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(54) Title: SYSTEM FOR PREVENTING INSTRUMENT RETENTION

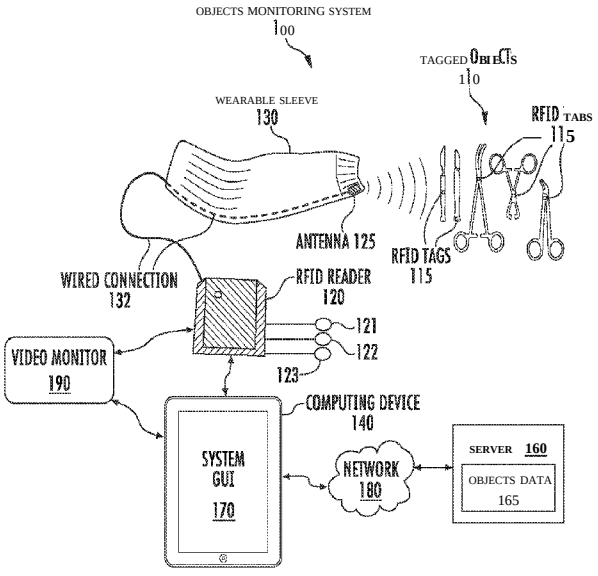

Fig. 2

(57) Abstract: A radio-frequency identification (RFFD)-based system for automatically tracking objects used in sur¬ gical procedures, and methods of use thereof, are disclosed. More particularly, an objects monitoring system is provided that includes a set of RFID tagged-objects (e.g., RFID tagged- surgical instruments), an RFID reader, an RFID read¬ er antenna installed in a disposable wearable article, a com¬ puting device, and optionally a centralized server. A method of operation of the presently disclosed objects monitoring system includes, but is not limited to, the steps of detecting the tagged objects during the surgical procedure and automat¬ ically generating a record and count of the "checked out" ob - jects, detecting the tagged objects upon completion of the surgical procedure and automatically generating a record and count of the "checked in" objects, automatically comparing and reconciling the record of "checked in" objects with the record of "checked out" objects, and automatically indicating the success or failure of the reconciliation process.

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SYSTEM FOR PREVENTING INSTRUMENT RETENTION

CROSS-REFERENCE TO RELATED APPLICATION

This application is a PCT International Application which claims the benefit of U.S. Provisional Patent Application No. 61/819,932, filed May 6, 2013, the content of which is herein incorporated by reference in its entirety.

BACKGROUND

It is of critical importance that the entry of objects (e.g., surgical instruments) into a surgical field and into a surgical site, as well as their removal, be carefully reconciled to avoid inadvertent retention of an object within a patient. Counting objects entering and exiting a surgical field is a conventional operating room procedure. Such practices greatly reduce the risk of an object being inadvertently retained within a patient. Such procedures typically involve the manual counting of objects entering and exiting the surgical field, as well as the visual examination of the surgical site. It is critical that such procedures be completed before the surgical site is closed. These manual processes of counting and visually examining the objects entering and exiting the surgical field, however, are prone to human error. Consequently, a risk of objects being inadvertently retained within the patient exists.

SUMMARY

The presently disclosed subject matter generally relates to methods of accounting for instruments used in surgical procedures and, more particularly, to a radio-frequency identification (RFID)-based system for automatically tracking objects used in surgical procedures, and methods of use thereof.

In some aspects, the presently disclosed subject matter provides a system for identifying and tracking one or more objects used in a surgical procedure, the system comprising a radio-frequency identification (RFID) reader, an article worn on a user's body, e.g., a wearable sleeve, a wrist- or hand-mounted device, or a device sown or otherwise incorporated into a garment, e.g., a surgical gown or a glove, worn by the user, comprising an antenna in electrical communication with the RFID reader, or a standalone RFID antenna, and one or more RFID tags for tagging, identifying, and tracking objects used in a surgical procedure.

In other aspects, the presently disclosed subject matter provides a method for identifying and tracking one or more objects used in a surgical procedure, the method comprising: providing a radio-frequency identification (RFID) reader, an article worn on a user's body, e.g., a wearable sleeve, a wrist- or hand-mounted device, or a device sown or otherwise incorporated into a garment, e.g., a surgical gown or a glove, worn by the user, comprising an antenna in electrical communication with the RFID reader, or a standalone RFID antenna, and one or more RFID tags for tagging, identifying, and tracking objects used in a surgical procedure; detecting one or more tagged objects using the RFID reader prior to or during the surgical procedure; generating a record and count of the one or more detected tagged objects prior to or during the surgical procedure; detecting one or more tagged objects using the RFID reader after the surgical procedure; generating a record and count of the one or more detected tagged objects after the surgical procedure; reconciling the record and count of the one or more detected tagged objects prior to or during the surgical procedure to the record and count of the one or more detected tagged objects after the surgical procedure; and indicating a success or failure of the reconciliation of the record and count of the one or more detected tagged objects prior to or during the surgical procedure to the record and count of the one or more detected tagged objects after the surgical procedure.

In yet other aspects, the presently disclosed subject matter provides a method for locating one or more objects used in a surgical procedure, the method comprising: providing a radio-frequency identification (RFID) reader, a wearable article comprising an antenna or a standalone antenna in electrical communication with the RFID reader, and one or more RFID tags for tagging, identifying, and tracking objects used in a surgical procedure; scanning an area suspected of comprising one or more objects used in a surgical procedure with the RFID reader; and detecting one or more objects used in a surgical procedure.

Certain aspects of the presently disclosed subject matter having been stated hereinabove, which are addressed in whole or in part by the presently disclosed subject matter, other aspects will become evident as the description proceeds when taken in connection with the accompanying Examples and Figures as best described herein below.

BRIEF DESCRIPTION OF THE FIGURES

Having thus described the presently disclosed subject matter in general terms, reference will now be made to the accompanying Figures, which are not necessarily drawn to scale, and wherein:

FIG. 1 illustrates a block diagram of an example of the presently disclosed objects monitoring system that uses RFID technology for automatically tracking objects used in surgical procedures;

FIG. 2 shows one example of implementing the presently disclosed objects monitoring system shown in FIG. 1;

FIG. 3, FIG. 4, and FIG. 5 show examples of a user interface of the presently disclosed objects monitoring system;

FIG. 6 illustrates a flow diagram of an example of a method of using the presently disclosed objects monitoring system to automatically track objects during surgical procedures; and

FIG. 7 illustrates a flow diagram of an example of a method of operation of the presently disclosed objects monitoring system according to a simplest configuration.

DETAILED DESCRIPTION

The presently disclosed subject matter now will be described more fully hereinafter with reference to the accompanying Figures, in which some, but not all embodiments of the presently disclosed subject matter are shown. Like numbers refer to like elements throughout. The presently disclosed subject matter may be embodied in many different forms and should not be construed as limited to the embodiments set forth herein; rather, these embodiments are provided so that this disclosure will satisfy applicable legal requirements. Indeed, many modifications and other embodiments of the presently disclosed subject matter set forth herein will come to mind to one skilled in the art to which the presently disclosed subject matter pertains having the benefit of the teachings presented in the foregoing descriptions and the associated Figures. Therefore, it is to be understood that the presently disclosed subject matter is not to be limited to the specific embodiments disclosed and that modifications and other embodiments are intended to be included within the scope of the appended claims.

I. RFID-BASED SYSTEM FOR AND METHOD OF AUTOMATICALLY TRACKING OBJECTS USED IN SURGICAL PROCEDURES

The presently disclosed subject matter provides a radio-frequency identification (RFID)-based system for automatically tracking objects used in surgical procedures, and methods of use thereof. More particularly, an objects monitoring system is provided that uses RFID technology, wherein the objects, such as surgical instruments, used in a surgical procedure include RFID tags for unique identification thereof. In the RFID-based objects monitoring system, an antenna of an RFID scanner/reader is embedded in an article, e.g., a wearable sleeve, a wrist- or hand-mounted device, or a device sown or otherwise incorporated into a garment, e.g., a surgical gown or a glove, worn by the user, comprising an antenna in electrical communication with the RFID reader, or a standalone RFID antenna, worn on the person of medical personnel participating in the surgical procedure. As objects are used during the surgical procedure, the RFID tags are scanned and their respective unique identification numbers are automatically transmitted from the RFID scanner/reader to a computing device and logged in a "checked out" list. Upon completion of the surgical procedure, the objects are again scanned and logged in a "checked in" list. The "checked out" and "checked in" lists are then reconciled. In the event that the "checked out" and "checked in" lists do not reconcile, a message or alarm is automatically generated by the computing device so that appropriate action can be taken to ensure that no objects are inadvertently retained within the patient.

One aspect of the presently disclosed RFID-based objects monitoring system is that it reduces, preferably entirely eliminates, the risk of inadvertent retention of an object within a patient as compared to conventional manual processes of counting and visually examining the objects that enter and exit the surgical field.

Another aspect of the presently disclosed RFID-based objects monitoring system is that it monitors the objects used in a surgical procedure without substantially altering the workflow of the participant that is wearing the article that includes the antenna of the RFID reader/scanner that is scanning the RFID-tagged objects.

In yet another aspect of the presently disclosed RFID-based objects monitoring system, in trauma situations that can arise in the operating room, the RFID-based objects monitoring system functions automatically under these circumstances and preserves the instrument count with no additional steps on the

behalf of operating room staff. By contrast, in current protocols, the instrument count is often abandoned in trauma situations.

Referring now to FIG. 1, is a block diagram of an example of the presently disclosed objects monitoring system **100** that uses RFID technology for automatically tracking objects used in surgical procedures. RFID is the wireless non-contact use of radio-frequency electromagnetic fields to transfer data, for the purposes of automatically identifying and tracking tags attached to objects. For example, the objects monitoring system **100** includes a set of tagged objects **110.** The tagged objects **110** are any objects that can be used in a surgical procedure, such as any types of surgical instruments. Examples of tagged objects **110** include, but are not limited to, scalpels, graspers, forceps, scissors, clamps, retractors, distractors, probes, snares, curets, needles, saws, sponges, surgical lap pads, and suction tools, as well as powered instruments, such as drills and dermatomes.

Each of the tagged objects **110** includes an RFID tag **115** that contains electronically stored information. The stored information can include a unique identification number of a given tagged object **110.** In addition to the unique identification number, the stored information can include other information, such as the type and brand of object (e.g., type and brand of scalpel, grasper, or clamp). The RFID tag **115** can be a passive RFID tag that has no power supply and relies on RF energy transferred from an RFID reader to extract the stored information. For example, objects monitoring system **100** further includes an RFID reader **120** having an RFID antenna **125** that is installed or otherwise embedded into an article worn on a user's body, e.g., a wearable sleeve, a wrist- or hand-mounted device, or a device sown or otherwise incorporated into a garment, e.g., a surgical gown or a glove, worn by the user, comprising an antenna in electrical communication with the RFID reader, or a standalone RFID antenna. For illustrative purposes only, the article worn on a user's body is depicted herein as a wearable sleeve **130.** In one example, the wearable sleeve **130** is a sterile, disposable sleeve that can be worn on one arm of a participant (e.g., a scrub nurse) in the surgical procedure, wherein the RFID antenna **125** is sewn, adhered, or otherwise installed into or onto the fabric of the wearable sleeve **130.** An example of the wearable sleeve **130** is shown and described with reference to FIG. 2.

The RFID reader **120** and RFID antenna **125** can be any standard RFID reader/antenna device for scanning the contents of an RFID tag, such as the RFID tags **115** of the respective tagged objects **110**. In particular, RFID reader **120** is used to

read the unique identification number of each of the tagged objects **110.** Namely, operating in combination with RFID reader **120,** the antenna **125** functions as an electromagnetic inductor for the purpose of interrogating the RFID tags **115** installed in the tagged objects **110.** The RFID reader **120** processes signals from the RFID tags **115** and converts them to unique identification numbers. In one example, RFID reader **120** is a portable, battery-powered RFID reader that may be clipped onto the wardrobe (e.g., the surgical gown) of the participant who is wearing the wearable sleeve **130.** In some embodiments, the range of the antenna **125** is limited to, for example, a few inches, e.g., about a 6-inch radius to about a 24-inch radius, so that only the tagged objects **110** that are in close proximity to the wearable sleeve **130** will be detected and read by the RFID reader **120.** The range can be adjustable by the user to control the distance of detection. In some embodiments, the antenna range has a 6-inch radius. An example of the RFID reader **120** is shown with reference to FIG. 2.

The objects monitoring system **100** further includes a computing device **140** that is in communication with the RFID reader **120.** The computing device **140** is used to collect and process the information that the RFID reader **120** reads from the RFID tags **115** of the respective tagged objects **110.** The computing device **140** can be any device that is capable of executing program instructions. For example, the computing device **140** may be a microcontroller device, a microprocessor device, or any computing device, such as a mobile phone, a handheld computing device, a tablet device, a laptop computer, a desktop computer, a centralized server, and the like. A certain amount of data storage (e.g., a memory device, not shown) may be associated with the computing device **140.**

Further, the computing device **140** communicates with the RFID reader **120** via a wired connection or preferably via a wireless connection. For example, the RFID reader **120** includes a communication interface **135** for transmitting information from the RFID tags **115** to the computing device **140.**

The communication interface **135** is implemented according to standard RF communication circuitry. In general, however, the communication interface **135** may be any wired and/or wireless communication interface for exchanging information with other devices connected to the network. Examples of wired communication interfaces may include, but are not limited to, USB ports, RS232 connectors, RJ45 connectors, Ethernet, and any combinations thereof. Examples of wireless communication interfaces may include, but are not limited to, an Intranet connection,

Internet, Bluetooth® technology, Wi-Fi, Wi-Max, IEEE 802.11 technology, radio frequency (RF), Infrared Data Association (IrDA) compatible protocols, Local Area Networks (LAN), Wide Area Networks (WAN), Shared Wireless Access Protocol (SWAP), any combinations thereof, and other types of wireless networking protocols.

Further, certain objects monitoring software **145** is installed and executing on the computing device **140.** The objects monitoring software **145** is used to manage the overall operations of the objects monitoring system **100** with respect to monitoring the tagged objects **110** that are used in a surgical procedure and ensuring that no tagged objects **110** are retained within a patient. Generally, the objects monitoring software **145** processes the unique identification numbers received from the RFID reader **120.** The objects monitoring software **145** keeps an active count and record of the tagged objects **110,** which can be accessed at any point in the surgical procedure. The objects monitoring software **145** keeps both an active checked out list and active checked in list.

For example, in the process of monitoring the tagged objects **110,** a checked out list **150** and a checked in list **155** are generated via the objects monitoring software **145.** Namely, the objects monitoring software **145** automatically generates the checked out list **150** during the surgical procedure and then automatically generates the checked in list **155** at the completion of the surgical procedure. The objects monitoring software **145** then reconciles the contents of the two lists to ensure that no tagged objects **110** are retained within a patient; namely, that all of the tagged objects **110** are accounted for. In the event that the checked out list **150** and checked in list **155** do not reconcile, a message or alarm is automatically generated by the objects monitoring software **145** so that appropriate action can be taken to ensure that no tagged objects **110** are inadvertently retained within the patient. More details of the operations of the objects monitoring software **145** are described with reference to FIG. 3 through FIG. 7.

While FIG. 1 shows one set of tagged objects **110,** one RFID reader **120,** and one computing device **140,** the objects monitoring system **100** can support a network of tagged objects **110,** RFID readers **120,** and computing devices **140.** For example, one or more computing devices **140** can be in communication with a server **160** via a network **180.** Network **180** can be any LAN and/or WAN for connecting to the Internet and/or to an Intranet via any wired or wireless means. Server **160** can be any centralized server or cloud server of, for example, a hospital. Server **160** can be used

to collect information from one or more computing devices **140** about the tagged objects **110** that are used in surgical procedures performed in that hospital. Accordingly, objects data **165** is stored on server **160,** wherein the objects data **165** may be the aggregated information with respect to tagged objects **110** that are used in the surgical procedures performed in that hospital.

While the server **160** and network **180** support a networking function within the objects monitoring system **100,** in another embodiment, the server **160** and network **180** can be omitted from the objects monitoring system **100.** In this case, the RFID reader **120** and the computing device **140** of objects monitoring system **100** are operating in a standalone, non-networked fashion.

In yet another embodiment of the objects monitoring system **100,** the objects monitoring system **100** can include more than one RFID reader **120** that are connected to a common computing device **140.** In this case, the objects monitoring software **145** is designed to process and reconcile information from more than one RFID reader **120.** Having more than one RFID reader **120** provides redundancy within the objects monitoring system **100** and yet further ensures that no tagged objects **110** are inadvertently retained within the patient. In one example, more than one antenna **125** is installed in wearable sleeve **130,** which are associated with the more than one RFID reader **120.** For example, two antennas **125** are installed in wearable sleeve **130,** wherein the two antennas **125** are associated with two RFID readers **120,** respectively. The two RFID readers **120** are in communication with a common computing device **140.**

In another example, more than one scrub nurse can be wearing a wearable sleeve **130** and with each scrub nurse having their own RFID reader **120,** wherein the RFID reader **120** of each scrub nurse is in communication with a common computing device **140.** For example, a first scrub nurse is wearing a first wearable sleeve **130** that is associated with a first RFID reader **120,** wherein the first RFID reader **120** is in communication with the computing device **140.** A second scrub nurse is wearing a second wearable sleeve **130** that is associated with a second RFID reader **120,** wherein the second RFID reader **120** is in communication with the same computing device **140** that is in communication with the first RFID reader **120.**

FIG. 2 shows one example of implementing the presently disclosed objects monitoring system **100** shown in FIG. 1. In this example, the tagged objects **110** are

shown as medical instruments (e.g., scalpels, graspers, forceps, scissors, and the like) that have respective RFID tags **115** attached thereto.

Typical frequency bands for the presently disclosed RFID tags can range, for example, from about 100 kHz to about 500 kHz, in particular embodiments, from about 120 kHz to about 150 kHz, and in more particular embodiments, about 125 kHz to about 134.2 kHz, for small ranges of about 10 cm (about 4 inches), about 13.56 MHz for larger ranges, e.g., about 1 m (about 39 inches), or between 860 MHz to about 960 MHz, e.g., about 902 MHz to about 928 MHz, for ranges from about 1 m (about 39 inches) to about 2 m (about 78 inches). In one example, the RFID tags **115** are 125 kHz RFID tags.

For example, an RFID tag **115** can be installed at any portion of the instrument that is large enough to accommodate the RFID tag **115** and at a location that does not interfere with the operation of the instrument. The RFID tag **115** can be installed, for example, by adhering to the surface of the instrument. The RFID tag **115** is suitably encapsulated or otherwise protected so that it can withstand sterilization processes.

FIG. 2 also shows an example of the wearable sleeve **130.** The wearable sleeve **130** is a sterile disposable sleeve. In this example, the wearable sleeve **130** is formed to be fitted on the user's arm and span from about the bicep area to the wrist area of the wearer. In this example, the antenna **125** is sewn, adhered, or otherwise installed into or onto the fabric of the wearable sleeve **130** near the wrist portions of the wearable sleeve **130.** The antenna **125** can be implemented in wearable sleeve **130** using, for example, a coil of un-insulated copper wire.

FIG. 2 also shows an example of the RFID reader **120.** In this example, the RFID reader **120** is a compact, battery-powered RFID reader that can, for example, be clipped to or held in the pocket of the surgical gown of the wearer of wearable sleeve **130** in any manner that does not impede the workflow of the user. The RFID reader **120** is non-sterile and non-disposable. Accordingly, the RFID reader **120** must be keep clear of the surgical field. RFID reader **120,** in some embodiments, also can be adjoined with one or more of barcode reader **121,** optical flashlight **122,** and/or infrared light **123.** Thus, objects monitoring system **100** also can be used to scan barcodes, scan labels requiring infrared light, and can have a flashlight function for use in dark cargo spaces. In other embodiments, barcode reader **121,** optical flashlight **122,** and/or infrared light **123** do not need to be physically adjoined with RFID reader **120,** but other otherwise part of objects monitoring system **100.** In any

event, barcode reader **121,** optical flashlight **122,** and/or infrared light **123** are in operational communication with other relevant components of objects monitoring system **100.**

A wired connection **132** is provided between RFID reader **120** and its antenna **125,** which is in wearable sleeve **130.** For example, an insulated flexible wire can be embedded or otherwise installed along the length of the wearable sleeve **130** from the antenna **125** at the cuff of wearable sleeve **130** to the opposite end of wearable sleeve **130** and extending outside of wearable sleeve **130,** as shown in FIG. 2, so that it can be electrically connected to the RFID reader **120.** In one example, one end of wired connection **132** is permanently connected to antenna **125,** while the opposite end of the wired connection **132** is connected to the RFID reader **120** in a non-permanent fashion. For example, one end of wired connection **132** can be connected to the RFID reader **120** via plug and jack interface (not shown). In this way, RFID reader **120** can be connected and disconnected from any wearable sleeve **130** as needed.

FIG. 2 also shows an example of computing device **140.** In this example, computing device **140** is a portable tablet device, such as, but not limited to, an Apple® iPad® or a Samsung Galaxy® Tab. The tablet device is non-sterile and non-disposable. Accordingly, the tablet device must be kept clear of the surgical field. In this example, the tablet device is connected wirelessly to both the RFID reader **120** and the server **160.** The objects monitoring software **145** provides a user interface. For example, a system graphical user interface (GUI) **170** is displayed on the tablet device, which is the computing device **140.** More details of an example of the system GUI **170** are shown and described with reference to FIG. 3, FIG. 4, and FIG. 5.

Referring once again to FIG. 2, objects monitoring system **100** also can include a video monitor or screen **190,** which can display information from RFID reader **120.** Video monitor or screen **190** can display information directly from RFID reader **120** or can display information processed by computing device **140.** In some embodiments, the information displayed on video monitor or screen **190** is the same as the information displayed through system GUI **170.** Video monitor or screen **190** can be mounted or worn on a user's wrist or forearm for convenience of viewing during operation. All the information collected by objects monitoring system **100** can be automatically collected by the system and displayed on video monitor or screen **190** and integrated with computing device **140** and associated network **180.**

Referring to FIG. 3, FIG. 4, and FIG. 5, the system GUI **170** includes various controls and indicators, as well as a viewing area for displaying a list of the tagged objects **110** that are detected via the RFID reader **120.** In one example, the system GUI **170** includes controls that allow the user to select either a "check out" mode or a "check in" mode of operation. For example, the system GUI **170** provides a "Check Out" pushbutton and a "Check In" pushbutton. In another example, a single pushbutton is provided that toggles between "check out" mode and "check in" mode. Further, the system GUI **170** may include certain status indicators. For example, the system GUI **170** provides a "Count Cleared" indicator and a "Count Error" indicator. The system GUI **170** may also use color to convey certain status or meaning.

Referring now to FIG. 3, at the beginning of the surgical procedure the user selects the "check out" mode of operation by selecting the "Check Out" pushbutton. In the "check out" mode of operation, the "Check In" pushbutton, the "Count Cleared" indicator, and the "Count Error" indicator are grayed out to indicate that they are inactive. In the "check out" mode of operation, as the tagged objects **110** enter the surgical field, the tagged objects **110** are detected by the RFID reader **120** and added to a list in the main viewing area of the system GUI **170,** which is the contents of the checked out list **150** generated by the objects monitoring software **145.** The contents of the checked out list **150** is continuously active and updated throughout the duration of the surgical procedure as the tagged objects **110** enter the surgical field. Accordingly, the display of the tagged objects **110** that are checked out is active and continuously updated in the system GUI **170** throughout the duration of the surgical procedure. Further, the total count of tagged objects **110** detected during the surgical procedure is dynamically updated.

Referring now to FIG. 4, at the completion of the surgical procedure the user selects the "check in" mode of operation by selecting the "Check In" pushbutton. In the "check in" mode of operation, the "Check Out" pushbutton is grayed out to indicate that it is inactive. In the "check in" mode of operation, as tagged objects **110** exit the surgical field, the tagged objects **110** are detected by the RFID reader **120** and the checked in list **155** is generated by objects monitoring software **145.** Since the contents of the checked in list **155** is to be reconciled with the contents of the checked out list **150,** such reconciliation can be indicated using color to indicate the status of each tagged object **110** that is displayed in the system GUI **170.** For example, as each tagged object **110** is detected exiting the surgical field, the line displaying the detected

tagged object **110** turns, for example, from black text to green text. When all tagged objects **110** exiting the surgical field match all tagged objects **110** that entered the surgical field, that is when the contents of the checked out list **150** matches the contents of the checked in list **155,** all line items are changed from black text to green text, the total count line turns from black text to green text, and the "Count Cleared" indicator is activated. Namely, the objects monitoring software **145** uses the "Count Cleared" indicator and the color green to indicate a successful reconciliation between the checked out list **150** and the checked in list **155.**

By contrast and referring now to FIG. 5, any tagged objects **110** in the checked out list **150** that are missing from the checked in list **155** can be indicated in the list by, for example, changing the black text to red text, as well as indicating the total count in red text. Further, the objects monitoring software **145** uses the "Count Error" indicator and the color red to indicate a failed reconciliation between the checked out list **150** and the checked in list **155.**

Other indicators, such as audible or tactile (e.g., vibration) indicators, also can be used to indicate a failed reconciliation. Further, upon a failed reconciliation, a phone call can be initiated or a text message or email message can be generated and directed to one or more participants in the surgical procedure. In other embodiments, a voice interface can be used, whereby the system will provide audible information regarding the type instrument, the number of instruments, or the proximity of the instrument to the probe.

The system GUI **170** of the objects monitoring software **145** is not limited to the GUI shown in FIG. 3, FIG. 4, and FIG. 5; this is exemplary only. The system GUI **170** can be designed in any fashion and may be different from one type of computing device **140** to another type of computing device **140.** For example, the system GUI **170** for a tablet device or mobile phone may be different than the system GUI **170** for a laptop or desktop computer.

FIG. 6 illustrates a flow diagram of an example of a method **600** using the presently disclosed objects monitoring system **100** to automatically track objects during surgical procedures. Method **600** may include, but is not limited to, the following steps.

At a step **610,** before the surgical procedure (or operation) begins, a scrub nurse puts on the wearable sleeve **130.** The wearable sleeve **130** is introduced to the operating room in a sterile package like other sterile, disposable surgical garments.

According to operating room protocols, a scrub nurse assists surgeons in the operating room. They are responsible for arranging all necessary equipment and handing them to the surgeon when called. At the end of the procedure, it is the scrub nurse's job to make sure that all of the equipment is accounted for.

At a step 615, the circulator nurse attaches the RFID reader 120 to the back of the scrub nurse's surgical gown and connects the wired connection 132 of the wearable sleeve 130 to the RFID reader 120. According to operating room protocols, a circulator is a nurse who works in surgical operating rooms monitoring the procedures. The circulator nurse does not scrub in, and performs job duties that cannot be done by staff that is scrubbed in. The circulator nurse works side by side with scrub nurses to help maintain a safe and sterile field in the operating room.

At a step 620, the computing device 140, such as the tablet device shown in FIG. 2, FIG. 3, FIG. 4, and FIG. 5, is readied and communication is established between, for example, the tablet device and the RFID reader 120.

At a step 625, using the computing device 140, such as the tablet device, the circulator nurse launches the objects monitoring software 145 and sets the objects monitoring software 145 to the "check out" mode of operation, as shown, for example, in FIG. 3.

At a step 630, the standard initial counting protocol is performed by the scrub nurse. Namely, an initial count of the tagged objects 110 is performed by the scrub nurse who is wearing the wearable sleeve 130. During this counting process, each time a tagged object 110 is handled and comes into close proximity to the wrist portion of the wearable sleeve 130, its RFID tag 115 is read and the ID number is transmitted from the RFID reader 120 to the computing device 140. Then, the objects monitoring software 145 records the ID number of that tagged object 110 in the checked out list 150 and the checked out-object count is incremented by 1. The contents of the checked out list 150 is displayed on the tablet device (i.e., at computing device 140) as shown, for example, in FIG. 3.

At a step 635, the surgical procedure progresses with the objects monitoring software 145 remaining in the "check out" mode of operation. Because the objects monitoring software 145 remains in "check out" mode during the course of the surgical procedure, if during the procedure the surgeon requests additional tagged objects 110, they can be added to the checked out list 150 and introduced to the surgery without any extra steps. Further, during the course of the surgical procedure,

objects monitoring software 145 ignores any subsequent detection of a tagged object 110 that is already recorded in the checked out list 150. However, the first detection of any tagged object 110 that is introduced to the surgical field at any time is recorded in the checked out list 150 and the checked out-object count is incremented by 1. That is, the objects monitoring software 145 keeps an active count and record of the tagged objects 110, which can be accessed at any point in the surgical procedure. The contents of the checked out list 150 continues to be displayed on the tablet device (i.e., at computing device 140) as shown, for example, in FIG. 3. Further, medical personnel can grab a plurality of surgical instruments tagged with RFID tags simultaneously, and the presently disclosed objects monitoring system can count and identify all of the tagged surgical instruments held, for example, in one hand.

At a step 640, upon completion of the surgical procedure, a final count of the tagged objects 110 is initiated. For example, using the computing device 140, such as the tablet device, the circulator nurse switches the objects monitoring software 145 from the "check out" mode to the "check in" mode of operation, as shown, for example, in FIG. 4 and FIG. 5.

At a step 645, the scrub nurse who is wearing the wearable sleeve 130 performs the standard final counting protocol. Once again, as each tagged object 110 is handled and comes into close proximity to the wrist portion of the wearable sleeve 130, its RFID tag 115 is read and the ID number is transmitted from the RFID reader 120 to the computing device 140. Then, the objects monitoring software 145 records the ID number in the checked in list 155 and the checked in-object count is incremented by 1. The contents of the checked in list 155 can be indicated on the tablet device (i.e., at computing device 140) as shown, for example, in FIG. 4 and FIG. 5.

At a step 650, throughout the check in process, the objects monitoring software 145 attempts to reconcile the contents of the checked out list 150 and the contents of the checked in list 155. Reconciled means the number of tagged objects 110 and the IDs of the tagged objects 110 is the same in both the checked out list 150 and the checked in list 155. The status of the reconciliation process can be indicated on the tablet device (i.e., at computing device 140) as shown, for example, in FIG. 4 and FIG. 5.

At a decision step 655, it is determined whether the reconciliation process has passed or failed. For example, if there are no discrepancies between the checked out

list **150** and the checked in list **155,** then all of the tagged objects **110** are accounted for and the reconciliation has passed and method **600** proceeds to step **660.** If any discrepancies between the checked out list **150** and the checked in list **155** exist, however, then all of the tagged objects **110** are not accounted for and the reconciliation has failed and method **600** proceeds to step **670.**

At a step **660,** the objects monitoring software **145** generates and delivers one or more indicators that the reconciliation process has passed. For example, the objects monitoring software **145** uses the "Count Cleared" indicator and the color green to indicate a successful reconciliation between the checked out list **150** and the checked in list **155.** Other indicators, such as audible or tactile (e.g., vibration) indicators, can also be used to indicate a successful reconciliation. Further, upon a successful reconciliation, a phone call can be initiated or a text message or email message can be generated and directed to one or more participants in the surgical procedure, such as to the circulator nurse. An example of the "Count Cleared" status is shown in FIG. 4. Method **600** ends or optionally proceeds to step **665.**

At an optional step **665,** the checked out list **150** and the checked in list **155,** along with a surgical procedure identifier is transmitted from the computing device **140** to the server **160** and stored in the objects data **165.** Method **600** ends.

At a step **670,** the objects monitoring software **145** generates and delivers one or more indicators that the reconciliation process has failed and of the ID and number of potentially missing tagged objects **110.** For example, the objects monitoring software **145** uses the "Count Error" indicator and the color red to indicate an unsuccessful reconciliation between the checked out list **150** and the checked in list **155.** Other indicators, such as audible or tactile (e.g., vibration) indicators, can also be used to indicate an unsuccessful reconciliation. Further, upon an unsuccessful reconciliation, a phone call can be initiated or a text message or email message can be generated and directed to one or more participants in the surgical procedure, such as to the circulator nurse. An example of the "Count Error" status is shown in FIG. 5.

At a step **675,** actions are taken to resolve the failed reconciliation according to standard protocols. For example, if the tagged objects **110** are found, they must simply be handled by the scrub nurse who is wearing the wearable sleeve **130** to be "checked in" and added to the checked in list **155.** If the missing tagged objects **110** are not found, standard procedures are followed, such as X-raying the patient, until such time that all of the tagged objects **110** are accounted for. Additionally, the

wearable sleeve **130** may be passed on close proximity to the patient to see if any tagged objects **110** are detected inside the patient. For example, the objects monitoring software **145** may have a "search" mode of operation, which graphically indicates any tagged objects **110** detected (inside or outside the patient) during a search operation. Method **600** returns to step **645.**

Accordingly, the objects monitoring software can be operated in a "find" or "search" mode, whereby medical personnel, e.g., a surgeon or a nurse, can use the presently disclosed system to find a missing surgical instrument. In this mode, the count is not affected, but the system can register whether an instrument is close to or in proximity to the probe, e.g., wearable sleeve **130.** In such embodiments, the range of the RFID antenna **125** can be extended beyond a 6-inch radius, e.g., to a 24-inch radius. Such embodiments also can include a vectoring system to allow locating the missing instrument.

The presently disclosed objects monitoring system also can be used to tally surgical instruments outside of the operating room. For example, a container comprising a plurality of RFID-tagged surgical instruments, e.g., a box of tagged surgical sponges, can be picked up by medical personnel wearing the presently disclosed objects monitoring system, which can count the tagged surgical instruments through the container without compromising, e.g., breaking, sterility. In such applications, the medical personnel does not need to be sterile to count the instruments.

FIG. 7 illustrates a flow diagram of an example of a method **700** of operation of the presently disclosed objects monitoring system **100** according to a simple configuration. Method **700** may include, but is not limited to, the following steps.

At a step **710,** during the surgical procedure and with the objects monitoring software **145** in the "check out" mode of operation, tagged objects **110** are automatically detected using the RFID reader **120.** Then, using the objects monitoring software **145,** a record and count of "checked out" tagged objects **110** is automatically generated. For example, the checked out list **150** is automatically generated.

At a step **715,** upon completion of the surgical procedure and with the objects monitoring software **145** in the "check in" mode of operation, tagged objects **110** are automatically detected using the RFID reader **120.** Then, using the objects monitoring software **145,** a record and count of "checked in" tagged objects **110** is

automatically generated. For example, the checked in list **155** is automatically generated.

At a step **720,** the record of "checked in" tagged objects **110** is automatically compared and reconciled with the record of "checked out" tagged objects **110.** For example, using the objects monitoring software **145,** the record of tagged objects **110** in the checked in list **155** is automatically compared and reconciled with record of "tagged objects **110** in the checked out list **150.**

At a step **725,** the success or failure of the reconciliation process is automatically indicated. For example, using the objects monitoring software **145,** the success or failure of the reconciliation process is automatically indicated, for example, via indicators of the system GUI **170** or by any other means, such as audible indictors, tactile indicators, phone calls, text messages, emails, and any combinations thereof.

The subject treated by the presently disclosed methods in their many embodiments is desirably a human subject, although it is to be understood that the methods described herein are effective with respect to all vertebrate species, which are intended to be included in the term "subject."

A "subject" can include a human subject for medical purposes, such as for the treatment of an existing condition or disease or the prophylactic treatment for preventing the onset of a condition or disease, or an animal subject for medical, veterinary purposes, or developmental purposes. Suitable animal subjects include mammals including, but not limited to, primates, e.g., humans, monkeys, apes, and the like; bovines, e.g., cattle, oxen, and the like; ovines, e.g., sheep and the like; caprines, e.g., goats and the like; porcines, e.g., pigs, hogs, and the like; equines, e.g., horses, donkeys, zebras, and the like; felines, including wild and domestic cats; canines, including dogs; lagomorphs, including rabbits, hares, and the like; and rodents, including mice, rats, and the like. An animal may be a transgenic animal. In some embodiments, the subject is a human including, but not limited to, fetal, neonatal, infant, juvenile, and adult subjects. Further, a "subject" can include a patient afflicted with or suspected of being afflicted with a condition or disease. Thus, the terms "subject" and "patient" are used interchangeably herein.

Following long-standing patent law convention, the terms "a," "an," and "the" refer to "one or more" when used in this application, including the claims. Thus, for example, reference to "a subject" includes a plurality of subjects, unless the context clearly is to the contrary (e.g., a plurality of subjects), and so forth.

Throughout this specification and the claims, the terms "comprise," "comprises," and "comprising" are used in a non-exclusive sense, except where the context requires otherwise. Likewise, the term "include" and its grammatical variants are intended to be non-limiting, such that recitation of items in a list is not to the exclusion of other like items that can be substituted or added to the listed items.

For the purposes of this specification and appended claims, unless otherwise indicated, all numbers expressing amounts, sizes, dimensions, proportions, shapes, formulations, parameters, percentages, parameters, quantities, characteristics, and other numerical values used in the specification and claims, are to be understood as being modified in all instances by the term "about" even though the term "about" may not expressly appear with the value, amount or range. Accordingly, unless indicated to the contrary, the numerical parameters set forth in the following specification and attached claims are not and need not be exact, but may be approximate and/or larger or smaller as desired, reflecting tolerances, conversion factors, rounding off, measurement error and the like, and other factors known to those of skill in the art depending on the desired properties sought to be obtained by the presently disclosed subject matter. For example, the term "about," when referring to a value can be meant to encompass variations of, in some embodiments, ± 100% in some embodiments ± 50%, in some embodiments ± 20%, in some embodiments ± 10%, in some embodiments ± 5%, in some embodiments ±1%, in some embodiments ± 0.5%, and in some embodiments ± 0.1% from the specified amount, as such variations are appropriate to perform the disclosed methods or employ the disclosed compositions.

Further, the term "about" when used in connection with one or more numbers or numerical ranges, should be understood to refer to all such numbers, including all numbers in a range and modifies that range by extending the boundaries above and below the numerical values set forth. The recitation of numerical ranges by endpoints includes all numbers, e.g., whole integers, including fractions thereof, subsumed within that range (for example, the recitation of 1 to 5 includes 1, 2, 3, 4, and 5, as well as fractions thereof, e.g., 1.5, 2.25, 3.75, 4.1, and the like) and any range within that range.

REFERENCES

All publications, patent applications, patents, and other references mentioned in the specification are indicative of the level of those skilled in the art to which the

presently disclosed subject matter pertains. All publications, patent applications, patents, and other references are herein incorporated by reference to the same extent as if each individual publication, patent application, patent, and other reference was specifically and individually indicated to be incorporated by reference. It will be understood that, although a number of patent applications, patents, and other references are referred to herein, such reference does not constitute an admission that any of these documents forms part of the common general knowledge in the art.

U.S. Patent Application Publication No. US20020044058 for Wrist Mounted RFID Reader and/or Antenna, to Heinrich et al., published April 18, 2002;

U.S. Patent Application Publication No. 20100097195 for Data Interface Process with RFID Data Reader Glove, to Majoros, et al., published April 22, 2010;

Fishkin, K.P., Hands-on RFID: Wireless Wearables for Detecting Use of Objects, in Ninth IEEE International Symposium on Wearable Computers, Oct. 18-21, 2005, pp. 38-41.

International PCT Patent Application Publication No. WO2007016101 for Method and System for Configuring and Data Populating a Surgical Device, to Charles, et al, published Feb. 8, 2007; and

European Patent Application Publication No. EP2460488 for Surgical Glove Appliance Device, to Kantrowitz and Mun, published June 6, 2012.

Although the foregoing subject matter has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be understood by those skilled in the art that certain changes and modifications can be practiced within the scope of the appended claims.

THAT WHICH IS CLAIMED:

1. A system for identifying and tracking one or more objects used in a surgical procedure, the system comprising a radio-frequency identification (RFID) reader, a wearable article comprising an antenna or a standalone antenna in electrical communication with the RFID reader, and one or more RFID tags for tagging, identifying, and tracking objects used in a surgical procedure.

2. The system of claim 1, wherein the RFID tag comprises a passive RFID tag.

3. The system of claim 1, wherein the RFID tag comprises one or more pieces of stored information selected from the group consisting of a unique identification number for an object, a chain of custody history of an object, a sanitation or cleaning history of an object, a type of object, and a brand of object.

4. The system of claim 1, further comprising a computing device in communication with the RFID reader.

5. The system of claim 4, wherein the computing device communicates with the RFID reader via a connection selected from the group consisting of a wired connection and a wireless connection.

6. The system of claim 4, wherein the computing device further comprises executable monitoring software.

7. The system of claim 1, further comprising a server.

8. The system of claim 1, wherein the one or more objects used in a surgical procedure comprises one or more surgical instruments.

9. The system of claim 8, wherein the one or more surgical instruments are selected from the group consisting of a scalpel, a grasper, forceps, scissors, a clamp, a retractor, a distractor, a probe, a snare, a curet, a needle, a saw, a sponge, a surgical lap pad, a suction tool, a drill, and a dermatome.

10. The system of claim 1, wherein the wearable article is disposable.

11. A method for identifying and tracking one or more objects used in a surgical procedure, the method comprising:

providing a radio-frequency identification (RFID) reader, a wearable article comprising an antenna or a standalone antenna in electrical communication with the RFID reader, and one or more RFID tags for tagging, identifying, and tracking objects used in a surgical procedure;

detecting one or more tagged objects using the RFID reader prior to or during the surgical procedure;

generating a record and count of the one or more detected tagged objects prior to or during the surgical procedure;

detecting one or more tagged objects using the RFID reader after the surgical procedure;

generating a record and count of the one or more detected tagged objects after the surgical procedure;

reconciling the record and count of the one or more detected tagged objects prior to or during the surgical procedure to the record and count of the one or more detected tagged objects after the surgical procedure; and

indicating a success or failure of the reconciliation of the record and count of the one or more detected tagged objects prior to or during the surgical procedure to the record and count of the one or more detected tagged objects after the surgical procedure.

12. The method of claim 11, wherein the indicating is accomplished via a graphical user interface, an audible alarm, a visible alarm, a tactile indicator, a phone call, a text message, an email communication, a voice interface, and combinations thereof.

13. The method of claim 11, wherein the one or more objects used in a surgical procedure comprise one or more sterile surgical instruments comprising a sterile container.

14. The method of claim 13, wherein the one or more sterile surgical instruments are identified and tracked outside of an operating room.

15. A method for locating one or more objects used in a surgical procedure, the method comprising:

providing a radio-frequency identification (RFID) reader, a wearable article comprising an antenna or a standalone antenna in electrical communication with the RFID reader, and one or more RFID tags for tagging, identifying, and tracking objects used in a surgical procedure;

scanning an area suspected of comprising one or more objects used in a surgical procedure with the wearable article or standalone antenna; and

detecting one or more objects used in a surgical procedure.

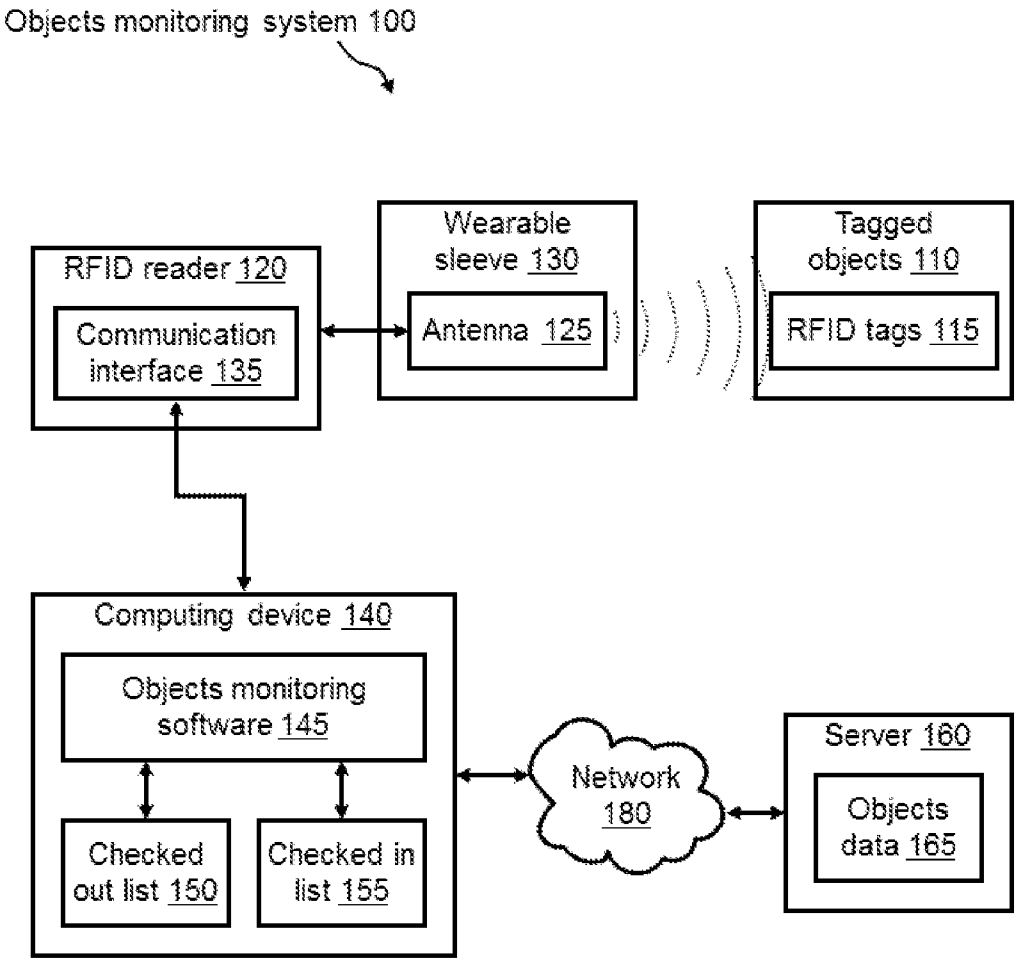

Objects monitoring system 100
RFID reader 120
Communication interface 135
Wearable sleeve 130
Antenna 125
Tagged objects 110
RFID tags 115
Computing device 140
Objects monitoring software 145
Checked out list 150
Checked in list 155
Network 180
Server 160
Objects data 165

Fig. 1

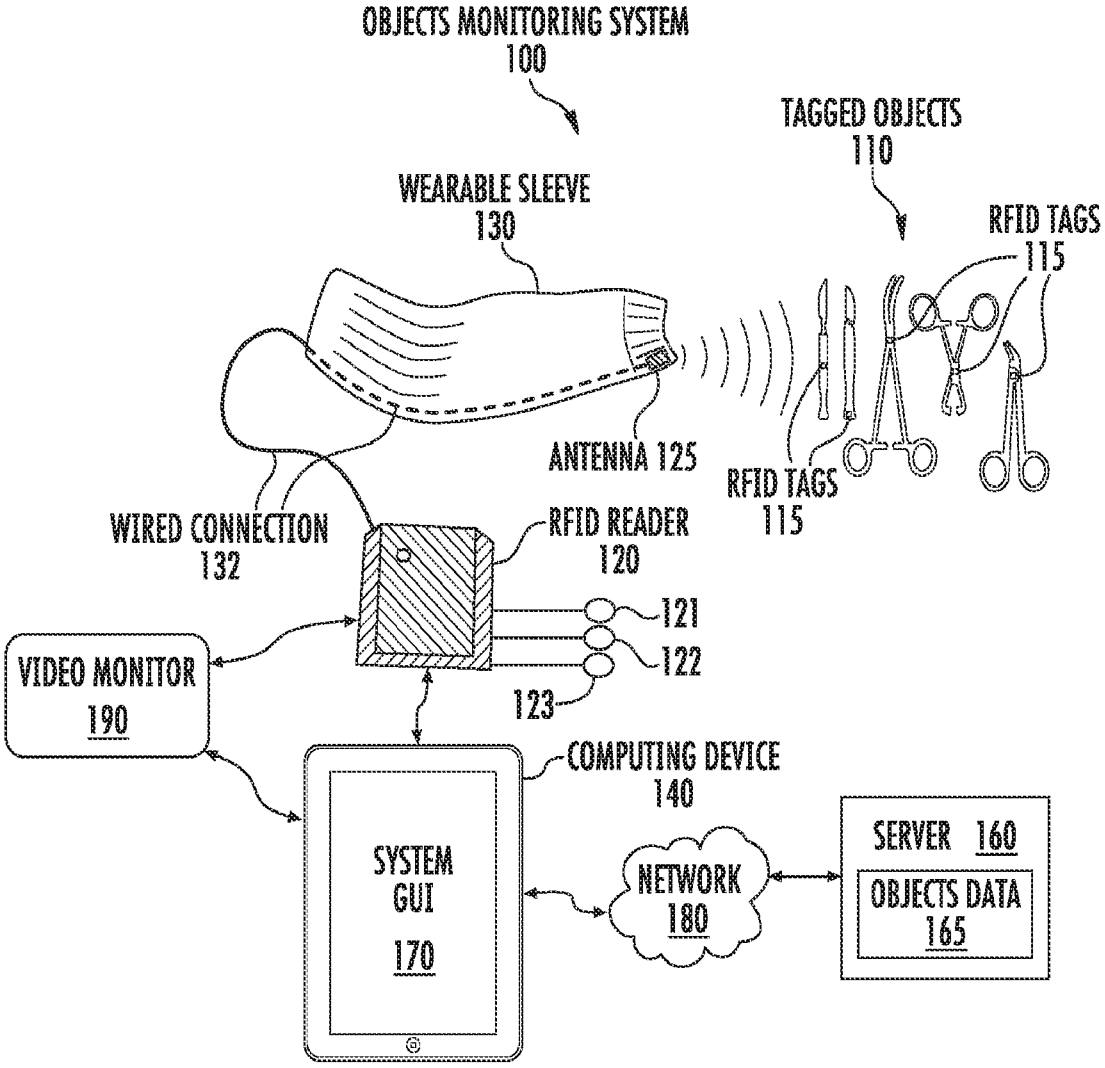

OBJECTS MONITORING SYSTEM
100
TAGGED OBJECTS
110
WEARABLE SLEEVE
130
RFID TAGS
115
ANTENNA 125
RFID TAGS
115
WIRED CONNECTION
132
RFID READER
120
121
122
123
VIDEO MONITOR
190
COMPUTING DEVICE
140
SYSTEM
GUI
170
NETWORK
180
SERVER 160
OBJECTS DATA
165

Fig. 2

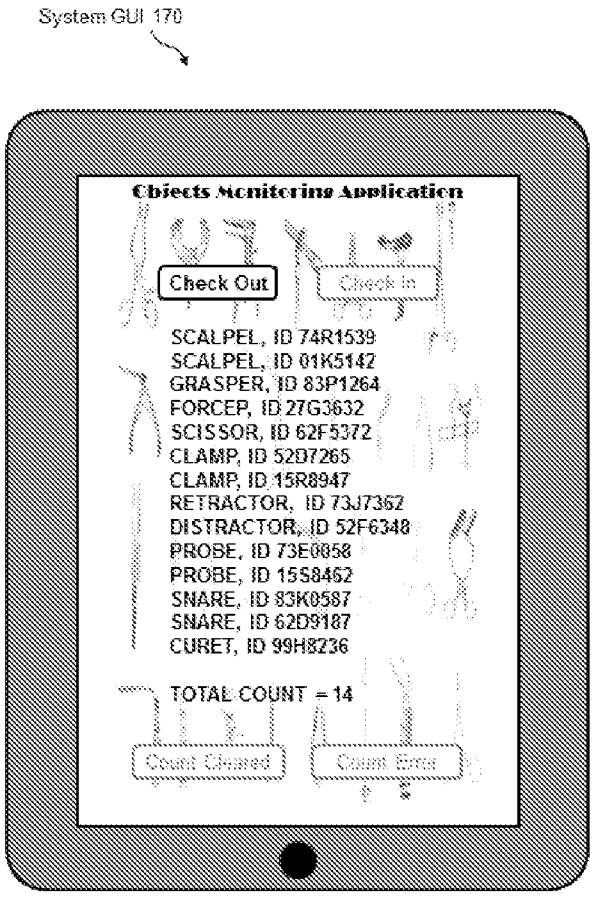
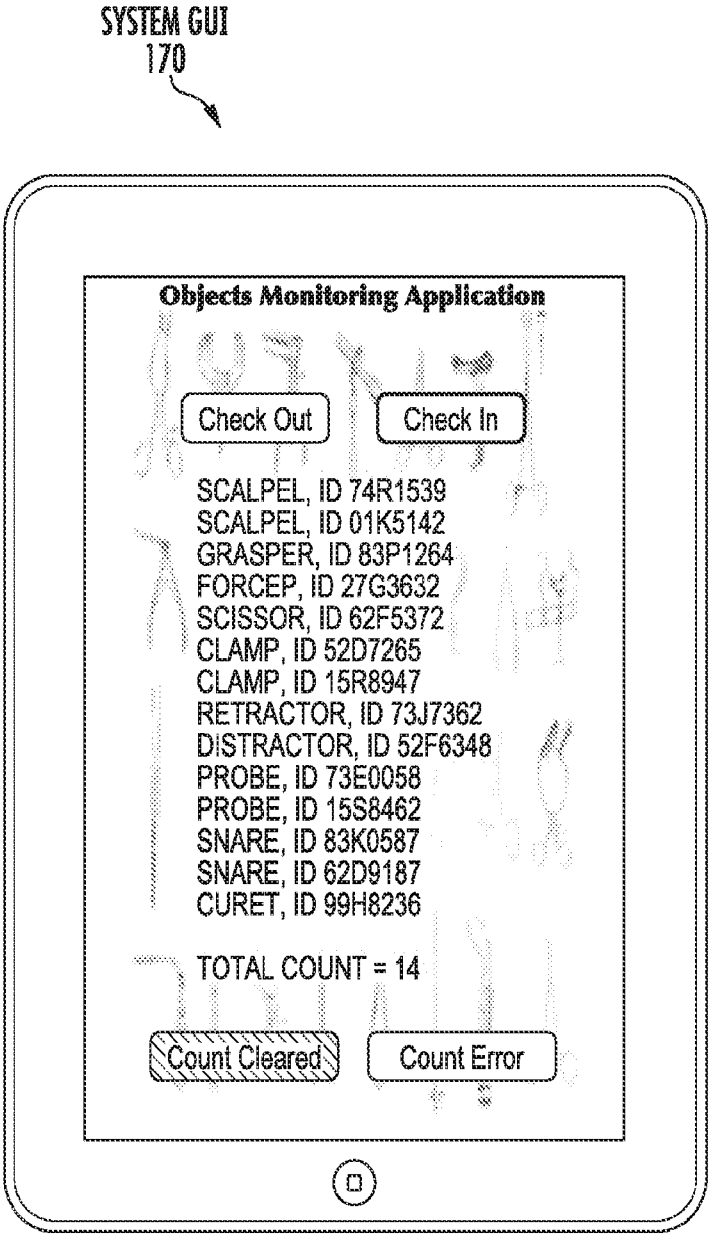

System GUI 170
Objects Monitoring Application
Check Out
Check In
SCALPEL, ID 74R1539
SCALPEL, ID 01K5142
GRASPER, ID 83P1264
FORCEP, ID 27G3632
SCISSOR, ID 62F5372
CLAMP, ID 52D7265
CLAMP, ID 15R8947
RETRACTOR, ID 73J7362
DISTRACTOR, ID 52F6348
PROBE, ID 73E0858
PROBE, ID 15S8462
SNARE, ID 83K0587
SNARE, ID 62D9187
CURET, ID 99H8236
TOTAL COUNT = 14
Count Cleared
Count Error

Fig. 3


SYSTEM GUI
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Objects Monitoring Application
Check Out
Check In
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SCALPEL, ID 01K5142
GRASPER, ID 83P1264
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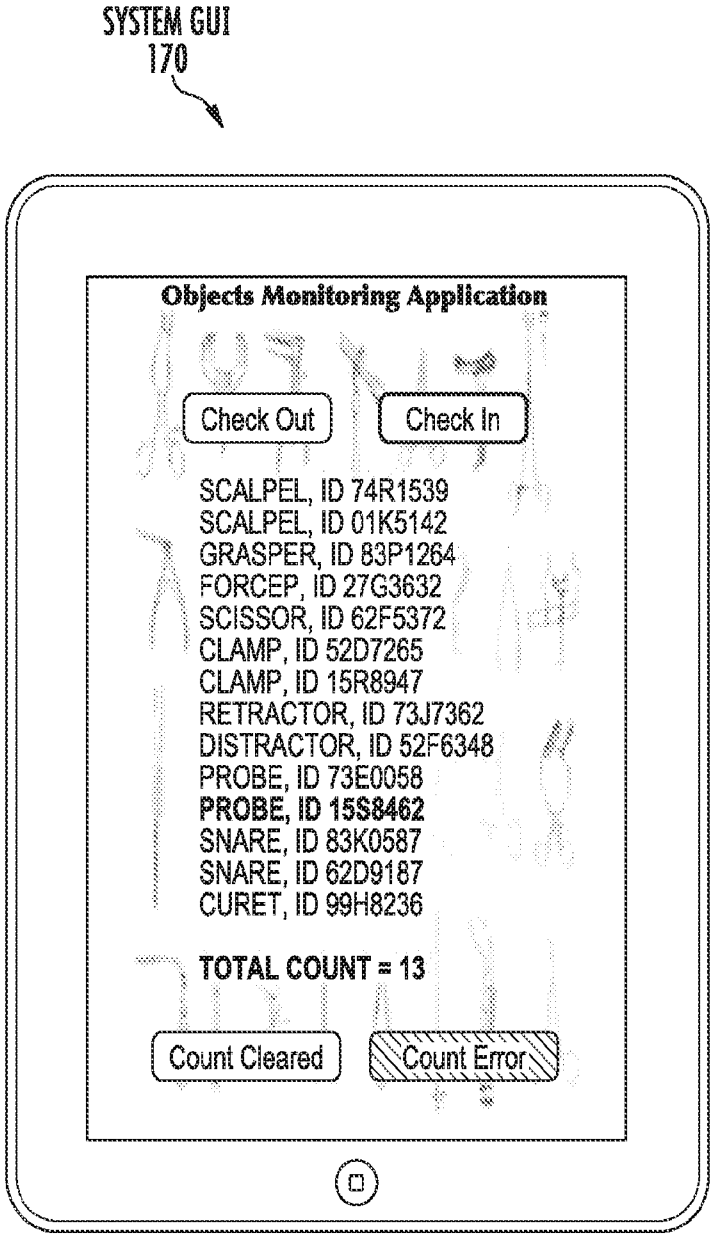
SCISSOR, ID 62F5372
CLAMP, ID 52D7265
CLAMP, ID 15R8947
RETRACTOR, ID 73J7362
DISTRACTOR, ID 52F6348
PROBE, ID 73E0058
PROBE, ID 15S8462
SNARE, ID 83K0587
SNARE, ID 62D9187
CURET, ID 99H8236
TOTAL COUNT = 14
Count Cleared
Count Error

Fig. 4


SYSTEM GUI
170
Objects Monitoring Application
Check Out
Check In
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GRASPER, ID 83P1264
FORCEP, ID 27G3632
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RETRACTOR, ID 73J7362
DISTRACTOR, ID 52F6348
PROBE, ID 73E0058
PROBE, ID 15S8462
SNARE, ID 83K0587
SNARE, ID 62D9187
CURET, ID 99H8236
TOTAL COUNT = 13
Count Cleared
Count Error

Fig. 5

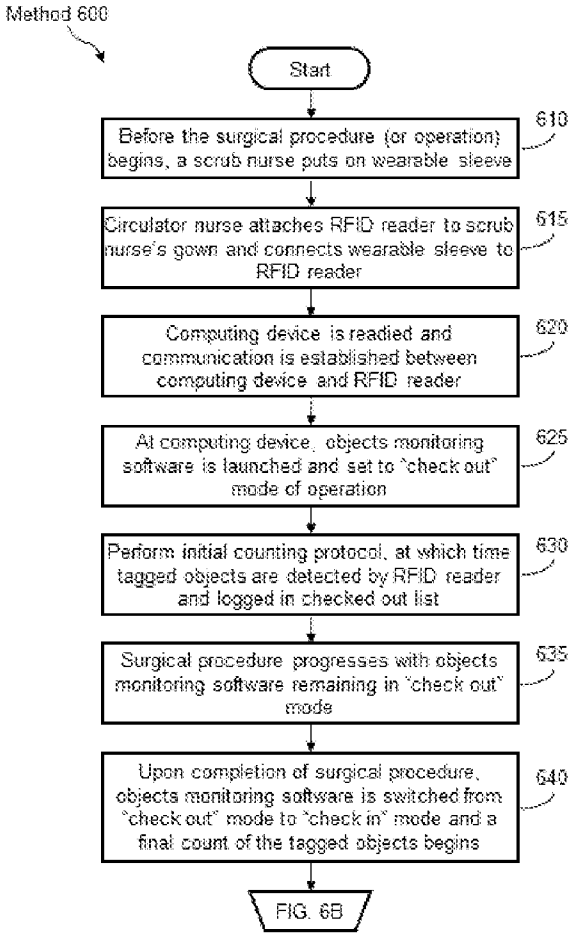
Method 600
Start
Before the surgical procedure (or operation) begins, a scrub nurse puts on wearable sleeve
610
Circulator nurse attaches RFID reader to scrub nurse's gown and connects wearable sleeve to RFID reader
615
Computing device is readied and communication is established between computing device and RFID reader
620
At computing device, objects monitoring software is launched and set to "check out" mode of operation
625
Perform initial counting protocol, at which time tagged objects are detected by RFID reader and logged in checked out list
630
Surgical procedure progresses with objects monitoring software remaining in "check out" mode
635
Upon completion of surgical procedure, objects monitoring software is switched from "check out" mode to "check in" mode and a final count of the tagged objects begins
640
FIG. 6B

Fig. 6A

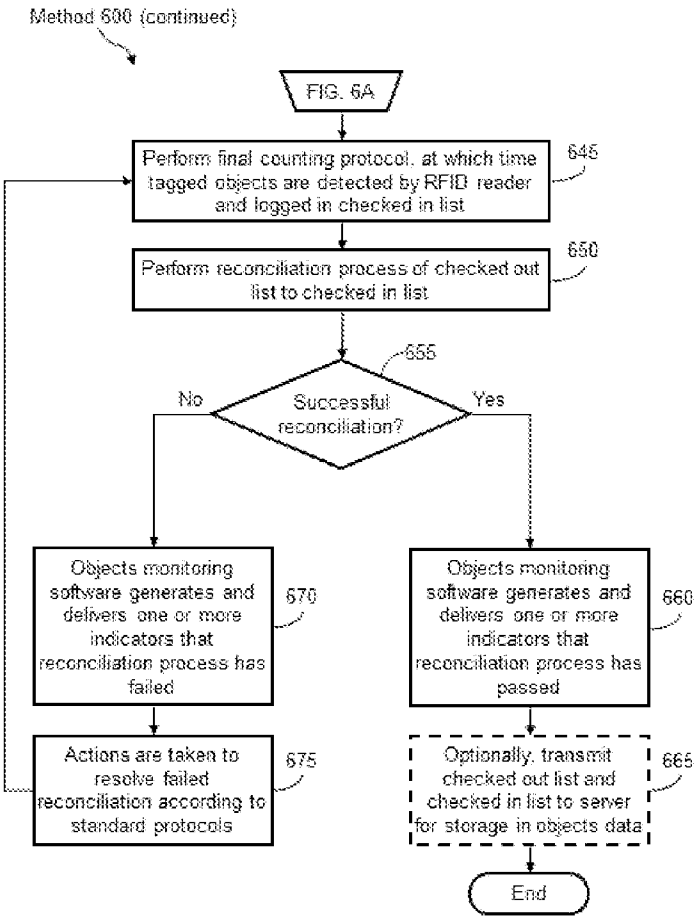
Method 600 (continued)
FIG. 6A
Perform final counting protocol, at which time tagged objects are detected by RFID reader and logged in checked in list
645
Perform reconciliation process of checked out list to checked in list
650
655
Successful reconciliation?
No
Yes
Objects monitoring software generates and delivers one or more indicators that reconciliation process has failed
670
Actions are taken to resolve failed reconciliation according to standard protocols
675
Objects monitoring software generates and delivers one or more indicators that reconciliation process has passed
660
Optionally, transmit checked out list and checked in list to server for storage in objects data
665
End

Fig. 6B

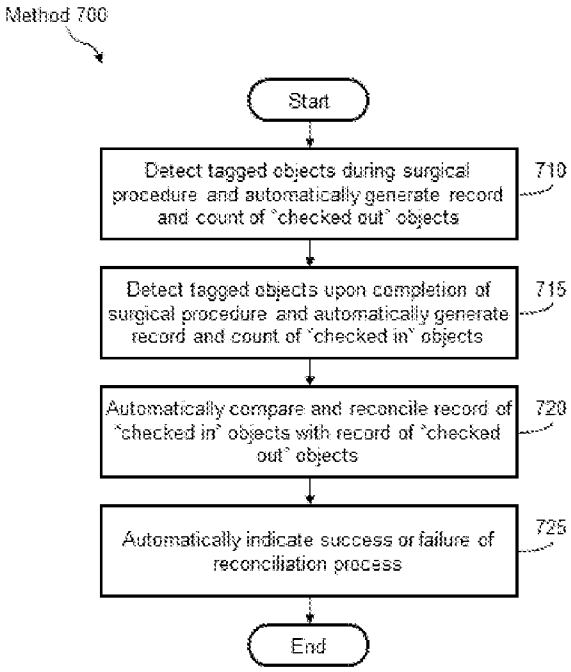
Method 700
Start
Detect tagged objects during surgical procedure and automatically generate record and count of 'checked out' objects
710
Detect tagged objects upon completion of surgical procedure and automatically generate record and count of 'checked in' objects
715
Automatically compare and reconcile record of 'checked in' objects with record of 'checked out' objects
720
Automatically indicate success or failure of reconciliation process
725
End

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2014/036973

A. CLASSIFICATION OF SUBJECT MATTER

G06K 17/00(2006.01)i, G06K 19/07(2006.01)i

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
G06K 17/00; G08B 1/08; D04B 1/14; G08B 21/00; A61B 19/00; G06Q 90/00; H04Q 5/22; G06K 19/07

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
Korean utility models and applications for utility models
Japanese utility models and applications for utility models

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
eKOMPASS(KIPO internal) & Keywords: RFID reader, wearable antenna, tag, surgical instrument, reconciling

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 2007-0125392 Al (STANLEY W. OLSON JR. et al.) 07 June 2007 See paragraphs [0001H0007] , [0010H0014] , [0032H0039] ; abst ract ; and figures 4-5 .	1-15
Y	US 2010-0271187 Al (DILEK DAGDELEN UYSAL et al.) 28 Oct ober 2010 See paragraphs [0006] , [0027] , [0042] , [0047] , [0078] , [0103] ; and f igure 4.	1-15
A	US 2013-0001305 Al (STEVEN FLECK et al.) 03 January 2013 See paragraphs [0002]- [0004] , [0098] , [0101] , [0143] ; and claim 1.	1-15
A	US 2012-0146784 Al (ROBERT WINFRED HINES et al.) 14 June 2012 See paragraphs [0024] , [0160H0161] , and [0181] .	1-15
A	US 2010-0289662 Al (JOHN DASILVA et al.) 18 November 2010 See paragraphs [0013H0017] , [0023] , and [0029] .	1-15

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 September 2014 (25.09.2014)	**25 September 2014 (25.09.2014)**

Name and mailing address of the ISA/KR
International Application Division
Korean Intellectual Property Office
189 Cheongsa-ro, Seo-gu, Daejeon Metropolitan City, 302-701, Republic of Korea
Facsimile No. +82-42-472-7140

Authorized officer
KANG, Sung Chul
Telephone No. +82-42-481-8405

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/US2014/036973

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2007-0125392 Al	07/06/2007	None	
US 2010-0271187 Al	28/10/2010	AU 2010-239209 Al	28/10/2010
		CA 2759927 Al	28/10/2010
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