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(54) **SYSTEMS AND METHODS FOR RFID-BASED MEDICAL IMPLANT IDENTIFICATION**

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(57) **ABSTRACT**

Methods and systems for identifying medical implants. Data input is supplied by an operator including implant identification number, procedure date, and/or other patient record information. An RF module writes the data input to an RFID tag associated with and/or attached to the medical implant. Once the implant is set, but prior to closure, the RF module reads the data from the tag to insure readability. A data record including the data input and other procedure specific information may be automatically transmitted to a patient record management system in a medical facility.

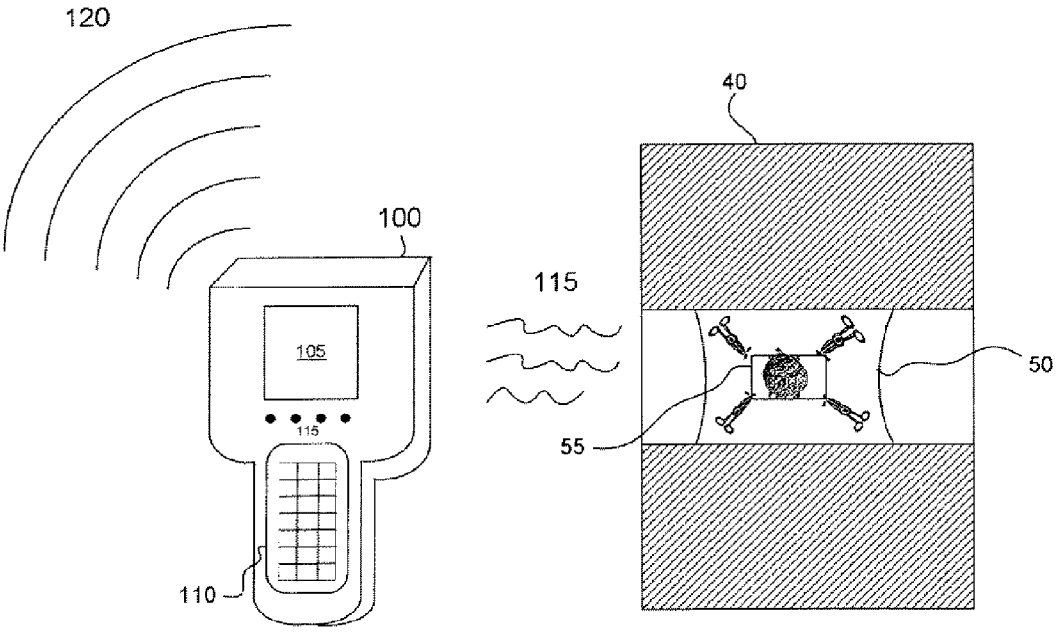


FIG. 1

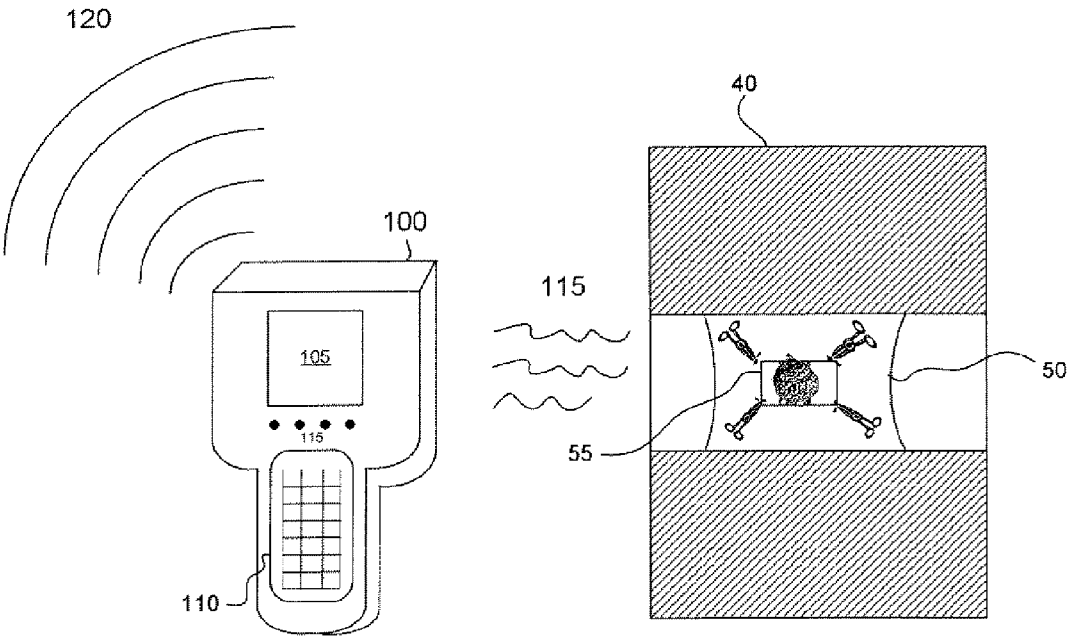


FIG. 2

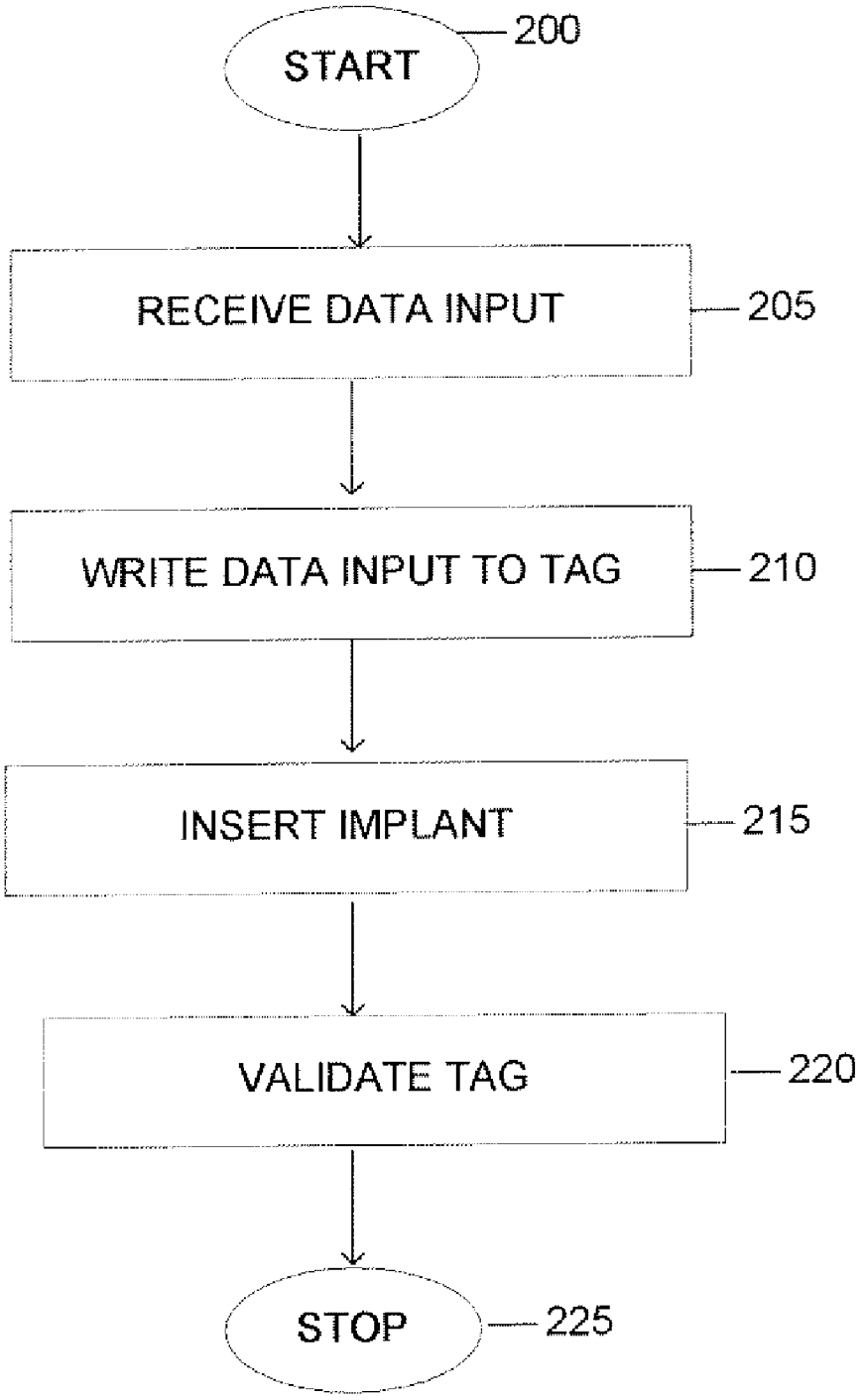
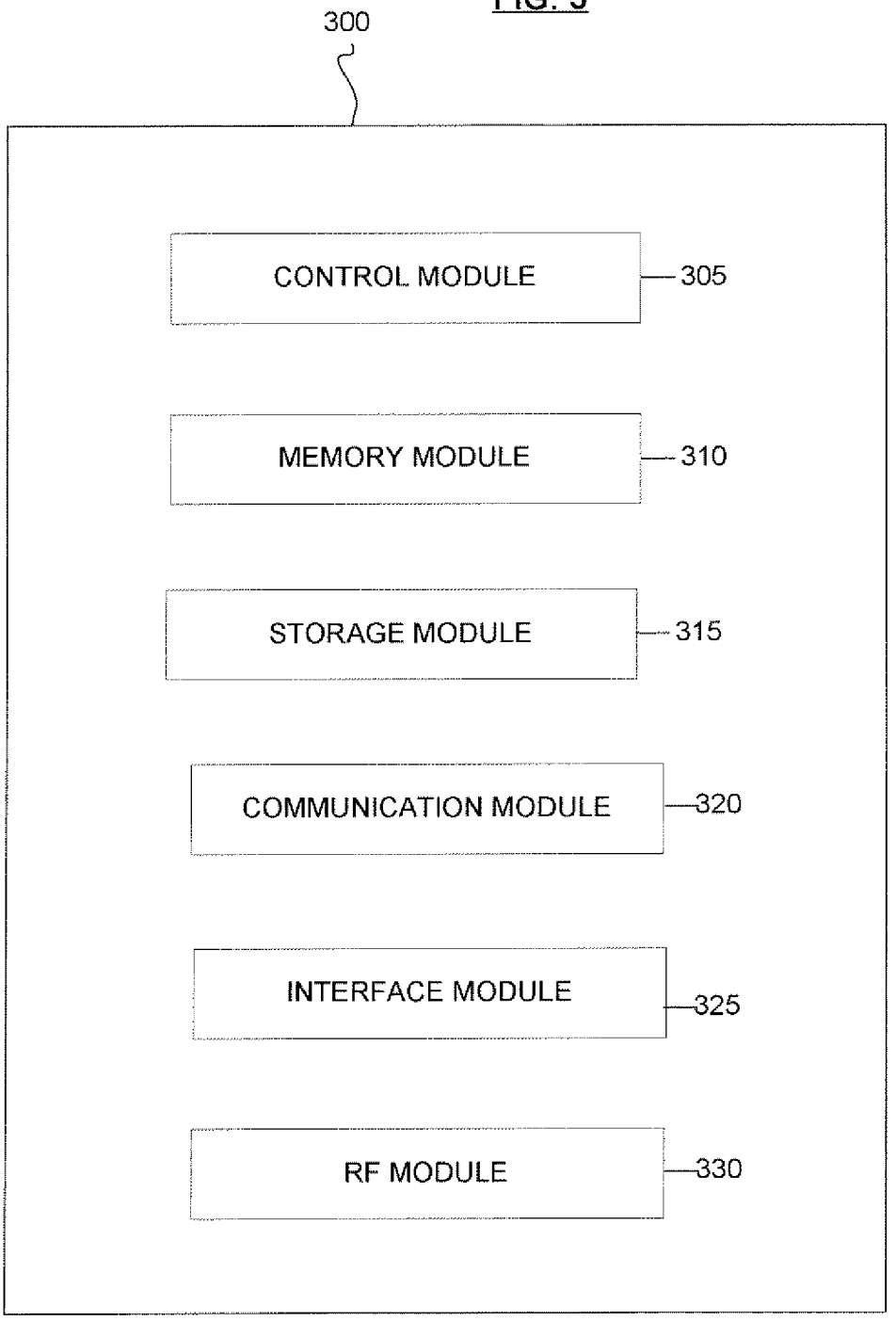

START
200
RECEIVE DATA INPUT
205
WRITE DATA INPUT TO TAG
210
INSERT IMPLANT
215
VALIDATE TAG
220
STOP
225

FIG. 3


300
CONTROL MODULE
305
MEMORY MODULE
310
STORAGE MODULE
315
COMMUNICATION MODULE
320
INTERFACE MODULE
325
RF MODULE
330

SYSTEMS AND METHODS FOR RFID-BASED MEDICAL IMPLANT IDENTIFICATION

CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation-in-part of commonly assigned U.S. patent application Ser. No. 11/108,130 filed on Apr. 18, 2005 and entitled ";Method and Apparatus for Implant Identification," the disclosure of which is hereby incorporated by reference in its entirety.

FIELD OF THE INVENTION

[0002] Embodiments of the invention generally relate to radio frequency identification systems, and more particularly to systems and methods for identification of medical implants using RFID-based identification techniques.

DESCRIPTION OF RELATED ART

[0003] Hips and knees receive continuous stress from walking, running, sporting activity, and/or injury. These joints are more commonly affected by the wearing of cartilage (degenerative arthritis) than the hand joints. Advances in medical technology have improved the prognoses of persons who suffer from degenerative joint-based ailments. Knee, hip, hand, wrist, shoulder and even spine-based medical implants may be used to provide increased motion for persons suffering from reduced and/or painful function of these joints. Joint replacement surgery, also known as arthroplasty, has become very common in modern medicine. Each year, orthopedic surgeons perform thousands of joint replacement surgeries in the U.S.—the majority of these procedures are on the large, weight bearing joints such as the hips and knees.

[0004] A wide range of metals and their alloys, polymers, ceramics and composites are used in manufacturing medical implant devices and prostheses. Most implanted devices are constructed of more than one kind of material (implants of complex composition). Metal alloys have been developed for these applications to provide improved physical and chemical properties, such as strength, durability and corrosion resistance. Also these materials need to be inert so as not offend soft body tissue or promote the growth of lesions, cysts and/or cancer.

[0005] Major classes of metals used in medical devices include stainless steels, cobalt- chromium alloys and titanium (as alloys and unalloyed). In addition, metal-on-polyethylene implants are common in hip and knee replacements, among other replacement parts. In knee or hip replacement surgery, the artificial joint is typically made out of a hard, lightweight metal such as titanium and an inert, non- corrosive material such as plastic. In the case of joint replacement in the hand, the new joint is most commonly composed of silicone rubber or the subject's own tissues such as a portion of tendon

[0006] Despite using hardened, corrosive resistant materials, wear and tear due to continual usage can affect some of those implants causing them to degrade over time. These orthopedic replacements, just like the natural orthopedic parts they replaced, are under daily and repeated stresses, developing wear and tear, thereby requiring examination on a timely basis. Therefore, because some implants have a limited and somewhat unpredictable life, there is a need to acquire information regarding the type, age, and current condition of the implant that is minimally invasive and ideally completely non-invasive to the patient.

[0007] Tracking and managing orthopedic implant replacements is an important health issue, and its effectiveness is paramount to the hundreds of thousands of individuals that currently have such replacements implanted in them, as well as the many who will receive orthopedic implants in the future. Such orthopedic replacements normally are implanted in a subject (i.e. a human being, animal or the like) as a replacement to a natural bone or in some instances, fusing bones together, thereby enabling subjects who receive those implants to function normally. The basics of prosthetic implants can be found in, for example, U.S. Pat. Nos. 5,858,020, 5,910,172, 6,013,104, and 6,749,639, the disclosures of which are incorporated herein by reference in their entirety.

[0008] Typically, each implant device contains a unique identification number, such as, for example, a manufacturer identification and/or serial number. Whenever an implant is placed, this number is recorded as a permanent record in a database. In the future this number can be referenced to track age of the implant, manufacturer for purposes of recall and adjustment, and can even be used postmortem to identify a person having the implant.

[0009] Currently there are no methods or equipment that exists today that allow one to safely and quickly ascertain the condition of orthopedic implants without the use of x-rays, or magnetic resonance imaging bulky machines that are placed in specialized rooms in hospitals. In order for orthopedic surgeons to ascertain whether such parts have undergone severe wear and tear, or are about to fail, the subject is interviewed in regard to how he/she feels, then the joint is x-rayed to ascertain the level of wear and tear. However, due to the correlation between exposure to x-rays and the development of cancers and due to the relatively high costs of non-x-ray-based diagnostic imaging systems these are less than ideal solutions. Therefore, there is a need in the art of orthopedic, and other medical implants for a more robust, less expensive, and safer procedure for collecting information about those implants.

[0010] Data carriers such as memory devices provide an alternative method for tracking and providing information about items. Memory devices permit linking large amounts of data with an object or item. Memory devices typically include a memory and logic in the form of an integrated circuit ("IC") and a mechanism for transmitting data to and/or from the device. For example, a radio frequency identification ("RFID") tag typically includes a memory for storing data, an antenna, an RF transmitter, and/or an RF receiver to transmit data, and logic for controlling the various components of the memory device. The basic structure and operation of RFID tags can be found in, for example, U.S. Pat. Nos. 4,075,632, 4,360,801, 4,390,880, 4,739,328 and 5,030,807, the disclosures of which are incorporated herein by reference in their entirety. RFID tags generally are formed on a substrate and can include, for example, analog RF circuits and digital logic and memory circuits. The RFID tags also can include a number of discrete components, such as capacitors, transistors, and diodes. The

RF transmission of data can be accomplished with modulated back scatter as well as modulation of an active RF transmitter.

[0011] Radio frequency identification (RFID) systems use an RF field generator (reader) to wirelessly extract identification information (i.e., UPC, product name, etc.) contained in RFID transponder tags that are attached to various products and objects requiring accurate identification. RFID tags are miniature electronic circuits that typically consist of a coil that acts as an antenna and a small silicon- based microprocessor with a memory, all encapsulated in a protective material. RFID tags store identification information, usually in the form of an identification number, product name and/or other information that corresponds to an object or item to which the tag is attached. This number may be used to index a database containing price, product name, manufacture and/or other information. When a transponder tag enters an RF field generated by a reader device, the circuit of the tag becomes energized causing the processor to perform a data operation, usually by emitting a signal containing the processor's stored information.

[0012] One advantage of RFID tags that makes them ideal for identifying medical implants is that they provide a long term data storage device that can hold more data than a bar code or other machine readable label. Another advantage is that because RF waves penetrate non-metallic materials, they do not require line of sight and they can read through materials such as plastic, glass and even human tissue. Also, while the tag circuits themselves are not impervious to environmental damage, they can be encased, embedded, or otherwise surrounded by hardened materials without degradation in performance. Yet another advantage of RFID tags is that their memory units can be rewritten to, that is updated to include new information wirelessly. All of these advantages may make RFID tags a particular useful identification technique for medical implants.

[0013] Though RFID tags exist, and as discussed in incorporated application **11/116,379** there use for identifying medical implants has been proposed, there is a need for identification system that incorporates RFID read and write technology with a data processing device that is portable enough to be used in a surgical environment but robust enough to interface with existing medical facility patient record management systems to enable accurate and efficient implant identification and tracking.

[0014] The description herein of various advantages and disadvantages associated with known apparatus, methods, and materials is not intended to limit the scope of the invention to their exclusion. Indeed, various embodiments of the invention may include one or more of the known apparatus, methods, and materials without suffering from their disadvantages.

SUMMARY OF THE INVENTION

[0015] Based on the foregoing, there is a need for a data processing system and a control and/or operating system for a data processing system for identifying medical implants based on radio frequency (RF) identification techniques. It would be desirable to provide systems and methods for of programming RFID tags associated with medical implants that can be used in an operating room environment to receive a data entry including information to be stored in the tag, validate the tag's readability once the implant is set, and to update a patient record management system with a data record including information regarding the implant and implant surgical procedure, that are efficient, accurate and less reliant on manual data entry.

[0016] Thus, it is a feature of various embodiments of the invention to provide systems and methods for programming an RFID transponder tag associated with a medical implant with data input information relating to the implant, the patient, the procedure and/or combinations of any of these.

[0017] Another feature of various embodiments of the invention provides systems and methods for validating data written to an RFID tag associated with a medical implant once the implant is set in the patient and at future times to recall information about the implant, patient, and or procedure to set the implant.

[0018] Yet another feature of various embodiments of the invention provides systems and method for transferring a data record regarding an implant surgical procedure to a patient record management system.

[0019] Still a further feature of various embodiments of the invention provides systems and methods for identifying medical implants upon subsequent visits to a medical practitioner that are rapid, non-invasive and relatively inexpensive to administer.

[0020] To achieve the above-noted features, and in accordance with the purposes as embodied and broadly described herein, an RFID-based medical implant identification process is provided. The medical implant identification process according to this embodiment comprises entering a first data input into a data processing system, writing the data input to a memory of an RFID tag associated with a medical implant, and validating the data in the tag after the medical implant is set.

[0021] In accordance with another exemplary embodiment, a control system for an RF- enabled data processing system for medical implant identification is provided. The control system according to this embodiment comprises a data input module for receiving a data input corresponding to a medical implant, an RF transceiver module adapted to write data from the data input to an RFID tag associated with the medical implant and to read the written data from the tag to validate that the data was written, and an output module adapted to provide a visual indication to an operator based on the validation.

[0022] In accordance with a further exemplary embodiment, a data processing system containing computer readable instructions stored therein for operating a medical implant identification system is provided. The data processing system according to this embodiment comprises instructions for receiving a data input, instructions for writing the data input to a memory of an RFID tag associated with a medical implant, and instructions for validating that the data is readable after the medical implant is set in the patient.

[0023] These and other embodiments and advantages of the present 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

[0024] Purposes and advantages of the embodiments will be apparent to those of ordinary skill in the art from the following detailed description in conjunction with the appended drawings in which like reference characters are used to indicate like elements, and in which:

[0025] **FIG. 1** is a perspective view of system for identifying medical implants in a surgical environment in accordance with at least one embodiment of the invention;

[0026] **FIG. 2** is a flow chart detailing the steps of a method for operating a control system for a medical implant identification apparatus and system in accordance with at least one embodiment of the invention; and

[0027] **FIG. 3** is a block diagram illustrating modules of a control system for a medical implant identification apparatus and system in accordance with at least one embodiment of the invention.

DETAILED DESCRIPTION OF THE DISCLOSURE

[0028] The following description is intended to convey a thorough understanding of the embodiments described by providing a number of specific embodiments and details involving systems and methods of programming and tracking medical implants using radio frequency identification techniques. It is understood, however, that the present invention is not limited to these specific embodiments and details, which are exemplary only. It is further understood that one possessing ordinary skill in the art, in light of known systems and methods, would appreciate the use of the invention for its intended purposes and benefits in any number of alternative embodiments, depending upon specific design and other needs.

[0029] As used herein, the expressions "RFID tag" and "RFID transponder tag" will refer to any active or passive type of electronic data storage device, read-only or read and write, that is wirelessly activated in the presence of a radio frequency (RF) field, including any currently available inductively coupled RFID tags, capacitively coupled RFID tags and even future RF-type tags not yet available. This includes tags operating in the 125 kHz, 13.56 MHz, 868-927 MHz, 2.45 GHz and 5.8 GHz frequency bands as well as other suitable frequency bands. Also, the tag may be a silicon-type IC tag, a printed tag printed with a conductive ink-based printing process or a tag formed by other suitable means.

[0030] As used herein, the terms "write" and "program" in the context of storing data to a memory structure contained in an RFID transponder tag circuit will be used synonymously to refer to the process of transmitting a radio frequency signal that has been modulated to contain identification information to be stored in the memory structure. The tag circuit includes an antenna, processor and memory structure. The tag circuit is able to receive the signal, recover the encoded information and store that information in the non-volatile memory structure so that it can be wirelessly accessed by RFID reader devices.

[0031] Through out this description, the terms "verify" or "validate" in the context of confirming that data has been successfully written to an RFID transponder tag will refer to using a RF module to create an RF field to "read" information from the tag and to compare the read information to a data input that was written to the tag. "Reading" in the context of reading data from an RFID tag will simply refer to creating an RF field to read information from a tag. This information may or may not be used to index a database containing more detailed information associated with the read information.

[0032] As used herein, the phrase "medical implant" will be given broad scope including implants such as artificial joints (i.e., hips, knees, hand portions), spinal implants, active medical device implants such as cardiac defibrillators, cardiac pacemakers, gastrointestinal pace makers, arterial stints, as well as other passive or active implantable medical devices.

[0033] As used herein, the expression "patient record management system" will be given broad interpretation to refer to any conventional or future computer-based record management system utilized in medical facilities to keep track of current and past patient information including personal information, health information, insurance information, procedure information and other necessary information.

[0034] Referring now to **FIG. 1**, a system for identifying medical implants in a surgical environment in accordance with at least one embodiment of the invention is depicted. In the example of **FIG. 1**, the system comprises a hand held data processing apparatus **100** adapted for use in a surgical environment such as an operating room. The apparatus **100** itself may comprise an interface including a display **105** and a keyboard **110**. The apparatus **100** may also comprise various other interface components instead of or in addition to those depicted in **FIG. 1** including, but not limited to, a biometric input device, voice input device, mouse, stylus, bar code scanner, printer, etc. In various embodiments, the apparatus **100** will also comprise an RF module adapted to generate both read and write RF signals. An operating room scene is depicted in the Figure including a patient **50** and corresponding implant surgery site **55**. A sheet or other suitable cover **40** is used to highlight the surgery site **55**.

[0035] In various embodiments, an operator inputs information relating to a medical implant into the apparatus **100** using the interface **105**, **110**. As will be discussed in greater detail herein, the apparatus **100** may include a bar code scanner for scanning a bar code label as an input or the device may receive manual input via the keyboard **110** or display. Alternatively, a wireless connection **120** to an external database may be used to gather additional information relating to the medical implant. In various embodiments, an RF module in the apparatus **100** will transmit an RF signal **115** to an RFID transponder tag associated with the medical implant. The RFID transponder tag may be contained in the implant, attached to the implant or otherwise physically associated with the implant In various embodiments, the RF module of the apparatus **100** will also perform a read operation by reading the information written to the tag. In various embodiments, this may be performed prior to setting the implant in the patient's body to insure that the tag is not defective. However, in various embodiments, because RF waves can penetrate soft tissue, this may also be performed after the implant is set but prior to surgical site closure to insure that the tag remains readable from inside the patient's body.

[0036] In various embodiments, as will be discussed in greater detail herein, the apparatus may create a data record following validation of the data stored in the tag after setting the implant and transmit the data record wirelessly over a wireless network **120** in a medical facility so that a database or other patient record management system can retain the data record.

[0037] It should be appreciated that although the apparatus **100** shown in **FIG. 1** is a unitary, hand-held apparatus, the apparatus **100** may, in various embodiments, he part of a distributed system or non-unitary system such as a desktop terminal with a wired or wireless bar code reader and a wired or wireless RFID reader/writer, both of which are in communication with the desktop terminal. The various embodiments of the invention are not dependent upon a particular configuration, but rather use an integrated control system for identifying medical implants. In various embodiments, the apparatus **100** may write the information input to the apparatus directly to the RFID transponder tag associated with the medical implant. In various embodiments, the apparatus **100** may use the input information to index a table and/or database containing more detailed information associated with input information and, write this detailed information as well as the input information to the RFID tag associated with the medical implant. The detailed information may reside in the apparatus **100** or in an external database that is queried by the apparatus **100** using wireless signals **120** broadcast over a wireless network as will he discussed in greater detail herein. It should be appreciated that a wired network connection may also be used if the possibility of interference to medical equipment precludes use of wireless networks. If the apparatus **100** is stationary device such as stationary bench or work station, the user may move a transponder tag and/or the implant transponder tag assembly into an RF field area of the apparatus to write the information to the tag.

[0038] The apparatus may also have an LED panel **115** comprising one or more LEDs **115** for providing a visual indication to an operator of the success or failure of RF-based read and write operations performed with the apparatus **115**. In addition, information relating to the success or failure may be output to the display **105** and/or to an integral speaker.

[0039] Referring now to **FIG. 2**, a flow chart detailing the steps of a method for operating a control system for a medical implant identification apparatus and system in accordance with at least one embodiment of the invention is illustrated. The method begins in step **200** and proceeds to step **205** where a data input is received by the system. In various embodiments, this may comprise receiving a data input supplied by an operator keying in an identification number or other unique indicia associated with a medical implant. In various embodiments, this may comprise scanning a bar code label attached to a medical implant or a storage/shipping container for the medical implant. In various embodiments, this may comprise entering a patient name, ID or other code that can be used to index a database containing information corresponding to the medical implant. In various embodiments, the data input may include a combination of information obtained through direct operator input and through querying a database such as, for example, a patient record management system. In various information all the information comprising the data input is temporarily stored.

[0040] Next, in step **210**, the data input is written to an RFID transponder tag associated with or attached to the medical implant. In various embodiments, the medical implant may be manufactured with an integral RFID tag. In various other embodiments, a tag may be attached to an implant after the implant's manufacturing process. In various embodiments, after writing the data input to the RFID tag, a read operation is automatically performed to confirm that the data was successfully written and that the tag is not defective.

[0041] Operation of the method then proceeds to step **215** where the implant is inserted into the patient. This step may involve a variety of different sub-steps not relevant to the particular inventive methods of the systems and method of the present invention depending upon what type of medical implant is being implanted into the patient. After the implant has been set, in step **220**, the tag is validated. In various embodiments, this will comprise holding a portable reader device over the portion of the patient's body where the implant is set and generating a read signal with the device. The read signal will energize the tag's circuit and cause it to transmit a signal including the information stored in the tag to the reader device. In various embodiments, validation will include comparing the information read from the tag to the data input that was written to the tag in step **210**. If the read data and data input are the same, the tag will be presumed validated. Otherwise, an error message may be output to alert the operator that the tag was not validated. As discussed above, in various embodiments, if in the validation step **220**, the tag is validated, a signal may be sent to a database such as a patient record management system including a record of the implant procedure, the record comprising at least part of the data input written to the tag. The record may also comprise information relating to the procedure such as, the surgeon, the surgical team, the date, the time, etc. Operation of the method ceases in step **225**.

[0042] After performing the steps of the method of **FIG. 2**, when a patient returns to a medical facility for subsequent visits, information regarding his/her medical implant as well as the procedure that implanted it may be instantly obtained by scanning over a portion of the patient's body containing the implant to read data from the RFID tag associated with the implant. In this manner, a physician may be able to obtain information about the patient, about the age of the implant, and even historical information such as number and date of checkups on the implants since it was surgically implanted without having to expose the patient to x-rays or other diagnostic imaging and without having to manually retrieve database information. In various embodiments, a complete medical record may be retrieved from the tag. In various other embodiments, only an identification number or one or more other data fields may be retrieved from the tag. The identification number and/or the one or more other data fields may then be used to index a database containing detailed information regarding the patient and the transactional history of the implant. This system may also be useful for alerting the patient for ongoing information regarding his/her implant. For example, if after an implant is set in a patient, the manufacturer discovers that the implant or a component thereof may not be functioning properly, the

manufacturer may issue a warning or even a recall. If the warning and/or recall information is input into the implant identification system, when the patient returns to his/her physician for a checkup on the implant, wirelessly scanning the implant will automatically alert the physician that the implant of this patient has a warning or recall associated with it so that the doctor can respond appropriately. Another advantage is that in some cases, such as emergency or trauma case, a patient may be incapable of alerting medical professionals of the presence of a particular medical implant. Therefore, by using the systems and methods of the present invention, a medical professional may be able to run a handheld scanner over patient's body prior to performing any treatment on that patient. If any RF-enabled medical implants are present, the professional will be alerted by the device and will he/she will be able to design a course of treatment that is not incompatible with the presence of the medical implant.

[0043] Referring now to **FIG. 3**, a block diagram illustrating modules of a control system for a medical implant identification apparatus and system in accordance with at least one embodiment of the invention is depicted. The system **300** comprises a plurality of modules including a control module **305**, a memory module **310**, a storage module **315**, a communication module **320**, an interface module **325** and an RF module **330**. In accordance with the various embodiments of the invention, each module may comprise a separate circuit, routine or application, may be based in hardware, in software, or both, may be firmware, may be discrete components of a modular system or merely subroutines/subcomponents of the same system, such as a single computer program stored in a memory structure of a device, such as a portable RF-based medical implant identification apparatus. The control module **305** may in various embodiments be a microprocessor, a digital signal processor (DSP), control system, virtual instrument, program kernel or other suitable command issuing structure. The memory module **310** may comprise a volatile memory structure such as random access memory. The storage module **315** may comprise a non-volatile memory such as flash memory, hard disk, CDRW, DVRW, holographic storage or other storage media. The communication module may comprise an Ethernet-based local area network (LAN) card, a wireless Ethernet card, a modem, Bluetooth transmitter, IR transmitter or other suitable two-communication device.

[0044] In various embodiments, an operator will interact with the system **300** through the user interface module **325**. As discussed herein, this module **325** may include a keyboard, mouse, stylus, biometric sensor, bar code scanner, display screen or other interface that allows a user to interact with the system such as to input information, issue commands, power the device on and off, perform file management, upgrade software and database information, monitor output, receive feedback and perform other administrative and non-administrative tasks.

[0045] In various embodiments when a user issues a command to commence a medical implant identification operation through the user interface module **325**, the control module **305** will cause the interface module **325** to prompt the user for a data input. As discussed herein the data input may be an identification number of the implant. Either automatically or based on an operator indication through the interface module **325**, the control module may activate a bar code scanner connected to the interface module **325** so that the operator can use the scanner to provide the data input. Also, the control module **305** may, in various embodiments, use the data input to interrogate a database in the storage module **315** to index a database of patient information. Alternatively, the control module **305** may activate the communications module **320** to access and interrogate a remote database, such as by issuing a command signal through a wireless transceiver, the command signal containing the data input. The data input, as well as any additional information received from either the storage module **315** and/or a remote database may be at least temporarily stored by the control module **305** in the memory module **310**.

[0046] Once the data input has been received and stored in the memory module **310**, the control module may prompt the user through the interface module **325** to perform an RF write operation to program the data input to an RFID transponder tag attached to or otherwise associated with the medical implant that corresponds to the data input. When the user responds to this prompt by selecting a write operation through the interface module **325**, the control module **305** may activate the RF module **330** to transmit a signal including the data input by way of an RF- based signal that is transmitted in an area containing the implant and/or the RFID tag. In various embodiments, after the signal has been transmitted, the control module **305** may activate the RF module **330** to perform a read operation by transmitting an RF-based signal to the tag, causing it to become energized and to transmit its stored information. The control module **305** may compare the information read from the RF module **330** during the read operation with the data input stored in the memory module **310**. If these two pieces of information match, the control module **305** may activate the interface module **325** to provide a positive indication to the user. Otherwise, the control module **305** may activate the interface module **325** to provide a negative indication to the user. In various embodiments, the control module **305**, after verifying a successful read operation may cause the communication module to transmit a data record to a remote database such as a patient record management system including a record of the data input and optionally, information relating to the procedure including a surgeon, surgical team, time, date, location, patient information, and other procedure specific information. Alternatively, the control module may store the record information in the storage module **315** until the operator issues a command through the interface module to upload the information to a remote database.

[0047] Subsequent access to the information stored in the implant's transponder tag may be facilitated by the operator selecting a scan patient option from a menu displayed by the interface module **325**. Upon selecting such an option, the control module **305** will activate the RF module **330** to generate an RF read signal and may also activate the interface module **325** to output an instruction to the operator to pass the device over the patient's body. Information obtained by the RF module **330** may be stored in the memory module **310**. Depending upon the extent of this information, the control module **305** may retrieve additional information from the storage module **315** or an external database using the communication module **320** using the read information as an index to obtain additional information. Or if, sufficient information is contained in the tag itself, the control module may automatically activate the

interface module **325** to display the stored information and/or any additional information. The control module may also cause the interface module **325** to prompt the operator to print a paper record on an attached output device that is part of the interface module **325** or may automatically activate such an output device. The control module may store any additional information provided in the subsequent record in the storage module **315**, such as, for example, doctor's notes. Alternatively, or in addition, the control module **305** may prompt the user through the interface module **325** to place the device back over the implant area so that the control module can activate the RF module **330** to transmit a write signal to the implant's transponder tag to write the additional information. As with the process of **FIG. 2**, the control module **305** may automatically perform a validation operation after updating the implant with the additional information. Alternatively, the control module **305** may prompt the user through the interface module **325** to perform such an operation to validate that the additional information was successfully written to the tag. The control module **305** may activate the interface module **325** to output a message regarding the success of this operation.

[**0048**] The embodiments of the present inventions are not to be limited in scope by the specific embodiments described herein. For example, although many of the embodiments disclosed herein have been described with reference to control and/or operating systems for systems and apparatuses for identifying medical implants using RF identification techniques, the principles herein are equally applicable to other aspects radio frequency-based identification indeed, various modifications of the embodiments of the present inventions, in addition to those described herein, will be apparent to those of ordinary skill in the art from the foregoing description and accompanying drawings. Thus, such modifications are intended to fall within the scope of the following appended claims. Further, although some of the embodiments of the present invention have been described herein in the context of a particular implementation in a particular environment for a particular purpose, those of ordinary skill in the art will recognize that its usefulness is not limited thereto and that the embodiments of the present inventions can be beneficially implemented in any number of environments for any number of purposes. Accordingly, the claims set forth below should be construed in view of the full breath and spirit of the embodiments of the present inventions as disclosed herein.

What is claimed:

1. An RFID-based medical implant identification process comprising:

entering a first data input into a data processing system;

writing the first data input to a memory of an RFID tag associated with a medical implant; and

validating the data input stored in the tag after the medical implant is set.

2. The process according to claim 1, wherein entering a first data input comprises manually entering an identification number of a medical implant into the data processing system.

3. The process according to claim 1, wherein entering a first data input comprises scanning a bar code label associated with a medical implant with a bar code reader in communication with the data processing system.

4. The process according to claim 1, wherein entering a first data input comprises loading a patient record from a patient record management system into the data processing system.

5. The process according to claim 1, wherein writing the data to a memory of an RFID tag comprises transmitting an RF signal containing the data with an RF writer in communication with the data processing system, energizing a circuit in the tag with the signal and storing the information in a memory structure connected to the circuit.

6. The process according to claim 1, wherein validating the data input stored in the tag comprises performing an RFID read operation of the RFID tag associated with the medical implant while the implant is in the patient's body but prior to closure.

7. The process according to claim 1, wherein the data processing system comprises an apparatus selected from the group consisting of a hand held RFID reader/writer, a hand held data processing system, a desktop data processing system, and combinations thereof.

8. The process according to claim 1, further comprising, after the step of validating, writing an electronic data record to a database.

9. The process according to claim 8, wherein writing an electronic data record to a database comprises writing a record including at least a procedure date and an implant identification number to a patient record management system.

10. The process according to claim 9, wherein writing a record including at least a procedure date and an implant identification number to a patient record management system comprises transmitting a signal from the data processing system to the patient record management system over a wireless network in a medical facility.

11. A control system for an RF-enabled data processing system for medical implant identification, the control system comprising:

a data input module for receiving a data input corresponding to a medical implant;

an RF transceiver module adapted to write data from the data input to an RFID tag associated with the medical implant and to read the written data from the tag to validate that the data was written; and

an output module adapted to provide a visual indication to an operator based on the validation.

12. The control system according to claim I **1**, wherein the data input is an identification number of the medical implant.

13. The control system according to claim 11, wherein the data input is a patient medical record from a patient record management system.

14. The control system according to claim 11, wherein the data input module comprises a device selected from the group consisting of a key hoard, a touch screen display, a bar code scanner, and mixtures thereof.

15. The control system according to claim 11, wherein the RF transceiver module is adapted read the written data from the tag after the medical implant is surgically placed in the patient.

16. The control system according to claim 11, further comprising a communication module adapted to access a remote patient record management system to obtain information corresponding to a patient associated with a medical implant.

17. The control system according to claim 16, wherein the communication module is adapted to write a record of the medical implant to the patient record management system after validating that data was written to the tag.

18. The control system according to claim 15, wherein the RF transceiver module is further adapted to detect any RFID-tagged surgical items remaining in a patient's body cavity as a result of placing the implant but prior to closure.

19. A data processing system containing computer readable instructions stored therein for operating a medical implant identification system, the instructions comprising:

instructions for receiving a data input;

instructions for writing the data input to a memory of an RFID tag associated with a medical implant; and

instructions for validating that the data is readable after the medical implant is set in the patient.

20. The data processing system according to claim 19, wherein the instructions for receiving a data input comprise instructions for receiving a keyboard input.

21. The data processing system according to claim 19, wherein the instructions for receiving a data input comprise instructions for receiving a data input from a bar code scanner.

22. The data processing system according to claim 19, wherein the instructions for receiving a data input comprise instructions for accessing a patient record management system and retrieving information form the patient record management system, said information comprising at least part of the data input.

23. The data processing system according to claim 19, wherein the instructions for writing the data input to a memory of an RFID tag associated with a medical implant comprise instructions for transmitting an RF write signal including the data input to the tag.

24. The data processing system according to claim 19, wherein the instructions for validating that the data is readable comprise instructions for transmitting an RF read signal to the tag, obtaining the stored information from the tag in response to the RF read signal, and comparing this information to the data input.

25. The data processing system according to claim 24, further comprising instructions for activating an indication means based on comparing the read information to the data input.

26. The data processing system according to claim 19, further comprising instructions for writing a record of the medical implant and data input to a database.

27. The data processing system according to claim 26, wherein the instructions for writing a record of the medical implant and data input to a database comprise instructions for wirelessly transmitting the record to a patient record management system over a wireless network in a medical facility.

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