



(51) International Patent Classification:

A61B 8/06 (2006.01) A61B 8/00 (2006.01)
A61B 8/08 (2006.01)

(21) International Application Number:

PCT/EP2017/083397

(22) International Filing Date:

18 December 2017 (18.12.2017)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/436,164 19 December 2016 (19.12.2016) US

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(81) Designated States (unless otherwise indicated, for every
kind of national protection available): AE, AG, AL, AM,
AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ,
CA, CH, CL, CN, CO, CR, CU, CZ, DE, DJ, DK, DM, DO,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN,
HR, HU, ID, IL, IN, IR, IS, JO, JP, KE, KG, KH, KN, KP,
KR, KW, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ,
OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA,
SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN,
TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every
kind of regional protection available): ARIPO (BW, GH,
GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ,

(54) Title: **ULTRASONIC TRANSDUCER ARRAY MONITORING DURING TRANSCRANIAL ULTRASOUND PROCEDURES**

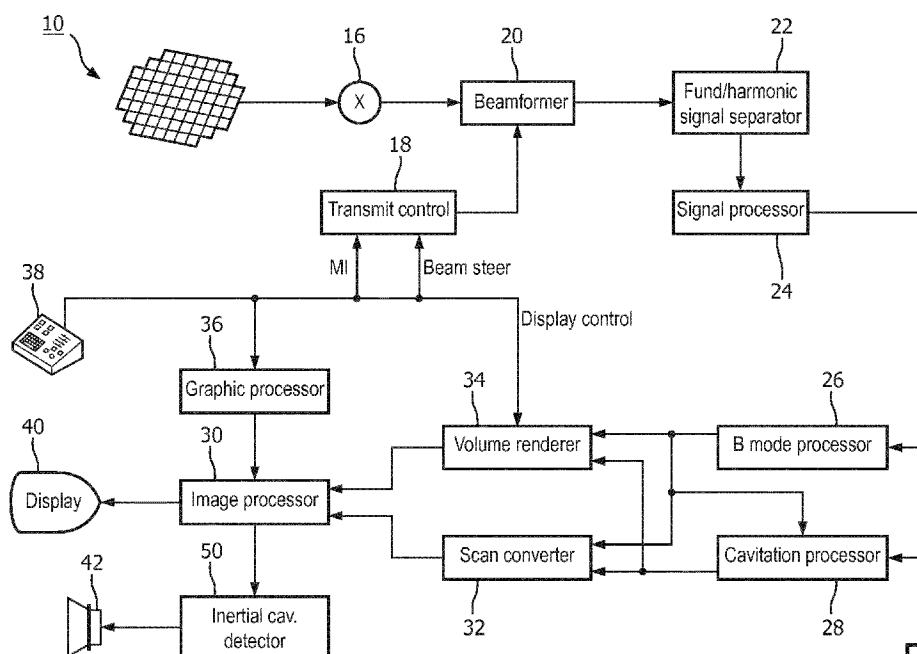


FIG. 1

(57) Abstract: An ultrasound system performs cranial therapy using a headset mounted to the head of a subject which contains a therapy transducer and a motion detecting transducer. At the outset of therapy, echo signals are acquired by the motion detecting transducer and stored. Thereafter, echo signals are acquired again by the motion detecting transducer and compared or correlated with the signals stored at the outset of therapy. When a difference is determined between the compared or correlated signals, an alert is issued by the system that transducer motion or acoustic decoupling may have occurred.



UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Declarations under Rule 4.17:

- *as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))*

Published:

- *with international search report (Art. 21(3))*

ULTRASONIC TRANSDUCER ARRAY MONITORING
DURING TRANSCRANIAL ULTRASOUND PROCEDURES

Related Application

5 This application claims the benefit of and
priority to U.S. Provisional No. 62/436,164, which is
incorporated by reference in its entirety.

Technical Field

10 This invention relates to medical ultrasound
systems and, in particular, to ultrasound systems
which perform imaging and therapy procedures.

Background

15 Ischemic stroke is one of the most debilitating
disorders known to medicine. The blockage of the
flow of blood to the brain can rapidly result in
paralysis or death. Attempts to achieve
recanalization through thrombolytic drug therapy such
20 as treatment with tissue plasminogen activator (tPA)
has been reported to cause symptomatic intracerebral
hemorrhage in a number of cases. Advances in the
diagnosis and treatment of this crippling affliction
are the subject of continuing medical research.

25 US Pat. 8,211,023 (Swan et al.) describes an
ultrasound system which provides microbubble-mediated
therapy to a thrombus such as one causing ischemic
stroke. Microbubbles are infused, delivered in a
bolus injection, or developed in the bloodstream and
30 flow to the vicinity of a thrombus. Ultrasound
energy is delivered to the microbubbles at the site
of the thrombus to disrupt or rupture the
microbubbles. This energetic microbubble activity
can in many instances aid in dissolving or breaking
35 up the blood clot and return a nourishing flow of

blood to the brain and other organs. Such microbubble activity can be used to deliver drugs encapsulated in microbubble shells, as well as microbubble-mediated sonothrombolysis. The Swan et al. patent shows the ultrasonic energy being delivered for sonothrombolysis from an ultrasound array probe controlled by an ultrasound system.

Summary

The present invention is driven from a recognition that, in clinically safe and effective sonothrombolysis treatments, the ultrasound array probe(s) delivering the ultrasound energy to the clot target region should be continuously effectively acoustically coupled to the head of the patient and continually aimed at the target volume. The target volume may include, for example, the thrombus and in some instances the surrounding area. However, a continuous coupling cannot be maintained if the transducer delivering the ultrasound has moved or been disturbed from effective acoustic coupling with the head of the patient. During traditional ultrasound imaging examinations, this coupling is monitored by observing the resulting image, which is not always convenient during a therapy procedure and is not available in non-imaging ultrasound procedures. Accordingly, it is desirable to monitor the probe placement on the head of the patient to assure that these conditions are continuously met during treatment.

While monitoring the transducer coupling is desirable, existing techniques are impractical. For example, real-time monitoring of device positioning with 3D CT or fluoroscopy is cumbersome and resource intensive. Magnetic resonance imaging is also

cumbersome, offers poor temporal resolution, and restricts *ad hoc* point-of-care procedures and patient monitoring during its long scan times. Ancillary devices to monitor the relative position of the
5 device and the skull, such as accelerometers or electromagnetic/ acoustic positioning devices, can be insensitive to small changes in angle of incidence or coupling material failure.

Accordingly, it is an object of the present
10 invention to monitor the acoustic coupling of a therapy transducer to the head of a patient to assure that it is continuously effectively acoustically coupled to the head of the patient.

It is a further object of the present invention
15 to monitor transducer placement on the head of a patient during therapy to assure that the transducer has not moved during treatment.

In accordance with the principles of the present invention, an ultrasound system which performs
20 transcranial ultrasound therapy monitors the positioning and acoustic contact of an ultrasound transducer during therapy to assure that the transducer has not moved and is continuously acoustically coupled to the head of the patient
25 during the procedure. In a preferred implementation, the signals received by one or more of the transducer elements of a transducer array are sampled from time to time and compared or correlated with the signals received by the same transducer element(s) at an
30 earlier time when the transducer array was positioned as desired on the head of a patient. If there has been a significant change in the received signals, the system issues an alert to medical personnel to check the acoustic coupling and positioning of the
35 transducer array on the head of the patient. This

technique can be applied to any transcranial ultrasound procedure, including *inter alia* blood-brain barrier disruption, thermal ablation, non-imaging monitoring techniques, and neuromodulation.

5 In the drawings:

FIGURE 1 illustrates in block diagram form an ultrasonic diagnostic imaging and therapy system for ultrasonic transcranial therapy.

10 FIGURE 2 illustrate the delivery of sonothrombolysis therapy in a two-dimensional (2D) imaging plane

FIGURE 3 illustrates the delivery of sonothrombolysis therapy in a three-dimensional image volume in conjunction with monitoring of transducer coupling and positioning in accordance with the principles of the present invention.

15 FIGURE 4 illustrates a probe and headset for sonothrombolysis therapy modeled on the head of a mannequin.

20 FIGURE 5 shows a typical waveform received by a transducer position monitoring transducer element in accordance with the principles of the present invention.

FIGURE 6a illustrates in block diagram form a first implementation of a transducer coupling and position monitoring subsystem in accordance with the present invention.

25 FIGURE 6b illustrates in block diagram form a preferred implementation of a transducer coupling and position monitoring subsystem in accordance with the present invention.

FIGURE 7 illustrates a method for monitoring transducer positioning during a therapy procedure.

35 FIGURE 8 illustrates the insonification of the cranium of a subject, the reception of transducer

motion monitoring signals, and the correlation of those signals before and after transducer motion has occurred.

Referring to FIGURE 1, an ultrasound system
5 constructed in accordance with the principles of the present invention is shown in block diagram form. It is understood that systems of the invention may include one or more transducer arrays included in one or more probes, as described hereinafter. A
10 transducer array 10 is provided for transmitting ultrasonic waves for therapy and other uses as described below and receiving echo information. In certain embodiments, the transducer array is a 2D transducer array. In the implementation of FIGURE 1
15 the array is shown as a two-dimensional array of transducer elements capable of steering therapeutic waves in three dimensions and providing 3D images and other information. The array is located in an ultrasound probe which mounts on a headset that
20 locates the array in acoustic contact with the temple on the side of the head for transcranial delivery of sonothrombolysis. The elements of the array are coupled to a transmit/ receive (T/R) switch 16 which switches between transmission and reception and
25 protects the receive channels of the system beamformer 20 from high energy transmit signals. The transmission of ultrasonic pulses from the transducer array 10 is directed by the transmit controller 18 coupled to the beamformer 20, which receives input
30 from the user's operation of the user interface or control panel 38.

The echo signals received by elements of the array 10 are coupled to the system beamformer 20 where the signals are combined into coherent
35 beamformed signals. For example, the system

beamformer 20 in this example has 128 channels, each of which drives an element of the array to transmit energy for therapy or imaging, and receives echo signals from one of the transducer elements. In this way, the array is controlled to transmit steered beams of energy and to steer and focus received beams of echo signals.

The beamformed receive signals are coupled to a fundamental/harmonic signal separator 22. The separator 22 acts to separate linear and nonlinear signals so as to enable the identification of the strongly nonlinear echo signals returned from microbubbles or tissue and, for the present invention, fundamental frequency signals for detection of probe movement. The separator 22 may operate in a variety of ways such as by bandpass filtering the received signals in fundamental frequency and harmonic frequency bands (including super-, sub-, and/or ultra-harmonic signal bands), or by a process for fundamental frequency cancellation such as pulse inversion or amplitude modulated harmonic separation. Other pulse sequences with various amplitudes and pulse lengths may also be used for both linear signal separation and nonlinear signal enhancement. A suitable fundamental/harmonic signal separator is shown and described in international patent publication WO 2005/074805 (Bruce et al.) The separated fundamental and/or nonlinear (harmonic) signals are coupled to a signal processor 24 where they may undergo additional enhancement such as speckle removal, signal compounding, and filtering for noise elimination.

The processed signals are coupled to a B mode processor 26 and a cavitation processor 28. The B mode processor 26 employs amplitude detection for the

imaging of structures in the body such as muscle, tissue, and blood cells. B mode images of structure of the body may be formed in either the harmonic mode or the fundamental mode. Tissues and microbubbles in the body both return both types of signals and the stronger harmonic returns of microbubbles enable microbubbles to be clearly segmented in an image in most applications. A cavitation processor 28 detects signal characteristics of cavitation and produces cavitation image and alert signals as described below. For example, subharmonic and ultraharmonic returns only from microbubbles further enable microbubbles to be clearly segmented in an image. The system may also include a Doppler processor which processes temporally distinct signals from tissue and blood flow for the detection of motion of substances in the image field including blood cells and microbubbles. The anatomic and cavitation signals produced by these processors are coupled to a scan converter 32 and a volume renderer 34, which produce image data of tissue structure, blood flow, microbubble cavitation, or a combined image of several of these characteristics. The scan converter converts echo signals with polar coordinates into image signals of the desired image format such as a sector image in Cartesian coordinates. The volume renderer 34 converts a 3D data set into a projected 3D image as viewed from a given reference point as described in US Pat. 6,530,885 (Entrekin et al.) As described therein, when the reference point of the rendering is changed the 3D image can appear to rotate in what is known as kinetic parallax. This image manipulation is controlled by the user as indicated by the Display Control line between the user interface 38 and the volume renderer 34. Also

described is the representation of a 3D volume by planar images of different image planes, a technique known as multiplanar reformatting. The volume renderer 34 can operate on image data in either
5 rectilinear or polar coordinates as described in US Pat. 6,723,050 (Dow et al.) The 2D or 3D images are coupled from the scan converter and volume renderer to an image processor 30 for further enhancement, buffering and temporary storage for display on an
10 image display 40.

A graphics processor 36 is also coupled to the image processor 30 which generates graphic overlays for displaying with the ultrasound images. These graphic overlays can contain standard identifying
15 information such as patient name, date and time of the image, imaging parameters, and the like, and can also produce a graphic overlay of a beam vector steered by the user as described below. For this purpose the graphics processor receives input from
20 the user interface 38. In an embodiment of the present invention the graphics processor can be used to overlay a cavitation image over a corresponding anatomical B mode image. The user interface is also coupled to the transmit controller 18 to control the
25 generation of ultrasound signals from the transducer array 10 and hence the images produced by and therapy applied by the transducer array. The transmit parameters controlled in response to user adjustment include the MI (Mechanical Index) which controls the
30 peak intensity of the transmitted waves, which is related to cavitational effects of the ultrasound, and steering of the transmitted beams for image positioning and/or positioning (steering) of a therapy beam as discussed below.

35 FIGURE 2 illustrates the conduct of

sonothrombolysis in two dimensions with a one-dimensional transducer array. In this example the transducer array 122 is a one-dimensional array which performs 2D imaging. This transducer array, like the
5 other arrays described herein, is covered with a lens 124 which electrically insulates the patient from the transducer array and in the case of a one-dimensional array may also provide focusing in the elevation (out-of-plane) dimension. The lens is pressed
10 against the skinline 100 for acoustic coupling to the patient. The transducer array 122 is backed with air or acoustic damping material 126 which attenuates acoustic waves emanating from the back of the array to prevent their reflection back into the transducer
15 elements. Behind this transducer stack is a device 130 for rotating the image plane 140 of the array. The device 130 may be a simple knob or tab which may be grasped by the clinician to manually rotate the circular array transducer in its rotatable transducer
20 mount (not shown). The device 130 may also be a motor which is energized through a conductor 132 to mechanically rotate the transducer as discussed in US Pat. 5,181,514 (Solomon et al.) Rotating the one-dimensional array transducer 122 as indicated by
25 arrow 144 will cause its image plane 140 to pivot around its central axis, enabling the repositioning of the image plane for full examination of the vasculature in front of the transducer array. As
discussed in the '514 patent, the planes acquired
30 during at least a 180° rotation of the array will occupy a conical volume in front of the transducer array, which may be rendered into a 3D image of that volumetric region. Other planes outside this
volumetric region may be imaged by repositioning,
35 rocking or tilting the transducer array in its

headset in relation to the skull beneath the skinline 100. If a stenosis, a blood clot 144, is found in the image of the plane being imaged, the therapeutic beam vector graphic 142 can be steered by the
5 clinician to aim and focus the beam at the stenosis 144 and therapeutic pulses applied to disrupt the microbubbles at the site of the stenosis to lyse the obstruction.

FIGURE 3 illustrates a 3D imaging/therapy
10 implementation of the present invention which uses a 2D matrix array transducer 10a. In this illustration the insulating lens (not shown) covering the transducer array 10a is held against the skinline 100 of the patient with the imaged volume 102 inside the
15 skull being diagnosed and treated. The user will see a 3D image of the volume 102 on the display 40 of the ultrasound system in either a multiplanar or volume rendered 3D projection. The user can manipulate the kinetic parallax control to observe the volume
20 rendered 3D image from different orientations. The user can adjust the relative opacity of the tissue and flow components of the 3D image to better visualize the vascular structure inside the brain tissue as described in US Pat. 5,720,291 (Schwartz)
25 or can turn off the B mode (tissue) portion of the display entirely and just visualize the flow of the vascular structure inside the 3D image volume 102.

When the site of the treatment such as a
thrombus 144 is being imaged in the volume 102, a
30 microbubble contrast agent is introduced into the patient's bloodstream. In a short time the microbubbles in the bloodstream will flow to the vasculature of the treatment site and appear in the 3D image. Therapy can then be applied by agitating
35 or breaking microbubbles at the site of the stenosis

in an effort to dissolve the blood clot. The clinician activates the "therapy" mode, and a therapy graphic 110 appears in the image field 102 on the display, depicting the vector path of a therapeutic
5 ultrasound beam with a graphic thereon which may be set to the depth of the thrombus. The therapeutic ultrasound beam is manipulated by a control on the user interface 38 until the vector graphic 110 is focused at the site of the blockage. The energy
10 produced for the therapeutic beam can be within the energy limits of diagnostic ultrasound or in excess of the ultrasound levels permitted for diagnostic ultrasound. The energy of the resulting microbubble ruptures will strongly agitate a blood clot, tending
15 to lyse the clot and dissolve it in the bloodstream. In many instances insonification of the microbubbles at diagnostic energy levels will be sufficient to dissolve the clot. Rather than breaking in a single event, the microbubbles may be vibrated and
20 oscillated, and the energy from such extended oscillation prior to dissolution of the microbubbles can be sufficient to lyse the clot. When vigorous activity of the microbubbles is desired to quickly lyse a blood clot or rapidly break up a large clot,
25 it may be decided to induce desirable cavitation at the site of the blockage to stimulate this activity. Inertial cavitation will produce the most vigorous activity, while stable cavitation will produce a lower level of microbubble agitation. The presence
30 of cavitation at the site of the occlusion and its type is detected by a cavitation detector 50, which analyzes characteristics of echo signals to determine whether cavitation is occurring and, if so, the type of cavitation. The two different forms of cavitation
35 produce ultrasonic backscatter of different

characteristics. Stable cavitation produces a strong subharmonic and/or ultraharmonic response, while unstable, or inertial cavitation produces broadband noise. The cavitation detector analyzes returning
5 echo signals for indications of these characteristics and informs the clinician when the required type of cavitation is identified, e.g., by coloring the site of the therapy in an ultrasound image with a color where adequate cavitation has been identified. If
10 the signature for inertial cavitation is detected, for example, and stable cavitation is desired, the inertial cavitation detector 50 causes speaker 42 to issue an alarm. The user responds to this information by reducing the ultrasound output power
15 (MI) being generated by the sonothrombolysis array. If cavitation is not detected at all, for example, by no indication of cavitation coloring of the site of the occlusion in the image, then the output power of the sonothrombolysis array is increased until
20 cavitation is detected. This output power scaling can be accomplished automatically without user intervention via an output power control loop, for example. The treatment is continued at the appropriate setting. Such usage allows the system to
25 compensate for the attenuation generated by different temporal bone windows and any varying attenuation due to different acoustic properties of brain tissue.

In accordance with the principles of the present invention, one or more elements of the array 10a are
30 used to receive ultrasonic scattering from a transmit beam and process the received signals to detect whether there has been any probe motion during therapy. In FIGURE 3 elements 10b and 10c on opposite sides of the array are shown receiving
35 backscattered ultrasound from a beam transmission

along vector 110 as indicated by the arrows directed back to elements 10b and 10c from the vector. A typical backscatter signal 70 produced by one of these transducer elements is shown in FIGURE 5. The backscatter signal may be received over the full depth of field of the image region 102, but preferably reception is gated over a selected depth of field. Desirably, the depth of field should include one or more landmarks that do not move during treatment and can be identified as indicia that the probe has remained stationary relative to the head. In general, landmarks may include any static tissue or bone of the head, as opposed to circulating blood or bubbles. This can be done by filtering or otherwise removing time-varying signals such as those returned by flowing microbubbles, for instance. Undesired strong signals returned from flowing microbubbles can be further eliminated by using only fundamental frequency signals of the backscatter for probe motion detection, which avoids reception of the strong nonlinear (harmonic) signals returned from microbubbles. A preferred gated range is one that detects only near-field scattering returned as the transmit beam passes through the skull, which will be repeatable from one transmit-receive interval to another so long as the transducer has not moved or lost some or all of its acoustic coupling with the head. Echoes returned from the near field thus use the skull bone as the landmark.

FIGURE 4 illustrates a headset 62 for a sonothrombolysis array probe 12 of the present invention mounted on the head 60 of a mannequin. The sides of the head of most patients advantageously provide suitable acoustic windows for transcranial ultrasound at the temporal bones around and in front

of the ears on either side of the head. In order to transmit and receive echoes through these acoustic windows the transducer arrays must be in good acoustic contact at these locations which may be done by holding the transducer arrays against the head with the headset 62. An implementation of the present invention may have a snap-on deformable acoustic standoff which allows the transducer array to be manipulated by its conformal contact surface and aimed at the arteries within the brain while maintaining acoustic contact against the temporal window. An array 10 is integrated into the probe housing 12 which allows it to address the requirements of stable positioning and tight coupling to the patient's temporal bone. The illustrated probe housing is curved by bending the probe handle by 90°, which makes the probe more stable when attached to the headset 62. The acoustic coupling objective is facilitated by integrating a mating spherical surface into the probe handle, which allows it to pivot in the headset 62 until it is strongly and tightly coupled to the temporal window of the patient.

Circuitry which processes signals from a motion detecting transducer element such as elements 10b and 10c in FIGURE 3 is shown in FIGURES 6a and 6b. FIGURE 6a shows an analog implementation in which the fundamental frequency signals from a motion monitoring element such as that shown in FIGURE 5 are coupled from the fundamental/harmonic signal separator 22 to a sample-and-hold circuit 72. The signal which is sampled by this circuit may be the detected envelope of the r.f. waveform, as it is not usually necessary to use the r.f. signal. Samples of the signal 70 are coupled to an analog signal storage

device 74 or 76, such as an analog shift register or an analog random access memory (ARAM), in accordance with the setting of a signal steering device shown as single pole, double throw switch 86. At the beginning of therapy, when the transducer array 10 is properly coupled to the head of the patient and aimed at the therapy site, samples of the signal received by the monitoring transducer element 10b or 10c are steered to the storage device 76 and stored to be used as a reference. Since the monitoring transducer elements 10b and 10c are elements of the same array 10a used for therapy, they are positionally related to the therapy elements in a fixed relationship. Thus, any motion experienced by elements 10b or 10c in relation to the patient will also be experienced by the therapy array elements. Thereafter, during treatment, signals are received by the monitoring transducer element(s) from time to time and samples are steered by switch 86 to storage device 74. Preferably, the current signal sample is correlated with the reference signal, or the previous signal, and compared to a threshold value to decide whether there has been transducer motion. Algorithmically, this correlation and decision-making process can be expressed as:

RF line 0 + RF line 1 = correlation coefficient + phase → decision 1

RF line 1 + RF line 2 = correlation coefficient + phase → decision 2

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In an alternative embodiment, the reference and current signal samples stored in storage devices 74 and 76 are clocked or read out of the storage devices in depth-corresponding unison and the reference samples previously stored in storage device 76 are

35

subtracted from the samples most recently stored in storage device 74 by a subtraction circuit 78 and the magnitude of the difference is applied to one input of a comparator 80, where the difference is compared to a threshold Th. So long as the magnitude of the difference is less than the threshold value, no output value is produced by the comparator 80. This will be the case when there has been no movement of the transducer 10 or acoustic decoupling from the head of the patient. When there has been no transducer movement or acoustic decoupling, the echo signals received at the two time intervals from identical transmit pulses will have traveled through the same tissue paths and be the same. Thus, the subtraction of the two (after allowing for signal noise) will be at or near a zero magnitude, indicating no movement or decoupling. But when there has been movement or decoupling, the later-received signals will differ from the reference signals and their difference will have a magnitude which will exceed the threshold Th. This will cause the comparator 80 to produce an output signal that will clock D-type flip-flop 82. In some procedures, particularly those performed with a non-imaging system, the setting of the flip-flop 82 can also cause a pause in the application of ultrasonic therapy. The now-set Q output of the flip-flop causes drive circuit 84 to produce an audio signal, which drives loudspeaker 42 to issue an alarm alerting a clinician. The clinician will then examine the headset and the ultrasound image to see if the headset needs to be adjusted on the head of the patient or the transducer treatment vector 110 re-aimed at the thrombus being lysed.

The motion detection circuit of FIGURE 6b is

similar to that of FIGURE 6a except that, instead of taking the difference between the current and reference waveforms 70, the two waveforms are cross-correlated by a correlator 90. The correlator 90 produces a cross-correlation estimate which is a quantitative estimate of the similarity of the instant and reference signals in question. Strong decreases in the cross-correlation estimate, indicative of transducer motion or acoustic decoupling, will exceed the threshold value T_h , causing the D flip-flop 82 to be set and the drive circuit 84 to cause the loudspeaker 42 to issue an audible alert. The implementation of FIGURE 6b also illustrates a digital implementation of a motion detection circuit. The signals 70 received from the signal separator 22 are digitally sampled by an A/D converter 92 and directed by steering circuit 86 to one of two digital storage devices 74' and 76', which may be digital shift registers or digital memories, for instance. Correlation is then estimated in the digital domain.

FIGURE 7 illustrates a method for using the ultrasound system of FIGURES 1, 4, 6a, 6b for a clinical therapy procedure. In step 44 the headset 62 containing the therapy and motion detecting transducer elements is properly positioned on the head of the patient, with the transducer acoustically coupled to the head and aimed at the therapy region in the skull. Thereafter the therapy procedure is started in step 46. In step 48 the signal received by one or more motion detecting transducer elements is stored in the storage device(s) for reference signals. As the therapy procedure continues, signals received by the motion detecting transducer element(s) are acquired from time to time and

compared or correlated with the reference signals acquired at the outset of the procedure. If the comparison/ correlation shows no significant variance in the signals previously and currently acquired, the
5 procedure continues. But if the two temporally different signals do not compare or correlate, an alert is issued by the system in step 54 to summon a clinician to check on the positioning of the transducer.

10 FIGURE 8 illustrates signals and correlation results from a reduction to practice of the present invention. Box a illustrates the cranium 170 of a subject, a dog in this instance, which is insonified by ultrasound from an element of transducer array 10.
15 Ultrasound is transmitted and received by a motion monitoring transducer element 10a of the array as shown by the bright areas of ultrasonic energy in box a. A motion monitoring transducer element can be one of the transducer elements of the therapy array, or
20 it can be a transducer element separate from the therapy array but positionally related thereto. The echo signal received by element 10a during one motion monitoring interval is shown in box b. If this transmission and reception is repeated at a
25 subsequent time with no intervening transducer motion, a virtually identical echo signal will be received as shown in box b, and the correlation of the earlier and later received signals will produce a correlation coefficient of "1", as shown in the upper
30 half of box d. In this experiment, a signal was again transmitted and received by element 10a after rotation of the array 10 in increments totaling 3°, which is shown in box c. The correlation of the earlier (box b) and later (box c) signals resulted in
35 correlation coefficients ranging from 0.7 to 0.8 as

indicated at 160. Since these correlation coefficients are below a pre-determined threshold of 0.9 (indicated by the dashed line in box d), they are indicative of unacceptable transducer motion and an alert is produced by the ultrasound system.

It is thus seen from the foregoing that a system of the present invention comprises a motion detecting transducer acoustically coupled to the head of a subject and a processing unit coupled to a storage device which stores instructions which, when executed by the processing unit, cause the processing unit to a) receive echo signals reflected from the head of the subject at a first time and at a second time; b) filter (e.g., by signal processor 24) time-varying signals from the echo signals, thereby providing a first signal signature corresponding to the first time (e.g., as shown in box b of FIGURE 8) and a second signal signature corresponding to the second time (e.g., as shown in box c of FIGURE 8); and c) analyze the first and second signal signature to determine if transducer motion has occurred (e.g., by estimating a correlation coefficient using a correlation algorithm as shown in box d of FIGURE 8).

Variations of the implementations of the present invention described above will readily occur to those skilled in the art. For instance, the storage device 74, 74' may not be necessary if the sampling of a current motion-indicating signal by circuit 72 or 92 is time-synchronized with the shifting or reading of a reference signal from the storage device 76, 76'. Instead of using separate storage devices 74 and 76 (or 74' and 76'), an embodiment can be implemented using a single storage device. Instead of using a single motion detection element, a subarray of elements can alternatively be used for motion

detection. If no motion or only negligible motion has occurred between the beginning of therapy and a later comparison or correlation, the reference signals stored in the reference signal storage device may be updated with current signals. The motion detecting element(s) may be elements of the therapy array, or elements in the probe separate from the therapy array which are dedicated to motion detection. The alert issued by the system when motion is detected may be audible as shown in FIGURE 1, or can be visual or both.

It should be noted that an ultrasound system suitable for use in an implementation of the present invention, and in particular the component structure of the ultrasound system described by FIGURES 1, 6a and 6b, may be implemented in hardware, software or a combination thereof. The various embodiments and/or components of an ultrasound system, for example, the modules, or components and controllers therein, also may be implemented as part of one or more computers or processors. The computer or processor may include a microprocessor. The microprocessor may be connected to a communication bus, for example, to access a PACS system or a data network. The computer or processor may also include a memory. The memory devices such as the storage devices 74, 76, 74' and 76' may include Random Access Memory (RAM) and Read Only Memory (ROM), an analog shift register or an analog random access memory (ARAM), or other digital or analog signal storage components. The computer or processor further may include a storage device, which may be a hard disk drive or a removable storage drive such as a floppy disk drive, optical disk drive, solid-state thumb drive, and the like. The storage device may also be other similar means for loading

computer programs or other instructions into the computer or processor.

As used herein, the term "computer" or "module" or "processor" or "workstation" may include any
5 processor-based or microprocessor-based system including systems using microcontrollers, reduced instruction set computers (RISC), ASICs, logic circuits, and any other circuit or processor capable of executing the functions described herein. The
10 above examples are exemplary only, and are thus not intended to limit in any way the definition and/or meaning of these terms.

The computer or processor executes a set of instructions that are stored in one or more storage
15 elements, in order to process input data. The storage elements may also store data or other information as desired or needed. The storage element may be in the form of an information source or a physical memory element within a processing
20 machine.

The set of instructions of an ultrasound system including those controlling the acquisition, processing, and transmission of ultrasound images as described above may include various commands that
25 instruct a computer or processor as a processing machine to perform specific operations such as the methods and processes of the various embodiments of the invention. The set of instructions may be in the form of a software program. The software may be in
30 various forms such as system software or application software and which may be embodied as a tangible and non-transitory computer readable medium. Further, the software may be in the form of a collection of separate programs or modules, a program module within
35 a larger program or a portion of a program module.

The software also may include modular programming in the form of object-oriented programming. The processing of input data by the processing machine may be in response to operator commands, or in
5 response to results of previous processing, or in response to a request made by another processing machine. In the ultrasound system shown in FIGURES 1, 6a, and 6b for instance, software instructions are conventionally employed by a digital processor to
10 create and control the display and user control functions described above, and to perform analysis such as comparison and correlation coefficient computations. The processor performs analysis in a system of the present invention by executing the
15 correlation algorithms given above, for instance.

Furthermore, the limitations of the following claims are not written in means-plus-function format and are not intended to be interpreted based on 35 U.S.C. 112, sixth paragraph, unless and until such
20 claim limitations expressly use the phrase "means for" followed by a statement of function devoid of further structure.

25

WHAT IS CLAIMED IS:

1. An ultrasound system adapted to perform therapy on the head of a subject comprising:

5 an array of transducer elements, configured to acoustically couple to the head of a subject, and adapted to transmit therapeutic ultrasonic energy toward a therapy site in the head of the subject;

10 a motion detecting transducer configured to receive echo signals from the head of the subject at a first time and a second time; and

15 a processor configured to analyze the echo signals received at the first and second times to determine whether transducer motion has occurred from the first time to the second time.

2. The ultrasound system of Claim 1, wherein the processor further comprises a motion detecting circuit configured to analyze the echo signals
20 received at the first and second times by comparison or correlation.

3. The ultrasound system of Claim 2, wherein the motion detecting transducer further comprises an
25 element of the same array adapted to transmit therapeutic ultrasonic energy.

4. The ultrasound system of Claim 3, wherein the motion detecting transducer further comprises a
30 plurality of transducer elements.

5. The ultrasound system of Claim 2, further comprising a storage device configured to store echo signals received by the motion detecting transducer.
35

6. The ultrasound system of Claim 5, further comprising a sampling circuit configured to produce analog signal samples of the echo signals received by the motion detecting transducer,

5 wherein the analog signal samples are stored by the storage device.

7. The ultrasound system of Claim 5, wherein the storage device further comprises a digital signal storage device.

8. The ultrasound system of Claim 7, further comprising a sampling circuit configured to produce digital signal samples of the echo signals received by the motion detecting transducer,

15 wherein the analog signal samples are stored by the digital signal storage device.

9. The ultrasound system of Claim 1, further comprising a fundamental/harmonic signal separator configured to produce fundamental frequency signals from the echo signals received by the motion detecting transducer.

10. The ultrasound system of Claim 1, further comprising a headset configured to maintain the array of transducer elements and the motion detecting transducer in acoustically coupled contact with the head of the subject.

11. The ultrasound system of Claim 1, wherein the motion detecting circuit is further configured to produce an alert in response to a determination that transducer motion has occurred.

12. A system for monitoring the stability of a headset containing a therapy transducer and a motion detecting transducer on the head of a subject comprising:

5 a processing unit; and
 storage coupled to said processing unit for storing instructions that when executed by the processing unit cause the processing unit to:
 receive echo signals reflected from the head at
10 a first time and a second time;
 filter time-varying signals from the echo signals, thereby providing a first signal signature corresponding to the first time and a second signal signature corresponding to the second time; and
15 analyze the first and second signal signatures to determine if transducer motion has occurred.

13. The system of Claim 12, wherein analyzing the signal signatures further comprises analyzing the
20 signals by comparison or correlation.

14. The system of Claim 13, wherein execution of the stored instructions further causes the processing unit to receive echo signals during
25 ultrasound therapy.

15. The method of Claim 13, wherein execution of the stored instructions further cause the processing unit to issue an alert if analyzing
30 determines that transducer motion has occurred.

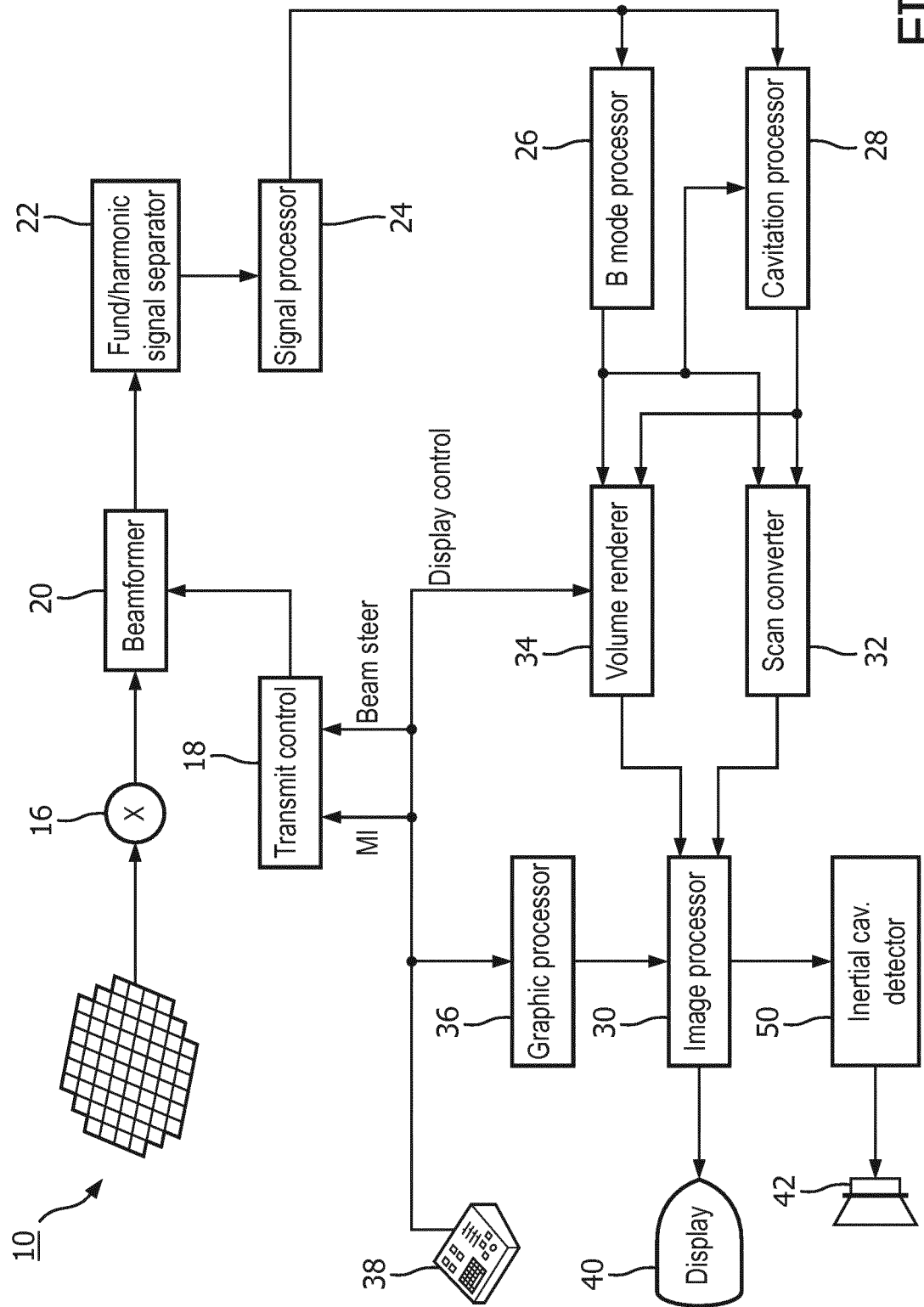


FIG. 1

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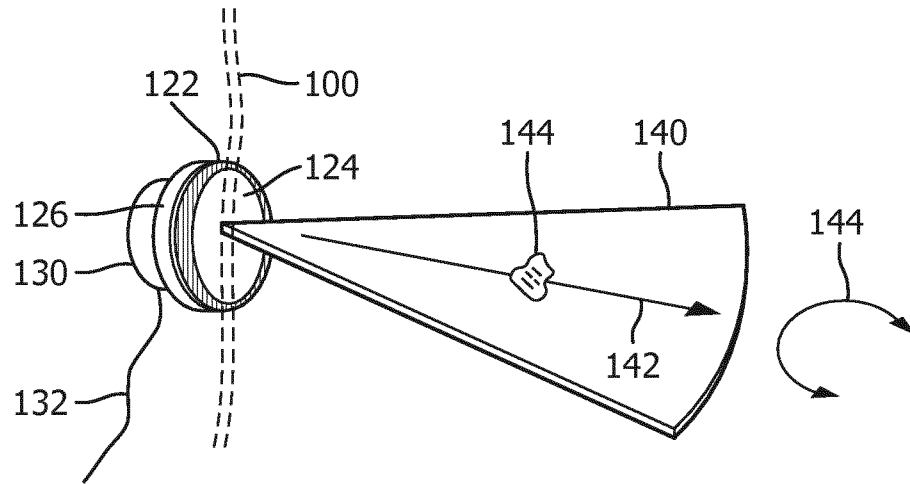


FIG. 2

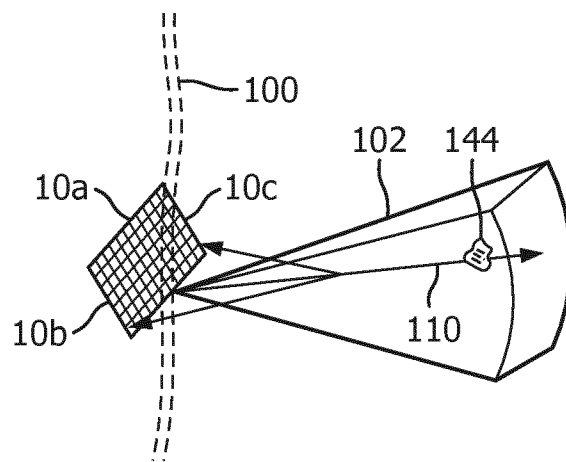


FIG. 3

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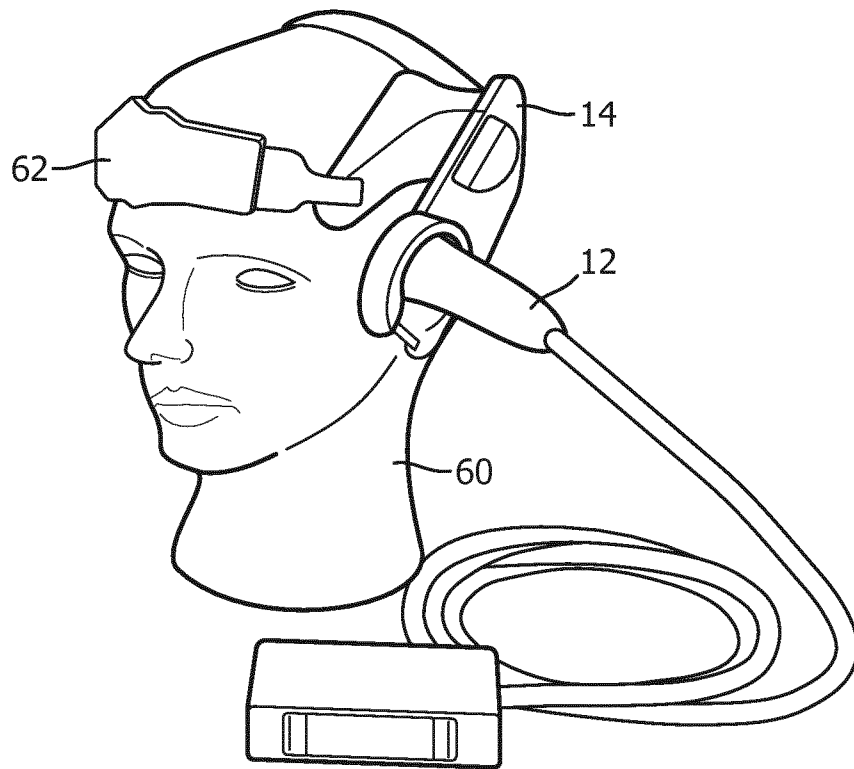


FIG. 4

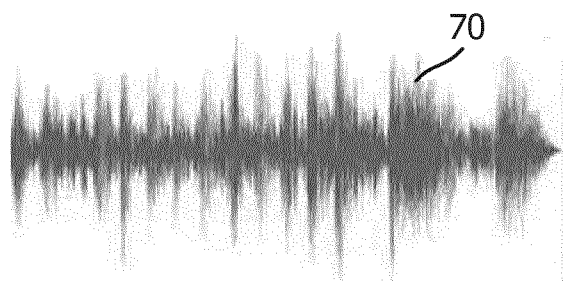


FIG. 5

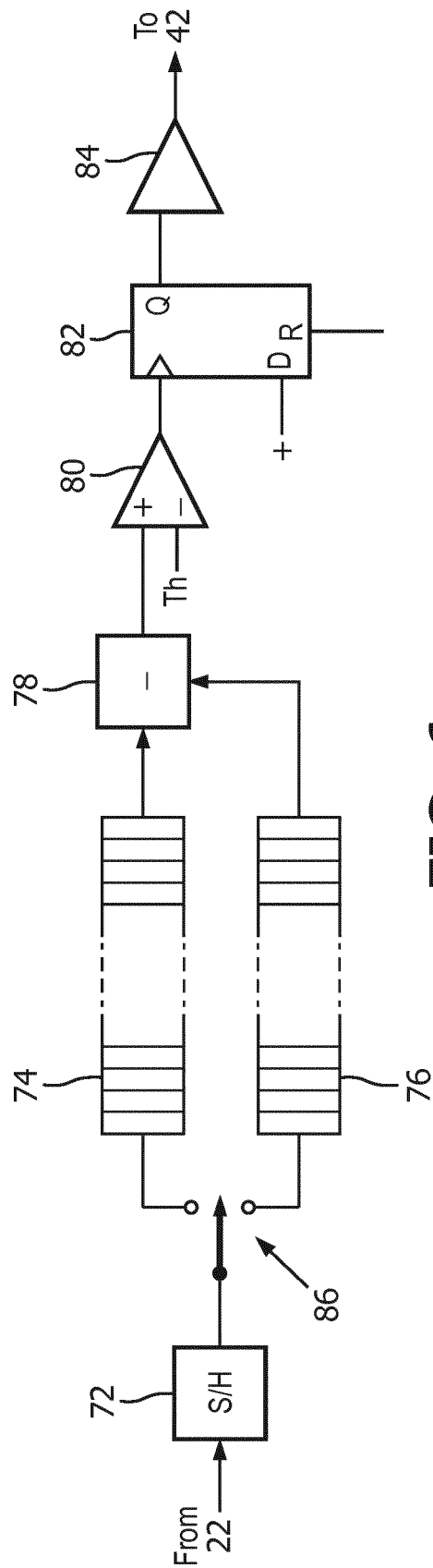


FIG. 6a

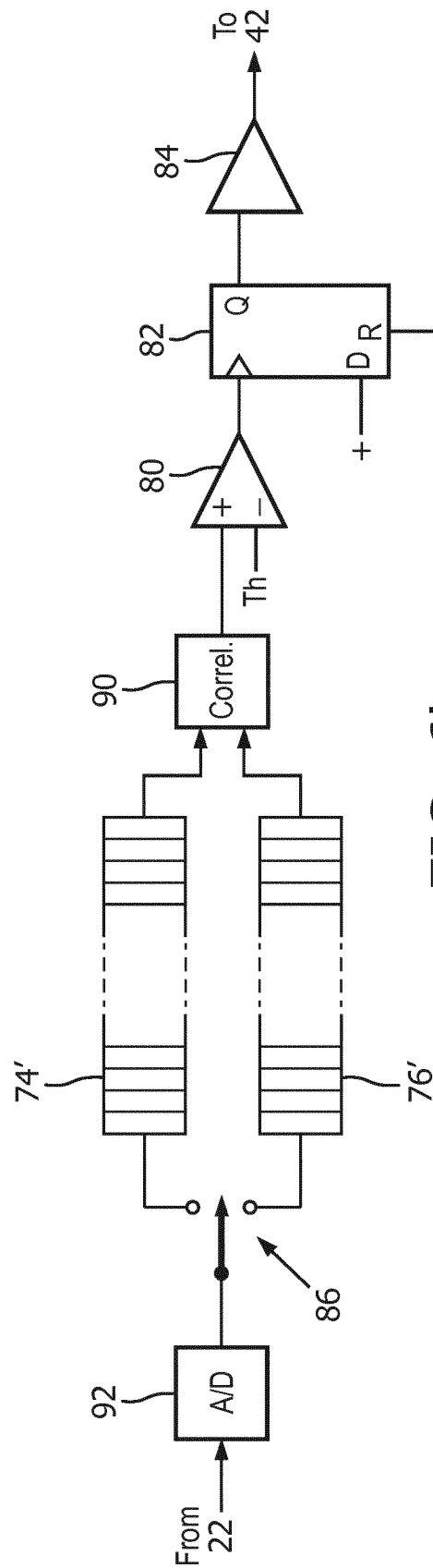


FIG. 6b

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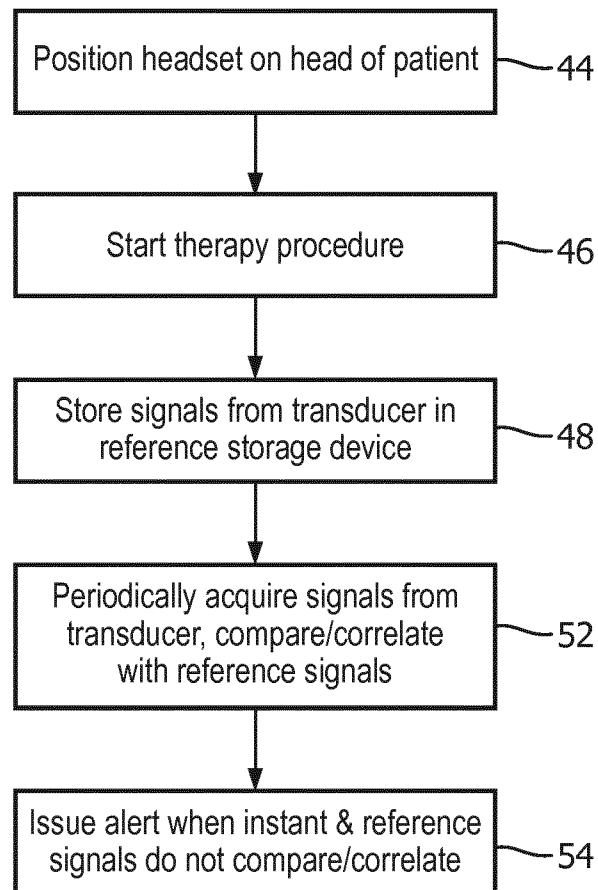


FIG. 7

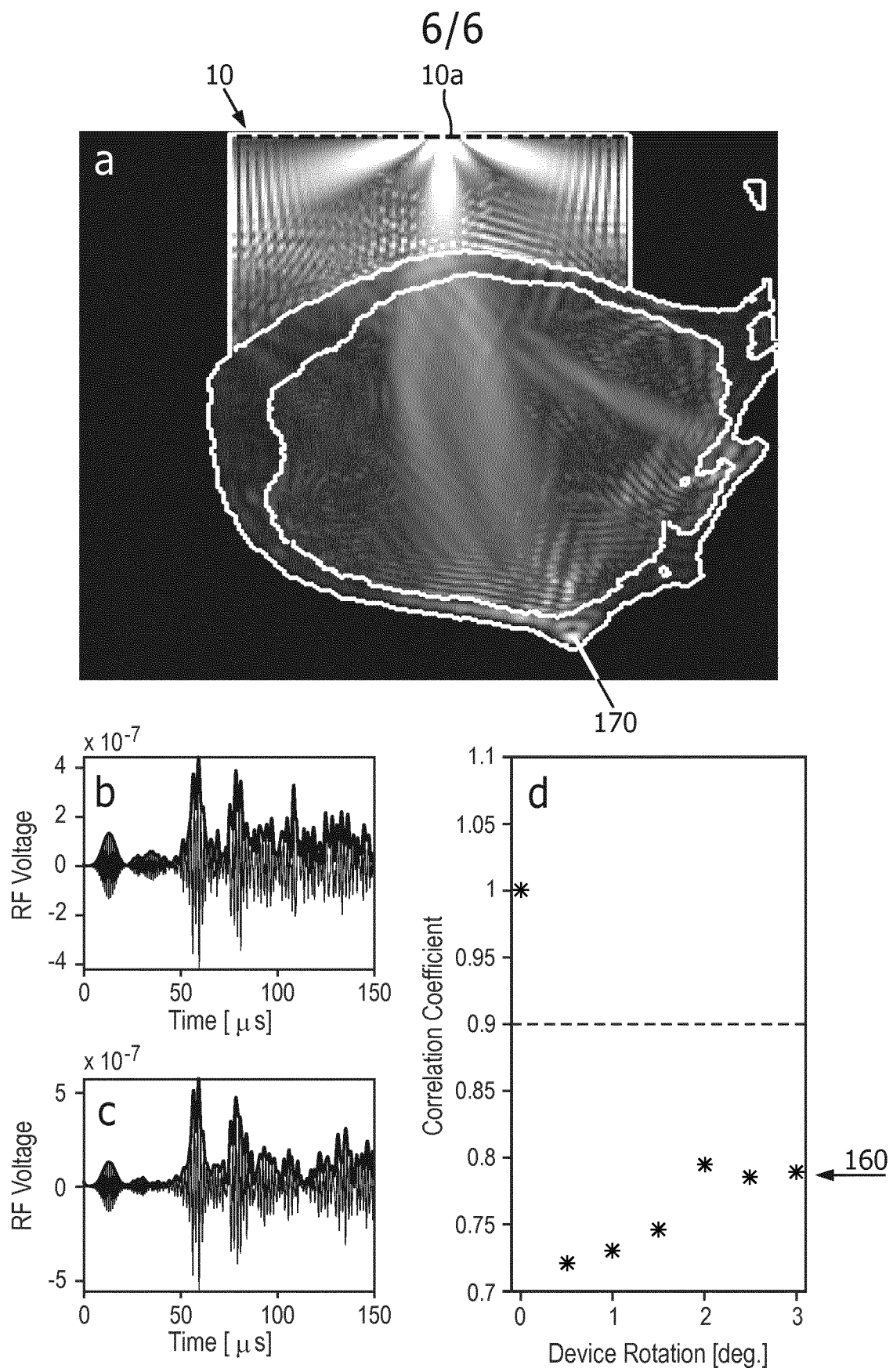


FIG. 8

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/083397

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61B8/06 A61B8/08 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)
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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Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	WO 02/45572 A2 (SPENTECH INC [US]) 13 June 2002 (2002-06-13) page 26, lines 17-30 -----	1-15
A	US 2002/103436 A1 (NJEMANZE PHILIP CHIDI [NG]) 1 August 2002 (2002-08-01) paragraph [0020] -----	1-15
A	WO 2006/068103 A1 (HITACHI MEDICAL CORP [JP]; OGIHARA MAKOTO [JP]; KUBOTA JUN [JP]; SASAKI 29 June 2006 (2006-06-29) paragraph [0044] ----- -/-	1-15



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents :

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

26 February 2018

Date of mailing of the international search report

06/03/2018

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Authorized officer

Gentil, Cédric

INTERNATIONAL SEARCH REPORT

International application No
PCT/EP2017/083397

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/EP2017/083397

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
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			WO 2014207665 A2	31-12-2014

专利名称(译)	经颅超声检查过程中的超声换能器阵列监测		
公开(公告)号	EP3554378A1	公开(公告)日	2019-10-23
申请号	EP2017821582	申请日	2017-12-18
[标]申请(专利权)人(译)	皇家飞利浦电子股份有限公司		
申请(专利权)人(译)	皇家飞利浦N.V.		
当前申请(专利权)人(译)	皇家飞利浦N.V.		
[标]发明人	SUTTON JONATHON THOMAS SHI WILLIAM TAO POWERS JEFFRY EARL SEIP RALF		
发明人	SUTTON, JONATHON, THOMAS SHI, WILLIAM, TAO POWERS, JEFFRY, EARL SEIP, RALF		
IPC分类号	A61B8/06 A61B8/08 A61B8/00		
CPC分类号	A61B8/06 A61B8/0808 A61B8/4209 A61B8/4488 A61B8/5207 A61N7/02 A61N2007/0021 A61N2007/0078 A61N2007/0095		
优先权	62/436164 2016-12-19 US		
外部链接	Espacenet		

摘要(译)

超声系统使用安装在受试者头部的头戴式耳机进行头颅治疗，该头戴式耳机包含治疗换能器和运动检测换能器。在治疗开始时，回波信号由运动检测传感器获取并存储。此后，由运动检测传感器再次获取回波信号，并与在治疗开始时存储的信号进行比较或相关。当在比较或相关信号之间确定差异时，系统发出可能已经发生换能器运动或声学解耦的警报。