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(54) **ABLATION PROBE WITH ULTRASONIC IMAGING CAPABILITIES**

ABLATIONSSONDE MIT ULTRASCHALLBILDGEBUNGSFUNKTION

SONDE D'ABLATION AYANT DES CAPACITÉS D'IMAGERIE ULTRASONORE

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Description

[0001] The present disclosure relates generally to devices and systems for imaging anatomical structures within the body. More specifically, the present disclosure relates to an ablation probe with ultrasonic imaging capabilities.

BACKGROUND

[0002] In ablation therapy, it is often necessary to determine various characteristics of body tissue at a target ablation site within the body. In interventional cardiac electrophysiology (EP) procedures, for example, it is often necessary for the physician to determine the condition of cardiac tissue at a target ablation site in or near the heart. During some EP procedures, the physician may deliver a mapping catheter through a main vein or artery into an interior region of the heart to be treated. Using the mapping catheter, the physician may then determine the source of a cardiac rhythm disturbance or abnormality by placing a number of mapping elements carried by the catheter into contact with the adjacent cardiac tissue and then operate the catheter to generate an electrophysiology map of the interior region of the heart. Once a map of the heart is generated, the physician may then advance an ablation catheter into the heart, and position an ablation electrode carried by the catheter tip near the targeted cardiac tissue to ablate the tissue and form a lesion, thereby treating the cardiac rhythm disturbance or abnormality. In some techniques, the ablation catheter itself may include a number of mapping electrodes, allowing the same device to be used for both mapping and ablation.

[0003] Various ultrasound-based imaging catheters and probes have been developed for directly visualizing body tissue in applications such as interventional cardiology, interventional radiology, and electrophysiology. For interventional cardiac electrophysiology procedures, for example, ultrasound imaging devices have been developed that permit the visualization of anatomical structures of the heart directly and in real-time. In some electrophysiology procedures, for example, ultrasound catheters may be used to image the intra-atrial septum, to guide transseptal crossing of the atrial septum, to locate and image the pulmonary veins, and to monitor the atrial chambers of the heart for signs of a perforation and pericardial effusion.

[0004] Many ultrasound-based imaging systems comprise an imaging probe that is separate from the mapping and ablation catheters used to perform therapy on the patient. As a result, a position tracking system is sometimes used to track the location of each device within the body. In some procedures, it may be difficult for the physician to quickly and accurately determine the condition of tissue to be ablated. Moreover, the images obtained using many ultrasound-based imaging systems are often difficult to read and understand without reference to im-

ages obtained from a separate imaging system such as a fluoroscopic imaging system.

[0005] WO 2008/046031 A2 discusses image guided catheters and methods of use. It shows an ultrasound imaging probe comprising a housing having a proximal and a distal tip section and a plurality of ultrasonic imaging sensors configured to transmit acoustic waves. The ultrasonic imaging sensors include a first ultrasonic imaging sensor configured to transmit acoustic waves in a direction distal to the distal tip section while further ultrasonic imaging sensors are side-facing transducers.

[0006] US 2003/0013958 A1 also discusses an ultrasound imaging probe similar to the ultrasound imaging probe discussed in WO 2008/046031 A2. EP1820464 discloses an ablation catheter system with transducer arrays to monitor the ablation.

SUMMARY

[0007] The present disclosure relates to devices and systems for imaging an ablation probe within the body. In Example 1, a combined ablation and ultrasound imaging probe for insertion within a body comprises: a housing having a proximal section and a distal tip section; an ablation electrode located at the distal tip section; a first ultrasonic imaging sensor located on the distal tip section, the first ultrasonic imaging sensor configured to transmit acoustic waves in a first direction distal to the distal tip section; and a plurality of second ultrasonic imaging sensors located on the distal tip section proximal to the first ultrasonic imaging sensor, each of the second ultrasonic imaging sensors configured to transmit an acoustic wave in a second direction different from the first direction.

[0008] In Example 2, the probe according to Example 1, wherein the ablation electrode comprises an RF ablation electrode.

[0009] In Example 3, the probe according to any of Examples 1-2, wherein each of the first and second ultrasonic imaging sensors are disposed within the distal tip section.

[0010] In Example 4, the probe according to any of Examples 1-3, wherein the first ultrasonic imaging sensor comprises a distal-facing ultrasonic imaging sensor located at a distal end of the distal tip section.

[0011] In Example 5, the probe according to any of Examples 1-4, wherein each of the second ultrasonic imaging sensors are coupled to a curved portion of the distal tip section.

[0012] In Example 6, the probe according to Example 5, wherein each of the second ultrasonic imaging sensors are configured to transmit acoustic waves at an angle of between about 10° to about 60° relative to a line perpendicular to a longitudinal axis of the housing.

[0013] In Example 7, the probe according to any of Examples 1-6, wherein the second ultrasonic imaging sensors are radially disposed about a circumference of the distal tip section.

[0014] In Example 8, the probe according to Example 7, wherein the second ultrasonic imaging sensors are radially spaced at equidistant intervals from each other about the circumference.

[0015] In Example 9, the probe according to any of Examples 1-8, wherein the probe further includes at least one mapping electrode.

[0016] In Example 10, an ablation and ultrasound imaging system comprises: a probe including a housing with a proximal section and a distal tip section, an ablation electrode, and a plurality of ultrasonic imaging sensors; the plurality of ultrasonic imaging sensors including a first ultrasonic imaging sensor located on the distal tip section and a plurality of second ultrasonic imaging sensors located on the distal tip section proximal to the first ultrasonic imaging sensor; an ablation therapy module configured for generating and supplying an electrical signal to the ablation electrode; an ultrasound imaging module configured for processing ultrasonic imaging signals received from the ultrasonic imaging sensors; and a user interface configured for displaying ultrasonically derived information generated by the ultrasonic imaging sensors on a display screen.

[0017] In Example 11, the system according to Example 10, wherein the first ultrasonic imaging sensor comprises a distal-facing ultrasonic imaging sensor disposed at a distal end of the distal tip section.

[0018] In Example 12, the system according to any of Examples 10-12, wherein each of the second ultrasonic imaging sensors are coupled to a curved portion of the distal tip section.

[0019] In Example 13, the system according to any of Examples 10-12, wherein the ultrasonic imaging module comprises: an imaging controller including an ultrasonic signal generator configured to generate control signals for controlling each ultrasonic imaging sensor; and an image processor configured for processing electrical signals received from each ultrasonic imaging sensor and generating a plurality of ultrasonic images.

[0020] In Example 14, the system according to any of Examples 10-13, further comprising a mapping processor in communication with one or more mapping electrodes on the probe.

[0021] In Example 15, the system according to any of Examples 10-14, wherein the display screen includes a plurality of imaging panes each configured for displaying an image associated with an associated ultrasonic imaging sensor.

[0022] In Example 16, the system according to Example 15, wherein the plurality of imaging panes are displayed in a side-by-side configuration on the display screen.

[0023] In Example 17, the system according to Example 15, wherein each imaging pane includes a B-mode ultrasonic image.

[0024] In Example 18, a user interface for displaying a composite image generated from an ablation probe with multiple ultrasonic imaging sensors comprises: a display

screen including a plurality of imaging panes each configured to display an ultrasonic image generated from an associated one of the ultrasonic imaging sensors; wherein each of the imaging panes are arranged side-by-side to form a composite ultrasonic image from each of the ultrasonic imaging sensors.

[0025] In Example 19, the user interface according to Example 18, wherein the ultrasonic images are B-mode images.

[0026] In Example 20, the user interface according to any of Examples 18-19, wherein the display screen includes a set of reference numbers indicating an imaging depth of the images generated by each ultrasonic imaging sensor.

[0027] While multiple embodiments are disclosed, still other embodiments of the present invention will become apparent to those skilled in the art from the following detailed description, which shows and describes illustrative embodiments of the invention. Accordingly, the drawings and detailed description are to be regarded as illustrative in nature and not restrictive.

BRIEF DESCRIPTION OF THE DRAWINGS

[0028]

Figure 1 is a functional block diagram showing a medical system in accordance with an illustrative embodiment;

Figure 2 is a schematic view showing a combined ablation and ultrasonic imaging probe in accordance with an illustrative embodiment;

Figure 3 is a schematic view showing the distal tip section of Figure 2 in greater detail;

Figure 4 is an end view showing the distal tip section of Figure 2 in greater detail;

Figure 5 is a flow diagram showing an illustrative process for visualizing anatomical structures within the body using the ultrasonic imaging system of Figure 1;

Figure 6 is a view showing an example display screen that can be used to display ultrasonic images generated using the ultrasonic imaging probe of Figure 2; and

Figure 7 is a view showing a number of ultrasonic images generated on the display screen of Figure 6.

DETAILED DESCRIPTION

[0029] Figure 1 is a functional block diagram showing a medical system 10 in accordance with an illustrative embodiment. The system 10, illustratively an ultrasonic cardiac imaging system for imaging the treatment of a heart 12, includes a combined ablation and ultrasonic imaging probe 14, a therapy module 16 for mapping and treating the heart 12, an ultrasound imaging module 18 for generating high resolution ultrasonic images (e.g., B-mode images) of anatomical structures (e.g., body tis-

sue) in or near the heart 12, and a user interface 20 configured for use by the physician 22 in controlling therapy provided by the probe 14, visualizing anatomical structures and/or other devices within the body, and/or determining the location and orientation of the probe 14 within the body. In some embodiments, for example, the system 10 comprises an ultrasonic imaging system that can be used in monitoring RF ablation therapy provided to a patient's heart 12 or in a cardiac vessel leading into or from the heart 12.

[0030] The therapy module 16 is used for identifying and treating a target tissue site or multiple sites within the body such as an aberrant conductive pathway. In the embodiment of Figure 1, the therapy module 16 comprises a radio frequency (RF) generator 24 that supplies an RF signal 26 to one or more ablation electrodes 28 located on a distal tip of the probe, and a mapping processor 30 that can be used to identify one or more potential therapeutic sites in or near the heart 12. The RF generator 24 is configured to deliver ablation energy to each ablation electrode 28 in a controlled manner to ablate any sites identified by the mapping processor 30. Other types of ablation sources in addition to or in lieu of the RF generator 24 can also be used for ablating target sites. Examples of other types of ablation sources can include, but are not limited to, microwave generators, acoustic generators, cryoablation generators, and laser/optical generators.

[0031] In some embodiments, the probe 14 further includes one or more mapping electrodes 32 coupled to the mapping processor 30. During operation, the mapping processor 30 detects and analyzes electrical signals within the myocardial tissue in order to identify potential treatment sites for ablation using the probe 14. In some embodiments, the ablation electrode 28 or multiple ablation electrodes 28 can be used for performing both mapping and ablation functions. In other embodiments, the electrode 28 is a dedicated ablation electrode, and one or more separate electrodes 32 on the probe 14 can be tasked to perform mapping functions. In other embodiments, a separate mapping catheter is used to map potential ablation sites within the body.

[0032] The mapping processor 30 is configured to derive activation times and voltage distribution from the electrical signals 34 obtained from each mapping electrode 32 to determine the presence of irregular electrical activity within the heart 12, which can then be graphically displayed as a map on the user interface 20. Further details regarding electrophysiology mapping are provided, for example, in U.S. Patent Nos. 5,485,849, 5,494,042, 5,833,621, and 6,101,409, each of which are expressly incorporated herein by reference in their entirety for all purposes.

[0033] In the embodiment of Figure 1, the ultrasound imaging module 18 includes an imaging controller 36 coupled to a number of ultrasonic imaging sensors 38 on the probe 14. An ultrasonic signal generator 40 is configured to provide one or more control signals 42 for con-

trolling each of the ultrasonic sensors 38. The imaging signals 44 received back from the ultrasonic sensors 38, in turn, are fed to an image processor 46, which processes the electrical signals 44 received back from the ultrasonic sensors 38 and generates a number of images, which as is discussed further herein, can be assembled together and displayed as a composite image on the user interface 20 to assist the physician 22 with inserting the probe 14 into position at a target location within the body and to perform an ablation procedure. In some embodiments, for example, the ultrasonic images obtained via the ultrasound imaging module 18 can be used to confirm tissue contact of the probe 14 with the heart 12 or surrounding anatomy, to determine the orientation of the probe 14 within the body, to determine the tissue depth of the tissue at a target ablation site, and/or to visualize the progression of a lesion being formed in the tissue.

[0034] The imaging controller 36 is configured to control the ultrasonic sensors 38 to generate ultrasonic images using a pulse-echo imaging technique, in which ultrasonic waves are transmitted by the ultrasonic sensors 38 in a transmit mode into the surrounding body, and the reflected waves are sensed by the ultrasonic sensors 38 operating in a receive mode. In some embodiments, the control signals 42 used for generating ultrasonic waves are applied to each of the ultrasonic sensors 38 simultaneously. Alternatively, and in other embodiments, a switching element 48 such as a microswitch or MUX can be controlled to selectively activate only a subset of the ultrasonic sensors 38. In one embodiment, for example, the ultrasound controller 30 can control the switching element 48 to selectively activate each individual ultrasonic sensor 38 in a sequence or pattern. During imaging, the sequential activation of each ultrasonic sensor 38 may help to reduce or prevent interference with the reflected ultrasonic waves received from other sensors 38, which helps to reduce cross-talk or other undesired artifacts in the imaging signal 44. In some embodiments, the sequential activation of the ultrasonic sensors 38 may permit the field of view of the ultrasonic sensors 38 to be overlapped slightly without causing interference in the imaging signals 44.

[0035] Various characteristics associated with the ultrasonic sensors 38 as well as the circuitry within the ultrasound imaging module 18 can be controlled to optimize the suitability of the ultrasonic sensors 38 to accurately detect tissue boundaries (e.g., blood or other bodily fluid), lesion formation and progression, as well as other characteristics of the tissue before, during, and/or after the ablation procedure. Example tissue characteristics that can be visualized using the probe 14 include, but are not limited to, the presence of fluid vaporization inside the tissue, the existence of a prior scar, and the size and shape of a lesion being formed. The depth at which the ultrasonic sensors 38 can visualize anatomical structures within the body is dependent on the mechanical characteristics of the elements 38, the electrical characteristics of the transducer circuitry including the drive frequency

of the control signal 42 provided by the signal generator 40, the boundary conditions and degree of attenuation between the ultrasonic sensors 38 and the surrounding anatomy, as well as other factors.

[0036] The imaging signals 44 sensed by each ultrasonic sensor 38 are fed to the imaging processor 46, which generates ultrasonically derived information that can be displayed on a display monitor 50 of the user interface. In some embodiments, the imaging processor 46 uses the imaging signals 44 to produce a number of images 48 on the display monitor 50. Other ultrasonically derived information can also be displayed on the display monitor 50 in conjunction with, or in lieu of, the images 48.

[0037] In some embodiments, an image merger 52 is configured to superimpose graphical information obtained from the imaging module 18 and superimpose that information on the display monitor 50 along with graphical information acquired from other sources (e.g., a fluoroscopic monitor) and/or position information from the therapy module 16 to form a composite medical image. In some embodiments, the imaging processor 46 may further superimpose colors, labels, and/or other artifacts onto the images 48 for identifying features within the images. For example, and in some embodiments, the imaging processor 46 may superimpose a first color (e.g., green) onto the images 48 to indicate the location where the distal tip section 60 of the probe 14 is near or in contact with the body tissue to be ablated and a second color (e.g., red) to indicate body tissue located further away from the distal tip section 60. In other embodiments, flashing colors or other features on the display monitor 50 may be utilized for qualitatively and/or quantitatively assessing contact with the body tissue.

[0038] In one embodiment described further with respect to Figures 6-7, the images received from each sensor 38 as well as other ultrasonically derived information can be arranged side-by-side on the display monitor 50, allowing the physician to quickly assess factors such as the contact site, tip/tissue orientation, lesion formation and progression, and tissue wall thickness (e.g., in thin-walled anatomical structures). The image 48 could be displayed, for example, on an existing monitor in an EP lab, on a dedicated display monitor, or simultaneously at multiple locations.

[0039] Although the system 10 is described in the context of a medical system for use in intracardiac electrophysiology procedures for diagnosing and treating the heart, in other embodiments the system 10 may be used for treating, diagnosing, or otherwise visualizing other anatomical structures such as the prostate, brain, gall bladder, uterus, esophagus, and/or other regions in the body. Moreover, many of the elements in Figure 1 are functional in nature, and are not meant to limit the structure that performs these functions in any manner. For example, several of the functional blocks can be embodied in a single device, or one or more of the functional blocks can be embodied in multiple devices.

[0040] Figure 2 is a schematic view showing a com-

bined ablation and ultrasonic imaging probe 54 in accordance with an illustrative embodiment for use with the system 10 of Figure 1. In the embodiment of Figure 2, the probe 54 comprises a catheter body including an elongate tubular housing 56 having a proximal section 58 and a distal tip section 60. The proximal section 58 of the housing 56 is coupled to a proximal hub 62, which includes a fluid port 64 for providing acoustic coupling/cooling fluid to the distal tip section 60 of the probe 54. The proximal hub 62 is electrically connected to both the therapy module 16 and the ultrasonic imaging module 18, as shown.

[0041] In the embodiment of Figure 2, the probe 54 includes one or more dedicated mapping electrodes 66, 68 that can be used to record cardiac electrical signals, and in some cases also the delivery of electrical signals to the patient. In some embodiments, the electrodes 66, 68 can also be used to facilitate position tracking of the catheter 54 using a position tracking system.

[0042] Figure 3 is a schematic view showing the distal tip section 60 of the probe 54 in greater detail. As can be further seen in Figure 3, the distal tip section 60 of the probe 54 includes an RF ablation electrode 70 and a plurality of ultrasonic imaging sensors 72, 74, 76, 78. In some embodiments, the RF ablation electrode 70 comprises a conductive material such as platinum, which in addition to serving as an electrode for providing ablation therapy, may also be used as a fluoroscopic marker to determine the location of the distal tip section 60 within the body using fluoroscopy.

[0043] In the embodiment shown, the ultrasonic imaging probe 54 includes a distal ultrasonic imaging sensor 72 located at a distal end 74 of the probe 54. The ultrasonic sensor 72 is configured to transmit and receive ultrasonic waves primarily in a forward direction away from the distal end 74 of the probe 54. A second set of ultrasonic imaging sensors 76, 78, 80 located on a curved portion of the distal tip section 60 proximal to the distal-facing ultrasonic imaging sensor 74, in turn, are configured to transmit and receive ultrasonic waves both laterally and in a forward direction away from the distal end 74 of the probe 54. In some embodiments, the ultrasonic sensors 72, 76, 78, 80 each comprise piezoelectric transducers formed of a polymer such as PVDF or a piezoceramic material such as PZT, and are inset within an exposed portion of the RF ablation electrode 70. A number of leads (not shown) extending through the interior space of the probe 54 connect the ultrasonic sensors 72, 76, 78, 80 to the ultrasonic imaging module 18.

[0044] During ultrasonic imaging, each of the ultrasonic sensors 72, 76, 78, 80 are configured to operate in alternating pulsing and sensing modes. When excited electrically in the pulsing mode, the ultrasonic sensors 72, 76, 78, 80 generate pressure waves which travel through the electrode 70 and into the surrounding environment. In the sensing mode, the ultrasonic sensors 72, 76, 78, 80 each produce an electrical signal as a result of receiving acoustic waves reflected back to the sensors

72, 76, 78, 80, which are then processed and displayed on the display monitor 50 of the user interface 20. These reflections are generated by the acoustic waves traveling through changes in density in the surrounding environment being imaged.

[0045] Figure 4 is an end view showing the distal tip section 60 of Figure 2 in greater detail. As can be further seen in Figure 4, and in some embodiments, the ultrasonic imaging probe 54 includes three ultrasonic sensors 76, 78, 80 equally spaced at an angle α of 120° about the circumference of the distal tip section 60 at a location proximal to the distal ultrasonic sensor 72. Although three ultrasonic sensors 76, 78, 80 are shown in the embodiment of Figure 4, a greater or lesser number of ultrasonic sensors may be employed. By way of example and not limitation, four ultrasonic sensors may be disposed at equidistant angles α of 90° about the circumference of the distal tip section 60 at a location proximal to the distal ultrasonic sensor 72. During imaging, the use of multiple ultrasonic sensors 76, 78, 80 spaced about the circumference of the distal tip section 60 ensures that at least one of the sensors 76, 78, 80 is in close proximity to the target tissue irrespective of the tip orientation relative to the target tissue. Such configuration also permits the physician to easily visualize the target tissue without having to rotate the probe 54 once the probe 54 is in contact with the tissue. In other embodiments, the location and relative position(s) of each ultrasonic sensor 72, 76, 78, 80 can vary from that shown in Figure 4.

[0046] In some embodiments, an acoustically transparent window or aperture 82, 84, 86, 88 within the electrode 70 facilitates the transmission of ultrasonic waves from the ultrasonic sensors 72, 76, 78, 80 into the surrounding anatomy. In some embodiments, an acoustic coupling fluid within the interior space of the distal tip section 60 serves to couple the acoustic energy transmitted and received via the ultrasonic sensors 72, 76, 78, 80 to the anatomy surrounding the probe 54.

[0047] In certain embodiments, and as further shown in Figures 3 and 4, each of the proximally-positioned ultrasonic sensors 76, 78, 80 may be located on a curved portion 82 of the ablation electrode 72, and are oriented such that the ultrasonic waves are transmitted at a slightly forward angle β of between about 10° to about 60° relative to a line perpendicular to the longitudinal axis L of the probe 54. During imaging, the off-set orientation of the proximally-positioned ultrasonic sensors 76, 78, 80 directs the ultrasonic waves in a slight forward direction, allowing the physician to better view anatomy and objects that are located at or near the distal end 74.

[0048] Figure 5 is a flow diagram showing an illustrative process 92 for visualizing anatomical structures within the body using a combined ablation and ultrasonic imaging probe. Figure 5 may represent, for example, several exemplary steps that can be used during an ablation procedure to visualize a target ablation site (e.g., myocardial tissue) using the ultrasonic imaging probe 54 of Figure 2 with the imaging system 10 of Figure 1.

[0049] The process 92 may begin generally at block 94, in which the ultrasonic imaging probe 54 is inserted into the body and advanced intravascularly to an area of interest within the body. In certain electrophysiology procedures, for example, the probe 54 may be inserted into the body via an artery or vein (e.g., the femoral artery) and advanced through the body under fluoroscopic guidance to an area of interest such as the fossa ovalis of the right atrium.

[0050] With the ultrasonic imaging probe 54 positioned at the area of interest, the physician may activate the ultrasonic imaging module 18 to generate images of the distal tip section 60 and the surrounding anatomy using one or more of the ultrasonic sensors 72, 76, 78, 80 (block 96). In certain embodiments, each of the ultrasonic sensors are activated continuously and simultaneously, generating multiple, simultaneous images. In other embodiments, the ultrasonic imaging module 18 may selectively activate the ultrasonic sensors in a sequence or pattern, generating multiple images each at a slightly different time.

[0051] The images received from each of the ultrasonic sensors can be assembled together into a composite image that can be displayed on a display screen, allowing the physician to quickly ascertain the location of the ablation electrode relative to the target tissue (block 98). In one embodiment, each of the images from the ultrasonic sensors can be used to generate a number of B-mode acoustic images of the area of interest. An example view showing a number of ultrasonic images that can be displayed on a display screen is further shown and described with respect to Figure 7. In certain embodiments, the ultrasonic images can be combined with images from a fluoroscope, CT-scan, MRI-scan, and/or other source to obtain a composite image (block 100).

[0052] Prior to or during ablation, the operation of one or more of the ultrasonic sensors can be adjusted to the specific imaging/detection distance required for the specific application (block 102). For cardiac ablation procedures, for example, the ultrasonic imaging module 18 can be configured to adjust the drive frequency of the ultrasonic drive signals to generate ultrasonic waves that penetrate a distance of between about 2 millimeters to 7 millimeters, and more specifically, about 5 millimeters into the tissue, which is the penetration depth typically needed to visualize and assess the formation of lesions in cardiac tissue. In some embodiments, the ultrasonic imaging module 18 can adjust the operating characteristics of each ultrasonic sensor 72, 76, 78, 80 automatically based on a database of ablation procedure scenarios pre-programmed within the imaging module 18.

[0053] As the probe 54 is moved around within the heart under direct visualization using the imaging module 18, the therapy module 16 can be operated to record electrical activity within the heart and derive mapping data (block 104). If an aberrant region is identified via the mapping processor 30, the distal tip section 60 of the probe 54 can be placed into contact with the targeted

ablation region (block 106). In some procedures, the images produced by the ultrasonic sensors 72, 76, 78, 80 can be used to confirm whether the probe 54 is in direct contact with the tissue to be treated. Once in position, the RF generator 24 is then operated to begin ablating the tissue (block 108). If necessary, the physician may readjust the positioning of the probe 54 until the ablation is complete. The process can then be performed for any additional target tissue sites that are identified.

[0054] Figure 6 is a view showing an example screen 110 that can be used to display ultrasonic images generated using the ultrasonic imaging probe 54 of Figure 2 and the user interface 20 of Figure 1. In the embodiment of Figure 6, the display screen 98 includes a number of image panes 112, 114, 116, 118 each corresponding to a separate image generated by one of the ultrasonic sensors 72, 76, 78, 80. In certain embodiments, and as shown, the image panes 112, 114, 116, 118 are arranged side-by-side with a first image pane 112 representing a B-mode ultrasonic image generating with the distal ultrasonic sensor 72, and a series of three image panes 114, 116, 118 that may be used to display a separate B-mode ultrasonic image generated by a corresponding one of the ultrasonic sensors 76, 78, 80 located on the probe 54 proximal to the distal ultrasonic sensor 72. A series of labels 120, 122, 124, 126 located adjacent to each image pane 112, 114, 116, 118 provides the physician with information regarding which ultrasonic sensor on the probe 54 corresponds to the image. Label "T" on the display screen 110, for example, may represent that the distal tip transducer 72 on the probe 54 whereas labels "1," "2," and "3" may represent ultrasonic sensors 76, 78, and 80, respectively.

[0055] A set of reference lines 128 located on each pane 112, 114, 116, 118 of the display screen 110 provide information regarding the depth at which the image is taken relative to the ultrasonic sensor 72, 76, 78, 80. For cardiac ablation procedures, for example, a set of reference numbers "1 mm," "2 mm," "3 mm," "4 mm," "5 mm" may be located adjacent to each image pane 112, 114, 116, 118, providing the physician with information regarding the depth at which the ultrasonic image was taken.

[0056] The number of image panes 112, 114, 116, 118 may vary depending on the number of ultrasonic sensors 72, 76, 78, 80 present on the probe 54. In those embodiments in which the ultrasonic sensors 72, 76, 78, 80 are sequentially timed during each cycle, the image panes 112, 114, 116, 118 may be arranged such that the first image taken during each cycle (e.g., from the distal tip sensor 72) is located on the left-hand side of the display screen 110, and each successive image taken during an imaging cycle is displayed time-wise from left to right on the display screen 110.

[0057] Figure 7 is a view showing an example of a number of B-mode ultrasound images generated on the display monitor screen 110 of Figure 6. Figure 7 may represent, for example, a number of ultrasonic images taken with the ultrasonic imaging probe 54 of Figure 2

during a cardiac ablation procedure in or near a patient's heart.

[0058] In the example screen 110 shown in Figure 7, a first B-mode image 130 in the first image pane 112 is displayed, indicating the presence of bodily tissue located at a depth of approximately 1.5 millimeters away from the distal tip ultrasonic sensor 72, and extending to a depth of approximately 2.0 millimeters. The lower portion of the image 130 represents the location at which the distal end 74 of the ablation electrode 70 contacts the bodily tissue, and may be demarcated on the screen 110 by highlighting, shading, or other visual feature. An upper portion of the image 130, in turn, can be used by the physician to gauge the depth of the anatomical structure, allowing the physician to quickly ascertain what anatomical structure is being imaged.

[0059] In the example shown, two distinct B-mode ultrasonic images 132, 134 are displayed on a second image pane 114, indicating the presence of multiple anatomical structures located in the acoustic path of one of the ultrasonic sensors (e.g., sensor 76). A first ultrasonic image 132 located on the image pane 114 may represent, for example, the presence of body tissue (e.g., a first vessel) immediately adjacent to the ablation electrode 70 at the location of ultrasonic sensor 76. A second ultrasonic image 134 located on the image pane 114, in turn, may represent the presence of a second anatomical structure feature (e.g., a second vessel) located further away from the ablation electrode 70 in the path of the ultrasonic sensor 76. The same anatomical structure may also appear on another B-mode ultrasonic image 136 displayed on a third image pane 116.

[0060] From each of the images 130, 132, 134, 136, the physician can quickly and easily determine the orientation of the distal tip section 60 relative to the target ablation area without having to rotate the probe 54 within the body, and without the use of position tracking sensors. For example, the presence of the ultrasonic image 132 from about 0 millimeters to about 2 millimeters on image pane 114 indicates that a side of the ablation electrode 70 is in direct contact with the body tissue, and is aligned closest to ultrasonic sensor 76. From this information, the physician can quickly determine the location of the tissue relative to the ablation electrode 70, and can perform the ablation procedure under direct visualization using the ultrasound images.

Claims

1. A combined ablation and ultrasound imaging probe (54) for insertion within a body, the probe comprising:
 - a housing (56) having a proximal section (58) and a distal tip section (60);
 - an ablation electrode (70) located at the distal tip section;
 - a first ultrasonic imaging sensor (72) located on

- the distal tip section, the first ultrasonic imaging sensor configured to transmit acoustic waves in a first direction distal to the distal tip section; and a plurality of three or more second ultrasonic imaging sensors (76, 78, 80) located on the distal tip section proximal to the first ultrasonic imaging sensor, and radially disposed about a circumference of the distal tip section (60), each of the second ultrasonic imaging sensors configured to transmit an acoustic wave in a second direction different from the first direction, wherein a plurality of acoustically transparent windows or apertures (82, 84, 86, 88) within the ablation electrode facilitate the transmission of ultrasonic waves from the plurality of first and second ultrasonic imaging sensors into surrounding anatomy.
2. The probe of claim 1, wherein the ablation electrode (70) comprises an RF ablation electrode.
 3. The probe of any preceding claim, wherein the first ultrasonic imaging sensor (72) comprises a distal-facing ultrasonic imaging sensor located at a distal end (74) of the distal tip section (60).
 4. The probe of any preceding claim, wherein each of the second ultrasonic imaging sensors (76, 78, 80) are coupled to a curved portion of the distal tip section (60).
 5. The probe of claim 4, wherein each of the second ultrasonic imaging sensors are configured to transmit acoustic waves at an angle (β) of between about 10° to about 60° relative to a line perpendicular to a longitudinal axis (L) of the housing.
 6. The probe of claim 1, wherein the second ultrasonic imaging sensors (76, 78, 80) are radially spaced at equidistant intervals from each other about the circumference.
 7. The probe of any preceding claim, wherein the probe further includes at least one mapping electrode.
 8. An ablation and ultrasound imaging system (10), comprising:

a probe (54) including a housing (56) with a proximal section (58) and a distal tip section (60), an ablation electrode (70), and a plurality of ultrasonic imaging sensors (72, 76, 78, 80); the plurality of ultrasonic imaging sensors including a first ultrasonic imaging sensor located on the distal tip section and configured to transmit acoustic waves in a first direction distal to the distal tip section; and a plurality of three or more second ultrasonic imaging sensors located on the distal tip section proximal to the first ultrasonic imaging sensor, and radially disposed about a circumference of the distal tip section (60), each of the second ultrasonic imaging sensors configured to transmit an acoustic wave in a second direction different from the first direction;

an ablation therapy module (16) configured for generating and supplying an electrical signal to the ablation electrode;

an ultrasound imaging module (18) configured for processing ultrasonic imaging signals received from the ultrasonic imaging sensors; and

a user interface (20) configured for displaying ultrasonically derived information generated by the ultrasonic imaging sensors on a display screen,

wherein a plurality of acoustically transparent windows or apertures (82, 84, 86, 88) within the ablation electrode facilitate the transmission of ultrasonic waves from the plurality of first and second ultrasonic imaging sensors into surrounding anatomy.
 9. The system of claim 8, wherein the ultrasonic imaging module (18) comprises:

an imaging controller (36) including an ultrasonic signal generator (40) configured to generate control signals for controlling each ultrasonic imaging sensor; and

an image processor (46) configured for processing electrical signals received from each ultrasonic imaging sensor and generating a plurality of ultrasonic images.
 10. The system of either of claims 8 or 9, further comprising a mapping processor (30) in communication with one or more mapping electrodes (66, 68) on the probe.
 11. The system of any of claims 8-10, wherein the display screen (50) includes a plurality of imaging panes each configured for displaying an image associated with an associated ultrasonic imaging sensor.
 12. The system of claim 11 wherein the plurality of imaging panes are displayed in a side-by-side configuration on the display screen.
 13. The system of claim 12, wherein each imaging pane includes a B-mode ultrasonic image.

Patentansprüche

1. Kombinierte Ablations- und Ultraschallbildgebungs-Sonde (54) für die Einführung in einen Körper, wel-

che Sonde aufweist:

- ein Gehäuse (56) mit einem proximalen Abschnitt (58) und einem distalen Spitzenabschnitt (60);
 eine Ablationselektrode (70), die sich an dem distalen Spitzenabschnitt befindet;
 einen ersten Ultraschallbildgebungs-Sensor (72), der sich an dem distalen Spitzenabschnitt befindet, wobei der erste Ultraschallbildgebungs-Sensor konfiguriert ist zum Senden akustischer Wellen in einer ersten Richtung distal zu dem distalen Spitzenabschnitt; und
 mehrere von drei oder mehr zweiten Ultraschallbildgebungs-Sensoren (76, 78, 80), die sich auf dem distalen Spitzenabschnitt proximal von dem ersten Ultraschallbildgebungs-Sensor befinden und radial um einen Umfang des distalen Spitzenabschnitts (60) herum angeordnet sind, wobei jeder von den zweiten Ultraschallbildgebungs-Sensoren konfiguriert ist zum Senden einer akustischen Welle in einer zweiten Richtung, die von der ersten Richtung verschieden ist,
 wobei mehrere akustisch transparente Fenster oder Öffnungen (82, 84, 86, 88) in der Ablationselektrode das Senden von Ultraschallwellen von den mehreren ersten und zweiten Ultraschallbildgebungs-Sensoren in die umgebende Anatomie erleichtern.
2. Sonde nach Anspruch 1, bei der die Ablationselektrode (70) eine HF-Ablationselektrode aufweist.
 3. Sonde nach einem vorhergehenden Anspruch, bei der der erste Ultraschallbildgebungs-Sensor (72) einen distal gewandten Ultraschallbildgebungs-Sensor aufweist, der sich an einem distalen Ende (74) des distalen Spitzenabschnitts (60) befindet.
 4. Sonde nach einem vorhergehenden Anspruch, bei der jeder der zweiten Ultraschallbildgebungs-Sensoren (76, 78, 80) mit einem gekrümmten Bereich des distalen Spitzenabschnitts (60) gekoppelt ist.
 5. Sonde nach Anspruch 4, bei der jeder der zweiten Ultraschallbildgebungs-Sensoren konfiguriert ist zum Senden akustischer Wellen unter einem Winkel (β) von zwischen etwa 10° bis etwa 60° relativ zu einer Linie senkrecht zu einer Längsachse (L) des Gehäuses.
 6. Sonde nach Anspruch 1, bei der die zweiten Ultraschallbildgebungs-Sensoren (76, 78, 80) radial in gleichen Abständen voneinander um den Umfang herum angeordnet sind.
 7. Sonde nach einem vorhergehenden Anspruch, bei

der die Sonde weiterhin zumindest eine Abbildungselektrode aufweist.

8. Ablations- und Ultraschallbildgebungs-System (10), welches aufweist:

eine Sonde (54) enthaltend ein Gehäuse (56) mit einem proximalen Abschnitt (58) und einem distalen Spitzenabschnitt (60), einer Ablationselektrode (70) und mehreren Ultraschallbildgebungs-Sensoren (72, 76, 78, 80);
 mehrere Ultraschallbildgebungs-Sensoren enthaltend einen ersten Ultraschallbildgebungs-Sensor, der sich auf dem distalen Spitzenabschnitt befindet und konfiguriert ist zum Senden akustischer Wellen in einer ersten Richtung distal zu dem distalen Spitzenabschnitt; und mehrere von drei oder mehr zweiten Ultraschallbildgebungs-Sensoren, die sich auf dem distalen Spitzenabschnitt proximal von dem ersten Ultraschallbildgebungs-Sensor befinden und radial um einen Umfang des distalen Spitzenabschnitts (60) herum angeordnet sind, wobei jeder der zweiten Ultraschallbildgebungs-Sensoren konfiguriert ist zum Senden einer akustischen Welle in einer zweiten Richtung, die von der ersten Richtung verschieden ist;
 ein Ablationstherapiemodul (16), das konfiguriert ist zum Erzeugen und Liefern eines elektrischen Signals zu der Ablationselektrode;
 ein Ultraschallbildgebungs-Modul (18), das konfiguriert ist zum Verarbeiten von Ultraschallbildgebungs-Signalen, die von den Ultraschallbildgebungs-Sensoren empfangen wurden; und
 eine Benutzerschnittstelle (20), die konfiguriert ist zum Anzeigen durch Ultraschall abgeleiteter Informationen, die durch die Ultraschallbildgebungs-Sensoren erzeugt wurden, auf einem Bildschirm,
 wobei mehrere akustisch transparente Fenster oder Öffnungen (82, 84, 86, 88) in der Ablationselektrode das Senden von Ultraschallwellen von den mehreren ersten und zweiten Ultraschallbildgebungs-Sensoren in die umgebende Anatomie erleichtern.

9. System nach Anspruch 8, bei dem das Ultraschallbildgebungs-Modul (18) aufweist:

eine Bildgebungs-Steuervorrichtung (36), enthaltend einen Ultraschallsignal-Generator (40), der konfiguriert ist zum Erzeugen von Steuersignalen für die Steuerung jedes Ultraschallbildgebungs-Sensors; und
 einen Bildprozessor (46), der konfiguriert ist zum Verarbeiten elektrischer Signale, die von jedem Ultraschallbildgebungs-Sensor empfan-

gen wurden, und zum Erzeugen mehrerer Ultraschallbilder.

10. System nach einem der Ansprüche 8 oder 9, weiterhin aufweisend einen Abbildungsprozessor (30) in Verbindung mit einer oder mehreren Abbildungselektroden (66, 68) auf der Sonde. 5
11. System nach einem der Ansprüche 8-10, bei dem der Bildschirm (50) mehrere Abbildungspaneel enthält, die jeweils konfiguriert sind zur Anzeige eines mit einem assoziierten Ultraschallbildgebungs-Sensor assoziierten Bildes. 10
12. System nach Anspruch 11, bei dem die mehreren Abbildungspaneel in einer seitenweisen Anordnung auf dem Bildschirm angezeigt werden. 15
13. System nach Anspruch 12, bei dem jedes Abbildungspaneel ein B-Modus-Ultraschallbild enthält. 20

Revendications 25

1. Sonde combinée d'ablation et d'imagerie par ultrasons (54) destinée à être insérée à l'intérieur d'un corps, la sonde comprenant : 30

un logement (56) qui comporte une section proximale (58) et une section de pointe distale (60) ;

une électrode d'ablation (70) qui est localisée au niveau de la section de pointe distale ; 35

un premier capteur d'imagerie par ultrasons (72) qui est localisé sur la section de pointe distale, le premier capteur d'imagerie par ultrasons étant configuré de manière à ce qu'il transmette des ondes acoustiques dans une première direction de façon distale par rapport à la section de pointe distale ; et 40

une pluralité constituée par trois seconds capteurs d'imagerie par ultrasons ou plus (76, 78, 80) qui sont localisés sur la section de pointe distale de façon proximale par rapport au premier capteur d'imagerie par ultrasons, et qui sont disposés de façon radiale sur une circonférence de la section de pointe distale (60), chacun des seconds capteurs d'imagerie par ultrasons étant configuré de manière à ce qu'il transmette une onde acoustique dans une seconde direction qui est différente de la première direction ; dans laquelle : 45

une pluralité de fenêtres ou d'ouvertures acoustiquement transparentes (82, 84, 86, 88) sont ménagées à l'intérieur de l'électrode d'ablation et facilitent la transmission d'ondes ultrasonores 55

depuis la pluralité constituée par le premier capteur d'imagerie par ultrasons et par les seconds capteurs d'imagerie par ultrasons à l'intérieur d'une anatomie avoisinante.

2. Sonde selon la revendication 1, dans laquelle l'électrode d'ablation (70) comprend une électrode d'ablation RF.

3. Sonde selon l'une quelconque des revendications précédentes, dans laquelle le premier capteur d'imagerie par ultrasons (72) comprend un capteur d'imagerie par ultrasons orienté de façon distale qui est localisé au niveau d'une extrémité distale (74) de la section de pointe distale (60). 15

4. Sonde selon l'une quelconque des revendications précédentes, dans laquelle chacun des seconds capteurs d'imagerie par ultrasons (76, 78, 80) est couplé à une partie incurvée de la section de pointe distale (60). 20

5. Sonde selon la revendication 4, dans laquelle chacun des seconds capteurs d'imagerie par ultrasons est configuré de manière à ce qu'il transmette des ondes acoustiques selon un angle (b) compris entre environ 10° et environ 60° par rapport à une ligne qui est perpendiculaire à un axe longitudinal (L) du logement. 25

6. Sonde selon la revendication 1, dans laquelle les seconds capteurs d'imagerie par ultrasons (76, 78, 80) sont espacés les uns des autres de façon radiale selon des intervalles équidistants sur la circonférence. 35

7. Sonde selon l'une quelconque des revendications précédentes, dans laquelle la sonde inclut en outre au moins une électrode de cartographie. 40

8. Système d'ablation et d'imagerie par ultrasons (10), comprenant : 45

une sonde (54) qui inclut un logement (56) qui comporte une section proximale (58) et une section de pointe distale (60), une électrode d'ablation (70) et une pluralité de capteurs d'imagerie par ultrasons (72, 76, 78, 80) ;

les capteurs de la pluralité de capteurs d'imagerie par ultrasons incluant un premier capteur d'imagerie par ultrasons qui est localisé sur la section de pointe distale et qui est configuré de manière à ce qu'il transmette des ondes acoustiques dans une première direction de façon distale par rapport à la section de pointe distale ; et une pluralité de trois seconds capteurs d'imagerie par ultrasons ou plus qui sont localisés sur la section de pointe distale de façon proximale 55

- par rapport au premier capteur d'imagerie par ultrasons, et qui sont disposés de façon radiale sur une circonférence de la section de pointe distale (60), chacun des seconds capteurs d'imagerie par ultrasons étant configuré de manière à ce qu'il transmette une onde acoustique dans une seconde direction qui est différente de la première direction ;
- un module de thérapie par ablation (16) qui est configuré pour générer et appliquer un signal électrique sur l'électrode d'ablation ;
- un module d'imagerie par ultrasons (18) qui est configuré pour traiter des signaux d'imagerie par ultrasons qui sont reçus depuis les capteurs d'imagerie par ultrasons ; et
- une interface utilisateur (20) qui est configurée pour afficher une information dérivée de façon ultrasonique qui est générée par les capteurs d'imagerie par ultrasons sur un écran d'affichage ; dans lequel :
- une pluralité de fenêtres ou d'ouvertures acoustiquement transparentes (82, 84, 86, 88) sont ménagées à l'intérieur de l'électrode d'ablation et elles facilitent la transmission d'ondes ultrasonores depuis la pluralité constituée par le premier capteur d'imagerie par ultrasons et par les seconds capteurs d'imagerie par ultrasons à l'intérieur d'une anatomie avoisinante.
9. Système selon la revendication 8, dans lequel le module d'imagerie par ultrasons (18) comprend :
- un contrôleur d'imagerie (36) qui inclut un générateur de signal ultrasonore (40) qui est configuré de manière à ce qu'il génère des signaux de commande pour commander chaque capteur d'imagerie par ultrasons ; et
- un processeur d'image (46) qui est configuré pour traiter des signaux électriques qui sont reçus depuis chaque capteur d'imagerie par ultrasons et pour générer une pluralité d'images ultrasonores.
10. Système selon l'une des revendications 8 et 9, comprenant en outre un processeur de cartographie (30) qui est en communication avec une électrode de cartographie ou plusieurs électrodes de cartographie (66, 68) sur la sonde.
11. Système selon l'une quelconque des revendications 8 à 10, dans lequel l'écran d'affichage (50) inclut une pluralité de sous-fenêtres d'imagerie dont chacune est configurée pour afficher une image qui est associée à un capteur d'imagerie par ultrasons associé.
12. Système selon la revendication 11, dans lequel les sous-fenêtres de la pluralité de sous-fenêtres d'imagerie sont affichées selon une configuration côte à
- côte sur l'écran d'affichage.
13. Système selon la revendication 12, dans lequel chaque sous-fenêtre d'imagerie inclut une image ultrasonore de mode B.

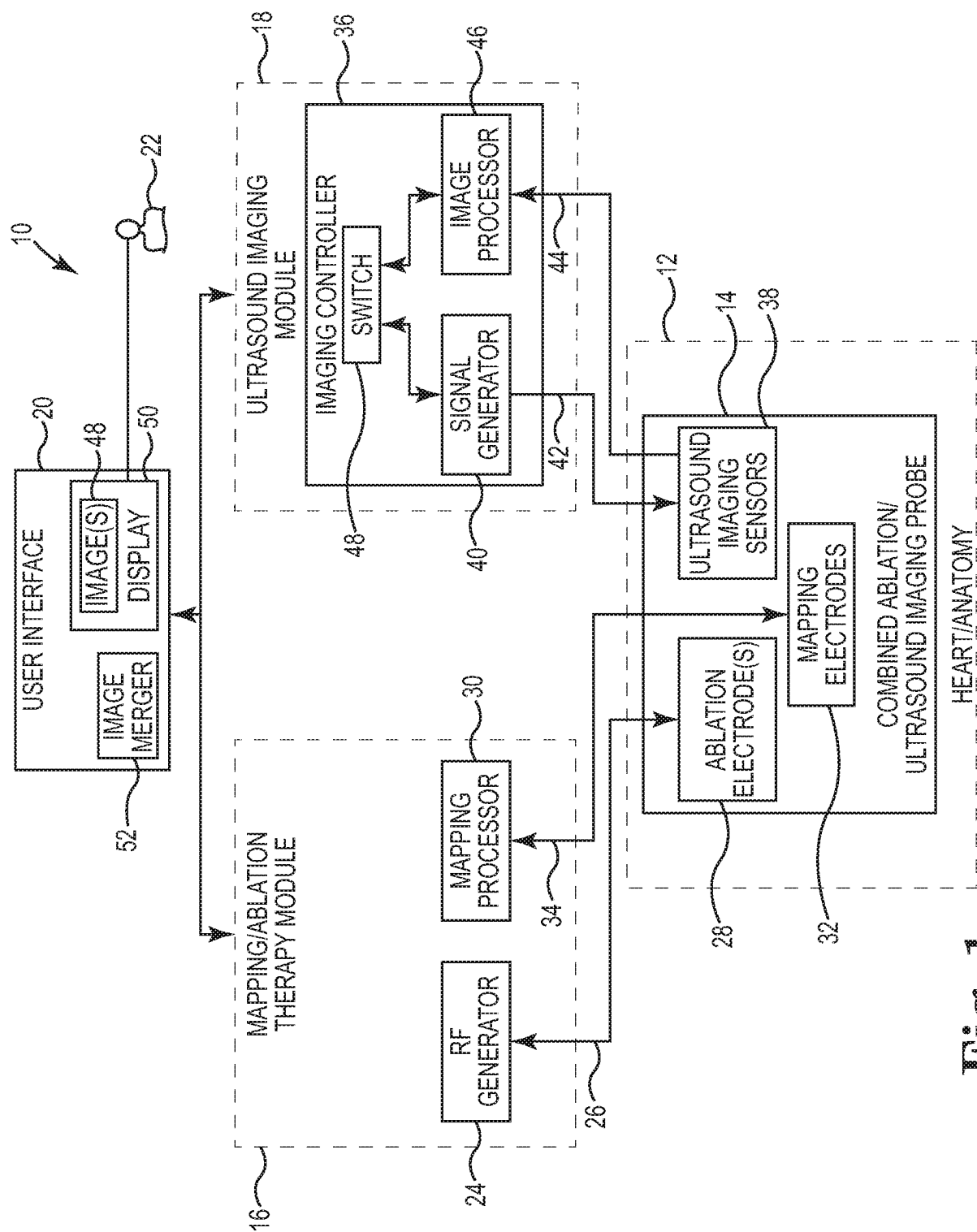


Fig. 1

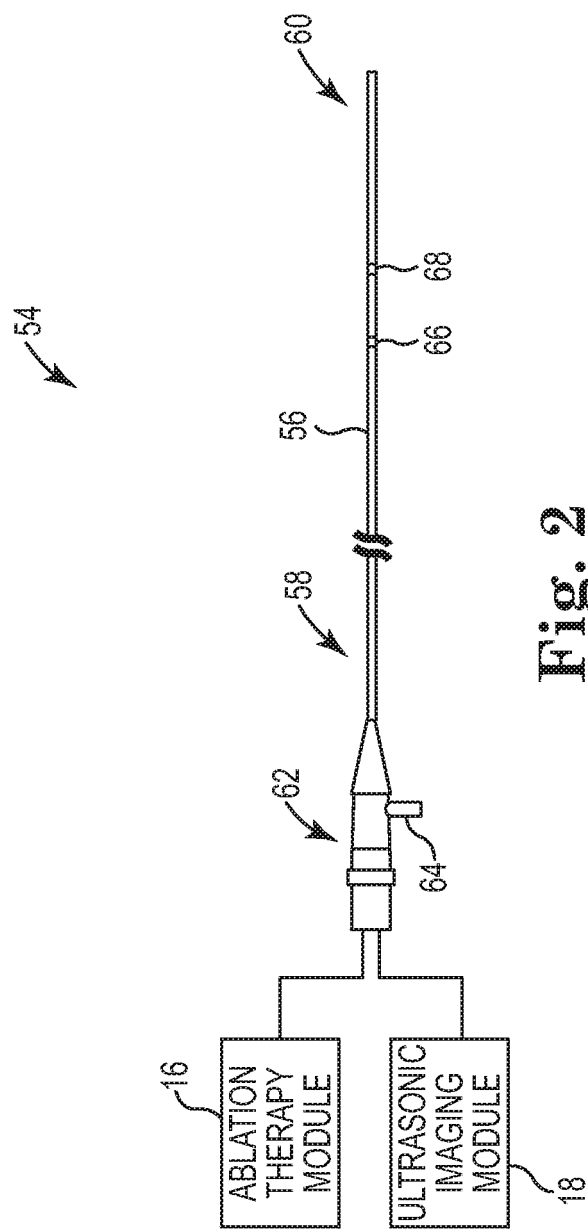
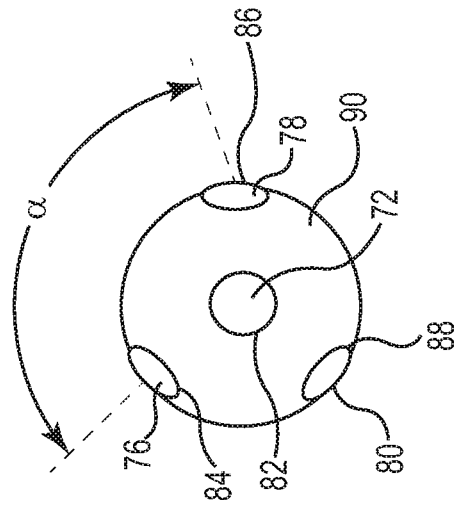
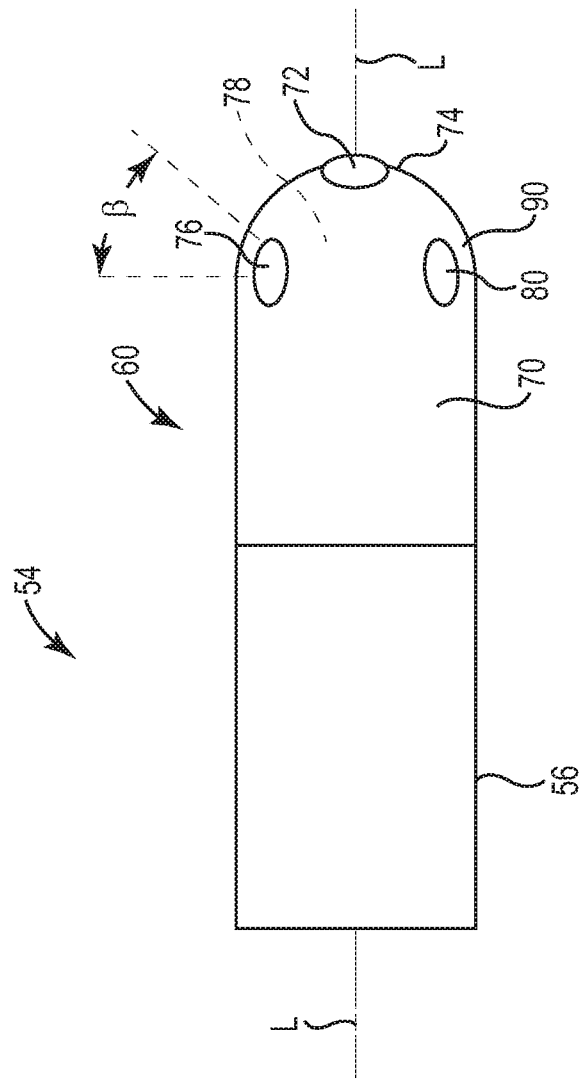
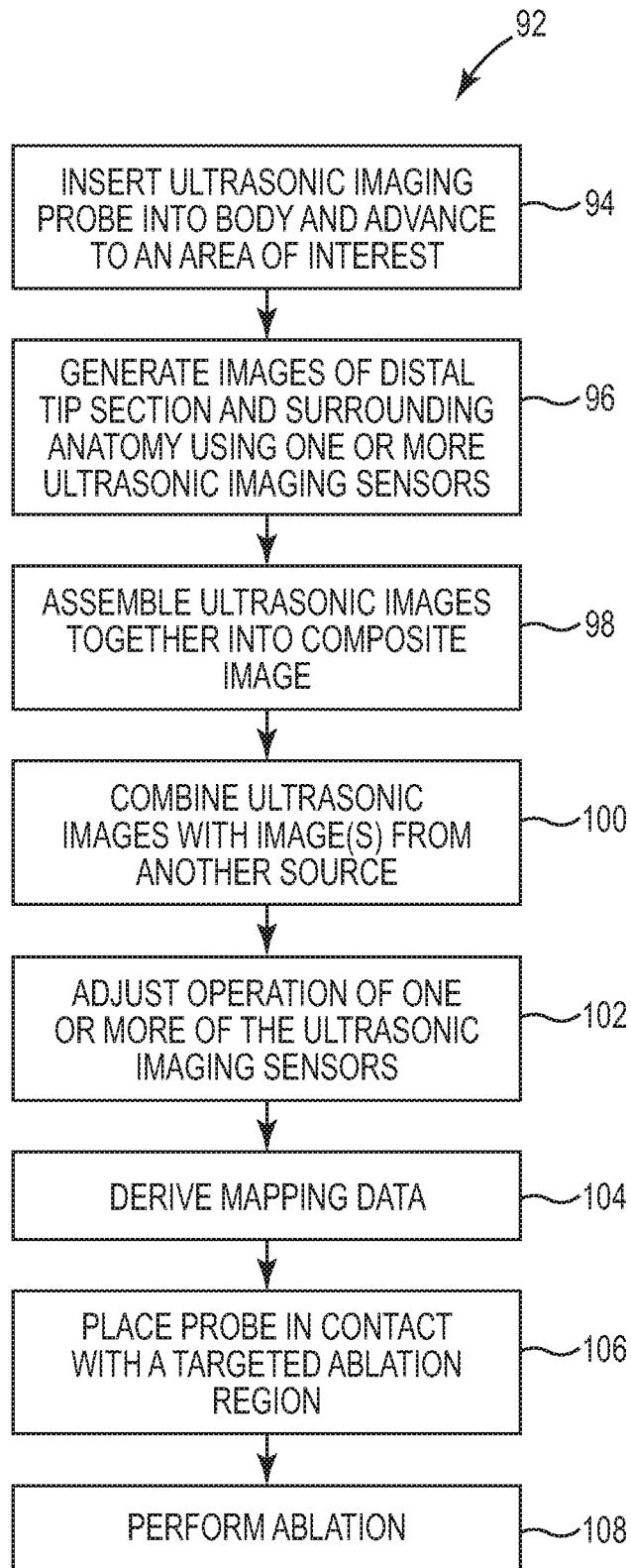


Fig. 2



**Fig. 5**

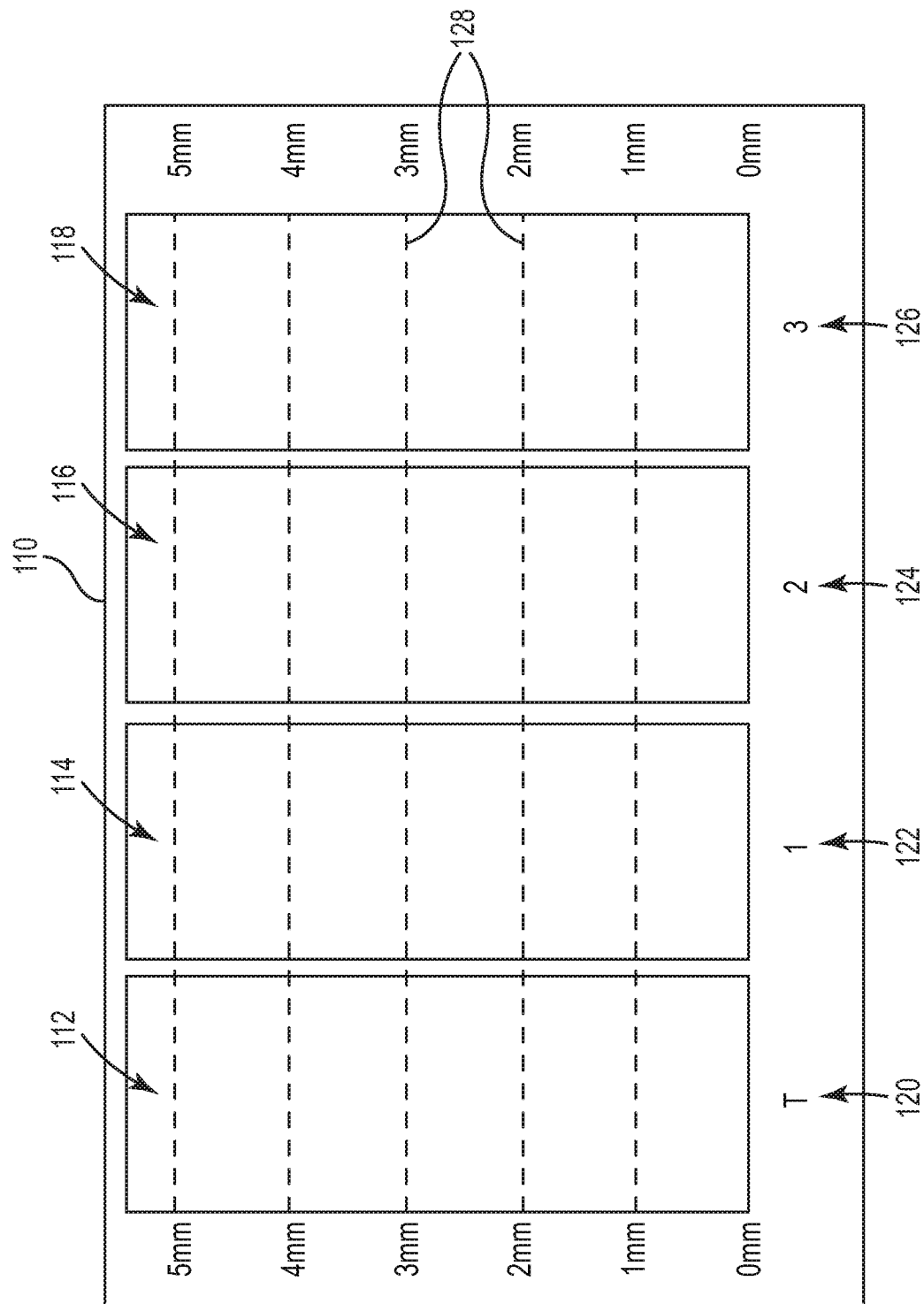


Fig. 6

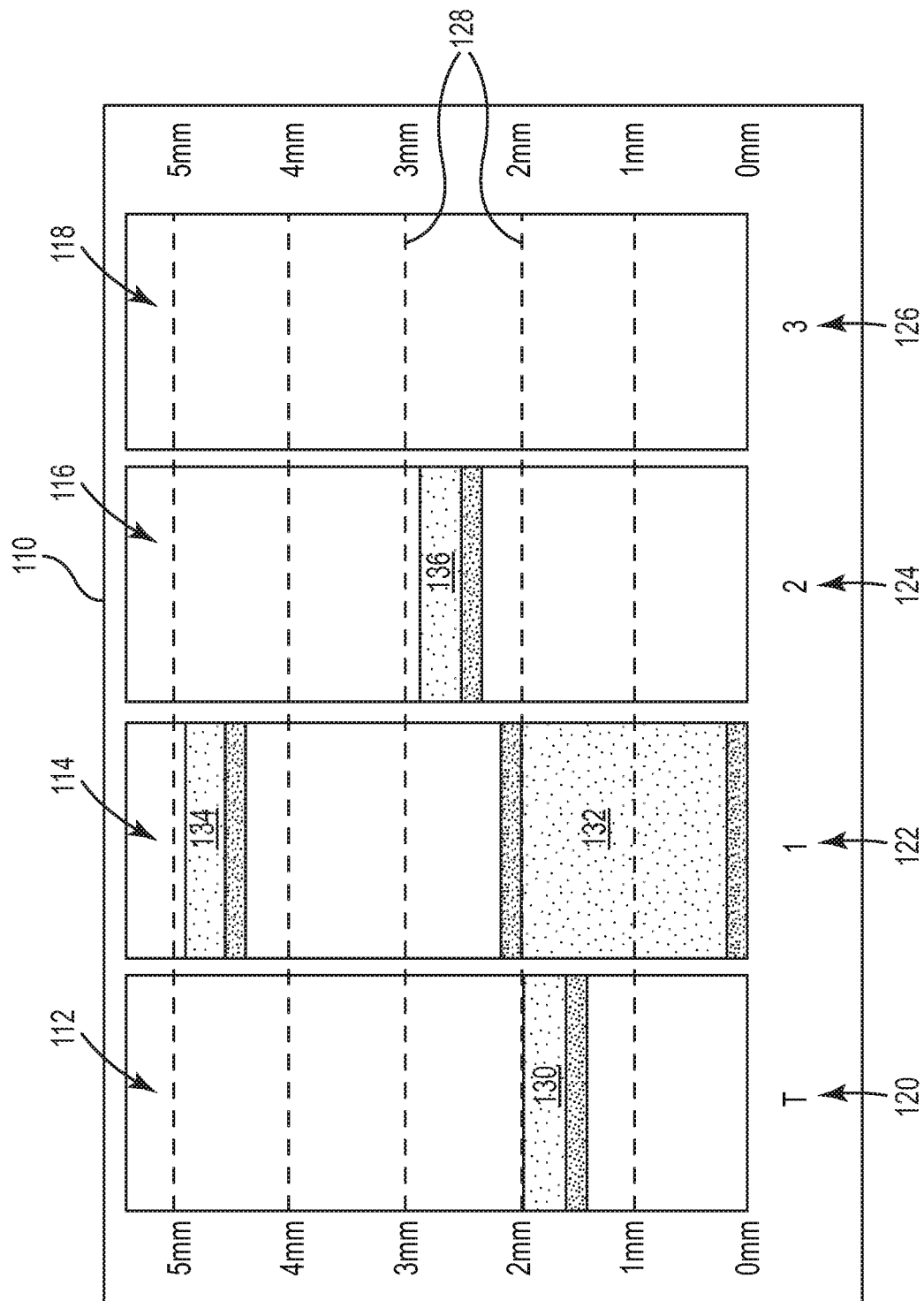


Fig. 7

REFERENCES CITED IN THE DESCRIPTION

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专利名称(译)	消融探头具有超声成像功能		
公开(公告)号	EP2713888A1	公开(公告)日	2014-04-09
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优先权	61/491944 2011-06-01 US		
其他公开文献	EP2713888B1		
外部链接	Espacenet		

摘要(译)

公开了用于超声成像解剖结构和在体内执行消融治疗的装置和系统。组合的消融和超声成像探头包括壳体，位于壳体的远侧末端部分上的消融电极，以及多个超声成像传感器，其配置用于可视化体内的解剖结构。在消融过程期间，超声成像传感器的任务是生成多个超声图像，这些超声图像可以在用户界面的显示屏上显示为合成图像。