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(71) Applicant *(for all designated States except US)*: **MEDICIS TECHNOLOGIES CORPORATION** [—/US]; 11818 North Creek Pkwy. North, Bothell, Washington 98011 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BOCKENSTEDT, Craig Robert** [US/US]; 5647 N.E. 199th Place, Kenmore, Washington 98028 (US). **LITTLE, Blake** [US/US]; 2505 241st St. S.E., Bothell, Washington 98021 (US). **ALBRIGHT, Ethan** [US/US]; 2719 175th St. S.E., Bothell, Washington 98012 (US).

(74) Agent: **WYLIE, Roger D.**; TOWNSEND AND TOWNSEND AND CREW LLP, Two Embarcadero Center, 8th Floor, San Francisco, California 94111 (US).

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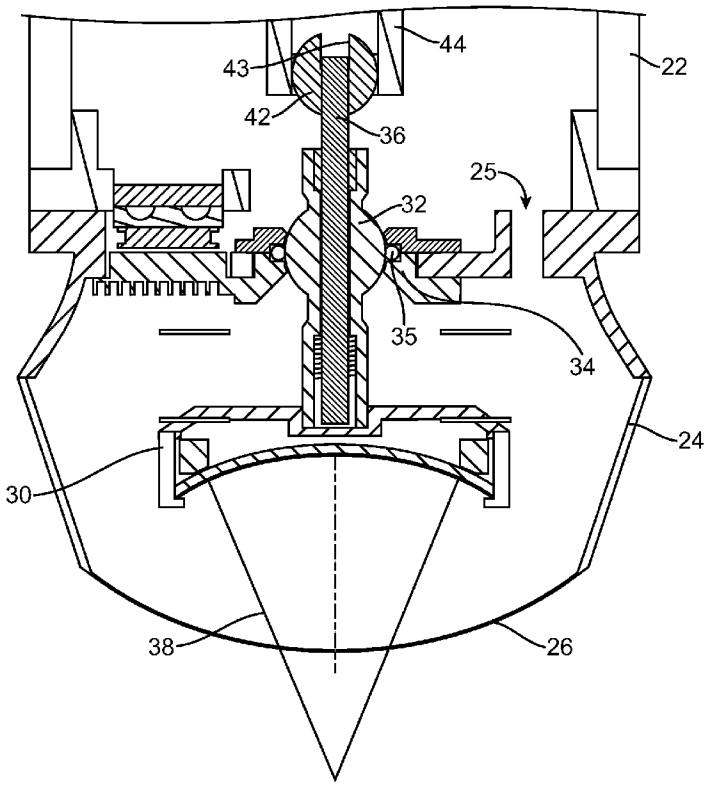

FIG. 4

(57) Abstract: Therapy heads and related medical systems having an actuation assembly for controlling the position/orientation of a directional energy applicator in at least two planes are disclosed. A therapy head (20) includes an enclosure, a partition separating a lower compartment (24) from an upper compartment (22), an aperture (34) in the partition, a control arm (32) extending through the aperture (34), an actuation assembly (28) positioned within the upper compartment (22), and a directional energy applicator (30) positioned in the lower compartment (24) for transmitting energy through a window (26). The control arm (32) includes an upper end (36) disposed within the upper compartment (24) and a lower end disposed within the lower compartment (22). The actuation assembly (28) is coupled with the upper end (36) of the control arm (32) such that the control arm (32) is movable by the actuation assembly (28) in at least two planes. The directional energy applicator (30) is coupled with the lower end of the control arm (32).

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THERAPY HEAD FOR USE WITH AN ULTRASOUND SYSTEM

CROSS-REFERENCES TO RELATED APPLICATIONS

[0001] The present application claims the benefit of U.S. Provisional Application No. 61/025,618 (Attorney Docket No. 021356-003200US), filed on Feb. 1, 2008, the full disclosure of which is incorporated herein by reference.

BACKGROUND

[0002] The present invention relates generally to handheld medical devices for precisely delivering energy into a human body, and more particularly to handheld medical devices and related systems having an actuation assembly for controlling the position/orientation of a directional energy applicator in at least two planes. The position/orientation control provided can be especially beneficial when used in a medical ultrasound therapy head that is used for non-invasive therapies.

[0003] A general problem in the application of high intensity focused ultrasound (HIFU) for therapeutic purposes is that it is often necessary to hold the therapeutic means stationary for some significant amount of time over the tissue to be treated. Alternatively, it may be necessary to scan the therapy beam at a slow, constant rate through the tissue to be treated. Both of these requirements present a barrier to the use of hand-held therapeutic devices, as it is often difficult or impossible for a person to either hold the device steady, or to scan at an acceptably slow and steady rate for the desired therapeutic effect.

[0004] A HIFU procedure may require that the ultrasound beam be scanned over the treatment volume at a constant rate (*e.g.*, 5mm/sec +/- 1mm/sec) to achieve the desired therapeutic effect. Additionally, the treatment volume must be scanned so that there is never more than a 2mm spacing between adjacent focal lines of treatment. These requirements are beyond the capabilities of most human beings. The solution in the past has been to incorporate a computer controlled motion device rigidly mounted to something that is stationary with respect to the patient (*e.g.*, the floor, wall or bed). Such a device is either absolutely stationary, or is able to scan at a precise rate in a precise pattern without any

human intervention. Such an arrangement has the disadvantages of size and bulk, complexity and reliability of the overall device.

[0005] Thus there remains a need in the art for a HIFU applicator that can be easily manipulated by a user while still providing reliable and uniform treatment.

[0006] There is also a need for a HIFU transducer that can keep track of the tissue volumes treated so as to prevent re-treatment of those same volumes.

[0007] There is still further a need for a therapy device that can assist the operator in identifying regions of tissue to be treated.

BRIEF SUMMARY

[0008] The following presents a simplified summary of some embodiments of the invention in order to provide a basic understanding of the invention. This summary is not an extensive overview of the invention. It is not intended to identify key/critical elements of the invention or to delineate the scope of the invention. Its sole purpose is to present some embodiments of the invention in a simplified form as a prelude to the more detailed description that is presented later.

[0009] Hand held therapy heads and related medical systems are provided that include an actuation assembly for selectively directing the output of an directional energy applicator, such as an ultrasound transducer. Such selective direction can be used during ultrasound therapies to increase the accuracy by which the energy is delivered over a treatment region, which may result in improved therapeutic effect.

[0010] In an embodiment, a therapy head is provided. The therapy head includes an enclosure adapted to be manipulated by hand, a partition separating a lower compartment of the enclosure from an upper compartment of the enclosure, an aperture in the partition, a control arm extending through the aperture, an actuation assembly positioned within the upper compartment, and a directional energy applicator for transmitting energy through a window included within the lower compartment. The control arm includes an upper end disposed within the upper compartment and a lower end disposed within the lower compartment. The control arm is movable within the aperture while the aperture is sealed between the upper and lower compartments. The actuation assembly is coupled with the upper end of the control arm such that the control arm is movable by the actuation assembly

in at least two planes. The directional energy applicator is coupled with the lower end of the control arm.

[0011] In another embodiment, a therapy head is provided. The therapy head includes an enclosure adapted to be manipulated by hand, a directional energy applicator disposed within the enclosure, and a means for maneuvering the directional energy applicator within the enclosure so as to direct the energy applicator over a two-dimensional treatment area. The enclosure includes a window through which the directional energy applicator transmits energy.

[0012] In another embodiment, a medical ultrasound system is provided. The medical ultrasound system includes a base unit movable to along side a patient, and an ultrasound head coupled with the base unit. The ultrasound head includes an enclosure adapted to be manipulated by hand, a partition separating a lower compartment of the enclosure from an upper compartment of the enclosure, an aperture in the partition, a control arm extending through the aperture, an actuation assembly positioned within the upper compartment, and an ultrasound transducer for transmitting ultrasound energy through a window included within the lower compartment. The control arm includes an upper end disposed within the upper compartment and a lower end disposed within the lower compartment. The control arm is movable within the aperture while the aperture is sealed between the upper and lower compartments. The actuation assembly is coupled with the upper end of the control arm such that the control arm is movable by the actuation assembly in at least two planes. The ultrasound transducer is coupled with the lower end of the control arm.

[0013] For a fuller understanding of the nature and advantages of the present invention, reference should be made to the ensuing detailed description and accompanying drawings. Other aspects, objects and advantages of the invention will be apparent from the drawings and the detailed description that follows.

BRIEF DESCRIPTION OF THE DRAWINGS

[0014] **FIG. 1** shows a medical ultrasound therapy system in accordance with an embodiment.

[0015] **FIG. 2** shows an ultrasound therapy head having an actuation assembly for varying the position/orientation of an ultrasound transducer in accordance with an embodiment.

[0016] **FIG. 3** is a perspective view showing internal assemblies of the ultrasound therapy head of **FIG. 2**.

[0017] **FIG. 4** is a cross-sectional view showing details of an articulated ultrasound transducer assembly coupled with a therapy head partition in accordance with an embodiment.

[0018] **FIG. 5** is a perspective view of the actuation assembly of the ultrasound therapy head of **FIGS. 2** and **3**.

[0019] **FIGS. 6A** is a perspective view of a central shaft and associated drive motor of the actuation assembly of **FIG. 5**.

[0020] **FIG. 6B** is a top view of the central shaft and associated drive motor of the actuation assembly of **FIG. 5**.

[0021] **FIG. 7A** is a perspective view of a translating/rotating hub of the actuation assembly of **FIG. 5** in accordance with an embodiment, showing the translating/rotating hub coupled with the central shaft shown **FIGS. 6A** and **6B**.

[0022] **FIG. 7B** is a top view of the translating/rotating hub coupled with the central shaft shown in **FIG. 7A**.

[0023] **FIG. 8** is a perspective view of the translating/rotating hub as rotationally constrained by a slotted concentric shaft in accordance with an embodiment.

[0024] **FIG. 9** is a perspective view of a control arm interface component coupled with the translating/rotating hub and associated drive mechanism for rotating the slotted concentric shaft in accordance with an embodiment.

[0025] **FIG. 10** is a side view illustration of a subassembly of the actuation assembly of **FIG. 5**, showing the control arm interface component as coupled with the central shaft and as rotationally constrained by the slotted concentric shaft.

[0026] **FIG. 11** is a perspective view illustration of an enclosure having an actuation assembly for repositioning/reorienting an ultrasound transducer within a therapy head in accordance with another embodiment.

[0027] **FIG. 12** is a perspective view illustration of the enclosure of **FIG. 11**, showing the actuation assembly displaced vertically from the enclosure.

[0028] **FIG. 13A** is a perspective view illustration of the enclosure of **FIG. 11**, showing the actuation assembly disposed within a partial view of the enclosure.

[0029] **FIG. 13B** is a perspective view illustration of the enclosure of **FIG. 11**, showing a partition between an upper compartment and a lower compartment and movement directions of an ultrasound transducer disposed within the lower compartment, in accordance with an embodiment.

[0030] **FIGS. 14A** and **14B** are cross-sectional views illustrating details of a coupling between a control arm and a therapy head partition and ranges of motion of the control arm in accordance with an embodiment.

[0031] **FIGS. 15**, **16**, and **17** illustrate therapy head handles, a rubberized jacket, and a therapy head shaped to provide an increased range of transducer motion, respectively, in accordance with embodiments.

DETAILED DESCRIPTION

[0032] In the following description, various embodiments of the present invention will be described. For purposes of explanation, specific configurations and details are set forth in order to provide a thorough understanding of the embodiments. However, it will also be apparent to one skilled in the art that the present invention may be practiced without the specific details. Furthermore, well-known features may be omitted or simplified in order not to obscure the embodiment being described.

[0033] Described herein are various embodiments of a therapy head for use with a medical system. More particularly, therapy heads and related medical systems are provided that include an actuation assembly for selectively directing the output of an directional energy applicator, such as an ultrasound transducer.

[0034] Referring now to the drawings, in which like reference numerals represent like parts throughout the several views, **FIG. 1** shows a medical ultrasound system **10**. The medical ultrasound system **10** includes a base unit **12**, an articulating arm **14** attached to the base unit, and a user interface device **16** attached to the articulating arm **14**. At the distal end of the articulating arm **14** is an ultrasound head **20**.

[0035] The exterior of the ultrasound head **20** is desirably a form factor that is easily handled by an operator. An example of one embodiment is shown in **FIG. 2**, but the ultrasound head may take many other forms. The ultrasound head **20** may have cables

extending from it and going to the base unit **12** through the articulating arm **14**, or the cables may optionally be exposed.

[0036] As shown in **FIG. 2**, the ultrasound head **20** includes an upper compartment **22**, and a lower compartment **24**, or cap. The upper compartment **22** is desirably dry and houses wires, cables, a motor assembly, and/or other features for a transducer, which is mounted in the lower compartment **24**. The lower compartment **24** preferably contains a coupling fluid, such as degassed water, used to transfer ultrasound energy from the transducer to and through a window **26** located near the bottom of the lower compartment. Disposed within the upper compartment **22** is an actuation assembly **28**. The actuation assembly **28** provides for control over the position/orientation of the transducer located within the lower compartment **24**.

[0037] In operation, a technician rolls the medical ultrasound system **10** to adjacent a patient. The technician grasps and moves the ultrasound head **20**, with the ultrasound head **20** remaining attached to the articulating arm **14**. The ultrasound head **20** is aligned so that the window **26** is in contact with the patient. The user interface device **16** may be operated to generate an appropriate treatment or diagnostic test. During use, the transducer mounted in the lower compartment **24** generates ultrasound energy, which may be used, for example, for the destruction of adipose tissue, as described in U.S. Published Application No. 2006/0122509. The actuation assembly **28** can be used to provide for simplified treatment procedures. For example, the ultrasound head **20** can be held in stationary contact with the patient while the actuation assembly **28** varies the position/orientation of the ultrasound transducer so as to apply therapeutic treatment to a local region of the patient using a scan pattern that provides a desired coverage, duration, spacing, etc.

[0038] **FIG. 3** illustrates internal assemblies of the therapy head **20** of **FIG. 2**. Mounted within the upper compartment **22** is the actuation assembly **28**. The actuation assembly **28** is coupled with a ultrasound transducer assembly **30** by way of a control arm **32**. The control arm **32** is configured to interface with and pivot within a receptacle **34** that is coupled with a partition that separates the upper compartment **22** from the lower compartment **24**. The lower compartment **24** is a sealed assembly that contains a coupling fluid, such as degassed water, that is used to transfer ultrasound energy transmitted by the transducer assembly **30**. The receptacle **34** includes at least one fluid seal (*e.g.*, a o-ring seal, a blade seal, etc.) to prevent fluid from entering the upper compartment **22** from the

lower compartment **24**. The control arm **32** includes a control arm upper end **36** disposed within the upper compartment **22**. In the position/orientation shown, the ultrasound transducer assembly **30** is shown as transmitting focused ultrasound energy through the window **26** as illustrated by the ultrasound energy profile **38**.

[0039] The actuation assembly **28** is operable to move the control arm upper end **36** so as to pivot the control arm **32** within the receptacle **34**. The range of motion of the actuation assembly and the control arm **32** produces a coverage area **40** within which focused ultrasound energy can be directed in a controlled fashion (*e.g.*, by using scanning patterns, scanning rates, energy transmission levels, etc.).

[0040] The control arm upper end **36** is coupled with the actuation assembly **28** by way of a pivot ball **42** (as best shown in **FIG. 4**), which is received within and positioned by a control arm interface component **44**. The control arm interface component **44** is coupled with a translating/rotating hub **46**, which directly controls the position/orientation of the control arm interface component **44**. The translating/rotating hub **46** is interfaced with a central shaft **48** so that rotation of the central shaft **48** controls the position of the translating/rotating hub **46** along the centerline of the actuation assembly **28**. As used herein, the centerline of the actuation assembly **28** is a reference axis that is aligned with the centerline of the actuation assembly **28**. A variety of interface configurations can be used to interface the hub **46** with the central shaft **48** so that rotation of the central shaft **48** causes translation of the hub **46** along the centerline of the actuation assembly **28** (*e.g.*, an acme screw assembly, a ball-screw assembly, etc.). As will be describe in detail below, the actuation assembly **28** is configured to rotate the hub **46** through a range of rotation about the centerline of the actuation assembly **28**. The combination of translation of the hub **46** along the centerline of the actuation assembly **28** and rotation of the hub **46** about the centerline of the actuation assembly **28** provides a range of motion to the control arm interface component **44** required to direct the ultrasound transducer assembly to any point within the coverage area **40**.

[0041] **FIG. 4** illustrates the details of the articulated ultrasound transducer assembly **30** coupled with a therapy head partition and with the control arm interface component **44**. The ultrasound transducer assembly **30** is coupled with the control arm **32** so as to be positioned/oriented within the lower compartment **24**. The control arm **32** is constrained by the receptacle **34** such that an instantaneous center of rotation for the control arm **32** is

restrained from translating relative to the receptacle **34**. The receptacle **34** is mounted to the partition that separates the upper compartment **22** from the lower compartment **24**. The receptacle **34** includes a seal groove containing an o-ring seal **35** for preventing coupling fluid (*e.g.*, degassed water) from escaping the lower compartment **24** into the upper compartment **22**. The partition that separates the upper compartment **22** from the lower compartment **24** can include an optional opening **25** that can be used as a pass through between the compartments for various purposes (*e.g.*, for sensors, wiring, electronics, water line(s), filters, etc.). The optional opening **25** can be sealed to prevent coupling fluid from escaping the lower compartment **24** into the upper compartment **22**. The control arm upper end **36** interfaces with the pivot ball **42**. The pivot ball **42** includes a central bore **43** that interfaces with a cylindrical outer surface of the control arm upper end **36**. The control arm interface component **44** includes mating surfaces designed to interface with the pivot ball **42** so as to constrain the pivot ball **42** from translating relative to the interface component **44** while allowing the pivot ball **42** to rotate relative to the interface component **44**. The interface between the pivot ball **42** and the control arm upper end **36** allows for the relative translation between these components that arises due to the rotation of the interface component **44** about or along the centerline of the actuation assembly **28** (shown in **FIG. 3**) and the resulting motion of the control arm **32** as it pivots within the receptacle **34**.

[0042] **FIG. 5** illustrates the actuation assembly **28**. The actuation assembly provides for controlled translation and rotation of the interface component **44** along and about the centerline of the actuation assembly **28**. The interface component **44** is coupled with the translating/rotating hub **46** in any number of ways. As examples, the interface component **44** can include a central bore and be press-fit onto the hub **46**, the interface component **44** and the hub **46** can be include interfacing splines, or the interface component **44** and the hub **46** can be combined into a single integral component. The hub **46** and the central shaft **48** are configured such that rotation of the central shaft **48** causes translation of the hub **46** along the centerline of the actuation assembly **28**. The actuation assembly **28** includes two rotary motors, which include a translation motor **50** and a rotation motor **52**. The translation motor **50** is rotationally coupled with the central shaft **48**, thereby controlling the translation of the interface component **44** along the centerline of the actuation assembly **28**. The rotation motor **52** controls the rotation of the interface component **44** about the centerline of the actuation assembly **28**. A translation motor encoder **54** is used to track the rotary

position of the translation motor **50** and a rotation motor encoder **56** is used to track the rotary position of the rotation motor **52**.

[0043] **FIGS. 6A** and **6B** illustrate details of the coupling between the translation motor **50** and the central shaft **48**. Rotation of the translation motor **50** is transferred to the central shaft **48** by way of a translation motor output gear **58**, which interfaces with a central shaft drive gear **60** that is coupled with the central shaft **48**. The translation motor encoder **54** monitors the rotary position of the translation motor **50** and the central shaft **48**. The central shaft drive gear **60** can be coupled with the central shaft **48** in a variety of ways (*e.g.*, by a key or by splines).

[0044] **FIGS. 7A** and **7B** illustrate details of the coupling between the central shaft **48** and the translating/rotating hub **46**. The central shaft **48** includes an outer surface **62** configured (*e.g.*, by an acme screw assembly or a ball screw assembly, etc.) so as to cause translation of the translating/rotating hub **46** along the centerline of the actuation assembly **28** in response to rotation of the central shaft **48**. The central shaft **48** is driven by the central shaft drive gear **60** and rotates within two end bearings **64**, **66**.

[0045] The hub **46** includes a partially circumferential slot **68**, which is used to control the rotation of the hub **46** about the centerline of the actuation assembly **28**. **FIG. 8** illustrates a slotted concentric shaft **70**, which interfaces with the circumferential slot **68** (shown in **FIG. 7**) so as to control the rotation of the hub **46** about the centerline of the actuation assembly **28**. The slotted concentric shaft **70** fits within the circumferential slot **68**, thereby allowing the hub **46** to translate along the slotted concentric shaft **70** while constraining the hub **46** from rotating about the slotted concentric shaft **70**. The two end bearings **64**, **66** provide for relative rotation between the central shaft **48** and the slotted concentric shaft **70**. The slotted concentric shaft **70** includes two end counter-bores configured to accept the two-end bearings **64**, **66**.

[0046] In operation, rotating the central shaft **48** causes the exterior surface **62** to interact with the hub **46** thereby causing the hub **46** to translate along the centerline of the actuation assembly **28**. The slotted concentric shaft **70** can be held stationary so that the hub **46** is constrained from rotating about the centerline of the actuation assembly **28** while the hub **46** translates along the centerline of the actuation assembly **28**.

[0047] **FIG. 9** illustrates components of the actuation assembly **28** that are used to control the rotation of the slotted concentric shaft **70**, and thereby control the rotation of the

interface component **44**. The slotted concentric shaft **70** is coupled with a partial gear **72**, which includes a gear sector sufficient to rotate the slotted concentric shaft **70** through its range of motion. The partial gear **72** is driven by an idler gear **74**. The idler gear **74** is driven by a pinion gear (not shown), which is driven by the rotation motor **52**. The rotation motor **52** is coupled with the rotary encoder **56**, which monitors the rotational position of the rotation motor **52**, thereby monitoring the rotational position of the slotted concentric shaft **70**, the hub **46**, and the interface component **44**.

[0048] The combined operation of the core actuation subassembly that provides for the translation and rotation of the interface component **44** is now described with reference to **FIG. 10**. The slotted concentric shaft **70** rotates within two support bearings **76, 78**. The rotation of the slotted concentric shaft **70** is controlled by the partial gear **72**, which is controlled via the rotation motor **52** as described above. The rotational position of the interface component **44** is directly controlled by the rotational position of the slotted concentric shaft **70** via the circumferential slot **68** in the translating/rotating hub **46**. The rotation of the central shaft drive gear **60** relative to the partial gear **72** causes the central shaft **48** to rotate relative to the hub **46**, which causes the central shaft outer surface **62** to interact with the hub **46** such that the hub **46** and the interface component **44** translate along the centerline of the actuation assembly **28**.

[0049] While the actuation assembly describe above includes two motors, it could be configured to include a single motor. For example, a single motor can be used to drive two or more axels by way of two or more gear connectors. One or more clutches can be used to engage/disengage the motor with the axels that drive the translating/rotating hub. A single motor can also be used to drive the axels that drive the translating/rotating hub by way of other known interconnections (*e.g.*, drive belts, chains, etc.).

[0050] The above described therapy head **20** provides a number of advantages. For example, the use of a pivotally mounted control arm avoids the use of complex mechanisms and seals (*e.g.*, through the use of mating spherical surfaces), while providing the ability to vary the position/orientation of the ultrasound transducer assembly so as to direct energy over a two-dimensional region of a patient. The use of concentric rotational shafts provides for a compact actuation assembly, which in turn provides for a more compact therapy head. The use of rotary drive motors allows for the use of an electric actuation assembly, thereby avoiding the need for additional subsystems (*e.g.*, hydraulic, pneumatic, etc.). The use of

rotary encoders allows for relatively fine positional control due to the ratio of motor rotation to translation and/or rotation of the interface component. The use of a rotational mechanism allows for the use of rotary bearings, which can be selected to meet operational life requirements.

[0051] An alternate embodiment of a therapy head will now be described with reference to **FIGS. 11, 12, 13A, 13B, 14A**, and **14B**. An enclosure **82** for use in a therapy head in accordance with the alternate embodiment is shown in **FIG. 11**. The enclosure **82** is desirably a casing suitable for housing an actuation assembly and transducer unit within. The enclosure **82** may be a single piece part, or a multi-piece unit having access to the interior for placement of the actuation assembly and transducer components prior to final assembly. In one embodiment utilizing a motor bracket **88**, the motor bracket **88** is visible at the top of the enclosure **82**. The enclosure **82** has a plurality of apertures located at the top, bottom and in the side walls. The side wall apertures are desirably shaped to receive parts of the actuation assembly **80** described below.

[0052] Inside the enclosure **82** are an actuation assembly **80**, a transducer **102** and a control arm **100** between the actuation assembly **80** and the transducer **102**. The control arm **100** connecting the actuation assembly **80** and the transducer **102** passes through a partition **108**. The actuation assembly **80** is positioned within an upper compartment **110** of the enclosure **82** while the transducer **102** is positioned within a lower compartment **112** of the enclosure **82**. The control arm **100** passes through the partition **108** through a single, fixed aperture. A ball joint **104** fitted within a boot **114** is desirably positioned in the fixed aperture, and the control arm **100** passes through the ball joint **104**. The actuation assembly **80** connects to the upper end of the control arm **100** via a movable lead-screw carriage **96**. The actuation assembly **80** can move the lead-screw carriage **96** in two dimensions (*e.g.*, longitudinally along a screw rail **94** and traverse relative to the screw rail **94** by moving the screw rail **94** laterally). The lead-screw carriage **96** has a variable connector on it allowing it to maintain contact with, and transmit mechanical force to, the control arm **100** when the lead-screw carriage **96** is being moved. The lead-screw carriage **96** can move the upper end of the control arm **100** like a joy stick, and cause a corresponding movement of the transducer **102** in the lower compartment **112**.

[0053] **FIG. 12** shows the actuation assembly **80** displaced vertically from the enclosure **82**. The actuation assembly **80** has an axle drive motor **84**, and an oscillation motor **86**

mounted on the motor bracket **88**. The axle drive motor **84** engages a gear mechanism **90**, **92** to drive a screw rail **94**. Riding on the screw rail **94** is a lead-screw carriage **96**. The screw rail **94** rides within an aperture **98** in the motor bracket **88** and a slot shaped aperture **82a** in the enclosure **82**. The oscillation motor **86** is coupled with the motor bracket **88** and causes the motor bracket **88** to rotate around pivot axis **88a**, which provides for transverse movement of the screw rail **94**. Using a combination of the motors **84**, **86** it is possible to move the control arm **100** like a joy stick, and move the transducer **102** about a fulcrum point within a ball joint **104**. The ball joint **104** has a limit stop **106** to prevent the ball joint **104** from being moved beyond a desired position.

[0054] In some embodiments, the control arm **100** is coupled with a lead-screw carriage **96** on the actuation assembly by way of a three-axis pivot. The three-axis pivot allows the control arm **100** to axially slide up and down relative to the lead-screw carriage **96** while preventing rotation of the lead-screw carriage **96** during axial motion along the lead screw **94**.

[0055] **FIG. 13A** shows the relative position of the actuation assembly within the enclosure **82**. A partition **108** separating the enclosure **82** into the upper compartment **110** and lower compartment **112** is shown in **FIG. 13B**. The oscillation and axial motion of an annular array style transducer **102** is shown via the arrows. The various apertures in the enclosure **82** have been omitted for clarity. The partition **108** is shown relative to the motion of the transducer **102**.

[0056] The transducer **102** moves at the end of the control arm **100** and focuses ultrasound energy outside the enclosure **82**. When the therapy head is properly coupled to a patient, the ultrasound energy will focus within the tissue of the patient for a desired therapeutic effect. Since the transducer **102** is on a control arm **100** of fixed length, constrained to move about a pivot point, the transducer **102** moves in a three dimensional arc creating a spherical shaped travel arc. When the transducer **102** is active, the focal zone of the transducer **102** creates a similar spherical shaped travel arc. This arc is referred to herein as the treatment arc, or the sweep area. If the transducer **102** is a fixed focus transducer, the sweep area is spherical. If the focal depth of the transducer **102** can be changed either mechanically or electronically, the sweep area shape can be changed. Either a curved sweep area or a flat sweep area can be created with the therapy heads described

herein. Advantageously, a flat sweep area can be created using the actuation assembly combined with an electronically controlled array transducer.

[0057] Depth adjustment of the focal point may be achieved through a variety of techniques. The transducer's focal zone can be mechanically adjusted by changing the vertical position of the transducer. This can be accomplished by using an actuator to cause the transducer to move up and down as it goes through the arc of motion. The depth of the transducer focal zone can also be controlled electronically, by steering the focal depth of the transducer using an annular array or phased array transducer. The depth of the transducer focal zone can also be adjusted by using a lens in the cap. A curved or flat cap can be used depending on the sweep area desired. With mechanically focused transducers, HIFU lesions can be formed in tissue at a depth determined by the mechanical focus and the distance from the transducer to the skin (standoff distance). Lesions of varying depth can be obtained by varying the standoff distance with a mechanical Z-axis control mechanism. The lesion depth can also be varied by replacing the Z-axis mechanism with a transducer separated into annular rings and electrically driving each ring independently. By varying the driving energy time delay to each ring appropriately, the focus depth can be varied. Accordingly, a flat sweep area can be created using a variety of techniques even though the transducer moves about a pivot point.

[0058] There are several standard designs for the width of the individual annular rings, such as, but not limited to, equal area or equal pitch designs. The focal power of the transducer changes as the focal depth is varied. Focal power is expressed as the ratio of the focal length to the transducer aperture (f-number), so for a given aperture of an array, changing the focus electronically changes the f-number and focal power. The f-number can be kept roughly constant in more sophisticated designs by switching on or off outer rings, thus changing the aperture while also changing the focus. In the diagnostic world, this technique is known as "expanding aperture."

[0059] The design of annular array transducers presents a number of important considerations. For example, the number of rings in an annular array is important. If there are too few rings, grating lobe secondary foci will occur in the near-field and could potentially cause deleterious effects like skin burn in a therapeutic application. If there are too many rings, as in an equal area design, the outer rings become so thin so as to be practically impossible to build. The issue of secondary foci can be ameliorated greatly by

building the array with a built-in mechanical focus, which also reduces the number of rings, and thus electronic channels, in the array. In simulations of annular array designs, an advantageous number of rings is shown to be 8 to 10 with an overall f-number of 1 to 2, with a 2 MHz operating frequency, and a transducer approximately 38mm in diameter. The rings in an annular array must be acoustically isolated from each other to achieve an acceptable focal beam pattern. Acoustic isolation can be achieved by simply separating the piezoelectric layer into individual rings with an appropriate tool, such as a nested set of concentric thin steel rings mounted on the horn of an ultrasonic impact grinder. The resulting array can then be supported by a backing structure and/or an undiced matching layer(s). Solid piezoelectric materials, almost always a ceramic, when diced into sections whereby any lateral extent of the section is between ~0.7 to 5 times the thickness of the ceramic, will vibrate at different frequencies due to coupling to lateral modes. Most annular array designs end up with one or more rings with aspect ratios in the above "forbidden zone" and produce unacceptable frequency variation across the array aperture. An annular array design can make use of 1-3 composite piezoelectric ceramic materials whereby the ceramic is diced into tall, thin posts with aspect ratios on the order 0.5 and the dicing kerfs filled with polymer material such as epoxy. These materials exhibit uniform frequency response, lower levels of lateral modes, higher electromagnetic coupling constants, and higher bandwidth in good designs. In therapeutic arrays designed to withstand high operating temperatures, the polymer filler material is typically an epoxy with a high glass transition temperature. In many cases, the individual rings of the array still need to be physically separated to some degree to achieve acceptable cross-coupling levels, as discussed above. Lesions can be created in lateral extent by then moving the transducer laterally with a mechanical X-Y scanning apparatus.

[0060] The use of a cap with a lens may be combined with either the mechanical or electronic (array transducer) focal depth adjustment techniques, or used with a standard single focal distance transducer. If the cap is curved, the therapy head can be pressed against the skin so the tissue of the patient conforms to the contours of the cap. When the transducer sweeps out an area, the area treated will be equidistant from the skin surface through out the sweep area. The cap in this case has a radius designed to match that of the transducer's sweep arc. If the cap is designed with a flat lens, a standard single focal distance transducer's focal zone will sweep out a curved treatment area under the skin.

[0061] **FIG. 14A** illustrates the ball-joint **104** in a "neutral" position with the control arm **100** positioned vertically. The ball joint **104** is constrained by the partition **108** and surrounded by a boot **114**. A hard stop or limit mechanism **106** is provided to prevent the ball joint **104** from moving outside the confines of the boot **114**. Electrical control for the transducer **102** can be routed through or along the shaft **100**, through the ball joint **104** and can be connected to the transducer **102**. **FIG. 14B** illustrates the ball joint **104** at the limit of one motion with the shaft tilted to one side, and the limit mechanism **106** at the hard stop of the boot **114**.

[0062] A therapy head can be configured to facilitate manipulation. For example, as illustrated in **FIG. 15**, a therapy head **120** can include handles **122**. As illustrated in **FIG. 16**, a therapy head **130** can include a rubberized jacket **132** or other ergonomic fittings to assist a user in holding the therapy head with one or two hands. As illustrated in **FIG. 17**, a therapy head **140** can be shaped to provide for an increased range of transducer motion.

[0063] The above embodiments provide a number of advantages, For example, the use a joystick like control arm to articulate a HIFU transducer provides a design parameter that can be varied to balance the size of the actuation assembly against the accuracy required. The transducer is mounted to the control arm, which then goes through a three axis pivot that acts as a point of rotation. By varying the ratio of the distance between the pivot point and the actuation assembly and the distance between the pivot point and the transducer, it is possible to increase or decrease the amount of transducer movement that can be achieved, which can also affect the accuracy of the HIFU focal point. For example, if the distance between the pivot point and the transducer is twice the distance as that between the pivot point and the actuation assembly, the actuation assembly foot print can be reduced since it would only need to be capable of a travel distance that is half of that required for the motion profile of the transducer. The ratio of distances described above could be adjusted to provide the most efficient balance between actuation assembly size and accuracy. If the ratio is 1 to 1, then any actuation assembly free play, due to gear backlash, assembled clearances, motor free play, etc., is translated to the HIFU transducer focal point on a 1:1 ratio.

[0064] The use of the joystick like control arm also allows for the calculation of the Z-elevation change in the focal point of the transducer for any position of the control arm.

An effect of the pendulum design is that as the transducer swings about the pivot point, the transducer focal point Z depth will change relative to a flat plane. This is driven by the distance between the pivot point and the transducer focal point. This distance creates an effective radius, so that the Z elevation change can be calculated as a function of actuation assembly position/rotation.

[0065] The use of the joystick like control arm also provides for straightforward integration of the actuation assembly. The control arm is mounted to the transducer and then goes through a pivot point at a known distance and ratio to the distance between the pivot point and the actuation assembly. Somewhere between the transducer and the actuation assembly, the control arm also transitions between the dry actuation assembly compartment and the wet transducer compartment. The single pivot point causes the associated surfaces to experience sliding contact, which provides the ability to use simple sealing members (*e.g.*, o-ring seals, blade seals, etc.).

[0066] Other variations are within the spirit of the present invention. Thus, while the invention is susceptible to various modifications and alternative constructions, certain illustrated embodiments thereof are shown in the drawings and have been described above in detail. It should be understood, however, that there is no intention to limit the invention to the specific form or forms disclosed, but on the contrary, the intention is to cover all modifications, alternative constructions, and equivalents falling within the spirit and scope of the invention, as defined in the appended claims.

[0067] The use of the terms "a" and "an" and "the" and similar referents in the context of describing the invention (especially in the context of the following claims) are to be construed to cover both the singular and the plural, unless otherwise indicated herein or clearly contradicted by context. The terms "comprising," "having," "including," and "containing" are to be construed as open-ended terms (i.e., meaning "including, but not limited to,") unless otherwise noted. The term "connected" is to be construed as partly or wholly contained within, attached to, or joined together, even if there is something intervening. Recitation of ranges of values herein are merely intended to serve as a shorthand method of referring individually to each separate value falling within the range, unless otherwise indicated herein, and each separate value is incorporated into the specification as if it were individually recited herein. All methods described herein can be performed in any suitable order unless otherwise indicated herein or otherwise clearly

contradicted by context. The use of any and all examples, or exemplary language (*e.g.*, "such as") provided herein, is intended merely to better illuminate embodiments of the invention and does not pose a limitation on the scope of the invention unless otherwise claimed. No language in the specification should be construed as indicating any non-claimed element as essential to the practice of the invention.

[0068] Preferred embodiments of this invention are described herein, including the best mode known to the inventors for carrying out the invention. Variations of those preferred embodiments may become apparent to those of ordinary skill in the art upon reading the foregoing description. The inventors expect skilled artisans to employ such variations as appropriate, and the inventors intend for the invention to be practiced otherwise than as specifically described herein. Accordingly, this invention includes all modifications and equivalents of the subject matter recited in the claims appended hereto as permitted by applicable law. Moreover, any combination of the above-described elements in all possible variations thereof is encompassed by the invention unless otherwise indicated herein or otherwise clearly contradicted by context.

WHAT IS CLAIMED IS:

1. A therapy head for application of directional energy to a patient, the therapy head comprising:

an enclosure adapted to be manipulated by hand;

a partition separating a lower compartment of the enclosure from an upper compartment of the enclosure, the lower compartment including a window;

an aperture in the partition;

a control arm extending through the aperture, the control arm having an upper end disposed within the upper compartment and a lower end disposed within the lower compartment, the control arm being movable within the aperture while the aperture is sealed between the upper and lower compartments;

an actuation assembly positioned within the upper compartment, the actuation assembly being coupled with the upper end of the control arm such that the control arm is movable by the actuation assembly in at least two planes; and

a directional energy applicator for transmitting energy through the window, the energy applicator being coupled with the lower end of the control arm.

2. The therapy head of claim 1, wherein the energy applicator comprises an ultrasound transducer.

3. The therapy head of claim 2, wherein the ultrasound transducer comprises an annular array or a phased array.

4. The therapy head of claim 2, wherein the ultrasound transducer comprises a high intensity focused ultrasound transducer.

5. The therapy head of claim 2, wherein the transducer has a fixed focal length and the window is shaped based upon the transducer's treatment sweep area.

6. The therapy head of claim 1, wherein the window comprises a lens.

7. The therapy head of claim 1, wherein the control arm is coupled with the partition.

8. The therapy head of claim 7, wherein the control arm is coupled with the partition such that an instantaneous center of rotation of the control arm is restrained

from translating relative to the partition and the control arm is rotatable about the instantaneous center around at least two axes of rotation.

9. The therapy head of claim 1, wherein the coupling between the control arm and the partition includes mating spherical surfaces.

10. The therapy head of claim 9, wherein the coupling between the control arm and the partition includes a fluid seal.

11. The therapy head of claim 1, wherein the actuation assembly comprises:

a centerline having a fixed position and orientation relative to the upper compartment;

a control arm interface component coupled with the control arm;

a first motor for positioning the control arm interface component along the centerline; and

a second motor for rotating the control arm interface component about the centerline.

12. The therapy head of claim 11, wherein:

the first motor drives a first rotating shaft, the first rotating shaft controlling the position of the control arm interface component along the centerline; and

the second motor drives a second rotating shaft, the second rotating shaft controlling the rotation of the control arm interface component about the centerline.

13. The therapy head of claim 1, wherein the actuation assembly comprises:

a first centerline having a fixed position and orientation relative to the upper compartment;

a bracket pivotally mounted about the first centerline;

a first motor for rotating the bracket about the first centerline;

a second centerline having a fixed position and orientation relative to the bracket;

a control arm interface component coupled with the control arm; and

a second motor for positioning the control arm interface component along the second centerline.

14. The therapy head of claim 13, wherein the second motor drives a rotating shaft, the rotating shaft controlling the position of the control arm interface component along the centerline.

15. The therapy head of claim 1, wherein the actuation assembly comprises:

a centerline having a fixed position and orientation relative to the upper compartment;

a control arm interface component coupled with the control arm; and

a motor for positioning the control arm interface component along the centerline and for rotating the control arm interface component about the centerline.

16. A therapy head comprising:

an enclosure having a window, the enclosure adapted to be manipulated by hand;

a directional energy applicator for transmitting energy through the window, the energy applicator being disposed within the enclosure; and

a means for maneuvering the directional energy applicator within the enclosure so as to direct the energy applicator over a two-dimensional treatment area.

17. The therapy head of claim 16, wherein the energy applicator comprises an ultrasound transducer.

18. The therapy head of claim 17, wherein the ultrasound transducer comprises a high intensity focused ultrasound transducer.

19. A medical ultrasound system comprising:

a base unit movable to along side a patient; and

an ultrasound head coupled with the base unit, the ultrasound head including:

an enclosure adapted to be manipulated by hand;

a partition separating a lower compartment of the enclosure from an upper compartment of the enclosure, the lower compartment including a window;

an aperture in the partition;

a control arm extending through the aperture, the control arm having an upper end disposed within the upper compartment and a lower end disposed within the

lower compartment, the control arm being movable within the aperture while the aperture is sealed between the upper and lower compartments;

an actuation assembly positioned within the upper compartment, the actuation assembly being coupled with the upper end of the control arm such that the control arm is movable by the actuation assembly in at least two planes; and

an ultrasound transducer for transmitting ultrasound energy through the window, the transducer being coupled with the lower end of the control arm.

20. The system of claim 19, wherein the ultrasound transducer comprises an annular array or a phased array.

21. The system of claim 19, wherein the transducer has a fixed focal length and the window is shaped based upon the transducer's treatment sweep area.

22. The system of claim 19, wherein the window comprises a lens.

23. The system of claim 19, wherein the ultrasound transducer comprises a high intensity focused ultrasound transducer.

24. The system of claim 19, wherein the control arm is coupled with the partition such that an instantaneous center of rotation of the control arm is restrained from translating relative to the partition and the control arm is rotatable about the instantaneous center around at least two axes of rotation.

25. The system of claim 19, wherein the actuation assembly comprises:

a centerline having a fixed position and orientation relative to the upper compartment;

a control arm interface component coupled with the control arm;

a first motor for positioning the control arm interface component along the centerline; and

a second motor for rotating the control arm interface component about the centerline.

26. The system of claim 25, wherein:

the first motor drives a first rotating shaft, the first rotating shaft controlling the position of the control arm interface component along the centerline; and

the second motor drives a second rotating shaft, the second rotating shaft controlling the rotation of the control arm interface component about the centerline.

27. The system of claim 19, wherein the actuation assembly comprises:

a first centerline having a fixed position and orientation relative to the upper compartment;

a bracket pivotally mounted about the first centerline;

a first motor for rotating the bracket about the first centerline;

a second centerline having a fixed position and orientation relative to the bracket;

a control arm interface component coupled with the control arm; and

a second motor for positioning the control arm interface component along the second centerline.

28. The system of claim 27, wherein the second motor drives a rotating shaft, the rotating shaft controlling the position of the control arm interface component along the centerline.

29. The system of claim 19, wherein the actuation assembly comprises:

a centerline having a fixed position and orientation relative to the upper compartment;

a control arm interface component coupled with the control arm; and

a motor for positioning the control arm interface component along the centerline and for rotating the control arm interface component about the centerline.

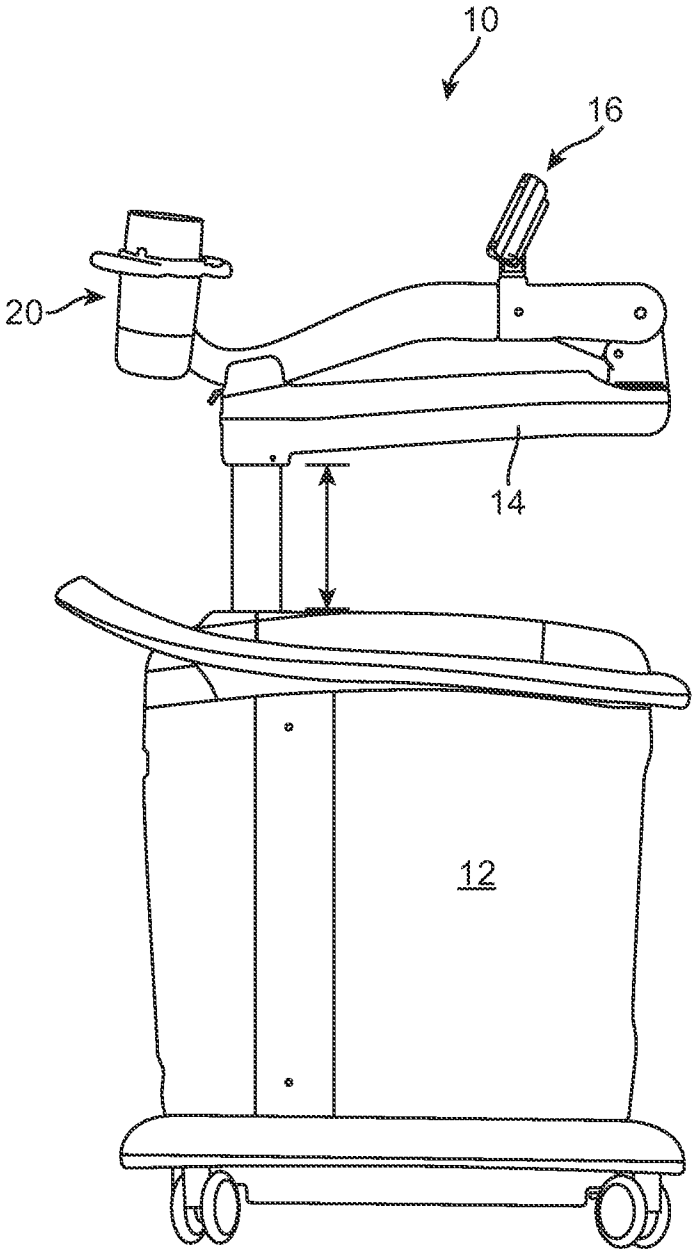

FIG. 1

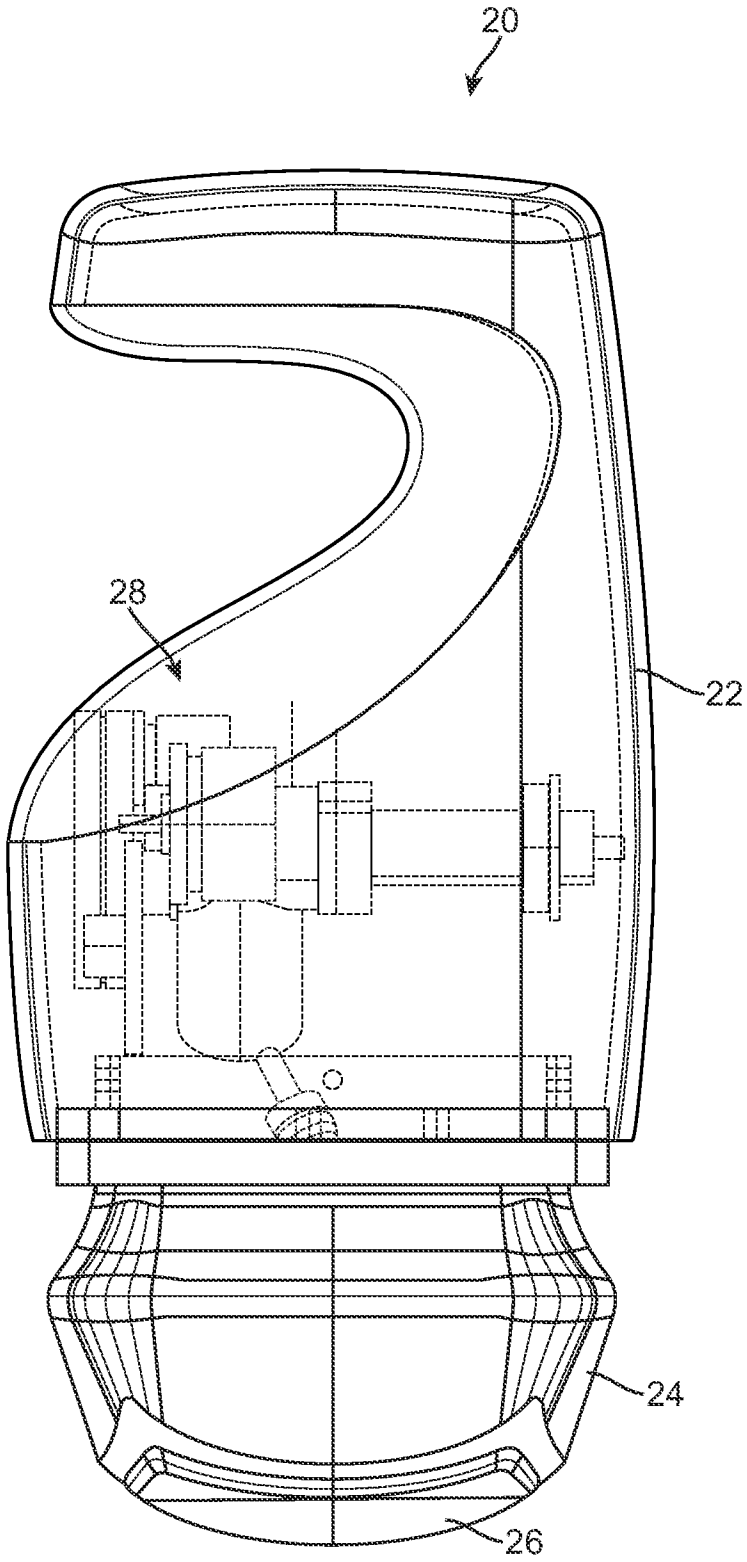

FIG. 2

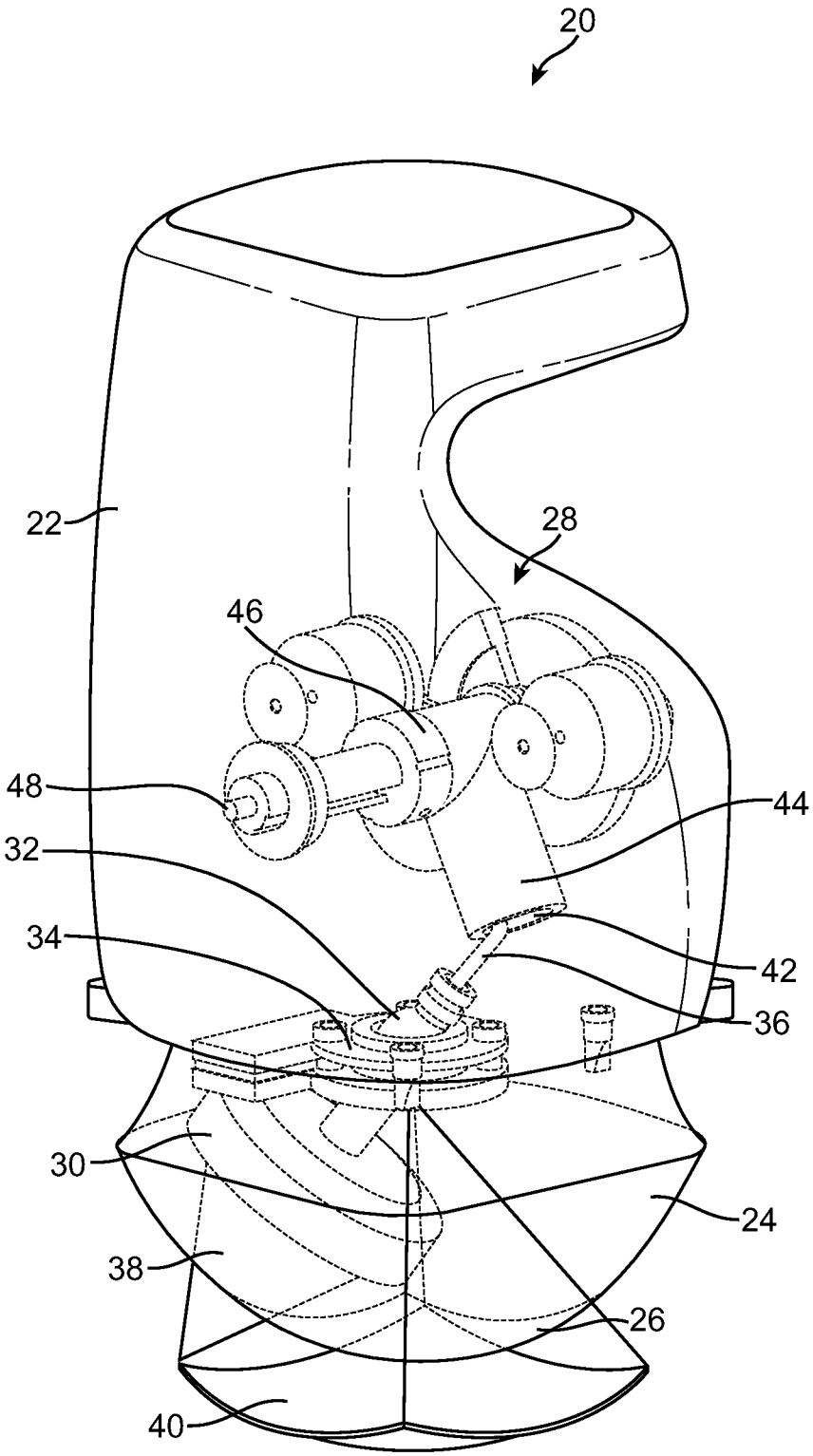

FIG. 3

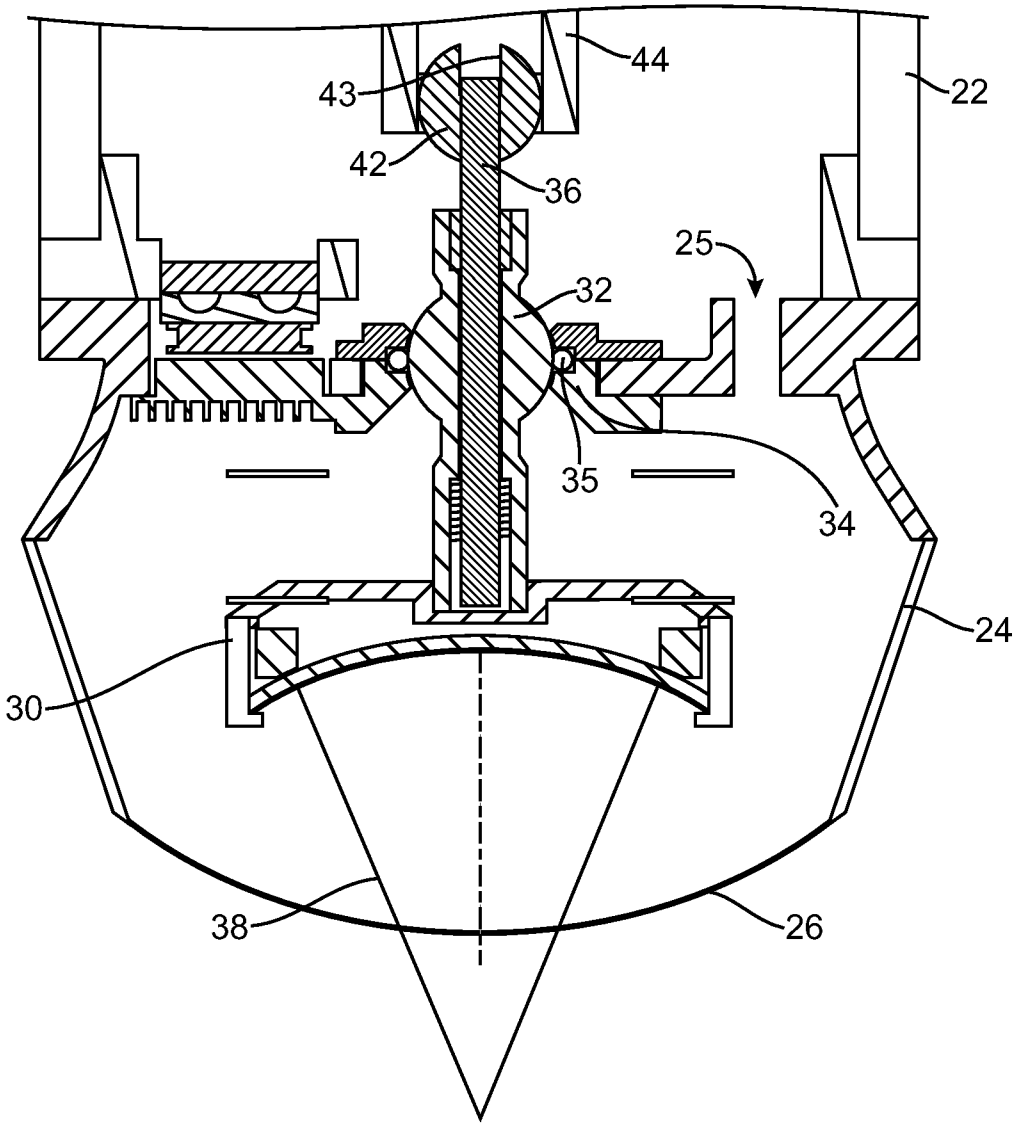

FIG. 4

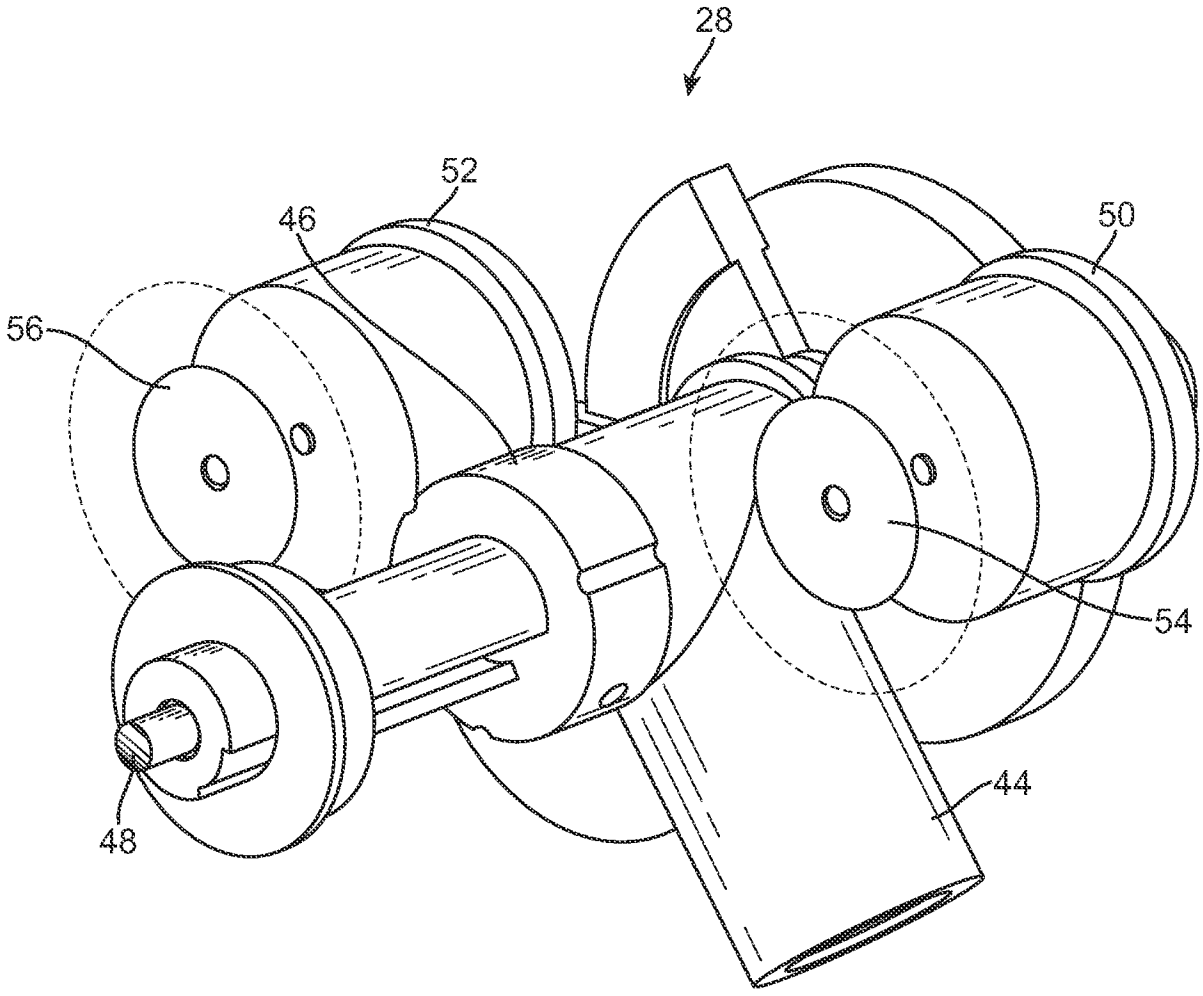

FIG. 5

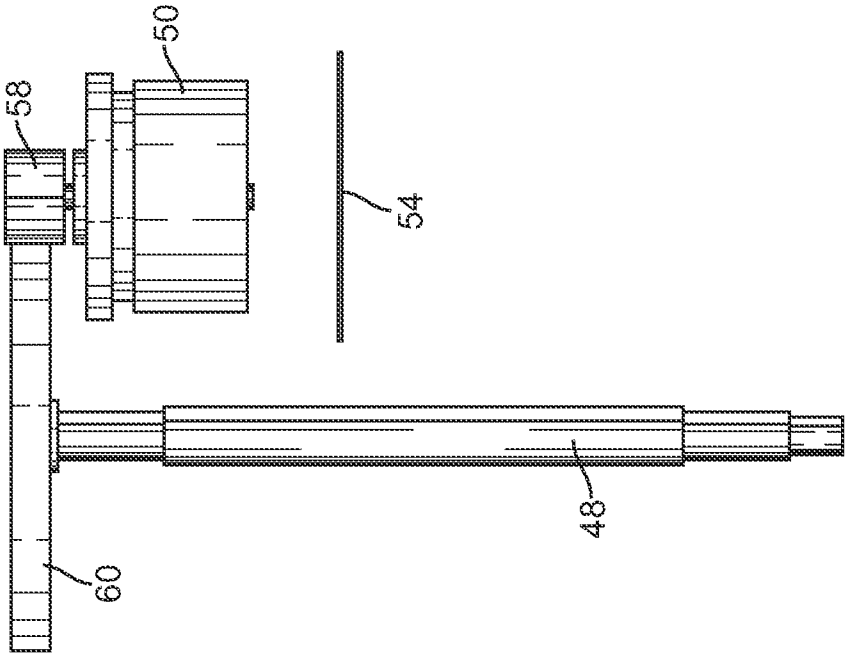

FIG. 6B

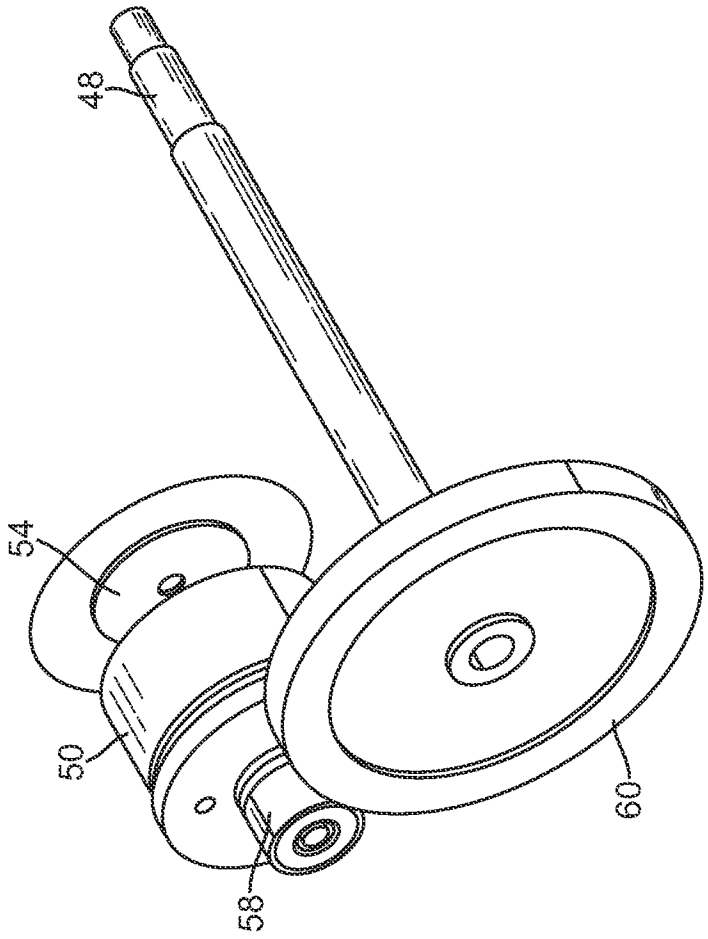

FIG. 6A

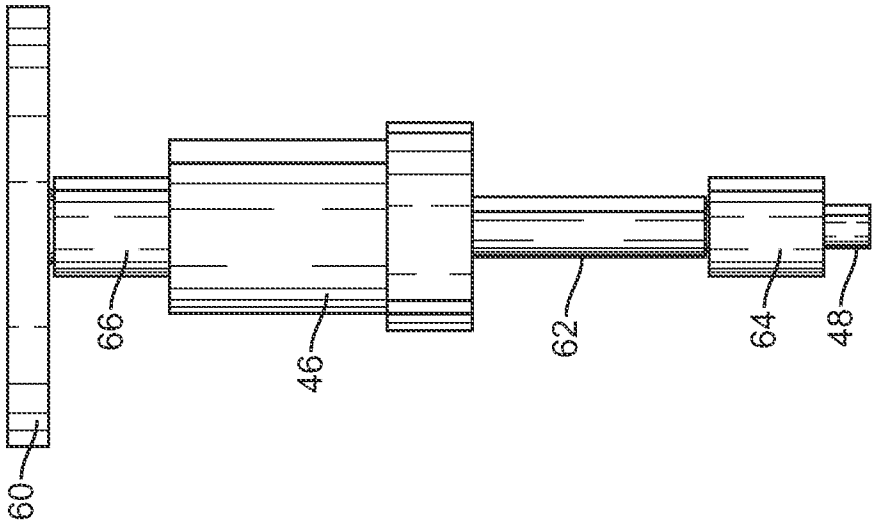

FIG. 7B

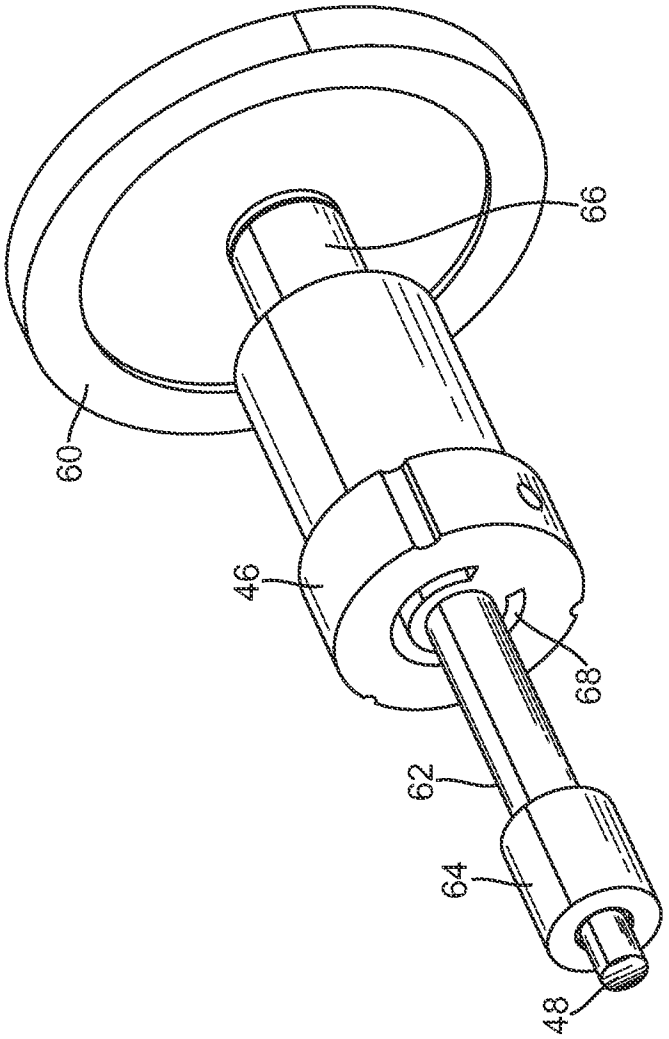

FIG. 7A

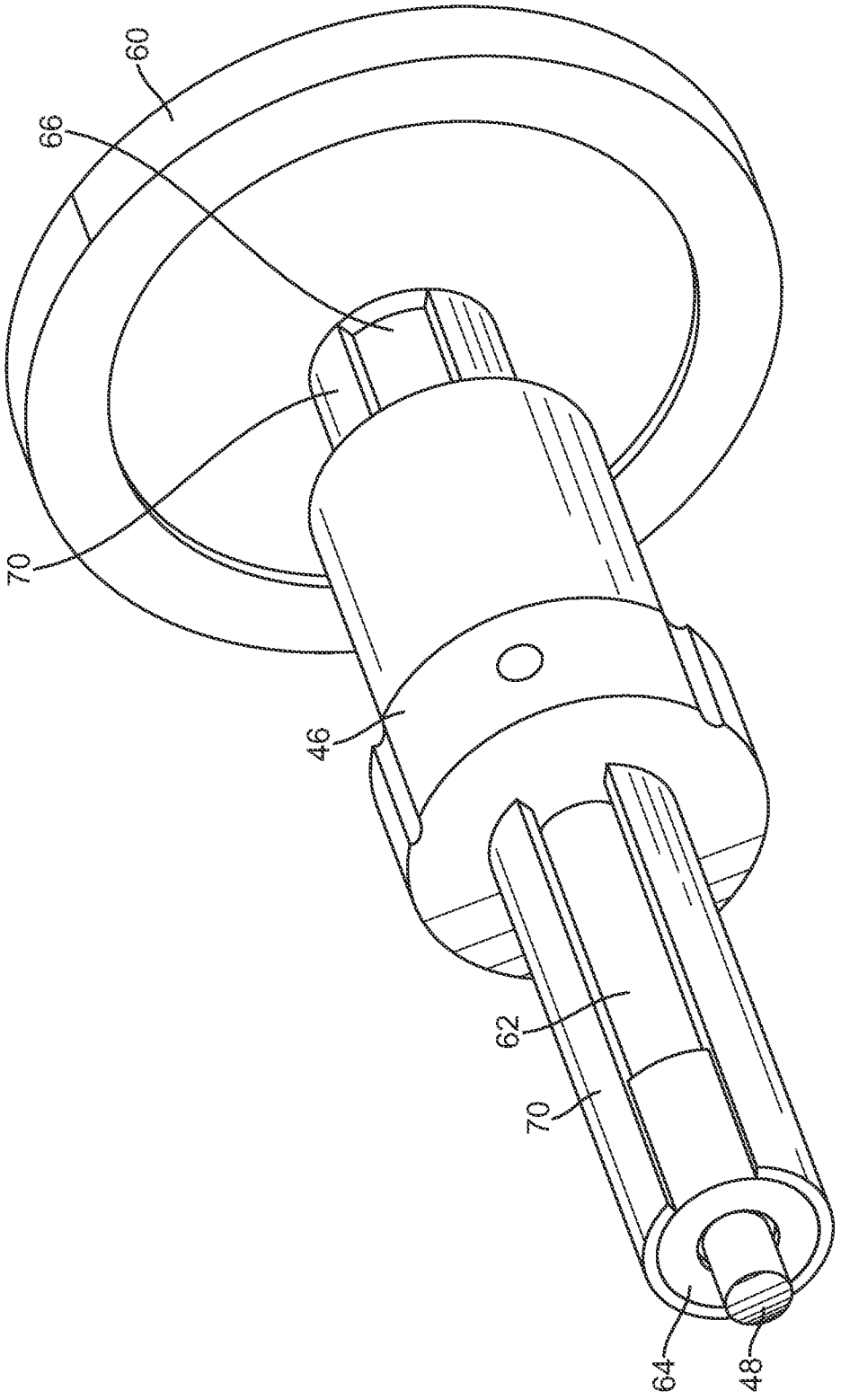

FIG. 8

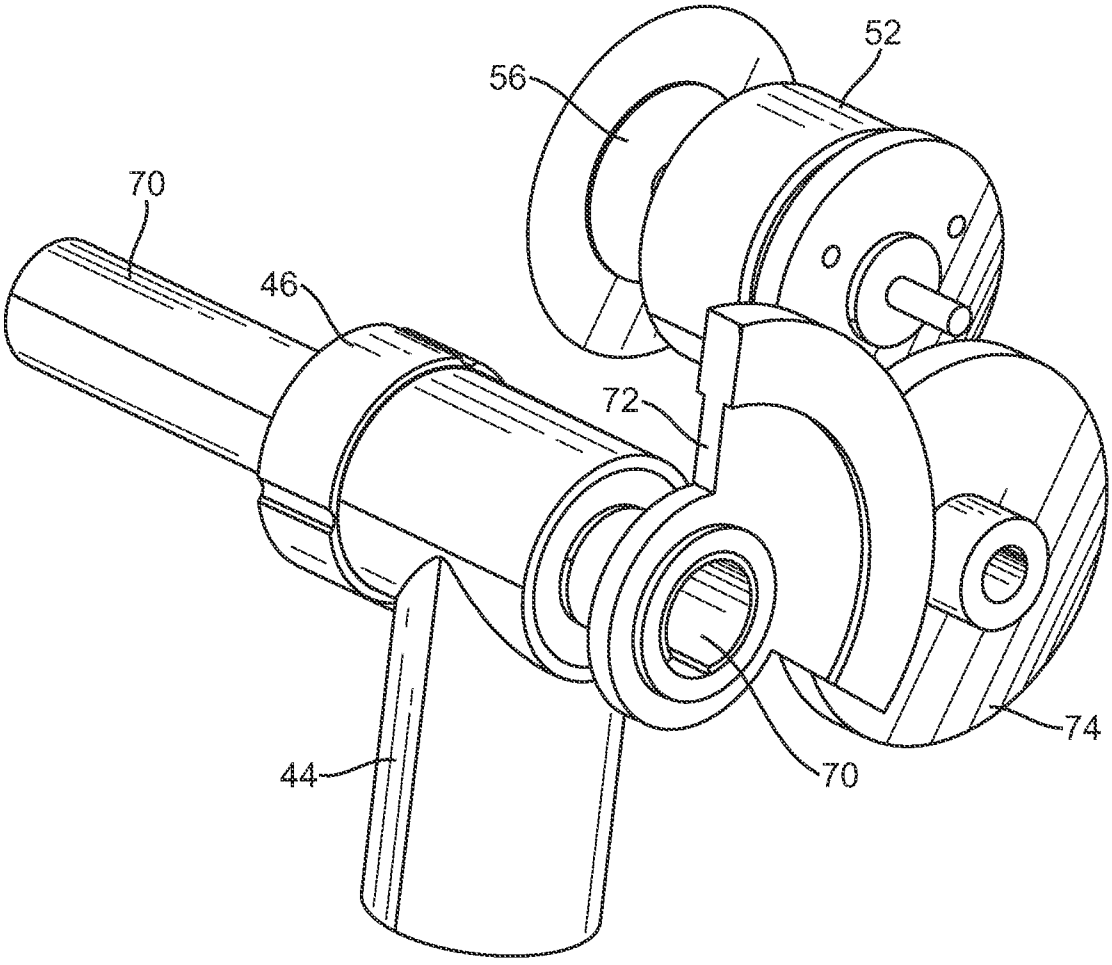

FIG. 9

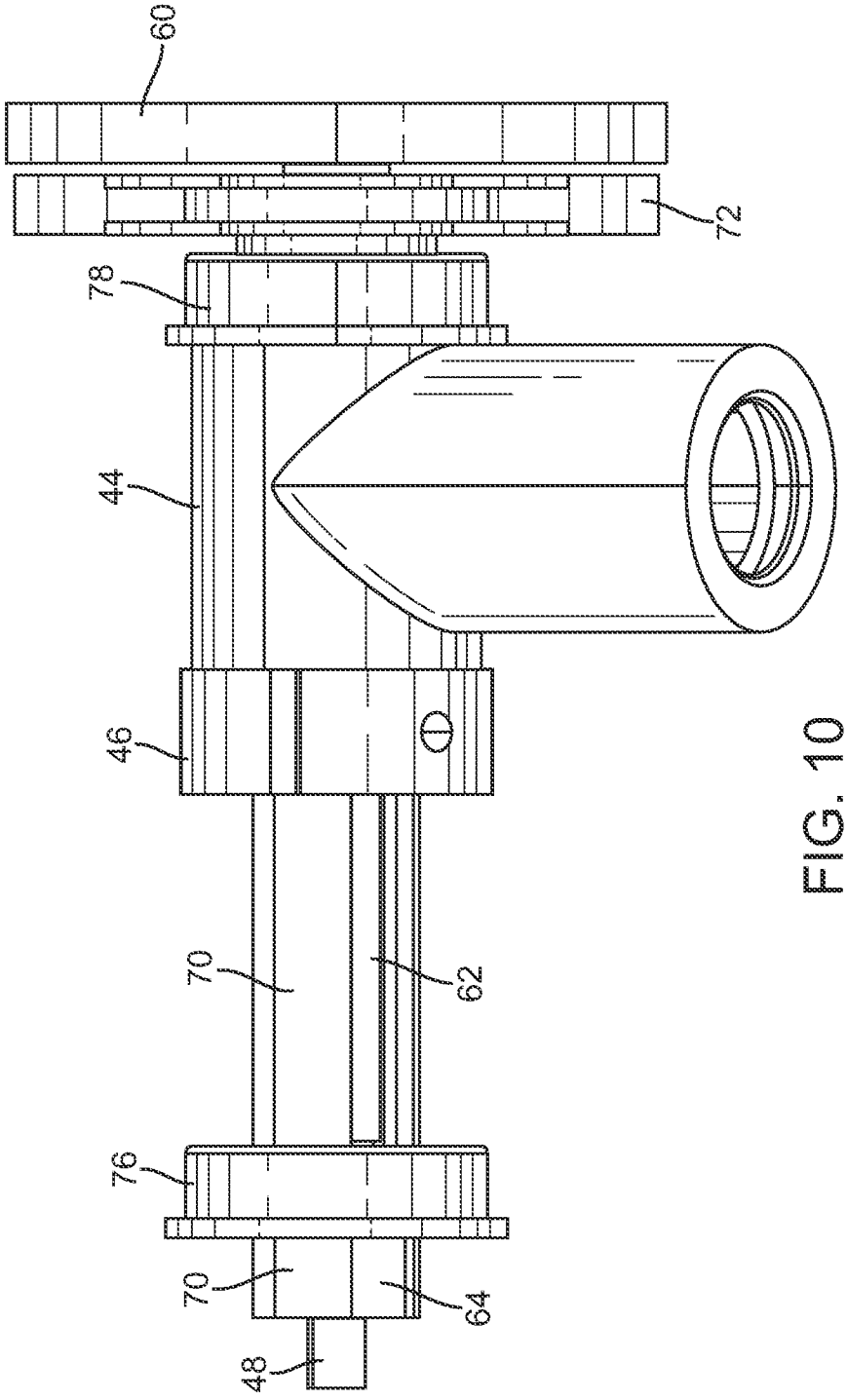

FIG. 10

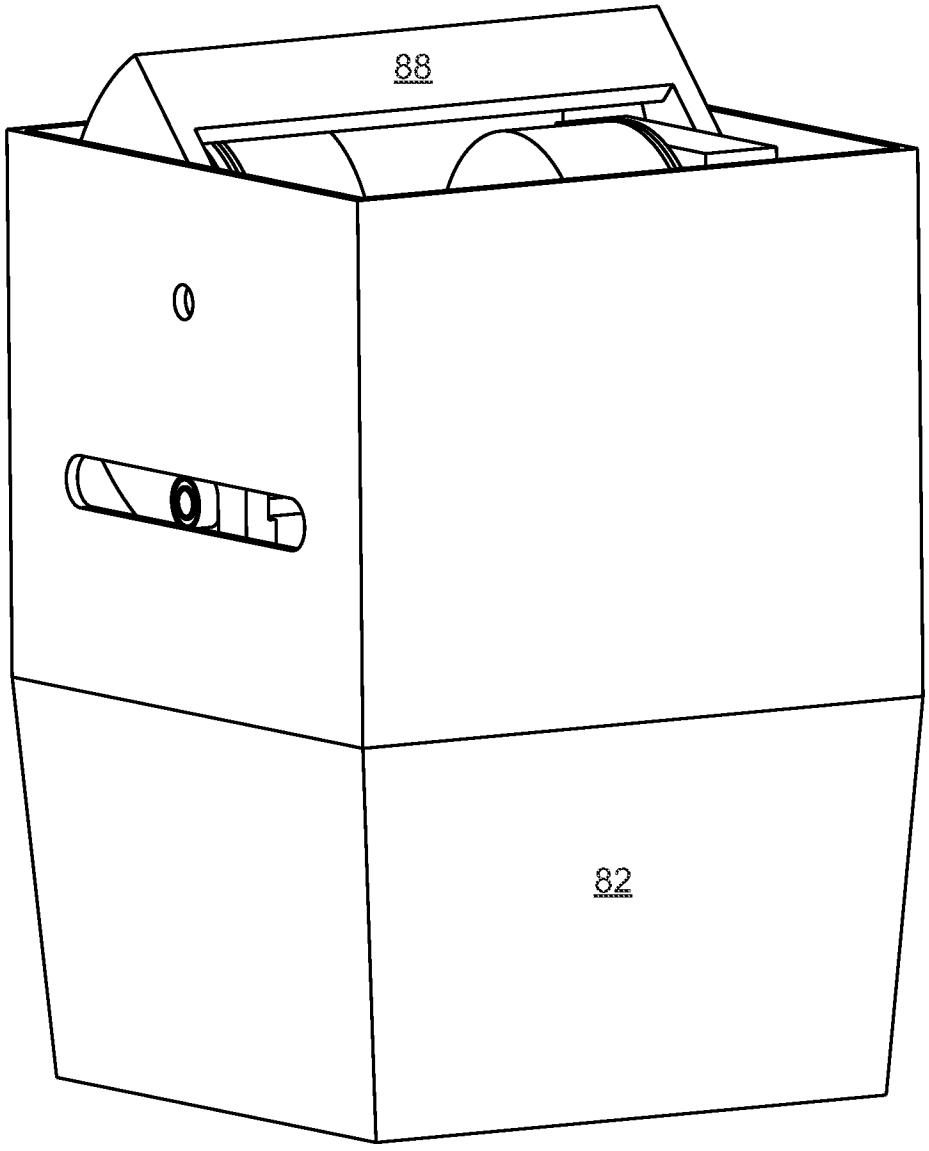

FIG. 11

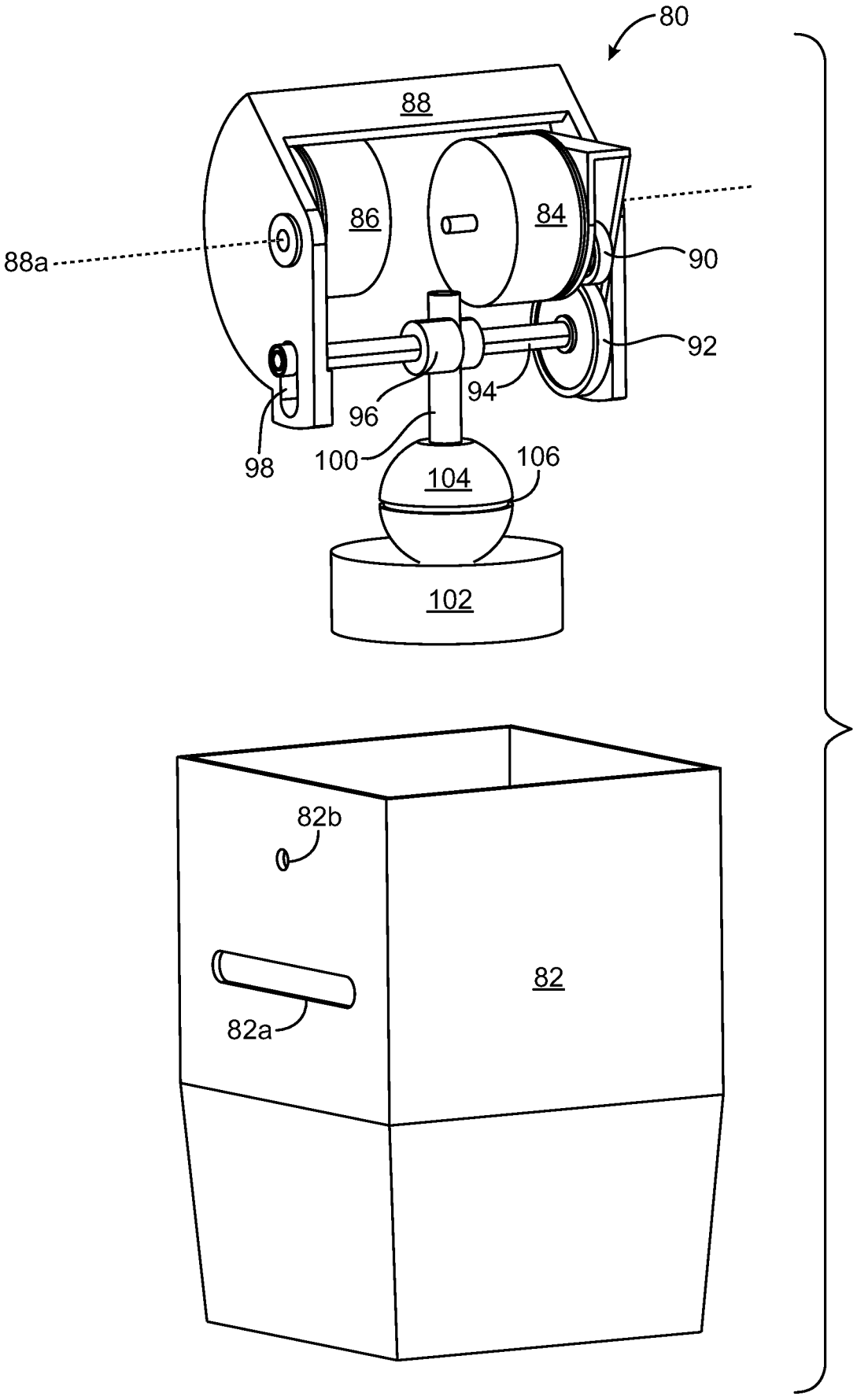

FIG. 12

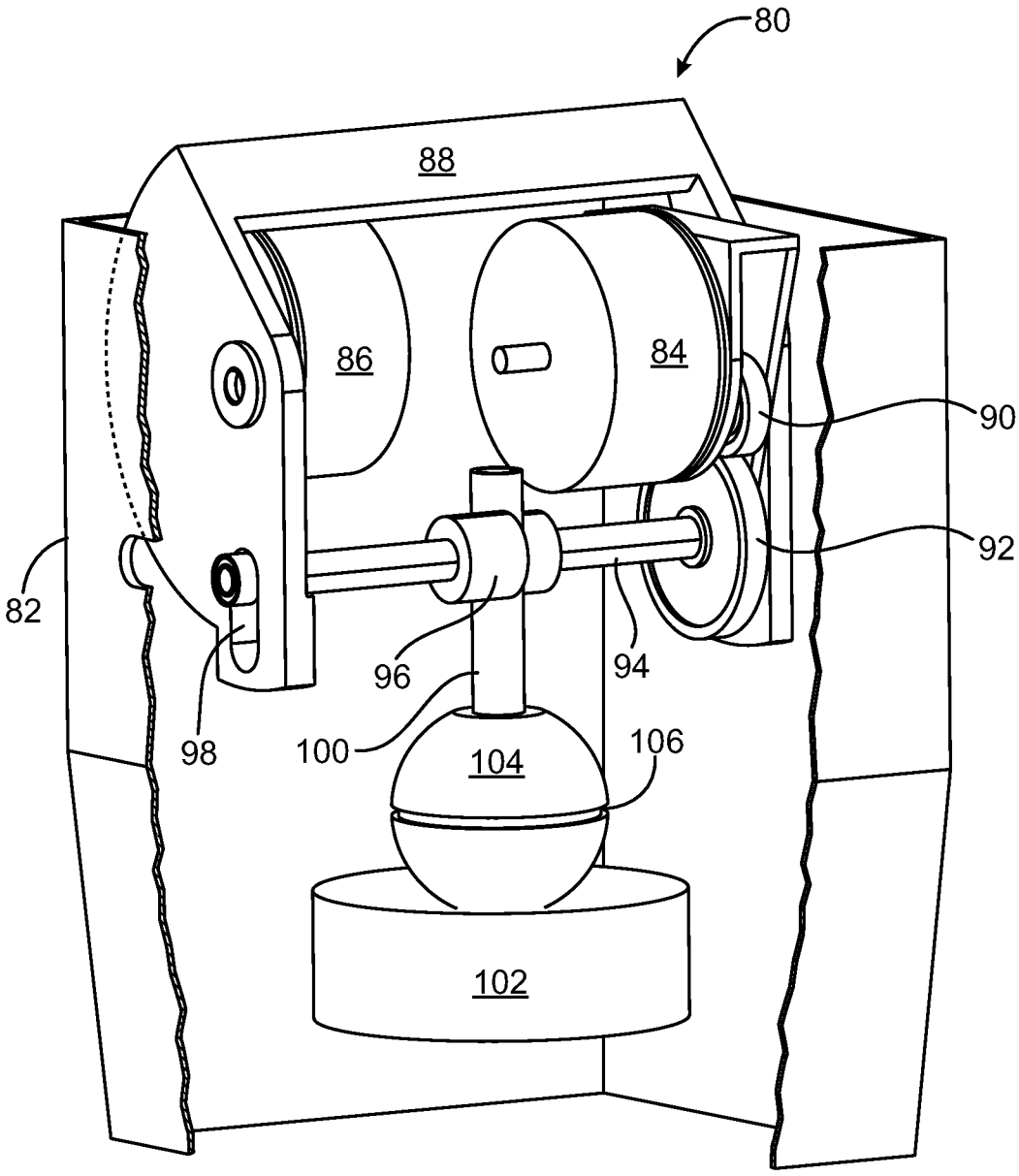

FIG. 13A

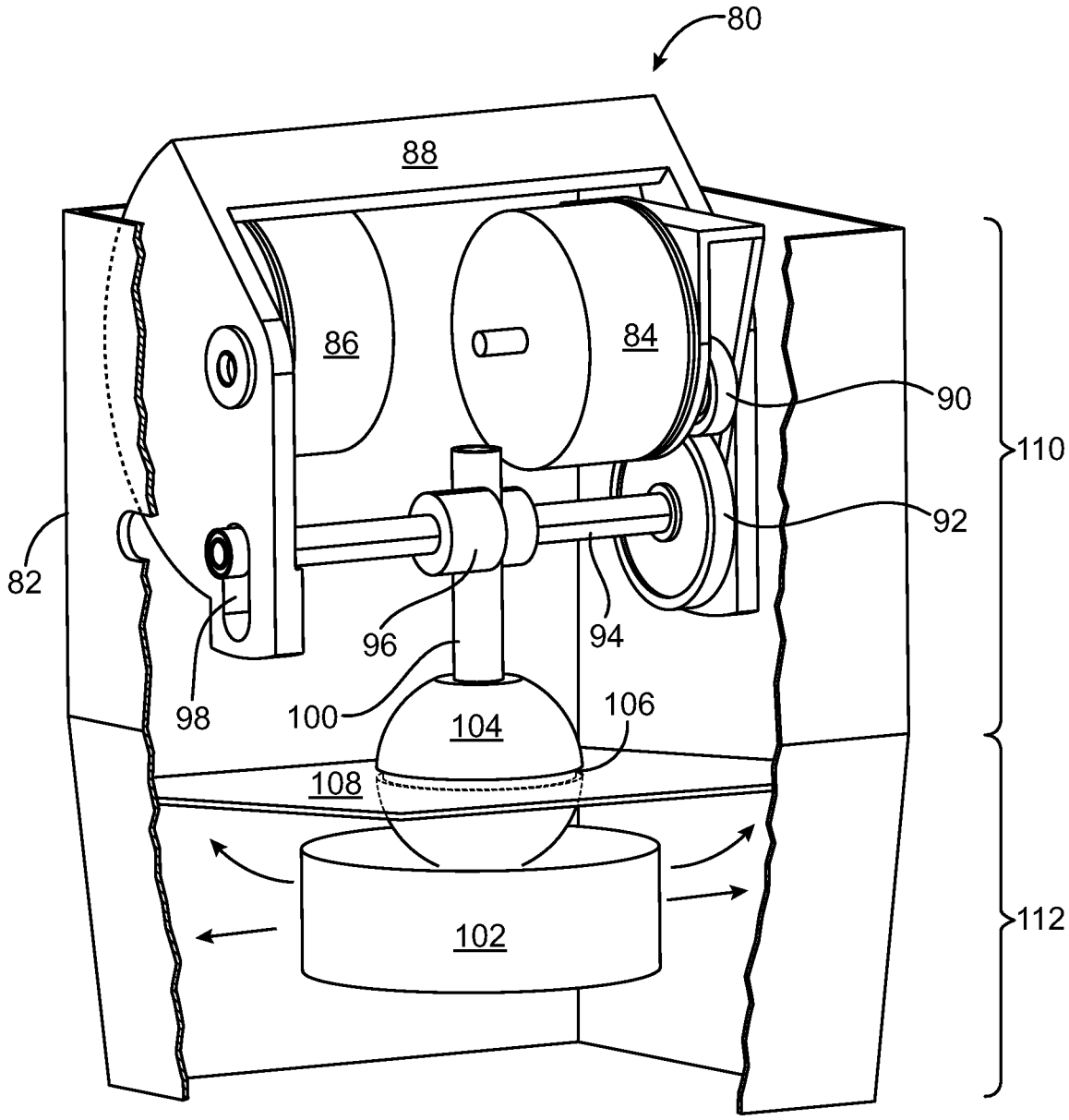

FIG. 13B

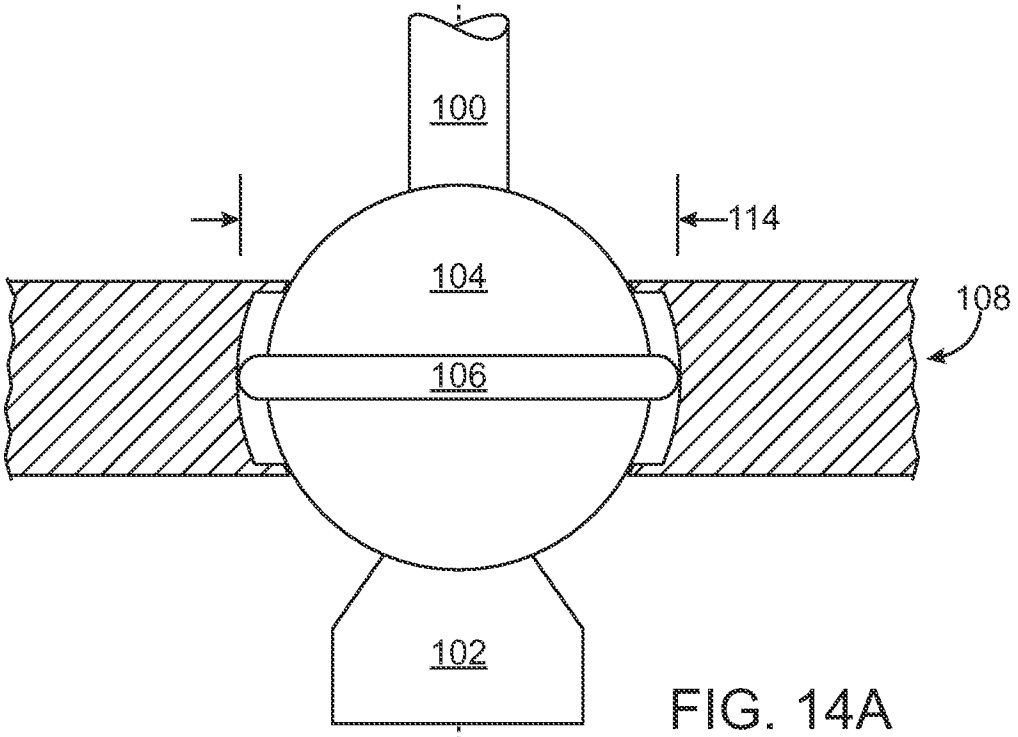

FIG. 14A

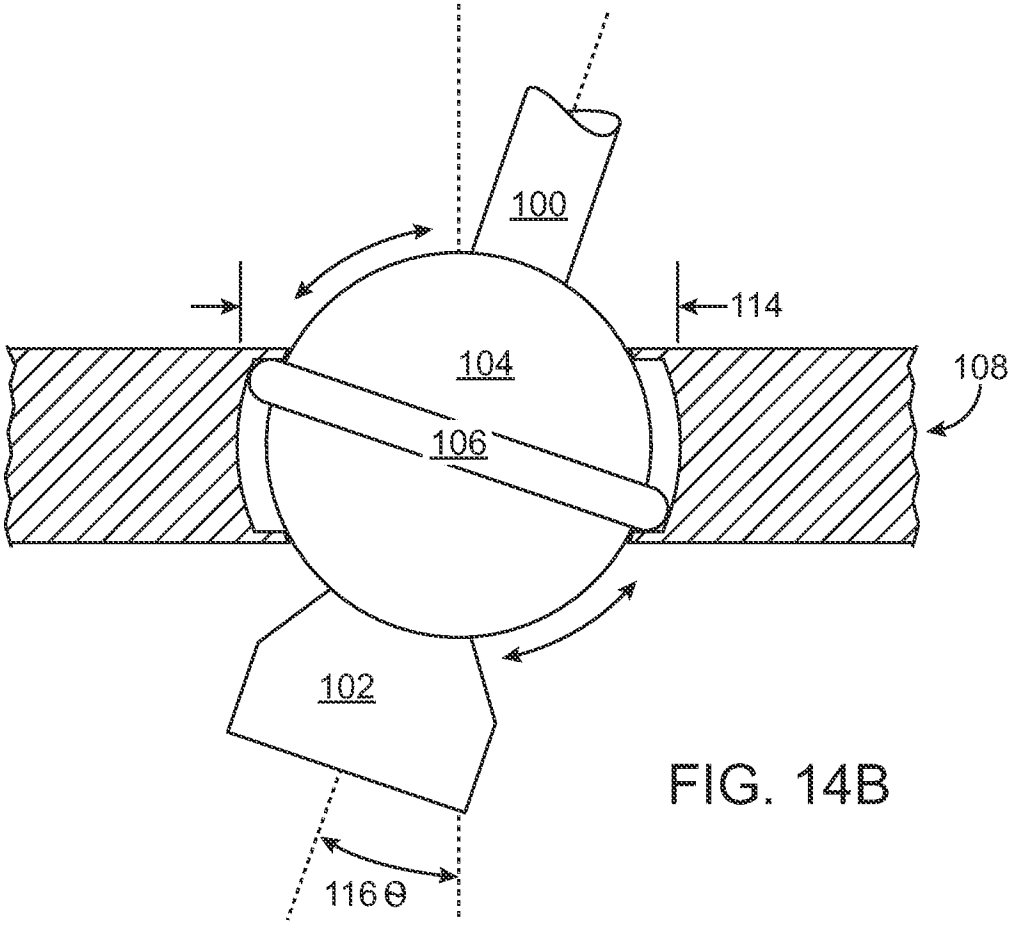

FIG. 14B

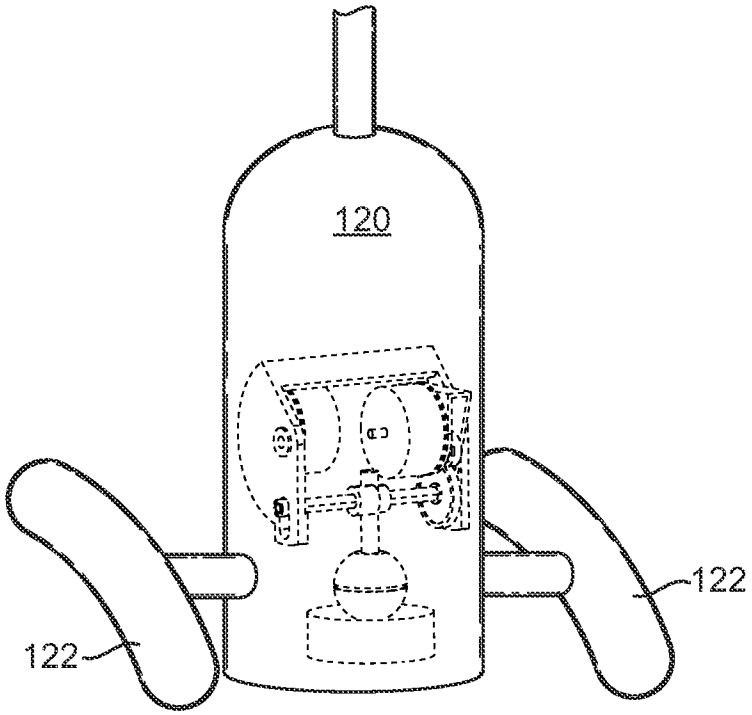

FIG. 15

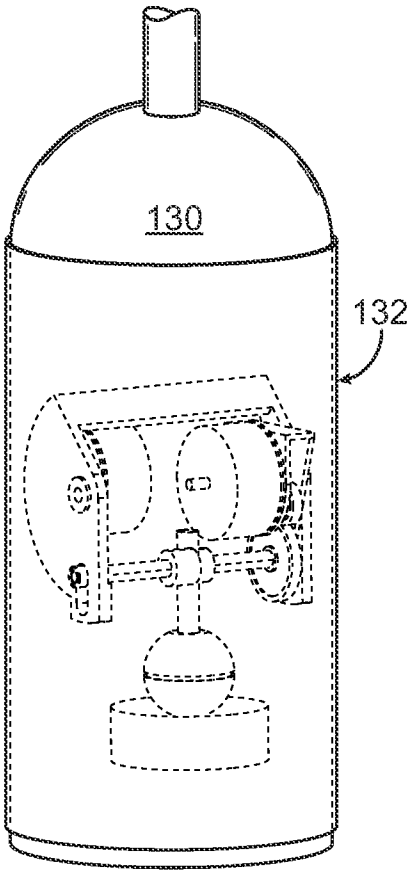

FIG. 16

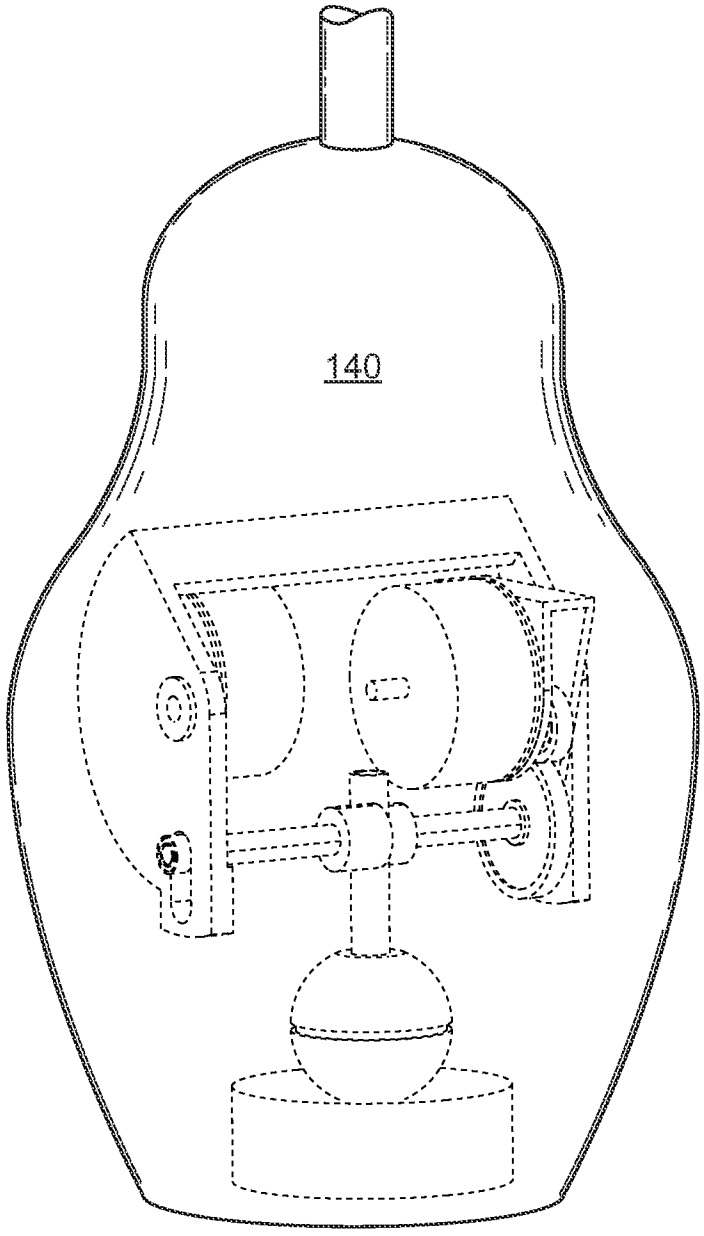

FIG. 17

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/032869

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61N7/02 G01N29/26 G10K11/35

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

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61N G01N G10K A61B

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

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 955 365 A (FRY FRANCIS J [US] ET AL) 11 September 1990 (1990-09-11) column 4, line 14 - column 5, line 59; figures 2,3	1-14, 16-28
Y		15,29
X	US 2005/154431 A1 (QUISTGAARD JENS U [US] ET AL) 14 July 2005 (2005-07-14) paragraphs [0028] - [0031], [0062], [0065] - [0068], [0077] - [0082], [0086], [0127], [0132], [0140] - [0143], [0213]; figures 2,4A	1-5,7, 10-12, 16-21, 23,25,26

-/--

[X] Further documents are listed in the continuation of Box C.

[X] See patent family annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
14 April 2009	24/04/2009

Name and mailing address of the ISA/	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Fax: (+31-70) 340-3016	Link, Tatiana

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2009/032869

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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