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(54) **HIGH FREQUENCY ULTRASOUND TRANSDUCER HOLDER AND ADJUSTABLE FLUID INTERFACE**

(76) Inventors: **Willet F. Whitmore III**, Longboat Key, FL (US); **Roger F. Wilson**, Sarasota, FL (US)

Correspondence Address:
STEPTOE & JOHNSON LLP
1330 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036 (US)

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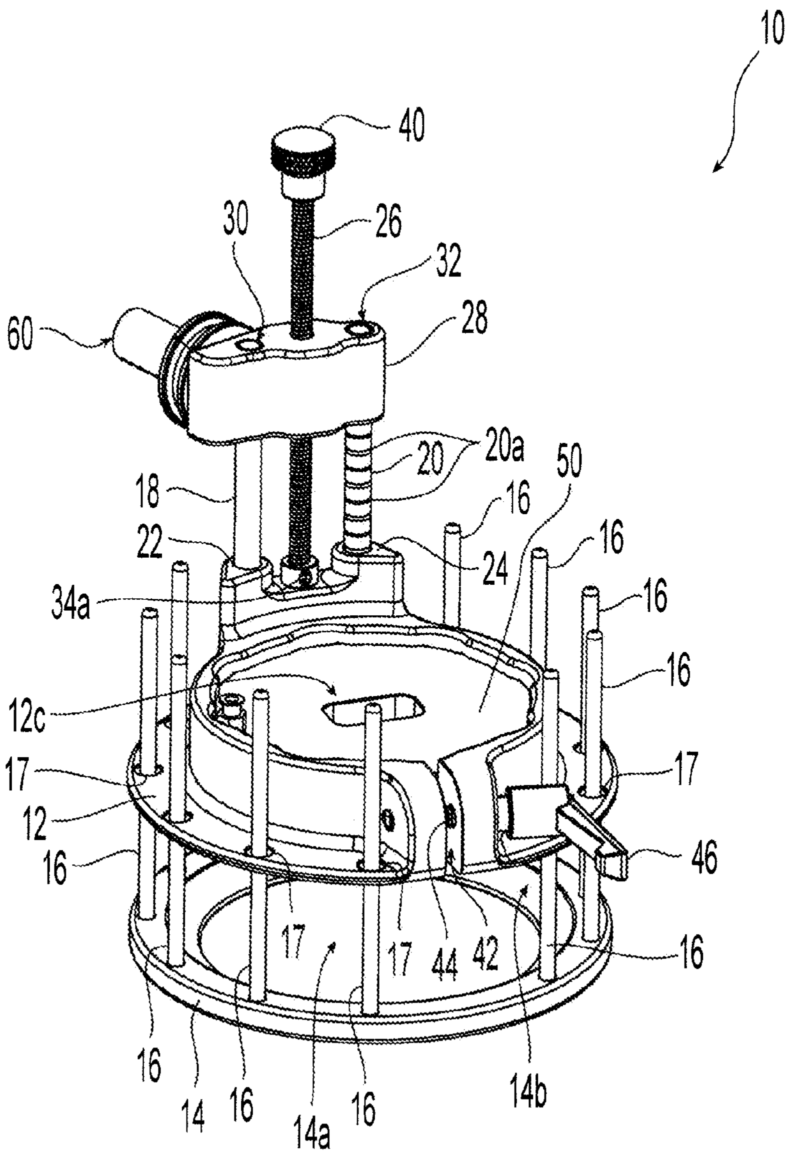
A61B 8/00 (2006.01)

(52) **U.S. Cl.** **600/459**

(57) **ABSTRACT**

An ultrasound transducer positioning system includes a curvilinear articulating arm, an ultrasound transducer, and a holder having a first region for receiving the transducer and a second region for a fluid interface disposed adjacent the first region. The holder is coupled to the curvilinear articulating arm and the second region is adjustable in size.



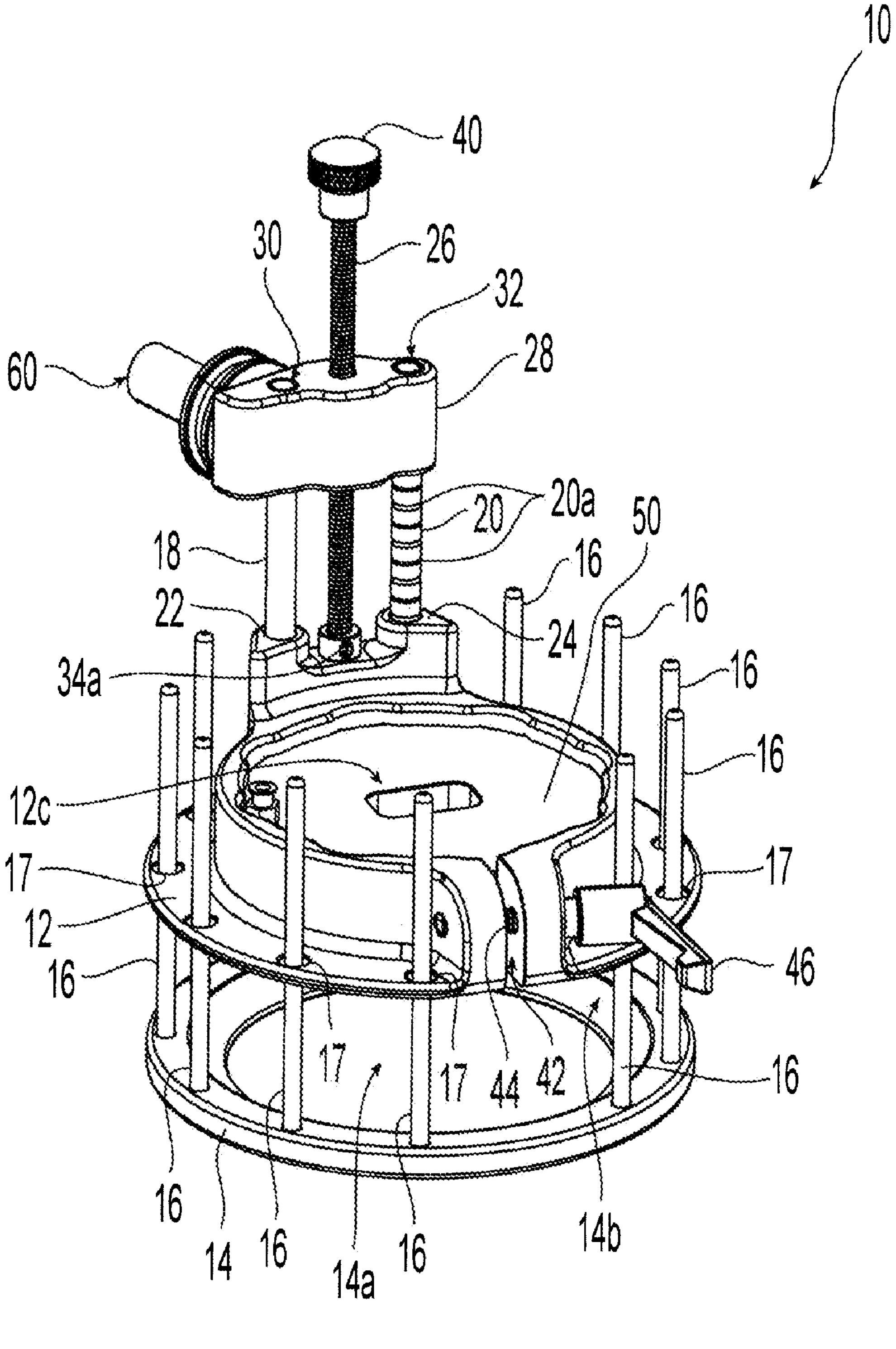

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Fig. 1A

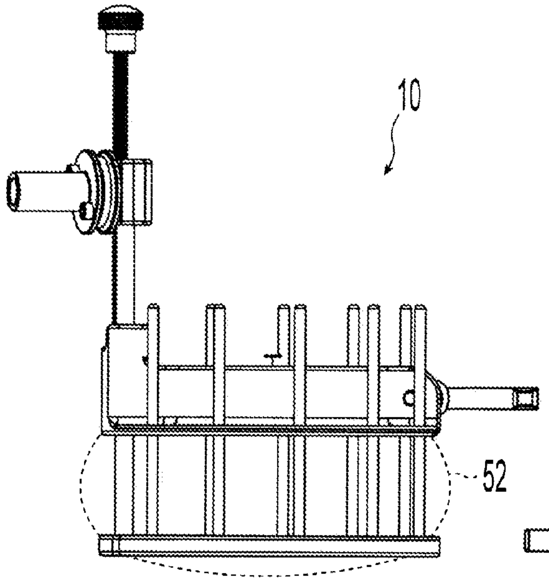

Fig. 1B

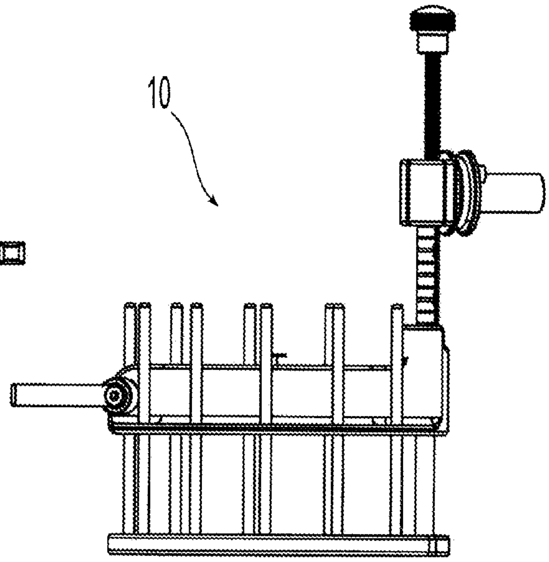

Fig. 1C

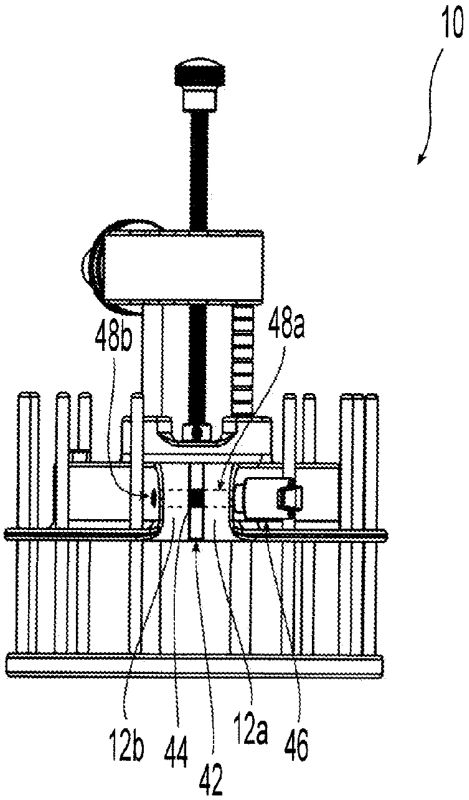

Fig. 1D

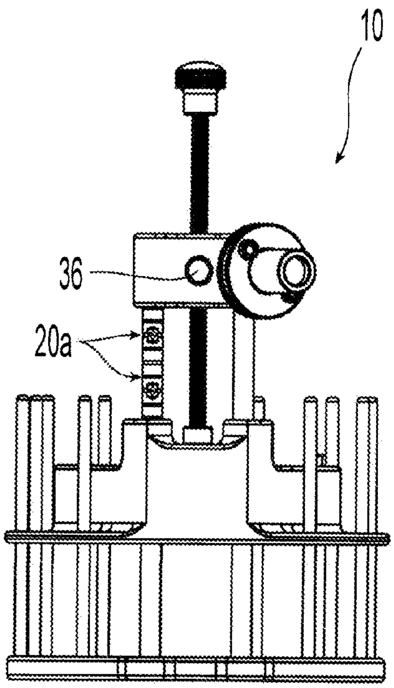

Fig. 1E

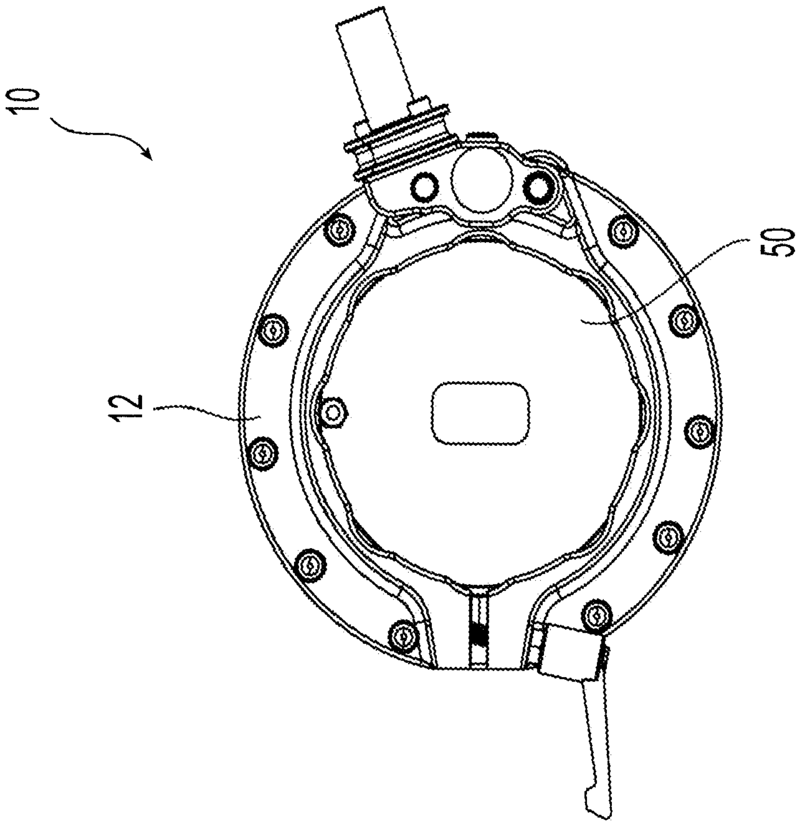

Fig. 1G

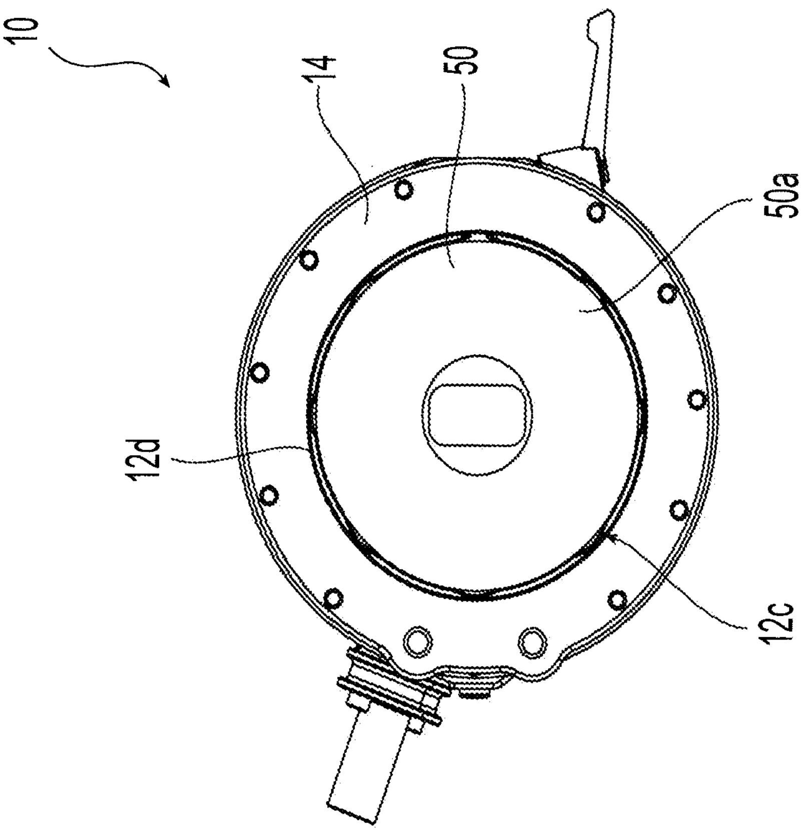

Fig. 1F

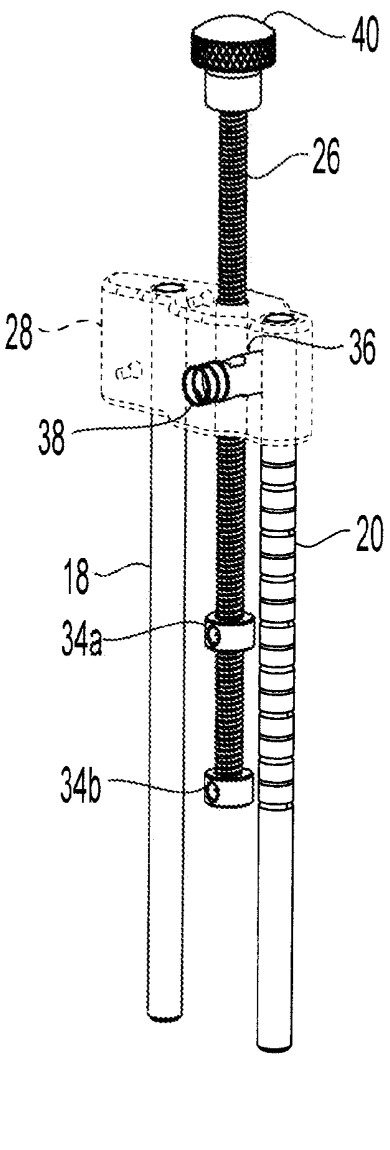

Fig. 1H

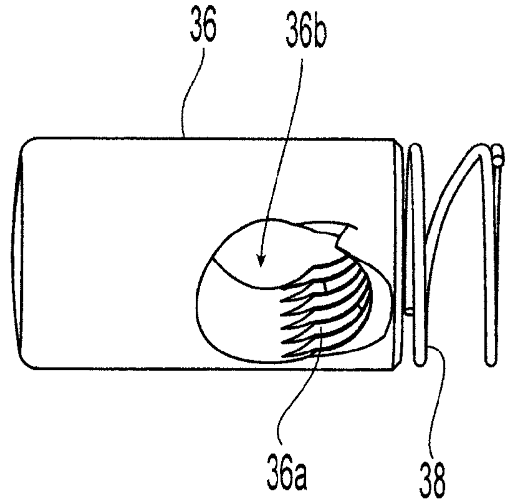

Fig. 1I

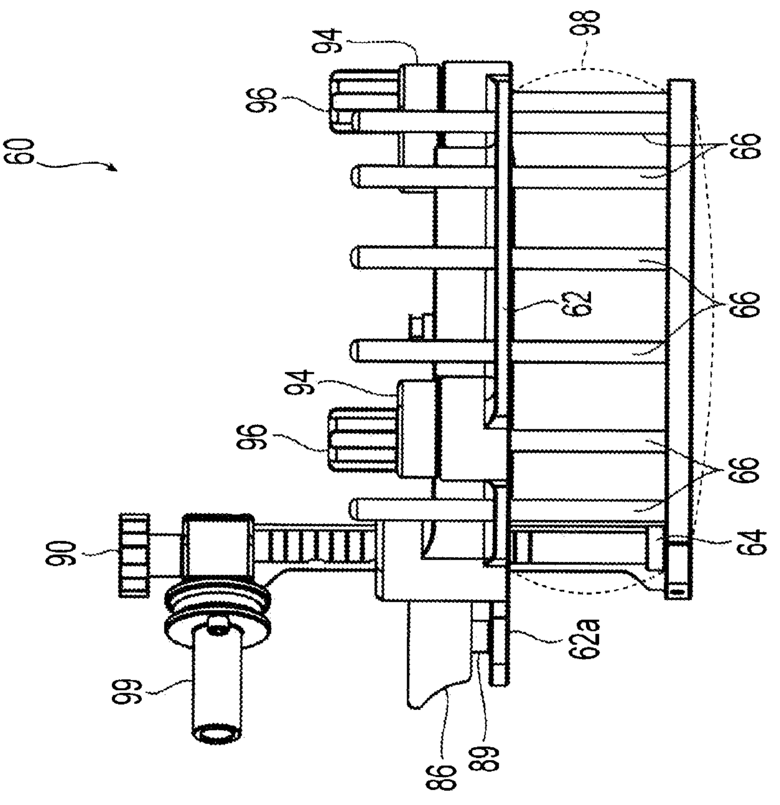
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Fig. 1K

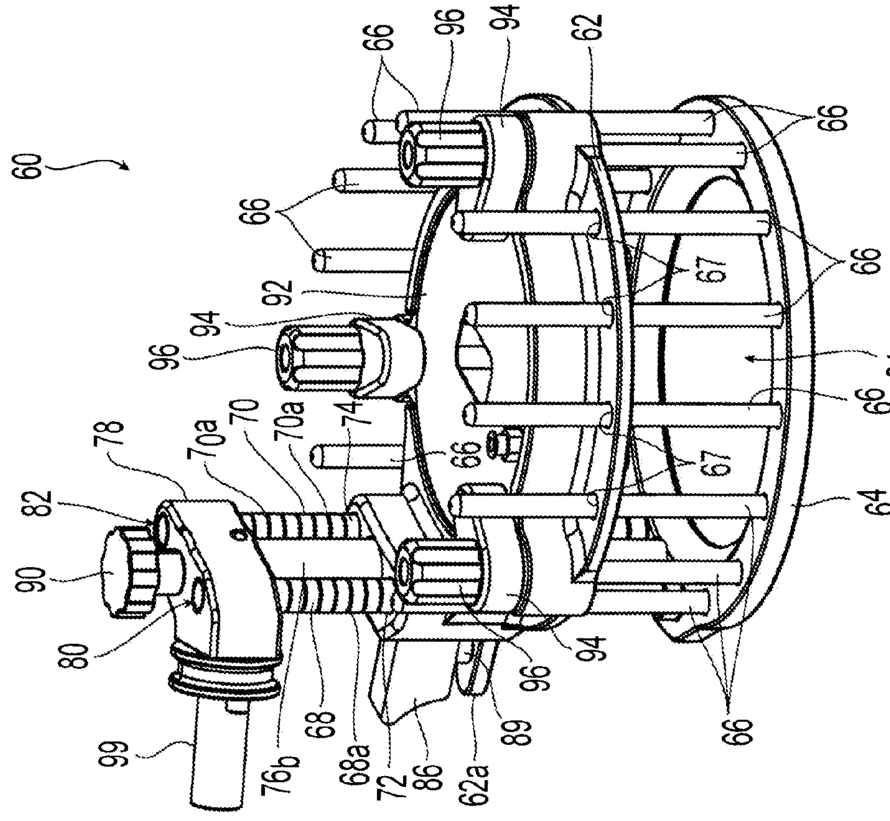
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Fig. 1J

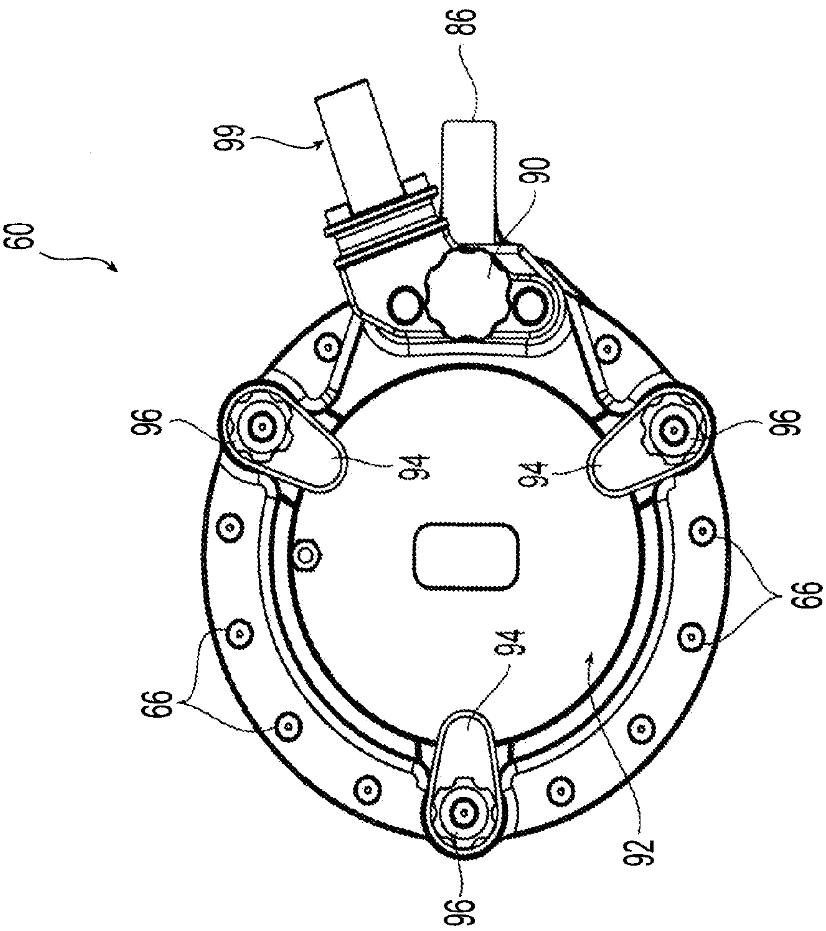
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Fig. 1M

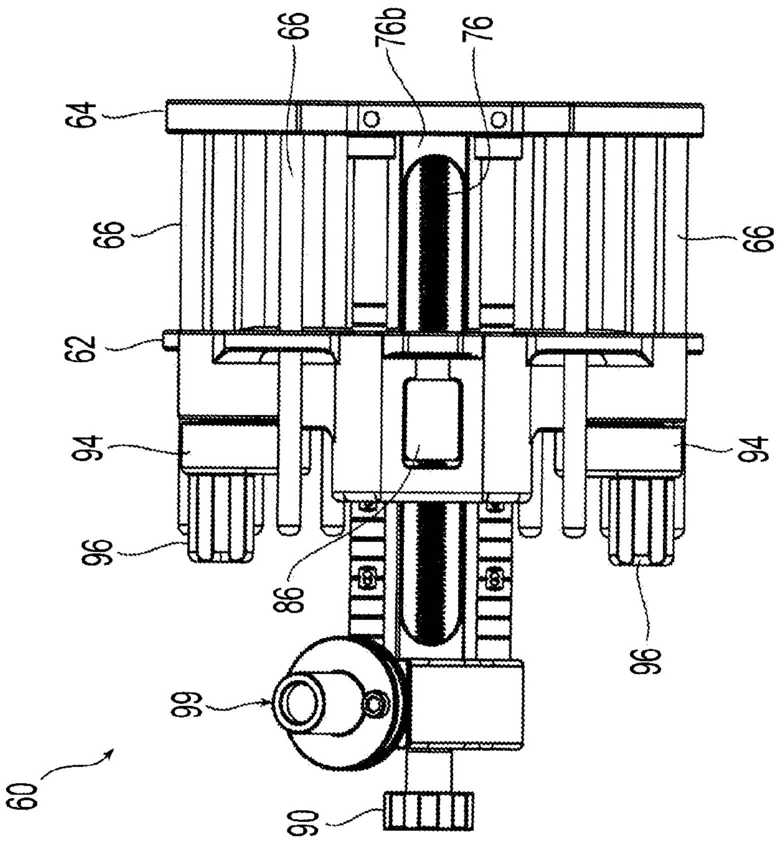
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Fig. 1L

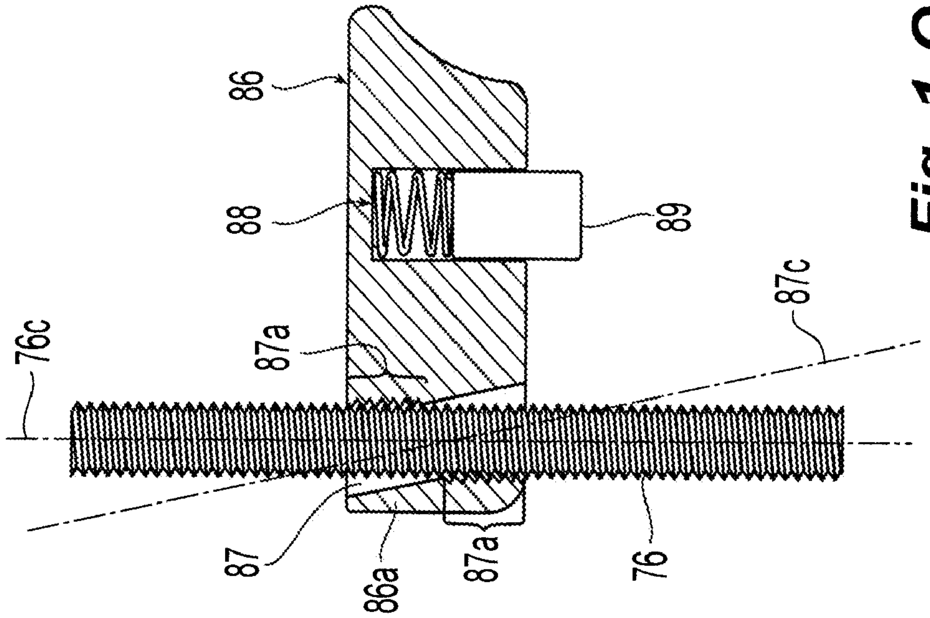

Fig. 1-O

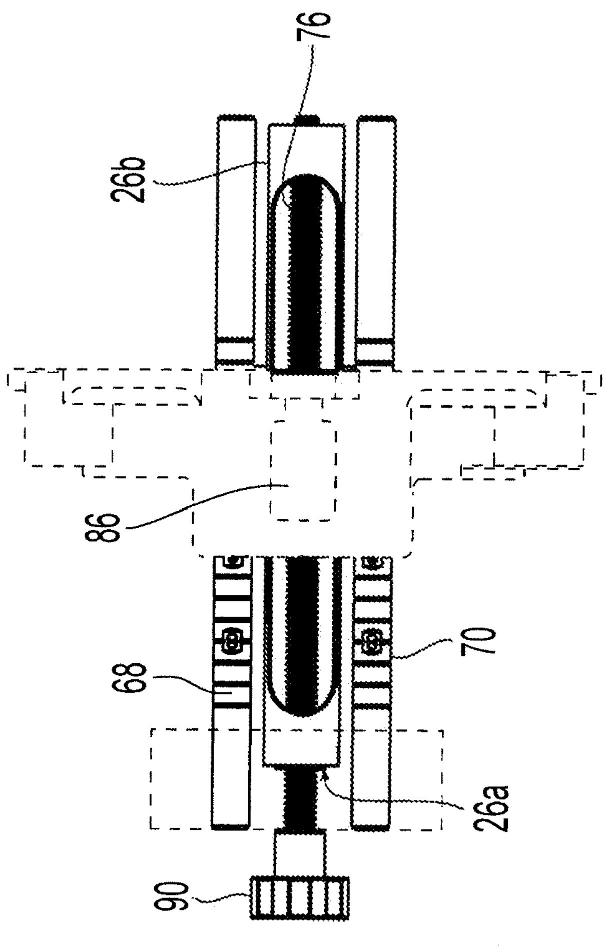

Fig. 1N

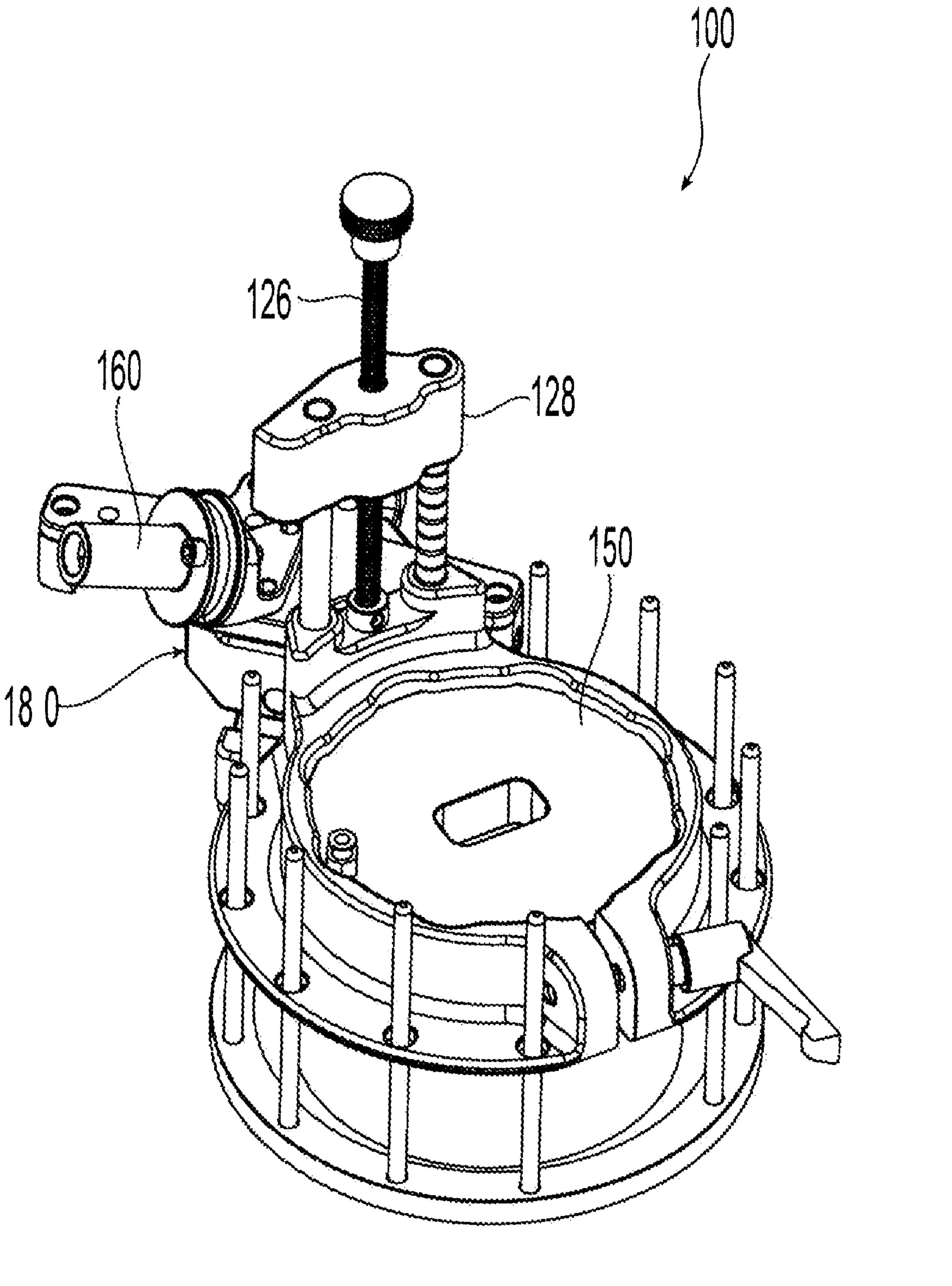

Fig. 2 A

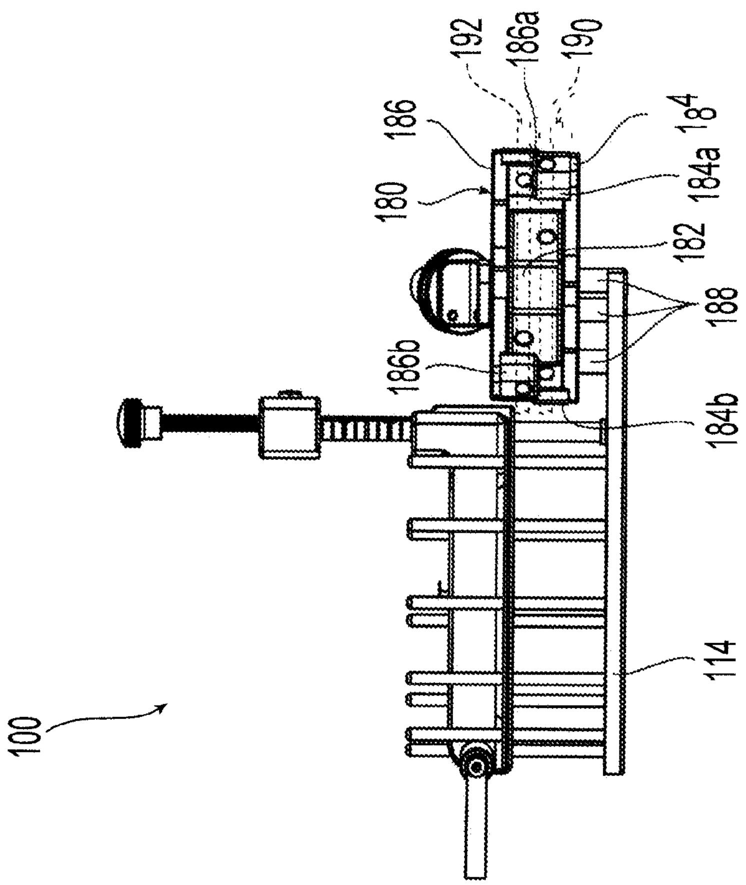
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Fig. 2C

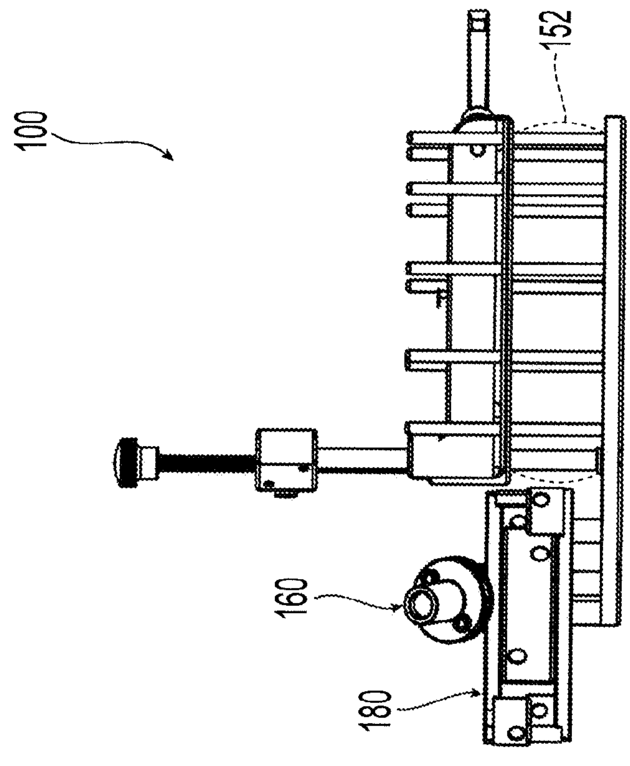
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Fig. 2B

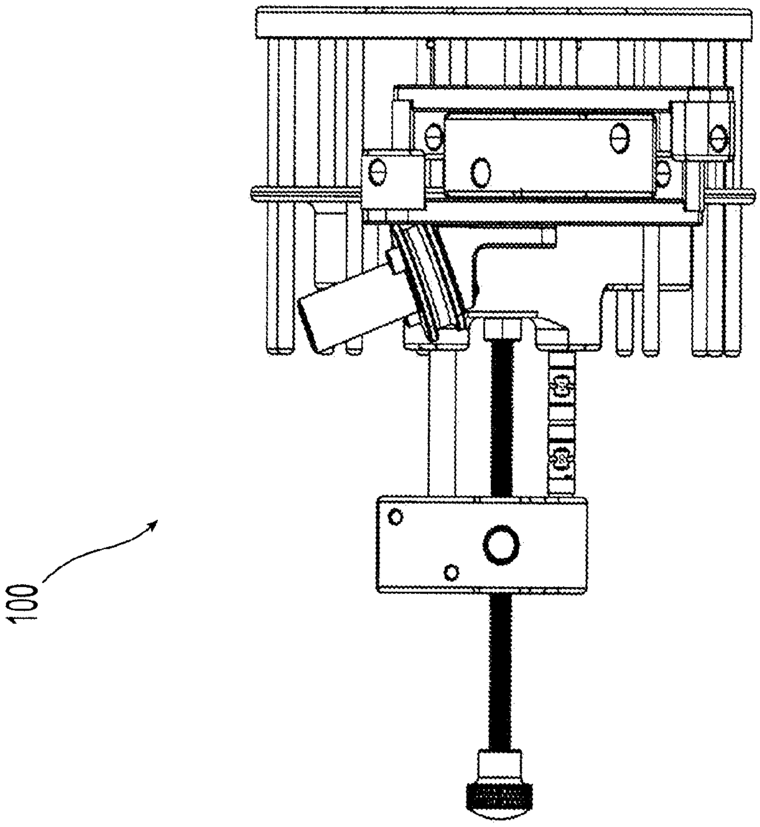


Fig. 2E

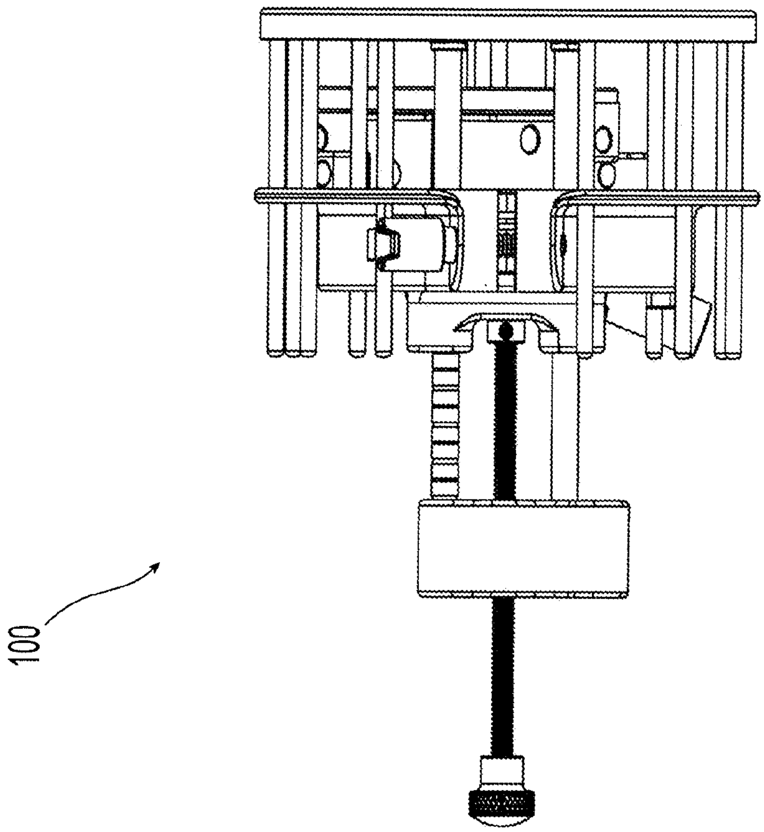


Fig. 2D

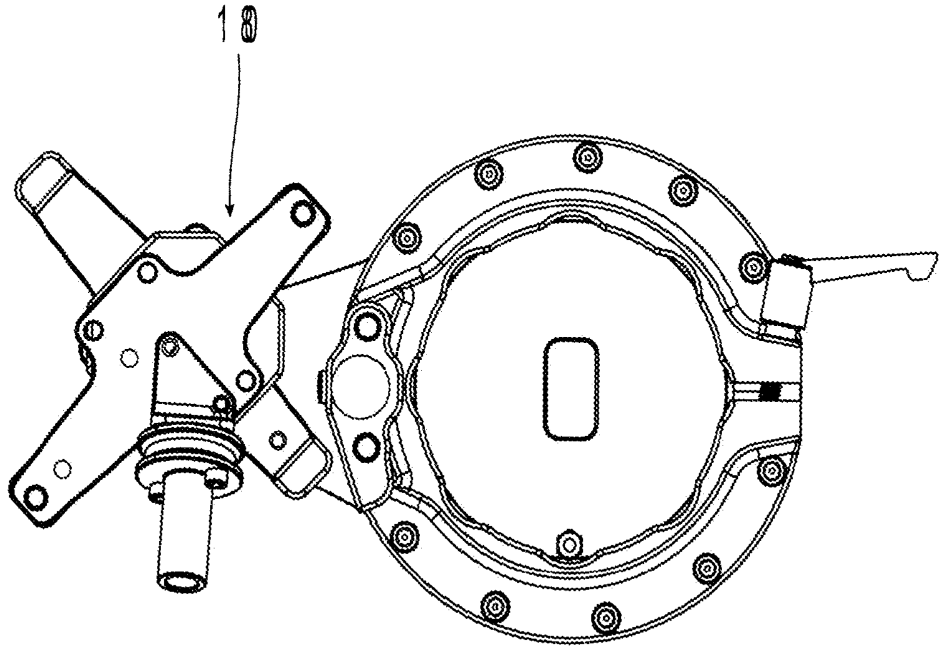
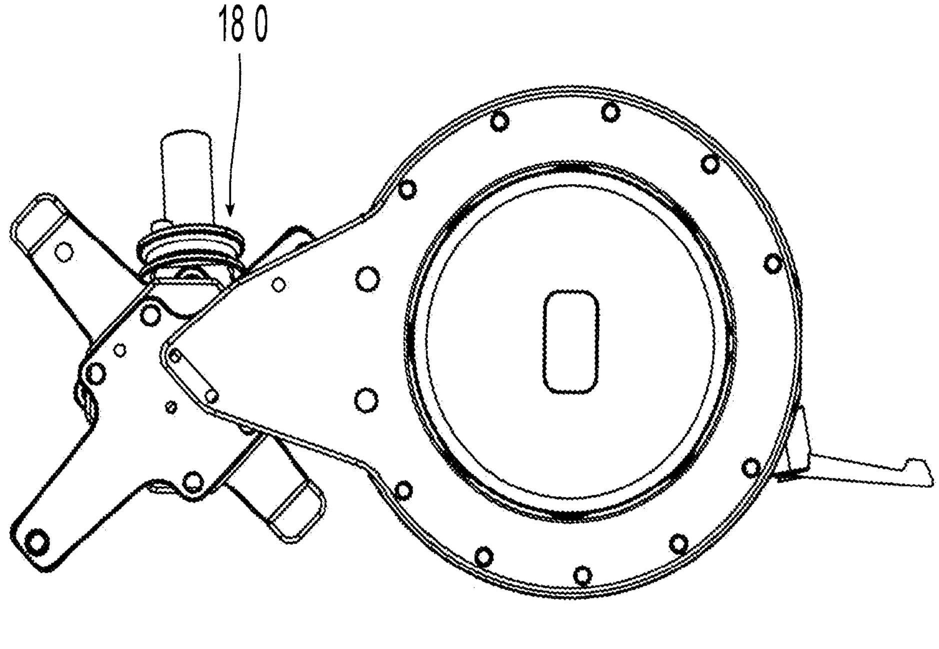


Fig .2F



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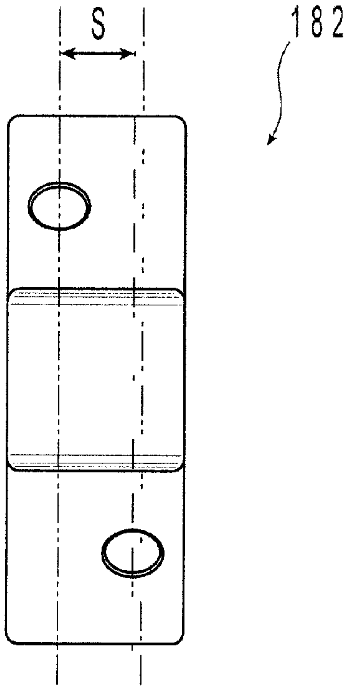

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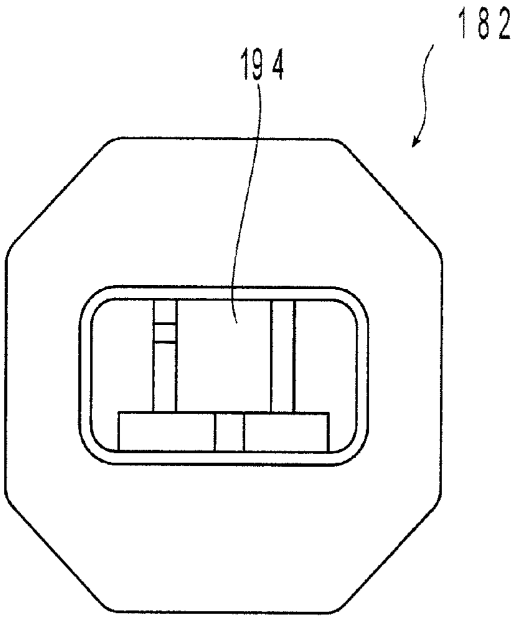

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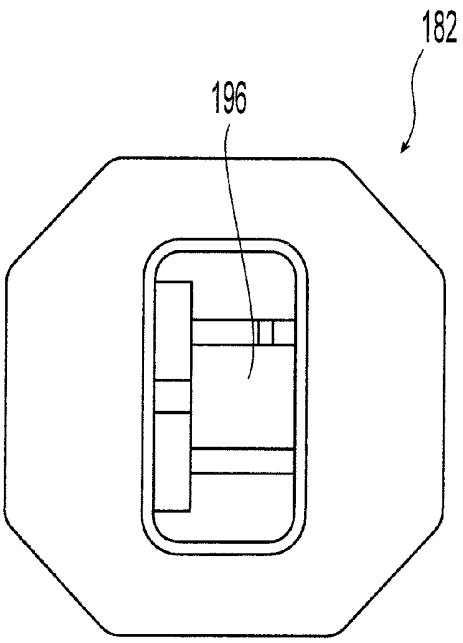


Fig. 2J

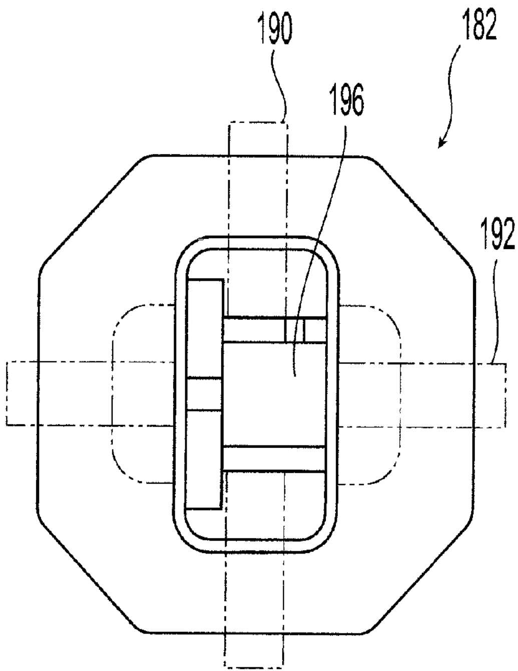


Fig. 2K

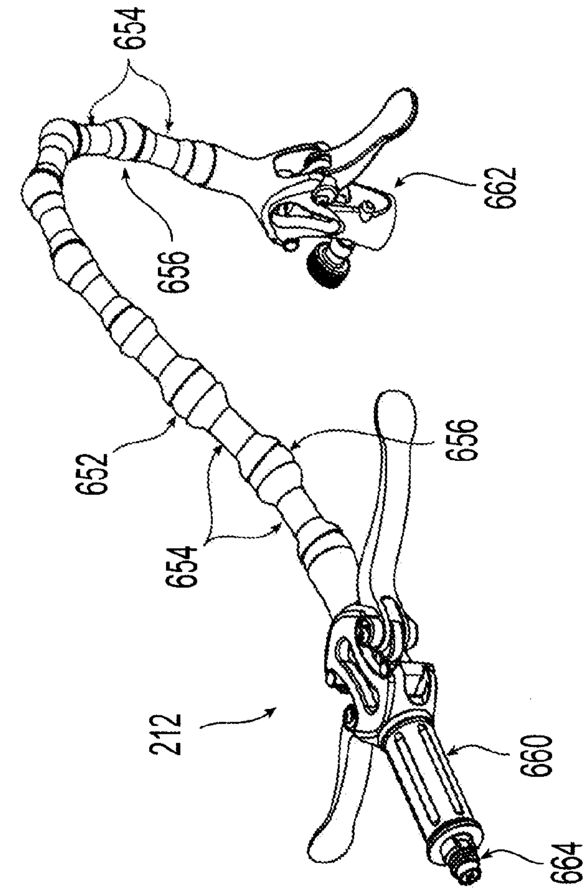
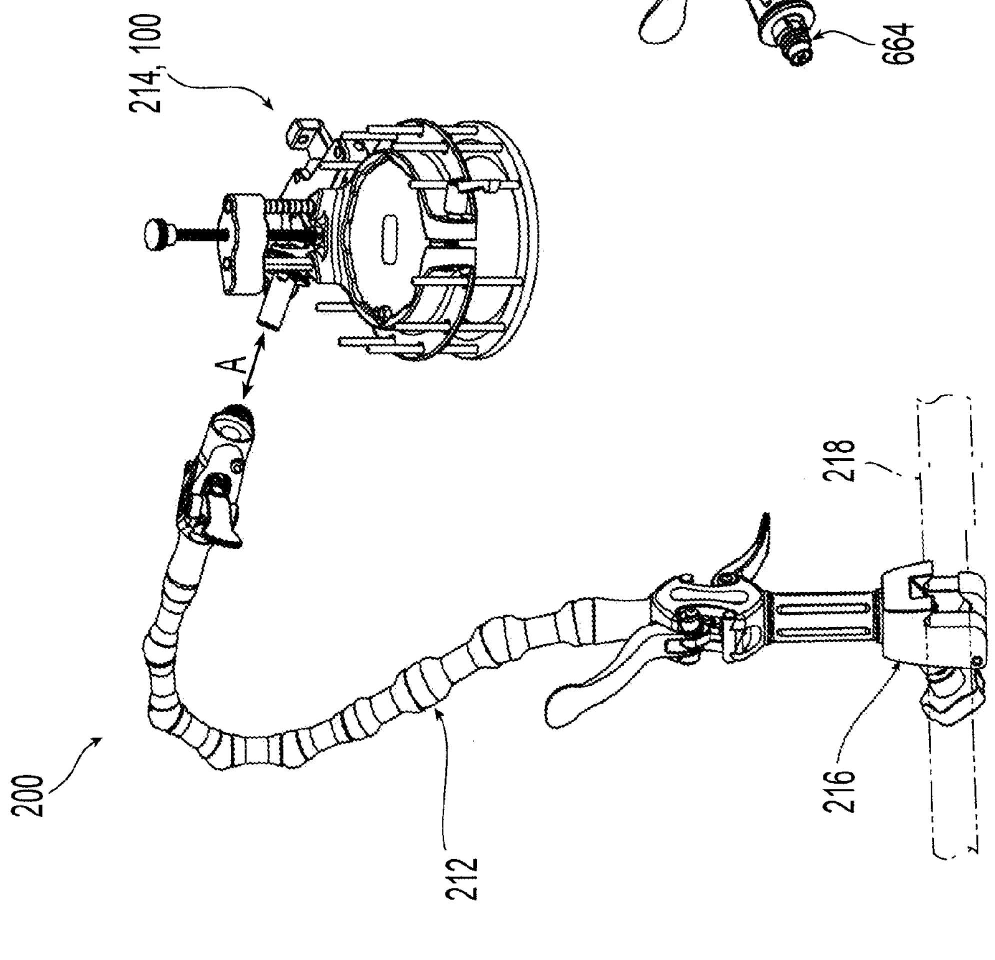


Fig. 4A



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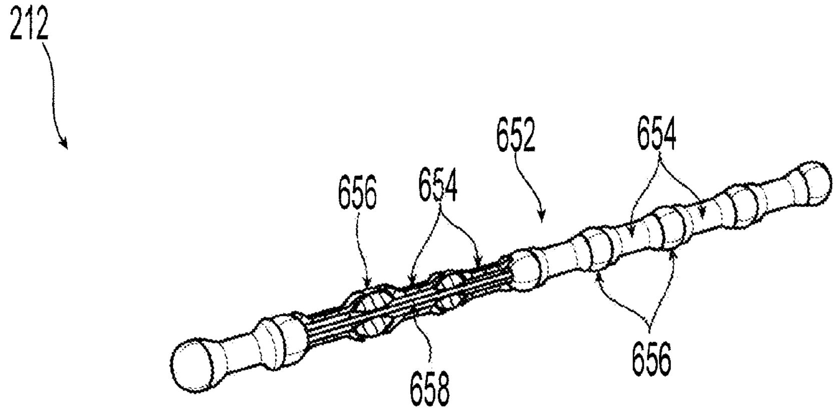
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Fig. 4B

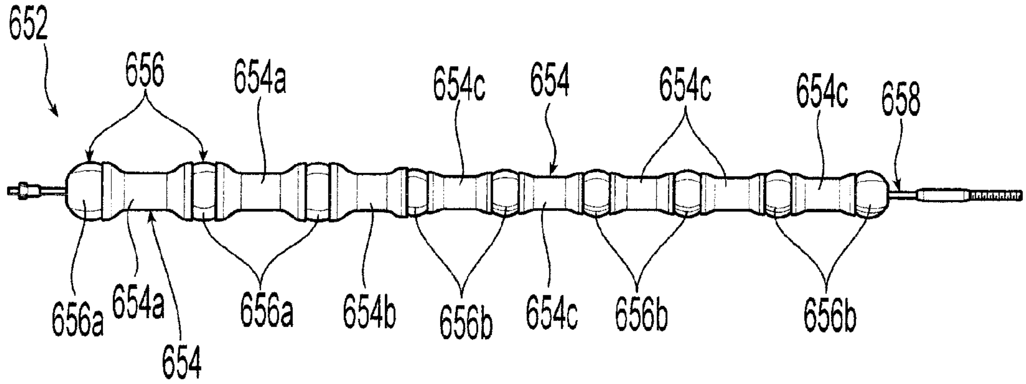
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Fig. 4C

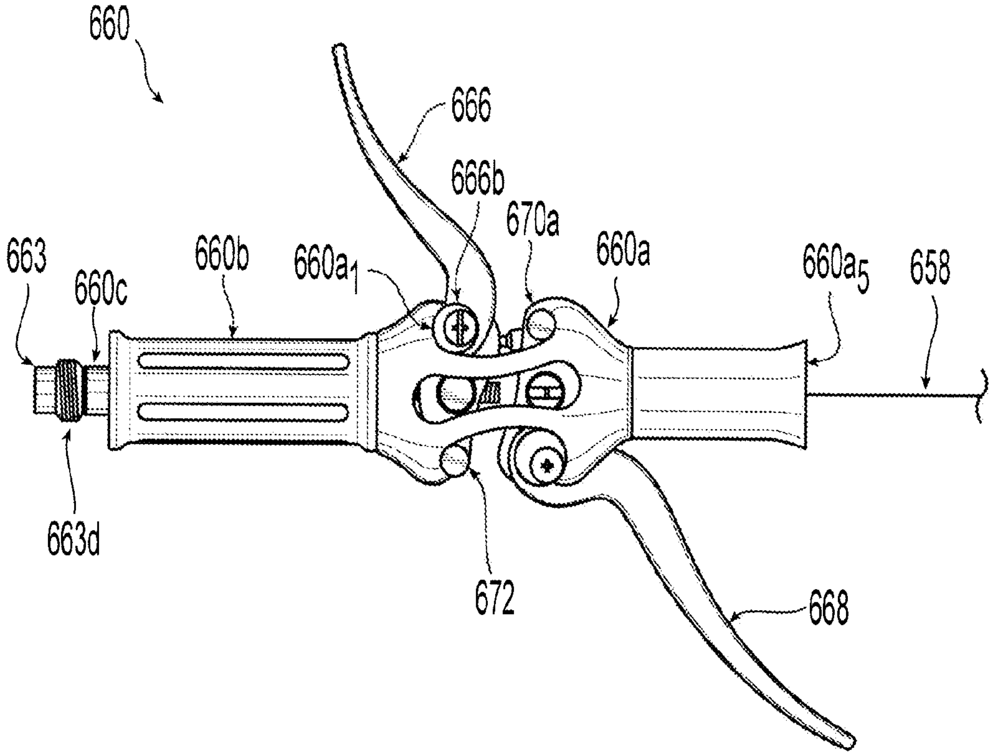
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Fig. 4D

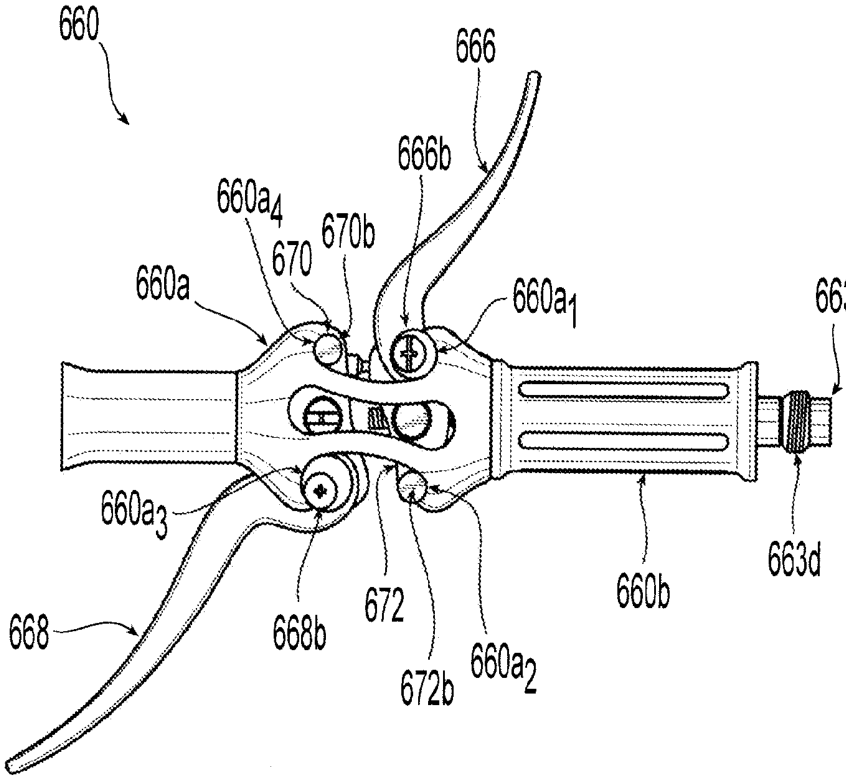
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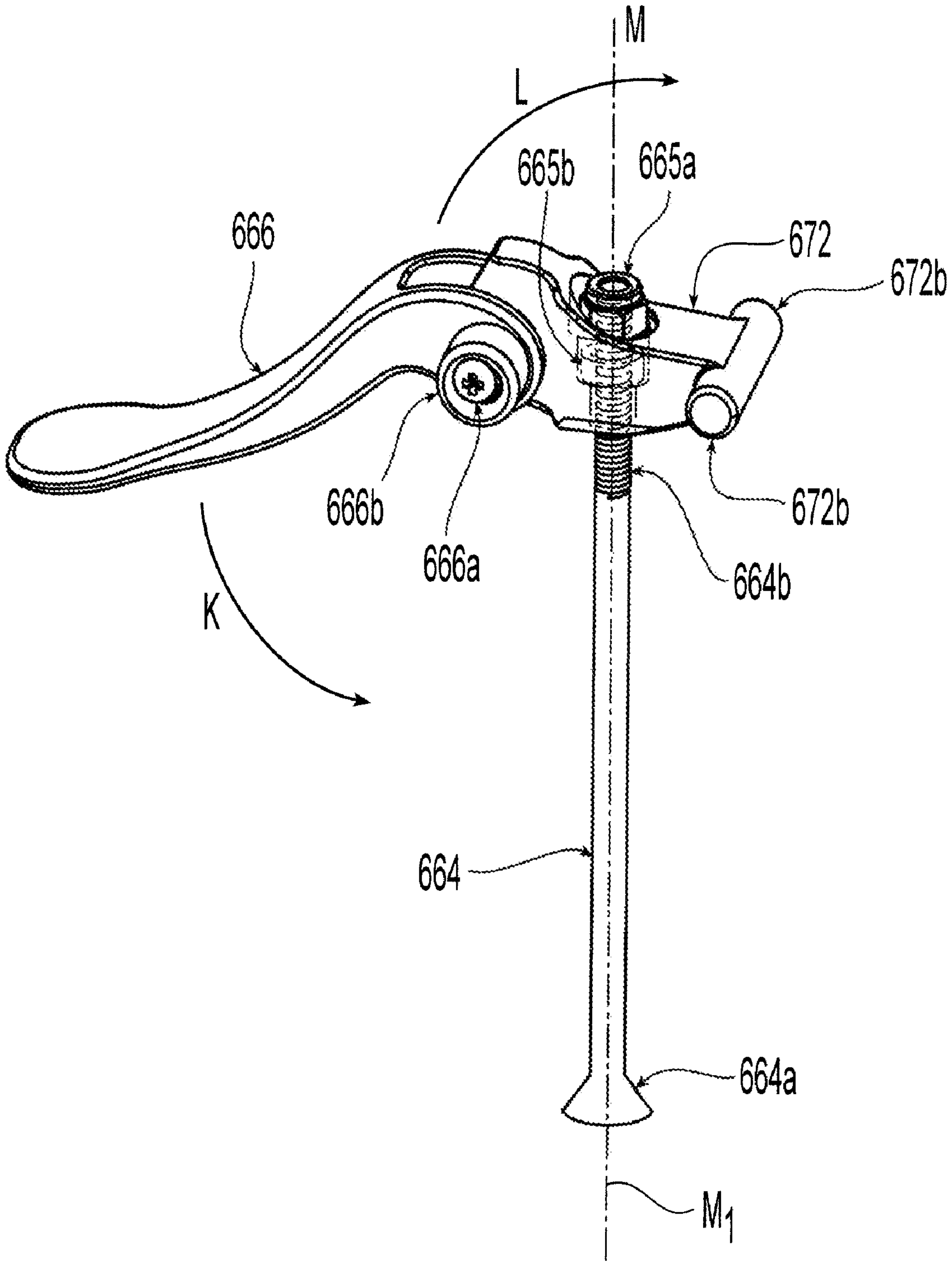
Fig. 4E



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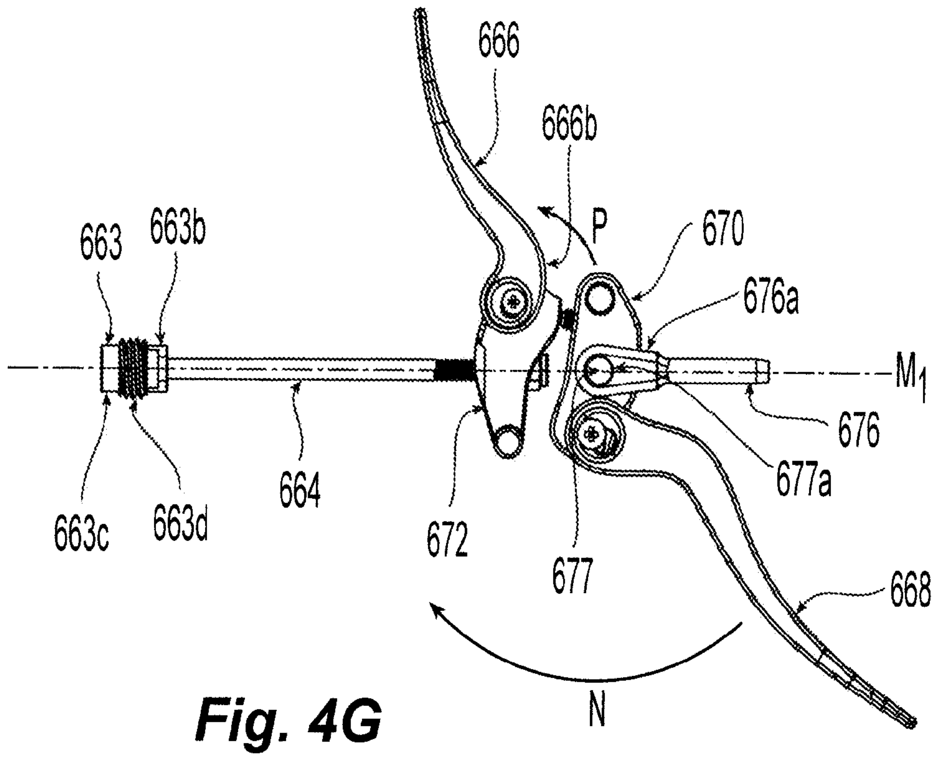
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Fig. 4G

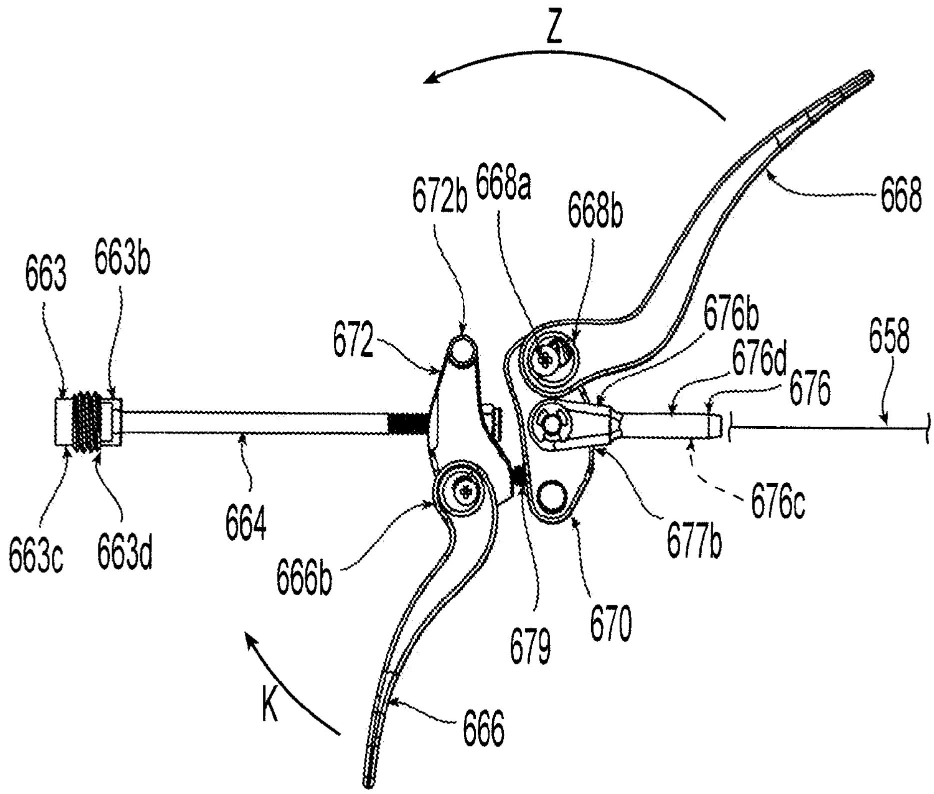
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Fig. 4H

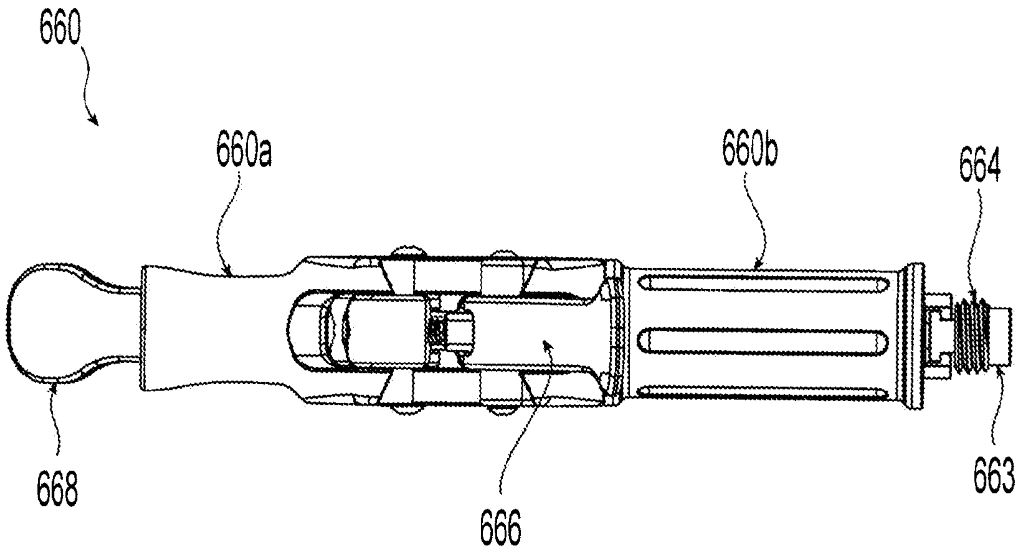


Fig. 4I

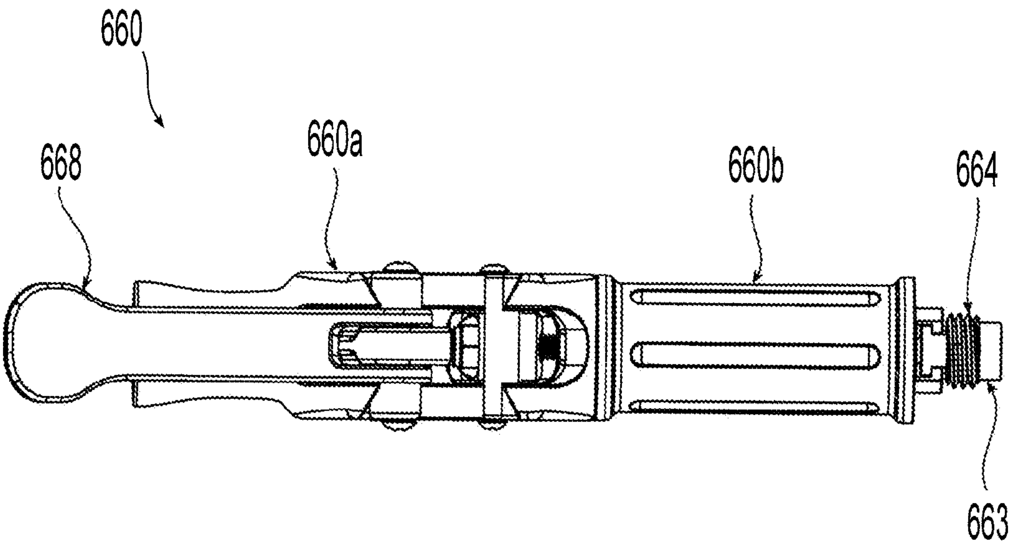


Fig. 4J

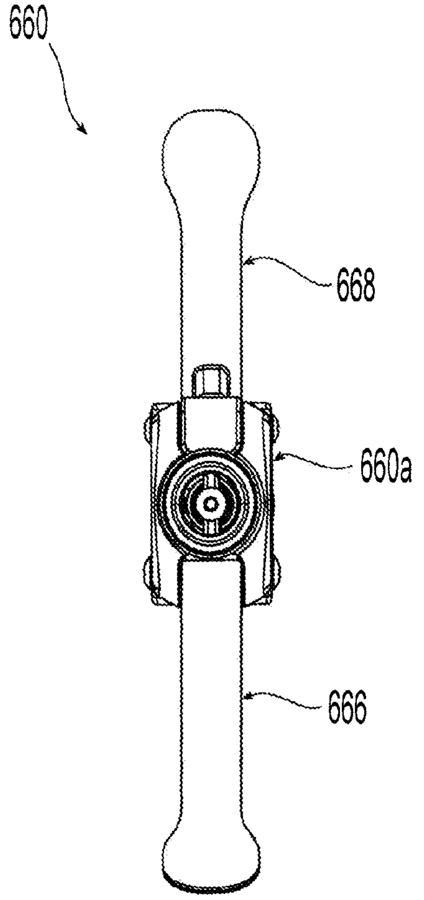


Fig. 4K

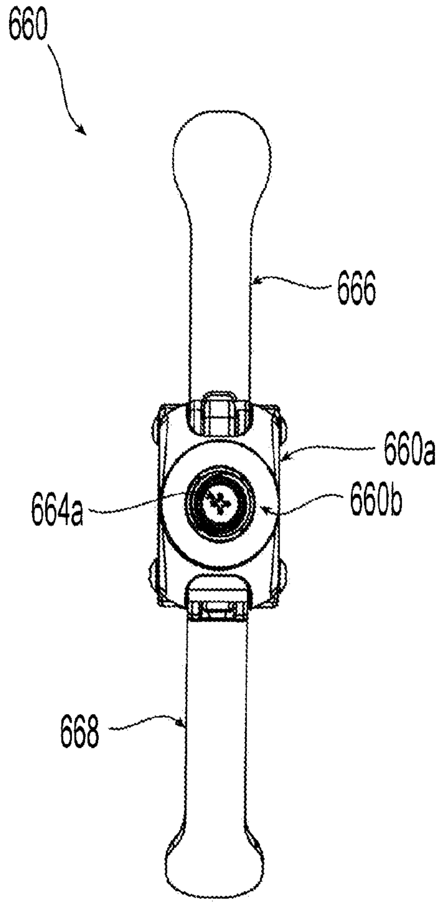
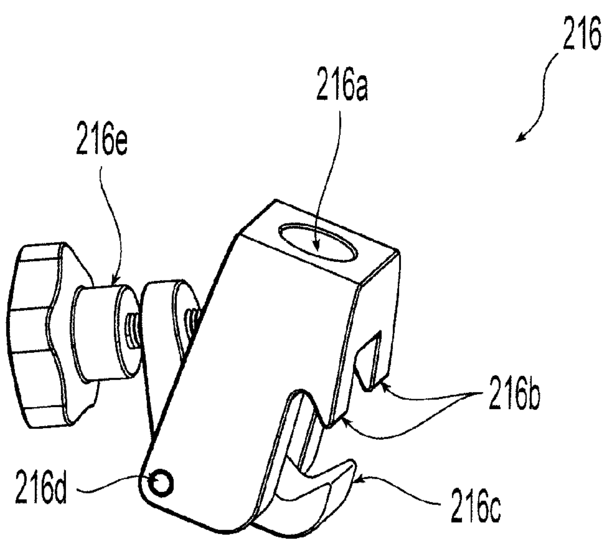


Fig. 4L



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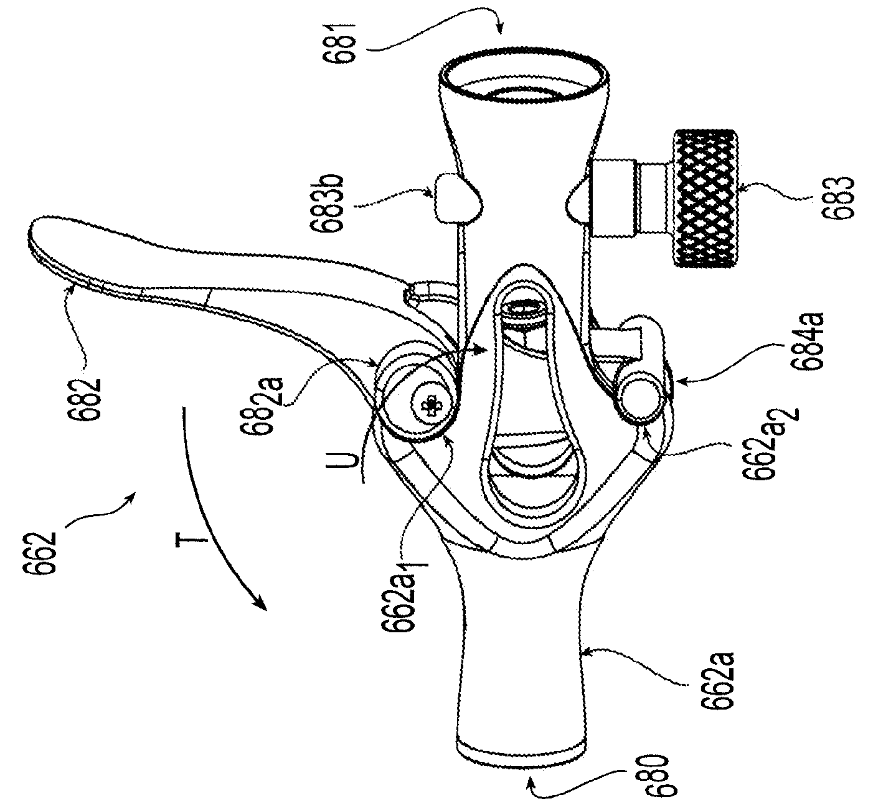
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Fig. 4-O

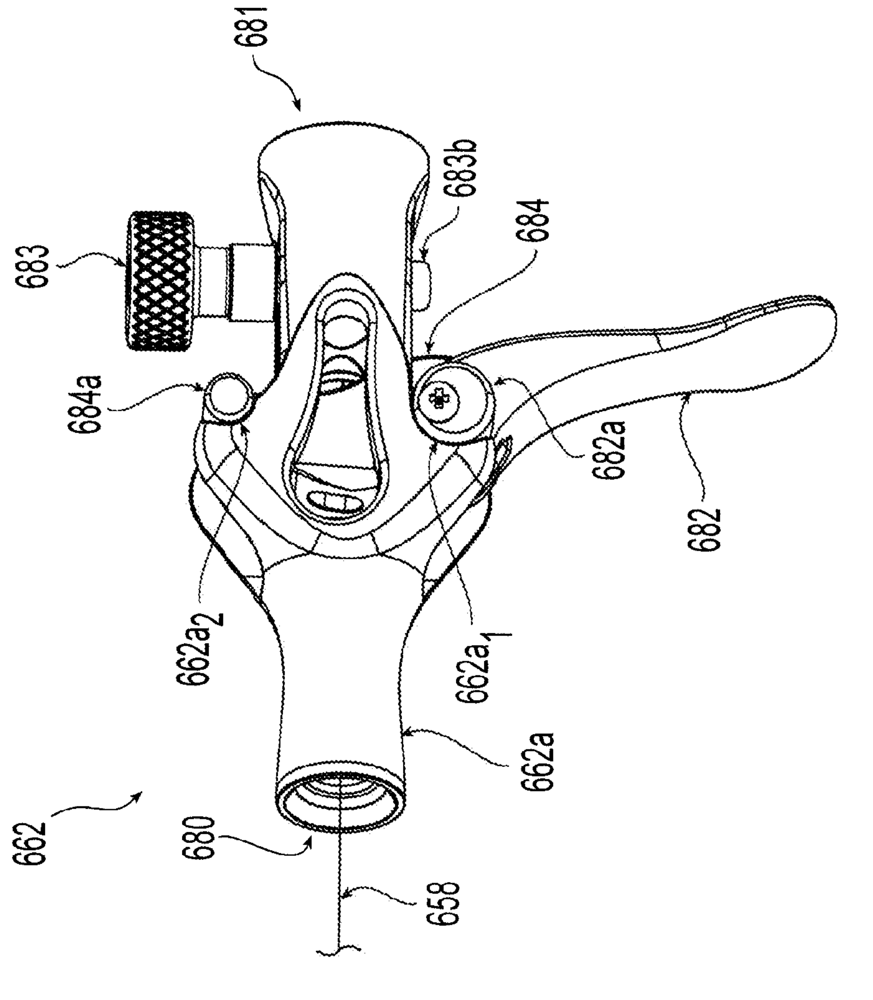
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Fig. 4N

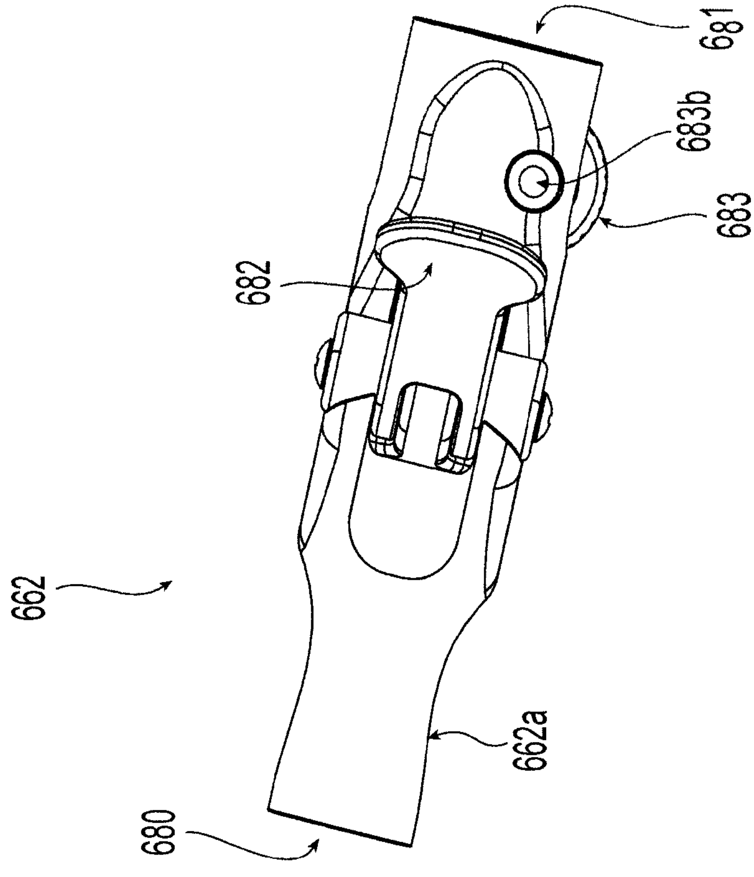
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Fig. 4Q

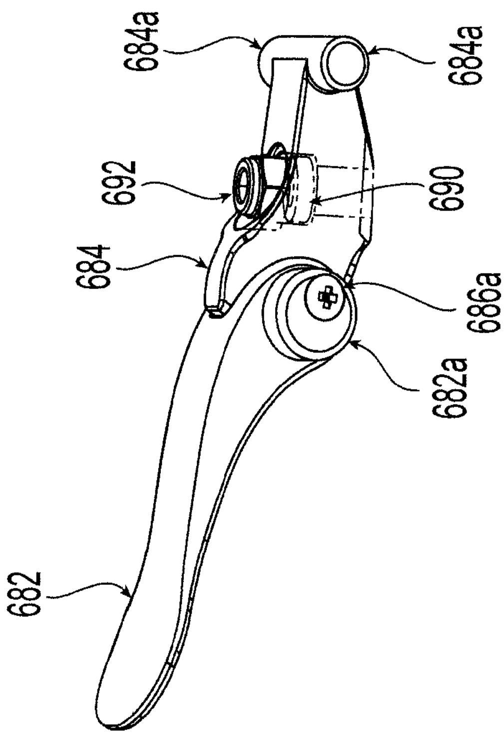
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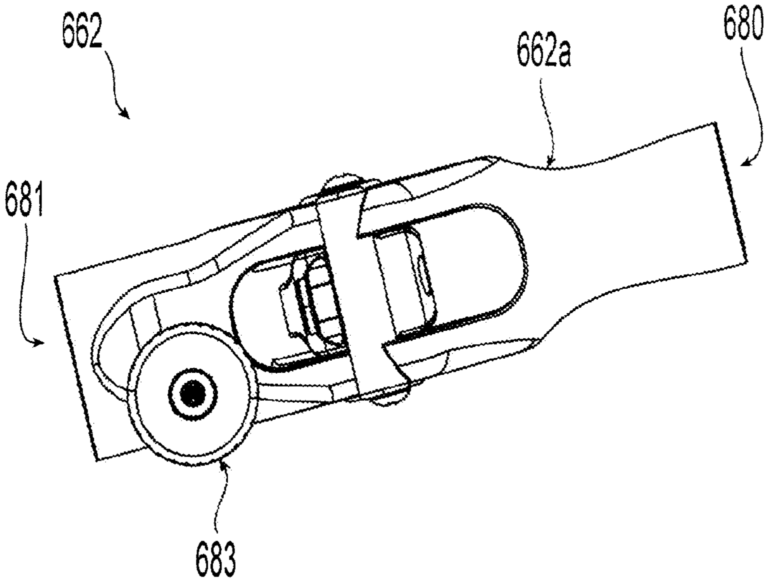
Fig. 4P



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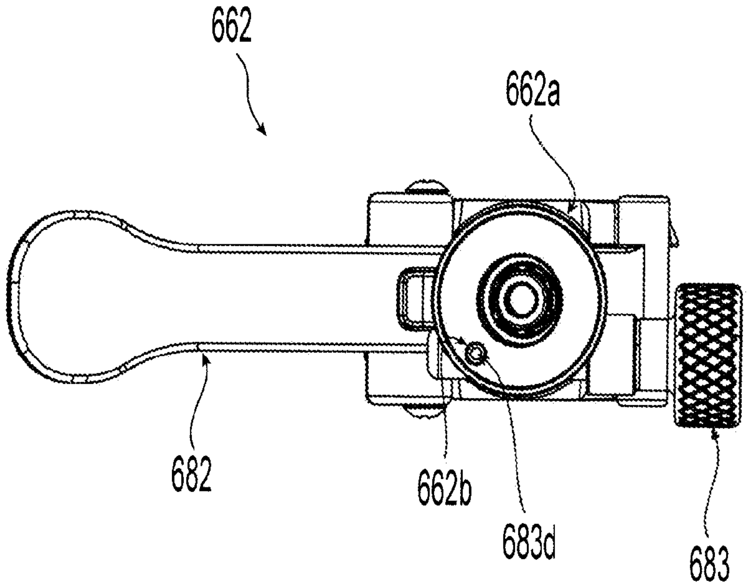

Fig. 4S

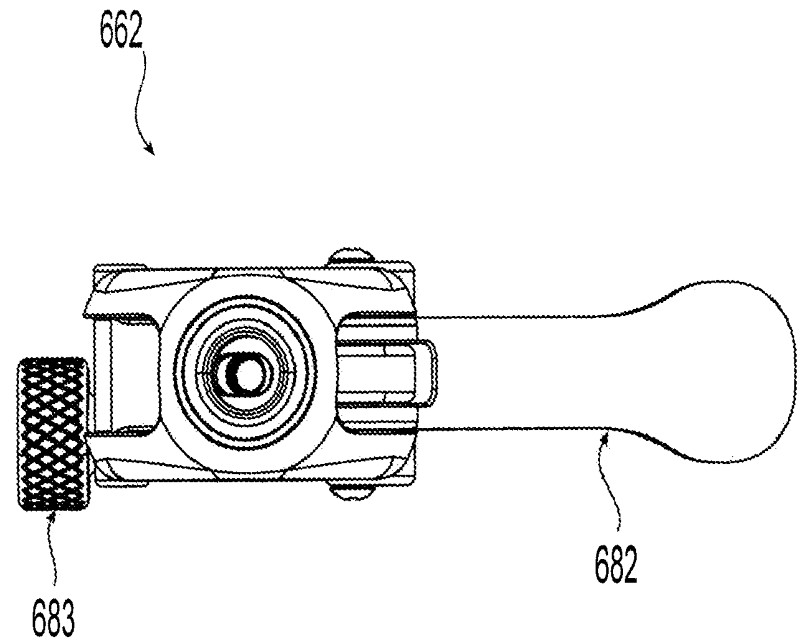

Fig. 4T

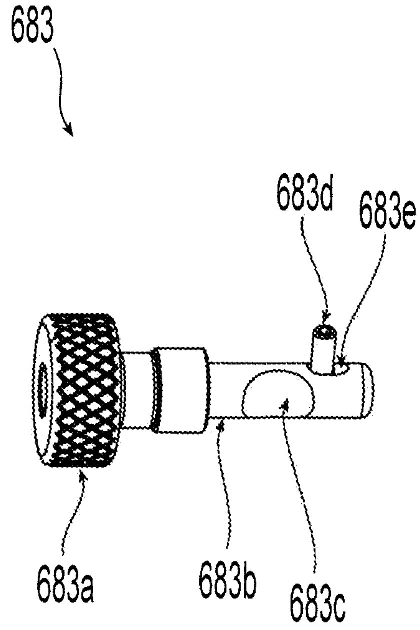

Fig. 4U

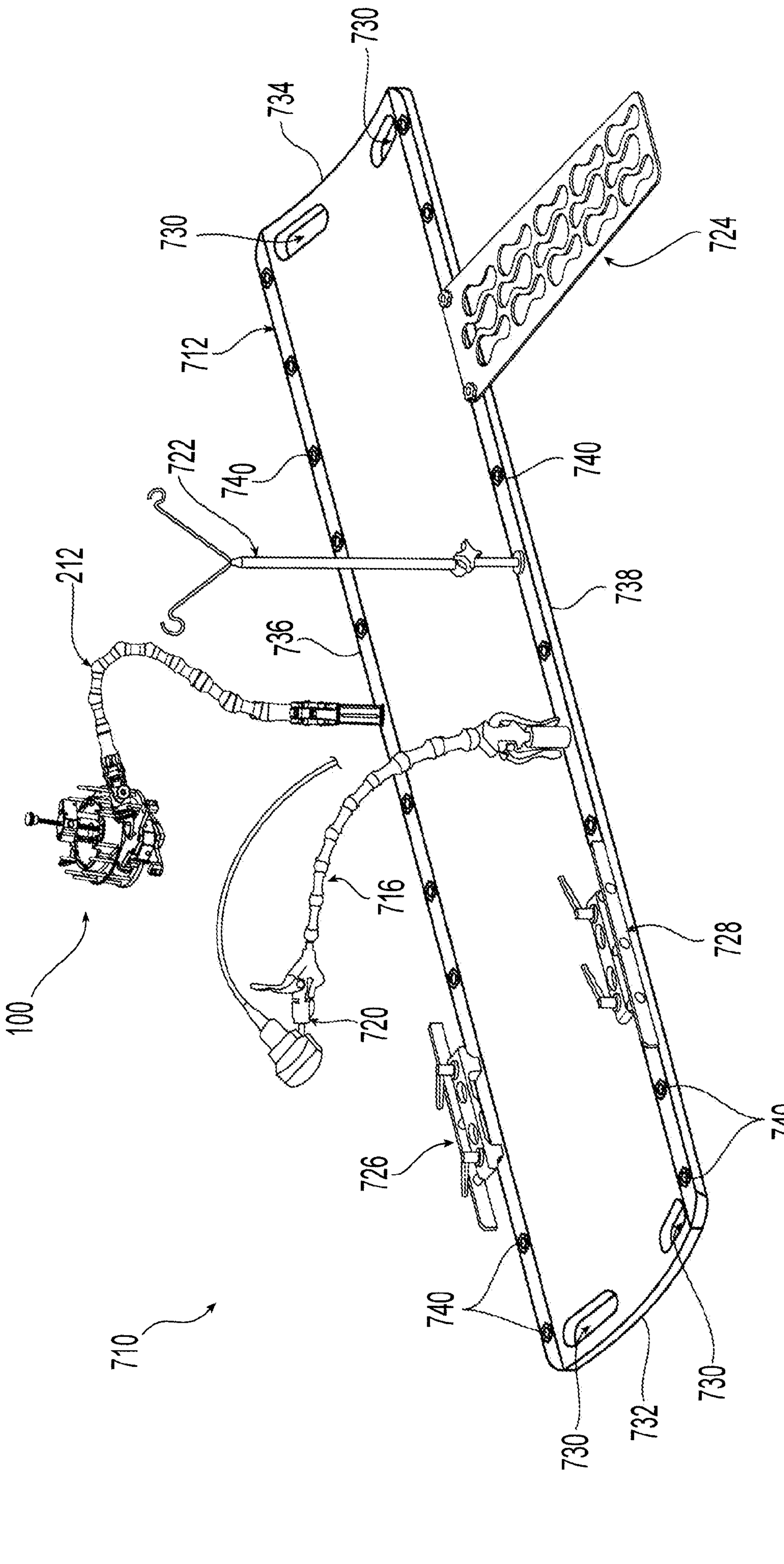
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Fig. 5

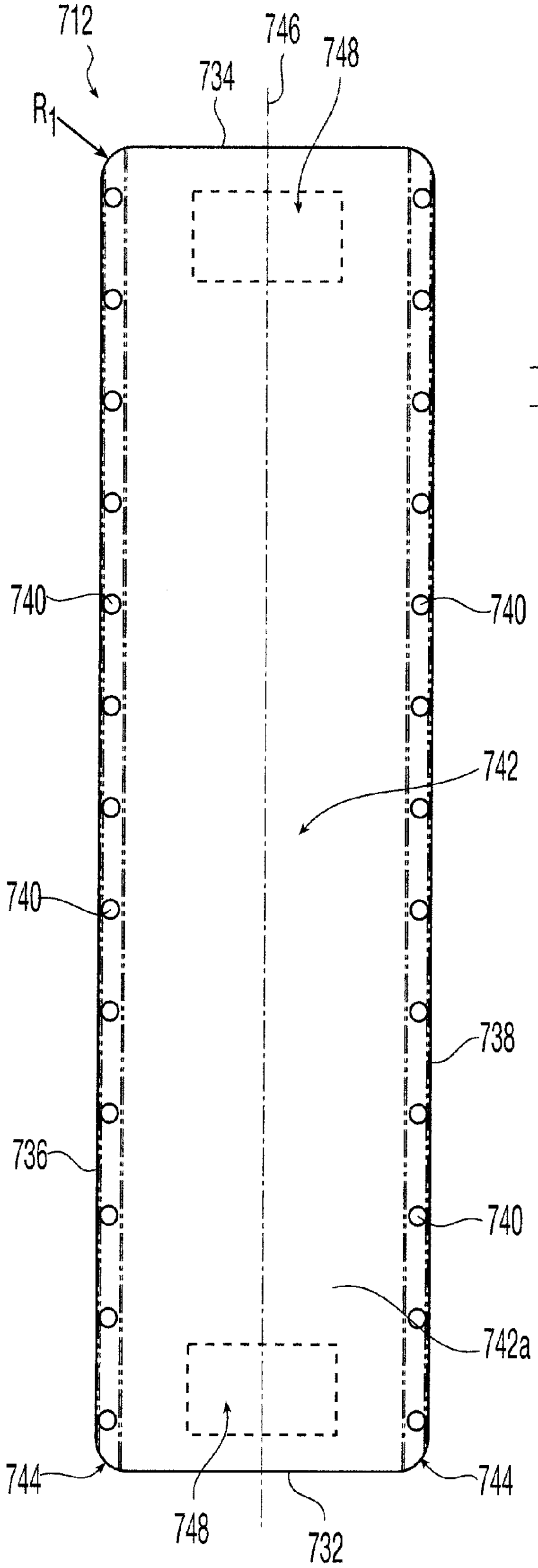

FIG. 6A

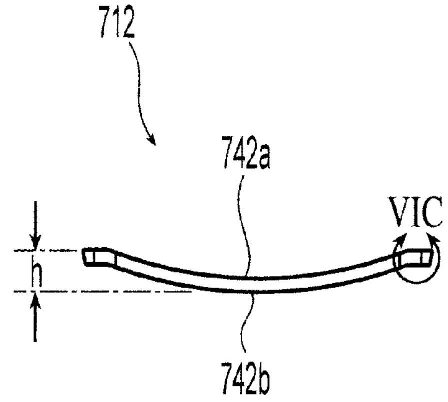

FIG. 6B

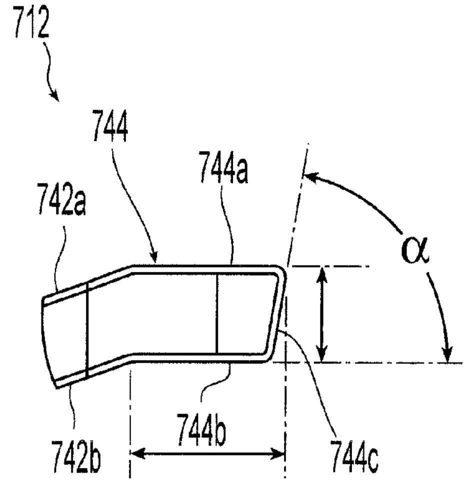

FIG. 6C

HIGH FREQUENCY ULTRASOUND TRANSDUCER HOLDER AND ADJUSTABLE FLUID INTERFACE

CROSS-REFERENCE TO RELATED APPLICATION

[0001] The benefits of Provisional Application No. 60/746,887 filed May 9, 2006 and entitled “High Frequency Ultrasound Transducer Holder and Adjustable Fluid Interface” are claimed under 35 U.S.C. §119(e), and the entire contents of this provisional application are expressly incorporated herein by reference thereto.

FIELD OF THE INVENTION

[0002] The invention relates to a high frequency ultrasound transducer holder and adjustable fluid interface.

BACKGROUND OF THE INVENTION

[0003] High frequency ultrasound (HIFU) is a recognized method of delivering treatment energy to subcutaneous lesions in the body. Most of the transducers that have been developed for this purpose have focal zones that are at a fixed distance from the face of the transducer where the sound waves are focused to achieve the energy concentration for treatment. This feature requires that either the transducer or the patient be moved for the treatment area to be shaped to a treatment volume as desired. In addition, some fluid medium must be present between the patient and the transducer that allows the ultrasound energy to be efficiently transmitted. Typically this fluid medium has been degassed water held within a flexible container. Since it is highly desirable to prevent immersion of the HIFU transducer and to be able to adjust the depth of the focal zone in relation to the patient, treatment tables for supporting the patient, the fluid interface and the transducer have been developed for these purposes. There remains a need for an improved HIFU transducer holder.

SUMMARY OF THE INVENTION

[0004] The invention relates to an ultrasound transducer positioning system including a curvilinear articulating arm, an ultrasound transducer, and a holder comprising a first region for receiving the transducer and a second region for a fluid interface disposed adjacent the first region, the holder being coupled to the curvilinear articulating arm. The second region is adjustable in size.

[0005] The first region may be defined by a generally circular clamp which may be a split ring. A lead screw may be coupled to the clamp. The second region may be defined between the clamp and an opposing members and the lead screw may extend to the opposing member. The opposing member may be a ring. The transducer may be retained by at least one member coupled to the clamp and abutting a portion of the transducer. In some embodiments, the at least one member may abut a portion of a face of the transducer. The fluid interface may be a flexible member. The system may further include at least one rail with indexing thereon, the rail extending between a bracket coupled to the curvilinear articulating arm and a clamp defining the first region.

[0006] The present invention is designed to provide a portable, self contained, adjustable fluid interface and HIFU transducer holder that will perform the required functions for accurate and effective treatment and keep the treatment field and transducer dry. This design obviates the need for a specialized table to support the transducer and fluid interface and to move the transducer and patient in a controlled relationship.

[0007] Among the advantageous features of the present invention are: it is readily attachable to a supporting positioning arm that has six degrees of freedom for initial positioning of the device; it has a receptacle for securely grasping the transducer; it has a generally cylindrical cage for supporting and aiding in the shaping and positioning of a disposable balloon that may be filled with a fluid interface medium such as degassed water.

[0008] The cage may be adjusted in length with both rapid and fine adjustment mechanisms which determine the distance of the transducer from the patient contacting surface of the device (thus controlling the depth of the focal zone). The balloon may be easily purged of air and is made of elastic material that causes minimal attenuation of the ultrasound energy. Depending on the position of the transducer in relation to the patient contacting surface of the device (i.e. the length of the balloon cage), the fluid volume in the balloon may be adjusted to achieve full contact of the balloon with both the entire active surface of the transducer and the patient. The end of the balloon cage opposite the transducer may have a circular lipped opening to allow for a large contact surface for the balloon with the patient. The lip may be smooth and tapered to contain the balloon in the cage while permitting desired patient contact with minimal chance for air gaps. Ultrasound gel or some equivalent may be used on the interface surfaces of the balloon where it comes in contact with the transducer and the patient to optimize energy transmission. In addition to a manual fine adjustment mechanism for the length of the cylindrical balloon cage that can account for the depth of the focal zone in the patient (Z axis), this device may also include a fine adjustment mechanism that allows manual position adjustment in the X-Y plane. This allows the operator to create a shaped treatment volume for a lesion in a patient.

BRIEF DESCRIPTION OF THE DRAWINGS

[0009] Preferred features of the present invention are disclosed in the accompanying drawings, wherein:

[0010] FIGS. **1**A-**1**I show a first embodiment of a high frequency ultrasound transducer holder for providing an adjustable fluid interface in accordance with the present invention including (**1**A) a side perspective view, (**1**B-**1**E) side views, (**1**F) a bottom view, (**1**G) a top view, (**1**H) a partial cross-sectional perspective view of the Z-axis adjustment mechanism, and (**1**I) a perspective view of a spring-loaded button of the Z-axis adjustment mechanism of FIG. **1**H, with each of the figures shown without a balloon for convenience except FIG. **1**B;

[0011] FIGS. **1**J to **1**-O show a variant of the first embodiment of a high frequency ultrasound transducer holder for providing an adjustable fluid interface in accordance with the present invention including (**1**J) a side perspective view, (**1**K-**1**L) side views, (**1**M) a top view, (**1**N) a partial cross-sectional perspective view of the Z-axis adjustment mechanism, and (**1**-O) a perspective view of a spring-loaded button of the Z-axis adjustment mechanism of FIG. **1**N, with each of the figures shown without a balloon for convenience except FIG. **1**K;

[0012] FIGS. 2A-2K show another embodiment of a high frequency ultrasound transducer holder for providing an adjustable fluid interface in accordance with the present invention including (2A) a side perspective view, (2B-2E) side views, (2F) a top view, (2G) a bottom view, (2H-J) side views of the center block for the positioning device for the X-Y axes, and (2K) a partial cross-sectional side view of the center block of FIGS. 2H-J, with each of the figures shown without a balloon for convenience except FIG. 2B;

[0013] FIG. 3 shows a perspective view of a high frequency ultrasound transducer holder system **200** according to the present invention;

[0014] FIGS. 4A-4C show the curvilinear articulating arm assembly of FIG. 3, including (4A) a perspective view, (4B) a partial cross-sectional perspective view, and (4C) a partial side view;

[0015] FIGS. 4D-4L show the base handle of FIG. 3, including (4D) a first side view, (4E) a second side view, (4F) a partial perspective view of a first set of components thereof, (4G) a partial side view of a second set of components thereof, (4H) another partial side view of the second set of components thereof, (4I) a front view, (4J) a back view, (4K) a top view, and (4L) a bottom view;

[0016] FIG. 4M shows a perspective view of a rail clamp for use with the present invention;

[0017] FIGS. 4N-4T show the free handle of FIG. 3, including (4N) a first side perspective view showing a portion of a tensioning wire therewith, (4-O) a second side perspective view, (4P) a partial perspective view showing a first set of components thereof, (4Q) a front perspective view, (4R) a back perspective view, (4S) a top perspective view, and (4T) a bottom perspective view;

[0018] FIG. 4U shows a side perspective view of the interface lock of the free handle of FIGS. 4N-4T;

[0019] FIG. 5 shows a perspective view of a support system according to the present invention; and

[0020] FIGS. 6A-6C show the tray of FIG. 5, including (6A) a top view, (6B) a cross-section taken perpendicular to the central axis of the tray, and (6C) a partial cross-section showing detail taken at VIC.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0021] Words of orientation as used herein such as "front," ""back,""top," and "vertical" are used for exemplary convenience only as non-limiting examples of the orientation of features and are not intended to have any particular limiting effect.

[0022] Referring initially to FIGS. 1A-1I, a first exemplary embodiment of a high frequency ultrasound transducer holder **10** for providing an adjustable fluid interface in accordance with the present invention is shown. Holder **10** includes an ultrasound probe clamp **12** and an opposing bottom ring **14**. A plurality of rods **16** are fixed circumferentially about ring **14** and extend through aligned holes **17** in clamp **12**. In addition, a pair of guide rails **18**, **20** are fixed circumferentially about ring **14** and extend through aligned holes **22**, **24**, respectively, in clamp **12**. Rail **20** may include indexing **20*a*** such as scoring, grooves, indicia including numerical indicia, etc., which for example may indicate the separation distance between portions of transducer holder **10** as will be described. A lead screw **26** extends through a hole (not shown) in probe clamp **12** centrally disposed between holes **22**, **24**. Each of guide rails **18**, **20** also are received in primary bracket **28** in holes **30**, **32** respectively therein. A spaced pair of internally threaded collars are threadably associated with lead screw **26** and each abut clamp **12**.

[0023] For movement of clamp **12** with respect to ring **14** in the Z-axis, both gross and fine movements may be achieved. As shown for example in FIG. 1H, a button **36** is disposed in primary bracket **28** and extends perpendicular to the Z-axis defined by or parallel to lead screw **26**. Button **36** is spring-loaded with a spring **38** abutting a face of button **36** and disposed within primary bracket **28**. Button **36** is partially internally threaded with partial threads **36*a*** disposed in a hole **36*b***. Hole **36*b*** is sized such that lead screw **26** extends therethrough. Due to the spring-loading provided by biasing member **38**, button **36** is biased such that partial threads **36*a*** thereof engage the threads of lead screw **26** when button **36** is not depressed. When a user depresses button **36** and compresses spring **38**, hole **36*b*** of button **36** accommodates movement of partial threads **36*a*** away from engagement with the threads of lead screw **26** so that gross movement of clamp **12** with respect to ring **14** may be permitted in the Z-axis. Fine movement of clamp **12** with respect to ring **14** may be permitted in the Z-axis when the partial threads **36*a*** of button **36** are engaged with the threads of lead screw **26** and a user rotates lead screw **26** about or parallel to the Z-axis by rotating lead screw **26** with knob **40**. In summary, vertical adjustment screw **26** allows fine tuning of the focal zone depth associated with transducer **50**, while button **36** may be depressed for making larger rapid vertical adjustments.

[0024] As shown in FIGS. 1A and 1D, clamp **12** is formed as a split ring with a gap **42** therein. A screw **44** with a handle **46** fixed to a free end thereof extends through holes **48*a***, **48*b*** and gap **42** may be increased or decreased in size by rotation of screw **44**, using handle **46**, to move opposing portions **12*a***, **12*b*** away from or toward each other. By decreasing the size of gap **42**, an ultrasound transducer **50** such as a HIFU transducer, is secured within clamp **12**, as shown for example in FIG. 1A. In an exemplary preferred embodiment, the outer diameter of transducer **50** closely matches the inner diameter of hole **12*c*** of clamp **12**, at a preferably predetermined size of gap **42**, so that transducer **50** may be mechanically held by clamp **12**. A flexible member such as a balloon **52** preferably is disposed and retained between (1) the combination of clamp **12** and bottom face **50*a*** of transducer **50** and (2) ring **14**.

[0025] As shown for example in FIG. 1B, balloon **52** is permitted to extend through hole **14*a*** in ring **14**, thus permitting this fluid reservoir to be in contact with both transducer **50** and the skin of a patient proximate ring **14**. Ring **14** preferably includes a tapering **14*b*** in thickness toward hole **14*a*** which for example may be spherical or another arcuate cross-section. This dished configuration facilitates resting of balloon **52** against ring **14**. Clamp **12** may include similar tapering **12*d*** with respect to central hole **12*c*** therein.

[0026] In a preferred exemplary embodiment, balloon **52** is stretchy, strong, and causes minimal attenuation of the signal from transducer **50** when gel is coated on both the transducer contact and patient contact surfaces; preferably, balloon **52** is filled with degassed water with air purged therefrom.

[0027] In a preferred exemplary embodiment, transducer **50** focuses ultrasound about 10 centimeters away from the bottom surface **50***a* thereof. In order to change the depth in the patient to which the energy is directed and focused, the spacing of clamp **12** and ring **14** with respect to each other is adjustable for example between about 1 centimeter and about 9 centimeters. Spacing of clamp **12** and transducer **50** retained in ring **14** for example may be adjusted with reference to numerical indicia **20***a* such as shown in FIG. **1**E.

[0028] A coupling **60** may be used to couple holder **10** to a curvilinear articulating arm as will be described.

[0029] Referring next to FIGS. **1**J-**1**-O, a variant exemplary embodiment of the first embodiment is shown. In particular, a high frequency ultrasound transducer holder **60** for providing an adjustable fluid interface includes an ultrasound probe clamp **62** and an opposing bottom ring **64**. A plurality of rods **66** are fixed circumferentially about ring **64** and extend through aligned holes **67** in clamp **62**. In addition, a pair of guide rails **68**, **70** are fixed circumferentially about ring **64** and extend through aligned holes **72**, **74**, respectively, in clamp **62**. Each of rails **68**, **70** may include indexing **68***a*, **70***a* such as scoring, grooves, indicia including numerical indicia, etc, which for example may indicate the separation distance between portions of transducer holder **60** as will be described. A lead screw **76** (show in FIGS. **1**L, **1**N, and **1**-O) extends through a hole (not shown) in probe clamp **62** centrally disposed between holes **72**, **74**. Each of guide rails **68**, **70** also are received in primary bracket **78** in holes **80**, **82** respectively therein. An internally threaded collar **76***a* is threadably associated with lead screw **76** and abuts a lead screw housing or guard **76***b*.

[0030] For movement of clamp **62** with respect to ring **64** in the Z-axis, as with the previous embodiment both gross and fine movements may be achieved. Turning for example in FIG. **1**N, a button **86** is associated with clamp **62** and extends perpendicular to the Z-axis defined by or parallel to lead screw **76**. Button **86** is spring-loaded, with a spring **88** abutting (1) a face of button **86** and (2) a face of a nut plunger **89** (which may for example be right cylindrical). Nut plunger **89** abuts a ledge or extension **62***a* of clamp **62**. Button **86** also is disposed adjacent clamp **62**, and abuts clamp **62** as will be described. In addition, button **86** includes a bore **87** that is partially internally threaded with threaded regions **87***a*, **87***b* disposed therein. Bore **87** is sized such that lead screw **76** extends therethrough. Bore **87** is disposed along an axis **87***c* transverse to the longitudinal axis **76***c* of lead screw **76**. Advantageously, the "rocker" style of button **86** does not rely on spring force entirely to engage lead screw **76**. With a balloon **98** disposed between clamp **62** and ring **64**, as the spacing between clamp **62** and ring **64** is decreased the balloon **98** exerts pressure against clamp **62** with the result that button **86** is levered with increasing force of engagement with the threads of lead screw **76**.

[0031] Due to the spring-loading provided by biasing member **88**, button **86** is biased such that partial threads **87***a*, **87***b* thereof engage the threads of lead screw **76** when button **86** is not depressed. When a user depresses button **86** and compresses spring **88**, bore **87** of button **86** accommodates movement of partial threads **87***a*, **87***b* away from engagement with the threads of lead screw **76** so that gross movement of clamp **62** with respect to ring **64** may be permitted in the Z-axis. In particular, by depressing button **86** proximate spring **88**, a portion of face **86***a* of button **86**"rocks" against clamp **62** to permit pivoting of button **86** with respect to lead screw **76**, thereby permitting disengagement of their respective threads and allowing gross movement. Conversely, gross movement may be arrested when the respective threads are engaged.

[0032] Fine movement of clamp **62** with respect to ring **64** may be permitted in the Z-axis when the partial threads **87***a*, **87***b* of button **86** are engaged with the threads of lead screw **76** and a user rotates lead screw **76** about or parallel to the E-axis by rotating lead screw **76** with knob **90**. In summary, vertical adjustment screw **76** allows fine tuning of the focal zone depth associated with transducer **92**, while button **86** may be depressed for making larger rapid vertical adjustments.

[0033] Unlike the first embodiment, holder **10**, the exemplary variant embodiment includes a clamp **62** that preferably is not in the form of a split ring. Instead, an ultrasound transducer **92**, such as a HIFU transducer, is secured within clamp **62**, as shown for example in FIGS. **1**J and **1**M. With respect to holder **60**, transducer **92** is "top-loaded" to facilitate installation of transducer **92** in clamp **62**. In other words, transducer **50** is placed within clamp **62** without having to traverse the region occupied between clamp **62** and ring **64**. In a preferred exemplary embodiment, paired retention washer **94** and associated retention knob **96** are used to secure transducer **92** within clamp **62**. Preferably, three point retention is used, e.g., three pairs of washers **94** and associated knobs **96** are used and may be disposed for example about 120° apart. Washers **94**, in the exemplary embodiment as shown, are oblong in shape and may be positioned to bear against transducer **92** threadably tightened so that when transducer **92** is seated in clamp **62**, it is retained therein. In particular, knobs **96** may include threaded shafts (not shown) that are threadably received in holes in clamp **62**, so that when a washer **94** is disposed between a knob **96** and clamp **62** the degree of tightness or looseness may be adjusted to permit transducer **92** to be retained in, or removed from clamp **62**. When transducer **92** is to be removed from clamp **62**, for example, each coupling is loosened so that washers **94** may be swiveled out of abutment with transducer **92**.

[0034] As shown for example in FIG. **1**K, balloon **98** is permitted to extend through hole **64***a* in ring **64**, thus permitting this fluid reservoir to be in contact with both transducer **92** and the skin of a patient proximate ring **64**. Ring **64** preferably includes a tapering and configuration as previously described with respect to the previous embodiment. Similarly, balloon **98** and transducer **92** for example may be designed and used as previously described.

[0035] Finally, a coupling **99** may be used to couple holder **10** to a curvilinear articulating arm as will be described.

[0036] Preferably, holder **60** is formed of materials so that it is substantially radiolucent and magnetic resonance imaging compatible (the use of stainless steel is kept minimal, for example by only using stainless steel screws and springs).

[0037] Advantageously, as may be seen by comparing FIGS. **1**A and **1**J, holder **60** of FIG. **1**J is a "low profile" holder. In particular, the locking mechanism including button **86** is associated directly with clamp **62**, rather than with bracket **28** as with holder **10**. In addition, lead screw **76** of holder **60** is separated from the region between clamp **62** and ring **64** by a barrier, guard **76***b* so that balloon **98** does not contact lead screw **76**. Such an arrangement ensures that balloon **98** is not compromised as a result of contacting sharp surfaces of screw **76**. In sum, holder **10** includes a lead screw **26** which does not extend to ring **14**. Because no guard is provided in that exemplary embodiment, lead screw **26** was positioned away from the region between clamp **12** and ring **14**, and as a result the overall height of holder **10** included much of the length screw **26** extending beyond clamp **12**. In contrast, because lead screw **76** of holder **60** extends to ring **64**, the same length of a lead screw **76** can be accommodated with a decrease in overall height of holder **60** compared to holder **10**. Of course, the separation distance between a transducer in clamp **12**, **62** and respective ring **14**, **64** is a major factor in setting the depth of the focus of the ultrasound.

[0038] Turning to FIGS. **2**A-2K, another exemplary embodiment of a high frequency ultrasound transducer holder **100** for providing an adjustable fluid interface in accordance with the present invention is shown. Holder **100** is substantially the same as holder **10** described above, and thus the descriptions of holder **10** with balloon **52** apply equally and apply equally to holder **100** with balloon **152**.

[0039] Holder **100** differs from holder **10** in that positioning adjustment may be achieved in the X-Y plane using a fine adjustment system **180**. While vertical adjustment screw **126** allows fine tuning of the focal zone depth associated with transducer **150** about or parallel to the Z-axis, fine adjustment system **180** provides additional positioning ability in the X-Y plane. In the exemplary embodiment shown, coupling **160** is fixed to fine adjustment system **180** instead of primary bracket **128** as was the case with respect to holder **10** and its primary bracket **28** and coupling **60**.

[0040] As shown for example in FIG. **2**C, fine adjustment system **180** includes a center block **182** disposed between a pair of plates **184**, **186**. Plate **184** is coupled to bottom ring **114** with spacers **188**. Lead screws **190**, **192** extend through block **182** and are spaced from one another in planes separated by a spacing s, as shown for example in FIGS. **2**C and **2**H. Lead screws **190**, **192** are disposed perpendicular to one another to permit movement in X and Y directions. Lead screw **190** also may be received in plate extensions **184***a*, **184***b* of plate **184**, while lead screw **190** also may be received in plate extensions **186***a*, **186***b* of plate **186**. A first lead screw nut **194** is captured within block **182** and receives lead screw **190** while a second lead screw nut **196** is captured within block **182** and receives lead screw **192**. Rotation of lead screws **190**, **192** thus permits fine positioning of holder **100** in the X-Y plane. In a preferred exemplary embodiment, positioning adjustment may be achieved in the range of about ±1.5 inches in each of the X and Y directions.

[0041] Referring to FIG. **3**, an exemplary embodiment of a high frequency ultrasound transducer holder system **200** according to the present invention is shown. Holder system **200** includes a curvilinear articulating arm assembly **212** and a ultrasound transducer holder **214** coupled to assembly **212** as indicated by arrow A. As will be further described, arm assembly **212** includes a clamp **216** at a first free end thereof for coupling system **200** to a structure such as the rail **218** (shown schematically in phantom) of an operating room table.

[0042] Turning to FIGS. **4**A-4C, an exemplary preferred curvilinear articulating arm assembly **212** is shown for use with a transducer holder **214**. Arm assembly includes a central arm **652** with a ball-sleeve arrangement that forms joints. In particular, central arm **652** includes a plurality of sleeves **654** with spherical balls **656** disposed therebetween thus forming ball and socket connections. In the exemplary embodiment shown in the figures, three balls **656***a* of a first size are disposed adjacent one another proximate one end of arm **652**, while the remaining balls **656***b* are of a second size smaller than the first size. Sleeves **654***a* of a first size and sleeves **654***c* of a second size smaller than the first size are provided for accommodating balls **656***a*, **656***b*, respectively, while a transition sleeve **654***b* is provided intermediate sleeves **654***a*, **654***c* as shown for accommodating a ball **656***a* on one side and a ball **656***b* on the other side thereof. Sleeves **654** are configured and dimensioned to receive balls **656***a*, **656***b* at ends thereof and thus permit articulating of sleeves with respect to each other. A tensioning wire **658** runs generally centrally through sleeves **654** and balls **656**, as will be further described shortly. Preferably, wire **658** is formed of metal. In an exemplary preferred embodiment, wire **658** is Type 302 stainless steel wire rope, 1×19 strand, $\frac{5}{32}$ inch diameter, with a breaking strength of 3300 lb. (McMaster-Carr part number 3458T27). One exemplary operation of a wire tensioning mechanism is shown and described in U.S. Pat. No. 3,858,578 to Milo, which is expressly incorporated herein by reference thereto. Preferably, curvilinear articulating arm assembly **212** may move with six degrees of freedom.

[0043] In the exemplary preferred embodiment, three additional balls **656***a* and three additional sleeves **654***a* are provided to the arm assembly **212** shown in FIGS. **4**A-4C, with arm assembly **212** having a fully extended (straightened) length of about 40 inches. In other embodiments, other desired lengths of arm assembly **212** may be accomplished by changing the number of balls and sleeves. For example, without the three additional balls **656***a* and three additional sleeves **654***a*, arm assembly **212** may have a length of about 32 inches.

[0044] A base handle **660** is coupled to central arm **652** on a first end thereof, preferably adjacent a ball **656***a*. In addition, a free handle **662** is coupled to central arm **652** on a second end thereof, preferably adjacent a ball **656***b*.

[0045] In one preferred exemplary embodiment, a series of larger balls **656***a* is provided proximate base handle **660** to provide stability to curvilinear articulating arm assembly **212**. If for example a user such as a surgeon orients assembly **212** by grasping it proximate free handle **662**, substantial bending forces may be exerted on central arm **652** proximate base handle **660**. Thus, the use of larger balls **656***a* proximate base handle **660** as compared to smaller balls **656***b* proximate free handle **662** provides a system with larger surface area balls near base handle **660** for additional resistance to rotational movement in that portion of central arm **652** and thus more stability. In alternate embodiments, more than two different sizes of balls **656** or more than two sets of sizes of balls **656** may be used, preferably increasing in size toward base handle **660**. In one alternate embodiment, each of the balls **656** in central arm **652** is of increasingly larger size from free handle **662** to base handle **660**. The use of only two sizes of balls **656** advantageously facilitates manufacture and construction of arm assembly **212** because of the need to only stock two sizes as compared to a larger number of sizes and concomitantly greater ease of construction because only two sizes need be assembled to form central arm **652**. In yet another alternate embodiment, central arm **652** may be formed of balls **656** that all are the same size.

[0046] Turning to FIG. **4**D-4L, base handle **660** will be described. Base handle **660** includes a body portion **660***a* with levers **666**, **668** pivotably associated therewith, as well as an extension **660***b* that turns screw coupling **663** and rotates in relation to and independent of body portion **660***a*. Base handle **660** further includes cam mechanisms **670**, **672** as will be described. Portion **663***b* of coupling **663** preferably is noncircular and mechanically engages and is fixed to a like-shaped and sized non-circular opening in portion **660***c* of extension **660***b* so that rotation of extensions **660***b* as by gripping and turning by a user imparts like-rotation of coupling **663** for example for demountable coupling to clamp **16** and further coupling to a surgical table rail **18**, as shown for example in FIG. **3**. In the preferred exemplary embodiment, coupling **663** comprises a threaded portion **663***d* which may be threadably received in a threaded hole **16***a* disposed in clamp **16**.

[0047] Coupling **663** is disposed proximate a first free end **664***a* of a stainless steel shaft **664** which extends therethrough and is provided with a head that abuts a shoulder disposed in end **663***c* of coupling **663**. Preferably, rotation of coupling **663** is independent of rotation of shaft **664**. Shaft **664** preferably extends through a hole in extension **660***b*.

[0048] Lever **666** is pivotably coupled to rocker arm **672** with a pin **666***a* that is disposed such that rotation of lever **666** results in eccentric movement of rocker arm **672**. As shown for example in FIGS. **4**D-4E, cylindrical projections **666***b* of lever **666** are received and rotate in arcuate cradle portions **660***a***1** of body portion **660***a*, while cylindrical projections **672***b* of rocker arm **672** are received and rotate in arcuate cradle portions **660***a***2** of body portion **660***a*. Rotation of lever **666** toward screw coupling **663** in direction K lifts pin **666***a*, and because rocker arm **672** rests on pin **666***a*, rocker arm **672** is rotated in direction L in an eccentric fashion.

[0049] As seen particularly in FIG. **4**F, shaft **664** includes a threaded portion **664***b* the free end of which is threadably associated with a nut **665***a*. Shaft **664** extends through a hole in rocker arm **672** and an unthreaded insert **665***b* with a hole therein which assists in guiding travel of rod **664** along the longitudinal axis thereof. Pivoting of lever **666** in direction K causes rotation of rocker arm **672**, and with shaft **664** coupled to nut **665***a* and nut **665***a* abutting insert **665***b*, rod **664** is translated in direction M.

[0050] When coupling **663** is threaded into a like threaded hole by rotation of extension **660***b*, arm assembly **212** is relatively loosely coupled by the connection of coupling **663** to the hole. To firmly couple arm assembly **212**, lever **666** may be pivoted in direction K so that threaded portion **663***d* of coupling **663** also moves in direction M and bears against the threads of the hole in which it is received. The leverage created by even slight movement of the threads against the threaded holes, on the order of tens of thousandths of an inch, creates a wedging effect that strongly locks arm assembly **212** to the hole.

[0051] Lever **668** of base handle **660** also is pivotably coupled to a rocker arm **670** with a pin **668***a* that is disposed such that rotation of lever **668** results in eccentric movement of rocker arm **670**. As shown for example in FIGS. **4**D-4H, cylindrical projections **668***b* of lever **668** are received and rotate in arcuate cradle portions **660***a***3** of body portion **660***a*, while cylindrical projections **670***b* of rocker arm **670** are received and rotate in arcuate cradle portions **660***a***4** of body portion **660***a*. Rotation of lever **668** toward screw coupling **663** in direction N lifts pin **668***a*, and because rocker arm **670** rests on pin **668***a*, rocker arm **670** is rotated in direction P in an eccentric fashion.

[0052] A forked member **676**, which for example may be formed of stainless steel, is coupled to rocker **670** and includes substantially parallel prongs **676***a*, **676***b* which mate with side walls of rocker **670** as shown. Rocker **670** is pivotably associated with forked member **676**, with a shaft **677** extending through aligned holes in prongs **676***a*, **676***b* and rocker **670**. Shaft **677** may be provided with a head **677***a* and an external retaining ring **677***b* secured in a shaft groove proximate an end opposite head **677***a* to retain forked member **676** in association therewith and thus with rocker **670**. An axial through hole **676***c* is provided in tubular portion **676***d* of forked member **676**. Tensioning wire **658** is coupled to forked member **676** by inserting an end portion of wire **658** in hole **676***c* and swaging tubular portion **676***d* so that wire **658**, which extends out of open end **660***a***5** of body portion **660***a*, is retained by compression within tubular portion **676***d*.

[0053] When lever **668** is rotated in direction N, shaft **676** translates along the longitudinal axis M1 toward coupling **663** creating substantial tension in tensioning wire **658** such that movement of curvilinear articulating arm assembly **212** may be substantially resisted. In particular, actuation of second lever **668** may increase or decrease the tension in wire **658** as desired by acting on rocker arm **670**. By increasing tension in wire **658**, central arm **652** preferably becomes increasingly resistant to movement although central arm **652** preferably still may be moved through its full range of motion. Thus, a user may orient curvilinear articulating arm assembly **212** as desired, and then increase the tension of wire **658** so that the orientation of arm **652** is releasably fixed. Lever **668** preferably has an angular range of movement about pin **668***a* of up to about 180° to permit substantial tension to be generated in tensioning wire **658**.

[0054] Rockers **670**, **672** preferably are associated with each other as with a spring plunger **679** extending from within one rocker **670** into a hole in the other rocker **672**. Spring plunger for example may be a stainless steel spring plunger with a round Delrin nose, without a lock element, with ¼"-20 threading, and 3-13 lb. end force (McMaster-Carr part number 84765A33). Spring plunger **679** is used as shown because under the force of gravity, first lever **666** may otherwise tend to move toward a closed position with in the direction of arrow K. Instead, spring plunger **679** applies pressure to rocker arm **672** to set lever **666** to tend to a default open position in which shaft **664** has not otherwise been raised toward open end **660***a***5** of body portion **660***a*.

[0055] In a preferred exemplary embodiment, rocker 670 moves with substantially greater eccentricity than rocker 672.

[0056] Clamp 216 for use with base handle 660 may be demountably attached to surgical table rail 218. As previously discussed, actuation of first lever 666 permits a user to apply a force on coupling 663 so that movement is resisted (e.g., in response to an 8 or 10 pound force applied to arm 652). In an alternate embodiment which will be further described later, screw coupling 664 as shown in FIG. 4A proximate base handle 660 of arm assembly 212 may be threadably associated with a threaded hole in another support surface.

[0057] A preferred exemplary embodiment of clamp 216 is shown in FIG. 4M. Clamp 216 includes a threaded hole 216a for threadably receiving threaded portion 664 of base handle 660. In addition, clamp 16 includes fixed jaw portion 216b and movable jaw portion 216c which is pivotable about axle 216d and lockable in place using screw mechanism 216e to firmly couple clamp 216 to a rail 218 secured between jaw portions 216b, 216c.

[0058] Next turning to FIGS. 4N-4U, free handle 662 will be described. Free handle 662 includes a wire receiving portion 680 and an end effector receiving portion 681. In particular, wire receiving portion 680 preferably is configured to receive a ball 656b therein, along with an end portion of wire 658. As described previously with respect to base handle 660, a pivotable lever 682 is associated with free handle 662 and preferably is coupled to tensioning wire 658 so that actuation of lever 682 may increase or decrease the tension in wire 658 as desired by acting on rocker arm 684. By increasing tension in wire 658, central arm 652 preferably becomes less flexible. Thus a user may orient curvilinear articulating arm assembly 212 as desired, and then increase the tension of wire 658 so that the orientation of arm 652 is releasably fixed. Free handle 662 has a body portion 662a, and lever 682 is rotatable with respect thereto. An interface lock 683 also is rotatably associated with body portion 662a proximate end effector receiving portion 681, as will be described shortly.

[0059] Lever 682 is pivotably coupled to rocker arm 684 with a pin 686a that is disposed such that rotation of lever 682 results in eccentric movement of rocker arm 684. Cylindrical projections 682a of lever 682 are received and rotate in arcuate cradle portions 662a1 of body portion 662a, while cylindrical projections 684a of rocker arm 684 are received and rotate in arcuate cradle portions 662a2 of body portion 662a. Rotation of lever 682 toward wire receiving portion 680 in direction T lifts pin 686a, and because rocker arm 684 rests on pin 686a, rocker arm 684 is rotated in direction U in an eccentric fashion.

[0060] Rocker arm 684 includes a hole in which a self-aligning setup washer 690 (a two-piece washer with one portion that rocks in another portion) is disposed. Setup washer 690 for example may be an 18-8 stainless steel self-aligning setup washer, $\frac{1}{4}$ inch in size, $\frac{17}{64}$ inch inner diameter, $\frac{1}{2}$ inch outer diameter, and 0.250 inch to 0.281 inch thick (McMaster-Carr part number 91944A028). A nut 692 also may abut setup washer 690 on the flat upper surface thereof and rock thereon. A threaded stud (not shown) may be swaged to the end of tensioning wire 658 opposite the end attached to forked member 676, thus coupling wire 658 to the threaded stud by compression. The threaded stud may in turn be threadably associated with nut 692. Wire 658 is provided with suitable length to span from forked member 676 to nut 692.

[0061] Pivoting of lever 682 in direction T causes rotation of rocker arm 684, and with tensioning wire 658 coupled to nut 692 and nut 692 abutting insert 690, tension in wire 658 may be increased. In particular, actuation of lever 682 may increase or decrease the tension in wire 658 as desired. By increasing tension in wire 658, central arm 652 preferably becomes increasingly resistant to movement although central arm 652 preferably still may be moved through its full range of motion. Thus, a user may orient curvilinear articulating arm assembly 212 as desired, and then increase the tension of wire 658 so that the orientation of arm 652 is releasably fixed. Lever 668 preferably has an angular range of movement about pin 686a of up to about 90° to permit tension to be generated in tensioning wire 658.

[0062] In the preferred exemplary embodiment, actuation of lever 682 free handle 662 permits initial tensioning of central arm 652 while still permitting restricted movement. And, actuation of lever 668 of base handle 660 permits substantially greater tensioning of central arm 652 while also still permitting restricted movement thereof, Advantageously, with tension created in wire 658 of central arm 652 to restrict movement thereof, the orientation of lever 668 such as with respect to a patient still may readily be reset or adjusted before lever 666 in base handle 660 is actuated to create sufficient force to prevent rotation of threaded portion 663d of coupling 663 in the hole in which it is received.

[0063] As shown in FIG. 4U, interface lock 683 includes a knurled knob portion 683a and a cylindrical post 683b that is provided with an arcuate cutout 683c. Interface lock 683 is coupled to body portion 662a with set screw 683d which is threadably received in a threaded hole 662b in body portion 662a. Set screw 683d is further received in a slot 683e in post 683b to lock post 683b in a position with arcuate cutout 683c oriented to be movable along the longitudinal axis of cylindrical post 683b. Cylindrical post 683b may be disposed in a disengaged position in which the axial position of post 683b is such that arcuate cutout 683c generally follows the inner cylindrical contour of end effector receiving portion 681. Also, cylindrical post 683b may be disposed in an engaged position in which the axial position of post 683b is such that a portion of cylindrical post 683b other than arcuate cutout 683c extends past the inner cylindrical contour of end effector receiving portion 681 toward the central longitudinal axis of end effector receiving portion 681.

[0064] In use, in order for example to couple articulating arm assembly 212 to an end effector such as a holder 214, 100, by capturing post 102 of holder 100 in end effector receiving portion 681 of free handle 662, post 102 is inserted therein while interface lock 683 is disposed in the aforementioned disengaged position. While lock 683 is in the disengaged position, post 102 may freely rotate about the central axis of receiving portion 681. Once a desired orientation is set, lock 683 may be translated along the major axis defined by slot 683a so that a portion of cylindrical post 683b of lock 683 is disposed in an engaged position and bears against post 102. Such interference between post 102 of holder 100 and post 683b of lock 683 provides sufficient pressure so that post **102** will remain fixed in rotational position and translation along the longitudinal axis thereof against the inner cylindrical contour of end effector receiving portion **681**.

[0065] Although an exemplary curvilinear articulating arm assembly is described herein, it should be understood that other preferably, curvilinear articulating arm assemblies instead may be used which preferably provide six degrees of freedom of movement and permit relatively rigid positioning such as described herein.

[0066] In some embodiments of the present invention, a transducer holder system such as system **200** may be coupled to a patient support other than a rail of a table. For example, referring next to FIG. **5**, an exemplary support system **710** according to the present invention is shown with a variety of components coupled thereto. Support system **710** includes a tray **712**, curvilinear articulating arm assemblies **212**, **716** having respective end effectors **100**, **720**, an IV pole **722**, an arm board **724**, and rail assemblies **726**, **728**. A variety of end effectors may be demountably attached for example to articulating arm assembly **716** to assist a technician or practitioner with a medical/imaging procedure or provide other features useful with respect to a patient. End effector **720**, for example, is configured as a self-centering abdominal probe bracket.

[0067] In one preferred exemplary embodiment, tray **712** may include two pairs of hold regions **730**, each pair being disposed proximate a free cranial end **732** or free caudal end **734** of tray **712**. In alternate embodiments, other numbers of hold regions **730** may be provided such as two or more, and hold regions **730** may be provided in other regions of tray **712** such as intermediate ends **732**, **734** proximate sides **736**, **738**. Hold regions **730** may be configured as hand holds, or alternatively may be configured to receive strapping so that tray **712** may be releasably coupled to another object such as an ambulance stretcher, hospital bed, operating room table, or imaging scanner table. In some embodiments, handles may be coupled to tray **712**. As also shown in FIG. **5**, attachment regions **740** are provided proximate sides **736**, **738** for demountably coupling components as previously described to tray **712**, as will be further described below. In the exemplary preferred embodiment, tray **712** is provided with thirteen attachment regions **740**, although in alternate embodiments another number of regions **740** may be provided such as at least one or tray **712** may be provided with a surgical rail or track permitting substantial freedom of coupling of components along the length thereof.

[0068] Turning to FIGS. **6A-6C**, additional features of tray **712** are shown. Although hand hold regions **730** are not included in the figure, such regions may be provided as shown in FIG. **5**. Attachment regions **740** are provided in spaced arrangement along the perimeter of tray **712**. Preferably, tray **712** includes a central arcuate portion **742** disposed between outer ledge portions **744**. Preferably, regions **740** are provided on outer ledge portions **744**. Central arcuate portion **742** preferably has an upper concave surface **742***a* for receiving a patient and optionally a cushion (not shown) for the patient to rest against, and optionally includes a lower convex surface **742***b*. Preferably, outer ledge portions **744** include upper and lower surfaces **744***a*, **744***b* connected by a sidewall **744***c* at an angle α with respect to surface **744***b*. In a preferred exemplary embodiment, sidewall **744***c* is disposed at an angle a between about 60° and about 100°, more preferably between about 70° and about 90°, and most preferably at about 80°.

[0069] In a preferred exemplary embodiment, tray **712** is formed of natural finish carbon fiber, R-51 foam core, and phenolic. Attenuation preferably is less than 1 mm Al equivalency. Thus, tray **712** is radiolucent and suitable for use with computed axial tomography (CT) scanners. In other embodiments, tray **712** is formed of a material suitable for use with magnetic resonance imaging (MR) scanners. In addition, tray **712** preferably supports a load of 900 lbs. evenly distributed along centerline **746**, about which tray **712** may be substantially symmetric as shown. Indicia **748** optionally may be provided, as shown for example proximate ends **732**, **734**. The indicia may for example indicate preferred orientation of tray **712** with respect to a patient lying thereon.

[0070] In the preferred exemplary embodiment, attachment regions **740** on each side of tray **712** are evenly spaced from each other by about 6 inches between centers thereof. To accommodate patients and equipment attached to tray **12**, in one preferred embodiment tray **712** has a length of about 78 inches, a width of about 21 inches, a generally uniform thickness of about 0.9 inch, and a height h of about 2.5 inches. Comers may be provided with a radius R1 of about 2 inches. In the preferred exemplary embodiment, attachment regions **740** preferably accommodate threaded inserts, which may be formed of aluminum.

[0071] In some embodiments, tray **712** is sized to hold an adult patient, and may be between about 180 cm and about 200 cm long. However, it will be appreciated that longer and shorter trays may be provided. In order to accommodate an adult patient, tray **712** may support an overall weight capacity of at least about 200 pounds, and preferably at least about 300 pounds. However, if a tray **712** is sized for use with a pediatric patient, tray **712** may only accommodate weights that do not exceed 200 pounds, and more preferably do not exceed 100 pounds.

[0072] Although the surface of portion **742** of tray **712** is substantially smooth in the preferred exemplary embodiment, in alternate embodiments the surface may be textured to provide additional resistance to motion of objects and/or a patient placed thereon.

[0073] Tray **712** thus is suitable for use in multiple environments, and thus may "move" with the patient from one environment (e.g., ambulance) to the next (e.g., CT scanner) without removing a patient supported thereon.

[0074] While various descriptions of the present invention are described above, it should be understood that the various features can be used singly or in any combination thereof. Therefore, this invention is not to be limited to only the specifically preferred embodiments depicted herein.

[0075] Further, it should be understood that variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains. For example, although a balloon **52** is disclosed herein for filling with a fluid interface medium such as degassed water to permit energy transmission, other types of fluid reservoirs and configurations may be used. Furthermore, any of a variety of couplings may be used to releasably attach holders **10**, **100**, **214** as disclosed herein to an articulating arm; such couplings should provide secure attachment. Accordingly, all expedient modifications readily attainable by one versed in the art from the disclosure set forth herein that are within the scope and spirit of the present invention are to be included as further embodiments of the present invention. The scope of the present invention is accordingly defined as set forth in the appended claims.

What is claimed is:

1. An ultrasound transducer positioning system comprising:

a curvilinear articulating arm;

an ultrasound transducer; and

a holder comprising a first region for receiving the transducer and a second region for a fluid interface disposed adjacent the first region, the holder being coupled to the curvilinear articulating arm;

wherein the second region is adjustable in size.

2. The system of claim 1, wherein the first region is defined by a generally circular clamp.

3. The system of claim 2, wherein the clamp comprises a split ring.

4. The system of claim 2, farther comprising a lead screw coupled to the clamp.

5. The system of claim 4, wherein:

the second region is defined between the clamp and an opposing member; and

the lead screw extends to the opposing member.

6. The system of claim 5, wherein the opposing member comprises a ring.

7. The system of claim 2, wherein the transducer is retained by at least one member coupled to the clamp and abutting a portion of the transducer.

8. The system of claim 7, wherein the at least one member abuts a portion of a face of the transducer.

9. The system of claim 1, wherein the fluid interface is a flexible member.

10. The system of claim 1, further comprising at least one rail with indexing thereon, the rail extending between a bracket coupled to the curvilinear articulating arm and a clamp defining the first region.

* * * * *

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当前申请(专利权)人(译)	CIVCO医疗器械CO.，INC.		
[标]发明人	WHITMORE WILLET F III WILSON ROGER F		
发明人	WHITMORE, WILLET F. III WILSON, ROGER F.		
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摘要(译)

超声换能器定位系统包括曲线关节臂，超声换能器和支架，支架具有用于接收换能器的第一区域和用于邻近第一区域设置的流体界面的第二区域。保持器连接到曲线铰接臂，第二区域的尺寸可调。