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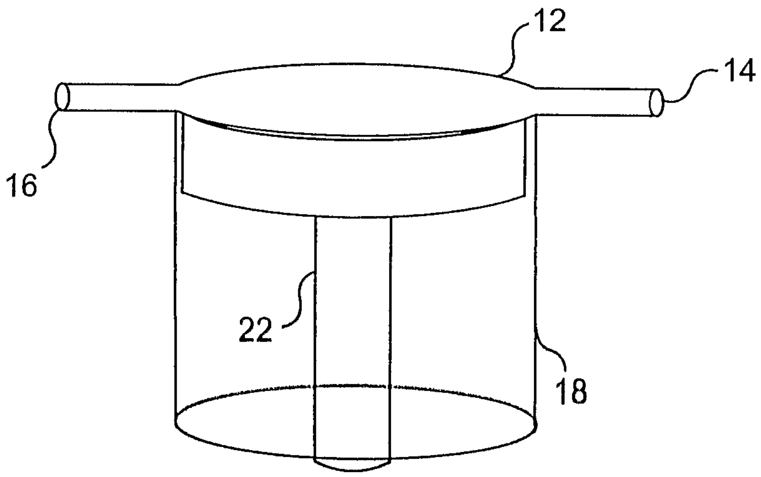
(54) Title: ACOUSTIC COUPLER USING AN INDEPENDENT WATER PILLOW WITH CIRCULATION FOR COOLING A TRANSDUCER



(57) Abstract: A water pillow for coupling acoustic energy into tissue. The pillow is configured to conform to a transducer to facilitate coupling of ultrasound energy. The pillow includes a pouch that accommodates the transducer to enable a snug fit between the pillow and the transducer. The pillow includes a liquid inlet and outlet to facilitate liquid circulation for cooling, is biocompatible, has a low attenuation, is conformal to the shape of the transducer, facilitates use of an adjustable pressure to achieve various standoffs, includes an integral pouch to facilitate an interference fit to the transducer, facilitates water circulation for cooling, is sterilizeable, and is disposable. Either the surface adapted to conform to a tissue interface, or the surface of adapted to conform to the transducer, or both, can include pores configured to weep liquid to facilitate acoustic coupling.

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ACOUSTIC COUPLER USING AN INDEPENDENT WATER PILLOW WITH CIRCULATION FOR COOLING A TRANSDUCER

Background

Ultrasound is widely used for imaging a patient's internal structures without risk of exposure to potentially harmful radiation, as may occur when using X-rays for imaging. An ultrasound examination is a safe diagnostic procedure that uses high frequency sound waves to produce an image of the internal structures of a patient's body. Many studies have shown that these sound waves are harmless and may be used with complete safety, even to visualize the fetus in pregnant women, where the use of X-rays would be inappropriate. Furthermore, ultrasound examinations generally require less time than examinations using other imaging techniques, and ultrasound examinations are typically less expensive than examinations using other imaging techniques.

More recently, the use of high intensity focused ultrasound (HIFU) for therapeutic purposes, as opposed to imaging, has received significant attention in the medical community. HIFU therapy employs ultrasound transducers that are capable of delivering 1,000-10,000 W/cm^2 to a focal spot, in contrast to diagnostic imaging ultrasound, where intensity levels are usually below 0.1 W/cm^2. A portion of the energy from these high intensity sound waves is transferred to a targeted location as thermal energy. The amount of thermal energy thus transferred can be sufficiently intense to cauterize undesired tissue, or to cause necrosis of undesired tissue (by inducing a temperature rise greater than about 70° C) without actual physical charring of the tissue. Tissue necrosis can also be achieved by mechanical action alone (i.e., by cavitation that results in mechanical disruption of the tissue structure). Further, where the vascular system supplying blood to an internal structure is targeted, HIFU can be used to induce hemostasis. The focal region of this energy transfer can be tightly controlled so as to obtain necrosis of abnormal or undesired tissue in a small target area without damaging adjoining normal tissue. Thus, deep-seated tumors can be destroyed with HIFU without surgical exposure of the tumor site.

An important component in any type of ultrasound therapy system is the mechanism for coupling the acoustic energy into the tissue. Good acoustic coupler is necessary to efficiently transfer the ultrasound energy from the transducer to the treatment site. The ideal acoustic coupler is a homogenous medium that has low attenuation, and an acoustic impedance similar to that of the tissue being treated. Due to its desirable acoustic transmission characteristics, water has commonly been used as the coupling medium in many therapeutic applications of ultrasound.

In previous hemostasis studies in which HIFU has been used to arrest bleeding of injured blood vessels and organs, the HIFU transducer was contained within a water-filled, conical, plastic housing with a thin, polyurethane membrane at the tip. This coupler was designed for superficial treatments, since it places the HIFU focus only several millimeters beyond the tip of the water-filled cone. While this coupling method has been useful for hemostasis experiments, it has many drawbacks that would make it impractical for a clinical setting. These disadvantages include requirements for degassing, sterilization, and circulation and containment issues. Due to the limitations of the current HIFU applicators, an alternative coupling medium is desirable.

Latex condoms have been used as a disposable sheath for rectal and vaginal ultrasound probes, and when filled with water, such sheaths facilitate acoustic coupling. With respect to HIFU therapy probes, a HIFU transducer can generate significant amounts of heat, which should be dissipated to protect the patient and to prolong the life of the transducer. Latex condoms, and ultrasound probe sheaths specifically intended for such ultrasound coupling, are not designed to facilitate circulation of a cooling liquid.

It would be desirable to provide a disposable acoustic coupler for use with ultrasound probes, configured to circulate a cooling liquid proximate an ultrasound transducer.

Summary

Disclosed herein is an acoustic coupler that facilitates acoustically coupling an acoustic device (such as an ultrasound imaging transducer or an ultrasound therapy transducer) to a physical mass, where the acoustic device is configured to direct acoustic energy into or through the physical mass. The physical mass is generally biological tissue, although no limitation is implied with respect to the type of physical mass to which the acoustic energy is directed. The acoustic coupler includes a liquid chamber (e.g., a water pillow) having a first surface configured to conform to a

transducer, and a second surface configured to conform to the physical mass into which the acoustic energy provided by the transducer is to be directed. The liquid chamber further includes a liquid inlet configured to be coupled to a liquid supply, and a liquid outlet configured to be coupled to a discharge volume. A pump can be used to circulate liquid through the liquid chamber to dissipate heat generated by the transducer. Generally, the liquid chamber is filled with water (or saline solution), although the use of water in this embodiment should not be considered to be a limitation on the concept.

Preferably, the first surface (configured to conform to the transducer) provides cooling to the front face of the transducer. The acoustic coupler further preferably exhibits one or more of the following characteristics: the acoustic coupler is formed from biocompatible materials, the acoustic coupler exhibits a low attenuation, a liquid pressure in the liquid chamber of the acoustic coupler can be varied to achieve various standoffs, the acoustic coupler is formed from materials that can be sterilized, and the acoustic coupler device can be viewed as disposable.

In one implementation, the acoustic coupler includes a pouch coupled to the liquid chamber. The pouch defines an open-ended volume configured to receive a transducer, so that the pouch can be used to attach the acoustic coupler to the transducer. Preferably, the pouch is formed from a flexible and elastomeric material, such that the acoustic coupler is attached to the transducer via an interference fit. The dimensions of the pouch can be varied to accommodate specific transducer configurations. In some embodiments, the pouch is configured to encompass the transducer and at least a portion of a handle or probe supporting the transducer.

The liquid inlet and liquid outlet of the liquid chamber are preferably configured to enhance a circulation of liquid in the liquid chamber. Various different configurations can be empirically tested to determine the effectiveness of a specific configuration. Exemplary configurations include disposing the liquid inlet substantially adjacent to the liquid outlet, as well as disposing the liquid inlet substantially opposed to the liquid outlet. In some embodiments, the liquid inlet and liquid outlet are separated by an acute angle. In some embodiments, the liquid inlet and liquid outlet are separated by an angle of between about 40° and about 100°.

At least one of the first surface (configured to conform to the front face of the transducer), and the second surface (configured to conform to the physical mass) can include at least one opening to allow liquid from the liquid chamber to wet the surface, thereby enhancing the acoustic coupler between the surface and the transducer and/or the physical mass. Preferably, a surface configured to "weep" liquid to facilitate coupling will include a plurality of small pores that release sufficient liquid to facilitate coupling, without releasing excessive amounts of liquid. Various different agents can be added to the liquid used to inflate the liquid chamber, to be released through such pores. Such agents can include ultrasound contrast agents, therapeutic agents, and sterilization agents.

A system configured to be used with such acoustic couplers preferably includes a liquid supply, a pump configured to circulate the liquid, and a cooling unit configured to thermally condition the liquid. A degassing unit, such as a second pump, is preferably included to remove gas bubbles from the liquid. In some embodiments, a liquid line coupling the liquid supply to the liquid inlet is larger than a liquid line coupling the liquid outlet to the liquid supply, to increase a flow resistance on the outlet of the liquid chamber relative to its inlet.

A related method for acoustically coupling a transducer to a physical mass while providing cooling to the transducer includes the steps of positioning a liquid chamber between the physical mass and the transducer, introducing a liquid into the liquid chamber, such that a first surface of the liquid chamber conforms to the transducer and a second surface of the liquid chamber conforms to the physical mass, and introducing additional liquid into the liquid chamber, thereby establishing a circulating flow of liquid that absorbs heat from the transducer, providing cooling to the transducer. Additional method steps relate to releasing a portion of liquid disposed within the liquid chamber from at least one of the first surface and the second surface to facilitate acoustically coupling the surface to the transducer and/or physical mass. Yet another method step relates to securing the liquid chamber to the transducer using a pouch defining an open-ended volume configured to achieve a snug fit with the transducer.

This Summary has been provided to introduce a few concepts in a simplified form that are further described in detail below in the Description. However, this Summary is not intended to identify key or essential features of the claimed subject matter, nor is it intended to be used as an aid in determining the scope of the claimed subject matter.

Drawings

Various aspects and attendant advantages of one or more exemplary embodiments and modifications thereto will become more readily appreciated as the same becomes better understood by reference to the following detailed description, when taken in conjunction with the accompanying drawings, wherein:

FIGURE 1A schematically illustrates a first embodiment of an acoustic coupler including a liquid chamber configured to acoustically couple a transducer to a physical mass, and to circulate a cooling liquid to cool the transducer, as well as a pouch configured to attach the acoustic coupler to the transducer;

FIGURE 1B schematically illustrates an exemplary acoustic device including a transducer and a handle;

FIGURE 1C schematically illustrates an acoustic coupler in FIGURE 1A that is attached to an acoustic device of FIGURE 1B;

FIGURE 1D is an enlarged view of the liquid chamber portion of the acoustic coupler of FIGURE 1A, illustrating that the liquid chamber includes a first surface configured to conform to the transducer, and a second surface configured to conform to a physical mass into which acoustic energy from the transducer is to be directed;

FIGURE 2A schematically illustrates a second embodiment of an acoustic coupler configured to be attached to a different type of acoustic device;

FIGURE 2B schematically illustrates another exemplary acoustic device including a transducer and a handle;

FIGURE 2C schematically illustrates the acoustic coupler of FIGURE 2A attached to the exemplary acoustic device of FIGURE 2B;

FIGURES 2D and 2E are views of the liquid chamber portion of the acoustic coupler of FIGURE 2A, illustrating that an opening or pores can be provided in a wall of the liquid chamber to enable liquid from the liquid chamber to be released, to enhance an acoustic coupler between the liquid chamber and at least one of the transducer and the physical mass;

FIGURE 2F schematically illustrates an alternative configuration for a liquid inlet and a liquid outlet portion of the liquid chamber of FIGURE 2A, wherein an angle of about 100° is defined between the liquid inlet and liquid outlet;

FIGURE 2G schematically illustrates an alternative configuration for a liquid inlet and a liquid outlet portion of the liquid chamber of FIGURE 2A, wherein an angle of about 40° is defined between the liquid inlet and liquid outlet;

FIGURE 2H is an image of the acoustic coupler of FIGURE 2A attached to the acoustic device of FIGURE 2B, illustrating how a liquid pressure in the liquid chamber can be varied to achieve a different standoff;

FIGURE 3 is a functional block diagram of a system including an acoustic coupler, such as illustrated in FIGURES 1A and 2A, a circulation pump, a liquid reservoir, a cooling unit, a flow meter, and a degassing unit;

FIGURE 4A schematically illustrates another exemplary acoustic device, including a generally spoon shaped transducer, and a handle;

FIGURE 4B illustrates additional details for the structure of the acoustic device of FIGURE 4A;

FIGURE 4C is an image of the acoustic device of FIGURE 4A and yet another embodiment of an acoustic coupler;

FIGURE 4D is an image of the acoustic coupler configured to be used with the acoustic device of FIGURE 4A;

FIGURE 4E is an image of the acoustic coupler of FIGURE 4D attached to the acoustic device of FIGURE 4A;

FIGURE 5A schematically illustrates yet another embodiment of an acoustic coupler being used to acoustically couple the transducer of an acoustic device to tissue;

FIGURE 5B is an enlarged view of the acoustic coupler of FIGURE 5A, illustrating that the pouch portion of the acoustic coupler is disposed in a central portion of the acoustic coupler, such that when the acoustic coupler is attached to an acoustic device, the acoustic coupler substantially encompasses the acoustic device, proximate to the transducer;

FIGURE 6 is a chart illustrating that exemplary acoustic couplers as described herein can achieve satisfactory cooling of a HIFU transducer; and

FIGURE 7 graphically illustrates the percentage of heat removed by an acoustic coupler including a liquid chamber, as a function of a focal depth of the transducer.

Description

Figures and Disclosed Embodiments Are Not Limiting

Exemplary embodiments are illustrated in referenced Figures of the drawings. It is intended that the embodiments and Figures disclosed herein are to be considered illustrative rather than restrictive.

FIGURE 1A schematically illustrates a first embodiment of an acoustic coupler 10 including a liquid chamber 12 configured to acoustically couple a transducer to a physical mass and to circulate a cooling liquid to cool the transducer, as well as a pouch 18 configured to attach the acoustic coupler to the transducer.

Liquid chamber 12 includes a liquid inlet 14 and a liquid outlet 16. Liquid, such as water or a saline solution, can be introduced into liquid chamber 12 via liquid inlet 14. Note that pouch 18 defines an open-ended volume that is sized and shaped to accommodate a transducer. Preferably, pouch 18 is formed from a flexible (elastomeric) material so that acoustic coupler 10 can be attached to a transducer (or an acoustic device including a transducer) by an interference fit between the acoustic coupler and the device.

FIGURE 1B schematically illustrates an exemplary acoustic device 19 including a transducer 20, a handle 22, and a lead 21 that couples the transducer to a power supply (not shown). In general, transducer 20 will be a HIFU therapy transducer configured to emit ultrasound waves sufficiently energetic to induce a therapeutic effect at a treatment site. The terms "therapeutic transducer," "HIFU transducer," and "high intensity transducer," as used herein, all refer to a transducer that is capable of being energized to produce ultrasonic waves that are much more energetic than the ultrasonic pulses produced by an imaging transducer and which can be focused or directed onto a discrete location, such as a treatment site in a target area. Such transducers generally generate more heat during use than ultrasound imaging transducers. Thus, HIFU transducers have a greater need for cooling than do imaging transducers. However, while the acoustic couplers disclosed herein are expected to be particularly beneficial when used with a HIFU transducer, it should be recognized that these acoustic couplers are not limited for use in connection with any specific transducer. Furthermore, it should be recognized that the acoustic couplers disclosed herein can be configured to be used with many different shapes of transducers, and with many different acoustic devices incorporating transducers.

FIGURE 1C schematically illustrates acoustic coupler 10 of FIGURE 1A attached to acoustic device 19 of FIGURE 1B. Note that transducer 20 is encompassed by the open-ended volume of pouch 18. As illustrated in FIGURE 1D, when acoustic coupler 10 is properly positioned relative to acoustic device 19, and liquid chamber 12 is filled with a liquid, a surface 24 of liquid chamber 12 substantially conforms to transducer 20. It should be recognized that there exists significant variation in acoustic devices incorporating transducers. For example, in some acoustic devices (particularly devices configured for HIFU therapy), a front face of the transducer is exposed. When acoustic coupler 10 is used with an acoustic device including a transducer whose front face is exposed, surface 24 will generally conform to the front face of the transducer. Some acoustic devices include a transducer to which an optional lens 20a (see FIGURE 1D) has been attached. For example, aluminum lenses are sometimes employed to achieve better focusing of a HIFU transducer. When acoustic coupler 10 is used with an acoustic device including a transducer to which such a lens has been coupled, surface 24 will generally conform to the front face of the lens. Because such lenses normally exhibit good heat transfer properties, cooling the lens will also cool the underlying transducer. Furthermore, some acoustic devices incorporate a relatively thin housing to enclose a transducer. When acoustic coupler 10 is used with an acoustic device in which the transducer is covered by such a housing, surface 24 will generally conform to the housing, covering the transducer. Again, such housings are generally formed from a relatively thin material, so that cooling the housing proximate the transducer will also cool the underlying transducer. Therefore, it should be recognized that in respect to the following disclosure and the claims that follow, where terms such as "substantially conforms to a transducer," "substantially conforms to the transducer," "conforms to a transducer," and "conforms to the transducer" are employed, such language is intended to encompass the ability of the acoustic coupler to conform to a lens that is coupled to the transducer, as well as conforming to a housing encapsulating the transducer.

Referring once again to FIGURE 1D, liquid chamber 12 further includes a surface 26 configured to conform to a physical mass 28 into which acoustic energy from the transducer is to be directed. Either or both surfaces 24 and surface 26 can be coated with mineral oil (or some other coupling medium or coupling gel) to ensure adequate acoustic coupling is achieved.

As noted above, the acoustic couplers disclosed herein preferably exhibit one or more of the following characteristics: biocompatibility, low attenuation, variability of liquid pressure in the liquid chamber enabling different standoffs to be achieved, sterilizability, and disposability. The acoustic couplers disclosed herein can be formed of a polymer material, such as polyurethane. Such a material is biocompatible, sterilizable, has a low attenuation, is flexible (so that the material readily conforms to a physical mass as well as to a transducer, or lens or housing as noted above), and is able to achieve an interference fit with an acoustic device (where dimensions of the pouch have been selected to accommodate a particular form factor for an acoustic device). In some embodiments, the pouch is oversized, so that a wider variation of form factors can be accommodated. In such embodiments, additional attachment mechanisms can be employed, such as straps, couplings, or elastic bands, to secure the acoustic coupler to the acoustic device.

FIGURE 2A schematically illustrates a second embodiment of an acoustic coupler configured to be attached to a different type of acoustic device. Acoustic coupler 10a includes a liquid chamber 12a, a liquid inlet 14a, a liquid outlet 16a, and a pouch 18a. Once again, pouch 18a defines an open-ended volume configured to receive a transducer. Note that the size and shape of pouch 18a of FIGURE 2A is different than the size and shape of pouch 18 in FIGURE 1A, because acoustic coupler 10a (FIGURE 2A) is configured to be used with a different acoustic device than is acoustic coupler 10 (FIGURE 1A).

FIGURE 2B schematically illustrates an exemplary acoustic device 19a including a transducer 20a, a handle 22a, and a lead 21a that couples the transducer to a power supply (not shown). Once again, transducer 20a will likely be a HIFU therapy transducer, although this exemplary use of the acoustic couplers with HIFU transducers is not intended to represent a limitation.

FIGURE 2C schematically illustrates acoustic coupler 10a of FIGURE 2A attached to acoustic device 19a of FIGURE 2B. Note that transducer 20a is substantially encompassed by the open-ended volume of pouch 18a. As illustrated in FIGURE 2D, acoustic coupler 10a includes a surface 24a configured to conform to a transducer (or to a lens attached to a transducer, or to a housing enclosing a transducer, generally as described above). Acoustic coupler 10a further includes a surface 26a configured to conform to a physical mass (not shown) into which acoustic energy from the transducer is to be directed. It should be noted that pouch 18a not only encompasses transducer 20a, but also a portion of handle 22a supporting transducer 20a. Preferably, pouch 18a has dimensions selected to accommodate the form factor of acoustic device 19a, so that an interference fit is achieved when transducer 20a and the portion of handle 22a supporting transducer 20a are introduced into pouch 18a. As noted above, some embodiments will incorporate an oversized pouch, to accommodate a wider range of acoustic device form factors, and then use other attachments to secure the acoustic coupler to the acoustic device.

Referring once again to FIGURE 2D, surface 26a can optionally include a least one opening configured to enable a liquid in liquid chamber 12a to wet surface 26a, thereby enhancing the acoustic coupler between surface 26a and the physical mass. While not specifically shown, it should be recognized that such openings can also be beneficially incorporated into surface 24a, to similarly enhance the acoustic coupler between surface 24a and the transducer (or a lens covering the transducer, or a housing covering the transducer, generally as described above). Preferably, the size, shape, and location of such openings are selected to generate a thin layer of liquid on the surface without releasing substantially more liquid than is required to facilitate coupling. In some specific applications, it may be desirable to continually flush the physical mass to which the acoustic device is being coupled with a liquid. (For example, an acoustic device configured to provide emergency treatment in field conditions may incorporate openings providing sufficient liquid flow to continually flush the physical mass.) In such embodiments, the openings will be sized, shaped, and oriented to achieve the desired flow. FIGURE 2E schematically illustrates a liquid chamber 12b, which includes a plurality of pores (generally indicated by an arrow 30a) configured to wet a surface 26b with liquid flowing from liquid chamber 12b. Particularly in embodiments where the wall or surface of the liquid chamber configured to couple with the physical mass toward which the acoustic device is directing acoustic energy includes at least one opening, that opening can be used to deliver a plurality of different agents to the surface. Such agents can include ultrasound contrast agents, therapeutic agents, and sterilization agents. Particularly with respect to the acoustic device configured to provide emergency treatment under field conditions noted above, disinfectant agents can be introduced into the liquid to prevent potential infections.

Referring once again to acoustic coupler 10 of FIGURE 1A, note that liquid inlet 14 and liquid outlet 16 are substantially opposite each other (i.e., an angle of about 180° is defined between them). In contrast, liquid inlet 14a and liquid outlet 16a of acoustic coupler 10a (FIGURE 2A) are substantially adjacent (i.e., they are separated by an angle of about 0°). It should be recognized that the relative orientations of the liquid inlet and the liquid outlet can effect a circulation of the liquid within the liquid chamber, which in turn, can affect the ability of the circulating liquid to dissipate heat generated by the transducer. The liquid inlet and liquid outlet of the liquid chamber are preferably configured to enhance a circulation of liquid in the liquid chamber. Various different configurations can be empirically tested to determine the effectiveness of a specific configuration. Exemplary configurations include disposing the liquid inlet substantially adjacent to the liquid outlet (as exemplified by acoustic coupler 10a of FIGURE 2A), as well as disposing the liquid inlet substantially opposite to the liquid outlet (as exemplified by acoustic coupler 10 of FIGURE 1A). In some embodiments, the liquid inlet and liquid outlet are separated by an acute angle, as is schematically illustrated in FIGURE 2D by a liquid inlet 13a and a liquid outlet 15a, where an acute angle 17a separates the liquid inlet from the liquid outlet. In some embodiments, the liquid inlet and liquid outlet are separated by an angle of between about 40° to about 100°. FIGURE 2F schematically illustrates an angle 17b of about 100°, while FIGURE 2G schematically illustrates an angle 17c of about 40°, either of which can be used as a separation angle between the liquid inlet and the liquid outlet (as well as any angle in between). Empirical studies with acoustic coupler 10 and acoustic coupler 10a have indicated that acoustic couplers having a liquid inlet that is substantially opposite to the liquid outlet exhibit higher heat removal rates. However, the difference between the heat removal rate for acoustic coupler 10 and acoustic coupler 10a was not significant for small, relatively low-power transducers, and only becomes significant when relatively larger transducers, generating more heat, are employed.

FIGURE 2H is an image of acoustic coupler 10a of FIGURE 2A attached to acoustic device 19a of FIGURE 2B, illustrating how a liquid pressure in liquid chamber 12a can be varied to achieve a different standoff. When a first liquid pressure is used, liquid chamber 12a inflates to a maximum height indicated by a line 23. Increasing the amount of liquid forced into the liquid chamber increases the pressure and causes liquid chamber 12a to inflate further (generally as indicated by a curve 25), so that it exhibits a different maximum height, generally as indicated by a line 27. Variation of the liquid pressure in the liquid chamber can thus be used to achieve different standoffs.

FIGURE 3 is a functional block diagram of a system 32 including an acoustic coupler 10b (such as illustrated in FIGURES 1A and 2A), a circulation pump 36, a liquid reservoir 34, a cooling unit 35, a flow meter 37, a temperature sensor 39, and an optional (but preferred) degassing unit 38. The function of circulation pump 36 is to provide a motive force for establishing a circulating liquid within the liquid chamber of acoustic coupler 10b. The function of liquid reservoir 34 is to provide a supply of the circulatory liquid, such as water or saline solution, and to receive cooled liquid from cooling unit 35. Note cooling unit 35 can be beneficially implemented using a combination fan and heat exchanger. Those of ordinary skill in the art will recognize that many types of cooling units can be employed, such as thermoelectric coolers and other types of electromechanical chillers.

It should be understood that the relative position of the cooling unit is not important. For example, FIGURE 3 indicates that the cooling unit is coupled in fluid communication with the liquid outlet of the acoustic coupler, such that the liquid returning from the acoustic coupler is cooled before being returned to the liquid supply for recirculation. An alternative configuration would be to position the cooling unit between the liquid supply and the liquid inlet of the acoustic coupler, such that the liquid is cooled before it is introduced into the liquid volume, rather than being cooled after it has exited the liquid volume.

Temperature sensor 39 can be disposed in a number of different locations. A temperature sensor can be introduced into the liquid chamber of acoustic coupler 10b, or into one or both of the liquid inlet and liquid outlet of acoustic coupler 10b. The purpose of the temperature sensor is to monitor the temperature of the circulating liquid, to determine if additional cooling or additional chilled liquid flow are required to sufficiently cool the transducer. Flow meter 37 can be implemented using one or more valves configured to enable a flow rate to be varied, and preferably includes a meter providing an indication of a current flow rate, as well as the one or more valves to control it. In an empirical system developed to test the concept disclosed herein, degassing unit 38 was implemented using an additional pump. Those of ordinary skill in the art will recognize that other conventional degassing techniques can be employed. In the empirical system noted above, a flow resistance on the liquid outlet of the acoustic coupler was increased relative to that of the liquid inlet, by providing a larger liquid line coupling the liquid inlet of the acoustic coupler to the liquid supply than was provided to couple the liquid outlet of the acoustic coupler to the cooling unit.

FIGURE 4A schematically illustrates another exemplary acoustic device 40, which includes a generally spoon shaped transducer 42 and a handle 44. Transducer 42 is a phased array transducer including 11 different transducer elements, six of which have complete annuli, and five of which have truncated annuli. Transducer 42 exhibits a focal range of about 3-6 cm.

FIGURE 4B illustrates additional details of transducer 42, clearly showing the plurality of different emitter elements that are included therein. Generally spoon-shaped transducer 42 includes 11 discrete emitter elements, all equal in area, each element being separated from its neighbors by about 0.3 mm. Six of the emitter elements have complete annuli, and five emitter elements have truncated annuli. The overall transducer dimensions are about 35 mm x 60 mm. Generally spoon-shaped transducer 42 has a center frequency of around 3 MHz, a focal length of about 3-6 cm, a geometric focus of about 5 cm, and a maximum focal intensity of about 3000 W/cm^2.

FIGURE 4C is an image of acoustic device 40 of FIGURE 4A, and yet another embodiment of an acoustic coupler. An ultrasound imaging probe 54 is coupled to acoustic device 40 (a HIFU therapy probe) via a mechanical coupling 57, to facilitate simultaneous imaging and therapy. An image plane 54a is provided by imaging probe 54, and acoustic device 40 provides a highly focused acoustic beam 42a. An acoustic coupler 46 has been attached to transducer 42. Acoustic coupler 46 includes a liquid inlet 50, a liquid outlet 52, a liquid chamber 49, and an open-ended pouch 48 (having a size and shape selected to correspond to a size and shape of transducer 42). Acoustic coupler 46 is attached to transducer 42 via an interference fit provided by pouch 48.

In an empirical study, acoustic coupler 46 was fashioned out of polyurethane, and a pump circulated water over the face of transducer 42 at a rate of approximately 60 ml/min. That rate was determined empirically to avoid over-inflation of the liquid chamber, and ensure that the transducer temperature did not rise above 40° C. Water was selected as the cooling medium, due to its ease of handling and its effectiveness as a transducer coolant.

FIGURE 4D is an image of acoustic coupler 46 before being attached to transducer 42, more clearly showing liquid inlet 50, liquid outlet 52, and pouch 48. FIGURE 4E is an image of acoustic coupler 46 of FIGURE 4D attached to acoustic device 40 of FIGURE 4A, illustrating that liquid chamber 49 includes a surface 58 configured to conform to transducer 42, and a surface 56 configured to conform to a physical mass into which transducer 42 emits highly focused beam 42a.

FIGURE 5A schematically illustrates yet another embodiment of an acoustic coupler being used to acoustically couple a transducer of an acoustic device to tissue. An acoustic device 80, including a therapeutic transducer 82, has been introduced into a body cavity and is positioned such that a highly focused acoustic beam 88, generated by transducer 82, can provide therapy to a target 86 in tissue 63. Prior to introducing acoustic device 80 into the body cavity, an acoustic coupler 60 is attached to the acoustic device. Acoustic coupler 60 similarly includes a liquid chamber 62, a pouch 64, a liquid inlet 66, and a liquid outlet 68. Significantly, dimensions of pouch 64 have been selected such that substantially the entire mass of a distal end of acoustic device 80 (including transducer 82) can be introduced into pouch 64. As is illustrated by FIGURE 5B, acoustic coupler 60 includes a surface 70, which both defines the open-ended volume of pouch 64, and is configured to conform to the shape and size of transducer 82. Acoustic coupler 60 also includes a surface 72, which both defines an outer extent of the acoustic coupler and is configured to conform to tissue 63. Pouch 64 can be configured to achieve an interference fit with the distal end of acoustic device 80. Particularly when used as indicated in FIGURE 5A, inflation of liquid chamber 62 should secure the acoustic coupler to the acoustic device, as well as securing the combination of the acoustic coupler and the acoustic device in the body cavity, even when the dimensions of the pouch are not sufficient to achieve an interference fit.

FIGURE 6 is a chart illustrating the performance of empirical acoustic couplers generally consistent with acoustic coupler 10 of FIGURE 1A (labeled "opposite" in FIGURE 6) and acoustic coupler 10a of FIGURE 2A (labeled "adjacent" in FIGURE 6). Both configurations of acoustic couplers were able to remove the heat generated by either a 3.5 MHz transducer or a 5.0 MHz transducer.

FIGURE 7 graphically illustrates the percentage of heat removed by an acoustic coupler (including a liquid chamber) relative to a focal depth of the transducer, indicating that increasing flow rates enable higher percentages of heat to be removed.

Although the present invention has been described in connection with the preferred form of practicing it and modifications thereto, those of ordinary skill in the art will understand that many other modifications can be made to the present invention within the scope of the claims that follow. Accordingly, it is not intended that the scope of the invention in any way be limited by the above description, but instead be determined entirely by reference to the claims that follow.

The invention in which an exclusive right is claimed is defined by the following:

1. An acoustic coupler adapted to be disposed between an acoustic transducer configured to emit acoustic energy and a physical mass, to acoustically couple the transducer with the physical mass, said acoustic coupler comprising a liquid chamber, the liquid chamber including:

(a) a liquid inlet configured to be coupled in fluid communication with a supply volume for holding a circulating liquid;

(b) a liquid outlet configured to be coupled in fluid communication with a discharge volume for the circulating liquid;

(c) a first surface configured to conform to the transducer; and

(d) a second surface configured to conform to the physical mass.

2. The acoustic coupler of Claim 1, further comprising a pouch coupled with the liquid chamber, the pouch being configured to secure the acoustic coupler to the transducer.

3. The acoustic coupler of Claim 2, wherein the pouch comprises an elastomeric material, and the pouch defines an open-ended volume configured to receive the transducer.

4. The acoustic coupler of Claim 2, wherein the pouch is configured to achieve an interference fit with the transducer.

5. The acoustic coupler of Claim 1, wherein the first surface has at least one opening configured to release a portion of a liquid in the liquid chamber, to wet the first surface and thereby facilitate more efficiently acoustically coupling the acoustic coupler with the transducer.

6. The acoustic coupler of Claim 1, wherein the second surface has at least one opening configured to release a portion of a liquid in the liquid chamber, to wet the second surface and thereby facilitate more efficiently acoustically coupling the acoustic coupler with the physical mass.

7. The acoustic coupler of Claim 1, wherein the acoustic coupler is formed of a biocompatible material.

8. The acoustic coupler of Claim 1, wherein the acoustic coupler comprises polyurethane.

9. The acoustic coupler of Claim 1, wherein a relative orientation of the liquid inlet and the liquid outlet have been selected to enhance a circulation of liquid through the liquid chamber.

10. The acoustic coupler of Claim 1, wherein a relative orientation of the liquid inlet and the liquid outlet comprises at least one of the following:

(a) an angular separation between the liquid inlet and the liquid outlet of between about 40 degrees and about 110 degrees;

(b) the liquid inlet and the liquid outlet are substantially opposite to each other; and

(c) the liquid inlet and the liquid outlet are substantially adjacent to each other.

11. The acoustic coupler of Claim 1, further comprising a temperature sensor disposed in at least one of the liquid inlet, the liquid outlet, and the liquid chamber.

12. The acoustic coupler of Claim 1, wherein the acoustic coupler is configured such that when the acoustic coupler is properly positioned relative to the transducer, the liquid chamber substantially encompasses the transducer.

13. An acoustic coupler adapted to be disposed between an ultrasound transducer configured to emit acoustic energy and a physical mass, to acoustically couple the ultrasound transducer with the physical mass, said acoustic coupler comprising:

(a) a liquid chamber, the liquid chamber comprising:

(i) a liquid inlet configured to be coupled in fluid communication with a supply volume for holding a circulating liquid;

(ii) a liquid outlet configured to be coupled in fluid communication with a discharge volume for the circulating liquid;

(iii) a first surface configured to conform to the ultrasound transducer; and

(iv) a second surface configured to conform to the physical mass, wherein at least one of the first surface and the second surface includes at least one opening configured to release a portion of liquid from the liquid chamber, to enhance coupling with at least one of the ultrasound transducer and the physical mass.

14. The acoustic coupler of Claim 13, further comprising a pouch coupled with the liquid chamber, the pouch being configured to secure the acoustic coupler to the ultrasound transducer.

15. The acoustic coupler of Claim 14, wherein the pouch is configured to achieve an interference fit with the ultrasound transducer.

16. The acoustic coupler of Claim 13, wherein the acoustic coupler is configured such that when the acoustic coupler is properly positioned relative to the ultrasound transducer, the liquid chamber substantially encompasses the ultrasound transducer.

17. A system for acoustically coupling an ultrasound transducer configured to emit acoustic energy with a physical mass, while providing cooling to the ultrasound transducer, the system comprising:

(a) an acoustic coupler comprising a liquid chamber including:

(i) a liquid inlet configured to introduce a liquid into the liquid chamber;

(ii) a liquid outlet configured to remove a liquid from the liquid chamber;

(iii) a first surface configured to conform to the ultrasound transducer; and

(iv) a second surface configured to conform to the physical mass, wherein at least one of the first surface and the second surface includes at least one opening configured to release a portion of liquid from the liquid chamber, to enhance coupling with at least one of the ultrasound transducer and the physical mass;

(b) a liquid supply coupled in fluid communication with the liquid inlet;

(c) a pump configured to fill the liquid chamber with the liquid that is used to acoustically couple the ultrasound transducer with the physical mass, and to circulate the liquid through the system; and

(d) a cooling unit coupled in fluid communication with the liquid supply, such that the cooling unit cools the liquid being circulated through the system to cool the ultrasound transducer.

18. The system of Claim 17, further comprising a degasser configured to remove gas bubbles from the liquid.

19. The system of Claim 17, wherein a liquid line coupling the liquid supply with the liquid inlet is relatively larger in size than a liquid line coupling the liquid outlet with the cooling unit.

20. The system of Claim 17, wherein the acoustic coupler further comprises a pouch coupled with the liquid chamber, the pouch being configured to secure the acoustic coupler to the ultrasound transducer.

21. A system for acoustically coupling an ultrasound transducer configured to emit acoustic energy with a physical mass, while providing cooling to the ultrasound transducer, the system comprising:

(a) an acoustic coupler comprising a liquid chamber including:

(i) a liquid inlet configured to introduce a liquid into the liquid chamber;

(ii) a liquid outlet configured to remove a liquid from the liquid chamber;

(iii) a first surface configured to conform to the ultrasound transducer; and

(iv) a second surface configured to conform to the physical mass;

(b) a liquid supply coupled in fluid communication with the liquid inlet;

(c) a pump configured to fill the liquid chamber with the liquid that is used to acoustically couple the ultrasound transducer with the physical mass, and to circulate the liquid through the system; and

(d) a cooling unit coupled in fluid communication with the liquid supply, such that the cooling unit cools the liquid being circulated through the system to cool the ultrasound transducer.

22. The system of Claim 21, wherein at least one of the first surface and the second surface includes at least one opening configured to release a portion of liquid from the liquid chamber, to enhance coupling with at least one of the ultrasound transducer and the physical mass.

23. The system of Claim 21, further comprising a degasser configured to remove gas bubbles from a liquid circulating through the system.

24. The system of Claim 21, wherein the acoustic coupler further comprises a pouch coupled with the liquid chamber, the pouch being configured to secure the acoustic coupler to the ultrasound transducer.

25. A method for acoustically coupling an ultrasound transducer configured to emit acoustic energy with a physical mass, while providing cooling to the ultrasound transducer, the method comprising the steps of:

(a) positioning a liquid chamber between the physical mass and the ultrasound transducer;

(b) introducing a liquid into the liquid chamber, such that a first surface of the liquid chamber conforms to the ultrasound transducer, and a second surface of the liquid chamber conforms to the physical mass; and

(c) introducing a circulating flow of the liquid through the liquid chamber, the flow of liquid absorbing heat from the ultrasound transducer, thus providing cooling to the ultrasound transducer.

26. The method of Claim 24, further comprising the step of releasing a portion of liquid in the liquid chamber via an opening in the first surface to facilitate acoustically coupling the first surface to the ultrasound transducer.

27. The method of Claim 24, further comprising the step of releasing a portion of liquid in the liquid chamber via an opening in the second surface to facilitate acoustically coupling the second surface to the physical mass.

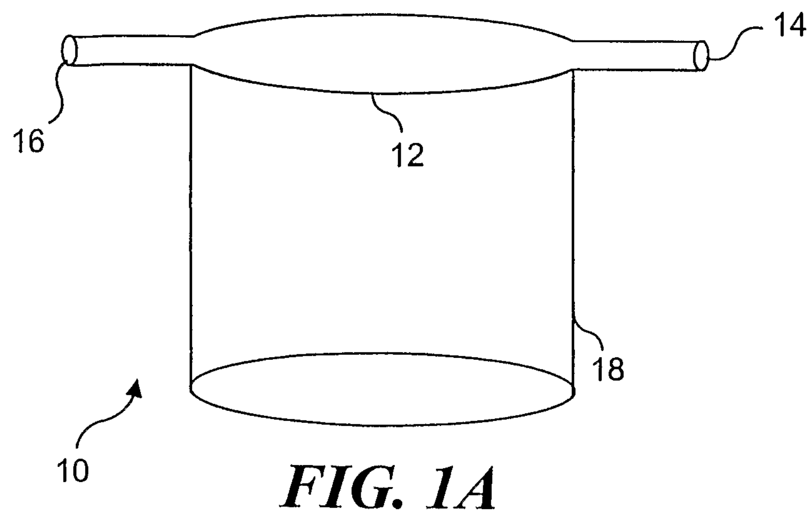


FIG. 1A

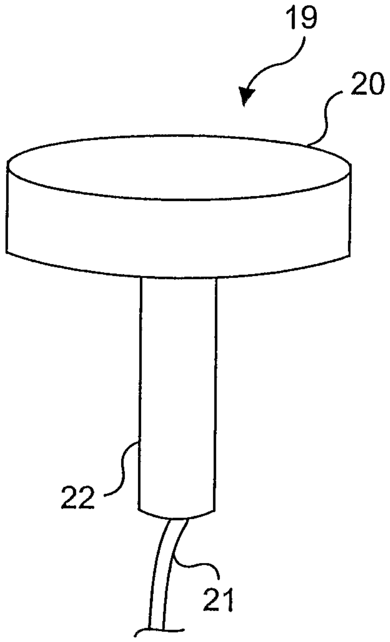


FIG. 1B

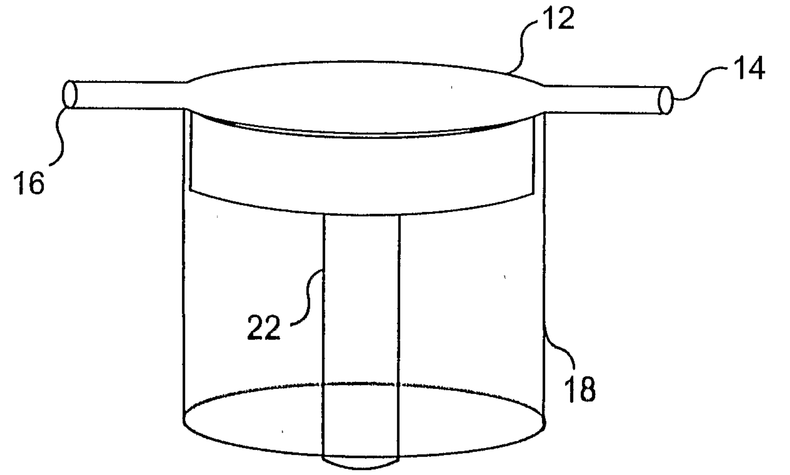


FIG. 1C

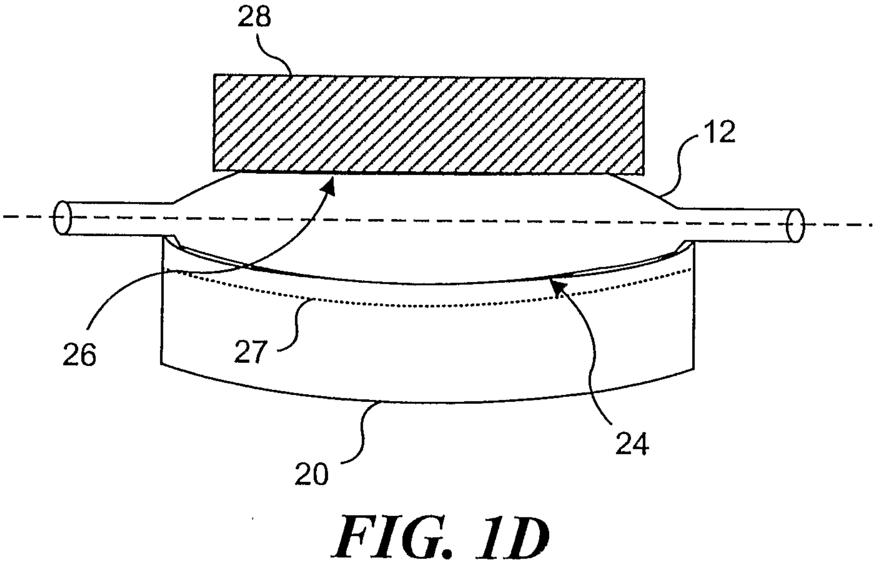


FIG. 1D

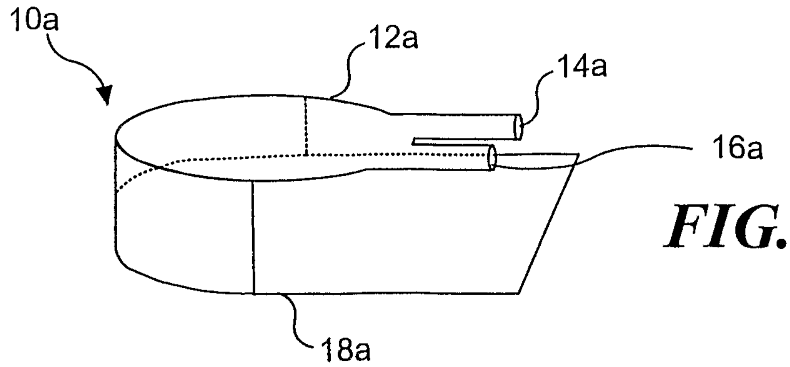


FIG. 2A

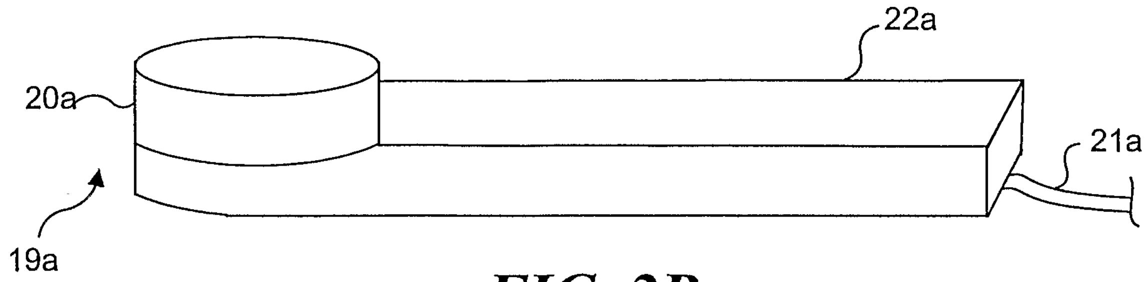


FIG. 2B

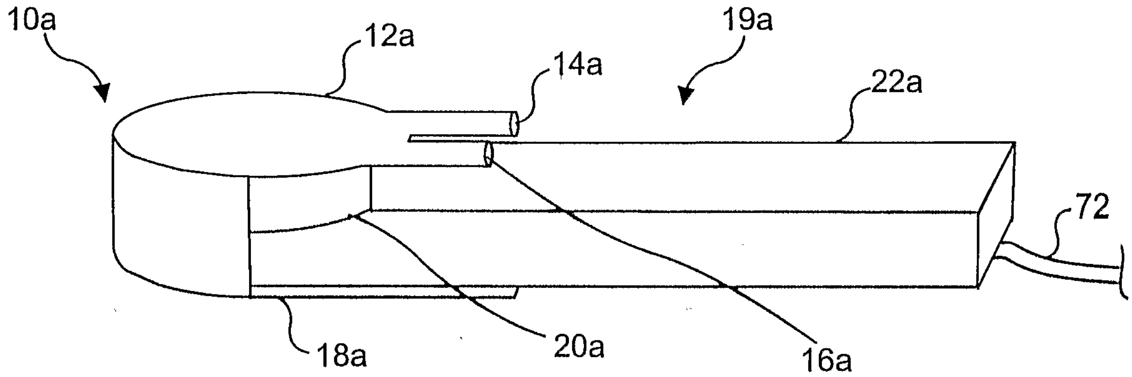


FIG. 2C

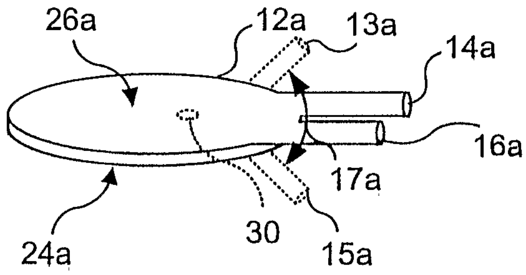


FIG. 2D

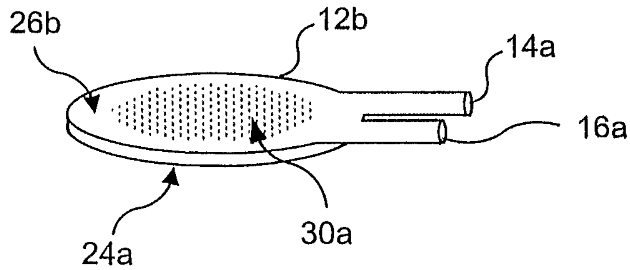


FIG. 2E

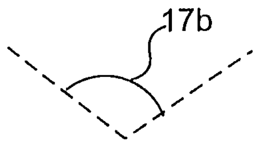


FIG. 2F

FIG. 2G

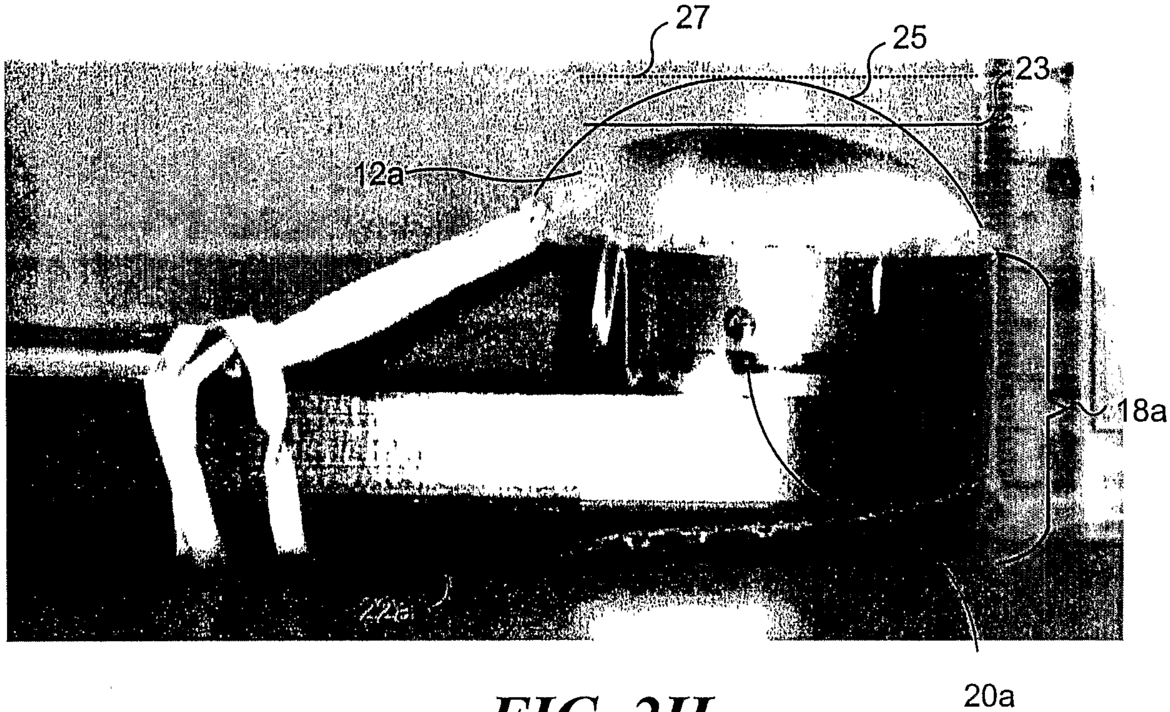

27
25
23
12a
18a
22a
20a

FIG. 2H

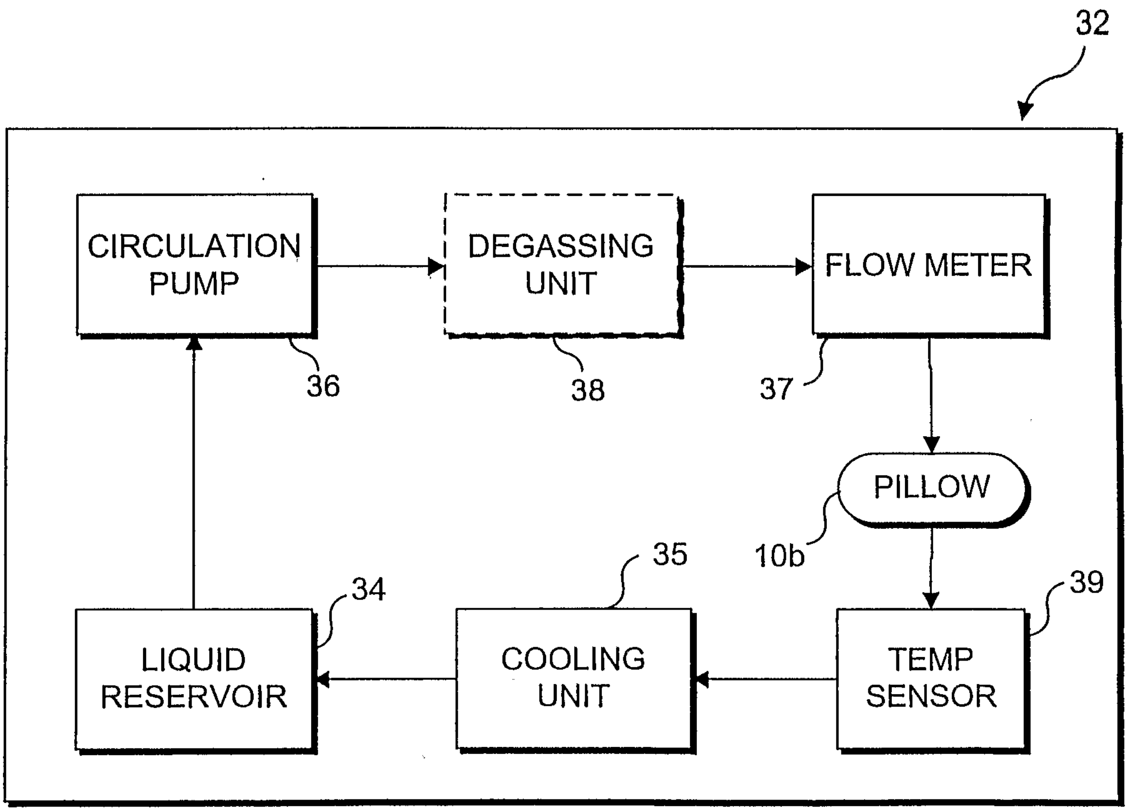

32
CIRCULATION PUMP
36
DEGASSING UNIT
38
FLOW METER
37
PILLOW
10b
LIQUID RESERVOIR
34
COOLING UNIT
35
TEMP SENSOR
39

FIG. 3

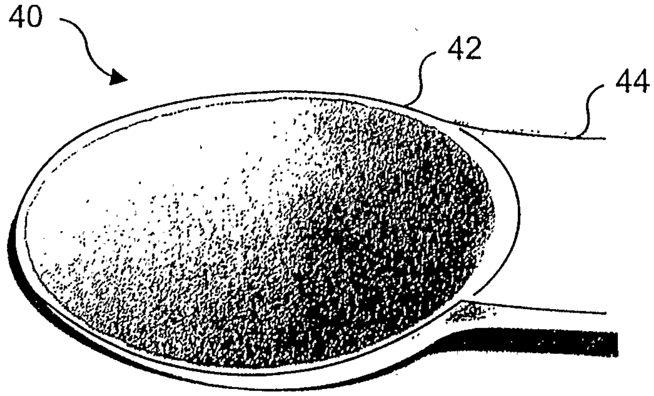

40
42
44

FIG. 4A

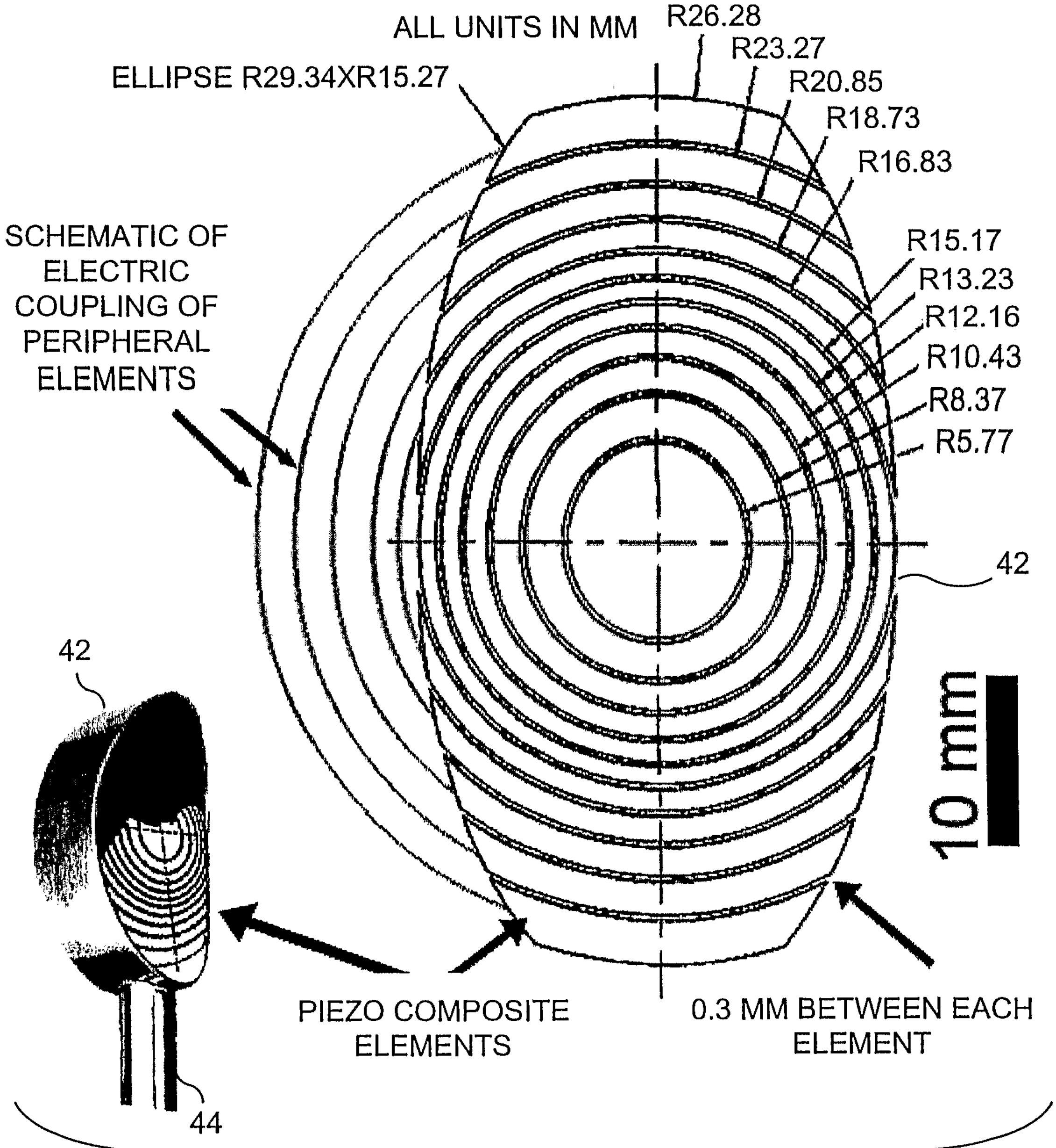

ALL UNITS IN MM
R26.28
R23.27
R20.85
R18.73
R16.83
ELLIPSE R29.34XR15.27
SCHEMATIC OF ELECTRIC COUPLING OF PERIPHERAL ELEMENTS
R15.17
R13.23
R12.16
R10.43
R8.37
R5.77
42
42
10 mm
44
PIEZO COMPOSITE ELEMENTS
0.3 MM BETWEEN EACH ELEMENT

FIG.4B

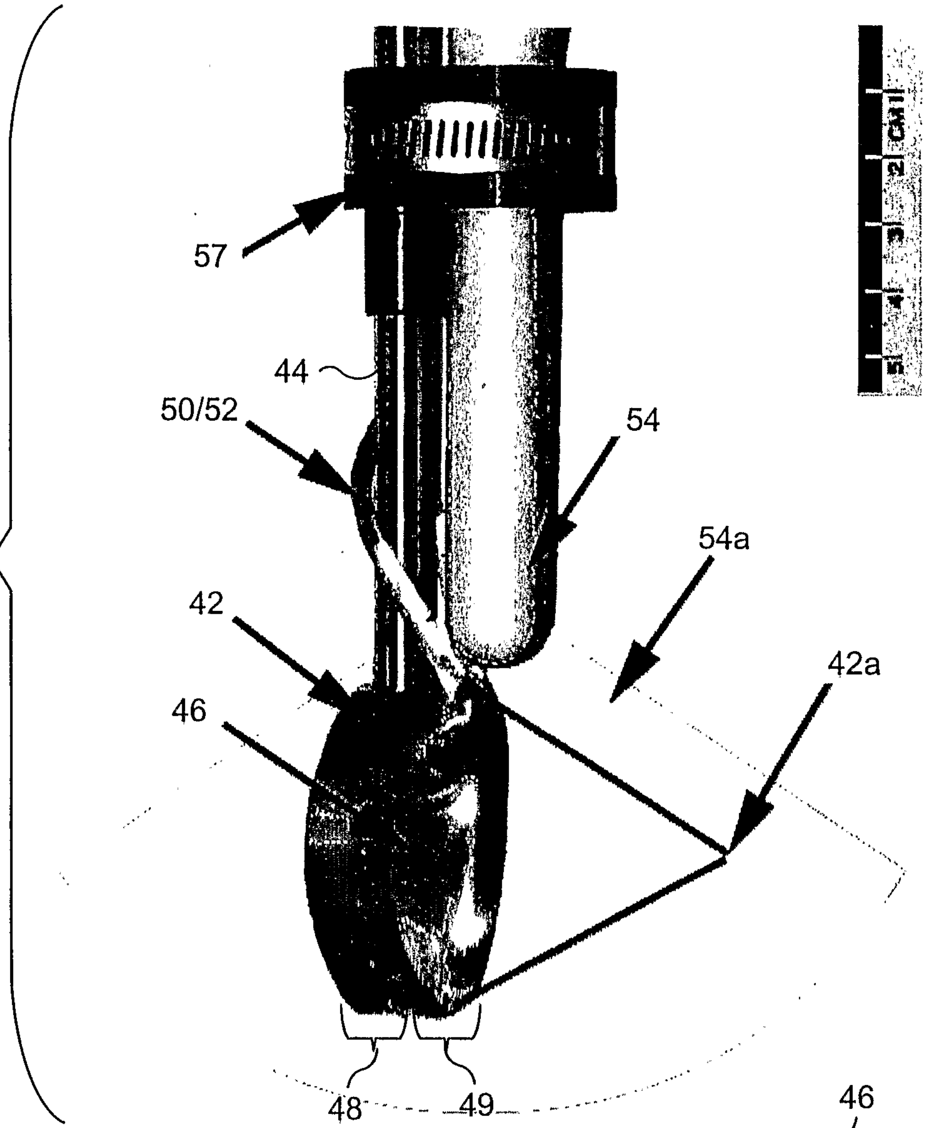


FIG. 4C

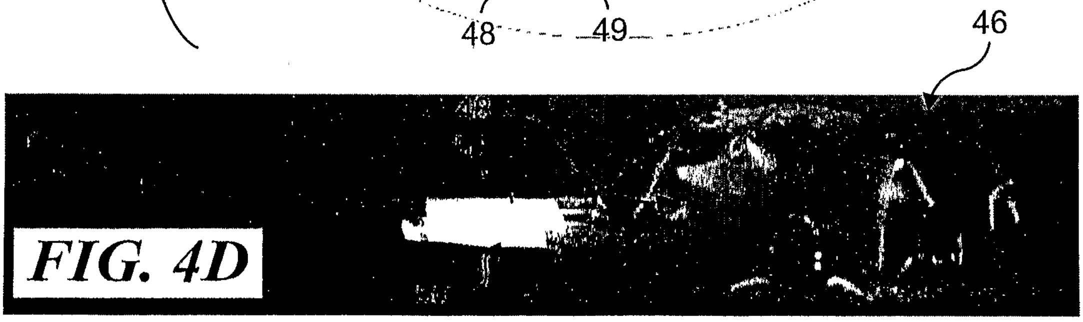
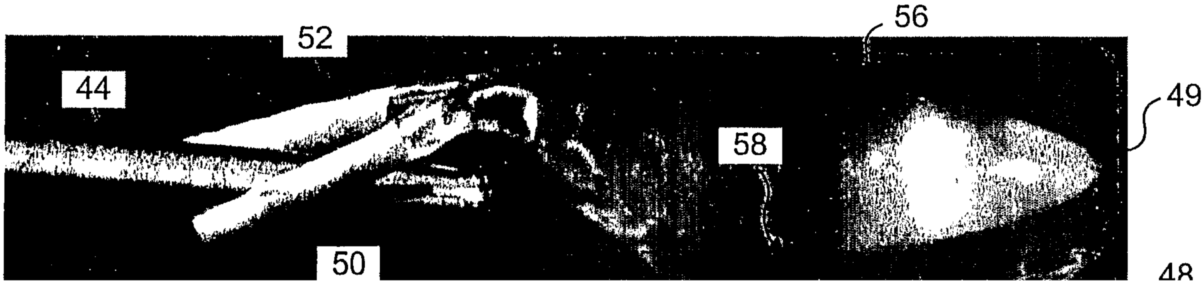


FIG. 4D



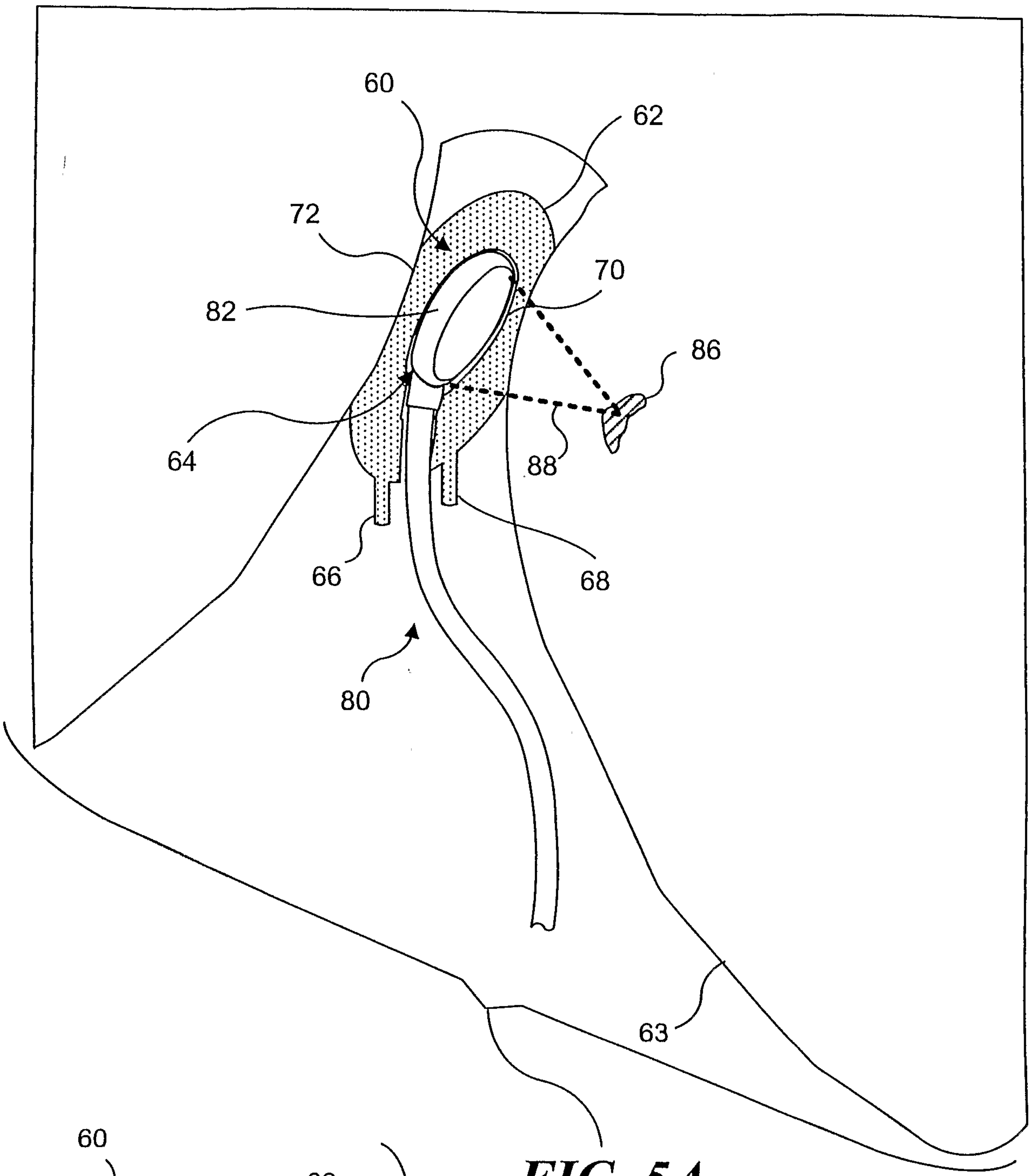


FIG. 5A

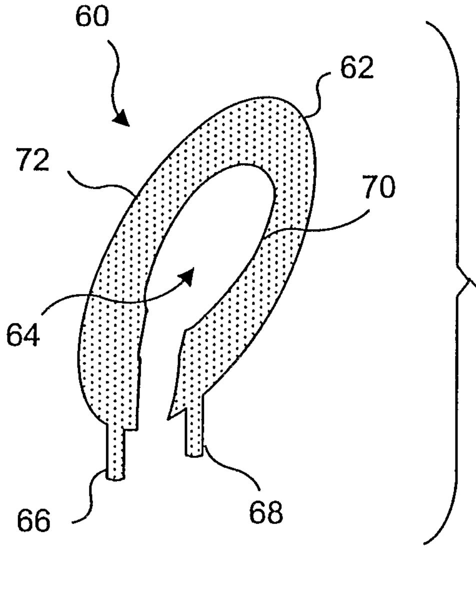


FIG. 5B

Transducer Frequency, Port Locations†	Electrical Power (W)	Power Lost as Heat (W)	Avg. Rate of Heat Removal (W)‡	Efficiency with respect to total electrical power**
3.5 MHz, Opposite	30	6.1	15.1	50.3
3.5 MHz, Opposite	50	10.1	24.3	48.6
3.5 MHz, Opposite	70	14.1	33.6	48.0
3.5 MHz, Adjacent	30	6.1	14.9	49.7
3.5 MHz, Adjacent	50	10.1	16.4	32.8
3.5 MHz, Adjacent	70	14.1	24.9	35.6
5.0 MHz, Opposite	30	15.6	17.8	59.3
5.0 MHz, Opposite	50	26.0	33.3	66.6
5.0 MHz, Opposite	70	36.3	48.9	69.9
5.0 MHz, Adjacent	30	15.6	16.2	54.0
5.0 MHz, Adjacent	50	26.0	30.5	61.0
5.0 MHz, Adjacent	70	36.3	46.1	65.9

FIG. 6

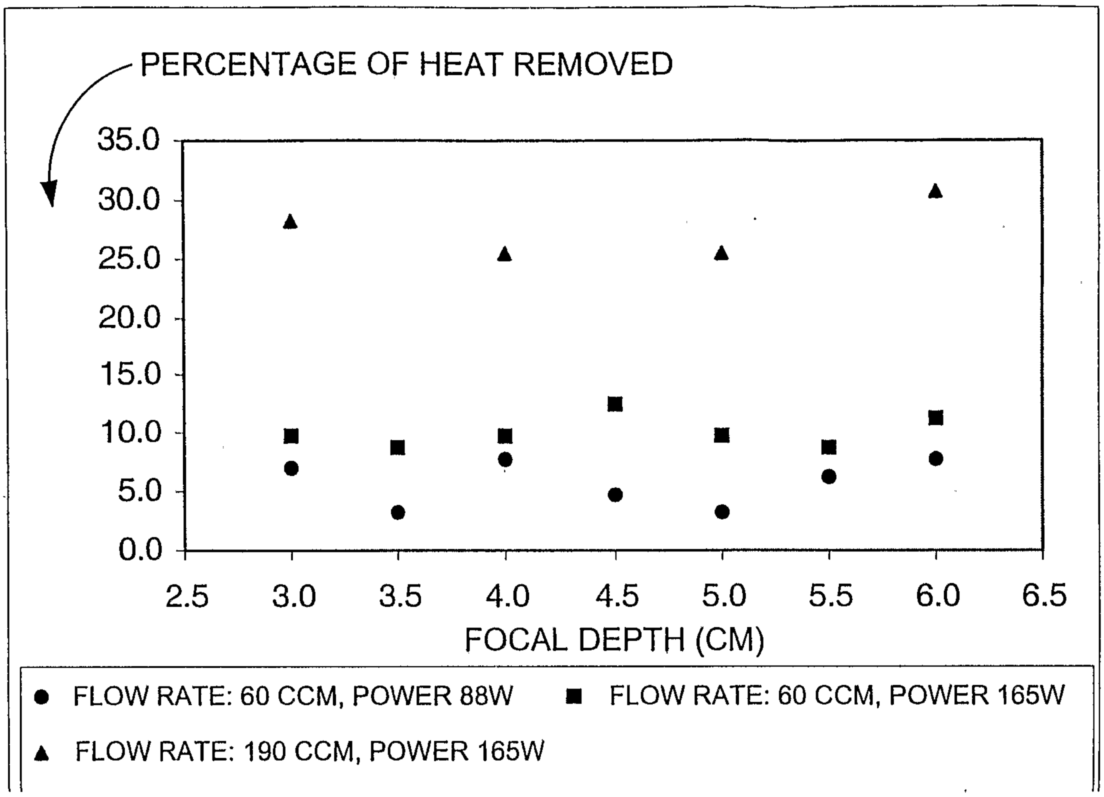

PERCENTAGE OF HEAT REMOVED
35.0
30.0
25.0
20.0
15.0
10.0
5.0
0.0
2.5
3.0
3.5
4.0
4.5
5.0
5.5
6.0
6.5
FOCAL DEPTH (CM)
FLOW RATE: 60 CCM, POWER 88W
FLOW RATE: 60 CCM, POWER 165W
FLOW RATE: 190 CCM, POWER 165W

FIG. 7