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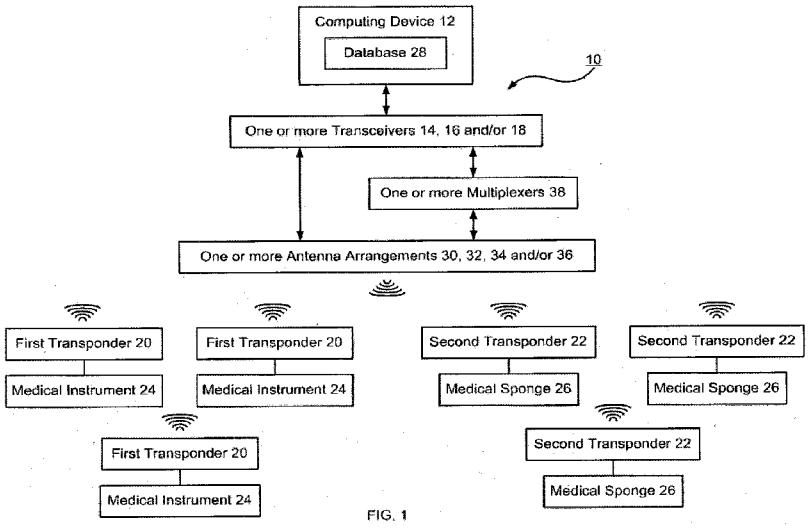

FIG. 1

(57) Abstract: An apparatus (10), devices (50, 150, 152) and methods (350, 400) for tracking and accounting for medical instruments (24) and/or sponges (26) in a sterile supply unit and/or a medical procedure room are provided. The tracking apparatus (10) includes a computing device (12) and one or more transceivers (14, 16, 18) coupled to the computing device (12). The one or more transceivers (14, 16, 18) are configured to communicate with a plurality of first and second transponders (20, 22), the transponders (20, 22) being coupled to respective ones of a plurality of medical instruments (24) and sponges (26). The computing device (12) is configured to track the medical instruments (24) and sponges (26) based on data transmitted from the first and second transponders (20, 22) and received by the one or more transceivers (14, 16, 18).

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APPARATUS, DEVICES AND METHODS FOR TRACKING AND ACCOUNTING FOR MEDICAL INSTRUMENTS AND/OR SPONGES

Field of the Invention

The present invention relates to the tracking of medical instruments and/or sponges in medical procedure rooms and/or sterile supply units and more particularly to an apparatus, devices and methods for tracking and accounting for medical instruments and/or sponges in medical procedure rooms and/or sterile supply units.

Background of the Invention

Instruments and sponges are used for medical procedures. While medical sponges are typically discarded after use, medical instruments are often sterilised and reused.

Despite best efforts at tracking the movement and location of medical instruments and sponges, medical instruments are known to go missing and, on occasion, medical instruments and used sponges are known to have been inadvertently left behind in the bodies of patients after procedures. The former adds to the operating costs of hospitals and clinics and the latter can have serious consequences ranging from bowel perforation and blood infection to death.

It is therefore desirable to have an apparatus that can track medical instruments and/or sponges in medical procedure rooms and/or sterile supply units reliably.

Summary of the Invention

Accordingly, in a first aspect, the present invention provides an apparatus for tracking and accounting for medical instruments and/or sponges. The apparatus includes a computing device and one or more transceivers coupled to the computing device. The one or more transceivers are configured to communicate with a

plurality of first transponders, the first transponders being coupled to respective ones of a plurality of medical instruments. The computing device is configured to track the medical instruments based on data transmitted from the first transponders and received by the one or more transceivers.

In a second aspect, the present invention provides a transponder device for a medical instrument. The transponder device includes a radio-frequency identification (RFID) tag, an enclosure housing the RFID tag, and a tab extending from the enclosure. The enclosure is made of a medical grade plastic material and the tab is made of a metallic material. A free end of the tab is arranged to be attached to the medical instrument.

In a third aspect, the present invention provides a medical instrument having the transponder device according to the second aspect attached thereto. The tab of the transponder device extends a distance of between about 5 mm and about 10 mm between the enclosure housing the RFID tag and the medical instrument.

In a fourth aspect, the present invention provides a receptacle for medical sponges. The receptacle includes a base and a wall arrangement extending from the base. The wall arrangement defines a volume for receiving one or more medical sponges with the base. The wall arrangement is arranged to be removably received over an antenna arrangement for tracking the one or more medical sponges.

In a fifth aspect, the present invention provides a method of tracking medical instruments in a sterile supply unit. The method includes receiving a plurality of medical instruments, each of the medical instruments being coupled to a transponder; obtaining data including location data on the medical instruments from the transponders; updating the location data of the medical instruments whenever the medical instruments are moved to a new location; performing a sterilization process on the medical instruments; and storing the sterilized medical instruments.

In a sixth aspect, the present invention provides a method of tracking and accounting for medical instruments and/or sponges in a medical procedure room.

The method includes providing details of a medical procedure to be performed; receiving a plurality of medical instruments for the medical procedure, each of the medical instruments being coupled to a first transponder; obtaining a count of the medical instruments received via the first transponders; obtaining a final count of the medical instruments via the first transponders at an end of the medical procedure to determine if any one of the medical instruments is missing.

Other aspects and advantages of the invention will become apparent from the following detailed description, taken in conjunction with the accompanying drawings, illustrating by way of example the principles of the invention.

Brief Description of the Drawings

Embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings, in which:

FIG. 1 is a schematic block diagram of an apparatus for tracking and accounting for medical instruments and/or sponges in accordance with one embodiment of the present invention;

FIG. 2 is an enlarged perspective view of a transponder device for a medical instrument in accordance with one embodiment of the present invention;

FIG. 3 is an enlarged perspective view of a medical instrument having the transponder device of FIG. 2 attached thereto;

FIG. 4 is a schematic top plan view of a first antenna arrangement in accordance with one embodiment of the present invention;

FIG. 5 is a schematic top plan view of a first antenna arrangement in accordance with another embodiment of the present invention;

FIG. 6 is a schematic perspective view of a second antenna arrangement in accordance with one embodiment of the present invention;

FIG. 7 is a perspective view of a first receptacle and a second receptacle for medical sponges in accordance with one embodiment of the present invention;

FIG. 8 is a perspective view of a clean bin setup in accordance with one embodiment of the present invention;

FIG. 9 is a perspective view of a soiled bin setup in accordance with one embodiment of the present invention;

FIG. 10 is a perspective view of a third antenna arrangement in accordance with one embodiment of the present invention;

FIG. 11 is a flowchart illustrating a method of tracking medical instruments in a sterile supply unit in accordance with one embodiment of the present invention; and

FIG. 12 is a flowchart illustrating a method of tracking and accounting for medical instruments and/or sponges in a medical procedure room in accordance with one embodiment of the present invention.

Detailed Description of Exemplary Embodiments

The detailed description set forth below in connection with the appended drawings is intended as a description of presently preferred embodiments of the invention, and is not intended to represent the only forms in which the present invention may be practiced. It is to be understood that the same or equivalent functions may be accomplished by different embodiments that are intended to be encompassed within the scope of the invention.

Referring now to FIG. 1, a schematic block diagram of an apparatus 10 for tracking and accounting for medical instruments and/or sponges is shown. The tracking apparatus 10 includes a computing device 12 and one or more transceivers 14, 16 and/or 18 coupled to the computing device 12. The one or more transceivers 14, 16 and/or 18 are configured to communicate with a plurality of first transponders 20 and/or a plurality of second transponders 22. The first transponders 20 are

coupled to respective ones of a plurality of medical instruments 24 and the second transponders 22 are coupled to respective ones of a plurality of medical sponges 26. The computing device 12 is configured to track the medical instruments 24 based on data transmitted from the first transponders 20 and received by the one or more transceivers 14, 16 and/or 18. The computing device 12 is further configured to obtain and keep a count of the medical sponges 26 based on data transmitted from the second transponders 22 and received by the one or more transceivers 14, 16 and/or 18. In the present embodiment, the computing device 12 includes a database 28 that is configured to store information on the medical instruments 24 and/or sponges 26.

Depending on the setting, one or more antenna arrangements 30, 32, 34 and/or 36 and, optionally, one or more multiplexers 38 are provided to receive the data transmitted from the first and second transponders 20 and 22 and to communicate the received data to the one or more transceivers 14, 16 and/or 18. Each of the one or more antenna arrangements 30, 32, 34 and/or 36 may be directly coupled to respective ones of the one or more transceivers 14, 16 and/or 18 or via the one or more multiplexers 38.

The computing device 12 may be any programmable machine and typically includes a central processing unit (CPU), memory, input and output devices, and buses interconnecting the components of the computing device 12. In one embodiment, the computing device 12 may be a touch screen personal computer (PC) connected to a local area network (LAN).

The one or more transceivers 14, 16 and/or 18 control data acquisition and communications within the system. The one or more transceivers 14, 16 and/or 18 perform radio communications via the one or more antenna arrangements 30, 32, 34 and/or 36 and pass information received from the first and second transponders 20 and 22 to the computing device 12. In the present embodiment, the one or more transceivers 14, 16 and/or 18 are radio-frequency identification (RFID) readers. In this embodiment, each of the one or more transceivers 14, 16 and/or 18 includes a

local controller and a reader interface layer. The local controller is able to convert a high frequency (HF) analog signal to a digital signal. The reader interface layer is able to compress thousands of identification signals and acts as a conduit between the RFID hardware elements and the application software on the computing device 12. In the present embodiment, the one or more transceivers 14, 16 and/or 18 are configured to receive a plurality of identifiers, the identifiers being transmitted from respective ones of the first and second transponders 20 and 22.

The first and second transponders 20 and 22 in the present embodiment are RFID tags. The RFID tags contain coded information and are programmed with a unique set of data. Identification numbers for the RFID tags may be based on 128-bit architecture. The first and second transponders 20 and 22 are configured to transmit information that uniquely identifies the RFID tags.

An identifier from one of the first transponders 20 may include one or more of a unique identifier, a transponder type identifier, an instrument set identifier, a maintenance cycle identifier, a utilization record identifier and a location identifier.

An identifier from one of the second transponders 22 may include one or more of a unique identifier, a transponder type identifier, a sponge type identifier, a sponge batch identifier, a sponge manufacturing date and a sponge expiry date.

The unique identifier may include encrypted code to identify a specific transponder.

The transponder type identifier may include code to identify a specific transponder type such as, for example, whether the transponder is an instrument tag, an instrument set tag, a sponge tag or a user identification (ID) tag.

The instrument set identifier helps to identify an instrument set that an instrument is associated with. Examples of the instrument set include, but are not limited to, a caesarean surgery instrument set, an open-heart surgery set, an organ

transplant surgery set, a bone fracture correction surgery set, a brain tumour removal surgery set, a skin surgery set, etc.

The maintenance cycle identifier specifies the frequency of maintenance required by an instrument, for example, whether the instrument is in need of maintenance after the fifth (5^{th}) use, the tenth (10^{th}) use or the hundredth (100^{th}) use, or if the instrument is to be discarded.

The utilization record identifier specifies the number of times an instrument has been used.

The location identifier specifies the location of an instrument, for example, whether the instrument is at a washing station, a packing station, a sterilization storage area, an operating theatre, a maintenance station, etc.

The sponge type identifier specifies the type of sponge to which the transponder is coupled, for example, the transponder may be coupled to a raytex gauze, an abdominal swab or a pad.

The sponge batch identifier serves to identify the sponge production batch number.

In the present embodiment, the integrated circuits (ICs) or chips of the first and second transponders 20 and 22 operate at a frequency of 13.56 megahertz (MHz) and support the International Organization for Standardization (ISO) standard for vicinity cards, namely ISO 15693. In such an embodiment, the one or more transceivers 14, 16 and/or 18 are configured to communicate with the first and second transponders 20 and 22 at a frequency of 13.56 megahertz (MHz). Advantageously, this prevents interference with other equipment in an operating room or medical procedure room.

The first and second transponders 20 and 22 in the present embodiment are passive RFID tags. Advantageously, this allows the first and second transponders 20 and 22 to operate without a separate external power source; the first and second

transponders 20 and 22 receive power remotely from the one or more transceivers 14, 16 and/or 18. The one or more transceivers 14, 16 and/or 18 transmit electromagnetic energy to the RFID tags 20 and 22 and the antennas of the RFID tags 20 and 22 backscatter Electronic Product Code (EPC) data back to the one or more transceivers 14, 16 and/or 18. Further advantageously, the dimensions of passive RFID tags are much smaller than active and semi-passive RFID tags, allowing these to be incorporated with the medical instruments 24 and the medical sponges 26.

In the present embodiment, the first transponders 20 are small, high performance RFID tags. In one embodiment, each of the first transponders 20 has a length of less than about 10 millimetres (mm) to achieve reading efficiency and a thickness of about 1 mm or less. Advantageously, this facilitates incorporation of the first transponders 20 with the medical instruments 24. In one embodiment, the first transponders 20 may be cingulated module tags. Advantageously, this facilitates encapsulation of the first transponders 20 into small items such as pharmaceutical vials. The first transponders 20 are waterproof and are able to withstand the high temperatures of an instrument sterilization process. In one embodiment, the first transponders 20 are able to withstand a temperature of between about minus (-) 40 degrees Celsius (°C) and about 120 °C. Advantageously, this allows the first transponders 20 to be washed and sterilized with the medical instruments 24 without first having to be removed to prevent damage. In other words, this allows the first transponders 20 to undergo sterilization with the instruments 24. A coiled antenna may be provided with the first transponders 20. In one embodiment, each of the first transponders 20 has a mass of less than 60 milligrams (mg). The first transponders 20 may have relatively short read-ranges of up to about 15 centimetres (cm).

A challenge was encountered in designing an enclosure to house each of the first transponders 20. Although metal would have been the most suitable material for the enclosure in view of the operating environment, a constraint was that such an enclosure would only work well at low frequencies. Other constraints encountered

include temperature considerations. The enclosure had to be able to withstand the high temperatures encountered during the instrument sterilization process. There was also an issue of how the enclosures for the first transponders 20 were to be securely attached to the medical instruments 24.

Notwithstanding the challenges encountered, the inventors were able to overcome the constraints with a specially designed enclosure for the first transponders 20. This is described below with reference to FIGS. 2 and 3.

Referring now to FIG. 2, a transponder device 50 for one of the medical instruments 24 and incorporating one of the first transponders 20 is shown. The transponder device 50 includes a radio-frequency identification (RFID) tag 20, an enclosure 52 housing the RFID tag 20, and a tab 54 extending from the enclosure 52. In the present embodiment, the enclosure 52 includes a holder 56 having an opening 58 for receiving the RFID tag 20 and a cap 60 to cover the opening 58 of the holder 56. A free end 62 of the tab 54 is arranged to be attached to the medical instrument 24.

The enclosure 52 serves to protect the RFID tag 20 during the instrument sterilization process and is made of a medical grade plastic material. In the present context, "medical grade plastic material" is a material whose properties make it suitable for use in the manufacture of medical products that require regular autoclave sterilization. Such a material is inherently low in toxicity and presents a low risk of unfavourable biological reactions. Additionally, such a material also presents low interactivity and interference with the radio frequencies used by the RFID tag 20.

The dimensions of the enclosure 52 are also selected to provide sufficient clearance between the RFID tag 20 and adjacent instruments that may interfere with radio frequency signal transmission. Additionally, the dimensions of the enclosure 52 cannot be too large as this will obstruct use of the medical instrument 24 to which the transponder device 50 is attached. In one embodiment, the enclosure 52 has a

length L of between about 10 mm and about 15 mm, a width W of between about 10 mm and about 13 mm and a thickness T of between about 0.4 mm and about 0.6 mm.

The tab 54 is made of a metallic material and serves to allow the plastic enclosure 52 to be securely attached or bonded to a medical instrument 24. In the present embodiment, the tab 54 is a stainless steel strip that is introduced during the molding of the enclosure 52 and is thus formed with the enclosure 52 during the molding process. Accordingly, as can be seen from FIG. 2, a portion of the tab 54 is embedded in the enclosure 52. In the embodiment shown, the tab 54 is T-shaped and is provided with a through hole 62 to receive a corresponding protrusion formed in the enclosure 52. Advantageously, this facilitates secure attachment of the tab 54 to the enclosure 52 and helps prevent dislodgement of the tab 54 from the enclosure 52.

In one embodiment, the cap 60 is attached to the holder 56 by ultrasonic welding in order to retain the RFID tag 20 securely in the enclosure 52. Advantageously, ultrasonic welding fuses or bonds the cap 60 to the holder 56 leaving no seams or crevices where blood or other residue can settle.

Referring now to FIG. 3, a medical instrument 24 having the transponder device 50 of FIG. 2 attached thereto is shown. As can be seen from FIG. 3, the tab 54 of the transponder device 50 extends a distance D between the enclosure 52 housing the RFID tag 20 and the medical instrument 24. Advantageously, besides facilitating secure attachment of the plastic enclosure 52 to the medical instrument 24, the tab 54 also serves to provide a radio frequency interference clearance gap between the RFID tag 20 and the metallic medical instrument 24. In one embodiment, the tab 54 of the transponder device 50 extends a distance D of between about 4 mm and about 10 mm between the enclosure 52 housing the RFID tag 20 and the medical instrument 24. Such a separation between the transponder device 50 and the medical instrument 24 is sufficiently narrow so as not to intrude into the use of the instrument 24.

In a preferred embodiment, the tab 54 of the transponder device 50 is attached to the medical instrument 20 by macro laser welding. Although there are various ways of bonding the transponder device 50 to the surgical instrument, it was discovered by the inventors that macro laser welding is most suitable for securely bonding two stainless steel objects together using only a small contact area and furthermore produces a durable bond with a clean and smooth finish at the welded surface, the latter being desirable for meeting the cleanliness standards for medical instruments 24 as macro laser welding helps ensure that there are no crevices where blood or other residue can settle.

Referring again to FIG. 1, the second transponders 22 of the present embodiment are small in size. In one embodiment, each of the second transponders 22 has a length of between about 15 mm and about 25 mm and a thickness of about 1 mm. The second transponders 22 are also waterproof and have high temperature resistance. In one embodiment, the second transponders 22 are able to withstand a temperature of between about -25 °C and about 180 °C. Advantageously, this allows the second transponders 22 to withstand a high temperature sterilization process. In one embodiment, each of the second transponders 22 includes a coil-type antenna and the second transponders 22 are encapsulated with epoxy to protect the antenna coils. In the same or a different embodiment, each of the second transponders 22 has an operating distance of up to 15 centimetres (cm). In one embodiment, each of the second transponders 22 is a read and write RFID tag.

The medical instruments 24 may be any implements, tools, or utensils that are used during a medical procedure. Non-limiting examples include scalpels, forceps, scissors and clamps.

The medical sponges 26 may be any gauze pads used to absorb blood or other fluids during a medical procedure. Examples of the medical sponges 26 include, but are not limited to, raytex gauzes, abdominal swabs, lahey swabs, tonsil squares and tonsil swabs.

The database 28 is a local database for data integrity and safety and is linked to a centralized server database with which data is synchronized. The database 28 stores information such as patient information, type of operation, location of operation, surgical team information, instrument usage details, sponge usage details and/or instrument location details. The database 28 captures sponge and instrument usage information during various operating stages with accountability details. The local database 28 works independently from the centralized server database and thus service updates do not affect normal system usage. Furthermore, integrity is achieved by having data that is locally present on the system. In case of an update failure, the same data can be recovered from the local database. Network issues will not affect the functioning of the tracking apparatus 10 as the data is locally present on the system.

The one or more antenna arrangements 30, 32, 34 and/or 36 serve as conduits between the one or more transceivers 14, 16 and/or 18 and the first and second transponders 20 and 22. The one or more antenna arrangements 30, 32, 34 and/or 36 emit radio signals to activate the first and second transponders 20 and 22 and to read and/or write data to and from them. In the present embodiment, the one or more antenna arrangements 30, 32, 34 and/or 36 are externally provided.

In one embodiment, a first antenna arrangement 30 is coupled via one of the one or more multiplexers 38 to a first transceiver 14, and a second antenna arrangement 32 is either directly coupled to one of the one or more transceivers 14, 16 and/or 18 or coupled via one of the one or more multiplexers 38. A third antenna arrangement 34 may be either directly coupled to one of the one or more transceivers 14, 16 and/or 18 or coupled via one of the one or more multiplexers 38. A fourth antenna arrangement 36 may be coupled directly to one of the one or more transceivers 14, 16 and/or 18.

Referring now to FIG. 4, a first antenna arrangement 30 is shown. The first antenna arrangement 30 is coupled to the first transceiver 14 and is configured to receive the data from the first transponders 20 coupled to respective ones of the

medical instruments 24. As can be seen from FIG. 4, the first antenna arrangement 30 is incorporated into an instrument tray 70. In the present embodiment, the first antenna arrangement 30 is a coiled antenna embedded within the instrument tray 70, the antenna being coiled within the plane of the instrument tray 70. The first antenna arrangement 30 may be provided in a range of sizes of up to 0.6 metre (m) by 1 m.

The coils of the first transponders 20 and the first antenna arrangement 30 have mutual inductance to one another. The coil of the first antenna arrangement 30 carries an alternating current producing a magnetic field in the vicinity of the first transceiver 14. This magnetic field charges up the coils of the first transponders 20 and switches on the circuitry inside the first transponders 20. The first transponders 20 respond by transmitting data back to the first transceiver 14.

Referring now to FIG. 5, an alternative embodiment of the first antenna arrangement 30 is shown. In the alternative embodiment shown, the first antenna arrangement 30 includes a first looped antenna 72 and a second looped antenna 74 embedded side-by-side within the instrument tray 70 in a planar arrangement.

Referring now to FIG. 6, a second antenna arrangement 32 for communicating with the second transponders 20 coupled to the medical sponges 26 is shown. The second antenna arrangement 32 includes a plurality of first antennas 100 arranged to define a boundary and a plurality of second antennas 102 in a base portion defined by the boundary. Advantageously, with such an arrangement of the first and second antennas 100 and 102, the second antenna arrangement 32 is able to read a plurality of tagged items received within the defined boundary regardless of the orientation of the tagged items including, for example, a pack of stacked up tagged items. This simplifies usage and improves the reliability of the tracking apparatus 10.

In the present embodiment, each of the first and second antennas 100 and 102 includes a plurality of copper tracks etched onto a printed circuit board (PCB).

In the embodiment shown, each of the first antennas 100 is formed as a single loop antenna. Advantageously, this helps to reduce interference. In one embodiment, opposing pairs of the first antennas 100 are coupled to one another to facilitate sequential reading of tagged items received within the defined boundary first by one pair of the first antennas 100 followed by the other pair. Advantageously, this increases the read sensitivity of the second antenna arrangement 32. In the embodiment shown, the second antennas 102 are formed concentrically one within another. Advantageously, this also increases the read sensitivity of the second antenna arrangement 32. In a preferred embodiment, the antennas 100 and 102 are optimized for operation with mid range high frequency (HF) readers and are designed to read only high frequency (HF) 13.56 MHz passive RFID tags. The antennas 100 and 102 are configured to operate within an approved frequency range and do not interfere with any other low frequency (LF) and ultra high frequency (UHF) frequency ranges.

The second antenna arrangement 32 may be employed for a clean bin application or a soiled bin application. In the clean bin application, the second antenna arrangement 32 is used to read and count tagged clean medical sponges or gauzes 26 in an operating theatre (OT) or medical procedure room. In the soiled bin application, the second antenna arrangement 32 is used to read and count tagged soiled medical sponges or gauzes 26 in the operating theatre or medical procedure room.

The arrangement of the multiple antennas 100 and 102 allows a user to randomly deposit the medical sponges or gauzes 26 into the clean or soiled bin instead of deliberately stacking or arranging them in the bins. This manner of depositing the medical sponges or gauzes 26 is more natural and intuitive. The arrangement of the antennas 100 and 102 in the soiled bin application allows soiled gauzes to be placed in any orientation in the soiled bin and is not affected by the degree of soiling of the gauzes. The activation of the antennas 100 and 102 in the second antenna arrangement 32 to read the tags 22 may be sequential or simultaneous.

A receptacle 150 or 152 for receiving the medical sponges 26 is provided over the second antenna arrangement 32. Embodiments of the receptacle 150 or 152 are described in greater detail below with reference to FIGS. 7, 8 and 9. The receptacle 150 or 152 is arranged to be removably received over the second antenna arrangement 32.

Referring now to FIG. 7, a first receptacle 150 and a second receptacle 152 for the medical sponges 26 are shown. Each of the first and second receptacles 150 and 152 includes a base 154 and 156 and a wall arrangement 158 and 160 extending from the base 154 and 156. The wall arrangement 158 and 160 defines a volume for receiving one or more of the medical sponges 26 with the base 154 and 156 and is arranged to be removably received over the second antenna arrangement 32 of FIG. 6 for tracking the one or more medical sponges 26. The wall arrangement 158 and 160 includes a first wall 162 and 164 and a second wall 166 and 168. A space 170 and 172 is defined between the first and second walls 162, 164, 166 and 168 for receiving the second antenna arrangement 32.

In the embodiment shown, the first or inner wall 162 and 164 is designed to slope away from top to bottom and is moulded such that where the base 154 and 156 and the wall arrangement 158 and 160 meet, a curved edge is formed. Advantageously, this reduces the presence of blind spots where the second transponders 22 cannot be detected.

The first receptacle or clean bin 150 is arranged to receive clean medical sponges 26 and the second receptacle or soiled bin 152 is arranged to receive soiled medical sponges 26. The clean bin 150 and the soiled bin 152 are substantially the same except for the heights H_{CB} and H_{SB} of the clean and soiled bins 150 and 152. As can be seen from FIG. 7, the height H_{CB} of the clean bin 150 is less than the height H_{SB} of the soiled bin 152. The difference in height between the clean bin 150 and the soiled bin 152 helps distinguish one from the other for hygiene reasons. Additionally, the greater depth of the soiled bin 152 is

advantageous for accommodating the larger volume of used medical sponges as these are typically in an opened-up and/or unfolded state.

The bin design allows the clean bin 150 and the soiled bin 152 to be removed and autoclaved separately from the electronic components. In one embodiment, the first and second receptacles 150 and 152 are formed of a medical grade plastic to protect the second antenna arrangement 32.

Referring now to FIG. 8, a clean bin setup 200 is shown. The clean bin setup 200 includes a receptacle 202 for receiving sterile medical sponges 26 and an antenna arrangement (not shown) for obtaining and keeping a count of the sterile medical sponges 26 and over which the receptacle 202 is received. The receptacle 202 and the antenna arrangement are provided on a mobile device, in this embodiment a cart 204 with a plurality of casters 206. The cart 204 includes a door 208 that can be locked.

The clean bin setup 200 is used to count the number of sterile medical sponges 26 introduced during a medical procedure. In use, the receptacle 202 may be covered with a sterile cloth before stacking or placing sterile medical sponges 26 into the receptacle 202 in accordance with the operating theatre or procedure room protocol.

In one embodiment, the casters 206 may be provided with back locks to lock the casters 206 and thus prevent the cart 204 from moving during the medical procedure.

In a wireless embodiment, the clean bin setup 200 is provided with a wireless adapter to link the clean bin setup 200 to a network for accessing the radio frequency identification (RFID) counting results. Advantageously, this allows preparation to be undertaken in a separate area that is remote from an operating table such as, for example, a preparation room next to an operating room. The wireless embodiment also allows the clean bin setup 200 to be placed anywhere around the operating table such that it will not be obstructive to medical personnel.

Furthermore, the absence of wires in the wireless embodiment reduces obstacles to personnel movement within the operating room.

Referring now to FIG. 9, a soiled bin setup 250 is shown. The soiled bin setup 250 includes a receptacle 252 for receiving soiled medical sponges 26 and an antenna arrangement for obtaining and keeping a count of the soiled medical sponges 26 and over which the receptacle 252 is received. In the present embodiment, the receptacle 252 and the antenna arrangement are provided on a base structure 258. A plurality of casters 256 is mounted to the base structure 258 to facilitate movement of the soiled bin setup 250. The antenna arrangement is received in the base structure 258. A plurality of latches 260 is provided to secure the receptacle 252 to the base structure 258.

The soiled bin setup 250 is used to count the number of medical sponges 26 utilised during the course of the procedure. In use, the receptacle 252 may be covered with a sterile plastic bag before stacking or throwing the soiled medical sponges 26 into the receptacle 252 in accordance with the operating theatre or procedure room protocol.

In one embodiment, the casters 256 may be provided with back locks to lock the casters 256 and thus prevent the soiled bin setup 250 from moving during the procedure.

The design of the base structure 258 allows removal of the receptacle 252 for cleaning and autoclaving.

Referring now to FIG. 10, a third antenna arrangement 34 is shown. The third antenna arrangement 34 is coupled to one of the one or more transceivers 14, 16 and/or 18. The third antenna arrangement 34 includes a first single loop antenna 300 and a second single loop antenna 302 positioned coaxially within the first single loop antenna 300. The first and second single loop antennas 300 and 302 are attached to a handle 304. A connection cable 306 is provided to connect the third

antenna arrangement 34 to one of the one or more transceivers 14, 16 and/or 18 or one of the one or more multiplexers 38.

As can be seen from FIG. 10, the third antenna arrangement 34 is a handheld antenna arrangement. The handheld antenna arrangement 34 is used to search for and locate any missing tagged medical instrument 24 or sponge 26 during the medical procedure. Advantageously, the provision of two (2) single loop antennas results in a more concentrated or higher field strength and thus achieves better penetrative ability than a single loop antenna. The first and second single loop antennas 300 and 302 may be used with any 13.56 MHz reader with an impedance of 50 Ω. In one embodiment, the first and second single loop antennas 300 and 302 are optimized for operation with a transceiver having an emitted transmitting power tuned to 1 W. In the same or a different embodiment, a reading range of between about 30 cm and 40 cm is achievable. In the present embodiment, the maximum reading distance is realized in the middle of the first and second single loop antennas 300 and 302 and the optimum orientation of the first and second single loop antennas 300 and 302 is when the first and second single loop antennas 300 and 301 are parallel to the first and second transponders 20 and 22.

In one embodiment, the connection cable 306 has a length of about 3.6 m. In the same or a different embodiment, the connection cable 306 is an RF cable.

Referring again to FIG. 1, a fourth antenna arrangement 36 is used to identify and validate a user of the tracking apparatus 10 at various stages of use such as, for example, before additional medical instruments 24 and sponges 26 are introduced for a medical procedure and at the start of a counting process. The fourth antenna arrangement 36 may be secured to a work surface area of the tracking apparatus 10.

The one or more multiplexers 38 are configured to select one of several analogue input signals from the various antenna arrangements and to forward the selected input to a single line.

Use of the tracking apparatus 10 of FIG. 1 will now be described below with reference to FIGS. 11 and 12.

Referring now to FIG. 11, a flowchart illustrating a method 350 of tracking medical instruments in a sterile supply unit is shown. The sterile supply unit, also known as the Central Sterile Supply Unit (CSSU) or Theatre Sterile Supply Unit (TSSU), is where an instrument set is washed, packed and sterilized.

The method 350 begins at step 352 when a plurality of medical instruments 24 is received. Each of the medical instruments 24 is coupled to a transponder 20. The medical instruments 24 arrive at the sterile supply unit in a contaminated condition after a medical procedure.

At step 354, data including location data on the medical instruments 24 is obtained from the transponders 20. This may be by scanning the set of medical instruments 24 received with a handheld reader to update the set location. In one embodiment, the set location is automatically marked as "Received in CSSU/TSSU".

At step 356, the received medical instruments 24 are compared to a predetermined package specification to determine if any medical instrument 24 is missing. The predetermined package specification specifies the medical instruments 24 required for a specific medical procedure. In the event of a missing instrument, the user is alerted, for example, via the display screen of the tracking apparatus 10. This helps ensure that the medical instruments 24 are correctly packed.

The set of medical instruments 24 is then moved from the receiving station to a washing station. The location data of the medical instruments 24 is updated at step 358 whenever the medical instruments 24 are moved to a new location. Accordingly, the set location is marked as "Washing Station" after the move and before the medical instruments 24 are washed.

After washing, the set of medical instruments 24 are transferred to a packing area and the set location is then updated as "Packing Area". At the packing area, the instruments 24 are checked again against the predetermined package specification to ensure that no instruments 24 are missing and all the instruments 24 are clean and intact. One or more medical instruments 24 in need of maintenance may be identified at step 360 based on usage data obtained from the transponders 20 of the medical instruments 24. In one embodiment, usage counts of the medical instruments 24 written into the transponders 20 are compared against predetermined usage thresholds of the medical instruments 24 to ascertain whether maintenance is required. If any defective instrument 24 is identified, the defective instrument 24 is sent for maintenance and a replacement instrument 24 is introduced so that the set of medical instruments 24 remains complete. The instruments 24 are then scanned, packed into a container and the container is sealed.

The container in which the instruments 24 are packed is then transferred to a sterilization area and the set location is updated as "Sterilization". At step 362, a sterilization process is performed on the medical instruments 24 in the container.

After sterilization, the instruments 24 in the container are transferred to a sterile storage room and location data of the medical instruments 24 is updated as "Storage". In one embodiment, the update is performed by scanning the instrument set using a fixed antenna. The sterilized medical instruments 24 are stored at step 364.

The tracking apparatus 10 registers that the medical instruments 24 are moved out of storage when the medical instruments 24 are moved to a procedure room.

As is evident from the foregoing, information is written to the transponders 20 of the medical instruments 24 and relayed to the database 28 during the entire process in the CSSU or TSSU. This information enables the system to track, for

instance, frequency of use, which surgical procedure an instrument has been or is to be used for, which set of instruments it belongs to, etc.

Referring now to FIG. 12, a flowchart illustrating a method 400 of tracking and accounting for medical instruments 24 and sponges 26 in a medical procedure room such as an operating theatre (OT) is shown.

The method 400 begins at step 402 with the provision of details of a medical procedure to be performed. The details of the medical procedure to be performed are provided to the tracking apparatus 10. This includes information relevant to the procedure such as, for example, details of the patient, type of procedure or surgery and the attending staff.

At step 404, a plurality of medical instruments 24 for the medical procedure is received. Each of the medical instruments 24 is coupled to a first transponder 20.

The medical instruments 24 received are registered and a count of the medical instruments 24 received is obtained at step 406 via the first transponders 20. In the present embodiment, registration is automatically performed and the count of the medical instruments 24 received is automatically obtained from the first transponders 20 by the tracking apparatus 10 when the medical instruments 24 are received on an instrument tray into which the first antenna arrangement 30 is incorporated. The first transponders 20 are scanned by the first antenna arrangement 30 when the medical instruments 24 are placed on the instrument tray.

At step 408, a verification is performed to determine if the medical instruments 24 received are valid for the medical procedure to be performed. The tracking apparatus 10 verifies if the instrument set type is valid for a specific surgery and provides an alert in the event the instrument set type received is inappropriate. The tracking apparatus 10 performs the verification by comparing the medical instruments 24 received to a predetermined case specification to determine if the medical instruments 24 received are valid for the medical procedure to be performed.

A plurality of medical sponges 26 is received at step 410. Each of the medical sponges 26 is coupled to a second transponder 22.

At step 412, a count of the medical sponges 26 received is obtained via the second transponders 22. In the present embodiment, the count of the medical sponges 26 is automatically obtained from the second transponders 22 by the tracking apparatus 10 when the medical sponges 26 are received in a first sponge receptacle or clean bin 150 placed over a second antenna arrangement 32.

Items required for the medical procedure, but that are not tagged to a transponder are manually recorded with the computing device 12 of the tracking apparatus 10.

An intermediate count is performed at step 414 during the medical procedure to determine if any item is missing. The intermediate auto-count is performed to verify and locate all the medical instruments 24 and sponges 26. The intermediate count may be performed more than once and at any time during the medical procedure. In one embodiment, an intermediate count is performed to determine if any medical instrument 24 or sponge 26 is missing prior to closure of the skin layer.

The count of the medical instruments 24 is updated at step 416 via the first transponders 20 when an additional medical instrument 24 is introduced for the medical procedure. Likewise, the count of the medical sponges 26 is updated via the second transponders 22 when one or more additional sponges 26 are introduced during the medical procedure

At the end of the medical procedure, a final count of the medical instruments 24 is obtained at step 418 via the first transponders 20 to determine if any one of the medical instruments 24 is missing and a final count of the medical sponges 26 is obtained at step 420 via the second transponders 22 to determine if any one of the medical sponges 26 is missing. The final count of the medical instruments 24 may be obtained when all the used instruments 24 are returned to the instrument tray. In the present embodiment, the final count of the medical sponges 26 is automatically

obtained from the second transponders 22 when the medical sponges 26 are received in a second sponge receptacle or soiled bin 152.

In the event that an instrument 24 or sponge 26 is found to be missing, a search is performed at step 422 to locate the missing item with the handheld antenna arrangement 34. When found, the count is updated.

A bypass procedure may be performed at step 424 with approval from an authorized staff. If all the instruments 24 and sponges 26 are accounted for, the system allows an "End of Surgery" procedure to be performed and details of the medical procedure printed. The "End of Surgery" procedure cannot be performed unless all the instruments 24 and sponges 26 have been accounted for. However, the system allows authorised personnel to bypass this safety check under certain conditions such as, for example, when one or more sponges 26 are intentionally left in the patient as part of the medical procedure or when an instrument 24 or sponge 26 has been accounted for physically but the transponder is malfunctioning.

A report containing details of the medical procedure may be generated by the tracking apparatus 10.

The used medical instruments 24 are returned to the sterile supply unit when the procedure is over.

As is evident from the foregoing discussion, the present invention provides an apparatus, devices and methods for tracking and accounting for medical instruments and/or sponges in medical procedure rooms and/or sterile supply units reliably. The medical instruments and/or sponges are each given a unique identity and this allows the tracking apparatus to automate the counting of medical instrument and sponge usage and records the count results electronically. Advantageously, this lowers the risk of having a surgical apparatus, a pad or any other sterile consumable left behind in a body of a patient after conclusion of a surgical procedure. Further advantageously, the present invention also facilitates

tracking of maintenance cycles for medical instruments and grouping of medical instruments for different medical procedures.

While preferred embodiments of the invention have been illustrated and described, it will be clear that the invention is not limited to the described embodiments only. Numerous modifications, changes, variations, substitutions and equivalents will be apparent to those skilled in the art without departing from the scope of the invention as described in the claims.

Further, unless the context clearly requires otherwise, throughout the description and the claims, the words "comprise", "comprising" and the like are to be construed in an inclusive as opposed to an exclusive or exhaustive sense; that is to say, in the sense of "including, but not limited to".

CLAIMS

1. An apparatus for tracking and accounting for medical instruments and/or sponges, comprising:

a computing device; and

one or more transceivers coupled to the computing device,

wherein the one or more transceivers are configured to communicate with a plurality of first transponders, the first transponders being coupled to respective ones of a plurality of medical instruments, and

wherein the computing device is configured to track the medical instruments based on data transmitted from the first transponders and received by the one or more transceivers.

2. The apparatus of claim 1, further comprising a first antenna arrangement coupled to one of the one or more transceivers and configured to receive the data from the first transponders, the first antenna arrangement being incorporated into an instrument tray.

3. The apparatus of claim 2, wherein the first antenna arrangement comprises a coiled antenna embedded within the instrument tray.

4. The apparatus of claim 2, wherein the first antenna arrangement comprises a first looped antenna and a second looped antenna embedded within the instrument tray in a planar arrangement.

5. The apparatus of claim 2, further comprising a multiplexer coupling the first antenna arrangement to the transceiver.

6. The apparatus of claim 1, wherein the one or more transceivers are configured to receive a plurality of identifiers, the identifiers being transmitted from respective ones of the first transponders.

7. The apparatus of claim 6, wherein each of the identifiers comprises one or more of a unique identifier, a transponder type identifier, an instrument set identifier, a maintenance cycle identifier, a utilization record identifier and a location identifier.

8. The apparatus of claim 1, wherein the one or more transceivers are configured to communicate with the first transponders at a frequency of 13.56 megahertz (MHz).

9. The apparatus of claim 1, wherein the computing device further comprises a database that is configured to store information on the medical instruments.

10. The apparatus of claim 1, wherein the one or more transceivers are further configured to communicate with a plurality of second transponders, the second transponders being coupled to respective ones of a plurality of medical sponges, and wherein the computing device is further configured to obtain and keep a count of the medical sponges based on data transmitted from the second transponders and received by the one or more transceivers.

11. The apparatus of claim 10, further comprising a second antenna arrangement coupled to one of the one or more transceivers and configured to receive the data from the second transponders, the second antenna arrangement comprising a plurality of first antennas arranged to define a boundary.

12. The apparatus of claim 11, wherein the second antenna arrangement further comprises a plurality of second antennas in a base portion defined by the boundary.

13. The apparatus of claim 11, further comprising a receptacle for receiving the medical sponges, the receptacle being removably received over the second antenna arrangement.

14. The apparatus of claim 1, further comprising a third antenna arrangement coupled to one of the one or more transceivers, the third antenna arrangement comprising a first single loop antenna and a second single loop antenna positioned coaxially within the first single loop antenna.

15. A transponder device for a medical instrument, comprising:

a radio-frequency identification (RFID) tag;

an enclosure housing the RFID tag, wherein the enclosure is made of a medical grade plastic material; and

a tab extending from the enclosure, wherein the tab is made of a metallic material and wherein a free end of the tab is arranged to be attached to the medical instrument.

16. The transponder device of claim 15, wherein the RFID tag is able to withstand a temperature of between about minus (-) 40 degrees Celsius (°C) and about 120 °C.

17. The transponder device of claim 15, wherein a portion of the tab is embedded in the enclosure.

18. The transponder device of claim 15, wherein the enclosure comprises a holder having an opening for receiving the RFID tag and a cap to cover the opening of the holder.

19. The transponder device of claim 18, wherein the cap is attached to the holder by ultrasonic welding.

20. The transponder device of claim 15, wherein the RFID tag has a length of less than about 10 millimetres (mm).

21. The transponder device of claim 15, wherein the RFID tag has a thickness of about 1 mm or less.

22. A medical instrument having the transponder device of any one of claims 15 to 21 attached thereto, wherein the tab of the transponder device extends a distance of between about 5 mm and about 10 mm between the enclosure housing the RFID tag and the medical instrument.

23. The medical instrument of claim 22, wherein the tab of the transponder device is attached to the medical instrument by macro laser welding.

24. A receptacle for medical sponges, comprising:

a base; and

a wall arrangement extending from the base and defining a volume for receiving one or more medical sponges with the base, wherein the wall arrangement is arranged to be removably received over an antenna arrangement for tracking the one or more medical sponges.

25. The receptacle of claim 24, wherein the wall arrangement comprises:

a first wall;

a second wall; and

a space defined between the first and second walls for receiving the antenna arrangement.

26. A method of tracking medical instruments in a sterile supply unit, comprising:

receiving a plurality of medical instruments, each of the medical instruments being coupled to a transponder;

obtaining data including location data on the medical instruments from the transponders;

updating the location data of the medical instruments whenever the medical instruments are moved to a new location;

performing a sterilization process on the medical instruments; and

storing the sterilized medical instruments.

27. The method of tracking medical instruments in a sterile supply unit of claim 26, further comprising comparing the received medical instruments to a predetermined package specification to determine if any medical instrument is missing.

28. The method of tracking medical instruments in a sterile supply unit of claim 26, further comprising identifying one or more medical instruments in need of maintenance based on usage data obtained from the transponders of the medical instruments.

29. A method of tracking and accounting for medical instruments and sponges in a medical procedure room, comprising:

providing details of a medical procedure to be performed;

receiving a plurality of medical instruments for the medical procedure, each of the medical instruments being coupled to a first transponder;

registering and obtaining a count of the medical instruments received via the first transponders;

obtaining a final count of the medical instruments via the first transponders at an end of the medical procedure to determine if any one of the medical instruments is missing.

30. The method of tracking and accounting for medical instruments and sponges in a medical procedure room of claim 29, further comprising verifying if the medical instruments received are valid for the medical procedure to be performed.

31. The method of tracking and accounting for medical instruments and sponges in a medical procedure room of claim 30, wherein the step of verifying if the medical instruments received are valid comprises comparing the medical instruments

received to a predetermined case specification to determine if the medical instruments received are valid for the medical procedure to be performed.

32. The method of tracking and accounting for medical instruments and sponges in a medical procedure room of claim 29, wherein registration is automatically performed and the count of the medical instruments received is automatically obtained from the first transponders when the medical instruments are received on an instrument tray.

33. The method of tracking and accounting for medical instruments and sponges in a medical procedure room of claim 29, further comprising performing an intermediate count during the medical procedure to determine if any item is missing.

34. The method of tracking and accounting for medical instruments and sponges in a medical procedure room of claim 33, further comprising locating the missing item with a handheld antenna.

35. The method of tracking and accounting for medical instruments and sponges in a medical procedure room of claim 34, further comprising performing a bypass procedure.

36. The method of tracking and accounting for medical instruments and sponges in a medical procedure room of claim 29, further comprising updating the count of the medical instruments via the first transponders when an additional medical instrument is added for the medical procedure.

37. The method of tracking and accounting for instruments and sponges in a medical procedure room of claim 29, further comprising:

receiving a plurality of medical sponges, each of the medical sponges being coupled to a second transponder;

obtaining a count of the medical sponges received via the second transponders; and

obtaining a final count of the medical sponges via the second transponders at the end of the medical procedure to determine if any one of the medical sponges is missing.

38. The method of tracking and accounting for medical instruments and sponges in a medical procedure room of claim 37, wherein the count of the medical sponges is automatically obtained from the second transponders when the medical sponges are received in a first sponge receptacle.

39. The method of tracking and accounting for medical instruments and sponges in a medical procedure room of claim 38, wherein the final count of the medical sponges is automatically obtained from the second transponders when the medical sponges are received in a second sponge receptacle.

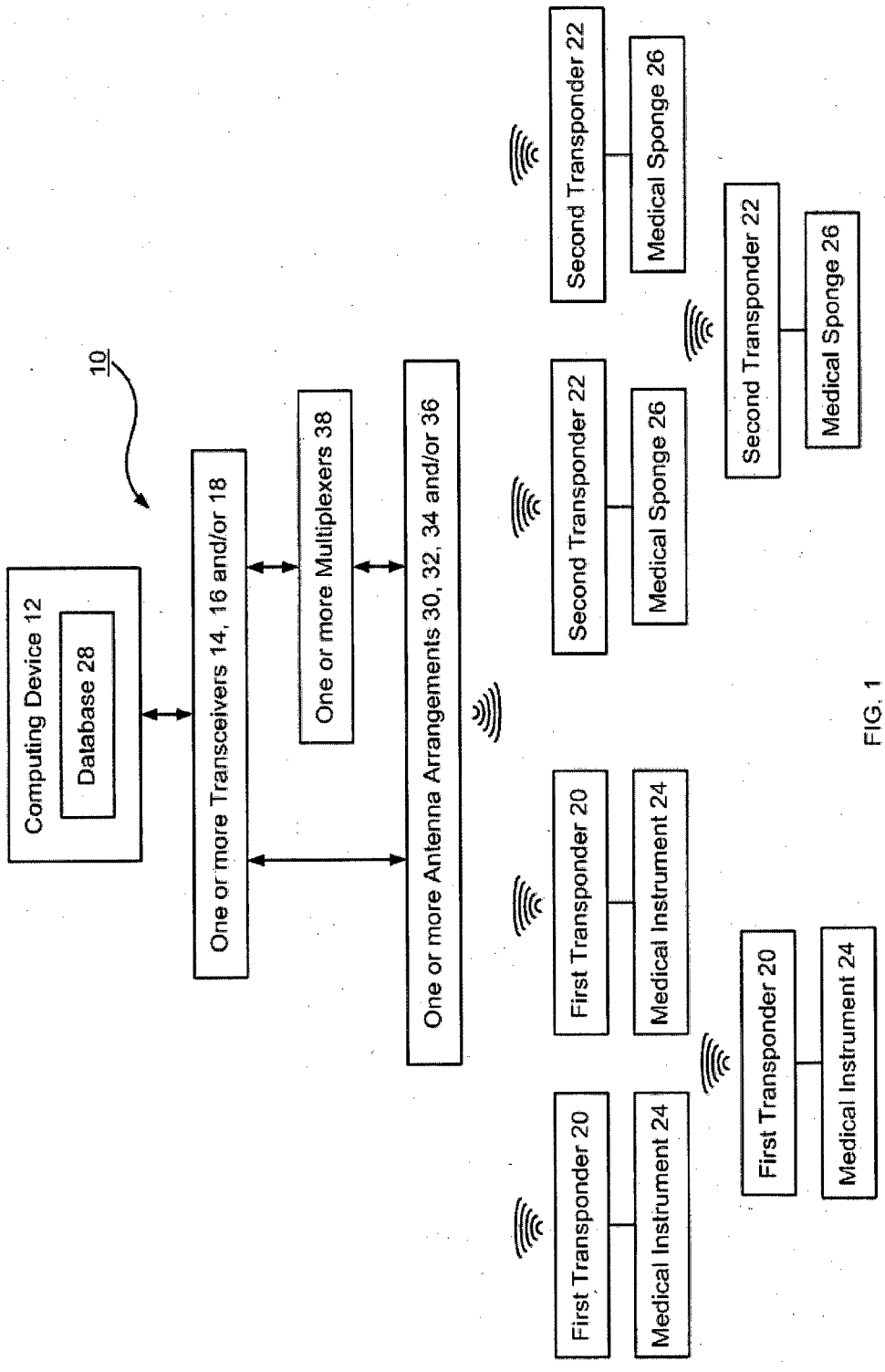
10
Computing Device 12
Database 28
One or more Transceivers 14, 16 and/or 18
One or more Multiplexers 38
One or more Antenna Arrangements 30, 32, 34 and/or 36
First Transponder 20
Medical Instrument 24
First Transponder 20
Medical Instrument 24
Second Transponder 22
Medical Sponge 26
Second Transponder 22
Medical Sponge 26
Second Transponder 22
Medical Sponge 26

FIG. 1

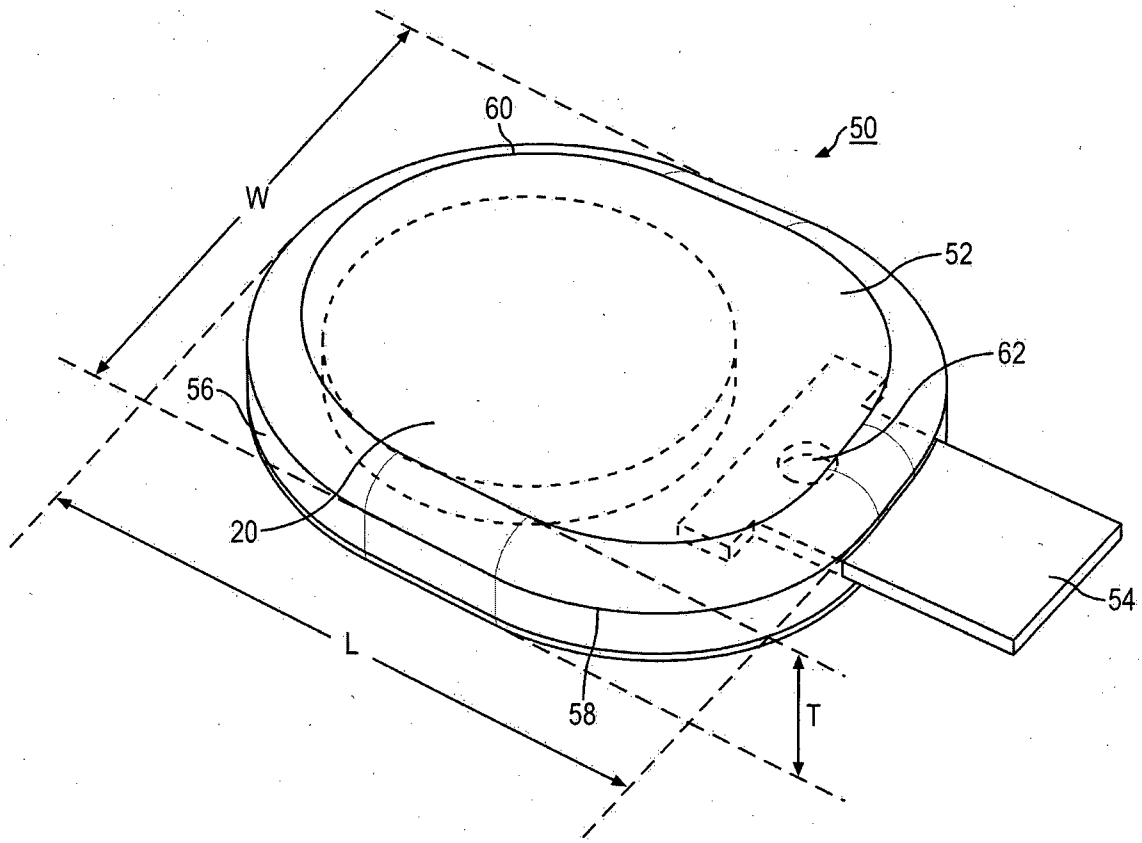

FIG. 2

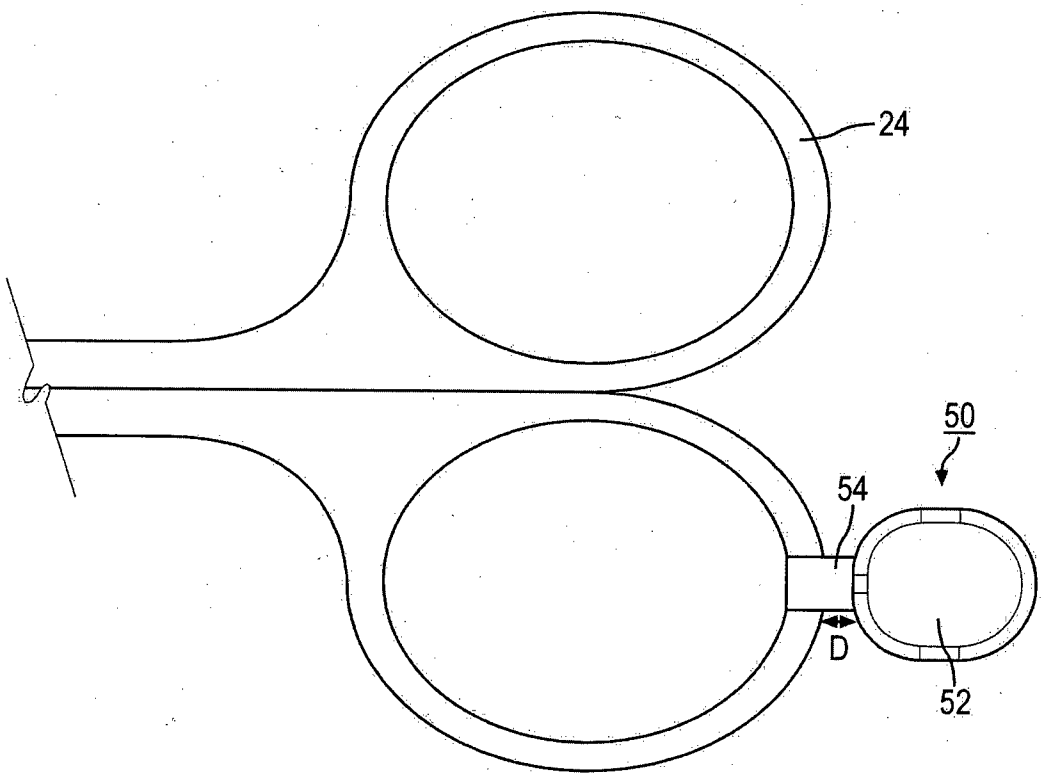

FIG. 3

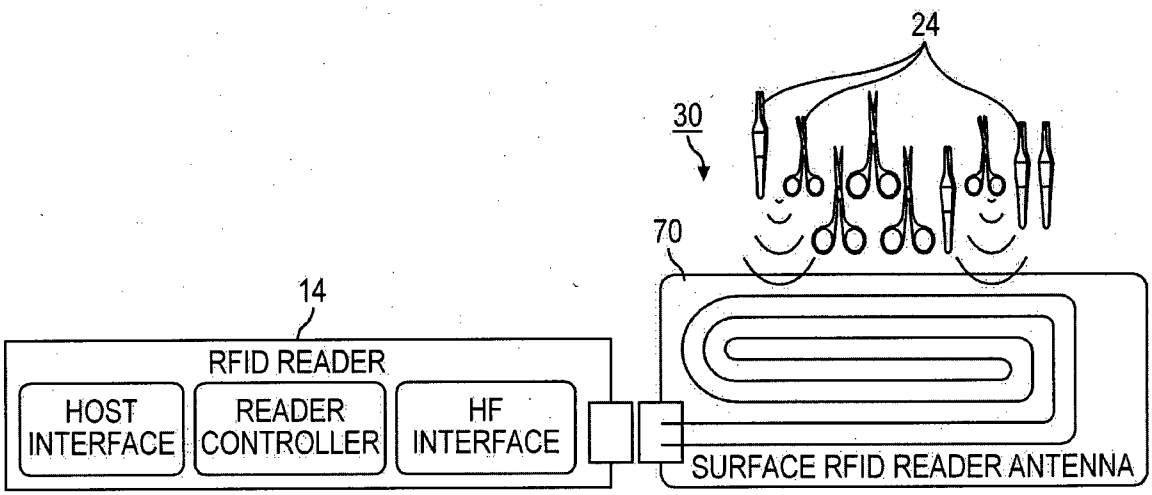
24
30
70
14
RFID READER
HOST INTERFACE
READER CONTROLLER
HF INTERFACE
SURFACE RFID READER ANTENNA

FIG. 4

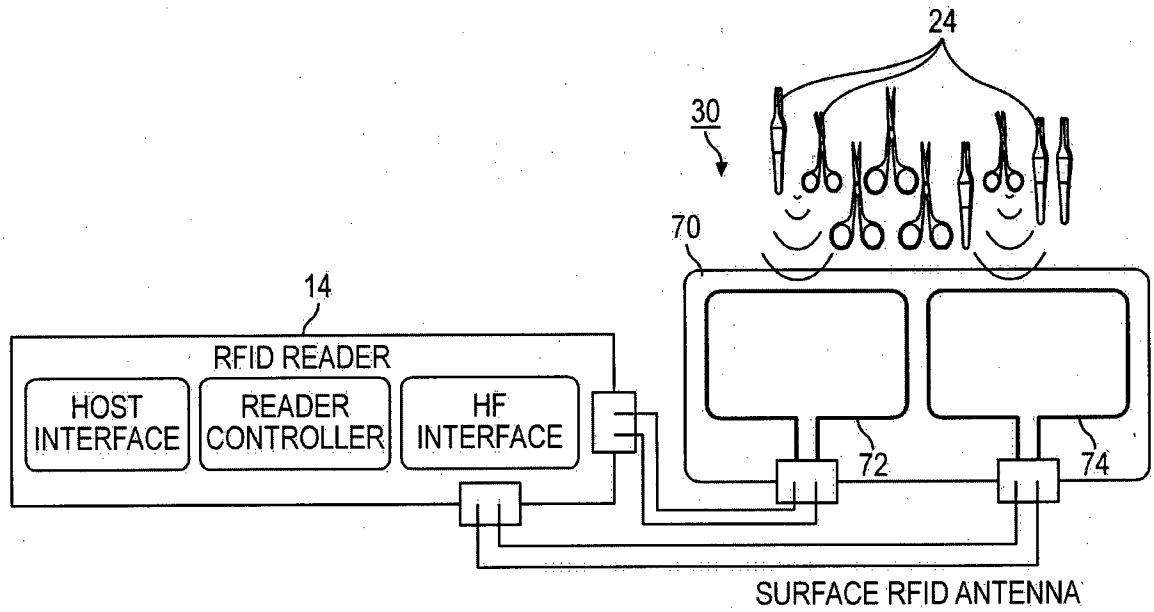
24
30
70
14
RFID READER
HOST INTERFACE
READER CONTROLLER
HF INTERFACE
72
74
SURFACE RFID ANTENNA

FIG. 5

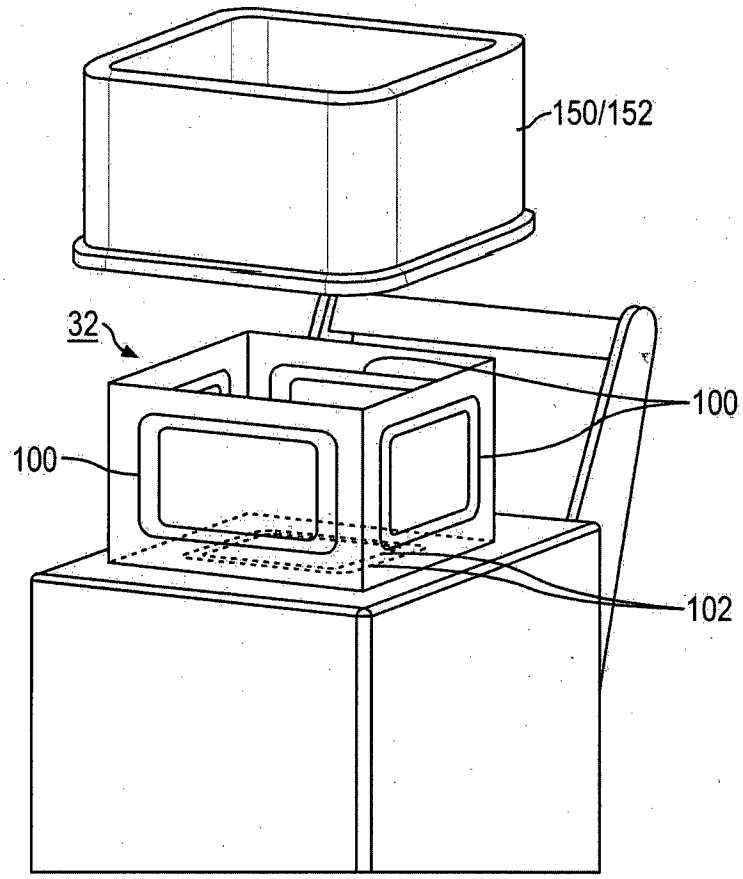

FIG. 6

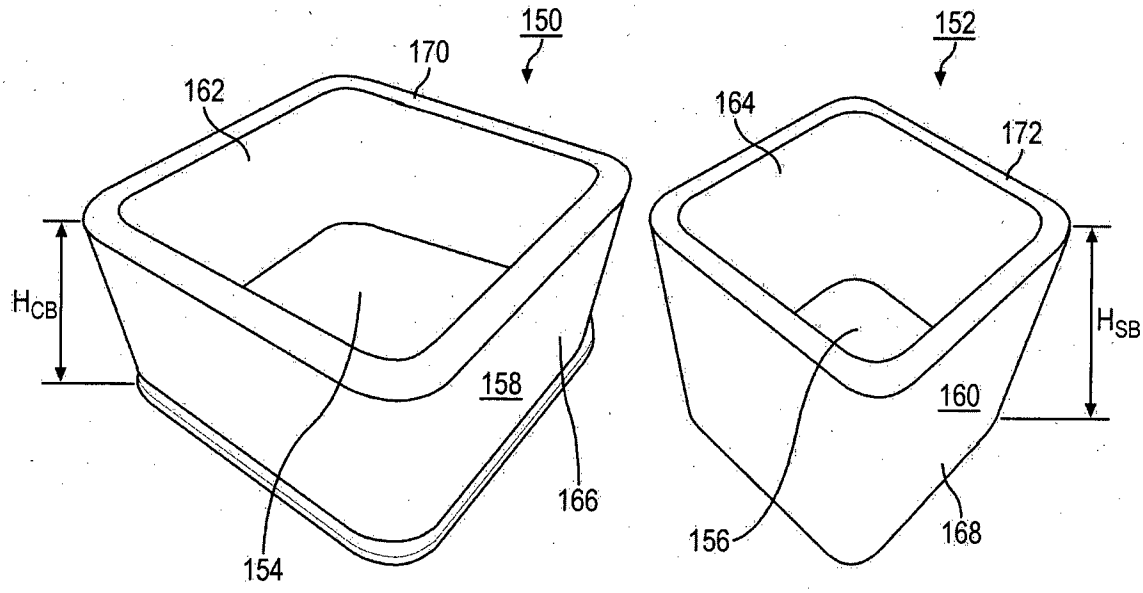

FIG. 7

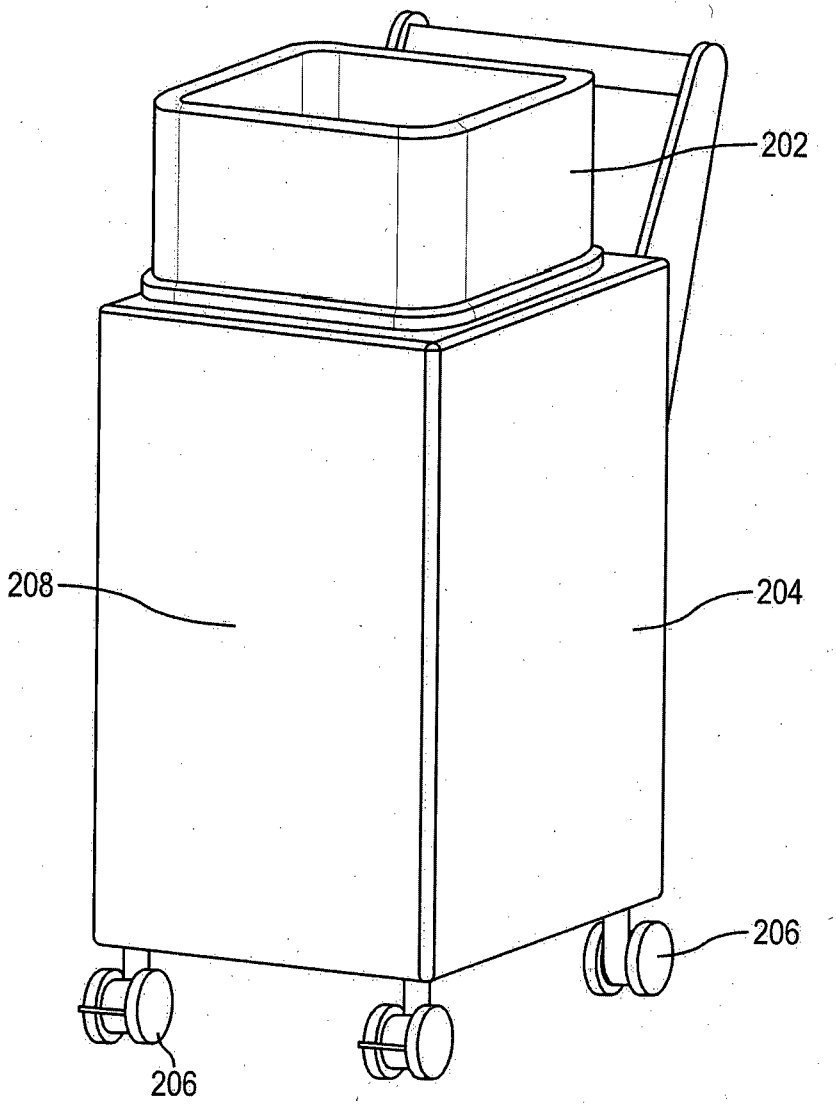

FIG. 8

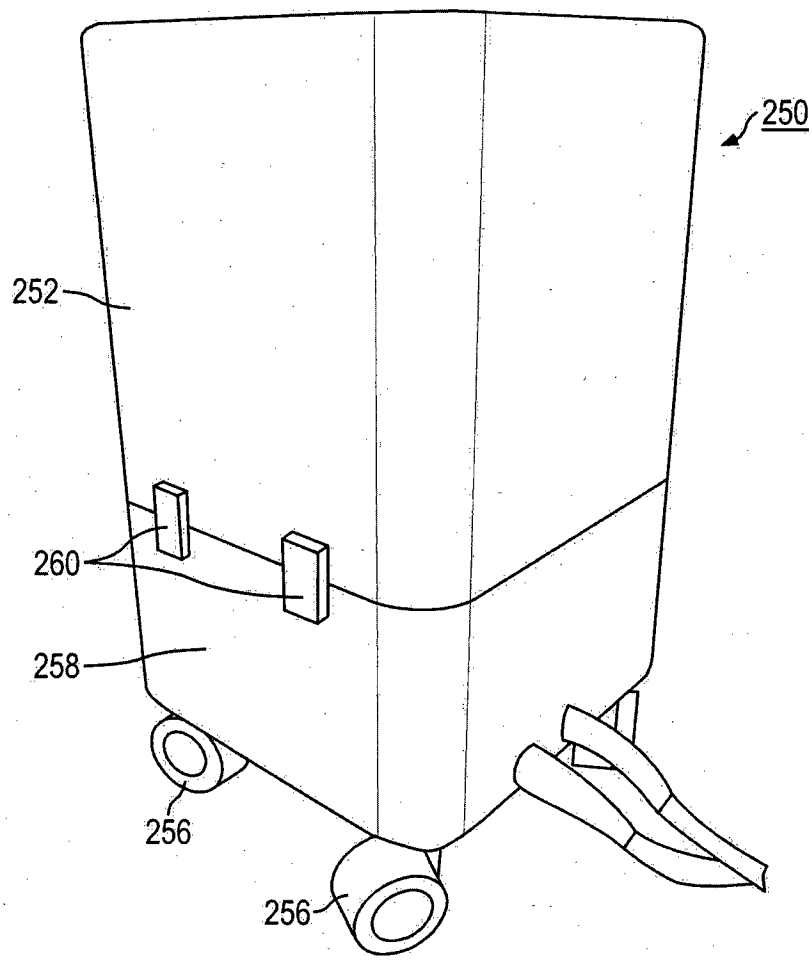

FIG. 9

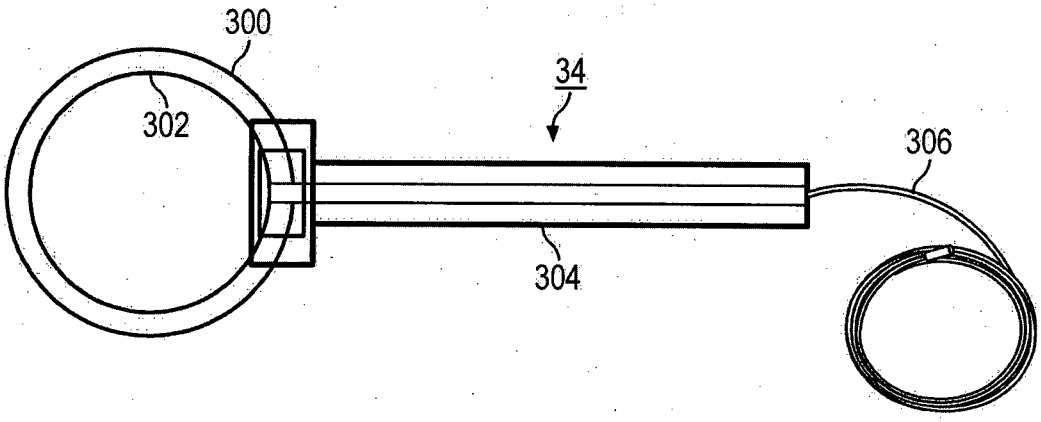

FIG. 10

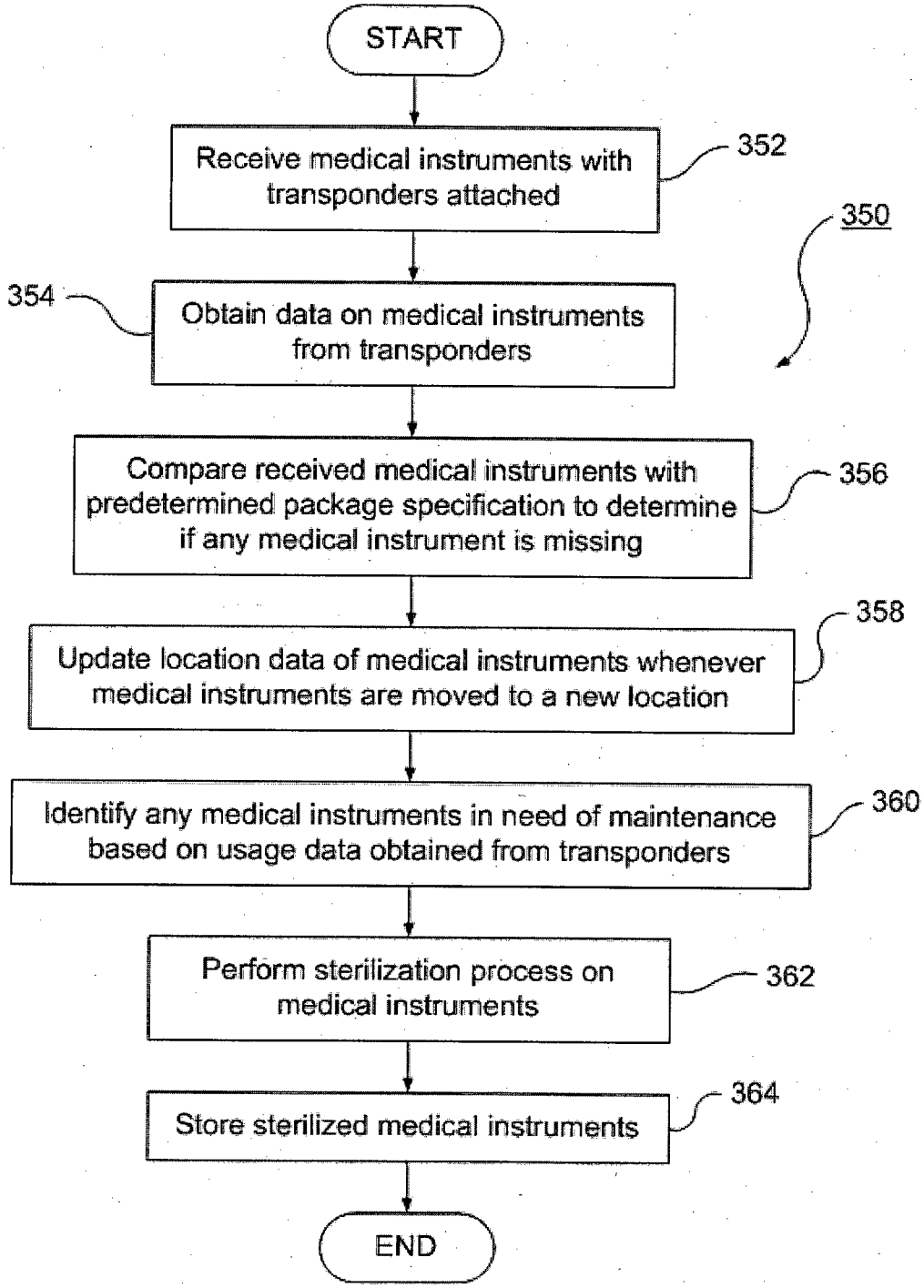
START
Receive medical instruments with transponders attached
352
350
354
Obtain data on medical instruments from transponders
Compare received medical instruments with predetermined package specification to determine if any medical instrument is missing
356
Update location data of medical instruments whenever medical instruments are moved to a new location
358
Identify any medical instruments in need of maintenance based on usage data obtained from transponders
360
Perform sterilization process on medical instruments
362
Store sterilized medical instruments
364
END

FIG. 11

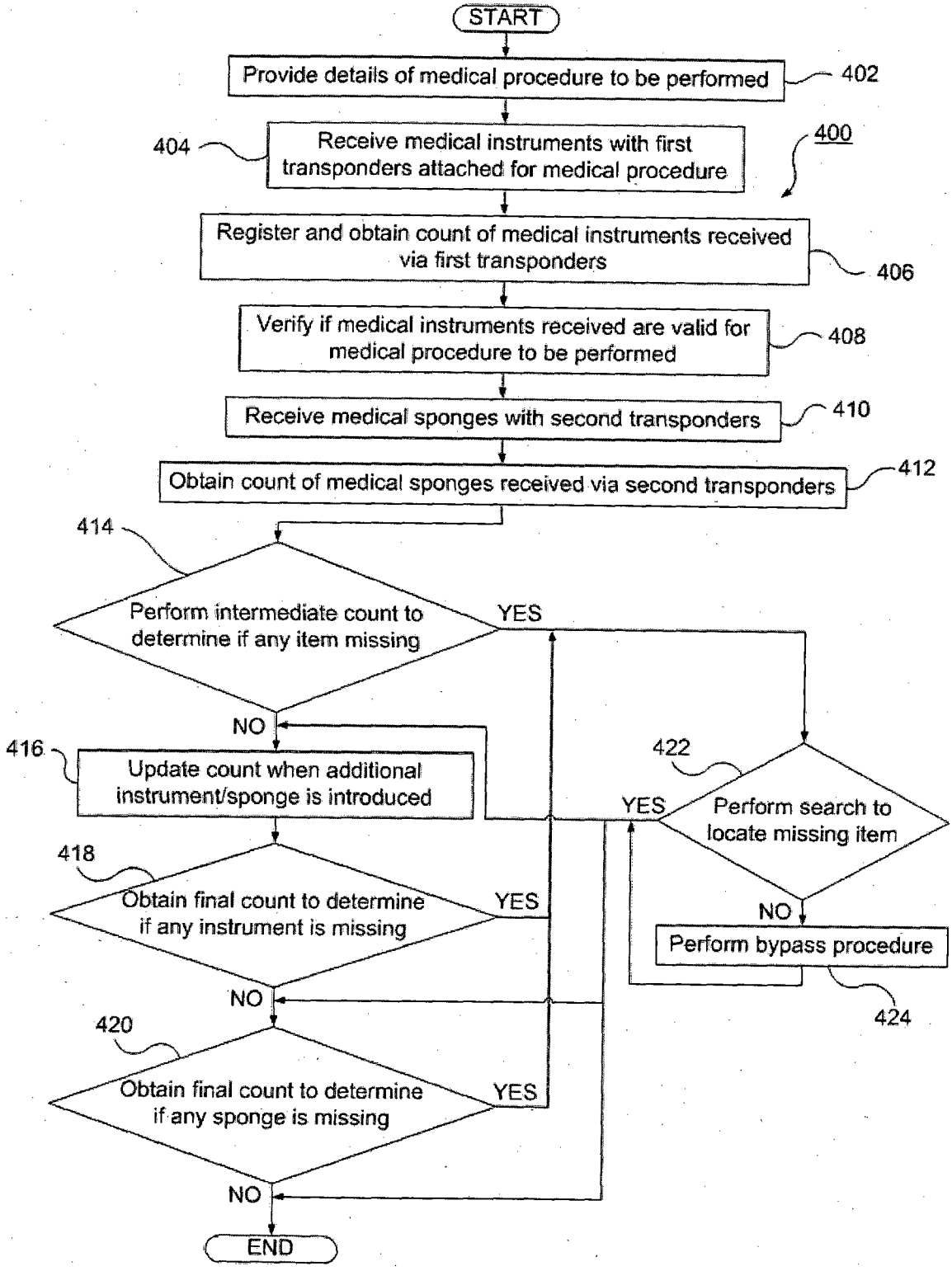
START
Provide details of medical procedure to be performed
402
404
Receive medical instruments with first transponders attached for medical procedure
400
Register and obtain count of medical instruments received via first transponders
406
Verify if medical instruments received are valid for medical procedure to be performed
408
Receive medical sponges with second transponders
410
Obtain count of medical sponges received via second transponders
412
414
Perform intermediate count to determine if any item missing
YES
NO
416
Update count when additional instrument/sponge is introduced
422
YES
Perform search to locate missing item
NO
Perform bypass procedure
424
418
Obtain final count to determine if any instrument is missing
YES
NO
420
Obtain final count to determine if any sponge is missing
YES
NO
END

FIG. 12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SG2013/000495

A. CLASSIFICATION OF SUBJECT MATTER

H04Q 3/00 (2006.01) ***H04Q 5/22 (2006.01)*** ***G06K 19/077 (2006.01)*** ***H05K 13/04 (2006.01)*** ***H01Q 1/40 (2006.01)***
H01Q 7/08 (2006.01) ***G08B 13/14 (2006.01)*** ***A61B 19/00 (2006.01)*** ***A61B 19/02 (2006.01)***

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)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, EPODOC: keywords (medical RFID, RFID protocol, surgical instrument, surgical sponge, gossypiboma, textiloma, medical grade plastic, track, monitor, bin) and the like terms.

Google Patents: Keywords same as above.

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
	Documents are listed in the continuation of Box C	

[X] Further documents are listed in the continuation of Box C [X] 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
5 March 2014	05 March 2014
Name and mailing address of the ISA/AU	**Authorised officer**
AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA Email address: pct@ipaustralia.gov.au Facsimile No.: +61 2 6283 7999	Marthinus Van Der Westhuizen AUSTRALIAN PATENT OFFICE (ISO 9001 Quality Certified Service) Telephone No. 0262832283

INTERNATIONAL SEARCH REPORT C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		International application No. **PCT/SG2013/000495**
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US 2010/0201487 A1 (HALBERTHAL et al.) 12 August 2010 Title, Abstract, Figs. 2, 5, 6, 7A, paragraphs [0001],[0003],[0007],[0011-0012],[0027],[0033-0039], [0042],[0046],[0049-0050], [0066], [0070-0078] Title, Abstract, Figs. 2, 6, 7A, paragraph [0001]	1, 6-13, 26-39 14
X Y	US 2011/0181394 A1 (BLAIR) 28 July 2011 Title, Abstract, Claim 10, Figs. 2, 8-11,14-15, 17, paragraphs [0005], [0009-0010], [0012-0013], [0016], [0019], [0043], [0050], [0057-0061], [0063], [0065-0067], [0070], [0079], [0082], [0094], [0096], [0098-0099], [0126], [0159] Title, Abstract, paragraphs [0005], [0010], [0012-0013], [0016], [0019], [0043]	1-13, 29-39 14
Y	US 2004/0183742 A1 (GOFF et al.) 23 September 2004 Abstract, Fig. 3	14
X	US 2008/0238677 A1 (BLAIR et al.) 02 October 2008 Title, Abstract, Figs. 6A, 6B, 7B, paragraph [0008], [0012], [0069], [0078].	15-23
X Y	US 2013/0001305 A1 (FLECK et al.) 03 January 2013 Figs. 3-4, 7, 11-12, 16a, 28-29, 41, paragraph [0002], [0004-0005], [0039], [0065-0066], [0070], [0082], [0084], [0096-0099], [0106], [0137], [0143] Abstract, paragraphs Fig. 16a, [0002],[0004-0005], [0039], [0066]	1, 6-13, 24-25, 29-31, 33-39 14
A	FERNANDEZ-CHIMENO et al., "RFID systems in medical environment: EMC issues". International Symposium on Electromagnetic Compatibility (EMC Europe), "9th International Symposium on EMC", Wrocklaw, 2010. [retrieved on 24 December 2013]. Retrieved from Internet http://upcommons.upc.edu/e-prints/bitstream/2117/12433/1/emceurope_2010_fernandez.pdf Whole of document	1-39
A	RFID Inc., "HF-13.56-MHz-Product-Brochure", [retrieved on 26 February 2014 from a 13 October 2011 entry to www.archive.org]. Retrieved from Internet http://web.archive.org/web/20111013054836/http://www.rfidinc.com/pdfs/HF-13.56-MHz-Product-Brochure.pdf Whole of document	1-39
A	ClearCount Medical Solutions, "SmartSponge Flex Brochure", [retrieved on 3 March 2014 from a 24 August 2013 entry to www.archive.org]. Retrieved from Internet http://clearcount.com/wp-content/uploads/docs/cct.brochure.pdf Whole of document	1-39

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Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
the subject matter listed in Rule 39 on which, under Article 17(2)(a)(i), an international search is not required to be carried out, including

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See Supplemental Box for Details

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.

☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.

☒ No protest accompanied the payment of additional search fees.

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Supplemental Box

Continuation of: **Box III**

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

This Authority has found that there are different inventions based on the following features that separate the claims into distinct groups:

- Claims 1-14 and 26-39 are directed to means for automated tracking and accounting of medical instruments. The feature of the means to track and account medical devices using transponders and transceivers is specific to this group of claims.
- Claims 15-23 are directed to RFID transponder devices that can be attached to medical devices. The features of the means for the RFID transponder devices to be attached to medical devices, the means of the medical devices to receive the said RFID transponders and the means of said transponder devices to be manufactured to be suitable for the medical environment is specific to this group of claims.
- Claims 24-25 are directed to a receptacle suitable for tracking medical sponges. The feature of the means of the receptacle to receive medical sponges by the design of the walls of the receptacle over an antenna arrangement for tracking medical sponges is specific to this group of claims.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

When there is no special technical feature common to all the claimed inventions there is no unity of invention.

In the above groups of claims, the identified features may have the potential to make a contribution over the prior art but are not common to all the claimed inventions and therefore cannot provide the required technical relationship. The only feature common to all of the claimed inventions and which provides a technical relationship among them is the means to use transponders to track and account for medical devices.

However this feature does not make a contribution over the prior art because it is disclosed in:

FERNANDEZ-CHIMENO et al., "RFID systems in medical environment: EMC issues". International Symposium on Electromagnetic Compatibility (EMC Europe), "9th International Symposium on EMC", Wrocklaw, 2010. [retrieved on 24 December 2013]. Retrieved from Internet

<http://upcommons.upc.edu/e-prints/bitstream/2117/12433/1/emceurope_2010_fernandez.pdf>

Therefore in the light of this document this common feature cannot be a special technical feature. Therefore there is no special technical feature common to all the claimed inventions and the requirements for unity of invention are consequently not satisfied *a posteriori*.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/SG2013/000495**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		**Patent Family Member/s**	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**

End of Annex

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.

INTERNATIONAL SEARCH REPORT Information on patent family members	International application No. **PCT/SG2013/000495**

This Annex lists known patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document/s Cited in Search Report		**Patent Family Member/s**	
Publication Number	**Publication Date**	**Publication Number**	**Publication Date**
US 2010/0201487 A1	12 Aug 2010	JP 2012517316 A	02 Aug 2012
		SG 164337 A1	29 Sep 2010
		US 2010201487 A1	12 Aug 2010
		US 8193938 B2	05 Jun 2012
		US 2012212330 A1	23 Aug 2012
		WO 2010092570 A1	19 Aug 2010
US 2011/0181394 A1	28 Jul 2011	None	
US 2004/0183742 A1	23 Sep 2004	AU 2005215971 A1	09 Sep 2005
		BR PI0507832 A	10 Jul 2007
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		CN 1934576 A	21 Mar 2007
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		US 7417599 B2	26 Aug 2008
		WO 2005081808 A1	09 Sep 2005
US 2008/0238677 A1	02 Oct 2008	EP 2087850 A2	12 Aug 2009
		US 2008238677 A1	02 Oct 2008
		US 7898420 B2	01 Mar 2011
		WO 2008112709 A1	18 Sep 2008
US 2013/0001305 A1	03 Jan 2013	US 8181860 B2	22 May 2012
		US 2011174877 A1	21 Jul 2011
		US 8256674 B2	04 Sep 2012
		US 2013001305 A1	03 Jan 2013
		US 8479989 B2	09 Jul 2013
		US 2013327826 A1	12 Dec 2013
		WO 2008033574 A2	20 Mar 2008

Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.