US009241687B2

(12) **United States Patent**
**McGee**

(10) **Patent No.: US 9,241,687 B2**
(45) **Date of Patent: *Jan. 26, 2016**

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

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( * ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 534 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **13/437,267**

(22) Filed: **Apr. 2, 2012**

(65) **Prior Publication Data**

US 2012/0310064 A1 Dec. 6, 2012

**Related U.S. Application Data**

(60) Provisional application No. 61/491,944, filed on Jun. 1, 2011.

(51) **Int. Cl.**

| | |
|---|---|
| ***A61B 18/14*** | (2006.01) |
| ***A61B 8/00*** | (2006.01) |
| ***A61B 8/08*** | (2006.01) |
| ***A61B 8/12*** | (2006.01) |
| *A61B 6/12* | (2006.01) |
| *A61B 6/00* | (2006.01) |

(52) **U.S. Cl.**

CPC ..... ***A61B 8/4477*** (2013.01); ***A61B 8/0883*** (2013.01); ***A61B 8/12*** (2013.01); ***A61B 8/445*** (2013.01); ***A61B 8/463*** (2013.01); *A61B 6/12* (2013.01); *A61B 6/487* (2013.01)

(58) **Field of Classification Search**

CPC ..... A61B 8/445; A61B 18/1492; A61B 2017/00022; A61B 2017/00106; A61B 2018/00577; A61B 2019/5276; A61B 2019/5278; A61B 2019/5285

USPC ..... 606/32–34, 41

See application file for complete search history.

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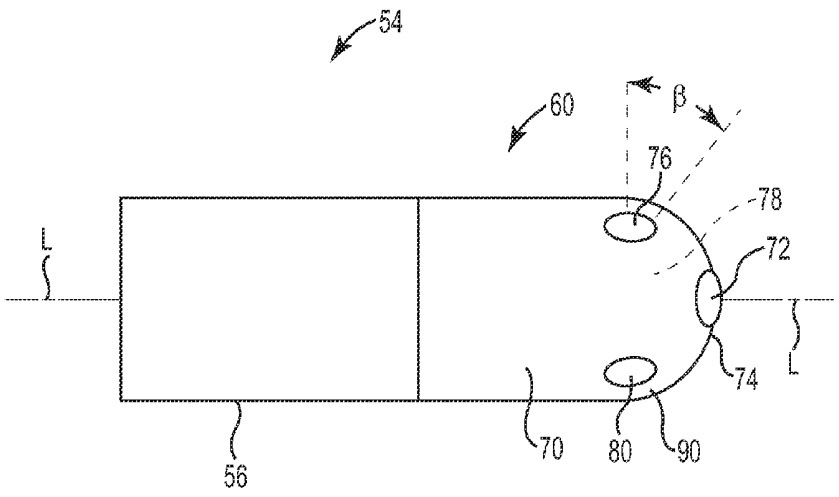
(57) **ABSTRACT**

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 a housing, an ablation electrode located on a distal tip section of the housing, and a number of ultrasonic imaging sensors configured for visualizing anatomical structures within the body. During an ablation procedure, the ultrasonic imaging sensors can be tasked to generate a number of ultrasonic images that can be displayed as a composite image on a display screen of a user interface.

**18 Claims, 6 Drawing Sheets**



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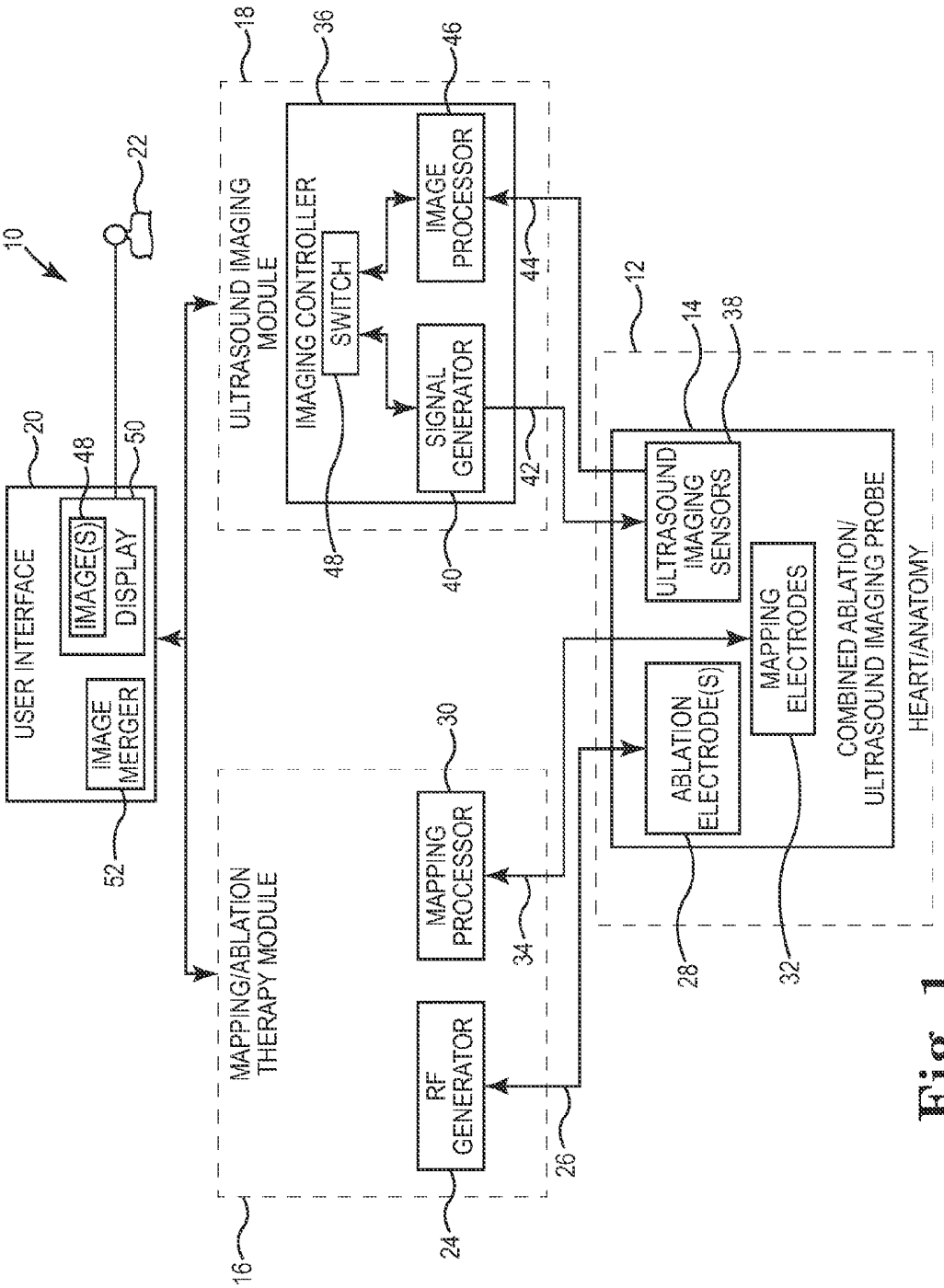
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USER INTERFACE
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IMAGE MERGER
IMAGE(S)
DISPLAY
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ULTRASOUND IMAGING MODULE
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IMAGING CONTROLLER
36
SWITCH
SIGNAL GENERATOR
IMAGE PROCESSOR
46
44
42
40
48
12
14
38
ULTRASOUND IMAGING SENSORS
ABLATION ELECTRODE(S)
MAPPING ELECTRODES
COMBINED ABLATION/ ULTRASOUND IMAGING PROBE
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MAPPING/ABLATION THERAPY MODULE
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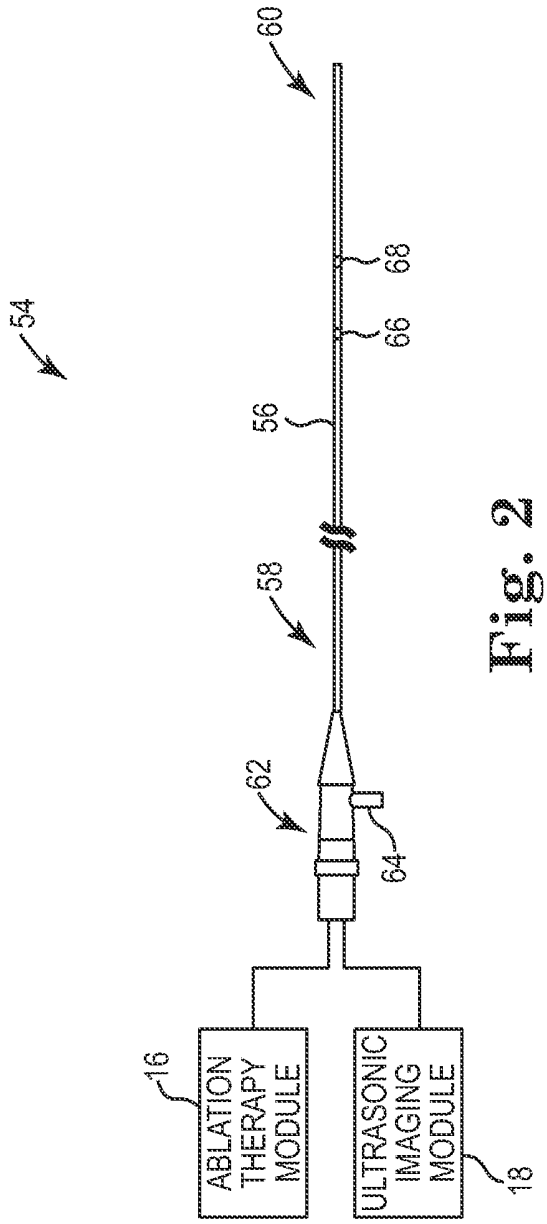
MAPPING PROCESSOR
30
34
RF GENERATOR
24
26

Fig. 1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ABLATION THERAPY MODULE
ULTRASONIC IMAGING MODULE
18

Fig. 2

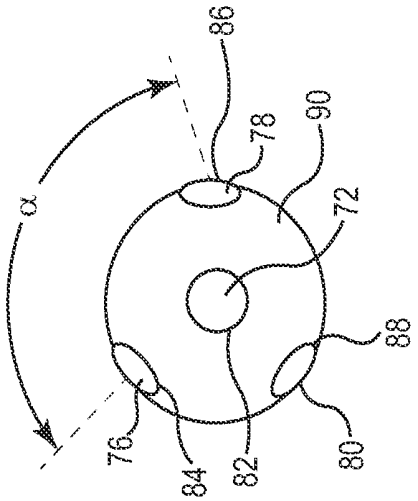


Fig. 4

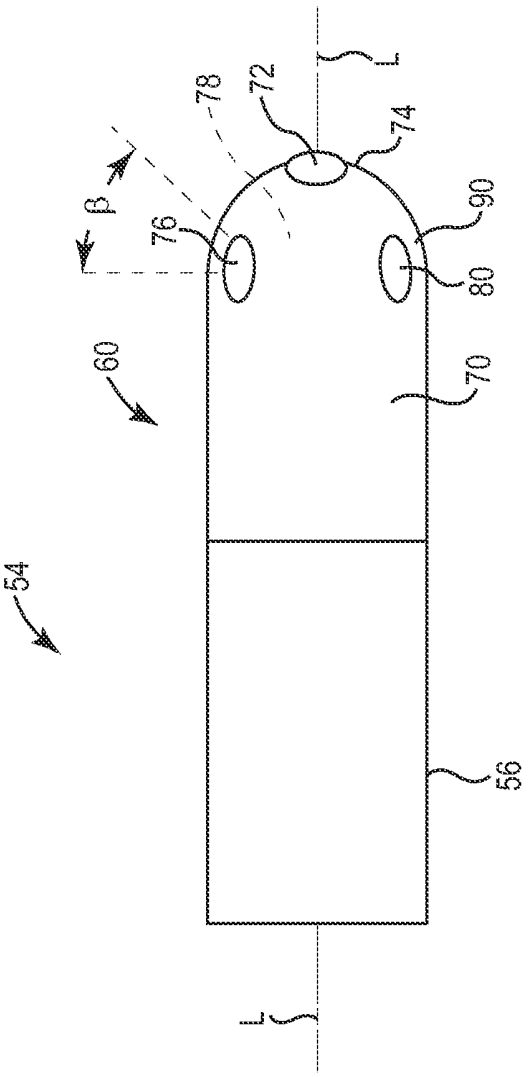


Fig. 3

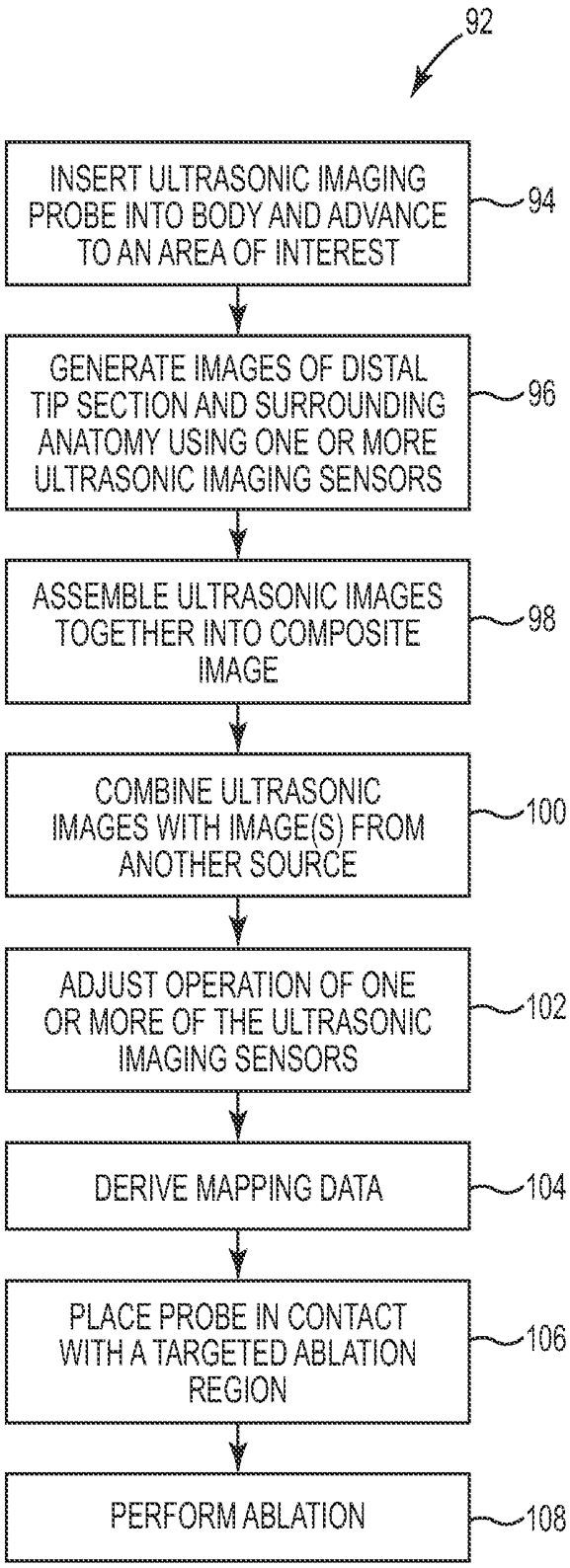
92
INSERT ULTRASONIC IMAGING PROBE INTO BODY AND ADVANCE TO AN AREA OF INTEREST
94
GENERATE IMAGES OF DISTAL TIP SECTION AND SURROUNDING ANATOMY USING ONE OR MORE ULTRASONIC IMAGING SENSORS
96
ASSEMBLE ULTRASONIC IMAGES TOGETHER INTO COMPOSITE IMAGE
98
COMBINE ULTRASONIC IMAGES WITH IMAGE(S) FROM ANOTHER SOURCE
100
ADJUST OPERATION OF ONE OR MORE OF THE ULTRASONIC IMAGING SENSORS
102
DERIVE MAPPING DATA
104
PLACE PROBE IN CONTACT WITH A TARGETED ABLATION REGION
106
PERFORM ABLATION
108

Fig. 5

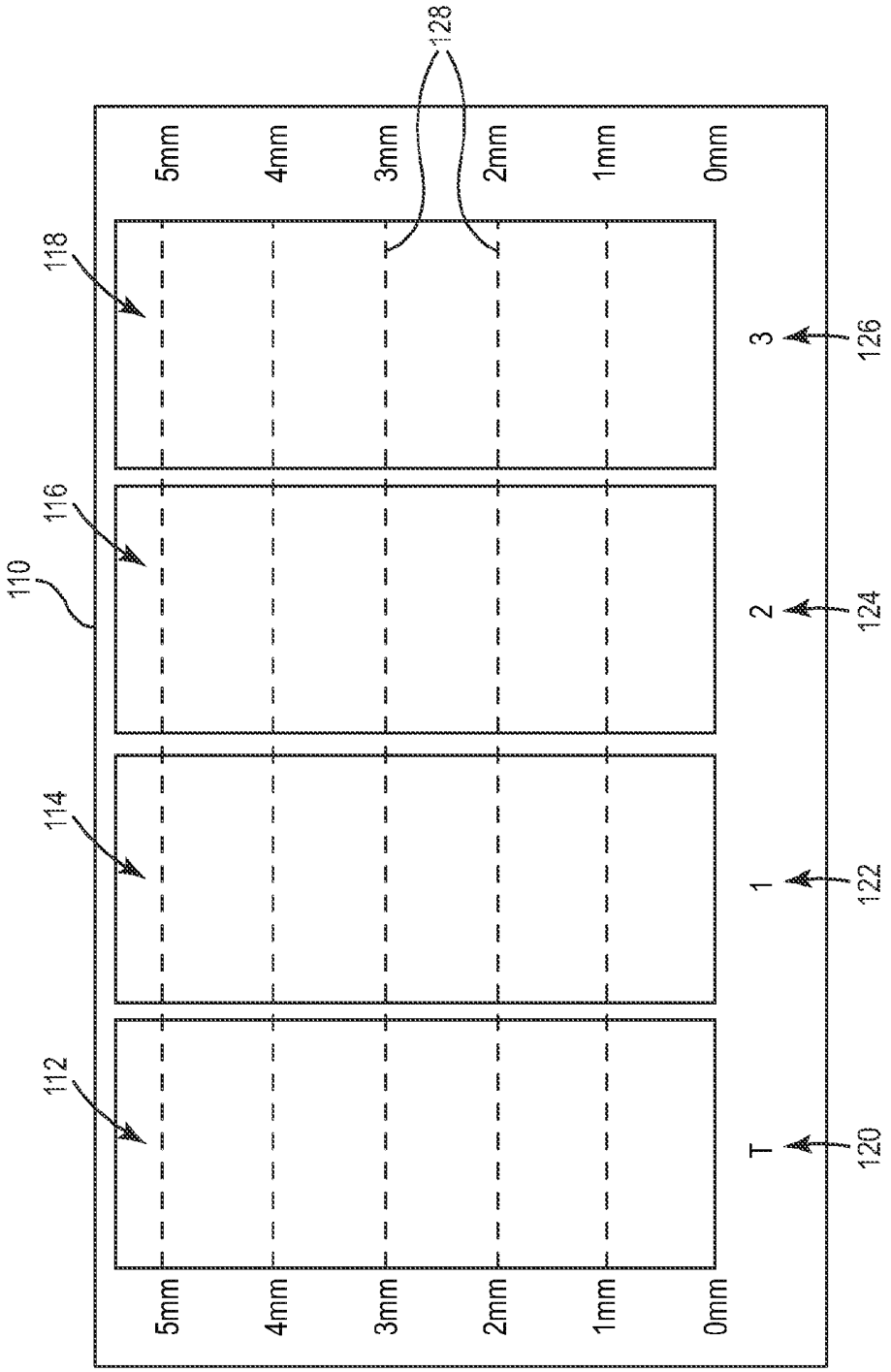
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Fig. 6

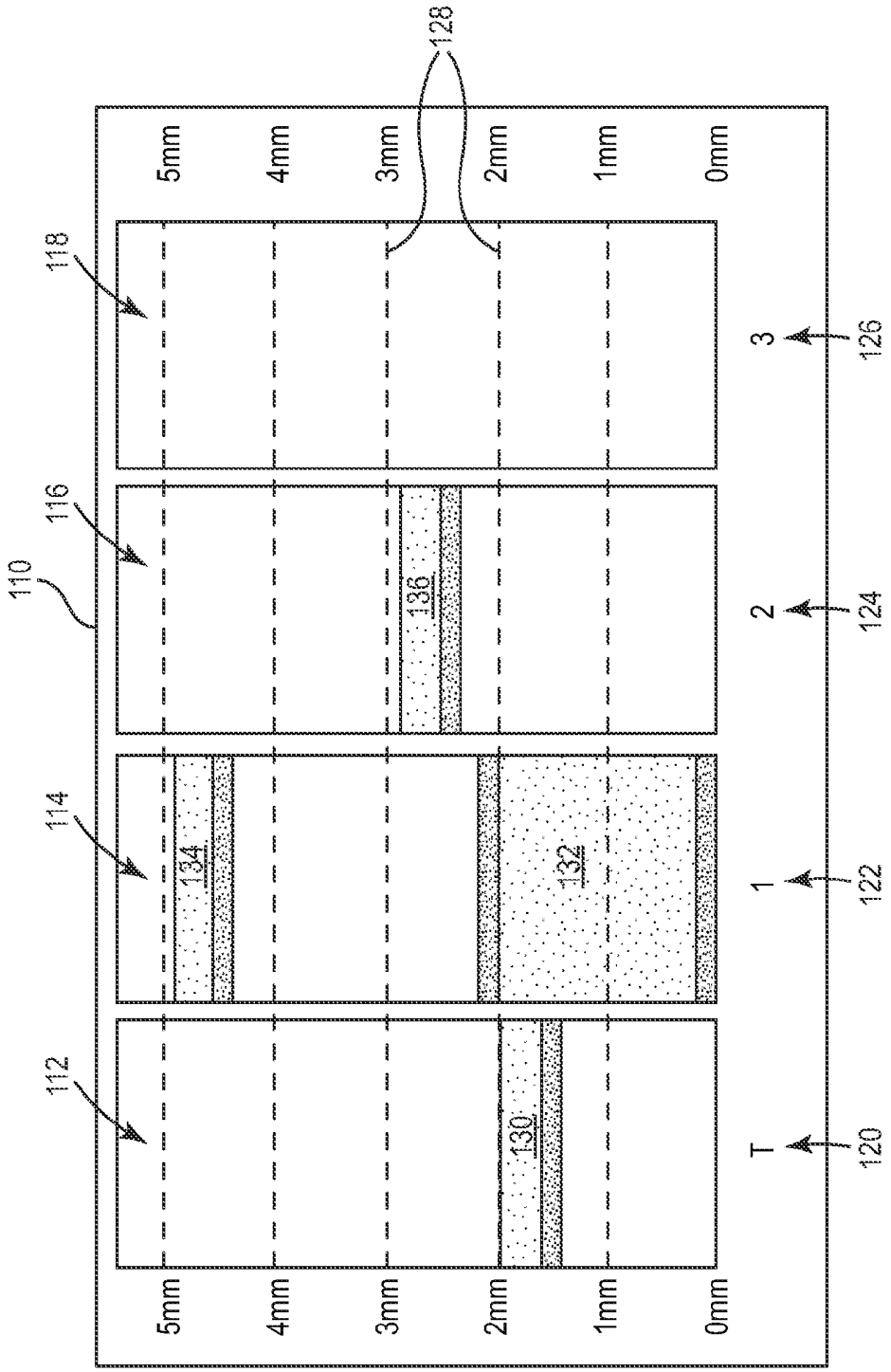
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Fig. 7

# ABLATION PROBE WITH ULTRASONIC IMAGING CAPABILITIES

## CROSS REFERENCE TO RELATED APPLICATION

This application claims priority to U.S. Provisional Application No. 61/491,944, filed Jun. 1, 2011, and entitled "ABLATION PROBE WITH ULTRASONIC IMAGING CAPABILITIES," which is incorporated herein by reference in its entirety for all purposes.

## TECHNICAL FIELD

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

## BACKGROUND

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.

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In Example 18, a user interface for displaying a composite image generated from an ablation probe with multiple ultrasonic imaging sensors comprises: a display screen including a plurality of imaging panes each configured to display an ultrasonic image generated from an associated one of the ultrasonic imaging sensors; wherein each of the imaging panes are arranged side-by-side to form a composite ultrasonic image from each of the ultrasonic imaging sensors.

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

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

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

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

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

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

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

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

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

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

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

FIG. **1** is a functional block diagram showing a medical system **10** in accordance with an illustrative embodiment. The system **10**, illustratively an ultrasonic cardiac imaging system for imaging the treatment of a heart **12**, includes a combined ablation and ultrasonic imaging probe **14**, a therapy module **16** for mapping and treating the heart **12**, an ultrasound imaging module **18** for generating high resolution ultrasonic images (e.g., B-mode images) of anatomical structures (e.g., body tissue) in or near the heart **12**, and a user interface **20** configured for use by the physician **22** in controlling therapy provided by the probe **14**, visualizing anatomical structures and/or other devices within the body, and/or determining the location and orientation of the probe **14** within the body. In some embodiments, for example, the system **10** comprises an ultrasonic imaging system that can be used in monitoring RF ablation therapy provided to a patient's heart **12** or in a cardiac vessel leading into or from the heart **12**.

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

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

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

In the embodiment of FIG. **1**, the ultrasound imaging module **18** includes an imaging controller **36** coupled to a number

of ultrasonic imaging sensors **38** on the probe **14**. An ultrasonic signal generator **40** is configured to provide one or more control signals **42** for controlling each of the ultrasonic sensors **38**. The imaging signals **44** received back from the ultrasonic sensors **38**, in turn, are fed to an image processor **46**, which processes the electrical signals **44** received back from the ultrasonic sensors **38** and generates a number of images, which as is discussed further herein, can be assembled together and displayed as a composite image on the user interface **20** to assist the physician **22** with inserting the probe **14** into position at a target location within the body and to perform an ablation procedure. In some embodiments, for example, the ultrasonic images obtained via the ultrasound imaging module **18** can be used to confirm tissue contact of the probe **14** with the heart **12** or surrounding anatomy, to determine the orientation of the probe **14** within the body, to determine the tissue depth of the tissue at a target ablation site, and/or to visualize the progression of a lesion being formed in the tissue.

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

Various characteristics associated with the ultrasonic sensors **38** as well as the circuitry within the ultrasound imaging module **18** can be controlled to optimize the suitability of the ultrasonic sensors **38** to accurately detect tissue boundaries (e.g., blood or other bodily fluid), lesion formation and progression, as well as other characteristics of the tissue before, during, and/or after the ablation procedure. Example tissue characteristics that can be visualized using the probe **14** include, but are not limited to, the presence of fluid vaporization inside the tissue, the existence of a prior scar, and the size and shape of a lesion being formed. The depth at which the ultrasonic sensors **38** can visualize anatomical structures within the body is dependent on the mechanical characteristics of the elements **38**, the electrical characteristics of the transducer circuitry including the drive frequency of the control signal **42** provided by the signal generator **40**, the boundary conditions and degree of attenuation between the ultrasonic sensors **38** and the surrounding anatomy, as well as other factors.

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

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

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

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.

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

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

FIG. **3** is a schematic view showing the distal tip section **60** of the probe **54** in greater detail. As can be further seen in FIG. **3**, the distal tip section **60** of the probe **54** includes an RF ablation electrode **70** and a plurality of ultrasonic imaging

sensors **72**, **74**, **76**, **78**. In some embodiments, the RF ablation electrode **70** comprises a conductive material such as platinum, which in addition to serving as an electrode for providing ablation therapy, may also be used as a fluoroscopic marker to determine the location of the distal tip section **60** within the body using fluoroscopy.

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

During ultrasonic imagining, each of the ultrasonic sensors **72**, **76**, **78**, **80** are configured to operate in alternating pulsing and sensing modes. When excited electrically in the pulsing mode, the ultrasonic sensors **72**, **76**, **78**, **80** generate pressure waves which travel through the electrode **70** and into the surrounding environment. In the sensing mode, the ultrasonic sensors **72**, **76**, **78**, **80** each produce an electrical signal as a result of receiving acoustic waves reflected back to the sensors **72**, **76**, **78**, **80**, which are then processed and displayed on the display monitor **50** of the user interface **20**. These reflections are generated by the acoustic waves traveling through changes in density in the surrounding environment being imaged.

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

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

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

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

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

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

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

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

As the probe **54** is moved around within the heart under direct visualization using the imaging module **18**, the therapy module **16** can be operated to record electrical activity within the heart and derive mapping data (block **104**). If an aberrant region is identified via the mapping processor **30**, the distal tip section **60** of the probe **54** can be placed into contact with the targeted ablation region (block **106**). In some procedures, the images produced by the ultrasonic sensors **72**, **76**, **78**, **80** can be used to confirm whether the probe **54** is in direct contact with the tissue to be treated. Once in position, the RF generator **24** is then operated to begin ablating the tissue (block **108**). If necessary, the physician may readjust the positioning of the probe **54** until the ablation is complete. The process can then be performed for any additional target tissue sites that are identified.

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

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

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

FIG. **7** is a view showing an example of a number of B-mode ultrasound images generated on the display monitor screen **110** of FIG. **6**. FIG. **7** may represent, for example, a number of ultrasonic images taken with the ultrasonic imaging probe **54** of FIG. **2** during a cardiac ablation procedure in or near a patient's heart.

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

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

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

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**. A combined ablation and ultrasound imaging probe for insertion within a body, the probe comprising:

a housing having a proximal section and a distal tip section;

an ablation electrode located at the distal tip section, the ablation electrode comprising a metal shell, the metal shell having a distal-facing aperture formed through the metal shell and a plurality of lateral-facing apertures formed through the metal shell and located proximal of the distal facing aperture, the plurality of lateral-facing apertures arrayed around a circumference of the metal shell;

a first ultrasonic imaging sensor located at least partially within the metal shell, the first ultrasonic imaging sensor configured to transmit acoustic waves in a first direction through the distal-facing aperture, the first direction orientated primarily distally away from the distal tip section; and

a plurality of second ultrasonic imaging sensors located at least partially within the metal shell and proximal to the first ultrasonic imaging sensor, the plurality of second

ultrasonic imaging sensors arrayed about the circumference of the metal shell and configured to transmit acoustic waves through the plurality of lateral-facing apertures in a plurality of second directions, respectively, the plurality of second directions orientated laterally away from the distal tip section and different from the first direction.

**2**. The probe of claim **1**, wherein the ablation electrode comprises an RF ablation electrode.

**3**. The probe of claim **1**, wherein each of the first and second ultrasonic imaging sensors are disposed entirely within the distal tip section.

**4**. The probe of claim **1**, wherein the plurality of apertures are evenly spaced about the circumference of the metal shell.

**5**. The probe of claim **1**, wherein each of the second ultrasonic imaging sensors are located along a curved portion of the metal shell.

**6**. The probe of claim **5**, wherein each of the second ultrasonic imaging sensors are configured to transmit acoustic waves at an angle of between about 10° to about 60° relative to a line perpendicular to a longitudinal axis of the housing.

**7**. The probe of claim **1**, wherein the plurality of second ultrasonic imaging sensors consists of three ultrasonic imaging sensors evenly arrayed at angles of 120° about the circumference of the metal shell.

**8**. The probe of claim **1**, wherein the plurality of second ultrasonic imaging sensors consists of four ultrasonic imaging sensors evenly arrayed at angles of 90° about the circumference of the metal shell.

**9**. The probe of claim **1**, wherein the probe further includes at least one mapping electrode.

**10**. An imaging and ablation probe for insertion within a body, the probe comprising:

a catheter having a distal tip section;

an ablation electrode located at the distal tip section, the electrode formed from an electrically conductive metal, the electrode having a distal aperture and a plurality of side apertures, all of said apertures formed through the electrically conductive metal of the electrode, the distal aperture distal with respect to each of the plurality of side apertures, the plurality of side apertures arrayed around a circumference of the electrode;

a first ultrasonic imaging sensor located within the electrode and configured to transmit acoustic waves through the distal aperture in a first direction, the first direction orientated primarily distally away from the electrode; and

a plurality of second ultrasonic imaging sensors within the electrode and configured to transmit acoustic waves, the plurality of second ultrasonic imaging sensors directly axially aligned with the plurality of side apertures, respectively, to transmit the transmit acoustic waves through the plurality of side apertures in a plurality of second directions, respectively, the plurality of second directions orientated laterally with respect to a longitudinal axis of the distal tip section.

**11**. The probe of claim **10**, wherein the electrode comprises an RF ablation electrode.

**12**. The probe of claim **10**, wherein each of the first and second ultrasonic imaging sensors are disposed entirely within the electrode.

**13**. The probe of claim **10**, wherein the plurality of side apertures are evenly spaced about the circumference of the electrode.

**14**. The probe of claim **10**, wherein each of the second ultrasonic imaging sensors are located along a curved portion of the electrode.

**15**. The probe of claim **14**, wherein each of the second ultrasonic imaging sensors is configured to transmit acoustic waves at an angle of between about 10° to about 60° relative to a line perpendicular to the longitudinal axis of the distal tip section.

**16**. The probe of claim **10**, wherein the plurality of side apertures consists of three apertures evenly spaced around the circumference of the electrode at angles of 120°.

**17**. The probe of claim **10**, wherein the plurality of side apertures consists of four apertures evenly spaced around the circumference of the electrode at angles of 90°.

**18**. An imaging and ablation probe for insertion within a body, the probe comprising:

a catheter having a distal tip section;

an RF ablation electrode located at the distal tip section, the RF ablation electrode formed from an electrically conductive metal, the electrode having a distal aperture and a plurality of side apertures, all of said apertures formed through the electrically conductive metal of the electrode, the distal aperture located distal with respect to each of the plurality of side apertures, the plurality of side apertures evenly spaced around a circumference of the electrode;

a first ultrasonic imaging sensor inset within the electrode and configured to transmit acoustic waves in a first direction through the distal aperture, the first direction orientated primarily distally from the electrode; and

a plurality of second ultrasonic imaging sensors inset within the electrode and each directly aimed in one of a plurality of different directions, respectively, and configured to transmit acoustic waves through the plurality of side apertures in the plurality of second directions, respectively, the plurality of second directions laterally directed with respect to the electrode and respectively different from each other and the first direction.

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| 专利名称(译) | 消融探头具有超声成像功能 | | |
| 公开(公告)号 | US9241687 | 公开(公告)日 | 2016-01-26 |
| 申请号 | US13/437267 | 申请日 | 2012-04-02 |
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| 发明人 | MCGEE, DAVID, L. | | |
| IPC分类号 | A61B18/14 A61B8/00 A61B8/08 A61B8/12 A61B6/12 A61B6/00 | | |
| CPC分类号 | A61B8/4477 A61B8/0883 A61B8/12 A61B8/445 A61B8/463 A61B6/12 A61B6/487 | | |
| 代理机构(译) | FAEGRE BAKER丹尼尔斯律师事务所 | | |
| 优先权 | 61/491944 2011-06-01 US | | |
| 其他公开文献 | US20120310064A1 | | |
| 外部链接 | Espacenet USPTO | | |


摘要(译)

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