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(54) **System and device for ultrasound thermography during a cardiac ablation procedure**

System und Gerät zur Ultraschallthermographie während einer Ablationsbehandlung am Herzen

Système et appareil pour la thermographie à ultrasons pendant une procédure d’ablation cardiaque

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(56) References cited:
**WO-A1-2008/050276 US-A1- 2004 127 791**
**US-A1- 2007 106 157 US-A1- 2008 033 417**
**US-A1- 2011 087 097 US-A1- 2011 160 593**
**US-B2- 7 806 829**

- **CHI HYUNG SEO ET AL: "The feasibility of using thermal strain imaging to regulate energy delivery during intracardiac radio-frequency ablation", IEEE TRANSACTIONS ON ULTRASONICS, FERROELECTRICS AND FREQUENCY CONTROL, IEEE, US, vol. 58, no. 7, 1 July 2011 (2011-07-01), pages 1406-1417, XP011329759, ISSN: 0885-3010, DOI: 10.1109/TUFFC.2011.1960**
- **C. H. SEO ET AL: "Thermal strain imaging: a review", PHYSICS IN MEDICINE AND BIOLOGY, vol. 1, 23 May 2011 (2011-05-23), pages 649-664, XP055178094, ISSN: 0031-9155, DOI: 10.1088/0031-9155/55/6/011**

- **DOUGLAS N STEPHENS ET AL: "Ultrasound compatible RF ablation electrode design for catheter based guidance of RF ablation - In vivo results with thermal strain imaging", ULTRASONICS SYMPOSIUM (IUS), 2010 IEEE, IEEE, 11 October 2010 (2010-10-11), pages 229-232, XP031952800, DOI: 10.1109/ULTSYM.2010.5935664 ISBN: 978-1-4577-0382-9**

## Description

BACKGROUND OF THE INVENTION

a. Field of the Invention

**[0001]** The present disclosure relates to monitoring of therapeutic procedures. In particular, the present disclosure relates to apparatus for monitoring and displaying lesion formation during therapeutic procedures, such as cardiac ablation procedures utilized in the treatment of cardiac arrhythmia.

b. Background Art

**[0002]** It is well known that atrial fibrillation results from disorganized electrical activity in the heart muscle (the myocardium). The surgical maze procedure has been developed for treating atrial fibrillation, and involves the creation of a series of surgical incisions through the atrial myocardium in a preselected pattern so as to create conductive corridors of viable tissue bounded by scar tissue.

**[0003]** As an alternative to the surgical incisions of the maze procedure, transmural ablations of the heart may be used. Such ablations may be performed from within the chambers of the heart (endocardial ablation), using endovascular devices (e.g., catheters) introduced through arteries or veins. Various ablation techniques may be used, including, but not limited to, cryogenic ablation, radiofrequency ablation, laser ablation, ultrasonic ablation, and microwave ablation. The ablation devices are used to create elongated transmural lesions - that is, lesions extending through a sufficient thickness of the myocardium to block electrical conduction - forming the boundaries of the conductive corridors in the atrial myocardium. Perhaps most advantageous about the use of transmural ablation rather than surgical incision is the ability to perform ablation procedures without first establishing cardiopulmonary bypass (CPB).

**[0004]** Ablation devices are commonly used in conjunction with diagnostic systems that aid the practitioner in navigating, positioning and orienting the ablation device. These systems can provide a visual reference, such as a three dimensional model or two dimensional image, allowing the physician to more easily determine the orientation of the ablation device relative to the target anatomy. Intracardiac echo (ICE) catheters are one commonly used diagnostic tool that provides a two dimensional image of both therapeutic catheters and cardiac anatomy.

**[0005]** US 2011/0160593 A1 relates to intracardiac catheter location and imaging, in particular to a system for use during an ablation procedure that provides the location and orientation of an ICE catheter by a position sensing and mapping system, which is used to project an intracardiac echocardiography image into a geometric model of the heart.

**[0006]** IEEE TRANSACTIONS ON ULTRASONICS, FERROELECRICS, AND FREQUENCY CONTROL, VOL. 58, NO. 7 JULY 2011, "The Feasibility of Using Thermal Strain Imaging to Regulate Energy Delivery During Intracardiac Radio-Frequency Ablation" relates to the usage of thermal strain imaging (TSI) to regulate energy delivery during intracardiac radio-frequency ablation, wherein it is determined that while TSI may not be practical for ablation monitoring based on precise temperature measurements, because it is more sensitive and unambiguous for small temperature changes in the range below 50°C, it may be useful to indicate when tissue temperature has reached or exceeded 50°C so ablation can be terminated.

**[0007]** It is desirable for the practitioner (e.g., the doctor or electrophysiologist) to be able to monitor local temperature changes at the ablation site to allow the practitioner to more readily judge the extent of lesion formation during ablation procedures.

BRIEF SUMMARY OF THE INVENTION

**[0008]** The present disclosure describes a diagnostic system as defined in claim 1. The system utilizes an ICE catheter having an ultrasound transducer used to generate ultrasound echo data sets representing the reflected ultrasonic energy received by the transducer. The system also utilizes a visualization, navigation, or mapping (VNM) system configured to generate a model of the heart, track the position of the ultrasound transducer within the model, generate one or more temperature voxels within the model, and generate a two dimensional rendering of the model.

**[0009]** The VNM system is also configured to receive multiple ultrasound echo data sets and for each data set generate a mapped value by mapping at least a portion of the ultrasound echo data set onto a voxel element. The system further includes a display device configured to display a graphical user interface, and an electronic control unit (ECU) in communication with the intracardiac echo catheter, the VNM system, and the display device. The ECU is configured to receive the ultrasound echo data sets, the two dimensional rendering, and one or more user inputs directing the control of system components. The ECU is also configured to generate a graphic user interface containing the two dimensional rendering of the model as well as other display and control components.

**[0010]** The VNM system of the present embodiment generates a temperature value by comparing the mapped values from multiple ultrasound echo data sets. The system can determine temperature changes by determining a frequency shift or echo time shift between the mapped values of different ultrasound echo data sets. The voxels of the model can have a display value indicating the color in which the voxel is to be displayed in the two dimensional rendering, where the display value is representative of the temperature change for that voxel.

**[0011]** The ICE catheter of the system may also generate a temperature signal that can be used by the VNM system to generate an absolute temperature value when combined with the temperature change value. The ECU can also receive a temperature threshold as a user input that can be compared to the absolute temperature value, and the ECU can change the display value of a voxel when the absolute temperature of that voxel exceeds the threshold.

**[0012]** A method of measuring temperature changes at a tissue treatment site comprises the steps of generating a model of the treatment area, locating at least one ICE catheter within the model, receiving an first ultrasound echo data set from the ICE catheter, and mapping the first ultrasound echo data set onto a plurality of voxel elements within the model. Then beginning treatment of the tissue, receiving a second ultrasound echo data set from the ICE catheter, mapping the second ultrasound echo data set onto a plurality of voxel elements within the model, and generating a temperature change value for each voxel element by comparing the mapped portion of the first ultrasound echo data set and the mapped portion of the second ultrasound data set. The method can determine the temperature change for each voxel by determining a frequency shift or an echo time shift from the mapped portion of the two echo data sets.

**[0013]** The method may also include a step that generates a two dimensional rendering of the model containing one or more of the voxel elements where the voxel elements are depicted using a color representative of the temperature change value. The method may also include the steps of receiving a temperature signal from the ICE catheter, and generating an absolute temperature value for each voxel element from the temperature change value for a given voxel and the temperature signal.

**[0014]** Where the method includes generating an absolute temperature value, the method may also include the step of generating a two dimensional rendering of the model containing one or more voxel elements where the voxel elements are depicted in a color representative of the absolute temperature value for each voxel element.

**[0015]** In another embodiment, the present disclosure describes a diagnostic device as defined in claim 8, which comprises an ECU in communication with an ICE catheter, a VNM system, and a display device. The ECU of the diagnostic device being configured to receive a plurality of ultrasound echo signals and a catheter position and orientation signal. The ECU is also configured to generate a model of a body cavity and locate the ICE catheter within the model using the catheter position and orientation signal. The model generated by the ECU can contain one or more voxel elements having a display value and a data value. The ECU of this embodiment is configured to generate a set of echo data elements from each received ultrasound echo signal where each echo data element is mapped onto one voxel element based on the catheter position and orientation signal. The ECU can generate a first echo data set and store the echo data elements as the data value of the corresponding voxel elements. The ECU can then generate a second set of echo data elements and map each echo data element from the second set onto a voxel. For each voxel having a data element from both data sets mapped onto it, the ECU can generate a display value representing a temperature change for the voxel using the data value and the mapped second data element.

**[0016]** In this embodiment, the temperature change can be generated by determining a frequency shift or echo time shift between the data value and the second data element for each voxel. The ECU can also be configured to generate a two dimensional rendering of the model containing one or more voxel elements where the voxel elements are depicted in a color representative of the display value of each voxel.

**[0017]** The ECU of this embodiment can also be configured to receive a temperature signal and generate an absolute temperature value from the display value and the temperature signal. Where the ECU generates an absolute temperature signal, the ECU can be configured to generate a two dimensional rendering of the model containing one or more voxel elements, the voxel elements being depicted in a color representative of the absolute temperature value. Where the ECU generates an absolute temperature signal, the ECU may also be configured to receive a user input indicating a temperature threshold, where the ECU will generate a two dimensional rendering depicting the voxel elements having an absolute temperature value less than the temperature threshold using a color representative of the absolute temperature value and the voxel elements having an absolute temperature equal to or greater than the temperature threshold using an alert color.

**[0018]** The foregoing and other aspects, features, details, utilities, and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

**[0019]**

FIG. 1 is a block diagram illustrating the operation of the system of the present disclosure prior to the start of a therapeutic treatment.

FIG. 2 is a block diagram illustrating the operation of the system of the present disclosure after the beginning of a therapeutic treatment.

FIG. 3 depicts an example of an intracardiac echo catheter suitable for use in the system of the present disclosure.

FIG. 4 depicts an example of the distal end of an echo catheter suitable for use in the system of the present disclosure.

FIG. 5a is a schematic view of the ultrasound transducer illustrating the plane of emitted ultrasonic energy.

FIG. 5b is a cross sectional view of the ultrasound transducer illustrating the plane of emitted ultrasonic energy.

DETAILED DESCRIPTION OF THE INVENTION

**[0020]** Referring now to the drawings wherein like reference numerals are used to identify identical components in the various views, FIGS. 1 and 2 are block diagrams illustrating the relationship between the elements of the system of the present disclosure.

**[0021]** The present disclosure provides a diagnostic system 10 capable of monitoring lesion formation during ablation. The diagnostic system includes an ICE catheter 12 containing one or more electrodes 13, an anatomical visualization, navigation, and mapping system ("VNM system") 14, an electronic control unit ("ECU") 16, and one or more display devices 18. The VNM system 14 is used to detect therapeutic and diagnostic devices within the body and locate the devices within a model 20 of the heart and surrounding vasculature. The VNM system 14 can track detected therapeutic and diagnostic devices as they move within the heart and update their locations in the model 20 such that the model 20 is updated in substantially real time. The VNM system can create a two dimensional rendering 22 of the model 20 depicting the position and orientation ("P&O") of the devices within the model 20, which may be used as part of a graphic user interface depicted on the display 18. When the VNM system 14 is used to display the P&O of an ICE catheter 12 within the heart, the echo plane of the ICE catheter 12 can be mapped within the model 20. Displaying the P&O of the ICE catheter 12 and its echo plane allows a physician to more easily navigate an ICE catheter 12 and thereby create an ICE image of a desired anatomical feature, such as an ablation target site. During the ablation procedure, the echo plane of the ICE catheter 12 can be used to estimate lesion formation by detecting temperature changes at the ablation site.

**[0022]** Referring now to FIGS. 3 and 4, which illustrate an example of an ICE catheter for use in the system of the present disclosure.

## ICE Catheter

**[0023]** The ICE catheter 12 may comprise a control handle 24, a long flexible body member 26, and a sensor array 28 containing an ultrasound sensor 30 and a plurality of electrodes 13. The sensor array 28 is fixed to the end of the flexible body member 26 and may be inserted intravenously and navigated to the heart by manipulating the length of the flexible body member 26 using the control handle 24.

**[0024]** As depicted in FIGS. 5a and 5b, the ultrasound transducer 30 emits ultrasonic energy pulses in a generally fan shaped echo plane 34, and receives echo pulses when the ultrasonic energy is reflected back to the transducer 30 by a scattering object intersected by a pulse in the echo plane 34. The transducer 30 produces ultrasound echo data 36 (shown in FIG. 2) representative of the received echo pulses that can be used to create an ICE image depicting objects located within the echo plane 34. The ultrasound echo data 36 can be unprocessed ultrasound transducer signals, or may be conditioned using one or more amplification and filtering circuits, such as, by way of example, backscatter A-line data.

**[0025]** ICE images may be gray scale images with tissue structures, catheters and other dense objects being displayed in white, while dark portions of the image tend to represent cavity space filled with fluid. The more echogenic (e.g., the denser) a material is, the brighter its representation will be displayed in the image. The image can be generated by the ICE catheter 12, or by the ECU 16 of the system after receiving the ultrasound echo data from the ultrasound transducer 30. For purposes of clarity and illustration only, the description below will be limited to an embodiment having the ICE image created by the ECU 16.

**[0026]** Referring now back to FIGS. 1 and 2, the ICE image generated by ECU 16 can be incorporated into a graphic user interface 38. The graphic user interface 38 is displayed on one or more of the display devices 18 of the system 10. In an alternative embodiment, the ICE image can be incorporated into the graphic user interface 38 such that the ICE image appears projected within the two dimensional rendering 22 of the model 20 maintained by the VNM system 14. Display of the ICE image within the rendering 22 of the model 20 allows a physician to more easily correlate features within the ICE image to anatomical features in the model 20.

**[0027]** The plurality of electrodes 13 or other sensors configured to be responsive to the VNM system 14 allow the system 10 to determine the P&O of the ICE catheter 12 within the model 20. The ICE catheter 12 is electrically coupled to the ECU 16 and may contain three or more electrodes 13 responsive to an electric field 40 (shown in FIGS. 1 and 2) generated by the VNM system 14. The electrodes 13 being configured to generate a position response signal 42 when positioned within an electric field 40 generated by the VNM system 14. The position response signal 42 may be received directly by the VNM system 14 or may be communicated to the VNM system 14 through the ECU 16. The electrodes 13 can be positioned within the sensor array 28 such that the VNM system 14 may determine the P&O of the ultrasound sensor 30 with six degrees of freedom in the model 20 maintained by the VNM system 14, thereby allowing the ICE image to be located within the model 20.

**[0028]** In an alternative embodiment, one or more electrodes 13 may be replaced with magnetic sensors responsive to a magnetic field generated by the VNM system 14. An example of such an ICE catheter 12 is described in copending United States Patent Application No. 12/982,968 filed December 31, 2010 entitled "INTRACARDIAC IMAGING SYSTEM UTILIZING A MULTIPURPOSE CATHETER".

## VNM System

**[0029]** The ECU 16 is electrically coupled to (*i.e.,* via wires or wirelessly) to the VNM system 14, which generates and maintains the model 20 of the heart and surrounding vasculature or other body structure. The VNM system 14 may further be configured to allow the user to identify features within the model 20 and include the location as well as other information associated with the identified feature, such as an identifying label. By way of example, identified features may include ablation lesion markers or anatomical features such as cardiac valves.

**[0030]** The VNM system 14 functionality may be provided as part of a larger visualization, navigation, or mapping system, for example, an ENSITE VELOCITY™ system running a version of ENSITE NAVX™ software commercially available from St. Jude Medical, Inc., and as also seen generally by reference to U.S. Patent No. 7,263,397 entitled "METHOD AND APPARATUS FOR CATHETER NAVIGATION AND LOCATION AND MAPPING IN THE HEART" to Hauck et al.

**[0031]** The VNM system 14 may comprise conventional apparatus known generally in the art, for example, the ENSITE VELOCITY™ system described above or other known technologies for locating/navigating a catheter in space (and for visualization), including for example, the CARTO™ visualization and location system of Biosense Webster, Inc., *(e.g.,* as exemplified by U.S. Patent No. 6,690,963 entitled "SYSTEM FOR DETERMINING THE LOCATION AND ORIENTATION OF AN INVASIVE MEDICAL INSTRUMENT", the AURORA® system of Northern Digital Inc., a magnetic field based localization system such as the gMPS system based on technology from MediGuide Ltd. of Haifa, Israel and now owned by St. Jude Medical, Inc. (*e.g.,* as exemplified by U.S. Patent Nos. 7,386,339, 7,197,354 and 6, 233, 476) or a hybrid magnetic field-impedance based system, such as the CARTO 3™ visualization and location system of Biosense Webster, Inc. (*e.g.,* as exemplified by U.S. Patent No. 7,536,218, and 7,848,789).

**[0032]** Some of the localization, navigation and/or visualization systems may involve providing a sensor for producing signals indicative of catheter location and/or orientation information, and may include, for example one or more electrodes 13 in the case of an impedance-based localization system such as the ENSITE VELOCITY™ system running ENSITE NAVX™ software, which electrodes may already exist in some instances, or alternatively, one or more coils (*i.e.,* wire windings) configured to detect one or more characteristics of a low-strength magnetic field, for example, in the case of a magnetic-field based localization system such as the gMPS system using technology from MediGuide Ltd. described above.

**[0033]** Although the exemplary VNM systems 14 described above each maintain a model 20 of the body cavity, acceptable alternative mapping devices for creating a model of cardiac structures include magnetic resonance imaging (MR) and x-ray computed tomography (CT).

**[0034]** While each of the electric-impedance, magnetic field, and hybrid magnetic field-impedance based systems disclosed above can act as the VNM system 14, the VNM system 14 of the remaining discussion will be assumed to be an impedance based system for the purposes of clarity and illustration unless otherwise noted.

## ECU

**[0035]** Referring now to FIGS. 1 and 2 depicting a block diagram of embodiments of the present invention, the ECU 16 will be discussed. The ECU 16 may include a programmed electronic controller having a processor 44 in communication with a memory 46 or other computer readable media (memory) suitable for information storage. Relevant to the present disclosure, the ECU 16 is configured, among other things, to receive user input 48 from one or more user input devices electrically connected to the system 10 and to issue commands (i.e., display commands) to the display devices 18 attached to the system 10 directing the depiction of the graphic user interface 38. The ECU 16 may be configured to be in communication with the ICE catheter 12 and the VNM system 14 to facilitate the creation of a graphic user interface 38 containing at least an ICE image, a two dimensional rendering 22 of the model 20, or both. The communication between the ICE catheter 12, the ECU 16, and the VNM system 14 may be accomplished in an embodiment through a communications network (e.g., a local area network or the internet) or a data bus.

**[0036]** It should be understood that although the VNM system 14, the ICE catheter 12, and the ECU 16 are shown separately, integration of one or more computing functions may result in a system including an ECU 16 on which may be run both (i) various control and image formation functions of the ICE catheter 12 and (ii) the modeling and position tracking functionality of the VNM system 14. For purposes of clarity and illustration only, the description below will be limited to an embodiment having the modeling and position tracking functionality of the VNM system 14 separate from the ECU 16.

## Frequency Shift Temperature Estimation

**[0037]** In addition to generating an ICE image, the ICE catheter 12 may be used to estimate lesion formation during an ablation procedure. By positioning the ultrasound transducer 30 such that the echo plane 34 intersects the ablation target site, changes in temperature at the site can be detected by measuring local frequency shifts or echo time shifts in the reflected ultrasound echo data 36. Detected temperature changes may be visualized using a plurality of temperature voxels 50 within the model 20 at the ablation target site. The system 10 allows local temperature changes to be detected despite the movement of the ICE catheter, the target anatomy - i.e., beating of the patient's heart, or a combination of the two - by mapping received ultrasound echo data 36 into the model 20. Mapping data into the model allows the ECU 16 to compare discrete ultrasound echo data points from the same tissue structures to determine a relative temperature change for each point. As the relative temperature changes are determined, the display values for each corresponding voxel 50 can be changed to reflect the new temperature change thereby causing the two dimensional rendering 22 to be updated accordingly.

**[0038]** In one embodiment of the system 10 of the present disclosure, the local temperature changes at the ablation site are determined using the ultrasound echo data 36 by measuring frequency shifts in the ultrasound backscatter A-line data as described in detail in Noninvasive Estimation of Tissue Temperature Responsive to Heating Fields Using Diagnostic Ultrasound, Seip, Ebbini, IEEE Transactions on Biomedical Engineering, Vol. 42, No. 8, August 1995. The frequency shift method computes a detailed autoregressive power spectrum from the A-line data generated by the ICE catheter 12 to model detected frequency shifts as tissue temperature changes. The frequency shift depends on the effect of a temperature change on two variables, the first being the average scatter spacing *d* in the tissue and the second being the speed of sound c in the tissue, which can be expressed as:

$$f_k(T) = \frac{kc(T)}{2d(T)} \quad k = 1,2,3,\ldots,\infty. \tag{1}$$

where *k* is the harmonic of the fundamental frequency, *c*(T) is the speed of sound in the medium as a function of temperature *T*, and *d*(T) is the average scatter spacing as a function of temperature.

**[0039]** The average scatter spacing *d* of a tissue increases as the temperature increases and decreases as the temperature decreases. This increase and decrease of *d* as a function of temperature is determined by the linear coefficient of thermal expansion a of the tissue or medium in general. The average scatter spacing *d* as a function of temperature is approximately given by:

$$d = d_0(1 + \alpha\Delta T) \tag{2}$$

where a is the linear coefficient of thermal expansion of the medium and $d_0$ is the average scatter spacing at a baseline temperature $T_0$.

**[0040]** The speed of sound *c* increases with increasing temperature in most tissues, including muscle and other tissues containing mostly water, but decreases with increasing temperature in fatty tissues. By differentiating (1) with respect to time *T* and using (2) within the result yields an expression for approximating a frequency shift $Df_k$ as function of temperature:

$$\Delta f_k(T) \approx \frac{k}{2d_0}\left[\frac{\partial c(T)}{\partial T}\bigg|_{T=T_0} - \alpha\, c_0\right]\Delta T \tag{3}$$

where $c_0$ is the value of the speed of sound in the medium at the baseline temperature of $T_0$. As can be seen in (3), a frequency shift detected in the ICE catheter 12 A-line data can be used to approximate a temperature change when the linear coefficient of thermal expansion a and the temperature dependence of the speed of sound in the medium $\frac{\partial c(T)}{\partial T}$ are known.

## Eco Time-Shift Temperature Estimation

**[0041]** In another embodiment of the system of the present disclosure, the local temperature changes at the ablation site are determined using the ultrasound echo data 36 by measuring echo time-shifts of ultrasound scatter locations in A-line data as described in detail in Two-Dimensional Temperature Estimation Using Diagnostic Ultrasound, Simon, VanBaren, Ebbini, IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. 45, No. 4, July 1998.

**[0042]** The thermal dependence of ultrasound echo time-shift is related to changes in the speed of sound in the medium and to thermal expansion of the medium. The former produces an apparent shift in scatter location, while the latter produces a physical shift. The observed time shift for an echo from a scatterer at an axial depth z can be described as:

$$\Delta t(z) = t(z) - t(z_0) = 2\int_0^z \left[ \frac{1+\alpha(d)\Delta T(d)}{c(d,T(d))} - \frac{1}{c(d,T_0)} \right] \partial d \qquad (4)$$

where $\alpha(d)$ is the linear coefficient of thermal expansion of the medium, at depth $d$, $\Delta T(d)$ is the change in temperature at depth $d$, and $c(d,T(d))$ and $c(d,T_0)$ are the speed of sound at depth $d$ at temperature $T$ and an initial temperature $T_0$, respectively. Differentiating (4) and substituting for the case where the thermal dependence on the speed of sound in tissue is approximately linear, as is the case with ablation temperatures, yields an expression for the change in temperature as a function of the time shift.

$$\Delta T(z) = \frac{c_0(z)}{2} \left( \frac{1}{\alpha(z) - \beta(z)} \right) \frac{\partial}{\partial z} (\Delta t(z)) \qquad (5)$$

where $\beta(z) = \frac{1}{c_0(z)} \cdot \frac{\partial c(z,T)}{\partial T} \Big|_{T=T0}$ and $c_0(z) = c(z, T_0)$. When the speed of sound in the medium and the coefficient of thermal expansion are invariant with respect to depth, then $c_0(z) = c_0$, $\alpha(z) = \alpha$, and $\beta(z)=\beta$.

**[0043]** The algorithm for estimating temperature in a two dimensional plane requires tracking the cumulative echo time-shift $\partial t(z,x,T_i)$ at each location and time $T_i$, and then differentiating it along the axial direction (z) and filtering both axial and lateral (x) directions. The symbol $T_i$ represents the time at which each $i$th frame was acquired, not the echo time delays $t$. The temperature estimation algorithm can be accomplished by the following steps:

1) Acquiring two dimensional echo data from the ICE catheter 12 prior to any heating of the target anatomy to establish a base line temperature $r(z,x,T_0)$, $i = 0$;

2) Start heating, i.e., by beginning the ablation treatment at the target site;

3) Acquiring another two dimensional echo data reading $r(z,x,T_i)$, $i = i + 1$;

4) Estimating the incremental time-shift map;

$$\partial \hat{t}_{incr}(z,x,T_i) = \hat{t}(z,x,T_i) - \hat{t}(z,x,T_{i-1}) \qquad (6)$$

at time $T_i$ using the current and previous frames $r(z,x,T_i)$ and $r(z,x,T_{i-1})$;

5) Computing the cumulative time-shift map;

$$\partial\hat{t}(z,x,T_i) = \sum_{k=1}^{i} \partial\hat{t}_{incr}(z,x,T_k) \qquad (7)$$

6) Differentiating the cumulative time-shift map $\hat{\partial t}(z,x,T_i)$ along the axial direction and filtering along the axial and lateral directions, using a two dimensional separable FIR filter;

7) Scaling the results of the sixth step by $kc_0/2$ to obtain the temperature-change map estimates $\hat{\partial\theta}(z,x,T_i)$ at time $T_i$; and

8) Returning to step three and repeating until all of the desired two dimensional echo data has been acquired.

**[0044]** The incremental time shifts can be very small and are commonly less than the echo sampling period. In order to obtain accurate incremental time-shifts in the echo subsample range an auto-correlation technique can be utilized to allow the incremental time-shift to be estimated from the phase of the axial component of a 2-D complex auto-correlation of two subsequent frames of echo data 36. The first step in of the auto-correlation function is to compute the analytic signal of the echo data using an FIR Hilbert Transformer $h(m)$. The 1-D discrete time Hilbert transform of the echo signal along the axial direction can be obtained by convolusion of the discrete time sampled echo data and the Hilbert Transformer $h(m)$, given by:

$$\breve{r}(m,n,s) = r(m,n,s) * h(m) \qquad (8)$$

where $r(m,n,s)$ is the discrete-time sampled echo data, where $m$ is the index along the axial direction, $n$ is the index along the lateral direction, and s is the frame index (wall clock time). An analytic signal can be obtained using (8) through:

$$\hat{r}(m,n,s) = r(m,n,s) - j\,\breve{r}(m,n,s). \qquad (9)$$

**[0045]** When using an echo image consisting of $M$ samples along the axial direction and $N$ samples along the lateral direction, the $q$-th lag, along the axial direction of the complex auto-correlation function at location (m, n) and time s is defined as:

$$\hat{\gamma}(m,n;q,0) = \sum_{m'=-\frac{M}{2}}^{\frac{M}{2}-1} \sum_{n'=-\frac{N}{2}}^{\frac{N}{2}-1} \hat{r}(m+m',n+n',s-1)\cdot \hat{r}^*(m+m'+q,n+n',s) \qquad (10)$$

where the superscript * denotes complex conjugation, and $M$ and $N$ are assumed to be even numbers for simplicity. From (10) the incremental time-shifts smaller than the sampling period can be estimated from the phase of the auto-correlation function computed at lags $q$=-1, $q$=0 and $q$=1 using:

$$\Delta\hat{t}(m,n) = \frac{2\angle\hat{\gamma}(m,n;0,0)}{\angle\hat{\gamma}(m,n;1,0) - \angle\hat{\gamma}(m,n;-1,0)} t_{sp}, \qquad (12)$$

where $t_{sp}$ is the time for one sampling period of the RF-echo, and $\angle$ is the angle operator. Estimates of $\hat{\Delta t}(m,n)$ can be truncated to the range $[-t_{sp}, t_{sp}]$ to avoid outliers when time-shift increments are smaller than $t_{sp}$.

**[0046]** The frequency domain and echo time-shift methods have been previously used with in relatively static configurations where neither the target tissue nor the ultrasound transducer is subject to appreciable movement during the temperature estimation procedure. When movement is introduced into the environment it becomes difficult to map newly received ultrasound echo data to allow an accurate comparison with existing echo ultrasound data.

**[0047]** An accurate comparison between the two data sets is difficult because when the ICE catheter and the target tissue move relative to one another or the orientation of the ICE catheter changes relative to the target tissue the ultrasound echo data from the new position or orientation cannot be directly compared to data from the prior position or orientation without having known spatial relationship between the earlier and later data. Without a system for tracking the ICE catheter's position in the heart there is no known relationship between the temporally distinct ultrasound echo data sets, which makes it very difficult to produce accurate temperature determinations when movement occurs. This static configuration limitation has previously rendered these temperature estimation techniques inappropriate for dynamic environments such as the atrial chambers of the heart or other active muscle systems.

**[0048]** The system of the present disclosure allows these temperature estimation techniques to be extended to dynamic environments through the interaction of the ICE catheter and VNM system when gathering the ultrasound echo data used in either temperature estimation algorithm.

**[0049]** The VNM system 14 enables temperature estimation in a dynamic environment by tracking the movements of the ICE catheter 12 within the heart, which allows the system to accurately map received ultrasound echo data 36 into the model 20 of the VNM system 14. Using the P&O of the ICE catheter 12, determined by the VNM system 14, each frame of received ultrasound echo data 36 can be mapped into the model 20 using voxel elements 50 to represent the tissue temperatures.

**[0050]** As features in the cardiac or other therapeutic environment move, such as the contraction of the cardiac chamber or movement of the ICE catheter 12 within the cardiac chamber, the ultrasound echo data 36 can be associated with the then existing P&O of the ICE catheter 12 and from that point be accurately mapped into the model 20. Thus, the model 20 and the ICE catheter's 12 known position in the model 20 at all times provides a known spatial relationship between any two temporally distinct set of ultrasound echo data 36 received by the ICE catheter 12. When ultrasound echo data 36 from multiple echo frames are mapped into the same voxel 50 the data 36 from previous echo frames can be used with the newly mapped frame to generate an estimated temperature change using one of the methods previously discussed.

**[0051]** Now referring back to FIGS. 1 and 2, to accurately estimate temperature changes attributable to a therapeutic procedure, a baseline or background ultrasound echo data set 36 for the target anatomy should be mapped into the model 20. The baseline echo data 36 can be gathered by the user while using the ICE catheter 12 to aid in navigating the therapeutic catheter into position, or when creating echo images of the target anatomy and surrounding tissue prior to ablation.

**[0052]** Once the baseline echo data 36 has been mapped into the voxels 50 within the model 20, data gathered during the therapeutic procedure can be used to generate temperature change estimates associated with the procedure. As the echo data 36 is mapped into the voxels 50 within the model 20, the display of the voxels 50 can be changed so as to create a visual reference of temperature at the therapeutic site. One such visual reference is a heat map, where the base line temperature is depicted as a green or blue color and, as the estimated temperature change of a voxel rises, its display color progresses along the visible light spectrum, with red representing the highest temperature change. A relative temperature change computed by the ECU 16 may be combined with temperature data from other temperature sensors present in the cardiac environment to generate an absolute temperature estimation for each voxel element 50.

**[0053]** Varying the display of the voxel elements 50 from a minimum baseline temperature to a maximum temperature set by the desired therapeutic temperature allows a user to easily determine which portions of the target anatomy have reached the desired therapeutic temperature. In one embodiment of the system 10 a voxel's 50 display color can be changed to one not normally within the range of heat map temperatures, such as a violet or purple color, making it more distinct from the surrounding tissue.

**[0054]** Although multiple embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this invention as defined in the appended claims. All directional references (e.g., upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise, and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not limiting.

## Claims

**1.** A diagnostic system for use during an ablation procedure comprising:

an intracardiac echo catheter (12) having an ultrasound transducer (30) configured to generate a first ultrasound echo data set representing a base line temperature at a first time and a second ultrasound echo data set representing a temperature at a second time different from the first time and representative of the received

ultrasonic energy during the ablation procedure;
a visualization, navigation, or mapping (VNM) system (14) configured to generate a model (20) of a body cavity, track the position of the ultrasound transducer (30) within the model (20), generate one or more voxel elements within the model (20), and generate a two dimensional rendering (22) of the model (20), the VNM system (14) being further configured to receive the first ultrasound echo data set and generate a first mapped value by mapping at least a portion of the first ultrasound echo data set representing tissue temperature at the first time onto the one or more voxel elements, the VNM system (14) being further configured to receive the second ultrasound echo data set and generate a second mapped value by mapping at least a portion of the second ultrasound data set representing tissue temperature at the second time onto the one or more voxel elements;
an electronic control unit (ECU) (16) in communication with the intracardiac echo catheter (12), the VNM system (14), and the display device (18) and being configured to receive the first ultrasound echo data set, the second ultrasound echo data set, the two dimensional rendering, and one or more user inputs directing the control of one or more of the intracardiac catheter (12) and the VNM system (14), the ECU (16) being further configured to generate a graphic user interface (38) containing at least the two dimensional rendering (22);
a display device (18) configured to display the graphical user interface; wherein the ECU (16) compares the first mapped value with the second mapped value to generate a temperature change value and to change display values of each corresponding voxel element for reflecting the temperature change thereby causing the two dimensional rendering (22) to be updated accordingly.

**2.** The diagnostic system of claim 1 wherein the temperature change value is generated by determining a frequency shift between the first mapped value and the second mapped value.

**3.** The diagnostic system of claim 1 wherein the temperature change value is generated by determining an echo time shift between the first mapped value and the second mapped value.

**4.** The diagnostic system of claim 1, each of the one or more voxel elements having a display value, the display value indicating the color in which the voxel is to be displayed within the two dimensional rendering, the display value being representative of the temperature change value.

**5.** The diagnostic system of claim 4, the intracardiac echo catheter (12) being further configured to generate a temperature signal and the VNM system being further configured to generate an absolute temperature value from the temperature change value and the temperature signal, wherein the display value is representative of the absolute temperature value.

**6.** The diagnostic system of claim 5, wherein the ECU (16) receives a temperature threshold value as a user input and the VNM system (14) changes the display value if the absolute temperature value meets or exceeds the temperature threshold value.

**7.** The diagnostic system of claim 1, the intracardiac echo catheter being further configured to generate a temperature signal and the VNM system being further configured to generate an absolute temperature value from the temperature change value and the temperature signal.

**8.** A diagnostic device for use during an ablation procedure comprising:

an electronic control unit (ECU) (16) in communication with an intracardiac echo catheter (12), a visualization, navigation, or mapping (VNM) system (14), and a display device (18), the ECU (16) being configured to receive a plurality of ultrasound echo signals during the ablation procedure and a catheter position and orientation signal, the ECU (16) being further configured to generate a model (20) of a body cavity and locate the intracardiac echo catheter (12) within the model (20) using the catheter position and orientation signal, the model (20) being configured to include one or more voxel elements representing tissue temperature having a display value and a data value, the ECU (16) being further configured to generate a set of echo data elements from each received ultrasound echo signal, each echo data element being mapped onto one of the one or more voxel elements based on the catheter position and orientation signal,
wherein the ECU is configured to generate a first set of echo data elements representing a base line temperature at a first time, map each element from the first set of echo data elements representing tissue temperature at the first time onto a mapped voxel element from the one or more voxel elements, and store the echo data element as the data value of the mapped voxel element, thereby creating a set of mapped voxel elements, the ECU is further configured to generate a second set of echo data elements representing a temperature at a

second time different from the first time, map one or more elements from the second set of echo data elements representing tissue temperature at the second time onto at least one voxel element from the set of mapped voxel elements;

wherein the ECU is further configured to compare for each mapped voxel element, on which an echo data element from the second set of of data elements is mapped, the data value of the mapped voxel element with the second data element for generating a temperature change value and to change the display values of each corresponding voxel element for reflecting the temperature change thereby causing a two dimensional rendering (22) of the model (20) to be updated accordingly.

**9.** The diagnostic device of claim 8 wherein the display value is generated by determining a frequency shift between the data value of the voxel element and the second data element.

**10.** The diagnostic device of claim 8 wherein the display value is generated by determining an echo time shift between the data value of the voxel element and the second data element.

**11.** The diagnostic device of claim 8, the ECU being further configured to generate the two dimensional rendering of the model (20) containing one or more voxel elements, the one or more voxel elements being depicted in a color representative of the display value of each of the one or more voxel elements.

**12.** The diagnostic device of claim 8, the ECU being further configured to receive a temperature signal and generate an absolute temperature value from the display value and the temperature signal.

**13.** The diagnostic device of claim 12, the ECU being further configured to generate a two dimensional rendering of the model containing one or more voxel elements, the one or more voxel elements being depicted in a color representative of the absolute temperature value.

**14.** The diagnostic device of claim 13, the ECU being further configured to receive a user input indicating a temperature threshold, wherein the two dimensional rendering depicts the one or more voxel elements that have an absolute temperature value less than the temperature threshold using a color representative of the absolute temperature value of the one or more voxel elements and the one or more voxel elements having an absolute temperature equal to or greater than the temperature threshold using an alert color.

**Patentansprüche**

**1.** Diagnosesystem zur Verwendung während eines Ablationsvorgangs, mit:

einem Herzechokatheter (12), der einen Ultraschalltransducer (30) aufweist, der konfiguriert ist zum Erzeugen eines ersten Ultraschallechodatensatzes, der eine Basislinientemperatur zu einem ersten Zeitpunkt darstellt, und eines zweiten Ultraschallechodatensatzes, der eine Temperatur zu einem von dem ersten Zeitpunkt verschiedenen zweiten Zeitpunkt darstellt, der repräsentativ ist für die empfangene Ultraschallenergie während des Ablationsvorgangs;

einem Visualisierungs-, Navigations- oder Abbildungs-(VNM)-System (14), das konfiguriert ist zum Erzeugen eines Modells (20) eines Körperhohlraums, zum Verfolgen der Position des Ultraschalltransducers (30) innerhalb des Modells (20), zum Erzeugen von einem oder von mehreren Voxel-Elementen innerhalb des Modells (20), und zum Erzeugen einer zweidimensionalen Wiedergabe (22) des Modells (20), wobei das VNM-System (14) ferner konfiguriert ist zum Empfangen des ersten Ultraschallechodatensatzes und zum Erzeugen eines ersten abgebildeten Werts durch Abbilden von mindestens einem Bereich des ersten Ultraschallechodatensatzes, der Gewebetemperatur zu dem ersten Zeitpunkt darstellt, auf das eine oder die mehreren Voxel-Elemente, wobei das VNM-System (14) ferner konfiguriert ist zum Empfangen des zweiten Ultraschallechodatensatzes und zum Erzeugen eines zweiten abgebildeten Werts durch Abbilden von mindestens einem Bereich des zweiten Ultraschalldatensatzes, der Gewebetemperatur zu dem zweiten Zeitpunkt darstellt, auf das eine oder die mehreren Voxel-Elemente;

einer elektronischen Steuerungseinheit (ECU) (16), die in Verbindung steht mit dem Herzechokatheter (12), dem VNM-System (14) und der Anzeigevorrichtung (18), und die konfiguriert ist zum Empfangen des ersten Ultraschallechodatensatzes, des zweiten Ultraschallechodatensatzes, der zweidimensionalen Wiedergabe und einer oder mehrerer Benutzereingaben, die die Steuerung des Herzkatheter (12) und/oder des VNM-Systems (14) anordnen, wobei die ECU (16) ferner konfiguriert ist zum Erzeugen einer graphischen Benutzerschnittstelle

(38), die mindestens die zweidimensionale Wiedergabe (22) aufweist;
einer Anzeigenvorrichtung (18), die konfiguriert ist zum Anzeigen der graphischen Benutzerschnittstelle;
wobei die ECU (16) den ersten abgebildeten Wert mit dem zweiten abgebildeten Wert vergleicht, um einen Temperaturänderungswert zu erzeugen und die Anzeigewerte jedes entsprechenden Voxel-Elements ändert zum Wiedergeben der Temperaturänderung, wodurch die zweidimensionale Wiedergabe (22) veranlasst wird, entsprechend aktualisiert zu werden.

**2.** Diagnosesystem nach Anspruch 1, bei dem der Temperaturänderungswert erzeugt wird durch Bestimmen einer Frequenzverschiebung zwischen dem ersten abgebildeten Wert und dem zweiten abgebildeten Wert.

**3.** Diagnosesystem nach Anspruch 1, bei dem der Temperaturänderungswert erzeugt wird durch Bestimmen einer Echozeitverschiebung zwischen dem ersten abgebildeten Wert und dem zweiten abgebildeten Wert.

**4.** Diagnosesystem nach Anspruch 1, bei dem das eine oder die mehreren Voxel-Elemente einen Anzeigewert aufweisen, wobei der Anzeigewert die Farbe angibt, in der das Voxel in der zweidimensionalen Wiedergabe anzuzeigen ist, und der Anzeigewert repräsentativ ist für den Temperaturänderungswert.

**5.** Diagnosesystem nach Anspruch 4, bei dem der Herzechokatheter (12) ferner konfiguriert ist zum Erzeugen eines Temperatursignals, und das VNM-System ferner konfiguriert ist zum Erzeugen eines absoluten Temperaturwerts aus dem Temperaturänderungswert und dem Temperatursignal, wobei der Anzeigewert repräsentativ ist für den absoluten Temperaturwert.

**6.** Diagnosesystem nach Anspruch 5, bei dem die ECU (16) einen Temperaturschwellenwert als Benutzereingabe erhält und das VNM-System (14) den Anzeigewert ändert, wenn der absolute Temperaturwert den Temperaturschwellenwert erfüllt oder übersteigt.

**7.** Diagnosesystem nach Anspruch 1, bei dem der Herzechokatheter ferner konfiguriert ist zum Erzeugen eines Temperatursignals, und das VNM-System ferner konfiguriert ist zum Erzeugen eines absoluten Temperaturwerts aus dem Temperaturänderungswert und dem Temperatursignal.

**8.** Diagnosevorrichtung zur Verwendung während eines Ablationsvorgangs, mit:

einer elektronischen Steuerungseinheit (ECU) (16), die in Verbindung steht mit einem Herzechokatheter (12), einem Visualisierung-, Navigations- oder Abbildungs-(VNM)-System (14) und einer Anzeigevorrichtung (18), wobei die ECU (16) konfiguriert ist zum Empfangen einer Mehrzahl von Ultraschallechosignalen während des Ablationsvorgangs, und eines Katheterpositions- und Orientierungssignals, wobei die ECU (16) ferner konfiguriert ist zum Erzeugen eines Modells (20) eines Körperhohlraums und zum Festlegen des Herzechokatheters (12) innerhalb des Modells (20), indem das Katheterpositions- und Orientierungssignal verwendet wird, wobei das Modell (20) konfiguriert ist, um ein oder mehrere Voxel-Elemente aufzuweisen, die Gewebetemperatur darstellen, die einen Anzeigewert und einen Datenwert aufweist, wobei die ECU (16) ferner konfiguriert ist zum Erzeugen eines Satzes von Echodatenelementen aus jedem empfangenen Ultraschallechosignal, wobei jedes Echodatenelement auf eines von dem einen oder den mehreren Voxel-Elementen basierend auf dem Katheterpositions- und Orientierungssignal abgebildet ist, wobei die ECU konfiguriert ist zum Erzeugen eines ersten Satzes von Echodatenelementen, der eine Basislinientemperatur zu einem ersten Zeitpunkt darstellt, zum Abbilden jedes Elements von dem ersten Satz von Echodatenelementen, die Gewebetemperatur zu dem ersten Zeitpunkt darstellen, auf ein abgebildetes Voxel-Element von dem einen oder den mehreren Voxel-Elementen, und zum Speichern des Echodatenelements als Datenwert des abgebildeten Voxel-Elements, wodurch ein Satz von abgebildeten Voxel-Elementen erzeugt wird, wobei die ECU ferner konfiguriert ist zum Erzeugen eines zweiten Satzes von Echodatenelementen, die eine Temperatur zu einem zweiten Zeitpunkt darstellen, der von dem ersten Zeitpunkt verschieden ist, zum Abbilden von einem oder von mehreren Elementen von dem zweiten Satz von Echodatenelementen, die Gewebetemperatur zu dem zweiten Zeitpunkt darstellen, auf mindestens ein Voxel-Element von dem Satz von abgebildeten Voxel-Elementen;
wobei die ECU ferner konfiguriert ist zum Vergleichen, für jedes abgebildete Voxel-Element, auf das ein Echodatenelement von dem zweiten Satz von Datenelementen abgebildet worden ist, des Datenwerts des abgebildeten Voxel-Elements mit dem zweiten Datenelement zum Erzeugen eines Temperaturänderungswerts, und zum Ändern der Anzeigewerte jedes entsprechenden Voxel-Elements zur Wiedergabe der Temperaturänderung, wodurch eine zweidimensionale Wiedergabe (22) des Modells (20) veranlasst wird, entsprechend aktualisiert zu werden.

**9.** Diagnosevorrichtung nach Anspruch 8, bei der der Anzeigewert erzeugt wird durch Bestimmen einer Frequenzverschiebung zwischen dem Datenwert des Voxel-Elements und des zweiten Datenelements.

**10.** Diagnosevorrichtung nach Anspruch 8, bei der der Datenwert erzeugt wird durch Bestimmen einer Echozeitverschiebung zwischen dem Datenwert des Voxel-Elements und dem zweiten Datenelement.

**11.** Diagnosevorrichtung nach Anspruch 8, bei der die ECU ferner konfiguriert ist zum Erzeugen der zweidimensionalen Wiedergabe des Modells (20), das ein oder mehrere Voxel-Elemente aufweist, wobei das eine oder die mehreren Voxel-Elemente in einer Farbe dargestellt sind, die den Anzeigewert von jedem von dem einen oder den mehreren Voxel-Elementen darstellt.

**12.** Diagnosevorrichtung nach Anspruch 8, bei der die ECU ferner konfiguriert ist zum Empfangen eines Temperatursignals und zum Erzeugen eines absoluten Temperaturwerts aus dem Anzeigewert und dem Temperatursignal.

**13.** Diagnosevorrichtung nach Anspruch 12, bei der die ECU ferner konfiguriert ist zum Erzeugen einer zweidimensionalen Wiedergabe des Modells, das ein oder mehrere Voxel-Elemente aufweist, wobei das eine oder die mehreren Voxel-Elemente in einer Farbe dargestellt sind, die dem absoluten Temperaturwert entspricht.

**14.** Diagnosevorrichtung nach Anspruch 13, bei der die ECU ferner konfiguriert ist zum Empfangen einer Benutzereingabe, die einen Temperaturschwellenwert angibt, wobei die zweidimensionale Wiedergabe das eine oder die mehreren Voxel-Elemente darstellt, die einen absoluten Temperaturwert haben, der kleiner als der Temperaturschwellenwert ist, indem eine Farbe verwendet wird, die den absoluten Temperaturwert des einen oder der mehreren Voxel-Elemente darstellt, und das eine oder die mehreren Voxel-Elemente eine absolute Temperatur haben, die gleich oder größer ist als der Temperaturschwellenwert, unter Verwendung einer Alarmfarbe.

## Revendications

**1.** Système de diagnostic pour être utilisé pendant une procédure d'ablation, comprenant :

un cathéter d'échographie intracardiaque (12) ayant un transducteur à ultrasons (30) configuré pour générer un premier jeu de données d'échographie ultrasonore représentant une température de référence à un premier moment et un second jeu de données d'échographie ultrasonore représentant une température à un second moment différent du premier moment et représentatif de l'énergie ultrasonique reçue pendant la procédure d'ablation ;
un système de visualisation, de navigation ou de mappage (VNM) (14) configuré pour générer un modèle (20) d'une cavité du corps, suivre la position du transducteur à ultrasons (30) dans le modèle (20), générer un ou plusieurs éléments de voxel dans le modèle (20) et générer un rendu bidimensionnel (22) du modèle (20), le système VNM (14) étant en outre configuré pour recevoir le premier jeu de données d'échographie ultrasonore et générer une première valeur mappée en mappant au moins une portion du premier jeu de données d'échographie ultrasonore représentant la température des tissus au premier moment sur l'un ou plusieurs éléments de voxel,
le système VNM (14) étant en outre configuré pour
recevoir le second jeu de données d'échographie ultrasonore et générer une seconde valeur mappée en mappant au moins une portion du second jeu de données ultrasonores représentant la température des tissus au second moment sur l'élément ou les éléments de voxel ;
une unité de contrôle électronique (ECU) (16) en communication avec le cathéter d'échographie intracardiaque (12), le système VNM (14) et le dispositif d'affichage (18) et étant configurée pour recevoir le premier jeu de données d'échographie ultrasonore, le second jeu de données d'échographie ultrasonore, le rendu bidimensionnel et une ou plusieurs entrées utilisateurs dirigeant le contrôle d'un ou de plusieurs du cathéter intracardiaque (12) et du système VNM (14), l'ECU (16) étant en outre configurée pour générer une interface utilisateur graphique (38)
contenant au moins le rendu bidimensionnel (22) ;
un dispositif d'affichage (18) configuré pour afficher l'interface utilisateur graphique ;
dans lequel l'ECU (16) compare la première valeur mappée avec la seconde valeur mappée pour générer une valeur de variation de température et changer les valeurs d'affichage de chaque élément de voxel correspondant pour refléter la variation de température, entraînant ainsi l'actualisation correspondante du rendu bidimensionnel (22).

2. Système de diagnostic selon la revendication 1 dans lequel la valeur de variation de température est générée en déterminant un décalage de fréquence entre la première valeur mappée et la seconde valeur mappée.

3. Système de diagnostic selon la revendication 1 dans lequel la valeur de variation de température est générée en déterminant un décalage de temps d'écho entre la première valeur mappée et la seconde valeur mappée.

4. Système de diagnostic selon la revendication 1, chacun des un ou plusieurs éléments de voxel ayant une valeur d'affichage, la valeur d'affichage indiquant la couleur dans laquelle le voxel doit être affiché dans le rendu bidimensionnel, la valeur d'affichage étant représentative de la valeur de variation de température.

5. Système de diagnostic selon la revendication 4, le cathéter d'échographie intracardiaque (12) étant en outre configuré pour générer un signal de température et le système VNM étant en outre configuré pour générer une valeur de température absolue à partir de la valeur de variation de température et du signal de température, dans lequel la valeur d'affichage est représentative de la valeur de température absolue.

6. Système de diagnostic selon la revendication 5, dans lequel l'ECU (16) reçoit une valeur de seuil de température comme entrée utilisateur et le système VNM (14) change la valeur d'affichage si la valeur de température absolue est égale ou dépasse la valeur de seuil de température.

7. Système de diagnostic selon la revendication 1, le cathéter d'échographie intracardiaque étant en outre configuré pour générer un signal de température et le système VNM étant en outre configuré pour générer une valeur de température absolue à partir de la valeur de variation de température et du signal de température.

8. Dispositif de diagnostic pour être utilisé pendant une procédure d'ablation, comprenant :

une unité de contrôle électronique (ECU) (16) en communication avec un cathéter d'échographie intracardiaque (12), un système de visualisation, de navigation ou de mappage (VNM) (14) et un dispositif d'affichage (18), l'ECU (16) étant configurée pour recevoir une pluralité de signaux d'échographie ultrasonore pendant la procédure d'ablation et un signal de position et d'orientation de cathéter, l'ECU (16) étant en outre configurée pour générer un modèle (20) d'une cavité corporelle et localiser le cathéter d'échographie intracardiaque (12) dans le modèle (20) en utilisant le signal de position et d'orientation de cathéter, le modèle (20) étant configuré pour inclure un ou plusieurs éléments de voxel représentant la température des tissus ayant une valeur d'affichage et une valeur de données, l'ECU (16) étant en outre configurée pour générer un jeu d'éléments de données d'échographie à partir de chaque signal d'échographie ultrasonore reçu, chaque élément de données d'échographie étant mappé sur l'un de l'un ou des plusieurs éléments de voxel à partir du signal de position et d'orientation du cathéter.
dans lequel l'ECU est configurée pour générer un premier jeu d'éléments de données d'échographie représentant une température de référence à un premier moment, mapper chaque élément à partir du premier jeu d'éléments de données d'échographie représentant la température de tissu au premier moment sur un élément de voxel mappé à partir de l'un ou des plusieurs éléments de voxel, et stocker l'élément de données d'échographie comme valeur de donnée de l'élément de voxel mappé, créant ainsi un jeu d'éléments de voxel mappés, l'ECU étant en outre configurée pour générer un second jeu d'éléments de données d'échographie représentant une température à un second moment différent du premier moment, mapper un ou plusieurs éléments à partir du second jeu d'éléments de données d'échographie représentant la température de tissu au second moment sur au moins un élément de voxel à partir du jeu d'éléments de voxel mappés ;
dans lequel l'ECU est en outre configurée pour comparer pour chaque élément de voxel mappé sur lequel un élément de données d'échographie à partir du second jeu d'éléments de données est mappé, la valeur de données de l'élément de voxel mappé avec le second élément de données pour générer une valeur de variation de température et changer les valeurs d'affichage de chaque élément de voxel correspondant pour refléter le changement de température, entraînant ainsi l'actualisation correspondante d'un rendu bidimensionnel (22) du modèle (20).

9. Dispositif de diagnostic selon la revendication 8 dans lequel la valeur d'affichage est générée en déterminant un décalage de fréquence entre la valeur de données de l'élément de voxel et le second élément de données.

10. Dispositif de diagnostic selon la revendication 8 dans lequel la valeur d'affichage est générée en déterminant un décalage de moment d'écho entre la valeur de donnée de l'élément de voxel et le second élément de données.

**11.** Dispositif de diagnostic selon la revendication 8, l'ECU étant en outre configurée pour générer le rendu bidimensionnel du modèle (20) contenant un ou plusieurs éléments de voxel, l'un ou les plusieurs éléments de voxel étant dépeints dans une couleur représentative de la valeur d'affichage de chacun de l'un ou des plusieurs éléments de voxel.

**12.** Dispositif de diagnostic selon la revendication 8, l'ECU étant en outre configurée pour recevoir un signal de température et générer une valeur de température absolue à partir de la valeur d'affichage et du signal de température.

**13.** Dispositif de diagnostic selon la revendication 12, l'ECU étant en outre configurée pour générer un rendu bidimensionnel du modèle contenant un ou plusieurs éléments de voxel, l'un ou les plusieurs éléments de voxel étant dépeints dans une couleur représentative de la valeur de température absolue.

**14.** Dispositif de diagnostic selon la revendication 13, l'ECU étant en outre configurée pour recevoir une entrée utilisateur indiquant un seuil de température, dans lequel le rendu bidimensionnel représente le un ou les plusieurs éléments de voxel qui ont une valeur de température absolue inférieure au seuil de température en utilisant une couleur représentative de la valeur de température absolue du un ou des plusieurs éléments de voxel et de l'un ou des plusieurs éléments de voxel ayant une température absolue égale à ou supérieure au seuil de température en utilisant une couleur d'alerte.

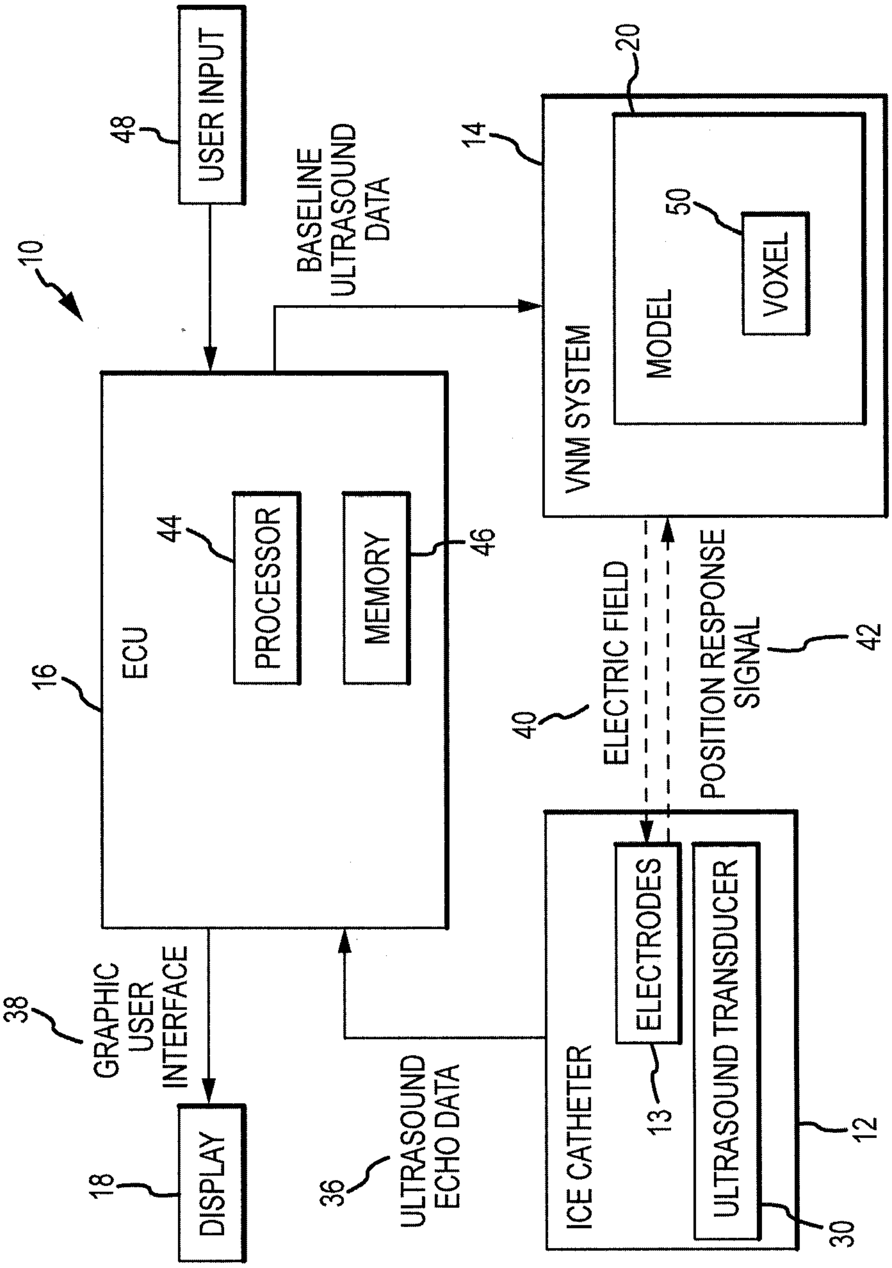
10
48
USER INPUT
BASELINE ULTRASOUND DATA
14
20
VNM SYSTEM
MODEL
50
VOXEL
16
ECU
44
PROCESSOR
MEMORY
46
40
ELECTRIC FIELD
POSITION RESPONSE SIGNAL
42
38
GRAPHIC USER INTERFACE
18
DISPLAY
36
ULTRASOUND ECHO DATA
ICE CATHETER
ELECTRODES
13
ULTRASOUND TRANSDUCER
30
12

FIG.1

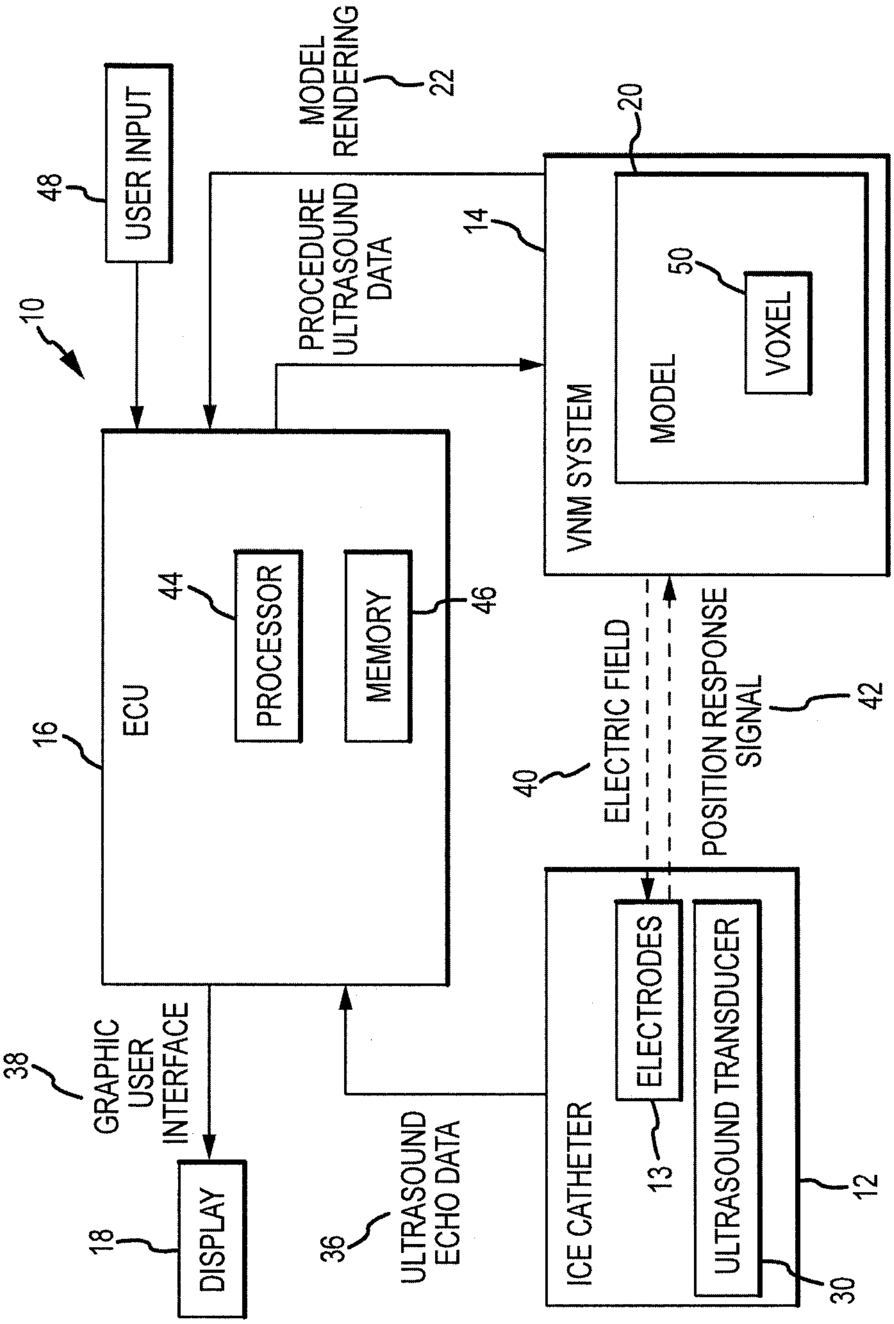
10
USER INPUT
48
MODEL RENDERING
22
PROCEDURE ULTRASOUND DATA
14
VNM SYSTEM
20
MODEL
VOXEL
50
ECU
16
PROCESSOR
44
MEMORY
46
ELECTRIC FIELD
40
POSITION RESPONSE SIGNAL
42
ICE CATHETER
12
ELECTRODES
13
ULTRASOUND TRANSDUCER
30
GRAPHIC USER INTERFACE
38
DISPLAY
18
ULTRASOUND ECHO DATA
36

FIG.2

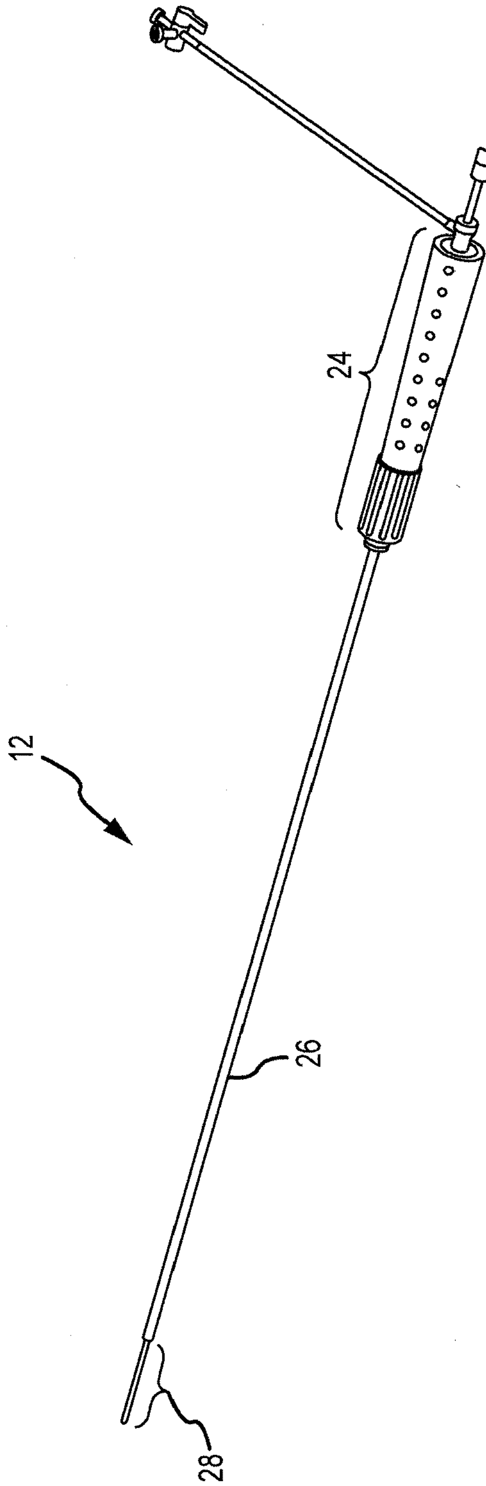


FIG.3

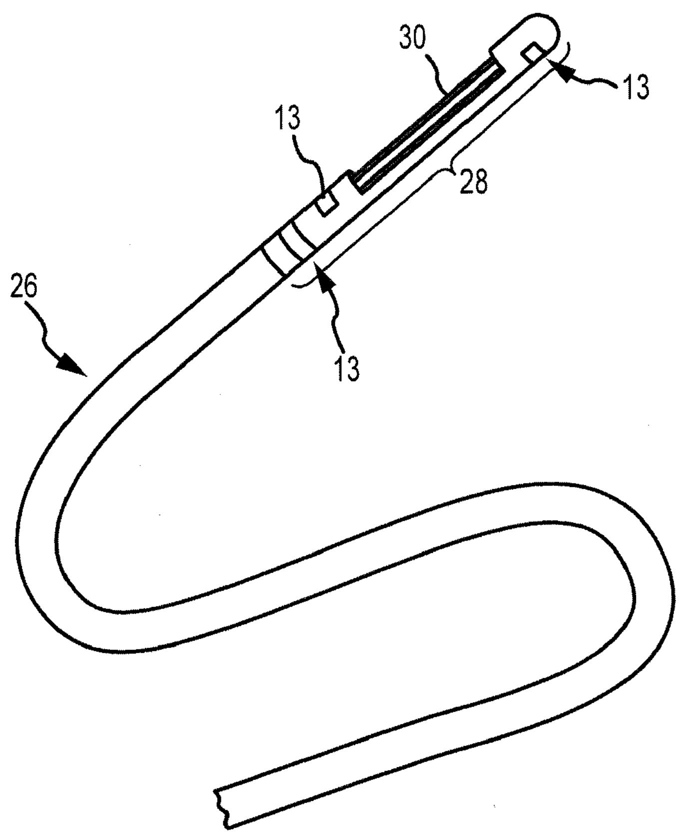


FIG.4

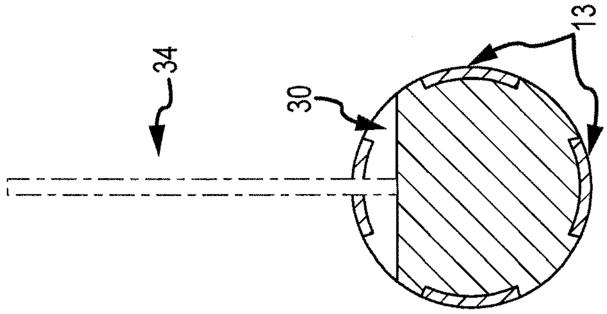


FIG.5b

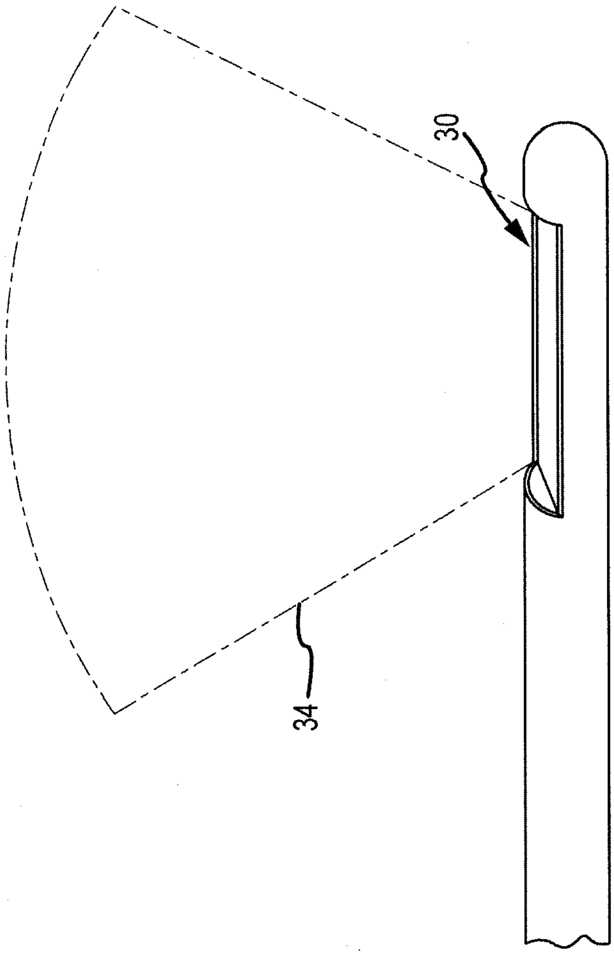


FIG.5a

## REFERENCES CITED IN THE DESCRIPTION

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### Patent documents cited in the description

- US 20110160593 A1 **[0005]**
- US 12982968 B **[0028]**
- US 7263397 B **[0030]**
- US 6690963 B **[0031]**
- US 7386339 B **[0031]**
- US 7197354 B **[0031]**
- US 6233476 B **[0031]**
- US 7536218 B **[0031]**
- US 7848789 B **[0031]**

### Non-patent literature cited in the description

- *IEEE TRANSACTIONS ON ULTRASONICS, FERROELECRICS, AND FREQUENCY CONTROL,* July 2011, vol. 58 (7 **[0006]**
- **SEIP ; EBBINI.** *IEEE Transactions on Biomedical Engineering,* August 1995, vol. 42 (8 **[0038]**
- **SIMON ; VANBAREN ; EBBINI.** *IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control,* July 1998, vol. 45 (4 **[0041]**