Abstract: A system to assist with keeping track of surgical items during a surgical procedure has a check-in station that includes an RF antenna, a data processing and storage unit, and a check-out station includes an RF antenna. The data processing and storage unit is adapted to identify a plurality of specific items checked in for the surgical procedure and Identify any of the plurality of specific items checked in that fail to check out for a conclusion of the surgical procedure. A device for providing a verified list of specific items for a surgical procedure includes an RF antenna and a package scanner arranged proximate a scanning region. The RF antenna is constructed to detect specific RF tags on each of the items contained within a package, and the package scanner is constructed to read an identification label on the package.
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SYSTEM AND COMPONENTS FOR TRACKING SURGICAL ITEMS

CROSS-REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Provisional Application Nos. 60/932,732; 60/932,733; 60/932,798; 60/932,812 and 60/932,813 all filed June 1, 2008, the entire contents of which are hereby incorporated by reference.

BACKGROUND

1. Field of Invention

This application relates to systems and components for tracking surgical items, and more particularly to systems and components for tracking surgical items that have RP (Radio Frequency) antennas.

2. Discussion of Related Art

The contents of all references, including articles, published patent applications and patents referred to anywhere in this specification are hereby incorporated by reference.

One dangerous medical error that can occur during surgery is unintentionally leaving a surgical instrument or sponge inside a patient. Commonly known as retained foreign object, this error can lead to inflammation, obstruction, perforation, sepsis, and sometimes death. The problem is thought to be avoidable when stringent manual counting guidelines are followed by Operating Room (OR) personnel ("Recommended practices for sponge, sharp, and instrument counts, aorn recommended practices committee, association of perioperative registered nurses." AORNJ, vol. 70, no. 6, pp. 1083-9, 1999). While these guidelines are very effective in reducing the risk, the problem persists (C. Kaiser, S. Friedman, K. Spurling, T. Slowick, and H. Kaiser, "The retained surgical sponge." Ann Surg, vol. 224, no. 1, pp. 79-84, 1996; A. Gonzalez-Ojeda, D. Rodriguez-Alcantar, H. Arenas-Marquez, E. Sanchez Perez-Verdia, R. Chavez-Perez, R. Alvarez-Quintero, and A. Perea-Sanchez, "Retained foreign bodies following intra-abdominal surgery" Hepatogastroenterology, vol. 46, no. 26, pp. 808-12; and C. Zhan and M. Miller, "Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization." JAMA, vol. 290, no. 14, pp. 1868-74, 2003). Some estimates report that the incidence can be as high as 1 in 1500 surgeries (A. Gawande, D. Studdert, E.

Human error is not the only drawback of manual counting. During sponge counting, nurses are unable to provide support for the surgeon as they are focused on accurately counting sponges. Each sponge count takes a couple of minutes, with at least three counts per surgical procedure. Under these counting procedures, the nurse is inevitably distracted from her primary role for a significant part of the time. Also, when a miscount is found, there is a significant increase in OR time since an x-ray of the patient is often required. Some hospitals x-ray every patient after any open-cavity operation, which requires a radiologist to be available after every surgery and unnecessarily exposes the majority of patients to radiation. There is thus a need for improved systems and devices for tracking surgical items in operating rooms.

**SUMMARY**

A system to assist with keeping track of surgical items during a surgical procedure according to some embodiments of the current invention has a check-in station that includes an RF antenna, a data processing and storage unit in communication with the check-in station, and a check-out station in communication with the data processing and storage unit. The check-out station includes an RF antenna. The data processing and storage unit is adapted to identify a plurality of specific items checked in for the surgical procedure and identify any of the plurality of specific items checked in that fail to check out for a conclusion of the surgical procedure. A device for providing a verified list of specific items for a surgical procedure according to some embodiments of the current invention includes an RF antenna arranged proximate a scanning region, and a package scanner arranged proximate the scanning region. The RF antenna is constructed and arranged to detect specific RF tags on each of the plurality of items contained within a package, and the package scanner is constructed and arranged to read an identification label on the package that provides information about contents of the package. A device for identifying a plurality of specific surgical items contained therein according to some embodiments of the current invention has a container and an RF antenna arranged proximate the container. The RF antenna is constructed and arranged to obtain a signal from an RF tag on each of the plurality of specific items in the container.
BRIEF DESCRIPTION OF THE DRAWINGS

The invention may be better understood by reading the following detailed description with reference to the accompanying figures, in which:

Figures 1 is a schematic illustration of a system to assist with keeping track of surgical items during a surgical procedure according to some embodiments of the current invention;

Figure 2 is a schematic illustration of an RFID device for providing a verified list of specific items for a surgical procedure according to some embodiments of the current invention;

Figures 3A and 3B are schematic illustrations of two different views of an RFID device for identifying a plurality of specific surgical items contained therein according to some embodiments of the current invention;

Figures 4 is a schematic illustrations of an RFID device for identifying a plurality of specific surgical items contained therein according to another embodiment of the current invention;

Figure 5 is a schematic illustration of a patient scanner according to an embodiment of the current invention;

Figure 6 is a schematic illustration of software architecture according to an embodiment of the current invention;

Figure 7 is a shows an example of a graphical user interface (GUI) according to an embodiment of the current invention;

Figure 8 is a table showing the number of antennas required to reliably find 40 sponges in a check-out bucket according to an example of one embodiment of the current invention;

Figure 9 shows time to read sponges with one antenna, 5 antennas, and 5 cycles with 5
antennas according to some embodiments of the current invention; and

Figure 10 is a table showing the time that a system takes to detect and account for sponges in different scenarios according to some embodiments of the current invention.

DETAILED DESCRIPTION

In describing embodiments of the present invention illustrated in the drawings, specific terminology is employed for the sake of clarity. However, the invention is not intended to be limited to the specific terminology so selected. It is to be understood that each specific element includes all technical equivalents which operate in a similar manner to accomplish a similar purpose.

Throughout this specification, the term RFID (Radio Frequency Identification) is used in reference to some specific embodiments of the current invention. Some general concepts of the current invention are not limited to only RFID devices. Other radio frequency devices that can be used to tag and identify tagged items are intended to be included within the general concepts of the current invention. For example, in addition to RFID protocols, the RuBee protocol as well as future RF protocols could be used in some embodiments.

In healthcare, RFID technology has two major areas of application: administrative and direct-patient applications. Administrative applications include supply chain, smart shelving, and equipment and/or pharmaceuticals tracking. RFID technology is becoming well established in these areas due to efficiencies established in commercial and industrial sectors. Direct-patient applications, on the other hand, are still in their infancy largely because they can have a direct impact on the patient's health. One example is VeriChip (M. Levine, B. Adiba, K. Mandl, I. Kohane, and J. Halamka, "What are the benefits and risks of fitting patients with radiofrequency identification devices." PLoS Medicine, vol. 4, no. 11, 2007) which was approved by the FDA in 2004 and offers implantable RFED chips containing personal medical information to help limit medical treatment errors.
Two general variants of RFID technology exist; active tags, which require an internal power source, and passive tags, which rely on the incoming radio frequency signal to power up and respond to commands. Both tag systems operate in several frequency ranges; low, high, ultra high, and microwave frequency ranges. Low frequency (LF) tags work in the 125-148 KHz range and utilize magnetic fields for communication. They are largely unaffected by the presence of fluids, non-ferrous metals, and most electromagnetic (EM) noise sources. High frequency (HF) tags work at 13.56 MHz, can read some distance through fluids, and are susceptible to noise and antenna detuning in the presence of metals. Higher frequency RFID devices utilize electric fields for communication which are attenuated by fluids and are therefore not effective for tracking fluid-soaked sponges. Finally, there are two families of anticollision protocols: binary tree and Aloha. The binary tree provides a deterministic approach to read every available tag, while Aloha derived protocols are purely stochastic and rely on probability to ensure that every tag is read. RFID is well suited for automating sponge counting in the OR. It allows us to uniquely identify each tag and reliably account for each one during surgery. We chose passive tags for some embodiments of the current invention as they do not require an internal energy source, last much longer than active tags, can be made in much smaller sizes, and can be manufactured at a significantly lower cost. Low frequency tags enable us to search for items within a patient with high reliability as organs, bones, and body fluids are transparent to magnetic fields. In addition, we choose tags that utilize a binary tree anticollision protocol as we need to account for every item before and after surgery with the highest certainty. Anticollision protocols can also allow us to perform parallel counting in some embodiments of the current invention.

An embodiment of the current invention is directed to an automated system for surgical item tracking (e.g., surgical instruments and sponges) that can increase the safety of surgical procedures. According to embodiments of the current invention, RFID technology is used to detect and uniquely identify each surgical item at various stages during surgery. The use of low frequency RFID can enable reliable detection of tags even when soaked in body fluids, in the vicinity of metallic objects such as surgical tools, or inside a patient’s body (K. Finkenzeller, *RFID handbook: fundamentals and applications in contactless smart cards and identification*, 2nd ed., 2003). A software-based inventory component can keep track of every item, and enable users to quickly identify the state of the procedure through a color-coded interface.
While a system according to embodiments of the current invention can track any item tagged with an RFID device, some specific examples are described herein that focus on retained sponges (a.k.a. gossypiboma), as they constitute the majority of retained foreign body cases. A check-in station verifies the content of a package and registers each tagged item in a database to keep an inventory. The check-in can be performed in a parallel or quasi-parallel procedure in some embodiments of the current invention since the items are uniquely tagged with an RF tag so that specific items are identified. A check-out station, according to an embodiment of the current invention, is a smart bucket where sponges are discarded that accounts for used sponges.

The number of items in use can be displayed to the user at all times. If zero, all items are accounted for. Otherwise, a patient scanner is available to detect whether a missing sponge is still inside the patient. The check-out can be performed in a parallel or quasi-parallel procedure since the items are uniquely tagged with an RF tag so that specific items are identified, rather than counting indistinguishable items in a bookkeeping approach. Embodiments of the current invention can substantially eliminate, or at least greatly reduce, false positives, i.e., counts that appear to be complete when a sponge is still missing. False positives are estimated to account for more than 80% of cases of retained foreign objects. Embodiments of the current invention can also substantially eliminate, or at least greatly reduce, unnecessary exposure to x-rays as only those patients that appear to have unaccounted items need to be x-rayed. Embodiments of the current invention can also substantially reduce the operational cost to the hospital by reducing nurse and OR time required for each intervention. Finally, real-time information on the state of retained foreign objects can allow the surgeon to close an incision without delay.

We have demonstrated that specific embodiments of the current invention can reliably account for substantially 100% of tagged sponges during surgery. This high level of reliability can be attained by RFID verification during check-in, and continuous counting with multiple orthogonal antennas at the check-out bucket. The read rate can be maximized in some embodiments of the current invention by utilizing random antenna selection between consecutive reads. The measured check-in time for a 10-sponge packet is just 2 seconds, while regular check-out time is between 1 to 5 seconds when several sponges are thrown into the bucket at the same time. Experiments also show that we can detect missing sponges inside an in vivo porcine model with an RFID patient scanner in less than 5 seconds. The invention is not
limited to selection of the antennas in a random pattern. An ordered pattern which sequences through the antennas could be used in other embodiments of the current invention, for example.

Figure 1 is a schematic illustration of a system 100 to assist with keeping track of surgical items during a surgical procedure according to an embodiment of the current invention. The system 100 has a check-in station 102, a data processing and storage unit 104 in communication with the check-in station, and a check-out station 106 in communication with the data processing and storage unit 104. The check-in station 102, according to an embodiment of the current invention, is shown schematically in more detail in Figure 2. The check-in station 102 has at least one RFID antenna 108 constructed and arranged to read RFED tags on items being checked in for use during a surgical procedure. For example, a plurality of surgical sponges 110 may be checked in, each of which includes an RFID tag such as RFID tag 112. Although the surgical items can be surgical sponges in an embodiment of the current invention, the general concepts of the invention are not limited to only this example. The items being checked in, such as the surgical sponges 110 according to one embodiment of the invention, may be checked in substantially simultaneously in their package 114. The check-in station 102 includes at least one additional scanning device 116 to scan the package 114 to obtain general information about items contained within the package 114. Scanner 116 can be a barcode reader according to an embodiment of the current invention. However, the invention is not limited to only this particular embodiment. Other embodiments can include a scanner 116 which is itself an RFID scanner. In this example, the package 114 contains a plurality of surgical sponges 110, each with an RFED tag uniquely identifying the particular sponge. The package 114 has an optical barcode 118 that can be scanned by the barcode reader 116. The check-in station 102 can include more than one RFID antenna for reading the RFID tags on the items being checked in.

For example, the check-in station 102 in the embodiment illustrated in Figure 2 includes a second RFID antenna 120 that can be arranged substantially in an orthogonal orientation with respect to the RFED antenna 108. The RFED scanners of the check-in station 102 are not limited to a specific frequency range within general concepts of the current invention.

In operation, the check-in station 102 can scan a plurality of surgical items being checked in as they are simultaneously presented in a scanning region of the check-in station 102. The RFBD antennas 108 and 120 may be activated substantially simultaneously and/or sequenced one
or more times, as desired, in order to obtain a good reading for each RFED tag on each item in
the scanning region of the check-in station 102. The barcode reader 116 scans and provides
general information, such as the number of items and the type of items in the package. This
information can be used to verify that all RFED tags on individual items have been detected.

Furthermore, the RFED tag on each individual item can be a unique identifier to uniquely identify
a specific item. Once the signals are obtained from the RFED antennas 108 and 120, and from
the barcode reader 116, signals can be processed within the check-in station 102 or transmitted
to an external processor or processors for further processing.

The check-in station 102 has an output port to transmit signals from the check-in station
102 to external devices. The output port can be a hard-wired port, such as an electrical and/or
fiber optic port, or a wireless port, for example. The external devices can be the data processing
and storage unit 104 and/or additional peripheral devices. For example, additional peripheral
devices can include a printer to print out a verified check-in list, or could be a data storage
device to store the verified check-in list. The data processing and storage unit 104 can receive
and store a list of surgical items checked in by the check-in station 102, according to an
embodiment of the current invention. Alternatively, the data processing and storage unit 104 can
receive data, either directly or indirectly, from the check-in station and process it to create a list
of surgical items checked in by the check-in station 102. Similarly, the list of surgical items
checked in can be verified, for example, by utilizing information from barcode reader 116, either
within the check-in station itself or within the data processing and storage unit 104.

The data processing and storage unit 104 can be a localized device such as a personal
computer or workstation, can be a multi-component device such as one or more storage units
which are physically separate but in communication with a data processing unit, or can be a
distributed system which can be distributed over a network and/or the internet, for example.
Data processing and storage unit 104 can include a database of surgical items 122 which may be
used, for example, as a lookup table to provide information about items being checked in on the
check-in station 102. The data processing and storage unit 104 may also include a database for
inventory of items checked in 124, such as a check-in inventory, a running real-time inventory,
and/or a check-out inventory of missing items. The data processing and storage unit 104 may
also include a user interface 126, which can include a display and/or data entry peripheral devices according to some embodiments of the current invention.

An embodiment of a check-out station 106 is shown schematically in Figures 3A and 3B. The check-out station 106 can be an RFID device for identifying a plurality of specific items contained therein. For example, the RFID device of the check-in station 106 may include a container 128 and a plurality of RFID antennas 130, 132, and 134. Check-out station 106 is not limited to only three RFID antennas. It may include more or less than three RFID antennas in other embodiments of the current invention. In one particular example, five RFID antennas were found to work well. In that example, four of the five RFID antennas were arranged around a periphery of the container 128, all of which were substantially orthogonal to one antenna arranged substantially parallel to a bottom portion of the container 128. However, the general concepts of this invention are not limited to only such numbers and arrangements of antennas and components. In cases in which surgical items are expected to be soaked in blood or other fluids, one can use low frequency RFID scanners and tags according to embodiments of the current invention. However, the general concepts of the current invention are not limited to only those particular embodiments.

The check-out station 106 is in the form of a container generally referred to as a "kick bucket" in the medical practice. The container 128 is essentially a bucket on wheels which has the plurality of antennas arranged around it in a configuration to enhance the probability of detecting all individual surgical items disposed into the bucket. Surgical sponges are commonly disposed in kick buckets. However, the invention is not limited to detecting only surgical sponges. There could be other types of wipes and even surgical tools, for example, disposed either intentionally or unintentionally into the container 28. Check-out station 106 may also include a power source, a signal processing unit, and/or a data port, according to some embodiments of the current invention. The data port can be a wireless data port and/or electrical or fiber optic data ports, for example.

Figure 4 is a schematic illustration corresponding to another embodiment of a check-out station 206 according to the current invention. In this embodiment, the check-out station includes a container that can be rotated either manually and/or in an automated fashion to
rearrange items in the container, such as clumped sponges or wipes, to facilitate detection of all items. The container can be rotated about an axis that is tilted with respect to the vertical direction of the room to further facilitate separation of clumped items. Additionally, the container can have a structure and/or there can be a fluid introduced into the container to further assist with separation of clumped items. A plurality of RFED antennas may be arranged around the periphery of the container in this embodiment and/or incorporated as a portion of the container along a variety of arrangements of electrical paths.

Processing units, terminals and displays may be directly attached to the check in station, check out station, and/or patient scanning devices and these may be networked via wireless or wired devices according to some embodiments of the current invention.

In operation, items that are brought into a surgical room that have a significant chance of being left in a patient after surgery can be checked in at the check-in station 102. Such items may include surgical sponges, for example. However, the invention is not limited to only surgical sponges. The items checked in at check-in station 102 can be verified, such as by scanning a package of a plurality of items with a barcode reader that indicates the number of items in the package in order to verify that each individual item has registered its unique RFID signature. One can imagine numerous possible alternative verification schemes that are intended to be included within the general concepts of the current invention. The RFID signatures uniquely identify each item being checked into the operating room. For example, in the case of surgical sponges, each surgical sponge is uniquely identified even though they may appear and function substantially identically to all other checked-in surgical sponges. A verified list of items checked in to the operating room is produced and can be updated as items are checked out in the check-out station 106. The system 100 can thus provide real-time tracking of specific items checked in to an operating room to determine if they remain checked in or checked out according to some embodiments of the current invention. Alternatively, the checked out items could be determined at or towards the end of the surgical procedure, rather than maintaining a live update, if desired. If an item that had been checked in fails to check out, during or at the end of the surgical procedure, the patient can be scanned with a scanning device that has an RFED antenna to determine if the missing item or items are still inside the patient. It may be possible, in many circumstances, to scan the patient prior to the conclusion of the surgery to immediately
extract the missing item. The system 100 may include visual and/or audible indicators of
missing items. For example, the data processing and storage unit 104 may include a display 126
that displays graphical information to a user indicating the status of surgical items checked in to
the operating room.

The patient scanner may include a handheld wand device or may include a mat or
blanket-like device, such as the mat or blanket device 136 illustrated schematically in Figure 5.
The patient scanner 136 could be placed under, over or held above the patient, for example.

EXAMPLES

An example according to an embodiment of the current invention provides an electronic
inventory that can keep track of substantially every surgical item used during surgery. RFID
devices are used for non-line-of-sight identification (i.e., a unique serial number for each sponge
can be received by wireless means). A check-in station, a check-out station, and a patient
scanner are used by OR personnel to track and/or find sponges throughout the surgery. All of
these components are controlled via a software system that utilizes a color-coded interface for
easy and fast assessment of the location of the items during surgery.

A. Check-in Station

The check-in station has two orthogonal RFID antennas surmounted on top by a
perpendicular UPC barcode reader (see Figure 2). The check-in station is small, simple, and
occupies very little space. The UPC barcode identifies a package and the number of items
within it. Before accepting the package, the system verifies that the
package has the expected number of items in it, which is gathered from barcode information. If
the package contains a bad RFID tag, the reader will recognize the discrepancy and subsequently
direct the removal of the package. In addition, the barcode provides us with a description of the
type of sponge associated with each RFID tag. Note that this barcode can be easily replaced by
an RFID-based Electronic Product Code (EPC) (S. Sarma, D. Brock, and D. Engels, "Radio
It is also possible to store the barcode information in the RPID tags already available inside the sponges. While this is possible, it would increase the price of the tags as they would require read/write memory to hold this information instead of just a unique read-only ID. In addition, sponge manufacturers would have to ensure that the RPID tags that they attach to the sponges are programmed with the correct information. Further, the same type of sponge may be packaged in different quantities, which requires different codes to be inserted in tags that are destined for different packages. As such, it is simpler to attach that information to the packaging means of a barcode or EPC.

When a package is accepted, every item is registered into the system inventory where it can be tracked throughout the surgery. As previously stated, each sponge is distinguishable by its RPEO tag which has a unique serial number. In addition, as previously stated, the tagged items can be checked in by a parallel or quasi parallel procedure if desired.

B. Check-out Station

A stainless-steel bucket, commonly known as a kickbucket, is the normal depository for used sponges in the OR. It is small, simple, and convenient. Our approach is to provide a new kickbucket with a similar form factor, enabling the OR to replace existing ones with minimum disruption. The kickbucket according to the current example is equipped with an RPED reader, five orthogonal antennas (four sides plus the bottom), and the means to talk to the software component that keeps track of the inventory (i.e. wireless serial port). Since every RPID tag is equipped with a unique serial number, no sponge is counted more than once. A design for such a kick bucket is depicted in Figure 3.

The kickbucket according to the current example continuously scans for sponges and updates the inventory accordingly. While 5 antennas may seem excessive, our results suggest that we may require all of them in this example to ensure that all the sponges are read reliably without any significant involvement from OR personnel. However, the general concepts of the current invention are not limited to this one example. Although the kickbucket of the current example is intended for use throughout the surgery, the OR staff can also use another, non-RFED
equipped kickbucket to dispose sponges, and transfer them all (possibly in a bag) into the RFTD-equipped kickbucket at the end of the surgical procedure, if desired.

**C. Patient Scanner**

When a sponge is considered "missing", current OR procedures dictate that an x-ray of the patient must be taken. This requires an x-ray machine to be brought into the OR, or that the patient be moved to an x-ray equipped location. A radiologist needs to be called to read the x-ray. The x-ray may not reveal the missing sponge, especially in cases where the sponge is likely to be surrounded by bones (e.g., heart surgery). A patient scanner can be used to detect, and somewhat localize, missing sponges in the patient. We use a blanket embedded with a large antenna in this example (e.g., see Figure 5) that allows us to reach deeper into the patient, increasing the chance of finding any missing sponge. Smaller antennas may also be embedded in the blanket to localize the missing sponge. Any sponge found by the patient scanner is identified as "In-Patient" in the software inventory.

While very convenient, some medical devices may react inappropriately to the presence of an RFID patient scanner. For example, a recent study by the FDA (S. Seidman, P. Ruggera, R. Brockman, B. Lewis, and M. Shein, "Electromagnetic compatibility of pacemakers and implantable cardiac defibrillators exposed to rfid readers," *International Journal of RFID Technology and Applications*, vol. 1, no. 3, 2007) shows that RFID can interfere with pacemakers and Implantable Cardiac Defibrillators. These patients can still benefit from the system's, according to the current embodiment, accurate inventory capability, but must resolve to other means of finding missing sponges when necessary (e.g., x-ray).

**D. Software System**

It is routine for most OR facilities to utilize computer monitors during surgical procedures. Our approach can incorporate our inventory software-based approach with the current OR computer infrastructure. In general, the software system can be multi-layered, extensible, and fault tolerant, enforcing when possible the policies in place to ensure compliance with the new procedure. The system according to the current embodiment uses two databases; the surgical items registry, and the inventory. The registry contains barcode information for each package (i.e. description, quantity). The inventory keeps track of all items that have been
checked-in as they pass through the system and makes sure that every item is accounted for after the surgery is complete. Any missing item will be reflected in the inventory, at which time the patient can be scanned by the patient scanner and/or x-ray. An overview of the different databases and the flow of the procedure are shown in Figure 6. The Graphical User Interface according to an embodiment of the current invention ties together all the different components of the system. A snapshot of the GUI can be seen in Figure 7. It contains three-panels, each with color-coded identifiers which can allow OR staff to quickly and easily identify any problem and assess the state of the procedure.

Experimental Results

The current example comprises of a FROSCH Electronics Low Frequency RFID reader with a built-in multiplexer, seven 18x18 cm PCB antennas, a 30x40 cm flat cable ribbon antenna for the patient scanner, a SYMBOL Omni-Directional barcode scanner, and approximately 100 passive low-frequency hitag 1/S RFID tags. All RFID tags where glued inside KENDALL 4x4 raytec sponges (one in each). Two PCB antennas were arranged orthogonal to one another in the check-in station, with the barcode scanner on top. The other five PCB antennas were arranged around the sides of the kick-bucket, while leaving the top open. Tag orientations inside the kick-bucket are random. Mutual inductance between tags that are in close proximity can change their frequency response and make them unresponsive to the tag reader. The packaged sponges can be arranged in such a way that they do not interfere with one another but there is no such control over the position of the used sponges in the bucket.

Our initial experiments examine the reliability and feasibility of the system using dry sponges with RFID tags. First, we identified the number of antennas required to reliably detect sponges in the check-out bucket. We deposited 40 tagged sponges in the bucket, and noted the number of sponges found when using different numbers of antennas and performing one or multiple read cycles. A read cycle consists of one read from each of the antennas, so five cycles with one antenna is identical to reading five consecutive times from the same antenna. The experiment was repeated 20 times, revolving the sponges each time so that they ended up in different positions. The table in Figure 8 shows that we required all five antennas, and multiple
read cycles in this example, to reliably detect all sponges in the bucket. Reading from five antennas multiple times will introduce some unavoidable latency. Figure 9 shows how the read latency increases as more sponges are deposited in the bucket. (Using one antenna could not reliably read the complete pool of sponges as the RFID tags lied in random orientations with only a subset appropriately aligned to the field lines of a single antenna at any one time. We had to redistribute the sponges several times in order to read all tags in one cycle.) Reading from multiple antennas resulted in less than 10% (1/2 second) additional latency. The overhead is low because the anti-collision procedure turns off tags as it reads them, and so consecutive reads from other antennas will find a smaller set of tags to read from. Performing 5 cycles introduces another few seconds of latency. As we are using a multiplexer, only one antenna at a time can send the refresh signal to make sure that the tags stay in silent mode. Tags that are not aligned with that antenna do not hear this signal and so they turn on again, and are read again by another antenna in consecutive cycles. The system was then tested on a more realistic setting at the Johns Hopkins Minimally Invasive Surgery Training Center (MISTIC) center. The system according to this example was used in five in-vivo pig surgeries, on three different sessions. Each operation consisted of an open abdominal and/or thoracic cavity surgery where organs were explored, and sometimes extracted, as they would be in a regular surgery. RFID tagged sponges were used in each intervention. Sponges were deliberately left inside the "patient" after surgery, and the system correctly determined the number of sponges missing each time.

We then performed a series of "hide-and-seek" tests where one person hid sponges in different locations within the animal, and another looked for the missing sponges with the patient scanner. Sponges were hidden around the stomach, in the pelvic hole, and behind the sternum and ribs, including areas around the heart. On each occasion, all of the missing sponges were successfully found in less than 5 seconds of scanning. Reverse experiments were also performed, where multiple (>5) sponges were left in the patient around the abdomen and the chest, and the patient scanner was used to find all sponges before a count was performed in the bucket, i.e., the person scanning did not know how many sponges were missing. Each time, the final count of the bag revealed all sponges were successfully found without having to rescan the patient. Once the animals were euthanized, we collected enough blood to test the reliability of the system after the sponges were immersed in blood. This way, we could perform a realistic evaluation of the reliability of the system under realistic surgical conditions (bearing in mind that...
wireless signals can be affected by fluids and metals). A different number of blood-soaked sponges were used on three different occasions: 25, 45, and 60. The sponges were redistributed randomly on each trial. We found that, with one cycle through all five antennas, the detection rate was about 95%. With multiple (5) repeated cycles the detection rate was between 98% and 100%. While dry sponges did achieve 100% detection rate, the blood-soaked sponges were not always all found. One solution was to agitate the sponges (i.e. shake the bag). We found that a small movement of the bag quickly resulted in 100% detection rate. However, we also found that randomly selecting the antenna between consecutive reads produced 100% read rate, without having to move the sponges. This finding basically reflects a benefit of anticollision from adjacent reads. The table in Figure 10 shows a summary of what a user would experience when using our system according to this example. The average time to check-in a sponge packet is just under 2 seconds. The average time to check-out sponges varies depending on the number of sponges in the bucket, with a steep increase in latency when 60 sponges were inside the bucket.

Finally, we performed experiments where metal instruments were "inadvertently" dropped in the bucket (a few surgical scissors). We had to move the sponges on 2 occasions, out of 15 tries, to be able to detect all sponges in the bucket. However, while it did take some additional effort to find them, all of the sponges were reliably, and accurately, accounted for by the system according to this example.

In the case of a protocol violation, an item that was never checked in may be used during surgery, at which point the final count cannot be trusted. We can distinguish any unchecked item at check-out and report the problem. The nurse must identify the number of sponges that are likely to have been missed during check-in (i.e. typical quantity in package) and make sure the Never-Checked-In count in the system software reflects this number. The patient should also be scanned with a patient scanner and/or x-ray.

Any damaged RFID tag will not be able to be checked-in by the system. The barcode scanner helps prevent this type of error from becoming a problem as it will make sure that all of the tags are readable before they are used in surgery. However, there is a finite probability that a tag that is working when checked-in stops working during the procedure. This will result in a
false negative. In this case, a manual count can be performed to verify the number of checked-out sponges.

While the system can detect and/or raise a flag for single errors like a damaged RFID tag, double-errors can occur in an unreliable manufacturing process. For example, if a 10-pack of sponges contains 11 sponges, and one of these sponges is either untagged or with a damaged tag, the system will accept the package, but only 10 sponges will be entered into the inventory. While extremely unlikely (as it requires that there is a packaging error and that one of the RFIDs in the package is damaged or missing), we should be aware of the possibility as this kind of error can ultimately result in an unreliable system. One possible solution is to have the OR nurse manually count sponges, during check-in, to verify the expected quantity in the box. Alternatively, a scale may be included as part of the check in station to automatically weigh each package as it is checked in according to some embodiments of the current invention.

In the case of a computer failure, the system may crash or lose its ability to continue operating due to a hardware failure, corrupted memory, or software bug. One solution is to replicate the inventory to a backup system as the surgery progresses, enabling the surgical staff to access the information if needed. Another approach is to have an online printer that prints the status of the inventory in real time, during surgery, as sponges are checked-in and/or checked-out. Both approaches allow OR staff to revert to manual counting when the system is unable to proceed.

The current invention is not limited to the specific embodiments of the invention illustrated herein by way of example, but is defined by the claims. One of ordinary skill in the art would recognize that various modifications and alternatives to the examples discussed herein are possible without departing from the scope and general concepts of this invention.
WE CLAIM:

1. A system to assist with keeping track of surgical items during a surgical procedure, comprising:
   - a check-in station comprising an RF antenna;
   - a data processing and storage unit in communication with said check-in station; and
   - a check-out station in communication with said data processing and storage unit, said check-out station comprising an RF antenna,
   wherein said data processing and storage unit is adapted to identify a plurality of specific items checked in for said surgical procedure and identify any of said plurality of specific items checked in that fail to check out for a conclusion of said surgical procedure.

2. A system according to claim 1, wherein said data processing and storage unit generates a verified check-in list of said plurality of specific items checked in based on information about said plurality of items obtained from said check-in station that is independent of information obtained from said RF antenna of said check-in station.

3. A system according to claim 1, wherein said data processing and storage unit generates a check-out list of said plurality of specific items, in real time, as said specific items are checked out during said surgical procedure.

4. A system according to claim 1, further comprising a user interface in communication with said data processing and storage unit, wherein said user interface provides information to a user about a status of at least one of said plurality of surgical items checked in for said surgical procedure.

5. A system according to claim 4, wherein said user interface is a graphical user interface comprising a graphical display.

6. A system according to claim 4, wherein said user interface comprises at least one of a visual or audible signaling device.

7. A system according to claim 1, further comprising a patient scanner comprising an
RF antenna, wherein said patient scanner is adapted to identify at least one of said plurality of specific items checked in after having been left in a patient during surgery.

8. A system according to claim 7, wherein said patient scanner is a hand-held wand.

9. A system according to claim 7, wherein said patient scanner is a mat constructed to be arranged under said patient.

10. A system according to claim 7, wherein said patient scanner is a sheet constructed to be arranged at least one of over or above said patient.

11. A system according to claim 1, wherein said check-in station further comprises a package scanner, wherein said RF antenna is constructed to detect RFID tags on each of said plurality of specific items contained within a package checked in with said check-in station, said package scanner being constructed to read an identification label on said package that provides information about contents of said package.

12. A system according to claim 11, wherein said package scanner is an optical scanner and said identification label on said package is a UPC label.

13. A system according to claim 11, wherein said package scanner is an RFE) scanner and said identification label on said package is an EPC label.

14. A system according to claim 11, wherein said check-in station further comprises a second RF antenna arranged proximate and in a substantially orthogonal orientation relative to the first-mention RF antenna.

15. A system according to claim 12, wherein said check-in station further comprises a second RF antenna arranged proximate and in a substantially orthogonal orientation relative to the first-mention RF antenna.

16. A system according to claim 1, wherein said check-in station further comprises a
signal processor in communication with said RF antenna of said check-in station.

17. A system according to claim 11, wherein said check-in station further comprises an output port adapted to transfer data obtained from said RF antenna and said package scanner to at least one of a printer, a data storage device, or said data processing and storage unit.

18. A system according to claim 17, wherein said output port is a wireless data port.

19. A system according to claim 1, wherein said check-out station further comprises:

a container; and

an RF antenna arranged proximate said container,

wherein said RF antenna is constructed and arranged to obtain a signal from an RF tag on a specific object in said container.

20. A system according to claim 19, wherein said check-out station comprises at least two RFID antennas.

21. A system according to claim 19, wherein said check-out station comprises five RFID antennas.

22. A system according to claim 19, wherein said check-out station further comprises a signal processor in communication with said RF antenna of said check-out station.

23. A system according to claim 19, wherein said check-out station further comprises an output port adapted to transfer data obtained from said RF antenna of said check-out station to at least one of a printer, a data storage device or said data processing and storage unit.

24. A system according to claim 23, wherein said output port is a wireless data port.

25. A system according to claim 22, wherein said check-out station further comprises an output port adapted to transfer data obtained from said RF antenna of said check-out station to at least one of a printer, a data storage device or said data processing and storage unit.
26. A system according to claim 19, wherein said check-out station is a container that comprises wheels and a bucket that is open at a top thereof to provide convenient use in a surgical environment.

27. A system according to claim 1, wherein said plurality of specific items checked in for said surgical procedure are surgical sponges.

28. A device for providing a verified list of specific items for a surgical procedure, comprising:
   - an RF antenna arranged proximate a scanning region; and
   - a package scanner arranged proximate said scanning region,
   wherein said RF antenna is constructed and arranged to detect specific RF tags on each of said plurality of items contained within a package, and
   wherein said package scanner is constructed and arranged to read an identification label on said package that provides information about contents of said package.

29. A device according to claim 28, wherein said package scanner is an optical scanner and said identification label on said package is a UPC label.

30. A device according to claim 28, wherein said package scanner is an RFID scanner and said identification label on said package is an EPC label.

31. A device according to claim 28, further comprising a second RF antenna arranged proximate said scanning region and in a substantially orthogonal orientation relative to the first-mention RF antenna.

32. A device according to claim 29, further comprising a second RF antenna arranged proximate said scanning region and in a substantially orthogonal orientation relative to the first-mention RF antenna.

33. A device according to claim 28, further comprising a signal processor in
communication with said RF antenna.

34. A device according to claim 28, further comprising an output port adapted to transfer data obtained from said RF antenna and said package scanner to at least one of a printer, a data processing unit or a data storage unit.

35. A device according to claim 33, further comprising an output port adapted to transfer data obtained from said RF antenna and said package scanner to at least one of a printer, a data processing unit or a data storage unit.

36. A device according to claim 28, wherein said plurality of specific items are surgical sponges.

37. A device for identifying a plurality of specific surgical items contained therein, comprising:
   a container; and
   an RF antenna arranged proximate said container,
   wherein said RF antenna is constructed and arranged to obtain a signal from an RF tag on each of said plurality of specific items after being disposed in said container while being contained therein.

38. A device according to claim 37, wherein said device comprises at least three RF antennas.

39. A device according to claim 37, wherein said device comprises five RF antennas.

40. A device according to claim 37, further comprising a signal processor in communication with said plurality of antennas.

41. A device according to claim 37, further comprising an output port adapted to transfer data obtained from said RF antenna to at least one of a printer, a data processing unit and a data storage unit.
42. A device according to claim 40, further comprising an output port adapted to transfer data from said signal processor to at least one of a printer, a data processing unit and a data storage unit.

43. A device according to claim 37, wherein said container comprises wheels and a bucket that is open at a top thereof to provide convenient use in a surgical environment.

44. A device according to claim 37, wherein said plurality of specific surgical items are surgical sponges.

45. A device according to claim 37, wherein said RF antenna is constructed and arranged to obtain a signal from an RF tag on each of said plurality of specific items after all of said plurality of specific items are disposed in said container and contained therein.

46. A device according to claim 38, wherein said at least three RF antennas are constructed and arranged to obtain a signal from an RF tag on each of said plurality of specific items after all of said plurality of specific items are disposed in said container and contained therein.
Figure 1
Figure 4
<table>
<thead>
<tr>
<th>Antennas</th>
<th>One Cycle</th>
<th>Five Cycles</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>63.9%</td>
<td>71.7%</td>
</tr>
<tr>
<td>2</td>
<td>74.7%</td>
<td>91.7%</td>
</tr>
<tr>
<td>3</td>
<td>84.4%</td>
<td>94.4%</td>
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<tr>
<td>4</td>
<td>91.4%</td>
<td>98.6%</td>
</tr>
<tr>
<td>5</td>
<td>97.2%</td>
<td>100.0%</td>
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Figure 8

Figure 9
<table>
<thead>
<tr>
<th>Test</th>
<th>Detail</th>
<th>Result</th>
</tr>
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<tbody>
<tr>
<td>Time to check-in</td>
<td>10 sponge pack</td>
<td>2 seconds</td>
</tr>
<tr>
<td>Time to find 7 sponges thrown into bucket as bucket gets filled (online reading)</td>
<td>Empty Bucket 25 sponges</td>
<td>2 seconds</td>
</tr>
<tr>
<td></td>
<td>45 sponges</td>
<td>3 seconds</td>
</tr>
<tr>
<td></td>
<td>60 sponges</td>
<td>6 seconds</td>
</tr>
<tr>
<td>Time to find all sponges simultaneously in the bucket (offline reading)</td>
<td>25 sponges</td>
<td>6 seconds</td>
</tr>
<tr>
<td></td>
<td>45 sponges</td>
<td>12 seconds</td>
</tr>
<tr>
<td></td>
<td>60 sponges</td>
<td>31 seconds</td>
</tr>
</tbody>
</table>

Figure 10
INTERNATIONAL SEARCH REPORT

International application No
PCT/US 08/06863

A CLASSIFICATION OF SUBJECT MATTER

IPC(8) - G08B 13/14 (2008.04)
USPC - 340/572.1

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

* FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
USPC 340/572 1

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC 340/572 1,340/573 1, 573 4, 539 12, 539 13, 606/1, 604/362 (keyword limited - see terms below)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(USPT,PGPB,JPAB), DialogPRO(Engineer tag), Google Scholar Search Terms surgical/surgery/medical, check-in/check-out, RF antenna, RFID, container, processor/memory/store, track, scanner/hand
-held/mat/sheet, UPC/EPC, RFID tag scanner, sponge

C DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category*</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No</th>
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<tr>
<td>Y</td>
<td>US 7,158,030 B2 (Chung) 02 January 2007 (02 01 2007) Figs 3, 11A-14</td>
<td>14, 15, 20, 21, 31, 32, 38, 39, and 46</td>
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D

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"&" document member of the same patent family

Date of actual completion of the international search
18 July 2008 (18 07 2008)

Date of mailing of the international search report
25 JUL 200b

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