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(54) **SYSTEM AND METHOD FOR MANAGING A MEDICAL PROCEDURE SITE WITH A TRACKING DEVICE**

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(57) **ABSTRACT**

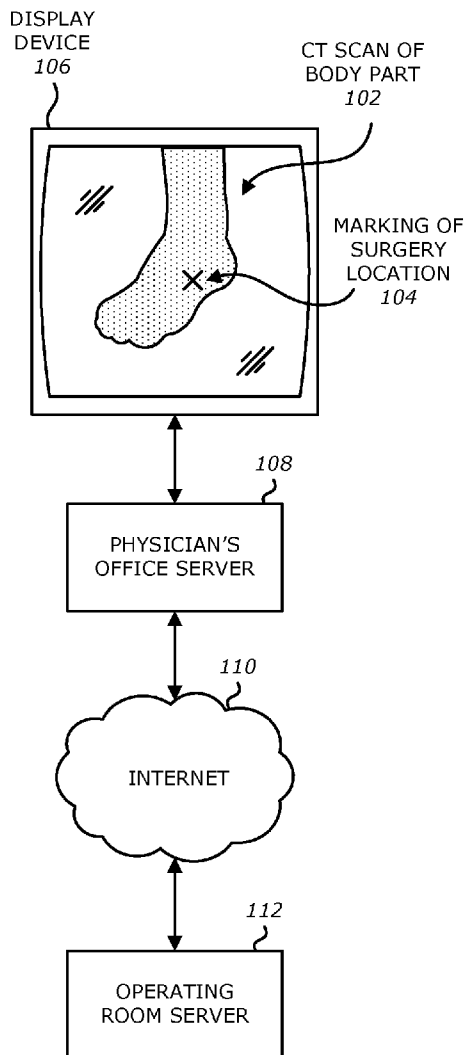
A system for ensuring the correct location/side of a medical procedure is described. The system includes a pointing device, a receiver, and a validator. The pointing device transmits location data to a receiver from several reference points and a planned medical procedure site on the body of the patient. The validator receives medical procedure plan data associated with the patient and compares the medical procedure plan data with the location data to verify the validity of the planned medical procedure site.

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(60) **Provisional application No. 61/230,992, filed on Aug. 3, 2009.**



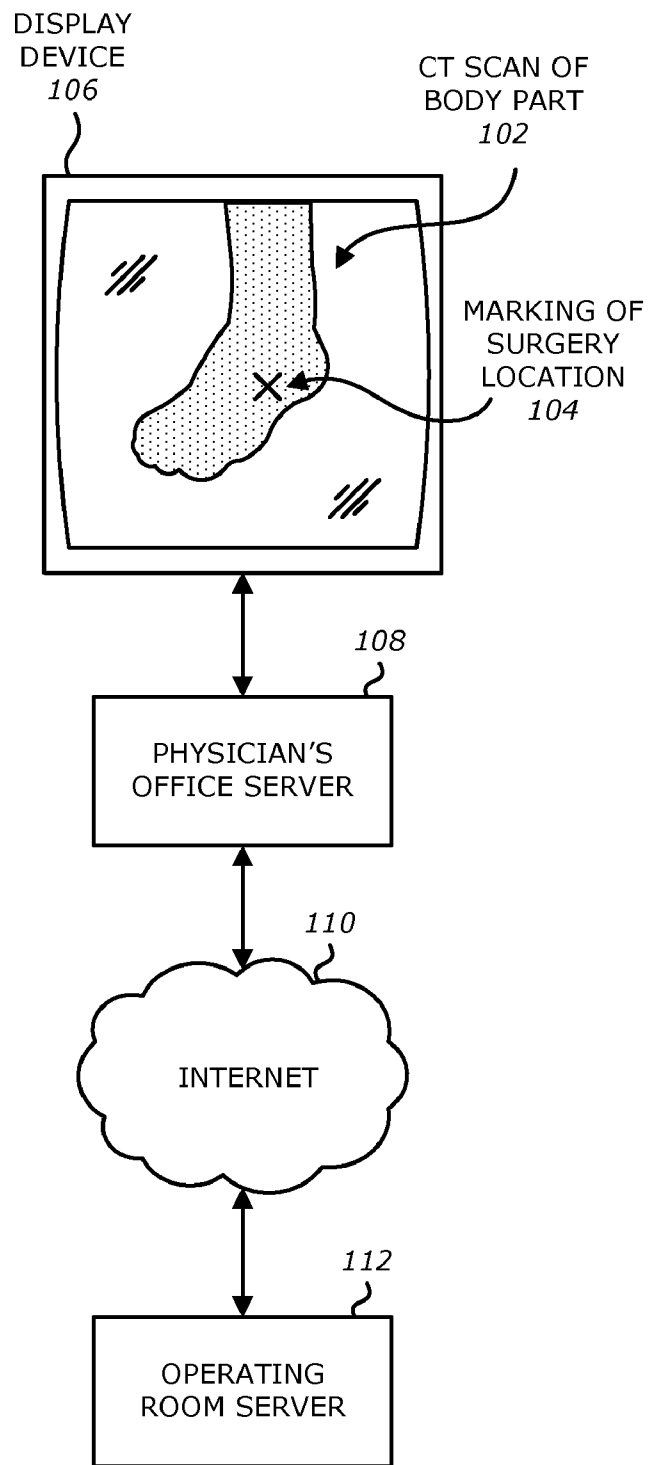
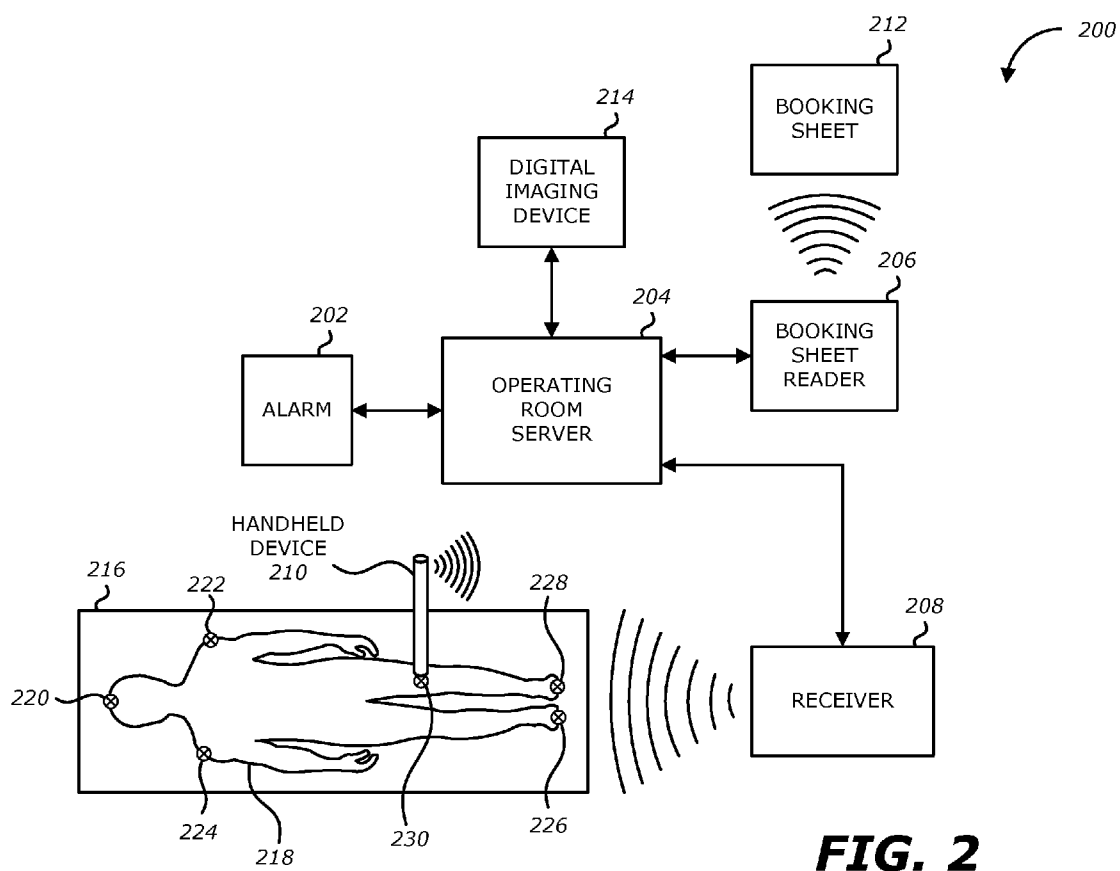


FIG. 1



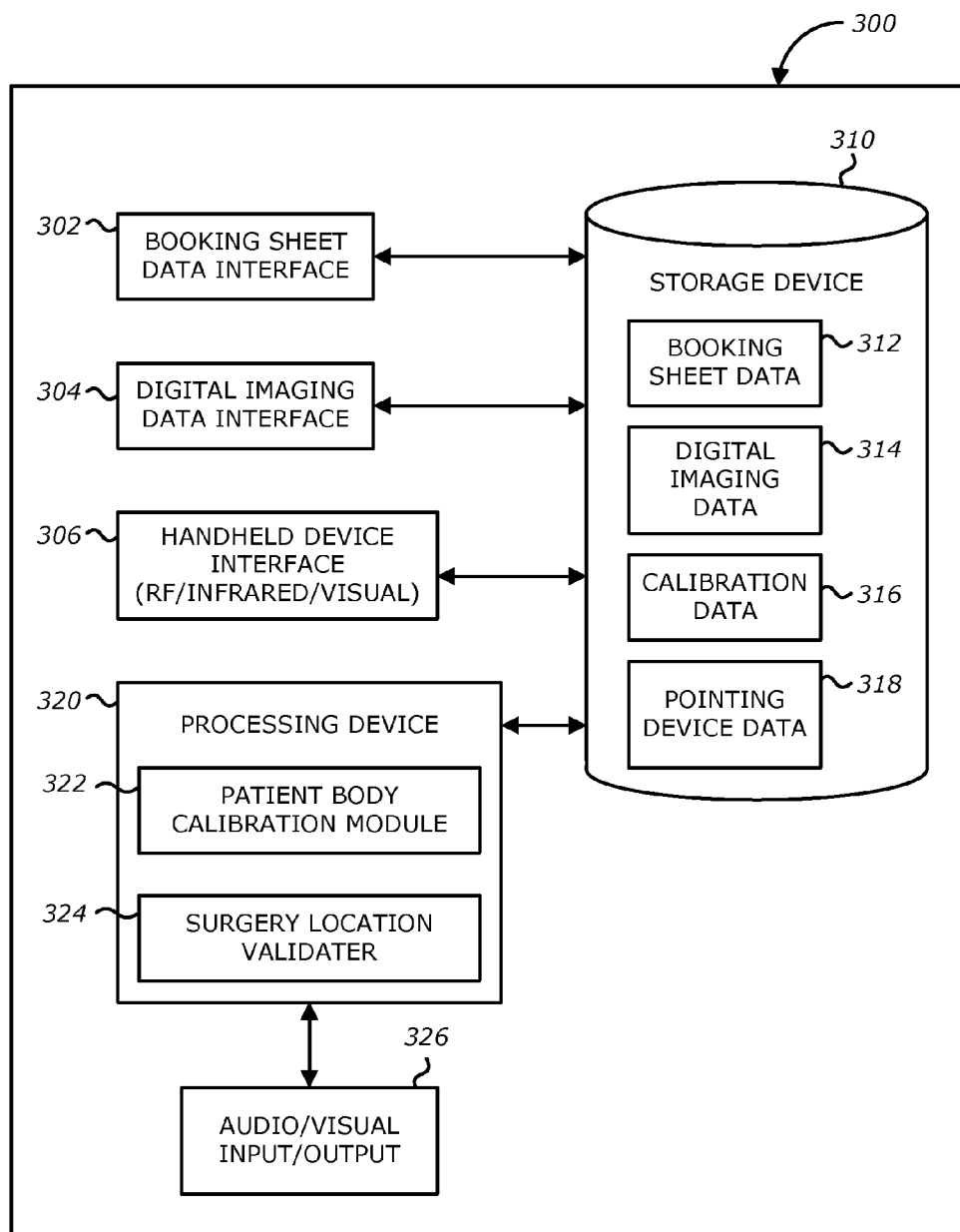


FIG. 3

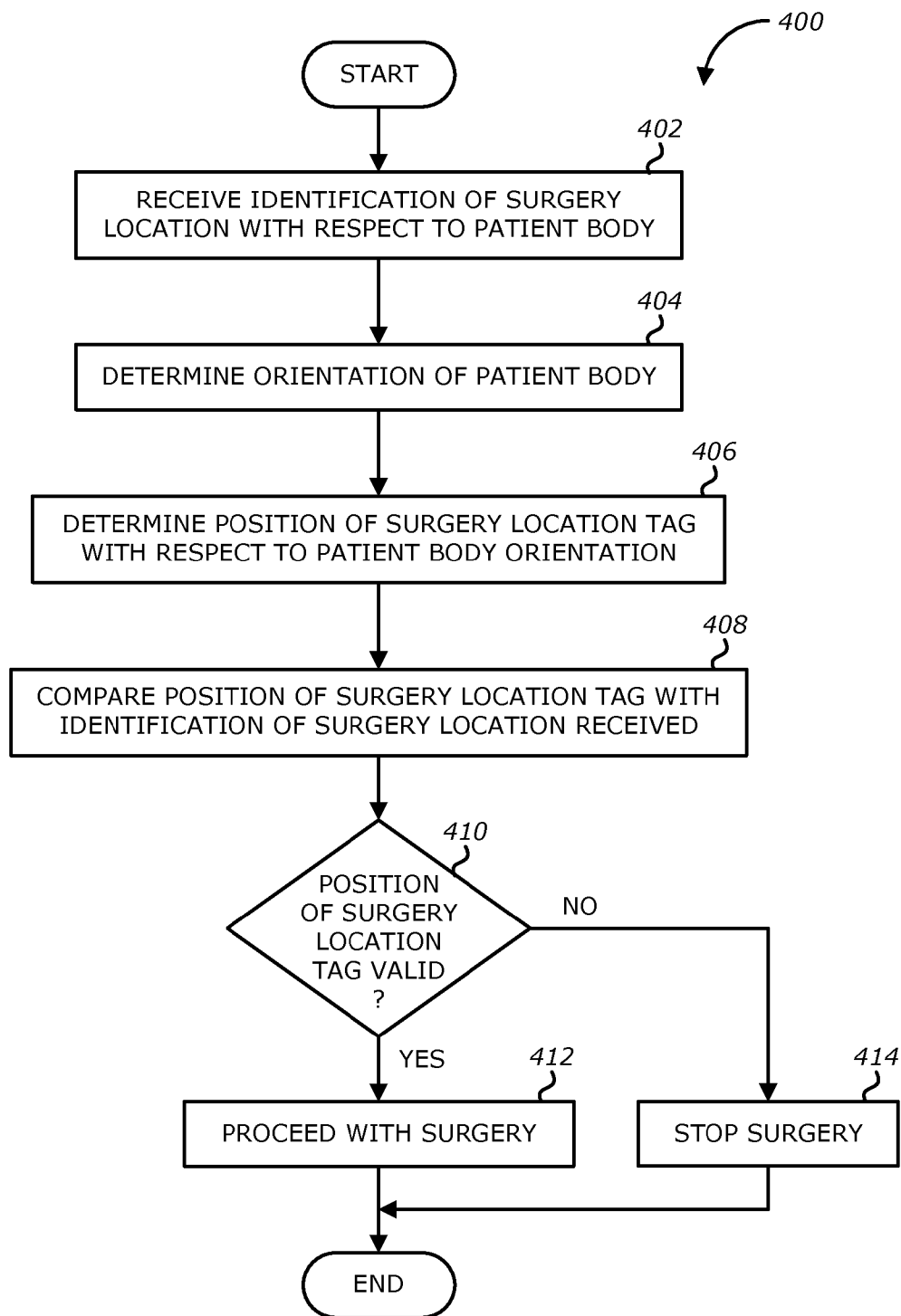


FIG. 4

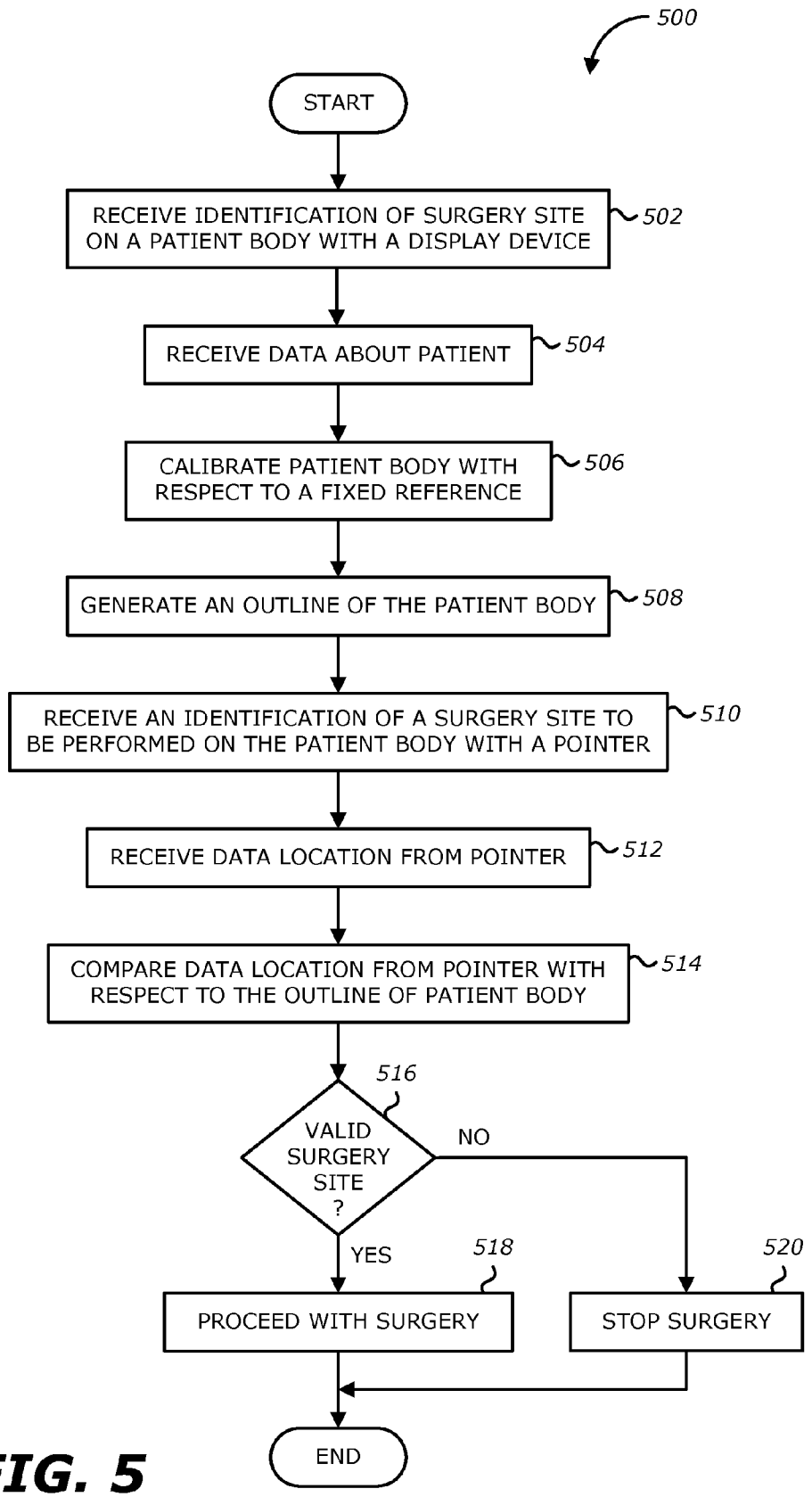


FIG. 5

SYSTEM AND METHOD FOR MANAGING A MEDICAL PROCEDURE SITE WITH A TRACKING DEVICE

RELATED APPLICATIONS

[0001] The present application claims priority from U.S. Provisional Patent Application Ser. No. 61/230,992 filed Aug. 3, 2009.

TECHNICAL FIELD

[0002] Embodiments of the present invention relate to medical devices, and more particularly, to a surgical site identification system.

BACKGROUND

[0003] Wrong side surgeries are increasing every year despite behavioral requirements by operative staff and time out procedures. Surgical sites can be marked by surgeon, patient and surgical nurse and yet mistakes are persistent.

[0004] A need exists for a system for ensuring that surgeries are performed on the correct side of a patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0005] The present invention is illustrated by way of example, and not by way of limitation, in the figures of the accompanying drawings and in which:

[0006] FIG. 1 is a block diagram illustrating one embodiment of a system for identifying a medical procedure site.

[0007] FIG. 2 is a block diagram illustrating one embodiment of a system for verifying a planned medical procedure site.

[0008] FIG. 3 is a block diagram illustrating one embodiment of a medical procedure site verification computer system.

[0009] FIG. 4 is a flow diagram illustrating one embodiment of a method for verifying a planned medical procedure site on a body of a patient.

[0010] FIG. 5 is a flow diagram illustrating another embodiment of a method for verifying a planned medical procedure site on a body of a patient.

DETAILED DESCRIPTION

[0011] Described herein is a system for verifying a medical procedure site or surgical location for ensuring medical procedure on a correct side of a body of a patient. The system includes a pointing device, a receiver, and a validator. The pointing device transmits location data to a receiver from several reference points on the body of the patient and a planned medical procedure site on the body of the patient. The validator receives medical procedure plan data associated with the patient and compares the medical procedure plan data with the location data to verify the validity of the planned medical procedure site.

[0012] FIG. 1 is a block diagram illustrating one embodiment of a system for indicating a medical procedure site. Prior to surgery, for example, at a doctor's office, a digital image 102 of a portion of a body of a patient is displayed on a display device 106. The digital image 102 may include for example, a CT scan, X ray, or other types of digital images.

[0013] The physician uses an input device such as a mouse to mark the location of a surgery site 104 on digital image 102. In one embodiment, the digital image 102 is oriented accord-

ing to the body of the patient. In other words, the left foot is represented as the left foot. Display device 106 communicates with physician's office server 108. The information of the surgery site is stored on physician's office server 108 and communicated to operating room server 112 via a computer network (Internet 110). For example, operating room server 112 may located at a hospital where the surgery is to take place. Other pertinent data (patient record) associated with the patient may also be transmitted to operating room server 112.

[0014] FIG. 2 is a block diagram illustrating one embodiment of a system 200 for verifying a planned surgery site 230. The body of the patient 218 is laid on an operating table 216. In one embodiment, patient 218 is faced up with his back against the table 216. System 200 includes a handheld device 210 such as a pointing device, a receiver 208 such as a pointing device reader, an operating room booking sheet 212, and a booking sheet reader 206, an operating room server 204, a digital imaging device 214, and an alarm system 202.

[0015] In one embodiment, booking sheet reader 206 includes a bar code scanner or any other type of machine readable marking configured to read data (e.g. a bar code) from operating booking sheet 212 and transmit the data to operating room server 204. Alternatively, data from booking sheet 212 may have been already communicated electronically from a physician's office or at pre-registration at the hospital to operating room server 204. In another embodiment, information about a patient is entered manually into operating room server 204.

[0016] Booking sheet 212 includes patient information such as a booking number, the name of the patient, date of birth, sex, address, telephone numbers, hospital, surgeon name, date of surgery, nature of surgical procedure, and side of which the surgical procedure is to be performed among others. Additional information can include allergies, insurance information, and diagnosis codes, etc. . . .

[0017] In one embodiment, a barcode generator is used to generate (not shown) a barcode on booking sheet 212. Barcode generator includes any software or hardware system commonly used to generate barcodes or other machine readable markings. Booking sheet 212 includes a uniquely generated barcode associated with the patient information. Those of ordinary skills in the art will recognize that other types of machine readable marking may be used such as Radio Frequency Identification (RFID). The barcode may be in the form of a sticker affixed to booking sheet 212.

[0018] In one embodiment, booking sheet 212 is generated prior to the surgery at the hospital. For example, booking sheet 212 may be generated at the time of registration of the patient.

[0019] Digital imaging device 214 includes a display device showing a digital image 102 along with the location of the surgery site as marked by the physician or surgeon in FIG. 1. In one embodiment, operating room server 204 verifies that the location of the surgery site 104 from digital image 102 corresponds to data from booking sheet 212. Operating room server 204 issues a warning notification with alarm system 202 when the location of the surgery site 104 from digital image 102 does not match the data from booking sheet 212.

[0020] In another embodiment, digital imaging device 214 display the digital image 102 overlap on another digital image generated by operating room server 204. For example, a CT scan of the left foot of the patient may be overlap with a live outline image of the body of the patient as generated by

operating room server **204**. The outline image may be a two-dimensional or three-dimensional picture.

[0021] In one embodiment handheld device **210** (e.g. infrared pen) wirelessly communicates coordinates and location data to receiver **208** (e.g. infrared receiver). The location data from handheld device **210** is relative to receiver **208**. Prior to the surgery on patient **218**, a staff or physician uses handheld device **210** to mark the location of several reference points along the body of patient **218** as instructed by the handheld device **210** or server **204**. For example, system **200** may request the staff to point to a reference point **220** on the head of patient **218**. Handheld device **210** may include a switch (not shown) on which the staff can click when the handheld device at the reference point. Location data from reference point **220** is then transmitted to receiver **208**. In another embodiment, upon depressing the switch, receiver **208** reads the location of handheld device **210** relative to receiver **208**.

[0022] FIG. 2 illustrates an example of reference points that include, left shoulder **222**, right shoulder **224**, right foot **226**, and left foot **228** among others. In one embodiment, the reference points form an outline of the body of patient **218**. A minimum number of reference points allows for receiver **208** or operating room server **204** to determine an orientation of the body of patient **218**. In other words, receiver **208** and operating room server **204** are capable, after receiving the reference points, of determining the left side and right side of patient **218**.

[0023] After pointing to the reference points, the user/staff is asked to place handheld device **210** on the planned surgery site **230** and to click the switch on handheld device **210**. Coordinates and location data of the planned surgery site **230** are then transmitted to receiver **208**. In another embodiment, upon depressing the switch, receiver **208** reads the location of handheld device **210** relative to receiver **208**.

[0024] As such, receiver **208** and operating room server **204** are then capable of determining whether the planned surgery site **230** is located on the left or right side of the patient **218** based on the data received from handheld device **210**.

[0025] In another embodiment handheld device **210** (e.g.—a marker) deposits a visual indicator (e.g. ink) on the skin of the patient. Receiver **208** (e.g. a camera) can be configured to detect the visual indicator and determine the relative position of the visual indicator with respect to the receiver.

[0026] The planned surgery site is the location where the surgeon is planning to operate on. It may or may not be the actual surgery site **104** as prescribed in booking sheet **212**. Thus, the term “planned surgery site” is used to distinguish from the “surgery site” as prescribed by the surgeon in digital image **102** or in booking sheet **212**.

[0027] The medical procedure is not limited to surgery, but also includes other surgical and non-surgical medical procedures such as filling a tooth cavity at a dentist, removing a tooth, examining an eye or ear, putting a cast on a limb, acupuncture on a hand, performing a CT scan or X ray on a body part, etc. . . .

[0028] FIG. 3 is a block diagram illustrating one embodiment of a surgery site verification computer system **300** of an operating room server **204**. Computer system **300** includes a booking sheet data interface **302**, a digital imaging data interface **304**, a handheld device interface **306**, a processing device **320**, a storage device **310**, and an audio/visual input/output **326**.

[0029] Booking sheet data interface **302** enables computer system **300** to communicate with booking sheet reader **206**. Digital imaging data interface **304** enables computer system **300** to communicate with digital imaging device **214**. Handheld device interface **306** enables computer system **300** to communicate with receiver **208**. Processing device **320** is configured to execute a patient body calibration module **322** and a surgery location validator module **324**. Patient body calibration module **322** is configured to determine the orientation of the body of the patient with respect to a fixed pre-determined reference (such as receiver **208**, operating table **216** or the operating room). In other words, patient body calibration module **322** is able to determine a left or right side of the patient **218**. Surgery location validator module **324** is configured to determine whether the planned surgery site is located on the left or right side of patient **218** and to compare the side of the planned surgery site with the side of the location marked on digital image **102** received at digital imaging interface **304**. In another embodiment, surgery location validator module **324** is configured to determine whether the planned surgery site is located on the left or right side of the patient and to compare the side of the planned surgery site with the side of the location prescribed from booking sheet **212** and received from booking sheet data interface **302**.

[0030] Storage device **310** is configured to store booking sheet data **312**, digital imaging data **314**, calibration data **316**, and handheld device data **318**. Calibration data **316** includes the orientation (where the left and right sides are) of the body of patient **218** as determined by patient body calibration module **322**. Handheld device data **318** includes coordinates/location data received from handheld device **210** or as determined by receiver **208**.

[0031] Audio/visual input/output **326** is configured to issue an audio and/or visual warning triggered by surgery location validator module **324** when the planned surgery site does not correspond to the surgery site prescribed in booking sheet **212** and/or as indicated in digital image **102** of the portion of the body of patient **218**.

[0032] In another embodiment, surgery location validator module **324** is configured to match the portion of the body of patient **218** with an orientation or outline of the body of patient **218**. For example, surgery location validator module **324** can determine that a CT scan of a left foot indicates that the surgery site is on the left side of the body.

[0033] FIG. 3 illustrates a diagrammatic representation of a machine in the exemplary form of a computer system **300** within which a set of instructions, for causing the machine to perform any one or more of the methodologies discussed herein, may be executed. In alternative embodiments, the machine may be connected (e.g., networked) to other machines in a LAN, an intranet, an extranet, or the Internet. The machine may operate in the capacity of a server or a client machine in client-server network environment, or as a peer machine in a peer-to-peer (or distributed) network environment. The machine may be a personal computer (PC), a tablet PC, a set-top box (STB), a Personal Digital Assistant (PDA), a cellular telephone, a web appliance, a server, a network router, switch or bridge, or any machine capable of executing a set of instructions (sequential or otherwise) that specify actions to be taken by that machine. Further, while only a single machine is illustrated, the term “machine” shall also be taken to include any collection of machines that individually

or jointly execute a set (or multiple sets) of instructions to perform any one or more of the methodologies discussed herein.

[0034] In one embodiment, the exemplary computer system **300** includes processing device **320**, a main memory (e.g., read-only memory (ROM), flash memory, dynamic random access memory (DRAM) such as synchronous DRAM (SDRAM), a static memory (e.g., flash memory, static random access memory (SRAM), etc.), and storage device **310**, which communicate with each other via a bus.

[0035] Processing device **320** represents one or more general-purpose processing devices such as a microprocessor, central processing unit, or the like. More particularly, the processing device may be complex instruction set computing (CISC) microprocessor, reduced instruction set computing (RISC) microprocessor, very long instruction word (VLIW) microprocessor, or processor implementing other instruction sets, or processors implementing a combination of instruction sets. Processing device **504** may also be one or more special-purpose processing devices such as an application specific integrated circuit (ASIC), a field programmable gate array (FPGA), a digital signal processor (DSP), network processor, or the like. The processing device **320** is configured to execute modules **322**, **324** for performing the operations and steps discussed herein with. In one embodiment, modules **322**, **324** may include hardware or software or a combination of both.

[0036] The computer system **300** may further include a network interface device, a video display unit (e.g., a liquid crystal display (LCD) or a cathode ray tube (CRT)), an alphanumeric input device (e.g., a keyboard), a cursor control device (e.g., a mouse), and a signal generation device **326** (e.g., a speaker).

[0037] Storage device **310** may include a computer-accessible storage medium on which is stored one or more sets of instructions (e.g., surgery site validator software **324**) embodying any one or more of the methodologies or functions described herein. The software **324** may also reside, completely or at least partially, within the main memory and/or within the processing device **320** during execution thereof by the computer system **300**, the main memory and the processing device **320** also constituting computer-accessible storage media. The software **324** may further be transmitted or received over a network via the network interface device.

[0038] The computer-accessible storage medium may also be used to store a calibration module **322** and a surgery site validator module **324** as presently described. Calibration module **322** and surgery site validator module **324** may also be stored in other sections of computer system **300**, such as static memory.

[0039] While the computer-accessible storage medium is shown in an exemplary embodiment to be a single medium, the term “computer-accessible storage medium” should be taken to include a single medium or multiple media (e.g., a centralized or distributed database, and/or associated caches and servers) that store the one or more sets of instructions. The term “computer-accessible storage medium” shall also be taken to include any medium that is capable of storing, encoding or carrying a set of instructions for execution by the machine and that cause the machine to perform any one or more of the methodologies of the present invention. The term

“computer-accessible storage medium” shall accordingly be taken to include, but not be limited to, solid-state memories, optical and magnetic media.

[0040] FIG. 4 is a flow diagram illustrating one embodiment of a method for verifying a planned surgery site on a body of a patient. The coordinates and location of several reference points along a perimeter or outline of the body of the patient is received at **402**. Based on the received data, the orientation of the patient body is determined at **404**. In particular, a left side and right side of the patient body is determined. At **406**, the system determines the location of the planned surgery site with respect to the orientation of the body. In particular, the system determines whether the planned surgery site is on the left or right side of the body of the patient. At **408**, the system compares whether the side of the planned surgery site matches the side of the surgery site as prescribed in a booking sheet of the patient or in a digital imaging of the patient. If there is a match, the surgery proceeds at **412**. If the data does not match, the surgery stops at **414**.

[0041] FIG. 5 is a flow diagram illustrating another embodiment of a method for verifying a planned surgery site on a body of a patient. At **502**, a display device is used to receive an identification of a surgery site on a patient body. At **504**, a system receives coordinate and location data about the body of a patient using a handheld device. For example, the system receives an outline of the body of the patient at several pre-determined reference points (right elbow, left shoulder, right hip, etc. . . .) along a perimeter of the body of the patient.

[0042] At **506**, the received data is calibrated with respect to a fixed reference such as a receiver or reader of the handheld device. At **508**, an outline of the patient body is generated using the received data. At **510**, the handheld device is also used to transmit coordinate and location data from a planned surgery site to the system. At **512**, the coordinate and location data are received from the handheld device. At **514**, the location data from the handheld device is compared with the outline of the patient body to determine whether the planned surgery site is on the right or left side of the body.

[0043] At **516**, the side of the planned surgery site is compared with the side of the surgery site as received at **502**. If both sides match or correspond, the handheld device instructs a user to proceed at **518**. Otherwise, the handheld device instructs the user to stop the surgery procedure at **520**. An audio (alarm) and/or visual message (e.g. red flashing lights or “you must stop. An error condition exists”) may be displayed on handheld device or alarm **202**, or another output device (not shown).

[0044] In the above description, numerous details are set forth. It will be apparent, however, to one skilled in the art, that the present invention may be practiced without these specific details. In some instances, well-known structures and devices are shown in block diagram form, rather than in detail, in order to avoid obscuring the present invention.

[0045] Some portions of the detailed descriptions above are presented in terms of algorithms and symbolic representations of operations on data bits within a computer memory. These algorithmic descriptions and representations are the means used by those skilled in the data processing arts to most effectively convey the substance of their work to others skilled in the art. An algorithm is here, and generally, conceived to be a self-consistent sequence of steps leading to a desired result. The steps are those requiring physical manipulations of physical quantities. Usually, though not necessarily,

these quantities take the form of electrical or magnetic signals capable of being stored, transferred, combined, compared, and otherwise manipulated. It has proven convenient at times, principally for reasons of common usage, to refer to these signals as bits, values, elements, symbols, characters, terms, numbers, or the like.

[0046] 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 convenient labels applied to these quantities. Unless specifically stated otherwise as apparent from the following discussion, it is appreciated that throughout the description, discussions utilizing terms such as “processing” or “computing” or “calculating” or “determining” or “reading” or “verifying” or “validating” or the like, refer to the action and processes of a computer system, or similar electronic computing device, that manipulates and transforms data represented as physical (electronic) quantities within the computer system’s registers and memories into other data similarly represented as physical quantities within the computer system memories or registers or other such information storage, transmission or display devices.

[0047] The present invention also relates to apparatus for performing the operations herein. This apparatus may be specially constructed for the required purposes, or it may comprise a general purpose computer selectively activated or reconfigured by a computer program stored in the computer. Such a computer program may be stored in a computer readable storage medium, such as, but is not limited to, any type of disk including floppy disks, optical disks, CD-ROMs, and magnetic-optical disks, read-only memories (ROMs), random access memories (RAMs), EPROMs, EEPROMs, magnetic or optical cards, or any type of media suitable for storing electronic instructions, and each coupled to a computer system bus.

[0048] The algorithms and displays presented herein are not inherently related to any particular computer or other apparatus. Various general purpose systems may be used with programs in accordance with the teachings herein, or it may prove convenient to construct more specialized apparatus to perform the required method steps. The required structure for a variety of these systems will appear from the description below. In addition, the present invention is not described with reference to any particular programming language. It will be appreciated that a variety of programming languages may be used to implement the teachings of the invention as described herein.

[0049] It is to be understood that the above description is intended to be illustrative, and not restrictive. Many other embodiments will be apparent to those of skill in the art upon reading and understanding the above description. The scope of the invention should, therefore, be determined with reference to the appended claims, along with the full scope of equivalents to which such claims are entitled.

What is claimed is:

1. A system comprising:

- a receiver configured to determine, location data of a plurality of reference points on a body of a patient and of a planned medical procedure site on the body of the patient with a handheld device; and
- a validator coupled to the receiver, the validator configured to receive medical procedure plan data associated with the patient and to compare the medical procedure plan data with the location data to verify the validity of the planned medical procedure site.

2. The system of claim 1 wherein the location data includes coordinates data relative to the receiver.

3. The system of claim 1 wherein the validator comprises: a calibration module configured to determine an orientation of the body of the patient based on the location data of the plurality of reference points on the body of the patient.

4. The system of claim 3 wherein the validator comprises: a medical procedure site validator configured to determine a side of the planned medical procedure site with respect to the orientation of the body of the patient, and to compare the side of the planned medical procedure site with the medical procedure plan data.

5. The system of claim 4 further comprising: an audio or visual warning device coupled to the surgical site validator, the audio or visual warning device configured to issue an audio or visual warning when the side of the planned medical procedure site and the side of the body of the patient as prescribed in the medical procedure plan data do not match.

6. The system of claim 1 wherein the surgical plan data associated with the patient includes data from a booking sheet, the booking sheet comprising an identification of the patient, a location of the medical procedure site on the body of the patient, a side of the body on which the medical procedure site is located, and a surgical procedure for the patient.

7. The system of claim 1 wherein the handheld device includes an infrared pen, wherein the receiver includes an infrared receiver configured to detect a location of the handheld device relative to the receiver.

8. The system of claim 1 wherein the handheld device includes a marker to deposit a visual indicator on the skin of the patient at the plurality of reference points and at the planned medical procedure site, wherein the receiver is configured to detect the visual indicators and determine their relative positions.

9. The system of claim 1 further comprising: a display device configured to display a digital image of at least a portion of the body of the patient;

an input device coupled to the display device, the input device configured to identify a medical procedure site on the display device; and

a server coupled to the input device, the server configured to receive the medical procedure site and the side of the medical procedure site with respect to the digital image.

10. The system of claim 9 wherein the server is configured to generate the medical procedure plan data.

11. A method for managing a surgical site on a patient comprising:

- receiving surgical plan data associated with the patient;
- determining location data of a plurality of reference points on a body of a patient and of a planned medical procedure site on the body of the patient with a handheld device, the location data relative to a receiver;
- determining an orientation of the body of the patient based on the location data of the plurality of reference points, and a side of the planned medical procedure site on the body of the patient relative to the orientation of the body of the patient; and

comparing the medical procedure plan data with the side of the planned medical procedure site to verify the validity of the planned medical procedure site.

comparing the medical procedure plan data with the side of the planned medical procedure site to verify the validity of the planned medical procedure site.

- 12. The method of claim 11 comprising:
issuing an audio or visual warning when the side of the planned medical procedure site and the side of the body of the patient as prescribed in the medical procedure plan data do not match.
- 13. The method of claim 11 wherein the surgical plan data associated with the patient includes data from a booking sheet, the booking sheet comprising an identification of the patient, a location of the medical procedure site on the body of the patient, a side of the body on which the medical procedure site is located, and a surgical procedure for the patient.
- 14. The method of claim 11 wherein the handheld device includes an infrared pen, wherein the receiver includes an infrared receiver configured to detect the location of the handheld device relative to the receiver.
- 15. The method of claim 11 wherein the handheld device includes a marker to deposit a visual indicator on the skin of the patient at the plurality of reference points and at the planned medical procedure site, wherein the receiver is configured to detect the visual indicators and determine their relative positions.
- 16. The method of claim 11 further comprising:
displaying on a display device a digital image of at least a portion of the body of the patient;
identifying a medical procedure site on the display device with an input device coupled to the display device;
determining a side of the medical procedure site with respect to the digital image; and
generating the medical procedure data plan based on the side of the medical procedure site.
- 17. A computer-readable storage medium, having instructions stored therein, which when executed, cause a computer system to perform a method comprising:
receiving surgical plan data associated with the patient;
determining location data of a plurality of reference points on a body of a patient and of a planned medical procedure site on the body of the patient with a pointing device, the location data relative to a receiver;
determining an orientation of the body of the patient based on the location data of the plurality of reference points,

- and a side of the planned medical procedure site on the body of the patient relative to the orientation of the body of the patient; and
comparing the medical procedure plan data with the side of the planned medical procedure site to verify the validity of the planned medical procedure site.
- 18. The computer-readable storage medium of claim 17 wherein the method further comprises:
issuing an audio or visual warning when the side of the planned medical procedure site and the side of the body of the patient as prescribed in the medical procedure plan data do not match.
- 19. The computer-readable storage medium of claim 17 wherein the surgical plan data associated with the patient includes data from a booking sheet, the booking sheet comprising an identification of the patient, a location of the medical procedure site on the body of the patient, a side of the body on which the medical procedure site is located, and a surgical procedure for the patient.
- 20. The computer-readable storage medium of claim 17 wherein the handheld device includes an infrared pen, wherein the receiver includes an infrared receiver configured to detect the location of the handheld device relative to the receiver.
- 21. The computer-readable storage medium of claim 17 wherein the handheld device includes a marker to deposit a visual indicator on the skin of the patient at the plurality of reference points and at the planned medical procedure site, wherein the receiver is configured to detect the visual indicators and determine their relative positions.
- 22. The computer-readable storage medium of claim 17 further comprising:
displaying on a display device a digital image of at least a portion of the body of the patient;
identifying a medical procedure site on the display device with an input device coupled to the display device;
determining a side of the medical procedure site with respect to the digital image; and
generating the medical procedure data plan based on the side of the medical procedure site.

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