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## (54) Title: COUPLING DETECTION FOR ULTRASOUND TREATMENT DEVICE

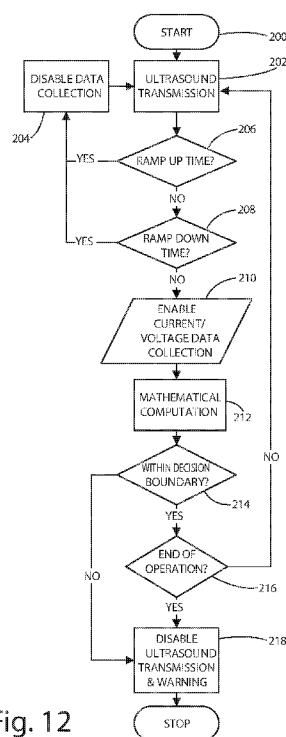


Fig. 12

(57) Abstract: A system and method of detecting coupling between an ultrasound treatment device and human tissue using voltage and/or current feedback mechanism at a singular frequency. The method includes the general steps of: determining the appropriate drive frequency for a transducer, determining the decision boundary for that transducer at the determined drive frequency, applying a drive signal at the determined drive frequency, sensing the current and/or voltage of the drive signal at the determined drive frequency and determining status of coupling based on a comparison of the sensed current and/or voltage with the determined decision boundary. When the decision boundary has been crossed, an alarm may be presented and/or the power may be reduced or eliminated. Current and/or voltage measurements at a secondary drive frequency may be used and compared to a secondary decision boundary to improve accuracy in some applications.

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COUPLING DETECTION FOR ULTRASOUND TREATMENT DEVICEBACKGROUND OF THE INVENTION

[0001] The present invention relates to ultrasound treatment devices, and more particularly to systems and methods for determining coupling between an ultrasound device and a treatment target.

[0002] The present invention relates to acoustic transducers which generate sound waves that have been utilized extensively in medical and non-medical applications, including but not limited to diagnostic and therapeutic applications. For example, high frequency ultrasound waves with frequencies above 5 MHz are often used to non-invasively visualize the organs, tissues, or blood flows inside human bodies for diagnostic purposes whereas ultrasound with frequencies lower than 5 MHz are frequently used to treat a variety of clinical conditions such as uterine fibroids, tumors, brain disorders, and etc. by triggering cell death via elevating tissue temperature or mechanical disruption.

[0003] In most cases, piezoelectric materials such as lead zirconate titanate (PZT) or lead titanate, metaniobate and bismuth titanate materials in the form of ceramics, crystal, or composite, are used to transform electrical energy into acoustical energy and high frequency acoustic waves are generated and transmitted into the body. As the ultrasound waves pass through the body, tissue medium absorbs the acoustic energy and dissipates it into heat. Through electrical steering or physical lenses, acoustic energy can be focused transcutaneously in a very confined volume inside the body where rapid temperature rises and tissue alterations occur within seconds. Typically, the acoustic transducer of such a device is in direct contact with the user's skin for energy transmission. However, because of the acoustic impedance mismatch, the air gap between the transducer surface and the skin can cause significant energy reflection and loss. To allow efficient acoustical energy transmission into the user's body, an acoustic coupling medium (e.g. ultrasound gel) is often applied to fill

the gap at the transducer/skin interface. However, inadequate couplant at the transducer/skin interface as well as inappropriate placement of the transducer on the skin can sometimes lead to inefficient energy delivery and thus reduce the efficacy of the device.

[0004] Ultrasound treatment devices (“UTD”) utilize focused ultrasound (“FUS”) energy to generate mild temperature rises within a localized region in different skin layers. The users using UTD need to be alerted when the transducer is decoupled from the skin due to inadequate couplant or misplacement of the transducer so that the acoustic transmission can be re-established by reapplying the couplant or adjusting the transducer position. It may be beneficial to detect the decoupling induced by the lack of the couplant and potential air pockets trapped inside the couplant as the acoustic energy partially reflected at the transducer/skin interface under such circumstances can generate skin irritation for the users.

[0005] At least one conventional ultrasound device implements a method of sensing coupling using a frequency sweep function (see, for example, US Pub. No. US2013/0012838 to Jaeger et al, filed on July 11, 2012). With this method, the frequency of the power applied to the acoustic transducer sweeps through a determined frequency window. Feedback from the frequency sweep is evaluated to determine coupling. The use of a frequency sweep function complicates operation and does not result in optimal operation in many applications.

### SUMMARY OF THE INVENTION

[0006] The present invention provides a system and method of detecting coupling between an ultrasound treatment device and human tissue or organ (e.g. skin) using voltage and/or current feedback mechanism at a singular frequency. In some applications, the system and method may involve supplemental voltage and/or current feedback at one or more supplemental frequencies.

[0007] In one embodiment, the method includes the general steps of (a) providing a transducer (e.g. electroacoustic element and waveguide assembly), (b) determine the appropriate drive frequency for that transducer, (c) determining the decision boundary for

that transducer at the determined drive frequency, (d) applying a drive signal to the transducer at the determined drive frequency, (e) sensing the current and/or voltage of the drive signal at the determined drive frequency and (f) determining status of coupling based on a comparison of the sensed current and/or voltage with the determined decision boundary. When the decision boundary has been crossed, the method may implement one or more additional steps, such as sounding an alarm (e.g. audible, visual and/or haptic) and/or reducing or eliminating the supply of power to the transducer.

[0008] In one embodiment, the step of determining the decision boundary for a specific transducer includes the general steps of: (a) applying a drive signal to a transducer at a singular frequency, (b) measuring the voltage or current sense values multiple times when the load medium is degassed water, (c) averaging the measured value, (d) determining the decision boundary, which can be a proportion of the average of the measured values and (e) setting the decision boundary in the device firmware or other nonvolatile memory.

[0009] In one embodiment, the method may include additional steps intended to assist in differentiating loss of coupling from a shift in resonant frequency as the transducer heats up during use. In such embodiments, the method may include the additional general steps of: (a) determining the decision boundary for that transducer waveguide assembly at a secondary frequency, (b) applying a drive signal to the transducer at the secondary drive frequency, (c) sensing the current and/or voltage of the drive signal at the secondary drive frequency and (d) determining status of coupling based on a comparison of the sensed current and/or voltage with the determined secondary decision boundary. In one embodiment, the use of a secondary drive frequency is implemented only when an analysis of the voltage and/or current at the primary drive frequency shows that it has crossed the decision boundary. In some applications, the present invention may include two or more secondary frequencies to assist in differentiating between a loss of coupling and a shift in resonant frequency.

[0010] In one embodiment, the ultrasound treatment device includes an ultrasound transducer with a minimum numbers of transmission layers where the acoustic impedances decrease in a cascade from the electroacoustic element (e.g. piezoelectric active element) to the transducer active surface. For example, the ultrasound transducer may include an electroacoustic element coupled to a one-piece solid waveguide. The electroacoustic element may be affixed on one side of the solid waveguide and the solid waveguide may have a target contact surface on the opposite side.

[0011] In one embodiment, the system includes current and/or voltage sense circuitry coupled to the drive input of the transducer. The output of the current and/or voltage sense circuitry may be coupled to a microcontroller or an application specific integrated circuit (ASIC) or a graphic processing unit (GPU) that analyzes the signal and determines coupling status. The current and/or voltage sense circuitry may be configured to provide an analog output. However, the current and/or voltage sense circuitry may alternatively be configured to provide a digital output.

[0012] In one embodiment, the system includes a peak detect circuit that processes the output of the current and/or voltage sense circuitry. The peak detect circuit may provide a near DC level that represents the maximum voltage value of the sense signal.

[0013] In one embodiment, the controller (e.g. microcontroller) includes an analog-to-digital converter that converts the analog output of the current and/or voltage sense circuitry into a digital signal. In such applications, the controller may also include digital signal analysis circuitry to analyze the digital signal as needed to allow determination of coupling status.

[0014] In one embodiment, the system may include a filter, such as a frequency filter, for filtering the output signal from the sense circuitry. The filter may be disposed between the sense circuitry and the controller and, in some applications, between the sense circuitry and the peak detect circuit. If desired, the filter may include an amplification stage.

[0015] In one embodiment, the system includes a drive signal generator that produces a time varying signal of sufficient electrical power to generate the proper acoustic energy for the application. In one embodiment, the drive signal generator generally includes a frequency synthesizer and voltage drive block that generate a signal at the appropriate frequency and transducer drive circuitry that may amplify the signal to appropriate level.

[0016] The present invention provides a simple and effective system and method for determining coupling status of an ultrasound treatment device. The method allows reliable evaluation of coupling without the need to repeatedly vary the frequency of the drive signal during operation. The method may involve preliminary steps that allow drive frequencies and decision boundaries to be determined and established on a product by product basis. In some applications, the method may involve evaluation at a secondary drive frequency to assist in differentiating between temperature-based current/voltage shifts and coupling-based current/voltage shifts. The ultrasound device may include an electroacoustic element affixed to a one-piece solid waveguide, which provides improved performance when implementing a method in accord with an embodiment of the present invention. In other applications, the waveguide may have a plurality of layers arranged so that each layer has progressively lower acoustic impedance than the previous layer, which will again provide better performance.

[0017] These and other objects, advantages, and features of the invention will be more fully understood and appreciated by reference to the description of the current embodiment and the drawings.

[0018] Before the embodiments of the invention are explained in detail, it is to be understood that the invention is not limited to the details of operation or to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention may be implemented in various other embodiments and of being practiced or being carried out in alternative ways not expressly disclosed herein. Also, it is to be understood that the phraseology and terminology used herein are for the

purpose of description and should not be regarded as limiting. The use of "including" and "comprising" and variations thereof is meant to encompass the items listed thereafter and equivalents thereof as well as additional items and equivalents thereof. Further, enumeration may be used in the description of various embodiments. Unless otherwise expressly stated, the use of enumeration should not be construed as limiting the invention to any specific order or number of components. Nor should the use of enumeration be construed as excluding from the scope of the invention any additional steps or components that might be combined with or into the enumerated steps or components. Any reference to claim elements as "at least one of X, Y and Z" is meant to include any one of X, Y or Z individually, and any combination of X, Y and Z, for example, X, Y, Z; X, Y; X, Z ; and Y, Z.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0019] Fig. 1 is a schematic block diagram of a transducer configured for use in connection with the present invention.

[0020] Fig. 2 is a schematic block diagram of an alternative transducer having an extended acoustic transmission line that can be used in connection with the present invention.

[0021] Fig. 3 are graphs showing impedance against frequency at different levels of coupling.

[0022] Fig. 4 are graphs showing impedance against frequency at different levels of coupling.

[0023] Fig. 5A are graphs of the low pass frequency components of the graphs of Fig. 4.

[0024] Fig. 5B are graphs of the high pass frequency components of the graphs of Fig. 4.

[0025] Fig. 6 shows current sense values for different devices taken with different levels of coupling.

[0026] Fig. 7 shows the current sense values of Fig. 6 after normalization.

[0027] Fig. 8 is a plurality of scatter plots showing current sense values at two secondary frequencies where the secondary frequencies vary from graph to graph.

[0028] Fig. 9 is a plurality of scatter plots showing current sense values at two secondary frequencies where the difference between the frequency #1 and frequency #2 vary from graph to graph.

[0029] Fig. 10 is a schematic block diagram an acoustic module in accordance with an embodiment of the present invention.

[0030] Fig. 11 is a graph of a sensed value against time showing ramp up and ramp down windows.

[0031] Fig. 12 is a flow chart showing the general method steps in one embodiment of the present invention.

[0032] Fig. 13 is a perspective view of an ultrasound device.

[0033] Fig. 14 is a partially sectional view of the acoustic module showing the transducer mounted to the solid waveguide.

## DESCRIPTION OF THE CURRENT EMBODIMENT

### [0034] I. Overview.

[0035] The present invention provides a system and method for determining coupling status between an ultrasound treatment device and a treatment target. The present invention is well-suited for use with ultrasound devices that incorporate a one-piece, solid waveguide (e.g. Fig. 1), but may also be suitable for use with certain multiple layered waveguides (e.g. Fig. 2). In one embodiment, the present invention is incorporated into the ultrasound device 10 of Figs. 13 and 14. In this embodiment, the ultrasound device 10 is a handheld unit that includes a transducer 12 having an electroacoustic element 14 and a solid waveguide 16. The electroacoustic element 14 is secured to the waveguide 16, for example, by epoxy or other suitable adhesive. The ultrasound device 10 includes a controller 112 configured to control the supply of power to the electroacoustic element 14. The controller 112 is configured to

determine the coupling status of the ultrasound device 10 and to take remedial action when it has determined that coupling is not adequate. In the illustrated embodiment the controller 112 is configured to determine coupling status by monitoring a characteristic of the power supplied to the electroacoustic element 14 at a singular frequency. For example, the controller 112 of the illustrated embodiment determines the coupling status by comparing a monitored voltage and/or current of the signal applied to the electroacoustic element 14 against a predetermined decision boundary for that transducer 12. In the illustrated embodiment, the operating frequency is determined individually for each transducer 12 and the decision boundary is determined individually for each transducer 12 based on the determined operating frequency. In some applications, the transducer 12 may undergo a significant change in resonant frequency as the transducer 12 heats up during operation. This change in resonant frequency may have enough affect on the monitored current and/or voltage to affect accuracy in determining coupling status. When desired, the controller 112 may implement additional steps to assist in differentiating between loss of coupling and temperature-based shifts in resonant frequency. For example, the method may include the additional steps of monitoring the current and/or voltage of the drive signal at a secondary drive frequency and comparing the sensed current and/or voltage with a predetermined secondary decision boundary.

[0036] Directional terms, such as “vertical,” “horizontal,” “top,” “bottom,” “upper,” “lower,” “inner,” “inwardly,” “outer” and “outwardly,” are used to assist in describing the invention based on the orientation of the embodiments shown in the illustrations. The use of directional terms should not be interpreted to limit the invention to any specific orientation(s).

[0037] II. Coupling Detection.

[0038] As noted above, the present invention provides a system and method for detecting coupling status in the context of an acoustic transducer. For example, the present

invention may be used in an ultrasound treatment device to detect coupling status during operation of the acoustic module. Generally, the system is configured to supply an AC drive signal to the transducer at a singular drive frequency while detecting coupling status based on the current and/or voltage of the drive signal. Experience has revealed that undesired decoupling can be caused by a variety of reasons. For example, in the context of an ultrasound device used to treat skin, several common reasons that can cause the device to decouple from the skin include: (1) insufficient couplant (e.g. ultrasound gel); (2) excessive air pockets or gaps between the transducer and the skin; and (3) misalignment between the transducer application surface and the skin. All of these issues result in an acoustic impedance mismatch between the ultrasound transducer and the load medium (e.g. skin). This acoustic impedance mismatch can reduce acoustic energy transmission to the target and adversely impact efficiency.

[0039] The current method is ideal for an ultrasound transducer with minimum numbers of transmission layers where the acoustic impedances decrease in a cascade from the piezoelectric active element to the transducer active surface. For example, the best performance may be achieved using a one-piece, solid waveguide. The method of the present invention may be less effective when used with an ultrasound transducer having an acoustic window or matching layers whose acoustic impedance is higher than the previous transmission layer and the thickness is a multiple of half acoustic wavelength.

[0040] The ultrasound device 10 can be a handheld or fixed device which typically includes a frequency synthesizer, a voltage/current regulator, a power amplifier and an ultrasound electroacoustic element 14. The general electronic components are subject to a wide variety of implementations. For example, the present invention may be implemented in connection with the ultrasound device with solid waveguide of the general type shown in US Serial No. 15/234,217, entitled ACOUSTIC MODULE AND CONTROL SYSTEM FOR HANDHELD ULTRASOUND DEVICE, which was filed on Aug. 11, 2016, by Access

Business Group International, LLC, and which is incorporated herein by reference in its entirety. An ultrasound device 10 in accordance with that disclosure is shown in Figs. 13 and 14. In this embodiment, the ultrasound device 10 is a handheld unit that includes an acoustic module 12 having an electroacoustic element 14 and a solid waveguide 16. The electroacoustic element 14 is secured to the waveguide 16, for example, by epoxy or other suitable adhesive. The ultrasound device 10 of this embodiment may include acoustic drive circuitry 100 in accordance with the schematic block diagram of Fig. 10, in which the frequency synthesizer and voltage/current regulator are integrated into the frequency synthesizer and voltage drive block 102 and the power amplifier is implemented in the transducer drive circuitry 104. The electroacoustic element 14 typically has relative high acoustic impedance whereas the impedance of the air is low, causing significant energy reflections as the acoustic waves pass through the transducer/air/skin interfaces. In contrast to the air, typical coupling medium has higher acoustic impedance close to water, leading to gradual impedance transition from the transducer to the skin and efficient acoustic energy transmission. When decoupling occurs, the acoustic load impedance at the transducer's surface falls in between ideal coupling (e.g. water) and complete no coupling (e.g. air). Such impedance mismatch causes changes of voltage and current of the driving circuitry and is used in the current method to detect the coupling condition between the device and the skin.

[0041] With current manufacturing methods, it is typical for each ultrasound device to have a somewhat different resonant frequency than other ultrasound devices of even the same design. These differences are typically the result of manufacturing variations, such as variations in the material used to manufacture each transducer and/or locational variations in the layer of adhesive joining the transducer to the waveguide. In the present invention, the method includes a number of optional steps that can be used to take into consideration any variations. For example, the method may include the general steps of determining the operating frequency of each acoustic module on a device-by-device basis and determining the

decision boundary for each acoustic module on a device-by-device basis at that acoustic module's operating frequency. The appropriate operating frequency for each ultrasound device 10 may be determined individually by subjecting that device 10 to a reference coupling state, applying an AC signal to the transducer 12 at a plurality of different frequencies (e.g. a frequency sweep through a range of potential frequencies) and monitoring a characteristic of the power applied to transducer 12 (e.g. the current and/or voltage of the AC signal) to determine the operating frequency that provides optimal current and/or voltage readings. The reference coupling state may vary from application to application, but in the illustrated embodiment includes coupling the transducer 12 to degassed water.

[0042] In the illustrated embodiment, the separately determined operating frequency of the transducer 12 will be used in implementing the coupling detection method. For example, the coupling detection method includes the general steps of (a) providing a transducer with an electroacoustic element and a waveguide, (b) determine the appropriate drive frequency for that transducer, (c) determining the decision boundary for that transducer at the determined drive frequency, (d) applying a drive signal to the transducer at the determined drive frequency, (e) sensing the current and/or voltage of the drive signal at the determined drive frequency and (f) determining status of coupling based on a comparison of the sensed current and/or voltage with the determined decision boundary. When the decision boundary has been crossed, the method may implement one or more additional steps, such as sounding an alarm (e.g. audible, visual and/or haptic) and/or reducing or eliminating the supply of power to the transducer.

[0043] In contrast to prior methods of using frequency sweep to detect coupling, the present invention provides a method of detecting the loss of coupling through measuring the voltage or current changes of the driving circuitry at a singular frequency or tandem frequency. The present method can also detect the loss of coupling by measuring the voltage/current at multiple individual frequencies in an arbitrary fashion.

[0044] As the coupling condition changes, the load acoustic impedance changes which in turn affect the overall electrical impedance of the transducer. A simple schematic based on KLM model is shown in Fig. 1. This schematic may be used to model an acoustic module having a transducer 12 with an electroacoustic element 14 affixed to a one-piece solid waveguide 16.

[0045] More complex acoustic modules can also be modeled using KLM modelling. For example, Fig. 2 shows an alternative ultrasound transducer 12' with a multiple-layered waveguide 16' in front of the electroacoustic element 14' (e.g. active piezoelectric element). In this alternative embodiment, the acoustic impedance for the front layers,  $Z_{\text{front}}$ , including the load medium can be back calculated recursively from the load to the piezoelectric active material using the following formula:

$$Z_{n,in} = Z_n \frac{Z_{n+1,in} + jZ_n \tan(k_n \cdot d_n)}{Z_n + jZ_{n+1,in} \tan(k_n \cdot d_n)}$$

Where the n-th layer is the layer close to the electroacoustic element 14' while  $d_n$  is its thickness and  $k_n = \omega/c_n$  is the corresponding ultrasound wave number.

[0046] Combining with KLM model of an embodiment including a solid waveguide (e.g. Fig. 1), the electrical impedance changes of the transducer 12 at the electronic end induced by the frontal load changes are simulated and shown in Fig. 3.

[0047] At the resonant frequency  $f_r$ , different coupling conditions show that maximum differences and the impact of impedance changes on the voltage or current of the driving circuitry at  $f_r$  can be measured in real time and utilized as a feedback of coupling detection. Voltage or current changes at off-resonant frequency (e.g.  $f_1$  or  $f_2$ ) can also be used as coupling detection indicators. The impedance differences between different coupling conditions at off-resonant frequencies are smaller than the differences at resonant frequency, but can be less susceptible to thermal variations of the transducer.

[0048] For certain ultrasound transducers with the acoustic impedance of the  $n^{th}$  layer higher than the  $(n - 1)^{th}$  and  $(n + 1)^{th}$  layer, local maximum and minimum can be seen on the impedance spectrum. Fig. 4 shows the acoustic impedance curve, while Figs. 5A and 5B show the low pass and high pass frequency components, respectively. Significant differences can be seen on the high frequency components of the electrical impedance where partial decoupling is dramatically higher than ideal coupling. Low frequency components show little or no differences under different coupling conditions, but as the temperature of the transducer changes, low frequency spectral shift might be seen.

[0049] In some applications, thermal variations of the transducer (e.g. transducer heat up during operation) can cause spectrum shift of the impedance curve, which may in some embodiments compromise the accuracy of single frequency coupling detection method proposed above. To overcome the spectrum shift, a supplemental coupling detection method may be implemented. For example, a supplemental coupling detection method includes measuring the voltage or current of the driving circuitry at multiple frequencies in an arbitrary (or non-arbitrary) order or a combination of different frequencies. A weighted linear regression model can also be implemented for coupling detection.

$$i_{all} = a_0 \cdot i_{f_r} + a_1 \cdot i_{f_1} + a_2 \cdot i_{f_2} + \dots$$

$$v_{all} = a_0 \cdot v_{f_r} + a_1 \cdot v_{f_1} + a_2 \cdot v_{f_2} + \dots$$

Where  $i$  and  $v$  are the current and voltage measurements of the driving circuitry respectively.  $a_0, a_1, a_2, \dots$  are the weights for each frequency components. The weights are assigned based on characteristics of the transducer structure. For example,  $a_0$  can be the largest since the maximum impedance changes occur at the resonant frequency. Depending on the direction of the spectrum shift, different  $a_1, a_2 \dots$  can be assigned. For example,  $a_1 > a_2$  can be used and  $a_2$  is penalized if the spectrum shift right or vice

versa. A neural network model can also be implemented for coupling detection for multiple frequencies scenario. For example, a N-layered neural network,

$$\text{Layer 1: } a_1 = g_1(W_1 \cdot S + B_1)$$

$$\text{Layer 2: } a_2 = g_2(W_2 \cdot a_1 + B_2)$$

$$\vdots$$

$$\text{Layer N: } a_N = g_N(W_N \cdot a_{N-1} + B_N)$$

Where S is the matrix representation of current and voltage measurements at different driving frequencies.  $W_1, W_2, \dots, W_N$  are the weights and  $B_1, B_2, \dots, B_N$  are the biases in different layers for all frequencies.  $g_1, g_2, \dots, g_N$  are the activation functions in different layers and they can have same or different forms such as Rectified Linear Units (ReLU), sigmoid, hyperbolic tangent, step, or sign functions, etc.

[0050] In practice, different transducers or ultrasound devices have different electrical as well as acoustical characteristics, leading to different ranges of voltage or current sensing values even when the load mediums are the same. For singular frequency coupling detection method, a generalized coupling decision boundary is determined based on the voltage or current sensing value of a reference load medium (e.g. water or air) for each individual transducer or ultrasound device. Examples of graphs reflecting the data for a plurality of different devices determining such a decision boundary using water as the reference is shown in Fig. 6. Although the devices represented in Fig. 6 are essentially the same (e.g. same model with same design specifications), they have different current sense values as a result of manufacturing variations. In these graphs, each device is referred to as a different sample (e.g. Sample#1 is a first device, Sample#2 is a second device and so on). To generate these graphs, a plurality of current sense values are collected while the device is in each of four different reference states: (a) coupled to degassed water, (b) subject to good

coupling, (c) subject to partial coupling and (d) with no coupling. The graphs in Fig. 6 show the average current sense values for each device in each reference state.

[0051] Once the reference data for a device (or a plurality of devices of the same design) is collected, the decision boundary can be determined using a variety of mathematical models. For purposes of disclosure, one exemplary method of determining the decision boundary will be described, but the method may vary from application to application. In the illustrated embodiment, the average current sense values for each coupling state of a plurality of devices are normalized to scale to 1.0 the average current sense value when coupled to degassed water. Fig. 7 shows the graphs of Fig. 6 normalized with respect to coupling with degassed water. Once normalized, the decision boundary or decision boundary formula can be selected based on one or more of the normalized average current sense values. In the illustrated embodiment, the decision boundary formula is selected to be a proportion of the normalized average current sense value for degassed water. Fig. 7 shows two lines D1 and D2 that represent potential decision boundaries or decision boundary formulas (i.e. 0.8 and 0.9 of the normalized average current sense value for degassed water), both of which may be acceptable depending on the application. A variety of mathematical models may be implemented to select a decision boundary formula based on the normalized current sense values for degassed water. However, selection of a decision boundary or decision boundary formula need not follow a specific mathematical model, but may be selected to provide the desired balance of consistent recognition of inadequate coupling against minimization of false determinations of inadequate coupling.

[0052] Although Figs. 6 and 7 show average current sense values for various reference coupling states, the present invention may be implemented using sensed values from only one reference coupling state. For example, in this embodiment, selection of the decision boundary may be based solely on the degassed water reference

coupling state without reference to the sensed values from other reference coupling states. To implement the singular frequency coupling detection for an ultrasound transducer using only the degassed water reference coupling state, the following general steps are carried out: (1) measure the voltage or current sense values multiple times when the load medium is degassed water; (2) average the measured value; (3) determine the decision boundary which can be a proportion of the reference values from the prior step; (4) set the decision boundary in the device firmware or non-volatile memory. During the device operation, device can send out an alarm as the voltage and/or current sense values cross the decision boundaries, which indicate poor coupling or no coupling. Ultrasound transmission can also be turned off through device firmware control when it is determined that coupling is inadequate. In this example, the decision boundary is selected based solely on the current sense values taken when coupled to degassed water. This is not necessary and the decision boundary may be determined based on current sense values taken at any one or more of the reference coupling states. For example, the decision boundary may be determined based on a weighted combination of the current sense values taken at any combination of the four reference coupling states reflected in Figs. 6 and 7 (or other reference states that may be selected on a case-by-base basis). Alternative reference states may involve the use of reference materials other than degassed water, including alternative materials that have different acoustic impedance than degassed water. Although the examples reflected in Figs. 6 and 7 are based on current sense values, the present invention may be implemented using current and/or voltage values.

[0053] In typical applications, such as the example discussed above, a separate decision boundary is determined for each ultrasound device, but that decision boundary is based on a decision boundary formula created from data collected from a plurality of ultrasound devices manufactured using that product design. For example, the method of

determining the decision boundary or decision boundary formula for an ultrasound device product design may involve collecting data from a plurality of separately manufactured devices of that design and using the data collected from the plurality of devices to determine a decision boundary formula that is common to all devices with that product design. In some applications, the decision boundary formula may include as a variable the device's operating frequency (or other variables that may vary from device to device) and may therefore result in a decision boundary that varies from device to device to the extent that the operating frequency varies. In other applications, the decision boundary formula may be independent of operating frequency (or any other variables that vary from device to device). In those other applications, the decision boundary may be identical from device to device. Although the present invention may be implemented in a method that uses a common decision boundary formula for devices of the same design, the present invention may be implemented in a method that determines a separate decision boundary formula or separate decision boundary for each device.

[0054] Acoustic properties of the acoustic transmission line of a transducer or device tend to vary as the transducer or device warms up, leading to the spectrum shift on the transducer impedance curve. To avoid transducer overheating, singular frequency coupling detection method could tend to set decision boundary toward perfect coupling (e.g. water), causing more unnecessary false positive (e.g. no coupling is positive). A tandem frequency coupling detection method is proposed to improve the detection accuracy for some applications. The current or voltage feedbacks at a pair of frequencies can be used to differentiate good coupling (coupled) against poor coupling (decoupled) with improved accuracy. The detection accuracy is based on careful selections of the two frequencies and the differences between them. In one application, the two frequencies may include the operating frequency (e.g. resonant frequency of the transducer) and a secondary frequency (e.g. an off-resonant frequency). In other

applications, the method may include consideration of the operating frequency and more than one secondary frequency. In still other applications, the method may take into consideration only one or more “off-resonance” frequencies.

[0055] For an ultrasound transducer with minimum numbers of transmission layers with decreasing acoustic impedances, as the transducer warms up, its frequency curve tends to shift towards higher frequency. Choosing a pair frequencies lower than the resonant frequency ( $f_r$ ) can provide better detection accuracy. Fig. 8 shows exemplary scatter plots for such a transducer with different starting frequencies ( $f_1$ ) but the same frequency difference ( $\Delta f$ ). More specifically, each scatter plot shows a plot of current sense values taken at a first frequency and a second frequency. The symbol used to represent each point on the scatter plot shows whether or not that sensed current value was obtained when the transducer was adequately coupled. The header for each plot provides the first frequency,  $f_1$ , and the change in frequency,  $\Delta f$ , used in obtaining the second frequency,  $f_2$ . In the scatter plots of Fig. 8, the first frequency varies from plot to plot, but the change in frequency remains the same. As can be seen, in each plot, the “coupled” and “decoupled” values are sufficiently distinct that a boundary curve can be determined to provide a high degree of separation between the “coupled” and “decoupled” values. The boundary curve can be determined using any of a variety of mathematical modeling algorithms for generating a boundary line or boundary curve. For example, the boundary curve may be determined using a quadratic supporting vector machine algorithm. Once determined, the boundary curve can be used as the decision boundary for determining coupling status during operation of the transducer.

[0056] Experience has revealed that change in frequency can also be adjusted to provide greater differentiation between “coupled” and “decoupled” sensed values measured at two different frequencies. This concept is illustrated in Fig. 9, which

includes exemplary scatter plots for a transducer with the same starting frequencies ( $f_1$ ), but different frequency differences ( $\Delta f$ ). Once the starting frequency ( $f_1$ ) is selected, the frequency differences ( $\Delta f$ ) can be adjusted. The effect of  $\Delta f$  is less significant comparing to the selection of  $f_1$ . However, if  $\Delta f$  is too large, the detection accuracy can decrease when  $f_1 < f_r < f_2$ . As with the scatter plots of Fig. 8, the plotted “coupled” and “decoupled” values are sufficiently distinct that a boundary curve can be determined to provide a high degree of separation between the “coupled” and “decoupled” values. As noted above, the boundary curve can be determined using any of a variety of mathematical modeling algorithms for generating a boundary line or boundary curve, such as a quadratic supporting vector machine algorithm. The determined boundary curve can be used as the decision boundary for determining coupling status during operation of the transducer. For multiple “off-resonant” frequencies scenarios, a neural network model can be implemented. In practice, for a plurality of ultrasound devices, signal (current or voltage) collected at resonant and “off-resonant” frequencies in different mediums (e.g. degassed water, air, isopropyl alcohol, etc.) can be firstly normalized to signal collected in air. By creating different decoupling scenarios, the neural network can then be trained, and the obtained weights and biases can be stored in nonvolatile memory (EEPROM) for a plurality of ultrasound devices for coupling detection. Depending on the scenarios of decoupling that need to be detected, a sigmoid or softmax function can be used in the final step of training the neural network.

[0057] The block diagram of Fig. 10 is representative of one implementation of electrical hardware (e.g. acoustic module drive circuitry 100) capable of implementing the coupling detection methods discussed above. This hardware may be incorporated into the ultrasound device 10 shown in Figs. 13 and 14. As noted above, the acoustic module drive circuitry 100 generally includes a frequency synthesizer and voltage drive block 102, a transducer drive circuitry block 104, a sense circuitry block 106, a

frequency filter block 108, a peak detect block 110 and a controller block 112. The controller block 112 includes analog digital converter and signal analysis block 114 and coupling status determination block 116.

[0058] In this embodiment, the electroacoustic element 14 (such as a PZT or ceramic) is driven by time varying signal of sufficient electrical power to generate the proper acoustic energy for the application. The frequency synthesizer and voltage driver block 102 provides the necessary signals to the transducer drive circuitry block 104. This block 102 may include essentially any suitable frequency synthesizer and voltage/current regulator. The transducer drive circuitry block 104 amplifies the drive signals to sufficient power levels and may also contain a matching network to ensure efficient energy transfer to the transducer at certain frequency or frequency range. The transducer drive circuitry block 104 may be implemented using essentially any suitable power amplifier circuitry. The sense circuitry block 106 may be configured to sense current and/or voltage. In this embodiment, the sense circuitry block 106 is configured to sense current. The current sense method of characterizing the electrical load, and thus the coupling condition, can be achieved with a variety of alternative sense circuitry implementations, such as a simple current sense resistor, current sense transformer, magnetic current sensing circuit, or other current sensing technology. In this embodiment, the primary purpose of the current sensing circuit block 106 is to convert the current to a proportionate voltage level that can be manipulated and measured by a controller (e.g. microcontroller 112) or other logical circuit. The frequency filter block 108 is an optional circuit block that is application specific. Depending on the waveguide materials and number of layers there may be frequency components of the signal that are not desirable in the sensed signal. The filtering may also be used to minimize or remove drift caused by thermal changes in the materials. In general, the frequency filter block 108 is useful for removing unwanted noise components that may complicate the

coupling detection and decision process. The peak detect functional block 110 is used to convert the time varying signal to a near DC level that represents the maximum voltage value of the sensed signal. The peak detect functional block 110 is helpful to take the burden off of the firmware and microcontroller 112 by removing the requirement for sampling rates that may be restrictive depending on the frequency of the drive signal. The peak detect functional block 110 may include essentially any peak detect circuitry. The output of the peak detect circuit 110 is sampled by an analog-to-digital converter that may or may not be integrated into the microcontroller 112. In the illustrated embodiment, the analog-to-digital converter is incorporated into the analog to digital cover and signal analysis block 114 implemented within the controller 112. Utilizing the information derived from the processed signal the microcontroller 112 provides feedback to the frequency synthesizer and voltage driver functional block 102 for the purpose of adjusting the acoustic output. The drive signals may be turned off to stop acoustic output, the drive signals may remain in their current state to allow the acoustic output to remain at its current output, or the drive signals may be adjusted to intentionally adjust the power output of the acoustic signal. This overall process creates a continuous control loop for intelligently and actively responding to various coupling conditions.

[0059] In the illustrated embodiment, the firmware provides the support required to control the ultrasound transmission of the ultrasound device 10. A firmware state machine executes the necessary steps to create the "On Cycle" sequence to power the ultrasound electroacoustic element 14. The "On Cycle" sequences are created by controlling the signal generator 102 output frequency and timing. The firmware can enable the ultrasound electroacoustic element 14 in continuous or pulsed mode. For both modes, at the start of the "On Cycle" (ramp up period) as well as the end of the "On Cycle" (ramp down period), the firmware may ignore the current/voltage sense

measurements or disable data collection to allow the settling of the current/voltage (See Fig. 11). Once the analog-to-digital count (ADC) measurements are settled, instantaneous data at single frequency or tandem frequencies are collected and mathematically calculated and compared with predetermined decision boundary during calibration (as discussed above). If the computed values are outside the decision boundary, the firmware will consider the ultrasound transducer 12 to be decoupled (or inadequately coupled) from the targeted medium and take remedial action. Although remedial actions may vary from application to application, in the illustrated embodiment, the firmware will disable the transducer acoustic/electrical output as well as send out alarm or warning.

[0060] An exemplary method of operation is shown in the flow chart of Fig. 12. In this embodiment, the process begins at block 200. Ultrasound transmission begins at block 202. The controller 112 may activate the acoustic drive circuitry 100 to supply power to the transducer 12. In this embodiment, data collection is disabled at block 204 if the controller 112 has determined that the process is within the ramp up time at block 206 or within the ramp down time at block 208. When outside the ramp-up and ramp-down times, the controller 112 enables current and/or voltage data collection at block 210. For example, the sense circuitry block 106 obtains sensed values of the current and/or voltage of the AC signal applied to the transducer 12. The output of the sense circuitry block 106 may pass through the frequency filter block 108 and the peak detect block 110. The signals may be received at the controller 112 via an analog to digital converter. The collected data is analyzed using the appropriate mathematical computations at block 212. The controller then determines if the sensed values have crossed the decision boundary at block 214. For example, the sensed values may be analyzed by the signal analysis block 114. This may include comparison of the sensed values against the decision boundary or boundaries, which may be determined using

one or more of the methods described above. If inadequate coupling is determined, the controller 112 will implement remedial action at block 218, which in this embodiment includes the steps of disabling ultrasound transmission and presenting a “decoupled” alarm (e.g. audible, visual or haptic alarms). Alternative remedial action may be taken by the controller 112. For example, rather than stopping transmission, the transmission power may simply be reduced. If coupling is adequate, the controller 112 determines whether the normal end of operation has been reached at block 216. For example, when the ultrasound device is configured to operate in timed pulses, the controller 112 will conclude that the end of operation has been reached when the pulse has been on for the desired pulse length. If the end of operation has not been reached, operation returns to block 202. If the end of operation has been reached, the controller 112 may disable the ultrasound and sound an “end of operation” alarm.

[0061] The application of current coupling detection method should take end-user into consideration, as most of the probable decoupling causes are results of unintended or intended use errors during use. As such, it may be desirable to adjust the detection threshold based on different use scenario, environment and user’s capability and limitation. It may also be helpful to provide an effective and usable mechanism to notify the user when the decoupling error occurs and to prompt user to resolve such error (such as repositioning the device or apply additional couplant). As a practical matter, the detection threshold may be verified by actual use, and provide reasonable acceptance range so it does not trigger ‘false positive’ or ‘false negative’ errors due to its sensitivity.

[0062] The above description is that of current embodiments of the invention. Various alterations and changes can be made without departing from the spirit and broader aspects of the invention as defined in the appended claims, which are to be interpreted in accordance with the principles of patent law including the doctrine of equivalents. This disclosure is presented for illustrative purposes and should not be interpreted as an exhaustive

description of all embodiments of the invention or to limit the scope of the claims to the specific elements illustrated or described in connection with these embodiments. For example, and without limitation, any individual element(s) of the described invention may be replaced by alternative elements that provide substantially similar functionality or otherwise provide adequate operation. This includes, for example, presently known alternative elements, such as those that might be currently known to one skilled in the art, and alternative elements that may be developed in the future, such as those that one skilled in the art might, upon development, recognize as an alternative. Further, the disclosed embodiments include a plurality of features that are described in concert and that might cooperatively provide a collection of benefits. The present invention is not limited to only those embodiments that include all of these features or that provide all of the stated benefits, except to the extent otherwise expressly set forth in the issued claims. Any reference to claim elements in the singular, for example, using the articles “a,” “an,” “the” or “said,” is not to be construed as limiting the element to the singular.

### CLAIMS

The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A method of detecting coupling status of an acoustic transducer having an electroacoustic element and waveguide assembly, comprising the steps of:

determining a drive frequency for the transducer;

determining a decision boundary for the transducer at the determined drive frequency;

applying a drive signal to the transducer at the determined drive frequency;

sensing a value of at least one of a current and voltage of the drive signal at the determined drive frequency; and

determining status of coupling based on a comparison of the sensed value with the decision boundary.

2. The method of claim 1 further including the step of taking remedial action when sensed value crosses the decision boundary.

3. The method of claim 2 wherein said step of taking remedial action includes at least one of presenting an alarm and reducing or eliminating a supply of power to the transducer.

4. The method of claim 1 wherein said step of determining a decision boundary for a transducer includes the steps of:

applying a drive signal to the transducer at a singular frequency; and

measuring at least one of a voltage and current of the drive signal multiple times when the transducer is in a reference coupling state.

5. The method of claim 4 wherein said step of determining the decision boundary for a transducer includes the steps of:

averaging the measured values; and

determining the decision boundary as a function of the averaged measured values.

6. The method of claim 5 further including the step of storing the decision boundary in nonvolatile memory associated with a controller for the transducer.
7. The method of claim 1 further comprising the steps of:
  - determining a secondary decision boundary for the transducer at a secondary frequency;
  - applying a secondary drive signal to the transducer at the secondary drive frequency;
  - sensing a secondary value of at least one of the current and voltage of the secondary drive signal at the secondary drive frequency; and
  - determining status of coupling based on a comparison of the sensed secondary value and the secondary decision boundary.
8. The method of claim 1 further comprising the steps of:
  - upon determining that the sensed value has crossed the decision boundary, applying a secondary drive signal to the transducer at a secondary drive frequency;
  - sensing a secondary value of at least one of the current and voltage of the secondary drive signal at the secondary drive frequency; and
  - determining status of coupling based on a comparison of the sensed secondary value and the secondary decision boundary.
9. An ultrasound device comprising:
  - an acoustic module having an electroacoustic element and a waveguide;
  - the electroacoustic element configured to generate acoustic energy;
  - the waveguide having a first surface and a second surface, the electroacoustic element affixed to the first surface, the second surface being disposed opposite the first surface and configured to engage a target;
  - acoustic module drive circuitry, the acoustic module drive circuitry including a controller configured to control the drive circuitry to supply a drive signal to the electroacoustic element at a singular drive frequency, the controller configured to compare a

sensed value of at least one of current and voltage of the drive signal at the singular drive frequency, the controller configured to take a remedial action when the sensed value crosses a decision boundary for the acoustic module at the drive frequency.

10. The ultrasound device of claim 9 wherein the remedial action is at least one of presenting an alarm and reducing or eliminating a supply of power to the electroacoustic element.

11. The ultrasound device of claim 9 wherein the waveguide is a one-piece waveguide.

12. The ultrasound device of claim 9 wherein the waveguide is a one-piece, solid aluminum waveguide.

13. The ultrasound device of claim 9 further including sense circuitry to sense at least one of current and voltage.

14. The ultrasound device of claim 13 further including a peak detect circuit.

15. The ultrasound device of claim 13 wherein the acoustic module drive circuitry includes a frequency synthesizer and voltage drive.

16. The ultrasound device of claim 15 wherein the acoustic module drive circuitry includes transducer drive circuitry coupled between the frequency synthesizer and voltage drive and the electroacoustic element, the transducer drive circuitry configured to amplify an output of the frequency synthesizer and voltage drive.

17. The ultrasound device of claim 16 further including a frequency filter coupled between the sense circuitry and the peak detect circuit.

18. The ultrasound device of claim 17 further including an amplifier stage disposed between the sense circuitry and the peak detect circuitry.

19. The ultrasound device of claim 18 wherein the amplifier stage is associated with the frequency filter.

20. The ultrasound device of claim 9 wherein the acoustic module drive circuitry includes nonvolatile memory storing the drive frequency and the decision boundary.

21. The ultrasound device of claim 9 wherein the controller is configured to control the drive circuitry to supply a drive signal to the electroacoustic element at a secondary drive frequency, the controller configured to compare a sensed secondary value of at least one of current and voltage of the drive signal at the secondary drive frequency, the controller configured to take a remedial action when the sensed secondary value crosses a secondary decision boundary for the acoustic module at the secondary drive frequency.

22. The ultrasound device of claim 21 wherein the acoustic module drive circuitry includes nonvolatile memory storing the drive frequency, the decision boundary, the secondary drive frequency and the secondary decision boundary.

23. The ultrasound device of claim 9 wherein the controller is configured to control the drive circuitry to supply a drive signal to the electroacoustic element at multiple drive frequencies; and

wherein the controller includes a pretrained neural network and is configured to output a decision of coupling status based on the pretrained neural network output at the multiple drive frequencies.

24. The ultrasound device of claim 23 wherein the acoustic module drive circuitry includes nonvolatile memory storing the drive frequencies as well as the trained neural network weights and biases.

25. A method for determining a decision boundary associated with acoustic coupling, comprising the steps of:

providing a plurality of acoustic transducers, each acoustic transducer including an electroacoustic element and a waveguide;

determining a drive frequency for each of the acoustic modules;

subjecting the acoustic module to a reference coupling state;

for each acoustic transducer, applying a drive signal to the acoustic transducer at the drive frequency for that acoustic transducer while in the reference coupling state;

for each acoustic transducer, sensing a value of at least one of a current and a voltage of the drive signal during said applying step; and

determining a decision boundary as a function of the sensed values for all of the acoustic transducer.

26. The method of claim 25 further comprising the steps of repeating said applying step and said sensing step a plurality of time for each acoustic transducer.

27. The method of claim 26 further comprising the step of calculating an average of the sensed values for each acoustic transducer to obtain an average sensed value for each acoustic transducer.

28. The method of claim 27 further comprising the step of normalizing the average sensed value for each acoustic transducer.

29. The method of claim 28 wherein the decision boundary is determined as a proportion of a normalized average sensed value.

30. The method of claim 29 wherein said subjecting step includes coupling the acoustic transducer to degassed water.

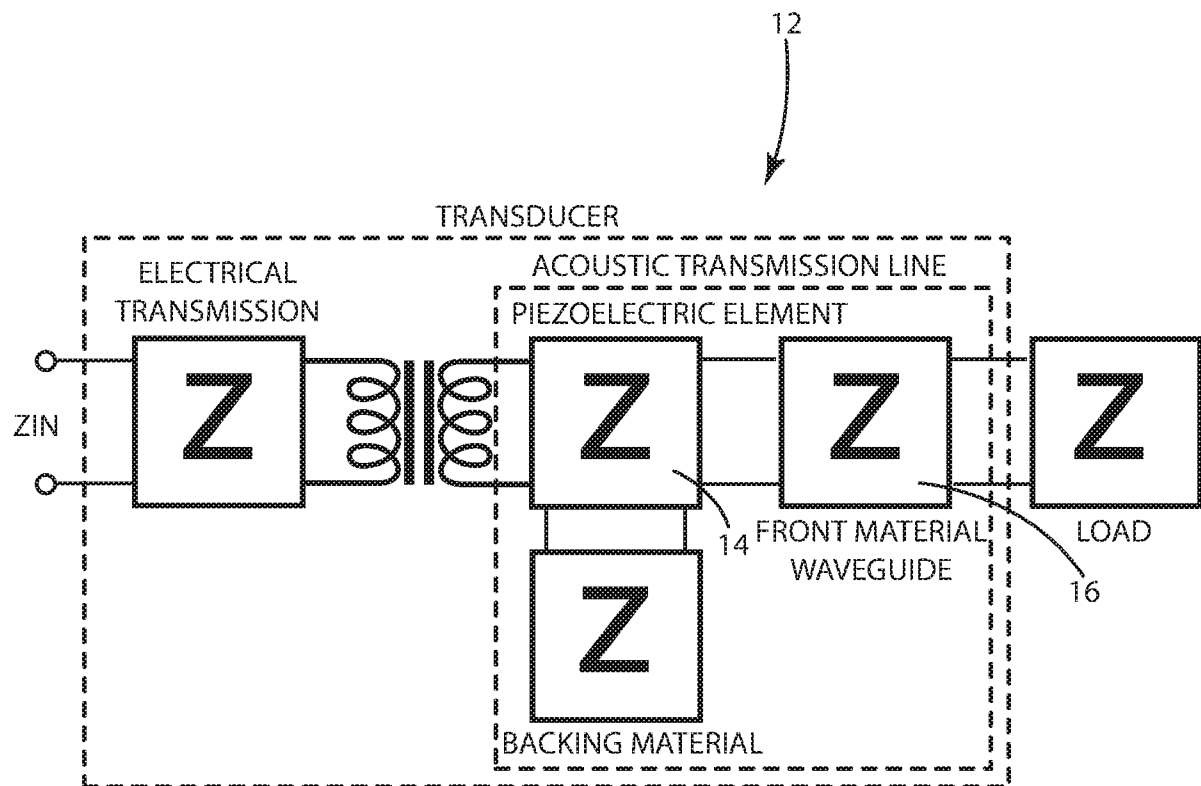


Fig. 1

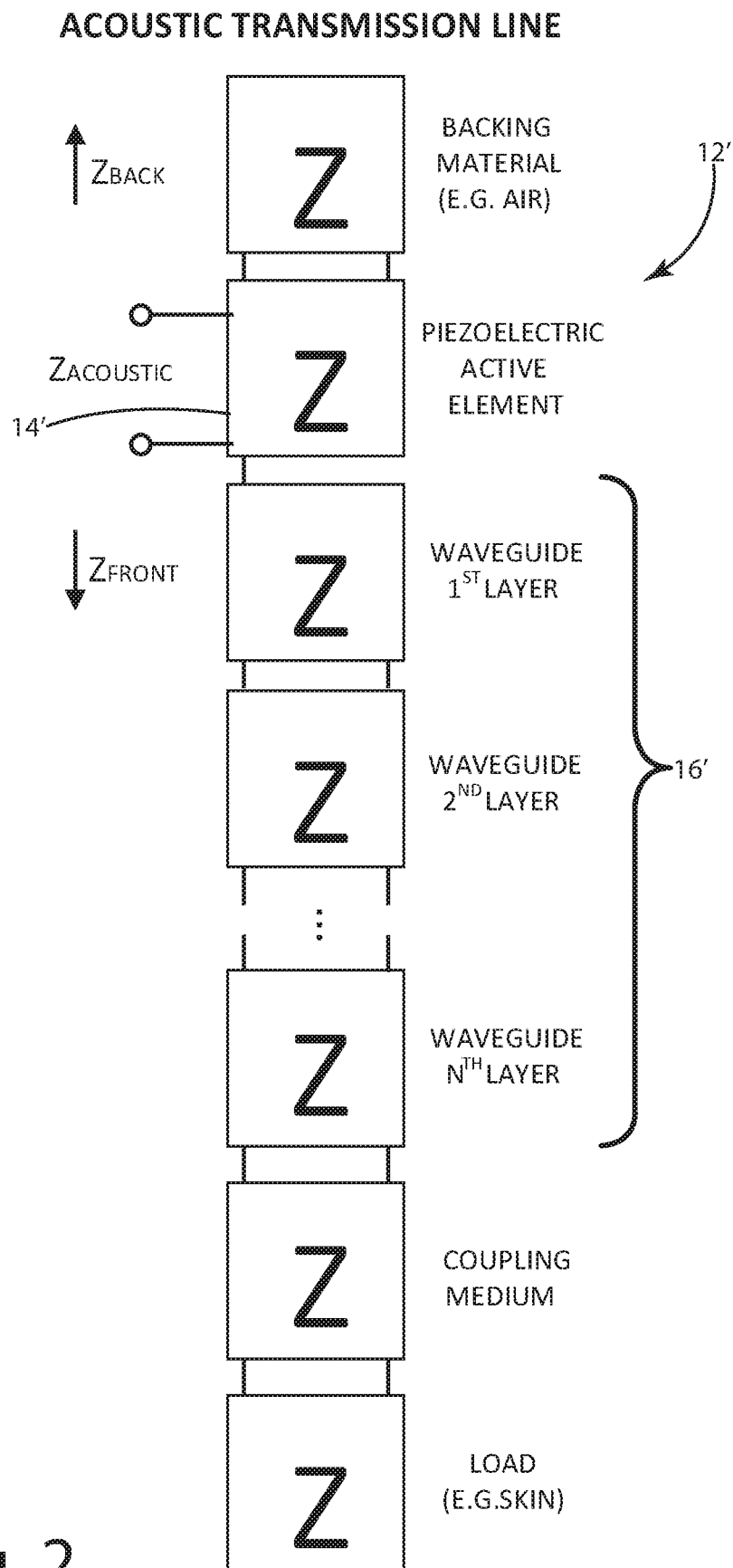


Fig. 2

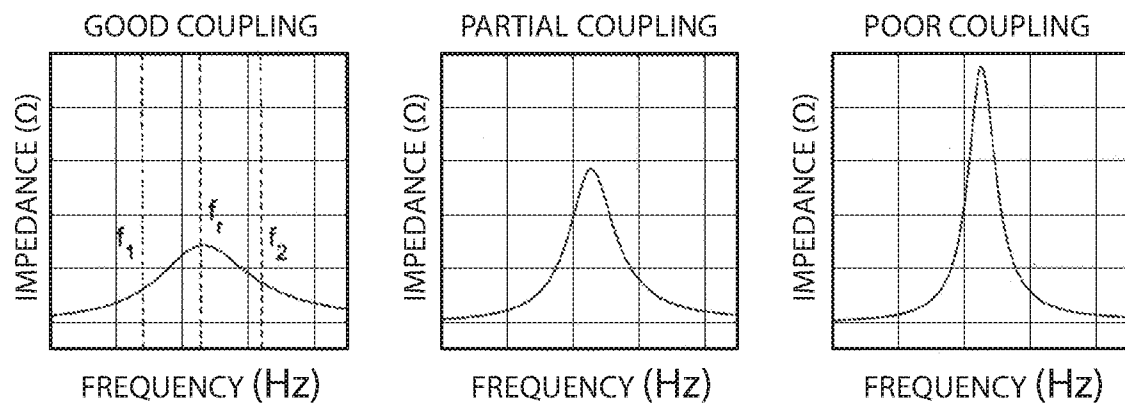


Fig. 3

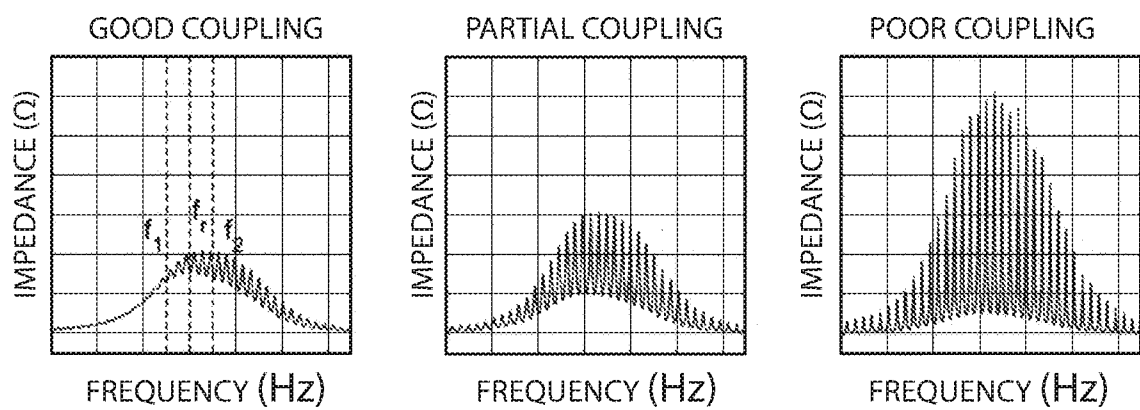


Fig. 4

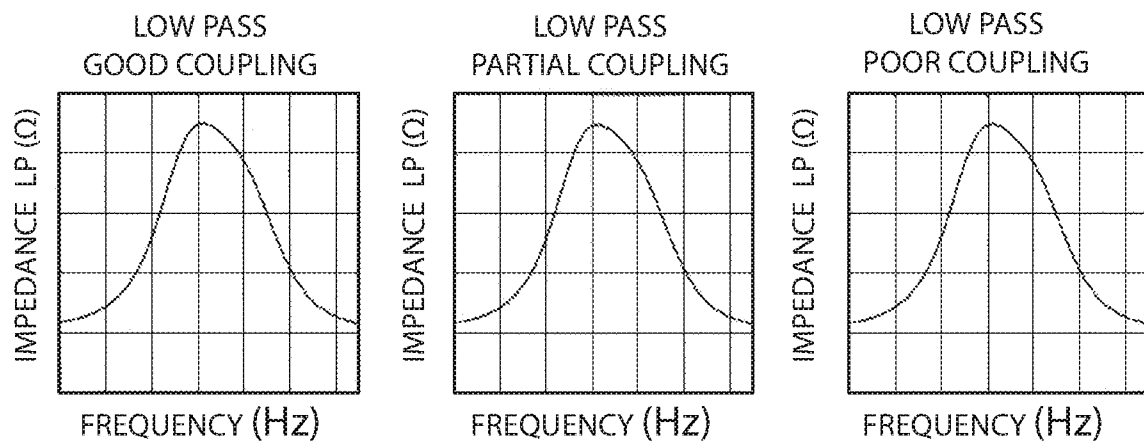


Fig. 5A

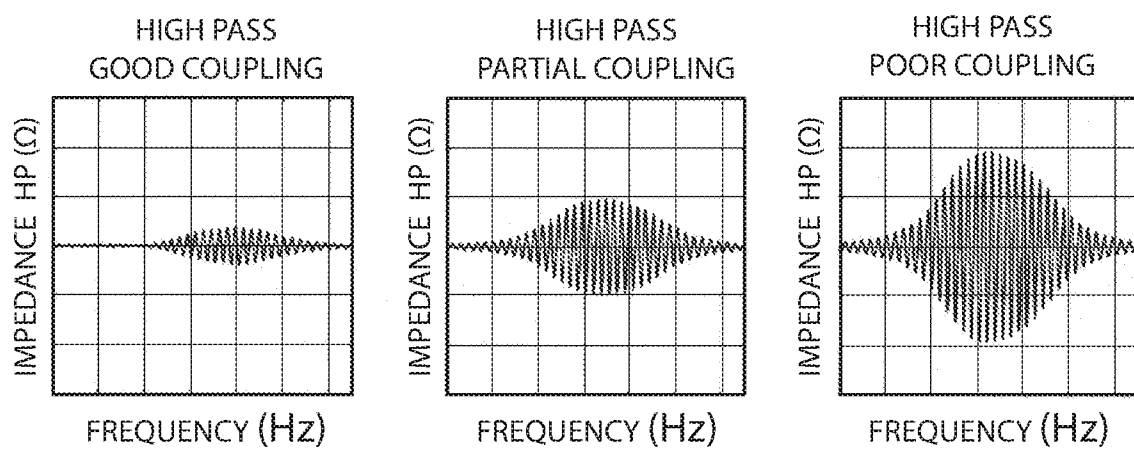


Fig. 5B

CURRENT SENSE UNDER DIFFERENT COUPLING CONDITIONS

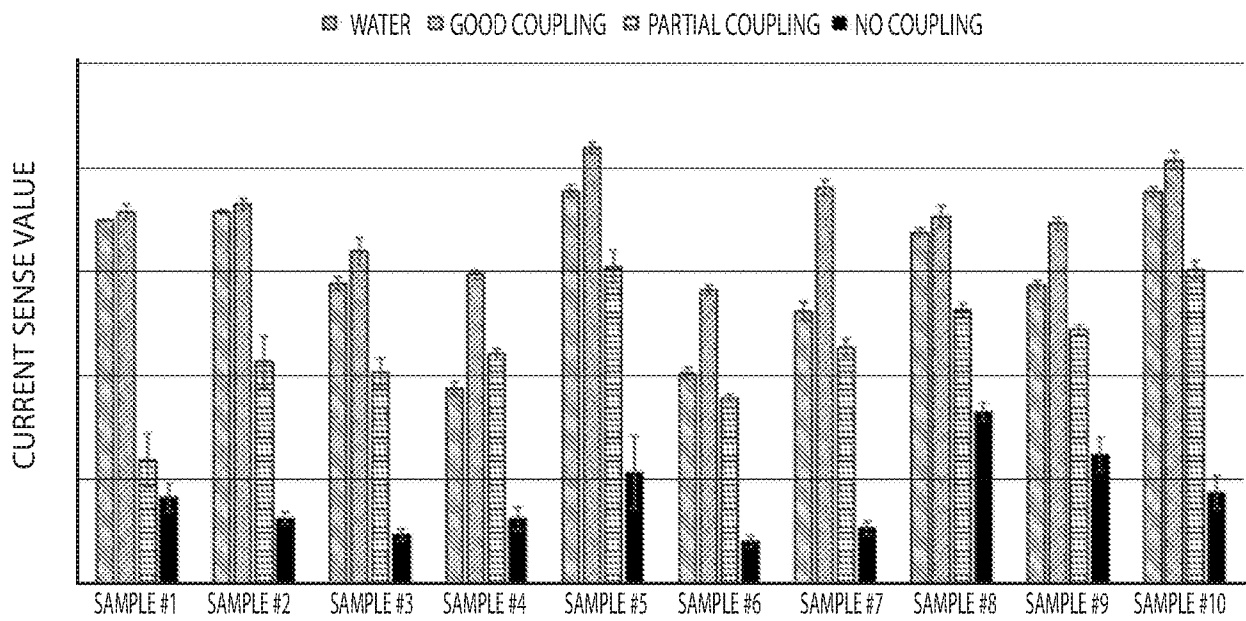


Fig. 6

NORMALIZED CURRENT SENSE UNDER DIFFERENT COUPLING CONDITIONS

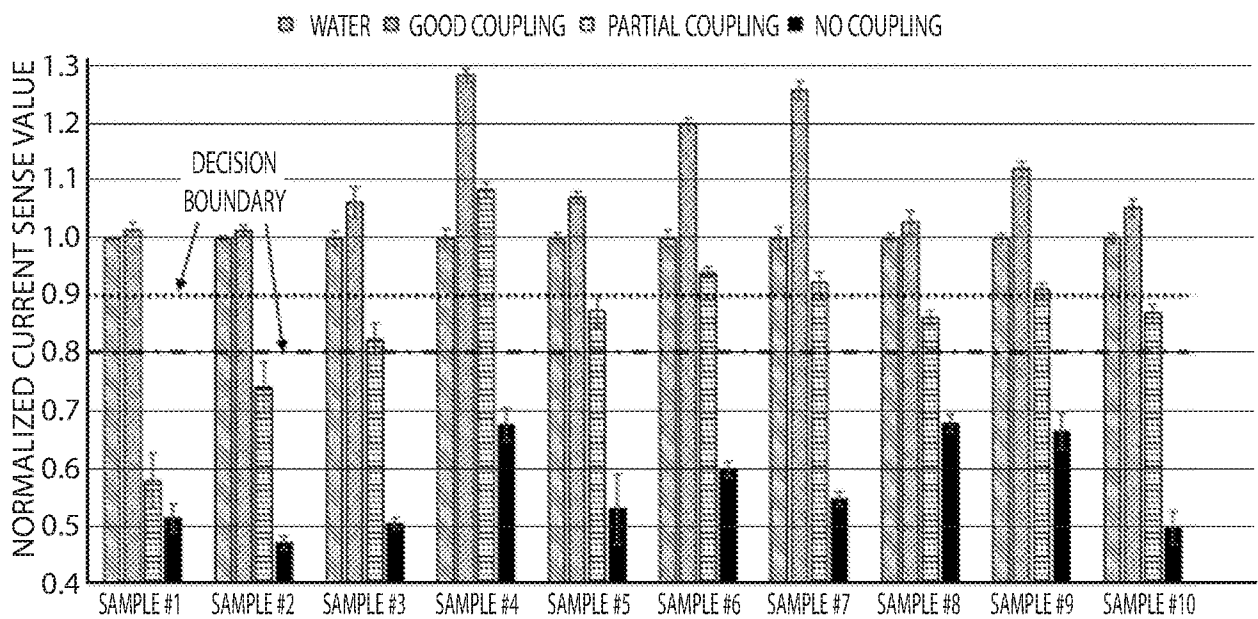


Fig. 7

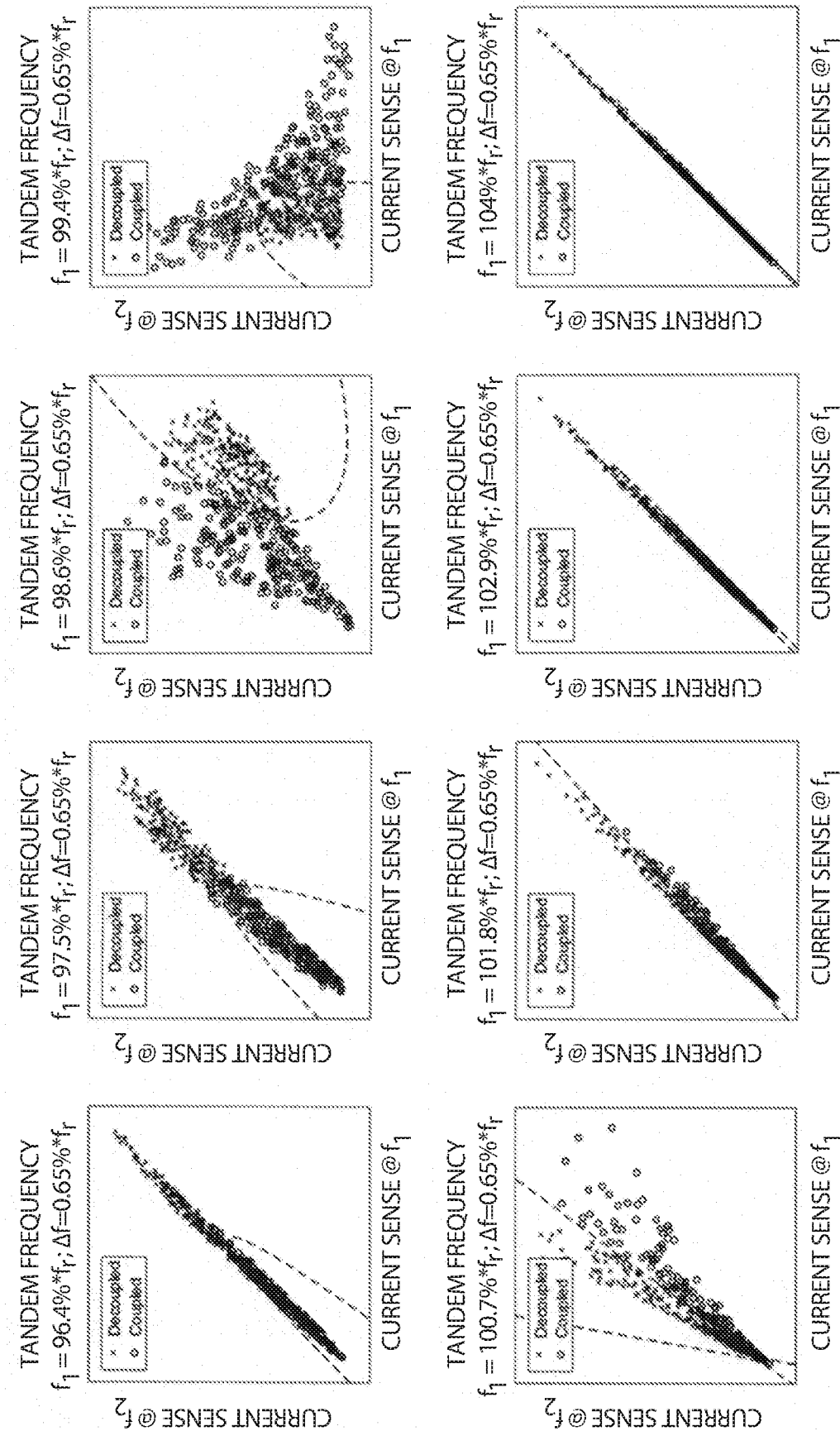


Fig. 8

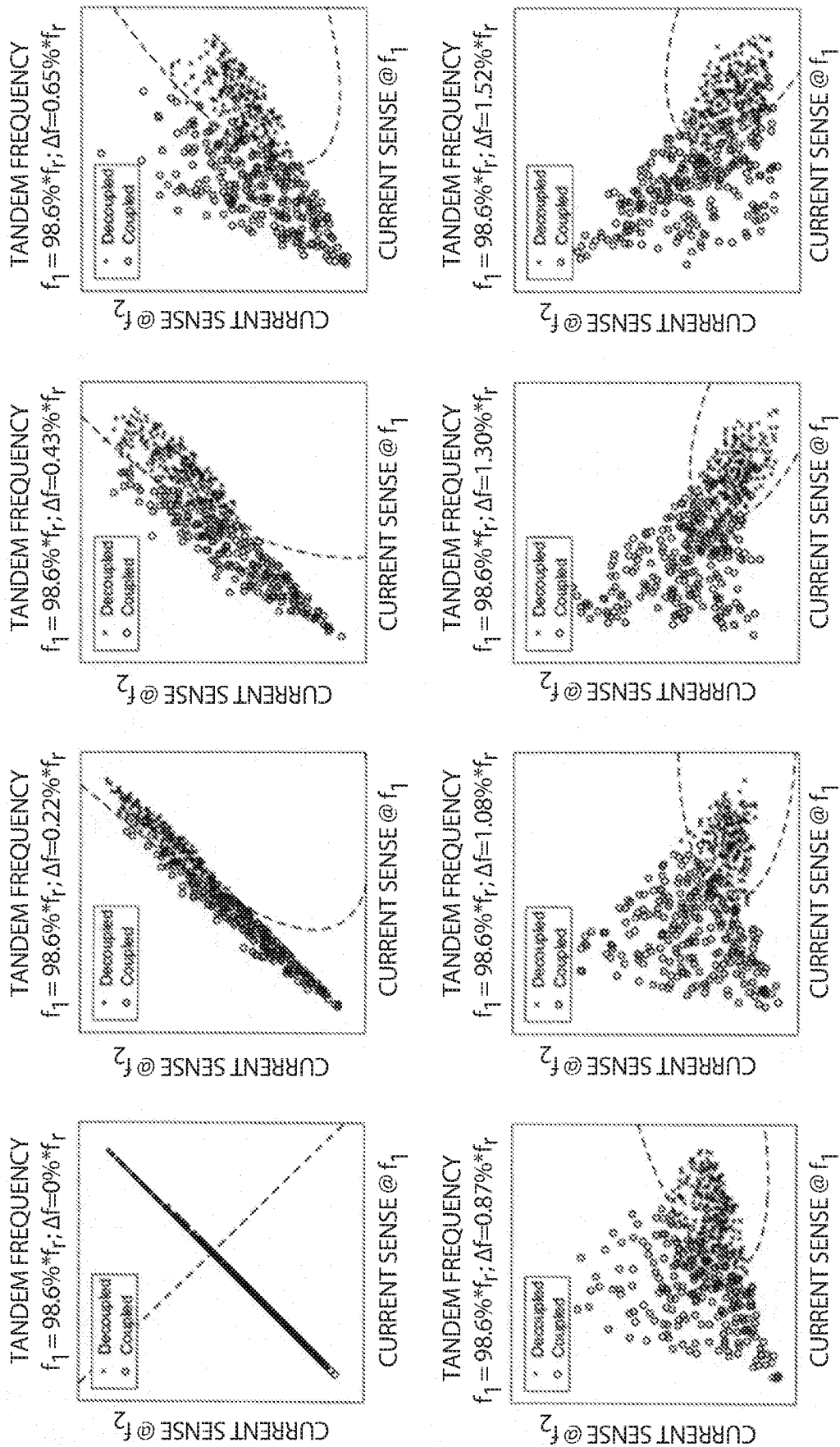


Fig. 9

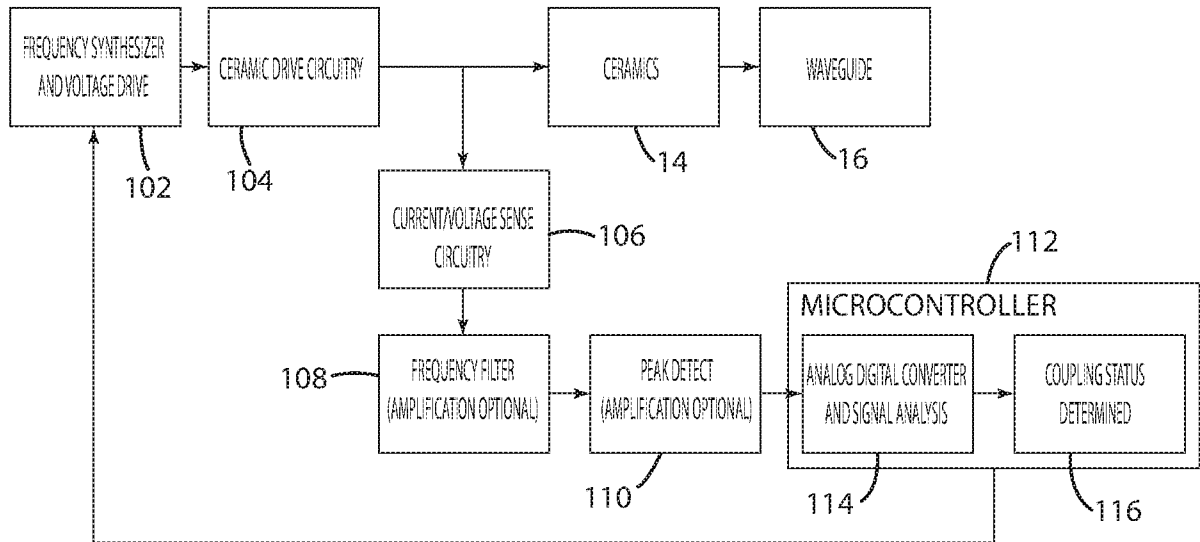


Fig. 10

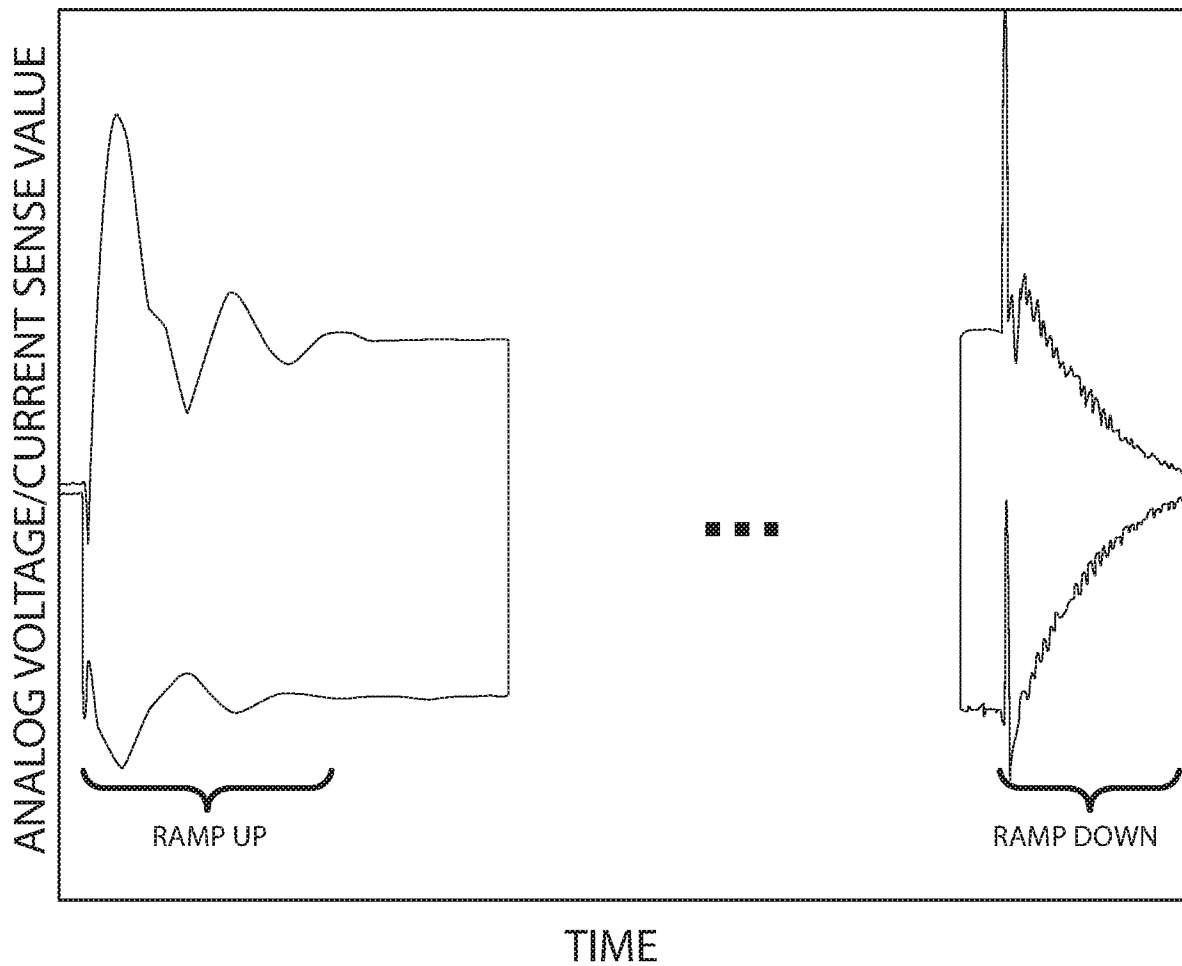


Fig. 11

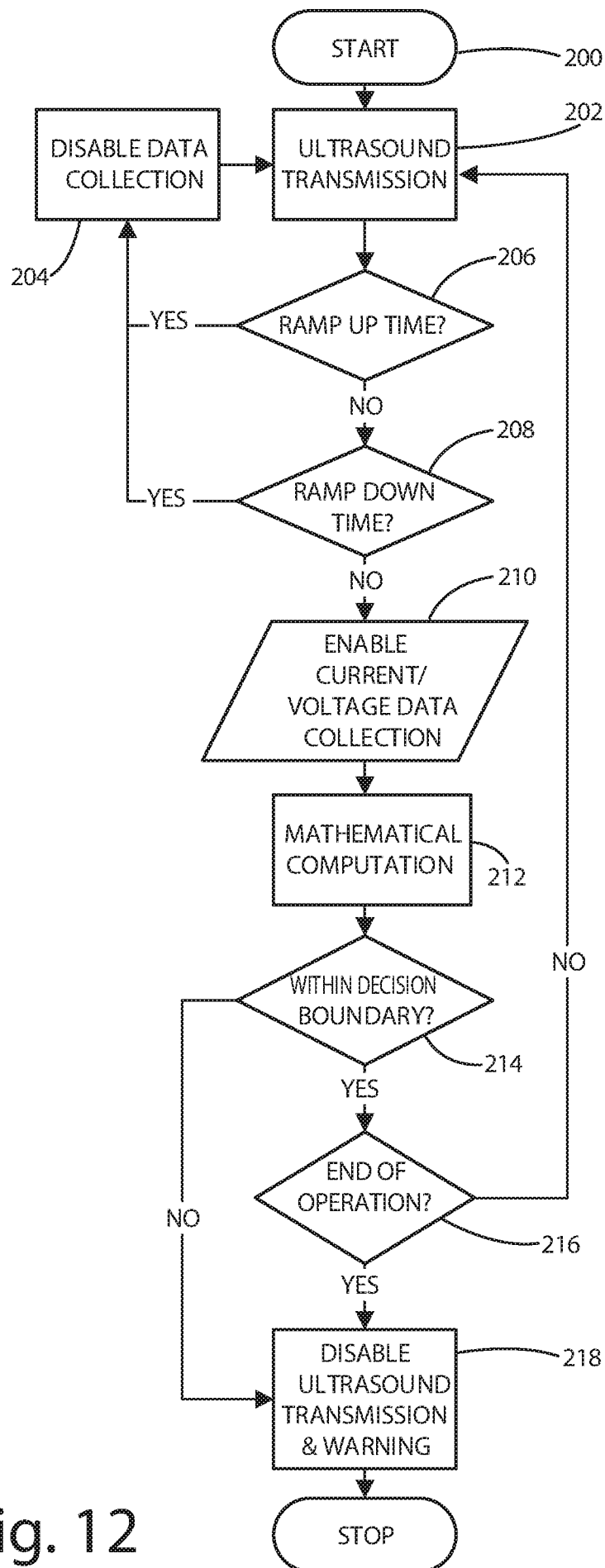


Fig. 12

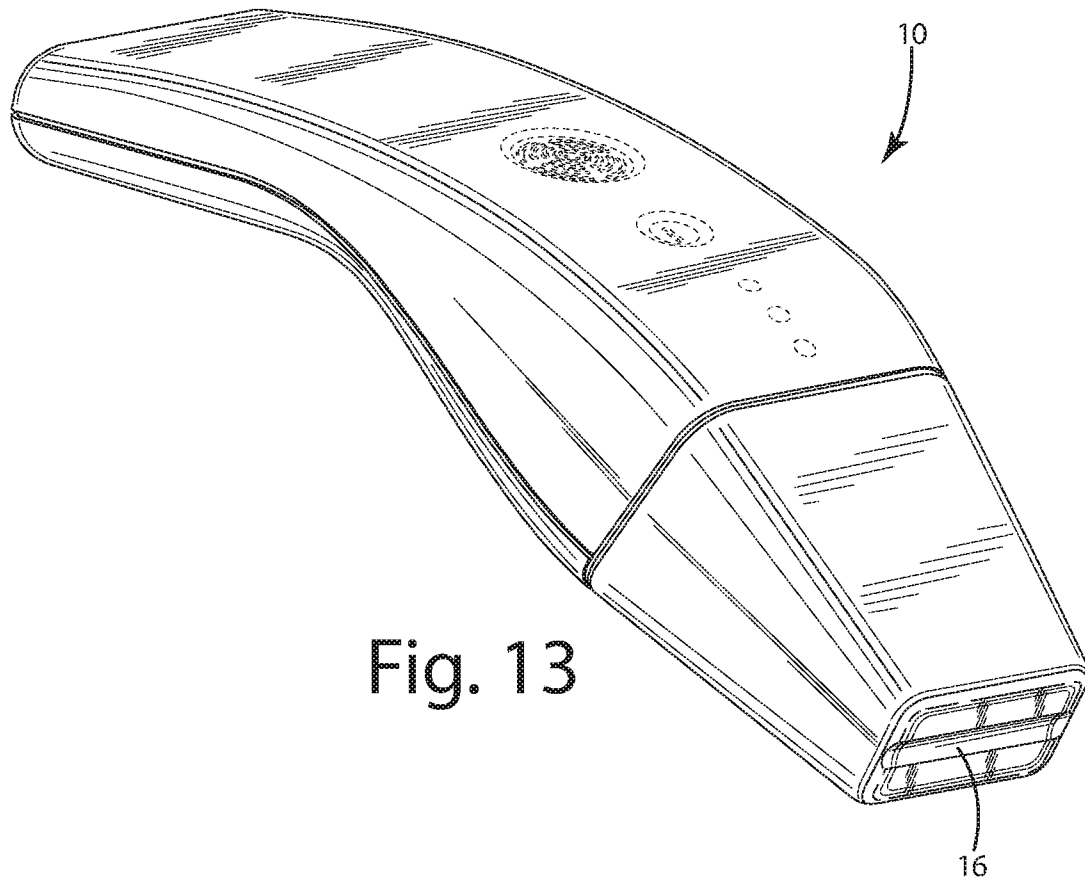


Fig. 13

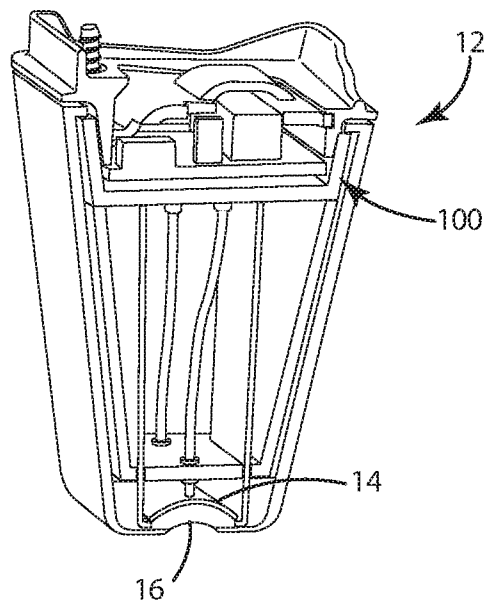


Fig. 14

## INTERNATIONAL SEARCH REPORT

International application No

PCT/US2018/026791

## A. CLASSIFICATION OF SUBJECT MATTER

INV. A61N7/00 A61B8/00  
ADD.

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

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61N A61B

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

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-Internal, WPI Data

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Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

19 June 2018

Date of mailing of the international search report

29/06/2018

Name and mailing address of the ISA/

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Fax: (+31-70) 340-3016

Authorized officer

Pereda Cubián, David

## INTERNATIONAL SEARCH REPORT

International application No  
PCT/US2018/026791

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

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Information on patent family members

International application No

PCT/US2018/026791

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