DIGITAL MEDIUM ENHANCED IMAGE-GUIDED PROCEDURE SYSTEM AND METHOD

Background of the Invention

The present invention relates to the art of image guided procedures. It finds particular application in conjunction with neurosurgical and orthopedic procedures and will be described with particular reference thereto. However, it is to be appreciated that the present invention is equally applicable to a wide range of image guided procedures in industrial applications, manufacturings, computer programs and games, video and audio disk players, as well as in human and veterinary surgically and minimally-invasive procedures.

Heretofore, images of a region of a patient in which surgery is planned have been made using magnetic resonance imaging systems, computed tomography, or other similar imaging modalities. These techniques generate a substantial amount of data, which is then manipulated through software to provide three-dimensional guidance within the imaged region. Typically, to facilitate diagnoses and treatment through image guidance, this data is manipulated using a computer supplemented with other specialized computer hardware to display selected views during surgery, e.g., orthogonal views, slices, perspective renderings, or the like.

Acquired images used for image guided surgery typically use anatomical reference markers which are commonly imaged with the patient. At the surgical site, acoustic,

infrared, video camera, or other tracking technologies are utilized to determine the location of the markers relative to the patient and the surgical site. Additional computer software is provided to register the coordinate system of the markers, hence the patient, with the image(s). Thereafter, the same system is used to monitor the current position of surgical tools instrumented with similar markers, and coordinate their position in physical space with their position in the image(s). In this manner, the current position of the tool or probe relative to obscured portions of the patient's anatomy is readily determined. This facilitates implementing minimally invasive techniques by allowing the surgeon to use the acquired image(s) to see below the visible surface of the patient. For example, the surgeon can use the software's graphic user interface to mark the entry point and proposed trajectory of a pedicel screw on a patient's spine. The marked image(s) can then be used to enable the surgeon to follow the trajectory created below the surface with the instrumented surgical tool to be sure that the screw will not impinge the spinal cord and that it will engage sufficient bone to anchor properly, and the like.

In prior image guided surgery systems, different tools have been used for different portions of the human anatomy. To accommodate the use of different tools, the surgeon typically needs to calibrate the tool to the system. That is, the system needs to know the length, diameter, distances between various portions of the tool and the markers mounted on the tool, relative locations of markers and a tool axis, and the like. Prior image guided surgery systems did not allow use of non-instrumented or standard surgical tools. Also, in prior image guided surgery systems, as new tools are developed or as tools are modified, information about the tools loaded into the system must be reloaded on the entire installed base. Similar reinstallation problems occur when improvements are made to the software.

Prior image guided surgery systems also relied on reusable surgical tools. This has several drawbacks. First, with use, tools with cutting edges become dull. Second, since the tools are sterilized between uses, infection to the patient

is possible due to a potential failure of the sterilization procedure.

Typically, image guided surgery systems are universal, i.e., applicable to any portion of the human anatomy that can be clearly imaged with reference markers. Computer software is provided to handle the imaging and alignment needs in virtually any region of the human anatomy. In some instances, the image guided surgery software is incorporated directly into the diagnostic imaging device. In other instances, additional expensive hardware is provided separately.

Prior image guided surgery systems have also relied on a capital equipment sales model, which has resulted in limited market acceptance. Prior image guided surgery systems have been large in size and cost-prohibitive for most. The shipping logistics has been expensive and cumbersome.

Image-guided tools have also been used in various industrial and manufacturing applications. For example, in environments which are hostile to human operators, such as areas of high radiation, tools have been manipulated remotely while an operator views images on a screen.

The present invention contemplates a new and improved method for image guided surgery, which overcomes the above-referenced problems and several others.

Summary of the Invention

In accordance with one aspect of the present invention, a system includes a computer for displaying images on a display. The computer is programmed with limited functionality. A single-use digital medium contains software to upgrade the computer temporarily to higher user functionality for a preselected procedure. A means disables the software from being reused to upgrade the computer after the preselected procedure.

In accordance with another aspect of the present invention, a digital medium is removed from a kit and inserted into a computer which has limited functionality. The software on the computer is temporarily upgraded with software from the

digital medium. After the procedure, the digital medium is deactivated or encrypted against reuse in the computer.

One advantage of the present invention resides in low or no capital cost to facilities for the equipment.

Another advantage of the present invention is that it enables automatic upgrade of the image guided procedure software and of the specifications, descriptions, and characteristics of the tools residing on the computer upon insertion of the digital medium.

Yet another advantage of the present invention is the assured sterility of the tools, accessories, and any other components of the system contained in the software-integrated disposable kit, which enter the sterile field.

Another advantage of the present invention is the assured sharpness and reliable maintenance of any other quality aspects of the tools and guides.

Another advantage includes simplified customer billing.

Still further advantages of the present invention will become apparent to those of ordinary skill in the art upon reading and understanding the following detailed description of the preferred embodiments.

Brief Description of the Drawings

The invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the invention.

FIGURE 1 is a perspective view of a mobile cart in combination with a computer with peripherals including but not limited to a joystick, a display, accessories including but not limited to cables, and a tracking system in accordance with the present invention;

FIGURE 2 is a perspective view of a software-integrated disposable kit in accordance with the present invention; and,

FIGURE 3 is a diagrammatic illustration of a schematic for the computer in accordance with the present invention.

Detailed Description of the Preferred Embodiments

Although described with reference to surgical applications, it is to be appreciated that the present invention has numerous other applications beyond the treatment of human patients. Such applications include computer programs or games, DVDs, CDs, and the like which are limited to a single or other specified number of uses. With reference to FIGURE 1, one embodiment of the invention mentioned herein includes a computer **10** that is mounted in a mobile cart **12** or other convenient location in a surgical suite outside of the sterile field. This may be on the wall or on a hospital cart that is not in use. In the illustrated embodiment, as the computer **10** is inserted into the cart, a series of electrical interconnections are made, including interconnection with a display e.g., a flat screen monitor **14**, interconnection with an electrical wall outlet, backup power supply unit contained within the cart, or some combination thereof, interconnection with one or several tracking system cameras **16**, and the like. The tracking system cameras **16** for tracking the location of markers including but not limited to acoustic sensors, infrared sensors, and the like, are mounted on mobile carts, suspended from the ceiling of the surgical suite, mounted in conjunction with other equipment in the surgical suite such as the lighting, the operating table, or the like. In one embodiment, the cart **12** includes a port for connecting the computer **10** with the central record storage system of the hospital via a network, a diagnostic imaging device **64**, or other source of electronic images of the patient. In other embodiments, the computer **10** includes a disk, tape, or other media drive for receiving the image information via a portable medium.

With reference to FIGURE 2, for each surgical application, there is a corresponding software-integrated disposable kit **20**. The kit **20** includes a sealed,

e.g., shrink-wrapped, carry-case or unit **22** which contains all of the necessary equipment for performing a specific surgical procedure indicated on a label **24** on the outside of the kit. A variety of kits **20** are provided, each labeled for a specific surgical procedure or limited group of closely related surgical procedures. Each kit **20** typically includes the appropriate surgical tools for the corresponding procedure, such as instrumented drill guides **26**, **28**, instrumented probes **30**, and other accessories as may be appropriate to the selected procedure. The tools are instrumented with markers **32** which are tracked by the cameras **16**, in the preferred embodiment. Additional markers **32** not attached to a tool may be included in the kit **20**. In other embodiments, the markers **32** are acoustic or infrared transmitters whose signals are received by corresponding acoustic or infrared cameras **16**. By tracking the markers **32** with one or several cameras **16**, the current location of each marker **32**, hence the associated tool, is readily determined by well-known triangulation techniques. In other embodiments, more than two cameras **16** or other sensors are provided for improved tracking even when the surgeon temporarily blocks access to one of the markers **32**. Each of the drill guides **26**, **28**, probes **30**, and other surgical tools and accessories are presterilized and wrapped in peel-open or other sterile packaging.

The kit **20** further includes several other components which are commonly used during image guided surgery. These components can include a universal tool tracker **34** which is mounted directly to a fixed location on the tool. The universal tool tracker **34** is used to track standard surgical tools that are not included as part of the kit **20**. A registration phantom **36** that is attached to the operating room table or directly to the imaging device is also included and is used to register an acquired image(s) to the patient's anatomy. Depending on the surgical procedure, other components may be included such as a head frame **38** with markers for attachment to the patient. All

the components contained in the kit **20** are again presterilized and prepackaged in sterile packaging.

The kit **20** further includes, but is not limited to, a user input device(s) **40** such as a joystick, mouse or keyboard with which the operator controls the software's graphic user interface. The user input device(s) **40** and their associated cable(s) are sterile and packaged in sterile packaging. During set-up for the procedure, the sterile packaging is opened and the cable(s) for the user input device(s) **40** is plugged into a corresponding port on the computer **10** or mobile cart **12**. Another embodiment includes a wireless user input device(s) that is recognized by the system, through an infrared port for example on the computer **10** or mobile cart **12**.

The kit **20** can further include implants **42** and other surgical accessories that are used in the selected surgical procedure. For example, the kit **20** can include pedicel screws **42**, rods **44**, and mounting clamps **46**, and the like as are appropriate for a surgical procedure on the spine. Different surgical procedures will, of course, have different surgical accessories in the kit **20**. The surgical accessories are sterile and sealed in sterile packaging.

The kit **20** further includes a one-time-use digital medium **50**, such as a small high-capacity diskette, CD-ROM, DVD, or the like. The digital medium **50** is configured to be received into a drive **52** in the computer **10**. The diskette **50** contains a portion of the software to be used during a surgical procedure, image processing algorithms specific to the application, dimensions and other specifications of the surgical tools and accessories in the kit **20**, and other information of use during the surgical procedure.

With reference to FIGURE 3, the computer **10** may include triangulation or tracking software and base or low-level graphics and other processing software **60**. A video-grabber card or other similar input/output device for capturing still-images or live video includes an input/output port and/or interface **62** for receiving electronic images directly from an imaging device

64. Images can also be received through the computer network port by accessing central record keeping via the hospital's network. Optionally, the computer **10** may include a drive for reading the electronic image information obtained from the imaging device **64** from disk, tape, or other similar media. The computer **10** also includes a graphics card or the like with a port and/or interface **66** for connecting to the display **14**. Likewise, the computer **10** includes a port and/or interface **68** for interconnection with the user input device **40**. The computer **10** may also contain a port, an infrared port for example, for wireless connection to the user input device(s). The computer **10** further includes a port and/or interface assembly **70**, which interfaces the tracking system's cameras **16** with the tracking software.

The one-time-use digital medium **50**, in the preferred embodiment is a mini-diskette, which includes information useful for a specific surgical application. The medium contains an area for high-level graphics processing software **72** with the most recently revised algorithms for the graphics processes which are specific to the selected surgical procedure. The disks for different surgical procedures may have different high-level graphics processing software and information. The high-level graphics processing software **72** interacts with the low-level graphic processing software **60** to enable the computer **10** to perform the image and graphics processing which it may be called upon to perform during the selected surgical procedure. Various other electronic keys, including media such as CD-ROM and DVD for example, for enabling the computer **10** for image guided surgery are also contemplated.

The digital medium **50** further includes an area **74** for software which describes tool specifications. That is, software to describe the specifications of each of the tools, probes, guides, and any other necessary accessories in the kit. In conjunction with the tool(s) physical specifications, markers **32**, and the tracking system's cameras **16**, the image guided surgery software recognizes the tool and correlates its position, trajectory, end point, and any other necessary

characteristics in physical space with it's virtual representation on the display **14**.

The digital medium **50** further includes an area **76** for 3D virtual representations, images, or information, in VRML format for example, of the instrumented tools contained in the kits. These files are used to create 3D virtual representations of each of the surgical tools. The 3D representations of the tools are superimposed on each acquired and registered image. These representations can be in wireframe or fully rendered format, for example, depending on the surgeon's preference. The 3D surgical tool information or image area **76** is accessed by the software on the computer and the digital medium and manipulated so the tools virtual representation in the image(s) is correlated to its 3D position in physical space as determined by the camera(s) **16**.

The digital medium **50** further includes an area **78** for software that describes other information such as instructions with guides concerning common steps taken during the surgical procedure. For example, this section may include software information concerning the depth and diameter of the holes to be tapped for the surgical screws in the kit. It may include information or guidelines for the use or placement of the accessories in the kit, images from a previous or similar procedure, anatomy atlas tables containing information on certain anatomical angles and distances specific to an application, and the like. This portion of the digital medium **50** may also include software for upgrading the low-level graphics processing software **60** to the latest released revision.

The invention further includes a means **80** to ensure one-time-use of the digital medium **50**. This means preferably resides in the computer **10**. In one embodiment, this means erases all or part of the digital medium at the end of the procedure. Alternately, the software is encrypted to block reuse. In another embodiment, the digital medium **50** is physically deformed to prevent reuse. After the procedure, the tools and the digital medium **50** are disposed. Alternatively, the tool and the medium **50** are returned to the company for

inspection, remanufacture, cleaning, sterilization, and/or repackaging. Alternatively, the digital medium can also be used to store data obtained during surgery i.e., notes, images, etc. In this case, the digital medium **50** is archived.

In a preferred marketing procedure, the computer **10** is of limited cost. The computer **10** is sold to the hospitals at nominal or no cost. The cost of the computer **10** is recovered by the sale of the single use kits **20**, the price of which is gauged to cover the cost of maintaining the computer **10** as well as the tools and accessories. This business model eliminates the traditional capital equipment sale process for conventional image guided surgery equipment. It also facilitates patient billing.

In one alternate embodiment, the digital medium is a computer game which is deactivated after a fixed number of uses, e.g., one. In another embodiment, the digital medium is a computer program for other than surgical procedures, such as software for business or manufacturing purposes, personal finance, and the like. The present technique is useful for enabling potential purchasers to try new software before deciding whether to buy it. In another embodiment, the digital medium carries a movie or other video program for limited time viewing. In yet another embodiment, the digital medium is a CD with a limited number of plays.

Having thus described the preferred embodiment, the invention is now claimed to be:

1. A system having a human-viewable display **(14)**, and a computer **(10)** for displaying and manipulating images on the display, characterized by:

the computer being programmed with limited functionality;

a single-use digital medium **(50)** containing software to upgrade the computer temporarily to higher user functionality for a preselected procedure; and,

a means **(80)** for disabling the software from being reused to upgrade the computer after the preselected procedure.

2. The system as set forth in claim 1, further including a software-integrated disposable kit **(20)** including:

the digital medium with procedure specific upgrade software; and,

tools **(20, 30, 34)** instrumented **(32)** to be tracked by the tracking system.

3. The system as set forth in claim 2 further including:

a tracking system for tracking system for tracking movement of the tools, the tracking system communicating with the computer to provide the computer with information for superimposing designations of the tools on displayed images.

4. The system as set forth in any one of claims 1-3 wherein the computer is preprogrammed with:

a portion of a procedure that provides minimal user functionality, full user functionality being enabled by procedure specific upgrade software obtained from the digital medium **(50)**.

5. The system as set forth in any one of claims 1-4, further including:

a mobile cart **(12)** that holds at least the computer **(10)**, display **(14)**, and standard peripherals **(40)**.

6. The system as set forth in any one of claims 1-5 wherein the computer **(10)** includes:

a drive **(52)** which receives and reads the digital medium **(50)**.

7. The system as set forth in any one of claims 1-6, further including:

a means **(80)** for deactivating or encrypting the digital medium against reuse at the end of a surgical procedure.

8. The system as set forth in any one of claims 1-7, wherein the computer includes:

an input/output interface **(62)** for capturing still-images and/or live video from an imaging device **(64)**;

a graphic input/output interface **(68)** for connecting to the display **(14)**;

an interface **(68)** for interconnection with at least one of a wired user input device **(40)** and a wireless user input; and,

an interface **(70)** for interconnection with tracking sensors **(16)** for monitoring position and movement of the instrumented tools.

9. The system as set forth in any one of claims 2-8 where in the software-integrated disposable kit **(20)** further includes:

a label **(24)** to identify a particular procedure to be performed using the kit;

sterile packaging **(22)** in which the tools are contained in sterile condition;

other accessories **(36, 38, 42, 44, 46)** in sterile condition in sterile packaging;

a user input device **(40)**; and

wherein the digital medium **(50)** is a disposable one-time use digital medium readable by the computer and contains an upgrade software specific to the procedure identified on the label.

10. The system as set forth in claim 9 wherein the user input devices include:

a disposable, sterilizable, wireless peripheral **(40)** for use at the procedure site for remote communication with the computer.

11. The system as set forth in any one of claims 1-10 wherein the digital medium includes:

a preprogrammed one-time use application specific software module **(72, 76)** to be used in the procedure; and

a preprogrammed software module **(74, 76)** describing the tools, implants, and other accessories.

12. The system as set forth in any one of claims 1-11 wherein the digital medium includes:

preprogrammed software **(74)** describing dimensional specifications of each of the tools, probes, guides, and any other instrumented accessories contained in the kit.

13. The system as set forth in any one of claims 1-12 wherein the digital medium includes:

preprogrammed software **(76)** with 3D virtual representations, images, or information or instrumented tools, accessories, implants, and any associated hardware contained in the kits used to create 3D virtual representations of the tools in the images on the display.

14. The system as set forth in any one of claims 1-13, the digital medium includes:

preprogrammed software **(72)** for superimposing instrumented tools, accessories, implants, and associated

hardware on the images in a wireframe or a user selected custom format.

15. The system as set forth in any one of claims 1-14 wherein the digital medium includes:

an area **(72)** which stores the software application which enables full user functionality;

an area **(74)** which stores specifications and characteristics of the tools;

an area **(76)** which stores 3D virtual representations, images, or information of the tools and accessories contained in the kit; and

an area **(78)** which stores additional information relevant to a particular procedure.

16. The system as set forth in any one of claims 1-15 wherein the tracking system includes:

one of acoustic sensors, infrared sensors, video cameras **(16)**, that are utilized to determine a location of the tools.

17. The system as set forth in claim 16 wherein the tracking system includes:

a mobile cart **(12)** for positioning the video cameras in a surgical suite.

18. The system as set forth in any one of claims 1-17 wherein the processor includes:

an interface for interconnection with a source of three-dimensional electronic diagnostic images;

an interface for interconnection with a human-readable display for displaying diagnostic images and superimposed representations of the tools;

an interface for interconnection with a user input control; and,

an interface for interconnection with optical sensors for monitoring position and movement of the tools.

19. A kit for use in the system of claims 1-18, the kit comprising:

an identification of a surgical procedure to be performed using the kit;

the surgical tools in sterile condition in sterile packaging which are used in the identified surgical procedure;

medical appliances in sterile condition in sterile packaging which are used in the identified surgical procedure;

an operator control in sterile condition in sterile packaging for electrical interconnection with a graphics processor outside a sterile field; and

the digital media preprogrammed with a portion of an image guided surgery processing program and descriptive information concerning the tools and the appliances in the kit which is readable by the processor.

20. A method of implementing a computer-implemented procedure, the method comprising:

opening a software-integrated disposable kit **(20)** and removing a digital medium **(50)** with a procedure specific software which temporarily upgrades limited functionality software to higher user functionality;

inserting the digital medium into a computer **(10)** which is preprogrammed with the limited functionality software to upgrade the functionality;

performing the procedure;

deactivating or encrypting the digital medium against reuse in the computer;

removing the digital medium from the computer.

21. The method as set forth in claim 20 further including:

archiving on the digital medium a record or history of the performed procedure, including the downloaded images, selected instruments, implants, length of procedure time, notes, or other relevant information obtained during the procedure.

22. The method as set forth in claim 21 further including:

replaying archived data for review and follow-up.

23. The method as set forth in any one of claims 20-27 further including:

prior to placing the digital medium in the kit, programming the digital medium with dimensional information about and depictions of tools contained in the kit.

24. The method as set forth in claim 23 further including:

preventing reuse of the tools.

25. The method as set forth in claim 24 further including:

disposing of the tools and the digital medium without reuse after the procedure.

26. The method as set forth in any one of claims 20-25 further including:

using the computer as a planning station before a procedure to define entry points and trajectories.

27. The method as set forth in any one of claims 20-26 further including:

prior to placing tools and accessories in the kit, sterilizing the tools and accessories.

28. An image guided procedure system comprising:

a set of tools which are instrumented to be tracked during image guided surgery;

a processor which is preprogrammed with less than all of the software which is used for manipulating images during the image guided procedure and for tracking the movement of the instrumented surgical tools during the image guided procedure;

a digital media which is preprogrammed with a remaining portion of the software for processing the image data and tracking movement of the instrumented tools and with descriptive information.

29. The system as set forth in claim 28 wherein the processor further includes:

a deactivator which deactivates the digital media against reuse at the end of an image guided procedure.

30. A method comprising:

providing a kit which includes (1) tools and accessories and (2) a digital medium which is preprogrammed with (i) at least a portion of a graphics processing program and (ii) information concerning the tools and accessories;

at a procedure site, removing the secure digital medium from the kit and inserting it into a processor which, between software with which the processor is preprogrammed and the software from the digital medium, processes electronic images, correlates a coordinate system of the procedure site with a coordinate system of the diagnostic images, tracks a location of the instrumented surgical tools in the coordinate system of the procedure site, and translates the instrument position into the coordinate system of the diagnostic image.

31. The method as set forth in claim 30 further including:

after the procedure, deactivating the digital media against reuse.