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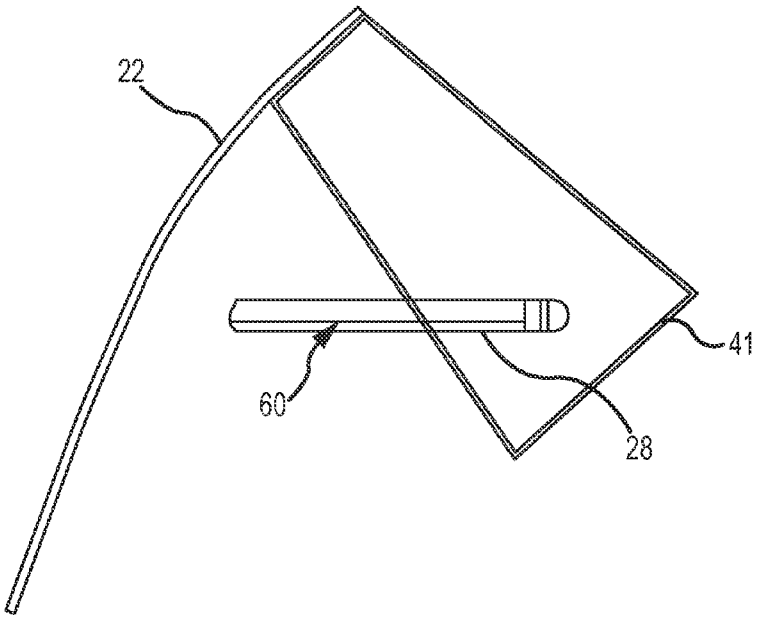

(57) Abstract: An ablation catheter is provided along with a system and method for delivery of ablation therapy to tissue in a body and for assessing effects of the ablation therapy. The catheter includes an elongate deformable shaft having a proximal end and a distal end and an ablation delivery element disposed at the distal end of the shaft. An electromagnetic radiation emitter such as an optic fiber is disposed within the shaft. The emitter is configured to emit electromagnetic radiation through an opening in the ablation delivery element towards the tissue causing generation of a photoacoustic wave from the tissue. An echographic probe disposed proximate the ablation catheter generates a signal in response to the photoacoustic wave indicative of one or more characteristics of the tissue which can be used to assess the effects of the ablation therapy and/or control the ablation therapy.

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ABLATION CATHETER WITH OPTIC ENERGY DELIVERY SYSTEM FOR PHOTOACOUSTIC TISSUE RESPONSE

BACKGROUND OF THE INVENTION

a. Field of the Invention

[0001] This invention relates to ablation catheters. In particular, the instant invention relates to an ablation catheter having an optic fiber used to deliver electromagnetic radiation to tissue and cause a photoacoustic response from the tissue to thereby allow assessment of characteristics of the tissue.

b. Background Art

[0002] Cardiac arrhythmias (including, but not limited to, atrial fibrillation, atrial flutter, atrial tachycardia and ventricular tachycardia) can create a variety of dangerous conditions including irregular heart rates, loss of synchronous atrioventricular contractions and stasis of blood flow which can lead to a variety of ailments and even death. Atrial fibrillation is the most common arrhythmia, affecting more than six million people in Europe alone. The number of people affected continues to grow rapidly because of an aging population and a strong correlation between atrial fibrillation and increased age. Atrial fibrillation is characterized by uncoordinated atrial activation, thereby disturbing the normal sinus rhythm. Fibrillation waves vary in size, shape, and timing, and result in an irregular, and frequently rapid, ventricular response. Atrial fibrillation is associated with a fivefold increase in stroke risk and has been associated with a number of other cardiovascular and cerebrovascular diseases and strongly affects quality of life.

[0003] It is believed that the primary cause of many arrhythmias is stray electrical signals within one or more heart chambers. In the case of atrial fibrillation, the signals originate from an area around the pulmonary veins. Treatments for atrial fibrillation attempt to restore the normal sinus rhythm or control the ventricular rate and include pharmacological treatments and cardioversion. If these types of treatments are unsuccessful, ablation of cardiac tissue can be used to create tissue necrosis and lesions in the tissue. An ablation catheter delivers ablative energy (e.g., radiofrequency energy, light energy, ultrasound, or thermal (cryo or heat based) energy) to the cardiac tissue to create a lesion in the tissue. The lesions disrupt undesirable electrical pathways by isolating areas of tissue and thereby limit or prevent stray electrical signals that lead to arrhythmias.

[0004] To be effective, ablation therapy preferably eliminates conductivity in any undesirable electrical pathway and prevents restoration of that conductivity. Excessive ablation, however, increases several risks associated with ablation therapy including perforation of tissue, coagulation of the blood which can result in creation of a thrombus, and tissue or steam pops resulting from the application of heat to water inside the tissue which may cause the water to boil and burst through the tissue wall. Excessive ablation can cause mechanical failure of the cardiac tissue and thereby degrade cardiac function. Perforation of the heart wall can creates a life-threatening complication. The difficulty in determining the appropriate level of ablation therapy results in a long term success rate of only around 70% (which can be raised to 85% through repeated procedures) despite a relatively high cost and with a relatively high rate of complications (around 4.9%).

[0005] Because of the negative consequences of delivering too little or too much ablation energy to tissue, it is desirable to continuously monitor the effects of ablation energy on the tissue to assess the effectiveness of ablation therapy. Current monitoring techniques such as measuring tissue elasticity, echogenicity and speed of sound, however, have limited benefits because these techniques have difficulty in identifying lesion boundaries and often rely on sensing mechanisms located far from the site of the ablation.

[0006] The inventors herein have recognized a need for assessing the effects of the ablation therapy that will minimize and/or eliminate one or more of the above-identified deficiencies.

BRIEF SUMMARY OF THE INVENTION

[0007] It is desirable to provide an ablation catheter and a system and method for delivery of ablation therapy to tissue in a body and for assessing the effects of the ablation therapy

[0008] A catheter in accordance with one embodiment of the present teachings includes an elongate deformable shaft having a proximal end and a distal end and an ablation delivery element disposed at the distal end of the shaft. The catheter further includes an electromagnetic radiation emitter disposed within the shaft. In one embodiment, the emitter comprises an optic fiber. The emitter is configured to emit electromagnetic radiation through an opening in the ablation delivery element. The electromagnetic radiation may comprise, for example, visible light, near infrared (NIR), or short wave infrared (SWIR).

[0009] A system for delivery of ablation therapy to tissue in a body and for assessing effects of the ablation therapy in accordance with one embodiment of the present teachings

includes an ablation catheter comprising an elongate deformable shaft having a proximal end and a distal end and an ablation delivery element disposed at the distal end of the shaft. The ablation catheter further includes an electromagnetic radiation emitter disposed within the shaft. The emitter is configured to emit electromagnetic radiation through an opening in the ablation delivery element towards the tissue to thereby cause generation of a photoacoustic wave from the tissue. The system further includes an echographic probe including an elongate deformable shaft having a proximal end and a distal end and an ultrasound transducer disposed at the distal end of the shaft of the echographic probe. The transducer is configured to generate a signal indicative of a characteristic of the tissue responsive to the photoacoustic wave.

[0010] A method for delivery of ablation therapy to tissue in a body and for assessing effects of the ablation therapy in accordance with one embodiment of the present teachings includes the step of emitting electromagnetic radiation from a distal end of an electromagnetic radiation emitter towards the tissue. The emitter is disposed within an ablation catheter having an elongate deformable shaft having a proximal end and a distal end and an ablation delivery element disposed at the distal end of the shaft. The emitter emits the electromagnetic radiation through an opening in the ablation delivery element towards the tissue and causes generation of a photoacoustic wave from the tissue. The method further includes the step of generating a signal indicative of a characteristic of the tissue responsive to the photoacoustic wave.

[0011] A catheter, system and method in accordance with the present invention are advantageous because the inventive catheter, system and method enable improved assessment of the effects of ablation therapy. In particular, the inventive catheter, system and method provide a technique for assessing the formation of lesions both during and after ablation of tissue that allows for assessment in close proximity to the site of the ablation. By locating the emitter in the ablation catheter and delivering electromagnetic radiation through an opening in the ablation delivery element at the distal end of the catheter, the radiation has to travel over only a short distance. The resulting photoacoustic wave generated by the tissue can be detected by the transducer on the echographic probe which is typically only several centimeters away

[0012] The foregoing and other aspects, features, details, utilities and advantages of the present invention will be apparent from reading the following description and claims, and from reviewing the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] Figure 1 is a diagrammatic view of a system for delivery of ablation therapy to tissue in a body and for assessing effects of the ablation therapy in accordance with one embodiment of the present teachings.

[0014] Figure 2 is a diagrammatic view of several components of the system of Figure 1.

[0015] Figure 3 is a cross-sectional view of an ablation catheter in accordance with the present teachings.

[0016] Figure 4 is a cross-sectional view of another ablation catheter in accordance with the present teachings.

[0017] Figure 5 is a cross-sectional view of another ablation catheter in accordance with the present teachings.

[0018] Figure 6 is a cross-sectional view of another ablation catheter in accordance with the present teachings.

[0019] Figure 7 is a front planar view of the ablation catheter of Figure 4.

[0020] Figure 8 is a flow chart diagram illustrating a method for delivery of ablation therapy to tissue in a body and for assessing effects of the ablation therapy in accordance with one embodiment of the present teachings.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0021] Referring now to the drawings wherein like reference numerals are used to identify identical components in the various views, Figure 1 illustrates a system 10 for delivery of ablation therapy to tissue 12 in a body 14 and for assessing effects of the ablation therapy in accordance with one embodiment of the present teachings. Although the illustrated system relates to diagnosis and treatment of cardiac tissues, it should be understood that the present invention may find application in the diagnosis and treatment of a variety of tissues. System 10 may include an electronic control unit (ECU) 16, a display 18, an ultrasound generator 20, an echographic probe 22, an ablation generator 24, a patch electrode 26, an ablation catheter 28, and an electromagnetic radiation source 30 that generates electromagnetic radiation that may comprise, for example, visible light, near infrared (NIR), or short wave infrared (SWIR).

[0022] ECU 16 is provided to control the operation of ultrasound generator 20, ablation generator 24 and radiation source 30 and process signals generated by echographic probe 22 and ablation catheter 28 to assess deliver of ablation therapy to tissue 12. ECU 16 may be specific to

system 10 or may be used in the control of other conventional systems in an electrophysiology (EP) lab including, for example, medical device position, navigation and/or visualization systems, imaging systems, EP monitoring systems and other systems. ECU 16 may comprise a programmable microprocessor or microcontroller or may comprise an application specific integrated circuit (ASIC). ECU 16 may include a central processing unit (CPU) and an input/output (I/O) interface through which ECU 16 may receive a plurality of input signals including signals from probe 22 and catheter 28 and generate a plurality of output signals including those used to control display 18, generators 20, 24 and radiation source 30.

[0023] Display 18 is provided to convey information to a physician to assist in diagnosis and treatment of tissue 12. Display 18 may comprise a conventional computer monitor or other display device. Display 18 may comprise a portion of the intracardiac ultrasound console under the trademark "VIEWMATE Z" by St. Jude Medical, Inc. Display 18 may provide a variety of information to the physician including images of tissue 12 or the geometry of the heart generated from signals by probe 22 and catheter 28, EP data associated with tissue 12 and graphs illustrating voltage levels over time for various electrodes on ablation catheter 28. Display 18 may also present a graphical user interface (GUI) to the physician.

[0024] Ultrasound generator 20 is provided to control generation of ultrasound signals by echographic probe 22. Generator 20 is conventional in the art and may operate under the control of ECU 16.

[0025] Echographic probe 22 provides real time imaging and visualization of tissue 12 and is used to evaluate tissue 12. Echographic probe may comprise an intracardiac echocardiography (ICE) catheter or a trans esophageal (TEE) echoprobe or trans thoracic (TTE) echoprobe. Probe 22 is conventional in the art and may comprise the ICE catheter sold under the trademark "VIEWFLEX PLUS" by St. Jude Medical, Inc. Probe 22 may include an elongate deformable shaft 32, a handle 34, and an ultrasound transducer 36.

[0026] Shaft 32 provides structural support to the other components of probe 22 and provides a housing for wires and other conductors extending to transducer 36. Shaft 32 is an elongate, tubular, flexible/deformable member configured for movement within body 14 (Figure 1) and has a proximal end 38 and a distal end 40 (as used herein, "proximal" refers to a direction toward the end of the catheter near the physician, and "distal" refers to a direction away from the physician and (generally) inside the body of a patient). Shaft 32 may be introduced into a blood vessel or other structure within body 14 through a conventional introducer. Shaft 32 may then

be steered or guided through body 14 to a desired location such as tissue 12 with a guiding introducer such as the Agilis™ NxT steerable introducer available from St. Jude Medical, Inc. or with guide wires or other means known in the art. Shaft 32 may be made from conventional polymeric materials such as polyurethane, polyfluoroethylene (PTFE) including PTFE sold under the registered trademark "TEFLON" by E.I. DuPont de Nemours & Co. Corp., polyether block amides, and nylon or thermoplastic elastomers such as the elastomer sold under the registered trademark "PEBAX" by Arkema, Inc. Shaft 32 supports transducer 36 and associated conductors, and possibly additional electronics used for signal processing or conditioning. Shaft 32 further defines one or more lumens configured to house the conductors and steering wires.

[0027] Handle 34 provides a location for the physician to hold probe 22 and may further provide means for steering or guide shaft 32 within body 14. For example, handle 34 may include means to actuate various steering wires (not shown) extending through shaft 32 to distal end 40 of shaft 32 to control translation and/or deflection of shaft 32. Handle 34 may also be conventional in the art and it will be understood that the construction of handle 34 may vary. It should be understood that catheter may be manipulated manually by a physician using handle 34 or automatically through, for example, robotic controls.

[0028] Transducer 36 is provided to convert electrical signals into ultrasound signals transmitted to tissue 12 and to convert reflected ultrasound signals from tissue 12 into electrical signals for processing by ECU 16 and imaging of tissue 12. Transducer 36 is conventional in the art and is disposed at distal end 40 of shaft 32. Referring to Figure 2, transducer 36 may transmit and receive ultrasound signals in a lateral direction (or a direction that is generally perpendicular to a longitudinal axis of shaft 32) creating an imaging plane 41 that is generally parallel to the longitudinal axis of shaft 32. In accordance with one aspect of the present teachings, transducer 36 is configured to generate a signal indicative of a characteristic of tissue 12 in response to one or more photoacoustic waves as described in greater detail hereinbelow. Transducer 36 may alternate between the transmission and receipt of ultrasound signals for regular pulse-echo imaging and the capture of photoacoustic signals for tissue evaluation at predetermined time periods.

[0029] Ablation generator 24 generates, delivers and controls RF energy used by catheter 28. Generator 24 is conventional in the art and may comprise the commercial unit available under the model number IBI-1500T RF Cardiac Ablation Generator, available from Irvine Biomedical, Inc., a St. Jude Medical Company. Generator 24 includes an RF ablation signal

source 42 configured to generate an ablation signal that is output across a pair of source connectors: a positive polarity connector which may connect to an electrode on catheter 28; and a negative polarity connector which may be electrically connected by conductors or lead wires to a patch electrode 26 on body 14. It should be understood that the term connectors as used herein does not imply a particular type of physical interface mechanism, but is rather broadly contemplated to represent one or more electrical nodes. Source 42 is configured to generate a signal at a predetermined frequency in accordance with one or more user specified parameters (e.g., power, time, etc.) and under the control of various feedback sensing and control circuitry as is know in the art. Source 42 may generate a signal, for example, with a frequency of about 450 kHz or greater. Generator 24 may also monitor various parameters associated with the ablation procedure including impedance, the temperature at the tip of catheter 28, ablation energy and the position of the catheter 28 and provide feedback to the physician regarding these parameters. The duty cycle of ablation generator 24 may be controlled such that ablation signals are not provided during time periods of pulse-echo imaging and/or receipt of photoacoustic signals by transducer 36. Pulse echo imaging may require a time period of 10 microseconds and the receipt of photoacoustic signals may take about half that time period (in the latter case, transmission of light into the tissue is nearly instantaneous; therefore, the time period for travel of the photoacoustic wave is the only significant contributor to the required time).

[0030] Patch electrode 26 provides an RF or navigational signal injection path and/or is used to sense electrical potentials. Electrode 26 may also have additional purposes such as the generation of an electromechanical map or as part of a position sensing and navigation system for catheter 28 or other devices in body 14. Electrode 26 is made from flexible, electrically conductive material and is configured for affixation to body 14 such that electrode 26 is in electrical contact with the patient's skin.

[0031] Ablation catheter 28 may be used for examination, diagnosis and treatment of internal body tissues such as tissue 12. In accordance with one embodiment of the invention, catheter 28 comprises a irrigated radio-frequency (RF) ablation catheter. It should be understood, however, that the present invention can be implemented and practiced with other types of ablative energy (e.g., cryoablation, ultrasound, etc.). Catheter 28 may be connected to a fluid source 44 having a biocompatible fluid such as saline through a pump 46 (which may comprise, for example, a fixed rate roller or peristaltic pump or variable volume syringe pump with a gravity feed supply from fluid source 44 as shown) for irrigation. Catheter 28 is also

electrically connected to ablation generator 24 for delivery of RF energy. Catheter 28 may include a cable connector or interface 48, a handle 50, a shaft 52 having a proximal end 54 and a distal end 56 and one or more diagnostic or treatment elements supported thereon. Referring briefly to Figures 3-7, in accordance with various embodiments of the invention, catheter 28 may further include an ablation delivery element 58 and an electromagnetic radiation emitter such as optic fiber 60. Catheter 28 may also include other conventional components not illustrated herein such as a temperature sensor, additional electrodes, one or more position sensors, and corresponding conductors or leads.

[0032] Referring again to Figure 1, connector 48 may provide mechanical, fluid and electrical connection(s) for fluid conduit 62 extending from pump 46 and cables 64 extending to and from ablation generator 26 and radiation source 30. Connector 48 is conventional in the art and is disposed at a proximal end of catheter 28.

[0033] Handle 50 provides a location for the physician to hold catheter 28 and may further provide means for steering or guiding shaft 52 within body 14. For example, handle 50 may include means to actuate various steering wires (not shown) extending through catheter 28 to distal end 56 of shaft 52 to control translation and/or deflection of shaft 52. Handle 50 may also be conventional in the art and it will be understood that the construction of handle 50 may vary. It should be understood that catheter 28 may be manipulated manually by a physician using handle 50 or automatically through, for example, robotic controls.

[0034] Referring again to Figures 3-7, shaft 52 provides structural support to the other components of catheter and may also permit transport, delivery and/or removal of fluids (including irrigation fluids and bodily fluids), medicines, and/or surgical tools or instruments to and from tissue 12. Shaft 52 is an elongate, tubular, flexible/deformable member configured for movement within body 14 (Figure 1) and has a central axis 66. Shaft 52 may be introduced into a blood vessel or other structure within body 14 through a conventional introducer. Shaft 52 may then be steered or guided through body 14 to a desired location such as tissue 12 with a guiding introducer such as the Agilis™ NxT steerable introducer available from St. Jude Medical, Inc. or with guide wires or other means known in the art. Shaft 52 may be made from a conventional polymeric materials such as polyurethane, polyfluoroethylene (PTFE) including PTFE sold under the registered trademark "TEFLON" by E.I. DuPont de Nemours & Co. Corp., polyether block amides, and nylon or thermoplastic elastomers such as the elastomer sold under the registered trademark "PEBAX" by Arkema, Inc. Shaft 52 supports steering wires (not

shown), ablation delivery element 58, optic fiber 60 and associated conductors, and possibly additional electronics used for signal processing or conditioning. Shaft 52 further defines one or more lumens configured to house fiber 60 and conductors. Referring to Figure 4, in accordance with one embodiment, shaft 52 defines an irrigation lumen 68 configured to deliver irrigation fluid from fluid source 44 to an external surface of ablation delivery element 58.

[0035] Ablation delivery element 58 is provided to deliver ablation energy to tissue 12 to create ablative lesions in tissue 12 and thereby disrupt stray electrical pathways in tissue 12. Element 58 is disposed proximate distal end 56 of shaft 52 (and may be disposed at a distal tip of shaft 52) and may be configured in a variety of ways depending on, among other things, the type of ablative energy to be delivered by element 58. In the illustrated embodiment, element 58 comprises a tip electrode. Referring again to Figure 4, in one embodiment, element 58 may define a plurality of fluid channels (not shown) in fluid communication with irrigation lumen 68 and terminating in outlet ports 70 for the purpose of delivering fluid to an external surface of element 58 in order to cool element 58 and to displace blood between element 58 and tissue 12. Referring to Figure 7, element 58 may further define a forward facing port 72 in communication with a distal end of fiber 60 to permit passage of electromagnetic radiation from fiber 60 to tissue 12.

[0036] Optic fiber 60 is provided to deliver electromagnetic radiation to tissue 12 in order to cause tissue 12 to generate a photoacoustic wave that can be sensed by transducer 36 on probe 22. Fiber 60 may be made from various glass compositions (e.g., silica) or plastics (e.g., polymethyl methaacrylate (PMMA) surrounded by fluorinated polymers). Fiber 60 includes a core and a cladding with the core having a higher refractive index than the cladding. Fiber 60 may further include a buffer layer and a jacket as is known in the art. Fiber 60 may, for example, comprise any of a variety of common fibers sold by Polymicro Technologies, Inc., Edmund Optics, Inc. or Keyence Corporation. Fiber 60 may comprise a multi-mode optic fiber. Fiber 60 is disposed within shaft 52 and may extend from proximal end 54 to distal end 56 of shaft 52. Fiber 60 itself has a proximal end and a distal end with the distal end terminating at port 72 in ablation delivery element 58. Fiber 60 delivers electromagnetic radiation from the distal end of fiber 60 through ablation delivery element 58 to tissue 12. Because radiation is delivered through element 58, the radiation only has to travel a short distance before impinging on tissue 12 thereby producing efficient delivery of radiation without scattering. Further, the delivery of irrigating fluid on the external surface of ablation delivery element 58 displaces

blood from the pathway between port 72 and tissue 12 thereby enhancing the effective delivery of the radiation.

[0037] Electromagnetic radiation source 30 is provided to generate a set of electromagnetic radiation for delivery to tissue 12 through fiber 60. Source 30 may comprise, for example, a light emitting diode (LED) or laser (e.g., a laser diode). Source 30 may produce a monochromatic or spectral radiation and the radiation may be polarized or unpolarized. Source 30 may generate radiation at various points along the electromagnetic spectrum including, for example, visible light, near infrared (NIR), or short wave infrared (SWIR). In particular, source 30 may generate radiation at different wavelengths (e.g. green and red in the visible spectrum) to provide sufficient contrast for identification of lesion boundaries. The radiation pulses emitted will typically be short (e.g., about 10 nanoseconds). Radiation source 30 may emit radiation in a controlled manner responsive to signals received from ECU 16. Referring to Figures 5-6, in an alternative embodiment, a local electromagnetic radiation source 74 may be supported by shaft 52 near distal end 56 of shaft 52. Source 74 functions in a manner similar to radiation source 30. Alternatively still, source 74 may itself serve as and the emitter of electromagnetic radiation and emit electromagnetic radiation directly from catheter 28 towards tissue 12 without transmission through an optic fiber 60. Source 74 may, for example, comprise a solid state laser generator.

[0038] Referring now to Figure 8, a method for delivery of ablation therapy to tissue in a body and for assessing effects of the ablation therapy will be described. The method may begin with the step 76 of delivering ablative energy to tissue 12. Responsive to control by the physician and/or ECU 16, ablation generator 24 may generate signals that cause ablation delivery element 58 to deliver radio-frequency ablation energy to tissue 12 in a conventional manner. The method may also include the step 78 of providing irrigation fluid to an external surface of the ablation delivery element 58. It should be understood that step 78 may be performed simultaneously with step 76. It should also be understood that step 78 may be performed continuously even when step 76 is not being performed for the purpose of temperature control and displacement of blood between element 58 and tissue 12. Irrigation fluid may be delivered from fluid source 44 through irrigation lumen 68 and fluid ports 70 formed in ablation delivery element 58.

[0039] The method may continue with the step 80 of emitting electromagnetic radiation from a distal end of optic fiber 60 or a similar radiation emitter (e.g., direct emission by source 74) towards tissue 12 to cause generation of one or more photoacoustic waves from tissue 12.

ECU 16 may direct ablation generator 24 to cease ablation of tissue 12 while contemporaneously directing radiation source 30 or emitter 74 to generate electromagnetic radiation and deliver that radiation to tissue 12 directly or through optic fiber 60. Ablation creates a thermal lesion in tissue 12 with clearly recognizable optical and structural changes to tissue 12. In particular, the optical absorption of tissue 12 changes. When electromagnetic radiation impinges on tissue 12, energy is absorbed by tissue 12 and adiabatically dissipated. The energy is converted to heat, leading to a transient thermoelastic expansion of tissue 12 which generates photoacoustic waves that can be detected by transducer 36 on echographic probe 22. The contrast in optical absorption between healthy tissue and tissue that has been ablated produces differences in the waves that can be detected by transducer 36. Further, the contrast in optical absorption, and the resulting difference in generated waves, by healthy tissue and ablated tissue, can be used to improve imaging of the lesion. Further information regarding the lesion can also be obtained by correlating the signal with other lesion assessment measures including conductance measurements. Ablation also creates a change in the coloration of tissue 12. This is the result of coagulation necrosis of the tissue 12, shutting down the microperfusion which supplies blood. Healthy tissue may be brown-red, while coagulated tissue is yellow-grey. The discoloration caused by ablation can be detected by photoacoustic imaging and used as a indicator of lesion depth.

[0040] The method may continue with the step 82 of generating a signal indicative of a characteristic of tissue 12 responsive to the photoacoustic wave. As noted above, transducer 36 on probe 22 may be used to detect the photoacoustic wave. Probe 22 is typically a few centimeters from the ablation site. This distance is too great for light transmission because the blood volume between probe 22 and the ablation site is too large and too variable to achieve (reproducible) power delivery and imaging. The photoacoustic wave, however, is able to traverse this distance and provide reliable information regarding tissue 12. In response to the photoacoustic wave, transducer 36 generates a signal which is provided to ECU 16 for processing. The detected characteristic may comprise a depth of a lesion in tissue 12, a size of a lesion in tissue 12, a degree of coagulation in tissue 12, a degree of conductivity in tissue 12, or a functionality of a lesion in tissue 12. The characteristic may also comprise a distance of tissue 12 from ablation delivery element 58. Once the process of causing generation of the photoacoustic wave and the receipt of that wave has occurred, the delivery of ablation energy may resume.

[0041] The method may continue with the step 84 of displaying an image of tissue 12 in response to the signal from transducer 36. In accordance with one embodiment, system 10 enables improved imaging of the ablation site based on the ability to contrast healthy tissue and tissue that has been subjected to ablation. The method may also include the step 86 of adjusting a position of ablation catheter 28 responsive to the signal generated by transducer 36. Based on information provided by the signal, the physician may manually adjust the position of catheter 28 including, for example, adjusting a distance between ablation delivery element 58 and tissue 12 or the orientation of ablation delivery element 58 relative to tissue 12. Similarly, the method may include the step of adjusting the position of echographic probe 22 responsive to the signal generated by transducer 36 including adjustment of the imaging plane 41. It should also be understood that this process could occur automatically through robotic control of probe 22 and catheter 28 responsive to control signals generated by ECU 16 in response to the signals generated by transducer 36. Further, it should be understood that, while the above-described embodiments focus on a photoacoustic response from tissue 12, information derived from a photoacoustic response of the intervening blood may be also or alternatively be used in adjusting the positions of probe 22 and catheter 28. Finally, it should be understood that the steps of the method described herein may be performed in a repeated, iterative fashion until, for example, the physician determines that sufficient ablation has occurred.

[0042] A catheter, system and method in accordance with the present teachings are advantageous because the inventive catheter, system and method enable improved assessment of the effects of ablation therapy. In particular, the inventive catheter, system and method provide a technique for assessing the formation of lesions both during and after ablation of tissue that allows for assessment in close proximity to the site of the ablation. By locating the electromagnetic radiation emitter in ablation catheter 28 and delivering electromagnetic radiation through ablation delivery element 58 at the distal end of catheter 28, the radiation has to travel over only a short distance. Further, blood between element 58 and tissue 12 may be displaced by fluid irrigation thereby increasing the efficiency of delivery. The resulting photoacoustic wave generated by tissue 12 can be detected by transducer 36 on echographic probe 22 which is typically only several centimeters away.

[0043] Although several embodiments of this invention have been described above with a certain degree of particularity, those skilled in the art could make numerous alterations to the disclosed embodiments without departing from the scope of this invention. All directional

references (e.g., upper, lower, upward, downward, left, right, leftward, rightward, top, bottom, above, below, vertical, horizontal, clockwise and counterclockwise) are only used for identification purposes to aid the reader's understanding of the present invention, and do not create limitations, particularly as to the position, orientation, or use of the invention. Joinder references (e.g., attached, coupled, connected, and the like) are to be construed broadly and may include intermediate members between a connection of elements and relative movement between elements. As such, joinder references do not necessarily infer that two elements are directly connected and in fixed relation to each other. It is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative only and not as limiting. Changes in detail or structure may be made without departing from the invention as defined in the appended claims.

[0044] Although the various embodiments of the devices have been described herein in connection with certain disclosed embodiments, many modifications and variations to those embodiments may be implemented. For example, particular features, structures, or characteristics described above may be combined in any suitable manner in one or more embodiments. Thus, the particular features, structures, or characteristics illustrated or described in connection with one embodiment may be combined, in whole or in part, with the features structures, or characteristics of one or more other embodiments without limitation unless illogical or non-functional. Also, where materials are disclosed for certain components, other materials may be used. The foregoing description and following claims are intended to cover all such modification and variations.

[0045] Any patent, publication, or other disclosure material, in whole or in part, that is said to be incorporated by reference herein is incorporated herein only to the extent that the incorporated materials does not conflict with existing definitions, statements, or other disclosure material set forth in this disclosure. As such, and to the extent necessary, the disclosure as explicitly set forth herein supersedes any conflicting material incorporated herein by reference. Any material, or portion thereof, that is said to be incorporated by reference herein, but which conflicts with existing definitions, statements, or other disclosure material set forth herein will only be incorporated to the extent that no conflict arises between that incorporated material and the existing disclosure material.

CLAIMS

What is claimed is:

1. An ablation catheter comprising:

an elongate deformable shaft having a proximal end and a distal end;

an ablation delivery element disposed at the distal end of said shaft; and,

an electromagnetic radiation emitter disposed within said shaft, said emitter configured to emit electromagnetic radiation through an opening in said ablation delivery element.

2. The ablation catheter of claim 1, wherein said ablation delivery element defines a port configured to allow passage of the electromagnetic radiation.

3. The ablation catheter of claim 1 wherein said shaft defines an irrigation lumen configured to deliver an irrigation fluid to an external surface of said ablation delivery element.

4. The ablation catheter of claim 1, wherein said emitter comprises an optic fiber configured to transmit the electromagnetic radiation from an electromagnetic radiation source.

5. The ablation catheter of claim 4 wherein said optic fiber comprises a multi-mode optic fiber.

6. The ablation catheter of claim 4 wherein said electromagnetic radiation source is disposed within said shaft proximate the distal end of said shaft.

7. The ablation catheter of claim 1 wherein said emitter comprises a laser generator.

8. A system for delivery of ablation therapy to tissue in a body and for assessing effects of the ablation therapy, comprising:

an ablation catheter, comprising:

an elongate deformable shaft having a proximal end and a distal end;

an ablation delivery element disposed at the distal end of said shaft; and,

an electromagnetic radiation emitter disposed within said shaft, said emitter configured to emit electromagnetic radiation through an opening in said ablation delivery element towards the tissue to thereby cause generation of a photoacoustic wave from the tissue;

an echographic probe, comprising:

an elongate deformable shaft having a proximal end and a distal end; and,

an ultrasound transducer disposed at the distal end of said shaft of said echographic probe and configured to generate a signal indicative of a characteristic of the tissue responsive to the photoacoustic wave.

9. The system of claim 8, wherein said ablation delivery element defines a port configured to allow passage of the electromagnetic radiation.

10. The system of claim 8 wherein said shaft of said ablation catheter defines an irrigation lumen configured to deliver an irrigation fluid to an external surface of said ablation delivery element.

11. The system of claim 8, wherein said emitter comprises an optic fiber configured to transmit the electromagnetic radiation from an electromagnetic radiation source.

12. The system of claim 11 wherein said optic fiber comprises a multi-mode optic fiber.

13. The system of claim 11 wherein said electromagnetic radiation source is disposed within said shaft of said ablation catheter proximate the distal end of said shaft of said ablation catheter.

14. The system of claim 8 wherein said emitter comprises a laser generator.

15. The system of claim 8 wherein the characteristic comprises a depth of a lesion in the tissue.

16. The system of claim 8 wherein the characteristic comprises a size of a lesion in the tissue.

17. The system of claim 8 wherein the characteristic comprises a functionality of a lesion in the tissue.

18. The system of claim 8, further comprising:
an ultrasound generator coupled to said echographic probe;
a electromagnetic radiation source coupled to said emitter;
an ablation generator coupled to said ablation catheter;
an irrigation pump coupled to said ablation catheter; and,
a display coupled to said echographic probe.

19. A method for delivery of ablation therapy to tissue in a body and for assessing effects of the ablation therapy, comprising the steps of:

emitting electromagnetic radiation from a distal end of an electromagnetic radiation emitter towards the tissue, said emitter disposed within an ablation catheter having an elongate deformable shaft having a proximal end and a distal end and an ablation delivery element disposed at the distal end of said shaft, said emitter emitting the electromagnetic radiation through an opening in said ablation delivery element towards the tissue and causing generation of a photoacoustic wave from the tissue;

generating a signal indicative of a characteristic of the tissue responsive to the photoacoustic wave.

20. The method of claim 19 wherein the signal is generated by an echographic probe having an elongate deformable shaft having a proximal end and a distal end and an ultrasound transducer disposed at the distal end of said shaft of said echographic probe.

21. The method of claim 19 further comprising the step of displaying an image of the tissue responsive to the signal.

22. The method of claim 19 further comprising the step of delivering a first set of ablative energy to the tissue from said ablation delivery element prior to said emitting step.

23. The method of claim 22 further comprising the step of delivering a second set of ablative energy to the tissue from said ablation delivery element following said generating step.

24. The method of claim 19 further comprising the step of providing irrigation fluid to an external surface of said ablation delivery element.

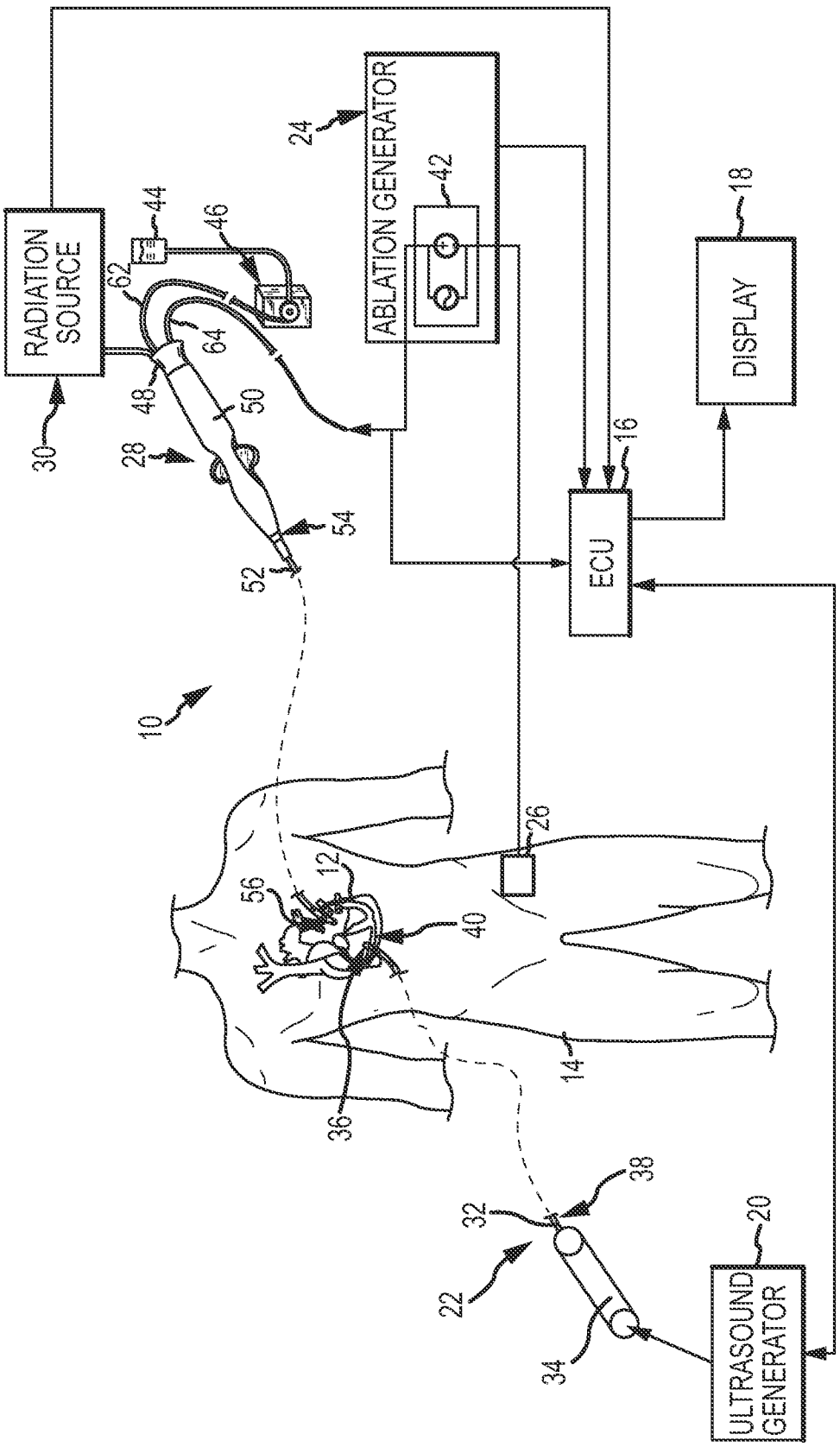
25. The method of claim 19 wherein said characteristic comprises a depth of a lesion in the tissue.

26. The method of claim 19 wherein said characteristic comprises a size of a lesion in the tissue.

27. The method of claim 19 wherein the characteristic comprises a functionality of a lesion in the tissue.

28. The method of claim 19 wherein said characteristic comprises a distance of the tissue from said ablation delivery element.

29. The method of claim 19, further comprising the step of adjusting a position of said ablation catheter responsive to the signal.


RADIATION SOURCE
ABLATION GENERATOR
DISPLAY
ECU
ULTRASOUND GENERATOR
10
12
14
16
18
20
22
24
26
28
30
32
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36
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40
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64

FIG.1

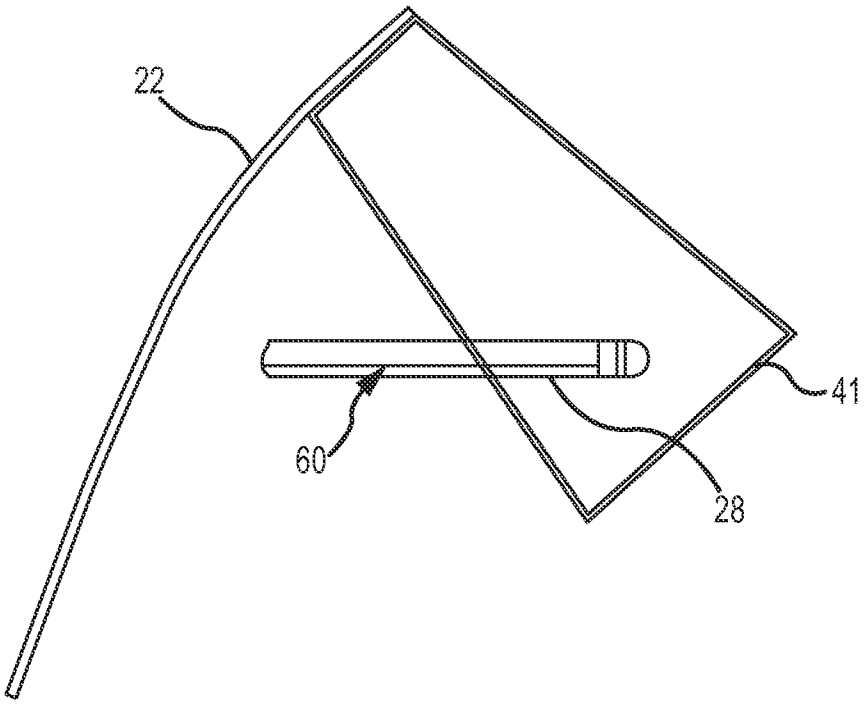

FIG.2

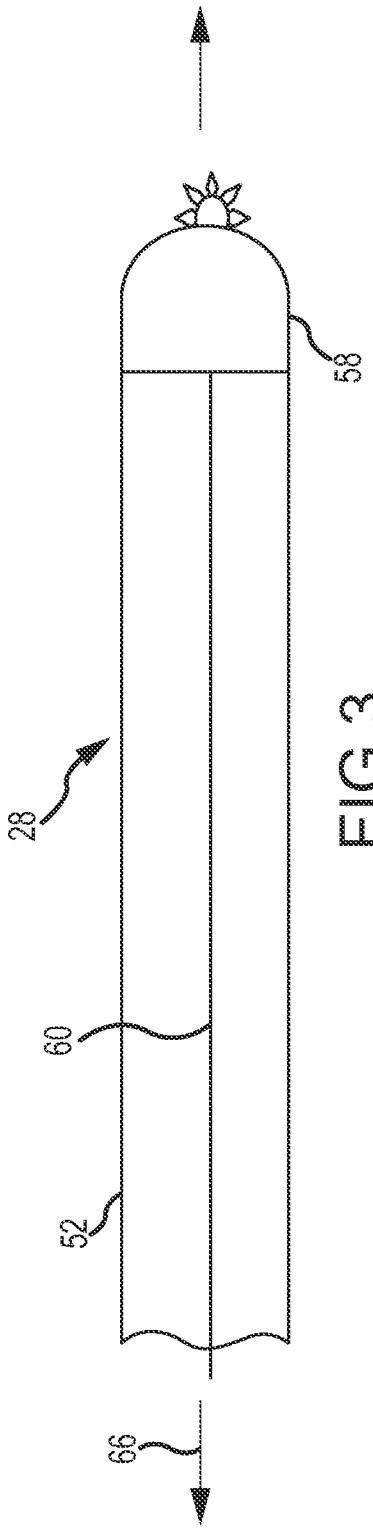

FIG.3

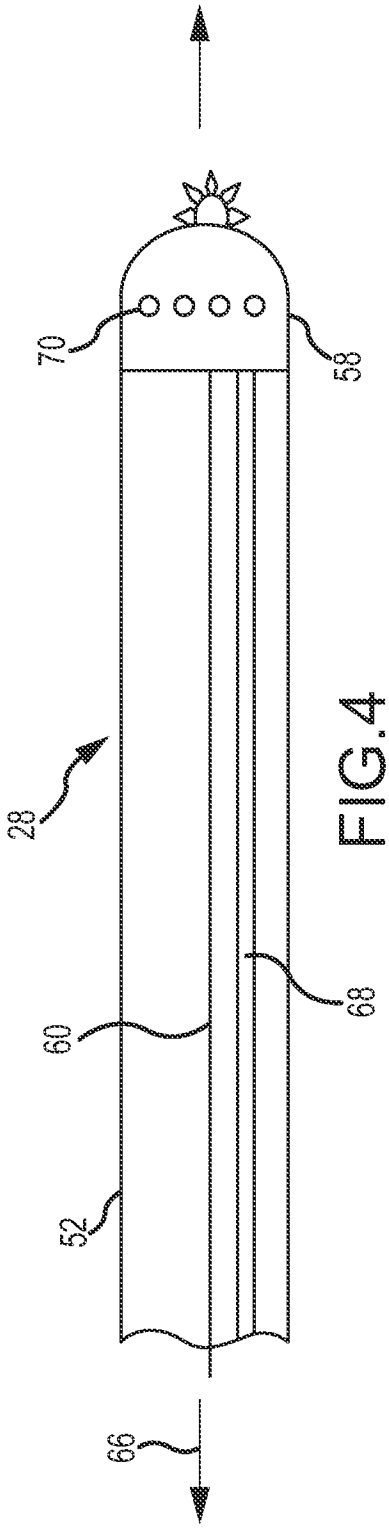

FIG.4

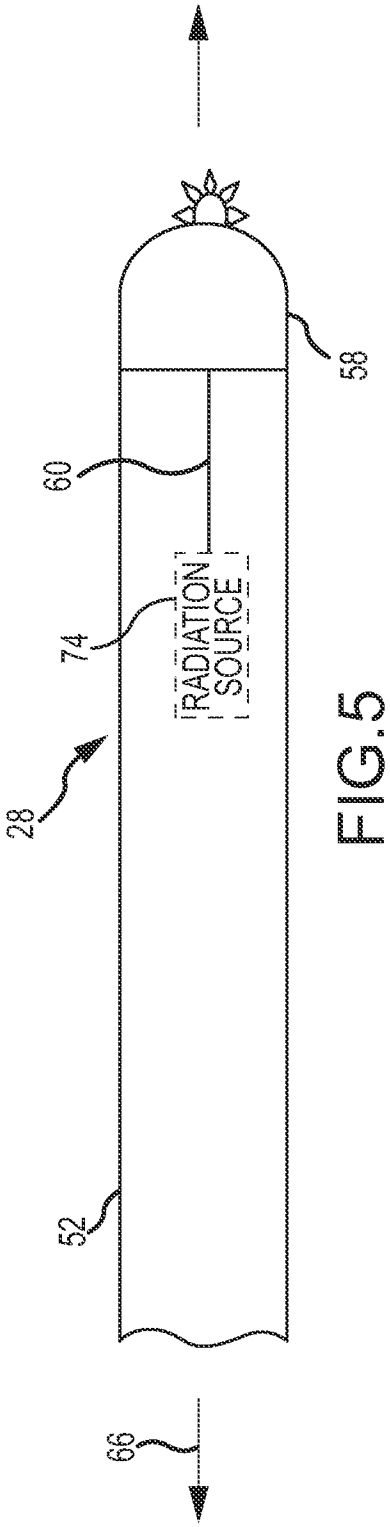

FIG.5

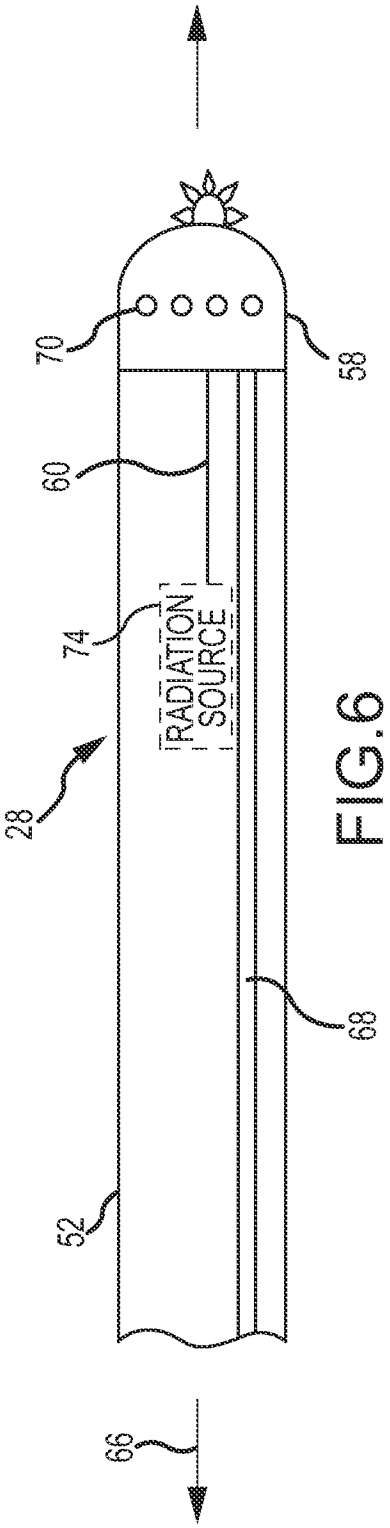

FIG.6

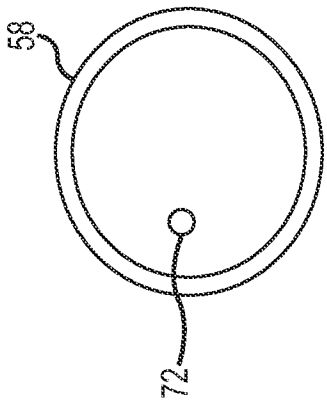

FIG.7

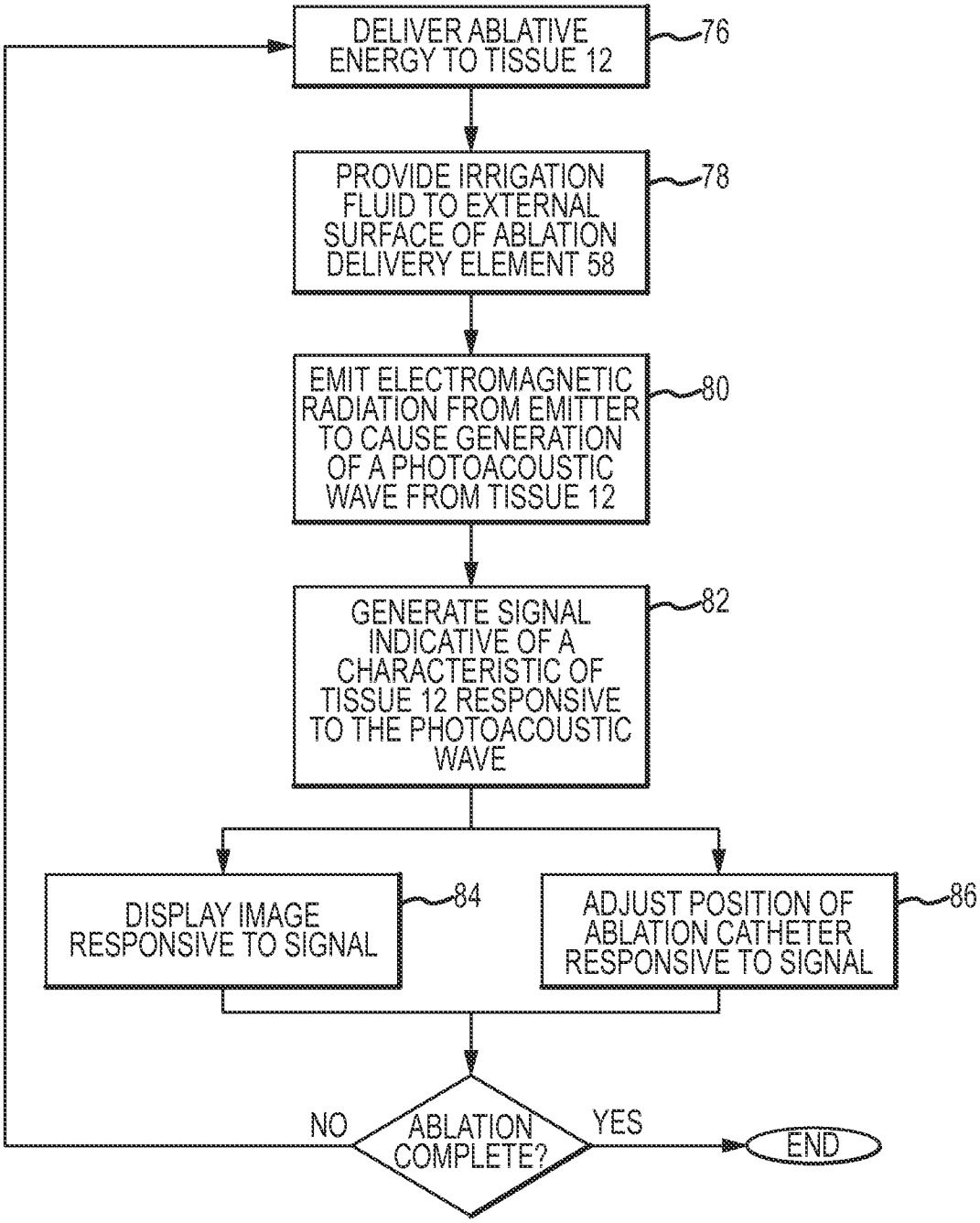
DELIVER ABLATIVE ENERGY TO TISSUE 12
76
PROVIDE IRRIGATION FLUID TO EXTERNAL SURFACE OF ABLATION DELIVERY ELEMENT 58
78
EMIT ELECTROMAGNETIC RADIATION FROM EMITTER TO CAUSE GENERATION OF A PHOTOACOUSTIC WAVE FROM TISSUE 12
80
GENERATE SIGNAL INDICATIVE OF A CHARACTERISTIC OF TISSUE 12 RESPONSIVE TO THE PHOTOACOUSTIC WAVE
82
DISPLAY IMAGE RESPONSIVE TO SIGNAL
84
ADJUST POSITION OF ABLATION CATHETER RESPONSIVE TO SIGNAL
86
ABLATION COMPLETE?
NO
YES
END

FIG.8

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2013/025899

A. CLASSIFICATION OF SUBJECT MATTER
IPC(8) - A61B 18/14 (2013.01)
USPC - 606/32
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC(8) - A61B 18/14, 18/18 (2013.01)
USPC - 606/32, 33, 41

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
CPC - A61B 18/1492 (2013.01)

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

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 2007/0265610 A1 (THAPLIYAL et al) 15 November 2007 (15.11.2007) entire document	1-3, 8-10, 15-17, 19-29 --- 4-7, 11-14, 18
Y	US 2002/0165595 A1 (HAAN et al) 07 November 2002 (07.11.2002) entire document	4-7, 11-14
Y	US 2009/0030412 A1 (WILLIS et al) 29 January 2009 (29.01.2009) entire document	18

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

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
28 March 2013	18 APR 2013
Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US, Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Authorized officer: Blaine R. Copenheaver PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774

Form PCT/ISA/210 (second sheet) (July 2009)