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NOTICE

The above identified patent application is available for licensing. Requests for information should be addressed to:

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Attorney Docket No. 80157 1 2 ACTIVE ACOUSTIC ARRAY FOR ULTRASONIC BIOMEDICAL APPLICATIONS 3 4 STATEMENT OF GOVERNMENT INTEREST 5 The invention described herein may be manufactured and used 6 by or for the Government of the United States of America for 7 governmental purposes without the payment of any royalties 8 thereon or therefor. 9 10 CROSS-REFERENCE TO RELATED PATENT APPLICATIONS 11 Not applicable. 12 13 BACKGROUND OF THE INVENTION 14 (1) Field of the Invention 15 16 The present invention relates to a device having an acoustic array, which device has utility in ultrasonic 17 18 biomedical applications, particularly in the detection of breast 19 cancer. (2) Description of the Prior Art 20 Current breast cancer screening techniques which rely on X-21 22 rays are painful to undergo and often ineffective for detecting early stages of cancer. Conventional ultrasound systems, i.e., 23 hand-held linear b-scan arrays, are limited by the maximum 24

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allowable levels of exposure to the ultrasound set forth by the
 Food and Drug Administration (FDA).

Ultrasound technology has been used in the medical field 3 4 for many applications ranging from monitoring the heart condition of individuals to monitoring fetal development. 5 There are a number of patents which illustrate various features of 6 ultrasound equipment used in medical applications. For example, 7 U.S. Patent No. 5,042,492 to Dubut illustrates a probe used in 8 ultrasound apparatus. The probe is formed with a concave attack 9 face using a continuous acoustic transition blade. The blade is 10 metallized and is in common contact with all the front 11 metallizations of a series of piezoelectric elements of the 12 probe. The rear metallizations of the elements terminate 13 electrically and independently backwards of the probe. The 14 probe has utility in ultrasound experiments where good focusing 15 is desired. 16

U.S. Patent No. 5,122,993 to Hikita et al. relates to a 17 18 piezoelectric transducer which converts electric signals into 19 sound waves or other mechanical vibrations or converts 20 mechanical vibrations into electric signals and which has 21 utility in the transmission/reception of sound waves into/from 22 the human body. The piezoelectric transducer has plural piezoelectric transducer elements which can generate mechanical 23 24 vibrations converging substantially on one point. The

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transducer is formed to control the convergent point by
 insulating piezoelectric transducer elements mechanically,
 arranging them concentrically and driving them independently and
 separately from each other.

U.S. Patent No. 5,680,863 to Hossack et al. relates to a 5 phased array transducer for an ultrasonic imaging system. The 6 transducer includes a flexible support element which supports an 7 array of piezoelectric transducer elements. Shape transducers 8 such as strain gauges or capacitive transducers are coupled to 9 the support element to generate a signal indicative of the 10 instantaneously prevailing curvature of the array. A user-11 controlled actuator is coupled to the support element to flex 12 the support element between at least first and second 13 configurations wherein the support element has separate 14 curvatures along the axis of the transducer in each of the first 15 and second configurations. 16

U.S. Patent No. 5,713,356 to Kruger relates to a photoacoustic breast scanner which uses incident electromagnetic waves to produce resultant acoustic waves. Multiple acoustic transducers are acoustically coupled to the surface of the tissue for measuring acoustic waves produced in the tissue when the tissue is exposed to a pulse of electromagnetic radiation. The multiple transducer signals are then combined to produce an

image of the absorptivity of the tissue, which image may be used
 for medical diagnostic purposes.

3 U.S. Patent No. 5,305,752 to Spivey et al. relates to an 4 acoustic imaging device. The devices consist of a ring of 5 acoustic transducers which encircle a medium to be imaged. The 6 medium is sequentially insonified by each transducer with 7 subsequent reception of the scattered waves by the remaining 8 transducers. The device may be used for imaging human tissue in 9 vivo and in vitro.

10 The current invention describes a stationary array 11 ameanable to repetitive averaging of the ultrasonic field at 12 lower intensity for longer periods.

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SUMMARY OF THE INVENTION

Accordingly, it is an object of the present invention to provide a device which may be used to screen human tissue for cancerous tissue.

18 It is a further object of the present invention to provide 19 a device as above which has particular utility in the detection 20 of breast cancer.

21 The foregoing objects are attained by the device of the 22 present invention.

In accordance with the present invention, a device fordetecting cancer in human tissue is provided. The device

broadly comprises an acoustic array shaped to conform to and
surround a portion of the human anatomy and means to
acoustically couple the acoustic array to the portion of the
human anatomy. The acoustic array is doubly curved having a
first curvature along a first axis and a second curvature along
a second axis perpendicular to said first axis.

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BRIEF DESCRIPTION OF THE DRAWINGS

Other details of the doubly curved inward radiating 9 acoustic array device of the present invention, as well as other 10 objects and advantages attendant thereto, are set forth in the 11 following detailed description and the accompanying drawings 12 wherein like reference numerals depict like elements, wherein: 13 14 FIG. 1 is a schematic representation of a device for 15 detecting cancer in human tissue in accordance with the present 16 invention;

FIG. 2 is a schematic representation of the segments forming the acoustic array used in the device of FIG. 1;

19 FIG. 3A is a sectional view of the acoustic array used in 20 the device of FIG. 1 surrounding a human breast;

21 FIG. 3B is an enlarged view of a portion of the acoustic 22 array;

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FIG. 3C is a rear view of the acoustic array of FIG. 3A; FIG. 4A is a top view of a flat sheet of piezoelectric material from which the acoustic array segments are formed; and FIG. 4B is a sectional view of a flat sheet of piezoelectric material from which the acoustic array segments are formed.

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DESCRIPTION OF THE PREFERRED EMBODIMENT(S) 8 Referring now to FIGS. 1, 2, 3A - 3C, and 4A - 4B, the 9 present invention relates to a device 10 having a doubly curved 10 acoustic array 12 which surrounds a portion 14 of the human 11 anatomy, such as a female breast. The acoustic array 12 is said 12 to be doubly curved because it has a first curvature along a 13 first axis and a second curvature along a second axis 14 substantially perpendicular to the first axis. The device 10 is 15 intended to screen for abnormal tissue using ultrasonic waves. 16 As can be seen from FIG. 2, the acoustic array 12 is 17 preferably formed in segments 16. Each segment 16 is formed by 18 a flat sheet 18 of piezoelectric material as discussed below. 19 As shown in FIG. 4, the piezoelectric material has a plurality 20

of rods 20 formed from the piezoelectric material, such as a 1 -22 3 piezocomposite material, extending between a first surface 22 23 of the sheet 18 and a second surface 24 of the sheet 18. Each 24 of the rods 20 is surrounded by a polymeric material 26 and thus

electrically and mechanically (or acoustically) insulated from
 adjacent rods 20. The rods 20 can have various cross sections,
 i.e., square, elliptical, etc.

A plurality of acoustic elements 28 are formed on the first 4 surface 22 of the sheet by metallizing the surface 22 to form a 5 specific pattern of acoustic elements 28 wherein the acoustic 6 elements 28 may be randomly or regularly distributed over the 7 array aperture. Any suitable metallizing technique known in the 8 art, such as electroplating, can be used to form the specific 9 pattern of acoustic elements 28. Preferably, each of the 10 acoustic elements 28 is joined to, and thus electrically 11 connected to, a first end of a plurality of rods 20. Each of 12 the acoustic elements 28 functions as an acoustic transmitter 13 and receiver. 14

A continuous electrode 30 is formed on the surface 24 of the sheet 18 by metallizing the surface 24 using any suitable technique known in the art, such as electroplating. Preferably, the continuous electrode 30 is formed from a copper based material. The continuous electrode 30 is formed so that it is in both physical and electrical contact with a second end of each of the rods 20 and acts as a common ground.

In a preferred embodiment of the present invention, the surface 22 comprises an outer surface of the sheet 18 and the surface 24 comprises an inner surface of the sheet 18.

As previously mentioned, the acoustic array 12 preferably 1 has a first curvature along a first axis and a second curvature 2 along a second axis. This is achieved by taking the flat sheet 3 18 forming each segment 16 and developing a desired curvature to 4 the sheet. This may be done using any suitable technique known 5 in the art. Preferably, the profile of each segment 16 is 6 obtained from the mercator projection of the curved surfaced 7 onto a flat plane. A thermoplastic, back fill material 26 8 surrounding the rods 20 is used to allow the segments 16 to be 9 curved at an elevated temperature and then cooled to provide a 10 particular parabolic geometry, such as that shown in FIGS. 1 and 11 In the present invention, a parabolic geometry is used so 3. 12 that the acoustic array 12 formed by the segments 16 has a shape 13 which conforms to and surrounds a portion 14 of the human 14 anatomy, such as a female breast. 15

Electrical wires or cables 34 extend through the backing 16 material 32. Each wire or cable 34 is connected to one of the 17 acoustic elements 28 at one end and to a voltage source 36 at 18 the opposite end. The voltage source 36 is used to excite one 19 of the acoustic elements 28 at a time and thus cause an 20 ultrasonic sound wave to be generated into the portion 14 of the 21 human anatomy. As previously mentioned, each of the acoustic 22 elements 28 acts as both a transmitter and a receiver. Thus, 23 24 when one of the acoustic elements 28 is excited, the other

acoustic elements 28 act as receivers for detecting the
 reflected sound wave.

3 The acoustic array 12 is acoustically coupled to the 4 portion 14 by a coupling material 38. The coupling material 38 5 must be a suitably contained lossless fluid. This fluid should 6 be a biocompatible, non-toxic material such as silicone or 7 water.

The device 10 further has a housing 40. The acoustic array 8 12 is positioned within the housing 40. The backing material 32 9 serves to decouple the acoustic array 12 from the housing 40 and 10 provides acoustic impedance for a wide spatial bandwidth. The 11 backing material 32 may comprise any suitable acoustically 12 absorptive material known in the art. The housing also contains 13 signal conditioning electronics 42 and the voltage source 36. 14 The signal conditioning electronics 42 receive electric signals 15 16 received by the acoustic elements 28 and are connected to the acoustic elements 28 via the wires or cables 34. The signal 17 conditioning electronics 42 may be used to filter the signals 18 received from the acoustic elements 28 to eliminate unwanted 19 noise and to perform such other signal conditioning techniques 20 as may be needed. 21

The device 10 further includes a central processing unit 44 and a display 46. The central processing unit 44 may comprise any suitable computer known in the art and may be programmed in

any desired language. The central processing unit 44 is in 1 communication with the signal conditioning electronics 42 and 2 receives signals therefrom. The central processing unit 44 then 3 converts the signals into acoustic images of the human tissue 4 under examination of selected volume in cross section. Multiple 5 pitch-catch views are combined to form each desired cross 6 sectional image. This effectively halves the acoustic path 7 length required in typical pulse-echo scenarios. In addition, 8 the stationarity of the acoustic array 12 allows for spatial 9 over sampling and time averaging schemes to be employed which 10 further relax the transmit ultrasonic power levels to within 11 current dosage maximums. The central processing unit 44 may use 12 any suitable technique known in the art to generate 3-13 dimensional images. The display 46 is used to display the 14 images generated by the central processing unit 44. 15

The central processing unit 44 is also preferably used to control the order in which the acoustic elements 28 are excited and to apply a broadband signal to the acoustic elements 28.

In operation, a first one of the acoustic elements 28 is excited by sending a first signal to it from the voltage source 36, such as an alternating voltage source, and placing an electric field (voltage) across the piezoelectric material forming an element within the sheet 18. The piezoelectric material in response to the electric field changes shape and

gets thicker or thinner based on the instantaneous alternating 1 voltage. This creates an initial acoustic wave having a 2 broadband frequency content which then enters the human tissue 3 under examination. When the initial acoustic wave encounters a 4 change in specific acoustic impedance, such as a tumor, part of 5 the acoustic wave is reflected and the remainder is transmitted. 6 The reflected and transmitted waves are then detected or 7 received by the other acoustic elements 28. The receiver 8 elements 28 then convey the received signal to the signal 9 conditioning electronics 42. This process is repeated over and 10 over so that each of the acoustic elements 28 in the array 12 is 11 12 used as a transmitter. In this way, a user of the device 10 can obtain an accurate picture of any tumor(s) in the human tissue 13 under examination as well as a determination of the size, shape, 14 and location of such tumor(s). 15

16 The device 10 and the acoustic array 12 are ideal for 17 making tomographic scans since the acoustic elements 28 are 18 spatially fixed with respect to each other. The inherent 19 measurement stability and repeatability provided by the acoustic 20 array 12 allows physicians or medical technicians to establish a 21 pre-cancer baseline image for a given patient for future 22 reference.

Another advantage of the present invention is that theacoustic array 12 can be sized for variations in breast size.

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While the present invention has been described in the
 context of detecting cancer in a human breast, it should be
 recognized that the device can be adapted to detect cancer in
 other portions of the human anatomy.

It is apparent that there has been provided herein a doubly 5 curved inward radiating acoustic array for ultrasonic medical 6 applications which fully satisfies the objects, means, and 7 advantages set forth hereinbefore. While the present invention 8 9 has been described in the context of specific embodiments thereof, other alternatives, modifications, and variations will 10 11 become apparent to those skilled in the art having read the 12 foregoing description. Accordingly, it is intended to embrace those alternatives, modifications, and variations. 13

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3 ACTIVE ACOUSTIC ARRAY FOR ULTRASONIC BIOMEDICAL APPLICATIONS 4

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ABSTRACT OF THE DISCLOSURE

6 The present invention relates to a device for detecting 7 cancer in human tissue. The device comprises an acoustic array 8 shaped to conform to and surround a portion of the human anatomy 9 and a material for acoustically coupling the acoustic array and the human anatomy portion. The acoustic array is formed from a 10 11 plurality of doubly curved segments. Each segment is formed by a piezoelectric ceramic polymer composite material with an 12 acoustic element pattern formed on one surface via the selective 13 deposition of a conductive material. The acoustic element 14 15 pattern contains a plurality of acoustic elements which act as both transmitters and receivers. The acoustic array further 16 includes a backing material which provides a desired mechanical 17 damping to each segment and defines the shape of the array. 18 The 19 device further includes a housing which includes signal conditioning electronics to condition signals received from the 20 acoustic array. A central processing unit is provided to create 21 22 cross sectional images of the human tissue under examination. A display unit is provided to display the cross sectional images. 23



FIG. 1



FIG. 3B

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FIG. 3C



FIG. 4B



FIG. 4A