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(54) SYSTEM FOR CONTROL AND MONITORING OF CONFORMAL THERMAL THERAPY

SYSTEM ZUR STEUERUNG UND ÜBERWACHUNG EINER KONFORMEN WÄRMETHERAPIE

SYSTÈME DE COMMANDE ET DE SURVEILLANCE D'UNE THERMOTHÉRAPIE

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Description

Technical Field

[0001] The present application relates to ultrasound therapy systems, and particularly to the operation of an array of ultrasound sources for use in such systems. More specifically, the present system and method is directed to control and monitoring of conformal thermal therapy procedures using active ultrasonic heating elements placed in a region of diseased tissue.

Related Applications

[0002] This application claims the benefit and priority of U.S. Provisional Application 61/538,982, entitled "System and Method for Control and Monitoring of Ultrasound Thermal Therapy," filed on Sept. 26, 2011.

Background

[0003] Ultrasonic transducers have been employed in ultrasound therapy systems to achieve therapeutic heating of diseased and other tissues. Arrays of ultrasound transducers operating to form a beam of ultrasonic energy cause a conversion of sound to thermal energy in the affected tissue areas or treatment volumes, and a subsequent beneficial rise in the temperature in the treatment volumes.

[0004] In image-guided ultrasound therapy systems, a patient and the ultrasound therapy apparatus are generally disposed in an imaging volume such as a magnetic resonance imaging (MRI) apparatus, which allows guidance of the applicator placement, and in addition allows monitoring of the treatment effect on the tissue by providing real-time data from which temperature maps can be calculated. A clinical operator can then monitor the progress of the therapy within the treatment volume or diseased tissue and manual or automated changes can be made to the ultrasound power signals based on input from the results and progress of the treatment. With proper monitoring of the heating effect, ultrasound therapy systems can be used to treat harmful cells and to controllably destroy tumors.

[0005] The temperature created by the absorption of sound in a sound-conducting medium is not uniform. When the acoustic field is not generally focused, the temperature rise is highest close to the source of sound and it decreases with distance from the source. The sound created by a piston-shaped transducer is highly directional. As such there will be an increase in temperature along the line perpendicular to the center of the face of the piston with only small increases in temperature in the volumes adjacent to that perpendicular line. The resultant shape of thermal energy deposition is similar to the flame from a match with a narrow tip and being slightly wider at the base.

[0006] In any material, local temperature differences

gradually disappear due to heat transfer from areas of high temperature to areas of lower temperature. In live tissue thermal diffusion and blood circulation are two of the main mechanisms by which heat transfer take place. If there is an area of increased temperature in tissue, these heat transfer phenomena work to reduce the peak temperature and increase the surrounding tissue temperature.

[0007] Work has been done to demonstrate the use of magnetic resonance imaging (MRI) guided transurethral ultrasound therapy systems for treatment of disease such as prostate cancer in men. See, e.g., Chopra, et al., "MRI-compatible transurethral ultrasound system for the treatment of localized prostate cancer using rotational control," Med Phys 35(4):1346-1357, 2008. Also see, U.S. Pub. 2007/0239062; U.S. Pat. 6,589,174 "Technique and apparatus for ultrasound therapy," 2003; U.S. Pat. 7,771,418 "Treatment of diseased tissue using controlled ultrasonic heating," 2010. Such systems, including cumulative published and patented work by or for the present applicant, all of which are hereby incorporated by reference, teach the use of transurethral ultrasonic energy to the diseased prostate to reach a desired target temperature in the diseased tissue to achieve the clinical result, which is usually the necrosis of the diseased tissue cells in the prostate. MRI guidance and temperature monitoring of the treatment in realtime enables control of the power to the ultrasound therapy transducers as well as control of the rotation of an array of such transducers disposed axially along an elongated applicator inserted into the patient's urethra in the vicinity of the diseased prostate.

[0008] It is understood that it is necessary to control the operation of such systems in use, as uncontrolled, or poorly controlled, operations can lead to unwanted injury to the patient through overheating the patient's tissue or applying the heat treatment to organs and tissues that should not be treated. See, e.g., U.S. Pub. 2007/0239062 "Method and apparatus for obtaining quantitative temperature measurements in prostate and other tissue undergoing thermal therapy treatment," 2007; U.S. Pub. 2006/0206105 "Treatment of diseased tissue using controlled ultrasonic heating," 2006.

[0009] One concern relates to the obvious harm of unwanted cell death from overheating healthy or critical organ tissue in the context of prostate treatment. Another concern relates to acoustic factors that can degrade or impede the operation of the therapy system if tissue proximal to the therapy system operated in a way that causes boiling (approximately 100 Celsius) or cavitation (formation of gas voids in the tissue) in the tissue. These effects may be beneficial or desired in some contexts, addressed elsewhere, but for the present purpose, unless stated otherwise, the preferred embodiments below rely on temperature control rather than mechanical, boiling, cavitation or other effects to achieve their desired result. These concerns are recognized but not suitably or perfectly solved for all situations in the presently-cited and similar

references in the field.

[0010] Still other work has been published describing the real and simulated effects of ultrasound thermal therapy systems. See, e.g., Burtnyk et al., "Quantitative analysis of 3-D conformal MRI-guided transurethral ultrasound therapy of the prostate: theoretical simulations," *Int J Hyperthermia* 25(2): 116-131, 2009; Burtnyk et al., "Simulation study on the heating of the surrounding anatomy during transurethral prostate therapy: A 3-D theoretical analysis of patient safety," *Med Phys* 37(6): 2862-2875, 2010. Again, the above and similar efforts indicate a recognition of the need to control, measure, predict and otherwise understand the effects of conformal thermal therapy systems.

[0011] U.S. Patent Application Publication No. 2007/0239062 discloses a method for obtaining quantitative temperature measurements in prostate and other tissue undergoing thermal therapy treatment. The method includes acquiring a reference image of a volume containing the diseased tissue, determining a baseline temperature distribution of the reference image, acquiring an image of the volume containing the diseased tissue while delivering a treatment to the volume, performing a phase subtraction between the image and the reference image to determine a change in phase and determining a current spatial temperature distribution in the volume containing the diseased tissue.

[0012] International Patent Application Publication No. WO 2011/091847 discloses a method and an apparatus of predicting or planning a temperature distribution in a body. The method comprises the steps of: a) obtaining a model of the body related to a temperature transport mechanism or temperature distribution in the body; b) simulating an application of heat to at least a part of the body such as targeted tissue; c) determining and/or predicting the temperature or heat distribution in at least a part of the body using the model of the body.

[0013] Yet another aspect of conformal thermal therapy treatment is that of time-dependence and the three-dimensional nature of heat conduction and diffusion. If a thermal treatment leads to a certain temperature next to a target boundary in the treatment zone, it is possible for the target temperature at the target boundary to be exceeded by heat transfer from an adjacent area with higher temperature.

[0014] The present disclosure and inventions address, among other aspects, the above issues and cover systems and methods for better thermal treatment in patients suffering from disease such as prostate cancer.

Summary

[0015] The invention relates to a system for treating a prostate, wherein the system has the features specified in the independent claim 1. Preferred embodiments are subject-matters of the dependent claims.

[0016] In particular, the present disclosure comprises a system for treating a prostate, the system comprising

an ultrasonic thermal therapy applicator in the form of an elongated cylindrical applicator sized and shaped for insertion into a male patient's urethra so as to be able to reach at least partially into a prostate of said patient; a controllable motor and mechanical driver assembly coupled to said applicator so as to cause the elongated cylindrical applicator to rotate about an axis thereof within the patient's urethra; a plurality of transducer elements in said applicator, each being controllably driven by an electrical driving signal and having an active surface and capable of generating an acoustic radiation field emanating radially outwardly from its active surface into said prostate; a thermometry module receiving data from an imaging system and executing instructions in a processor to determine a current temperature distribution map within said prostate; a temperature prediction module receiving said current temperature distribution map as data, and using programmed thermal response model instructions, generating data representative of a future temperature distribution within said prostate; and a controller receiving at least said future temperature distribution, comparing said future temperature distribution to an indicated reference temperature at least in some region within said prostate, and modifying the controllable electrical driving signals to said plurality of transducer elements in said applicator, so that the system is configured to carry out a substantially real-time feed forward predictive control to an energy output of the therapy applicator.

[0017] Embodiments hereof are directed to systems for improving the outcome of ultrasound ablation in patients. In some respects, the present disclosure provides a method, that is not part of the invention, of predicting the temperature of tissue affected by the ultrasound beam and heat transfer within the tissue, and using the prediction to control the treatment and the parameters of the ablation.

[0018] Some embodiments are directed to ultrasound ablation in the prostate gland using an elongated ultrasound therapy device inserted into the urethra of a patient. The device typically includes a plurality of ultrasonic elements disposed within said elongated portion. Once the device has been inserted, it can be programmably rotated within the urethra and deliver ultrasonic energy of variable intensity into the prostate.

[0019] In some aspects, the present method, that is not part of the invention, and system improve the performance of ultrasound ablative treatment by tackling the potential problem of treating certain difficult axial shapes of treatment volume. In one embodiment simulations of thermal diffusion and/or perfusion around treated tissue are used in real

time to determine whether treatment should continue. In another embodiment, such heat transfer calculations are combined with predictions of ultrasonic heat deposition in order to make this decision. In a further embodiment, these calculations can be utilized for making decisions about how to proceed with therapy, for example but not limited to, what settings to use for power and rotation

angle in the treatment.

[0020] Still other aspects are directed to conformal thermal therapy of diseased target volumes where the energy source device is located outside the target volumes as is done in FUS and HIFU therapies. The time-predictive features below will enable more precise and safer thermal treatments in these applications.

[0021] The aforementioned calculations and simulations can also be used in the treatment planning stage before ultrasound therapy commences.

Brief Description of the Drawings

[0022] For a fuller understanding of the nature and advantages of the present invention, reference is made to the following detailed description of preferred embodiments and in connection with the accompanying drawings, in which:

Fig. 1 illustrates a control scheme for an image guided thermal therapy process;

Fig. 2 illustrates a snapshot of the active heating of a target volume at time $t=t_0$;

Fig. 3 illustrates another snapshot, sometime after that of the previous figure, at $t=t_1$;

Fig. 4 shows a flowchart of one embodiment of the invention, in which treatment is halted and the treatment plan reevaluated if the temperature is predicted to exceed the target temperature at the control point due to heat transfer;

Fig. 5 shows a flowchart of another embodiment in which treatment is halted and the treatment plan is reevaluated if a combination of the heat transfer calculations and predictions of the next energy deposition step would cause the target temperature to be exceeded;

Fig. 6 shows a flowchart of a further embodiment in which parameters of the next ultrasonic energy emission, such as rotation rate and amplitude, are modified according to predictive calculations that incorporate heat transfer and the effect of said energy deposition;

Fig. 7 illustrates an exemplary block diagram of a thermal therapy system according to one or more of the present embodiments;

Fig. 8 illustrates a geometry that can be used in describing the conformal heating therapy within a control zone and control point(s) thereof;

Fig. 9 illustrates key radial points used in describing the present system and process;

Fig. 10 illustrates a radial temperature profile from the present treatments;

Figs. 11 and 12 illustrate exemplary decision paths in a method for controlling a thermal therapy device that includes monitoring and time-predictive aspects from one or more control points near a target volume boundary; and

Fig. 13 illustrates a thermal therapy such as FUS or

HIFU where the source of the energy is placed outside the diseased target volume.

Detailed Description

[0023] As discussed above, better ultrasound thermal therapy applicators can improve treatment of diseases such as tumors, and for example as used in transurethral treatment of prostate cancers in male patients.

[0024] Traditional treatment using ultrasound thermal therapy typically employs one or more temperature control points along the target boundary as discussed in some of the references listed above. Safer and more effective treatments are enabled using the present system. Since temperature at the control points will increase due to the deposited/absorbed energy of the ultrasound, care must be exercised to not exceed a maximum temperature and/or thermal dose within healthy tissues or organs proximal to the location to which the thermal therapy is being applied. Nerve and vascular and other healthy organs and tissues can become damaged if the thermal therapy is applied at either the wrong locations or if the therapy exceeds a safe energy level or duration. The determination of the appropriate energy levels and other parameters for the therapy are the subject of studies and surgical planning processes, which are sometimes aided by computer simulations so as to approximate a therapy routine before subjecting a patient thereto.

[0025] Fig. 1 illustrates a basic control method 10, that is not part of the invention, for obtaining a desired temperature at a control point in a region of interest undergoing thermal therapy treatment. A desired target temperature is input into the therapy system or process, which can include hardware, executable instructions, program code and stored data. A controller 102 is used to generate control signals according to the desired target temperature and deliver the control signals to treatment hardware 104. The output of the treatment hardware 104 affects the actual temperature at the control point, which is generally a function of time. That is, the actual temperature is generally influenced by the action of the treatment hardware 104 and changes in time. As mentioned, MRI thermometry is used to generate temperature maps 106, substantially in realtime according to some embodiments, though a delay for imaging and processing is allowable. The mapping of the MRI imaging to temperature maps 106 is fed back into the loop 100 so as to inform controller 102 and adjust the control signals to treatment hardware 104 in the subsequent steps of the treatment. This general method 10 is followed until the treatment's goals are satisfied (e.g., a given temperature is reached in the treatment region) or an alarm or other action interrupts the process.

[0026] Fig. 2 illustrates a cross section of a prostate 20 undergoing thermal therapy and shown at some instant in time t_0 . The prostate 20 has an organ boundary 200. The therapy can be prescribed to be applied to a portion of the prostate 20 or to the entirety of the prostate

20. In some embodiments, to avoid unwanted heating outside the prostate, a treatment boundary may be defined, for example in a treatment planning step prior to or during application of the thermal therapy treatment. In an embodiment, a treatment zone is defined to be that substantially within a general treatment target boundary 202 outlining a sub-region of the entirety of prostate 20. This treatment volume, zone or region boundary 202 may be drawn by an operator using a user interface to the image guided therapy system and software. The target boundary 202 may alternatively be computed automatically using computer software and algorithms for detection of the diseased region and calculation of a safe sub-region requiring thermal therapy. A combination of human and machine detection and determination of the treatment target boundary 202 is also possible. In other embodiments, thermal treatment may target substantially the entire volume of the patient's prostate.

[0027] As mentioned herein and in related references, an elongated transurethral prostate therapy applicator 206 is inserted longitudinally into the patient's prostate and into a space within the prostate 20 so as to perform conformal thermal therapy using the applicator. As described, the thermal therapy applicator is rotated about its axis using a computer-controlled motor as described in earlier patents and applications, including: U.S. Pats. 6,589,174; 7,771,418; U.S. Pubs. 2007/0239062; 2011/0034833; U.S. Pat. Appl. Nos. 12/932,914; 12/932,923; 12/932,920; and 13/065, 106.

[0028] As represented in the figure, and according to certain designs of applicator 206, the thermal therapy (e.g., ultrasound energy) is directionally emitted from an active face of applicator 206. Here, a flame-shaped profile or zone 208 represents the general emission (and deposition) of energy into the prostate tissue at a given moment during the treatment. During treatment, ultrasonic energy is transmitted from the active face of the transducer elements of applicator 206 into the diseased tissue proximal to and in the path of the heating zone 208. The extent to which heating profile 208 extends into the patient depends on a number of physical factors including: the power applied to the transducer elements of applicator 206, the composition of the intervening tissue of prostate 20 such as its thermal conductivity, the operating frequencies of the transducer element, perfusion (cooling by heat removal through vascular blood flow), nonlinear effects, and other factors. The heating in lobe 208 tapers off near the edges of treatment lobe 208, and as such, this zone is defined by the manner in which the user chooses to measure it. But in any case, it is generally shaped and extends according to the factors given above. Therefore, a general depth or radius of thermal treatment can be described or quantified, which may be time-dependent as explained further below.

[0029] Therefore, the extent of the treatment radius or length of treatment zone 208 defines a control point 209 associated with the intersection of treatment zone 208 and the target boundary 202 of the volume undergoing

treatment. This can be described in terms of the distance from the center of applicator 206 which is clinically affected by the applied heating energy of the applicator device.

[0030] The therapy applicator 206 is made to rotate about its central axis so as to sweep through the desired treatment volume defined by a treatment boundary 202. The rotation 207 is performed at a predetermined, calculated, planned, or dynamic rotation rate during the therapy process. In the shown example, the applicator 206 rotates in a clockwise direction 207 as seen in this cross sectional slice. Therefore the direction of the treatment zone lobe 208 and control point 209 at any given moment would depend on the angular position of applicator 206. The patient and prostate 20 are spatially at rest or fixed in the laboratory/clinical frame of reference. The slower the rate of rotation 207, the longer the applicator's active surface dwells at or around an angular position and the greater the accumulated thermal dose and heating of the target tissue along zone 208 and at control point 209.

[0031] Fig. 3 illustrates a progression of the prostate treatment of the previous figure at a somewhat later time t1. Continuing its clockwise rotation about its axis, applicator 206 has progressed at t1 to a new angular position (discretely or continuously) so that at the snapshot illustrated its active heating energy lobe 308 is applied downwards as shown and in a direction where the prostate 20 is relatively small in extent. Comparing Figs. 2 and 3 one observes that the extent or length of the heating lobes (209, 309) has been adjusted as necessary, dynamically, so as to avoid exceeding the thermal thresholds outside the treatment target boundary 202. In other words, as the target boundary's distance from the center of the applicator 206 varies (in time and angular position) the system adjusts the heating output of the applicator 206 so its therapeutic effects are substantially confined to the desired volume within treatment target boundary 202. Those skilled in the art would appreciate that the present system relies on heat conduction and diffusion, and would understand the maximum achievable temperature gradients in such a context. It has been understood from histological studies, what tissue types are capable of surviving various temperature elevations, and an acceptable thermal therapy plan can be prescribed in most or all cases so that the diseased tissue is treated and the healthy or critical adjacent tissue survives the treatment. Therefore, as explained above, practitioners and system designers will apply segmentation and control techniques so as to optimally treat the tissues within the target boundary 202 while substantially not damaging tissues outside but proximal to boundary 202. Also, the power and rate of rotation of the active transducers of applicator 206 are modulated and controlled to conformally provide the desired amount of heat output and treatment lobe sizes 208, 308 as a function of time and angular location within prostate 20.

[0032] The above nature of the present treatment method, that is not part of the invention, and system can

therefore benefit from the best controls that can be applied to them. In this disclosure, some aspects are directed to such controls and computational tools to best account for the dynamic nature of the problem being solved. The inventors appreciate that the applied heat and resulting temperature rise at each location and each slice in the 3D treatment volume are time-dependent. For example, it is recognized how to handle situations where the heating and temperature rise at some location are affected by previous instants in time, and that present heating will affect future conditions along the treatment path and in neighboring spatial locations.

[0033] To achieve the present results, the inventors utilize among other things, the ability to non-invasively measure temperature at frequent intervals within the patient's anatomy. As described herein and in related applications, imaging thermometry, e.g., using MRI images obtained in real time or substantially in real time are used to monitor the progress of the thermal therapy. A succession of such MRI thermal maps is obtained at each cross section of the prostate undergoing therapy. It is not critical that the slice thicknesses of the therapy and the thermometry components of the system be the same. Interpolation, curve fitting and other techniques can be used to smooth out, over-sample, under-sample or otherwise account for any differences in such spatial or temporal resolution.

[0034] In an aspect, the thermometry temperature measuring scans are taken as data that is input into a calculation engine. This temperature map data is operated on and supplemented with calculated thermal predictions. In one or more embodiments, each thermal image will be processed using a predictive thermal diffusion-perfusion method. Software allowing computer simulations of the temperature dispersion in a region of interest is incorporated into the therapy system. As discussed in more detail below, relevant factors including the measured temperature profiles are used to guide and adjust the progress of a thermal therapy treatment. The capabilities of the system include spatial and temporal interpolation, extrapolation, fitting, and algorithmic computations using bioheat transfer relationships that apply to the prostate organ during treatment. Therefore, the system avoids unwanted temperature overshoots and permits maximal use of safety zones incorporating such predictive knowledge to obtain the most efficient and fastest conformal thermal therapy treatments within the organ. This is applied either on a slice-by-slice basis in two dimensions (2D) or across multiple slices in three dimensions (3D).

[0035] Fig. 4 illustrates an exemplary logic flow diagram in a method 40, that is not part of the invention, for applying thermal therapy under image guidance. Upon commencement of the start of treatment 410, ultrasonic energy is delivered at time t and step 420. A temperature map is acquired using MRI temperature mapping in a MRI imaging system during this step. A future temperature map accounting for dynamic thermal behavior in the

tissue under treatment is calculated at step 430. The calculation or simulation of the future temperature may include physical phenomena such as conduction, diffusion, perfusion, nonlinear effects, and so on. The expected progress of the target temperature isotherm at time $t+n$, where n can be any time interval (e.g., one second increments or an interval related to the frequency of acquisition of imagery in an image guidance system), is calculated or simulated as described below in an example.

[0036] The calculated or simulated future temperature from step 430 is compared against the target boundary temperature at step 440. If the thermal inertia as determined from the future temperature computation and prediction will cause the maximal target isotherm to cross the target boundary 202 then a special output may be generated. The special output may be a signal to cause a stopping or reducing of the rate of therapy. This can be achieved by reducing or shutting off the driving signals (power) to one or more transducer elements in applicator 206, at step 450. This process is described with respect to an exemplary embodiment of course and other implementations are reasonable and would be apparent to one skilled in the art upon reviewing this description. In an embodiment, this can also result in stoppage of the rotation (mechanical movement) of the applicator 206 within the patient, as the movement is driven by a controllable electrical-mechanical prime mover. In some embodiments, prediction that the temperature excursion will spread beyond the target boundary 202 results in an audible and/or visible alarm being raised, and in yet other embodiments, a portion of the target boundary 202 that is going to be breeched will be highlighted on a graphical interface. Otherwise, if no unwanted temperature excursions are predicted, and the requirements for concluding the treatment have not been met (470) the treatment will continue as planned (460). If the treatment goals are achieved in 470 the treatment method is terminated at 490. Feedback and output to the operator of the system or to a log of the system's activity can be recorded and kept in the patient's medical record, a secure storage data repository, on an operator's work station console, transmitted to another device or computer, and so on. Maximal and minimal values of the controlled parameters may be defined and a ceiling or floor value of such parameters can be enforced.

[0037] Another example 50 is depicted in a flowchart shown in Fig. 5. A difference is that the progression of the ultrasound energy deposition will be predicted and added to the predicted thermal diffusion-perfusion map at 530. This may provide a useful prediction of the possibility of target boundary breach in some embodiments.

[0038] Several techniques for computing the thermal effects in a system such as described can be appreciated by those skilled in the art. The present disclosure is meant to apply generally to these types of bioheat transfer equations, and the examples below are not provided by way of limitation. So other physical effects can be modeled by suitable terms, some of which are described in the

literature known to those skilled in the art and the publications mentioned herein, which are incorporated by reference for this purpose. For example, a thermal heat diffusion calculation can be based on a bioheat transfer equation, e.g.:

$$\rho c_t \frac{\partial T}{\partial t} = \nabla \cdot (k_t \nabla T) - w_b c_b (T - T_b) + Q$$

where ρ is tissue density; c_t is tissue specific heat; k_t is thermal conductivity; w_b is blood perfusion; c_b is the blood specific heat; T_b is the blood temperature; T is the tissue temperature; and Q is the ultrasound heat deposition.

[0039] Fig. 6 illustrates an exemplary treatment method 60, that is not part of the invention, including a substantially real-time feed forward predictive control to the energy output of the therapy applicator 206. The operation of the therapy proceeds as described in Fig. 5, except that if calculations show that the target temperature will be exceeded, the treatment need not necessarily be halted. Instead, ultrasound device operating parameters may be modified and the predicted temperature map may be re-calculated. If recalculation of the temperature map once more results in unwanted temperatures, the control parameters may be modified in a different way. The operator will determine the number of attempts made to modify the device control parameters in order to obtain a permissible temperature map, before the treatment is halted and the treatment plan reevaluated.

[0040] The control method can include changing the direction of rotation in areas of rapidly changing radius so that there is little risk of overshoot. Since this treatment happens on several slices at the same time, there is the potential for one slice to require treatment in one direction while another slice requires treatment in the opposite direction. If this is the case then a value judgment will have to be made balancing the benefits of speed and safety.

[0041] The illustrated logic flow diagrams are merely exemplary in that many other steps may be performed in addition to those shown. Also, other steps may be substituted for the shown steps, and the ordering of the steps may be accomplished in any way necessary to achieve a given outcome in certain situations. The steps described can be implemented using a combination of electronic circuitry, e.g., processors, and software instructions that run on those processors. The software instructions may be coded and stored on a machine readable medium such as a digital memory device coupled to a computing device or networks with access by the processors.

[0042] A database of information may be generated by tracking the results of one or more therapy procedures so as to obtain useful predictive results that can be applied to future treatments.

[0043] A control system and method, that is not part of the invention, are therefore described. In various embodiments, the system includes modules and components

that can include hardware and software and information and signals. Inputs are processed and outputs are generated to enable the operation of the system and method.

[0044] Exemplary inputs usable in the present invention include: treatment planning information, such as geometric information describing a patient's prostate shape and location, tissue characteristics of the patient or the target zone, the desired treatment target boundary, the relative positioning of the patient's urethra, etc.; temperature information, such as the temperature of one or more control points (e.g., one control point along the treatment boundary at each 2D slice along the active length of the elongated treatment applicator), target temperatures, treatment radius, maximal acceptable temperatures, temperature differences between an actual, calculated or desired temperature; applicator information, such as identification of active elements, the relative positions of the elements, the size of the elements, and whether the elements are powered.

[0045] Exemplary controls include: power gain coefficients (Kp); angular (Omega) gain coefficients (Kw); minimum and maximum tuning radius; algorithms for calculating needed power and rotation rates; states of each element or status of the applicator device as a whole; frequency or range of useful frequencies; and updating of the states of the elements and applicator. These aspects are further described below.

[0046] Exemplary outputs available from the present invention include: power and frequency of the driving signals applied to the applicator and its active elements; and the rate of rotation of the applicator about its central axis.

[0047] Fig. 7 illustrates a block diagram of some major components of an image-guided thermal therapy system 70 according to the invention. A computer, server, processor, or other electronic processing apparatus 700 is central to monitoring and controlling the therapy procedure. The computer 700 may include or be coupled to a user interface 710 that allows operators to observe and control or have input to and derive output from the computer 700 and other elements of the system 70. It will be apparent to those skilled in the art that computer 700 may be a dedicated or general type machine, and that this computer may further include data storage and processing components, and that it may be coupled to a database, a network or other computing elements.

[0048] Computer 700 delivers signals to a motor controller 730 that controls and provides motor driving signals to a motor 735 to cause movement and rotation of the thermal therapy device 740. Such motors and controllers have been described in earlier applications by the present applicant and assignee, referenced above.

[0049] Ultrasound therapy device 740 includes a plurality of ultrasonic transducer elements arranged in an ultrasound array 742 that is generally mounted along a long axis of the therapy device and suited for insertion into a body cavity to treat a diseased organ, e.g. transurethrally treating the prostate. The ultrasound elements of array 742 generate ultrasound energy 744 that is de-

posited into selected regions of diseased tissue. The ultrasound array 742 is driven with electrical signals provided through electrical coupling 725, which driving signals are generated by an amplifier 720 that is controlled by computer 700.

[0050] Of course the overall arrangement and configuration of the system 70 can take on numerous forms, and some components may be further sub-divided or may be combined as deemed appropriate for a given application. The present example is being provided for the purpose of illustration.

[0051] As stated before, the patient (not shown) and the ultrasound therapy device 740 and other components are provided in a medical imaging environment 755. For example, a MRI device 750 may be used to collect thermal maps or other image data relating to the patient and the therapy. The imagery are provided to computer 700 for processing and further control of the therapy procedure. Decisions may be made by human operators or by machines, e.g. computer 700, to determine the energy levels to apply, the individual transducer controls, the mechanical rotation of the motor 735, or other alarm and control decisions.

[0052] In the present example, a processor in computer 700 executes instructions that allow performance of some or all of the steps of the methods described above. These include determination (sometimes with human or pre-determined input) of maximum temperature levels, maximum thermal doses, and other predictive calculations to conduct the present thermal therapy treatment without exceeding a safe energy or temperature limit in the patient.

[0053] The above system can be operated in a number of modes. In one mode, the system is initialized. In the initialization mode the system is not heating the target tissue. Reference images are collected and temperature maps are displayed to the operator and background noise levels are analyzed.

[0054] The system can also be operated in a "point and shoot" mode of operation. This mode provides heat build up capability at selected locations of the target tissue. This mode is off by default, but can be activated for example in testing scenarios to heat tissue along a certain direction proximal to and radially emanating from the applicator's active surface towards the treatment boundary. The applicator is not rotating about its axis in the point and shoot mode. In an example, the applicator is controllably rotated to point towards a determined angular location, then all selected transducer elements of the applicator are turned on and provided with driving signals to raise the temperature of the control point at the boundary surface to a target temperature, e.g., 55 Celsius. Individual elements can be turned on or off or have their power modulated or applied in a duty cycle if such elements' control points reach their target temperature (or are predicted to reach the target temperature) before the other elements reach theirs.

[0055] Yet another mode of operation is a heat and

rotation mode, which can be the primary or main mode of operation of the therapy system during operation. In an embodiment, rotation of the therapy applicator is performed at a controllable rate of rotation about its axis.

5 The control point for points or a given element (e.g., in a slice of the treatment volume) may be indicated at the intersection of a normal line emanating radially from the element's active surface and the target boundary in that element's slice of the treatment volume. Rotation may be initiated instantly or substantially upon commencement of the treatment procedure.

10 **[0056]** Still another mode of operation is a cool down mode. Power is secured to the elements of the therapy applicator and rotation of the applicator is halted. Temperature maps are obtained and the operator monitors the cooling of the treatment volume following treatment. Once the tissue has sufficiently cooled down, the system and the operator can stop monitoring the temperature maps in the patient. The applicator can then be removed from the patient's body or a new treatment plan can be initiated.

15 **[0057]** The present discussion has made reference to temperature at a control point, plurality of discrete control points, or a continuous series of control points, lines, curves, surfaces or volume. Fig. 8 illustrates this notion in more detail. As discussed earlier, a treatment plan, preferably involving imaging of a patient's anatomy and disease, results in a defined target boundary 82. The target boundary 82 may be substantially conforming to a boundary of the diseased organ or a boundary of diseased tissue within the afflicted organ, or by some safety offset from the periphery of the target volume. Consider a 2D image plane in pixels (U,V) 81 having a coordinate system origin at the bottom left corner of the image. Therefore this image plane is in units of pixels. A world plane slice is represented by plane (X, Y) 83, which is measured from an origin that represents the lower left corner of the image. Therefore this world plane is in units of distance, e.g., millimeters. The target boundary 82 can be represented as polar coordinate sets having radial and angular coordinates. Of course this framework is illustrative and not limiting in the present example.

25 **[0058]** The center of the therapy applicator is at location 80, which here means that the elongated body of the therapy device runs in and out of the page normal to the slices (U,V) 81 and (X, Y) 83. In this framework, the control point in this plane is at 84 where a ray 85 intersects the target boundary surface 82. Angular positions are measured by angle theta (Θ) from the X axis. Interpolation can be used to obtain a more precise value for the location of the control point 84 if it lies between two adjacent units of measurement. Similarly, interpolation of the temperature at the control point is also possible for greater accuracy and smoothness during the thermal therapy procedure. If the ultrasound beam 85 is considered to have a certain width where it intersects the target boundary surface 82, multiple control points on either side of or surrounding, adjacent to or proximal to position

84 where $\Theta_0 = \Theta_T + n \Delta \Theta$ and n is an integer between $-N$ and N (including $n=0$).

[0059] Fig. 9 illustrates the polar geometry which the present system may employ for representing temperature and other data mapped within a slice along the length of elongated applicator 206. In the (X, Y) frame 90 a center of the coordinate system 92 coincides with the center of the applicator and patient's urethra containing the applicator. The active surface or face of the applicator is directed at an angular position θ (Θ) at a given moment in time. A radial line 94 emanates from the active face of a transducer element in the shown slice. Distances along this line 94 can be measured relating to its origin 92. For example, the radius of the applicator device is R_A ; the minimum radius for thermometry is R_{MIN} ; the control boundary radius is R_T at which point the control point is defined; R_{MAX} represents the maximum thermometry radius and is typically between the target boundary and the edge of the prostate boundary and is usually within the limits of the prostate organ where water content enables a reliable temperature determination in MRI thermometry applications; and R_p represents the radius where the prostate boundary is located.

[0060] Fig. 10 illustrates an exemplary temperature profile 1000 along a radius such as shown in the previous figure at a given moment in time. A temperature 1010 is defined, determined or measured at the origin of the polar coordinate system. Note that at the center near the applicator the temperature may be determined from thermocouple or other temperature sensors or thermometers, and this can be combined with or augment the imaging thermometry data described earlier. The temperature 1000 has a peak value T_{MAX} 1020 at some radial distance from the applicator in this slice at this time. The temperature falls off and has another value 1030 at the control point at radius R_T .

[0061] Fig. 11 illustrates an exemplary sequence of steps in a thermal therapy process 1100 using the present systems and methods. The treatment commences at 1102. Individual elements of the treatment applicator device, whose point and shoot state is normally initialized to OFF, are determined as active in 1104 according to a procedure or treatment plan. A heating profile and one or more control point temperatures are calculated at 1106. Predictive temperature calculations are performed at 1108 using known data and a model for thermal performance of the system and patient's anatomy.

[0062] Fig. 12 illustrates a continued series of steps in providing an output control signal at 1260 to hardware implementing the present thermal therapy. Aspects used in making therapy control decisions 1100, 1200 include: predicted temperature overshoot (exceeding a desired or set goal temperature at one or more locations) (1124, 1126); a state of a therapy applicator or individual elements of the applicator (1104, 1120, 1130, 1140, etc., 1110); current device settings, speeds of rotation, power to individual elements; and alarm settings. Output control signals are sent to the treatment device hardware (1260),

e.g., driving signal generators, amplifiers, motors. A maximum rotation rate may be defined (1204) for the device, which may be used to scale the power to a given element (1250) because in an embodiment of the device the elements all rotate at a common rate and therefore if one element is computed to ideally rotate at a different rate it cannot be so rotated. Instead, the power to that element may be scaled appropriately (1250) to compensate for its actual (versus its desired) rotation rate. Also, a maximum or full power to one or more elements may be defined. Therefore, a cap of either or both the rotation rate and the power of the therapy device elements can be devised and set.

[0063] Fig. 13 illustrates another conformal thermal therapy mechanism 1300 that is not part of this invention. Unlike other embodiments, here the therapy is delivered from a location outside the diseased target tissue volume rather than from within the target volume. Examples of such external thermal treatments include focused ultrasound surgery (FUS) or high intensity focused ultrasound (HIFU) and others. In the example of Fig. 13, heating ultrasound energy is created in a transducer or array of transducers 1310 that supply acoustic waves 1312 directed towards a focal spot 1320 in a target volume 1304 of a patient's body 1302. At any given time, the energy source 1310 is spatially directed either directly through moving the source 1310 or by applying phased driving signals to elements of the source 1310 so that its beam of energy 1312 is spatially moved about a treatment zone 1304. The focal spot 1320 is the primary location of heating, especially from superposition of waves and energy at this focal spot. Heat is conducted and transported outwardly from heated focal spot 1320 according to the laws of heat transfer described above, including through perfusion in the volume at and near focal spot 1320.

[0064] By scanning or translating or shifting the location of focal spot 1320 it is possible to tile or paint a thermal dose or temperature rise within the diseased target volume 1304 to treat a disease therein. A mechanism for moving or scanning the focal spot 1320 is depicted schematically by 1330 and can be any of the continuous or discrete schemes for movement of the focal spot 1320 that are known or devised in this field.

[0065] A salient point is that the heating of the tissue within target treatment volume 1304 is occurring from the inside out (from focal spot 1320 or a plurality of such focal spots, whether or not applied simultaneously). So even though the source of energy 1310 is not inside the boundary 1304, the heat affecting the treatment of the tissue in volume 1304 is effectively emanating substantially from within the volume 1304 as far as the equations of heat are concerned. Accordingly, the time-predictive methods described above apply and are applied to this scenario in some embodiments. A control point, or a plurality of control points, or a control surface or boundary may be defined at or near or corresponding to a diseased volume of tissue. Computations are performed to predict a future value of temperature or thermal dose distribution

at or near such control points. The result of these computations are then used to control the spatial scan rate of the source 1310, the power and driving signals applied to the source 1310 or individual elements thereof, and so on as discussed earlier. In this way the system of 1300 can better deliver conformal thermal therapy in a diseased volume, preferably in conjunction with real time thermometry such as image guided thermal imaging in and around the diseased target volume.

[0066] The present invention should not be considered limited to the particular embodiments described above. Various modifications, equivalent processes, as well as numerous structures to which the present invention may be applicable, will be readily apparent to those skilled in the art to which the present invention is directed upon review of the present disclosure.

Claims

1. A system for treating a prostate (20), comprising:

an ultrasonic thermal therapy applicator (206, 740, 742) in the form of an elongated cylindrical applicator sized and shaped for insertion into a male patient's urethra so as to be able to reach at least partially into a prostate (20) of said patient;

a controllable motor (735) and mechanical driver assembly coupled to said applicator (206, 740, 742) so as to cause the elongated cylindrical applicator (206, 740, 742) to rotate about an axis thereof within the patient's urethra;

a plurality of transducer elements in said applicator (206, 740, 742), each being controllably driven by an electrical driving signal (720) and having an active surface and capable of generating an acoustic radiation field emanating radially outwardly from its active surface into said prostate;

a thermometry module receiving data from an imaging system and executing instructions in a processor to determine a current temperature distribution map within said prostate (20);

characterized by the system further comprising:

a temperature prediction module receiving said current temperature distribution map as data, and using programmed thermal response model instructions, generating data representative of a future temperature distribution within said prostate;

and

a controller (102, 700) receiving at least said future temperature distribution, comparing said future temperature distribution to an indicated reference temperature at least in

some region within said prostate (20), and modifying the controllable electrical driving signals to said plurality of transducer elements in said applicator (206), so that the system is configured to carry out a real-time feed forward predictive control to an energy output of the therapy applicator (206, 740, 742).

2. The system of claim 1, said controller (102) further controlling an electrical driving signal that controls a movement of said controllable motor so as to cause a corresponding controlling of an angular motion of said applicator (206, 740, 742) within the urethra of the patient.

3. The system of claim 1, further comprising a user interface module allowing an operator to enter inputs into said system and to receive outputs from said system.

4. The system of claim 3, said user interface comprising a graphical representation of a temperature distribution within said prostate (20) and further comprising a graphical indication of at least a portion of said target treatment volume delineated by a target boundary surrounding said portion of the target treatment volume.

5. The system of claim 1, further comprising a special event module that generates an alarm condition in the event that a temperature excursion is predicted to occur at a future time according to a pre-programmed threshold for such an alarm condition.

6. The system of claim 5, said alarm condition being associated with an audible or visible alarm signal to an operator of the system.

7. The system of claim 5, said alarm condition causing a reduction or interruption of at least some electrical driving signals to at least some elements of said applicator (206).

8. The system of claim 5, said alarm condition causing a reduction or interruption of a rotation of said motor and mechanical driver assembly so as to slow down or halt a rotation of said applicator (206, 740, 742) within the urethra.

Patentansprüche

1. System zur Behandlung der Prostata (20), aufweisend:

einen Ultraschall-Wärmetherapie-Applikator (206, 740, 742) in Form eines länglichen zylindrischen

drischen Applikators, der zum Einsetzen in die Harnröhre eines männlichen Patienten bemessen und geformt ist, um zumindest teilweise bis in die Prostata (20) des Patienten reichen zu können;

einen steuerbaren Motor (735) und eine mechanische Antriebsbaugruppe, die mit dem Applikator (206, 740, 742) gekoppelt ist, um zu bewirken, dass sich der längliche zylindrische Applikator (206, 740, 742) um eine Achse hiervon innerhalb der Harnröhre des Patienten dreht; eine Vielzahl von Schallkopfelementen in dem Applikator (206, 740, 742), von denen jedes steuerbar durch ein elektrisches Ansteuersignal (720) angetrieben wird und eine aktive Oberfläche aufweist und ein akustisches Strahlungsfeld erzeugen kann, das von seiner aktiven Oberfläche radial nach außen in die Prostata austritt; ein Thermometriemodul, das Daten von einem Bildgebungssystem empfängt und Anweisungen in einem Prozessor ausführt, um eine aktuelle Temperaturverteilungskarte innerhalb der Prostata (20) zu bestimmen;

dadurch gekennzeichnet, dass das System darüber hinaus aufweist:

ein Temperaturvorhersagemodul, das die aktuelle Temperaturverteilungskarte als Daten empfängt und unter Verwendung von programmierten Anweisungen eines Wärmereaktionsmodells Daten erzeugt, die für eine zukünftige Temperaturverteilung in der Prostata repräsentativ sind;

und

eine Steuerung (102, 700), die mindestens die zukünftige Temperaturverteilung empfängt, mindestens in einem bestimmten Bereich innerhalb der Prostata (20) die zukünftige Temperaturverteilung mit einer angegebenen Referenztemperatur vergleicht und die an die Vielzahl der Schallkopfelemente in dem Applikator (206) laufenden steuerbaren elektrischen Ansteuersignale modifiziert, so dass das System dazu konfiguriert ist, eine Echtzeit-Vorhersage-Vorwärtssteuerung an einer Energieabgabe des Therapieapplikators (206, 740, 742) durchzuführen.

2. System nach Anspruch 1, wobei die Steuerung (102) ferner ein elektrisches Ansteuersignal steuert, das eine Bewegung des steuerbaren Motors steuert, um eine entsprechende Steuerung einer Winkelbewegung des Applikators (206, 740, 742) innerhalb der Harnröhre des Patienten zu bewirken.
3. System nach Anspruch 1, ferner umfassend ein Benutzerschnittstellenmodul, das es einem Bediener

ermöglicht, Eingaben in das System einzugeben und Ausgaben von dem System zu empfangen.

4. System nach Anspruch 3, wobei die Benutzerschnittstelle eine grafische Darstellung einer Temperaturverteilung innerhalb der Prostata (20) umfasst und ferner eine grafische Anzeige von mindestens einem Teilbereich des Zielbehandlungsvolumens umfasst, der durch eine Zielgrenze, die den Teilbereich des Zielbehandlungsvolumens umgibt, begrenzt ist.
5. System nach Anspruch 1, ferner ein Modul für besondere Ereignisse umfassend, das eine Alarmbedingung erzeugt, falls eine Temperaturabweichung zu einem zukünftigen Zeitpunkt gemäß einem vorprogrammierten Schwellenwert für eine solche Alarmbedingung vorhergesagt wird.
6. System nach Anspruch 5, wobei die Alarmbedingung mit einem für einen Bediener des Systems hörbaren oder sichtbaren Alarmsignal verbunden ist.
7. System nach Anspruch 5, wobei die Alarmbedingung eine Reduzierung oder Unterbrechung mindestens einiger elektrischer Ansteuersignale für mindestens einige Elemente des Applikators (206) bewirkt.
8. System nach Anspruch 5, wobei die Alarmbedingung eine Reduzierung oder Unterbrechung einer Drehung des Motors und der mechanischen Antriebsbaugruppe bewirkt, um eine Drehung des Applikators (206, 740, 742) innerhalb der Harnröhre zu verlangsamen oder zu stoppen.

Revendications

1. Système pour traiter une prostate (20), comprenant :
un applicateur de thermothérapie (206, 740, 742) ultrasonique prenant la forme d'un applicateur cylindrique allongé dimensionné et formé pour être inséré dans l'urètre d'un patient masculin de façon à pouvoir arriver au moins en partie dans une prostate (20) dudit patient ;
un moteur (735) commandable et un ensemble d'entraînement mécanique couplé audit applicateur (206, 740, 742) de façon à amener l'applicateur cylindrique allongé (206, 740, 742) à tourner autour d'un axe correspondant à l'intérieur de l'urètre du patient ;
une pluralité d'éléments transducteurs dans ledit applicateur (206, 740, 742), chacun étant entraîné de façon commandable par un signal d'entraînement (720) électrique et ayant une surface active et capable de générer un champ

de rayonnement acoustique émanant vers l'extérieur dans le plan radial, depuis sa surface active jusque dans ladite prostate ;
 un module de thermométrie recevant les données provenant d'un système d'imagerie et exécutant les instructions dans un processeur pour déterminer une carte de répartition de la température actuelle à l'intérieur de ladite prostate (20) ;
caractérisé par le système comprenant en outre :

un module de prévision de température recevant ladite carte de répartition de la température actuelle sous la forme de données et utilisant les instructions de modèle de réponse thermique programmé, générant les données représentatives d'une future répartition de température à l'intérieur de ladite prostate ; et
 un dispositif de commande (102, 700) recevant au moins ladite future répartition de température, comparant ladite future répartition de température à une température de référence indiquée au moins dans une certaine région à l'intérieur de ladite prostate (20) et modifiant les signaux d'entraînement électriques commandables en ladite pluralité d'éléments transducteurs dans ledit applicateur (206), de sorte que le système soit configuré pour réaliser un contrôle prédictif en temps réel amené à une production d'énergie de l'applicateur thérapeutique (206, 740, 742).

2. Système selon la revendication 1, ledit dispositif de commande (102) commandant en outre un signal d'entraînement électrique commandant un mouvement dudit moteur commandable de façon à entraîner une commande correspondante d'un déplacement angulaire dudit applicateur (206, 740, 742) à l'intérieur de l'urètre du patient.
3. Système selon la revendication 1, comprenant en outre un module d'interface utilisateur permettant à un opérateur de saisir des entrées dans ledit système et de recevoir des signaux provenant dudit système.
4. Système selon la revendication 3, ladite interface utilisateur comprenant une représentation graphique d'une répartition de température à l'intérieur de ladite prostate (20) et comprenant en outre une indication graphique d'au moins une partie dudit volume de traitement cible délimitée par une limite cible entourant ladite partie du volume de traitement cible.
5. Système selon la revendication 1, comprenant en

outre un module d'événement spécifique qui génère un état d'alarme dans l'événement lorsqu'une sortie de température doit se produire à un moment futur en fonction d'un seuil préprogrammé pour un tel état d'alarme.

6. Système selon la revendication 5, ledit état d'alarme étant associé à un signal d'alarme sonore ou visuel adressé à un opérateur du système.
7. Système selon la revendication 5, ledit état d'alarme provoquant une réduction ou une interruption d'au moins une partie des signaux d'entraînement électriques vers au moins certains éléments dudit applicateur (206).
8. Système selon la revendication 5, ledit état d'alarme provoquant une réduction ou une interruption d'une rotation dudit moteur et de l'ensemble d'entraînement mécanique de façon à ralentir ou arrêter une rotation dudit applicateur (206, 740, 742) à l'intérieur de l'urètre.

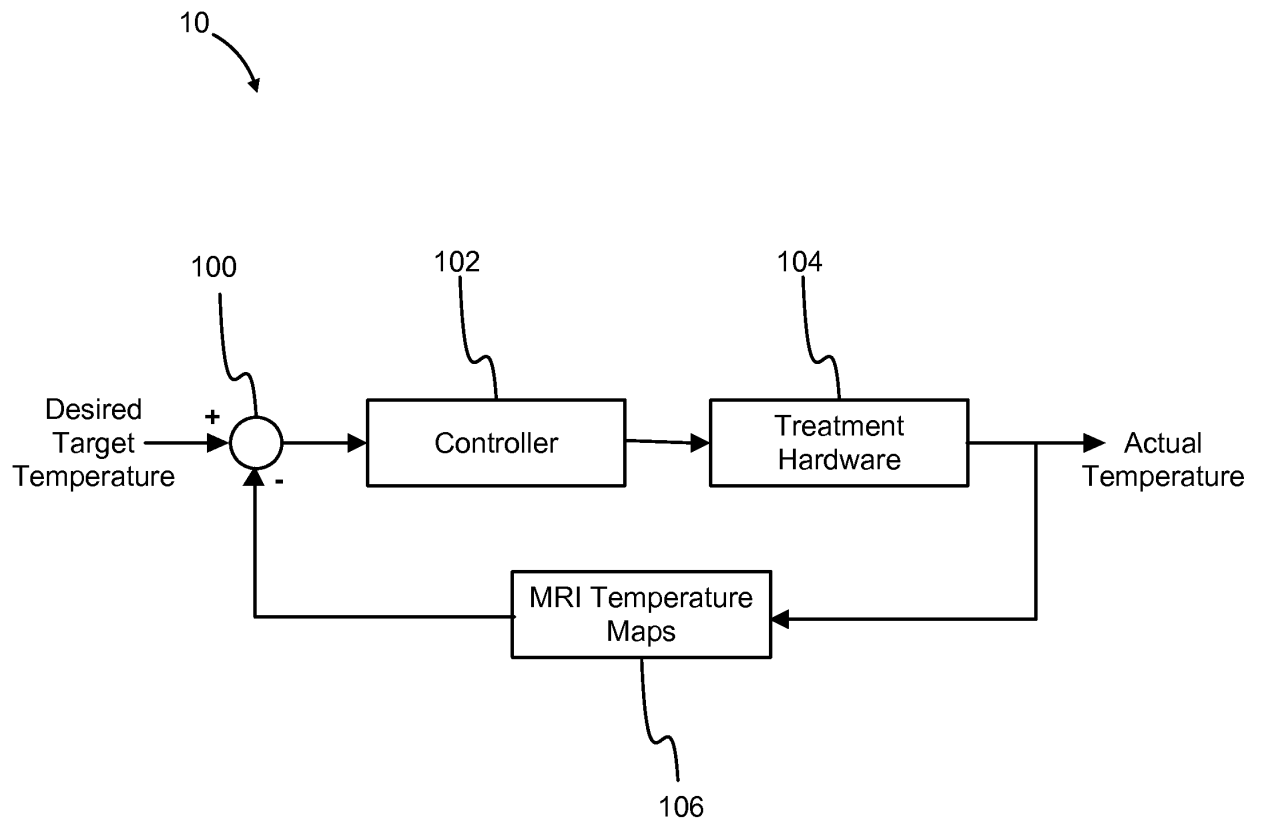


Fig. 1

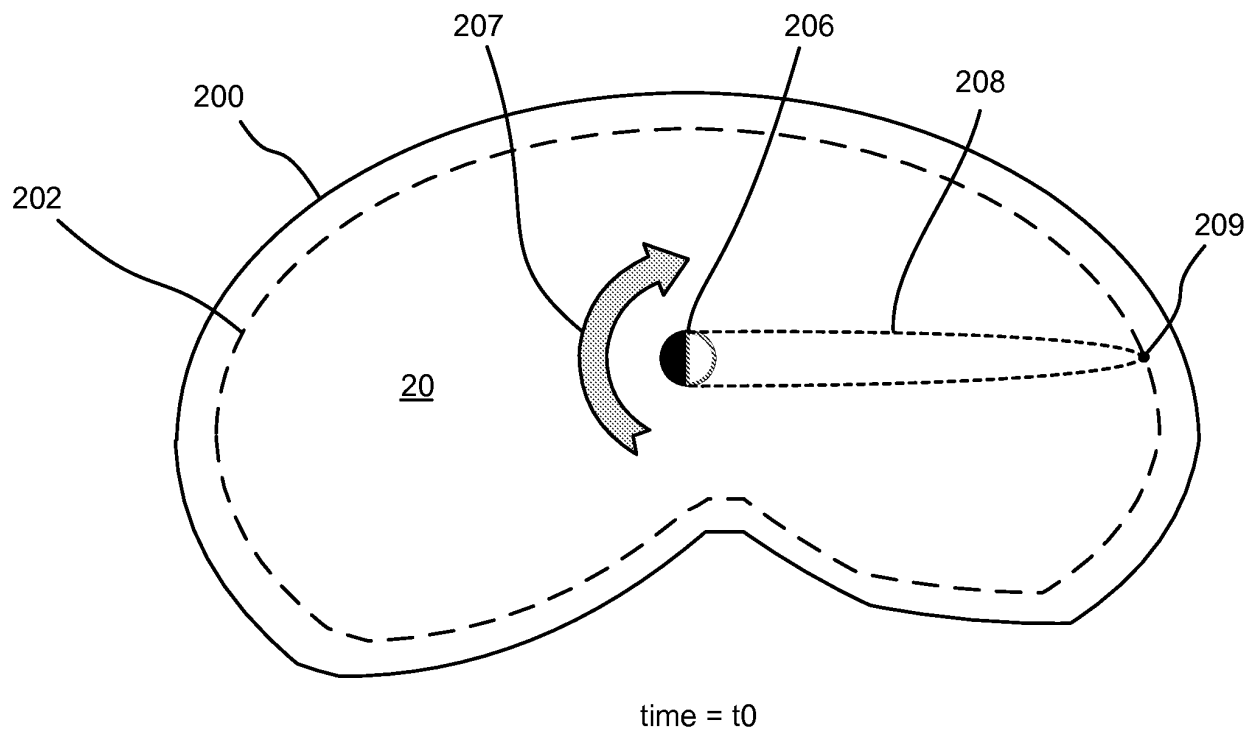


Fig. 2

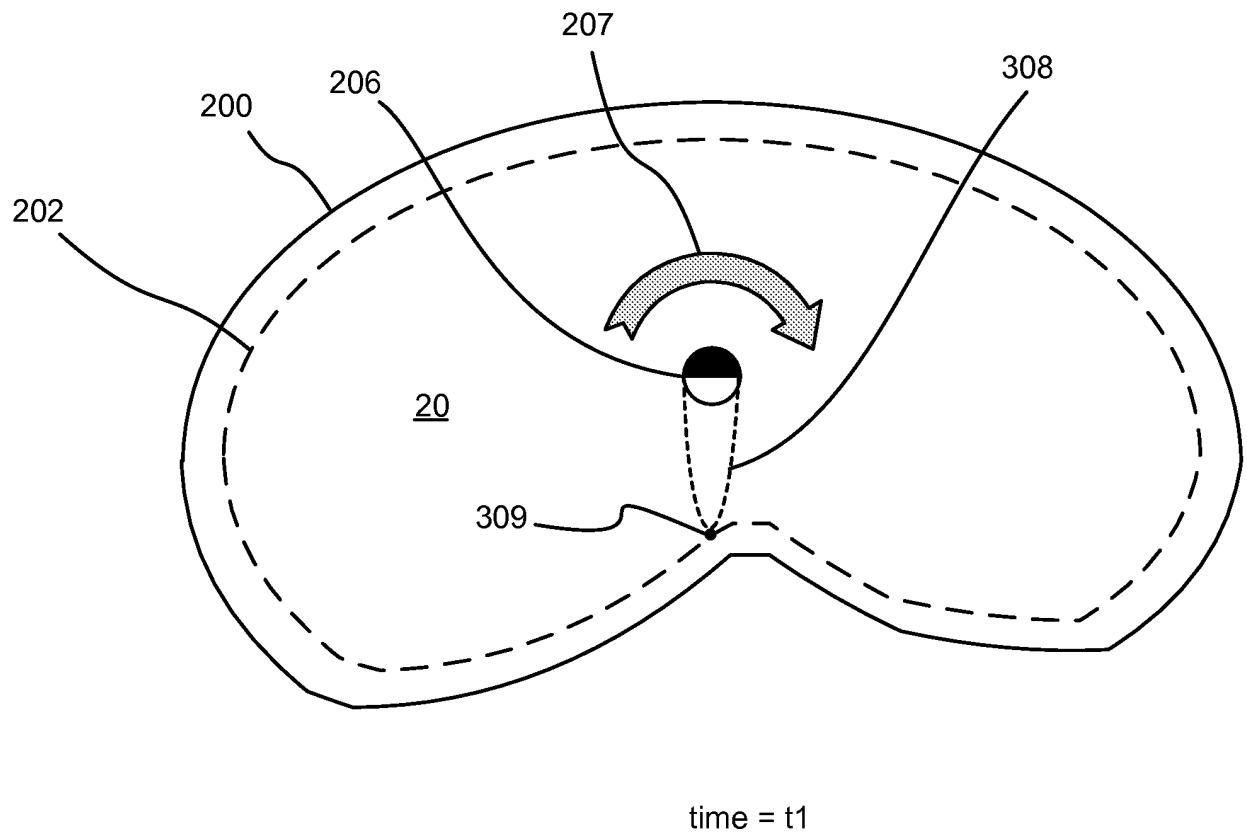


Fig. 3

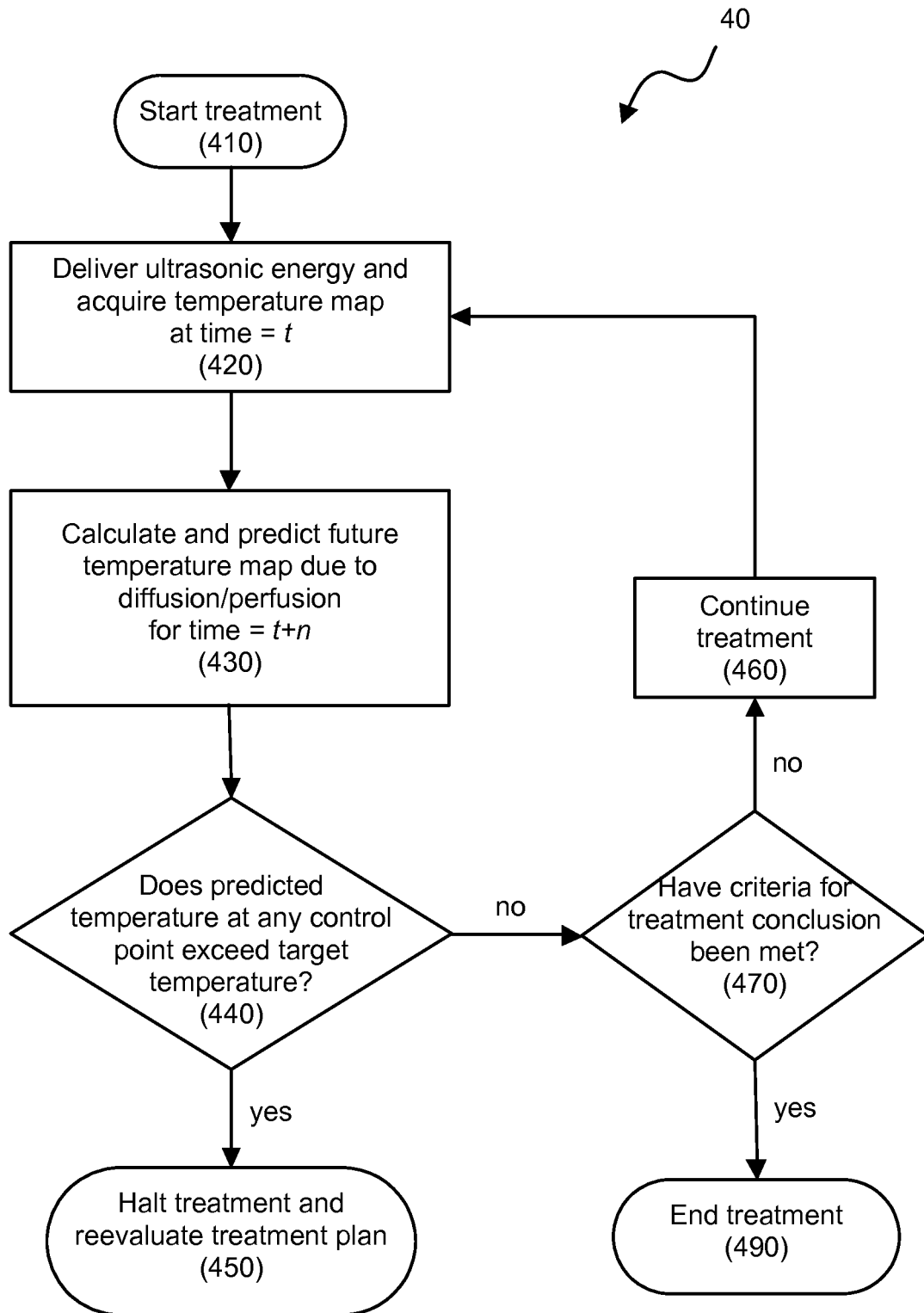


Fig. 4

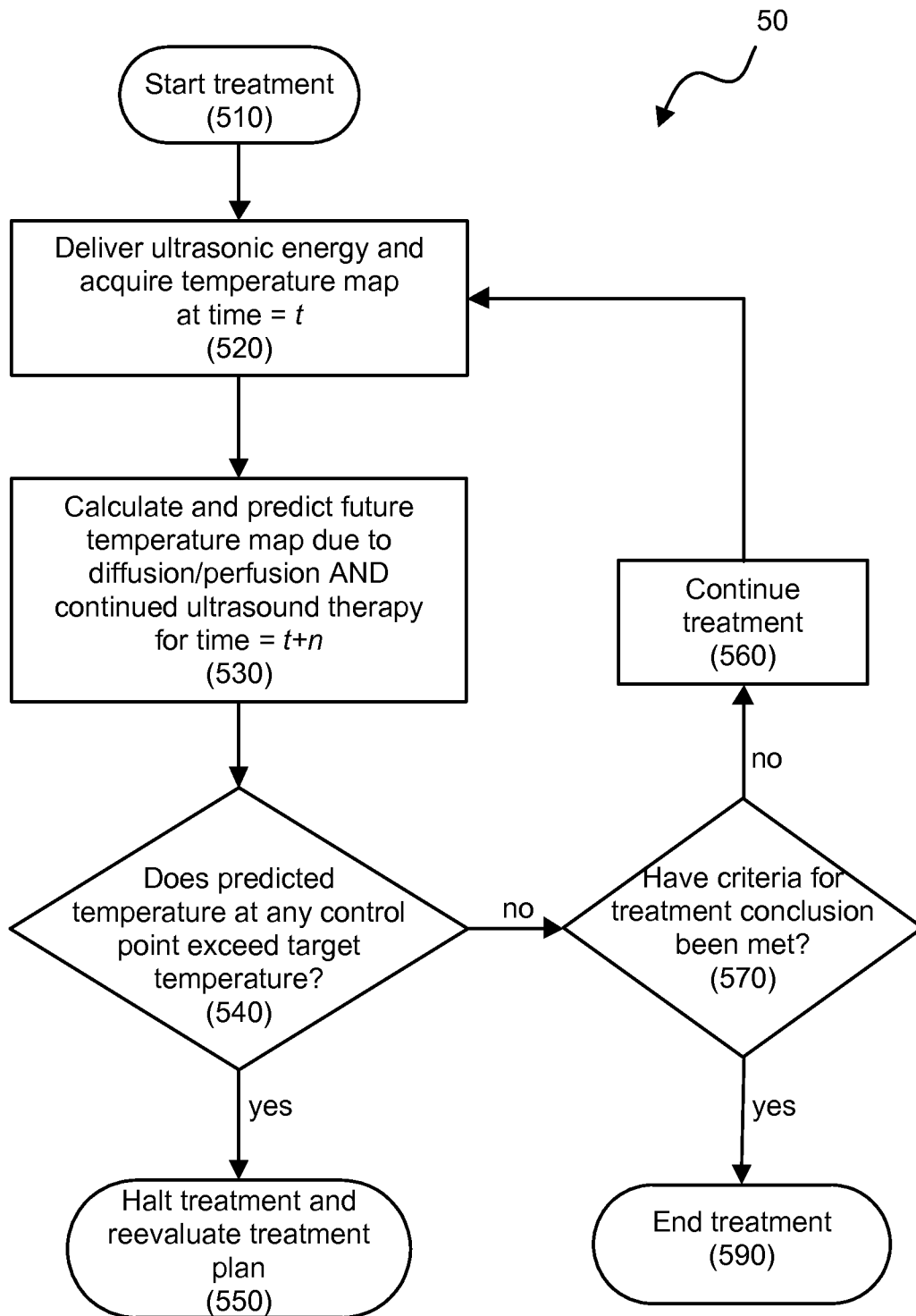


Fig. 5

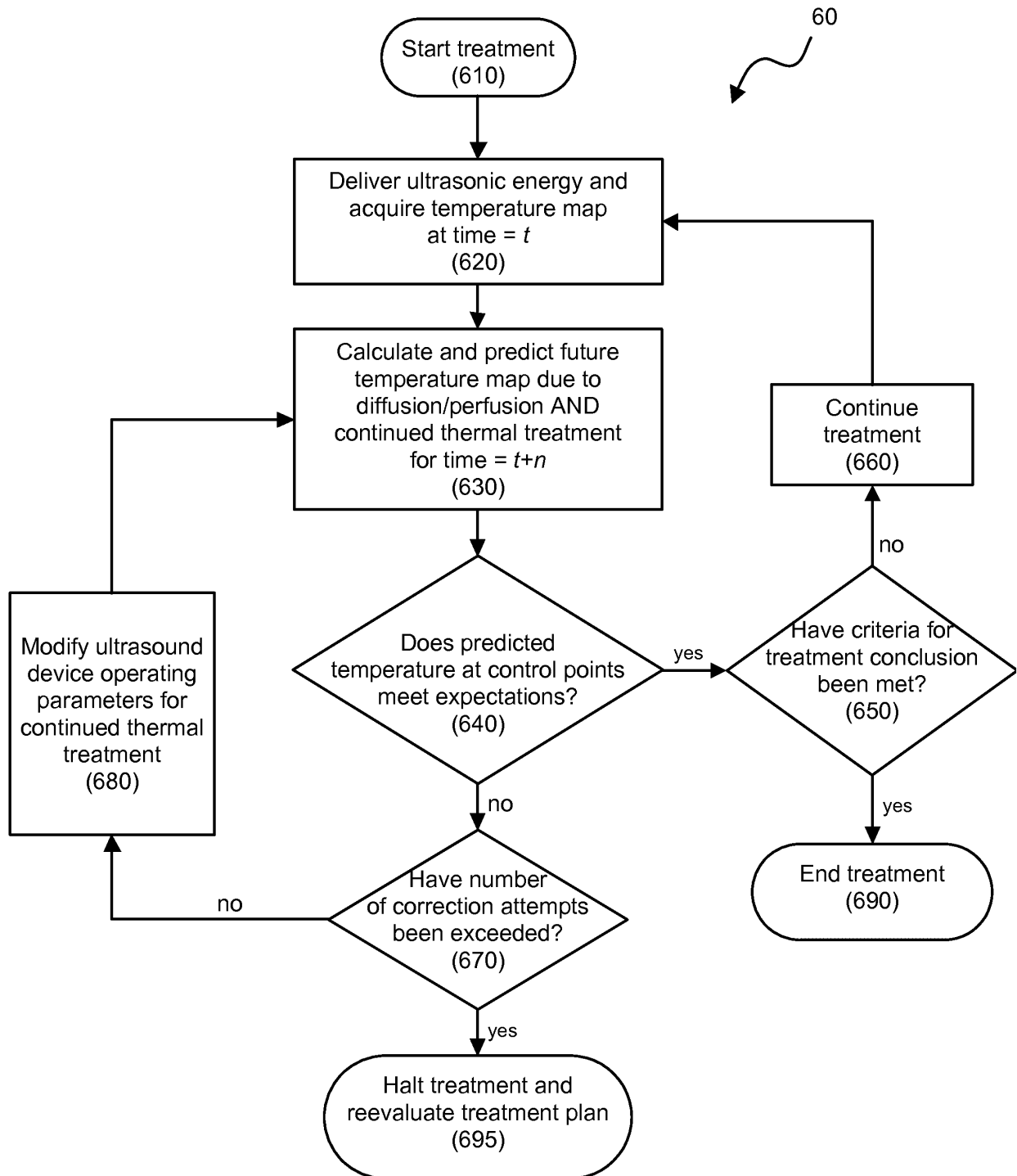


Fig. 6

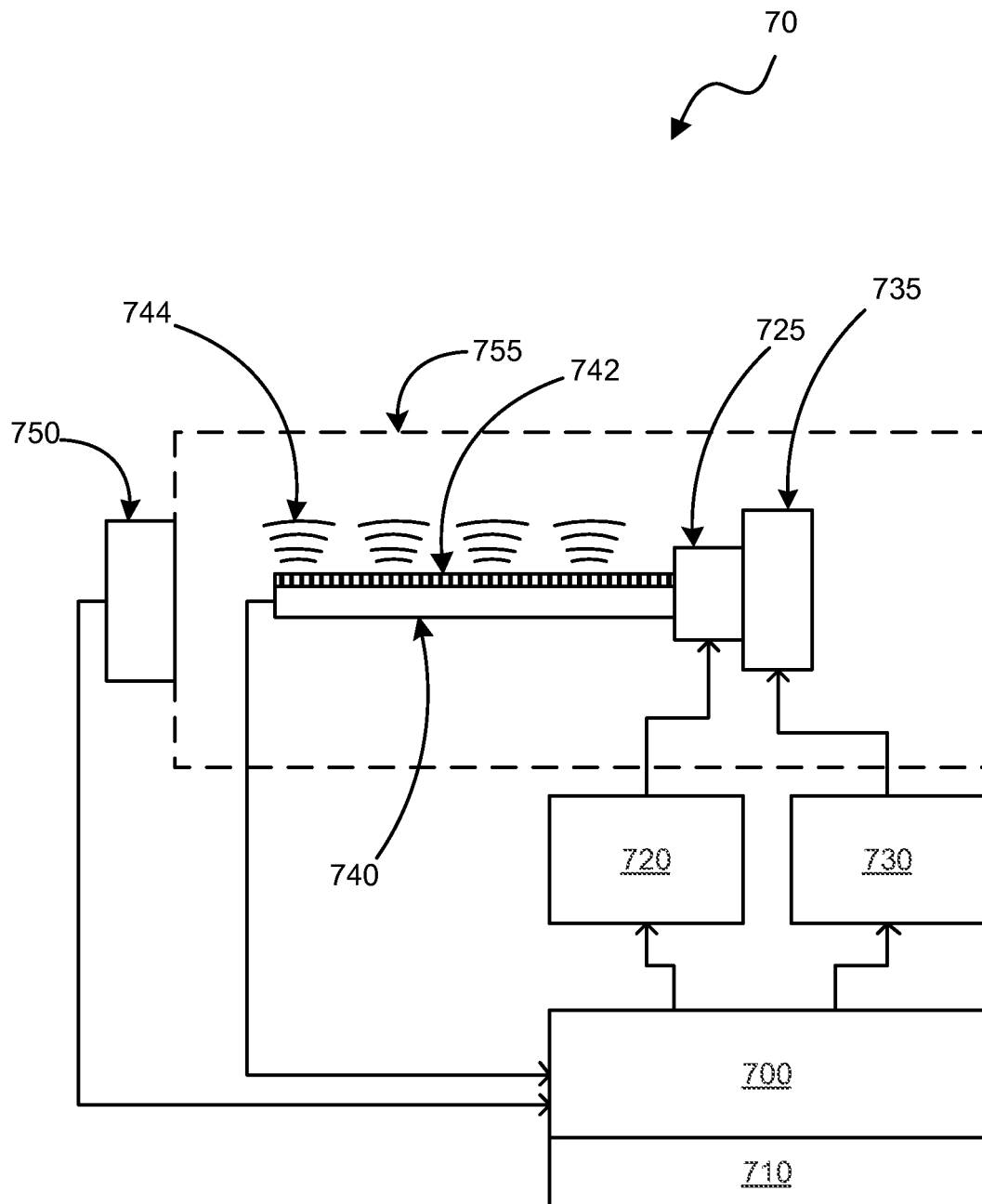


Fig. 7

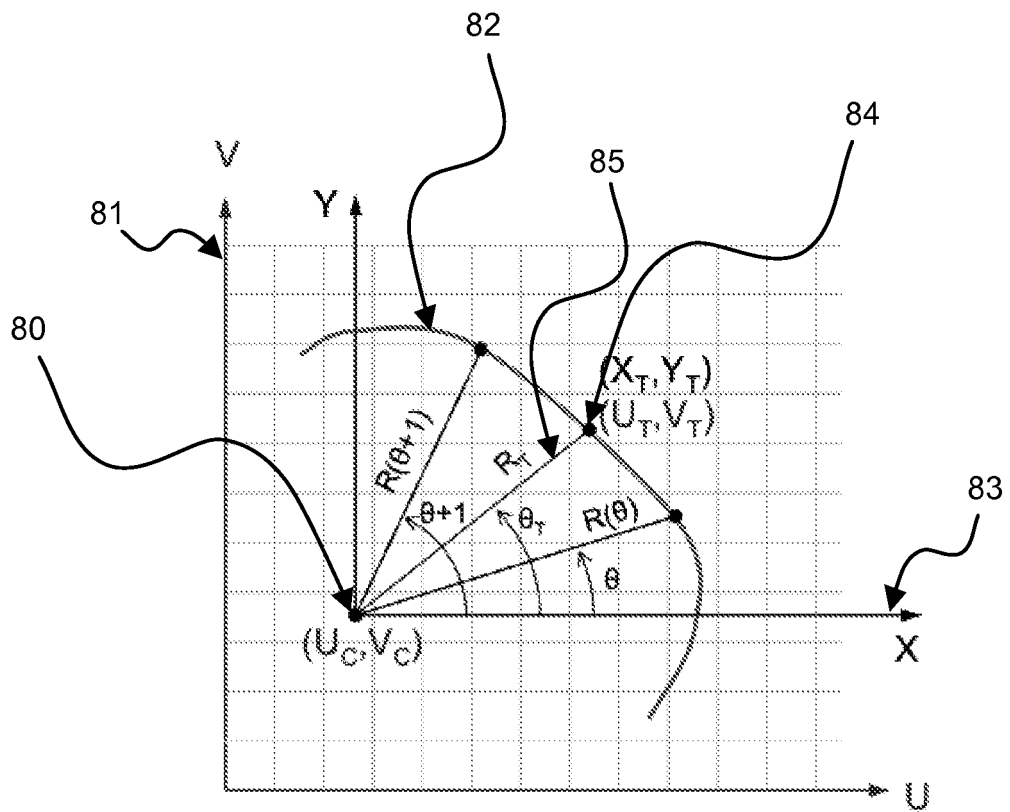


Fig. 8

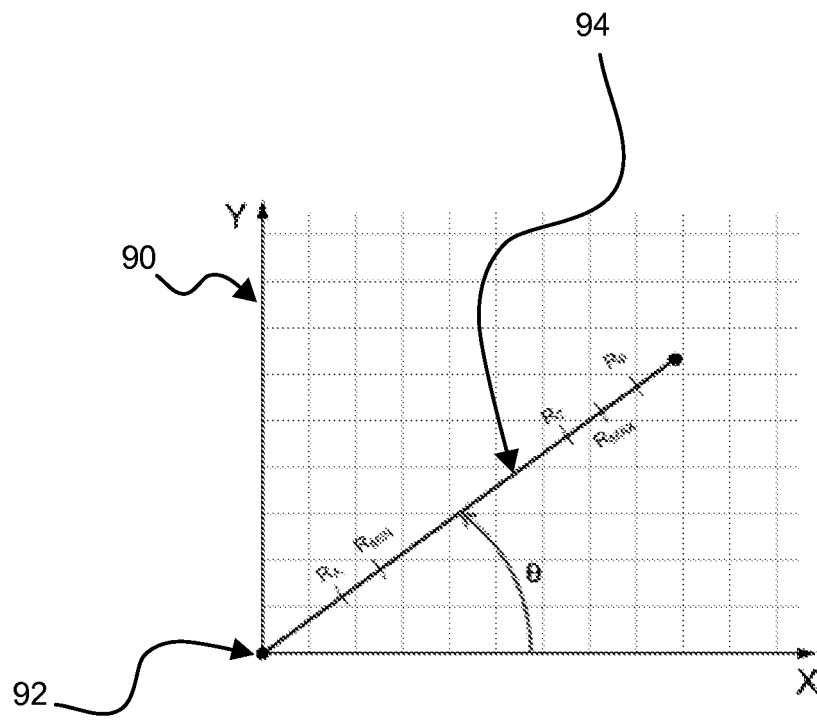


Fig. 9

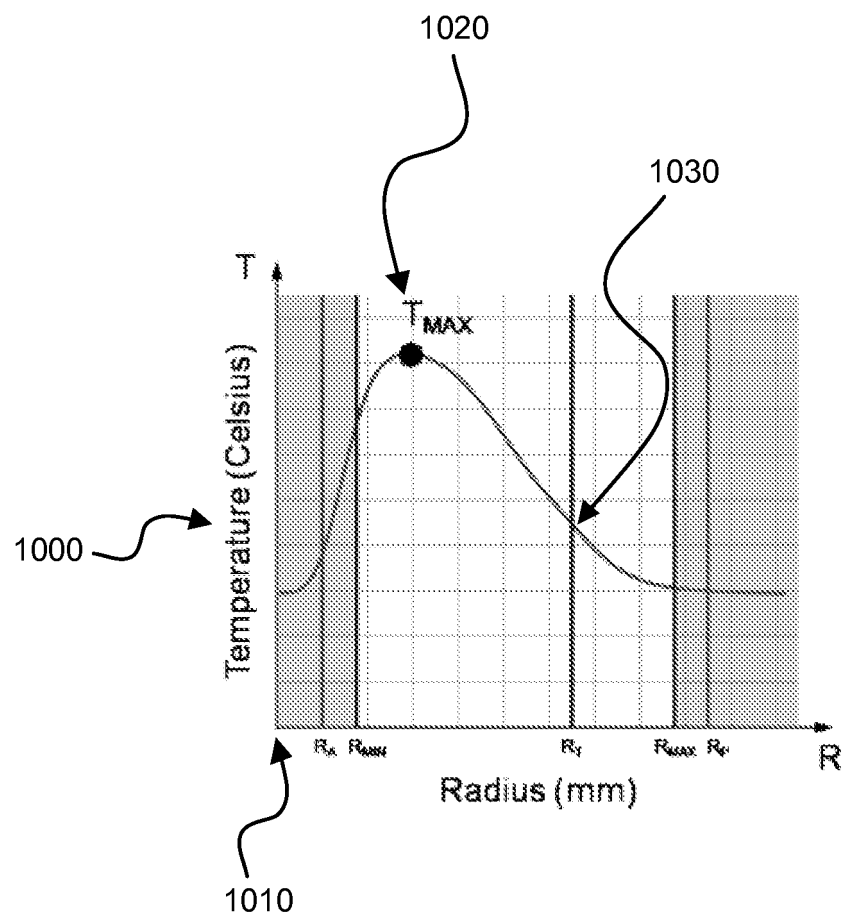


Fig. 10

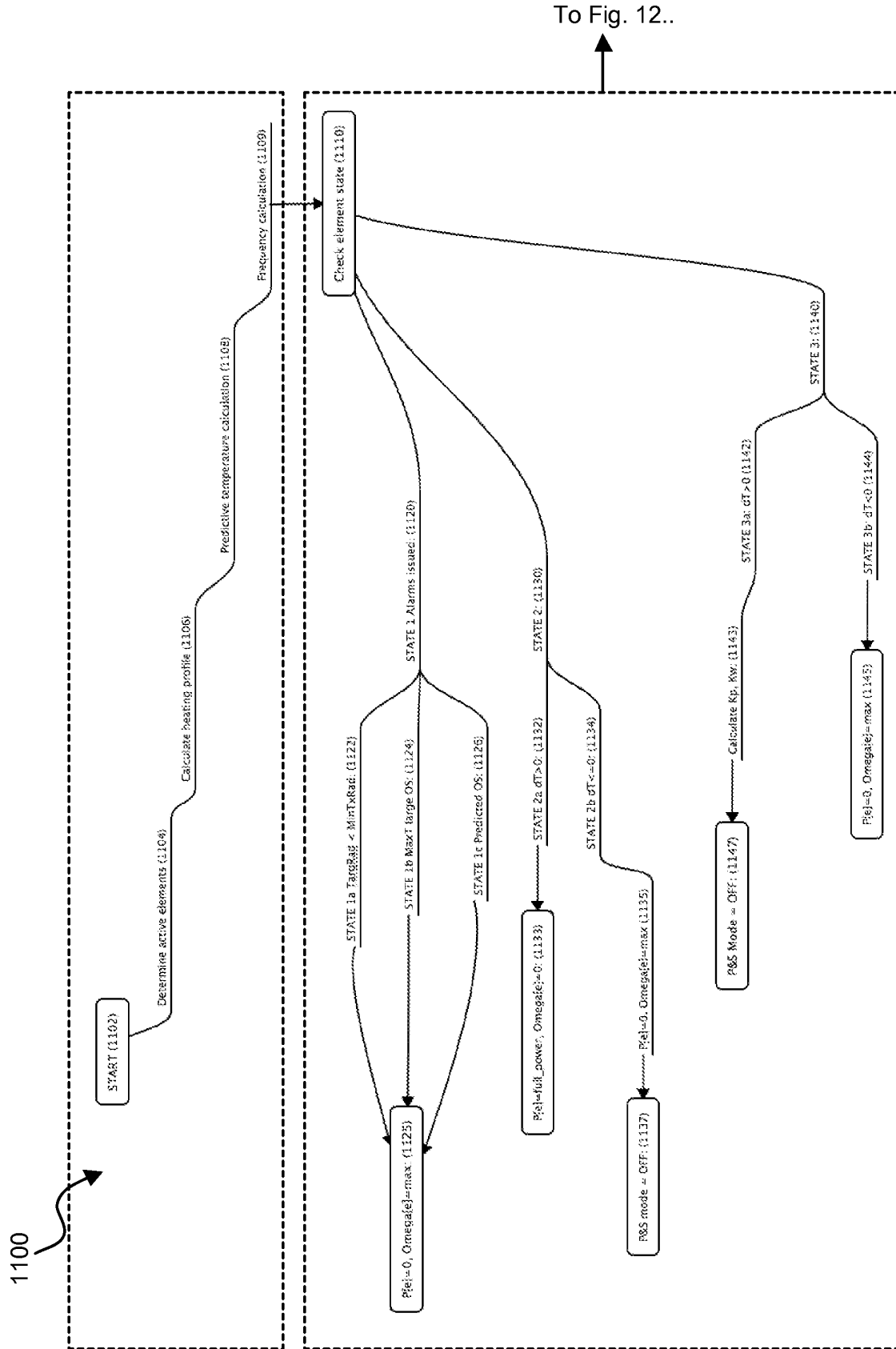


Fig. 11

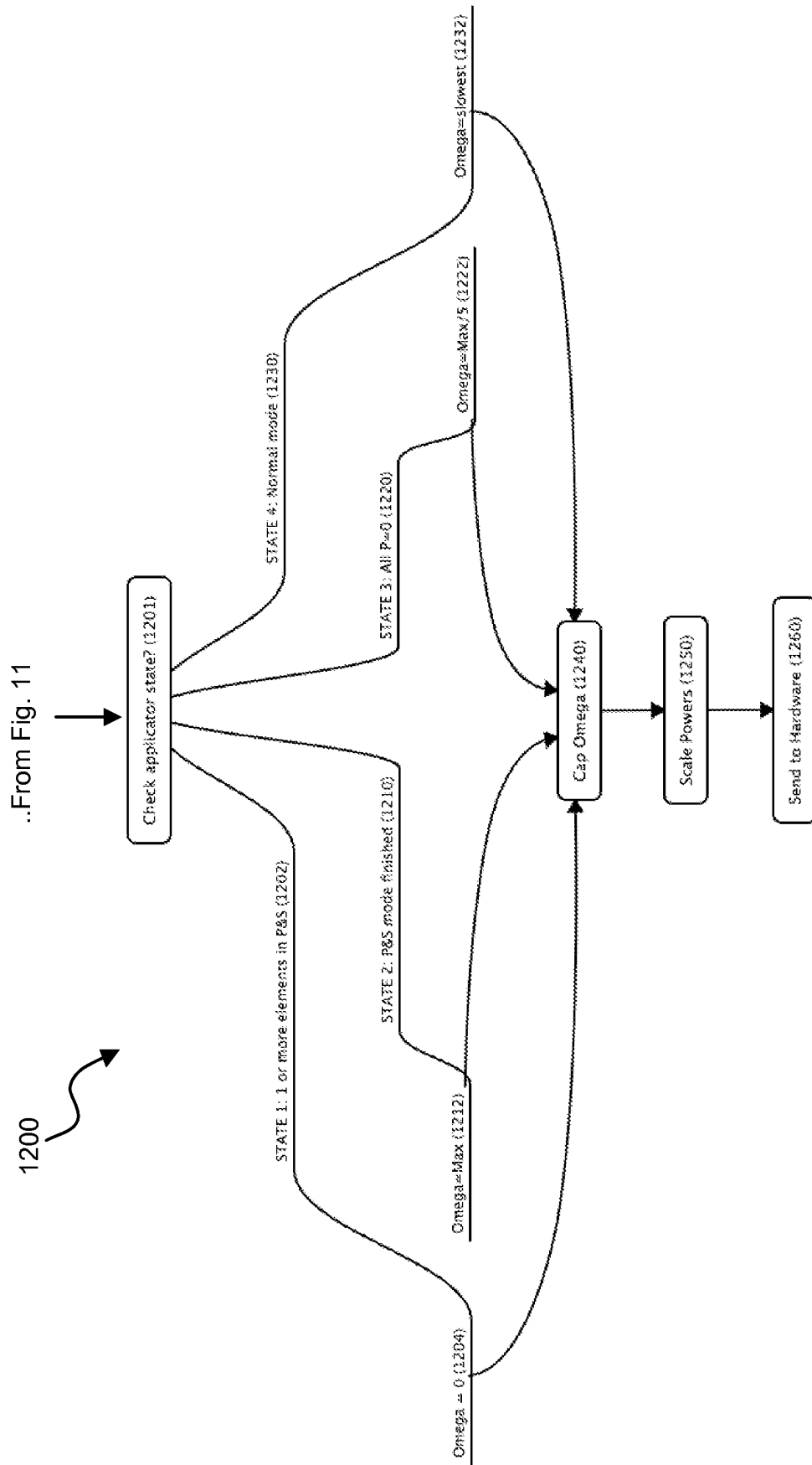


Fig. 12

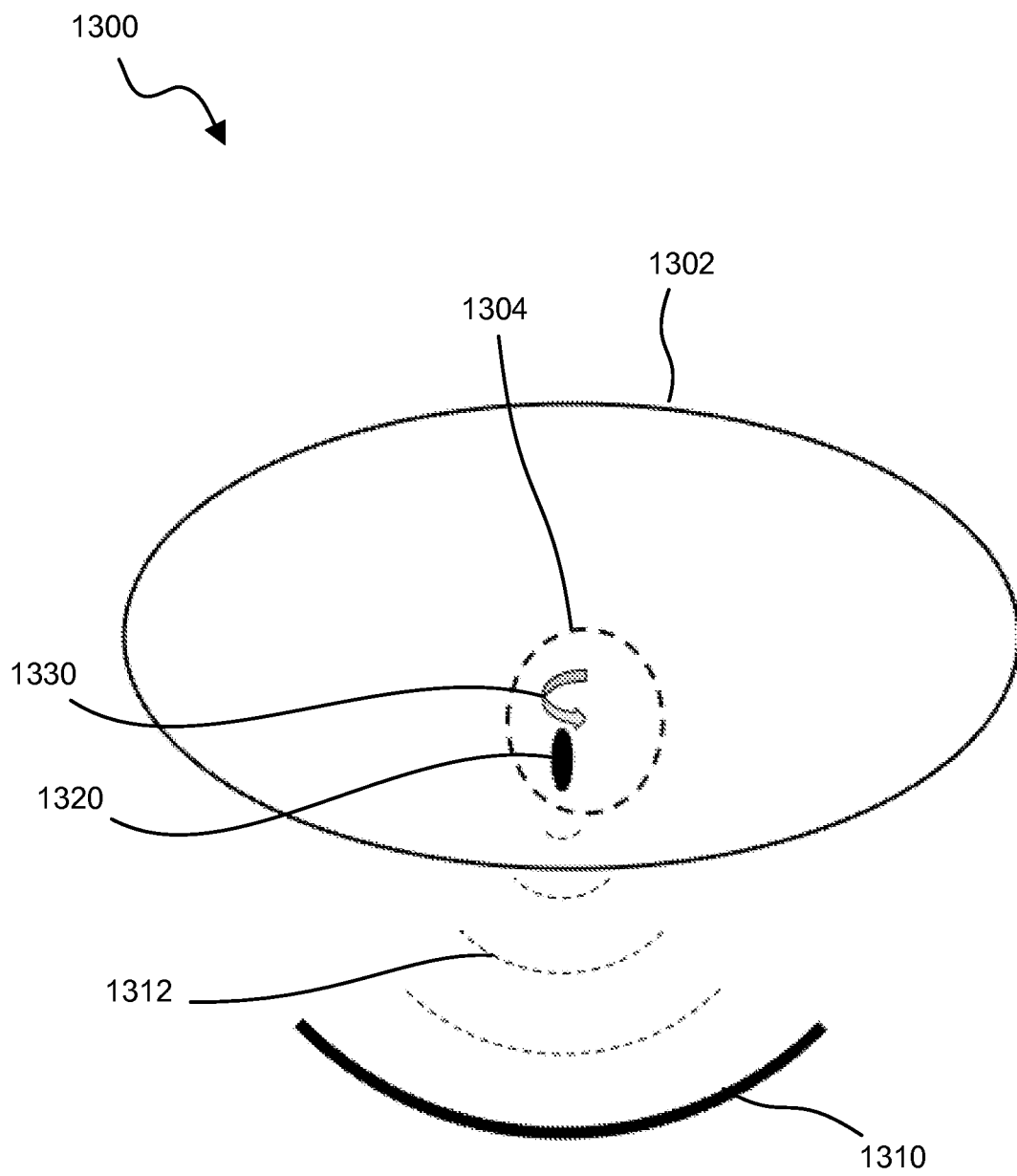


Fig. 13

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	用于控制和监测适形热疗法的系统和方法		
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申请号	EP2012835517	申请日	2012-09-26
[标]申请(专利权)人(译)	医疗PROFOUND MAHON CAMERON BURTNYK MATHIEU		
申请(专利权)人(译)	PROFOUND MEDICAL INC. MAHON , CAMERON BURTNYK , MATHIEU		
当前申请(专利权)人(译)	PROFOUND MEDICAL INC. MAHON , CAMERON BURTNYK , MATHIEU		
[标]发明人	MAHON CAMERON BURTNYK MATHIEU		
发明人	MAHON, CAMERON BURTNYK, MATHIEU		
IPC分类号	A61N7/02 A61B5/00		
CPC分类号	A61N7/02 A61B5/015 A61B5/055 A61B5/4381 A61B5/4836 A61B2017/00119 A61B2018/00791 A61B2090/374 A61N7/022 A61N2007/0078 A61N2007/0095		
优先权	61/538982 2011-09-26 US		
其他公开文献	EP2760545B1 EP2760545A2		
外部链接	Espacenet		

摘要(译)

公开了一种用于热疗的系统和方法，其考虑了组织温度的预测计算，并且可以用于控制保形热疗程序和装置的操作。在一些实施方案中，组织消融区域是前列腺的一部分或全部。在优选实施例，该方法包括基于以下信息中的一些或全部的模拟和/或未来温度的计算：当前温度，组织中的热扩散，组织中的血液灌注，以及计划的超声能量沉积。计算的温度图可用于设计，控制或终止治疗。