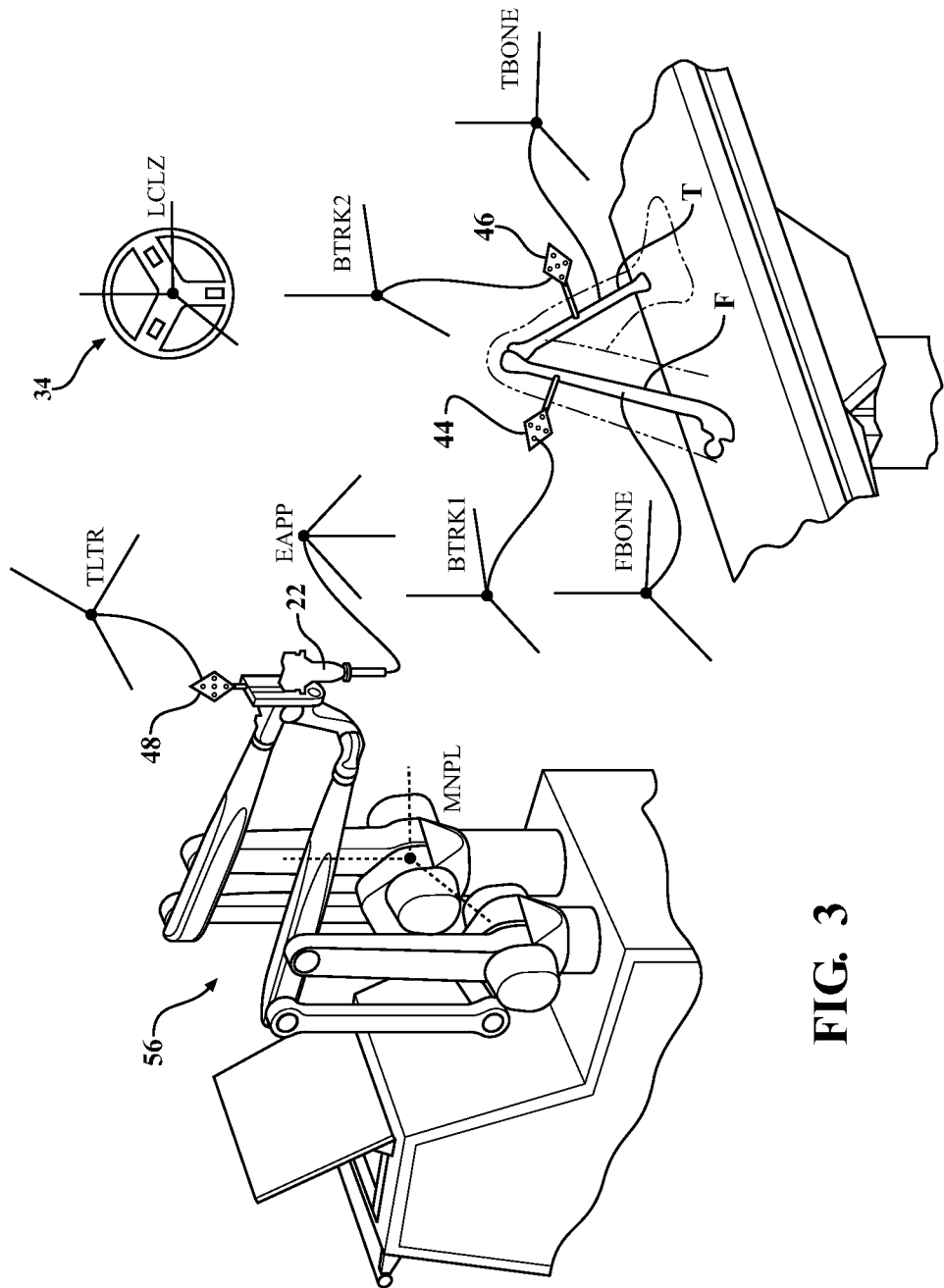
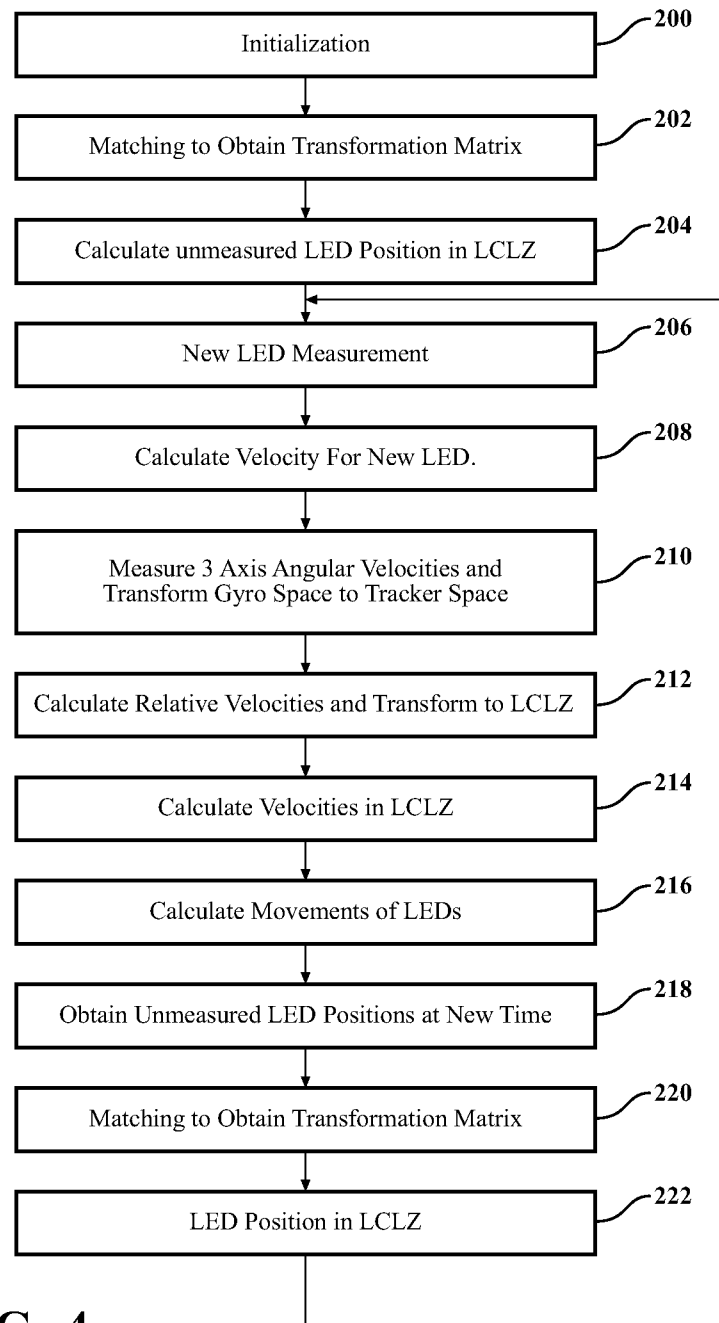
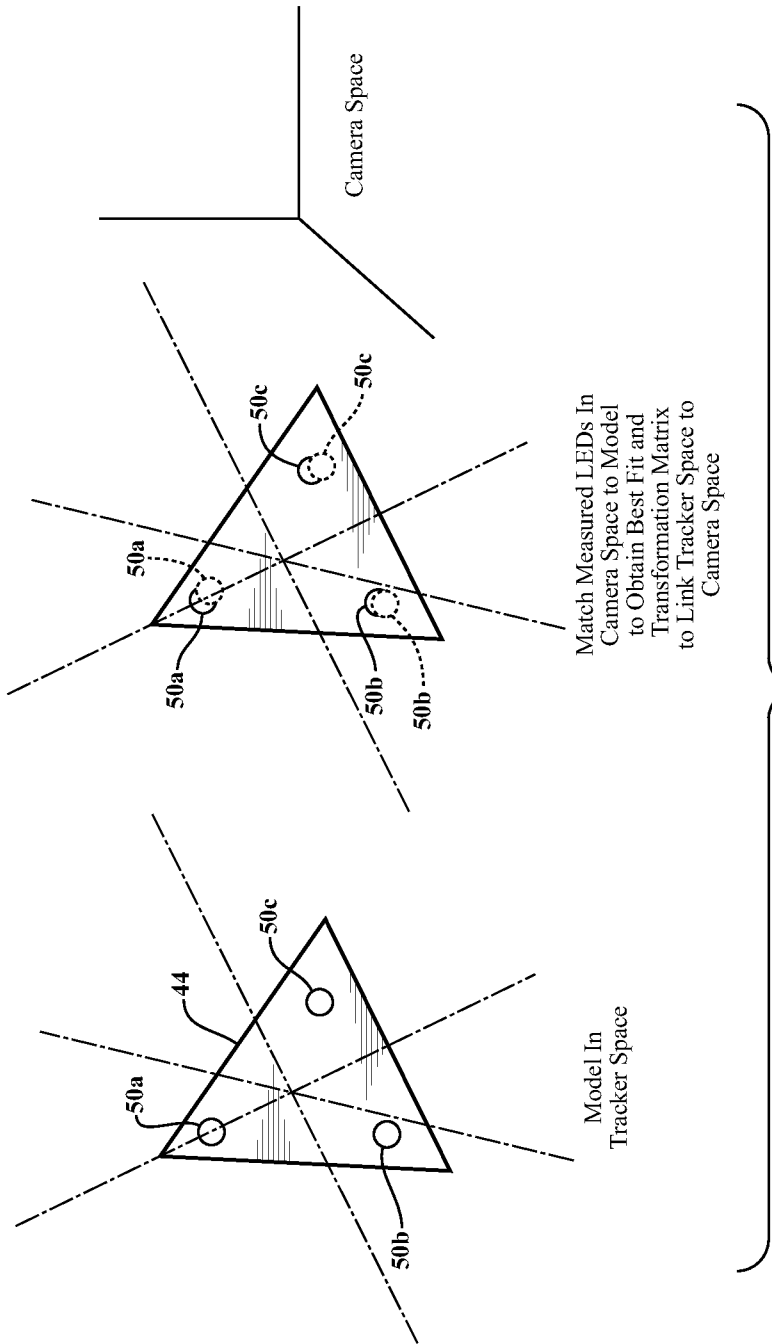
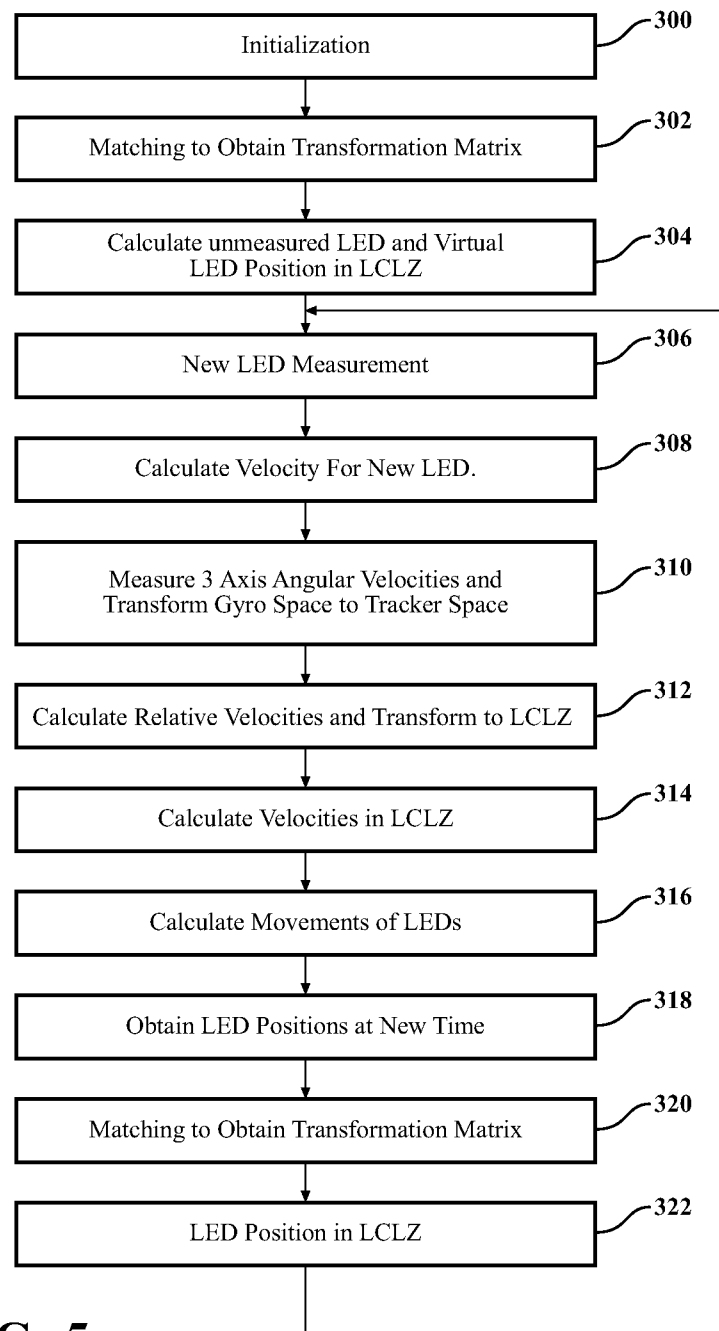


FIG. 3

**FIG. 4**



**FIG. 5**

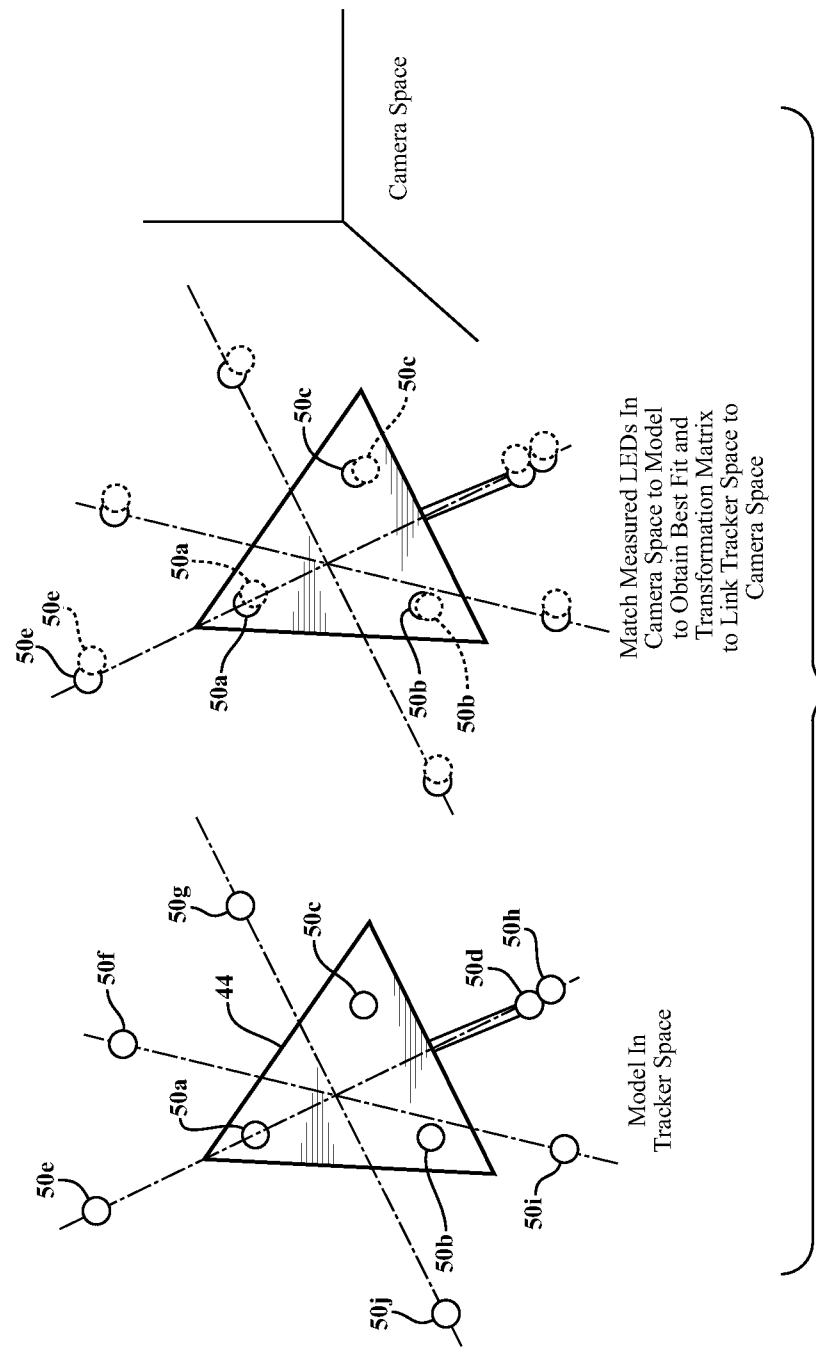
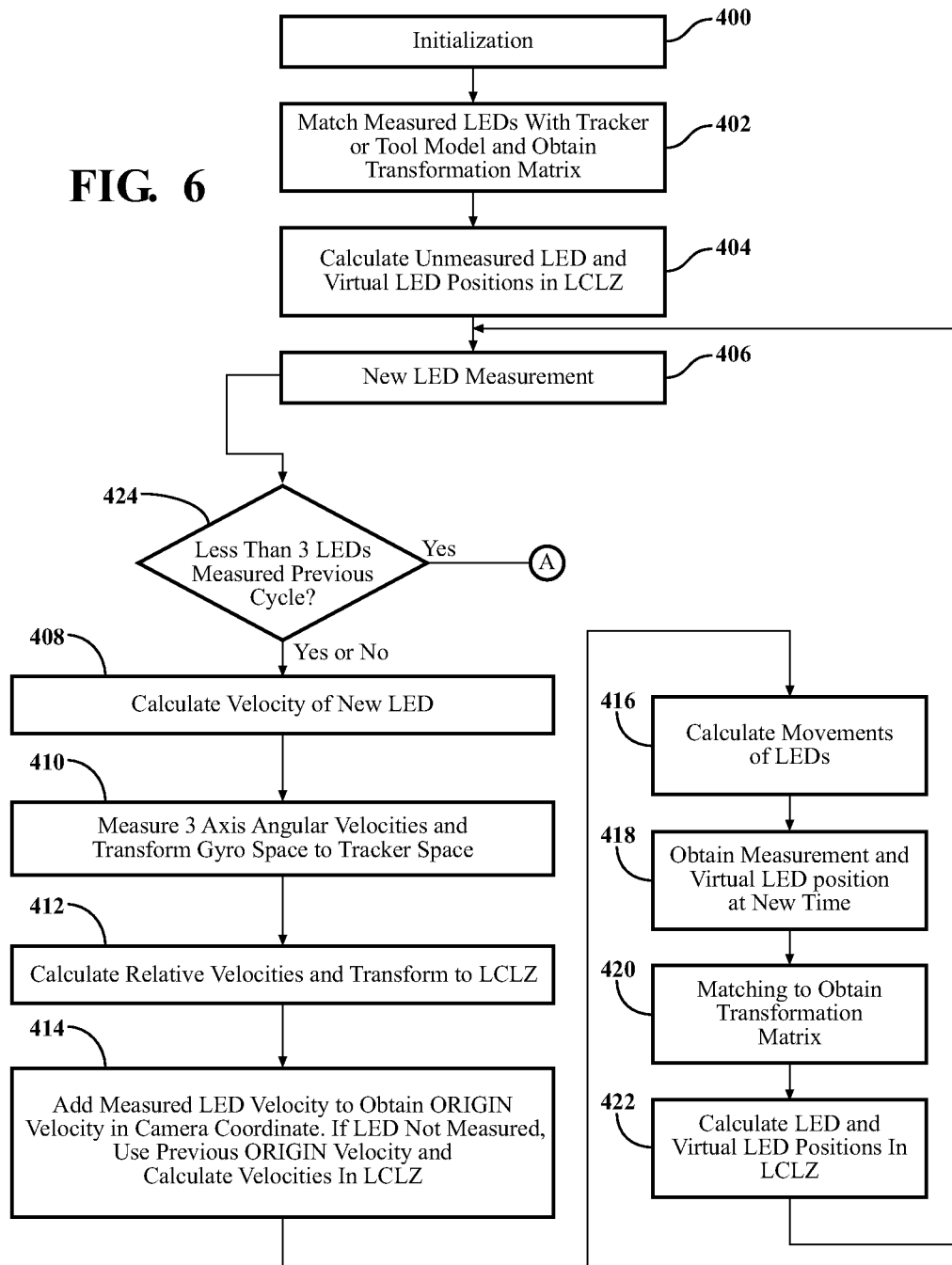
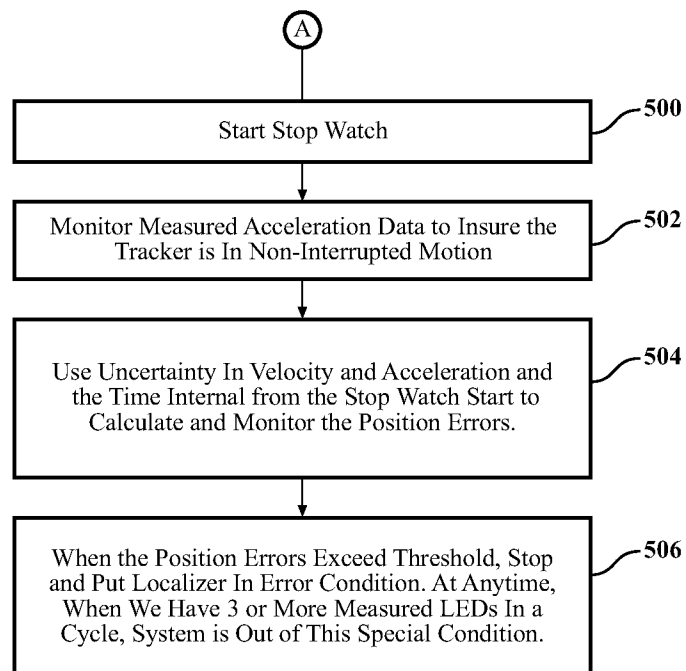


FIG. 5A

FIG. 6

**FIG. 7**

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2013/061642

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B19/00
ADD.

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

B. FIELDS SEARCHED

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

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

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

EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|---|-----------------------|
| X | WO 2011/128766 A2 (PICARD FREDERIC [GB]; MARTIN PHILIPPE P [FR]; CLAASEN GOENTJE C [FR]) 20 October 2011 (2011-10-20) | 32-36 |
| Y | paragraphs [0030], [0062], [0063], | 31 |
| A | [0174] - [0224] pages 1-6 | 1 |
| X | ----- US 6 611 141 B1 (SCHULZ WALDEAN A [US] ET AL) 26 August 2003 (2003-08-26) | 32-34 |
| A | figures 1,3 | 1,31,35 |
| Y | ----- US 5 408 409 A (GLASSMAN EDWARD [US] ET AL) 18 April 1995 (1995-04-18) | 31 |
| | figure 1 | |
| | ----- -/- | |



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search

20 January 2014

Date of mailing of the international search report

03/02/2014

Name and mailing address of the ISA/

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Schießl, Werner

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2013/061642

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| A | DE 10 2004 061764 A1 (PIECK SEBASTIAN [DE]; WAHRBURG JUERGEN [DE]) 6 July 2006 (2006-07-06) figures 1-5 ----- | 1,31,32, 35 |
| A | US 2001/011175 A1 (HUNTER MARK W [US] ET AL) 2 August 2001 (2001-08-02) figures 1-5 paragraph [0036] ----- | 1,31,32, 35 |

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/061642

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 37-55
because they relate to subject matter not required to be searched by this Authority, namely:
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box II.1

Claims Nos.: 37-55

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery and therapy since the claimed method for tracking an object during a surgical procedure encompasses tracking of a surgical cutting instrument, see para. 16, 41, 125 and 126, and "tracking" involves the determination of at least two different positions, i.e. a movement, of said cutting instrument.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2013/061642

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|--|--|
| WO 2011128766 A2 | 20-10-2011 | US 2013064427 A1 WO 2011128766 A2 | 14-03-2013 20-10-2011 |
| US 6611141 B1 | 26-08-2003 | AU 2204200 A CA 2356271 A1 EP 1153292 A1 JP 4612194 B2 JP 2002533721 A US 6611141 B1 WO 0039576 A1 | 31-07-2000 06-07-2000 14-11-2001 12-01-2011 08-10-2002 26-08-2003 06-07-2000 |
| US 5408409 A | 18-04-1995 | EP 0456103 A2 JP H0763472 B2 JP H04231034 A US 5086401 A US 5299288 A US 5408409 A | 13-11-1991 12-07-1995 19-08-1992 04-02-1992 29-03-1994 18-04-1995 |
| DE 102004061764 A1 | 06-07-2006 | NONE | |
| US 2001011175 A1 | 02-08-2001 | AU 2617801 A DE 10083670 B4 DE 10083670 T1 US 6235038 B1 US 2001011175 A1 WO 0134050 A2 | 06-06-2001 28-09-2006 14-03-2002 22-05-2001 02-08-2001 17-05-2001 |