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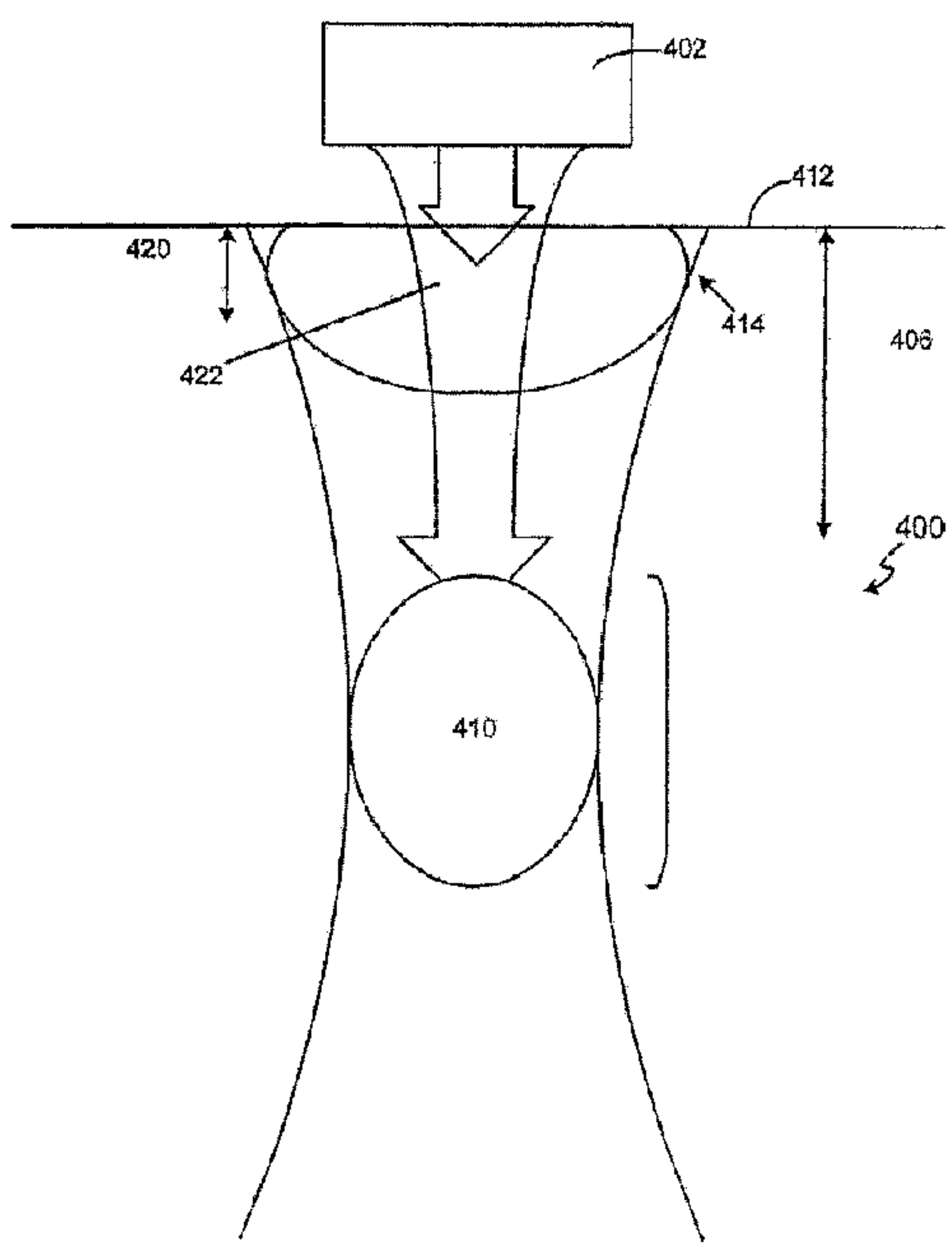
(54) **Titre :** SYSTEME ET PROCEDE DE TRAITEMENT PAR ULTRASONS A PROFONDEUR VARIABLE
(54) **Title:** SYSTEM AND METHOD FOR VARIABLE DEPTH ULTRASOUND TREATMENT



(57) **Abrégé/Abstract:**
A non-invasive variable depth ultrasound treatment method and system comprises a variable depth transducer system configured for providing ultrasound treatment to a patient. An exemplary variable depth transducer system can comprise a transducer configured to provide treatment to more than one region of interest, such as between a deep treatment region of interest and a superficial region of interest, and/or a subcutaneous region of interest. The variable depth transducer can comprise a transduction element having a piezoelectrically active layer, matching layers and/or other materials for generating radiation or acoustical energy. The variable depth transducer may be configured to operate at moderate frequencies within the range from approximately 750 kHz to 20 MHz or more. In addition, the transduction element may be configured with a variable depth device comprising one or more materials configured to allow for control and focusing/defocusing of the acoustic energy to more than one region of interest.

ABSTRACT

A non-invasive variable depth ultrasound treatment method and system comprises a variable depth transducer system configured for providing ultrasound treatment to a patient. An exemplary variable depth transducer system can comprise a transducer configured to provide treatment to more than one region of interest, such as between a deep treatment region of interest and a superficial region of interest, and/or a subcutaneous region of interest. The variable depth transducer can comprise a transduction element having a piezoelectrically active layer, matching layers and/or other materials for generating radiation or acoustical energy. The variable depth transducer may be configured to operate at moderate frequencies within the range from approximately 750 kHz to 20 MHz or more. In addition, the transduction element may be configured with a variable depth device comprising one or more materials configured to allow for control and focusing/defocusing of the acoustic energy to more than one region of interest.

SYSTEM AND METHOD FOR VARIABLE DEPTH ULTRASOUND TREATMENT

Field of Invention

This invention generally relates to an ultrasound system, and more particularly, to a method and system for variable depth ultrasound treatment.

Background of the Invention

Many conventional applications of therapeutic ultrasound have employed low frequency transducers. These transducers have operational frequencies that typically range from 500 kHz to 1.5 MHz. Such low frequency transducers are often preferred because they allow for acoustical energy to be focused deep into the body, without harming the overlying tissue structures.

A conventional application of non-invasive therapeutic ultrasound using a low frequency transducer is depicted in Fig. 1. A conventional therapeutic system 100 comprises a transducer 102 that uses low frequency energy to treat a deep treatment region 110. Deep treatment region 110 is located at a deep depth 106 below a superficial region 112, e.g., tissue layers and structures, and a subcutaneous region 114 of a patient. Deep depth 106 may range from several millimeters to 5-7 centimeters or more. Conventional system 100 cannot treat superficial regions 112 or subcutaneous regions 114 through use of low-frequency transducer 102, thus limiting the applications of such systems. For example, some cosmetic surgeries may also need to provide treatment to superficial and/or subcutaneous, as well as deep treatment regions, thus eliminating the use of lower frequency transducers.

Another undesirable side effect of low-frequency therapy is that the acoustic energy must pass through intervening tissue layers before reaching the desired deep treatment area. The intervening layers tend to defocus the rays and absorb some of the acoustic energy. This causes the focal spot size to widen, making it difficult to control the location of the focal spot.

Summary of the Invention

In accordance with various aspects of the present invention, a variable depth ultrasound treatment method and system are provided. An exemplary method and system comprise a variable depth transducer system configured for providing ultrasound treatment to more than one region of interest, such as between at least two of a deep treatment region of interest, a superficial region of interest, and/or a subcutaneous region of interest.

In accordance with various exemplary embodiments, a variable depth transducer system can be configured for spatial control, such as by changing the distance from an exemplary transducer to a reflecting surface, or changing the angles of energy focused or unfocused to the region of interest, and/or configured for temporal control, such as by controlling changes in the frequency, drive amplitude and timing of the exemplary transducer. As a result, changes in the location of the treatment region, the shape and size and/or volume of the spot or region of interest, as well as the thermal conditions, can be dynamically controlled versus time.

In accordance with an exemplary embodiment of the present invention, the variable depth transducer can comprise a transduction element having a piezoelectrically active layer, matching layers and/or other materials for generating radiation or acoustical energy. The variable depth transducer may be configured to operate at moderate frequencies to provide variable depth treatment. For example, an exemplary variable depth transducer system can be configured for providing treatment to a superficial region of interest, and/or to a subcutaneous region of interest utilizing moderate frequencies below 20 MHz, such as within a range from approximately 750 kHz to 20 MHz, or higher frequencies of 35 MHz or more.

In accordance with another exemplary embodiment of the present invention, the transduction element may be configured with a variable depth element comprising one or more materials configured to allow for control and focusing/defocusing of the acoustic energy to more than one region of interest, such as between a deep treatment region of interest and a superficial region of interest, and/or a subcutaneous region of interest. The materials utilized for the variable depth element for control and focusing/defocusing may be configured in a variety of manners and shapes, such as substantially flat, curved, or other arrangements for bending, reflecting and/or redirecting radiation and acoustical energy. In addition, the variable depth element may be configured within, or comprise a device coupled to, the transduction element in a variety of manners to provide for focusing/defocusing and control of the treatment energy.

In accordance with another exemplary embodiment of the present invention, an exemplary transducer may be configured to enable energy deposition not only proximate a fundamental frequency of a piezoelectric material within the transduction element, but also at harmonic frequencies of the material, above a fundamental frequency, as well as resonances below a fundamental frequency. These multiple resonances may be controlled and enabled through various focusing techniques and transducer structures, including the adding of matching layers and/or backing layers to shape the resonant characteristics of the transducer.

In accordance with another exemplary embodiment of the present invention, a variable depth acoustic transducer can also be configured for generating high acoustic power for treatment purposes, while also providing for good imaging capabilities. For example, to allow for the treatment spot size to be optimally controlled at various treatment depths, an exemplary embodiment of the present invention may comprise a transducer configured into an array of sub-elements, each sub-element configured for processing acoustic waves with a sufficient bandwidth for good axial resolution.

In accordance with another exemplary embodiment of the present invention, a variable depth transducer may be configured in a probe arrangement to provide treatment. The variable depth transducer may also be configured with various mechanical devices to allow for optimal treatment and therapy, for example to provide controlled positioning of the variable depth transducer, such as through a non-invasive configuration. Further, the variable depth transducer may also be configured for one-dimensional two-dimensional and annular arrays, and/or for three-dimensional treatment applications.

In accordance with another aspect of the present invention, an exemplary variable depth treatment system and method may also be configured to provide therapeutic heating, cooling and/or imaging of a treatment region as well as acoustically monitoring the temperature profile or other tissue parameter monitoring of the treatment region and the general vicinity thereof. For example, in accordance with an exemplary embodiment, an exemplary variable depth system may be configured with a dynamic feedback arrangement based on monitoring of temperature or other tissue parameters, and/or based on imaging information to suitably adjust the spatial and/or temporal characteristics of the variable depth transducer.

Brief Description of the Drawings

The subject matter of the invention is particularly pointed out and distinctly claimed in the concluding portion of the specification. The invention, however, both as to organization and method of operation, may best be understood by reference to the following description taken in conjunction with the claims and the accompanying drawing figures, in which like parts may be referred to by like numerals:

Fig. 1 illustrates a diagram of treatment using a prior art ultrasound treatment system;

Fig. 2 illustrates a block diagram of an ultrasound treatment system in accordance with an exemplary embodiment of the present invention;

Fig. 3 illustrates a block diagram of a variable depth ultrasound treatment system in accordance with an exemplary embodiment of the present invention;

Fig. 4 illustrates a diagram of a variable depth ultrasound treatment system in accordance with an exemplary embodiment of the present invention;

Figs. 5A and 5B illustrate exemplary embodiments for variable depth ultrasound transducers for treatment in accordance with the present invention;

Fig. 6 illustrates another exemplary embodiment for a variable depth ultrasound transducer for treatment in accordance with the present invention;

Fig. 7 illustrates an exemplary embodiment for electronic focusing of a transducer in accordance with the present invention;

Fig. 8 illustrates an exemplary diagram of treatment characteristics of an exemplary transducer operating at the fundamental frequency and other frequencies and/or resonances above and below the fundamental in accordance with the present invention;

Fig. 9 illustrates an exemplary embodiment of a two-dimensional array in accordance with the present invention;

Fig. 10 illustrates an exemplary embodiment of a probe format for treatment in accordance with the present invention;

Fig. 11 illustrates an exemplary embodiment of a mechanism for treatment in accordance with the present invention;

Figs. 12A and 12B illustrate an exemplary embodiment of an annular array in accordance with the present invention;

Fig. 13 illustrates a cross-sectional view of an exemplary embodiment of a combined imaging/therapy and/or tissue parameter monitoring acoustic transducer assembly in accordance with the present invention; and

Figs. 14A-14C illustrates exemplary embodiments of an imaging, therapy and tissue parameter monitoring subsystems in accordance with the present invention.

Detailed Description

The present invention may be described herein in terms of various components and processing steps. It should be appreciated that such components and steps may be realized by any number of hardware components configured to perform the specified functions. For example, the present invention may employ various medical treatment devices, visual imaging and display devices, input terminals and the like, which may carry out a variety of functions under the control of one or more control systems or other control devices. In addition, the present invention may be practiced in any number of medical or treatment contexts and that the exemplary embodiments relating to a variable depth ultrasound treatment as described herein are merely a few of the exemplary applications for the invention. For example, the principles, features and methods discussed may be applied to any medical or other tissue or treatment application.

In accordance with various aspects of the present invention, a non-invasive variable depth ultrasound treatment method and system are provided. An exemplary method and system comprise a variable depth acoustic transducer system configured for providing ultrasound treatment to more than one region of interest in a patient. For example, with reference to an exemplary embodiment illustrated in a block diagram of Fig. 2, an exemplary system 200 for ultrasound treatment includes a variable depth transducer system 202 that provides treatment to a region of interest 210. Variable depth transducer system 202 may comprise a transducer 204 configured with a variable depth device 206. In providing treatment, variable depth ultrasound system 202 may provide therapy, imaging and/or temperature or other tissue parameter monitoring to region of interest 210. Region of interest 210 can comprise a deep treatment region, a superficial region, and/or a subcutaneous region of interest or any other region of interest located within a patient. To facilitate coupling of variable depth ultrasound system 202 to region of interest 210, variable depth ultrasound system 202 can further comprise a coupling system 208 configured for acoustic coupling of ultrasound energy and signals.

An exemplary variable depth transducer system 210 is further exemplified in a block diagram illustrated in Fig. 3. Variable depth transducer system 300 may comprise a control system 304, a transducer 302 a variable depth element 306 and a coupling system 308. Control system 304 is configured for control and operation of transducer 302 to provide treatment to more than one region of interest. Transducer 302 and variable depth device 306 are configured to provide variable depth ultrasound treatment to a treatment region.

Coupling system 308 is configured for coupling of transducer 302 and variable depth device 306 to a region of interest.

Control system 304 may be configured for use within an ultrasound therapy system, an ultrasound imaging system, and/or an ultrasound imaging, therapy and/or treatment monitoring system, including motion control subsystems. In accordance with an exemplary embodiment, a control system 304 may comprise a processor, a display, and/or one or more input devices. The processor may comprise a personal computer, a Unix system, or any other conventional processing unit. The display may comprise a monitor, LCD screen, or any other device configured to display an image. An input/output device may comprise a keyboard, a mouse, a touch-screen, or any other device for inputting information. The information from the input device and images displayed may be received or transmitted in any format, such as manually, by analog device, by digital device, and/or by any other mechanisms. The processor, display, and/or input device may be coupled together in any manner. By coupling, the devices comprising control system 304 may be directly connected to each other or may be connected through one or more other devices or components that allow a signal to travel to/from one component to another. The various coupling components for the devices comprising control system 304 can include but are not limited to the internet, a wireless network, a conventional wire cable, an optical cable or connection through any other medium that conducts signals, and any other coupling device or communication medium.

Coupling system 308 is configured for the coupling ultrasound energy and signals between transducer 302 and variable depth device 306 and a region of interest. Coupling system 308 may facilitate such coupling through use of various coupling mediums, including air and other gases, water and other fluids, gels, solids, and/or any combination thereof, or any other medium that allows for signals to be transmitted between transducer 302/variable depth device 306 and the region of interest. In addition to providing a coupling function, in accordance with an exemplary embodiment, coupling system 308 can also be configured for providing temperature control during the treatment application. For example, coupling system 308 can be configured for controlled cooling of an interface surface or region between transducer 302/variable depth device 306 and the region of interest by suitably controlling the temperature of the coupling medium. The suitable temperature for such coupling medium can be achieved in various manners, and utilize various feedback systems, such as thermocouples, thermistors or any other device or system configured for temperature measurement of a coupling medium. Such controlled cooling can be configured to further facilitate spatial control of variable depth transducer system 300.

Exemplary variable depth transducer 302 can be configured in various manners. For example, a variable depth transducer system can be configured for spatial control, such as by controlled changing of the distance from an exemplary transducer to a reflecting surface, or controlled changing of the angles of energy focused or unfocused to the region of interest, e.g., variable depth transducer 302 can be configured with variable depth element 306 comprising a frequency dependent lens configured for control of focal depth and position by changing the frequency of excitation of variable depth transducer 302. In addition, variable depth transducer 302 can also be configured for temporal control, such as by controlling changes in the frequency, drive amplitude and timing of the exemplary transducer. Thus, an exemplary variable depth transducer can be configured with spatial and/or temporal control. As a result, changes in the location of the treatment region, the shape and size and/or volume of the spot or region of interest, as well as the thermal conditions, can be dynamically controlled versus time.

Variable depth element 306 can be suitably coupled to transducer 302 to facilitate variable depth treatment. By coupling, transducer 302 may be directly and/or movably connected to variable depth device 306, or may be connected through one or more various components or elements that enable energy and/or signals to travel to/from one component to another. Transducer 302 and variable depth element 306 may also be combined into a single device, wherein variable depth device 306 is configured within transducer 302, e.g., as a part of a transduction element of transducer 302.

Variable depth element 306 is configured to enable variable depth treatment system 300 to provide treatment to more than one region of interest, such as between a deep treatment region of interest, a superficial region of interest, and/or a subcutaneous region of interest, or other regions in between. Such treatment can occur within a single region of interest, or within more than one region of interest, at the same time. For example, with momentary reference to Fig. 4, an exemplary embodiment of a variable depth treatment system 400 is shown. Variable depth treatment system 400 may be configured for operating within moderate frequencies ranging from approximately 750 kHz to 20 MHz or more. Variable depth treatment system 400 may be configured with a variable depth transducer system 402 comprising a transducer configured with a variable depth device. Variable depth transducer system 402 may be coupled to a control system for receiving and transmitting signals to/from a region of interest.

During operation, variable depth transducer system 402 may be configured to transmit or receive signals to treat a deep treatment region 410 located at deep depth 406 within a patient. For example, depth 406 for deep treatment region 410 may range from approximately 50 mm to 7 cm or more.

Variable depth transducer system 402 may also be configured to treat a second inner region 422 of a patient. Inner region 422 may comprise a superficial layer 412 of a patient and/or a subcutaneous layer 414 of patient. Inner region 422 is located at a shorter depth 420 within tissue layers of a patient. For example, depth 420 may range from approximately 0 mm to 5cm or more within a patient, wherein the 0 mm range comprises the outer surface of superficial layer 412 of the patient. In other words, superficial layer 412 of the patient may comprise any area on or near the surface of the patient. Treatment by variable depth treatment system 400 may include treatment of both deep region 410 and inner region 422, or within only one region of interest.

Variable depth element 306 can be configured in various manners to facilitate treatment of more than one region of interest, such as inner region 422 and/or deep-seated region 410. In accordance with an exemplary embodiment of the present invention, transducer 302 may be configured with variable depth element 306 comprising one or more materials configured to allow for control and focusing/defocusing of the acoustic energy to more than one region of interest. For example, with reference to exemplary embodiments illustrated in Figs. 5A and 5B, a variable depth transducer system 500 can comprise a transducer 502, electrical leads 510, and a variable depth device 528 or 530 suitably configured with transducer 502 to facilitate treatment.

Transducer 502 can include a transduction element comprising a piezoelectrically active material, such as lead zirconante titanate (PZT), or any other piezoelectrically active material, such as a piezoelectric ceramic, crystal, plastic, and/or composite materials, as well as lithium niobate, lead titanate, barium titanate, and/or lead metaniobate. In addition to or instead of a piezoelectrically active material, variable depth transducer 502 may comprise any other materials configured for generating radiation and/or acoustical energy. Variable depth transducer 502 may also comprise one or more matching layers and/or backing layers to suitably shape the resonant character of transducer 502. For example, variable depth transducer 502 may be configured, along with transduction element, with one or more matching layers and/or backing layers coupled to a piezoelectrically active material or any other material configured for generating radiation and/or acoustical energy.

For temporal control, the thickness of the transduction element of variable depth transducer 502 may be selected to provide a center operating frequency of moderate range, for example from approximately 750 kHz to 30 MHz or more. Lower frequencies, e.g., between approximately 750 kHz and 8 MHz, can facilitate deeper penetration and higher frequencies, while moderate frequencies, e.g., between approximately 8 to 20 MHz or more, can facilitate greater resolution. Selecting the frequency for operation can be based on the degree and balance of energy penetration and resolution that is desired for an application.

Electrical leads 510 may be configured to enable power to be transmitted to and signals received from variable depth transducer 502, and can comprise any wiring type, configuration and arrangement for use with ultrasound transducers. Variable depth transducer 502 may also be coupled to electrical leads 510 in various manners. For example, while Fig. 5 depicts electrical leads 510 coupled to only one end of variable depth transducer 502, electrical leads 510 may also be coupled together on an opposite end, or any other location along variable depth transducer 502.

To facilitate spatial control, in an exemplary embodiment, variable depth device 528 can comprise one or more reflective materials 504 configured to provide control and focusing of acoustic or radiation energy from variable depth transducer 502 towards a region of interest 518. In accordance with an exemplary embodiment, reflective materials 504 can comprise acoustic mirrors, lenses, reflectors or prisms configured for focusing of acoustic or radiation energy. The exemplary mirrors, reflectors or prisms may comprise any material for reflecting, bending or redirecting acoustic or radiated energy. For example, such materials may include stainless steel, aluminum, or any other metal alloy, glass, plastic, or any other material capable of bending, redirecting and/or reflecting back acoustical energy from a surface to another direction.

In accordance with one exemplary embodiment, reflective materials 504 may be suitably inclined at approximately a 45 degree angle with respect to variable depth transducer 502; however, reflective materials 504 may be configured to be inclined at any angle with respect to variable depth transducer 502 such that energy transmitted from variable depth transducer 502 is bent, redirected or reflected from reflective materials 504 towards a region of interest 518. Changing the angle of inclination can suitably control the focusing of acoustic energy to any one region of interest 518, such as to a deep treatment region of interest, a superficial region of interest, or a subcutaneous region of interest.

Variable depth devices 528 and 530 may be configured in a variety of manners, such as substantially flat, curved, or other suitable arrangements for reflecting, bending or redirecting acoustic or radiated energy. For example, with reference to Fig. 5A, variable depth device 528 can comprise mirrors 504 configured in a substantially flat manner. However, with reference to Fig. 5B, variable depth device 530 can also comprise mirrors 506 configured in a curved arrangement to allow for focusing of energy from variable depth transducer 502 to a region of interest 520. While Fig. 5B illustrates mirrors 506 as substantially spherical and symmetric, mirrors 506 may also be curved in an aspherical and/or asymmetric manner such that energy transmitted from variable depth transducer 502 is bent, redirected, or reflected from mirrors 506 towards a region of interest 520. Still further, mirrors 506 can also be configured in other shapes and arrangements, such as jagged, saw tooth, wavy or other non-planar surfaces, or any other surface or compound surfaces configured for reflecting, bending or redirecting acoustic or radiated energy.

Moreover, while Fig. 5A depicts variable depth device 528 with mirrors 504 configured to be substantially flat, and Fig. 5B depicts variable depth device 530 with mirrors 506 configured to be curved, variable depth devices 528, 530 may also be configured with any combination of substantially flat, curved mirrors, and/or other planar, non-planar or other arrangements for facilitating spatial control. In accordance with an exemplary embodiment utilizing spatial and temporal control, variable depth device devices 528 and 530 can be configured with a frequency dependent mirror or lens configured for spatial control of the focal depth and position by changing the frequency of excitation of variable depth transducer 502.

As a result, an exemplary transducer system 500 can be configured for providing treatment to a superficial region of interest and/or to a subcutaneous region of interest utilizing moderate frequencies below approximately 20 MHz. For example, an exemplary transducer system 500 can provide treatment to superficial regions and/or to subcutaneous regions that are more commonly addressed in cosmetic applications with an operating frequency range from approximately 750 kHz to 35 MHz or more.

Variable depth transducer system 500 can be configured in various arrangements to provide non-invasive treatment. For example, in accordance with an exemplary embodiment, variable depth devices 528, 530 may be configured with variable depth transducer 502 within a housing 536. Housing 536 can comprise any configuration of transducer housing for containing transducers and for interfacing with a patient to allow treatment, such as facilitate non-invasive treatment. Coupling of signals from transducer 502 and variable depth device 504, 506 through housing 536 to a region of interest may be facilitated through any coupling medium, such as air and other gases, water and other fluids, gels, solids, any combination thereof, and/or any other medium that allows for signals to be transmitted from transducer 502/variable depth devices 528, 530 to a region of interest.

In addition to comprising separate devices and components, variable depth transducer 302 and variable depth element 306 may also comprise the same device, i.e., variable depth element 306 is configured within transducer 302. For example, with reference to an exemplary embodiment illustrated in Fig. 6, a variable depth transducer 600 can comprise a variable depth transducer 602 configured as a variable depth device to provide for control and focusing of acoustic energy 620 towards a region of interest 630.

Variable depth transducer 602 may comprise a transduction element comprised of a piezoelectrically active material, such as lead zirconante titanate (PZT), or any other piezoelectrically active material, such as a piezoelectric ceramic, crystal, plastic, and/or composite materials, as well as lithium niobate, lead titanate, barium titanate, and/or lead metaniobate. Variable depth transducer 602 may also comprise one or more matching and/or backing layers configured along with the piezoelectrically active material. In addition to or instead of a piezoelectrically active material, variable depth transducer 602 may comprise any other materials configured for generating radiation and/or acoustical energy.

In accordance with an exemplary embodiment, variable depth transducer 602 is configured in a curved manner to enable focusing of acoustic energy 620 to region of interest 630. The curvature can be substantially spherical and/or symmetric manner, or curved in an aspherical and/or asymmetric manner. Furthermore, variable depth transducer 602 can comprise any other configuration to enable focusing of acoustic energy 620 to region of interest 630, such as to a deep treatment region of interest, a superficial region of interest, and/or a subcutaneous region of interest. For example, variable depth transducer 602 can be configured in any planar or non-planar arrangement.

For temporal control, the thickness of the transduction element of variable depth transducer 602 may be selected to provide a center operating frequency of moderate range, for example from approximately 750 kHz to 20 MHz. Lower frequencies, e.g., between approximately 750 kHz and 8 MHz, can facilitate deeper penetration and higher frequencies, e.g., between approximately 8 to 30 MHz or more, facilitate greater resolution. As a result, an exemplary transducer system 600 can be configured for providing treatment to a superficial region of interest and/or to a subcutaneous region of interest utilizing moderate frequencies below 20 MHz. For example, an exemplary transducer system 600 can provide treatment to superficial regions and/or to subcutaneous regions that are more commonly addressed in cosmetic applications with an operating frequency range from approximately 750 kHz to 1.5 MHz or more.

Electrical leads 610 are configured to enable power to be transmitted to and signals received from variable depth transducer 602, and can comprise any wiring type, configuration and arrangement for use with ultrasound transducers. Variable depth transducer 602 may also be coupled to electrical leads 610 in various manners. For example, while Fig. 6 depicts electrical leads 610 coupled to only one side of variable depth transducer 602, electrical leads 610 may also be coupled together on an opposite end, or any other location along variable depth transducer 602.

In addition to having a variable depth transducer 602 configured as a variable depth device to provide for control and focusing of acoustic energy 620 towards a region of interest 630, in accordance with an exemplary embodiment, a variable depth transducer may also be configured electronically to provide for control and focusing of acoustic energy. For example, with reference to an exemplary embodiment depicted in Fig. 7, an exemplary electronic focusing transducer system 700 is illustrated. Electronic focusing transducer system 700 is configured with a variable depth transducer 702. Like transducers 502 and 602, variable depth transducer 702 may comprise a piezoelectrically active material, composite materials, one or more matching layers, and/or any other materials configured for generating radiation and/or acoustical energy. Variable depth transducer 702 may also comprise a one-dimensional or two-dimensional array of transducers.

In accordance with an exemplary embodiment, variable depth transducer 702 comprises one or more transducers and/or transduction elements that can be activated by various drive frequencies with suitable phase delay. For example, variable depth transducer 702 can be activated by a first drive frequency 704, and then subsequently activated by at least one or more delayed drive frequencies 706 or 708. The phase delay in drive frequencies allows for focusing of acoustical energy to occur both tangentially 720 and axially 730.

The drive frequencies 704, 706, 708 transmitted to variable depth transducer 702 may comprise substantially similar frequencies and/or different frequencies, wherein all frequencies are in the moderate range, i.e., between approximately 750 kHz to 20 MHz. The delay between drive frequencies 704, 706, 708 may range from 0 ms to approximately a full period of the drive frequency. For example, the delay may comprise zero or approximately 1/1000th of a drive frequency period up to 15/16th, 31/32nd or more of a drive frequency period, with variations comprising any fraction of a full wavelength in time delay.

Electronic phase delay focusing of variable depth transducer 702 may be done tangentially and/or axially. For example, drive frequencies 704, 706, 708 and/or the phase associated with drive frequencies 704, 706, 708 may be varied to provide focusing tangentially and/or axially. In accordance with an exemplary embodiment, variable depth transducer 702 may comprise subaperatures that may be turned on and off to also provide focusing tangentially and/or axially. Phased focusing may prevent over-treatment of a region of interest by automating the focus and treatment times for a treatment region. Thus, for example, electronic control of variable depth transducer 702 may be facilitated by shunting various subapertures together to control the effective acoustic size of the source/receiver.

Thus, an exemplary transducer system can comprise a variable depth transducer 502, 602, 702 or any other transducer configuration for providing control and focus of acoustical and radiation energy to more than one region of interest within a patient. Such an exemplary transducer system can comprise a transducer configured with or coupled to a variable depth device or feature to provide energy to more than one region of interest. Moreover, an exemplary transducer system can provide treatment to superficial regions and/or to subcutaneous regions that are more commonly addressed in cosmetic applications with an operating frequency range below 30 MHz, or more, even from approximately 750 kHz to 8 MHz that is not attainable by prior art low-frequency transducers.

In accordance with another aspect of the present invention, a variable depth acoustic transducer can also be configured for generating high acoustic power for treatment purposes, while also providing for good imaging capabilities. To allow for the treatment spot size to be optimally controlled at various treatment depths, an exemplary embodiment of the present invention may comprise a transducer configured into an array of sub-elements.

For example, in accordance with an exemplary embodiment with reference again to Figure 6, variable depth transducer 602 can comprise a plurality of sub-transduction elements, wherein any of the plurality of sub-transduction elements may be configured to provide for focusing energy 620, e.g., any of the plurality of sub-transduction elements can be configured for processing acoustic waves with a sufficient bandwidth for good axial resolution. The sub-transduction elements may be configured such that all are curved, e.g., with the same or varying curvatures, or with one or more sub-transduction elements being substantially flat, with the remaining sub-transduction elements being curved. Further, the sub-transduction elements can be configured in any other shapes configured to provide for control and focusing of acoustic energy 620 towards a region of interest 630.

In accordance with another exemplary embodiment of the present invention, an exemplary variable depth transducer system 300 may be configured to enable energy deposition not only proximate a fundamental frequency of a piezoelectric material within the transduction element, but also at other frequencies, such as harmonic frequencies of the material, above a fundamental frequency, as well as resonances below a fundamental frequency. These harmonic and below fundamental resonances may be controlled and enabled through various focusing techniques and transducer structures, including the adding of matching layers and/or backing layers to shape the resonant characteristics of the transducer.

For example, energy can be suitably provided to a treatment region at a frequency near the peak acoustic output or peak acoustic transmit efficiency of transducer 302 when a piezoelectrically active material is driven near its fundamental frequency. Different sized and shaped piezoelectric materials have different fundamental frequencies for various electrode configurations. In accordance with an exemplary embodiment, energy can also be deposited when the piezoelectric material is driven above its fundamental frequency, e.g., at harmonics, or when driven below the fundamental frequency. The use of the multiple frequency characteristics of transducer 302 may be controlled and enabled through various transducer configurations, acoustic control and/or focusing techniques.

In accordance with an exemplary embodiment, the multiple frequencies may be enabled through the concentration of acoustic energy through the variable depth device 306. Enablement of the multiple frequencies allows for treatment at various depths corresponding to the different frequencies. For example, with additional reference to the acoustic output versus frequency curve illustrated in Fig. 8, variable depth transducer system 300 may treat multiple regions, represented by curve 800. Driving moderate frequencies through transducer 302 and variable depth device 306 may enable treatment of a first deep region

804, treatment of a second shallower region 808, and treatment of a third inner region 812. With respect to treatment techniques, various therapy, imaging and/or temperature monitoring applications may be provided to regions 804, 808, and/or 812. While three treatment regions are depicted in Fig. 8, variable depth transducer system 300 may be configured to enable multiple frequencies for treatment of two, four, or more regions.

In accordance with another aspect of the invention, the variable depth transducer 302 may be configured to provide one, two or three-dimensional treatment applications for focusing acoustic energy to one or more regions of interest. For example, as discussed above, variable depth transducer 302 can be suitably diced to form a one-dimensional array, e.g., transducer 602 comprising a single array of sub-transduction elements.

In accordance with another exemplary embodiment, variable depth transducer 302 may be suitably diced in two-dimensions to form a two-dimensional array. For example, with reference to Fig. 9, an exemplary two-dimensional array 900 can be suitably diced into a plurality of two-dimensional portions 902. Two-dimensional portions 902 can be suitably configured to focus on the treatment region at a certain depth, and thus provide respective slices 904 of the treatment region. As a result, the two-dimensional array 900 can provide a two-dimensional slicing of the image place of a treatment region, thus providing two-dimensional treatment.

In accordance with another exemplary embodiment, variable depth transducer 302 may be suitably configured to provide three-dimensional treatment. For example, to provide-three dimensional treatment of a region of interest, with reference again to Fig. 3, a three-dimensional system can comprise variable depth transducer 302 configured with an adaptive algorithm, such as, for example, one utilizing three-dimensional graphic software, contained in a control system, such as control system 304. The adaptive algorithm is suitably configured to receive two-dimensional imaging, temperature and/or treatment information relating to the region of interest, process the received information, and then provide corresponding three-dimensional imaging, temperature and/or treatment information.

In accordance with an exemplary embodiment, with reference again to Fig. 9, an exemplary three-dimensional system can comprise a two-dimensional array 900 configured with an adaptive algorithm to suitably receive 904 slices from different image planes of the treatment region, process the received information, and then provide volumetric information 906, e.g., three-dimensional imaging, temperature and/or treatment information. Moreover, after processing the received information with the adaptive algorithm, the two-dimensional array 900 may suitably provide therapeutic heating to the volumetric region 906 as desired.

Alternatively, rather than utilizing an adaptive algorithm, such as three-dimensional software, to provide three-dimensional imaging and/or temperature information, an exemplary three-dimensional system can comprise a single variable depth transducer 302 configured within a probe arrangement to operate from various rotational and/or translational positions relative to a target region.

For example, with reference to Fig. 10, a probe 1010 can be configured to rotate around a perimeter 1014 of a treatment region to provide three-dimensional imaging and temperature information. Probe 1010 may comprise a variable depth transducer system, such as, for example with reference to Fig. 3, variable depth transducer 302 configured with variable depth device 306. In the exemplary embodiment, probe 1010 may be coupled to control system 304 through a connector 1012. Connector 1012 may comprise a wire, optical cable, wireless connection, or any other device capable of sending and/or receiving information from control system 304 to variable depth transducer 302 and variable depth device 306 housed within probe 1010.

Probe 1010 may be configured to rotate around an axis 1016 to provide three-dimensional information. The rotational movement can comprise movement in either a clockwise or counterclockwise direction, or both. Further, the rotational movement could include complete or partial rotations. Thus, the rotational movement could include movement between only two positions, or between any other number of rotational positions. Still further, probe 1010 can be configured to translate or sweep along axis 1016 to provide a larger field-of-view and thus facilitate additional three-dimensional information. Accordingly, the probe system 1000 may comprise rotational and/or translational movement suitably configured to provide three-dimensional information.

Rotational and/or translational movement of probe 1010 may be controlled by manually placing probe 1010 in various desired rotational positions around the treatment region 1014. The movement of variable depth transducer 302 within probe 1010 in various rotational and/or translational positions can also be controlled by any mechanical scanning device now known or hereinafter devised for automated movement. For example, with reference to an exemplary embodiment illustrated in Fig. 11, automated rotational and/or translational movement may be achieved through use of a robotic arm mechanism 1100.

Robotic arm mechanism 1100 comprises a manually and/or electromechanically actuated robotic arm 1112 coupled with a probe 1110 and a control 1114.

Probe 1110 may comprise a variable depth transducer system, such as variable depth transducer 302 configured with variable depth device 306. Movement of probe 1110 is mechanically provided through the operation of robotic arm 1112. Robotic arm 1112 may comprise one or more sub-segments that allow precise movement and precise measurement of position in one or more up to any direction. Robotic arm 1112 may be driven by control system 1114. Control system 1114 may comprise a drive box, gears or any other device for providing mechanical movement of robotic arm 1112. Control system 1114 may also comprise a processor, a display, and/or an input/output device. Probe 1110 may be further coupled to control system 1114 through a wire or optical cable configured alongside or within robotic arm 1112, a wireless connection, or any other device capable of sending and/or receiving information from control system 1114 to variable depth transducer 302 and variable depth device 306 housed within probe 1110.

Control system 1114 may provide movement and control of robotic arm 1112 with up to six degrees of freedom. Control system 1114 may allow for movement of robotic arm 1112 to be referenced with one or more fixed positions in space. Control system 1114 may also allow for movement of robotic arm 1112 to be referenced with one or more fixed positions on a patient.

While the three-dimensional systems may include a single acoustic transducer configured with a two-dimensional array 900 and an adaptive algorithm to provide three-dimensional imaging, temperature monitoring and therapeutic heating to a treatment region; the three-dimensional system may also be configured to include both an adaptive algorithm and rotational and/or translational movement to provide additional information. As such, an even larger area of treatment may be obtained through the use of both the adaptive algorithm and the rotational and/or translational movement.

Continuing with this example, the three-dimensional system can be suitably configured to capture imaging and temperature information and provide therapeutic heating from variable depth transducer 302 once variable depth transducer 302 becomes fixedly maintained at various rotational positions. The three-dimensional system can also be suitably configured to capture imaging and temperature information and provide therapeutic heating just prior to, or just after, becoming fixedly positioned. The three-dimensional system can also be configured to capture imaging and temperature information and provide therapy during movement around the various rotational positions.

In addition to one, two or three-dimensional arrays, an exemplary variable depth transducer can also be configured within an annular array to provide planar, focused and/or defocused acoustical energy to more than one region of interest. For example, in accordance with an exemplary embodiment, with reference to Figs. 12A and 12B, an annular array 1200 comprising a plurality of rings 1202, 1204, 1206 to N. Rings 1202, 1204, 1206 to N can be mechanically and electrically isolated into a set of individual elements, and can create planar, focused, or defocused waves. For example, such waves can be centered on-axis, such as by methods of adjusting corresponding transmit and/or receive delays, $\tau 1$, $\tau 2$, $\tau 3$ ... τN. An electronic focus can be suitably moved along various depth positions, and can enable variable strength or beam tightness, while an electronic defocus can have varying amounts of defocusing. In accordance with an exemplary embodiment, a lens can also be provided to aid focusing or defocusing such that any time differential delays can be reduced. Movement of annular array 1200 in one, two or three-dimensions, or along any path, such as through use of probe 1000 and/or robotic arm mechanism 1100, may be implemented to scan and/or treat a volume or any corresponding space within a region of interest.

In accordance with another exemplary embodiment of the present invention, an exemplary variable depth treatment system and method may also be configured to provide therapeutic heating, cooling and/or imaging of a treatment region as well as acoustically monitoring the temperature profile or other tissue parameter monitoring of the treatment region and the general vicinity thereof. In accordance with an exemplary embodiment, an exemplary variable depth system may be configured with a dynamic feedback arrangement based on monitoring of temperature or other tissue parameters, and/or based on imaging information to suitably adjust the spatial and/or temporal characteristics of the variable depth transducer. Such imaging and other temperature or tissue parameter information can be suitably collected from ultrasound signals transmitted from an exemplary variable depth transducer, or from separate devices configured for collecting such information, e.g., a laser device configured with a receiver for profiling temperature, imaging or other such information.

For example, with reference again to Figure 4, such feedback information can be utilized to dynamically adjust the height, e.g., with a standoff, or distance of a transduction element within variable depth transducer system 402 from superficial layer 412. Such adjustment of the distance and/or location of variable depth transducer system 402 can be controlled either manually or mechanically. Changing the distance of variable depth transducer system 402 can result in a change in the depth of penetration of the acoustical energy within a region of interest, for example, from an inner region 422 to a deep region 410. The depth of penetration of the acoustical energy can also be suitably changed by changing the temperature of any couplant configured between variable depth transducer system 402 from superficial layer 412, and/or the temperature of any coolant.

Feedback information may be suitably generated or provided by any one or more acoustical sources, such as B-scan images, A-lines, Doppler or color flow images, surface acoustic wave devices, hydrophones, elasticity measurement, or shear wave based devices. In addition, optical sources can also be utilized, such as video and/or infrared cameras, laser Doppler imagers, optical coherence tomography imagers, and temperature sensors. Further, feedback information can also be suitably provided by semiconductors, such as thermistors or solid state temperature sensors, by electronic and electromagnetic sensors, such as impedance and capacitance measurement devices and/or thermocouples, and by mechanical sensors, such as stiffness gages, strain gages or stress measurement sensors, or any suitably combination thereof. Moreover, various other switches, acoustic or other sensing mechanisms and methods may be suitably employed to enable transducer 402 to be acoustically coupled to one or more regions of interest.

As discussed above, in accordance with various exemplary embodiments, an exemplary variable depth transducer can be configured as a combined imaging and therapy and/or tissue parameter monitoring transducer. For example, an exemplary variable depth transducer can comprise a single transducer providing imaging/therapy or imaging/therapy/tissue parameter monitoring, as set forth in U.S. Patent Nos. 6,050,943 and 6,500,121, both entitled "Imaging, Therapy and Temperature Monitoring Ultrasonic System". For example, with reference to Figure 13, a combined imaging/therapy acoustic transducer assembly 1300 can include a piezoelectric ceramic plate 1310. The air-backed side of the ceramic plate 1310 can be partially diced to have a plurality of curved (*e.g.* concave) portions 1315 to form a linear array structure. The thickness of the diced ceramic plate can be selected to provide a center frequency, for example from 500 kHz to 20 MHz with lower frequencies yielding deeper penetration and higher frequencies providing greater resolution. The concave portions 1315 constituting the transducer array can be spaced to achieve good lateral resolution in the imaging function.

On the face of each of the concave portions 1315, a metal electrode 1320 can be provided to connect the ceramic plate 1310 to the system control electronics (not shown in the figure) via a cable 1330 and a terminal 1340. The other face of the ceramic plate 1310 is configured such as to receive a common metal electrode 1325. The common electrode 1325 is also connected to the system control electronics via a cable 1335 and a terminal 1345.

In addition, although a concave portion is described above, it should also be noted that portion 1315 may also comprise a substantially flat configuration with a natural focus arrangement, e.g., without a focusing lens. Moreover, portion 1315 can also be configured with a substantially flat configuration having a convex or concave lens arrangement. Accordingly, portion 1315 may be configured in various manners.

On the common electrode 1325, one or more acoustic matching layers 1350 can be bonded using an adhesive such as an epoxy. When a loaded epoxy is used as the adhesive, the acoustic matching layer 1350 can be simply cast thereon since they adhere naturally to each other. The acoustic matching layer 1350 is intended to obtain appropriate impedance matching between the ceramic plate 1310 and the target tissue. Consequently, efficient transfer of acoustic power from the ceramic plate 1310 to the target tissue can be maintained to achieve an appropriate temperature increase in the target tissue, resulting in desired therapeutic results. When the acoustic matching layer 1350 (or layers) is bonded to the ceramic plate 1310 (precisely, to the common electrode 1325) with a loaded epoxy, the acoustic impedance can be easily adjusted by changing the amount of metal particles loaded in the epoxy. At the same time, acoustic matching layer(s) 1350 can increase the bandwidth of the emitted acoustic waves in the frequency domain. This aspect is suitable for the effective imaging function.

Without acoustic matching layer(s) 1350, the bandwidth of the emitted acoustic waves is determined mainly based on the design of the ceramic plate 1310 which actually generates the acoustic waves. This results in the limited degrees of freedom for adjusting the bandwidth. Providing one or more acoustic matching layer(s) 1350 makes it possible to properly adjust the bandwidth in a wide range without substantially changing the design of the ceramic plate 1310. Typically, the thickness of the acoustic matching layer 1350 is set to be on the order of a quarter of a wavelength of the acoustic waves. In addition, it is preferable that the acoustic impedance of the acoustic matching layer 1350 be set to be approximately equal to the square root of the acoustic impedance of the ceramic plate 1310 times the acoustic impedance of the target tissue or, more preferably, the acoustic impedance of the ceramic plate raised to the ϑ power, times the acoustic impedance of the target tissue raised to the K power. Also, multiple matching layers may be used, of course, with suitable changes in layer impedances.

The acoustic matching layer 1350 can be made of various types of materials, such as ceramics, plastics, metals and a composite material thereof. Preferably the matching layer may exhibit good thermal conductivity and low acoustic attenuation. Matching layer (or layers) 1350 may be cut or diced, such as shown on Figure 13, to maintain high acoustic isolation, *i.e.*, low acoustic crosstalk. However, any heating of the matching layer(s) of ceramic may be controlled via the duty cycle of the drive signal or via active or passive cooling methodologies. In addition, any other conventional cooling technique and/or methodology may be utilized. Although not shown on Figure 13, it should be appreciated that transducer assembly 1300 may be provided with a back layer (not shown) suitably configured to modify the bandwidth of the transducer and/or serve as a heat sink.

The ceramic plate 1310 and other related components configured as set forth above are coupled to the target tissue via a fluid 1370 circulating between the acoustic matching layer 1350 and an acoustically-transparent membrane 1360. The fluid 1370 also functions as a coolant for the ceramic plate 1310 and the acoustic matching layer 1350 and may also aid in controlling the temperature of the tissue at the interface. Temperature control via a circulating fluid, thermoelectric cooling module and/or pneumatic or other devices may also be utilized in accordance with various aspects of the present invention. Furthermore, the acoustic transducer assembly 1300 having the aforementioned configuration is enclosed in a water-tight housing (not shown in the figure).

The circulating fluid 1370 has two major functions as mentioned above. One of them is to couple the ceramic plate 1310 and the acoustic matching layer 1350 to the target tissue. The other is to remove the waste heat away from the acoustic transducer assembly 1300. In particular, the energy conversion efficiency of the acoustic transducer assembly 1300 is typically about 80%, and consequently, some portion of the input electrical power becomes the waste heat. When a large amount of electrical power is input to the combined imaging/therapy acoustic transducer assembly 1300, the assembly 1300 is heated up. This may result in reduced efficiency and altered operational characteristics, which are likely to produce adverse effects on the therapeutic purposes. The circulating fluid 1370 therefore keeps the acoustic transducer assembly 1300 at a stable and constant temperature by cooling it off. The fluid 1370 is typically water. Alternatively, any suitable mineral oil, plant oil, or other suitable liquid could be used as the fluid 1370.

While Figure 13 illustrates an exemplary embodiment for providing a combined imaging/therapy and/or tissue parameter monitoring within a single transducer, various other configuration and embodiments can be suitably realized, including those disclosed herein and/or hereinafter developed, and any combination of the components within assembly 1300 configured to provide combined imaging/therapy and/or tissue parameter monitoring can be implemented within various exemplary embodiments.

With reference to Figure 14A, an imaging subsystem 1410 which is interfaced to an exemplary imaging/therapy and/or tissue parameter monitoring acoustic transducer assembly 1300 is described below. The imaging subsystem 1410 connected to the acoustic transducer assembly 1300 via a cable 1410 includes a beam forming control unit. The unit is operated so that the acoustic transducer assembly 1300 scans the region-of-interest, including the treatment region, in the target tissue 1480 with the acoustic waves. The returning acoustic signal is received by the acoustic transducer assembly 1300, and then sent to the imaging subsystem 1410 to generate ultrasonic images of the treatment region. The thus generated image is displayed on a video display terminal 1450 to assist the user in appropriately positioning the acoustic transducer assembly 1300 with respect to the treatment region in the target tissue 1480 prior to actually commencing the therapeutic treatment process.

With reference to Figure 14C, a therapy subsystem (a therapeutic heating system) 1420, which is interfaced to the exemplary combined imaging/therapy acoustic transducer assembly 1300, is connected to the combined imaging/therapy acoustic transducer assembly 1300 via a cable 1410 includes power RF drivers which are interfaced to the linear array of the acoustic transducer assembly 1300, *i.e.*, to each of the respective portions 1315 of the ceramic plate 1310 shown in Figure 13. The power RF drivers are also connected to the common electrode 1325 provided on the other face of the ceramic plate 1310. By appropriately applying RF signal voltages to the ceramic plate 1310 from the thus connected power RF drivers, high power acoustic energy is generated. The drivers are controlled in-time so that the acoustic transducer assembly 1300 transmits, steers, and/or focuses the acoustic waves to the region-of-interest including the treatment region in the target tissue 1480. Heating power and heating time as well as transducer anodization are all controlled during the therapeutic treatment process to achieve the proper heating pattern and therapeutic dosage.

Tissue parameter monitoring, such as temperatures, can be monitored in a manner calculated to avoid tissue motion artifacts. For example, in the case where a localized region is heated, the heated region is interrogated with a pulse echo signal substantially immediately thereafter. In such a case the echo from the heated region will be changed in time and amplitude. For example, the acoustic attenuation in tissue approximately doubles from 50°C to 70°C. The region is measured immediately before and after heating and thus, tissue motion artifacts are avoided, as well as any acoustic propagation effects.

In the case where only a small region is treated at a time, an isothermal region about the hot spot is engendered. Therefore, the time-of-flight and the amplitude of wave incident on the heated region is the same before and after the therapeutic energy is delivered. Thus, the amplitude change and time change measured after therapy will be due substantially to the tissue treated.

With reference to Figure 14C, where a combined imaging/therapy transducer assembly 1300 is used to heat a small region 1480, with a temperature monitoring subsystem 1430 is connected to display 1450. Temperature monitoring subsystem 1430 is also connected to transducer assembly 1300, such as by a suitable cable 1410. In accordance with this example, the whole volume is scanned, and by sweeping the pulse echo the effective thermal dose (time/temperature history) (*e.g.* recrossed volume) can be determined. The term thermal dose relates to the temperature and time of duration integral function by which, for example, a determination of necrosity can be made.

The present invention has been described above with reference to various exemplary embodiments. However, those skilled in the art will recognize that changes and modifications may be made to the exemplary embodiments without departing from the scope of the present invention. For example, the various operational steps, as well as the components for carrying out the operational steps, may be implemented in alternate ways depending upon the particular application or in consideration of any number of cost functions associated with the operation of the system, e.g., various of the steps may be deleted, modified, or combined with other steps. Further, it should be noted that while the method and system for ultrasound treatment with a variable depth transducer is described above is suitable for use by a medical practitioner proximate the patient, the system can also be accessed remotely, i.e., the medical practitioner can view through a remote display having imaging information transmitted in various manners of communication, such as by satellite/wireless or by wired connections such as IP or digital cable networks and the like, and can direct a local practitioner as to the suitably placement for the transducer. Moreover, while the various exemplary embodiments may comprise non-invasive configurations, an exemplary variable depth transducer system can also be configured for at least some level of invasive treatment application. These and other changes or modifications are intended to be included within the scope of the present invention, as set forth in the following claims.

WE CLAIM:

1. A non-invasive ultrasound treatment system for providing treatment to a patient, the non-invasive ultrasound treatment system comprising:

a variable depth transducer comprising a transduction element and a variable depth element, the variable depth transducer operable to provide non-invasive treatment to tissue at least two depths in a patient, the transduction element comprising at least one surface configured to emit acoustic energy, the variable depth element comprising a frequency dependent device configured for spatial control of a focal depth and position of the treatment to the tissue by changing a frequency of the acoustic energy emitted by the at least one surface of the transduction element; and

a controller in communication with the variable depth transducer, the controller comprising a control of the spatial control and a control of a frequency range of the acoustic energy;

wherein the frequency dependent device is a reflective device.

2. The system according to claim 1, wherein the frequency dependent device is configured to change a distance from the transduction element to the frequency dependent device, thereby adjust the focal depth of the treatment to the tissue.

3. The according to claim 2, wherein the controller is configured to control the distance from the transduction element to the frequency dependent device.

4. The system according to any one of claims 1 to 3, wherein the tissue comprises at least one of a superficial layer and a subcutaneous superficial layer of a patient.

5. The system according to claim 4, wherein the superficial layer includes tissue on or near a surface of the patient.

6. The system according to any one of claims 1 to 5, wherein the transduction element is configured to emit acoustic energy at the frequency ranging from about 750 kHz to about 20 MHz.

7. The system according to any one of claims 1 to 6, wherein the variable depth transducer is configured for providing at least two of treatment, imaging and temperature monitoring of the tissue.

8. The system according to any one of claims 1 to 7, further comprising a coupling system configured for acoustic coupling between the variable depth transducer system and the tissue.

9. The system according to claim 8, wherein the coupling system is configured for temperature control of the variable depth transducer system to facilitate adjustment of the focal depth of the acoustical energy emitted by the at least one surface of the transduction element.

10. The system according to any one of claims 1 to 9, wherein the controller further comprises a display unit for displaying at least one of imaging information, positional information, and temperature information of a treatment region comprising the tissue.

11. The system according to any one of claims 1 to 10, wherein the controller further comprises a robotic arm arrangement for controlling movement of the variable depth transducer system.

12. An ultrasound system for providing energy deposition at more than one depth, the system comprising:

a variable depth transducer system comprising a transducer and a variable depth element, the variable depth transducer operable to provide energy deposition into tissue comprising at least a deep region and an inner region, the transducer comprising at least one surface configured to emit ultrasound energy at a frequency, the variable depth element comprising a frequency dependent device configured for spatial control of a focal depth of the energy deposition into the tissue by changing the frequency of the ultrasound energy emitted from the at least one surface of the transducer; and

a controller in communication with the transducer and the variable depth element, the controller comprising a control of a frequency range of the ultrasound energy emitted from the at least one surface of the transducer;

wherein the variable depth element is a reflective element.

13. The system according to claim 12, further comprising a coupling system configured for acoustic coupling between the variable depth transducer system and a region of interest comprising the tissue.

14. The system according to claim 13, wherein the coupling system is configured for temperature control of the transducer to facilitate adjustment of focal depth of the energy deposition into the tissue.

15. The system according to any one of claims 12 to 14, wherein the variable depth transducer system is configured to provide the energy deposition into the inner region comprising at least one of a superficial region and a subcutaneous region.

16. The system according to any one of claims 12 to 15, further comprising a mechanical scanning device configured to move the variable depth transducer system in at least one of a translational movement and a rotational movement.

17. The system according to any one of claims 12 to 16, wherein the at least one surface of the transducer comprises a plurality of transduction elements configured to be activated by a plurality of frequencies separated by at least one phase delay.

18. The system according to any one of claims 12 to 17, wherein the energy deposition to the inner region is at a first depth and the energy deposition to the deep treatment region is at a second depth, wherein the first depth is from 0 mm to 5 cm, the second depth is from 50 mm to 7 cm, and the first depth is less than the second depth.

19. The system according to any one of claims 12 to 18, wherein the at least one surface of the transducer configured to emit ultrasound energy at the frequency ranging from about 750 kHz to about 20 MHz

20. The system according to any one of claims 12 to 19, wherein the frequency dependent device is a reflective device.

21. The system according to any one of claims 12 to 20, wherein the frequency dependent device is a frequency dependent lens.

22. The system according to any one of claims 12 to 20, wherein the frequency dependent device is a frequency dependent mirror device.

23. The system according to any one of claims 12 to 22, wherein the frequency dependent device is configured to change a distance from the at least one surface of the transducer to the frequency dependent device, thereby adjust the focal depth.

24. The system according to claim 23, wherein the controller is configured to control the distance from the at least one surface of the transducer to the frequency dependent device.

25. The system according to any one of claims 12 to 24, wherein the variable depth transducer is configured to provide energy deposition to three different focal depths in the tissue comprising the at least a deep region and an inner region

26. An ultrasound system for providing energy deposition at more than one depth, the system comprising:

a variable depth transducer system comprising a transducer having at least one surface configured to emit energy to a region of interest at a frequency, and a variable depth element comprising a frequency dependent device configured to simultaneously convert the energy, emitted by the at least one surface of the transducer, into at least three different frequencies and provide energy deposition to at least three different depths in the region of interest; and

a controller in communication with the transducer and the variable depth element, the controller comprising a control of a frequency range of the energy emitted by the at least one surface of the transducer;

wherein the variable depth element is a reflective element.

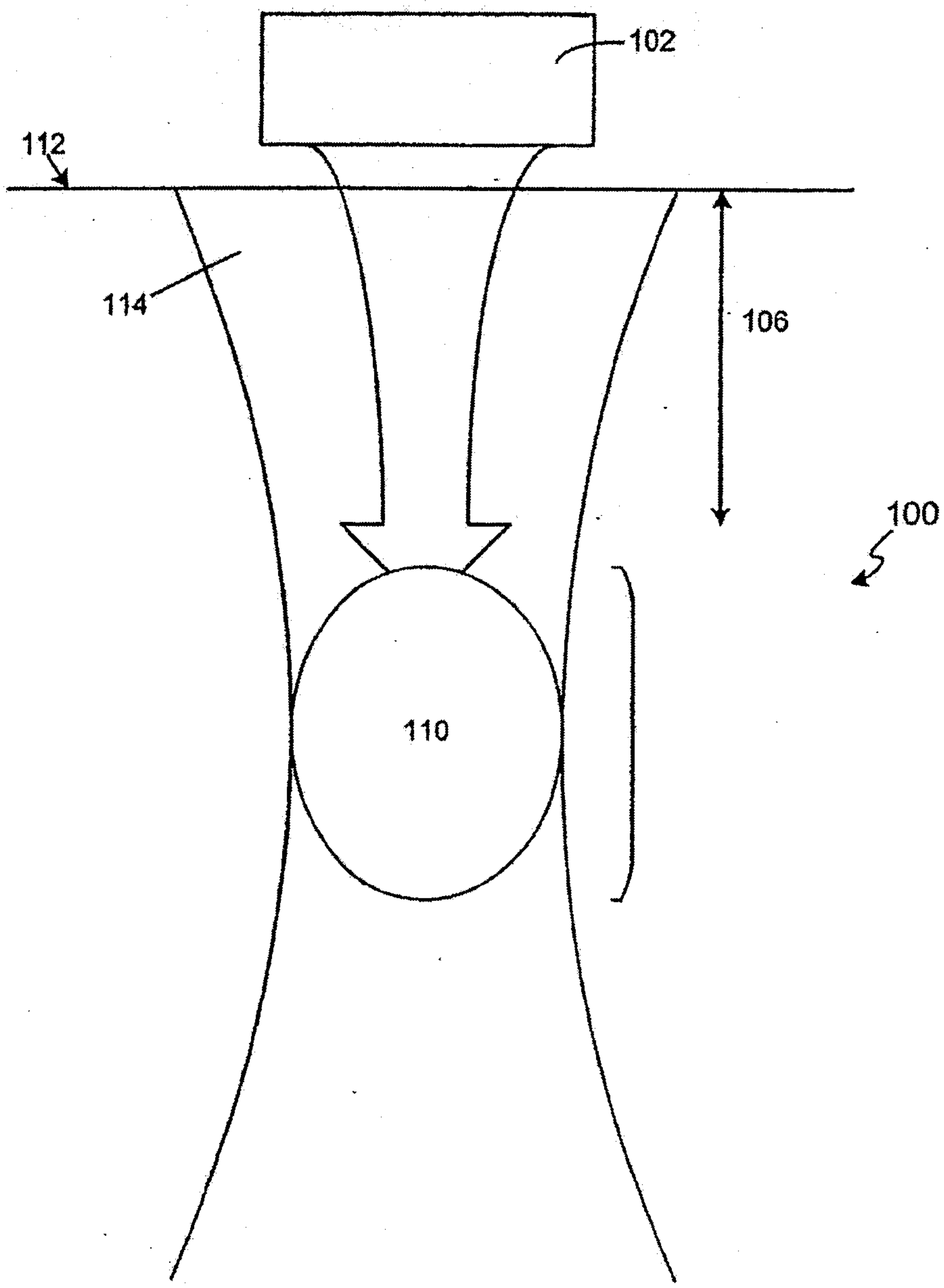


FIG. 1
PRIOR ART

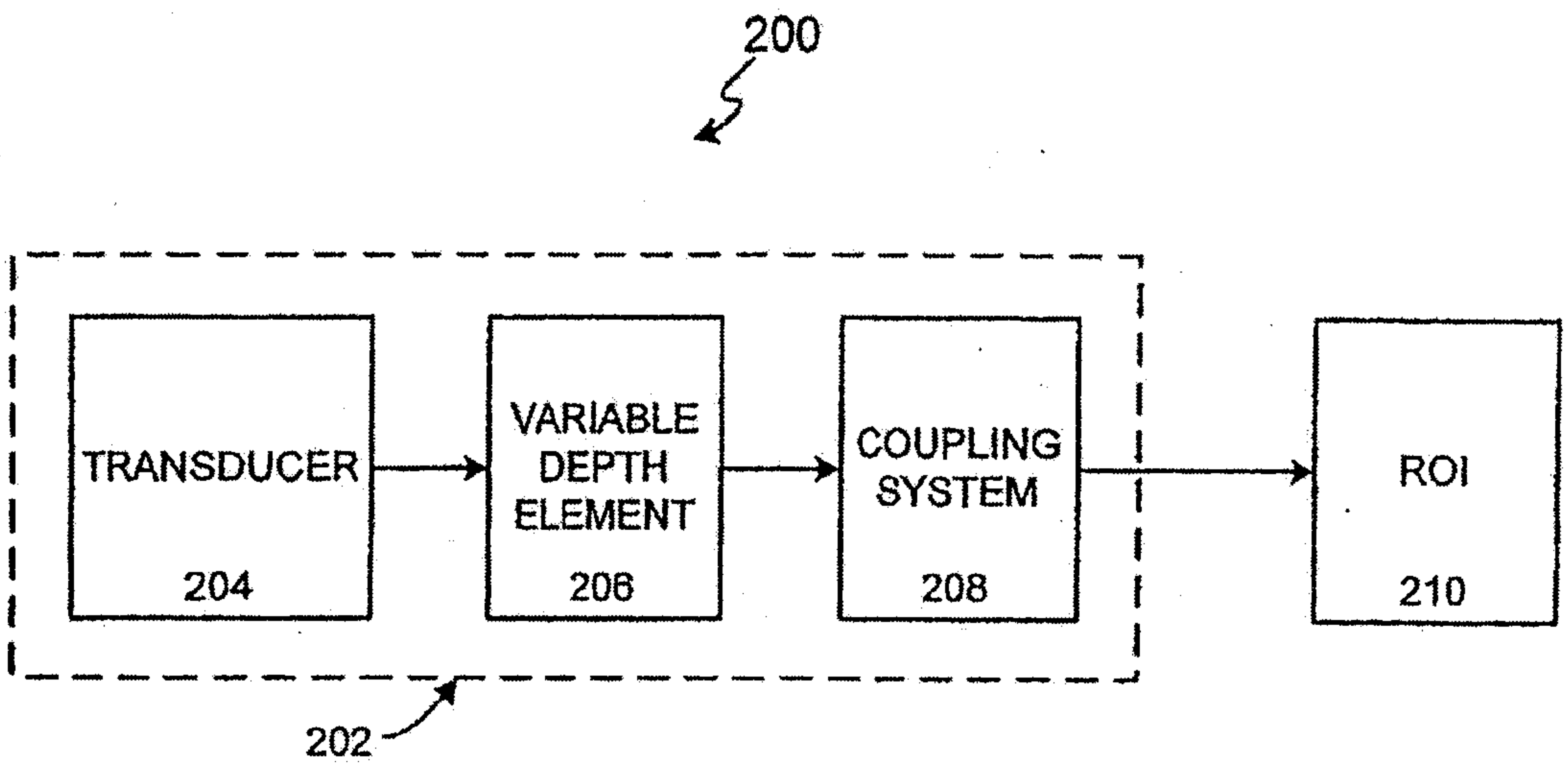

200
TRANSDUCER
204
VARIABLE DEPTH ELEMENT
206
COUPLING SYSTEM
208
ROI
210
202

FIG. 2

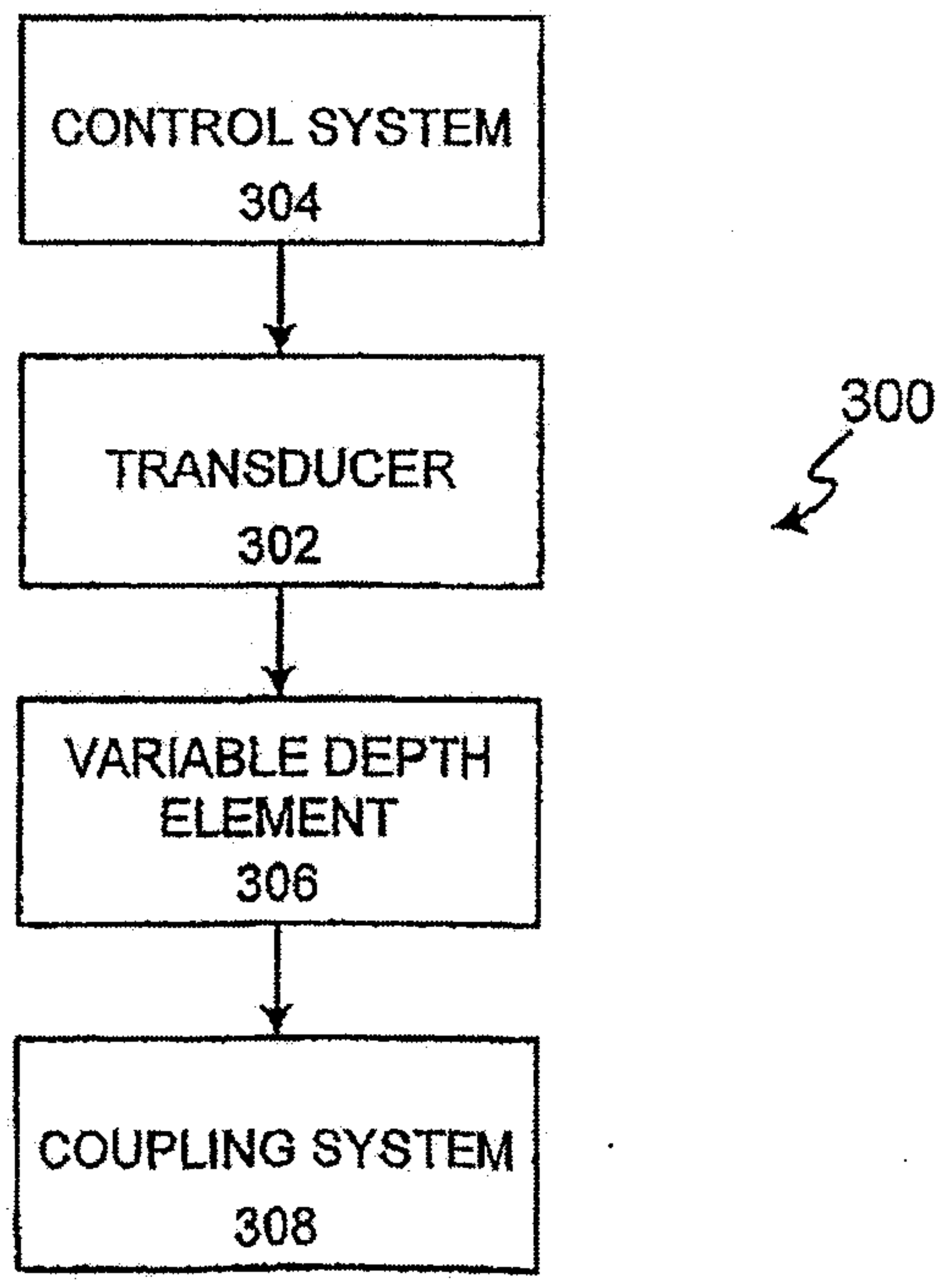

CONTROL SYSTEM
304
TRANSDUCER
302
300
VARIABLE DEPTH ELEMENT
306
COUPLING SYSTEM
308

FIG. 3

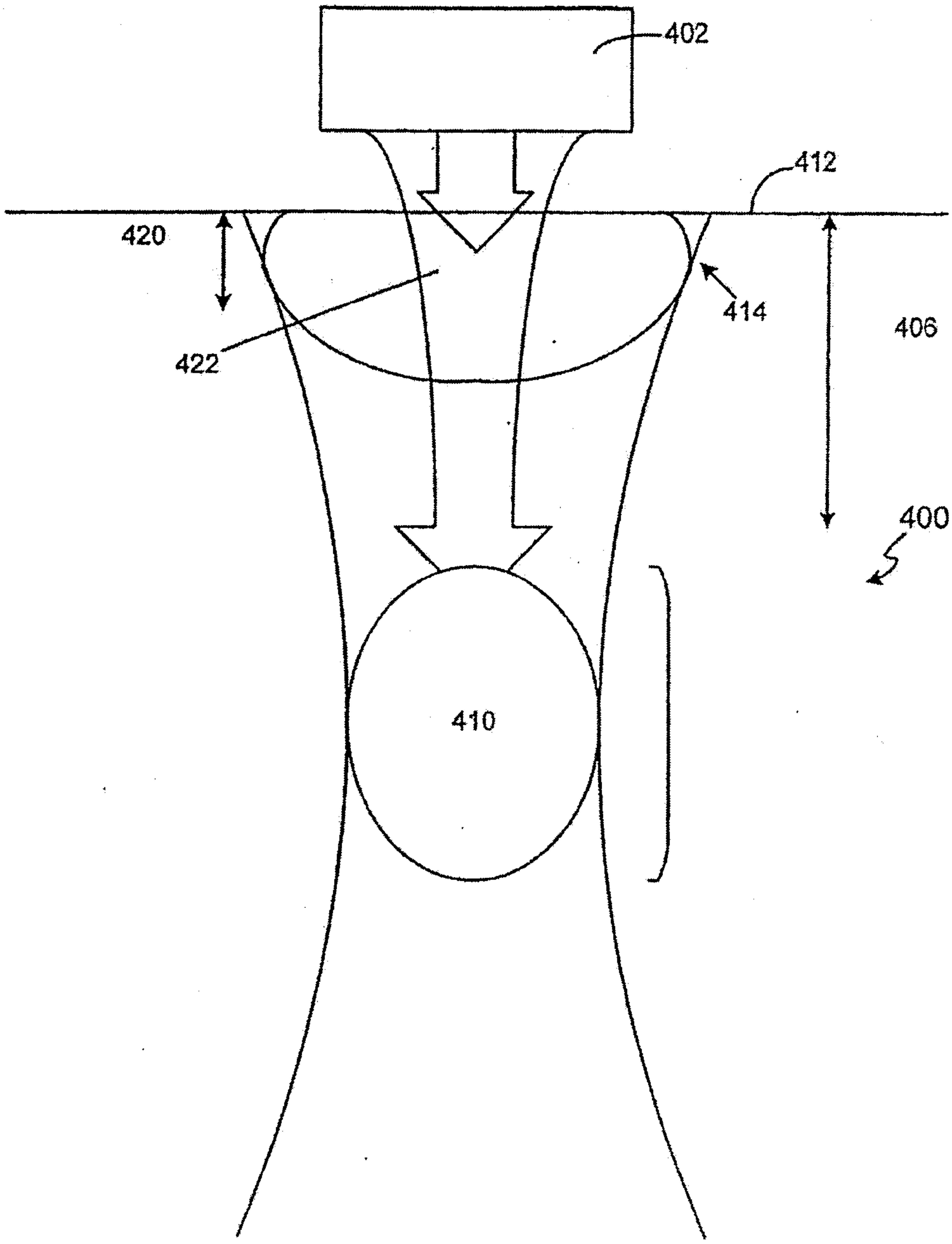


FIG. 4

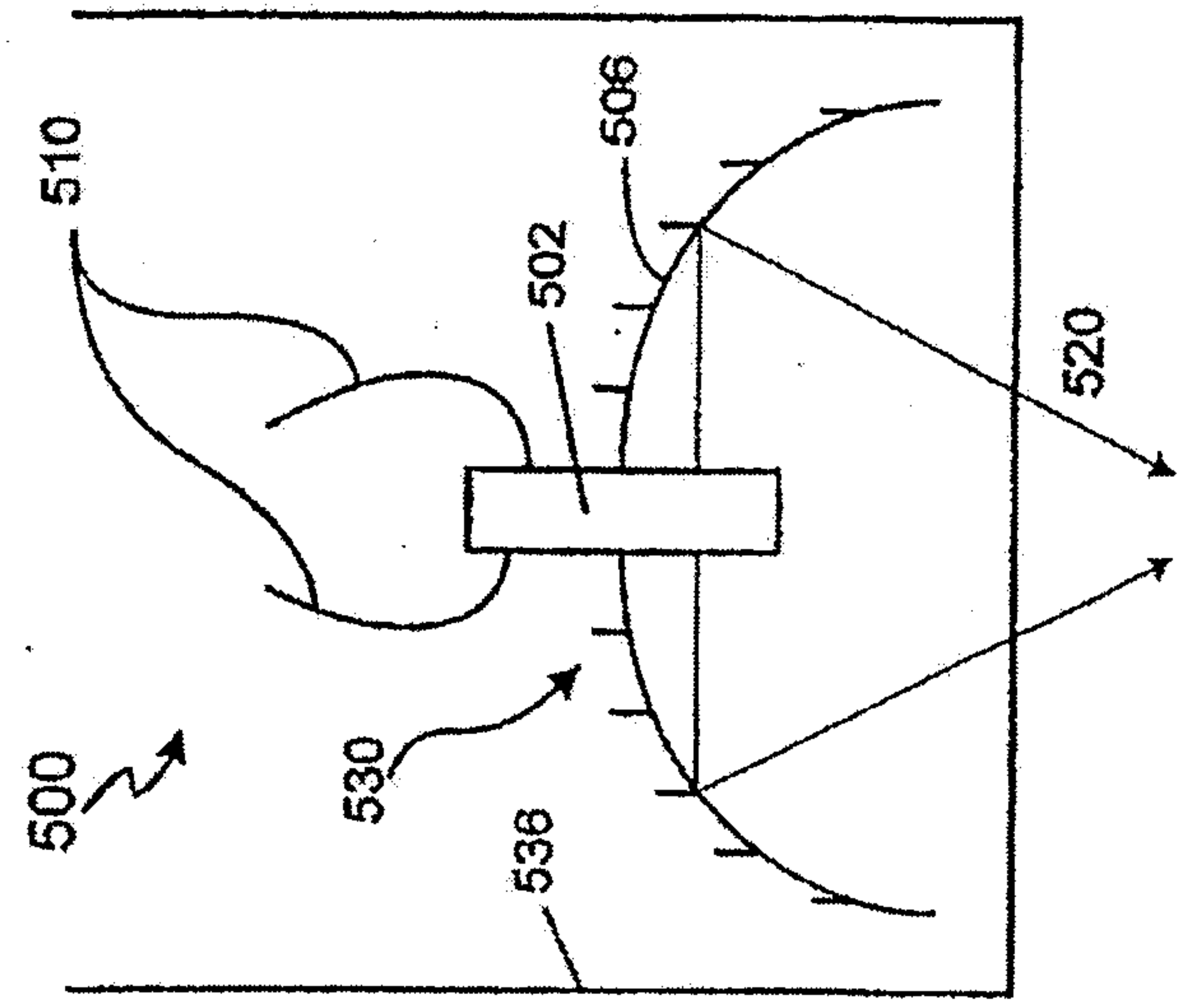


FIG. 5B

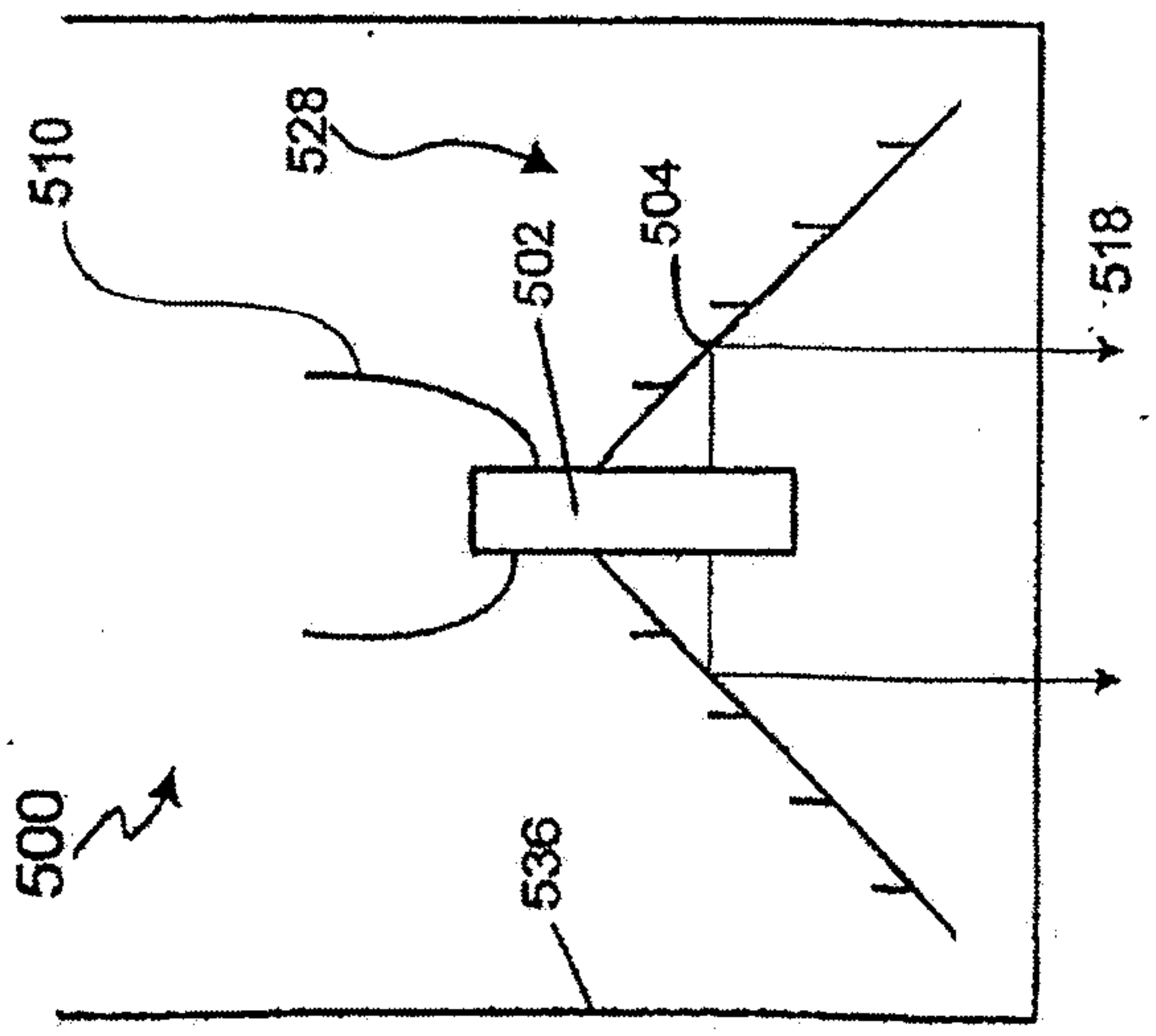


FIG. 5A

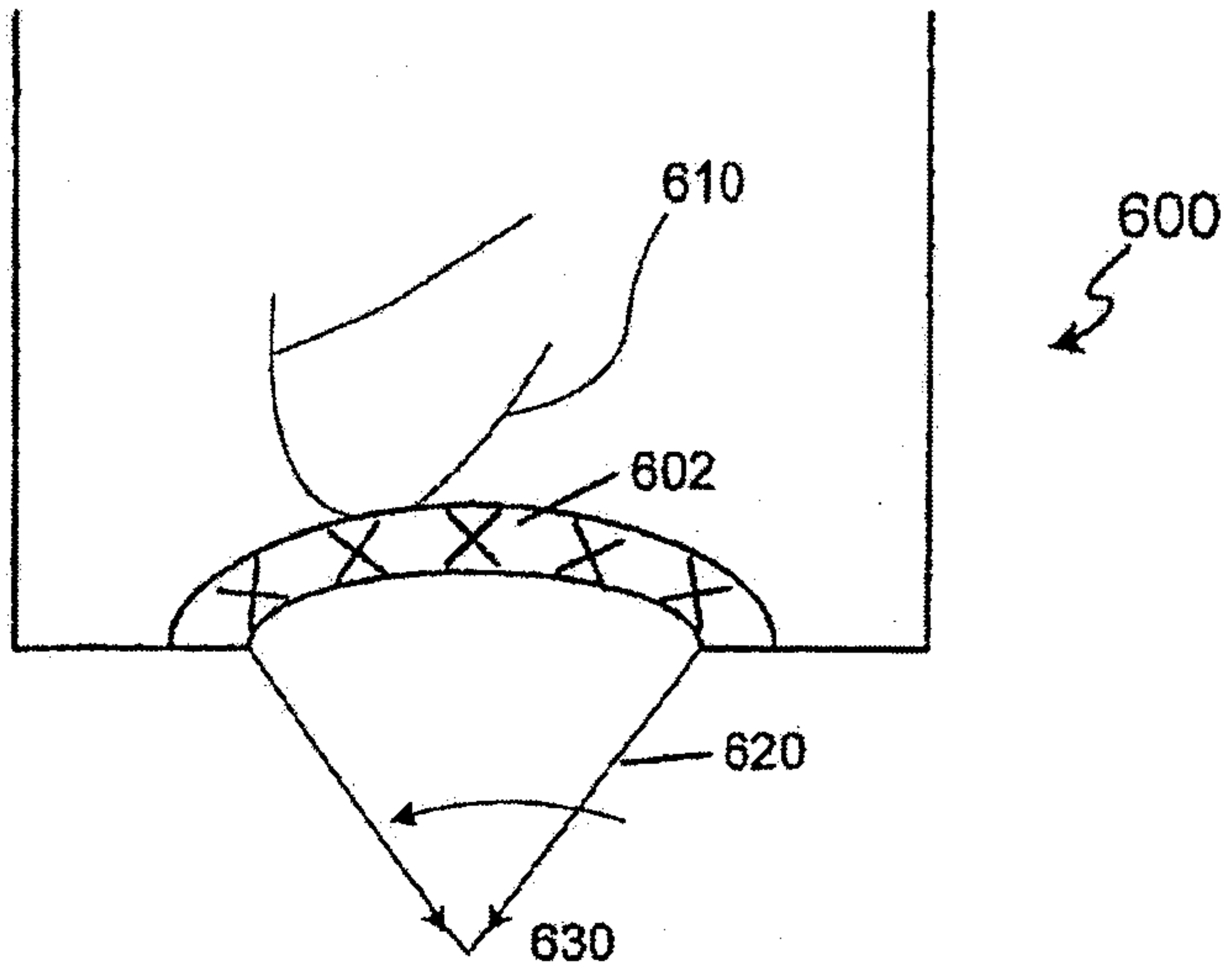


FIG. 6

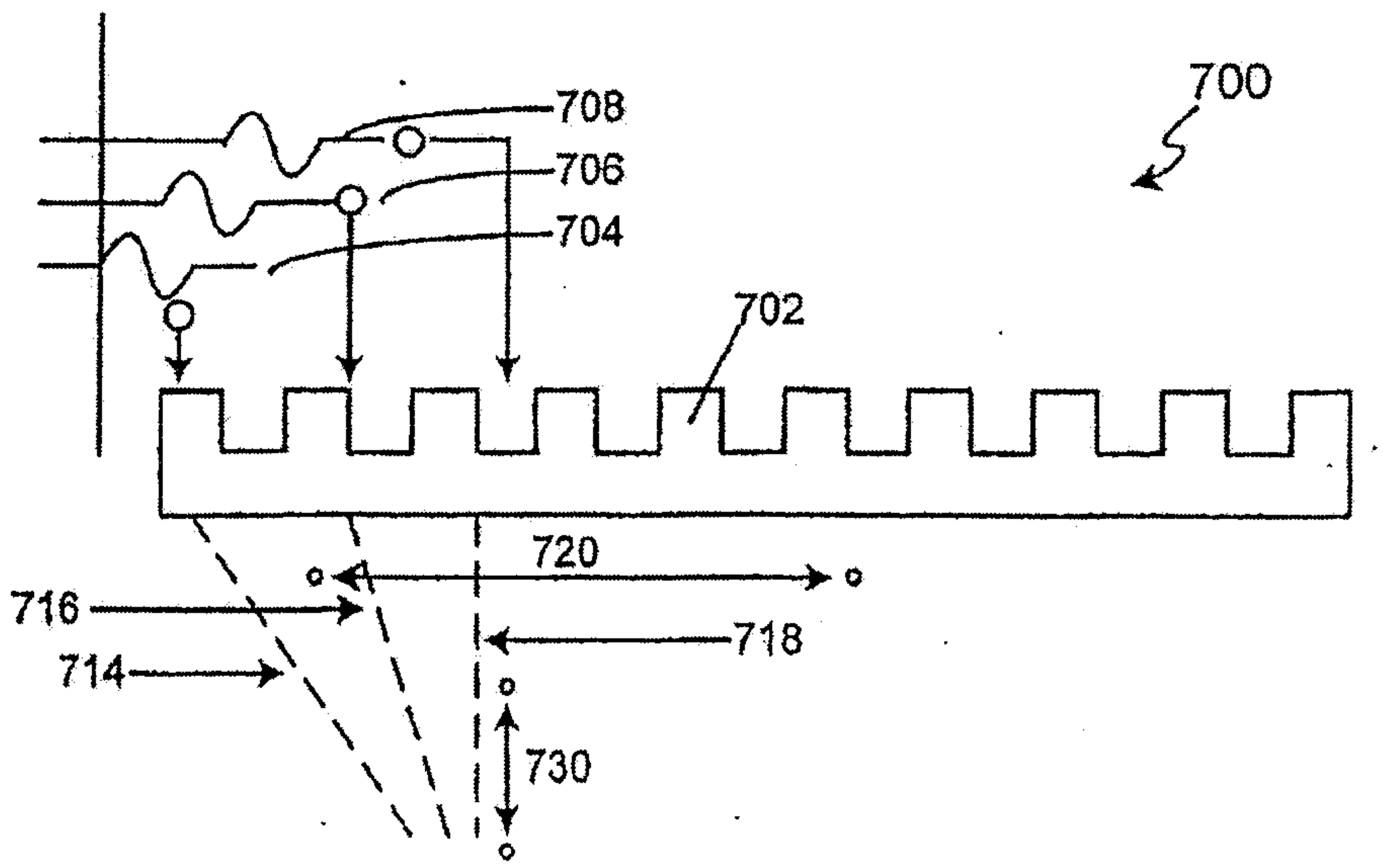


FIG. 7

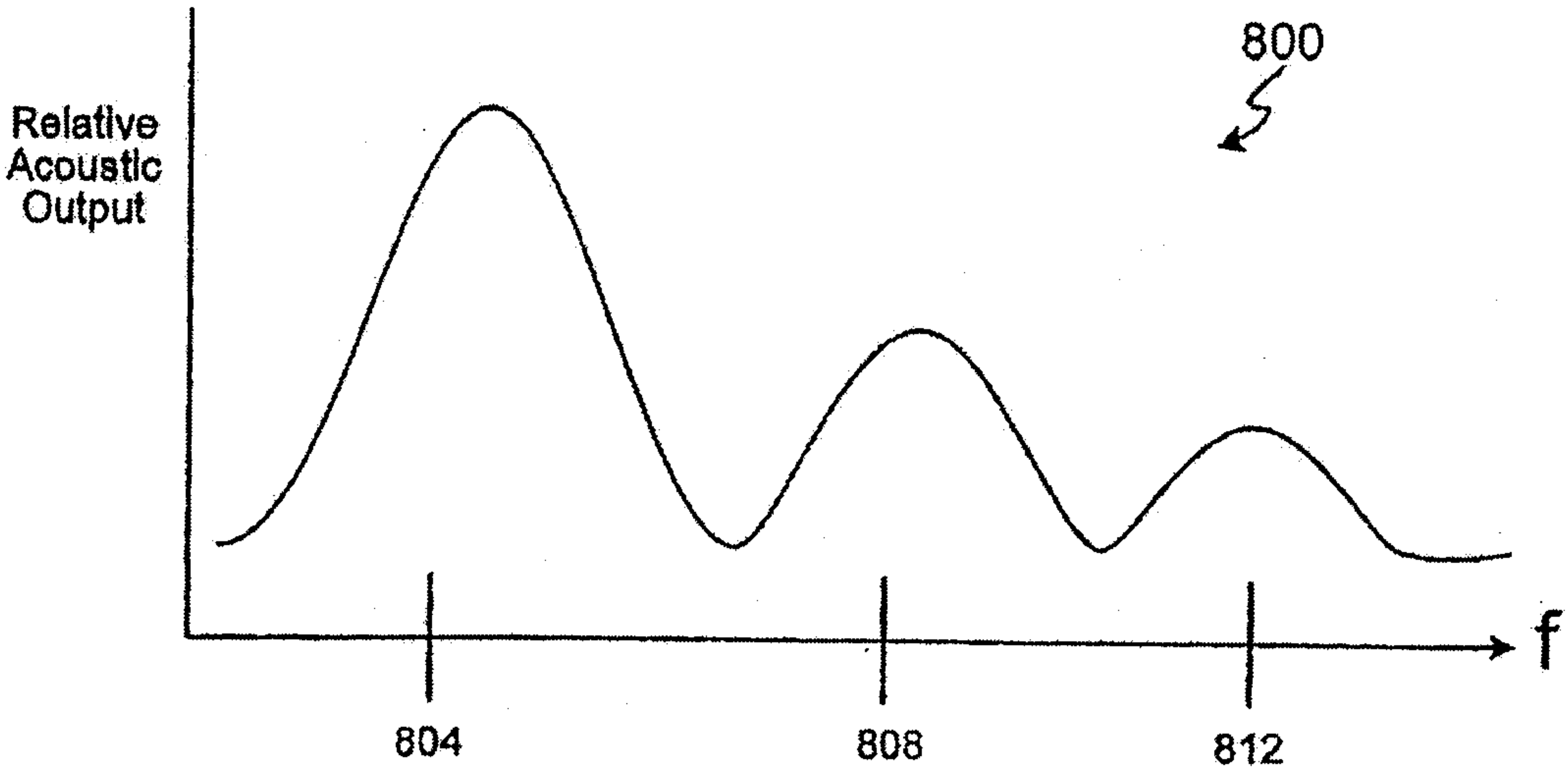


FIG. 8

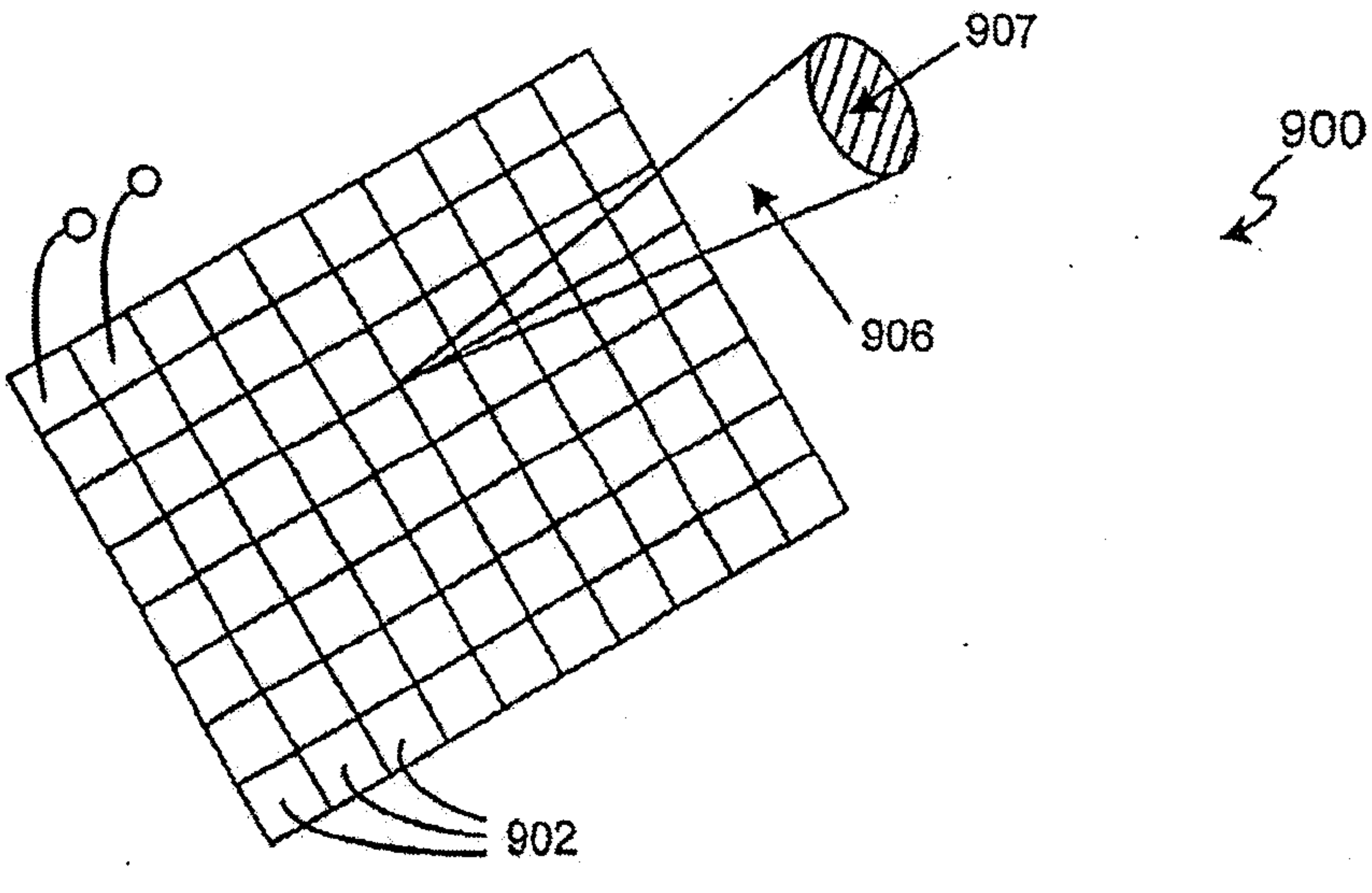


FIG. 9

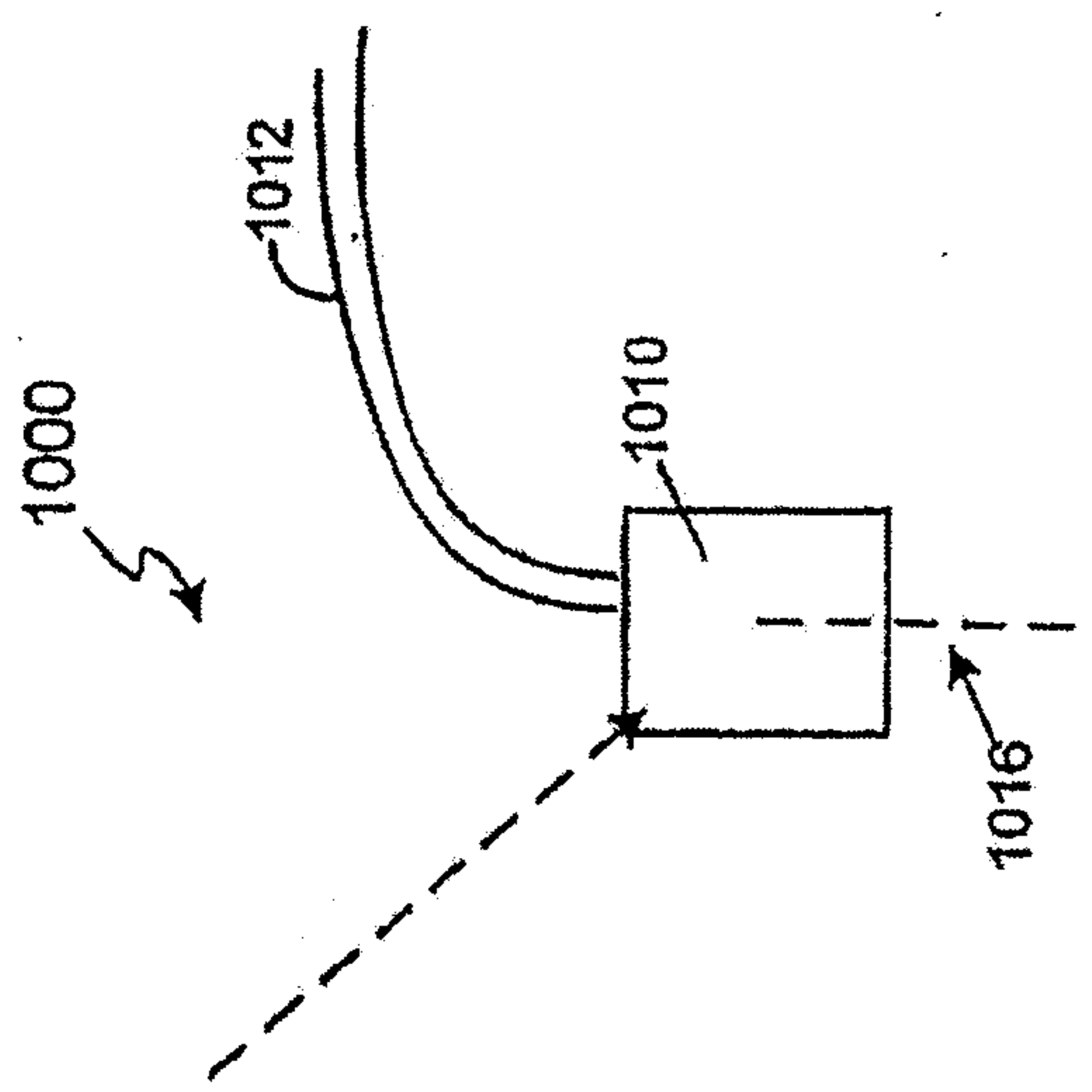


FIG. 10

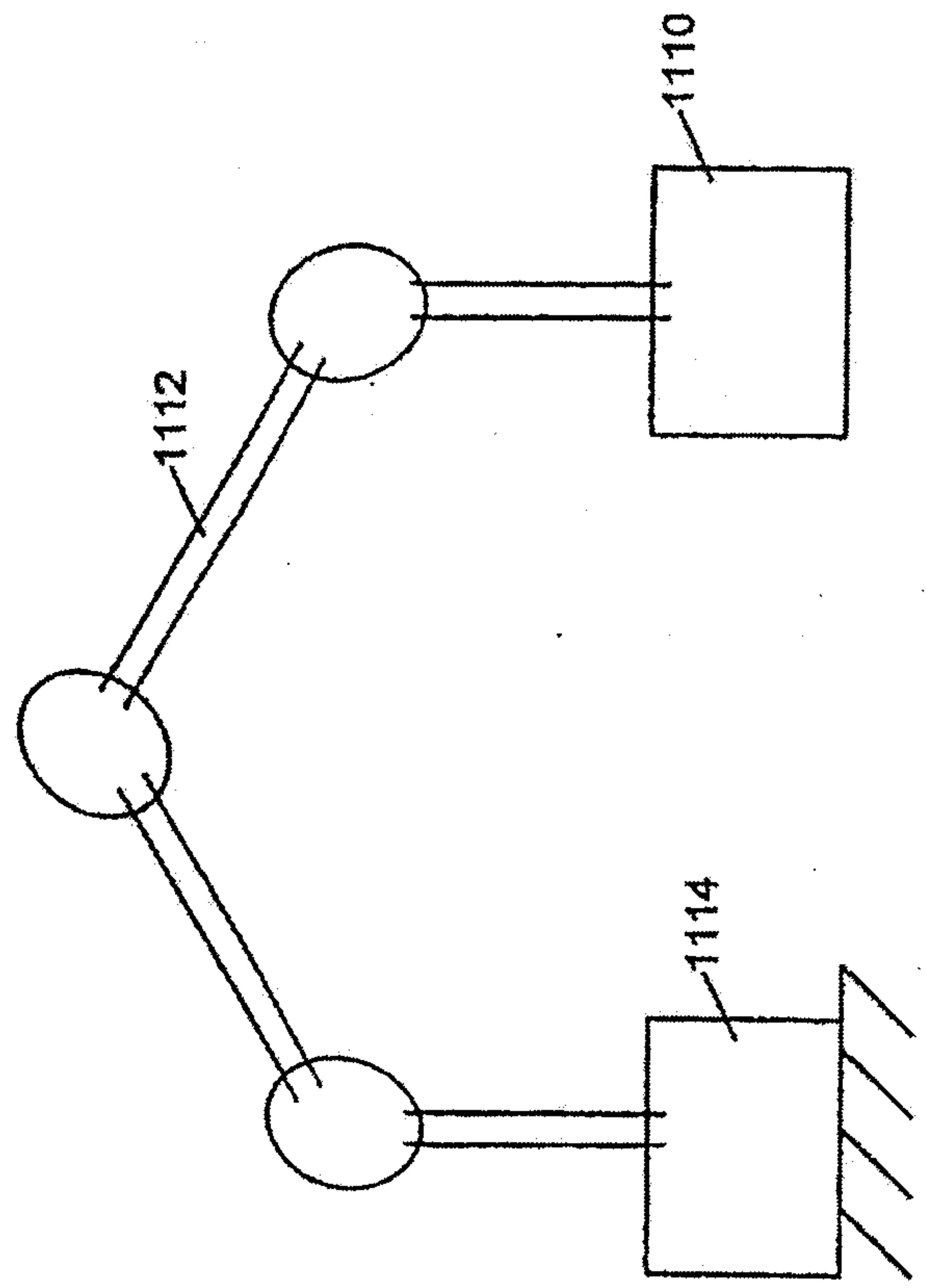


FIG. 11

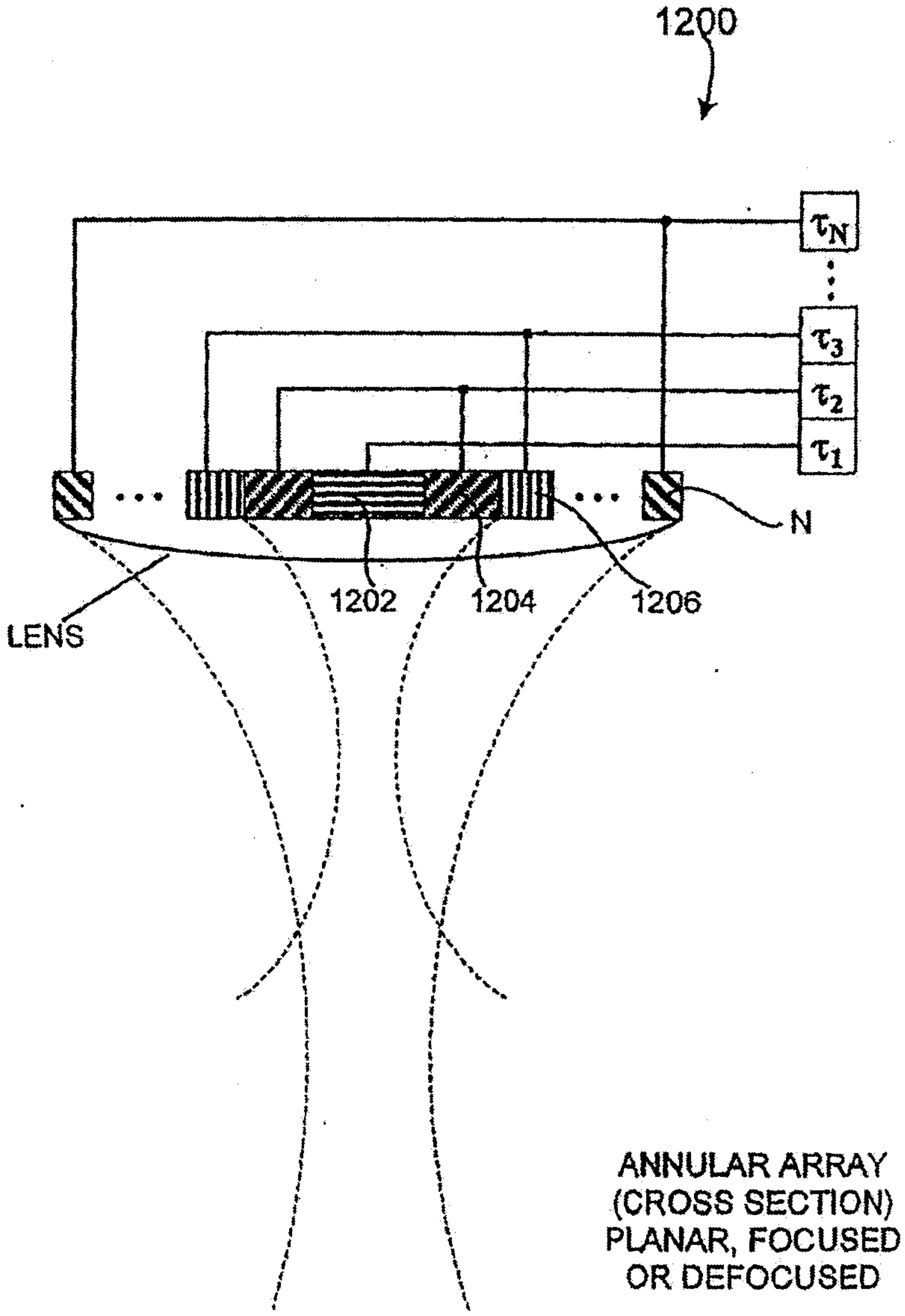

1200
τ_N
τ_3
τ_2
τ_1
N
1202
1204
1206
LENS
ANNULAR ARRAY
(CROSS SECTION)
PLANAR, FOCUSED
OR DEFOCUSED

FIG. 12A

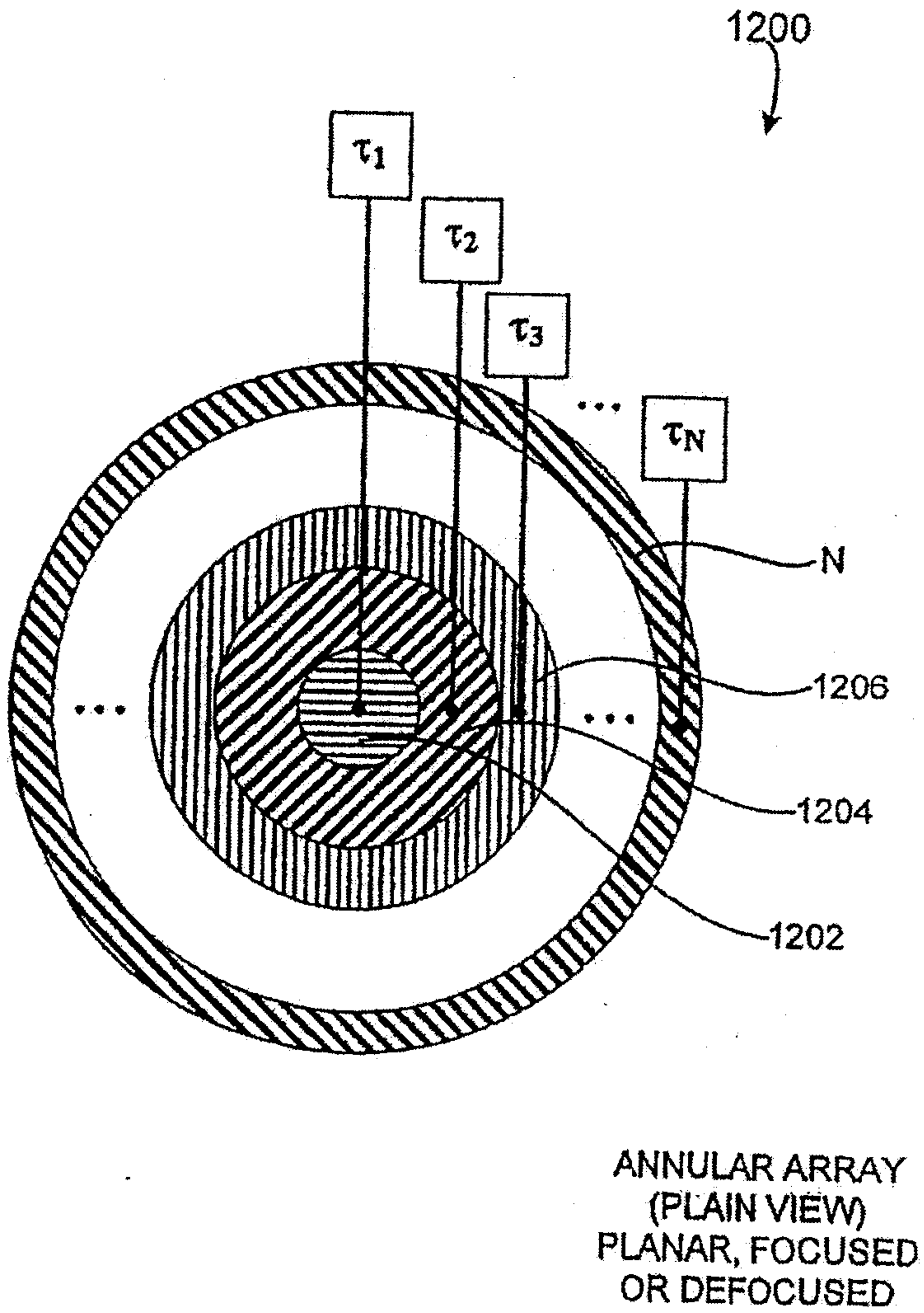

1200
τ_1
τ_2
τ_3
τ_N
N
1206
1204
1202
ANNULAR ARRAY
(PLAIN VIEW)
PLANAR, FOCUSED
OR DEFOCUSED

FIG. 12B

REPLACEMENT SHEET
10/13

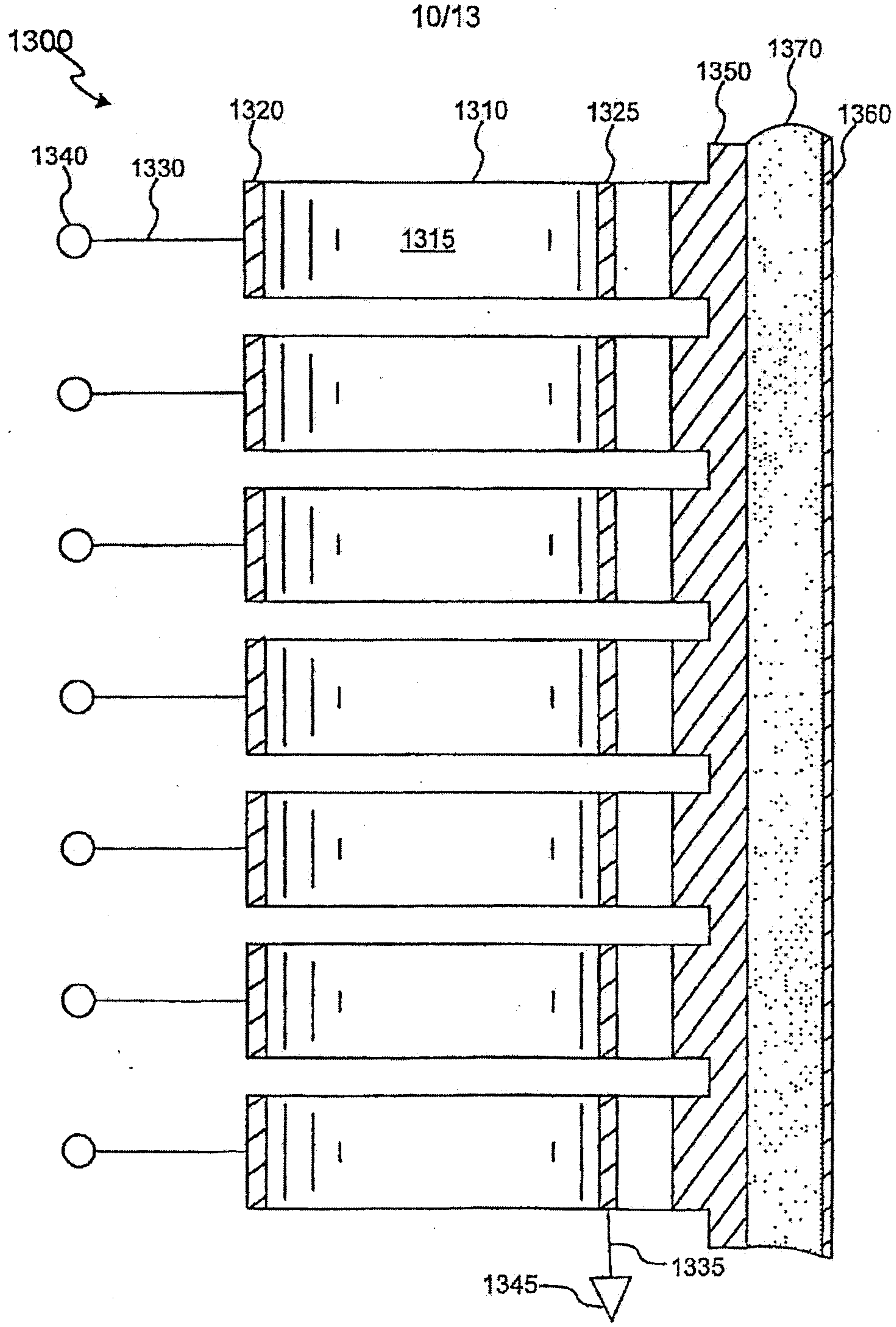


FIG. 13

SUBSTITUTE SHEET (RULE 26)

REPLACEMENT SHEET
11/13

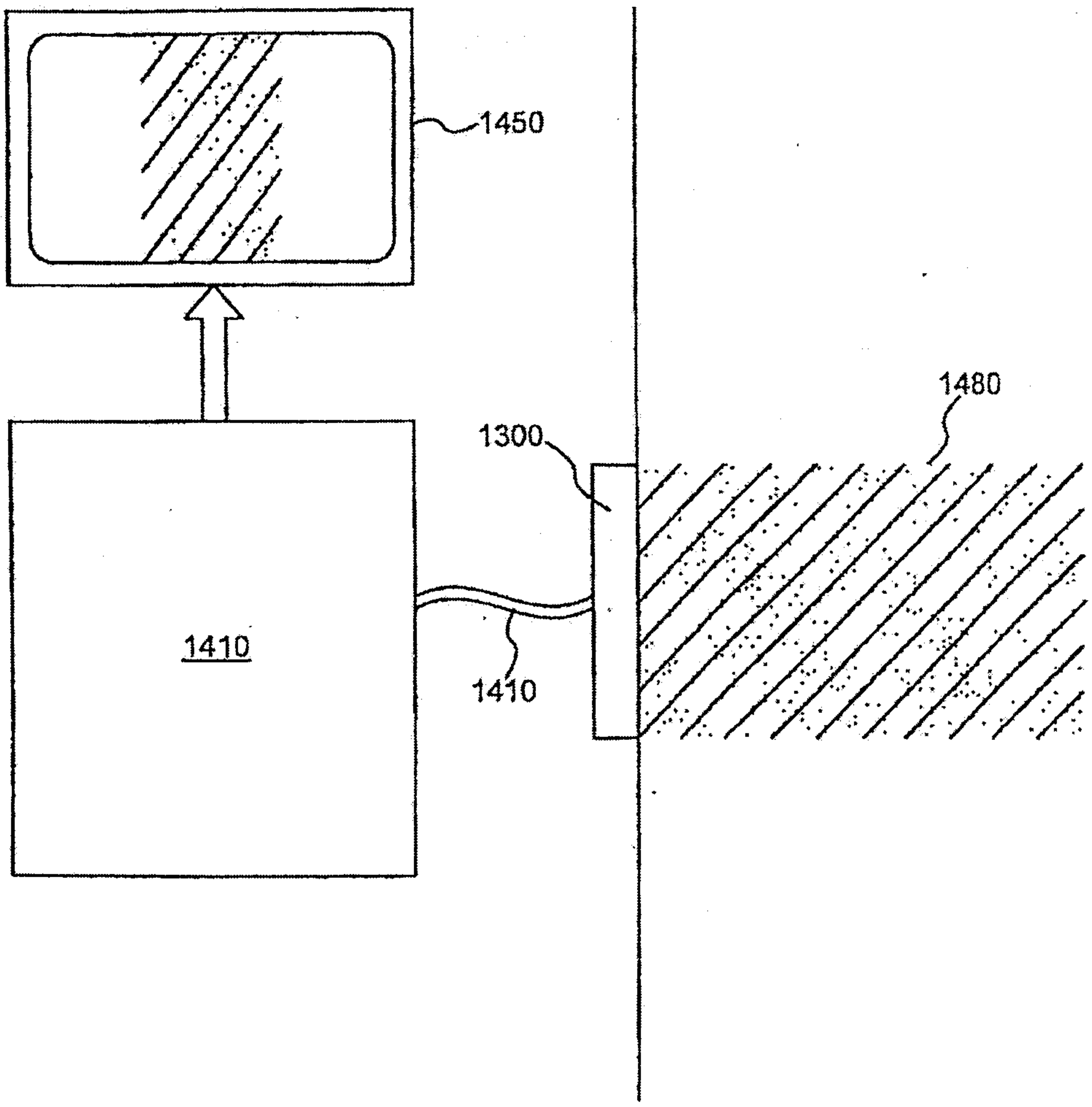


FIG. 14A

REPLACEMENT SHEET
12/13

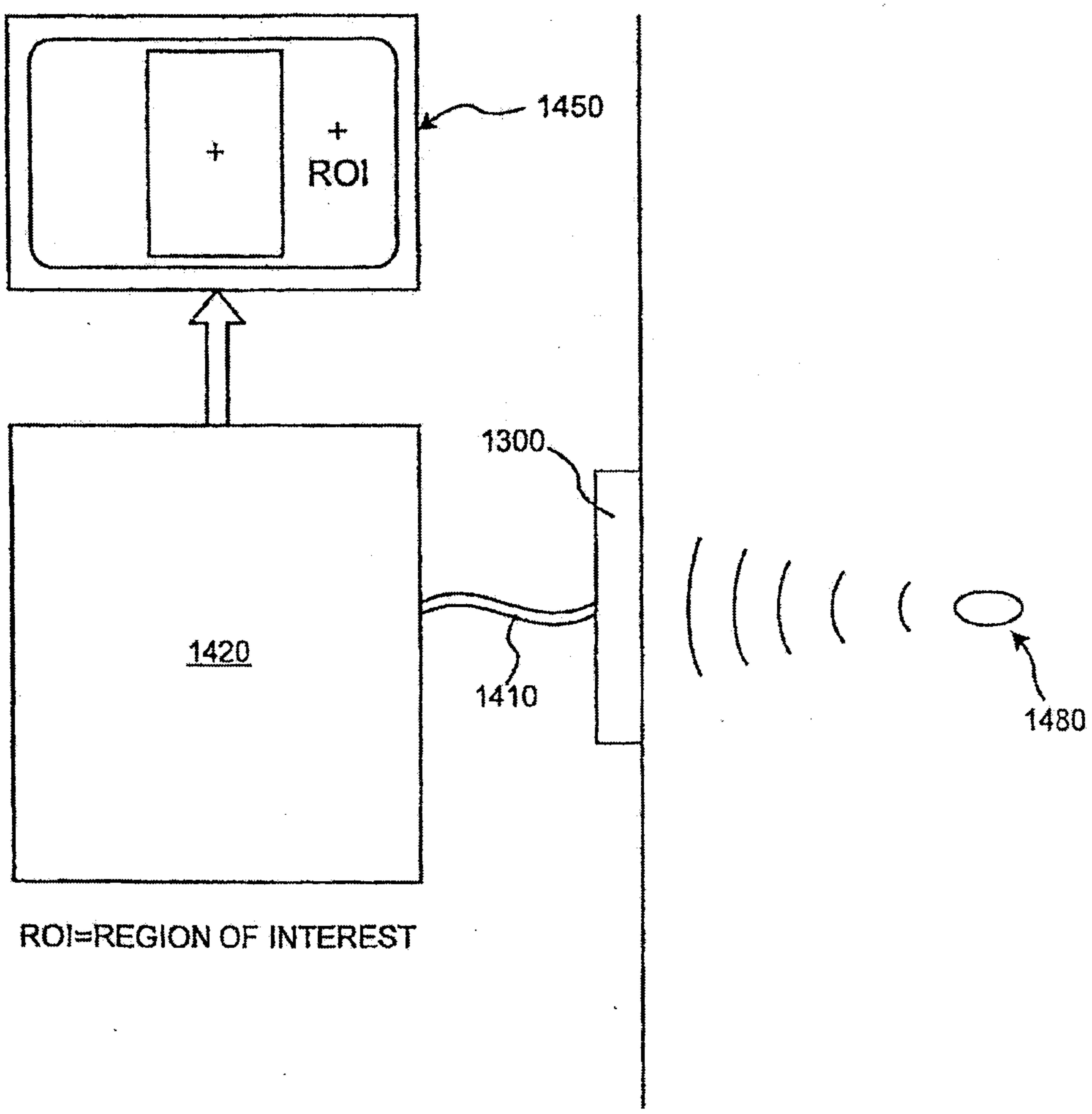


FIG. 14B

REPLACEMENT SHEET

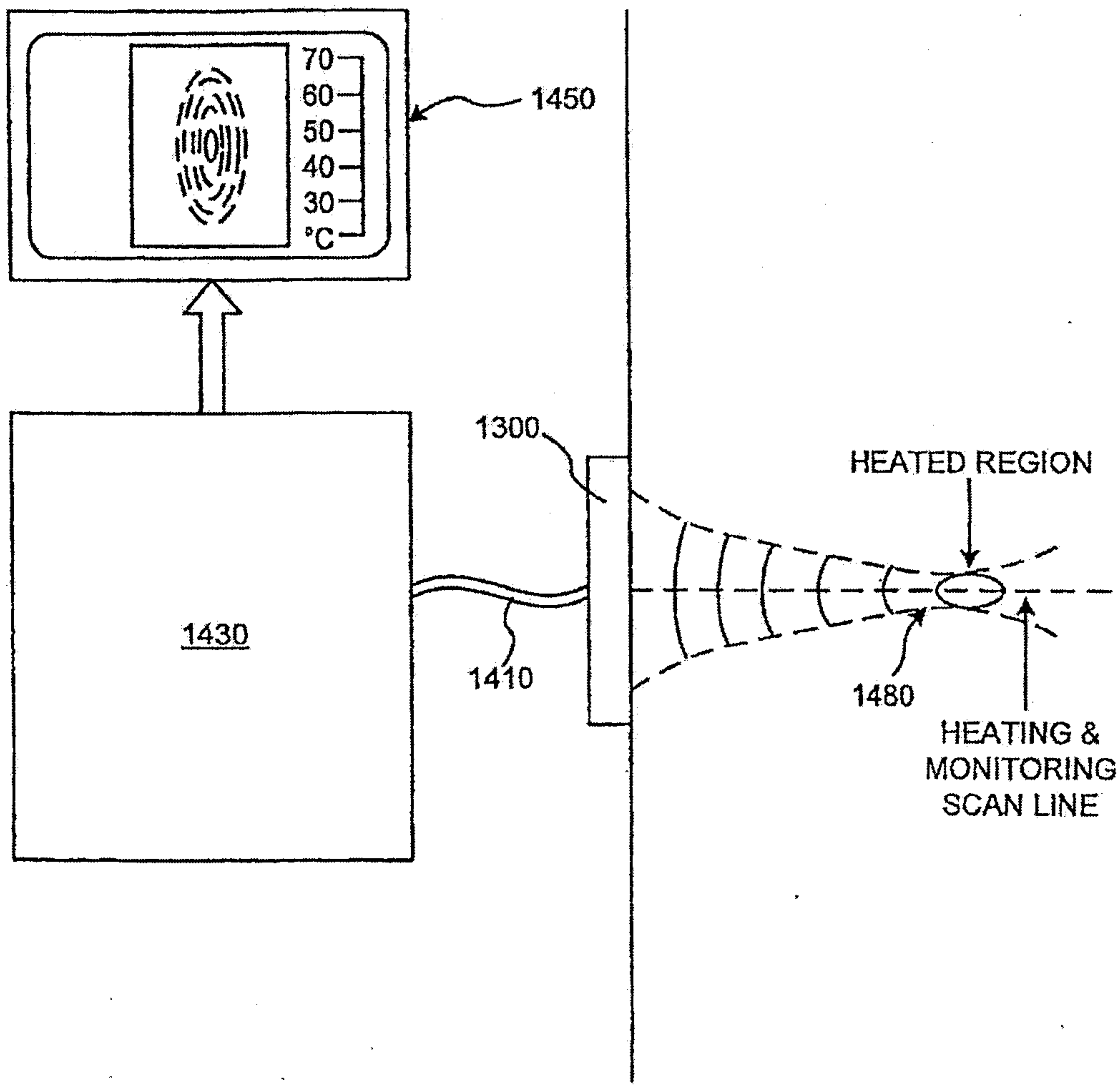
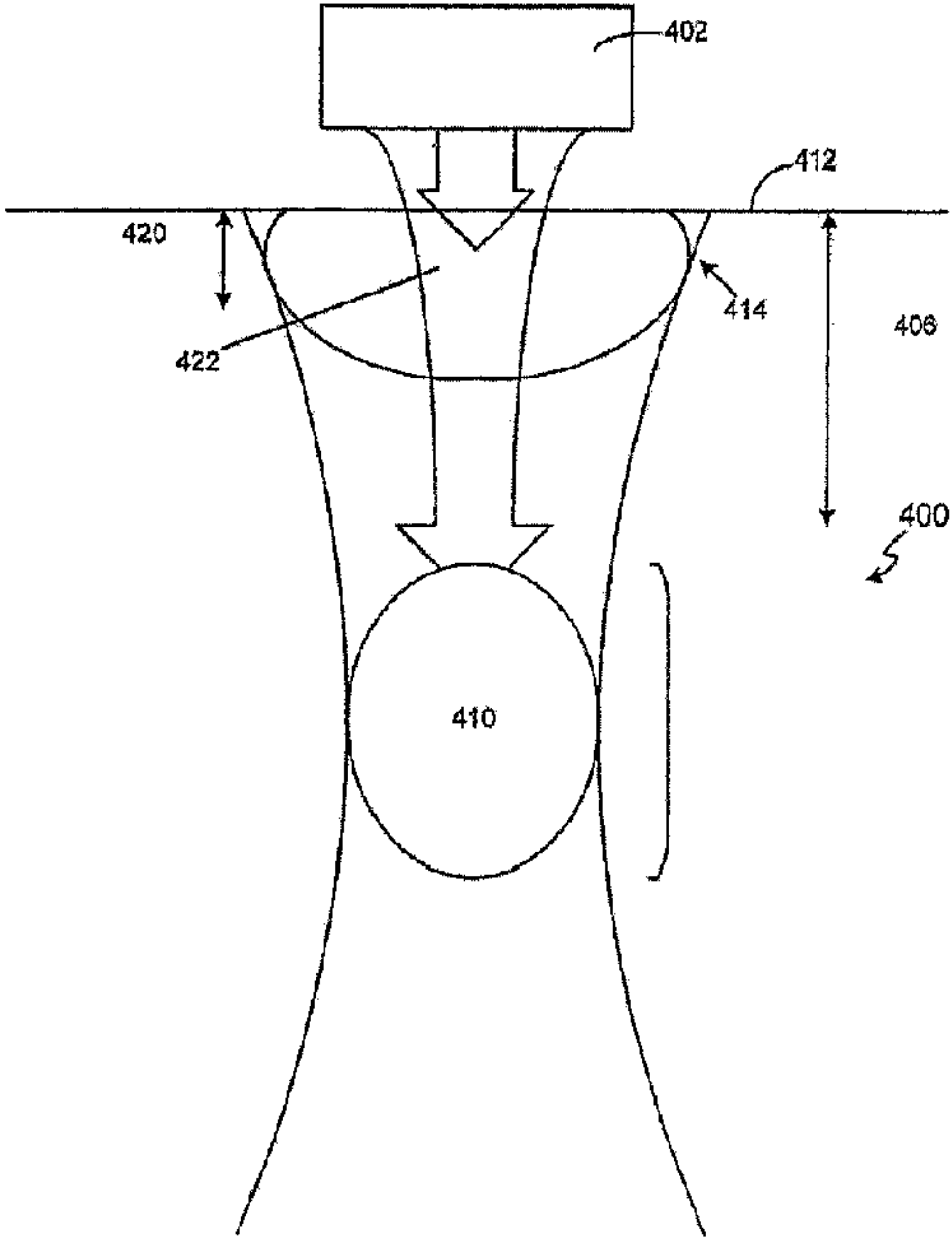


FIG. 14C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