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

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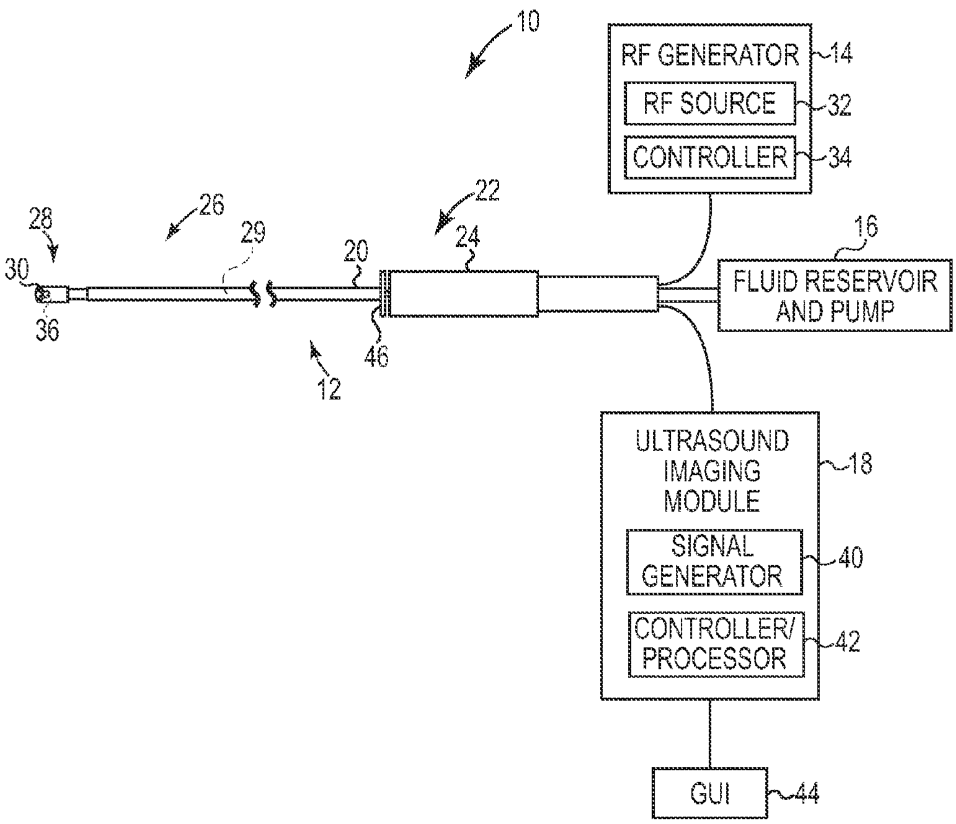
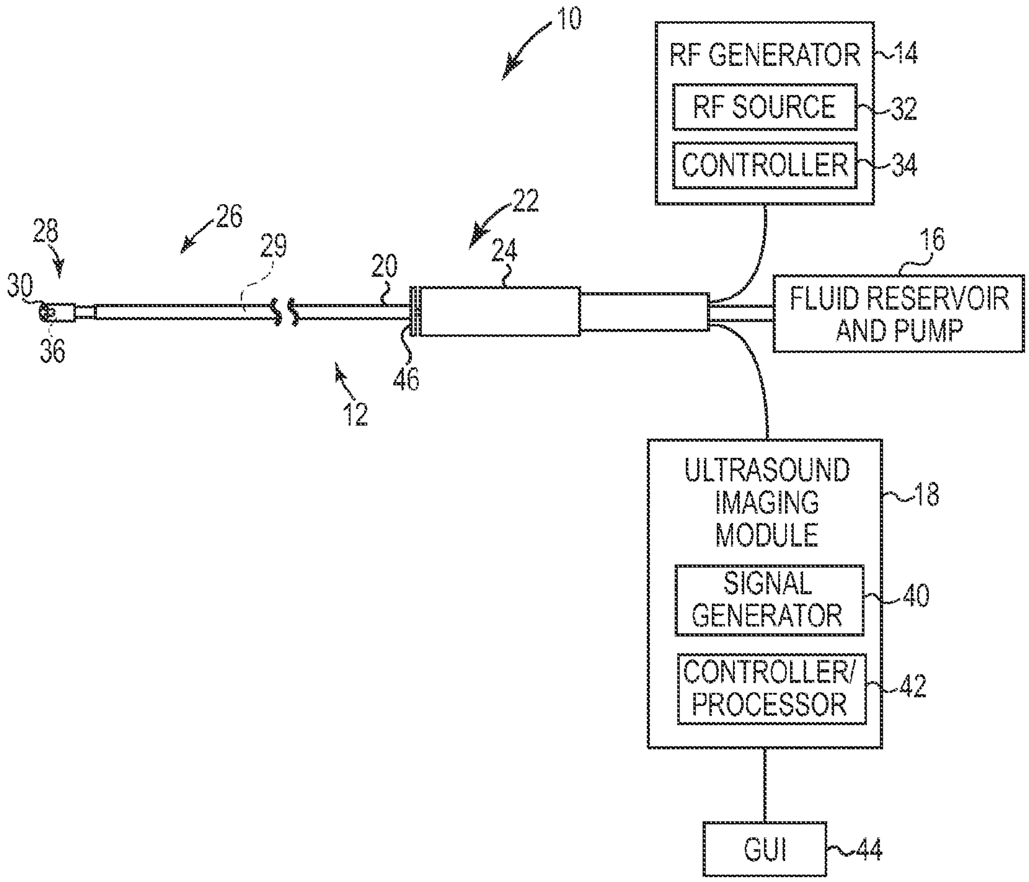
(57) **ABSTRACT**

Devices and systems for ultrasonically imaging anatomical structures and performing ablation therapy within the body are disclosed. A combined ablation and ultrasound imaging probe includes an ablation electrode tip including an ablation electrode configured for delivering ablation energy, and a number of ultrasonic imaging sensors configured for imaging the tissue surrounding the probe. The ultrasonic imaging sensors are supported within the interior of the tip via a tip insert, and deliver ultrasonic waves through acoustic openings formed through the tip. The tip insert separates an interior lumen within the tip into a proximal fluid chamber and a distal fluid chamber. During an ablation procedure, the ultrasonic imaging sensors can be tasked to generate a number of ultrasonic images that can be displayed on a user interface.

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RF GENERATOR
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RF SOURCE
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CONTROLLER
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12
ULTRASOUND IMAGING MODULE
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SIGNAL GENERATOR
40
CONTROLLER/ PROCESSOR
42
GUI
44

Fig. 1

imaging sensors **36***b*, **36***c*, **36***d* each oriented circumferentially at 120° intervals apart from each other about the tip **28** for use in imaging tissue located adjacent to the sides of the tip **28**. In other embodiments, a greater or lesser number of laterally-facing ultrasonic imaging sensors are employed for imaging tissue adjacent to the sides of the probe tip **28**.

**[0048]** In the embodiment of FIG. **2**, the ablation electrode tip **28** has an open irrigated configuration including a number of irrigation ports **30** used to deliver cooling fluid to cool the tip **28** and the surrounding tissue. In other embodiments, the ablation electrode tip **28** has a closed irrigation configuration in which the cooling fluid is recirculated through the tip **28** without being ejected into the surrounding tissue. In some embodiments, the ablation electrode tip **28** comprises six irrigation ports **30** each disposed circumferentially at 60° intervals apart from each other about the tip **28** and at a location proximal to the distal-facing ultrasonic sensor **36***a* and distal to the location of the laterally-facing ultrasonic sensors **36***b*, **36***c*, **36***d*. In other embodiments, a greater or lesser number of fluid irrigation ports **30** are employed. In some embodiments, the fluid irrigation ports **30** are circular in shape, and have a diameter in the range of approximately 0.005 inches to 0.02 inches. The size, number, and/or positioning of the irrigation ports **30** can vary, however. In some embodiments, for example, the ablation electrode tip **28** further includes a number of fluid irrigation ports **30** located circumferentially about the tip **28** proximally of the laterally-facing ultrasonic imaging sensors **36***b*, **36***c*, **36***d*. During ablation therapy, the cooling fluid is used to control the temperature and reduce coagulum formation on the ablation electrode tip **28**, thus preventing an impedance rise of the tissue in contact with the tip **28** and increasing the transfer of RF ablation energy delivered from the tip **28** into the tissue.

**[0049]** FIG. **3** is a cross-sectional view of the ablation electrode tip **28**. As can be further seen in FIG. **3**, the ablation electrode tip **28** includes an interior lumen **56** that houses the ultrasonic imaging sensors **36***a*, **36***b*, **36***c*, **36***d*, electrical conduits **58**, **60**, **62**, **63** for transmitting power to and receiving signals back from the sensors **36***a*, **36***b*, **36***c*, **36***d*, and an electrical conduit **64** for supplying RF ablation energy to the RF electrode **48**. In some embodiments, the electrical conduits **58**, **60**, **62**, **63**, **64** comprise insulated tubular members that contain wire leads used to electrically connect the RF generator **14** to the RF electrode **48** and the ultrasonic imaging module **18** to the ultrasonic imaging sensors **36***a*, **36***b*, **36***c*, **36***d*. A fluid conduit **66** extending through the probe **12** supplies cooling fluid from the fluid reservoir and pump **16** to the interior lumen **56** of the ablation electrode tip **28**, which is then transmitted into the surrounding tissue through the irrigation ports **30**. A thermocouple lead **68** extending through the probe **12** terminates distally at a thermocouple **70** located within the interior lumen **56** for sensing the temperature of the ablation electrode tip **28** during the ablation procedure.

**[0050]** A proximal tip insert **72** is used for coupling the ablation electrode tip **28** to the distal end **50** of the probe body **20**. A distal tip insert **74** is configured to support the laterally-facing ultrasonic imaging sensors **36***b*, **36***c*, **36***d* within the ablation electrode tip **28**, and divides the interior lumen **56** into a proximal fluid chamber **76** and a distal fluid chamber **78**. A number of fluid channels **80** extending lengthwise along the length of the distal tip insert **74** fluidly connect the proximal fluid chamber **76** to the distal fluid chamber **78**. During ablation, the presence of the distal tip insert **74** within the ablation electrode tip **28** creates a back pressure as the cooling fluid enters the proximal fluid chamber **76**, causing the fluid to circulate before being forced through the channels **80** and into the distal fluid chamber **78**.

**[0051]** FIG. **4** is a cross-sectional view of the ablation electrode tip **28** along line **4-4** in FIG. **3**. As can be further seen in conjunction with FIG. **4**, and in some embodiments, the distal tip insert **74** includes three fluid channels **80** for supplying cooling fluid from the proximal fluid chamber **76** to the distal fluid chamber **78**. As can be further seen in FIG. **4**, and in some embodiments, the ablation electrode tip **28** includes three laterally-facing ultrasonic imaging sensors **36***b*, **36***c*, **36***d* equally spaced from each other at an angle $\alpha$ of 120° about the circumference of the distal tip insert **74**. Although three laterally-facing ultrasonic sensors **36***b*, **36***c*, **36***d* are shown in the embodiment of FIG. **4**, a greater or lesser number of ultrasonic imaging sensors may be employed. By way of example and not limitation, four ultrasonic imaging sensors may be disposed at equidistant angles $\alpha$ of 90° about the circumference of the distal tip insert **74**. During imaging, the use of multiple laterally-facing ultrasonic imaging sensors **36***b*, **36***c*, **36***d* spaced about the circumference of the distal tip insert **74** ensures that the field of view of at least one of the sensors **36***b*, **36***c*, **36***d* is in close proximity to the target tissue irrespective of the tip orientation relative to the target tissue. Such configuration also permits the physician to easily visualize the target tissue without having to rotate the probe **12** once the probe **12** is in contact with the tissue.

**[0052]** To conserve space within the ablation electrode tip **28**, the fluid channels **80** are each circumferentially offset from the ultrasonic imaging sensors **36***b*, **36***c*, **36***d*. In the embodiment shown in which three laterally-facing ultrasonic imaging sensors **36***b*, **36***c*, **36***d* are employed, each of the fluid channels **80** are disposed circumferentially at equidistant angles $\beta_1$ of 120° about the circumference of the distal tip insert **74**, and are circumferentially offset from each adjacent ultrasonic imaging sensor by an angle $\beta_2$ of approximately 60°. The angle $\beta_1$ between each of the fluid channels **80** and the angle $\beta_2$ between each fluid channel **80** and adjacent ultrasonic imaging sensor **36***b*, **36***c*, **36***d* can vary in other embodiments depending on the number of fluid channels and/or ultrasonic imaging sensors provided. In some embodiments, the fluid channels **80** each have an equal cross-sectional area and are equally positioned around the center of the distal tip insert **74**. The number and configuration of the fluid channels can vary. In one embodiment, for example, the fluid channels are circumferentially aligned with the acoustic pathway of the ultrasonic imaging sensors in the manner described, for example, in co-pending application Ser. No. ______, entitled “Ablation Probe With Fluid-Based Acoustic Coupling For Ultrasonic Tissue Imaging,” the contents of which are incorporated herein by reference in their entirety for all purposes.

**[0053]** FIG. **5** is a cross-sectional view of the RF electrode **48** along line **5-5** in FIG. **2**. As can be further seen in FIG. **5**, the RF electrode **48** comprises a tubular-shaped shell **82** including six irrigation ports **30** equally spaced from each other at an angle $\phi$ of 60° about the circumference of the shell **82**. The number, size, and angle $\phi$ between each of the irrigation ports **30** can vary in other embodiments. To minimize interference of the irrigation fluid with the transmission of ultrasonic waves from the ultrasonic imaging sensors **36**, and in some embodiments, the centers of the irrigation ports **30** are offset circumferentially from the centers of the side-facing acoustic openings **54***b*, **54***c*. In those embodiments in which the ablation electrode tip **28** includes three lateral-facing ultrasonic imaging sensors **36***b*, **36***c*, **36***d* and six irrigation ports **30**, for example, the irrigation ports **30** can be circumferentially offset from each adjacent side acoustic opening **54***b*, **54***c* by an angle of approximately 30°. This circumferential offset may vary in other embodiments depending on the number and configuration of imaging sensors **36** as well as other factors. In some embodiments, the irrigation ports **30** are circular in shape, and have a diameter within a range of approximately 0.005 to 0.02 inches.

**[0054]** FIG. **6** is a perspective view of the proximal tip insert **72** of FIG. **3**. As can be further seen in FIG. **6**, the proximal tip insert **72** comprises a hollow metal insert body **84** having a proximal section **86** and a distal section **88**. The proximal section **86** is configured to attach to the distal end **50** of the probe body **20**. The distal section **88**, in turn, has an enlarged outer diameter relative to the proximal section **86**, and is configured to attach to the RF electrode shell **82**. In some embodiments, the proximal tip insert **72** is coupled to both the distal end **50** of the probe body **20** and to the RF electrode shell **82** via frictional fit, solder, welding, and/or an adhesive attachment. A shoulder **90** at the transition from the proximal section **86** to the distal section **88** serves as a flange to align the distal end **50** of the probe body **20** flush with the RF electrode shell **82**.

**[0055]** A first lumen **92** disposed through the proximal tip insert **72** provides a conduit for the electrical and fluid conduits **58**, **60**, **62**, **64**, **66** that supply electrical signals and cooling fluid to the ablation electrode tip **28**. A second lumen **94** disposed through the proximal tip insert **72** provides a conduit for the steering mechanism used for deflecting the probe **12**.

**[0056]** FIG. **7** is a perspective view of the distal tip insert **74** of FIG. **3**. As shown in FIG. **7**, the distal tip insert **74** comprises a cylindrically-shaped metal body **98** having a proximal section **100** and a distal section **102**. In the embodiment of FIG. **7**, the outer extent **104** of the proximal section **100** is sized to fit within the RF electrode shell **82** adjacent to the location of the side acoustic openings **54***b*, **54***c*, and includes three fluid channels **80**. The outer extent **104** further includes a number of recesses **106** each configured to receive a corresponding one of the lateral-facing ultrasonic imaging sensors **36***b*, **36***c*, **36***d* therein. In some embodiments, the recesses **106** are sized and shaped to receive the ultrasonic imaging sensors **36***b*, **36***c*, **36***d* such that the sensors **36***b*, **36***c*, **36***d* lie substantially flush with the outer extent **104**. An exposed opening **108** located at the proximal end of the distal tip insert **74** provides a channel to feed the electrical conduits for the ultrasonic imaging sensors **36***b*, **36***c*, **36***d* into the recesses **106**.

**[0057]** The distal section **102** of the distal tip insert **74** is configured to support the distal-facing ultrasonic imaging sensor **36***a* within the ablation electrode tip **28**. The outer extent **110** of the distal section **102** is reduced in diameter relative to the proximal section **100**. This reduction in diameter creates an annular-shaped distal fluid chamber **78** (see FIG. **3**) that receives cooling fluid via the fluid channels **80**.

**[0058]** An aperture **112** within the proximal section **100** of the insert body **98** is configured to receive the distal end of a thermocouple used for sensing the temperature of the ablation electrode tip **28**. As can be further seen in FIGS. **8-9**, a second, central bore **114** extending through the proximal and distal sections **108**, **110** of the insert body **104** is configure to receive the distal-facing ultrasonic imaging sensor **36***a* and a portion of the electrical conduit **63** that connects the sensor **36***a* to the ultrasonic imaging module **18**. In some embodiments, a number of side apertures **116** disposed through the distal section **102** are used to permit alignment and mounting of the distal-facing ultrasonic imaging sensor **36***a*.

**[0059]** Various modifications and additions can be made to the exemplary embodiments discussed without departing from the scope of the present invention. For example, while the embodiments described above refer to particular features, the scope of this invention also includes embodiments having different combinations of features and embodiments that do not include all of the described features. Accordingly, the scope of the present invention is intended to embrace all such alternatives, modifications, and variations as fall within the scope of the claims, together with all equivalents thereof.

What is claimed is:

**1**. An ablation probe for treating and imaging body tissue, the ablation probe comprising:

an ablation electrode tip including an ablation electrode configured for delivering ablation energy to body tissue;

a plurality of acoustic openings disposed through the ablation electrode tip;

a distal tip insert disposed within an interior lumen of the ablation electrode tip, the distal tip insert including a plurality of fluid channels; and

a plurality of ultrasonic imaging sensors coupled to the distal tip insert, the ultrasonic imaging sensors configured to transmit ultrasonic waves through the acoustic openings.

**2**. The probe of claim **1**, wherein the ablation electrode tip comprises a tubular-shaped metal shell.

**3**. The probe of claim **1**, wherein the distal tip insert includes a plurality of recesses each configured for receiving an ultrasonic imaging sensor.

**4**. The probe of claim **1**, wherein the interior lumen of the ablation electrode tip includes a proximal fluid chamber and a distal fluid chamber, and wherein the proximal and distal fluid chambers are separated by the distal tip insert and are fluidly coupled to each other via the fluid channels.

**5**. The probe of claim **1**, wherein distal tip insert comprises a substantially cylindrically-shaped insert body having a proximal section and a distal section.

**6**. The probe of claim **5**, wherein the fluid channels extend lengthwise along the proximal section of the distal insert body.

**7**. The probe of claim **1**, wherein the ultrasonic imaging sensors are disposed circumferentially about the distal tip insert.

**8**. The probe of claim **7**, wherein the fluid channels are disposed circumferentially about the distal tip insert.

**9**. The probe of claim **8**, wherein the fluid channels are circumferentially offset from the ultrasonic imaging sensors.

**10**. The probe of claim **1**, further comprising an elongate probe body coupled to the ablation electrode tip.

**11**. The probe of claim **1**, further comprising a proximal tip insert coupling a distal section of the elongate probe body to the ablation electrode tip.

**12**. The probe of claim **1**, further comprising a plurality of irrigation ports disposed through the ablation electrode tip.

**13**. The probe of claim **12**, wherein the irrigation ports are located about the ablation electrode tip distally and/or proximally of the acoustic openings.

**14**. The probe of claim **1**, wherein the ultrasonic imaging sensors comprise a plurality of laterally-facing ultrasonic imaging sensors configured for transmitting ultrasonic waves from a side of the ablation electrode tip.

**15**. The probe of claim **14**, wherein the laterally-facing ultrasonic imaging sensors are each coupled to a recess within the distal tip insert.

**16**. The probe of claim **1**, wherein the ultrasonic imaging sensors comprise at least one distally-facing ultrasonic imaging sensor configured for transmitting ultrasonic waves in a forward direction away from a distal end of the ablation electrode tip.

**17**. The probe of claim **16**, wherein the distal-facing ultrasonic imaging sensor is coupled to an internal bore within the distal tip insert.

**18**. An ablation probe for treating and imaging body tissue, the ablation probe comprising:

an elongate probe body having a proximal section and a distal section;

an ablation electrode tip coupled to the distal section of the elongate probe body, the ablation electrode tip including an ablation electrode configured for delivering ablation energy to body tissue;

a plurality of acoustic openings disposed through the ablation electrode tip;

a distal tip insert disposed within an interior lumen of the ablation electrode tip, the distal tip insert separating the interior lumen into a proximal fluid chamber and a distal fluid chamber;

a plurality of laterally-facing ultrasonic imaging sensors each coupled to a corresponding recess within the distal tip insert, the laterally-facing ultrasonic imaging sensors each configured to transmit ultrasonic waves from a side of the ablation electrode tip;

a plurality of fluid channels disposed about an outer extent of the distal tip insert and circumferentially offset from the ultrasonic imaging sensors; and

a distally-facing ultrasonic imaging sensor coupled to the distal insert, the distally-facing ultrasonic imaging sensor configured for transmitting ultrasonic waves in a forward direction away from a distal end of the ablation electrode tip.

**19**. An ablation and ultrasound imaging system, comprising:

a probe configured for delivering ablation energy to body tissue, the probe comprising:

an ablation electrode tip;

a plurality of acoustic openings disposed through the ablation electrode tip;

a distal tip insert disposed within an interior lumen of the ablation electrode tip, the distal tip insert including a plurality of fluid channels; and

a plurality of ultrasonic imaging sensors coupled to the distal tip insert, the ultrasonic imaging sensors configured to transmit ultrasonic waves through the acoustic openings;

an ablation therapy module configured for generating and supplying an electrical signal to the ablation electrode tip; and

an ultrasound imaging module configured for processing ultrasonic imaging signals received from the ultrasonic imaging sensors.

**20**. The system of claim **19**, wherein the ultrasonic imaging module comprises:

a signal generator configured to generate control signals for controlling each ultrasonic imaging sensor; and

an image processor configured for processing electrical signals received from each ultrasonic imaging sensor and generating a plurality of ultrasonic images.

* * * * *

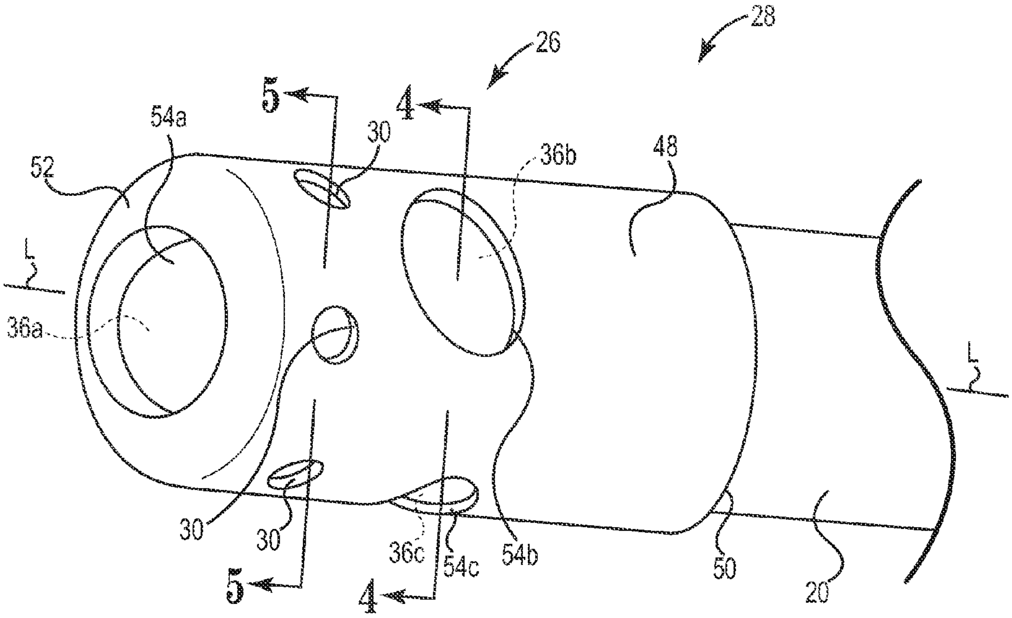


Fig. 2

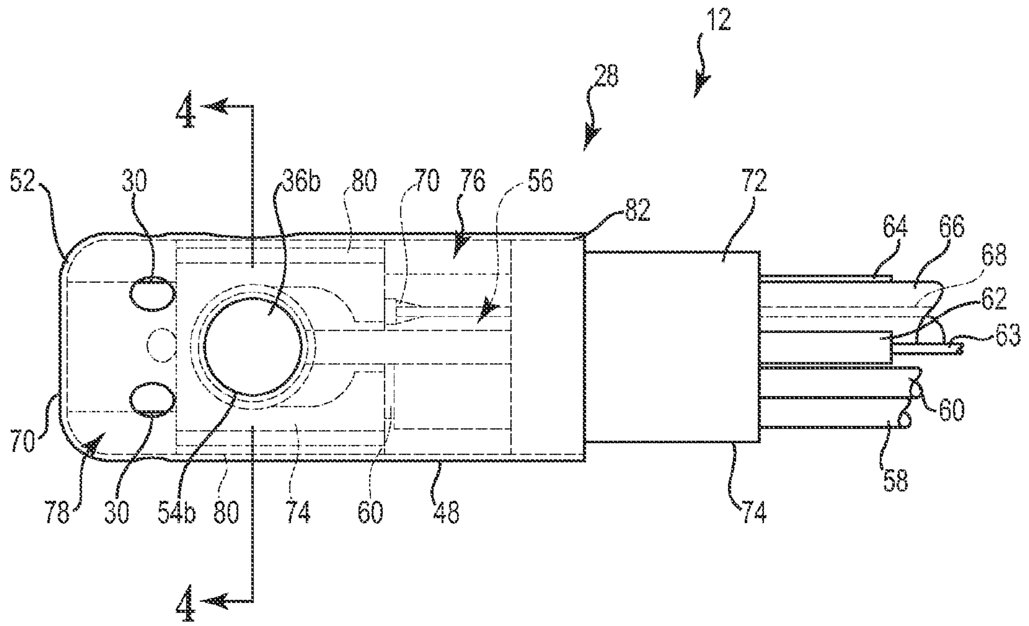
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Fig. 3

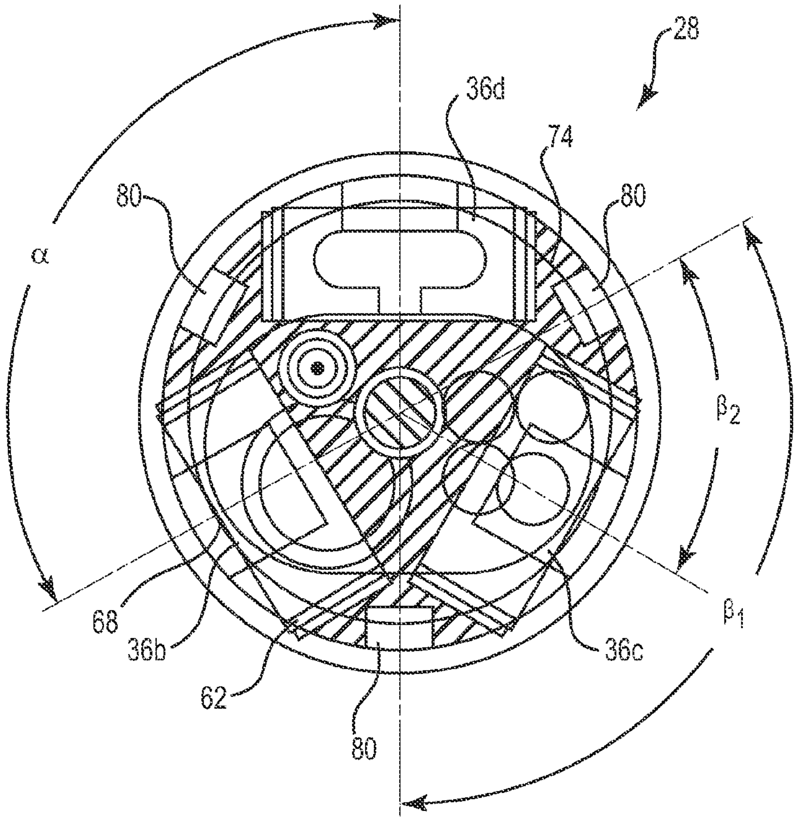


Fig. 4

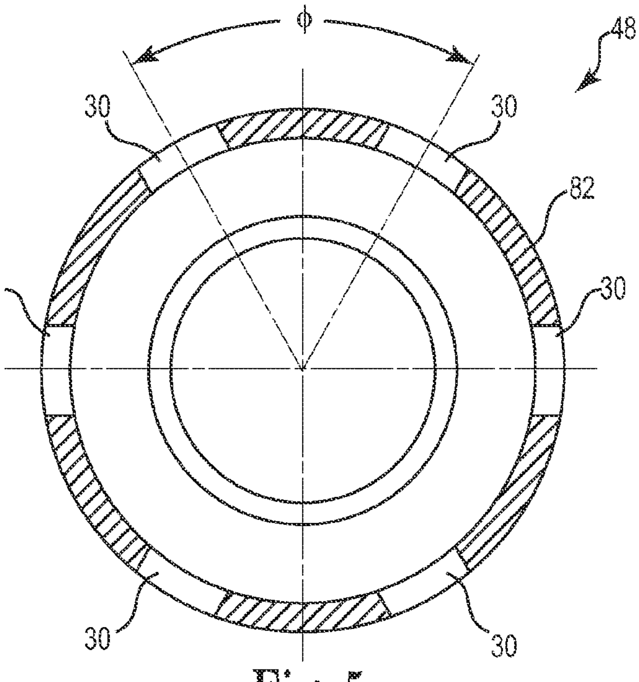


Fig. 5

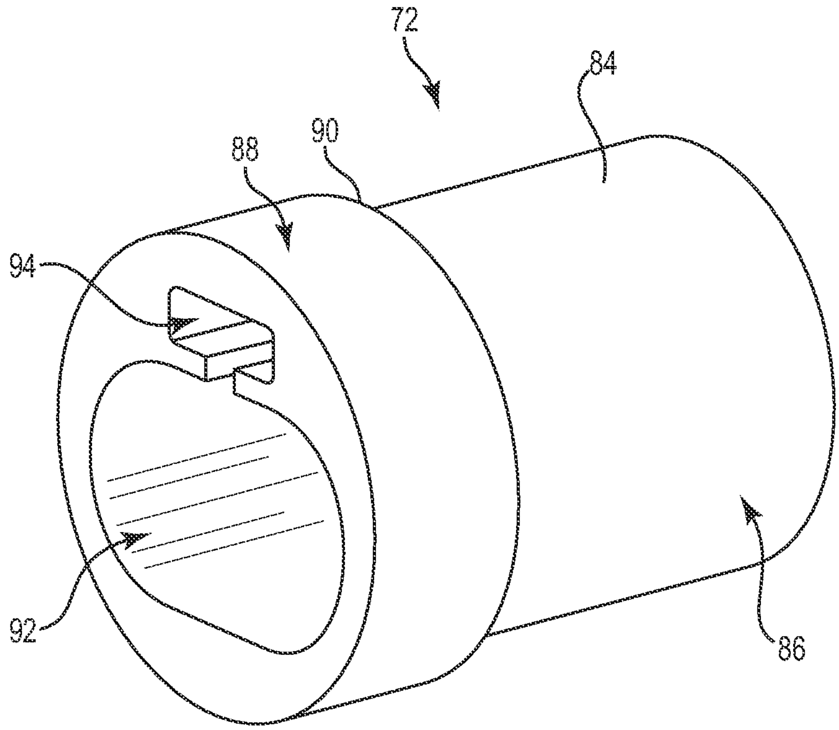


Fig. 6

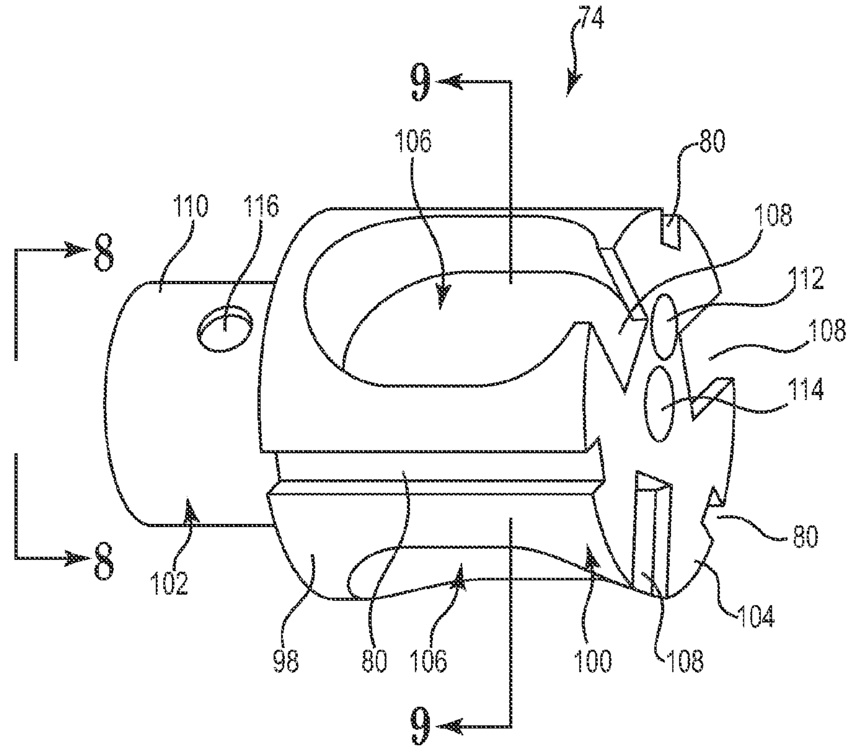


Fig. 7

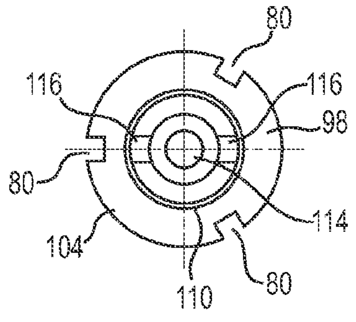


Fig. 8

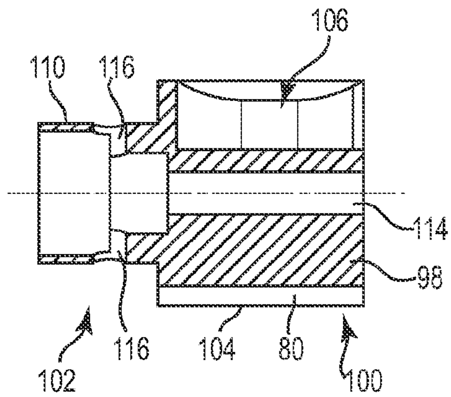


Fig. 9

# ABLATION PROBE WITH ULTRASONIC IMAGING CAPABILITY

## CROSS-REFERENCE TO RELATED APPLICATION

[0001] This application claims priority to Provisional Application No. 61/580,705, filed Dec. 28, 2011, which is herein incorporated by reference in its entirety.

## TECHNICAL FIELD

[0002] The present disclosure relates generally to devices and systems for imaging tissue within the body during an ablation procedure. More specifically, the present disclosure relates to an ablation probe with ultrasonic imaging capabilities.

## BACKGROUND

[0003] In ablation therapy, it is often necessary to determine various characteristics of body tissue at a target ablation site within the body. In interventional cardiac electrophysiology (EP) procedures, for example, it is often necessary for the physician to determine the condition of cardiac tissue at a target ablation site in or near the heart. During some EP procedures, the physician may deliver a mapping catheter through a main vein or artery into an interior region of the heart to be treated. Using the mapping catheter, the physician may then determine the source of a cardiac rhythm disturbance or abnormality by placing a number of mapping elements carried by the catheter into contact with the adjacent cardiac tissue and then operate the catheter to generate an electrophysiology map of the interior region of the heart. Once a map of the heart is generated, the physician may then advance an ablation catheter into the heart, and position an ablation electrode carried by the catheter tip near the targeted cardiac tissue to ablate the tissue and form a lesion, thereby treating the cardiac rhythm disturbance or abnormality. In some techniques, the ablation catheter itself may include a number of mapping electrodes, allowing the same device to be used for both mapping and ablation.

[0004] Various ultrasound-based imaging catheters and probes have been developed for directly visualizing body tissue in applications such as interventional cardiology, interventional radiology, and electrophysiology. For interventional cardiac electrophysiology procedures, for example, ultrasound imaging devices have been developed that permit the visualization of anatomical structures of the heart directly and in real-time. In some electrophysiology procedures, for example, ultrasound catheters may be used to image the intra-atrial septum, to guide transseptal crossing of the atrial septum, to locate and image the pulmonary veins, and to monitor the atrial chambers of the heart for signs of a perforation and pericardial effusion.

[0005] Many ultrasound-based imaging systems comprise an imaging probe that is separate from the mapping and ablation catheters used to perform therapy on the patient. As a result, a position tracking system is sometimes used to track the location of each device within the body. In some procedures, it may be difficult for the physician to quickly and accurately determine the condition of tissue to be ablated. Moreover, the images obtained using many ultrasound-based imaging systems are often difficult to read and understand without reference to images obtained from a separate imaging system such as a fluoroscopic imaging system.

## SUMMARY

[0006] The present disclosure relates generally to devices and systems for imaging anatomical structures within the body during an ablation procedure.

[0007] In Example 1, an ablation probe for treating and imaging body tissue comprises: an ablation electrode tip including an ablation electrode configured for delivering ablation energy to body tissue; a plurality of acoustic openings disposed through the ablation electrode tip; a distal tip insert disposed within an interior lumen of the ablation electrode tip, the distal tip insert including a plurality of fluid channels; and a plurality of ultrasonic imaging sensors coupled to the distal tip insert, the ultrasonic imaging sensors configured to transmit ultrasonic waves through the acoustic openings.

[0008] In Example 2, the probe according to Example 1, wherein the ablation electrode tip comprises a tubular-shaped metal shell.

[0009] In Example 3, the probe according to any of Examples 1 or 2, wherein the distal tip insert includes a plurality of recesses each configured for receiving an ultrasonic imaging sensor.

[0010] In Example 4, the probe according to any of Examples 1-3, wherein the interior lumen of the ablation electrode tip includes a proximal fluid chamber and a distal fluid chamber, and wherein the proximal and distal fluid chambers are separated by the distal tip insert and are fluidly coupled to each other via the fluid channels.

[0011] In Example 5, the probe according to any of Examples 1-4, wherein distal tip insert comprises a substantially cylindrically-shaped insert body having a proximal section and a distal section.

[0012] In Example 6, the probe according to Example 5, wherein the fluid channels extend lengthwise along the proximal section of the distal insert body.

[0013] In Example 7, the probe of according to any of Examples 1-5, wherein the ultrasonic imaging sensors are disposed circumferentially about the distal tip insert.

[0014] In Example 8, the probe according to any of Examples 1-7, wherein the fluid channels are disposed circumferentially about the distal tip insert.

[0015] In Example 9, the probe according to any of Examples 1-8, wherein the fluid channels are circumferentially offset from the ultrasonic imaging sensors.

[0016] In Example 10, the probe according to any of Examples 1-9, further comprising an elongate probe body coupled to the ablation electrode tip.

[0017] In Example 11, the probe according to any of Examples 1-10, further comprising a proximal tip insert coupling a distal section of the elongate probe body to the ablation electrode tip.

[0018] In Example 12, the probe according to any of Examples 1-11, further comprising a plurality of irrigation ports disposed through the ablation electrode tip.

[0019] In Example 13, the probe according to Example 12, wherein the irrigation ports are located about the ablation electrode tip distally and/or proximally of the acoustic openings.

[0020] In Example 14, the probe according to any of Examples 1-13, wherein the ultrasonic imaging sensors comprise a plurality of laterally-facing ultrasonic imaging sensors configured for transmitting ultrasonic waves from a side of the ablation electrode tip.

[0021] In Example 15, the probe according to Example 14, wherein the laterally-facing ultrasonic imaging sensors are each coupled to a recess within the distal tip insert.

[0022] In Example 16, the probe according to any of Examples 1-15, wherein the ultrasonic imaging sensors comprise at least one distally-facing ultrasonic imaging sensor configured for transmitting ultrasonic waves in a forward direction away from a distal end of the ablation electrode tip.

[0023] In Example 17, the probe according to Example 16, wherein the distal-facing ultrasonic imaging sensor is coupled to an internal bore within the distal tip insert.

[0024] In Example 18, an ablation probe for treating and imaging body tissue comprises: an elongate probe body having a proximal section and a distal section; an ablation electrode tip coupled to the distal section of the elongate probe body, the ablation electrode tip including an ablation electrode configured for delivering ablation energy to body tissue; a plurality of acoustic openings disposed through the ablation electrode tip; a distal tip insert disposed within an interior lumen of the ablation electrode tip, the distal tip insert separating the interior lumen into a proximal fluid chamber and a distal fluid chamber; a plurality of laterally-facing ultrasonic imaging sensors each coupled to a corresponding recess within the distal tip insert, the laterally-facing ultrasonic imaging sensors each configured to transmit ultrasonic waves from a side of the ablation electrode tip; a plurality of fluid channels disposed about an outer extent of the distal tip insert and circumferentially offset from the ultrasonic imaging sensors; and a distally-facing ultrasonic imaging sensor coupled to the distal insert, the distally-facing ultrasonic imaging sensor configured for transmitting ultrasonic waves in a forward direction away from a distal end of the ablation electrode tip.

[0025] In Example 19, an ablation and ultrasound imaging system comprises: a probe configured for delivering ablation energy to body tissue, the probe comprising an ablation electrode tip, a plurality of acoustic openings disposed through the ablation electrode tip, a distal tip insert disposed within an interior lumen of the ablation electrode tip, the distal tip insert including a plurality of fluid channels, and a plurality of ultrasonic imaging sensors coupled to the distal tip insert, the ultrasonic imaging sensors configured to transmit ultrasonic waves through the acoustic openings; an ablation therapy module configured for generating and supplying an electrical signal to the ablation electrode tip; and an ultrasound imaging module configured for processing ultrasonic imaging signals received from the ultrasonic imaging sensors.

[0026] In Example 20, the system according to Example 19, wherein the ultrasonic imaging module comprises: a signal generator configured to generate control signals for controlling each ultrasonic imaging sensor; and an image processor configured for processing electrical signals received from each ultrasonic imaging sensor and generating a plurality of ultrasonic images.

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

## BRIEF DESCRIPTION OF THE DRAWINGS

[0028] FIG. **1** is a schematic view of a combined ablation and imaging system in accordance with an illustrative embodiment;

[0029] FIG. **2** is a perspective view showing the distal section of the combined ablation and ultrasonic imaging probe of FIG. **1** in greater detail;

[0030] FIG. **3** is a cross-sectional view of the ablation electrode tip;

[0031] FIG. **4** is a cross-sectional view of the ablation electrode tip along line **4-4** in FIG. **2**;

[0032] FIG. **5** is a cross-sectional view of the RF electrode along line **5-5** in FIG. **2**;

[0033] FIG. **6** is a perspective view of the proximal tip insert of FIG. **3**;

[0034] FIG. **7** is a perspective view of the distal tip insert of FIG. **3**;

[0035] FIG. **8** is an end view of the distal tip insert of FIG. **7** along line **8-8** in FIG. **7**; and

[0036] FIG. **9** is a cross-sectional view of the distal tip insert along line **9-9** in FIG. **7**.

[0037] While the invention is amenable to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and are described in detail below. The intention, however, is not to limit the invention to the particular embodiments described. On the contrary, the invention is intended to cover all modifications, equivalents, and alternatives falling within the scope of the invention as defined by the appended claims.

## DETAILED DESCRIPTION

[0038] FIG. **1** is a schematic view of a combined ablation and imaging system **10** in accordance with an illustrative embodiment. As shown in FIG. **1**, the system **10** includes a combined ablation and ultrasonic imaging probe **12**, an RF generator **14**, a fluid reservoir and pump **16**, and an ultrasonic imaging module **18**. The probe **12** comprises an elongate probe body **20** having a proximal section **22** equipped with a handle assembly **24**, and a deflectable distal section **26** including an ablation electrode tip **28**. The probe body **20** includes an internal cooling fluid lumen **29** fluidly coupled to the fluid reservoir and pump **16**, which supplies a cooling fluid, such as saline, through the probe body **20** to a number of irrigation ports **30** in the ablation electrode tip **28**. The probe body **20** may further include additional lumens or other tubular elements for supporting electrical conductors, additional fluid lumens, a thermocouple, an insertable stylet, as well as other components. In some embodiments, the probe body **20** comprises flexible plastic tubing with a braided metal mesh to increase the rotational stiffness of the body **20**.

[0039] The RF generator **14** is configured for generating RF energy for performing ablation procedures using the ablation electrode tip **28**. The RF generator **14** includes an RF energy source **32** and a controller **34** for controlling the timing and level of the RF energy delivered by the tip **28**. During an ablation procedure, the RF generator **14** is configured to deliver ablation energy to the tip **28** in a controlled manner to ablate any sites identified or targeted for ablation. Other types of ablation sources in addition to or in lieu of the RF generator **14** can also be used for ablating target sites. Examples of other types of ablation sources can include, but are not limited to, microwave generators, acoustic generators, cryoablation generators, and laser/optical generators.

**[0040]** The ultrasonic imaging module **18** is configured for generating high resolution ultrasonic images (e.g., A, M, or B-mode images) of anatomical structures within the body based on signals received from several ultrasonic imaging sensors **36** located within the probe tip **28**. In the embodiment of FIG. **1**, the ultrasonic imaging module **18** includes an ultrasonic signal generator **40** and an image processor **42**. The ultrasonic signal generator **40** is configured to provide electrical signals for controlling each of the ultrasonic sensors **36**. The imaging signals received back from the ultrasonic imaging sensors **36**, in turn, are fed to the image processor **42**, which processes the signals and generates images that can be displayed on a graphical user interface (GUI) **44**. In certain embodiments, for example, the ultrasonic images displayed on the GUI **44** can be used to assist the physician with advancing the probe **12** through the body and to perform an ablation procedure. In cardiac ablation procedures, for example, the ultrasonic images generated from the ultrasound signals can be used to confirm tissue contact of the probe **12** within the heart or surrounding anatomy, to determine the orientation of the probe **12** within the body, to determine the tissue depth of the tissue at a target ablation site, and/or to visualize the progression of a lesion being formed in the tissue.

**[0041]** Various characteristics associated with the ultrasonic imaging sensors **36** as well as the circuitry within the ultrasonic imaging module **18** can be controlled to permit the sensors **36** to accurately detect tissue boundaries (e.g., blood or other bodily fluids), lesion formation and progression, as well as other characteristics of the tissue before, during, and/or after the ablation procedure. Example tissue characteristics that can be visualized using the probe **12** include, but are not limited to, the presence of fluid vaporization inside the tissue, the existence of a prior scar, the size and shape of a lesion being formed, as well as structures adjacent to heart tissue (e.g., lungs, esophagus). The depth at which the ultrasonic imaging sensors **36** can visualize anatomical structures within the body is dependent on the mechanical characteristics of the sensors **36**, the electrical characteristics of the sensor circuitry including the drive frequency of the signal generator **40**, the boundary conditions and degree of attenuation between the sensors **36** and the surrounding anatomy, as well as other factors.

**[0042]** In some embodiments, the probe **12** further includes a steering mechanism to permit the operator to deflect and steer the probe **12** within the body. In one embodiment, for example, a steering member such as a steering knob **46** rotatably coupled to the handle **24** can be used to deflect the ablation electrode tip **28** in one or multiple directions relative to a longitudinal axis of the probe body **20**. Rotational movement of the steering knob **46** in a first direction relative to the handle **24** causes a steering wire within the probe body **20** to move proximally relative to the probe body **20**, which, in turn, bends the distal section **26** of the probe body **20** into a particular shape such as an arced shape. Rotational movement of the steering knob **46** in the opposite direction, in turn, causes the distal section **26** of the probe body **20** to return to its original shape, as shown. To assist in the deflection, and in some embodiments, the probe body **20** includes one or more regions made of a lower durometer material than the other portions of the probe body **20**.

**[0043]** Although the system **10** is described in the context of a medical system for use in intracardiac electrophysiology procedures for diagnosing and treating the heart, in other embodiments the system **10** may be used for treating, diagnosing, or otherwise visualizing other anatomical structures such as the prostate, brain, gall bladder, uterus, esophagus, and/or other regions in the body. Moreover, many of the elements in FIG. **1** are functional in nature, and are not meant to limit the structure that performs these functions in any manner. For example, several of the functional blocks can be embodied in a single device or one or more of the functional blocks can be embodied in multiple devices.

**[0044]** FIG. **2** is a perspective view showing the distal section **26** of the probe **12** of FIG. **1** in greater detail. As can be further seen in FIG. **2**, the ablation electrode tip **28** includes an RF ablation electrode **48** configured for delivering ablation energy to body tissue surrounding the tip **28**. In the embodiment of FIG. **2**, the RF ablation electrode **48** comprises a tubular-shaped metal shell that extends from a distal end **50** of the probe body **20** to a distal end **52** of the tip **28**. A number of exposed openings **54*a***, **54*b***, **54*c*** disposed through the ablation electrode tip **28** form acoustic openings that permit ultrasonic waves transmitted by the ultrasonic imaging sensors **36*a***, **36*b***, **36*c***, **36*d*** to pass through the tip **28** and into the surrounding tissue. The reflected ultrasonic waves received back from the tissue pass through the acoustic openings **54*a***, **54*b***, **54*c*** and are sensed by the ultrasonic imaging sensors **36*a***, **36*b***, **36*c***, **36*d*** operating in a receive mode. In some embodiments, the acoustic openings **54*a***, **54*b***, **54*c*** comprise exposed openings or apertures formed through the wall of the ablation electrode tip **28**.

**[0045]** In addition to serving as an ablation electrode, the RF ablation electrode **48** also functions as a housing that contains the ultrasonic imaging sensors **36*a***, **36*b***, **36*c***, **36*d***, the electrical conductors coupling the RF ablation electrode **48** to the RF generator **14**, the electrical conductors coupling the ultrasonic imaging sensors **36*a***, **36*b***, **36*c***, **36*d*** to the ultrasonic imaging module **18**, one or more steering wires of the steering mechanism, as well as other components. In certain embodiments, the RF ablation electrode **48** comprises an electrically conductive alloy such as platinum-iridium, which in addition to serving as an electrode for providing ablation therapy, is also used as a fluoroscopic marker to determine the location of the ablation electrode tip **28** within the body using fluoroscopy.

**[0046]** In the embodiment of FIG. **2**, the probe **12** includes a distal-facing ultrasonic imaging sensor **36*a*** located at or near the distal end **52** of the ablation electrode tip **28**. In other embodiments, multiple distal-facing ultrasonic imaging sensors **36*a*** are located at or near the distal end **52** of the ablation electrode tip **28**. Each ultrasonic sensor **36*a*** is configured to transmit ultrasonic waves primarily in a forward or distal direction away from the distal end **52** of the ablation electrode tip **28**. A second set of ultrasonic imaging sensors **36*b***, **36*c***, **36*d*** disposed within the tip **28** at a location proximal to the distal-facing ultrasonic imaging sensor **36*a*** are configured to transmit ultrasonic waves primarily in a lateral or side-facing direction away from the side of the ablation electrode tip **28**. The reflected waves received back from the ultrasonic imaging sensors **36*a***, **36*b***, **36*c***, **36*d*** produces signals that can be used by the ultrasonic imaging module **18** to generate images of the surrounding body tissue.

**[0047]** In some embodiments, the ultrasonic imaging sensors **36*a***, **36*b***, **36*c***, **36*d*** each comprise piezoelectric transducers formed of a piezoceramic material such as lead zirconate titanate (PZT) or a piezoelectric polymer such as polyvinylidene fluoride (PVDF). In some embodiments, the ablation electrode tip **28** includes three laterally-facing ultrasonic

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摘要(译)

公开了用于超声成像解剖结构和在体内执行消融治疗的装置和系统。组合的消融和超声成像探头包括消融电极尖端和多个超声成像传感器，消融电极尖端包括配置用于输送消融能量的消融电极，多个超声成像传感器配置用于对探针周围的组织成像。超声成像传感器通过尖端插入件支撑在尖端的内部，并通过尖端形成的声学开口传递超声波。尖端插入件将尖端内的内腔分隔成近端流体腔室和远端流体腔室。在消融过程期间，超声成像传感器的任务是生成可以在用户界面上显示的多个超声图像。