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(54) **ULTRASOUND TRANSDUCER**

(71) Applicant: **CardioSonic Ltd.**, Tel-Aviv (IL)

(72) Inventors: **Ariel Sverdlik**, Tel-Aviv (IL); **Or Shabtay**, Kibbutz Farod (IL)

(73) Assignee: **CardioSonic Ltd.**, Tel-Aviv (IL)

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(58) **Field of Classification Search**

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USPC ..... 600/437–469; 601/2–3

See application file for complete search history.

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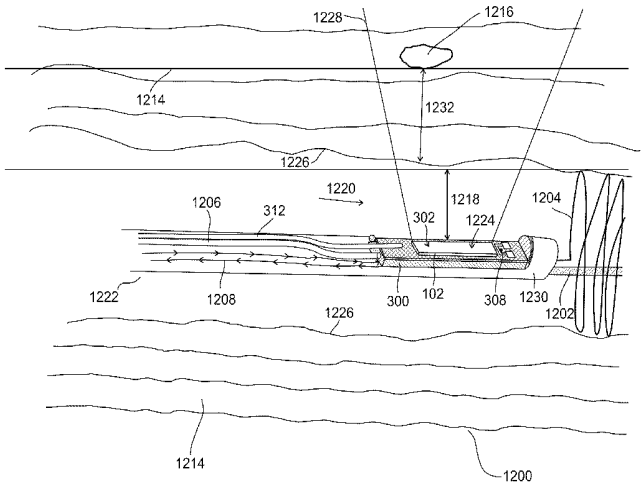
(57) **ABSTRACT**

There is provided in accordance with an exemplary embodiment of the invention an ultrasound transducer for intrabody medical therapy comprising; an element adapted to transmit ultrasound energy; at least two electrodes configured to apply a voltage across at least some volume of the element; and a gas bubble containment area adapted to retain the gas bubble when in blood.

**18 Claims, 23 Drawing Sheets**



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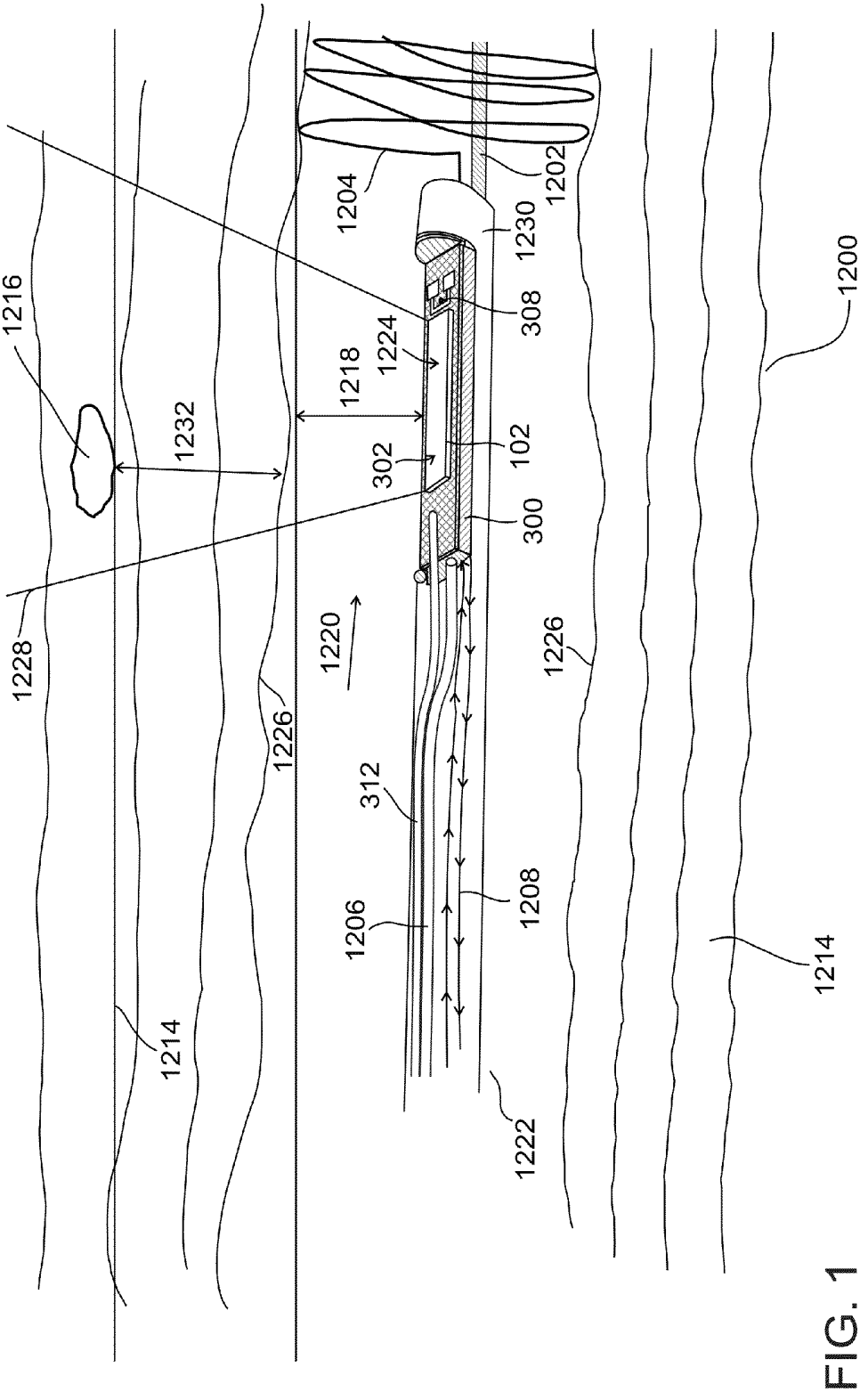
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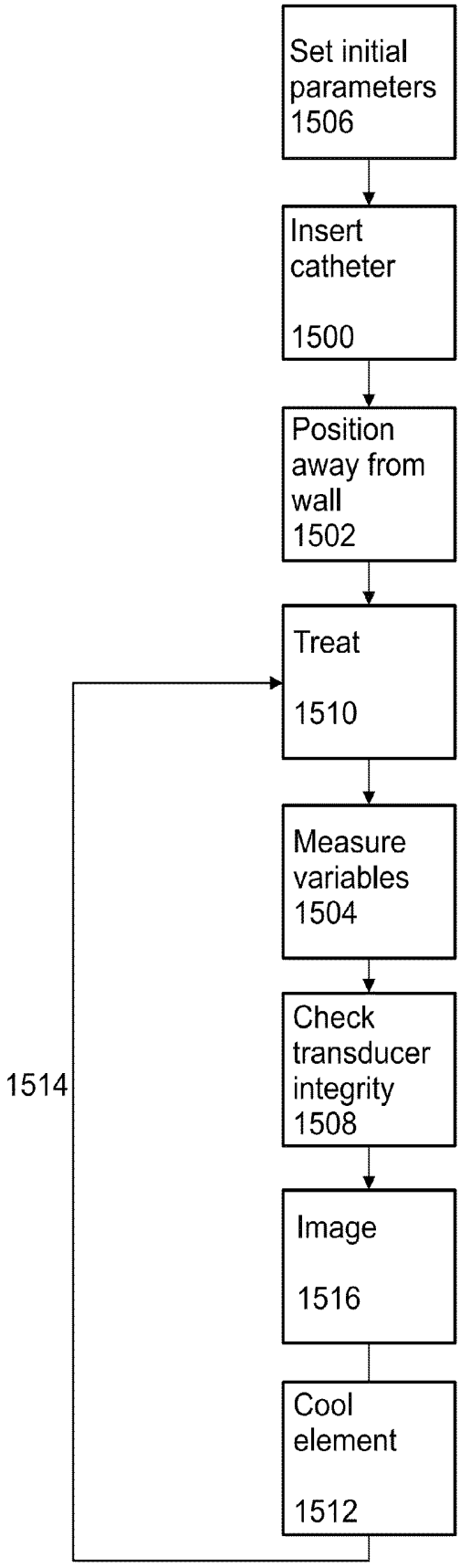
FIG. 1

FIG. 2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Position away from wall 1502
Treat 1510
Measure variables 1504
Check transducer integrity 1508
Image 1516
Cool element 1512
1514

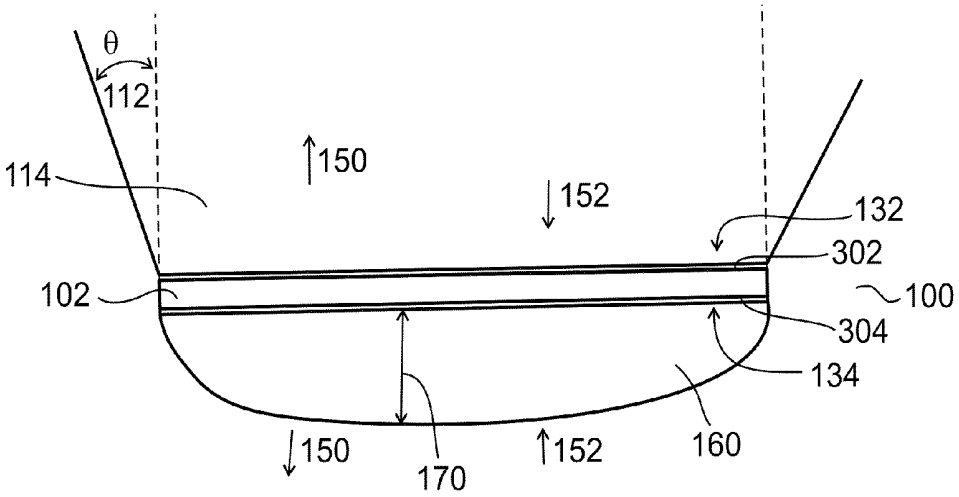


FIG. 3A

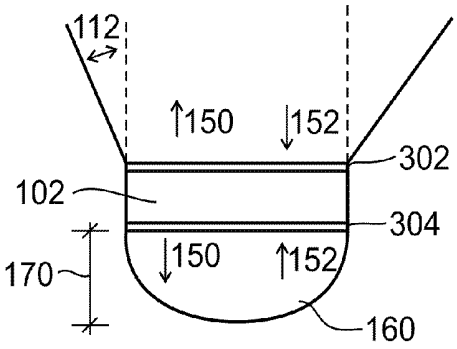


FIG. 3B

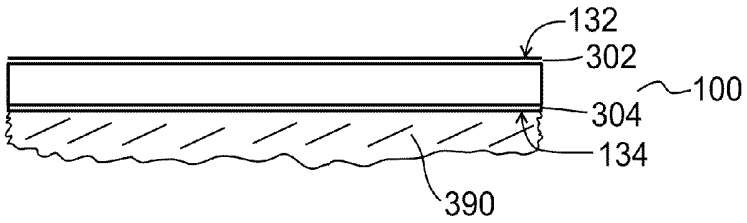


FIG. 3C

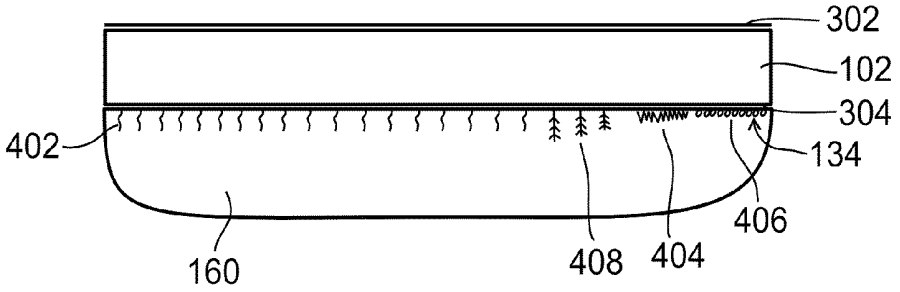


FIG. 4A

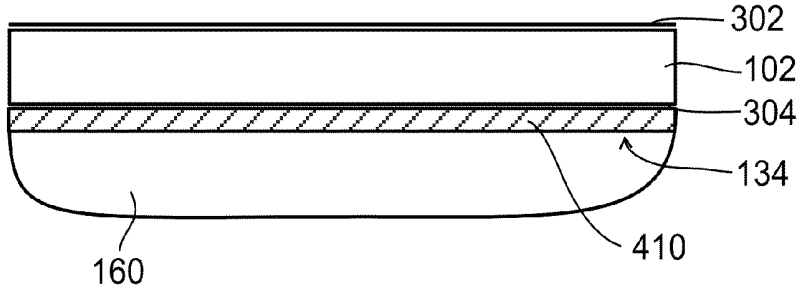


FIG. 4B

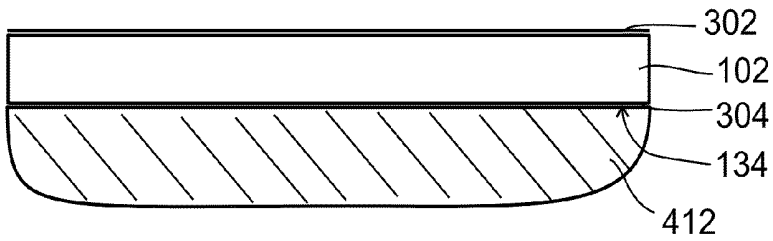


FIG. 4C

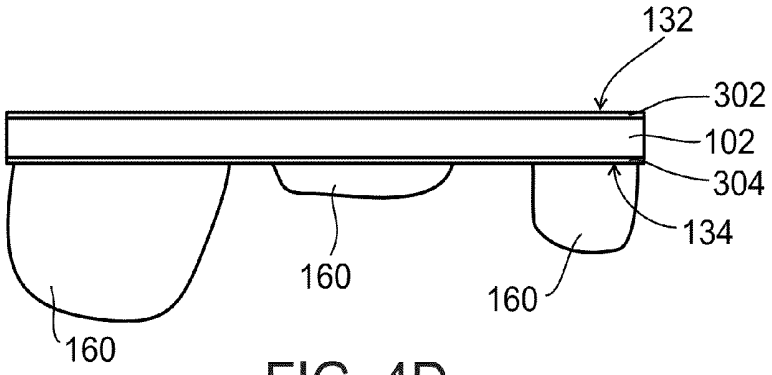


FIG. 4D

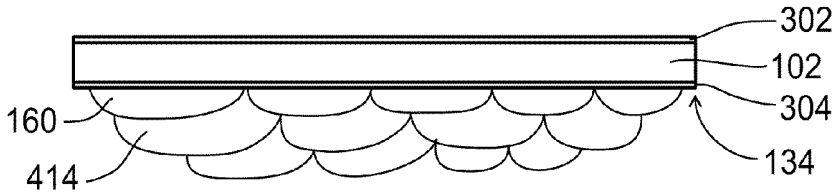


FIG. 4E

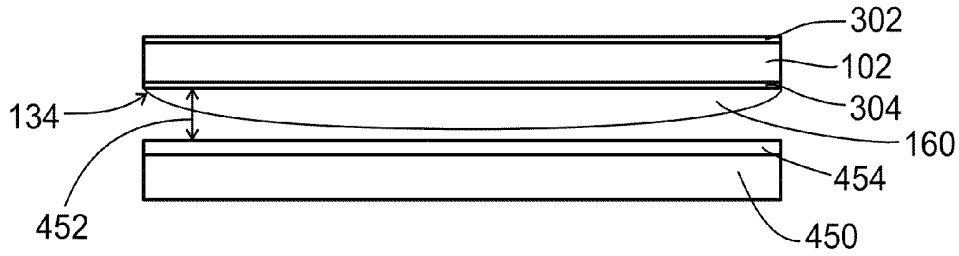


FIG. 4F

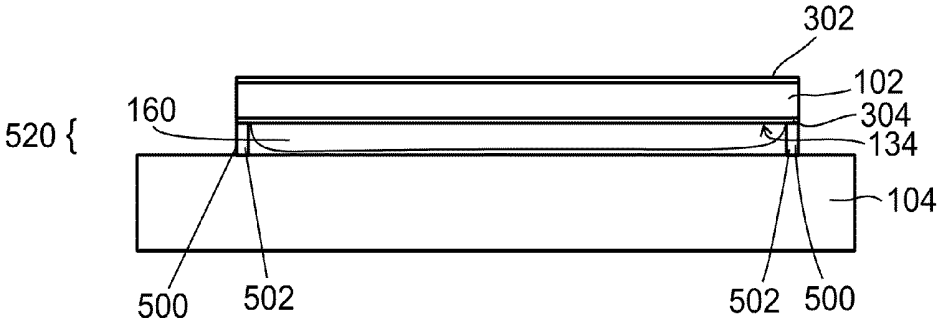


FIG. 5A

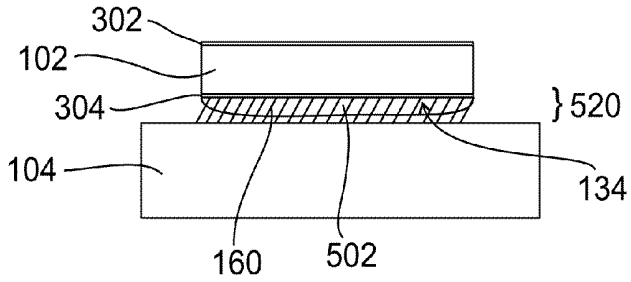


FIG. 5B

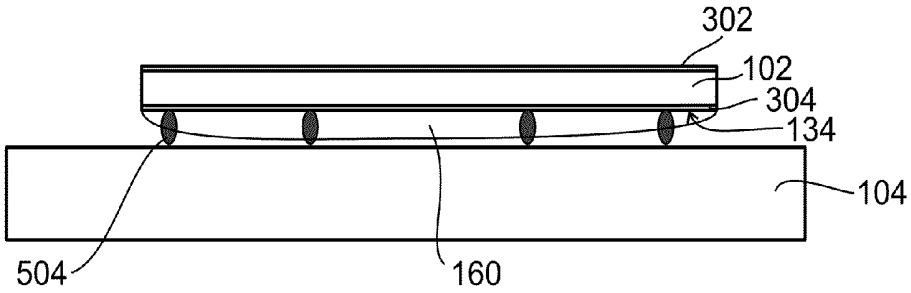


FIG. 5C

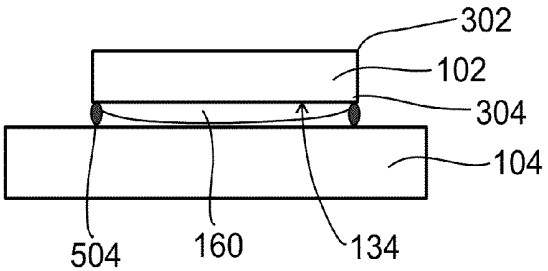


FIG. 5D

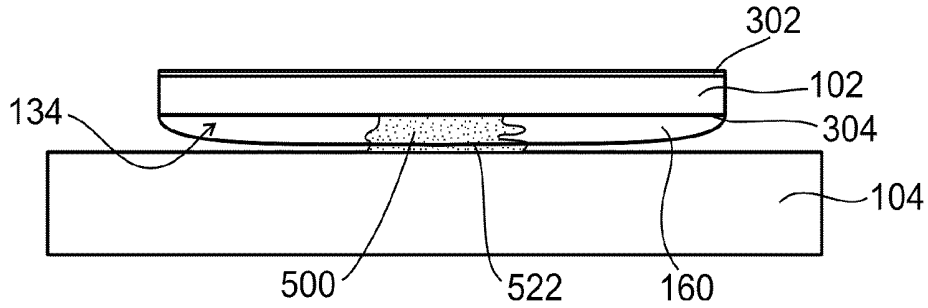


FIG. 5E

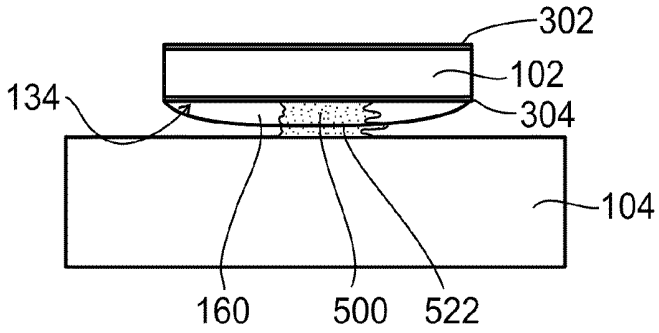


FIG. 5F

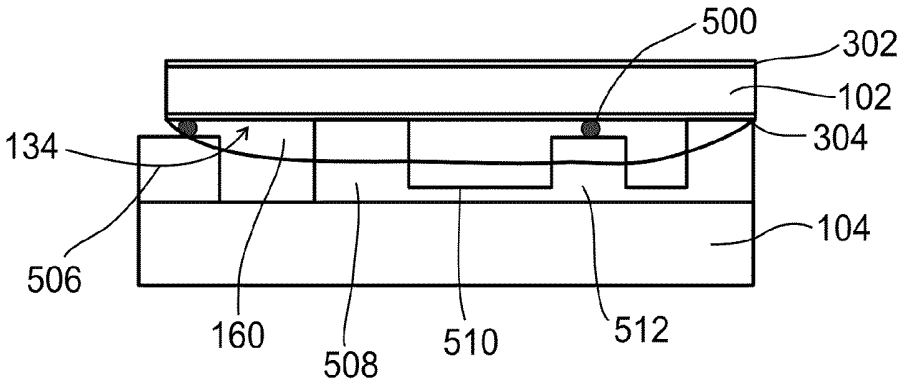


FIG. 5G

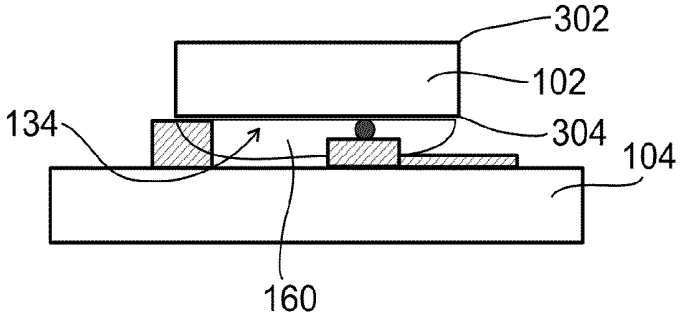


FIG. 5H

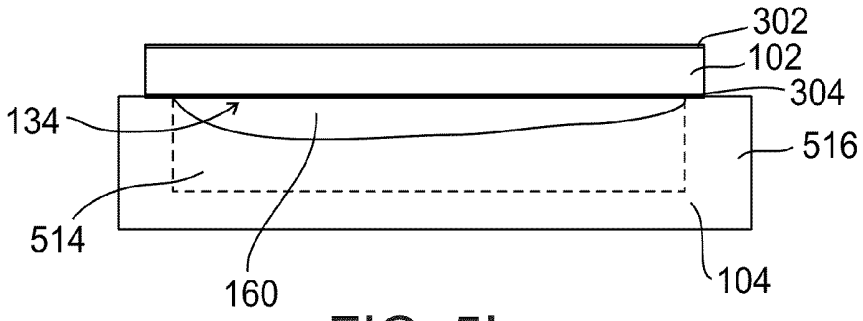


FIG. 5I

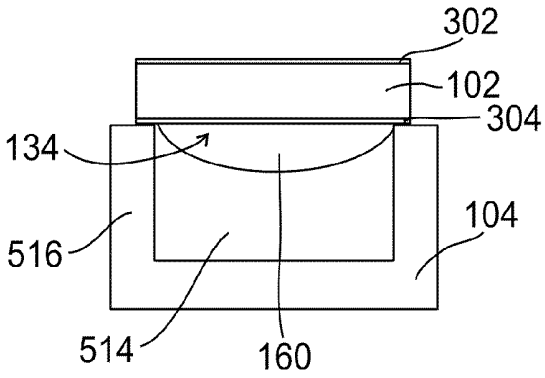


FIG. 5J

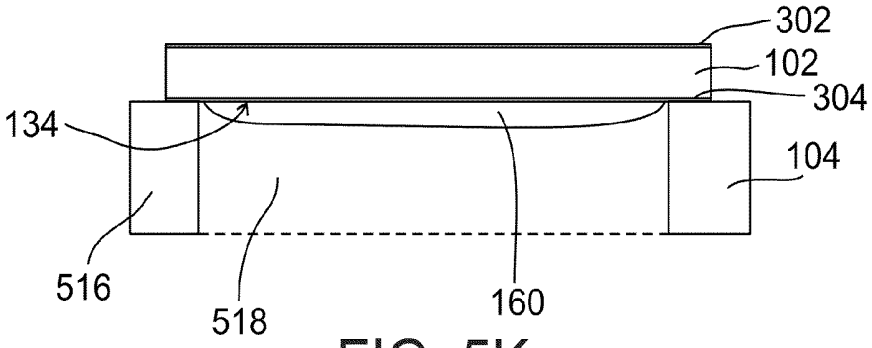


FIG. 5K

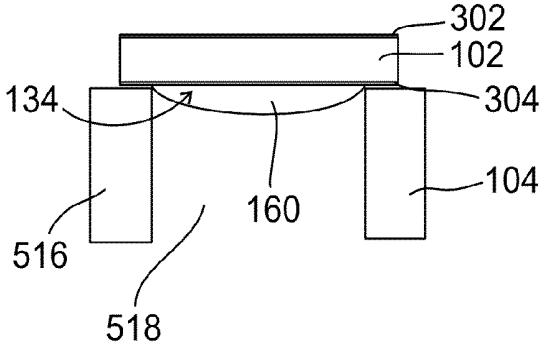


FIG. 5L

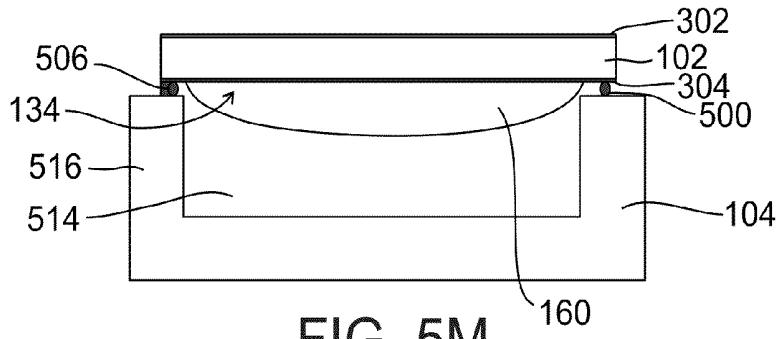


FIG. 5M

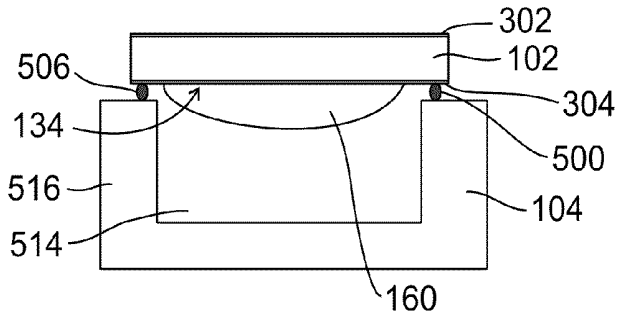


FIG. 5N

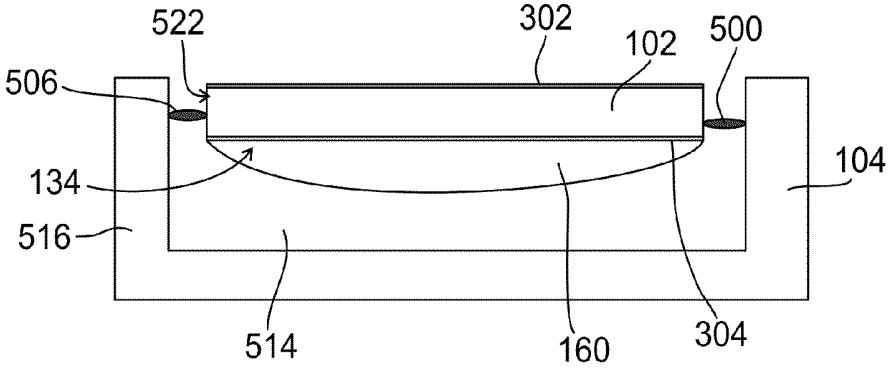


FIG. 5O

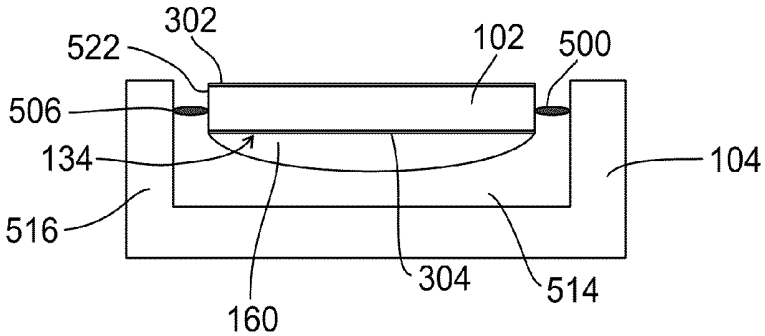


FIG. 5P

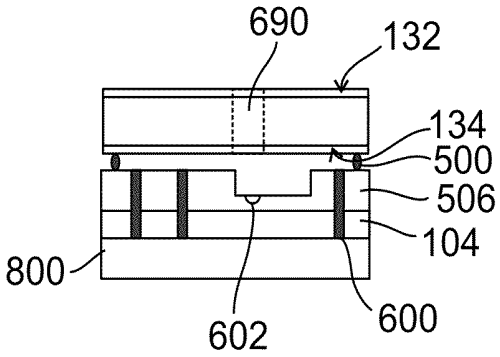
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FIG. 6A

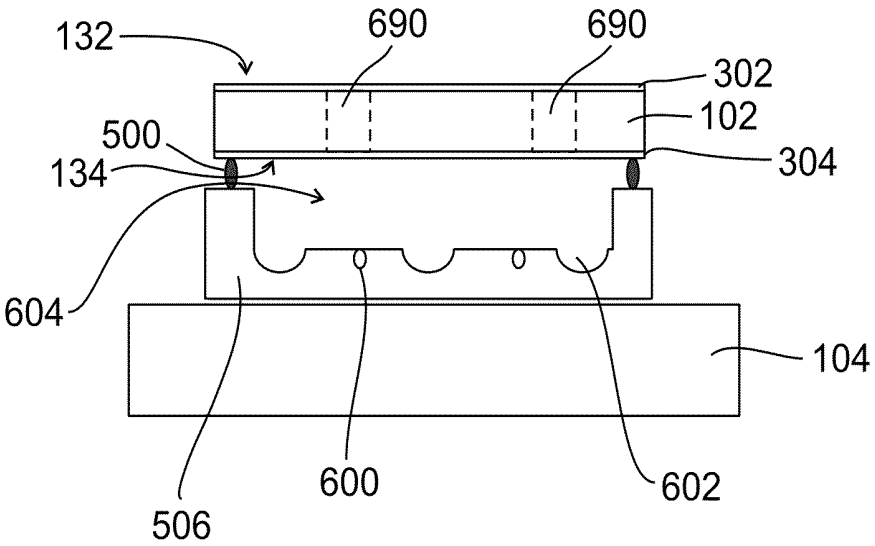
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FIG. 6B

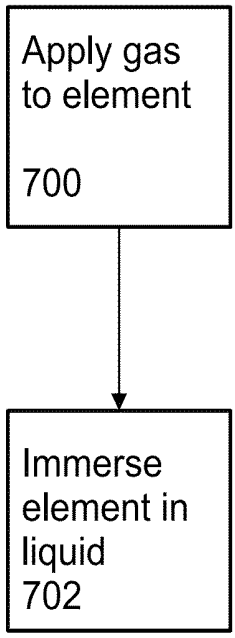
Apply gas to element
700
Immerse element in liquid
702

FIG. 7A

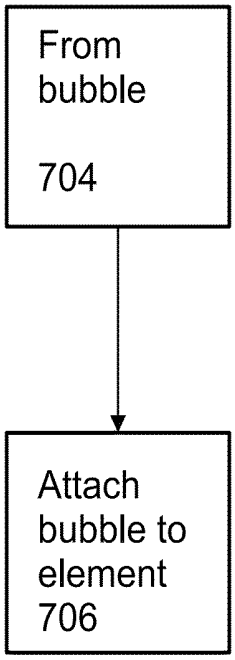
From bubble
704
Attach bubble to element
706

FIG. 7B

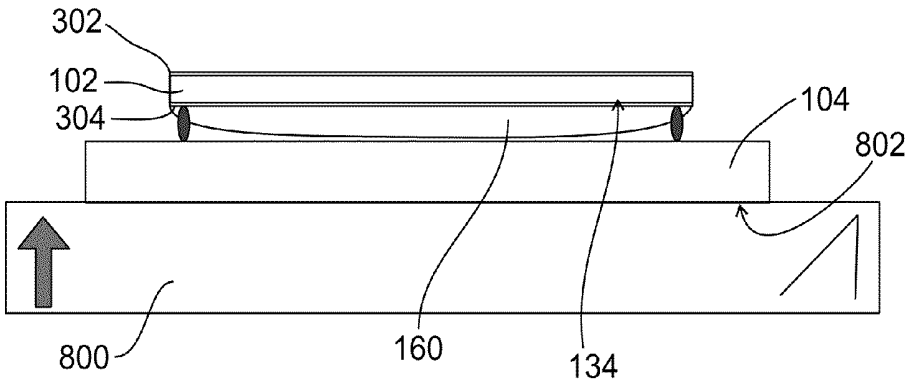
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FIG. 8A

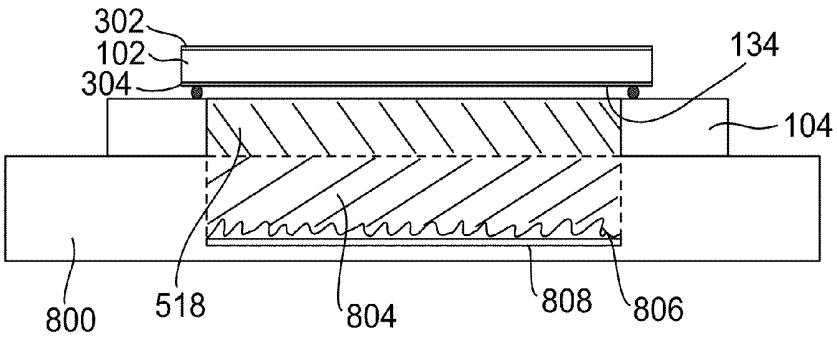
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FIG. 8B

FIG. 9A

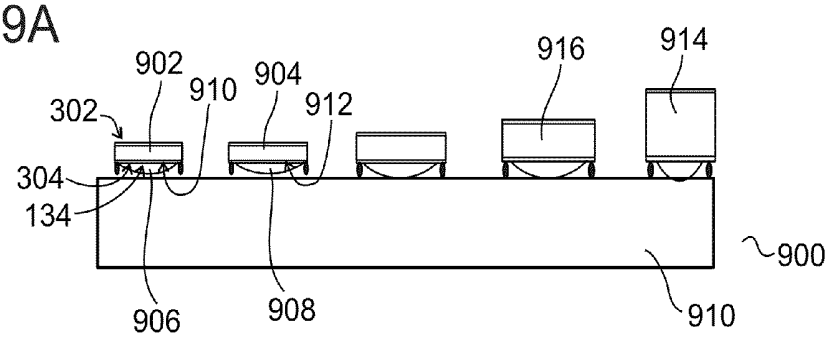



FIG. 9B

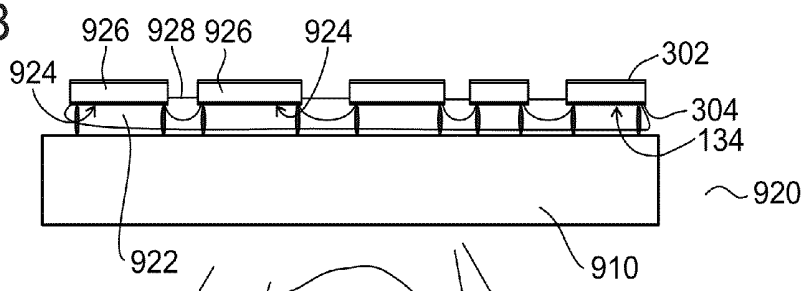



FIG. 9C

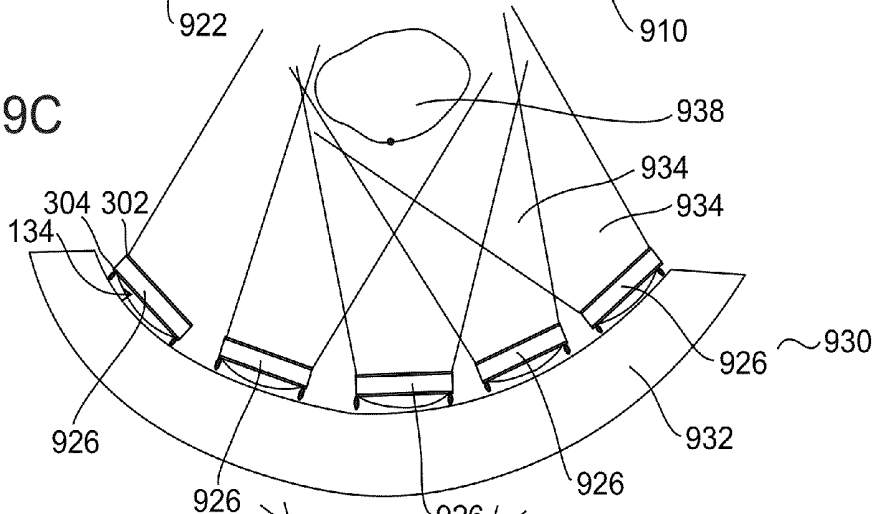
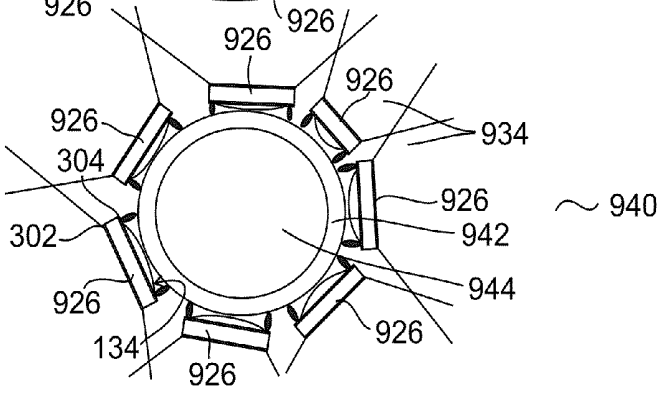



FIG. 9D



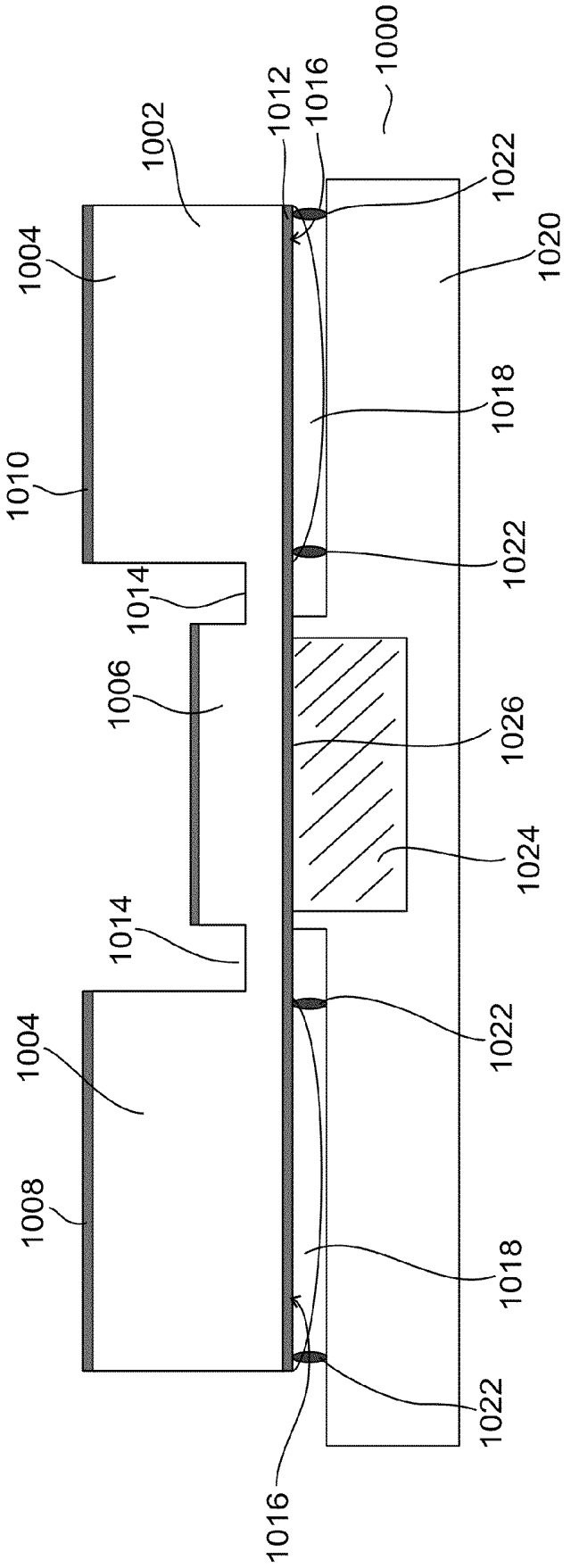

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FIG. 10

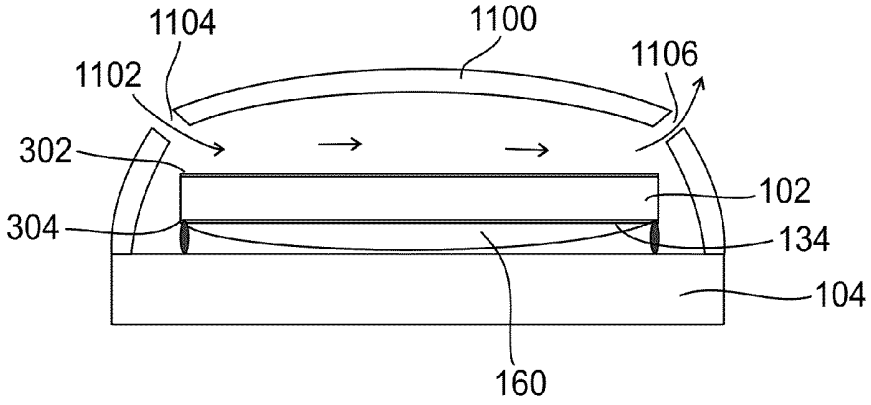


FIG. 11A

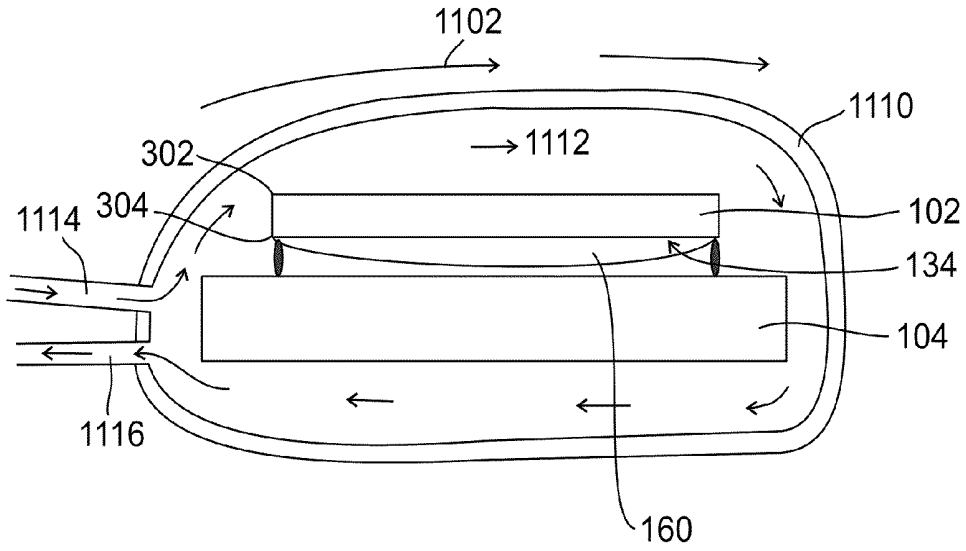


FIG. 11B

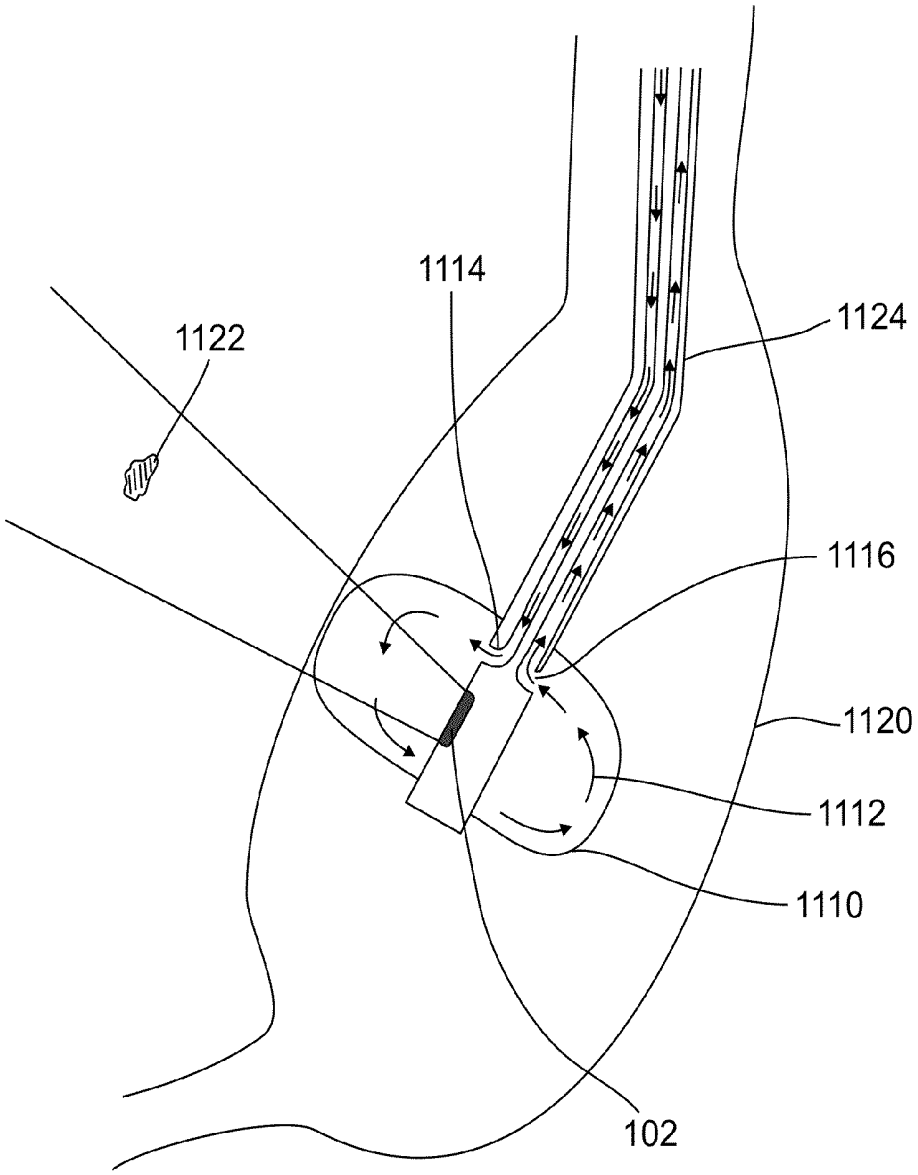


FIG. 11C

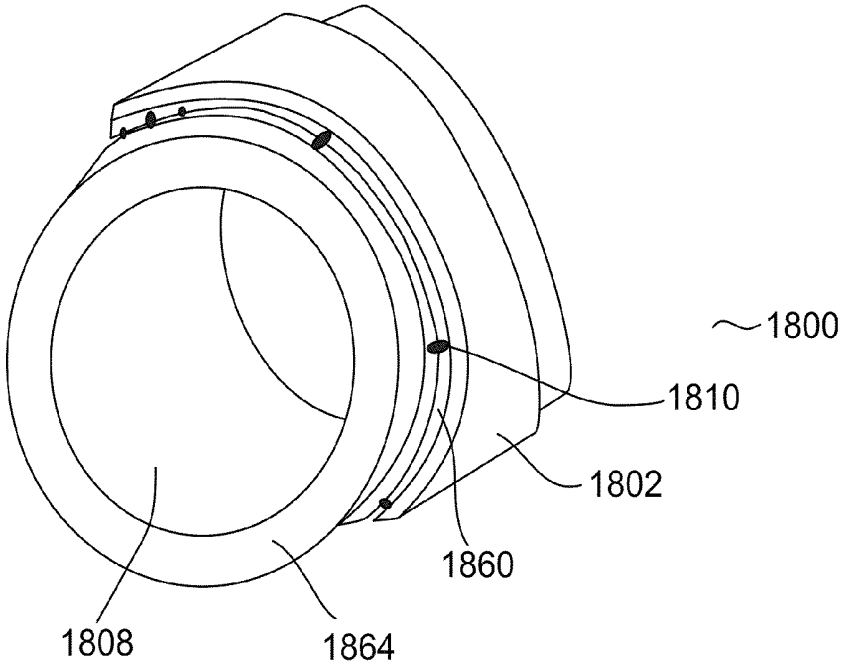


FIG. 12A

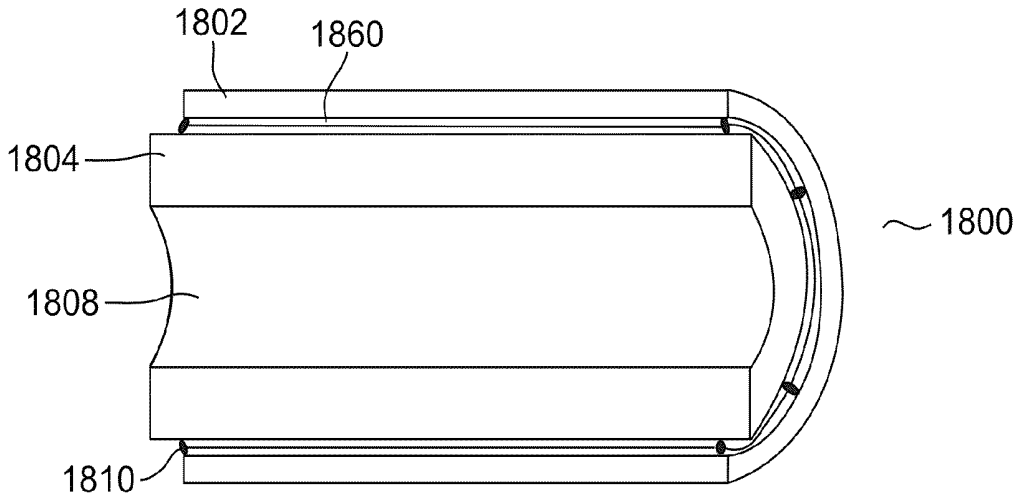


FIG. 12B

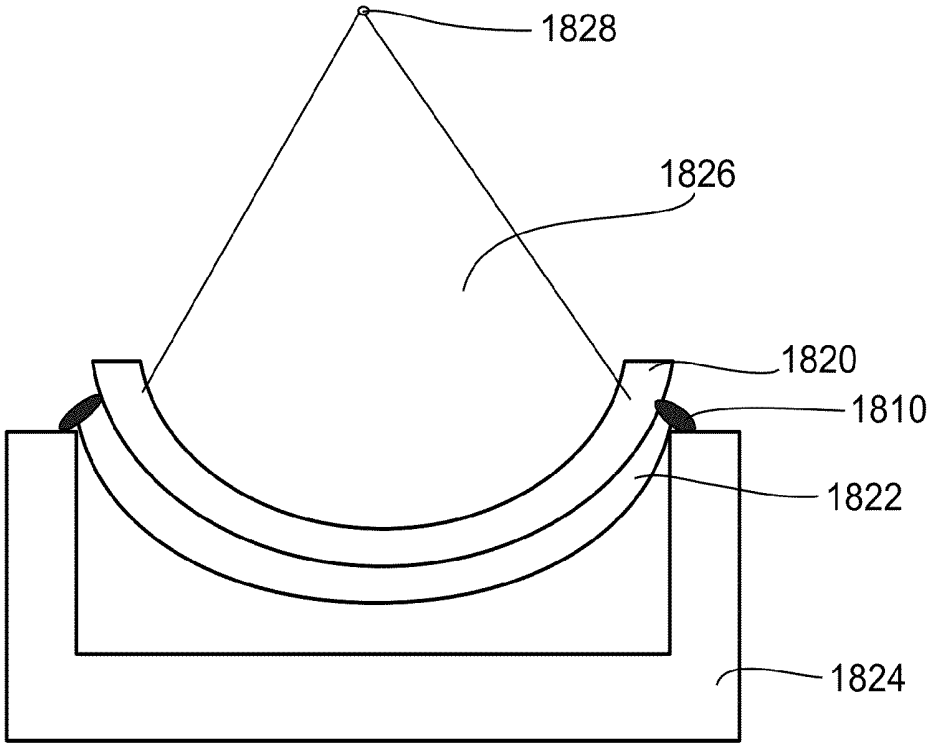


FIG. 12C

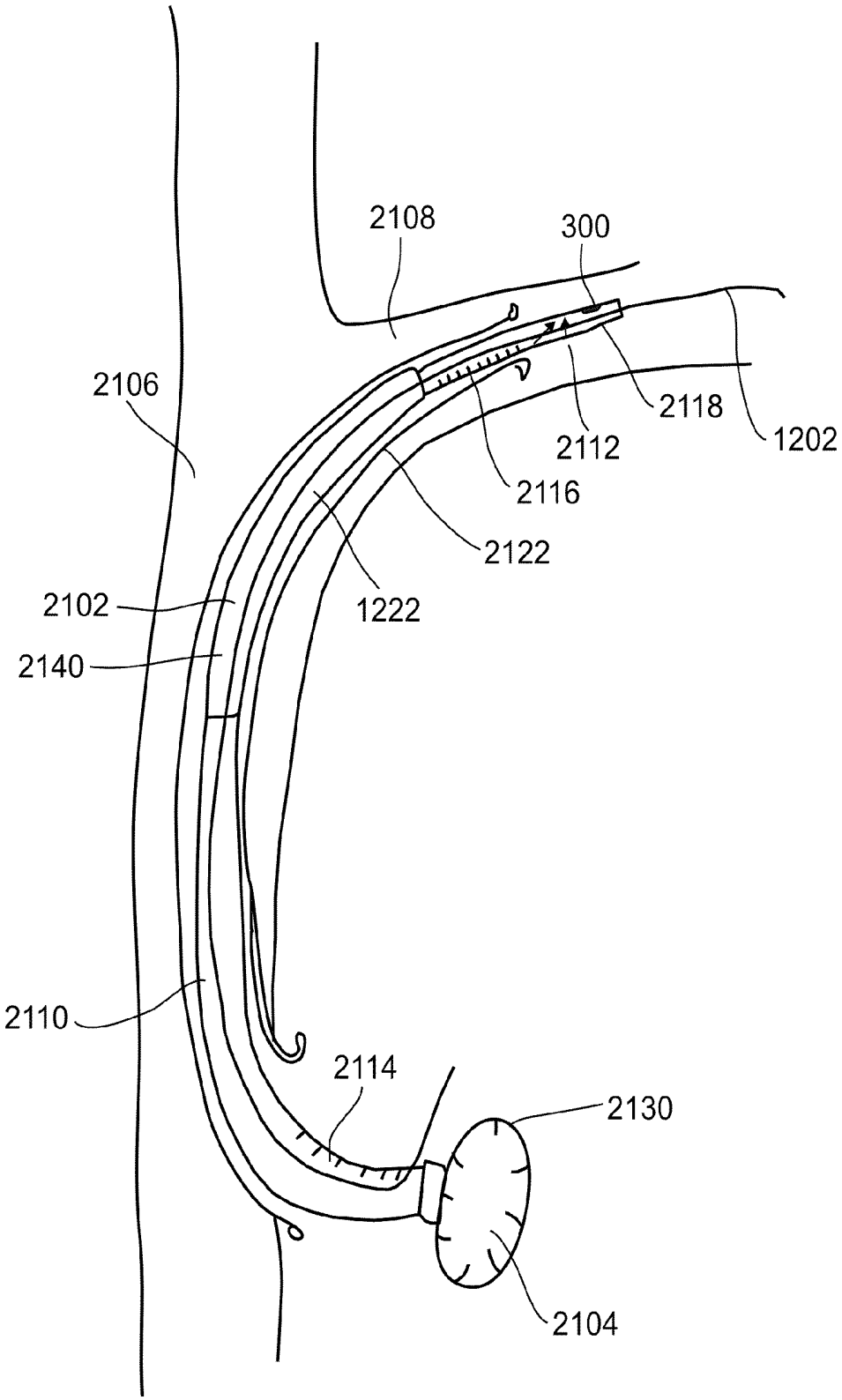
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FIG. 13

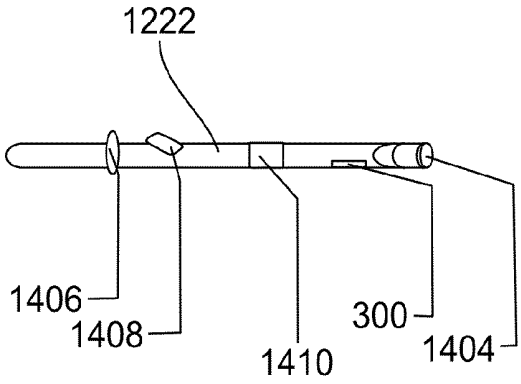



FIG. 14A

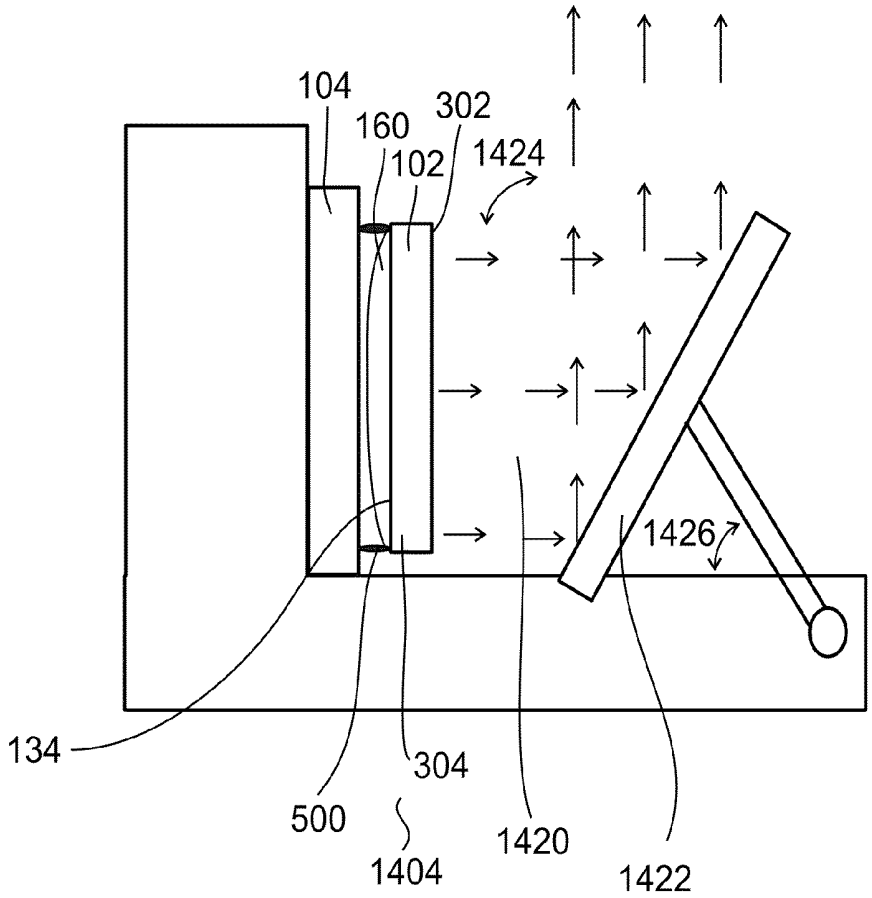



FIG. 14B

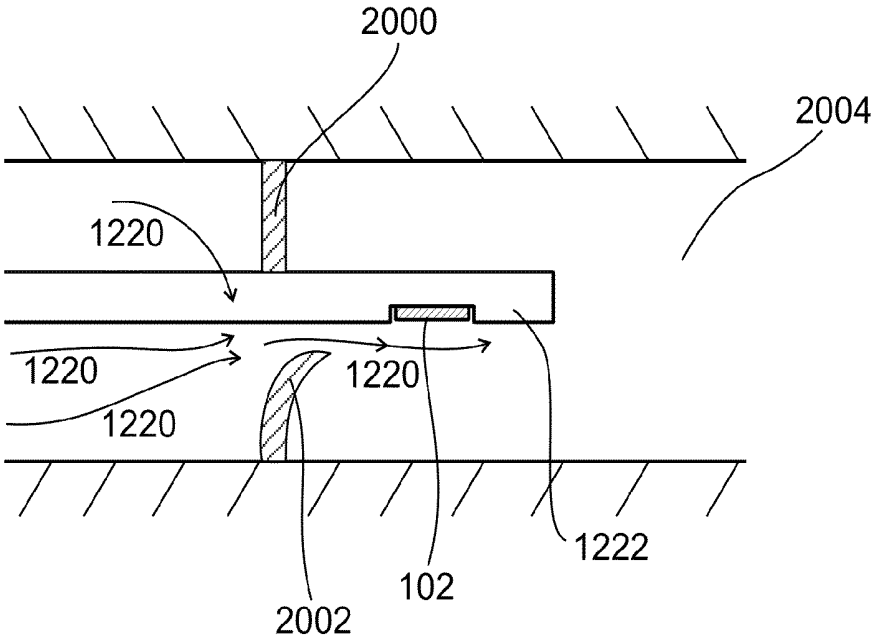



FIG. 15C

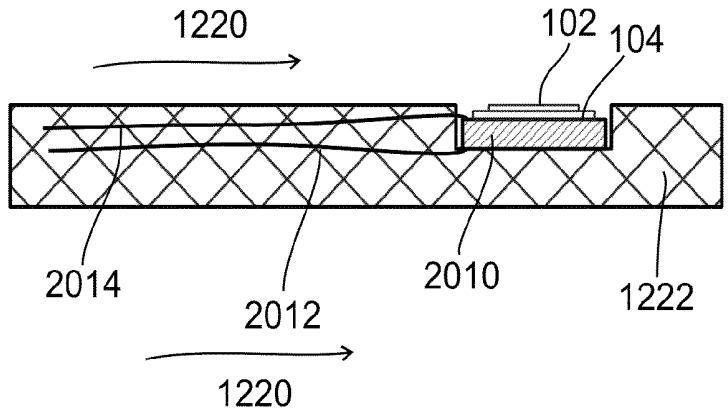



FIG. 15A

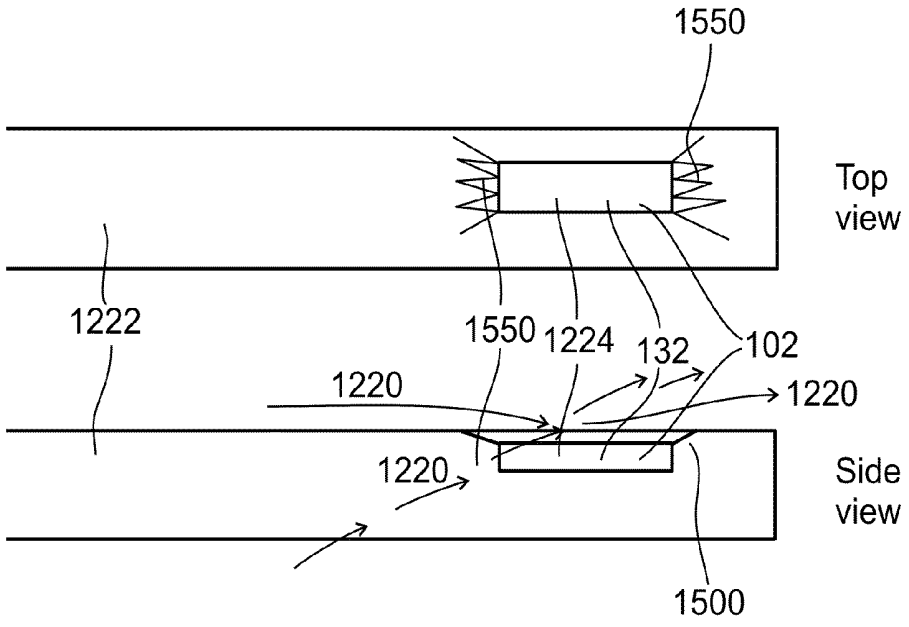

1550
Top
view
1222
1550
1224
132
102
1220
1220
1220
Side
view
1500

FIG. 15B

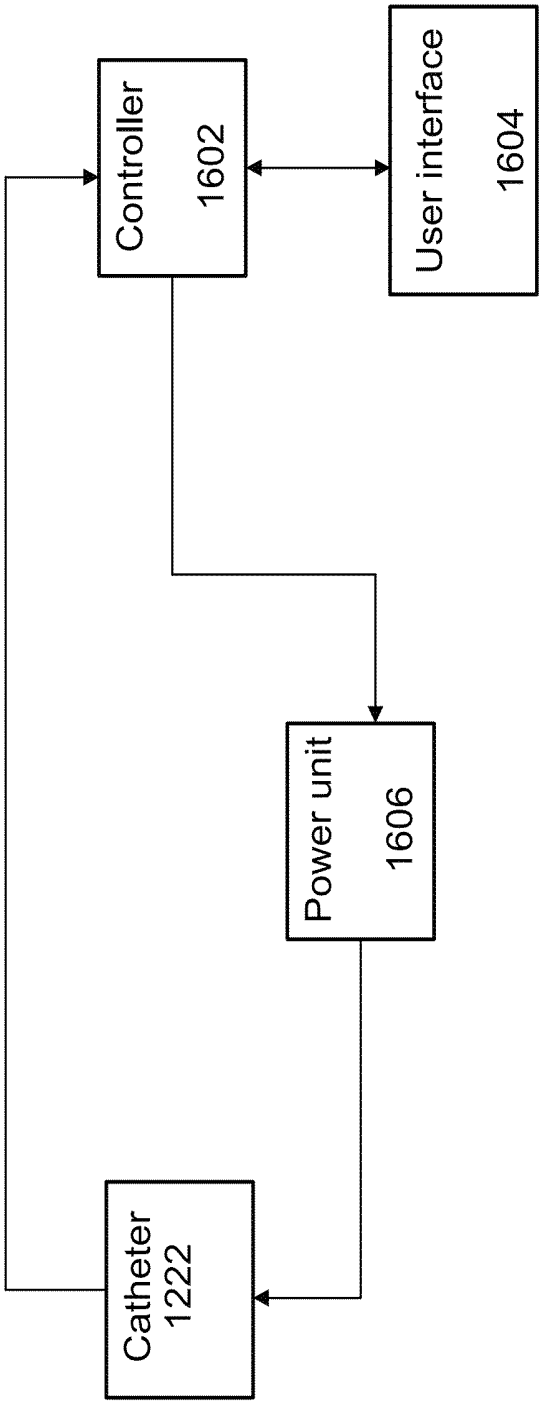

Controller
1602
User interface
1604
Power unit
1606
Catheter
1222
1600

FIG. 16

# ULTRASOUND TRANSDUCER

## RELATED APPLICATIONS

This application is a division of U.S. patent application Ser. No. 13/049,151 filed on Mar. 16, 2011, which claims the benefit of priority under 35 USC 119(e) of U.S. Provisional Patent Application No. 61/393,947 filed on Oct. 18, 2010, the contents of which are incorporated herein by reference in their entirety.

The present application is related to co-filed, co-pending and co-assigned patent applications:

U.S. patent application Ser. No. 13/049,013 filed on Mar. 16, 2011, titled: "AN ULTRASOUND TRANSDUCER AND USES THEREOF", showing for example, a method for feedback and control of the ultrasonic transducer;

U.S. Provisional patent application Ser. No. 13/049,022 filed on Mar. 16, 2011 titled: "AN ULTRASOUND TRANSDUCER AND COOLING THEREOF", showing for example, a method for blood flow cooling of the ultrasonic transducer;

U.S. Patent Application No. 61/453,234 filed on Mar. 16, 2011 titled: "SEPARATION DEVICE FOR ULTRASOUND TRANSDUCER" by Ariel SVERDLIK and Or SHABTAY, showing for example, a device to prevent the transducer from touching the blood vessel wall; and

U.S. Provisional Patent Application No. 61/453,239 filed on Mar. 16, 2011 titled: "TISSUE TREATMENT" by Ariel SVERDLIK, Iris SZWARCFITER and Or SHABTAY, showing for example, a method of selectively targeting and treating tissues using ultrasound;

the disclosures of which are incorporated herein by reference.

## FIELD AND BACKGROUND OF THE INVENTION

The present invention, in some embodiments thereof, relates to an ultrasound transducer and, more particularly, but not exclusively, to a system for delivering ultrasound energy for medical treatment, for example, intravascular treatment. Maguire and Peacock, in EP 1769759 disclose:

"A medical device assembly and method provides an ultrasound transducer (904) mounted onto a delivery member, such as the elongate body (802) of a catheter shaft, without a support structure bridging between a separation area between the transducer and the shaft. Mounting flanges extend from either end of the transducer and are mounted at first and second locations along the catheter shaft such that the transducer is not in mechanical contact with the catheter shaft between those mounting locations to provide for air backing between the transducer and the catheter shaft so as to isolate ultrasound transmission radially away from the catheter shaft and toward the tissue surrounding the shaft. The transducer is substantially "airbacked" when mounted onto a delivery member in accordance with the present invention."

Sverdlik et al, in PCT/IL2008/000234, filed Feb. 21, 2008 disclose:

"Described is a method of stabilizing blood vessel wall abnormality. The method includes ultrasonically heating at least a portion of the blood vessel wall having the abnormality; monitoring a parameter related to a property of at least a portion of the heated portion of the blood vessel wall; and stopping the heating when the monitored parameter changes by a predetermined factor or after the monitored parameter changes in a slow enough rate."



Additional background art includes:

U.S. Pat. No. 5,699,804
U.S. Pat. No. 7,410,486
U.S. Pat. No. 7,621,929
U.S. Pat. No. 7,717,948
U.S. Pat. No. 7,771,372
US patent application 2008228111
US patent application 2009216246
US patent application 2010091112

## SUMMARY OF THE INVENTION

An aspect of some embodiments of the invention relates to an ultrasound transducer for medical therapy comprising an element adapted to transmit ultrasound energy. Optionally, the element is coupled to a gas bubble. Alternatively or additionally, the element is suspended, providing for a relatively low damping force during function.

There is provided in accordance with an exemplary embodiment of the invention an ultrasound transducer for intrabody medical therapy comprising; an element adapted to transmit ultrasound energy; at least two electrodes configured to apply a voltage across at least some volume of the element; and a gas bubble containment area adapted to retain the gas bubble when in blood.

In an exemplary embodiment of the invention, the transducer further comprises, a support board that is coupled to the element, wherein the gas bubble is retained in a space between the board and the element. Optionally, at least some surface area of at least the element and the board comprise a coating adapted to retain the bubble to the element. Optionally, the coating comprises parylene. Optionally, the board comprises a depression or an aperture, and the element is positioned over at least some volume of the depression or the aperture.

In an exemplary embodiment of the invention, the element is rectangular.

In an exemplary embodiment of the invention, the element comprises irregularities on a surface to couple the bubble to the element by increasing an area of the surface.

In an exemplary embodiment of the invention, the gas comprises selecting from the group consisting of: air, oxygen, nitrogen, carbon dioxide, carbon tetrafluoride.

In an exemplary embodiment of the invention, at least two bubbles coupled to a side of the element.

In an exemplary embodiment of the invention, the transducer comprises a housing, the housing coupled to the board. Optionally, the housing comprises a heat sink thermally coupled to the element.

In an exemplary embodiment of the invention, the transducer further comprises a canopy surrounding the element; and fluid between the element and the canopy. Optionally, the fluid comprises a circulating fluid.

There is provided in accordance with an exemplary embodiment of the invention an ultrasound transducer for medical therapy comprising a support board, an element adapted to transmit ultrasound energy, the element suspended by the board; and at least two electrodes configured to apply a voltage across at least some volume of the element.

In an exemplary embodiment of the invention, the element is configured to produce a relatively non-diverging ultrasound beam.

In an exemplary embodiment of the invention, the element is suspended a distance above the board. Optionally, the element is suspended by a material raised above a surface of the board. Optionally, the material includes copper. Optionally, the material includes an electrically conductive glue.

In an exemplary embodiment of the invention, the element is suspended over an aperture or a depression in the board by walls of the aperture or depression. Optionally, the element is suspended over the board along the periphery of the element. Optionally, the element is suspended over the board away from the periphery of the element.

In an exemplary embodiment of the invention, the board further comprises at least one heat conductive element thermally coupled to the element. Optionally, a cross section of the support board is annular.

In an exemplary embodiment of the invention, two or more elements adapted to transmit ultrasound energy, at least one of the two or more elements is supported above the board, and at least one gas bubble coupled to at least one of the two or more elements.

In an exemplary embodiment of the invention, the transducer further comprises: an element comprising at least one region adapted to at least transmit and at least one region adapted to at least receive, the element positioned over the board; at least two electrodes configured to apply a voltage across at least some volume of the regions; and at least one gas bubble coupled to the at least one region adapted to at least transmit.

In an exemplary embodiment of the invention, the transducer further comprises: two or more elements adapted to transmit ultrasound energy, at least two of the two or more elements are supported by the board; at least two electrodes configured to apply a voltage across at least some volume of the two or more elements; and a gas bubble coupled to at least two elements of the at least two elements. Optionally, the two or more elements are used as a phased array.

There is provided in accordance with an exemplary embodiment of the invention an ultrasound transducer for medical therapy comprising: an element adapted to transmit ultrasound energy; at least two electrodes configured to apply a voltage across at least some volume of the element; and a support board, the element suspended by the board and the board comprises at least one channel to direct flow of a fluid between the board and the element.

In an exemplary embodiment of the invention, the element comprises at least one region adapted to at least transmit ultrasound treatment.

In an exemplary embodiment of the invention, the element comprises at least one region adapted to at least receive ultrasound imaging.

In an exemplary embodiment of the invention, the board comprises a depression comprising a damping material, and wherein the one region adapted to at least receive is coupled to the damping material.

There is provided in accordance with an exemplary embodiment of the invention a method of making an ultrasound transducer for medical therapy comprising: applying a gas to an element adapted to transmit ultrasound energy; forming a bubble comprising a gas surrounded by a film of a liquid; and retaining the bubble by immersing the element in a liquid.

There is provided in accordance with an exemplary embodiment of the invention a catheter for medical therapy comprising: a distal end; and a proximal end comprising: an ultrasound transducer comprising an acoustic element; and a temperature sensor for estimating the temperature of the element. Optionally, the sensor is positioned downstream from the element.

There is provided in accordance with an exemplary embodiment of the invention a catheter for medical therapy comprising: a distal end; and a proximal end comprising: an ultrasound transducer comprising an acoustic element; and at least one cooling element thermally coupling the element to a heat sink.

In an exemplary embodiment of the invention, the heat sink comprises one or more braids in a shaft of the catheter.

In an exemplary embodiment of the invention, the cooling element comprises one or more channels on the surface of the catheter, the grooves configured to direct flow of a fluid over the element.

In an exemplary embodiment of the invention, the cooling element controls the flow rate of a fluid over the element.

In an exemplary embodiment of the invention, the distal end is made out of relatively stiff materials and a proximal end is made out of relatively flexible materials.

In an exemplary embodiment of the invention, a shaft of the catheter is configured to transmit torque in a one to one ratio from the distal end to the proximal end.

There is provided in accordance with an exemplary embodiment of the invention an ultrasound transducer for medical therapy comprising: an element adapted to transmit ultrasound energy; at least two electrodes configured to apply a voltage across at least some volume of the element; and a support board, wherein the support board is coupled to the element at 0.06%-17% of a surface area of the board.

In an exemplary embodiment of the invention, the transducer further comprises electrically conductive glue to couple the element to the board.

There is provided in accordance with an exemplary embodiment of the invention an ultrasound system for medical therapy comprising: an ultrasound transducer; a catheter comprising the transducer at a distal end; and a controller, the controller configured to apply electrical power to the transducer to output ultrasound energy at a frequency of 10-60 Mhz and at an intensity of over 10 Watts per square centimeter.

There is provided in accordance with an exemplary embodiment of the invention a catheter for medical therapy comprising: a distal end; and a proximal end comprising: an ultrasound transducer comprising an acoustic element; wherein the catheter is designed to not contact a vessel wall while the transducer is aimed at the vessel wall.

In an exemplary embodiment of the invention, an ultrasound beam produced by the transducer is non-focused.

Unless otherwise defined, all technical and/or scientific terms used herein have the same meaning as commonly understood by one of ordinary skill in the art to which the invention pertains. Although methods and materials similar or equivalent to those described herein can be used in the practice or testing of embodiments of the invention, exemplary methods and/or materials are described below. In case of conflict, the patent specification, including definitions, will control. In addition, the materials, methods, and examples are illustrative only and are not intended to be necessarily limiting.

Implementation of the method and/or system of embodiments of the invention can involve performing or completing selected tasks manually, automatically, or a combination thereof. Moreover, according to actual instrumentation and equipment of embodiments of the method and/or system of the invention, several selected tasks could be implemented by hardware, by software or by firmware or by a combination thereof using an operating system.

For example, hardware for performing selected tasks according to embodiments of the invention could be implemented as a chip or a circuit. As software, selected tasks according to embodiments of the invention could be implemented as a plurality of software instructions being executed

by a computer using any suitable operating system. In an exemplary embodiment of the invention, one or more tasks according to exemplary embodiments of method and/or system as described herein are performed by a data processor, such as a computing platform for executing a plurality of instructions. Optionally, the data processor includes a volatile memory for storing instructions and/or data and/or a non-volatile storage, for example, a magnetic hard-disk and/or removable media, for storing instructions and/or data. Optionally, a network connection is provided as well. A display and/or a user input device such as a keyboard or mouse are optionally provided as well.

## BRIEF DESCRIPTION OF THE DRAWINGS

Some embodiments of the invention are herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of embodiments of the invention. In this regard, the description taken with the drawings makes apparent to those skilled in the art how embodiments of the invention may be practiced.

In the drawings:

FIG. **1** is an illustration of a catheter, in accordance with an exemplary embodiment of the invention;

FIG. **2** is a flow chart of a treatment method, in accordance with an exemplary embodiment of the invention;

FIGS. **3**A-B are views of an ultrasound transducer coupled to a bubble, in accordance with an exemplary embodiment of the invention;

FIG. **3**C is a side view of the transducer, with bubble replaced by a material, in accordance with some embodiments of the invention.

FIGS. **4**A-F are illustrations of some embodiments to couple the bubble to the acoustic element, in accordance with some embodiments of the invention;

FIGS. **5**A-P are illustrations of some embodiments of the ultrasound transducer coupled to the bubble suspended over a board, in accordance with some embodiments of the invention;

FIGS. **6**A-B are illustrations of some possible features on board, in accordance with some embodiments of the invention;

FIG. **7**A-B are block diagrams of methods of making a transducer, in accordance with an exemplary embodiment of the invention;

FIGS. **8**A-B are illustrations of a housing used with the transducer, in accordance with some embodiments of the invention;

FIGS. **9**A-D are illustrations of some embodiments of a multielement transducer, in accordance with some embodiments of the invention;

FIG. **10** is an illustration of an exemplary design of a multiregional transducer, in accordance with some embodiments of the invention;

FIGS. **11**A-C are illustrations of some embodiments of a transducer with a canopy, in accordance with some embodiments of the invention;

FIGS. **12**A-C are illustrations of some embodiments of transducer shapes, in accordance with some embodiments of the invention;

FIG. **13** is an illustration of an exemplary design of a catheter for guiding the transducer inside the body, in accordance with an exemplary embodiment of the invention;

FIGS. **14**A-B illustrate some embodiments of possible positions of the transducer on the catheter, in accordance with some embodiments of the invention;

FIGS. **15**A-C illustrate some embodiments of elements to cool and/or control the flow of a fluid over the transducer element, in accordance with an some embodiments of the invention; and

FIG. **16** is a block diagram of a control system, in accordance with an exemplary embodiment of the invention;

## DESCRIPTION OF SPECIFIC EMBODIMENTS OF THE INVENTION

The present invention, in some embodiments thereof, relates to an ultrasound transducer and, more particularly, but not exclusively, to a system for delivering ultrasound energy for medical treatment, for example, intravascular treatment.

An aspect of some embodiments of the invention relates to an ultrasound transducer comprising an acoustic element coupled to a gas bubble. Optionally, two or more bubbles are coupled to the element. Optionally, the bubble is created when the transducer is inserted into a fluid.

In an exemplary embodiment of the invention, two or more electrodes are positioned to create a voltage across at least some volume of the element.

An aspect of some embodiments of the invention relates to the gas bubble remaining coupled to the element during vibrations, for example 5-60 Mhz, 10-20 Mhz, or other smaller, intermediate or larger frequency ranges, that produce an ultrasound intensity sufficient for medical therapy, for example 20 watts/cm$^2$, 30 watts/cm$^2$, 50 watts/cm$^2$, 100 watts/cm$^2$, or other smaller, intermediate or larger intensities.

In an exemplary embodiment of the invention, the relatively high acoustic intensity output is achieved by the use of the bubble.

In an exemplary embodiment of the invention, the bubble is coupled to the element by surface tension. Alternatively or additionally, the coupling surface area of the element is increased, for example, by one or more of, hair-like projections, tree-like projections, small spheres, jagged irregularities. Alternatively or additionally, the coupling force is increased by a coating at least on the element, for example, a hydrophilic coating and/or a hydrophobic coating. Alternatively or additionally, static electricity forms and/or increases the coupling.

An aspect of some embodiments of the invention relates to making an ultrasound transducer comprising a bubble coupled to an acoustic element. In an exemplary embodiment of the invention, the method of making comprises forming the bubble by submersion of the element in a liquid such as water, saline, blood. Alternatively or additionally, the method comprises forming the bubble from a liquid and/or coupling the bubble to the element.

In an exemplary embodiment of the invention, the bubble is filled with a gas, for example, one or more of, room air, oxygen, nitrogen, carbon dioxide, carbon tetrafluoride.

An aspect of some embodiments of the invention relates to an acoustic element suspended over and/or above a support board, at a relatively small number of locations, for example, 1, 2, 8, 12 or other smaller, intermediate or larger numbers, and/or at a relatively small surface area of the element, for example, about 0.06%-about 17% of the surface area of the element, for example, one location is about 0.06% of the surface area, eight locations are about 0.5% of the surface area. Optionally, the acoustic element is coupled to a bubble. Optionally, the suspension areas are at a peripheral location of the element. Alternatively or additionally, the suspension

areas are away from the periphery. In an exemplary embodiment of the invention, suspension relatively decreases the damping forces on the element.

In an exemplary embodiment of the invention, surface features on the board control and/or direct flow of a liquid between the board and the element. Optionally, the surface features are grooves.

In an exemplary embodiment of the invention, at least some area of the element is suspended over and/or above a depression and/or an aperture in the board and/or in a housing. Optionally, at least some of the depression and/or aperture is configured for a function, for example, one or more of, reflection, transmission, damping.

In an exemplary embodiment of the invention, the transducer comprising at least two elements suspended over and/or above a board. Optionally, at least one element is coupled to at least one bubble. Alternatively or additionally, at least one bubble is coupled to at least two elements.

An aspect of some embodiments of the invention relates to a transducer comprising at least two regions configured for at least two different functions. Optionally, at least one region is configured for imaging (e.g., transmitting and/or receiving) and/or at least one region is configured for treatment. Optionally, two or more regions (e.g., at two or more different location) configured for treatment are designed to operate at two or more different frequencies.

An aspect of some embodiments of the invention relates to at least one cooling element reducing the temperature of the element. Optionally, cooling occurs according to the temperature measured by the sensor. Optionally, cooling occurs by a flow of a liquid (e.g., blood, saline, dye) over the element, for example, by injection of the liquid, by passive flow of the liquid (e.g., blood flow), by acoustic pressure induced flow, by active control of the flow rate of the liquid, by directing flow of the liquid using one or more flow channels (e.g., on the catheter). Alternatively or additionally, cooling occurs by transfer of heat to blood, for example, through the surface of the catheter shaft and/or the transducer surface. Optionally, cooling is increased using active heat flux such as a thermoelectric cooler.

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not necessarily limited in its application to the details of construction and the arrangement of the components and/or methods set forth in the following description and/or illustrated in the drawings and/or the Examples. The invention is capable of other embodiments or of being practiced or carried out in various ways.

Overview

For purposes of better understanding some embodiments of the invention, as illustrated in FIGS. **3-20** of the drawings, reference is first made to an example of an ultrasound treatment catheter **1222** inside a blood vessel, as illustrated in FIG. **1**, and/or a method of treatment, as illustrated in FIG. **2**, where exemplary embodiments of the invention may be used.

At **1506**, one or more initial parameters are set (e.g., for treatment, for imaging) in accordance with an exemplary embodiment of the invention, for example, frequency, energy intensity, duty cycle, pulse duration, pulse repetition frequency, duration of treatment, focused and/or unfocused mode, maximum temperature for element **102**. In an exemplary embodiment of the invention, the initial parameters are set according to a treatment plan, for example, as described with reference to U.S. Appl. No. 61/453,239, incorporated herein by reference in its entirety. Optionally, the treatment plan is based on clear anatomical landmarks, such as arterial bifurcations.

At **1500**, catheter **1222** in inserted into the body of a patient, in accordance with an exemplary embodiment of the invention. Standard vascular access methods can be used, for example, from the femoral artery. Optionally, catheter **1222** is threaded using a guidewire **1202** (e.g., standard 0.014 over the wire, rapid exchange) to the target treatment site (e.g., an artery such as the iliac, renal, carotid, aorta) under image guidance, such as fluoroscopy. Alternatively or additionally, catheter **1222** is directed inside a guiding sheath to the anatomical treatment location.

In an exemplary embodiment of the invention, the initial parameters are set manually (e.g., by a user) using an interface coupled to a controller. Alternatively or additionally, parameters are automatically determined, such as by a software module of the controller.

In an exemplary embodiment of the invention, catheter **1222** comprises at least one transducer **300**, positioned for example, on the side, such as inside a window cut into the catheter shaft **1230**. Alternatively, a support for transducer **300** is "U" shaped.

At **1502**, contact between an acoustic element **102** of transducer **300** and a surface and/or a wall **1226** of a vessel, cavity and/or lumen is reduced and/or prevented, for example, by a separation element and/or device **1204**, in accordance with an exemplary embodiment of the invention. Device **1204** maintains a distance **1218** between element **102** and wall **1226** of at least 1 mm. In an exemplary embodiment of the invention, maintaining at least distance **1218** reduces or prevents overheating of element **102**. Optionally, a fluid located in distance **1218** transfers heat away from element **102**.

Additional details about separation element **1204** are discussed with reference to U.S. Appl. No. 61/453,234, incorporated herein by reference in its entirety.

At **1510**, electrical energy is applied to transducer **300**, for example, according to parameters set at **1506**, in accordance with an exemplary embodiment of the invention.

In an exemplary embodiment of the invention, target tissue **1216** is treated by an ultrasound beam **1228** from transducer **300**. In some embodiments, treating comprises a thermal effect (e.g., heating to above 55 degrees Celsius) and/or a cavitation effect. In some embodiments, damage and/or treatment to tissues (e.g., normal, healthy) surrounding target tissue **1216** is reduced and/or prevented. In some embodiments, treatment and/or damage to a volume of tissue between target tissue **1216** and wall **1226** is reduced and/or prevented. Selectively targeting tissue is discussed in more detail with reference to U.S. Appl. No. 61/453,239.

Optionally, at **1504**, one or more variables are measured and/or estimated as part of treatment feedback, for example, a flow rate of blood **1220** inside the vessel (e.g., using transducer **300** in Doppler mode), a temperature of transducer **300** (e.g., using sensor **308**), distance **1218** (e.g., using acoustic feedback), distance **1232** (e.g., using transducer **300** in imaging mode), and/or impedance of transducer **300** (e.g., electrical measurements), in accordance with an exemplary embodiment of the invention.

In some embodiments, variables measured at **1504** are used to calibrate and/or adjust parameters at **1506**, for example, by a look-up table of correlated values. Optionally, measurements as in **1504** occur during and/or after the treatment. Optionally or additionally, adjustment of parameters as in **1506** occurs during and/or after the treatment.

Optionally, at **1508**, the integrity of transducer **300** is verified, for example, for mechanical failure and/or presence of foreign matter (e.g., thrombus), in accordance with an exemplary embodiment of the invention. Integrity is verified, for

example, by measuring changes in the impedance of transducer **300**. Optionally, verification of integrity occurs during and/or after treatment.

Measuring the integrity of transducer **300** is described in more detail with reference to U.S. application Ser. No. 13/049,013, incorporated herein by reference in its entirety.

Optionally, at **1516**, transducer **300** is used in an imaging mode to obtain feedback about a target tissue **1216**. One or more non-limiting examples of target tissues **1216** include, fat, nerves, vasa vasora, lymph, tumor, connective tissue, plaque (e.g., atherosclerotic). Target tissue **1216** may be located a distance **1232** away from the inner surface of wall **1226**. Examples of the maximum distance **1232** of target tissue **1216** that can be imaged using transducer **300** include 0.5 mm, 1 mm, 2 mm, 5 mm, 10 mm, or other smaller, intermediate or larger distances. Alternatively or additionally, one or more non-limiting examples of ultrasound imaging methods to estimate the extent of thermal damage in the target tissue and/or surrounding tissue include, measuring the ultrasound backscatter coefficient, ultrasound elastography, measuring US absorption and/or scattering from the treatment region, spectral signature mapping, classification according to a classification matrix of tissues, and/or the ultrasonic effect.

Optionally, at **1512**, element **102** is cooled, in accordance with an exemplary embodiment of the invention. Optionally, cooling occurs by transfer of heat from element **102** to a surrounding fluid such as blood **1220**, saline, urine, water, angiography contrast fluids, cerebrospinal fluid, lymph, mucous, stomach acid. Alternatively or additionally, cooling occurs by injection of a cooled volume of a liquid (e.g., saline, radio-opaque dye) through tube **1206**, and/or circulation of a liquid through tube **1208**. Alternatively or additionally, cooling is increased using active heat flux, such as the thermoelectric cooler.

In some embodiments, cooling of element **102** is controlled by the controller, using feedback obtained about the temperature of element **102**, for example, from sensor **308**.

Additional details about cooling element **102** are discussed with reference to U.S. application Ser. No. 13/049,022, incorporated herein by reference in its entirety.

Optionally, at **1514**, one or more of **1504**, **1516**, **1508**, **1510** and/or **1512** are repeated, for example, in a feedback cycle.

Bubble Transducer—Element

Referring now to the drawings, FIGS. **3**A-B illustrate an ultrasound transducer **100** for medical therapy, in accordance with an exemplary embodiment of the invention. FIG. **3**A is a side view, and FIG. **3**B is a cross sectional view of transducer **100**. Transducer **100** is designed for high intensity output, for example, up to 100 watts per square centimeters, to cause tissue damage (e.g., heating), while being sufficiently small, for example, about 10 mm (length)×about 1.5 mm (width)× about 0.8 mm (thickness), to be inserted inside blood vessels of the human body on a catheter.

In an exemplary embodiment of the invention, an element **102** is adapted to produce and/or transmit a beam **114** of ultrasound energy. Without being bound to theory, a rectangular element **102** produces an ultrasound beam with relatively low divergence when vibrating, (e.g., for simplification, expansion (arrows **150**) and/or contraction (arrows **152**)) in response to a sinusoidal voltage applied between a first surface **132** and a second surface **134**.

In an exemplary embodiment of the invention, element **102** is vibrated to produced a beam **114** intensity of at least 1-10 watts/cm$^2$, 20 watts/cm$^2$, 30 watts/cm$^2$, 50 watts/cm$^2$, 100 watts/cm$^2$ or other smaller, intermediate or larger intensities.

In an exemplary embodiment of the invention, at least two electrodes **302** and/or **304** are configured to apply a voltage across at least some volume of the element **102**, for example, electrode **302** is located on at least some surface **132** and/or electrode **304** is located on at least some surface **134**.

In an exemplary embodiment of the invention, electrodes **302** and/or **304** are made out of an electrically conductive biocompatible material such as fired silver. Optionally, electrodes **302** and/or **304** are relatively thin, for example, 5-10 micrometers, or other smaller, intermediate or larger thicknesses. Optionally, electrodes **302** and/or **304** are coupled to element **102** by a process such as a firing process.

In an exemplary embodiment of the invention, element **102** is made out of a material suitable to produce ultrasound energy, for example, a piezo-electric such as lead zirconate titanate (PZT), for example, piezo-electric quartz and/or ceramic.

In an exemplary embodiment of the invention, the thickness of element **102** (e.g. space between electrodes **302** and **304**) is about 50 micrometers, about 100 micrometers, about 200 micrometers, about 400 micrometers, or other smaller, intermediate or larger thicknesses are used.

In an exemplary embodiment of the invention, the voltage applied causes element **102** to be vibrated at a frequency, for example, of about 5 Mhz, about 10 Mhz, about 20 Mhz, about 50 Mhz, about 60 Mhz, or other smaller, intermediate or larger frequencies are used.

In an exemplary embodiment of the invention, the thickness of element **102** is related to the expected frequency of vibration of element **102**, optionally linearly related, for example, a thickness of 100 micrometers for a frequency of 20 Mhz, a thickness of 200 micrometers for a frequency of 10 Mhz.

In an exemplary embodiment of the invention, the shape of element **102** is rectangular. Alternatively, element **102** is square. Alternatively, other shapes are used, for example, one or more of, annular, semi-annular, concave. Alternatively or additionally, element **102** is flat with an array of electrodes. Alternatively or additionally, an array of elements **102** is used. Alternatively or additionally, several elements **102** are used, wherein elements **102** are spaced apart and/or angled apart. Alternatively or additionally, element **102** produces an ultrasound beam in two opposite directions simultaneously, for example, if the bubble is not used.

In an exemplary embodiment of the invention, element **102** is planar.

In an exemplary embodiment of the invention, element **102** is relatively long, for example, having a length of about 1 mm, about 2 mm, about 4 mm, about 6 mm, about 8 mm, about 10 mm, or other smaller, intermediate or larger lengths are used.

In an exemplary embodiment of the invention, the width of element **102** is relatively short, for example, about 0.2 mm, about 0.6 mm, about 1.0 mm, about 1.4 mm, about 2.0 mm, or other smaller, intermediate or larger widths are used.

In an exemplary embodiment of the invention, beam **114** is unfocused, for example, beam does not converged at a point, for example, beam diverges relatively little. Alternatively, beam **114** is focused, for example, as described with reference to FIG. **12**C.

In an exemplary embodiment of the invention, beam **114** produced by the rectangular element **102** is relatively straight, spreading an angle **112** of about fifteen (15) degrees relative to a normal to surface **132** of element **102**, when measured along the length. Non-limiting ranges of angle **112** include about 0.1 degrees to about 30 degrees. Without being bound to theory, angle **112** is inversely related to surface **132** and/or

inversely related to the frequency of vibration of element **102** (e.g., smaller element **102** and/or lower frequency increase angle **112**).

A potential advantage of a relatively thin element **102** vibrating at a relatively high frequency is the reduction and/or prevention of the risk of mechanical failure (e.g., breaking, fracturing). Inventors hypothesize that the high frequency vibration and/or a relatively thin height results in a rate of heat transfer from element **102** (e.g., to a surrounding fluid), that is sufficient to prevent and/or reduce damage to element **102** due to heat build up.

In an exemplary embodiment of the invention, transducer **100** has a resonance and an anti-resonance. Optionally, transducer **100** has several resonant frequencies and several anti-resonances formed from local maxima, such as on an efficiency graph. Optionally, transducer **100** is used at a working frequency equal to the anti-resonance. The anti-resonance was found empirically to provide a relatively higher efficiency in terms of a ratio of conversion of electrical energy to sound, as opposed to conversion of electrical energy to heat.

In an exemplary embodiment of the invention, element **102** uses different anti-resonance values for the working frequency when available. For example one anti-resonance may be used for moderate heating of the tissue, another for power heating of the tissue and yet another for monitoring.

Bubble Transducer—Gas Bubble

In an exemplary embodiment of the invention, at least one gas bubble **160** is coupled to at least some area of a side element **102**, for example, to side **134**, such as to electrode **134**. In an exemplary embodiment of the invention, bubble **160** relatively increases the efficiency of element **102** in converting electrical power to acoustic energy.

In an exemplary embodiment of the invention, the gas in bubble **160** is room air. Alternatively, the gas in bubble **160** is for example, one or more of, oxygen, nitrogen, carbon dioxide, carbon tetrafluoride.

In an exemplary embodiment of the invention, bubble **160** is formed by surface tension of a liquid (e.g., water, saline, blood) around the gas, such as during immersion of element **102** into the liquid.

In an exemplary embodiment of the invention, a thickness **170** of bubble **160** (e.g. measured approximately in the center) is about 1 micrometer, 10 micrometers, about 50 micrometers, about 100 micrometers, about 200 micrometers, or other smaller, intermediate or larger thicknesses are used. In an exemplary embodiment of the invention, bubble **160** is about the size of surface area of side **134** of element **102**.

In an exemplary embodiment of the invention, bubble **160** prevents an ultrasound beam from passing through. Bubble **160** can be used to create ultrasound beam **114** from one direction of element, for example, from surface **132**.

As illustrated in FIG. **4**A, in accordance with some embodiments of the invention, the surface area of side **134** is increased to relatively increase the coupling force between bubble **160** and side **134**. One or more examples of increasing the surface area of side **134** include, hair-like projections **402**, jagged surface variations **404**, microspheres **406** and/or tree like projections **408**.

As illustrated in FIG. **4**B, in accordance with some embodiments of the invention, a coating **410** on at least a portion of side **134** is used to relatively increase the coupling force between bubble **160** and side **134**. Optionally coating **410** is hydrophobic. Alternatively or additionally, coating is hydrophilic. One or more non-limiting examples of coating **410** include, Parylene available from Para Tech Coating Inc., Galxyl available from GALENTIS. In some embodiments, coating **410** is applied for example, by chemical vapor deposition. In some embodiments coating **410** is relatively thin, for example, 5 micrometers.

As illustrated in FIG. **4**C, in accordance with some embodiments of the invention, bubble **160** is formed before immersion of element **102** into the liquid, for example, from a liquid film **412** such as microbubbles in an acoustic ultrasound contrast agent, for example, as described with reference to FIG. **7**B.

As illustrated in FIG. **4**D, in some embodiments of the invention, two or more bubbles **160** are coupled to side **134** of element **102**.

As illustrated in FIG. **4**E, in some embodiments of the invention, a second bubble **414** is coupled to one or more bubbles **160** coupled to side **134**. Optionally second bubble **414** is coupled, for example, by static and/or surface tension. Optionally, there is a space between bubbles. In some embodiments of the invention, two or more bubbles **414** are used to create bubble shapes to relatively increase the efficiency of element **102**, for example, the vibration of element **102** can be mathematically modeled, with two or more bubbles **414** designed accordingly.

As illustrated in FIG. **4**F, in an exemplary embodiment of the invention, bubble **160** is coupled to side **134** by increasing the surface tension on bubble **160**. In an exemplary embodiment of the invention, a base **450** creates a space **452** between base **450** and side **134**, thereby increasing the surface tension. Optionally, base **450** is coated with a coating **454** to relatively increase the surface tension, for example coating like **410**. One or more non-limiting examples of base **450** will be discussed in more detail below, such as board **104** and/or housing **800**.

In some embodiments of the invention, bubbles **160** and/or **414** are of one or more sizes. Alternatively or additionally, bubbles **160** and/or **414** contain one or more types of gases.

In an exemplary embodiment of the invention, bubble **160** is coupled to most or all of area of side **134**.

FIG. **3**C is a side view of transducer **100**, with bubble **160** replaced by a material **390**, in accordance with some embodiments of the invention. In some embodiments of the invention, material **390** has an effect similar to bubble **160**, for example, relatively increasing the efficiency of transducer **100**. Optionally, material **390** is a foam like material filled with the gas. Alternatively or additionally, material **390** is a heat conductive, electrically isolating polymeric pad.

Experimental Results Showing Some Potential Advantages

Inventors performed experiments to test a first hypothesis that the presence of the bubble improves the efficiency (e.g., converting electrical energy into ultrasound energy) of a transducer under an intensity setting sufficient for medical therapy, a second hypothesis that the structure of the transducer provides for coupling of the bubble to a side of the transducer, even during the intensity setting sufficient for medical therapy, and a third hypothesis that the structure of the transducer (e.g., relatively thin) reduces and/or eliminates the risk of mechanical failure of the transducer under the intensity setting sufficient for medical therapy.

Inventors performed five experiments, in which they immersed one of the five transducers in water to form a bubble. An intensity setting sufficient to perform a medical treatment procedure was applied to the transducer, for example, as described with reference to **1510** in FIG. **2**. The efficiency of the transducer was measured using a hydrophone to measure the acoustic intensity output, and/or 'off the shelf' instruments to measure the applied electrical power.

The results showed a surprisingly high efficiency (e.g., conversion of applied electrical power to ultrasound energy), for example, up to 60%.

Subsequently, inventors increased the intensity to a relatively high level, higher than would be required for the medical treatment procedure.

As shown in the table below, the results show a decrease in efficiency at the relatively higher intensity relative to the efficiency measured at the relatively lower intensity. The differences in efficiencies are statistically significant, having p value <0.01 for all 5 experiments.

After removing the transducers and drying them at room temperature in room air for 12 hours, the transducers were re-immersed in the water, and the efficiency under the intensity level sufficient to perform a medical procedure was re-measured as shown in the table below. The transducers used in the experiment are based on FIGS. **4**F, **5**M and **5**N, having a coating of Parylene applied by chemical vapor deposition. The bubble is retained by surface tension, for example, in a containment area (e.g., the depression in the board).

| Transducer # | Efficiency under an intensity level sufficient for medical treatment (set 1) | Efficiency under a higher intensity than required for medical treatment (set 2) | Efficiency after 12 hours of drying and sufficient intensity for medical treatment (set 3) |
|---|---|---|---|
| A | 43% | 36.4% | 40% |
| B | 56% | 40.7% | 56% |
| C | 60% | 49.6% | 60% |
| D | 54% | 39.0% | 55% |
| E | 60% | 49.3% | 61% |

Surprisingly, the results showed that the efficiency of all 5 transducers after drying (set 3) was approximately equivalent to the first set of efficiency measurements (set 1).

As a control, before removing transducer D from the water for drying, transducer D was left for 12 hours in the water. The efficiency after 12 hours in the water remained at 39%.

Without being bound to theory, inventors believe that the results can be explained by the presence of the bubble during the first set of measurements, followed by the escape of the bubble during the second set of measurements, followed by the reformation of the bubble during the third set.

Inventors believe that the surprising results of a higher efficiency at the first set of measurements, relative to the second set, is due to the presence of the bubble.

Inventors believe that the surprising results of a higher efficiency at the first set of measurements, relative to the second set, support the hypothesis that the bubble remains coupled to the element, even under the intensity and/or the frequency sufficient for medical therapy.

Inventors believe that the surprising results of an increase in efficiency after drying the transducers (set 3), to about the same level as the first set of measurements, support the hypothesis that mechanical failure of the transducer is reduced and/or prevented, even under a higher intensity level than is required for medical therapy.

In summary, in accordance with the first hypothesis, the experimental results support the theory that the bubble significantly improves the efficiency of the transducer. In accordance with the second hypothesis, the experimental results support the theory that the bubble remains coupled to the transducer during an intensity and/or a frequency setting sufficient for medical therapy, even though the element is vibrating. In accordance with the third hypothesis, the experimental results support the theory that the structure of the transducer reduces and/or eliminates the risk of mechanical failure during the intensity setting sufficient for medical therapy.

Additional Potential Advantages

A potential advantage of the relatively high efficiency (e.g., 60%) of transducer **100** is a relatively low rate of heat transferred to the blood, potentially preventing and/or reducing the risk of adverse events such as thrombus formation.

A potential advantage of the relatively small surface area **132** of element **102** and/or a relatively straight bream **114** and/or a relatively high energy output intensity is that focusing of beam **114** is not required, for example, to target and/or treat tissues.

One or more potential advantages of the non-focused ultrasonic beam include:

- A relatively large treatment volume cross-section as a result of the size of the transducer face (as compared to focused ultrasound that provides for a relatively smaller treatment volume).
- A relatively even spread of ultrasonic energy in the cross section of the beam. No need for precise positioning from the wall of the blood vessel or from the target tissue like in focused ultrasound.

Method of Making the Transducer

FIGS. **7**A-B illustrate some exemplary methods of making the ultrasound transducer (e.g., transducer **100**), in accordance with an exemplary embodiment of the invention.

FIG. **7**A illustrates a method coupling and/or forming bubble **160** during submersion of element **102** into a liquid, in accordance with an exemplary embodiment of the invention.

At **700**, gas (e.g., room air, nitrogen, oxygen, carbon dioxide) is applied to element **102**, such as to side **134**, for example, by immersing element **102** and/or side **134** in the gas, in accordance with an exemplary embodiment of the invention.

At **702**, element **102** is immersed in the liquid (e.g., blood, saline), such as during a medical procedure, in accordance with an exemplary embodiment of the invention. In an exemplary embodiment of the invention, bubble **160** is formed and/or coupled to element **102**, for example, by surface tension and/or by methods as described with reference to FIGS. **4**A and/or **4**B.

FIG. **7**B illustrates a method of coupling an exiting and/or formed bubble **160** to element **102**, in accordance with some embodiments of the invention.

At **704**, bubble **160** is formed and/or obtained, for example, from a liquid such as microbubbles in an acoustic ultrasound contrast agent in accordance with some embodiments of the invention.

At **706**, bubble **160** is coupled to element **102**, for example, as described with reference to FIG. **4**C.

Supported Element

FIGS. **5**A-P illustrate some exemplary embodiments of the invention, wherein a transducer (e.g., element **102**, with at least two electrodes **302** and/or **304**, optionally with bubble **160** coupled to side **134**), is supported above at least some area of a support board **104**. Optionally, element **102** is suspended over at least some volume of a depression **514** and/or an aperture **518** of the board **104**. In an exemplary embodiment of the invention, at least one region and/or area of element **102** is used to suspend element **102**.

In an exemplary embodiment of the invention, board **104** is a printed circuit board.

In an exemplary embodiment of the invention, at least some part of board **104** (e.g. part supporting element **102**) is made from a rigid material, for example, one or more of, a hard polymer, glass-fiber, carbon fiber. Alternatively or addi-

tionally, at least some part of board **104** is made from a flexible material, such as polyimide.

In an exemplary embodiment of the invention, the shape of board **104** is for example, rectangular. Non-limiting examples of dimensions of a rectangular board **104** are 10×1.5 mm, with a uniform thickness of 150 micrometers.

In an exemplary embodiment of the invention, a relatively small surface area of element **102** (e.g., side **134**) is used to couple element **102** to board **104**, for example, about 0.06%-about 17% of the surface area of the element, for example, one location (e.g., drop) is about 0.06% of the surface area, eight locations are about 0.5% of the surface area of side **134**.

In an exemplary embodiment of the invention, element **102** is suspended a distance **520** above board **104**, for example, 0.1 micrometers, 1 micrometers, 10 micrometers, 17 micrometers, 100 micrometers, 150 micrometers, 200 micrometers, or other smaller, intermediate or larger distances. Optionally, the bubble is located in the space formed by distance **520**. Optionally, the size of the bubble is determined according to distance **520**.

FIG. **5**A-**5**F illustrate a material **500** to suspend element **102** above board **104**, in accordance with an exemplary embodiment of the invention. In an exemplary embodiment of the invention, material **500** suspends element **102** above board **104** at 1 coupling area, 2 coupling areas, 4 coupling areas, 8 coupling areas, 12 coupling areas, or other smaller, intermediate or larger numbers of coupling areas. In an exemplary embodiment of the invention, material **500** is for example, one or more of, glue, wire solder, paste solder. In an exemplary embodiment of the invention, the shape of material **500** is for example, one or more of, irregular (e.g., a blob) **522**, a sphere **504**, a strip **502**. Optionally, material **500** is electrically conductive, for example, electrically coupled to electrode **302** and/or **304**. Alternatively or additionally, material **500** is thermally conductive.

FIG. **5**A is a side view, and FIG. **5**B is a cross sectional view of material **500** arranged along the periphery of the width of element **102**, for example, as strip **502**, in accordance with some embodiments of the invention. Illustrated is the non-limiting example of 2 materials **500** arranged as strips **502** along both widths.

FIG. **5**C is a side view, and FIG. **5**D is a cross sectional view of material **500** arranged along the periphery of the length of element **102**, for example, as sphere **504**, in accordance with some embodiments of the invention. Illustrated is the non-limiting example of 8 materials **500** arranged as spheres **504** along both lengths.

FIG. **5**E is a side view, and FIG. **5**F is a cross sectional view of material **500** arranged away from the periphery of element **102** (e.g., centrally located). Illustrated is the non-limiting example of the use of one material **500**, having irregular shape (e.g., blob) **522**.

FIG. **5**G is a side view, and FIG. **5**H is a cross sectional view of a material, for example, a metal such as copper **506**, used to suspend element **102** above board **104**, in accordance with some embodiments of the invention. Optionally, copper **506** is printed on board **104**, for example, using standard printed circuit board techniques. In some embodiments, a relatively thicker layer **508** of copper **506** is used to suspend element **102**, for example, a thickness of 50-200 micrometers. Optionally, a relatively thinner layer **510**, for example, 1-150 micrometers of copper **506** is used, for example, to conduct electricity and/or heat. Alternatively or additionally, a relatively medium thickness layer **512** (e.g., thickness between thick layer **508** and thin layer **510**) is used to suspend element **102**, for example with material **500** bridging the remaining gap.

In an exemplary embodiment of the invention, copper **506** is located on the surface of board **104** according to function, for example, to support element **102** and/or to conduct electricity and/or heat. Optionally, copper **506** coats at least some area of board **104**.

In an exemplary embodiment of the invention, embodiments according to FIGS. **5**A-H are selected in part according to electrification and/or cooling requirements, for example, relatively more contact areas provide relatively increased electrical power and/or cooling.

A potential advantage of relatively few contact areas as in FIGS. **5**A-H is reducing damping forces on element **102**.

FIG. **5**I is a side view and FIG. **5**J is a cross sectional view, of element **102** suspended over at least some volume of a depression **514** in board **104**, in accordance with some embodiments of the invention.

FIG. **5**K is a side view, and FIG. **5**L is a cross sectional view of element **102** suspended over at least some volume of an aperture **518** in board **104**, in accordance with some embodiments of the invention. Optionally, element **102** is suspended over at least some volume of depression **514** and/or aperture **518** by walls **516** of board **104** forming depression **514** and/or aperture **518**, for example, at least at two areas, such as at the periphery of width of element **102** and/or at least at one area, such as away from the periphery (e.g., centrally).

In an exemplary embodiment of the invention, embodiments according to FIGS. **5**I-L are selected according to the size of the bubble.

FIG. **5**M is a side view and FIG. **5**N is a cross sectional view, of material **500** suspending element **102** over at least some volume of a depression **514** in board **104**, in accordance with some embodiments of the invention.

FIG. **5**O is a side view and FIG. **5**P is a cross sectional view, of material **500** suspending at least some volume of element **102** inside at least some volume of depression **514**. Optionally, material **500** couples a side **522** (e.g., along width) of element **102** to the inside wall **516** of depression **514**.

In an exemplary embodiment of the invention, embodiments according to FIGS. **5**M-**5**P are selected according to bubble size, electrification requirements and/or cooling requirements.

Inventors hypothesize that a potential advantage of a free standing, and/or suspended element **102** is increased efficiency in producing acoustic and/or ultrasound energy. Without being bound to theory, inventors hypothesize that the increased efficiency is a result of a relatively small amount of resistance and/or damping of element **102**, for example, as a result of the relatively small surface area of side **134** used to couple element **102** to board **104**.

Board Features

FIG. **6**A is a side view, and FIG. **6**B is a cross sectional view illustrating some possible features on board **104** to control heat removal and/or control flow **604** of a liquid (e.g., blood, saline, water) under element **102**, in accordance with some embodiments of the invention. Optionally, element **102** comprises one or more holes **690**, such as from side **132** to side **134**. Optionally, holes **690** allow for flow **604** of the liquid between sides **132** and **134**.

In some embodiments of the invention, heat conductivity away from element **102**, such as to board **104** is controlled, for example, by thermal conductive elements such as gold and/or copper filled holes **600**. In some embodiments, holes **600** are thermally coupled to element **102**, for example, through material **500** and/or copper **506**. Other non-limiting examples of heat sinks to which holes **600** can conduct heat from element **102** to, include a heat sink (e.g., housing **800** as will

be described below), a thermoelectric cooler, flowing liquid **604** (e.g., blood, water, saline, dye).

In some embodiments of the invention, the total surface area of holes **600** facing element **102** is relatively larger than the total surface area of material **500** contacting element **102**.

In some embodiments of the invention, one or more flow channels **602** control flow **604** of the liquid, for example, between element **102** and board **104**. Optionally, element **102** is not coupled to bubble **160**. Optionally, flow channels are grooves on the surface of board **104**, for example, shaped by copper **506**.

A potential advantage of controlling flow **604** under element **102** is to reduce and/or prevent the formation of thrombus due to stagnation of blood. Another potential advantage is to increase the rate of heat removal from element **102** to the flowing liquid **604** (e.g., blood, water, saline, dye).

Housing

FIGS. **8**A-B illustrate the use of a housing **800** coupled board **104**, in accordance with some embodiments of the invention. In some embodiments, housing **800** provides one or more functions, for example, mechanical support, radio-opacity, acoustic damping, acoustic reflection, focusing.

In some embodiments of the invention, housing **800** is coupled to catheter **1222**, for example, at least some part of catheter **1222** has housing **800**.

In some embodiments of the invention, housing **800** is coupled to board **104**, for example, to side **802** of board (e.g., side not coupled to element **102**). One or more examples of methods to couple housing **800** to board **104** include gluing, welding, crimping, screws.

In some embodiments of the invention, housing **800** provides mechanical support to board **104** and/or element **102**, for example, by being made out of a rigid material such as steel, stainless steel, ceramics, hard polymers, carbon fiber. Optionally at least some of housing **800** is a peltier element

In some embodiments, housing **800** acts as a heat sink to increase the rate and/or amount of heat removed from element **102**, for example, by being thermally coupled to element **102** through board **104** (e.g., through material **500** and/or copper **506** and/or holes **600**).

In some embodiments, housing **800** contains radio-opaque direction markers such as an arrow **804** and/or an angle **806** (e.g., 45 degrees) to assist in orienting element **102** under fluoroscopic image guidance.

In some embodiments, housing **800** comprises a depression **804** and/or aperture, optionally in continuity with aperture **518** in board **104**. Optionally, a bubble resides inside depression **804** and/or aperture **518**. In some embodiments, at least some of element **102** is positioned over at least some volume of depression **804**. Optionally, depression **804** dampens the acoustic energy transmitted by side **134** of element **102**, for example, in some embodiment wherein element **102** is not coupled to bubble **160**. One or more examples of methods to cause damping include, filling at least some of the volume of depression **804** with a damping material such as tungsten, irregular surface variations **806** (e.g., jagged edges) to randomly reflect acoustic energy from side **134**. Alternatively or additionally, depression **804** reflects ultrasound, for example, by a flat reflecting surface **808**, such as steel. Alternatively or additionally, depression **804** focuses ultrasound energy, for example, by a concave reflecting surface.

A potential advantage of housing **800** is to relatively increase the ability of element **102** to perform imaging, for example, by damping vibrations so that element **102** can receive returning echoes. Another potential advantage of housing **800** is to focus the ultrasound energy.

Multielement Transducers

FIGS. **9**A-9D illustrate some exemplary embodiments of a multielement transducer (e.g., two or more elements), in accordance with an exemplary embodiment of the invention.

FIG. **9**A illustrates a multielement transducer **900**, wherein a side **910** of at least one element **902** is coupled to at least one bubble **906**, in accordance with an exemplary embodiment of the invention. Optionally, a second side **912** of a second element **904** is coupled to at least one second bubble **908**. Alternatively, second element **904** is not coupled to bubble **908**.

FIG. **9**B illustrates a multielement transducer **920**, wherein a bubble **922** is coupled to at least two sides **924** of at least two elements **926**, in accordance with some embodiments of the invention. Optionally, elements **926** are connected by one or more connectors **928**, wherein connector **928** is coupled to bubble **922**.

FIG. **9**C illustrates a multielement transducer **930** designed to focus at least two ultrasound beams **934** from at least two elements **926** at a focal area and/or volume **938** (e.g., tissue), in accordance with some embodiments of the invention. Optionally, board **932** is shaped (e.g., concave) to result in focal area and/or volume **938**.

FIG. **9**D illustrates a multielement transducer **940**, designed to direct one or more ultrasound beams **934** over a relatively wide area, in accordance with some embodiments of the invention. Optionally, beams **934** cover a cross sectional area and/or volume of 360 degrees, for example, to provide treatment (e.g., damage by heat and/or mechanic effect) of a cross section of a blood vessel. Alternatively, beams **934** cover a cross sectional area and/or volume of less than 360 degrees. In some embodiments, board **942** is shaped to result in the coverage of beams **934**, for example, having a cross sectional shape of a circle (e.g., ring) and/or semi-circle (e.g., arc). Optionally, board **942** contains a lumen **944**.

In some embodiments, elements of transducers **900** **920** **930** and/or **940** are suspended over a support board **910** **932** and/or **942**.

In some embodiments of the invention, elements described with reference to FIGS. **9**A-9D perform one or more functions, for example, imaging and/or treatment. Optionally, one or more elements are made out of one or more materials, for example, according to the function and/or application. For example, one or more elements designed for treatment are made out of a high intensity PZT formulation such as Navy Type III (available from Morgan Matroc as PZT-8). For example, one or more elements designed for imaging are made out of a PZT formulation designed for sensing such as Navy Type II (available from Morgan Matroc as PZT-5A). Alternatively or additionally, one or more elements are designed with one or more variations in dimensions, for example, according to the function and/or application. Alternatively or additionally, elements are individually controllable, for example, through a switch. For example, element **914** is made out of PZT NAVY TYPE III, and/or has a thickness of 200 micrometers, and/or is controlled to produce ultrasound at a frequency of 10 Mhz, and/or is used for treatment such as damage by heating. For example, element **916** is made out of PZT Navy Type II, and/or has a thickness of 100 micrometers, and/or is used for imaging by being controlled to produce ultrasound at a frequency of 20 Mhz, and/or controlled to receive the reflected echoes.

In some embodiments of the inventions, two or more elements are controlled to act as a phased array, for example, to direct the ultrasound beam and/or increase the intensity of the ultrasound beam at one or more locations.

Multiregional Transducer

FIG. **10** is an illustration of an exemplary design of a multiregional transducer **1000** to perform two or more functions, for example, acoustic feedback (e.g., imaging) and/or treatment, in accordance with some embodiments of the invention.

In some embodiments of the invention, element **1002** comprises two or more regions, for example, one or more regions **1004** for producing ultrasound energy for treatment and/or one or more regions **1006** for producing ultrasound energy for imaging. In some embodiments, one or more imaging regions **1006** receive returning ultrasound echoes. Optionally, the echoes are processed (e.g., by a controller) to provide imaging data, such as of target tissues.

In some embodiments of the invention, element **102** is positioned over at least some area of a board **1020**.

In some embodiments, regions **1004** and/or **1006** are separated by an inert region **1014**, for example, a region of element **1002** that does not have a voltage applied across (e.g., one or zero electrodes across the inert region).

In some embodiments, electrodes at least on one side of regions with the same function (e.g., treatment regions **1004** and/or imaging regions **1006**) are electrically coupled to function at substantially the same time under the same control, for example, electrodes **1008** and/or **1010** of treatment regions **1004** are electrically coupled. Optionally, regions with different functions (e.g., **1004** and/or **1006**) share a common electrode **1012** on an opposite side (e.g., sides **1016** and/or **1026**).

In some embodiments, region **1004** is designed for treatment (e.g., damage to tissue by heat), for example, by producing relatively higher intensity ultrasound energy. Optionally, the thickness of region **1004** is related to the expected frequency of the produced ultrasound energy, for example, 200 micrometers for 10 Mhz. Alternatively or additionally, side **1016** of region **1004** is coupled to at least one bubble **1018**. Alternatively or additionally, region **1004** is suspended over board **1020**, for example, by materials **1022** (e.g., glue, solder, copper).

In some embodiments, two or more regions (e.g., at two or more different location) configured for treatment are designed to operate at two or more different frequencies, for example, region **1004** on the left side of FIG. **10** can be designed to treat at 10 Mhz, and/or region **1004** on the right side of FIG. **10** can be designed to treat at 20 Mhz. Alternatively or additionally, two or more regions are electrified separately (e.g., have separate electrodes), for example, region **1004** on the left at a sinusoidal pattern of 10 Mhz and/or region on the right at 20 Mhz.

In an exemplary embodiment of the invention, two or more regions have different resonance frequencies. Alternatively, at least some of the resonance frequencies are the same.

In some embodiments of the inventions, two or more regions are controlled to act as a phased array, for example, to direct the ultrasound beam and/or increase the intensity of the ultrasound beam at one or more locations.

In some embodiments, region **1006** is designed for acoustic feedback (e.g., imaging), for example, for producing ultrasound energy and/or receiving the returning echo. Optionally, the thickness of region **1006** is related to the expected frequency of the produced ultrasound energy, for example, 100 micrometers for 20 Mhz. Alternatively or additionally, at least some area of side **1026** of region **1006** is coupled to at least some volume and/or area of a depression **1024** in board **1020**, optionally containing a damping material such as tungsten.

In some embodiments of the invention, the ultrasound beam produced by imaging regions **1004** and the ultrasound beam produced by treatment region **1006** substantially overlap.

A potential advantage of transducer **1000** is the ability to perform imaging and/or treatment without having to reposition and/or reorient transducer **1000**.

Cover

FIGS. **11**A-C illustrate a canopy and/or cover for the transducer, in accordance with some embodiments of the invention.

FIG. **11**A illustrates a canopy **1100** for the transducer that provides for an external fluid **1102** (e.g., blood) to circulate between element **102** and canopy **1100**, in accordance with some embodiments of the invention. Optionally, external fluid **1102** enters through one or more apertures **1104** in canopy **1100** and exits through one or more apertures **1106** in canopy **1100**. In some embodiments, canopy **1100** is permeable to ultrasound energy, for example, made out of polyester, polyimides, polyolefins, latex, PeBax, nylon, silicon, PTFE. Optionally, canopy **1100** does not affect the ultrasound beam (e.g., direction, spread). Alternatively, canopy **1100** is shaped and/or designed to affect the ultrasound beam, for example, diverge the beam and/or filter the beam (e.g., the first harmonic), such as a lattice made out of metal having a spacing of about half a wavelength of the ultrasound beam that will affect the target tissue.

FIG. **11**B illustrates a canopy **1110** for the transducer that isolates transducer from an external fluid **1102** (e.g., blood), in accordance with some embodiments of the invention. Optionally, canopy **1110** is a balloon, for example, made out of a material such as latex, PeBax, nylon, silicon, PTFE. In some embodiments, an internal fluid **1112** (e.g., saline, water, radio-opaque dye) occupies the volume between element **102** and canopy **1100**. Optionally, fluid **1112** circulates between element **102** and canopy **1100**, for example, from an inlet port **1114** to an outlet port **1116**.

A potential advantage of canopy **1100** and/or **1110** is to provide for fluid **1102** and/or **1112** to circulate in order to remove heat generated by element **102** during function (e.g., vibration). Another potential advantage is to protect the transducer and/or element **102** from mechanical damage, for example, inadvertent contact with foreign objects. Another potential advantage is to reduce and/or prevent the formation of thrombus on the surface of transducer, for example, if the circulating fluid **1112** is not blood.

FIG. **11**C illustrates the use of an embodiment of the transducer, for example as shown in FIG. **11**B, as part of a catheter **1124** and/or endoscope, to treat tissues **1122** in body orifices and/or cavities that do not naturally contain a sufficient amount of an in-situ fluid that can bridge a distance between element **102** and tissues, for example, stomach **1120**. The ultrasound beam **1126** produced by element **102** travels through fluid **1112**, then through canopy **1110** into the tissues lining stomach **1120** to reach target tissue **1122**.

In some embodiments, the transducer as shown in FIG. **11**C is used to treat tissues from outside of the body, for example, through the skin and/or through an incision in the skin.

In some embodiments, the cover is used to focus the ultrasound beam, for example, to treat a target tissue.

Exemplary Element Shapes

FIG. **12**A is a front view, and FIG. **12**B is a cross sectional view (e.g., along the long axis) of a transducer **1800** with an annular and/or ring cross section (e.g., element **1802**, bubble **1860** and/or board **1804** have an annular and/or ring cross section), in accordance with some embodiments of the inven-

tion. Alternatively, transducer **1800** (e.g., element **1802**, bubble **1860** and/or board **1804**) is semi-annular and/or arc shaped, for example, having an arc length of less than 360 degrees. Optionally, transducer **1800** contains a lumen **1808**. In some embodiments, element **1802** is suspended above board **1804**, for example, through a coupling material **1810** (e.g., glue, solder, copper). A potential advantage is treatment of a cross sectional area and/or volume of tissue around a blood vessel.

FIG. **12**C is a cross sectional view of a transducer with an element **1820** for focusing an ultrasound beam **1826** at a focal point **1828**. Optionally, element **1820** has a concave cross section, for example, a slice from a cylinder. Alternatively, element **1820** is concave in shape, for example, a plane sliced from a sphere. In some embodiments the concave shape is selected for a desired focal length. A potential advantage is obtaining relatively high intensity of ultrasound energy at the focal point.

Catheter—Exemplary Design

Referring back to FIG. **1**, in an exemplary embodiment of the invention, catheter **1222** is small enough to fit into blood vessels for treatment. Exemplary non-limiting sizes of catheter **1222** are 5 French, 7 French, 9 French, 11 French, 15 French, 21 French, or other smaller, intermediate or larger sizes.

In an exemplary embodiment of the invention, non-limiting examples of the size of the acoustic element are about 6 mm (length)×about 1 mm (width)×about 0.2 mm (thickness). Optionally, the length and/or width of the board are relatively larger than those of the element, non-limiting examples of dimensions include, about 10.5 mm (length)×about 1.5 mm (width)×about 0.15 mm (thickness). Optionally or additionally, the width of the housing is relatively similar to that of the element, in some embodiments, the length is slightly shorter, non-limiting examples of dimensions include, about 8.5 mm (length)×about 1.5 mm (width)×about 0.5 mm (thickness). The described dimensions are non-limiting, and other smaller, intermediate or larger sizes can be used.

In an exemplary embodiment of the invention, catheter **1222** comprises one or more lumens containing, for example, one or more of, wires (e.g., twisted pair, such as to measure the temperature using sensor **308**), cables (e.g., coaxial cable, such as for delivering electrical power to electrodes **302** and/or **304**), cooling elements, tubes for transporting fluid (e.g., saline, coolant, radioopaque dye), guidewire, positioning devices.

FIG. **13** illustrates an exemplary design of catheter **1222** for guiding transducer **300** into an anatomical body site for medical treatment. Catheter **1222** is shown inside a branch vessel **2108** (e.g., renal, carotid, subclavian) off a main vessel **2106** (e.g., aorta).

In an exemplary embodiment of the invention, catheter **1222** has a relatively small diameter of about 6 Fr, or about 4 Fr, about 8 Fr, or other smaller, intermediate or larger sizes are used.

In some embodiments, an end of catheter **1222** comprising transducer **300** is referred to as 'proximal', an end of catheter **1222** that remains outside the body is referred to as 'distal'.

In an exemplary embodiment of the invention, a catheter shaft **2102** is designed to transmit rotation torque from a rotation controller **2104** to transducer **300**, in about a one to one ratio through torturous anatomy (e.g., blood vessel), while reducing and/or preventing kinks. Optionally, a stiff portion **2110** of shaft **2102** is made out of a material sufficiently stiff to transmit torque in an approximately 1:1 ratio, such as a Braided shaft, made of materials such as nitinol, stainless steel and/or Helical Hollow Strand (HSS) available from Fort Wayne Metals and/or Hypotube with laser cutting available from Johnson Matthey Medical and/or polytetrafluoroethylene, nylon, polyurethane, PET, PEEK, ECTFE, ETFE. Optionally, stiff portion is the length of shaft **2102** (e.g., as will be described below) minus the length of catheter tip **2118** (e.g., as will be described below).

In an exemplary embodiment of the invention, catheter tip **2118** of shaft **2102** (e.g., including transducer **300**) is made out of a flexible material, for example, one or more materials including, Hypotube with laser cutting available from Johnson Matthey Medical, polytetrafluoroethylene, Nylon, polyurethane, Pebax, Tetrafluoroethylene, Hexafluoropropylene, Vinylidene Fluoride. Optionally, the length of tip **2118** is relatively short, for example, 1 cm, 2 cm, 5 cm, 10 cm, or other smaller, intermediate or larger lengths are used. A potential advantage of a relatively short and/or soft tip **2118** is reducing and/or preventing mechanical damage to the walls of blood vessels as catheter **1222** is moved axially forward and/or rotated. Another potential advantage is the ability to position tip **2118**, for example, away from the wall of the blood vessel.

In some embodiments, a central portion **2140** is a continuation of stiff portion **2110**. Alternatively, portion **2102** is a continuation of tip **2118**. Alternatively, central portion **2140** is designed according to the expected anatomical structure associated with the procedure, for example, having a stiffness other than portion **2110** and/or tip **2118**.

In an exemplary embodiment of the invention, a length of catheter **1222**, is approximately the length required to reach the treatment site using intravascular routes, for example, 65 cm, 100 cm, 120 cm, 150 cm, or other smaller, intermediate and/or larger lengths. A potential advantage is to reduce the loss of torque and/or to provide for relatively higher shaft **2102** flexibility.

In an exemplary embodiment of the invention, radioopaque markers **2112**, located for example on tip **2118**, assist in orienting and/or positioning under fluoroscopic guidance. Optionally, markers **2112** are flat. Optionally, markers **2112** show direction, for example, by being arrow shaped. Alternatively or additionally, markers **2112** show degree of rotation, for example, by comparing the angle of the image appearing on x-ray to a 45 (forty-five) degree angle marker **2112**.

In an exemplary embodiment of the invention, axial movement markers **2114** indicate the amount of forward and/or reverse motion of catheter **1222**. Optionally, markers **2114** are located on a portion of catheter shaft **2102** located outside the body. Alternatively or additionally, markers **2116** are radio-opaque and/or located on tip **2118**, for example relatively close to transducer **300**, to be visible on fluoroscopic images.

In some embodiments of the invention, the degree of rotation of catheter **1222** (e.g. along the long axis) is shown on controller **2104** by markers **2130**.

In some embodiments of the invention, catheter **1222** is directed into position inside an outer sheath **2122**. Optionally, sheath **2122** is made out of a material with relatively low friction against catheter **1222**, for example, polytetrafluoroethylene (PTFE), polyethylene, polyurethane.

In some embodiments of the invention, catheter **1222** is steerable, even without the guide wire.

In some embodiments of the invention, catheter **1222** is passed through an 8 Fr "hockey-stick" guide catheter. Optionally, other sizes for the guide catheter are available, relative to the size of catheter **1222**, for example, about 6 Fr, about 10 Fr, or other smaller, intermediate or larger sizes.

Potential advantages of catheter **1222** include one or more of, precise and/or easy torque following, simple treatment

beam directivity feedback and/or control from standard angiographic equipment (e.g 0, 90, 180, 270 degrees), no need for high operator skills, and/or ability to use contrast agents during treatment.

In some embodiments of the invention, catheter **1222** includes one or more elements to move transducer **300**. Optionally, the element is a piezoelectric element that can be vibrated by applying electrical power. Alternatively or additionally, the element moves transducer **300** for relatively fine positioning, for example, an electrically controlled motor. In some embodiments, the element vibrates and/or moves transducer **300** to position the strongest part of the ultrasound beam at the target tissue.

In some embodiments the controller can be calibrated according to the expected intensity profile of the produced ultrasound beam, for example, the controller vibrates and/or moves transducer **300** in order to obtain a desired position for thermally affecting the tissues.

Catheter—Exemplary Positions of Transducer

FIG. **14**A illustrates one or more possible positions of the transducer on catheter **1222**, in accordance with some embodiments of the invention. Optionally, a transducer **300** is positioned at the side of catheter **1222** (e.g., inside a window), for example, as described with reference to FIG. **1**. Alternatively or additionally, transducer **1404**, for example, as illustrated in FIG. **14**B, is positioned at the front of catheter **1222**. Alternatively or additionally, a transducer **1408** is placed on an angle, for example, using an angled housing. Alternatively or additionally, an annular or semi-annular transducer **1406**, for example, as described with reference to FIGS. **12**A-B, is positioned on catheter **1222**. Alternatively or additionally, a multielement transducer **1410**, for example as described with reference to FIGS. **9**A-**9**D, is positioned on catheter **1222**.

There are one or more potential advantages associated with one or more positions of transducer system **300** on catheter **1222**. For example, the side position can be easier to orient, control and/or position to target tissues at the periphery of the blood vessel, such as tissues located in the adventitia. For example, the front position may be useful for treating a branch point, where a single vessel splits into two. Another advantage is to send an ultrasound beam towards an object inside the lumen of a vessel (eg. thrombus). For example, the angular position can be used to target tissues located in areas difficult to target with the side and/or front orientations.

FIG. **14**B illustrates a forward facing transducer **1404**, in accordance with some embodiments of the invention. Optionally, a reflector **1422** reflects a beam **1420** produced by element **102**. Optionally, an angle of reflection **1424** is controllable and/or adjustable (e.g., manually by user, automatically by controller), for example, by adjusting an angle **1426** of reflector **1422**. Alternatively, the angle **1424** is preset during manufacturing. A potential advantage is the ability to treat tissue volumes without repositioning the catheter. Another potential advantage is the reduction and/or prevention of the risk of element **102** contacting the vessel wall.

In an exemplary embodiment of the invention, catheter **1222** should not be positioned against the vessel wall, unless element **102** is cooled, for example, using a cooling system as described in the section "CATHETER-OPTIONAL COOLING SYSTEM".

Catheter—Optional Cooling System

Referring back to FIG. **1**, a cooling system thermally coupled to element **102** comprises a temperature sensing element, such as sensor **308**, to measure and/or estimate the temperature of element **102**, and/or a cooling element (e.g., as will be described below) to control and/or maintain the temperature of element **102** (e.g., below a threshold), in accordance with an exemplary embodiment of the invention. One or more examples of sensor **308** include thermocouple, fiber optic temperature sensor, temperature sensing diode, resistance thermometers.

In an exemplary embodiment of the invention, the temperature of element **102** (e.g., as estimated by sensor **308**) is controlled to be below about 50 degrees Celsius, about 47 degrees Celsius, about 45 degrees Celsius, about 42 degrees Celsius, about 37 degrees Celsius, or other smaller, intermediate or larger thresholds are used.

Without being bound to theory, in accordance with an exemplary embodiment of the invention, a 6 mm long×1 mm wide transducer emitting ultrasound energy at an intensity of 100 Watts/square centimeter, generates about 11-24 Watts of excess heat (variation according to efficiency of operation) for removal. The amount of heat generated varies linearly with the size of the element and/or the intensity of emitted ultrasound energy.

In an exemplary embodiment of the invention, one or more sensors **308** are located, for example, downstream (e.g., according to the direction of flow **1220** of a liquid such a blood) relative to element **102**. In an exemplary embodiment of the invention, sensor **308** measures the temperature of blood that has flowed **1220** over a surface **1224** of element **102**. In an exemplary embodiment of the invention, the temperature of the blood that has flowed **1220** over surface **1224** is used as an estimate of the temperature of element **102**.

In some embodiments, a liquid channel **1206** delivers a relatively cold liquid (e.g., saline, radio-opaque dye) to remove excess heat, for example, by causing the liquid to flow over surface **1224** of element **102**. Optionally, the volume and/or frequency (e.g., pattern) of the liquid released (e.g., manually by a user, automatically by a controller) is estimated according to feedback of the temperature of element **102**. Optionally, sensor **308** measures the temperature of the liquid after it has flowed over surface **1224**.

In some embodiments, a heat conductor **1208** removes heat from element **102**, inside catheter **1222**. Optionally, heat conductor **1208** circulates a relatively cold fluid (e.g., saline, dye) towards element **102** to remove excess heat that is then transferred away from element **102** by the circulating fluid (e.g., direction arrows of system **1208**).

As illustrated in FIG. **15**A, in some embodiments of the invention, a thermoelectric cooler **2010** (e.g., electrified by wires **2014**) thermally coupled to element **102**, is used to relatively increase the rate and/or amount of heat removed from element **102**. Optionally, cooler **2010** acts as a housing.

In some embodiments of the invention, cooler **2010** is thermally coupled to a heat sink, for example, comprising one or more braids **2012** of catheter **1222** shaft. Optionally, braids **2012** are made out of a thermally conductive material, such as metal (e.g., silver, gold, nickel, steel, copper, platinum). Optionally, braids **2012** are thermally coupled to blood flowing **1220** on the surface of catheter **1222**. A potential advantage of braids **2012** is the ability to spread heat from element **102** onto a relatively large surface area of catheter **1222**, where it can be transferred to blood and/or other fluids (e.g., saline, urine, water, angiography contrast fluids, cerebrospinal fluid, lymph, mucous, stomach acid).

As illustrated in FIG. **15**B, in some embodiments of the invention, one or more flow channels **1550** (e.g., grooves and/or indentations) formed at the surface of catheter **1222** direct flow of a fluid (e.g., blood) over the treatment surface **1224** and/or side **132** of element **102**, for example, to transfer heat from element **102** to the fluid.

FIG. **15**C illustrates a design for a flow controller **2000** to control (e.g., increase and/or decrease) flow **1220** of a fluid

(e.g., blood) over element **102**, for example, to cool element **102** by increasing the rate of heat transfer to the blood, in accordance with some embodiments of the invention. In some embodiments, flow controller **2000** is manually controlled by a user and/or automatically controller by a controller.

In some embodiments of the invention, flow controller **2000** comprises a gate (e.g., flap) **2002** to control blood flow **1220** over element **102**, for example, by increasing and/or decreasing the cross sectional area of gate **2002** through which blood can flow **1220**. Alternatively or additionally, controller **2000** controls blood flow **1220** by increasing and/or decreasing the cross sectional area of vessel **2004**, for example, by inflating and/or deflating a balloon.

Another potential advantage of increasing and/or forming flow **1220** of a fluid (e.g., blood, saline) over element **102** is to reduce and/or prevent the formation of thrombus on element **102**.

Kit

In some embodiments of the invention, catheters **1222** are sold as a kit, for example, there are multiple catheters **1222** to choose from for the treatment procedure. Optionally, the kit contains catheters **1222** having elements **102** designed for different treatment frequencies, for example, 10 Mhz, 20 Mhz, or other smaller, intermediate or larger frequencies. Optionally or additionally, catheters **1222** have different lengths for different anatomical treatment positions, for example, 55 cm to reach the renal artery, 95 cm to reach the carotid artery. Optionally or additionally, catheters **1222** are designed for specific anatomical treatment locations, for example, having elements **102** located at different positions on catheter **1222** such as to treat renal nerves at the renal artery ostium. Optionally or additionally, some catheters **1222** have elements **102** that can perform imaging functions.

Exemplary Control System

FIG. **16** illustrates an ultrasound treatment system **1600**, in accordance with an exemplary embodiment of the invention. System **1600** provides for the control of the ultrasound treatment and/or monitoring of the treatment using catheter **1222**.

In an exemplary embodiment of the invention, an operator (e.g., physician performing the procedure) programs a controller **1602** (e.g., computer) for treatment using a user interface **1604** (e.g., keyboard, mouse, monitor). Optionally, treatment is monitored, for example, by viewing feedback parameters on interface **1604**.

In an exemplary embodiment of the invention, one or more functions and/or parameters and/or settings are programmed and/or set into controller **1602**, for example:

- Frequency of the ultrasound energy produced by vibration of element **102**, for example, by a sinusoidal wave form.
- Intensity is the produced ultrasound energy divided by the surface area of element **102**.
- Impedance of element **102**.
- Pulse duration is the length of a pulse measured in time.
- Duty cycle is the percentage of time in a pulse that ultrasound energy is transmitted.
- Duration of treatment is the time during which US energy is being delivered.
- Acoustic feedback is feedback obtained by analyzing returning ultrasound signals, for example, the voltage across element **102** as a function of time.
- Flow rate is the estimated (e.g., average) rate of flow of fluid (e.g., blood) across the surface of element **102** and/or the wall of the treatment target (e.g., blood vessel).
- Efficiency is the estimated efficiency of converting electrical energy into ultrasound energy by element **102**.
- Temperature of operation is the approximate temperature of element **102** and/or the liquid (e.g., blood, saline) that should not be exceeded.
- Cooling system cools element **102** to the temperature of operation. Optionally, cooling system is used in combination with blood flow.
- Impulse excitation is the application of an impulse function (e.g., delta function) to element **102**, causing element **102** to vibrate with a decreasing amplitude. In some embodiments of the invention, the integrity of system **300** is verified and/or checked by applying an impulse function (eg. delta function) to element **102**, resulting in a voltage pattern across element **102** (eg. vibration and/or ringing pattern) over time. Optionally, the voltage pattern is used to estimate the reduction in efficiency of element **102**, for example, by using a calibration look-up table, by performing calculations. The reduction in efficiency can be a result of, for example, one or more of, foreign material on surface of element **102** (eg. thrombus), element **102** contacting the vessel wall, mechanical damage to element **102**.
- Navigation system controls the movement and/or positioning and/or orientation of catheter **1222** and/or transducer **300**.
- Treatment pattern is the combination of one or more of the above variables.
- Pressure is the pressure of the liquid (e.g., blood) during treatment and/or imaging.
- Electric power is the applied power to the transducer.
- Reflected electric power from the transducer back to the controller.
- Voltage is the measured and/or applied voltage on the transducer.
- Current is the measured and/or applied current in the transducer.

| Parameter | Theoretical range | Exemplary Treatment range | Exemplary Treatment sub range |
|---|---|---|---|
| Frequency (MHz): | | | |
| Treatment | 1-60 | 8-30 | 10-22 |
| Imaging | 1-60 | 10-60 | 10-25 |
| Intensity (Watts/sq cm) | 1-200 | 10-100 | 10-60 |
| Duty cycle (%) | 0.1-100 | 10-100 | 50-100 |
| Pulse duration (seconds) | 0.01-1000 | 0.1-4 | 0.1-2 |
| Duration of treatment (Seconds) per location | 0.1-1000 | 2-120 | 3-60 |
| Efficiency (%) | 1-70% | 20-70% | 35-70% |
| Temperature (Celsius) | 10-100 | 15-80 | 25-80 |

In an exemplary embodiment of the invention, controller **1602** produces an electrification waveform that is sinusoidal according to the set "Frequency" with an amplitude associated with the set "Intensity".

In an exemplary embodiment of the invention, controller **1602** monitors and/or maintains one or more set parameters, according to one or more adjustable parameters. Optionally, controller **1602** adjusts one or more parameters, for example, according to changes (e.g., increase and/or decrease of 10%) between the current measurement and/or one or more previous measurements. Controller **1602** automatically selects one or more parameters to adjust, for example, according to one or more of, a look-up table (e.g., stored in a memory), calculations, using feedback (e.g., slowly changing a parameter and/or monitoring expected changes).

In an exemplary embodiment of the invention, power unit **1606** provides voltage and/or current (e.g., alternating and/or oscillating) to electrodes **302** and/or **304**, causing element **102** to vibrate (e.g., expand and/or contract) at the set frequency, outputting a set power intensity.

Potential Advantages

The following are some potential advantages, in accordance with an exemplary embodiment of the invention:

Miniature and/or thin ultrasonic transducer that can generate a relatively high intensity ultrasonic output continuously at a relatively high frequency.

Relatively high efficiency ultrasonic transducer structure.

Manufacturing of ultrasonic transducer structure (e.g., board) uses common microelectronic manufacturing processes, that provide for miniaturization with a relatively high accuracy and/or repeatability.

General

It is expected that during the life of a patent maturing from this application many relevant ultrasound transducers will be developed and the scope of the term transducer is intended to include all such new technologies a priori.

As used herein the term "about" refers to ±10%

The terms "comprises", "comprising", "includes", "including", "having" and their conjugates mean "including but not limited to".

The term "consisting of" means "including and limited to".

The term "consisting essentially of" means that the composition, method or structure may include additional ingredients, steps and/or parts, but only if the additional ingredients, steps and/or parts do not materially alter the basic and novel characteristics of the claimed composition, method or structure.

As used herein, the singular form "a", "an" and "the" include plural references unless the context clearly dictates otherwise. For example, the term "a compound" or "at least one compound" may include a plurality of compounds, including mixtures thereof.

Throughout this application, various embodiments of this invention may be presented in a range format. It should be understood that the description in range format is merely for convenience and brevity and should not be construed as an inflexible limitation on the scope of the invention. Accordingly, the description of a range should be considered to have specifically disclosed all the possible subranges as well as individual numerical values within that range. For example, description of a range such as from 1 to 6 should be considered to have specifically disclosed subranges such as from 1 to 3, from 1 to 4, from 1 to 5, from 2 to 4, from 2 to 6, from 3 to 6 etc., as well as individual numbers within that range, for example, 1, 2, 3, 4, 5, and 6. This applies regardless of the breadth of the range.

Whenever a numerical range is indicated herein, it is meant to include any cited numeral (fractional or integral) within the indicated range. The phrases "ranging/ranges between" a first indicate number and a second indicate number and "ranging/ranges from" a first indicate number "to" a second indicate number are used herein interchangeably and are meant to include the first and second indicated numbers and all the fractional and integral numerals therebetween.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable subcombination or as suitable in any other described embodiment of the invention. Certain features described in the context of various embodiments are not to be considered essential features of those embodiments, unless the embodiment is inoperative without those elements.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims.

All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention. To the extent that section headings are used, they should not be construed as necessarily limiting.

What is claimed is:

**1**. A catheter for medical therapy comprising:

a distal end; and

a proximal end adapted to be inserted into the body, comprising:

an ultrasound transducer positionable within a blood vessel;

a separation element configured to distance said ultrasound transducer at least a minimal distance away from a wall of said blood vessel, said minimal distance sufficient to allow blood to flow between said transducer and said wall;

said ultrasound transducer comprising:

an acoustic element for delivering ultrasound energy at an intensity sufficient for medical therapy; and

a temperature sensor mounted on said transducer and positioned adjacent said acoustic element, said temperature sensor positioned to contact blood flowing over a surface of said acoustic element to provide an indication of a temperature of said blood when said transducer and said temperature sensor that is mounted on it are distanced away from a wall of said blood vessel by said separation element;

wherein said catheter is connected to circuitry configured to apply electrical power to said transducer; said circuitry further configured to modify said applied electrical power according to said indication obtained from said temperature sensor.

**2**. A catheter according to claim **1**, wherein said temperature sensor is positioned downstream from said acoustic element.

**3**. A catheter according to claim **2**, wherein said circuitry is configured for estimating a temperature of said acoustic element using said indication of temperature of said blood.

**4**. A catheter according to claim **1**, wherein said circuitry is configured to maintain a temperature of said acoustic element under about 50 degrees Celsius while said transducer is used for medical therapy.

**5**. A catheter according to claim **1**, wherein said catheter further comprises a cooler operative to reduce a temperature of said acoustic element when said transducer is positioned within a blood vessel.

**6**. A catheter according to claim **5**, wherein said cooler comprises cold fluid that is aimed at said acoustic element to reduce a temperature of said acoustic element.

**7**. A catheter according to claim **6**, wherein said cold fluid is blood cooled by said cooler.

8. A catheter according to claim 6, wherein said cold fluid is one of saline and dye.

9. A catheter according to claim 1, wherein said temperature sensor is connected via a twisted pair of wires to at least one of a board onto which the acoustic element is mounted and a housing of said element.

10. A catheter according to claim 1, wherein said sensor is a thermocouple.

11. A catheter according to claim 1, comprising a plurality of temperature sensors.

12. A catheter according to claim 1, wherein said minimal distance is at least 1 mm.

13. The catheter according to claim 1, wherein said transducer is coated at least in part by a thin coating.

14. The catheter according to claim 1, wherein said separation element extends radially away from a shaft of said catheter.

15. A method for removing excess heat from an acoustic element of a catheter for medical therapy, comprising

positioning said catheter in a blood vessel such that said acoustic element is distanced away from a wall of said blood vessel, such that blood is allowed to flow between said acoustic element and said wall;

estimating a temperature of said acoustic element by measuring, via a temperature sensor positioned adjacent said acoustic element, a temperature of said blood after blood flows passed said surface; and

controlling activation of said acoustic element according to said blood temperature.

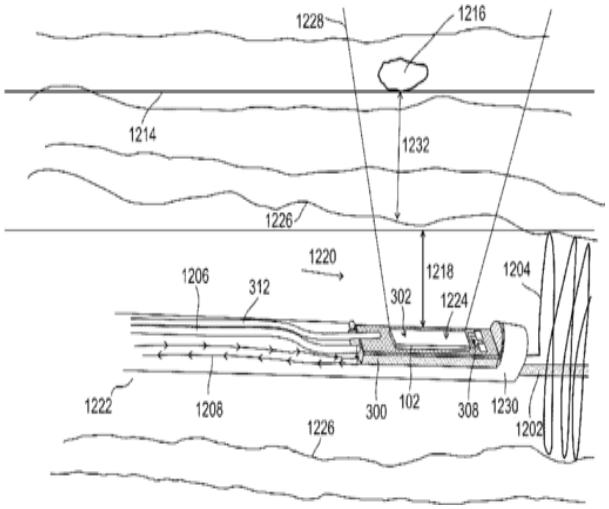
16. The method according to claim 15, further comprising delivering a liquid to flow over said acoustic element.

17. A method according to claim 16, wherein said liquid is one of saline and dye.

18. A method according to claim 16, wherein said liquid is colder than blood.

* * * * *

| | | | |
|---|---|---|---|
| 专利名称(译) | 超声换能器 | | |
| 公开(公告)号 | US9326786 | 公开(公告)日 | 2016-05-03 |
| 申请号 | US14/049238 | 申请日 | 2013-10-09 |
| 申请(专利权)人(译) | CARDIOSONIC LTD. | | |
| 当前申请(专利权)人(译) | CARDIOSONIC LTD. | | |
| [标]发明人 | SVERDLIK ARIEL<br>SHABTAY OR | | |
| 发明人 | SVERDLIK, ARIEL<br>SHABTAY, OR | | |
| IPC分类号 | A61B8/14 A61M37/00 A61B17/22 A61B17/32 A61N7/02 A61N7/00 A61B17/00 | | |
| CPC分类号 | A61B17/320068 A61B17/2202 A61M37/0092 A61N7/02 A61N7/022 A61B2017/00106 A61B2017/22008 A61B2017/22051 A61B2017/22081 A61B2090/378 A61N2007/0078 | | |
| 优先权 | 61/393947 2010-10-18 US | | |
| 其他公开文献 | US20140039477A1 | | |
| 外部链接 | Espacenet USPTO | | |


摘要(译)

根据本发明的示例性实施例，提供了一种用于体内医学治疗的超声换能器，包括：适于传输超声能量的元件;至少两个电极，被配置为在元件的至少一些体积上施加电压;气泡容纳区域适于在血液中保持气泡。