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## (54) ULTRASOUND DIAGNOSIS AND TREATMENT APPARATUS

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## Description

### Field of the Invention

**[0001]** This invention relates to apparatus for the generation of sound waves, in particular to apparatus for transcranial Doppler sound devices for medical treatment of patients suffering from blood vessel occlusions or restriction in the brain characteristic of a stroke.

### Background

**[0002]** Blood circulation through the body is essential for maintenance and growth of cells and tissues. Any condition that restricts blood flow can have mild to disastrous consequences. For example, when blood flow in the brain is impeded, stroke can result. Stroke is a medical affliction that has severe consequences for most people who suffer it. Stroke is classified into four types, two of which are caused by blood clots (ischaemic stroke) and two of which are caused by haemorrhage (haemorrhagic stroke). Cerebral thrombosis and cerebral embolism account for up to 80 per cent of all strokes.

**[0003]** Treatment options for stroke are limited. For example, only tissue plasminogen activator (tPA) has been approved by the United States Food and Drug Administration as a pharmaceutical therapeutic treatment for ischaemic stroke.

**[0004]** It has been shown that the use of ultrasound waves and the Doppler frequency shift can be used to monitor the flow of blood through vessels (eg. Tegeler and Ratanakorn, 1999). Apparatus have been developed to exploit the potential of ultrasound to locate the interface between tissue types in the body, in particular, in the head, using transcranial Doppler ultrasound technology (TCD). US patent no. 4,817,621 described apparatus to locate reliably blood vessels in the brain and to determine blood flow through vessels in the head using TCD. The apparatus relied on the combination of two parallelogram-like linkage systems to support and locate an ultrasound transducer near the head of a patient to locate occluded blood vessels in the brain using TCD. More recently, it has been shown that monitoring of patients with TCD, in addition to treatment with tPA may increase the effectiveness of tPA in the treatment of ischaemic stroke (Alexandrov et al. 2004), using commonly available TCD devices and operators skilled in using the devices to locate occlusions.

**[0005]** Transcranial Doppler technology has been shown to be useful in the identification and treatment of small vessel, knock (WO2004/103184) associated with small vessel occlusion leading to stroke. The treatment taught in WO2004/103184 requires significant effort by an operator to find and diagnose the occluded blood vessels characteristic of stroke. While it has been shown that currently available ultrasound transducers and systems may be used for monitoring occluded blood vessels in stroke might also be a beneficial treatment method alle-

viating the symptoms of stroke, the ability to use TCD as a therapeutic treatment is currently constrained by the ease of use of said currently available systems. Clinicians who have used currently available TCD systems have noted that vascular tests that require the use of said TCD systems are among the most difficult to perform (Alexandrov et al., 2004). The ability of clinicians to diagnose and treat stroke with the promising TCD ultrasound technology may be limited by the apparatus with which to

5 diagnose and treat the condition. For example, the current method of identifying the presence of occlusions in brain blood vessels is a manual grading system, known as the thrombolysis in brain ischaemia (TIBI) flow grading system. One of the problems with a head cap or band 10 mounted or any other body or head mounted automatic diagnostic or treatment ultrasound device is that stability 15 of movement of the sensor with patient movement or simply device attachment slippage can affect measures and data integrity.

**[0006]** What is needed is an apparatus and method to more efficiently locate occluded blood vessels or vessels having restriction in the brain characteristic of stroke and to treat the occlusions or restrictions to alleviate the stroke symptoms.

**[0007]** US2005015009A1 discloses apparatus for imaging of vessels using sound waves, comprising: a scanning acoustic transducer assembly including elements for producing at least one sound wave beam; means for electronic beam steering; means for mounting an acoustic source/detector combination on a stabilizer; means for focusing of elements of an acoustic transducer/receiver array on selected target sites in an automated fashion; and means to accept sound signals from a sound-emitting element.

**[0008]** WO0158337A2 discloses apparatus for imaging and treatment of a thrombosis using ultrasound, comprising: a probe comprising two transducer elements for producing two sound wave beams; a driver configured to have an adjustable frequency output for adjusting the 40 parameters of said sound wave beams; a mounting attachment structured to hold the probe; and means to detect sound signals from one of the transducer elements.

**[0009]** In this document the words "including" and "comprising" are used interchangeably and with the 45 same meaning, which is intended to indicate non-limiting incorporation of elements.

### Brief Description of the Figures

**[0010]**

Figure 1 shows an embodiment of an ultrasound transducer useful in the invention.

Figure 2a shows a table of data providing near-field lengths and far-field divergence of ultrasound waves generated by typical ultrasound transducers.

Figure 2b shows a table of data showing the variation in velocity of ultrasound waves through selected ma-

terials found in living organisms.

Figure 3a shows an embodiment of multiple ultrasound transducers focussed electronically.

Figure 3b shows an embodiment of a concave lens being used to focus a linear array of ultrasound transducers.

Figure 4 shows embodiments of arrays of transducers, including curved and linear arrays.

Figure 5 shows embodiments of phased arrays of transducers which can be steered and focussed electronically.

Figure 6 shows an embodiment of the invention as an adjustable servo-array of ultrasound transducers.

Figure 7 shows an embodiment of invention in a sequence of operation of a phased array of ultrasound transducers.

Figure 8a shows an example of electric focussing of an ultrasound transducer.

Figure 8b shows an example of a phased array of ultrasound transducers.

Figure 9a shows an example of the pulse rate of an ultrasound transducer.

Figure 9b shows and example of depth resolution of an ultrasound transducer.

### Summary of the Invention

**[0011]** In one aspect the invention provides apparatus for imaging or treatment of occlusions or restrictions in vessels using sound waves, comprising: at least one servo-controllable sound transducer member including at least one sound-emitting element for producing at least one sound wave beam, the sound transducer member controllable by a feedback control signal originating from an occlusion in fluid flow, a restriction in fluid flow, or a combination thereof; means to adjust the parameters of said at least one sound wave beam; means to spatially locate said at least one sound-emitting element or means to orient said at least one transducer member; means to automatically or semi-automatically focus sound waves generated by said at least one sound-emitting element into a beam; and means to accept sound signals from sound-emitting element or elements. Preferably the apparatus includes means to move said at least one transducer member and means to control movement of said at least one transducer member automatically or semi-automatically. Preferably the sound-emitting element and the means to accept sound signals are the same. Preferably the at least one sound-wave beam is pulsed. Preferably the at least one sound-wave beam is focussed electronically. The invention may include two or more sound-emitting elements forming an array and the array may be curved. The at least one sound-wave-beam may incorporate a plurality of frequencies of sound waves in combinations of concurrent frequencies generated by the sound-emitting elements in the array or in a series of frequencies over time. The array may be comprised of sound- emitting elements in any of fixed position, adjust-

able position, or scanning position. The apparatus may include fiducial registration means and communication mean for communicating the position of the at least one sound-emitting element and maintaining the at least one sound-emitting element in optimal positioning during sonication.

**[0012]** The sound-emitting elements may be moveable singly or in a coordinated manner, including simultaneously. The sound-emitting elements may be servo-controllable, including feedback control. The servo-control means may be self-tracking and include means for determining out-of-range positioning of said at least one sound-emitting element. The feedback control may incorporate a signal characteristic of an occlusion in a fluid flow. The apparatus may include a plurality of sound-emitting elements in at least two layers of at least two arrays. Preferably each transducer member is operable to enable a continuously adjustable focus point comprising of two or more sound beams emitted by at least two sound- emitting elements. Preferably the apparatus includes means to transform sound signals from analogue to digital forms or digital to analogue forms. Preferably the apparatus includes means to store transformed digital data. Preferably the apparatus includes means to display analogue or digital data. Preferably the apparatus includes video display means for displaying data. The apparatus may include voice coil control means. Preferably the apparatus is operable in real-time or near real time. Preferably the apparatus includes fiducial registration means for maintaining targeted sonication. Preferably the apparatus is used for detecting and sonicating vessels in the brain of a being. Preferably the sound waves are ultrasound waves.

**[0013]** In another aspect, the invention provides a method for locating an occlusion in a vessel or a restriction in a vessel, including the steps of: identifying regions of a body in which an occlusion or restriction might be found; selecting a region of interest for sonication with sound waves; sonicating the region of interest with at least one sound-wave beam produced by a servo-controllable sound transducer member by moving said sound-wave beam across said region of interest; receiving reflected sound signals from said region of interest, wherein at least one of said sound signals is a feedback control signal originating from an occlusion in fluid flow, a restriction in fluid flow, or a combination thereof; and calculating the Doppler effect parameters of flow and turbulence from said reflected sound signals.

**[0014]** In one embodiment, the invention provides a method for distinguishing anatomical features of an organism including the steps of sonicating a region of interest in a subject with at least one sound-wave beam, whereby the frequency of said at least one sound-wave beam is suitable for determining a particular tissue type, receiving reflected sound signals from said region of interest, calculating the Doppler effect parameters of said reflected sound signals and characterising said Doppler effect parameters according to parameters associated

with known tissue types.

**[0015]** The method of the invention may include the step of modifying the characteristics of the at least one sound-wave beam to target a region of interest wherein the Doppler effect parameters are indicative of reduced flow attributable to an occlusion or a restriction. The method may include the step of sonicating the region of interest thereby causing agitation or dissipation of the occlusion by prolonged sonication or recanalisation of a restriction. The method may include the step of automatically or semi-automatically evaluating and optimising the effect of sonication on an occlusion for feedback modification of said at least one sound-wave beam, said evaluating and optimising including tissue safety guidelines. The method may include that the step of automatically or semi-automatically evaluating and optimising the effect of sonication includes maintaining a fiducial registration between sound waves beams and a registration signal. The method may include the step of calculating and displaying any one or a combination of an index, measure, or marker or suitable representation indicating the progress of dissipation of an occlusion in a vessel or recanalisation of a vessel having an occlusion or restriction. The method may be carried out automatically or semi-automatically substantially without human control. The method may be carried out wherein the region of the body is the head. Preferably the region of the head is the circle of Willis. The method may include the two or more sound-wave beams moving across said region of interest in either a simultaneous or sequential manner. The method may include having the at least one sound-wave beam pulsed. The method may include the parameters calculated from said reflected sound signals being any one or a combination of power, spectral, amplitude, phase coupling or frequency characteristics characteristic of a spatial representation of anatomical features in said region of interest or occlusive material. Preferably the power or amplitude spectral analysis are carried out using Fast Fourier Transform techniques. Preferably the at least one sound-wave beam is continuous. The method may include the at least one sound-wave beam being initially transmitted with a first frequency or amplitude and subsequently with periodic changes resulting a second and further frequency or frequencies or amplitude(s) relative to the first beam frequency so that the mark-to-space ratio of the apparent changing and pulse formation is continuous. Preferably the sound-wave beam is comprised of ultrasound waves. The method may include the step of conducting a spatial voxelated analysis of received signals.

#### Detailed Description of the Drawings and Preferred Embodiments

**[0016]** It is an object of the present invention to provide an apparatus that reduces the need for significant operator interaction with a sound-wave generating device used in the identification and treatment of embolism or

stenosis. It is a further object of the invention to provide a method of semi-automatic or automatic location of embolism or stenosis using sound waves. It is a further object of the invention to provide an apparatus for the automatic or semi-automatic location of blood vessel emboli or stenosis in the brain. It is a further object of the invention to provide a means to semi-automatically or automatically locate an occlusion or restriction in a blood vessel. It is a further object of the invention to provide a means to semi-automatically or automatically treat said emboli or occlusion or restriction with sound waves. It is a further object of the invention to provide an apparatus to utilise the energy of transcranial Doppler ultrasonography in thrombolysis and recanalisation of blood vessels in the brain.

**[0017]** The following description refers to the preferred embodiment of the invention using ultrasound waves. It will be understood that sound waves of other frequencies than ultrasound are suitable for other embodiments within the scope of the invention. For example, in another embodiment, the invention includes apparatus that utilises low-frequency pulsatile sound waves that may be focussed to achieve similar results as the preferred ultrasound waves. In this document, the word, "occlusion", includes any one of, or a combination of, an embolism, thrombus, or other biological matter, non-biological matter, including gases, from whatever source. In this document, the word, "stenosis", includes any restriction in a fluid-containing vessel.

**[0018]** An example transducer member 24 comprising a single ultrasound-emitting element is illustrated in Figure 1, the ultrasound-emitting element includes a piezoelectric element 21, backing material 22, and electrodes 23. The ultrasound-emitting element converts electric voltage applied across the ultrasound-emitting element into ultrasonic sound-wave energy. When a beam of ultrasonic sound-wave energy is directed toward heterogeneous biological material of interest, the ultrasonic sound-wave energy is reflected at the interfaces of biological structures within the biological material. The reflected energy causes an ultrasound-receiving element to vibrate and to produce a voltage signal which can be processed to decipher the reflective properties of the biological material. It will be understood by persons skilled in the art that a single ultrasound element may function either as an ultrasound-emitting element, an ultrasound-receiving element, or both an ultrasound-emitting and an ultrasound-receiving element. An ultrasound beam produced by an ultrasound-emitting element may be pulsed or unpulsed in duration. A pulsed beam is pulsed at a rate required for the biological material of interest as illustrated in Figure 9a. Figure 9b shows the time sequence of an ultrasound beam resolving two surfaces, It will be understood that axial or depth resolution is the ability to determine the axial resolution of two objects located tandem to the ultrasonic beam. The axial resolution is determined by the spatial pulse length.

**[0019]** The transducer diameter can be selected to suit

various depth ranges required for different treatment applications. Figure 2a shows the properties of a range of depths of commercially available ultrasound transducers and Figure 2b shows the variability of velocity of ultrasound beams in different biological materials, which is exploited in the invention. The velocity of the ultrasound signal depends on the constitution of the material through which the signal travels, the velocity being directly proportional to the density through which the ultrasound is transmitted. The transmission through tissue is 1540 m sec<sup>-1</sup> or, alternatively, a 1 cm transmission depth requires 13  $\mu$ sec to be traversed by an ultrasound wave.

**[0020]** The ultrasonic beams generated by a transducer can be focussed with focussing means. Preferably the lateral and depth positioning of the ultrasonic beam focus point can be adjusted by way of electronic focussing, illustrated in Figure 8a. An embodiment of a focussed transducer member 25 with an ultrasound-emitting element, shown in Figure 3a, can provide improved lateral resolution at depth. Focussing types can include curved mirrors, acoustic crystals, acoustic lens, or phased array (employing electronic focussing). The operation of ultrasound-emitting elements in a phased array is shown in Figure 8b.

**[0021]** The ultrasound-emitting elements may be positioned in an array within a transducer member 25 and may take alternative forms. Figure 4 shows that such forms may include curved arrays 26 and linear arrays 27. The application of voltage to an array of ultrasound-emitting elements of a transducer member may be pulsed out-of-phase to achieve steering and focussing of an ultrasound beam as illustrated in Figure 5. The invention includes that each of said at least one transducer members 25 may be comprised of any combination of ultrasound-emitting and receiving elements.

**[0022]** Illustrated in Figure 6 is an embodiment of the invention. It will be understood that a particular embodiment will incorporate a selection of features to achieve the objects of the invention and that the embodiment in Figure 6 is illustrative only. A sensor enabling said ultrasonic-beam transmission and/or handling may be comprised of piezo or PVD material, or other suitable material or a suitable sensor capable of generating and/or receiving ultrasonic beam signals. Said at least one transducer member may include a combination of one or more members in fixed-position array, adjustable-position array 1, scanning-position single-member 2 or multiple-element transducer members, fixed-position single-member or multiple-element transducer members.

**[0023]** The focussing point 5 of an ultrasonic beam can be achieved through any combination of servo-driven control of an adjustable-position array-transducer member 3, servo-driven control of the scanning-position single-member 2 or multiple-element transducer member 4, the switching combination of fixed-array beams 6 or any combination thereof. Preferably the location of ultrasound transducers is achieved through servo-movement.

**[0024]** Said ultrasonic beams can be accurately positioned via ultrasonic grid arrays or reference markers located on a device case or housing 7 or at any point within said beams as a measure of final beam-positioning feedback for high resolution and focus accuracy for said converging ultrasonic beams. The beam-positioning feedback enables the servo-control position circuitry 8, in turn, to reflect the positional requirement for said ultrasonic beams, either in accordance with an operator's remote selection, by way of communication means, or locally selected by way of direct communication, input into said servo-control position circuitry through manipulation of ultrasonic beams 1 and focal point 5. Transducer members 4 may be adjusted so that the direction of the ultrasonic beams 1 can be oriented either two-dimensionally or three-dimensionally according to the positioning of at least one servo-adjust spigot 3. A secondary ultrasound member comprising a single transducer member, or alternatively at least two transducer elements, may comprise of either a single ultrasonic beam 2 or multi-array ultrasonic beams 4. Furthermore, multi-layer, multi-array ultrasonic beams may be used where a singular or group of three-dimensional (in space) positioning ultrasonic beam focus capability by way of aperture adjustment 11, such as piezo-aperture control.

**[0025]** As stated, the scope of the invention includes alternative embodiments to that herein illustrated and may include embodiments wherein the sound transducers are arranged in arrays and in multiple layers of arrays. Embodiments include those where the sound transducers are arranged in a single array, the sound beams generated by a plurality of transducers in an array focussed at a single target. The transducers in an array may be in fixed position or moveable.

**[0026]** The apparatus may include a fiducial registration means (not shown) for maintaining the optimal positioning of sound-emitting elements for continued sonication when the subject moves, for example. Preferably said fiducial registration means are additional sensors attached to ultrasonic transducers and transceiver devices attached to a subject. Communication between fiducial registration means may be through wire connectors or wireless communication means. Said fiducial registration means includes means for attachment to the subject and means for communicating between the subject and the servo-control means 8. The control means includes means to measure the correct registration of signals from the fiducial registration means. The fiducial registration means is placed in fixed position at the commencement of sonication with a suitable adhesive material such as self-adhesive locators attached to a subject. When the communication between the fiducial registration means and the control means indicate a departure from the initial optimal signal registration, the control system may prompt the operator by way of a prompting means that the sound-emitting means is out of alignment. Said prompting may occur automatically. Such a method and device enhances the ultrasonic beam targeting

method, where for example, a subject ultrasonic transducer attachment device, such as one located on glasses or a headcap, moves during automatic or remote-controlled recanalisation or sonication of the subject.

**[0027]** The invention includes that the variability of velocity of ultrasound waves in different tissues may be exploited to characterise the tissues in a region of interest in a subject where it is suspected that there might be an occlusion or a restriction in fluid flow, for example, blood flow. Sonicating a region of interest with multiple frequencies of sound-wave beams, each selected frequency being associated with a tissue type as indicated in Figure 2b, wherein the multiple frequencies are generated by any of at least one sound-emitting element at spaced intervals or two or more sound-emitting elements concurrently or in a pre-determined series of frequencies allows the characterisation of an occlusion or restriction in fluid flow as being attributable to a cause such as a gas bubble or bubbles, solid material, blood, tissue, vessel, skin, organs or other material.

**[0028]** The invention includes an apparatus having an arrangement of ultrasound transducers that enables the automatic mapping or visualisation of the progress of the dissolution of the target embolus.

**[0029]** The invention includes means capable of servo-feedback to ultrasonic turbulence (such as fast Fourier transformation) representation of the turbulence associated with blood vessel occlusion. Preferably the servo-feedback is optimised for the most effective vessel recanalisation.

**[0030]** The invention advantageously utilises sound waves produced by an ultrasound transducer to locate blood vessels that might show embolism. One embodiment of the invention includes a method for identifying an embolism or stenosis. In a first step of said method, regions of the body in which emboli might be found are identified. Preferably the region of the body is the head. More preferably the region of the body is the circle of Willis in the head. In a second step, a particular region of interest is selected. In a third step parameters of flow and turbulence are calculated for subsequent automatic ultrasound beam localisation in a fourth step, said parameters including the spectral power or amplitude or phase coupling or frequency segmented characteristics of flow and turbulence of flow blood.

**[0031]** In said first step of identifying regions of the body in which emboli might be found, at least one ultrasound transducer generates an ultrasound beam which is moved across the surface of the region of the body in a scanning motion. Said ultrasound transducer or transducers may be fixed in an array in space relatively to one another or moveable in space relative to one another. Alternatively, said transducers may be fixed in arrays in layers. Said beams from said ultrasound transducers in said scanning motion may be operated in said scanning motion either simultaneously or sequentially across said body regions.

**[0032]** In the second step the Doppler effect on echo

beams received by the transducers is calculated. The analysis characterises the flow characteristics associated with the variation in frequency detected from the original ultrasonic transmission beam frequency. The analysis incorporates referencing and compensating for beam signals associated with normal echo beams such as flows associated with heart pumping or respiration and distinguishes such echo beams from beam signals of interest. The analysis further incorporates compensating for beam signals such as those associated with flow artefacts associated with ghost echoes, and those attributable to partial flows around occlusions and/or locally enhanced flows near occlusions.

**[0033]** Said ultrasound transducers generating the pulsed or unpulsed ultrasound beams may also receive the transmitted return echoes of transmitted beams. Where ultrasound beams are transmitted from a transducer in a continuous, i.e. unpulsed wave, a beam is initially transmitted with a first frequency or amplitude and subsequently with periodic changes resulting a second and further frequency or frequencies or amplitude(s) relative to the first beam frequency so that the mark-to-space ratio of the changing (apparent) pulse formation (but continuous) enables the computation of distance by decoding and determining the received (apparent) pulse from the last or a specific transmission pulse (known from the changes amplitude, frequency, phase or any combination thereof characteristics in the second and later characteristics of the continuous beam, known receive time and known speed of beam enables distance calculation related to deflected beam and Doppler shifted return pulse, for example).

**[0034]** The changes in frequency based upon the principles of Doppler frequency modification provide a composited signal comprised of various blood flow characteristics associated with said scanning beam. Contained within said composited signal is a range of data which may be extracted by means of frequency power and frequency segment characterisation.

**[0035]** Preferably the sound waves generated by an ultrasound-emitting element are within the ultrasound frequency range. It will be understood that the invention is not restricted to an apparatus or method comprising ultrasound waves, but that an apparatus or method according to the invention can accommodate frequency bands other than those within the ultrasound frequency band.

**[0036]** Frequency power or amplitude spectral analysis can be conducted using same or similar means to Fast Fourier Transform, whereupon various components of the flow and flow turbulence signals associated with said ultrasound beam are represented in terms of power or amplitude of each respective frequency or range of frequencies of said beams. The frequencies or range of frequencies in turn represent the various changes or modifications through the Doppler principle of the original transmission ultrasonic beam. In turn the combination or characteristic "fingerprint" of the combinations of fre-

quency power and absolute frequencies present provide an indication of Suspicious Regions of Interest (SROI) wherein an embolism might be located.

**[0037]** For the desirable target scanning and detection of SROI certain properties will be detected in a sequence of more and more sensitive scans, conducted in a spatial voxelated (3D spatial biological substance segmented into triangular voxels each associated to a mathematical matrix to enable recall with spatial localisation of x, y, z coordinates) visualisation (means to represent said voxels into an image or image view or travel path through said biological subject) until the most sensitive scan sequence is conducted and the subsequent SROI also marked.

**[0038]** The properties of the characteristics or "finger-prints" and the sequence of progressively more sensitive scans will determine the sensitivity and specificity of the present device and method for detection SROI in relation in particular to vessel occlusions.

**[0039]** The invention includes that the unique combination of blood flow or absolute and specific frequency of the blood and the spectral power enables a determination of the location of a specific occlusion and a determination of the nature of the material causing the occlusion.

**[0040]** The invention includes a method that utilises such characteristics and associated determinations to firstly, detect the spatial location of such occlusions and, secondly, determine the specific location of the occluding material in order to determine where to direct the ultra-sonic beam to assist with the agitation or dissipation of such an occlusion to advantageously be most effective in eliminating or reducing the occlusions. Similarly, the beams can be directed in such a manner that the paths or trajectory of the beams provide minimal power and energy transfer to healthy cells but the focus or combined beams enhance the ability to diffuse of break-up such blockage material, in the fastest but safe manner.

**[0041]** The invention includes apparatus and methods for focussing a plurality of beams of ultrasound waves with the concentration of said beams causing the agitation or dissipation of an occlusion in a blood vessel.

**[0042]** The invention includes apparatus that generates ultrasound waves and measures the Doppler effect on reflected waves in a stable manner. In operation the apparatus scans the target areas of the body for known spatial flow characteristics of relatively strong and distinct blood vessels. The locational map of the spatial characteristics or a simplified syntactic representation of the blood vessel spatial characteristics are stored in memory, in particular, specific coordinates that respond to certain known vessel location properties.

**[0043]** By utilising a biological referencing system said apparatus or method can periodically check the movement of the apparatus against said biological reference point and appropriately adjust the display or data coordinates in accordance to the compensation of such detected movement. This enables an operator to continue

to read and view relatively stable readings, data or image display. Also the servo mechanisms of the apparatus can compensate for the movement of the Apparatus during operation and continue to treat or diagnose the selected areas or regions of interest.

**[0044]** The method includes the use of Doppler signal data to calculate parameters associated with fluid flow, including the speed, volume, and intensity of flow. This includes the ability to determine the rate of change in any parameter over time. By calculating these parameters at spaced intervals and calculating the differences in the parameters over the intervals the progress of dissipation of an occlusion or recanalisation of a restriction may be conveniently measured. The changes in the parameters can be conveniently used to determine the effectiveness of the sonication procedure, in particular, that the procedure has effectively dissipated an occlusion or recanalised a restriction so that the cause of the reduced fluid flow has been removed substantially from the vessel. In particular, the rate of change of any parameter may be included in the calculation of any index, marker, measure, or representation of the progress of the sonication.

**[0045]** Figure 7 shows a typical sequence of operation of an embodiment of the invention in apparatus and method for identifying and sonication a thrombosis In the following sequence of steps, wherein the number of the step below is indicated at its corresponding place in Figure 7.

- 30 1. Start ultra-sound occlusion-related detection and target treatment.
2. Ultrasonic Beam Focus Control.
3. Scan for Suspicious Region Of interest (SROI). The Doppler stroke-treatment ultrasound phased-array transducers can be steered across larger regions to enable a means to scan for SROI.
- 35 4. Once the SROI candidate(s) are detected the finer resolution focus mode can be applied to determine the Region Of Interest (ROI). The ROI as with SROI can be subjected to further FFT or acoustic footprint analysis, characterisation and comparison (with deviation consideration) and final operator verification.
- 40 5. Scan for ROI comprising finer beam focus and ultrasonic spectral (FFT), phase, amplitude or any combinational analysis thereof. FFT spectral "footprint" or acoustic characteristic footprint, associated with occlusion blood flow can be detected firstly on the course scan and detect mode [SROI] Acquire ultrasonic data for archive, analysis, retrieval, remote view, remote control purposes.
- 45 6. Transform ultrasonic return echo data into frequency spectral (FFT), phase and/or amplitude characteristics. ROI can be detected by way of computing the acoustic or FFT foot print across a region using sweep mode and then utilisation representing characteristic of blood turbulence or flow characteristics associated with vascular partial or total occlusion.
- 50 7. Compare acquisitioned ultrasonic acoustic echo

data characteristics with those of reference finger-prints for likely acoustic characteristic representing stroke-related occlusion acoustic flow related turbulence.

8. Reference data base presenting FFT characteristics and ultrasonic characteristics or footprint associated with SROI or ROI detection determination.  
9. Deviation Characteristics- being the allowable detection tolerances against the data base of acoustic "occlusion" "fingerprint" data base comparison events.

10. Using any combination of neural network, artificial intelligence, or other analysis methods compare reference data base of typical "finger-prints" of stroke-related occlusions, along with acceptable deviation characteristics, in order to compute valid detection of occlusion and coordinates for optimal treatment focus and targets.

11. Co-ordinate data associated with ROI and assonating target data available for phase array or other type of ultrasonic transducer focussing control.

12. Ultrasonically enhanced Thrombosis Treatment Operator validation and Focus Treatment Focus Targeting.

13. Once operator verification is acknowledged user can select to automatically lock in ultrasonic-enhanced thrombosis mode, where upon phase array multiple beam focus treatment can be applied.

14. User display and user interface allowing manual, automatic or computer assisted ultrasound stroke-related occlusion detection and/or treatment.

15. Knowledge decision base option for artificial intelligent occlusion detection and ultrasonic control analysis option. Artificial Intelligence reference to support neural network processing decision matrix. Can be updated by system expert users or remote intelligence base. Current system can be designated as expert user to enable artificial intelligence supporting increased accuracy in detection and control of stroke-related occlusion (emboli).

16. Spatial cycling or "massaging" modes possible with variation of frequency or sequences of treatment frequencies as well as variation of spatial positioning to enable optimal working at the edges and/or solid occluding material in order to control optimal diffusion and safe agitation or dissipation of dissolving of material (minimise further occlusion with risk of large break-away material)..

17. Treatment temporal analysis and progress tracking in order to enable adjustment for intensity or and power of ultrasonic treatment from most gentle and safest treatment to most aggressive and rapid emergency treatment modes.

18. Screen shows treatment target display marking of SROI and also audible or other local or remote system alert.

19. Screen target display marking of ROI and also audible or other local or remote system alert.

20. Screen target display marking of ROI and SROI and also audible or other local or remote system alert.

5 [0046] The invention includes apparatus having remote video capabilities for observing the output of ultrasound beams generated from an ultrasound transducer at a location remote to the subject on which the beams are focussed.

10 [0047] The apparatus include the possibility of remote manual adjustment to the control on ultrasound beam parameters.

[0048] The apparatus may include a three-dimensional bio-optical means wherein the ultrasound signal received by an ultrasound transducer is transformed into computer graphics for easy viewing and interpretation by an operator.

[0049] The apparatus may include a method for transforming TCD output signals into graphical representations for a computer or other viewing screen. It will be understood that the screen may be any screen capable of displaying a digital or analogue signal.

[0050] The Invention includes an array of ultrasound-emitting elements wherein each element of said array is capable of focussing ultrasound waves at a focal point. The invention includes ultrasound elements that are piezo-electric crystals in an ultrasound transducer.

[0051] The invention may include apparatus operable with voice coil technology for the positioning of ultrasound transducers on a patient's head.

[0052] The invention includes an apparatus for TCD ultrasound that automatically or semi-automatically scans and maps the location of blood vessel occlusions, using the methods described herein. Said automatic or semi-automatic mapping is effected by the use of means, such as a computer database and program or programs in which normalitive sound-wave data is stored for automatic comparison with sound-wave data acquired from the sonication of an SROI or ROI according to the procedure illustrated in Figure 7. Said database may contain data representative of a two dimensional or three-dimensional map for the SROI or ROI in a subject or a representative normalised subject. Said means may further include computer program or programs for displaying representations of the acquired data in comparison with normalitive data, such as on a video display unit...Said computer program or programs may suitable processing techniques for reflected ultrasound waves such as fast Fourier transformation techniques, and determining the most likely regions for occlusions by comparing fast Fourier outputs for free-flowing or occluded vessels. Said video display unit may show a representation of the region being sonicated, preferably in real-time according to the information stored in the database. Said computer program may further display acquired sonication data on said video display unit to indicate the position of sonication in two-dimensional or three-dimensional space in relation to known anatomical characteristics of a subject.

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**[0053]** The method of the invention includes a diagnostic capability to detect an occlusion either by way of the measurement of fluid flow in a ROI or turbulence in the vicinity of an occlusion. Said diagnostic capability may include a comparison of sound-wave data indicating the presence of fluid spurts within a vessel or fluid flow rates associated with recanalisation of stenosis in such a way as to enable the distinction between the presence of an occlusion or a stenosis. Said diagnostic capability includes the calculation of fluid flow and turbulence in the region of the occlusion or stenosis by way of using sound-wave data for measurement of any of fluid flow rate, fluid flow quantity, fluid turbulence, or intensity.

**[0054]** The apparatus or method further includes displaying an index, measure, marker, or series of markers or other suitable representation characteristic of the progress of recanalisation of a vessel during any or both of diagnosis or treatment on said video display unit. The apparatus or method further may include the incorporation of said index, measure, or series of markers into a means, such as a computer program, for optimising the at least one sound-wave beam incorporating at least one frequency in order to provide better control over the rate of recanalisation and sonication power.

**[0055]** The invention includes many embodiments. For example, the invention includes apparatus wherein a first ultrasound transducer is fixed in relation to a target occlusion characteristic of embolism in a blood vessel. A second ultrasound transducer is positioned in relation to said first transducer such that both transducers focus the emitted beams of ultrasound waves onto an occlusion in said blood vessel. The second transducer may be positioned using a servo device. It will be apparent to those skilled in the art that more than two ultrasound transducers may be included in the invention and that each transducer may be positioned relative to the others so that the target occlusion is located at a common focal point for the beams of ultrasound waves. Preferably the invention includes an array of transducers. Preferably the array is a structured array. The advantageous effect of the multiple ultrasound transducers with a common focal point will be to focus the maximum ultrasound energy on the occlusion and result in the most effective embolism dispersing treatment.

**[0056]** The invention provides a method to optimise the focus of the ultrasound beam or beams using servo-movement. One or more servo mechanisms and/or ultrasonic phased array transducer control systems can be deployed to enable a continuously variable positioning of focus point in order to enable optimal energy focus of one or more beams. The said energy focus is able to be divided at one or more precise locations with high spatial resolution in order to focus energy away from healthy tissue (is desirable and as desirable), where at the same time focussing energy of a set of beams at the location of vascular occluding material, in order to disintegrate or diffuse or disperse said occluding material in an optimal and safe treatment manner.

**[0057]** Furthermore, the at least one treatment beam of ultrasonic frequency can comprise one or more frequencies optimized for functions enabling any sequence or simultaneous combination of optimal a) gaseous partial or total occlusive material detection; b) solid material partial or total occlusive material detection; or c) gaseous partial or total thrombolysis and recanalisation of partial or fully occluded blood vessels.

**[0058]** The invention provides an apparatus to facilitate the safe dispersion or dissolving of an occlusion (thrombolysis or recanalisation of blood vessel). One of the risks associated with ultrasonically enhanced thrombolysis is the risk that dislodged occluding material can "break away" or disintegrate in large and unsafe particle sizes, which in turn can cause further occlusion or risks of occlusion or partial vessel blockages. In particular, vessel blockages such as within the legs or lower body may be recanalised and cause particles to travel higher in the circulatory system such as in the brain. In these regions the vessels can be smaller and lead to further blockages and more serious consequences such as ischaemic stroke.

**[0059]** The invention provides an apparatus for simultaneous diagnosis and treatment to regulate towards safe thrombolysis and recanalisation of blood vessels. The present invention includes the diagnosis or identification of a particle or total occlusion of a vessel while at the same time or separately providing ultrasonically enhanced thrombolysis or vessel recanalisation.

**[0060]** The focus adjustment and targeting of the at least one ultrasonic beam, along with accurate spatial resolution and power control (of targeted ultrasound treatment) enables a controlled dispersion of occluding material in a vessel by allowing different patterns or massaging (movement of beam focus around, over and near occluding material) and different ultrasonic frequencies or combination or sequences of frequencies (different frequencies effect different material types and also effect the dispersion rate and size of dispersed occluding material particles) or any combination thereof to be applied to the region of vessel occlusion or partial occlusion. The treatment of an occluded vessel can thus be controlled, targeted and regulated in order to minimize the particle dispersion size and risk for further occlusion.

**[0061]** The present invention enables one or more ultrasonic frequencies either sequentially or simultaneously to be generated as a means to both enhance diagnosis and imaging and also enhance ultrasonic vessel recanalisation treatment.

**[0062]** The present invention includes a three-dimensional mapping capability and tracking of the maximum power generation by the at least one ultrasound transducer. This enables a register or matrix representing the computation of ultrasonic power generation at any point in time and any spatial location under scan. Said "matrix or register" computes the probable power dissipation of ultrasound scan beams based on the beam dispersion characteristics. Furthermore, the intersection of beams

along with the focus characteristics are computed and provide a resulting reference data set to enable or to ensure that maximal safe power thresholds are achieved at all locations and that the additional ultrasonic power required to rapidly diffuse vessel occlusion is only directed specifically where required and where safe, i.e., targeted at surrounding healthy tissues.

**[0063]** The present invention provides the capability to enable ultrasonically-enhanced thrombolysis and vessel recanalisation to be moderated in treatment intensity (power) in accordance with or in harmony with "clot-busting drug" characteristics of action. This consideration can minimize risk of side effects of each said treatment, such as haemorrhage risk with "clot-busting drug" treatment, or excessive ultrasound power and cell harm with ultrasound treatment.

**[0064]** The present invention provides that data such as the drug administration rate, drug composition or type, and patient risk category to haemorrhage, such as haemophiliacs, can be entered into a clot drug-profusion device and also ultrasound power and focus control, for example.

**[0065]** The present invention most advantageously enables the intravenous or manual administration of clot-busting drugs to be regulated or monitored in such a manner as to regulate the balance between the strength of the clot balanced or administration optimized to minimize the risk of side effects the occluding material and minimally targeted clot-busting drug administration, with risks of haemorrhage side effects, with the aggressive or high powered application of ultrasonically enhanced thrombosis treatment, with the risk of healthy cell harm and also dispersion of further clot-causing material.

**[0066]** The present invention enables the ultrasonic control and the "clot-busting drug" administration to be servo-controlled in such a manner that optimal speed of thrombosis and recanalisation of the vessel(s) and also optimal safety or mitigation to patient risks are possible.

## References.

### [0067]

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## Claims

1. Apparatus for imaging or treatment of occlusions or restrictions in vessels using sound waves, comprising:

at least one servo-controllable sound transducer member (24) including at least one sound-emitting element (21) for producing at least one sound wave beam, the sound transducer member controllable by a feedback control signal originating from an occlusion in fluid flow, a restriction in fluid flow, or a combination thereof; means to adjust the parameters of said at least one sound wave beam; means to spatially locate said at least one sound-emitting element or means to orient said at least one transducer member; means to automatically or semi-automatically focus sound waves generated by said at least one sound-emitting element into a beam; and means to accept sound signals from sound-emitting element or elements.

2. Apparatus according to claim 1 including means to move said at least one transducer member (24).

3. Apparatus according to claim 2 including means to control movement of said at least one transducer member (24) automatically or semi-automatically.

4. Apparatus according to any one of claims 1 to 3 wherein the sound-emitting element (21) and the means to accept sound signals are the same.

5. Apparatus according to any one of claims 1 to 4 wherein the at least one sound beam is pulsed.

6. Apparatus according to any one of claims 1 to 5 wherein the at least one sound wave beam is focussed electronically.

7. Apparatus according to any of claims 1 to 6 wherein two or more sound-emitting elements (21) form an array.

8. Apparatus according to claim 7 wherein the array is curved.

9. Apparatus according to claim 7 or claim 8 wherein the at least one sound beam incorporates a plurality of frequencies of sound waves in combinations of

concurrent frequencies generated by the sound-emitting elements (21) in the array or in series of frequencies over time.

10. Apparatus according to any one of claims 7 to 9 wherein the array is of sound-emitting elements (21) is any of fixed position, adjustable position, or scanning position. 5

11. Apparatus according to any of claims 1 to 10 wherein the sound-emitting elements (21) are moveable singly or in coordinated manner including simultaneously. 10

12. Apparatus according to any one of claims 1 to 11 wherein the servo-control means is self-tracking and including means for determining out-of-range positioning of said at least one sound-emitting element (21). 15

13. Apparatus according to any one of claims 7 to 10 further including a plurality of sound-emitting elements (21) in at least two layers of at least two arrays. 20

14. Apparatus according to any one of claims 1 to 11 wherein each transducer member (24) is operable to enable a continuously adjustable focus point comprising of two or more sound beams emitted by at least two sound-emitting elements (21). 25

15. Apparatus according to any one of claims 1 to 14 including means to transform a sound signal from analogue to digital forms or digital to analogue forms. 30

16. Apparatus according to any one of claims 1 to 15 including means to store transformed digital data. 35

17. Apparatus according to any one of claims 1 to 16 including means to display analogue or digital data. 40

18. Apparatus according to claim 16 including video display means for displaying data or indicating to an operator of the status of the sonication. 45

19. Apparatus according to any one of claims 1 to claim 18 including voice coil control means. 50

20. Apparatus according to any one of claims 1 to 19 wherein said apparatus is operable in real-time or near real-time. 55

21. Apparatus according to any one of claims 1 to 20 including fiducial registration means for maintaining targeted sonication and communication means for communicating between fiducial registration means and servo-control means. 55

22. Apparatus according to claim 21 including means for

prompting an operator when said apparatus is out of registration.

23. Apparatus according to claim 21 wherein the communication means includes wireless communication capacity.

24. Apparatus according to any one of claims 1 to 23 for use in detecting and sonicating vessels in the brain of a being. 10

25. Apparatus according to any one of claims 1 to 24 wherein the sound waves are ultrasound waves. 15

26. Method for locating an occlusion in a vessel or a restriction in a vessel, including the steps of:

identifying regions of a body in which an occlusion or restriction might be found; selecting a region of interest for sonication with sound waves;

sonicating the region of interest with at least one sound-wave beam produced by a servo-controllable sound transducer member by moving said sound-wave beam across said region of interest;

receiving reflected sound signals from said region of interest, wherein at least one of said sound signals is a feedback control signal originating from an occlusion in fluid flow, a restriction in fluid flow, or a combination thereof; and calculating the Doppler effect parameters of flow and turbulence from said reflected sound signals. 30

## Patentansprüche

1. Vorrichtung für die Sichtbarmachung oder Behandlung von Verschlüssen oder Verengungen in Gefäßen unter Verwendung von Schallwellen, umfassend:

wenigstens ein servo-steuerbares Elektroakustikwandler-Element (24) umfassend wenigstens ein schall-emittierendes Element (21) für die Erzeugung von wenigstens einem Bündel von Schallwellen, wobei das Elektroakustikwandler-Element steuerbar ist über ein Rückkopplungs-Steuersignal, welches von einem Verschluss im Fluidstrom, einer Verengung im Fluidstrom oder einer Kombination dieser herührt; Mittel zur Einstellung der Parameter dieses wenigstens einen Schallwellenbündels; Mittel zur räumlichen Lokalisierung dieses wenigstens einen schall-emittierenden Elements oder Mittel zum Orientieren dieses wenigstens einen Elektroakustikwandler-Elements;

Mittel zum automatischen oder semi-automatischen Fokussieren der von diesem wenigstens einen schall-emittierenden Element erzeugten Schallwellen in ein Schallwellenbündel; und Mittel zum Empfangen von Schallsignalen von einem schall-emittierenden Element oder schall-emittierenden Elementen.

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2. Vorrichtung nach Anspruch 1 umfassend Mittel zum Bewegen dieses wenigstens einen Elektroakustikwandler-Elements (24). 10

3. Vorrichtung nach Anspruch 2 umfassend Mittel zum automatischen oder semi-automatischen Steuern der Bewegung dieses wenigstens einen Elektroakustikwandler-Elements (24). 15

4. Vorrichtung nach einem der Ansprüche 1 bis 3, bei der das schall-emittierende Element (21) und die Mittel zum Empfangen von Schallsignalen das gleiche sind. 20

5. Vorrichtung nach einem der Ansprüche 1 bis 4, bei der wenigstens ein Schallwellenbündel gepulst ist. 25

6. Vorrichtung nach einem der Ansprüche 1 bis 5, bei der wenigstens ein Schallwellenbündel elektronisch fokussiert wird.

7. Vorrichtung nach einem der Ansprüche 1 bis 6, bei der zwei oder mehrere schall-emittierende Elemente (21) ein Array bilden. 30

8. Vorrichtung nach Anspruch 7, bei der das Array bogengleich ist.

9. Vorrichtung nach Anspruch 7 oder 8, bei der wenigstens ein Schallwellenbündel eine Mehrzahl von Frequenzen von Schallwellen einschließt in Kombinationen von konkurrierenden Frequenzen, erzeugt von den schall-emittierenden Elementen (21) in dem Array oder in Serien von Frequenzen im Zeitablauf. 35

10. Vorrichtung nach einem der Ansprüche 7 bis 9, bei der das Array von schall-emittierenden Elementen (21) eines ist ausgewählt aus solchen mit fester Position, einstellbarer Position oder scannender Position.

11. Vorrichtung nach einem der Ansprüche 1 bis 10, bei der die schall-emittierenden Elemente (21) einzeln beweglich sind oder in koordinierter Form, umfassend das simultane Bewegen. 40

12. Vorrichtung nach einem der Ansprüche 1 bis 11, bei der die servo-steuerbaren Elemente selbstüberwachend (self-tracking) sind und Mittel für die Bestimmung einer Position nicht im zulässigen Bereich 45

(out-of-range) dieses wenigstens einen schall-emittierenden Elements (21) einschließen.

13. Vorrichtung nach einem der Ansprüche 7 bis 10, welche weiterhin eine Mehrzahl von schall-emittierenden Elementen (21) in wenigstens zwei Schichten oder wenigstens zwei Arrays umfasst.

14. Vorrichtung nach einem der Ansprüche 1 bis 11, bei der jedes Elektroakustikwandler-Element (24) bedienbar ist, um einen kontinuierlich einstellbaren Fokuspunkt zu ermöglichen, umfassend zwei oder mehrere Schallwellenbündel, die von wenigstens zwei schall-emittierenden Elementen (21) emittiert werden.

15. Vorrichtung nach einem der Ansprüche 1 bis 14, umfassend Mittel zur Umformung eines Schallsignals aus analogen in digitale Formen oder aus digitalen in analoge Formen.

16. Vorrichtung nach einem der Ansprüche 1 bis 15, umfassend Mittel zum Speichern umgeformter digitaler Daten. 20

17. Vorrichtung nach einem der Ansprüche 1 bis 16, umfassend Mittel zum Darstellen analoger oder digitaler Daten.

18. Vorrichtung nach Anspruch 16 umfassend Video-Anzeigemittel für das Darstellen von Daten oder Anzeigen des Status der Sonifikation an eine Bedienungsperson. 25

19. Vorrichtung nach einem der Ansprüche 1 bis 18, umfassend Schwingspulen-Steuerungsmittel.

20. Vorrichtung nach einem der Ansprüche 1 bis 19, bei der diese Vorrichtung in Realzeit oder nahezu in Realzeit bedienbar ist. 30

21. Vorrichtung nach einem der Ansprüche 1 bis 20, umfassend Bezugswerte-Registrierungsmittel für das Aufrechterhalten zielgerichteter Sonifikation und Kommunikationsmittel für das Kommunizieren zwischen den Bezugswerte-Registrierungsmittel und Servo-Steuerungsmitteln. 35

22. Vorrichtung nach Anspruch 21 umfassend Mittel um einer Bedienungsperson anzuzeigen, wenn diese Vorrichtung nicht aufzeichnet.

23. Vorrichtung nach Anspruch 21, bei der die Kommunikationsmittel eine drahtlose Kommunikationsmöglichkeit umfassen. 40

24. Vorrichtung nach einem der Ansprüche 1 bis 23 für die Verwendung zum Erfassen und mit Ultraschall 45

Behandeln von Gefäßen im Gehirn von Lebewesen.

25. Vorrichtung nach einem der Ansprüche 1 bis 24, bei der die Schallwellen Ultraschallwellen sind.

26. Verfahren zur Lokalisierung eines Verschlusses in einem Gefäß oder einer Verengung in einem Gefäß, umfassend die Schritte:

Identifizieren von Regionen eines Körpers, in denen ein Verschluss oder eine Verengung gefunden werden könnte;

Auswählen einer Region von Interesse für die Sonifikation mit Schallwellen; mit Ultraschall Behandeln der Region von Interesse mit wenigstens einem Schallwellenbündel, erzeugt von einem servo-steuerbaren Elektroakustikwandler-Element durch Bewegen dieses Schallwellenbündels über diese Region von Interesse;

Empfangen eines reflektierten Schallsignals aus dieser Region von Interesse, wobei wenigstens eines dieser Schallsignale ein Rückkopplungs-Steuersignal ist, welches von einem Verschluss im Fluidstrom, einer Verengung im Fluidstrom oder einer Kombination daraus herrührt; und

Berechnen der Doppler-Effekt-Parameter der Strömung und Turbulenz aus diesen reflektierten Schallsignalen.

## Revendications

1. Appareil pour une imagerie ou un traitement d'occlusions ou de restrictions dans des vaisseaux utilisant des ondes sonores, comprenant :

au moins un élément transducteur sonore à servocommande (24) comprenant au moins un élément émetteur de son (21) pour produire au moins un faisceau d'ondes sonores, l'élément transducteur sonore étant commandable par un signal de commande de rétroaction provenant d'une occlusion dans un flux de fluide, d'une restriction dans un flux de fluide, ou d'une combinaison de celles-ci ;

un moyen pour ajuster les paramètres dudit au moins un faisceau d'ondes sonores ;

un moyen pour localiser spatialement ledit au moins un élément émetteur de son ou un moyen pour orienter ledit au moins un élément transducteur ;

un moyen pour focaliser automatiquement ou semi-automatiquement des ondes sonores générées par ledit au moins un élément émetteur de son en un faisceau ; et

un moyen pour accepter des signaux sonores provenant d'un ou plusieurs éléments émetteurs

de son.

2. Appareil selon la revendication 1, comprenant un moyen pour déplacer ledit au moins un élément transducteur (24).

3. Appareil selon la revendication 2, comprenant un moyen pour commander le mouvement dudit au moins un élément transducteur (24) automatiquement ou semi-automatiquement.

4. Appareil selon l'une quelconque des revendications 1 à 3, dans lequel l'élément émetteur de son (21) et le moyen pour accepter des signaux sonores sont le même élément.

5. Appareil selon l'une quelconque des revendications 1 à 4, dans lequel l'au moins un faisceau sonore est pulsé.

6. Appareil selon l'une quelconque des revendications 1 à 5, dans lequel l'au moins un faisceau d'ondes sonores est focalisé électroniquement.

7. Appareil selon l'une quelconque des revendications 1 à 6, dans lequel au moins deux éléments émetteurs de son (21) forment un réseau.

8. Appareil selon la revendication 7, dans lequel le réseau est courbé.

9. Appareil selon la revendication 7 ou la revendication 8, dans lequel l'au moins un faisceau sonore incorpore une pluralité de fréquences d'ondes sonores en combinaisons de fréquences concurrentes générées par les éléments émetteurs de son (21) dans le réseau ou en série de fréquences au cours du temps.

10. Appareil selon l'une quelconque des revendications 7 à 9, dans lequel le réseau d'éléments émetteurs de son (21) est l'un quelconque parmi à position fixe, à position ajustable, ou à position de balayage.

11. Appareil selon l'une quelconque des revendications 1 à 10, dans lequel les éléments émetteurs de son (21) sont déplaçables individuellement ou d'une manière coordonnée y compris simultanément.

12. Appareil selon l'une quelconque des revendications 1 à 11, dans lequel le moyen de servocommande est autosuiveur et comprend un moyen pour déterminer un positionnement hors plage dudit au moins un élément émetteur de son (21).

13. Appareil selon l'une quelconque des revendications 7 à 10, comprenant en outre une pluralité d'éléments émetteurs de son (21) dans au moins deux couches

d'au moins deux réseaux.

14. Appareil selon l'une quelconque des revendications 1 à 11, dans lequel chaque élément transducteur (24) est fonctionnel pour permettre un point de focalisation ajustable de manière continue comprenant au moins deux faisceaux sonores émis par au moins deux éléments émetteurs de son (21). 5

15. Appareil selon l'une quelconque des revendications 1 à 14, comprenant un moyen pour transformer un signal sonore de formes analogiques vers numériques ou de formes numériques vers analogiques. 10

16. Appareil selon l'une quelconque des revendications 1 à 15, comprenant un moyen pour stocker des données numériques transformées. 15

17. Appareil selon l'une quelconque des revendications 1 à 16, comprenant un moyen pour afficher des données analogiques ou numériques. 20

18. Appareil selon la revendication 16, comprenant un moyen d'affichage vidéo pour afficher des données ou indiquer à un opérateur l'état de la sonication. 25

19. Appareil selon l'une quelconque des revendications 1 à 18, comprenant un moyen de commande de bobine acoustique. 30

20. Appareil selon l'une quelconque des revendications 1 à 19, dans lequel ledit appareil est fonctionnel en temps réel ou en quasi temps réel.

21. Appareil selon l'une quelconque des revendications 1 à 20, comprenant un moyen d'enregistrement de repère de centrage pour maintenir une sonication ciblée et un moyen de communication pour communiquer entre le moyen d'enregistrement de repère de centrage et le moyen de servocommande. 35 40

22. Appareil selon la revendication 21, comprenant un moyen pour avertir un opérateur lorsque ledit appareil est hors enregistrement. 45

23. Appareil selon la revendication 21, dans lequel le moyen de communication comprend une capacité de communication sans fil.

24. Appareil selon l'une quelconque des revendications 1 à 23, pour une utilisation dans la détection et la sonication de vaisseaux dans le cerveau d'un être. 50

25. Appareil selon l'une quelconque des revendications 1 à 24, dans lequel les ondes sonores sont des ondes ultrasonores. 55

26. Procédé pour localiser une occlusion dans un vais-

seau ou une restriction dans un vaisseau, comprenant les étapes consistant à :

identifier des régions d'un corps dans lesquelles une occlusion ou une restriction pourrait être trouvée ;  
 sélectionner une région d'intérêt pour une sonication avec des ondes sonores ;  
 réaliser une sonication de la région d'intérêt avec au moins un faisceau d'ondes sonores produit par un élément transducteur sonore à servocommande par déplacement dudit faisceau d'ondes sonores à travers ladite région d'intérêt ;  
 recevoir des signaux sonores réfléchis provenant de ladite région d'intérêt, au moins l'un desdits signaux sonores étant un signal de commande de rétroaction provenant d'une occlusion dans un flux de fluide, d'une restriction dans un flux de fluide, ou d'une combinaison de celles-ci ; et  
 calculer les paramètres d'effet Doppler de flux et de turbulence à partir desdits signaux sonores réfléchis.

Figure 1

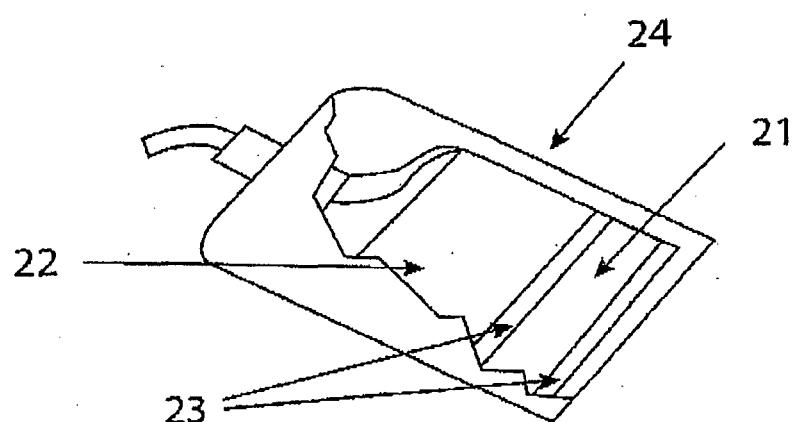


Figure 2a

**Near-field lengths and far-field divergence  
of commercially available transducers**

Transducer diameter (mm)	Frequency (MHz)	Near-field length (cm)	Far-field divergence
8	10	10.4	1"21'
8	5	5.2	4"25'
12	2.5	1.1	1"48'
12	5.0	11.7	1"48'
15	1.0	9.1	2"52'
20	1.0	6.5	5"23'

Figure 2b

**Approximate Velocities of  
Ultrasound In Selected Material**

Material	Velocity (m/sec)
Fat	1.475
Brain	1.560
Liver	1.570
kidney	1.560
Spleen	1.570
Blood	1.570
Muscle	1.580
Lens of Eye	1.620
Skull Bone	3.360
Soft Tissue (Mean Value)	1.540
Air	331

Figure 3a

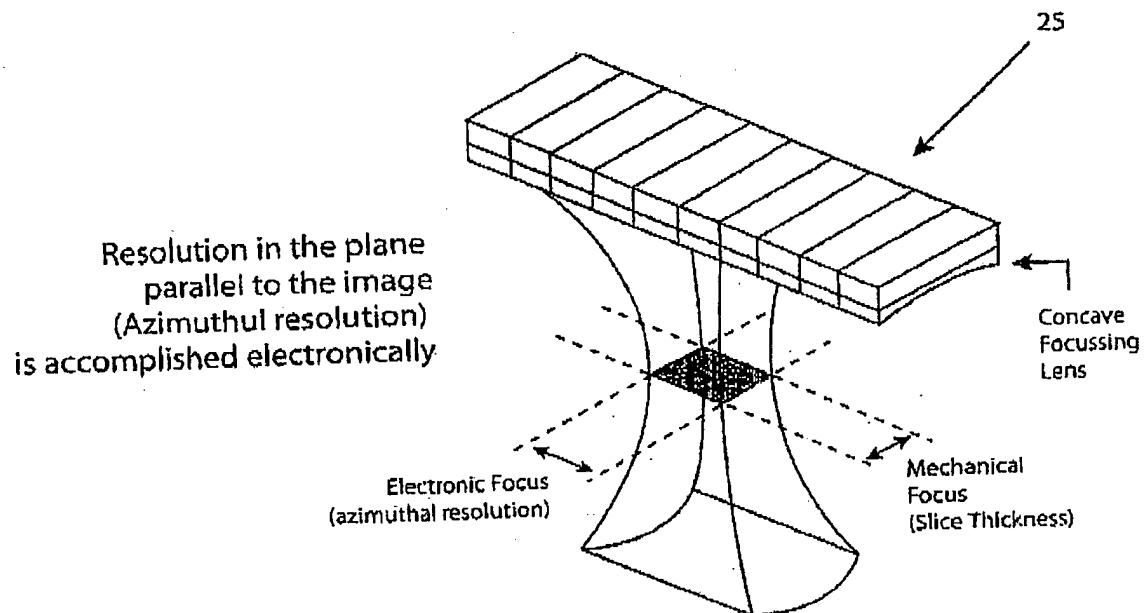


Figure 3b

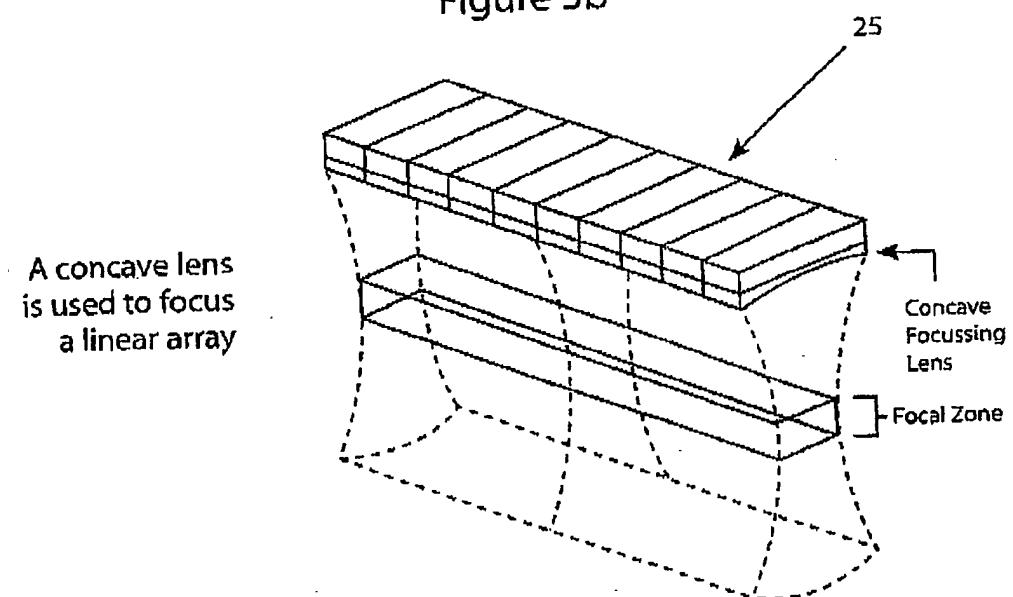


Figure 4

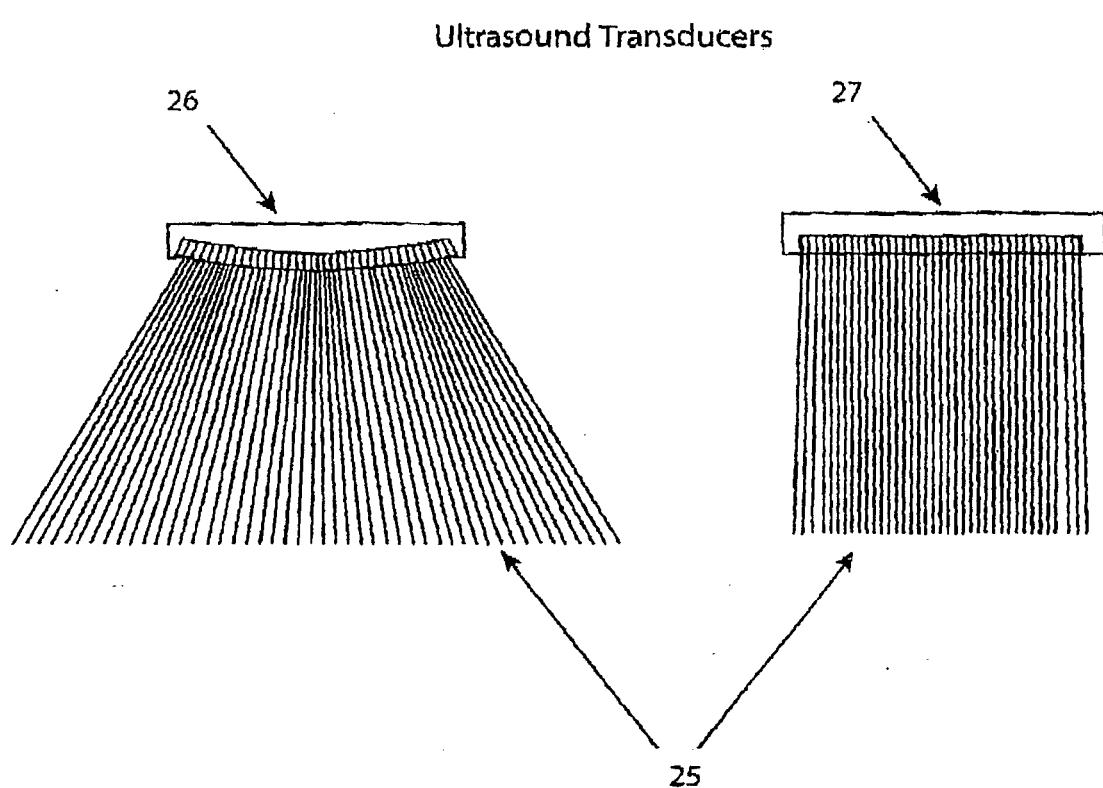


Figure 5

Ultrasound Transducers  
Phased Array

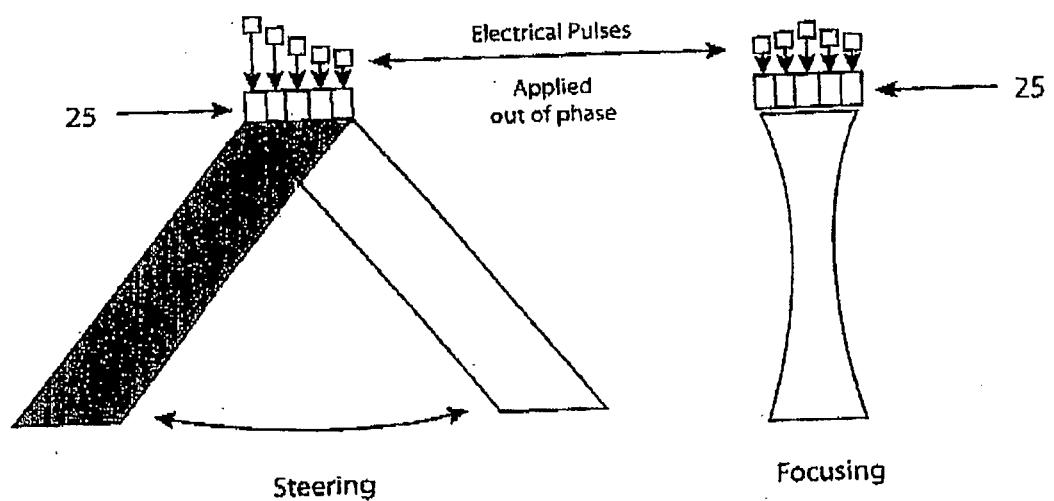


Figure 6

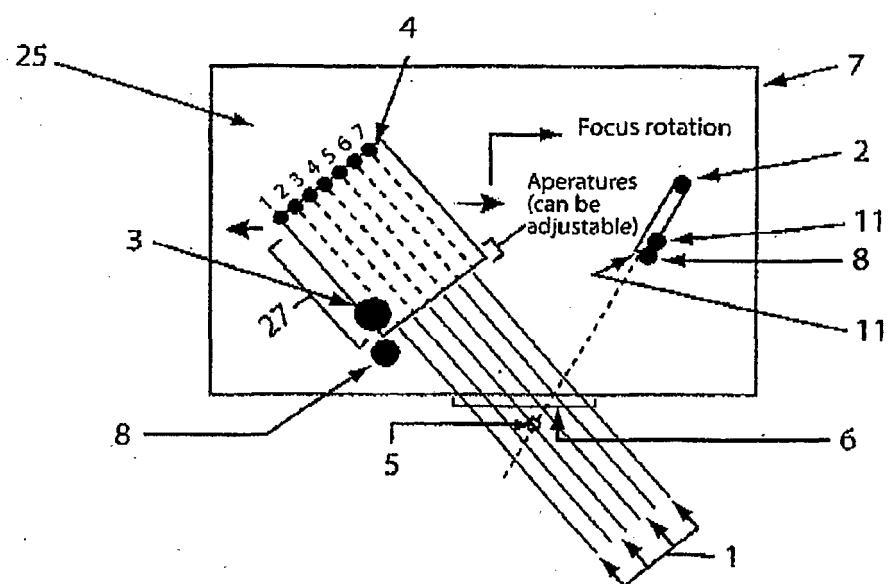


Figure 7

## TYPICAL SEQUENCE OF OPERATION USING ELECTRONICALLY CONTROLLED PHASED ARRAY TRANSDUCERS

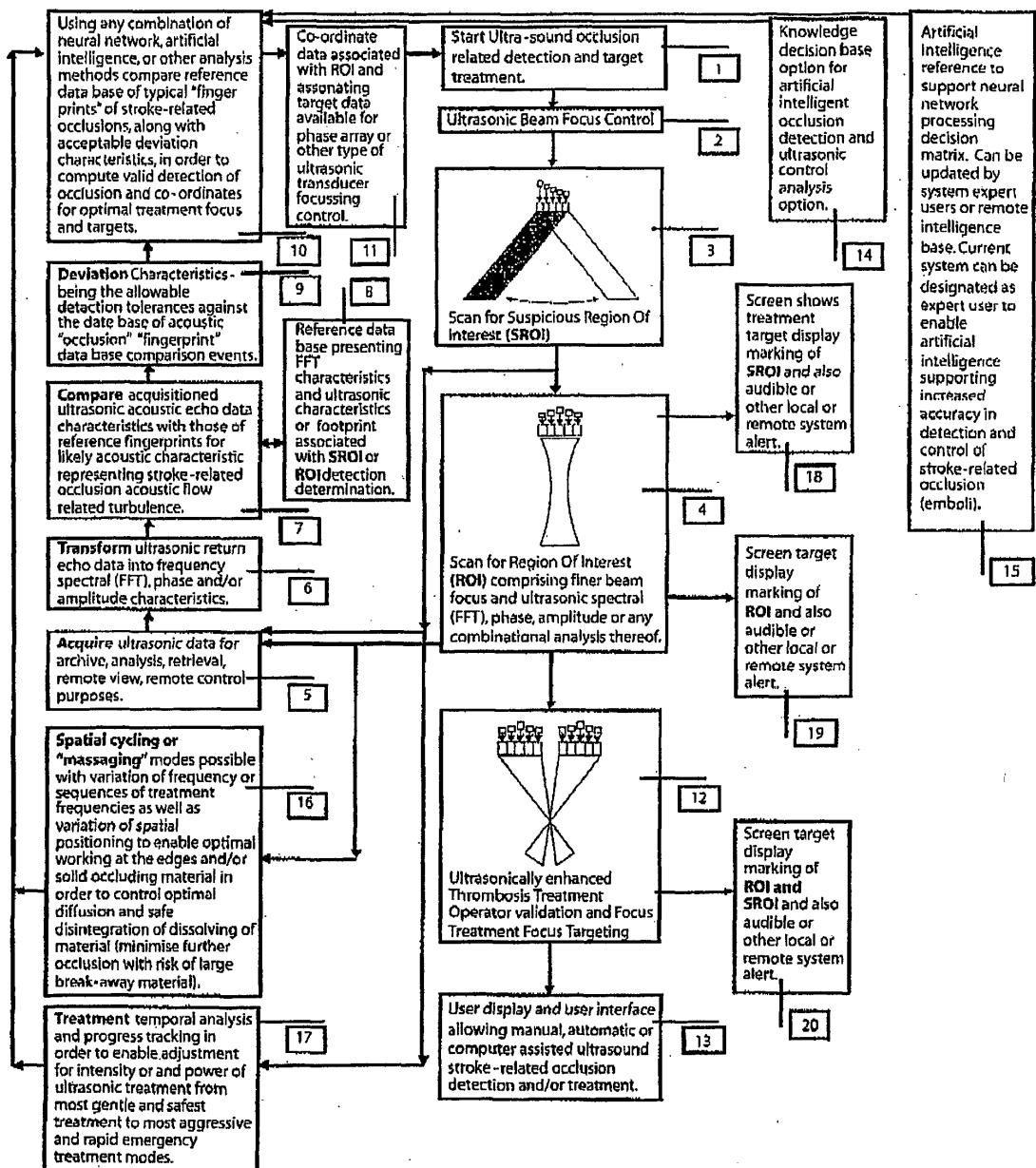


Figure 8a

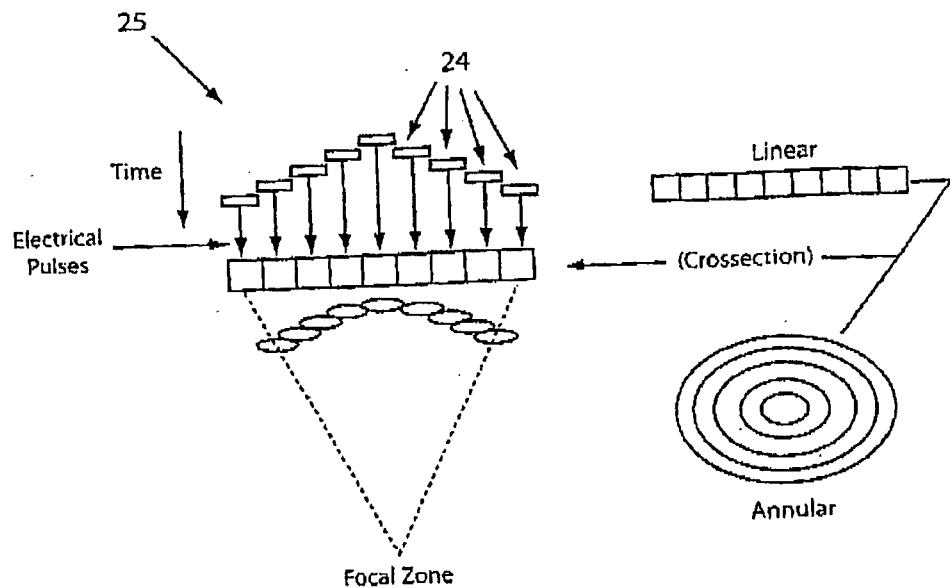


Figure 8b

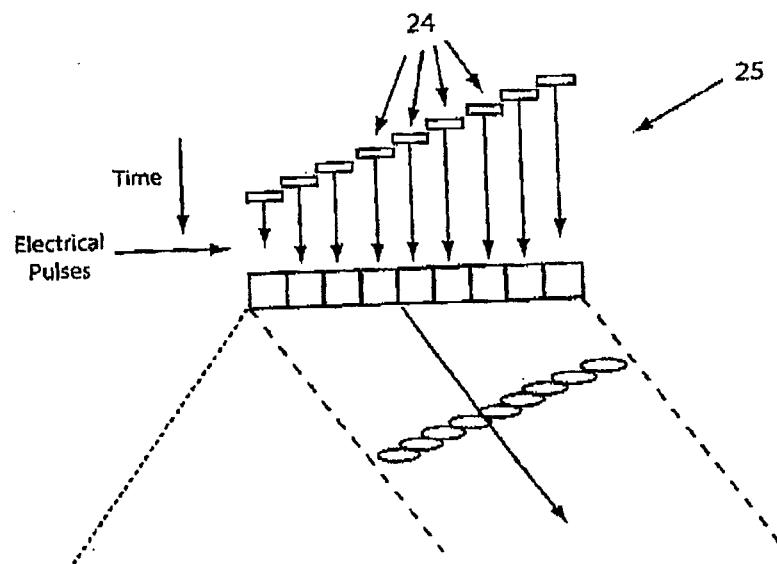


Figure 9a

## Pulse rate

- Number of separate pulses that are produced each second
- Remember – the transducer must act as a transmitter and a receiver
- Common pulse rate for abdominal imaging is 1,000 pulses/second
- Different and unrelated to frequency

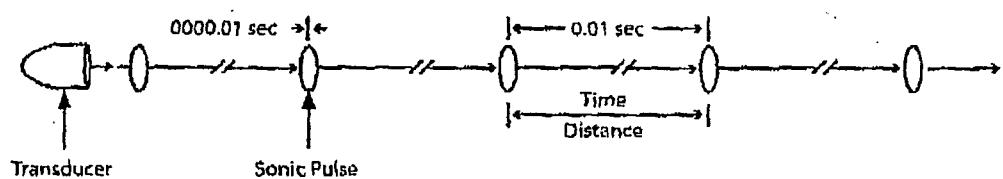
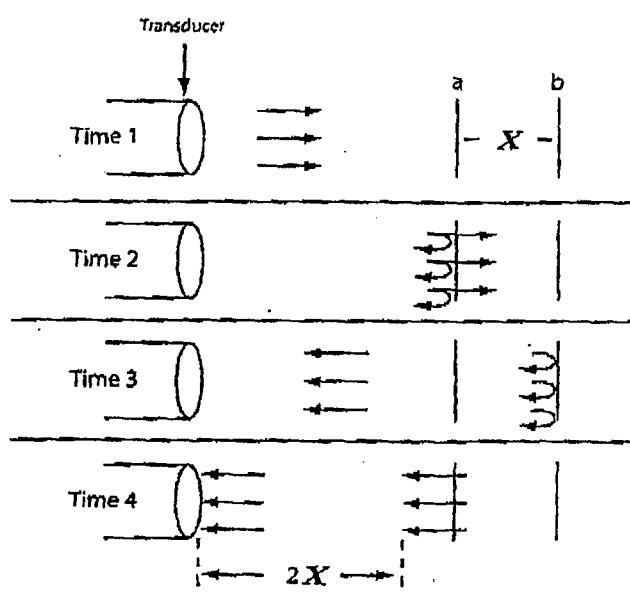


Figure 9b

## Depth (axial) Resolution

This figure shows a time sequence of an ultrasonic pulse resolving two surfaces, a and b, separated by  $X$  distance



**REFERENCES CITED IN THE DESCRIPTION**

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#### 摘要(译)

本发明提供了用于在多普勒技术中使用脉冲或未脉冲聚焦声波(优选超声波)对血管中的闭塞进行半自动或自动成像或治疗的装置和方法。该装置包括至少一个声换能器构件,该声换能器构件包括至少一个用于产生至少一个声波束的发声元件;装置是指调整所述至少一个声波束的参数;“空间定位”是指在空间上定位所述至少一个发声元件;装置,用于移动所述至少一个换能器构件;装置,用于自动或半自动地控制所述至少一个换能器构件的运动;意味着将由所述至少一个发声元件产生的声波自动或半自动地聚焦成光束;并且意味着接受来自发声元件或元件的声音信号。本发明提供了一种半自动或自动定位血管闭塞的方法,包括识别可能发现栓子的身体区域的步骤;选择感兴趣的区域进行超声处理;通过在所述感兴趣区域上移动所述声束,用至少一个声波束对所述感兴趣区域进行超声处理;接收来自感兴趣区域的反射声音信号;并根据所述反射声音信号计算流量和湍流的多普勒效应参数。