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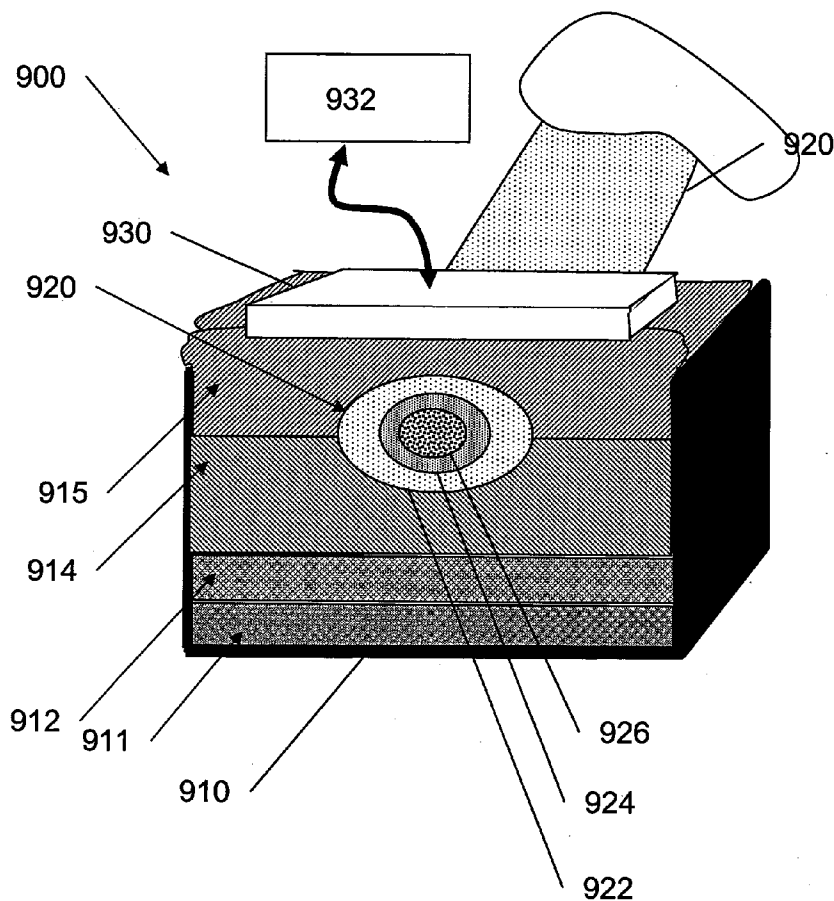
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(57) Abstract: The Ultrasonic Tomographical method and system is provided using measurements of time of flight low frequency acoustic waves. Differences in first signal arrival times from plurality of known transmitters' locations to plurality of known receivers' location are used, wherein the transmitters and receivers are at an angle to the surface of the observed object. 3D mapping of the acoustic propagation speed is reconstructed, revealing anatomical details and physiological properties.

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## **3D QUANTITATIVE ULTRASONIC METHOD FOR BONE INSPECTION AND DEVICE FOR ITS IMPLEMENTATION**

### **FIELD OF THE INVENTION**

The present invention relates to a quantitative-imaging ultrasound technology and equipment. In particular, it may be used in diagnostics of diseases of bone, surrounded bone soft tissues, and soft tissues.

### **BACKGROUND OF THE INVENTION**

Significant numbers of ultrasonic methods exist, which provide imaging soft tissues of a human body. They are based for example on Compound Imaging approach, Stereoscopic imaging, Harmonic imaging, Spatial Compounding Approach and others methods. These methods are disclosed for example in the patents: U.S. Patent 6,517,487; U.S. Patent Applications 20030055334, 20030055337, 20040193047, 20050033140, 20050049479, 20050124886, 20050117694, and others.

Ultrasonic imaging methods known in the art are unsuitable for assessing the skeleton of a human body and therefore the conventional ultrasonic imaging systems are used for studying soft tissue and are not optimized for assessing the skeleton.

One of the reasons for the unsuitability of ultrasonic imagers to perform bone studies is a high attenuation coefficient of a bone compared with a soft tissue.

Ultrasonic methods for simultaneously quantitative and imaging measurements are known in the art.

For example, United States Patent Application 20030018263; to Morris, et al; entitled Multi-Zone Transmitter For Quantitative Ultrasound And Image Measurement; filed: July 20, 2001; discloses an ultrasonic transmission unit for an imaging/quantitative ultrasound device provides for coaxial transducer crystals which may be operated independently with a first crystal operated alone for quantitative measurement and the first and second crystal operated together to provide a broad illumination for imaging of structure.

U.S. Patent Application 20050107700 proposes a thin film piezoelectric material employs a metallic backer plate to provide high output, non-resonant ultrasonic transmissions suitable for quantitative ultrasonic measurement and/or imaging. Thin film polymer piezoelectric materials such as polyvinylidene fluoride (PDVF) may also be used as an ultrasonic transducer as described in the U.S. Patents No. 6,305,060 and U.S. Patent No. 6,012,779.

However, the disclosed methods do not provide 3D imaging considered objects.

Ultrasonic investigations of skeleton can be carried out with the aim of the Quantitative UltraSonography (QUS) methods. The main ultrasonic parameters evaluated in QUS measurement are the Speed of Sound (SOS) and the frequency dependence of attenuation.

Ultrasonic Attenuation (BUA) technique is described by Langton C M, Palmer S B, Porter R W, The Measurement of Broadband Ultrasonic Attenuation in Trabecular Bone, Engineering in Medicine, 13 3, 89-91 (1984). Whilst it now forms the basis of clinical QUS bone assessment, this empirical method is not entirely satisfactory. The BUA technique essentially measures insertion loss, found by comparing the amplitude spectrum of an ultrasonic pulse through bone with that through a reference medium, typically water. The assumption is made that the attenuation,  $a(f)$ , is a linear function of frequency,

f, between 200 - 600 kHz. However, a number of authors argued that the assumption of linear relationship does not have any physical basis. (Elinor R Hughes MIOA, Timothy G Leighton FIOA, Graham W Petley, Paul R White "Ultrasonic assessment of bone health" (<http://www.isrt.soton.ac.uk>))

United States Patent 6,371,916; entitled Acoustic Analysis of Bone Using Point-Source-Like Transducers; to Buhler, et al.; filed: September 3, 1999; discloses an improved apparatus and method for providing a measurement of the characteristic behavior of an acoustic wave in a bone of a subject. A preferred embodiment has first and second transducers and a mounting arrangement for mounting the transducers in spaced relationship with respect to the bone. The first transducer may transmit acoustic energy over a broad solid angle, thereby behaving as a point source of acoustic energy. Additionally or alternatively, the second transducer may collect acoustic energy over a broad solid angle, thereby behaving as a point receiver. A signal processor in communication with the second transducer provides a measurement that is a function of at least one of transient spectral or transient temporal components of the signal received by the second transducer.

The disclosed invention provides determining an index of porosity (indirect qualitative but not quantitative parameter of porosity estimation) and non-connectivity of a bone, but the method not allows obtain 3D imaging of bones in a human body.

Inspection methods based on refracted energy are used in industry. For example, Time of Flight Diffraction technique (TOFD) is disclosed U.S. Patent Application 20020134178; to Knight, et al.; entitled Ultrasonic Testing System.

In this method a probe with different beam angles is used to detect planar defects through varying an angle of orientation. Usually two probes, one transmitter and one receiver, are arranged on an object surface. The transmitter sends a relatively wide beam for maximizing the field of the scan. Both probes are aligned geometrically on either side of a considered object and an A-scan taken at a sequential position along the length of the object. The data collection

on site by the TOFD method is faster than most conventional methods because it uses wide ultrasonic beams for imaging. It is a technique for precise depth assessment. However, this technique does not apply for investigations anisotropic and heterogeneous materials and is not used in medicine.

Contrary to X-ray CT, Ultrasonic tomography of elastic wave velocities has not found general practical usage in the medical imaging. The main problems are gas and bone inclusions and associated deviation of the ultrasound beam due to reflection and refraction because the systems are heterogeneous mediums.

The use of elastic wave refraction for investigations bone structures of a human body for medical diagnostics is described in the U.S. Patents No. 6,221,019 and U.S. Patents No. 5,143,072. The disclosed methods assume that the refracted waves travel in the field with a boundary between layers with different acoustic impedance. It is the boundary between tissue and bone.

In the disclosed patents, a transmitter and a receiver are placed on the skin of a patient facing to a bone. Ultrasonic waves are transmitted along a transmission path from the transmitter to the bone through the soft tissue surrounding the bone, along the surface of the bone and back through the soft tissue to the receiver location 1 and location 2. The travel times of the fastest signals between the transmitter and receiver (for location 1 and for location 2) are measured and the acoustic velocity of the bone is calculated based on the distance between the transmitter and the receiver's two locations, the thickness of the soft tissue and the acoustic velocity in the soft tissue. The reflected waves are used for estimations of the acoustic velocity and thickness of soft tissues. The measured parameter, Speed Of Sound (SOS) of a cortical bone is calculated from the obtained measured data.

However, this method has the several serious shortcomings.

- The method is based only on two layers soft tissues and bone in its algorithm

-The method cannot account for anisotropy and heterogeneous nature of bone's mediums and thus produces an average estimation that lead to significant mistakes and to insensitive of the method (inspected parameter increased from one part of an inspected bone and at the same time reduced from another its a part).

-It does not map the distribution of structure's changes in a bone by means of the estimated parameters distribution in the bone - heterogeneous medium.

- The method only evaluates the bone medium unknown and changeable by depth from quality observed bone upper cortical layer and only in single direction.

-The method does not provide a 3D imaging of the inspected bone volume.

-The method suffers an additional inaccuracy and inconvenience by the necessity to measure a thickness and a longitudinal wave velocity in soft tissues by applying an additional Pulse-Echo method.

- The method does not estimate the mineral part (matrix) of an inspected bone and porosity values also as porosity distributions in a bone's volume.

- The method requires the referent data for fracture risk estimations.

- The method does not provide location and estimation fracture risk.

### **SUMMARY OF THE INVENTION**

The present invention relates generally to a quantitative-imaging ultrasound technology and equipment. In particular, it helps to diagnostics bone's diseases of different types and different structures and soft tissues surrounding the bone.

The method according to the invention may be used for concrete individual without a reference data.

Almost all types bone of a human body may be evaluated by applying of the inventive technology, for example: spine; hip; heel; fingers; etc. Different types bone structures may be studied, for example: cortical bone; trabecular bone; marrow in a bone; cartilages and others substances. The method and system according to the invention helps for diagnostics by creating anatomical pictures revealing the shape, dimensions, relative positioning of observed organs and by evaluating quality through obtained qualitative estimations.

The invention applies modified geophysics methods of elastic wave propagation in the layered system including heterogeneous mediums and characterized an acoustic impedance gradient.

According to the invention, skin, tissue, fat, periosteum, cartilage and bone may be considered as an example of the layered objects with an acoustic impedance gradient including heterogeneous mediums.

The invention uses the known approach from the oil geophysics for determining porosity to calculation of the bone's media estimation. The invention uses modified Wyllie relationship which can be found in Wyllie, M.R., An experimental investigation of factors affecting elastic wave velocities in porous media., Geophysics, vol. 23, No. 3, 1958.

The method according to the invention provides Ultrasonic Tomography of elastic wave velocities and porosity for the medical imaging by obtaining estimations distributions in an inspected volume.

The invention overcomes the problems of gas and bone inclusions and associated deviation of the ultrasound beam due to reflection and refraction.

The TOFD technique helps to eliminate some of the shortcoming of the Geophysical Tomographical method and provides different approaches to upper layer and to lower located layers. The invention uses similarly to the TOFD

method emitting and receiving of ultrasonic oscillations at an angle, but it is a constant angle in distinction from TOFD method.

It is an object of some aspects of the present invention to provide a 3D Measuring-Imaging Ultrasonic Tomographical technology and a novel system for investigations of almost all bone types for example spine, hip, heel, phalanges and others, and different bone's structures in a human body such as cortical bone; trabecular bones bone, marrows in a bone as well as soft tissue surrounding the bone.

The results of investigations are maps of longitudinal wave velocity and porosity values distributions in an inspected volume and estimation bone mineral part through value longitudinal wave velocity in matrix of an inspected bone. The images reveal anatomical and physiological details of an observed object as vertical and horizontal sections or 3D image.

The method allows bone diagnostics, provide data for a disease diagnose, assess and location fracture risk, provide monitor a response to treatment assessing the elastic wave velocity and porosity.

Plurality of measurements provides statistical treatment of an obtained data and correct systematic mistakes of the measurements.

The statistical treatment of the data provides information about individual properties of a specific observed patient and reveals changing in observed organs such as size, its dimension and parameters values. The changes are estimated relative to corresponding for matrix bone part elastic wave's velocities values. A spread of a data provides estimations of a mineral healthy part of a bone relative to a mineral sore part of a bone.

The method allows mapping the distributions of porosity values thus revealing location with high risk of bone fracture and estimation for fracture risk. The technology provides monitoring of bone structures through monitoring its properties changes in time.

In a preferred embodiment of the present invention sensors are arrayed in a 1D array (or two 1D arrays) with constant distance between sensors. Using 1D sensor array, sensors are moved along the surface of the observed object and in a direction substantially normal to the array. Measurements are taken at substantially equally spaced intervals. Each sensor of a 1D array acts in it's a turn as transmitter and in it's the turn as receiver. One sensor transmits ultrasonic oscillations and plurality of the remaining sensors of sensor's array is used to detect ultrasonic wave refracted by the object. Alternatively, a 2D array of sensors (or sensor's matrix) is used.

A method for obtaining acoustic properties of a subject according to the current invention comprises at least some of the steps:

- The first transducer of the first line in a 2D array of transducers is used as a transmitter and transmits ultrasonic oscillations to an observed body part at preferred angle of 45 degrees. Elastic waves passage in non-linear routes in the observed object having acoustic impedance gradient and including heterogeneous mediums. Each of remaining transducers in the row between the transmitter and the end of the row is used as a receiver and receives ultrasonic oscillations, which passed through observed object.
- The measurements are repeated wherein the second transducer acts as a transmitter. Similarly, the measurements are repeated for the third transducer, forth transducer, etc, till the end of the row of transducers.
- Similar measurements are performed for the reciprocal paths starting this the last transducer in the row acting as a transmitter and the rest of the transducers acts as receivers.

- The measurements for the reciprocal paths are repeated wherein the second from the last transducer acts as a transmitter. Similarly, the measurements are repeated for the third from the last transducer, etc.
- Longitudinal wave travel times of the fastest signal between each transmitter and each receiver are measured.
- Values of the longitudinal wave travel time changes  $\Delta\tau_m$  are calculated in each cell (elementary volume) relative to above placed cell. The value is calculated by longitudinal wave travel times values for adjoining routes in direct and reciprocal directions by the formula  $\Delta\tau_m = \tau_m + \tau_{m-1} - \tau_{dir} - \tau_{rec}$ . Where  $\tau_m$  is the average value between longitudinal wave travel time for direct and reciprocal directions for one sensors arrangement (were m is a number of a sensor's location) from points m to point (-)m;  $\tau_{m-1}$  is an average value between longitudinal wave travel time for direct and reciprocal directions for sensors arrangement from point (m-1) to point (-m+1);  $\tau_{dir}$  is an average value between longitudinal wave travel time for direct and reciprocal directions for sensors arrangement from point (-m) to point (m-1) and  $\tau_{rec}$  is an average value between longitudinal wave travel time for direct and reciprocal directions for sensors arrangement from point m to point (-m+1).
- The subsequent values of longitudinal wave travel times are calculated in each cell of each vertical axis from vertical cells columns. It is carried out by the known (or beforehand measured value) longitudinal wave travel time value in the first from the surface cell  $t_1$  and by longitudinal wave travel times changes for considered cells  $\Delta\tau_m$  ( $\Delta\tau_2, \Delta\tau_3, \Delta\tau_4 \dots \Delta\tau_m$ ) by the successive addition the calculated values:  $\tau_2 = \tau_1 + \Delta\tau_1$ ;  $\tau_3 = \tau_2 + \Delta\tau_2 \dots$  and.....  $\tau_m = \tau_{m-1} + \Delta\tau_{m-1}$ .
- Calculations of an average longitudinal wave velocity values in an each cell are calculated based on calculated values of shortest longitudinal wave travel times in each cell and by a length of travel longitudinal wave in a considered cell. We use the approximation that longitudinal wave

travel way in subsequent cells of layered system after cells of the first layer is a constant value. It calculates by half-length of the circle with radius  $b$ , where  $b$  is the distance between adjoining transducers,  $\pi b$ . And accounting for the length of travel time in the known and different from other layers first layer the length of route in the cells are calculated according to  $2\sqrt{2} \times b$  for the incident angle at the first layer of 45 degrees.

- The statistical treatment such as creating a histogram of obtained longitudinal wave velocity values is applied for the purpose evaluation value longitudinal wave velocity in a matrix (skeleton) mineral part of an observed bone medium  $V_t$ . It is estimated by virtue of a density of a probability distribution for longitudinal wave velocity values by maximum value for considered solid medium. The value will be used for estimation changes in bone mediums for a concrete observed individual.
- Bone porosity  $n$  is defined as the ratio of a porous volume  $W_{por}$  to an entire considered bone volume  $W$  by equation:

$$n = W_{por} / W.$$

The values of porosity  $n$  for each cell of an observed volume are calculated by the modified Wyllie relationship from oil geophysics. The calculations are done using calculated values of average longitudinal wave velocity value in a cell  $V_p$ , value longitudinal wave velocity in a matrix (skeleton) mineral part of an observed bone medium  $V_t$ , and the value longitudinal velocity in a filling  $-V_{fill}$ , such way the material properties are estimated for example the porosity, elastic wave velocity and elastic wave velocity in matrix of an inspected bone.

- Maps of 2D or 3D images of longitudinal wave velocity and porosity values are formed by pixel-by-pixel in horizontal and vertical sections of

an observed object. Forming the object map is carried out with help significant number obtained estimations longitudinal wave velocity (or porosity) values and according to changed value of distance between transmitter and receiver and corresponded beam penetration value for considered distance in each considered cell

$$y = \ell \sqrt{\frac{V_n^2}{V_1^2} - 1}$$

The phased array transducers replace with constant step which is equaled to distance between sensors – b. Such way we have the certain dimensions of considered elementary cells and its successions. The maps provide structural properties estimations as trabecular and as cortical bone. They provide an inspected bone geometry including size and shape and thickness of an inspected bone. The pictures offer information about microarchitecture, porosity trabecular and cortical bone.

- Analysis of obtained maps (vertical and horizontal sections of obtained estimations distributions - pictures of an observed body) reveals zones of bone weakness, the zones with high Fracture Risk, their dimensions and locations. Weak locations are characterizing by reduction elastic wave velocities values and by high porosity values.
- Statistical treatment of a data carried out on information taken at different times for the same individual and reveals changes in properties of observed organs such as: its size, dimension and calculated elastic parameters values for example bone mineral skeleton and bone porosity.

Each healthy organ has its own value longitudinal wave velocity and physic-mechanics properties estimations. For example, the approximate longitudinal wave velocity values in different human parts are: in soft ~1540 m/s, in bone ~ 1700 - 5000 m/s, in fatty tissue ~ 1450 m/s, in liver ~ 1550 m/s, in blood ~ 1570 m/s, in muscle ~ 1580 m/s. Changes in the velocities may indicate

diseased or injured tissue such as fractured or osteoporotic bone. The approach is useful in the case bone inspections because for bone mediums the broad diapason of elastic wave velocity changes exists.

One aspect of the invention is to provide an Ultrasonic Tomograph and technology for measuring objects such as parts of a human patient and obtain a map of acoustical parameters of the object. Additionally, tomograph may calculate physiological parameters such as bone properties (porosity) quality bone mineral part, bone structure and detect bone weaknesses such as fractures, etc. The Ultrasonic Tomograph comprises a signal generator which produces alternating electronic signal in the form of short pulses. The generated signal is directed by scanner position controller to one of the transducers in the sensor array. Optionally, scanner position controller controls the angulations of transducers from left to right. Signals from transducers indicative of received ultrasonic signals are directed from transducers array to signal processing unit which receives signals, amplify, filter and process the signal to measures shortest travel times in the direct and reciprocal paths. The measured travel time, in digital format are transferred to processor which calculates the differential data. Image formation unit uses the differential data to produce maps of acoustical parameters to be displayed.

Another aspect of the invention is to provide a Three Dimensional Ultrasonic System for evaluation of limbs. The 3D Ultrasonic system comprises: an optional "U" shaped solid frame used for supporting an optional set special plates and special material filled top pillow. Alternatively, set from special plates is placed on an examination table, the limb is placed above it and a top pillow is used for covering the limb. A 2D transducers' array is placed on top and in contact with the top pillow that interfaces between the curved limb and the flat array. The sensor array receives signals from, and transmits signals to a controller that comprises the electronics for generating excitation signal and analysis of the detected acoustic signals.

The Ultrasonic Tomograph according to another embodiment of the invention comprises additional unit System Set Sensors in contact with inspected individual. It includes the special addition parts such as special pillows, if it is necessary in the case special types of an inspected object (patient with different shapes and dimensions) and changeable for considered individual and human's part set plates for providing a needed layered system with an acoustic impedance gradient including heterogeneous mediums. The wedges provide elastic waves emission and reception with an angle to an investigated part of a human body in the unit. A 2D transducers' array is placed on top of plate which in contact bottom with the top pillow. The sensor array receives signals from, and transmits signals to a controller which comprises the electronics for generating excitation signal and analysis of the detected acoustic signals.

The ultrasonic pulse travels in an observed mediums system and is reflected, refracted, scattered or transmitted through its' inhomogeneities. The sensors are positioned in the needed positions on an investigated object surface.

The affect ultrasonic oscillations are picked by receivers and are converted to electrical signals. The unit Signal Processing Measurer Time receives signals. Signals are amplified (by the unit's amplifier) them, processed, filtered and converted to the digital form in the unit. It also measures shortest travel times by needed number routes in direct and reciprocal directions. Signals are stored on the disk in the unit Memory, if it is necessary. The additional units are Memory and Processor. It produces the deferential treatment of the data according to used algorithm for a layered system with an elastic wave velocities gradient, including heterogeneous mediums. It calculates: consecutive changes of travel times in each cell relative to an above placed cell, longitudinal wave travel times in cells, longitudinal wave velocity, porosity values in each cell of an observed part of a human body concluding bone mediums and statistical treatment obtain data with estimation elastic wave velocity value for matrix bone's part.

The Unit Image Controller Formation carries out images building which with Display displaying obtained images in the screen and printing the results, if it is required.

It is an aspect of the current invention to provide a method for diagnosing part of a human body comprising the steps of: transmitting by turn plurality of ultrasonic beams from evenly spaced locations in relation to the an observed part of the human body and at an angle to the surface of said observed part of the human body; receiving plurality of ultrasonic signal indicative of refraction of said ultrasonic beams that were transmitted, at evenly spaced locations in relation to said observed part of the human body, and at an angle to the surface of said observed part of the human body; measuring transit times of said ultrasonic beams between plurality of pairs of said evenly spaced locations; evaluating ultrasonic wave velocity in mineral bone part, calculating corresponding velocity and porosity values for multitude elementary volumes of an inspected object and building up 2D and 3D images of propagation ultrasonic wave velocity and porosity for said observed part of the human body based on said measured transit times.

Optionally the angle between transmitted beam and the surface of the part of the human patient and the angle between received beam and the surface of the part of the human patient is substantially 45 degrees.

Optionally the method further comprising the step of calculating a map of bone porosity based on said calculated map of ultrasonic propagation speed for said observed part of the human body.

Optionally the method further comprising the steps of: by virtue of obtained maps of bone porosity and ultrasonic wave velocity analysis estimation risk for bone fracture; and indicating at least one location having higher than average risk for bone fracture.

Optionally the transmitting ultrasonic beams and receiving ultrasonic signals is done using a one dimensional array of evenly spaced ultrasonic transducers.

Optionally the method further comprising the steps of: translating said one dimensional array of evenly spaced ultrasonic transducers to plurality of evenly spaced intervals in the direction perpendicular to said array; and reconstructing a three dimensional map of ultrasonic propagation speed for said observed part of the human body based on two dimensional maps of ultrasonic propagation speed obtained at each of said intervals.

Optionally the transmitting ultrasonic beams and receiving ultrasonic signals is done using a two dimensional array of evenly spaced ultrasonic transducers.

Optionally the method further comprising the step of placing gel filled pillow between said observed part of the human body and said two dimensional array of evenly spaced ultrasonic transducers.

Optionally the frequency of said transmitted ultrasonic beam is between 50 kHz and 600 kHz.

It is another aspect of the current invention to provide an ultrasonic system comprising: an array of evenly spaced ultrasonic transducers capable of transmitting ultrasonic beam at an angle to said array in response to excitation pulse, and capable of producing signal in response to received ultrasonic beam at an angle to said array; a signal generator generating short excitation pulse at frequency between 50 kHz and 600 kHz; a scanning controller receiving said generated excitation pulse and directing said pulse to a selected transducer in said array of transducers; a time measuring unit receiving signal indicative of refraction of said transmitted beam received by at least one of said transducers in said array of transducers, and calculating transit time for said beam, between transmitting transducer and receiving transducer;

a processor receiving plurality of calculated transit times corresponding to plurality of transmitting transducer and receiving transducer pairs, and calculating differential data based on said transit times; and

an image formation unit generating a map of ultrasonic propagation speed based on differential data.

Optionally the angle between transmitted beam and said transducer array and the angle between received beam and said array is substantially 45 degrees.

Optionally the image formation unit further capable of generating a map of bone porosity based on said map of ultrasonic propagation speed for an observed part of human body refracting said transmitted ultrasonic beams.

Optionally the image formation unit further capable of estimating risk for bone fracture based on said calculated maps of bone porosity and velocity and indicating at least one location having risk for bone fracture

Optionally said transducer array is one-dimensional array of evenly spaced ultrasonic transducers.

Optionally said scanning controller further translates said one dimensional array of evenly spaced ultrasonic transducers to plurality of evenly spaced intervals in the direction perpendicular to said array; and said image formation unit reconstructs a three dimensional map of ultrasonic propagation speed based on two dimensional maps of ultrasonic propagation speed obtained at each of said intervals.

Optionally the array of transducers is a two dimensional array of evenly spaced ultrasonic transducers.

Optionally the ultrasonic system further comprising gel filled pillow positioned between an examined object and said two dimensional array of evenly spaced ultrasonic transducers.

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

### **BRIEF DESCRIPTION OF THE DRAWINGS**

The invention is herein described, by way of example only, with reference to the accompanying drawings. With specific reference now to the drawings in detail, it is stressed that the particulars shown are by way of example and for purposes of illustrative discussion of the preferred embodiments of the present invention only, and are presented in the cause of providing what is believed to be the most useful and readily understood description of the principles and conceptual aspects of the invention. In this regard, no attempt is made to show structural details of the invention in more detail than is necessary for a fundamental understanding of the invention, the description taken with the drawings making apparent to those skilled in the art how the several forms of the invention may be embodied in practice.

In the drawings:

FIG. 1 schematically depicts principle of the Geophysical Tomographical method for a layered system with an elastic wave velocities gradient including heterogeneous mediums.

FIG. 2 schematically depicts the division of one vertical slice of the 3D observed volume of the subject into a 2D array of elementary voxels arranged in columns and rows and shows the locations of the transducers.

- FIG. 3 schematically depicts a layered observed subject including heterogeneous mediums, each with elastic wave velocity gradient, and the elastic wave propagations in the layered subject.
- FIG. 4 schematically depicts some details of a two layers subject, demonstrating that a composite, multi-layered subject may be expressed as an equivalent two layers subject.
- FIG. 5 demonstrates the adjoining and the reciprocal routes of propagating elastic wave in the vertical slice according to the applied algorithm according to the invention.
- FIG. 6 demonstrates some details of elementary volume selection.
- FIG. 7 schematically depicts a succession of measurements in the direct direction.
- FIG. 8 schematically depicts a succession of measurements in the reciprocal direction.
- FIG. 9 schematically depicts a functional block diagram of the ultrasonic tomography system according to a preferred embodiment of the current invention.
- FIG. 10 illustrates the experimental ultrasonic system with scanning transducers movement which was used for the experimental demonstration and verification of the invention.
- Table 1 depicts obtained data and its treatment according to the algorithm of the current invention
- Table 2 depicts calculated values derived from the measured data.
- Table 3 depicts the calculated longitudinal wave velocity values for specimen 1.

- FIG. 11 shows experimental results of measured map of porosity values in a slice of pig's leg, measured using the method according to the current invention.
- FIG. 12 shows experimental results of measured histogram of longitudinal wave velocity of an inspected bone medium, measured using the method according to the current invention.
- Table 4 depicts the calculated porosity values for specimen 1.
- FIG. 13 shows experimental results of measured map of porosity values in a slice of pig's leg, measured using the method according to the current invention.
- FIG. 14 illustrates experimental results demonstrating the possibilities of the proposed technology by of comparison images obtained for pig's leg before and after mechanical damages.
- FIG. 15 schematically depicts an apparatus for inspection of organ such as a limb according to another preferred embodiment of the current invention.

## **DESCRIPTION OF THE PREFERRED EMBODIMENTS**

Before explaining at least one embodiment of the invention in detail, it is to be understood that the invention is not limited in its application to the details of construction and the arrangement of the components set forth in the following description or illustrated in the drawings. The invention is capable of other embodiments or of being practiced or carried out in various ways. Also, it is to be understood that the phraseology and terminology employed herein is for the purpose of description and should not be regarded as limiting.

In discussion of the various figures described herein below, like numbers refer to like parts.

The drawings are generally not to scale. For clarity, non-essential elements were omitted from some of the drawings.

As used herein, an element or step recited in the singular and proceeded with the word "a" or "an" should be understood as not excluding plural elements or steps, unless such exclusion is explicitly recited.

The Ultrasonic Tomographical method simultaneously measuring and imaging according to a preferred embodiment of the present invention includes a few principal approaches.

The first, it is the physical principle elastic wave's distributions in the layered system with an acoustic impedance gradient including heterogeneous mediums. Investigated parts of a human body, including bones substances, may be considered as the similar system.

Figure 1 schematically depicts principle of the Geophysical Tomographical method for a layered system consisting of heterogeneous mediums with an elastic wave velocities gradient.

The effect of the heterogeneous media was taken in account in the geophysical Tomographical method. Fig. 1 depicts the principle of the geophysical Tomographical method. The basis of this approach is the elastic waves refraction in layered systems associated with heterogeneous mediums (depicted as inclusions 1 in an inspected object 6), which have an elastic wave velocities gradient. Inspection system 60 comprises of sensors  $R_1$  to  $R_{10}$  arranging along a linear profile on the surface 7 of object 6. The transducers  $T_1$  and  $T_2$  are situated at the opposite ends of the profile. Transducers  $T_1$  and  $T_2$  are used for transmitting sound wave as well as receiving sound waves.

Curved routes of wave propagating from Transducer  $T_1$  to the sensors  $R_{1-10}$  and Transducer  $T_2$  (direct routes 2) are depicted in solid lines. Reciprocal routs 3, from transducer  $T_2$  toward receivers  $R_{10}$  to  $R_1$  and transducer  $T_1$  are depicted in dashed lines.

The method is described, for example, in the work "Ore seismic" by N.A.Karaev and G.Ya. Rabinovich. – Moscow: Geoinformmark Closed Joint-Stock Company, 2000. – 366p, ill., and by L.A.Pevzner, V.L.Pokidov, V.A.Tsimer in the work "The seismic investigation of complex medium". Alma-Ata. Science, 1984. However this method is not used for the medical purposes.

Refracted wave propagations are commonly used in geophysics. It is applied, for example, in the ultrasonic logging. The fact of non-linear beams routes is known from literature and is similar to propagation light beams in heterogeneous mediums system which characterized for example by temperature gradient. The phenomenon is expressed by the fundamental Fermat principle. Similarly to light beams, elastic waves change its linear routes and traverse the route that offers the fastest time of travels. The geophysical method utilizes angle transducers aimed at right angle (90 degrees) to the surface of the observed object.

The geophysical methods were not applied in medicine as they can not to provide the needed resolution for medical investigations.

Russian patents RU 2115919 and 2115920 describe the obtained parameters of deformation and its distributions using ultrasonic logging. The ultrasonic logging applies measurements of direct and reciprocal directions. However, the disclosed geophysical method provides one dimensional (1D) distributions estimation, and it is used for industrial applications and not for medicine.

In a preferred embodiment of the present invention transducers are arrayed in a One dimensional (1D) array (a lines) with a constant step between sensors of a sensor's array, or in a two dimensional (2D) array (a grid). If a 1D array is used, the array may be scanned in a direction substantially perpendicular to it to act as an equivalent 2D array. Alternatively, the system of the measurements may comprise two scanned phased array probes relative each other.

FIG. 2 schematically depicts the division of one vertical slice of the 3D observed volume of the subject into a 2D array of elementary pixel arranged in columns and rows and shows the locations of the transducers.

For simplicity, one vertical slice of the observed three-dimensional (3D) object is depicted. It is to be understood that plurality of such two-dimensional (2D) slices may be combined to create representation of the full 3D object. For example, plurality of adjoining parallel slices may be used to create a 3D representation of the observed volume. The pixel may be chosen as cubical having an elementary volume of  $b*b*b = b^3$ , but may have distorted sizes in the third dimensions by the axis beam penetration, that may be account. In the depicted example, the vertical slice is in the X-Y plane, while adjoining slices may be spaced in the Z direction with constant step is equaled to  $b$ .

Any number of slices, sensors and number of columns and rows may be chosen within the general aspects of the current invention.

Sensors  $S_1$  to  $S_m$  are preferably equally spaces, with spacing  $b$  along a line on the surface 19 of the observed object 13.

It is desirable fact the greater acoustic beams penetration to an inspected body and the condition of heterogeneous substances for acoustic inspections must be kept. The condition of heterogeneous substances inspection by means of acoustic methods express through ratio applying longitudinal wave length  $\lambda_{wave}$  and dimension of a considered material grain  $d$  such that  $\lambda_{wave} \leq d$ . According to the conditions, the preferred frequency for bone mediums inspections is in the range of 50 kHz to 600 kHz. It satisfies the two conditions.

The method according to the current invention allows "low frequency tomography" of large objects. Additionally, high frequency ultrasonic waves deflect from the bones and gas filled cavities and thus the bones and structures behind the bones cannot be imaged. In contrast, the low frequencies used according to the invention refract by the bones and thus may be imaged.

In contrast to geophysical systems as depicted in figure 1, wherein only two transmitters were used, and wherein said two transmitters were located at the two opposing ends of the sensors' profile, the system according to the current invention uses sensors that act as transceivers capable of both emitting and receiving acoustic signals.

Preferably, the transceivers are constructed such that the emitted and received acoustic waves are at an angle to the surface. For example, a wedge may be used to cause the angulations. Preferably, the waves are emitted and received at an angle of 45 degrees to the surface. The angle value influences the beam penetrations into the investigated object. Preferably, the emitted wave is directed towards the sensor used as receiver at 45 degrees, and the receiver is similarly angled. For need angle providing applying the system sensors is accomplished by rotating the wedge, by positioning two oppositely angled transceivers at a location, by mechanically tilting the transceiver or by electronically changing the effective line of sight of a piezoelectric phased array.

For clarity, the first line 12 of elementary pixels in the slice is differently marked. For example pixel  $12_{(3)}$  is the pixel directly underneath sensor  $S_3$ . The pixels in the rest of the slice are marked according to their row and column, for example  $13_{(i,j)}$ .

Preferably, index matching jell is used to efficiently couple acoustic energy into and out of the object.

Preferably, acoustic properties of the layer directly against the sensors are known. This could be achieved by realizing that the first layer of the system is additional known plate or/and pillow and in the human body is the skin sometimes with known properties. The value may be calculated also, but need to account that length routes of elastic wave in the pixel of the first layer are differed from cells of other layers. Additionally or alternatively, a "pillow" filled with jell may be placed between the object and the sensor array. Alternatively, a "pillow" is fulfillment from the special solid material that has properties of the water and be placed between the object and the sensor array. Alternatively, the

object may be immersed in a container of liquid with known acoustic properties. Immersion and jell-pillow may be used for interfacing a generally curved surface of a human body and the flat surface of the sensor array.

FIG. 3 schematically depicts a layered observed subject consisting of heterogeneous mediums, each with elastic wave velocity gradient, and the elastic wave propagations in the layered subject.

The layered system characterized an acoustic impedance gradient including heterogeneous mediums and the possible beams travels in the system are proposed in the FIG. 4. The beam travels are submitted to the Snell's reflection law:

$$\sin \alpha / \sin \beta = V_A/V_B,$$

Where  $\sin \alpha$  is Sine of the incident angle on the boundary between mediums A and B with different acoustic impedance,  $\sin \beta$  is the refracted angle in the second medium,  $V_A$  and  $V_B$  are longitudinal wave velocities in the first and the second mediums for case the system from two layers.

An observed subject is composed from a few layers including heterogeneous mediums with an elastic wave velocity gradient. In the example of figure 3, five layers are seen with gradient velocities. The condition may be expressed as:

$$V_1 < V_2 < V_3 < V_4 < V_5$$

According to the Snell's refraction law for the considered boundaries between the mediums 1 and 2 of the considered subject depicted in figure 3, the propagating wave will obey:

$$\frac{\sin \alpha}{\sin \beta_2} = \frac{V_1}{V_2}, \quad (1)$$

Where  $\sin \alpha$  is sine the incident angle on the boundary between mediums 1 and 2 with different acoustic impedance,  $\sin \beta_2$  is the angle of the refracted

beam in the second medium,  $V_1$  and  $V_2$  are the longitudinal wave velocities in the first and the second mediums.

From the equation 1 we can write down:

$$\sin \beta_2 = \sin \alpha \times \frac{V_2}{V_1} \quad (2)$$

Similarly, for the boundary 2 which is the boundary between mediums 2 and 3:

$$\frac{\sin \beta_2}{\sin \beta_3} = \frac{V_2}{V_3}$$

Where  $\sin \beta_2$  is sine of the incident angle on the boundary between mediums 2 and 3 with different acoustic impedance,  $\sin \beta_3$  is the refracted angle in the third medium,  $V_2$  and  $V_3$  are the longitudinal wave velocities in the second and the third mediums.

$\sin \beta_3$  may be expressed as:

$$\sin \beta_3 = \sin \beta_2 \times \frac{V_3}{V_2}$$

and thus as as:

$$\sin \beta_3 = \sin \alpha \times \frac{V_3}{V_1}$$

For the boundary 3, the boundary between the mediums 3 and 4 we can write:

$$\frac{\sin \beta_3}{\sin \beta_4} = \frac{V_3}{V_4}$$

Where  $\sin \beta_3$  is sine the incident angle on the boundary between the mediums 3 and 4 with different acoustic impedance,  $\sin \beta_4$  is the refracted angle in the fourth medium,  $V_3$  and  $V_4$  are the longitudinal wave velocities in the third and the fourth mediums;

Sin  $\beta_4$  may be expressed as as:

$$\sin \beta_4 = \sin \alpha \times \frac{V_4}{V_1},$$

And by analogy for the boundary n-1, which is a the boundary between the mediums n-1 and n the relations may be written as:

$$\frac{\sin \beta_{n-1}}{\sin \beta_n} = \frac{V_{n-1}}{V_n}$$

And thus as:

$$\sin \beta_n = \sin \alpha \times \frac{V_n}{V_1},$$

Hence, a multi-layered object with an elastic wave velocities gradient comprising layers may be expressed as an equivalent two-layers object.

FIG. 4 schematically depicts some details of a two layers subject, demonstrating that a composite, multi-layered subject may be expressed as an equivalent two layers subject.

The region AKCH represents the first layer and CHDG as the  $n$ -th layer of the layered object.

The longitudinal wave velocities in the layers are depicted by  $V_1$  and  $V_n$  respectively.

The distance  $AK = \lambda$ , it is half of a distance between transmitter and receiver for each from a sensor's arrangement.  $h_1$  is the thickness of the first layer,  $\sin \alpha$  is the sine of the incident angle in the considered boundary and the  $\sin \beta_n$  is the sine of the refracted angle in the medium  $n$ .

According to Snell's relationship for the layers:

$$\frac{\sin \alpha}{\sin \beta_n} = \frac{V_1}{V_n}$$

The expression  $\sin \beta_n \times V_1 = \sin \alpha \times V_n$  describes an average velocity value considered oscillations travel from point A to point G.

According to Fermat's principle, ultrasonic oscillations travel in the fastest routes.

Defining the distances: EG as  $x$ , and AD as  $y$ , and

$S_{AG}$  as the shortest distance from point A to point G;  $S_{AG}$  may be expressed as:

$$S_{AG} = \sqrt{\ell^2 + y^2}$$

And thus the shortest time  $\tau_{short}$  may be written as:  $S_{AG} / (\sin \alpha \times V_n)$  or as

$$\tau_{short} = \frac{\sqrt{\ell^2 + y^2}}{\sin \alpha \times V_n}$$

$$\sin \alpha = \frac{\ell - x}{\sqrt{(\ell - x)^2 + h_1^2}}; \sin \beta_n = \frac{x}{\sqrt{x^2 + (y - h_1)^2}}; \frac{\sin \alpha}{\sin \beta_n} = \frac{(\ell - x) \times \sqrt{x^2 + (y - h_1)^2}}{x \times \sqrt{(\ell - x)^2 + h_1^2}} = \frac{V_1}{V_n}$$

$$\tau_{short} = \frac{\sqrt{\ell^2 + y^2} \times \sqrt{(\ell - x)^2 + h_1^2}}{(\ell - x) \times V_n}$$

Similarly, the shortest time may be written and as the corresponding distances divided by the corresponding velocity values:  $S_{AO}/V_1 + S_{OG}/V_n$  or as:

$$\tau_{short} = \frac{\sqrt{h_1^2 + (\ell - x)^2}}{V_1} + \frac{\sqrt{x^2 + (y - h_1)^2}}{V_n}$$

We can write the equation from the shortest time:

$$\frac{\sqrt{\ell^2 + y^2} \times \sqrt{(\ell - x)^2 + h_1^2}}{(\ell - x) \times V_n} = \frac{\sqrt{h_1^2 + (\ell - x)^2}}{V_1} + \frac{\sqrt{x^2 + (y - h_1)^2}}{V_n}$$

We can then divide the both part of the equation by  $\sqrt{(\ell - x)^2 + h_1^2}$  to get:

$$\frac{\sqrt{\ell^2 + y^2}}{(\ell - x) \times V_n} = \frac{1}{V_1} + \frac{\sqrt{x^2 + (y - h_1)^2}}{V_n \times \sqrt{(\ell - x)^2 + h_1^2}}$$

The equation may be written as:

$$\sqrt{\ell^2 + y^2} = \frac{(\ell - x)V_n}{V_1} + \frac{V_1 \times x}{V_n}$$

$$y^2 = \frac{(\ell - x)^2 V_n^2}{V_1^2} + 2\ell x - x^2 - x^2 - \ell^2 + \frac{V_1^2 x^2}{V_n^2};$$

$$y^2 = (\ell - x)^2 \left( \frac{V_n^2}{V_1^2} - 1 \right) + x^2 \left( \frac{V_1^2}{V_n^2} - 1 \right);$$

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Or as 
$$y^2 = (\ell - x)^2 \left( \frac{\sin^2 \beta_n}{\sin^2 \alpha} - 1 \right) + x^2 \left( \frac{\sin^2 \alpha}{\sin^2 \beta_n} - 1 \right)$$

The dependence is described by the equation of the second order. It is a non-linear function.

The maximal depth of a beam penetration for refracted wave is determined by the gradient velocity values ( $V_n/V_1$ ) of mediums and by the distance between a transmitter and a receiver  $2\lambda$ .

If  $x=0$ :

$$y = \ell \sqrt{\frac{V_n^2}{V_1^2} - 1}$$

Hence, a system of the Ultrasonic Tomographical measurements may be based on changing distance between transducers and receivers which are situated on one surface of an inspected object.

We can assert that obtained significant number routes are distributed in the same system consisting of heterogeneous mediums with an elastic wave velocity gradient.

FIG 5 demonstrates the adjoining and the reciprocal routes of propagating elastic wave in the vertical slice according to the applied algorithm according to the invention.

The invention utilizes the algorithm, which provides differential measurement and treatment of an obtained data. Figure 5 demonstrates the adjoining and reciprocal routes in the vertical slice according to the applied inventive algorithm. It shows the measurement system and propagation elastic wave according to the invention in the profile.

The sensors  $S_i$ ,  $S_{i+1}$  and sensors  $S_{j-1}$ ,  $S_j$  are situated on the surface 19 in locations A, B, C, and D respectively.

Transmitters (or transducers used as transmitters) from points A and D emit ultrasonic oscillations at an angle to an investigated object surface 19 one at a time at its turn. The oscillations are received by receivers ((or transducers

used as receivers) that situated at locations C and D which are angulated accordingly.

Four routes may be plotted in the direct direction: AC, AD, BC, and BD.

Similarly, we obtain the four routes in reciprocal direction: CA, DA, CB, and DB, where the transmitters are situated in the points C and D and receivers in the points A and B.

The FIG. 5 explains the proposed algorithm according to the invention which is to add up and subtraction of the longitudinal wave travel times for the certain combination of the adjoining and reciprocal routes. If we add up and subtract the average values of the longitudinal wave travel times that are needed for longitudinal wave travels between the routes in direct and reciprocal directions we can obtain the travel times difference for a considered cell relative to the above placed cell.

It should be noted that the angulations of the emitted and received beams such as depicted by the lines AE, BF and GC, HD is preferably 45 degree to surface 19, however, smaller or larger angulations are optional.

FIG. 6 demonstrates some details of elementary volume selection. Figure 6 explains the approach.

The obtained difference in travel times relates the considered cell 225 relative to above placed cell correspond to the change sensor's arrangement with step *b* on the surface 19 along central line joining the points O and M as depicted in figure 6.

The Prior art, such as ultrasonic logging method, consider two signals for selection of the part of an inspected object. In contrast, the inventive algorithm uses a combination of the signals for revealing properties of a specific elementary volume in the observed object.

Consider the difference of obtained average between direct and reciprocal directions times for signal traveling between pointes A – D and pointes B – C. The obtained difference  $\tau_{AD} - \tau_{BC}$  characterizes the changes in the selected half arc in the picture. Consider the difference of obtained average times for signal traveling between pointes A – C and pointes B – C. The obtained difference  $\tau_{AC} - \tau_{BC}$  characterizes another selected part of the considered arc. Consider the difference of obtained average times for signal between pointes B – D and pointes C – B. The obtained difference  $\tau_{BD} - \tau_{CB}$  characterizes the additional selected part of the considered arc.

The needed elementary volume may be obtained by the way subtraction of the signals that characterize the select parts of the half of the ring, which selected in the pictures of the FIG. 5 and 6.

$$\Delta\tau_m = (\tau_{AD} - \tau_{BC}) - (\tau_{AC} - \tau_{BC}) - (\tau_{BD} - \tau_{CB}) = \tau_{AD} + \tau_{BC} - \tau_{AC} - \tau_{BD}$$

The needed part of an inspected object is the shaded part in FIG. 5.

The considered difference  $\Delta\tau_m$  is the difference between smallest time ultrasonic oscillations travels by the curvilinear routes in the considered cell ( $\tau_{EM} + \tau_{MH}$ ) and in the above placed cell ( $\tau_{EO} + \tau_{HO}$ ).

$$\Delta\tau_m = \tau_{AE} + \tau_{EM} + \tau_{MH} + \tau_{HD} + \tau_{BF} + \tau_{FO} + \tau_{OG} + \tau_{GC} - \tau_{AE} - \tau_{EO} - \tau_{OG} - \tau_{GC} - \tau_{DH} - \tau_{HO} - \tau_{OF} - \tau_{FB}$$

$$\Delta\tau_m = \tau_{EM} + \tau_{MH} - (\tau_{EO} + \tau_{HO})$$

The calculations of a longitudinal wave average velocity value for each cell are carried out by calculated values of longitudinal wave travel times in each cell and by a length of a travel longitudinal wave in a cell.

We apply the approach by substitution of the considered composed multi-layered object with an equivalent two layers. The observed layer is determined by the considered elementary volume (cell), in which longitudinal wave propagations are executed by non-linear routes. We account that the travel way

in an elementary cell of an examined composed system by estimated value, calculated as the length half of a circle with radius  $b$  that is  $\pi b$ . We assume that the length of a travel in the single first known layer is  $2\sqrt{2} \times b$  for the incident angle of the first layer  $45^\circ$ , where  $b$  is the distance between transducers. The proposed technology may be used for inspection homogeneous substances also, but the length of a travel signal in elementary cells will be calculated according to the equation  $2\sqrt{2} \times b$ .

The invention proposes differential way measurements and treatments of an obtained data that provide evaluation each elementary volume from an inspected object.

Figures 7 and 8 schematically depict the method of data acquisition according to the current invention: FIG. 7 schematically depicts a succession of measurements in the direct direction, while FIG. 8 schematically depicts a succession of measurements in the reciprocal direction. For simplicity, the 1D array of sensors is shown. Extension of the method to the 2D sensor array is done by activation each row of sensors at a time.

For simplicity, parts in the drawing were marked on only few of the crowded drawings.

According to a preferred embodiment of the invention, electronic signal is transmitted from the scanning controller 39 to one of the transducers  $S_i$  in the row of transducers 26 which is in contact with the surface 19 of the observed object 27 having internal structure 29.

Figure 8(1) depicts the situation in which the first sensor  $S_1$  in the row is used as a transmitter. The first sensor  $S_1$  is angled to the right by using a wedge or other angulation means.

Paths of acoustic beams from sensor  $S_1$  arriving to other sensors in the row which are used as receivers and are angulated to the left along the marked paths. Direct paths are marked as  $D_{i,j}$  wherein  $i$  is the index of the transmitter

and  $j$  is the index of the receiver. Electronic signals from the receivers are transmitted to the time measuring unit 21 which detects and measure the arrival time of acoustic signal to the sensor, thus determine the time of flight from sensor  $i$  to sensor  $j$  along the direct path  $D_{i,j}$ , which is the time  $\tau_{i,j}$ . For simplicity, only  $D_{1,n}$  and  $D_{1,n-1}$  are marked in drawing 7(10). Time measuring unit 21 may process one signal from one sensor at a time or may be a parallel processing unit processing plurality of signals at a time. To increase the Signal to Noise Ratio (SNR), several pulses may be analyzed and averaged  $\tau_{i,j}$  is used.

In figure 7(2), the second sensor  $S_2$  in the row is used as a transmitter and remaining sensors as receivers. The sensor  $S_2$  is angled to the right by using a wedge or other angulation's means. Paths of acoustic beams from sensor  $S_2$  arriving to other sensors in the row which are used as receivers and are angulated to the left along the marked paths. Optionally, sensor  $S_1$  is idle at that time.

The measurement process repeats until most of the sensors are used as transmitters as depicted in Figures 8(k-1) and 8(k), wherein  $k$  is smaller than the number of sensors in the array  $n$  since generally the same sensor is not used as both transmitter and receiver at the same time, and in fact a minimal gap (one sensor in the case depicted here) may be between the closest sensors used.

Reciprocal paths  $R_{i,j}$  are similarly marked in dashed lines in Figures 9(1), 9(2), 9(k-1) and 9(k).

For measuring reciprocal paths, the receivers are angulated to the right while the transmitters are angulated to the left.

It is understood that order of measurements may optionally vary. Order may be changed systematically or even randomly within the same row or among the rows and columns in a 2D array. However, it is preferred that all transmitter-receiver pairs in each row would be measured at least ones.

FIG. 9 schematically depicts a functional block diagram of the ultrasonic tomography system according to a preferred embodiment of the current invention.

Ultrasonic Tomograph 200 is used to measure objects such as parts of a human patient 27 and obtain a map of material's and structural properties distribution in observed object. Additionally, tomograph 200 may detect bone weaknesses such as fractures and by way estimate Fracture risk and reveal its location, etc.

Signal generator 18 produces alternating electronic signal in the form of short pulses. The generated signal is directed by scanner position controller 39 to one of the transducers 26 in the sensor array 20. Scanner position controller 29 also controls the angulations of transducers 26. For example, each transducer 26 may comprise two transducers oppositely angulated. Alternatively, scanner position controller 39 may control electro-mechanical devices such as solenoids (not shown) within array 20 for changing angulations of transducers 26. Additionally, and optionally scanner position controller 39 may control an electro-mechanical device such as a stepper motor (not shown) within array 20 for scanning the array of transducers over the surface of observed object 27.

Signals from transducers 26, indicative of received ultrasonic signals are directed from transducers array 20 to signal processing unit 21. Signal processing unit 21 receives signals, amplify, filter and process the signal to measures shortest travel times in the direct and reciprocal paths. The measured travel time, in digital format are transferred to processor 22 which calculates the differential data according to the disclosed algorithm. Optionally, a storage device 23, such as a digital memory or a disk is used for storing the data produced by signal processor 21. Optionally, storage device 23 serves other digital units such as processor 22 and/or image formation unit 24.

Image formation unit 24 uses the differential data to produce maps of acoustical parameters to be displayed by display 25. Optionally, image formation

unit 24 converts acoustical parameters, calculated as properties of elements of pixel array 13 to physiological properties of the observed object.

It should be noted that processor 22 and image formation unit 24 may be in a form of a general purpose computer such as a PC or a laptop and that processing and image formation may be programmed in computer languages such as C++, Excel or MatLab.

FIG. 10 illustrates the experimental ultrasonic system with scanning transducers movement which was used for the experimental demonstration and verification of the invention.

Experimental system 100 uses a single transmitter 110 and a single receiver 105. Both transmitter 110 and receiver 105 are immersed in liquid 102 contained by container 101. The observed object 121 is immersed in the liquid and rests on plate 122 at the bottom of container 101. A pig's leg having soft tissue 198 (the bone was wrapped with chicken meat for the needed inspected system creation) and bone 120 was used in this experiment. Two pig legs samples were imaged.

In the experiment, the container was 40 cm long in the X direction, and 28.2 cm in its center were imaged. The container's depth was 12 cm in the Y direction. The container width was 17 cm in the Z direction.

Transmitter 110, which is angulated as depicted in the drawing, receives electronic signal from pulse generator 119 and produces ultrasonic beam 111. Beam 111 is diffracted by liquid and the observed object 121 and arrives at the receiver 105. A measuring unit 211 was used for extracting time of travel information.

Mechanical translators (schematically depicted by the double headed arrows 210 and 205) were used for manually translate transmitter 110 and receiver 105 respectively to the proper locations.

An old “concrete tester” made by C.S.I. (Holland) was used for this experiment. This device was not optimized for the purpose, yet it demonstrated the feasibility of the method according to the current invention.

Table 1 depicts obtained data and its treatment according to the algorithm of the current invention. Distance between sensors and between profiles was 8 mm.

The treatment of the data is executed according to the algorithm is:

$$\Delta t = (\tau_{m, \text{dir}} + \tau_{m, \text{rec}})/2 + (\tau_{-m+1, \text{dir}} + \tau_{-m+1, \text{rec}})/2 - (\tau_{\text{dir, dir}} + \tau_{\text{dir, rec}})/2 - (\tau_{\text{rec, dir}} + \tau_{\text{rec, rec}})/2$$

The sample was immersed in water and the velocity in the water is 1480m/s (at 20<sup>0</sup> C ).

Distance between sensors' locations and between the slices was 8 mm. The length of the route which the wave traveled in a cell of the first layer is  $2 \times \sqrt{2} \times 8 = 22,63 \text{ mm}$ . The time of longitudinal wave travel in the first layer is thus computed to be 15.29 $\mu$ s.

$$t_1 = \frac{22,63 \times 10^{-3}}{1480} = 15,29 \mu s$$

The length of longitudinal wave travels in each cell is equal  $2\pi b = 3.14 \times 8$  mm, which was computed to be  $S = 25.12$  mm.

The calculated values are depicted in the table 2.

Table 3 depicts the calculated longitudinal wave velocity values for specimen 1.

The map of longitudinal wave velocity distributions in object was obtained from the obtained data using Microsoft “Excel” programming.

FIG. 11 demonstrates the wave velocity map, which was obtained as the result of the inspections of the specimen 2 of pig's leg, which included both soft

tissues and bone mediums.

The density of probability distribution of longitudinal wave velocity values (histogram) helps obtain the value longitudinal wave velocity in the skeleton mineral part of the considered bone  $V_t$ . The value indirect characterizes the mineral part of a considered bone medium for the concrete individual. It is the point of counting out of changes in bone substance for a concrete individual. The graph of the statistical treatment of the data is shown in the FIG. 12.

According to the graph the value  $V_t = 5150\text{m/s}$  may be taken as the longitudinal wave velocity in the matrix (skeleton) of the bone for the specimen 1. The values of porosity  $n$  by the changed Wyllie relationship and known from literature as called "Equation of average time" equation were calculated. It is expressed by longitudinal wave velocity values.

The equation is following: 
$$\frac{1}{V_p} = \frac{1-n}{V_t} + \frac{n}{V_{fill}}$$

The porosities values were calculated using the values corresponding elastic waves travel times in the considered material  $V_p$ , in the matrix's part of the inspected medium  $V_t$  and in the filling of the medium  $V_{fill}$  (filling was water in the considered case).

Evaluation of porosity values is possible on the specimens by comparing significant number of specimens for statistical treatment bone mediums.

Porosity was calculated for specimen 1 of pig's leg, for its main bone. Data from the table 3 was used.

The following equation is applied for calculating porosity values:

$$n = \frac{(V_t - V_p) V_{fill}}{V_p (V_t - V_{fill})}$$

The porous medium in a bone substance is filled by marrow. Approximately the value velocity in the filling may be taken as equal to 1550 m/s.

The obtained porosity values are depicted in table 4.

FIG. 13 shows the porosity values distribution in the specimen 1 from pig's leg, which includes it's the main bone mediums.

The experiments confirm the viability of the technology according to the current invention ad its applications for diagnosing human body inspections as well as for technical uses. Additional experiments were performed using different types beef with bones. Results of inspections are presented as maps of obtained longitudinal wave velocities values and distributions of porosity values.

The pig's leg specimen was evaluated before and after impacting it with few heavy blows to its middle part. Comparison of the obtained images "before" and "after" blows is depicted in figures 14(a) and 14(b) respectively. FIG. 14(a) and 14(b) depict the maps of longitudinal wave velocity values distributions in the section of the inspected pig's leg. The cavities and crack are revealed by velocities values reduction from the considered comparison.

Similarly, Voids created by cuts in the soft tissue of specimen were revealed.

FIG 15 schematically depicts an apparatus for inspection of organ such as a limb according to another preferred embodiment of the current invention.

Three Dimensional Ultrasonic System 900 is used for evaluation of limb 920 which can include different system layers a cross section through the system is seen as well as an isometric view.

An optional "U" shaped solid frame 910 from system plates 911, 912, 914 providing acoustic impedance gradient of inspected body is used for supporting

an inspected object Alternatively, the number plates may be changed according to considered object and considered patient. Alternatively, bottom system plates is placed on an examination table, the limb is placed above it and a top pillow 915 is used for covering the limb. Alternatively, only top pillow is used with or without a frame. Bottom system plats is not needed if examination of structures in the lower part (away from transducer 930) is not important. For example, the spinal structures of a patient may be examined with patient in prone position with only a top pillow on his back and without the use of a frame or system plats.

In figure 15, a cross section of the examined limb schematically shows the skin 922, the soft tissue between the skin 922 and the bone 924 and the bone marrow 926.

A 2D transducers' array 930 is placed on top of the top pillow which interfaces between the curved limb and the flat array. Array 930 receives signals from, and transmits signals to controller 932 which comprises the electronics depicted in figure 9.

It is appreciated that certain features of the invention, which are, for clarity, described in the context of separate embodiments, may also be provided in combination in a single embodiment. Conversely, various features of the invention, which are, for brevity, described in the context of a single embodiment, may also be provided separately or in any suitable sub combination.

Although the invention has been described in conjunction with specific embodiments thereof, it is evident that many alternatives, modifications and variations will be apparent to those skilled in the art. Accordingly, it is intended to embrace all such alternatives, modifications and variations that fall within the spirit and broad scope of the appended claims. All publications, patents and patent applications mentioned in this specification are herein incorporated in their entirety by reference into the specification, to the same extent as if each individual publication, patent or patent application was specifically and

individually indicated to be incorporated herein by reference. In addition, citation or identification of any reference in this application shall not be construed as an admission that such reference is available as prior art to the present invention.

Route	Distance	Measurement time in the route (-m) to (m), $\tau_m$ , $\mu\text{s}$		Measurement time in the route (-m+1) to (m-1), $\tau_{m-1}$ , $\mu\text{s}$		Measurement time in the route (-m+1) to (m), $\tau_{dir}$ , $\mu\text{s}$		Measurement time in the route (-m) to (m-1), $\tau_{rec}$ , $\mu\text{s}$	
		Direct, $\tau_{m,dir}$	Reciprocal, $\tau_{m,rec}$	Direct, $\tau_{-m+1,dir}$	Reciprocal, $\tau_{-m+1,rec}$	Direct, $\tau_{dir,dir}$	Reciprocal, $\tau_{dir,rec}$	Direct, $\tau_{rec,dir}$	Reciprocal, $\tau_{rec,rec}$
1	2	3	4	5	6	7	8	9	10
<b>Section 10.8cm</b>									
5to32	10,8	172	172	162	160	168	167	169	169
6to31	10	162	160	151	153	157	157	157	156
7to30	9,2	151	153	142	140	146	143	147	147
8to29	8,4	142	140	129	132	137	137	136	136
9to28	7,6	129	132	111	122	113	126	118	121
10to27	6,8	111	122	100	107	103	109	100	107
11to26	6	100	107	92	93	96	99	98	96
12to25	5,2	92	93	89	88	89	88	88	89
<b>Section 10cm</b>									
5to30	10	161	163	152	152	157	156	157	158
6to29	9,2	152	152	140	143	147	147	147	148
7to28	8,4	140	143	130	132	136	136	137	136
8to27	7,6	130	132	111	118	118	121	121	127
9to26	6,8	111	118	102	102	100	107	106	112
10to25	6	102	102	92	91	98	96	103	96
11to24	5,2	92	91	88	86	88	89	86	86
<b>Section 9.2cm</b>									
5to28	9,2	151	151	141	141	147	148	147	138
6to27	8,4	141	141	131	131	137	136	136	136
7to26	7,6	131	131	112	120	121	127	122	126
8to25	6,8	112	120	106	108	106	112	112	111
9to24	6	106	108	92	90	103	96	100	102
10to23	5,2	92	90	88	87	86	86	86	86

Table 1

Distance, cm	$\Delta t, \mu s$ according to the algorithm			$t_m, \mu s$ (15,29+ $\Delta t$ )			Longitudinal wave velocity, V, m/s s/ $t_m$		
	Section, cm								
	10,8	10	9,2	10,8	10	9,2	10,8	10	9,2
10,8	-3,5	0	2	11,8	15,3	17,3	2129	1642	1452
10	-0,5	-1	-0,5	14,8	14,3	14,8	1697	1757	1697
9,2	1,5	0	-1	16,8	15,3	14,3	1495	1641	1757
8,4	-1,5	2	2,5	13,8	17,3	17,8	1820	1452	1411
7,6	8	4	-2,5	23,3	19,3	12,8	1078	1301	1963
6,8	10,5	-3	6,5	25,8	12,3	21,8	973	2042	1152
6	1,5	4		16,8	19,3		1495	1302	
5,2	4			19,3			1301		

Table 2

<b>The longitudinal wave velocity values, m/s</b>					
<b>Distance</b>	<b>Distance, cm</b>				
<b>cm</b>	<b>4,5</b>	<b>5,3</b>	<b>6,1</b>	<b>6,9</b>	<b>7,7</b>
10,4	3213	2834	3443	2534	4388
11,2	3213	3709	2407	3213	2407
12	3443	3709	3443	3709	3011
12,8	3709	2834	2092	28334	2834
13,6	3709	2834	2534	4020	4388
14,4	2834	3213	4510	4490	3443
15,2	1718	1603	2092	4490	2005
16	2534	3011	3709	2407	3213
16,8	2407	2834	3443	3213	4388
17,6	3011	3443	4020	2834	1659
18,4	4388	2676	2534	2834	3213
19,2	2534	4020	3011	2834	4020

Table 3

<b>Porosity values</b>					
<b>Distance, cm</b>	<b>4,5</b>	<b>5,3</b>	<b>6,1</b>	<b>6,9</b>	<b>7,7</b>
10,4	0,260	0,352	0,213	0,444	0,075
11,2	0,260	0,167	0,491	0,260	0,491
12	0,213	0,167	0,213	0,167	0,306
12,8	0,167	0,352	0,629	0,352	0,352
13,6	0,167	0,352	0,444	0,121	0,075
14,4	0,352	0,260	0,061	0,063	0,213
15,2	0,860	0,952	0,629	0,063	0,675
16	0,444	0,306	0,167	0,491	0,260
16,8	0,491	0,352	0,213	0,260	0,075
17,6	0,306	0,213	0,121	0,352	0,906
18,4	0,075	0,398	0,444	0,352	0,260
19,2	0,444	0,121	0,306	0,352	0,121

**Table 4**

## CLAIMS

1. A method for diagnosing part of a human body comprising the steps of:

transmitting plurality of ultrasonic beams from evenly spaced locations in relation to the observed part of the human body and at an angle to the surface of said observed part of the human body;

receiving plurality of ultrasonic signal indicative of refraction of said ultrasonic beams that were transmitted, at evenly spaced locations in relation to said observed part of the human body, and at an angle to the surface of said observed part of the human body;

measuring transit times of said ultrasonic beams between plurality of pairs of said evenly spaced locations; and

evaluating ultrasonic wave velocity in mineral bone part;

calculating corresponding velocity and porosity values for multitude elementary volumes of an inspected object and

2. The method of Claim 1, further comprising the step of building up 2D and 3D images of propagation ultrasonic wave velocity and porosity for said observed part of the human body based on said measured transit times.

3. The method of claim 1 wherein the angle between transmitted beam and the surface of the part of the human patient and the angle between received beam and the surface of the part of the human patient is substantially 45 degrees.

4. The method of claim 1 further comprising the step of calculating a map of bone porosity based on said calculated map of ultrasonic propagation speed for said observed part of the human body.

5. The method of claim 3 further comprising the steps of:

estimating risk for bone fracture based on said built maps of bone porosity and ultrasonic wave velocity values; and

indicating at least one location having high risk for bone fracture.

6. The method of claim 1 wherein transmitting ultrasonic beams and receiving ultrasonic signals is done using a one dimensional array of evenly spaced ultrasonic transducers.

7. The method of claim 6 further comprising the steps of:

translating said one dimensional array of evenly spaced ultrasonic transducers to plurality of evenly spaced intervals in the direction perpendicular to said array;  
and

reconstructing a three dimensional map of ultrasonic wave velocity propagation for said observed part of the human body based on two dimensional maps of ultrasonic wave velocity propagation obtained at each of said intervals.

8. The method of 1 wherein transmitting ultrasonic beams and receiving ultrasonic signals is done using a two dimensional array of evenly spaced ultrasonic transducers.

9. The method of claim 8 further comprising the step of placing special material filled top pillow between said observed part of the human body and said two dimensional array of evenly spaced ultrasonic transducers.

10. The method of claim 8 further comprising the special plate is placed under an observed part of the human body.

11. The method of claim 1 wherein frequency of said transmitted ultrasonic beam is between 50 kHz and 600 kHz.

12. An ultrasonic system comprising:

an array of evenly spaced ultrasonic transducers capable of transmitting ultrasonic beam at an angle to said array in response to excitation pulse, and capable of producing signal in response to received ultrasonic beam at an angle to said array;

a signal generator generating short excitation pulse;

a scanning controller receiving said generated excitation pulse and directing said pulse to a selected transducer in said array of transducers;

a time measuring unit receiving signal indicative of refraction of said transmitted beam received by at least one of said transducers in said array of transducers, and calculating transit time for said beam, between transmitting transducer and receiving transducer;

a processor receiving plurality of calculated transit times corresponding to plurality of transmitting transducer and receiving transducer pairs, and calculating differential data based on said transit times; and

an image formation unit generating a map of ultrasonic propagation speed based on differential data.

13. The ultrasonic system of claim 12 wherein the angle between transmitted beam and said transducer array and the angle between received beam and said array is substantially 45 degrees.

14. The ultrasonic system of claim 12 wherein image formation unit further capable of generating a map of bone porosity based on said map of ultrasonic propagation speed for an observed part of human body refracting said transmitted ultrasonic beams.

15. The ultrasonic system of claim 12, wherein the image formation unit further capable of calculating risk for bone fracture based on said calculated map of bone porosity and indicating at least one location.

16. The ultrasonic system of claim 12 wherein said transducer array is one dimensional array of evenly spaced ultrasonic transducers.

17. The ultrasonic system of claim 16 wherein said scanning controller further translates said one dimensional array of evenly spaced ultrasonic transducers to plurality of evenly spaced intervals in the direction perpendicular to said array;

and said image formation unit reconstructs a three dimensional map of ultrasonic propagation speed based on two dimensional maps of ultrasonic propagation speed obtained at each of said intervals.

18. The ultrasonic system of claim 12 wherein the array of transducers is a two dimensional array of evenly spaced ultrasonic transducers.

19. The ultrasonic system of claim 18 further comprising special material filled pillow positioned between an examined object and said two dimensional array of evenly spaced ultrasonic transducers.

20. The ultrasonic system of claim 19 further comprising special material filled pillow positioned on the side of the object away from said two-dimensional array of evenly spaced ultrasonic transducers.

21. The ultrasonic system of claim 12 wherein frequency of said short excitation pulse is between 50 kHz and 600 kHz.

22. The method of claim 12 wherein wavelength of acoustic frequency is chosen so that the acoustic wavelength in the observed object  $\lambda_{\text{wave}}$  is smaller than the grain dimension of an inspected material  $d$ .

23. The ultrasonic system of claim 18 further includes addition artificial plates positioned between an examined object and said two dimensional array of evenly spaced.

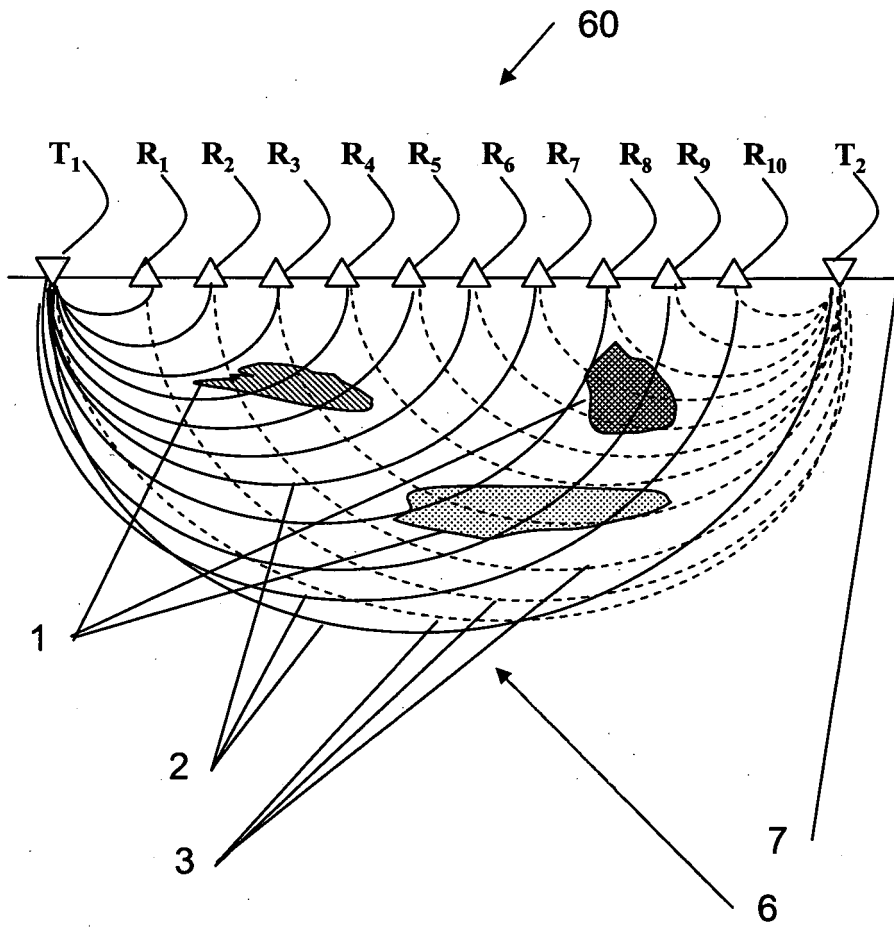


Fig 1 (prior art)

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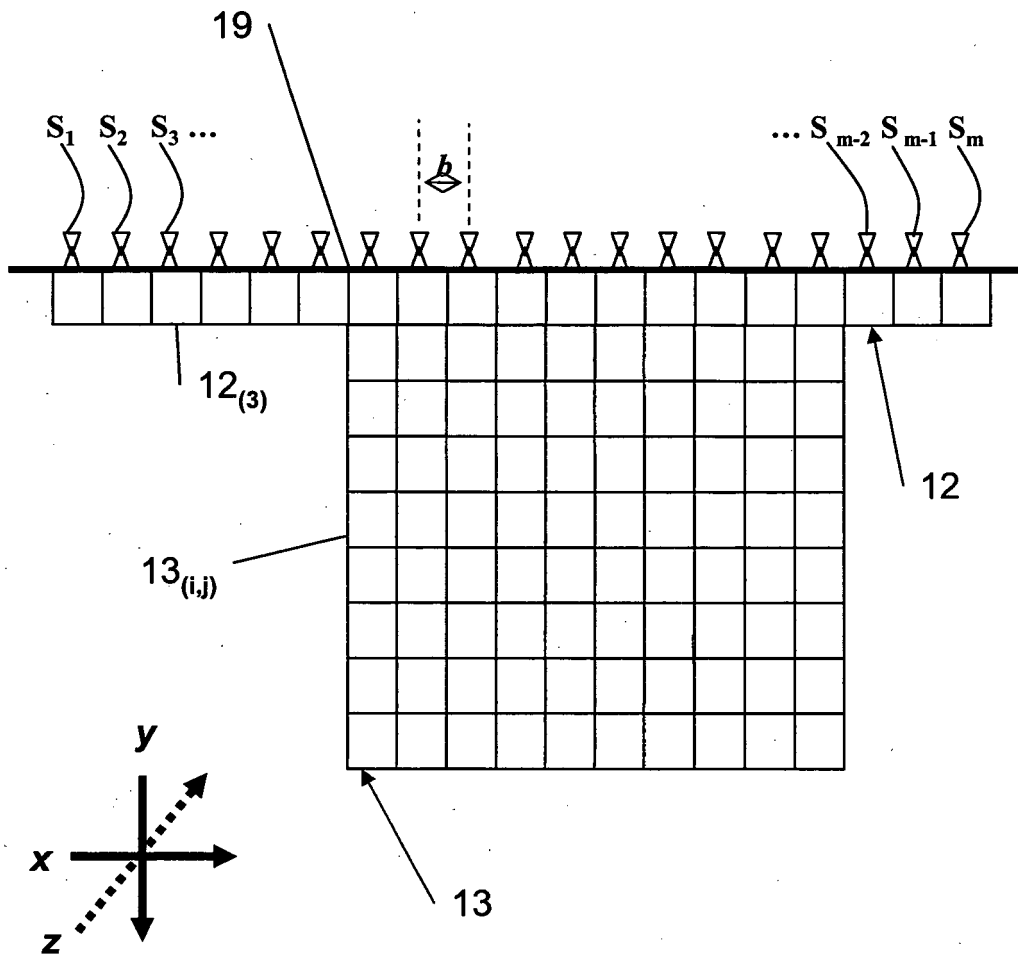


Fig 2

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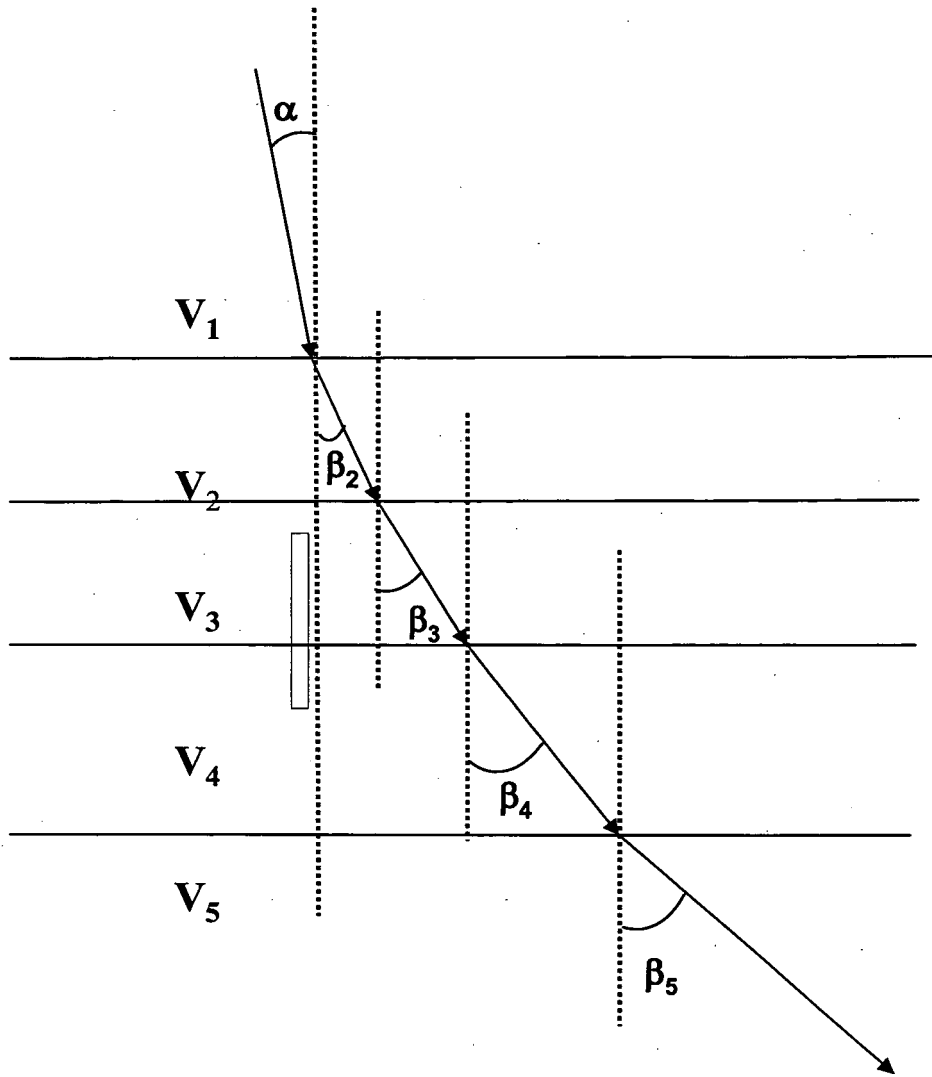


Fig 3

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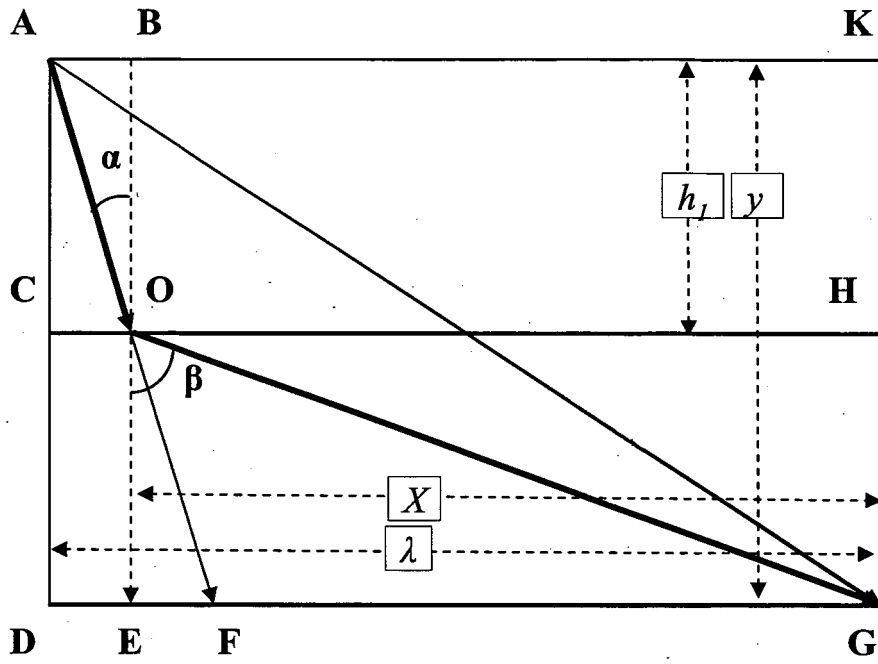


Fig 4

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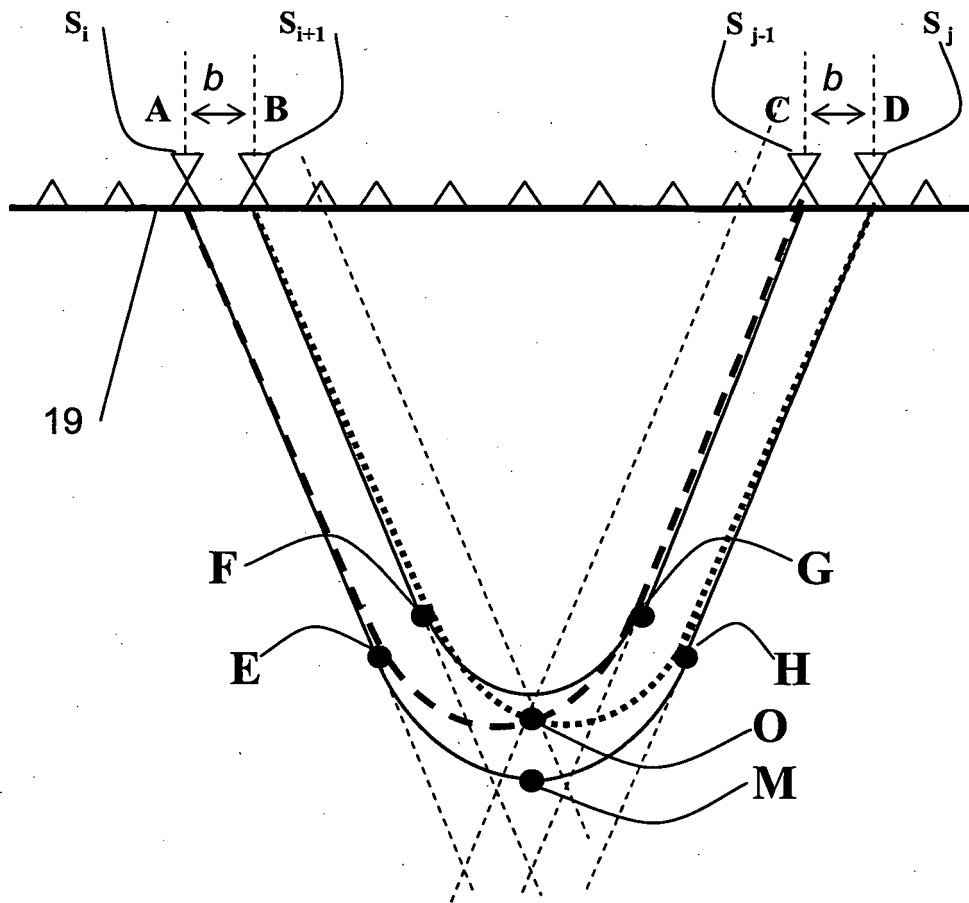


Fig 5

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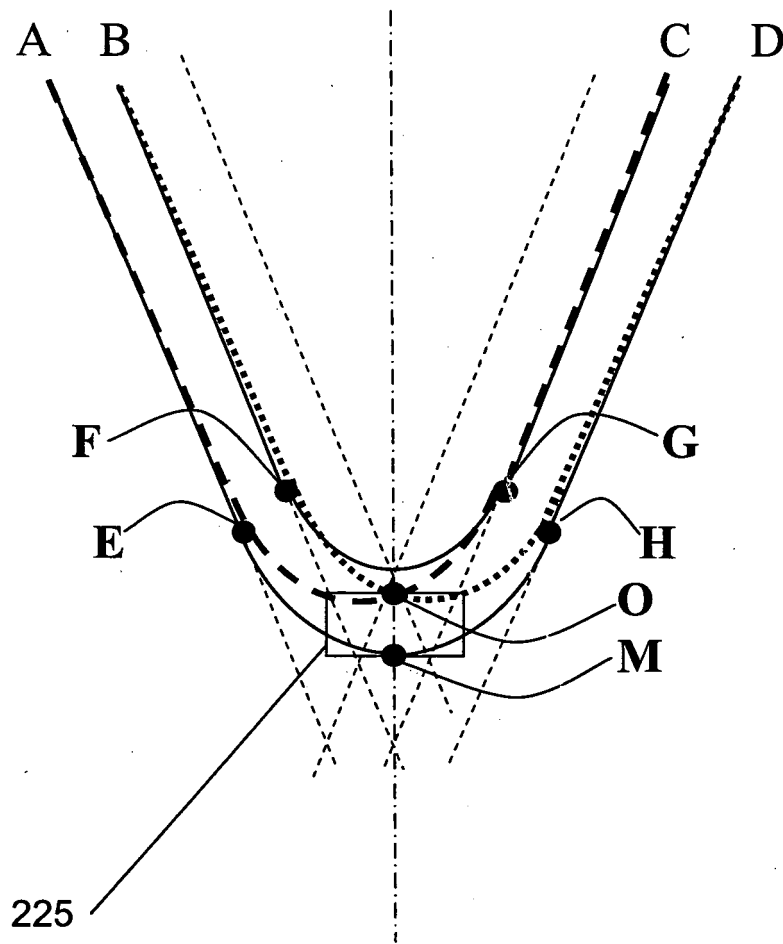


Fig 6

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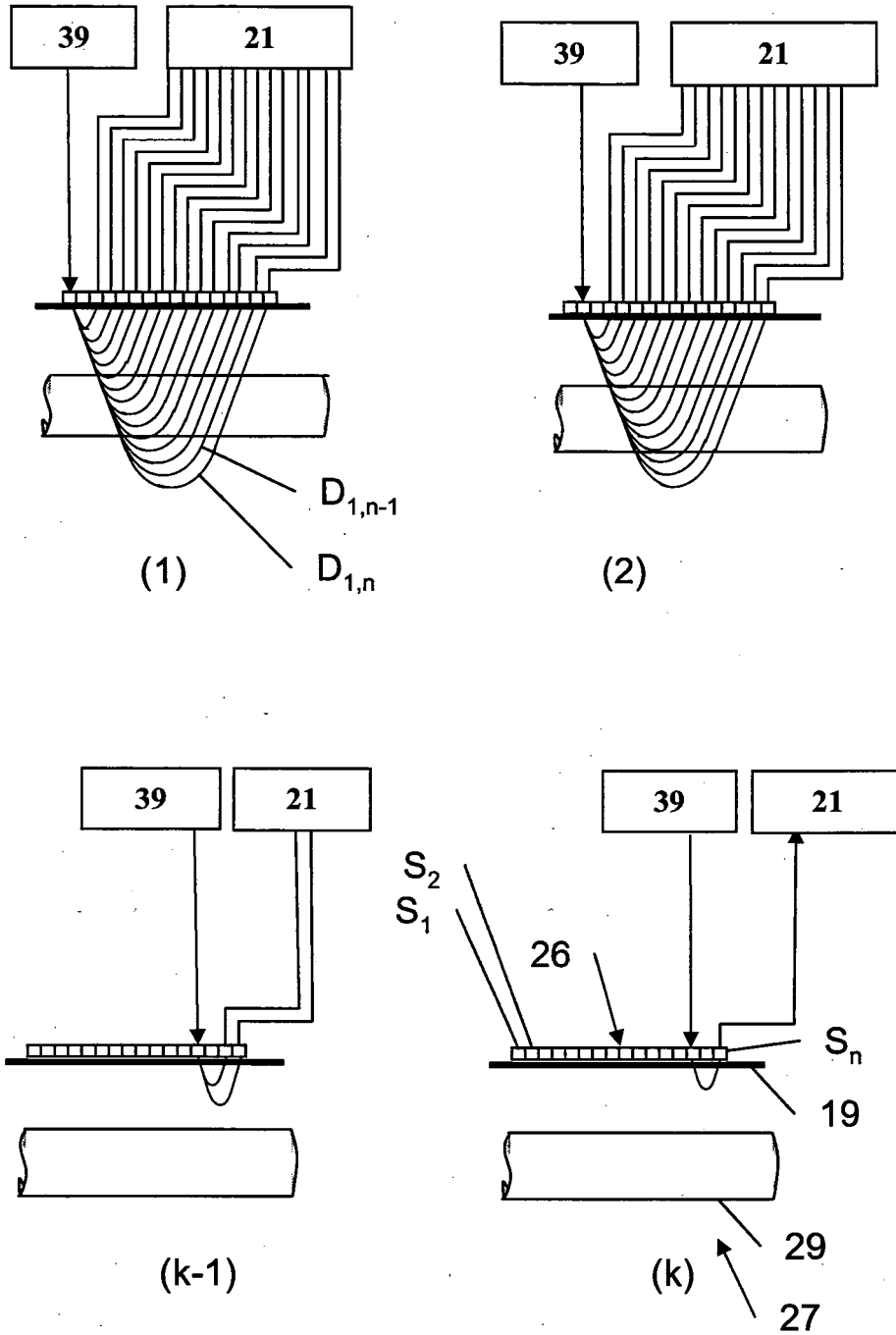


Fig 7

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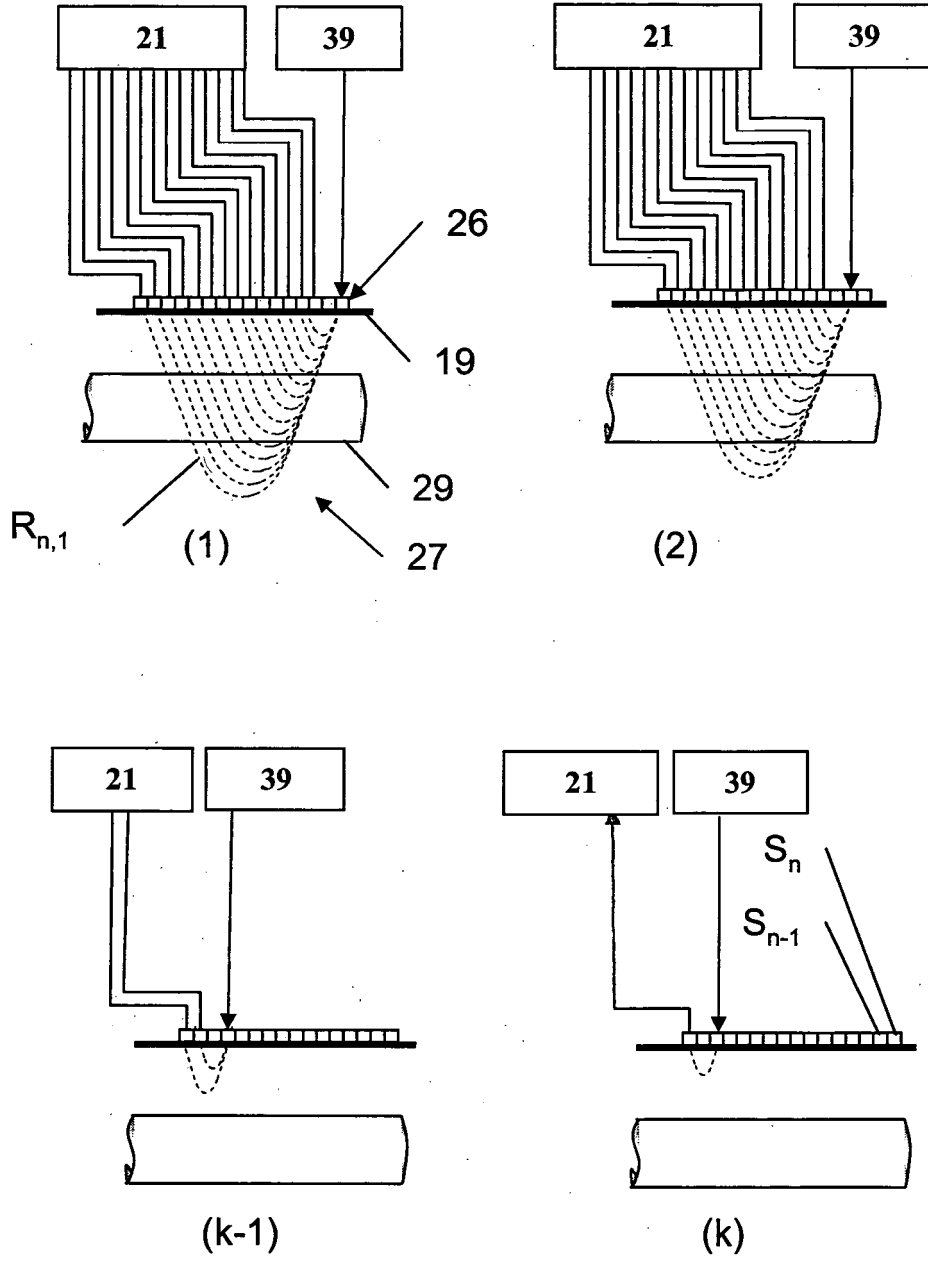


Fig 8

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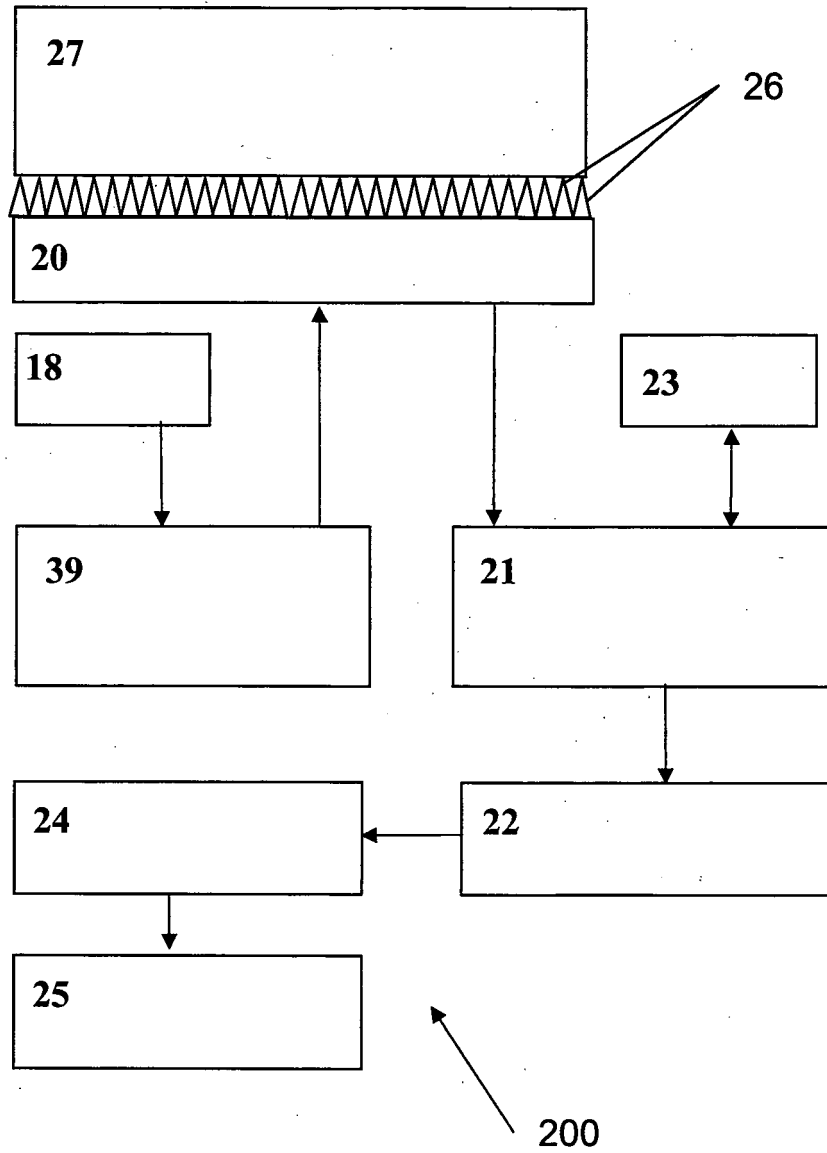


Fig 9



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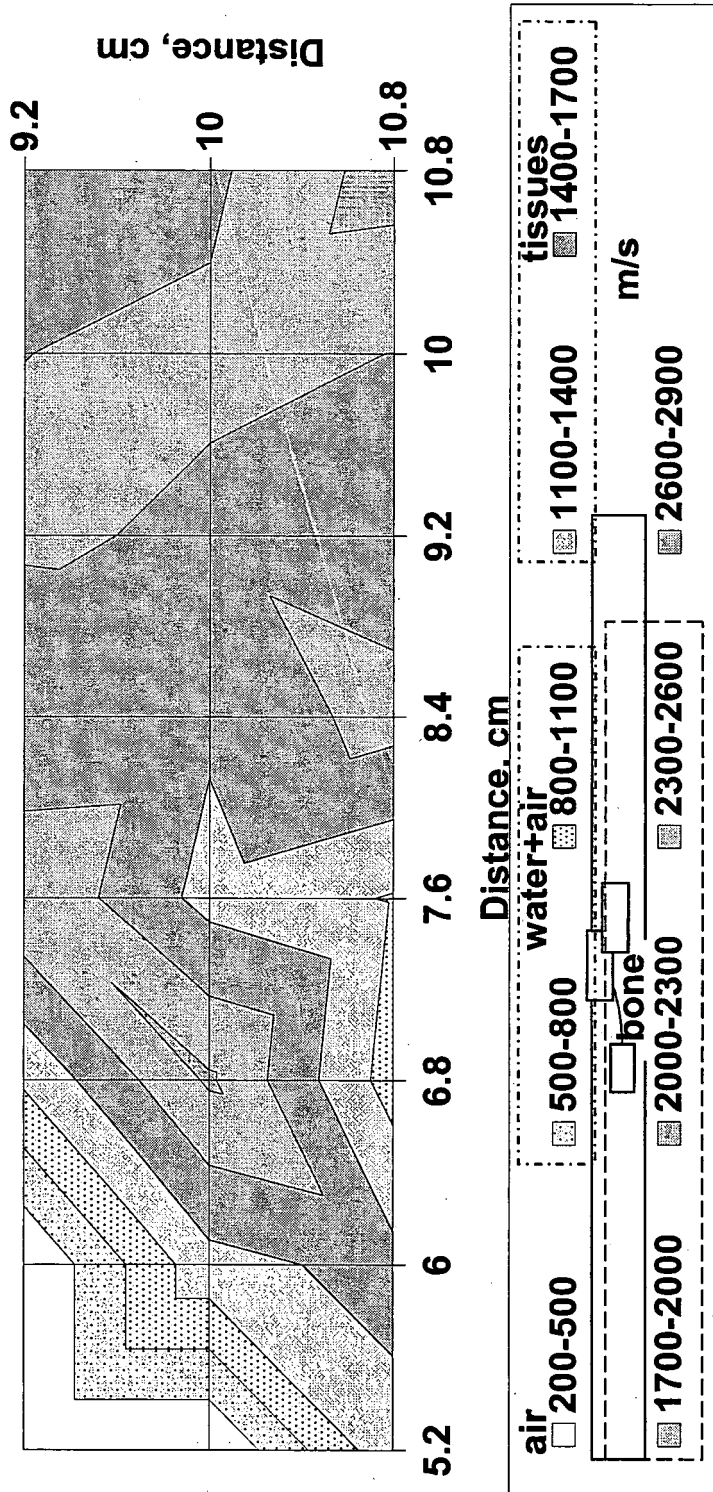


Fig 11

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**The distribution of the longitudinal wave velocity in the bone medium of the specimen 1**

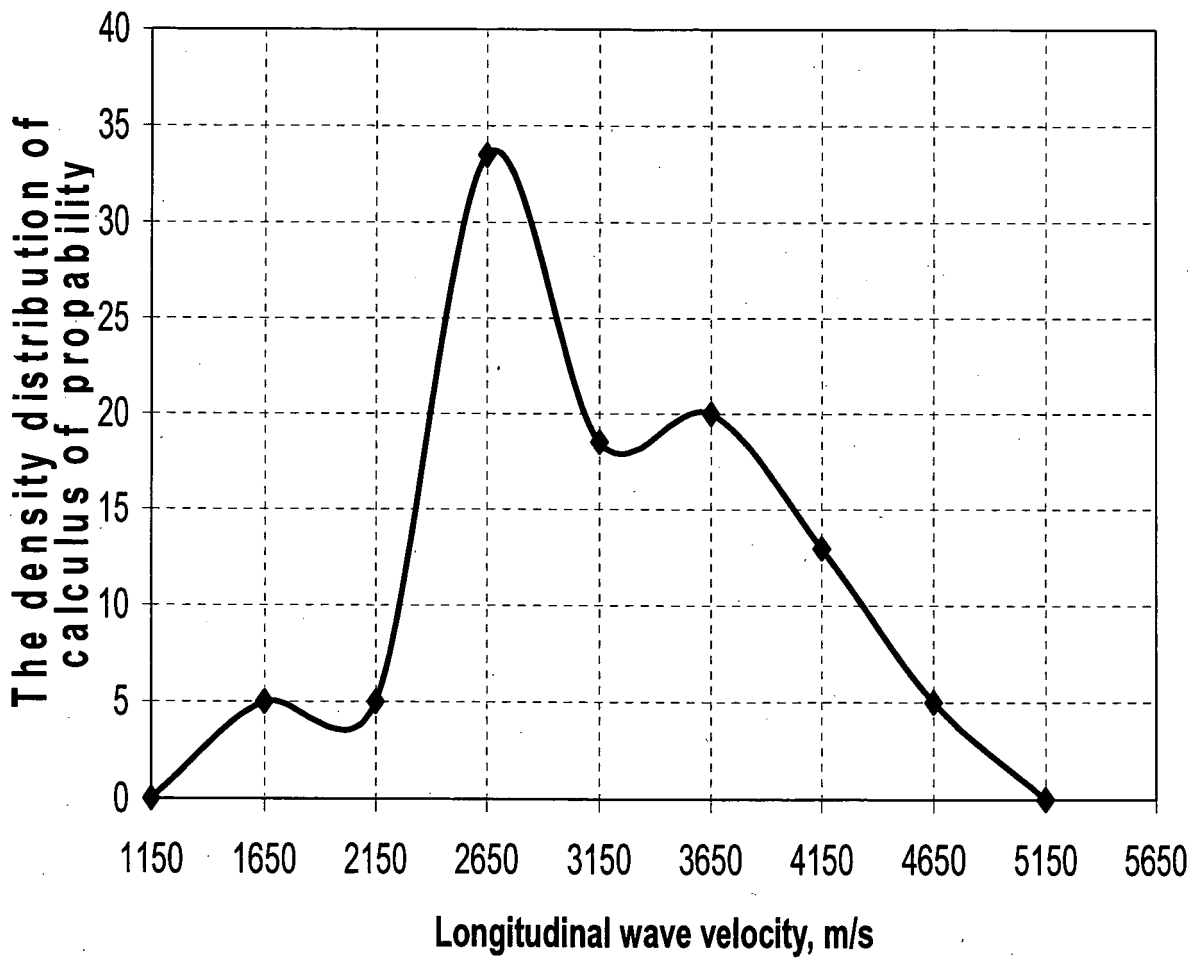


Fig 12

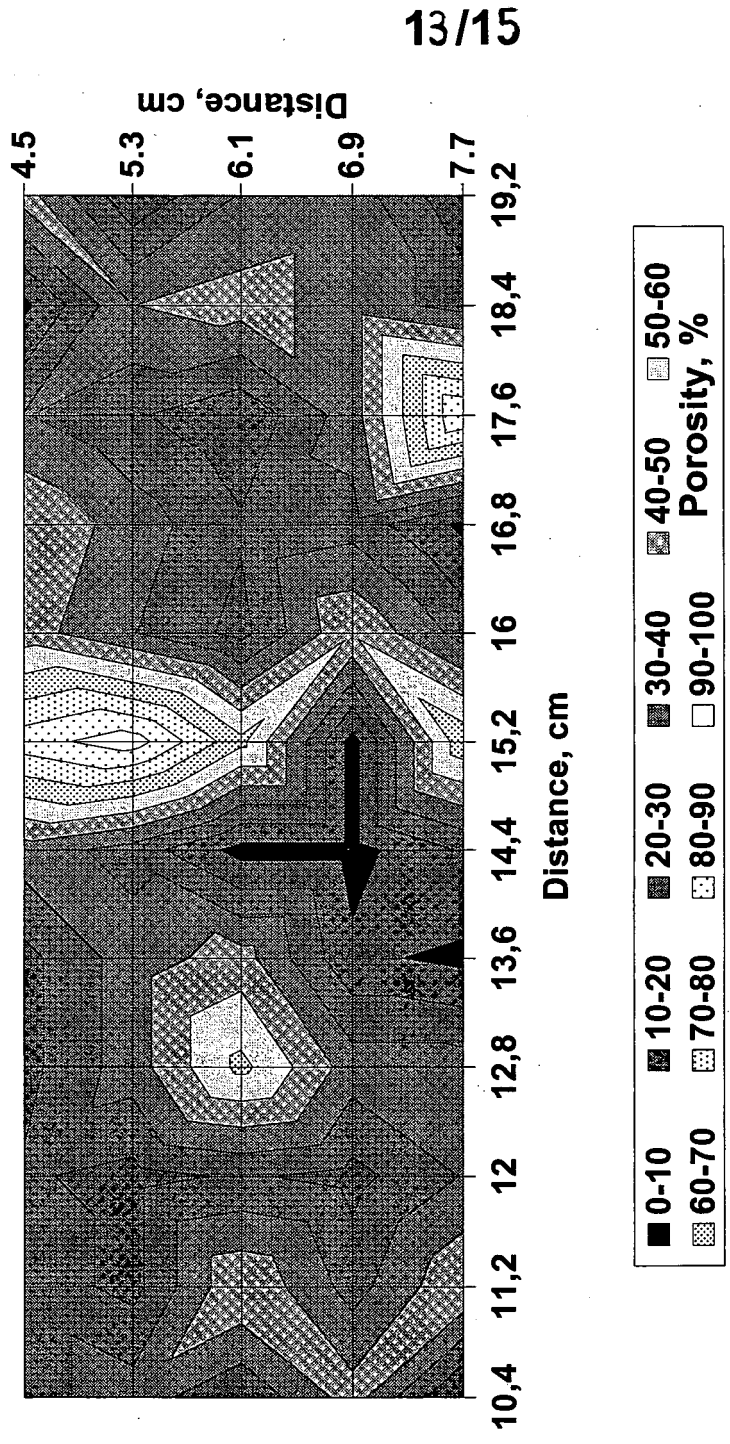
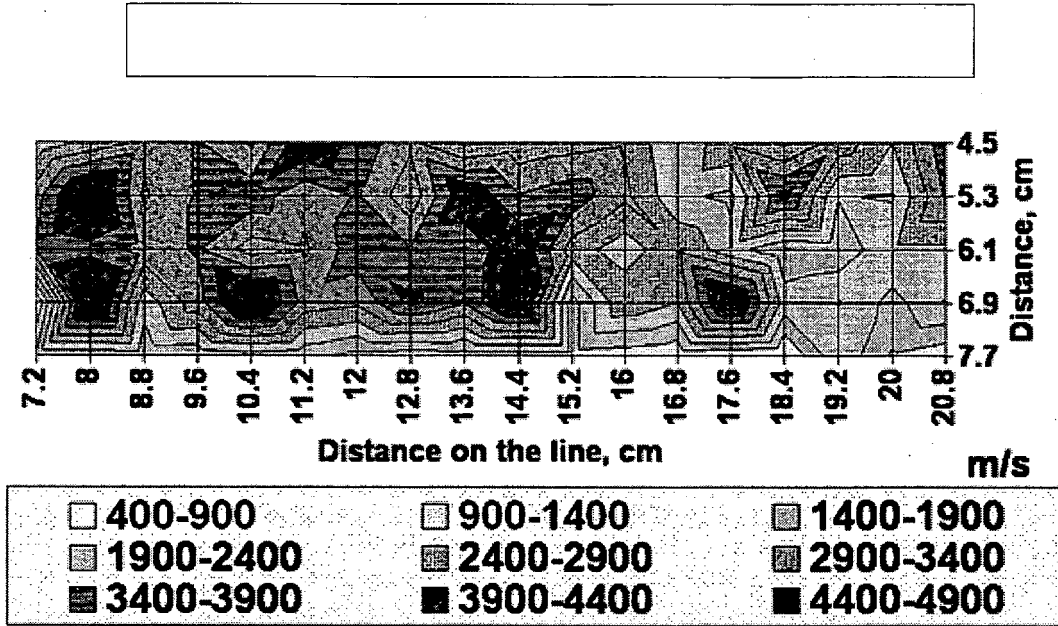
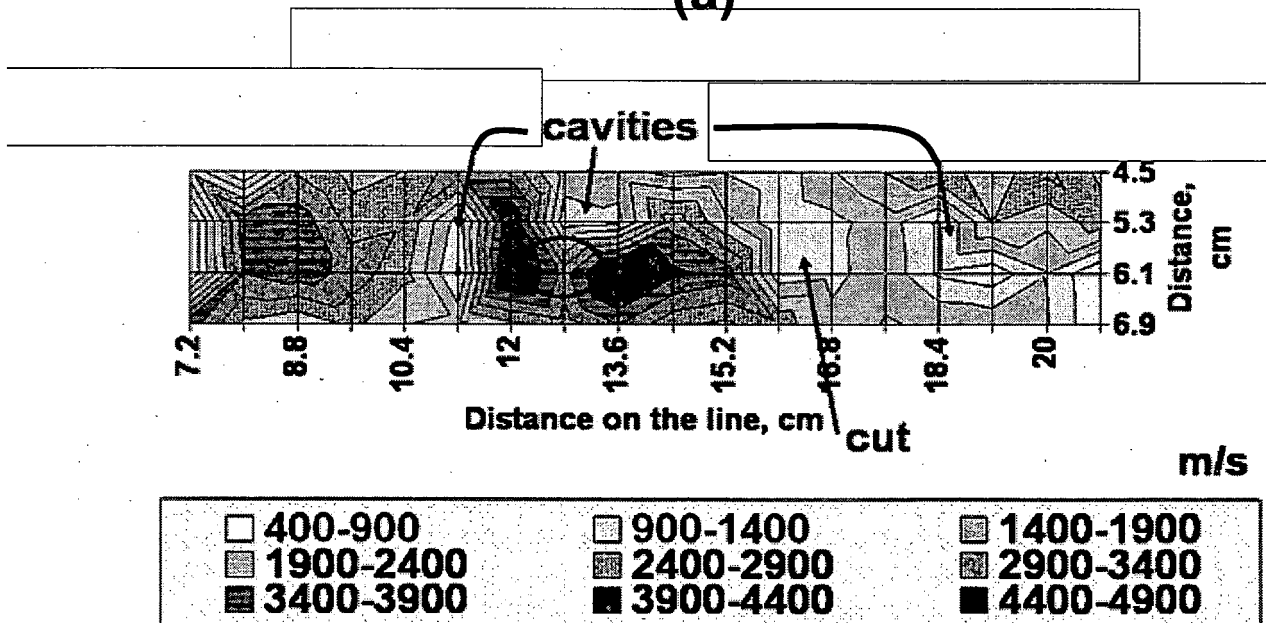


Fig 13

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(a)



(b)

Fig 14

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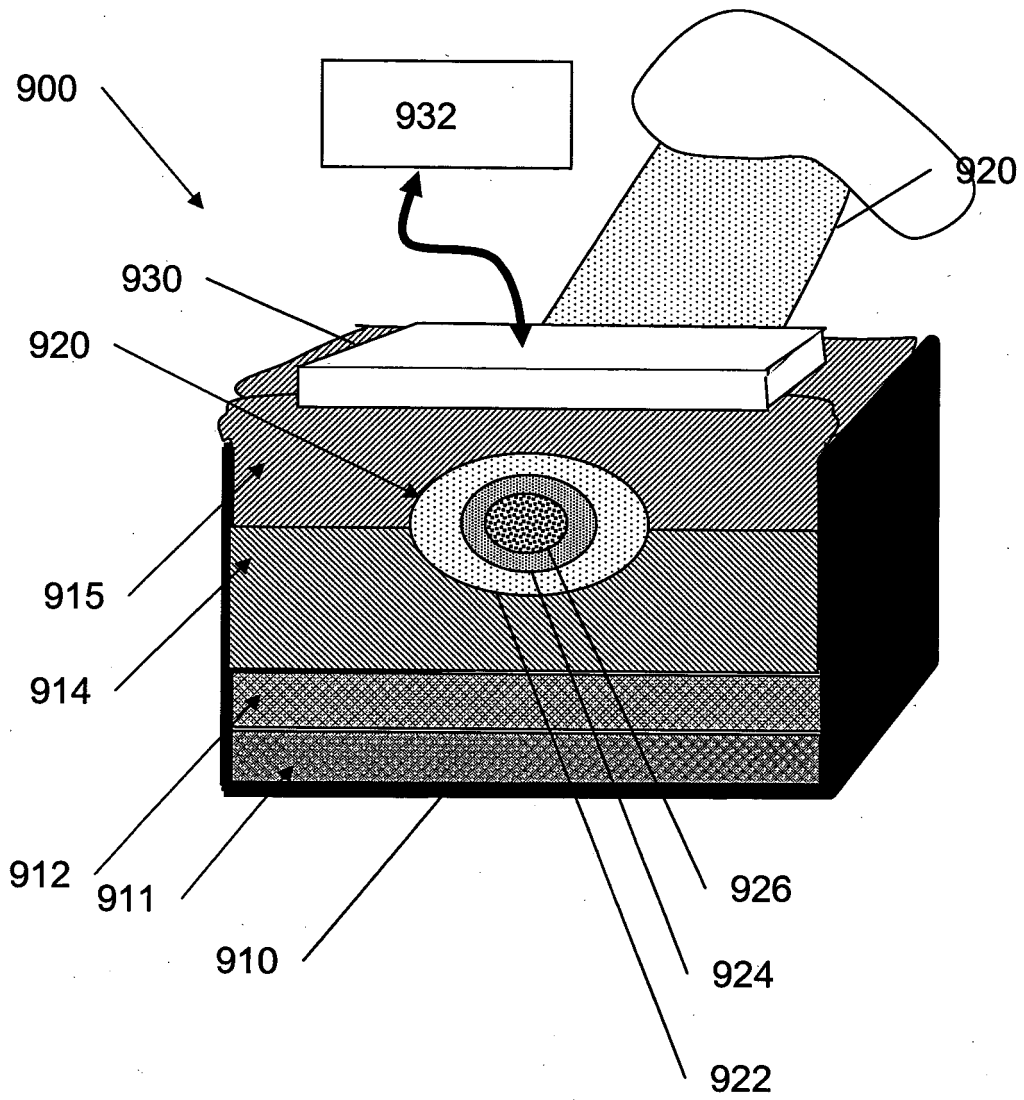


Fig 15

专利名称(译)	三维定量超声波骨检查方法及其实现装置		
公开(公告)号	<a href="#">EP2077759A2</a>	公开(公告)日	2009-07-15
申请号	EP2007827257	申请日	2007-10-24
[标]申请(专利权)人(译)	MINDELIS GESEL GOUREVITCH ALLA		
申请(专利权)人(译)	MINDELIS , GESEL GOUREVITCH , ALLA		
当前申请(专利权)人(译)	MINDELIS , GESEL GOUREVITCH , ALLA		
[标]发明人	GOUREVITCH ALLA		
发明人	GOUREVITCH, ALLA		
IPC分类号	A61B8/08 A61B8/00 A61B5/00 A61B8/13		
CPC分类号	A61B5/417 A61B8/0875 A61B8/13 A61B8/4477 A61B8/4488 A61B8/4494 A61B8/483 A61B8/485 A61B8/5223		
优先权	60/853759 2006-10-24 US		
其他公开文献	EP2077759A4 EP2077759B1		
外部链接	<a href="#">Espacenet</a>		

#### 摘要(译)

使用飞行时间低频声波的测量来提供超声波断层摄影方法和系统。使用从多个已知发射器位置到多个已知接收器位置的第一信号到达时间的差异，其中发射器和接收器与观察对象的表面成一角度。重建声传播速度的3D映射，揭示解剖细节和生理特性。