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(54) **IMAGE GUIDED FOCUSED ULTRASOUND TREATMENT DEVICE AND AIMING APPARATUS**

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

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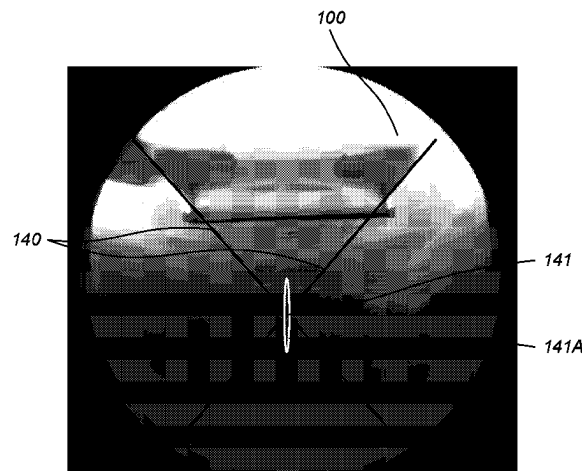
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(57) **ABSTRACT**

Apparatus, methods and kits are provided for X-ray guided
focused ultrasound treatment that simplify focused ultra-
sound treatment. The apparatus comprises an arm, a cradle,
a focused ultrasound (FUS) transducer having a central axis
that is affixed in to the cradle and configured to transmit an
ultrasound therapeutic energy beam to a treatment location
within a patient and an imaging workstation connected to an

(Continued)



X-ray imaging unit. The FUS is further connected to a controller to control application of the FUS. The kits are utilizing coupling member (s).

13 Claims, 19 Drawing Sheets

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- (52) **U.S. Cl.**
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 See application file for complete search history.

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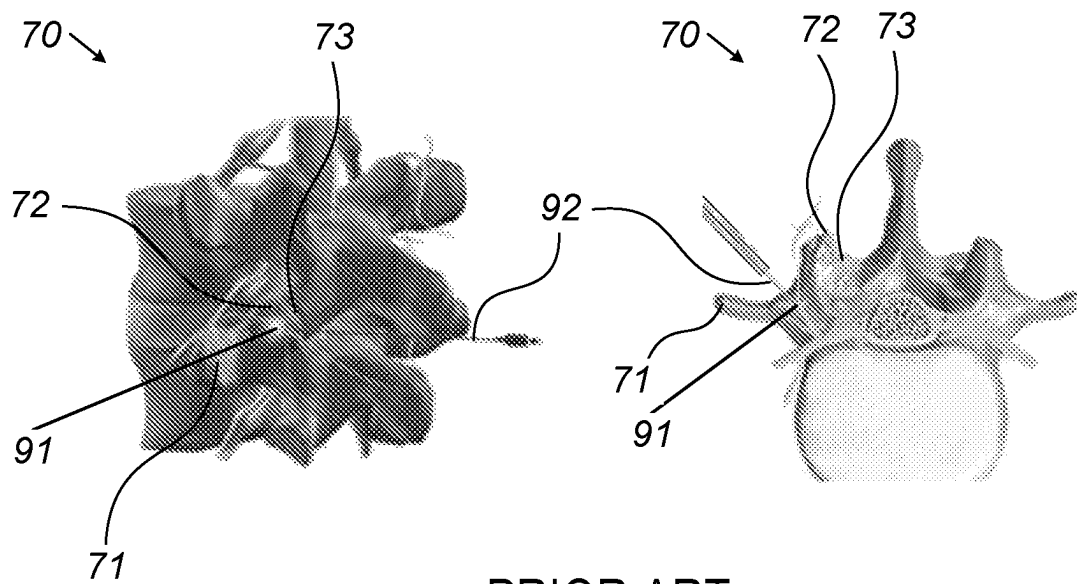
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PRIOR ART

FIGURE 1

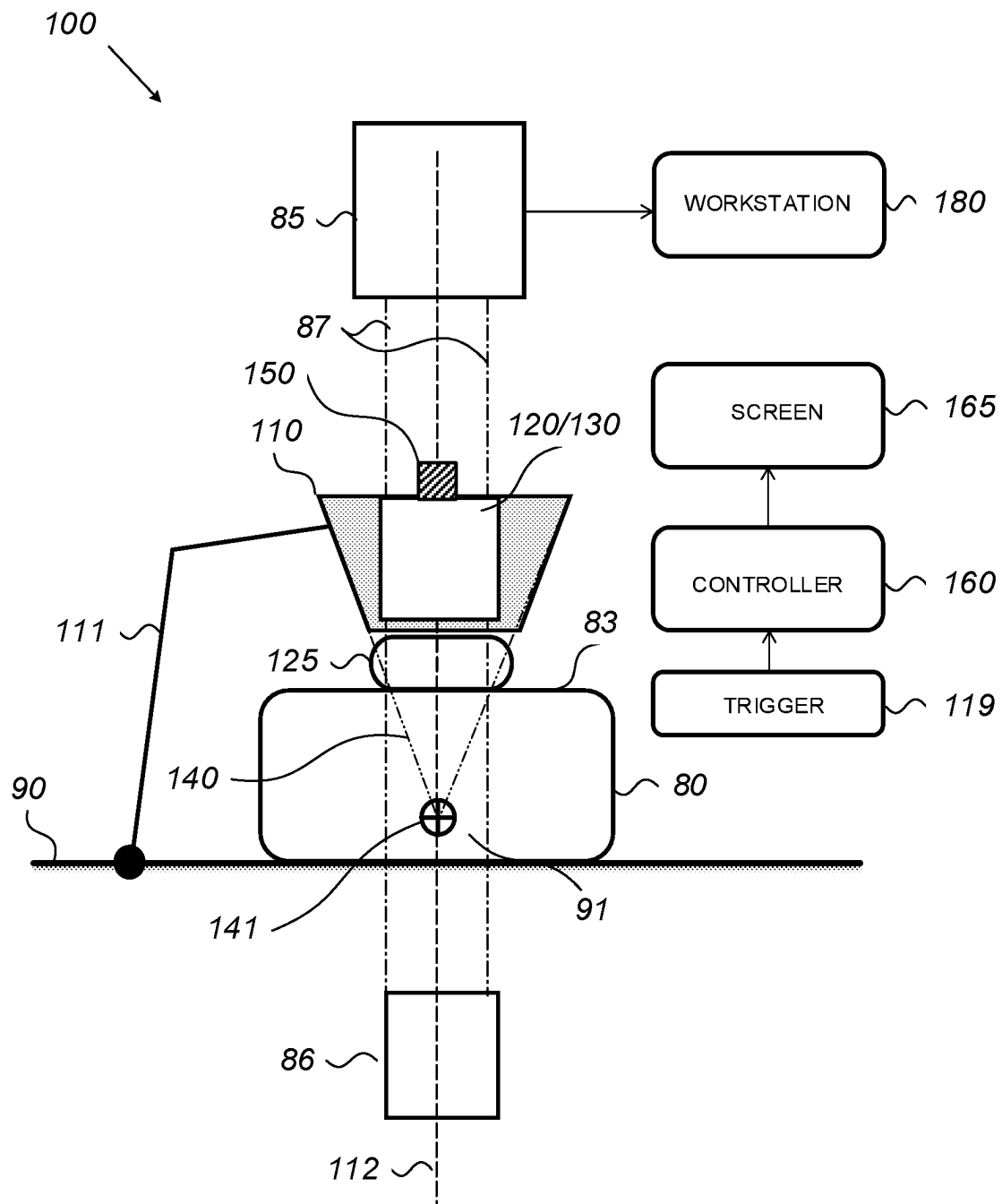


FIGURE 2

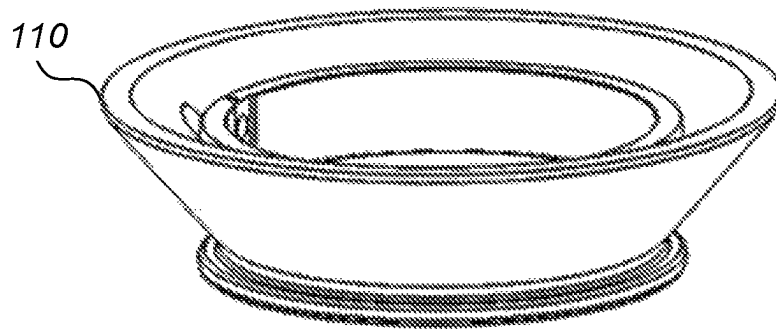


FIGURE 3A

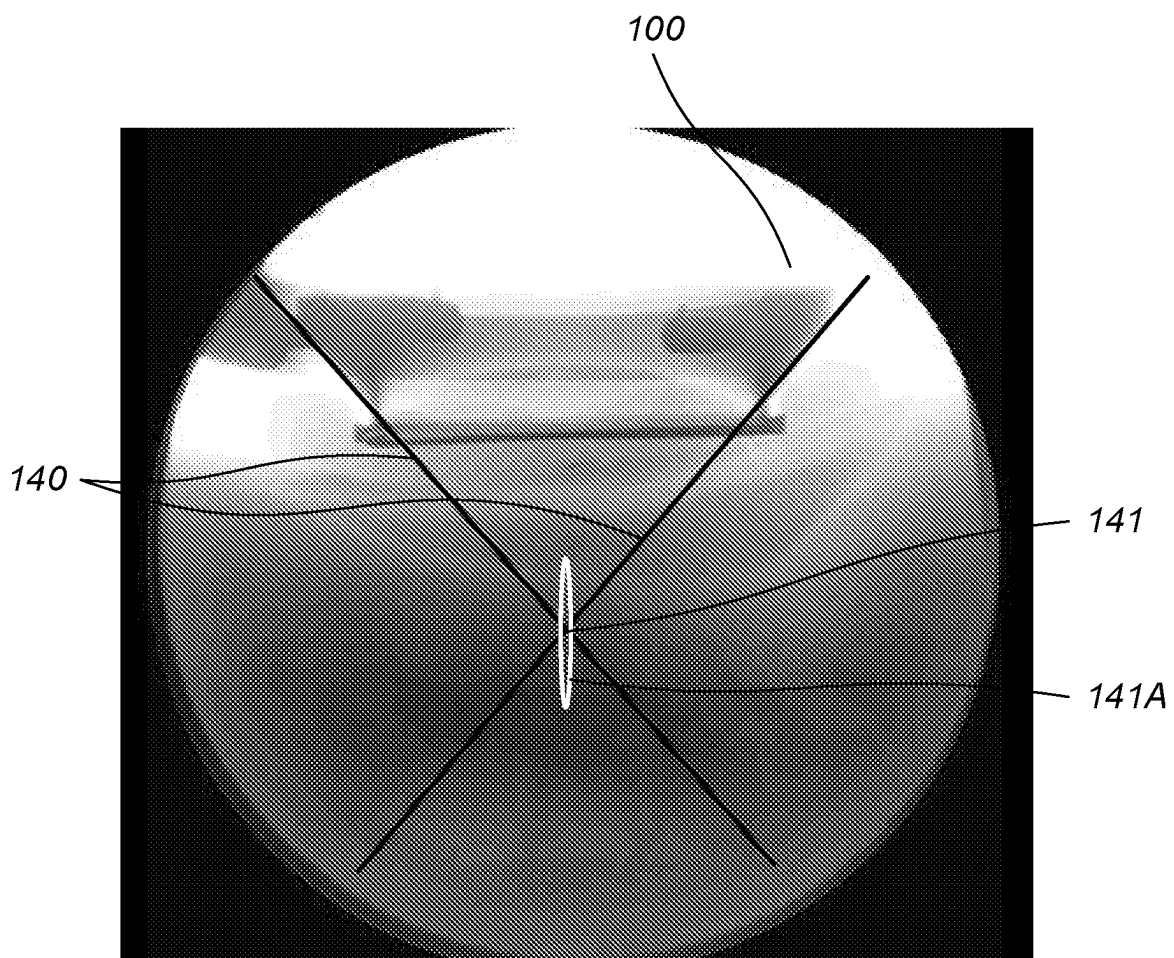


FIGURE 3B

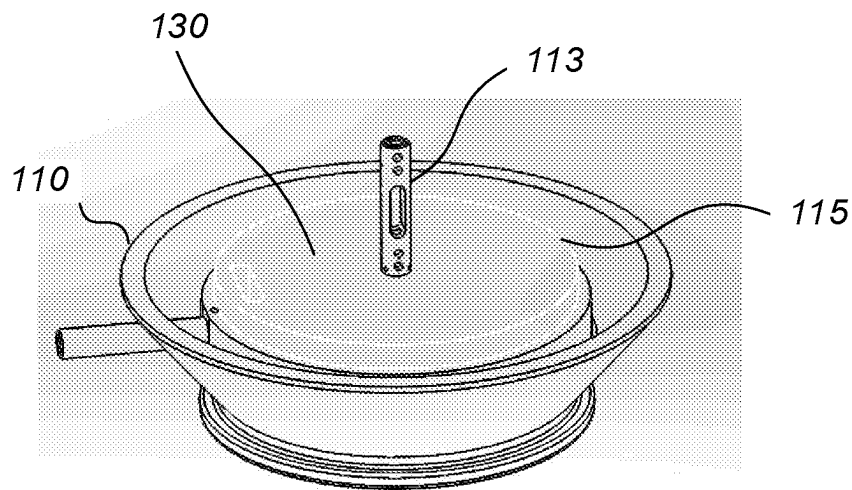


FIGURE 4A

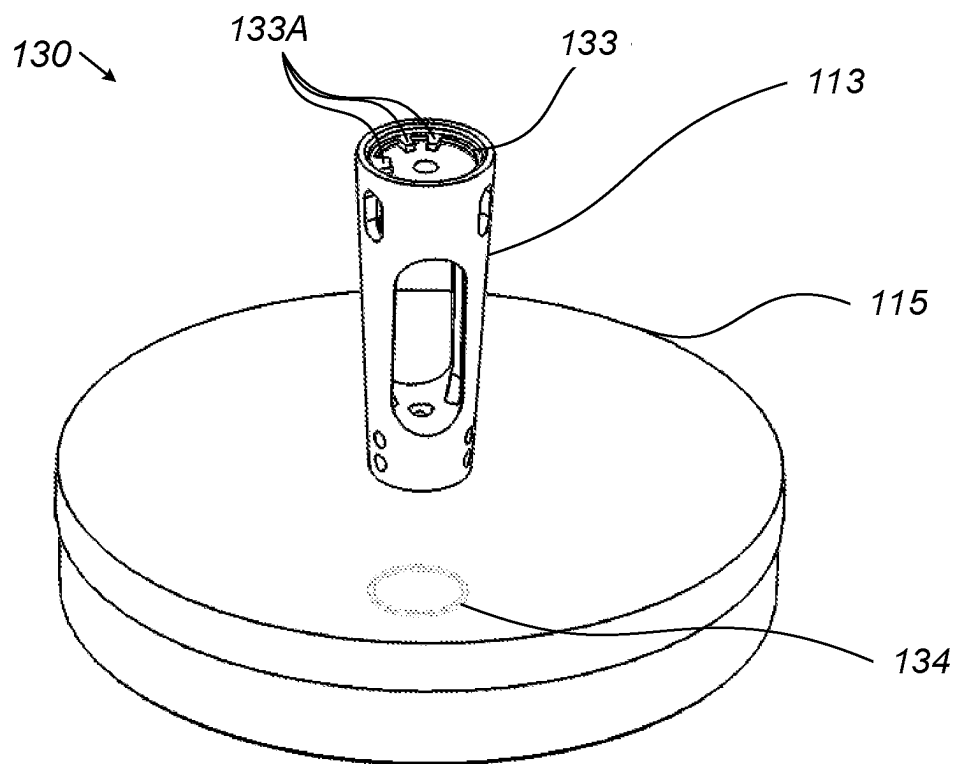


FIGURE 4B

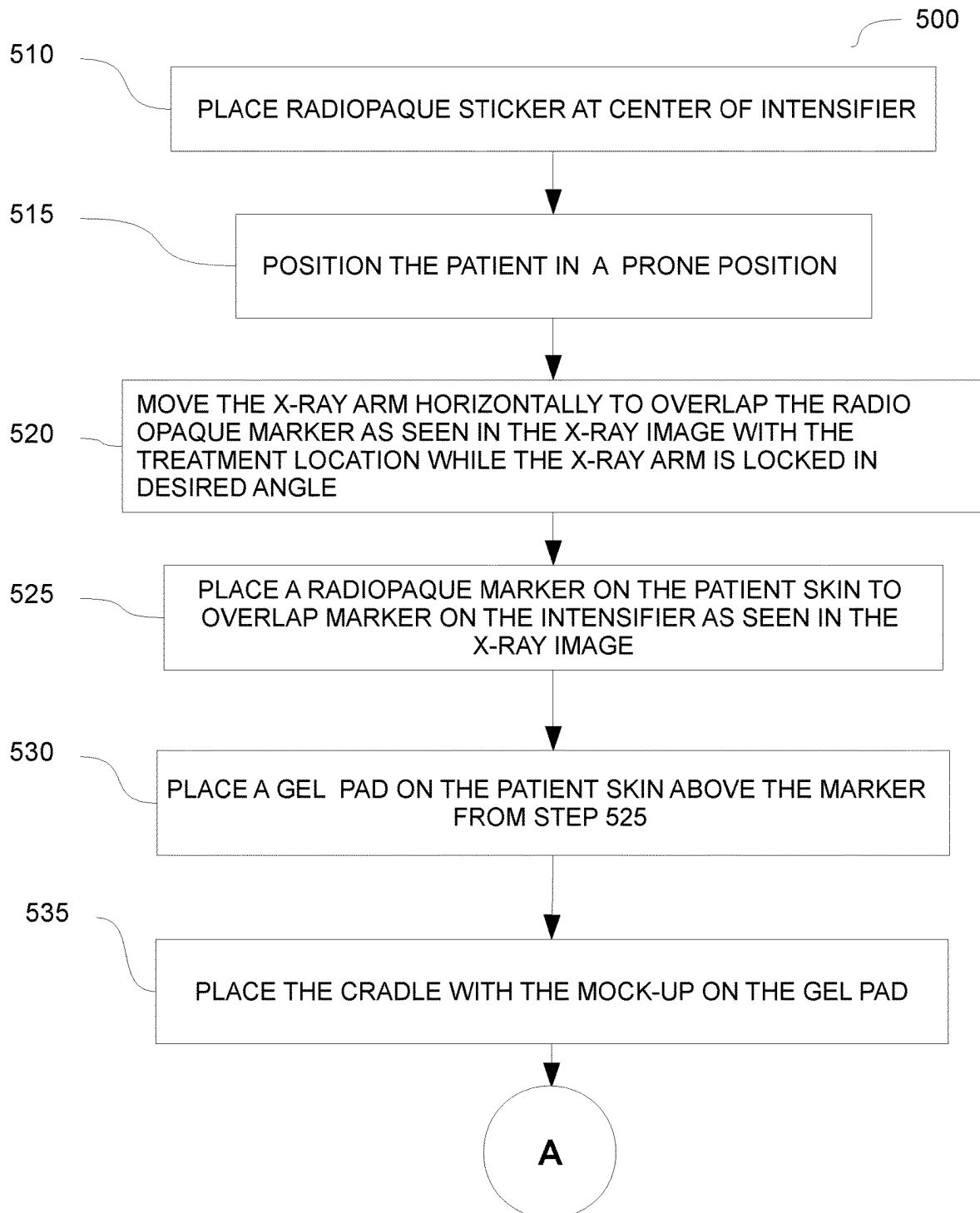


FIGURE 5A

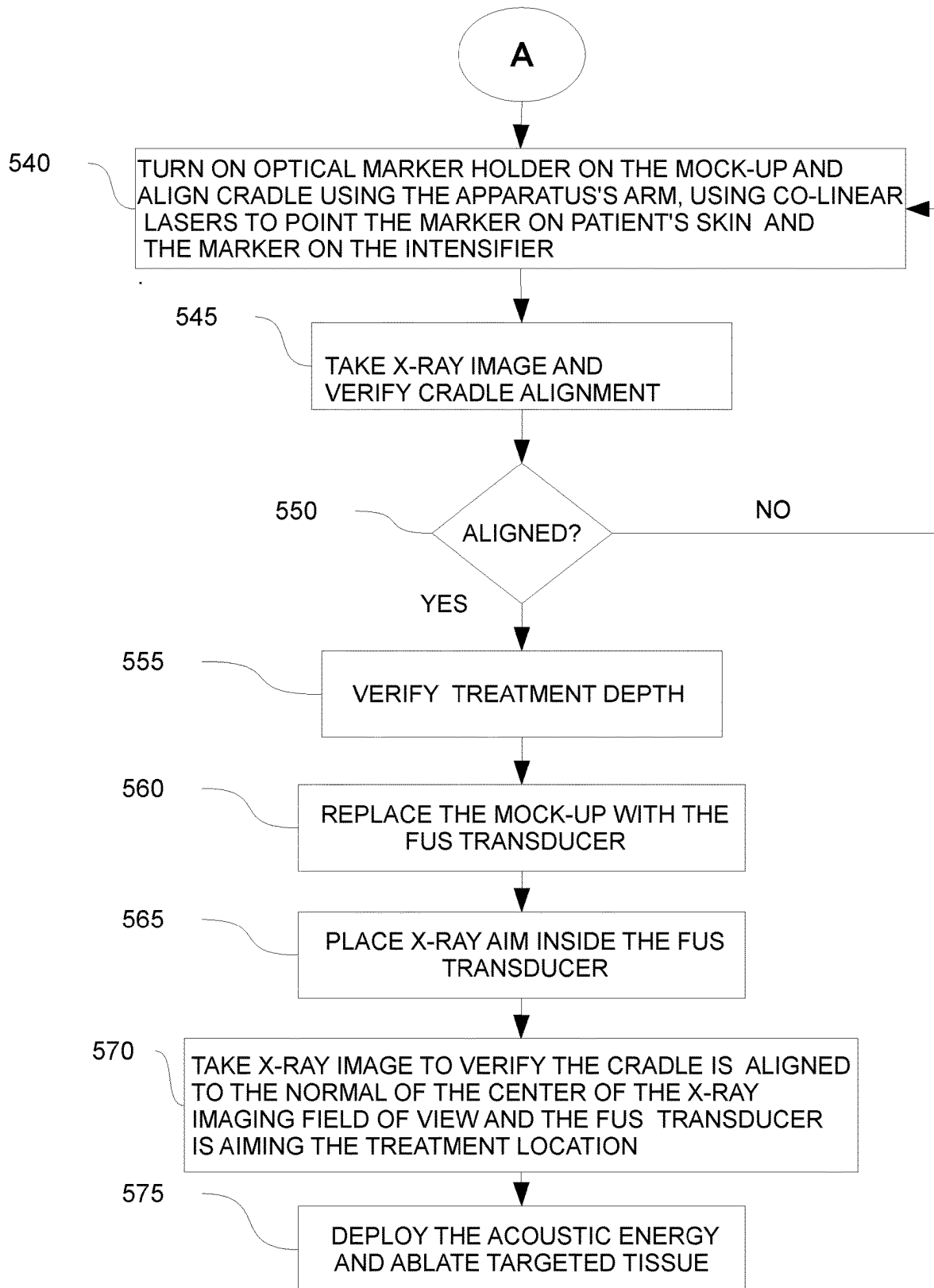


FIGURE 5B

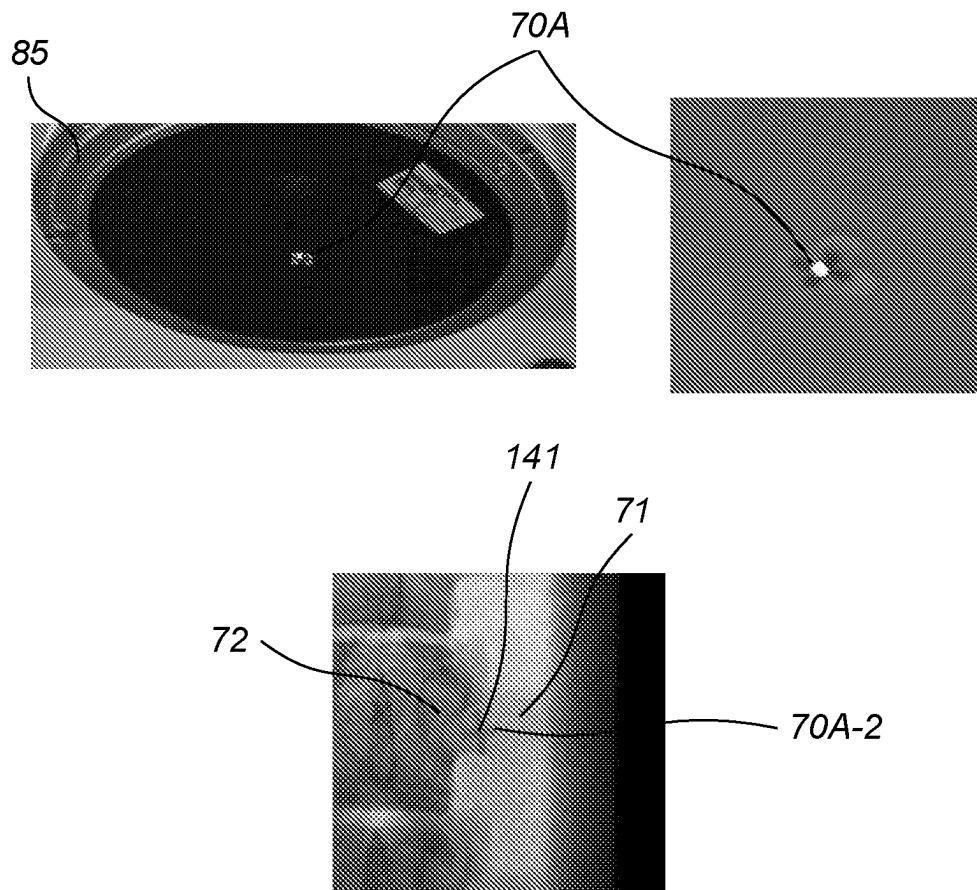


FIGURE 6A

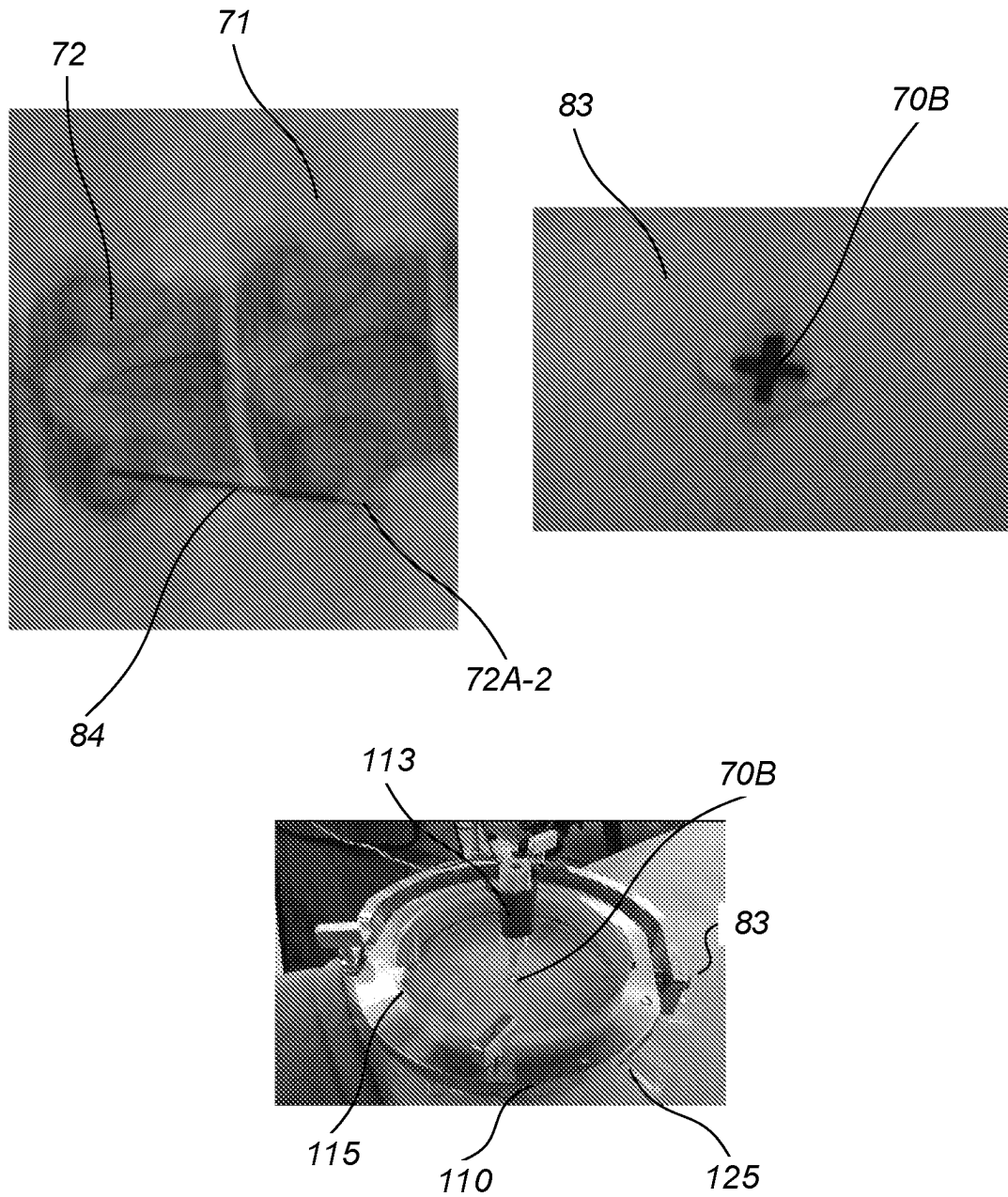


FIGURE 6B

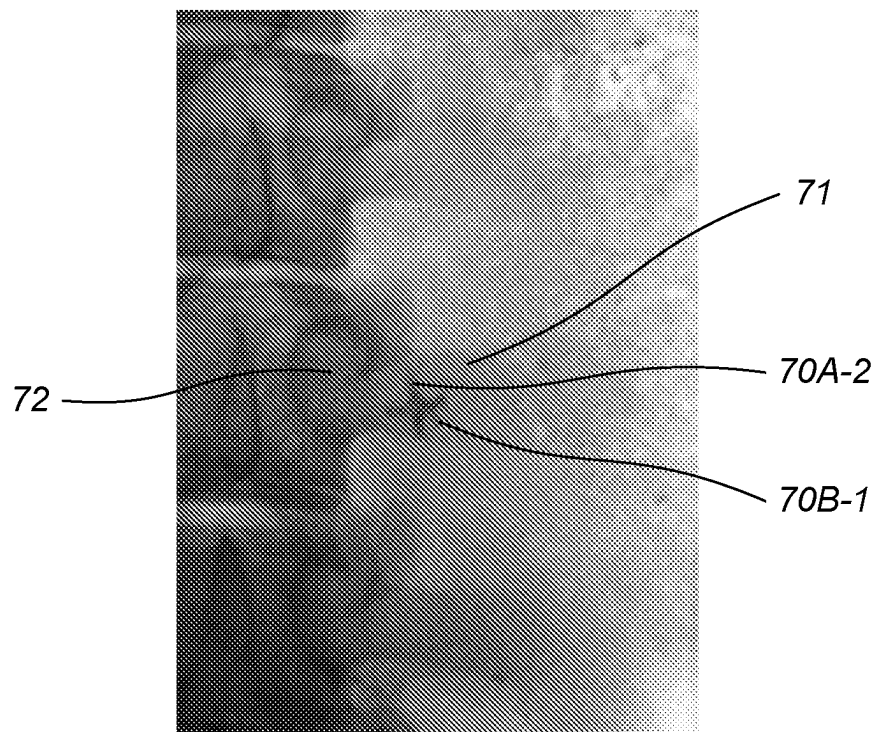


FIGURE 6C

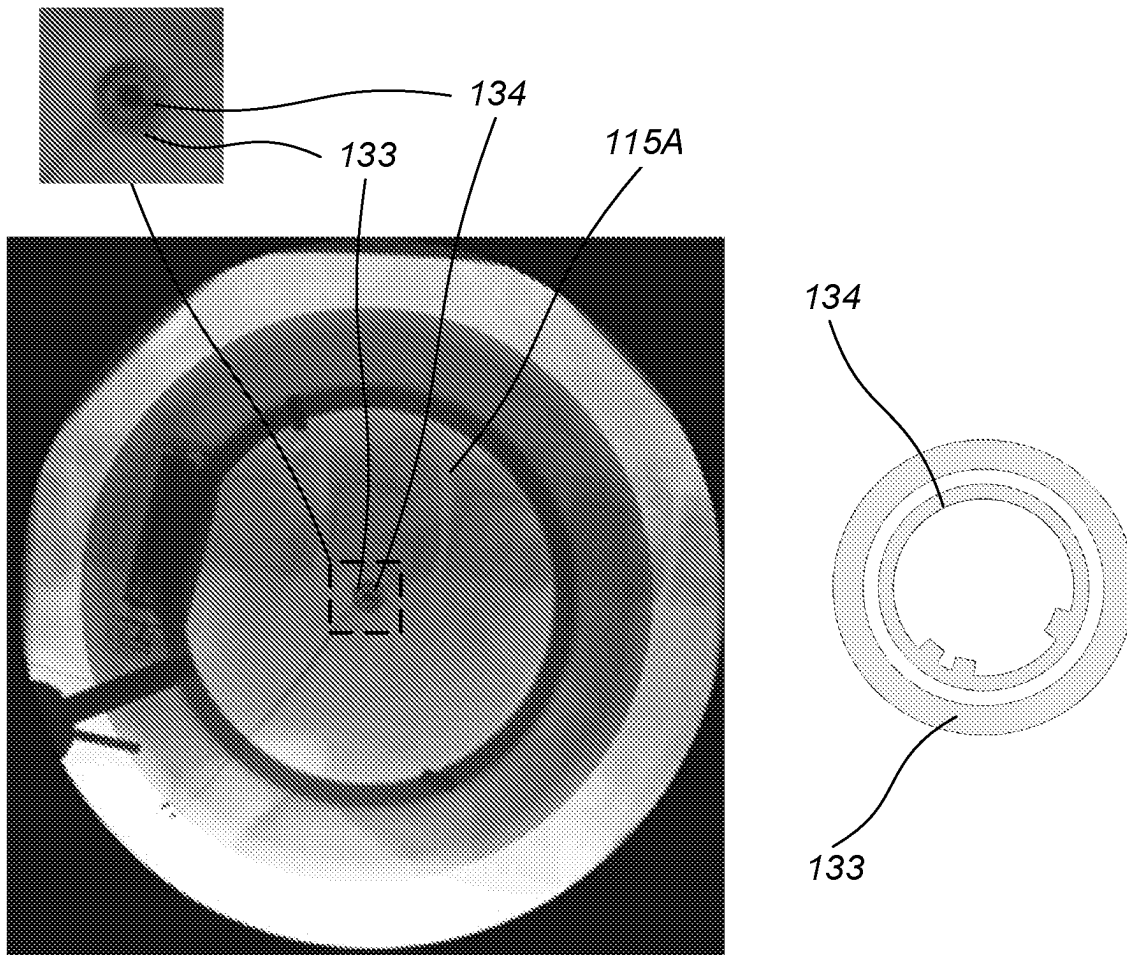


FIGURE 7A

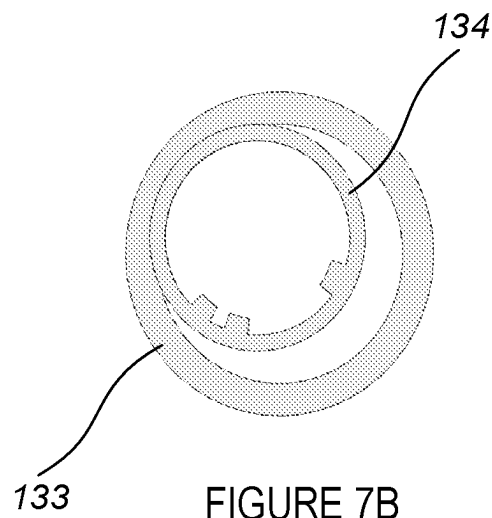


FIGURE 7B

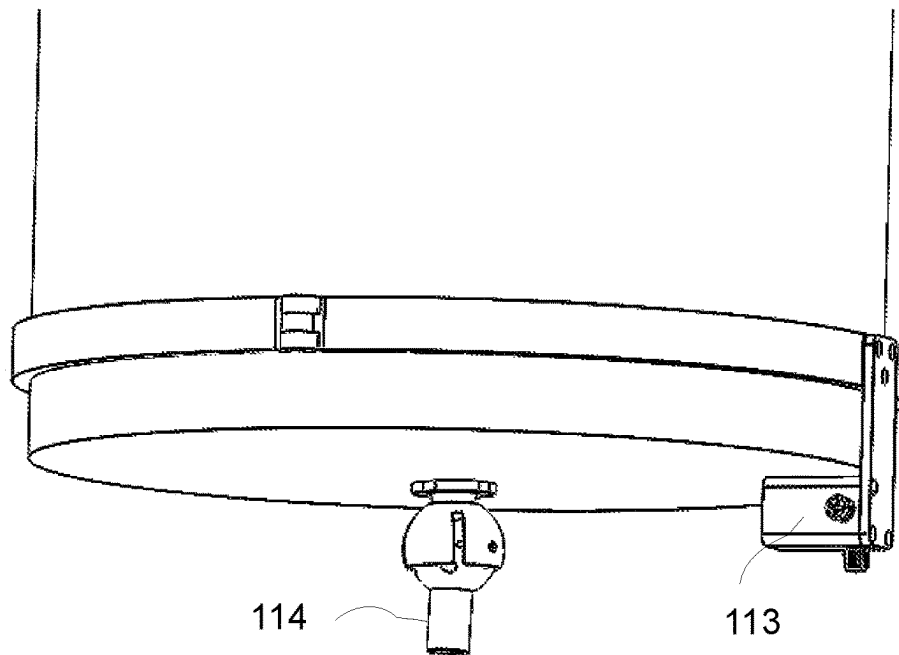


FIGURE 8A

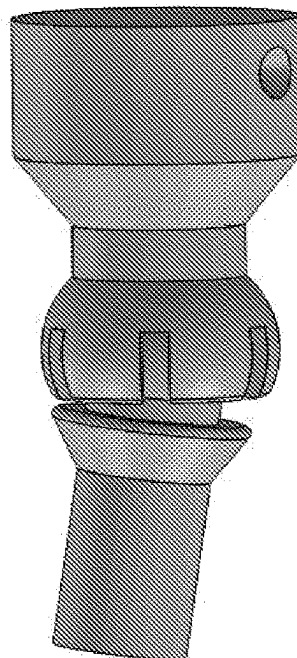


FIGURE 8B

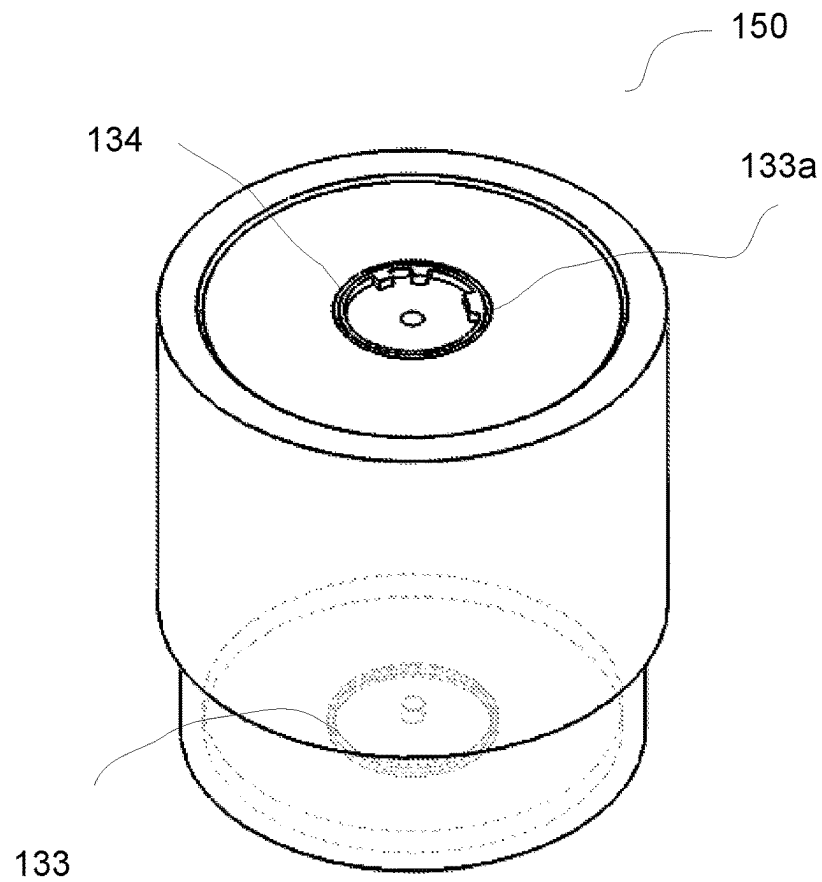


FIGURE 9A

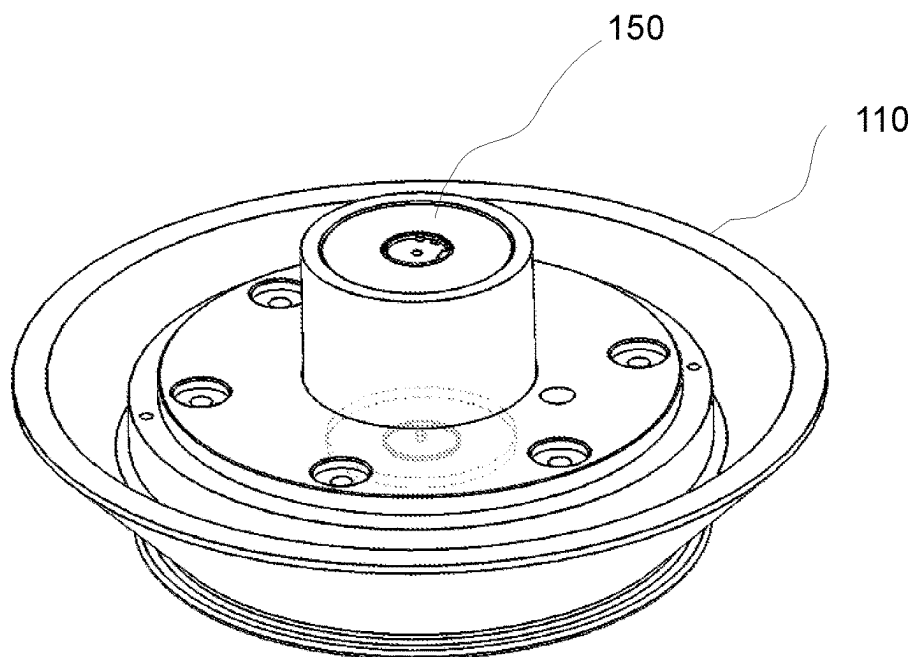


FIGURE 9B

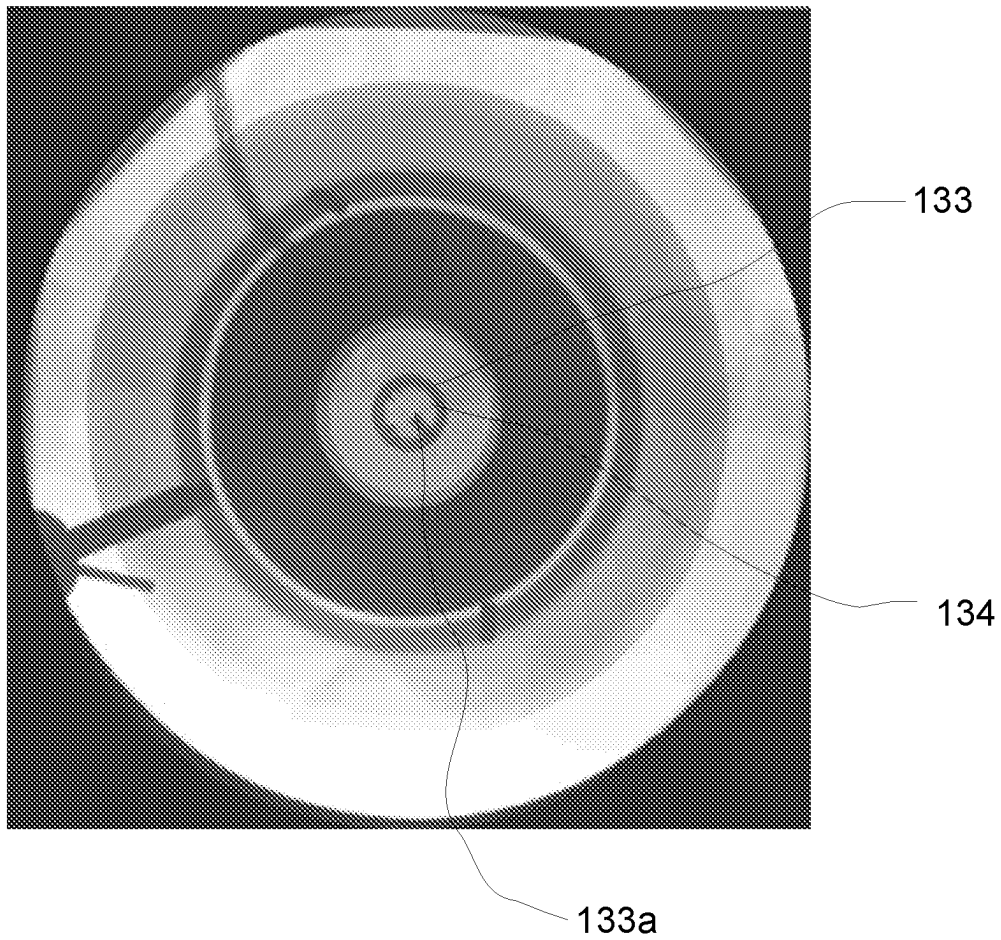


FIGURE 10

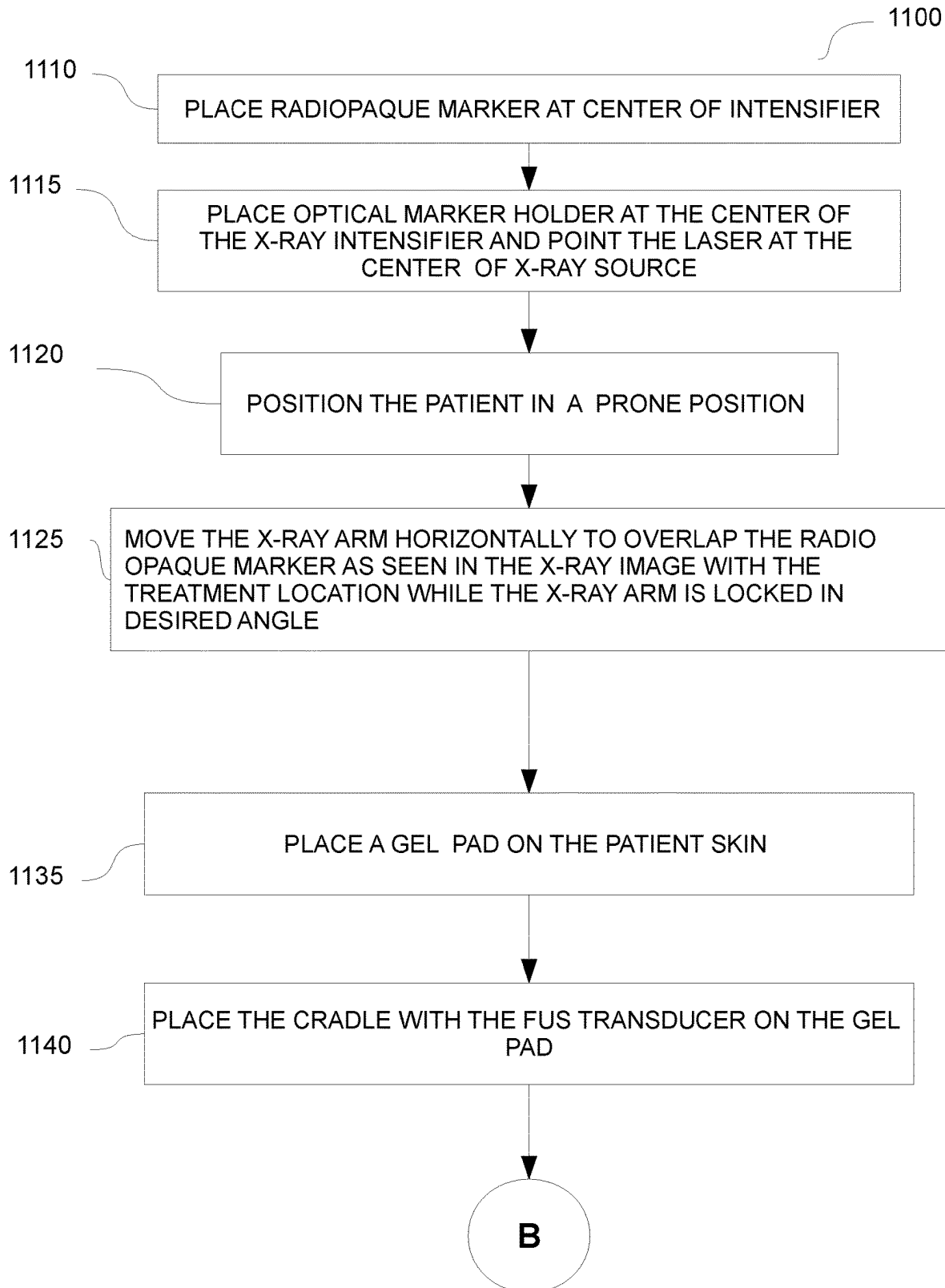


FIGURE 11A

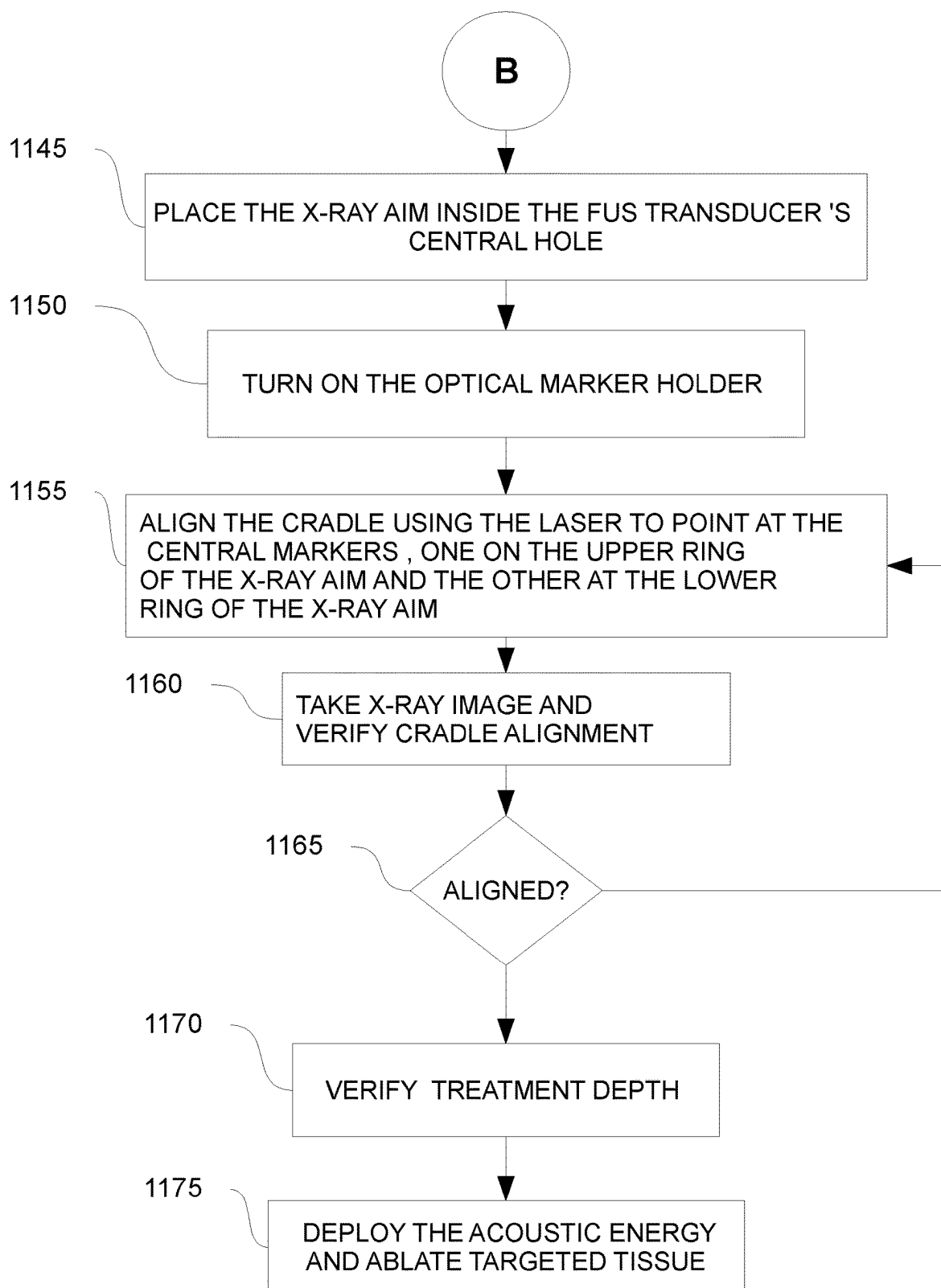


FIGURE 11B

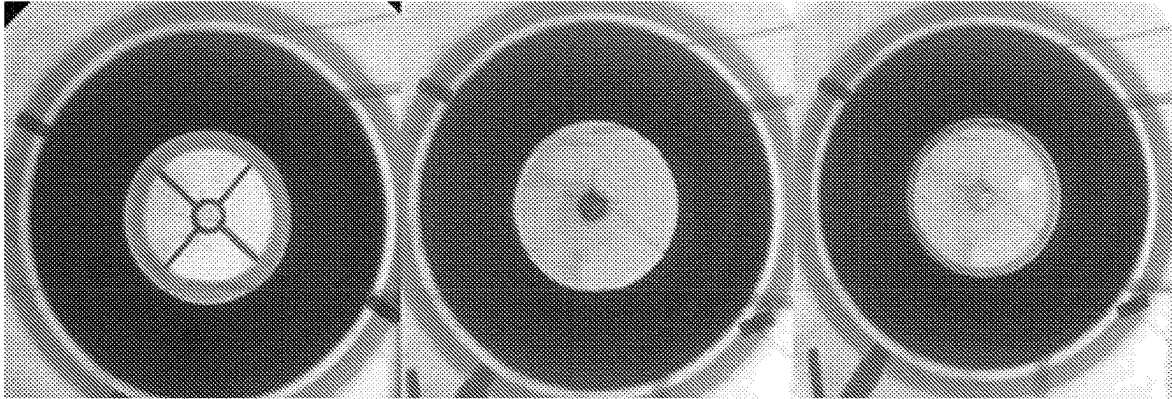


FIGURE 12A

FIGURE 12B

FIGURE 12C

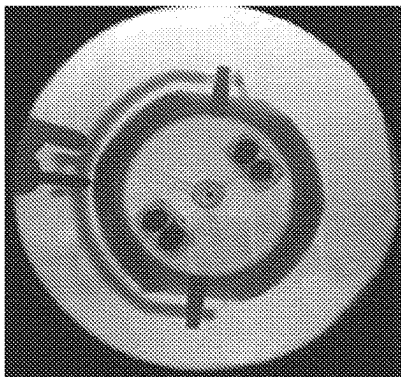


FIGURE 12D

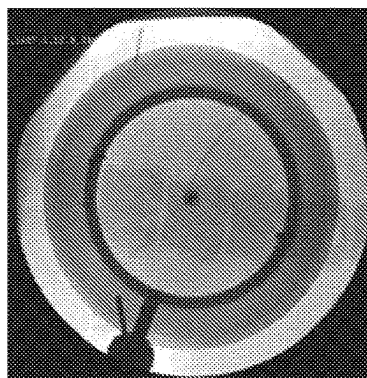


FIGURE 12E

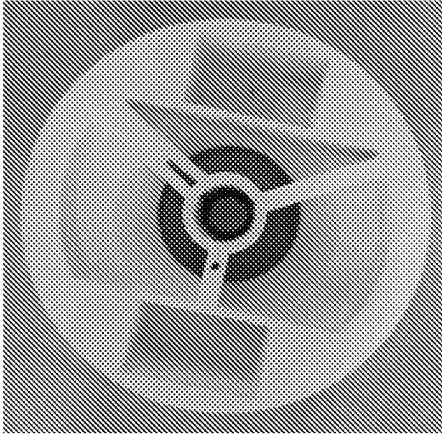


FIGURE 12F

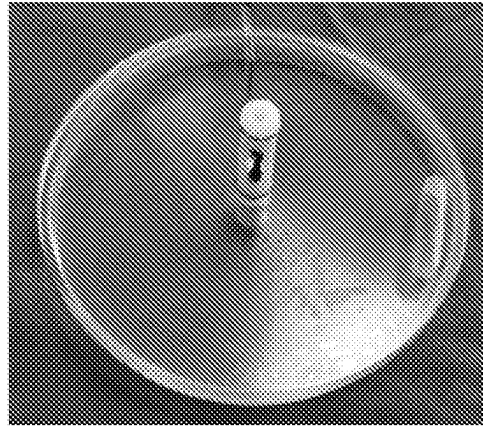


FIGURE 12G

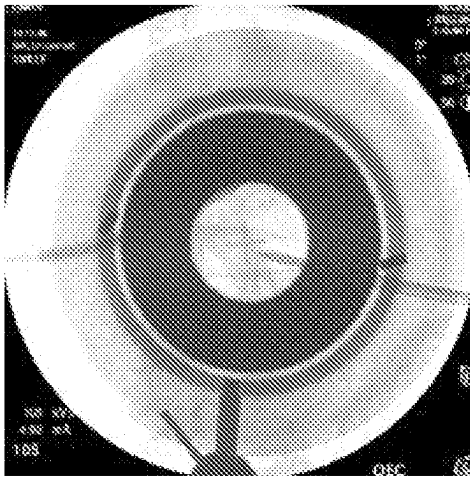


FIGURE 12H



FIGURE 13A

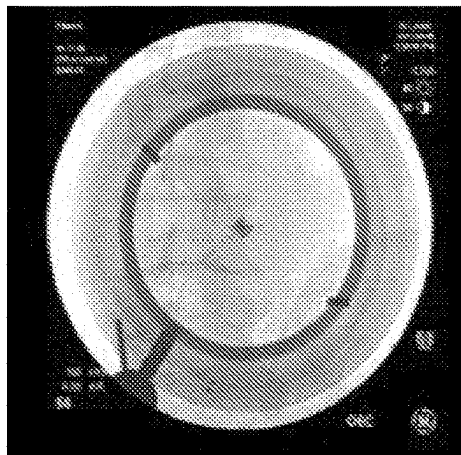


FIGURE 13B

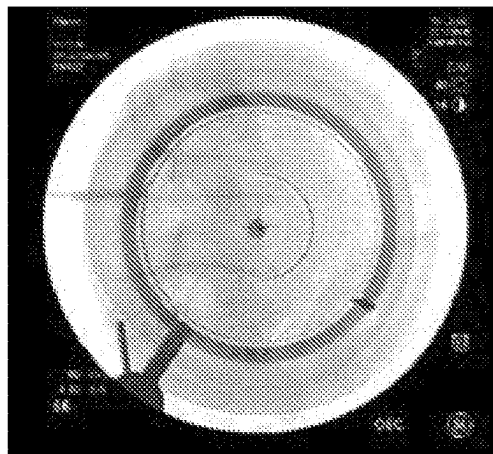


FIGURE 13C

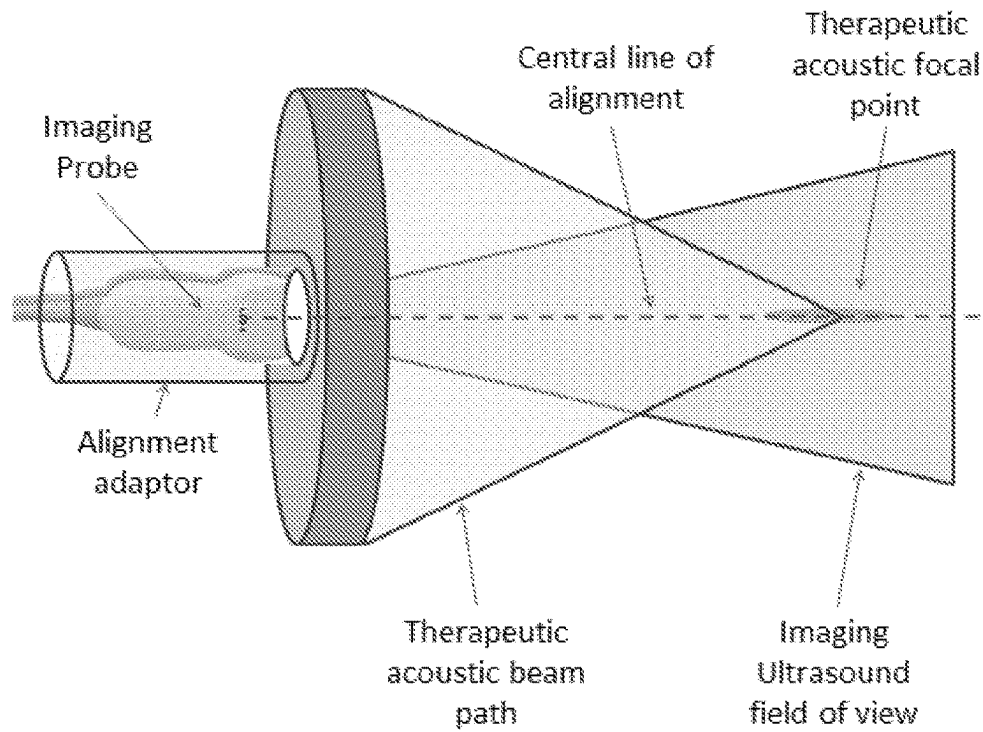


FIGURE 14A

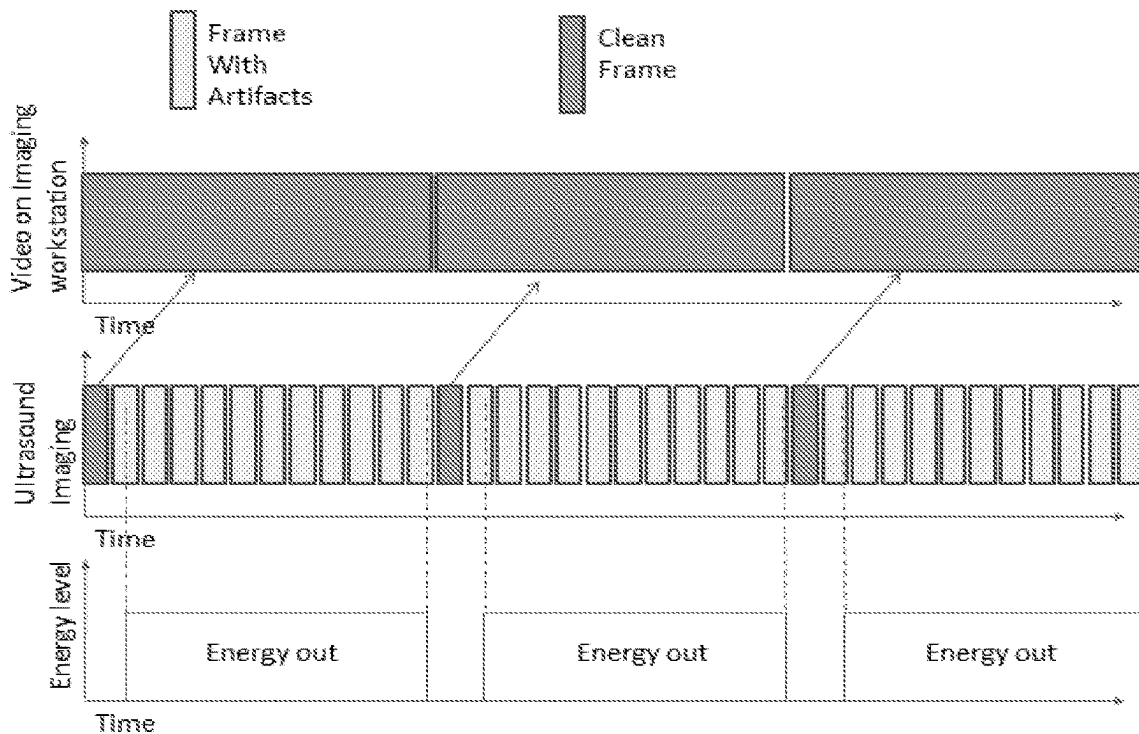


FIGURE 14B

1

IMAGE GUIDED FOCUSED ULTRASOUND TREATMENT DEVICE AND AIMING APPARATUS

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a National Phase Application of PCT International Application No. PCT/US16/46328, International Filing Date Aug. 10, 2016, claiming priority of U.S. Patent Applications Nos. 62/203,114, filed Aug. 10, 2015, 62/238,263, filed Oct. 7, 2015, and 62/333,896, filed May 10, 2016, which are hereby incorporated by reference.

BACKGROUND OF THE INVENTION

1. Technical Field

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

2. Discussion of Related Art

FIG. 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.

SUMMARY OF THE INVENTION

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.

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 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.

These, additional, and/or other aspects and/or advantages of the present invention are set forth in the detailed descrip-

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tion which follows; possibly inferable from the detailed description; and/or learnable by practice of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

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.

In the accompanying drawings:

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

FIG. 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.

FIGS. 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.

FIG. 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.

FIGS. 5A-5B is a high level flowchart illustrating a method, according to some embodiments of the invention.

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

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

FIGS. 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.

FIGS. 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.

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

FIGS. 11A-11B is a high level flowchart illustrating another method, according to some embodiments of the invention.

FIGS. 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.

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

FIG. 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

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.

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. The invention is applicable to other embodiments that may be practiced or carried out in various ways as well as to combinations of the disclosed embodiments. 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.

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.

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.

FIG. 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.

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-inferior (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.

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.

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.

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-inferior (S-I), 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 pre-defined orientation and position of cradle 110.

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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**.

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.

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**.

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.

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

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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.

FIG. 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 FIG. 3B. FIG. 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.

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.

FIG. **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**.

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**.

FIG. **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**.

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**.

FIGS. **5A-5B** is a high level flowchart illustrating a method, according to some embodiments of the invention. At step **510**, at least one radio opaque marker is placed at center of X-ray intensifier **85** (see, e.g., **70A** in FIG. **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.

At step **520**, X-Ray arm **87** (see, e.g., FIG. **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 FIG. **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., FIG. **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.

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., FIG. **6B**).

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., FIG. **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., FIG. **7A**). If x-ray aiming markers **133**, **134** are not seem concentric in the X-Ray image from step **545** (see, e.g., FIG. **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.

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. Complimentary 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.

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., FIG. 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.

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.

FIG. 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 origi-

nating 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.

The optical marker holder **113** (FIG. 8A) or a mirror **114** (FIG. 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 (FIG. 2) by projecting a laser beam to the center of the C Arm source **86** (FIG. 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 FIG. 8A the mirror **114** has an angular alignment capability while the optical marker **113** can be adjusted to aim the center of this mirror.

FIG. 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.

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 (FIG. 7A, FIG. 10). If the rings do not seem concentric in the image (FIG. 7B) or the physician identifies movement, the physician shall repeat the positioning procedure.

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 (FIG. 7A-7B), which must remain visible around the inner ring **133** to indicate alignment within the error limits.

Reference is now made to FIGS. 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.

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.

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.

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 FIG. 6A). In certain embodiments, X-Ray intensifier **85** may be positioned in an angle to the treatment

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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 **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**.

At step **1150**, the at least one optical marker holder (FIGS. **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** (FIG. **9A**). In case the aiming markers **133**, **134** appear concentric in the X-ray image, the cradle is aligned (FIG. **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 (FIG. **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.

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**).

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.

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. FIGS. **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 FIG. **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.

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 FIG. **12D** shows a design with many artifacts, and where FIG. **12E** shows a clear design which is also optically transparent, as can be seen in FIGS. **12F-12G**.

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 FIGS. **12H-12G**.

FIGS. **13A-13C** are high level schematic illustrations of x-ray images of the treatment target with and without the

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FUS transducer in the cradle respectively, according to some embodiments of the invention. FIG. **13A** illustrate the A-P images of the FUS transducer as shown on the device workstation during the procedure.

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.

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. FIG. **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.

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 FIG. **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 it 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.

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. Although various features of the invention may be described in the context of a single embodiment, the features may also be provided separately or in any suitable combination. Conversely, although the invention may be described herein in the context of separate embodiments for clarity, the invention may also be implemented in a single embodiment. Certain embodiments of the invention may include features from different embodiments disclosed above, and certain embodiments may incorporate elements from other embodiments disclosed above. The disclosure of elements of the invention in the context of a specific embodiment is not to be taken as limiting their use in the specific embodiment alone. Furthermore, it is to be

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understood that the invention can be carried out or practiced in various ways and that the invention can be implemented in certain embodiments other than the ones outlined in the description above.

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.

The invention claimed is:

1. An apparatus for a focused ultrasound (FUS) treatment operable in association with an X-Ray imaging system having an X-Ray intensifier, the apparatus comprising:

- a cradle having a conical shape;
- an aiming apparatus affixable within the cradle or affixable to the X-Ray intensifier;
- a FUS transducer comprising annular elements and operable to produce different geometric focal lengths, the FUS transducer affixable within the cradle and configured to transmit a FUS therapeutic energy beam to a treatment location, wherein an intersection point of projections of boundaries of the conical shape of the cradle corresponds to a focal point of the FUS transducer such that the conical shape of the cradle is configured to be used as a marker to guide a focusing of the FUS therapeutic energy beam to the treatment location;
- a controller coupled to the FUS transducer and configured to control the FUS therapeutic energy beam being transmitted by the FUS transducer; and
- an imaging workstation comprising a processing module, the processing module is configured to detect, over at least one lateral X-Ray image of the cradle, the projections of the boundaries of the conical shape of the cradle to thereby aid navigation of the FUS therapeutic energy beam to the treatment location.

2. The apparatus of claim 1, further comprising an articulated arm having a distal arm end affixed to the cradle, wherein the articulated arm is configured to enable at least one of:

- motion of the cradle in at least one of anterior-posterior (A-P), superior-inferior (S-I), and medial-lateral directions with respect to the procedure platform, and
- at least one of tilt, yaw, pitch and roll motions of the cradle with respect to the distal arm end, to thereby aim the FUS therapeutic energy beam onto the treatment location.

3. The apparatus of claim 1, wherein the imaging workstation comprises a screen, and wherein the processing module is configured to:

- receive at least one lateral X-Ray image of the cradle from the X-Ray imaging system;

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display, on the screen, the at least one lateral X-Ray image;

display, on the screen, over the at least one lateral X-Ray image, the projections of the boundaries of the conic shape of the cradle.

4. The apparatus of claim 1, wherein the imaging workstation comprises a screen, and wherein the processing module is configured to:

- detect, in at least one X-Ray image, an area presenting the treatment location surrounded by the cradle,
- save a clear image of the area thereof,
- detect and replace, in at least one additional X-Ray image, a dark area surrounded by the cradle with the clear image of the area thereof to thereby generate at least one updated X-Ray image, and
- display, on the screen, the at least one updated X-Ray image.

5. The apparatus of claim 1, wherein the aiming apparatus comprises: a mock-up removably affixable within the cradle, and at least one optical marker holder affixed to the mock-up.

6. The apparatus of claim 5, wherein the aiming apparatus comprises at least two ring x-ray markers, wherein each ring x-ray marker of the at least two ring x-ray markers is affixed to the at least one optical marker holder at a predetermined position along the at least one optical marker holder and has-different size as compared to other ring x-ray markers of the at least two ring x-ray markers.

7. The apparatus of claim 6, further comprising at least one radio opaque marker configured to be placed on the X-ray intensifier, and at least one of a visual marker and a radio-opaque marker configured to be placed on a skin of a patient above the treatment location.

8. The apparatus of claim 1, wherein the aiming apparatus comprises a depth camera, at least two distance sensors, and at least two angular sensors, configured to be located on at least one of: the cradle, the FUS transducer, the X-Ray intensifier and any combination thereof.

9. The apparatus of claim 1, wherein the aiming apparatus is affixable within the recess of the FUS transducer such that a central longitudinal axis of the aiming apparatus coincides with a central longitudinal axis of the FUS transducer.

10. The apparatus of claim 1, wherein the aiming apparatus comprises at least one of:

- an optical marker holder removably attachable to the X-Ray intensifier, or
- a mirror removably attachable to the X-Ray intensifier and an optical marker holder removably attachable to an edge of the X-Ray intensifier.

11. The apparatus of claim 1, further comprising a coupling accessory to acoustically couple the FUS transducer with a skin of a patient.

12. The apparatus of claim 11, wherein the coupling accessory is at least one of a balloon filled with an acoustic fluid or a gel pad.

13. The apparatus of claim 1, further comprising an imaging ultrasound (US) transducer removably affixable within a recess in the FUS transducer, the imaging US transducer is configured to generate US images of treatment location to thereby aid in navigation of the FUS therapeutic energy beam to the treatment location.

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