(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
25 September 2014 (25.09.2014)

WIPO | PCT

(10) International Publication Number
WO 2014/147601 A2

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

(21) International Application Number:
PCT/IB2014/060403

(22) International Filing Date:
3 April 2014 (03.04.2014)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
61/803,040 18 March 2013 (18.03.2013) US
61/865,508 13 August 2013 (13.08.2013) US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

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

Published:

— *without international search report and to be republished upon receipt of that report (Rule 48.2(g))*

— *with information concerning request for restoration of the right of priority in respect of one or more priority claims (Rules 26bis.3 and 48.2(b)(vii))*

(54) Title: METHOD FOR DETERMINING THE LOCATION AND ORIENTATION OF A FIDUCIAL REFERENCE

(57) Abstract: A rigid positioning and orienting portion of a handheld surgical apparatus has a 3D tracking marker monolithically integrated within its structure, and is thereby trackable using a suitable a tracker. The tracker may be a 2D imaging tracker and may be a non- stereo optical tracker. The tracking marker may be monolithically integrated during the manufacture of the apparatus. A surgical monitoring system employing the surgical apparatus, further comprises the tracker, and a single fiducial reference bearing at least three identifiable location points disposed along at least two non-parallel lines. Based on prior scan data of the fiducial reference, the location and orientation of the fiducial reference are determined using the location points despite only a portion of the fiducial being observable by a scanner during the prior scan. An associated method is provided for determining the location and orientation of the tracking marker based on predetermined locations points and image information from a tracker.

WO 2014/147601 A2

METHOD FOR DETERMINING THE LOCATION AND ORIENTATION OF A FIDUCIAL REFERENCE

BACKGROUND OF THE INVENTION

Field of the Invention.

[0001] The invention relates to location monitoring hardware and software systems. More specifically, the invention relates to determining the location and orientation of fiducial references during medical procedures.

Description of the Related Art

[0002] Visual and other sensory systems for observing and monitoring surgical procedures are known in the art. 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] In a first aspect an apparatus is provided comprising a rigid positioning and orienting portion and a three-dimensional tracking marker is monolithically integrated with the rigid positioning and orienting portion. The apparatus of the invention may be a medical instrument comprising a rigid positioning and orienting portion and a three-dimensional tracking marker monolithically integrated with the rigid positioning and orienting portion. More particularly, the medical instrument may be a medical hand instrument. More specifically, the medical hand instrument may be a surgical hand instrument. The monolithically integrated tracking marker may be shaped for having its location and/or its orientation determined. More particularly, the monolithically integrated tracking marker may be shaped for having its location and/or its orientation determined by a two-dimensional imaging tracker. The tracking marker may comprise positioning and orienting markings for having its location and/or its orientation determined and the positioning and orienting markings may be monolithically integrated with the tracking marker. In some embodiments the positioning and orienting markings may be scribed or engraved on the monolithically integrated tracking marker.

[0004] In a another aspect a surgical monitoring system is provided comprising a tracker having a field of view; a surgical instrument comprising a rigid positioning and orienting portion; and a three-dimensional tracking marker monolithically integrated with the rigid positioning and orienting portion of the surgical instrument and trackable by the tracker within the field of view of the tracker. The tracking marker may shaped and/or marked for having its location and/or its orientation determined by the tracker, which may be a two-dimensional imaging tracker. Positioning and orienting marks may be monolithically integrated with the monolithically integrated tracking marker.

[0005] In another aspect a method is provided for making a three dimensionally tracakble rigid positioning and orienting portion of an apparatus, the method comprising making a three-dimensional tracking marker monolithically integrated with the rigid positioning and orienting portion. Positioning and orienting markings may be monolithically

integrated with the tracking marker during manufacture of the rigid positioning and orienting portion.

[0006] In a further aspect a surgical monitoring system is provided comprising a tracker having a field of view; and a surgical instrument comprising a three-dimensional tracking marker bearing markings, the markings comprising a plurality of contrasting portions arranged in a rotationally asymmetric pattern; wherein the three-dimensional tracking marker is trackable by the tracker within the field of view of the tracker and is monolithically integrated with a rigid positioning and orienting portion of the surgical instrument. The markings may be monolithically integrated with the tracking marker and may be scribed, engraved, stamped, or embossed on the tracking marker. The tracker may a non-stereo optical tracker. The surgical monitoring system may further comprise a single fiducial reference bearing at least three identifiable location points disposed along at least two non-parallel lines. In some embodiments the at least three identifiable location points may be a plurality of identifiable location points. The plurality of location points may be distributed in three dimensions.

[0007] In a further aspect a method is provided for determining the location and orientation in three dimensions of a fiducial reference comprises disposing the fiducial reference to render a portion of the fiducial reference observable by a scanner; obtaining from the scanner scan data of the portion of the fiducial reference that is observable by the scanner; obtaining from a database predetermined geometric information about location points on the fiducial reference, the geometric information comprising three-dimensional coordinates of the location points relative to the structure of the fiducial reference; identifying within the scan data at least three location points having coordinates arranged along at least two non-parallel lines in the predetermined geometric information; and determining the three-dimensional location and orientation of the fiducial reference from the scan data and from the coordinates of the at least three identified location points in the predetermined geometric information. The at least three location points may comprise a plurality of location points and the plurality of points may be distributed in three dimensions.

The at least three location points may be four location points having coordinates arranged along two non-parallel lines. The method may further comprise storing the predetermined geometric information in the database.

[0008] The same method as applied above for determining the location and orientation of a marked fiducial reference using scan data from a scanner when the fiducial reference is only partially observable by the scanner may also be applied to the tracking markers. In this respect a method is provided for determining the location and orientation of a tracking marker in three dimensions, the method comprising disposing the tracking marker to render a portion of the tracking marker observable by a tracker; obtaining from the tracker image information of the portion of the tracking marker that is observable by the tracking marker; obtaining from a database predetermined geometric information about location points on the tracking marker, the geometric information comprising three-dimensional coordinates of the location points relative to a structure of the tracking marker; identifying within the image information at least three location points having coordinates arranged along at least two non-parallel lines in the predetermined geometric information; and determining the three-dimensional location and orientation of the tracking marker from the image information and from the coordinates of the at least three identified location points in the predetermined geometric information. The at least three location points may comprise a plurality of location points. The plurality of points may be distributed in three dimensions. The at least three location points may be four location points having coordinates arranged along two non-parallel lines. The method may further comprise storing the predetermined geometric information in the database.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] 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:

[00010] Figure **1** is a schematic diagrammatic view of a network system in which embodiments of the present invention may be utilized.

[00011] 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.

[00012] Figures **3A-J** are drawings of hardware components of the surgical monitoring system according to embodiments of the invention.

[00013] Figures **4A-C** is a flow chart diagram illustrating one embodiment of the registering method of the present invention.

[00014] 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.

[00015] 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.

[00016] Figure **7** is a drawing of a biopsy needle showing an embodiment of a monolithically integrated tracking marker.

[00017] Figure **8a** is a more detailed view of the fiducial reference of Figures **3 A-E** and Figures **3 G-J**.

[00018] Figure **8b** shows a partial version of the fiducial reference of Figures **3 A-E** and Figures **3 G-J**.

[00019] 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

[00020] 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.

[00021] 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.

[00022] 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.

[00023] 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.

[00024] 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.

[00025] 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 equipments 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.

[00026] 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; therefore 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.

[00027] 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.

[00028] 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.

[00029] 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.

[00030] 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.

[00031] 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.

[00032] 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.

[00033] 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).

[00034] 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).

[00035] 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").

[00036] 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.

[00037] 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. In some embodiments, the tracker may be a non-stereo optical tracker, for example a camera. The camera may, for example, operate in the visible or near-infrared range. The term "image information" is used in the present specification to describe information obtained by the tracker, whether optical or otherwise, and usable for determining the location of the markers and their orientation and movement continually in 'real time' during a procedure.

[00038] 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).

[00039] 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**, 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**).

[00040] 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).

[00041] 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.

[00042] 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-I**, 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.

[00043] 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.

[00044] The present invention relates to embodiments of surgical hardware and software monitoring systems and methods which allow 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, represented as single fiducial key **10** in Figure **3A**, to orient tracking marker **12** of the monitoring system with regard to the critical area of the surgery. Single 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. The tracker may be a non-stereo optical tracker. For example a dental surgery, the dental tracking marker **12** may be used to securely locate the fiducial **10** near the surgical area. The single 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.

[00045] 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. Further embodiments of such additional tracking markers are discussed in detail below at the hand of Figures **6** and **7**.

[00046] 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 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.

[00047] Using the dental surgery example, the patient is scanned to obtain an initial scan of the surgical site. The particular configuration of single 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.

[00048] 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 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**.

[00049] 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.

[00050] Once single 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.

[00051] 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**, single 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.

[00052] 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.

[00053] In a further embodiment of the system utilizing the invention, a surgical instrument or implement, herein termed a "hand piece" (see Figures **5**, **6** and **7**), 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.

[00054] An alternative embodiment of some hardware components are shown in Figures **3G-I**. Single 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.

[00055] 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.

[00056] 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.

[00057] 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.

[00058] 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 90 degrees relationship; optionally having a high contrast pattern engraving and a rigid, quick mounting mechanism to a standard hand piece. In other embodiments the tracking markers are

monolithically integrated with a rigid positioning and orienting portion of the hand piece, as described in more detail at the hand of Figures **6** and **7**.

[00059] In another aspect of the invention 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 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.

[00060] Once the process starts **[402]**, as described in Figures 4**A** and 4**B**, the system obtains a scan data set **[404]** from, for example, a CT scanner and checks for a default CT scan Hounsfield unit (HU) value **[at 406]** 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 scan segments with Hounsfield data values outside expected values associated with the fiducial key values **[at 410]**, following the collection of the remaining points **[at 412]**. 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 the X, Y, and Z axes **[at 422]**. 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 with the designed fiducial data **[430]**. If the cumulative error is larger than the maximum allowed error **[432]** then the user is notified **[at 434]** and the process ends **[at 436]**. If not, then the coordinate system is defined at the XYZ cross point **[at 438]**, and the scan profile is updated for the HU units **[at 440]**.

[00061] Turning now to Figure **4C**, image information is obtained from the tracker, being a suitable camera or other sensor **[442]**. The image information is analyzed to determine whether a tracking marker is present in the image information **[444]**. 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 can be notified that no tracking marker has been found in the image information **[450]**, 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 **[450]**, the offset and relative orientation of the tracking marker to the fiducial reference is obtained from a suitable database **[452]**. 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.

[00062] 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 the three-dimensional orientation of the fiducial reference based on the image information **[454]** and the registration process ends **[458]**. 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 **[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.

[00063] 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**, additional instrument or implement **506**, for example a hand piece which may be a dental drill, may be observed by camera **508** serving as tracker of the monitoring system.

[00064] 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**. Other apparatus with suitable tracking markers may be in use in the process of the surgery at surgery site **600**. By way of non-limiting example, endoscope **606** may have a further tracking marker, and biopsy needle **608** may also be present bearing a tracking marker at surgery site **600**. Sensor **610**, serving as tracker for the system, may be for example a camera, infrared sensing device, or RADAR. In particular, the tracker may be a two-dimensional imaging tracker that produces a two dimensional image of the surgery site **600** for use as image information for the purposes of embodiments of the invention, including two dimensional image information of any tracking markers in the field of view of the tracker. More particularly, tracker **610** may be a non-stereo optical tracker. Surgery site **600**, endoscope **606**, biopsy needle **608**, fiducial key **602** and tracking marker **604** may all be in the field of view of tracker **610.**

[00065] Figure **6**, shows one embodiment of a tracking marker used to track biopsy needle **608**. Figure **7** shows another embodiment of a tracking marker of, for example, biopsy needle **608**. In this embodiment tracking marker **618** is monolithically integrated with a rigid positioning and orienting portion of biopsy needle **608**. In the present specification the phrase "monolithically integrated" is used to describe items that are fashioned together from one piece of material; this to be contrasted with a situation where the items are joined together after manufacture, either detachably or through a non-integral coupling. In this particular example a suitable rigid positioning and orienting portion of biopsy needle **608** is its handle **612**. Handle **612** may, for example be molded, cast, machined or otherwise fashioned from one monolithic piece of material and tracking marker **618** is fashioned,

formed or made from the same monolithic piece of material. Tracking marker **618** may be formed during the same process as that within which the rigid handle portion **612** of the biopsy needle **608** is made.

[00066] Handle **612** itself may in some embodiments comprise two or more sections, but, when assembled, the two or more sections create a rigid whole that dictates where and how the working end of the apparatus, in this case the point of biopsy needle **608**, will be positioned and oriented in three dimensions relative to handle **612.** To the extent that tracking marker **618** is monolithically integrated with a rigid part of the handle **612** of biopsy needle **608**, and the position and orientation of monolithically integrated tracking marker **618** relative to the point of biopsy needle **608** is fixed and known, knowledge of the three-dimensional position and orientation of tracking marker **618** within the field of view of tracker **610** provides the user with the location and orientation of the point of biopsy needle **608**. In such an embodiment, based on for example two halves of handle **612** of biopsy needle **608**, the relevant rigid positioning and orienting portion of biopsy needle **608** is the half of handle **612** with which tracking marker **618** is monolithically integrated.

[00067] The monolithic integration of three-dimensional tracking markers with a rigid positioning and orienting portion of an instrument is not limited to surgical devices. It may be applied to any medical instrument having a suitable rigid positioning and orienting portion and, indeed, to any apparatus having a suitable rigid positioning and orienting portion.

[00068] As with tracking markers described in other embodiments, tracking marker **618** may be shaped in three dimensions so as to allow its orientation to be determined from a two-dimensional image of biopsy needle **608** within the field of view of tracker **610.** In further embodiments, monolithically integrated tracking marker **618** may have a monolithically integrated marking so as to allow its orientation to be determined from a two-dimensional image of biopsy needle **608** within the field of view of tracker **610**. In further

embodiments tracking marker may be both shaped and marked to allow its orientation, its location, or both to be determined.

[00069] In yet further embodiments, positioning and orienting markings may be scribed, engraved, stamped, embossed or otherwise formed on tracking marker **618**. Useful markings for determining the location and orientation of tracking marker **618** may comprise a plurality of contrasting portions arranged in a rotationally asymmetric pattern and at least one of the contrasting portions has a perimeter that has a mathematically describable curved section. The perimeter of the contrasting portion may comprise a conic section, including for example an ellipse or a circle. The markings may be monolithically integrated with the tracking marker. In other embodiments the markings may be scribed, engraved, stamped, embossed or otherwise formed on tracking marker **618**. Geometric information about the asymmetric pattern may be stored in a database. A suitable controller, for example processor **214** and memory **217** of computer **210** of Figure **2**, may be used to compare the image information obtained from tracker **610** with the geometric information about tracking marker **618** in order to determine the three dimensional location and orientation of tracking marker **618** and its associated biopsy needle **608.**

[00070] In a further aspect of the invention a method for making a three dimensionally trackable rigid positioning and orienting portion of an apparatus comprises monolithically forming a three-dimensional tracking marker integral with the rigid positioning and orienting portion of the apparatus. The method may further comprise monolithically forming positioning and orienting markings integral with the tracking marker. The method may further comprise scribing, engraving, stamping, embossing or otherwise forming positioning and orienting markings on the three-dimensional tracking marker.

[00071] Figure **8a** shows fiducial key **13**. By way of non-limiting example, we select fiducial key **10** already discussed with respect to Figures **3A-E** and Figures **3G--J**. In general, the fiducial key may be marked or shaped, or both, in order to allow its location and

orientation to be determined in three dimensions. In the embodiment described herewith, fiducial key **10** is marked to allow its location and orientation to be determined in three dimensions. As shown in Figure **8a**, five identifiable location points on fiducial key **10** are shown, being marked as "A", "B", "C", "D", "E". At least five different non-parallel lines may be drawn between these highly identifiable points. At least four different distinctive triangles may be formed from lines joining the five points. It is clear that, with a minimum of three identifiable points, for example "A", "B", and "C", the position and orientation of fiducial key **10** may be determined uniquely. In the case of Figure **8a** there are several other points that may be similarly employed to form other triangles that may be used in similar fashion.

[00072] We now consider Figure **8b**, which shows the same tag **10**, but it is either broken or only partially observable so as to present only portion **10'** for observation by a suitable scanner. The term "observable" is used here to describe the image-wise detectability of the fiducial reference by the scanner with the scanner employing whatever particular penetrating radiation it is designed to employ. Under both of these circumstances only points "A", "B", "C", and "E" are visible to a scanner (not shown in Figure **8a**). In order to fully determine the location and orientation of tag **10'** in three-dimensional space, points "A" and "B", for example, together with either of points "C", or "E" suffices. The more points that are available, the more accurately the position and orientation in three dimensions may be determined.

[00073] It is clear from Figures **8a** and **8b** that the identification of two sets of points lying along two mutually non-parallel directions on fiducial reference **10**, or portion **10'** of fiducial reference **10**, allows the determination of the location and orientation of fiducial reference **10** in three-dimensional space.

[00074] In some embodiments, four identifiable points, distributed as two sets of two points each along two straight non-parallel lines may be employed to fully determine the

three dimensional location and orientation of fiducial reference **10**, or portion **10'** of fiducial reference **10**. Referring to Figures **8a** and **8b**, the line between points "A" and "B", on the one hand, and the line between points "C" and "E" on the other hand, may be employed in this embodiment.

[00075] The embodiment wherein three identified location points are employed is therefore merely a special a case in which two of the four points are the same point and the required two non-parallel lines share a common point.

[00076] In a more general case, the identifiable points on fiducial reference **10**, or on portion **10'** of fiducial reference **10**, required to fully determine the location and orientation of fiducial reference **10**, or portion **10'** of fiducial reference **10**, need not be located along two straight lines, but the three-dimensional spatial relationship between the points must be known.

[00077] The underlying requirement to fully determine the location and orientation of fiducial reference **10**, or of a portion **10'** of fiducial reference **10**, is for there to be at least three identifiable location points, for example "A", "B", and "C", defining two non-parallel lines, observable by the scanner, and identifiable from a from a preexisting database in which their three-dimensional locations are known relative to the structure of fiducial reference **10**.

[00078] In general a plurality of identifiable points arranged in a general distribution on fiducial reference **10**, or on portion **10'** of fiducial reference **10**, may be employed, the accuracy of the method improving with the number of identifiable points employed.

[00079] In the different surgical examples described in this specification, the entire fiducial reference employed does not have to be observable to the scanner, as long as at least three pre-identified points are observable by the scanner and the three-dimensional locations

of those three pre-identified points are known relative to the structure of the fiducial reference from a suitable database.

[00080] More specifically, the method described above for determining the location and orientation in three dimensions of a general fiducial reference of any of the above embodiments comprises disposing the fiducial reference to render a portion of the fiducial reference observable by a scanner; obtaining from the scanner scan data of the portion of the fiducial reference that is observable by the scanner; obtaining from a database predetermined geometric information about location points on the fiducial reference, the geometric information comprising three-dimensional coordinates of the location points relative to the structure of the fiducial reference; identifying within the scan data at least three location points having coordinates arranged along at least two non-parallel lines in the predetermined geometric information; and determining the three-dimensional location and orientation of the fiducial reference from the scan data and from the coordinates of the at least three identified location points in the predetermined geometric information. The at least three location points may comprise a plurality of location points and the plurality of points may be distributed in three dimensions.

[00081] The same method as applied above for determining the location and orientation of a marked fiducial reference using scan data from a scanner when the fiducial reference is only partially observable by the scanner may also be applied to the tracking markers. In this respect a method is provided for determining the location and orientation of a tracking marker in three dimensions, the method comprising disposing the tracking marker to render a portion of the tracking marker observable by a tracker; obtaining from the tracker image information of the portion of the tracking marker that is observable by the tracking marker; obtaining from a database predetermined geometric information about location points on the tracking marker, the geometric information comprising three-dimensional coordinates of the location points relative to a structure of the tracking marker; identifying within the image information at least three location points having coordinates arranged along at least two non-parallel lines in the predetermined geometric information; and determining

the three-dimensional location and orientation of the tracking marker from the image information and from the coordinates of the at least three identified location points in the predetermined geometric information. The at least three location points may comprise a plurality of location points. The plurality of points may be distributed in three dimensions. The at least three location points may be four location points having coordinates arranged along two non-parallel lines. The method may further comprise storing the predetermined geometric information in the database.

WHAT IS CLAIMED IS:

1. An apparatus comprising a rigid positioning and orienting portion and a three-dimensional tracking marker monolithically integrated with the rigid positioning and orienting portion.

2. The apparatus of claim 1, wherein the monolithically integrated tracking marker is shaped for having at least one of its location and its orientation determined.

3. The apparatus of claim 1 or 2, wherein the monolithically integrated tracking marker is shaped for having at least one of its location and its orientation determined by a two-dimensional imaging tracker.

4. The apparatus of any of claims 1 to 3, wherein the monolithically integrated tracking marker comprises positioning and orienting markings for having at least one of its location and its orientation determined.

5. The apparatus of claim 4, wherein the positioning and orienting markings are monolithically integrated with the tracking marker.

6. The apparatus of claim 4, wherein the positioning and orienting markings are one of scribed, engraved, stamped, and embossed on the tracking marker.

7. The apparatus of any of claims 1 to 6, wherein the monolithically integrated tracking marker is at least one of shaped and marked for having at least one of its location and its orientation determined.

8. The apparatus of claim 7, wherein the monolithically integrated tracking marker comprises positioning and orienting markings for having at least one of its location and its orientation determined.

9. The apparatus of claim 8, wherein the positioning and orienting markings are monolithically integrated with the rigid positioning and orienting portion.

10. The apparatus of any of claims 1 to 9, wherein the monolithically integrated tracking marker is at least one of shaped and marked for having at least one of its location and its orientation determined by a tracker when the tracking marker is within a field of view of the tracker.

11. The apparatus of any of claims 1 to 10, wherein the monolithically integrated tracking marker is at least one of shaped and marked for having at least one of its location and its orientation determined by a two-dimensional imaging tracker when the tracking marker is within a field of view of the tracker.

12. The apparatus of any of claims 1 to 11, wherein said rigid positioning and orienting portion includes a medical instrument.

13. The apparatus of any of claims 1 to 12, wherein said rigid positioning and orienting portion includes a medical hand instrument.

14. The apparatus of any of claims 1 to 13, wherein said rigid positioning and orienting portion includes a surgical hand instrument.

15. A surgical monitoring system comprising:

a. a tracker having a field of view;

b. a surgical instrument comprising a rigid positioning and orienting portion; and

c. a three-dimensional tracking marker monolithically integrated with the rigid positioning and orienting portion of the surgical instrument and trackable by the tracker when within the field of view of the tracker.

16. The surgical monitoring system of claim 15, wherein the monolithically integrated tracking marker is at least one of shaped and marked for having at least one of its location and its orientation determined by the tracker.

17. The surgical monitoring system of claim 15 or 16, wherein the tracker is a two-dimensional imaging tracker.

18. The surgical monitoring system of any of claims 15 to 17, wherein the monolithically integrated tracking marker comprises positioning and orienting markings for having at least one of its location and its orientation determined.

19. The surgical monitoring system of claim 18, wherein the positioning and orienting markings are monolithically integrated with the tracking marker.

20. A method for making a three dimensionally trackable rigid positioning and orienting portion of an apparatus, the method comprising the steps of creating the apparatus; and monolithically forming a three-dimensional tracking marker integral with the rigid positioning and orienting portion of the apparatus.

21. The method of claim 20, further comprising the step of monolithically forming positioning and orienting markings integral with the tracking marker.

22. The method of claim 21, wherein the forming is one of scribing, engraving, stamping, and embossing.

23. A surgical monitoring system comprising:

a. a tracker having a field of view; and

b. a surgical instrument comprising a three-dimensional tracking marker bearing markings, the markings comprising a plurality of contrasting portions arranged in a rotationally asymmetric pattern;

wherein the three-dimensional tracking marker is trackable by the tracker within the field of view of the tracker and is monolithically integrated with a rigid positioning and orienting portion of the surgical instrument.

24. The surgical monitoring system of claim 23, wherein the markings are monolithically integrated with the tracking marker.

25. The surgical monitoring system of claim 24, wherein the markings comprise a plurality of contrasting portions arranged in a rotationally asymmetric pattern.

26. The surgical monitoring system of claim 25, wherein at least one of the contrasting portions comprises a perimeter describable by a mathematically curved section.

27. The surgical monitoring system of claim 25, wherein at least one of the contrasting portions comprises a perimeter describable by a conic section.

28. The surgical monitoring system of claim 23, wherein the markings are one of scribed, engraved, stamped, and embossed on the tracking marker.

29. The surgical monitoring system of any of claims 23 to 28, wherein the tracker is a non-stereo optical tracker.

30. The surgical monitoring system of any of claims 23 to 29, further comprising a single fiducial reference bearing at least three identifiable location points disposed along at least two non-parallel lines.

31. The method of claim 30, wherein the at least three location points comprise a plurality of location points.

32. The method of claim 31, wherein the plurality of location points may be distributed in three dimensions.

33. A method for determining the location and orientation of a monolithically integrated tracking marker in three dimensions, the method comprising

--disposing the tracking marker to render a portion of the tracking marker observable by a tracker;

--obtaining from the tracker image information of the portion of the tracking marker that is observable by the tracker;

--obtaining from a database predetermined geometric information about location points on the tracking marker, the geometric information comprising three-dimensional coordinates of the location points relative to a structure of the tracking marker;

--identifying within the image information at least three location points having coordinates arranged along at least two non-parallel lines in the predetermined geometric information; and

--determining the three-dimensional location and orientation of the tracking marker from the image information and from the coordinates of the at least three identified location points in the predetermined geometric information.

34. The method of claim 33, wherein the at least three location points comprise a plurality of location points.

35. The method of claim 34, wherein the plurality of points is distributed in three dimensions.

36. The method of any of claims 33 to 35, wherein the at least three location points are four location points having coordinates arranged along two non-parallel lines.

37. The method of any of claims 33 to 36, further comprising storing the predetermined geometric information in the database.

38. A method for determining the location and orientation of a fiducial reference in three dimensions, the method comprising

a. disposing the fiducial reference to render a portion of the fiducial reference observable by a scanner;

b. obtaining from the scanner scan data of the portion of the fiducial reference that is observable by the scanner;

c. obtaining from a database predetermined geometric information about location points on the fiducial reference, the geometric information comprising three-dimensional coordinates of the location points relative to the structure of the fiducial reference;

d. identifying within the scan data at least three location points having coordinates arranged along at least two non-parallel lines in the predetermined geometric information; and

e. determining the three-dimensional location and orientation of the fiducial reference from the scan data and from the coordinates of the at least three identified location points in the predetermined geometric information.

39. The method of claim 38, wherein the at least three location points comprise a plurality of location points.

40. The method of claim 39, wherein the plurality of points is distributed in three dimensions.

41. The method of any of claims 38 to 40, wherein the at least three location points are four location points having coordinates arranged along two non-parallel lines.

42. The method of any of claims 38 to 41, further comprising storing the predetermined geometric information in the database.

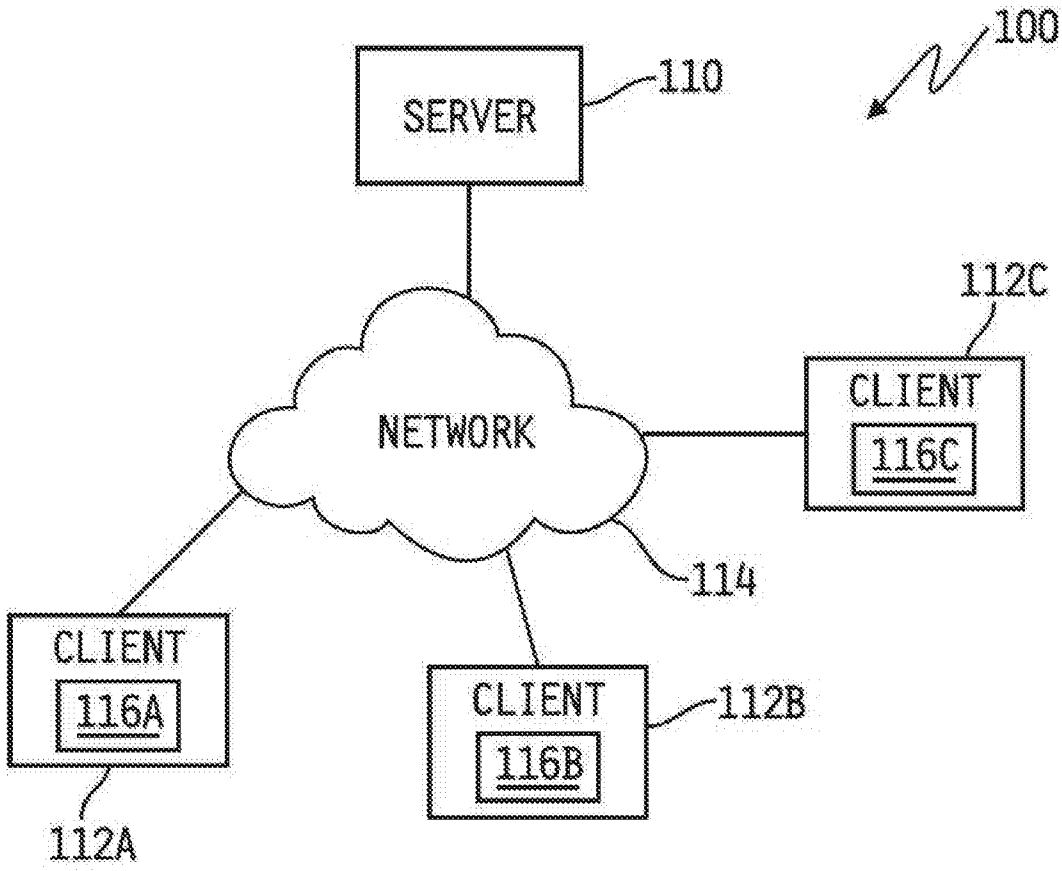

100
SERVER
110
NETWORK
112C
CLIENT
116C
114
CLIENT
116A
112A
CLIENT
116B
112B

FIG.1

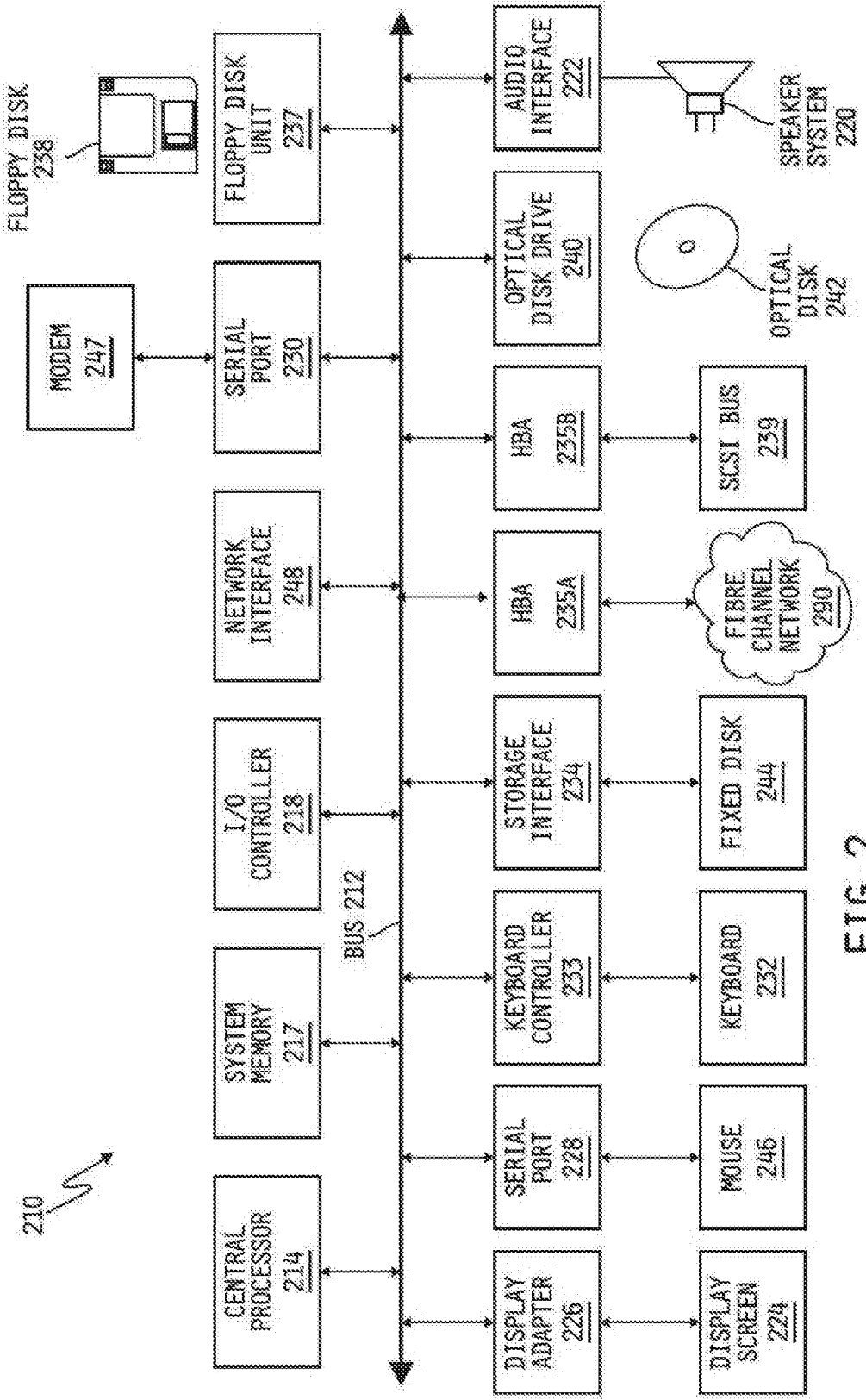

210
CENTRAL PROCESSOR 214
SYSTEM MEMORY 217
I/O CONTROLLER 218
NETWORK INTERFACE 248
SERIAL PORT 230
MODEM 247
FLOPPY DISK 238
FLOPPY DISK UNIT 237
BUS 212
DISPLAY ADAPTER 226
SERIAL PORT 228
KEYBOARD CONTROLLER 233
STORAGE INTERFACE 234
HBA 235A
HBA 235B
OPTICAL DISK DRIVE 240
AUDIO INTERFACE 222
DISPLAY SCREEN 224
MOUSE 246
KEYBOARD 232
FIXED DISK 244
FIBRE CHANNEL NETWORK 290
SCSI BUS 239
OPTICAL DISK 242
SPEAKER SYSTEM 220

FIG. 2

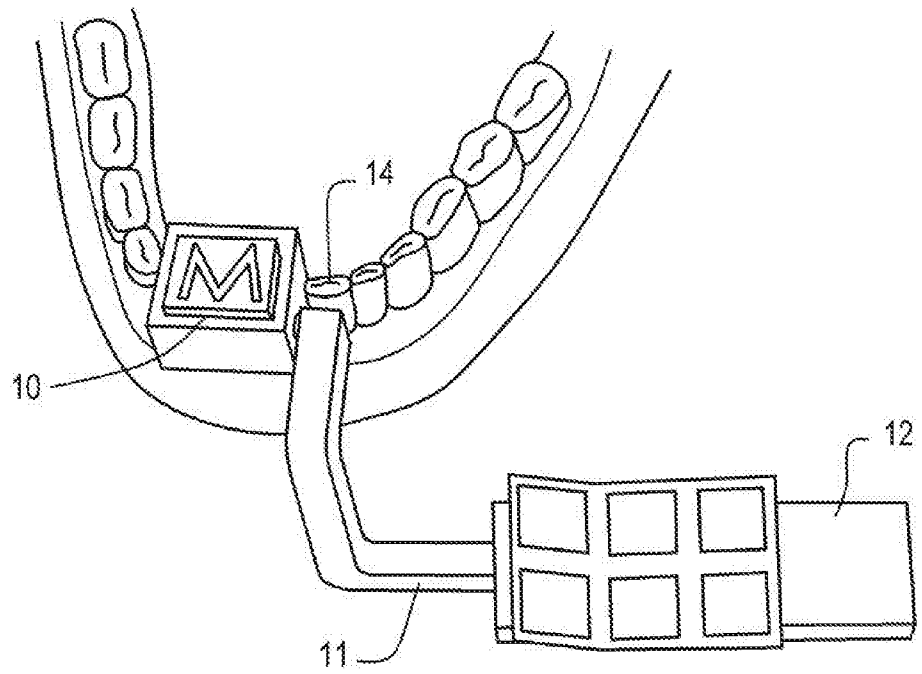


Fig. 3A

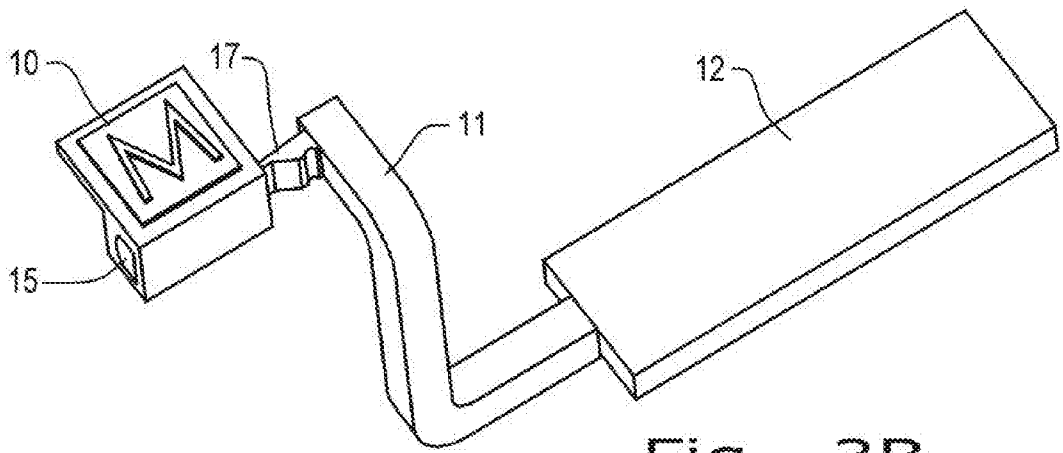


Fig. 3B

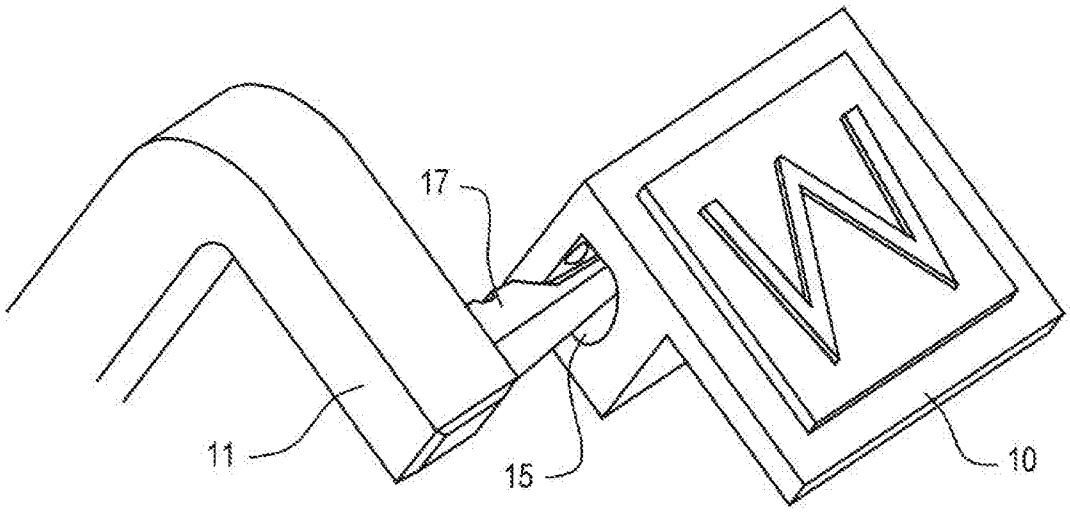


Fig. 3C

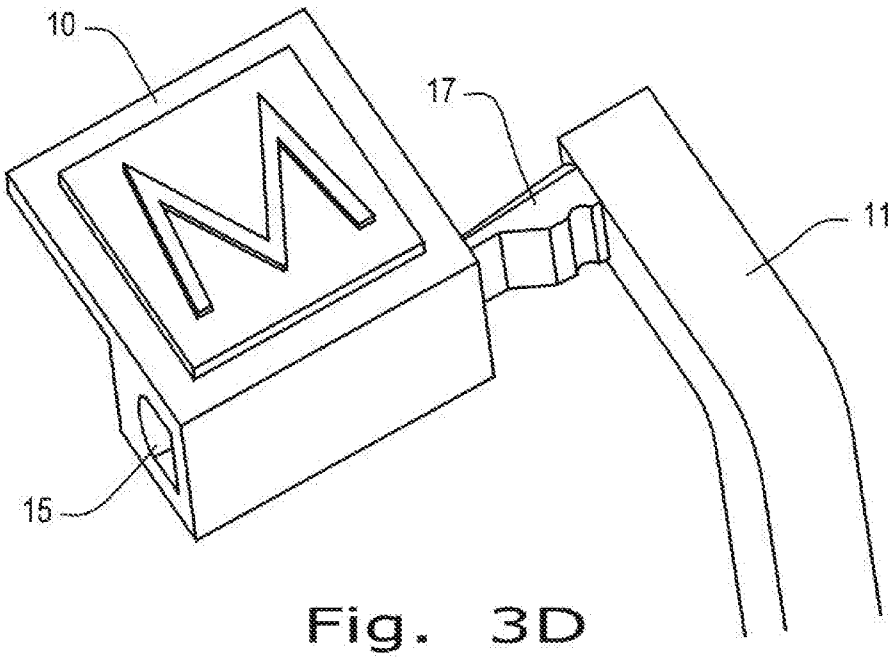


Fig. 3D

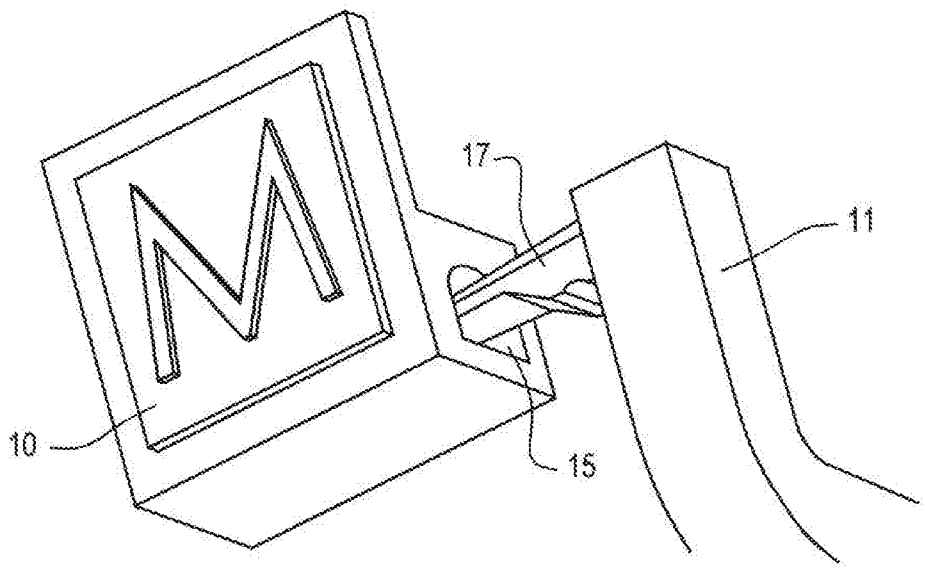


Fig. 3E

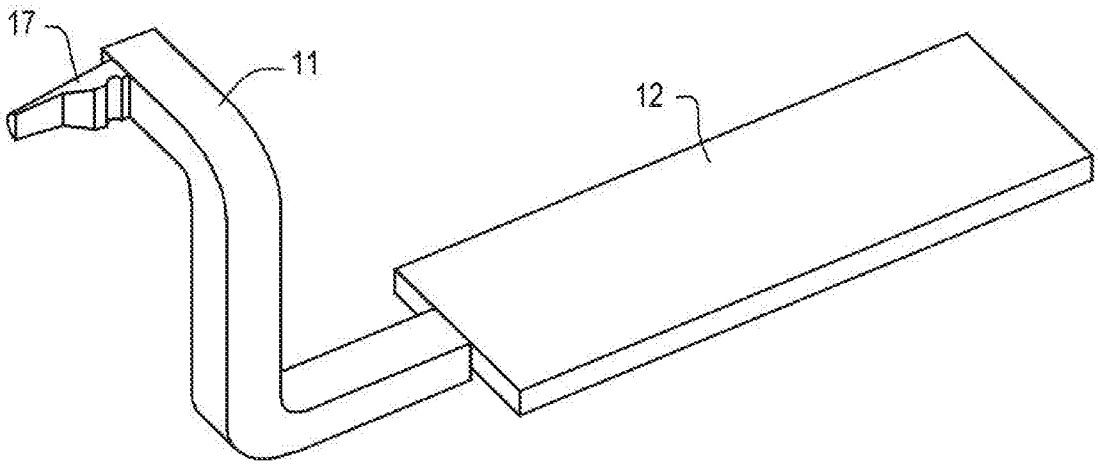


Fig. 3F

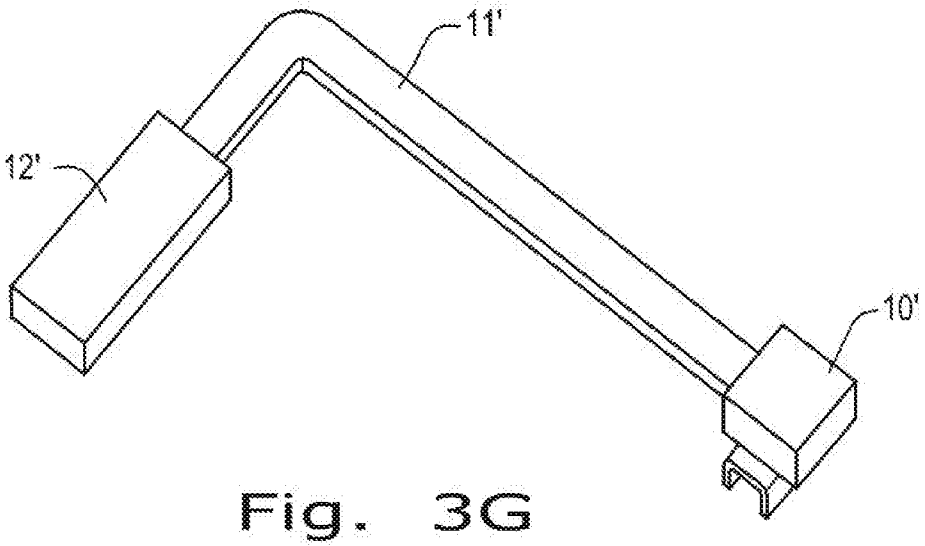


Fig. 3G

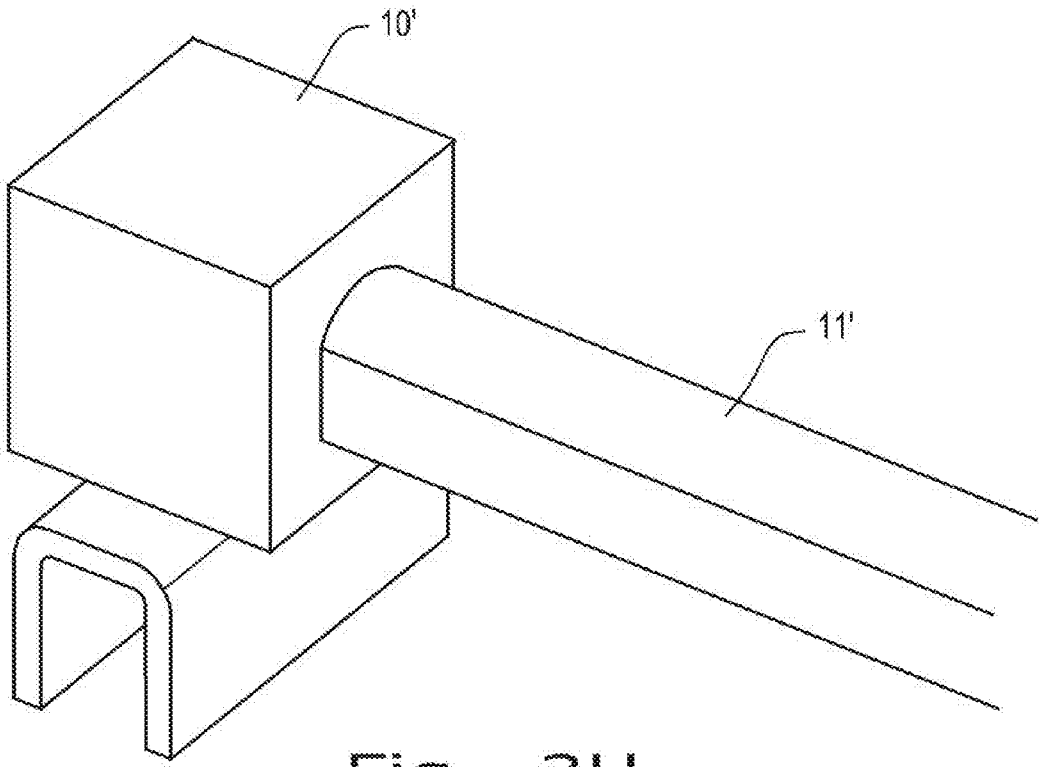


Fig. 3H

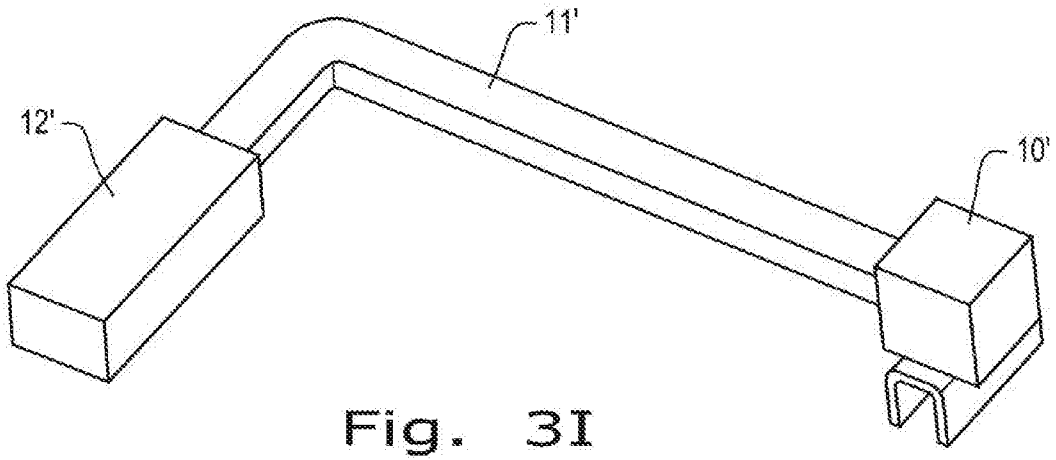


Fig. 3I

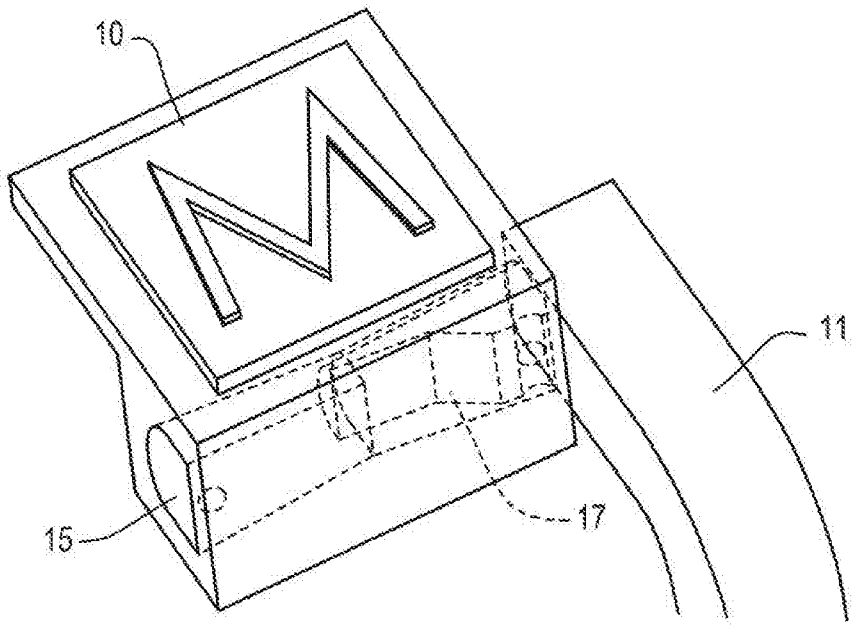


Fig. 3J

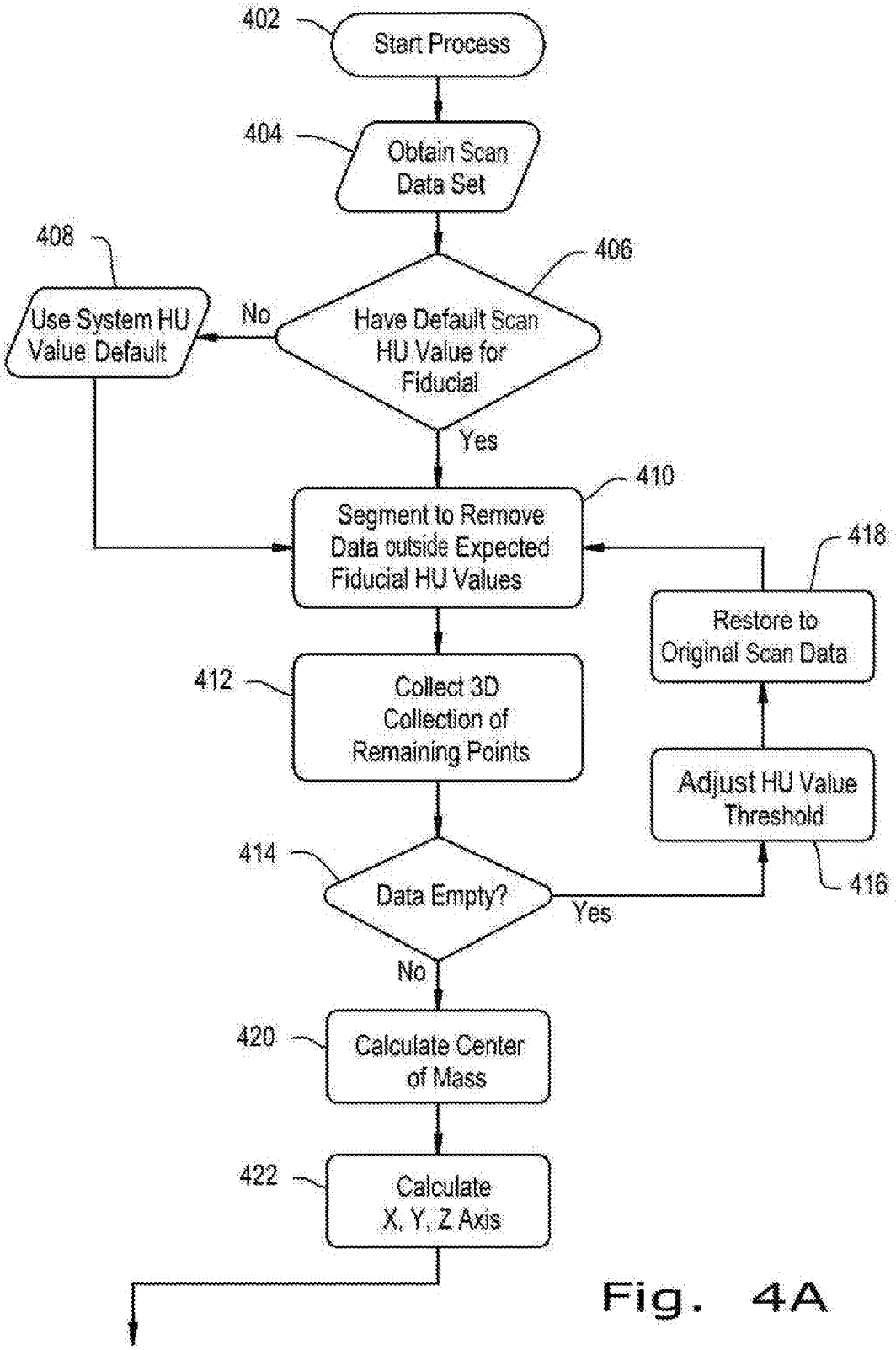

402
Start Process
404
Obtain Scan Data Set
406
Have Default Scan HU Value for Fiducial
No
408
Use System HU Value Default
Yes
410
Segment to Remove Data outside Expected Fiducial HU Values
412
Collect 3D Collection of Remaining Points
414
Data Empty?
Yes
No
416
Adjust HU Value Threshold
418
Restore to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

Fig. 4A

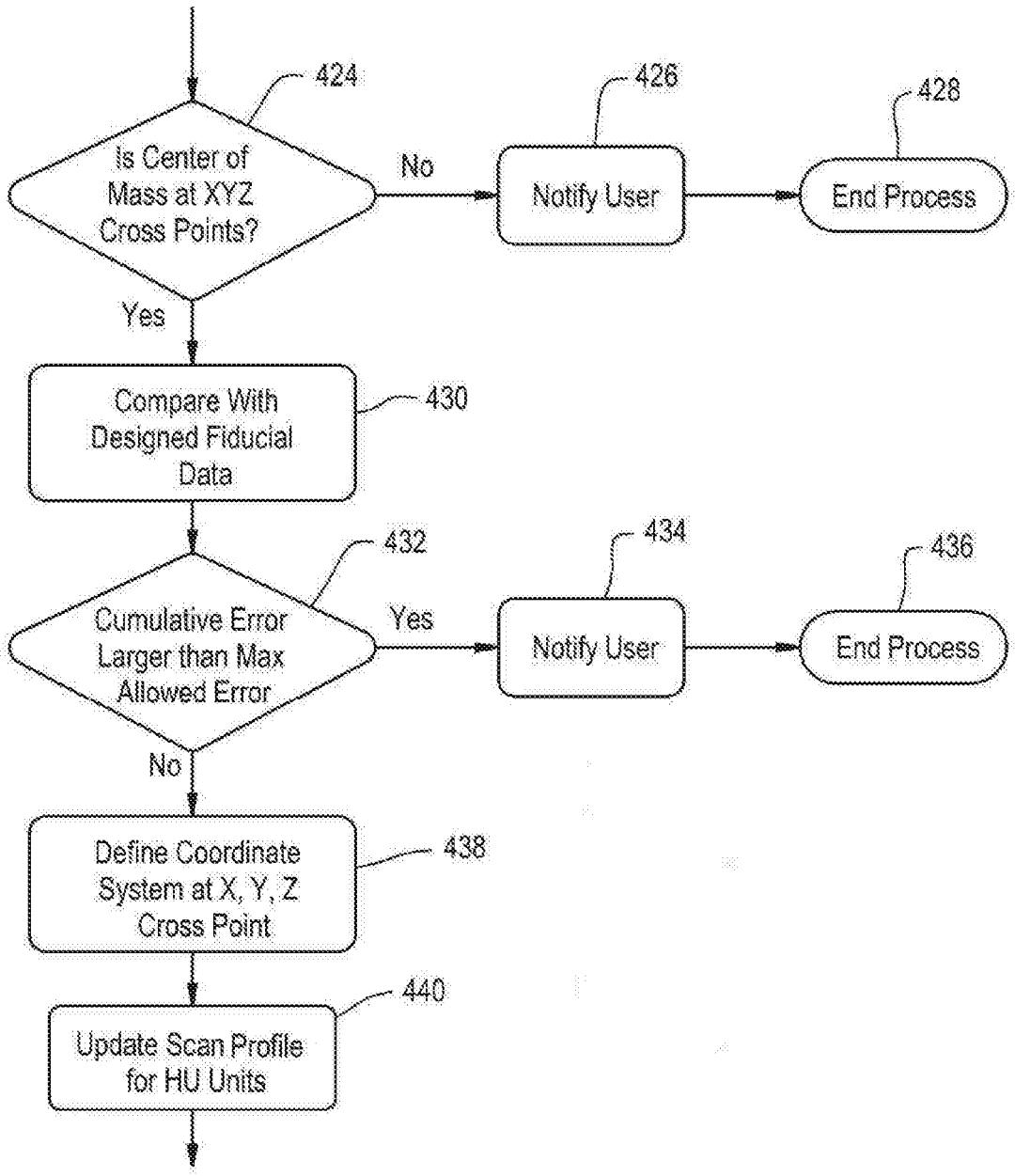

424
Is Center of Mass at XYZ Cross Points?
No
426
Notify User
428
End Process
Yes
Compare With Designed Fiducial Data
430
432
Cumulative Error Larger than Max Allowed Error
Yes
434
Notify User
436
End Process
No
Define Coordinate System at X, Y, Z Cross Point
438
Update Scan Profile for HU Units
440

Fig. 4B

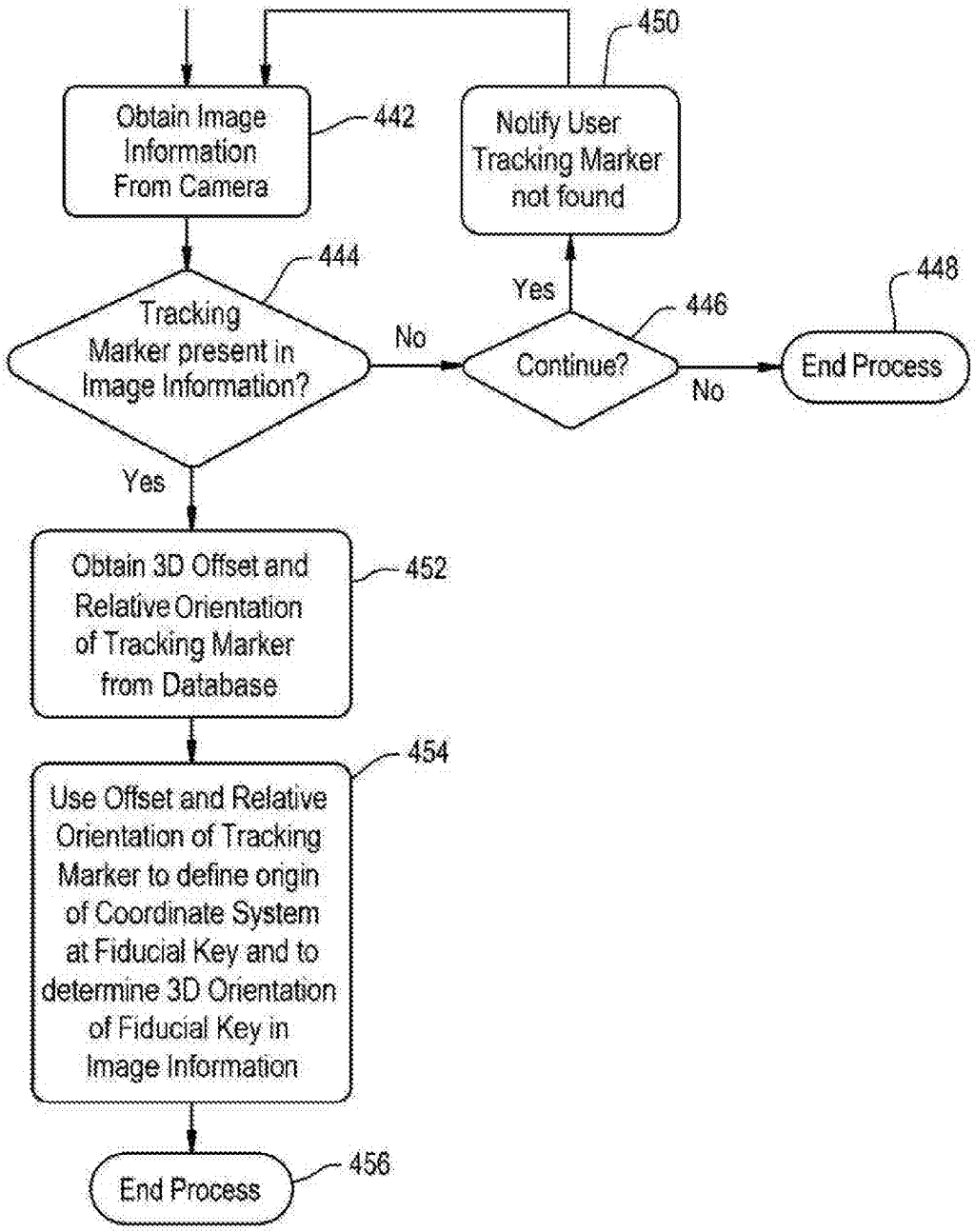

Obtain Image Information From Camera
442
Tracking Marker present in Image Information?
444
No
Yes
Notify User Tracking Marker not found
450
Continue?
446
Yes
No
End Process
448
Obtain 3D Offset and Relative Orientation of Tracking Marker from Database
452
Use Offset and Relative Orientation of Tracking 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

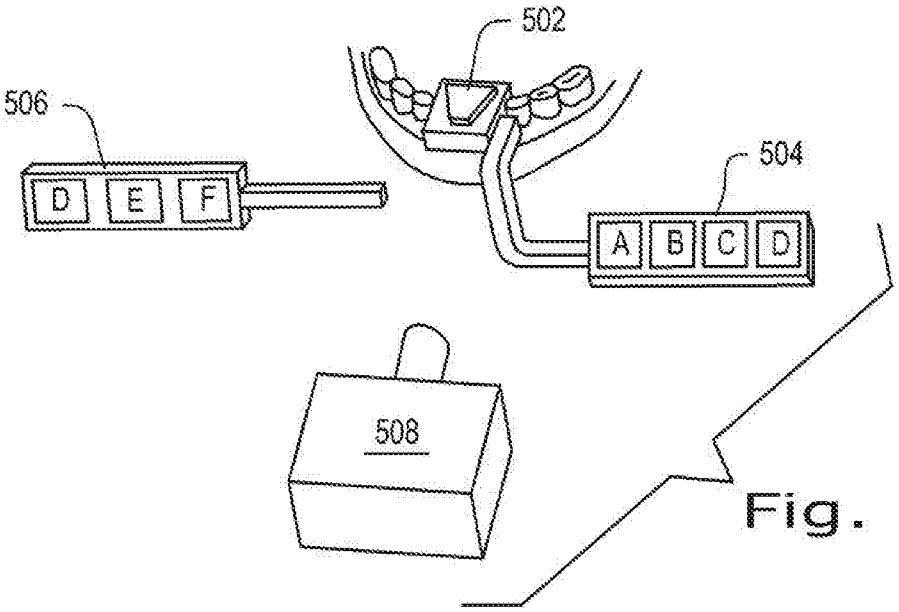

502
506
504
D E F
A B C D
508

Fig. 5

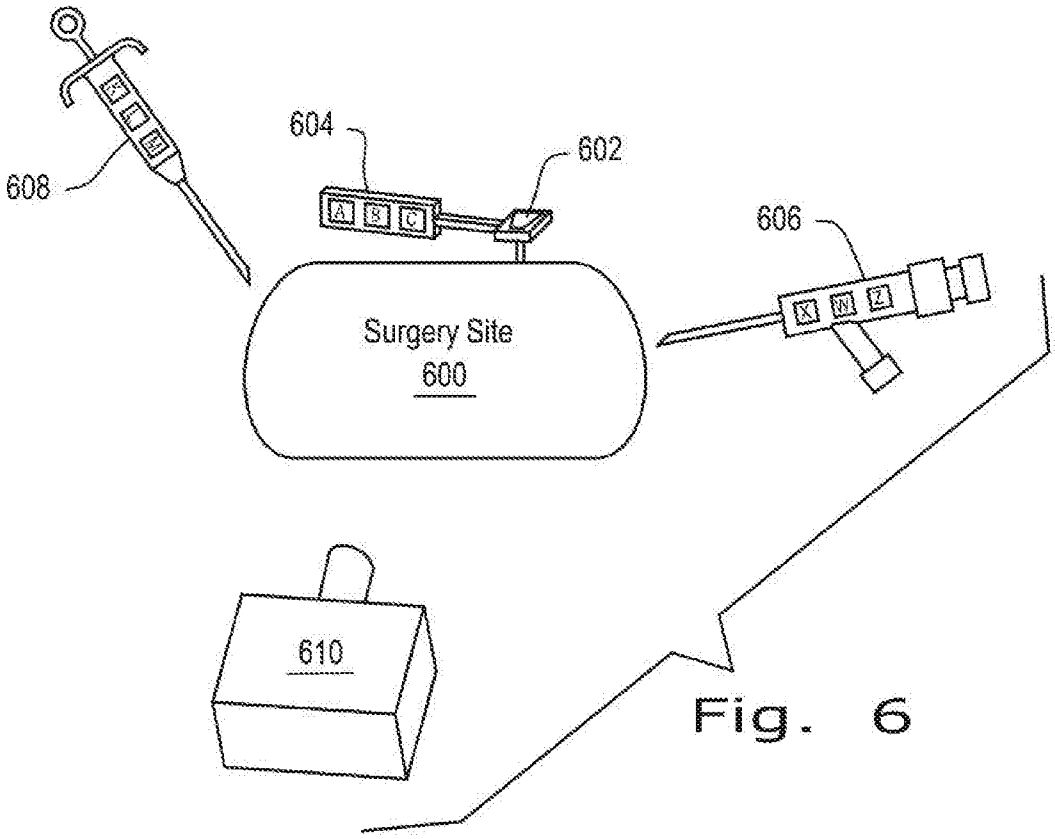

604
602
606
608
A B C
Surgery Site
600
610

Fig. 6

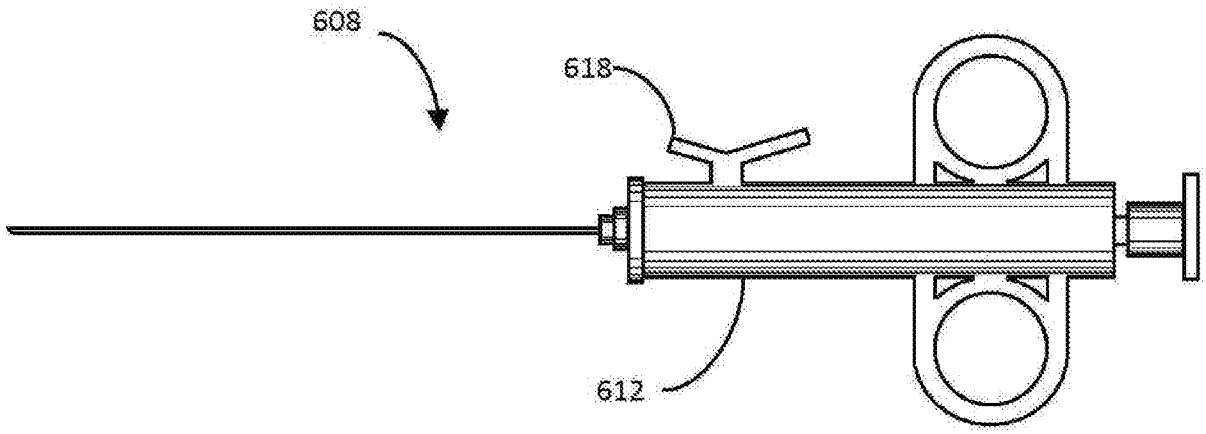


Fig. 7

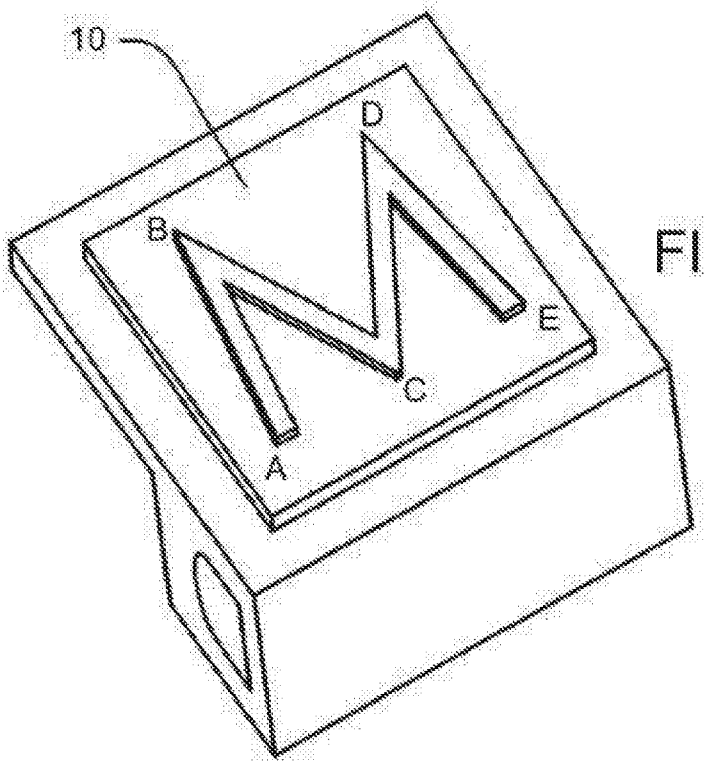


FIG. 8a

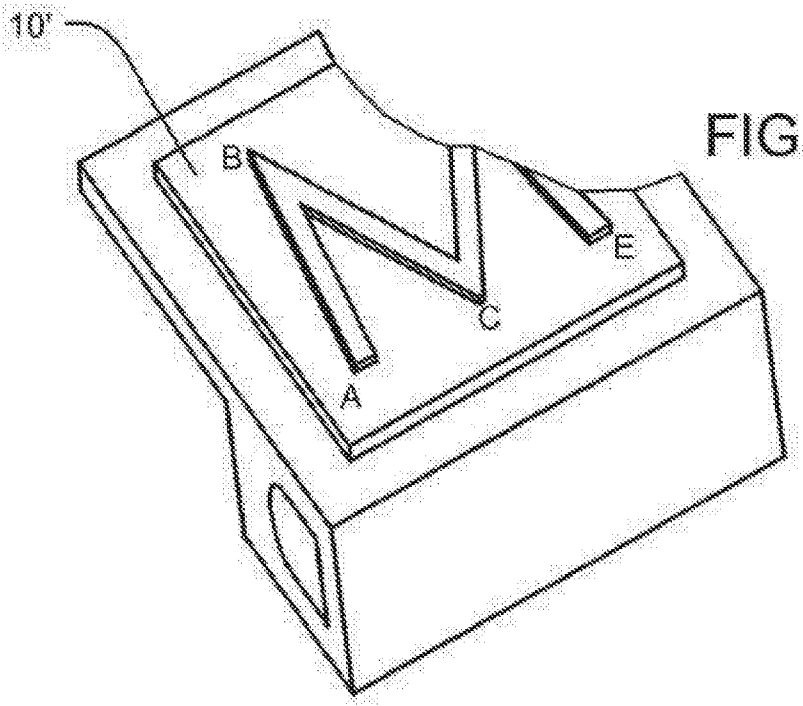


FIG. 8b