(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) **EP 2 465 008 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
17.06.2020 Bulletin 2020/25

(21) Application number: **10808849.3**

(22) Date of filing: **13.08.2010**

(51) Int Cl.:
G03B 17/02 *(2006.01)* ***A61B 1/00*** *(2006.01)*

(86) International application number:
PCT/US2010/045533

(87) International publication number:
WO 2011/020068 (17.02.2011 Gazette 2011/07)

(54) SYSTEM AND METHOD FOR PROVIDING A SINGLE USE IMAGING DEVICE FOR STERILE ENVIRONMENTS

SYSTEM UND VERFAHREN ZUR BEREITSTELLUNG EINER EINWEG-BILDGEBUNGSVORRICHTUNG FÜR STERILE UMGEBUNGEN

SYSTÈME ET PROCÉDÉ ASSOCIÉS À UN DISPOSITIF D'IMAGERIE À USAGE UNIQUE POUR ENVIRONNEMENTS STÉRILES

(84) Designated Contracting States:
AL AT BE BG CH CY CZ DE DK EE ES FI FR GB GR HR HU IE IS IT LI LT LU LV MC MK MT NL NO PL PT RO SE SI SK SM TR

(30) Priority: **13.08.2009 US 541067**

(43) Date of publication of application:
20.06.2012 Bulletin 2012/25

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(56) References cited:
US-A- 5 589 874
US-A- 5 830 121
US-A1- 2001 041 825
US-A1- 2005 131 279
US-A1- 2005 261 551
US-A1- 2006 293 563
US-A1- 2007 030 345
US-A1- 2008 076 967

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Description

BACKGROUND

[0001] The invention relates generally to imaging devices used during surgical procedures to visualize a surgical area, and more particularly, but not necessarily entirely, to an imaging device for use with and communicating with a control unit and a system, method and process of communicating between an imaging device and a control unit.

[0002] Endoscopic surgery is experiencing rapid growth in the medical field. Endoscopy is a minimally invasive surgical procedure that is used to analyze the interior of a body cavity or interior surfaces of an organ by inserting a tubular member into the body cavity through a minor or minimal incision. A conventional endoscope is generally an instrument with a light source and an image sensor or device for visualizing the interior a body cavity. A wide range of applications have been developed for the general field of endoscopes including, but not necessarily limited to: arthroscope, angioscope, bronchoscope, choledochoscope, colonoscope, cytoscope, duodenoscope, enteroscope, esophagogastroduodenoscope (gastroscope), laparoscope, laryngoscope, nasopharyngo-neproscope, sigmoidoscope, thoracoscope, and utererscope (hereinafter referred to generally as "endoscope"). The advantages of endoscopy include smaller surgical incisions and less soft tissue damage. As a result, there is significantly less discomfort and pain for the patient as well as a decrease in recovery time.

[0003] The advantages of minimally invasive surgery performed with the help of an endoscope are well known and understood in the medical field. As a result, there have been a growing number of devices for use with endoscopes for delivering, for example, diagnostic, monitoring, treatment, operating instruments, tools, and accessories (collectively, "tools") into the observation field and working space of the physician's endoscope.

[0004] As part of forming an image of the surgical site, the endoscope includes a light source and an image sensor. Endoscopes may also incorporate more than one tubular member for observation or operation within the body, such as a working channel for passing diagnostic, monitoring, treatment, or surgical tools through the endoscope. Endoscopes include glass lenses and an adjustable ocular or eye piece, a lateral connection for a light conductor, an adaptor that allows focusing, and a camera head. This configuration is also called a video endoscope.

[0005] It is axiomatic that strict sterilization of the operating room and surgical equipment is required during any surgery. The strict hygiene and sterilization conditions required in a "surgical theater," i.e., operating or treatment room, necessitate the highest possible sterility of all medical devices and equipment. Part of that sterilization process is the need to sterilize anything that comes in contact with the patient, including the endoscope and its attachments and components. In recent years there has been a trend of providing a single use endoscope and components as a packaged, sterilized product, similar to a package containing a surgical implant, such as a knee or hip implant. In terms of endoscopy, instead of using endoscopes that have been reconditioned for each new surgery through traditional sterilization procedures, it means using a single use endoscope and components that are delivered to the hospital in a sterilized package. Due to this trend, it has become increasingly difficult to ensure that each endoscope and its components are properly cared for, used and sterilized for single use and not simply re-sterilized using traditional sterilization procedures.

[0006] Traditional drawbacks or problems of video endoscopes include a lack of image quality, the need for sterilization and high manufacturing cost. To address these and potentially other problems, the invention utilizes a unique system and a unique non-invasive method for providing and controlling single use imaging devices.

SUMMARY OF THE INVENTION

[0007] The invention is a system as defined by claim 1 and a non-invasive method as defined by claim 9.

[0008] An embodiment may comprise a single use camera used for general purpose surgical procedures including, but not limited to: arthroscopic, laparoscopic, gynecologic, and urologic. An embodiment may comprise an imaging device that is a sterile and designed to ensure single use. An embodiment may be an imaging device that comprises a single imaging sensor, either CCD (charge coupled device) or CMOS (complementary metal oxide semiconductor), encased in a molded plastic housing. The imaging device may further comprise the means to be attached to an optical coupling device, using C-Mount and CS-Mount threads or another proprietary or unique connection method. It is within the disclosure to include integrated optical systems, such that no specific coupling means is required. The imaging device may further comprise a cable or wireless method to transmit data to and from a camera control unit.

[0009] In an embodiment, information will be recorded in the memory of the imaging device each time it is used in a procedure or quality control (QC) checked at the manufacturer. This information may be used to evaluate usage time, expiration date, etc. An embodiment may comprise features to ensure that the imaging device is only used once and that the imaging device is safe for use. In an embodiment the imaging device may be fully covered in plastic with a neutral sensor heat sink exposed to ensure the camera head meets cardiac floating (CF) and body floating (BF) ISO standards. An embodiment may comprise an imaging device that may be stamped with the current time when plugged into a console in the field after a quality control check has been performed. This time may be used as a baseline for usage. If the

imaging device is powered off for a predetermined period of time, which may be equivalent to a sterilization cycle, then the imaging device will not function. The imaging device may display an onscreen message telling the user that the camera has already been used and will not allow current operation. These features ensure the imaging device will not be used more than one time per sterilization cycle and further ensures that proper sterilization is performed by the manufacturer or other authorized source. This function is to protect the patient and the doctor from an invalid or unsafe use.

[0010] In an embodiment of an active imaging device may be attached to a control unit. The control unit will check the last sterilization date and ensure that the imaging device is no older than a predetermined safety date. If the imaging device is older than the required date, an onscreen warning will tell the user that the imaging device has expired and is unsafe for use. These features will protect the patient and the doctor from using a non-sterile imaging device.

[0011] In an embodiment a security code or some other means of identifying, and validating for use, an imaging device by a control unit maybe provided in order to verify that the imaging device is authorized for use. A validating security code or procedure of validation may be distributed to control units from a central database over the internet, by direct transfer from portable storage device such as USB device containing memory, another computer, or other storage device.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] The features and advantages of the disclosure will become apparent from a consideration of the subsequent detailed description presented in connection with the accompanying drawings in which Figure 17 illustrates the method and the processor steps performed by the system of the invention. All other figures show embodiments not forming part of the invention:

FIG. 1 is an illustration of an embodiment of the features of the disclosure and made in accordance with the teachings and principles of the disclosure;
FIG. 2 is an illustration of an embodiment of an imaging system made in accordance with the teachings and principles of the disclosure;
FIG. 3 is an illustration of an imaging system having wireless features made in accordance with the teachings and principles of the disclosure;
FIG. 4 is an illustration of an embodiment of a control unit disconnected from an imaging device, but illustrated as remaining connected to complementary apparatuses, and made in accordance with the teachings and principles of the disclosure;
FIG. 5 is an illustration of an embodiment of a control unit display made in accordance with the teachings and principles of the disclosure;
FIG. 6 is an illustration of an embodiment of a retractable display of a control unit in a retracted or closed position and made in accordance with the teachings and principles of the disclosure;
FIG. 6A is an illustration of an embodiment of a retractable display of a control unit in an open position and made in accordance with the teachings and principles of the disclosure;
FIG. 7 is a cross-sectional view of an embodiment of an imaging device head made in accordance with the teachings and principles of the disclosure;
FIG. 8 is a cross-sectional view of an embodiment of an imaging device head made in accordance with the teachings and principles of the disclosure;
FIG. 9 is a cross-sectional view of an embodiment of an imaging device head made in accordance with the teachings and principles of the disclosure;
FIG. 10 is a cross-sectional view of an embodiment of an imaging device head having a ball joint made in accordance with the teachings and principles of the disclosure;
FIG. 11 is a cross-sectional view of an embodiment of an imaging device head made in accordance with the teachings and principles of the disclosure;
FIG. 12 is a layout view of an embodiment of an imaging system made in accordance with the teachings and principles of the disclosure;
FIG. 13 is a schematic diagram of a memory of an embodiment of an imaging system made in accordance with the teachings and principles of the disclosure;
FIG. 14 illustrates an embodiment of a method in accordance with the teachings and principles of the disclosure;
FIG. 15 illustrates an embodiment of a method in accordance with the teachings and principles of the disclosure;
FIG. 16 illustrates an embodiment of a method in accordance with the teachings and principles of the disclosure;
FIG. 17 illustrates an embodiment of a method of use according to the teachings and principles of the invention;
FIG. 18 illustrates an embodiment of a method of reclaiming an imaging device after use according to the teachings and principles of the disclosure; and
FIG. 19 illustrates an embodiment of a method of making an imaging device for use in a sterilized environment according to the teachings and principles of the disclosure.
FIG. 20 illustrates an embodiment of a method for updating an imaging device system.
FIG. 21 illustrates an embodiment of a system for providing updates to an imaging system.

DETAILED DESCRIPTION

[0013] For the purposes of promoting an understanding of the principles in accordance with the disclosure,

reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the disclosure is thereby intended. Any alterations and further modifications of the inventive features illustrated herein, and any additional applications of the principles of the disclosure as illustrated herein, which would normally occur to one skilled in the relevant art and having possession of this disclosure, are to be considered within the scope of the appended claims.

[0014] Before the devices, systems, methods and processes for providing and reclaiming single use imaging devices are disclosed and described, it is to be understood that this disclosure is not limited to the particular embodiments, configurations, or process steps disclosed herein as such embodiments, configurations, or process steps may vary somewhat. It is also to be understood that the terminology employed herein is used for the purpose of describing particular embodiments only and is not intended to be limiting since the scope of the disclosure will be limited only by the appended claims, if any, and equivalents thereof.

[0015] In describing and claiming the subject matter of the disclosure, the following terminology will be used in accordance with the definitions set out below.

[0016] It must be noted that, as used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the context clearly dictates otherwise.

[0017] As used herein, the terms "comprising," "including," "containing," "characterized by," and grammatical equivalents thereof are inclusive or open-ended terms that do not exclude additional, unrecited elements or method steps.

[0018] As used herein, the phrase "consisting of' and grammatical equivalents thereof exclude any element, step, or ingredient not specified in the claim.

[0019] As used herein, the phrase "consisting essentially of' and grammatical equivalents thereof limit the scope of a claim to the specified materials or steps and those that do not materially affect the basic and novel characteristic or characteristics of the claimed disclosure.

[0020] With reference primarily to FIG. 1, an embodiment of the features of the disclosure will be discussed generally. FIG. 1 illustrates a system 100 for providing a digital image using a remote imaging device 110 that may be tethered electronically and physically to a control unit 120. The control unit 120 may be configured to exchange data with imaging device 110 in order to provide single use functionality and safety in a sterile environment, such as an operating room, a doctor's office or dental office. Additionally, the control unit 120 may be electrically connected to a computer 130 or external monitor 140 for increased functionality.

[0021] Referring now to FIG. 2 where the imaging system 100 will be discussed in greater detail. As is illustrated in FIG. 2, the imaging device 110 can be connected or disconnected from the control unit 120 by way of an electronic connector 114 on the imaging device 110 that is configured to electronically and physically interact with a corresponding electronic connector 126 on the control unit 120. The ability to disconnect the imaging device 110 from the control unit 120 provides the ability to easily replace a used imaging device 110 for a sterilized, renewed imaging device 110. The imaging device 110 may have a head portion 112 generally positioned remotely from the electronic connector 114, thereby allowing greater mobility of the head portion 112 during use.

[0022] Also illustrated in FIG. 2 is an embodiment of the control unit 120 having an electronic connector 126 therein for receiving the corresponding electronic connector 114 of the imaging device 110. The control unit 120 may also have a display 128 for conveying information during a procedure to an operator or user. The display 128 may also comprise interactive functionality allowing an operator to enter commands or change what information is being displayed. Such functionality may be provided by a touch screen system as is commonly known. The control unit may also have video inputs 122 and video outputs 124 for transferring image data to other apparatuses for increased functionality. As illustrated in FIG. 1, common apparatuses maybe a computer 130 or an external monitor 140.

[0023] Referring now to FIG. 3 an imaging system 300 will be discussed having wireless capability and features. As is illustrated in FIG. 3, the imaging device 310 may communicate with a control unit 320 by way of wireless transmissions such as Wifi, infrared, bluetooth etc. Other forms of wireless non-tethered connectivity may also be used for providing communication between the imaging device 310 and control unit 320, including but not limited to, radio frequency from any available spectrum, infrared of all configurations, ultrasonic, and optical. The imaging device 310 may comprise a head portion 312 that houses an imaging sensor, memory and associated circuitry, which will be discussed in greater detail below. The head portion 312 may further comprise a wireless transceiver 314 for communicating with a corresponding wireless transceiver 322 housed in the control unit 320. The ability to separate the head portion 312 from the control unit 320 via wireless transmissions may provide for the easy replacement of used imaging devices for sterilized and renewed imaging devices. In other words, the wireless communication may be enabled by an electronic communication circuit that is a wireless communication transceiver configured to communicate wirelessly with a corresponding transceiver on said control unit using any of the above noted wireless technologies. The wireless functionality also allows for greater mobility of the head portion 312 during use. It will be appreciated that the wireless features and functionality may be incorporated into any of the embodiments disclosed herein or embodiments that fall within the scope of this disclosure.

[0024] Also illustrated in FIG. 3 is an embodiment of

the control unit 320 having wireless capabilities and features. A transceiver 322 may be provided in or as part of the control unit 320 for receiving and transmitting wireless data to the imaging device 310. The control unit 320 may also have a display 328 for conveying information during a procedure to an operator or user. The display 328 may also comprise interactive functionality allowing an operator to enter commands or change what information is being displayed. Such functionality may be provided by a touch screen system as is commonly known. The control unit 320 may also have video inputs 321 and video outputs 324 for transferring image data to other apparatuses for increased functionality. As illustrated in FIG. 1 common apparatuses may be a computer 130 or an external monitor 140. It is within the scope of this disclosure to include an imaging system comprising both wired and wireless communication capabilities.

[0025] Illustrated in FIG. 4 is an embodiment of the control unit 420 disconnected from an imaging device that is illustrated as being connected to complementary apparatuses. A connector 426 may be provided therein for transferring data to and from an imaging device. The ability to separate the imaging device may provide for the easy replacement of used imaging devices with sterilized and renewed imaging devices. The control unit 420 may also have a display 428 for conveying to an operator information during a procedure. The display 428 may also comprise interactive functionality allowing an operator to enter commands or change what information is being displayed. Such functionality may be provided by a touch screen system as is commonly known. The control unit may also have video inputs 421 and video outputs 424 for transferring image data to other apparatuses for increased functionality. Common apparatuses may be a computer 430 or an external monitor 440 there by increasing the technical functionality of the system 400. A computer 430 may be used for storing the digital output from the imaging system or may be used to enhance and provide further adjustment within the system. An external monitor 440 may be used to show real time digital images to aid an operator in the use of the system, or later review and study the recorded digital imagery.

[0026] Referring now to FIG. 5 an embodiment of a control unit display 428 that may be part of a control unit 420 will be discussed in greater detail. The display 428 may be a digital display of liquid crystal design (LCD), or the display may be some other technology beside LCD, and may have touch screen functionality and capability for an operator or user to input commands into the system 400. The embodiment discussed herein may have input portions 428a and 428b whereby an operator or user may input commands into the system 400. The embodiment may further comprise a status portion 428c informing a user about the operational status of the components of the system 400. For example, display portion 428c may display an error message related to the condition of an attached imaging device 410 if the imaging device 410 has already been used or has been deemed unfit for a procedure. The display 428 may also have a dedicated message portion 428d providing instructions and further information to an operator or user. The configuration of the display 428 may change during use to accommodate further functionality. A plurality of displays 428 is contemplated by, and falls within the scope of, this disclosure and may be used alternatively or in conjunction with this embodiment. An embodiment may comprise a key pad or a button pad for control purposes within a control unit.

[0027] Illustrated in FIGS. 6 and 6A is an embodiment of a retractable display 428 of a control unit 420. The display 428 may have a first or retracted position within the control unit 420 (illustrated best in FIG. 6) that may be used to protect the display 428 when it is not being used. The display 428' of FIG. 6A illustrates how the display may be deployed into a more user readable position, as it has been extended and rotated outward. As illustrated in FIGS. 6 and 6A, the display may be slid in and out of a passage and rotated about an axis to orient the display 428 in a wide range of positions.

[0028] Illustrated in FIG. 7 is a cross-sectional view of an embodiment of an imaging device head 712. The imaging device head 712 may comprise a housing 710 made of a suitably rigid material, such as plastic or metal. The housing 710 may be sealed against fluids and gases so as to protect the internal circuitry and provide a suitable surface for sterilization and renewal. The imaging device head 712 may further comprise a user input panel 720 having buttons 721 and 722 for operation of the imaging device head 712. Additional, buttons may be provided and the functionality of the buttons can be customized for a given procedure or a given operator. The control panel 720 may be internally connected to other circuitry of the imaging device head 712 by an electrical connector 726.

[0029] As illustrated further in FIG. 7, imaging device head 712 may comprise an optical mount system 750, such as a C-mount system for receiving threaded accessories, for example one inch threaded accessories. A window 755 may also be incorporated into the embodiment for facilitating the transmission of light from an optical accessory to an image sensor 775. The image sensor 775 may be mounted to a supporting printed circuit board or supportive substrate 770. An electronic connector 778 may be incorporated to electronically connect the image sensor 775 to a main circuit or main printed circuit board 760. A main wiring harness 782 may be incorporated into a wired tether 780 thereby electrically connecting the components of the imaging device head 712 to a control unit.

[0030] The imaging device head 712 may further comprise a memory 788 or memory circuit allowing the storage of data within the imaging device head 712. It will be appreciated that memory may be any data storage device that is capable of recording (storing) information (data). Data that may be stored or written into memory 788 may include an identifying serial number that uniquely identifies an imaging device. Other data that may be stored or

written into memory 788 may include data such as the amount of the time the imaging device has been used, i.e., the hours of operation, or the amount of time the imaging device has been powered on. Data that may be written into memory 788 may include sterilization data or renewal data, representing the working condition of the imaging device. Data that may be stored or written into memory 788 may include data such as manufacturing date, date of last verification or quality control check, location of manufacture, i.e., may include name, city, state, street address and so forth, last control unit that the imaging device head was attached to, imaging device head diagnostic information, specific procedural settings for the imaging device head, or preferred settings for an operator or user, such as a surgeon. Data representing the above characteristics, or other indicia, of the imaging device may be recorded into memory within the imaging device.

[0031] The memory 788 may be encryption protected so as to avoid tampering or unintended use. It should be noted that a memory 788 may be placed anywhere in the imaging device and not just the imaging device head without departing from the scope of the disclosure. The memory 788 may comprise a permanent or semi-permanent portion allowing varying degrees of data durability.

[0032] Illustrated in FIG. 8 is a cross-sectional view of an embodiment of an imaging device head 812. The imaging device head 812 may comprise a housing 810 made of a suitably rigid material such as plastic or metal. The housing 810 may be sealed against fluids and gases so as to protect the internal circuitry and provide a suitable surface for sterilization and renewal. The imaging device head 812 may further comprise a user input panel 820 having buttons 821 and 822. Additional, buttons may be provided and the functionality of the buttons can be customized for a given procedure and or a given operator. The control panel 820 may be internally connected to other circuitry of the imaging device head 812 by an electrical connector 826.

[0033] As illustrated further in the embodiment of FIG. 8, the imaging device head 812 may comprise an optical mount system 850, such as a C-mount system for receiving threaded accessories, for example one inch threaded accessories. A window 855 may also be incorporated into the embodiment for facilitating the transmission of light from an optical accessory to an image sensor 875. The image sensor 875 may be mounted to a supporting printed circuit board or supportive substrate 870. An electronic connector 878 may be incorporated to electronically connect the image sensor 875 to a main circuit or main printed circuit board 860. In order to provide heat dissipation from the image sensor 875 and other circuitry, a heat sink 861 may be provided. The heat sink 861 may be physically connected to the image sensor 875 and it may also be connected to the housing 810, such that heat energy can be conducted or transferred to the external portion of the imaging device head 812. The heat sink 861 may be a neutral sensor heat sink exposed externally to ensure the camera head meets cardiac floating (CF) and body floating (BF) ISO standards. An embodiment of the heat sink 861 may be made of aluminum and have fins for added heat transfer surface area. A main wiring harness 882 may be incorporated into a wired tether 880 thereby electrically connecting the components of the imaging device head 812 to a control unit.

[0034] The imaging device head 812 may further comprise a memory 888 or memory circuit allowing the storage of data within the imaging device head 812. Data that may be stored or written into memory 888 may include an identifying serial number that uniquely identifies an imaging device. Other data that may be stored or written into memory 888 may include data such as the amount of the time the imaging device has been used, i.e., the hours of operation, or the amount of time the imaging device has been powered on. Data that may be written into memory 888 may include sterilization data or renewal data, representing the working condition of the imaging device. Data that may be stored or written into memory 888 may include data such as manufacturing date, date of last verification or quality control check, location of manufacture, i.e., may include name, city, state, street address and so forth, last control unit that the imaging device head was attached to, imaging device head diagnostic information, specific procedural settings for the imaging device head, or preferred settings for an operator or user, such as a surgeon. Data representing the above characteristics, or other indicia, of the imaging device may be recorded into memory within the imaging device.

[0035] The memory 888 may be encryption protected so as to avoid tampering or unintended use. It should be noted that a memory may be placed anywhere in the imaging device and not just the imaging device head without departing from the scope of the disclosure. The memory 888 may comprise a permanent or semi-permanent portion allowing varying degrees of data durability.

[0036] Illustrated in FIG. 9 is a cross-sectional view of an embodiment of an imaging device head 912. The imaging device head 912 may comprise a housing 910 made of a suitably rigid material such as plastic or metal. The housing 910 may be sealed against fluids and gases so as to protect the internal circuitry and provide a suitable surface for sterilization and renewal. The imaging device head 912 may further comprise a user input panel 920 having buttons 921 and 922. Additional, buttons maybe provided and the functionality of the buttons can be customized for a given procedure and or a given operator. The control panel 920 may be internally connected to other circuitry of the imaging device head 912 by an electrical connector 926.

[0037] As illustrated further in the embodiment of FIG. 9, the imaging device head 912 may comprise an optical mount system 950, such as a C-mount system for receiving threaded accessories, for example one inch threaded accessories. A window 955 may also be incorporated into the embodiment for facilitating the transmission of

light from an optical accessory to an image sensor 975. The image sensor 975 may be mounted to a supporting printed circuit board or supportive substrate 970. An electronic connector 978 may be incorporated to electronically connect the image sensor 975 to a main circuit or main printed circuit board 960. In order to provide heat dissipation from the image sensor 975 and other circuitry, a heat sink may be provided, similar to the heat sink provided in FIG. 8. The heat sink may be physically connected to the image sensor 975 and it may also be connected to the housing 910, such that heat energy can be conducted or transferred to the external portion of the imaging device head 912. A main wiring harness 982 may be incorporated into a wired tether 980 thereby electrically connecting the components of the imaging device head 912 to a control unit.

[0038] The imaging device head 912 may further comprise a memory 988 or memory circuit allowing the storage of data within the imaging device head 912. Data that may be stored or written into memory 988 may include an identifying serial number that uniquely identifies an imaging device. Other data that may be stored or written into memory 988 may include data such as the amount of the time the imaging device has been used, i.e., the hours of operation, or the amount of time the imaging device has been powered on. Data that may be stored or written into memory 988 may include data such as manufacturing date, date of last verification or quality control check, location of manufacture, i.e., may include name, city, state, street address and so forth, last control unit that the imaging device head was attached to, imaging device head diagnostic information, specific procedural settings for the imaging device head, or preferred settings for an operator or user, such as a surgeon. Data representing the above characteristics, or other indicia, of the imaging device may be recorded into memory within the imaging device.

[0039] The memory 988 may be encryption protected so as to avoid tampering or unintended use. It should be noted that a memory may be placed anywhere in the imaging device and not just the imaging device head without departing from the scope of the disclosure. The memory 988 may comprise a permanent or semi-permanent portion allowing varying degrees of data durability.

[0040] The imaging device head 912 may comprise a ball joint 990 with a corresponding seal and socket, thereby providing increased mobility between the housing 910 and the tether 980 during articulation of the imaging device by an operator or user.

[0041] With reference primarily to FIG. 10, an embodiment of an imaging device ball joint 990 will be discussed in further detail. FIG. 10 is illustrative of a cross-sectional view of a ball joint 990, which provides greater freedom of articulation for an operator when moving the imaging device head 912 relative to the wiring tether 980. The ball joint 990 may comprise a substantially spherical rotatable portion or ball 991. The ball 991 may be configured to mechanically operate in communication with a corresponding socket 992, such that the ball 991 may substantially freely rotate while being retained within the socket 992. A seal may be provided withing the ball joint 990 by the inclusion of a seal ring 993. The seal ring 993 may also provide mechanical resistence within the ball joint 990. The ball 991 may further include an opening 994 therethrough allowing wiring 995 to pass through the ball joint 990.

[0042] With reference to FIG. 11, an embodiment of an imaging device 1100 comprising wireless transmission functionality will be discussed. A cross-sectional view of an embodiment of an imaging device head 1112 is shown in FIG. 11. The imaging device head 1112 may comprise a housing 1110 made of a suitably rigid material such as plastic or metal. The housing 1110 may be sealed against fluids and gases so as to protect the internal circuitry and provide a suitable surface for sterilization and renewal. The imaging device head 1112 may further comprise a user input panel 1120 having buttons 1121 and 1122. Additional, buttons may be provided and the functionality of the buttons can be customized for a given procedure and or a given operator. The control panel 1120 may be internally connected to other circuitry of the imaging device head 1112 by an electrical connector 1126. The imaging device head 1112 may communicate with a control unit by way of wireless transmissions such as Wifi, infrared, bluetooth etc. Other forms of wireless non-tethered connectivity may also be used for providing communication between the imaging device head 1112 and the control unit, including but not limited to, radio frequency from any available spectrum, infrared of any configuration, ultrasonic, and optical.

[0043] As illustrated further in the embodiment of FIG. 11, the imaging device head 1112 may comprise an optical mount system 1150, such as a C-mount system for receiving threaded accessories, for example one inch threaded accessories. A window 1155 may also be incorporated into the embodiment for facilitating the transmission of light from an optical accessory to an image sensor 1175. The image sensor 1175 may be mounted to a supporting printed circuit board or supportive substrate 1170. An electronic connector 1178 may be incorporated to electronically connect the image sensor 1175 to a main circuit or main printed circuit board 1160. The circuitry of the imaging device head 1112 may electrically be connected to a wireless transceiver 1111 for transmitting and receiving data from a wirelessly configured control unit as illustrated in FIG. 3.

[0044] The imaging device head 1112 may further comprise a memory 1188 or memory circuit allowing the storage of data within the imaging device head 1112. Data that may be stored or written into memory 1188 may include an identifying serial number that uniquely identifies an imaging device. Other data that may be stored or written into memory 1188 may include data such as the amount of the time the imaging device has been used, i.e., the hours of operation, or the amount of time the imaging device has been powered on. Data that may be

stored or written into memory 1188 may include data such as manufacturing date, date of last verification or quality control check, location of manufacture, i.e., may include name, city, state, street address and so forth, last control unit that the imaging device head was attached to, imaging device head diagnostic information, specific procedural settings for the imaging device head, or preferred settings for an operator or user, such as a surgeon. Data representing the above characteristics, or other indicia, of the imaging device may be recorded into memory within the imaging device.

[0045] The memory 1188 may be encryption protected so as to avoid tampering or unintended use. It should be noted that a memory may be placed anywhere in the imaging device and not just the imaging device head without departing from the scope of the disclosure. The memory 1188 may comprise a permanent or semi-permanent portion allowing a varying degrees of data durability.

[0046] It will be appreciated that the ball joint illustrated in FIGS. 9 and 10 may be used by any embodiment of the disclosure without departing from the spirit or scope of the disclosure. Thus, for example, the ball joint 990 maybe used with imaging device head 712, 812, 912, or 1112. Similarly, it will be appreciated that the heat sink 861 (illustrated in FIG. 8) may be used by any embodiment of the disclosure without departing from the scope of the disclosure.

[0047] Referring now to FIG. 12 an embodiment of a system for acquiring imagery in a sterilized environment will be discussed. The system may comprise an imaging device 1201 having a memory 1202, an image sensor 1204, and supporting circuitry 1206. The system may further comprise and control unit 1220 having a processor 1221, time circuit or realtime clock 1222, a counting or incrementing circuit 1224 and a control unit memory 1226. The components will generally be provided in a housing, but are shown hear in block diagram form for simplicity and discussion purposes. It is contemplated that any of the above circuits can operate from either a control unit or an imaging device.

[0048] As can be seen in FIG. 13 the memory 1202 of the imaging device 1201 may comprise the following arrays of data storage:

a. Hours of camera head operation;
b. Number of times camera has been used;
c. Unique identification i.e. serial number, id, etc.;
d. Manufacture date;
e. Date of last verification/quality check;
f. Location of manufacture i.e. (Address, state, city etc.);
g. Last console that the camera head was connected to;
h. Camera console diagnostic information;
i. Procedural specific camera head settings (i.e. video settings, button settings, etc.);
j. Last Sterilization date (used to ensure safety to product); and
k. Surgeon settings.

[0049] Additional data may be stored within the memory 1202 that would enhance the imaging device and is considered to be within the scope of the disclosure.

[0050] With reference to FIG. 14, a method of using an imaging system consistent with the embodiments disclosed herein will be discussed. In use, a sterilized single use imaging device 1201 will be provided that may comprise memory 1202 at 1410. At 1420 a user may connect the single use imaging device 1201 to a complementary control unit 1220 both electronically and physically. At 1430 the control unit 1220 may initiate a process of reading memory 1202 and registers the serial number of the imaging device 1201. At 1440 the system causes a value to be recorded into memory 1202 indicating that the imaging device 1201 has been used. At 1450 the system records into memory 1202 the date and time the imaging device 1201 is connected to the control unit 1220. At 1460 a timing process is initiated by the control unit from the base line time recorded at 1450 and tracks or times the duration that the imaging device 1201 is used and the duration is recorded into memory 1202 at 1470. After use, the imaging device 1201 is disconnected from the control unit 1220 at 1480 and then discarded for renewal or reclamation.

[0051] Referring now to FIG. 15, a method of renewing and reclaiming a single use imaging device 1201 will be discussed. At 1510 the imaging device 1201 may be connected to a testing control unit or a master control unit. At 1520 the testing control unit or master control unit causes the data stored in memory 1202 to be recorded into storage on the testing control unit or master control unit as stored, in order for the specific imaging device 1201 to be renewed. At 1525 a value is placed in memory 1202 indicating that the imaging device has been renewed and is ready for use such that when connected to another control unit for use it will operate. The location and date of the renewal may then be recorded into memory 1202 at 1530. At 1540 the imaging device 1201 can be sterilized and (at 1550) placed in a protective sterilized package.

[0052] With reference to FIG. 16 an alternative embodiment of a method of use will be discussed illustrating safety settings of the embodiment. At 1610 the memory imaging device head may be stamped with time of manufacture when it is plugged into the master control unit or master console after assembly in the field, i.e., in an operating room, and after a quality control check has been performed. At 1620 a check may be made to determine if the imaging device has been powered off for a predetermined number of minutes, such as a time frame that is close to what a typical sterilization cycle would last. At 1630, if the imaging device has been powered off the predetermined amount of time the control unit will display an onscreen message telling the user the imaging device has already been used, and will not allow further operation, such that no image will be produced through

video feed. This feature will ensure the imaging device, i.e., the camera, will not be used more than one time per sterilization cycle. This feature also protects the patient and the doctor from an invalid or unsafe use.

[0053] Referring to FIG. 17 an embodiment of a method of use will be discussed. During use, an imaging device may be connected to a control unit. Upon connection, an electronic communication connection is formed between the imaging device and the control unit. At 1702 the imaging device may be powered on by power supplied by the control unit. At 1704 a processor in the control unit may cause data regarding imaging device identification that may be stored in a memory within the imaging device to be read. At 1706 a processor in the control unit may cause data regarding the manufacturing date of the imaging device to be read from memory within the imaging device. The processor in the control unit may then compare the data to a predetermined data value range. At 1707 an error message may be displayed if the read data is outside the predetermined data value range and the imaging device will be stopped from operating. At 1708 a processor in the control unit may cause data regarding the reclamation of the imaging device to be read from memory within the imaging device. The data regarding reclamation of the imaging device may include data representing whether or not the imaging device has been previously used. The processor may then compare the data to a predetermined data value range. At 1709 an error massage may be displayed if the read data is outside the predetermined data value range and the imaging device will be stopped from operating. At 1710 a processor in the control unit may cause data regarding the reclamation date of the imaging device to be read from memory within the imaging device. The processor may then compare the data to a predetermined data value range. At 1711 an error massage may be displayed if the read data is outside the predetermined data value range and the imaging device will be stopped from operating. At 1712 a processor in the control unit may cause usage information of the current procedure to be monitored to note whether imaging device has been unpowered for a predetermined period of time and then re-powered. If this condition occurs it is possible that the imaging device has been tampered with or that an attempt has been made to sterilize the imaging device and use it a second time. The predetermined period of time may correspond to the amount of time a typical sterilization process would normally take. The processor then compares the data to a predetermined data value range. At 17013 an error massage may be displayed if the data read is outside the predetermined data value range and the imaging device will be stopped from operating. At 1714 a processor in the control unit may cause a value to be placed in memory in the imaging device indicating that the imaging device has been used. At 1716 a processor in the control unit may cause the date and time of use to be recorded in memory in the imaging device. Additional information may be recorded into the memory of the imaging device such as, for example, duration of use, procedure settings, and user settings and any other data suitable for recording to memory. The imaging device may be disconnected from the control unit and thereby powered off at 1718.

[0054] Referring now to FIG. 18 a method of reclaiming an image device after use will be discussed. It should be noted that a single use imaging device may comprise the durability to be used a plurality of times, however sterilization requirements may prevent an imaging device from being used more than once without a process for reclaiming the imaging device, thereby returning it to a sterilized condition. A method of reclamation for an imaging device may comprise the process of powering on the imaging device at 1802, when the imaging device is electrically connected to a control unit. At 1804 a processor in the control unit may cause data representing identification information for the imaging device to be stored in storage in the control unit. A control unit may be a master control unit configured for reclaiming the imaging devices. The master control unit may track a plurality of imaging devices thereby keeping a catalog of associated information such as use and condition of the device or devices. At 1806 a processor in the control unit may cause that data representing a manufacturing date to be read and compared to a predetermined value or range of values. If the read data is out of the predetermined range value, an error report may be issued at 1807. At 1808 a processor in the control unit may cause data representing use data written in memory of the imaging device to be read and recorded into storage in the control unit. At 1810 a processor may cause data representing a date and time of reclamation to be recorded into memory in the imaging device. At 1812 a processor in the control unit may cause that data representing the number of uses of the imaging device to be read and recorded into storage in the control unit. The processor may compare the read data to a predetermined value or range of values to determine whether the imaging device is fit for continued use. If the predetermined value is exceeded an error message maybe displayed (at 1813) and the imaging device may be retired. At 1814 a processor in the control unit may initiate a test or quality control check of all the circuitry in the imaging device to ensure that the device is functional. At 1815 it may be determined that the imaging device failed the quality control check and an error massage may be displayed. At 1816 the imaging device can be reset for use. The resetting process may comprise writing data to the memory of the imaging device indicating that the imaging device has been reclaimed and sterilized. At 1816 the device may be disconnected from the control unit and physically sterilized and repackaged.

[0055] With reference primarily to FIG. 19 an embodiment of a method for making an imaging device having memory therein for use in a sterilized environment will be discussed. At 1902 an imaging device may be powered on upon being connected to a control unit. The control unit may be a master control unit configured for the manufacturing process. At 1904 a processor in the con-

trol unit may cause that data representing an identification serial number for the imaging device to be written into memory of the imaging device. At 1906 a processor in the control unit may cause that data representing the location of manufacture be recorded to memory in the imaging device. At 1908 a processor may cause that data representing the date of manufacture may be recorded into memory on the imaging device. At 1910 a processor in the control unit may initiate a test or quality control check of all the circuitry in the imaging device to ensure that the device is functional. At 1912 the imaging device may be unplugged from the control and sterilized for packaging.

[0056] Referring to an embodiment illustrated in FIG. 20, a system having a security code or some other means of identifying, and validating for use, an imaging device by a control unit, in order to verify that the imaging device is authorized for use will now be described. A validating security code or procedure of validation may be distributed to control units from a central database over the internet, by direct transfer from portable storage device such as USB device containing memory, another computer, or other storage device. With reference to FIG. 20 an embodiment of a method for providing updates with in a medical imaging system will be discussed. At 2002 a control unit may be powered on to receive a security update. At 2004 security update data may provided comprising validation codes that correspond to imaging devices to be connected to the control unit. Such validation codes may enable the system to insure that users of the system may be prevented from using imaging devices that have been selected for non-use by a manufacturer or distributor. Selection criteria for non-use may include safety considerations, recall considerations, anti counterfeit measures, and sales and contract considerations. At 2006 the data may be transferred into storage or memory of the control unit in order to provide that data for later comparison to security codes provided by imaging devices. It is within the scope of this disclosure to include all means for transferring data, including but not limited to, transmission over a network, transfer via on site transmission from a storage medium that is portable, such as a disk, memory drive, or short distance wireless transmission. At 2008 the system may be powered off.

[0057] With reference primarily to FIG. 21 an embodiment of an imaging system have the feature of updating data will be discussed. An imaging system 2100 may comprise a control unit 2102 and a data server 2104. The control unit 2106 may be electronically in communication with the data server 2104 over a network such as the internet 2106. The control unit 1202 may receive update data over the internet 2106 from data server 2104. The control unit 2102 may also receive update data directly from a memory transfer device 2108 such as a memory stick, thumb drive, jump drive, hard drive, optical disk to name a few. The control unit 2102 may also receive update data from another computer or portable device 2110 such as a PDA or laptop that is presented to the control unit 2102 on site. Data transfer may be made with a physical connection and or by a wireless transfer of data.

[0058] It is to be understood that the above-described arrangements are only illustrative of the application of the principles of the disclosure. Numerous modifications and alternative arrangements may be devised by those skilled in the art without departing from the scope of the appended claims are intended to cover such modifications and arrangements. Thus, while the disclosure has been shown in the drawings and described above with particularity and detail, it will be apparent to those of ordinary skill in the art that numerous modifications, including, but not limited to, variations in size, materials, shape, form, function and manner of operation, assembly and use may be made without departing from the scope of the appended claims.

Claims

1. A system (100) comprising:

a monitor (140);
a control unit (120) comprising a processor, wherein the control unit (120) is electronically connected to the monitor (140); and
a sterilised imaging device (110) for use with and communicating with the control unit (120);
wherein the sterilised imaging device (110) comprises:

a housing (710; 810; 910);
an image sensor (775; 875; 975);
an optic mount (750; 850; 950) in said housing configured for receiving optics;
an opening (755; 855; 955) proximate to said optic mount and configured to facilitate transmission of light from said optics to said image sensor;
an electronic communication circuit (114; 322; 1111) configured for providing electronic communication between said imaging device (110) and said control unit (120); and
a memory (788; 888; 988) comprising data representing characteristics of the imaging device;
wherein the data comprises:

a) the date of the last sterilization;
b) a serial number for providing identification of the imaging device or a unique identification code;
c) the number of hours of operation of the imaging device;
d) the number of times the imaging device has been used; and
e) a date of manufacture;

wherein the processor is configured to:

i) read the serial number or the unique identification code stored in said memory (788; 888; 988) (1704);
ii) read the date of manufacture stored in said memory (788; 888; 988), compare the date of manufacture to a predetermined data value range, display an error message on the monitor (140) when the date of manufacture is outside the predetermined data value range and stop the imaging device (110) from operating (1706, 1707);
iii) read the number of times the imaging device has been used stored in said memory (788; 888; 988), compare the number of times the imaging device has been used to a predetermined data value range, display an error message on the monitor (140) when the number of times the imaging device has been used is outside the predetermined data value range and stop the imaging device (110) from operating (1708, 1709);
iv) read the date of the last sterilization stored in said memory (788; 888; 988), compare the date of the last sterilization to a predetermined data value range, display an error message on the monitor (140) when the date of the last sterilization is outside the predetermined data value range and stop the imaging device (110) from operating (1710, 1711);
v) monitor whether the imaging device has been unpowered for a predetermined period of time and then re-powered, compare the time of unpowering to a predetermined data value range, display an error message on the monitor (140) when the time of unpowering is outside the predetermined data value range and stop the imaging device (110) from operating (1712, 1713);
vi) if none of the data of steps (i) to (v) is outside the predetermined data value range, the processor is further configured to record in the memory (788; 888; 988) that the imaging device has been used (1714);
vii) record in the memory (788; 888; 988) the date and time of use of the imaging device (1716).

2. The system (100) of claim 1, wherein the data further comprises a date of last verification/quality check.

3. The system (100) of claim 1, wherein the data further comprise a location of manufacture.

4. The system (100) of claim 1, wherein the data further comprise the last control unit to which the imaging device (110) was connected.

5. The system (100) of claim 1, wherein the data further comprise diagnostic information.

6. The system (100) of claim 1, wherein the data further comprise procedural specific settings or specific settings for a specific user.

7. The system (100) of any one of the preceding claims, wherein said electronic communication circuit:

a) is a tether (780; 880; 980) of wires having an electronic connector (778; 878; 978) configured to mate with a corresponding electronic connector on said control unit (720; 820; 920), wherein optionally and preferably said tether of wires comprises a ball (991) configured to mechanically communicate with a corresponding socket structure (992) of said housing (910), wherein optionally and more preferably an "O" ring seal is disposed about said ball thereby forming a seal between said ball and said corresponding socket; or
b) is a wireless communication transceiver configured to communicate wirelessly with a corresponding transceiver on said control unit.

8. The system (100) of any one of the preceding claims, wherein wireless communication is used to provide identifying information and wherein the wireless communication uses a wireless technology selected from a group comprising: radio frequencies, infrared, ultrasonic, and optical.

9. A method for providing a sterilised imaging system for use in sterile environments comprising:

providing a system (100) as set forth in any one of claims 1 to 8;
electrically connecting said imaging device (110) to said control unit (120); and
recording data into the memory of the imaging device (110) after connection to the control unit (120), said data representing characteristics of the imaging device (110);
wherein the method is not a method for treatment of the human or animal body by surgery.

Patentansprüche

1. System (100), umfassend:

einen Monitor (140);
eine Steuereinheit (120), umfassend einen Prozessor, wobei die Steuereinheit (120) elektronisch mit dem Monitor (140) verbunden ist; und
eine sterilisierte Bildgebungsvorrichtung (110) zur Verwendung und Kommunikation mit der Steuereinheit (120);
wobei die sterilisierte Bildgebungsvorrichtung (110) umfasst:

ein Gehäuse (710; 810; 910);
einen Bildsensor (775; 875; 975);
eine optische Halterung (750; 850; 950) in dem Gehäuse, die zum Empfangen von Optiken konfiguriert ist;
eine Öffnung (755; 855; 955) in der Nähe der optischen Halterung und konfiguriert, um die Übertragung von Licht von der Optik zu dem Bildsensor zu erleichtern;
eine elektronische Kommunikationsschaltung (114; 322; 1111), die zum Bereitstellen einer elektronischen Kommunikation zwischen der Bildgebungsvorrichtung (110) und der Steuereinheit (120) konfiguriert ist; und
einen Speicher (788; 888; 988), der Daten umfasst, die Eigenschaften der Bildgebungsvorrichtung darstellen;
wobei die Daten umfassen:

a) das Datum der letzten Sterilisation;
b) eine Seriennummer zur Identifizierung der Bildgebungsvorrichtung oder einen eindeutigen Identifikationscode;
c) die Anzahl der Betriebsstunden der Bildgebungsvorrichtung;
d) die Häufigkeit, mit der die Bildgebungsvorrichtung verwendet wurde; und
e) ein Herstellungsdatum;

wobei der Prozessor konfiguriert zum:

i) Lesen der Seriennummer oder des eindeutigen Identifikationscodes, der in dem Speicher (788; 888; 988) (1704) gespeichert ist;
ii) Lesen des in dem Speicher (788; 888; 988) gespeicherten Herstellungsdatums, Vergleichen des Herstellungsdatums mit einem vorbestimmten Datenwertbereich, Anzeigen einer Fehlermeldung auf dem Monitor (140), wenn das Herstellungsdatum außerhalb des vorbestimmten Datenwertbereichs liegt und Stoppen des Betriebs (1706, 1707) der Bildgebungsvorrichtung (110);
iii) Lesen der Häufigkeit, mit der die Bildgebungsvorrichtung in dem Speicher (788; 888; 988) gespeichert wurde, Vergleichen der Häufigkeit, mit der die Bildgebungsvorrichtung verwendet wurde, mit einem vorbestimmten Datenwertbereich, Anzeigen einer Fehlermeldung auf dem Monitor (140), wenn die Häufigkeit, mit der die Bildgebungsvorrichtung verwendet wurde, außerhalb des vorbestimmten Datenwertbereichs liegt und Stoppen des Betriebs (1708, 1709) der Bildgebungsvorrichtung (110);
iv) Lesen des Datums der letzten in dem Speicher (788; 888; 988) gespeicherten Sterilisation, Vergleichen des Datums der letzten Sterilisation mit einem vorgegebenen Datenwertbereich, Anzeigen einer Fehlermeldung auf dem Monitor (140), wenn das Datum der letzten Sterilisation außerhalb des vorbestimmten Datenwertbereichs liegt und Stoppen des Betriebs (1710, 1711) der Bildgebungsvorrichtung (110);
v) Überwachen, dass die Bildgebungsvorrichtung für einen vorbestimmten Zeitraum nicht mit Strom versorgt wurde und dann erneut mit Strom versorgt wurde, Vergleichen der Zeit der Nichtversorgung mit Strom mit einem vorbestimmten Datenwertbereich, Anzeigen einer Fehlermeldung auf dem Monitor (140), wenn die Nichtversorgung mit Strom außerhalb des vorbestimmten Datenwertbereichs liegt und Stoppen des Betriebs (1712, 1713) der Bildgebungsvorrichtung (110);
vi) wenn keine der Daten der Schritte (i) bis (v) außerhalb des vorbestimmten Datenwertbereichs liegen, der Prozessor ferner konfiguriert ist zum Aufzeichnen, in dem Speicher (788; 888; 988), dass die Bildgebungsvorrichtung verwendet wurde (1714);
vii) Aufzeichnen des Datums und der Uhrzeit der Verwendung der Bildgebungsvorrichtung (1716) im Speicher (788; 888; 988).

2. System (100) nach Anspruch 1, wobei die Daten 2 ferner ein Datum der letzten Überprüfung/Qualitätsprüfung umfassen.

3. System (100) nach Anspruch 1, wobei die Daten ferner einen Herstellungsort umfassen.

4. System (100) nach Anspruch 1, wobei die Daten ferner die letzte Steuereinheit umfassen, mit der die Bildgebungsvorrichtung (110) verbunden war.

5. System (100) nach Anspruch 1, wobei die Daten ferner Diagnoseinformationen umfassen.

6. System (100) nach Anspruch 1, wobei die Daten ferner prozedurspezifische Einstellungen oder spezifische Einstellungen für einen spezifischen Benutzer umfassen.

7. System (100) nach einem der vorstehenden Ansprüche, wobei die elektronische Kommunikationsschaltung:

a) ein Kabel (780; 880; 980) aus Drähten mit einem elektronischen Verbinder (778; 878; 978) ist, der konfiguriert ist, um mit einem entsprechenden elektronischen Verbinder an der Steuereinheit (720; 820; 920) zusammenzupassen, wobei gegebenenfalls und vorzugsweise das Kabel aus Drähten eine Kugel (991) umfasst, die konfiguriert ist, um mechanisch mit einer entsprechenden Buchsenstruktur (992) des Gehäuses (910) zu kommunizieren, wobei gegebenenfalls und mehr bevorzugt eine "O"-Ringdichtung um die Kugel angeordnet ist, wodurch eine Dichtung zwischen der Kugel und der entsprechenden Buchse gebildet wird; oder
b) ein drahtloser Kommunikationstransceiver ist, der konfiguriert ist, um drahtlos mit einem entsprechenden Transceiver an der Steuereinheit zu kommunizieren.

8. System (100) nach einem der vorstehenden Ansprüche, wobei die drahtlose Kommunikation verwendet wird, um identifizierende Informationen bereitzustellen, und wobei die drahtlose Kommunikation eine drahtlose Technologie verwendet, die ausgewählt ist aus einer Gruppe, umfassend: Funkfrequenzen, Infrarot, Ultraschall und Optik.

9. Verfahren zum Bereitstellen eines sterilisierten Bildgebungssystems für die Verwendung in sterilen Umgebungen, umfassend:

Bereitstellen eines Systems (100) wie es in einem der Ansprüche 1 bis 8 dargelegt ist; elektrisches Verbinden der Bildgebungsvorrichtung (110) mit der Steuereinheit (120); und
Aufzeichnen von Daten in den Speicher der Bildgebungsvorrichtung (110) nach dem Verbinden mit der Steuereinheit (120), wobei die Daten Eigenschaften der Bildgebungsvorrichtung (110) darstellen;
wobei das Verfahren kein Verfahren zur Behandlung des menschlichen oder tierischen Körpers durch Chirurgie ist.

Revendications

1. Système (100) comprenant :

un moniteur (140) ;
une unité de commande (120) comprenant un processeur, dans lequel l'unité de commande (120) est électroniquement connectée au moniteur (140) ; et
un dispositif d'imagerie stérilisé (110) pour utilisation avec et en communication avec l'unité de commande (120) ;
dans lequel le dispositif d'imagerie stérilisé (110) comprend :

un logement (710 ; 810 ; 910) ;
un capteur d'image (775 ; 875 ; 975) ;
un montage optique (750 ; 850 ; 950) dans ledit logement configuré pour recevoir une optique ;
une ouverture (755 ; 855 ; 955) à proximité dudit montage optique et configurée pour faciliter une transmission de lumière depuis ladite optique vers ledit capteur d'image ;
un circuit de communication électronique (114 ; 322 ; 1111) configuré pour fournir une communication électronique entre ledit dispositif d'imagerie (110) et ladite unité de commande (120) ; et
une mémoire (788 ; 888 ; 988) comprenant des données représentant des caractéristiques du dispositif d'imagerie ;
dans lequel les données comprennent :

a) la date de la dernière stérilisation ;
b) un numéro de série pour fournir une identification du dispositif d'imagerie ou un code d'identification unique ;
c) le nombre d'heures de fonctionnement du dispositif d'imagerie ;
d) le nombre de fois que le dispositif d'imagerie a été utilisé ; et
e) une date de fabrication ;

dans lequel le processeur est configuré pour :

i) lire le numéro de série ou le code d'identification unique stocké dans ladite mémoire (788 ; 888 ; 988) (1704) ;
ii) lire la date de fabrication stockée dans ladite mémoire (788 ; 888 ; 988), comparer la date de fabrication à une plage prédéterminée de valeurs de données, afficher un message d'erreur

sur le moniteur (140) lorsque la date de fabrication est à l'extérieur de la plage prédéterminée de valeurs de données et arrêter le fonctionnement (1706, 1707) du dispositif d'imagerie (110) ;
iii) lire le nombre de fois que le dispositif d'imagerie a été utilisé stocké dans ladite mémoire (788 ; 888 ; 988), comparer le nombre de fois que le dispositif d'imagerie a été utilisé à une plage prédéterminée de valeurs de données, afficher un message d'erreur sur le moniteur (140) lorsque le nombre de fois que le dispositif d'imagerie a été utilisé est à l'extérieur de la plage prédéterminée de valeurs de données et arrêter le fonctionnement (1708, 1709) du dispositif d'imagerie (110) ;
iv) lire la date de la dernière stérilisation stockée dans ladite mémoire (788 ; 888 ; 988), comparer la date de la dernière stérilisation à une plage prédéterminée de valeurs de données, afficher un message d'erreur sur le moniteur (140) lorsque la date de la dernière stérilisation est à l'extérieur de la plage prédéterminée de valeurs de données et arrêter le fonctionnement (1710, 1711) du dispositif d'imagerie (110) ;
v) surveiller si le dispositif d'imagerie a été non alimenté pendant une période de temps prédéterminé puis réalimenté, comparer le temps de non-alimentation à une plage prédéterminée de valeurs de données, afficher un message d'erreur sur le moniteur (140) lorsque le temps de non-alimentation est à l'extérieur de la plage prédéterminée de valeurs de données et arrêter le fonctionnement (1712, 1713) du dispositif d'imagerie (110) ;
vi) si aucune des données des étapes (i) à (v) n'est à l'extérieur de la plage prédéterminée de valeurs de données, le processeur est en outre configuré pour enregistrer dans la mémoire (788 ; 888 ; 988) que le dispositif d'imagerie a été utilisé (1714) ;
vii) enregistrer dans la mémoire (788 ; 888 ; 988) la date et le temps d'utilisation du dispositif d'imagerie (1716).

2. Système (100) selon la revendication 1, dans lequel les données comprennent en outre une date de dernière vérification/dernier contrôle de qualité.

3. Système (100) selon la revendication 1, dans lequel les données comprennent en outre un emplacement de fabrication.

4. Système (100) selon la revendication 1, dans lequel les données comprennent en outre la dernière unité de commande à laquelle le dispositif d'imagerie (110) a été connecté.

5. Système (100) selon la revendication 1, dans lequel les données comprennent en outre des informations de diagnostic.

6. Système (100) selon la revendication 1, dans lequel les données comprennent en outre des réglages procéduraux spécifiques ou des réglages spécifiques pour un utilisateur spécifique.

7. Système (100) selon l'une quelconque des revendications précédentes, dans lequel ledit circuit de communication électronique :

a) est un câble (780 ; 880 ; 980) de fils ayant un connecteur électronique (778 ; 878 ; 978) configuré pour s'accoupler à un connecteur électronique correspondant sur ladite unité de commande (720 ; 820 ; 920), dans lequel éventuellement et de préférence ledit câble de fils comprend une bille (991) configurée pour communiquer mécaniquement avec une structure de douille correspondante (992) dudit logement (910), dans lequel éventuellement et plus préférablement un joint « torique » est disposé autour de ladite bille en formant ainsi un joint entre ladite bille et ladite douille correspondante ; ou
b) est un émetteur-récepteur de communication sans fil configuré pour communiquer sans fil avec un émetteur-récepteur correspondant sur ladite unité de commande.

8. Système (100) selon l'une quelconque des revendications précédentes, dans lequel une communication sans fil est utilisée pour fournir des informations d'identification et dans lequel la communication sans fil utilise une technologie sans fil choisie dans un groupe comprenant : fréquences radio, infrarouge, ultrasonore, et optique.

9. Procédé pour fournir un système d'imagerie stérilisé pour utilisation dans des environnements stériles comprenant :

la fourniture d'un système (100) selon l'une quelconque des revendications 1 à 8 ;
la connexion électrique dudit dispositif d'imagerie (110) à ladite unité de commande (120) ; et
l'enregistrement de données dans la mémoire du dispositif d'imagerie (110) après connexion à l'unité de commande (120), lesdites données

représentant des caractéristiques du dispositif d'imagerie (110) ;
dans lequel le procédé n'est pas un procédé de traitement du corps humain ou animal par chirurgie.

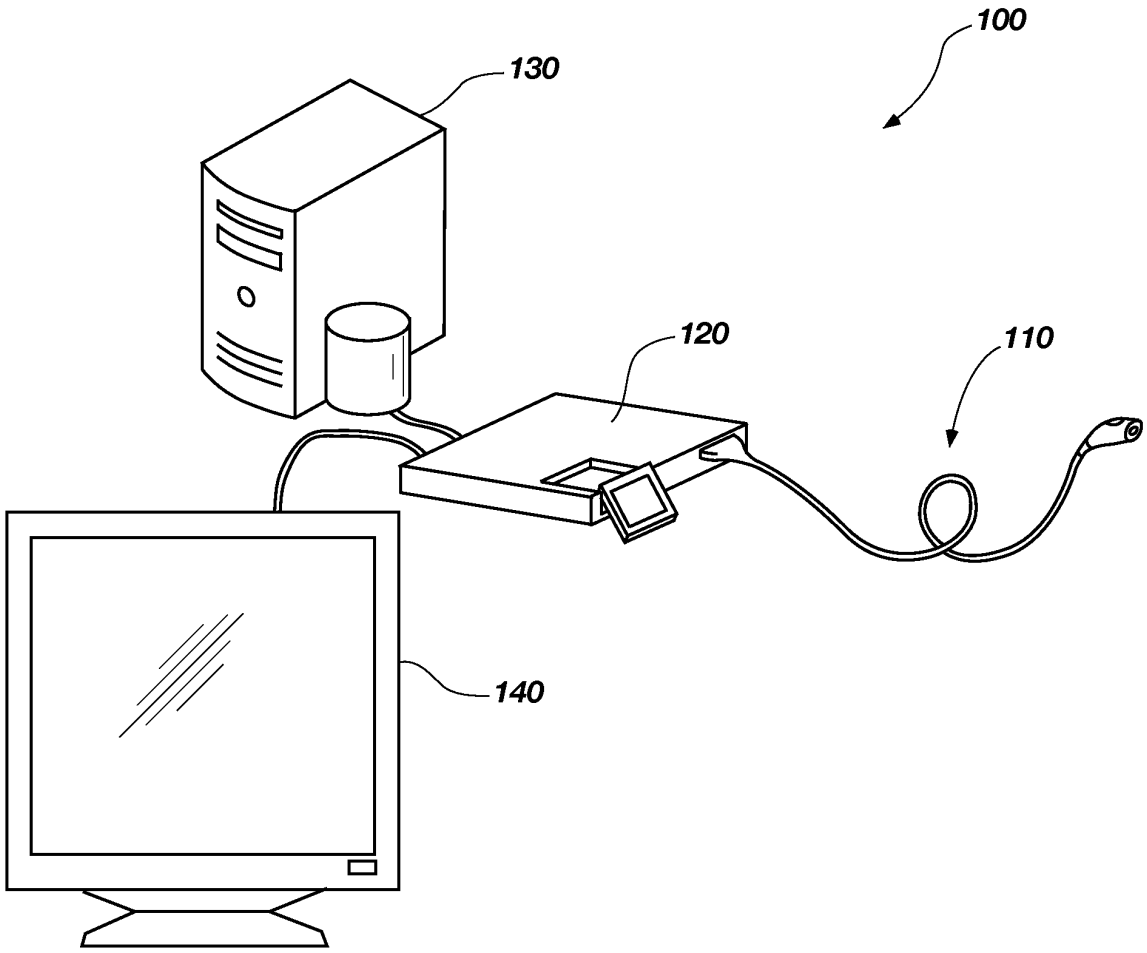

FIG. 1

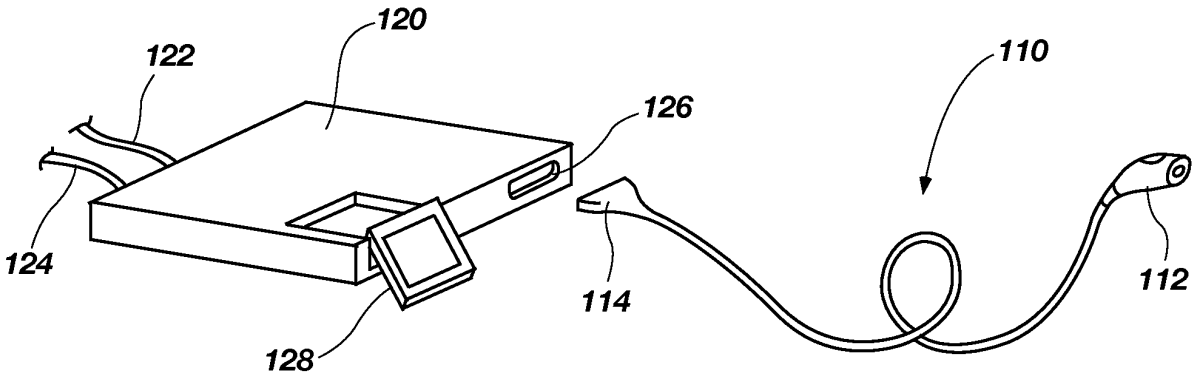

FIG. 2

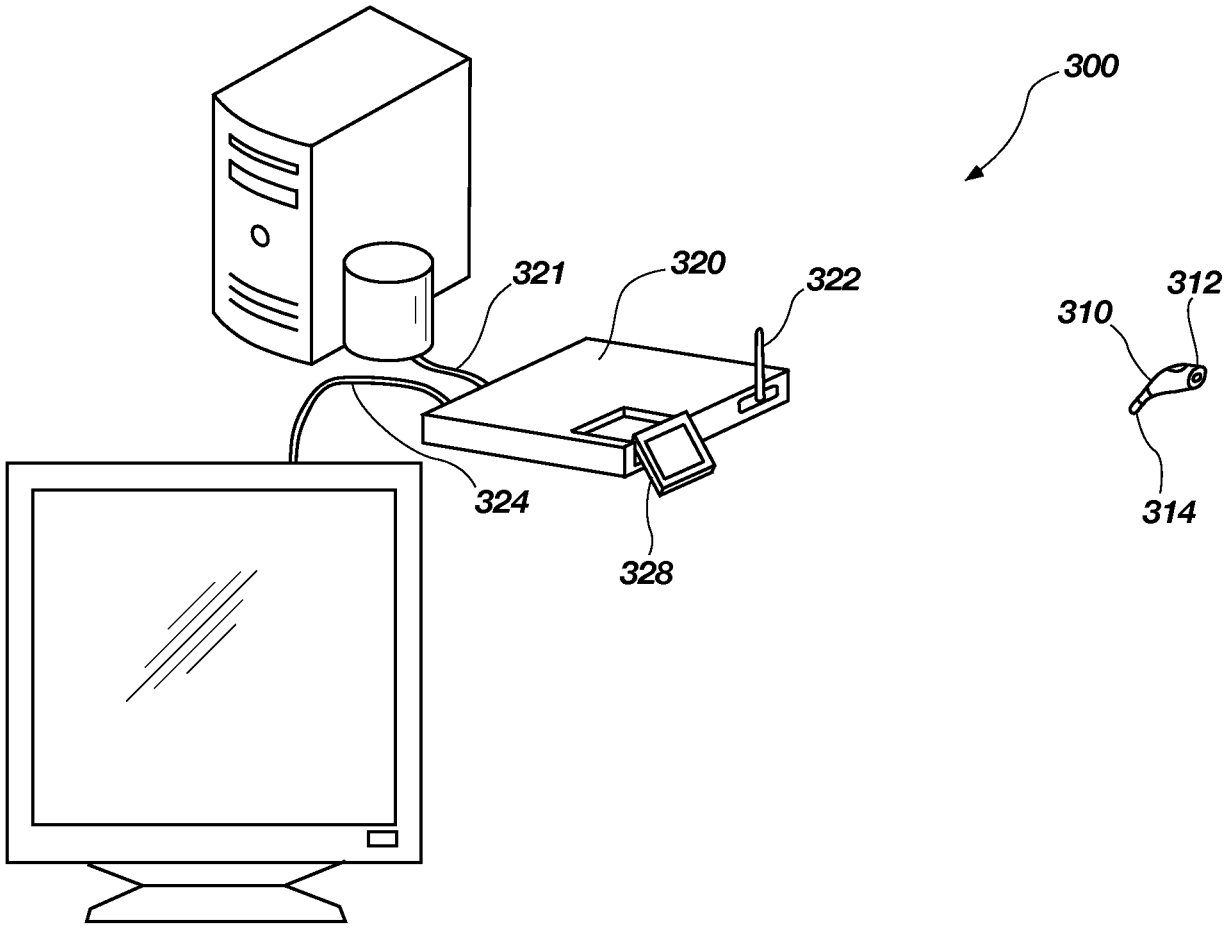

FIG. 3

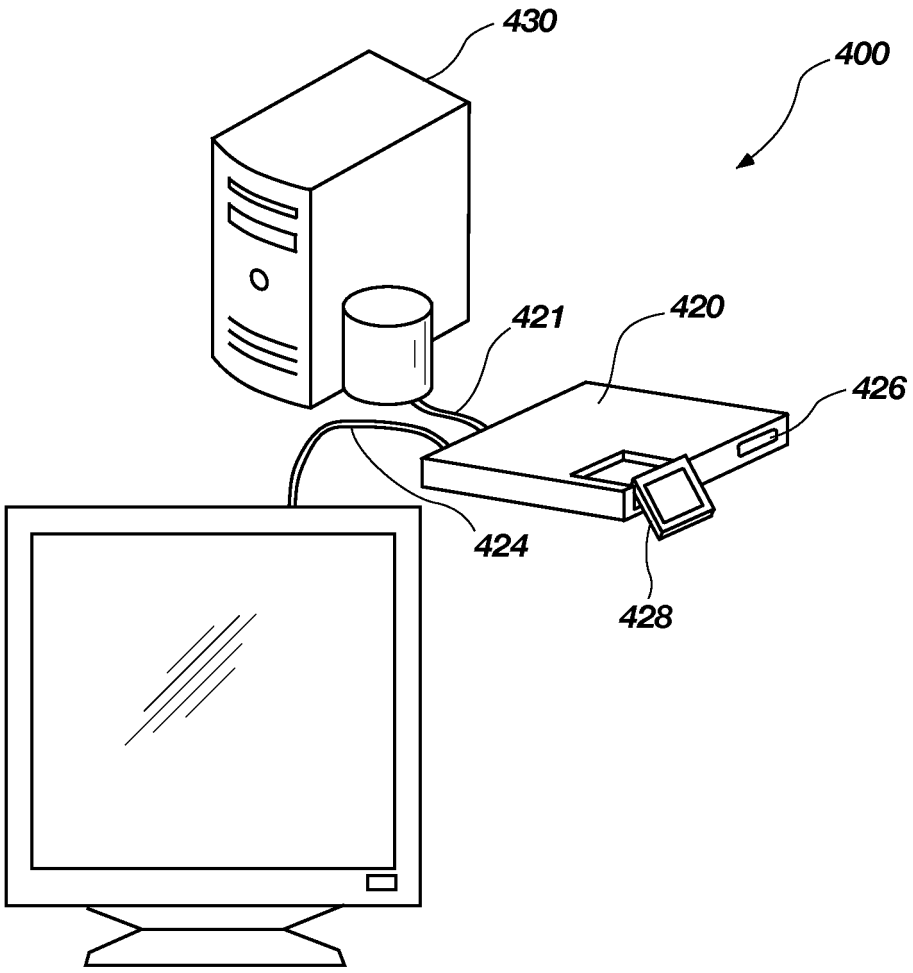

FIG. 4

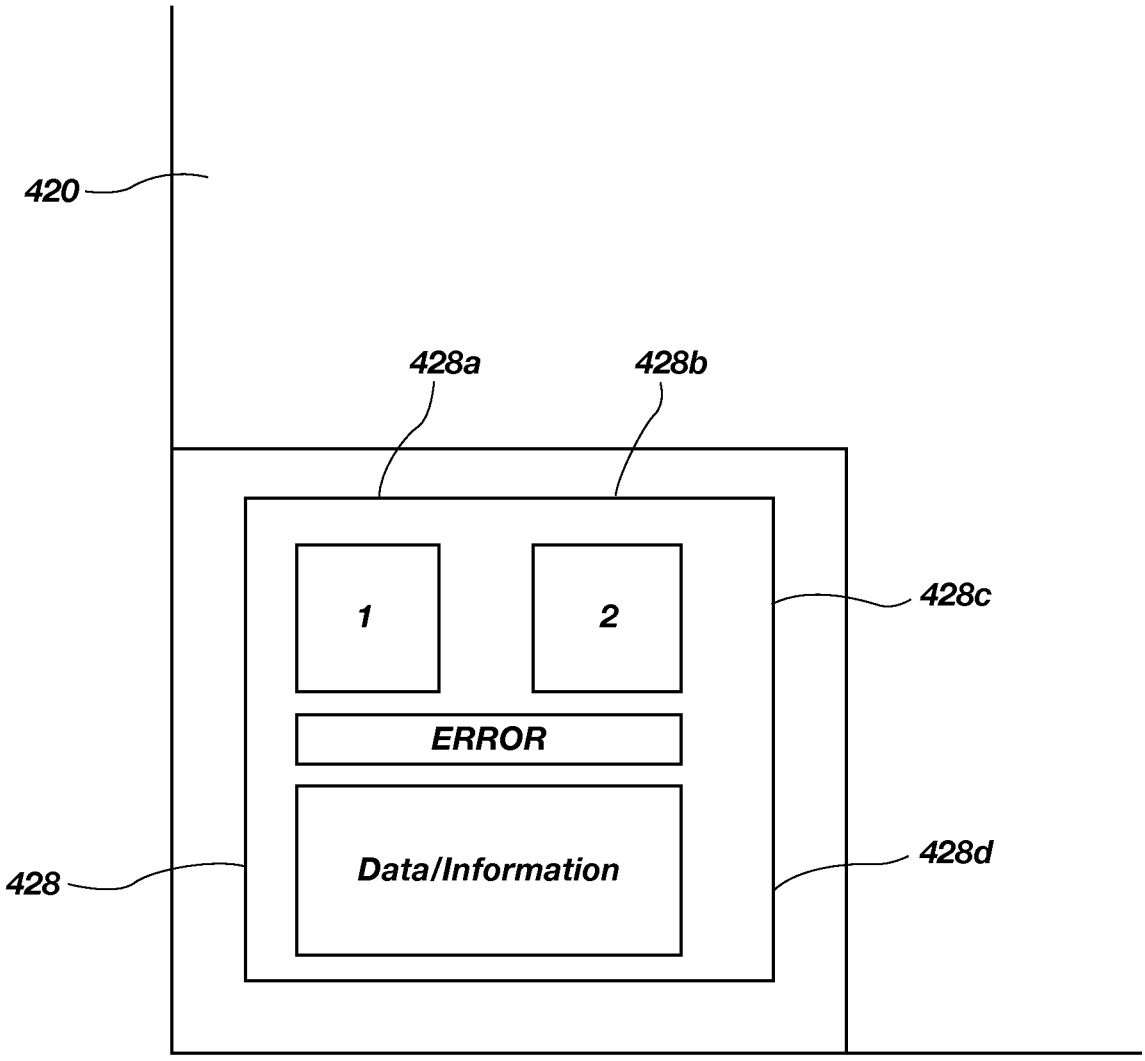

FIG. 5

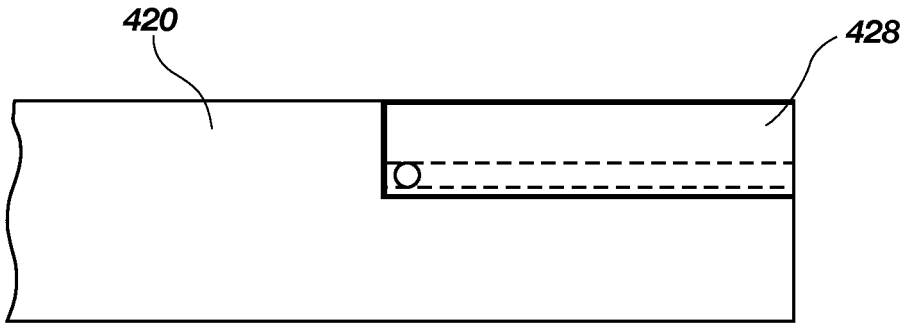

FIG. 6

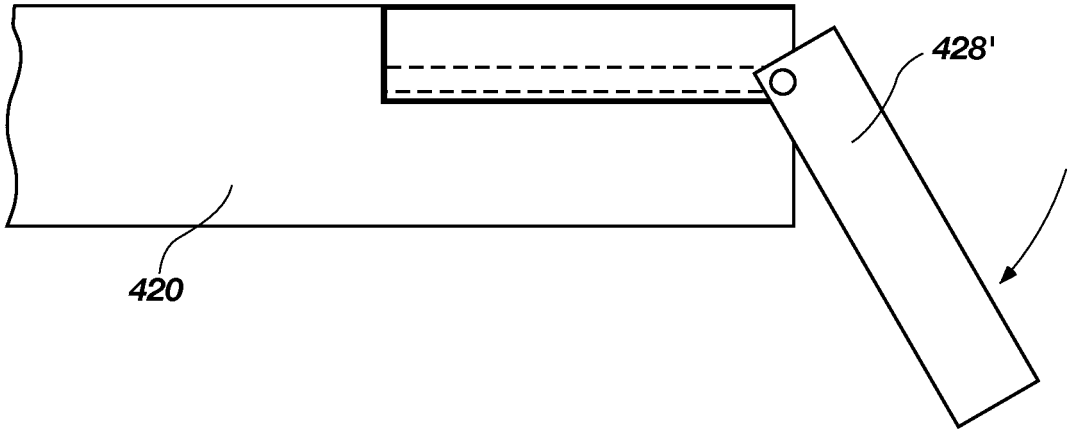

FIG. 6a

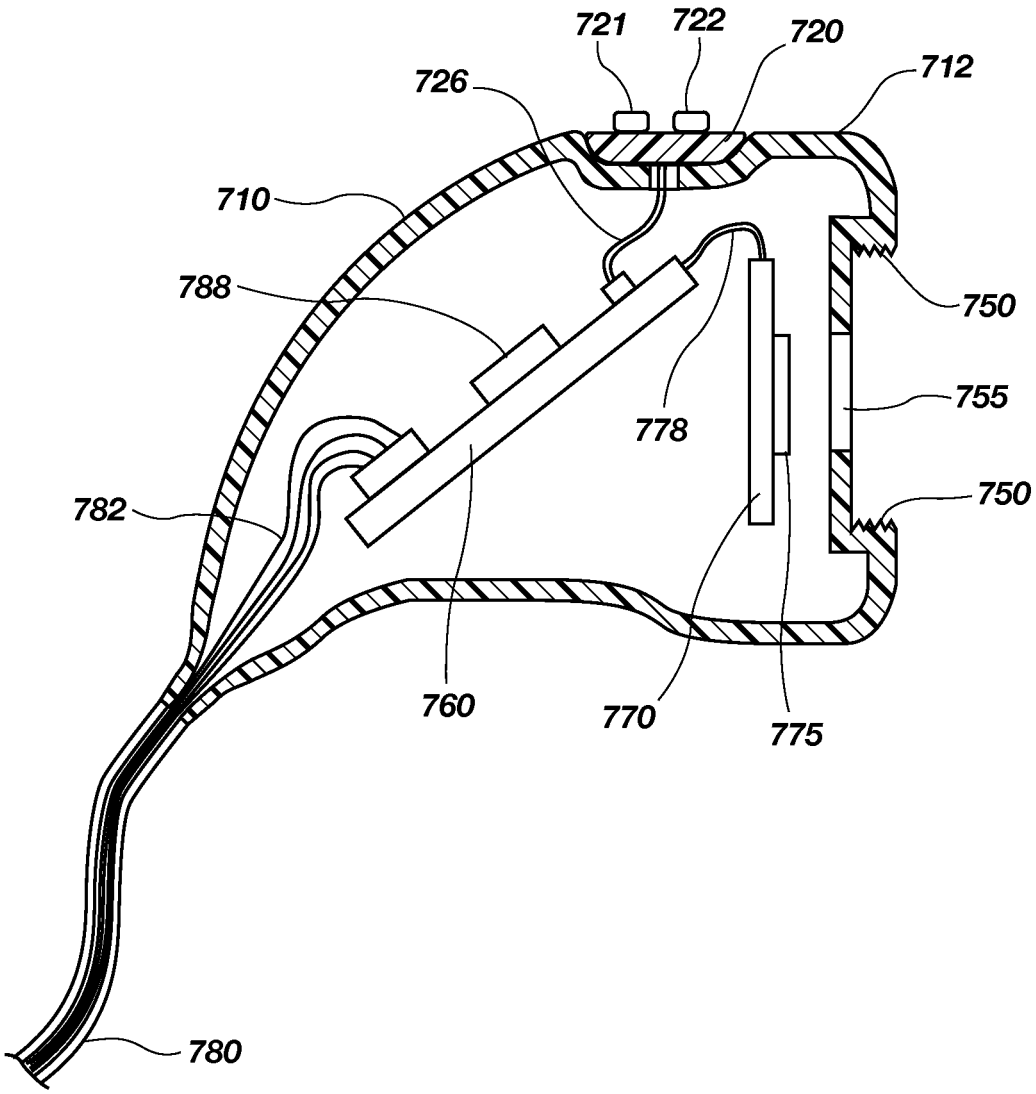

FIG. 7

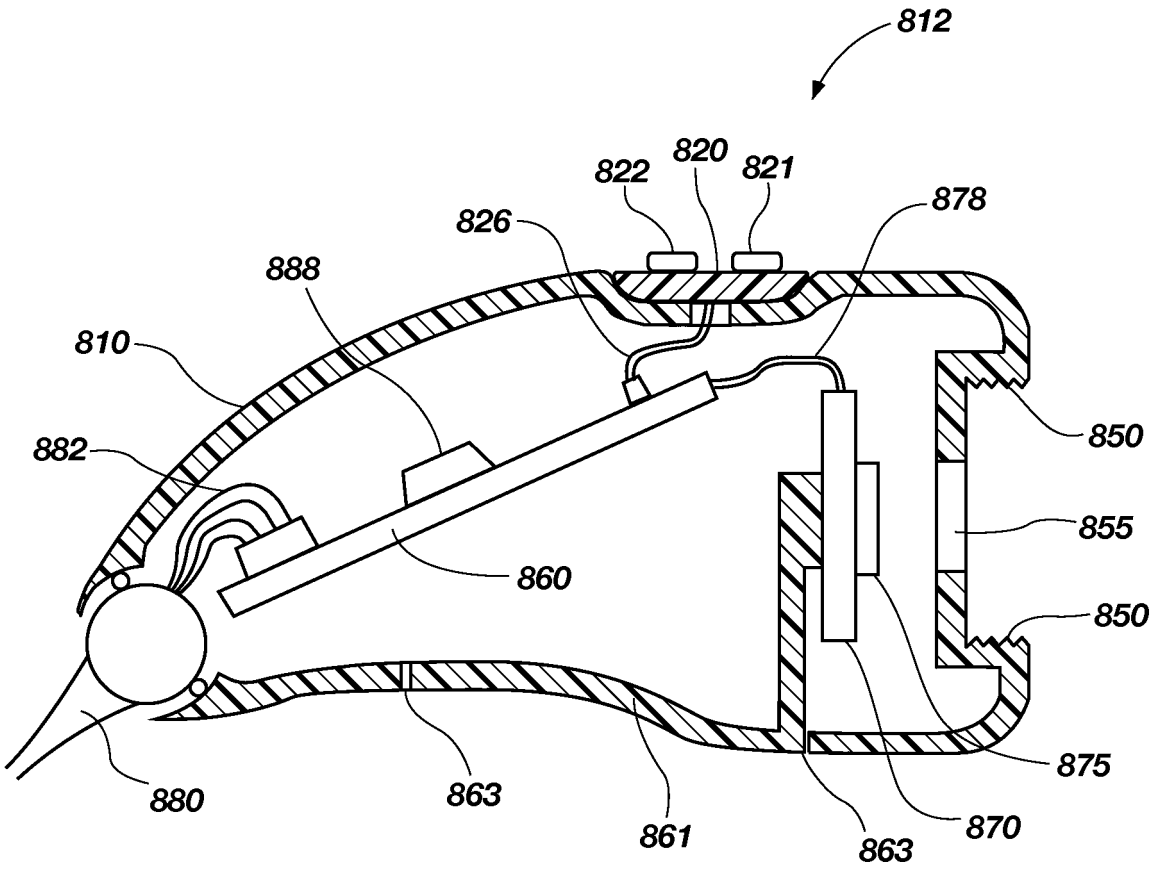
812
822
820
821
878
826
888
810
882
850
855
860
850
875
880
863
861
863
870

FIG. 8

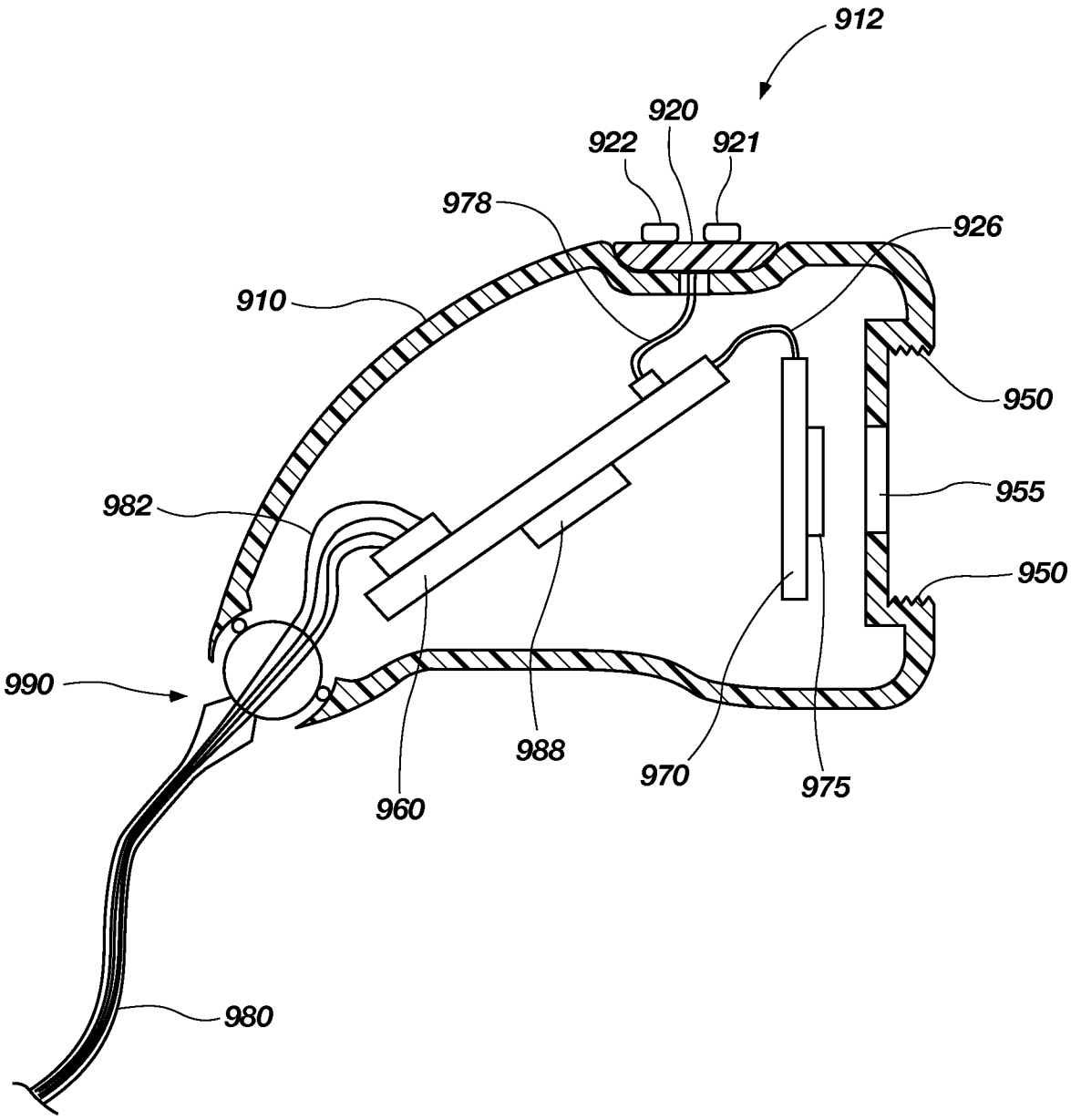
912
920
922
921
978
926
910
950
955
982
950
990
988
970
975
960
980

FIG. 9

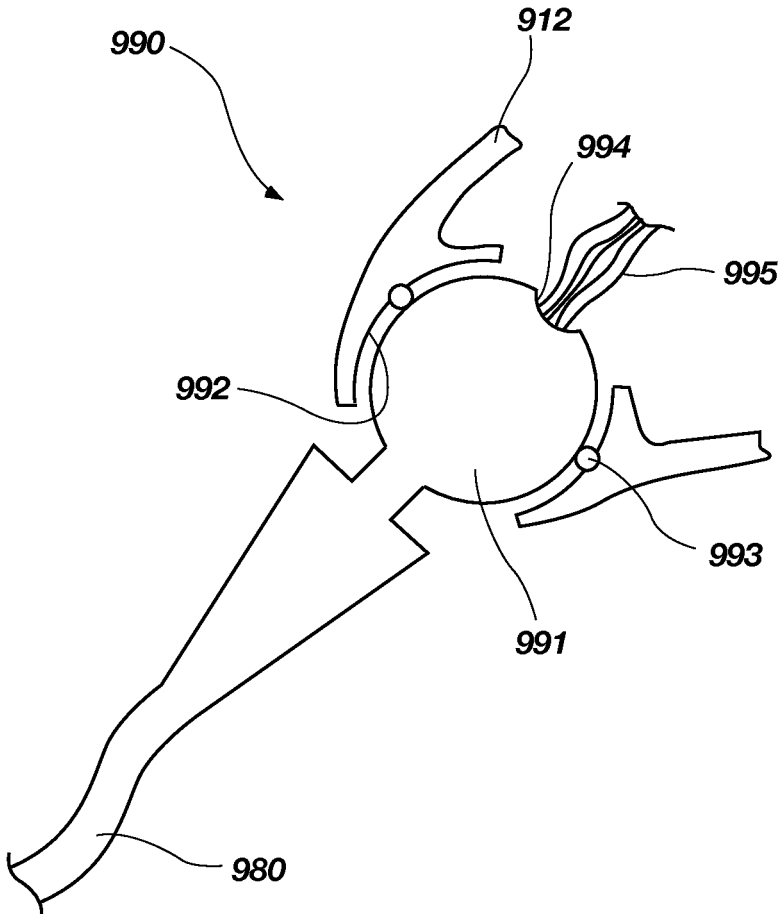

FIG. 10

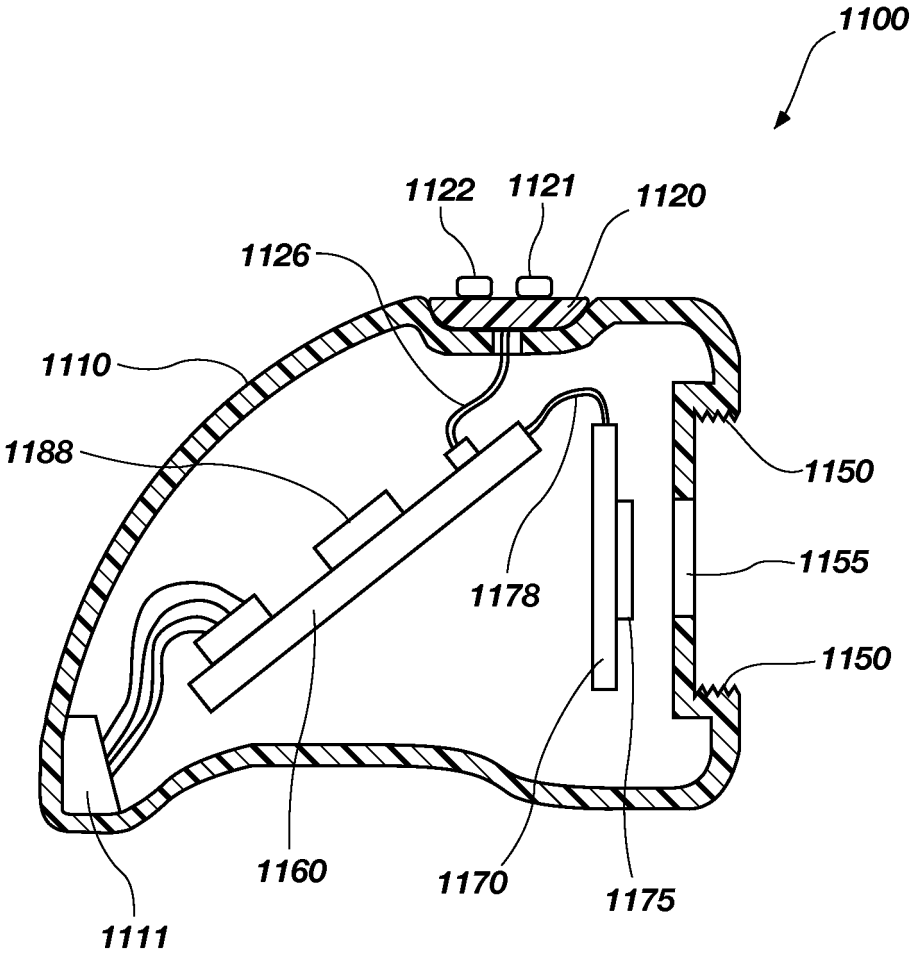
1100
1122
1121
1120
1126
1110
1188
1150
1155
1178
1150
1160
1170
1175
1111

FIG. 11

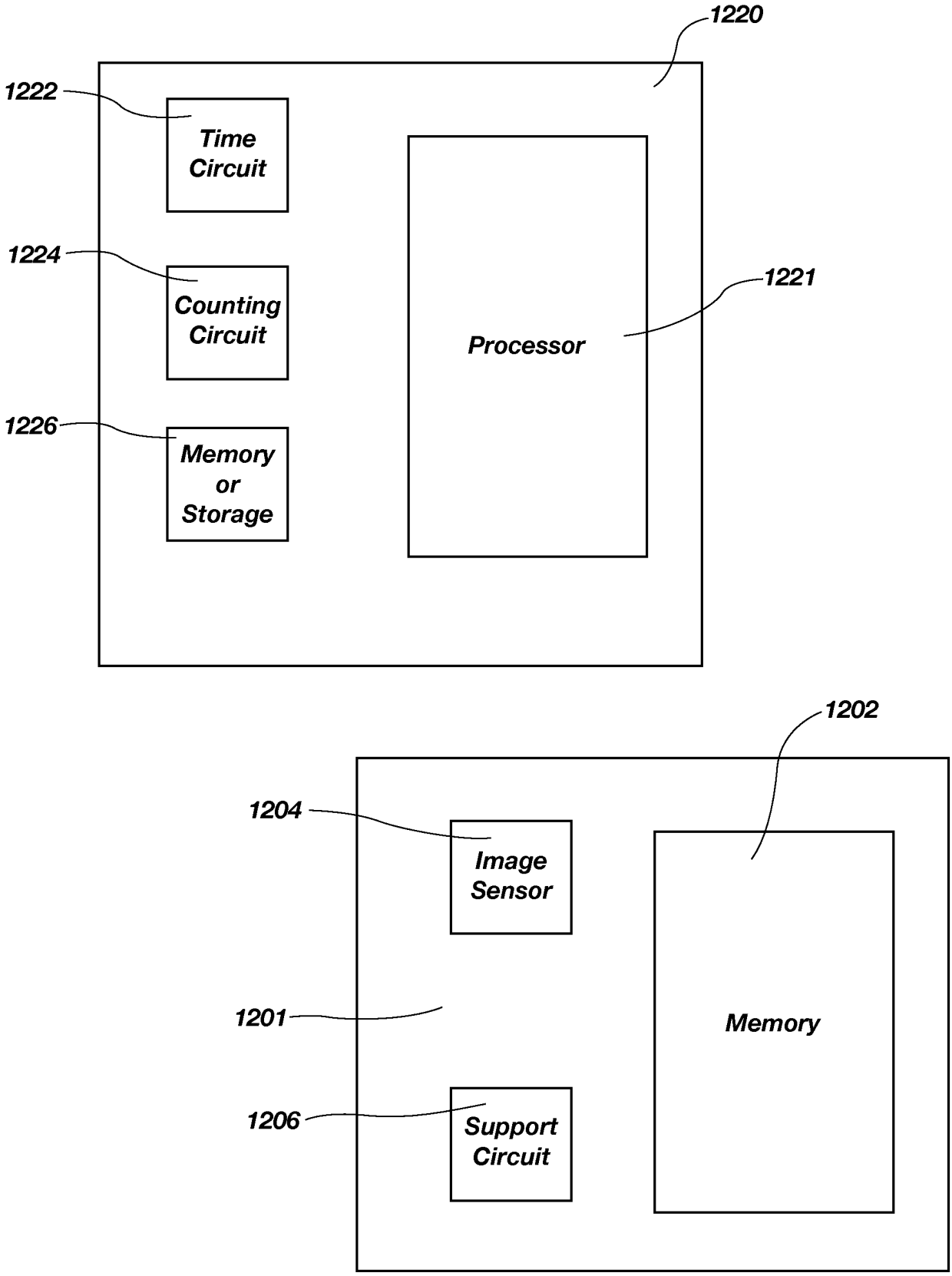
1220
1222
Time Circuit
1224
Counting Circuit
1226
Memory or Storage
Processor
1221
1202
1204
Image Sensor
1201
1206
Support Circuit
Memory

FIG. 12

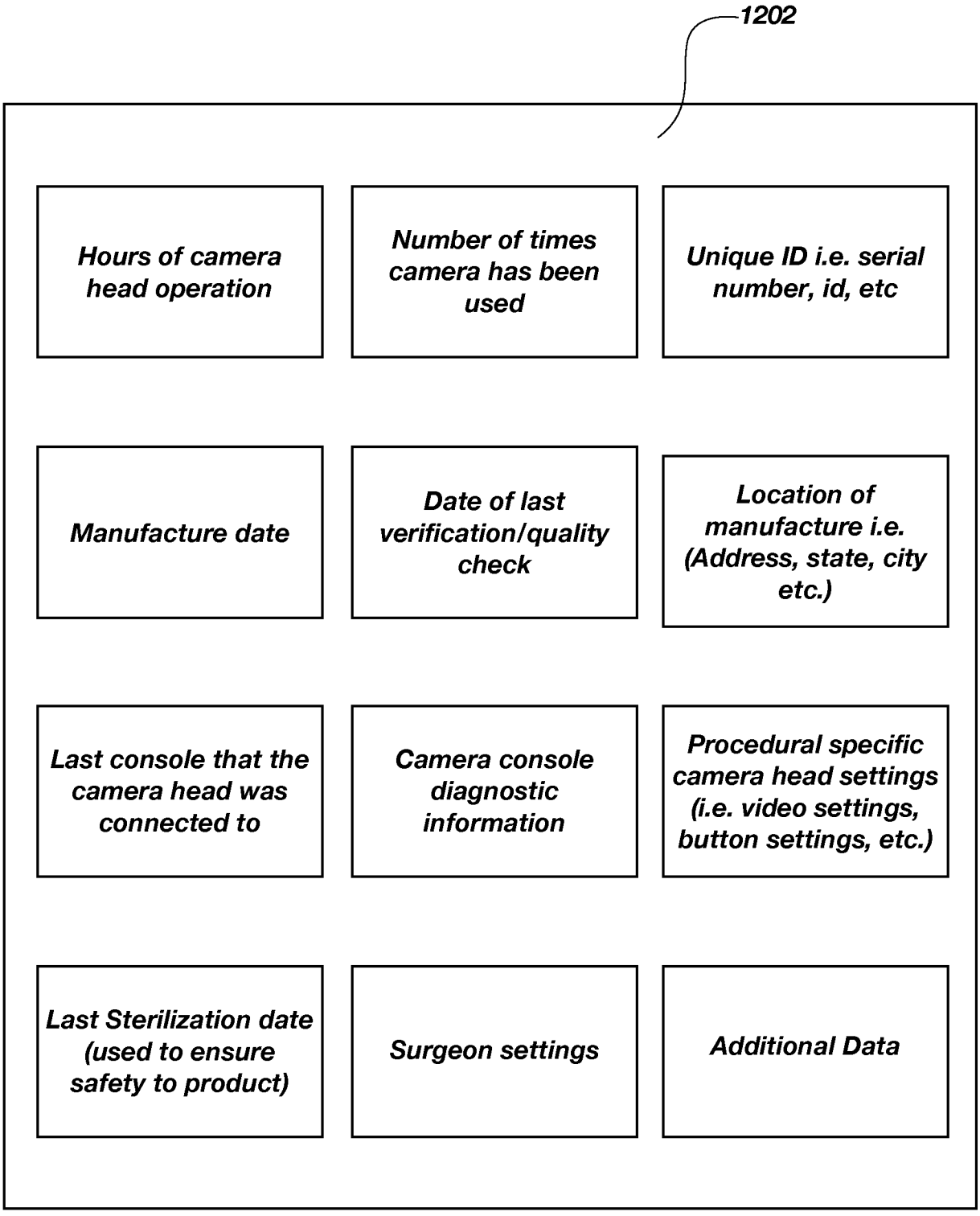
1202
Hours of camera head operation
Number of times camera has been used
Unique ID i.e. serial number, id, etc
Manufacture date
Date of last verification/quality check
Location of manufacture i.e. (Address, state, city etc.)
Last console that the camera head was connected to
Camera console diagnostic information
Procedural specific camera head settings (i.e. video settings, button settings, etc.)
Last Sterilization date (used to ensure safety to product)
Surgeon settings
Additional Data

FIG. 13

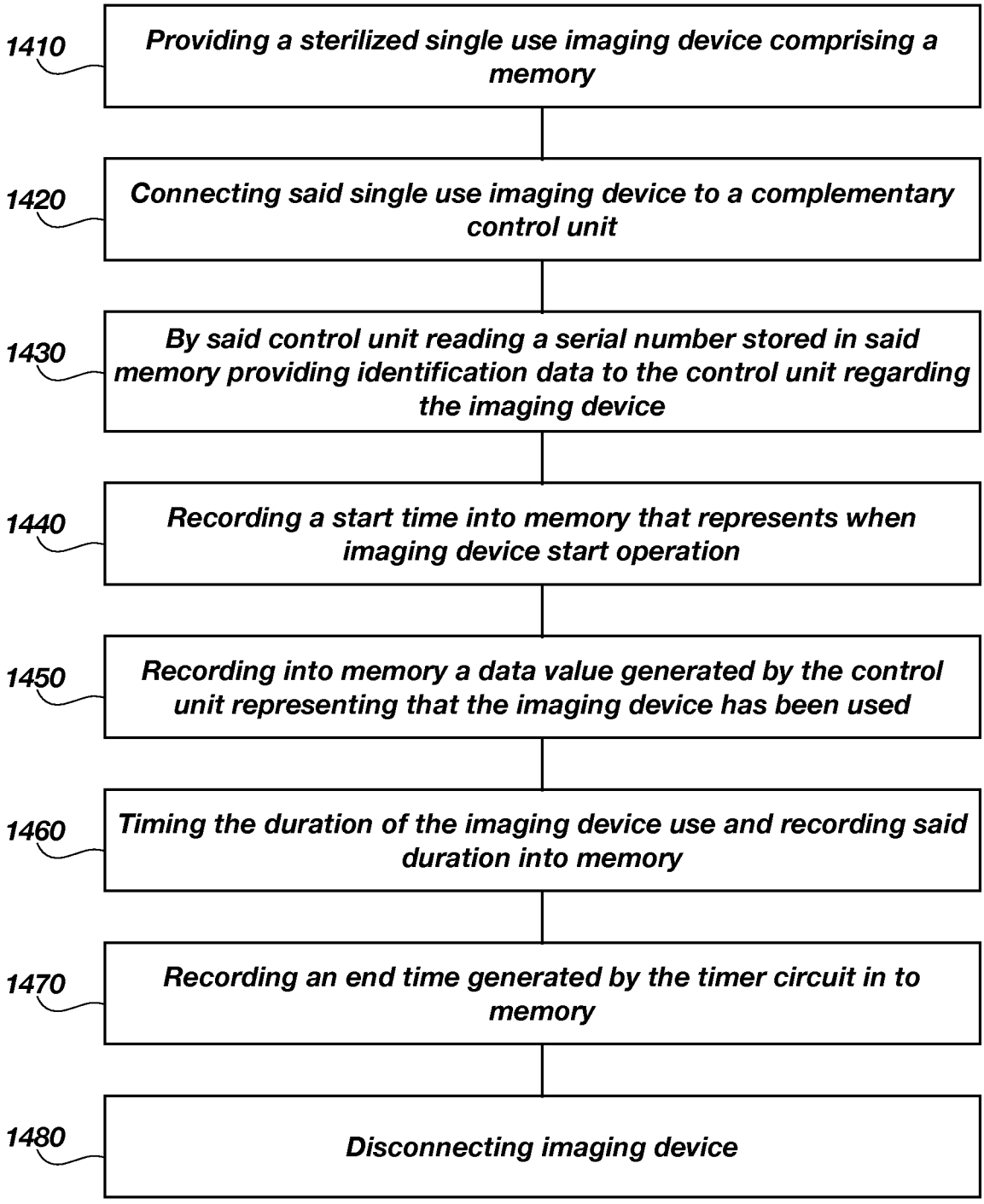
1410
Providing a sterilized single use imaging device comprising a memory
1420
Connecting said single use imaging device to a complementary control unit
1430
By said control unit reading a serial number stored in said memory providing identification data to the control unit regarding the imaging device
1440
Recording a start time into memory that represents when imaging device start operation
1450
Recording into memory a data value generated by the control unit representing that the imaging device has been used
1460
Timing the duration of the imaging device use and recording said duration into memory
1470
Recording an end time generated by the timer circuit in to memory
1480
Disconnecting imaging device

FIG. 14

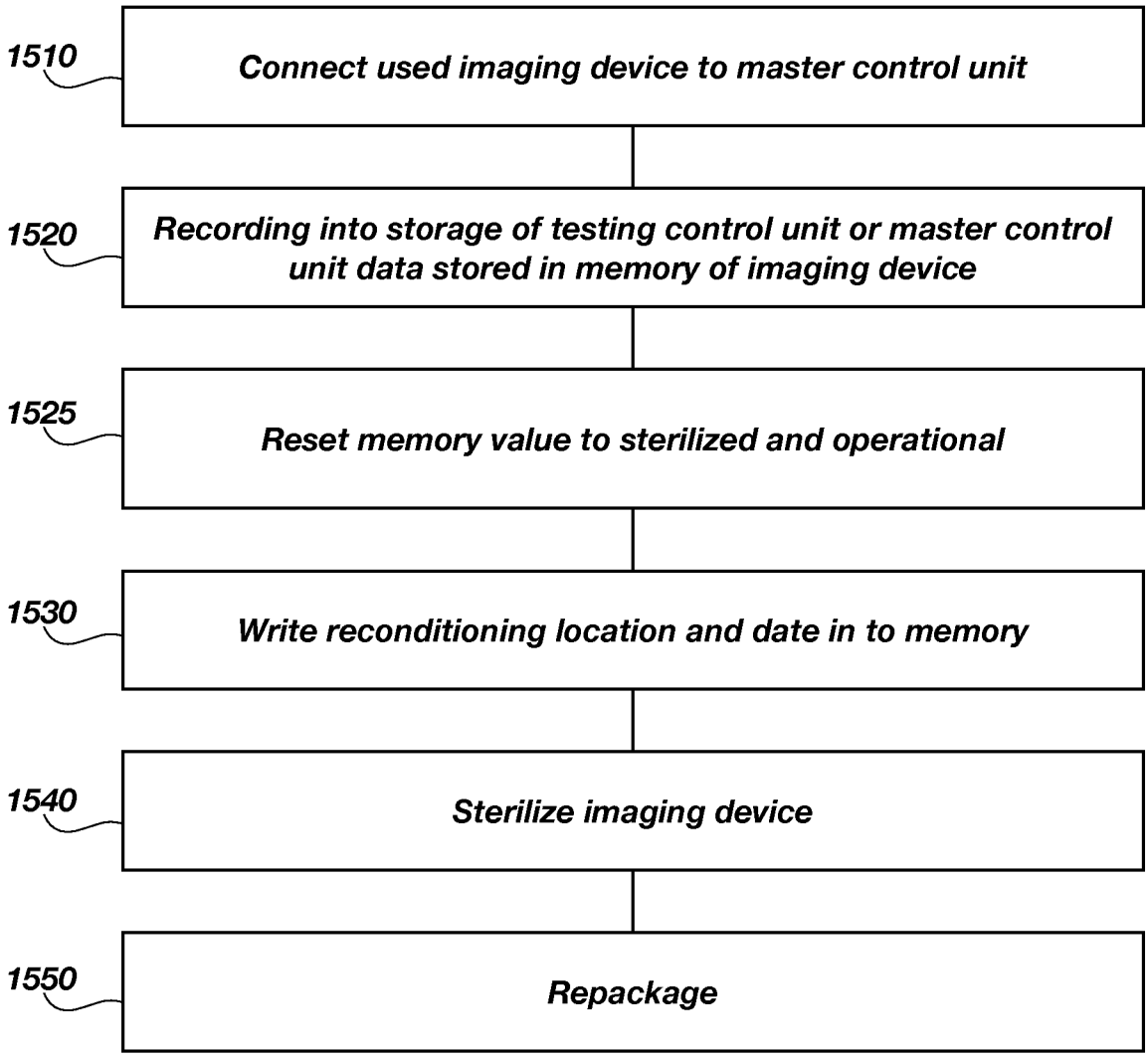
1510
Connect used imaging device to master control unit
1520
Recording into storage of testing control unit or master control unit data stored in memory of imaging device
1525
Reset memory value to sterilized and operational
1530
Write reconditioning location and date in to memory
1540
Sterilize imaging device
1550
Repackage

FIG. 15

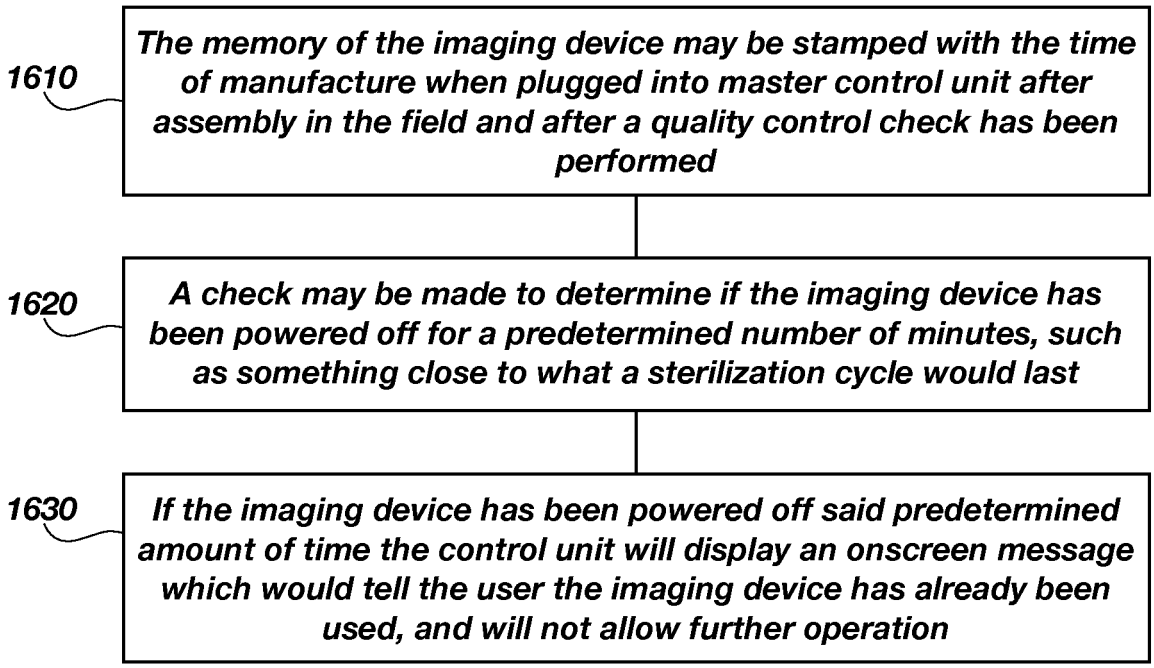
1610
The memory of the imaging device may be stamped with the time of manufacture when plugged into master control unit after assembly in the field and after a quality control check has been performed
1620
A check may be made to determine if the imaging device has been powered off for a predetermined number of minutes, such as something close to what a sterilization cycle would last
1630
If the imaging device has been powered off said predetermined amount of time the control unit will display an onscreen message which would tell the user the imaging device has already been used, and will not allow further operation

FIG. 16

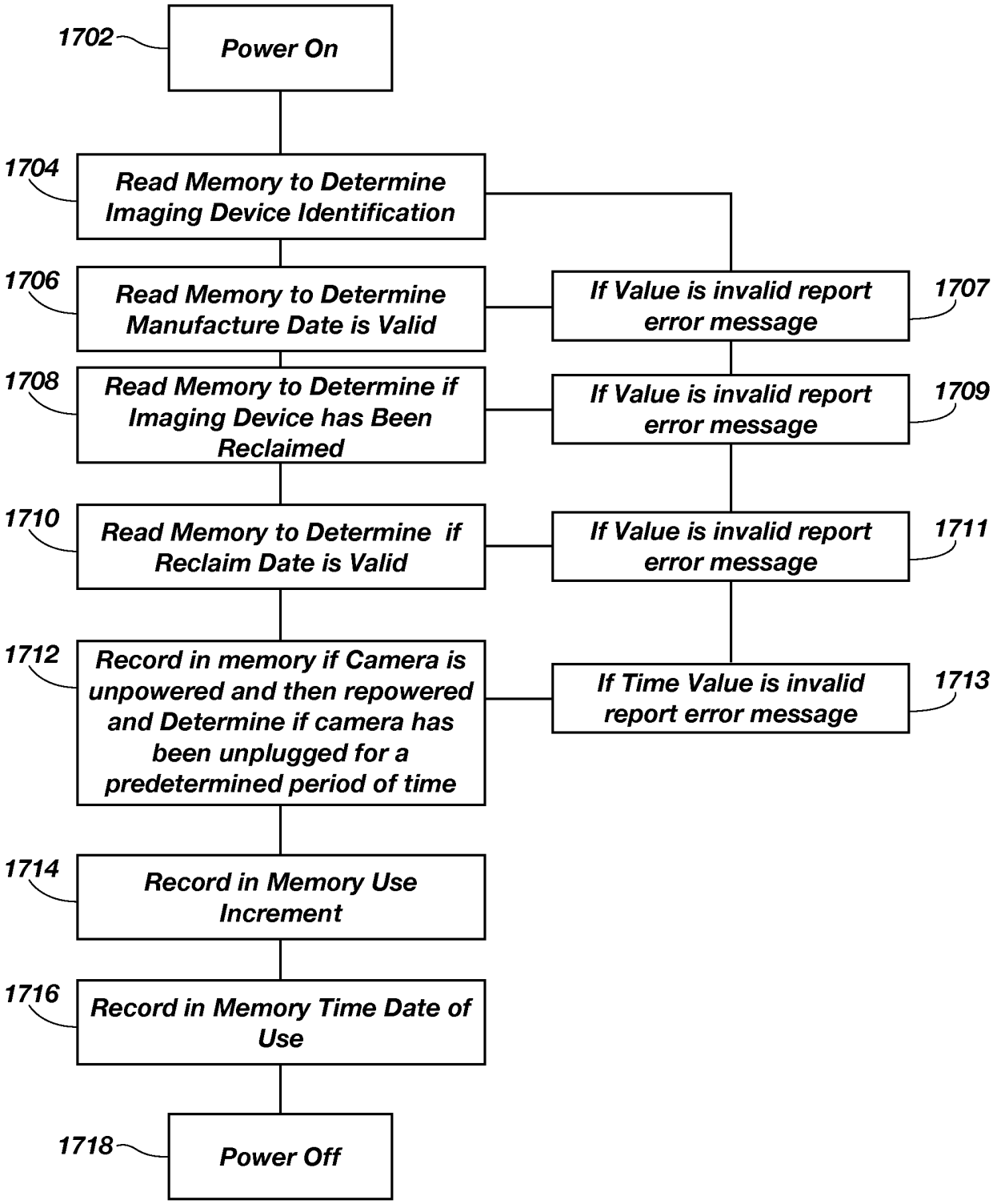
1702
Power On
1704
Read Memory to Determine Imaging Device Identification
1706
Read Memory to Determine Manufacture Date is Valid
1707
If Value is invalid report error message
1708
Read Memory to Determine if Imaging Device has Been Reclaimed
1709
If Value is invalid report error message
1710
Read Memory to Determine if Reclaim Date is Valid
1711
If Value is invalid report error message
1712
Record in memory if Camera is unpowered and then repowered and Determine if camera has been unplugged for a predetermined period of time
1713
If Time Value is invalid report error message
1714
Record in Memory Use Increment
1716
Record in Memory Time Date of Use
1718
Power Off

FIG. 17

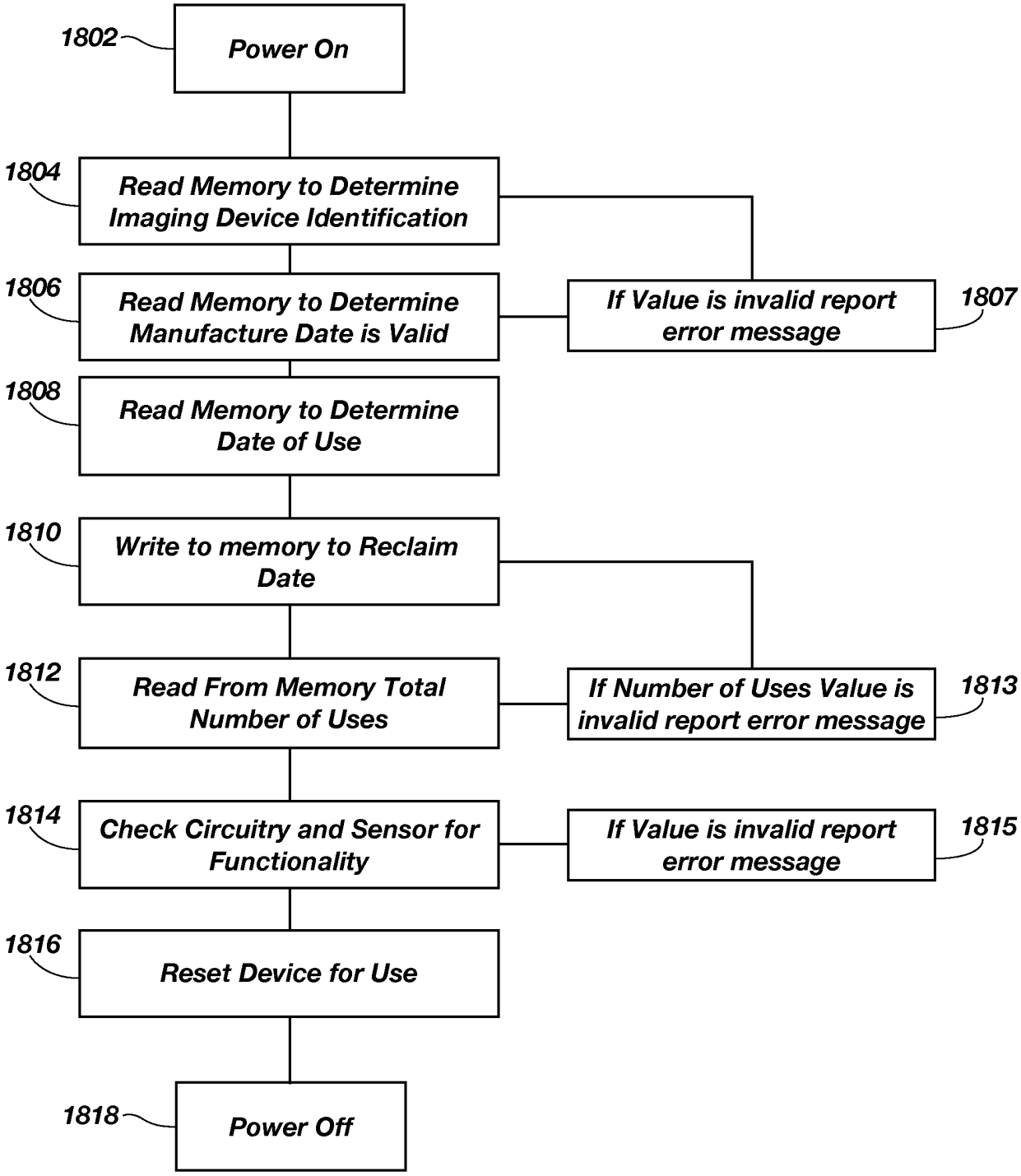
1802
Power On
1804
Read Memory to Determine Imaging Device Identification
1806
Read Memory to Determine Manufacture Date is Valid
If Value is invalid report error message
1807
1808
Read Memory to Determine Date of Use
1810
Write to memory to Reclaim Date
1812
Read From Memory Total Number of Uses
If Number of Uses Value is invalid report error message
1813
1814
Check Circuitry and Sensor for Functionality
If Value is invalid report error message
1815
1816
Reset Device for Use
1818
Power Off

FIG. 18

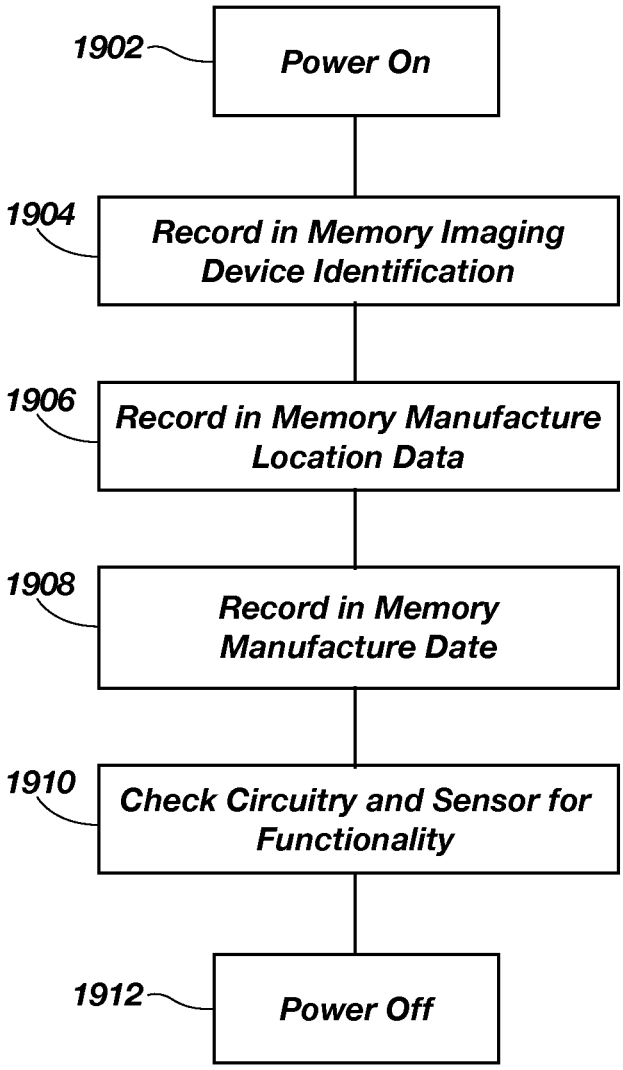
1902
Power On
1904
Record in Memory Imaging Device Identification
1906
Record in Memory Manufacture Location Data
1908
Record in Memory Manufacture Date
1910
Check Circuitry and Sensor for Functionality
1912
Power Off

FIG. 19

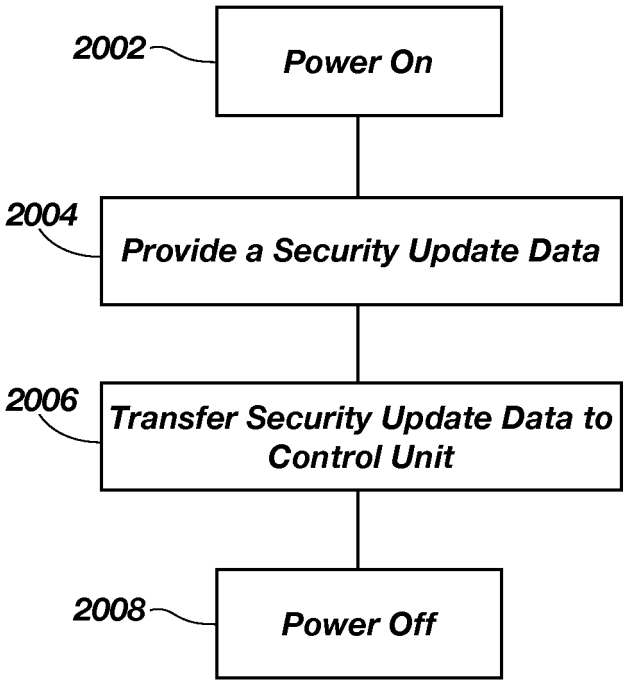
2002
Power On
2004
Provide a Security Update Data
2006
Transfer Security Update Data to Control Unit
2008
Power Off

FIG. 20

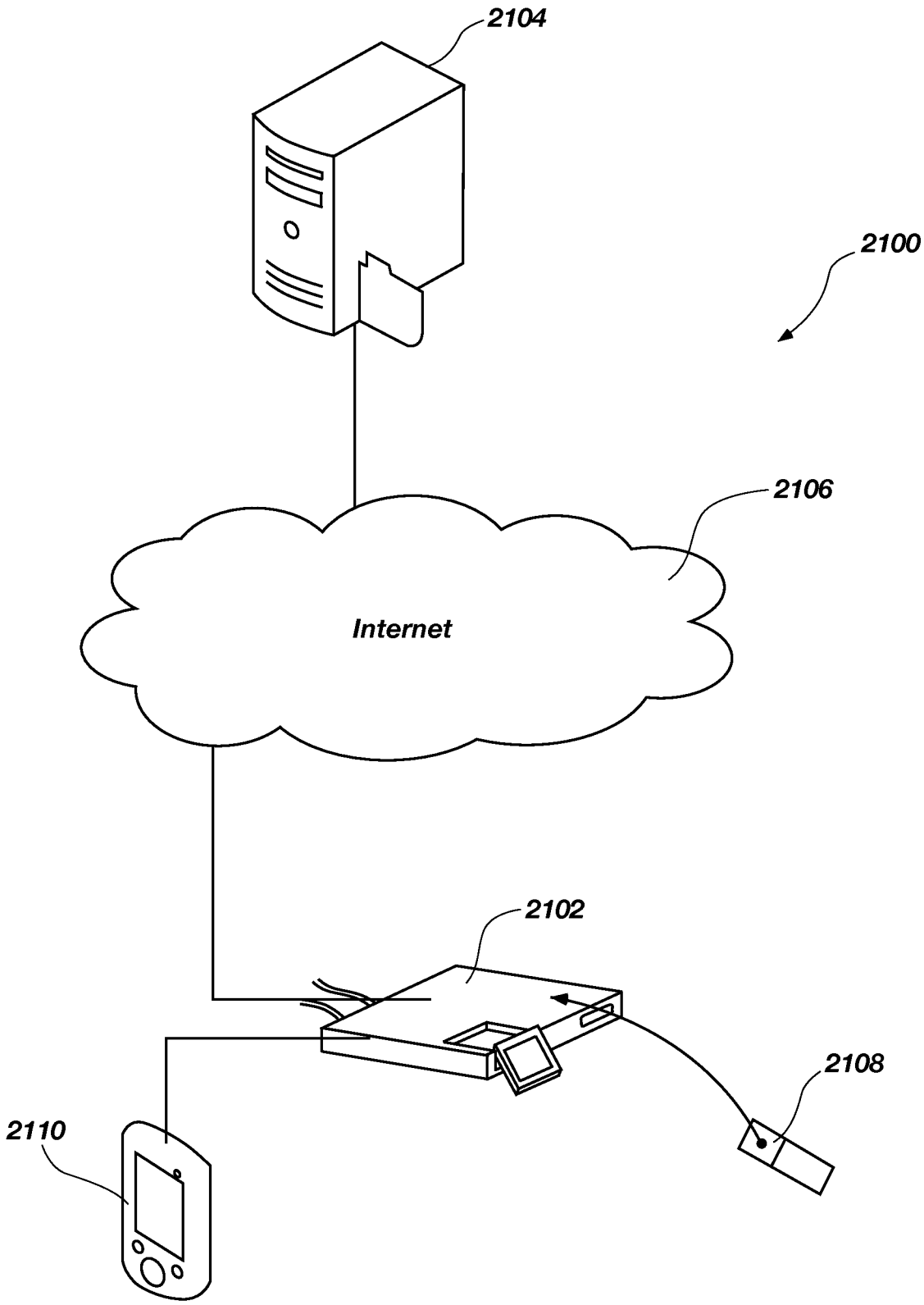

FIG. 21

专利名称(译)	与无菌环境单次使用成像设备相关的系统和方法		
公开(公告)号	EP2465008B1	公开(公告)日	2020-06-17
申请号	EP2010808849	申请日	2010-08-13
申请(专利权)人(译)	OLIVE医疗公司		
当前申请(专利权)人(译)	DePuy公司SYNTHES PRODUCTS，INC.		
[标]发明人	TALBERT JOSHUA D HENLEY JEREMIAH D WICHERN DONALD M		
发明人	TALBERT, JOSHUA, D. HENLEY, JEREMIAH, D. WICHERN, DONALD, M.		
IPC分类号	G03B17/02 A61B1/00		
CPC分类号	A61B1/0002 A61B1/00055 A61B1/00057 A61B1/00059 A61B1/00062 A61B1/042 G03B17/02 G02B23/24		
优先权	12/541067 2009-08-13 US		
其他公开文献	EP2465008A4 EP2465008A1		
外部链接	Espacenet		

摘要(译)

公开和描述了用于为无菌环境提供一次性成像装置的系统，设备和方法。 用于通用外科手术（包括但不限于：关节镜，腹腔镜，妇科和泌尿科手术）的单次使用高清相机可以包括无菌的成像设备，并设计成可确保单次使用。 成像装置可以具有被封装在壳体中的单个成像传感器，即CCD（电荷耦合器件）或CMOS（互补金属氧化物半导体）。 成像设备还可包括使用C型安装螺纹或其他专有或独特的连接方法将其连接到光学耦合设备的能力。 成像装置可以进一步包括电缆，该电缆用于向照相机控制单元和从照相机控制单元传输数据。

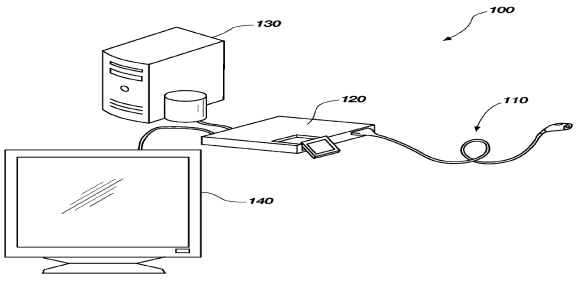

FIG. 1

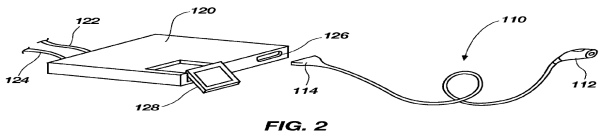

FIG. 2