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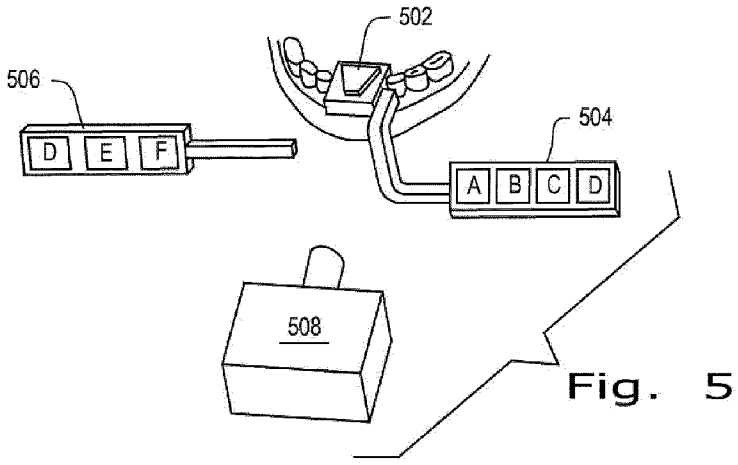

Fig. 5

(57) Abstract: A position monitoring system comprises a fiducial reference, a tracker for obtaining image information of surgical site, and a computer system with processor, memory, a software program, and access to a database with scan data of the surgical site with the fiducial reference fixed to the site. Uniquely identifiable tracking markers are fixed to the fiducial reference and to a surgical implement. The computer determines the relative positions and orientations of the markers based on live image information from the tracker, relates and displays on one or more display systems the current position and orientation of the fiducial reference and the surgical implement. The computer renders on the one or more display systems a surgical guidance graphic user interface (700) showing planned and actual locations for the surgical implement to impinge on the area of surgical patient, an allowed range of angles of incidence for the surgical implement, and an actual instantaneous angle of incidence of the surgical implement. When the implement is a drill, the graphic user interface may display the drilling depth (740).

WO 2016/139149 A1

SURGICAL LOCATION MONITORING SYSTEM AND METHOD WITH SURGICAL GUIDANCE GRAPHIC USER INTERFACE

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The invention relates to location monitoring hardware and software systems. More specifically, the field of the invention is that of surgical equipment and software for monitoring surgical conditions.

Description of the Related Art

[0002] Visual and other sensory systems are known, with such systems being capable of both observing and monitoring surgical procedures. With such observation and monitoring systems, computer aided surgeries are now possible, and in fact are being routinely performed. In such procedures, the computer software interacts with both clinical images of the patient and observed surgical images from the current surgical procedure to provide guidance to the physician in conducting the surgery. For example, in one known system a carrier assembly bears at least one fiducial marker onto an attachment element in a precisely repeatable position with respect to a patient's jaw bone, employing the carrier assembly for providing registration between the fiducial marker and the patient's jaw bone and implanting the tooth implant by employing a tracking system which uses the registration to guide a drilling assembly. With this relatively new computer implemented technology, further improvements may further advance the effectiveness of surgical procedures.

SUMMARY OF THE INVENTION

[0003] The present invention is a surgical hardware and software monitoring system and method which allows for surgical planning while the patient is available for surgery, for example while the patient is being prepared for surgery so that the system may model the surgical site. In one embodiment, the model may be used to track contemplated surgical procedures and warn the physician regarding possible boundary violations that would indicate an inappropriate location in a surgical procedure. In another embodiment, the hardware may track the movement of instruments during the procedure and in reference to the model to enhance observation of the procedure. In this way, physicians are provided an additional tool to improve surgical planning and performance.

[0004] The system uses a particularly configured fiducial reference, to orient the monitoring system with regard to the critical area. The fiducial reference is attached to a location near the intended surgical area. For example, in the example of a dental surgery, a splint may be used to securely locate the fiducial reference near the surgical area. The fiducial reference may then be used as a point of reference, or a fiducial, for the further image processing of the surgical site. The fiducial reference may be identified relative to other portions of the surgical area by having a recognizable fiducial marker apparent in the scan.

[0005] The system of embodiments of the invention involves automatically computing the three-dimensional location of the patient by means of a tracking device that may be a tracking marker. The tracking marker may be attached in fixed spatial relation either directly to the fiducial reference, or attached to the fiducial reference via a tracking pole that itself may have a distinct three-dimensional shape. In the dental surgery example, a tracking pole is mechanically connected to the base of the fiducial reference that is in turn fixed in the patient's mouth. Each tracking pole device has a particular observation

pattern, located either on itself or on a suitable tracking marker, and a particular geometrical connection to the base, which the computer software recognizes as corresponding to a particular geometry for subsequent location calculations. Although individual tracking pole devices have distinct configurations, they may all share the same connection base and thus may be used with any fiducial reference. The particular tracking information calculations are dictated by the particular tracking pole used, and actual patient location is calculated accordingly. Thus, tracking pole devices may be interchanged and calculation of the location remains the same. This provides, in the case of dental surgery, automatic recognition of the patient head location in space. Alternatively, a sensor device, or a tracker, may be in a known position relative to the fiducial key and its tracking pole, so that the current data image may be mapped to the scan image items.

[0006] The fiducial reference and each tracking pole or associated tracking marker may have a pattern made of radio-opaque material so that when imaging information is scanned by the software, the particular items are recognized. Typically, each instrument used in the procedure has a unique pattern on its associated tracking marker so that the tracker information identifies the instrument. The software creates a model of the surgical site, in one embodiment a coordinate system, according to the location and orientation of the patterns on the fiducial reference and/or tracking pole(s) or their attached tracking markers. By way of example, in the embodiment where the fiducial reference has an associated pre-assigned pattern, analysis software interpreting image information from the tracker may recognize the pattern and may select the site of the base of the fiducial to be at the location where the fiducial reference is attached to a splint. If the fiducial key does not have an associated pattern, a fiducial site is designated. In the dental example this may be at a particular spatial relation to the tooth, and a splint location may be automatically designed for placement of the fiducial reference.

[0007] In a first aspect of the invention there is provided a surgical monitoring system comprising a fiducial reference configured for removably attaching to a location proximate a surgical site, for having a three-dimensional location and orientation determinable based on scan data of the surgical site, and for having the three-dimensional location and orientation determinable based on image information about the surgical site; a tracker arranged for obtaining the image information; and a controller configured for spatially relating the image information to the scan data and for determining the three-dimensional location and orientation of the fiducial reference. In one embodiment of the invention the fiducial reference may be rigidly and removably attachable to a part of the surgical site. In such an embodiment the fiducial reference may be repeatably attachable in the same three-dimensional orientation to the same location on the particular part of the surgical site.

[0008] The fiducial reference is at least one of marked and shaped for having at least one of its location and its orientation determined from the scan data and to allow it to be uniquely identified from the scan data. The surgical monitoring system further comprises a first tracking marker in fixed three-dimensional spatial relationship with the fiducial reference, wherein the first tracking marker is configured for having at least one of its location and its orientation determined by the controller based on the image information and the scan data. The first tracking marker may be configured to be removably and rigidly connected to the fiducial reference by a first tracking pole. The first tracking pole may have a three-dimensional structure uniquely identifiable by the controller from the image information. The three-dimensional structure of the first tracking pole allows its three-dimensional orientation of the first tracking pole to be determined by the controller from the image information.

[0009] The first tracking pole and fiducial reference may be configured to allow the first tracking pole to connect to a single unique location on the fiducial reference in a first single unique three-dimensional orientation. The fiducial reference may be configured for

the attachment in a single second unique three-dimensional orientation of at least a second tracking pole attached to a second tracking marker. The first tracking marker may have a three-dimensional shape that is uniquely identifiable by the controller from the image information. The first tracking marker may have a three-dimensional shape that allows its three-dimensional orientation to be determined by the controller from the image information. The first tracking marker may have a marking that is uniquely identifiable by the controller and the marking may be configured for allowing at least one of its location and its orientation to be determined by the controller based on the image information and the scan data.

[00010] The surgical monitoring system may comprise further tracking markers attached to implements proximate the surgery site and the controller may be configured for determining locations and orientations of the implements based on the image information and information about the further tracking markers.

[00011] In another aspect of the invention there is provided a method for relating in real time the three-dimensional location and orientation of a surgical site on a patient to the location and orientation of the surgical site in a scan of the surgical site, the method comprising removably attaching a fiducial reference to a fiducial location on the patient proximate the surgical site; performing the scan with the fiducial reference attached to the fiducial location to obtain scan data; determining the three-dimensional location and orientation of the fiducial reference from the scan data; obtaining real time image information of the surgical site; determining in real time the three-dimensional location and orientation of the fiducial reference from the image information; deriving a spatial transformation matrix for expressing in real time the three-dimensional location and orientation of the fiducial reference as determined from the image information in terms of the three-dimensional location and orientation of the fiducial reference as determined from the scan data.

[00012] The obtaining of real time image information of the surgical site may comprise rigidly and removably attaching to the fiducial reference a first tracking marker in a fixed three-dimensional spatial relationship with the fiducial reference. The first tracking marker may be configured for having its location and its orientation determined based on the image information. The attaching of the first tracking marker to the fiducial reference may comprise rigidly and removably attaching the first tracking marker to the fiducial reference by means of a tracking pole. The obtaining of the real time image information of the surgical site may comprise rigidly and removably attaching to the fiducial reference a tracking pole in a fixed three-dimensional spatial relationship with the fiducial reference, and the tracking pole may have a distinctly identifiable three-dimensional shape that allows its location and orientation to be uniquely determined from the image information.

[00013] In yet a further aspect of the invention there is provided a method for real time monitoring the position of an object in relation to a surgical site of a patient, the method comprising removably attaching a fiducial reference to a fiducial location on the patient proximate the surgical site; performing a scan with the fiducial reference attached to the fiducial location to obtain scan data; determining the three-dimensional location and orientation of the fiducial reference from the scan data; obtaining real time image information of the surgical site; determining in real time the three-dimensional location and orientation of the fiducial reference from the image information; deriving a spatial transformation matrix for expressing in real time the three-dimensional location and orientation of the fiducial reference as determined from the image information in terms of the three-dimensional location and orientation of the fiducial reference as determined from the scan data; determining in real time the three-dimensional location and orientation of the object from the image information; and relating the three-dimensional location and orientation of the object to the three-dimensional location and orientation of the fiducial reference as determined from the image information. The determining in real time of the three-dimensional location and orientation of the object from the image information may comprise rigidly attaching a tracking marker to the object.

[00014] In one alternative embodiment, the tracker itself is attached to the fiducial reference so that the location of an object having a marker may be observed from a known position. The tracker may be a non-stereo tracker and may in particular be a non-stereo optical tracker. In some embodiments the tracker may be a non-stereo tracker employing a plurality of sensor devices.

[00015] In a further aspect of the invention, a position monitoring system is provided for a surgical procedure comprising: a single fiducial reference comprising a fiducial key and a fiducial extension rigidly and removably attached to the fiducial key, the fiducial key adapted to be fixed to an area of surgical patient; a first marker attached to the fiducial key in a predetermined fixed relative position and orientation; a non-stereo optical tracker able to determine the position and orientation of the first marker; a computer system having scan data of the patient with the fiducial reference fixed to the area of surgical patient, the computer system coupled to the tracker and including a processor with memory and a software program having a series of instructions which when executed by the processor determines the relative position and orientation of the first marker based on image information from the tracker, and relates the current position and orientation of the fiducial reference to the scan data; and a display system in communication with the computer system, the display system adapted to show the current position and orientation of the fiducial reference relative to the patient scan data during the surgical procedure. The fiducial key may be configured and arranged to fit the part of the patient being scanned. The first marker may be attached to the fiducial key by means of a tracking pole. The fiducial extension may comprise the tracking pole and the tracking pole may be at least one of shaped and marked to be identifiable in the scan data.

[00016] The fiducial key may be fixed to the area of the surgical patient such that the fiducial reference is at least partially non-visible during the surgical procedure. At least one of the fiducial key and the fiducial extension may consist of a specific material that is distinctly identifiable in at least one of an X-ray image, Magnetic Resonance Image

(MRI), computerized tomograph (CT), sonograph, and cone beam computerized tomograph (CBCT). At least one of the fiducial key and the fiducial extension may have a distinct shape which allows its position and orientation to be determined from the scan data. In other embodiments, at least one of the fiducial key and the fiducial extension may have a label in a predetermined position such that the orientation of the fiducial reference is determined from the scan data. The first marker may one of shaped or marked to be identifiable in the scan and the scan data may comprise data of a scan obtained with the marker attached to the fiducial key.

[00017] In a further aspect of the invention, the system may further comprise a multipodal screw fixture for fixing the fiducial key to the area of the surgical patient.

[00018] In a further aspect of the invention, a method is provided for monitoring a surgical site, comprising: attaching a fiducial key to a location proximate to a surgical site; rigidly and removably attaching a fiducial extension to the fiducial key; creating a first scan of the surgical location with the fiducial key attached to the location proximate to a surgical site and the fiducial extension rigidly and removably attached to the fiducial key; rigidly attaching a marker to the fiducial key; obtaining image information from a non-stereo optical tracker proximate the surgical site; communicating the image information from the optical tracker to a computing device; and calculating and displaying a model of the surgical site by means of the computing device based on the scan, the identity of at least one of the fiducial key and the fiducial extension, and the image information received from said tracker. The attaching the fiducial key may comprise multipodally attaching the fiducial key by means of a surgical screw and a plurality of surgical nails.

[00019] In a further aspect, a position monitoring system is provided for a surgical procedure comprising: a single fiducial reference adapted to be fixed to an area of surgical patient; a first marker attached to the fiducial reference in a predetermined fixed relative

position and orientation; a second marker adapted to be fixed to a surgical implement in a predetermined fixed relative position and orientation; a non-stereo optical tracker able to determine the position and orientation of the first marker; one or more display systems, at least a first of the one or more display systems adapted to show a current position and orientation of the fiducial reference relative to the patient scan data during the surgical procedure; a computer system in communication with the tracker and the one or more display systems, the computer system having scan data of the patient with the fiducial reference fixed to the area of surgical patient, the computer system comprising: a processor with memory; a software program having a series of instructions which when executed by the processor determines the relative position and orientation of the first and second markers based on image information from the tracker, and relates a current position and orientation of the fiducial reference to the scan data; and a surgical guidance graphic user interface software which when executed by the processor renders on at least one of the first and a second of the one or more display systems a surgical guidance graphic user interface showing at least a planned location for the surgical implement to impinge on the area of surgical patient, an actual instantaneous impingement location for the surgical implement, an allowed range of angles of incidence for the surgical implement to impinge on the instantaneous impingement location, and an actual instantaneous angle of incidence of the surgical implement; wherein the locations and angles of incidence are based on the relative position and orientation of the first and second markers.

[00020] In another perspective on this embodiment, a surgical guidance graphic user interface software is provided which when executed by a processor of a computer system in communication with one or more display systems renders on at least one of a first and a second of the one or more display systems a surgical guidance graphic user interface comprising at least: a planned location for a surgical implement to impinge on an area of surgical patient; an instantaneous actual impingement location for the surgical implement; an allowed range of angles of incidence for the surgical implement to impinge on the instantaneous impingement location; and an instantaneous actual angle of incidence of the

surgical implement; wherein the locations and angles of incidence are determinable by the processor from relative positions and orientations of first and second markers fixed to the area of surgical patient and to the surgical instrument respectively. When the surgical implement is a surgical drill, the surgical guidance graphic user interface may further comprise a graphic drilling depth gauge and a graphic depth indicator depicting on the drilling depth gauge a position of a working tip of a bit of the surgical drill. The depth indicator may be determinable by the processor from the relative positions and orientations of the first and second markers. The first marker may be fixed to the area of surgical patient via a fiducial reference detectable in a scan of the area of surgical patient; and the processor may be configured to determine the relative positions and orientations of the first and second markers based on scan data from the scan and on image information about the area of surgical patient obtainable from a tracker in communication with computer system.

[00021] In a further aspect of the invention, a method is provided for monitoring a surgical site, comprising: attaching a fiducial key to a location proximate to a surgical site; creating a first scan of the surgical location with the fiducial key attached to the location proximate to a surgical site; rigidly attaching a first tracking marker to the fiducial key; rigidly attaching a second tracking marker to a surgical implement; obtaining image information from a non-stereo optical tracker proximate the surgical site; communicating the image information from the optical tracker to a computing device; calculating and displaying on a display system by means of the computing device a model of the surgical site based on the scan, the identity of the fiducial key, and the image information received from said tracker; and rendering on the display system a surgical guidance graphic user interface showing at least a planned location for the surgical implement to impinge on the area of surgical patient, an actual instantaneous impingement location for the surgical implement, an allowed range of angles of incidence for the surgical implement to impinge on the instantaneous impingement location, and an actual instantaneous angle of incidence of the surgical implement. The determining the angles and locations may be based on relative

positions and orientations of the first and second markers. In some embodiments, in which the surgical implement is a surgical drill, the rendering the surgical guidance graphic user interface further comprises rendering on the display system a graphic drilling depth gauge and a graphic depth indicator depicting on the drilling depth gauge a position of a working tip of a bit of the surgical drill.

BRIEF DESCRIPTION OF THE DRAWINGS

[00022] The above mentioned and other features and objects of this invention, and the manner of attaining them, will become more apparent and the invention itself will be better understood by reference to the following description of an embodiment of the invention taken in conjunction with the accompanying drawings, wherein:

[00023] Figure **1** is a schematic diagrammatic view of a network system in which embodiments of the present invention may be utilized.

[00024] Figure **2** is a block diagram of a computing system (either a server or client, or both, as appropriate), with optional input devices (e.g., keyboard, mouse, touch screen, etc.) and output devices, hardware, network connections, one or more processors, and memory/storage for data and modules, etc. which may be utilized as controller and display in conjunction with embodiments of the present invention.

[00025] Figures **3A-N** are drawings of hardware components of the surgical monitoring system according to embodiments of the invention.

[00026] Figures **4A-C** is a flow chart diagram illustrating one embodiment of the registering method of the present invention.

[00027] Figure **5** is a drawing of a dental fiducial key with a tracking pole and a dental drill according to one embodiment of the present invention.

[00028] Figure **6** is a drawing of an endoscopic surgical site showing the fiducial key, endoscope, and biopsy needle according to another embodiment of the invention.

[00029] Figure **7** is a drawing of surgical guidance graphic user interface for monitoring a surgical drill employed with the surgical monitoring system according to an embodiment of the invention.

[00030] Figure **8** is a flow chart of a method for monitoring a surgical site by means of a surgical guidance graphic user interface according to an embodiment of the invention.

[00031] Corresponding reference characters indicate corresponding parts throughout the several views. Although the drawings represent embodiments of the present invention, the drawings are not necessarily to scale and certain features may be exaggerated in order to better illustrate and explain the present invention. The flow charts and screen shots are also representative in nature, and actual embodiments of the invention may include further features or steps not shown in the drawings. The exemplification set out herein illustrates an embodiment of the invention, in one form, and such exemplifications are not to be construed as limiting the scope of the invention in any manner.

DESCRIPTION OF EMBODIMENTS OF THE PRESENT INVENTION

[00032] The embodiments disclosed below are not intended to be exhaustive or limit the invention to the precise form disclosed in the following detailed description. Rather, the embodiments are chosen and described so that others skilled in the art may utilize their teachings.

[00033] The detailed descriptions that follow are presented in part in terms of algorithms and symbolic representations of operations on data bits within a computer memory representing alphanumeric characters or other information. The hardware components are shown with particular shapes and relative orientations and sizes using particular scanning techniques, although in the general case one of ordinary skill recognizes that a variety of particular shapes and orientations and scanning methodologies may be used within the teaching of the present invention. A computer generally includes a processor for executing instructions and memory for storing instructions and data, including interfaces to obtain and process imaging data. When a general-purpose computer has a series of machine encoded instructions stored in its memory, the computer operating on such encoded instructions may become a specific type of machine, namely a computer particularly configured to perform the operations embodied by the series of instructions. Some of the instructions may be adapted to produce signals that control operation of other machines and thus may operate through those control signals to transform materials far removed from the computer itself. These descriptions and representations are the means used by those skilled in the art of data processing arts to most effectively convey the substance of their work to others skilled in the art.

[00034] An algorithm is here, and generally, conceived to be a self-consistent sequence of steps leading to a desired result. These steps are those requiring physical manipulations of physical quantities, observing and measuring scanned data representative of matter around the surgical site. Usually, though not necessarily, these quantities take the form of electrical or magnetic pulses or signals capable of being stored, transferred, transformed, combined, compared, and otherwise manipulated. It proves convenient at times, principally for reasons of common usage, to refer to these signals as bits, values, symbols, characters, display data, terms, numbers, or the like as a reference to the physical items or manifestations in which such signals are embodied or expressed to capture the underlying data of an image. It should be borne in mind, however, that all of these and similar terms

are to be associated with the appropriate physical quantities and are merely used here as convenient labels applied to these quantities.

[00035] Some algorithms may use data structures for both inputting information and producing the desired result. Data structures greatly facilitate data management by data processing systems, and are not accessible except through sophisticated software systems. Data structures are not the information content of a memory, rather they represent specific electronic structural elements that impart or manifest a physical organization on the information stored in memory. More than mere abstraction, the data structures are specific electrical or magnetic structural elements in memory, which simultaneously represent complex data accurately, often data modeling physical characteristics of related items, and provide increased efficiency in computer operation.

[00036] Further, the manipulations performed are often referred to in terms, such as comparing or adding, commonly associated with mental operations performed by a human operator. No such capability of a human operator is necessary, or desirable in most cases, in any of the operations described herein that form part of the present invention; the operations are machine operations. Useful machines for performing the operations of the present invention include general-purpose digital computers or other similar devices. In all cases the distinction between the method operations in operating a computer and the method of computation itself should be recognized. The present invention relates to a method and apparatus for operating a computer in processing electrical or other (e.g., mechanical, chemical) physical signals to generate other desired physical manifestations or signals. The computer operates on software modules, which are collections of signals stored on a media that represents a series of machine instructions that enable the computer processor to perform the machine instructions that implement the algorithmic steps. Such machine instructions may be the actual computer code the processor interprets to implement the instructions, or alternatively may be a higher level coding of the instructions that is interpreted to obtain the actual computer code. The software module

may also include a hardware component, wherein some aspects of the algorithm are performed by the circuitry itself rather as a result of an instruction.

[00037] The present invention also relates to an apparatus for performing these operations. This apparatus may be specifically constructed for the required purposes or it may comprise a general-purpose computer as selectively activated or reconfigured by a computer program stored in the computer. The algorithms presented herein are not inherently related to any particular computer or other apparatus unless explicitly indicated as requiring particular hardware. In some cases, the computer programs may communicate or relate to other programs or equipment through signals configured to particular protocols, which may or may not require specific hardware or programming to interact. In particular, various general-purpose machines may be used with programs written in accordance with the teachings herein, or it may prove more convenient to construct more specialized apparatus to perform the required method steps. The required structure for a variety of these machines will appear from the description below.

[00038] The present invention may deal with "object-oriented" software, and particularly with an "object-oriented" operating system. The "object-oriented" software is organized into "objects", each comprising a block of computer instructions describing various procedures ("methods") to be performed in response to "messages" sent to the object or “events” which occur with the object. Such operations include, for example, the manipulation of variables, the activation of an object by an external event, and the transmission of one or more messages to other objects. Often, but not necessarily, a physical object has a corresponding software object that may collect and transmit observed data from the physical device to the software system. Such observed data may be accessed from the physical object and/or the software object merely as an item of convenience; therefor where “actual data” is used in the following description, such “actual data” may be from the instrument itself or from the corresponding software object or module.

[00039] Messages are sent and received between objects having certain functions and knowledge to carry out processes. Messages are generated in response to user instructions, for example, by a user activating an icon with a "mouse" pointer generating an event. Also, messages may be generated by an object in response to the receipt of a message. When one of the objects receives a message, the object carries out an operation (a message procedure) corresponding to the message and, if necessary, returns a result of the operation. Each object has a region where internal states (instance variables) of the object itself are stored and where the other objects are not allowed to access. One feature of the object-oriented system is inheritance. For example, an object for drawing a "circle" on a display may inherit functions and knowledge from another object for drawing a "shape" on a display.

[00040] A programmer "programs" in an object-oriented programming language by writing individual blocks of code each of which creates an object by defining its methods. A collection of such objects adapted to communicate with one another by means of messages comprises an object-oriented program. Object-oriented computer programming facilitates the modeling of interactive systems in that each component of the system may be modeled with an object, the behavior of each component being simulated by the methods of its corresponding object, and the interactions between components being simulated by messages transmitted between objects.

[00041] An operator may stimulate a collection of interrelated objects comprising an object-oriented program by sending a message to one of the objects. The receipt of the message may cause the object to respond by carrying out predetermined functions, which may include sending additional messages to one or more other objects. The other objects may in turn carry out additional functions in response to the messages they receive, including sending still more messages. In this manner, sequences of message and response may continue indefinitely or may come to an end when all messages have been responded to and no new messages are being sent. When modeling systems utilizing an

object-oriented language, a programmer need only think in terms of how each component of a modeled system responds to a stimulus and not in terms of the sequence of operations to be performed in response to some stimulus. Such sequence of operations naturally flows out of the interactions between the objects in response to the stimulus and need not be preordained by the programmer.

[00042] Although object-oriented programming makes simulation of systems of interrelated components more intuitive, the operation of an object-oriented program is often difficult to understand because the sequence of operations carried out by an object-oriented program is usually not immediately apparent from a software listing as in the case for sequentially organized programs. Nor is it easy to determine how an object-oriented program works through observation of the readily apparent manifestations of its operation. Most of the operations carried out by a computer in response to a program are "invisible" to an observer since only a relatively few steps in a program typically produce an observable computer output.

[00043] In the following description, several terms that are used frequently have specialized meanings in the present context. The term "object" relates to a set of computer instructions and associated data, which may be activated directly or indirectly by the user. The terms "windowing environment", "running in windows", and "object oriented operating system" are used to denote a computer user interface in which information is manipulated and displayed on a video display such as within bounded regions on a raster scanned video display. The terms "network", "local area network", "LAN", "wide area network", or "WAN" mean two or more computers that are connected in such a manner that messages may be transmitted between the computers. In such computer networks, typically one or more computers operate as a "server", a computer with large storage devices such as hard disk drives and communication hardware to operate peripheral devices such as printers or modems. Other computers, termed "workstations", provide a user interface so that users of computer networks may access the network resources, such

as shared data files, common peripheral devices, and inter-workstation communication. Users activate computer programs or network resources to create “processes” which include both the general operation of the computer program along with specific operating characteristics determined by input variables and its environment. Similar to a process is an agent (sometimes called an intelligent agent), which is a process that gathers information or performs some other service without user intervention and on some regular schedule. Typically, an agent, using parameters typically provided by the user, searches locations either on the host machine or at some other point on a network, gathers the information relevant to the purpose of the agent, and presents it to the user on a periodic basis.

[00044] The term "desktop" means a specific user interface which presents a menu or display of objects with associated settings for the user associated with the desktop. When the desktop accesses a network resource, which typically requires an application program to execute on the remote server, the desktop calls an Application Program Interface, or "API", to allow the user to provide commands to the network resource and observe any output. The term "Browser" refers to a program which is not necessarily apparent to the user, but which is responsible for transmitting messages between the desktop and the network server and for displaying and interacting with the network user. Browsers are designed to utilize a communications protocol for transmission of text and graphic information over a worldwide network of computers, namely the “World Wide Web” or simply the “Web”. Examples of Browsers compatible with the present invention include the Internet Explorer program sold by Microsoft Corporation (Internet Explorer is a trademark of Microsoft Corporation), the Opera Browser program created by Opera Software ASA, or the Firefox browser program distributed by the Mozilla Foundation (Firefox is a registered trademark of the Mozilla Foundation). Although the following description details such operations in terms of a graphic user interface of a Browser, the present invention may be practiced with text based interfaces, or even with voice or visually activated interfaces, that have many of the functions of a graphic based Browser.

[00045] Browsers display information, which is formatted in a Standard Generalized Markup Language ("SGML") or a HyperText Markup Language ("HTML"), both being scripting languages, which embed non-visual codes in a text document through the use of special ASCII text codes. Files in these formats may be easily transmitted across computer networks, including global information networks like the Internet, and allow the Browsers to display text, images, and play audio and video recordings. The Web utilizes these data file formats to conjunction with its communication protocol to transmit such information between servers and workstations. Browsers may also be programmed to display information provided in an eXtensible Markup Language ("XML") file, with XML files being capable of use with several Document Type Definitions ("DTD") and thus more general in nature than SGML or HTML. The XML file may be analogized to an object, as the data and the stylesheet formatting are separately contained (formatting may be thought of as methods of displaying information, thus an XML file has data and an associated method).

[00046] The terms "personal digital assistant" or "PDA", as defined above, means any handheld, mobile device that combines computing, telephone, fax, e-mail and networking features. The terms "wireless wide area network" or "WWAN" mean a wireless network that serves as the medium for the transmission of data between a handheld device and a computer. The term "synchronization" means the exchanging of information between a first device, e.g. a handheld device, and a second device, e.g. a desktop computer, either via wires or wirelessly. Synchronization ensures that the data on both devices are identical (at least at the time of synchronization).

[00047] In wireless wide area networks, communication primarily occurs through the transmission of radio signals over analog, digital cellular, or personal communications service ("PCS") networks. Signals may also be transmitted through microwaves and other electromagnetic waves. At the present time, most wireless data communication takes place across cellular systems using second generation technology such as code-division

multiple access ("CDMA"), time division multiple access ("TDMA"), the Global System for Mobile Communications ("GSM"), Third Generation (wideband or "3G"), Fourth Generation (broadband or "4G"), personal digital cellular ("PDC"), or through packet-data technology over analog systems such as cellular digital packet data (CDPD") used on the Advance Mobile Phone Service ("AMPS").

[00048] The terms "wireless application protocol" or "WAP" mean a universal specification to facilitate the delivery and presentation of web-based data on handheld and mobile devices with small user interfaces. "Mobile Software" refers to the software operating system, which allows for application programs to be implemented on a mobile device such as a mobile telephone or PDA. Examples of Mobile Software are Java and Java ME (Java and JavaME are trademarks of Sun Microsystems, Inc. of Santa Clara, California), BREW (BREW is a registered trademark of Qualcomm Incorporated of San Diego, California), Windows Mobile (Windows is a registered trademark of Microsoft Corporation of Redmond, Washington), Palm OS (Palm is a registered trademark of Palm, Inc. of Sunnyvale, California), Symbian OS (Symbian is a registered trademark of Symbian Software Limited Corporation of London, United Kingdom), ANDROID OS (ANDROID is a registered trademark of Google, Inc. of Mountain View, California), and iPhone OS (iPhone is a registered trademark of Apple, Inc. of Cupertino, California) , and Windows Phone 7. "Mobile Apps" refers to software programs written for execution with Mobile Software.

[00049] The terms “scan,” “fiducial reference”, “fiducial location”, “marker,” “tracker” and “image information” have particular meanings in the present disclosure. For purposes of the present disclosure, “scan” or derivatives thereof refer to x-ray, magnetic resonance imaging (MRI), computerized tomography (CT), sonography, cone beam computerized tomography (CBCT), or any system that produces a quantitative spatial representation of a patient. The term “fiducial reference” or simply “fiducial” refers to an object or reference on the image of a scan that is uniquely identifiable as a fixed

recognizable point. In the present specification the term "fiducial location" refers to a useful location to which a fiducial reference is attached. A "fiducial location" will typically be proximate a surgical site. The term "marker" or "tracking marker" refers to an object or reference that may be perceived by a sensor proximate to the location of the surgical or dental procedure, where the sensor may be an optical sensor, a radio frequency identifier (RFID), a sonic motion detector, an ultra-violet or infrared sensor. The term "tracker" refers to a device or system of devices able to determine the location of the markers and their orientation and movement continually in 'real time' during a procedure. As an example of a possible implementation, if the markers are composed of printed targets then the tracker may include a stereo camera pair. The tracker may include a non-stereo optical camera or a stereo camera pair, which may operate in the visible or infrared region of the spectrum. The term "image information" is used in the present specification to describe information obtained by the tracker, whether optical or otherwise, about one or more tracking markers and usable for determining the location of the markers and their orientation and movement continually in 'real time' during a procedure. In some embodiments, an imaging device may be employed to obtain real time close-up images of the surgical site quite apart from the tracker. In this specification, such imaging devices are described by the term "in situ imager" and the in situ imager may comprise an "illuminator" and an "imaging sensor". The term "vectorized" is used in this specification to describe fiducial keys and tracking markers that are at least one of shaped and marked so as to make their orientation in three dimensions uniquely determinable from their appearance in a scan or in image information. If their three-dimensional orientation is determinable, then their three-dimensional location is also known.

[00050] Figure **1** is a high-level block diagram of a computing environment **100** according to one embodiment. Figure **1** illustrates server **110** and three clients **112** connected by network **114**. Only three clients **112** are shown in Figure **1** in order to simplify and clarify the description. Embodiments of the computing environment **100** may have thousands or millions of clients **112** connected to network **114**, for example the Internet. Users (not

shown) may operate software **116** on one of clients **112** to both send and receive messages network **114** via server **110** and its associated communications equipment and software (not shown).

[00051] Figure **2** depicts a block diagram of computer system **210** suitable for implementing server **110** or client **112**. Computer system **210** includes bus **212** which interconnects major subsystems of computer system **210**, such as central processor **214**, system memory **217** (typically RAM, but which may also include ROM, flash RAM, or the like), input/output controller **218**, external audio device, such as speaker system **220** via audio output interface **222**, external device, such as display screen **224** via display adapter **226**, serial ports **228** and **230**, keyboard **232** (interfaced with keyboard controller **233**), storage interface **234**, disk drive **237** operative to receive floppy disk **238** (or other equivalent memory device, such as a read-write compact disk, CD, or digital video disk, DVD, or a universal serial bus, USB, for coupling with a memory stick or flash memory), host bus adapter (HBA) interface card **235A** operative to connect with Fibre Channel network **290**, host bus adapter (HBA) interface card **235B** operative to connect to SCSI bus **239**, and optical disk drive **240** operative to receive optical disk **242**. Also included are mouse **246** (or other point-and-click device, coupled to bus **212** via serial port **228**), modem **247** (coupled to bus **212** via serial port **230**), and network interface **248** (coupled directly to bus **212**).

[00052] Bus **212** allows data communication between central processor **214** and system memory **217**, which may include read-only memory (ROM) or flash memory (neither shown), and random access memory (RAM) (not shown), as previously noted. RAM is generally the main memory into which operating system and application programs are loaded. ROM or flash memory may contain, among other software code, Basic Input-Output system (BIOS), which controls basic hardware operation such as interaction with peripheral components. Applications resident with computer system **210** are generally stored on and accessed via computer readable media, such as hard disk drives (e.g., fixed

disk **244**), optical drives (e.g., optical drive **240**), floppy disk unit **237**, or other storage medium. Additionally, applications may be in the form of electronic signals modulated in accordance with the application and data communication technology when accessed via network modem **247** or interface **248** or other telecommunications equipment (not shown).

[00053] Storage interface **234**, as with other storage interfaces of computer system **210**, may connect to standard computer readable media for storage and/or retrieval of information, such as fixed disk drive **244**. Fixed disk drive **244** may be part of computer system **210** or may be separate and accessed through other interface systems. Modem **247** may provide direct connection to remote servers via telephone link or the Internet via an Internet service provider (ISP) (not shown). Network interface **248** may provide direct connection to remote servers via direct network link to the Internet via a POP (point of presence). Network interface **248** may provide such connection using wireless techniques, including digital cellular telephone connection, Cellular Digital Packet Data (CDPD) connection, digital satellite data connection or the like.

[00054] Many other devices or subsystems (not shown) may be connected in a similar manner (e.g., document scanners, digital cameras and so on), including the hardware components of Figures **3A-N**, which alternatively may be in communication with associated computational resources through local, wide-area, or wireless networks or communications systems. Thus, while the disclosure may generally discuss an embodiment where the hardware components are directly connected to computing resources, one of ordinary skill in this area recognizes that such hardware may be remotely connected with computing resources. Conversely, all of the devices shown in Figure **2** need not be present to practice the present disclosure. Devices and subsystems may be interconnected in different ways from that shown in Figure **2**. Operation of a computer system such as that shown in Fig. **2** is readily known in the art and is not discussed in detail in this application. Software source and/or object codes to implement the present disclosure may be stored in computer-readable storage media such as one or more of

system memory **217**, fixed disk **244**, optical disk **242**, or floppy disk **238**. The operating system provided on computer system **210** may be a variety or version of either MS-DOS® (MS-DOS is a registered trademark of Microsoft Corporation of Redmond, Washington), WINDOWS® (WINDOWS is a registered trademark of Microsoft Corporation of Redmond, Washington), OS/2® (OS/2 is a registered trademark of International Business Machines Corporation of Armonk, New York), UNIX® (UNIX is a registered trademark of X/Open Company Limited of Reading, United Kingdom), Linux® (Linux is a registered trademark of Linus Torvalds of Portland, Oregon), or other known or developed operating system.

[00055] Moreover, regarding the signals described herein, those skilled in the art recognize that a signal may be directly transmitted from a first block to a second block, or a signal may be modified (e.g., amplified, attenuated, delayed, latched, buffered, inverted, filtered, or otherwise modified) between blocks. Although the signals of the above-described embodiments are characterized as transmitted from one block to the next, other embodiments of the present disclosure may include modified signals in place of such directly transmitted signals as long as the informational and/or functional aspect of the signal is transmitted between blocks. To some extent, a signal input at a second block may be conceptualized as a second signal derived from a first signal output from a first block due to physical limitations of the circuitry involved (e.g., there will inevitably be some attenuation and delay). Therefore, as used herein, a second signal derived from a first signal includes the first signal or any modifications to the first signal, whether due to circuit limitations or due to passage through other circuit elements which do not change the informational and/or final functional aspect of the first signal.

[00056] The present invention relates to a surgical hardware and software monitoring system and method which allows for surgical planning while the patient is available for surgery, for example while the patient is being prepared for surgery so that the system may model the surgical site. The system uses a particularly configured piece of hardware,

namely a fiducial reference, represented as fiducial key **10** in Figure **3A**, to orient tracking marker **12** of the monitoring system with regard to the critical area of the surgery. Fiducial key **10** is attached to a location near the intended surgical area, in the exemplary embodiment of the dental surgical area of Figure **3A**, fiducial key **10** is attached to a dental splint **14**. Tracking marker **12** may be connected to fiducial key **10** by tracking pole **11**. In embodiments in which the fiducial reference is directly visible to a suitable tracker (see for example Figure **5** and Figure **6**) that acquires image information about the surgical site, a tracking marker may be attached directly to the fiducial reference, being fiducial key **10** in the present embodiment. For example a dental surgery, the dental tracking marker **14** may be used to securely locate the fiducial **10** near the surgical area. The fiducial key **10** may be used as a point of reference, or a fiducial, for the further image processing of data acquired from tracking marker **12** by the tracker. In some applications, the fiducial key **10** may be disposed in a location or in such orientation as to be at least in part non-visible to the tracker of the system.

[00057] In other embodiments additional tracking markers **12** may be attached to items independent of the fiducial key **10** and any of its associated tracking poles **11** or tracking markers **12**. This allows the independent items to be tracked by the tracker.

[00058] In a further embodiment at least one of the items or instruments near the surgical site may optionally have a tracker attached to function as tracker for the monitoring system of the invention and to thereby sense the orientation and the position of the tracking marker **12** and of any other additional tracking markers relative to the scan data of the surgical area. By way of example, the tracker attached to an instrument may be a miniature digital camera and it may be attached, for example, to a dentist's drill. Any other markers to be tracked by the tracker attached to the item or instrument must be within the field of view of the tracker.

[00059] Using the dental surgery example, the patient is scanned to obtain an initial scan of the surgical site. The particular configuration of fiducial key **10** allows computer software stored in memory and executed in a suitable controller, for example processor **214** and memory **217** of computer **210** of Figure **2**, to recognize its relative position within the surgical site from the scan data, so that further observations may be made with reference to both the location and orientation of fiducial key **10**. In some embodiments, the fiducial reference includes a marking that is apparent as a recognizable identifying symbol when scanned. In other embodiments, the fiducial reference includes a shape that is distinct in the sense that the body apparent on the scan has an asymmetrical form allowing the front, rear, upper, and lower, and left/right defined surfaces that may be unambiguously determined from the analysis of the scan, thereby to allow the determination not only of the location of the fiducial reference, but also of its orientation. The marking and/or shape of fiducial key **10** allows it to be used as the single and only fiducial key employed in the surgical hardware and software monitoring system. By comparison, prior art systems typically rely on a plurality of fiducials. Hence, while the tracker may track several tracking markers within the monitoring system, only a single fiducial reference or key **10** of known shape or marking is required. By way of example, Figure **5**, later discussed in more detail, shows markers **506** and **502** tracked by tracker **508**, but there is only one fiducial reference or key **502** in the system. Figure **6** similarly shows three markers **604**, **606**, and **608** being tracked by tracker **610**, while there is only a single fiducial reference or key **602** in the system.

[00060] In addition, the computer software may create a coordinate system for organizing objects in the scan, such as teeth, jaw bone, skin and gum tissue, other surgical instruments, etc. The coordinate system relates the images on the scan to the space around the fiducial and locates the instruments bearing tracking markers both by orientation and position. The model generated by the monitoring system may then be used to check boundary conditions, and in conjunction with the tracker display the arrangement in real time on a suitable display, for example display **224** of Figure **2**.

[00061] In one embodiment, the computer system has a predetermined knowledge of the physical configuration of fiducial key **10** and examines slices/sections of the scan to locate fiducial key **10**. Locating of fiducial key **10** may be on the basis of its distinct shape, or on the basis of distinctive identifying and orienting markings upon the fiducial key or on attachments to the fiducial key **10** as tracking marker **12**. Fiducial key **10** may be rendered distinctly visible in the scans through higher imaging contrast by the employ of radio-opaque materials or high-density materials in the construction of the fiducial key **10**. In other embodiments the material of the distinctive identifying and orienting markings may be created using suitable high density or radio-opaque inks or materials.

[00062] Once fiducial key **10** is identified, the location and orientation of the fiducial key **10** is determined from the scan segments, and a point within fiducial key **10** is assigned as the center of the coordinate system. The point so chosen may be chosen arbitrarily, or the choice may be based on some useful criterion. A model is then derived in the form of a transformation matrix to relate the fiducial system, being fiducial key **10** in one particular embodiment, to the coordinate system of the surgical site. The resulting virtual construct may be used by surgical procedure planning software for virtual modeling of the contemplated procedure, and may alternatively be used by instrumentation software for the configuration of the instrument, for providing imaging assistance for surgical software, and/or for plotting trajectories for the conduct of the surgical procedure.

[00063] In some embodiments, the monitoring hardware includes a tracking attachment to the fiducial reference. In the embodiment pertaining to dental surgery the tracking attachment to fiducial key **10** is tracking marker **12**, which is attached to fiducial key **10** via tracking pole **11**. Tracking marker **12** may have a particular identifying pattern. The trackable attachment, for example tracking marker **12**, and even associated tracking pole **11** may have known configurations so that observational data from tracking pole **11** and/or tracking marker **12** may be precisely mapped to the coordinate system and thus progress of the surgical procedure may be monitored and recorded. For example, as particularly

shown in Figure **3J**, fiducial key **10** may have hole **15** in a predetermined location specially adapted for engagement with insert **17** of tracking pole **11**. In such an arrangement, for example, tracking poles **11** may be attached with a low force push into hole **15** of fiducial key **10**, and an audible haptic notification may thus be given upon successful completion of the attachment.

[00064] It is further possible to reorient the tracking pole during a surgical procedure. Such reorientation may be in order to change the location of the procedure, for example where a dental surgery deals with teeth on the opposite side of the mouth, where a surgeon switches hands, and/or where a second surgeon performs a portion of the procedure. For example, the movement of the tracking pole may trigger a re-registration of the tracking pole with relation to the coordinate system, so that the locations may be accordingly adjusted. Such a re-registration may be automatically initiated when, for example in the case of the dental surgery embodiment, tracking pole **11** with its attached tracking marker **12** are removed from hole **15** of fiducial key **10** and another tracking marker with its associated tracking pole is connected to an alternative hole on fiducial key **10**. Additionally, boundary conditions may be implemented in the software so that the user is notified when observational data approaches and /or enters the boundary areas.

[00065] The tracker of the system may comprise a single optical imager obtaining a two-dimensional image of the site being monitored. The system and method described in the present specification allow three-dimensional locations and orientations of tracking markers to be obtained using non-stereo-pair two-dimensional imagery. In some embodiments more than one imager may be employed as tracker, but the image information required and employed is nevertheless two-dimensional. Therefore, the two imagers may merely be employed to secure different perspective views of the site, each imager rendering a two-dimensional image that is not part of a stereo pair. This does not exclude the employment of stereo-imagers in obtaining the image information about the site, but the system and method are not reliant on stereo imagery of the site.

[00066] In a further embodiment of the system utilizing the invention, a surgical instrument or implement, herein termed a "hand piece" (see Figures **5** and **6**), may also have a particular configuration that may be located and tracked in the coordinate system and may have suitable tracking markers as described herein. A boundary condition may be set up to indicate a potential collision with virtual material, so that when the hand piece is sensed to approach the boundary condition an indication may appear on a screen, or an alarm sound. Further, target boundary conditions may be set up to indicate the desired surgical area, so that when the trajectory of the hand piece is trending outside the target area an indication may appear on screen or an alarm sound indicating that the hand piece is deviating from its desired path.

[00067] An alternative embodiment of some hardware components are shown in Figures **3G-I**. Fiducial key **10'** has connection elements with suitable connecting portions to allow a tracking pole **11'** to position a tracking marker **12'** relative to the surgical site. Conceptually, fiducial key **10'** serves as an anchor for pole **11'** and tracking marker **12'** in much the same way as the earlier embodiment, although it has a distinct shape. The software of the monitoring system is pre-programmed with the configuration of each particularly identified fiducial key, tracking pole, and tracking marker, so that the location calculations are only changed according to the changed configuration parameters.

[00068] A further aspect of the invention relates to the mounting of fiducial key **10** and is described at the hand of Figure **3K**, showing a multipodal surgical screw fixture for fiducial key **10**. This arrangement addresses dental surgery, though it is by no means limited to dental surgery applications. It is particularly useful in cases where a dental patient lacks teeth near the surgical site. In the dental surgery application, surgical screw **22** is used to fasten mount **23** of fiducial key **10** of Figures **3A**, **3B**, **3C**, **3D**, **3E**, and **3J** to the bone structure of the mandible or maxilla via hole **24**. This may be viewed as an alternative mounting to that shown in Figures **3G**, **3H**, and **3I**. Practitioners in the field will appreciate that such a mounting procedure presents some challenges in securing a

desired and stable orientation for fiducial key **10** and any fiducial extensions or tracking poles and tracking markers that may be attached to it. To provide the mount of fiducial key **10** with more stability and adjustability, it is provided with three surgical nail legs **26**, **27**, and **28** arranged to engage with the gums covering the maxilla or mandible. Together with surgical screw **22**, legs **26**, **27**, and **28** provide fiducial key **10** with a stable and adjustable tripod mount, allowing a method of stably and adjustably mounting fiducial key **10** multipodally proximate the surgical site. In other embodiments different numbers of nail legs may be employed, but they are a plurality in all embodiments. In general, fiducial key **10** or **10′** is therefore attached multipodally to the bone structure of the patient proximate the surgical site by means of at least one surgical screw and a plurality of surgical nails.

[00069] In a further aspect of the invention, Figures **3L**, **3M**, and **3N** show three different embodiments of fiducial extensions, being extensions **18**, **18′** and **18″** respectively, representing in conjunction with fiducial key **10** respectively fiducial references **20**, **20′** and **20″**. Fiducial extensions **18**, **18′** or **18″** may respectively be rigidly but removably attached to fiducial key **10** using, by way of example, the same mechanism as employed to attach tracking pole **11** to fiducial key **10**. That is, fiducial extensions **18**, **18′** and **18″** may respectively comprise insert **19, 19′, 19″** of the same shape as insert **17** of tracking pole **11**. This arrangement ensures that, even though fiducial extensions **18**, **18′** and **18″** may easily be removably attached to fiducial key **10** of Figures **3A**, **3B**, **3C**, **3D**, **3E**, and **3J** by means of hole **15**, the collective fiducial references **20**, **20′** and **20″** that result from the combining of fiducial key **10** and fiducial extensions **18**, **18′** and **18″** are rigid to a degree that allows all mutually relative three dimensional locations on the surface of each of fiducial references **20**, **20′** and **20″** to be known to an accuracy suitable for use in surgical imaging. Fiducial extensions **18**, **18′** and **18″** may be radio-opaque and thereby function without the need for radio-opaque markings. In other embodiments, fiducial extensions **18**, **18′**, and **18″** may be transparent to scan radiation and may bear a radio-opaque pattern to provide the required fiducial function.

[00070] Fiducial extensions **18**, **18′** and **18″** may comprise a three dimensional shape or markings that extend the radio-opaque fiducial shape or markings of fiducial key **10** beyond the physical confines of fiducial key **10**. As a result, even though respective fiducial references **20**, **20′** and **20″** are comprised of two components, being fiducial key **10** and respectively fiducial extensions **18**, **18′** and **18″**, each of these combinations **20**, **20′** and **20″** nevertheless constitutes a single fiducial reference in operation within the monitoring system of the present invention. This stands in contrast to prior art fiducial arrangements based on the mutually independent placement of a plurality of individual point fiducials that are typically located relative to one another subsequent to placement.

[00071] As the arrangement of any of fiducial references **20**, **20′** and **20″** extends further in three dimensions than that of fiducial key **10**, it allows the three-dimensional location and orientation of respective fiducial reference **20**, **20′** or **20″** to be determined with greater accuracy. Since the relative three-dimensional positions of locations on fiducial reference **20**, **20′** or **20″** are pre-known with great accuracy, the image of fiducial reference **20**, **20′** or **20″** in the scan data allows the system of the present invention to detect with good accuracy distortions that may occur in the scanning process. Such distortions are well known to practitioners in the field. In use, the scan data may simply be modified by processor **214** of computer system **210** (see Figure **2**) to adjust the location information of fiducial reference **20**, **20′** or **20″** in the scan data. The same correction may be extended to the entire scan.

[00072] Fiducial extension **18** of Figure **3L** represents the simple case of fiducial key **10** and the pattern on it being effectively extended in length to produce a larger distance over which to spatially calibrate scan data. This provides greater accuracy in spatially calibrating the scan data to the known exact dimensions of fiducial reference **20**, and also provides greater scope for detecting spatial distortions in the scan data. In Figure **3L** the pattern is shown as repeating the same symbol, but, in a more general embodiment, any other usefully identifiable symbols may be employed in the extended pattern.

[00073] Figure **3M** shows fiducial extension **18′** as a three-dimensionally shaped extension that makes the three-dimensional shape of fiducial reference **20′** substantially different from that of fiducial key **10**. That is, fiducial extension **18′** is not only an extension of fiducial key **10**, or of a pattern on fiducial key **10**, but comprises portions that extend along directions that are non- parallel to any side or edge of fiducial key **10**. While pattern symbols are shown on fiducial extension **18′**, but, in alternative embodiments, fiducial extension **18′** may be opaque to scan radiation and may itself provide the required fiducial function, rather than being reliant on a radio-opaque marking for the fiducial function.

[00074] Figure **3N** shows fiducial extension **18″** as a multi-pronged three-dimensionally shaped extension that makes the three-dimensional shape of fiducial reference **20″** substantially different from that of fiducial key **10**. That is, fiducial extension **18″** is not only an extension of fiducial key **10**, or of a pattern on fiducial key **10**, but comprises multiple portions that extend along directions that are non-parallel to any side or edge of fiducial key **10**. Pattern symbols are shown on a portion of fiducial extension **18″**. The pronged portions of fiducial extension **18″** is shown as having no markings and may themselves be made of radio-opaque material so as to provide a fiducial function in a scan. In other embodiments, all of fiducial extension **18″** may be substantially transparent to scan radiation and may bear suitably radio-opaque fiducial markings to produce a fiducial function in a scan.

[00075] In yet further embodiments, tracking pole **11** of Figures **3A**, **3B**, **3C**, **3D**, **3E** and **3J** or tracking pole **11′** of Figures **3G**, **3H**, and **3I** may be employed as fiducial extension in the same fashion as fiducial extensions **18**, **18′** and **18″**. To this end tracking pole **11** or **11′** may either have a distinctive shape and be made from radio-opaque material, or it may be made from materials substantially transparent to scan radiation and bear upon its surface markings composed of radio-opaque materials.

[00076] In yet further embodiments, tracking marker **12** of Figures **3A**, **3B**, and **3F**, or tracking marker **12′** of Figures **3G** and **3I** may be employed additionally as fiducial extension to fiducial keys **10** or **10′** respectively. To this end tracking marker **12** or **12′** may either be made from radio-opaque material, or it may be made from materials substantially transparent to scan radiation and the markings it bears upon its surface may instead be composed of suitable radio-opaque materials. In some embodiments the markings on the surface of tracking marker may serve a dual function as both fiducial markings and tracking markings. In other embodiments, the tracking markings and fiducial markings may be different markings.

[00077] In yet further embodiments, tracking markers **12** or **12′** may serve a dual function as both tracking markers and fiducial extensions as described above, but suitably distinctively shaped fiducial markers may be embedded within tracking markers **12** or **12′** while tracking markings are present on the surfaces of tracking markers **12** or **12′**.

[00078] The materials of the hardware components may vary according to regulatory requirements and practical considerations. Generally, the key or fiducial component is made of generally radio-opaque material such that it does not produce noise for the scan, yet creates recognizable contrast on the scanned image so that any identifying pattern associated with it may be recognized. In addition, because it is generally located on the patient, the material should be lightweight and suitable for connection to an apparatus on the patient. For example, in the dental surgery example, the materials of the fiducial key must be suitable for connection to a plastic splint and suitable for connection to a tracking pole. In the surgical example the materials of the fiducial key may be suitable for attachment to the skin or other particular tissue of a patient.

[00079] The tracking markers are clearly identified by employing, for example without limitation, high contrast pattern engraving. The materials of the tracking markers are

chosen to be capable of resisting damage in autoclave processes and are compatible with rigid, repeatable, and quick connection to a connector structure. The tracking markers and associated tracking poles have the ability to be accommodated at different locations for different surgery locations, and, like the fiducial keys, they should also be relatively lightweight as they will often be resting on or against the patient. The tracking poles must similarly be compatible with autoclave processes and have connectors of a form shared among tracking poles.

[00080] The tracker employed in tracking the fiducial keys, tracking poles and tracking markers should be capable of tracking with suitable accuracy objects of a size of the order of 1.5 square centimeters. The tracker may be, by way of example without limitation, a stereo camera or stereo camera pair. While the tracker is generally connected by wire to a computing device to read the sensory input, it may optionally have wireless connectivity to transmit the sensory data to a computing device. In other embodiments, the tracker may be a non-stereo optical tracker.

[00081] In embodiments that additionally employ a trackable piece of instrumentation, such as a hand piece, tracking markers attached to such a trackable piece of instrumentation may also be light-weight; capable of operating in a 3-object array with a 90 degree relationship; optionally having a high contrast pattern engraving and a rigid, quick mounting mechanism to a standard hand piece.

[00082] In another aspect there is presented an automatic registration method for tracking surgical activity, as illustrated in Figures **4A-C**. Figure **4A** and Figure **4B** together present, without limitation, a flowchart of one method for determining the three-dimensional location and orientation of the fiducial reference from scan data. Figure **4C** presents a flow chart of a method for confirming the presence of a suitable tracking marker

in image information obtained by the tracker and determining the three-dimensional location and orientation of the fiducial reference based on the image information.

[00083] Once the process starts **[402]**, as described in Figures **4A** and **4B**, the system obtains **[404]** a scan data set from, for example, a CT scanner and checks **[at 406]** for a default CT scan Hounsfield unit (HU) value for the fiducial which may or may not have been provided with the scan based on a knowledge of the fiducial and the particular scanner model, and if such a threshold value is not present, then a generalized predetermined default value is employed **[408]**. Next the data is processed by removing **[at 410]** scan segments with Hounsfield data values outside expected values associated with the fiducial key values, following the collection **[at 412]** of the remaining points. If the data is empty **[at 414]**, the CT value threshold is adjusted **[at 416]**, the original value restored **[at 418]**, and the segmenting processing scan segments continues [at **410**]. Otherwise, with the existing data a center of mass is calculated **[at 420]**, along with calculating **[at 422]** the X, Y, and Z axes. If the center of mass is not at the cross point of the XYZ axes **[at 424]**, then the user is notified **[at 426]** and the process stopped **[at 428]**. If the center of mass is at the XYZ cross point then the data points are compared **[430]** with the designed fiducial data. If the cumulative error is larger than the maximum allowed error **[at 432]** then the user is notified **[at 434]** and the process ends **[at 436]**. If not, then the coordinate system is defined **[at 438]** at the XYZ cross point, and the scan profile is updated for the HU units **[at 440]**.

[00084] Turning now to Figure **4C**, image information is obtained **[442]** from the tracker, being a suitable camera or other sensor. The image information is two-dimensional and is not required to be a stereo image pair. The image information may be sourced from a single imaging device in the tracker, or may be sourced from multiple imaging devices in the tracker. It bears pointing out that the presence of multiple imaging devices in a tracker does not automatically imply stereo imaging. The image information is analyzed to determine **[444]** whether a tracking marker is present in the image information. If not, then

the user is queried **[446]** as to whether the process should continue or not. If not, then the process is ended **[448].** If the process is to continue, then the user may be notified **[450]** that no tracking marker has been found in the image information, and the process returns to obtaining image information **[442]**. If a tracking marker has been found based on the image information, or one has been attached by the user upon the above notification **[at 450]**, the offset and relative orientation of the tracking marker to the fiducial reference is obtained **[452]** from a suitable database. The term "database" is used in this specification to describe any source, amount or arrangement of such information, whether organized into a formal multi-element or multi-dimensional database or not. A single data set comprising offset value and relative orientation may suffice in a simple implementation of this embodiment of the invention and may be provided, for example, by the user or may be within a memory unit of the controller or in a separate database or memory.

[00085] The offset and relative orientation of the tracking marker is used to define the origin of a coordinate system at the fiducial reference and to determine **[454]** the three-dimensional orientation of the fiducial reference based on the image information and the registration process ends **[456]**. In order to monitor the location and orientation of the fiducial reference in real time, the process may be looped back from step **[454]** to obtain new image information from the camera **[at step 442]**. A suitable query point may be included to allow the user to terminate the process. Detailed methods for determining orientations and locations of predetermined shapes or marked tracking markers from image data are known to practitioners of the art and will not be dwelt upon here. The coordinate system so derived is then used for tracking the motion of any items bearing tracking markers in the proximity of the surgical site. Other registration systems are also contemplated, for example using current other sensory data rather than the predetermined offset, or having a fiducial with a transmission capacity.

[00086] In a further aspect of the invention, shown in the flow chart of Figure **4D**, a method **[460]** is provided for monitoring a surgical site, comprising: attaching **[462]** a

fiducial key to a location proximate to a surgical site; rigidly and removably attaching **[464]** a fiducial extension to the fiducial key; creating **[466]** a first scan of the surgical location with the fiducial key attached to the location proximate to a surgical site and the fiducial extension rigidly and removably attached to the fiducial key; rigidly attaching **[468]** a marker to the fiducial key; obtaining **[470]** image information from a non-stereo optical tracker proximate the surgical site; communicating **[472]** the image information from the optical tracker to a computing device; and calculating **[474]** and displaying a model of the surgical site by means of the computing device based on the scan, the identity of at least one of the fiducial key and the fiducial extension, and the image information received from said tracker. The attaching **[462]** the fiducial key may comprise multipodally attaching the fiducial key by means of a surgical screw and a plurality of surgical nails.

[00087] In some embodiments, vectorized tracking markers employed may be passive. The term "passive" is used in the present specification to describe markers that do not rely on any own electronic, electrical, optoelectronic, optical, magnetic, wireless, inductive, or other active signaling function or on any incorporated electronic circuit, whether powered or unpowered, to be identified, located, or tracked. The term "own active signaling" is used in this specification to describe a signal that is temporally modulated by, on, or within the tracking marker. The tracking markers do not rely on motion, location, or orientation sensing devices, whether powered or unpowered, to be tracked. They cannot sense their own motion, location, or orientation, nor have they any ability to actively communicate. They bear distinctive markings and/or have distinctive shapes that allow them to be identified, located, and tracked in three dimensions by a separate tracker such as, for example without limitation, tracker 610 of Figure 6 or tracker 508 of Figure 5 described below, both as regards their location and as regards their orientation. In some embodiments, the tracker may be an optical tracker, more particularly, a non-stereo optical tracker. In other embodiments, the tracker may be a stereo tracker. Any one or more of identification, location, and tracking of the markers is solely on the basis of their

distinctive markings and/or distinctive shapes. All fiducial references described in the present specification, may also be passive. This specifically includes fiducial references 10 and 10′ in Figures 3A to 3J, key or fiducial reference 502 of Figure 5 and fiducial reference 602 of Figure 6.

[00088]

[00089] One example of an embodiment of the invention is shown in Figure **5**. In addition to fiducial key **502** mounted at a predetermined tooth and having a rigidly mounted tracking marker **504**, an additional instrument or implement **506**, for example a hand piece which may be a dental drill, may be observed by a camera **508** serving as tracker of the monitoring system. The camera may be, for example, a non-stereo optical camera.

[00090] Another example of an embodiment of the invention is shown in Figure **6**. Surgery site **600**, for example a human stomach or chest, may have fiducial key **602** fixed to a predetermined position to support tracking marker **604**. Endoscope **606** may have further tracking markers, and biopsy needle **608** may also be present bearing a tracking marker at surgery site **600**. Sensor **610** may be for example a camera, infrared sensing device or RADAR. The camera may be, for example, a non-stereo optical camera.

[00091] Another aspect of the invention is described at the hand of Figure **7** in which a surgical guidance graphic user interface (GUI) **700** is shown for display on a suitable display screen, for example, but not limited to, display screen **224** of Figure **2**. Surgical guidance graphic user interface (GUI) **700** allows the user to track the progress and accuracy of a surgical drilling procedure as regards location, extent and angle. GUI **700** may be implemented in software for execution by processor **214** of Figure **2** based on information gathered and processed by the surgical hardware and software monitoring system of embodiments of the present invention.

[00092] Figure **5** shows a suitable implementation of the surgical hardware and software monitoring system employing, for example, a suitable surgical implement such as surgical drill **506** to be guided by means of the GUI **700**. Surgical drill **506** bears a suitable tracking marker of the type shown as tracking marker **12** in Figure **3a**. As described above, processor **214** obtains image information about the surgical site obtained from tracker **508** of the system. The image information contains information about the tracking marker that allows processor **214** to determine the exact three-dimensional position and orientation of the tracking marker and thereby the exact three-dimensional position and orientation of drill **506**.

[00093] Processor **214** may display GUI **700** in a separate graphic window on display screen **224**. In other embodiments processor **214** may display GUI **700** in the same graphic window as where it displays the surgical site. In yet further embodiments processor **214** may orient the surgical site within the graphic window of display screen **224** so as to align the image of the surgical site with GUI **700**. In yet further embodiments processor **214** may display GUI **700** on a display screen that is separate or distinct from the display screen showing the surgical site.

[00094] Returning now to GUI **700** of Figure **7**, graphic crosshairs **710a** and **710b** cross at the point where a surgical hole is to be drilled for fitting, for example, a surgical screw. Graphic aiming rings **712**, **714**, **716** and **718** are arranged concentrically about the crossing point of graphic crosshairs **710a** and **710b**. Graphic drilling depth gauge **740** comprises a number of graphic depth indicators **742a** to **742g**. A graphic rendition of the tip of the bit of drill **506** may be displayed on GUI **700** to graphically indicate exactly what instantaneous drilling depth has been attained at any moment in time. In one implementation, graphic depth indicator **742a** may represent the maximum depth to which the drill bit is planned to penetrate. In this way, the penetration depth of the drill bit may be tracked "live", thereby providing the user clarity on the consequences of his manipulation of drill **506**.

[00095] Broken graphic circle **722** represents the radial circumference of the bit of drill **506**, disposed such that the center of graphic circle **722** shows the point where the drill bit is actually in contact with the surgical site. In this specification we shall use the term "graphic drill bit perimeter" to describe circle **722**. This is to be contrasted with the crossing point of graphic crosshairs **710a** and **710b** which are located at the point where the drill bit is theoretically intended to make contact with the surgical site. To aid in the aiming process, one of the graphic aiming rings, chosen to be graphic aiming ring **712** in Figure **7**, may be displayed with the same diameter as that of the drill bit as represented by broken graphic circle **722**. Graphic aiming rings **714**, **716** and **718** may be accordingly adjusted by processor **214** to have diameters of fixed ratio with respect to graphic aiming ring **712**.

[00096] Processor **214** may be pre-programmed with the data describing the drill bit, including but not limited to its diameter and length. The data may be entered permanently into a surgical screw database accessible by processor **214**.

[00097] Thus far, means have been described to track the contact point of the drill bit on the surgical site and the depth of penetration of the drill bit into the surgical site. However, the angle of incidence of the drill bit upon the surgical site is a third quantity that requires tracking. Since processor **214** has access to the scan data and the image information of the surgical site, an allowed variation of angle of incidence may be determined by processor **214**, or the allowed variation of angle of incidence may be specified by the user. In Figure **7**, the allowed variation of angle of incidence is graphically shown as the area enclosed by line **732**. Various graphical means may be employed to represent the allowed variation of angle of incidence. In Figure **7** closed graphic curve **732** is taken to be a projection onto the plane of crosshairs **710a** and **710b** of a point along the axis of the bit of drill **506**. Solid dot **730** shows the instantaneous location of the projection of the point in question along the axis of the bit. In some embodiments, dot **730** may be graphically rendered as a circle or other symbol. In the present specification the term "angle indicator" is used to describe

dot (or alternative symbol) **730**. The user therefore knows to maintain angle indicator **730** inside closed graphic curve **732**, which is referred to in this specification as the "angular perimeter".

[00098] In some embodiments, angle indicator **730** may be graphically rendered as a symbol different from a dot. In some embodiments, angle indicator **730** may be rendered in a different shape or color when it leaves the area defined by angular perimeter **732**. This provides the user with a visible warning that the angle indicator has moved out of the allowable range. Angular perimeter **732** may be automatically updated "live" by processor **214** based on latest information regarding the actual location **722** of the bit of drill **506** and information regarding the surgical site. In keeping with this, the angle indicator is always rendered based on the actual position of the tip of the implement, which, in the case of Figure **7**, is drill **506**. In general angular perimeter **732** will be a closed graphic curve of complex shape, dictated by restrictions induced by the physiology of the surgical site.

[00099] It will be understood by practitioners in the field that the extent of closed graphic curve **732** is dictated by the choice of point along the axis of the drill bit that is projected onto the plane of crosshairs **710a** and **710b**. The further that point is from the operating tip of the drill bit, the larger the extent of closed graphic curve **732**. The point along the axis of the drill bit is therefore maintained as fixed for a particular surgical procedure, but may be varied from procedure to procedure, as elected by the user.

[000100] The surgical guidance graphic user interface (GUI) **700** described in the present specification is not limited in its use to the tracking of surgical drills, and may be applied also to the tracking of other implements employed in surgery and medicine, particularly rigid implements that allow a fixed spatial relationship between an attached

tracking marker and the rigid implement in question. One particularly useful application is in tracking dental drills during dental surgery.

[000101] In a further aspect of the invention, shown at the hand of the flow chart of Figure **8**, method **[800]** is provided for monitoring a surgical site, comprising: attaching **[810]** a fiducial key to a location proximate to a surgical site; creating **[820]** a first scan of the surgical location with the fiducial key attached to the location proximate to a surgical site; rigidly attaching **[830]** a first tracking marker to the fiducial key; rigidly attaching **[840]** a second tracking marker to a surgical implement; obtaining **[850]** image information from a non-stereo optical tracker proximate the surgical site; communicating **[860]** the image information from the optical tracker to a computing device; calculating **[870]** and displaying **[880]** on a display system by means of the computing device a model of the surgical site based on the scan, the identity of the fiducial key, and the image information received from said tracker; and rendering **[890]** on the display system a surgical guidance graphic user interface showing at least a planned location for the surgical implement to impinge on the area of surgical patient, an actual instantaneous impingement location for the surgical implement, an allowed range of angles of incidence for the surgical implement to impinge on the instantaneous impingement location, and an actual instantaneous angle of incidence of the surgical implement. The determining the angles and locations may be based on relative positions and orientations of the first and second markers. In some embodiments, in which the surgical implement is a surgical drill, the rendering the surgical guidance graphic user interface further comprises rendering on the display system a graphic drilling depth gauge and a graphic depth indicator depicting on the drilling depth gauge a position of a working tip of a bit of the surgical drill.

WHAT IS CLAIMED IS:

1. A method for monitoring a surgical site, comprising:

attaching a fiducial key (602) to a location proximate to a surgical site (600);

creating a first scan of the surgical site with the fiducial key attached to the location proximate to a surgical site;

rigidly attaching a first tracking marker (604) to the fiducial key;

rigidly attaching a second tracking marker (606,608) to a surgical implement;

obtaining image information from an optical tracker (610) proximate the surgical site;

communicating the image information from the optical tracker to a computing device (210);

calculating and displaying on a display system (226), using the computing device, a model of the surgical site based on the scan, the identity of the fiducial key, and the image information received from said tracker; and

rendering on the display system a surgical guidance graphic user interface (700) showing at least a planned location for the surgical implement to impinge on the area of surgical patient, an actual instantaneous impingement location for the surgical implement, an allowed range of angles of incidence for the surgical implement to impinge on the instantaneous impingement location, and an actual instantaneous angle of incidence of the surgical implement.

2. The method of claim 1, further comprising determining the angles and locations based on relative positions and orientations of the first and second markers.

3. The method of claim 1 or 2, wherein the surgical implement is a surgical drill and the rendering the surgical guidance graphic user interface further comprises rendering on the display system:

a graphic drilling depth gauge (740); and

a graphic depth indicator depicting on the drilling depth gauge a position of a working tip of a bit of the surgical drill.

4. The method of claim 3 wherein the depth indicator is determinable by the processor from the relative positions and orientations of the first and second markers.

5. The method of claim 4 wherein:

the first marker is fixed to the area of surgical patient via a fiducial reference detectable in a scan of the area of surgical patient; and

the processor is configured to determine the relative positions and orientations of the first and second markers based on scan data from the scan and on image information about the area of surgical patient obtainable from a tracker in communication with computer system.

6. A position monitoring system for a surgical procedure comprising:

a fiducial reference (602) adapted to be fixed to an area of surgical patient;

a first marker (604) attached to the fiducial reference in a predetermined fixed relative position and orientation;

a second marker (606,608) adapted to be fixed to a surgical implement in a predetermined fixed relative position and orientation;

an optical tracker (610) able to determine the position and orientation of the

first marker;

one or more display systems (224), at least a first of the one or more display systems adapted to show a current position and orientation of the fiducial reference relative to the patient scan data during the surgical procedure;

a computer system (210) in communication with the tracker and the one or more display systems, the computer system having scan data of the patient with the fiducial reference fixed to the area of surgical patient, the computer system comprising:

a processor with memory;

a software program having a series of instructions which when executed by the processor determines the relative position and orientation of the first and second markers based on image information from the tracker, and relates a current position and orientation of the fiducial reference to the scan data; and

a surgical guidance graphic user interface software which when executed by the processor renders on at least one of the first and a second of the one or more display systems a surgical guidance graphic user interface (700) showing at least a planned location for the surgical implement to impinge on the area of surgical patient, an actual instantaneous impingement location for the surgical implement, an allowed range of angles of incidence for the surgical implement to impinge on the instantaneous impingement location, and an actual instantaneous angle of incidence of the surgical implement;

wherein the locations and angles of incidence are based on the relative position and orientation of the first and second markers.

7. The position monitoring system of claim 6 wherein the surgical implement is a surgical drill and the system further comprising:

a graphic drilling depth gauge (740); and

a graphic depth indicator depicting on the drilling depth gauge a position of a working tip of a bit of the surgical drill.

8. The position monitoring system of claim 7 wherein the depth indicator is determinable by the processor from the relative positions and orientations of the first and second markers.

9. The position monitoring system of claim 8 wherein:

the first marker is fixed to the area of surgical patient via a fiducial reference detectable in a scan of the area of surgical patient; and

the processor is configured to determine the relative positions and orientations of the first and second markers based on scan data from the scan and on image information about the area of surgical patient obtainable from a tracker in communication with computer system.

10. A surgical guidance graphic user interface software stored as a series of instructions stored on nonvolatile memory which when executed by a processor of a computer system in communication with one or more display systems renders on at least one of a first and a second of the one or more display systems a surgical guidance graphic user interface (700) comprising at least:

a planned location (732) for a surgical implement to impinge on an area of surgical patient;

an instantaneous actual impingement location (730) for the surgical implement;

an allowed range of angles of incidence for the surgical implement to impinge on the instantaneous impingement location; and

an instantaneous actual angle of incidence of the surgical implement;

wherein the locations and angles of incidence are determinable by the processor from relative positions and orientations of first and second markers fixed to the area of surgical patient and to the surgical instrument respectively.

11. The surgical guidance graphic user interface software of claim 10 wherein the surgical implement is a surgical drill and the surgical guidance graphic user interface further comprises:

a graphic drilling depth gauge (740); and

a graphic depth indicator depicting on the drilling depth gauge a position of a working tip of a bit of the surgical drill.

12. The surgical guidance graphic user interface software of claim 11 wherein the depth indicator is determinable by the processor from the relative positions and orientations of the first and second markers.

13. The surgical guidance graphic user interface software of claim 12 wherein:

the first marker is fixed to the area of surgical patient via a fiducial reference detectable in a scan of the area of surgical patient; and

the processor is configured to determine the relative positions and orientations of the first and second markers based on scan data from the scan and on image information about the area of surgical patient obtainable from a tracker in communication with computer system.

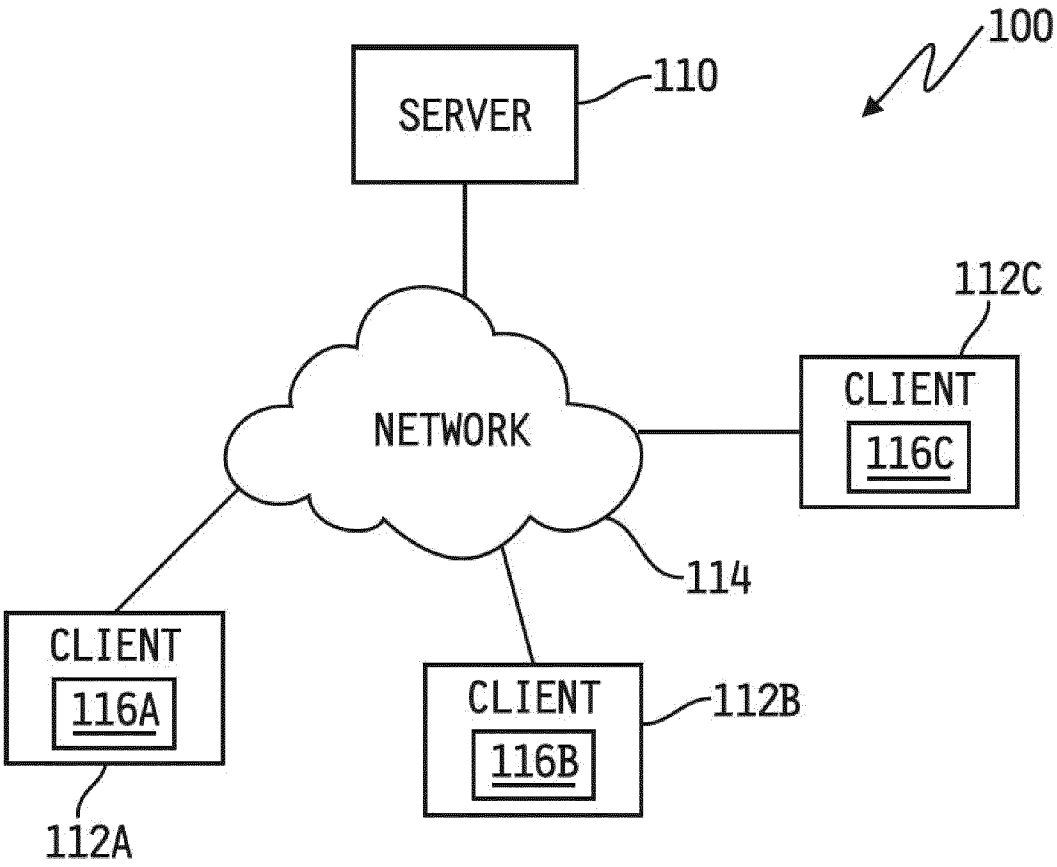
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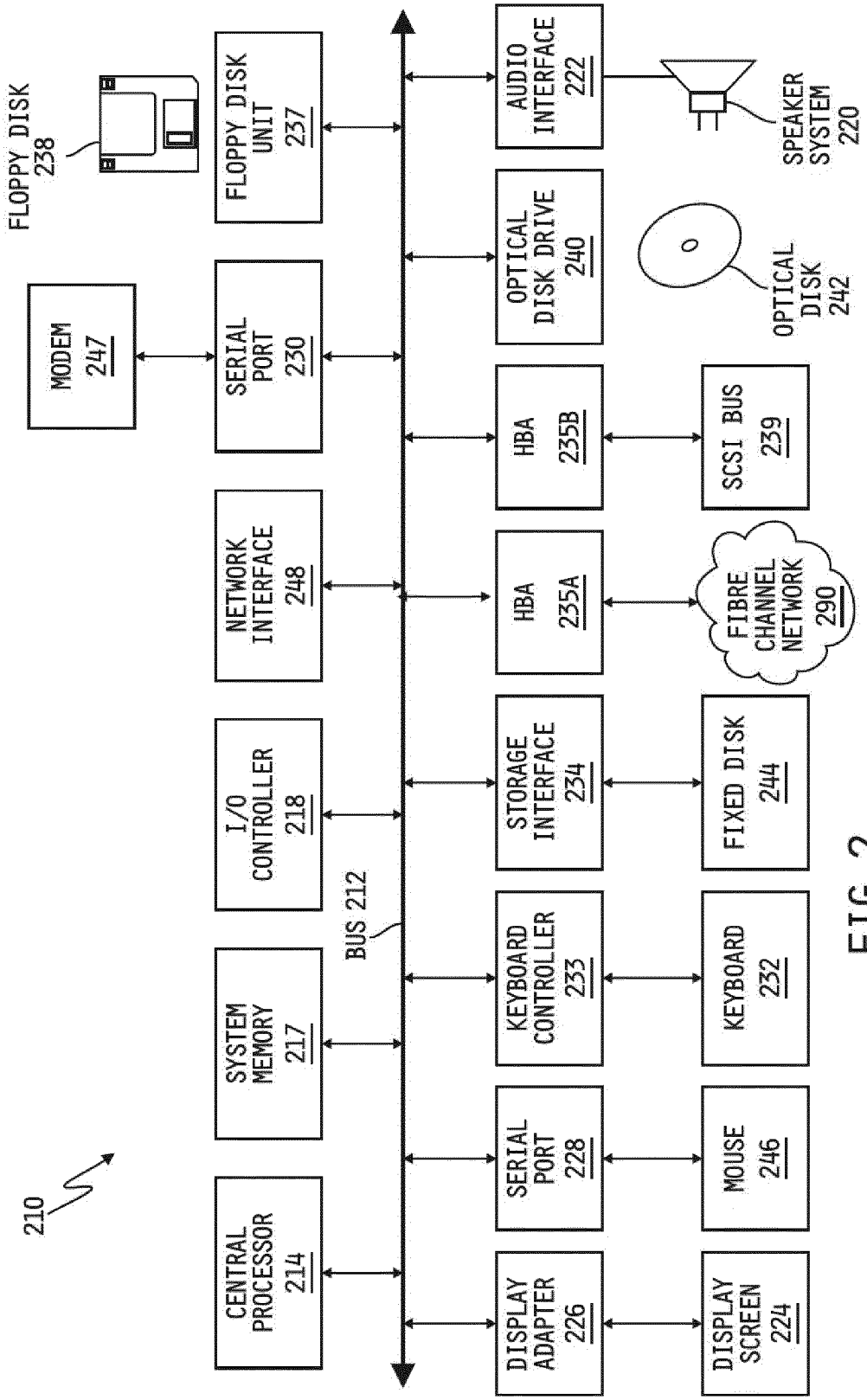
FIG.1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CENTRAL PROCESSOR 214
SYSTEM MEMORY 217
I/O CONTROLLER 218
NETWORK INTERFACE 248
SERIAL PORT 230
FLOPPY DISK UNIT 237
FLOPPY DISK 238
MODEM 247
BUS 212
DISPLAY ADAPTER 226
SERIAL PORT 228
KEYBOARD CONTROLLER 233
STORAGE INTERFACE 234
HBA 235A
HBA 235B
OPTICAL DISK DRIVE 240
AUDIO INTERFACE 222
DISPLAY SCREEN 224
MOUSE 246
KEYBOARD 232
FIXED DISK 244
FIBRE CHANNEL NETWORK 290
SCSI BUS 239
OPTICAL DISK 242
SPEAKER SYSTEM 220

FIG.2

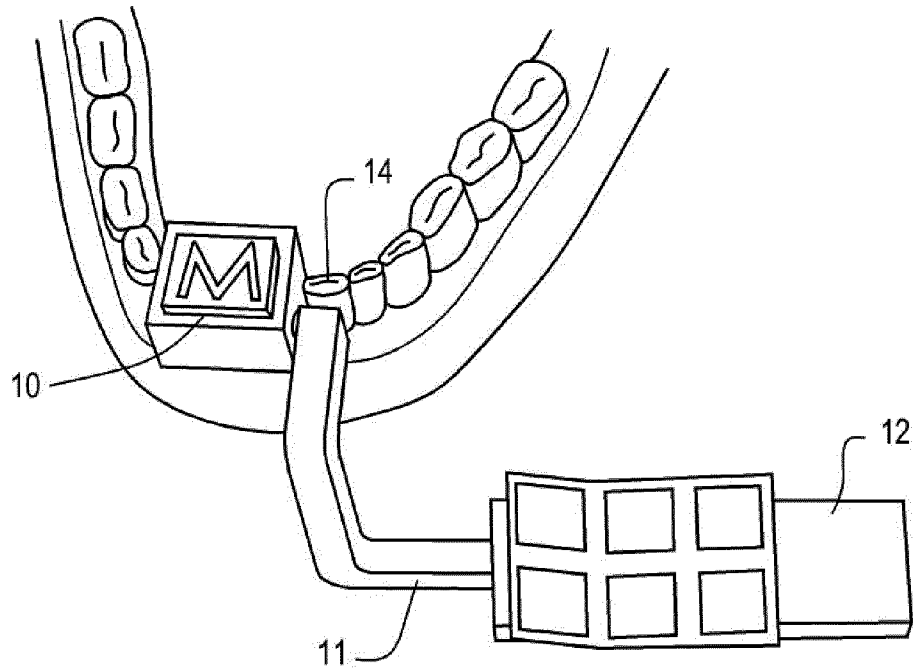

Fig. 3A

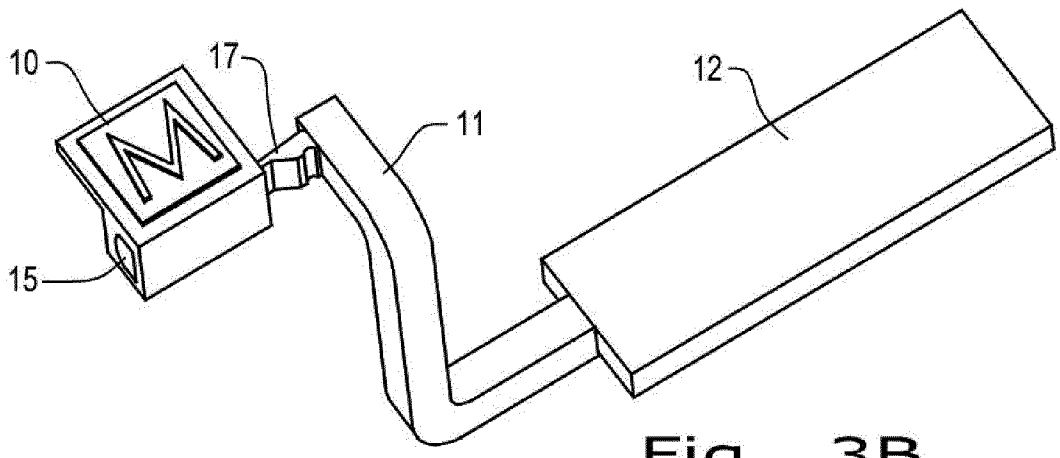

Fig. 3B

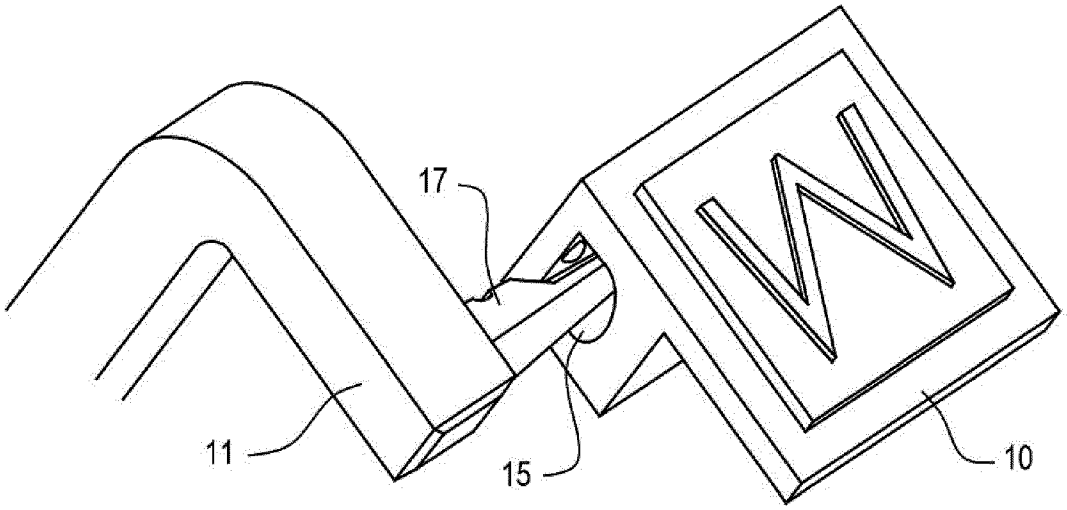

Fig. 3C

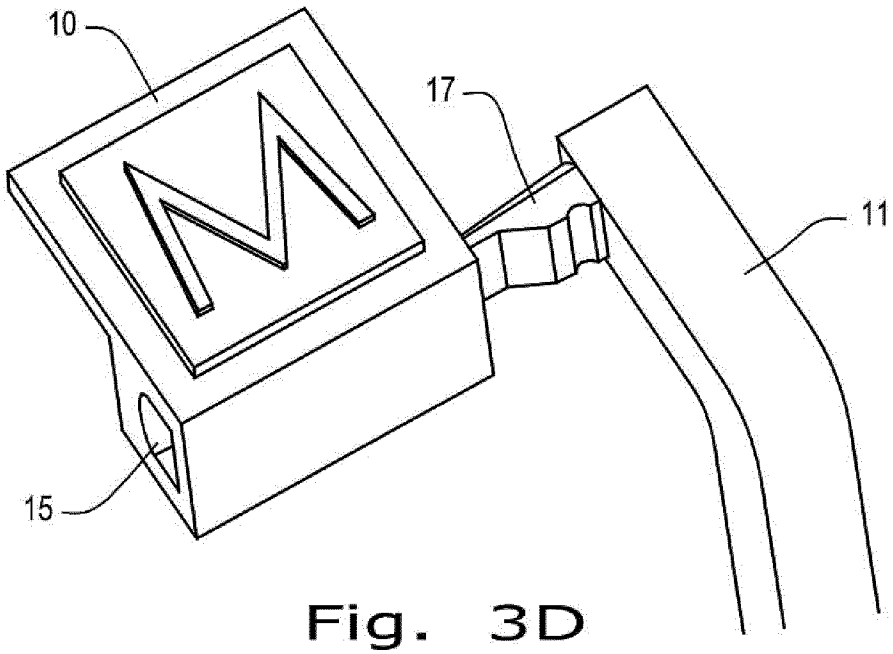

Fig. 3D

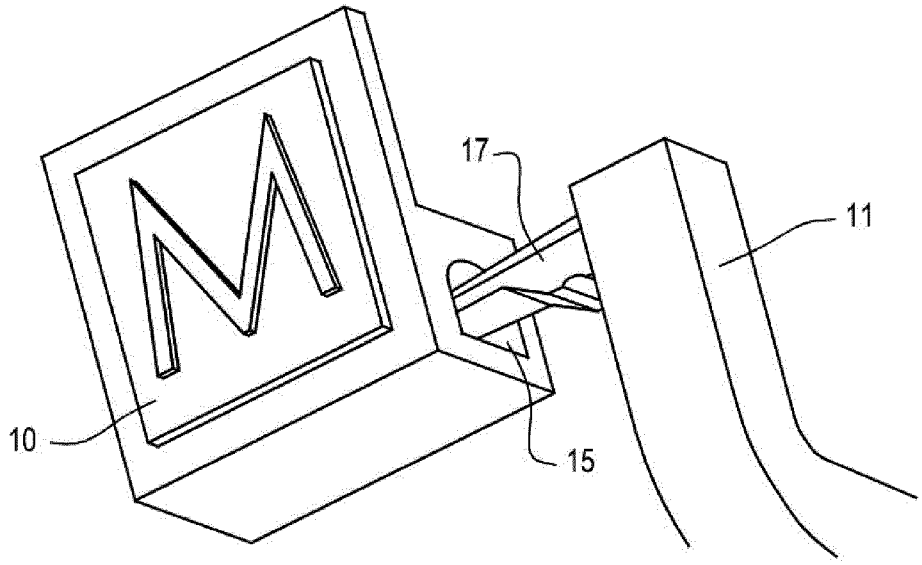

Fig. 3E

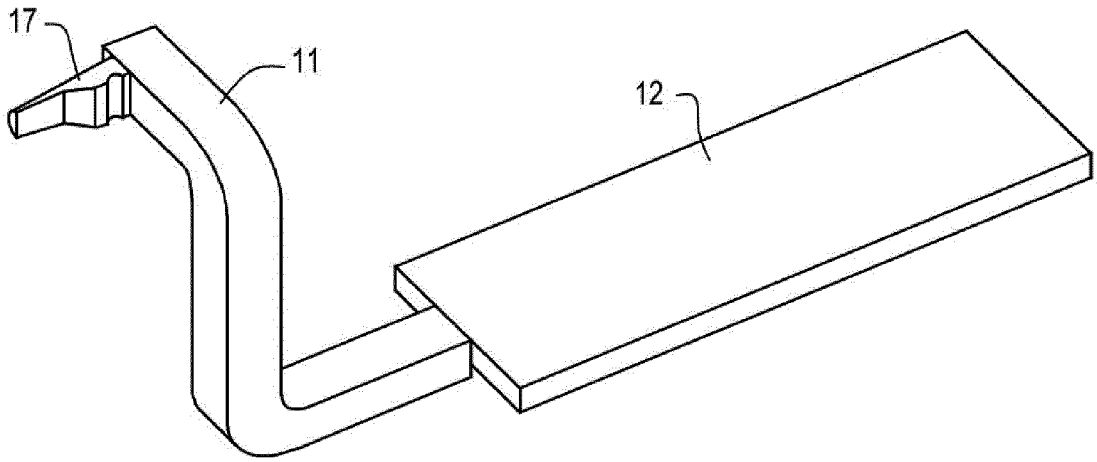

Fig. 3F

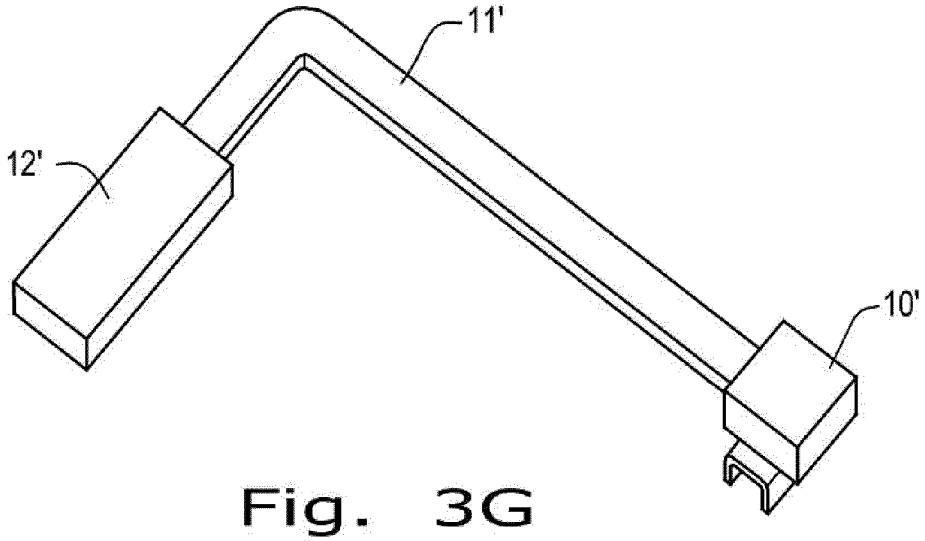

Fig. 3G

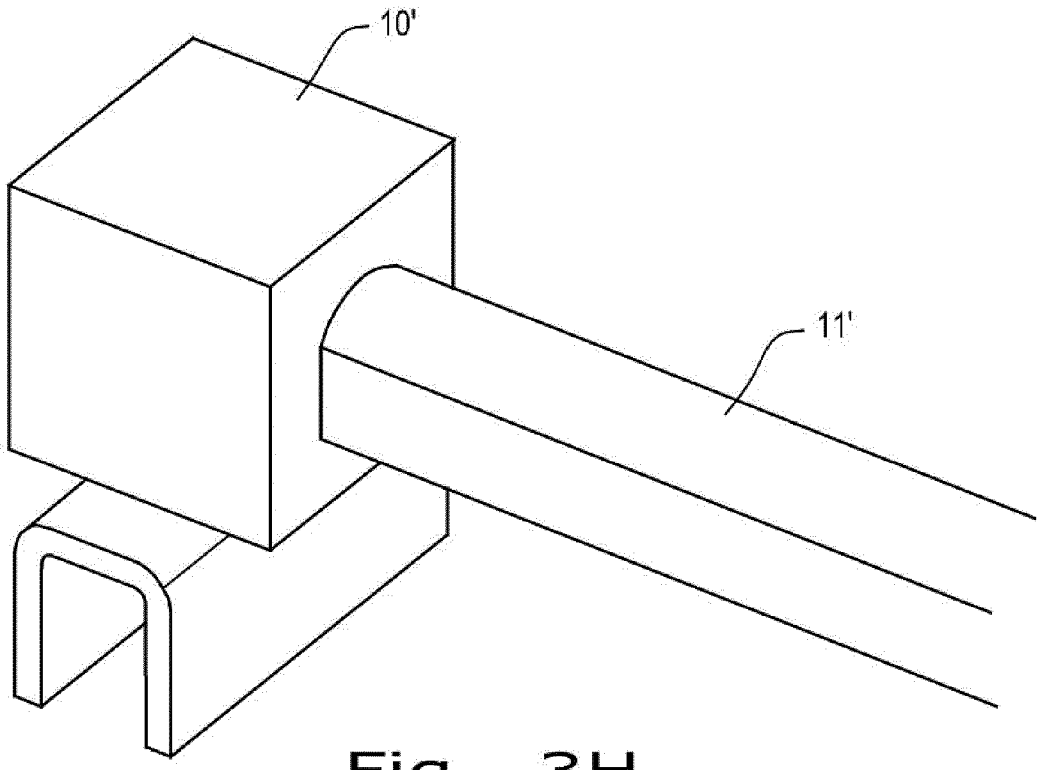

Fig. 3H

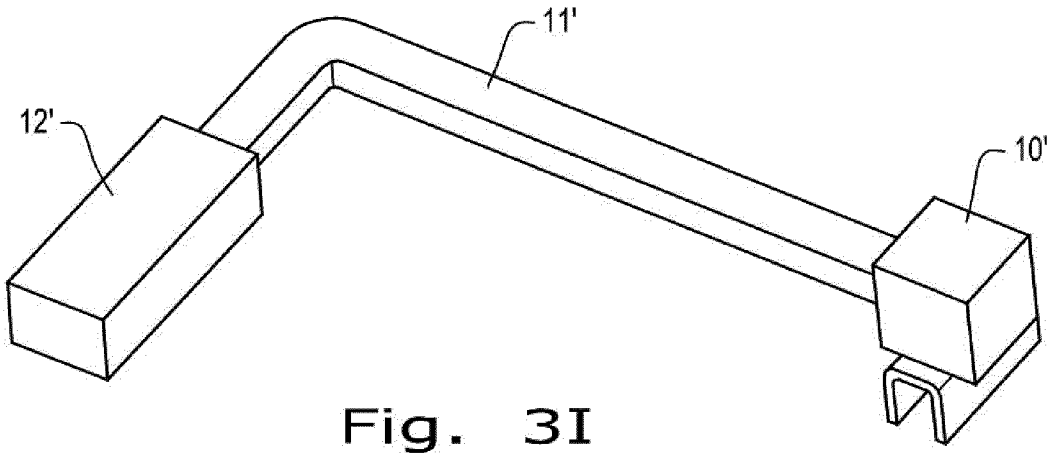

Fig. 3I

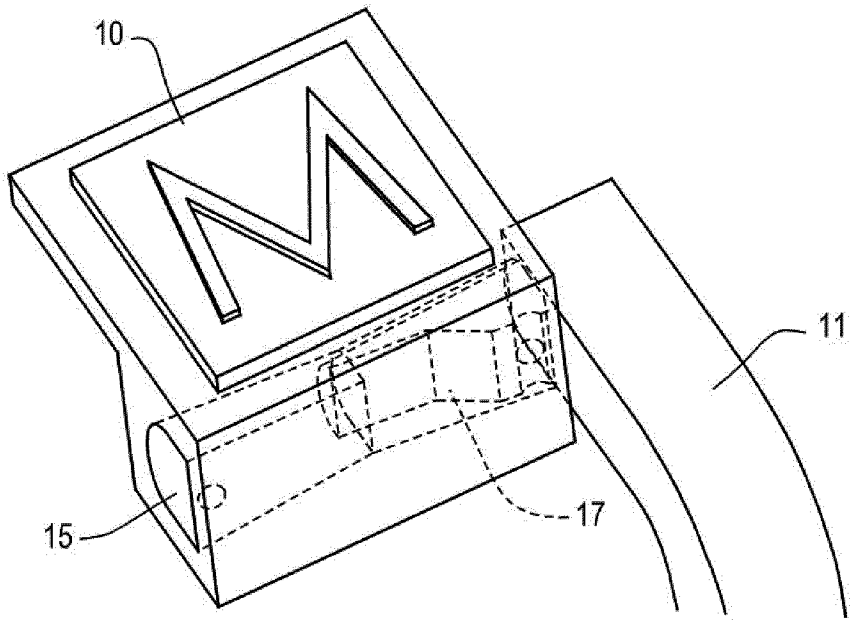

Fig. 3J

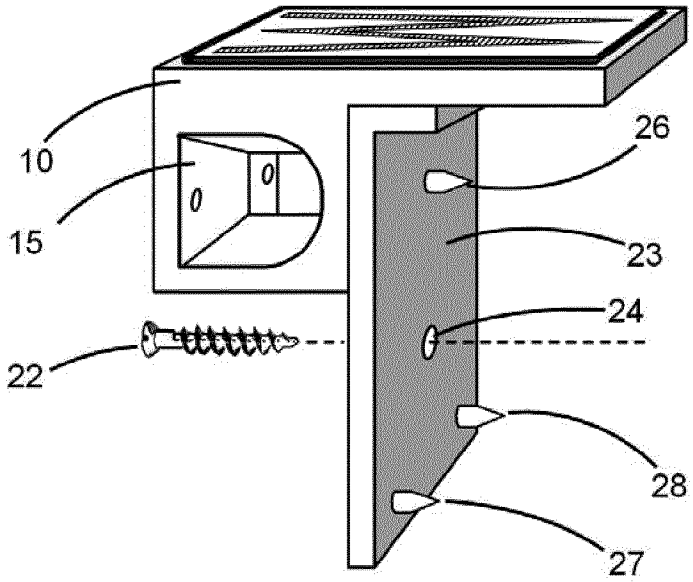

Fig. 3K

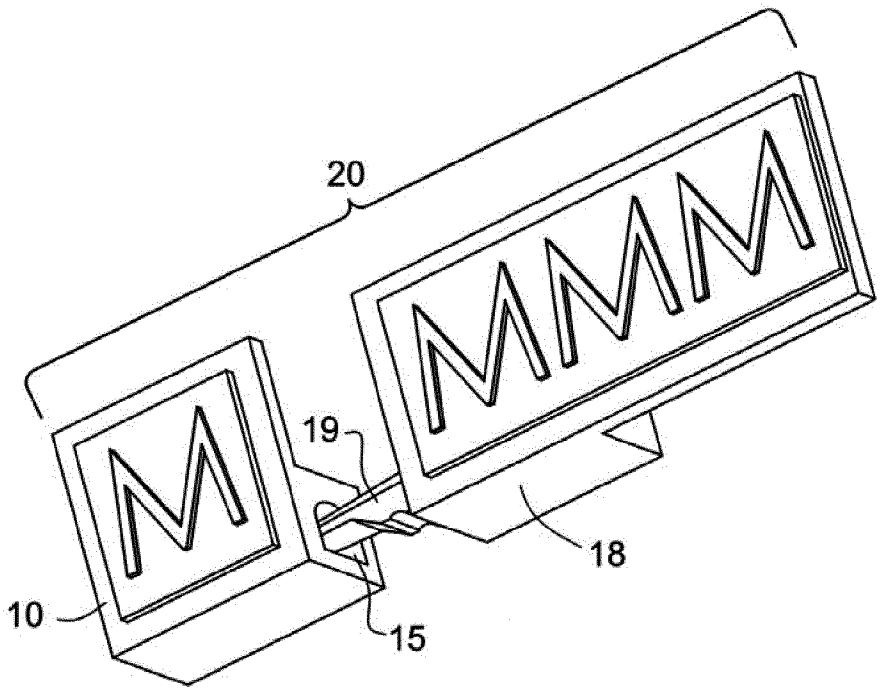

Fig. 3L

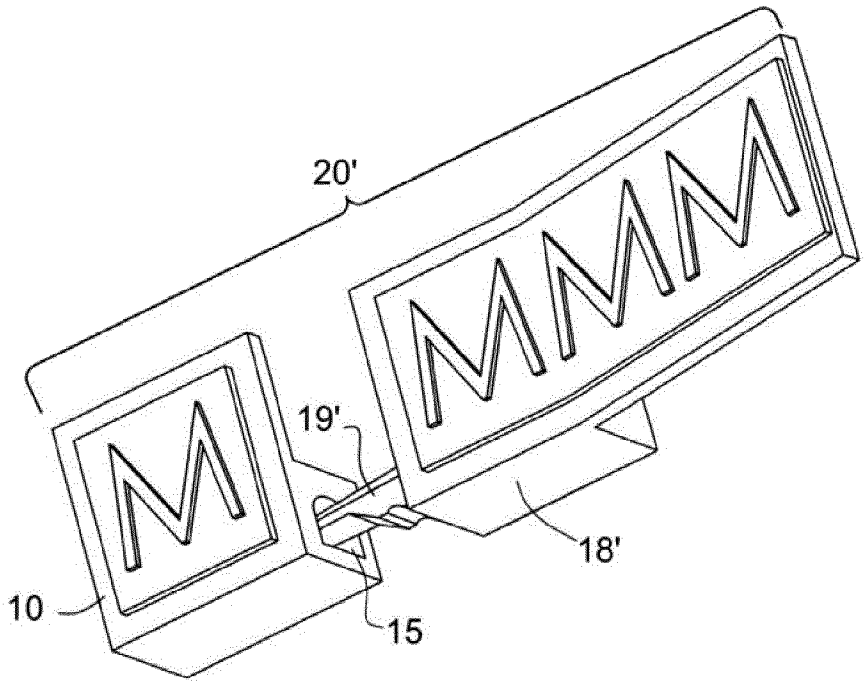

Fig. 3M

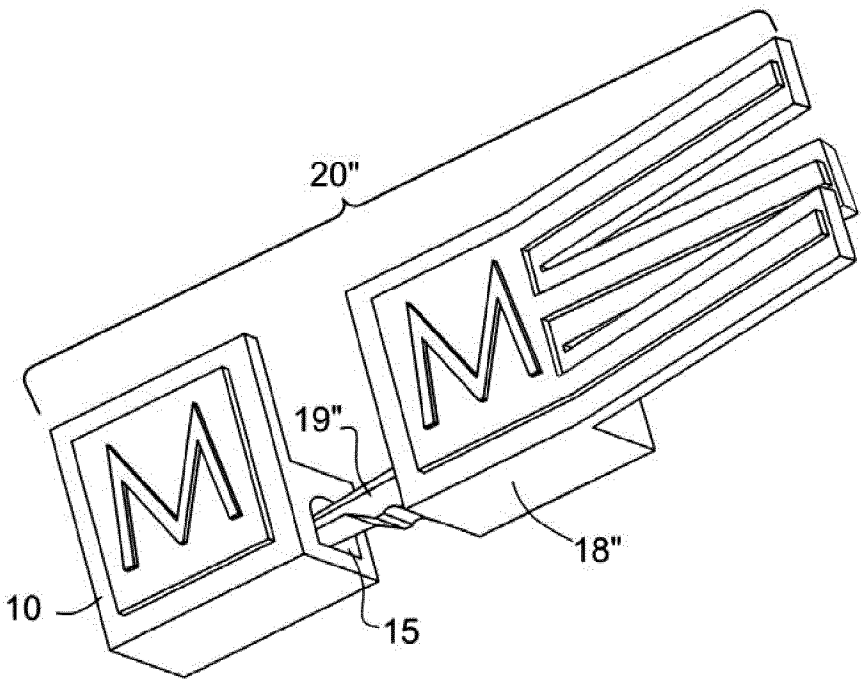

Fig. 3N

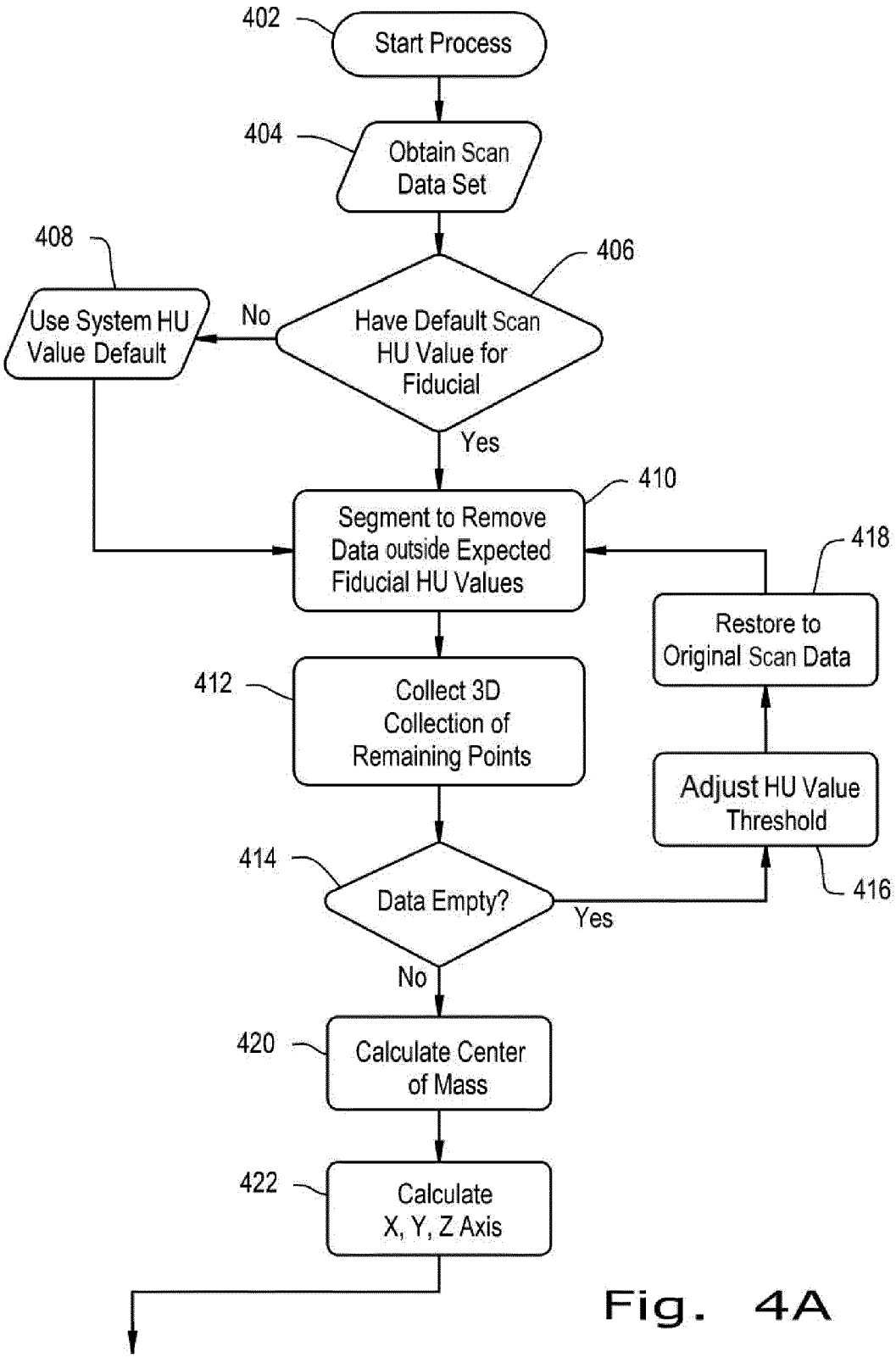
402
Start Process
404
Obtain Scan Data Set
406
Have Default Scan HU Value for Fiducial
No
408
Use System HU Value Default
Yes
410
Segment to Remove Data outside Expected Fiducial HU Values
412
Collect 3D Collection of Remaining Points
414
Data Empty?
Yes
No
416
Adjust HU Value Threshold
418
Restore to Original Scan Data
420
Calculate Center of Mass
422
Calculate X, Y, Z Axis

Fig. 4A

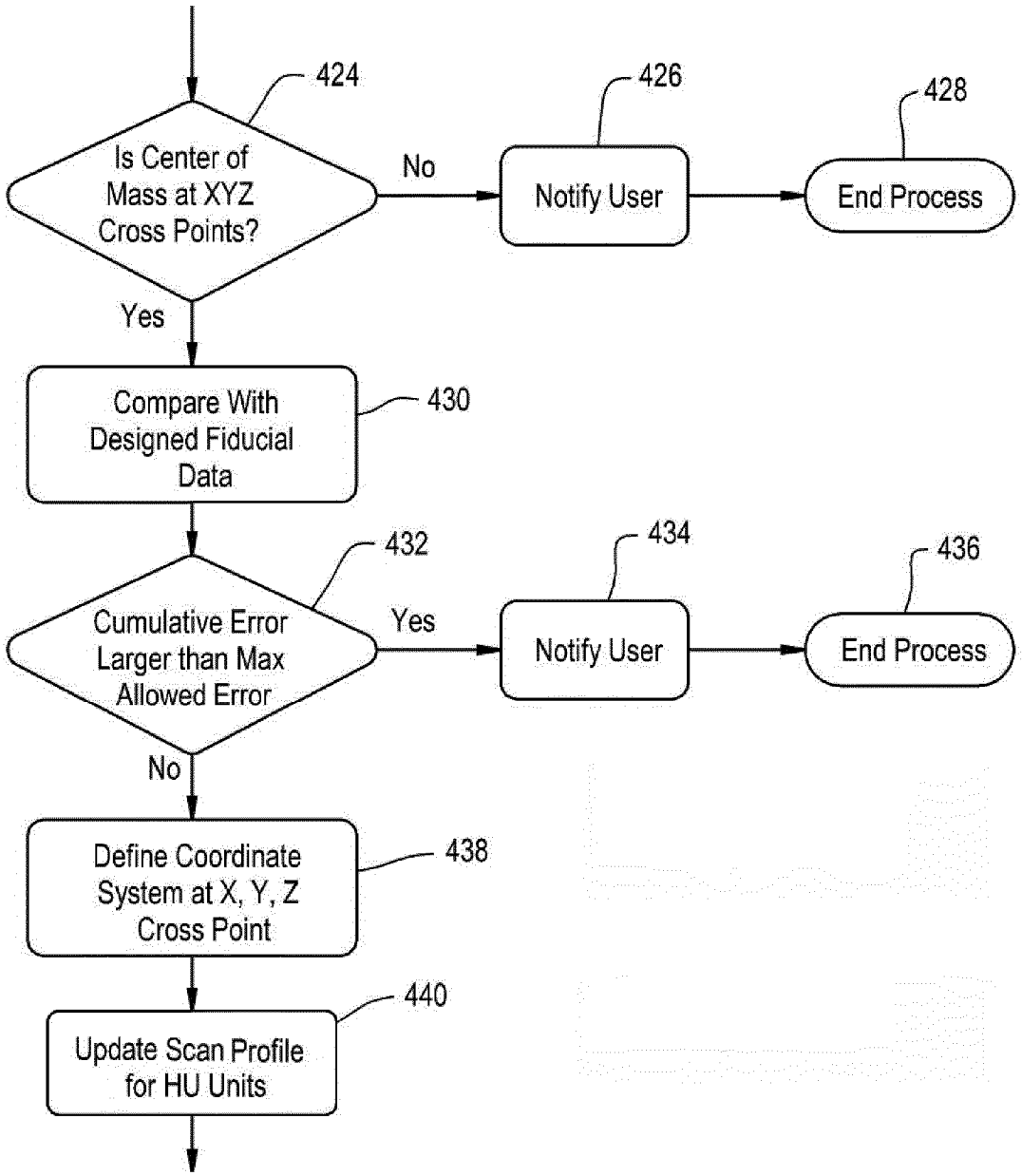
424
Is Center of Mass at XYZ Cross Points?
No
426
Notify User
428
End Process
Yes
Compare With Designed Fiducial Data
430
432
Cumulative Error Larger than Max Allowed Error
Yes
434
Notify User
436
End Process
No
Define Coordinate System at X, Y, Z Cross Point
438
440
Update Scan Profile for HU Units

Fig. 4B

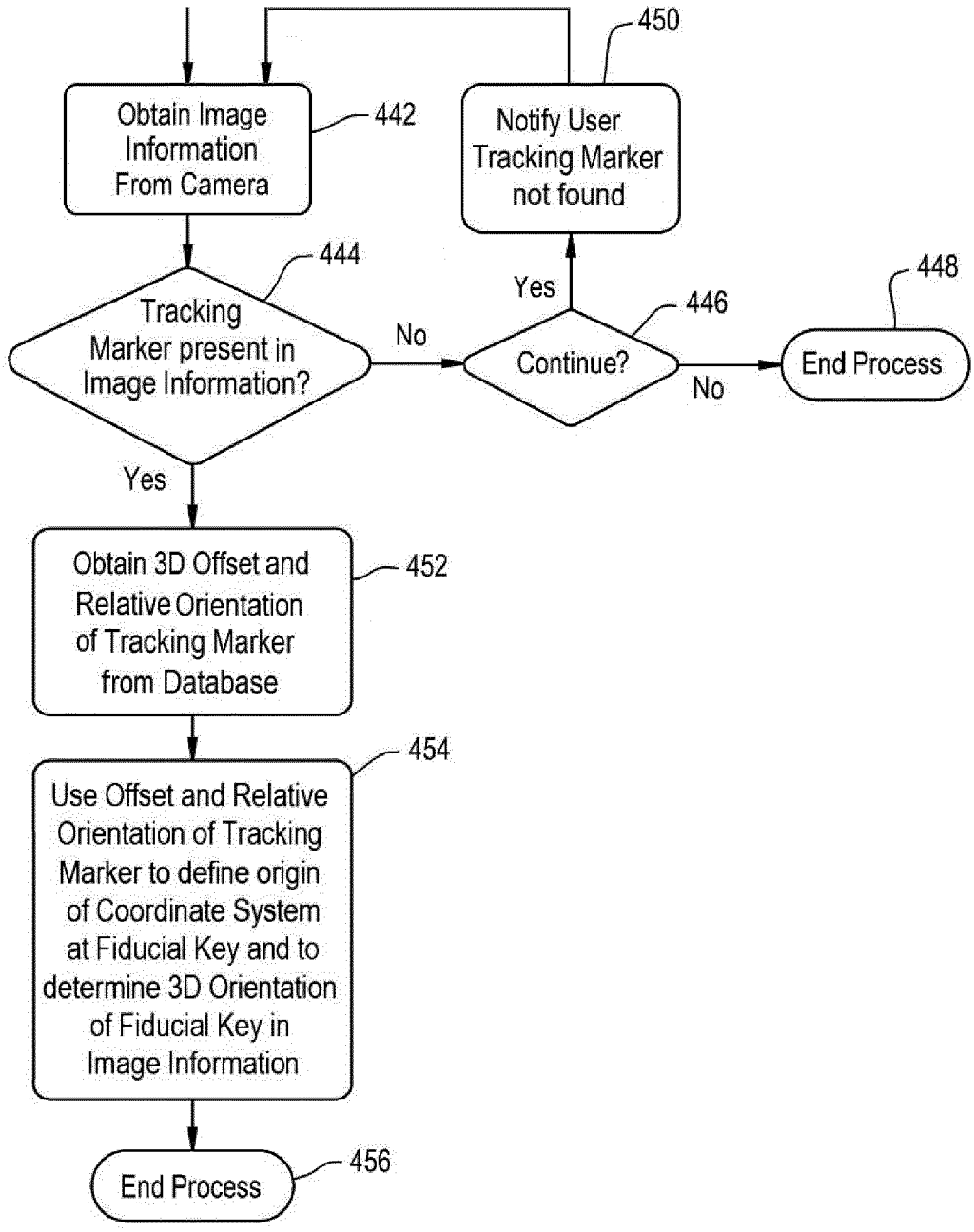
Obtain Image Information From Camera
442
Notify User Tracking Marker not found
450
Tracking Marker present in Image Information?
444
No
Yes
Continue?
446
Yes
No
End Process
448
Obtain 3D Offset and Relative Orientation of Tracking Marker from Database
452
Use Offset and Relative Orientation of Tracking Marker to define origin of Coordinate System at Fiducial Key and to determine 3D Orientation of Fiducial Key in Image Information
454
End Process
456

Fig. 4C

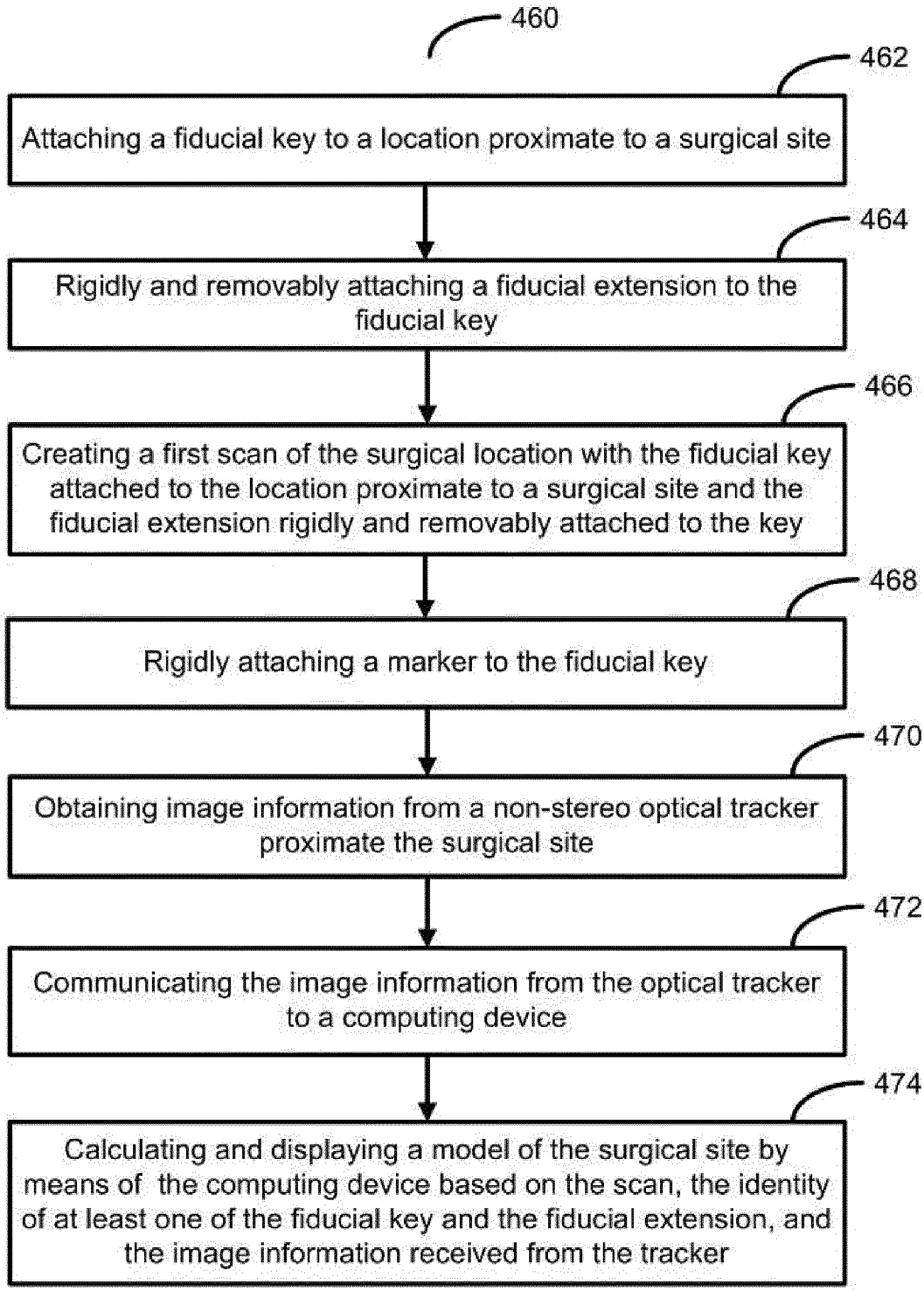
460
462
Attaching a fiducial key to a location proximate to a surgical site
464
Rigidly and removably attaching a fiducial extension to the fiducial key
466
Creating a first scan of the surgical location with the fiducial key attached to the location proximate to a surgical site and the fiducial extension rigidly and removably attached to the key
468
Rigidly attaching a marker to the fiducial key
470
Obtaining image information from a non-stereo optical tracker proximate the surgical site
472
Communicating the image information from the optical tracker to a computing device
474
Calculating and displaying a model of the surgical site by means of the computing device based on the scan, the identity of at least one of the fiducial key and the fiducial extension, and the image information received from the tracker

Fig. 4D

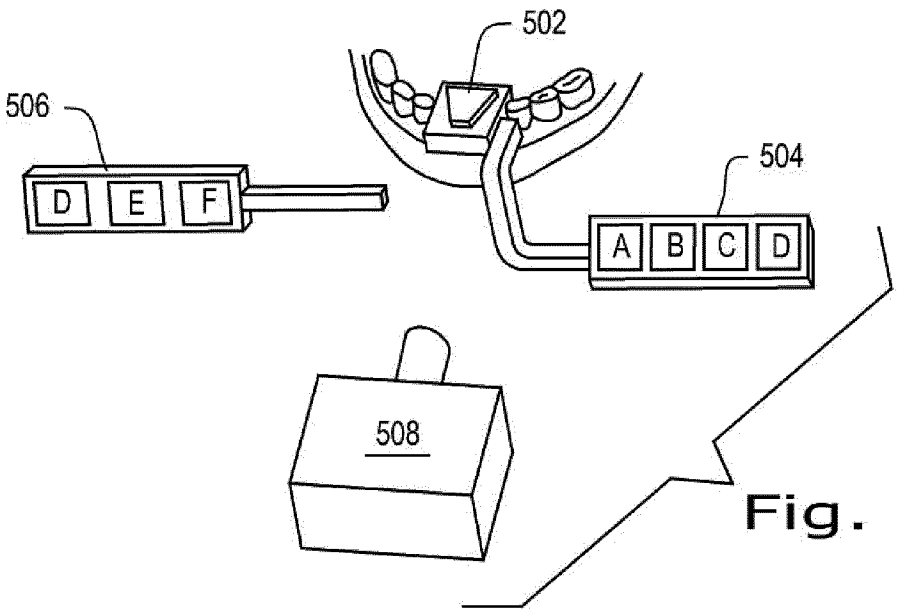

Fig. 5

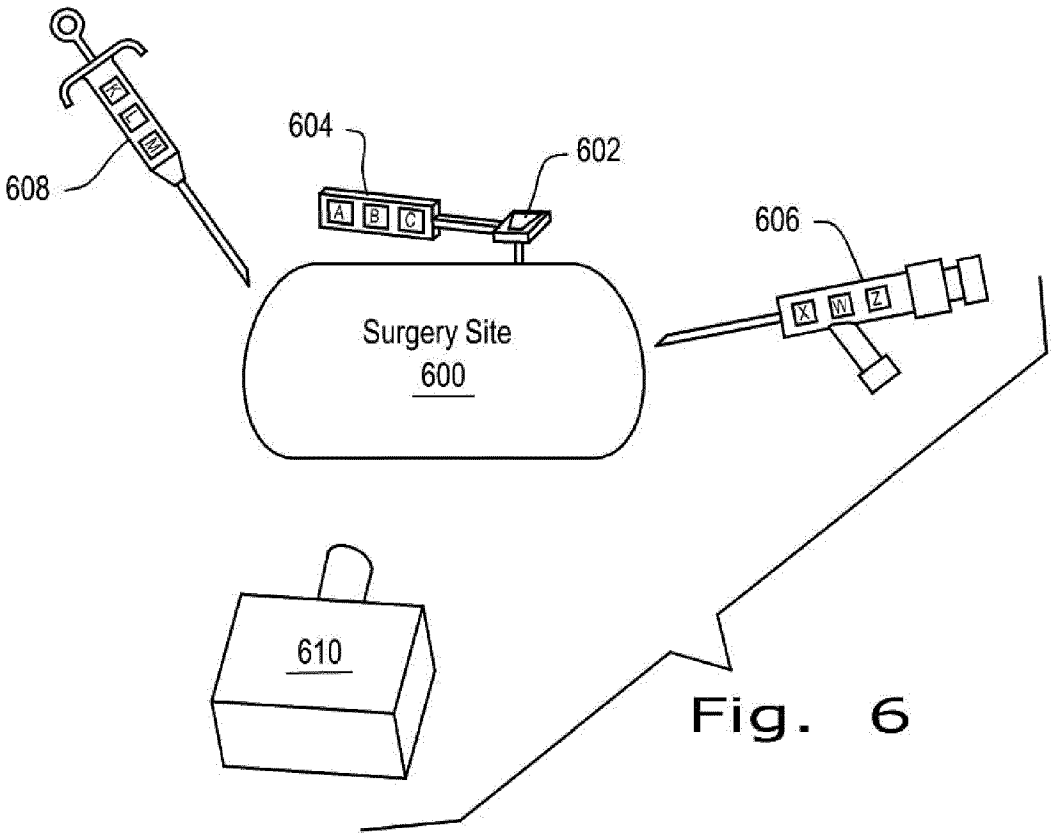

Fig. 6

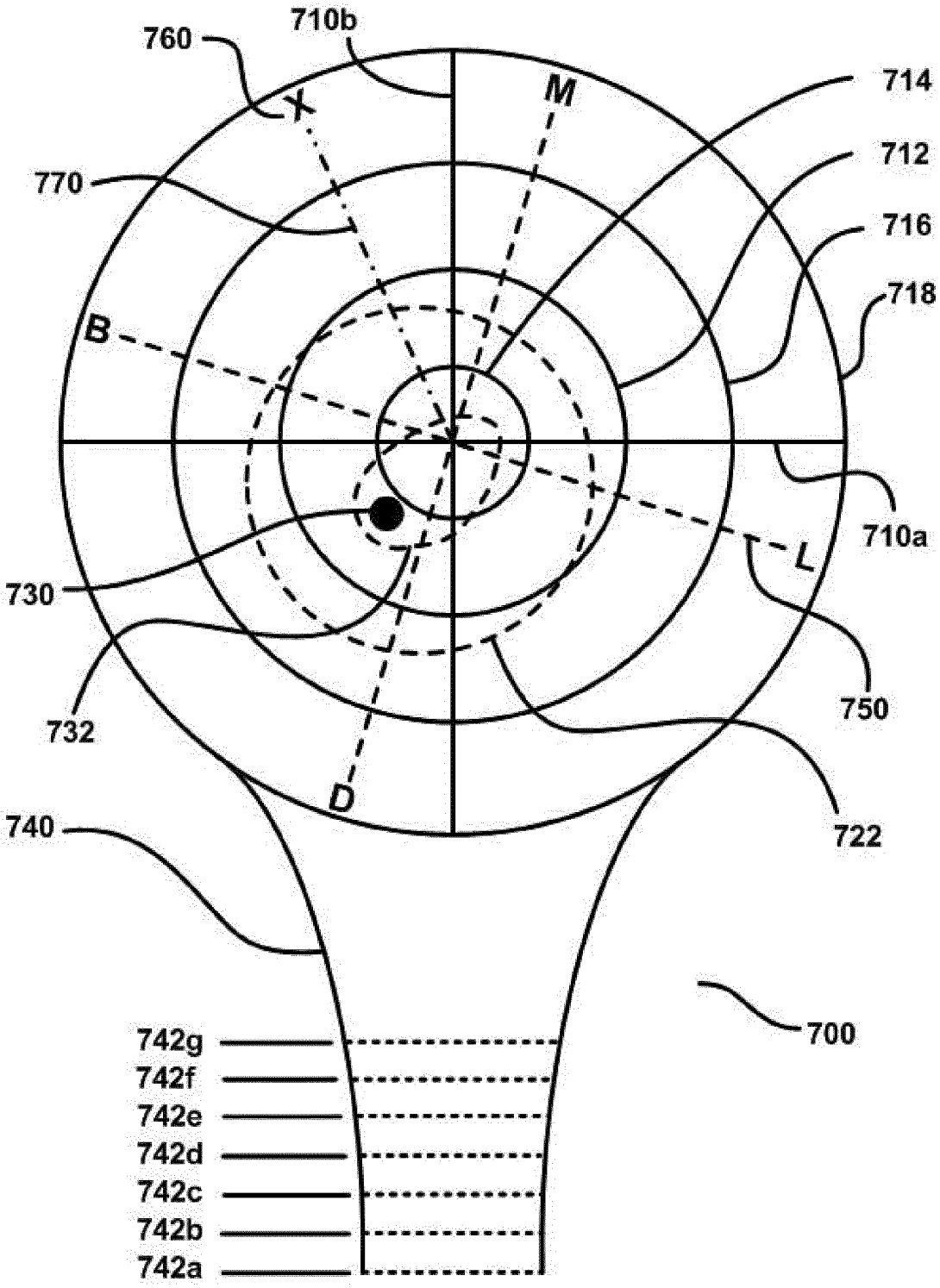
760
710b
714
X
M
712
770
716
718
B
710a
L
730
750
732
D
740
722
700
742g
742f
742e
742d
742c
742b
742a

Fig. 7

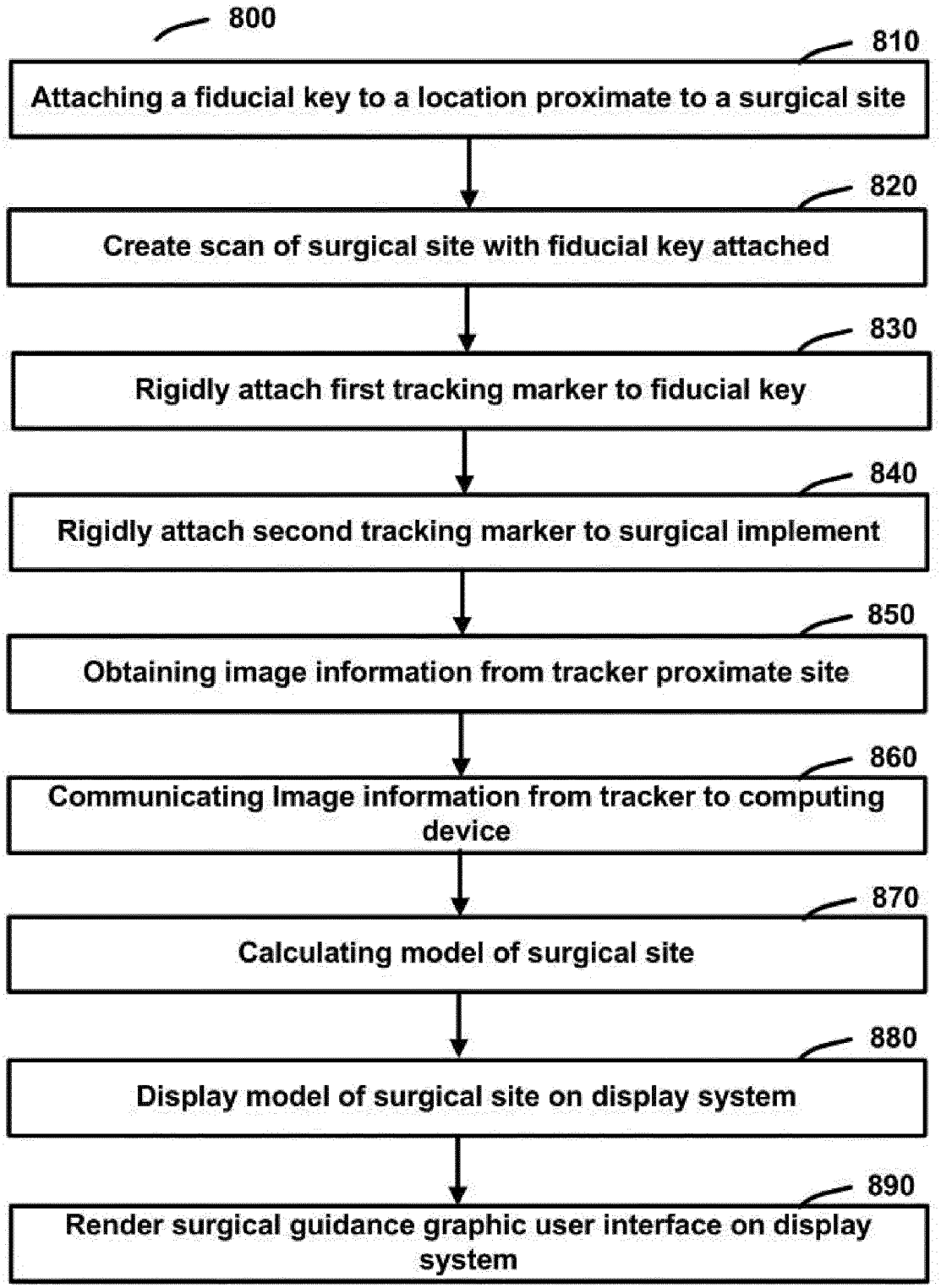
800
810
Attaching a fiducial key to a location proximate to a surgical site
820
Create scan of surgical site with fiducial key attached
830
Rigidly attach first tracking marker to fiducial key
840
Rigidly attach second tracking marker to surgical implement
850
Obtaining image information from tracker proximate site
860
Communicating Image information from tracker to computing device
870
Calculating model of surgical site
880
Display model of surgical site on display system
890
Render surgical guidance graphic user interface on display system

Fig. 8

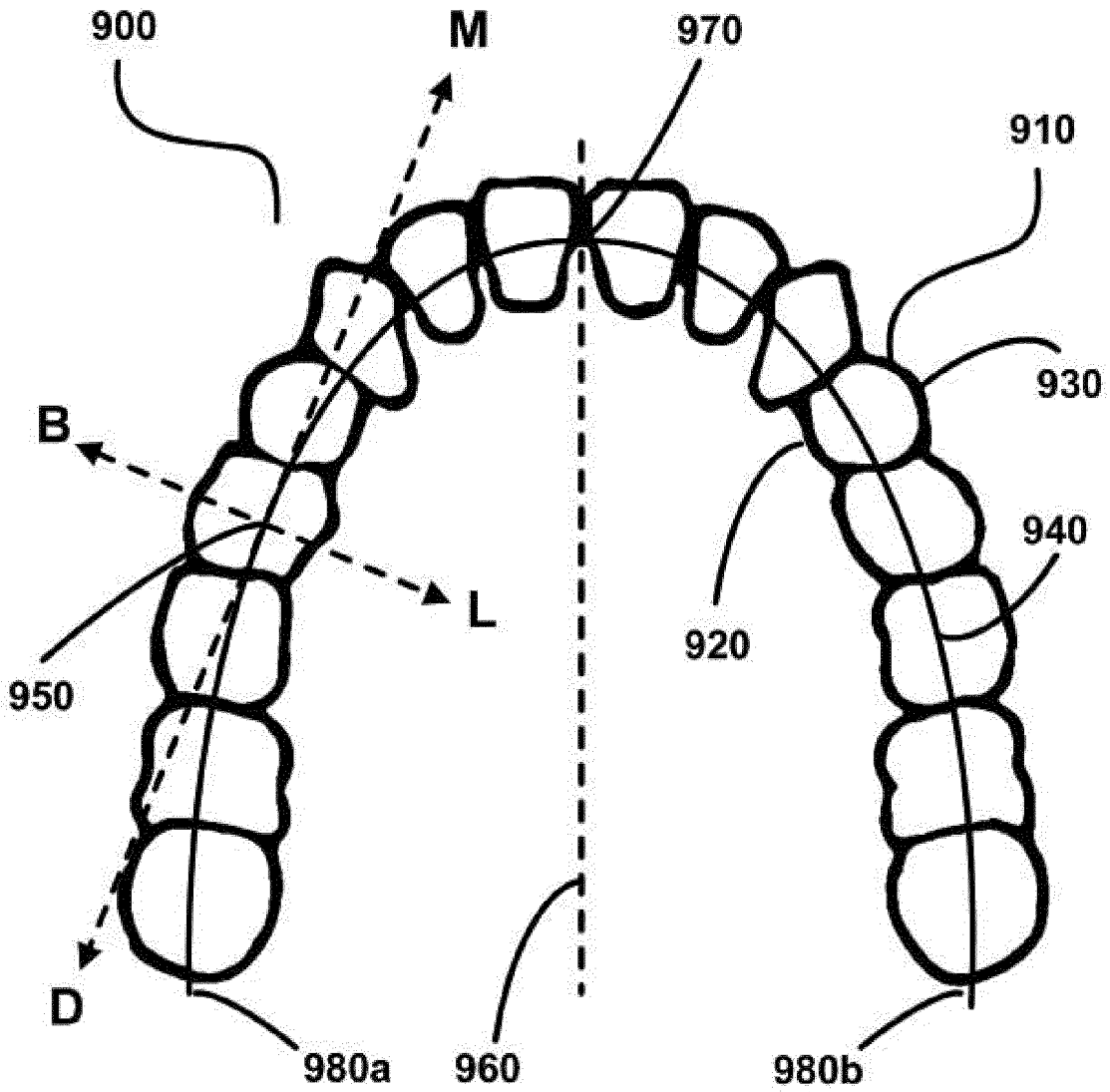

Fig. 9

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2016/054110

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B34/00 A61C1/08 A61B34/20 A61B34/10
ADD.

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61B A61C

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2014/201968 A1 (TAIWAN IMPLANT TECHNOLOGY CO LTD [CN]) 24 December 2014 (2014-12-24) pages 3,8-10; figures 1,2,3	6-13
X	EP 1 442 715 A2 (SURGICAL NAVIGATION TECH [US]) 4 August 2004 (2004-08-04) paragraphs [0048], [0049], [0086]; figures 1,5	6-13
X	WO 03/096920 A1 (PLUS ENDOPROTHETIK AG [CH]; STIFTER JAN [CH]; BROERS HOLGER [DE]) 27 November 2003 (2003-11-27) claim 1; figures 6,7	6-13

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

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

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

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

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

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

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

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

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

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
31 May 2016	10/06/2016

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Assion, Jean-Charles

2

Form PCT/ISA/210 (second sheet) (April 2005)

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 2014/147601 A2 (NAVIGATE SURGICAL TECHNOLOGIES INC [CA]; DAON EHUD UDI [CA]; BECKETT M) 25 September 2014 (2014-09-25) the whole document	6-13
Y	US 2013/122463 A1 (CSILLAG RAPHAEL YITZ [US]) 16 May 2013 (2013-05-16) paragraph [0037]; figure 5	6-13
Y	WO 2013/010138 A2 (PREC THROUGH IMAGING LLC [US]; MOFFSON ALLEN M [US]; PRSHA JEFFREY A [] 17 January 2013 (2013-01-17) paragraphs [0086], [0087]; figures 1,5	6-13
A	WO 2013/055707 A1 (CLEAR GUIDE MEDICAL LLC [US]) 18 April 2013 (2013-04-18) paragraph [0140]	6,10

2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP2016/054110

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

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

1. [X] Claims Nos.: 1-5
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

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

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

1. [ ] As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fees, this Authority did not invite payment of additional fees.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

[ ] The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No
PCT/EP2016/054110

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2014201968 A1	24-12-2014	CN 104224329 A	24-12-2014
		WO 2014201968 A1	24-12-2014
EP 1442715 A2	04-08-2004	AT 366084 T	15-07-2007
		AT 499051 T	15-03-2011
		AT 515235 T	15-07-2011
		AT 520367 T	15-09-2011
		DE 602004007307 T2	22-11-2007
		EP 1442715 A2	04-08-2004
		EP 1836978 A1	26-09-2007
		EP 1844719 A2	17-10-2007
		EP 1844726 A2	17-10-2007
		US 2004152970 A1	05-08-2004
		US 2004152972 A1	05-08-2004
WO 03096920 A1	27-11-2003	AT 409006 T	15-10-2008
		AU 2003215562 A1	02-12-2003
		EP 1507488 A1	23-02-2005
		JP 2005525868 A	02-09-2005
		US 2005182320 A1	18-08-2005
		WO 03096920 A1	27-11-2003
WO 2014147601 A2	25-09-2014	CA 2907554 A1	25-09-2014
		EP 2996609 A2	23-03-2016
		KR 20160013003 A	03-02-2016
		WO 2014147601 A2	25-09-2014
US 2013122463 A1	16-05-2013	US 2013122463 A1	16-05-2013
		WO 2013074784 A1	23-05-2013
WO 2013010138 A2	17-01-2013	CA 2841747 A1	17-01-2013
		EP 2731536 A2	21-05-2014
		JP 2014520637 A	25-08-2014
		US 2014199650 A1	17-07-2014
		US 2016137345 A1	19-05-2016
		WO 2013010138 A2	17-01-2013
WO 2013055707 A1	18-04-2013	CA 2851659 A1	18-04-2013
		EP 2763591 A1	13-08-2014
		JP 2015505679 A	26-02-2015
		US 2013218024 A1	22-08-2013
		WO 2013055707 A1	18-04-2013