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(54) Title: MULTIPLE APERTURE ULTRASOUND IMAGING SYSTEMS AND METHODS

(57) Abstract: Systems and methods of ultrasound imaging are provided. In some embodiments, unfocused and diverging ultrasound signals can be transmitted into a target medium from an apparent point source located aft of a concave probe surface. The echoes can be received, and a location of a reflector within the target medium can be determined. The location can be determined by obtaining element position data describing a position of the spherical center point of the apparent point source r and a position of the receive element, calculating a total path distance as a sum of a first distance between the spherical center point and the reflector and a second distance between the reflector and the receive element, and determining a locus of possible points at which the reflector may lie. A data set can then be produced for the entire target medium.



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MULTIPLE APERTURE ULTRASOUND IMAGING SYSTEMS AND METHODS**PRIORITY CLAIM**

[0001] This patent application claims priority to U.S. provisional patent application no. 63/306,936, titled "MULTIPLE APERTURE ULTRASOUND IMAGING SYSTEMS AND METHODS" and filed on February 4, 2022, which is herein incorporated by reference in its entirety. This application is related to the following US Patents: US 9,146,313, US 9,883,848, US 10,226,234, US 10,064,605, and US 9,668,714.

INCORPORATION BY REFERENCE

10 [0002] Unless otherwise specified herein, all patents, publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

FIELD

15 [0003] This invention generally relates to ultrasound imaging and more particularly to systems and methods for using symmetric and asymmetric synthetic aperture waveforms for use with Ping Based Multiple Aperture Imaging (PMA) or computed echo tomography (CET).

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BACKGROUND

[0004] In conventional ultrasonic imaging, a focused beam of ultrasound energy is transmitted into body tissues to be examined and the returned echoes are detected and plotted to form an image. While ultrasound has been used extensively for diagnostic purposes, conventional ultrasound has been greatly limited by depth of scanning, speckle noise, poor lateral resolution, obscured tissues, and other such problems.

[0005] To insonify body tissues, an ultrasound beam is typically formed and focused either by a phased array or a shaped transducer. Phased array ultrasound is a commonly used method of steering and focusing a narrow ultrasound beam for forming images in medical ultrasonography. A phased array probe has many small ultrasonic transducer elements, each of which can be pulsed individually. By varying the timing of ultrasound pulses (e.g., by pulsing elements one by one in sequence along a row), a pattern of constructive interference is set up that results in a beam directed at a chosen angle. This is known as beam steering.

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Such a steered ultrasound beam may then be swept through the tissue or object being examined. Data from multiple beams are then combined to make a visual image showing a slice through the object.

[0006] Traditionally, the same transducer or array used for transmitting an ultrasound beam is used to detect the returning echoes. This design configuration lies at the heart of one of the most significant limitations in the use of ultrasonic imaging for medical purposes: poor lateral resolution. Theoretically, the lateral resolution could be improved by increasing the width of the aperture of an ultrasonic probe, but practical problems associated with increased aperture sizes have kept apertures small. Unquestionably, ultrasonic imaging has been very useful even with this limitation, but it could be more effective with better resolution.

[0007] Synthetic aperture imaging has long been utilized in ultrasound imaging. The benefits of utilizing segments of an array to image from multiple separate spatial locations and directions include enabling a “wider” areal and angular field of view that can facilitate the ultrasound illumination of and reception from otherwise difficult to access regions as well as improved image resolution quality. The ultrasound reflection data from the different segments of the array can then be stitched together into a single ultrasound image by beamforming it separately or together, or combinations thereof.

[0008] Similarly, transmissions into the imaged medium are received at subsequently different times. The longer the wait before data collection, the deeper the field of view. Therefore, one or more transmissions from the array could lead to several data collections that could be combined in memory and used to display a synthetic image or view by stitching the beamformed images from temporally separated data segments together. Usually the transducer (sometimes referred to as probe) contains an array of transmitter/receiver/transceiver elements arranged in and directed within a plane. This is usually referred to as a 1D array and is used to view a plane in the imaged medium. The element array may be straight and “linear,” or arranged in a symmetric convex shape, referred to in the industry as “curvilinear” or in a convex curve. The transducer may also contain a square or rectangular array where the piezoelectric elements are arranged immediately adjacent to each other in both the height and width dimensions, also referred to as a matrix with the elements directed normal to the plane or surface containing the elements. For instance, a matrixed array could contain 256 elements that is 16 elements high by 16 elements wide. The transducer element matrix is often “cut” out of a sub-straight of piezoelectric materials or formed in a MEMS

manufacturing process to construct a formation of Piezoelectric Micro-Machined Ultrasound Transducers (pMUT) or Capacitive Micro-Machined Ultrasound Transducers (cMUT).

[0009] Significant improvements have been made in the field of ultrasound imaging with the creation of multiple aperture imaging, examples of which are shown and described in Applicant's prior patents and applications. Multiple aperture imaging methods and systems allow for ultrasound signals to be both transmitted and received via separate apertures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0010] The novel features of the invention are set forth with particularity in the claims that follow. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0011] FIG. 1 is a schematic illustration of a multiple aperture imaging probe with three transducer arrays and several points to be imaged.

[0012] FIG. 2 illustrates divergent beam transmission with a virtual source located behind a transducer array.

[0013] FIG. 3 shows converging or focused ultrasound waves generated by a conventional linear or matrixed array by the application of specifically designed waveforms to the transmit elements of the transducer array.

[0014] FIG. 4 is a schematic illustration of a data "cube" according to one embodiment of the present disclosure.

[0015] FIG. 5 shows a standard unfocused pulse being initiated from an element on a transducer array.

[0016] FIG. 6 shows a virtual point source behind the array could alternately or additionally be used, with elements fired using waveforms/pulses based on time delays required to create the desired semi-circular divergent or convergent wave pattern.

[0017] FIG. 7 illustrates how a uniform unfocused transmit waveform can be generated over specific targeted regions of the imaged medium even though there is a physical separation between arrays and a differing "view" angle caused by the concavity of the probe.

[0018] FIG. 8 illustrates a system that can include three separate arrays having transducer elements used to generate convergent waveforms to target a specific point.

[0019] FIG. 9 illustrates convergent wave transmission using multiple elements spread across two segments of a multi segment concave probe.

[0020] FIG. 10 illustrates an embodiment in which a smoothly curved concave transducer array including transmit elements configured to produce multiple transmissions that can cover multiple subregions within the field of interest with adequately uniform divergent waves using a proper choice of transmit array elements.

5 [0021] FIG. 11 shows convergent wave transmission using multiple elements within a smooth concave transducer array.

[0022] FIG. 12 shows an embodiment of divergent wave transmission using multiple transducers from an array within a 3D curved probe with a 2D transducer array module.

10 [0023] FIG. 13 shows a similar embodiment to that of FIG. 12, except the transducer array comprises a sparse transducer array.

[0024] FIGS. 14 and 15 are similar to the embodiments of FIGS. 12 and 13, respectively, except they show convergent or focused wave transmission using multiple elements within a regular 3D curve probe, with a 2D transducer array (or 2D sparse transducer array).

15 **SUMMARY**

[0025] A method of imaging an object with ultrasound energy, the method comprising the steps of: transmitting an un-focused and diverging ultrasound signal into a target medium from an apparent point source located aft of a concave probe surface; receiving echoes from a reflector in the target medium with an omnidirectional receive element that is different than
20 the apparent point source; determining a position of the reflector within the target medium by obtaining element position data describing a position of the spherical center point of the apparent point source r and a position of the receive element, calculating a total path distance as a sum of a first distance between the spherical center point and the reflector and a second distance between the reflector and the receive element, and determining a locus of possible
25 points at which the reflector may lie; and producing a data set for the entire target medium.

[0026] In some aspects, the receive elements of the probe are comprised of a shell of piezoelectric material shaped as a concave curve wherein the position of the receive element is a position on the curved shell.

30 [0027] In one aspect, the shape of the concave probe may be either symmetric or asymmetric.

[0028] In one aspect, the probe is made of piezoelectric, cMTU or pMUT materials in a concave shape.

[0029] In one aspect, the elements or arrays of the probe are not physically attached.

- [0030] In one aspect, the elements of the probe are arranged in a sparse and non-linear pattern.
- [0031] In one aspect, the array or arrays of elements are shaped in 3 dimensions around two or more axes.
- 5 [0032] In one aspect, the array of elements is contained in a flexible material that may move or articulate around two or more axes.
- [0033] In one aspect, the method further includes repeating the receiving, determining and producing steps with a plurality of receive elements.
- [0034] In one aspect, the method further includes where a plurality of receive elements
10 may be used to combine data for a common receive aperture.
- [0035] In one aspect, the method further includes repeating the receiving, determining and producing with the elements of a plurality of receive apertures.
- [0036] In one aspect, less than 10 transducers are used together to transmit the un-focused and diverging ultrasound signal.
- 15 [0037] A method of imaging an object with ultrasound energy, the method comprising the steps of: transmitting a focused and converging ultrasound signal into a target medium to an apparent point source located forward of a concave probe surface; receiving echoes from a reflector in the target medium with an omnidirectional receive element that is different than the apparent point source; determining a position of the reflector within the target medium by
20 obtaining element position data describing a position of the spherical center point of the apparent point source and a position of the receive element, calculating a total path distance as a sum of a first distance between the spherical center point and the reflector and a second distance between the reflector and the receive element, and determining a locus of possible points at which the reflector may lie; and producing a data set for the entire medium.
- 25 [0038] In one aspect, the receive elements of the probe are comprised of a shell of piezoelectric material shaped as a concave curve wherein the position of the receive element is a position on the curved shell.
- [0039] In one aspect, the shape of the concave probe may be either symmetric or asymmetric.
- 30 [0040] In one aspect, the probe is made of piezoelectric, cMTU or pMUT materials in a concave shape.
- [0041] In one aspect, the elements or arrays of the probe are not physically attached.
- [0042] In one aspect, the elements of the probe are arranged in a sparse and non-linear pattern.

[0043] In one aspect, the array or arrays of elements are shaped in 3 dimensions around two or more axes.

[0044] In one aspect, the array of elements is contained in a flexible material that may move or articulate around two or more axes.

5 [0045] In one aspect, the method further includes repeating the receiving, determining and producing steps with a plurality of receive elements.

[0046] In one aspect, the method further includes where a plurality of receive elements may be used to combine data for a common receive aperture.

10 [0047] In one aspect, the method further includes repeating the receiving, determining and producing with the elements of a plurality of receive apertures.

DETAILED DESCRIPTION

[0048] The various embodiments will be described in detail with reference to the accompanying drawings. References made to particular examples and implementations are 15 for illustrative purposes and are not intended to limit the scope of the invention or the claims.

[0049] Although the various embodiments are described herein with reference to ultrasound imaging of various anatomic structures or implanted medical devices, it will be understood that many of the methods and devices shown and described herein may also be used in other applications, such as imaging and evaluating non-anatomic structures and 20 objects.

[0050] The present disclosure describes the use of synthetic ultrasound transmit waveforms to the transducer elements that collectively generate favorable ultrasound profiles in the imaged medium in conjunction with ping-based Multiple Aperture Ultrasound (MAUI) transducers used for Computed Echo Tomography (CET). MAUI transmits focused or 25 unfocused pings into the medium and enables reception on multiple elements that may or may not be part of a contiguous array. CET, unlike conventional phased array ultrasound systems, can use transmissions from only a small number of transducers. It can use as many transducers as desired for focused or convergent transmissions; however, unfocused or divergent transmissions do not require many transducers to form the unfocused wave. Often 30 less than 10 transducers are used together to form a focused or unfocused transmission. This weaker signal, when combined with the other methods used in CET enable imaging tissues types that have varying speeds of sound and attenuation.

[0051] The methods of focused and unfocused transmission used in CET enable many type of probe configurations. MAUI transducers are often concave, and can be asymmetric

or adjustable in one or more directions. Probes can be adjustable or even made of a pliable or mesh material. Linear or matrixed arrays can be used with CET; however, concave configurations of MAUI probes often provide better data and associated imaging do to proximity with the target and access to tissues along differing viewpoints along the probe face relative to the target medium. The methods of CET or as it's also known Ping Based Multiple Aperture Imaging (PMA) is explained in US Pat. No. 9,220,478, which also demonstrates the use of several types of concave, 3D and adjustable ultrasound element array transducers and probes.

[0052] This disclosure, then, provides and describes the use of synthetic aperture transmission and reception in PMA using concave, 3D and adjustable or mesh arrays. Significant advantages in imaging capability and quality result from using either divergent, convergent directed ultrasound wavefronts or a combination of these to generate an ultrasound image.

[0053] This disclosure provides implementation and operation in an ultrasound imaging system that is provided with the necessary hardware features to transmit designed ultrasonic wave pulses/pings or sequences of pulses/ pings by synthesizing and applying appropriate electrical signals to appropriate elements in the probe/array. Further this disclosure demonstrates the utilization of received ultrasound reflections from the imaged medium and how to buffer and process the transduced ultrasound reflection data using calculations outlined in the prior work. CET data sets can be used to form images for a user or analyzed without image formation with artificial intelligence as described in PCT/US2020/056652. This includes variations/enhancements of this method or using other beamforming methods. The calculations to process the received reflection data to render the ultrasound image may be performed using computer software running locally on the system or operating on a remote system or using firmware or electronic hardware.

[0054] The invention will be used improve the image quality that can be obtained with synthetic aperture ping-based imaging using 2D or 3D convex, concave, or linear segmented arrays or flexible array probes though not limited to these probe designs. The invention enables the harnessing of multiple transmit elements to generate stronger ultrasound transmits/pings and the tailoring and direction of the transmit energy of these pings to improve image quality. Improvements in image resolution, contrast signal to noise ratio, contrast to noise ratio, image field size, imaged depth and image speed are feasible using multi-element transmit through judicious selection of transmit combinations.

[0055] Examples include directing ultrasound energy using convergent wavefront transmits to improve image quality at larger depths, directing divergent wavefronts to regions of interest to image the region from multiple angles, using wide area divergent pings to speed the imaging process and locating and steering the transmits to avoid ultrasound

5 disrupting/attenuating features in the image field to improve the image in their lee. Imaging different portions of the body or viewing these from desired viewing angles may require the use of different transmit pings or combinations of pings used to generate images.

[0056] In operation, a MAUI or PMA ultrasound imaging system will be programmed to transmit a series of pings that may vary in the location of source, divergence, extent, and
10 direction by applying excitation voltage signals to the selected transmit element with appropriate delays to generate the desired ultrasound wavefronts. Each ping and the associated received echoes on all selected channels create a data set or string for that channel. Channel data can be combined to create a larger data set of the imaged medium. This larger data set then takes advantage of channels having differing views of the medium. Methods for
15 solving speed of sound variations so that these data sets can be combined or discussed in prior works. The received reflection data from a series of pings will be used to generate a data set frame by processing it with the ping-appropriate beamforming calculations. All or a portion of the data set can be selected by the end user for presentation as an image. The data from the individual transmits/pings may be weighted when generating a final image frame to
20 equalize (or enhance) differences in transmit/ping energy. Images generated from different combinations of pings may also generated in succession for display or averaging based on image requirements with or without weighting factors applied to the images.

[0057] This disclosure provides the use of multiple elements that may or may not straddle multiple arrays or segments of a multi aperture probe or a variable geometry probe to
25 generate transmissions of strong convergent or divergent directed ultrasound waves over all or subregions of the imaged medium/field that are sufficiently uniform over that subregion to enable the generation of good ultrasound images.

[0058] Additionally, this disclosure provides for the combination and subsequent stitching of data acquired through multiple such transmissions into a single data set or single
30 image frame.

[0059] In some embodiments, the judicious choice and design of such transmissions is provided so as to adequately cover the region of interest whilst avoiding intervening obstructions that may reduce image quality.

[0060] Additionally, weighting factors may be used to (de)emphasize stronger ping/transmit data in image beamforming.

[0061] The application of these techniques enables the acquisition of images with better quality (resolution contrast, signal to noise ratio, contrast to noise ratio) and at larger depths using multiple aperture ping technology in the medium than feasible with real point source (single element) ultrasound transmissions. These techniques can also be used to similarly enhance the image quality in otherwise obscured (by strong absorbers/reflectors) portions of the image through a judicious design of ping/transmit patterns with or without the use of appropriate weighting factors with these transmits.

[0062] Differing combinations of convergent and divergent transmissions are likely more effective with specific types of tissue and anatomical features and optimized transmission sequences can be designed and used to image different target organs and views to generate the best image of the region of interest from the selected viewing/imaging angle. For instance, imaging through the skull may require more divergent imaging and imaging into the lung may require more convergent imaging.

Ping-Based Multiple Aperture Imaging

[0063] Some embodiments of the systems and methods described herein are based on a unique imaging modality referred to as Ping-Based Multiple Aperture imaging (“PMA” imaging). An introductory description of PMA is provided below. Additional details, examples, embodiments, and applications of methods and structures useful in performing ping-based multiple aperture imaging are described in Applicant’s prior patent applications referenced above.

[0064] Briefly, PMA imaging involves transmitting a series of un-focused two-dimensional or three-dimensional “pings” into a medium from a “transmit aperture” (which may be made up of one transducing structure or a group of transducers operating in concert) then receiving and storing signals produced by echoes and/or through-transmissions of each ping. Signals are received by many “receive elements” (each made up of one or more transducing structures) which may be grouped into “apertures.” The receiving transducers produce time-varying analog signals with amplitudes proportional to an intensity of energy impinging on the transducer. Such analog signals may be digitally sampled at a sampling rate, and digital samples may then be stored. The value of each digital sample may be proportional to the intensity of received ultrasound. Each digital sample may represent an “echo” of some reflective or transmissive structure in the medium. Digital samples received by a single receive transducer element may be organized in “strings” of data samples, which

may be sub-divided into “sub-strings” as described in some embodiments herein. An image may be formed by mapping the samples to locations within the imaged medium and assigning brightness (and/or color) values to each image point (e.g., a pixel or voxel) in proportion to the value of contributing data samples.

5 [0065] While terms such as “bright” and “dark” are used herein to refer to image points and data samples, the skilled artisan will recognize that such terms are not absolute, as the brightness or contrast of a displayed image may be adjusted. Instead, the terms are used in a relative sense to distinguish those data samples and image points representative of highly reflective or “echogenic” structures which are typically but not necessarily referred to as
10 being more “bright” than minimally-reflective structures which are typically but not necessarily referred to as “dark.” Of course, some imaging systems may be configured with an opposite convention in which samples with greater energy intensity are displayed as dark points while samples with less energy intensity are displayed as brighter points. In either convention, in the context of the systems and methods described herein, the term “bright” is
15 intended to refer to points representing points of greater received energy intensity (regardless of whether the energy is received after reflection from or transmission through an imaged structure), while “darker” points are those with relatively lower received energy intensity.

Beamforming Images in from Ping Based Multiple Aperture Imaging Systems

[0066] A complete sub-image of the medium may be obtained from signals produced by
20 each receive element. Sub-images obtained from elements of a common aperture may be combined with one another to produce a “first-level” image. Sub-images and/or first-level images from multiple ping-transmissions (transmitted from the same or different transmit apertures) may be combined to produce “second-level” images. Second-level images from multiple receive apertures may be combined to produce “third-level” images. Many
25 permutations of image-layer combination sequences are possible and therefore sub, first, second, and third level images need not necessarily be formed in the sequence implied by the names.

[0067] If the transmit elements and/or the receive elements are spaced from one another
in two or three dimensions, the “images” (including sub-images) may be three-dimensional
30 volumes made up of three-dimensional voxels. Any two-dimensional section of such a volume may be selected and displayed as a matrix of two-dimensional pixels. The term “image point” will be used to refer to discrete elements (e.g., pixels or voxels) of a two-dimensional or three-dimensional image.

[0068] As signals are received by a transducer element, the signals may be converted into a sequence of digital data, which may be stored in a volatile and/or non-volatile memory device. Each entry in such a sequence of data entries may be referred to as a “data sample”. The term “data sample” may also refer to values obtained by aggregating multiple data entries (e.g., averaging, taking a minimum or a maximum, etc.) or values obtained by interpolating between two or more data entries.

[0069] In order to form a sub-image from a collection data samples, each sample (individually, aggregated, or interpolated) must be mapped to its possible location within the image through a process referred to herein as “beamforming.” Each data sample represents a range of potential locations (a locus) within the image determined by the location of the transmit element and receive element, the difference in time between ping transmission and signal reception, and the speed-of-sound through the imaged medium.

[0070] In a multiple aperture imaging system in which the transmitter is located at a different point than the receiver, the locus of possible locations for each sample takes the shape of a two-dimensional ellipse or a three-dimensional ellipsoid with the transmit element and the receive element located at the foci of the ellipse or ellipsoid reference US Patent 9,146,313 titled “Point Source Transmission and Speed-of-Sound Correction Using Multiple-Aperture Ultrasound Imaging. The term “locus” (and its plural “loci”) will be used to refer to either an ellipse or an ellipsoid. The imaging system converges on the correct location of each image point by adding together multiple data samples with loci intersecting the same image point. Each data sample contributing to a single image point may be referred to as a “contributor” to that image point. The point at which the ellipses or ellipsoids intersect is reinforced (i.e., has a greater total brightness than its individual contributors) and represents the correct location of the point to be displayed or recorded.

[0071] This process is susceptible to a unique form of error referred to herein as neighbor noise. If a particular data sample contains a high degree of noise causing its locus to be substantially brighter than other contributors to an image point, a larger region of the neighbor noise sample may be displayed, creating a noise artifact in the shape of the locus. Such individual neighbor noise samples may create significant distortions of an image by highlighting regions that do not correspond to physical structure in the imaged medium. Distortions caused by neighbor noise may be identified through any of a number of techniques, some of which are described below. Once identified, neighbor noise can be minimized when forming an image by one or more of the techniques described herein.

Identifying Neighbor Noise Data Samples by Averaging

[0072] Highly echogenic reflectors that are substantially brighter than other contributors to the same image points are a problem that can cause neighbor noise. Here a “too bright” contributor that is overwhelming other contributors may create bright artifacts or other false information. This is particularly problematic for image points that would otherwise be relatively “dark” but-for the strong echogenic reflector located in the data samples. In an opposite but related fashion, less-echogenic reflectors can be erroneously displayed as much darker than expected because other contributors to the same image point will tend to cancel the effects of a “too dark” contributor. In both cases therefore, it may be beneficial to identify data samples (or ellipses) representing neighbor noise.

[0073] In general, for a single image point, data samples resulting from different combinations of transmitted ping and receive element may reveal brighter or darker echoes of a reflector due to differences in path length, look angle, obstacles, materials, time of ping transmission, or other factors. Nonetheless, under normal conditions, the degree of such variations can be expected to remain within predictable ranges which may be determined based on empirical testing and/or mathematical modeling/simulation. Echo values that fall significantly outside of such expected ranges are likely to be noise or other forms of error. Therefore, it may be desirable to systematically define “abnormally bright” values, identify data samples contributing “abnormally bright” values to any image point, and to minimize the deleterious impact of such abnormally bright samples.

[0074] In some embodiments, instead of evaluating every image point within the medium for high noise, the set of image points to be evaluated may be reduced to a candidate set of image points. For example, in some embodiments image points with brightness values less than a predetermined value (e.g., ≤ 0.9 on a scale of 0.0 to 1.0) may be selected for analysis to detect neighbor noise contributors. In other embodiments, image points with brightness values greater than a predetermined lower value (e.g., 0.1 on a scale of 0.0 to 1.0) but less than a predetermined upper value (e.g., 0.8) may be selected for analysis to detect neighbor noise contributors.

[0075] In some embodiments, image points to be evaluated for the existence of neighbor noise data samples may be identified based on an analysis of adjacent image points, or image points within a region. For example, if after applying all contributors, a particular image point has a brightness value substantially higher than all adjacent image points or all image points within a region, that image point may be selected for evaluation of contributors as possible neighbor noise contributors. In other embodiments, an image point to be evaluated

for the existence of neighbor noise data samples may be identified by evaluating data samples contributing to a group of image points in a region so as to detect an “edge” between relatively darker and lighter image points in the region. An example of such a process is described in the section below.

5 [0076] Whether evaluating all image points or a sub-set of image points selected by a method such as those described above, various processes may be used for identifying neighbor noise contributors to a particular image point. In one example embodiment, such a process may comprise transmitting a ping from a transmit aperture, receiving reflected and/or transmitted signals from the ping, digitizing and storing sampled digital data representing the received signals, and beamforming the stored data to map data samples to image points.
10 Then for each image point to be evaluated: determining an aggregate value of the set of data samples contributing to the image point, and identifying neighbor noise contributors as those data samples with values varying from the aggregate value by greater than an expected variance.

15 [0077] In various embodiments, the step of evaluating data samples to identify neighbor noise contributors may be performed before and/or after various coherent or incoherent summation steps as described in the various applications referenced above and incorporated herein by reference. For example, in some embodiments, raw data samples may be evaluated before any data summation steps in order to detect edge regions or other distinguishable
20 features with a much greater degree of detail than may be possible after data summation.

[0078] In various embodiments, the “aggregate value” of a set of data samples contributing to a particular image point may be the arithmetic mean (simple average), median (the midpoint of all values of samples in the set), the mode (the most frequent value in the set), the maximum (the largest value of the set), the minimum (the smallest value of the set)
25 or other value describing or obtained from the set of data samples.

[0079] In various embodiments, the variance from an aggregate value defining a neighbor noise data sample may be defined in numerous ways. For example, the variance may be a fixed numerical value, a multiple of the aggregate value, a percent change from the aggregate value, a number of standard deviations above the aggregate value, a percentile of the set of
30 data samples contributing to the image point, or other metrics of variance from the aggregate value.

[0080] In some embodiments, neighbor noise contributors to an image point may be defined as samples with brightness values at least N times greater than the mean, median,

mode, maximum, or other aggregate value of the set of contributors to the image point. In such embodiments, N may be at least about 1.0 up to about 2.0 or more.

[0081] In other embodiments, neighbor noise contributors may be defined as samples with brightness values more than N standard deviations greater than the mean value of contributors to the image point. In other embodiments, neighbor noise contributors may be defined as samples with brightness values greater than the maximum value of the set of contributors, or N times the maximum, or more than M% greater than the maximum. In other embodiments, neighbor noise contributors may be defined as samples with brightness values greater than the N times the mode, where the “mode” is defined as the most frequently occurring value in the set of data samples contributing to the image point. In some embodiments, the mode may be determined based on rounded values of the data samples (e.g., by rounding each value of the set to a predetermined number of digits and then determining the most frequent value).

Convergent and Divergent Beamforming in Ping Based Multiple Aperture Imaging

[0082] In some embodiments, mathematical or other evaluations of the raw data samples collected by multiple transducer elements from a PMA system may be done before image beamforming in order to identify data samples to be adjusted. In some embodiments, such pre-beamforming evaluation may be used for other analyses such as object recognition or others.

[0083] FIG. 1 demonstrates a ping based multiple aperture probe 100 against a skin surface S, with arrays 12, 14, and 16. Subarrays or often individual elements within each array are indicated as points a, b, c, d, e, f, g, h and i. However, sub-arrays can be located across physical gaps between arrays and should not be considered limited to individual elements on an individual array. A ping transmission is represented by the wavefront 13 (dashed wavefront(s)) generated by a transmit aperture at ‘a’ on array 12 and is indicated by wavelets. Point A in the medium or tissue 20 is meant to represent a hard structure (e.g., calcium or hardened plaque from atherosclerosis, or other hard objects such as bone), which would immediately reflect or scatter the transmitted wavefront 13 in multiple directions represented here as reflected wavefront 15 (solid wavefront(s)). The reflected wavefront emanating from point A may provide a relatively bright signal to the receive elements in arrays 12, 14, and 16. The transmitted wavefront 13 may also continue on through the medium or tissue 20 to point B, which is meant to represent an anechoic structure (e.g., a blood vessel or other soft tissue) that would provide a relatively weaker reflected wavefront 17 back to the elements on arrays 12, 14, and 16.

[0084] Echoes from points A and B can be received by receive elements in arrays 12, 14, and 16 and used by the probe 100 to create data sets and frames used to form multiple aperture ultrasound images or for analysis by artificial intelligence engines. An electronic controller(s) or processor(s) associated with any probe on a PMA enabled system can begin the process of analyzing the data in the region of interest. Data being collected after Analog to Digital conversion is stored into data strings for a first receiver element. This receiver element may be part of an array, or it may be an independent element used as an omnidirectional receiver. It need not be used in conjunction with other elements to collect and compound data in real time. A second receiver element can be used to produce a second string of data coming off of the same ping utilized to provide receiver element data to the first receiver element. Similarly, echo data coming off of the same ping transmission can be used by a plurality of receive elements (e.g., third, fourth, fifth, etc. receiver elements).

[0085] A processor in the PMA system, in the probe itself or in communication with the probe (e.g., wirelessly) may then be configured to conduct an average of all data set values for all data strings. In some implementations, the data string may be collected for an entire region of interest (i.e., large sample period). In other implementations, the data may be collected for only a specific pixel (i.e. specific sample period). The processor can then initiate the beamforming process to create pixelated images of the region of interest. In the case of 3D imaging, the same process can be utilized to create voxel images. The process can be repeated for multiple pings and echo data strings.

[0086] Transmission of unfocused pings into the medium where the origin is not at the surface of the array, then becomes more challenging with a Ping Based Multiple Aperture Probe. US 9,883,848 taught several techniques associated with virtual point sources. This work provides more clarification on the use of divergent and convergent beam formation using PMA and CET.

[0087] To begin, FIG. 2 illustrates a transmitted ultrasound wavefront 5 generated on a conventional linear or matrixed array 1 by the application of a designed set of excitation waveforms to the transmit elements 7 of the transducer array 1. In this example, the array can include a chosen or resultant virtual point source 2 that can be located over a range of locations behind the array through proper design of the excitation waveforms. The virtual point source 2 can be configured to transmit a circular (2D) or spherical (3D) virtual transmit wave 5. If the virtual transmit wave is electronically initiated from the virtual point 2, then each of the elements of the transducer array can be controlled to fire based on a delay calculation of when the circular (2D) or spherical (3D) virtual transmit wave passes through

that element. The consolidation of those firings then creates an actual physical wave into the medium with the selected virtual point source.

[0088] FIG. 3 shows converging or focused ultrasound waves generated by a conventional linear or matrixed array 1 by the application of specifically designed waveforms to the transmit elements 7 of the transducer array 1. Here, the virtual point source 2 (or focus) can be electronically synthesized to be any of a number of locations in front of the array 1. That is, if the pulse from each transmit element 7 were to arrive at a single location at one time, a converging circle or sphere can be constructed that would condense in size down until it hit the virtual point source 2. The time when that virtual circle or sphere would pass through the transducer elements of the array 1 is when the transducer elements in the array should be fired. The coordination of those impulse firings then creates an actual physical wave into the medium which has as its target the virtual point source 2 that was selected. This enables transmissions from multiple transducers elements to be “focused” on a single point inside the medium. Echoes returning from the point source 5 are then collected by each individual receiver.

[0089] Referring to FIGS. 2-3, with a coordinate system origin 6 (0, 0), reflection time from an image field point 3 in the imaged medium with coordinates (x_f, z_f) can be calculated based on the total length of flight path from the virtual source 2 located at (x_m, z_m) to the image field point 3 (x_f, z_f) and from it to the receive element 4 of the transducer array. Knowledge of these reflection times can then be used by the system (such as with an electronic controller) to generate the image in a beamforming process. This beamforming process as well as the calculation of appropriate transducer excitation voltage waveforms require knowledge of the speed of sound in the imaged medium, commonly fixed at 1540 m/s for soft tissue. (More details can be found in U.S. Patent Application No. 16/506,570.)

[0090] A simple Beamforming calculation used to pixel-wise generate the ultrasound image with convergent or divergent waves for a normally directed transmission from a simple linear aperture/array is given as:

$$B(x_f, z_f) = \sum_{m=1}^M \sum_{i=1}^N s_{m,i} (\tau_{m,f} + \tau_{f,i})$$

$$\tau_{m,f} = \frac{1}{c} \cdot \left\{ \text{sign}(z_m - z_f) \cdot \sqrt{(x_m - x_f)^2 + (z_m - z_f)^2} + \text{sign}(z_m) \cdot \sqrt{H(|x_f| + \text{sign}(z_m) \cdot L/2) \cdot (|x_m| + \text{sign}(z_m) \cdot L/2)^2 + z_m^2} \right\}$$

with:

$$\tau_{m,f} = \frac{1}{c} \cdot \left\{ \text{sign}(z_m - z_f) \cdot \sqrt{(x_m - x_f)^2 + (z_m - z_f)^2} + \text{sign}(z_m) \cdot \sqrt{H(|x_f| + \text{sign}(z_m) \cdot L/2) \cdot (|x_m| + \text{sign}(z_m) \cdot L/2)^2 + z_m^2} \right\}$$

$$\tau_{f,i} = \sqrt{(x_i - x_m)^2 + (z_m)^2}$$

[0091] where:

5 [0092] $s_{m,i}$ is the reflected signal recorded by the i^{th} receive element for the m^{th} ping/transmit; $t_{m,f}$ is the pulse arrival time delay for a pixel located at (x_f, z_f) in the image field and $t_{f,i}$ is the receive time delay for the reflection from that pixel and the i^{th} receive element in the probe/aperture/ array; (x_m, z_m) is the location of the virtual source and is positive for a convergent or negative for a divergent transmit source; L is the width of the linear probe aperture or array and c is the mean speed of sound in the imaged medium;
10 $B(x_m, z_m)$ is the amplitude or brightness of the beam formed image (pixel) at location (x_f, z_f) ; N is the number of receive elements in the probe/array/receive (sub) aperture and M is the number of different transmits/pings used to generate the image frame. H is the Heaviside step function and is equal to 0 for arguments less than or equal to zero and 1 for arguments
15 greater than zero. The origin for the spatial coordinates is at the center of the linear array.

[0093] FIG. 4 is a schematic illustration of a data “cube” according to one embodiment of the present disclosure. The “cube” comprises reflection data acquired through a series of transmits of virtual (and/or real) sources that can be beamformed based on their individual virtual source location and summed or stitched into a single image. Different transmits can
20 target different lateral or depth-wise spatial locations and only data pertaining to the targeted region beamformed and folded into the image. The embodiment of FIG. 4 represents the ability to assemble a data “cube” made up of samples from either divergent ultrasound waveforms, convergent ultrasound waveforms, or combinations of both. The system can receive channel data samples in time t , with the number of samples being proportional to the
25 sampling rate and imaged depth. Samples from transmit sources/pings along index m ($1 \dots M$) coupled with receiver elements along index i ($1 \dots N$), can be coalesced from different transmits pings to create data columns within a full data “cube”. The data cube (M, N, t) can then be beamformed and integrated into a single image frame.

[0094] The techniques and methods described above can be extended to segmented or
30 multiple aperture probes to enhance their performance. For example, FIG. 5 shows a standard unfocused pulse 3 being initiated from an element 4 on a transducer array 1. Such a pulse could come from any element 2 on any of the arrays 1. FIG. 6 progresses by showing a virtual point source 2 behind the array which could alternately or additionally be used. FIG 6

also shows additional elements in sub-aperture 4 being fired to form waveforms/pulses based on time delays required to create the desired semi-circular divergent or convergent wave pattern.

5 **[0095]** In some embodiments the elements 4 in the arrays 1 may be cut from the same substrate. In other embodiments, the elements may be physically formed and shaped using micro-machined piezoelectric materials such as Capacitive Micromachined Ultrasound Transducer (cMUT) or Piezoelectric Micromachined Ultrasound Transducer (pMUT). In these cases, the element itself can be shaped to provide further benefit for the type of convergent or divergent waveforms to provide optimum imaging. For instance, a 1D array
10 may require rectangular shaped elements to better receive data in plane. Whereas a 2D or 3D array may require circular or elliptical shaped elements to transmit and received data from all angles. Element size, shape and location is discussed further in US 10,586,846.

[0096] Difficulties arise in creating uniform unfocused pulses when the transmit elements for the virtual source need to span across physical separations between elements, arrays or
15 angles due to concavity or spacing, but transmission locations and directions that require spanning such gaps may still be designed and utilized to provide the adequate wave uniformity over certain regions within the imaged medium and enabling the entire medium to be imaged without gaps. US Pat. No. 10,064,605 highlights several methods used to calculate the acoustic center of each element. Element positions can be fixed based on
20 calibration against a phantom or adjusted electronically in real time based on identification of common landmarks being imaged by multiple transducer elements. Alignment on fixed positions probes need not be done in real time or even regularly. Alignment on flexible or adjustable arrays and probes can be helpful in providing sharper imaging when using multiple aperture ultrasound imaging.

25 **[0097]** FIG.7 illustrates how a uniform unfocused transmit waveform can be generated over specific targeted regions of the imaged medium even though there is a physical separation between arrays and a differing “view” angle caused by the concavity of the probe. When a physical separation exists between elements or arrays being utilized in a multiple aperture ultrasound probe, as shown in FIG. 7, and where the divergent virtual point source 2
30 is located in between or directly behind the physical separate, an “imaging dead zone” 5 may be located in the immediate near field in front of the separation. In this area, due to wave interference effects, suitable reflections may not exist to provide enough data to beamform an acceptable image, compared to the region 6 as shown which does provide good transmit pulse quality and subsequently high quality data and imaging). Shifting the virtual point source 2

to a different location 3 can serve to reduce the size of a dead zone, especially when multiple virtual point source transmissions are utilized in the collection and creation of the data set for the image. The size of the imaging dead zone may also vary based on the physical size of the separation and/or the angle of the planes of the separate elements or arrays. For instance, where there is a wide separation, but the angle between the elements or arrays is large, the dead zone may be negligible. Conversely, where the angle is almost zero, the dead zone could be as large as the separation itself. Methods described in US 9,668,714 can then be used to applying weighting factors to data being collected and ultimately assembled in the data set and pixel/voxel.

10 **[0098]** In the embodiment of FIG. 8, the system can include three separate arrays 1 having transducer elements 4. As shown, waves can be generated from three different transducer elements 4 that are physically separate. Traditionally, a focal point 2 is located mostly equidistant from each element in each array. In this example, there is a similarity that the convergent waves 3 were formed from a sub-aperture 4 focused on the same point.

15 Common convergent focal point targets could be insonified by sup-apertures of transmit elements from any of the arrays 1 in the probe as long as they are substantially equidistant. However, FIG. 8 demonstrates that the focal point need not be equidistant from each element or array. In this example, the convergent/focused wave insonified region 3 is shown bounded by the intersection of the three convergent waves. The focal point may favor one side of the targeted tissue area, as shown. This technique could then be utilized thousands of times over so that focal points would be located throughout the targeted tissue area and stitching the images from each of the targeted regions to into a single image. When imaging at larger depths using MAUI imaging, it may be necessary to only use portions of the probe to provide a transmission to the target to favor getting adequate transmission strength through to the target while avoid strong reflectors at shallow depths.

20 **[0099]** FIG. 9 illustrates convergent wave transmission using multiple elements 4 spread across two segments 1 of a multi segment concave probe. In the embodiment of FIG. 9, only a portion of the multiple aperture probe is used to transmit converging energy to a deep focal target on the left side of the area of interest, resulting in a convergent/focused wave 3. The virtual point source 2 is shown. In this embodiment, region 5 illustrates an area with poor transmit pulse quality and region 6 illustrates a region with good transmit pulse quality. Shifting the virtual point source 2 to a different location inside the medium can serve to reduce the size of a dead zone, especially when multiple virtual point source transmissions are utilized in the collection and creation of the data set for the image. The size of the

imaging dead zone may also vary based on the physical size of the separation and/or the angle of the planes of the separate elements or arrays. For instance, where there is a wide separation, but the angle between the elements or arrays is large, the dead zone may be negligible. Conversely, where the angle is almost zero, the dead zone could be as large as the separation itself. Methods described in US 9,668,714 can then be used to applying weighting factors to data being collected and ultimately assembled in the data set and pixel/voxel.

5 [00100] FIG. 10 illustrates an embodiment in which a smoothly curved concave transducer array 1 including transmit elements 4 configured to produce multiple transmissions that can cover multiple subregions within the field of interest with adequately uniform divergent waves 5 using a proper choice of transmit array elements 2. Multiple images can be stitched together to produce the final image. The probe need not be symmetrical. In this embodiment, the virtual point source 3 is positioned behind the array 1. Ping-based MAUI transmissions can be created that are uniform and unfocused provided that the element positions are known prior to waveform generation.

10 [00101] FIG. 11 shows convergent wave transmission using a subset of elements 4 from within a smooth concave transducer array 1 comprised of a larger number of elements 2. In this embodiment, a uniform convergent transmit wave can be formed from the transducer array, with a virtual point source 3 positioned at the focus (e.g., in front of the array). This probe need not be symmetrical. Ping-based MAUI transmissions can be created that are uniform and converging provided the element positions are known prior to waveform generation.

20 [00102] FIG. 12 shows an array 1 that has transducers located in an array that is curved around multiple axes into a concave shape. In some embodiments, a flat 2D rectangular transducer could be used to the same effect. These arrays are described more fully in US 10,835,208. This embodiment may be used to create a divergent wave transmission by using multiple transducer elements 2 from the array 1. Further, the array 1 need not be fixed or static. It can be adjustable or a flexible mesh. Calibration of such adjustable arrays is described in US 9,510,806. 3D curved probe 1 can be constructed in multiple ways. In one embodiment, the 3D probe may be made of multiple flat segments of 2D planar arrays to approximate the 3D curvature. In another embodiment, a custom curved array can be constructed using cMUT or pMUT transducer in a shaped substrate. The transducer array 1 can be configured to generate ultrasound wavefronts, as described herein. In the illustrated example, a subgroup 4 of transmit elements 2 are configured to generate a divergent wave with a virtual source point 3 located behind the transmit elements, resulting in an insonified

region 5 as shown. FIG. 13 shows a similar embodiment to that of FIG. 12, except the transducer array comprises a sparse transducer array 2. PMA systems using Computed Echo Tomography do not require elements to be adjacent to each other or even in the same plane. Elements need not be in the same arrays, but their positions must be known as described in US 9,510,806. Elements may be sparse, random, physically separated and can be out of plane with each other and still used effectively within the same PMA transmit and receive sequence. Methods related to these types of arrays are described further in US 10,854,846.

[00103] FIGS. 14 and 15 are similar to the embodiments of FIGS. 12 and 13, respectively, except they show convergent or focused wave transmission using multiple elements within a 3D curved probe array that is curved around multiple axes into a concave shape. In some embodiments, a flat 2D rectangular transducer could be used to the same effect. In these embodiments, the virtual point source 3 is located at the focal point of the transducer array, as shown, resulting in insonified regions 5 both before and after the virtual point source.

[00104] Additional geometric corrections may be required if the transmissions are directed or received in directions other than normal to the array or the geometry of the probe is not linear, but the principle of determining transmit and receive path length and time to beamform the received data into an image stands.

[00105] Regardless of the array type 1D, 2D or 3D used with a PMA system, each ping and the associated received echoes on all selected channels create a data set or string for that channel. Channel data can be combined to create a larger data set of the imaged medium. It will be understood by those familiar with the art, that using a combination of virtual point sources during transmission to include both convergent and divergent transmission and the subsequent collection and combination of channel data into a larger data set may provide optimum image quality. This larger data set then takes advantage of channels having differing views of the medium. Methods for solving speed of sound variations so that these data sets can be combined or discussed in prior works. All or a portion of the data set can be selected by the end user for presentation as an image. The data from the individual transmits/pings may be weighted when generating a final image frame to equalize (or enhance) differences in transmit/ping energy.

[00106] Any of the foregoing embodiments may be used in combination with a multiple aperture imaging probe of any desired construction. Examples of multiple aperture ultrasound imaging probes are provided in Applicant's prior patent applications referenced herein.

[00107] Embodiments of the systems and methods described above may also be beneficially applied to multiple aperture ultrasound imaging systems utilizing focused phased array transmit pulses rather than point source transmit pulses (pings). Similarly, embodiments of the systems and methods described above may also be beneficially applied to single-aperture imaging systems using multiple sub-apertures for ping transmission. In still further embodiments, the methods described above may also be applied to conventional ultrasound systems using phased array-transmissions from a single-aperture probe.

[00108] Although this invention has been disclosed in the context of certain preferred embodiments and examples, it will be understood by those skilled in the art that the present invention extends beyond the specifically disclosed embodiments to other alternative embodiments and/or uses of the invention and obvious modifications and equivalents thereof. Various modifications to the above embodiments will be readily apparent to those skilled in the art, and the generic principles defined herein may be applied to other embodiments without departing from the spirit or scope of the invention. Thus, it is intended that the scope of the present invention herein disclosed should not be limited by the particular disclosed embodiments described above, but should be determined only by a fair reading of the claims that follow.

[00109] In particular, materials and manufacturing techniques may be employed as within the level of those with skill in the relevant art. Furthermore, reference to a singular item, includes the possibility that there are plural of the same items present. More specifically, as used herein and in the appended claims, the singular forms "a," "and," "said," and "the" include plural referents unless the context clearly dictates otherwise. As used herein, unless explicitly stated otherwise, the term "or" is inclusive of all presented alternatives, and means essentially the same as the commonly used phrase "and/or." It is further noted that the claims may be drafted to exclude any optional element. As such, this statement is intended to serve as antecedent basis for use of such exclusive terminology as "solely," "only" and the like in connection with the recitation of claim elements, or use of a "negative" limitation. Unless defined otherwise herein, 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.

CLAIMS

What is claimed is:

- 5 1. A method of imaging an object with ultrasound energy, the method comprising the steps of:
- transmitting an un-focused and diverging ultrasound signal into a target medium from an apparent point source located aft of a concave probe surface;
- receiving echoes from a reflector in the target medium with an omnidirectional
10 receive element that is different than the apparent point source;
- determining a position of the reflector within the target medium by obtaining element position data describing a position of the spherical center point of the apparent point source r and a position of the receive element, calculating a total path distance as a sum of a first distance between the spherical center point and the reflector and a second distance between
15 the reflector and the receive element, and determining a locus of possible points at which the reflector may lie; and
- producing a data set for the entire target medium.
2. The method of claim 1, wherein the receive elements of the probe are comprised of a
20 shell of piezoelectric material shaped as a concave curve wherein the position of the receive element is a position on the curved shell.
3. The method of claim 2 where the shape of the concave probe may be either symmetric or asymmetric.
25
4. The method of claim 2 where the probe is made of piezoelectric, cMTU or pMUT materials in a concave shape.
5. The method of claim 2 where the elements or arrays of the probe are not physically
30 attached.
6. The method of claim 2 where the elements of the probe are arranged in a sparse and non-linear pattern.

7. The method of claim 2 where the array or arrays of elements are shaped in 3 dimensions around two or more axes.
8. The method of claim 2 where the array of elements is contained in a flexible material that may move or articulate around two or more axes.
9. The method of claim 1, further comprising repeating the receiving, determining and producing steps with a plurality of receive elements.
10. The method of claim 1, further comprising where a plurality of receive elements may be used to combine data for a common receive aperture.
11. The method of claim 1, further comprising repeating the receiving, determining and producing with the elements of a plurality of receive apertures.
12. The method of claim 1, wherein less than 10 transducers are used together to transmit the un-focused and diverging ultrasound signal.
13. A method of imaging an object with ultrasound energy, the method comprising the steps of:
transmitting a focused and converging ultrasound signal into a target medium to an apparent point source located forward of a concave probe surface;
receiving echoes from a reflector in the target medium with an omnidirectional receive element that is different than the apparent point source;
determining a position of the reflector within the target medium by obtaining element position data describing a position of the spherical center point of the apparent point source and a position of the receive element, calculating a total path distance as a sum of a first distance between the spherical center point and the reflector and a second distance between the reflector and the receive element, and determining a locus of possible points at which the reflector may lie; and
producing a data set for the entire medium.
14. The method of claim 13, wherein the receive elements of the probe are comprised of a shell of piezoelectric material shaped as a concave curve wherein the position of the receive

element is a position on the curved shell.

15. The method of claim 14 where the shape of the concave probe may be either symmetric or asymmetric.

5

16. The method of claim 14 where the probe is made of piezoelectric, cMTU or pMUT materials in a concave shape.

10

17. The method of claim 14 where the elements or arrays of the probe are not physically attached.

18. The method of claim 14 where the elements of the probe are arranged in a sparse and non-linear pattern.

15

19. The method of claim 14 where the array or arrays of elements are shaped in 3 dimensions around two or more axes.

20

20. The method of claim 14 where the array of elements is contained in a flexible material that may move or articulate around two or more axes.

21. The method of claim 13, further comprising repeating the receiving, determining and producing steps with a plurality of receive elements.

25

22. The method of claim 13, further comprising where a plurality of receive elements may be used to combine data for a common receive aperture.

23. The method of claim 13, further comprising repeating the receiving, determining and producing with the elements of a plurality of receive apertures.

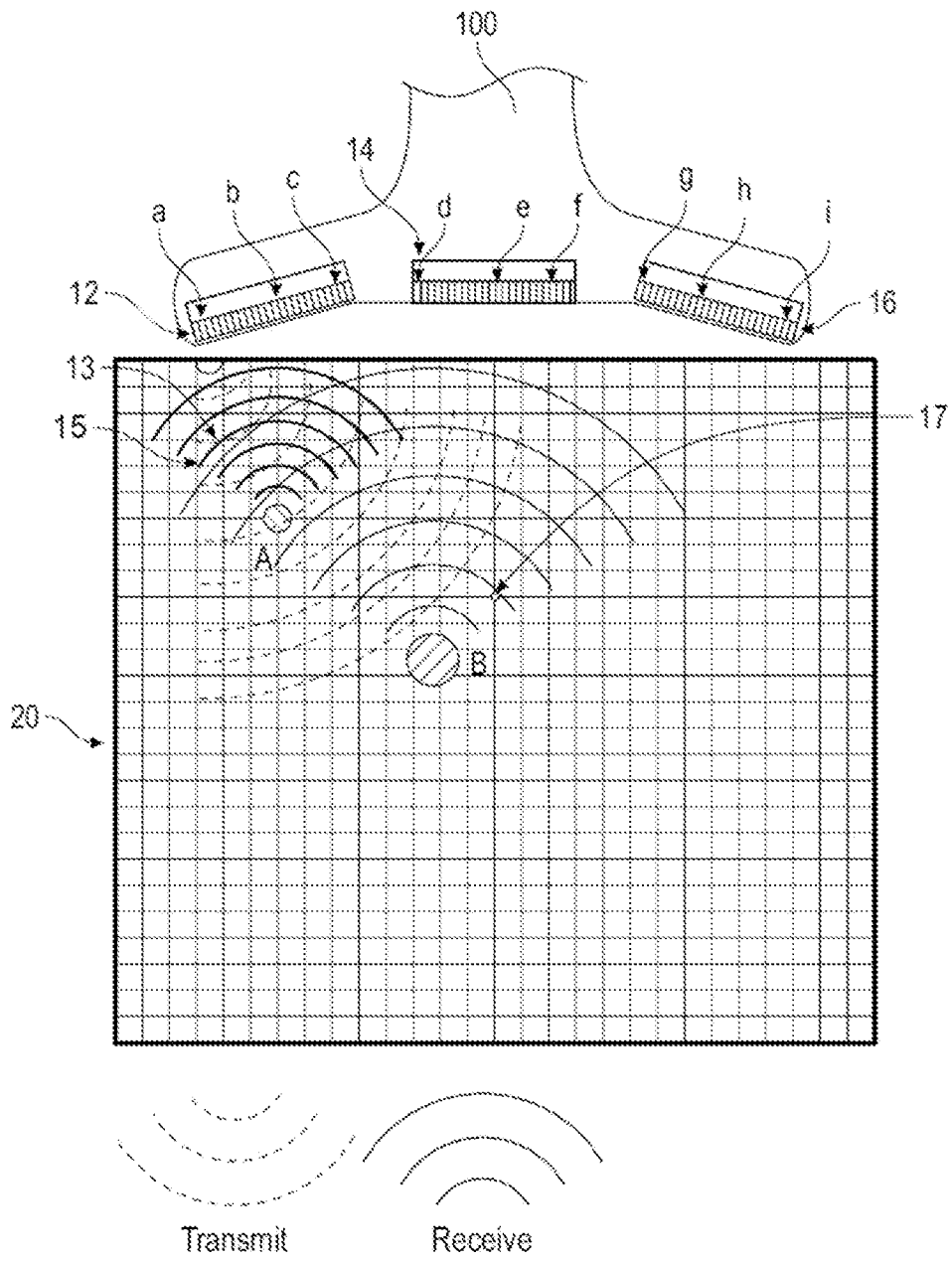


FIG. 1

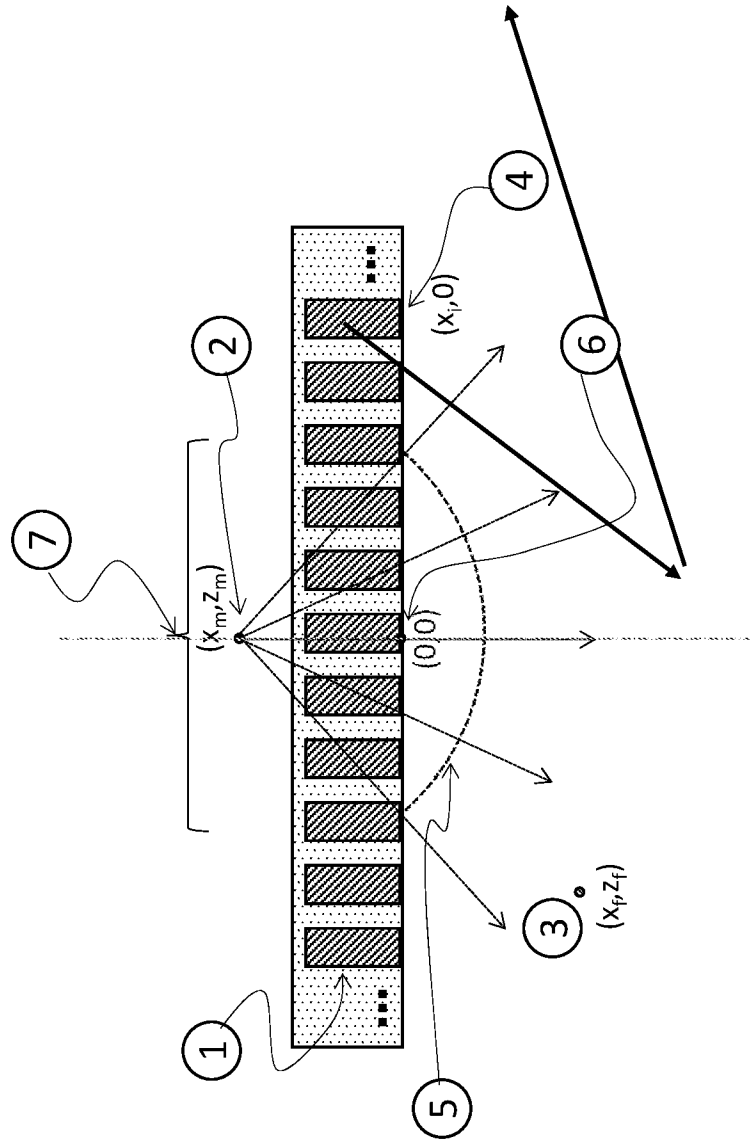


FIG. 2

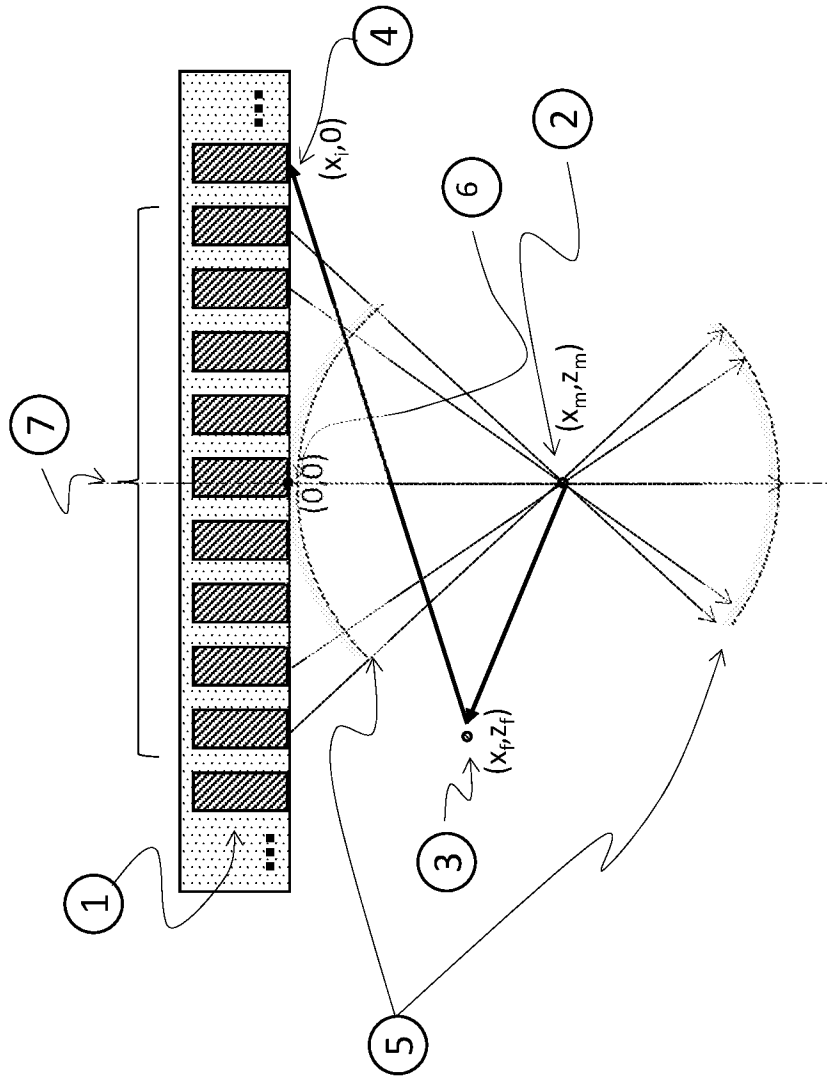


FIG. 3

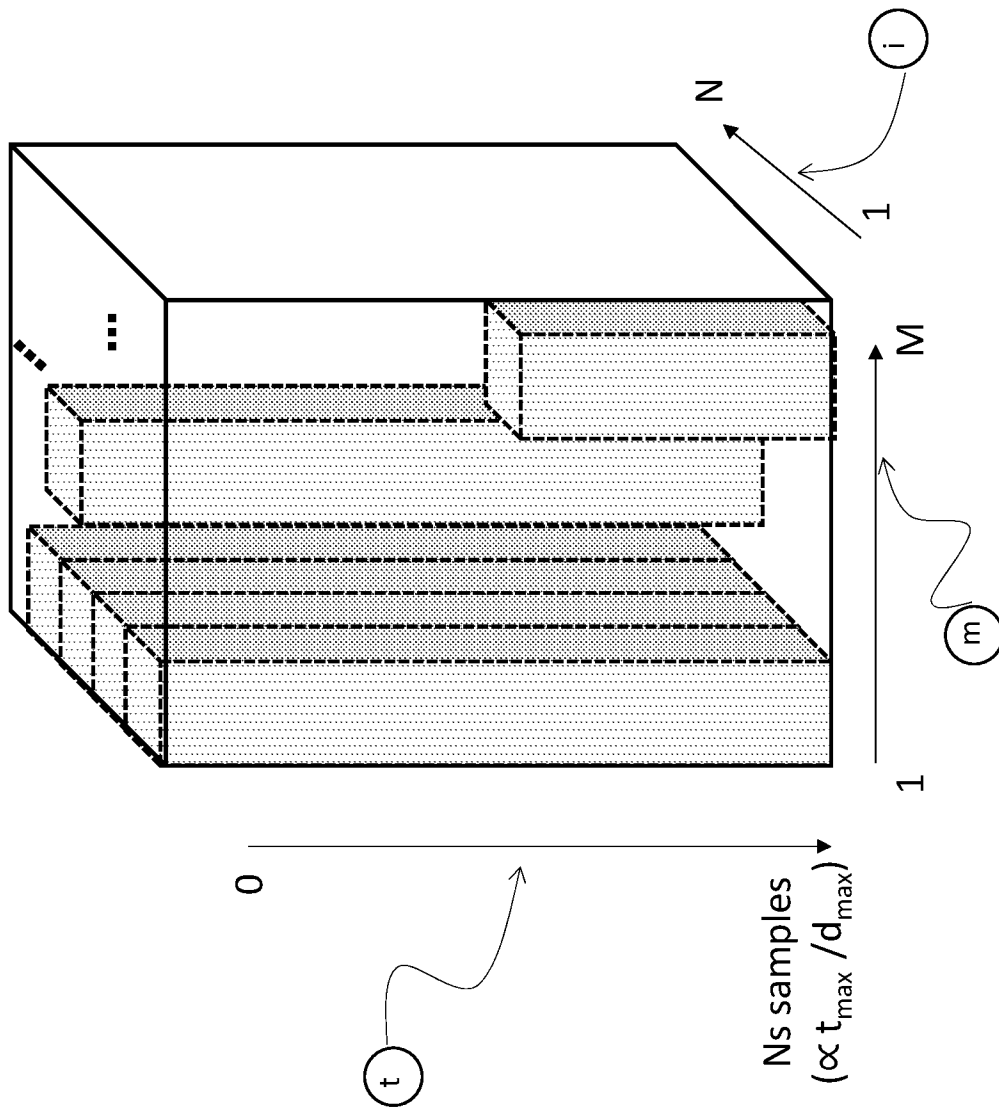


FIG. 4

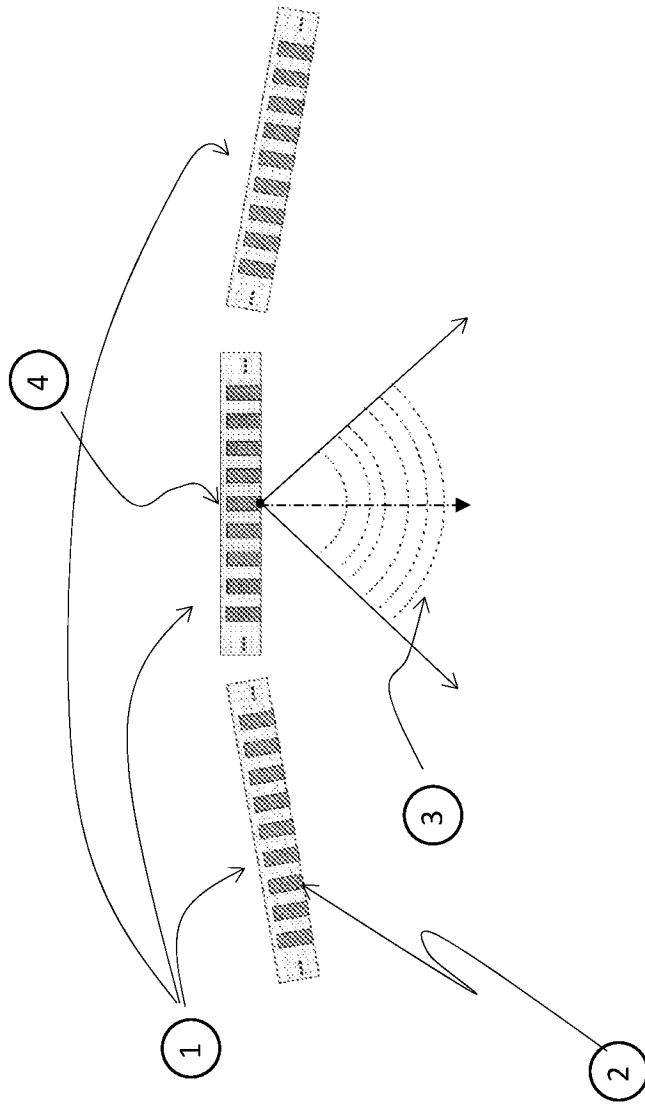


FIG. 5

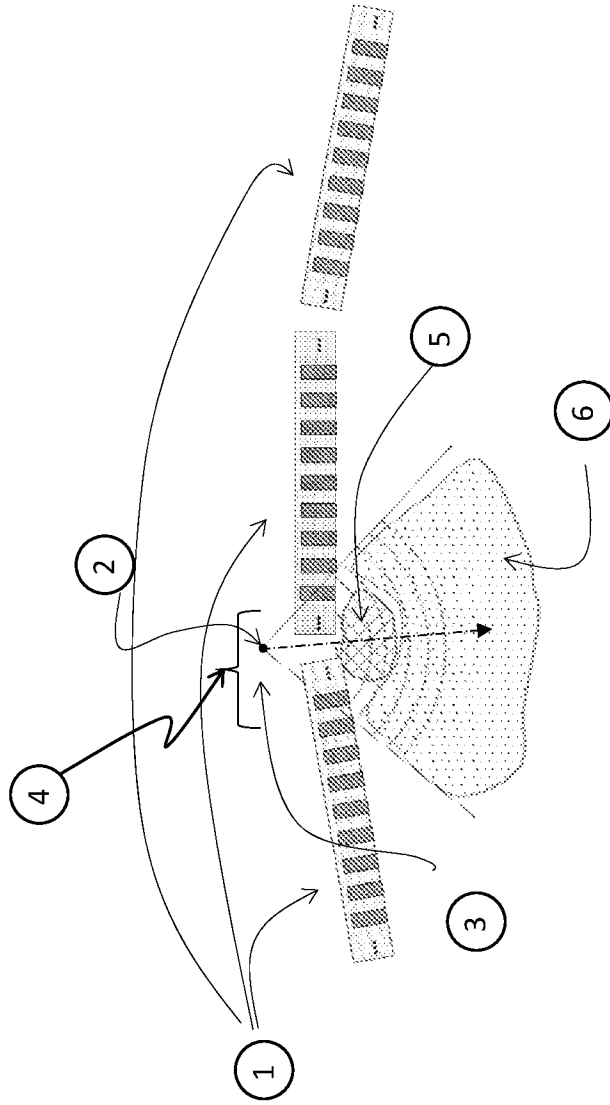


FIG. 7

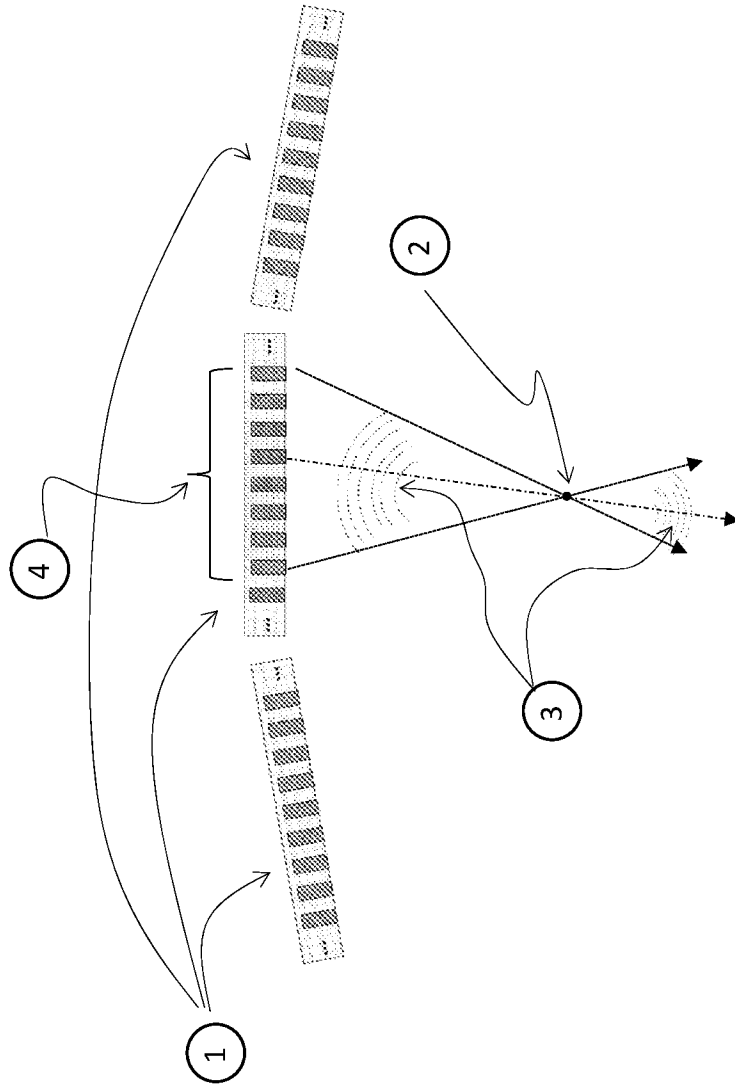


FIG. 8

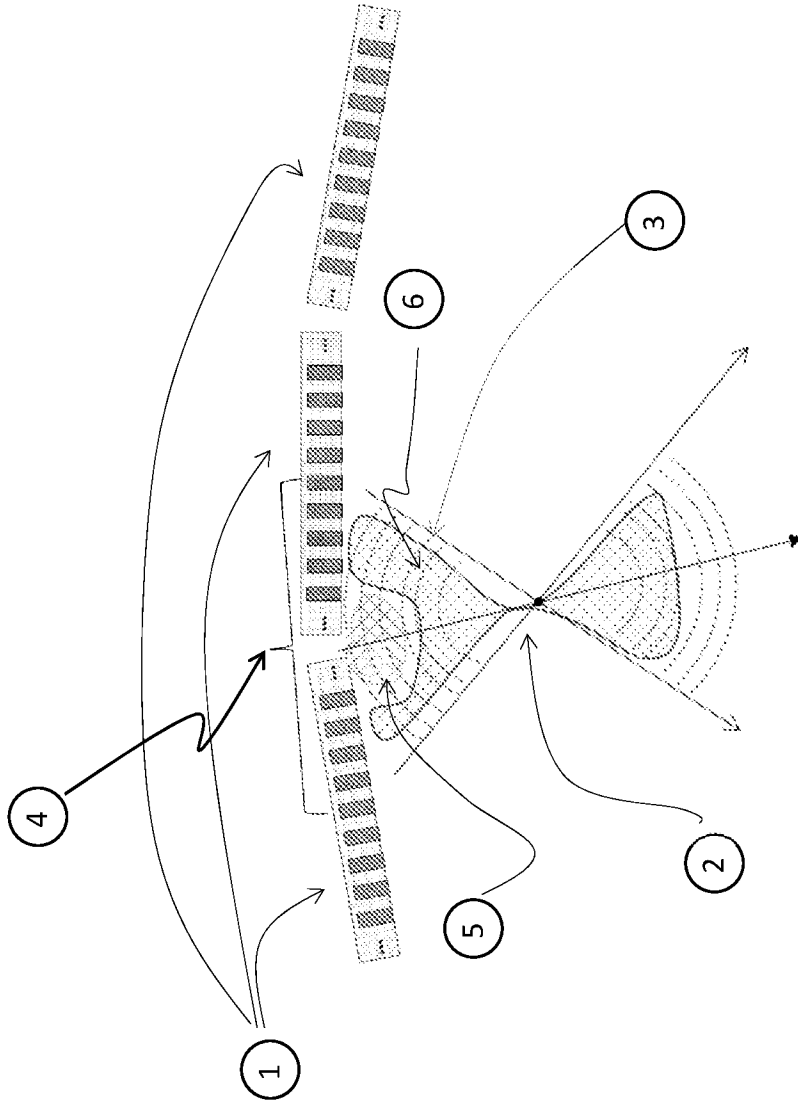


FIG. 9

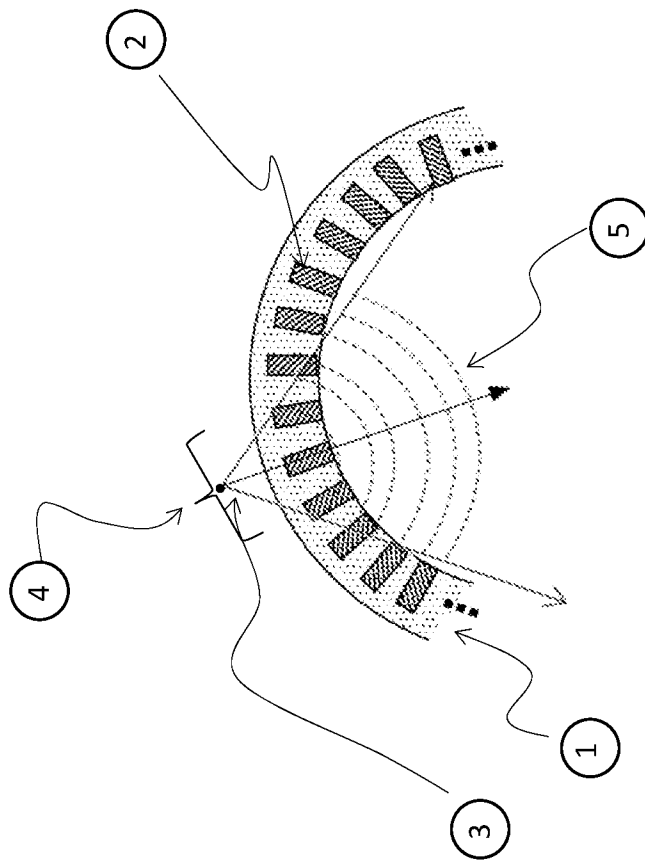


FIG. 10

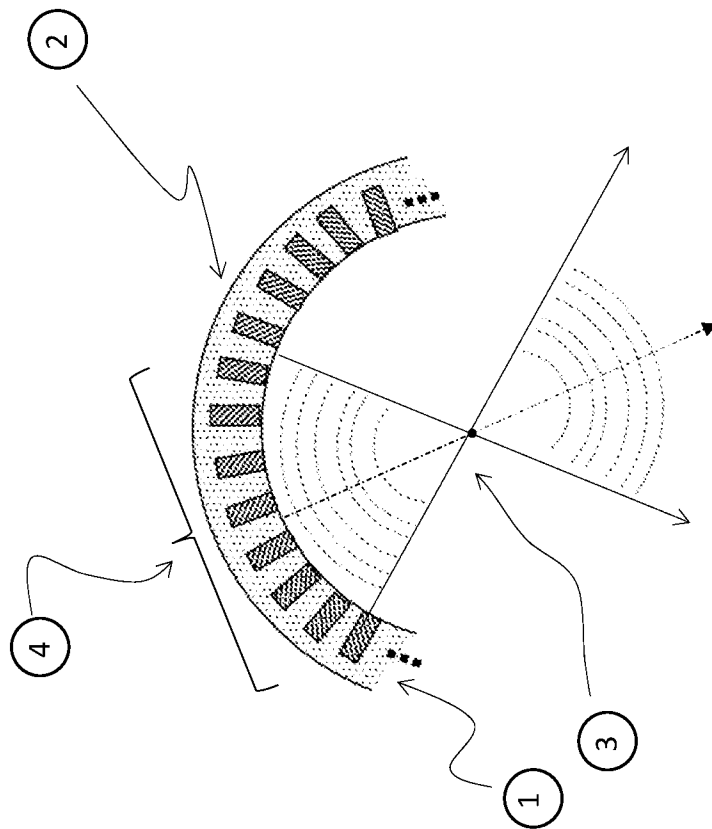


FIG. 11

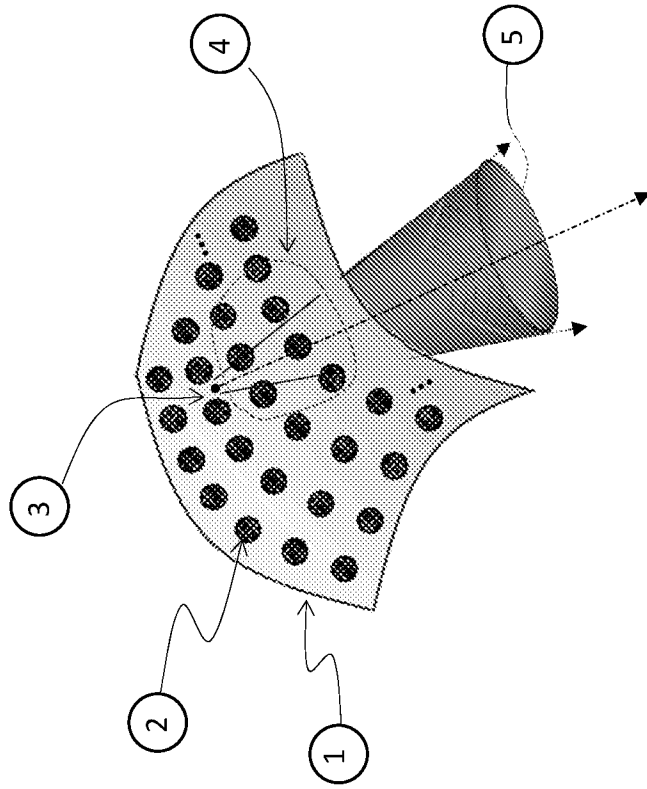


FIG. 12

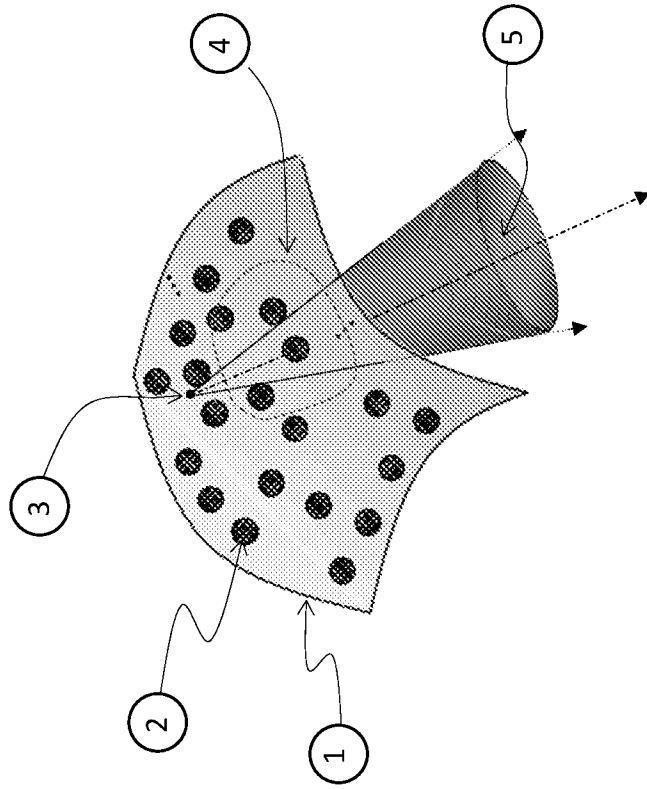


FIG. 13

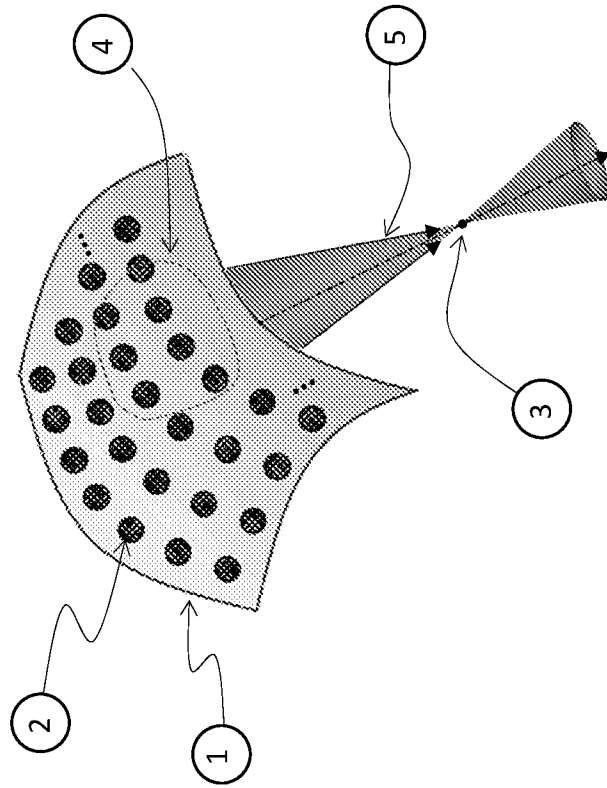


FIG. 14

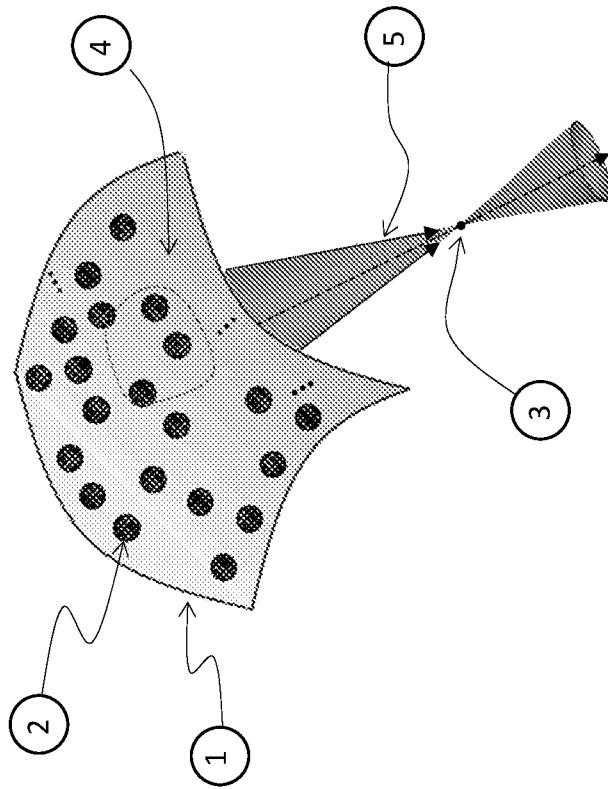


FIG. 15

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 23/62069

| A. CLASSIFICATION OF SUBJECT MATTER IPC - INV. A61B 8/08, A61B 8/14, G01S 15/02, G01S 7/52, G01S 7/539 (2023.01) ADD. A61B 6/02 (2023.01) CPC - INV. A61B 8/52, G01S 15/8913, G01S 7/52025, A61B 8/14, A61B 8/4483 ADD. A61B 8/5207, A61B 8/4477 According to International Patent Classification (IPC) or to both national classification and IPC | | |
|--|--|--|
| B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) See Search History document Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched See Search History document Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) See Search History document | | |
| C. DOCUMENTS CONSIDERED TO BE RELEVANT | | |
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| D, X ----- D, Y | US 2015/0080727 A1 (Specht et al.) 19 March 2015 (19.03.2015); entire document, especially, abstract, FIG.1, 4, 8-10A, para [0013], [0015]-[0017], [0093], [0098]-[0102], [0107], [0109], [0121]-[0123], [0135], [0136],[0151], [0155], [0158], [0160]-[0163], [0167]-[0169], [0184], [0202], [0220] and claims 2, 4 | 1,2,4,5, 9-14,16,17,21-23 ----- - 3,6-8,15,18-20 |
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| Y | US 2016/0095579 A1 (Smith et al.) 07 April 2016 (07.04.2016); entire document, especially, abstract, FIG.3A,4, para [0039]-[0040], [0095] | 7, 19 |
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