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(54) **APPARATUS AND METHOD FOR INTRA-CARDIAC MAPPING AND ABLATION**

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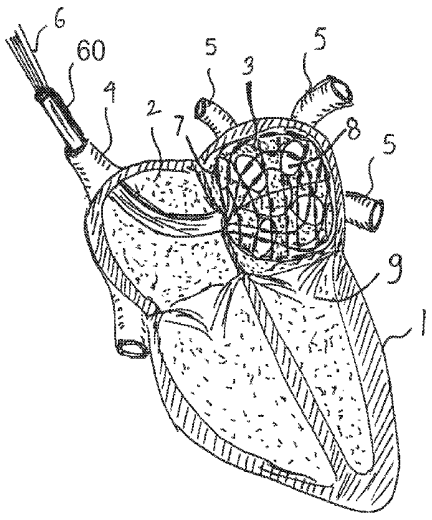
(57) **ABSTRACT**

An intra-cardiac mapping system is based on locating the ports through which blood flows in or out the heart chambers. For many procedures, such as ablation to cure atrial fibrillation, locating the pulmonary veins and the mitral valve accurately allows to perform a Maze procedure. The location of the ports and valves is based on using the convective cooling effect of the blood flow. The mapping can be performed by a catheter-deployed expandable net or a scanning catheter. The same net or catheter can also perform the ablation procedure.

67 Claims, 8 Drawing Sheets



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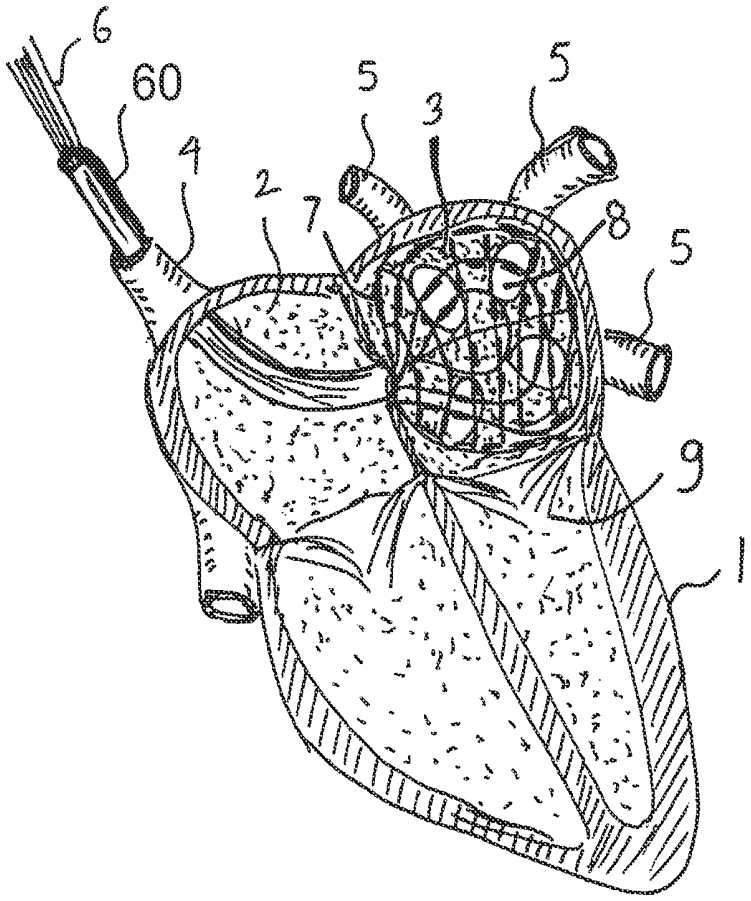


Fig 1

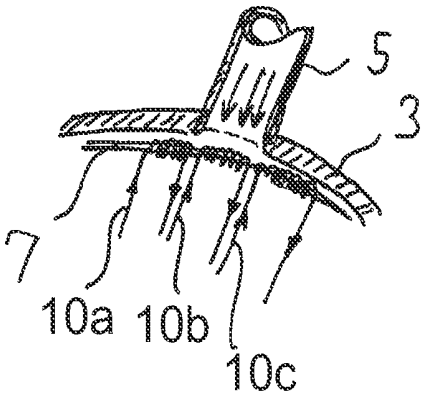
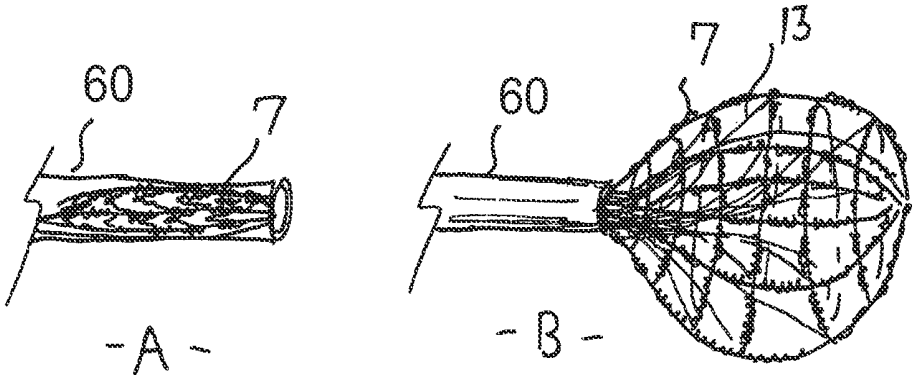


Fig 2



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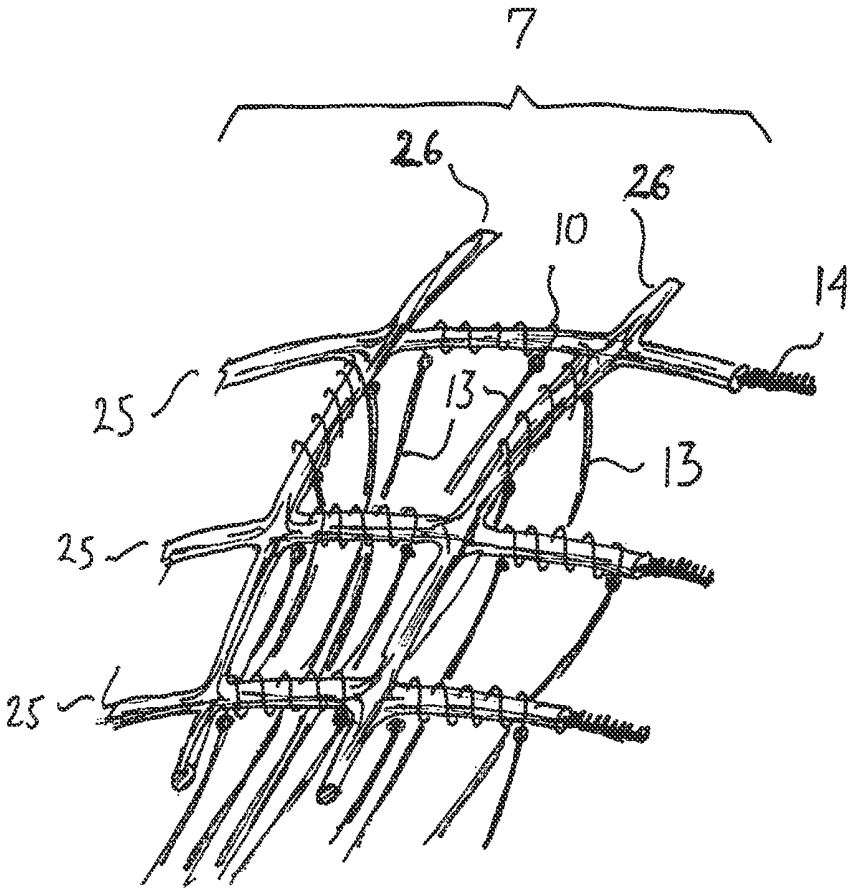

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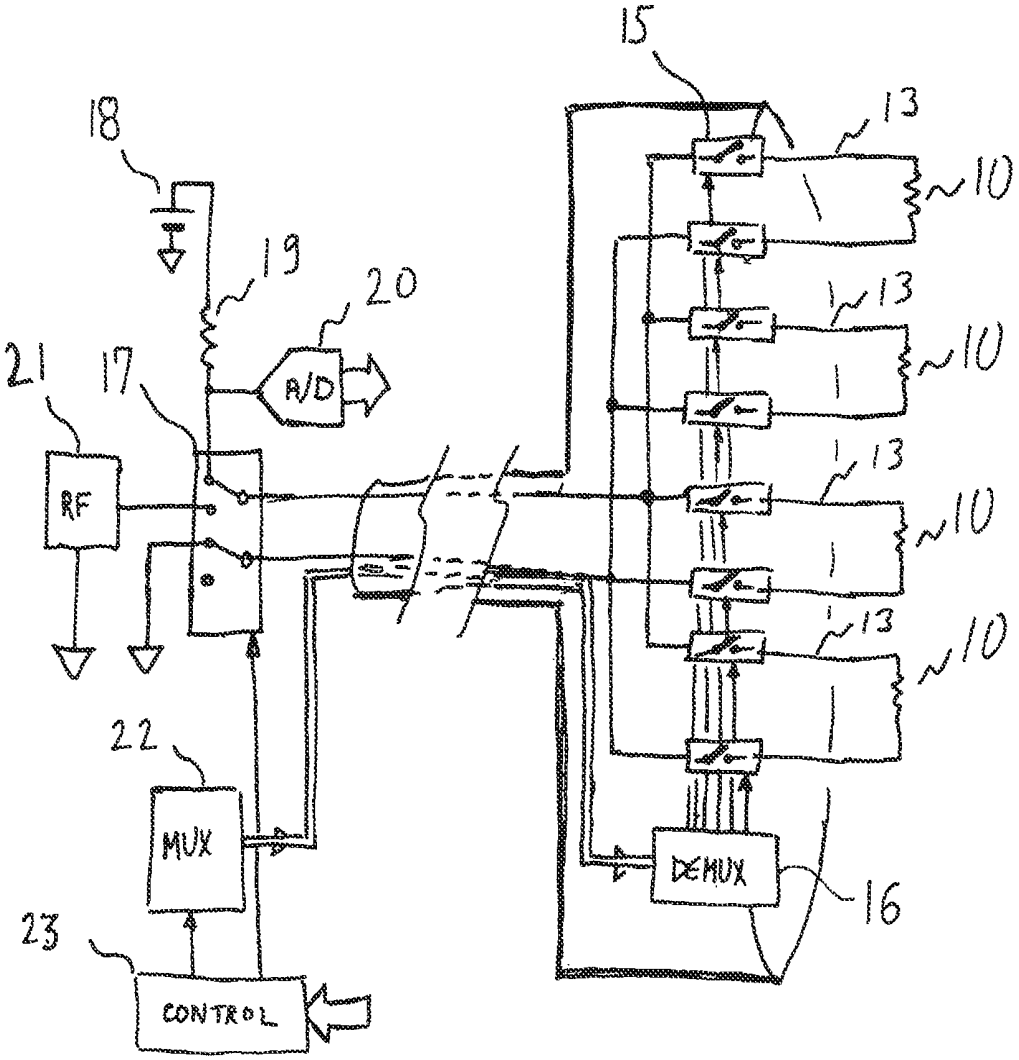
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CONTROL

Fig 5

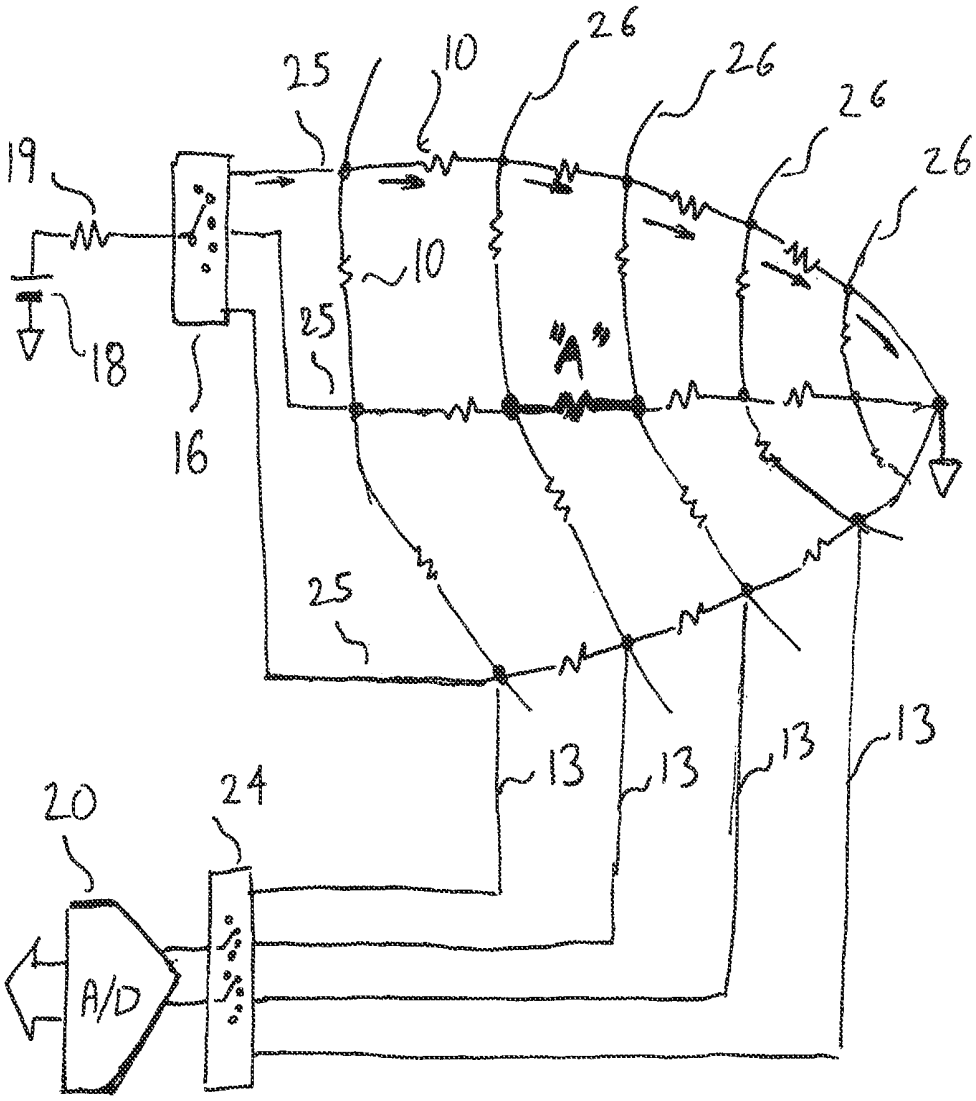


Fig 6

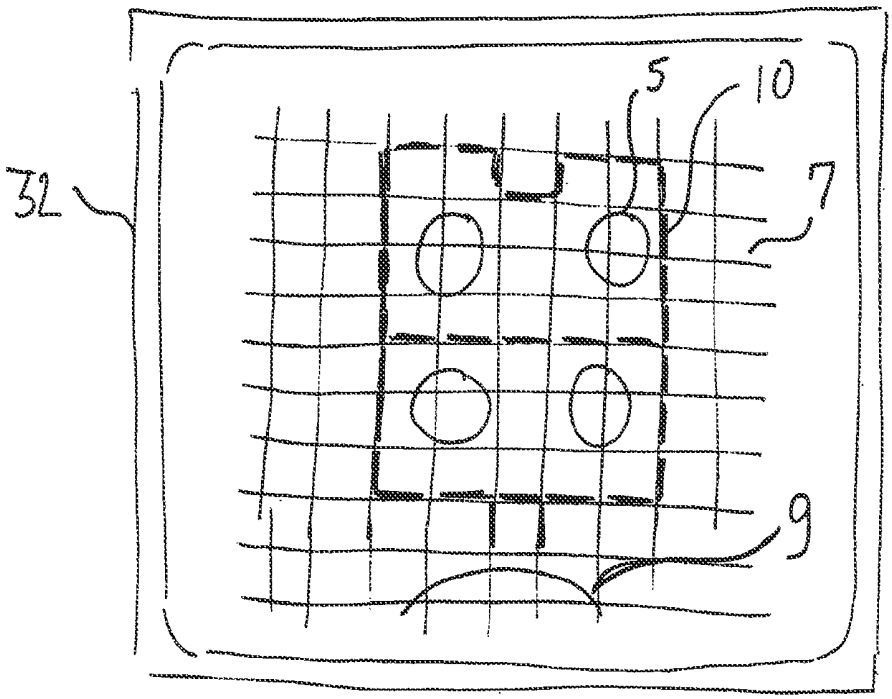
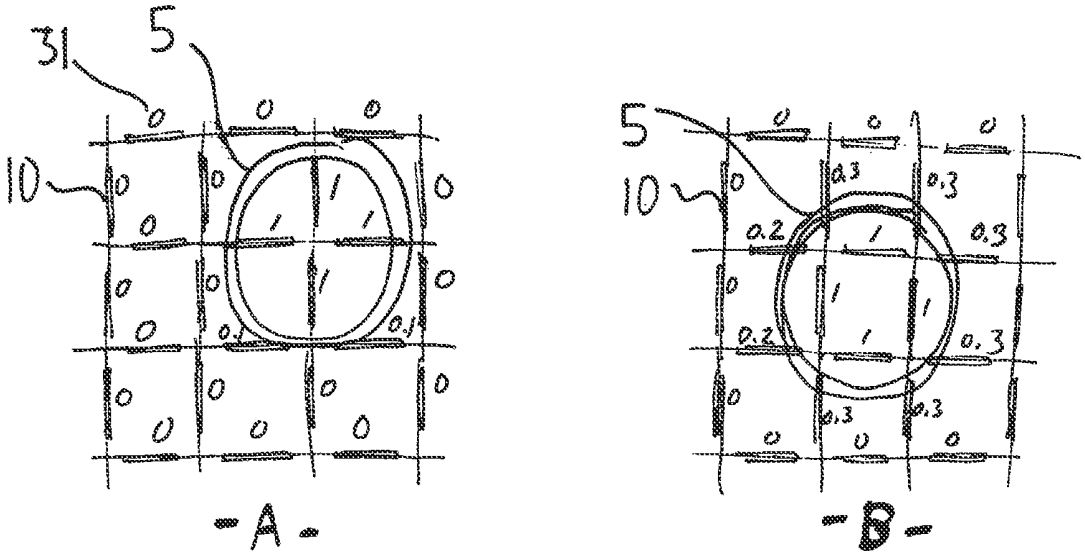


Fig 7



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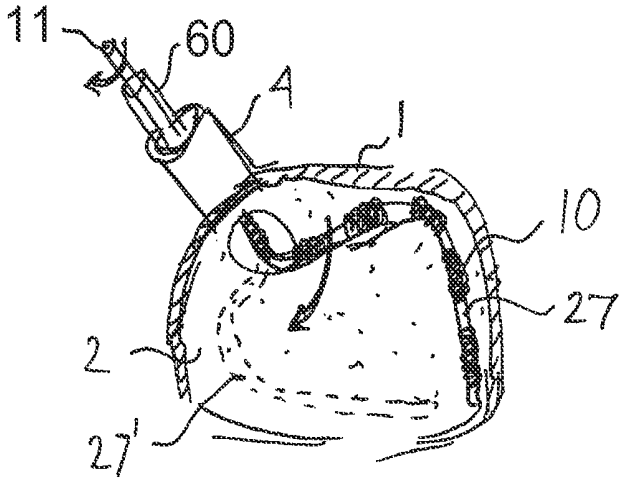

Fig 9

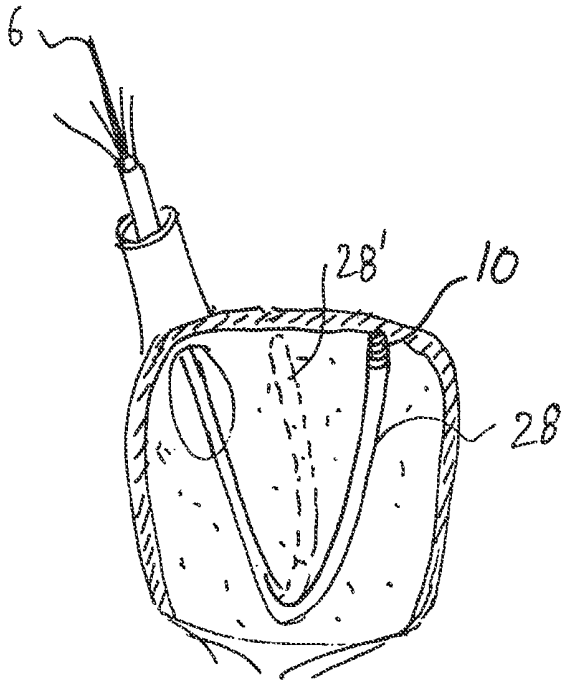

Fig 10

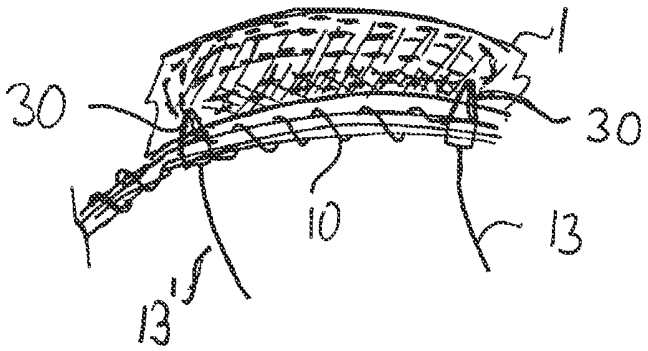

Fig 11

APPARATUS AND METHOD FOR INTRA-CARDIAC MAPPING AND ABLATION

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of prior U.S. patent application Ser. No. 11/475,950, filed Jun. 28, 2006, now U.S. Pat. No. 8,920,411, the entire disclosure of which is hereby incorporated herein by reference.

TECHNICAL FIELD

This disclosure generally relates to minimally invasive heart surgery, also known as percutaneous cardiac surgery and particularly relates to percutaneous mapping and ablation.

BACKGROUND

Atrial fibrillation is a well known disorder in which spurious electrical signals cause an irregular heart beat. The disorder has a well known cure known as the Maze procedure, in which a border is ablated around the sources of the spurious signals, typically in the left atrium but sometimes in the right atrium. The procedure is very commonly performed under direct vision, but difficult to perform percutaneously via a catheter because of the associated risk. Any error in navigation inside the heart can cause fatal damage. The key to a percutaneous procedure is mapping of the inside of the right and left atrium. Access to the right atrium is simple via the superior vena cava; the left atrium can be reached i) by perforating the transatrial septum, ii) via the aorta and the left ventricle or iii) via the pulmonary veins.

Prior approaches to map the inside of the atrium relied on electrical activity picked up from the atrium wall. These approaches require intimate electrical contact, not always possible because of scar tissue and deposits. These approaches may fail to accurately map the edges of the openings where the veins enter the atrium; information that is useful for correct placement of the ablation pattern. Other mapping methods, such as using an array of ultrasonic transducers, are not practical since such arrays typically will not fit through a catheter of a reasonable size (8-10 mm diameter). A superior mapping apparatus and method, that enables safe execution of the Maze and other intra-cardiac procedures is desirable.

A good survey article on the subject is: "Ablation of Atrial Fibrillation: Energy Sources and Navigation Tools: A survey" by Ruediger Becker and Wolfgang Schoels (J. of Electrocardiology, Vol 37, 2004, pp 55-61). The article includes an extensive bibliography.

SUMMARY

Embodiments of an intra-cardiac mapping system are based on locating openings or ports and values through which blood flows in or out of the heart chambers. For many procedures, such as ablation to cure atrial fibrillation, accurately locating the pulmonary veins and the mitral valve allows performance of a Maze procedure. The openings, ports and valves may be located based on the convective cooling effect of the blood flow. The mapping can be performed by a catheter-deployed expandable net or a scanning catheter. The same net or catheter can also perform the ablation procedure.

In one embodiment, a method for intra-cardiac mapping comprises: introducing a plurality of flow sensors into an intra-cardiac cavity: locating points in a wall forming said cavity based on sensing blood flow; and mapping said walls of said cavity based on said points. The method for intra-cardiac mapping may include said blood flow being sensed by its convective cooling effect on a heated sensor. The method for intra-cardiac mapping may include said sensing being done by a steerable linear array. The method for intra-cardiac mapping may include said mapping being used for treating atrial fibrillation by RF ablation. The method for intra-cardiac mapping may include being used for treating atrial fibrillation by microwave ablation. The method for intra-cardiac mapping may include said mapping being used for treating atrial fibrillation by cryogenic ablation. The method for intra-cardiac mapping may include said mapping being used for treating atrial fibrillation by laser ablation. The method for intra-cardiac mapping may include said blood flow being sensed by the resistance change of a heated resistive wire.

In another embodiment, a method for intra-cardiac mapping comprises: introducing an expandable sensing mesh into said cavity via a catheter; using said mesh to locate openings in walls forming said cavity based on the convective heat transfer of blood flowing through said holes; and mapping inside of said cavity based on location of said openings. The method for intra-cardiac mapping may include said blood flow being sensed by its convective cooling effect on a heated sensor. The method for intra-cardiac mapping may include said sensing being done by a steerable linear array. The method for intra-cardiac mapping may include said mapping being used for treating atrial fibrillation by RF ablation. The method for intra-cardiac mapping may include said mapping being used for treating atrial fibrillation by microwave ablation. The method for intra-cardiac mapping may include said mapping being used for treating atrial fibrillation by cryogenic ablation. The method for intra-cardiac mapping may include said mapping being used for treating atrial fibrillation by laser ablation. The method for intra-cardiac mapping may include said blood flow being sensed by the resistance change of a heated resistive wire. The method for intra-cardiac mapping may include said mesh comprising small coils of nickel wire wound on a mesh of a flexible insulator. The method for intra-cardiac mapping may include an electronic switch used to minimize the number of electrical wires passing through said catheter.

In yet another embodiment, a method for treating atrial fibrillation comprises: introducing at least one flow sensor into an intra-cardiac cavity; locating points in a wall forming said cavity based on sensing blood flow; mapping walls of said cavity based on said points; and ablating a pattern into walls of said cavity based on said mapping. The method for treating atrial fibrillation may include said blood flow being sensed by its convective cooling effect on a heated sensor. The method for treating atrial fibrillation may include said sensing being done by a steerable linear array. The method for treating atrial fibrillation may include said mapping being used for treating atrial fibrillation by RF ablation. The method for treating atrial fibrillation may include said mapping being used for treating atrial fibrillation by microwave ablation. The method for treating atrial fibrillation may include said mapping being used for treating atrial fibrillation by cryogenic ablation. The method for treating atrial fibrillation may include said mapping being used for treating atrial fibrillation by laser ablation. The method for treating atrial fibrillation may include said blood flow being sensed by the resistance change of a heated resistive wire. The method for treating atrial fibrillation may include said flow sensors also acting as electrodes for said ablation. The method for treating atrial fibrillation may include said flow sensor being based on tem-

perature sensing and a same sensor being used to monitor temperature during said ablation. The method for treating atrial fibrillation may include said ablation being unipolar. The method for treating atrial fibrillation may include said ablation being bipolar. The method for treating atrial fibrillation may include said ablated pattern being a Maze procedure.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings, identical reference numbers identify similar elements or acts. It is to be understood that the attached drawings are for purposes of illustrating the concepts of the invention and may not be to scale. For example, the sizes, relative positions, shapes, and angles of or associated with elements in the drawings are not necessarily drawn to scale, and some elements may be arbitrarily enlarged and positioned to improve drawing legibility. Further, the particular shapes of the elements as drawn may differ from their actual shapes and, in this regard, may be selected instead of the respective actual shapes for ease of recognition in the drawings.

FIG. **1** is a cross sectional view of the heart showing the mapping mesh deployed in the left atrium.

FIG. **2** is a cross sectional view of the sensing device.

FIGS. **3**A and **3**B are isometric views of the mesh in both folded and expanded position.

FIG. **4** is an isometric enlarged view of a portion of the mesh.

FIG. **5** is an electrical schematic of a mapping and ablation system.

FIG. **6** is an electrical schematic of a simplified mapping system.

FIG. **7** is a schematic view of the display console of the system.

FIGS. **8**A and **8**B are graphical views of a mapping that illustrate an interpolation principle.

FIG. **9** is a cross sectional view of an alternate embodiment, using mechanical or manual scanning in one axis.

FIG. **10** is a cross sectional view of an alternate embodiment, using mechanical scanning in two dimensions.

FIG. **11** shows the use of the invention for bipolar ablation.

DETAILED DESCRIPTION

In the following description, certain specific details are set forth in order to provide a thorough understanding of various disclosed embodiments. However, one skilled in the relevant art will recognize that embodiments may be practiced without one or more of these specific details, or with other methods, components, materials, etc. In other instances, well-known structures associated with apparatuses and methods for intracardiac mapping and ablation have not been shown or described in detail to avoid unnecessarily obscuring descriptions of the embodiments.

Unless the context requires otherwise, throughout the specification and claims which follow, the word "comprise" and variations thereof, such as, "comprises" and "comprising" are to be construed in an open, inclusive sense, that is as "including, but not limited to."

Reference throughout this specification to "one embodiment" or "an embodiment" means that a particular feature, structure or characteristic described in connection with the embodiment is included in at least one embodiment. Thus, the appearances of the phrases "in one embodiment" or "in an embodiment" in various places throughout this specification are not necessarily all referring to the same embodiment. Furthermore, the particular features, structures, or characteristics may be combined in any suitable manner in one or more embodiments.

As used in this specification and the appended claims, the singular forms "a," "an," and "the" include plural referents unless the content clearly dictates otherwise. It should also be noted that the term "or" is generally employed in its non-exclusive sense including "and/or" unless the content clearly dictates otherwise.

The headings and Abstract of the Disclosure provided herein are for convenience only and do not interpret the scope or meaning of the embodiments.

FIG. **1** shows a sensing and ablation mesh **7** inserted into a left atrium **3** of a heart **1** according to one illustrated embodiment.

By way of example, the mesh **7** may be delivered via a catheter **60** inserted via a superior vena cava **4** and penetrating a transatrial septum from a right atrium **2** of the heart **1**. The mesh **7** is communicatively coupled to the rest of the system, for example, by electrical wires **6**.

Before any ablation takes place, the inside of the left atrium **3** is mapped in order to locate the openings or ports **8** leading to the pulmonary veins **5**, as well as the mitral valve **9**. A typical Maze procedure ablates a "fence" around openings or ports **8** to stop propagation of spurious electrical signals which cause the heart **1** to contract at the wrong times.

The mapping may locate some or all of the openings or ports **8** through which blood flows in and out of the left atrium **3**, as the Maze procedure is mainly concerned with the location of these openings or ports **8**. By the way of example, in the left atrium **3**, the four openings or ports **8** leading to the pulmonary veins **5** as well as the mitral valve **9** may be located. The location of these openings or ports **8** may be based on the fact that the convective cooling effect of the blood is significant, and a slightly heated mesh **7** pressed against the walls of the left and/or right atrium **3**, **2** will be cooler at the areas which are spanning the openings or ports **8** carrying blood.

FIG. **2** shows the ablation mesh **7** covered by miniature heating and/or temperature sensing elements **10***a*-**10***c* flow (collectively 10, only three illustrated in the figure). Each one of these elements **10***a*-**10***c* comprises a few turns of a resistive wire, for example nickel wire, wound on an electrically insulated mesh. A low current is passed through each element **10**, raising a temperature of the element **10** by about 1 degree C. above normal blood temperature. A first element **10***b*, which lies across an opening or port **8** of one of the pulmonary veins **5**, will be cooled by blood flow. The other elements are against a wall **3** and hence do not lie across any of the openings or ports **8**.

By identifying the relatively cooler elements **10***a*, **10***c* on the mesh **7**, the location of the openings or ports **8** may be found.

This method does not require intimate contact with the wall **3**, as the cooling effect is significant even a few millimeters away from the opening.

The same elements **10** can be used as ablation electrodes during an ablation stage. It was found that the power required to raise the temperature of the mesh **7** by a small but easily detectable amount is very small, on the order of 10-50 mW per element **10**. If the elements **10** are made of a material that has a significant change in resistance with temperature, the temperature drop can be sensed by measuring a voltage across the element **10** when driven by a constant current. A good choice for element material is nickel wire, which is inert, highly resistive and has a significant temperature coefficient of resistance (about 0.6% per deg C.). Since the resistance of

the elements **10** is low (typically 0.1-1 ohm), the electrical noise is very low and temperature changes as low as 0.1 deg can be easily detected. For even higher detection sensitivity, the voltage waveform can be sampled in sychronization with the heart rate or the average voltage removed and only the change amplified. Such methods are referred to as "AC coupling". A further refinement to reduce the electrical noise is to pass the signal through a digital band pass filter having a center frequency tracking the heart rate. To avoid any potential tissue damage, the temperature of the elements **10** of the mesh **7** is only slightly above the blood temperature, typically 0.1-3 degrees C. above blood temperature.

FIG. **3**A shows the mesh **7** in a compressed configuration "A" and FIG. **3**B shows the mesh **7** in an expanded configuration "B". Since the mesh **7** has to fit into a catheter **60**, the mesh **7** should be very flexible. Besides elements **10** discussed earlier, there is also a large number of leads **13** coming out of the mesh **7**. Leads **13** can be loose, as shown in FIG. **3**B, or may be bonded to the mesh **7**. To avoid feeding a large number of wires all the way to an operating console, an electronic selector switch may be employed, which may, for example, be mounted in the catheter **60**. This reduces the number of electrical wires from over 100 to about 10. The mesh **7** can be self-expanding (elastic) or balloon-expandable. Self expanding allows normal blood flow during the procedure. For balloon expandable devices, the expansion balloon should be removed before the mapping, to avoid blocking the flow of blood.

FIG. **4** shows the mesh **7** in more detail. Insulated longitudinal (i.e., parallel to catheter) wires **25** are crossed by cross wires **26**. Each section of the mesh **7** is covered by a few turns of thin (0.05-0.2 mm) nickel wire **10** having leads **13**. The leads **13** can be regular thin copper wire. The longitudinal wires **25** can be stiffer than the cross wires **26**, therefore can be made self-expanding by incorporating a core **14** made of coiled flexible metal wire such as Nitinol. A metallic core may interfere with the ablation process at higher frequencies and can be replaced by simply making the longitudinal wires **25** of a polymeric material thicker than the cross wires **26**. The cross wires **26**, which may form rings around wires **25**, should be very flexible to compress into the catheter **60**. The cross wires **26** could incorporate a very thin wire or coiled up wire. Use of a flexible mesh **7** not only allows percutaneous delivery, but also permits the mesh **7** to follow the atrial volume change each heartbeat. The mesh **7** should stay in contact with or close to the atrial wall during the cardiac cycle, otherwise the measurement and the ablation may only be performed during parts of the cardiac cycle. The diameter of the longitudinal wires **25** and cross wires **26** are typically 0.2-1 mm. The mesh **7** may include about 10-20 longitudinal wires **25** and about 10-20 cross wires **26**. The insulation can be any polymeric material such as thin enamel or polymer coating. Practically any polymer can be used, as the maximum temperature it will be subject to, including during the ablation phase, is around 100 degrees C.

FIG. **5** shows an electrical system, according to one illustrated embodiment. The elements **10** may be resistive heaters wound on the mesh **7**. Each of the elements **10** is connected by electronic element switches **15** (typically FET or MOS-FET type) to a single pair of wires leading out of the body to a mode selection switch **17**. Element switches **15** are selected by de-multiplexer or selector **16**. The de-multiplexer or selector **16** is controlled by a small number of wires or even a single wire if data is sent in serial form, by a multiplexer **22**. Element switches **15** and de-multiplexer or selector **16** may be built into the catheter **60**, which may, for example, be located near the point of deployment of the mesh **7**. The element switches **15** have to carry significant power during the ablation phase.

The mode selection **17** selects between a mapping mode (position shown in the drawing) and an ablation mode (second position of switch). In the mapping mode, a current is created by a voltage source **18** and resistor **19** (e.g., forming a constant current source) and routed into a selected element **10** by the element switches **15**. For each measurement, the two element switches **15** that are connected to the scanned element **10** are in an enabled state (ON), the rest of the element switches being in a disabled state (OFF). The voltage drop across an element **10** is measured by an analog to digital (A/D) converter **20** and fed to a control computer **23**. For greater accuracy, four terminal sensing can be employed. In a preferred embodiment, the detection is AC coupled, therefore the DC voltage drops along the wires are of no consequence, and no four-terminal sensing is needed. For AC coupling, the control computer **23** may include a 0.5 Hz low pass filter, which may be implemented in software. The slight disadvantage of the AC coupled method approach is speed, as the low signal frequency (e.g., about 1 Hz), requires a few seconds per measurement. Other temperature sensors and/or approaches, such as thermistors or thermocouples, can be used in conjunction with the elements **10**. Mapping is achieved by turning on all of the elements **10** (e.g., sequentially) and measuring the temperature of each. A map may be formed in the control computer **23** and the lower temperature spots on the mesh correspond to the openings or ports **8** leading to the veins or valves.

When the mode selection switch **17** is in the ablation mode, a generator **21** (e.g., Radio Frequency (RF)) is connected (e.g., sequentially) to selected elements **10** by the control computer **23** addressing the multiplexer **22** which controls the element switches **15** via the de-multiplex selector **16**. The complete operation, including scanning and ablation, can be completed in less than 5 minutes. The configuration illustrated in FIG. **5** implies unipolar ablation; however bipolar ablation can be used as well and is discussed below. Clearly other sources of ablation can be used besides RF. Frequencies from DC to microwaves can be used, as well as delivery of laser power via optical fibers or cryogenics via thin tubes. For laser ablation element switches **15** are optical switches, while for cryogenic ablation the element switches **15** are valves, and in some embodiments may take the form of heated elements such as resistive wires.

During ablation it is desirable to monitor the temperature of the mode selection switch **17** to the mapping position several times during the ablation procedure. The measured temperatures can be displayed on a display **32** (FIG. **7**). RF ablation is typically performed at frequencies of 100 KHz-1 MHz and power levels which depend on the size of the elements **10**, but can be as high as 100 W. Various RF ablation techniques and equipment are well known in the art.

FIG. **6** shows an embodiment in which the mapping system is separate from the ablation system. In this system, the mesh **7** has very few connecting wires. As illustrated, each longitudinal wire **25** has a single output wire and each cross wire **26** has a single output wire **13**. For a 10×10 mesh **7** with 100 nodes, only twenty-one wires are needed (ten plus ten plus ground wire), instead of two hundred wires. This allows all wires to be brought directly out of the catheter **60**. This also allows placement of selector switches **16** and **24** together with the control system. For example, if the element marked as "A" is selected; a current is selected to run through the longitudinal wire **25** which includes element A. The voltage drop is sensed by the two circumferential wires **13** that connect directly to A. Since no current flows in the other elements at

the time of measurement, the voltage drop is only caused by element A. It is sensed by A/D converter **20** via double pole selector **24**.

After a map is established, it is displayed on a display screen **32** as shown in FIG. **7**. The surgeon can select which elements **10** will cause tissue ablation in the atrium. The pattern formed is along the line of the standard Maze procedure. The location of the pulmonary veins **5** and the mitral valve **9** is inferred from the temperature date and drawn on the display screen.

FIGS. **8**A and **8**B demonstrate the principle of accurate location of the veins and valves even if the grid is relatively coarse. The exact location can be interpolated based on the fact that when only part of the element **10** is exposed to the blood flow. By the way of example, if the temperature of the mesh **7** is 1 degree C. above blood temperature and equals the blood temperature under normal blood flow (this was experimentally verified), the temperatures of a group of elements **10** will be as shown in FIG. **8**A when aligned with the opening or port **8** of vein **5**. The number near each element **10** is the temperature drop. When moved, some of the elements **10** will only be partially positioned in the flow path under vein **5**, as shown by FIG. **8**B. The temperatures of those elements **10** will be between 0 and 1 degree above blood temperature. The exact temperature drop between 0 to 1 corresponds with the exact shift. This allows accurate determination of the location and size of each opening or port **8**, data used by the control computer **23** to draw the map shown in FIG. **7**. A grid spacing of 10 mm allows about 1 mm accuracy.

An alternative to a full mesh is a partial mesh, or even a single sensor, that is mechanically scanned across the area to be mapped. FIG. **9** shows a linear sensor array **27** pushed into the atrium **2** via vein **4** by the catheter **60**. The linear sensor array **27** has a linear array of elements **10** similar to those used in the full mesh **7**. After a linear mapping is performed the linear sensor array **27** is rotated (as shown by broken line **27'**) a small amount (10-20 degrees) by stem **11** (similar to electrical wires **6**) and a new scan is performed. The same procedures previously described may be used for ablation.

FIG. **10** shows the use of a single steerable catheter **28** as a mapping and ablation tool. Steerable catheters are controlled remotely by mechanical, magnetic, hydraulic or other means. A steerable catheter **28** can be used to scan the inside of the atrium **3** by bending, as shown in broken line **28'**. The location is monitored by external or internal sensors. A position of a tip of the steerable catheter **28** can also be monitored by fluoroscopy. The catheter tip contains a heating and/or ablation element **10**. Steerable catheters **28** may advantageously carry a wide range of ablation systems, since only one connection and one point is needed.

A full mesh trades a higher complexity for better speed and accuracy when compared to linear arrays or single point scanning.

The previous examples were of unipolar ablation, with the ablation current returning to ground via the patient's body. The disclosed system can also be used for bipolar ablation as shown in FIG. **11**. In unipolar ablation the same voltage is connected to both leads **13** and **13'** of an element **10**. In bipolar abalation the voltage is connected to lead **13** while the other end, **13'**, is grounded. It is important that the element **10** will be of sufficient resistance to cause most of the ablation current to flow through heart tissue **1**. Electrodes **30** make contact with tissue **1** while the wire used in the element **10** is covered by an insulator. The advantage of bipolar ablation is better control of ablation depth. Typical ablation temperatures are 60-80 degrees C. At a higher temperature the tissue **1** becomes less conductive, forcing the ablation current to seek a new path. This promotes full ablation of the tissue **1**. The element **10** can also be designed to assist ablation by creating heat when ablation voltage is applied across it.

One possible advantage of at least some of the presently disclosed embodiments over electrical potential mapping methods is that the presently disclosed embodiments do not require perfect contact between the mesh **7** and the tissue **1**. The presently disclosed embodiments may also advantageously be less sensitive to the surface properties of the tissue, such as scar tissue or plaque.

If the mesh is separated from the tissue by a thin layer of blood, both the temperature sensing and the ablation functions of the presently disclosed embodiments will still function properly.

The word "element" in this disclosure has to be interpreted in a broad sense as any element capable of sensing blood flow. Clearly the elements do not need to be heaters, as cooling elements will work equally well. If a material is injected into the blood flow, any sensor capable of detecting this material can be used to detect blood flow. By the way of example, if the blood is cooled or warmed slightly before returning to the heart only temperatures sensors are needed. Since temperature differences as low as 0.1 degree C. can be detected reliably, it is fairly simple to heat or cool the blood slightly before it returns to the heart (even by a simple external pad).

The above description of illustrated embodiments, including what is described in the Abstract, is not intended to be exhaustive or to limit the embodiments to the precise forms disclosed. Although specific embodiments of and examples are described herein for illustrative purposes, various equivalent modifications can be made without departing from the spirit and scope of the disclosure, as will be recognized by those skilled in the relevant art.

The various embodiments described above can be combined to provide further embodiments. All of the U.S. patents. U.S. patent application publications, U.S. patent applications, foreign patents, foreign patent applications and non-patent publications referred to in this specification and/or listed in the Application Data Sheet are incorporated herein by reference, in their entirety. Aspects of the embodiments can be modified, if necessary, to employ systems, circuits and concepts of the various patents, applications and publications to provide yet further embodiments.

These and other changes can be made to the embodiments in light of the above-detailed description. In general. in the following claims, the terms used should not be construed to limit the claims to the specific embodiments disclosed in the specification and the claims, but should be construed to include all possible embodiments along with the full scope of equivalents to which such claims are entitled. Accordingly, the claims are not limited by the disclosure.

What is claimed is:

1. A treatment system, comprising:

a structure;

a plurality of elements carried by the structure, the structure and the plurality of elements sized to be receivable in an intra-cardiac cavity of a heart, the intra-cardiac cavity formed at least in part by a tissue wall having an interior surface, the interior surface interrupted by one or more ports in fluid communication with the intra-cardiac cavity, each of the plurality of elements including at least one characteristic that is responsive to blood flow, the plurality of elements positionable in spaced apart distribution within the intra-cardiac cavity by the structure, each of the elements in the spaced apart distribution positioned on a respective portion of the structure, each of the respective portions of the structure positionable

adjacently to at least one of a portion of the interior surface or a portion of one of the one or more ports, at least a first one of the plurality of elements spaced on the structure from at least a second one of the plurality of elements such that the at least the first one of the plurality of elements is positioned on a respective first portion of the structure extendable across a portion of the one of the one or more ports and the at least the second one of the plurality of elements is positioned on a respective second portion of the structure which is positionable in the intra-cardiac cavity to not overlie the one of the one or more ports; and

a control computer coupled to receive signals from at least two of the plurality of elements, the signals indicative of a blood flow at least proximate respective ones of the at least two of the plurality of elements in a mapping mode, the control computer configured to provide, based at least on the received signals indicative of the blood flow, a visual representation in the form of a map of a location of each of one or more regions of the interior surface of the tissue wall concurrently with a location of each of at least one of the one or more ports on the interior surface of the tissue wall with respect to the one or more regions.

2. The treatment system of claim **1** wherein the at least one characteristic of each of the plurality of elements is responsive to convective heat transfer by the blood flow and wherein the control computer is configured to provide the visual representation in the form of the map of the location of each of one or more regions of the interior surface of the tissue wall concurrently with the location of each of at least one of the one or more ports on the interior surface of the tissue wall with respect to the one or more regions based at least on the received signals indicative of the blood flow.

3. The treatment system of claim **2**, further comprising:

a current source selectively coupleable to selected ones of the plurality of elements, wherein each of the selected elements has a voltage thereacross in response to a current applied to the selected element via the current source, the voltage indicative of the convective heat transfer at least proximate a respective one of the selected elements.

4. The treatment system of claim **3**, further comprising:

a plurality of switches, the switches selectively operable to couple the selected ones of the plurality of elements between at least a current source and a voltage measurement circuit.

5. The treatment system of claim **4**, further comprising:

a multiplexer coupled to the control computer and operable to multiplex signals from the control computer; and

a demultiplexer coupled to receive the multiplexed signals from the multiplexer and operable to demultiplex the multiplexed signals and further coupled to provide the demultipexed signals to control the switches.

6. The treatment system of claim **5**, further comprising:

a mode switch selectively operable to switch between the mapping mode and an ablation mode in which a portion of the surface of the tissue wall is ablated.

7. The treatment system of claim **6**, further comprising:

an ablation source coupled to transfer energy to or from the tissue wall during the ablation mode.

8. The treatment system of claim **6**, further comprising:

a radio frequency generator coupled to provide a varying current to at least one element of the plurality of elements to provide energy to the tissue wall from the at least one element during the ablation mode.

9. The treatment system of claim **6**, wherein the mode switch couples the switches to the current source in the mapping mode and couples the switches to the radio frequency generator in the ablation mode.

10. The treatment system of claim **1** wherein two or more of the plurality of elements are arranged on the structure as a linear array.

11. The treatment system of claim **1** wherein the structure is percutaneously steerable.

12. The treatment system of claim **1** wherein the structure is a mesh expandable between a compressed configuration and an expanded configuration.

13. The treatment system of claim **12** wherein the mesh is a self-expanding mesh.

14. The treatment system of claim **12** wherein the mesh is formed of a plurality of longitudinal wires and a plurality of cross wires, the longitudinal wires stiffer than the cross wires.

15. The treatment system of claim **1**, further comprising:

a catheter including a receptacle sized to receive the structure when the structure is in a compressed configuration.

16. The treatment system of claim **1** wherein each of the plurality of elements is formed by a number of resistive wires.

17. The treatment system of claim **16** wherein the number of resistive wires are metallic wires.

18. The treatment system of claim **16** wherein the number of resistive wires are polymer wires.

19. The treatment system of claim **1** wherein each of at least two of the plurality of elements is selectively operable to ablate the tissue wall and to sense a temperature at least proximate the tissue wall, and the control computer is configured to adjust a transfer of energy between respective ones of the at least two of the plurality of elements and the tissue wall by the respective element based at least in part on the sensed temperature.

20. The treatment system of claim **1**, further comprising:

a current source;

an analog-to-digital converter;

a first selector operable to electrically couple the current source to selected ones of the plurality of elements in the mapping mode; and

a second selector operable to electrically couple the analog-to-digital converter to measure voltages across the selected ones of the plurality of elements in the mapping mode.

21. The treatment system of claim **1**, further comprising:

a display coupled to the control computer to display the map.

22. The treatment system of claim **1** wherein the control computer is further configured to provide the visual representation in the form of the map of the location of the each of the one or more regions of the interior surface of the tissue wall and the location of each of at least two of the one or more ports.

23. The treatment device of claim **1**, further comprising:

at least one electrode receivable in the intra-cardiac cavity, each of the at least one electrode selectively operable to ablate the tissue wall.

24. The treatment device of claim **23** wherein the control computer is further configured to cause selected ones of the at least one electrode to ablate the interior surface of the tissue wall at a location determined based at least on the visual representation, the determined location located on the interior surface away from locations on the interior surface of the tissue wall interrupted by each of the one or more ports.

25. The treatment device of claim **23** wherein the visual representation specifies a size of each port of the one or more ports, and the control computer is configured to cause selected ones of the at least one electrode to ablate the interior surface of the tissue wall at a location determined based at

least in part on the size of each port of the one or more ports specified by the visual representation, the determined location located on the interior surface away from each of the one or more ports.

26. The treatment device of claim **23** wherein the control computer is configured to cause selected ones of the at least one electrode to ablate the interior surface of tissue wall at a location other than locations determined from at least the visual representation of the location of each of at least one of the one or more ports on the interior surface of the tissue wall with respect to the one or more regions.

27. The treatment device of claim **23** wherein at least one of the plurality of elements is selectively operable as an electrode.

28. The treatment device of claim **1** wherein the structure is expandable from an unexpanded configuration to an expanded configuration in the intra-cardiac cavity, and wherein the plurality of elements comprises a first group of the elements provided on a first elongate member and a second group of the elements provided on a second elongate member, the second elongate member extending along a direction that intersects a direction that the first elongate member extends along when the structure is in the expanded configuration.

29. The treatment device of claim **1**, further comprising:

a plurality of electrodes receivable in the intra-cardiac cavity, each of the plurality of electrodes selectively operable to ablate the tissue wall, wherein the structure carries the plurality of electrodes.

30. The treatment device of claim **29** wherein the structure is expandable from an unexpanded configuration to an expanded configuration in the intra-cardiac cavity, and wherein the plurality of electrodes comprises a first group of the electrodes provided on a first elongate member and a second group of the electrodes provided on a second elongate member, the second elongate member extending along a direction that intersects a direction that the first elongate member extends along when the structure is in the expanded configuration.

31. The treatment device of claim **30** wherein the control computer is further configured to cause energy to be transferred from at least one electrode in the first group of the electrodes to at least one electrode in the second group of the electrodes to ablate the tissue wall.

32. A treatment method employing a treatment system, the method comprising:

receiving signals in a mapping mode from a plurality of elements in a cavity defined at least in part, by a tissue wall, wherein a surface of the tissue wall is interrupted by one or more ports positioned in fluid communication with the cavity, the signals indicative of a blood flow at least proximate the elements of the plurality of elements;

computationally differentiating by a control computer between one or more regions of the surface of the tissue wall and the one or more ports based at least in part on the signals received from the plurality of elements;

producing a map by the control computer representing both the surface of the tissue wall and at least one of the one or more ports based at least on the computational differentiation between the one or more regions of the surface of the tissue wall and the one or more ports; and

providing current to at least one electrode in an ablation mode, the current sufficient to cause the at least one electrode to ablate the surface of the tissue wall at a location corresponding to a selected one of the one or more regions of the surface of the tissue wall represented by the map.

33. The method of claim **32** wherein receiving signals in the mapping mode includes receiving signals that are indicative of a convective heat transfer by the blood flow.

34. The method of claim **32**, further comprising:

displaying the map on a display during an ablation procedure.

35. The method of claim **32**, further comprising:

multiplexing signals from a control computer;

providing the multiplexed signals to a demultiplexer;

demultiplexing the multiplexed signals; and

operating a plurality of switches to activate selected ones of the at least one element according to the demultiplexed signals.

36. The method of claim **35** wherein operating the plurality of switches to activate selected ones of the at least one element according to the demultiplexed signals includes sequentially activating each of the selected ones of the switches.

37. The method of claim **36**, further comprising:

selectively coupling the switches between a current source in the mapping mode and an ablation source in the ablation mode.

38. The method of claim **37** wherein selectively coupling the switches between the current source in the mapping mode and the ablation source in the ablation mode includes selectively coupling the switches to a radio frequency generator in the ablation mode.

39. The method of claim **32**, further comprising:

determining a temperature of tissue being ablated based on the signals received from the plurality of elements.

40. The method of claim **32**, further comprising:

repeatedly switching between the mapping and the ablation modes during a single ablation procedure.

41. The method of claim **32** wherein providing current to the at least one electrode in the ablation mode includes providing current to the at least one electrode that is proximate to one of the one or more ports in the surface of the tissue wall, where the ports are a set of ports of pulmonary veins in the surface of the tissue wall.

42. The method of claim **32** wherein the tissue wall forms at least a portion of a heart, and further comprising:

percutaneously positioning the plurality of elements and the at least one electrode in the portion of the heart in a compressed configuration.

43. The method of claim **32** wherein the tissue wall forms at least a portion of a heart and the at least one element is carried by a flexible structure, and further comprising:

percutaneously positioning the structure in the portion of the heart in an unexpanded configuration; and

expanding the structure into an expanded configuration within the portion of the heart.

44. The method of claim **32** wherein providing current to the at least one electrode in an ablation mode includes providing the current to selected ones of the at least one electrode to form a Maze pattern about at least one of the one or more ports to treat atrial fibrillation.

45. The treatment method of claim **32** wherein at least one of the plurality of elements is selectively operable as an electrode.

46. The treatment method of claim **32** further comprising:

determining a size of a port of the one or more ports based at least in part, on the signals received from at least some of the plurality of elements.

47. A treatment device, comprising:

a structure sized to be percutaneously received in an intra-cardiac cavity formed at least in part by a tissue wall, a

surface of the tissue wall interrupted by one or more ports that provide fluid communication with the intra-cardiac cavity; and

a plurality of elements that are operable in a mapping mode to produce a respective value indicative of a blood flow at least proximate both of at least one of the one or more ports and a region of the surface of the tissue wall to which respective ones of the elements are positionable at least proximate, the elements of the plurality of elements positionable in the intra-cardiac cavity in a state being carried by the structure in spaced apart relation to one another; and

a control computer configured to produce a map that represents the surface of the tissue wall of the intra-cardiac cavity and a respective relative location of the one or more ports based at least in part on each value indicative of blood flow at least proximate the at least one of the one or more ports and the region of the surface of the tissue wall.

48. The treatment device of claim **47** wherein each respective value is indicative of a convective heat transfer by the blood flow.

49. The treatment device of claim **48** wherein each respective value indicative of the convective heat transfer is a voltage measurable across the respective element in response to a current through the respective element.

50. The treatment device of claim **47** wherein the structure is expandable between an unexpanded configuration and an expanded configuration.

51. The treatment device of claim **50** wherein the structure is a mesh and at least one of the plurality of elements is formed by a resistive wire.

52. The treatment device of claim **50** wherein at least one of the plurality of elements is formed by a resistive wire.

53. The treatment device of claim **52** the resistive wire is a nickel wire.

54. The treatment device of claim **52** wherein the resistive wire is a polymer wire.

55. The treatment device of claim **50** wherein the plurality of elements comprises a first group of the elements provided on a first elongate member and a second group of the elements provided on a second elongate member, the second elongate member extending along a direction that intersects a direction that the first elongate member extends along when the structure is in the expanded configuration.

56. The treatment device of claim **50**, further comprising:

a plurality of electrodes receivable in the intra-cardiac cavity, each of the plurality of electrodes selectively operable to ablate the tissue wall in an ablation mode, wherein the structure carries the plurality of electrodes.

57. The treatment device of claim **56** wherein the plurality of electrodes comprises a first group of the electrodes provided on a first elongate member and a second group of the electrodes provided on a second elongate member, the second elongate member extending along a direction that intersects a direction that the first elongate member extends along when the structure is in the expanded configuration.

58. The treatment device of claim **47** wherein the structure is a self-expanding mesh.

59. The treatment device of claim **47** wherein the structure is formed of a plurality of longitudinal wires and a plurality of cross wires, the longitudinal wires stiffer than the cross wires.

60. The treatment device of claim **47** wherein the structure is sized to be received in a receptacle of a catheter when the structure is in a compressed configuration.

61. The treatment system of claim **47**, further comprising:

a plurality of switches, the switches selectively operable to actuate selected ones of the plurality of elements.

62. The treatment system of claim **61**, further comprising:

a demultiplexer coupled to receive multiplexed signals from a remotely located multiplexer over a communications path including less wires than a total number of the elements in the plurality of elements, the demultiplexer operable to demultiplex the signals and further coupled to provide the demultipexed signals to control the switches.

63. The treatment system of claim **47** wherein at least some of the plurality of elements are arranged as a linear array on the structure.

64. The treatment system of claim **63** wherein the structure is percutaneously steerable.

65. The treatment system of claim **47** wherein the plurality of elements are further operable to produce a value indicative of an ablation temperature of the tissue.

66. The treatment device of claim **65** wherein at least one of the plurality of elements is selectively operable as an electrode.

67. The treatment device of claim **47** wherein at least a first and a second one of the plurality of elements are positioned on the structure with respect to one another such that the first one of the plurality of elements is positionable in the intra-cardiac cavity at a location overlying one of the ports of the one or more ports when the control computer receives the signals from the plurality of elements and the second one of the plurality of elements is positionable in the intra-cardiac cavity at a location not overlying one of the ports of the one or more ports when the control computer receives the signals from plurality of elements.

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专利名称(译)	用于心脏内映射和消融的装置和方法		
公开(公告)号	US9119633	公开(公告)日	2015-09-01
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[标]申请(专利权)人(译)	卡尔蒂姆公司		
当前申请(专利权)人(译)	KARDIUM INC.		
[标]发明人	GELBART DANIEL LICHTENSTEIN SAMUEL VICTOR		
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CPC分类号	A61B18/1492 A61B5/028 A61B5/6858 A61B18/082 A61B18/10 A61B5/6853 A61B18/18 A61B18/20 A61B2018/0016 A61B2018/0022 A61B2018/00267 A61B2018/00357 A61B2018/00577 A61B2018/00642 A61B2018/00714 A61B2018/00791 A61B2018/0212 A61B2018/0237 A61B2018/124 A61B2018/1407 A61B2562/046 A61B5/015 A61B5/02055 A61B5/027 A61B5/743 A61B18/02 A61B34/10 A61B34/25 A61B90/37 A61B2018/00351 A61B2018/00875 A61B2034/101		
其他公开文献	US20130184706A1		
外部链接	Espacenet USPTO		

摘要(译)

心内标测系统基于定位血液流入或流出心腔的端口。对于许多手术，例如消融治疗心房颤动，准确定位肺静脉和二尖瓣允许执行迷宫手术。端口和阀门的位置基于使用血流的对流冷却效果。可以通过导管部署的可扩展网或扫描导管来执行映射。相同的网或导管也可以执行消融手术。