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DESCRIPTION

BACKGROUND OF THE INVENTION

TECHNICAL FIELD

[0001] The present invention relates to the field of focused ultrasound (FUS), and more particularly, to the field of X-Ray guided FUS devices.

DISCUSSION OF RELATED ART

[0002] Figure 1 is a high level schematic illustration of a prior art radiofrequency (RF) nerve ablation procedure. The RF ablation procedure includes thermal destroying of medial branch nerves that innervate a painful and inflamed joint **70.** The RF ablation procedure is performed in a clinic or a hospital setting with the guidance of X-Ray, which is used by the treating physician to guide the tip of a needle **92** to a junction of a transverse articular process **71** and a superior articular process **72** of facet joint **73** of a targeted vertebra, placing the needle along the path of medial nerve branch **91.** Needle **92** generates heat at its tip via the RF energy and thermally coagulates the tissue in a small cylindrical shape around its tip, which also contains the medial nerve branch. The prior art ablation procedure is an invasive, uncomfortable and painful procedure that carries risk of infection and bleeding for the patients.

[0003] US8727987 describes a mechanical manipulator for controlling the movement of high intensity focused ultrasound (HIFU) transducers, especially for medical use, such as in the treatment of cancers. A base harness having two or three legs is mounted on the treatment table. A central shaft mounted on the base harness carries a diagnostic probe as well as a plurality of treatment probes. The treatment probes may be moved through three degrees of freedom using computer controlled motors. The treatment probes may be moved linearly, in jaw motion and in a pitch motion.

[0004] US5285772 discloses a therapy system for treating a subject with focused acoustic waves for use with a separately available x-ray examination device for forming a high-grade acoustic therapy work station with x-ray locating disclosed. The therapy system includes a therapy head having an x-ray impermeable mark used to align the therapy system with a subject during the x-ray locating, and an acoustic sensing component, which identifies the distance between an acoustic wave source in the therapy head and a region of the subject to be treated, for relatively positioning the subject and the therapy head so that the region is in the focus of the acoustic waves.

SUMMARY OF THE INVENTION

[0005] The following is a simplified summary providing an initial understanding of the invention. The summary does not necessarily identify key elements nor limits the scope of the invention, but merely serves as an introduction to the following description.

[0006] The invention is defined in independent claim 1, preferred embodiments are described in the dependent claims.

[0007] Disclosed is:
An X-Ray guided apparatus for an image guided focused ultrasound treatment, comprises: an articulated arm attached at its base to a procedure platform; a cradle affixed to the distal end of the arm; an aiming apparatus affixed in the cradle; a focused ultrasound (FUS) transducer having a central axis that is affixed in to the cradle and configured to transmit an ultrasonic therapeutic energy beam to a treatment location within a patient, wherein the FUS transducer is connected to a controller to control application of focused ultrasound by the transducer; and an imaging workstation connected to an imaging unit configured to derive imaging data from an X-Ray imaging system. The cradle has a conic shape, wherein projections of the conic shape boundaries are consistent with the FUS therapeutic beam generated by the FUS transducer, and wherein a lateral projection apex of the conic shape corresponds to a focal point of the FUS transducer

[0008] The apparatus relies on an imaging device such as an X-ray system to assist in aiming the position and orientation of the FUS transducer to guide the focal spot to the treatment location.

[0009] These, additional, and/or other aspects and/or advantages of the present invention are set forth in the detailed description which follows; possibly inferable from the detailed description; and/or learnable by practice of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] For a better understanding of embodiments of the invention and to show how the same may be carried into effect, reference will now be made, purely by way of example, to the accompanying drawings in which like numerals designate corresponding elements or sections throughout.

[0011] In the accompanying drawings:

Figure 1 is a high level schematic illustration of a prior art RF ablation procedure.

Figure 2 is a high level schematic illustration of an X-Ray guided focused ultrasound treatment apparatus and its components, according to some embodiments of the invention.

Figures 3A-3B are high level schematic illustrations and a lateral X-ray image of a cradle used in the X-Ray guided apparatus, according to some embodiments of the invention.

Figure 4A-4B is high level schematic illustrations and images of an aiming apparatus, (Mock-up with the optical markers and x-ray markers) used in the X-Ray guided apparatus according to some embodiments of the invention.

Figures 5A-5B is a high level flowchart illustrating a method.

Figures 6A-6C is an example of the treatment application, according to some embodiments of the invention used in the X-Ray guided apparatus.

Figures 7A-7B is a high level schematic illustration of the aiming markers of the aiming apparatus.

Figures 8A-8B are high level schematic illustrations and images of optical markers of different design used in the X-Ray guided device according to some embodiments of the invention

Figures 8A-8B are high level schematic illustrations and images of optical markers of different design used in the X-Ray guided device according to some embodiments of the invention

Figures 9A-9B are high level schematic illustrations of a modified x-ray aim of different design, used in the X-Ray guided apparatus according to some embodiments of the invention.

Figure 10 is an X-Ray image of the modified x-ray aim at a suitable alignment.

Figures 11A-11B is a high level flowchart illustrating another method.

Figures 12A-12H are X-ray-images of the FUS transducer including different types of x-ray aims and aiming apparatus, used in the X-Ray guided device according to some embodiments of the invention.

Figures 13A-13C are screen dumps of the baseline images (Figures **13A and 13B**) and the result (Figure **13C**) of the device imaging workstation image processing of AP images with the transducer in place, according to some embodiments of the invention

Figure 14A-14B is a schematic diagram showing the alignment of the imaging and therapeutic ultrasound probes in the ultrasound guided device thereby positioning the therapeutic acoustic focal point in the center of the ultrasound image.

DETAILED DESCRIPTION OF THE INVENTION

[0012] In the following description, various aspects of the present invention are described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the present invention. However, it will also be apparent to one

skilled in the art that the present invention may be practiced without the specific details presented herein. Furthermore, well known features may have been omitted or simplified in order not to obscure the present invention. With specific reference to the drawings, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

[0013] Before at least one embodiment of the invention is explained in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

[0014] Unless specifically stated otherwise, as apparent from the following discussions, it is appreciated that throughout the specification discussions utilizing terms such as "processing", "computing", "calculating", "determining", "enhancing" or the like, refer to the action and/or processes of a computer or computing system, or similar electronic computing device, that manipulates and/or transforms data represented as physical, such as electronic, quantities within the computing system's registers and/or memories into other data similarly represented as physical quantities within the computing system's memories, registers or other such information storage, transmission or display devices.

[0015] An X-Ray guided apparatus and method for an image guided focused ultrasound (FUS) treatment are provided. The apparatus comprises an articulated arm attached at its base to a procedure platform, a cradle affixed to the distal end of the arm, an aiming apparatus, a FUS transducer and x-ray aim, having a central axis that is affixed in to the cradle and configured to transmit an ultrasonic therapeutic energy beam to a treatment location within a target patient, wherein the FUS transducer is connected to a controller configured to control application of focused ultrasound by the transducer, and an imaging workstation connected to an imaging unit configured to derive imaging data from an X-Ray imaging system. The apparatus may be used in a clinical or hospital setting that is equipped with appropriate imaging device, such as C-Arm, Fluoroscopy or any generic X-ray imaging system. The apparatus may be guided by a pre-operative imaging system, in which the images taken by different imaging system (e.g., CT, an MRI or any other system) may be fused, registered and overlaid with the images generated during the FUS treatment procedure. The apparatus may be used in combination with a C-Arm, an O-Arm, a G-Arm, X-Ray computed tomography (CT) or any other X-Ray device. The apparatus may be compatible with any ultrasound imaging system.

[0016] Figure 2 is a high level schematic illustration of an X-Ray guiding apparatus **100** for an image guided FUS treatment, according to some embodiments of the invention. Apparatus **100**

comprises an articulated arm **111** attached at its base to a procedure platform **90.** In certain embodiments, procedure platform **90** may comprise at least one of: an operating room table, an imaging table and a dedicated cart, wherein the cart is designed to carry the electronics and other device's accessories and wherein the cart wheels are designed to be locked to avoid the cart's movement. Apparatus **100** may further comprise a cradle **110** attached to the distal end of arm **111.** Apparatus **100** may further comprise a coupling accessory **125** configured to acoustically couple transducer surface **120** to a surface **83** of a tissue **80.**

[0017] Apparatus **100** may further comprise a FUS transducer **120** having a central axis **112** configured to be affixed within cradle **110** and to transmit a FUS energy beam **140** to a treatment location **141** within a patient. Apparatus **100** may further comprise a trigger **119,** configured to terminate the delivery of FUS energy **140.** Apparatus **100** may further comprise a controller **160** configured to control FUS energy delivery by therapeutic FUS transducer **120** which could be controlled by user interface.. Apparatus **100** may further comprise a screen **165.** Screen **165** provides the physician technical information, such as, but not limited to, power level chosen, sonication duration, informative maintenance and service messages. Screen **165** may contain the clinical information which in essence the workstation **180** provides, and vice versa workstation **180** may provide the technical information. Apparatus **100** may further comprise an aiming apparatus **130** configured to be affixed within cradle **110.** In certain embodiments, cradle **110** may be further configured such that both FUS transducer **120** and aiming apparatus **130** may be affixed within it simultaneously. In certain embodiments, an x-ray aim **150** may be attached to the FUS transducer **120** to enable x-ray guidance. In certain embodiments, cradle **110** may comprise several motion degrees of freedom, such as, but not limited to, anterior-posterior (A-P), superior-interior (S-I), left-right (L-R). In certain embodiments, cradle **110** may be configured to accommodate smoothly the insertion, lock and release of the aiming apparatus and the FUS transducer. In certain embodiments, cradle **110,** FUS transducer **120,** aiming apparatus **130** and x-ray aim **150** are built as a single unit.

[0018] Apparatus **100** may further comprise an X-Ray imaging system, comprising an X-Ray intensifier **85** and an X-Ray source **86,** wherein X-Ray intensifier **85** and X-ray source **86** are connected as an X-ray imaging system. In certain embodiments, the X-Ray imaging system may be configured to image a region **91** of tissue **80** that includes a treatment location **141.** In certain embodiments, the X-ray imaging may be performed before and during the FUS treatment. In certain embodiments, apparatus **100** may configured to be compatible with at least one of the following X-ray types: a C-arm, an O-arm, a G-arm and any other generic X-Ray type.

[0019] Apparatus **100** may further comprise a workstation **180** connected to X-ray intensifier **85** of the X-ray imaging system, wherein workstation **180** configured to derive an imaging data from the X-Ray imaging system. In certain embodiments, controller **160** and screen **165** may be combined within workstation **180.**

[0020] In certain embodiment, articulated arm **111** may be a mechanical arm or robotic arm that is attached to procedure platform **90.** In certain embodiments, articulated arm **111** may

comprise several degrees of freedom, such as, but not limited to, anterior-posterior (A-P), superior-interior (SI), left-right (L-R), and tilt such as, yaw, pitch and roll, to allow the alignment of FUS energy beam **140** to a desired treatment location **141** within the patient. In certain embodiments, articulated arm **111** may be adjusted manually and/or electronically and/or automatically to align it in the predefined orientation and position of cradle **110.**

[0021] In certain embodiments, apparatus **100** may further comprise a manual or controlled remote maneuvering module configured to remotely control the position and the orientation of articulated arm **111.** The maneuvering module may comprise at least one rod connected to articulated arm **111** in a non-limiting manner, and a control unit configured to control the motion of articulated arm **111.** The rod may be made of at least one of: a metal, a plastic, a wood and a carbon. The remote control of articulated arm **111** can minimize the exposure of the operating physician to X-radiation. In certain embodiments, the control unit of the maneuvering module may be implemented within controller **160** and/or workstation **180.**

[0022] In certain embodiments, coupling accessory **125** is designed to mimic the inner shape of FUS transducer **120** to enhance the acoustic coupling quality and provide the desired flexibility to enhance the coupling with patient skin **83.** In certain embodiments, coupling accessory **125** may be a balloon or membrane filled with fluid or gel. The balloon or membrane may be affixed to cradle **110** using rubber and/or ring that secure coupling accessory **125** attached to cradle **110** during the procedure.

[0023] In certain embodiments, coupling accessory **125** may comprise a gel pad. Gel pad **125** may be designed to mimic the inner shape of FUS transducer **120** including its margins in order to enable angular maneuver flexibility. The margin may provide the operating physician the possibility to manipulate cradle **110** and FUS transducer **120** in different angular positions without adversely affecting the coupling between FUS transducer and gel pad **125.** In certain embodiments, gel pad **125** may be designed in a shape that wraps around cradle **110** in order to affix gel pad **125** to cradle **110** during the insertion of FUS transducer **120.** Gel pad **125** may also be designed as a convex shape on the side that is attached to patient skin **83.** The convex shape may provide the operating physician the possibility to manipulate cradle **110** in different angular position without affecting the coupling between gel pad **125** and patient skin **83.** In certain embodiments, coupling accessory **125** may be at least one of: an optically transparent, an acoustically transparent and radiologically transparent. In certain embodiments, coupling accessory **125** may be designed to guide the positioning of the transducer 120 to a predefined angle of penetration of the acoustic beam **140** into the tissue **80.**

[0024] In certain embodiments, FUS transducer **120** may be configured to deliver FUS energy **140** to different depths according to the position of treatment location **141** using at least one of: different sizes of coupling accessory **125** and / or by tuning phased array transducer elements as electronic steering.

[0025] In certain embodiments, FUS transducer **120** may be further configured to project FUS beam energy **140** in a focused manner onto treatment location **141** as the focal spot location,

utilizing adjacent bone structures and avoiding damage to adjacent soft tissues. In certain embodiments, FUS transducer **120** may comprise at least one of: a single element or a phased array of elements or two or more annular elements. In certain embodiments, FUS transducer **120** may comprise at least two annular ring elements geometrically focused at a depth within a range **141A** in a closed environment of treatment location **141** (see, e.g., **Fig. 3B**). The annular elements arrangement of FUS transducer **120** allows locating the acoustic focus of FUS beam **140** either proximal or distal to the geometric focal depth by operating each of the at least two annular elements to vibrate at different phase. This allows a single FUS transducer **120** to mimic a series of transducers with the same aperture size but with different geometric focal lengths. This allows the operating physician to adjust, during the procedure, the depth of the acoustic focus of FUS beam **140** to match the depth of treatment location **141,** and thereby improve the efficacy of the treatment. In certain embodiments, the different annular elements of the transducer could be driven in slightly different frequency (incoherent mode) which results in continuous change of the relative phase between the elements in order to create elongated acoustic focus. In certain embodiments, at least one of the annular ring elements of FUS transducer **120** may be configured to be turned off in order to avoid from FUS energy beam **140** to hit vertebra bone protrusions or other acoustically absorbing structures in the beam path which should not be exposure to the high intensity acoustic energy. In certain embodiments, central axis **112** of FUS transducer **120** may be tilted relatively to the patient back so that energy beam **140** is transmitted onto treatment location **141** on the vertebra at an angle to the bone structure, thus avoiding a situation where FUS energy **140** may be blocked (e.g., by the vertebra protrusions and lamina). Certain angles may be selected to allow the incidence angle with respect to the bone surface to be smaller than the refraction angle, such that most of FUS energy **140** is absorbed by the bone and not reflected. In certain embodiments, apparatus **100** and projected FUS energy **140** may be used to optimize the incidence angle of the acoustic energy with respect to the bone to maximize absorption of energy by the bone. When beam angle is perpendicular to the bone the absorption of acoustic energy by the bone is maximal.

[0026] Figure 3A is a high level schematic illustration of cradle **110.** In certain embodiments, cradle **110** is designed to have a geometrical conic shape such that the projections of the cone boundaries are consistent with FUS beams **140** generated by FUS transducer **120.** In certain embodiments, the cone shape of cradle **110** is designed such that the lateral projected apex of the cone (e.g., the intersection point of the projections the cone boundaries) corresponds to the focal depth of the FUS energy beams **140.** Accordingly, the conic shape of cradle **110** may be used as a marker, visible on the X-Ray image, in order to guide the focusing of FUS energy beam **140** onto treatment location **141,** as illustrated in **Figure 3B. Figure 3B** is a high level schematic illustration of a lateral X-ray image of cradle **110,** according to some embodiments of the invention. In certain embodiments, workstation **180** may further comprise a software module configured to receive the lateral X-ray image of cradle **110,** to send the lateral X-ray image of cradle **110** to screen **165** and, to recognize, using image processing well known in the art, by means of at least one computer processor, the projections of the cone boundaries of cradle **110** and to display these projections on the lateral X-ray image of cradle **110.** In the preferred embodiment, the intersection point of the projections the cone boundaries represents

the lateral projected apex of the cone, which corresponds to the focal depth of the FUS energy beams **140.** Accordingly, the lateral projected apex of the cone may be used to assist the operating physician in navigating FUS energy beam **140** accurately and safely to treatment location **141.** The conical geometry of cradle **110** is invariant in wide range of lateral projection images of the lateral views. Accordingly, the cone shape including its apex can be recovered from a range of views. In certain embodiments, cradle **110** may comprise at least one of: a radio opaque material, a radiolucent material coated with radio opaque material and a semi radio opaque material.

[0027] In certain embodiments, image guided interventional procedures, in particular frameless stereotactic procedures, involve a stereoscopic optical image sensor that tracks object tagged with special markers to aid registration and navigation of FUS energy beam **140** to a target location **141.** Such markers are typically large spheres that can be easily identified within the field of view, or encoded black and white barcode like labels that can also uniquely identify a specific object and track it within the field of view. Spheres are particularly popular because its shape is almost invariant to viewing angle transformations. In 3D imaging modalities like CT or MR, markers are one or two dimensional and are made of a radio opaque or magnetic material to make them visible. For X-Ray (fluoroscopy) guidance, 2D templates with radio opaque markers are typically used for registration with pre-operative 3D imaging data and tracking.

[0028] Figure 4A is a high level schematic illustration of an aiming apparatus **130** positioned in cradle **110,** according to some embodiments of the invention. In certain embodiments, an aiming apparatus **130** may comprise a mockup **115** configured to be positioned in cradle **110.** In certain embodiments, mockup **115** may comprise a transparent material (e.g., Perspex) to allow the operating physical to keep patient skin **83** in a field of view. In certain embodiments, mockup **115** may comprise a radiolucent material (e.g., Perspex and Carbon Fibers) to generate clear X-Ray images of target location **141.**

[0029] In certain embodiments, aiming apparatus **130** may further comprise at least one optical marker holder **113.** In certain embodiments, optical marker holder **113** may comprise at least one laser pointer. In certain embodiments, at least one optical marker holder **113** may be aligned to create a straight line along central axis **112** of FUS transducer **120** and cradle **110.** In certain embodiments, at least one optical marker holder **113** may be configured to create additional lines to verify the position of cradle **110** and FUS transducer **120** with respect to the normal of the X-ray imaging system field of view **85.**

[0030] Figure 4B is a high level schematic illustration of mockup **115** and optical marker holder **113** of aiming apparatus **130,** according to some embodiments of the invention. In certain embodiments, aiming apparatus **130** may further comprise at least two x-ray aiming markers **133, 134** positioned on the vertical axis of at least one optical marker holder **113.** In certain embodiments, x-ray aiming markers **133, 134** may be rings. At least one x-ray aiming marker **133, 134** may comprise at least one groove **133A.** In certain embodiments, at least one of mockup **115** and x-ray aiming markers **133, 134** may be asymmetric, wherein the

asymmetry may be visible both optically and on radiologically, enabling the operating physician to correlate both views and conclude on direction and angle of movement as needed to co-align cradle **110** with X-ray intensifier **85** along central axis **112.**

[0031] In certain embodiments, at least one of mockup **115** and optical markers holder **113,** may have at least one X-Ray fiducial marker to enable the finding of mockup **115** orientation in the X-ray images. In certain embodiments, optical markers holder **113** may have individual on and off switches, affixed or placed adjacent to mockup **115.**

[0032] Figures 5A-5B is a high level flowchart illustrating a method. At step **510,** at least one radio opaque marker is placed at center of X-ray intensifier **85** (see, e.g., **70A** in **Figure 6A**). At step **515,** the patient is positioned in a prone position at procedure platform **90.** After the patient is positioned on the table, the relative height of the table and C-Arm is adjusted so both the patient spine and the cradle can be seen within the X-Ray field of view. Once the height is set, it will remain locked throughout the procedure. This adjustment is done via lateral X-Ray image and manipulation of the table height and C-Arm height.

[0033] At step **520,** X-Ray arm **87** (see, e.g., **Figure 2**) is moved horizontally to place radio opaque marker **70A** as seen in the X-Ray image to overlap treatment location **141** within the patient (see, e.g., **70A-2** in **Figure 6A**). In certain embodiments, X-Ray intensifier **85** may be positioned in an angle to the treatment location **141,** to overlap the radio opaque marker **70A** onto treatment location **141.** It is important to note that if an angle is set, it is done before step **520.** This angle would be the desired angle of view, which is also the angle of FUS energy penetration to the patient body. At step **525,** a radio opaque marker **70B** is placed on patient's skin **83** in a specific location that the operating physician selects following verification of treatment location **141** using radio opaque marker **70A-2** during an X-ray image by temporarily placing at least one temporary marker **84** (e.g., tip of needle) on the patient skin **83** (see, e.g., **Figure 6B**). In certain embodiments, marker **70B** may be only / also visual marker. This marker has no significant acoustic absorption to avoid near field heating and damage to the patient skin by the FUS energy.

[0034] At step **530,** coupling accessory **125** is placed on skin **83** of the patient above marker **70B,** as in step **525.** At step **535,** cradle **110** with mockup **115** is placed on coupling accessory **125** (see e.g., **Figure 6B**).

[0035] At step **540,** at least one optical marker holder **113** on mockup **115** is turned on and cradle **110** is aligned using articulated arm **111** of apparatus **100** and pointing by co-linear lasers to radio opaque marker **70B** on patient's skin **83** and radio opaque marker **70A** on intensifier **85.** At step **545,** an X-Ray image is taken to verify the alignment of cradle **110** and mockup **115** to the normal of the center of the X-ray imaging system field of view along axis **112.** At step **550,** the verification of the alignment is performed. If radio opaque markers **70A-2, 70B-1** on the X-Ray image from step **545** are overlapped, it means that cradle **110** and mockup **115** are aligned with the normal of the center of the X-ray imaging system field of view along axis **112** (see, e.g., **Figure 6C**). If radio opaque markers **70A-2, 70B-1** are not

overlapped on the X-Ray image from step **545,** the step **535** should be performed again. In certain embodiments, the alignment of cradle **110** and mockup **115** with the normal of the center of the X-ray imaging system field of view may be verified also using at least two x-ray aiming markers **133, 134** positioned on vertical axis of at least one optical marker holder **113.** Once cradle **110** and mockup **115** are aligned with the normal of the center of the X-ray imaging system field of view along axis **112,** x-ray aiming markers **133, 134** will appear concentric in the X-ray image from step **545** (see, e.g., **Figure 7A**). If x-ray aiming markers **133, 134** are not seem concentric in the X-Ray image from step **545** (see, e.g., **Figure 7B**), step **535** should be repeated. A certain range of position and angular error of aiming apparatus **130** may be permitted. An indication of the permitted error can be presented to the operating physician by the shape and/or size of x-ray aiming markers **133, 134,** such as the gap between the aiming markers diameters, which must remain visible around inner x-ray aiming marker **133** to indicate alignment within the error limits. In certain embodiments the decision on the quality of alignment of the cradle and aiming apparatus, at this step, could be done based on optical markers alone without the need for X-Ray imaging.

[0036] In certain embodiments, the alignment of cradle **110** can be performed based on depth images produced by a depth camera located on cradle **110** or FUS transducer **120** facing intensifier **85.** Cradle **110** may be aligned such that the flat face of intensifier **85** is parallel to cradle **110** according to the depth image analysis, and the shape of intensifier **85** is centered with the center of cradle **110** or FUS transducer **120,** such that cradle **110,** intensifier **85** and central axis **112** are collinear. In certain embodiments, the alignment of cradle **110** can be performed based on at least two distance sensors, such as but not limited to ultrasonic, RF, IR or laser sensors, located on cradle **110** or FUS transducer **120** facing intensifier **85.** These sensors can measure the distance from intensifier **85** and indicate the alignment needed in order to bring cradle **110** to a parallel alignment relative to intensifier **85** face. Complimentary to the distance sensors, a camera located on cradle **110** or FUS transducer **120** facing intensifier **85** will produce an image of intensifier **85** round shape to indicate the position of cradle **110,** relative to the intensifier **85,** and the direction to move cradle **110** in order to co-align central axis **112,** intensifier **85** and cradle **110.** In certain embodiments, alignment of cradle **110** can be performed based on at least two dual axis tilt-meters or angulation sensors, located on cradle **110** or FUS transducer **120** and on intensifier **85.** These sensors can measure the angle of cradle **110** or FUS transducer **120** and of intensifier **85** and indicate the alignment needed in order to bring cradle **110** to a parallel alignment relative to intensifier **85** face. This could be done based on absolute angle measurements or following calibration done at a baseline parallel orientation. Complementary to the angle sensors, a camera located on cradle **110** or FUS transducer **120** facing intensifier **85** will produce an image of intensifier **85** round shape to indicate the position of cradle **110,** relative to intensifier **85,** and the direction to move cradle **110** in order to co-align the central axis of intensifier **85** and cradle **110.** The tilt-meters or angulation sensors can be wired or wireless and use any existing technology to measure the required angle.

[0037] At step **555,** C-Arm **87** of the X-Ray imaging system is tilted laterally, preferably to an angle perpendicular to cradle axis **112** to verify the depth of treatment location **141,** using the

FUS beam path **140** recognized by the software module of workstation **180** (see, e.g., **Figure 3B**). The tilting of C-Arm **87** should be performed preferably on a single axis. When using other types of imaging for guidance, such as CT, Ultrasound and other, the location of the transducer focus could be extrapolated from the image. Once the treatment depth is verified, within the applicable focus range, C-Arm **87** should be moved back to its previous vertical position. C-Arm **87** should be re-positioned in accordance with the angle of mockup **115,** pointing optical markers holder **113** on radio opaque markers **70A** and **70B.** In certain embodiments, an X-Ray image may be taken again to verify the alignment.

[0038] At step **560,** mockup **115** is removed from cradle **110** and transducer **120** is inserted into cradle **110.** At step **565,** an x-ray aim **150,** is placed inside FUS transducer **120.** At step **570,** an X-ray image is taken to verify that cradle **110** and FUS transducer **120** are aligned with the normal of the center of the X-ray imaging system field of view along axis **112,** as in step **550** using x-ray aim **150.** At step **575,** FUS acoustic energy beam **140** is deployed and the ablation of target position **141** is performed. In certain embodiments, the FUS acoustic energy could be first deployed at a low level to verify targeting, per patient, feedback before deploying an ablation level energy pulse.

[0039] Figure 8A-8B are high level schematic illustrations of optical marker holder being located in a different location, according to some embodiments of the invention. In these embodiments of the invention, since the laser beam originating from the optical marker **113** or mirror **114** is aligned with the central axis line of the C Arm **112,** and the radio opaque marker in the center of the intensifier plate is adjusted to coincide with the treatment target on the X-ray image, the use of a mockup **115** is not required. Instead, an X-ray / optical aim attached directly to the FUS transducer can be used.

[0040] The optical marker holder **113 (Figure 8A)** or a mirror **114 (Figure 8B)** may be attached to the center of C Arm (X-Ray) intensifier plate **85.** The optical marker holder **113** or mirror **114** may be designed to allow angular alignment relative to the intensifier plate, either manually and/or automatically, and to be aligned with the central axis **112** of the C Arm **(Figure 2)** by projecting a laser beam to the center of the C Arm source **86 (Figure 2).** The optical marker **113** or mirror **114** may be attached to or consist of a radio opaque marker that is visible on X-ray image. The optical marker **113** or mirror **114** may be placed on the center of the radio opaque marker as applicable. In **Figure 8A** the mirror **114** has an angular alignment capability while the optical marker **113** can be adjusted to aim the center of this mirror.

[0041] Figure 9A-9B are a high level schematic illustrations of modified x-ray aim **150** affixed in FUS transducer **120,** according to some embodiments of the invention. Modified x-ray aim **150** may be used as an optical aim and also an x-ray aim.

[0042] Modified x-ray aim **150,** which is placed in the socket or recess of FUS transducer **120** along central axis **112** of the FUS transducer, may contain two or more x-ray aiming markers, such as rings **133, 134,** that are placed along the vertical axis of the FUS transducer. In order to align the FUS transducer to point to the target, the optical marker needs to appear at the

center of the upper and lower rings **133, 134.** In order to verify that the FUS transducer is aligned accurately to the C Arm central axis **112,** the radio opaque rings **133,134** need to appear concentric on the X-ray image **(Figures 7A, Figure 10).** If the rings do not seem concentric in the image **(Figure 7B)** or the physician identifies movement, the physician shall repeat the positioning procedure.

[0043] A certain range of position and angular error of modified x-ray aim **150** may be permitted. An indication of the permitted error can be presented to the physician by the shape and/or size of the x-ray aiming markers **133, 134,** such as the gap between the ring diameters **(Figure 7A-7B),** which must remain visible around the inner ring **133** to indicate alignment within the error limits.

[0044] Reference is now made to **Figures 11A-11B,** which is a schematic flow diagram of a method **1100** for image guided focused ultrasound treatment to a patient, in some embodiments of this configuration.

[0045] At step **1110,** a radio opaque marker may be placed at the center of the X-ray intensifier plate. An optical marker holder may then be placed at the center of the X-ray intensifier as per step **1115,** and aimed at the X-ray source.

[0046] At step **1120,** the patient is positioned in a prone position at a procedure platform **90.** After the patient is positioned on the table, the relative height of the table and C-Arm is adjusted so that both the patient spine and the cradle can be seen within the X-Ray field of view. Once the height is set, it will remain lock throughout the procedure. This adjustment is done via lateral X-Ray image and manipulation of the table height and C-Arm height.

[0047] At step **1125,** X-ray arm **87** is moved horizontally to place the radio opaque marker **70A** as seen in the X-ray image to overlap the treatment location **141** within the patient (see, e.g., **70A-2** in **Figure 6A**). In certain embodiments, X-Ray intensifier **85** may be positioned in an angle to the treatment location **141,** to overlap the radio opaque marker **70A** onto treatment location **141.** It is important to note that, if an angle is set, it is done before step **520.** This angle would be the desired angle of view, which is also the angle of FUS energy penetration to the patient body.

[0048] At step **1135,** coupling accessory **125** is placed on skin **83.** At step **1140,** the cradle **110** with the FUS transducer **120** is placed on coupling accessory **125.At** step **1145,** the modified x-ray aim **150** is placed inside the central hole of the FUS transducer **120.**

[0049] At step **1150,** the at least one optical marker holder **(Figures 8A-8B)** on the X-ray intensifier 85 is turned on, and the alignment of the cradle is performed, using the laser to point at the central markers as per step **1155,** one on the upper ring **133** of the modified x-ray aim **150** and the other at the lower ring **134** of the modified x-ray aim **150 (Figure 9A).** In case the aiming markers **133, 134** appear concentric in the X-ray image, the cradle is aligned **(Figure 6A).** If aiming markers **133, 134** are not seemed concentric in the X-ray image, step **1155**

should be repeated. A certain range of position and angular error of the modified x-ray aim may be permitted. An indication of the permitted error can be presented to the physician by the shape and/or size of the aiming markers **133, 134,** such as the gap between the ring diameters **(Figure 7A-7B),** which must remain visible around the inner ring **133** to indicate alignment within the error limits. In certain embodiments, the decision on the quality of alignment of the cradle and aiming apparatus could be done based on optical markers alone without the need for X-Ray imaging.

[0050] At step **1170,** the treatment depth should be verified. The X-ray arm shall be tilted laterally, preferably at 90 degrees to the Cradle axis **112** to verify the depth of the treatment location, using the imaging workstation beam path and focal point overlay **(Fig 3B).**

[0051] In case the treatment location depth is verified within the applicable focus range, the physician will deploy the acoustic energy, and ablate targeted tissue as per step **1175.** In certain embodiments, the acoustic energy could be first deployed at a low level to verify targeting per patient feedback before deploying an ablation level energy pulse.

[0052] According to certain embodiments, the X-ray aim **150** and the aiming apparatus **130** shape may be designed in a manner that reduces the interference to the image quality. **Figures 12A-12G** are high level schematic illustrations of X-ray images of the FUS transducer **120** with various X-ray aims **150 (12A-12C),** of which Figure **12D-12G** are high level schematic illustrations of X-ray images of aiming apparatus **130** at different designs, according to some embodiments of the invention. Image **12H** shows as reference the transducer without any aim inserted into it.

[0053] In all the X-ray aims presented, the design is optimized to minimize artifacts by eliminating non-aim related sharp interfaces between materials with different levels of radio opaqueness to make image as clear as possible. Similar effect, (to a bigger degree) can be seen in the design of the aiming apparatus, where **Figure 12D** shows a design with many artifacts, and where **Figure 12E** shows a clear design which is also optically transparent, as can be seen in **Figures 12F-12G.**

[0054] In addition, the bottom of the X-ray aim **150** has a thick disk-shaped plastic part which increases the overall radio opaqueness of the aim and allows a more balanced (in terms of gain and image saturation), imaging of the anatomy through the FUS transducer **120** opening as seen in **Figures 12H-12G.**

[0055] Figures 13A-13C are high level schematic illustrations of x-ray images of the treatment target with and without the FUS transducer in the cradle respectively, according to some embodiments of the invention. **Figures 13A** illustrate the A-P images of the FUS transducer as shown on the device workstation during the procedure.

[0056] After the positioning process is over and the cradle is aligned with central axis **112** and fixed, the workstation may identify the circular shape of the cradle in the image, save it and use

the clear image of its inner area including the treatment target **(Fig 13B)** to replace the dark area caused by the radiopacity of the transducer **(Fig 13A)** using image processing, thereby avoiding obstruction of the patient anatomy. This produces a clear image of the treatment target with the transducer inside the cradle **(Fig 13C)** when ready for sonication. The physician may then observe the image, which shows now a radiologically "transparent transducer", which provides the anatomical information that was blocked by the opaque transducer. The importance of such image is to assist the physician to identify and verify the treatment location and alert in case of potential patient movement. These features are essential for the enhancement of the device safety profile and efficacy outcome.

[0057] Another embodiment of this apparatus is using an ultrasound (US) imaging probe instead of using imaging of an X ray device, to view the treatment target and align the FUS transducer to it. **Figure 14A** is a schematic illustration of the US imaging probe mounted in the center of the FUS transducer. An alignment adaptor is used to align the US imaging probe to conjoin with the transducer central axis.

[0058] As the simultaneous operation of the imaging probe and transducer US sonication significantly degrades the quality of the ultrasound images and even completely blocks the imaging capabilities, an alternated pulsed method is described in **Figure 14B.** The FUS energy will be pulsed with short time cease periods in which an image without artifacts or degradation would be captured from the ultrasound imaging stream to be presented on the imaging workstation until replaced by the next non-distorted image, captured at the next energy cease time period. This way the refresh rate of the imaging would be lower but can still produce an image feedback during sonication. The non-distorted images can be identified using basic image processing techniques as the predicted level of image degradation is significant. Alternatively the pulse to create the therapeutic sound wave may be created in such a manner to minimize artifacts and degradation of ultrasound image. It is important to note that the uniqueness of the implementation above is that is allows any generic ultrasound imaging system with the required imaging characteristics for the clinical indication to be used, as is, without any need for modification or connection to a gate signal, as guidance for a Focused Ultrasound system.

[0059] In the above description, an embodiment is an example or implementation of the invention. The various appearances of "one embodiment", "an embodiment", "certain embodiments" or "some embodiments" do not necessarily all refer to the same embodiments.

[0060] The invention is not limited to the diagrams or to the corresponding descriptions. For example, flow need not move through each illustrated box or state, or in exactly the same order as illustrated and described. Meanings of technical and scientific terms used herein are to be commonly understood as by one of ordinary skill in the art to which the invention belongs, unless otherwise defined. While the invention has been described with respect to a limited number of embodiments, these should not be construed as limitations on the scope of the invention, but rather as exemplifications of some of the preferred embodiments. Other possible variations, modifications, and applications are also within the scope of the invention.

Accordingly, the scope of the invention should not be limited by what has thus far been described, but by the appended claims and their legal equivalents.

REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US8727987B [0003]
- US5285772A [0004]

Patentkrav

1. Røntgenstyret fokuseret ultralyds- (FUS) behandlingsapparat (100), hvilket apparat (100) omfatter:

en ledarm (111) med en base og en distal ende, ledarmen er fastgjort ved basen til en indgrebsplatform (90);

en understøtning (110) fastgjort til den distale ende af armen (111);

et sigteapparat (130), som kan fastgøres aftageligt inde i understøtningen (110); og

en FUS-omformer (120), som kan fastgøres aftageligt inde i understøtningen (110) og konfigureret til at sende en terapeutisk FUS-energistråle (140) til et behandlingssted (141), hvor FUS-omformeren (120) er forbundet til en styreenhed (160) for at styre den terapeutiske FUS-energistråle (140), som sendes af FUS-omformeren (120);

kendetegnet ved, at:

understøtningen (110) er kegleformet, hvor fremspring fra de kegleformede grænser svarer til den terapeutiske FUS-stråle (140) genereret af FUS-omformeren, og hvor en lateral fremspringstop af kegleformen svarer til et fokuspunkt af FUS-omformeren (120).

2. Apparatet ifølge krav 1, hvor ledarmen muliggør bevægelse i det mindste i følgende frihedsgrader: frem-tilbage (anterior-posterior A-P), op-ned (superior-interior (S-I), og venstre-højre (left-rigth L-R), hældning, drejning, stigning og rulning for at muliggøre placering af understøtningen ved en ønsket vinkel i forhold til behandlingsstedet.

3. Apparatet ifølge krav 1, yderligere omfattende en billeddannelsesarbejdsstation forbundet med en røntgenforstærker i et røntgenbilleddannelsessystem, hvor billeddannelsesarbejdsstationen omfatter:

et displaysystem; og

en bearbejdsningsmodul, konfigureret til:

at modtage et lateralt røntgenbillede af understøtningen fra nævnte røntgenbilleddannelsessystem;

at vise det laterale røntgenbillede på nævnte displaysystem;

i det laterale røntgenbillede at genkende fremspringene af de kegleformede grænser af understøtningen; og

på displaysystemet at vise fremspringene af de kegleformede grænser af understøtningen i forhold til nævnte laterale røntgenbillede.

4. Apparatet ifølge krav 3, hvor bearbejdningsmodulet er yderligere konfigureret til:

at modtage et A-P-røntgenbillede af understøtningen fra røntgenbilleddannelses-systemet;

i A-P-røntgenbilledet at identificere en cirkelform af understøtningen og et indre område inde i cirkelformen, som omfatter det forudbestemte behandlingssted, for derved at give et tydeligt billede af det indre område deraf,

at opdatere et røntgenbillede ved at erstatte et mørkt område forårsaget af en radiopacitet af FUS-omformeren, under anvendelse af billedbehandling, med det tydelige billede af det indre område for at frembringe et tydeligt billede af det forudbestemte behandlingssted; og

på displaysystemet at vise det opdaterede røntgenbillede.

5. Apparatet ifølge et hvilket som helst af kravene 1-4, hvor sigteapparatet omfatter: en attrap som kan fastgøres aftageligt inde i understøtningen; og mindst en optisk markørholder.

6. Apparatet ifølge krav 5, hvor sigteapparatet yderligere omfatter to eller flere røntgenmarkører med forskellige størrelser anbragt langs en vertikal akse af den mindst ene optiske markørholder.

7. Apparatet ifølge krav 6, yderligere omfattende mindst en uigennemskinnelig radiomarkør, som skal anbringes ved en omtrentlig midte af en røntgenforstærker af røntgenbilleddannelsessystemet, og en markør som skal anbringes på huden af en patient, hvor markøren som skal anbringes på huden er mindst en af en visuel markør, en uigennemskinnelig radiomarkør, eller et uigennemskinneligt radiomarkørmærkat.

8. Apparatet ifølge krav 6, yderligere omfattende et dybdekamera anbragt på en af understøtningen eller FUS-omformeren, og som vender mod røntgenforstærkeren af røntgenbilleddannelsessystemet, og hvor en justering af understøtningen udføres baseret på dybdebilleder frembragt af nævnte dybdekamera.

9. Apparatet ifølge krav 6, yderligere omfattende mindst to afstandssensorer anbragt på en af understøtningen eller FUS-omformeren, og som vender mod røntgenforstærkeren af røntgenbilleddannelsessystemet.

10. Apparatet ifølge krav 6, yderligere omfattende mindst to dobbeltaksehældningsmålere eller vinkeldannelsessensorer anbragt på en af understøtningen eller FUS-omformeren og på røntgenforstærkeren af røntgenbilleddannelsessystemet.

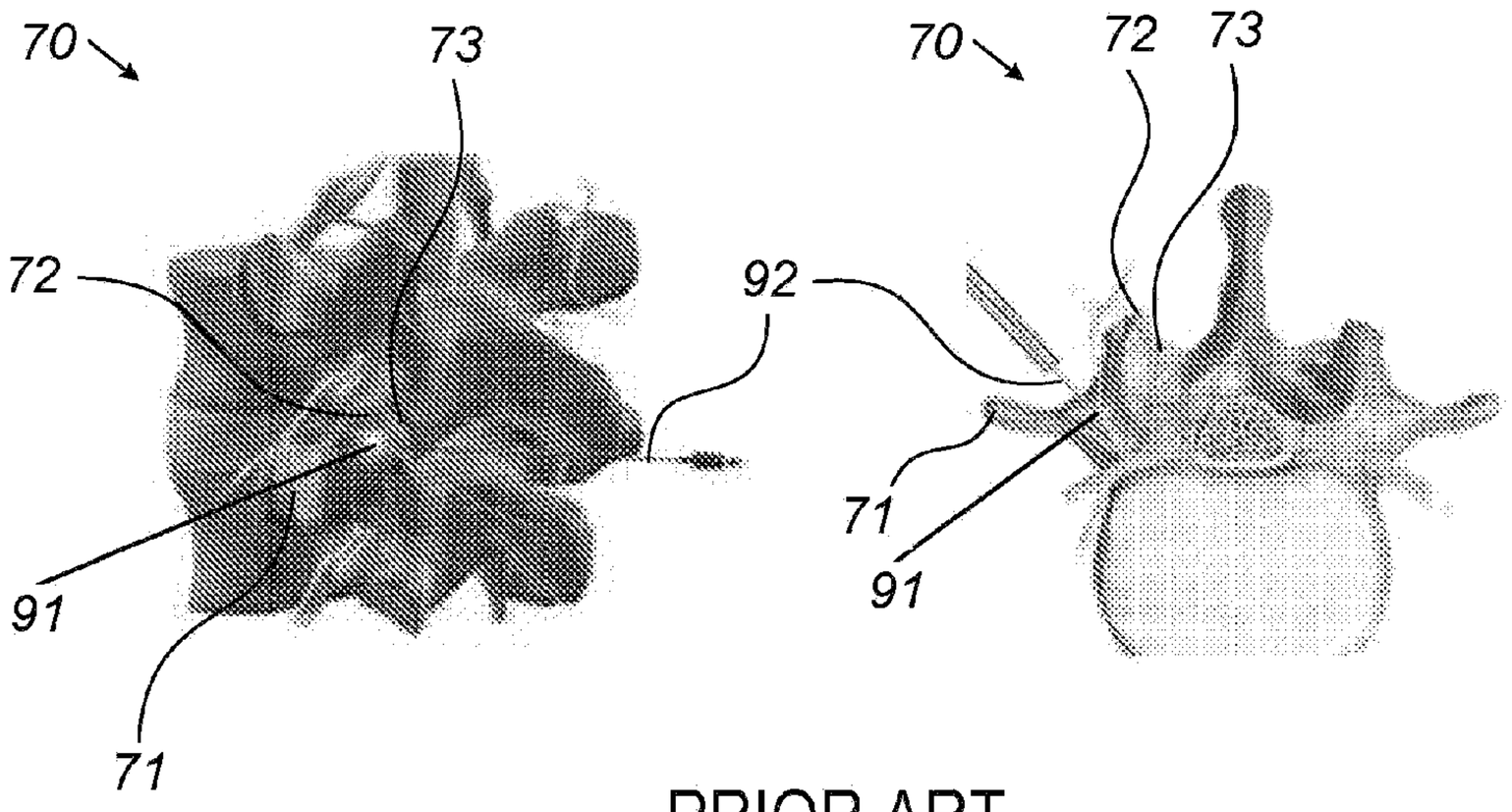
11. Apparatet ifølge et hvilket som helst af kravene 1-10, hvor sigteapparatet er et modificeret røntgensigte anbragt i en holder af FUS-omformeren og omfatter mindst to sigtemarkører anbragt langs en vertikal akse af FUS-omformeren.

12. Apparatet ifølge krav 11, hvor sigteapparatet er et optiske sigte.

13. Kit omfattende apparatet ifølge et hvilket som helst af kravene 1-12 og yderligere omfattende et forbindelsesudstyr konfigureret til akustisk at forbinde FUS-omformeren med huden på en patient.

14. Kittet ifølge krav 13, hvor forbindelsesudstyret er en af: en ballon fyldt med en akustisk fluid eller gel, eller en gelpude.

DRAWINGS



PRIOR ART

FIGURE 1

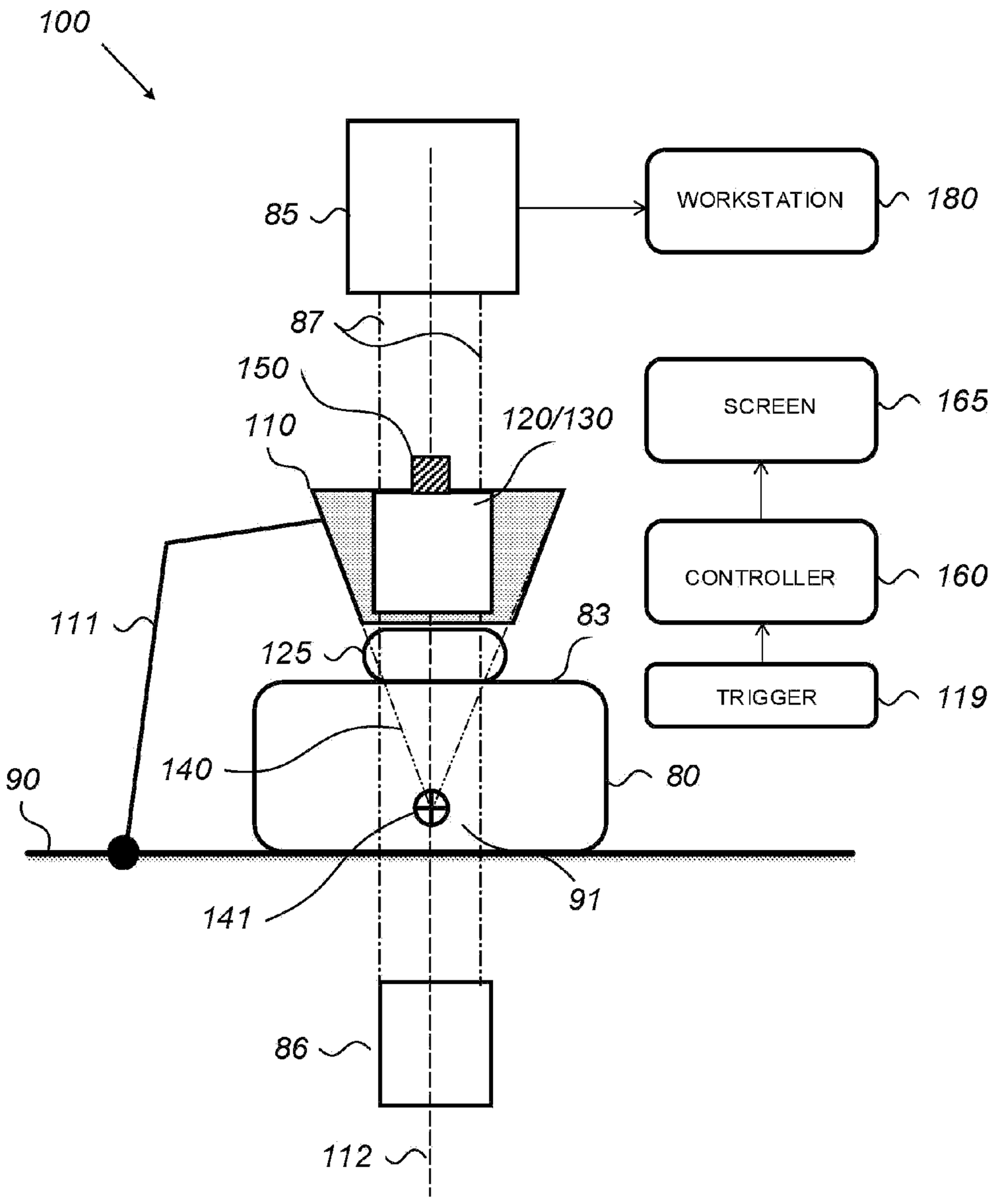

100
85
87
150
110
120/130
111
125
83
140
90
80
141
91
86
112
WORKSTATION
180
SCREEN
165
CONTROLLER
160
TRIGGER
119

FIGURE 2

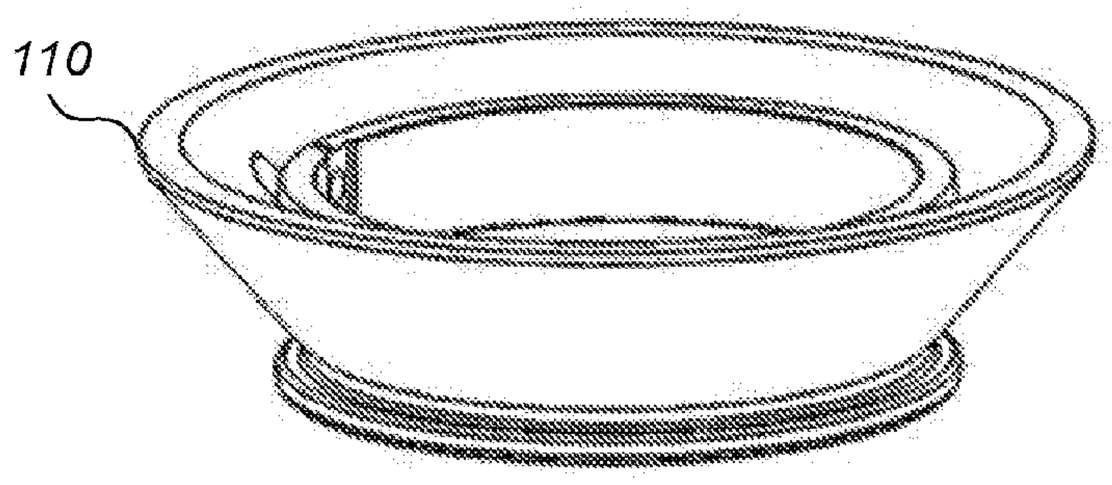


FIGURE 3A

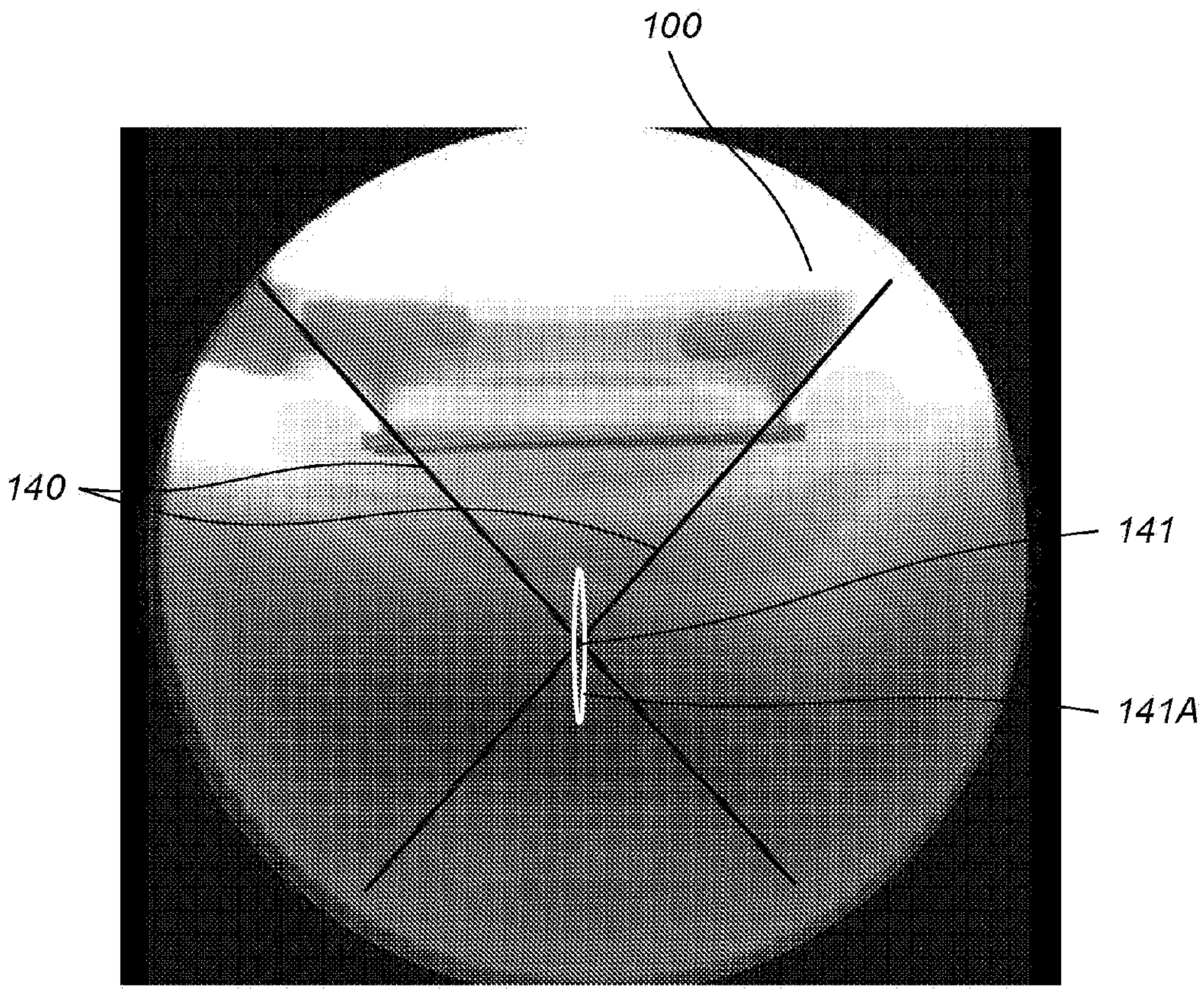


FIGURE 3B

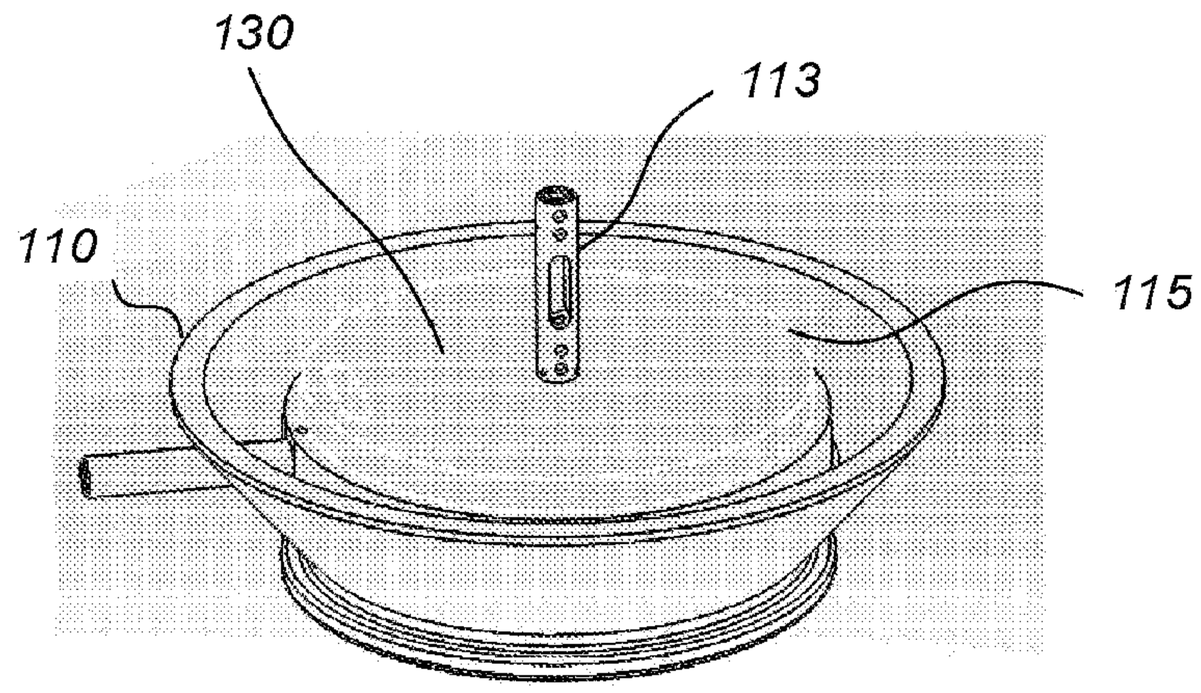


FIGURE 4A

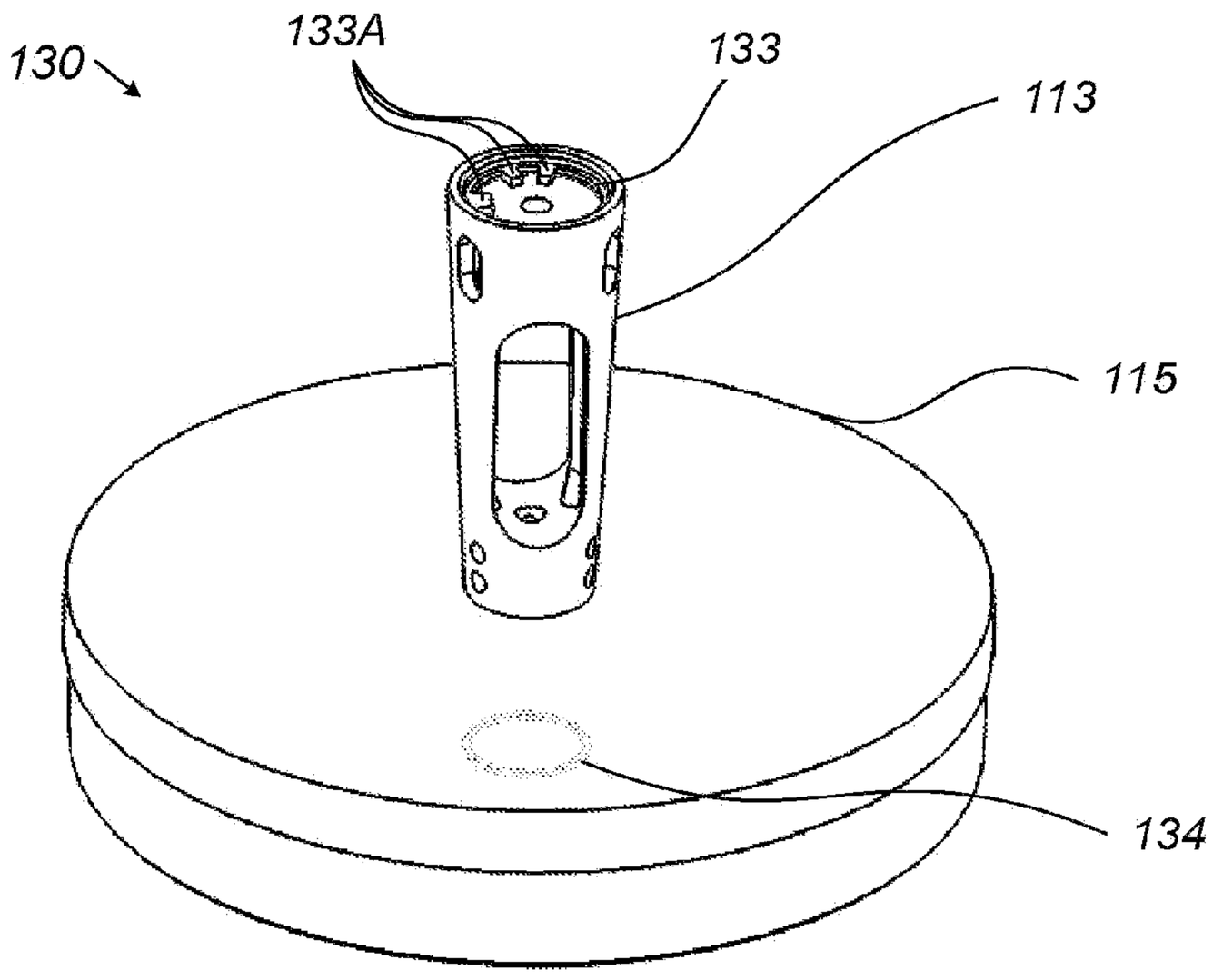


FIGURE 4B

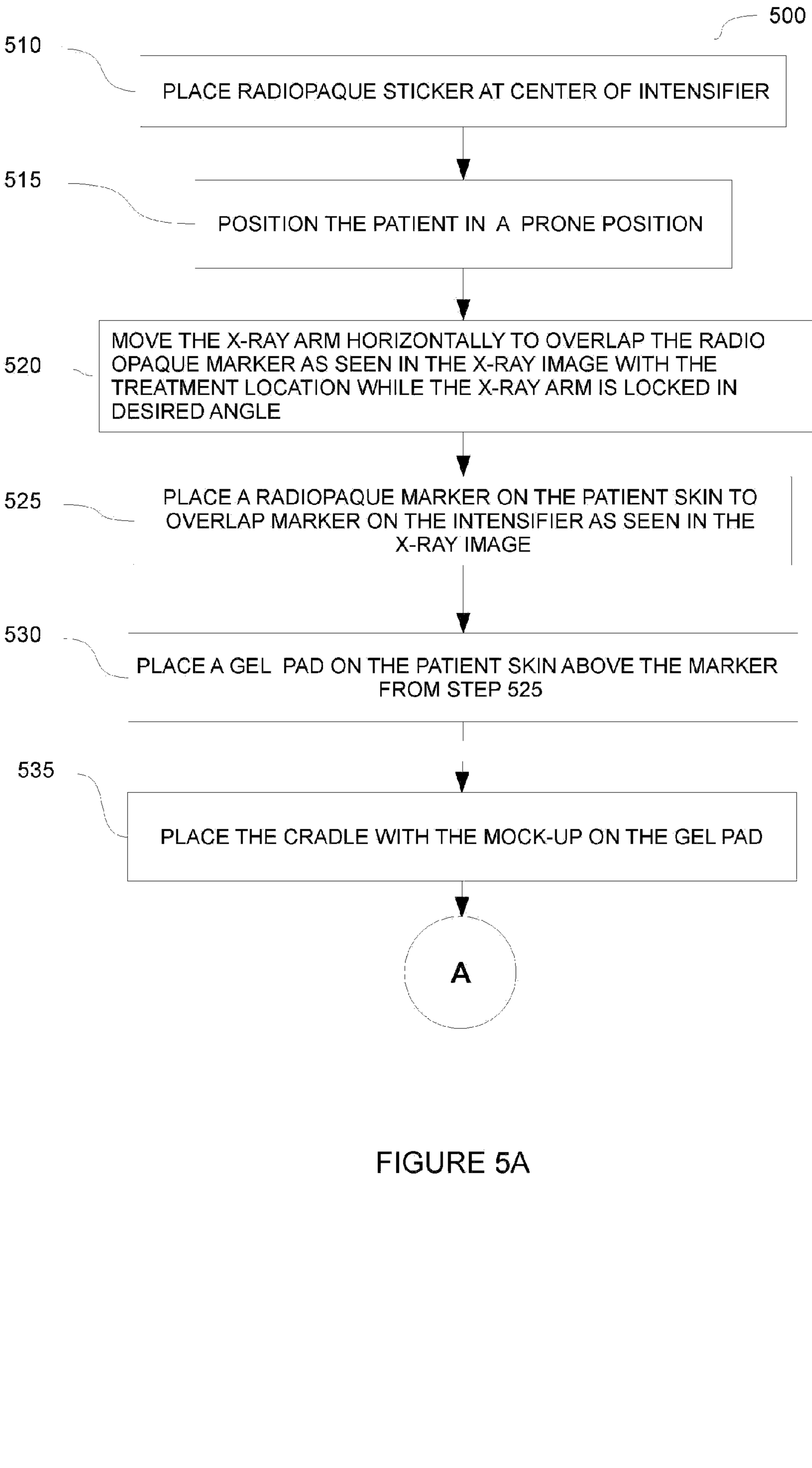

500
510
PLACE RADIOPAQUE STICKER AT CENTER OF INTENSIFIER
515
POSITION THE PATIENT IN A PRONE POSITION
520
MOVE THE X-RAY ARM HORIZONTALLY TO OVERLAP THE RADIO OPAQUE MARKER AS SEEN IN THE X-RAY IMAGE WITH THE TREATMENT LOCATION WHILE THE X-RAY ARM IS LOCKED IN DESIRED ANGLE
525
PLACE A RADIOPAQUE MARKER ON THE PATIENT SKIN TO OVERLAP MARKER ON THE INTENSIFIER AS SEEN IN THE X-RAY IMAGE
530
PLACE A GEL PAD ON THE PATIENT SKIN ABOVE THE MARKER FROM STEP 525
535
PLACE THE CRADLE WITH THE MOCK-UP ON THE GEL PAD
A

FIGURE 5A

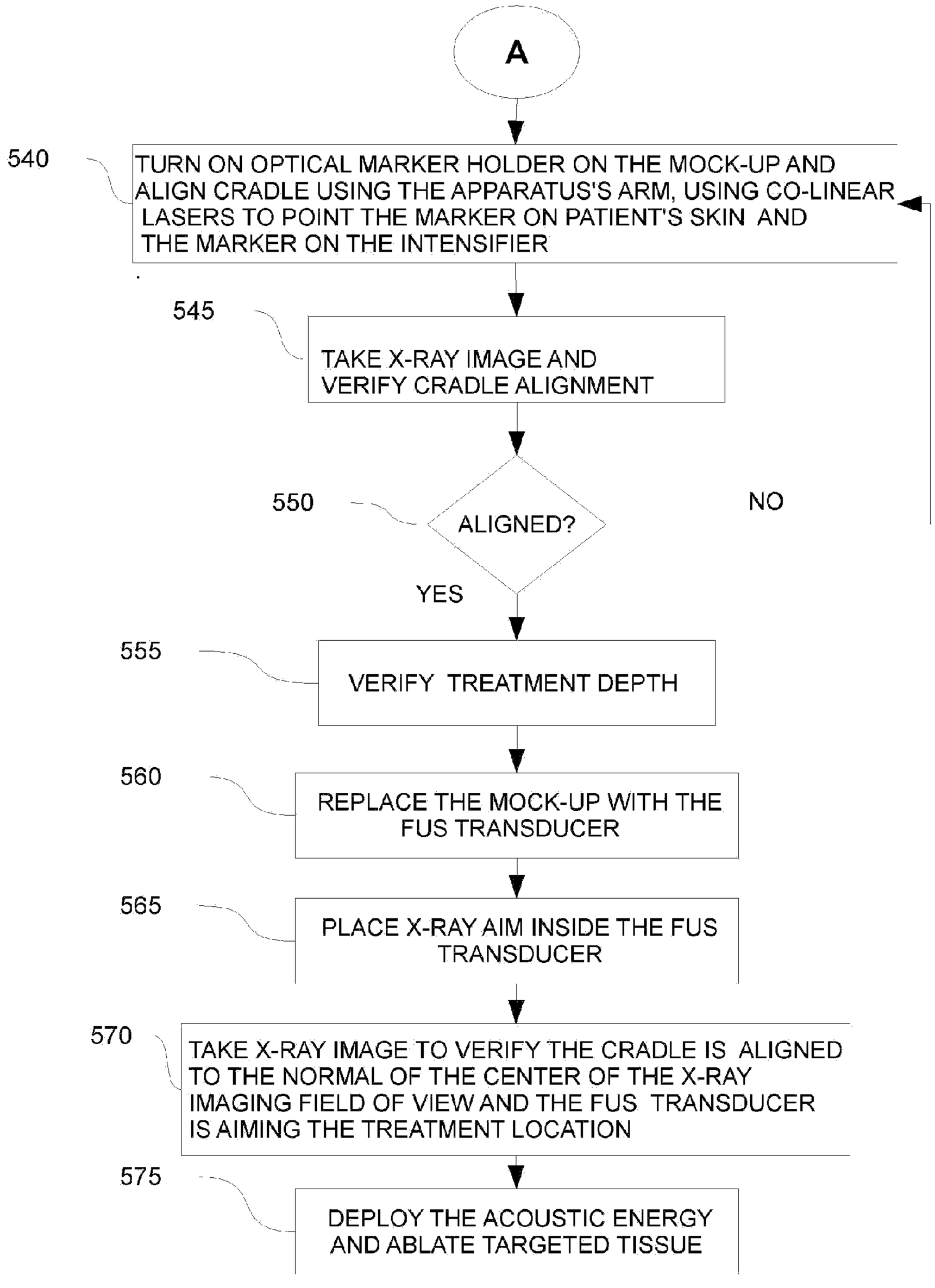

A
540
TURN ON OPTICAL MARKER HOLDER ON THE MOCK-UP AND ALIGN CRADLE USING THE APPARATUS'S ARM, USING CO-LINEAR LASERS TO POINT THE MARKER ON PATIENT'S SKIN AND THE MARKER ON THE INTENSIFIER
545
TAKE X-RAY IMAGE AND VERIFY CRADLE ALIGNMENT
550
ALIGNED?
NO
YES
555
VERIFY TREATMENT DEPTH
560
REPLACE THE MOCK-UP WITH THE FUS TRANSDUCER
565
PLACE X-RAY AIM INSIDE THE FUS TRANSDUCER
570
TAKE X-RAY IMAGE TO VERIFY THE CRADLE IS ALIGNED TO THE NORMAL OF THE CENTER OF THE X-RAY IMAGING FIELD OF VIEW AND THE FUS TRANSDUCER IS AIMING THE TREATMENT LOCATION
575
DEPLOY THE ACOUSTIC ENERGY AND ABLATE TARGETED TISSUE

FIGURE 5B

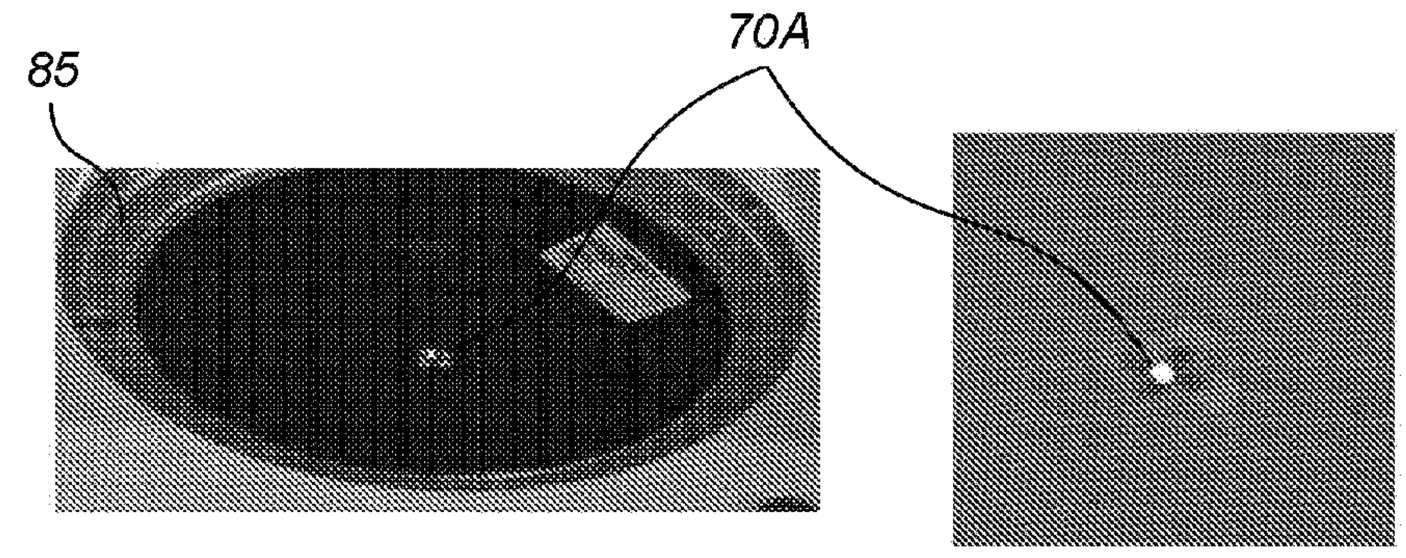


FIGURE 6A

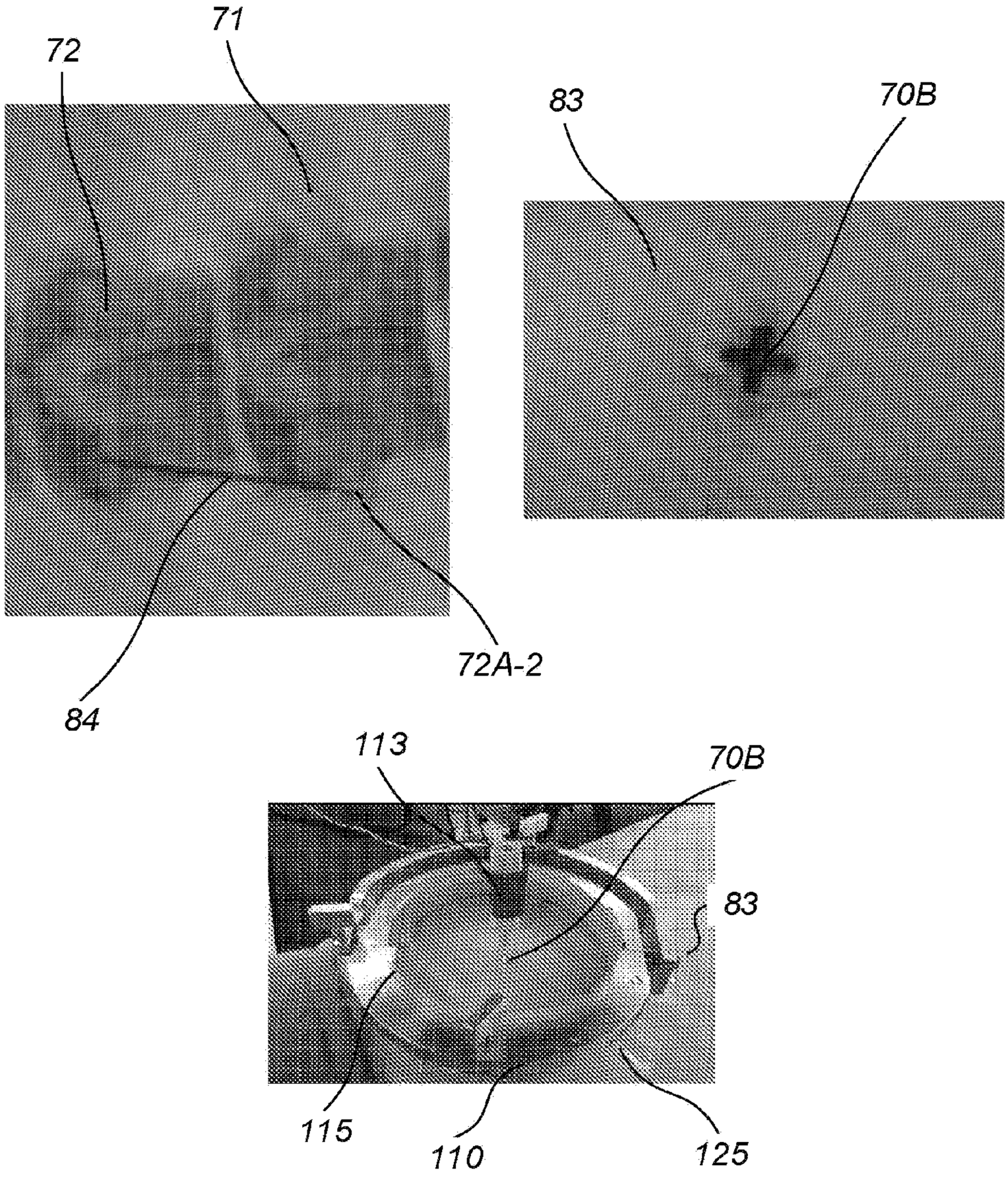


FIGURE 6B

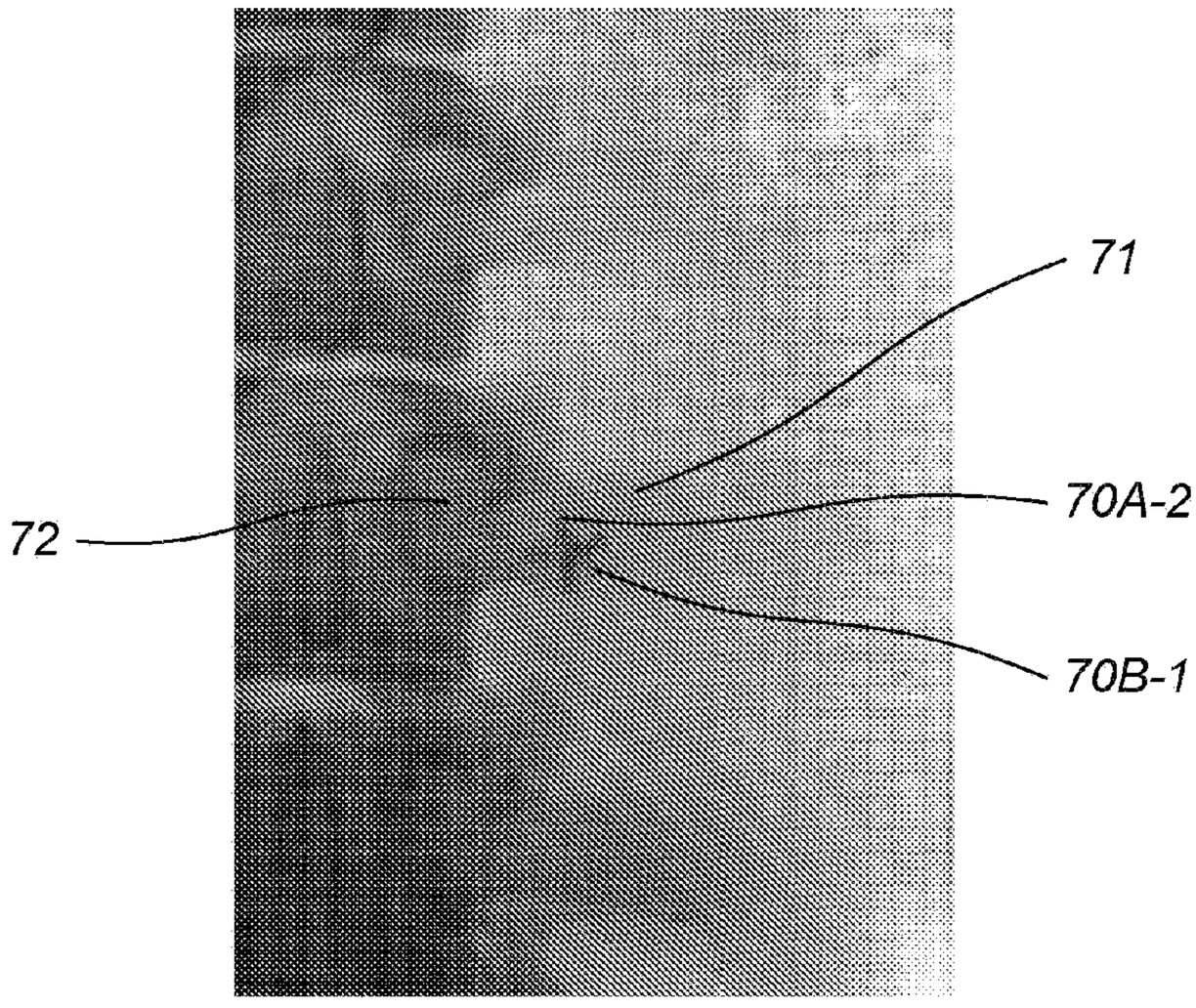
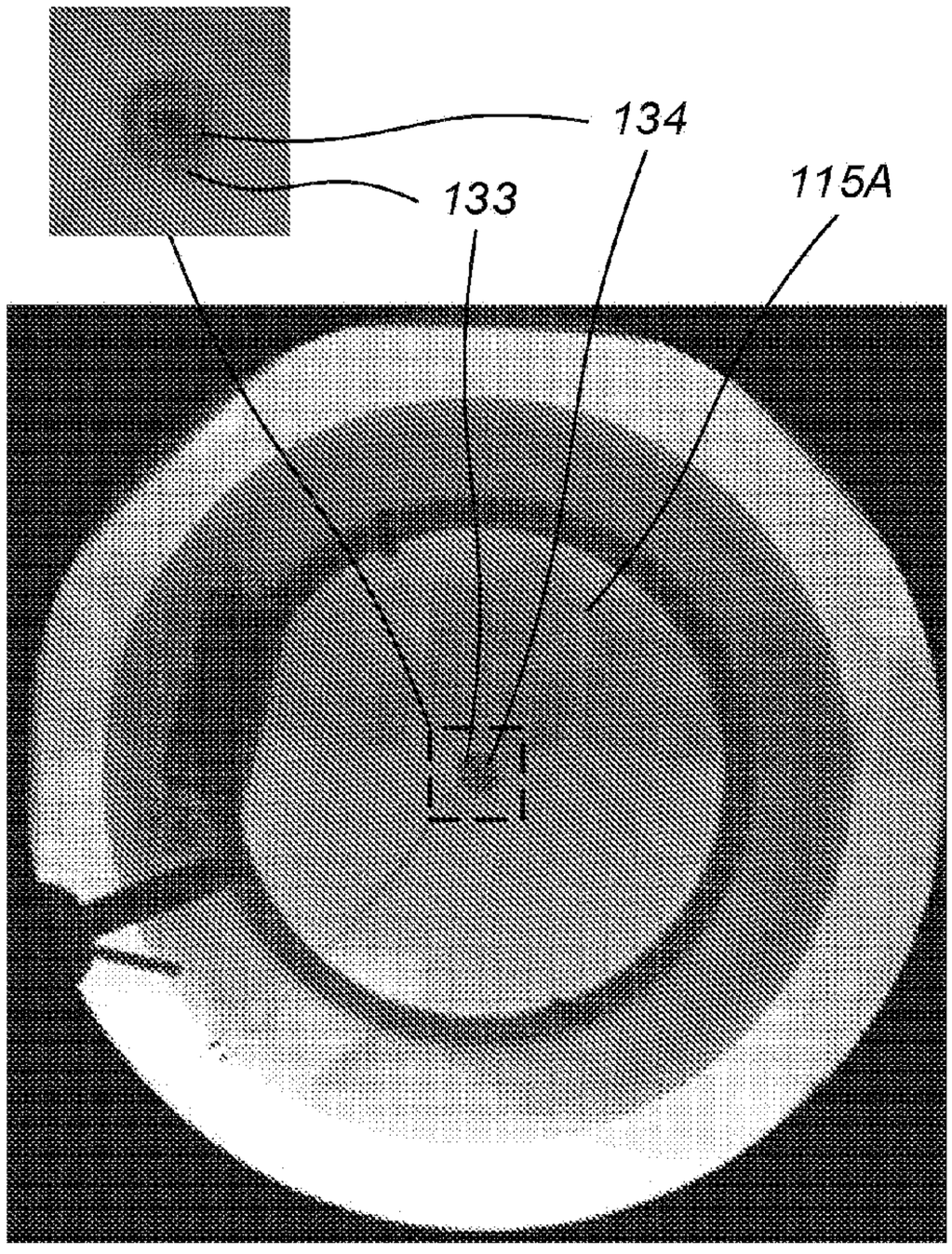


FIGURE 6C



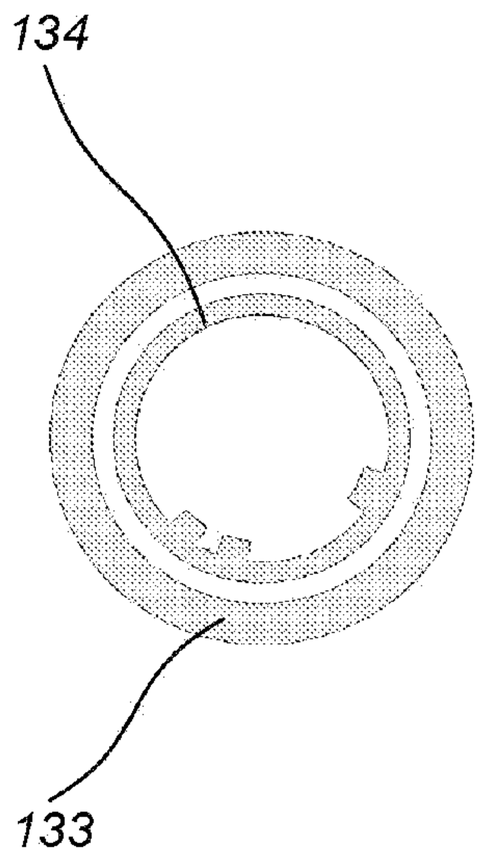


FIGURE 7A

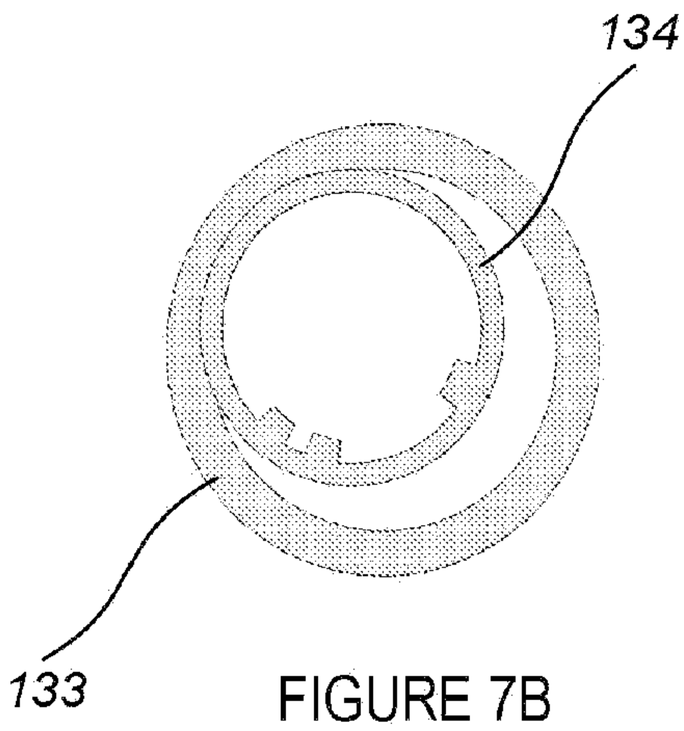


FIGURE 7B

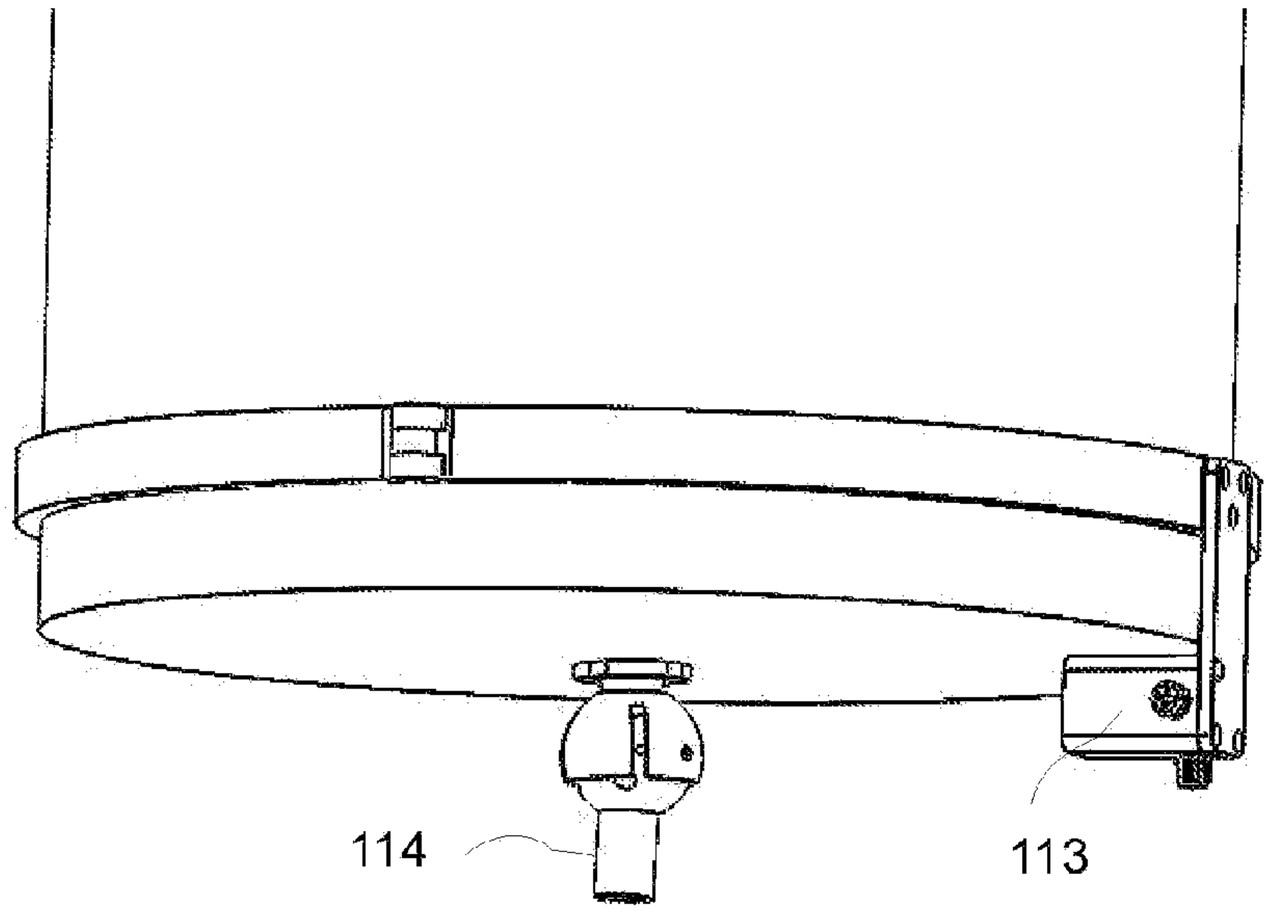


FIGURE 8A

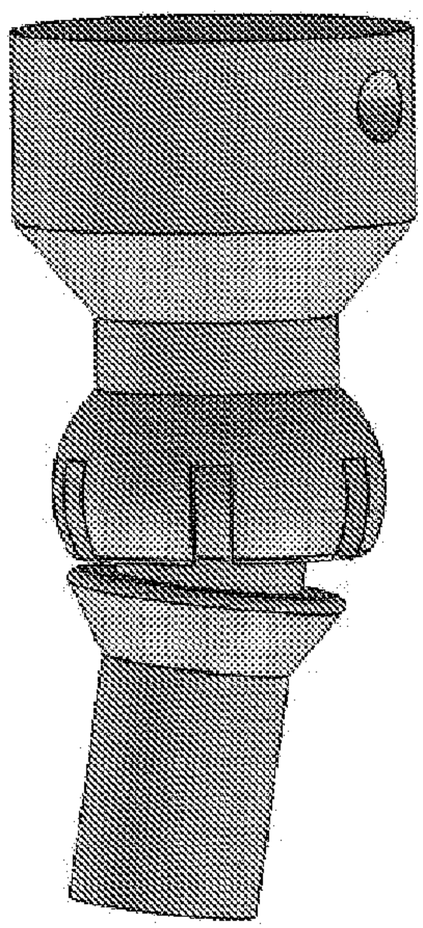


FIGURE 8B

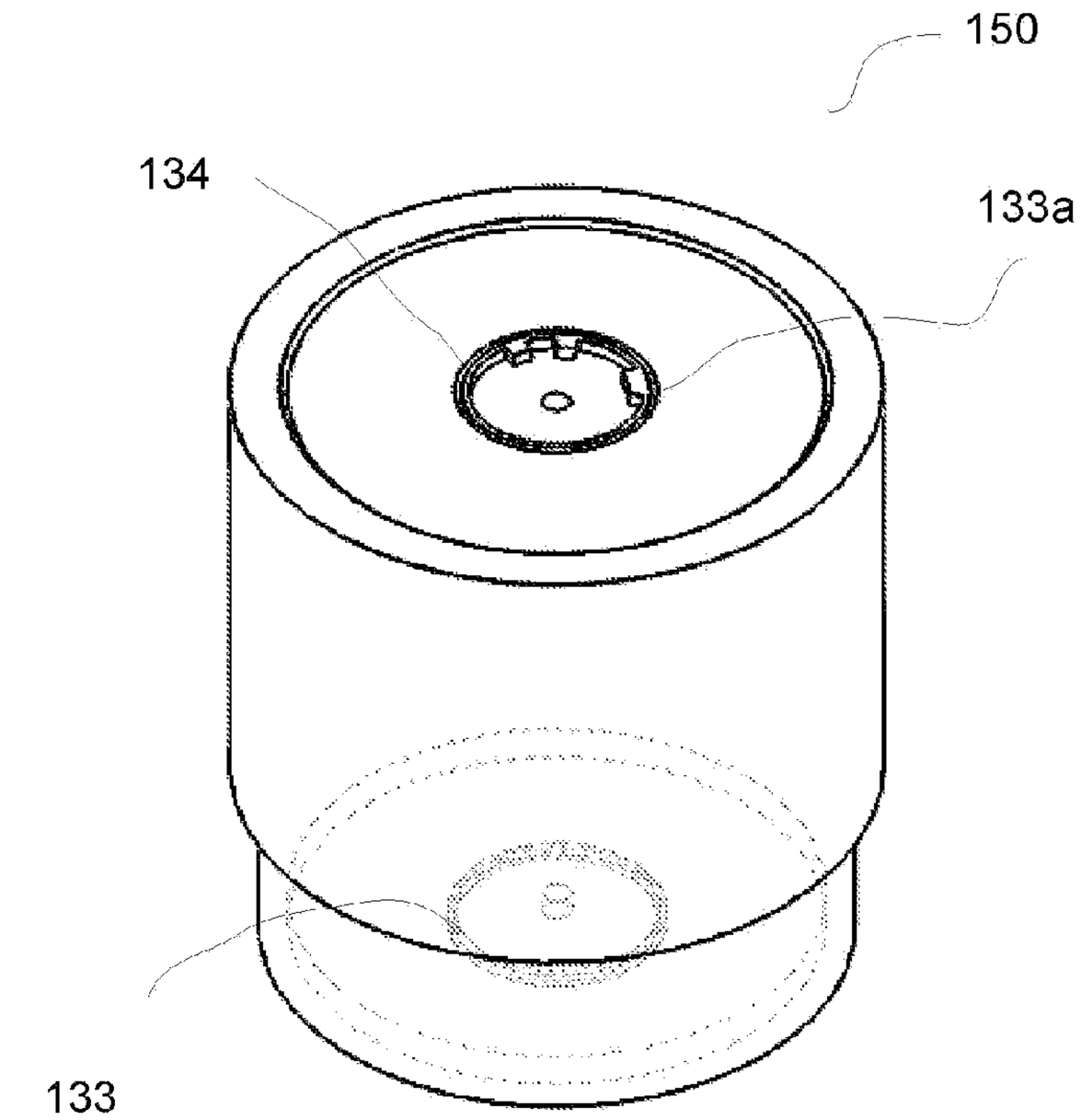


FIGURE 9A

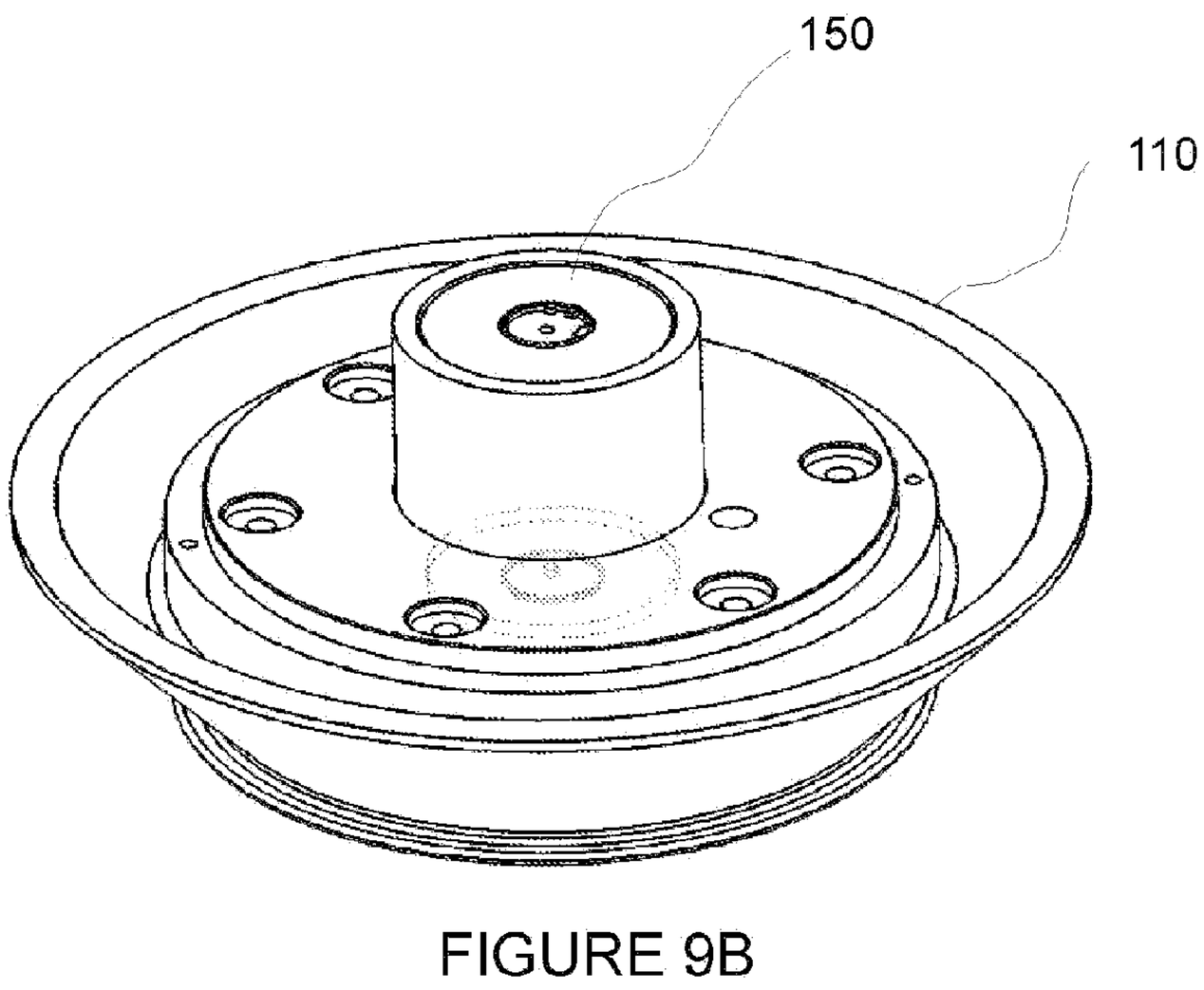


FIGURE 9B

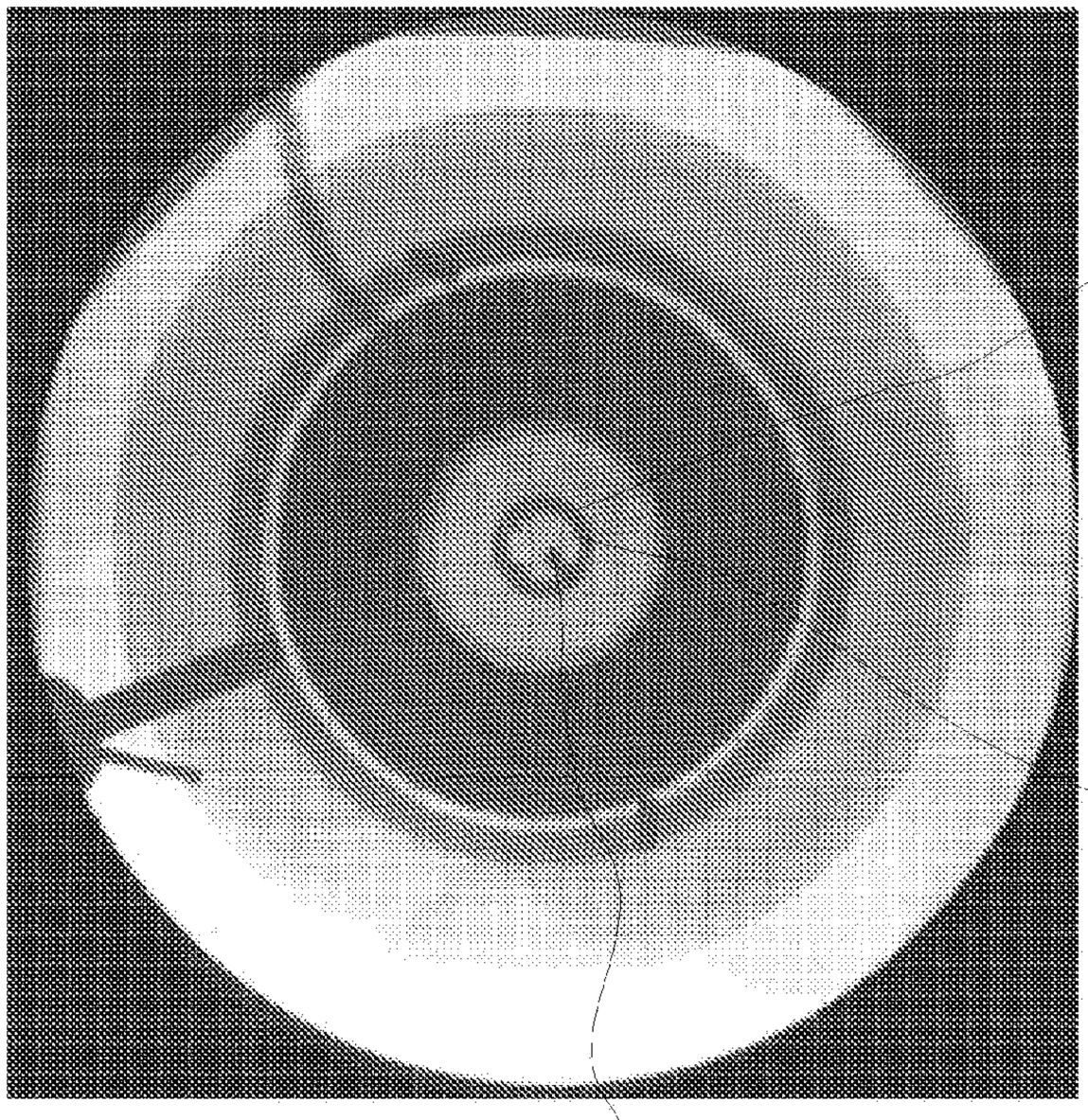


FIGURE 10

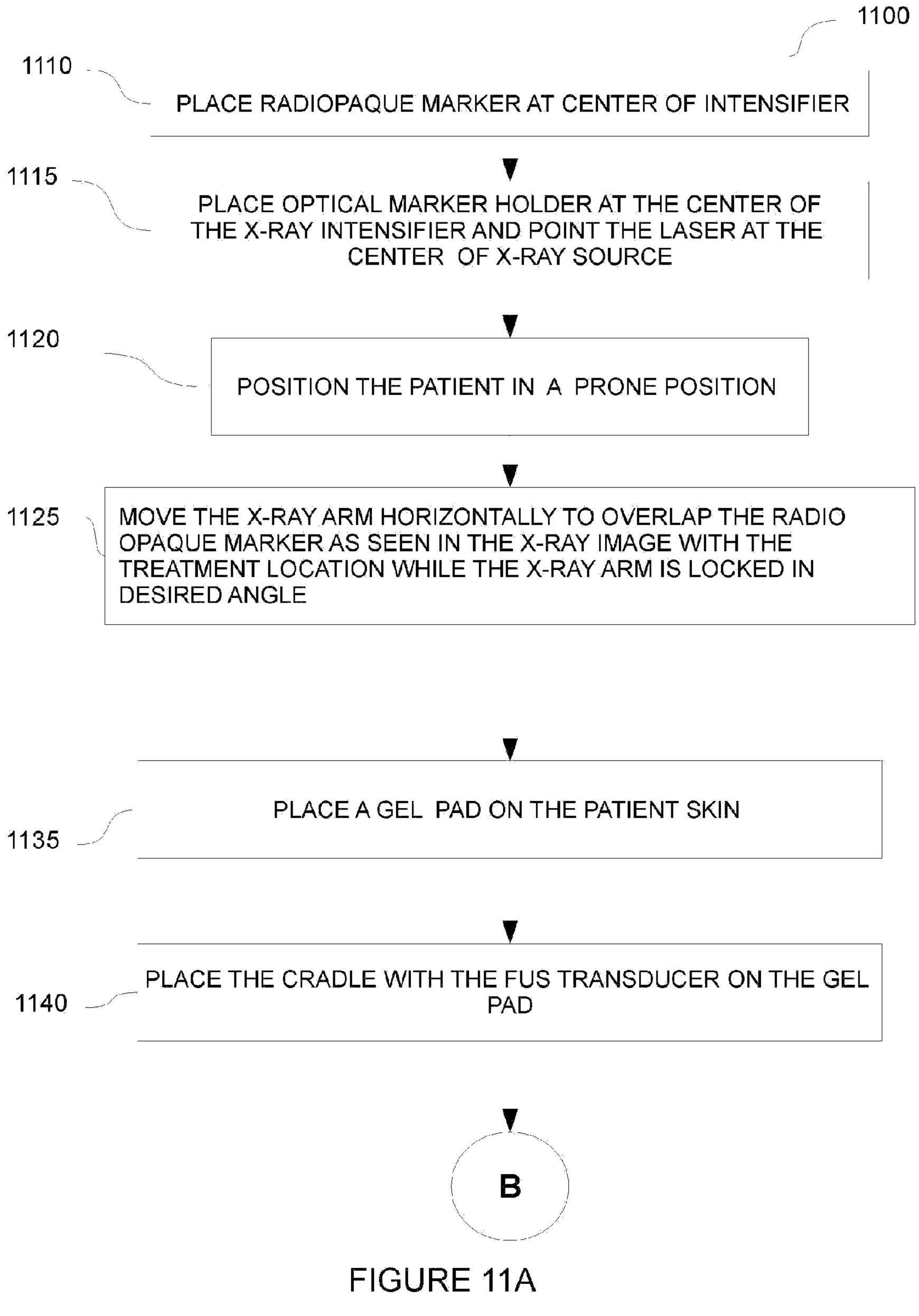

1100
1110
PLACE RADIOPAQUE MARKER AT CENTER OF INTENSIFIER
1115
PLACE OPTICAL MARKER HOLDER AT THE CENTER OF THE X-RAY INTENSIFIER AND POINT THE LASER AT THE CENTER OF X-RAY SOURCE
1120
POSITION THE PATIENT IN A PRONE POSITION
1125
MOVE THE X-RAY ARM HORIZONTALLY TO OVERLAP THE RADIO OPAQUE MARKER AS SEEN IN THE X-RAY IMAGE WITH THE TREATMENT LOCATION WHILE THE X-RAY ARM IS LOCKED IN DESIRED ANGLE
1135
PLACE A GEL PAD ON THE PATIENT SKIN
1140
PLACE THE CRADLE WITH THE FUS TRANSDUCER ON THE GEL PAD
B

FIGURE 11A

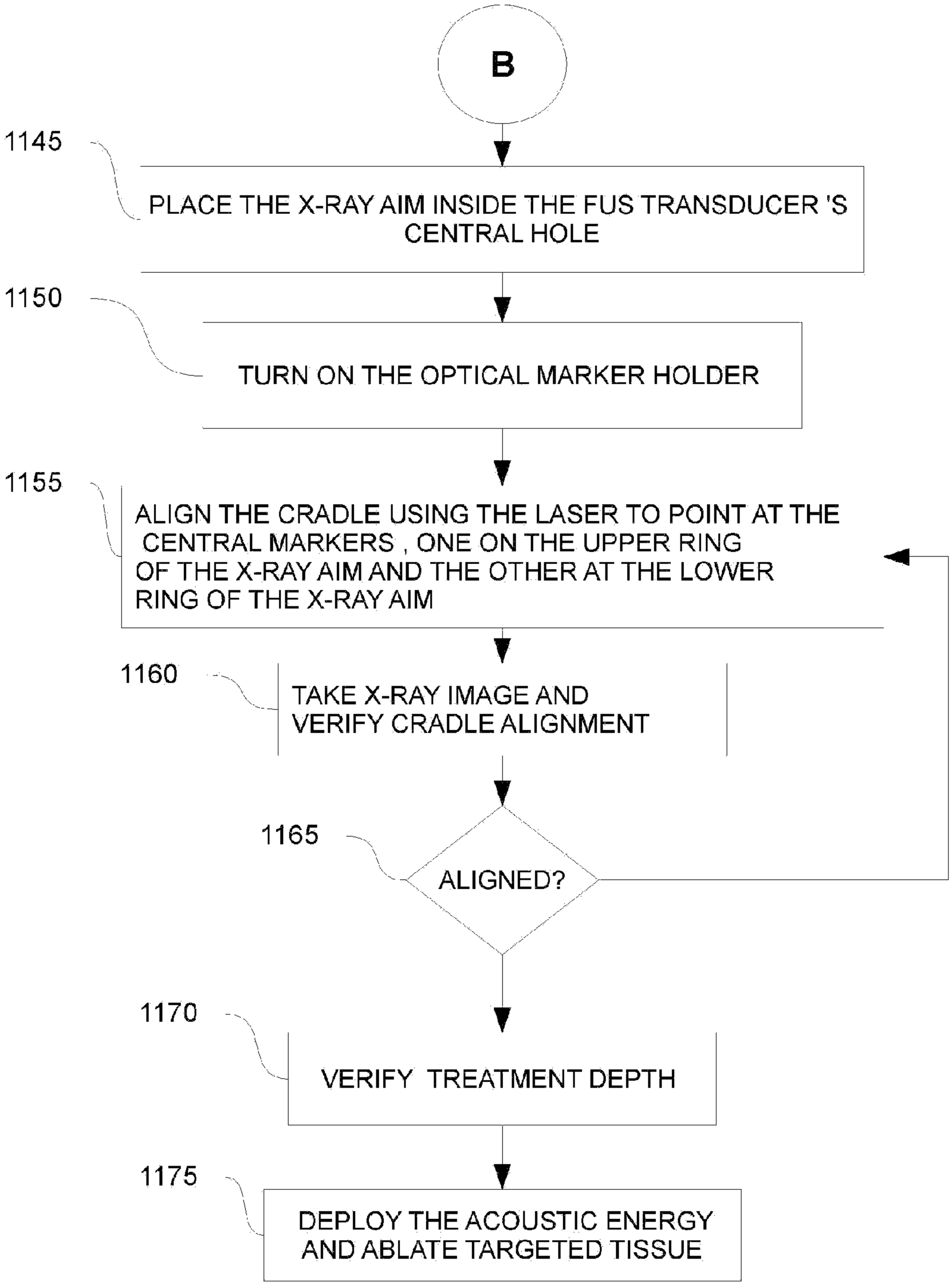

B
1145
PLACE THE X-RAY AIM INSIDE THE FUS TRANSDUCER 'S CENTRAL HOLE
1150
TURN ON THE OPTICAL MARKER HOLDER
1155
ALIGN THE CRADLE USING THE LASER TO POINT AT THE CENTRAL MARKERS , ONE ON THE UPPER RING OF THE X-RAY AIM AND THE OTHER AT THE LOWER RING OF THE X-RAY AIM
1160
TAKE X-RAY IMAGE AND VERIFY CRADLE ALIGNMENT
1165
ALIGNED?
1170
VERIFY TREATMENT DEPTH
1175
DEPLOY THE ACOUSTIC ENERGY AND ABLATE TARGETED TISSUE

FIGURE 11B

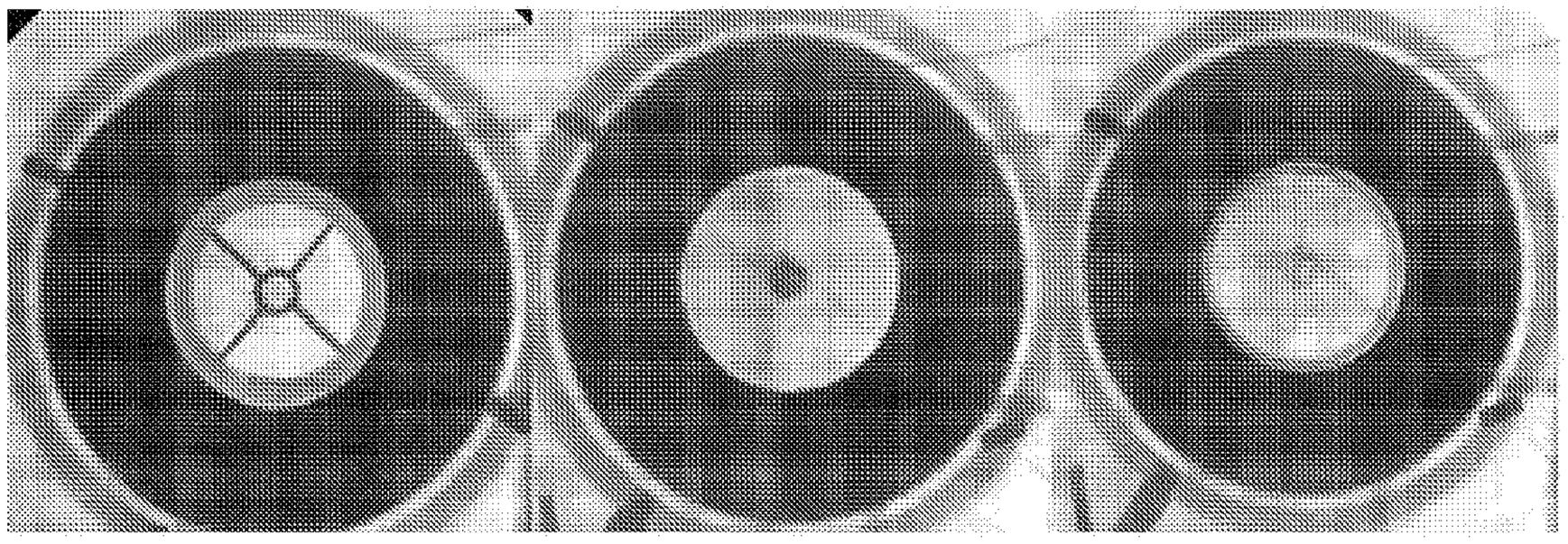
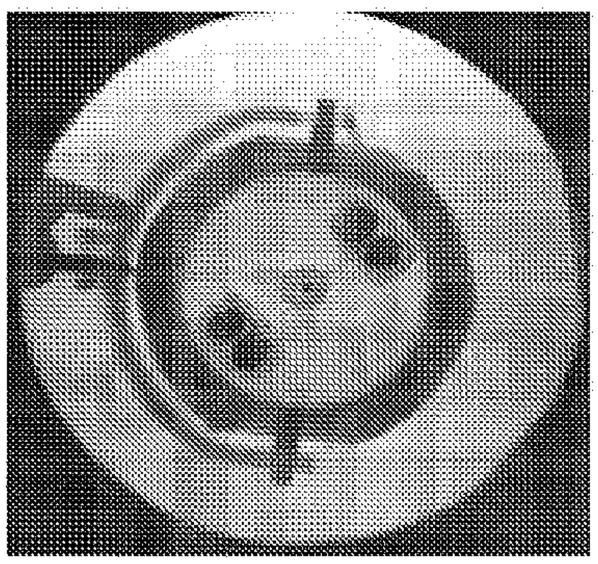


FIGURE 12A FIGURE 12B FIGURE 12C



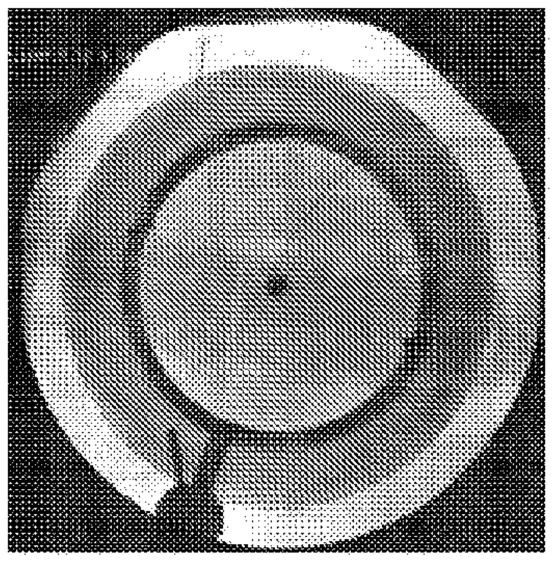


FIGURE 12D FIGURE 12E

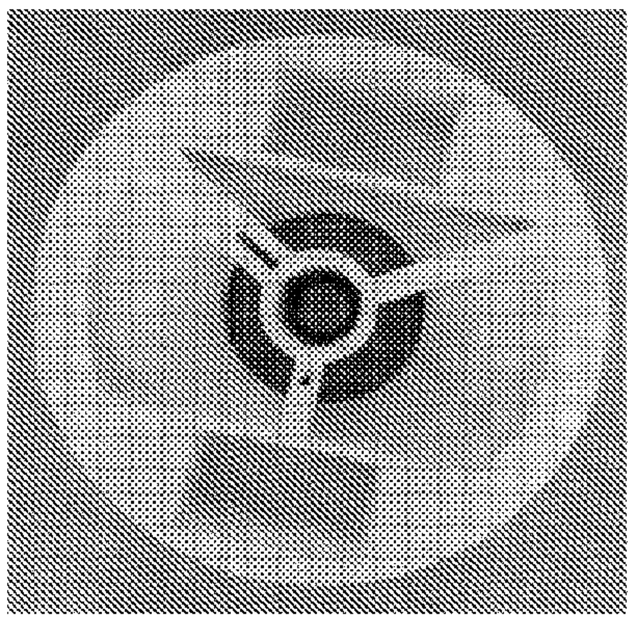


FIGURE 12F

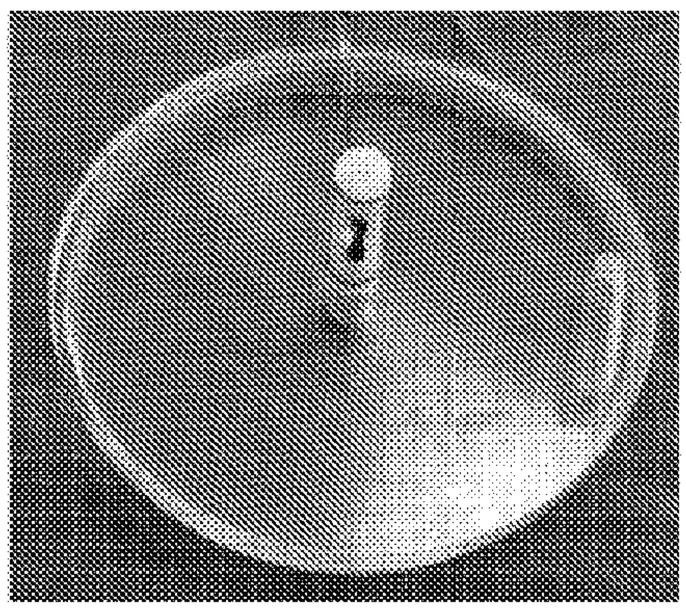


FIGURE 12G

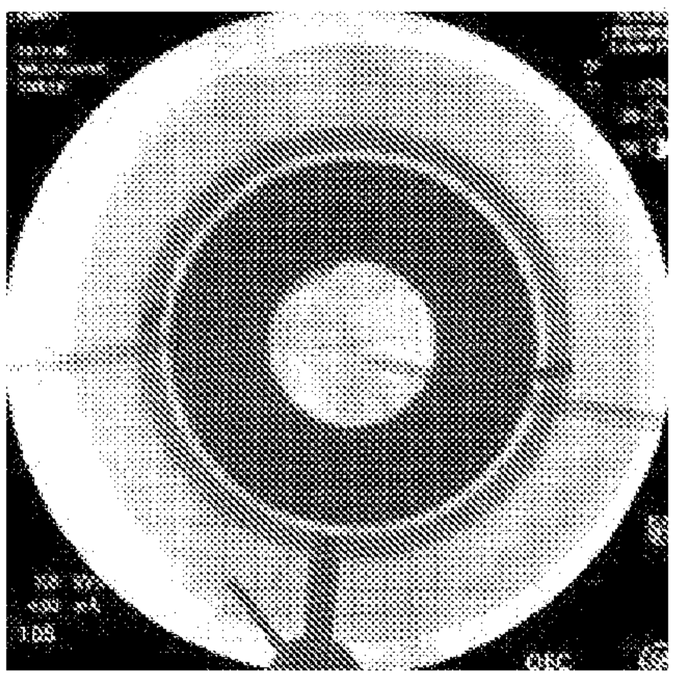


FIGURE 12H

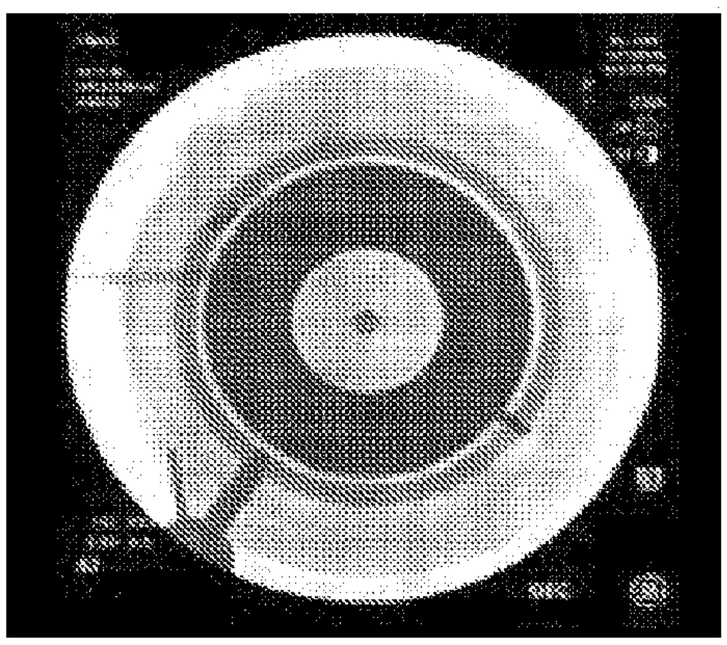


FIGURE 13A

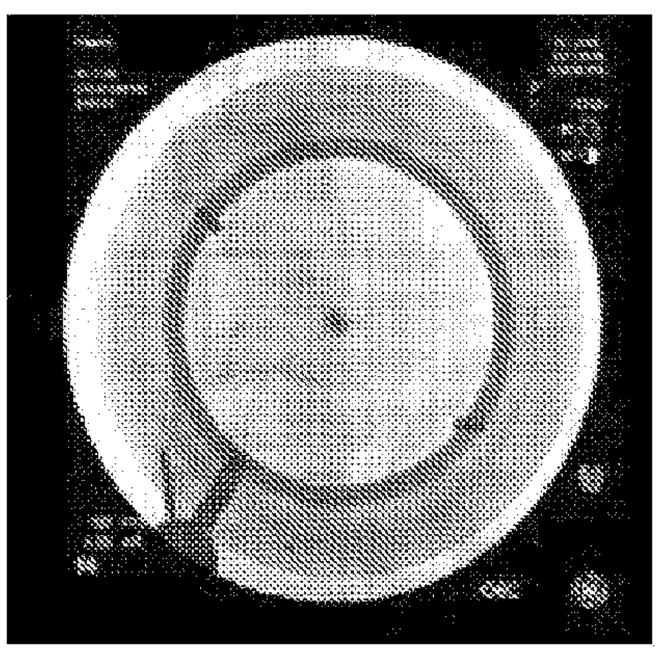


FIGURE 13B

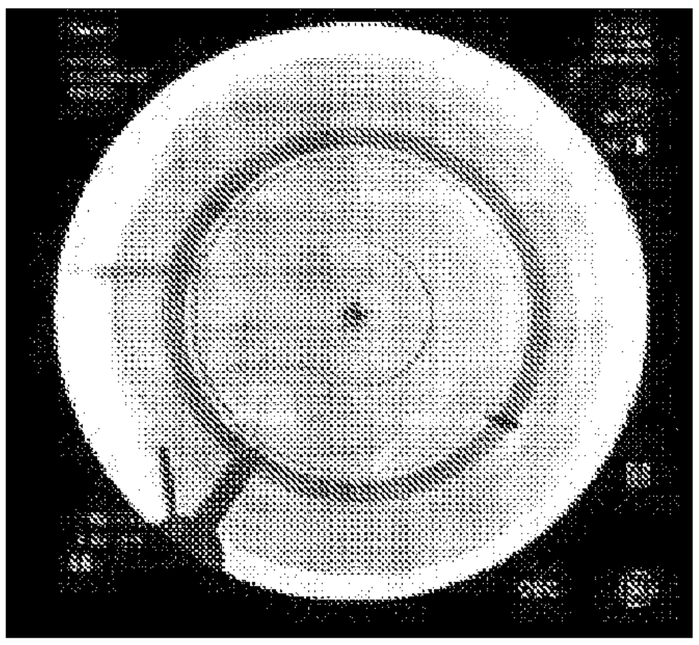


FIGURE 13C

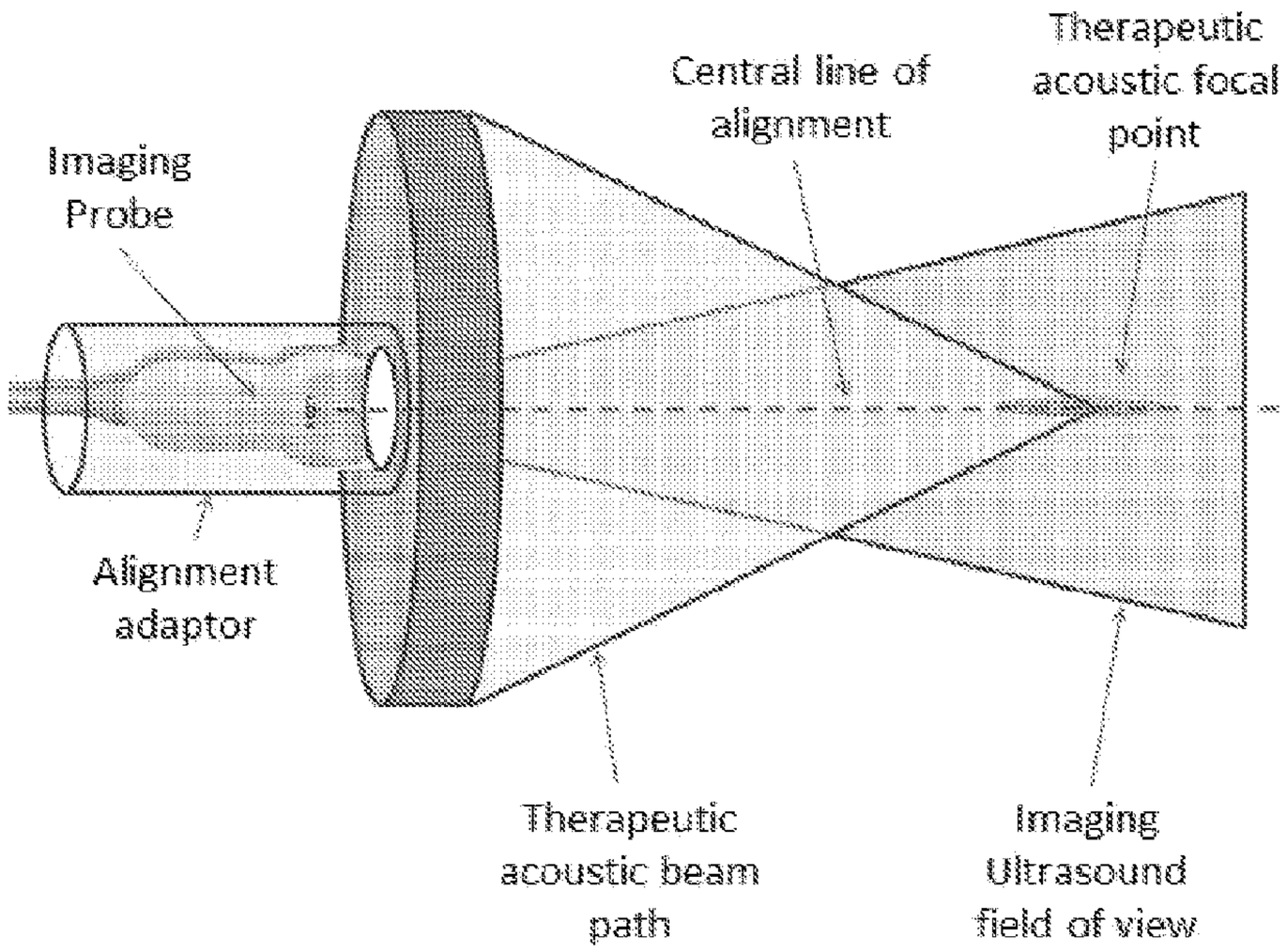


FIGURE 14A

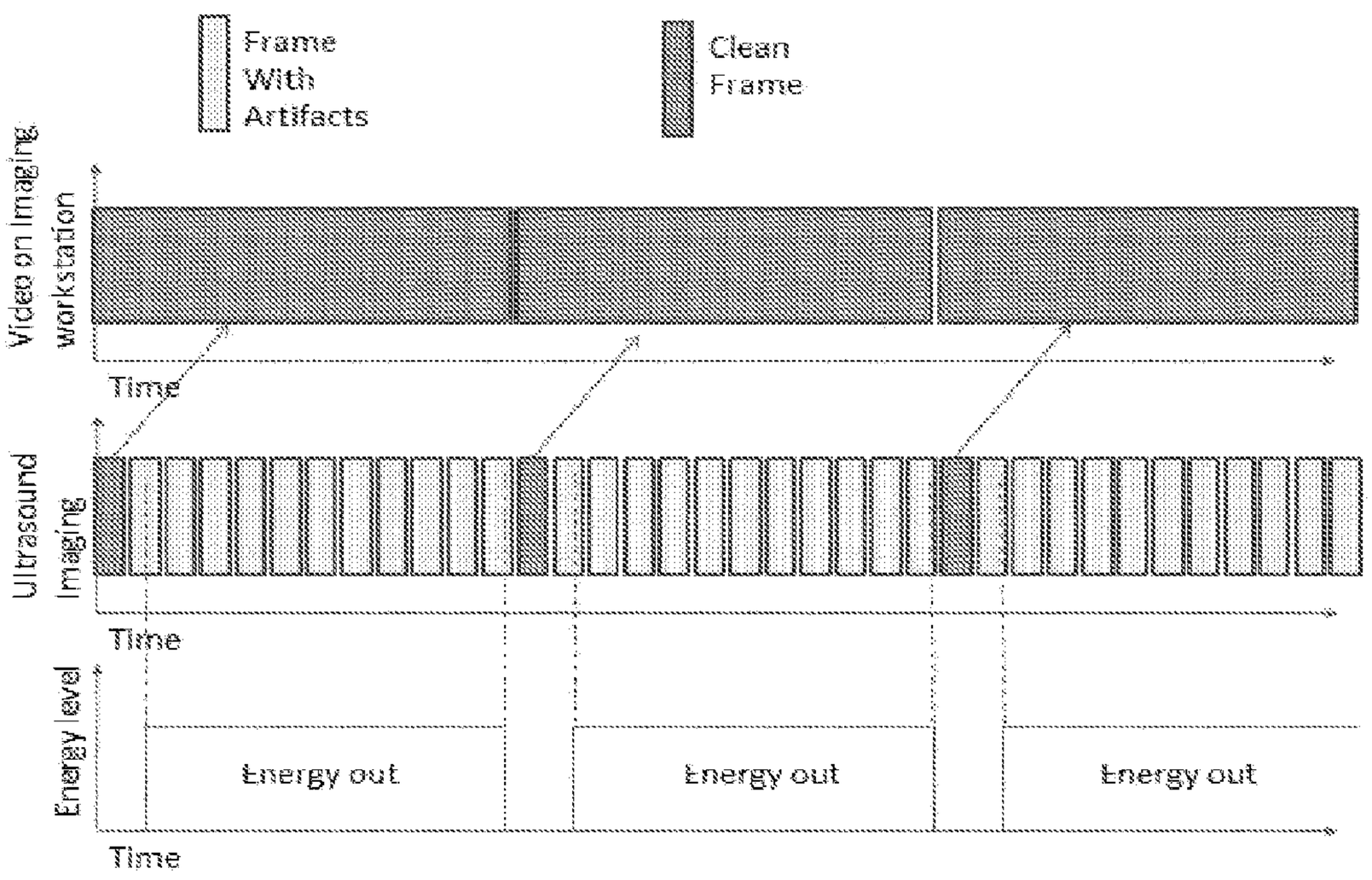


FIGURE 14B