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(54) **SYSTEM AND METHOD FOR ULTRASONICALLY SENSING AND ABLATING TISSUE**

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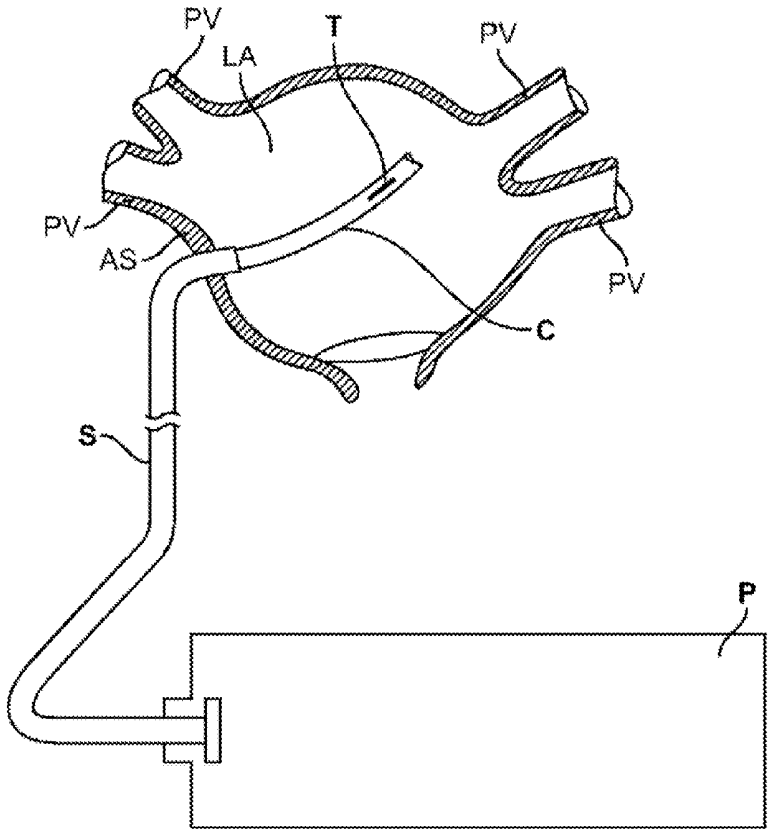
(57) **ABSTRACT**

Echo-anatomically mapping tissue includes advancing a catheter having an ultrasound transducer toward tissue. A console adjacent the proximal end of the catheter controls catheter movement, and the ultrasound transducer senses tissue. First and second regions of the tissue are ultrasonically sensed while moving the ultrasound transducer along first, and second sensing patterns, respectively. A first 3-dimensional surface map of the first region, and a second 3-dimensional surface map of the second region are generated. The 3-dimensional surface maps are combined to form a combined surface map. Anatomical features may be identified in the first or second sensed regions. The tissue may be ultrasonically ablated while moving the ultrasound transducer along a first ablation path. The first ablation path may form a lesion around the identified anatomical features, and may be selected from a catalog of ablation paths or it may be prescribed by a physician.



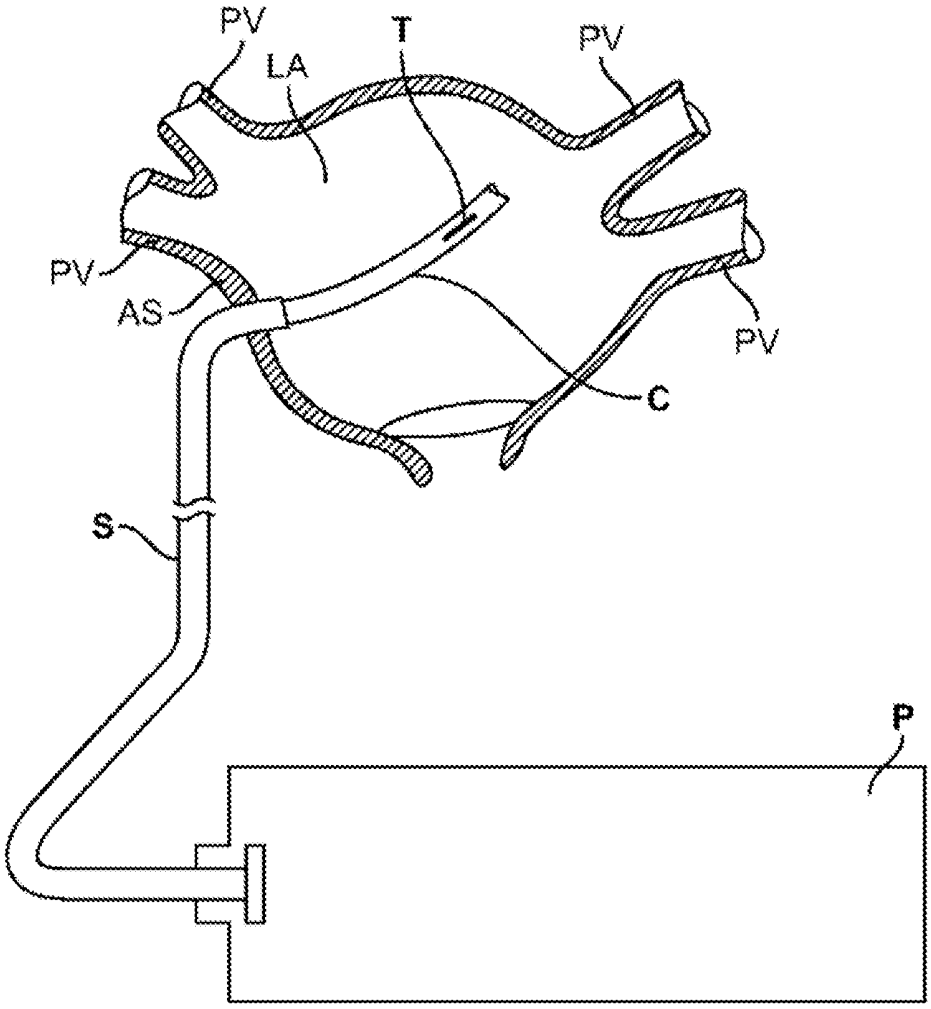


FIG. 1

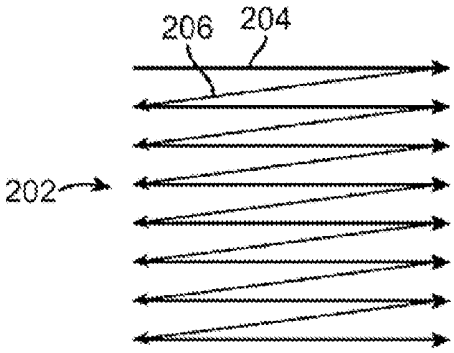


FIG. 2A

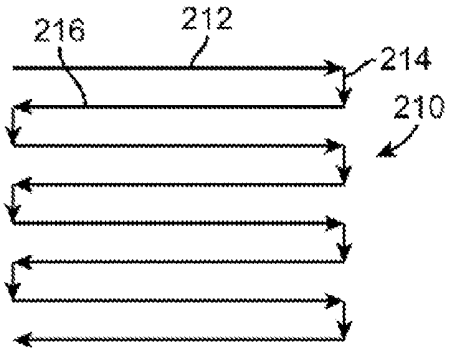


FIG. 2B

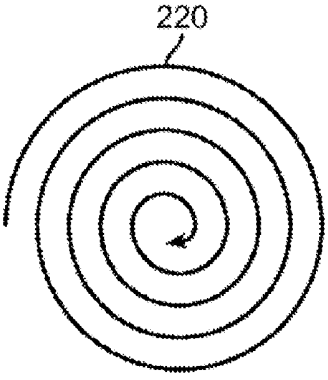


FIG. 2C

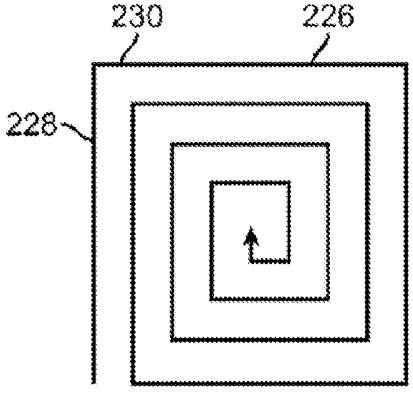


FIG. 2D

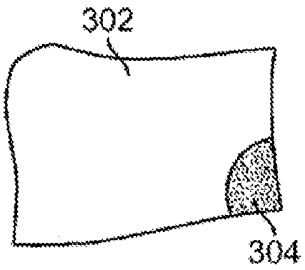


FIG. 3A

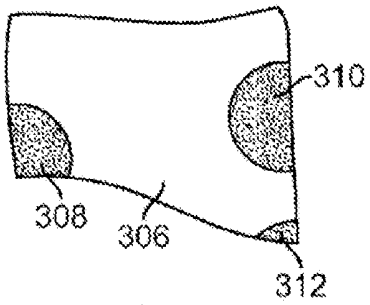


FIG. 3B

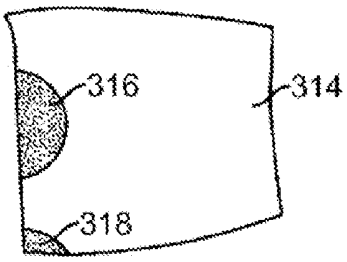


FIG. 3C

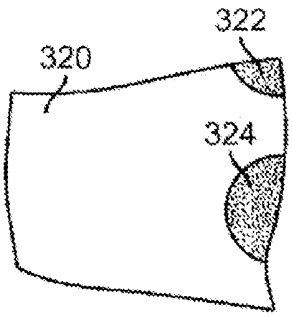


FIG. 3D

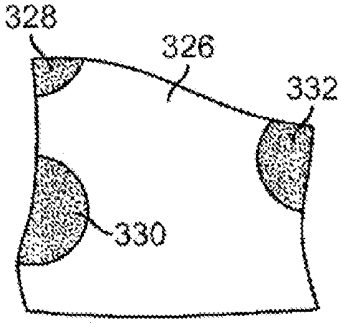


FIG. 3E

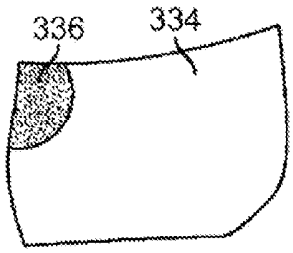


FIG. 3F

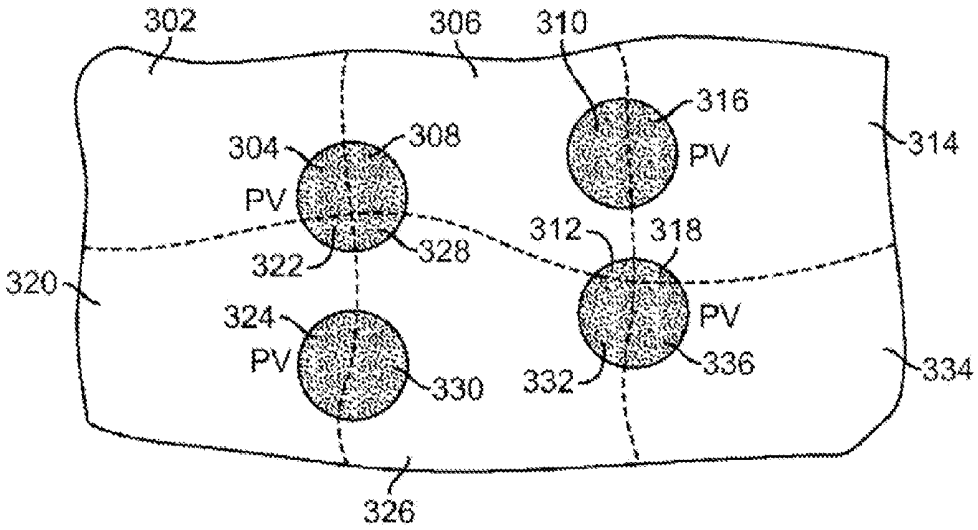


FIG. 3G

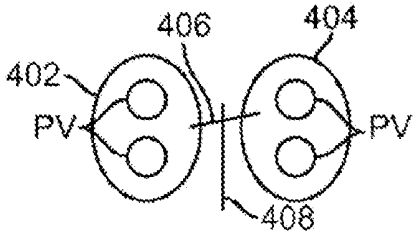


FIG. 4A

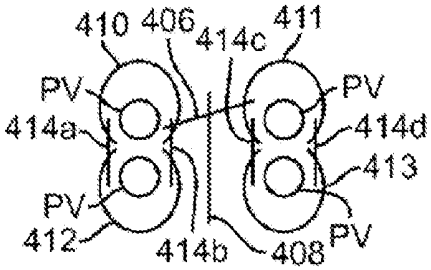


FIG. 4B

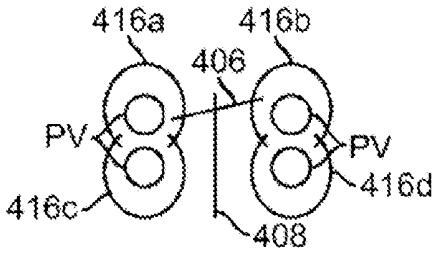


FIG. 4C

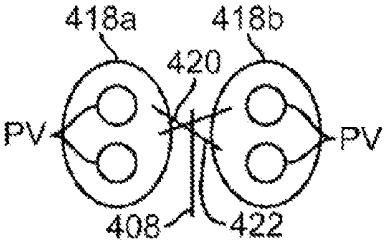


FIG. 4D

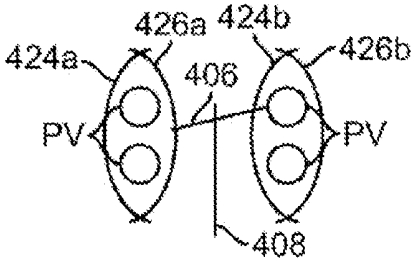


FIG. 4E

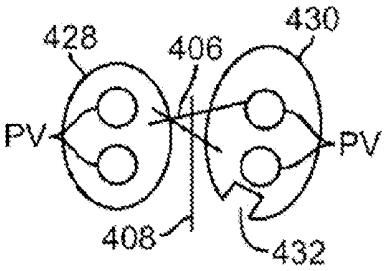


FIG. 4F

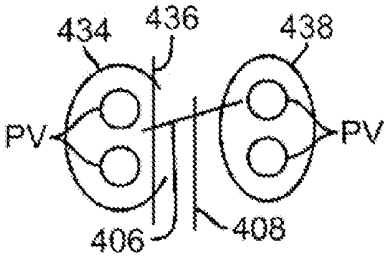


FIG. 4G

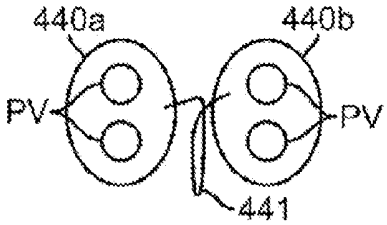


FIG. 4H

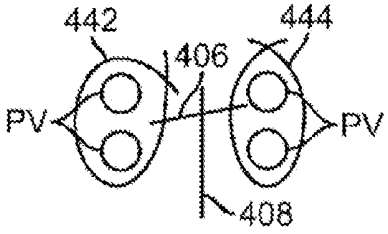


FIG. 4I

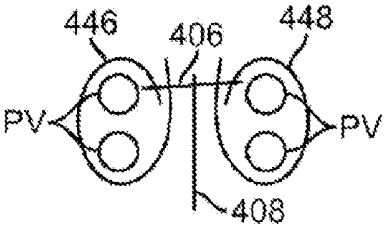


FIG. 4J

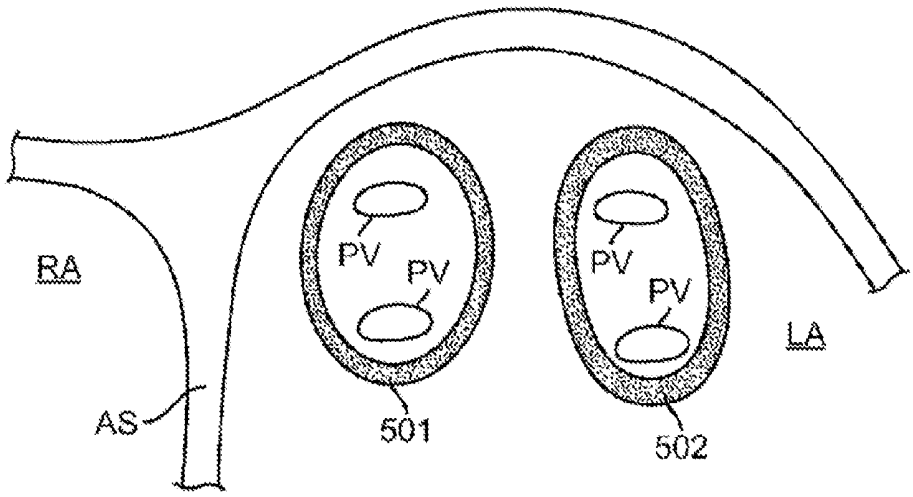


FIG. 5A

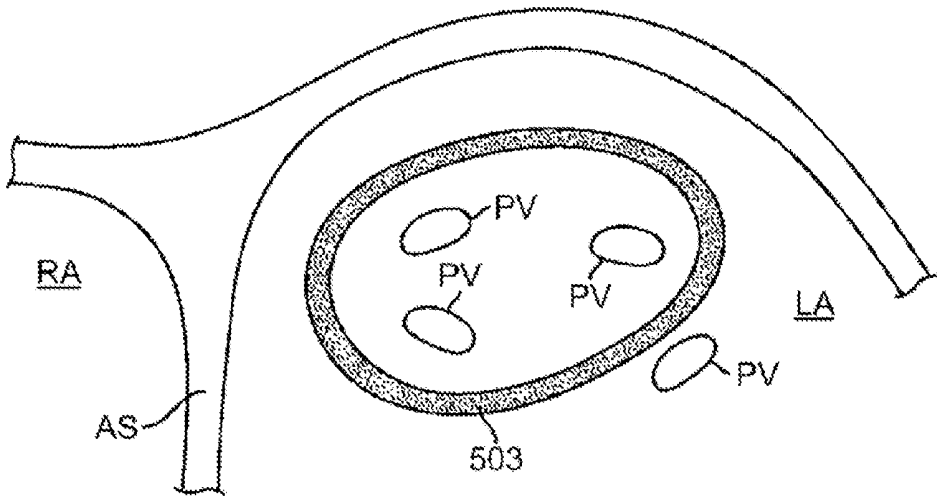


FIG. 5B

SYSTEM AND METHOD FOR ULTRASONICALLY SENSING AND ABLATING TISSUE

CROSS-REFERENCE

[0001] This application is a continuation application of Ser. No. 12/695,857 (Attorney Docket No. 31760-712.201), filed Jan. 28, 2010 which is a non-provisional of, and claims the benefit of, U.S. Provisional Patent Application No. 61/148,809 (Attorney Docket No. 31760-712.101), both of which are incorporated herein by reference in its entirety and to which application we claim priority under 35 U.S.C. §120.

[0002] The present application is also related to the following U.S. patent application Ser. No. 11/747,862 (Attorney Docket No. 31760-703.201); Ser. No. 11/747,867 (Attorney Docket No. 31760-703.202); Ser. No. 12/480,929 (Attorney Docket No. 31760-704.201); Ser. No. 12/480,256 (Attorney Docket No. 31760-705.201); Ser. No. 12/483,174 (Attorney Docket No. 31760-706.201); Ser. No. 12/482,640 (Attorney Docket No. 31760-707.201); Ser. No. 12/505,326 (Attorney Docket No. 31760-708.201); Ser. No. 12/505,335 (Attorney Docket No. 31760-709.201); Ser. No. 12/620,287 (Attorney Docket No. 31760-711.201); Ser. No. 12/609,759 (Attorney Docket No. 31760-713.201); Ser. No. 12/609,274 (Attorney Docket No. 31760-716.201); Ser. No. 12/609,705 (Attorney Docket No. 31760-718.201); and U.S. Provisional Patent Application No. 61/254,997 (Attorney Docket No. 31760-31760-720.101). The entire contents of each of the above listed patent applications is incorporated herein by reference.

BACKGROUND OF THE INVENTION

[0003] 1. Field of the Invention

[0004] The present application generally relates to systems and methods for creating ablation zones in human tissue. More specifically, the present application relates to the treatment of atrial fibrillation of the heart by using ultrasound energy. While the present application emphasizes treatment of atrial fibrillation, one of skill in the art will appreciate that this is not intended to be limiting, and that the systems and methods disclosed herein may also be used to treat other tissues and conditions, including other arrhythmias like ventricular fibrillation.

[0005] The condition of atrial fibrillation is characterized by the abnormal (usually very rapid) beating of the left atrium of the heart which is out of synch with the normal synchronous movement (normal sinus rhythm') of the heart muscle. In normal sinus rhythm, the electrical impulses originate in the sino-atrial node (' SA node') which resides in the right atrium. The abnormal beating of the atrial heart muscle is known as 'fibrillation' and is caused by electrical impulses originating instead at points other than the SA node, for example, in the pulmonary veins (PV).

[0006] There are pharmacological treatments for this condition with varying degree of success. In addition, there are surgical interventions aimed at removing the aberrant electrical pathways from PV to the left atrium (LA') such as the 'Cox-Maze III Procedure'. This procedure has been shown to be 99% effective but requires special surgical skills and is time consuming. Thus, there has been considerable effort to copy the Cox-Maze procedure using a less invasive percutaneous catheter-based approach. Less invasive treatments have been developed which involve use of some form of energy to ablate (or kill) the tissue surrounding the aberrant focal point where the abnormal signals originate in PV. The most common methodology is the use of radio-frequency ('RF') electrical energy to heat the muscle tissue and thereby ablate it. The aberrant electrical impulses are then prevented from traveling from PV to the atrium (achieving the 'conduction block') and thus avoiding the fibrillation of the atrial muscle. Other energy sources, such as microwave, laser, and ultrasound have been utilized to achieve the conduction block. In addition, techniques such as cryoablation, administration of ethanol, and the like have also been used. Some of these methods and devices are described below.

[0007] There has been considerable effort in developing catheter based systems for the treatment of AF using radiofrequency (RF) energy. One such method includes a catheter having proximal and distal electrodes at the catheter tip. The catheter can be bent in a coil shape, and positioned inside a pulmonary vein. The tissue of the inner wall of the PV is then ablated in an attempt to kill the source of the aberrant heart activity.

[0008] Another source used in ablation is microwave energy. One such intraoperative device consists of a probe with a malleable antenna which has the ability to ablate the atrial tissue.

[0009] Still another catheter based method utilizes the cryogenic technique where the tissue of the atrium is frozen below a temperature of −60 degrees C. This results in killing of the tissue in the vicinity of the PV thereby eliminating the pathway for the aberrant signals causing the AF. Cryo-based techniques have also been a part of the partial Maze procedures described above. More recently, Dr. Cox and his group have used cryoprobes (cryo-Maze) to duplicate the essentials of the Cox-Maze III procedure.

[0010] Other recent approaches for the treatment of AF involve the use of ultrasound energy. The target tissue of the region surrounding the pulmonary vein is heated with ultrasound energy emitted by one or more ultrasound transducers. One such approach includes a catheter distal tip portion equipped with a balloon and containing an ultrasound element. The balloon serves as an anchoring means to secure the tip of the catheter in the pulmonary vein. The balloon portion of the catheter is positioned in the selected pulmonary vein and the balloon is inflated with a fluid which is transparent to ultrasound energy. The transducer emits the ultrasound energy which travels to the target tissue in or near the pulmonary vein and ablates it. The intended therapy is to destroy the electrical conduction path around a pulmonary vein and thereby restore the normal sinus rhythm. The therapy involves the creation of a multiplicity of lesions around individual pulmonary veins as required.

[0011] Yet another catheter device using ultrasound energy includes a catheter having a tip with an array of ultrasound elements in a grid pattern for the purpose of creating a three dimensional image of the target tissue. An ablating ultrasound transducer is provided which is in the shape of a ring which encircles the imaging grid. The ablating transducer emits a ring of ultrasound energy at 10 MHz frequency.

[0012] In many of the above approaches, the devices and systems involve the ablation of tissue inside a pulmonary vein or of the tissue at the location of the ostium. This may require complex positioning and guiding of the treatment devices to the target site. The ablation is achieved by means

of contact between the device and the tissue. Also, many of these systems often require a catheter to be repositioned multiple times within the heart in order to map the atrium or other chamber. Repositioning may require complex manipulation of the catheter and thus this process can be cumbersome.

[0013] Other ablation systems may be used to map tissue surfaces. For example, one commercially available system uses a high energy focused ultrasound (HIFU) catheter to capture two-dimensional images of a prostate gland relating to blood flow in the target tissue. The user then manually marks tissue components on the individual 2-dimensional images. Thereafter, the images are formed into a three-dimensional model, and a chosen area is ablated in a pinpoint manner. A table, which maps transducer parameters to expected lesion size, is employed to aid in ablation. During the process, the transducer must be repeatably positioned at the same location in order for the method to be effectively carried out. While promising, this system is not optimized for ablation of cardiac tissue. Therefore, it would also be advantageous to provide an ablation system that can ultrasonically sense and scan the portion of the heart to be ablated, and that can create a 3-dimensional surface map of the tissue surface based on the scanned data.

[0014] It would further be advantageous if such systems could identify anatomical features such as pulmonary veins on the surface map, and suggest an ablation path surrounding the anatomical features. It would also be advantageous if such systems could ablate along the suggested ablation path using the same catheter that was used for sensing and scanning. At least some of these objectives will be met by the present invention.

[0015] In the cardiac field methods exits for treating cardiac arrhythmias with no discrete target. A description of the heart chamber anatomy, such as the physical dimensions of the chamber, is obtained and an activation map of a patient's heart is created using locatable catheters. A conduction velocity map is derived from the activation map. Then, a refractory period map is acquired. Appropriate values from the conduction velocity map and the refractory period map are used to create a dimension map, which is then analyzed to determine ablation lines or points. This mapping is promising, but it would also be advantageous to provide a single system that ultrasonically ablates and senses the cardiac tissue and generates 3-dimensional tissue map. It would be additionally useful to provide a system that is configured to identify desired anatomical features on the 3-dimensional tissue map. Further, it would be beneficial to provide a catalog of lesion paths to choose from when ablating on a path around one or more desired anatomical features. At least some of these objectives will be met by the present invention.

[0016] 2. Description of Background Art

[0017] Patents related to the treatment of atrial fibrillation include, but are not limited to the following: U.S. Pat. Nos. 6,997,925; 6,996,908; 6,966,908; 6,964,660; 6,955,173; 6,954,977; 6,953,460; 6,949,097; 6,929,639; 6,872,205; 6,814,733; 6,780,183; 6,666,858; 6,652,515; 6,635,054; 6,605,084; 6,547,788; 6,514,249; 6,502,576; 6,416,511; 6,383,151; 6,305,378; 6,254,599; 6,245,064; 6,164,283; 6,161,543; 6,117,101; 6,064,902; 6,052,576; 6,024,740; 6,012,457; 5,718,241; 5,405,346; 5,314,466; 5,295,484; 5,246,438; and 4,641,649.

[0018] Patent Publications related to the treatment of atrial fibrillation include, but are not limited to International PCT Publication Nos. WO 2005/117734; WO 99/02096; and U.S. Patent Publication Nos. 2007/0219448; 2005/0267453; 2003/0050631; 2003/0050630; and 2002/0087151.

[0019] Scientific publications related to the treatment of atrial fibrillation include, but are not limited to: Haissaguerre, M. et al., Spontaneous Initiation of Atrial Fibrillation by Ectopic Beats Originating in the Pulmonary Veins, New England J. Med., Vol. 339:659-666; J. L. Cox et al., The Development of the Maze Procedure for the Treatment of Atrial Fibrillation, Seminars in Thoracic & Cardiovascular Surgery, 2000; 12: 2-14; J. L. Cox et al., Electrophysiologic Basis, Surgical Development, and Clinical Results of the Maze Procedure for Atrial Flutter and Atrial Fibrillation, Advances in Cardiac Surgery, 1995; 6: 1-67; J. L. Cox et al., Modification of the Maze Procedure for Atrial Flutter and Atrial Fibrillation. II, Surgical Technique of the Maze III Procedure, Journal of Thoracic & Cardiovascular Surgery, 1995; 110:485-95; J. L. Cox, N. Ad, T. Palazzo, et al. Current Status of the Maze Procedure for the Treatment of Atrial Fibrillation, Seminars in Thoracic & Cardiovascular Surgery, 2000; 12: 15-19; M. Levinson, Endocardial Microwave Ablation: A New Surgical Approach for Atrial Fibrillation; The Heart Surgery Forum, 2006; Maessen et al., Beating Heart Surgical Treatment of Atrial Fibrillation with Microwave Ablation, Ann Thorac Surg 74: 1160-8, 2002; A. M. Gillinov, E. H. Blackstone and P. M. McCarthy, Atrial Fibrillation: Current Surgical Options and their Assessment, Annals of Thoracic Surgery 2002; 74:2210-7; Sueda T., Nagata H., Orihashi K., et al., Efficacy of a Simple Left Atrial Procedure for Chronic Atrial Fibrillation in Mitral Valve Operations, Ann Thorac Surg 1997; 63:1070-1075; Sueda T., Nagata H., Shikata H., et al.; Simple Left Atrial Procedure for Chronic Atrial Fibrillation Associated with Mitral Valve Disease, Ann Thorac Surg 1996; 62:1796-1800; Nathan H., Eliakim M., The Junction Between the Left Atrium and the Pulmonary Veins, An Anatomic Study of Human Hearts, Circulation 1966; 34:412-422; Cox J. L., Schuessler R. B., Boineau J. P., The Development of the Maze Procedure for the Treatment of Atrial Fibrillation, Semin Thorac Cardiovasc Surg 2000; 12:2-14; and Gentry et al., Integrated Catheter for 3-D Intracardiac Echocardiography and Ultrasound Ablation, IEEE Transactions on Ultrasonics, Ferroelectrics, and Frequency Control, Vol. 51, No. 7, pp 799-807.

BRIEF SUMMARY OF THE INVENTION

[0020] The present application generally relates to systems and methods for creating ablation zones in human tissue. More specifically, the present application relates to the treatment of atrial fibrillation of the heart using ultrasound energy. While the present application emphasizes treatment of atrial fibrillation, one of skill in the art will appreciate that this is not intended to be limiting, and that the systems and methods disclosed herein may also be used to treat other arrhythmias such as ventricular fibrillation, as well as other tissues and conditions.

[0021] In a first aspect of the present invention, a method for echo-anatomically mapping tissue comprises advancing a catheter toward a target treatment tissue. The catheter comprises a proximal end, a distal end, an ultrasound transducer adjacent the distal end, and a console adjacent the proximal end. The console is configured to control move-

ment of the catheter, and the ultrasound transducer is configured to sense the target treatment tissue. A first region of the target treatment tissue is sensed with the ultrasound transducer while moving the ultrasound transducer along a first sensing pattern. A first 3-dimensional surface map of the first region is generated. A second region of the target treatment tissue is sensed with the ultrasound transducer while moving the ultrasound transducer along a second sensing pattern. A second 3-dimensional surface map of the second region is generated. The first and the second 3-dimensional surface maps are combined to form a combined surface map.

[0022] The advancing step may comprise percutaneously introducing the catheter into vasculature of a patient and transseptally passing the catheter through an atrial septal wall of the patient's heart into a left atrium. Sensing of the first or the second region may comprise operating the transducer in amplitude mode (A-mode). The first or the second sensing pattern may comprise a raster pattern or a spiral pattern. Sensing of the first or the second regions may also comprise delivering a beam of ultrasound energy from the transducer to the target treatment tissue. The sensing of the first or the second regions may be performed without establishing direct contact between the transducer and the tissue. The first sensed region may be the same or different than the second sensed region. The first sensing pattern may be the same or different than the second sensing pattern.

[0023] Generating the first or the second 3-dimensional surface map may comprise visually displaying the combined surface map.

[0024] The method may further comprise identifying anatomical features in the first sensed region or the second sensed region. The anatomical features in the first or the second region may comprise one or more pulmonary veins. The identifying step may comprise capturing data indicating distance between the transducer and the target treatment tissue at a plurality of points along the first or the second sensing patterns.

[0025] The method may also comprise ablating the target treatment tissue with the ultrasound transducer while moving the ultrasound transducer along a first ablation path. The first ablation path may form a lesion around the identified anatomical features. The lesion may block aberrant electrical pathways in the tissue so as to reduce or eliminate atrial fibrillation. The ablating step may comprise selecting the first ablation path from a catalog of available lesion paths based on the identified anatomical features. The first ablation path may be automatically selected from the catalog of available lesion paths, or a physician may prescribe the first ablation path. The method may further comprise accepting or rejecting the selected ablation path by a physician or other operator. A physician or other operator may also modify the selected ablation path. The catalog of available lesion paths may be stored on a memory element coupled to the console. The method may further comprise adding, deleting, or modifying lesion paths stored on the memory element. The ablating may be performed without establishing direct contact between the transducer and the tissue. The method may comprise drawing the first ablation path by a physician or other operator, or the first ablation path may be suggested by the console.

[0026] The method may further comprise visually displaying the combined surface map. The method may also comprise superimposing the first ablation path on the combined surface map, and the resulting superimposed map may be visually displayed. The method may further comprise monitoring deviations from the selected lesion path during the ablating. The ablating may be corrected so as to minimize deviations from the selected lesion path. The correction may comprise moving the transducer. Sensing of the first or the second region may also be synchronized with a patient's the cardiac cycle. The method may further comprise determining lesion thickness along the first ablation path.

[0027] These and other embodiments are described in further detail in the following description related to the appended drawing figures.

INCORPORATION BY REFERENCE

[0028] All publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.

BRIEF DESCRIPTION OF THE DRAWINGS

[0029] The novel features of the invention are set forth with particularity in the appended claims. A better understanding of the features and advantages of the present invention will be obtained by reference to the following detailed description that sets forth illustrative embodiments, in which the principles of the invention are utilized, and the accompanying drawings of which:

[0030] FIG. **1** schematically illustrates an exemplary catheter system for ultrasonically sensing and ablating cardiac tissue.

[0031] FIGS. **2**A-**2**D illustrate exemplary sensing patterns.

[0032] FIGS. **3**A-**3**F illustrate exemplary 3D maps for six neighboring portions of the atrial tissue surface.

[0033] FIG. **3**G illustrates a 3D map obtained by combining the six maps of FIGS. **3**A-**3**F.

[0034] FIGS. **4**A-**4**J illustrate exemplary lesion paths.

[0035] FIGS. **5**A-**5**B illustrate exemplary ablation lesions.

DETAILED DESCRIPTION OF THE INVENTION

[0036] Overview. The present disclosure emphasizes, but is not limited to catheter systems and methods for ultrasonically sensing and ablating tissue to treat atrial fibrillation. A catheter equipped with an ultrasonic transducer is used to sense and scan at least some portion of atrial heart tissue surface. The ultrasonically sensed data is then used to generate a 3-dimensional (3D) echo-anatomical map of the tissue surface. One or more anatomical features are then identified based on the generated 3-dimensional map. The anatomical features may then be electrically isolated using tissue ablation. In one embodiment, the anatomical features are pulmonary veins (PVs).

[0037] Once the anatomical features are identified, a lesion path is chosen so as to surround the anatomical features. In one embodiment, the lesion path is chosen from among a catalog of available lesion paths, based on the location of the identified anatomical features. Alternatively, a physician may prescribe the lesion path by drawing the lesion path around identified features. Once the lesion path is chosen, the catheter is used to ultrasonically ablate the tissue along the lesion path and around the identified anatomical features.

[0038] Sensing and ablation system. FIG. **1** is a diagrammatic illustration of an exemplary catheter system for ultrasonically sensing and ablating tissue to treat atrial fibrillation, according to one embodiment of the present invention. The system comprises a sensing and ablation catheter C transseptally disposed across an atrial septal wall AS into the left atrium LA of a patient's heart adjacent the pulmonary veins PV, and a console P outside of the patient. Catheter C comprises a proximal portion and a distal portion. The distal portion of the catheter C is configured for introduction into an atrium of the heart, either percutaneously or surgically, and comprises an ultrasonic transducer subassembly T (hereinafter also referred to as transducer T).

[0039] The transducer T is capable of ultrasonically sensing tissue, as well as ultrasonically ablating tissue, without necessarily establishing direct physical contact with tissue. The distal portion of the catheter C is configured to be moveable in a controlled fashion so that it may trace out sensing patterns and lesion paths. In one embodiment, and as shown in FIG. **1**, the catheter device C is housed within a sheath S.

[0040] The console P is configured to couple to the proximal portion of the catheter C in order to direct the distal tip of catheter C to move in one or more directions, thereby guiding the transducer T along one or more sensing patterns or lesion paths. The console P also controls the operation of transducer T by delivering electrical energy to the transducer T in order to generate ultrasonic energy for sensing and ablating tissue, and by recording scan signals produced by transducer T as it senses the tissue surface.

[0041] As mentioned above, the console P controls the catheter C to move in a pattern, such as a raster pattern, in order to scan some portion of the tissue. Based on the received scan signals, console P then generates a 3-dimensional map of the tissue portion.

[0042] Based on the 3-dimensional map of the tissue portion, the console P presents one or more anatomical features, such as PVs, that are to be electrically isolated. The console P then suggests a lesion path based on the map and the location of the anatomical features, or a physician may select or prescribe the lesion path. Upon confirmation or modification of the lesion path by a user, the console P directs the catheter C to ablate the tissue along the lesion path.

[0043] In one embodiment, console P houses, or is coupled to, a memory element that stores a catalog of available lesion paths, from which catalog the lesion path is selected. The catalog may be configurable, and lesion paths may be added, deleted or modified. In one embodiment, the system further comprises a computer display or monitor in order to present the tissue map, the identified anatomical features, and the suggested lesion path to the user.

[0044] Additional details about the catheter C, transducer T, console P, and sheath S are disclosed in U.S. Provisional Patent Application No. 61/254,997 (Attorney Docket No. 027680-001900US), previously incorporated by reference. Other disclosure applicable to the ablation system described above is included in patent applications previously incorporated herein by reference.

[0045] Sensing mode. In operation, the transducer T functions in one of two modes: a sensing mode and an ablation mode. When operating in sensing mode, the transducer T is directed to move in a sensing pattern over a portion of atrial tissue surface, and to capture a set of ultrasonically generated data indicating the distance between the transducer T and the atrial tissue at a plurality of points along the traversed sensing pattern. In one embodiment, transducer T operates in Amplitude-mode (A-mode) to sense a distance between the transducer T and the tissue surface.

[0046] The sensing pattern may be a raster pattern, as shown in the examples of FIGS. **2**A-**2**B. FIG. **2**A illustrates a raster pattern **202** where the raster pattern scans horizontally from left to right **204** and a diagonal return **206** from right to left allows the next horizontal scan to begin again from left to right and the pattern is repeated multiple times. FIG. **2**B illustrates a variation of a raster scan **210** in which scanning occurs horizontally **212** from left to right. At the end of the horizontal scan, the scan is vertically moved downward as indicated by arrow **214**, and then the scan continues from right to left **216**. Another vertical adjustment moves the scan downward again, and then the scan from left to right begins again. This pattern is repeated multiple times. FIGS. **2**C-**2**D illustrate exemplary scan patterns having spiral shapes. For example, in FIG. **2**C, the scan pattern has a curved pattern that spirals centrally inward to a central point, with each spiral having a smaller radius than the previous spiral. FIG. **2**D illustrates a square spiral, where the scan pattern **226** has a series of vertical **228** and horizontal **230** scans that are joined together to form an inwardly directed square spiral. One of skill in the art will appreciate that the directions left, right, vertical and horizontal may be changed, and therefore are not intended to be limiting. The sensed data is then used by the console P to generate a 3-dimensional surface map of the sensed portion of the atrial tissue. Thus the present system is useful for echo-anatomical mapping of the target tissue surface, such as a portion of, or the entire surface of the left or right atrium of the heart. The surface map may include the entire target treatment surface, or it may include only a section of the treatment surface. Because the catheter may require repositioning several times during mapping of the entire surface, it may be easier to map a section of the target surface, reposition the catheter, and then map another section. Also, in addition to positioning requirements, scanned sections may be limited to certain areas due to memory or data processing limitations of the system.

[0047] This process of sensing and obtaining scan signals is repeated as needed in order to generate one or more further 3-dimensional maps for one or more neighboring portions of the atrial tissue surface, thereby covering the surface area that is to be mapped with sensing patterns. As one example, FIGS. **3**A-**3**F show 3-dimensional maps for six neighboring portions of the atrial tissue surface having four pulmonary veins PV. FIG. **3**A illustrates an upper left portion **302** of the target tissue and shows an upper left portion **304** of a first PV. FIG. **3**B illustrates an upper center portion **306** of the target tissue and shows an upper right portion **308** of the first PV, an upper left portion **310** of a second PV and an upper left portion **312** of a third PV. FIG. **3**C illustrates an upper right portion **314** of the target tissue and shows an upper right portion **316** of the second PV and an upper right portion **318** of the third PV. FIG. **3**D illustrates a lower left portion **320** of the target tissue and shows a lower left portion **322** of the first PV and a lower left portion **324** of a fourth PV. FIG. **3**E illustrates a lower center portion **326** of the target tissue and shows a lower right portion **328** of the first PV, a lower right portion **330** of the fourth PV and a lower left portion **332** of the third PV. FIG. **3**F illustrates a

lower right portion **334** of the target tissue and shows a lower right portion **336** of the third PV. The PVs are depicted as grey portions, indicating "holes" or regions of large distance between the transducer T and tissue. Once generated, these one or more 3-dimensional maps may be combined by the console P to form a combined 3-dimensional map of the scanned atrial tissue surface. FIG. **3**G shows an exemplary combined 3-dimensional map obtained by combining the six maps of FIGS. **3**A-**3**F. Thus, the present system is capable of mapping a portion of, or mapping the entire inner surface of an atrium, or other tissue surface. Note that in some applications of the present invention it may be determined that obtaining a single 3-dimensional map may be sufficient to allow identification of one or more PVs (instead of obtaining and combining a plurality of 3-dimensional maps, as described above). In the following description, the term "combined map" shall also refer to such a single 3-dimensional real time echo-anatomical map obtained in such embodiments. In preferred embodiments, the map is also compatible with other mapping and ablation systems, such as the CARTO® electroanatomical mapping system (Biosense Webster, Diamond Bar, Calif.), CT scanning systems, and the EnSite Array™ from St. Jude Medical, or other similar systems.

[0048] The combined echo-anatomical map is then used to identify the location of one or more PVs, which may appear as holes or similar artifacts on the map. The identification of the PV locations may be done algorithmically by the console P, or it may be done by a human user, or by using a combination of user input and programmed logic. Optionally, the echo-anatomical map may be presented to a user on a computer display in order to allow visual identification and/or visual verification of the PV locations.

[0049] In one embodiment, once the PVs are located, a lesion path is selected from among the catalog of available lesion paths. FIGS. **4**A-**4**J show example lesion paths in a catalog of lesion paths. FIG. **4**A illustrates oval or circular lesions **402**, **404** encircling two pulmonary veins each (e.g. two left pulmonary veins and two right pulmonary veins). A linear lesion **406** connects each of the oval lesions **402**, **404** and a transverse lesion **408** extends from the linear lesion **406** downward toward the mitral valve (not illustrated). FIG. **4**B illustrates another embodiment where an arcuate lesion **410** preferably U-shaped, or horseshoe shaped, is superior to, and partially encircles a first upper PV, and a second arcuate lesion **411**, that may take the same form as lesion **410** is superior to, and partially encircles a second upper PV. An arcuate lesion **412**, preferably U-shaped, or horseshoe-shaped is inferior to, and partially encircles a third PV, and another arcutate lesion **413** that may take the same form as lesion **412** is inferior to, and partially encircles a fourth PV. In this exemplary embodiment, the first PV is superior to the third PV and the fourth PV is inferior to the second PV. Also, in this exemplary embodiment, the first and third PVs are disposed to the left of the second and fourth PVs. Thus, some of the PVs may be left pulmonary veins, and some of the PVs may be right pulmonary veins. Linear lesions **414***a*, **414***b* connect the superior arcuate lesion **410** with the inferior lesion **412** so that the first and third PVs are completely encircled. Linear lesions **414***c*, **414***d* connect the superior arcuate lesion **411** with the inferior lesion **413** so that the second and fourth PVs are completely encircled. Linear lesion **406** connects the lesions encircling the pairs of PVs and a transverse lesion **408** extends from the linear lesion **406** downward toward the mitral valve (not illustrated). FIG. **4**C illustrates still another embodiment where lesions **416***a*, **416***b*, **416***c*, and **416***d* arc around each of four PVs, such that two pairs of arcs **416***a*, **416***c*, and **416***b*, **416***d* merge together such that each pair completely encircles two PVs. A horizontal lesion **406** and a transverse lesion **408** connect the lesions encircling two PVs. FIG. **4**D illustrates yet another embodiment of a lesion pattern where two oval or circular lesions **418***a*, **418***b* each completely encircle two PVs. Two linear lesions **420**, **422** join the two oval lesions **418***a*, **418***b* forming an "X." A transverse lesion **408** extends from the "X" downward toward the mitral valve (not shown). FIG. **4**E illustrates another embodiment of lesion where two arcs **424***a*, **426***a* completely encircle two PVs. The first arc **424***a* partially encircles one side of the pair of PVs, and the second arc **426***a* partially encircles the opposite side of the pair of PVs. The ends of the two arcs **424***a*, **426***a* crossover or intersect with one another to form a closed loop. Similarly, another pair of arcs **424***b*, **426***b* completely encircle a second pair of PVs. The third arc **424***b* partially encircles one side of the second pair of PVs, and the fourth arc **426***b* partially encircles the opposite side of the second pair of PVs. The ends of the third and fourth arcs **424***b*, **426***b* crossover one another or intersect with one another to form a closed loop. The pattern also includes a linear lesion **406** and a transverse lesion **408** that generally take the same form as previously described. FIG. **4**F illustrates another lesion pattern having an oval or circular lesion **428** encircling two PVs. A second oval or circular lesion **430** encircles another two PVs, and also has a square or rectangular notch **432** to exclude the notched region from being encircled by the lesion. A linear lesion **406** connects the two lesions **428**, **430** and a transverse lesion **408** extends therefrom. FIG. **4**G shows another exemplary lesion pattern with an arc **434** partially encircling two PVs and a linear lesion **436** crossing both ends of the arc **434** so that the resulting lesion completely encircles both PVs. A second oval or circular lesion **438** completely encircles two other PVs and a linear lesion **408** connects the two lesions **436**, **438**. A transverse lesion **408** extends from the linear lesion **406**. FIG. **4**H shows another exemplary lesion having a curved lesion **441** connecting two circular or oval lesions **440***a*, **440***b* each encircling two PVs. The curved lesion **441** has two ends that overlap with each of the oval lesions **440***a*, **440** *b*, and the curved lesion also overlaps itself, forming a lower loop similar to the Greek letter gamma. FIG. **4**I illustrates a first loop **442** that encircles two PVs, and a second loop **444** that encircles two additional PVs. Each loop has overlapping ends such that the two PVs are completely encircled. A linear lesion **406** connects the two loops **442**, **444** and a transverse lesion **408** extends from the linear lesion **406**. FIG. **4**J shows another embodiment where loops **446**, **448** encircle two PVs each. However, in this embodiment, the ends of the loops do not overlap with one another and thus, while the PVs are completely encircled, a total conduction block has not been created, as the aberrant electrically activity can pass between the ends of the loops which do not overlap. Therefore, a linear lesion **406** extends through the open portions of each loop, and between both loops **446**, **448**, creating the conduction block. A transverse lesion **408** extends from the linear lesion **406**.

[0050] The catalog of ablation patterns may be stored on a memory element coupled to the console P, or otherwise be made accessible to the console P. The choice of the particular

lesion path to be used for ablation is based on the identified locations of the PVs in the combined 3-dimensional map of the atrial tissue, with the lesion path chosen to surround the PVs in order to electrically isolate them and thereby treat atrial fibrillation.

[0051] In one embodiment, the console P may be programmed to suggest a lesion path based on image analysis techniques applied to the obtained tissue map in order to locate artifacts, such as holes or ovals, which indicate the location of PVs. The user (for example, a surgeon) may then accept the suggested lesion path, modify the suggested lesion path, choose another lesion path from the catalog, or draw a new lesion path. In such an embodiment, the console P may superimpose the selected lesion path onto the obtained surface map and present them to the user, thereby allowing the user to make any needed modifications prior to ablation.

[0052] Additionally and optionally, the console P may be configured to learn from the user's (i.e., surgeon's) input with respect to lesion choices and lesion path modifications, by storing such information and associating it with the corresponding tissue maps and identified PV locations, for future reference. This allows the console P to personalize lesion path choices to particular surgeons, to suggest lesion paths based on past choices aggregated over a number of surgeons, etc.

[0053] Additional details on sensing and mapping may be found in U.S. patent application Ser. No. 12/609,759 (Attorney Docket No. 027680-001110US); Ser. No. 12/609,274 (Attorney Docket No. 027680-001410US); and Ser. No. 12/609,705 (Attorney Docket No. 027680-001610US), each previously incorporated herein by reference. Other details which may be applicable are disclosed in other patent applications previously incorporated herein by references.

[0054] Ablation mode. Once a lesion path is chosen, the console P causes the transducer T to switch to operating in ablation mode. In ablation mode, the electrical energy delivered to the transducer T, and therefore the ultrasonic energy delivered by the transducer T to the tissue, is higher than in sensing mode, and sufficient to ablate the tissue. In this mode, the console P directs the catheter C to move the transducer T along the chosen lesion path while the transducer T ultrasonically ablates atrial tissue along the chosen lesion path, thereby creating an ablation lesion around the one or more PVs.

[0055] FIGS. **5**A and **5**B show example lesions created in the left atrium LA of the heart. In this embodiment, the left atrium LA has four pulmonary veins PV. The left atrium is separated from the right atrium via an atrial septal wall AS. FIG. **5**A shows an exemplary lesion **501** created around two PVs and lesion **502** created around another two PVs. Both lesions **501**, **502** may be circular, elliptical, oval, or another shape (e.g. square, rectangular, etc.) and completely encircle two PVs. FIG. **5**B shows an exemplary lesion **503** created around three PVs in the left atrium LA. The lesion **503** may be circular, oval, elliptical, or any other shape (e.g. square, rectangular, etc.) that completely encircles the three PVs. In an optional embodiment, the console P may be configured to monitor deviations from the chosen lesion path and to provide corrections by adjusting the movement of the catheter C. For example, the console P may be configured to monitor a distance between the chosen lesion path and the tissue site that is being ultrasonically ablated by the transducer T, and move the distal portion of the catheter C (and with it the transducer T) towards the chosen lesion path in order to decrease that distance, thereby repositioning the transducer T along the chosen lesion path. In another optional embodiment, the console P may be configured to detect the transducer's T passing over veins and provide a visual indication thereof (for example, by flashing a red light when going over a vein and a green light otherwise), thereby giving an opportunity to the surgeon to intervene or to provide corrections at a later time.

[0056] Additionally and optionally, the console P may be configured to synchronize the operation of the transducer T, in sensing mode and/or in ablation mode, with the cardiac cycle. This is to enable greater accuracy in sensing and/or in ablation given the beating of the heart. Such synchronization may be accomplished by configuring the console P to receive input from a monitoring device such as an electrocardiograph (EKG), a computed tomography (CT) scanner, an electroanatomical mapping system (CARTO), or other such devices. The operation of the transducer T is then synchronized to accommodate or better account for the movement of the heart. For example, the console P may synchronize with the cardiac cycle and cause the transducer T to operate within periodic time slices in the cardiac cycle where the movement of the heart tissue is at a minimum, such as during physical diastole when the heart is stationary for the longest period of time during the cardiac cycle.

[0057] Additionally and optionally, the console P may be programmed to analyze the scan signals, received from the transducer T in sensing mode, and infer information about the thickness of the produced ablation. For example, this may be accomplished by comparing the times at which various tissue boundaries reflect the ultrasound emitted by the transducer T, and inferring the distance between such tissue boundaries (i.e., the thickness of the tissue between the boundaries). When applied to the two tissue boundaries on each side of an ablated layer, the ablation thickness may be inferred. Such thickness values may be used to more accurately time the exposure of atrial tissue to ultrasonic ablation energy, thereby providing for substantially transmural ablation and electrical isolation of the PVs. Additional details about characterizing the lesion is disclosed in patent applications previously incorporated herein by reference.

[0058] While the above is a complete description of the preferred embodiments of the invention, various alternatives, modifications, and equivalents may be used. Therefore, the above description should not be taken as limiting the scope of the invention which is defined by the appended claims.

What is claimed is:

1. A method for echo-anatomically mapping tissue, said method comprising:

advancing a catheter toward a target treatment tissue, the catheter comprising a proximal end, a distal end, a transducer adjacent the distal end, and a console adjacent the proximal end, wherein the console is configured to control movement of the catheter, and wherein the transducer is configured to have a sensing mode to sense the target treatment tissue and an ablation mode to ablate the target treatment tissue;

sensing a first region of the target treatment tissue with the transducer while in the sensing mode while moving the transducer with a first sensing pattern;

generating a first surface map of the first region;

sensing a second region of the target treatment tissue with the transducer while in the sensing mode while moving the transducer with a second sensing pattern;

combining the first surface map with the second surface map to form a combined surface map;

generating an ablation path based on the combined surface map;

switching the transducer from the sensing mode to the ablating mode; and

ablating the target treatment tissue with the transducer.

2. The method of claim **1**, wherein advancing a catheter toward a target treatment tissue comprises percutaneously introducing the catheter into vasculature of a patient and transeptally passing the catheter through an atrial septal wall of the patient's heart into a left atrium.

3. The method of claim **1**, wherein the target treatment tissue comprises left atrial tissue.

4. The method of claim **1**, wherein sensing the first or second region comprises operating the transducer in amplitude mode (A-mode).

5. The method of claim **1**, wherein the first or the second sensing patterns comprise a raster pattern or a spiral pattern.

6. The method of claim **1**, wherein sensing the first or the second regions comprise delivering a beam of ultrasound energy from the transducer to the target treatment tissue.

7. The method of claim **1**, wherein sensing the first or the second regions is performed without establishing direct contact between the transducer and the tissue.

8. The method of claim **1**, wherein the first sensed region is different than the second sensed region.

9. The method of claim **1**, wherein the first sensed region is the same as the second sensed region.

10. The method of claim **1**, wherein the first sensing pattern is different than the second sensing pattern.

11. The method of claim **1**, wherein the first sensing pattern is the same as the second sensed region.

12. The method of claim **1**, wherein the anatomical features in the first or the second region comprise one or more pulmonary veins.

13. The method of claim **12**, wherein the identifying step comprises capturing data indicating distance between the transducer and the target treatment tissue at a plurality of points along the first or the second sensing patterns.

14. The method of claim **1**, ablating the target treatment tissue with the ultrasound transducer is performed moving the ultrasound transducer along the ablation path, and wherein the ablation path forms a lesion around the identified anatomical features

15. The method of claim **14**, wherein the lesion blocks aberrant electrical pathways in the tissue so as to reduce or eliminate atrial fibrillation.

16. The method of claim **14**, further comprising prescribing the first ablation path by a physician.

17. The method of claim **14**, wherein generating the ablation path is performed by selecting the ablation path from a catalog of available lesion paths based on the identified anatomical features.

18. The method of claim **17**, wherein the ablation path is automatically selected from the catalog of available lesion paths.

19. The method of claim **18**, further comprising accepting or rejecting the selected ablation path by a physician or other operator.

20. The method of claim **18**, further comprising modifying the selected ablation path by a physician or other operator.

21. The method of claim **17**, wherein the catalog of available lesion paths is stored on a memory element coupled to the console.

22. The method of claim **17**, further comprising adding, deleting, or modifying lesion paths stored on the memory element.

23. The method of claim **1**, wherein ablating the target treatment tissue is performed without establishing direct contact between the transducer and the tissue.

24. The method of claim **1**, further comprising drawing the ablation path by a physician or other operator.

25. The method of claim **1**, further comprising superimposing the ablation path on the combined surface map.

26. The method of claim **25**, further comprising visually displaying the first ablation path superimposed on the combined surface map.

27. The method of claim **1**, further comprising monitoring deviations from the selection lesion path during ablating.

28. The method of claim **27**, further comprising minimizing correcting the ablating so as to minimize deviations from the selected lesion path.

29. The method of claim **28**, wherein the correcting comprises moving the transducer.

30. The method of claim **1**, further comprising synchronizing the sensing of the first or the second region with a patient's cardiac cycle.

31. The method of claim **1**, further comprising determining lesion thickness along the ablation path.

32. The method of claim **1**, wherein the first surface map of the first region comprises a first 3-dimensional surface map of the first region.

33. The method of claim **32**, wherein the second surface map of the first region comprises a second 3-dimensional surface map of the first region.

34. The method of claim **33**, wherein combining the first surface map with the second surface map comprises combining the first and second 3-dimensional surface map into the combined surface map, and wherein the combined surface map comprises a 3-dimensional combined surface map.

* * * * *

专利名称(译)	用于超声检测和消融组织的系统和方法		
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摘要(译)

回声解剖映射组织包括使具有超声换能器的导管朝向组织前进。邻近导管近端的控制台控制导管移动，并且超声换能器感测组织。在沿着第一和第二感测图案分别移动超声换能器的同时超声感测组织的第一和第二区域。生成第一区域的第一三维表面图和第二区域的第二三维表面图。将三维表面图组合以形成组合表面图。可以在第一或第二感测区域中识别解剖特征。在沿着第一消融路径移动超声换能器的同时，可以对组织进行超声消融。第一消融路径可以在所识别的解剖特征周围形成损伤，并且可以从消融路径的目录中选择，或者可以由医生规定。