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(54) Title: OPTIMIZING ENERGY TRANSMISSION IN A LEADLESS TISSUE STIMULATION SYSTEM

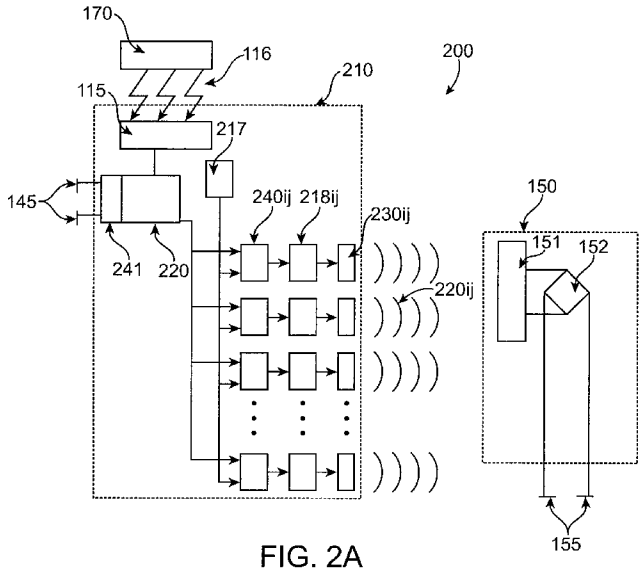


FIG. 2A

(57) Abstract: Method and systems for optimizing acoustic energy transmission in implantable devices are disclosed. Transducer elements transmit acoustic locator signals towards a receiver assembly, and the receiver responds with a location signal. The location signal can reveal information related to the location of the receiver and the efficiency of the transmitted acoustic beam received by the receiver. This information enables the transmitter to target the receiver and optimize the acoustic energy transfer between the transmitter and the receiver. The energy can be used for therapeutic purposes, for example, stimulating tissue or for diagnostic purposes.

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# OPTIMIZING ENERGY TRANSMISSION IN A LEADLESS TISSUE STIMULATION SYSTEM

## BACKGROUND OF THE INVENTION

**[0001]** Field of the Invention. This invention generally relates to optimizing acoustic or ultrasound energy transmission and energy conversion and more particularly to optimizing acoustic energy transmission and conversion in implantable devices.

**[0002]** Stimulation of cardiac tissue using a leadless cardiac stimulation system has been disclosed earlier by the applicant. Generally, such a system comprises an arrangement of one or more acoustic transducers, and associated circuitry, referred to as a controller-transmitter, and one or more implanted receiver-stimulator devices. The controller-transmitter generates and transmits acoustic energy, which is received by the receiver-stimulator, and the receiver-stimulator in turn converts the acoustic energy into electrical energy, which is delivered to the tissue through electrodes.

**[0003]** The controller-transmitter may be externally coupled to the patient's skin, but will usually be implanted, requiring that the controller-transmitter have a reasonable size, similar to that of implantable pacemakers, and that the controller-transmitter be capable of operating for a lengthy period, typically three or more years, using batteries,. The small size and long operational period require that the system efficiently utilize the acoustic energy from the controller-transmitter with minimal dissipation or dispersion of the transmitted energy and efficient conversion of the energy by the receiver-stimulator.

**[0004]** Charych (USPN 6,798,716) describes various strategies for locating an acoustic receiver. Charych describes methods for charging wireless devices (receivers) from a controller-transmitter that is powered through a plug, providing power in excess of 1000W. In contrast, a leadless cardiac stimulation system, where the power flow is 6 orders of magnitude lower, requires completely different methods and systems for locating the receiver, which are not described by Charych.

**[0005]** Briefly, in its simplest form, the receiver-stimulator comprises one or more acoustic piezoelectric receiver elements, one or more rectifier circuits, and electrodes. The piezoelectric receiver elements couple power from the acoustic field generated by the

controller-transmitter and convert it into electric power. If applied directly to the tissue this AC electrical power does not stimulate the tissue because its frequency is too high for excitation/stimulation. In order to initiate a paced heart beat, or provide other therapeutic stimulation to tissues, the rectifier circuits convert all or some of the available AC electrical power to an electrical pulse that is applied to the cardiac tissue through the electrodes. The acoustic field is generated and transmitted either by an externally placed or an implantable controller-transmitter that is remote from the location of the receiver-stimulator.

**[0006]** The acoustic energy generated by the controller-transmitter is generally referred to as an acoustic beam or ultrasound beam and is characterized by acoustic intensity (I) measured in Watts/square meter. In order to create an acoustic intensity of Io over an area Ao the controller-transmitter must expend at least Io*Ao Watts of power. Only the portion of this acoustic beam that intersects the receiver-stimulator will be available as electrical power. If the area Ao is larger than the cross sectional area or aperture of the receiver Ar, then the ratio Ar/Ao represents that fraction of the power in the acoustic beam that is available to the receiver-stimulator. Therefore the optimally efficient acoustic beam is very narrow and only intersects the receiver elements of the receiver-stimulator.

**[0007]** The controller-transmitter has one or more piezoelectric transducers that convert electrical power into acoustic power creating the acoustic beam that is directed at the receiver-stimulator. The ability of the controller-transmitter to generate this acoustic beam over a small area is characterized by its focal or directivity gain. In general the larger the cross sectional area (referred to as the aperture) of the controller-transmitter transducers, the higher the directivity gain will be. This requires the controller-transmitter to have a wide aperture transmitter that focuses acoustic energy at the receiver-stimulator. It also requires the controller-transmitter to steer or direct the acoustic beam at the receiver-stimulator. This can be accomplished by using a phased array that uses beam-forming techniques to steer the acoustic beam at the receiver-stimulator. Steering can be accomplished by adjusting the phases and amplitudes of the electrical drive signals to the transducer array, which results in adjusting the direction and focal distance of the transmitted beam.

**[0008]** If the location of the receiver-stimulator or the controller-transmitter does not change over time, the controller-transmitter could be configured at the time of implant to optimally select a focused beam profile that is aimed at the receiver-stimulator location determined at the implantation time. However, in the case of the leadless system, the

receiver-stimulator can be expected to move due to cardiac motion, breathing, or body orientation. Moreover, the controller-transmitter may move slightly due to body orientation or body movements or migration. Therefore, to accommodate the movement of the controller-transmitter and the receiver-stimulator, inventors herein have realized that successful operation in the simplest implementation would require a relatively broad beam acoustic emission. However, in this mode of operation most of the transmitted acoustic energy may pass by the receiver-stimulator and not used efficiently. Hence, inventors herein have further realized that to improve efficiency the transmit beam needs to be significantly sharpened or focused, and reliable operation would require continuous, specific knowledge of the location of the receiver-stimulator.

**[0009]** For the above reasons, it would be desirable to provide a leadless system that efficiently transmits and receives acoustic energy. It would also be desirable for the transmitted beam to be adjusted, to be as focused as possible at targeting the receiving element(s) of the receiver-stimulator. It would be particularly desirable if the location of the receiver-stimulator is known to the controller-transmitter, and, thereby, a focused acoustic beam could be aimed and transmitted toward the receiver-stimulator. It would also be desirable if the receiver-stimulator is located using mechanisms that minimize the size and complexity of the receiver-stimulator such that additional circuitry or energy consumption is not imposed upon the receiver-stimulator.

## BRIEF SUMMARY OF THE INVENTION

**[0010]** Systems and methods are provided for efficiently delivering acoustic energy from an implanted or externally applied acoustic transmitter to an implanted acoustic receiver. The acoustic energy is converted by the receiver into electrical energy which can be used for a variety of purposes. The electrical energy will typically be delivered to electrodes in contact with tissue in order to stimulate tissue, for example, in cardiac pacing for bradycardia, for termination of tachyarrhythmia, for bi-ventricular resynchronization therapy for heart failure, or the like. The systems and methods of the present invention could also be used in a variety of other applications, including applications for nerve stimulation, brain stimulation, voluntary muscle stimulation, gastric stimulation, bone growth stimulation, pain amelioration, sensing and communication of local diagnostic information, and the like, where an acoustic transmitter has to efficiently transmit energy to an implanted receiver. The implanted acoustic receiver could act as a tissue stimulator (receiver-stimulator) or act more generally as an acoustic energy converter (receiver-converter). Efficient transmission can be

achieved by deploying strategies for locating the receiver and then transmitting a focused acoustic beam specifically aimed at the receiver and thereby improving operational efficiency of the system. These systems and methods are particularly useful when the transmitter is an implantable device dependent on a limited source of energy, such as a battery.

**[0011]** By "locator signal" we mean an acoustic signal transmitted by the transducer element(s) of a controller-transmitter assembly to elicit a "location signal."

**[0012]** By "location signal" we mean a signal that is either passively or actively generated by the receiver-stimulator. The location signal may be in response to a "locator signal" transmitted by the controller-transmitter or may be periodically transmitted by the receiver-stimulator. The location signal is used by the controller-transmitter to determine the location of the receiver relative to the controller-transmitter, thus allowing the controller-transmitter to direct a focused, efficient acoustic beam at the receiver-stimulator.

**[0013]** One exemplary embodiment of the invention is a system for focusing acoustic energy into a human body. The system comprises an array of acoustic transducers configured to transmit acoustic energy into the body; circuitry for focusing the acoustic energy at specific regions in the body; an acoustic receiver adapted to receive the acoustic energy and convert the acoustic energy into electrical energy; a pair of electrodes connected to the acoustic receiver and adapted to transfer the electrical energy to the body; wherein the circuitry is further configured to detect the electrical energy transferred through the body by these electrodes to determine whether the acoustic energy is focused on the acoustic receiver. The circuitry could have one or more pairs of electrodes that are configured to determine whether the acoustic energy is focused on the acoustic receiver. The circuitry could also be configured for sequentially transmitting the acoustic energy.

**[0014]** Another exemplary embodiment of the invention described herein is a system for stimulating tissue comprising an implantable acoustic controller-transmitter comprising an array of acoustic transducers configured to transmit focused acoustic energy; one or more implantable acoustic receiver-stimulators adapted to receive the acoustic energy and convert the acoustic energy into electrical energy, wherein the receiver-stimulator further comprises electrodes configured to be in electrical communication with the tissue; and the electrical energy is delivered between the electrodes; and wherein the controller-transmitter is configured to determine the location of one or more of the receiver-stimulators relative to the

controller-transmitter so that the controller-transmitter can direct the focused acoustic energy to one or more of the receiver-stimulators.

**[0015]** Another embodiment of this invention is a method and system for determining the location of an acoustic receiver in the body. An array of acoustic transducers is used to transmit acoustic energy at a specific location in the body. The acoustic receiver is configured with electrodes that generate an electric location signal whenever it receives acoustic energy. Separate detection electrodes can detect the electric location signal indicating when the array of acoustic transducers is focused on the acoustic receiver and revealing the location of the receiver. The transducer array could be configured to sequentially steer the acoustic energy until the location signal is detected or a preset time limit has been reached. The transmitted acoustic energy could be a focused acoustic beam. The location signal could be detected by a sensing circuit on the controller-transmitter.

**[0016]** In another embodiment of the invention, the controller-transmitter would be further configured to adjust the transducer array to transmit focused acoustic energy to the region of the tissue associated with detecting the location signal. This focused energy could be adequate to stimulate tissue and, in particular, cardiac tissue. In yet another embodiment, this focused energy would be generated based on characteristics of the location signal.

**[0017]** In yet another embodiment of this invention, an implantable acoustic controller-transmitter comprises an adjustable transducer array configured to transmit acoustic energy into tissue; an implantable acoustic receiver-converter comprises a transducer assembly adapted to receive the acoustic energy and convert the acoustic energy to electrical energy, where the transmitter is configured to transmit an acoustic locator signal towards the receiver, and the receiver is configured to generate a location signal. The location signal could be either an electrical output or an acoustic transmission in response to the locator signal. The locator signal could be focused acoustic energy. Alternatively, the focused acoustic energy that is transmitted by the transmitter can be converted to electrical energy by the receiver-converter and stored in the receiver-converter as electrical energy to be discharged at the appropriate moment. The electrical energy could also be used to operate various circuitry, such as the control circuitry, diagnostic sensing circuitry or communication circuitry.

**[0018]** Another exemplary embodiment of this invention is a system for stimulating tissue comprising an implantable acoustic controller-transmitter with an acoustic transducer array adapted to transmit acoustic energy into tissue; and an implantable acoustic receiver-

stimulator which receives acoustic energy and converts the acoustic energy to electrical energy and which has a first electrode assembly connected to the receiver-stimulator and adapted to be in electrical communication with the tissue, wherein the receiver-stimulator periodically transmits a location signal, and wherein the controller-transmitter detects the location signal. The location signal could be an electrical output or an acoustic transmission that could be sensed by the controller-transmitter. Based on the characteristics of the location signal, the transducer array could be adjusted to transmit focused acoustic energy towards the receiver-stimulator. The characteristics of the location signal would include frequency, duration, amplitude, phase, and time of flight of the location signal. The invention is also a method for optimizing acoustic energy transmission in tissue between an implantable controller-transmitter and one or more implantable receiver-stimulators comprising transmitting an acoustic locator signal from the controller-transmitter towards the receiver-stimulator, wherein the controller-transmitter comprises an adjustable transducer array; and generating a location signal from the receiver-stimulator in response to receiving the locator signal. The method could include detecting the location signal using the controller transmitter and adjusting the transducer array. The transducer array can transmit focused acoustic energy towards the receiver-stimulator. Additionally, the method could include adjusting the transducer array sequentially to transmit focused locator signals to regions of the tissue until the receiver-stimulator location signal is detected by the controller-transmitter or a pre-set time limit has been reached; and adjusting the transducer array to transmit focused acoustic energy to the region associated with the detected location signal. The method could further include converting the acoustic energy using the receiver-stimulator, and applying the converted energy to the tissue. The energy could be of sufficient magnitude to stimulate tissue.

## BRIEF DESCRIPTION OF THE DRAWINGS

**[0019]** Figure 1 is a block diagram illustrating a tissue stimulation system.

**[0020]** Figures 2A-B illustrate one embodiment of this invention.

**[0021]** Figure 3 illustrates the acoustic array scanning a region for location signals in response to locator signals.

**[0022]** Figure 4 shows the phases resolved into different components.

**[0023]** Figures 5A-5C show various electrode configurations.

**[0024]** Figures 6A-6D show methods for minimizing scan time for target detection.

**[0025]** Figures 7A – 7C illustrate an embodiment using frequency shifting for acoustic beam steering and optimizing energy transmission.

## DETAILED DESCRIPTION OF THE INVENTION

**[0026]** A leadless tissue stimulation system is shown in Figure 1 as system **100**. An implantable or external controller-transmitter module **110** generates acoustic waves **120** of sufficient amplitude and frequency and for a duration and period such that the receiver-stimulator module **150** electrically stimulates tissue. An external programmer **170** wirelessly communicates with an implantable controller-transmitter module **110**, typically by radio frequency telemetry means **116**, to adjust operating parameters. The implantable controller-transmitter module comprises a telemetry receiver **115** for adjusting the transmit acoustic characteristics, control circuitry **140** and signal generator **117**, a power amplifier **118**, and an output transducer assembly **119** for generating the acoustic beam **120** transmitted to receiver-stimulator **150**. Understandably, the controller-transmitter **110** transfers acoustic energy to the receiver-stimulator **150** leadlessly. Control circuitry **140** contains an electrical signal sensing circuit element **141** connected to one or more sensing electrodes **145** disposed on the outer casing of the controller-transmitter or connected via cables to the controller-transmitter. Alternatively, electrical sensing circuit **141** may be a typical electrogram sensing circuit or may be an electrical spike detection circuit.

**[0027]** The receiver-stimulator **150** comprises a piezoelectric receiving transducer **151**, rectifier circuitry **153**, and tissue contacting electrodes **155**. In this embodiment, acoustic energy received and rectified by the receiver-stimulator is directly applied to the electrodes **155**. Alternatively, the receiver-stimulator module may comprise multiple transducer/rectifier channels in a variety of combinations, which may be in series or parallel orientations, or the construction may perform impedance matching, and/or for signal filtering as previously disclosed in co-pending application 11/315,524 (attorney docket no. 02834-0001010US), to increase the efficiency of the receiver-stimulator.

**[0028]** One embodiment of the present invention is shown in Figure 2A as system **200.** The controller-transmitter module **210** is placed either inside the body, but remote from myocardial tissue, or outside the body in contact with the body surface. The external programmer **170** communicates with the controller-transmitter module, typically by radio

frequency telemetry **116**. The telemetry module **115** inside the controller-transmitter unit **210** provides two-way communications directly with the control circuitry **220**. A separate continuous wave (CW) signal generator **217** inside the controller-transmitter **210** provides the acoustic operating frequency for the system. The control circuitry **220** and signal generator **217** are both connected to each channel of a two dimensional acoustic transducer array **260** (shown in Fig. 2B), where each channel comprises a transmit/receive transducer element **230ij,** a power amplifier **218ij** and phase shifter module **240ij**. The phase shifter module **240ij**, ensures that during acoustic transmissions, each channel transmits with the correct phase so as to form a efficient, focused narrow acoustic beam intended to precisely intercept the receiver-stimulator. A control signal from control circuitry **220** defines the transmit phases. The output of the phase shifter **240ij** then passes to the power amplifier **218ij** of the channel, which is also under the control of the control circuitry **220**, and which can be either in an OFF state, a full ON state, or at selected levels of intermediate power which might be required for beam shading. The output of the power amplifier passes directly to the channel transducer element **230ij**. One embodiment of using the phase shifter for each output channel has been described above. Other techniques can also be employed, such as direct formatting of the transmit beam by the control circuitry **220**.

**[0029]** The controller-transmitter **210** would scan a spatial region by sending narrow acoustic beams (the locator signals), looking for a response (the location signal), from the receiver-stimulator. If the focused, directed acoustic beam intersects the receiver-transmitter the acoustic energy is converted by the receiver-stimulator and delivered as an electrical output onto the electrodes **155**. This electrical output would generate an electrical signal that would be detected by sensing electrodes **145** and detection circuits **241** of the controller-transmitter **210**. If the controller-transmitter does not detect an electrical signal within a reasonable time frame, the inference would be that the directed acoustic beam did not intersect the receiver-stimulator and the directed acoustic beam was "off target." Such time frames may be predetermined or determined based on location signal characteristics. Then, the controller-transmitter would adjust the focused, directed beam to another portion of the region where the receiver-stimulator may be located, possibly chosen to be close to the previous region, and repeat the locator signal transmission thereby scanning the spatial region iteratively. In this manner, an electrical signal will be generated and detected if the receiver-stimulator is in the spatial region being scanned. The controller-transmitter then uses the focused, directed beam parameters that resulted in a detected electrical signal (location

signal) as the target (transmission region) for the efficient transmission of a narrow acoustic beam of acoustic energy towards the receiver-stimulator. Alternatively, the controller-transmitter could then analyze characteristics of the detected electrical signal to determine whether the directed transmitter beam was adequately targeting the receiver-stimulator.

**[0030]** The scanning process is shown in more detail in Figure 3. The phased array **260** of the controller-transmitter is composed of individual transducers **230ij**. For convenience the array is oriented in the x-y plane at z = 0. The spatial volume to be scanned **305** encompasses all of the possible locations for the receiver-stimulator, and, again for convenience, is located in the z > 0 half space with respect to the phased array **260**. The extent of **305** is constrained by anatomical limits and may vary depending on the specific stimulation application. The spatial volume **305** is broken up into multiple volumes **302kl,** which are individually scanned or tested. The volumes **302kl** may overlap; however, it is desirable to have the entire collection of volumes cover the region **305**. The array is aimed at a volume **302kl** by setting the appropriate phase parameters for the array elements **230ij**.

**[0031]** The following method, provided as an example, can be used for determining the correct phase parameter for each of the array elements. A spatial location v1 for the volume **302kl** is picked; it is typically, but not necessarily, the center of the volume. A spatial location v2 for the array element **230ij** is chosen; typically, but not necessarily, the center of the array element. Note in general that v1 and v2 are 3D vectors with x, y and z components.

The phase is given by

$$\phi = \left( 2\pi \frac{\|v1 - v2\|_2}{\lambda} \right) \bmod 2\pi \qquad \text{(Equation 1)}$$

where $\| \ \|_2$ is the standard Euclidean norm or distance function and mod is the modulo arithmetic operator and $\lambda$ is the wavelength of the acoustic wave. Alternatively, the phase parameters may not be computed modulo $2\pi$ but rather modulo $n2\pi$ where n is the maximum phase delay, in wavelengths, across elements of the array **260** when aiming at the farthest angular extent of region **305**. This is slightly more efficient and therefore preferred because the first cycle of the transmitted array will be targeted at the volume **302kl** whereas modulo $2\pi$ phase results in the first n cycles of the transmitted wave being out of focus.

**[0032]** Typically the x, y width of each volume **302kl** will be selected as the width of the narrowest acoustic beam that is possible from the array **260**. This minimal acoustic beam width $w$ is approximated by

$$w = \frac{\lambda}{D} r$$

where $\lambda$ is the wavelength of the acoustic wave, D is the lateral size of the array **260**, and r is the range or distance along the z axis from the array **260** to the volume **302kl**. Therefore, if the array **260** is rectangular, i.e., different lateral widths in the x and y dimension, then the minimal beam width and hence x and y dimensions of the volume **302kl** will be different. Also note that since the minimal acoustic beam width increases with range r, the volume **302kl** is in general wedge shaped, expanding in lateral dimension with increased range r. The acoustic beam itself tapers off from a center peak rather than ending abruptly therefore it is desirable for the volumes **302kl** to have some overlap, for example 50% overlap. This provides finer targeting of the receiver-stimulator and hence more efficient transfer of acoustic energy.

**[0033]** The maximum lateral width, W, of the interrogation region **305** is approximated by

$$W = \frac{\lambda}{d} r$$

where $\lambda$ is the wavelength of the acoustic wave, d is the lateral size of an individual array element **230i**, and r is the range or distance along the z axis from the array **260** to the volume **302kl**. Similar to the individual volumes **302kl** the entire scan region **305** has a wedge shape expanding out in lateral dimension with increasing range r.

**[0034]** If **305** lies entirely in the far field of the array **260** then depth or z focusing is not required and each volume **302kl** can be extended over the entire z depth of region **305**. However, if **305** overlaps with the near field transmission region of the phased array **260**, multiple layers of volumes **302kl, 303kl, etc.** must be scanned in the z dimension as well. Generally speaking, the boundary between the near and far field regions is given by

$$r = \frac{D^2}{4\lambda}$$

**[0035]** Of course, in situations where the possible target location region is either in the far field or moves only within a fixed focal zone, then scanning in the z dimension may not be required.

**[0036]** Another method for quickly and efficiently determining the required phasing for the elements of the transmit array in the controller-transmitter is described below. As described previously, the required phasing can be calculated; however, this is computationally expensive, which consumes valuable energy and time, particularly because it involves the calculation of a square root. One alternative is to pre-compute the required phases for each element **230ij** of the array **260** for each scan location **302kl**. This, however, quickly results in a significant amount of required memory. There is the additional burden of the time required to read the phases out of memory and load them into the phase shifter **240ij** for each of the array elements **230ij**. This time can be reduced by increasing the clock speed of the digital electronics in the controller-transmitter or paralleling the loading process.

**[0037]** Figure 4 describes how the required phases can be broken down into three separate components. The first two are phase gradients in the x and y direction. These are linear functions of the x and y location of the array elements and hence are relatively inexpensive to compute.

**[0038]** If the receiver-stimulator is very far away from the controller-transmitter only these first two components of the phase are required. However, if the receiver-stimulator is around the border region of the far-field of the array and certainly if it is within the near field, a third component shown as the pre-phasing component is required. This pre-phasing component is not a linear function of the position of the transmit element within the array and is therefore more expensive to compute.

**[0039]** The basic scheme is to calculate the pre-phasing component infrequently and to compute the linear component of the phases whenever the array needs to be steered to a new location. Several options exist for determining the pre-phasing component. One is to calculate the pre-phasing as the phase required to steer to a centered target (directly perpendicular, no off angle-steering) at a nominal expected range (distance) between the controller-transmitter and the receiver-stimulator. This can be done using the equation (Equation 1) shown above. The pre-phasing compensates for the fact that the receiver-stimulator is not strictly in the far-field, which is only true if it is infinitely far away from the controller-transmitter. If it were in the far-field the pre-phasing component would simply be zero, i.e., all elements in the array

transmitting with the same phase. These pre-phases can be calculated and stored in read-only memory (ROM) and downloaded as part of the manufacturing of the controller-transmitter or alternatively determined once when the controller-transmitter is implanted. The latter scheme has the advantage of more exact knowledge of the range between the controller-transmitter and receiver-stimulator.

**[0040]** The linear phase gradients can be computed by the control circuitry and then downloaded to each of the phase controllers **241ij** or the phase controllers can determine the linear phase components using either a look up table or dedicated computation circuitry.

**[0041]** Another alternative is to calculate the pre-phasing based on the nominal location of the receiver-stimulator (i.e., not just the range but also the angular location). This works well if the receiver-stimulator is located at a significant angle from perpendicular to the controller-transmitter. If there is not significant movement of the receive-stimulator relative to the controller-transmitter, the pre-phasing component only needs to be computed once saving significant computational overhead.

**[0042]** The electrical output produced through electrodes **155** as part of the scanning process may be considered a stimulation or pacing output, if sufficient energy is contained in the output to excite the tissue adjacent to electrodes **155**; however, it is not required that the tissue be stimulated to detect the electrical signal at electrodes **145**. In fact, it is advantageous for the electrical output to not be a stimulating pulse because the energy required to produce an electrical output that is detectable by electrodes **145** and detection circuits **241** is significantly lower than the energy required to stimulate tissue. This lower energy requirement is primarily achieved by shortening the duration of the locator signal and resulting electrical output at electrodes **155** to a value that is significantly below that used to stimulate tissue. For example, signal durations for cardiac tissue stimulation are in the range of 200μs to 2000μs, while typical durations are in the 400μs to 500μs range. The minimal duration of a locator signal is affected by various parameters: the operating frequency of the system, the Q of both transmitter and receiver transducers as well as the size of the transmit array and overall receiver structure if it contains multiple transducers. A minimal time of 10 cycles is a reasonable estimate. For an ultrasound system operating in the 500 kHz to 1MHz frequency range this sets the minimum locator signal duration at 10 to 20μs–at least 20 times shorter than the typical duration for tissue stimulation. This results in at least 20 times less

energy used for transmitting the locator signal than that used to stimulate the tissue, making this embodiment attractive.

**[0043]** Short duration locator signals require different detection circuits **241** than that used for conventional ECG processing or even pacing spike detection. ECG signals are typically processed with an amplifier bandwidth of 0.5 Hz to 100 Hz. Pacing spike detectors typically have a bandwidth of 1 kHz to 2.5 kHz. A 10-20μs electrical signal produced in response to 10-20μs locator signal requires a bandwidth of up to 100 kHz.

**[0044]** Research on both animal models and humans indicate that it is common to observe signal attenuation of 65-80dB for a pacing signal generated from within the heart and sensed on surface ECG electrodes. Therefore a 1 volt electrical pulse delivered across electrodes **155** would result in a 560 microvolt to 100 microvolt signal on electrodes **145**. State of the art amplifiers can achieve noise figures in the range of $20nV/(Hertz)^{1/2}$, resulting in noise on the order of 6 microvolts over a 100kHz bandwidth, resulting in a very reasonable signal to noise ratio for detection of a location signal. However, such high bandwidth, high gain amplifiers consume more power than conventional ECG amplifiers which are amplifying lower bandwidth higher amplitude signals. It is therefore advantageous to only turn on these amplifiers when they are required, i.e., immediately following transmission of acoustic locator signals.

**[0045]** Additionally it is important to note that the location signal is generated and sensed from two electrodes that are spatially close to each other. The positions of both, receiver-stimulator electrodes **155** and controller-transmitter electrodes **145**, are constrained by practical limitations. Hence, the electrical signal produced by electrodes **155** will have a dipole radiation pattern and the sensitivity of the electrodes **145** will have a dipole pattern as well. Figure 5a shows a typical dipole arrangement. Sensing electrodes **145** are input into a differential amplifier **410**. The dashed line **401** indicates a region, a "blind spot", where a signal source cannot be sensed by the electrodes **145**. This is because a signal source placed along this line is equidistant to both electrodes **145** and the differential amplifier subtracts these two equal signals producing a null output. Correspondingly, the dashed line **402** indicates a region where a signal source will be sensed with maximum output from the amplifier **410**. A similar behavior occurs as a result of the transmission of the electrical signal through electrodes **155**. Therefore, the overall attenuation will be the result of the superposition of two dipole patterns. In order to avoid potential "blind spots" in these dipole

patterns it is, therefore, advantageous to use more than two electrodes **145** on the controller-transmitter. Figure 5b shows how the addition of a third electrode eliminates the problem of this "blind spot". Two amplifiers **420a** and **420b** are used to amplify signals from two separate dipoles oriented 90 degrees apart. The two signal outputs, **242a** and **242b** of **420a** and **420b**, respectively, are then analyzed for the presence of the location signal. Even more improvements can be made by the addition of more electrodes that are spatially separated from the first three electrodes as shown in Figure 5c. This has the additional benefit of avoiding any "blind spots" in the dipole pattern generated by electrodes **155** at the receiver-stimulator. One electrode **146** is chosen as a reference and all other electrodes **145** are amplified relative to this reference using amplifiers **410i** each of which produces a signal **420i**. The dipole signal **244** from any pair of electrodes can then be calculated by taking the difference between two of the output signals **420i**, using **243** which can be implemented either as a hardware differential amplifier or in software as the subtraction of two digitized signals. As discussed above, the amplifiers **410i** are necessarily high bandwidth, high gain amplifiers and therefore consume significant power. Therefore, it is advantageous to only use those that provide the largest amplitude location signals. Assuming that the motion of the receiver-stimulator and controller-transmitter will significantly change the amplitude of the location signal, once the electrode pair that produces the largest location signal is determined, only the amplifiers used to produce this signal need to be used, significantly reducing power consumption.

**[0046]** An important consideration is the time taken to determine the location of the receiver-stimulator. Obviously, this time should be as short as possible. If this time is comparable to the cardiac cycle, then motion of the heart between determination of the location and subsequent delivery of stimulation energy becomes problematic. It is also advantageous to minimize the required scan time when the leadless stimulator is used concomitantly with a standard pacemaker to achieve therapeutic bi-ventricular pacing. In this case, as disclosed in pending application 11/315,023 (Attorney Docket No. 021834-000820US), the controller-transmitter transmits acoustic energy to stimulate the heart immediately following the detection of a right ventricular (RV) pacing artifact in the concomitantly implanted device. Preferably, the determination of the receiver-stimulator position is done after the detection of the RV pacing artifact so that the effect of cardiac motion between position determination and stimulation is minimized.

**[0047]** Figure 6 shows several methods for minimizing the required scan time. Figure 6a shows a partition of the space to be scanned into different target regions. The partition assumes there is no depth targeting and therefore the scan space is in the x-y plane at a fixed z location. The method can be easily extended to the case of depth targeting. The speed of sound in the soft tissue and blood is approximately 1.5 mm/μsec. Considering a large distance between the controller-transmitter and receiver-stimulator of 200 mm results in a maximum time of flight of approximately 133 μsec. Figure 6b shows a simple scan method where the time between locator signals, P, is chosen to be greater than the expected time of flight. A method for processing the output signal **244** is described as follows. Detection of the location signal **510**, following a locator signal **505**, indicates that the receiver-stimulator is contained in the volume corresponding to the locator signal **505** (volume 15 in Figure 6a). Furthermore, the time of flight which is proportional to the range between the controller-transmitter and the receiver-stimulator can be measured by the time delay between transmission of the locator signal and detection of the location signal.

**[0048]** Figure 6c demonstrates a faster scanning method. In this case, the time between transmit pulses (locator signals), P, is shorter than the actual time of flight and is limited only by the duration of each individual locator signal and the setup time for the controller-transmitter to prepare for the next locator signal. This results in multiple locator signals in flight simultaneously between the controller- transmitter and receiver-stimulator, considerably reducing the scanning time. Once a location signal is detected, determination of the actual locator signal that produced the location signal requires knowledge of the nominal time of flight between the controller-transmitter and receiver-stimulator as shown in Figure 6c. This optimized scheme is applicable if the previous location and hence time of flight to the receiver-stimulator is known and only small movements of the receiver-stimulator relative to the controller-transmitter are expected. The time between locator signals, P, can be set to the maximum expected range of motion. For example, if the maximum possible motion is 40 mm then P must be at least 40/1.5 or 27 μsec.

**[0049]** During initial operation, when the location of the receiver-stimulator and hence nominal time of flight is totally unknown, a hybrid technique as shown in Figure 6d can be used. A rapid scan of the entire region is performed using a technique similar to that shown in Figure 6c until a location signal is detected. Once a location signal is detected a slower scan similar to that shown in Figure 6b is performed for the volumes near the detected location

signal (starting with volume 13 then 14, etc.) This will pinpoint the exact volume (in this case 15) and allow back calculation of the actual time of flight.

**[0050]** In some cases, a longer duration between locator signals than that used in Figure 6b may be required. This can happen if there is sufficient acoustic energy from the locator signal is reflected off anatomical structures in the body and the receiver-stimulator responds to these reflected locator signals. Generally, this is handled by increasing the time between locator signals such that any reverberation or reflection from a previous locator signal has decayed before transmitting another locator signal. However, the likelihood of this problem occurring can be substantially reduced by prior knowledge of the nominal time of flight. This allows the controller-transmitter to look for a location signal over a narrow time window eliminating false detections due to reflected locator signals.

**[0051]** Another strategy for minimizing the scan time and the energy expended on the scan itself is to perform an intelligent search. One approach is to start the scan by transmitting a locator signal to the previous known position of the receiver-stimulator. Therefore, if the receiver-stimulator has not moved outside of the scan volume, only one locator signal is required. If more scanning is required, another strategy is to expand the search out from the last known position for the receiver-stimulator. Another approach is to remember the previous history of motion of the receiver-stimulator and use this to intelligently scan for it. This will greatly reduce the number of scans whenever the primary motion of the receiver-stimulator is periodic for example due primarily to cardiac and respiratory motion.

**[0052]** It should be noted that more than one receiver-stimulator could be implanted and operated using the different approaches described above for optimizing energy transmission. The location of each receiver-stimulator relative to other receiver-stimulators can be registered during the time of implantation. Following implantation, when the receiver-stimulators move due to cardiac motion, breathing, etc., they are likely to move in concert with each other. However, the relative location of the receiver-stimulators with respect to the controller-transmitter, which impacts the optimal energy transmission by the controller-transmitter, is likely to change due to cardiac motion, breathing, etc. To address this issue, if the location of the first receiver-stimulator is identified using one of the approaches described above, the location of the other receiver-stimulators is immediately computed, based on the relative location of the other receiver-stimulators that was registered during implantation.

**[0053]** Alternatively, each receiver-stimulator (when multiple receiver-stimulators are implanted) can be "addressed" using a locator signal with a unique frequency or phase. The approaches described earlier can then be used sequentially for each receiver-stimulator to optimize the energy transmission from the controller-transmitter. Or more simply, if multiple receiver-stimulators are implanted with sufficient difference in location, each could be located directly by the previously described methods, based on knowledge of previous location and the fact that relative locations between devices are unlikely to change significantly.

**[0054]** While the location signal has been detailed as an electrical signal it should be understood that the location signal may be of any nature that can be detected by a controller-transmitter. For example it could be a passive echo from the device or the receiver could be adapted to transmit an acoustic signal in response to the locator signal.

**[0055]** Another embodiment of the invention described here for optimizing energy transmission from a controller-transmitter is illustrated in Figures 7A-7C. In Fig. 7A, one element of the controller-transmitter array ("C-T Array") transmits a wide beam acoustic burst (locator signal), which is received by the receiver-stimulator ("R-S"). As the signal is being received in the receiver-stimulator, it is frequency shifted and retransmitted isotropically back to the controller-transmitter, as depicted in Fig. 7B. This retransmission occurs as the locator signal is being received by the receiver-stimulator. The location of the receiver-stimulator with respect to each element of the C-T array is recorded into the memory of the controller-transmitter as the detected phase received per channel. Then, at the clinically appropriate time, the controller-transmitter uses the recorded phase measurements to transmit acoustic energy as a focused beam to the receiver-stimulator to be delivered to electrodes for stimulation of tissue, as shown in Fig. 7C.

**[0056]** The amount of energy contained in the locator signal generated from a single element in the phase measurement mode described above may be substantially greater than that used for stimulation. However, because the correct phase measurements have been obtained, significantly less energy will be transmitted for the stimulation by the entire array than would have been required to achieve the same level of energy delivered to the tissue using a wide beam. Now each element of the array would transmit a focused beam that is much more efficient, compared to the wide beam each element would have transmitted in the absence of the correct phase measurement. Additionally, in the method described above,

phase measurements were obtained without additional computations, thus further minimizing the energy consumption.

**[0057]** Upon creation of the focused beam used for stimulation, not all elements of the array need necessarily be driven at the same amplitude. If one pathway or the other from the receiver-stimulator to the array of elements shows either more or less attenuation, this may be overcome by transmitting with either more or less energy, respectively, or by completely turning off severely impacted array elements. Further, it is well known in the art of array design, that aperture shading (lower amplitude emissions from the edges of the array) has the effect of flattening the acoustic beam, for a greater uniformity within the beam. This can also be accomplished, guided by pre-programmed computations in the controller-transmitter.

**[0058]** Additional aspects of the invention are described below. In one embodiment where no locator signal is required, the receiver-stimulator first receives acoustic energy from the controller-transmitter, stores part of the received energy and directs the rest to the tissue. The stored energy could be anywhere from 0 to 100%, and ideally about 5%, of the received energy. Based on a variable, fixed or periodic timeout within the receiver-stimulator, but before the next transmission of acoustic energy from the controller-transmitter, the stored energy is used by the receiver-stimulator to generate a location signal. The location signal may be an electrical signal, or it may be an acoustic transponder signal transmitted to the controller-transmitter, or a similar signal generated by the receiver-stimulator as a homing beacon to signal the location of the receiver-stimulator. The controller-transmitter receives the location signal and computes the location of the receiver-stimulator, using information, such as amplitude, phase, arrival time, or the like from the location signal. Having identified the location of the receiver-stimulator, the controller-transmitter is then able to focus the transmitted acoustic beam to the location or region of the receiver-stimulator and thereby transmit energy or exchange communication optimally.

**[0059]** Alternatively, the controller-transmitter transmits a locator signal in the form of sufficient acoustic energy to a passive receiver-stimulator that uses all the energy received to generate a location signal. In this embodiment the receiver-stimulator would be adapted to have a state machine that switches between using acoustic energy for location signals and using acoustic energy for functional purposes such as stimulation. The location signal is received by the controller-transmitter, which determines the location of the receiver-

stimulator based on signal characteristics contained in the location signal and then generates a focused beam that is targeted at the location or region of the receiver-stimulator.

**[0060]** As indicated above, it should be noted that the acoustic receiver of the present invention can function as a receiver-stimulator or a receiver-converter, where the receiver-converter can act as a diagnostic tool. While the examples illustrate the receiver-stimulator embodiments, the energy optimization techniques described above are equally applicable for a receiver-converter.

**[0061]** While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention, which is defined by the appended claims.

WHAT IS CLAIMED IS:

1. A system for focusing acoustic energy into a human body comprising:

an array of acoustic transducers configured to transmit acoustic energy into the body;

circuitry for focusing the acoustic energy at specific regions in the body;

an acoustic receiver adapted to receive the acoustic energy and convert the acoustic energy into electrical energy;

a pair of electrodes connected to the acoustic receiver and adapted to transfer the electrical energy to the body;

wherein the circuitry is further configured to detect the electrical energy transferred through the body by these electrodes to determine whether the acoustic energy is focused on the acoustic receiver.

2. A system for stimulating tissue comprising:

an implantable acoustic controller-transmitter comprising an array of acoustic transducers configured to transmit focused acoustic energy;

one or more implantable acoustic receiver-stimulators adapted to receive the acoustic energy and convert the acoustic energy into electrical energy;

wherein the receiver-stimulator further comprises two electrodes configured to be in electrical communication with the tissue; and the electrical energy is delivered between the two electrodes; and

wherein the controller-transmitter is configured to determine the location of one or more of the receiver-stimulators relative to the controller-transmitter so that the controller-transmitter can direct the focused acoustic energy to one or more of the receiver-stimulators.

3. A system for stimulating tissue comprising:

an implantable acoustic controller-transmitter comprising an array of acoustic transducers configured to transmit acoustic energy into the tissue;

one or more implantable acoustic receiver-stimulators adapted to receive the acoustic energy and convert the acoustic energy into electrical energy; and

a first electrode assembly connected to the receiver-stimulator so as to receive the electrical energy and adapted to be in electrical communication with the tissue,

wherein the controller-transmitter is configured to transmit an acoustic locator signal towards the receiver-stimulator, and the receiver-stimulator is configured to generate a location signal in response to the locator signal.

4. The system of claim 3, wherein the controller-transmitter is further configured to detect the location signal; and the transducer array is configured to sequentially steer the acoustic beam to transmit the locator signal to regions of the tissue until the location signal is detected or a preset time limit has been reached.

5. The system of claim 4, wherein the transducer array is configured to transmit the locator signal as a focused acoustic beam.

6. The system of claim 4, wherein the controller-transmitter is further configured to adjust the transducer array to transmit focused acoustic energy to the region of the tissue associated with detecting the location signal.

7. The system of claim 6, wherein the acoustic energy is sufficient to stimulate tissue.

8. The system of claim 7, wherein the tissue is cardiac tissue.

9. The system of claim 3, wherein the location signal is an electrical output applied to the first electrode assembly.

10. The system of claim 9, further comprising a sensing circuit, and a second electrode assembly adapted to be in electrical communication with the body, wherein the location signal is detected by the sensing circuit.

11. The system of claim 10, wherein the sensing circuit and the second electrode assembly are located on the implantable controller-transmitter.

12. The system of claim 10, wherein the sensing circuit is located on a separate implantable device.

13. The system of claim 10, wherein the sensing circuit and the second electrode assembly are located on a device with the second electrode assembly in electrical communication with the external surface of the body.

14. The system of claim 10, wherein the sensing circuit is a spike detector circuit.

15. The system of claim 10, wherein the sensing circuit and the second electrode assembly comprise a spike detector assembly on the implantable controller-transmitter.

16. The system of claim 10, wherein the locator signal is focused acoustic energy and the detected electrical output indicates that the transducer array is focused on the receiver-stimulator.

17. The system of claim 15, comprising circuitry configured to characterize the electrical output detected by the spike detector assembly using one or more parameters including amplitude and polarity to determine the location of the receiver-stimulator; and adjust the transducer array based on the parameters to focus acoustic energy towards the receiver-stimulator.

18. The system of claim 17, wherein optimal energy transmission is indicated by the electrical output being above a pre-determined threshold or detection within a pre-determined time frame.

19. The system of claim 18, wherein the transducer array is further sequentially adjusted to transmit focused acoustic energy as locator signals towards a sequence of regions of the tissue and the detection of the electrical output by the spike detector assembly following any one of the transmissions indicates that the acoustic energy is focused on the receiver-stimulator.

20. The system of claim 18, wherein the electrical output is less than the amplitude required to stimulate tissue, and wherein the tissue is cardiac tissue.

21. The system of claim 18, wherein the electrical output is sufficient to stimulate tissue, and wherein the tissue is cardiac tissue.

22. A system for efficiently transferring acoustic energy comprising:

an implantable acoustic controller-transmitter comprising an acoustic transducer array configured to transmit acoustic energy into tissue;

an implantable acoustic receiver-converter adapted to receive the acoustic energy and convert the acoustic energy to electrical energy, wherein the controller-transmitter is configured to transmit an acoustic locator signal towards the receiver-converter, and the receiver-converter is configured to generate a location signal in response to the locator signal.

23. The system of claim 22, wherein the transducer array is configured to transmit a wide beam acoustic locator signal.

24. The system of claim 22, wherein the transducer array is configured to sequentially transmit focused acoustic locator signals until the receiver-converter generates a location signal or a preset time limit has been reached.

25. The system of claim 22, wherein the location signal is an electrical output, wherein the electrical output is detected by a sensing circuit which uses an electrode assembly adapted to be in electrical communication with tissue.

26. The system of claim 22, wherein the receiver-converter is adapted to generate an acoustic output and the location signal is an acoustic transmission.

27. The system of claim 24, wherein the focused acoustic energy is transmitted by the controller-transmitter, converted to electrical energy by the receiver-converter; and the receiver-converter is adapted to store the electrical energy.

28. The system of claim 24, wherein the focused acoustic energy is transmitted by the controller-transmitter; converted to electrical energy by the receiver-converter; and the receiver-converter is adapted to use the electrical energy to operate one or more of control circuitry, diagnostic sensing circuitry, and communication circuitry.

29. The system of claim 28, wherein the receiver-converter is further adapted to transmit sensed diagnostic data.

30. A system for stimulating tissue comprising: an implantable acoustic controller-transmitter comprising an acoustic transducer array adapted to transmit acoustic energy into tissue; and an implantable acoustic receiver-stimulator which receives acoustic energy and converts the acoustic energy to electrical energy and which has a first electrode assembly connected to the receiver-stimulator and adapted to be in electrical communication

with the tissue, wherein the receiver-stimulator periodically transmits a location signal, and wherein the controller-transmitter detects the location signal.

31. The system of claim 30, wherein the location signal is an electrical output, wherein the electrical output is detected by a sensing circuit which uses a second electrode assembly adapted to be in electrical communication with tissue.

32. The system of claim 30, wherein the receiver-stimulator is adapted to generate an acoustic output and the location signal is an acoustic transmission.

33. The system of claim 30, wherein the transducer array is adjusted using electrical drive signals to transmit focused acoustic energy towards the receiver-stimulator based on the characteristics of the location signal that is detected by the controller-transmitter.

34. The system of claim 33, wherein the focused energy is at sufficient levels to stimulate cardiac tissue.

35. The system of claim 33, wherein the electrical drive signals to the transducer array is adjusted based on one or more parameters including frequency, duration, amplitude, phase, and time of flight of the location signal to transmit focused acoustic energy towards the receiver-stimulator.

36. A method for optimizing acoustic energy transmission in tissue between an implantable controller-transmitter and one or more implantable receiver-stimulators comprising:

transmitting an acoustic locator signal from the controller-transmitter towards the receiver-stimulator, wherein the controller-transmitter comprises an adjustable transducer array; and

generating a location signal from the receiver-stimulator in response to receiving the locator signal.

37. The method of claim 36 further comprising detecting the location signal using the controller-transmitter; and adjusting the transducer array to transmit focused acoustic energy towards the receiver-stimulator.

38. The method of claim 36 comprising adjusting the transducer array sequentially to transmit focused locator signals to regions of the tissue until the receiver-stimulator location signal is detected by the controller-transmitter or a pre-set time limit has been reached; and adjusting the transducer array to transmit focused acoustic energy to the region associated with the detected location signal.

39. The method of claim 36, further comprising adjusting the transducer array to transmit a wide beam acoustic locator signal.

40. The method of claim 36, wherein the location signal is an electrical output and further detecting the electrical output using a sensing circuit.

41. The method of claim 36, wherein the location signal is an acoustic output.

42. The method of claim 36, further comprising:
detecting the location signal using the controller-transmitter;
adjusting the transducer array based on the location signal; and
transmitting focused acoustic energy towards the receiver-stimulator.

43. The method of claim 38, wherein the receiver-stimulator is adapted with a first electrode assembly and the electrode assembly is in electrical communication with the tissue, further comprising:
converting the acoustic energy using the receiver-stimulator, and
applying the converted energy to the first electrode assembly.

44. The method of claim 43, further comprising stimulating the tissue.

45. The method of claim 44, where the tissue is cardiac tissue.

46. The method of claim 37, further comprising:
characterizing the location signal using one or more characteristics of the location signal including frequency, duration, amplitude, phase, and time of flight;
determining a region of the tissue containing the receiver-stimulator based on the location signal;

adjusting the transducer array toward the receiver-stimulator based on the location signal; and

transmitting operationally efficient acoustic energy towards the receiver-stimulator.

47. The system of claim 1, wherein the circuitry further comprises one or more pairs of electrodes that are configured to determine whether the acoustic energy is focused on the acoustic receiver.

48. The system of claim 47, wherein the circuitry is further configured for sequentially transmitting the acoustic energy.

49. The system of claim 5, wherein the controller-transmitter is further configured to adjust the transducer array to transmit focused acoustic energy to the region of the tissue associated with detecting the location signal.

50. The system of claim 49, wherein the acoustic energy is sufficient to stimulate tissue.

51. The system of claim 50, wherein the tissue is cardiac tissue.

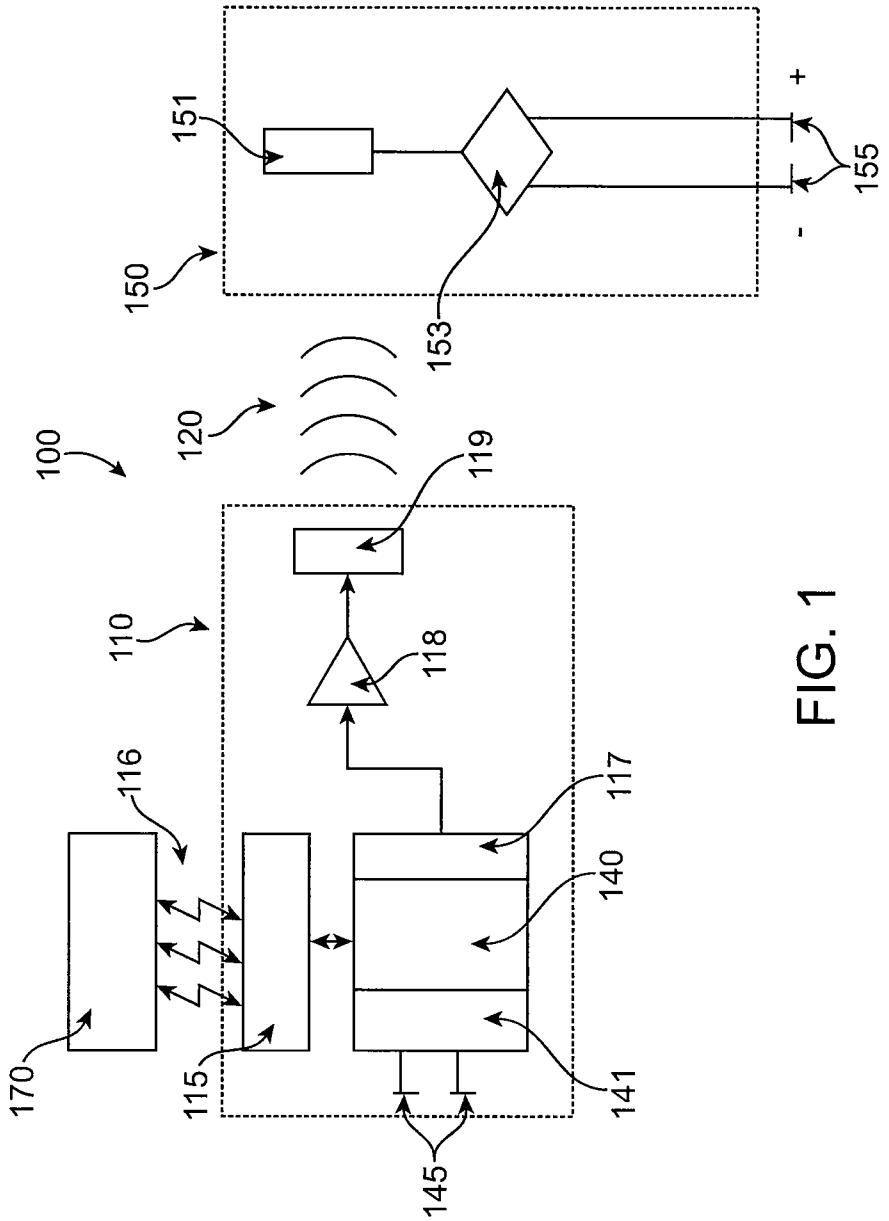
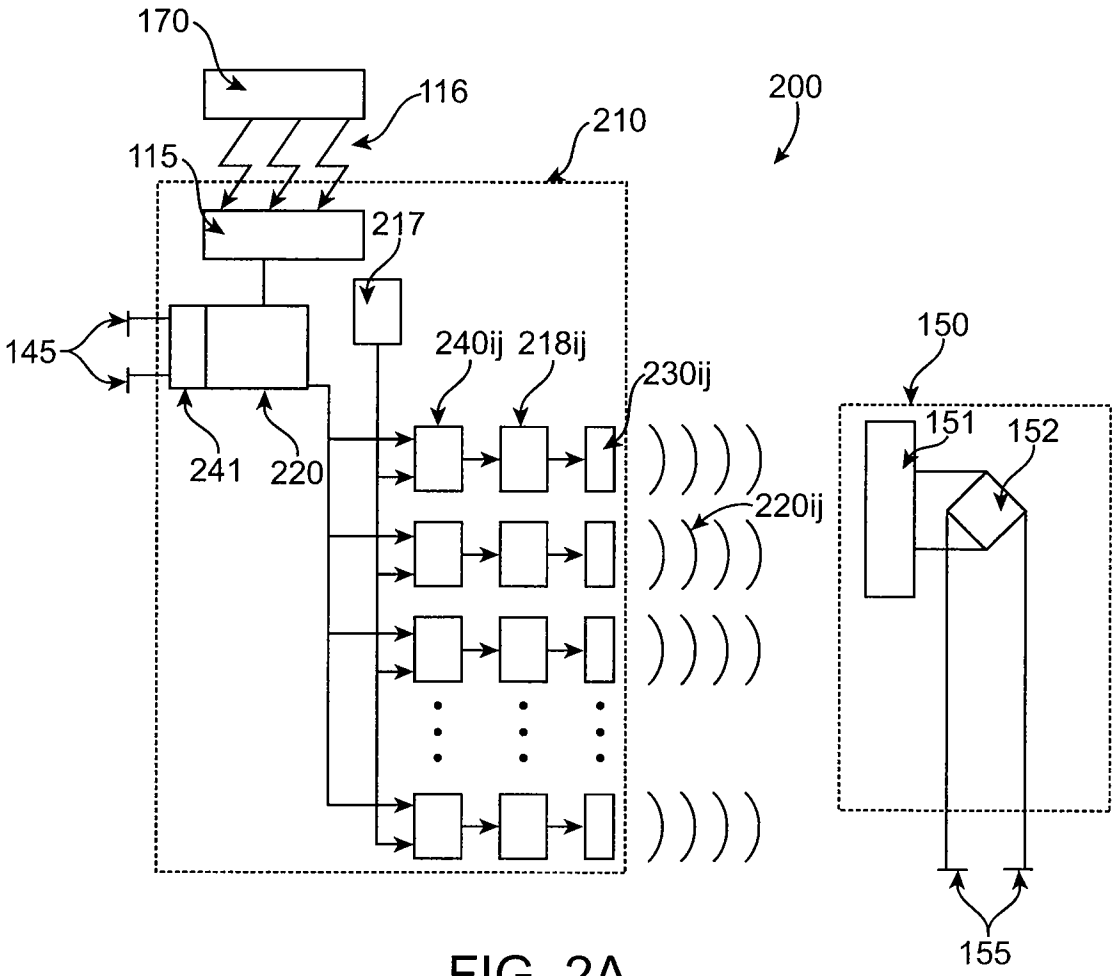



FIG. 1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220
220ij
155

FIG. 2A

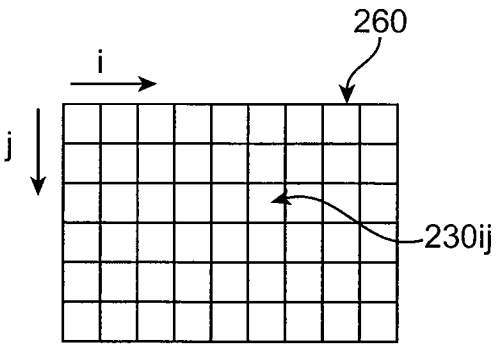
260
i
j
230ij

FIG. 2B

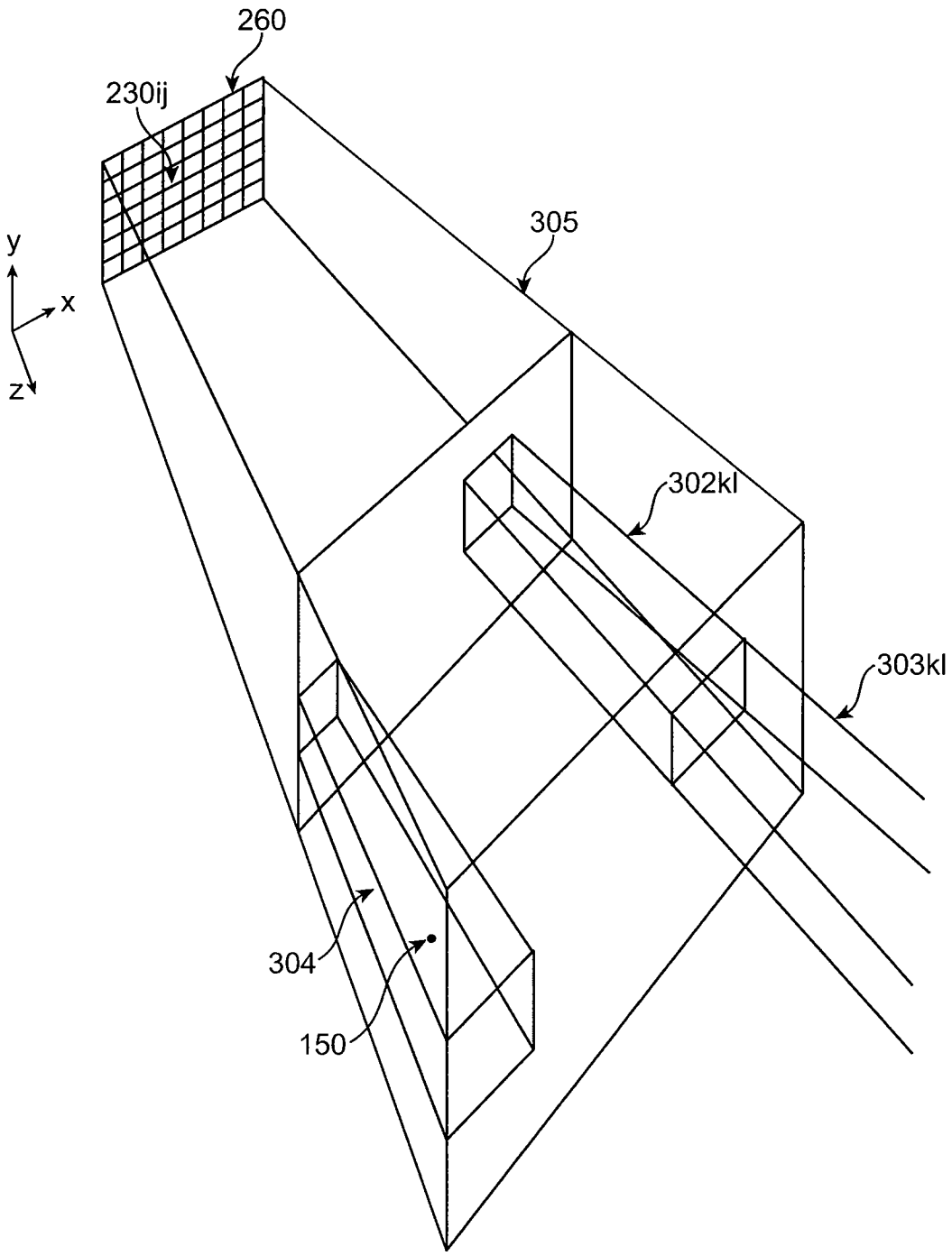


FIG. 3

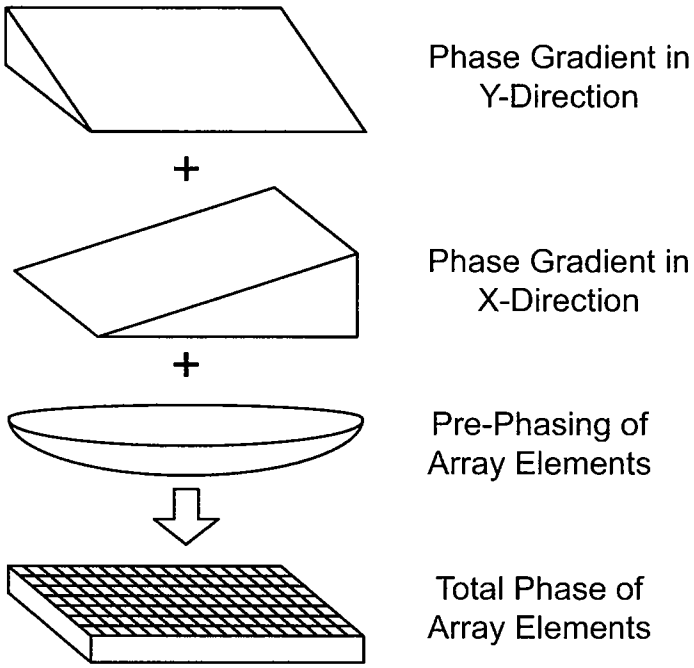
Phase Gradient in
Y-Direction
+
Phase Gradient in
X-Direction
+
Pre-Phasing of
Array Elements
Total Phase of
Array Elements

FIG. 4

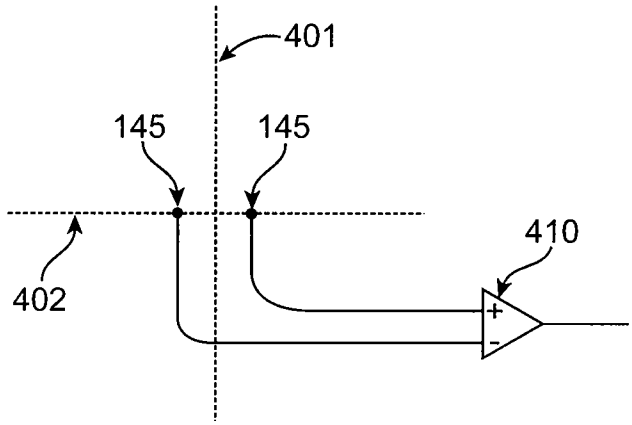


FIG. 5A

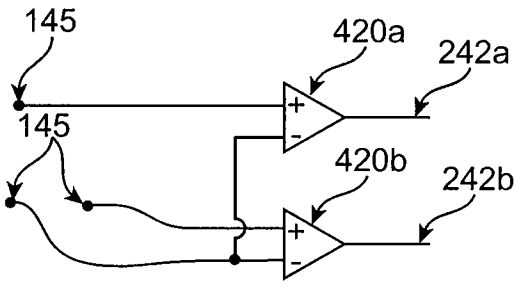


FIG. 5B

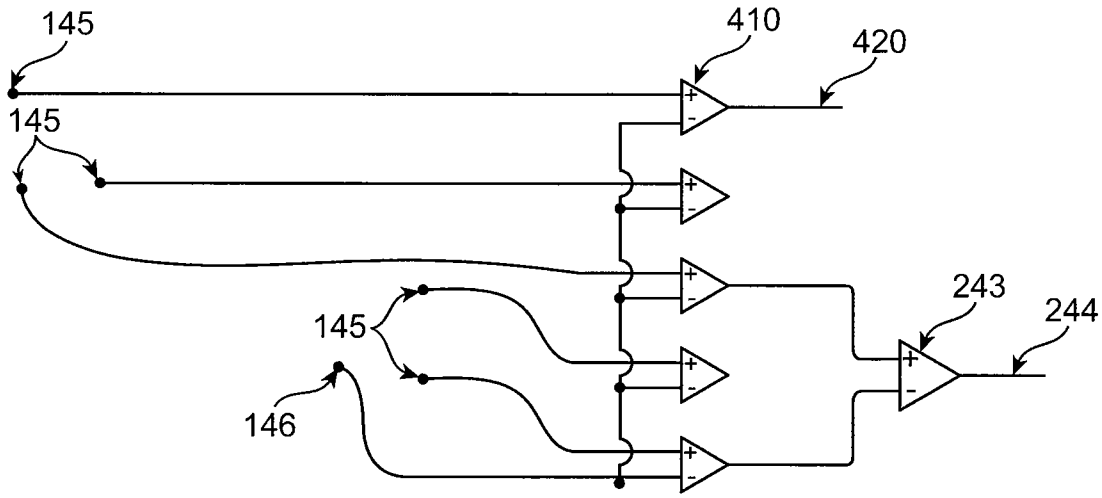


FIG. 5C

Partition of space to be scanned

| | | | | |
|---|---|---|---|---|
| 1 | 2 | 3 | 4 | 5 |
| 6 | 7 | 8 | 9 | 10 |
| 11 | 12 | 13 | 14 | 15 |
| 16 | 17 | 18 | 19 | 20 |

FIG. 6A

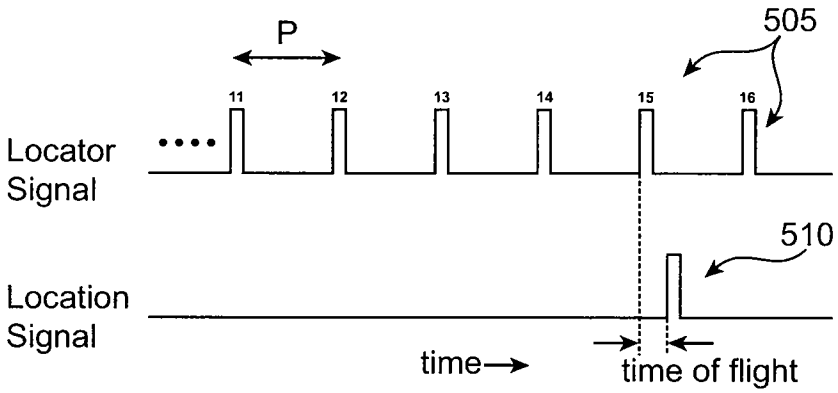


FIG. 6B

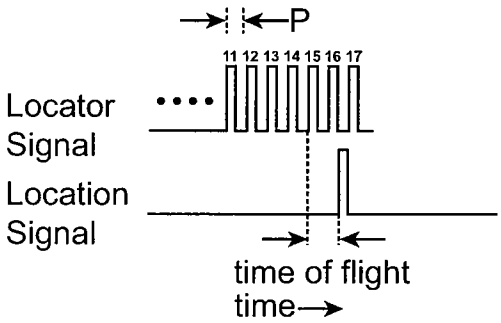


FIG. 6C

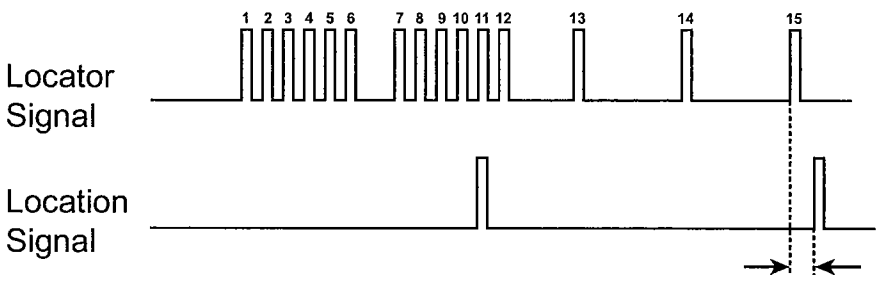


FIG. 6D

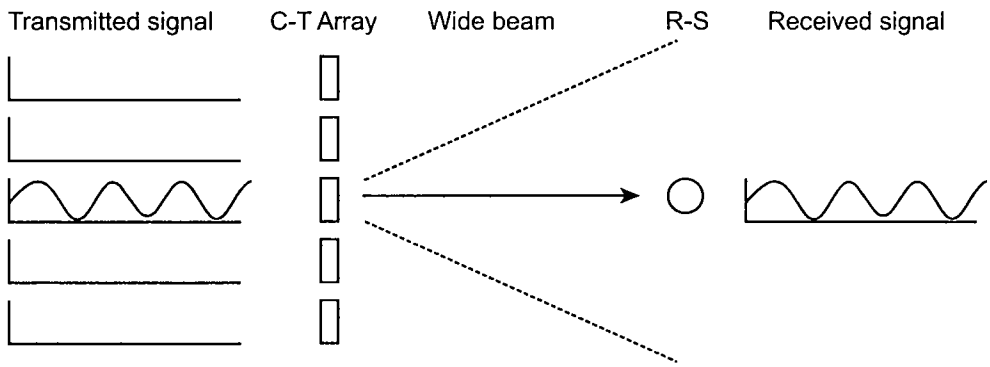


FIG. 7A

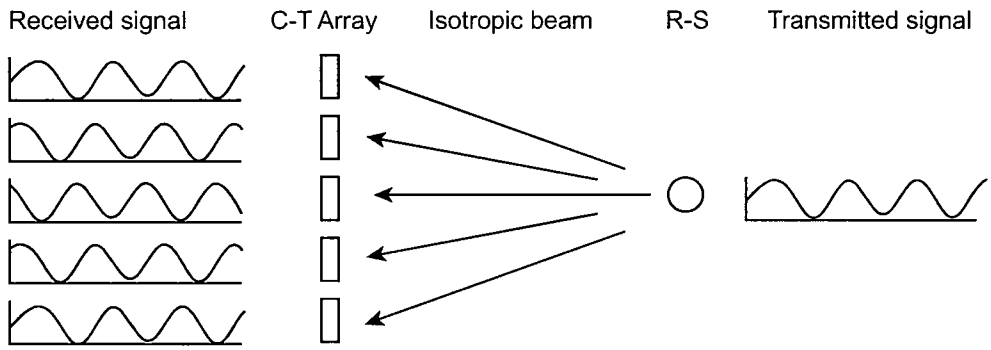


FIG. 7B

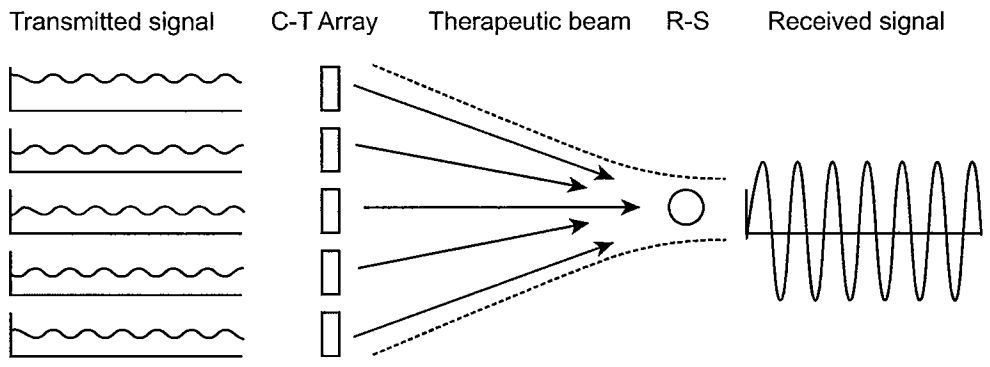


FIG. 7C

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US08/63669

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61H 01/00 (2008.04)
USPC - 601/46
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)
IPC(8) - A61H 01/00 (2008.04)
USPC - 601/46

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
MicroPatent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X<br>---<br>Y | US 2006/0136004 A1 (COWAN et al) 22 June 2006 (22.06.2006) see whole document | 1-22, 24-38, 40-51<br>---<br>23, 39 |
| Y | US 2004/0260214 A1 (ECHT et al) 23 December 2004 (23.12.2004) see whole document | 23, 39 |

☐ Further documents are listed in the continuation of Box C. ☐

* Special categories of cited documents:
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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"&" document member of the same patent family

| Date of the actual completion of the international search | Date of mailing of the international search report |
|---|---|
| 30 June 2008 | 17 JUL 2008 |
| Name and mailing address of the ISA/US<br>Mail Stop PCT, Attn: ISA/US, Commissioner for Patents<br>P.O. Box 1450, Alexandria, Virginia 22313-1450<br>Facsimile No. 571-273-3201 | Authorized officer:<br>Blaine R. Copenheaver<br>PCT Helpdesk: 571-272-4300<br>PCT OSP: 571-272-7774 |

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