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(54) **METHOD OF FLUOROSCOPIC SURGICAL
REGISTRATION**

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A61B 90/50 (2016.01)

A61B 90/98 (2016.01)

A61G 13/12 (2006.01)

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(52) **U.S. Cl.**

CPC *A61B 34/20* (2016.02); *A61B 34/30* (2016.02); *A61B 90/361* (2016.02); *A61B 90/50* (2016.02); *A61B 90/98* (2016.02); *A61B 2034/105* (2016.02); *A61B 2034/2072* (2016.02); *A61B 2090/061* (2016.02); *A61B 2090/376* (2016.02); *A61B 2090/392* (2016.02); *A61G 13/124* (2013.01)

ABSTRACT

Related U.S. Application Data

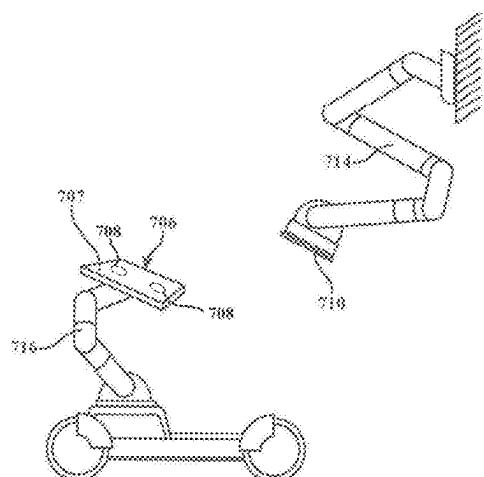
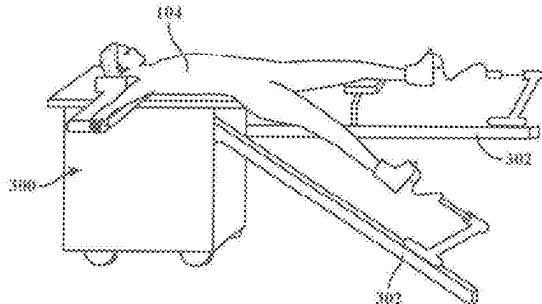
- (63) Continuation of application No. 16/817,337, filed on Mar. 12, 2020, now Pat. No. 12,324,630.
(60) Provisional application No. 62/817,539, filed on Mar. 12, 2019.

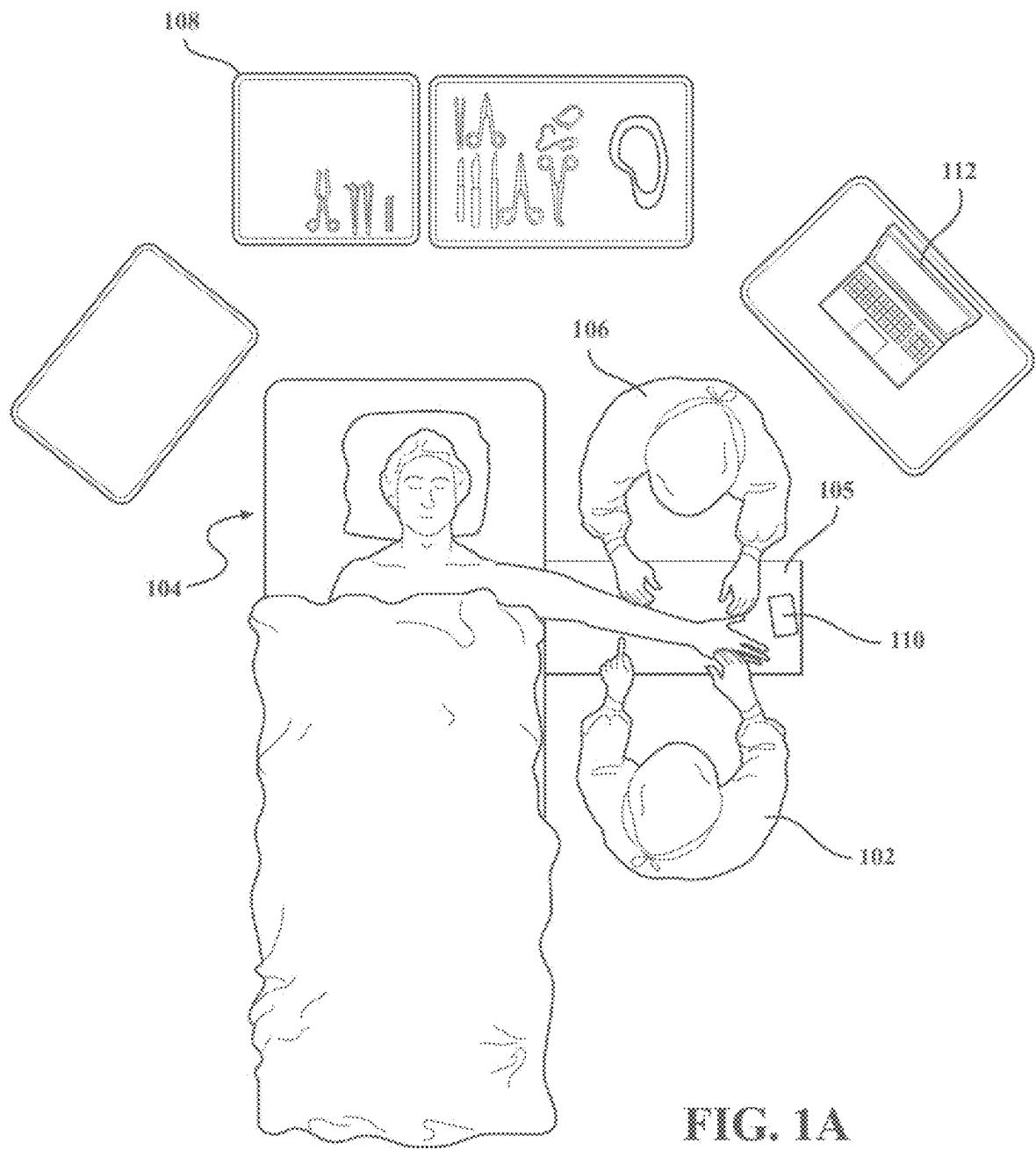
Methods and systems for x-ray and fluoroscopic image capture and, in particular, to a versatile, multimode imaging system incorporating a hand-held x-ray emitter operative to capture digital or thermal images of a target; a stage operative to capture static x-ray and dynamic fluoroscopic images of the target; a system for the tracking and positioning of the x-ray emission; a device to automatically limit the field of the x-ray emission; and methods of use and use of such systems to register a virtual model of an anatomic structure to the corresponding anatomic structure.

Publication Classification

(51) **Int. Cl.**

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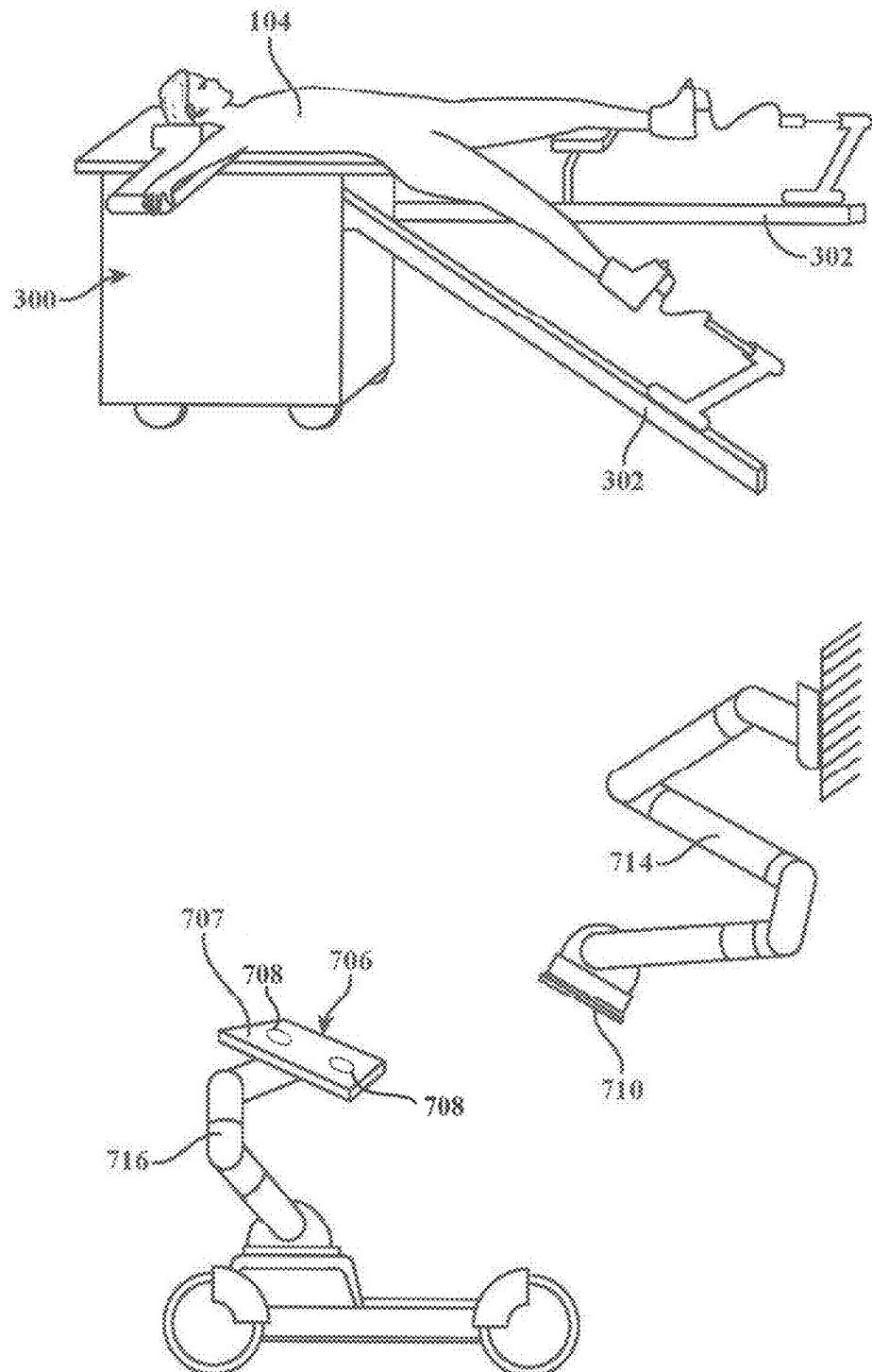


FIG. 1B

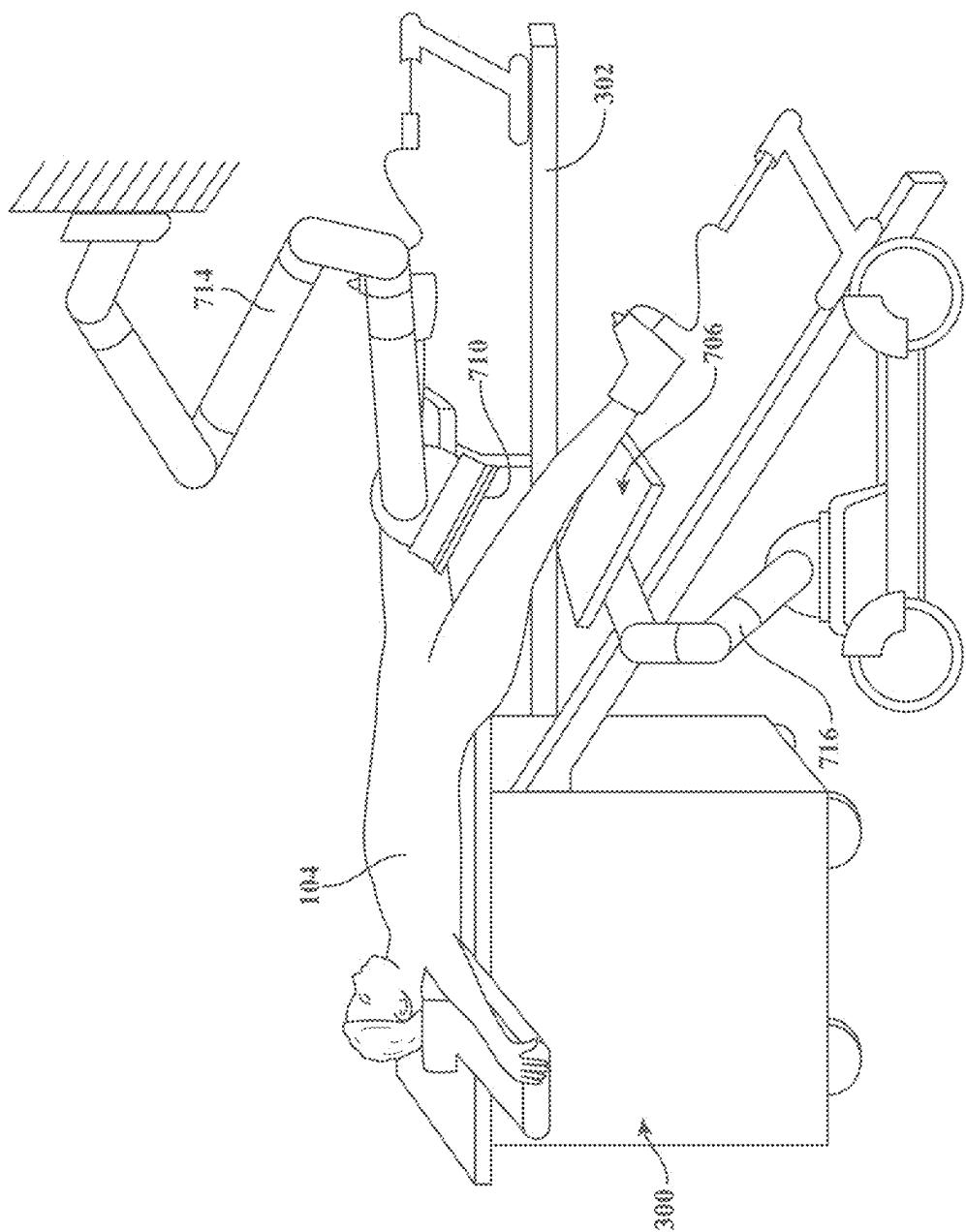


FIG. 1C

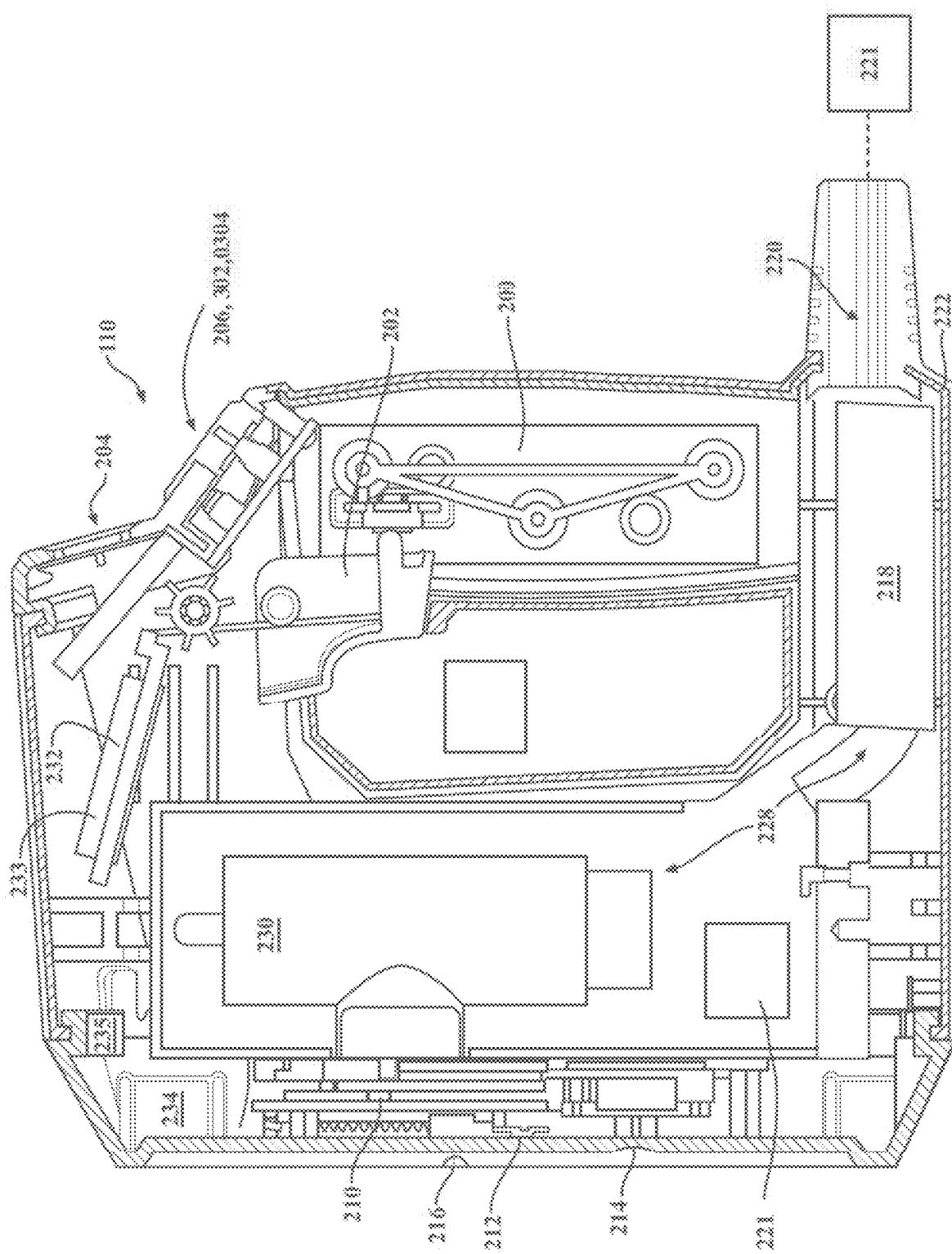


FIG. 2

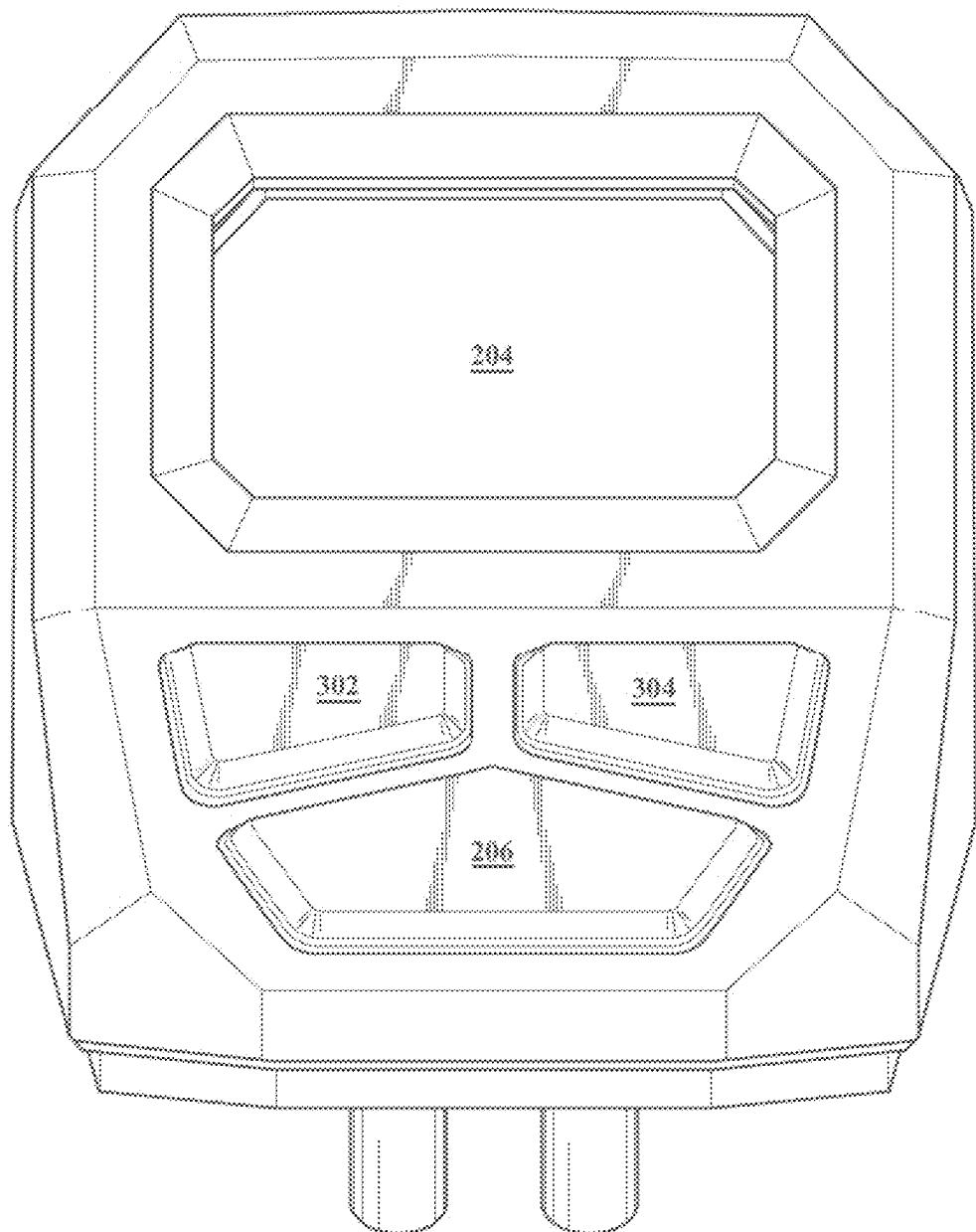


FIG. 3

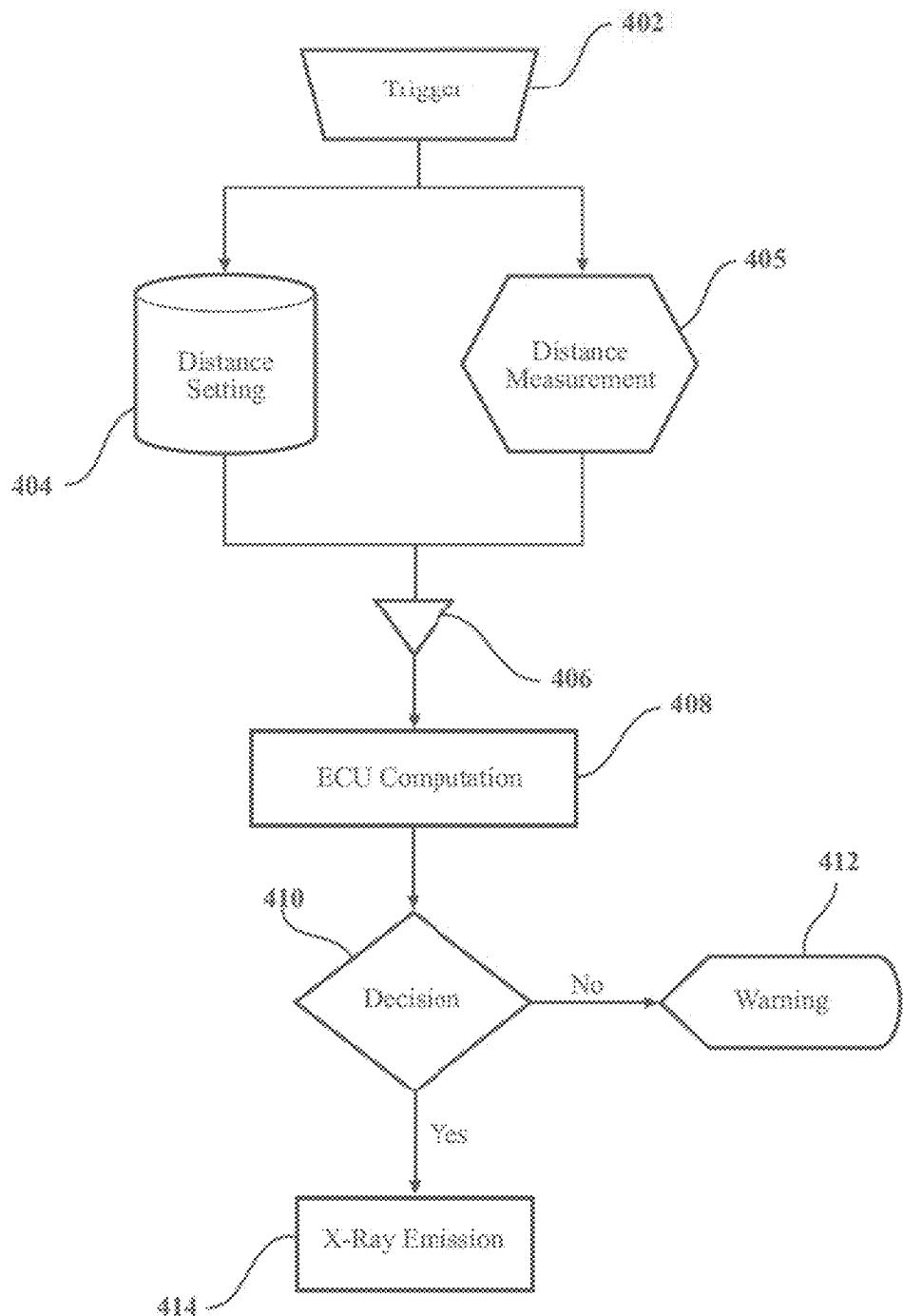
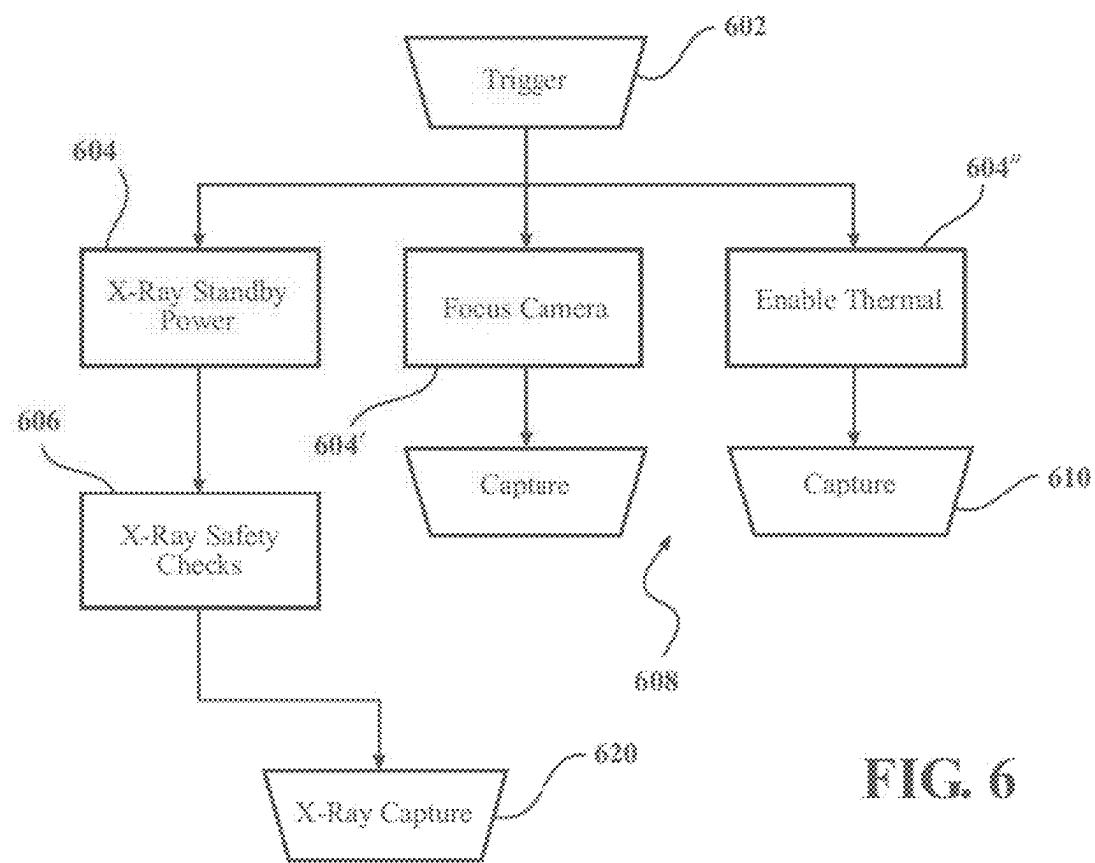
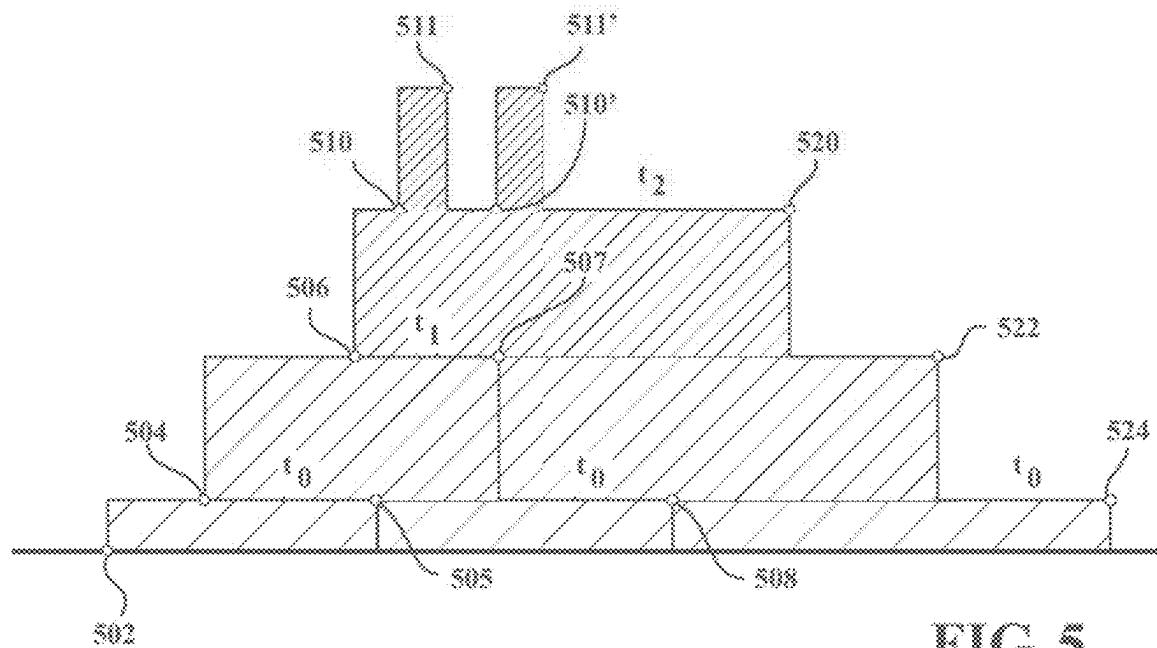


FIG. 4



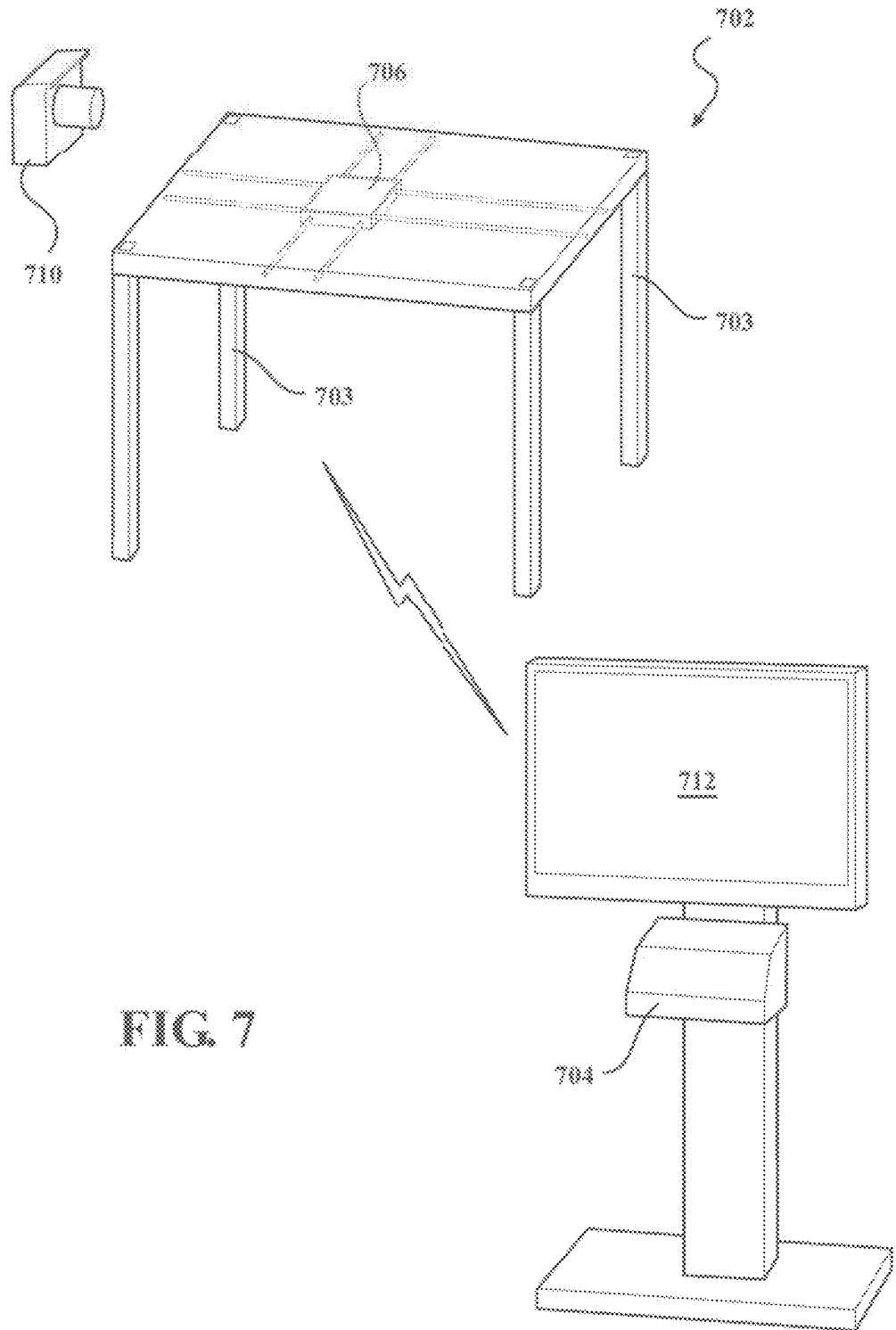


FIG. 7

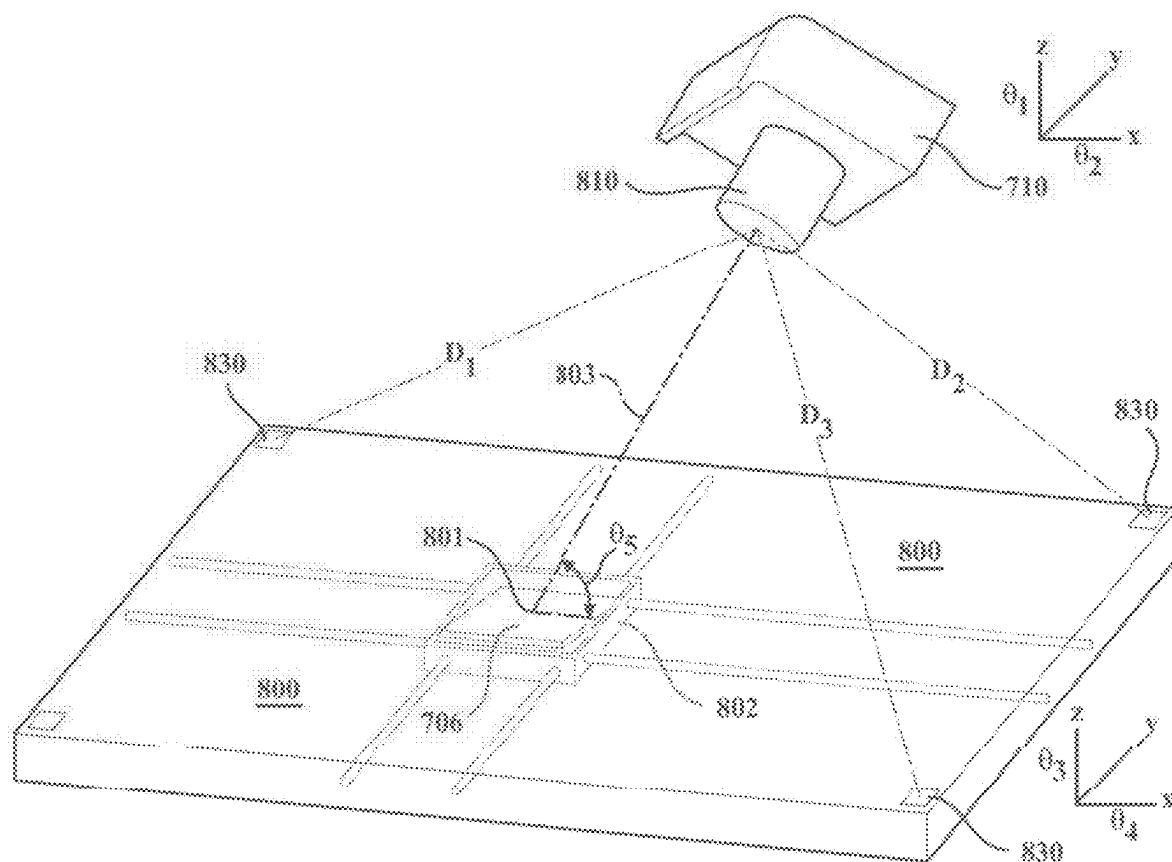


FIG. 8A

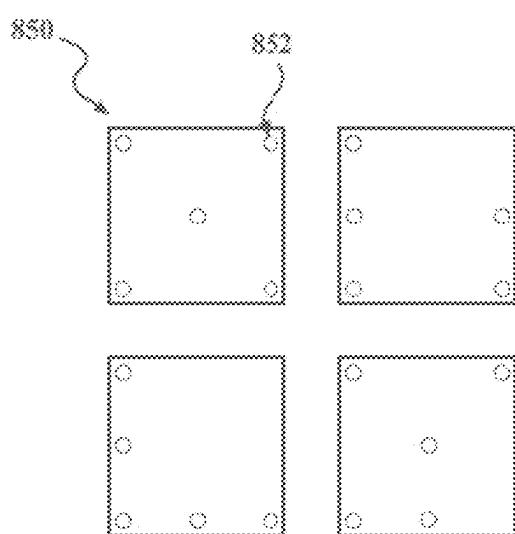


FIG. 8B

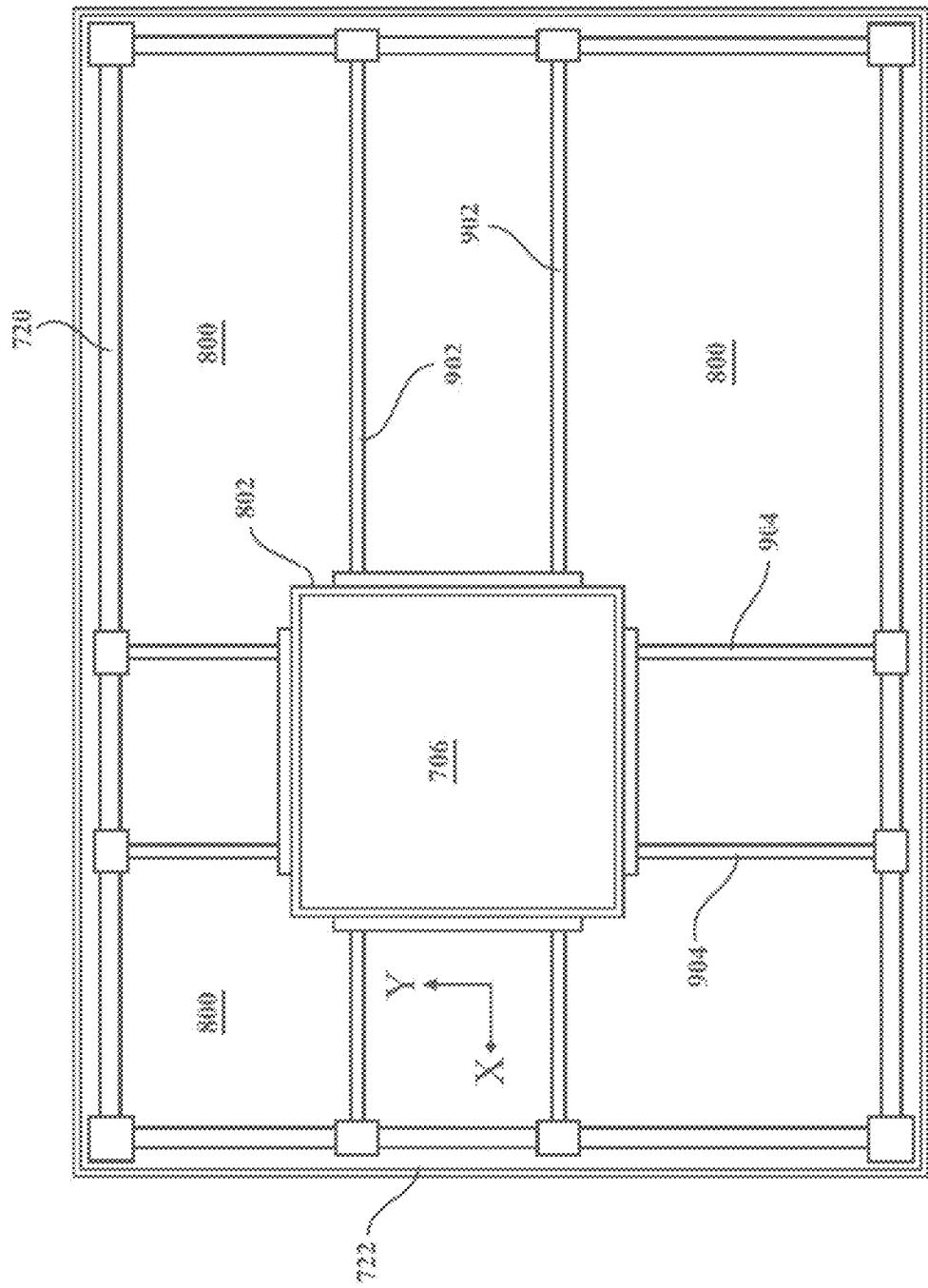


FIG. 9

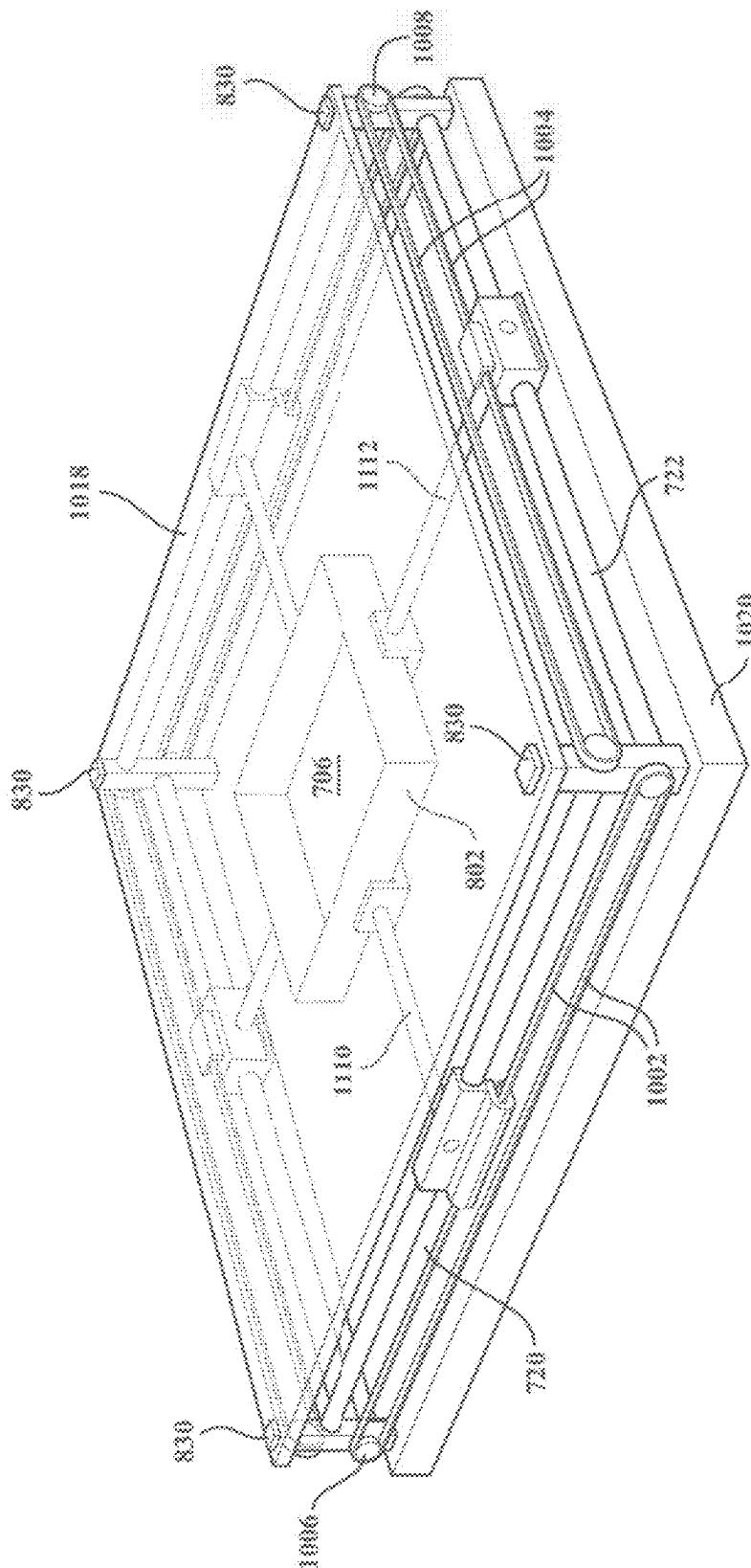


FIG. 10A

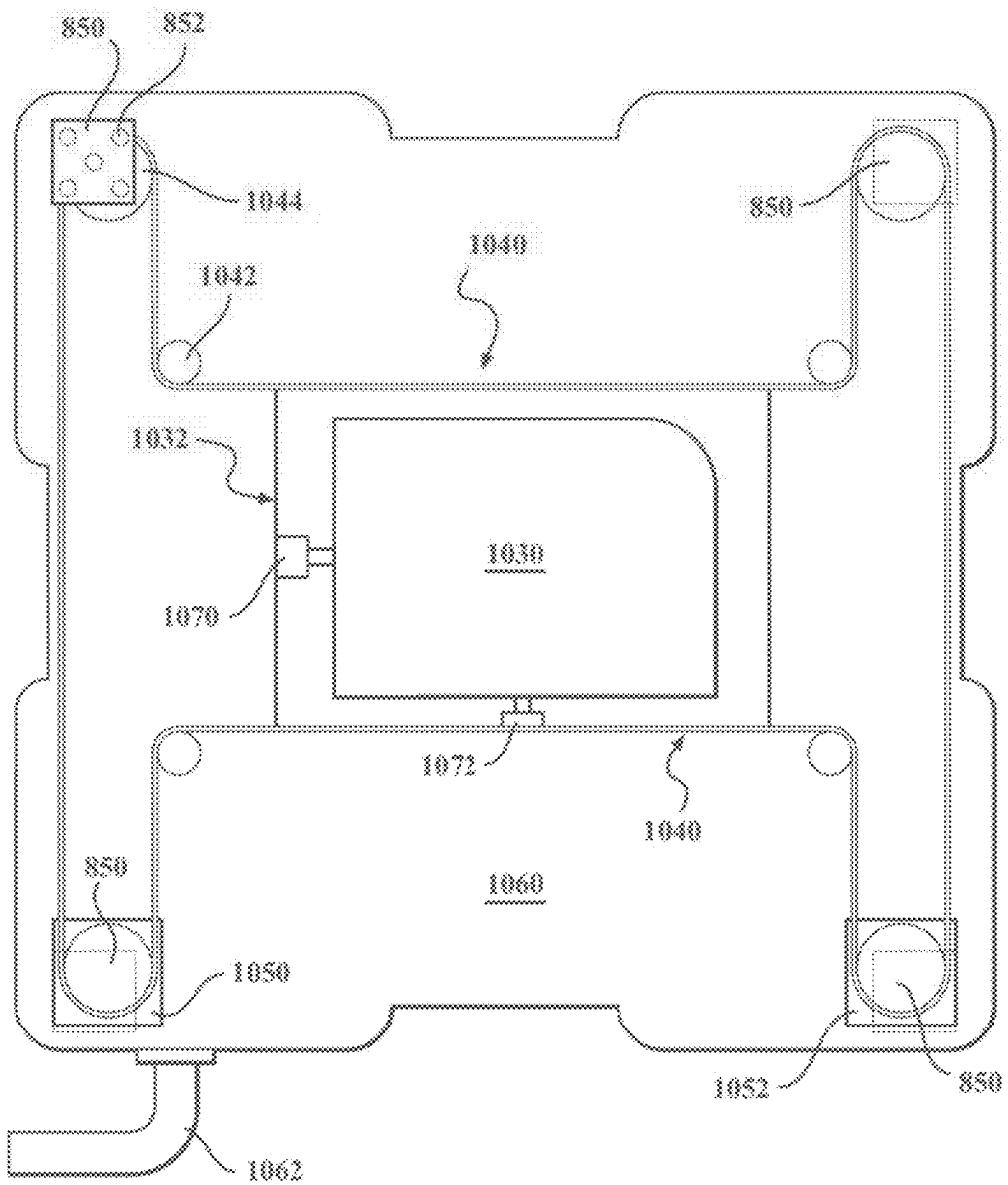


FIG. 10B

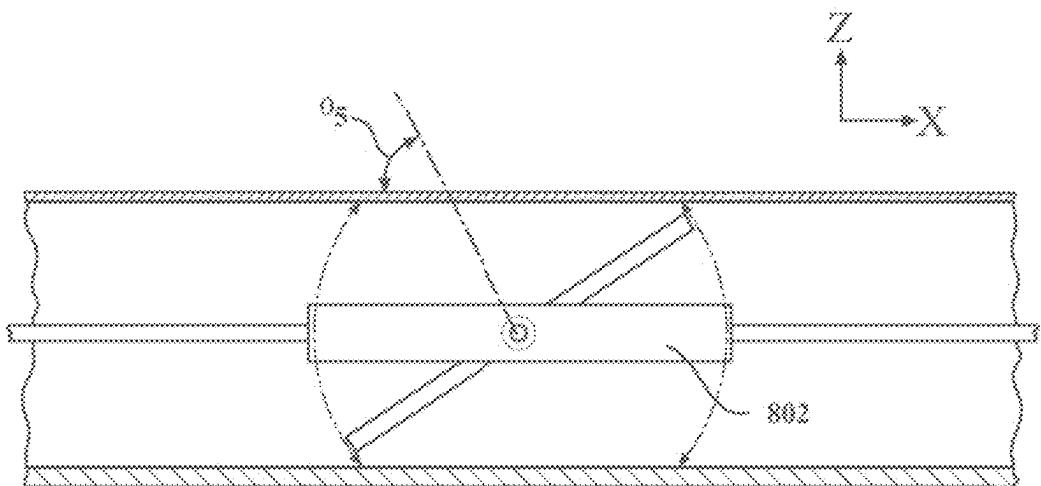


FIG. 11A

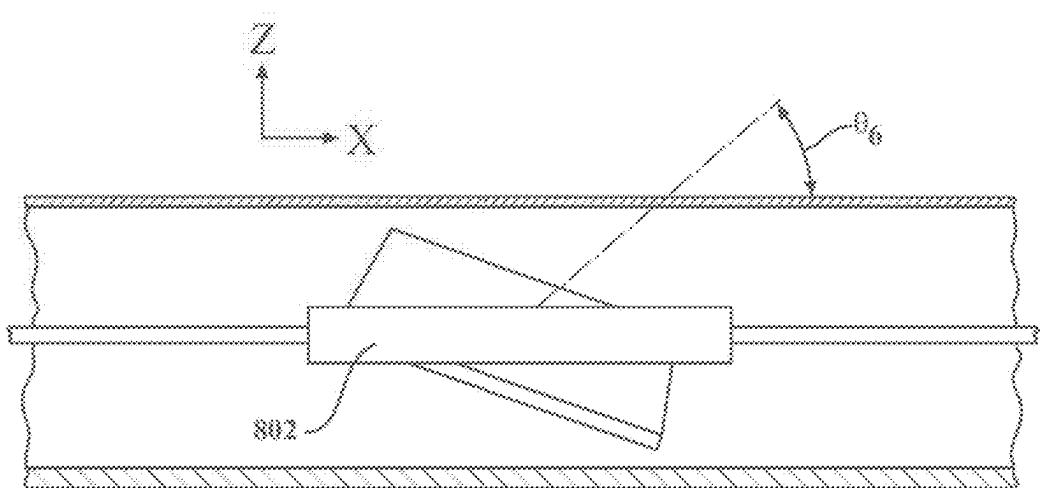
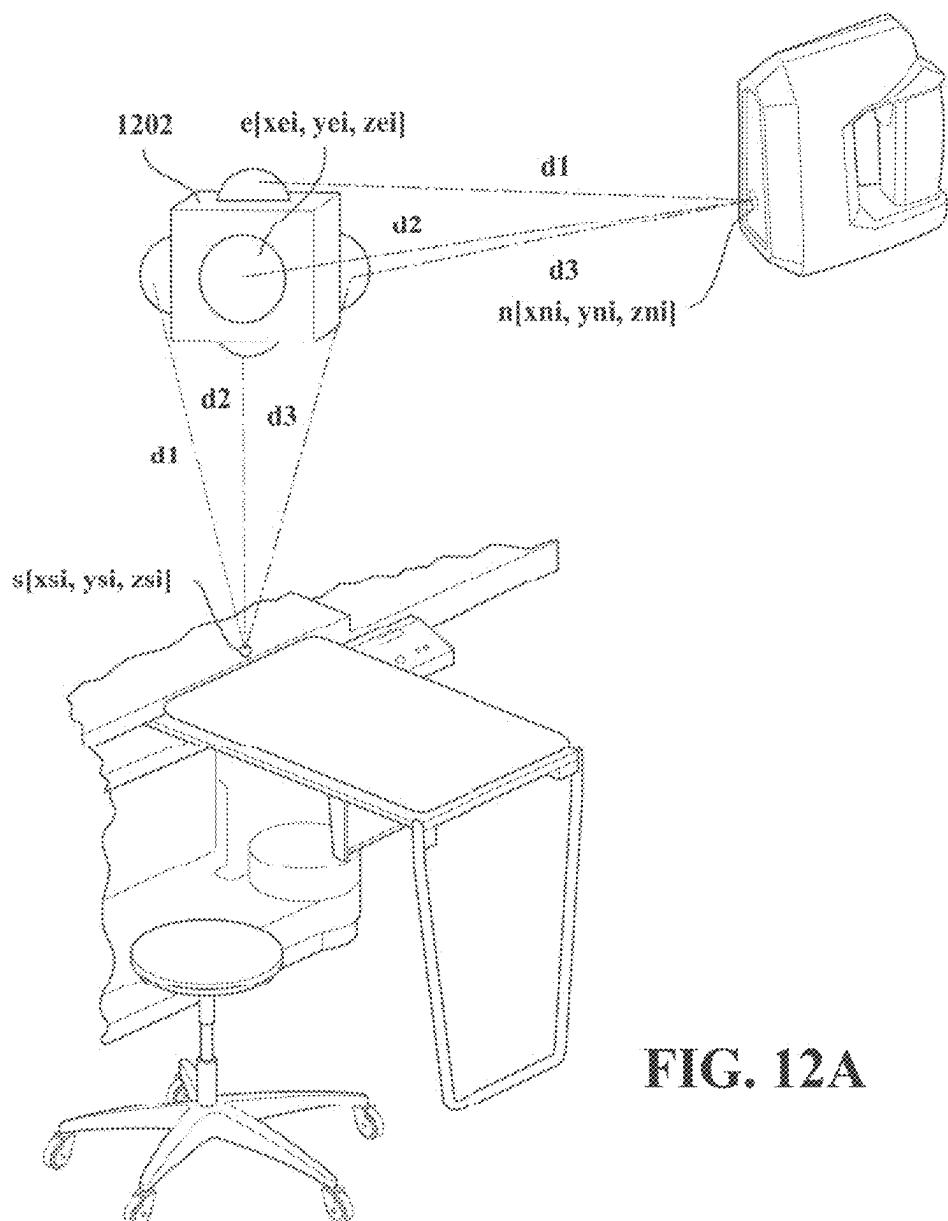


FIG. 11B



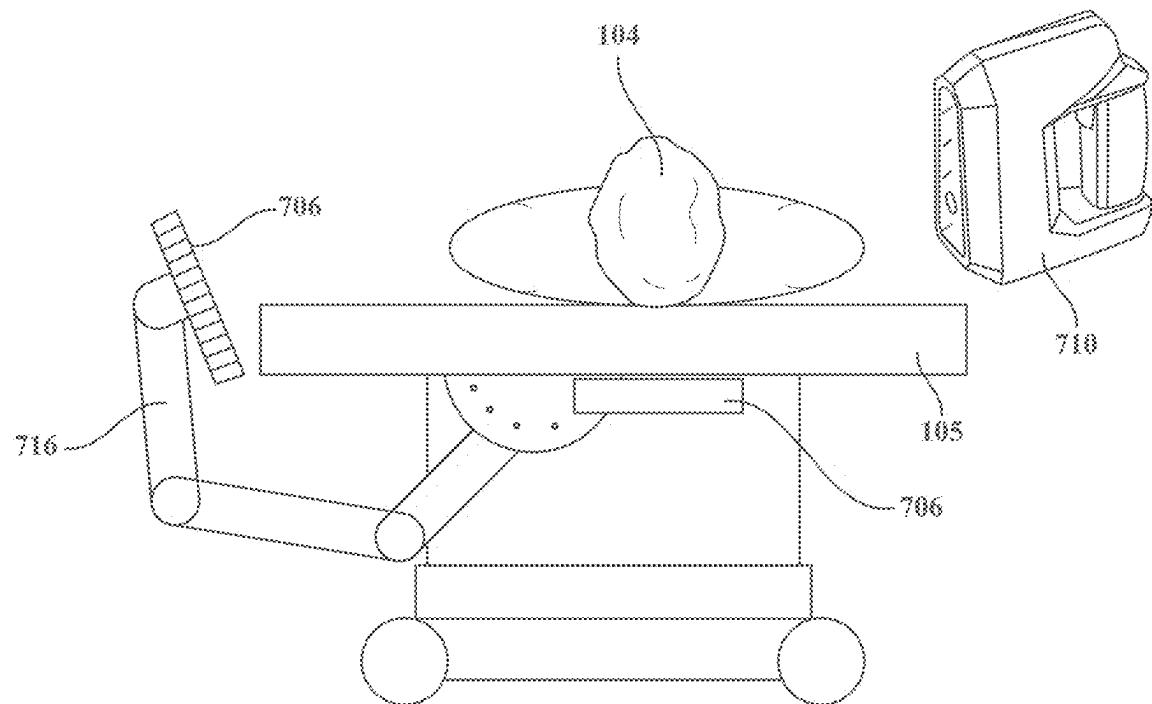


FIG. 12B

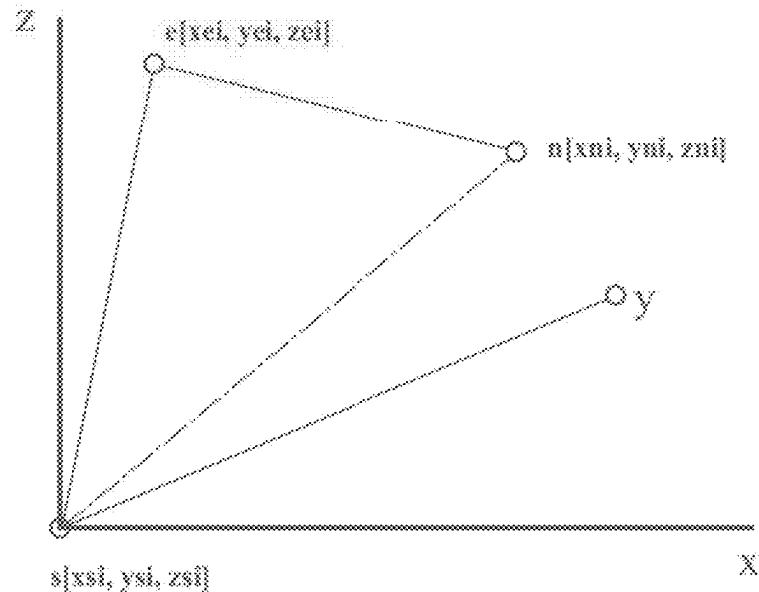


FIG. 13

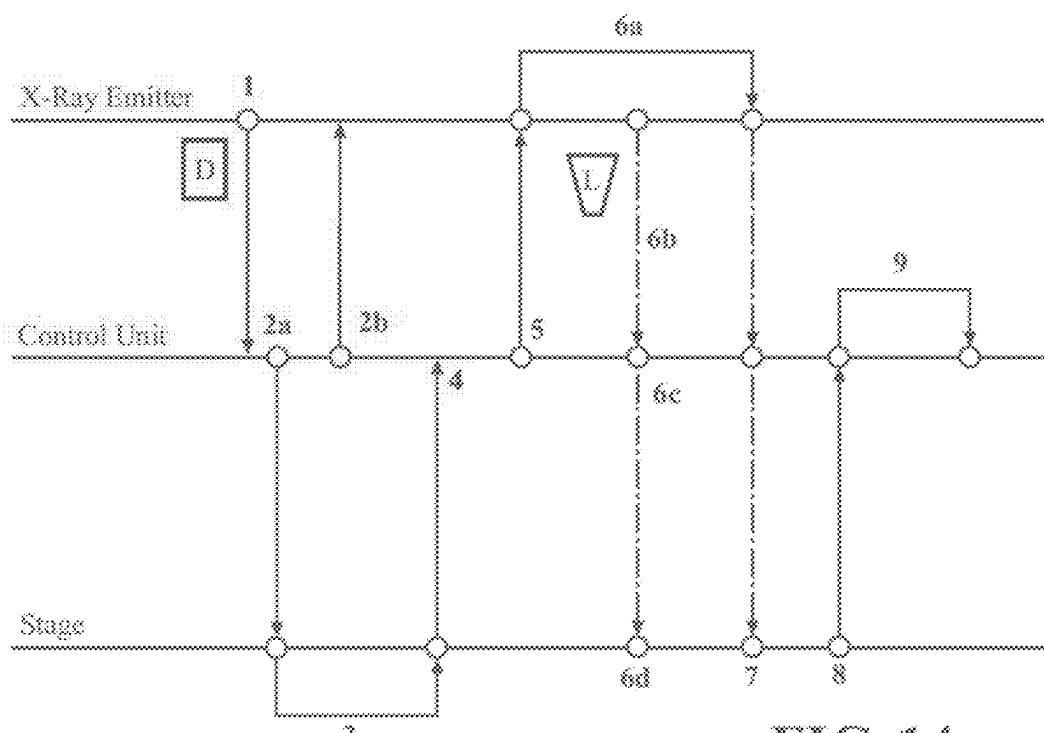
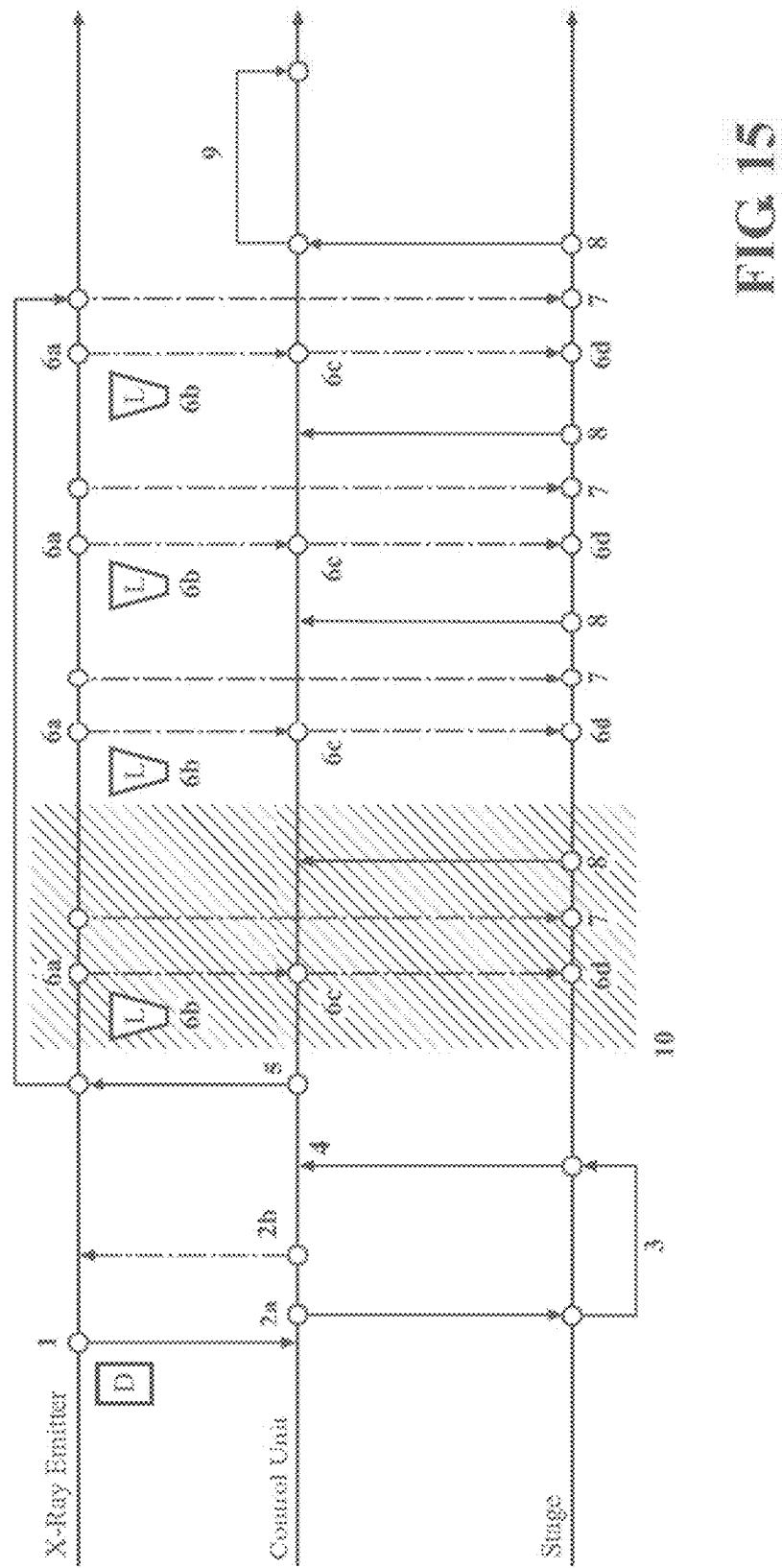
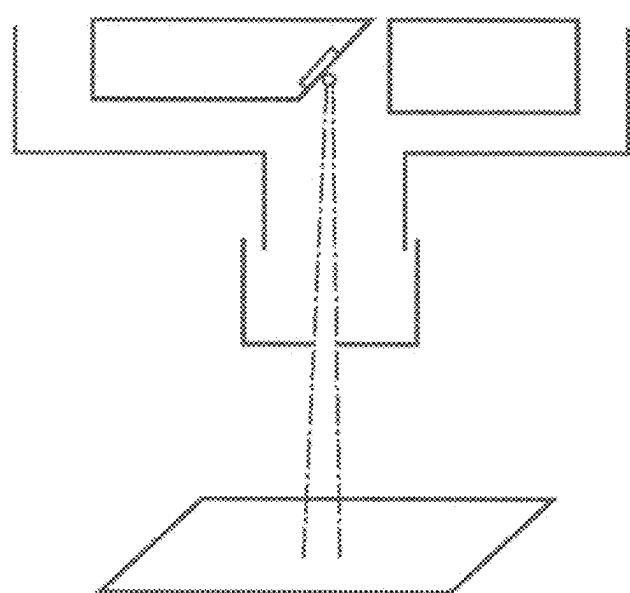
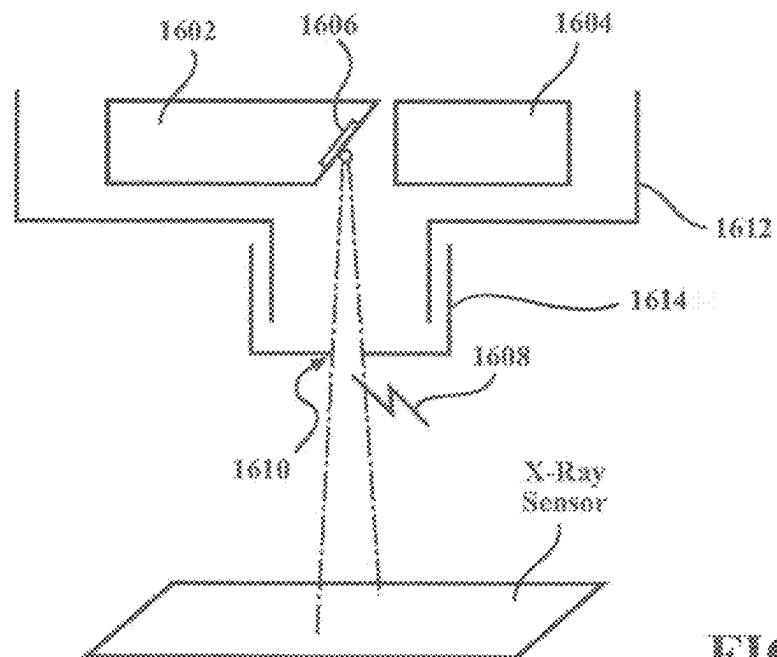


FIG. 14





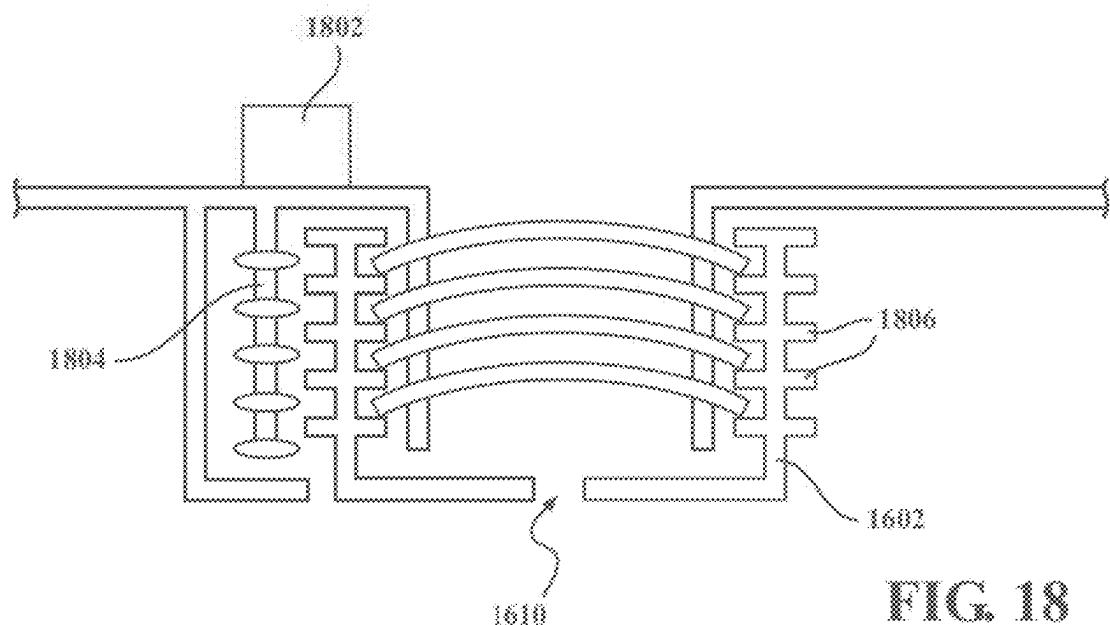


FIG. 18

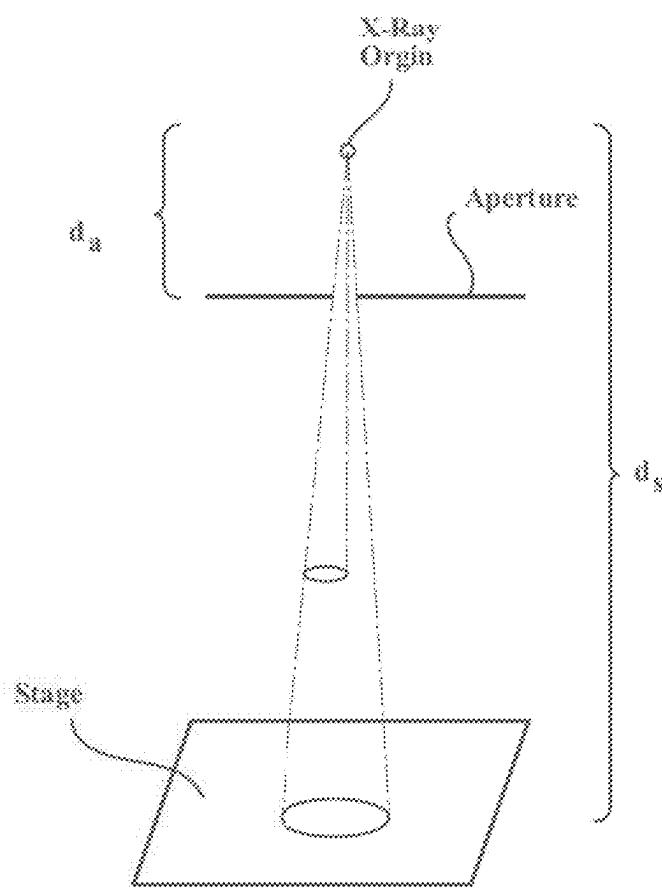
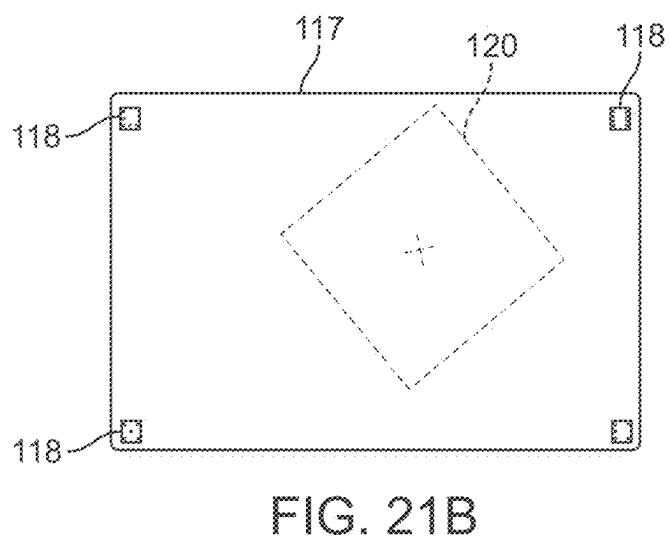
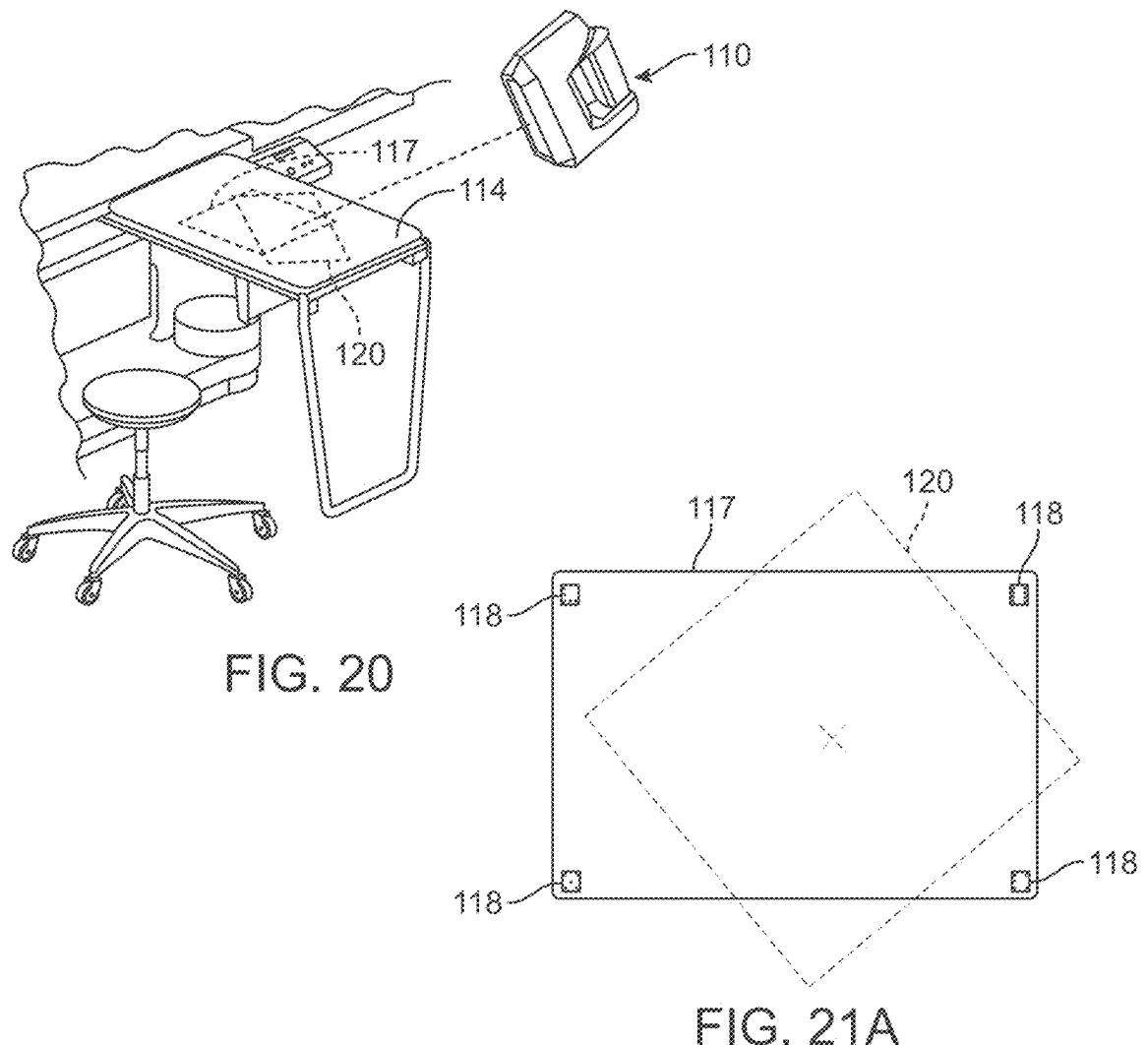


FIG. 19



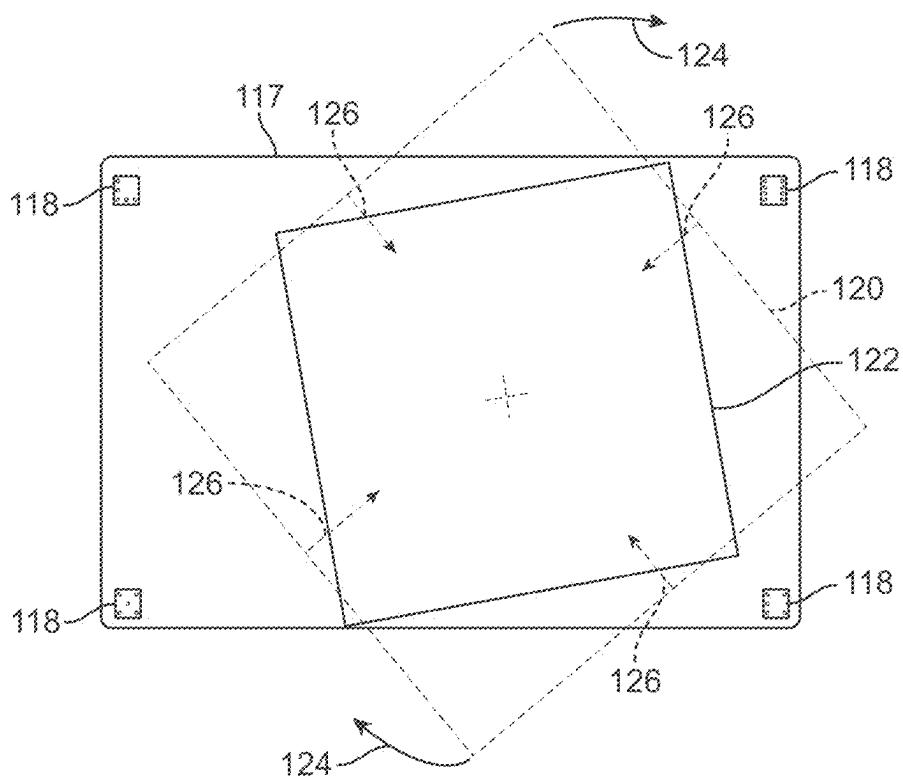


FIG. 22A

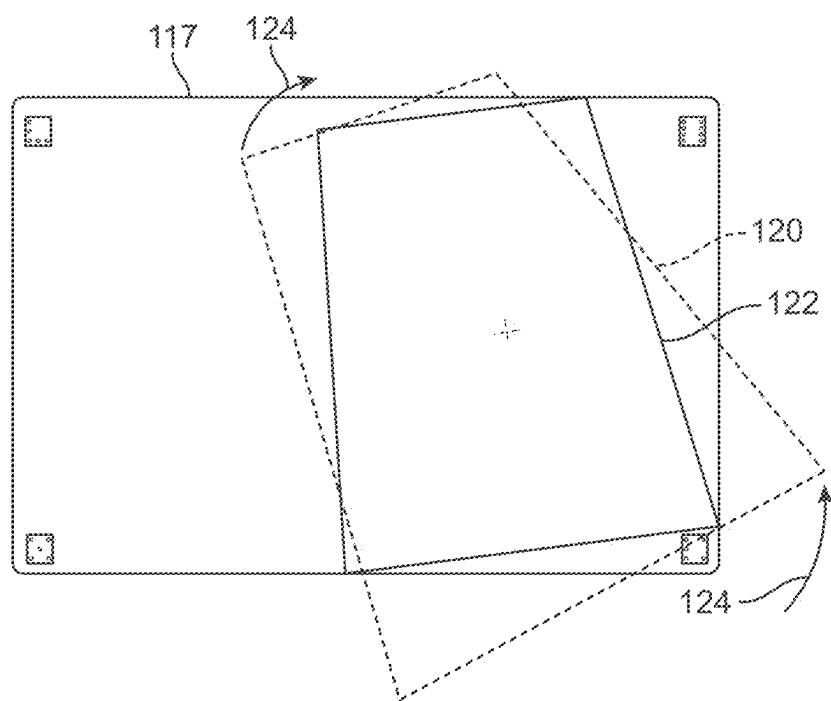


FIG. 22B

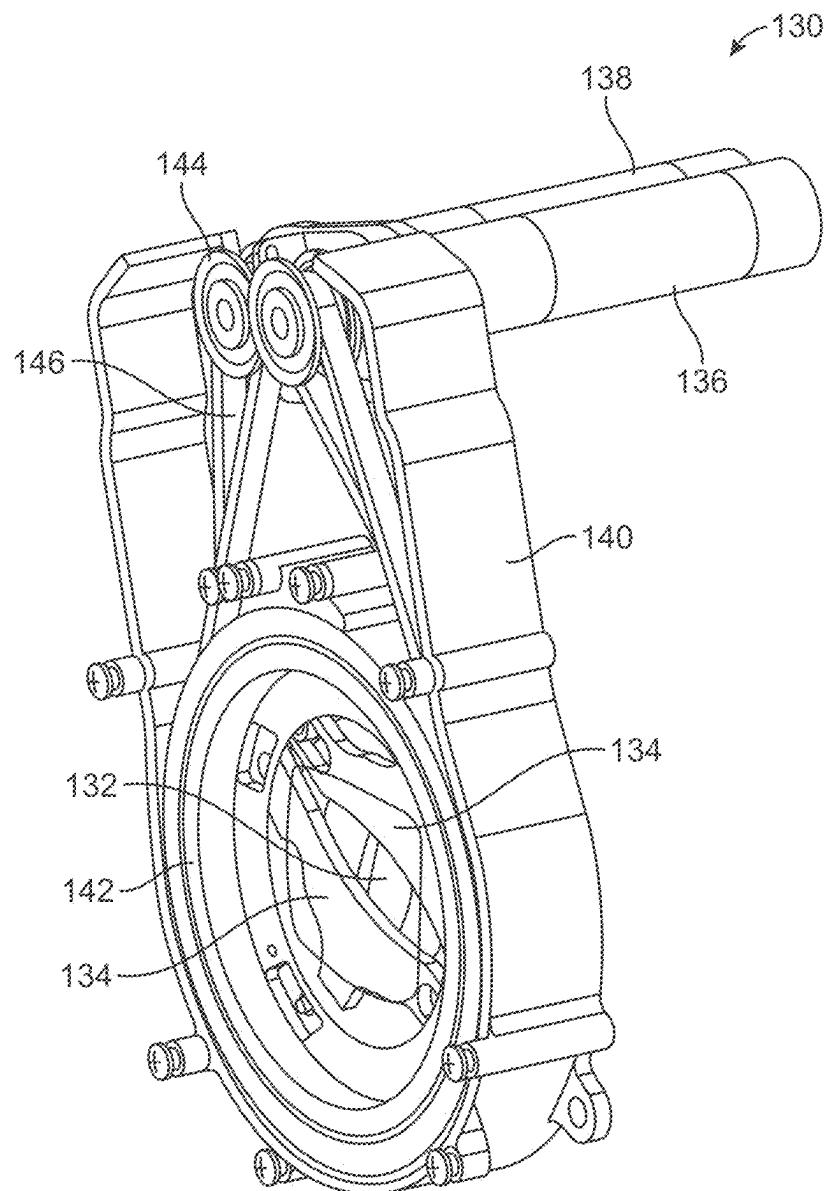


FIG. 23

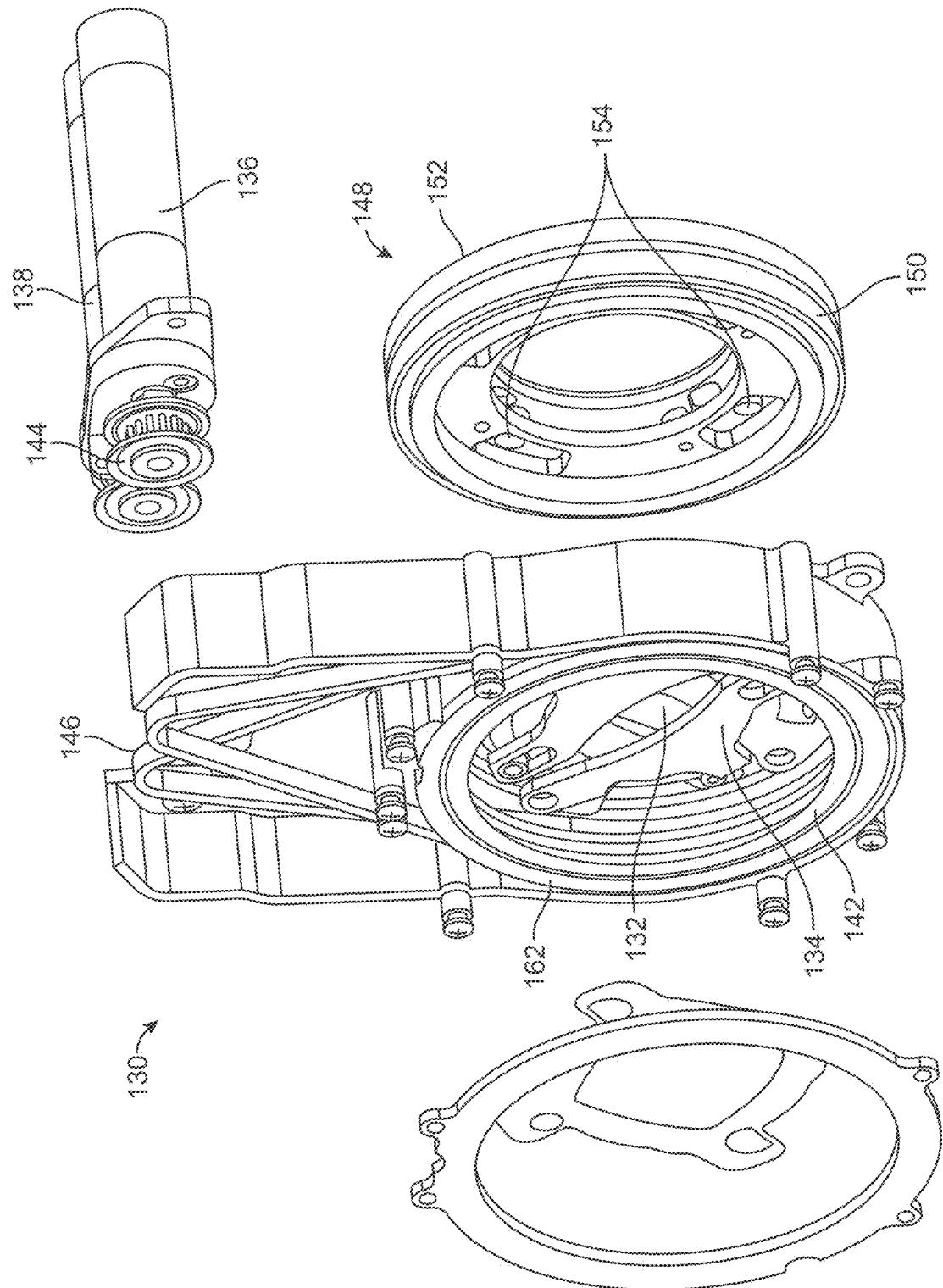


FIG. 24A

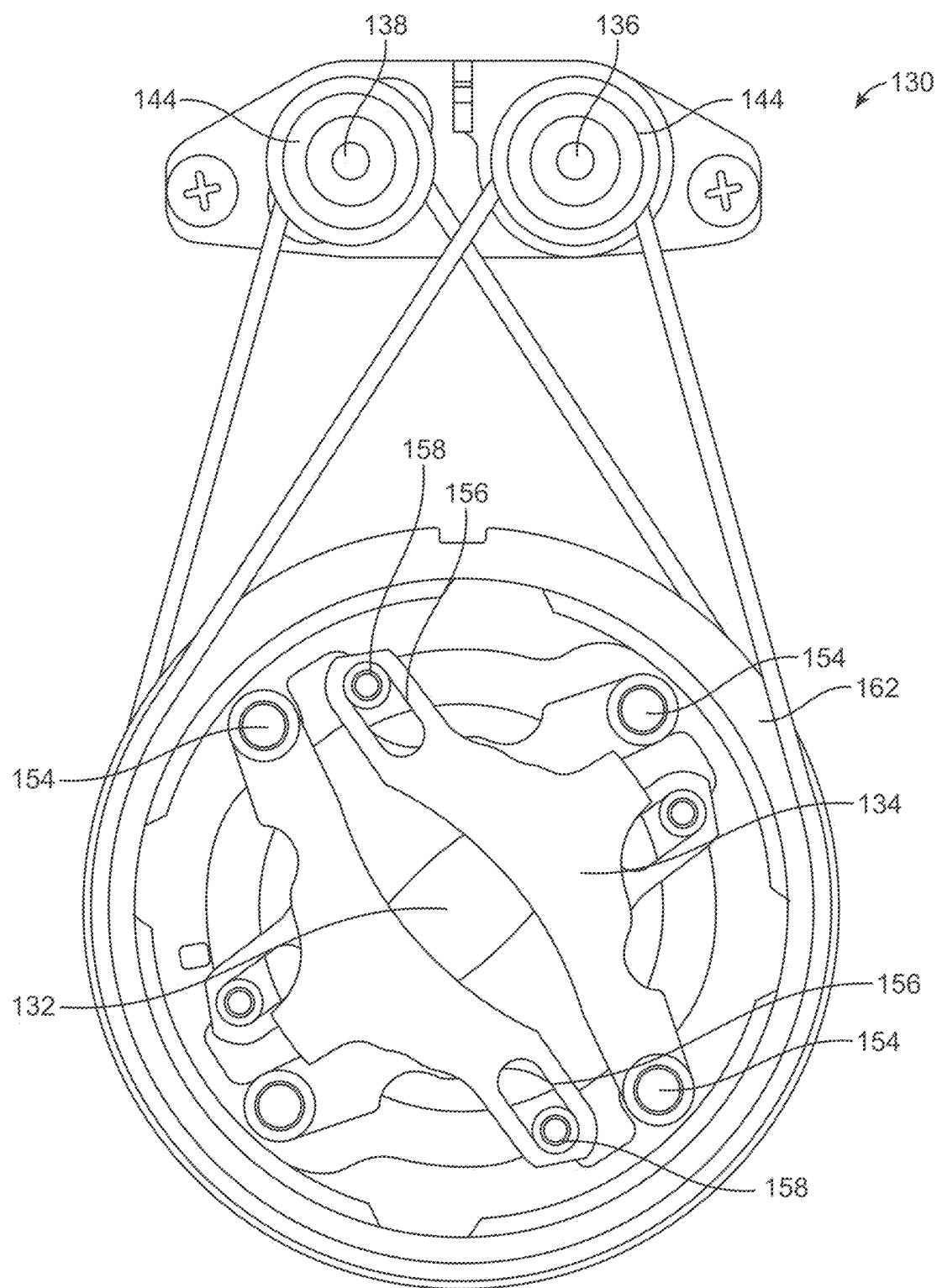


FIG. 24B

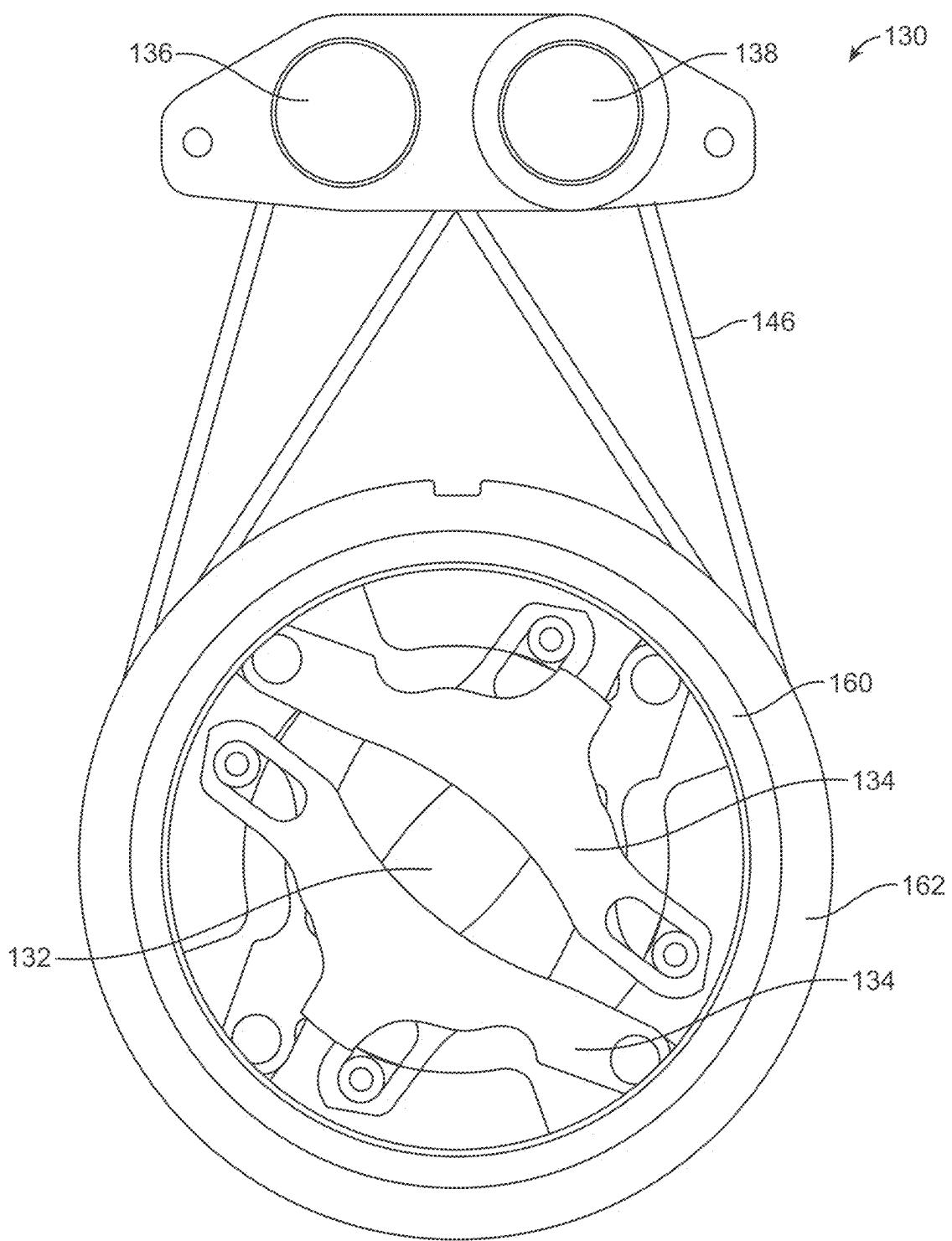


FIG. 24C

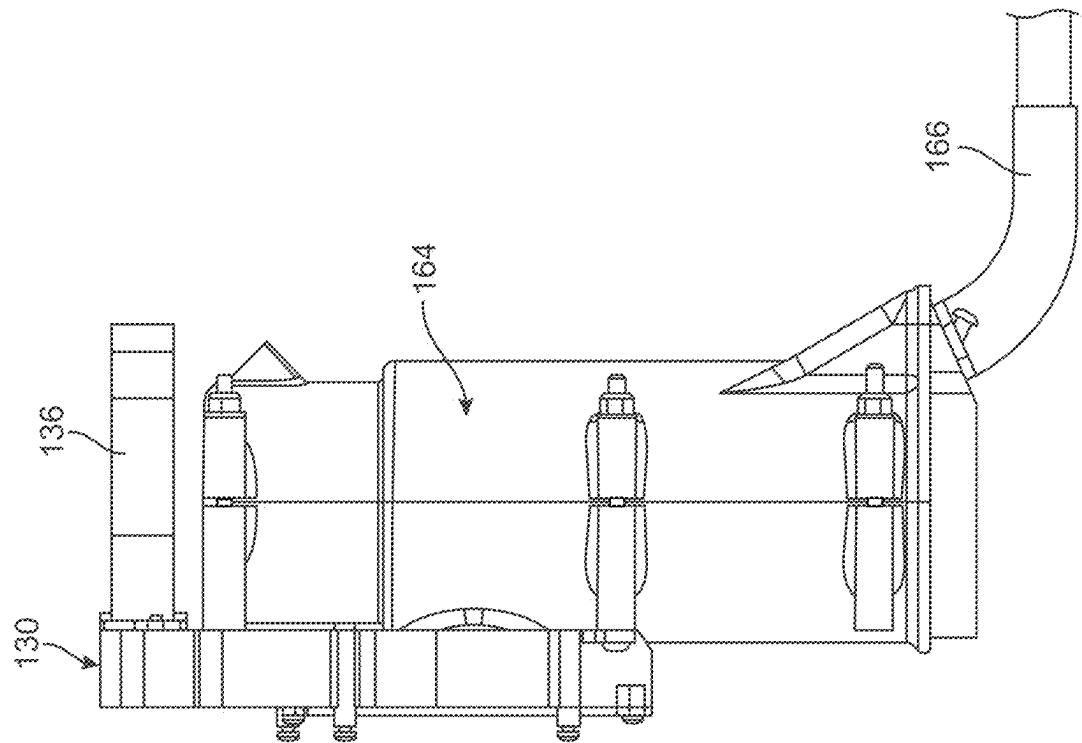


FIG. 25B

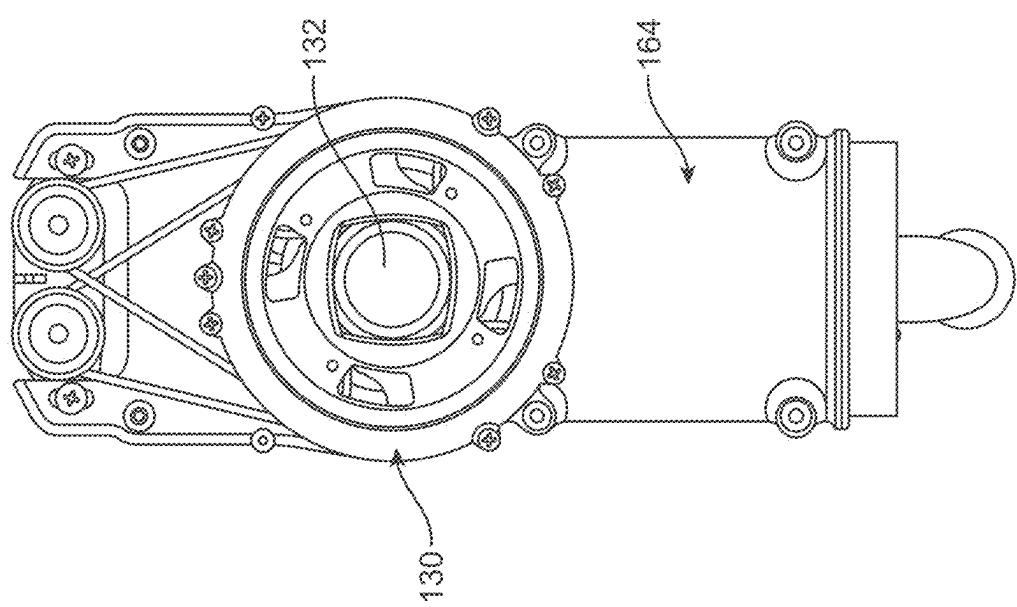


FIG. 25A

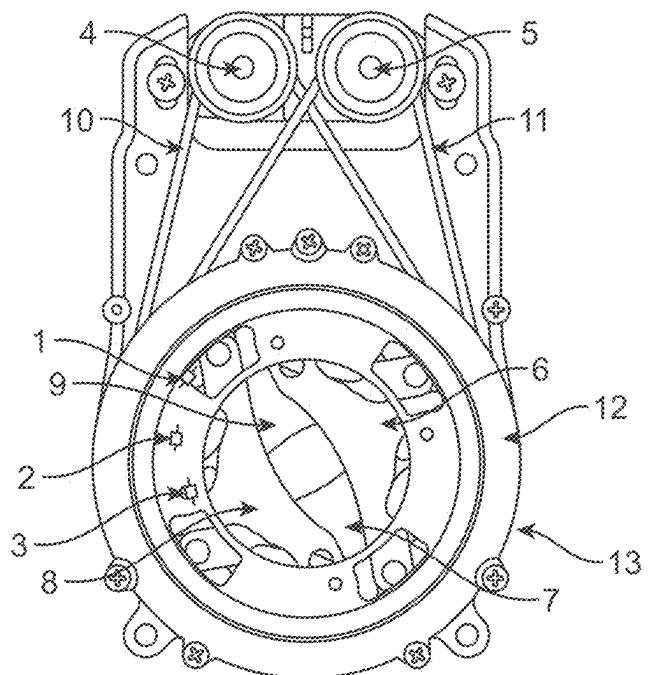


FIG. 26A

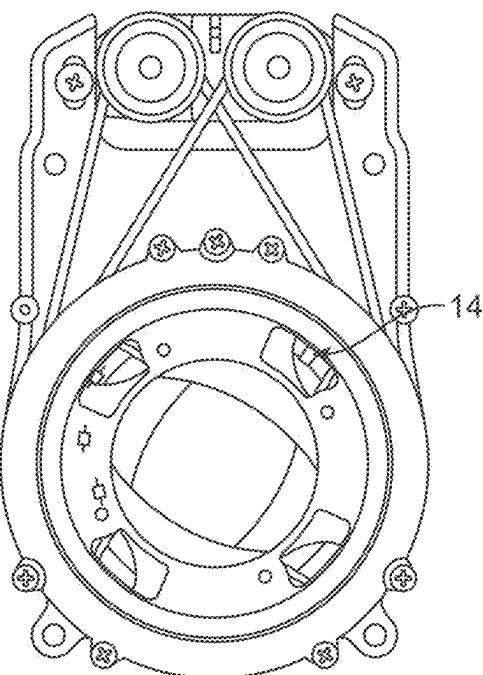


FIG. 26B

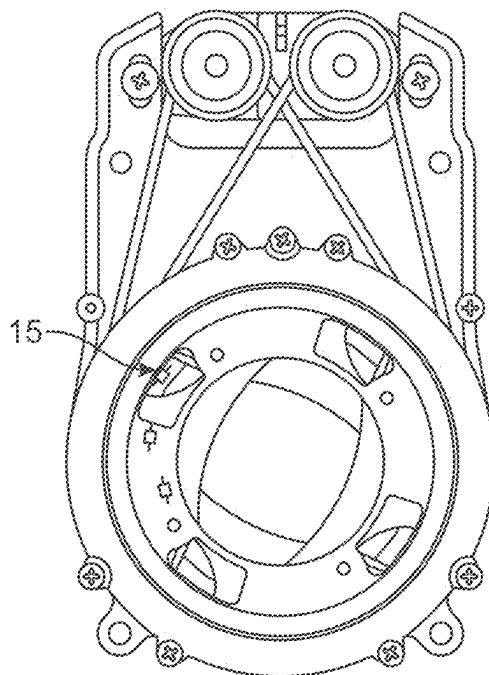


FIG. 26C

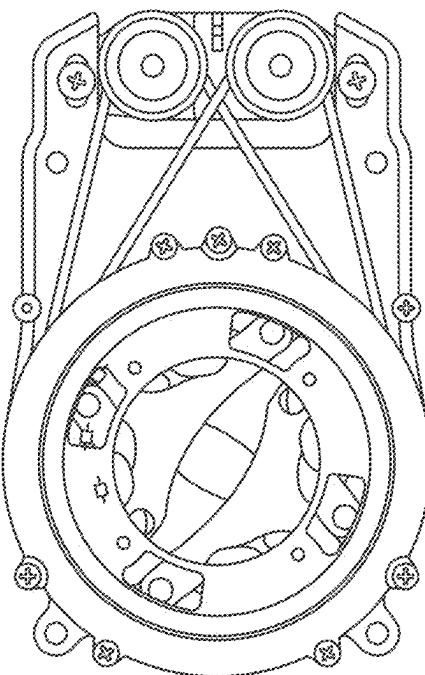


FIG. 26D

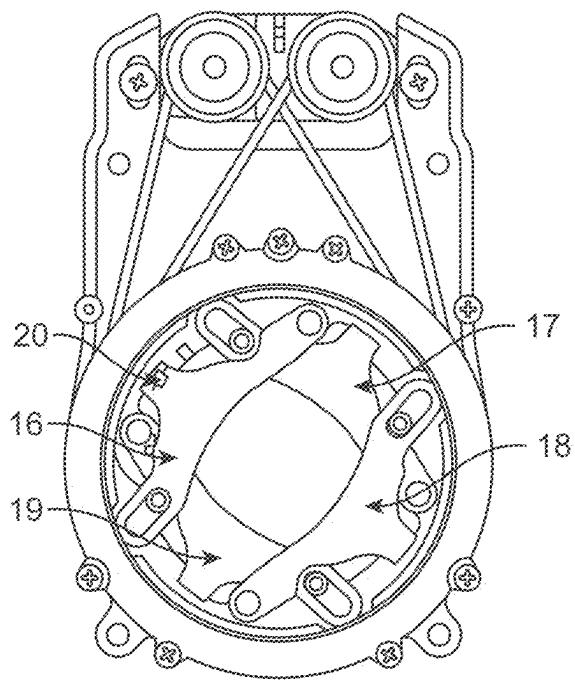


FIG. 26E

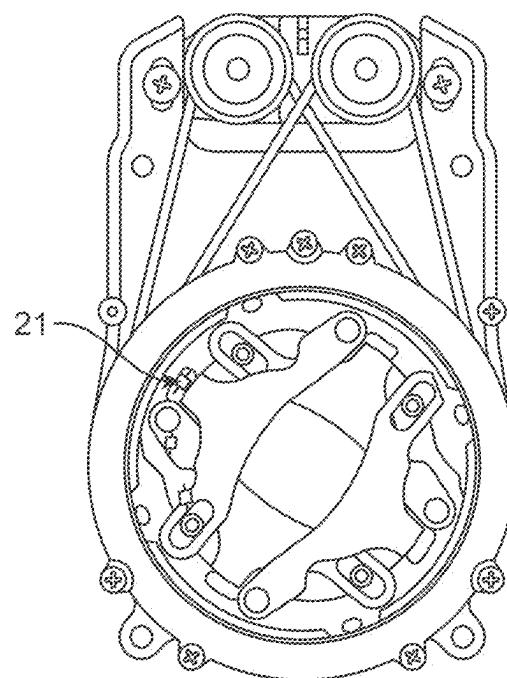


FIG. 26F

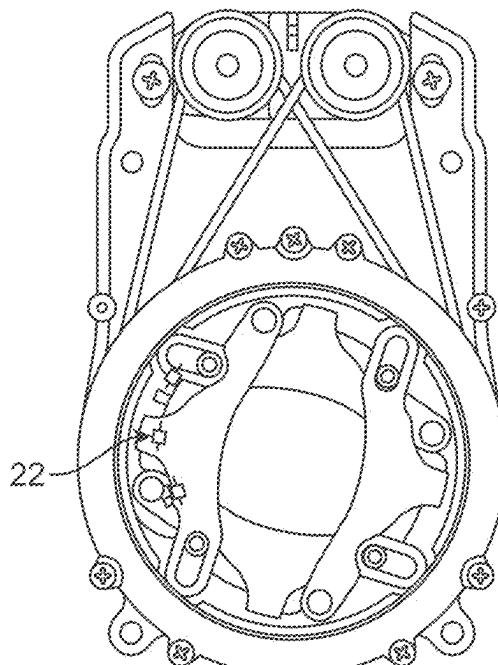


FIG. 26G

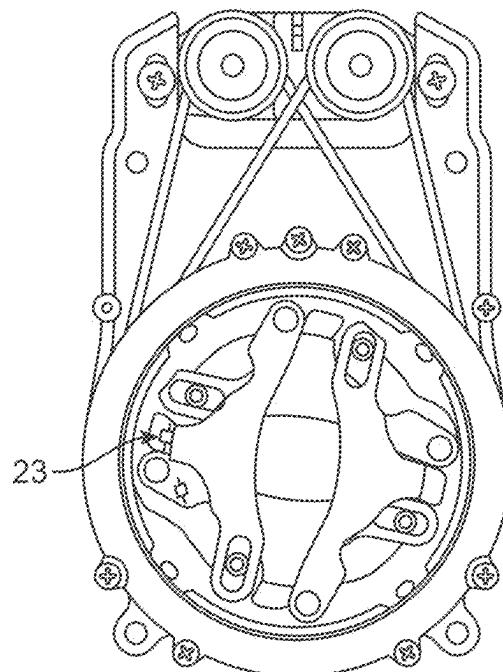


FIG. 26H

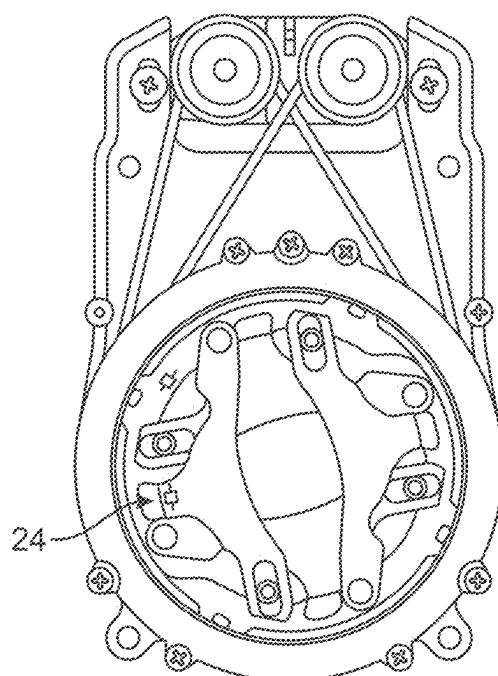


FIG. 26I

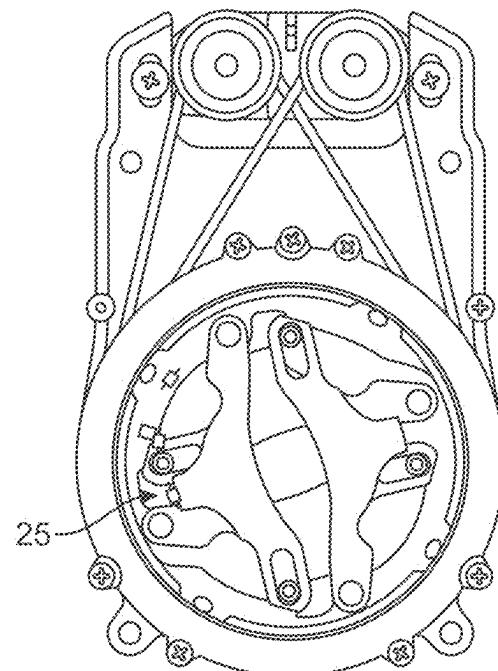


FIG. 26J

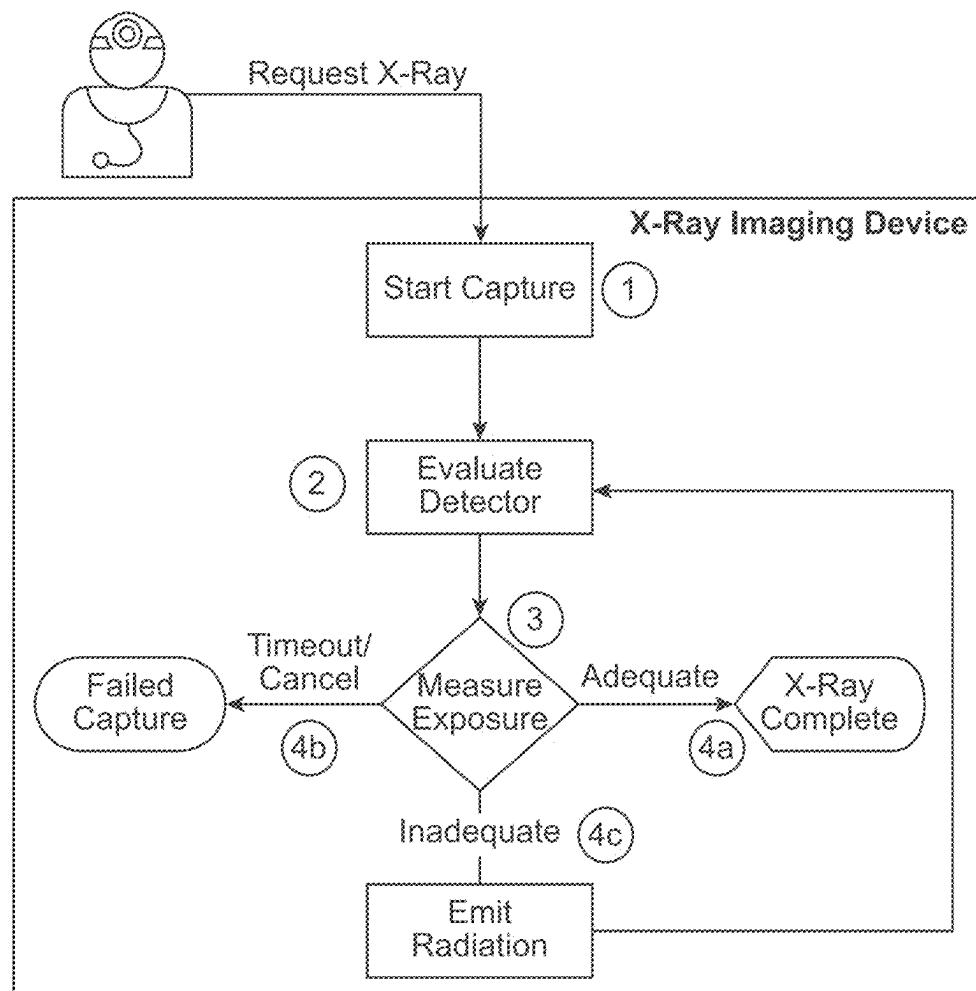


FIG. 27

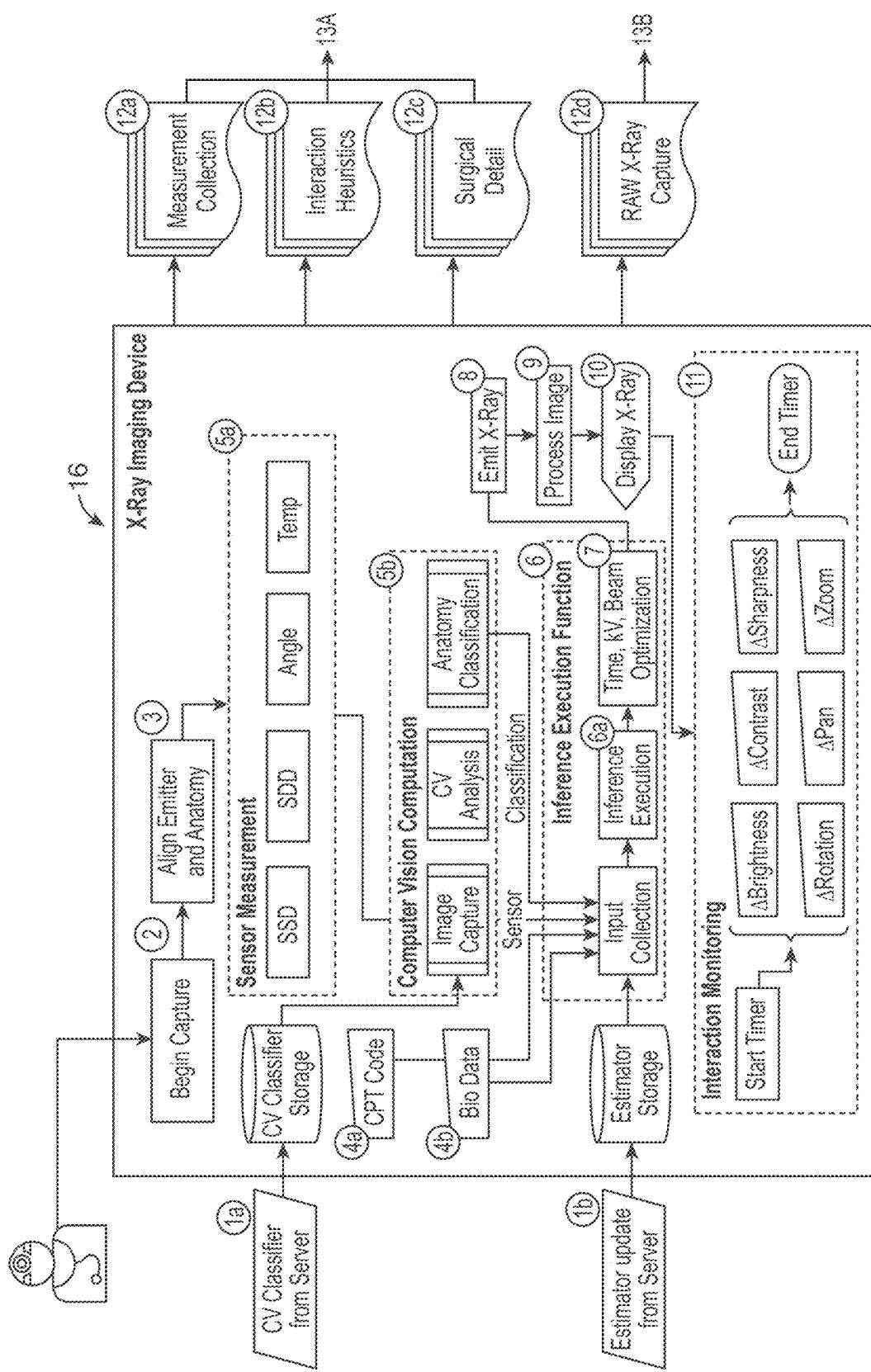


FIG. 28A

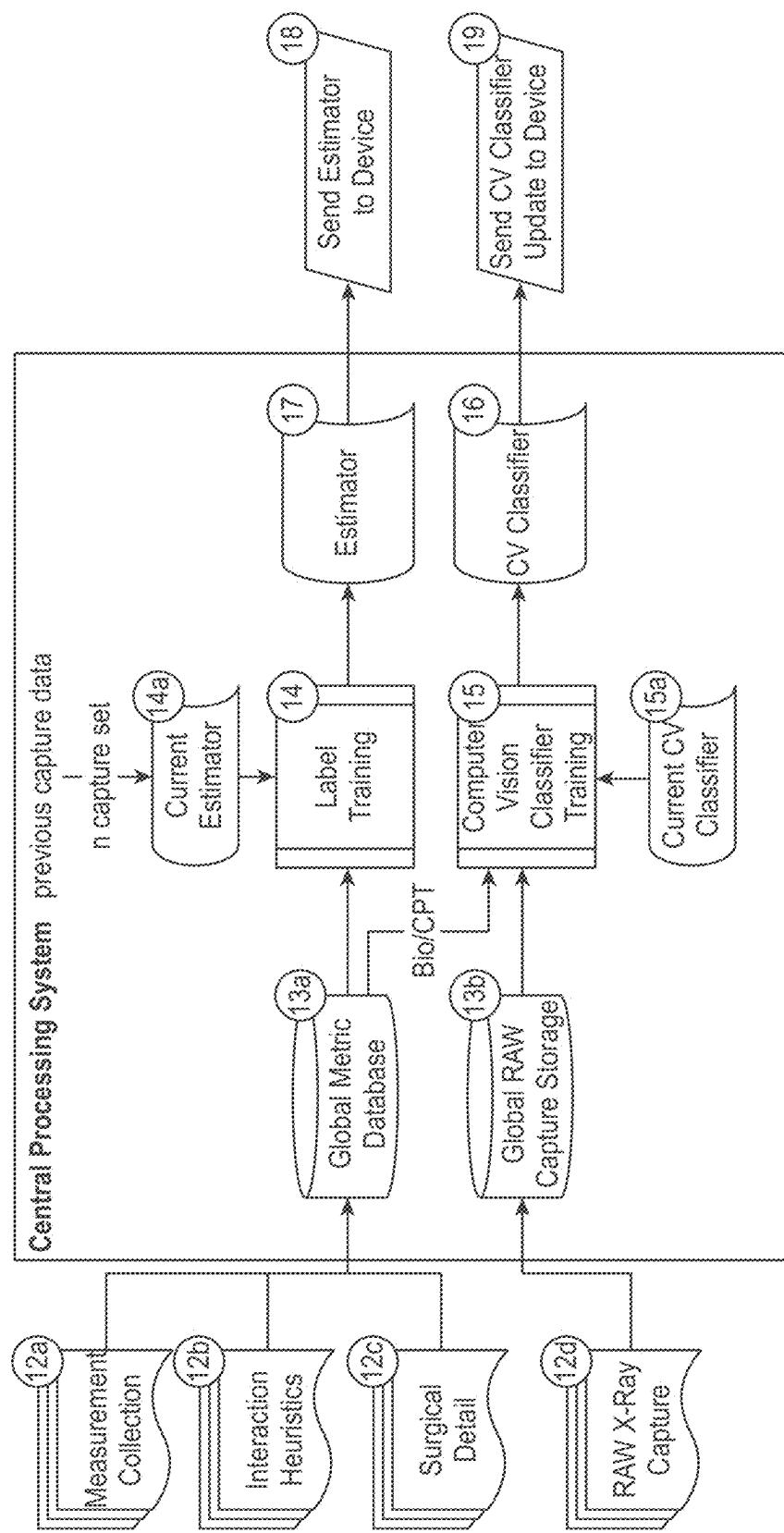


FIG. 28B

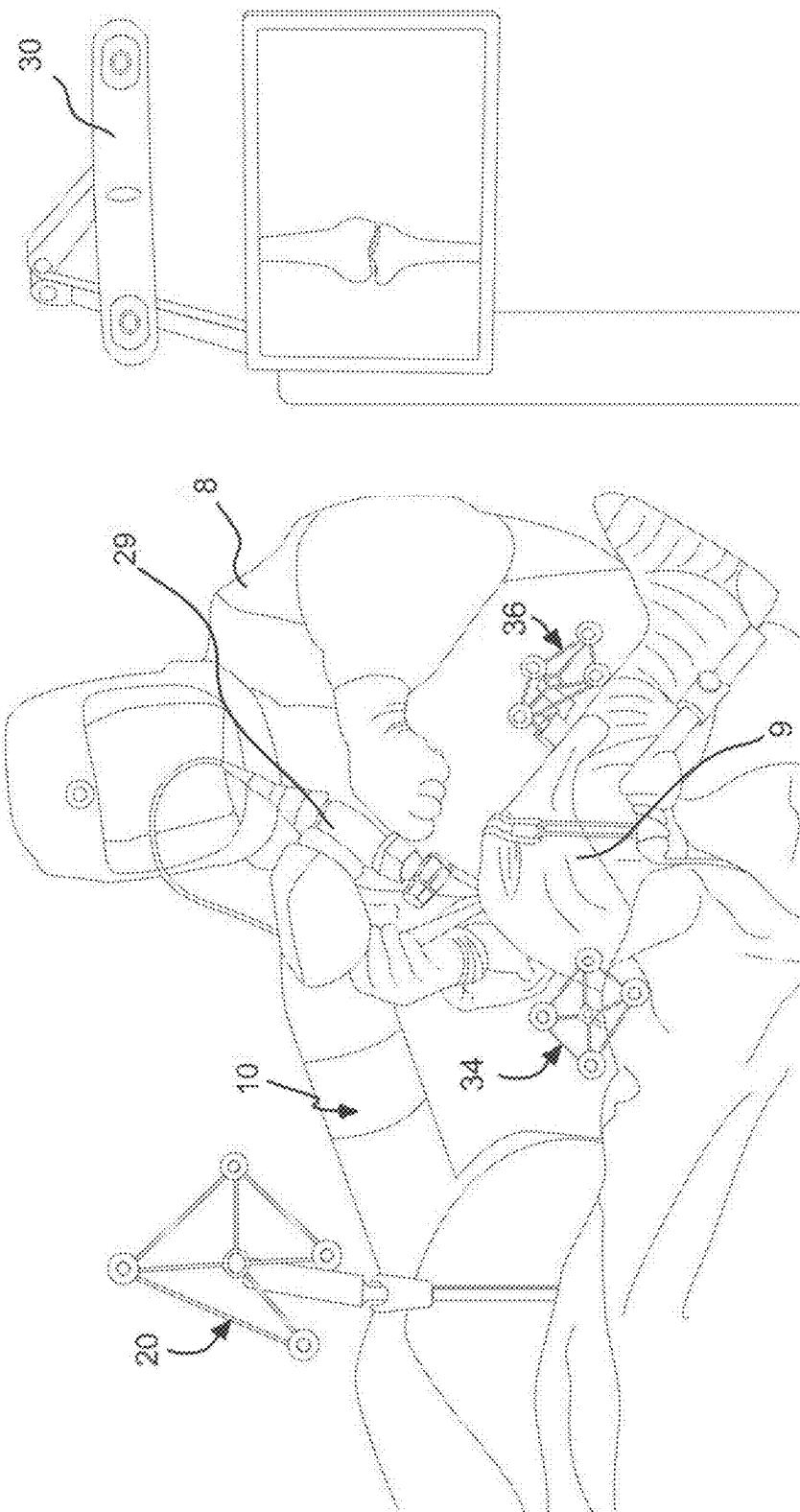


FIG. 29A

Attorney Docket No.: CAU01NZU0000

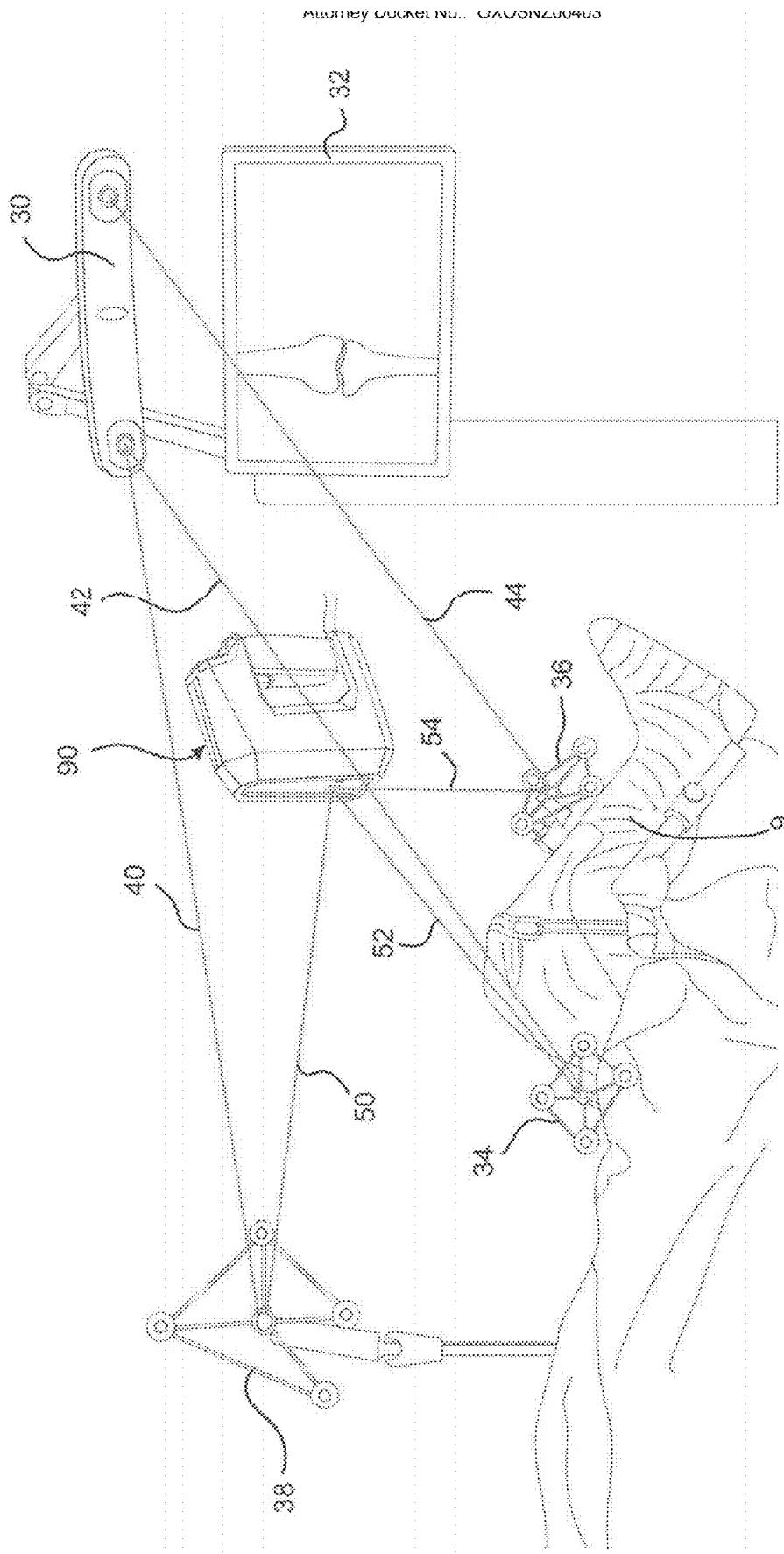
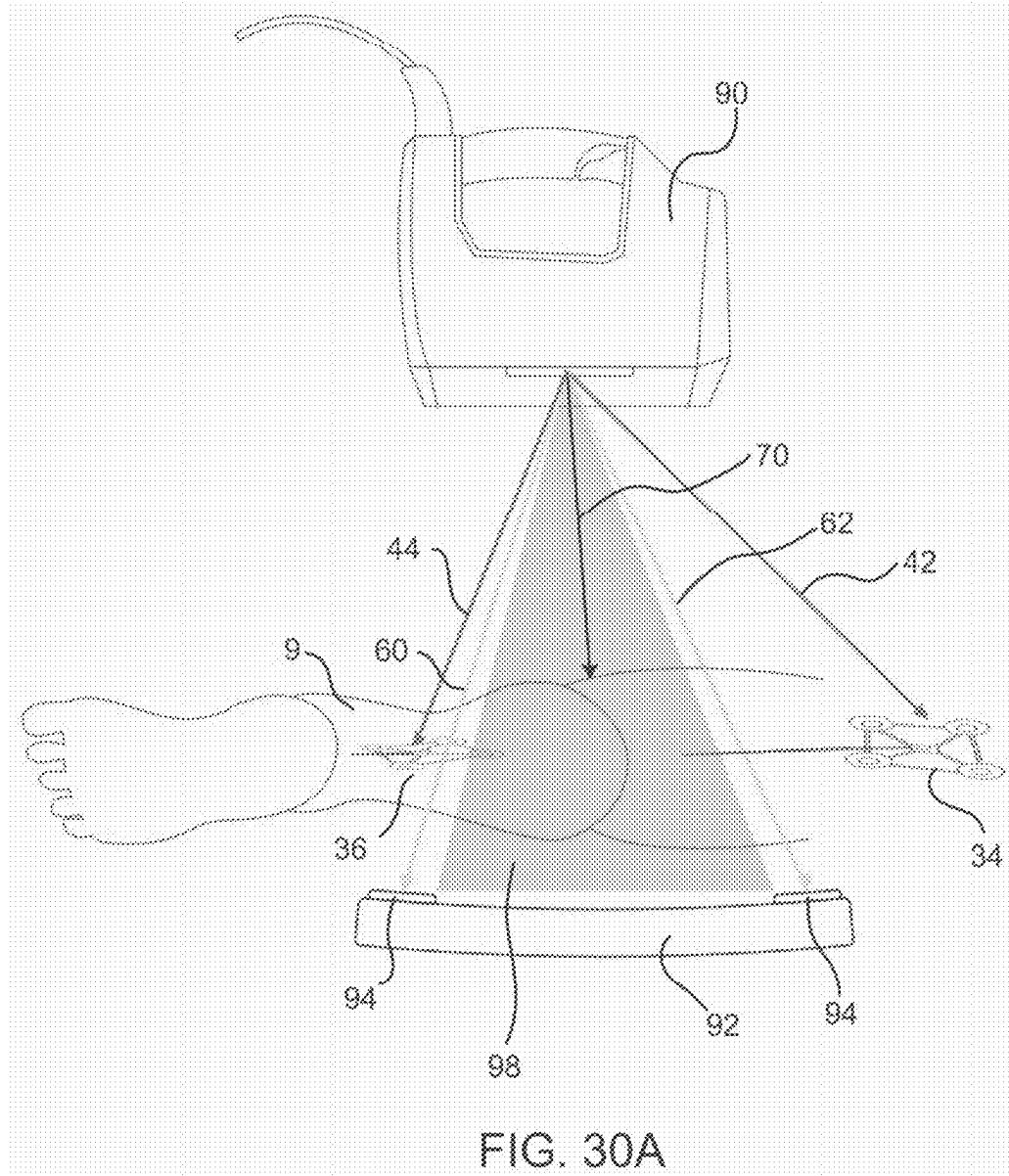


FIG. 29B



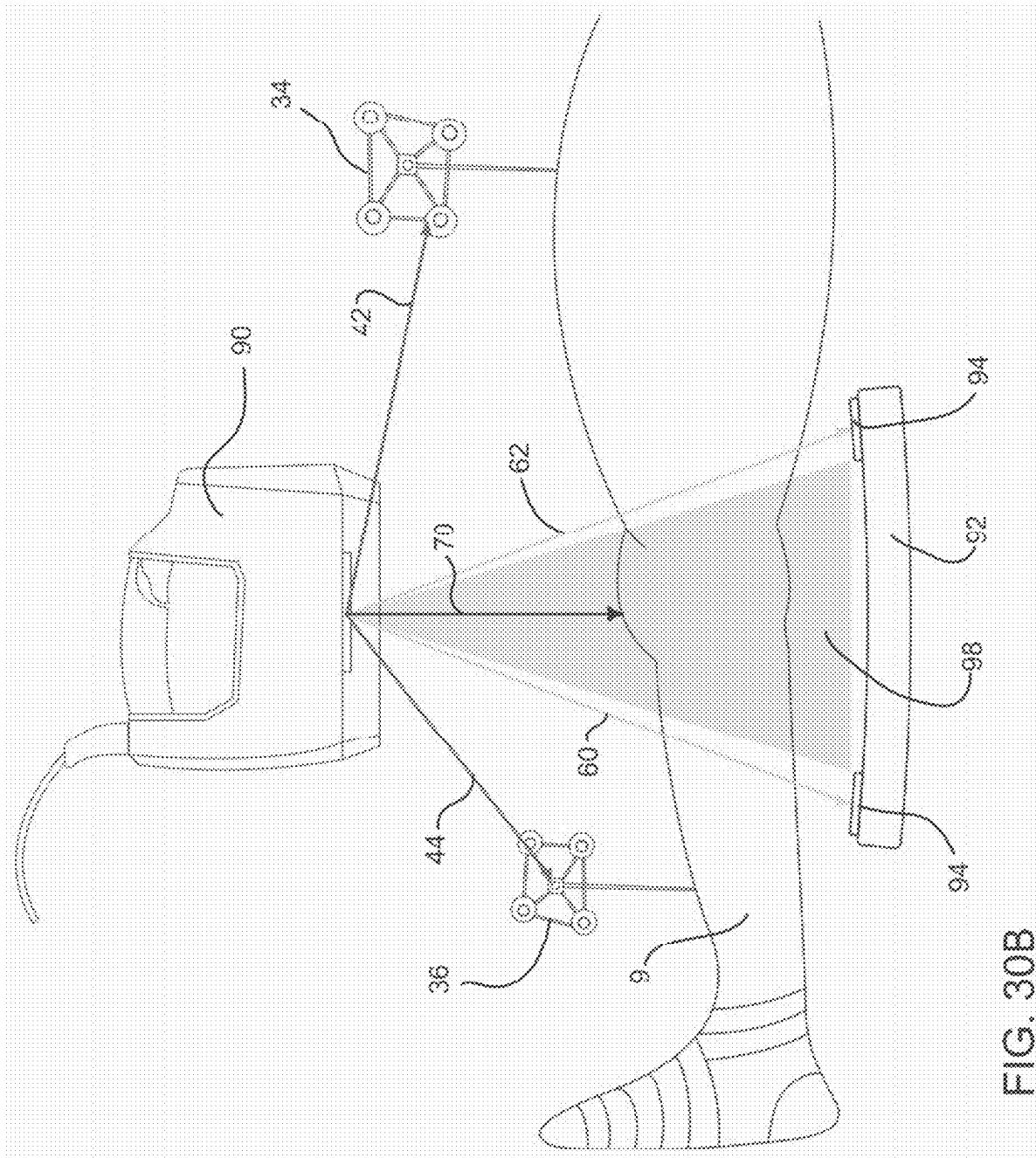


FIG. 30B

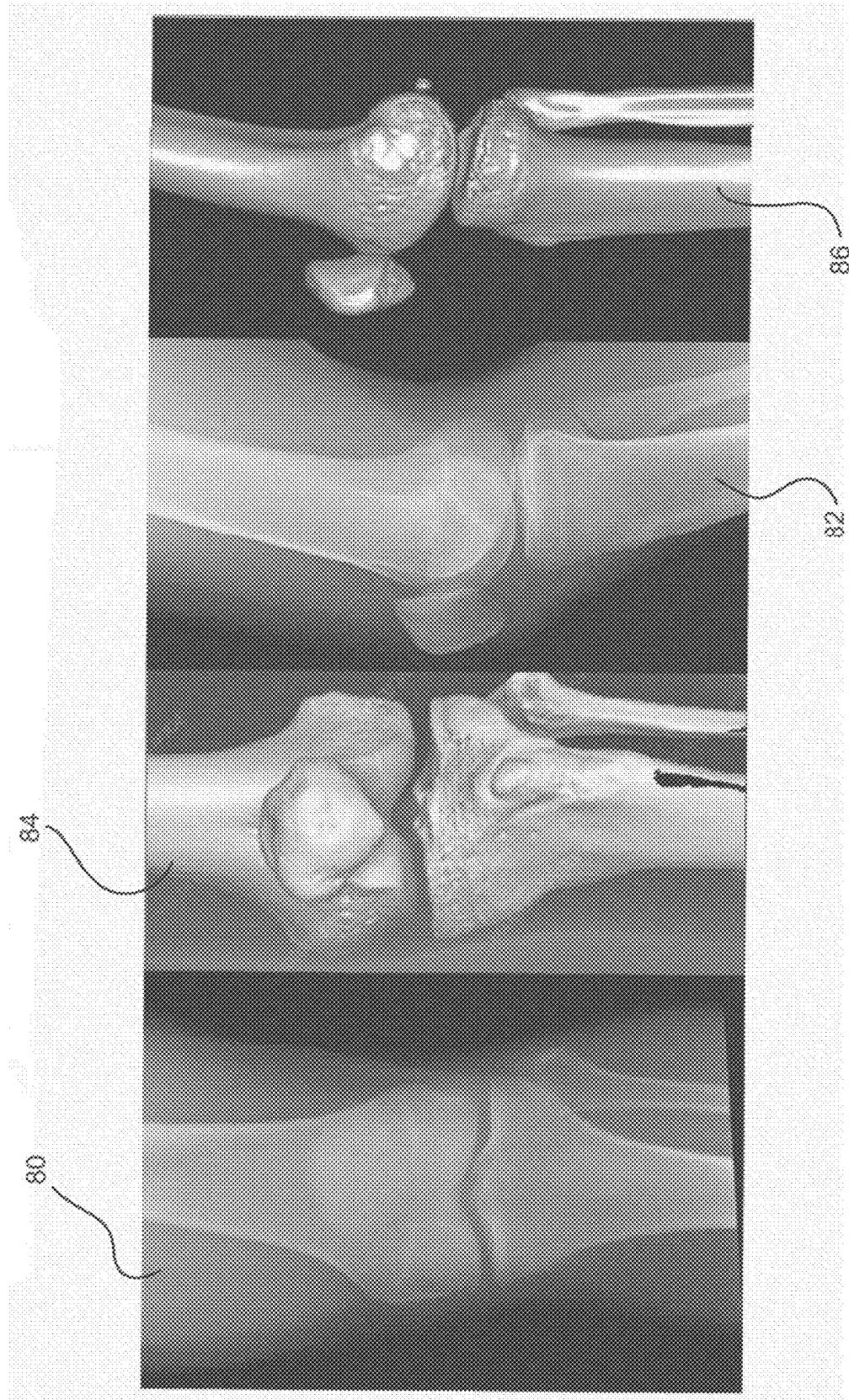


FIG. 31

METHOD OF FLUOROSCOPIC SURGICAL REGISTRATION

REFERENCE TO RELATED APPLICATIONS

[0001] This application is a continuation of U.S. patent application Ser. No. 16/817,337 filed Mar. 12, 2020, which claims benefit of priority to U.S. Provisional Applications 62/817,539 filed Mar. 12, 2019, the entirety of which is incorporated by reference herein. This application is also related to PCT Application Number PCT/US2020/022422 filed Mar. 12, 2020, the entirety of which is incorporated by reference herein.

FIELD OF THE INVENTION

[0002] Robot-assisted surgery is an emerging technology in the medical field. Surgical robots that assist the surgeon in achieving greater precision are becoming more prevalent in many surgical subspecialties. The advantages include greater accuracy with complex procedures, decreased complications and more rapid recovery when used in minimally invasive procedures and associated improvement in patient satisfaction. Positioning of the robotic effectors relative to the subject anatomy is critical for the execution of complex robot-assisted surgical procedures. The process of aligning the robot to the anatomy in space is called "registration". This invention describes a novel approach to the registration procedure for robotic surgical instruments. By leveraging well known computed tomography techniques and novel x-ray positioning systems, the registration process can be greatly improved. The present invention relates to the field of image guidance of robot-assisted surgery, and particularly the use of fluoroscopic image guided orthopedic robotic surgery systems with intraoperative registration.

BACKGROUND OF THE INVENTION

[0003] Total knee arthroplasty (TKA) is an orthopaedic procedure to minimize pain and restore functionality caused by end stage osteoarthritis. Conventional TKA is performed manually with non-patient specific instrumentation guided with alignment rods and rotational guides. Although there have been significant improvements in manual instrumentation, post-operative complications are still reported by a significant number of patients. Misalignment of the TKA causes faster wear, loosening, fracture, and instability. Most cases of misalignment require a corrective interventional surgery, which leads to an increase in cost and risk to the patient. TKA is one of the first and most prevalent applications of robotic assisted surgery in orthopedics.

[0004] Robotic surgery, or robot-assisted surgery, uses robotic equipment to assist surgeons in performing procedures and allow higher precision and control than conventional techniques. Orthopedic surgical robots equip surgeons with intraoperative visual, auditory, and tactile feedback that aid in performing accurate cuts of the distal femur and proximal tibia. The use of surgical robots for minimally invasive surgeries (MIS) that previously required complex open procedures resulted in many benefits, including fewer post-operative complications (e.g., infections), faster healing and recovery, reduced anesthesia time and exposure, and reduced intraoperative blood loss. Surgical robotic systems designed for total and partial joint replacement MIS, allow

surgeons to execute their plans with improved accuracy while also protecting and preserving the soft tissue envelope.

[0005] Robotic-arm assisted total knee arthroplasty (RATKA), provides surgeons with the technology to produce a virtual three-dimensional template of a TKA preoperatively. This is completed by acquiring an initial imaging assessment generated by a CT, MRI, or flat-panel fluoroscopy. The images are then used to generate a three-dimensional representation of the patient's specific anatomy. The three-dimensional representation of the patient's anatomy assists the surgeon with creating a patient specific implant design, generating biomechanical analysis, and defining bone cutting guide blocks. Using preoperative planning, the surgeon can define an initial volume to be removed from the patient's anatomy.

[0006] Existing surgical navigation systems are designed around tracking the motion or movement of markers (e.g., fiducials) to provide navigational assistance that orients robotic surgical systems to the patient or to the part of the patient's body acted on by the surgical system. Early surgical navigation systems utilized paired point matching, in which pairs of distinct points are defined preoperatively and matched intraoperatively. Although paired point matching reduces required power for processing, the accuracy of the registration is low.

[0007] A general process for use of current surgical navigation systems includes: obtaining patient images of the bone structure generated by CT, MRI, or flat-panel fluoroscopy; fixing a reference, such as optical markers with a fiducial mark or electro-magnetic markers, on the patient; registering the patient which includes defining the relationship between the obtained images and the implanted fiducials; and tracking instrument and patient by showing real-time feedback to the surgeon. Markers are fixed relative to the tissue/patient, for example, by using bone screws or bone fixations. Registration may be performed using a point-to-point method, surface matching, or automatic registration based on images taken with fixed markers (e.g., on the patient's anatomy).

[0008] Current navigation systems have numerous limitations that interfere with surgical procedures. Registration and continuous re-registration of the fiducials requires interrupting a surgical procedure in order to collect additional points, which prolongs surgical procedure time and decreases efficiency. If there are not enough fiducials, visible marker positions may not be able to be determined, which decreases or prohibits registration. Certain embodiments of conventional registration systems are cumbersome and have high complexity requiring additional training or staff to be present at the time of the surgical procedure.

[0009] In some cases, navigation systems desynchronize over time due to the patient's shifting anatomy during the surgical procedure. The surgeon registers the patient initially at the beginning of the surgical procedure, using one or more markers attached to the patient's anatomy. Only the local area to the fiducial marker(s) remains accurate to the physical reality of the patient's anatomy. The error between reality and the assumed reality based on the patient's initial registration increases as distance from the known fiducials increases. Therefore, in known conventional surgical procedures, as the surgical procedure progresses, the navigation system becomes more desynchronized and thus increases the

likelihood of complications and error, as the assumptions of reality are no longer accurate.

SUMMARY OF THE INVENTION

[0010] Disclosed herein is a procedure utilizing fluoroscopic imaging devices for the purposes of robotic surgery registration. Generally, once the patient is in the operative suite, the surgeon will implant anchoring fiducials to the adjacent anatomy of the subject area. Robotic surgery systems rely on the presence of these anchor fiducials to maintain a reference to the target anatomy during the procedure. After the position of the anchors has been registered, the robotic system will prompt the surgeon to identify the location of specific coordinates of anatomy using a fiducial wand. This process of specific identification of a large number of points can be tedious and difficult, requiring a large amount of surgical time and resources. The procedure and devices disclosed herein streamlines this process by using position aware fluoroscopic instruments to mathematically calculate the relationship between the anchor fiducials and the subject anatomy through the mapping of the preoperative CT to contemporaneously captured x-ray images.

[0011] The invention relates to an improved versatile, multimode radiographic systems and methods, allowing the surgeon to operate on a patient without interference, and capture static and dynamic x-rays and other still and video imagery without repositioning equipment, the subject or the surgeon.

[0012] In one variation, the present disclosure includes methods of preparing a surgical robot for navigating an end effector relative to an anatomic structure using a virtual model of the anatomic structure where the anatomic structure includes a plurality of fiducial markers secured relative to the anatomic structure.

[0013] For example such a method can include positioning an emitting apparatus to a location relative to the anatomic structure where the emitting apparatus is configured to obtain positioning information comprising a distance and an orientation of the emitting apparatus relative to each of the plurality of fiducial markers; emitting energy from the emitting apparatus onto the anatomic structure, such that the energy is received by an imaging sensor which produces an image signal sufficient to produce a fluoroscopic image of the anatomic structure and where the emitting apparatus produces a positioning information data associated with the fluoroscopic image; and mapping the fluoroscopic image of the anatomic structure to the virtual model of the anatomic structure using the positioning information data such that the surgical robot is able to use the virtual model of the anatomic structure and the plurality of fiducial markers to navigate a robotic end effector relative to the anatomic structure.

[0014] In another variation, the method includes a method of registering a virtual model of an anatomic structure where the anatomic structure includes a plurality of fiducial markers secured relative to the anatomic structure.

[0015] For instance, such a method can include positioning an emitting apparatus to a location relative to the anatomic structure where the emitting apparatus is configured to obtain positioning information comprising a distance and an orientation of the emitting apparatus relative to each of the plurality of fiducial markers; emitting energy from the emitting apparatus onto the anatomic structure, such that the energy is received by an imaging sensor which produces an image signal sufficient to produce a fluoroscopic image of

the anatomic structure and where the emitting apparatus produces a positioning information data associated with the fluoroscopic image; and mapping the fluoroscopic image of the anatomic structure to the virtual model of the anatomic structure using the positioning information data such that the virtual model of the anatomic structure and the plurality of fiducial markers can be used to navigate a device relative to the anatomic structure.

[0016] In another variation, the method can further comprise a plurality of position tracking elements each respectively producing a unique signal, such that an area defined by the plurality of position tracking elements is identifiable by the respective signal of the position tracking element, wherein positioning the emitting apparatus further comprises relaying the position of the emitting apparatus includes using the emitting apparatus to provide an orientation data of the emitting apparatus and determine a distance from each of the plurality of tracking elements; and using the orientation data in combination with the distance from each of the plurality of tracking elements to determine the position of the emitting apparatus.

[0017] In another variation, the method can further include obtaining a distance measurement between the emitting apparatus and the anatomic structure, wherein the positioning information data associated with the fluoroscopic image includes the distance measurement. The distance measurement can be obtained by a sensor on the emitting apparatus. The method can also include measuring a distance between the anatomic structure either the operating surface or the imaging sensor using one or more sensors positioned in the operating surface and/or the imaging sensor. Such an additional measurement ensures that a thickness of the anatomic structure can be accurately measured even if the anatomic structure is spaced from the operating surface and/or the imaging sensor.

[0018] In another variation of the method, the emitting apparatus comprises at least one camera device configured to identify the fiducial markers.

[0019] A variation of the method can include obtaining a second fluoroscopic image having a different orientation of the anatomic structure from the fluoroscopic image.

[0020] The methods described herein can allow for moving the emitting apparatus in free-space while the emitting apparatus is uncoupled from any support structure. Alternatively, or in combination, the emitting apparatus can be affixed to a support or boom structure.

[0021] The method can also further include measuring a distance to each of the plurality of fiducial markers using a second camera system in communication with the surgical robot.

[0022] The method can also include emitting energy from the emitting apparatus during measuring a distance to each of the plurality of fiducial markers using the second camera system.

[0023] Both x-ray emitters and detectors are described. One variation of a novel emitter allows for portable control of the emitter. Such an emitter can be lightweight and extremely maneuverable. Variations include that the portable emitter that is a handheld unit. Alternatively, the portable emitter can be affixed to a mounting structure that is either automated/controllable or simply bears the weight of the emitter to prevent the user from constantly holding the emitter. In additional variations, the emitter can be designed so that it is releasably coupleable with a mounting structure,

which allows improved portability when needed and coupling to a mounting structure when desired. The emitter may include both an x-ray emitter along with at least one additional imaging modality such as a digital camera for producing a visual image, a thermal image, and an infrared image of a patient for the purposes of aiding diagnostic, surgical, and non-surgical interventions. Clearly, the systems and methods described herein can be used for non-medical applications where non-invasive imaging is desirable.

[0024] Ergonomic controls make acquisition of images easier and faster and a built-in display facilitates easy-to-use control functions. The device senses its distance from the subject and will block the activation and discharge of radiation if the x-ray tube is not at a safe distance; i.e., too close to the patient. The minimum distance can be defined in software and is adjustable based on intended use and other factors. The system automatically and intelligently manages its power state through the implementation and use of an inertial measurement unit (IMU) and various timing components.

[0025] The x-ray emitter may be used with any available x-ray detector. One option is to mount the emitter in a fixture including a properly aligned detector plate, much like a traditional c-arm, though much smaller and more capable. An alternate variation is described herein and includes use of an emitter with a distinct x-ray capture stage, disclosed in detail, which automatically pivots, orients and aligns itself with the emitter to maximize exposure, quality and safety.

[0026] The inventive x-ray stage comprises a statically fixed platform, positioned during the outset of surgery, with an open cavity containing an x-ray sensor, an x-ray sensor positioning system, an emitter tracking system, a shielding system and a control unit. Optionally, the system can utilize an external display monitor or any other method for reviewing the captured image.

[0027] A variation of the improved systems described can include a non-invasive imaging system for examining an object for medical and non-medical inspections. Such a non-invasive imaging system can include an emitting apparatus configured to emit energy; an imaging sensor configured to generate an imaging signal upon the receipt of the energy when the emitting apparatus and imaging sensor are in an operationally aligned position; a platform having an external surface for positioning of the object and comprising at least one positioning mechanism located adjacent to the external surface; at least one positioning mechanism coupled to the imaging sensor allowing for movement of the imaging sensor adjacent to the external surface; at least one position tracking element affixed relative to the platform; where the emitting apparatus is moveable relative to the external surface of the platform; and a control system configured to determine a first coordinate measurement between the at least one position tracking element and the imaging sensor, the control system configured to determine a second coordinate measurement between the emitting apparatus and the at least one position tracking element, where the control system uses the first coordinate measurement and the second coordinate measurement to control actuation of the positioning mechanism moving the imaging sensor into the aligned position during or after movement of the emitting apparatus.

[0028] A variation of the improvements described herein also includes an improved method for non-invasively imaging an object. For example, such a method can include

moving an emitting apparatus to a location relative to the object; determining a position of the emitting apparatus relative to at least one position tracking element; relaying the position of the emitting apparatus to a motor system that adjusts an imaging sensor into an operative alignment with the emitting apparatus; emitting energy from the emitting apparatus when the imaging sensor is in operative alignment with the emitting apparatus; and transmitting an image signal from the imaging sensor to a display.

[0029] Another variation of the method can include non-invasively imaging an object, by moving an emitting apparatus to a location relative to the object; emitting energy from the emitting apparatus to the object such that the energy is received by an imaging sensor configured to generate an image data; determining a position and orientation of the emitting apparatus relative to at least one position tracking element located in a fixed position relative to the image sensor; adjusting an image data based using the position and orientation of the emitting apparatus; and transmitting the image data to a display.

[0030] Variations of the system can include platforms that have a planar surface allowing for positioning of the object. Alternatively, a platform can include a support frame that allows securing of the object over a free-space such that the portion of the object located in the free-space can be viewed or inspected either entirely or substantially around the perimeter of the object.

[0031] In the systems, devices and methods described herein, which position the emitter and sensor in alignment or operative alignment, the degree of alignment can include any industry specifications that dictate alignment. For example, for medical applications, alignment of the systems and methods described herein can include a degree of alignment required to comply with the U.S. Code of Federal Regulations applying to the FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES (e.g., 21 C.F.R. part 1020 incorporated by reference herein.) E.g., under 21 C.F.R. Neither a length nor a width of the x-ray field in the plane of the image receptor (sensor) shall exceed that of the visible area of the image receptor (sensor) by more than 3 percent of the source-to-image receptor distance (SID) and the sum of the excess length and the excess width shall be no greater than 4 percent of the SID and Any error in alignment shall be determined along the length and width dimensions of the x-ray field which pass through the center of the visible area of the image receptor. In other applications, or alternate jurisdictions, the alignment discussed herein can vary to meet the respective requirements. Alternatively, variations of the systems, devices, and methods can include such metrics as obtaining a near orthogonal positioning between an emitter and receptor.

[0032] As with alignment, a minimum or maximum distance between an emitter and receptor can be established by industry standards. In one example, using the above FDA regulations, a maximum source-image receptor distance of less than 45 cm and means shall be provided to limit the source-skin distance to not less than 19 cm.

[0033] In use, the stage precisely tracks the position and angle of the x-ray emission, positioning and tilting the embedded sensor exactly to capture a precise, high quality x-ray image. The stage uses less power, corrects for any

skew or perspective in the emission, allows the subject to remain in place, and allows the surgeon's workflow to continue uninterrupted.

[0034] In a "clinical" embodiment, an x-ray capture stage is statically positioned, with the emitter using the positioning to ensure the emission is only fired when the emission can be positively captured by the active area of the capture stage. Firing is also immediately terminated if acquisition of this positive capture is lost.

[0035] This application is related to U.S. application Ser. No. 15/716,099 filed Sep. 26, 2017, which claims benefit to Ser. No. 15/706,018 filed Sep. 15, 2017 which claims priority to U.S. Provisional Patent Application Ser. No. 62/394,909, filed Sep. 15, 2016; U.S. Provisional Patent Application Ser. No. 62/394,956, filed Sep. 15, 2016; U.S. Provisional Patent Application Ser. No. 62/471,191, filed Mar. 14, 2017; and U.S. Provisional Patent Application Ser. No. 62/504,876, filed May 11, 2017; and wherein the entire content of each Application is incorporated herein by reference. This application also incorporates PCT applications PCT/US2017/051774 filed Sep. 15, 2017 and PCT/US2019044727 filed Aug. 1, 2019 by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0036] FIG. 1A depicts an example of an operating room layout for use of the x-ray imaging system in a standard surgery of an extremity case.

[0037] FIGS. 1B and 1C depict an alternate example of an operating room layout for use of the imaging system with a specialized operating table that improves access to an area of a patient.

[0038] FIG. 2 is a simplified, schematic representation of an x-ray emitter according to the invention.

[0039] FIG. 3 illustrates one embodiment of a control panel for use with an emitter.

[0040] FIG. 4 shows a safety lockout procedure for an x-ray emitter.

[0041] FIG. 5 depicts a representative sequence for emitter power management.

[0042] FIG. 6 illustrates a process by which a device captures concurrent images at the request of a user.

[0043] FIG. 7 is a drawing that illustrates the overall components of a preferred embodiment of a capture stage.

[0044] FIG. 8A is an oblique view of a sensor positioning system.

[0045] FIG. 8B illustrates infrared (IR) positioning tiles.

[0046] FIG. 9 is diagram that shows x, y movement of a sensor tray viewed from above.

[0047] FIG. 10A is an oblique diagram showing a band-operated image capture stage.

[0048] FIG. 10B is a schematic diagram of a band-operated stage with an identification of important components.

[0049] FIG. 11A is a side view showing a sensor tilt operation.

[0050] FIG. 11B is a side view showing a sensor panning operation.

[0051] FIG. 12A illustrates an arrangement whereby emitter need not be provided on an image stage platform.

[0052] FIG. 12B illustrates additional arrangements of the imaging system where a sensor can be configured to capture lateral views by moving above a plane of the table.

[0053] FIG. 13 is a view of an infrared emission device emitting infrared from 5 points allowing for relative position calculation in 3-dimensional space.

[0054] FIG. 14 illustrates a safety lockout of the capture stage based upon the disposition of the emitter.

[0055] FIG. 15 illustrates the capture of a fluoroscopic image.

[0056] FIG. 16 is a view showing the x-ray emission device with an aperture creating the widest cone.

[0057] FIG. 17 a view showing the x-ray emission device with an aperture creating a narrow cone.

[0058] FIG. 18 shows a control unit operative to adjust the aperture and cone.

[0059] FIG. 19 is a labeled view illustrating relative distances.

[0060] FIG. 20 illustrates a situation where an emitting apparatus casts an energy profile that exceeds a profile of an imaging sensor.

[0061] FIG. 21A represents a situation in which an emission profile extends beyond a sensor such that the emitter is not in operative alignment with the sensor.

[0062] FIG. 21B represents a situation in which an emission profile is scaled to remain within a perimeter of an imaging sensor and is in operative alignment with the sensor.

[0063] FIGS. 22A and 22B illustrates an example of the effect of an adjustable collimator to produce an adjusted emission profile that is scaled and/or rotated to remain within the perimeter of an imaging sensor.

[0064] FIG. 23 shows a variation of an adjustable collimator that can be used in or with an emitting apparatus.

[0065] FIG. 24A shows an exploded view of an example of an adjustable collimator.

[0066] FIG. 24B illustrates a front view of some of the components of the adjustable collimator of FIG. 24A.

[0067] FIG. 24C illustrates a rear view of some of the components of the adjustable collimator of FIG. 24A.

[0068] FIGS. 25A and 25B illustrate an example of an emitter having an adjustable collimator.

[0069] FIGS. 26A to 26J illustrates an example of a validation method for the collimator discussed herein.

[0070] FIG. 27 illustrates an example of a traditional automatic exposure process.

[0071] FIG. 28A illustrates an improved system that relies upon one or more databases to provide machine learning for determination of exposure settings for a radiological image.

[0072] FIG. 28B illustrates a process of improving the automatic exposure process and databases using feedback from the systems described herein.

[0073] FIG. 29A is an illustration of a surgical assisted total knee arthroplasty.

[0074] FIG. 29B illustrates a positioning system with a system as described herein used to register a virtual model of the knee anatomy for use by the surgical robot.

[0075] FIG. 30A illustrates capture of lateral view with coordinates.

[0076] FIG. 30B illustrates capture of anteroposterior view with coordinates.

[0077] FIG. 31 shows Mapping X-Rays to CT w/position.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0078] FIG. 1A depicts an example of operating room layout for use of an imaging system in a standard surgery of an extremity case. In this example, the surgeon 102 is operating on the patient's left hand. The patient 104 is lying in the supine position with the left upper extremity prepped and draped on a hand table 105 in the abducted position. The

surgeon sits adjacent to the patient's side while a surgical assistant 106 sits across the hand table adjacent to the patient's head. Surgical instruments and equipment are laid out on the back table 108 immediately behind the surgical assistant.

[0079] In one variation, the imaging system uses x-ray imaging. As such, a sterilized x-ray emitter 110 according to the invention is placed on the surgical hand table 105 for use. A monitor 112 is positioned on a stand immediately adjacent to the hand table whereby x-ray, fluoroscopic, thermal and digital images can be wirelessly transferred from the x-ray imaging system to the screen for surgeon view. The emitter 110 allows the surgeon to hold it with one hand while operating another instrument such as a drill in the other hand. A detector stage according to the invention may be placed on or in the table 105 to gather radiographic imagery for storage and/or viewing on an external monitor such as device 112. As discussed herein, the emitter can be handheld or can be affixed to a mounting structure that is either automated/controllable or simply bears the weight of the emitter to prevent the user from constantly holding the emitter.

[0080] FIG. 1B illustrates an additional variation of a system including a sensor 706 and an emitter 710 for use with a specialized operating table 300. As shown, the operating table 300 includes structures 302 that stabilize the patient while allowing increased access around the patient's organs since a portion of the organ is suspended in free space. In this variation, a shell 707 containing the sensor 706 (as discussed below) is coupled to a first boom or arm 716. The arm/boom 716 allows for movement of the sensor 706. In an alternate variation, the boom 716 can be automated such that the sensor 706 is coupled directly to a controllable boom 716. Likewise, the emitter 710 is coupled to a second arm or boom 714 that can be affixed to a wall, ceiling or portable frame structure. FIG. 1C illustrate positioning of the sensor 706 and boom 716 adjacent to a body part of the patient 104 such that the emitter 710 can be positioned as desired by the operator or medical practitioner. In variations of the system, the boom or arm can also house components of the device, such as a heat sink, power supply, etc. allowing for a more compact and easy to maneuver emitter. In addition, either boom can be designed with features to aid the physician in performing the procedure. For example, the boom can incorporate a locking system so that the physician can position either the sensor 706 and/or emitter 710 and then lock the associated boom into position. Additionally, or in combination, booms can incorporate memory positioning such that the boom can automatically retract away from the surgical space to a pre-determined location such that it automatically moves out of the way of the physician when performing a procedure. In addition, memory locations can include the "last location" of the emitter or sensor, such that the system can automatically reposition the components in their last position prior to being moved away from the surgical space.

[0081] As discussed herein, the systems described herein can include one or more distance sensors 708 located on the image sensor and/or the operating table or other region of the working area. The distance sensor(s) 708 allow measurement of any space between the body part or anatomy placed on the image sensor, operating table, and/or working area. As noted below, such an additional measurement will allow correct measurement of the thickness of the body structure

if there is a gap or space between the image sensor, operating table, and/or working area and the body structure.

[0082] FIG. 2 is a simplified, schematic representation of an x-ray emitter according to the invention. The general configuration of the device is to be hand held, lightweight and extremely portable. The device preferably has a rounded, contoured handle to ergonomically fit the surgeon's hand and better direct fluoroscopy, digital and thermal imagery to the extremity and surgical field. Note that the drawing of FIG. 2 is not intended to depict any particular ornamental appearance.

[0083] The back of the emitter 110 has a control panel whereby at least three different modes of operation can be activated: fluoroscopic mode, digital picture mode, or infrared thermal imaging mode. Once activated, each mode is controlled in the front of the device by a trigger 202. Pressing the trigger once activates the device to take a single image (i.e., single x-ray or digital picture). Different modes of operation may be activated in different. As one example, holding the trigger 12 down may activate live fluoroscopy, digital video, or infrared thermal imaging. FIG. 2 also illustrates the emitter 110 as being coupled to a power supply 221. The power supply can be a battery 221 located remote from or within the emitter 110. Alternatively, or in combination, the power supply 221 can be coupled via wiring between the emitter 110 and power supply 221. In an additional variation, the battery 221 can be positioned within the emitter 110 and used in addition to a remote power supply 221 such that the emitter 110 can be disconnected from the external power supply temporarily with the internal battery 221 being used to provide power.

[0084] FIG. 3 illustrates one embodiment of the control panel for use with the emitter. The control panel is located on the rear of the emission handle and controls the various inputs and outputs of the system. The control panel is easily accessible for the user and is ergonomically designed to ease the manipulation of the emitter. The control panel comprises a large, clear screen 204 (i.e., LCD or OLED), a control button 302 located on the left of the unit, a control button 304 located on the right of the unit, and a center, clickable toggle button 206 located in the center.

[0085] Display screen 204 displays images and a digital control panel to control fluoroscopic, digital camera and infrared settings. The control panel may include a touch screen. Toggle button 206 controls power input in fluoroscopic and infrared modes, and digital zoom in the picture mode. The preferred emitter configuration houses a dynamic x-ray collimating cone 210, digital camera lens 212, infrared camera 214 and distance sensor 216. The digital and infrared cameras preferable use charge-coupled device (CCD) technology. The distance sensor may be infrared, acoustic or other operative technology known to those of skill in the art of proximity and distance measurement. The sensor 216 continuously senses its distance from the patient and will block the activation and discharge of radiation if the x-ray tube is too close, for example, if less than 19 centimeters directly from patient. In addition, the system can include any number of auditory, visual, or tactile indicators to allow a physician or user of the system to determine that the sensor is within an acceptable distance or ready to fire. In additional variations, the auditory, visual, and/or tactile indicators are positioned such that the operative state of the system is identifiable without the need for the user to remove his/her focus from the object being examined. In one example, a

visible indicator (e.g., one or more LEDs) is positioned on the emitter, which provides clearly distinguishable feedback regarding the distance, alignment, or any other operational conditions of the system.

[0086] The handle 200 tapers to the bottom of the device, which may house high-voltage power supply 218, external charging port 220 and battery docking station 222. Upon activation of the trigger 202 in x-ray or fluoroscopic modes, high voltage from power supply 218 is fed to x-ray generation unit 230 via the high voltage connector assembly 228. Power produced by power supply 218 is converted to a suitable input voltage that can be used by the x-ray generation unit 230. This power ranges from 1 kV to 120 kV, but typically ranges between 30 kV to 90 kV in conjunction with clinical application.

[0087] The x-ray generation unit 230 is based upon existing high-voltage emitters, though custom designed for small size required of the instant application. A suitable thickness of electrical insulating material surrounds the high voltage power supply 218, connector assembly 228 and the x-ray generation unit 230 to prevent radiation loss and preserve good beam quality. All three components 218, 228, 230 are placed immediately adjacent to each other to minimize high voltage leakage and possible interference with low voltage components in the system. In an alternative embodiment, components 218, 228, 230 may be disposed in an external control unit (not shown).

[0088] A suitable layered combination of silicone rubber and epoxy encapsulates the x-ray generation unit 230 (except where x-rays are emitted into collimator) in order to shield radiation losses and dissipate high temperatures generated by x-ray tube operation. Radiation is produced by the x-ray tube and transmitted via the collimating cone 210 at the head of the device. Fluoroscopic settings including peak kilovoltage (kV), amperage (mA), and digital brightness, which are controlled by the digital control panel on the back of the neck.

[0089] The digital camera lens 212 and infrared thermal camera 214 are immediately adjacent to the collimating cone 210, and these components are also shielded by insulation. The digital camera 214 is controlled by the placing the device in digital mode using the control panel. Pictures are generated via the trigger 202 located on the device handle.

[0090] Similarly, the infrared thermal camera 214 is controlled by the placing the device in infrared mode using the control panel. Live, infrared thermal imaging is generated by holding the trigger down. Digital x-rays, traditional digital visible and thermal images may be transferred and displayed on the external screen 112 shown in FIG. 1. Depending upon the level of cooperation between the emitter and the detector described herein below, x-ray images may be transferred directly to the external monitor for viewing. A memory 233 may be used to store any type of gathered image, and such images may be encrypted upon capture in accordance with co-pending U.S. patent application Ser. No. 15/466,216, the entire content of which is incorporated herein by reference. An audio pickup 235 may be provided for procedure memorization or other purposes, and the recordings may also be stored in memory 233, optionally in encrypted form as well.

[0091] The device is powered by an external, plugin power supply with external charging port 220. The digital display, control interfaces, and trigger are controlled via the control system microprocessor electronic control unit 232 powered by a low voltage power amplifier system 234. The

low voltage amplifying system 234 and the microprocessor control system 232 are also conveniently located away from the high voltage power supply to further minimize interference.

[0092] The following Table lists the various control modes associated with the emitter using the buttons and toggle switch on the control panel of FIG. 3:

Control	Mode		
	X-Ray	Digital	Thermal
Center (206)	Switch to Digital	Switch to Thermal	Switch to X-Ray
Left Button (302)	Increase Output Power	Toggle Macro	Decrease Exposure
Right Button (304)	Decrease Output Power	Zoom In	Increase Exposure

[0093] For a variety of reasons, both practical and certification, it is important to maintain a minimum distance between the subject and the x-ray generator. This distance can change depending on a number of factors and can be configured in the emitter's software. FIG. 4 shows a process by which the device manages a safety lockout procedure of the x-ray emitter. The process to determine the safety lockout is as follows:

[0094] 402. The user initiates the x-ray emission process by depressing the trigger while in x-ray mode. This could be for either a fluoroscopic or still x-ray image.

[0095] 404. A distance setting is retrieved from the emitter's distance setting database.

[0096] 405. The distance measurement unit is activated and captures the distance between the end of the emitter and the subject directly in front of the emitter.

[0097] 406. The distance setting and distance measurements are relayed to the emitter's ECU Computation unit.

[0098] 408. At 408, the ECU Computation unit uses the distance measurement, distance setting and an internal generator offset to determine if the emitter should fire.

[0099] 410. The fire/warn decision at 410 is determined by the ECU and relayed to the hardware units.

[0100] 412. At 412, if the ECU determines that the subject is too close to the emitter, the unit will activate a warning procedure, displaying a message on the LCD panel and activating any lockout warning lights.

[0101] 414. If at 414 the ECU determines that the subject is at a safe distance, the emitter will begin the x-ray generation and emission process, signaling all internal and external components.

[0102] Due to the fact that the device can move freely in 3-dimensional space, the projected cone from the x-ray emitter varies in size based on the distance to the target. As such, the invention allows managed control over the cone size based on the distance of the x-ray emission device from a sensor positioned on the stage.

[0103] FIG. 16 illustrates a simplified rendition of an applicable x-ray source, which includes an anode 1602 and cathode 1604. The anode typically includes a tungsten or molybdenum target 1606. High voltage across the anode and cathode causes x rays to be produced at the target, which forms a cone 1608 that exits through an aperture 1610 in casing 1612.

[0104] One aspect of the invention includes a telescoping chamber positioned in the direction of the aperture and

sensor. The distance from the x-ray source to the output aperture can be increased or decreased by rotating the exterior chamber along a threaded interior mount. Moving the aperture closer to the source creates a wider angle, while moving it farther from the source reduces the angle, as shown in FIG. 17.

[0105] Making reference to FIG. 18, a control unit 1802 in the hand-held emitter controls the telescoping aperture. Based upon the process below, the control unit 1802 rotates a threaded shaft 1804, whereupon the threads engage with grooves 1806 in telescoping chamber 1614, causing aperture 1610 to toward and away from the x-ray source.

[0106] Referring to FIG. 19, the control methodology is as follows. First, the distance between the device's x-ray origin and the x-ray sensor is calculated. If the distance is outside an acceptable range of x-ray emission then no x-rays will be emitted. However, if the distance between the x-ray origin and the sensor (d_s) are within the acceptable range, the aperture will be automatically moved into place. The distance between the x-ray origin and the aperture (d_a) is then calculated and the control unit rotates the aperture chamber to the correct distance.

[0107] If R_s represents the radius of the x-ray emission as it contacts the sensor, then the angle between the normalized vector of the sensor plate and the dispersion cone can be represented as $\theta = \tan^{-1}(R_s/d_s)$. The distance that the aperture will need to be located from the emission origin to emit the correct dispersion of x-rays can calculated as $d_a = R_a / \tan(\theta)$ where R_a represents the radius of the aperture. The control unit then allows the x-ray emission device to emit an x-ray which projects a cone at an angle θ onto the sensor.

[0108] While the telescoping cone adjustment mechanism described with reference to FIGS. 16-19 is preferred, those of skill in the art will appreciate that a more conventional adjustable aperture (i.e., with translatable x-ray absorbing or blocking blades) may instead be used. The same math used above is applicable to this embodiment; that is, if the distance is outside an acceptable range of x-ray emission then no x-rays will be emitted. Conversely, if the distance between the x-ray origin and the sensor (d_s) are within the acceptable range, the aperture will be automatically opened or closed to facilitate firing of the source.

[0109] Different markets have different safety requirements. Additionally, depending on the subject (elderly, pediatric, otherwise healthy) the lockout may be adjusted to ensure that there are no safety issues associated with the emission. The device also preferably includes the capability to intelligently conserve power by utilizing the inertial measurement unit (IMU), distance sensor unit, as well as the operator initiated command inputs. The various durations for the power stages of the unit are user configurable so that the device can match the user's specific style and cadence.

[0110] The systems and methods described herein can also use multiple sensors for error correction and/or to improve positioning. For example, if an emitter and detector/sensor are in a given position and the system loses tracking of one or more sensors on the platform ordinarily the loss in tracking might cause a reduction in the frames per second (FPS) of the output image. To address this situation, the emitter can include one or more inertial measurement units that can track movement of the emitter to adjust the intervening frame especially when needed. The IMU will then be used to adjust the intervening frames to increase the FPS of

the output. In some variations, with IMU's of sufficient accuracy, the IMU can be used in place of or in addition to sensors on the platform.

[0111] A representative sequence for power management is shown in FIG. 5.

[0112] 502. The user initiates the power sequence on the device by pushing a physical button (i.e., 208 in FIG. 2) on the emitter. This engages the device's electronics and moves the device into ON mode.

[0113] 504. Picking up the device is detected by the IMU in the emitter and immediately raises the power level to STANDBY. This STANDBY state initializes all power systems and raises the charge of the power supply to a medium level.

[0114] 505. If the user sets the device down or is otherwise not interacted with, either through movement of the emitter or through the initiation in the control panel or control computer, the device will automatically power down to the OFF stage after a duration of t0.

[0115] 506. The user has picked up the unit and has engaged the unit, either through altering of settings on the control panel itself or by bringing the device within range of a subject as detected by the onboard distance sensor. This further elevates the power level of the device by fully charging the power system to a state where the device is ready to fire, bringing the device into READY mode.

[0116] 507. If, after a duration of t1 without actively engaging the unit, the emitter will power itself down to the STANDBY level.

[0117] 510. The user initiates an x-ray capture by depressing the trigger 202 on the emitter. Assuming that all other safety checks are cleared, this further engages the power supply and emits the stream of x-ray photons at the subject until a state of 511, at which time the emission is complete. The user can continue to emit x-ray photons indefinitely at 510', 511', however, as the device returns to READY mode.

[0118] 511. After a duration of t2 during which time the emitter has not been fired, the device will automatically power itself down to the STANDBY level at 520.

[0119] As shown with points 508, 522, 524, the device will follow the above timings to transition the device from the ON stages and finally to the OFF stage as the various durations elapse without positive engagement to maintain or change the power state. By utilizing these steps, the device can conserve power while maintaining in a ready state without any interaction from the user.

[0120] FIG. 6 illustrates a process by which the device captures concurrent images at the request of the user. Using the settings on the emitter's control screen, or by specifying a concurrent capture in the control unit, the emitter will initiate a process to capture any combination of x-ray, traditional digital and/or thermal images. The process to capture the images is as follows:

[0121] 602. The user initiates the capture sequence on the device by pulling the trigger of the emitter. This begins the capture process and concurrent imaging process for whatever grouping of sensors is enabled.

[0122] 604. The emitter immediately engages the X-Ray standby mode, preparing to fire the x-ray generator.

[0123] 604'. Concurrently, if enabled, the traditional camera component focuses on the desired subject. This preferably occurs as soon as the trigger is depressed.

[0124] 604". Concurrently, if enabled, the thermal camera is powered on and begins its start sequence. This also preferably occurs as soon as the trigger is depressed.

[0125] 606. The x-ray system begins its safety checks, as illustrated in FIG. 4.

[0126] 608. The digital imaging camera captures a traditional image of the subject. The image is preferably automatically transferred to the control unit for display on an external monitor.

[0127] 610. The thermal camera captures a thermal image of the subject. The image is preferably automatically transferred to the control unit for display on an external monitor.

[0128] 620. In the preferred embodiment, after both 608 and 610 have completed, and all safety checks from 606 have been verified, the x-ray unit will fire an emission, generating an x-ray image in the sensor. The image is preferably automatically transferred to the control unit for display on an external monitor. Thus, the x-ray system will charge, verify safety, and discharge the x-ray only after all other systems have executed to minimize operational interference.

X-Ray Detector Implementations

[0129] The emitter described herein must be used in conjunction with an x-ray detector to gather radiographic imagery. The emitter is not limited in terms of detector technology, and may be used with any available flat-panel detector, even film. However, given fully portable nature of the emitter, steps should be taken to ensure that the emitter is properly oriented with respect to the detector to gather clear imagery while avoiding spurious or unwanted x-ray emissions. One option is to mount the emitter in a fixture including a properly aligned detector plate, much like a traditional c-arm though much smaller and more capable. A preferred option, however, is to use the emitter with the x-ray capture stages described below, one of which includes an embedded sensor that automatically pivots, orients and aligns itself with the emitter to maximize exposure quality and safety.

[0130] The preferred x-ray capture stage includes a statically fixed platform, positioned during the outset of surgery, with an interior cavity containing an x-ray sensor, an x-ray sensor positioning system, an emitter tracking system, a shielding system and a control unit. The x-ray capture stage is adapted to receive an x-ray emission from a separate emitter device, including the portable, hand-held unit described herein. The x-ray capture stage preferably also incorporates wireless (or wired) communications capabilities enabling review of a captured x-ray or fluoroscopic image to be reviewed on an external display monitor or any other arrangement for the captured image including external storage.

[0131] There are broadly two capture stage embodiments. In a clinical embodiment, the stage tracks the emission and simply locks out the x-ray firing if it is not in line. A tracking stage embodiment also permits or locks out emission in accordance with alignment, but also precisely tracks the position and angle of the x-ray emission, positioning and tilting the embedded sensor to capture a precise, high quality x-ray image. This arrangement uses less power, corrects for any skew or perspective in the emission and allows the subject to remain in place, thereby enabling the surgeon's workflow to continue uninterrupted and capture x-rays without repositioning equipment, the subject or the surgeon.

[0132] FIG. 7 is a simplified view of a preferred embodiment of the x-ray capture stage, which includes a platform 702 with a hollow cavity including the embedded sensor 706. In one configuration, the stage might have legs 703 and be used as a table. In another configuration, the stage might be wrapped in a bag and positioned underneath a patient. Thus, the platform 702 can be wrapped in a sterile drape and surgical procedures can be performed upon a platform such as table 105 in FIG. 1.

[0133] The capture stage cooperates with a separate x-ray emission device 710. There are a number of different configurations and implementations of the x-ray emission device besides the hand held unit described in detail above, including wall-mounted, armature-mounted, and floor-mounted. Any implementation is compatible with the operative x-ray stage as long as the electronic systems of the emitter can communicate with the interface of the operative x-ray stage central control unit to provide for pivoting, orientation or alignment.

[0134] The platform 702 is in electrical communication with a central control unit 704. A display monitor 712, electronically connected to the control unit 704, which may be used to both display images and provide overall system control. Generally, a user will interact with the emitter 710; however, in some cases, a user may interact with the central control unit 704 directly to manipulate images, setup specific capture scenarios, control parameters or adjust other settings. The system may also use a tablet, mobile phone or any other display device electronically connected to the central control unit for display purposes. The central control unit 704 and display may be combined in a single device, such as a laptop computer or other mobile computing device. Optionally, the central control unit can be electronically connected to multiple display units for educational or other purposes.

[0135] FIG. 8A is an oblique view of an x-ray capture stage according to the invention. In one specific arrangement the stage comprises a hollow, sealed, shell that is roughly 20"x30", although the overall size of the invention can be changed to conform to other surgical applications. The shell creates a cavity 800 housing an x-ray detection sensor 706 operative to capture an x-ray emission from an x-ray emitter. Suitable x-ray sensors are available from a variety of commercial manufacturers. The sensor 706 is attached to a motorized movement system used to pan and tilt the sensor within the cavity. This motorized system ensures that the sensor is precisely positioned for maximum image quality and capture view.

[0136] The x-ray sensor 706 is preferably mounted to a movable tray 802 that travels under controlled movement within the cavity 800. The tray and sensor can move in the x-y direction and tilt along both axes as described below. FIG. 9 is a diagram of a capture stage seen from above. The sensor 706 in tray 802 is mounted to translate on a series of motorized rails 720, 722, allowing the sensor to position itself anywhere along the x and y axis within the shell. At least one of the x and y tracks may be a threaded rod, for example, each being driven by a motor for precise lateral movement of the tray 802 in the x and y dimensions. As a further alternative the x-y movement of the tray may be controlled with bands 1002, 1004 in FIG. 10A. Such bands are precisely controlled by rods 1006, 1008, causing tray supports 1110, 1112 to translate tray 808. Note that while

four tray supports 902, 904 are depicted in FIG. 9, single supports 1110, 1112 may alternatively be used as shown in FIG. 10A.

[0137] FIG. 10B is a schematic diagram of a band-operated stage with an identification of important components. The X-ray detector is shown at 1030, and the detector carrier is depicted at 1032. This particular embodiment is driven by an H-shaped belt 1040. Items 1042 and 1044 are small and large offset bearings, respectively. The belt is driven by motors 1050, 1052. The stage housing is shown at 1060, and power is brought in via cable 1062. The detector tilt motors are indicated at 1070, 1072. IR positioning tiles and IR emitters described with reference to FIG. 8B, are shown at 850 and 852, respectively. The typical IR emitters described herein are active beacons since they actively emit a signal or energy that is received by the emitter to aid in determining a position of the emitter. Alternatively, or in combination, additional variations of the methods, systems and devices described herein can include passive markings or objects to aid in determining orientation of the emitter. The systems, devices and method can include camera or emitter that simply record a specific pattern (e.g., a QR symbol or some unique object in the surgical area such as a clock, table, fixture, etc.). The system will then rely on a computer to use these patterns in place of, or in combination with, IR beacons to determine a position of the emitter. In this latter case, the emitter position is calculated by the computer or other processing unit.

[0138] In all stage embodiments, the upper cover of the platform or shell is covered with a radiolucent material (i.e., 1018 in FIG. 10A). However, the lower base of the platform (i.e., 1020 in FIG. 10A) is preferably coated with an x-ray absorbing material such as lead. This coating prevents the excess x-rays from penetrating through the field and being absorbed by the operator of the emitter. This x-ray absorbing undercoating also prevents excess x-ray emission from bouncing off the floor and scattering throughout the facility. The sides of the platform may be constructed from a radio-opaque material as well.

[0139] FIGS. 11A, 11B are diagrams that show a pan and tilt mechanism. In FIG. 11A, the sensor tray 802 is positioned within the cavity and the sensor 706 is tilted around the y-axis. In FIG. 11B, the sensor tray 802 is tilted along both the x-axis and the y-axes. This panning and tilting allows the sensor to be precisely positioned to capture an x-ray image while minimizing the distortion created by the offset angle of the emission device. That is, the capture stage and x-ray emitter are coordinated to minimize skew and maximize capture of both x-ray and fluoroscopic images. By moving the sensor within the stage, the user does not need to reposition the subject to get a clear, usable x-ray or fluoroscopic image.

[0140] In the case of a handheld emitter, wherein the emission device is physically decoupled from the stage, it is important to position the sensor relative to the emitter for quality and safety reasons. Different techniques may be used to accomplish this goal. As shown in FIGS. 8 and 10, a plurality of position tracking implements 830 may be mounted to the ends or corners of the tray. While these implements may be used in all four corners, only one is necessary for accurate triangulation. These implements may be based upon ultrasonic tone generation or infrared emission. In these embodiments, acoustic or infrared signals generated in the platform are detected by the emitter device,

causing the sensor to translate and tilt to maximize capture. A further embodiment may utilize magnetic position and orientation sensors and detectors of the type used in surgical navigation to orient the tray and x-ray sensor.

[0141] The emitters 830 are used to measure the distance from a point 810 on the hand-held unit 710 to three (or more) fixed points 830 attached the stage. These distances are depicted as D₁, D₂ and D₃ in FIG. 8A. Based upon these distances, the system employs a tracking method to precisely locate a center point 801 on the sensor 706 and angle (θ_5) of the emission from the source to the platform. An exemplary implementation of this tracking system would include a combination of infrared sensors within the platform and the hand-held unit, as well as a gyroscope in the stage and hand-held unit to detect the angle θ_5 .

[0142] The positioning of the detector uses a number of sensors in concert. When the user picks up the hand-held unit, the system enters a ready state. The infrared beacons on the corners of the table illuminate. The positioning tracking camera on the hand-held unit immediately starts analyzing the infrared spectrum captured within a 140-degree field of view. The camera is searching for patterns of infrared light. Each corner 830 has a specific pattern that determines which corner of the stage the infrared camera in the hand-held unit is looking at.

[0143] Making reference to FIG. 8B, an IR positioning emitter tile 850 sits at each corner of the operative or clinical stage. The diagram is an example of four unique tiles. When using the mounted positioning beacons, the pattern will be different. These tiles contain a number of infrared emitters 852, usually five individual emitters, arranged in a specific pattern. Each tile contains a different pattern of the five IR emitters. As the operator moves the x-ray emitter around the stage, the IR positioning camera captures and analyses the IR emissions from the tiles. Because each tile has a unique pattern, the camera is able to determine its exact position in relation to the table. Additionally, because each tile has a unique pattern of multiple lights, the system can determine the exact position from the tile in XYZ space.

[0144] Optionally, or in addition to this unique IR layout, the IR emitters can flash in a syncopated manner. By modulating the frequency of the flashes, it is possible to add an additional uniqueness signature to each tile, allowing patterns to repeat in a scenario with a large number of tiles. Because of this unique arrangement, only a single corner of the unit, or single positioning beacon, needs to be visible to the emitter to allow the system to fully function. That is, due to the layout of the pattern, the camera can triangulate its position in space relative to each corner. By using the triangulation data, as well as the orientation data from the IMU unit on the emitter, the system can determine the center point of the emission. The stage will then move the center point to that area of the stage and tilt the detector to be as perpendicular to the emission as possible. While the sensor is moving itself into position, the collimator on the emitter adjust the output of the beam to ensure that it is illuminating the detector panel only.

[0145] The position information from the combination of the sensors 830 is routed through the control unit (i.e., 704 in FIG. 7), which interpolates the raw sensor data into an aim point on the platform. The platform then moves the sensor tray 802 to the specified point. The platform then tilts the sensor into the correct orientation (θ_5) to remove as much skew as possible. Stated differently, assuming the x-ray

source in emitter **710** emits radiation with respect to an axis **803**, the goal is to place the axis **803** as close as possible to the center point **801** of the sensor, with the plane of the sensor being as perpendicular as possible to the axis **201** to minimize skew.

[0146] The x, y, pan and tilt positioning of the tray and sensor may be accomplished without position emitters in the platform portion of the system. FIGS. 12A and 13 illustrate an alternative system and method of position calculation that removes the dependency of having position emitters embedded in the table. Instead, the position of the x-ray emitter in relation to the capture stage and x-ray detection sensor can be calculated based on external position emitters. As noted above, the emitter can be purely hand-held to allow a practitioner to move the emitter in free-space. Alternatively, the emitter can be moveable with (or coupleable to) a support structure that maintains the emitter in position relative to the object without requiring the physician to continuously hold the emitter.

[0147] The process to determine the location of the x-ray emission device in accordance with this embodiment is as follows:

[0148] The external positional emission device(s) are installed onto a fixed location and contain a series of infrared emitters. This emission device releases infrared patterns from 5 sides of a cubic object **1202** resulting in infrared energy being sent out from slightly different origins.

[0149] The stage detects the infrared pattern and calculates the relative position from the stage to the center of each infrared emitter in 3-dimensional space. This position will be considered $[x_{si}, y_{si}, z_{si}] = [-xei, -yei, -zei]$ with s representing the stage, e representing the infrared emission device, and i representing the index of the infrared emission device (if leveraging multiple infrared emitters).

[0150] The x-ray emission device continually detects the infrared signal patterns and determines the relative location of the emission device to the center of each infrared emitter in space. This relative position is relayed to an emission position control unit for each emitter. This position may be considered $[x_{hi}, y_{hi}, z_{hi}] = [-xei, -yei, -zei]$, with h representing the x-ray emission device, e representing the infrared emission device, and i representing the index of the infrared emission device.

[0151] The emission position control unit will receive the relative positions of the x-ray emission device ($[x_{hi}, y_{hi}, z_{hi}]$). Using these relative positions, the emission position control unit calculates the position of the x-ray emission device relative to the stage (FIG. 13), resulting in $[x_{hi}-x_{si}, y_{hi}-y_{si}, z_{hi}-z_{si}]$. This operation is performed for each infrared emission device (i), which can then be used to deduce the margin of error.

[0152] After the stage applies the position along with the other pieces of data as mentioned in the original filing, the stage moves and rotates the x-ray sensor plate into the correct position to capture the x-ray image.

[0153] FIG. 12B illustrates a variation where an emitter **710** can apply energy to a sensor/detector **706** that is configured to move as discussed herein but can also move to enable a lateral image. In the illustrated variation, the sensor/detector **706** moves outside of the center X axis of the table **105** to capture lateral views of the patient **104**. However, variations of the sensor **706** can include configurations where the table is non-planar and is configured to receive the sensor **706** above a plan in which the patient is positioned.

FIG. 12B also illustrates an additional concept where multiple detectors **706** are used as described herein. In such a variation, the sensors **706** would be moved as described herein, but the sensor having the best operational alignment would be used to generate a signal.

Safety Lockout Procedures

[0154] Just as it is important to limit emissions from the emitter to specific target distances, for a variety of reasons, both practical and certification, it is important to only fire the x-ray generator when the emitter is properly aimed at the capture stage. By preventing the x-ray generator from emitting photons while not pointed at the stage, the safety of the system is improved and the performance of an emitter is increased. FIG. 14 illustrates the process by which the device manages the safety lockout of the emitter and captures an x-ray image, with the numbers corresponding to the numbers in FIG. 14:

[0155] 1. User initiates the capture process by signaling through the emission device **110**, typically by depressing a trigger. The emitter sends a data packet (D) to the controller containing the request for capture, the distance measurements (d_1, d_2, \dots) and the angle of the emitter.

[0156] 2a. The Controller validates that the emitter is in a safe orientation.

[0157] 2b. If the Controller discovers that the emitter is not in a safe, valid orientation, the controller sends an error message to the emitter. This prevents the emitter from firing and signals to the user that there is a problem.

[0158] 3. The stage positions the sensor in accordance with the position of the emitter. The stage will tilt the sensor so that it is in the correct orientation to capture a clear image. The orientation will be as close to the complementary angle of the emission as possible.

[0159] 4. The stage then sends a confirmation message to the controller after the position has been established.

[0160] 5. The controller forwards the start message to the emitter. The emitter will then execute any additional safety or preparation tasks. If the emitter believes the environment is safe to fire, the emitter will then fire the x-ray.

[0161] 6a. The emitter fires a pulse of x-ray photons at the stage for the requested amount of time.

[0162] 6b. During the emission of the x-ray photon stream, the emitter constantly streams any updates to the position and angle to the central controller.

[0163] 6c. The controller records these positional updates and relays them to the stage.

[0164] 6d. The stage will rapidly and constantly update the position and angle of the sensor to optically stabilize the x-ray image.

[0165] 7. The sensor captures the emission of x-ray photons from the emitter and builds an image.

[0166] 8. Upon completion of the x-ray emission, the sensor relays the data to the control unit.

[0167] 9. The control unit then cleans up the image from the sensor using a variety of known optical enhancement techniques. If applicable, the control unit will leverage the stored movement data from the emitter to further enhance the output.

[0168] The above process allows the emitter to ensure that the emission will be directed at the sensor and the stage as opposed to any other arbitrary target. By moving the sensor into place below the emission target, the user can create a

resolute, flexible image of the exact desired portion of the subject without having to reposition the subject.

[0169] FIG. 15 illustrates the process by which the device captures a fluoroscopic image. The process for capturing a fluoroscopic image is very similar to capturing a static x-ray image; however, the fluoroscopic process will repeat several emissions and image captures to create a moving image. The process to insure the safe emission as well as capture the fluoroscopic image, with the numbers corresponding to the numbers in FIG. 15:

[0170] 1. User initiates the capture process by signaling through the emission handle, usually by depressing a trigger. The emitter sends a data packet (D) to the controller containing the request for capture, the distance measurements (d_1, d_2, \dots) and the angle of the emitter.

[0171] 2a. The Controller validates that the emitter is in a safe orientation.

[0172] 2b. If the Controller discovers that the emitter is not in a safe, valid orientation, the controller sends an error message to the emitter. This prevents the emitter from firing and signals the user that there is a problem.

[0173] 3. The stage positions the sensor in accordance with the position of the emitter. The stage will tilt the sensor so that it is in the correct orientation to capture a clear image. The orientation will be as close to the complementary angle of the emission as possible.

[0174] 4. The stage then sends a confirmation message to the controller after the positioning.

[0175] 5. The controller forwards the start message to the emitter. The emitter will then execute any additional safety or preparation tasks.

[0176] In the fluoroscopic mode, the emitter will repeat the following steps while the emitter device continues to request additional fluoroscopic frames, as follows:

[0177] 6a. The emitter fires a pulse of x-ray photons at the stage for the requested amount of time.

[0178] 6b. During the emission of the x-ray photon stream, the emitter constantly streams any updates to the position and angle to the central controller. If at any time during the fluoroscopic process, the operative stage detects the emission is not aimed at the stage, the stage will send a termination signal to the emission device and skip directly to step 9.

[0179] 6c. The controller records these positional updates and relays them to the stage.

[0180] 6d. The stage rapidly and continuously updates the position and angle of the sensor to optically stabilize the x-ray image.

[0181] 7. The sensor captures the emission of x-ray photons from the emitter and builds an image.

[0182] 8. The sensor immediately transfers the image to the control unit. At this time, a brief cleanup process is executed and the image is displayed on the external viewing device. This fluoroscopic frame is saved to memory.

[0183] The constant repetition of this process creates a moving image on the external display. The process will repeat until the user releases the trigger of the emission device.

[0184] 9. Once the user releases the trigger of the emission device, the control unit "cleans up" the stored frames from the sensor using a variety of known enhancement techniques. If applicable, the control unit will also apply any stored movement data from the emitter to further enhance

the output. The control unit will then combine the fluoroscopic frames into a single video for repeated playback.

[0185] The above process allows the user to see a live fluoroscopic view of the subject in real time. By storing the images and reprocessing after the capture is complete, the device can create a high quality, single fluoroscopic video for display and review at a later time.

Self-Adjusting Collimator

[0186] As noted above, the systems of the present disclosure allow for moving an emitting apparatus to a location relative to the object and determine a position of the emitting apparatus relative to at least one position tracking element where the at least one position tracking element, measures a distance between the emitting apparatus and the object and preventing emitting energy until the distance is less than a pre-determined distance. Variations of the systems described herein can use a self-adjusting collimator that optimizes a profile or boundary of the emission onto the working surface of a sensor. As with other variations described herein, these systems can relay the position of the emitting apparatus to a motor system that adjusts an imaging sensor into an operative alignment with the emitting apparatus where relaying the position of the emitting apparatus includes using the emitting apparatus to both provide an orientation data of the emitting apparatus and determine a distance from each of the plurality of tracking elements. However, the use of a self-adjusting collimator allows for automatic maximization of an emission profile on the imaging sensor.

[0187] To illustrate the benefit of an adjustable collimator, FIG. 20 illustrates a representation of an x-ray emitter 110 directed towards a table 114 having an imaging sensor (not shown) located therein. The perimeter of the working area 117 of the imaging sensor is shown to illustrate the area that will produce an image upon exposure to an x-ray emission. As shown, a profile of an x-ray emission 120 from x-ray emitter 110 extends beyond the perimeter of the working area 117 of the imaging sensor causing the x-ray emitter to be out of operative alignment with the sensor. In such a case, the system as described herein will not permit firing or initializing of the x-ray emitter 110. The illustration of FIG. 20 is intended to illustrate a concept of the system being out of operative alignment. As noted herein, the imaging sensor can be coupled to a motor system to permit movement of the sensor into alignment with the emission profile 120. Alternatively, the table (or operating surface) 114 can include a plurality of position tracking elements (not illustrated in FIG. 20) that allows determination of the position and distance of the emitter 110 relative to a non-moving sensor or the sensor's working area 117.

[0188] FIG. 21A represents a situation in which an emission profile 120 extends beyond the sensor 116 such that the emitter is not in operative alignment with the sensor 116. For purposes of illustration, the sensor 116 shown in FIGS. 21A and 21B is stationary and tracking elements 118 permit the system to determine the relative location, orientation, and distance of the emitter (not shown) relative to the sensor 116. Also, the emission profile 120 is illustrated as a representation of a boundary of the emission provided by the emitter. For purposes of illustration, the profile 120 illustrated is a profile that would occur if an axis of the emitter is perpendicular to the sensor 116.

[0189] As noted herein, if the system cannot establish operative alignment given the condition shown by FIG. 21A,

the operator will be prompted to adjust a position of the emitter. In some variations, the system can provide feedback such as an audible or visual indicator of non-alignment. FIG. 21B shows a situation after repositioning of the emitter such that the emission profile 120 falls within the boundary of the sensor 116. However, as shown, this emission profile 120 is not maximized to the dimensions of the sensor 116. Failure to maximize the emission profile 120 relative to the sensor can require the operator to take additional radiological images of the subject to adjust for a smaller profile.

[0190] FIG. 22A illustrates the effect of an adjustable collimator. Again, for purposes of illustration, the emission profiles shown represent illumination by an emitter that is perpendicular to a sensor. FIG. 22A shows an unadjusted emission profile 120 that would ordinarily be considered out of operative alignment with the imaging sensor 116 given that a portion of the emission area bound by the profile 120 falls outside of the sensor 116. However, a variation of the system described herein will rely on the position tracking elements 118 as well as components affixed to the emitter (as described above) to determine positional information such as an orientation of the emitter as well as a distance between the emitter and the sensor 116. The system will use the positional information to adjust a collimator on the emitter to rotate and/or scale emission by the emitter to produce an adjusted emission profile 122. As shown, in this variation, the adjusted emission profile 122 is reduced in size (denoted by arrows 126) and also rotated (denoted by arrows 124) to scale the emission profile 120 into an adjusted emission profile 122 that maximizes an exposure onto the imaging sensor. It is noted that the adjusted emission profile can be scaled or rotated as needed. Moreover, variations of the system will produce an adjusted profile during real-time movement of the emitter relative to the sensors 118.

[0191] FIG. 22B illustrates an unadjusted emission profile 120 along with the adjusted emission profile 122, where in both cases, the profile resembles an isosceles trapezoidal shape due to an axis of the emission path not being perpendicular or normal to the sensor 116. However, in this variation, the system uses the positional information to produce an adjusted profile 122 that maximizes an exposure area on the image sensor 116.

[0192] While the variations disclosed herein rely on tracking elements 118 as well as sensors within the emitting unit (as described herein). Variations of the system that produce an adjusted emission profile can also be used with positional data that is derived from external cameras, sensors, or mechanical supports to determine relative movement between an emitting apparatus and an imaging sensor.

[0193] FIG. 23 shows a variation of an adjustable collimator 130 that can be used in or with an emitting apparatus (not shown in FIG. 23). As illustrated, the adjustable collimator 130 can rotate and/or scale an aperture or emission window 132 to produce an adjusted emission profile upon an imaging sensor (as discussed in FIGS. 20 to 22B). This variation of the adjustable collimator 130 uses a number of blades or leaves 134 that can move and rotate to adjust an orientation of the aperture 132. The blades 134 prevent passage of the emitted energy such that energy is limited to pass through the aperture or emission window 132.

[0194] The movement and rotation of the blades can be driven by any number of motors or drives. In the variation shown, the adjustable collimator 130 includes a motor assembly having a first drive 138 coupled to a proximal

slewing bearing 152 and a second drive 136 coupled to a distal slewing bearing. The drives 136 and 138 adjust the rotation of the blade 134 as well as a sizing of the aperture 132. For example, rotation of the motors 136 and 138 in opposite directions causes rotation of the slewing bearings in the opposite direction and produces movement of the blades 134 to cause opening/closing of the aperture 132. In the example shown, if the first drive 138 moves in a clockwise direction and the second drive 136 moves in a counter-clockwise direction, then the blades 134 will move towards each other causing a size of the aperture 132 to decrease. Likewise, if the first drive 138 moves in a counter-clockwise direction and the second drive 136 moves in a clockwise direction, then the blades 134 will move away each other causing a size of the aperture 132 to increase. If the drives 138 and 136 move in the same direction, this will cause rotation of the proximal and distal slewing bearings 150 and 152 in the same direction, which will cause rotation of the blades, which causes rotation of the aperture 132.

[0195] The adjustable collimator 130 maintains an aperture 132 having a near-square shape since all of the blades 134 move to adjust the size of the aperture. Additional variations of the device can include any number of additional motors or actuators to also control an angular orientation of the blades. In such a case, the aperture 132 is not limited to a square profile and can assume an isosceles trapezoidal shape. Such a feature can assist in maintaining a square emission profile (such as that shown in FIG. 22A) regardless of the orientation of an axis of the emission energy to the imaging sensor.

[0196] The variation of an adjustable collimator 230 shown in FIG. 23 also includes a chassis or housing 140 that houses the drive mechanism (e.g., bearings, pulley 144, belts 146, etc.) that translates the movement of the gears 144 driven by motors 136, 138 into rotation and movement of the blades. Furthermore, the adjustable collimator 230 will include any number of positioning tracking systems that enables the system to maintain information regarding a size and rotational orientation of the aperture. For example, a first moveable disk (or encoder wheel) 142 is shown as part of an optical encoder system that can use any conventional light source, sensor, mask, and photosensor (e.g., a photodiode).

[0197] FIG. 24A shows an exploded view of an example of an adjustable collimator 130 to illustrate a variation of the mechanism used to rotate and scale the aperture 132 formed by the blades 134. As illustrated pulleys 144 coupled to the motors 136 and 138 rotate belts 146 that are coupled to a cam/pin assembly 148. The blades 134 are housed in the cam/pin assembly 148 but for purposes of illustration, the cam/pin assembly 148 is shown without the blades. The assembly 148 comprises a cam wheel 150 and a proximal slewing bearing 152 that are each coupled to a respective motor 136 and 138 via the belt system 146. The blades 134 coupled to one or more pins 154 within the assembly 148 of slewing bearings 150 and 152 such that rotation of the slewing bearings 150 and 152 causes a scaling of the aperture 132 as discussed above. This scaling is caused through movement of the blades 134 closer or farther apart. The rotation of the aperture 132 is caused by rotation of the slewing bearings 150 and 152 in the same direction.

[0198] FIG. 24B illustrates a front view of some of the components of the adjustable collimator 130 (a number of components are removed for the sake of illustration). As

shown, the aperture 132 is defined by area surrounded by the blades 134. Each blade is coupled to a pin 154 at one end. The opposite end of the blade 134 includes a bearing 158 within a slot 156. Actuation of the motor 138 causes movement of the bearing 158 within the slot 156 while the blade 134 pivots about the pin 154, which causes the blades to move closer together or farther apart (depending upon the direction of rotation) at the aperture 132 to produce a scaling of the aperture 132. Rotation of the aperture 132 occurs when motor 136 causes rotation of the cam wheel 150 (shown in FIG. 24A). As noted above, rotation of the aperture 132 requires rotation of the slewing bearings 150 and 152 in the same direction.

[0199] FIG. 24C illustrates a rear view of some of the components of the adjustable collimator 130 (a number of components are removed for the sake of illustration). As shown, the collimator 130 includes a second moveable disk (or encoder wheel) 160 that is shown as part of an optical encoder system that can use any conventional light source, sensor, mask, and photosensor (e.g., a photodiode) to track movement of the blades 134.

[0200] FIGS. 25A and 25B illustrate an example of an emitter 164 having an adjustable collimator 130 as discussed above. As shown, the adjustable collimator can rotate and scale the aperture 132 based on information regarding the distance and orientation of the emitter from the system's position tracking elements. The scaling and rotation of the aperture 132 can be automatic or can occur on demand. FIGS. 25A and 25B show a variation of the emitter having cabling 166. In other variations, the emitter and adjustable collimator can be used on a fully portable emitter as described herein.

[0201] The optical encoders 160 in FIG. 24C ensures leaf or blade positioning to ensure patient safety. The encoder 160 can also assist in determining any number of conditions that could create a failure state: For example, the encoders can detect conditions, including but not limited to: drive belts skipping a tooth on the gear, drive belts breaking or losing tension, motor malfunctions, broken ring gear, broken leaf pin, etc. Detection of such failure state can prevent the emission source from triggering to avoid exposing the patient or operator to excess radiation.

[0202] FIGS. 26A to 26J illustrates an example of a validation method for the collimator discussed herein. The rolling collimator has two processes that are executed to validate the mechanical operation and alignment of the device. Due to the emission of ionizing radiation from the x-ray tube, it is imperative that the mechanical function of the device be validated before use, discovering any physical damage before exposing the operator to additional radiation. The freely mobile, untethered design of the device creates an additional challenge for the collimator: indexing the position of the wheels to an arbitrary alignment of the x-ray detector. The collimator executes a homing process to determine the min/max aperture positions and the 0° position of the device. The homing process establishes the zero-orientation reference required for collimator aperture control. The leaf detection process validates the physical operation of the device by verifying the full range of aperture sizing.

[0203] FIG. 26A shows a random position of the leafs of the collimator device. This position could be the orientation of the device after a previous operation, from a previous procedure or any other scenario. The device has no knowledge of the aperture or orientation until after the homing

process. The device consists of (1) (2) (3) optical sensors to monitor the position of leaves, (4) (5) motors to drive a distal slew ring (12) and a proximal slew ring (13) connected by a pair of belts (10) (11). The four collimation leaves (6) (7) (8) (9) are connected to the slew rings in pairs.

[0204] The optical sensors (1) (2) (3) operate by detecting the presence or absence of leaf material directly in front of the sensor. The sensor is considered open if there is no material in front of the sensor. It is considered closed if the presence of the material is detected.

Homing Procedure:

[0205] Step 1: Open Position—The homing procedure is executed any time the device is powered on, any time the device has been in an idle state or any time the device has detected drift. The device begins by rotating the proximal ring until the device detects movement in the distal ring by linkage. FIG. 26B shows the non-determinate position of this scenario, illustrated by the visibility of the home keyway (14). This alignment allows the optical sensor 1 to detect an open state when the keyway is directly in front of the sensor. This is the fully open position of the collimator.

[0206] Step 2: 0 Degree Position, Maximum Aperture—FIG. 26C shows the 0 degree, maximum aperture position. Once the fully open position has been determined, the device will rotate the proximal and distal rings concurrently, rotating the leaf assembly. The system will monitor the status of optical sensor 1 until such a time as the sensor registers open (15). This open signal indicates that the keyway has rotated into the position of the sensor at the fully open position. The system then registered this as the fully open, 0 degree position.

[0207] Step 3: 0 Degree Position, Minimum Aperture—The device will then turn the distal slew ring until such a time as it detects movement in the proximal slew ring. When this movement is detected, the system will then register the 0 degree, minimum aperture position as shown in FIG. 26D.

[0208] These positions are then registered for the current operational session. With the motor position recorded, the device can calculate the relative movement of the motors and slew rings to any other necessary position.

Damage Detection Procedure:

[0209] As described above, a fully operational, undamaged collimator is essential to the safety and performance of the collimation system. Furthermore, detecting and damage or drift is critical before any emission is released through the device. In order to guarantee performance, the device will consecutively check the positioning status of each leaf.

[0210] At minimum a single check of each leaf is necessary; however, due to the safety nature of this process the exemplary device uses a three position check. The optical sensor array (1) (2) (3) is used to validate individual leaf performance but any number of sensors could be used to execute the process. The order of the checks is can vary. Once the three step process has been completed for the first leaf (16), the process will move on to validate leaf two (17), leaf three (18) and leaf four (19). The process is applicable to any number of leaves.

[0211] Step 1: Maximum Aperture Validation—Sometime after the homing process has been completed, the device will roll the leaf assembly into Optical Sensor 1 closed position (20) FIG. 26E by moving both proximal and distal rings as necessary to create the fully opened aperture. The device will then immediately move into Optical Sensor 1 open position by moving the rings to reduce the aperture FIG. 26F. If the calculated movements of the device match the physical feedback of Optical Sensor 1 (21) the device has validated the maximum aperture position for leaf 1 (16).

[0212] Step 2: Median Aperture Validation—Sometime after the homing process has been completed, the device will roll the leaf assembly into Optical Sensor 2 closed position (22) FIG. 26G by moving both proximal and distal rings as necessary to create the median aperture. The device will then immediately move into Optical Sensor 2 open position by moving the rings to reduce the aperture FIG. 26H. If the calculated movements of the device match the physical feedback of Optical Sensor 2 (23) the device has validated the maximum aperture position for leaf 1 (16).

[0213] Step 3: Minimum Aperture Validation—Sometime after the homing process has been completed, the device will roll the leaf assembly into Optical Sensor 3 closed position (24) FIG. 26I by moving both proximal and distal rings as necessary to create the minimum aperture. The device will then immediately move into Optical Sensor 3 open position by moving the rings to reduce the aperture FIG. 26J. If the calculated movements of the device match the physical feedback of Optical Sensor 3 (25) the device has validated the maximum aperture position for leaf 1 (16).

[0214] Once Step 3 has completed for Leaf 1, the device will then repeat the procedure for each leaf, guaranteeing that each leaf is in the expected position.

[0215] FIGS. 27 and 28A-28B illustrate another aspect in which a radiological system having a sensor configuration as described herein can improve the quality of an x-ray or fluoroscopic capture.

[0216] The quality of an x-ray or fluoroscopic capture is related to a number of physical attributes of the subject. These elements dictate a set of technique factors (eg: power, current, time, etc.) that control the emission characteristics of the radiation source/emitter. It is the responsibility of the device operator to set these factors in such a combination that the individual viewing the radiological image can identify the necessary visual elements without exposing the subject to excess radiation.

[0217] Setting these technique factors can be complex. In order to relieve the operator of the burden of setting these techniques manually, existing fluoroscopic devices have implemented an automatic process. The typical approach uses a software or a hardware dose detector on the plate that gradually fills as radiation is added to the exposure. This conventional approach has a number of problems.

[0218] One major issue with the conventional approach is movement. Because the radiation is exposing the subject for an extended time period, any movement whatsoever, either in the subject, the operator, the machine, vascularity inside the subject, etc., creates motion artifacts that severely degrade the image.

[0219] Another issue is that penetration requirements are not known before the exposure; therefore, as the source

emits radiation at a given power level (kV), frequently there is not be enough penetration to render an image. This failure to render an image exposes the patient, operator and staff to radiation without producing any useful radiological image. In such a case, these individuals are exposed to excess radiation that does not serve any clinical purpose.

[0220] Innovation in the fluoroscopic device space, including but not limited to the systems described herein, creates a new generation of machines with complex sensor arrays, capable of directly measuring a number of the physical elements required for exposure calculation.

[0221] By utilizing these sensors across the full spectrum of devices and subjects, as well as robust machine learning techniques, it is possible to compute the necessary techniques before exposure, eliminating motion artifacts and creating an outstanding capture, all while reducing dose.

[0222] The following descriptions provide exemplary details of the invention in order to provide an understanding of the invention. Small engineering adjustments could be employed to practice the invention without employing these specifics. While the invention is described for use in x-ray imaging for surgical purposes, it could be used in other medical applications including but not limited to general medical imaging, veterinary, and bone densitometry. It could be used for non-medical applications such as industrial imaging, metal fatigue inspections, weld-inspection, for security inspections, and the like.

[0223] FIG. 27 shows a diagram of an example of a conventional methodology for automatic x-ray exposure process. The doctor or operator begins the exposure (step 1) by requesting the x-ray be taken. The x-ray device will then evaluate the detector (step 2), tracking the amount of radiation received on the imaging sensor plate. An internal measurement of x-ray machine will determine if this energy is a sufficient amount of exposure to generate an image (step 3). If the device determines that an adequate amount of radiation is collected (step 4a), it will deem the exposure complete and display the x-ray. If the user cancels the x-ray or the dose has been accumulating for too much time, the machine will cancel the exposure (step 4b.) Otherwise, (step 4c) the device will continue to emit radiation, returning back to the evaluation step until the image is created, time runs out or the user cancels the exposure.

[0224] The traditional process has a number of drawbacks, the two largest are that: exposure begins without a guarantee that an image will appear and that the time taken to evaluate the exposure introduces movement artifacts in the final image, creating an unusable x-ray. In either case, the patient, operator and staff are exposed to unnecessary radiation, which is a major safety hazard.

[0225] FIGS. 28A and 27B illustrates an improved approach over the conventional methodology described in FIG. 27. The improved approach can determine the optimal technique factors to create a resolute and effective radiological image without exposing the operator, staff and patient to unnecessary or excessive radiation. By utilizing a radiological imaging device with a comprehensive sensor array and an enterprise wide application of machine learning techniques, the system 16 can calculate and refine the techniques before any radiation is emitted. This allows an operator to precisely align the device and understand if the machine is capable of imaging the anatomy.

[0226] FIG. 28B illustrates an example of how statistical data can be compiled for use in the imaging process of FIG.

28A. In practice, a number of statistical models are transmitted to the system **16** from a central server (shown in FIG. **28B**). These models, referred to as the Computer Vision Classifier (**1a**) and the Estimator Update (**1b**) are stored locally on the machine and ready for use prior to the operator requesting the exposure.

[0227] Turning to FIG. **28A**, the process can begin with the operator initiating the capture (**2**). The operator then uses the positioning system of the device to align the emitter and anatomy (**3**), completing the safety checks, then executing the automatic technique detection (as described above). Depending on the exact topography of the x-ray system, CPT Code information (**4a**) and or Biometric Information (**4b**) may be entered by an operator or extracted from another system by automatic means.

[0228] As the system prepares to emit the energy for either x-ray or fluoroscopic capture, two concurrent measurement collections are happening: on-device sensor collection (**5a**) and computer vision classification (**5b**).

[0229] The sensor collection uses the array on the device to collect a multitude of input parameters, including, but not limited to, source-to-skin distance (SSD), source to detector distance (SDD), angle of incidence, ambient, x-ray tube and device temperature, etc. These parameters are all fed into the inference execution function (**6**).

[0230] The computer vision classifier utilizes the imaging camera on the device to capture pictures of the subject anatomy. These images are passed into the CV analysis function, using the captured images as well as the CV Classifier data that is stored locally on the device, provided by the central server. These processes make a determination about that subject of the capture and passes that recommendation to the Inference Execution Engine.

[0231] Once the inputs are collected from the device's various subsystems, those values, along with the Estimator Update provided by the central server, are run against the device's inference execution engine (**6a**). The output of that function family is the determined x-ray technique: time, kV and beam current (**7**).

[0232] The device output is set to the computed values, radiation is emitted for the given settings (**8**), the image is captured and processed (**9**) and the image is displayed to the user. (**10**)

[0233] As soon as the x-ray is displayed to the operator, the system immediately begins monitoring the operator interaction in the Interaction Monitoring system (**11**). This system records every interaction the operator has with the image, that includes changes in brightness, sharpness, contrast, position, zoom, rotation, etc. The amount of time the operator spends examining the x-ray or fluoroscopic capture is also recorded.

[0234] In steps **12a-12d**, the system will submit capture data to the central processing system. The submitted data includes the four major components of the capture: (**12a**) Direct Measurement Information, such a SSD, temperature, etc. (**12b**) interaction heuristics, such as the changes in brightness or the amount of time spent examining a capture. (**12c**) includes the surgical detail, such as the biometric information, any associated CPT code as well as the computer vision captures and resulting classification output. (**12d**) includes the raw capture data from the detector itself as well as capture associated information, such as machine details, software versions, etc.

[0235] This capture information is stored on the central processing system in respective databases **13a** and **13b** for future processing.

[0236] At a scheduled time, the central processing system will train the estimator labels (**14**) using a sophisticated regression analysis. By examining the statistical relationship between the sensor data, capture data and surgical data across a large section of universally captured x-rays, as well as the results of the previous estimator generation (**14a**), the system can fit data to more accurate labels. The output of the training step is a new estimator (**17**).

[0237] Like the label training step (**14**), the x-ray and fluoroscopic capture data, surgical detail data and classifier data will be trained using a classifier refinement process (**15**). This process uses the large capture cross section from the huge number of input x-rays to create a more accurate classifier (**16**).

[0238] Depending on the topography of the x-ray machines in the field, the central processing system will transmit the new estimator (**18**) and classifier (**19**) to the devices as soon as possible. They will then load these updates into the device local storage (**1a**) and (**1b**) and apply the new algorithms to further enhance the accuracy and reduce the dose of the automatic exposure.

[0239] The systems described herein can also be used for preparing a surgical robot for navigating an end effector relative to an anatomic structure using a virtual model of the anatomic structure where the anatomic structure includes a plurality of fiducial markers secured relative to the anatomic structure.

[0240] The following description provides exemplary details of the use of the systems described herein in order to provide an understanding of the registration process. Any engineering adjustments could be employed to practice the invention without employing these specifics. While the invention is described for use in x-ray positioning assisted registration for total knee arthroplasty, it could be used in other medical procedures such as total hip, spine procedures and any other robotically assisted surgery that requires precise positioning.

[0241] The process begins by following the typical RATKA setup procedure. While this varies from device to device, typically a user starts the process by loading an operation plan into the robot. This operative plan then sets the robots' parameters for the plan surgery going forward.

[0242] Next, a surgeon will implant or otherwise secure a series of fiducials into the patient's anatomy adjacent to the target. Typically, this will include an implanted fiducial into the femur and an implanted fiducial into the tibia. These two bones are chosen as they statically link the fiducials to the relative position of the operative target. A fiducial marker or fiducial is an object placed in the field of view of an imaging system that appears in the image and is used as a point of reference or a measure.

[0243] FIG. **29A** generally shows an illustration of a layout of an orthopedic theatre when performing a RATKA with a surgical robot. As shown, a surgical robot **10** and a robotic end effector **29**, in this case an oscillating cutting tool. The illustration shows three positioning fiducials **32**, **34**, **36** for purposes of illustration. However, any number of fiducials can be used. The illustration also shows a positioning camera **30** and the subject anatomy **2**. As illustrated, a physician or other medical caregiver **8** can manipulate or

operate the end effector 29 and/or surgical robot 10 in those cases where the surgical robot assists in performing the procedure.

[0244] Once the fiducials have been implanted or otherwise positioned, the surgeon can then use a position-aware fluoroscopic imaging system to capture images of the target anatomy. While a freely positioned fluoroscopic is commonly used, a traditional c-arm could be utilized as long as the device contains an applicable positioning camera and analytics system.

[0245] FIG. 29B illustrates the surgical robot positioning camera 30 mapping the position of the positioning fiducials 32, 34, 36, by measuring the distance to each respective fiducial 32, 34, 36 as represented by lines 40, 42, 44. FIG. 29B also illustrates a freely positioned x-ray source 100 that is configured to map the position of the positioning fiducials each respective fiducial 32, 34, 36 by measuring the distance between the x-ray source 90 and each fiducial as represented by lines 50, 52, 54. Although not shown, the medical practitioner can freely reposition the x-ray source 90 to obtain desired images. Alternatively, x-ray source 90 can be coupled to a stand or boom that allows the medical practitioner to position the x-ray source relative to the anatomy 2. As illustrated, the virtual model of the anatomy can be displayed on a monitor 32. In additional variations, the monitor 32 can display the fluoroscopic image with the virtual image in any manner (e.g., overlaid, adjacent, separate toggled view, etc.)

[0246] Once the fluoroscopic imaging device 90 is in position, it tracks the position of the implanted fiducials 32, 34, 36 in addition to an image receptor device (not shown in FIG. 29B and discussed below). The medical practitioner then uses the registration process as indicated on the robot to capture an initial image. The order of image capture is not important as long as the robot understands the relative position of the image and the fiducials.

[0247] FIG. 30A illustrates an x-ray capture of a lateral view of the subject anatomy 2 using a freely positioned x-ray source 90. At the time of x-ray emission 108, the x-ray source 90 records the distance 42, 44 to a proximal 22 and a distal 24 positioning fiducials, a distance 60, 62 to the x-ray detector plane 92 and a distance to subject anatomy 70. The x-ray emission 98 is recorded by the x-ray detector 92 to produce an image as discussed above using sensors 94. As noted above, the detector plane 92 (or the operating table) can include any number of distance sensors (e.g., similar to the distance sensors located in the emitter unit 90). These distance sensors can measure the distance between the anatomy 9 and the detector plate 92. Such a measurement reduces error in determining a thickness of the anatomy by determining any offset between the anatomy 9 and the detector plate 92 and/or the operating table. Such an offset is considered when measuring distance 70 to ensure that the system is properly measuring a thickness of the anatomy.

[0248] The positioning system can optionally execute a series of image correct algorithms to correct for typical x-ray magnification, pin cushion, barrel, mustache distortion or geometric lens and noise.

[0249] FIG. 30B generally shows the x-ray capture of an anteroposterior view of the subject anatomy 2 using the freely positioned x-ray source 90. At the time of x-ray emission 98, the x-ray source 90 records the distance 42, 44 to the proximal 22 and distal 24 positioning fiducials, the distance 60, 62 to the x-ray detector plane and distance 70

to subject anatomy. The x-ray emission 98 is recorded by the x-ray detector 92. As noted above, a distance between the detector 92 and the anatomy 9 can be measured along with a distance of the emitter 90 to the anatomy 9 to determine a thickness of the anatomy 9 being imaged.

[0250] FIG. 31 shows x-ray captures/images 80 and 82 taken respectively from the processes illustrated in FIGS. 30B and 30A respectively. The captures/images 80 and 82 are shown adjacent to their corresponding views of the relative to the preoperative anatomical 3D reconstruction/virtual model 84 and 86.

[0251] Once the image correction algorithms have been executed on the captured images the system will use the additional positioning information to map the x-ray views to the preoperative 3D reconstruction. As the system matches the features to the source projections, the system will report the relative values of the fiducial position to the surgical robot.

[0252] The robotic surgery system will use these relative coordinates to record the position of the subject anatomy relative to the surgical end effector. This will allow the surgical robot's standard intraoperative execution to proceed without utilizing point-based registration or other types of registration. The systems described herein use the collected data (e.g., location of the emitter to the detector plate, distances of the emitter to the anatomy, distances of the emitter to the sensors, thickness of the anatomy, etc.) to reduce any distortion of the image from magnification artifacts to produce a fluoroscopic image that can be matched to one of the image slices that forms the virtual model. By reducing the distortions, the system can produce flat or planar fluoroscopic images that can then be matched to individual fluoroscopic images/slices that form the virtual 3D model.

[0253] As known by those skilled in the art, a preoperative 3D reconstruction comprises any number of individual fluoroscopic images or slices that are combined to produce the virtual 3D model of the anatomy. As shown in FIG. 31, the fluoroscopic image 80 taken by the system/emitter is a two-dimensional image (e.g., in the X-Y plane). Therefore, a second fluoroscopic image 82 is taken from a second viewing angle (e.g., in the Y-Z plane). By individually matching these images to images from the 3D model in their respective planes (e.g., 80 to 84 and 82 to 86), the system allows for mapping/registering of the location of the fiducial markers to the virtual anatomic model. The matching of the fluoroscopic image to the respective slice of the 3D model can be performed manually by the operator, a separate computing system and/or the robotic system.

[0254] This mapping process informs the robot the position of the emission relative to the position of the fiducials. By correlating the CT slices planar image that match to the obtained image (e.g., X-Y plane image 80 or Y-Z plane image 82), and by providing all the offsets measure by the system, the robotic system can determine the position of the virtual CT slice relative to the fiducials. This mapping process informs the robot where the 3D reconstruction is in real space relative to the fiducials. In some cases, a single image can be used, but using two fluoroscopic images increases accuracy.

[0255] While the above descriptions provide exemplary details of the invention in order to provide an understanding of the invention, routine engineering adjustments may be employed to practice the invention without departing from

the spirit or scope of the invention. Further, while the invention is described for use in x-ray imaging for surgical purposes, it could be used in other medical applications such as general medical imaging, veterinary and bone densitometry. The system and method may also be used for non-medical applications such as industrial imaging, metal fatigue inspections, weld-inspection, for security inspections, and the like.

1. A method of preparing a surgical robot for navigating an end effector relative to an anatomic structure positioned on an operating surface using a virtual model of the anatomic structure, the method comprising:

positioning an emitting apparatus of an X-ray system relative to an imaging sensor of the X-ray system;
obtaining first positioning information associated with the emitting apparatus;
emitting X-ray energy from the emitting apparatus onto the anatomic structure such that the X-ray energy is received by the imaging sensor to produce a fluoroscopic image, and where the emitting apparatus produces second positioning information associated with the fluoroscopic image, the second positioning information comprising a distance and an orientation of the emitting apparatus relative to a plurality of fiducial markers secured relative to the anatomic structure; and
mapping the fluoroscopic image of the anatomic structure to the virtual model of the anatomic structure using the first positioning information and the second positioning information such that the surgical robot is able to use the virtual model of the anatomic structure and the plurality of fiducial markers to navigate a robotic end effector relative to the anatomic structure.

2. The method of claim 1, where the emitting apparatus is movable in free space relative to the imaging sensor.

3. The method of claim 1, where the emitting apparatus is a handheld emitting apparatus.

4. The method of claim 1, where the first positioning information comprises a distance and an orientation of the emitting apparatus relative to one or more tracking elements secured relative to the imaging sensor.

5. The method of claim 4, where the emitting apparatus comprises at least one camera device configured to identify the one or more tracking elements.

6. The method of claim 4, where the one or more tracking elements comprise magnetic tracking elements.

7. The method of claim 1, where the emitting apparatus comprises an inertial measurement unit, and the first positioning information comprises orientation data from the inertial measurement unit.

8. The method of claim 1, where the second positioning information comprises a distance between the emitting apparatus and either the operating surface or the imaging sensor.

9. The method of claim 1, where the second positioning information comprises a distance between the anatomic structure and the imaging sensor.

10. The method of claim 1, where mapping the fluoroscopic image of the anatomic structure to the virtual model

of the anatomic structure comprises matching the fluoroscopic image to a slice of the virtual model of the anatomic structure.

11. A method of registering a virtual model of an anatomic structure, the method comprising:

positioning an emitting apparatus of an X-ray system relative to an imaging sensor of the X-ray system;
obtaining first positioning information associated with the emitting apparatus;
emitting X-ray energy from the emitting apparatus onto the anatomic structure such that the energy is received by the imaging sensor to produce a fluoroscopic image, and where the emitting apparatus produces second positioning information associated with the fluoroscopic image, the second positioning information comprising a distance and an orientation of the emitting apparatus relative to a plurality of fiducial markers secured relative to the anatomic structure; and
mapping the fluoroscopic image of the anatomic structure to the virtual model of the anatomic structure using the first positioning information and the second positioning information such that the virtual model of the anatomic structure and the plurality of fiducial markers can be used to navigate a device relative to the anatomic structure.

12. The method of claim 11, where the emitting apparatus is movable in free space relative to the imaging sensor.

13. The method of claim 11 wherein the emitting apparatus is a handheld emitting apparatus.

14. The method of claim 11, where the first positioning information comprises a distance and an orientation of the emitting apparatus relative to one or more tracking elements secured relative to the imaging sensor.

15. The method of claim 14, wherein the emitting apparatus comprises at least one camera device configured to identify the one or more tracking elements.

16. The method of claim 14, where the one or more tracking elements comprise magnetic tracking elements.

17. The method of claim 11, where the emitting apparatus comprises an inertial measurement unit, and the first positioning information comprises orientation data from the inertial measurement unit.

18. The method of claim 17, where the second positioning information comprises a distance between the emitting apparatus and either an operating surface or the imaging sensor.

19. The method of claim 11, where the second positioning information comprises a distance between the anatomic structure and the imaging sensor.

20. The method of claim 11, where mapping the fluoroscopic image of the anatomic structure to the virtual model of the anatomic structure comprises matching the fluoroscopic image to a slice of the virtual model of the anatomic structure.

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