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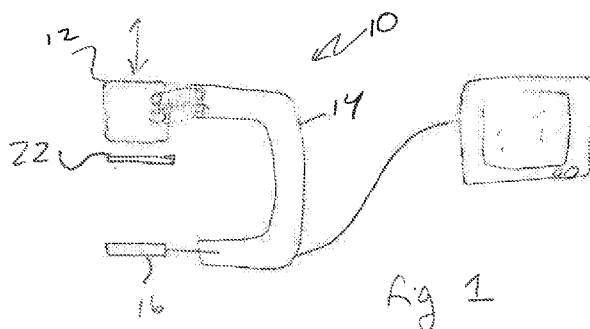
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(54) Title: FLUOROSCOPE WITH MOVABLE HEAD AND BARRIER TO VARY SOURCE TO SKIN DISTANCE



(57) Abstract: For radiation safety, a fluoroscope has an adjustable X-ray source-to-intensifier distance (SID) and an X-ray transparent spacer positioned between the source and receptor. As a distance between the source and the intensifier is changed, the spacer is moved or a different sized transparent spacer is used, to ensure a safe minimum skin-to-source distance (SSD) is maintained.



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FLUOROSCOPE WITH MOVABLE HEAD AND BARRIER TO VARY SOURCE TO SKIN DISTANCE

RELATED APPLICATIONS

[0001] The present application claims the benefit of and priority to U.S. Provisional Application No. 62/519,707, filed June 14, 2017, which is herein incorporated by reference in its entirety.

TECHNICAL FIELD

[0002] The subject technology relates to medical imaging devices and to fluoroscopy devices in particular.

BACKGROUND

[0003] Fluoroscopy is a means of producing real-time moving, continuous or static images of the interior structure of an object or person by using X-rays. The primary applications for such a device include medical imaging, non-destructive testing and various quality control applications. In this primary application, a physician may visualize the internal structure and organs, hard and soft tissues, blood flow analysis, cardiovascular processes, urological function and many other aspects of human anatomy. The advantages presented by using fluoroscopy in a medical capacity rests primarily in being able to observe human internal structures without the necessity to open the body for a direct or invasive procedure. Similarly, in non-destructive testing and quality control, aspects of structures, cables, components, physical properties and other characterizations can be made about an object without damaging the object in any material way.

[0004] The modern era of the fluoroscope began in 1940's with the Westinghouse Corporation inventing the first analog X-ray image intensifier. This allowed brighter pictures to be produced while producing less radiation in general. The repeatability and

safety aspects of that invention led to the fluoroscope becoming a standard of care for surgical interventions in many situations / procedures. The ability to visualize the internal structures, organs and functions of the human body without necessarily cutting the patient open, or subjecting the patient or operator to unsafe doses of radiation led to safer, cleaner procedures with better outcomes.

[0005] That trend has continued up to the present with continual improvements to provide the fluoroscope operator and patient (user and subject) with higher quality diagnostic information with safer applications of radiation dosage while improving the outcomes of the procedure. Advancements in adjacent technologies have also fueled the continual innovation of the fluoroscope with the analog electronic era giving way to the digital electronic era to continue to push the advancement of these core principles: lower dose, higher quality data and better outcomes.

SUMMARY

[0006] The disclosed technology relates to a fluoroscope having an adjustable source to intensifier distance (SID). In one embodiment, to comply with safety regulations, a X-ray transparent spacer is positioned between the X-ray source and the intensifier. As the distance between the X-ray source and the intensifier is changed, the X-ray transparent spacer is moved or a different sized transparent spacer is used to ensure compliance with a minimum skin to source distance (SSD).

[0007] In one embodiment, a mechanical linkage moves the transparent spacer as the X-ray source is moved with respect to the intensifier. In yet another embodiment, sensors detect the SID and an electromechanical drive mechanism moves the X-ray transparent spacer to a correct distance from the X-ray source. In yet another embodiment, a processor provides an alert to an operator to use a correctly sized X-ray transparent spacer depending on the detected SID.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] Figure 1 illustrates a fluoroscope with an adjustable head to intensifier distance in accordance with one embodiment of the disclosed technology;

[0009] Figure 2 illustrates a mechanism for maintaining a minimum source to skin (SSD) distance as a space between the X-ray source and the intensifier is changed in accordance with an embodiment of the disclosed technology;

[0010] Figure 3 illustrates a number of differently sized spacers that can be positioned between an X-ray ray source and an intensifier in accordance with an embodiment of the disclosed technology;

[0011] Figures 4a and 4b show another embodiment of a fluoroscope in accordance with some embodiments of the disclosed technology; and

[0012] Figure 5 shows a fluoroscope in accordance with some embodiments of the disclosed technology.

[0013] Figure 6 shows a fluoroscope in accordance with another embodiment of the disclosed technology.

[0014] Figure 7 shows a frame for maintaining a minimum SSD in accordance with an embodiment of the disclosed technology.

DETAILED DESCRIPTION

[0015] In the modern era, there are many manufacturers of fluoroscopes. Two primary categories of medical fluoroscope exist: fixed room devices and mobile fluoroscope devices. The fixed room devices are typically large, immobile devices installed in purpose-built specialty operating areas. Mobile fluoroscope devices are smaller and mobile. These units are typically moved from location to location to perform imaging tasks. The mobile fluoroscopic devices are also commonly referred to as “C-arms” due to the physical shape of the gantry holding the X-ray generator and the X-ray

intensifier/detector on opposing ends, which is shaped in the lateral perspective at least somewhat like the letter “C”.

[0016] The US Food and Drug Administration regulates C-arms largely as class II devices and provides regulations governing their manufacture and use in the United States. The relevant code sections may be found in 21 C.F.R. Parts 800-1299 and specifically in 21 C.F.R. §1020.32 (Fluoroscopic Equipment). Within the FDA guidance and regulations provided, several small distinctions in size and characteristics of the C-arm can create different allowances or rules for operation. One of the primary distinctions lies in a geometric dimension referred to as “Source to Intensifier Distance” or (SID). The SID is the distance between the focal spot or origin point of the X-ray beam produced (where the X-rays are generated within the X-ray tube) and the Image Receptor or Intensifier that captures the resultant X-ray beam after passing through the patient or object under examination.

[0017] In 21 C.F.R. §1020.32(g)(2), a distinction is made for a device having an SID less than 45 cm. This distinction leads to several specific guidelines and regulations for devices having an SID larger than 45 cm., commonly referred to as a “Full Size C-arm” and devices having an SID smaller than 45 cm. commonly referred to as a “Mini C-arm.” This distinction leads to the advantages provided by the innovations contemplated in this application. The favorable guidelines allowed for the mini c-arm in aspects such as source to skin distance and dosimetry testing compliance are preferable when imaging small anatomy. Typically, a mini C-arm is used for “extremity use only” meaning shoulder to fingertip and knee to toe of the patient. The FDA requires a label advising the user of exactly that limitation. While this limitation allows for favorable design considerations, the geometry can be limiting to users who are addressing obese or large patients, or dealing with specific geometries of tables, apparatus and other objects interfering with positioning of the device near the patient.

[0018] The disclosed technology relates to a fluoroscope device that can operate under the favorable design guidelines and conditions of the Mini C-arm while being able to accommodate larger anatomy and specific surgical impediments. To that end, the

following descriptions and embodiments outline such a solution that would allow the operator to choose the SID and allow the unit to operate as a Mini C-arm in a first configuration and to operate as a full size C-arm in an alternate configuration.

[0019] Figure 1 shows one embodiment of a fluoroscope constructed in accordance with an embodiment of the disclosed technology. The fluoroscope 10 has an X-ray source 12 that secured to a supporting C-arm 14. The C-arm 14 also supports a X-ray receptor 16, which can include an X-ray image intensifier, flat panel X-ray detector or the like (referred to hereinafter as the receptor 16). Image data collected by the X-ray receptor 16 are gathered and processed in an image processor (not separately shown) and displayed on a monitor 20 for a physician or their assistant to view. In addition, the image data may be stored on a computer readable media or transmitted to a remote location for storage and analysis.

[0020] As discussed above, an operator of the fluoroscope 10 can change the distance between the X-ray source 12 and the X-ray receptor 16 in order to accommodate larger patients or to facilitate different imaging angles. In one embodiment, a linkage mechanism between the X-ray source 12 and the C-arm 14 allows the distance between the X-ray source 12 and the X-ray receptor 16 to be adjusted. As the distance is adjusted, an X-ray transparent spacer 22 is positioned between the X-ray source and the X-ray receptor 16 that prevents a patient's skin from coming any closer to the X-ray source than is permitted by the government safety regulations. In some embodiments, when the X-ray source to intensifier distance (SID) is greater or equal to 45 cm., the transparent spacer 22 is positioned so that a minimum source to skin distance (SSD) is 20 cm. or greater. When the X-ray source to receptor distance is less than 45 cm., the X-ray transparent spacer 22 is positioned so that the minimum source to skin distance is 10 cm. or greater. The transparent spacer 22 is made of an X-ray transparent material, such as plastic, and is positioned between the patient's skin and the X-ray source. In some embodiments, the transparent spacer 22 is automatically moved as the SID is changed. In other embodiments, an operator is prompted to change or move the transparent spacer 22 depending on the SID.

[0021] Figure 2 shows one embodiment of a mechanism for moving the transparent spacer 22 as the position of the X-ray source 12 is changed with respect to the receptor 16. In this embodiment, a parallel linkage 30 couples the X-ray source 12 to an end of the C-arm 14. The linkage 30 could have a friction fit so that it can be moved without loosening a locking mechanism or the linkage 30 may include such a locking mechanism to hold the X-ray source 12 at a desired position with respect to the C-arm 14. With the linkage 30, a user can move the X-ray source 12 either towards or away from the receptor 16.

[0022] In one embodiment, the linkage 30 includes a link with a convex-shaped lobe 32. The transparent spacer 22 includes a cam follower 40 that rides on the convex-shaped lobe 32. Springs or other tensioning devices 42 between the transparent spacer 22 and the X-ray source 12 hold the cam follower 40 onto the convex-shaped lobe 32. When the X-ray source 12 is moved downwards towards the receptor 16, the radius of the convex-shaped lobe 32 is sized so the distance between the X-ray source and the cam follower 40 decreases. As the X-ray source 12 is moved away from the receptor 16, the cam follower 40 follows an increasing radius of the convex-shaped lobe 32 to push the X-ray transparent spacer 22 away from the x-ray source 12, thereby increasing the SSD of the fluoroscope 10.

[0023] In addition to mechanical mechanisms for changing the SSD, it will be appreciated that electromechanical mechanisms could also be used. For example, the distance between the X-ray source 12 and the receptor 16 can be measured with an optical or acoustic distance measuring detector. Similarly, sensors or micro-switches on the linkage can also be used measure the rotational positions of the linkage members. Based on the measured or determined linkage position, a drive mechanism such as motor-driven screws or the like can operate to move the transparent spacer 22 towards or away from the X-ray source.

[0024] In some embodiments, the position of transparent spacer 22 can be moved continuously and in other embodiments, the position of the transparent spacer can move in quantized amounts (e.g. 2 cm. changes, 5 cm. changes, etc.) as the distance between

the X-ray source 12 and the receptor 16 changes. For example, an electromechanical movement can have defined stopping points or the radius of the convex-shaped lobe could be stepped instead of being continuously variable.

[0025] In some embodiments, the X-ray source 12 remains fixed with respect to the C-arm 14 and the receptor 16 is movable towards or away from the X-ray source as shown in Figure 6. A detector (optical, acoustic, mechanical micro-switches or the like) determines the distance between the receptor 16 and the X-ray source 12 and the drive mechanism moves the X-ray transparent spacer 22 accordingly.

[0026] In some embodiments, different sized spacer cones 50 are inserted into a space between the X-ray source and the receptor 16. Figure 3 shows a pair of spacer cones 52, 56. The spacer cones are solid or hollow and preferably made of an X-ray transparent material (e.g. plastic) and have height that is selected such that when a spacer cone is secured to the X-ray source, a body is prevented from coming within the minimum SSD determined for the particular source to intensifier distance. In other embodiments, the spacer cones 52, 56 can be formed as a frame or cage having a size that limits how close a patient's anatomy can get to the X-ray source in order to maintain the desired SSD. Such a frame can intercept a portion of the X-ray beam or can be designed such that the beam passes through an opening in the frame. Frames or cages of different sizes can be placed between the X-ray source and the receptor 16 depending on the measured SID and the desired SSD.

[0027] In some embodiments, the source to intensifier distance is measured or determined with a sensor and a controller displays a message on a display associated with the fluoroscope asking the operator to install the correctly sized spacer cone. In some embodiments, the spacer cones fit with a receptacle slot on the X-ray source and can be mechanically, optically or electrically encoded so that a controller can confirm that the correct spacer cone is installed before X-rays are produced.

[0028] As indicated above, in a smaller configuration such as a mini C-arm, the device would be allowed a minimum source to skin distance of 10cm with an optional 10cm spacer provided. In a full-size configuration, the source to skin distance is selected

to be a minimum of 20 cm. with an optional 10 cm. spacer cone. Allowing the SID to change from a size that is less than 45 cm. to a size greater than 45 cm. but retain the properties of both Mini C-arm and Full Size C-arm when in use provides a great advantage in terms of radiation safety and physical configuration. The lower radiation dose applied by a Mini C-arm coupled with the larger area to operate would certainly be desirable to the operator and consumer in terms of safety and clinical outcome.

[0029] A corresponding requirement to this advantageous SID change would be a means of changing the minimum source to skin distance (SSD) mandated by 21 C.F.R. Being able to change the SSD either independently or in concert with the SID presents distinct advantages. This motion could be mechanical, electromechanical, synchronized with SID or not synchronized with SID.

[0030] In alternate embodiments, the X-ray assembly by itself could be moved further from the image receptor, or the image receptor could be moved further away from the X-ray assembly, or a combination of the two motions could achieve the same change in SID.

[0031] The mechanism of motion of the X-ray source or the receptor to modify the SID could be linear, curved, orthogonal, achieved with linkage, drives, belts, gears, screws, springs, dampers, and many other conceivable mechanisms. The control can be electronically powered or mechanically controlled. Motorized or manual, the movement effects the same outcome of the advantage of the variable SID.

[0032] The spacing of the source to skin distance could also be accomplished in any number of ways. The floor of the surface closest to the image receptor could be made to move to increase or decrease the SSD as desired. If this adjustment is made mechanically it could simply be made electronically as well.

[0033] The SSD adjustment could be accomplished by a mechanical or an electronic linkage to the SID adjustment mechanism in concert or at least in a coordinated fashion.

[0034] The same could be accomplished by using a series of spacers of varying thicknesses either alone or in combination to create different desirable SSDs. Such

spacers could be mechanically or electrically placed between the X-ray source and the intensifier as required.

[0035] The limits of travel for both the SID adjustment means as well as the SSD adjustment means could be tracked and monitored by micro-switches, potentiometers, mechanical gauges, or other means to allow the system to register the current configuration of the components e.g. which position the X-ray source is in relative to the image intensifier and what the position the SSD spacing mechanism is relative to the X-ray source.

[0036] Figures 4 and 4b show an X-ray source that is made to vary in distance from the receptor to a size less than 45cm (SID minimal position) and greater than 45cm (SID Maximal Position). The embodiment in Figures 4(a) and 4(b) shows a device that would align to two preferred heights and operate only in those two designed positions. The linkage could be designed to allow different ranges and means of motion to allow for more than two preferred positions, to infinite stepless operable selections between the maximum and minimum range. (Such as with a manual linear rack, or motorized rack or other means.)

[0037] Figure 5 shows a sketch of a fluoroscope having a variable SSD in accordance with some embodiments of the disclosed technology. A variable SID would be valuable for accommodating patients and users in more scenarios. Obeying both criteria could be accomplished by providing a variable SID that has an accompanying means of expanding the SSD as well. The source or receptor could move relative to each other to vary the SID. As shown, a source includes an adjustable mounting height on the end of the C-arm. A radiotranslucent barrier (or an open frame as shown in Figure 7 with a hole to pass X-rays and frame body to prevent contact with the source) holds the SSD at a desired distance. The SSD can be changed by moving the barrier closer or further from the source. Pegs or worm gear posts can lift or lower the SSD barrier relative to the source. A microswitch can enable/disable X-rays if the barrier is in the wrong position.

[0038] In some embodiments, a patient's anatomy is secured to a support platform (not shown) disposed between the X-ray source and the intensifier. As shown in Figure 6,

the distance from the X-ray source to the support platform can be used as a proxy for the SSD if the anatomy is secured to the platform so that it cannot move closer to the X-ray source during operation of the fluoroscope. In this embodiment, the distance that the support platform can move towards the X-ray source is controlled based on the SID so that the anatomy cannot be positioned closer to the X-ray source that is allowed by safety regulations assuming an average anatomy size (e.g., 5-8 cm. in thickness). The position of the support structure towards or away from the X-ray source can be controlled with mechanical or electromechanical actuators, servo motors, gears or the like.

[0039] In any of the embodiments described, it is advantageous to provide a sterile barrier that accommodates both the smaller and larger SSD as well as any mechanical movements utilized in achieving the variable SID. As such, one embodiment may be a plastic sheeting or sheath covering the portions of the unit that would require sterility in operation. The sterile barrier could be designed with an integral or fitted elastomeric bands that would allow the sterile barrier to accommodate multiple geometries without breaking the sterile barrier. This would allow the sterile barrier to remain fitted to the device and also gather any undesirable pocketing or gathering that could negatively impact sterility.

[0040] Embodiments of the subject matter and the operations described in this specification can be implemented in digital electronic circuitry, or in computer software, firmware, or hardware, including the structures disclosed in this specification and their structural equivalents, or in combinations of one or more of them. Embodiments of the subject matter described in this specification can be implemented as one or more computer programs, i.e., one or more modules of computer program instructions, encoded on computer storage medium for execution by, or to control the operation of, data processing apparatus. For example, a processor or controller in the fluoroscope can be configured or programmed to detect the SID and to alert a user to place the appropriate spacer in front of the X-ray source. In some embodiments, the processor is programmed to detect the space between the X-ray source and the transparent spacer 22 or the size of the spacer cone 52,56 that is installed in the fluoroscope to ensure compliance with the

safety regulations before the processor enables the X-ray source to begin producing X-rays.

[0041] A computer storage medium can be, or can be included in, a computer-readable storage device, a computer-readable storage substrate, a random or serial access memory array or device, or a combination of one or more of them. Moreover, while a computer storage medium is not a propagated signal, a computer storage medium can be a source or destination of computer program instructions encoded in an artificially-generated propagated signal. The computer storage medium also can be, or can be included in, one or more separate physical components or media (e.g., multiple CDs, disks, or other storage devices). The operations described in this specification can be implemented as operations performed by a data processing apparatus on data stored on one or more computer-readable storage devices or received from other sources.

[0042] The term “data processing apparatus” encompasses all kinds of apparatus, devices, and machines for processing data, including by way of example a programmable processor, a computer, a system on a chip, or multiple ones, or combinations, of the foregoing. The apparatus can include discrete digital hardware, special purpose logic circuitry, e.g., an FPGA (field programmable gate array) or an ASIC (application-specific integrated circuit). The apparatus also can include, in addition to hardware, code that creates an execution environment for the computer program in question.

[0043] To provide for interaction with a user, the fluoroscope may include a display device, e.g., an LCD (liquid crystal display), LED (light emitting diode), or OLED (organic light emitting diode) monitor, for displaying information to the user and a keyboard and a pointing device, e.g., a mouse or a trackball, by which the user can provide input to the processor associated with the system. In some implementations, a touch screen can be used to display information and to receive input from a user. Other kinds of devices can be used to provide for interaction with a user as well; for example, feedback provided to the user can be any form of sensory feedback, e.g., visual feedback, auditory feedback, or tactile feedback; and input from the user can be received in any form, including acoustic, speech, or tactile input.

[0044] From the foregoing, it will be appreciated that specific embodiments of the invention have been described herein for purposes of illustration, but that various modifications may be made without deviating from the scope of the invention. For example, in some embodiments, the size or shape of the C-arm can be adjusted (e.g. via a telescoping arm) to change the distance between the X-ray source and the receptor. Accordingly, the invention is not limited except as by the appended claims.

CLAIMS

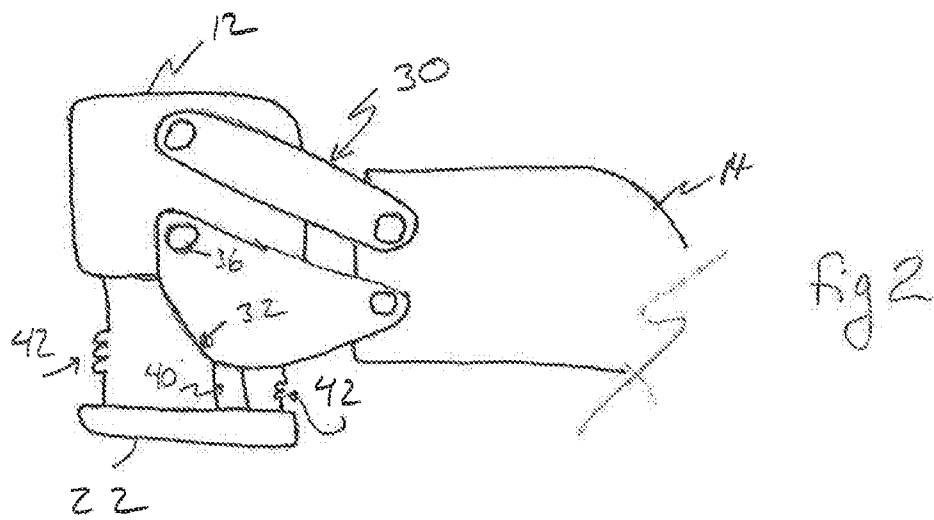
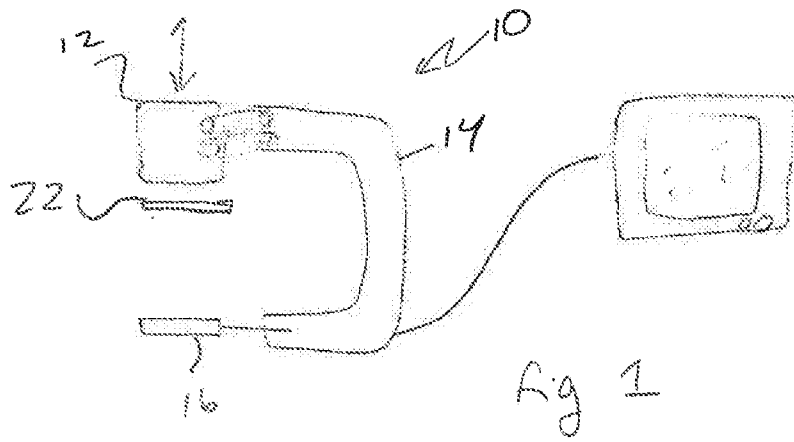
We claim:

1. A fluoroscope, comprising:
an X-ray source;
an X-ray receptor;
a support arm that supports the X-ray source and X-ray receptor in a spaced relation;
a mechanism for changing a distance between the X-ray source and the X-ray receptor; and
means for maintaining a minimum source to skin distance (SSD) between the X-ray source and the X-ray receptor depending on the distance between the X-ray source and X-ray receptor.
2. The fluoroscope of claim 1, further comprising an X-ray transparent spacer between the X-ray source and the X-ray receptor, wherein the mechanism for changing the distance comprises a linkage that allows the X-ray source to move closer to, or farther away from, the X-ray receptor and wherein the means for maintaining the minimum source to skin distance comprises a cam surface on the linkage that moves the X-ray transparent spacer away from the X-ray source as the distance between the X-ray source and the X-ray receptor is increased.
3. The fluoroscope of claim 1, wherein the means for maintaining the minimum source to skin distance comprises a number of various sized spacers configured to be inserted between the X-ray source and the X-ray receptor depending on the distance between the X-ray source and the X-ray receptor.
4. The fluoroscope of claim 1, further comprising (i) an X-ray transparent spacer between the X-ray source and the X-ray receptor and (ii) a sensor to detect a

distance between the X-ray source and the X-ray receptor, wherein the means for maintaining the minimum source to skin distance comprises an actuator that moves the X-ray transparent spacer .

5. The fluoroscope of claim 4, wherein the sensor is optical.
6. The fluoroscope of claim 4, wherein the sensor is electrical.
7. The fluoroscope of claim 4, wherein the sensor is acoustic.
8. The fluoroscope of claim 1, further comprising (i) a sensor to detect a distance between the X-ray source and the X-ray receptor and a processor configured to provide instructions to a user to place an X-ray transparent spacer between the X-ray source and the X-ray receptor to maintain a minimum source to skin distance.
9. The fluoroscope of claim 8, wherein the X-ray transparent spacer is coded and the processor is configured to read a code on the transparent spacer before X-rays are produced by the fluoroscope.
10. A fluoroscope, comprising:
 - an X-ray source;
 - an X-ray receptor;
 - a support arm that supports the source and receptor in a spaced relation;
 - a mechanism for changing a distance between the source and the receptor;
 - a platform between the source and the receptor, the platform configured to support a portion of a body imaged by the fluoroscope; and
 - an adjustment member that changes a minimum distance between the platform and the source, from a first value to a second value, as the distance between the source and the receptor exceeds a threshold.

11. A fluoroscope, comprising:
- an X-ray source;
 - an X-ray receptor;
 - a support arm that supports the source and receptor in a spaced relation;
 - a mechanism for changing a position of the receptor with respect to the source in order to vary a distance between the source and the receptor; and
 - a spacer positioned between the source and the receptor that defines a minimum distance between the source and a patient's skin, wherein the minimum distance is changeable depending on the distance between the source and the receptor.



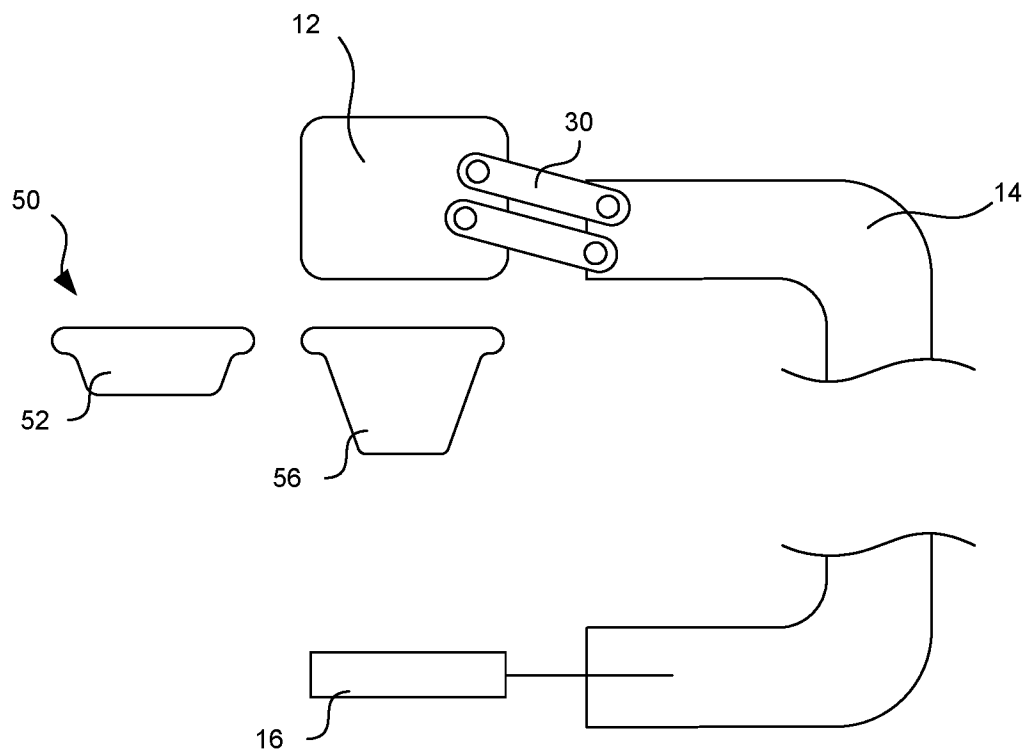


FIG. 3

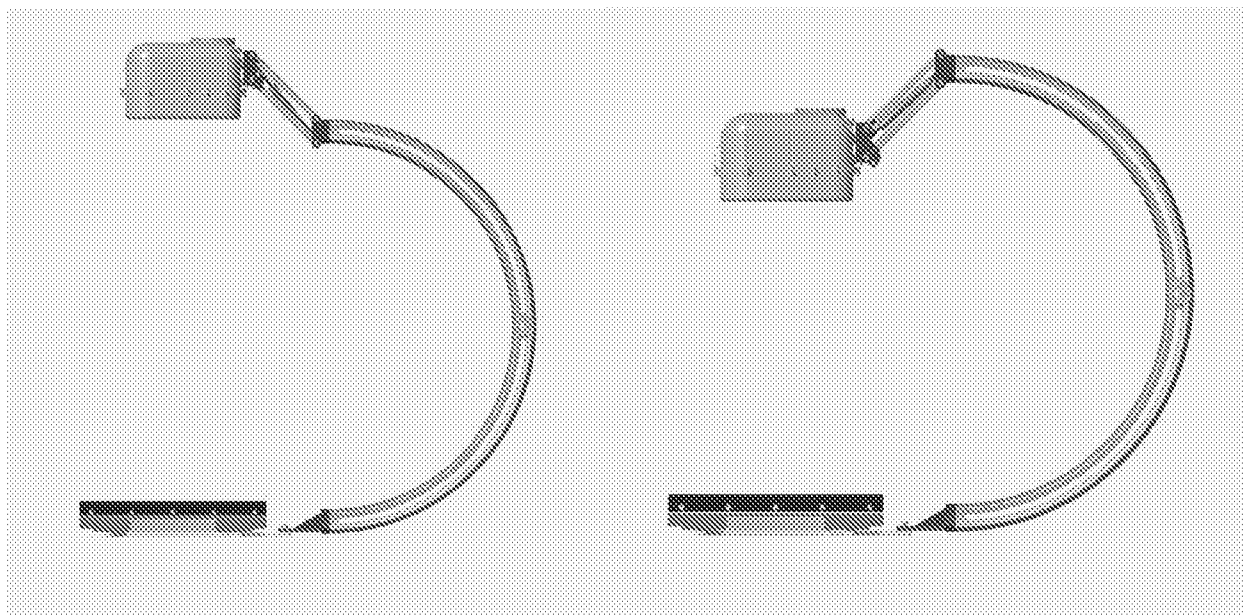


Figure 4(a): One Embodiment of Maximal SID Position
Position

Figure 4(b): One Embodiment of Minimal SID

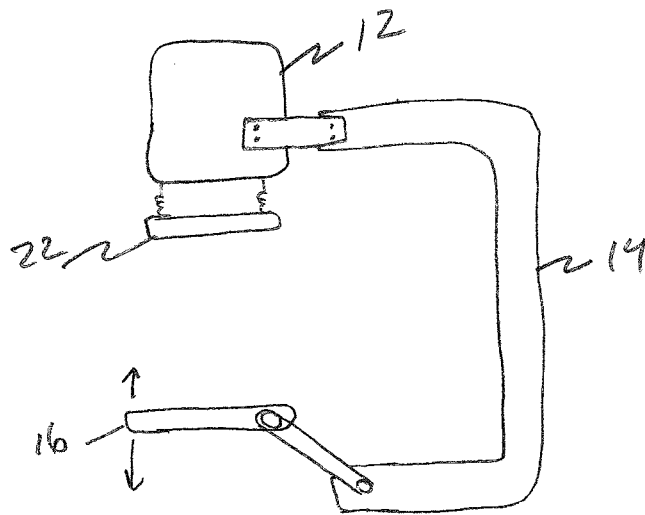


Fig 6

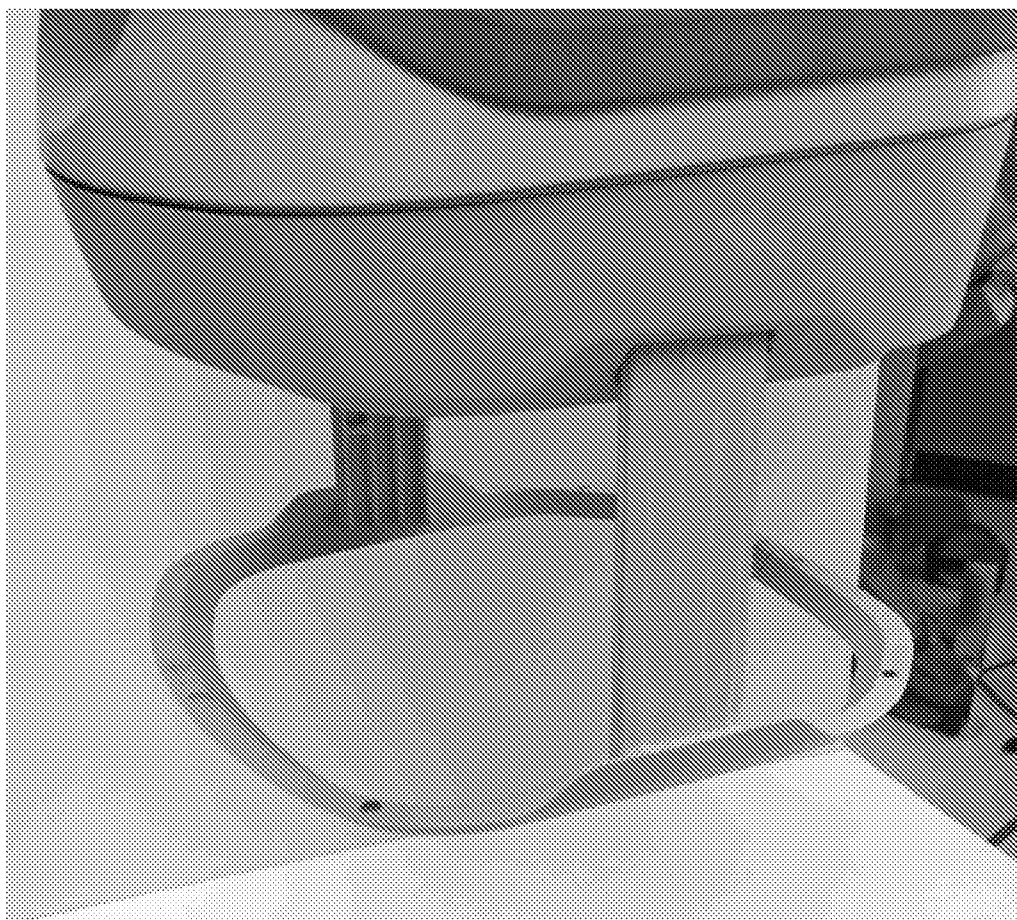


Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2018/037409

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61B 6/04; H05G 1/02 (2018.01)

CPC - A61B 6/4452; A61B 6/44; A61B 6/4429; A61B 6/58; A61B 6/588 (2018.08)

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

See Search History document

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

USPC - 378/11; 378/190; 378/193; 378/195; 378/196; 378/197 (keyword delimited)

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

See Search History document

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 7,810,996 B1 (GIPHART et al) 12 October 2010 (12.10.2010) entire document	1-11
A	US 2012/0148031 A1 (EAVES) 14 June 2012 (14.06.2012) entire document	1-11
A	US 2005/0002489 A1 (SCHEUERING) 06 January 2005 (06.01.2005) entire document	1-11
A	US 2007/0237309 A1 (MARINELLI et al) 11 October 2007 (11.10.2007) entire document	1-11
A	US 2006/0269044 A1 (FEHRE et al) 30 November 2006 (30.11.2006) entire document	1-11
A	US 2007/0140429 A1 (HOHEISEL) 21 June 2007 (21.06.2007) entire document	1-11
A	US 4,856,036 A (MALCOLM et al) 08 August 1989 (08.08.1989) entire document	1-11
A	US 2014/0192962 A1 (ORTHOSCAN, INC.) 10 July 2014 (10.07.2014) entire document	1-11

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

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