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Marti et al.

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(45) **Date of Patent: Aug. 19, 2025**

(54) **OPTICAL TRACKING DEVICE WITH BUILT-IN STRUCTURED LIGHT MODULE**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **18/422,814**

(22) Filed: **Jan. 25, 2024**

(65) **Prior Publication Data**

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Related U.S. Application Data

(63) Continuation of application No. 18/099,805, filed on Jan. 20, 2023, now Pat. No. 11,896,320, which is a (Continued)

(51) **Int. Cl.**
A61B 34/20 (2016.01)
A61B 34/10 (2016.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 34/20*** (2016.02); ***A61B 34/10*** (2016.02); ***A61B 90/37*** (2016.02); ***G06T 7/0012*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC A61B 34/10; A61B 34/20; A61B 34/25; A61B 34/30; A61B 34/32; A61B 90/37;
(Continued)

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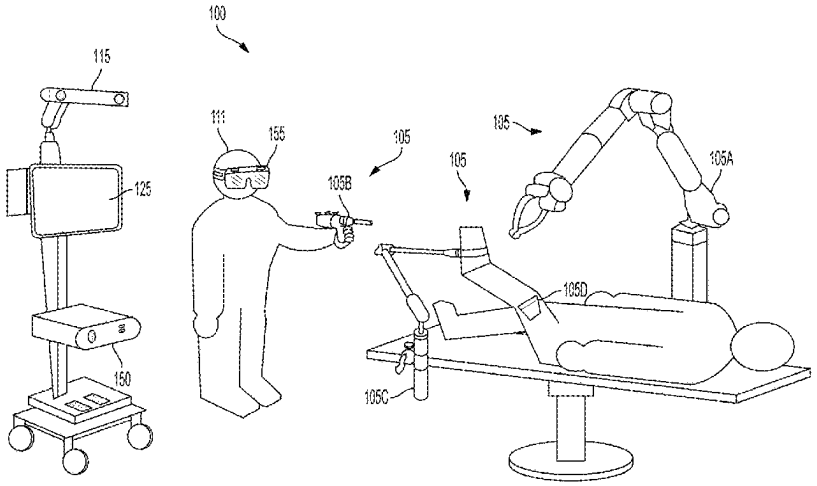
(57) **ABSTRACT**

A system is disclosed that includes an optical tracking device and a surgical computing device. The optical tracking device includes a structured light module and an optical module that includes an image sensor and is spaced from the structured light module at a known distance. The surgical computing device includes a display device, a non-transitory computer readable medium including instructions, and processor(s) configured to execute the instructions to generate a depth map from a first image captured by the image sensor during projection of a pattern into a surgical environment by the structured light module. The pattern is projected in a near-infrared (NIR) spectrum. The processor(s) are further configured to execute the stored instructions to reconstruct a 3D surface of anatomical structure(s) based on the generated depth map. Additionally, the processor(s) are configured to execute the stored instructions to output the reconstructed 3D surface to the display device.

16 Claims, 19 Drawing Sheets



Related U.S. Application Data

continuation of application No. 17/604,116, filed as application No. PCT/US2021/028890 on Apr. 23, 2021, now Pat. No. 11,583,345.

(60) Provisional application No. 63/014,803, filed on Apr. 24, 2020.

(51) **Int. Cl.**

A61B 90/00	(2016.01)
G06T 7/00	(2017.01)
G06T 7/20	(2017.01)
G06T 7/521	(2017.01)
G06T 7/70	(2017.01)
G06T 7/80	(2017.01)
G06T 17/20	(2006.01)
H04N 23/56	(2023.01)

(52) **U.S. Cl.**

CPC ***G06T 7/20*** (2013.01); ***G06T 7/521*** (2017.01); ***G06T 7/70*** (2017.01); ***G06T 7/85*** (2017.01); ***G06T 17/20*** (2013.01); ***H04N 23/56*** (2023.01); *A61B 2034/105* (2016.02); *A61B 2034/2057* (2016.02); *A61B 2090/371* (2016.02); *G06T 2207/10012* (2013.01); *G06T 2207/10048* (2013.01); *G06T 2207/30004* (2013.01); *G06T 2207/30204* (2013.01); *G06T 2207/30244* (2013.01)

(58) **Field of Classification Search**

CPC A61B 90/92; A61B 90/96; A61B 2017/00203; A61B 2017/00207; A61B 2017/00973; A61B 2034/105; A61B 2034/107; A61B 2034/2051; A61B 2034/2055; A61B 2034/2057; A61B 2034/2063; A61B 2034/2065; A61B 2034/256; A61B 2090/309; A61B 2090/364; A61B 2090/365; A61B 2090/367; A61B 2090/3945; A61B 2090/3979; A61B 2090/502; G06T 7/0012; G06T 7/20; G06T 7/246; G06T 7/285; G06T 7/521; G06T 7/70; G06T 7/73; G06T 7/85; G06T 17/00; G06T 17/20; G06T 2207/10012; G06T 2207/10021; G06T 2207/10024; G06T 2207/10048; G06T 2207/20084; G06T 2207/30004; G06T 2207/30204; G06T 2207/30244; G06T 2210/41; H04N 5/2226; H04N 5/2624; H04N 23/56; G16H 20/40; G16H 30/40; Y02A 90/10

See application file for complete search history.

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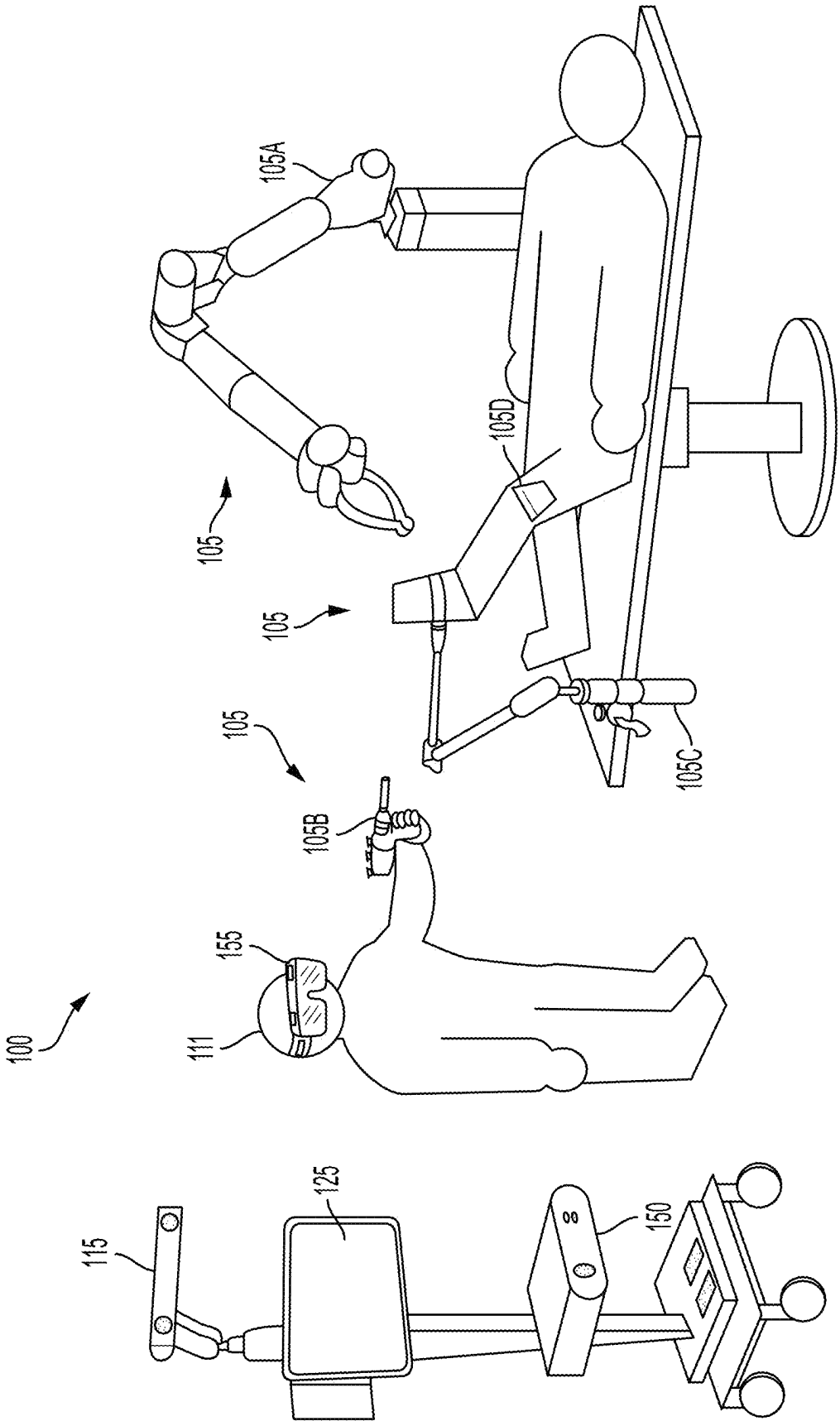

FIG. 1

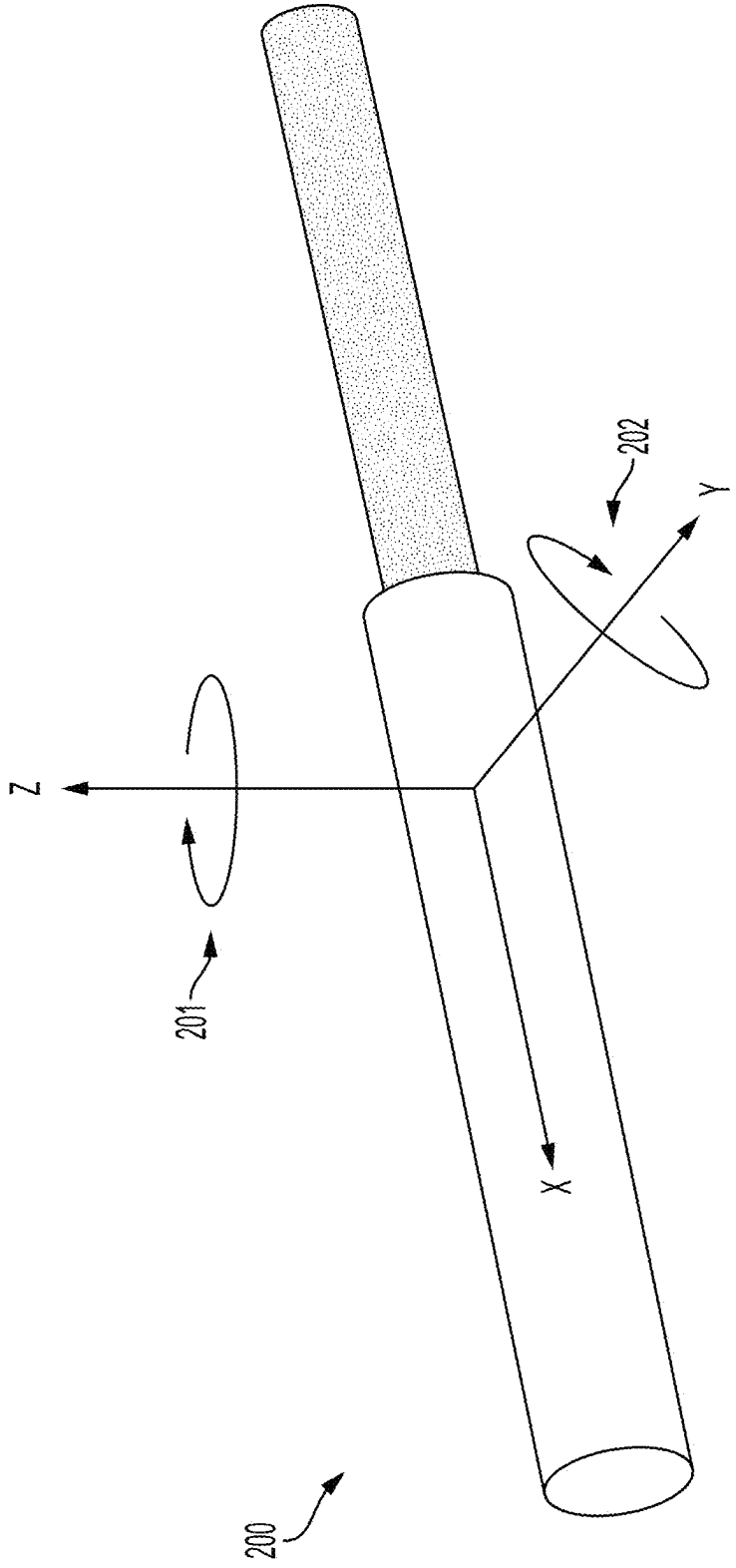

FIG. 2

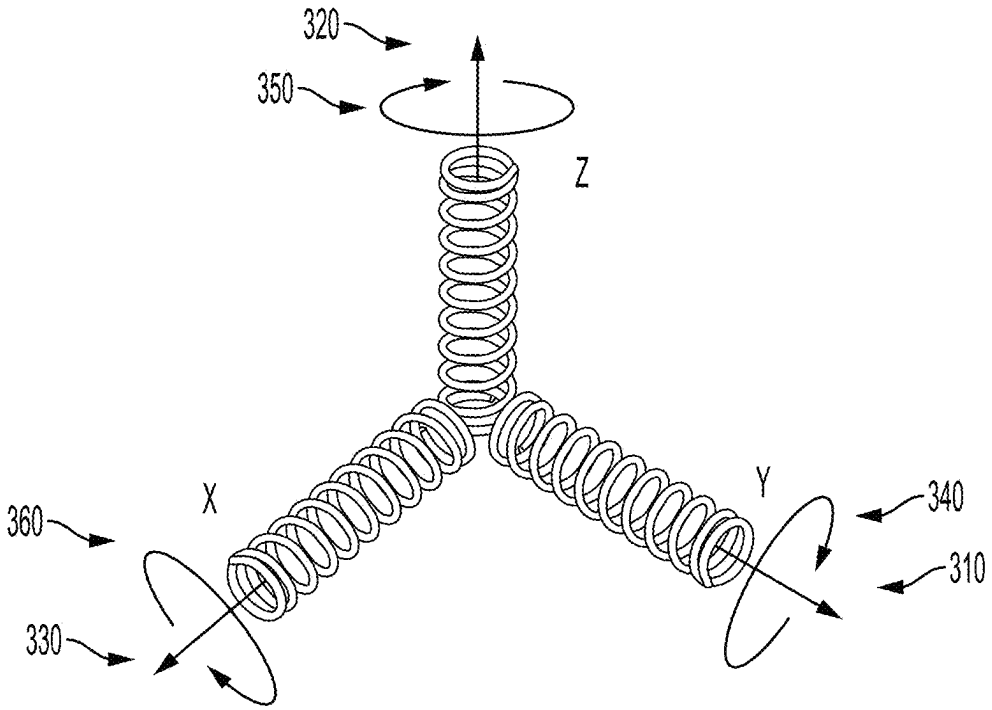

FIG. 3A

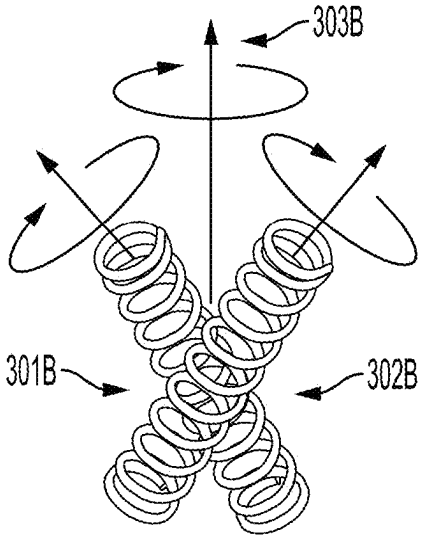

FIG. 3B

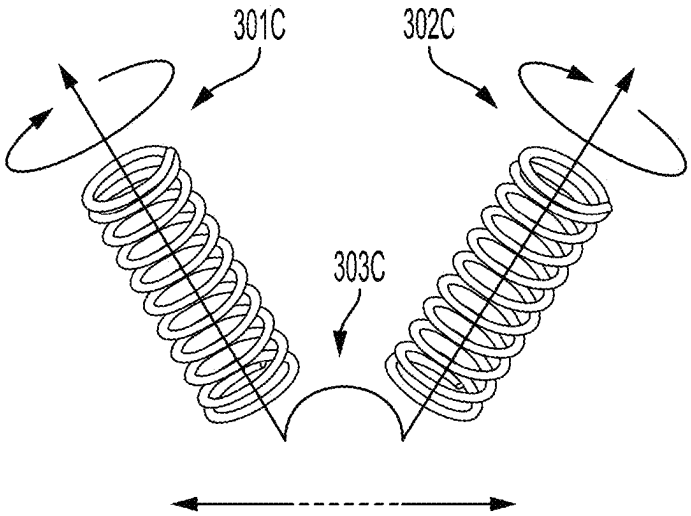

FIG. 3C

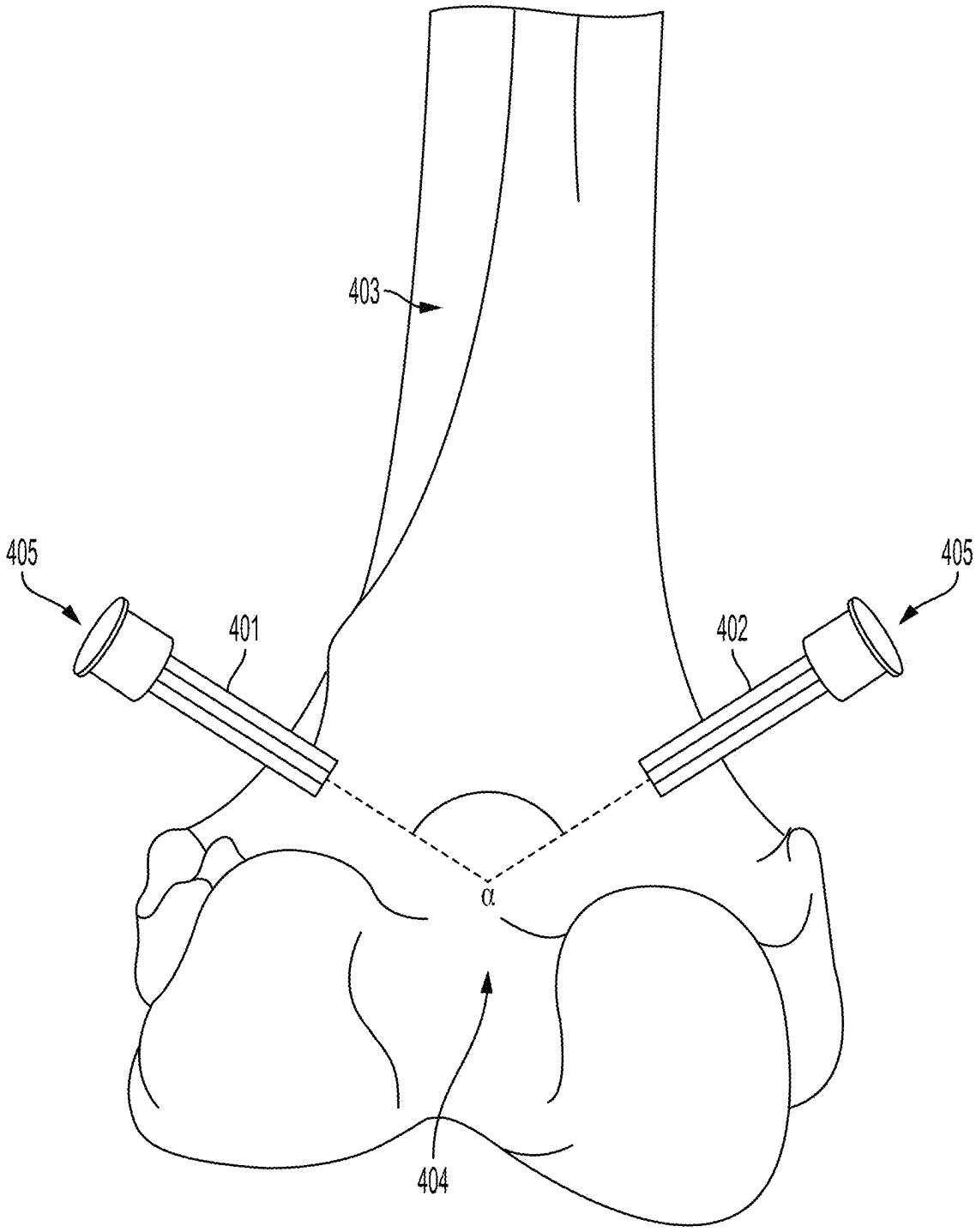

FIG. 4

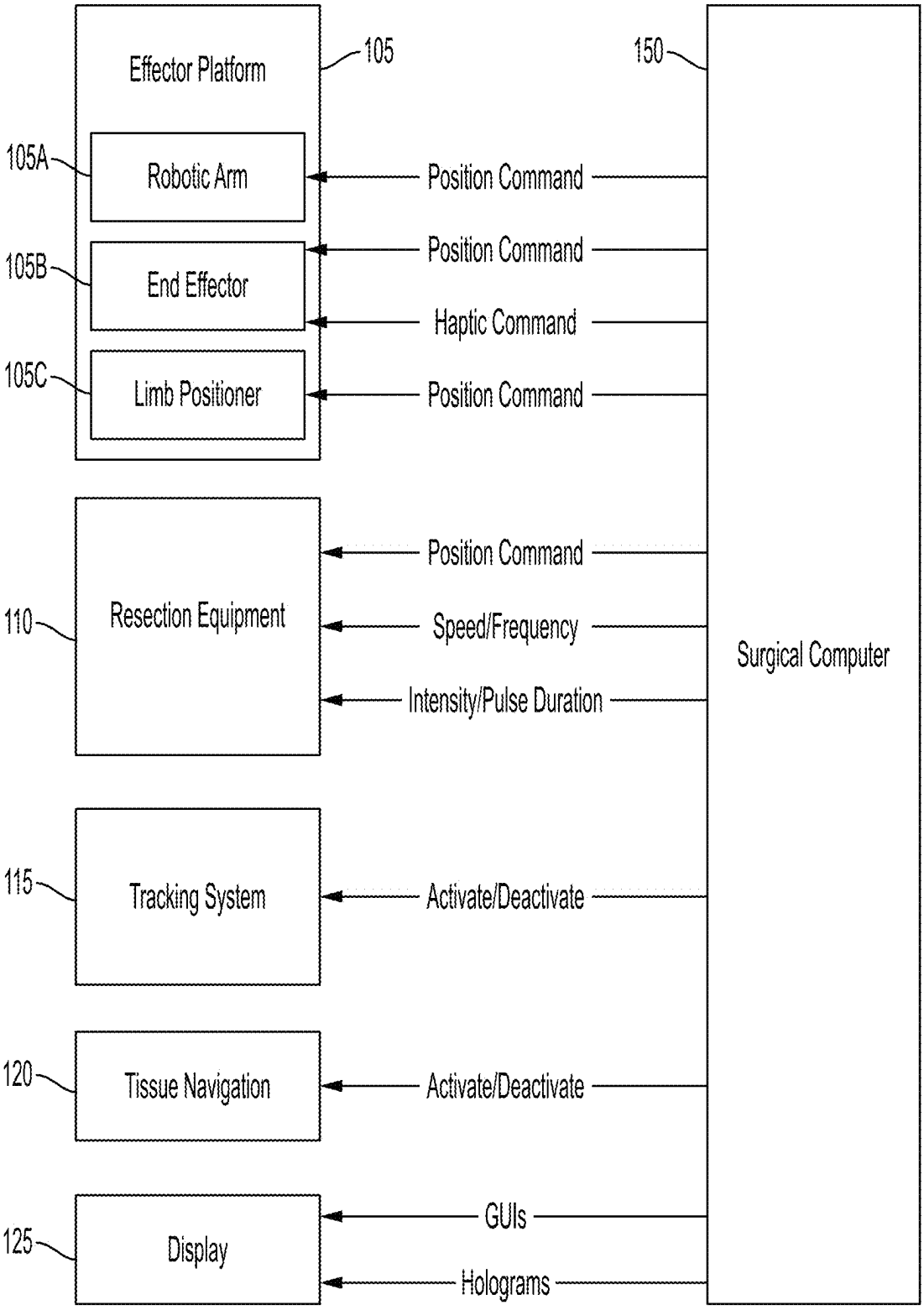
Effector Platform
105
150
105A
Robotic Arm
Position Command
Position Command
105B
End Effector
Haptic Command
105C
Limb Positioner
Position Command
Position Command
110
Resection Equipment
Speed/Frequency
Intensity/Pulse Duration
Surgical Computer
115
Tracking System
Activate/Deactivate
120
Tissue Navigation
Activate/Deactivate
125
Display
GUIs
Holograms

FIG. 5A

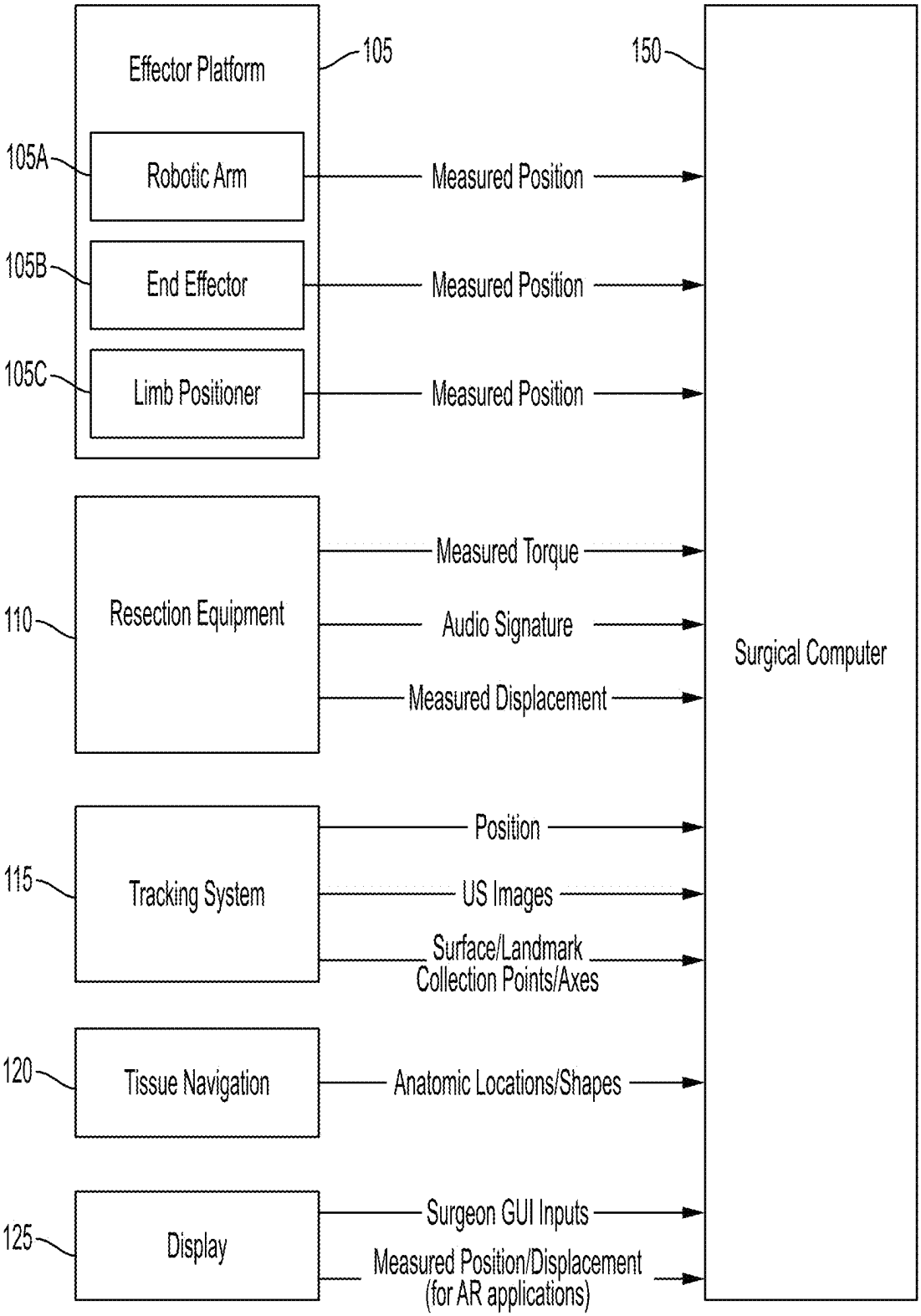
Effector Platform
105
150
105A
Robotic Arm
Measured Position
105B
End Effector
Measured Position
105C
Limb Positioner
Measured Position
Resection Equipment
110
Measured Torque
Audio Signature
Measured Displacement
Surgical Computer
Tracking System
115
Position
US Images
Surface/Landmark
Collection Points/Axes
Tissue Navigation
120
Anatomic Locations/Shapes
Display
125
Surgeon GUI Inputs
Measured Position/Displacement
(for AR applications)

FIG. 5B

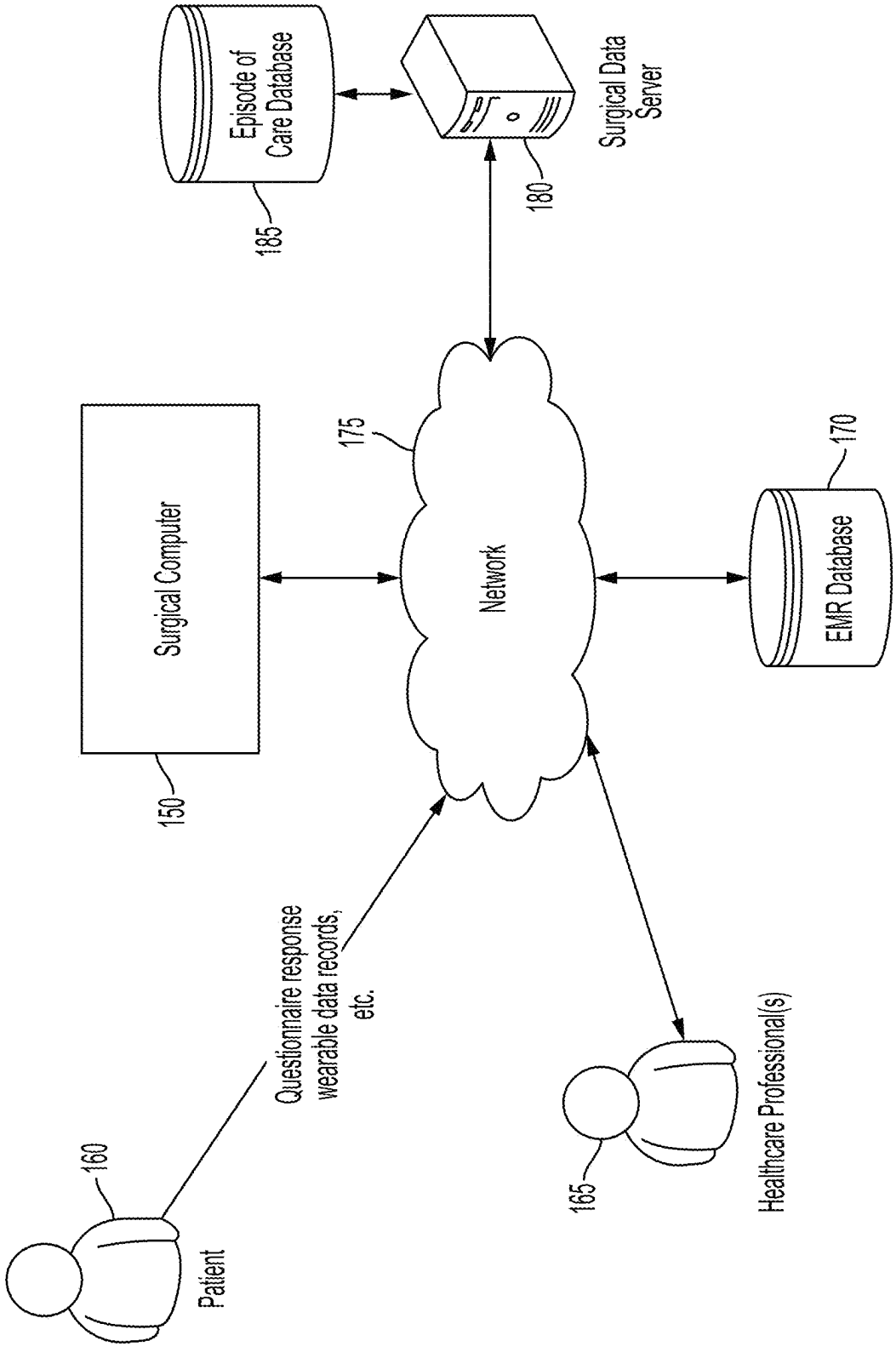
Episode of Care Database
185
Surgical Data Server
180
175
Network
170
EMR Database
Surgical Computer
150
Questionnaire response wearable data records, etc.
160
Patient
165
Healthcare Professional(s)

FIG. 5C

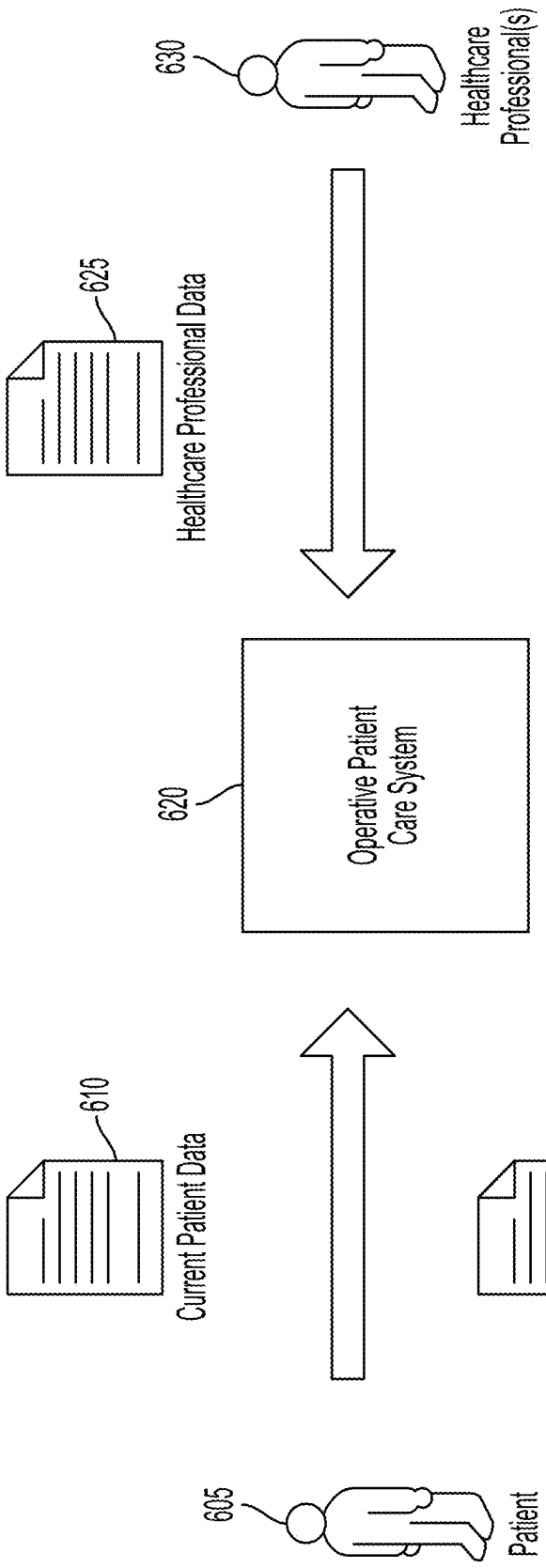
630
Healthcare Professional(s)
625
Healthcare Professional Data
620
Operative Patient Care System
610
Current Patient Data
615
Historical Patient Data
605
Patient

FIG. 6

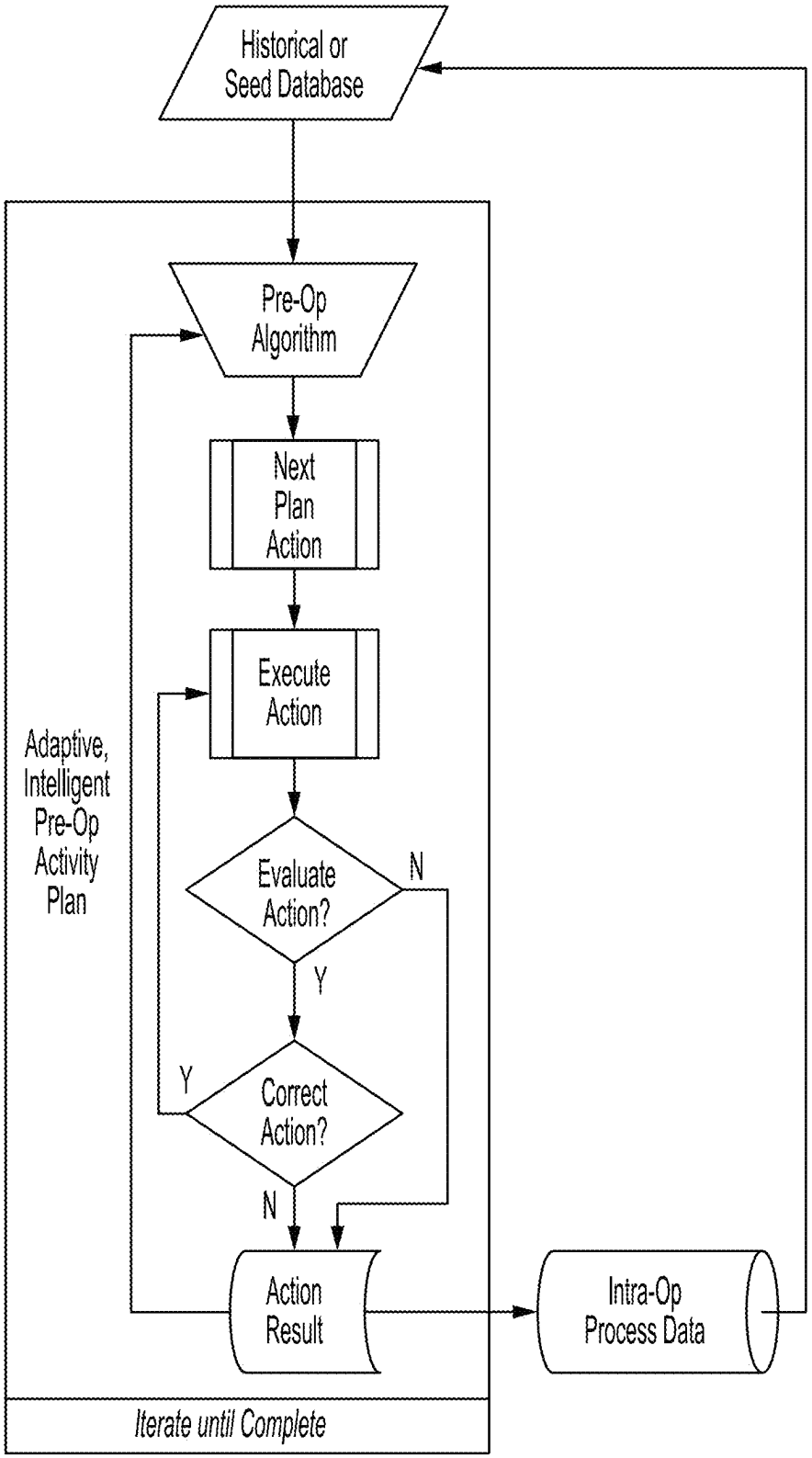
Historical or Seed Database
Pre-Op Algorithm
Next Plan Action
Execute Action
Evaluate Action?
N
Y
Correct Action?
Y
N
Action Result
Intra-Op Process Data
Adaptive, Intelligent Pre-Op Activity Plan
Iterate until Complete

FIG. 7A

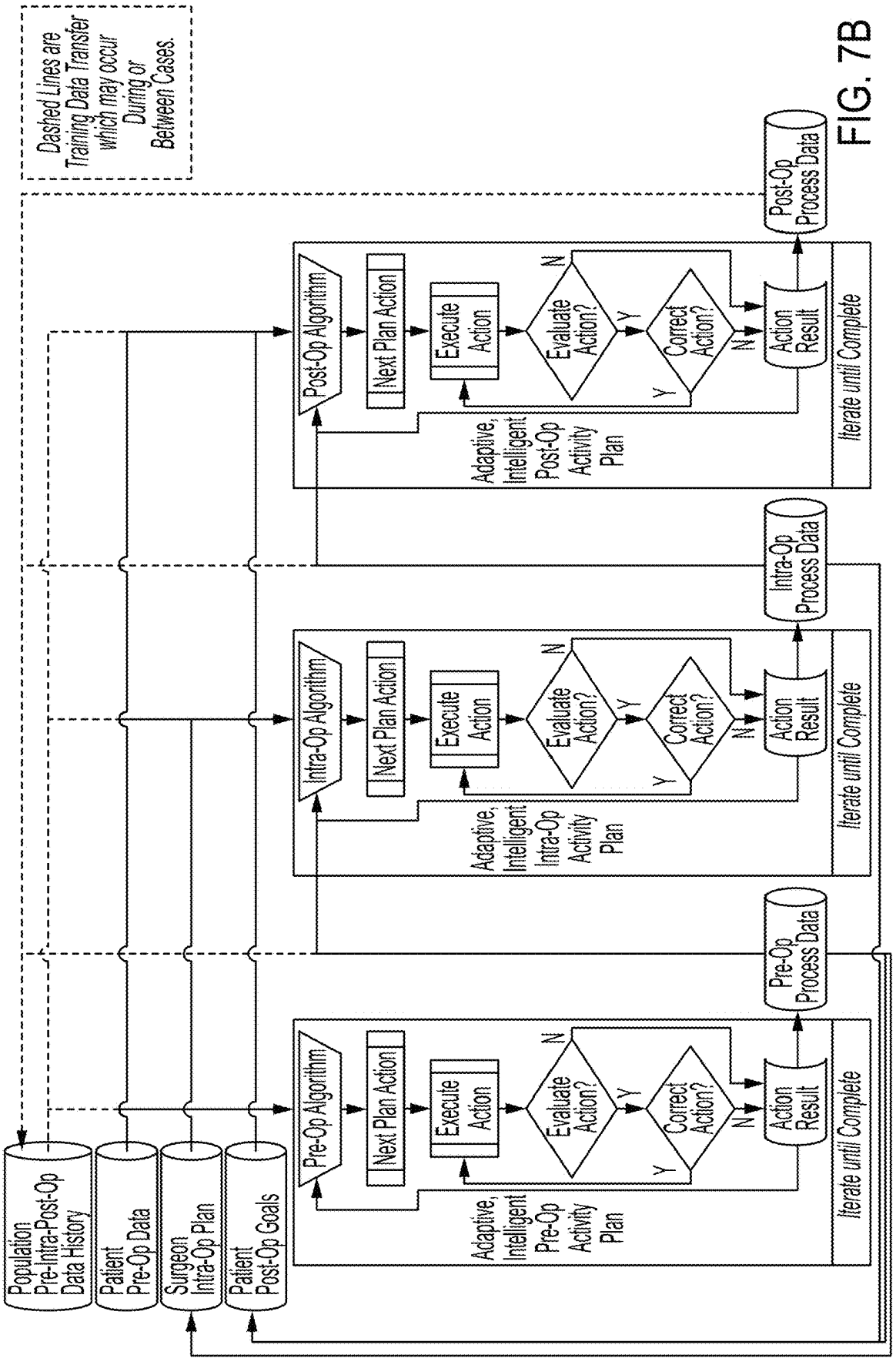
Dashed Lines are Training Data Transfer which may occur During or Between Cases.
Population Pre-Intra-Post-Op Data History
Patient Pre-Op Data
Surgeon Intra-Op Plan
Patient Post-Op Goals
Pre-Op Algorithm
Next Plan Action
Execute Action
Evaluate Action?
Correct Action?
Action Result
Adaptive, Intelligent Pre-Op Activity Plan
Iterate until Complete
Pre-Op Process Data
Intra-Op Algorithm
Next Plan Action
Execute Action
Evaluate Action?
Correct Action?
Action Result
Adaptive, Intelligent Intra-Op Activity Plan
Iterate until Complete
Intra-Op Process Data
Post-Op Algorithm
Next Plan Action
Execute Action
Evaluate Action?
Correct Action?
Action Result
Adaptive, Intelligent Post-Op Activity Plan
Iterate until Complete
Post-Op Process Data
Y
N

FIG. 7B

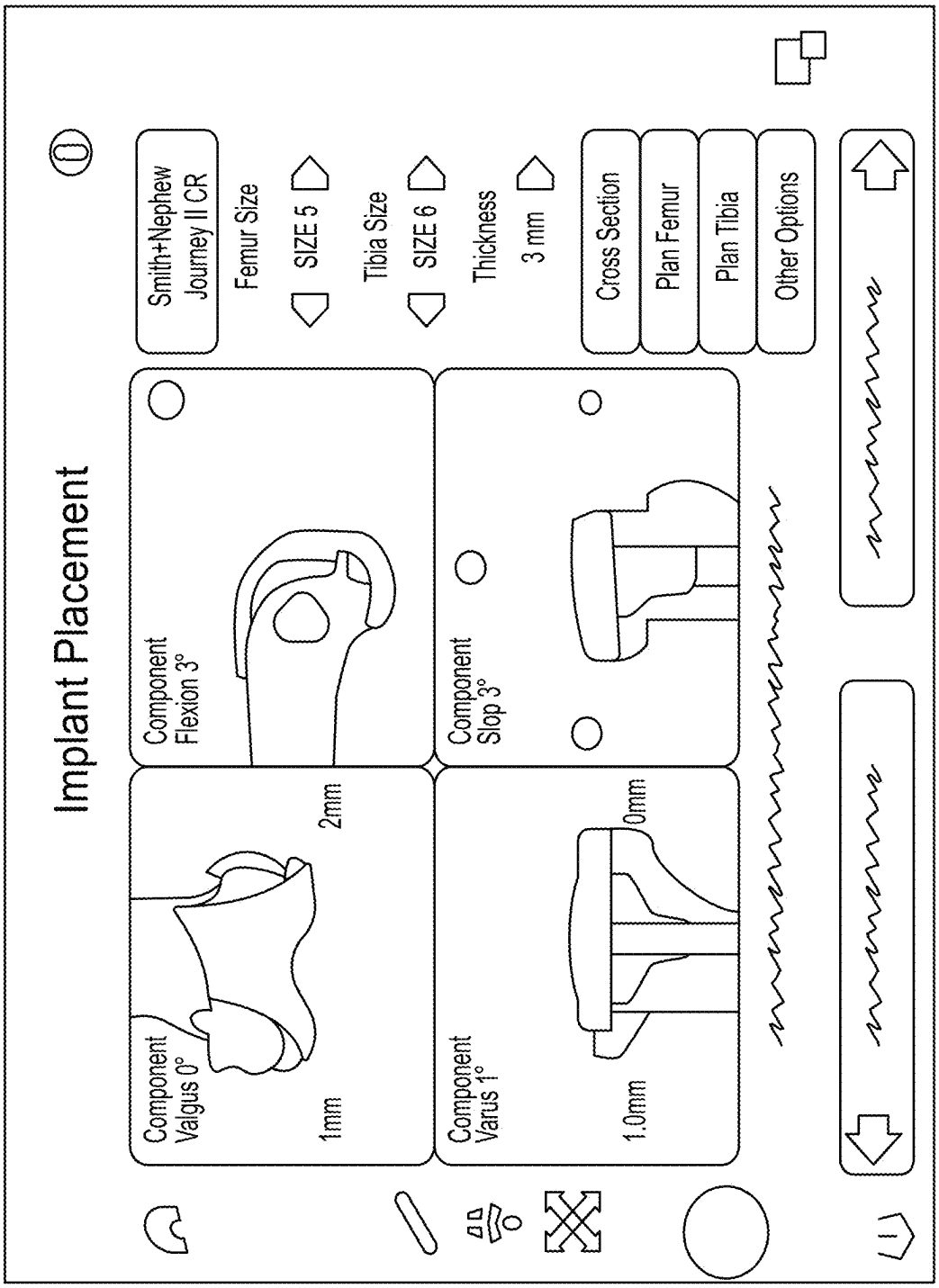
Implant Placement
Component Valgus 0°
1mm
2mm
Component Flexion 3°
Component Varus 1°
1.0mm
0mm
Component Slop 3°
Smith+Nephew Journey II CR
Femur Size
SIZE 5
Tibia Size
SIZE 6
Thickness
3 mm
Cross Section
Plan Femur
Plan Tibia
Other Options
T+ 0.5 minutes

FIG. 7C

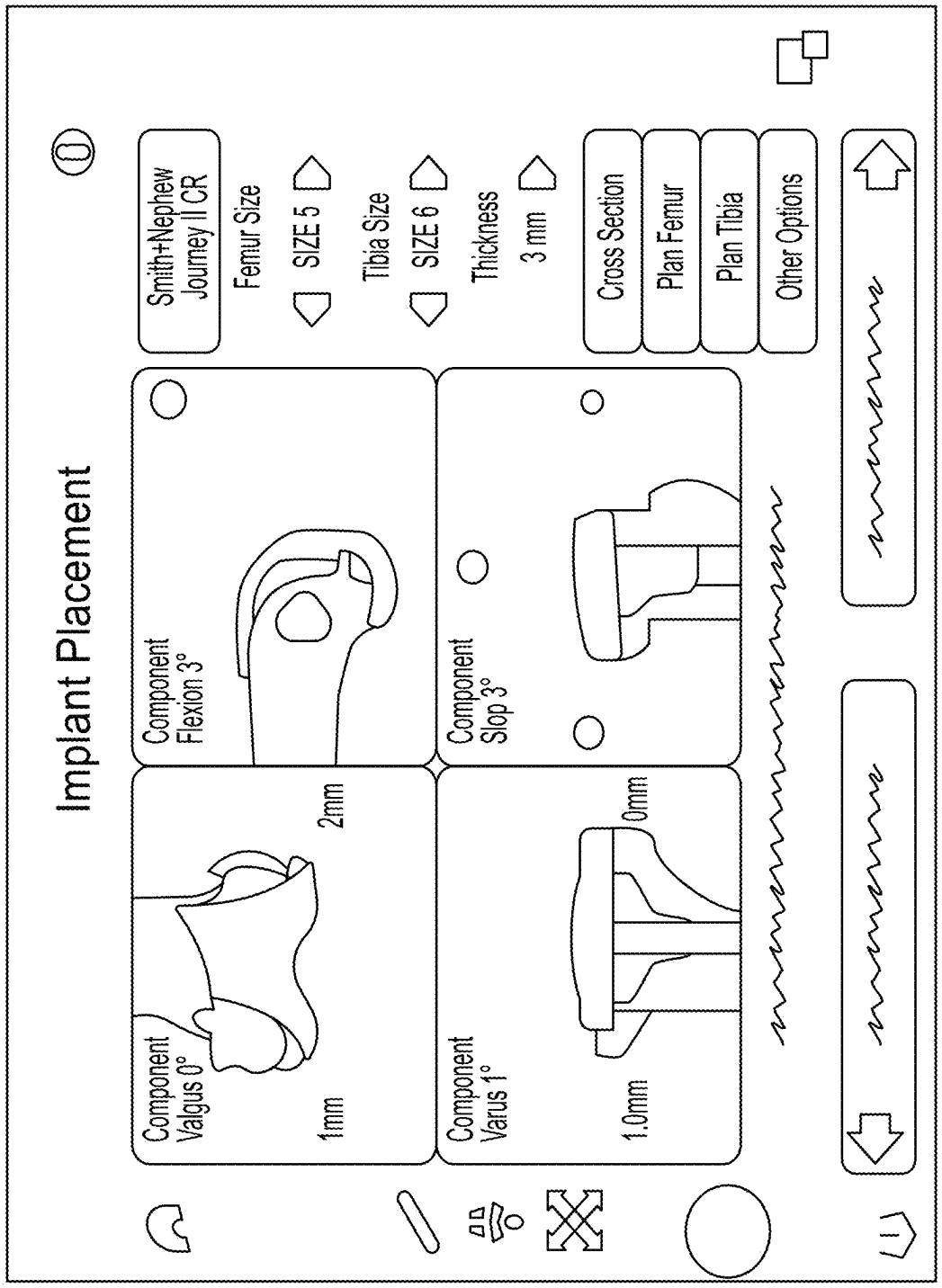

FIG. 7C CONTINUED

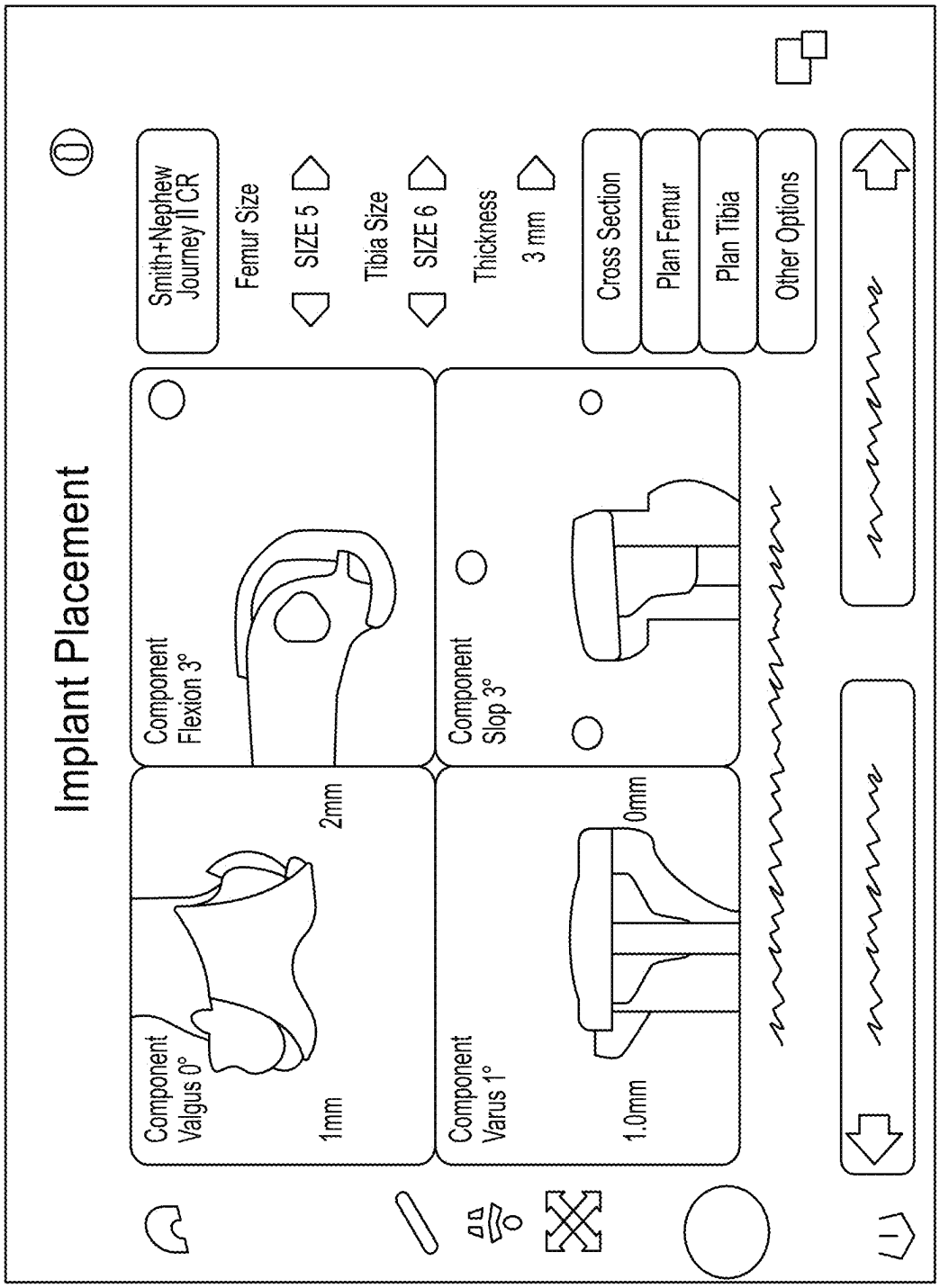

FIG. 7C CONTINUED

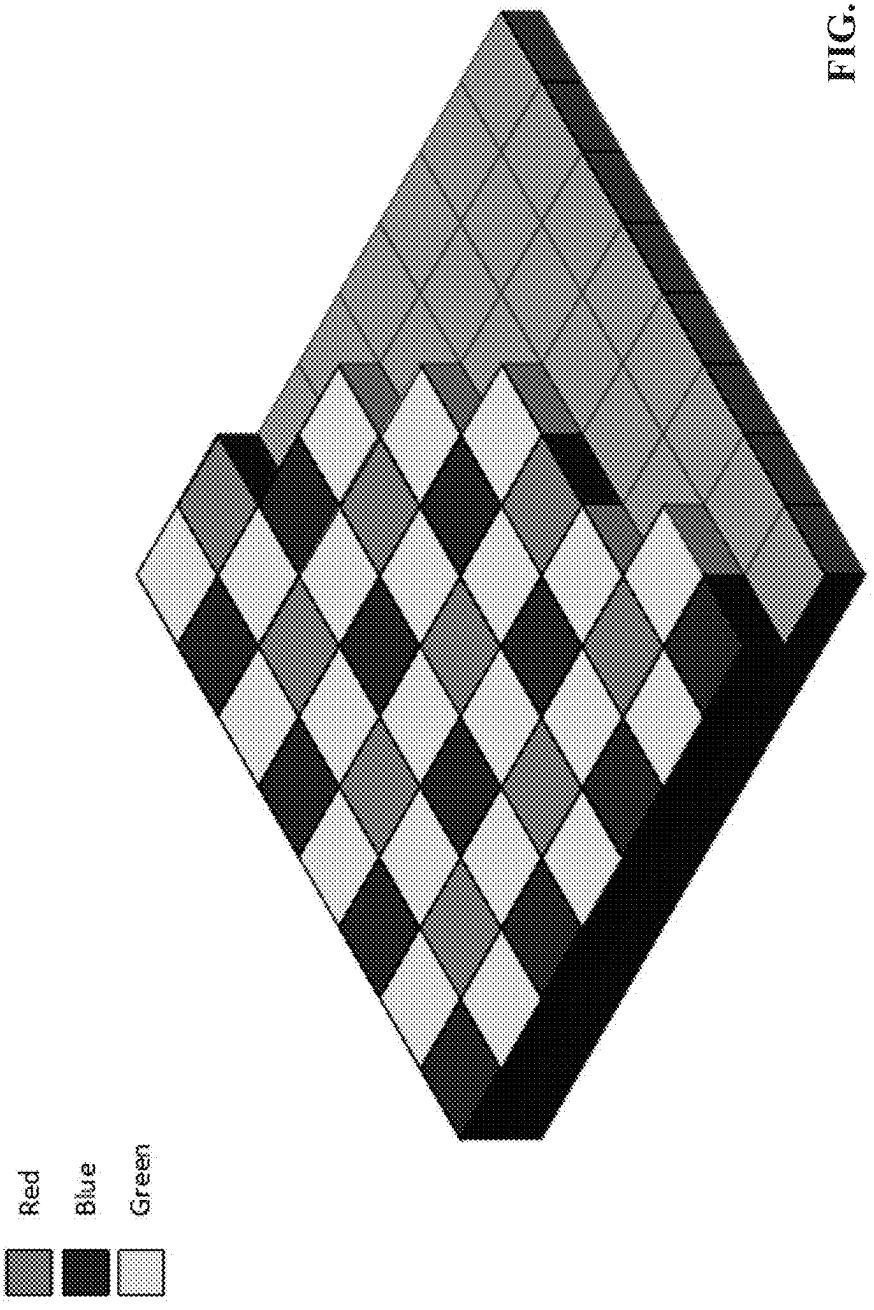

FIG. 8

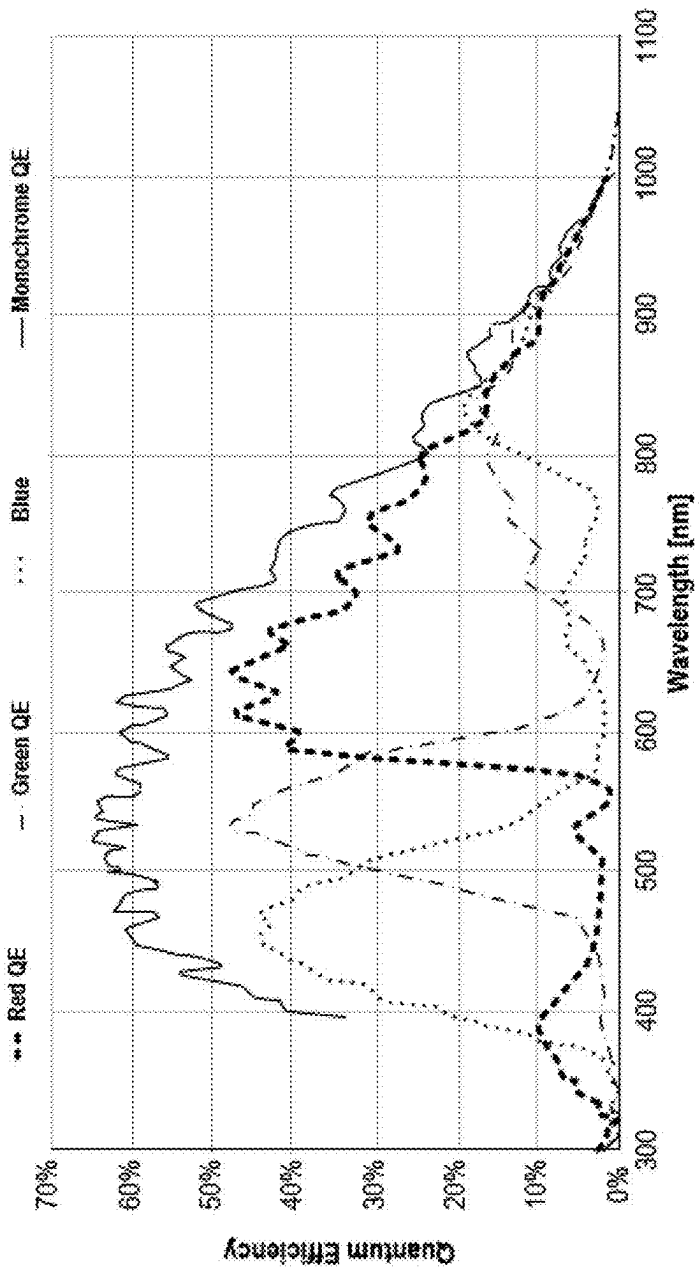
Red QE
Green QE
Blue
Monochrome QE
Quantum Efficiency
70%
60%
50%
40%
30%
20%
10%
0%
300
400
500
600
700
800
900
1000
1100
Wavelength [nm]

FIG. 9

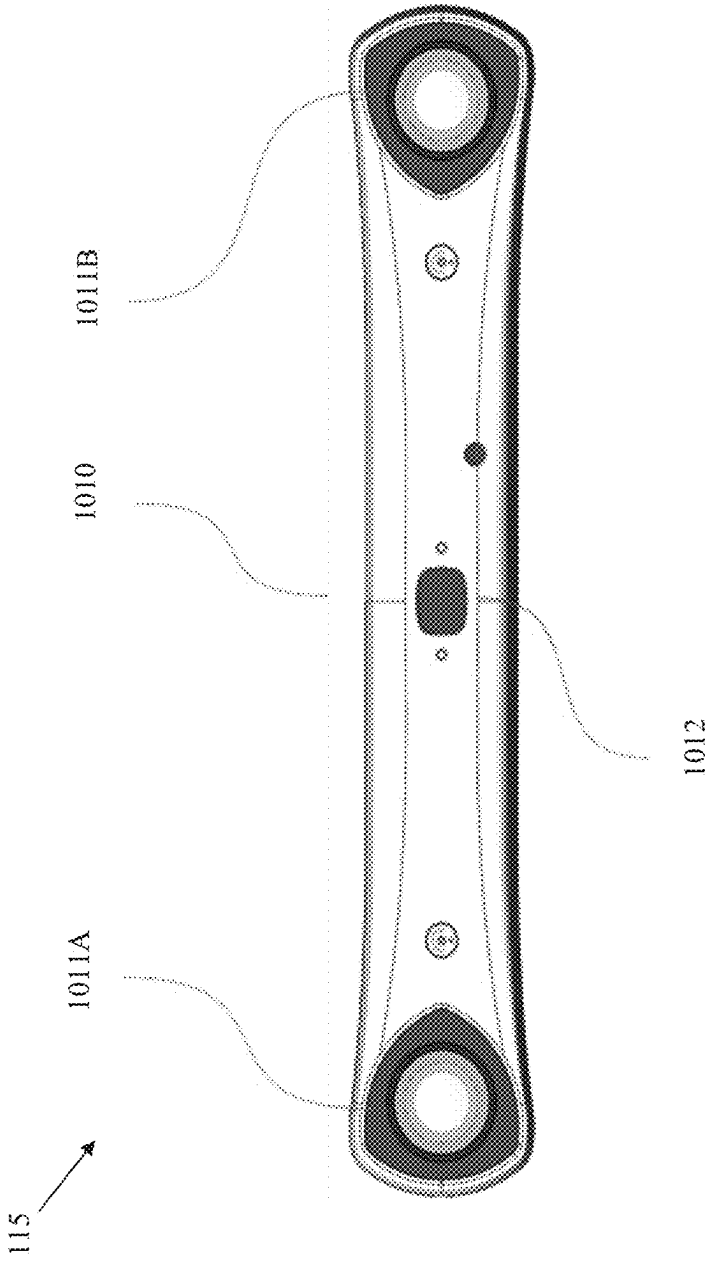

FIG. 10

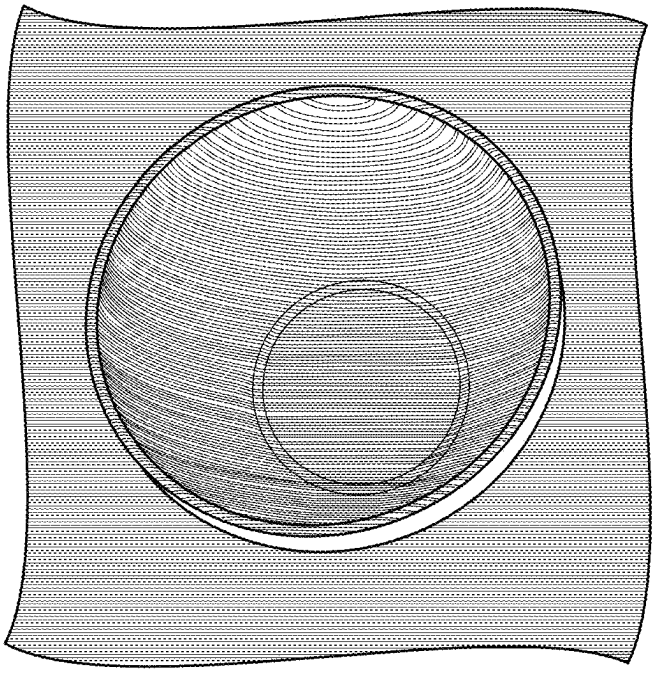

FIG. 11B

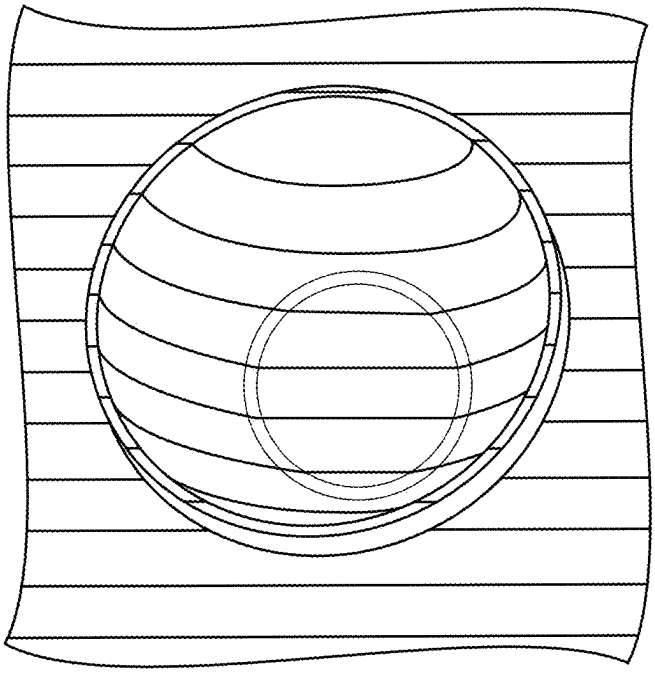

FIG. 11A

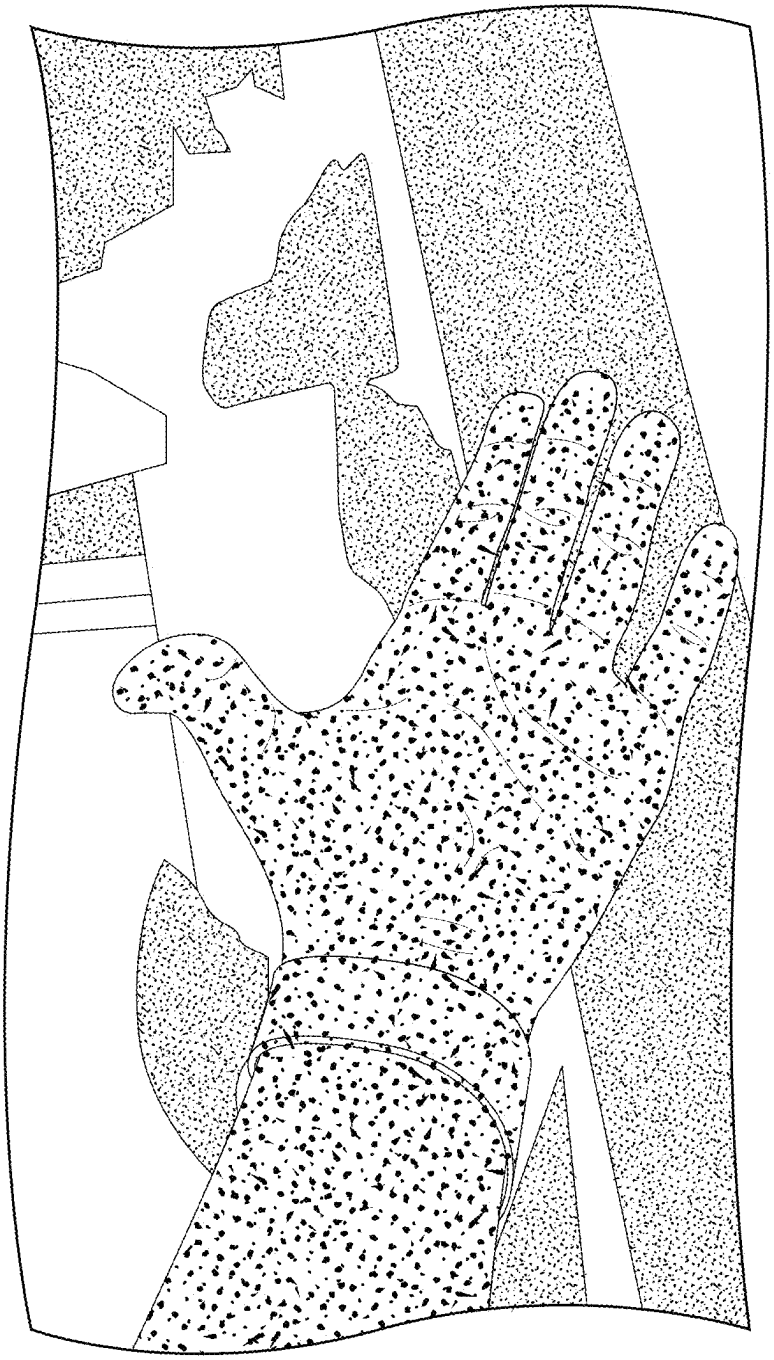

FIG. 12

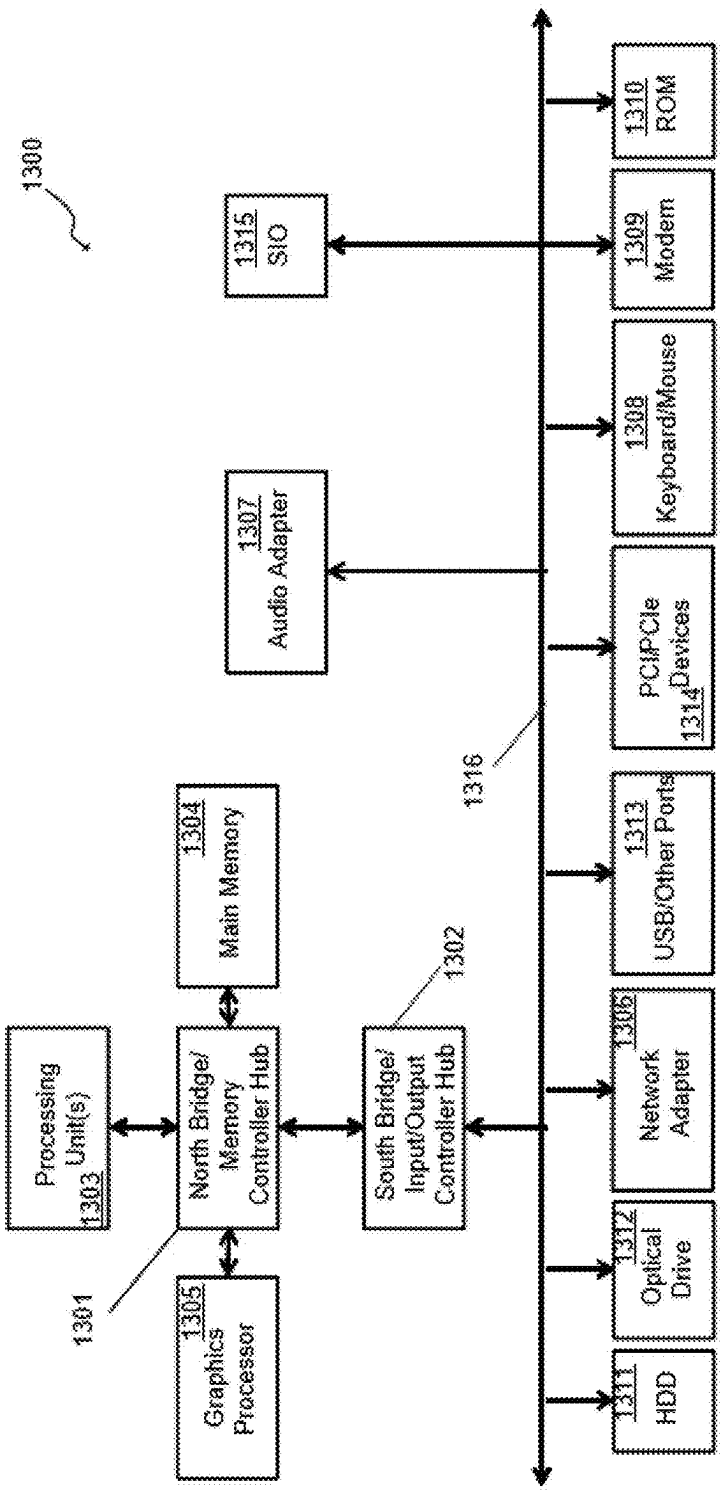
1300
1315 SIO
1307 Audio Adapter
1316
1304 Main Memory
1302
Processing Unit(s) 1303
North Bridge/ Memory Controller Hub
South Bridge/ Input/Output Controller Hub
1301
1305 Graphics Processor
1310 ROM
1309 Modem
1308 Keyboard/Mouse
PCI/PCIe 1314 Devices
1313 USB/Other Ports
1306 Network Adapter
1312 Optical Drive
1311 HDD

FIG. 13

OPTICAL TRACKING DEVICE WITH BUILT-IN STRUCTURED LIGHT MODULE

This application is a continuation of U.S. patent application Ser. No. 18/099,805, filed Jan. 20, 2023, which is a continuation of U.S. patent application Ser. No. 17/604,116, filed Oct. 15, 2021, issued as U.S. Pat. No. 11,583,345, which is a U.S. national stage filing under 35 U.S.C. § 371 of International PCT Application No. PCT/US2021/028890, filed Apr. 23, 2021, which claims the benefit of U.S. Provisional Application Ser. No. 63/014,803, filed on Apr. 24, 2020, each of which is incorporated herein by reference in its entirety.

TECHNICAL FIELD

The present disclosure describes optical tracking systems and apparatuses that more efficiently and effectively reconstruct three-dimensional surfaces of anatomical structures and contemporaneously track objects in surgical environments.

BACKGROUND

Optical tracking systems are employed in surgical environments to track surgical tools, patient anatomy, and other objects. Many conventional optical tracking systems operate in the near IR (NIR) spectrum (from about 740 nm to about 900 nm) in order not to disturb the eyes of the surgical staff. A conventional NIR-based optical tracking system is composed of a pair of optical modules that each comprise an objective, a Complementary Metal-Oxide Semiconductor (CMOS) image sensor, and a NIR passband optical filter (or alternatively a high pass filter—near 740 nm). In such a conventional system, CMOS image sensors can be considered low pass filters because they do not detect wavelength higher than 1000 nm.

As is generally understood in the art, quantum efficiency (QE) quantifies the effectiveness of an image sensor to produce electronic charge (electrons) from incident photons. A higher QE results in the conversion of more photons to electrons. A standard monochrome CMOS image sensor has a QE diminished by 10-15% within the NIR spectrum (740-900 nm) compared to the NIR-enhanced CMOS image sensor. Although visible CMOS image sensors are generally sensitive in the NIR bandwidth, semiconductor manufacturers have developed image sensors that are "enhanced" within this spectrum. The primary market for these NIR-enhanced image sensors is currently surveillance applications. In such applications, the enhancements are intended to reduce or eliminate the light generated by the surveillance system to reduce its visibility to humans.

Images captured by conventional NIR-based optical tracking systems are typically black for the background with a white spot located at each position of an emitting light source in the NIR spectrum. Light sources in NIR-based systems can be direct (e.g., IR-LEDs) or indirect (e.g., a reflective material reflecting a light source located around the objectives of the tracking system). NIR-based acquisitions may be optimized to reduce the noise in images by combining a very low integration time (typically 80 μs) on the CMOS image sensor with an NIR source of high intensity. Ideally, the emission of the infrared energy and the integration time is synchronized to increase the signal/noise ratio. Due to their optimized acquisition, IR-based optical tracking systems generally yield sub-millimeter accuracy.

There has recently been a rise of a new generation of optical tracking systems based on conventional monochrome or color image sensors. These systems retrieve conventional monochrome/color images from the image sensors and process them to detect salient points (e.g., tags, X-point, QR-codes, or any cues in the images). Once these points are detected, they are processed in a manner similar to NIR-based systems (e.g., triangulation, pose estimation, etc.). The use of image-based tracking systems allows for the overlay of information, such as trajectories to follow with a surgical tool, the reconstructed anatomy of the patient, or any other relevant real-time information, on the acquired images. The overlay helps the surgeon locate anatomical landmarks and trajectories to follow and thus allows quicker performance of the procedure.

Unfortunately, using visible images to perform optical tracking in a surgical environment has a number of drawbacks. For example, the optical tracking requires analysis of the full image to detect fiducial markers, which is a CPU-intensive process. Additionally, the detection in such optical tracking systems is typically less reliable in comparison to NIR-based systems, which results in lower overall update rate, inaccuracies, and jitter.

Optical tracking systems are generally integrated in robotic or computer assisted surgery systems (CASS). A typical application includes a marker fixed on the patient and another marker fixed on a surgical instrument (or on an end-effector of a robot). In order to determine the pose of the anatomy of the patient with respect to the marker fixed on the patient, a registration process is required.

An example of patient registration can include gathering a three-dimensional (3D) dataset that reproduces with relative accuracy the geometry of the normal and pathological tissues in the region to be operated on, which is generally obtained by using computed tomography (CT) or magnetic resonance imaging (MRI) scans of that region. The role of patient registration is to obtain a close-to-ideal reference reproducibility of the scanner dataset in order to correlate the position or offset of the gathered dataset with the patient's position during the surgical procedure. Accordingly, patient registration eliminates the necessity of maintaining the same strict position of the patient during both preoperative scanning and surgery and provides the surgeon or surgical robot with the necessary reference information to act accurately on the patient, even if the patient has moved during the surgical procedure.

Patient registration is usually performed using a probe (e.g., a pointer or a digitizer) or a laser scanner. The probe allows acquisition of points on the surface of the patient's anatomical structure (e.g. skin and/or bones) either by touching it or by scanning it. The system further uses registration algorithms (e.g., point-point registration and/or iterative closest point (ICP)) to express pre-operative scans within the coordinate system of a tracked marker.

Alternatively, the concept of registration may be replaced by an in situ scan of the anatomy during the surgical operation process, which may be extended with bone morphing techniques. Instead of the classical registration, this approach avoids the use of pre-operative scanners for surgery planning. However, current CASS applications lack massive digitalization of the surgical procedure and registration is time-consuming and inefficient according to some implementations and inaccurate and ineffective according to others.

SUMMARY

Methods, non-transitory computer readable media, and optical tracking systems are illustrated that improve optical

tracking and surface acquisition. According to certain embodiments, a system is disclosed that includes an optical tracking device and a surgical computing device. The optical tracking device including a structured light module and at least one optical module including an image sensor and spaced from the structured light module at a known distance. The surgical computing device includes a display device, a non-transitory computer-readable medium comprising instructions stored thereon, and one or more processors coupled to the non-transitory computer-readable medium and configured to execute the stored instructions to generate at least one depth map from a first image captured by the image sensor during projection of a pattern into a surgical environment by the structured light module. The pattern is projected in a near-infrared (NIR) spectrum. The one or more processors are further configured to execute the stored instructions to reconstruct a three-dimensional surface of one or more anatomical structures in the surgical environment based on the generated at least one depth map. Additionally, the one or more processors are configured to execute the stored instructions to output the reconstructed three-dimensional surface to the display device.

According to certain embodiments, the at least one optical module comprises first and second optical modules comprising first and second image sensors, respectively, in a stereo configuration.

According to certain embodiments, the first and second image sensors are spaced at a known distance and rigidly coupled to a casing of the optical tracking device.

According to certain embodiments, the first and second image sensors are fixed on a baseline of the optical tracking device and the one or more processors are further configured to execute the stored instructions to calibrate a first pose of the first image sensor with respect to a second pose of the second image sensor.

According to certain embodiments, the one or more processors are further configured to execute the stored instructions to process a second image captured by the image sensor in a visible light spectrum to determine tracking information comprising at least a three-dimensional position of each of one or more fiducials within the surgical environment.

According to certain embodiments, the first and second images are captured in a common coordinate system.

According to certain embodiments, a plurality of the first and second images are alternately captured by the image senor.

According to certain embodiments, the one or more processors are further configured to execute the stored instructions to output an indication of one or more objects to the display device along with the reconstructed three-dimensional surface, wherein the one or more objects are associated with the one or more fiducials and located based on the tracking information.

According to certain embodiments, the system further includes at least one infrared light (IR) emitting diode (LED) light source surrounding, at least in part, the at least one optical module.

According to certain embodiments, the structured light module is configured to project one or more of a plurality of sequential patterns, a plurality of stripes, a random pattern, a pseudo-random pattern, or a plurality of points.

According to certain embodiments, the one or more processors are further configured to execute the stored instructions to generate a plurality of three-dimensional surfaces of the one or more anatomical structures from a plurality of depth maps generated from a plurality of images captured by the image sensor during projection of the pattern into the surgical environment by the structured light module.

According to certain embodiments, the one or more processors are further configured to execute the stored instructions to stitch the plurality of three-dimensional surfaces to reconstruct the three-dimensional surface of the one or more anatomical structures.

According to certain embodiments, the one or more processors are further configured to execute the stored instructions to densify the reconstructed three-dimensional surface of the one or more anatomical structures based on the plurality of three-dimensional surfaces.

According to certain embodiments, the one or more processors are further configured to execute the stored instructions to generate a three-dimensional sequence of movement of the one or more anatomical structures occurring between capture of one or more of the plurality of images.

According to certain embodiments, the at least one optical module further comprises at least one lens and an NIR filter.

BRIEF DESCRIPTION OF THE DRAWINGS

The accompanying drawings, which are incorporated in and form a part of the specification, illustrate the embodiments of the invention and together with the written description serve to explain the principles, characteristics, and features of the invention. In the drawings:

FIG. **1** depicts an operating theatre including an illustrative computer-assisted surgical system (CASS) in accordance with an embodiment.

FIG. **2** depicts an example of an electromagnetic sensor device according to some embodiments.

FIG. **3**A depicts an alternative example of an electromagnetic sensor device, with three perpendicular coils, according to some embodiments.

FIG. **3**B depicts an alternative example of an electromagnetic sensor device, with two nonparallel, affixed coils, according to some embodiments.

FIG. **3**C depicts an alternative example of an electromagnetic sensor device, with two nonparallel, separate coils, according to some embodiments.

FIG. **4** depicts an example of electromagnetic sensor devices and a patient bone according to some embodiments

FIG. **5**A depicts illustrative control instructions that a surgical computer provides to other components of a CASS in accordance with an embodiment.

FIG. **5**B depicts illustrative control instructions that components of a CASS provide to a surgical computer in accordance with an embodiment.

FIG. **5**C depicts an illustrative implementation in which a surgical computer is connected to a surgical data server via a network in accordance with an embodiment.

FIG. **6** depicts an operative patient care system and illustrative data sources in accordance with an embodiment.

FIG. **7**A depicts an illustrative flow diagram for determining a pre-operative surgical plan in accordance with an embodiment.

FIG. **7**B depicts an illustrative flow diagram for determining an episode of care including pre-operative, intraoperative, and post-operative actions in accordance with an embodiment.

FIG. **7**C depicts illustrative graphical user interfaces including images depicting an implant placement in accordance with an embodiment.

FIG. **8** depicts a Bayer arrangement of color filters on the pixel array of an image sensor in accordance with an embodiment.

FIG. **9** depicts a plot of quantum efficiency versus wavelength broken down into each color channel in accordance with an embodiment.

FIG. **10** depicts a stereo optical tracking system having two optical modules and a structured light projector in accordance with an embodiment.

FIGS. **11**A-**11**B depict examples of a vertical strip pattern projected on an object and seen by a camera in accordance with an embodiment.

FIG. **12** depict an example of a raw image that projects a pseudo-random pattern in the infrared spectrum in accordance with an embodiment.

FIG. **13** depicts a block diagram of an illustrative surgical computing device in which aspects of the illustrative embodiments are implemented.

DETAILED DESCRIPTION

Systems, methods, and apparatuses are described herein which relate generally to an optical tracking system designed for augmented reality (AR) applications. More specifically, the optical tracking system described herein comprises optical modules that use RGB color sensors instead of monochrome ones. This improvement allows the optical tracking system to retrieve both standard color images and accurate tracking data in an interleaved manner This change opens the door of the next generation of computer-assisted surgery (CAS) applications, including a deeper digitalization of the surgical area. For example, the enhanced tracking information may be used to provide AR overlays (e.g., displaying operational information directly on comprehensive images of the surgical area). The optical tracking system described herein may also be used to retrieve more information from the surgical area to improve the overall surgical process flow (e.g., check for correct workflow, check that the correct color-coded implant—pedical screw—is used, etc.).

The systems, methods, and apparatuses described herein are particularly well adapted for surgical procedures that utilize surgical navigation systems, such as the NAVIO® surgical navigation system. Such procedures can include knee replacement and/or revision surgery, as well as shoulder and hip surgeries. NAVIO is a registered trademark of BLUE BELT TECHNOLOGIES, INC. of Pittsburgh, PA, which is a subsidiary of SMITH & NEPHEW, INC. of Memphis, TN.

As used in this document, the singular forms "a," "an," and "the" include plural references unless the context clearly dictates otherwise. Unless defined otherwise, all technical and scientific terms used herein have the same meanings as commonly understood by one of ordinary skill in the art. Nothing in this disclosure is to be construed as an admission that the embodiments described in this disclosure are not entitled to antedate such disclosure by virtue of prior invention. As used in this document, the term "comprising" means "including, but not limited to."

Definitions

For the purposes of this disclosure, the term "real-time" is used to refer to calculations or operations performed on-the-fly as events occur or input is received by the operable system. However, the use of the term "real-time" is not intended to preclude operations that cause some latency between input and response, so long as the latency is an unintended consequence induced by the performance characteristics of the machine.

Although much of this disclosure refers to surgeons or other medical professionals by specific job title or role, nothing in this disclosure is intended to be limited to a specific job title or function. Surgeons or medical professionals can include any doctor, nurse, medical professional, or technician. Any of these terms or job titles can be used interchangeably with the user of the systems disclosed herein unless otherwise explicitly demarcated. For example, a reference to a surgeon also could apply, in some embodiments to a technician or nurse.

The systems, methods, and devices disclosed herein are particularly well adapted for surgical procedures that utilize surgical navigation systems, such as the NAVIO® surgical navigation system. NAVIO is a registered trademark of BLUE BELT TECHNOLOGIES, INC. of Pittsburgh, PA, which is a subsidiary of SMITH & NEPHEW, INC. of Memphis, TN.

CASS Ecosystem Overview

FIG. **1** provides an illustration of an example computer-assisted surgical system (CASS) **100**, according to some embodiments. As described in further detail in the sections that follow, the CASS uses computers, robotics, and imaging technology to aid surgeons in performing orthopedic surgery procedures such as total knee arthroplasty (TKA) or total hip arthroplasty (THA). For example, surgical navigation systems can aid surgeons in locating patient anatomical structures, guiding surgical instruments, and implanting medical devices with a high degree of accuracy. Surgical navigation systems such as the CASS **100** often employ various forms of computing technology to perform a wide variety of standard and minimally invasive surgical procedures and techniques. Moreover, these systems allow surgeons to more accurately plan, track and navigate the placement of instruments and implants relative to the body of a patient, as well as conduct pre-operative and intra-operative body imaging.

An Effector Platform **105** positions surgical tools relative to a patient during surgery. The exact components of the Effector Platform **105** will vary, depending on the embodiment employed. For example, for a knee surgery, the Effector Platform **105** may include an End Effector **105**B that holds surgical tools or instruments during their use. The End Effector **105**B may be a handheld device or instrument used by the surgeon (e.g., a NAVIO® hand piece or a cutting guide or jig) or, alternatively, the End Effector **105**B can include a device or instrument held or positioned by a Robotic Arm **105**A. While one Robotic Arm **105**A is illustrated in FIG. **1**, in some embodiments there may be multiple devices. As examples, there may be one Robotic Arm **105**A on each side of an operating table T or two devices on one side of the table T. The Robotic Arm **105**A may be mounted directly to the table T, be located next to the table T on a floor platform (not shown), mounted on a floor-to-ceiling pole, or mounted on a wall or ceiling of an operating room. The floor platform may be fixed or moveable. In one particular embodiment, the robotic arm **105**A is mounted on a floor-to-ceiling pole located between the patient's legs or feet. In some embodiments, the End Effector **105**B may include a suture holder or a stapler to assist in closing wounds. Further, in the case of two robotic arms **105**A, the surgical computer **150** can drive the robotic arms **105**A to work together to suture the wound at closure. Alternatively, the

surgical computer **150** can drive one or more robotic arms **105**A to staple the wound at closure.

The Effector Platform **105** can include a Limb Positioner **105**C for positioning the patient's limbs during surgery. One example of a Limb Positioner **105**C is the SMITH AND NEPHEW SPIDER2 system. The Limb Positioner **105**C may be operated manually by the surgeon or alternatively change limb positions based on instructions received from the Surgical Computer **150** (described below). While one Limb Positioner **105**C is illustrated in FIG. **1**, in some embodiments there may be multiple devices. As examples, there may be one Limb Positioner **105**C on each side of the operating table T or two devices on one side of the table T. The Limb Positioner **105**C may be mounted directly to the table T, be located next to the table T on a floor platform (not shown), mounted on a pole, or mounted on a wall or ceiling of an operating room. In some embodiments, the Limb Positioner **105**C can be used in non-conventional ways, such as a retractor or specific bone holder. The Limb Positioner **105**C may include, as examples, an ankle boot, a soft tissue clamp, a bone clamp, or a soft-tissue retractor spoon, such as a hooked, curved, or angled blade. In some embodiments, the Limb Positioner **105**C may include a suture holder to assist in closing wounds.

The Effector Platform **105** may include tools, such as a screwdriver, light or laser, to indicate an axis or plane, bubble level, pin driver, pin puller, plane checker, pointer, finger, or some combination thereof.

Resection Equipment **110** (not shown in FIG. **1**) performs bone or tissue resection using, for example, mechanical, ultrasonic, or laser techniques. Examples of Resection Equipment **110** include drilling devices, burring devices, oscillatory sawing devices, vibratory impaction devices, reamers, ultrasonic bone cutting devices, radio frequency ablation devices, reciprocating devices (such as a rasp or broach), and laser ablation systems. In some embodiments, the Resection Equipment **110** is held and operated by the surgeon during surgery. In other embodiments, the Effector Platform **105** may be used to hold the Resection Equipment **110** during use.

The Effector Platform **105** also can include a cutting guide or jig **105**D that is used to guide saws or drills used to resect tissue during surgery. Such cutting guides **105**D can be formed integrally as part of the Effector Platform **105** or Robotic Arm **105**A, or cutting guides can be separate structures that can be matingly and/or removably attached to the Effector Platform **105** or Robotic Arm **105**A. The Effector Platform **105** or Robotic Arm **105**A can be controlled by the CASS **100** to position a cutting guide or jig **105**D adjacent to the patient's anatomy in accordance with a pre-operatively or intraoperatively developed surgical plan such that the cutting guide or jig will produce a precise bone cut in accordance with the surgical plan.

The tracking system **115** uses one or more sensors to collect real-time position data that locates the patient's anatomy and surgical instruments. For example, for TKA procedures, the tracking system **115** may provide a location and orientation of the end effector **105**B with respect to patient anatomy during the procedure. In addition to positional data, data from the tracking system **115** also can be used to infer velocity/acceleration of anatomy/instrumentation, which can be used for tool control. In some embodiments, the tracking system **115** may use a tracker array attached to the end effector **105**B to determine the location and orientation of the end effector. The position of the end effector **105**B may be inferred based on the position and orientation of the tracking system **115** and a known relationship in three-dimensional space between the tracking system and the end effector **105**B. Various types of tracking systems may be used in various embodiments of the present invention including, without limitation, Infrared (IR) tracking systems, electromagnetic (EM) tracking systems, video or image based tracking systems, and ultrasound registration and tracking systems. Using the data provided by the optical tracking system **115**, the surgical computer **150** can detect objects and prevent collision. For example, the surgical computer **150** can prevent the robotic arm **105**A and/or the end effector **105**B from colliding with soft tissue.

Any suitable tracking system can be used for tracking surgical objects and patient anatomy in the surgical theatre. For example, a combination of IR and visible light cameras can be used in an array. Various illumination sources, such as an IR LED light source, can illuminate the scene allowing three-dimensional imaging to occur, as described and illustrated in more detail below. In some embodiments, this can include monoscopic, stereoscopic, tri-scopic, quad-scopic, etc. imaging. In addition to the camera array, which in some embodiments is affixed to a cart, additional cameras can be placed throughout the surgical theatre. For example, handheld tools or headsets worn by operators/surgeons can include imaging capability that communicates images back to a central processor (e.g., of the surgical computer **150**) to correlate those images with images captured by the camera array. This can give a more robust image of the environment for modeling using multiple perspectives. Furthermore, some imaging devices may be of suitable resolution or have a suitable perspective on the scene to pick up information stored in quick response (QR) codes or barcodes. This can be helpful in identifying specific objects not manually registered with the system. In some embodiments, the camera may be mounted on the robotic arm **105**A.

Although, as discussed herein, the majority of tracking and/or navigation techniques utilize image-based tracking systems (e.g., IR tracking systems, video or image based tracking systems, etc.). However, electromagnetic (EM) based tracking systems are becoming more common for a variety of reasons. For example, implantation of standard optical trackers requires tissue resection (e.g., down to the cortex) as well as subsequent drilling and driving of cortical pins. Additionally, because optical trackers require a direct line of sight with a tracking system, the placement of such trackers may need to be far from the surgical site to ensure they do not restrict the movement of a surgeon or medical professional.

Generally, EM based tracking devices include one or more wire coils and a reference field generator. The one or more wire coils may be energized (e.g., via a wired or wireless power supply). Once energized, the coil creates an electromagnetic field that can be detected and measured (e.g., by the reference field generator or an additional device) in a manner that allows for the location and orientation of the one or more wire coils to be determined. As should be understood by someone of ordinary skill in the art, a single coil, such as is shown in FIG. **2**, is limited to detecting five (5) total degrees-of-freedom (DOF). For example, sensor **200** may be able to track/determine movement in the X, Y, or Z direction, as well as rotation around the Y-axis **202** or Z-axis **201**. However, because of the electromagnetic properties of a coil, it is not possible to properly track rotational movement around the X axis.

Accordingly, in most electromagnetic tracking applications, a three coil system, such as that shown in FIG. **3**A is used to enable tracking in all six degrees of freedom that are possible for a rigid body moving in a three-dimensional

space (i.e., forward/backward **310**, up/down **320**, left/right **330**, roll **340**, pitch **350**, and yaw **360**). However, the inclusion of two additional coils and the 90° offset angles at which they are positioned may require the tracking device to be much larger. Alternatively, as one of skill in the art would know, less than three full coils may be used to track all 6 DOF. In some EM based tracking devices, two coils may be affixed to each other, such as is shown in FIG. **3**B. Because the two coils **301**B and **302**B are rigidly affixed to each other, not perfectly parallel, and have locations that are known relative to each other, it is possible to determine the sixth degree of freedom **303**B with this arrangement.

Although the use of two affixed coils (e.g., **301**B and **302**B) allows for EM based tracking in 6 DOF, the sensor device is substantially larger in diameter than a single coil because of the additional coil. Thus, the practical application of using an EM based tracking system in a surgical environment may require tissue resection and drilling of a portion of the patient bone to allow for insertion of a EM tracker. Alternatively, in some embodiments, it may be possible to implant/insert a single coil, or 5 DOF EM tracking device, into a patient bone using only a pin (e.g., without the need to drill or carve out substantial bone).

Thus, as described herein, a solution is needed for which the use of an EM tracking system can be restricted to devices small enough to be inserted/embedded using a small diameter needle or pin (i.e., without the need to create a new incision or large diameter opening in the bone). Accordingly, in some embodiments, a second 5 DOF sensor, which is not attached to the first, and thus has a small diameter, may be used to track all 6 DOF. Referring now to FIG. **3**C, in some embodiments, two 5 DOF EM sensors (e.g., **301**C and **302**C) may be inserted into the patient (e.g., in a patient bone) at different locations and with different angular orientations (e.g., angle **303**C is non-zero).

Referring now to FIG. **4**, an example embodiment is shown in which a first 5 DOF EM sensor **401** and a second 5 DOF EM sensor **402** are inserted into the patient bone **403** using a standard hollow needle **405** that is typical in most OR(s). In a further embodiment, the first sensor **401** and the second sensor **402** may have an angle offset of "?" **404**. In some embodiments, it may be necessary for the offset angle "?" **404** to be greater than a predetermined value (e.g., a minimum angle of 0.50°, 0.75°, etc.). This minimum value may, in some embodiments, be determined by the CASS and provided to the surgeon or medical professional during the surgical plan. In some embodiments, a minimum value may be based on one or more factors, such as, for example, the orientation accuracy of the tracking system, a distance between the first and second EM sensors. The location of the field generator, a location of the field detector, a type of EM sensor, a quality of the EM sensor, patient anatomy, and the like.

Accordingly, as discussed herein, in some embodiments, a pin/needle (e.g., a cannulated mounting needle, etc.) may be used to insert one or more EM sensors. Generally, the pin/needle would be a disposable component, while the sensors themselves may be reusable. However, it should be understood that this is only one potential system, and that various other systems may be used in which the pin/needle and/or EM sensors are independently disposable or reusable. In a further embodiment, the EM sensors may be affixed to the mounting needle/pin (e.g., using a luer-lock fitting or the like), which can allow for quick assembly and disassembly. In additional embodiments, the EM sensors may utilize an alternative sleeve and/or anchor system that allows for minimally invasive placement of the sensors.

In another embodiment, the above systems may allow for a multi-sensor navigation system that can detect and correct for field distortions that plague electromagnetic tracking systems. It should be understood that field distortions may result from movement of any ferromagnetic materials within the reference field. Thus, as one of ordinary skill in the art would know, a typical OR has a large number of devices (e.g., an operating table, LCD displays, lighting equipment, imaging systems, surgical instruments, etc.) that may cause interference. Furthermore, field distortions are notoriously difficult to detect. The use of multiple EM sensors enables the system to detect field distortions accurately, and/or to warn a user that the current position measurements may not be accurate. Because the sensors are rigidly fixed to the bony anatomy (e.g., via the pin/needle), relative measurement of sensor positions (X, Y, Z) may be used to detect field distortions. By way of non-limiting example, in some embodiments, after the EM sensors are fixed to the bone, the relative distance between the two sensors is known and should remain constant. Thus, any change in this distance could indicate the presence of a field distortion.

In some embodiments, specific objects in the surgical environment can be manually registered by a surgeon with the system preoperatively or intraoperatively. For example, by interacting with a user interface, a surgeon may identify the starting location for a tool or a bone structure. By tracking fiducial markers associated with that tool or bone structure, or by using other conventional image tracking modalities, a processor may track that tool or bone as it moves through the environment in a three-dimensional model. In other examples, 2D to 3D methods could be used as a pre-alignment or planning step that provides a guideline and plan or positioned raw-data that could be used to see the bone modelling portion of the robotic system.

In some embodiments, certain markers, such as fiducial markers that identify individuals, tools, or bones in the theater may include passive or active identifiers that can be picked up by a camera or camera array associated with the optical tracking system **115**. For example, an IR LED can flash a pattern that conveys a unique identifier to the source of that pattern, providing a dynamic identification mark. Similarly, one or two dimensional optical codes (barcode, QR code, etc.) can be affixed to objects in the theater to provide passive identification that can occur based on image analysis. If these codes are placed on an object, they also can be used to determine an orientation of an object by comparing the location of the identifier with the extents of an object in an image. For example, a QR code may be placed in a corner of a tool tray, allowing the orientation and identity of that tray to be tracked. Other tracking modalities are explained throughout. For example, in some embodiments, augmented reality headsets can be worn by surgeons and other staff to provide additional camera angles and tracking capabilities.

In addition to optical tracking, certain features of objects can be tracked by registering physical properties of the object and associating them with objects that can be tracked, such as fiducial markers fixed to a tool or bone. For example, a surgeon may perform a manual registration process whereby a tracked tool and a tracked bone can be manipulated relative to one another. By impinging the tip of the tool against the surface of the bone, a three-dimensional surface can be mapped for that bone that is associated with a position and orientation relative to the frame of reference of that fiducial mark. By optically tracking the position and orientation (pose) of the fiducial mark associated with that

bone, a model of that surface can be tracked with an environment through extrapolation.

The registration process that registers the CASS **100** to the relevant anatomy of the patient also can involve the use of anatomical landmarks, such as landmarks on a bone or cartilage. For example, the CASS **100** can include a 3D model of the relevant bone or joint and the surgeon can intraoperatively collect data regarding the location of bony landmarks on the patient's actual bone using a probe that is connected to the CASS. Bony landmarks can include, for example, the medial malleolus and lateral malleolus, the ends of the proximal femur and distal tibia, and the center of the hip joint. The CASS **100** can compare and register the location data of bony landmarks collected by the surgeon with the probe with the location data of the same landmarks in the 3D model. Alternatively, the CASS **100** can construct a 3D model of the bone or joint without pre-operative image data by using location data of bony landmarks and the bone surface that are collected by the surgeon using a CASS probe or other means. The registration process also can include determining various axes of a joint. For example, for a TKA the surgeon can use the CASS **100** to determine the anatomical and mechanical axes of the femur and tibia. The surgeon and the CASS **100** can identify the center of the hip joint by moving the patient's leg in a spiral direction (i.e., circumduction) so the CASS can determine where the center of the hip joint is located.

A tissue navigation system (not shown in FIG. **1**) provides the surgeon with intraoperative, real-time visualization for the patient's bone, cartilage, muscle, nervous, and/or vascular tissues surrounding the surgical area. Examples of systems that may be employed for tissue navigation include fluorescent imaging systems and ultrasound systems.

The display **125** provides graphical user interfaces (GUIs) that display images collected by the tissue navigation system as well other information relevant to the surgery. For example, in one embodiment, the display **125** overlays image information collected from various modalities (e.g., CT, MRI, X-ray, fluorescent, ultrasound, etc.) collected pre-operatively or intra-operatively to give the surgeon various views of the patient's anatomy as well as real-time conditions. The display **125** may include, for example, one or more computer monitors. As an alternative or supplement to the display **125**, one or more members of the surgical staff may wear an Augmented Reality (AR) Head Mounted Device (HMD). For example, in FIG. **1** the surgeon **111** is wearing an AR HMD **155** that may, for example, overlay pre-operative image data on the patient or provide surgical planning suggestions. Various example uses of the AR HMD **155** in surgical procedures are detailed in the sections that follow.

Surgical computer **150** provides control instructions to various components of the CASS **100**, collects data from those components, and provides general processing for various data needed during surgery. In some embodiments, the surgical computer **150** is a general purpose computer. In other embodiments, the Surgical Computer **150** may be a parallel computing platform that uses multiple central processing units (CPUs) or graphics processing units (GPU) to perform processing. In some embodiments, the surgical computer **150** is connected to a remote server over one or more computer networks (e.g., the Internet). The remote server can be used, for example, for storage of data or execution of computationally intensive processing tasks.

Various techniques generally known in the art can be used for connecting the surgical computer **150** to the other components of the CASS **100**. Moreover, the computers can connect to the surgical computer **150** using a mix of technologies. For example, the end effector **105**B may connect to the surgical computer **150** over a wired (i.e., serial) connection. The tracking system **115**, tissue navigation system, and display **125** can similarly be connected to the surgical computer **150** using wired connections. Alternatively, the tracking system **115**, tissue navigation system, and display **125** may connect to the surgical computer **150** using wireless technologies such as, without limitation, Wi-Fi, Bluetooth, Near Field Communication (NFC), or ZigBee.

Powered Impaction and Acetabular Reamer Devices

Part of the flexibility of the CASS design described above with respect to FIG. **1** is that additional or alternative devices can be added to the CASS **100** as necessary to support particular surgical procedures. For example, in the context of hip surgeries, the CASS **100** may include a powered impaction device. Impaction devices are designed to repeatedly apply an impaction force that the surgeon can use to perform activities such as implant alignment. For example, within a total hip arthroplasty (THA), a surgeon will often insert a prosthetic acetabular cup into the implant host's acetabulum using an impaction device. Although impaction devices can be manual in nature (e.g., operated by the surgeon striking an impactor with a mallet), powered impaction devices are generally easier and quicker to use in the surgical setting. Powered impaction devices may be powered, for example, using a battery attached to the device. Various attachment pieces may be connected to the powered impaction device to allow the impaction force to be directed in various ways as needed during surgery. Also, in the context of hip surgeries, the CASS **100** may include a powered, robotically controlled end effector to ream the acetabulum to accommodate an acetabular cup implant.

In a robotically-assisted THA, the patient's anatomy can be registered to the CASS **100** using CT or other image data, the identification of anatomical landmarks, tracker arrays attached to the patient's bones, and one or more cameras. Tracker arrays can be mounted on the iliac crest using clamps and/or bone pins and such trackers can be mounted externally through the skin or internally (either posterolaterally or anterolaterally) through the incision made to perform the THA. For a THA, the CASS **100** can utilize one or more femoral cortical screws inserted into the proximal femur as checkpoints to aid in the registration process. The CASS **100** also can utilize one or more checkpoint screws inserted into the pelvis as additional checkpoints to aid in the registration process. Femoral tracker arrays can be secured to or mounted in the femoral cortical screws. The CASS **100** can employ steps where the registration is verified using a probe that the surgeon precisely places on key areas of the proximal femur and pelvis identified for the surgeon on the display **125**. Trackers can be located on the robotic arm **105**A or end effector **105**B to register the arm and/or end effector to the CASS **100**. The verification step also can utilize proximal and distal femoral checkpoints. The CASS **100** can utilize color prompts or other prompts to inform the surgeon that the registration process for the relevant bones and the robotic arm **105**A or end effector **105**B has been verified to a certain degree of accuracy (e.g., within 1 mm).

For a THA, the CASS **100** can include a broach tracking option using femoral arrays to allow the surgeon to intraoperatively capture the broach position and orientation and calculate hip length and offset values for the patient. Based on information provided about the patient's hip joint and the planned implant position and orientation after broach track-

ing is completed, the surgeon can make modifications or adjustments to the surgical plan.

For a robotically-assisted THA, the CASS **100** can include one or more powered reamers connected or attached to a robotic arm **105**A or end effector **105**B that prepares the pelvic bone to receive an acetabular implant according to a surgical plan. The robotic arm **105**A and/or end effector **105**B can inform the surgeon and/or control the power of the reamer to ensure that the acetabulum is being resected (reamed) in accordance with the surgical plan. For example, if the surgeon attempts to resect bone outside of the boundary of the bone to be resected in accordance with the surgical plan, the CASS **100** can power off the reamer or instruct the surgeon to power off the reamer. 2D to 3D modeling methods can provide greater confidence with respect to bone volume predictions, such as for areas of the bone that are inaccessible to a probe. The CASS **100** can provide the surgeon with an option to turn off or disengage the robotic control of the reamer. The display **125** can depict the progress of the bone being resected (reamed) as compared to the surgical plan using different colors. The surgeon can view the display of the bone being resected (reamed) to guide the reamer to complete the reaming in accordance with the surgical plan. The CASS **100** can provide visual or audible prompts to the surgeon to warn the surgeon that resections are being made that are not in accordance with the surgical plan.

Following reaming, the CASS **100** can employ a manual or powered impactor that is attached or connected to the robotic arm **105**A or end effector **105**B to impact trial implants and final implants into the acetabulum. The robotic arm **105**A and/or end effector **105**B can be used to guide the impactor to impact the trial and final implants into the acetabulum in accordance with the surgical plan. The CASS **100** can cause the position and orientation of the trial and final implants vis-à-vis the bone to be displayed to inform the surgeon as to how the trial and final implant's orientation and position compare to the surgical plan, and the display **125** can show the implant's position and orientation as the surgeon manipulates the leg and hip. The CASS **100** can provide the surgeon with the option of re-planning and re-doing the reaming and implant impaction by preparing a new surgical plan if the surgeon is not satisfied with the original implant position and orientation.

Preoperatively, the CASS **100** can develop a proposed surgical plan based on a three dimensional model of the hip joint and other information specific to the patient, such as the mechanical and anatomical axes of the leg bones, the epicondylar axis, the femoral neck axis, the dimensions (e.g., length) of the femur and hip, the midline axis of the hip joint, the ASIS axis of the hip joint, and the location of anatomical landmarks such as the lesser trochanter landmarks, the distal landmark, and the center of rotation of the hip joint. The CASS-developed surgical plan can provide a recommended optimal implant size and implant position and orientation based on the three dimensional model of the hip joint and other information specific to the patient. The CASS-developed surgical plan can include proposed details on offset values, inclination and anteversion values, center of rotation, cup size, medialization values, superior-inferior fit values, femoral stem sizing and length.

For a THA, the CASS-developed surgical plan can be viewed preoperatively and intraoperatively, and the surgeon can modify CASS-developed surgical plan preoperatively or intraoperatively. The CASS-developed surgical plan can display the planned resection to the hip joint and superimpose the planned implants onto the hip joint based on the planned resections. The CASS **100** can provide the surgeon with options for different surgical workflows that will be displayed to the surgeon based on a surgeon's preference. For example, the surgeon can choose from different workflows based on the number and types of anatomical landmarks that are checked and captured and/or the location and number of tracker arrays used in the registration process.

According to some embodiments, a powered impaction device used with the CASS **100** may operate with a variety of different settings. In some embodiments, the surgeon adjusts settings through a manual switch or other physical mechanism on the powered impaction device. In other embodiments, a digital interface may be used that allows setting entry, for example, via a touchscreen on the powered impaction device. Such a digital interface may allow the available settings to vary based, for example, on the type of attachment piece connected to the power attachment device. In some embodiments, rather than adjusting the settings on the powered impaction device itself, the settings can be changed through communication with a robot or other computer system within the CASS **100**. Such connections may be established using, for example, a Bluetooth or Wi-Fi networking module on the powered impaction device. In another embodiment, the impaction device and end pieces may contain features that allow the impaction device to be aware of what end piece (cup impactor, broach handle, etc.) is attached with no action required by the surgeon, and adjust the settings accordingly. This may be achieved, for example, through a QR code, barcode, RFID tag, or other method.

Examples of the settings that may be used include cup impaction settings (e.g., single direction, specified frequency range, specified force and/or energy range); broach impaction settings (e.g., dual direction/oscillating at a specified frequency range, specified force and/or energy range); femoral head impaction settings (e.g., single direction/single blow at a specified force or energy); and stem impaction settings (e.g., single direction at specified frequency with a specified force or energy). Additionally, in some embodiments, the powered impaction device includes settings related to acetabular liner impaction (e.g., single direction/single blow at a specified force or energy). There may be a plurality of settings for each type of liner such as poly, ceramic, oxinium, or other materials. Furthermore, the powered impaction device may offer settings for different bone quality based on preoperative testing/imaging/knowledge and/or intraoperative assessment by surgeon. In some embodiments, the powered impactor device may have a dual function. For example, the powered impactor device not only could provide reciprocating motion to provide an impact force, but also could provide reciprocating motion for a broach or rasp.

In some embodiments, the powered impaction device includes feedback sensors that gather data during instrument use and send data to a computing device, such as a controller within the device or the Surgical Computer **150**. This computing device can then record the data for later analysis, such as via radio-opaque tattoos that provide pre-operative, intra-operative, and/or post-operative registration capabilities. Examples of the data that may be collected include, without limitation, sound waves, the predetermined resonance frequency of each instrument, reaction force or rebound energy from patient bone, location of the device with respect to imaging (e.g., fluoro, CT, ultrasound, MRI, etc.) registered bony anatomy, and/or external strain gauges on bones.

Once the data is collected, the computing device may execute one or more algorithms in real-time or near real-

time to aid the surgeon in performing the surgical procedure. For example, in some embodiments, the computing device uses the collected data to derive information such as the proper final broach size (femur); when the stem is fully seated (femur side); or when the cup is seated (depth and/or orientation) for a THA. Once the information is known, it may be displayed for the surgeon's review, or it may be used to activate haptics or other feedback mechanisms to guide the surgical procedure.

Additionally, the data derived from the aforementioned algorithms may be used to drive operation of the device. For example, during insertion of a prosthetic acetabular cup with a powered impaction device, the device may automatically extend an impaction head (e.g., an end effector) moving the implant into the proper location, or turn the power off to the device once the implant is fully seated. In one embodiment, the derived information may be used to automatically adjust settings for quality of bone where the powered impaction device should use less power to mitigate femoral/acetabular/pelvic fracture or damage to surrounding tissues.

Robotic Arm

In some embodiments, the CASS **100** includes a robotic arm **105**A that serves as an interface to stabilize and hold a variety of instruments used during the surgical procedure. For example, in the context of a hip surgery, these instruments may include, without limitation, retractors, a sagittal or reciprocating saw, the reamer handle, the cup impactor, the broach handle, and the stem inserter. The robotic arm **105**A may have multiple degrees of freedom (like a Spider device), and have the ability to be locked in place (e.g., by a press of a button, voice activation, a surgeon removing a hand from the robotic arm, or other method).

In some embodiments, movement of the robotic arm **105**A may be effectuated by use of a control panel built into the robotic arm system. For example, a display screen may include one or more input sources, such as physical buttons or a user interface having one or more icons, that direct movement of the robotic arm **105**A. The surgeon or other healthcare professional may engage with the one or more input sources to position the robotic arm **105**A when performing a surgical procedure.

A tool or an end effector **105**B attached or integrated into a robotic arm **105**A may include, without limitation, a burring device, a scalpel, a cutting device, a retractor, a joint tensioning device, any type of dimensional measuring device, or the like. In one particular example, the robotic arm **105**A can be positioned to obtain relatively accurate measurements of bone size or shape. In another examples, the robotic arm **105**A can have jaws or another device that opens to a width of a known implant size so the surgeon can make quick decisions about correct sizing or placement of the implant. In embodiments in which an end effector **105**B is used, the end effector may be positioned at the end of the robotic arm **105**A such that any motor control operations are performed within the robotic arm system. In embodiments in which a tool is used, the tool may be secured at a distal end of the robotic arm **105**A, but motor control operation may reside within the tool itself.

The robotic arm **105**A may be motorized internally to both stabilize the robotic arm, thereby preventing it from falling and hitting the patient, surgical table, surgical staff, etc., and to allow the surgeon to move the robotic arm without having to fully support its weight. While the surgeon is moving the robotic arm **105**A, the robotic arm may provide some resistance to prevent the robotic arm from moving too fast or having too many degrees of freedom active at once. The position and the lock status of the robotic arm **105**A may be tracked, for example, by a controller or the Surgical Computer **150**.

In some embodiments, the robotic arm **105**A can be moved by hand (e.g., by the surgeon) or with internal motors into its ideal position and orientation for the task being performed. In some embodiments, the robotic arm **105**A may be enabled to operate in a "free" mode that allows the surgeon to position the arm into a desired position without being restricted. While in the free mode, the position and orientation of the robotic arm **105**A may still be tracked as described above. In one embodiment, certain degrees of freedom can be selectively released upon input from user (e.g., surgeon) during specified portions of the surgical plan tracked by the Surgical Computer **150**. Designs in which a robotic arm **105**A is internally powered through hydraulics or motors or provides resistance to external manual motion through similar means can be described as powered robotic arms, while arms that are manually manipulated without power feedback, but which may be manually or automatically locked in place, may be described as passive robotic arms.

A robotic arm **105**A or end effector **105**B can include a trigger or other means to control the power of a saw or drill. Engagement of the trigger or other means by the surgeon can cause the robotic arm **105**A or end effector **105**B to transition from a motorized alignment mode to a mode where the saw or drill is engaged and powered on. Additionally, the CASS **100** can include a foot pedal (not shown), a voice-activated control system, or AR system that causes the system to perform certain functions when activated. In one example, the user views a knee, aligns it with a template and then informs the AR system that the current view represents an aligned bone. That reference view informs the initial robotic arm **105**A position that can then be further fine-tuned by the operator. More specifically, the system positions the robotic arm **105**A using the input to triangulate a rough starting pose. In the case of a passive arm, the magnetic clutch could lock down when any of the joints reach their desired position. The operator simply moves the arm until all of the joints lock in place in this example. The user is subsequently free to make fine adjustments (with or without an AR assist).

In another example, the surgeon can activate the foot pedal to instruct the CASS **100** to place the robotic arm **105**A or end effector **105**B in an automatic mode that brings the robotic arm or end effector into the proper position with respect to the patient's anatomy in order to perform the necessary resections. The CASS **100** also can place the robotic arm **105**A or end effector **105**B in a collaborative mode that allows the surgeon to manually manipulate and position the robotic arm or end effector into a particular location. The collaborative mode can be configured to allow the surgeon to move the robotic arm **105**A or end effector **105**B medially or laterally, while restricting movement in other directions. As discussed, the robotic arm **105**A or end effector **105**B can include a cutting device (saw, drill, and burr) or a cutting guide or jig **105**D that will guide a cutting device. In other embodiments, movement of the robotic arm **105**A or robotically controlled end effector **105**B can be controlled entirely by the CASS **100** without any, or with only minimal, assistance or input from a surgeon or other medical professional. In still other embodiments, the movement of the robotic arm **105**A or robotically controlled end effector **105**B can be controlled remotely by a surgeon or other medical professional using a control mechanism sepa-

rate from the robotic arm or robotically controlled end effector device, for example using a joystick or interactive monitor or display control device.

The examples below describe uses of the robotic device in the context of a hip surgery; however, it should be understood that the robotic arm may have other applications for surgical procedures involving knees, shoulders, etc. One example of use of a robotic arm in the context of forming an anterior cruciate ligament (ACL) graft tunnel is described in WIPO Publication No. WO 2020/047051, filed Aug. 28, 2019, entitled "Robotic Assisted Ligament Graft Placement and Tensioning," the entirety of which is incorporated herein by reference.

A robotic arm **105**A may be used for holding the retractor. For example in one embodiment, the robotic arm **105**A may be moved into the desired position by the surgeon. At that point, the robotic arm **105**A may lock into place. In some embodiments, the robotic arm **105**A is provided with data regarding the patient's position, such that if the patient moves, the robotic arm can adjust the retractor position accordingly. In some embodiments, multiple robotic arms may be used, thereby allowing multiple retractors to be held or for more than one activity to be performed simultaneously (e.g., retractor holding & reaming).

The robotic arm **105**A may also be used to help stabilize the surgeon's hand while making a femoral neck cut. In this application, control of the robotic arm **105**A may impose certain restrictions to prevent soft tissue damage from occurring. For example, in one embodiment, the Surgical Computer **150** tracks the position of the robotic arm **105**A as it operates. If the tracked location approaches an area where tissue damage is predicted, a command may be sent to the robotic arm **105**A causing it to stop. Alternatively, where the robotic arm **105**A is automatically controlled by the Surgical Computer **150**, the Surgical Computer may ensure that the robotic arm is not provided with any instructions that cause it to enter areas where soft tissue damage is likely to occur. The Surgical Computer **150** may impose certain restrictions on the surgeon to prevent the surgeon from reaming too far into the medial wall of the acetabulum or reaming at an incorrect angle or orientation.

In some embodiments, the robotic arm **105**A may be used to hold a cup impactor at a desired angle or orientation during cup impaction. When the final position has been achieved, the robotic arm **105**A may prevent any further seating to prevent damage to the pelvis.

The surgeon may use the robotic arm **105**A to position the broach handle at the desired position and allow the surgeon to impact the broach into the femoral canal at the desired orientation. In some embodiments, once the Surgical Computer **150** receives feedback that the broach is fully seated, the robotic arm **105**A may restrict the handle to prevent further advancement of the broach.

The robotic arm **105**A may also be used for resurfacing applications. For example, the robotic arm **105**A may stabilize the surgeon while using traditional instrumentation and provide certain restrictions or limitations to allow for proper placement of implant components (e.g., guide wire placement, chamfer cutter, sleeve cutter, plan cutter, etc.). Where only a burr is employed, the robotic arm **105**A may stabilize the surgeon's handpiece and may impose restrictions on the handpiece to prevent the surgeon from removing unintended bone in contravention of the surgical plan.

The robotic arm **105**A may be a passive arm. As an example, the robotic arm **105**A may be a CIRQ robot arm available from Brainlab AG. CIRQ is a registered trademark of Brainlab AG, Olof-Palme-Str. 9 81829, München, FED REP of GERMANY. In one particular embodiment, the robotic arm **105**A is an intelligent holding arm as disclosed in U.S. patent application Ser. No. 15/525,585 to Krinninger et al., U.S. patent application Ser. No. 15/561,042 to Nowatschin et al., U.S. patent application Ser. No. 15/561,048 to Nowatschin et al., and U.S. Pat. No. 10,342,636 to Nowatschin et al., the entire contents of each of which is herein incorporated by reference.

Surgical Procedure Data Generation and Collection

The various services that are provided by medical professionals to treat a clinical condition are collectively referred to as an "episode of care." For a particular surgical intervention the episode of care can include three phases: pre-operative, intra-operative, and post-operative. During each phase, data is collected or generated that can be used to analyze the episode of care in order to understand various features of the procedure and identify patterns that may be used, for example, in training models to make decisions with minimal human intervention. The data collected over the episode of care may be stored at the Surgical Computer **150** or the Surgical Data Server **180** as a complete dataset. Thus, for each episode of care, a dataset exists that comprises all of the data collectively pre-operatively about the patient, all of the data collected or stored by the CASS **100** intra-operatively, and any post-operative data provided by the patient or by a healthcare professional monitoring the patient.

As explained in further detail, the data collected during the episode of care may be used to enhance performance of the surgical procedure or to provide a holistic understanding of the surgical procedure and the patient outcomes. For example, in some embodiments, the data collected over the episode of care may be used to generate a surgical plan. In one embodiment, a high-level, pre-operative plan is refined intra-operatively as data is collected during surgery. In this way, the surgical plan can be viewed as dynamically changing in real-time or near real-time as new data is collected by the components of the CASS **100**. In other embodiments, pre-operative images or other input data may be used to develop a robust plan preoperatively that is simply executed during surgery. In this case, the data collected by the CASS **100** during surgery may be used to make recommendations that ensure that the surgeon stays within the pre-operative surgical plan. For example, if the surgeon is unsure how to achieve a certain prescribed cut or implant alignment, the Surgical Computer **150** can be queried for a recommendation. In still other embodiments, the pre-operative and intra-operative planning approaches can be combined such that a robust pre-operative plan can be dynamically modified, as necessary or desired, during the surgical procedure. In some embodiments, a biomechanics-based model of patient anatomy contributes simulation data to be considered by the CASS **100** in developing preoperative, intraoperative, and post-operative/rehabilitation procedures to optimize implant performance outcomes for the patient.

Aside from changing the surgical procedure itself, the data gathered during the episode of care may be used as an input to other procedures ancillary to the surgery. For example, in some embodiments, implants can be designed using episode of care data. Example data-driven techniques for designing, sizing, and fitting implants are described in U.S. patent application Ser. No. 13/814,531 filed Aug. 15, 2011 and entitled "Systems and Methods for Optimizing Parameters for Orthopaedic Procedures"; U.S. patent application Ser. No. 14/232,958 filed Jul. 20, 2012 and entitled

"Systems and Methods for Optimizing Fit of an Implant to Anatomy"; and U.S. patent application Ser. No. 12/234,444 filed Sep. 19, 2008 and entitled "Operatively Tuning Implants for Increased Performance," the entire contents of each of which are hereby incorporated by reference into this patent application.

Furthermore, the data can be used for educational, training, or research purposes. For example, using the network-based approach described below in FIG. **5**C, other doctors or students can remotely view surgeries in interfaces that allow them to selectively view data as it is collected from the various components of the CASS **100**. After the surgical procedure, similar interfaces may be used to "playback" a surgery for training or other educational purposes, or to identify the source of any issues or complications with the procedure.

Data acquired during the pre-operative phase generally includes all information collected or generated prior to the surgery. Thus, for example, information about the patient may be acquired from a patient intake form or electronic medical record (EMR). Examples of patient information that may be collected include, without limitation, patient demographics, diagnoses, medical histories, progress notes, vital signs, medical history information, allergies, and lab results. The pre-operative data may also include images related to the anatomical area of interest. These images may be captured, for example, using Magnetic Resonance Imaging (MRI), Computed Tomography (CT), X-ray, ultrasound, or any other modality known in the art. The pre-operative data may also comprise quality of life data captured from the patient. For example, in one embodiment, pre-surgery patients use a mobile application ("app") to answer questionnaires regarding their current quality of life. In some embodiments, preoperative data used by the CASS **100** includes demographic, anthropometric, cultural, or other specific traits about a patient that can coincide with activity levels and specific patient activities to customize the surgical plan to the patient. For example, certain cultures or demographics may be more likely to use a toilet that requires squatting on a daily basis.

FIGS. **5**A and **5**B provide examples of data that may be acquired during the intra-operative phase of an episode of care. These examples are based on the various components of the CASS **100** described above with reference to FIG. **1**; however, it should be understood that other types of data may be used based on the types of equipment used during surgery and their use.

FIG. **5**A shows examples of some of the control instructions that the Surgical Computer **150** provides to other components of the CASS **100**, according to some embodiments. Note that the example of FIG. **5**A assumes that the components of the Effector Platform **105** are each controlled directly by the Surgical Computer **150**. In embodiments where a component is manually controlled by the Surgeon **111**, instructions may be provided on the Display **125** or AR HMD **155** instructing the Surgeon **111** how to move the component.

The various components included in the Effector Platform **105** are controlled by the Surgical Computer **150** providing position commands that instruct the component where to move within a coordinate system. In some embodiments, the Surgical Computer **150** provides the Effector Platform **105** with instructions defining how to react when a component of the Effector Platform **105** deviates from a surgical plan. These commands are referenced in FIG. **5**A as "haptic" commands. For example, the End Effector **105**B may provide a force to resist movement outside of an area where resection is planned. Other commands that may be used by the Effector Platform **105** include vibration and audio cues.

In some embodiments, the end effectors **105**B of the robotic arm **105**A are operatively coupled with cutting guide **105**D. In response to an anatomical model of the surgical scene, the robotic arm **105**A can move the end effectors **105**B and the cutting guide **105**D into position to match the location of the femoral or tibial cut to be performed in accordance with the surgical plan. This can reduce the likelihood of error, allowing the vision system and a processor utilizing that vision system to implement the surgical plan to place a cutting guide **105**D at the precise location and orientation relative to the tibia or femur to align a cutting slot of the cutting guide with the cut to be performed according to the surgical plan. Then, a surgeon can use any suitable tool, such as an oscillating or rotating saw or drill to perform the cut (or drill a hole) with perfect placement and orientation because the tool is mechanically limited by the features of the cutting guide **105**D. In some embodiments, the cutting guide **105**D may include one or more pin holes that are used by a surgeon to drill and screw or pin the cutting guide into place before performing a resection of the patient tissue using the cutting guide. This can free the robotic arm **105**A or ensure that the cutting guide **105**D is fully affixed without moving relative to the bone to be resected. For example, this procedure can be used to make the first distal cut of the femur during a total knee arthroplasty. In some embodiments, where the arthroplasty is a hip arthroplasty, cutting guide **105**D can be fixed to the femoral head or the acetabulum for the respective hip arthroplasty resection. It should be understood that any arthroplasty that utilizes precise cuts can use the robotic arm **105**A and/or cutting guide **105**D in this manner.

The Resection Equipment **110** is provided with a variety of commands to perform bone or tissue operations. As with the Effector Platform **105**, position information may be provided to the Resection Equipment **110** to specify where it should be located when performing resection. Other commands provided to the Resection Equipment **110** may be dependent on the type of resection equipment. For example, for a mechanical or ultrasonic resection tool, the commands may specify the speed and frequency of the tool. For Radiofrequency Ablation (RFA) and other laser ablation tools, the commands may specify intensity and pulse duration.

Some components of the CASS **100** do not need to be directly controlled by the Surgical Computer **150**; rather, the Surgical Computer **150** only needs to activate the component, which then executes software locally specifying the manner in which to collect data and provide it to the Surgical Computer **150**. In the example of FIG. **5**A, there are two components that are operated in this manner the Tracking System **115** and the Tissue Navigation System **120**.

The Surgical Computer **150** provides the Display **125** with any visualization that is needed by the Surgeon **111** during surgery. For monitors, the Surgical Computer **150** may provide instructions for displaying images, GUIs, etc. using techniques known in the art. The display **125** can include various portions of the workflow of a surgical plan. During the registration process, for example, the display **125** can show a preoperatively constructed 3D bone model and depict the locations of the probe as the surgeon uses the probe to collect locations of anatomical landmarks on the patient. The display **125** can include information about the surgical target area. For example, in connection with a TKA, the display **125** can depict the mechanical and anatomical axes of the femur and tibia. The display **125** can depict varus

and valgus angles for the knee joint based on a surgical plan, and the CASS **100** can depict how such angles will be affected if contemplated revisions to the surgical plan are made. Accordingly, the display **125** is an interactive interface that can dynamically update and display how changes to the surgical plan would impact the procedure and the final position and orientation of implants installed on bone.

As the workflow progresses to preparation of bone cuts or resections, the display **125** can depict the planned or recommended bone cuts before any cuts are performed. The surgeon **111** can manipulate the image display to provide different anatomical perspectives of the target area and can have the option to alter or revise the planned bone cuts based on intraoperative evaluation of the patient. The display **125** can depict how the chosen implants would be installed on the bone if the planned bone cuts are performed. If the surgeon **111** choses to change the previously planned bone cuts, the display **125** can depict how the revised bone cuts would change the position and orientation of the implant when installed on the bone.

The display **125** can provide the surgeon **111** with a variety of data and information about the patient, the planned surgical intervention, and the implants. Various patient-specific information can be displayed, including real-time data concerning the patient's health such as heart rate, blood pressure, etc. The display **125** also can include information about the anatomy of the surgical target region including the location of landmarks, the current state of the anatomy (e.g., whether any resections have been made, the depth and angles of planned and executed bone cuts), and future states of the anatomy as the surgical plan progresses. The display **125** also can provide or depict additional information about the surgical target region. For a TKA, the display **125** can provide information about the gaps (e.g., gap balancing) between the femur and tibia and how such gaps will change if the planned surgical plan is carried out. For a TKA, the display **125** can provide additional relevant information about the knee joint such as data about the joint's tension (e.g., ligament laxity) and information concerning rotation and alignment of the joint. The display **125** can depict how the planned implants' locations and positions will affect the patient as the knee joint is flexed. The display **125** can depict how the use of different implants or the use of different sizes of the same implant will affect the surgical plan and preview how such implants will be positioned on the bone. The CASS **100** can provide such information for each of the planned bone resections in a TKA or THA. In a TKA, the CASS **100** can provide robotic control for one or more of the planned bone resections. For example, the CASS **100** can provide robotic control only for the initial distal femur cut, and the surgeon **111** can manually perform other resections (anterior, posterior and chamfer cuts) using conventional means, such as a 4-in-1 cutting guide or jig **105**D.

The display **125** can employ different colors to inform the surgeon of the status of the surgical plan. For example, un-resected bone can be displayed in a first color, resected bone can be displayed in a second color, and planned resections can be displayed in a third color. Implants can be superimposed onto the bone in the display **125**, and implant colors can change or correspond to different types or sizes of implants.

The information and options depicted on the display **125** can vary depending on the type of surgical procedure being performed. Further, the surgeon **111** can request or select a particular surgical workflow display that matches or is consistent with his or her surgical plan preferences. For example, for a surgeon **111** who typically performs the tibial cuts before the femoral cuts in a TKA, the display **125** and associated workflow can be adapted to take this preference into account. The surgeon **111** also can preselect that certain steps be included or deleted from the standard surgical workflow display. For example, if a surgeon **111** uses resection measurements to finalize an implant plan but does not analyze ligament gap balancing when finalizing the implant plan, the surgical workflow display can be organized into modules, and the surgeon can select which modules to display and the order in which the modules are provided based on the surgeon's preferences or the circumstances of a particular surgery. Modules directed to ligament and gap balancing, for example, can include pre- and post-resection ligament/gap balancing, and the surgeon **111** can select which modules to include in their default surgical plan workflow depending on whether they perform such ligament and gap balancing before or after (or both) bone resections are performed.

For more specialized display equipment, such as AR HMDs, the Surgical Computer **150** may provide images, text, etc. using the data format supported by the equipment. For example, if the Display **125** is a holography device such as the Microsoft HoloLens™ or Magic Leap One™, the Surgical Computer **150** may use the HoloLens Application Program Interface (API) to send commands specifying the position and content of holograms displayed in the field of view of the Surgeon **111**.

In some embodiments, one or more surgical planning models may be incorporated into the CASS **100** and used in the development of the surgical plans provided to the surgeon **111**. The term "surgical planning model" refers to software that simulates the biomechanics performance of anatomy under various scenarios to determine the optimal way to perform cutting and other surgical activities. For example, for knee replacement surgeries, the surgical planning model can measure parameters for functional activities, such as deep knee bends, gait, etc., and select cut locations on the knee to optimize implant placement. One example of a surgical planning model is the LIFEMOD™ simulation software from SMITH AND NEPHEW, INC. In some embodiments, the Surgical Computer **150** includes computing architecture that allows full execution of the surgical planning model during surgery (e.g., a GPU-based parallel processing environment). In other embodiments, the Surgical Computer **150** may be connected over a network to a remote computer that allows such execution, such as a Surgical Data Server **180** (see FIG. **5**C). As an alternative to full execution of the surgical planning model, in some embodiments, a set of transfer functions are derived that simplify the mathematical operations captured by the model into one or more predictor equations. Then, rather than execute the full simulation during surgery, the predictor equations are used. Further details on the use of transfer functions are described in WIPO Publication No. 2020/037308, filed Aug. 19, 2019, entitled "Patient Specific Surgical Method and System," the entirety of which is incorporated herein by reference.

FIG. **5**B shows examples of some of the types of data that can be provided to the Surgical Computer **150** from the various components of the CASS **100**. In some embodiments, the components may stream data to the Surgical Computer **150** in real-time or near real-time during surgery. In other embodiments, the components may queue data and send it to the Surgical Computer **150** at set intervals (e.g., every second). Data may be communicated using any format known in the art. Thus, in some embodiments, the compo-

nents all transmit data to the Surgical Computer **150** in a common format. In other embodiments, each component may use a different data format, and the Surgical Computer **150** is configured with one or more software applications that enable translation of the data.

In general, the Surgical Computer **150** may serve as the central point where CASS data is collected. The exact content of the data will vary depending on the source. For example, each component of the Effector Platform **105** provides a measured position to the Surgical Computer **150**. Thus, by comparing the measured position to a position originally specified by the Surgical Computer **150** (see FIG. **5**B), the Surgical Computer can identify deviations that take place during surgery.

The Resection Equipment **110** can send various types of data to the Surgical Computer **150** depending on the type of equipment used. Example data types that may be sent include the measured torque, audio signatures, and measured displacement values. Similarly, the Tracking Technology **115** can provide different types of data depending on the tracking methodology employed. Example tracking data types include position values for tracked items (e.g., anatomy, tools, etc.), ultrasound images, and surface or landmark collection points or axes. The Tissue Navigation System **120** provides the Surgical Computer **150** with anatomic locations, shapes, etc. as the system operates.

Although the Display **125** generally is used for outputting data for presentation to the user, it may also provide data to the Surgical Computer **150**. For example, for embodiments where a monitor is used as part of the Display **125**, the Surgeon **111** may interact with a GUI to provide inputs which are sent to the Surgical Computer **150** for further processing. For AR applications, the measured position and displacement of the HMD may be sent to the Surgical Computer **150** so that it can update the presented view as needed.

During the post-operative phase of the episode of care, various types of data can be collected to quantify the overall improvement or deterioration in the patient's condition as a result of the surgery. The data can take the form of, for example, self-reported information reported by patients via questionnaires. For example, in the context of a knee replacement surgery, functional status can be measured with an Oxford Knee Score questionnaire, and the post-operative quality of life can be measured with a EQ5D-5L questionnaire. Other examples in the context of a hip replacement surgery may include the Oxford Hip Score, Harris Hip Score, and WOMAC (Western Ontario and McMaster Universities Osteoarthritis index). Such questionnaires can be administered, for example, by a healthcare professional directly in a clinical setting or using a mobile app that allows the patient to respond to questions directly. In some embodiments, the patient may be outfitted with one or more wearable devices that collect data relevant to the surgery. For example, following a knee surgery, the patient may be outfitted with a knee brace that includes sensors that monitor knee positioning, flexibility, etc. This information can be collected and transferred to the patient's mobile device for review by the surgeon to evaluate the outcome of the surgery and address any issues. In some embodiments, one or more cameras can capture and record the motion of a patient's body segments during specified activities postoperatively. This motion capture can be compared to a biomechanics model to better understand the functionality of the patient's joints and better predict progress in recovery and identify any possible revisions that may be needed.

The post-operative stage of the episode of care can continue over the entire life of a patient. For example, in some embodiments, the Surgical Computer **150** or other components comprising the CASS **100** can continue to receive and collect data relevant to a surgical procedure after the procedure has been performed. This data may include, for example, images, answers to questions, "normal" patient data (e.g., blood type, blood pressure, conditions, medications, etc.), biometric data (e.g., gait, etc.), and objective and subjective data about specific issues (e.g., knee or hip joint pain). This data may be explicitly provided to the Surgical Computer **150** or other CASS component by the patient or the patient's physician(s). Alternatively or additionally, the Surgical Computer **150** or other CASS component can monitor the patient's EMR and retrieve relevant information as it becomes available. This longitudinal view of the patient's recovery allows the Surgical Computer **150** or other CASS component to provide a more objective analysis of the patient's outcome to measure and track success or lack of success for a given procedure. For example, a condition experienced by a patient long after the surgical procedure can be linked back to the surgery through a regression analysis of various data items collected during the episode of care. This analysis can be further enhanced by performing the analysis on groups of patients that had similar procedures and/or have similar anatomies.

In some embodiments, data is collected at a central location to provide for easier analysis and use. Data can be manually collected from various CASS components in some instances. For example, a portable storage device (e.g., USB stick) can be attached to the Surgical Computer **150** into order to retrieve data collected during surgery. The data can then be transferred, for example, via a desktop computer to the centralized storage. Alternatively, in some embodiments, the Surgical Computer **150** is connected directly to the centralized storage via a Network **175** as shown in FIG. **5**C.

FIG. **5**C illustrates a "cloud-based" implementation in which the Surgical Computer **150** is connected to a Surgical Data Server **180** via a Network **175**. This Network **175** may be, for example, a private intranet or the Internet. In addition to the data from the Surgical Computer **150**, other sources can transfer relevant data to the Surgical Data Server **180**. The example of FIG. **5**C shows 3 additional data sources: the Patient **160**, Healthcare Professional(s) **165**, and an EMR Database **170**. Thus, the Patient **160** can send pre-operative and post-operative data to the Surgical Data Server **180**, for example, using a mobile app. The Healthcare Professional(s) **165** includes the surgeon and his or her staff as well as any other professionals working with Patient **160** (e.g., a personal physician, a rehabilitation specialist, etc.). It should also be noted that the EMR Database **170** may be used for both pre-operative and post-operative data. For example, assuming that the Patient **160** has given adequate permissions, the Surgical Data Server **180** may collect the EMR of the Patient pre-surgery. Then, the Surgical Data Server **180** may continue to monitor the EMR for any updates post-surgery.

At the Surgical Data Server **180**, an Episode of Care Database **185** is used to store the various data collected over a patient's episode of care. The Episode of Care Database **185** may be implemented using any technique known in the art. For example, in some embodiments, a SQL-based database may be used where all of the various data items are structured in a manner that allows them to be readily incorporated in two SQL's collection of rows and columns. However, in other embodiments a No-SQL database may be employed to allow for unstructured data, while providing the

ability to rapidly process and respond to queries. As is understood in the art, the term "No-SQL" is used to define a class of data stores that are non-relational in their design. Various types of No-SQL databases may generally be grouped according to their underlying data model. These groupings may include databases that use column-based data models (e.g., Cassandra), document-based data models (e.g., MongoDB), key-value based data models (e.g., Redis), and/or graph-based data models (e.g., Allego). Any type of No-SQL database may be used to implement the various embodiments described herein and, in some embodiments, the different types of databases may support the Episode of Care Database **185**.

Data can be transferred between the various data sources and the Surgical Data Server **180** using any data format and transfer technique known in the art. It should be noted that the architecture shown in FIG. **5**C allows transmission from the data source to the Surgical Data Server **180**, as well as retrieval of data from the Surgical Data Server **180** by the data sources. For example, as explained in detail below, in some embodiments, the Surgical Computer **150** may use data from past surgeries, machine learning models, etc. to help guide the surgical procedure.

In some embodiments, the Surgical Computer **150** or the Surgical Data Server **180** may execute a de-identification process to ensure that data stored in the Episode of Care Database **185** meets Health Insurance Portability and Accountability Act (HIPAA) standards or other requirements mandated by law. HIPAA provides a list of certain identifiers that must be removed from data during de-identification. The aforementioned de-identification process can scan for these identifiers in data that is transferred to the Episode of Care Database **185** for storage. For example, in one embodiment, the Surgical Computer **150** executes the de-identification process just prior to initiating transfer of a particular data item or set of data items to the Surgical Data Server **180**. In some embodiments, a unique identifier is assigned to data from a particular episode of care to allow for re-identification of the data if necessary.

Although FIGS. **5**A-**5**C discuss data collection in the context of a single episode of care, it should be understood that the general concept can be extended to data collection from multiple episodes of care. For example, surgical data may be collected over an entire episode of care each time a surgery is performed with the CASS **100** and stored at the Surgical Computer **150** or at the Surgical Data Server **180**. As explained in further detail below, a robust database of episode of care data allows the generation of optimized values, measurements, distances, or other parameters and other recommendations related to the surgical procedure. In some embodiments, the various datasets are indexed in the database or other storage medium in a manner that allows for rapid retrieval of relevant information during the surgical procedure. For example, in one embodiment, a patient-centric set of indices may be used so that data pertaining to a particular patient or a set of patients similar to a particular patient can be readily extracted. This concept can be similarly applied to surgeons, implant characteristics, CASS component versions, etc.

Further details of the management of episode of care data is described in U.S. Patent Application No. 62/783,858 filed Dec. 21, 2018 and entitled "Methods and Systems for Providing an Episode of Care," the entirety of which is incorporated herein by reference.

Open Versus Closed Digital Ecosystems

In some embodiments, the CASS **100** is designed to operate as a self-contained or "closed" digital ecosystem. Each component of the CASS **100** is specifically designed to be used in the closed ecosystem, and data is generally not accessible to devices outside of the digital ecosystem. For example, in some embodiments, each component includes software or firmware that implements proprietary protocols for activities such as communication, storage, security, etc. The concept of a closed digital ecosystem may be desirable for a company that wants to control all components of the CASS **100** to ensure that certain compatibility, security, and reliability standards are met. For example, the CASS **100** can be designed such that a new component cannot be used with the CASS unless it is certified by the company.

In other embodiments, the CASS **100** is designed to operate as an "open" digital ecosystem. In these embodiments, components may be produced by a variety of different companies according to standards for activities, such as communication, storage, and security. Thus, by using these standards, any company can freely build an independent, compliant component of the CASS platform. Data may be transferred between components using publicly available application programming interfaces (APIs) and open, shareable data formats.

To illustrate one type of recommendation that may be performed with the CASS **100**, a technique for optimizing surgical parameters is disclosed below. The term "optimization" in this context means selection of parameters that are optimal based on certain specified criteria. In an extreme case, optimization can refer to selecting optimal parameter(s) based on data from the entire episode of care, including any pre-operative data, the state of CASS data at a given point in time, and post-operative goals. Moreover, optimization may be performed using historical data, such as data generated during past surgeries involving, for example, the same surgeon, past patients with physical characteristics similar to the current patient, or the like.

The optimized parameters may depend on the portion of the patient's anatomy to be operated on. For example, for knee surgeries, the surgical parameters may include positioning information for the femoral and tibial component including, without limitation, rotational alignment (e.g., varus/valgus rotation, external rotation, flexion rotation for the femoral component, posterior slope of the tibial component), resection depths (e.g., varus knee, valgus knee), and implant type, size and position. The positioning information may further include surgical parameters for the combined implant, such as overall limb alignment, combined tibiofemoral hyperextension, and combined tibiofemoral resection. Additional examples of parameters that could be optimized for a given TKA femoral implant by the CASS **100** include the following:

Parameter	Reference	Exemplary Recommendation (s)
Size	Posterior	The largest sized implant that does not overhang medial/lateral bone edges or overhang the anterior femur. A size that does not result in overstuffing the patella femoral joint
Implant Position-Medial Lateral	Medial/lateral cortical bone edges	Center the implant evenly between the medial/lateral cortical bone edges
Resection Depth-Varus Knee	Distal and posterior lateral	6 mm of bone

-continued

Parameter	Reference	Exemplary Recommendation (s)
Resection Depth-Valgus Knee	Distal and posterior medial	7 mm of bone
Rotation-Varus/Valgus	Mechanical Axis	1° varus
Rotation-External	Transepicondylar Axis	1° external from the transepicondylar axis
Rotation-Flexion	Mechanical Axis	3° flexed

Additional examples of parameters that could be optimized for a given TKA tibial implant by the CASS **100** include the following:

Parameter	Reference	Exemplary Recommendation (s)
Size	Posterior	The largest sized implant that does not overhang the medial, lateral, anterior, and posterior tibial edges
Implant Position	Medial/lateral and anterior/posterior cortical bone edges	Center the implant evenly between the medial/lateral and anterior/posterior cortical bone edges
Resection Depth-Varus Knee	Lateral/Medial	4 mm of bone
Resection Depth-Valgus Knee	Lateral/Medial	5 mm of bone
Rotation-Varus/Valgus	Mechanical Axis	1° valgus
Rotation-External	Tibial Anterior Posterior Axis	1° external from the tibial anterior paxis
Posterior Slope	Mechanical Axis	3° posterior slope

For hip surgeries, the surgical parameters may comprise femoral neck resection location and angle, cup inclination angle, cup anteversion angle, cup depth, femoral stem design, femoral stem size, fit of the femoral stem within the canal, femoral offset, leg length, and femoral version of the implant.

Shoulder parameters may include, without limitation, humeral resection depth/angle, humeral stem version, humeral offset, glenoid version and inclination, as well as reverse shoulder parameters such as humeral resection depth/angle, humeral stem version, Glenoid tilt/version, glenosphere orientation, glenosphere offset and offset direction.

Various conventional techniques exist for optimizing surgical parameters. However, these techniques are typically computationally intensive and, thus, parameters often need to be determined pre-operatively. As a result, the surgeon is limited in his or her ability to make modifications to optimized parameters based on issues that may arise during surgery. Moreover, conventional optimization techniques typically operate in a "black box" manner with little or no explanation regarding recommended parameter values. Thus, if the surgeon decides to deviate from a recommended parameter value, the surgeon typically does so without a full understanding of the effect of that deviation on the rest of the surgical workflow, or the impact of the deviation on the patient's post-surgery quality of life.

Operative Patient Care System

The general concepts of optimization may be extended to the entire episode of care using an Operative Patient Care System **620** that uses the surgical data, and other data from the Patient **605** and Healthcare Professionals **630** to optimize outcomes and patient satisfaction as depicted in FIG. **6**.

Conventionally, pre-operative diagnosis, pre-operative surgical planning, intra-operative execution of a prescribed plan, and post-operative management of total joint arthroplasty are based on individual experience, published literature, and training knowledge bases of surgeons (ultimately, tribal knowledge of individual surgeons and their 'network' of peers and journal publications) and their native ability to make accurate intra-operative tactile discernment of "balance" and accurate manual execution of planar resections using guides and visual cues. This existing knowledge base and execution is limited with respect to the outcomes optimization offered to patients needing care. For example, limits exist with respect to accurately diagnosing a patient to the proper, least-invasive prescribed care; aligning dynamic patient, healthcare economic, and surgeon preferences with patient-desired outcomes; executing a surgical plan resulting in proper bone alignment and balance, etc.; and receiving data from disconnected sources having different biases that are difficult to reconcile into a holistic patient framework. Accordingly, a data-driven tool that more accurately models anatomical response and guides the surgical plan can improve the existing approach.

The Operative Patient Care System **620** is designed to utilize patient specific data, surgeon data, healthcare facility data, and historical outcome data to develop an algorithm that suggests or recommends an optimal overall treatment plan for the patient's entire episode of care (preoperative, operative, and postoperative) based on a desired clinical outcome. For example, in one embodiment, the Operative Patient Care System **620** tracks adherence to the suggested or recommended plan, and adapts the plan based on patient/care provider performance. Once the surgical treatment plan is complete, collected data is logged by the Operative Patient Care System **620** in a historical database. This database is accessible for future patients and the development of future treatment plans. In addition to utilizing statistical and mathematical models, simulation tools (e.g., LIFEMOD®) can be used to simulate outcomes, alignment, kinematics, etc. based on a preliminary or proposed surgical plan, and reconfigure the preliminary or proposed plan to achieve desired or optimal results according to a patient's profile or a surgeon's preferences. The Operative Patient Care System **620** ensures that each patient is receiving personalized surgical and rehabilitative care, thereby improving the chance of successful clinical outcomes and lessening the economic burden on the facility associated with near-term revision.

In some embodiments, the Operative Patient Care System **620** employs a data collecting and management method to provide a detailed surgical case plan with distinct steps that are monitored and/or executed using a CASS **100**. The performance of the user(s) is calculated at the completion of each step and can be used to suggest changes to the subsequent steps of the case plan. Case plan generation relies on a series of input data that is stored on a local or cloud-storage database. Input data can be related to both the current patient undergoing treatment and historical data from patients who have received similar treatment(s).

A Patient **605** provides inputs such as Current Patient Data **610** and Historical Patient Data **615** to the Operative Patient Care System **620**. Various methods generally known in the art may be used to gather such inputs from the Patient **605**. For example, in some embodiments, the Patient **605** fills out a paper or digital survey that is parsed by the Operative Patient Care System **620** to extract patient data. In

other embodiments, the Operative Patient Care System **620** may extract patient data from existing information sources, such as electronic medical records (EMRs), health history files, and payer/provider historical files. In still other embodiments, the Operative Patient Care System **620** may provide an application program interface (API) that allows the external data source to push data to the Operative Patient Care System. For example, the Patient **605** may have a mobile phone, wearable device, or other mobile device that collects data (e.g., heart rate, pain or discomfort levels, exercise or activity levels, or patient-submitted responses to the patient's adherence with any number of pre-operative plan criteria or conditions) and provides that data to the Operative Patient Care System **620**. Similarly, the Patient **605** may have a digital application on his or her mobile or wearable device that enables data to be collected and transmitted to the Operative Patient Care System **620**.

Current Patient Data **610** can include, but is not limited to, activity level, preexisting conditions, comorbidities, prehab performance, health and fitness level, pre-operative expectation level (relating to hospital, surgery, and recovery), a Metropolitan Statistical Area (MSA) driven score, genetic background, prior injuries (sports, trauma, etc.), previous joint arthroplasty, previous trauma procedures, previous sports medicine procedures, treatment of the contralateral joint or limb, gait or biomechanical information (back and ankle issues), levels of pain or discomfort, care infrastructure information (payer coverage type, home health care infrastructure level, etc.), and an indication of the expected ideal outcome of the procedure.

Historical Patient Data **615** can include, but is not limited to, activity level, preexisting conditions, comorbidities, prehab performance, health and fitness level, pre-operative expectation level (relating to hospital, surgery, and recovery), a MSA driven score, genetic background, prior injuries (sports, trauma, etc.), previous joint arthroplasty, previous trauma procedures, previous sports medicine procedures, treatment of the contralateral joint or limb, gait or biomechanical information (back and ankle issues), levels or pain or discomfort, care infrastructure information (payer coverage type, home health care infrastructure level, etc.), expected ideal outcome of the procedure, actual outcome of the procedure (patient reported outcomes [PROs], survivorship of implants, pain levels, activity levels, etc.), sizes of implants used, position/orientation/alignment of implants used, soft-tissue balance achieved, etc.

Healthcare Professional(s) **630** conducting the procedure or treatment may provide various types of data **625** to the Operative Patient Care System **620**. This Healthcare Professional Data **625** may include, for example, a description of a known or preferred surgical technique (e.g., Cruciate Retaining (CR) vs Posterior Stabilized (PS), up- vs down-sizing, tourniquet vs tourniquet-less, femoral stem style, preferred approach for THA, etc.), the level of training of the Healthcare Professional(s) **630** (e.g., years in practice, fellowship trained, where they trained, whose techniques they emulate), previous success level including historical data (outcomes, patient satisfaction), and the expected ideal outcome with respect to range of motion, days of recovery, and survivorship of the device. The Healthcare Professional Data **625** can be captured, for example, with paper or digital surveys provided to the Healthcare Professional **630**, via inputs to a mobile application by the Healthcare Professional, or by extracting relevant data from EMRs. In addition, the CASS **100** may provide data such as profile data (e.g., a Patient Specific Knee Instrument Profile) or historical logs describing use of the CASS during surgery.

Information pertaining to the facility where the procedure or treatment will be conducted may be included in the input data. This data can include, without limitation, the following: Ambulatory Surgery Center (ASC) vs hospital, facility trauma level, Comprehensive Care for Joint Replacement Program (CJR) or bundle candidacy, a MSA driven score, community vs metro, academic vs non-academic, postoperative network access (Skilled Nursing Facility [SNF] only, Home Health, etc.), availability of medical professionals, implant availability, and availability of surgical equipment.

These facility inputs can be captured by, for example and without limitation, Surveys (Paper/Digital), Surgery Scheduling Tools (e.g., apps, Websites, Electronic Medical Records [EMRs], etc.), Databases of Hospital Information (on the Internet), etc. Input data relating to the associated healthcare economy including, but not limited to, the socioeconomic profile of the patient, the expected level of reimbursement the patient will receive, and if the treatment is patient specific may also be captured.

These healthcare economic inputs can be captured by, for example and without limitation, Surveys (Paper/Digital), Direct Payer Information, Databases of Socioeconomic status (on the Internet with zip code), etc. Finally, data derived from simulation of the procedure is captured. Simulation inputs include implant size, position, and orientation. Simulation can be conducted with custom or commercially available anatomical modeling software programs (e.g., LIFEMOD®, AnyBody, or OpenSIM). It is noted that the data inputs described above may not be available for every patient, and the treatment plan will be generated using the data that is available.

Prior to surgery, the Patient Data **610**, **615** and Healthcare Professional Data **625** may be captured and stored in a cloud-based or online database (e.g., the Surgical Data Server **180** shown in FIG. **5**C). Information relevant to the procedure is supplied to a computing system via wireless data transfer or manually with the use of portable media storage. The computing system is configured to generate a case plan for use with a CASS **100**. Case plan generation will be described hereinafter. It is noted that the system has access to historical data from previous patients undergoing treatment, including implant size, placement, and orientation as generated by a computer-assisted, patient-specific knee instrument (PSKI) selection system, or automatically by the CASS **100** itself. To achieve this, case log data is uploaded to the historical database by a surgical sales rep or case engineer using an online portal. In some embodiments, data transfer to the online database is wireless and automated.

Historical data sets from the online database are used as inputs to a machine learning model such as, for example, a recurrent neural network (RNN) or other form of artificial neural network. As is generally understood in the art, an artificial neural network functions similar to a biologic neural network and is comprised of a series of nodes and connections. The machine learning model is trained to predict one or more values based on the input data. For the sections that follow, it is assumed that the machine learning model is trained to generate predictor equations. These predictor equations may be optimized to determine the optimal size, position, and orientation of the implants to achieve the best outcome or satisfaction level.

Once the procedure is complete, all patient data and available outcome data, including the implant size, position and orientation determined by the CASS **100**, are collected and stored in the historical database. Any subsequent calculation of the target equation via the RNN will include the

data from the previous patient in this manner, allowing for continuous improvement of the system.

In addition to, or as an alternative to determining implant positioning, in some embodiments, the predictor equation and associated optimization can be used to generate the resection planes for use with a PSKI system. When used with a PSKI system, the predictor equation computation and optimization are completed prior to surgery. Patient anatomy is estimated using medical image data (x-ray, CT, MRI). Global optimization of the predictor equation can provide an ideal size and position of the implant components. Boolean intersection of the implant components and patient anatomy is defined as the resection volume. PSKI can be produced to remove the optimized resection envelope. In this embodiment, the surgeon cannot alter the surgical plan intraoperatively.

The surgeon may choose to alter the surgical case plan at any time prior to or during the procedure. If the surgeon elects to deviate from the surgical case plan, the altered size, position, and/or orientation of the component(s) is locked, and the global optimization is refreshed based on the new size, position, and/or orientation of the component(s) (using the techniques previously described) to find the new ideal position of the other component(s) and the corresponding resections needed to be performed to achieve the newly optimized size, position and/or orientation of the component(s). For example, if the surgeon determines that the size, position and/or orientation of the femoral implant in a TKA needs to be updated or modified intraoperatively, the femoral implant position is locked relative to the anatomy, and the new optimal position of the tibia will be calculated (via global optimization) considering the surgeon's changes to the femoral implant size, position and/or orientation. Furthermore, if the surgical system used to implement the case plan is robotically assisted (e.g., as with NAVIO® or the MAKO Rio), bone removal and bone morphology during the surgery can be monitored in real time. If the resections made during the procedure deviate from the surgical plan, the subsequent placement of additional components may be optimized by the processor taking into account the actual resections that have already been made.

FIG. **7**A illustrates how the Operative Patient Care System **620** may be adapted for performing case plan matching services. In this example, data is captured relating to the current patient **610** and is compared to all or portions of a historical database of patient data and associated outcomes **615**. For example, the surgeon may elect to compare the plan for the current patient against a subset of the historical database. Data in the historical database can be filtered to include, for example, only data sets with favorable outcomes, data sets corresponding to historical surgeries of patients with profiles that are the same or similar to the current patient profile, data sets corresponding to a particular surgeon, data sets corresponding to a particular element of the surgical plan (e.g., only surgeries where a particular ligament is retained), or any other criteria selected by the surgeon or medical professional. If, for example, the current patient data matches or is correlated with that of a previous patient who experienced a good outcome, the case plan from the previous patient can be accessed and adapted or adopted for use with the current patient. The predictor equation may be used in conjunction with an intra-operative algorithm that identifies or determines the actions associated with the case plan. Based on the relevant and/or preselected information from the historical database, the intra-operative algorithm determines a series of recommended actions for the surgeon to perform. Each execution of the algorithm produces the next action in the case plan. If the surgeon performs the action, the results are evaluated. The results of the surgeon's performing the action are used to refine and update inputs to the intra-operative algorithm for generating the next step in the case plan. Once the case plan has been fully executed all data associated with the case plan, including any deviations performed from the recommended actions by the surgeon, are stored in the database of historical data. In some embodiments, the system utilizes preoperative, intraoperative, or postoperative modules in a piecewise fashion, as opposed to the entire continuum of care. In other words, caregivers can prescribe any permutation or combination of treatment modules including the use of a single module. These concepts are illustrated in FIG. **7**B and can be applied to any type of surgery utilizing the CASS **100**.

Surgery Process Display

As noted above with respect to FIGS. **1** and **5**A-**5**C, the various components of the CASS **100** generate detailed data records during surgery. The CASS **100** can track and record various actions and activities of the surgeon during each step of the surgery and compare actual activity to the preoperative or intraoperative surgical plan. In some embodiments, a software tool may be employed to process this data into a format where the surgery can be effectively "played-back." For example, in one embodiment, one or more GUIs may be used that depict all of the information presented on the Display **125** during surgery. This can be supplemented with graphs and images that depict the data collected by different tools. For example, a GUI that provides a visual depiction of the knee during tissue resection may provide the measured torque and displacement of the resection equipment adjacent to the visual depiction to better provide an understanding of any deviations that occurred from the planned resection area. The ability to review a playback of the surgical plan or toggle between different phases of the actual surgery vs. the surgical plan could provide benefits to the surgeon and/or surgical staff, allowing such persons to identify any deficiencies or challenging phases of a surgery so that they can be modified in future surgeries. Similarly, in academic settings, the aforementioned GUIs can be used as a teaching tool for training future surgeons and/or surgical staff. Additionally, because the data set effectively records many elements of the surgeon's activity, it may also be used for other reasons (e.g., legal or compliance reasons) as evidence of correct or incorrect performance of a particular surgical procedure.

Over time, as more and more surgical data is collected, a rich library of data may be acquired that describes surgical procedures performed for various types of anatomy (knee, shoulder, hip, etc.) by different surgeons for different patients. Moreover, information such as implant type and dimension, patient demographics, etc. can further be used to enhance the overall dataset. Once the dataset has been established, it may be used to train a machine learning model (e.g., RNN) to make predictions of how surgery will proceed based on the current state of the CASS **100**.

Training of the machine learning model can be performed as follows. The overall state of the CASS **100** can be sampled over a plurality of time periods for the duration of the surgery. The machine learning model can then be trained to translate a current state at a first time period to a future state at a different time period. By analyzing the entire state of the CASS **100** rather than the individual data items, any causal effects of interactions between different components of the CASS **100** can be captured. In some embodiments, a

plurality of machine learning models may be used rather than a single model. In some embodiments, the machine learning model may be trained not only with the state of the CASS **100**, but also with patient data (e.g., captured from an EMR) and an identification of members of the surgical staff. This allows the model to make predictions with even greater specificity. Moreover, it allows surgeons to selectively make predictions based only on their own surgical experiences if desired.

In some embodiments, predictions or recommendations made by the aforementioned machine learning models can be directly integrated into the surgical workflow. For example, in some embodiments, the Surgical Computer **150** may execute the machine learning model in the background making predictions or recommendations for upcoming actions or surgical conditions. A plurality of states can thus be predicted or recommended for each period. For example, the Surgical Computer **150** may predict or recommend the state for the next 5 minutes in 30 second increments. Using this information, the surgeon can utilize a "process display" view of the surgery that allows visualization of the future state. For example, FIG. **7**C depicts a series of images that may be displayed to the surgeon depicting the implant placement interface. The surgeon can cycle through these images, for example, by entering a particular time into the display **125** of the CASS **100** or instructing the system to advance or rewind the display in a specific time increment using a tactile, oral, or other instruction. In one embodiment, the process display can be presented in the upper portion of the surgeon's field of view in the AR HMD. In some embodiments, the process display can be updated in real-time. For example, as the surgeon moves resection tools around the planned resection area, the process display can be updated so that the surgeon can see how his or her actions are affecting the other factors of the surgery.

In some embodiments, rather than simply using the current state of the CASS **100** as an input to the machine learning model, the inputs to the model may include a planned future state. For example, the surgeon may indicate that he or she is planning to make a particular bone resection of the knee joint. This indication may be entered manually into the Surgical Computer **150** or the surgeon may verbally provide the indication. The Surgical Computer **150** can then produce a film strip showing the predicted effect of the cut on the surgery. Such a film strip can depict over specific time increments how the surgery will be affected, including, for example, changes in the patient's anatomy, changes to implant position and orientation, and changes regarding surgical intervention and instrumentation, if the contemplated course of action were to be performed. A surgeon or medical professional can invoke or request this type of film strip at any point in the surgery to preview how a contemplated course of action would affect the surgical plan if the contemplated action were to be carried out.

It should be further noted that, with a sufficiently trained machine learning model and robotic CASS, various elements of the surgery can be automated such that the surgeon only needs to be minimally involved, for example, by only providing approval for various steps of the surgery. For example, robotic control using arms or other means can be gradually integrated into the surgical workflow over time with the surgeon slowly becoming less and less involved with manual interaction versus robot operation. The machine learning model in this case can learn what robotic commands are required to achieve certain states of the CASS-implemented plan. Eventually, the machine learning model may be used to produce a film strip or similar view or display that predicts and can preview the entire surgery from an initial state. For example, an initial state may be defined that includes the patient information, the surgical plan, implant characteristics, and surgeon preferences. Based on this information, the surgeon could preview an entire surgery to confirm that the CASS-recommended plan meets the surgeon's expectations and/or requirements. Moreover, because the output of the machine learning model is the state of the CASS **100** itself, commands can be derived to control the components of the CASS to achieve each predicted state. In the extreme case, the entire surgery could thus be automated based on just the initial state information.

Using the Point Probe to Acquire High-Resolution of Key Areas During Hip Surgeries

Use of the point probe is described in U.S. patent application Ser. No. 14/955,742 entitled "Systems and Methods for Planning and Performing Image Free Implant Revision Surgery," the entirety of which is incorporated herein by reference. Briefly, an optically tracked point probe may be used to map the actual surface of the target bone that needs a new implant. Mapping is performed after removal of the defective or worn-out implant, as well as after removal of any diseased or otherwise unwanted bone. A plurality of points is collected on the bone surfaces by brushing or scraping the entirety of the remaining bone with the tip of the point probe. This is referred to as tracing or "painting" the bone. The collected points are used to create a three-dimensional model or surface map of the bone surfaces in the computerized planning system. The created 3D model of the remaining bone is then used as the basis for planning the procedure and necessary implant sizes. An alternative technique that uses X-rays to determine a 3D model is described in U.S. patent application Ser. No. 16/387,151, filed Apr. 17, 2019 and entitled "Three-Dimensional Selective Bone Matching" and U.S. patent application Ser. No. 16/789,930, filed Feb. 13, 2020 and entitled "Three-Dimensional Selective Bone Matching," the entirety of each of which is incorporated herein by reference.

For hip applications, the point probe painting can be used to acquire high resolution data in key areas such as the acetabular rim and acetabular fossa. This can allow a surgeon to obtain a detailed view before beginning to ream. For example, in one embodiment, the point probe may be used to identify the floor (fossa) of the acetabulum. As is well understood in the art, in hip surgeries, it is important to ensure that the floor of the acetabulum is not compromised during reaming so as to avoid destruction of the medial wall. If the medial wall were inadvertently destroyed, the surgery would require the additional step of bone grafting. With this in mind, the information from the point probe can be used to provide operating guidelines to the acetabular reamer during surgical procedures. For example, the acetabular reamer may be configured to provide haptic feedback to the surgeon when he or she reaches the floor or otherwise deviates from the surgical plan. Alternatively, the CASS **100** may automatically stop the reamer when the floor is reached or when the reamer is within a threshold distance.

As an additional safeguard, the thickness of the area between the acetabulum and the medial wall could be estimated. For example, once the acetabular rim and acetabular fossa has been painted and registered to the pre-operative 3D model, the thickness can readily be estimated by comparing the location of the surface of the acetabulum to the location of the medial wall. Using this knowledge, the CASS **100** may provide alerts or other

responses in the event that any surgical activity is predicted to protrude through the acetabular wall while reaming.

The point probe may also be used to collect high resolution data of common reference points used in orienting the 3D model to the patient. For example, for pelvic plane landmarks like the ASIS and the pubic symphysis, the surgeon may use the point probe to paint the bone to represent a true pelvic plane. Given a more complete view of these landmarks, the registration software has more information to orient the 3D model.

The point probe may also be used to collect high-resolution data describing the proximal femoral reference point that could be used to increase the accuracy of implant placement. For example, the relationship between the tip of the Greater Trochanter (GT) and the center of the femoral head is commonly used as reference point to align the femoral component during hip arthroplasty. The alignment is highly dependent on proper location of the GT; thus, in some embodiments, the point probe is used to paint the GT to provide a high-resolution view of the area. Similarly, in some embodiments, it may be useful to have a high-resolution view of the Lesser Trochanter (LT). For example, during hip arthroplasty, the Dorr Classification helps to select a stem that will maximize the ability of achieving a press-fit during surgery to prevent micromotion of femoral components post-surgery and ensure optimal bony ingrowth. As is generated understood in the art, the Don Classification measures the ratio between the canal width at the LT and the canal width 10 cm below the LT. The accuracy of the classification is highly dependent on the correct location of the relevant anatomy. Thus, it may be advantageous to paint the LT to provide a high-resolution view of the area.

In some embodiments, the point probe is used to paint the femoral neck to provide high-resolution data that allows the surgeon to better understand where to make the neck cut. The navigation system can then guide the surgeon as they perform the neck cut. For example, as understood in the art, the femoral neck angle is measured by placing one line down the center of the femoral shaft and a second line down the center of the femoral neck. Thus, a high-resolution view of the femoral neck (and possibly the femoral shaft as well) would provide a more accurate calculation of the femoral neck angle.

High-resolution femoral head neck data also could be used for a navigated resurfacing procedure where the software/hardware aids the surgeon in preparing the proximal femur and placing the femoral component. As is generally understood in the art, during hip resurfacing, the femoral head and neck are not removed; rather, the head is trimmed and capped with a smooth metal covering. In this case, it would be advantageous for the surgeon to paint the femoral head and cap so that an accurate assessment of their respective geometries can be understood and used to guide trimming and placement of the femoral component.

Registration of Pre-Operative Data to Patient Anatomy Using the Point Probe

As noted above, in some embodiments, a 3D model is developed during the pre-operative stage based on 2D or 3D images of the anatomical area of interest. In such embodiments, registration between the 3D model and the surgical site is performed prior to the surgical procedure. The registered 3D model may be used to track and measure the patient's anatomy and surgical tools intraoperatively.

During the surgical procedure, landmarks are acquired to facilitate registration of this pre-operative 3D model to the patient's anatomy. For knee procedures, these points could comprise the femoral head center, distal femoral axis point, medial and lateral epicondyles, medial and lateral malleolus, proximal tibial mechanical axis point, and tibial A/P direction. For hip procedures these points could comprise the anterior superior iliac spine (ASIS), the pubic symphysis, points along the acetabular rim and within the hemisphere, the greater trochanter (GT), and the lesser trochanter (LT).

In a revision surgery, the surgeon may paint certain areas that contain anatomical defects to allow for better visualization and navigation of implant insertion. These defects can be identified based on analysis of the pre-operative images. For example, in one embodiment, each pre-operative image is compared to a library of images showing "healthy" anatomy (i.e., without defects). Any significant deviations between the patient's images and the healthy images can be flagged as a potential defect. Then, during surgery, the surgeon can be warned of the possible defect via a visual alert on the display **125** of the CASS **100**. The surgeon can then paint the area to provide further detail regarding the potential defect to the Surgical Computer **150**.

In some embodiments, the surgeon may use a non-contact method for registration of bony anatomy intra-incision. For example, in one embodiment, laser scanning is employed for registration. A laser stripe is projected over the anatomical area of interest and the height variations of the area are detected as changes in the line. Other non-contact optical methods, such as white light interferometry or ultrasound, may alternatively be used for surface height measurement or to register the anatomy. For example, ultrasound technology may be beneficial where there is soft tissue between the registration point and the bone being registered (e.g., ASIS, pubic symphysis in hip surgeries), thereby providing for a more accurate definition of anatomic planes.

As discussed herein, an embodiment may allow for the creation of one or more 3D models from 2D image data. 2D image data can be acquired with less cost than volumetric image data such as MRI or CT images. It should be understood that although the term "3D image data" is primarily used herein, the models may include one or more of CAD, IGES, STL, VRML, DXF, OBJ, or similar file/application types. In some embodiments, as discussed herein, it may be possible, during the subdivision of an anatomical model, to create an extremely large library of bone shapes (i.e., more than are generally available with a database of standard non-permutable bone shapes standard statistical shape model (SSM) technique). Accordingly, as discussed herein, some embodiments may utilize a semi-automated system. In some embodiments, the semi-automated system may receive additional input from a user (e.g., a medical imaging expert who provides quality control), thereby leveraging the medical expertise of the user to simplify the computational requirements of the system. In some embodiments, the semi-automated system may not receive any additional input from a user.

Referring back to FIG. **1**, the CASS **100** uses computers, robotics, and imaging technology to aid surgeons in performing surgical procedures. The CASS **100** can aid surgeons in locating patient anatomical structures, guiding surgical instruments, and implanting medical devices with a high degree of accuracy. Surgical navigation systems such as the CASS **100** often employ various forms of computing technology to perform a wide variety of standard and minimally invasive surgical procedures and techniques. Moreover, these systems allow surgeons to more accurately plan, track, and navigate the placement of instruments and

implants relative to the body of a patient, as well as conduct pre-operative and intra-operative body imaging.

The CASS **100** includes an optical tracking system **115** in some examples, which uses one or more sensors to collect real-time position data that locates the anatomy of the patient **120** and surgical instruments such as a resection tool **105**B in the surgical environment. In contrast to conventional NIR-based tracking systems that use a monochrome sensor, the optical tracking system **115** described herein utilizes red-green-blue (RGB) sensor(s), although grayscale image sensors can also be used in other examples. Furthermore, the optical tracking system **115** removes the NIR pass-band filter used in conventional systems to capture color information. As is generally understood, the RGB sensors acquire visible data using an additive color model where red, green, and blue light are combined in various ways to reproduce a broad array of colors. Conversely, NIR is beyond human visual perception and covers wavelengths of the electromagnetic spectrum from approximately 750 to 2500 nm.

In some embodiments, the optical tracking system **115** acquires color images and tracking images in an interleaved manner. For example, an acquisition frame may be dedicated to capturing a conventional RGB image followed by an NIR image that is used for tracking. In this configuration, the color image acquisition process may be optimized using techniques generally known in the art, such as longer integration time, computation of the color image with demosaicing algorithms, color/gamma correction, white balance, automatic exposure, or the like. Where NIR is used for tracking, the tracking image acquisition process may be optimized to capture NIR images of the fiducials with as low noise as possible. For example, the optical tracking system **115** may use a short integration time similar to classical systems to maximize signal/noise ratio with respect to NIR light emission.

The color images acquired by the RGB sensor of the optical tracking system **115** provide a visual perception of the surgical area, while the tracking images can be used for tracking the 3D positions of fiducial markers in the surgical area. In this context, the term "fiducial marker" (or simply, "fiducial") refers generally to any object placed in the field of view of the optical tracking system **115** for use as a point of reference. In general, the optical tracking system **115** can track fiducials using any technique known in the art including, without limitation, triangulation-based techniques and pose estimation methods. Additionally, the 3D position of the fiducials may be used to derive the 6D pose (orientation and position) of each respective marker using techniques generally known in the art. As used herein, color images refers to Bayer raw images and grayscale images in addition to color images.

Fiducial markers may be used to identify individuals, tools, or bones in the surgical operating theater and may include passive or active identifiers that can be picked up by a camera or camera array associated with the optical tracking system **115**. For example, an infrared (IR) light-emitting diode (LED) can flash a pattern that conveys a unique identifier to the source of that pattern, providing a dynamic identification mark. Similarly, one or two dimensional optical codes (e.g., barcode, quick response (QR) code, etc.) can be affixed to objects in the theater to provide passive identification that can occur based on image analysis. If these codes are placed on an object, they can also be used to determine an orientation of an object by comparing the location of the identifier with the extents of an object in an image. For example, a QR code may be placed in a corner of a tool tray, allowing the orientation and identity of that tray to be tracked. Other tracking modalities may also be employed. For example, in some embodiments, the augmented reality (AR) head-mounted display (HMD) **155** worn by the Surgeon **111** or other staff, can be used to provide additional camera angles and tracking capabilities. Examples of devices that can be used to implement the AR HMD **155** include, without limitation, Microsoft's HoloLens™, Lenovo's ThinkReality™ headset, and the Magic Leap One™.

As the total update rate of the hybrid optical tracking system **115** described herein is fast, it is possible to use the tracking information and extrapolate/interpolate it with the color image. Another advantage of the optical tracking system **115** is that both the tracking information and the color image are in the same, or substantially similar, referential space, thereby allowing for the combination of a 2D image with 3D information without having to change the referential.

The surgical computer **150** may use the detected fiducial locations to register surgical data to the color images. For example, the CASS **100** may guide the surgeon **111** based on pre-operative/intra-operative data using either the monitor **125** or the HMD **155**. Pre-operative information such as trajectories, cutting planes, or scanner images/3D anatomical reconstructions may be registered on the patient's anatomy directly on the color images to create an AR images of the surgical area.

In other embodiments, the color image acquired with the optical tracking system **115** is used to improve the surgical process flow or gather additional data from the surgical area using computer vision processing techniques. For example, in some embodiments, the surgical computer **150** uses the color image to detect and track tags using computer tracking libraries such as the ARToolKit. Such functionality may be used, for example, to read barcodes on surgical items, implants during the operation and, as such, have a better control on the surgical process flow. For example, in other embodiments, the surgical computer **150** uses the color image to segment or detect specific visible elements like patient anatomy.

In some embodiments, the images acquired by the optical tracking system **115** are used to confirm that the surgeon is correctly performing a surgical procedure. For example, pedicle screws are used in spinal fusion surgeries to add extra support and strength to the fused spine while it heals. The screws have different colors depending on their diameter. Color segmentation algorithms generally known in in the art can be applied to the color images from the optical tracking system **115** to determine which screws are being inserted by the surgeon **111** and where in the patient's anatomy the insertion is taking place. By comparing this information to a surgical plan or other information describing the correct insertion procedure, mistakes can be readily identified, and the surgical staff can be alerted (e.g., via the monitor **125** or the HMD **155**) so that a correction can be applied.

In other embodiments, the color images may be used to perform depth map computations to sense more information within the volume seen by the optical tracking system **115**. As is generally understood in the art, the task of converting multiple 2D images into a 3D model involves the generation of multiple depth maps that comprise information relating to the distance of the surfaces of scene objects from a viewpoint. Once the depth maps are generated, they are combined to create a final mesh. In this context, the images acquired by the optical tracking system **115** could add 3D

points during the registration process. Adding the 3D sense points may shorten the process and/or make it more robust and accurate.

In other embodiments, the color images acquired by the optical tracking system **115** are used to provide patients with a way to visualize the results of future surgical operations on the patient's physical appearance. In this configuration, after the registration process and pre-operative planning is performed, the result of the operation can be displayed in real-time on a patient's images. For example, in the context of dental surgeries, patients may be provided with an interactive "before and after" image of their mouth, showing the current view and a future view following the proposed surgery. This allows patients to approve of the surgery based on its predicted outcome or request changes that may be viewed immediately.

In some embodiments, the image sensor is an "oversampled binary image sensor," often referred to as a High Dynamic Range (HDR) sensor. As is generally understood in the art, an oversampled binary image sensor is an image sensor with non-linear response capabilities. With this configuration, the acquisition could no longer be interleaved as a first photon counting may be performed when the NIR light source is on (for tracking) and later photon counting could take place to get the classic color image. As such, the acquisition would be simultaneous rather than interleaved.

It should be noted that the configuration of the optical tracking system **115** shown in FIG. **1** is exemplary and the placement of the device acquiring tracking data can vary in other embodiments. For example, in one embodiment, the optical tracking system **115** is mounted overhead on the ceiling of the surgical operating theatre. In other embodiments, the functionality of the optical tracking system **115** is integrated into the HMD **155**. For example, in some embodiments, the HMD **155** is part of an AR headset (e.g., Microsoft Hololens™).

Aside from processing data from the optical tracking system **115**, the surgical computer **150** provides control instructions to various components of the CASS **100**, collects data from those components, and provides general processing for various data needed during surgery. In some embodiments, the surgical computer **150** may be a parallel computing platform that uses multiple central processing units (CPUs) or graphics processing units (GPU) to perform processing. In some embodiments, the surgical computer **150** is connected to a remote server over one or more computer networks (e.g., the Internet). The remote server can be used, for example, for storage of data or execution of computationally intensive processing tasks.

Various techniques generally known in the art can be used for connecting the surgical computer **150** to the other components of the CASS **100**. Moreover, the components can connect to the surgical computer **150** using a variety of technologies. For example, the optical tracking system **115** and the monitor **125** may connect to the surgical computer **150** over a wired (i.e., serial) connection. Alternatively, the optical tracking system **115** and monitor **125** may connect to the Surgical computer **150** using wireless technologies such as, without limitation, Wi-Fi, Bluetooth, Near Field Communication (NFC), or ZigBee.

The following sections provide the theoretical basis for utilizing an RGB sensor in place of an NIR monochrome image sensor for tracking purposes. As would be generally understood by one skilled in the art, RGB sensors utilize Bayer filters. FIG. **8** shows a Bayer arrangement of color filters on the pixel array of an image sensor. Note that, for the purposes of this disclosure, color has been replaced by grayscale as indicated by the key in the top left hand corner of FIG. **8**. The Bayer filter mosaic comprises a color filter array (CFA) for arranging RGB color filters on a square grid of photosensors. Its particular arrangement of color filters is included in most single-chip digital image sensors used in digital cameras, camcorders, and scanners to create a color image. The filter pattern is 50% green, 25% red and 25% blue, hence the pattern also sometimes referred to as BGGR, RGBG, GRGB, or RGGB. There are also some mosaics that 1×red, 1×green, 1×blue, 1×NIR which could be used in some embodiments to obtain better NIR images in the tracking.

The raw output of Bayer-filter cameras is commonly referred to as a Bayer pattern image. Because each pixel is filtered to record only one of three colors, the data from each pixel cannot fully specify each of the red, green, and blue values on its own. To obtain a full-color image, various demosaicing algorithms can be used to interpolate a set of complete red, green, and blue values for each pixel. These algorithms make use of the surrounding pixels of the corresponding colors to estimate the values for a particular pixel.

An important property of such individual filters (i.e., red, green, blue) is their similar behavior in the NIR bandwidth. FIG. **9** presents a plot of QE versus wavelength broken down into each color channel. Note that, although the curves present nice peaks in their respective red, green, blue spectrum, they all present the same QE between 820 nm and 1000 nm. Therefore, a NIR energy source will be seen similarly by a red, green, or blue pixel. This demonstrates that the optical tracking system **115** described herein, utilizing a RGB sensor and no NIR filter, will behave similar to the conventional NIR system, given that fiducials emit or reflect a strong NIR signal.

One difference of the optical tracking system **115** as compared with a conventional system is the QE of the RGB version, which is 10-15% lower than a conventional NIR-based system (because the conventional system is NIR-enhanced). This lower sensitivity can be compensated for by having a higher light energy emission. An additional difference is that the optical tracking system **115** may be more sensitive to polluting light in the image because the RGB sensor does not filter the visible spectrum. However, this difference can be accounted for within the system by using a shorter integration time and higher light emission.

Because RGB image sensors are sensitive to the IR spectrum, the sensor(s) can be combined with an NIR projector (e.g. pseudo-random point projector) in some examples of this technology, as described and illustrated in detail below. Using an NIR projector enables to capture images with low integration time that are used for tracking purposes. In particular, the color images can be reconstructed with debayerisation algorithms or the NIR projector can be used to construct a depth or dense map.

FIG. **10** illustrates an exemplar optical tracking system **115** that is a stereo system having first and second optical modules **1011**A and **1011**B and a structured light projector **1012**. In some embodiments, the optical tracking system **115** may form part of a lighting system. The optical modules **1011**A and **1011**B each have a camera, lenses, and optional filters (e.g., NIR filters to make the system more robust to environmental lighting pollution. Optical modules **1011**A and **1011**B may optionally be surrounded by light-sources (e.g. IR-LEDs) that are used when fiducials are passive fiducial markers made of NIR reflective material. Using light in the NIR range makes the light invisible to humans' eyes and, as such, avoids disturbing the users.

The optical tracking system **115** may be composed of any number of cameras. For example, a monocular camera requires markers composed of four or more fiducials. Alternatively, textures and/or tags composed of multiple salient points may be used instead of four or more fiducials. In some embodiments, a stereo camera may be used as it provides more accurate 3D position in comparison to the monocular approach. Both cameras are fixed on a baseline in some examples such that the exact pose of one camera with respect to the other is factory calibrated.

In some embodiments, a cluster of three or more cameras may be used in the optical tracking system **115**. In such a configuration, the cameras are first fixed around a tracking zone, which is an area visible by multiple cameras. The respective poses are found via a calibration process performed prior to operating the system, which includes moving a specific marker (also referred to herein as an artifact) within the tracking zone. In this configuration, pose estimation is possible when a marker is simultaneously seen by two or more cameras.

Several technologies may be used for the structured light module **1012**. For example, light may be projected in known patterns, such as projecting a narrow band of light onto a 3D shaped surface to produce a line of illumination that appears distorted from other perspectives than that of the projector and can be used for geometric reconstruction of the surface shape. Optionally, the structured light module **1012** can be configured to project several sequential patterns (e.g., via time multiplexing) to facilitate a dense 3D surface reconstruction.

A faster and more versatile method is the projection of patterns having many stripes at once, examples of which are disclosed in FIGS. **11**A-**11**B, or of arbitrary fringes, as this allows for the acquisition of a plurality of samples simultaneously. Color techniques also may be used. Within this configuration, the pose and optical parameters of the projector with respect of the camera(s) must be known to provide accurate 3D surface reconstructions. The structured light module **1012** can be factory-calibrated so that tracking and acquired 3D surfaces are expressed in the same referential.

In another embodiment, light may be projected by the structured light module **1012** in random or pseudo-random patterns, such as by projecting random or pseudo-random points, an example of which is illustrated in FIG. **12**. These points are seen by the camera(s) and stereo reconstruction techniques can be applied to retrieve the 3D surface. The advantages of having a structured light module **1012** included within or integral with the optical tracking system **115** include that the cameras of the optical modules **1011**A and **1011**B can both be used to track fiducials and reconstruct 3D surfaces such that both data captures are implicitly represented within the same referential and the optical tracking system **115** can perform both tracking and surface acquisition at the same time, sequentially or interleaved.

In some embodiments, the optical tracking system **115** is part of the CASS **100** setup, and the structured light module **1012** is used to capture a 3D surface of the anatomy of the patient during the registration process. Alternatively, the captured surface can be completed with the acquisition of some points using a tracked probe. The area of interest also may be delimited with the probe or through image processing on images acquired by the camera(s) of the optical module **1011**A and **1011**B.

In some examples, the structured light module **1012** is used to reconstruct the 3D anatomy of the patient. Combining tracking (e.g., a marker affixed to the anatomy or fiducials stuck on skin) allows to capture multiple scans in a known referential. These examples enable densifying the 3D reconstructed surface with multiple scans taken at the same place, stitching the different 3D scans to get a more complete reconstruction of the anatomy, and/or retrieving a 3D sequence of a moving anatomy. A dynamic 3D reconstruction of patient anatomy may be used in multiple applications ranging from defining a prosthesis size that matches the anatomy, registration, better defining a metrological information in situ (e.g., size of a tumor, dimension of an orthosis can be directly defined on the reconstructed 3D surface), providing a 3D mesh used for rapid prototyping in the operating room or other surgical environment, and/or to localizing and digitizing electrodes/sensors in any coordinate system in neuroscience applications.

In some examples, the structured light module **1012** linked to a navigated surgery system (e.g., the CASS **100**) may be used to digitize the operating theater. With these examples, extensive data from the optical tracking system **115** (e.g., marker poses, raw images from the optical modules **1011**A and **1011**B, and/or 3D reconstructed surface) together with external sensors may be used in deep learning algorithms. Examples of such applications include teaching a surgical robot to perform a gesture/action automatically, automatic segmentation of anatomical structures within the raw image to better define anatomical areas (e.g., during the registration process), automatic analysis of the surgical workflow to analyze the efficiency of the surgeon; and/or automatic recording of the operation for quality, insurance, etc.

In yet other embodiments, the structured light module **1012** together with the raw image(s) obtained by the optical modules **1011**A and **1011**B may be used as a human computer interaction (HCI) device. In this configuration, the operator is detected and may interact with the CASS **100** by way of hand or body gestures, which may be used to control a surgical workflow, for example, instead of a pedal. In another examples, the user can directly interact with a Graphical User Interface (GUI) of the CASS **100** through a virtual mouse control.

In some examples, the structured light module **1012** may be rigidly fixed to the optical tracking system **115**, as illustrated in FIG. **10**. In other examples, the structured light module **1012** can be integral with a separate handheld device with an affixed marker. In this configuration, the optical tracking system **115** is both tracking the marker on the handheld device and on the reference marker located on the patient. In yet other examples, navigation can be operated in a marker-less manner by only using a structured light device.

One advantage of the optical tracking system **115** disclosed herein is to provide a seamless improvement of existing CASS **100** applications without requiring new hardware. Another advantage is to use the same camera(s) both for optical tracking and for 3D surface acquisition within a structure light module **1012**. The embodiments disclosed herein reduce the need to calibrate the structured light module **1012** with respect to the optical tracking system **115**. Further, having the structured light module **1012** in the optical tracking system **115** enables additional applications that contribute to the digitalization of the operating theatre, including faster and/or automatic registration process, acquisition of the anatomy during surgical procedures to advise on the optimal implant, or design and/or manufacture of an implant/orthosis during a surgical operation, for example.

FIG. **13** illustrates a block diagram of an illustrative data processing system **1300** in which aspects of the illustrative embodiments are implemented. The data processing system

1300 is an example of a computer, such as a server or client, in which computer usable code or instructions implementing the process for illustrative embodiments of the present invention are located. In some embodiments, the data processing system 1300 may be a server computing device. For example, data processing system 1300 can be implemented in a server or another similar computing device operably connected to a CASS 100 as described above. The data processing system 1300 can be configured to, for example, transmit and receive information related to a patient and/or a related surgical plan with the CASS 100. Accordingly, the data processing system 1300 can be the surgical computer 150, or be integral with the surgical computer in some examples. In other examples, the data processing system 1300 can be integral with or communicably coupled to the optical tracking system 115, and other types of deployments can also be used in other examples.

In the depicted example, data processing system 1300 can employ a hub architecture including a north bridge and memory controller hub (NB/MCH) 1301 and south bridge and input/output (I/O) controller hub (SB/ICH) 1302. Processing unit 1303, main memory 1304, and graphics processor 1305 can be connected to the NB/MCH 1301. Graphics processor 1305 can be connected to the NB/MCH 1301 through, for example, an accelerated graphics port (AGP).

In the depicted example, a network adapter 1306 connects to the SB/ICH 1302. An audio adapter 1307, keyboard and mouse adapter 1308, modem 1309, read only memory (ROM) 1310, hard disk drive (HDD) 1311, optical drive (e.g., CD or DVD) 1312, universal serial bus (USB) ports and other communication ports 1313, and PCI/PCIe devices 1314 may connect to the SB/ICH 1302 through bus system 1316. PCI/PCIe devices 1314 may include Ethernet adapters, add-in cards, and PC cards for notebook computers. ROM 1310 may be, for example, a flash basic input/output system (BIOS). The HDD 1311 and optical drive 1312 can use an integrated drive electronics (IDE) or serial advanced technology attachment (SATA) interface. A super I/O (SIO) device 1315 can be connected to the SB/ICH 1302.

An operating system can run on the processing unit 1303. The operating system can coordinate and provide control of various components within the data processing system 1300. As a client, the operating system can be a commercially available operating system. An object-oriented programming system, such as the Java™ programming system, may run in conjunction with the operating system and provide calls to the operating system from the object-oriented programs or applications executing on the data processing system 1300. As a server, the data processing system 1300 can be an IBM® eServer™ System® running the Advanced Interactive Executive operating system or the Linux operating system. The data processing system 1300 can be a symmetric multiprocessor (SMP) system that can include a plurality of processors in the processing unit 1303. Alternatively, a single processor system may be employed.

Instructions for the operating system, the object-oriented programming system, and applications or programs are located on storage devices, such as the HDD 1311, and are loaded into the main memory 1304 for execution by the processing unit 1303. The processes for embodiments described herein can be performed by the processing unit 1303 using computer usable program code, which can be located in a memory such as, for example, main memory 1304, ROM 1310, or in one or more peripheral devices.

A bus system 1316 can be comprised of one or more busses. The bus system 1316 can be implemented using any type of communication fabric or architecture that can provide for a transfer of data between different components or devices attached to the fabric or architecture. A communication unit such as the modem 1309 or the network adapter 1306 can include one or more devices that can be used to transmit and receive data.

While various illustrative embodiments incorporating the principles of the present teachings have been disclosed, the present teachings are not limited to the disclosed embodiments. Instead, this application is intended to cover any variations, uses, or adaptations of the present teachings and use its general principles. Further, this application is intended to cover such departures from the present disclosure as come within known or customary practice in the art to which these teachings pertain.

In the above detailed description, reference is made to the accompanying drawings, which form a part hereof. In the drawings, similar symbols typically identify similar components, unless context dictates otherwise. The illustrative embodiments described in the present disclosure are not meant to be limiting. Other embodiments may be used, and other changes may be made, without departing from the spirit or scope of the subject matter presented herein. It will be readily understood that various features of the present disclosure, as generally described herein, and illustrated in the Figures, can be arranged, substituted, combined, separated, and designed in a wide variety of different configurations, all of which are explicitly contemplated herein.

The present disclosure is not to be limited in terms of the particular embodiments described in this application, which are intended as illustrations of various features. Many modifications and variations can be made without departing from its spirit and scope, as will be apparent to those skilled in the art. Functionally equivalent methods and apparatuses within the scope of the disclosure, in addition to those enumerated herein, will be apparent to those skilled in the art from the foregoing descriptions. It is to be understood that this disclosure is not limited to particular methods, reagents, compounds, compositions or biological systems, which can, of course, vary. It is also to be understood that the terminology used herein is for the purpose of describing particular embodiments only, and is not intended to be limiting.

With respect to the use of substantially any plural and/or singular terms herein, those having skill in the art can translate from the plural to the singular and/or from the singular to the plural as is appropriate to the context and/or application. The various singular/plural permutations may be expressly set forth herein for sake of clarity.

It will be understood by those within the art that, in general, terms used herein are generally intended as "open" terms (for example, the term "including" should be interpreted as "including but not limited to," the term "having" should be interpreted as "having at least," the term "includes" should be interpreted as "includes but is not limited to," et cetera). While various compositions, methods, and devices are described in terms of "comprising" various components or steps (interpreted as meaning "including, but not limited to"), the compositions, methods, and devices can also "consist essentially of" or "consist of" the various components and steps, and such terminology should be interpreted as defining essentially closed-member groups.

In addition, even if a specific number is explicitly recited, those skilled in the art will recognize that such recitation should be interpreted to mean at least the recited number (for example, the bare recitation of "two recitations," without other modifiers, means at least two recitations, or two or more recitations). Furthermore, in those instances where a convention analogous to "at least one of A, B, and C, et

cetera" is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (for example, "a system having at least one of A, B, and C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, et cetera). In those instances where a convention analogous to "at least one of A, B, or C, et cetera" is used, in general such a construction is intended in the sense one having skill in the art would understand the convention (for example, "a system having at least one of A, B, or C" would include but not be limited to systems that have A alone, B alone, C alone, A and B together, A and C together, B and C together, and/or A, B, and C together, et cetera). It will be further understood by those within the art that virtually any disjunctive word and/or phrase presenting two or more alternative terms, whether in the description, sample embodiments, or drawings, should be understood to contemplate the possibilities of including one of the terms, either of the terms, or both terms. For example, the phrase "A or B" will be understood to include the possibilities of "A" or "B" or "A and B."

In addition, where features of the disclosure are described in terms of Markush groups, those skilled in the art will recognize that the disclosure is also thereby described in terms of any individual member or subgroup of members of the Markush group.

As will be understood by one skilled in the art, for any and all purposes, such as in terms of providing a written description, all ranges disclosed herein also encompass any and all possible subranges and combinations of subranges thereof. Any listed range can be easily recognized as sufficiently describing and enabling the same range being broken down into at least equal halves, thirds, quarters, fifths, tenths, et cetera. As a non-limiting example, each range discussed herein can be readily broken down into a lower third, middle third and upper third, et cetera. As will also be understood by one skilled in the art all language such as "up to," "at least," and the like include the number recited and refer to ranges that can be subsequently broken down into subranges as discussed above. Finally, as will be understood by one skilled in the art, a range includes each individual member. Thus, for example, a group having 1-3 cells refers to groups having 1, 2, or 3 cells. Similarly, a group having 1-5 cells refers to groups having 1, 2, 3, 4, or 5 cells, and so forth.

The term "about," as used herein, refers to variations in a numerical quantity that can occur, for example, through measuring or handling procedures in the real world; through inadvertent error in these procedures; through differences in the manufacture, source, or purity of compositions or reagents; and the like. Typically, the term "about" as used herein means greater or lesser than the value or range of values stated by 1/10 of the stated values, e.g., ±10%. The term "about" also refers to variations that would be recognized by one skilled in the art as being equivalent so long as such variations do not encompass known values practiced by the prior art. Each value or range of values preceded by the term "about" is also intended to encompass the embodiment of the stated absolute value or range of values. Whether or not modified by the term "about," quantitative values recited in the present disclosure include equivalents to the recited values, e.g., variations in the numerical quantity of such values that can occur, but would be recognized to be equivalents by a person skilled in the art.

Various of the above-disclosed and other features and functions, or alternatives thereof, may be combined into many other different systems or applications. Various presently unforeseen or unanticipated alternatives, modifications, variations or improvements therein may be subsequently made by those skilled in the art, each of which is also intended to be encompassed by the disclosed embodiments.

The invention claimed is:

1. A system comprising:

an optical tracking device comprising a structured light module and an optical module comprising an image sensor and spaced from the structured light module at a known distance; and

a surgical computing device comprising a display device, a non-transitory computer-readable medium comprising instructions stored thereon, and a processor coupled to the non-transitory computer-readable medium and configured to execute the stored instructions to:

generate a depth map from a first image captured by the image sensor during projection of a first near-infrared (NIR) pattern into a surgical environment by the structured light module;

process a second image captured by the image sensor during projection of a second NIR pattern into the surgical environment by the structured light module;

reconstruct a three-dimensional surface of one or more anatomical structures in the surgical environment based on the generated depth map and the second image;

output the reconstructed three-dimensional surface to the display device; and

generate a plurality of three-dimensional surfaces of the one or more anatomical structures from a plurality of depth maps generated from a plurality of images captured by the image sensor during projection of the first and second NIR patterns into the surgical environment by the structured light module.

2. The system of claim **1**, wherein the optical module comprises first and second optical modules comprising first and second image sensors, respectively, in a stereo configuration.

3. The system of claim **2**, wherein the first and second image sensors are spaced at a known distance and rigidly coupled to a casing of the optical tracking device.

4. The system of claim **2**, wherein the first and second image sensors are fixed on a baseline of the optical tracking device and the processor is further configured to execute the stored instructions to calibrate a first pose of the first image sensor with respect to a second pose of the second image sensor.

5. The system of claim **1**, further comprising an infrared light (IR) emitting diode (LED) light source surrounding, at least in part, the optical module.

6. The system of claim **1**, wherein the structured light module is configured to project one or more of a plurality of sequential patterns, a plurality of stripes, a random pattern, a pseudo-random pattern, or a plurality of points.

7. The system of claim **1**, wherein the processor is further configured to execute the stored instructions to stitch the plurality of three-dimensional surfaces to reconstruct the three-dimensional surface of the one or more anatomical structures.

8. The system of claim **1**, wherein the processor is further configured to execute the stored instructions to densify the reconstructed three-dimensional surface of the one or more anatomical structures based on the plurality of three-dimensional surfaces.

9. The system of claim **1**, wherein the processor is further configured to execute the stored instructions to generate a three-dimensional sequence of movement of the one or more

anatomical structures occurring between capture of one or more of the plurality of images.

10. The system of claim **1**, wherein the optical module further comprises a lens and an NIR filter.

11. A surgical computing device connectable to an optical tracking device, the optical tracking device comprising a structured light module and an optical module comprising an image sensor and spaced from the structured light module at a known distance, the surgical computing device comprising:

a display device;

a processor; and

a non-transitory computer-readable medium coupled to the processor, the non-transitory computer-readable medium storing instructions that, when executed by the processor, cause the surgical computing device to:

generate a depth map from a first image captured by the image sensor during projection of a first near-infrared (NIR) pattern into a surgical environment by the structured light module,

process a second image captured by the image sensor during projection of a second NIR pattern into the surgical environment by the structured light module,

reconstruct a three-dimensional surface of one or more anatomical structures in the surgical environment based on the generated depth map and the second image,

output the reconstructed three-dimensional surface to the display device, and

generate a plurality of three-dimensional surfaces of the one or more anatomical structures from a plurality of depth maps generated from a plurality of images captured by the image sensor during projection of the first and second NIR patterns into the surgical environment by the structured light module.

12. The surgical computing device of claim **11**, wherein the non-transitory computer-readable medium comprises further instructions that, when executed by the processor, cause the surgical computing device to densify the reconstructed three-dimensional surface of the one or more anatomical structures based on the plurality of three-dimensional surfaces.

13. The surgical computing device of claim **11**, wherein the non-transitory computer-readable medium comprises further instructions that, when executed by the processor, cause the surgical computing device to generate a three-dimensional sequence of movement of the one or more anatomical structures occurring between capture of one or more of the plurality of images.

14. A computer-implemented method comprising:

generating, by a surgical computing device surgical connected to an optical tracking device comprising a structured light module and an optical module comprising an image sensor and spaced from the structured light module at a known distance, a depth map from a first image captured by the image sensor during projection of a first near-infrared (NIR) pattern into a surgical environment by the structured light module;

processing, by the surgical computing device, a second image captured by the image sensor during projection of a second NIR pattern into the surgical environment by the structured light module;

reconstructing, by the surgical computing device, a three-dimensional surface of one or more anatomical structures in the surgical environment based on the generated depth map and the second image;

outputting, by the surgical computing device, the reconstructed three-dimensional surface to a display device; and

generating, by the surgical computing device, a plurality of three-dimensional surfaces of the one or more anatomical structures from a plurality of depth maps generated from a plurality of images captured by the image sensor during projection of the first and second NIR patterns into the surgical environment by the structured light module.

15. The computer-implemented method of claim **14**, further comprising:

densifying, by the surgical computing device, the reconstructed three-dimensional surface of the one or more anatomical structures based on the plurality of three-dimensional surfaces.

16. The computer-implemented method of claim **14**, further comprising:

generating, by the surgical computing device, a three-dimensional sequence of movement of the one or more anatomical structures occurring between capture of one or more of the plurality of images.

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