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

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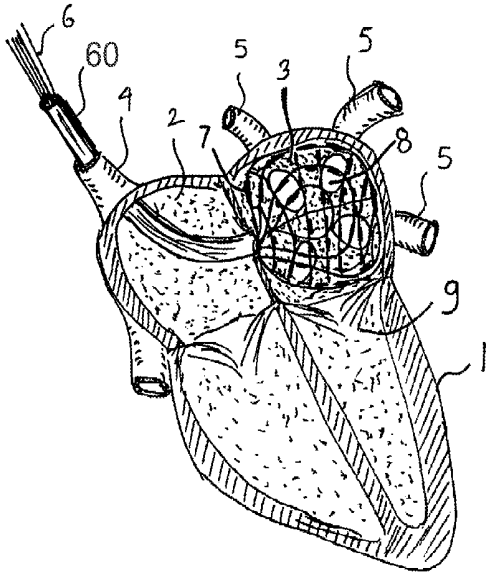
(57) **ABSTRACT**

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.

36 Claims, 8 Drawing Sheets



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Preliminary Amendment filed in copending U.S. Appl. No. 15/725,731 dated Oct. 24, 2017.
Preliminary Amendment filed in copending U.S. Appl. No. 15/784,647 dated Nov. 7, 2017.
Preliminary Amendment filed in copending U.S. Appl. No. 15/725,662 dated Oct. 24, 2017.
Office Action issued in copending U.S. Appl. No. 14/804,924 dated Nov. 17, 2017.
Response to Office Action filed in copending U.S. Appl. No. 13/785,910 dated Nov. 30, 2017.
Amendment filed in copending U.S. Appl. No. 13/785,910 dated Feb. 27, 2018.
Examination Report issued in European Application No. 13793216.6 dated Nov. 24, 2017.
Office Action issued in Chinese Application No. 201510432392.3 dated Nov. 17, 2017. English translation provided.
Examination Report issued in European Application No. 15188407.9 dated Dec. 11, 2017.
Office Action issued in copending U.S. Appl. No. 13/785,910 dated Jan. 12, 2018.
Amendment filed in copending U.S. Appl. No. 14/804,924 dated Feb. 27, 2018.

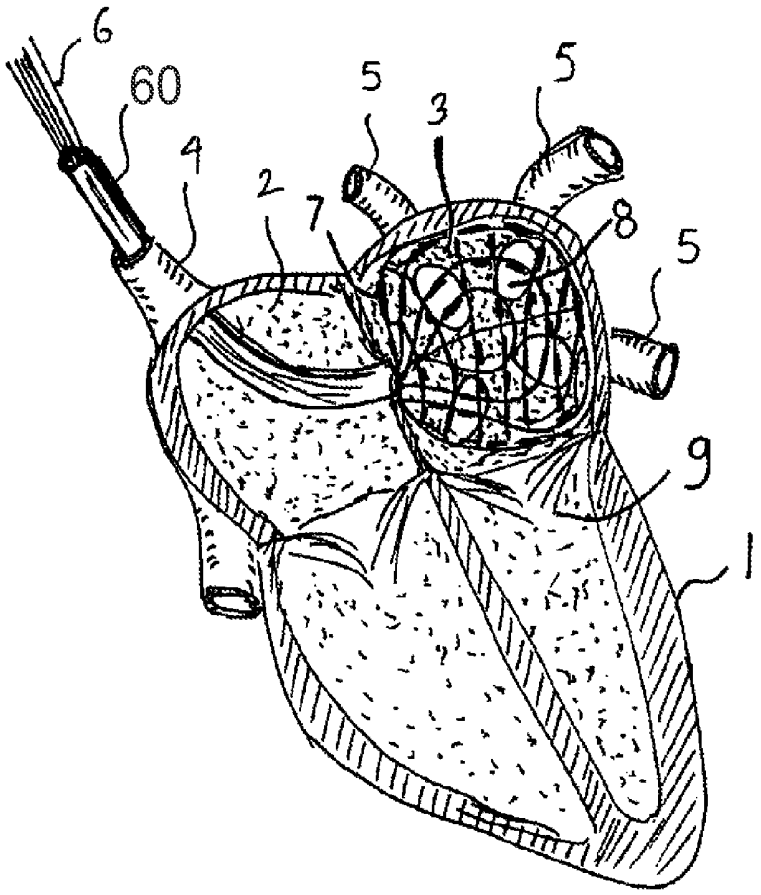

Fig 1

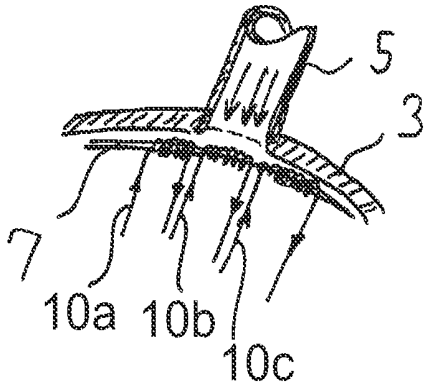

FIG. 2

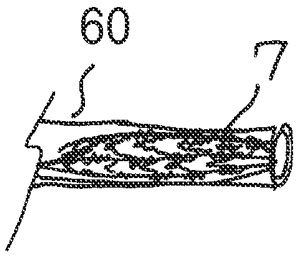

FIG. 3A

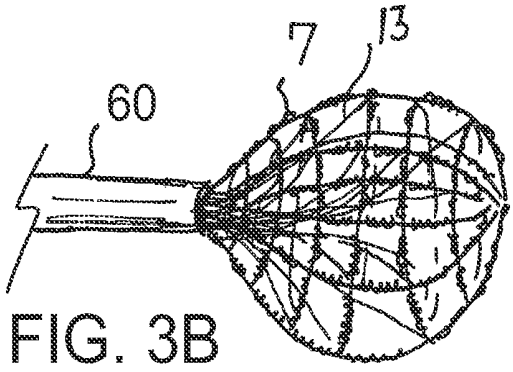

FIG. 3B

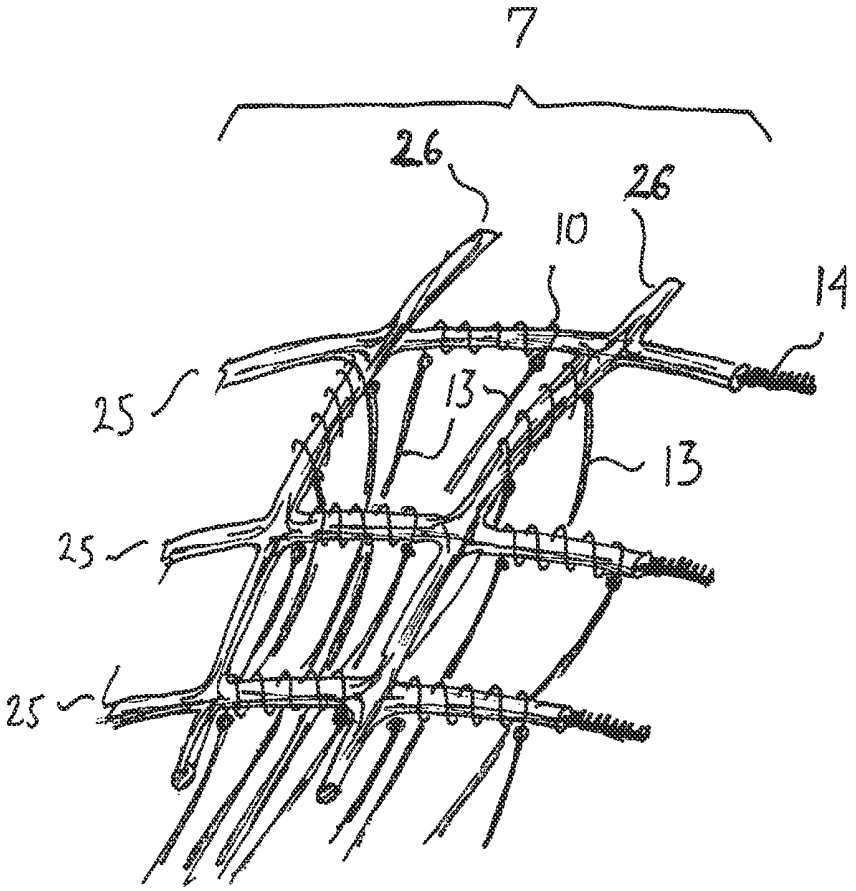

Fig 4

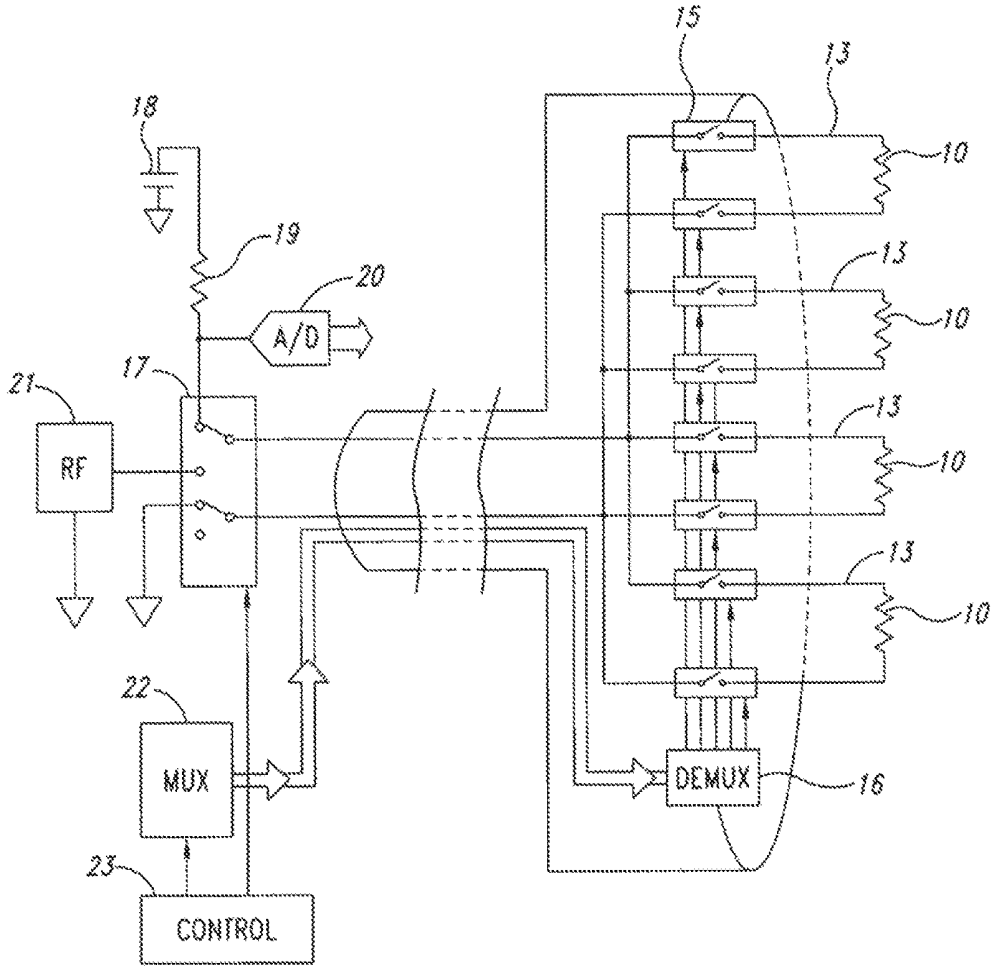
15
13
18
10
19
13
20
A/D
10
17
21
13
RF
10
13
10
22
MUX
DEMUX
16
23
CONTROL

FIG. 5

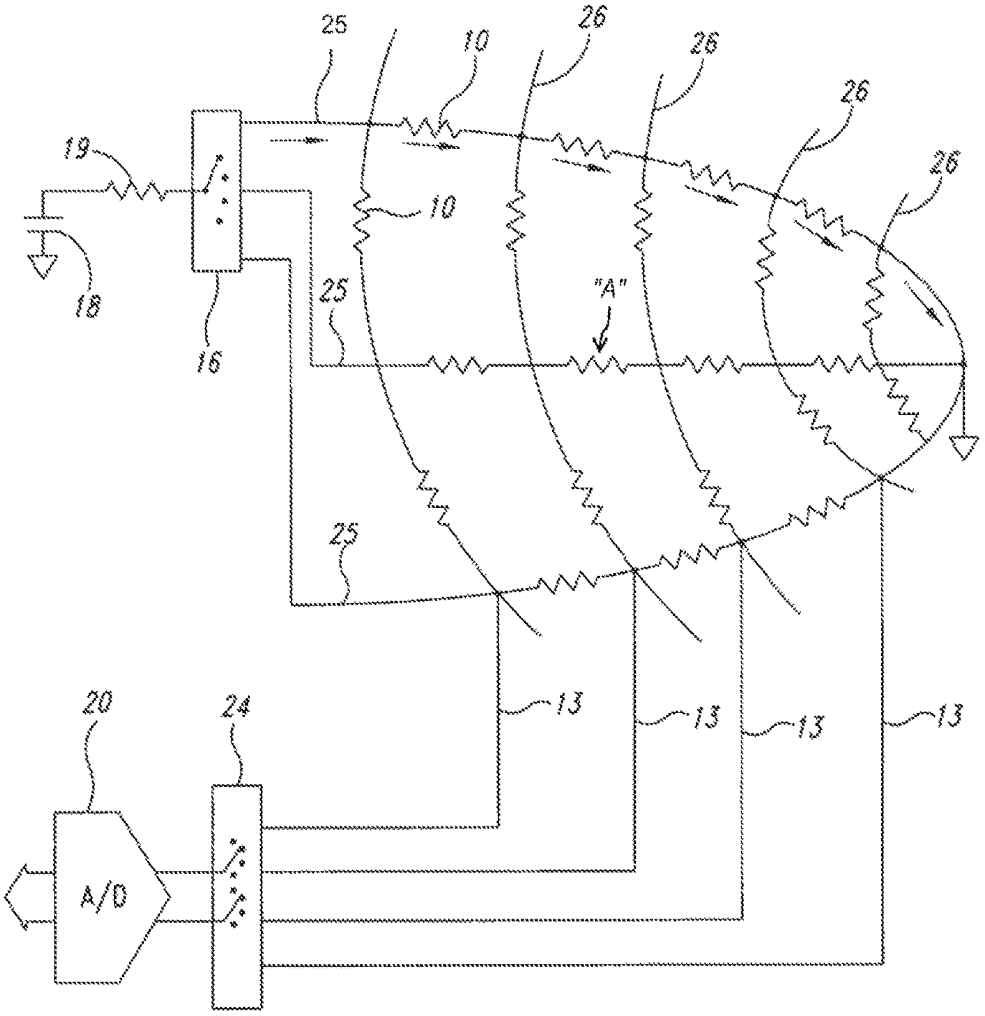

FIG. 6

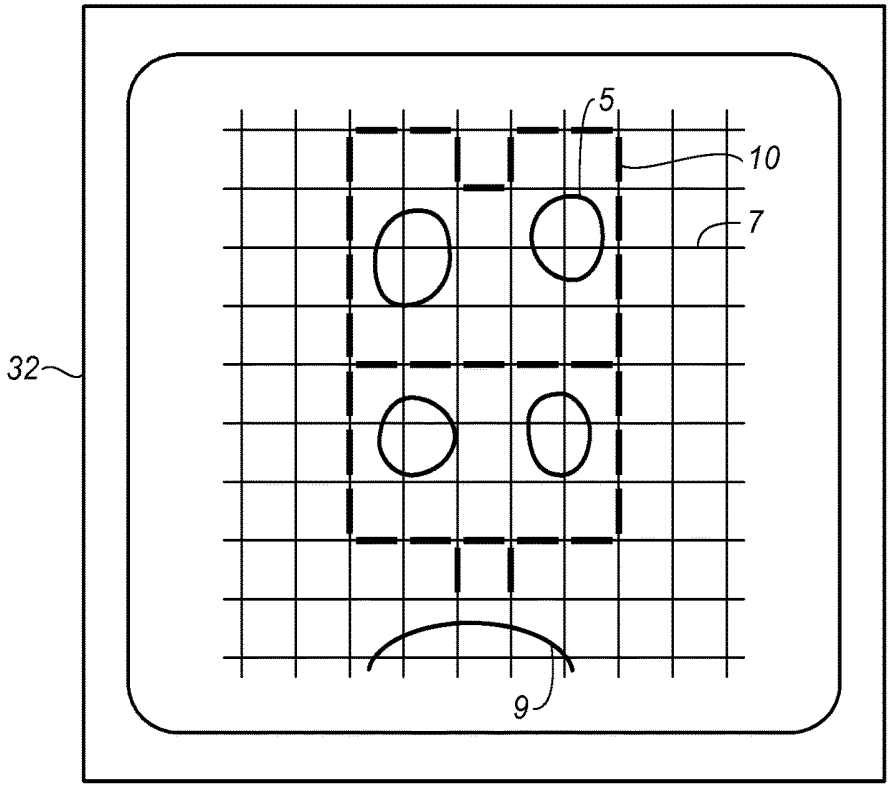

FIG. 7

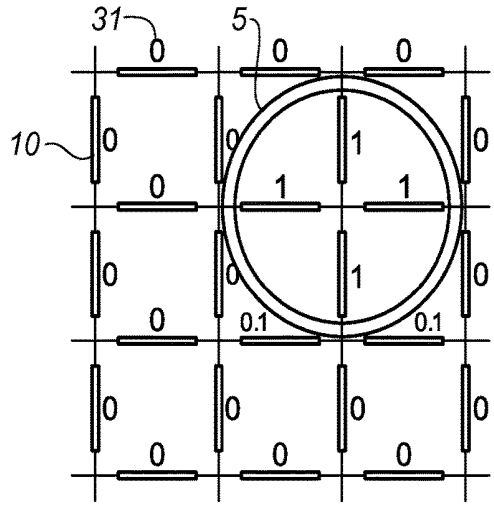

FIG. 8A

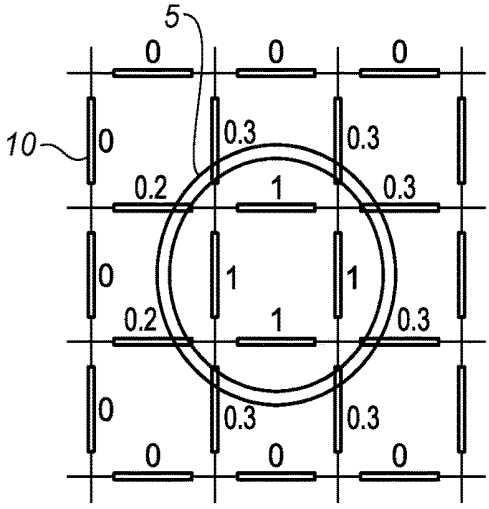

FIG. 8B

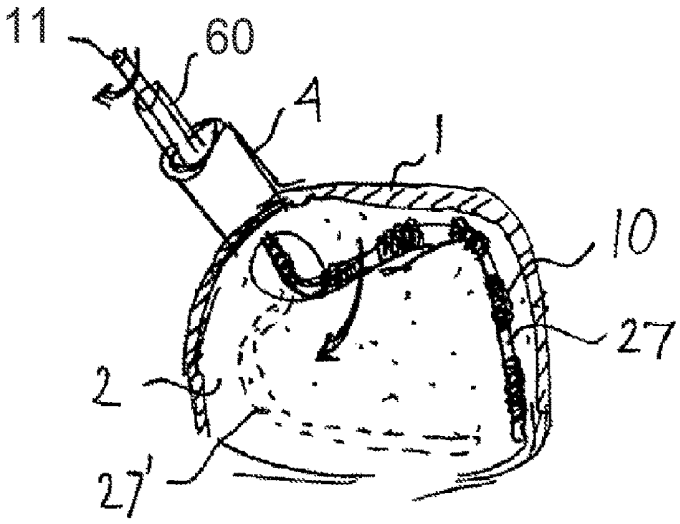

Fig 9

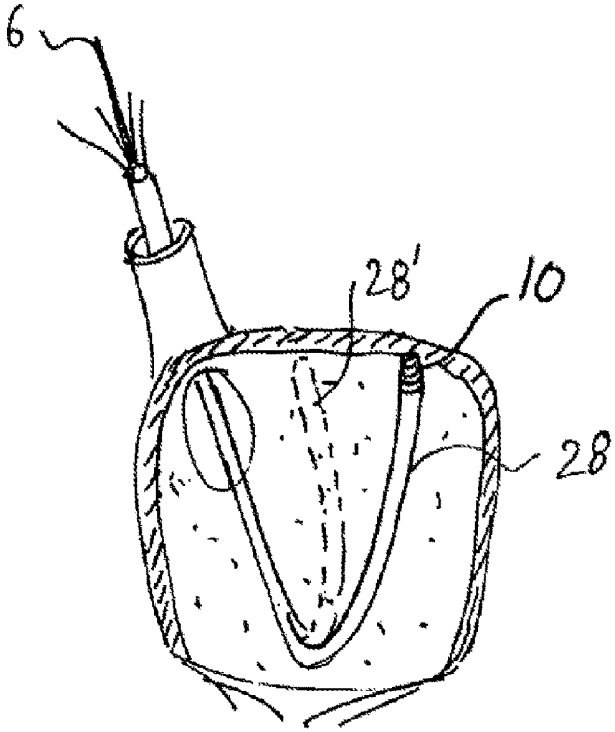

Fig 10

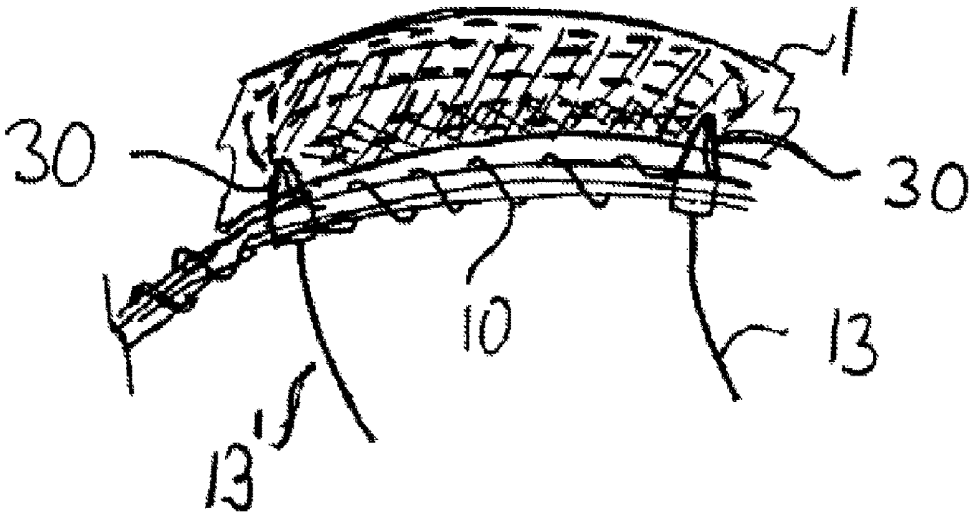

Fig 11

APPARATUS AND METHOD FOR INTRA-CARDIAC MAPPING AND ABLATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of prior U.S. patent application Ser. No. 13/785,931, filed Mar. 5, 2013, now U.S. Pat. No. 9,119,633, issued on Sep. 1, 2015, which 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, issued on Dec. 30, 2014, the entire disclosure of each of these applications 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 fibrilla-

tion 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 temperature 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 intra-cardiac 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 system comprising:

a plurality of elements configured at least to be introduced into an intra-cardiac cavity; and

a control computer coupled to the plurality of elements and configured at least to:

locate points on a wall of the intra-cardiac cavity based at least on sensing blood flow with the plurality of elements;

map the wall of the intra-cardiac cavity based at least on the located points; and

update the map based at least on a repositioning of the plurality of elements in the intra-cardiac cavity.

2. The system of claim **1**, wherein the control computer is configured at least to locate the points on the wall of the intra-cardiac cavity based at least on sensing temperature with the plurality of elements.

3. The system of claim **1**, wherein the control computer is configured at least to locate the points on the wall of the intra-cardiac cavity at least in response to reception of signals from the plurality of elements, the signals indicative of convective heat transfer by the blood flow.

4. The system of claim **1**, further comprising a source coupled to at least a first one of the plurality of elements to provide electric current thereto, the electric current sufficient to cause heating of at least a portion of the first one of the plurality of elements, wherein the control computer is configured at least to locate at least one of the points on the wall of the intra-cardiac cavity based at least on sensing of electrical resistance of the heated portion of the first one of the plurality of elements.

5. The system of claim **1**, wherein the control computer is communicatively coupled to a display to cause the map to be displayed by the display.

6. The system of claim **5**, wherein each element of the plurality of elements is responsive to convective heat transfer to sense the blood flow, and wherein the control computer is configured at least to cause the display to generate, within the displayed map, one or more visual representations indicating one or more regions of the wall of the intra-cardiac cavity and one or more visual representations indicating one or more ports in a surface of the wall of the intra-cardiac cavity based at least on the sensed blood flow.

7. The system of claim **1**, wherein each element of the plurality of elements is operable to sense respective temperature, and wherein the control computer is configured at least to cause display of one or more visual representations indicating one or more regions of the wall of the intra-cardiac cavity and one or more visual representations indicating one or more ports in a surface of the wall of the intra-cardiac cavity, at least a first one of the one or more ports displayed with a particular size determined by the control computer based at least on the respective temperature sensed by each element of some of the plurality of elements.

8. The system of claim **1**, wherein each element of the plurality of elements is operable to sense respective temperature, wherein the control computer is configured at least to cause display of one or more visual representations indicating one or more regions of the wall of the intra-cardiac cavity and one or more visual representations indicating one or more ports in a surface of the wall of the intra-cardiac cavity, and wherein the control computer is configured at least to determine a location of at least a first one of the one or more ports based at least on the respective temperature sensed by each element of some of the plurality of elements.

9. The system of claim **1**, wherein the control computer is configured at least to cause, based at least on the sensed blood flow, display of (a) one or more visual representations indicating one or more regions of the wall of the intra-cardiac cavity, and (b) one or more visual representations indicating one or more ports in a surface of the wall of the intra-cardiac cavity, and wherein the control computer is configured at least to cause display of a plurality of displayed elements concurrently with the display of (a) and (b), each displayed element of the plurality of displayed elements corresponding to a respective element of the plurality of elements.

10. The system of claim **9**, wherein the control computer is configured at least to cause the plurality of displayed elements to be displayed with spatial relationships that are consistent with spatial relationships of the plurality of elements.

11. The system of claim **9**, wherein the control computer is configured at least to receive a selection of at least some of the plurality of the displayed elements and cause corresponding ones of the plurality of elements to ablate respective portions of the surface of the wall of the intra-cardiac cavity at least in response to the selection.

12. The system of claim **11**, wherein the control computer is configured at least to, at least in response to the selection, cause particular ones of the selected at least some of the plurality of displayed elements to be visually emphasized from particular ones of the plurality of displayed elements that are not selected.

13. The system of claim **9**, wherein the control computer is configured at least to cause the plurality of displayed elements to be displayed with spatial relationships with respect to the one or more visual representations indicating the one or more ports that are consistent with spatial relationships between the plurality of elements and the one or more ports in the surface of the wall of the intra-cardiac cavity.

14. The system of claim **13**, wherein the control computer is configured at least to receive a selection of a group of the plurality of the displayed elements surrounding at least a first visual representation indicating a first one of the one or more ports and cause corresponding ones of the plurality of elements to ablate respective portions of the surface of the wall of the intra-cardiac cavity surrounding the first one of the one or more ports at least in response to the selection.

15. The system of claim **9**, wherein the control computer is configured at least to cause display of a first visual representation of a superposition of a first group of the plurality of displayed elements and a first particular visual representation indicating a first one of the one or more ports.

16. The system of claim **15**, wherein the control computer is configured at least to cause a second visual representation of a superposition of another group of the plurality of displayed elements and a second particular visual representation indicating a first one of the one or more regions of the wall to be concurrently displayed with the first visual representation, the another group of the plurality of displayed elements surrounding the first group of the plurality of displayed elements.

17. The system of claim **15**, wherein the control computer is configured at least to cause the first visual representation to be displayed in response to at least a first sensing of blood

flow with the plurality of elements in the intra-cardiac cavity, and the control computer is configured at least to cause the first visual representation to be updated in response to a second sensing of blood flow with the plurality of elements in the intra-cardiac cavity, the updated first visual representation including a third visual representation of a superposition of a second group of the plurality of displayed elements and a visual representation indicating the first one of the one or more ports, the second sensing of blood flow other than the first sensing of blood flow, and at least one displayed element in the second group other than each displayed element in the first group.

18. The system of claim **15**, wherein the control computer is configured at least to cause the first visual representation to be displayed in response to at least a first sensing of blood flow with the plurality of elements in the intra-cardiac cavity, and the control computer is configured at least to cause the first visual representation to be updated in response to a second sensing of blood flow with the plurality of elements in the intra-cardiac cavity, the updated first visual representation indicating a positional movement between at least one of the displayed elements in the first group of the plurality of displayed elements and a visual representation indicating the first one of the one or more ports represented in the visual representation, the second sensing of blood flow other than the first sensing of blood flow.

19. The system of claim **1**, wherein each element of the plurality of elements is operable to sense temperature, and wherein the control computer is configured at least to determine a positional movement of at least a first one of the plurality of elements based at least on temperature change sensed by each element of at least some of the plurality of elements.

20. The system of claim **19**, wherein the at least some of the plurality of elements include or includes the first one of the plurality of elements.

21. The system of claim **1**, wherein each element of the plurality of elements is operable to sense temperature, and wherein the control computer is configured at least to determine a positional movement of at least a first one of the plurality of elements based at least on sensed electrical resistance change of each element of at least some of the plurality of elements.

22. The system of claim **21**, wherein the at least some of the plurality of elements include or includes the first one of the plurality of elements.

23. The system of claim **1**, further comprising a source coupled to at least a first one of the plurality of elements to provide electric current thereto, the electric current sufficient to cause heating of at least a portion of the first one of the plurality of elements, wherein the control computer is configured at least to determine a positional movement of at least the first one of the plurality of elements based at least on sensing of temperature of the heated portion of the first one of the plurality of elements.

24. The system of claim **1**, further comprising a source coupled to at least a first one of the plurality of elements to provide electric current thereto, the electric current sufficient to cause heating of at least a portion of the first one of the plurality of elements, wherein the control computer is configured at least to determine a positional movement of at least the first one of the plurality of elements based at least on sensing of electrical resistance of the heated portion of the first one of the plurality of elements.

25. The system of claim **1**, wherein each element of the plurality of elements is operable to perform ablation of tissue, and the control computer is configured at least to switch operation of at least some elements of the plurality of elements between a mapping mode in which at least part of a mapping process to generate the map is performed and an ablation mode in which at least some of the ablation is performed.

26. The system of claim **25**, wherein the control computer is configured at least to switch operation of the at least some elements of the plurality of elements between the mapping mode and the ablation mode during the ablation.

27. The system of claim **1**, further comprising a structure upon which the plurality of elements are arranged, the structure expandable between a first configuration suitable for percutaneous delivery of the structure and a second configuration in which the structure is expanded relatively to the first configuration.

28. The system of claim **1**, wherein the control computer is configured at least to cause display of one or more visual representations indicating the plurality of elements concurrently with one or more visual representations indicating temperature information from a sensing of temperatures with the plurality of elements.

29. The system of claim **1**, wherein each element of the plurality of elements is operable to sense temperature, wherein the control computer is configured at least to cause display of one or more visual representations indicating each element of at least some elements in the plurality of elements concurrently with one or more visual representations indicating respective temperature information at least proximate each respective one or more visual representations indicating each element of the at least some elements, each respective temperature information indicative of temperature sensed by a respective one of the at least some elements in the plurality of elements.

30. The system of claim **1**, wherein the control computer is configured at least to cause display of one or more visual representations indicating each element of at least some elements in the plurality of elements concurrently with one or more visual representations indicating respective information at least proximate each respective one or more visual representations indicating each element of the at least some elements, each respective information indicative of particular blood flow at least proximate a respective one of the at least some elements in the plurality of elements.

31. A method executed by a control computer for controlling a medical device, the medical device comprising a plurality of elements deliverable into an intra-cardiac cavity, and the method comprising:

locating points on a wall of the intra-cardiac cavity based at least on sensing blood flow with the plurality of elements;

mapping the wall of the intra-cardiac cavity based at least on the located points; and

updating the map based at least on a repositioning of the plurality of elements in the intra-cardiac cavity.

32. A system comprising:

a plurality of elements configured at least to be introduced into an intra-cardiac cavity; and

a control computer coupled to the plurality of elements and configured at least to:

locate first points on a wall of the intra-cardiac cavity based at least on first blood flow information sensed by the plurality of elements positioned at respective locations in the intra-cardiac cavity;

draw a displayed visual representation indicating at least part of the wall of the intra-cardiac cavity based at least on the located first points;

locate second points on the wall of the intra-cardiac cavity based at least on second blood flow information sensed by the plurality of elements positioned at particular locations in the intra-cardiac cavity other than the respective locations; and

update the displayed visual representation based at least on the located second points.

33. The system of claim **32**,

wherein the control computer is configured at least to cause generation, based at least on the located first points, of a displayed first visual representation including a concurrently displayed (a) one or more first representations indicating one or more regions of the wall of the intra-cardiac cavity and (b) one or more first representations indicating one or more ports in a surface of the wall of the intra-cardiac cavity, and cause generation, based at least on the located second points, of a displayed second visual representation including a concurrently displayed (i) one or more second representations indicating the one or more regions of the wall of the intra-cardiac cavity and (ii) one or more second representations indicating the one or more ports in the surface of the wall of the intra-cardiac cavity, and

wherein the displayed first visual representation is different than the displayed second visual representation.

34. A method executed by a control computer for controlling a medical device, the medical device comprising a plurality of elements deliverable into an intra-cardiac cavity, and the method comprising:

locating first points on a wall of the intra-cardiac cavity based at least on first blood flow information sensed by the plurality of elements positioned at respective locations in the intra-cardiac cavity;

drawing a displayed visual representation indicating at least part of the wall of the intra-cardiac cavity based at least on the located first points;

locating second points on the wall of the intra-cardiac cavity based at least on second blood flow information sensed by the plurality of elements positioned at particular locations in the intra-cardiac cavity other than the respective locations; and

updating the displayed visual representation based at least on the located second points.

35. A system comprising:

a plurality of elements configured at least to be introduced into an intra-cardiac cavity; and

a control computer coupled to the plurality of elements and configured at least to:

provide a visual representation including one or more representations indicating one or more regions of a wall of the intra-cardiac cavity concurrently with one or more representations indicating one or more ports in a surface of the wall of the intra-cardiac cavity with respect to the one or more representations of the one or more regions based at least on a first sensing of blood flow with the plurality of elements in the intra-cardiac cavity, wherein the visual representation includes one or more representations of a superposition of one or more representations indicating a first group of the plurality of elements and a representation indicating a first one of the one or more ports; and

update the visual representation based at least on a second sensing of blood flow with the plurality of elements in the intra-cardiac cavity, the updated visual representation including one or more representations of a superposition of one or more representations indicating a second group of the plurality of elements and a representation indicating the first one of the one or more ports, the second sensing of blood flow other than the first sensing of blood flow.

36. A method executed by a control computer for controlling a medical device, the medical device comprising a plurality of elements deliverable into an intra-cardiac cavity, and the method comprising:

providing a visual representation including one or more representations indicating one or more regions of a wall of the intra-cardiac cavity concurrently with one or more representations indicating one or more ports in a surface of the wall of the intra-cardiac cavity with respect to the one or more representations of the one or more regions based at least on a first sensing of blood flow with the plurality of elements in the intra-cardiac cavity, wherein the visual representation includes one or more representations of a superposition of one or more representations indicating a first group of the plurality of elements and a representation indicating a first one of the one or more ports; and

updating the visual representation based at least on a second sensing of blood flow with the plurality of elements in the intra-cardiac cavity, the updated visual representation including one or more representations of a superposition of one or more representations indicating a second group of the plurality of elements and the representation indicating the first one of the one or more ports, the second sensing of blood flow other than the first sensing of blood flow.

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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		
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申请(专利权)人(译)	KARDIUM INC.		
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其他公开文献	US20160008062A1		
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。